



AIIMS BHUBANESWAR

1st National Seminar on
Safety & Quality In Health Care



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8th Dec 2018

Organized by
**Department of Hospital Administration
AIIMS, Bhubaneswar**

Venue
Main Auditorium, AIIMS, Bhubaneswar

The department of Hospital Administration welcomes you to the 1st National Seminar on
Safety & quality in health care

Patient safety is a fundamental element of healthcare. It represents one of the qualities of care dimensions and is crucial to delivering quality healthcare services. The patient safety program incorporates Surgical safety, Medication safety, Hospital Infection control, prevention of adverse events, facility management etc.

Patient safety has been increasingly recognized as an issue of global importance and in 2002, WHO member states has agreed on a world health assembly resolution on patient safety.

Subsequently the Govt. of India, Ministry of Health and family Welfare has developed National Patient Safety Implementation framework 2018-2025 for implementation in India. In this backdrop, The Department of Hospital Administration, AIIMS, BBSR in collaboration with Harvard T.H. Chan School of Public Health USA are organizing a one day seminar on patient safety at AIIMS, BBSR on 8th Dec 2018.

Topic`s Highlight's

1. Surgical safety
2. Medication safety
3. Sentinel event monitoring and control
4. Facilities management
5. Patient care portal
6. Quality in health - Global Scenario

A Validated Value-Based Model to Improve Hospital-Wide Perioperative Outcomes

Adaptability to Combined Medical/Surgical Inpatient Cohorts

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Objectives: Authors hypothesized that building safe hospital systems to improve value-based surgical outcomes is predicated on workflow redesign for dynamic risk stratification, coupled with “real-time” mitigation of risk. We developed a comanagement model for hospitalized surgical cohort, and determined whether this iterative process redesign for surgery will be adaptable to disparate hospital systems and will be beneficial for combined medical/surgical adult inpatients.

Context: Concerns about preventable harm in hospitalized patients have generated a plethora of both, process-driven and outcome-based strategies in US Healthcare. Although comparison between hospitals is a common mechanism to drive quality, other innovative approaches are needed for real-time risk mitigation to improve outcomes.

Methods: Prospective implementation of Surgical Continuum of Care (SCoC) model in hospitals initially for surgery patients; subsequently Continuum of Care (CoC) for medical/surgical population. Redesign of hospital care delivery model: patient cohorting, floor-based team building, and intensivist/hospitalist staffing of progressive care unit (PCU). Work flow redesign for clinical effectiveness: multidisciplinary team rounds, acuity stratified care rounding based on dynamic risk assessment into a novel HAWK (high risk)/DOVE (low risk) patient grouping, intensivist/hospitalist comanagement of surgical patients, and targeted response.

Study: Pre- and postintervention with concurrent cohort control design.

Setting: Academic medical centers for SCoC and integrated health system hospital for CoC.

Patient Groups: SCoC Pilot Study—Campus A: Preintervention control group 1998–2000, Intervention Group 2001–2004; Campus B: Comparator Control Group 1998–2004.

SCoC Validation Study—Campus C: Preintervention Group 2001–2005; Intervention Group 2006–2008. CoC Study—Campus D: Hospital-wide Group 2009.

Metrics: Mortality, length of stay (LOS): overall, surgical intensive care unit and PCU, readmission rates, and cost. Case mix index for risk adjustment.

Results: Total >100,000 admissions. There was a significant reduction in overall surgical mortality in both, pilot ($P < 0.002$) and validation ($P <$

0.02) SCoC studies and overall hospital mortality in the medical/surgical CoC study (risk-adjusted mortality index progressively declined in CoC study from 1.16 pre-CoC to 0.77 six months post-CoC implementation; significant at 75% confidence level). Case mix index was unchanged during study period in each campus. Nested study in validation cohort of hospital-wide versus surgery alone (observed/expected mortality index) demonstrated significant benefit to SCoC in intervention group. The mortality benefit was primarily derived from risk-stratified rounding and actively managing risk prone population in the PCU. Surgical intensive care unit, PCU, and total hospital patient-days significantly decreased in SCoC pilot study ($P < 0.05$), reflecting enhanced throughput. LOS reduction benefit persisted in SCoC validation and CoC studies. In addition to decreased LOS, cost savings were in PCU (range, \$851,511–2,007,388) and top diagnosis-related groups, for example, \$452 K/yr for diagnosis-related group 148.

Conclusions: SCoC is patient-centered, outcomes-driven, value-based approach for hospital-wide surgical patient safety. The principles of this value paradigm are adaptable to other hospitals as demonstrated in our longitudinal study in 3 hospital systems, and the initial experience of CoC suggests that this model will have benefit beyond surgical hospital cohort.

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Reports from analysis of preventable harm in New York and Colorado/Utah hospital systems formed the basis of Institute of Medicine (IOM) report in 1998 that adverse events occur in 2.9% to 3.7% of hospitalizations leading to death in 6.6% and 13.6%, respectively.^{1–3} When extrapolated to more than 33.6 million admissions in US hospitals in 1997, the data implied that 44,000 to 98,000 die each year from medical errors.² The IOM Quality of Healthcare in America Committee, formed in June 1998, developed recommendations for patient safety in a 4-tiered approach; the crux/ultimate target of all recommendations was “creating safety systems inside healthcare organizations through implementation of safe practices at the delivery level.”¹ The impetus provided by IOM report generated a series of process-oriented and outcomes-driven approaches.

For the surgical patients, improvement in perioperative outcomes is predicated on improving team performance (eg, time-out/check list), reliable processes (eg, Surgical Care Improvement Project, Institute for Healthcare Improvement), development and adherence to appropriateness criteria (eg, bariatric surgery), and development of comparative quality evaluation programs (eg, National Surgical Quality Improvement Program [NSQIP]).^{4,5} Another mechanism to impact surgical quality is through multihospital collaborations focusing on salient process of care measures, in hospital outcomes and appropriateness of care.⁶ Exchange of information

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regarding outcomes and analysis of causes of mortality resulted in reduction of mortality from surgical procedures.⁷

Against this backdrop, we initiated a pilot study in 2001 termed Surgical Continuum of Care (SCoC) to assess the effect on in-hospital surgical patient mortality and cost effectiveness. This is conceived of as a microsystem or mesosystem intervention at hospital-wide surgical patient population, to reduce mortality by enhancing continuity and comanagement throughout hospital stay, minimize errors at transition points, increase throughput, and reduce length of stay (LOS). We hypothesized that SCoC will be an effective response to the IOM directive at saving lives through “safe practices” and “teamwork” for the surgical patient. In addition to mitigation of harm from medical errors, we conceived SCoC as a proactive medical/surgical collaborative management of patient cohort at risk for deterioration and preemptive attention to comorbidities. Although SCoC began as an error prevention strategy, it developed into a patient safety program beyond error prevention by an iterative process. Dynamic risk stratification and preemptive management of the high-risk cohort were enabled by an interdisciplinary stratified rounding. Early recognition of complications/physiologic deterioration was the goal of the pilot SCoC during the second year and beyond, during a time when the rapid response teams (RRT) were not the norm. Having developed the structure and content through a longitudinal pilot, and validated the SCoC benefits in a second health system, we have explored its applicability in a combined medical/surgical adult hospital cohort, continuum of care (CoC), and used a total electronic health record (EHR) platform to enhance its functionalities.

Our overarching hypothesis in 2001 was that a surgical patient with physiologic deterioration during the hospital course would have had a variable period of occult deterioration before the “critical event” that results in activation of code team for cardiopulmonary arrest (Fig. 1). When the critical event sets in, our ability to rescue the patients is very limited, and in the small cohort that

survives, the quality of life is poor. During the “prodrome” preceding the critical event we posit that the clinical status goes through periods of “compensated stability,” followed perhaps by “decompensating pseudostability,” leading to “physiologic derangement.” The salient goals of this model are as follows: system redesign to rescue this cohort before physiologic derangement occurs and predictive modeling to identify individual patients for acuity stratified proactive management.

METHODS

Study Design

Prospective implementation of a patient safety program with retrospective analysis of data. The study was carried out in 3 phases conducted in tandem.

1. Pilot Study of Surgical SCoC: pre- and postintervention in Campus A, with sister Campus B serving as concurrent cohort control.
2. Validation study of SCoC in Campus C, with pre- and postintervention analysis, and nested analysis of intervention cohort versus entire medical center cohort.
3. Feasibility study of hospital-wide CoC in Campus D, with pre- and postimplementation cohorts, and risk-adjusted mortality index trending over time.

Intervention

Care delivery redesign with hospitalist comanagement of adult surgical patients in SCoC studies and hospital-wide adult population in CoC study. Cohorting of patients and floor-based multidisciplinary team building. Acuity stratified rounding, or HAWK rounding, with targeted response for mitigation of risk. Creation of safety net unit, progressive care unit (PCU), staffed by hospitalist, charged with quality and efficiency ownership.

Metrics

Mortality, LOS, cost, readmission rates.

Pilot Study

The pilot study was conducted between March 2001 and December 2004 in the Surgery Care Center at the Moses Division of Montefiore Medical Center, a 650-bed tertiary teaching hospital in New York (Campus A). This was the intervention group. The Surgery Care Center consisted of the patients admitted to the following surgical specialties: General Surgery, Dental/Maxillo-Facial Surgery, Otolaryngology, Minimally Invasive Surgery including Bariatric Surgery, Head and Neck Surgery, Orthopedics, Plastic Surgery, Urology, Neurosurgery, and Vascular Surgery.

Included in the study were all patients aged 18 years or older discharged from the Surgery Care Center between the years 1998 and 2004. Patients excluded from analysis included all cardiothoracic surgery and neurosurgery patients and surgical patients transferred to the medical service after surgery. The surgical inpatients were placed in one of the following areas based on their acuity levels: Level 1—patients admitted to the surgical intensive care unit (SICU); Level 2—patients admitted to the PCU; Level 3—stable patients admitted to regular floor beds; and Level 4—palliative care patients. The 12-bed SICU had a 24/7 intensivist-led collaborative model of care with 16-hour per day in-hospital presence and 8 hours on call with critical care fellows in hospital. Beginning 2002, the SICU had 24/7 in-house intensivist presence. Admissions to and discharges from the SICU were decided by the intensivist. The PCU, initially a 9-bed unit (1998–2002) expanded to a 12-bed unit in 2003. Admissions to and discharges from the PCU were determined by individual surgical attending physicians guided by hospital pol-

Perioperative Deterioration: Outcome Depends on Patient Status

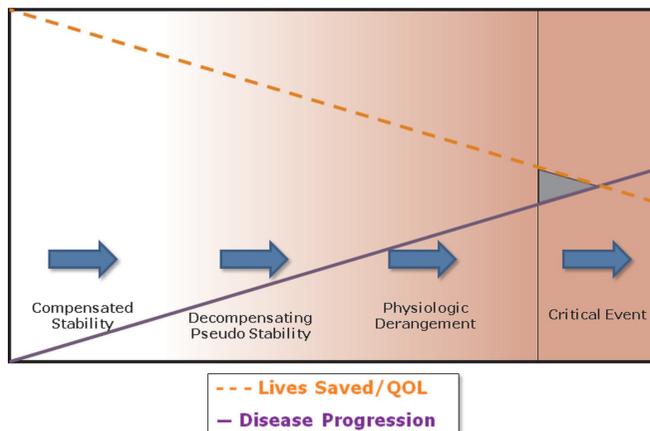


FIGURE 1. Conceptual model of perioperative deterioration of surgical inpatient: outcome depends on patient status at time of intervention. (—), Disease progression, passing through stages of stability, pseudostability, derangement, and critical event. (---), Lives saved, decreases with advancing stage of disease progression. (▲) Shaded triangle depicts the small cohort of patients saved following “code team” activation in response to cardiac arrest/cardiopulmonary failure.

icy. Patient care was provided by respective surgical teams comprised of attending physicians, residents, and midlevel providers.

Surgical emergencies and acutely deteriorating surgical patients located on the floors were taken care by the primary surgical teams with the support of in-house critical care fellows. The traditional code team led by the third year medical resident responded to cardiac arrest in surgical patients.

Implementation of the Pilot SCoC

The SCoC program was implemented in March 2001. Rationale and description of the model was submitted to hospital executive leadership as a quality improvement initiative. Enquiry with institutional or institutional review board for exempt status was affirmed. The SCoC team included a critical care trained hospitalist who had the following roles:

(1) Coordinate the functions of the PCU and provide concurrent medical management for surgical patients; (2) Conduct/participate in daily rounds with surgical teams in the PCU; and (3) Be a resource to surgical residents on the floors to address early physiological deterioration of surgical patients and coordinate their care.

Surgical teams and nursing staff on the floors were instructed in respective staff meetings to call the hospitalist whether immediate assistance was needed or whether they had concern that their patient may deteriorate. The hospitalist responsibility included responding to these calls in a time-sensitive manner. Additional roles of the hospitalists included postanesthesia care unit rounding, daily triage of Level II patients, and functioning as the “gatekeeper” of the PCU.

The Weiler division at Montefiore Medical Center (Campus B), a 370-bed tertiary teaching hospital, served as the control group for the period 2001–2004. It had a 14-bed intensivist-run medical/SICU and a 3-bed PCU. The surgical patients at Weiler were cared for by the individual surgical teams comprised of the surgical attending physicians and residents. The surgical faculty and residents, under one department of surgery rotated between the 2 hospitals. Nursing in both hospitals was under the same administration.

The quality initiatives set forth by hospital administration were implemented equally in the 2 campuses during the study period, except for SCoC.

Validation Study

The validation study was performed between October 2005 and December 2008 at Long Island Jewish Medical Center (LIJMC), a 452-bed tertiary adult care teaching hospital (Campus C). LIJMC has a 14-bed ICU and 16-bed PCU shared by medical and surgical patients until 2007 when a dedicated 13-bed SICU was constructed for the surgical patients alone. Throughout the study period the SICU functioned as a closed-model SICU with 24/7 intensivist coverage with 12-hour in-house intensivist presence and 12-hour on-call with postgraduate year 4 and postgraduate year 5 surgical residents providing ICU care. In 2006, the model changed to 24/7 in-house intensivist presence with additional robotic telepresence of the day intensivist to establish continuity of care.

The SCoC program was planned in July 2005 and presentation made to the medical board in August 2005 as a patient safety initiative for approval. Institutional review board exempt status was obtained for SCoC implementation and for mortality analysis. Physician assistants (PA), recruited by the department of surgery to assist surgical resident teams to comply with 80 hours work week and outpatient experience, were representing their respective team patients during SCoC rounds. The SCoC team included 2 intensivists who dedicated 50% of their time as the hospitalist for the SCoC program and 1 full-time equivalent who acted as the director of PAs. The role and responsibilities of the hospitalist were identical to that in the pilot study within and outside of the PCU. The surgical teams

consisted of attending, surgical residents, and PAs who conducted routine patient rounds daily.

The surgery care center consisted of the following specialties at LIJMC: Cardiothoracic Surgery, Dental Medicine, Obstetrics and Gynecology, Neurosurgery, Ophthalmology, Otolaryngology including Head and Neck, General Surgery, Urology, and Vascular Surgery. Inclusion and exclusion criteria were similar to the pilot study for the validation study period between October 2005 and December 2008.

During the validation study, patients were further stratified using specific criteria as “HAWKS,” high-risk patients located on the surgical floors who require close attention and monitoring for impending deterioration, or “DOVES,” stable surgical patients located on the floors or nearing discharge. We coined these terms: HAWKS for high-risk patients who needed to be “watched like a HAWK,” and DOVES for patients who are stable and are expected to fly peacefully like doves during the hospitalization. The HAWKS were identified by the SCoC hospitalist with input from surgical teams during the multidisciplinary rounds and during the rest of the day. Criteria for HAWK status are the following: (1) Patients transferred from SICU/PCU to the floor; (2) Patients with 2 or more comorbidities: severe diabetes mellitus, renal dysfunction, chronic obstructive pulmonary disease, congestive heart failure, cardiac arrhythmia, and morbid obesity; (3) Complex surgical procedures, especially lasting for greater than 4 hours; (4) Need for intervention in postanesthesia care unit, for example, oliguria, hypoxemia, hyper/hypotension; (5) Physiologic deterioration, metabolic disturbances disproportionate to the expected postoperative course as deemed by the surgical team, and (6) Nonoperative patients with high risk of deterioration (eg, pancreatitis with Ranson score >3). Daily multidisciplinary rounds, attended by nurse managers, case managers, social workers, resident/PA from each surgical team, SCoC hospitalist, and head PA were added in the validation study. The hospitalist or the PA located in the PCU did “HAWK” rounds on these patients every 4 hours, or if needed, more frequently until their status was upgraded to a “DOVE” by the hospitalist. The hospitalist also transferred the HAWKS to a higher level of care such as the PCU or ICU, if needed. The hospitalist or PA collaborated with the nurses and the surgical residents regularly with regard to the HAWKS, thereby increasing awareness of high-risk patients on the floors. Hospital-wide RRT were introduced by the hospital in 2006. The role of the SCoC hospitalist in the PCU was identical to the one in the pilot study. The physician extenders were mandated to attend the “Fundamentals in Critical Care Support” course. Surgical residents went through simulation-based training for management of acute physiological deterioration and central line insertions at the patient safety institute to improve their response to HAWKS.

Hospital-Wide CoC Study

The CoC study was done between June 2009 and November 2009 with data collected 6 months pre- and postimplementation of CoC for estimating the benefit of intervention.

The study was done at Geisinger Wyoming Valley Medical Center (GWV) located in Wilkes-Barre, PA, a 242-bed hospital (Campus D) serving as 1 of the 2 hub hospitals of Geisinger Health System. GWV had a 14-bed medical/surgical ICU with an open model progressing toward a intensivist-run closed model and a telemetry/step-down unit. All adult medical and surgical patients admitted to GWV during the study period were included. Cardiothoracic surgery patients and patients located in the Heart Hospital were excluded. The CoC program elements were presented to all stakeholders in multiple forums at Geisinger including the system-wide Clinical Operations Leadership Team, and System Leadership Council, Clinical Leadership Group, and Medical Staff meeting, Performance Improvement Committee and Nursing Cancer En-

hancement Program, Heads of Departments, Hospitalist Group, Care Manager Group, and to individual physicians and private practice groups, during a 3-month period. On implementation of CoC, the following interventions were done to redesign healthcare delivery of inpatients at GWV. The redesign of this iteration of CoC consisted of the following: (a) Hospital anatomy redesign: (i) reorganization of hospitalist led, floor-based teams; (ii) aggregation (cohorting) of patients to specific floors based on medicine/surgery/specialties; and (iii) concurrent floor-based, standardized, multidisciplinary CoC rounds in morning hours; (iv) acuity stratified HAWK rounds on the floors at periodic intervals; and (v) real-time communication system programmed in Vocera technology (Vocera Communications Inc. San Jose, CA). A new 13-bed PCU was created and staffed by hospitalists with experience in critical care. Hospitalists were reassigned to be floor-based and charged with oversight responsibility for coordinating care and ensuring quality for patients in their assigned floor, in addition to their own patient panel. Hospitalist-led multidisciplinary rounds were conducted on each of the floors with nurses, care managers, pharmacists, dieticians, and physical/occupational therapists. A multidisciplinary rounding (MDR) tool was developed to facilitate and standardize rounds using the Epic EHR system. Vocera wireless communication devices were used for real-time communication between hospitalists and other stakeholders. The HAWK and DOVE system of risk stratification was also adopted with the addition of the HAWK identifier located in the EHR.

Data Collection

For the pilot SCoC study, the metrics measured were LOS of surgical patients and all-cause mortality of surgical patients in the ICU, PCU, and total surgery care center. Data were collected for the years 1998–2004 from the office of planning and finance. LOS and mortality data were obtained from the hospital administration. The hospital used the PHAMIS Last Word healthcare information system. This is an integrated hardware and software system and consists of modular applications that collect, store, and organize patient central information as a single relational database that is used to support decision-making in patient care, finance, and administration. This system was queried to track surgical discharges by attending physicians within the surgery care center. The list of surgeons within the department of surgery was also obtained from the source database. Data acquired included the following: (1) Total number of patients in each unit each year; (2) Case mix index (CMI) as measure of patient severity/complexity for patients in these units; (3) average LOS in SICU, PCU, surgical floor; (4) Total hospital LOS for those patients with a stay in SICU; (5) Total hospital LOS for those patients with a stay in PCU; (6) Mortality in SICU, PCU, and floor; (7) Surgery care center mortality at Moses Campus 1998–2004; (8) Surgery care center mortality at Weiler Campus 1998–2004; (9) Direct variable costs of patient care in 2004 diagnosis-related group (DRG; in dollars) was used to estimate the cost of care delivered (direct variable costs includes nursing, pharmacy, laboratory, radiology, room, and board and excludes operating room, recovery room, surgeon, and other professional costs of care); At LIJMC, the mortality data were obtained from the Krasnoff that uses SPARCS data and filters on principal service “SURG.” The O/E ratios for hospital-wide mortality compared with surgery and the readmission rates were obtained from the Premier Healthcare Alliance data system. The LOS data were obtained from monthly reports sent to the Department of Surgery from the clinical decision support system at LIJHS. At GWV the comparative mortality data between Campus D and the hospital-wide group (HWG) was obtained from the CareScience Quality Manager and Premier Healthcare Alliance QUEST databases. The LOS data were collected by the Siemens

hospital financial database. In all 3 studies severity of illness was measured using DRG-weighted CMI.

Statistical Analysis

Data are presented as means \pm SD and proportions as appropriate. Continuous data were analyzed with the 2-tailed Student *t* test when normally distributed and with Mann-Whitney *U* test if they were not normally distributed. Proportions and rates were compared by χ^2 test or Fisher exact test. Since our sample sizes were large enough, there was little need to perform/report Fisher exact test, and the comparisons were done by χ^2 test. To estimate the effect of the SCoC on crude mortality, we conducted linear regression analyses of yearly mortality data before and after the implementation of the SCoC model; each year was treated as 1 data point. The goal of this analysis was to compare the slopes of the regressions analyses using the Student *t* test computed as the difference between the slopes divided by the standard error of the difference between the slopes to establish whether the implementation of the SCoC had a statistically significant impact on crude mortality. In the pilot study, the slopes for <2001 and >2001 were estimated by fitting a regression spline model with a single knot at the year 2001. Statistical significance was accepted to correspond to a 2-tailed *P* value of 0.05 or less. Statistical analyses were done with SPSS version 15 for Windows (SPSS Inc, Chicago, IL).^{8–10}

QUEST

High-performing hospitals is a 3-year large scale collaborative of 160 hospitals focused on accelerating the improvement of healthcare cost, quality and safety, which is lead by Premier and the Institute for Healthcare Improvement.¹¹ The safety measure includes a mortality ratio goal of achieving the top quartile of performance. Mortality is a severity-adjusted rate using the CareScience methodology.¹¹ Mortality is risk-adjusted independently and given its own expected outcome (risk) that is matched to the observed outcome (raw rate). The index (O/E Ratio) is then calculated from these 2 elements. Expected outcome rates for any facility or grouping of patients are based on the characteristics of those patients and a model of the relationship between patient characteristics and outcomes. The model is estimated statistically by means of regression analysis of a sample drawn from a defined population of hospital discharges. This comparative database includes approximately 14.5 million discharges from 570 acute care facilities in the Premier database.¹¹ The choice of relatively “low” significance (at 75% and 90% when compared with 95% and 99%) reflects the philosophy behind the Care Science risk model, that the data should drive quality improvement—that it should be highly sensitive but not very specific—in tolerating false positives to avoid false negatives.

RESULTS

Pilot Study

Hospital Mortality

Overall surgical mortality was the main outcome measure to demonstrate the benefit of SCoC. Table 1 shows total Surgery Care Center mortality in Campus A categorized by year, into 2 cohorts: preintervention (1998–2000) mortality rate range 1.3% to 1.5% and postintervention (2001–2004) mortality rates of 0.9% to 1.1%. This 25% reduction of mortality post-SCoC implementation was highly statistically significant, analyzed statistically by χ^2 test. Linear regression showed a significant progressive decline in mortality trending over the 7-year period. Whereas there was a difference in the slope between 1998–2000 and 2001–2004, because of insufficient time points (3 years pre- and 4 years postimplementation) a

TABLE 1. Pilot SCoC: Total Surgery Care Center Mortality: Campus A

	Year	No. Patients	No. Deaths	Mortality Rate*
HCG	1998	5850	88	1.5%
	1999	6187	85	1.4%
	2000	5462	70	1.3%
IG	2001	5501	63	1.1%
	2002	5703	62	1.1%
	2003	5533	52	0.9%
	2004	5333	55	1.0%

*Linear regression 1998–2004, $P < 0.0001$.

χ^2 test, < 2001 versus ≥ 2001 , $P = 0.0002$.

CMI unchanged 1998 to 2004.

Comparator: Campus B $\rightarrow < 2001$ versus ≤ 2001 : 1.25% versus 1.20%, $P = ns$.

HCG indicates historic control group; IG, intervention group; SCoC, surgical continuum of care.

TABLE 2. Pilot SCoC: SICU Outcomes (n = 3563)

Year	No. Admissions	No. Deaths*	Average LOS	SICU Patient Days*	Average Hospital LOS	Total Hospital Patient Days†
1998	568	49	4.7	2669.6	16.6	9428.8
1999	564	43	4.4	2481.6	14.7	8290.8
2000	511	42	5.2	2657.2	15.5	7920.5
2001	462	31	4.8	2217.6	14.3	6606.5
2002	446	35	4.9	2185.4	15.1	6734.6
2003	535	30	4.2	2247.0	14.6	7811.0
2004	477	31	4.3	2051.1	14.5	6916.5

* χ^2 test, < 2001 versus ≥ 2001 , $P = < 0.05$.

†SICU mortality rate: no significant change ($P = 0.10$).

SCoC indicates surgical continuum of care; SICU, surgical intensive care unit; LOS, length of stay.

valid statistical difference using the spline regression model with a knot at 2001 could not be demonstrated. To control for secular trends, we used Campus B as comparator (n = 21,809 cases). Although there was a trend in mortality reduction in Campus B year-over-year, there was no statistical difference in the mortality rates in cohort analysis of years 1998–2000 versus 2001–2004. Taken together, the data suggests that, whereas there were secular trends in mortality reduction year-on-year in both campuses during 1998–2004, the cohort comparison of 1998–2000 versus 2001–2004 showed highly statistically significant reduction only in Campus A related to SCoC implementation.

SICU Outcomes

Reducing SICU bed utilization and expanding PCU beds were part of the implementation plans for SCoC. Despite the fact that less acuity cases were admitted to PCU reducing SICU admissions, there was a reduction in the mortality in SICU post-SCoC: 8.2% during 1998–2000 and 6.7% 2001–2004 ($P = 0.10$) as shown in Table 2. Even though not statistically significant because of the small denominator, the mortality reduction in SICU could be attributed to 24/7 staffing during this period, as well as reduced readmission to SICU attributable to SCoC. The efficiency created by SCoC outside the SICU resulted in significant reduction of total hospital patient days for patients being

discharged from SICU to the regular beds or to PCU. Net cost savings resulted from reduction of SICU patient days and total hospital patient days of SICU patients.

PCU Outcomes

To improve patient outcomes from the regular floors, and to reduce SICU utilization, the number of PCU beds was increased from 9 to 12 with expanded criteria and on-site hospitalist, who collaborates with surgical teams. The increase in admissions to PCU during 2001–2004 (Table 3) was attributable to 2 groups of patients: the group of patients with lower ICU severity who were SICU cohorts during the pre-SCoC period; and HAWK patients brought into PCU for rescue from the regular floors. More cases during 2003 and 2004 in the PCU may reflect the following: (1) new program expansion (eg, neurosurgery, bariatric surgery, vascular surgery); (2) patients admitted for monitoring posthigh complexity procedures; or (3) postsurgical admission of high-risk population who were placed in PCU before transitioning to regular beds. Active hospitalist management interdigitating with surgical resident/attending-based teams enabled efficient discharge process. As PCU hospitalist participates in HAWK rounding; patients are managed as HAWKs on the regular floors until discharge, optimizing medical status and preventing deterioration.

PCU was the central focus for mortality reduction, with on-site hospitalist coverage possessing critical care training, interdigitating with surgical teams. This prevented delays in management of medical problems. In the pre-SCoC model, the patients in the PCU were managed by the respective surgical teams; the management sequence of patients requiring immediate attention followed the “classic” academic health center chain of command, namely, nurse paging surgical resident covering the floors, who intern communicates with surgical chief resident. This “delay chain” included calls to attending and requesting medical consultation. The hospitalist staffing of PCU obviated all these delays and the comanagement model between the PCU hospitalist and surgical teams established ongoing goals of care, improving efficiency, and reducing mortality significantly.

Outcome Summary of Pilot Study

The salient findings of the pilot study are summarized in Table 4. The overall mortality in the “Surgery Care Center” at Campus A reduced from 1.4% pre-SCoC to 1.05% post-SCoC

TABLE 3. Pilot SCoC: PCU Outcomes

Year	Average LOS			Total Patient Days	No. Deaths
	Total Cases	Total Hospitals	PCU		
1998	709	15.8	3.9	2775	9
1999	777	12.8	3.4	2609	17
2000	806	12.9	3.4	2778	11
2001	838	10.3	2.7	2356	5
2002	853	9.7	2.6	2539	4
2003	961	9.4	2.3	2288	1
2004	1217	8.9	2.1	2648	8

Mortality estimate by $\chi^2 < 2001$ versus ≥ 2001 .

$P < 0.0001$; linear regression model 1998 to 2004, $P < 0.0002$.

Average LOS < 2001 versus ≥ 2001 , $P < 0.001$; total hospital days of PCU.

Patients < 2001 versus ≥ 2001 , $P < 0.001$.

SCoC indicates surgical continuum of care; PCU, progressive care unit; LOS, length of stay.

TABLE 4. Pilot SCoC: Outcome Summary

Variable	IG	HCG	P
SLOS	4.4 ± 4.6	4.5 ± 4.3	0.52
PLOS	2.7 ± 1.7	3.7 ± 2.0	0.0001
HLOS/S	15.5 ± 11.4	18.4 ± 11.4	0.01
HLOS/P	11.1 ± 8.4	15.3 ± 9.8	0.0001
SICU mortality	127/1920 (6.7%)	134/1643 (8.2%)	0.10
PCU mortality	17/3693 (0.4%)	35/2181 (1.6%)	0.0001
Overall mortality	232/21,838 (1.06%)	243/17,256 (1.4%)	0.002

SCoC indicates surgical continuum of care; IG, intervention group; HCG, historic control group; SICU, surgical intensive care unit; PCU, progressive care unit; SLOS, SICU length of stay in days; PLOS, PCU length of stay in days; HLOS/S, total hospital length of stay for SICU patients, in days; HLOS/P, total hospital length of stay for PCU patients, in days.

TABLE 5. Validation SCoC: Total Surgical Mortality

	Cases	Deaths	Mortality Rate*	CMI
2001	4576	102	2.0	1.76
2002	4845	88	1.82	1.74
2003	4480	86	1.92	1.65
2004	4178	77	1.84	1.71
2005	3988	77	1.93	1.70
2006	4021	68	1.69	1.72
2007	4022	62	1.54	1.70
2008	3891	61	1.57	1.71

*2001–2005 versus 2006–2008, $P < 0.03$.

SCoC indicates surgical continuum of care; CMI, case mix index.

implementation, with PCU playing a major role in saving lives as the “safety net” location for transferring “HAWKs” from the floors and comanaging medical/surgical issues. As the total deaths in SICU each year post-SCoC was lower than the preimplementation years, it did not reach statistical significance. The significant improvements attributable to SCoC in increasing PCU throughput and reducing the LOS of patients transferred out of PCU and SICU (HLOS/P and HLOS/S, respectively) are shown.

Validation Study

Mortality Analysis

We compared the annual mortality rates for 5 years pre-SCoC (2001–2005) with 3 years’ post-SCoC implementation (2006–2008) shown in Table 5. The regression of slope analysis showed a significant trend in benefit in mortality related to intervention, with a break in the slope between 2005 and 2006 ($P < 0.02$). The CMI remained virtually unchanged during the 8-year period. The overall surgical mortality rates for the pre- and poststudy cohorts were: 430/22,067 (1.95%) versus 191/11,934 (1.60%), respectively ($P < 0.02$).

As we demonstrated that the mortality reduction was not because of secular trend, we performed further drill down analysis using Premier dataset with the purpose of demonstrating SCoC mediated risk-adjusted mortality reduction. This SCoC validation analysis was performed as a “nested” study, comparing medical center-wide mortality with surgical DRG mortality, shown as risk-adjusted mortality index from Premier dataset. Table 6 shows that medical center mortality index improved from 1.26 in 2005 to 1.1 in the years 2006/2007 because of medical center-wide quality programs. The corresponding improvement in mortality index for surgical DRGs was from 1.16 in 2005 to 0.85 in 2007. This data implies

TABLE 6. Validation SCoC: Morality Comparison

	Year	Cases	No. Deaths	Mortality Rate	Expected Mortality Rate	Observed/Expected Mortality Rate Index*
LII-surgery	2005	3124	62	1.98%	1.72%	1.16
LII-surgery	2006	3011	49	1.63%	1.81%	0.9
LII-surgery	2007	2946	41	1.39%	1.63%	0.85
LIJMC	2005	29,870	763	2.55%	2.02%	1.26
LIJMC	2006	30,219	744	2.46%	2.24%	1.1
LIJMC	2007	30,584	669	2.19%	2.02%	1.08

*Mortality Odds Ratio Index: LIJMC, 2005 (1.2) versus LII-Surgery, 2007 (1.6). Significant at 95% confidence level.

Comparison of risk-adjusted mortality index (observed/expected mortality rates) of Total Medical Center (LIJMC) versus Surgery Care Center (LII-Surgery).

SCoC indicates surgical continuum of care; LII-Surgery, Surgery Care Center; LIJMC, Long Island Jewish Medical Center.

that the medical center wide mortality index improvement is largely contributed by surgical DRGs: this deduction is further strengthened by the mortality index odds ratio of medical center/surgical DRG of 1.2 in 2005 versus 1.6 in 2007, demonstrating additive improvement attributable to SCoC over medical center wide quality initiatives.

LOS Analysis

The LOS for surgical patients was analyzed both as month-to-date, as well as annualized, compared with budget, pre- (2003–2005) and post- (2006–2007) SCoC implementation. The immediate impact of SCoC in LOS is demonstrated in Figure 2A and B. Figure 2A shows the monthly LOS for calendar year 2005: the actual LOS was consistently above budget by 0.4 to 0.5 days before SCoC. On seeking hospital medical board approval in August 2005, we implemented process redesign during September to November 2005: restructuring of team rounding, presentation of the program to surgical faculty and resident teams, reorganization of team PA roles, and team training. SCoC was implemented in stages between October and December 2005 upon recruitment of physician/PA leaders. The LOS benefit was observed in December 2005, immediately upon the start of multidisciplinary team rounds, and persisted for the rest of the study duration. Figure 2B also demonstrates 2 periods (July–August and October) with “beach erosions,” the first period corresponding to the beginning of academic year with new resident teams and the second period requiring the cohort of surgery presentation of team specific data at the departmental conference seeking corrective behaviors. The LOS reduction in cohort analysis in Figure 3 shows that the LOS was actual greater than budget pre-SCoC, and actual less than budget post-SCoC; the actual LOS was 0.7 days below budget during the second year of SCoC.

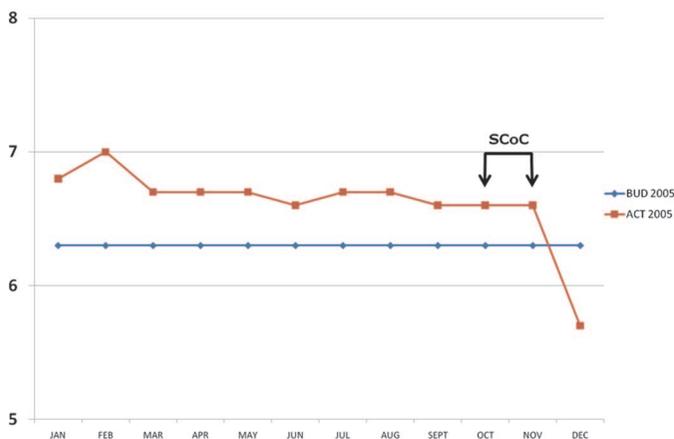
Readmission Analysis

One final analysis performed in the validation study was to investigate whether the improvement in shorting LOS affected readmission rates adversely. We used the Premier dataset. The medical center had excellent readmission rates as shown in Table 7 in 2005 before SCoC implementation. In 2006/2007, there was no adverse impact on readmission rates; if any, there was improvement in readmissions as shown by the statistical significance of $P = 0.006$, and $P = 0.004$ for surgical readmissions in 2005, compared with $P < 0.001$ in 2006/2007.

Hospital-Wide CoC Study

After an assessment of feasibility of implementation and adaptability of SCoC to a hospital-wide medical/surgical cohort

A Validation SCoC: Pre-implementation Analysis of LOS



B Validation SCoC: Post-implementation Analysis of LOS

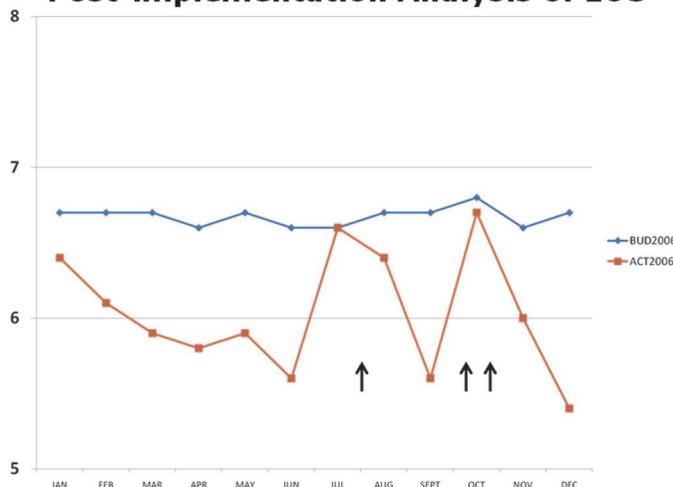


FIGURE 2. Monthly LOS depicted in days in surgical service in Campus C, before (A) and after (B) implementation of SCoC. Timing of SCoC implementation shown in (A). In (B), single arrow (↑) shows attenuation of LOS benefit in July, resulting from new surgical resident group requiring education regarding SCoC and team meetings; and double arrow (↑↑) depicting LOS recidivism requiring sharing the information with the department faculty, eliciting behavior change.

Validation SCoC: Comparative Analysis of LOS

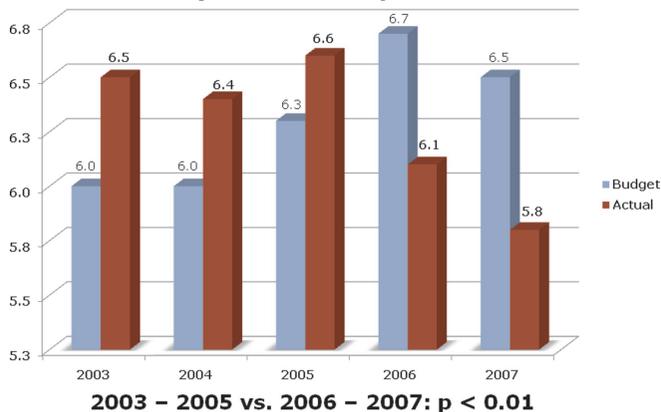


FIGURE 3. Comparative analysis of LOS in surgery. Budgeted < Actual during pre-SCoC years and Budgeted > Actual post-SCoC implementation.

(CoC study), and engagement of all stakeholders through multiple presentations to individual groups and medical board during February–May 2009, we initiated the program in June 2009. Mortality rate comparison between Campus D—HWG and standard practice of nationwide pool was done using CareScience and QUEST databases. The risk-adjusted mortality data are depicted in Table 8. We performed a 1-year analysis (6 months pre-CoC vs. 6 months post-CoC): the risk-adjusted mortality index declined from 1.09 in pre-CoC cohort to 0.89 in post-CoC cohort. Because of the fact that this 6-month analysis does not provide sufficient data points, the mortality reduction was significant at 75% confidence level. Nevertheless, the clinical importance of lives saved transcends statistical significance.

Figure 4 shows QUEST mortality drilldown report as a function of monthly data of Campus D, in comparison with top

TABLE 7. Validation SCoC: Hospital Readmission Rates Pre and Post

Group	Year	Observed	Expected	P
Hospital	2005	9.71%	10.57%	<0.001
	2006	9.66%	10.57%	<0.001
	2007	9.93%	10.57%	<0.001
GS/VASC*	2005	8.85%	9.92%	0.006
	2006	8.02%	9.88%	<0.001
	2007	8.49%	10.28%	<0.001
SURG/CT** excl	2005	7.02%	7.70%	0.004
	2006	6.18%	7.53%	<0.001
	2007	6.83%	7.60%	<0.001

*General Surgery/Vascular Surgery.

**Surgical Service, exclusive of Cardio Thoracic Surgery.

Data Source: Premier, Inc. Charlotte, NC.

SCoC indicates surgical continuum of care.

performance mortality index threshold of 0.89. As in the CareScience report, this report affirms the benefit of CoC in progressively reducing risk-adjusted mortality to 0.77, below the top performance threshold.

Finally, CoC mirrored the SCoC in terms of LOS benefit as shown in Figure 5.

Lives Saved and Cost

Our pilot data estimated that if SCoC model is implemented in all surgery care centers in the United States, 22 lives could be saved per approximately 400-bed institution. However, since the CoC model seems to benefit both medical and surgical cohorts, based on our recent HWG data, we estimate that approximately 10 lives could be saved in each 100-bed institution: based on the total bed strength in all United States-registered hospitals of 951,045, we estimate that the CoC model if fully implemented could save 95,000 lives per year. Any incremental staffing cost is overshadowed by overall cost savings from this program. In the pilot study, we

TABLE 8. Hospital-Wide CoC: Mortality Rate Comparison

Month	Total Outcome		Actual	Expected	Deviation	O/E Ratio**
	Cases	Cases				
Dec 2008	945	931	3.4%	3.0%	0.5%	1.16
Jan 2009	914	900	3.2%	3.0%	0.2%	1.07
Feb 2009	879	867	2.8%	2.3%	0.4%	1.18
Mar 2009	906	894	2.6%	2.7%	-0.1%	0.96
Apr 2009	1018	1005	2.7%	2.7%	0.0%	1.00
May 2009	922	914	3.0%	2.5%	0.4%	1.16
Totals	6440	6351	3.0%	2.8%	0.2%*	1.09
Jun 2009	916	898	2.7%	2.8%	-0.1%	0.95
Jul 2009	999	984	2.9%	2.8%	0.1%	1.04
Aug 2009	923	912	2.1%	2.5%	-0.4%	0.83
Sep 2009	984	974	2.1%	2.6%	-0.6%*	0.78
Oct 2009	1045	1033	2.1%	2.6%	-0.5%	0.83
Nov 2009	930	918	2.4%	2.6%	-0.2%	0.92
Totals	5797	5719	2.4%	2.7%	-0.3%*	0.89

Risk-adjusted mortality index, shown as O/E Ratio for 6 months pre- and 6 months post-CoC.

*Significant at 75% confidence level.

**Observed/expected ratio.

Data Source: CareScience Quality Manager.

CoC indicates continuum of care.

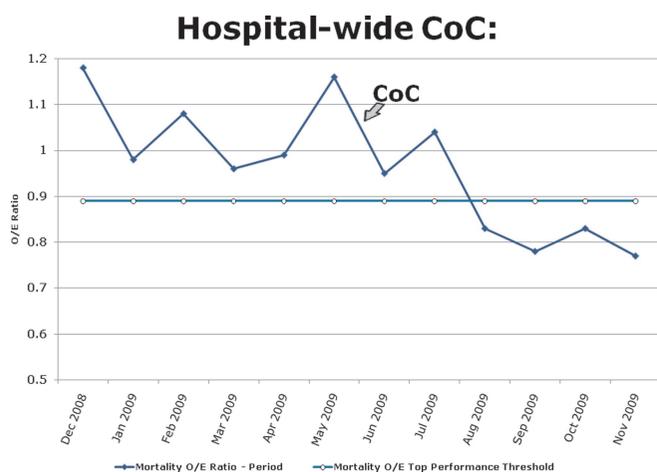


FIGURE 4. Risk-adjusted mortality index in Campus D for medical/surgical total adult inpatient cohort, depicted for 6 months pre- and postimplementation of CoC. QUEST performance report of index hospital (GWV, Campus D) versus national pool of top performance threshold.

calculated the cost savings by estimating the reduction of SICU utilization, enhanced PCU throughput by LOS reduction, and the reduction in total hospital days for patients discharged from SICU and PCU: the range of cost savings was \$851,511 to \$2,007,388 per year. In the validation study we performed before-and-after type of analysis comparing overall costs for top DRGs. For DRG 148, a common DRG for small/large bowel procedures in general surgery, the reduction of variable cost (radiology, blood bank, pharmacy, and nursing) was \$452,000 per year, 2005 versus 2006.

DISCUSSION

Patient-centered care has been the axiom in IOM's definition of high quality health systems, commonwealth fund's high perfor-

mance health system, and Medical Home model.^{3,12} Our SCoC/CoC model could be considered an acute care in-patient correlate of "Medical Home" model in outpatient primary care.¹³ In the patient-centered Medical Home model, the practice takes ownership of timely, appropriate, and comprehensive care across the lifespan, delivered by a team of individuals led by patient's personal physician. The second cornerstone of the Medical Home model is patient-centeredness, with tailoring of care to meet the needs/preferences of patients.¹³ The third aspect is new-model practice, emphasizing electronic clinical information technology. In essence, CoC model emphasizes all these 3 tenets in the inpatient setting: continuity through transition points, proactive intervention to preempt complications, and early recognition of deterioration for timely rescue, team performance, patient-centered tailored approach, and our more recent addition of EHRs platform for real-time information sharing and clinically effective rounding.

When we developed the SCoC, medical comanagement of high-risk surgical patients (pre-emptive care) and attention to signs of early deterioration (targeted response) were the salient components, before the popularization of the RRT concept. Earlier observations by Silber and Leape about "failure to rescue" and adverse events in hospitalized patients led subsequent investigators to auger in the concepts of RRT, medical emergence teams (MET) and critical care outreach teams to prevent cardiopulmonary arrest, admission to ICU, and reduce mortality.¹⁴⁻¹⁷ Silber et al, in their analysis of 5972 Medicare patients undergoing elective surgery, concluded that "failure to rescue" was associated more with hospital characteristics than with patients' admission severity of illness, and implied that hospitals providing better care succeeded in preventing sicker patients from developing adverse occurrences.¹⁷ As single institutional observational studies suggested benefit, subsequent randomized trials and multi-institutional studies failed to uniformly confer advantage to RRT/medical emergence team.^{16,18} Although this concept was being tested for its rigor, it was already adopted across US hospitals as an early warning system to improve hospital patient mortality and cardiac arrests.

Because our SCoC and CoC programs involve proactive management of patients multidisciplinary teams and because the acuity stratified "HAWK" rounding addresses patient status prior to the physiologic deterioration, we hypothesize that the patients are seen frequently in the occult stage of "pseudo-stability" prior to reaching "physiologic derangement," that triggers RRT using either the standard criteria or modified early warning score.¹⁹ Figure 6 is a working model demonstrating the "CoC" zone preceding the "rapid response" zone with earlier attention during disease progression pathway resulting in better return of investment both in terms of lives saved and cost of care. The addition of the formal "HAWK" listing in our validation study and further enhancement of this acuity stratification and quality rounding using EHR and formal MDR tool will enable us to bend the disease progression curve, enabling a wider window to improve mortality further (Fig. 7). Another difference between SCoC and RRT is that, in RRT the team responding to physiologic deterioration often has no prior knowledge of the patient both pre- and post-RRT. The patients are either transferred to higher level of care or the care returned to the primary team. In SCoC, this "episodic" care is avoided, since the targeted response team has members of SCoC team, and there is continuity of patient care during the time around physiologic deterioration.

During the initial phases of implementation of both our pilot and validation studies, the common refrain from the practicing surgeons at these institutions was that the SCoC is focused on discharging patients too soon without consideration for quality and that the readmissions will increase. On sharing the benefits of SCoC on an ongoing basis, our colleagues became convinced that quality

GWV Medical/Surgical Inpatient Length of Stay Nov 2008 - Nov 2009

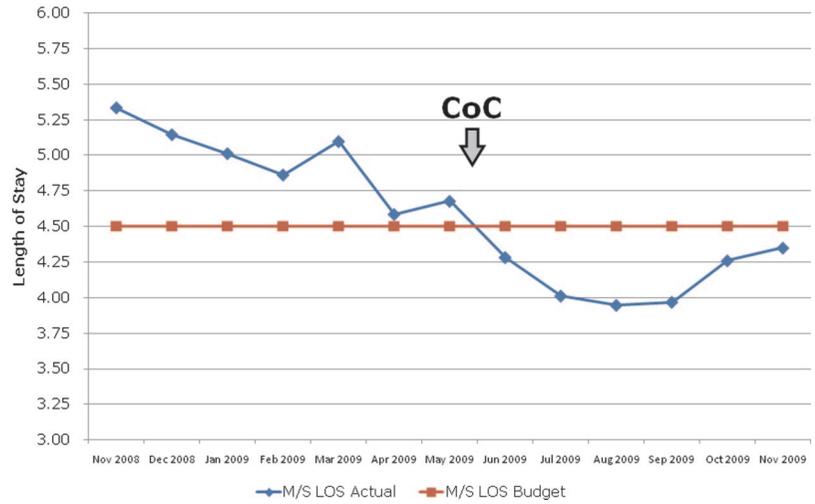


FIGURE 5. Monthly LOS report in Campus D, pre- and postimplementation of CoC. (■) Budgeted versus (◆) Actual LOS in days.

Acute Care System Redesign: 3 Zones vs. ROI
ROI In Disease Progression Management

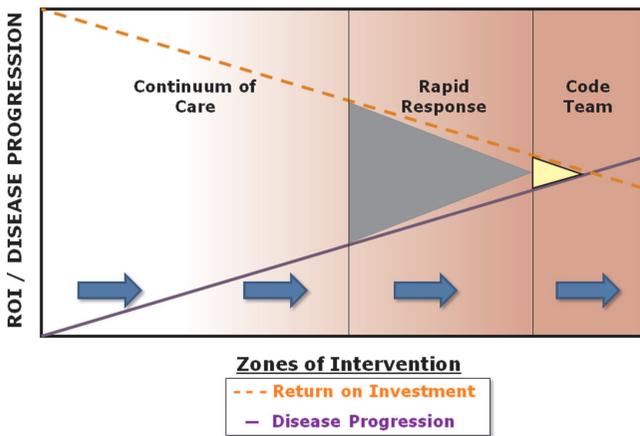


FIGURE 6. A reconfigured conceptual model of Figure 1, showing hypothesized return on investment (ROI) in terms of lives saved and cost, expected from RRTs and CoC program. (—) Disease progression. (- - -) ROI. The small triangle and larger triangle represent hypothetic benefits from Code Team and RRT activation respectively. Potential larger benefit of CoC due to patient attention prior to physiologic de-ramentation is noticed.

Acute Care System Redesign Patient Safety Strategies

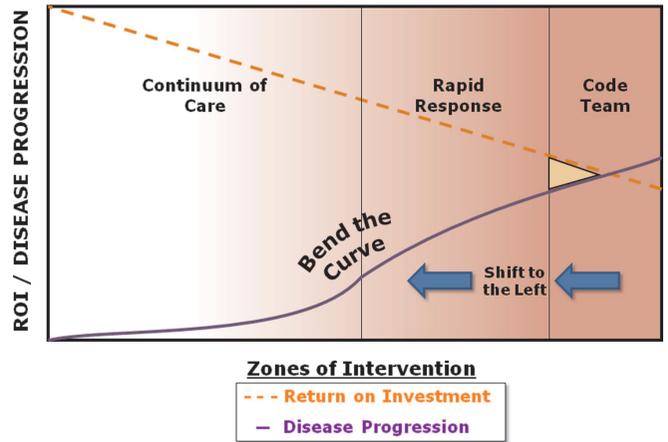


FIGURE 7. Our patient safety model to impact mortality of hospitalized adult patients, involving hospital anatomy/work-flow redesign ('shift to the left') and risk modification of individual patients by HAWK rounding ('bend the curve') to enhance return on investment (ROI). (—) indicates disease progression; (- - -), ROI.

care is synonymous with shorter LOS and the readmissions did not get worse as a result of SCoC. In fact, although further studies will be needed to address the veracity of our claims, we feel that the snapshot of data on readmissions in our validation cohort suggests that the SCoC benefits readmission rates by medical optimization of the surgical patients prior to discharge. Lending weight to our suggestion are the studies addressing readmission diagnoses, especially among Medicare beneficiaries, that 70.5% of readmissions within 30 days of surgical discharge were for a medical condition.²⁰ Perhaps, attention to medical issues in the surgical cohort during hospitalization could have resulted in reduced readmission rates observed in this study. As the evidence is overwhelming that good

quality care does not equate with expensive care, the associations are inconsistent between hospitals' cost of care and quality of care and between hospitals' cost of care and mortality rates.²¹ Most evidence does not support that low-cost hospitals discharge patients earlier with higher readmission rates.^{21,22} Our data support that reduction in mortality, the overall measure used here for quality, is consistent with shorter hospital stay, and may in fact reduce readmission rates.

In a retrospective court study of Medicare fee-for service beneficiaries, comanagement of hospitalized surgical patients by any medical physician increased from 33.3% in 1996 to 40.8% in 2006, and this increase was attributable to comanagement by hospitalists, which increased from 1.71% in 1996 to 12.5% in 2006.^{23,24} The benefits of medical comanagement are notable in orthopedic/geriatric patients that include the following: reduced time to surgery, LOS

and readmissions, fewer complications and transfers to ICU, increased likelihood to discharge home, and improved stakeholder satisfaction.^{25–29} Patients cared for in major teaching hospitals were substantially less likely to be comanaged.²³ Since 1995 there has been a substantial increase in the care of hospitalized patients by hospitalists, with 37% of inpatient E&M codes in 2006 from Medicare sample set.³⁰ Hospitalists are increasingly involved in reducing LOS/costs, improving transition in care/readmissions, and enhancing quality; however, the evidence of benefit is conflicting in both observational and randomized studies.³¹ Earlier studies of hospitalists in surgical literature were orthopedic surgery.^{28,32} Our study invokes hospitalists' role in improving perioperative outcomes and efficiency of inpatient care. Hospitalists served as the key group of physicians in medical comanagement of the surgical patients and staffed the PCU, HAWK rounding, and targeted response team. Integration of the CoC physician, a hospitalist with surgical teams and training in critical care (eg, FCCS training), had salutary effect in optimizing outcomes in our study.

MDR can be considered a tool or a sustained improvement implementation system, and has been used in ICUs and other specialized settings such as trauma management and cardiology, such as “AHA—get with the guidelines program.”^{33,34} MDR is used in hospitals to improve discharge process and transitions of care (TOC), and increasingly to minimize readmissions. When CoC was introduced in our study in Campus D, there was already an established MDR, termed interdisciplinary team rounds, for TOC. The addition of clinical care/quality focus to the interdisciplinary team or TOC rounds and the implementation of CoC MDR tool to enable addressing all quality domains resulted in further improvements in mortality and LOS as shown in Figure 5 and Table 8.

In the ICU setting severity scoring systems were purportedly not designed to determine when an individual patient should receive a specific therapy.³⁵ Examples of such scoring systems are APACHE, Mortality Probability Model, and SAPS 3. Severity scores have proved to be remarkably reliable predictions of short-term mortality for cohorts of patients admitted with critical illness.³⁵ Our interest in-risk scoring is not only in predicting mortality probability, but more importantly stratifying the cohort at risk and individualizing timely intervention to mitigate the risk. Our approach of developing “actionable risk scoring” has iteratively improved in the 3 successive studies: from a subjective categorization of high-risk patients for PCU admission in the pilot study, to developing a paper-based “HAWK/DOVE” risk groups for acuity stratified rounding in the validation study, and now toward EHR-based “HAWK” stratification in the current CoC study. We are developing a composite numeric score utilizing validated scales (POSSUM, TISS) and perioperative comorbidities for predictive modeling and actionable rounding using EHR.³⁶ In an analysis of 84,730 patients undergoing general/vascular surgery during 2005–2007, using data from ACS-NSQIP, Ghaferi et al found that the difference between low- mortality hospitals and high-mortality hospitals are not in the incidence of complications, but in the mortality resulting from major complications.³⁷ This study supports the growing evidence, popularized by the study of Silber et al, “failure to rescue” as a measure of hospital quality.¹⁷ Several factors come into play in these better performers: better/earlier recognition of clinical perturbations, faster communication, and availability of system resources and enlistment of protocols/care pathways to manage complications.

Because variation of surgical mortality is multifactorial, several approaches such as selective referral, process compliance, and outcomes measurement reflect different philosophies to improve surgical quality.³⁸ One tactic suggested to reduce perioperative mortality from high-risk surgeries is selective referral to high vol-

ume centers.³⁹ Such regionalization is an impractical national health policy initiative, and further, since some community low-volume hospitals have good outcomes, this regionalization is unnecessary. A potential alternative paradigm to this approach has been suggested, namely, to focus referrals of high-risk patients only.⁴⁰ This may well be an option, but in the interim, an alternative equitable quality initiative is to enable all hospitals to risk assess patients better and improve perioperative care by tailored timely response. In this regard, in addition to our proposed approach of local, iterative process improvement, surgical collaboratives based on hospital groups such as NSQIP, SCOAP, and Michigan Surgical Quality initiative have generated quality improvement strategies.^{37,38,41–43}

Our study has several limitations. In a longitudinal study, secular trend, despite efforts to control, may still be a confounding variable. The Institute for Healthcare Improvement advises that linking the effect of interventions by individual institutions to the number of lives saved should be done with caution, because the confidence intervals of the mortality numbers are bound to be large, and appropriate adjustments for secular trends and case mix are often missed.⁴⁴ We have attempted to correct for these limitations to the best of our ability, short of a randomized controlled trial with a control hospital without changes in quality measures other than SCoC/CoC, because such a randomized controlled trial will be unethical. Both in our validation and CoC cohort, we compared mortality benefit using standardized mortality ratios. Such standardized mortality ratio and CMI assume “constant risk fallacy”; however, these are not bias-free, because of potential “differential measurement error” and “inconsistent proxy measures of risk.”⁴⁵

One of the effective methods of creating a culture of safety and sustainability of quality initiatives is education. Education modules to change physician practices with emphasis on quality through evaluation of outcomes are increasingly emphasized.⁴⁶ Educational programs, sponsored by American College of Surgeons, founded on principles of continuous professional development and practice-based learning and improvement, involve a 4-step cycle that encompasses outcomes and quality.⁴⁷ Simulations and simulators are key to acquisition and maintenance of skills, learning patient management through physiologic scenario development and improving team performance. We incorporated simulation-mediated performance improvement during our validation study by the creation of a basic curriculum for surgical residents and physician extenders and building new scenarios based on patterns of morbidity/mortality by annual and ad hoc reviews of failures. This is still work in progress, and will be important in the refinement of the current CoC model.

Our study demonstrates that a redesign of a hospital care delivery model to focus on mortality reduction (outcomes-driven) with acuity-stratified rounding and multidisciplinary team building coupled with targeted response based on dynamic risk profile of individual patients (patient-centered) can be accomplished with cost effectiveness (value-based). The tactics of accomplishing the overall strategic goals can be tailored to suit the local milieu of individual hospitals and systems with clinical effectiveness. Listed are some of the lessons learned for the success of SCoC/CoC: (a) flexibility in staffing model (ICU outreach with hospitalist staffed PCU in our pilot; intensivist/hospitalist with PA coleadership is validation; and floor-based hospitalist-led team approach in hospital-wide CoC study); (b) need for leadership approval and buy-in from all constituencies through individual and group discussions during implementation; (c) education and teambuilding across all stake holders such as MDs, PAs, nursing, care managers, etc; (d) periodic feedback communication at hospital-wide meetings; and (e) demonstration to the surgeons that their “ownership” of patients and referral relationships are not abrogated by implementation of medical comanage-

ment, and that this is a quality improvement program. This model of SCoC for surgical cohort and CoC for overall hospital adult patient population is complementary to other reliability science paradigms such as ProvenCare. Generalizability of our basic principles is evidenced by its use in 3 disparate systems and in settings that are resident-based, PA-based, and hospitalist-based. Our ongoing studies in CoC will further refine the system's redesign in EHR platform and personalized medicine for individualizing care to each hospitalized patient using predictive modeling and real-time risk mitigation with effective communication. Of course, the holy grail is how to enhance quality with concurrent reduction in cost beyond reducing LOS, because "cost" is an elusive target.

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Discussions

DR. DANIEL DEMPSEY (PHILADELPHIA, PENNSYLVANIA): Dr. Gheferi, Dr. Birkmeyer, and Dr. Dimick, in the December 2009 issue of *Annals of Surgery* (250:1029–1034) looked at Medicare patients undergoing 6 big general surgery or cardiac operations, and they found that the complication rates were the same in the best and

the worst hospitals, but that the failure-to-rescue rates were 2 to 3 times higher in the worst hospitals (the bottom 20%).

Silber and others at Penn, almost 20 years ago, pointed out that this failure to rescue was a hospital systems issue more than a doctor or a patient issue.

What Dr. Ravikumar et al have suggested is that by reengineering the way we provide postoperative inpatient care, we can decrease mortality, decrease LOS, maybe even save a little money. The authors acknowledged the lack of a prospective randomized design and the possibility of confounding variables or even the Hawthorne effect, but they tried to address this with a cohort 3-phase study.

I have 4 brief questions for Dr. Ravikumar. First, during the validation study, there were 191 deaths in the intervention group and 436 deaths in the larger, preintervention group. Did you conduct any peer review or case analysis on a sample of these deaths to see whether there really were fewer preventable deaths in the intervention group?

Second, how do we define the HAWKS; that is, those patients that bear closer monitoring or treatment? What are the most meaningful quantitative variables that help us identify these patients?

Third, can we accomplish the same thing that you described with telemedicine?

Finally, are there cohorts of patients for whom this makes more sense? For instance, it makes perfect sense to me that my orthopedic colleagues' patients could benefit measurably by being seen postoperatively by a nonsurgical hospitalist, but I find it a little harder to believe that my own patients would benefit similarly.

DR. RICHARD SHEMIN (LOS ANGELES, CALIFORNIA): High quality coordinated care requires hospital resources and increased personnel. These new costs can be balanced by fewer complications and perhaps reduced LOS or less time in the ICU.

Do you have any financial data to show whether the net impact of the new personnel justifying the cost? Clearly, the improved patient outcomes are the most important thing.

DR. MICHAEL ZENILMAN (BROOKLYN, NEW YORK): I would like to follow-up on Dr. Shemin's comment about cost. We recently established a similar system in Brooklyn: Early activation of codes, RRT, a closed ICU, and surgical hospitalists on call at night who regularly round through the recovery room, all the step-down beds, all the ICUs, and the emergency room. We found an increased utilization of the operating room at night, and more rapid time to the operating room. However, one of the things we found was the relative value units for the surgeons that are on call are pitifully low, which confirms that this is not a very cost-effective way of utilizing surgeons.

Do you have any relative value unit data on your hospitalists? How did you get the hospital to buy into this expensive concept?

DR. HENRY PITT (INDIANAPOLIS, INDIANA): The Leapfrog group suggested that ICU attending physicians are also an important part of this equation, not just the hospitalists. At Indiana University Hospital, when our group arrived several years ago, there was no dedicated surgical ICU team or house staff. Thus, one of the early changes implemented was the creation of a surgical ICU attending surgeon and house staff team. Over the past 5 years, we have clearly been able to show that the ICU observed-to-expected mortality ratios improved and that the overall surgical mortality improved. At your various institutions, did you already have ICU attending physicians? Did the presence of ICU attending physicians play any part in your improvement in mortality?

DR. STEVEN C. STAIN (ALBANY, NEW YORK): It would appear that the surgeons may be abrogating some of their postoperative care for their patients. That may have some important implications if payers decide to uncouple technical parts of the operation and their postoperative care.

Were there other changes in the hospitals that may have contributed to the improvement in their outcomes besides the additional continuity of care that was provided?

DR. LAWRENCE WAY (SAN FRANCISCO, CALIFORNIA): I have a similar comment. Last year, Dr. Marco Patti and I presented a article before the Association. We studied the state of California database for 3 major operations and found that the morbidity and mortality rates associated with these procedures decreased gradually and continually over the 15-year period that we studied; whether the hospitals used special programs, whether they were high-volume hospitals or low-volume hospitals or academically affiliated or nonacademically affiliated. We attributed this trend to some kind of systems effect complexity, but if a new program is started with this wave sort of rolling the way, you will need to use some kind of control to isolate the benefits of the program against the trend.

DR. THANJAVUR S. RAVIKUMAR (WILKES BARRE PENNSYLVANIA): Dr. Dempsey asked about mortality analysis pre- and postintervention in our validation study. Although we did not perform mortality analysis in the preintervention cohort, we did analyze our mortalities in the postintervention period, using a relational access database to group them into preventable versus nonpreventable. The causative factors in preventable mortalities were then grouped into team factors, technical factors, etc. We then used a simulation center for corrective actions, that is, team building, technical skills, training, etc. In addition, this led my residency program director to develop a patient safety curriculum that included creation of physiologic scenarios in our simulation center; such postoperative scenarios included myocardial infarction, occult bleeding, ARDS, cardiac tamponade, and sepsis. This strategy is useful in our iterative process redesign to identify areas for improvement by looking into our failures.

DR. DEMPSEY'S second question related to defining the HAWKS. It began with a subjective assessment of high-risk patients from the multidisciplinary rounds between surgeons and hospitalists. This evolved into a better clinical science, with the HAWK listing comprising: any patient discharged from ICU; patients undergoing complex surgical procedures especially with increased blood loss; those recovering postoperative intervention during the first 4 hours (eg, oliguria): More over, we are in the process of creating a numeric scoring system based on a combination of known physiologic scores such as POSSUM and criteria developed by our mortality analysis. We hope to load the scoring methodology into our EHR, to develop actionable items using decision support tools based on patients' composite risk profile. This will standardize our HAWK listing and rounding.

In response to the third question related to telemedicine, we did, in fact, pilot the use of InTouch Robot from remote rounding by our CoC physicians, at all hours including the middle of the night; it may be a cost-effective strategy to use telerounding instead of additional full-time equivalent.

With regard to the fourth question about the benefit in orthopedics versus other specialties, orthopedics is indeed the first specialty in which the surgical hospitalist movement found its relevance almost 20 years ago. Huddlestone et al²⁸ reported the benefit of hospitalist-based efficiency improvement in orthopedic surgery. However, the role of hospitalists described in our program will have a much broader impact not only in all specialties, but in

quality domains. This question ties in with a similar question posed by Dr. Stain, whether our CoC program may result in abdication of postoperative care responsibilities by surgeons. I feel strongly that the postoperative care and ownership of patients remains with the surgeon. The CoC provides a safety net when we are all busy in the operating room and must leave the lowest man on the totem pole to cover the floor and adverse events happen before we return for evening rounds; thus the CoC is a 24/7 proactive safety net program, creating enhanced bedside care analogous to a virtual ICU.

The questions posed by Dr. Shermin and Dr. Zenilman related to financial impact. I shared with you 2 snapshots of financial benefit, one PCU-based and the other DRG-based. This is an underestimate of the benefit of CoC program that more than pays for the investment. Based on 5815 registered US hospitals with about 950,000 beds, this CoC program can potentially save 92,000 to 94,000 lives per year with no incremental cost at the minimum, and probably with cost savings. Dr. Zenilman, we have not used surgeons as hospitalists in our program.

Dr. Pitt asked about the ICU contribution in mortality reduction. For all of the hospitals in which we performed the study, we achieved either actual or virtual leapfrog criteria of 24/7 ICU coverage. Our goal is not to impact on ICU, and the mortality

benefits we presented, were all outside of the ICU setting. We further showed that the CoC program can reduce ICU utilization by moving patients into PCU, who would otherwise have been admitted to ICU.

In response to Dr. Stain's comments, I again wish to emphasize that this program is not intended to make surgeons abrogate their postoperative responsibility, but rather act as a safety net built around the surgical program. Dr. Stain and Dr. Way asked about how we controlled for beneficial impact resulting from other safety/quality measures occurring concurrently. We did our best to control for the secular trends. We used comparator hospitals in the same system as controls in the pilot study or used a nested design of surgery versus whole hospital in the validation study wherein the whole hospital served as a broad-based quality improvement strategy while surgery alone used the CoC intervention. More recently, we used national risk adjustment models such as QUEST and CareScience for intervention-based time trend comparisons. Our goal is not to compare one hospital versus others. Rather, to measure the benefit of our real time risk mitigation program by repeated comparisons with national hospitals for risk-adjusted mortality index improvement.



**World Health
Organization**

Patient Safety

A World Alliance for Safer Health Care

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Medical Curriculum Foreword

Medicine has changed greatly over the last century. Our knowledge of the physiology, biochemistry and genetics of human life has improved, as has our understanding of the diseases that affect health.

As the technical ability to treat disease has grown, the complexity of medical practice has increased significantly. The same drugs and surgeries that can save lives have the potential to cause harm. Modern health care is delivered in teams, not by individuals. Modern clinicians rely on the support of intricate health-care systems to enable them to carry out their task. Errors can occur at each stage in any of these processes. There is a constant threat of accidental harm, which cannot easily be removed.

High risk organisations, such as the airline industry, meticulously apply layers of protection to their routine work to reduce risk to acceptable levels. Systems are built so that human error – which is to some extent inevitable – does not cause catastrophe. Flying has now become very safe.

In recent years, a science of patient safety has developed. Harm to patients is not inevitable and can be avoided. To achieve this, clinicians and institutions must learn from past errors, and learn how to prevent future errors. We need to adapt our ways of working to make safe health care a robust and achievable goal.

Traditionally, curricula for doctors and medical students have focused on pure clinical skills: diagnosis of illness, treatment of disease, after-care and follow-up. However, team working, quality improvement and risk management have been overlooked. These skills are fundamental to patient safety.

It is therefore fitting that the WHO Patient Safety has developed this curriculum which will enable and encourage medical schools to include patient safety in their courses. Reducing harm caused by health care is a global priority. Incorporating the knowledge of how to do this into the medical student curriculum is an urgent necessity.

This Curriculum Guide is only a start. A plan is underway to adapt it for use by other health-care professionals including nurses and pharmacists. It is only one strand of what we need to build safer health-care systems. However, there is no doubt that engaging clinicians from the earliest stages of their training is crucial.

This Guide is a timely, valuable project, and I look forward to seeing its early and widespread use.



Sir Liam Donaldson
Chair, WHO Patient Safety

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Acronyms

AHRQ	Agency for Healthcare Research and Quality
APSEF	Australian Patient Safety Education Framework
ARCS	accelerated recovery colectomy surgery
CAT	computed axial tomography
CDC	Centers for Disease Control and Prevention
CPI	clinical practice improvement
CT	computed tomography
D&C	dilation and curettage
ECG	electrocardiogram
EMQ	extended matching question
HBV	hepatitis B virus
HIV	human immunodeficiency virus
HRO	high reliability organization
ICU	intensive care unit
IHI	Institute for Healthcare Improvement
IPE	interprofessional education
IV	intravenous
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
LOS	length of stay
MCQ	multiple choice question
MEQ	modified essay question
Mini-CEX	mini clinical evaluation exercise
MRI	magnetic resonance imaging
MRSA	methicillin-resistant staphylococcus aureus
MSF	multisource feedback
NASA	National Aeronautics and Space Agency
NCPA	National Center for Patient Safety
NPSEF	National Patient Safety Education Framework
NSAID	non-steroidal anti-inflammatory drugs
OR	operating room
OSCE	objective structured clinical examination
PBL	problem-based learning
PDSA	plan-do-study-act
SBA	short best answer question paper
TB	tuberculosis
UK	United Kingdom
USA	United States of America
WHO	World Health Organization

PART A: TEACHER'S GUIDE

WHO Patient Safety
Curriculum Guide
for Medical Schools

1. Background

Why do medical students need patient safety education?

Health care outcomes have significantly improved with the scientific discoveries of modern medicine. However, studies from a multitude of countries show that with these benefits come significant risks to patient safety. We have learnt that hospitalized patients are at risk of suffering an adverse event, and patients on medication have the risk of medication errors and adverse reactions. A major consequence of this knowledge has been the development of patient safety as a specialized discipline. Clinicians, managers, health-care organizations, governments (worldwide) and consumers must become familiar with patient safety concepts and principles. Everyone is affected. The tasks ahead of health care are immense and require all those involved care to understand the extent of harm to patients and why health care must move to adopt a safety culture. Patient safety education and training is only beginning to occur at all levels. Medical students, as future doctors and health-care leaders, must also be prepared to practise safe health care. Though medical curricula are continually changing to accommodate the latest discoveries and new knowledge, patient safety knowledge is different from other because it applies to all areas of practice.

Medical students, as future clinicians, will need to know how systems impact on the quality and safety of health care, how poor communication can lead to adverse events and much more. Students need to learn how to manage these challenges. Patient safety is not a traditional stand alone discipline; rather, it is one that integrates into all areas of medicine and health care. The World Health Organization's (WHO) World Alliance for Patient Safety, and other projects such as this one, aims to implement patient safety worldwide. Patient safety is everyone's business, all the way from patients to politicians. As medical students are among the

future leaders in health care, it is vital that they are knowledgeable and skilful in their application of patient safety principles and concepts. The WHO Patient Safety Curriculum Guide for Medical Schools sets the stage for medical students to begin to practise patient safety in all their clinical activities.

Building students' patient safety knowledge needs to occur throughout medical school. Patient safety skills and behaviours should begin as soon as the students enter a hospital, clinic or health service. By getting students to focus on each individual patient, having them treat each patient as the unique human being they are and using their knowledge and skills carefully students themselves can be role models for others in the health-care system. Most medical students have high aspirations when they enter medicine, but the reality of the system of health care sometimes deflates their optimism. We want students to be able to maintain their optimism and believe that they can make a difference, both to the individual lives of patients and the health-care system.

What is the Curriculum Guide?

The Curriculum Guide is a comprehensive programme for implementation of patient safety education in medical schools worldwide. It comprises two parts. Part A is a teacher's guide, which has been designed to assist teachers to implement the Curriculum Guide. We are aware that patient safety is a new discipline and many clinicians and faculty staff are unfamiliar with many of the concepts and principles. This lays the foundations for capacity-building in patient safety education and Part B provides a comprehensive, ready-to-teach, topic-based patient safety programme that can be implemented either as a whole or on a per topic basis.

Why was the Curriculum Guide developed?

Since the Harvard study [1] in 1991 first described the extent of harm to patients, other countries have found similar results, notwithstanding the differences in their cultures and health systems. The realization that health care actually harms patients has increased scrutiny of patient care in the context of an increasingly complex health system. This complexity has been intensified by rapidly changing medical technology and service demands [2,3]. Doctors, nurses and allied health-care workers are expected to work while managing this complexity, provide evidence-based health-care services and keep patients safe. However, unless they are properly educated and trained in patient safety concepts and principles they will struggle to do this.

Patient safety education for health professionals in the higher education sector has not kept up with workforce requirements [3-7]. Reporting of specific curricula on medical error or patient safety courses in undergraduate medical education has only recently started to gain ground in the published literature [5,8]. The need for patient safety education of medical clinicians was confirmed by a study of a multi-institutional assessment of patient safety knowledge among 693 medical trainees [9]. This study found that knowledge levels of patient safety across a broad band of training, degrees and specialities were substantially limited, and that trainees were unable to self-assess their own knowledge deficiencies in patient safety.

A number of factors have impeded patient safety education. First, the lack of recognition by medical educators that teaching and learning patient safety is an essential part of the undergraduate medical curriculum, and that patient safety skills can be taught [10,12]. Being a new area, many medical educators are unfamiliar with the literature

are unsure how to integrate patient safety learning into existing curriculum. [11-13] Second, educators need to be open to new areas of knowledge [3]. One of the difficulties in introducing new curricula is a reluctance to address knowledge that originates from outside medicine such as systems thinking and quality improvement methods [12]. It has also been suggested that the historical emphasis on treatment of disease rather than prevention of illness creates a culture that finds it difficult to give merit to a “non-event”, that is, an adverse event that is preventable [3]. A third factor relates to entrenched attitudes regarding the traditional teacher–student relationship—one that may be hierarchical and competitive [10] and where an “expert” disseminates information to the student [3,4].

In 2007, the Association for Medical Education in Europe [10] called for patient safety education to be integrated throughout the undergraduate course, including the first year, when awareness of the nature and the extent of threats to patient safety can be raised and generic skills can be developed. This Curriculum Guide seeks to fill the gap in patient safety education by providing a comprehensive curriculum designed to build foundation knowledge and skills for medical students that will better prepare them for clinical practice in a range of environments.

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2. How were the Curriculum Guide topics selected?

The Curriculum Guide covers 11 topics, including 16 of a total of 22 learning topics that were included in the evidence-based Australian Patient Safety Education Framework (APSEF).^{*} An additional topic not in APSEF was selected to support learning in infection control targeted by the WHO programme to reduce infections through better control. Figure 1 sets out the topics selected for inclusion or exclusion.

What is the Australian Patient Safety Education Framework?[1]

APSEF was developed using a four-stage approach: literature review, development of learning areas and learning topics, classification into learning domains, and conversion into a performance-based format. An extensive consultation and validation process was undertaken in Australia and internationally. Published in 2005, the Framework is a simple, flexible and accessible template describing the knowledge, skills and behaviours that all health-care workers need to ensure safe patient care. The Framework is divided into level of knowledge, skills and behaviours depending on a

person's position and clinical responsibility in an organization. The Framework is designed to assist organizations and people develop educational curricula and training programmes. We have developed the Curriculum Guide using the Framework in terms of content and rationale.

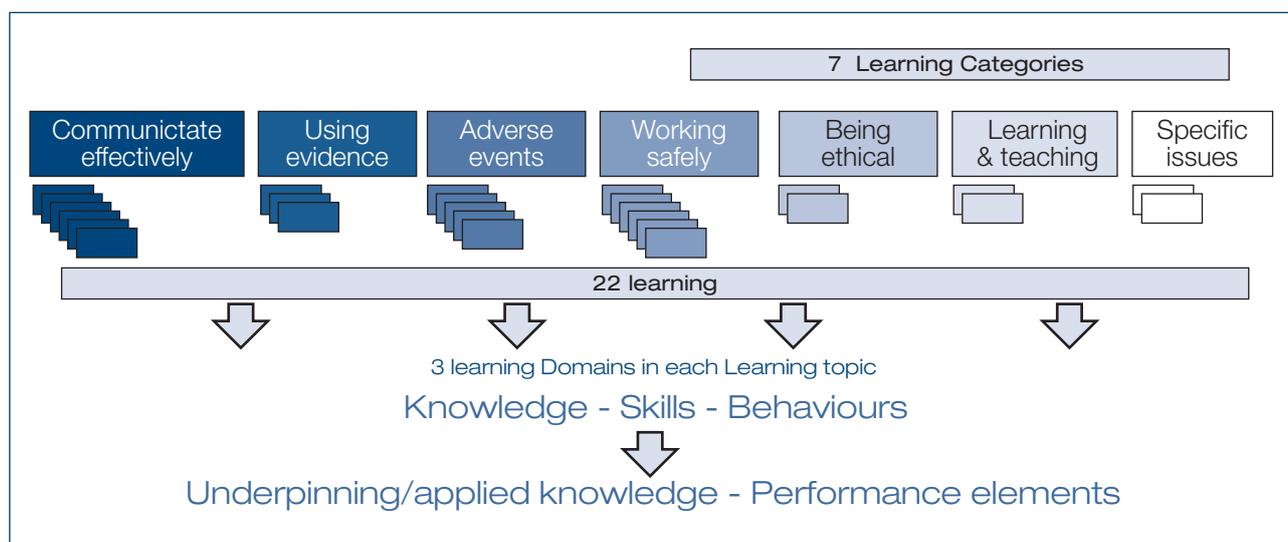
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Australian Patient Safety Education Framework learning areas and topics

There are 7 learning areas (categories) and 22 learning topics in APSEF. Table 1 sets out the Curriculum Guide topics and the relationship with APSEF.

Figure 1. How is the NPSEF structured?



Source: National Patient Safety Education Framework, Australia.

^{*} The topics left out were ones that we considered would already be covered in a medical school curriculum such as consent, evidenced-based practice and learning and teaching. Information technology was excluded because of the disparity in access to technology among university medical schools and health services.

2. How were the Curriculum Guide topics selected?

Table 1: APSEF plus WHO topics

APSEF topic	Included in curriculum	WHO topic
Communicating effectively		
Involving patients and carers as partners in health care	yes	Topic 8
Communicating risk	yes	Topic 6
Communicating honestly with patients after an adverse event (open disclosure)	yes	Topic 8
Obtaining consent	no	Highly likely already covered
Being culturally respectful and knowledgeable	yes	Topic 8
Identifying, preventing and managing adverse events and near misses		
Recognizing, reporting and managing adverse events and near misses	yes	Topics 6,7
Managing risk	yes	Topic 6
Understanding health-care errors	yes	Topics 1,5
Managing complaints	yes	Topics 6,8
Using evidence and information		
Employing best available evidence-based practice	no	
Using information technology to enhance safety	no	
Working safely		
Being a team player and showing leadership	yes	Topic 4
Understanding human factors	yes	Topic 2
Understanding complex organizations	yes	Topic 3
Providing continuity of care	Not directly covered	
Managing fatigue and stress	yes	Topics 2,6
Being ethical		
Maintaining fitness to work or practise	yes	Topic 6
Ethical behaviour and practice	yes	Topics 1,6
Continuing learning		
Being a workplace learner	no	
Being a workplace teacher	no	
Specific issues		
Preventing wrong site, wrong procedure and wrong patient treatment	yes	Topic 10
Medicating safely	yes	Topic 11
Infection control (not part of Australian framework)	yes	Topic 9

2. How were the Curriculum Guide topics selected?

There were three main stages in the development of the Framework content and structure:

1. Initial review of knowledge and development of framework outline.
2. Additional searching for content and assignment of knowledge, skills, behaviours and attitudes.
3. Development of performance-based format.

Stage 1 – Review of knowledge and development of framework outline

A search was conducted to identify the current body of knowledge relating to patient safety (as described in the next section). The literature, books, reports, curricula and web sites collected were then reviewed to identify the major activities associated with patient safety that had a positive effect on quality and safety. These activities were then grouped into categories termed learning areas. Each learning area was analysed and further broken down into major subject areas, termed learning topics. See below for details of the literature review process and the Framework content structure.

The rationale for the inclusion of each learning area and topic has been articulated in the body of the Framework and is summarized below.

Stage 2 – Additional searching for content and assignment of knowledge, skills, behaviours and attitudes

Each learning topic formed the basis for a more extensive search, including additional terms such as education, programmes, training, adverse events, errors, mistakes and organization/institution/health facility/health service. All the activities (knowledge, skills, behaviours and attitudes) for each topic were listed until no more activities were forthcoming and the sources exhausted. This list was then culled for duplication, practicality and redundancy. The remaining activities were then categorized into

knowledge, skills or behaviours and attitudes.

The final step in this stage was to allocate each activity to the appropriate level corresponding to the degree of responsibility of particular categories of health-care workers for patient safety:

Level 1 (Foundation) identifies the knowledge, skills, behaviours and attitudes that every health-care worker needs to have.

Level 2 is designed for health-care workers who provide direct clinical care to patients and work under the supervision of, and for those with managerial, supervisory and/or advanced clinical responsibilities.

Level 3 is for health-care workers who have managerial or supervisory responsibilities or are senior clinicians with advanced clinical responsibilities.

Level 4 (Organizational) identifies the knowledge, skills, behaviours and attitudes required for clinical and administrative leaders with organizational responsibilities. Level 4 is not part of the progressive learning that underpins the first three levels.

The learning areas and topics were endorsed by the Reference Group and Steering Committee. Extensive consultation with the wider health system and community within Australia as well as internationally completed the review and endorsement process for the learning areas and topics and their content.

The outcome of this stage is shown in Table 2. This example is taken from the learning topic “involving patients and carers as partners in health care”.

2. How were the Curriculum Guide topics selected?

Table 2. APSEF content matrix

	Level 1 Foundation <i>For categories 1–4 health-care workers</i>	Level 2 <i>For categories 2 and 3 health-care workers</i>	Level 3 <i>For category 3 health-care workers</i>	Level 4 Organizational <i>For category 4 health-care leaders</i>
Learning objectives	Provide patients and carers with the information they need when they need it	Use good communication and know its role in effective health-care relationships	Maximize opportunities for staff to involve patients and carers in their care and treatment	Develop strategies for staff to include patients and carers in planning and delivering health-care services
Knowledge				
Skills				
Behaviours	and attitudes			

Stage 3—Development of performance-based format

The completed context matrix was translated into a performance-based format, which takes full advantage of the modular nature of the Framework. The most extensive consultation occurred at this stage of the Framework’s development. Individual health-care workers were interviewed about aspects of every performance element in the Framework and the entire Framework document was distributed across the health-care sector for feedback.

The Curriculum Guide topics

1. What is patient safety?
2. What is human factors and why is it important to patient safety?
3. Understanding systems and the impact of complexity on patient care
4. Being an effective team player.
5. Understanding and learning from errors.
6. Understanding and managing clinical risk.
7. Introduction to quality improvement methods.
8. Engaging with patients and carers.
9. Minimizing infection through improved infection control.
10. Patient safety and invasive procedures.
11. Improving medication safety.

Rationale for each Curriculum Guide topic

Topic 1: What is patient safety?

Health professionals are increasingly being required to incorporate patient safety principles and concepts into everyday practice. In 2002, WHO Member States agreed on a World Health Assembly resolution on patient safety because they saw the need to reduce the harm and suffering of patients and their families as well as the compelling evidence of the economic benefits of improving patient safety. Studies show that additional hospitalization, litigation costs, infections acquired in hospitals, lost income, disability and medical expenses have cost some countries between US\$ 6 billion and US\$ 29 billion a year [2,3].

A number of countries have published studies highlighting the overwhelming evidence showing that significant numbers of patients are harmed due to their health care, either resulting in permanent injury, increased length of stay (LOS) in hospitals or even death. We have learnt over the last decade that adverse events occur not because bad people intentionally hurt patients but rather that the system of health care today is so

complex that the successful treatment and outcome for each patient depends on a range of factors, not just the competence of an individual health care provider. When so many people and different types of health-care providers (doctors, nurses, pharmacists and allied health) are involved, it is very difficult to ensure safe care unless the system of care is designed to facilitate timely and complete information and understanding by all the health professionals. This topic presents the case for patient safety.

Topic 2: What is human factors and why is it important to patient safety?

Human factors, engineering or ergonomics is the science of the interrelationship between humans, their tools and the environment in which they live and work [3]. Human factors engineering will help students understand how people perform under different circumstances so that systems and products can be built to enhance performance. It covers the human-machine and human-to-human interactions such as communication, teamwork and organizational culture.

Other industries such as aviation, manufacturing and the military have successfully applied knowledge of human factors to improve systems and services. Students need to understand how human factors can be used to reduce adverse events and errors by identifying how and why systems break down and how and why human beings miscommunicate. Using a human factors approach, the human-system interface can be improved by providing better-designed systems and processes. This involves simplifying processes, standardizing procedures, providing backup when humans fail, improving communication, redesigning equipment and engendering a consciousness of behavioural, organizational and technological limitations that lead to error.

Topic 3: Understanding systems and the impact of complexity on patient care

Students are introduced to the concept that a health-care system is not one but many systems made up of organizations, departments, units, services and practices. The huge number of relationships between patients, carers, health-care providers, support staff, administrators, bureaucrats, economists and community members as well as the relationships between the various health- and non-health-care services add to this complexity. This topic gives medical students a basic understanding of complex organizations using a systems approach. The lessons from other industries are used to show students the benefits of a systems approach.

When students think in systems they will be better able to understand why things break down and have a context for thinking about solutions. Medical students need to understand how an individual doctor or nurse working in a hospital can do their very best in treating and caring for their patients but alone that will not be enough to provide a safe and quality service. This is because patients depend on many people doing the right thing at the right time for them; in other words, they depend on a system of care.

Topic 4: Being an effective team player

Medical students' understanding of teamwork involves more than identification with the medical team. It requires students to know the benefits of multidisciplinary teams and how effective multidisciplinary teams improve care and reduce errors. An effective team is one in which the team members communicate with one another as well as combining their observations, expertise and decision-making responsibilities to optimize patient care [4].

The task of communication and flow of information between health providers and patients

2. How were the Curriculum Guide topics selected?

can be complicated due to the spread of clinical responsibility among members of the health-care team [5,6]. This can result in patients being required to repeat the same information to multiple health providers. More importantly, miscommunication has also been associated with delays in diagnosis, treatment and discharge as well as failures to follow up on test results [7-11].

Students need to know how effective health-care teams work, as well as techniques for including patients and their families as part of the health-care team. There is some evidence that multidisciplinary teams improve the quality of services and lower costs [12-14]. Good teamwork has also been shown to reduce errors and improve care for patients, particularly those with chronic illnesses [15-17]. This topic presents the underlying knowledge required to become an effective team member. However, knowledge alone will not make a student a good team player. They need to understand the culture of their workplace, and how it impacts upon team functioning.

Topic 5: Understanding and learning from errors

Understanding why health-care professionals make errors is necessary for appreciating how poorly designed systems and other factors contribute to errors in the health-care system. While errors are a fact of life, the consequences of errors on patient welfare and staff can be devastating. Medical students and other health-care professionals need to understand how and why systems break down and why mistakes are made so they can act to prevent and learn from them. An understanding of health-care errors also provides the basis for making improvements and implementing effective reporting systems [18]. Students will learn that a systems approach to errors, which seeks to understand all the underlying factors involved, is significantly better

than a person approach, which seeks to blame people for individual mistakes. Leape's seminal article in 1994 showed a way to examine errors in health care, that focused on learning and fixing errors instead of blaming those involved [19]. Although his message has had a profound impact on many health-care practitioners, there are still many embedded in a blame culture. It is crucial that students begin their vocation understanding the difference between blame and systems approaches.

Topic 6: Understanding and managing clinical risk

Clinical risk management is primarily concerned with maintaining safe systems of care. It usually involves a number of organizational systems or processes that are designed to identify, manage and prevent adverse outcomes. Clinical risk management focuses on improving the quality and safety of health-care services by identifying the circumstances and opportunities that put patients at risk of harm and acting to prevent or control those risks. Risk management involves every level of the organization so it is essential that medical students understand the objectives and relevance of the clinical risk management strategies in their workplace. Managing complaints and making improvements, understanding the main types of incidents in the hospital or clinic that are known to lead to adverse events, knowing how to use information from complaints, incident reports, litigation, coroners' reports and quality improvement reports to control risks [20] are all examples of clinical risk management strategies.

Topic 7: Introduction to quality improvement methods

Over the last decade, health care has successfully adopted a variety of quality improvement methods used by other industries. These methods provide clinicians with the tools to: (i) identify a problem; (ii) measure the problem; (iii) develop a range of interventions designed to fix the problem; and (iv) test whether the interventions worked. Health-care leaders such as Tom Nolan, Brent James, Don Berwick and others have applied quality improvement principles to develop quality improvement methods for health clinicians and managers. The identification and examination of each step in the process of health-care delivery is the bedrock for this methodology. When students examine each step in the process of care they begin to see how the pieces of care are connected and measurable. Measurement is critical for safety improvement. This topic introduces the student to improvement methods and the tools, activities and techniques that can be incorporated into their practice.

Topic 8: Engaging with patients and carers

Students are introduced to the concept that the health-care team includes the patient and/or their carer, and that patients and carers play a key role in ensuring safe health care by: (i) helping with the diagnosis; (ii) deciding about appropriate treatments; (iii) choosing an experienced and safe provider; (iv) ensuring that treatments are appropriately administered; and (v) identifying adverse events and taking appropriate action [21,22]. The health-care system underutilizes the expertise patients can bring such as their knowledge about their symptoms, pain, preferences and attitudes to risk. They are a second pair of eyes if something unexpected happens. They can alert a health-care worker if the medication they are about to receive is not what they usually take, which acts as a warning to the team that checks should be made. Research

has shown that there are fewer errors and better treatment outcomes when there is good communication between patients and their carers, and when patients are fully informed and educated about their medications [23-30]. Poor communication between doctors, patients and their carers has also emerged as a common reason for patients taking legal action against health-care providers [31,32].

Topic 9: Minimizing infection through improved infection control

WHO has a global campaign on infection control. We thought it important that this area be included in the Curriculum Guide not only for consistency but also because along with surgical care and medications these areas constitute a significant percentage of adverse events suffered by patients. The problem of infection control in health-care settings is now well established, with health care-associated infections being a major cause of death and disability worldwide. There are numerous guidelines available to help doctors and nurses minimize the risks of cross-infection. Patients who have surgery or an invasive procedure are known to be particularly prone to infections and account for about 40% of all hospital-acquired infections. The topic sets out the main causes and types of infections to enable medical students to identify those activities that put patients at risk of infection and to prepare students to take the appropriate action to prevent transmission.

Topic 10: Patient safety and invasive procedures

WHO has a project on safe surgery. One of the main causes of errors involving wrong patients, sites and procedures is the failure of health-care providers to communicate effectively (inadequate processes and checks) in preoperative procedures. Other examples of wrong site/procedure/patient are: (i) the wrong patient in

2. How were the Curriculum Guide topics selected?

the operating room (OR); (ii) surgery performed on the wrong side or site; (iii) wrong procedure performed; (iv) failure to communicate changes in the patient's condition; (v) disagreements about stopping procedures; and (vi) failure to report errors.

Minimizing errors caused by misidentification involves developing best-practice guidelines for ensuring the correct patient receives the right treatment [6]. Students can learn to understand the value of all patients being treated in accordance with the correct site/procedure/patient policies and protocols. Such learning would include the benefit of protocols as well as knowledge of the underlying principles supporting a uniform approach to treating and caring for patients.

One study of hand surgeons found that 21% of surgeons surveyed (n=1050) reported performing wrong site surgery at least once during their careers [33].

Topic 11: Improving medication safety

An adverse drug reaction has been defined by WHO [34] as any response to a medication that is noxious, unintended and occurs at doses used for prophylaxis, diagnosis or therapy. Patients are vulnerable to mistakes being made in any one of the many steps involved in ordering, dispensing and administering medications.

Medication errors have been highlighted in studies undertaken in many countries, including Australia, which [35] show that about 1% of all hospital admissions suffer an adverse event related to the administration of medications. The causes of medication errors include a wide range of factors including: (i) inadequate knowledge of patients and their clinical conditions; (ii) inadequate knowledge of the medications; (iii) calculation errors; (iv) illegible handwriting; (v) confusion

regarding the name of the medication; and (vi) poor history taking [37].

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3. Aims of the Curriculum Guide

The aims of the Curriculum Guide are to:

- prepare medical students for safe practice in the workplace;
- inform medical schools of the key topics in patient safety;
- enhance patient safety as a theme throughout the medical curriculum;
- provide a comprehensive curriculum to assist teaching and integrating patient safety learning;
- further develop capacity for patient safety educators in medical schools;
- promote a safe and supportive environment for teaching students about patient safety;
- introduce or strengthen patient safety education in medical schools worldwide;
- raise the international profile of patient safety teaching and learning;
- foster international collaboration on patient safety education research in the higher education sector.

Underpinning principles

Capacity-building is integral to curriculum change

The main reason that WHO embarked on this project was to assist medical schools to develop patient safety education in their medical schools. The requirement of medical schools to develop and integrate patient safety learning into the medical curricula is a challenge for many medical schools because of the limited education and training of faculty staff in patient safety concepts and principles. One cannot expect medical schools to develop new curricula or review existing curricula if they are unfamiliar with the requirements of the discipline of patient safety.

Medical educators come from many backgrounds (clinicians, clinician educators, non-clinician educators, managers, health professionals) and their collective experience is necessary to deliver a

rigorous medical programme. Many are experts in their particular disciplines and usually keep up to date using the accepted professional pathways for their area. Patient safety knowledge requires additional learning that falls outside these traditional routes. To be an effective patient safety teacher, health professionals need to be provided with the knowledge, tools and skills necessary for implementing patient safety education in their institutions. This is why a Teacher's Guide (Part A) has been developed to accompany the Curriculum Guide. It provides practical advice and information for each stage of curriculum development and renewal, from assessing capacity to staff development to programme design and implementation.

A flexible curriculum to meet individual needs

We recognize that the curriculum of most medical programmes is already filled beyond capacity. This is why we have designed each topic as stand alone, thus allowing for wide variations in patient safety education implementation. The topics are also designed so they can be integrated into existing curricula, particularly in the doctor-patient stream. The topics in the Curriculum Guide have each been designed with enough content for a 60–90 minute educational session and feature a variety of ideas and methods for teaching and assessing so that educators can tailor material according to their own unique needs, context and available resources. There is no requirement to absolutely follow the outline provided. Teachers need to pay attention to the local environment, culture and student learning experiences and then select the most appropriate teaching method for the content selected.

Easily understood language for a targeted yet global audience

The Teacher's Guide (Part A) of the Curriculum Guide is written for medical educators (those with

the capacity to introduce or enhance patient safety education at various levels), while the Curriculum Guide (Part B: Topics) is written for teachers and students. The Curriculum Guide was written with a global audience in mind and in language easily understood by those with English as both a first and second language.

A curriculum guide for all countries, cultures and contexts

Every attempt has been made to ensure that the content in this curriculum takes into account the wide variety of contexts in which medical educators and students teach and learn. An Expert Group, representing all WHO regions, has assessed the curriculum to ensure cultural appropriateness. Although some of the teaching activities and suggestions for students may not be culturally appropriate in every country, we are mindful that in all countries we need to change many of the aspects of clinical care. Much professional behaviour once thought appropriate is today no longer acceptable when taking patient safety considerations into account. For example, junior doctors or nurses will rarely speak up when they see a senior clinician about to make an error; this is universal and applies to all cultures to varying degrees. However, patient safety principles require that everyone is responsible for patient safety and should speak up even when they are lower in the medical and health-care hierarchy. Teachers will need to make a judgement about the health-care environment and whether it is ready and prepared for the introduction of patient safety.

Teaching and assessment strategies are designed to take into account both diversity in available resources and environmental differences, considerations that may be in terms of a developed versus developing country or a classroom versus a simulation centre.

A curriculum guide that is based on learning in a safe and supportive environment

We are mindful that students respond best when the learning environment is one that is safe, supportive, challenging and engaging. Patient safety learning occurs in many places—beside the bed, in simulated environments and in the classroom. It is essential that students are supported in their learning and not made to feel humiliated or inadequate. The activities in the Curriculum Guide are designed to be implemented in a supportive learning environment where students feel comfortable asking questions, volunteer what they do not understand and share their understanding in an honest and open way.

4. Structure of the Curriculum Guide

Teacher's Guide (Part A)

The Teacher's Guide (Part A) relates to building capacity for patient safety education, programme planning and design. Suggestions are provided regarding how patient safety education might be approached and implemented using the material presented in Part B. In Part A, we try to guide the reader through some important steps designed to support and achieve the implementation phase of curriculum development.

Curriculum Guide topics (Part B)

The topics represent the actual patient safety education curriculum.

5. Implementing the Curriculum Guide

How to use this Curriculum Guide

This Curriculum Guide provides you with resources for teaching medical students about patient safety. It identifies the topics to be taught, how it might be taught and how you can assess the different topics in the curriculum. Case examples have been selected are available at the end of each topic. These cases can be used to demonstrate a particular aspect of the topic under discussion. We recognize that the best learning occurs when the case study used reflects local experiences, therefore, we encourage teachers to modify the cases so that they reflect the experiences of the health-care providers and locally available resources.

How to review your curriculum for patient safety learning

- **Identify the learning outcomes**

To start the process of curriculum development or renewal it is important to first identify the learning outcomes for patient safety. Part B contains the topics that have been chosen for this Curriculum Guide; whereas learning outcomes are further discussed in Part A.

- **Know what is already in the medical curriculum**

We use the word curriculum to refer to the broad spectrum of teaching and learning practices, including the strategies for developing skills and behaviours as well as using appropriate assessment methods to test whether the learning outcomes have been achieved. Medical students are guided in their learning by a medical curriculum that sets out the requisite knowledge, skills and behaviours required to demonstrate competency at the completion of their medical degree.

Before new material is introduced into a curriculum it is important to know what curriculum already exists as well as students' clinical

experiences in the hospitals and/or the different clinical environments. It may be that students are already experiencing some patient safety education in the hospitals and clinics that is not written down. The curriculum may already cover some aspects of this patient safety curriculum such as the importance of protocols in handwashing to avoid infection transmission. Getting a picture of existing material in the medical curriculum is necessary to identify those opportunities for enhancing patient safety teaching.

The patient safety curriculum we have designed is described in Part B of this document. We have identified the topics, resources, teaching strategies and assessment methods that will make patient safety teaching easier to introduce and integrate into the curriculum.

- **Build on what is already in the curriculum**

A good approach to patient safety education is to enhance existing parts of the medical curriculum rather than see patient safety as a new subject to teach. There are elements of patient safety that are new and will be additional to the existing curriculum, but there are many aspects of patient safety that can be added onto or achieved with further development of a subject or topic that already exists.

We have found that mapping topics or areas in the existing curriculum will help identify opportunities to include patient safety concepts and principles. Areas such as clinical skills development, professional and personal development, patient–doctor and community–doctor themes, health law, medical ethics, clinical ethics and communication are all suitable for including patient safety concepts and principles. The University of Sydney developed a template to review their medical curriculum and offer it as an example that can be followed (see Table 3).

Table 3. Map of patient safety content in the existing medical programme (example)

Session/area of the curriculum	Year	Where is the patient safety content?	Potential patient safety learning	How is patient safety being taught?	How is patient safety being assessed?	Comments
Ethics	1	Respect for patient autonomy	Honesty after an adverse event	Lecture	Ethics essay, MCQ, OSCE	Many patient safety principles have an ethical basis that can be used to make explicit the patient safety lesson

Mapping medical curriculum will also help identify the opportunities for including patient safety concepts in an integrated fashion.

How to assess the capacity of faculty to integrate patient safety teaching into the existing curriculum

One of the biggest challenges facing all medical schools is the growing shortage of clinician teachers generally. There are few who know how to integrate patient safety principles and concepts into their clinical teaching. Many good clinicians intuitively adopt patient safety methods into their practice but may not know how to articulate what they do. Perhaps this is because they view any discussions about “systems” as the province of administrators and managers. Others may not think patient safety teaching important or relevant to their practice. Engaging clinicians in the area will be the first challenge for you. Building capacity of the faculty can take time, but there are a number of steps that can be taken to engage clinicians in patient safety teaching.

Survey

One way to find out who is interested in teaching patient safety is to conduct a survey of the clinicians who teach medical students. In some institutions there may be hundreds of teachers and in others not so many. Identify the clinicians who are in the best position to incorporate patient safety

teaching and make sure they are included in the survey. The mapping exercise described above will help identify those people who currently teach and in a position to integrate patient safety concepts. The survey could include questions in relation to interest or knowledge of patient safety and practice in patient safety methods. This process could also identify those people who may be interested in forming a group or committee to oversee the development of the patient safety curriculum.

Focus group

Run a focus group of clinicians to find out what the current state of knowledge is about patient safety. This will also provide information about the clinicians’ attitudes towards including patient safety learning in the curriculum.

Face-to-face meetings

Individual meetings with clinicians will help to convey a clear message about patient safety education. This provides an opportunity to explain the basis and urgency for patient safety education as well as establish a relationship for later work.

Convene a round table

Invite a select group of clinicians who you think may be interested and those who are possible champions of a round table discussion about patient safety education for medical students. (The benefit of a round table format is that there is

no one expert obviously in charge and the group seeks to discuss and resolve the issues together in a collegial fashion.)

Conduct a seminar on patient safety

Seminars are typical venues for building new knowledge. Seminars can be good for exposing clinicians new to the area to experts or respected clinicians who know about patient safety. Seminars can either be a half day or a full day. Topics that could be included in such a seminar include: (i) what is patient safety; (ii) the evidence of why patient safety is important; (iii) how to develop a curriculum for patient safety; (iv) how to teach patient safety; and (v) how to assess patient safety. It is important to remember to maintain context of the programme, which is to build capacity for faculty staff and clinicians to teach patient safety to medical students.

How to identify like-minded colleagues or associates

If you undertake the activities set out above in relation to building capacity this will help identify like-minded people interested in teaching patient safety. Another way is to convene a meeting and send an open invitation to faculty staff and clinician teachers. Make sure to schedule the meeting at a time convenient for as many people as possible in order to attract maximum attendance (for example, clinicians who see patients during the day may want to come but cannot because of work demands). Another way is to put an article in the faculty newsletter or university news. This will let people know about patient safety, and even if they are not interested in getting involved, the article will raise awareness of the need to include patient safety education in the curriculum.

Patient safety teaching requires the engagement of interested and knowledgeable staff who either self-select, or have been appointed or nominated

as a result of previous contacts or meetings about patient safety. It is also a good idea to check the availability of experts from other faculties and disciplines such as nursing, engineering (human factors knowledge), psychology (behavioural psychology, process and improvement theories) and pharmacy (medication safety).

Techniques to find out where patient safety could fit into the medical curriculum

Brainstorming is a technique that requires and encourages everyone to suggest ideas for solving a problem. The problem being how to best introduce patient safety learning into the curriculum. Each medical school will be different; they will have different resources, capacity and interest in patient safety. Patient safety may not yet be a community or government concern so the urgency to include patient safety education may not be a priority.

Convening introductory workshops on the Curriculum Guide for medical students will provide an opportunity for members of the faculty to become familiar with the core topics in patient safety. It will also allow them to express any reservations they have about the programme and clarify any concerns or questions.

Patient safety is best considered in the context of multidisciplinary learning. Staff should be encouraged to reflect on the feasibility of combining some of the patient safety sessions with other health professionals. While this Curriculum Guide has been designed for medical students, it can easily be adapted to other health-care students. Other professions and disciplines have much to contribute, particularly in teaching some of these topics. Engineers may be able to teach about systems, safety cultures and human factors engineering. Psychologists and behavioural scientists, nursing and pharmacy

faculty can teach about how their disciplines have made safety improvements. Striving for diversity gives the maximum chance to enable students to learn from other disciplines, particularly in the context of a team approach to patient safety.

Reaching agreement

As in all discussions about curriculum there will be different views about what should be included and what should be left out. The important thing is to start and build on that. This means that compromise may be better in the long run—getting something started rather than debating and discussing the issues for lengthy periods of time. Another technique is to introduce new topics into the curriculum using a pilot, which could identify any problems and be used as a guide for future topics. It also allows faculty staff members who are unsure of the value of patient safety learning to get used to the idea.

The next section gives more details about developing and integrating the Curriculum Guide into existing curriculum.

6. How to integrate patient safety into your medical school curriculum

General comments

Patient safety is a relatively new discipline and introducing any new material into an existing medical curriculum is always challenging. What should be taught? Who should teach it? Where and how will it fit in with the rest of the curriculum? What does it replace?

If your medical school is in the process of renewing an existing curriculum or if you belong to a new medical school, this is an ideal time to make a case for allocating space for patient safety education. However, most medical school curricula are well established and already full. It is unusual to find a block of free time waiting for a new area of study.

This section provides ideas on how to integrate patient safety teaching and learning into an existing

medical curriculum. The benefits and challenges of different approaches will be covered to help you determine the likely best fit for your school and to help you anticipate and plan what is required.

The nature of patient safety education:

- it is new;
- it spans a number of fields not traditionally taught in medical schools such as human factors, systems thinking, effective teamwork behaviours and managing error;
- it links with many existing and traditional medical school subjects (applied sciences and clinical sciences) (see Box 1 for examples);
- it contains new knowledge and performance elements (see Box 2 for examples);
- it is highly contextual.

Box 1. Linking patient safety education with traditional medical school subjects

An example of how a patient safety topic such as correct patient identification has specific applications in numerous disciplines in medicine:

Discipline	Patient safety application
Obstetrics	How are newborn babies identified as belonging to their mother so that babies are not accidentally mixed up and leave hospital with the wrong parent(s)?
Surgery	If a patient needs a blood transfusion, what checking processes are in place to ensure they receive the correct blood type?
Ethics	How are patients encouraged to speak up if they do not understand why the doctor is doing something to them that they were not expecting?

Box 2. Linking patient safety education with new knowledge and performance elements

Patient safety competencies for a particular topic can be divided into knowledge and performance requirements. Ideally, learning will occur in both categories, e.g. correct patient identification

Domain	Patient safety example
Broad knowledge	Understanding that patient identification mix-ups can and do occur, especially when care is delivered by a team. Learning what situations increase the likelihood of a patient mix-up such as having two patients with the same condition, patients who cannot communicate and staff being interrupted mid-task.
Applied knowledge	Understanding the importance of correct patient identification when taking blood for cross-matching. Understanding how errors can occur during this task and learning about the strategies used to prevent error in this situation.
Performance	Demonstrating how to correctly identify a patient by asking the patient their name as an open-ended question such as "What is your name?" rather than as a closed question such as "Are you John Smith?"

The field of patient safety is also very broad. Given this breadth and the need for contextualizing patient safety principles, there are likely to be many opportunities in your curriculum to incorporate effective patient safety education into existing sessions. However, some areas of patient safety are relatively new to medicine and may not be so easy to graft onto an existing session and hence are likely to need their own time slot in the curriculum.

How to establish best fit using generic curriculum structures

Once you have reviewed your existing curriculum, determined what patient safety areas are already taught and decided what patient safety topics you want to teach, it is time to think about how to incorporate the new content into your curriculum.

When thinking about your medical school's curriculum consider the following questions:

- How is your overall curriculum structured?
- When and where in the curriculum are particular subjects and topics taught that might lend themselves to inclusion of patient safety content?
- How are individual topics structured in terms of learning objectives, delivery methods and assessment methods?
- How is your curriculum delivered?

Once you have answered these questions it will become more apparent where and how patient safety can be included in your curriculum.

How is your overall curriculum structured?

- Is it a traditional curriculum? Students first learn about the basic and behavioural sciences and once these are complete, concentrate on the clinical disciplines. Education tends to be discipline-specific rather than integrated.

In this setting, clinical application and performance elements of patient safety may be best introduced in the later years of the course. However, broad knowledge of patient safety principles can still be effectively introduced in the early years.

- Is it an integrated curriculum? Basic, behavioural and clinical sciences and clinical skills are covered in parallel throughout the course and learning is integrated.

In this setting, there are advantages to vertical integration of knowledge, application and performance elements of patient safety education throughout the course.

Knowledge and performance requirements of patient safety:

- Are ideally learnt in the context of the clinical setting; relevance is more apparent once students understand how health care is delivered and are more familiar with the workplace environment.
- Will be more likely to change practice if students have the opportunity to use what they have learnt shortly after it is covered in the curriculum.

When teaching a patient safety topic, there are advantages if the knowledge and performance requirements are covered together. A clear understanding of the scope of a problem inpatient safety will provide motivation and insight when learning about performance requirements.

Students are also less likely to feel demoralized about the risks facing patients from the health-care system they will soon be a part of; if they explore solutions (applications) and learn practical strategies (performance elements) to make them safer doctors at the same time, they will be more positive. For logistical reasons it may not be

possible to cover the knowledge and performance requirements of a patient safety topic at the same time. For example, there is a lecture on medication error in the second year but the students do not practise safe drug administration techniques until a clinical skills workshop in the fourth year. If this is the case, it will be helpful to inform students in the second year that they will learn safe drug administration in the fourth year, and then in the fourth year, refer back to the lecture they had in the second year on medication error. This way motivation for safe practice will not be lost and students will feel more confident about their potential to graduate as a safe practitioner.

If your curriculum is traditional, then knowledge and performance requirements of patient safety are best taught in later years when students have more knowledge of the clinical disciplines, exposure to patients and clinical skills training. The context for the knowledge and performance requirements should match the students' ability to put into practice their new knowledge. Introductory patient safety knowledge can still be included in the early years in subjects such as

public health, epidemiology, ethics or other behavioural science-based subjects. Suitable topics for early introduction include: (i) what is patient safety; (ii) introduction to human factors engineering; and (iii) systems and complexity in health care.

If your curriculum is integrated and students are taught clinical skills from the first year, then patient safety topics are best introduced early and vertically integrated throughout the entire course. This makes patient safety a constant theme and provides opportunities to reinforce and build upon earlier learning. Ideally, students should be exposed to patient safety education prior to and upon entering the clinical environment.

When and where in the curriculum are particular subjects and topics taught that might lend themselves to inclusion of patient safety teaching?

Box 3 sets out opportunities for examining integration of patient safety topics.

Box 3. Integration of patient safety topics

Patient safety topic	Subjects that could house patient safety topics.
Minimizing infection through improved infection control	Microbiology Procedural skills training Infectious diseases Clinical placements
Improving medication safety	Pharmacology Therapeutics
Being an effective team player	Advanced life-support training Orientation programmes Communication skills training (interprofessional)
What is patient safety?	Ethics Introduction to the clinical environment Clinical and procedural skills training

Any clinical discipline can potentially house a patient safety topic if a sample case is part of the session and is relevant to that discipline. For example, a case involving a medication error in a child could be used as the starting point for teaching about understanding and learning from errors while studying paediatrics. Similarly, during the surgical rotation a clinician could teach the topic “patient safety and invasive procedures”. Medicine or obstetrics could house the topic of “understanding and learning from errors” if the case was relevant to that particular discipline. The learning, however, is generic and relevant for all disciplines and all students.

How are individual curriculum topics structured in the following areas?

- learning objectives
- delivery methods
- assessment methods.

Implementation of new patient safety content into your curriculum will be more efficient if the associated learning objectives, delivery and assessment methods are consistent with the structure of objectives, delivery and assessment methods of existing subjects.

How is your curriculum delivered?

- lectures
- clinical placements
- online activities
- on the ward activities
- small group tutorial teaching
- problem-based learning (PBL)
- simulation/skills laboratories
- traditional tutorials.

It will probably be easier to incorporate patient safety topics into pre-existing educational delivery methods familiar to students and staff.

Examples of models for implementation

Example 1: Patient safety as a stand alone subject in a traditional curriculum occurring in the final years. See chart 1.

- educational methods could consist of a combination of lectures, small group discussions, project work, practical workshops or simulation-based exercises;
- adding a layer of patient safety to prior knowledge before entering the workforce.

Chart 1: Implementation of patient safety as a stand alone subject in a traditional curriculum

Years 1 and 2: basic, applied and behavioural sciences																			
Years 3 and 4: clinical disciplines and clinical skills																			

Patient safety topics

6. How to integrate patient safety into your medical school curriculum

Example 2: Patient safety as a stand alone subject in an integrated curriculum. See chart 2.

Patient safety could be a stand alone subject with links to other subjects, e.g. lectures at the start of term that relate to topics that will come up in tutorials or on placement over the course of the year.

Chart 2: Implementation of patient safety as a stand alone subject in an integrated curriculum

Year 1	Topics 1 and 2: What is patient safety?; introduction to human factors engineering	PBL					
Year 2	Topics 3 and 5: understanding systems and the impact of complexity on patient care; understanding and learning from errors	Clinical skills workshops and clinical placements					
Year 3	Topics 4, 7, 9 and 10: being an effective team player; methods for quality improvement; minimizing infection through improved infection control; reducing risks associated with invasive procedures						
Year 4	Topics 6, 8 and 11: how to manage clinical risk; engaging with patients and carers; improving medication safety						

6. How to integrate patient safety into your medical school curriculum

Example 3: Integrating patient safety into pre-existing subjects—example A. See chart 3.

A number of subjects could set aside some sessions where the main objective of the tutorial or lecture is to cover a patient safety topic.

In the fourth year there could be a lecture on medication safety as part of therapeutics, a workshop on safe drug administration in the clinical skills programme and a PBL case that demonstrates the multifactorial nature of error using a case of medication error.

Chart 3: Implementation of patient safety as a stand alone subject in an pre-existing subjects (A)

Year 1	PBL					Patient safety case					
	Clinical skills		Patient safety activity								
	Lecture	Patient Safety topic									
Year 2	PBL					Patient safety case					
	Clinical skills		Patient safety activity								
	Lecture	Patient Safety topic									
Year 3	PBL					Patient safety case					
	Clinical skills		Patient safety activity								
	Lecture	Patient Safety topic									
Year 4	PBL					Patient safety case					
	Clinical skills		Patient safety activity								
	Lecture	Patient Safety topic									

6. How to integrate patient safety into your medical school curriculum

Example 4: Integrating patient safety into pre-existing subjects—example B. See Chart 4.

Work together with subject leaders to incorporate elements of patient safety into selected educational sessions. Although the main focus of

the session is not a patient safety topic, elements of patient safety education are weaved into the session. For this to occur, session objectives should include an element of patient safety. See Box 4 for examples.

Chart 4: Implementation of patient safety as a stand alone subject in an pre-existing subjects (B)

Year 1	PBL		Patient safety case		Patient safety case		
	Clinical skills	Patient safety activity					
	Lecture	Patient safety topic					
Year 2	PBL			Patient safety case			Patient safety case
	Clinical skills	Patient safety activity					
	Lecture	Patient safety topic					
Year 3	PBL	Patient safety case		Patient safety case			
	Clinical skills	Patient safety activity					
	Lecture	Patient safety topic					
Year 4	PBL		Patient safety case			Patient safety case	
	Clinical skills	Patient safety activity					
	Lecture	Patient safety topic					

Box 4. Examples of how patient safety topics can be weaved in with pre-existing sessions

Pre-existing session	Patient safety education component
Clinical skills tutorial at the bedside	Patients are always provided with an explanation and consent to being part of the educational process at the start of the session. Tutors role model respecting patients wishes. Patients are always included as part of the team. Tutors invite patient to join case discussion as they have information important to their care.
Procedural skills session on IV cannulation	Sterile technique and sharps disposal are included. Involve patient in risk discussion about infection. Practise consent.
Lecture on blood transfusion	Patient risk and ways to minimize risk are included as part of the lecture. Verification protocols to ensure correct patient.
PBL on pulmonary embolism where the index case is commenced on an oral anticoagulant	Students are encouraged to discuss the importance of patient education when prescribing potentially dangerous medication.

The more patient safety topics are integrated into the established curriculum, the easier it will be to incorporate the performance requirements in a meaningful way, and provide context for patient safety concepts.

However, there should be a word of caution: the more that patient safety is integrated into the existing curriculum, the more it is dispersed, dependent on a greater number of teachers and it becomes harder to coordinate effective delivery. You will need to find the balance between integration of the new material and ability to coordinate its delivery. It is a good idea to keep a detailed record of what patient safety is integrated into the existing curriculum, how it is being taught and how it is being assessed. From an educational perspective, integration of patient safety is ideal; however, this aim needs to be balanced by the practicalities of implementation. When asked by a university or accrediting body where and how patient safety is taught to medical students the faculty needs to have information that is sufficiently detailed to allow an observer to attend such a session and see patient safety education being delivered. It may be that a

combination of the above approaches is more appropriate for your setting.

Once you have an overall plan of what, where and how you want to incorporate patient safety into your curriculum, it will be easier to add to the curriculum in a piecemeal fashion, topic by topic over time, rather than trying to add every aspect of your plan at once. This way you can learn as you go, and start achieving small goals early.

Integration of patient safety into a problem-based learning programme

Many medical schools use PBL as a major component for delivering curriculum. One of the many benefits of PBL is the integration of basic, behavioural and clinical science material in the context of solving a clinical problem. If the clinical problem also includes aspects of the realities of the health-care delivery system then there will be opportunities to explore issues relating to patient safety. PBL is well suited to patient safety teaching and learning. This section provides ideas to help you effectively include patient safety material into your PBL programme.

There are many variations of the PBL process. The relevance of some of the ideas we present will depend on which PBL model your school has adopted. In this section, PBL is assumed to have the following characteristics:

- small group learning with a facilitator (tutor or teacher) present;
- a clinical case is used as the starting point for learning;
- as students attempt to understand the case through group discussion, issues and problems arise that will form the basis of further study;
- students undertake self-directed study (resources may be provided to help guide students with their study);
- students come together as a group to share their learning and collectively improve their understanding of the issues that arose from the clinical case;
- PBL sessions have specified learning objectives and PBL learning is assessable.

The nature of the PBL process is aligned with strategies that promote patient safety in the workplace such as:

- collaborative learning;
- reviewing cases, identifying problems and issues as a group;
- sharing the workload and exploring/researching problems as an individual;
- learning from and teaching peers;
- group problem solving;
- respecting roles and responsibilities;
- showing respect to colleagues.

Many of the skills developed in the PBL process will assist students to be effective future members of health-care teams involved in continuous quality improvement in the workplace.

How learning issues emerge from the problem-based learning case

For a PBL session to achieve its aims the clinical case needs to be written in a way that promotes curiosity and discussion.

Example of a PBL case:

Jeremy So is a 15-year-old boy who arrives at the local medical clinic with noisy breathing and itch. His father says he was fine 30 minutes ago and that he just became unwell quite suddenly. On examination, Jeremy looks distressed and nervous. He has a puffy face, his lips are huge and he can hardly open his eyes as they are so swollen. He has red blotches on his skin and he is scratching his body. Every time he breathes in he makes a noise.

From this case a number of questions may arise in the minds of the students:

- What is the most likely diagnosis? What else could it be?
- What could have caused the problem?
- How does the diagnosis explain all the clinical features?
- What is the underlying pathophysiology of the condition—can the features be explained by understanding the pathophysiology?
- What is likely to happen to Jeremy if he does not get treatment?
- What is the treatment?

Example of the same case written to elicit discussion of medical error as well as answers to the above questions:

Jeremy is a 15-year-old boy who arrives at the local medical clinic with noisy breathing and itch. His father says he was fine 30 minutes ago and that he just became unwell quite suddenly. On examination, Jeremy looks distressed and nervous. He has a puffy face, his lips are huge and he can hardly open his eyes as they are so

swollen. He has red blotches on his skin and he is scratching his body. Every time he breathes in he makes a noise.

Jeremy's father says his son was like this once before after having some medicine called penicillin and he was told never to have penicillin again because it could kill him. Jeremy saw a doctor this morning because of a runny nose, sore throat and fever. The doctor prescribed amoxicillin, which Jeremy started earlier today. Jeremy's father wonders if his son might also be allergic to this new medicine amoxicillin.

With the case written in this way some additional questions for discussion may arise:

- How might Jeremy have been given amoxicillin when he has a known serious allergy to penicillin?
- Why Jeremy was prescribed an antibiotic when the most likely cause of his symptoms is a viral upper respiratory tract infection?
- This problem was preventable; has someone made a mistake?
- How can this type of situation be prevented? What is the doctor's role? What is the patient/carer's role in prevention of this situation?
- How much should the doctor explain to Jeremy and his father about how the mistake was made?

In addition to a well-written case, clearly stated learning objectives help keep students' discussion on the intended path. It may be that only the teacher has access to the learning objectives and can guide students in the right direction if need be. So, in this sample case, as well as objectives that relate to the pathophysiology, clinical manifestations and treatment of severe allergic reactions, one or two of the objectives could be focused on patient safety issues.

For example:

- list a doctor's responsibilities when prescribing medication.
- list strategies to minimize patients being given medications that may harm them.

Some schools may provide students with pre-determined questions as part of the PBL process.

For example:

- What are doctors' responsibilities when prescribing a new medication?
- How is a thorough allergy history performed?
- Define the following terms: medical error, adverse event, near miss.

Suggestions for adjusting problem-based learning sessions to include elements of patient safety

- Include information in the case that relates to a patient safety issue. To achieve this, include aspects of the realities of the health-care delivery system, which will provide opportunities to explore issues relating to patient safety.
- Make the case relevant to your local health-care environment.
- The case may include a near miss or adverse event such as the above example.
- The case may include a threat to patient safety thus helping students to recognize where the hazards in the system are.

A case may include a nurse (or medical student) noticing some important information that the doctor has overlooked. The case can describe the nurse being assertive (speaking up), the doctor being receptive to the nurse and the patient's care being improved as a result.

The patient safety issue may be a major or minor component of the case.

- If your school has learning objectives for each PBL case, include patient safety knowledge

in the objectives.

- If your school has pre-determined questions for PBL cases, include questions about patient safety.
- If your school provides resources and/or reference material for students doing PBL cases, include patient safety literature.
- If your school provides tutor notes as part of the PBL process, include patient safety literature.
- Use PBL cases that cover broad patient safety concepts early in the programme (such as the multifactorial nature of error or human factors) and cases that include specific applications of patient safety concepts later in the programme. This will help students reinforce major concepts over time and apply their knowledge to different situations.

Integration of patient safety into a procedural skills training programme

Invasive procedures have the potential to harm patients. This is especially so when procedures are being done by learners who are still lacking in experience. Procedures can cause harm through complications, pain and emotional distress, not being effective and not being necessary in the first place. The knowledge, skill and behaviour of the doctor performing the procedure can help to minimize some of the potential risks for patients. Integrating patient safety education with procedural skills training at an undergraduate level will help medical students to be mindful of their responsibilities to patients when embarking on invasive procedures. This section provides some suggestions on how to integrate patient safety education with procedural skills training in your school.

As a starting point, consider the following questions:

1. When, where and how are procedural skills taught in your school?
2. What are the skills taught?

3. When do students start to perform these procedures on patients? Ideally, the patient safety messages should precede or coincide with this.

Patient safety topics to consider including in a procedural skills training programme

Broad patient safety topics that are relevant for all procedures:

- The learning curve. Understand that an inexperienced clinician is more likely to cause harm and/or fail a procedure compared to an experienced clinician. What strategies can be used to help minimize harm while still allowing for learning to take place; for example, the role of careful preparation, planning, background knowledge, observation of others performing the procedure, simulation, supervision, feedback and follow-up of patients (topics 2, 5 and 6).
- What is the required background knowledge a doctor needs to acquire about a procedure before undertaking that procedure (topics 6 and 10)?
- Sterile precautions (topic 11).
- Communicating risk (topics 6 and 9).
- Correct patient Identification, correct side, correct patient (topic 10).
- Follow-up of test results (topics 2, 6, 9 and 10).

Patient safety knowledge and skills applied to the performance of specific procedures:

- Common problems/hazards/traps, trouble shooting (topics 2 and 5).
- Common and serious complications and how to minimize them (topic 1 and 5).
- Advice for patients regarding follow-up (topics 6 and 9).
- Equipment familiarity (topic 2).
- Specific applications of broad patient safety topics (all topics).

For example: Correct patient identification when taking a blood sample. How to label sample tubes to minimize chance of misidentification: label at the bedside, check patients name with an open-ended question, make sure the patient's name matches the label on the sample tube and the label on the request form, i.e. perform a "three-way check".

A variety of educational methods can be used to introduce the broad patient safety topics as they apply to performing invasive procedures—for example, lectures, readings, group discussion, tutorials, online activities and even PBL.

The best time to learn the knowledge and performance requirements of a patient safety topic is when learning the steps of the procedure. This may occur in a practical tutorial at the bedside, using simulation in a skills laboratory or as a tutorial without a "hands-on" component. Students could be asked to read a particular article or guidelines prior to attending the teaching session.

Tutorials on particular procedures provide an excellent opportunity to reinforce generic principles, to detail patient safety applications for a particular procedure and for students to practise performance elements of patient safety.

If your school utilizes immersive scenario-based simulation training, for example, to learn basic and advanced life support, there is an opportunity to incorporate team training into that programme. The advantages of this type of training for incorporating patient safety issues are the realistic situations that mirror many real-life challenges that can emerge from the scenario. For example, knowing *what* to do in an emergency situation is different from actually *doing* it, especially when working as part of a team. The real elements introduced are time pressure, stress, teamwork, communication, equipment familiarity, decision-

making in action and knowing the environment. Similar to other forms of experiential learning, there are opportunities to practise the performance requirements demonstrating safe practice.

Note: Immersive scenario-based teaching using simulation can be a highly effective way for students to learn, but can also be quite confronting for students and not always a comfortable way to learn. Attention to creating a safe and supportive learning environment is very important if this educational method is used. See the section on underpinning educational principles for more details on creating a safe and supportive learning environment.

Clinical skills training programme

Clinical skills training includes learning how to take a history, how to perform a physical examination, clinical reasoning, test ordering and interpretation, procedural skills and communication skills such as providing information, counselling and obtaining informed consent.

A range of methods are used to teach clinical skills such as bedside tutorials, practising with simulated patients, practising with peers, observing videos of expert performance, participation in the clinical environment and presenting cases.

Consider when and how your school delivers its clinical skills programme.

A number of patient safety topics will be appropriate for inclusion in a clinical skills programme. And since the programme may offer opportunities to practise performance elements of patient safety, it is important that good habits be developed early. Note that bedside tutorials offer rich opportunities for tutors to role model safe practice—for example, patient-centred communication and hand hygiene.

Clinical skills training may provide opportunities for students to learn about and practise the following patient safety performance elements:

- communicating risk;
- asking permission;
- accepting refusal;
- being honest with patients;
- empowering patients—helping patients be active participants in their own care;
- keeping patients and relatives informed;
- hand hygiene;
- patient-centred focus during history taking and physical examination;
- clinical reasoning—diagnostic error, consideration of risk benefit ratio of procedures, investigations and management plans.

How to collaborate with ward-based teachers and teachers of clinical skills

For patient safety principles to be integrated broadly throughout the curriculum, the cooperation of many individual teachers will need to occur, particularly if patient safety education is to be delivered in small group settings such as PBL and clinical skills tutorials.

We mentioned in the beginning of this section that many teachers will not be familiar with patient safety concepts and specific knowledge and performance requirements will be new. For example, students may see clinicians in the workplace asking patients their name in a hurried and disrespectful manner, taking shortcuts that may compromise patient safety or display a “blame and shame” attitude when things go wrong. Tutors will need to reflect on their own practice if they are to be effective patient safety teachers and role models.

The following strategies may assist to engage clinical teachers in patient safety teaching:

- conduct a patient safety workshop or lecture series for teachers;

- invite guest speakers to promote patient safety;
- engage/excite teachers about the inclusion of patient safety in the curriculum;
- parallel patient safety education in the postgraduate setting;
- clearly state patient safety learning objectives in tutor notes;
- provide tutors notes on patient safety topics;
- assess patient safety content in exams.

Using case studies

Build local case studies

Case studies can either demonstrate how not to do something (learning from a person’s negative experience) or how to do something right (learning from a person’s positive experience). For example, if a case study is being developed for the topic “being an effective team player”, then the local case study would have elements of teams that are familiar to the local institutions, local clinics or hospitals.

The following steps will assist in building local cases relevant to the topic being taught.

- Review the sections of each topic in this Curriculum Guide outlining:
 - the relevance of the topic to the workplace;
 - the learning objectives for the topic.
- Write down the activities that are captured in the objectives.
- Obtain case studies from:
 - the Curriculum Guide; or
 - ask doctors and nurses in the hospital or clinic to provide cases that can be identified.
- Develop a story that contains the elements set out in the objectives.

The context of the case study should be familiar to the students and clinicians. For example, if there are no intensive care units (ICUs) locally available, then the case studies should avoid mentioning ICUs or placing the case study in an ICU.

How to modify the case studies in the Curriculum Guide

Most of the case studies are written to illustrate a behaviour or process. Many of the cases we have selected and those supplied by the WHO Expert Group relate to more than one topic such as understanding errors, communication, teamwork and engaging with patients. We have listed all of the cases under each topic that we think could be used to demonstrate an appropriate learning objective. Different types of cases have been used, ranging from health services that rely heavily on technology to ones with limited access to technological services. This means that many of the case studies will apply to most medical schools; if not, the case studies can be modified by changing the environment in which the case takes place. The case can also have another type of health provider involved when the one identified in the case study does not exist. For example, patients can be changed from male to female or female to male (if clinically appropriate), can have family members present or absent, or come from a rural area or a city. After a case study has been modified to take into account local elements, give the case study to a colleague to see if it makes sense and is relevant to the topic, local environment and context.

7. Educational principles essential for patient safety teaching and learning

For patient safety education to result in safe practice and improved patient outcomes it needs to be meaningful to students. As with any teaching, one of the major challenges is to ensure transfer of the learning to the workplace. What can educators do to encourage students to apply their learning in a practical way on the job?

The following strategies can help.

Context is highly relevant in teaching patient safety

Contextualize patient safety principles

Patient safety principles need to be made relevant to the daily activities of health-care workers. Aim to show students when and how patient safety knowledge can be applied in practice. This means using examples that students can relate to.

Use examples that are realistic for your setting

Think about the sort of work most of your students will be doing after they graduate and have this in mind when choosing clinical contexts in which to incorporate patient safety education. Including a case about malnutrition, morbid obesity or malaria is not particularly useful if these conditions are extremely uncommon in your clinical practice setting. Use situations and settings that are common and relevant for the majority of your graduates.

Identify practical applications

Help students identify the situations in which they can apply their patient safety knowledge and skills. This way they are more likely to recognize opportunities for safe practice in the workplace as they arise. For example, correct patient identification is important in:

- sending off blood samples;
- administering medication;
- putting labels on imaging request forms;

- writing in patients files;
- writing on patients medication charts;
- performing procedures;
- working with patients who have difficulty with communication.

Use examples that are of interest or soon will be relevant to students

Draw on situations that the students may find themselves in when they are junior doctors and/or as medical students on clinical placement. For example, if the topic is about being a patient advocate, it is far better to use an example of a student being assertive with a surgeon rather than the senior hospital doctor needing to be assertive with hospital management. This way, the relevance of the material will be more apparent to students, resulting in better motivation for learning (see Box 5 for an example).

Box 5. Practical application example

While observing a surgical operation a medical student notices that the surgeon is closing the wound and there is still a pack inside the patient. The student is not sure if the surgeon is aware of the pack and is wondering whether to say something.

Give students the opportunity to practise applying their patient safety knowledge and skills

By giving students the opportunity to practise “safe practice”, it will hopefully become habitual, and students will be more inclined to approach clinical situations with a patient safety mindset.

Practising “safe practice” can occur as soon as students commence their medical training—for example, in:

- tutorials or private study, e.g. brainstorming solutions for hazardous situations;
- a simulation setting, e.g. skills laboratory,

- simulation laboratory, role play;
- the clinical environment, e.g. hand hygiene when seeing patients, correct patient identification when drawing blood from a patient;
- patient interactions—when advising, students can practise encouraging patients to be informed, ask questions and be proactive in ensuring care progresses as planned.

Create an effective learning environment

Aspects of the learning environment can also have a bearing on the effectiveness of teaching and learning. An ideal learning environment is one that is safe, supportive, challenging and engaging.

Safe and supportive learning environments

A safe and supportive learning environment is one in which:

- students feel comfortable to ask “stupid” questions;
- volunteer what they do not understand;
- share what they do understand in an honest and open way.

Students who feel safe and supported tend to be more open to learning, enjoy being challenged and are more prepared to actively participate in learning activities.

If students feel unsafe and not supported they will tend to be reluctant to disclose knowledge deficits and less likely to engage actively for fear of feeling embarrassed or being humiliated in front of their teachers and peers. The student’s primary aim becomes self-preservation rather than learning. Attention to creating a safe and supportive learning environment not only makes learning more enjoyable, but also, importantly, makes learning more effective. The teacher has a significant role in making the learning environment a comfortable place for students.

Suggestions for helping to create a safe and supportive learning environment:

- Introduce yourself to students and ask the students to introduce themselves. Show an interest in them as individuals as well as showing an interest in their learning.
- At the start of your teaching session, explain how the session will run. This will let the students know what to expect, and also what is expected of them.
- Orient learners to the environment you are teaching in. This is especially important if you are in the clinical environment or a simulation environment. Students need to know what is expected of them if they are in a new setting. Simulation environments can be confusing as some aspects are real, some aspects are not, and the learner is asked to pretend that some aspects are real. Make sure the learners know the level of immersion required for the role play, and how realistically you expect them to treat the situation. It may be embarrassing for a student to talk to an intravenous (IV) cannulation insertion practice arm as if it were a real patient when the teacher’s intention was just to use the IV insertion practice arm for practising the manual aspects of the task.
- Invite students to ask questions and speak up if there is anything they do not understand. This sends the message that not knowing is okay.
- Never criticize or humiliate a student for lack of knowledge or poor performance. Rather, this should be viewed as a learning opportunity.
- If active participation is required, ask for volunteers rather than singling people out yourself.
- Consider demonstrating how to do something yourself before asking students to have a turn. For example, when teaching about how to create a sterile field before doing a lumbar

puncture, it is much more efficient to demonstrate how to do it correctly at the outset, rather than have a student do it in front of their peers before having been taught how and making mistakes that need to be corrected.

- When asking questions of a group of students it is best to ask the question first, then give students time to think about the question and then look for someone to provide a response. Avoid choosing a student before asking the question. Some students will find this unnerving and may have trouble thinking clearly if a whole class is waiting for their response.
- If, as the teacher, you are asked a question you do not know the answer to, do not try to hide this fact or apologize for not knowing. To respond in such a way would send a message to the students that not knowing is unacceptable. A useful quote to remember is, “the three most important words in medical education are ‘I don’t know’” [1].
- When providing feedback on performances in the clinical (or simulation) setting, make it a two-way conversation. Ask students for their opinion before giving your own and include aspects of performance that were done well and areas that need more work. Help students develop a plan for addressing the areas that need more attention.

Challenging and engaging learning environments

Students who are challenged by the teacher are likely to progress their learning more rapidly. A challenging learning environment is one where students are encouraged to think about and do things in new ways. Assumptions are challenged and new skills are developed. Students value these kinds of learning activities. It is important to emphasize the difference between a challenging learning environment and an intimidating learning environment. In fact, a safe and supportive

learning environment is a prerequisite for challenging students. When students feel safe and supported they are open to being challenged, when they are challenged they will be more inclined to engage in the process.

Another important facet to effective teaching is the use of engaging learning activities, which require students to exercise their brain, mouth or hands, not just their ears. Try to avoid activities where students are simply passive recipients of information. The more active the activity, the more likely it is to impact on the students learning.

Experiential learning activities such as interviewing a patient, practising a procedural skill in a workshop and role play are usually very engaging simply by virtue of the fact that they require students to do things. Small group work such as PBL also tends to be engaging because of the collaborative nature of the activity, the tendency of the case to generate questions in the minds of the learners and the need to solve problems.

It can be challenging to deliver lectures that are engaging. The following strategies may help:

- try to be interactive;
- pose questions to the students;
- have students discuss an issue or share their experience in pairs;
- tell a story to illustrate a point;
- use case examples or problems that students can easily relate to as the starting point for the lecture;
- relate theoretical concepts to concrete examples;
- have students critique a video, case, statement, solution or problem.

Activities such as observing a hospital activity, reading an article or observing an invasive procedure can be made more engaging if students have a task to complete as part of the

process. Ideally, the task would help develop critical reflection skills. For example, if students are required to attend morbidity and mortality meetings, they could have some pre-set questions to address based on their observations.

Teaching styles

Individual educators tend to adopt a preferred style of teaching if the option exists [2]. The preferred style is likely to be determined by a combination of the teacher's beliefs about what works best, their aptitudes and what they feel most comfortable with.

Styles can range from teacher-led where the teacher adopts the expert role and presents information to the learners via a lecture or demonstrates how to do something via role modelling, to student centred where the teacher may simply facilitate students to learn for themselves and from peers—for example, PBL or small group project work. Teachers who adopt the student centred approach may see their role as a motivator and guide for students as they work through a learning activity. The teacher's skills may be in formulating engaging learning activities, facilitating group discussion, asking thought provoking questions and/or providing effective feedback.

Each teaching style has advantages and disadvantages, which will vary with the content to be taught, the number of students, the students' preferred learning styles (if known), the teacher's abilities and the time and resources available for the teaching session. Advantages of student-centred styles include the encouragement of collaboration, communication and proactive group problem solving skills among students: all useful experiences for being an effective team member in the workplace. It is helpful to be aware not only of your preferred teaching style, but also to be aware of other ways of teaching that may be

equally or more effective in particular circumstances. The ability to be flexible is encouraged. It may be that you will need to adjust your usual methods to fit in with the overall curriculum delivery design at your school.

Harden identifies six important roles of the teacher: [3]

- information provider;
- role model;
- facilitator;
- assessor;
- planner;
- resource producer.

As an information provider in the field of patient safety, it is important to be well informed about it. This requires knowledge of basic patient safety principles, why it is important in the clinical setting and what staff can do to promote patient safety in the workplace. Spending time reflecting on one's own practice and approaches to hazards in the workplace will help identify relevant teaching points for your students. There are many ways a clinical teacher can role model safe practice. When you are in the clinical setting with patients, students will notice how you:

- interact with patients and families;
- respect the wishes of patients and families;
- inform patients and families of risks;
- consider risk–benefit ratios in determining management plans;
- respond to and invite questions from patients and families;
- wash your hands between patients;
- adopt a team approach;
- welcome advice from colleagues;
- adhere to workplace protocols;
- acknowledge uncertainty;
- acknowledge and learn from your own and others' errors [4];
- problem solve systems issues;
- look after yourself and your colleagues.

You can be a very effective patient safety teacher simply by being a safe practitioner yourself in the presence of students who are eager to learn.

Considering the patient in patient safety learning

Patient safety education can be incorporated into many different educational settings from the clinical environment to the lecture theatre and PBL tutorial room simply by being mindful of where the learning opportunities are. The following half questions may give you ideas about how to create a patient safety learning moment:

- What are the hazards for the patient here...
- What do we need to be mindful of in this situation...
- How can we minimize the risks...
- What would make this situation more risky for the patient...
- What should we do if X should occur...
- What will be our plan B...
- What would we say to the patient if X occurred...
- What are our responsibilities...
- Who else can help with this situation...nursing staff? Patient?
- What happened? How can we prevent this in the future...
- What can we learn from this situation...
- Let's look at the risk–benefit ratio of your suggested plan...

Some of the best teaching students will experience comes from patients themselves. Their role in medical education has a long history, usually in relation to describing their experience of a disease or illness. However, they can also teach students about communication, risk communication, ethics, responses to adverse events and more.

A cautionary note

Remember that students may become demoralized if there is undue emphasis on risk, errors and patient harm. An effective patient safety teacher will be able to balance this by addressing the positive aspects of the area such as solutions to problems, progress in patient safety and equipping students with concrete strategies to improve their practice. It is also important to remind students of the success of the majority of patient care episodes. Patient safety is about making care even better.

Resource material

Teaching on the run series

(<http://www.meddent.uwa.edu.au/go/about-the-faculty/education-centre/teaching-on-the-run/teaching-resources>).

National Center for Patient Safety of the US
Department of Veterans Affairs
(www.patientsafety.gov)

ABC of learning and teaching in medicine Edited by Peter Cantillon, Linda Hutchinson and Diana Wood, British Medical Journal Publishing Group, 2003.(<http://hsc.unm.edu/som/med/medseries%20on%20Medical%20Journal%20series%20on%20Medical%20Education.htm>)

ABC of Patient Safety, Edited by John Sandars and Gary Cook, Malden, MA, Blackwell Publishing Ltd, 2007.

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4. Pilpel D, Schor R, Benbasset J. Barriers to acceptance of medical error: the case for a teaching programme. *Medical education*, 1998, 32(1):3–7.

8. How to assess patient safety

The purposes of assessment

Assessment is an integral part of any curriculum. The content and format of assessment procedures strongly influence the study behaviour and learning outcomes of the students. It is essential that assessments used in the patient safety curriculum support the exit learning outcome objectives as well as providing appropriate motivation and direction for the students. Assessments should be meaningful and give confidence to teachers, course planners and external stakeholders such as accreditation bodies, standards boards and the future employers of our students. WHO recommends that guidelines such as the international best practice in developing assessment guidelines are considered when assessing elements in medical curricula.

Formative assessments

Formative assessments are a vital and inherent part of the learning process for students. A wide range of such activities is possible within all components of a medical programme. Self-assessment is the ability of students to assess their own learning needs and choose educational activities that meet these needs. (The preponderance of evidence suggests that students have a limited ability to accurately self-assess and may need to focus more on external assessment.)

Summative assessment

All components of assessment that the students have to pass, or have to complete before progression from one part of the course to another may occur, are regarded as summative. In general terms, they fall into two types of assessment: end-of-course examinations and in-course assessments.

End-of-course summative assessments

Such assessments can typically be at the end of an eight-week block, end of term, end of year or end of programme. The bulk of this chapter

covers the requirements of end-of-course assessments.

In-course summative assessments

There is a range of course assessments that can easily be introduced in the patient safety curriculum. Many schools could incorporate these elements into existing portfolios or the “record of achievement”.

Some features of “best assessment” practices in patient safety

The following assessment principles will apply to achieving the aims of patient safety curriculum. The assessments should:

- drive learning in the intended direction of meeting the exit learning outcomes of a newly graduated doctor capable of safe patient care;
- have a strong formative element, with regular opportunities for remediation and counselling throughout the course;
- be integrated with, for example, clinical competence and not be discipline based;
- be included in examinations of clinical competence and professional behaviours in all stages of the course;
- be included in examinations of basic sciences, e.g. integrated in population health sciences at all stages of the course;
- be progressive and ensure proportions of material from previous stages will be included in all subsequent exams;
- be developed with the expectation that they will meet quality assurance standards;
- claim fairness by engaging students and staff in the process of development;
- be motivating and provide direction for what students need to learn to practise safely;
- be feasible and acceptable to both faculty and students;
- conform to the “house style” to add to the professional appearance of the procedures.

Defining what is to be tested

Blueprinting

Students internationally are concerned about the amount of material in the curriculum that they have to learn, and are made anxious by not knowing what might be assessed. Blueprinting is a way of defining the range of competencies (or knowledge) to be tested. These will be drawn directly from the learning outcomes of the curriculum. It is important to ensure that the planned assessment adequately samples the range of competencies by the end of the medical degree.

Some competencies need to be systematically assessed to ensure that students build on their knowledge and integrate into their clinical practice. To create a blueprint, the dimensions of the grid are created to cover the expected competencies. One should ensure there is even weighting of the components being assessed and, therefore, adequate sampling of the material. For example, Table 4 shows different components of patient safety that might be assessed in end-of-year assessments throughout the five years of an undergraduate medical degree.

Table 4. A blueprint showing end-of-course assessments for components of the patient safety curriculum

Assessable learning outcomes	Year that curriculum modules are first assessed in a typical programme			
	Year 1	Year 2	Year 3	Year 4
Health law	X			
Health-care systems		X		
Communication		X		
Safe patient care			X	
Quality improvement				X

Select appropriate test methods

It is important to emphasize that assessment in patient safety is aligned with the agreed learning outcomes. It is unlikely that any particular assessment format is suitable to assess everything required. It is best to be aware of the range of assessment methods and make a decision based on an understanding of their strengths and limitations. Let the purpose of the assessment, for example, “to assess knowledge of health-care law in the unconscious patient” drive the choice of format, in this case a modified essay question (MEQ) or a multiple choice question (MCQ).

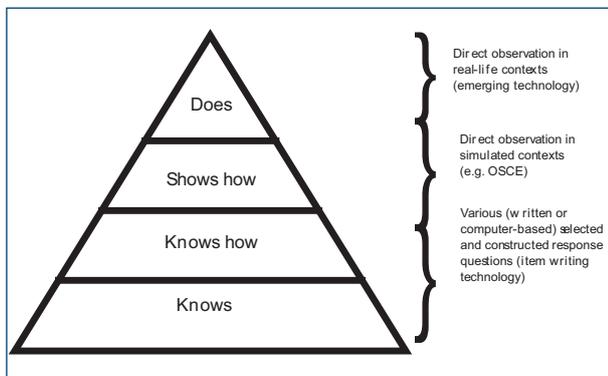
Quality improvement methods may be best assessed via a student project. There are a number of basic concepts in assessment to help decide which type of assessment format is most

appropriate. One of the most well known of these is Miller’s triangle, which suggests that a student’s performance is made up of four levels (see Figure 2):

- knows
- knows how
- shows how
- does.

For example, “showing how” is related to specific competencies that are appropriate for the level of expertise of the student. These can be examined by, for example, an objective structured clinical examination (OSCE) station.

Figure 2. Miller's triangle



Source: Miller GE. The assessment of clinical skills/competence/performance. *Academic Medicine*, (Supplement), 1990, 65:S63-S67.

Again, looking at Figure 2, one can see that knowledge (knows) can be tested by MCQs, for example.

Typical assessment formats within a medical school might include:

Written:

- multiple choice items (1 from 4/5);
- extended matching questions (EMQ);
- structured short answer questions;
- modified essay question (MEQ);
- extended written work (e.g. project reports, posters);
- portfolio/log books.

Clinical/practical:

- multiple station exams;
- direct observation of performance (e.g. observed long cases, mini clinical evaluation exercise [Mini-CEX]);
- 360 degree or multisource feedback (MSF);
- structured reports (e.g. attachment assessments);
- oral presentations (e.g. projects, case-based discussion);
- structured oral exams.

There are some strengths and weaknesses with all of these formats and which need to be considered when choosing the right assessment for a particular learning outcome within a patient safety curriculum.

Written

Multiple choice question/extended matching question

MCQ and EMQ are very attractive formats in that they can test a wide sample of the curriculum, can be machine marked and give reliable scores of a student's ability. However, their main drawback in testing aspects of clinical competence, such as patient safety, is that they tend to test knowledge only. This is appropriate with, for example, health-care law and aspects of patient safety in public health. It is not appropriate in testing, for example, ethical reasoning. An example of an MCQ is given in Appendix 2. The EMQ has been designed to address the issue of guessing in multiple choice exams.

Modified essay questions/key feature

The traditional essay is used in some places. There is great advantage in allowing students to evidence their critical thinking, reasoning and problem solving skills. However, marking essays for large classes are resource intensive and subject to much variability in judges marks. However, MEQs or key feature formats are designed to be answered in 5–10 minutes, and encourage short note responses to appropriate scenarios. Providing a model answer and marking scheme helps examiners maintain some standardization. Several MEQs on a range of different subjects can be asked in the time it takes to write one essay sampling just one area of the curriculum. An example is given in Appendix 2.

Portfolio/logbook

A spectrum of assessment methods to evidence with respect to key learning outcomes, ranging from a log of clinical activities, through a record of achievements throughout a segment of the programme, to documentation supporting an annual appraisal, complete with learning plans. A particularly useful component of the portfolio is the critical incident. Here students are asked to reflect in a structured way on clinical situations they have observed where patient safety was an issue.

Clinical/practical

There is a wealth of research evidence to suggest that having more than one observer improves the accuracy of competency assessments. It is very important that considerations of patient safety are incorporated within the marking rubrics, examiner training and feedback sessions of each of the assessments that is used in the medical school context. If the topic is assessed separately, it will drive students to learn patient safety as something extra to be added on, rather than as an integral part of safe patient care.

Objective structured clinical examination (OSCE)

OSCE comprises of a circuit of short simulated clinical cases assessed either by a standardized patient or the clinical teacher. Patient safety can be incorporated as at least one item within the checklist for each simulated scenario. Alternatively, a single case can be entirely dedicated to a patient safety case—e.g. communicating an adverse event to a simulated patient recovering from routine abdominal surgery. Cases in which the student is required to look at treatment charts, X-rays or investigations are sometimes called static stations as they do not require the student to be observed. This allows, for example, prescribing errors to be simulated and the students actions recorded. An example is given in Appendix 2.

Multisource feedback (MSF)

MSF are collated views from a range of health-care workers or peers about the student in the clinical learning environment. Ideally, checklist items about safe patient care and good communication would be included in the rating form.

Mini clinical evaluation exercise (mini-CEX)

A mini-CEX is where the supervisor observes a student performing a history, examination or communication exercise on a real patient and rates the student on several domains. Aggregated scores of several encounters are used to determine the competency of the student. Once again, it is important to ensure that elements of patient safety are included on the rating form. It is particularly important in a mini-CEX to have good preparation of clinical raters and ensuring that trainers of supervisors include references to patient safety in the training sessions.

End of clinical placement assessments/global rating scales

This assessment aims to give a credible view of a student's progress and is usually completed by the supervisor, based on personal knowledge or after consultation with colleagues. Patient safety criteria need to be included.

Case-based discussion (CBD)

The CBD is a structured discussion of clinical cases by the supervisor focusing on clinical reasoning and decision-making. It takes real cases in which the student has been involved. This is a relatively underexplored technique for examining the understanding of patient safety issues as related to real cases.

Matching assessment to expected learning outcomes

It is always important to match assessments to intended learning outcomes. Most medical curricula will have learning outcomes, some more detailed than others. In Table 5, the complete list of learning outcomes for patient safety can be easily matched with appropriate assessments.

A sample of patient safety outcomes have been modified from the Australian Junior Doctor Curriculum Framework. The Framework has been aligned with many sources, including the Australian Patient Safety Education Framework, and shows that patient safety concepts are completely integrated.

Table 5. Sample of typical end of medical programme learning outcomes for patient safety showing typical assessment formats

Competencies	Assessment format
<i>Safe patient care: systems</i>	
Understand the complex interaction between the health-care environment, doctor and patient	Essay
Aware of mechanisms that minimize error, e.g. checklists, clinical pathways	
<i>Safe patient care: risk and prevention</i>	MCEQ/MEQ
Know the main sources of error and risk in the clinical workplace	Essay/MEQ
Understand how personal limitations contribute to risk	Viva/Portfolio
Promote risk awareness in the workplace by identifying and reporting potential risks to patients and staff	Portfolio
<i>Safe patient care: adverse events and near misses</i>	
Understand the harm caused by errors and system failures	Essay/MEQ
Aware of principles of reporting adverse events in accordance with local incident reporting systems	MEQ
Understand principles of the management of adverse events and near misses	MEQ
<i>Safe patient care: public health</i>	
Understand the key health issues of your community	MCQ
Aware of procedures for informing authorities of “notifiable diseases”	MCQ
Understand principles disease outbreak management	MEQ
<i>Safe patient care: infection control</i>	
Understand prudent antibiotic/antiviral selection	MCQ
Practise correct handwashing and aseptic techniques	OSCE
Always use methods to minimize transmission of infection between patients	OSCE
<i>Safe patient care: radiation safety</i>	
Know the risks associated with exposure to radiological investigations and procedures	MCQ/MEQ
Know how to order radiological investigations and procedures appropriately	MEQ
<i>Safe patient care: medication safety</i>	
Know the medications most commonly involved in prescribing and administration errors	MCQ
Know how to prescribe and administer medications safely	OSCE
Know the procedures for reporting medication errors and near misses in accordance with local requirements	Portfolio

8. How to assess patient safety

Communication	Assessment format
<i>Patient interaction: context</i>	
Understand the impact of the environment on communication, e.g. privacy, location	MEQ
Use good communication and know its role in effective health-care relationships	OSCE
Develop strategies to deal with the difficult or vulnerable patient	OSCE
<i>Patient interaction: respect</i>	
Treat patients courteously and respectfully showing awareness and sensitivity to different backgrounds	OSCE/mini-CEX
Maintain privacy and confidentiality	
Provide clear and honest information to patients and respect their treatment choices	OSCE/mini-CEX
<i>Patient interaction: providing information</i>	
Understand the principles of good communication	OSCE/mini-CEX/MSF
Communicate with patients and carers in ways they understand	OSCE
Involve patients in discussions about their care	Portfolio
<i>Patient interaction: meetings with families or carers</i>	
Understand the impact of family dynamics on effective communication	Portfolio
Ensure relevant family/carers are included appropriately in meetings and decision-making	Portfolio
Respect the role of families in patient health care	MEQ/portfolio
<i>Patient interaction: breaking bad news</i>	
Understand loss and bereavement	MEQ
Participate in breaking bad news to patients and carers	OSCE
Show empathy and compassion	OSCE
<i>Patient interaction: open disclosure</i>	
Understand the principles of open disclosure	MEQ
Ensure patients are supported and cared for after an adverse event	OSCE
Show understanding to patients following adverse events	OSCE
<i>Patient interaction: complaints</i>	
Understand the factors likely to lead to complaints	MEQ/portfolio
Respond appropriately to complaints using the local procedures	OSCE
Adopt behaviours to prevent complaints	OSCE

Resource material

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Multisource feedback

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Multiple choice questions

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Objective structured clinical examination

Newble DI. Techniques for measuring clinical competence: objective structured clinical examinations. *Medical Education*, 2004, 35:199–203.

Portfolios

Wilkinson T et al. The use of portfolios for assessment of the competence and performance of doctors in practice. *Medical Education*, 2002, 36(10):918–924.

9. How to evaluate patient safety curricula

Introduction

In this section we have summarised some general principles of evaluation. Following the publication of this document, WHO plans to make available standard evaluation tools for this curriculum.

As individuals, we engage in evaluation every day: what to eat, what clothes to wear, how good that movie was. Evaluation is an important component of any curriculum, and should be included in your strategy for implementing patient safety curricula at your institution or in your hospital/classroom. It can be as simple as having students complete a questionnaire after exposure to a patient safety session to see what they thought, or as complex as a faculty-wide review of the entire curriculum, which may involve surveys and focus groups with students and staff, observation of teaching sessions and other evaluation methods.

Evaluation involves three main steps:

- developing an evaluation plan;
- collecting and analysing information;
- disseminating the findings to appropriate stakeholders for action.

How evaluation differs from assessment

Information on assessment and evaluation can be confusing due to the fact that some countries use the two terms interchangeably. The easiest way to remember the difference between assessment and evaluation is that assessment is about measuring student performance, while evaluation is about examining how and what we teach. In assessment, data are collected from a single source (the student), whereas in evaluation, data may be collected from a number of sources (students, patients, teachers and/or other stakeholders).

Assessment = student performance.

Evaluation = quality of courses/programmes, quality of teaching.

Step 1: Developing an evaluation plan

What is being evaluated?

A fundamental first step in developing an evaluation plan is identifying the evaluation object: is it a single patient safety session? Is it the entire curriculum? Are we evaluating the faculty's capacity for implementation? Are we evaluating teacher performance/effectiveness? Objects for evaluation can be classified either as policy, programme, product or individual [1]—and all can be applied in the educational setting.

Who are the stakeholders?

There are often many stakeholders involved in the evaluation of patient safety education. However, it is important to identify a primary audience as this will impact the question(s) you want your evaluation to answer. The primary audience may be the university, the faculty, hospital administration, teachers, students or patients/the public. For example, you may be the primary stakeholder if you are a teacher wanting to know how your students are responding to the introduction of patient safety education in your course.

What is the purpose of the evaluation?

After identifying the primary audience/stakeholder(s), the next thing to decide is what you are trying to achieve from the evaluation. What question(s) are you trying to answer? These may differ depending on your role in patient safety education. Table 6 gives examples of the kinds of questions that might be asked depending on the primary stakeholder.

Table 6: Examples of stakeholder questions

Stakeholder	Possible questions for evaluation
Hospital administrators/clinical staff	Does teaching patient safety to interns result in a decreased number of adverse events?
University faculty	How can this patient safety curriculum best be implemented in our institution?
Individual teachers	Am I delivering the curriculum effectively? Are students enjoying it? Are they learning?

What form(s) of evaluation is/are most appropriate?

Evaluation types or forms can be categorized as follows: proactive, clarificative, interactive, monitoring and impact [2]. The forms differ in

terms of primary purpose of the evaluation, the stage of programme/curriculum implementation you are at, the kinds of questions you are asking and the key approaches required. Table 7 provides a summary of each form of evaluation.

Table 7: Forms of evaluation (adapted from Owen [1])

Purpose	Proactive	Clarificative	Interactive	Monitoring	Impact
Orientation	Synthesis	Clarification	Improvement	Justification; fine tuning	Justification; accountability
Major focus	Context for curriculum	All elements	Delivery	Delivery; outcomes	Delivery; outcomes
State of programme/ curriculum	None (not yet implemented)	Development phase	Development phase	Settled; implemented	Settled; implemented
Timing relative to implementation	Before	During	During	During	After
Key approaches	Needs assessment Review of the literature	Evaluability assessment Logic development Accreditation	Responsiveness Action research Developmental Empowerment Quality review	Component analysis Devolved performance assessment Systems analysis	Objectives-based Needs-based Goal-free Process-outcome Realistic Performance audit
Gathering evidence	Review of documents, databases Site visits Focus groups, nominal group technique, Delphi technique for needs assessment	Combination of document analysis, interview and observation Findings include programme plan and implications for organization. Can lead to improved morale	On-site observation Questionnaires Interviews Focus groups Degree of data structure depends on approach. May involve providers (teachers) and programme participants (students)	A systems approach requires availability of management information systems, the use of indicators and the meaningful use of performance information	Pre-ordinate research designs Treatment and control groups where possible Observation Tests and other quantitative data Determining all the outcomes requires use of more exploratory methods and qualitative evidence

Table 7 (Continued): Forms of evaluation (adapted from Owen [1])

Purpose	Proactive	Clarificative	Interactive	Monitoring	Impact
Types of questions	<ul style="list-style-type: none"> - Is there a need for the programme? - What do we know about the problem that the programme will address? - What is recognized as best practice? 	<ul style="list-style-type: none"> - What are the intended outcomes and how is the programme designed to achieve them? - What is the underlying rationale for the programme? - What elements need to be modified to maximize intended outcomes? - Is the programme plausible? - Which aspects of the programme are amenable to subsequent monitoring or impact evaluation? 	<ul style="list-style-type: none"> - What is the programme trying to achieve? - How is it going? - Is the delivery working? - Is delivery consistent with the programme plan? - How could delivery be changed to make it more effective? - How could this organization be changed to make it more effective? 	<ul style="list-style-type: none"> - Is the programme reaching the target population? - Is implementation meeting stated objectives and benchmarks? - How is implementation going between sites? - How is implementation now compared to a month/6 months/1 year ago? - Are our costs rising or falling? - How can we finetune the programme to make it more efficient? More effective? - Are there any programme sites that need attention to ensure more effective delivery? 	<ul style="list-style-type: none"> - Has the programme been implemented as planned? - Have the stated goals been achieved? - Have the needs of students, teachers and others served by the programme been achieved? - What are the unintended outcomes? - How do differences in implementation affect programme outcomes? - Is the programme more effective for some participants than for others? - Has the programme been cost-effective?

Step 2: Collecting and analysing information

Collection

There are a number of data sources and collection methods to consider in an evaluation of patient safety curricula or any other evaluation object. How many and which ones you use depends on your evaluation's purpose, form, scope and scale. Potential data sources include:

- students (prospective, current, past, withdrawn);
- self (engaging in self-reflection);
- colleagues (teaching partners, tutors, teachers external to the course);
- discipline/instructional design experts;
- professional development staff;
- graduates and employers (e.g. hospitals);
- documents and records (e.g. teaching materials, assessment records).

Data may be collected from the above listed sources in a variety of ways, including self-reflection, questionnaires, focus groups, individual interviews, observation and documents/records.

Self-reflection

Self-reflection is an important activity for a medical or clinical educator and has an important role in evaluation. An effective method for reflection involves:

- writing down your experience of teaching (in this case, patient safety education) or feedback received from others;
- describing how you felt and whether you were surprised by those feelings;
- re-evaluating your experience in the context of assumptions made: [3]
 - Were they good assumptions? Why, or why not?

Engaging in self-reflection will allow for the development of new perspectives and a greater commitment to action in terms of improving or

enhancing curriculum and/or teaching.

Questionnaires

Questionnaires are easily the most common method of data collection, providing information on people's knowledge, beliefs, attitudes and behaviour [4]. If you are interested in research, and publishing the evaluation results, it may be important to use a previously validated and published questionnaire. This will save you both time and resources, and will allow you to compare your results with those from other studies using the same instrument. It is always useful as a first step to search the literature for any such tools that may already be in existence.

More often than not, however, teachers/faculties/universities choose to develop questionnaires for their own individual use. Questionnaires may be comprised of open- and/or closed-ended questions and can take a variety of formats such as tick-box categories, rating scales or free text. Good questionnaire design is integral to the collection of quality data, and much has been written about the importance of layout and how to construct appropriate items [3-5]. You may wish to consult one of the references or resources provided prior to developing your questionnaire for evaluation of patient safety teaching or curricula.

Focus groups

Focus groups are useful as an exploratory method and means of eliciting student or tutor perspectives [6]. They often provide more in-depth information than questionnaires and allow for more flexible, interactive exploration of attitudes towards and experiences of curriculum change. They can be used in conjunction with questionnaires or other data collection methods as a means of checking or triangulating data, and can vary in terms of structure and delivery from the conversational and flexible to the strictly

regimented and formal. Depending on resources available and level of analysis sought, you may wish to audio or video record focus groups in addition to or in place of taking notes.

Individual interviews

Individual interviews provide the opportunity for more in-depth exploration of one's attitudes towards potential curriculum change and experiences with the curriculum once it has been implemented. As with focus groups, they can be unstructured, semi-structured or structured in format. Although individual interviews provide information on a narrower range of experience than focus groups, they also allow the interviewer to explore more deeply the views and experiences of a particular individual. One-on-one interviews may be a useful method for obtaining evaluation data from colleagues or faculty leaders/administrators.

Observation

For some forms of evaluation it may be useful to conduct observations of patient safety educational sessions to obtain an in-depth understanding of how material is being delivered and/or received. Observations should involve the use of a schedule to provide a framework for observations. The schedule can be relatively unstructured (e.g. a simple notes sheet) or highly structured (e.g. the observer rates the object of evaluation on a variety of pre-determined dimensions and makes comments on each).

Documents/records

As part of your evaluation, you may also wish to examine documental or statistical information such as teaching materials used or student performance data gathered. Other information such as hospital data on adverse events may also be useful, depending on your evaluation question(s).

Analysis

Your data collection may involve just one of the above or other methods, or it may involve several. In either case, there are three interconnected elements to consider in terms of data analysis [1]:

- data display—organizing and assembling information collected in a meaningful way;
- data reduction—simplifying and transforming the raw information into a more workable or usable form;
- conclusion drawing—constructing meaning from the data with respect to your evaluation question(s).

Step 3: Disseminating findings and taking action

All too often the conclusions and recommendations of evaluations are not acted upon—the first step in avoiding this is ensuring that this valuable information is fed back in a meaningful way to all relevant stakeholders. If the evaluation is on the quality of patient safety teaching, then results (e.g. from student questionnaires, peer-observed teaching sessions) must be relayed to and discussed not only with administration, but also with the teachers. Brinko [7] provided an excellent review of best practice on the process of giving feedback be it for students or colleagues. It is important that any feedback is received in a way that encourages growth or improvement. If the evaluation focuses on effectiveness of the patient safety curriculum, any conclusions and recommendations for improvement must be communicated to all who had a hand in implementing the curriculum (e.g. at the institution, faculty, teacher and student levels). The format for dissemination must be meaningful and relevant. Effective communication of evaluation outcomes, findings and recommendations is a key catalyst for improvements in patient safety teaching and curriculum design.

Resources

You may find the following resources useful for various stages of your evaluation planning and implementation:

Centre for the Advancement of Learning and Teaching, University of Tasmania. *Project evaluation toolkit*, 2005 (<http://www.utas.edu.au/pet/index.html>, accessed 15 May 2008).

DiCicco-Bloom B, Crabtree BF. The qualitative research interview. *Medical Education*, 2006, 40:314–321.

Learning Technology Dissemination Initiative, Hariat Watt University. *The evaluation cookbook*, 1999 (<http://www.icbl.hw.ac.uk/ltdi/cookbook/>, accessed 15 May 2008).

Nelson C. *Evaluation of a patient safety training program*. Santa Monica, RAND Health, 2005 (http://www.rand.org/pubs/technical_reports/2005/RAND_TR276.pdf, accessed 15 May 2008).

Neuman WL. *Social research methods: qualitative and quantitative approaches*, 6th ed. Boston, Pearson Educational Inc, Allyn and Bacon, 2006.

Payne DA. *Designing educational project and program evaluations: a practical overview based on research and experience*. Boston, Kluwer Academic Publishers, 1994.

University of Wisconsin-Extension. *Program Development and Evaluation*, 2008 (<http://www.uwex.edu/ces/pdande/evaluation/>, 15 May 2008.)

Wilkes M, Bligh J. *Evaluating educational interventions*. *British Medical Journal*, 1999, 318:1269–1272.

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5. Taylor-Powell E. *Questionnaire design: asking questions with a purpose*. University of Wisconsin-Extension, 1998 (<http://learningstore.uwex.edu/pdf/G3658-2.pdf>, 15 May 2008).
6. Barbour RS. Making sense of focus groups. *Medical Education*, 2005, 39:742–750.
7. Brinko K. The practice of giving feedback to improve teaching: what is effective? *Journal of Higher Education*, 1993, 64(5):574–593.

10. Web-based tools and resources

Each topic has a set of tools that have been selected from the World Wide Web and designed to assist health practitioners improve the care delivered to patients. We have only included tools that are freely available on the Internet. All of the sites were accessible as of May 2008.

Included in the list are examples of guidelines, checklists, web sites, databases, reports and fact sheets and an outcome focused quality improvement initiative designed to assist health-care teams, professionals and administrators implement a patient safety activity or lead an organization towards a safety culture.

Very few of the tools have been through a rigorous validation process. Most measures in quality tend to be about processes of care and quality that apply to small groups of patients in highly contextualized environments [1] such as an ICU or a ward in a rehabilitation unit.

Most patient safety initiatives require health professionals to measure the steps they take in the delivery care process. This is because one will not be able to tell if the planned changes made any difference to patient care or the outcome. Focusing on measurement has been a necessary and important step in teaching patient safety; if you do not measure, how do you know that an improvement has been made? Even though students will not be expected to measure their clinical outcomes by the time they graduate, they should be familiar with the plan-do-study-act (PDSA) cycle that forms the basis of measurement. Many of the tools on the Internet are based on the PDSA cycle.

Reference

1. Pronovost PJ, Miller MR, Wachter RM. Tracking progress in patient safety: an elusive target *Journal of American Medical Association*, 2006, 6:696–699.

11. Activities to assist patient safety understanding

Introduction

Medical students and junior doctors are accustomed to learning new information by studying and then working hard to apply their new knowledge and skills in patient care. In the case of patient safety, just “trying harder” will not work [1]. Hence, a great deal of thought needs to be given to the timing and format of educational delivery.

The purpose of this chapter is to outline the various strategies that can be used to assist patient safety understanding. These are the same as the variety of teaching strategies that are used for teaching other aspects of medicine. The challenge for the educator is to see if patient safety elements can be incorporated into existing teaching and learning activities. If so, it avoids patient safety topics being seen as an “add on” — and hence extra work — rather than simply being part of a holistic approach to clinical education.

A fundamental principle, in keeping with the principles of effective teaching, is that opportunities for “active learning” should be maximized, during which the learners engage with the learning process in a meaningful fashion, rather than being passive recipients of information.

Active learning can be summarized with the following statement: [2]

Don't tell students when you can show them, and don't show them when they can do it themselves.

Lowman has outlined some teaching strategies for increasing the effectiveness of active learning, including: [3]

- use information that is of interest to learners and involves real-life events;
- present dramatic or provocative material;
- reward learners;
- tie themes together with as many topics as possible;

- activate prior knowledge using pretests and concept maps and gathering background information;
- challenge learners by presenting topics that are more difficult from time to time;
- demonstrate the behaviours you are seeking to promote.

Lectures [4]

In a lecture, the teacher presents a topic to a large group of students. This traditionally occurs in a face-to-face setting; however, recently some universities give students the option of viewing the lecture online via pod-casting.

Lectures should have both:

- aims — indicating the general theme of the lecture, e.g. the aim of this lecture is to introduce you to the topic of patient safety;
- objectives — relating directly to the learning and that should be achievable by the end of the lecture, e.g. by the end of this lecture you will be able to list three major studies that highlight the extent of harm caused by health-care delivery.

Lectures should last about 45 minutes, as concentration falls after this time. It is, therefore, important that they do not contain too much material — aim for four or five key points at the most.

Lectures are often structured as follows, with three principal elements (set, body, close):

- the set, or introduction, is the initial period of the lecture when the lecturer explains why the topic is important and outlines the objectives of the session;
- the body is the main content part of the lecture;
- the conclusion should revisit the objectives and the key points of the presentation.

Benefits:

- able to convey information to large numbers of students at one time;
- useful for providing an overview of broad topics, to impart factual information and introduce theoretical concepts;
- provide up-to-date information and ideas that are not easily accessible in texts or papers;
- can explain or elaborate on difficult concepts and ideas and how these should be addressed.

Challenges:

- keeping large numbers of students actively engaged;
- junior staff generally prefer more experiential techniques;
- presentation skills;
- usually there is some dependence on technology;
- content (medical harm) can be discouraging.

Examples:

- introduction to patient safety;
- introduction to human factors.

Learning on the run during clinical placements

Teaching that occurs in the context of ward rounds or in bedside teaching sessions.

Benefits:

- ward-based teaching provides one of the best opportunities to teach and observe history and examination skills as well as communication and interpersonal skills—the teacher can also role model safe, ethical, professional practice;
- patient safety issues are everywhere in the clinical environment;
- contextualized;
- real—hence highly relevant;
- interesting and often challenging.

Challenges:

- lack of time due to work pressures;
- lack of knowledge of how to incorporate patient safety topics into bedside teaching;
- opportunistic—not possible to prepare and difficult to deliver a uniform curriculum.

Examples:

- hand hygiene issues on the ward;
- patient identification processes.

Resource:

Teaching on the run series

(<http://www.meddent.uwa.edu.au/go/about-the-faculty/education-centre/teaching-on-the-run/teaching-resources>).

Small group activities—learning with others

Learning done in the setting of a small group, usually with a tutor. The main feature is student participation and interactivity, used in relation to a particular problem, with more onus on the students to be responsible for own learning, e.g. PBL, project work.

Benefits:

- sharing own stories;
- learning from peers;
- multiple perspectives;
- learning teamwork and communication skills.

Challenges:

- group dynamics;
- resource implications in terms of tutor time;
- expertise of the tutor.

Examples:

- human factors considerations of commonly used clinical equipment;
- teamwork in the clinical environment.

Resources:

University of Colorado, Denver, Health Sciences Programme
<http://www.uchsc.edu/CIS/SmGpChkList.html>.
Scottish Council for Postgraduate Dental and Medical Education
<http://www.nes.scot.nhs.uk/Courses/ti/SmallGroups.pdf>.

Case discussion

A group of students—often with a tutor—discuss a clinical case.

Benefits:

- can use an actual or made-up case to illustrate patient safety principles;
- contextualized—makes concepts real and relevant;
- learn to solve problems as they arise in the workplace;
- enables linking of abstract concepts to the real situation.

Challenges:

- choosing/developing realistic cases that encourages students to become actively engaged in the discussion;
- using the case effectively to challenge thinking and generate thoughtful learning;
- encouraging students to generate the problem solving themselves.

Resources:

- incident analyses from parent hospital;
- agency for health-care research and quality weekly morbidity and mortality cases;
- <http://webmm.ahrq.gov/>

Games

Encompasses a spectrum from computer games to situational role play.

Benefits:

- fun, enjoyable;
- challenging;
- can illustrate teamwork, communication.

Challenges:

- relating the game to the workplace;
- clearly defining the purpose of the game upfront.

Resource:

- Examples of teamwork generating games
<http://wilderdom.com/games/InitiativeGames.html>

Independent study

Study undertaken by the student on their own, e.g. assignment work, essays.

Benefits:

- student can proceed at own pace;
- student can focus on own knowledge gaps;
- opportunity for reflection;
- cheap, easy to schedule;
- flexible for learner.

Challenges:

- motivation;
- lack of exposure to multiple inputs;
- may be less engaging;
- marking the work and providing the feedback is time consuming for the teacher.

Buddying a patient in hospital (patient tracking)

A student follows the course of an individual patient throughout their hospital stay. Includes accompanying the patient for all investigations and procedures.

Benefits:

- includes the opportunity to learn about the health-care system;

- see things from the patient’s perspectives;
- see how different health-care areas interact together.

Challenges:

- time tabling;
- shaping the experience into a learning exercise;
- limited opportunity for students to:
 - share their learning;
 - get feedback from peers;
 - get assessed.

Role play (docu-drama)

One of the oldest known educational methods. Allows students to act out roles of health-care professionals in particular situations. These fall into two types:

- students improvise the dialogue and actions to fit a pre-determined scenario;
- students “act out” the roles and dialogue of a case study situation.

Benefits:

- cheap;
- requires little training;
- always available;
- interactive—enables learners to try on “what if” scenarios;
- experiential—introduces and sensitized learners to the roles that patients, their families and health-care practitioners and administrators play in patient safety situations;
- allows the learner to adopt a more senior role, or the role of a patient;
- can demonstrate different perspectives;
- ideal for exploring factors in association with interprofessional teamwork and communication in the prevention of patient safety errors.

Challenges:

- writing the scripts;
- developing sufficiently meaningful situations that allow for choices, decisions, conflicts;
- time consuming;
- not all students are involved (some only get to watch);
- students can get off the topic and the role play fizzles out.

Resource:

Kirkegaard M, Fish, J. Doc-U-Drama: using drama to teach about patient safety. *Family Medicine*, 2004, 36(9):628–630.

Simulation

In the context of health care, simulation is defined as “an educational technique that allows interactive, and at times immersive activity by recreating all or part of a clinical experience without exposing patients to the associated risks” [5]. It is likely that in the future increased access to various forms of simulation training will emerge because of the increasing ethical imperative to avoid patient harm [6].

A number of different simulation modalities are available, including:

- screen-based computer simulators;
- low-tech models or mannequins used to practise simple physical manoeuvres;
- standardized patients (patient actors);
- sophisticated computerized (“realistic”) full-body patient mannequin simulators;
- virtual reality devices.

Benefits: [7]

- no risk to patients;
- many scenarios can be presented, including uncommon but critical situations in which a rapid response is needed;
- participants can see the results of their decisions and actions; errors can be allowed to

occur and reach their conclusion (in real life a more capable clinician would have to intervene);

- identical scenarios can be presented to different clinicians or teams;
- the underlying causes of the situation are known;
- with mannequin-based simulators clinicians can use actual medical equipment, exposing limitations in the human–machine interface;
- with full recreations of actual clinical environments complete interpersonal interactions with other clinical staff can be explored and training on teamwork, leadership and communication provided;
- intensive and intrusive recording of the simulation session is feasible, including audiotaping and videotaping; there are no issues of patient confidentiality—the recordings can be preserved for research, performance assessment or accreditation.

Challenges:

- some modalities are very expensive;
- specialized expertise required for teaching and for upkeep of some of the training devices.

Resource:

Society for Simulation in Healthcare
(www.ssih.org).

Improvement projects

Quality improvement is a continuous cycle of planning, implementing strategies, evaluating the effectiveness of these strategies and reflection to see what further improvements can be made. Quality improvement projects are typically described in terms of the PDSA cycle [8] as follows:

- plan—the change, based on perceived ability to improve a current process;
- do—implement the change;
- study—analyse the results of the change;

- act—what needs to happen next to continue the improvement process?

Benefits:

PDSA approaches encourage clinicians to develop and be actively engaged in strategies that they hope will lead to improvement. It also promotes evaluation of these changes once the strategies have been implemented. Therefore, this can be a very useful approach to have students involved at a ward or clinical unit level, ideally as part of a multidisciplinary team approach to patient safety. Most quality improvement projects by their very nature have a patient safety element to them.

- motivating
- empowering
- learn about change management
- learn to be proactive
- learn to problem solve.

Challenges:

- sustaining momentum and motivation
- time commitment.

Example:

- hand hygiene issues in a clinical environment.

Resources

Teaching Quality Improvement Presentation, Institute for Healthcare Improvement
<http://www.ihl.org/NR/rdonlyres/60C85294-F1F9-49D9-8D89-F3DFBD2376A5/1150/TeachingQualityImprovementPresentation.pdf>

Bingham JW. Using a health-care matrix to assess patient care in terms of aims for improvement and core competencies. *Joint Commission Journal on Quality and Patient Safety*, 2005, 31(2:February):98–105.

AHRQ mortality and morbidity web site (<http://www.webmm.ahrq.gov/>).

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2. Davis BG. *Tools for teaching*. San Francisco Jossey-Bass Publishers, 1993.
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5. Maran NJ, Glavin RJ. Low- to high-fidelity simulation - a continuum of medical education? *Medical Education*, 2003, 37(Suppl. 1):22–28.
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12. How to foster and engage in a transnational approach to patient safety education

Patient safety impacts on all countries

In 2002, WHO Member States agreed on a World Health Assembly resolution on patient safety because they saw the compelling evidence of the need to reduce the harm and suffering of patients and their families, and the economic benefits of improving patient safety. The extent of patient harm from their health care has been exposed by the publication of international studies from a number of countries including Australia, Canada, Denmark, New Zealand, the United Kingdom and the United States of America. The concerns of patient safety are international, and it is widely recognized that adverse events are considerably underreported. While the bulk of patient safety research might be done in Australia, the United Kingdom and the United States, patient safety advocates wish to see patient safety adopted in all countries around the world, not just those that have had the resources to study and publish their patient safety initiatives. This internationalization of patient safety requires novel approaches to the education of future doctors and health-care practitioners.

Globalization

The global movements of doctors in training have produced many opportunities for enhancing postgraduate medical education and training. The mobility of students and teachers, and the international interconnectedness of experts in curriculum design, instructional methods and assessment, married with local campus and clinical environments, have led to a concordance in what constitutes good medical education. There have been initiatives to attack the problems of variable standards across the world in the outputs of medical schools. The International Institute of Medical Educators has identified the Global Minimum Education Requirements with the express purpose of defining the minimum competencies that all physicians must have, regardless of where they receive their general medical education or training [1].

The World Federation of Medical Education has also published standards for international best practice in medical school accreditation.

There is evidence that developing countries that have invested heavily in future generations of health-care workers have seen their assets stripped by the predations of the health-care systems of richer developing nations during times of workforce shortages [2].

The globalization of health-care delivery has forced medical education to recognize the challenges of preparing medical students who are not only able to work in their country of training, but also work in other health-care systems. Harden [3] described a three-dimensional model of medical education based on the:

- student (local or international);
- teacher (local or international);
- curriculum (local, imported or international).

In the traditional approach to teaching and learning patient safety, local students and local teachers use a local curriculum. In the international medical graduate or overseas student model, students from one country pursue in another country a curriculum taught and developed by teachers in the latter. In the branch-campus model, students, usually local, have an imported curriculum taught jointly by international and local teachers.

A second important consideration in the internationalization of medical education is the affordability of e-learning technologies that allow a global interconnectivity where the provider of a teaching resource, the teacher of that resource and the student do not all have to be on campus, in a hospital or out in a community at the same time.

The old style of curriculum emphasizes the mobility of students, teachers and curriculum

across the boundaries of two countries, by mutual agreement, with a high expectation that the country of practice would provide much of the training when the student graduates.

The new way is a transnational approach in which internationalization of patient safety education is integrated and embedded within a curriculum and involves collaboration between a number of schools in different countries. In this approach, the principles of patient safety are taught in the global context rather than the context of a single country.

This model offers a range of considerable challenges and opportunities for international collaboration in patient safety education. This Curriculum Guide serves as an excellent base in this regard. It is important that the standards of international medical education bodies, for example, the World Federation of Medical Education, are reviewed to ensure that the principles of patient safety are included. Similarly, a dialogue is held with national accrediting bodies of medical schools around the world to ensure that patient safety principles are included in their accreditation checklists.

At a more local level, it is important for countries to customize and adapt materials. A good example of a transnational approach to medical education is the experience with international virtual medical schools [4]. Here a number of international universities have collaborated to form a virtual medical school, dedicated to enhanced learning and teaching. This model could be adaptable to patient safety.

Common components of a transnational virtual patient safety curriculum could be:

- a virtual library that would provide access to up-to-date resources, tools and learning activities and access to international patient safety literature (for example, the topics

included in this curriculum);

- a research section that would both facilitate and encourage international collaboration;
- a curriculum map that identifies common areas of global interest in patient safety—it is vital that staff and students are able to customize programmes to meet their local and individual needs;
- a collaboration section that includes online discussions among students from different countries who participate as part of a collaborative learning environment in an international community of learners; a place for teachers to share experiences;
- an “ask-the-expert” facility with online access to patient safety experts from different countries;
- a bank of virtual patient safety cases with emphasis on a ethical hazards, disclosure and apology;
- an approach to patient safety that includes cultural awareness and respects competences;
- an assessment bank of patient safety items for sharing—for example, the Hong Kong International Consortium for Sharing Student Assessment Banks is a group of international medical schools that maintains a formative and summative bank of assessment items across all aspects of medical courses.

Content experts in patient safety and educational developers are in limited supply and often work in isolation. This impedes the sharing of information, innovation and development and often results in unnecessary duplication of resources and learning activities. A transnational approach to patient safety education will ensure that there is true international capacity-building in patient safety education and training. It is one way that developed nations can assist developing nations by sharing their substantial curriculum development resources.

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PART B: CURRICULUM GUIDE TOPICS

WHO Patient Safety
Curriculum Guide
for Medical Schools

Introduction to the Curriculum Guide topics

Why do medical students need patient safety education?

Health-care outcomes have significantly improved with the scientific discoveries of modern medicine. But we also know as a result of studies undertaken in many countries that along side these benefits are significant risks to patient safety. We know that hospitalized patients and patients on medications have increased risks of adverse events. A major consequence of this knowledge has been the development of patient safety as a specialized discipline. Patient safety is not a traditional stand alone discipline; rather, it is one that integrates into all areas of medicine and health care.

Medical students as the future clinicians and leaders in health care will need to know about patient safety: how systems impact on the quality and safety of health care, how poor communication can lead to adverse events and much more. Students need to learn how to manage these challenges.

The WHO World Alliance for Patient Safety aims to implement patient safety worldwide. Patient safety is everyone's business—health professionals, cleaners and catering staff, managers, bureaucrats, consumers and politicians. As medical students are among the future leaders in health care, it is vital that they are knowledgeable and skilful in their application of patient safety principles and concepts. This Curriculum Guide equips medical students with essential patient safety learning so they can practise safely in all their clinical activities.

The time to build students' patient safety knowledge is right at the beginning of their entry into medical school. Students need to practise their patient safety skills and behaviours as soon as they enter a hospital, clinic or health service.

By getting students to focus on each individual patient, having them treat each patient as the unique human being they are, practising their knowledge and skills for the patient's benefit alone, students themselves can be role models for others in the health-care system. Most medical students have high aspirations when they enter medicine, nevertheless the reality of the system of health care sometimes deflates their optimism. We want students to be able to maintain their optimism and believe that they can make a difference, both to the individual lives of patients and the system of health care.

How to approach patient safety teaching: managing the barriers

Effective student learning depends on teachers using a range of educational methods such as imparting knowledge, demonstrating skills, instilling attitudes—all are essential for patient safety education. Teachers of patient safety should use:

- problem-based teaching (facilitated group learning);
- simulated-based learning (role plays and games);
- lecture-based teaching (interactive/didactic);
- mentoring and coaching (role models).

Patients judge their doctors not by how much they know but by how they perform. The challenge for medical students when they progress into the clinical environment is to apply their scientific generalized knowledge to a specific patient. In doing so, the student is going beyond "what" they know to knowing "how" to apply their knowledge. The best way for students to learn "how" is by doing. Patient safety practice requires students to act safely—to check names, to seek information about medications, to ask questions. The best ways for students to learn about patient safety are by having hands-on experience or practice in a simulated environment. The student

needs expert coaching rather than a knowledgeable physician talking about underpinning theories. When teachers observe and give feedback about student performance the student will continuously improve and eventually master many of the patient safety skills.

Mentoring and coaching is also particularly relevant to patient safety education. Students naturally try to copy and model their behaviour on their teachers and senior doctors; how they behave will be very influential on how students behave or will behave when they qualify. Most students come to medicine with high ideals—wanting to be a healer, to show compassion and to be an ethical health professional. However, what they frequently see is rushed care, rudeness to colleagues and professional self-interest. Slowly, their high ideals are compromised and become more pragmatic and they just try to fit in with the medical culture around them.

Patient safety education recognizes these strong influences and factors. These negative influences can be moderated and their impact on students minimized by talking with students about the culture and the impact of such cultures on the quality and safety of patients. Recognizing the barriers and talking about them will give the student a sense of the system as a problem (and not the people) and that it is possible to change it for the better. The barriers are not the same for every country, culture or even hospital or clinic within one region. The country barriers might be the laws and regulations governing the health system. These laws may prevent some of the patient safety concepts being implemented. Different cultures have their own approaches to hierarchies and the ways conflicts are resolved. The extent to which students are encouraged to be assertive in the presence of senior doctors, particularly in circumstances where a patient might be at risk of harm, will depend on the

situation and the readiness of the medical profession for change. In some societies, patient safety concepts might not easily fit in with the cultural norms. These barriers are explored in more depth in the following section.

The barriers most evident to students are those that surface in hospitals and clinics. These mainly relate to senior doctors and nurses who are unable to adapt to the new health care challenges, or who are able but actively discourage any change. Their voices can change a student from an advocate for patient safety to a passive learner of textbook medicine. The way the different health professionals, such as nurses, social workers or physiotherapists, maintain their own cultures and continue to work in silos is also a significant barrier.

As teachers become familiar with this curriculum, they will quickly realize that what they are teaching may not be practised in the real world—this is particularly the case with patient safety. Some clinicians may feel that teaching patient safety to medical students is an unachievable goal because of the many barriers. Yet, when barriers are named and talked about, they do not seem so daunting. Even discussion within the student group about the realities and the barriers can inform and teach. At the very least, it will allow a critique of the system.

How the topics relate to clinical practice

Table 8 shows how the Curriculum Guide can be integrated into clinical care using handwashing as an example. The same principles apply to many other areas of health care such as teamwork, medication safety and engaging with patients. This example is used because getting health professionals to stop the transmission of infection by washing their hands using the correct techniques seems such an obvious and easy

thing to achieve. But despite hundreds of campaigns to educate staff about universal precautions we do not appear to have fixed this

problem and hospital-acquired infection rates are climbing worldwide.

Table 8. Integrating curriculum with clinical care: handwashing example

Problem area: minimizing the spread of infection	Curriculum Guide topic and relevance to practise
<p>Problem caused by poor infection control.</p>	<p>Topic 1 “What is patient safety?” describes the evidence of the harm and suffering caused by adverse events. Patients suffering an infection die or spend extended time in hospital or are permanently disabled as a result of their infection. Infections can be avoided and minimized when patients apply correct handwashing techniques and when health professionals comply with universal precautions. Knowing the causes of infections (adverse events) and the steps that can be taken to minimize any opportunity for transmission is the first step to prevention.</p>
<p>People know that infection is a problem, however, just knowing does not seem to change practice. People tend to use correct handwashing techniques for a while, but then they forget.</p>	<p>Topic 2 “What is human factors and why is it important to patient safety?” explains how and why humans work they way they do, which includes making errors. An understanding of human factors will assist people to identify opportunities for errors and know how they can be avoided or minimized. Understanding the factors involved in errors and their root causes will assist people to understand the context of their actions. Telling people to try harder (wash their hands correctly) will not change anything. They need to see their own actions in context of the environment they work in and the equipment they use. When health-care workers believe that a patient’s infection was caused by their actions they are more likely to change practise and use universal precautions.</p>

Problem area: minimizing the spread of infection	Curriculum Guide topic and relevance to practise
<p>People want to maintain proper infection control but there are too many patients to care for and not enough time to wash hands properly.</p>	<p>Topic 3 “Understanding systems and the impact of complexity on patient care” shows how patient care comprises multiple steps and multiple relationships. Patients depend on health professionals treating them in the right way; they depend on a system of health care. Medical students need to know that good health care is a team effort and not just one person. They need to understand that washing hands is not an optional extra but an important step in caring for the patient. Understanding how one’s actions, and each component of care, fit together in a continuous process that has either good outcomes (the patient gets better) or bad outcomes (the patient suffers an adverse event) is an important patient safety lesson. When they understand that the actions of one person on the team can undermine the patient’s treatment goals, they quickly see their work in a different context—a patient safety context.</p>
<p>There are no alcohol rubs or cleaning agents on the wards because the clerk forgot to order them.</p>	<p>Topic 4 “Being an effective team player” is integral to the work of doctors. If no alcohol rubs are available it is up to every member of the team to notify the appropriate person to ensure availability. Just complaining that one cannot wash because someone forgot to order alcohol rubs does not help the patients get better. Being mindful at work and looking for opportunities to assist patients and the team is part of being professional and a team player. Adverse events are often caused by many seemingly trivial things—not washing hands, no medication chart available, delayed attendance of a doctor. Reminding someone to order the alcohol rubs is not trivial in the context that it can prevent an infection.</p>

Problem area: minimizing the spread of infection	Curriculum Guide topic and relevance to practise
<p>A surgeon left the theatre briefly to answer a mobile phone. He returned to theatre and continued the operation wearing the same gloves. The patient experienced a postoperative wound infection.</p>	<p>Topic 5 “Understanding and learning from errors” shows that blaming people does not work, and that if people fear being blamed no one will report or learn from the event. A systems approach to errors seeks to find out the underlying causes of errors and make sure they are not repeated. An examination of the causes of the infection may show that the surgeon left the theatre and did not maintain a sterile environment. Blaming him will achieve nothing. Further analysis may show that the surgeon and the rest of the team had been routinely violating infection control guidelines because they did not think infection was a problem. Without the data they were lulled into a false sense of security.</p>
<p>The patient above who received the infection made a written complaint to the hospital about their care and management.</p>	<p>Topic 6 “Understanding and managing clinical risk” shows students the importance of having systems in place to identify problems and fix them before they happen. Complaints can tell a doctor, nurse or hospital manager if there are particular problems. This patient’s letter of complaint about their infection may be the tenth letter in a month, which could tell the hospital that there may be a problem with infection. Reporting incidents and adverse events is also a systematic way of gathering information about the safety and quality of care.</p>
<p>The hospital decides that it has a problem with infection in a particular theatre and wants to know more about the problem.</p>	<p>Topic 7 “Introduction to quality improvement methods” identifies two major methods for measuring and making improvements in clinical care—students need to know to measure processes of care and measure whether the changes led to an improvement.</p>

Problem area: minimizing the spread of infection	Curriculum Guide topic and relevance to practise
<p>The hospital now knows that one of the theatres has a higher infection rate than the others. Patients are complaining and the hospital was recently in the media about its infection problem.</p>	<p>Topic 8 “Engaging with patients and carers” shows students the importance of honest communication with patients after an adverse event and the importance of giving complete information to patients about their care and treatment. Engaging with patients is necessary to maintain trust of the community.</p>
<p>The hospital decides that infection is a particular problem and that everyone needs to be reminded of the importance of complying with universal precautions.</p>	<p>Topic 9 “Minimizing infection through improved infection control” describes the main types and causes of infections as well as covers the relevant steps and protocols for minimizing the transmission of infection.</p>
<p>The hospital decides to review infection control in theatres because surgical site infections comprise a significant percentage of the adverse events being reported by staff.</p>	<p>Topic 10 “Patient safety and invasive procedures” demonstrates to students that patients having surgery or an invasive procedure are at a higher risk of infection or receiving the wrong treatment. An understanding of the failures caused by poor communication, lack of leadership, inadequate attention to processes, non-compliance with guidelines and over work will help the students to appreciate the multiple factors that are at play in surgery.</p>
<p>In reviewing surgery using a quality improvement method (one that asks “what happened” instead of “who did it”) it was discovered in the search for an intervention that might assist lower the infection rate that the appropriate administration of prophylactic antibiotics can prevent infections. But this protocol also required that a complete medication history was available for each patient to make sure other medications they were taking were safe.</p>	<p>Topic 11 “Improving medication safety” is relevant to students because medication errors cause a significant proportion of adverse events. The scale of medication error is immense and students need to identify factors that lead to errors and know the steps to take to minimize them. Medication safety would ensure that students know about the potential for adverse drug reactions and that one has to consider each medication and its potential interaction with other medications as well as the predicted side-effects of a single medication.</p>

Confronting the real world: helping students to become patient safety leaders

One of the main challenges to patient safety reform is the preparedness of the hospital or clinic to be open to new ways of delivering health care. Change can be very difficult for organizations and practitioners who are used to treating patients in a particular way. They do not necessarily see anything wrong with how they deliver care, and are not convinced they need to change. They may feel threatened or challenged when someone, particularly a junior person, sees things differently and may even do things differently. In these circumstances, unless students are supported with positive coaching and discussion about their experiences, much of the teaching and learning about patient safety at medical school will be undermined.

Medical students learn very quickly about how doctors behave and what is expected of them, and because they are novices they wish to fit in as soon as possible. Many students and junior doctors think their survival of the early years and their careers depends on their fitting in. The system of medical progression relies on reports from supervising clinicians about the performance and development of students and young doctors. Medical students are low in the medical hierarchy and very dependent upon supervisors for their instructions and learning.

For students, maintaining the confidence of a supervisor is paramount. Their progression depends on favourable reports from supervisors based on informal and formal feedback and subjective and objective assessments about their competence and commitment. Patient safety requires that doctors talk about their mistakes and learn from them, but students may fear that disclosing their own mistakes or the mistakes of senior clinicians to supervisors may have

repercussions for them or the doctors involved. Over-reliance on supervisors for teaching and assessment may encourage students to conceal their mistakes and to perform clinical tasks when requested knowing they are not competent in those tasks.

Students may be reluctant to talk to their supervisors about patient safety or express their concerns about an ethical issue. This may also include a reluctance to advise their supervisors about a patient safety issue particularly if it involves a critique of the actions of a senior clinician. They may be fearful of receiving an unfavourable report or being seen as “lacking in commitment” or “having a bad attitude”. Students may hold founded or unfounded fears that speaking up for a patient or disclosing errors may lead to unfavourable reports, decreased employment opportunities, reduced chances for gaining access to training programmes, or all three.

Discussions about medical errors are difficult for doctors in all cultures. Openness to learning from errors will often depend on the personalities of the senior people. In some cultures and hospitals, openness about errors may be new and so it will be very difficult for doctors. In these cases, it may be appropriate for the students to talk about errors in a student teaching session. In other places, error discussions may occur in closed meetings and in more advanced hospitals the team may talk about errors openly and have many policies in place to assist health-care workers navigate their way through an error. But eventually every country will have to confront the human suffering caused by human and system errors. Once the suffering is openly acknowledged by hospitals and clinics it is difficult to stay the same. Many will adopt different approaches to hierarchies and patient care services. These approaches view the team as the main instrument

of health-care delivery; envisaging a flatter hierarchy in which everyone caring for the patient can appropriately contribute.

It may help students if they can understand why the expectations and attitudes of some senior staff seem at odds with what they have learnt about patient safety. Health care has not been designed with patient safety in mind, it has evolved over time with many aspects of care being a consequence of tradition rather than what we would consider safe, efficient and effective care appropriate to contemporary health care. Many attitudes within medicine are deeply rooted in a professional culture that originated in a time when hierarchical structures were common place in society, when medicine was seen as a life vocation that involved a 24 hours a day commitment, when doctors were considered infallible, good doctors did not make mistakes, training was through apprenticeship, patient outcomes (good and bad) were due to the doctor's skills—not the team. Doctors were not professionally accountable to anyone other than themselves and non-paying patients in some places were predominantly viewed as learning material. Although much has changed, some remnants of the old culture have persisted and shaped the attitudes of staff who trained in the days before safety and quality became an important outcome measure of successful health care.

Modern societies want safe quality care and this requires health care to adopt a safety culture. This safety culture has started to permeate health-care workplaces around the world and students will encounter both traditional attitudes and attitudes that stem from a safety culture. The challenge for all students, irrespective of their culture and country, is to practise safe health care, even when those around them do not.

It is helpful to be able to differentiate between old approaches that may negatively impact on patient care and new ways that foster patient-centred care. It is also important to acknowledge that this cultural shift may create some tension for the student or trainee who is keen to practice with safety in mind, but whose direct senior is not aware of, or in favour of, new approaches. It is important that students talk to their supervisors before they start practising the suggested new ways.

We do not expect students to put themselves or their careers at risk in the interest of changing the system. But we do encourage students to think about how they might approach their training and maintain a patient safety perspective at the same time. Table 9 provides a framework that gives students some ideas for managing the conflicts they may experience while they are in supervised placements in hospitals or clinics.

Table 9. Framework for managing conflicts in medical situations

Area or attribute	Example	Old way	New way
<i>Medical hierarchies:</i> handwashing	Doctor does not clean hands between patients.	Student says nothing and conforms to inadequate technique. Imitate senior doctor.	(1) Seek clarification of the correct technique for handwashing with the doctor or other senior person. (2) Say nothing but use safe handwashing techniques. (3) Say something in respectful manner to the doctor concerned and continue to use safe handwashing techniques.
<i>Medical hierarchies:</i> site of surgery	Surgeon does not participate in checking the correct site for surgery or verifying the correct patient. The surgeon is resentful of the preoperative checking protocol, believing it to be a waste of time, and pressures the rest of the team to hurry up.	Adopt the approach of the surgeon and do not participate in checking—decide that checking is too menial a task for a doctor anyway.	(1) Actively help the rest of the team to complete the checking protocol.
<i>Medical hierarchies:</i> medication	Student knows that a patient has a known serious allergy to penicillin and observes a senior doctor prescribe penicillin.	Say nothing for fear of being seen to disagree with a senior doctor's decision. Presume that the doctor must know what they are doing anyway.	(1) Immediately share concern about allergy with the doctor. Student views this as being a helpful part of the team and also their responsibility as a patient advocate.
<i>Paternalism:</i> consent	Student asked to get consent from a patient for a surgical procedure the student has never heard of before.	Accept task. Do not let senior staff know level of ignorance about procedure. Talk to the patient about the procedure in a vague and superficial way so as to get the patient's signature on the consent form.	(1) Decline the task and suggest that a doctor with some familiarity with the procedure would be more appropriate for this task. (2) Accept the task, but explain you know little about the procedure so will need some teaching about it first and request that one of the doctors comes along to help/supervise.

Area or attribute	Example	Old way	New way
<i>Paternalism:</i> role of patients in their care	<p>The patients are ignored during the ward round and not engaged in discussion about their situation.</p> <p>Family members are asked to leave the bedside when the doctors are doing their ward rounds.</p>	<p>Accept the situation and do nothing. Assume that this is the way things are done around here. Conform to behaviours that do not include or engage with patients and their families.</p>	<p>(1) Take the lead in greeting the patient: "Hello Mr Ruiz, we are reviewing all of our patients this morning. How are you feeling today?"</p> <p>(2) If there is time pressure to keep moving, explain to the patient and their family, "I will come back to talk to you after the ward round".</p> <p>(3) Find out your patients' concerns before the round and raise them with the senior doctors on the round at the bedside, e.g. "Mr Carlton is hoping to avoid the surgery, is this an option for him?"</p> <p>(4) Invite and encourage patients to speak up during the ward round.</p> <p>(5) Ask your supervisor whether they think patients and their relatives can add value to the ward round discussion and so improve the efficiency of the unit.</p>
<i>Infallibility of doctors:</i> hours of work	<p>A junior doctor on the ward announces with pride that they have been at work for the last 36 hours.</p>	<p>Admire the doctor for their stamina and commitment to their work.</p>	<p>(1) Ask the doctor how they feel and whether it is wise or even responsible to still be working?</p> <p>(2) Ask the doctor when they are due to finish and how they are going to get home? Are they safe to even drive a car?</p> <p>(3) Make some helpful suggestions: "is there someone who can carry your pager so you can go home and get some rest" or "I didn't think it was allowed for doctors to work such long hours, you should complain about your roster".</p>
<i>Infallibility of doctors:</i> attitude to mistakes	<p>Mistakes are only made by people who are incompetent or unethical. Good doctors do not make mistakes.</p>	<p>Accept the culture that says doctors who make mistakes are "bad" or "incompetent". Try harder to avoid making a mistake. Remain silent, or find someone or something else to blame when you have made a mistake. Look at the mistakes others make and tell yourself you would not be that stupid.</p>	<p>(1) Understand that everyone will make mistakes at some time and that the causes of errors are multifactorial involving latent factors not immediately obvious at the time the error was made. Look after your patients, yourself and your colleagues in the event of an error and actively promote learning from error.</p>

Area or attribute	Example	Old way	New way
<i>Infallibility of doctors: making mistakes</i>	Senior doctor makes a mistake and tells patient it was a complication. Doctors do not talk about their mistakes in peer review meetings.	Accept that the way to handle a mistake is to rationalize that it was a problem associated with the patient rather than their health care. Quickly learn that doctors do not disclose errors to patients or their colleagues and model behaviour of senior doctor.	<p>(1) Talk to a supervisor about open disclosure to patients and whether the hospital or clinic has a policy about providing information to a patient after an adverse event.</p> <p>(2) Ask the patient if they would like more information about their care and if so advise the doctor that the patient would like more information.</p> <p>(3) Tell your supervisor or team leader when you make a mistake and ask how a similar mistake can be avoided in the future.</p> <p>(4) Fill out an incident form if appropriate</p>
<i>Infallibility of doctors: omniscience</i>	A doctor who acts “god like” and looks down on other health professionals and patients.	Aspire to be like this doctor and admire how everyone bows down to them.	(1) Recognize the arrogance in such attitudes and model behaviour on doctors who work in teams and share their knowledge and responsibilities.
<i>Blame/shame</i>	<p>A doctor who makes a mistake is ridiculed or humiliated by his supervisor.</p> <p>A hospital disciplines a staff member for an error.</p>	Say nothing and model behaviour on other doctors who talk negatively about a health professional involved in an incident.	<p>(1) Offer support and understanding to a colleague who is involved in an incident.</p> <p>(2) Talk to colleagues and supervisor about better ways to understand mistakes than just blaming the person involved.</p> <p>(3) Focus on the mistake: ask “What happened?” rather than “Who was involved?” and try to generate discussion within the team/tutorial group about the multiple factors that might have been involved.</p>
<i>Teamwork: my team is the medical team</i>	<p>Students and junior doctors identify only other doctors as being part of their team.</p> <p>The doctors in the ward do their rounds without a member of the nursing staff present.</p>	Change behaviour to reflect that of the rest of the doctors and identify only with the medical members of the team.	<p>(1) Be mindful that the team from a patient’s perspective is everyone who cares for and treats the patient – nurses, ward staff, allied health, including the patient and their family members.</p> <p>(2) Always suggest including other members of the health-care team in conversations and discussions about a patient’s care and treatment.</p> <p>(3) Acknowledge and maximize the benefit of an interprofessional team.</p>

Definition of terms

International Classification for Patient Safety (v.1.0) for Use in Field Testing in 2007–2008

Adverse event:	an incident which results in harm to a patient.
Adverse reaction:	unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred.
Agent:	a substance, object or system which acts to produce change.
Attributes:	qualities, properties or features of someone or something.
Circumstance:	any factor connected with or influencing an event, agent or person(s).
Contributing factor:	a circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident.
Detection:	an action or circumstance that results in the discovery of an incident.
Disability:	any type of impairment of body structure or function, activity limitation and/or restriction of participation in society, associated with past or present harm.
Disease:	a physiological or psychological dysfunction.
Error:	failure to carry out a planned action as intended or application of an incorrect plan.
Event:	something that happens to or involves a patient.
Harm:	impairment of structure or function of the body and/or any deleterious effect arising there from.
Hazard:	a circumstance, agent or action that can lead to or increase risk.
Health:	a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.
Health care:	services received by individuals or communities to promote, maintain, monitor or restore health.
Health care-associated harm:	harm arising from or associated with plans or actions taken during the provision of health care rather than an underlying disease or injury.
Incident characteristics:	selected attributes of an incident.
Incident type:	a descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features.
Injury:	damage to tissues caused by an agent or circumstance.
Mitigating factor:	an action or circumstance which that prevents or moderates the progression of an incident towards harming a patient.
Near miss:	an incident that did not cause harm.
Patient:	a person who is a recipient of health care.

Patient characteristics:	selected attributes of a patient.
Patient safety:	freedom, for a patient, from unnecessary harm or potential harm associated with health care.
Patient safety incident:	an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.
Preventable:	accepted by the community as avoidable in the particular set of circumstances.
Risk:	the probability that an incident will occur.
Safety:	freedom from hazard.
Side-effect:	a known effect, other than that primarily intended, related to the pharmacological properties of a medication.
Suffering:	the experience of anything subjectively unpleasant.
Violation:	deliberate deviation from an operating procedure, standard or rules.

Key to Icons



Slide Number



Topic Number



Groups



Lecture



Simulation exercises



Books



Web



DVD

Topic 1: What is patient safety?

Why is patient safety relevant to health care?

1

There is now overwhelming evidence that significant numbers of patients are harmed from their health care either resulting in permanent injury, increased length of stay (LOS) in hospitals and even death. We have learnt over the last decade that adverse events occur not because bad people intentionally hurt patients but rather that the system of health care today is so complex that the successful treatment and outcome for each patient depends on a range of factors, not just the competence of an individual health-care provider. When so many people and different types of health-care providers (doctors, nurses, pharmacists, social workers, dieticians and others) are involved this makes it very difficult to ensure safe care, unless the system of care is designed to facilitate timely and complete information and understanding by all the health professionals.

Patient safety is an issue for all countries that deliver health services, whether they are privately commissioned or funded by the government. Prescribing antibiotics without regard for the patient's underlying condition and whether antibiotics will help the patient, or administering multiple drugs without attention to the potential for adverse drug reactions, all have the potential for harm and patient injury. Patients are not only harmed by the misuse of technology, they can also be harmed by poor communication between different health-care providers or delays in receiving treatment.

Patient safety is a broad subject incorporating the latest technology such as electronic prescribing and redesigning hospitals and services to washing hands correctly and being a team player. Many of the features of patient safety do not involve financial resources; rather, they involve commitment of individuals to practise safely. Individual doctors and nurses can improve patient

safety by engaging with patients and their families, checking procedures, learning from errors and communicating effectively with the health-care team. Such activities can also save costs because they minimize the harm caused to patients. When errors are reported and analysed they can help identify the main contributing factors.

Understanding the factors that lead to errors is essential for thinking about changes that will prevent errors from being made.

Keywords

Patient safety, system theory, blame, blame culture, system failures, person approach, violations and patient safety models.

Learning objective

2

The objective of this module is to understand the discipline of patient safety and its role in minimizing the incidence and impact of adverse events, and maximizes recovery from them.

Learning outcomes: knowledge and performance

3

4

Patient safety knowledge and skills covers many areas: medication safety, procedural and surgical skills, effective teamwork, accurate and timely communication and more. The topics in this Curriculum Guide have been selected based on the evidence of relevance and effectiveness. This topic takes an overview of patient safety and sets the scene for deeper learning in some of these areas. For example, we introduce the term "sentinel event" in this topic but we go deeper into its meaning and relevance to patient safety in topic 6.

What students need to do (performance requirements):

- apply patient safety thinking in all clinical activities;
- demonstrate ability to recognize the role of patient safety in safe health-care delivery.

What students need to know

(knowledge requirements):

- the harm caused by health-care errors and system failures;
- the lessons about error and system failure from other industries;
- the history of patient safety and the origins of the blame culture;
- the difference between system failures, violations and errors;
- a model of patient safety.

WHAT STUDENTS NEED TO KNOW (KNOWLEDGE REQUIREMENTS)

The harm caused by health-care errors and system failures

5

Even though the extent of adverse events in the health system has long been recognized [1-8], the degree to which they are acknowledged and managed varies greatly across health systems and across health professions. Poor information and understanding about the extent of harm, and the fact that most errors do not cause any harm at all, may explain why it has taken so long to make patient safety a priority. In addition, mistakes affect one patient at a time and staff working in one area may only experience or observe an adverse event infrequently. Errors and system failures do not all happen at the same time or place, which can mask the extent of errors in the system.

The collection and publication of patient outcome data is not yet routine for all hospitals and clinics. However, the significant number of studies that have relied upon patient outcome data [7,9,10] show that most adverse events are preventable. In a landmark study by Leape et al. [10] found that more than two thirds of the adverse events they studied were preventable, 28% were due to the negligence of a health professional and 42% were

caused by other factors not related to such negligence. They concluded that many patients were injured as a result of poor medical management and substandard care. Bates et al. [11] found that adverse drug events were common and that serious adverse drug events were often preventable. They further found that medications harmed patients at an overall rate of about 6.5 per 100 admissions in large US teaching hospitals. Although most resulted from errors at the ordering stage, many also occurred at the administration stage. They suggested that prevention strategies should target both stages of the drug delivery process. Their research, based on self-reports by nurses and pharmacists and daily chart review, is a conservative figure because doctors do not routinely self-report medication errors.

Many studies confirm that medical error is prevalent in our health system and that the costs are substantial. In Australia [13], medical error in one year resulted in as many as 18 000 unnecessary deaths and more than 50 000 disabled patients. In the United States [14], medical error resulted in at least 44 000 (and perhaps as many as 98 000) unnecessary deaths each year and one million excess injuries.

In 2002, WHO Member States agreed on a World Health Assembly resolution on patient safety because they saw the need to reduce the harm and suffering of patients and their families and the compelling evidence of the economic benefits of improving patient safety. Studies show that additional hospitalization, litigation costs, infections acquired in hospitals, lost income, disability and medical expenses have cost some countries between US\$ 6 billion and US\$ 29 billion a year [12,14].

The extent of patient harm from health care has been exposed by the publication of the international studies listed in Table 10. They

confirm the high numbers of patients involved and show the adverse event rate in four countries.

Table 10: Data on adverse events in health care from several countries

	Study	Study focus (date of admissions)	Number of hospital admissions	Number of adverse events	Adverse event rate (%)
1	United States (Harvard Medical Practice Study)	Acute care hospitals (1984)	30 195	1 133	3.8
2	United States (Utah–Colorado study)	Acute care hospitals (1992)	14 565	475	3.2
3	United States (Utah–Colorado study) ^a	Acute care hospitals (1992)	14 565	787	5.4
4	Australia (Quality in Australian Health Care Study)	Acute care hospitals (1992)	14 179	2 353	16.6
5	Australia (Quality in Australian Health Care Study) ^b	Acute care hospitals (1992)	14 179	1 499	10.6
6	United Kingdom	Acute care hospitals (1999–2000)	1 014	119	11.7
7	Denmark	Acute care hospitals (1998)	1 097	176	9.0

Source: World Health Organization, Executive Board 109th session, provisional agenda item 3.4, 5 December 2001, EB 109/9.

a Revised using the same methodology as the Quality in Australian Health Care Study (harmonising the four methodological discrepancies between the two studies).

b Revised using the same methodology as Utah–Colorado Study (harmonising the four methodological discrepancies between the two studies). Studies 3 and 5 present the most directly comparable data for the Utah–Colorado and Quality in Australian Health Care studies.

The studies listed in Table 10 used retrospective medical record reviews to record the extent of patient injury as a result of health care [15-18]. Since then, Canada, England and New Zealand have published similar adverse event data [19]. While the rates of injury differ in the countries that publish data, there is unanimous agreement that the harm is of significant concern. The catastrophic deaths that are reported in the media, while horrific for the families and health professionals involved, are not representative of the majority of adverse events in health care. Patients are more likely to suffer less serious but nevertheless debilitating events such as wound infections, decubitus ulcers and unsuccessful back operations [19]. Surgical patients are more at risk than others [20].

To assist management of adverse events many health systems categorize adverse events by level of seriousness. The most serious adverse events are called sentinel events, which cause serious injury or death. Some countries call these the “should never be allowed to happen” events. Many countries now have or are putting in place systems to report and analyse adverse events. Some countries have even mandated reporting of sentinel events. The reason for categorizing adverse events is to ensure that the most serious ones with the potential to be repeated are analysed by a quality improvement method to make sure that the causes of the problem are uncovered and steps taken to prevent another incident. These methods are covered in topic 7.

Table 11 sets out the types of sentinel events that are required reporting by governments in Australia and the United States.

Table 11. Sentinel events reported in the Australia and the United States [19]

Type of adverse event	USA (% of 1579)	Australia (% of 175)
Suicide of in patient or within 72 hours of discharge	29	13
Surgery on wrong patient or body part	29	47
Medication error leading to death	3	7
Rape/assault/homicide in an in patient setting	8	N/A
Incompatible blood transfusion	6	1
Maternal death (labour, delivery)	3	12
Infant abduction/wrong family discharge	1	-
Retained instrument after surgery	1	21
Unanticipated death of a full-term infant	-	N/A
Severe neonatal hyperbilirubinaemia	-	N/A
Prolonged fluoroscopy	-	N/A
Intravascular gas embolism	N/A	-

N/A indicates that this category is not on the official reportable Sentinel Event list for that country

Human and economic costs

There are significant economic and human costs associated with adverse events. The Australian Patient Safety Foundation estimated for the state of South Australia the costs of claims and premiums on insurance for large medical negligence suits to be about \$18 million (Australian) in 1997–1998 [21]. The National Health Service in the United Kingdom pays out around £400 million in settlement of clinical negligence claims every year [22]. The US Agency for Healthcare Research and Quality (AHRQ) reported in December 1999 that preventing medical errors has the potential to save approximately US\$ 8.8 billion per year [23]. Also reporting in 1999, the Institute of Medicine report, *To err is human—building a safer health system*, estimated that between 44 000 and 98 000 people die each year from medical errors in hospitals alone, thus making medical errors the

eighth leading cause of death in the United States. The Institute of Medicine also estimated that preventable errors cost the nation about US\$ 17 billion annually in direct and indirect costs.

The human costs of pain and suffering include loss of independence and productivity for both patients and the families and carers remains un-costed. While debates [24–27] within the medical profession about the methods used to determine the rates of injury and their costs to the health system continue, many countries have accepted that the safety of the health-care system is a priority area for review and reform.

Lessons about error and system failure from other industries

6

The large-scale technological disasters in spacecraft, ferries, off-shore oil platforms, railway networks, nuclear power plants and chemical

installations in the 1980s led to the development of organizational frameworks for safer workplaces and safer cultures. The central principle underpinning efforts to improve the safety in these industries was that accidents are caused by multiple factors, not single factors in isolation: individual situational factors, workplace conditions and latent organizational and management decisions were commonly involved.

Analysis of these disasters also showed that the more complex the organization, the greater potential for a larger number of system errors in the organization or operation.

Sociologist Barry Turner, who examined organizational failures in the 1970s was the first to appreciate that tracing the “chain of events” was critical to an understanding of the underlying causes of accidents [28,29]. Reason’s work on the cognitive theory of latent and active error types and risks associated with organizational accidents built on his work [30,31]. Reason analysed the features of many of the large-scale disasters occurring in the 1980s and noted that latent human errors were more significant than technical failures. Even when faulty equipment or components were present, he observed that human action could have averted or mitigated the bad outcome.

An analysis of the Chernobyl catastrophe [32] showed that organizational errors and violations of operating procedures that were typically viewed as evidence of a “poor safety culture” [33] at Chernobyl were really organizational characteristics that contributed to the incident. The lesson learnt from the Chernobyl investigation was that the extent to which a prevailing

organizational culture tolerates violations of rules and procedures is critical. This was a feature present in the events preceding the Challenger crash* [3]. That investigation showed how violations had become the rule rather than the exception. Vaughan analysed the Challenger crash findings and described how violations are the product of continued negotiations between experts searching for solutions in an imperfect environment with incomplete knowledge**. This process of identifying and negotiating risk factors, he suggested, leads to the normalization of risky assessments.

Reason [35] took these lessons from industries to make sense of the high number of adverse events inside health care. He stated that only a systems approach (as opposed to the more common “person” approach—of blaming an individual doctor or nurse) will create a safer health-care culture because it is easier to change the conditions people work in than change human actions. To demonstrate a systems approach he used examples from the technological hazard industries that show the benefits of built-in defences, safeguards and barriers***. When a system fails, the immediate question should be why it failed rather than who caused it to fail; e.g. which safeguards failed? Reason created the “Swiss cheese” Model [36] to explain how faults in the different layers of the system can lead to accidents/mistakes/incidents.

Figure 3 uses Reason’s Swiss cheese model and shows the steps and multiple factors (latent factors, error producing factors, active failures and defences) that are associated with an adverse event.

*The viton O-ring seals failed in the solid rocket boosters shortly after launch. The Rogers Commission also found that other flaws in shuttle design and poor communication may have also contributed to the crash.

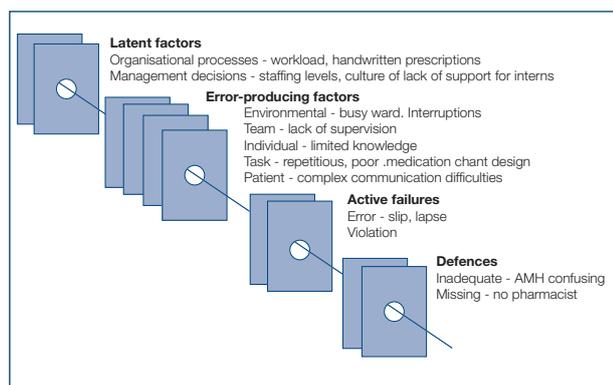
**For nearly a year before the Challenger’s last mission the engineers were discussing a design flaw in the field joints. Efforts were made to redesign a solution to the problem but before each mission, both NASA and Thiokol officials (a company that designed and built the boosters) certified the solid rocket boosters were safe to fly. (See Challenger: a major malfunction by Malcolm McConnell, Simon & Schuster, 1987. Challenger had previously flown nine missions before the fatal crash.

***Engineered defensive systems include automatic shut-downs (alarms, forcing functions, physical barriers). Other defensive mechanisms are dependent on people such as pilots, surgeons, anaesthetists, control room operators. Procedures and rules are also defensive layers.

The diagram shows that a fault in one layer of the organization is usually not enough to cause an accident. Bad outcomes in the real world usually occur when a number of faults occur in a number of layers (for example, rule violations, inadequate resources, inadequate supervision, inexperience) and momentarily line up to permit a trajectory of accident opportunity. For example, if a junior doctor was properly supervised in a timely way, then a medication error may not occur. To combat errors at the sharp end, Reason invoked the “defence in-depth” principle [36]. Successive layers of protection (understanding, awareness, alarms and warnings, restoration of systems, safety barriers, containment, elimination, evacuation, escape and rescue) are designed to guard against the failure of the underlying layer. The organization is designed to anticipate failure thus minimizing the hidden “latent” conditions that allow actual or “active” failures to cause harm.

Figure 3. Swiss cheese model

7



Source: Coombes ID et al. Why do interns make prescribing errors? A qualitative study, Medical Journal of Australia, 2008, 188(2): 89–94. Adapted from Reason’s model of accident causation.

History of patient safety and the origins of the blame culture

8

The way we have traditionally managed failures and mistakes in health care has been called the person approach—we single out the individuals directly involved in the patient care at

the time of the incident and hold them accountable. This act of “blaming” in health care has been a common way for resolving health-care problems. We refer to this as the “blame culture”. Since 2000, there has been a dramatic increase in the number of references to the “blame culture” in the health literature [37]. This is possibly due to the realization that system improvements cannot be made while we focus on blaming individuals. Our willingness to “blame” is thought to be one of the main constraints on the health system’s ability to manage risk [36,38-41] and improve health care. Putting this into the context of health care, if a patient is found to have received the wrong medication causing an allergic reaction we look for the person—be they medical student, nurse or doctor—who gave the wrong drug and blame that person for the patient’s condition. Individuals who are identified as responsible are also shamed. The person responsible may receive remedial training, a disciplinary interview or told never to do it again. We know that simply insisting the health-care workers just “try harder” does not work. Policy and procedures may also change to tell health-care workers how to avoid an allergic reaction in a patient. The focus is still on the individual staff members rather than on how the system failed to protect the patient and prevent a wrong medication being administered.

Why do we blame?

A demand for answers as to why “the event” occurred is not an uncommon response. It is human nature to want to blame someone and far more “satisfying” for everyone involved in investigating an incident if there is someone to blame. Social psychologists have studied how people make decisions about what caused a particular event, explaining it as attribution theory. The premise of this theory is that people naturally want to make sense of the world, so when unexpected events happen, we automatically start figuring out what caused it.

Pivotal to our need to blame is the belief that punitive action sends a strong message to others that errors are unacceptable and that those who make them will be punished. The problem with this assumption is that it is predicated on a belief that the offender somehow chose to make the error rather than adopt the correct procedure: that the person intended to do the wrong thing. Because individuals are trained and/or have professional/organizational status, we think that they “should have known better” [42]. Our notions of personal responsibility play a role in the search for the guilty party. Expressions such as “the buck stops here” or “carrying the can” are widely used. Professionals accept responsibility for their actions as part of their training and code of practice. It is easier to attribute legal responsibility for an accident to the mistakes or misconduct of those in direct control of the operation than on those at the managerial level [42].

Charles Perrow [43] in 1984 was one of the first to write about the need to stop “pointing the finger” at individuals when he observed that between 60% and 80% of system failures were attributed to “operator error” [1]. The prevailing cultural response to mistakes, at that time, was to punish individuals rather than address any system problems that may have contributed to the error(s). Underpinning this practice was the belief that, since individuals are trained to perform tasks, then a failure of that task must relate to the failure of individual performance, thus deserving punishment. Perrow believed that these sociotechnical breakdowns are a natural consequence of complex technological systems [31]. Others [44] have added to this theory by emphasizing the human factor at an individual and institutional level.

Reason [36], building on the earlier work of Perrow [43] and Turner [29], provided this rationale for managing human error:

- Human actions are almost always constrained and governed by factors beyond an individual’s immediate control. (A medical student working in a surgical ward is constrained by the hospital’s management of the theatres.)
- People cannot easily avoid those actions that they did not intend to perform. (A medical student may not have intended to obtain consent from a patient for an operation but was unaware of the rules in relation to informed consent.)
- Errors have multiple causes: personal, task-related, situational and organizational factors. (If a medical student entered the theatre without correct scrubbing it may be because the student was never shown the correct way, has seen others not comply with scrubbing guidelines, the cleaning agent had run out, there was an emergency that the student wanted to see and there was no time, etc.)
- Within a skilled, experienced and largely well-intentioned workforce, situations are more amenable to improvement than people. (If staff were prevented from entering theatres until appropriate cleaning techniques were followed, then the risk of infection would be diminished.)

Reason warned against being wise after the event—so-called “hindsight bias”—because most people involved in serious accidents do not intend something to go wrong and generally do what seems like the “right” thing to do at the time, though they “may be blind to the consequences of their actions” [31].

Today most complex industrial/high technological managers realize that a blame culture will not bring safety issues to the surface [45]. While many health-care systems are beginning to recognize this we are yet to move away from the person

approach—in which finger pointing or cover-ups are common—to an open culture where processes are in place to identify failures or breaks in the “defences”. Organizations that place a premium on safety routinely examine all aspects of the system in the event of an accident, including equipment design, procedures, training and other organizational features [46].

Difference between system failures, violations and errors

9

Using a systems approach to errors and failures in the system does not mean that system thinking implies a “blame-free” culture. In all cultures, individual health professionals are required to be accountable for their actions and to maintain competence and practise ethically. In learning about systems thinking, students should appreciate that they as trusted health professionals are still required to act responsibly and are accountable for their actions [47]. Part of the difficulty is that many health professionals daily break professional rules such as using proper handwashing techniques, or letting junior and inexperienced providers work without proper supervision. Students may see doctors on the wards or in the clinics who cut corners and think that it is the way things are done. Such behaviours are not acceptable. Reason studied the role of violations in systems and argued that, in addition to a systems approach to error management, we need effective regulators with the appropriate legislation, resources and tools to sanction unsafe clinician behaviour [48].

Violations

Reason defined a violation as a deviation from safe operating procedures, standards or rules [48]. He linked the categories of routine and optimizing violations to personal characteristics and necessary violations to organizational failures.

Routine violation

Doctors who fail to wash their hands in between patients because they feel they are too busy is an example of a routine violation. Reason stated that these violations are common and often tolerated. Other examples in health care would be inadequate handovers, not following a protocol and not attending on-call requests.

Optimizing violation

Doctors who let a medical student perform a procedure unsupervised because they are with their private patients is an example of an optimizing violation. This category involves a person being motivated by personal goals such as greed or thrills from risk taking, performing experimental treatments and performing unnecessary procedures.

Necessary violation

Nurses and doctors who knowingly miss out important steps in medication dispensing because of time constraints and the number of patients to be seen is an example of a necessary violation. A person who deliberately does something they know to be dangerous or harmful does not necessarily intend a bad outcome but poor understanding of professional obligations and a weak infrastructure for managing unprofessional behaviour in hospitals provide fertile ground for aberrant behaviour to flourish.

By applying systems thinking to errors and failures, we can ensure that when such an event occurs we do not automatically rush to blame the people closest to the error—those at the so called “sharp” end of care. Using a systems approach we can examine the entire system of care to find out what happened rather than who did it. Only after careful attention to the multiple factors associated with an incident can there be an assessment as to whether any one person was responsible.

A model of patient safety

10

The urgency of patient safety was raised over a decade ago when the US Institute of Medicine convened the National Roundtable on Health Care Quality. Since then the debate and discussions about patient safety worldwide have been informed by lessons learnt from other industries, the application of quality improvement methods to measure and improve patient care and the development of tools and strategies to minimize errors and failures. All of this knowledge has strengthened the place of the safety sciences in the context of medical practice and health-care services generally. The need to improve health care through redesigning processes of care has been acknowledged by WHO and its representative countries as well as by most health professions.

The emergence of patient safety as a discipline in its own right has been made possible because of other disciplines such as cognitive psychology, organizational psychology, engineering and sociology. Applying the theoretical knowledge from these disciplines has led to the development of postgraduate courses in quality and safety and patient safety education in pre-vocational and vocational medical programmes.

Applying patient safety principles and concepts in the workplace does not mean that a health provider has to have formal qualifications in quality and safety. Rather, it requires one to apply a range of skills and be wary of patient safety considerations in every situation and recognizing that things can go wrong. Reason, a cognitive psychologist, emphasized that practitioners should make a habit of sharing their experiences of adverse events. Being an effective team member has risen in importance as we better understand the role of accurate and timely communication in patient safety. Training to become an excellent team member starts in medical school. Learning how to substitute roles and appreciate the other's

perspective is central to effective teamwork.

As the health professions have gained more confidence with the evidence and the steps that are required to make the health-care system safer, it is timely that patient safety as a discipline in its own right should be defined and conceptualised. Emanuel and other patient safety leaders defined patient safety as follows:

A discipline in the health-care sector that applies safety science methods towards the goal of achieving a trustworthy system of health-care delivery. Patient safety is also an attribute of health-care systems; it minimizes the incidence and impact of, and maximizes recovery from adverse events [49].

This definition provides the scope for the conceptual model for patient safety. Emanuel et al. [49] designed a simple model with which to see patient safety. It divides health-care systems into the following four main domains:

1. those who work in health care;
2. those who receive health care or have a stake in its availability;
3. the infrastructure of systems for therapeutic interventions (health-care delivery processes);
4. the methods for feedback and continuous improvement.

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This model shares fifty similar features with other models [50] of quality design including:

- understanding the system of health care;
- recognizing that performance varies across services;
- the methods for improvement including how to implement and measure a change;
- understanding the people who work in the system and their relationships with one another and the organization.

WHAT STUDENTS NEED TO DO (PERFORMANCE REQUIREMENTS)

Apply patient safety thinking in all clinical activities

There are many opportunities for students in their clinical work to incorporate patient safety knowledge into practice.

Relationships with patients

Relate and communicate with each individual patient as a unique human being who has their own experience of their disease or illness. Applying clinical skills alone will not necessarily achieve the best outcomes for patients. In addition, the student needs information from the patient about how they view their illness or condition and its impact on them and their families. Safe and effective care depends on the patient disclosing their experience of the illness, their social circumstances, their attitudes to the risk involved and their values and preferences for how they wish to be treated.

Students and clinical teachers must ensure that patients understand that medical students are not qualified doctors. When introduced to patients or their families a medical student should always be described as “medical students”. It is important not to describe students as “junior doctors”, “student doctors”, “young doctors”, “assistants” or “colleagues” as this can lead the patient to thinking that the student is qualified. An important aspect of patient safety is honesty to patients so it is important that students advise patients of their correct status, even if that means correcting what their clinical teacher has said.

Sometimes clinical teachers introduce students in a way that is designed to instil confidence in the student and the patient, without realizing that they may “stretch the truth” in doing so. As it can be awkward trying to correct what the clinical teacher

has said at this point, it is a good idea to check with a clinical teacher how they usually introduce students to patients beforehand, especially the first time you are working and learning with a particular clinical teacher. Students must explain and make it clear to patients and their families that they are medical students studying to become doctors.

12

Understand the multiple factors involved in failures

13

Students should look beyond a medical mistake or failure in care and understand that there may be many factors associated with an adverse event. This will involve the student asking questions about the underlying factors and encouraging others to consider an error from a systems perspective. They could be the first in a team meeting or discussion group to ask questions about possible causes of errors by using the phrase, for example, “What happened” rather than “Who was involved”. The five “whys” (keep on asking why something happened when given an answer) is a method used to keep discussions about causes focused on the system rather than the people.

Statement: The nurse gave the wrong drug.

Why?

Statement: Because she misheard the name of the drug ordered by the doctor.

Why?

Statement: Because the doctor was tired and it was in the middle of the night and the nurse did not want to ask him to repeat the name.

Why?

Because she knew that he was known to have a temper and would shout at her.

Why?

Because he was very tired and had been operating for the last 16 hours ...

Why?

Because...

Avoid blaming when an error occurs

It is important that medical students support each other and health professionals when they are involved in an adverse event. Unless students are open about errors there will be little opportunity to learn from them. However, often medical students are excluded from meetings where discussions about adverse events occur. Also, the hospital or clinic may not hold such meetings to discuss adverse events. This does not necessarily mean that clinicians want to hide their errors; it may mean they are unfamiliar with patient safety strategies to learn from them. They may also worry about medico-legal fears and possible interference from administrators. Even so, as patient safety concepts become more widely known and discussed in health care, more opportunities are arising for reviewing care and making the improvements necessary to minimize errors. Students can ask their supervisors if the hospital conducts mortality and morbidity meetings or other peer review forums where adverse events are reviewed. Students, irrespective of level of training and education must appreciate the importance of reporting their own errors to their supervisors.

Practise evidence-based care

Students should learn how to apply evidenced-based practice. They should be aware of the role of guidelines and appreciate how important it is to follow them. When a student is placed in a clinic or hospital they should seek out information about the common guidelines and protocols that are used.

Maintain continuity of care for patients

The health system is made up of many parts that interrelate to produce a continuum of care for patients and families. Understanding the journey that patients make through the health-care system (of which a hospital or clinic is just a part) is necessary to understand how the system can

fail. Important information can be missed or incorrect. This can lead to inadequate care or errors. The continuity of care chain is broken, leaving the patient vulnerable to a poor outcome.

Student awareness of the importance of self-care

Students should be responsible for their own well-being and that of their peers and colleagues. Medical students should be encouraged to have their own doctor and be aware of their own health status. If a student is in difficulty (mental illness or drug or alcohol impairment), they should be encouraged to seek professional help.

Act ethically everyday

Learning to be a good doctor requires observation of respected senior clinicians as well as practical clinical experience involving patients. One of the privileges medical students have is the opportunity as students to learn medicine “at the bedside” and treating “real patients”. Most patients understand that medical students have to learn and that the future of medicine depends on training. Yet, it is also important that students remember that their opportunity to interview and examine patients is a privilege that is granted by each individual. In most situations, patients cannot be examined by a student unless they give their consent. Students should always ask permission from each patient before they physically touch or seek personal information from them. They should also be aware that patients may withdraw this privilege at any time and request that the student stop what they doing.

It is important that clinical teachers advise patients that their cooperation in educational activities is entirely voluntary. Clinical teachers and medical students must obtain verbal consent from patients before students interview or examine them. When a patient is being asked to allow a student to examine them they should be told that the

examination is primarily for educational purposes. An appropriate form of words is, “Would you mind if these students ask you about your illness and/or examine you so that they can learn more about your condition?”

It is important that all patients understand that their participation is voluntary and that a decision not to participate will not compromise their care. Verbal consent is sufficient for most educational activities but there will be times when a written consent is required. Students should be requested to make inquiries if they are in doubt about the type of consent required.

Particular care should be taken when involving patients in teaching activities because the benefit to the patient is secondary to the educational needs of the students. Patient care and treatment is usually not dependent on student engagement.

Explicit guidelines for clinical teachers and medical students provide protection for everyone. If no guidelines exist it is a good idea to request that the faculty develop a policy on the relationship between students and the patients they are allowed to treat in their role as students. Properly designed guidelines will protect patients, promote high ethical standards and avoid misunderstandings.

Most medical schools are aware of the problem of the “hidden curriculum” in medical education. Studies show that students on clinical placements have felt pressured to act unethically [52], and they report that these situations are difficult to resolve. All students and doctors in training potentially face similar ethical dilemmas. On the rare occasion in which a clinical supervisor directs medical students to participate in patient management that is perceived to be unethical or misleading to the patient, faculty staff should deal with the matter. Many students may not even be

confident enough to raise such matters with their supervisors and are unsure of how to act. Raising this in teaching about patient safety is very important. This role confusion can lead to student stress and can have a negative impact on morale and the development of the students’ professionalism. It can also place patients at risk. Learning how to report concerns about unsafe or unethical care is fundamental to patient safety and relates to the capacity of the system to support reporting.

Students should be aware of their legal and ethical obligations to put the interests of patients first [8]. This may include refusal to comply with an inappropriate instruction or direction. The best way to resolve the conflict (or at least gain a different perspective) is for the student to speak privately with the clinician or responsible staff person concerned. The patient concerned should not be part of this discussion. The student should explain the problem(s) and why they are unable to comply with the instruction or direction. If the clinician or responsible staff person ignores the issues raised and continues to instruct the medical student to proceed, then discretion should be used to proceed or withdraw from the situation. If it is decided to continue, then patient consent must be confirmed. If the patient does not consent, the student must not proceed.

If a patient is unconscious or anaesthetized, the student should explain why they cannot proceed. It may be necessary to point out the requirement of the faculty to comply with these guidelines. It may also be appropriate to discuss the situation with another person in the faculty or clinical school. If medical students are uncertain about the appropriateness of any behaviour by any other person involved in patient care, they should discuss the matter with a senior colleague of choice, usually the associate dean.

All students who feel that they have been subjected to unfair treatment because of a refusal to do something that seems to be wrong should seek advice from senior colleagues.

Demonstrates ability to recognize the role of patient safety in safe health-care delivery

14

The timing of a medical student's entry into a hospital or clinical environment varies across universities—some medical students are exposed from their first year, other students are exposed later in their medical training and education. Prior to entering a clinical environment students should:

- **Ask questions about other parts of the health system that are available to the patient**

The success of a patient's care and treatment depends on understanding of the total health system available to the particular patient. If a patient comes from a poor area where there is no refrigeration, then sending a patient home with insulin that needs refrigeration will not assist the patient. An understanding of systems (topic 3) will help the student appreciate how different parts of the health system are connected and how continuity of care for the patient is dependent on all parts of the system communicating effectively and in a timely way.

- **Ask for information about the hospital or clinic processes that are in place to identify adverse events**

Most hospitals or clinics will have a reporting system to identify adverse events. It is important that students are aware of these events and understand how the hospital manages them. If there are no reporting requirements in the hospital, then the student can ask the appropriate people how the hospital manages such events. At the least,

this may generate some interest in the topic. (Reporting and incident management are covered in topics 3, 4 and 6.)

HOW TO TEACH THIS TOPIC

Teaching strategies/formats

The prevalence data used in this topic have been published in the literature and cover a number of countries but not all of them. Some teachers may wish to put the case for patient safety using prevalence data from their country. If it is not available, then another way would be to access databases maintained by the health service and see if some of the data can be used to demonstrate the potential or real harm to patients from their health care. For example, the Institute for Healthcare Improvement (IHI) in the United States has published *Trigger tool for measuring adverse events*, which is designed to assist health-care professionals measure their adverse event rates. If there are no measures available to a country or hospital, then try to obtain data for one area of care such as infection rates. Infection rates in a particular country may be available and this could be used to demonstrate the extent of transmission of infection that is a potentially preventable.

This topic can be broken up into sections to be included in existing curricula or can be taught in small groups or as a stand alone lecture. If the topic is being delivered as a lecture, then the slides at the end of the topic may be helpful for presenting the information.

Part A of the Curriculum Guide sets out a range of teaching methods for patient safety since giving a lecture is not always the best approach.



A small group discussion session

A teacher could use any of the activities listed below to stimulate discussion about patient safety. Another way is to have one or more

students prepare a seminar on the topic of patient safety using the information in this topic. They could then lead a discussion about the areas covered in the topic. The students could follow the headings as outlined below and use any of the activities below to present the material. The tutor facilitating this session should also be familiar with the content so information can be added about the local health system and clinical environment.

Harm caused by health-care errors and system failures:

- use examples from the media (newspapers and television) that have been published/broadcasted;
- use de-identified case examples from your own hospitals and clinics;
- use a case study to construct a flowchart of the patient's journey;
- use a case study to brainstorm all of the things that went wrong and the times when an action might have prevented the adverse outcome for the patient;
- invite a patient who has experienced an adverse event to talk to the students.

Difference between system failures, violations and errors:

- use a case study to analyse the different avenues for managing an adverse event;
- participate or be an observer in a root cause analysis.



An interactive/didactic session

Invite a respected senior clinician and/or other health-care professionals from within your country to talk about health-care errors in the workplace. If no one is available, then use a video of an influential and respected physician talking about errors and how the system of health care exposes everyone to them. A search of the internet will locate video clips of speeches that have been made by patient safety leaders. Having

someone talk about errors and how they impact on patients and staff is a powerful introduction of patient safety to students. Students can react to the presentation. The teacher can then go through the information in this topic to demonstrate to students how and why attention to patient safety is essential for safe clinical practice. The slides can be PowerPoint or converted to overhead slides for a projector. Start the session with the case study and get the students to identify some of the issues presented in the story. Use the accompanying slides at the end of this topic as a guide.

Other ways to present different sections in this topic are listed below.

Lessons about error and system failure from other industries:

- invite a staff member from another discipline such as engineering or psychology to talk about system failures, cultures of safety and role of error reporting in safety;
- invite someone from the aviation industry to talk about their response to human errors.

History of patient safety and the origins of the blame culture:

- invite a senior respected clinician to talk about the damage of "blaming" in the context of medical care;
- invite a quality and safety officer to talk about systems in place to minimize errors and manage adverse events.



Simulation

Different scenarios could be developed about adverse events and the need to report and analyse errors.

Teaching and learning activities

There are many other opportunities for students to learn about patient safety such as during their clinical placements in hospitals or clinics. The

following are some examples of activities that students could perform, either alone or in pairs;

- follow a patient on their journey through the health-care service;
- ask students to spend a day with another health professional (nurse, physiotherapist, social worker, pharmacist, dietician and interpreter) and to identify the main role and functions of that profession;
- ask students when they have student–patient encounters to routinely seek information about the illness or condition from the patient’s perspective;
- ask students to make inquiries of their hospital or health service about whether there are processes or teams to investigate and report on adverse events—if there are avenues, ask the students to seek permission from the relevant supervisor for them to observe or take part;
- ask students to find out if the hospital conducts mortality and morbidity meetings or other peer review forums where adverse events are reviewed;
- require the students to talk among themselves about errors they have observed in the hospital using a no blame approach;
- ask the students to select a ward or clinic where they are placed and inquire about a main protocol used by the staff; get the students to ask how the guideline was written and how staff know about it and how to use it and when to deviate from it.

CASE STUDIES

Caroline’s story

This case illustrates the importance of attention to continuity of care and how a system of care can go badly wrong.

On 10 April 2001, Caroline, aged 37, was admitted to a city hospital and gave birth to her

third child in an uncomplicated caesarean delivery. Dr A was the obstetrician and Dr B was the anaesthetist who set the epidural catheter. On 11 April, Caroline reported that she felt a sharp pain in her spine and on the night before the epidural was removed she accidentally bumped the epidural site. During this time, Caroline repeatedly complained of pain and tenderness in the lumbar region. The anaesthetist, Dr B, examined her and diagnosed “muscular” pain. Still in pain and limping, Caroline was discharged (transferred) from the city hospital on 17 April.

For the next seven days Caroline remained at her home in the country. She telephoned her obstetrician, Dr A, about her fever, shaking, intense low back pain and headaches. On 24 April, the local medical officer, Dr C, examined Caroline and her baby and recommended they both be admitted to the district hospital for back pain and jaundice, respectively.

The admitting doctor at the district hospital, Dr D, recorded that Caroline’s back pain appeared to be situated at the S1 joint rather than at the epidural site. On 26 April, the baby’s jaundice had improved, but Caroline had not yet been seen by the general practitioner, Dr E, who admitted he had forgotten about her. The medical registrar, Dr F, examined Caroline and diagnosed sacroiliitis. He discharged her with prescriptions for oxycodone, paracetamol and diclofenac. He also informed Caroline’s obstetrician, Dr A, of his diagnosis.

Caroline’s pain was assisted by the medications until 2 May when her condition deteriorated. Her husband then took Caroline, who was in a delirious state, to the local country hospital. Shortly after arriving at the hospital on 3 May she started convulsing and mumbling incoherently. The local medical officer, Dr C, recorded in the medical records “? excessive opiate usage, sacroiliitis”.

Her condition was critical by this stage and she was rushed by ambulance to the district hospital.

By the time she arrived at the district hospital, Caroline was unresponsive and needing intubation. Her pupils were noted to be dilated and fixed. Her condition did not improve and on 4 May she was transferred by ambulance to a second city hospital. At 13:30 on Saturday, 5 May, she was determined to have no brain function and life support was withdrawn.

A postmortem examination revealed an epidural abscess and meningitis involving the spinal cord from the lumbar region to the base of the brain with cultures revealing a methicillin-resistant staphylococcus aureus (MRSA) infection. Changes to the liver, heart and spleen were consistent with a diagnosis of septicaemia. The coronial investigation concluded that Caroline's abscess could and should have been diagnosed earlier than it was.

The following discussion of the coroner's report into the death of Caroline highlights many of the issues addressed in the topics outlined in this Curriculum Guide. The observation that surfaced again and again in this story was the inadequacy in recording detailed and contemporaneous clinical notes and the regular incidence of notes being lost. The anaesthetist, Dr B, was so concerned about Caroline's unusual pain that he consulted the medical library, but he did not record this in her clinical notes. He also failed to communicate the risk of what he now thought to be "neuropathic" pain to Caroline or ensure that she was fully investigated before being discharged. There were also concerns that evidence-based guidelines were not followed with respect to Dr B scrubbing prior to the epidural insertion as it was the view of an independent expert that the bacteria that caused the abscess was most likely to have originated from the staff or

environment at the city hospital.

It was clear that Caroline would be managed by others after her discharge; however, she was not involved as a partner in her health care by being given instructions about the need to seek medical attention if her back pain worsened. Similarly, no referral letter or phone call was made to her local medical officer, Dr C.

It was the coroner's opinion that each of the doctors who examined Caroline after she returned to the country was hasty in reaching a diagnosis, mistakenly believing that any major problem would be picked up by someone else down the track. Her local medical officer, Dr C, only made a very cursory examination of Caroline as he knew she was being admitted to the district hospital. The admitting doctor, Dr D, thought there was a 30% chance of Caroline having an epidural abscess but did not record it in the notes because he believed it was obvious. In a major departure from accepted medical practice, Dr E agreed to see Caroline and simply forgot about it.

The last doctor to examine Caroline at the district hospital was the medical registrar, Dr F, who discharged her with prescriptions for strong analgesics without fully investigating his provisional diagnosis of sacroiliitis, which he thought could have been postoperative or infective. With regards to medicating safely, Dr F's handwritten notes to Caroline were considered vague and ambiguous in instructing her to increase the dose of oxycodone if the pain increased, while at the same time monitoring specific changes. The notes Dr F made on a piece of paper detailing his examination and the possible need for magnetic resonance imaging (MRI) were never found.

The one doctor who the coroner believed could have taken global responsibility for Caroline's care

was her obstetrician, Dr A. He was phoned at least three times after her discharge from the city hospital with reports of her continuing pain and problems, but failed to realize the seriousness of her condition.

From the birth of her child to her death 25 days later, Caroline was admitted to four different hospitals and there was a need for proper continuity of care in the handover of responsibilities from each set of medical and nursing staff to another. The failure to keep adequate notes with provisional/differential diagnoses and investigations and provide discharge summaries and referrals led to a delay in the diagnosis of a life-threatening abscess and ultimately Caroline's death.

Reference

Inquest into the death of Caroline Barbara Anderson, Coroner's Court, Westmead, Sydney Australia, 9 March 2004. (Merrilyn Walton was given written permission by Caroline's family to use in teaching medical students and other health professionals so that they could learn about patient safety from the perspective of patients and families.)

TOOLS AND RESOURCES



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HOW TO ASSESS THIS TOPIC

A range of assessment methods are suitable for this topic including essay, MCQ paper, short best answer question paper (SBA), case-based discussion and self-assessment. Students can be encouraged to develop a portfolio approach to patient safety learning. The benefit of a portfolio approach is that at the end of the student's medical training they will have a collection of all their patient safety activities. Students will be able to use this to assist job applications and their future careers.

The assessment of knowledge of the potential harm to patients, the lessons from other

industries, violations and the blame free approach and models for thinking about patient safety is all assessable using any of the following method:

- portfolio;
- case-based discussion;
- OSCE station;
- written observations about the health system and the potential for error (in general);
- reflective statements (in particular) about:
 - the hospital and clinical environment and the potential for patient harm;
 - the consequences of adverse events on patient trust in health care;
 - the systems in place for reporting medical errors;
 - the role of senior clinicians in managing adverse events;
 - the role patients have in the health-care system.

The assessment can be either formative or summative; rankings can range from unsatisfactory to giving a mark. See examples of some of these assessment methods in Appendix 2.

HOW TO EVALUATE THIS TOPIC

Evaluation is important in reviewing how a teaching session went and how improvements can be made. See the Teacher's Guide (Part A) for a summary of important evaluation principles.

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SLIDES FOR TOPIC 1: WHAT IS PATIENT SAFETY?

Didactic lectures are not usually the best way to teach students about patient safety. If a lecture is being considered, it is a good idea to plan for student interaction and discussion during the lecture. Using a case study is one way to generate group discussion. Another way is to ask the students questions about different aspects of health care that will bring out the issues contained in this topic such as the blame culture, nature of error and how errors are managed in other industries.

The slides for topic 1 are designed to assist the teacher deliver the content of this topic. The slides can be changed to fit the local environment and culture. Teachers do not have to use all of the slides and it is best to tailor the slides to the areas being covered in the teaching session.

Topic 2: What is human factors and why is it important to patient safety?

Why human factors is important

1

Human factors examines the relationship between human beings and the systems with which they interact [1] by focusing on improving efficiency, creativity, productivity and job satisfaction, with the goal of minimizing errors. A failure to apply human factors principles is a key aspect of most adverse events in health care. Therefore, all health-care workers need to have a basic understanding of human factors principles. Health-care workers who do not understand the basics of human factors are like infection control professionals not knowing about microbiology.

Keywords

Human factors, ergonomics, systems, human performance.

Learning objective

Understand human factors and its relationship to patient safety.

2

Learning outcomes: knowledge and performance

What a student needs to know (knowledge requirements):

3

- explain the meaning of the term “human factors”;
- explain the relationship between human factors and patient safety.

What a student needs to do (performance requirement):

4

- apply human factors thinking to your work environment.

WHAT STUDENTS NEED TO KNOW (KNOWLEDGE REQUIREMENTS)

The meaning of the terms “human factors” and “ergonomics”

5

The terms human factors and ergonomics

(as it is sometimes called) are used to describe interactions between three interrelated aspects: individuals at work, the task at hand and the workplace itself.

Human factors is an established science that uses many disciplines (such as anatomy, physiology, physics and biomechanics) to understand how people perform under different circumstances. We define human factors as: *the study of all the factors that make it easier to do the work in the right way.*

Another definition of human factors is the study of the interrelationship between humans, the tools and equipment they use in the workplace, and the environment in which they work [1].

One can apply Human factors knowledge to wherever humans work. In health care, human factors knowledge can help design processes that make it easier for doctors and nurses to do the job right. Human factors applications are highly relevant to patient safety because embedded in the discipline of human factors engineering are the basic sciences of safety. Human factors can show us how to make sure we use safe prescribing practices, communicate well in teams and hand over information to other health-care professionals. These tasks, once thought to be basic, have become quite complicated as a result of the increasing complexity of health-care services and systems. Much of health care is dependent on the humans—the doctors and nurses—providing the care. Human factors experts believe that mistakes can be reduced by focusing on the health-care providers and studying how they interact with and are part of the environment. Human factors can make it easier for health-care providers to care for patients.

Human factors principles can be adapted to any

environment, and industries such as aviation, manufacturing and the military have applied knowledge of human factors to improve systems and services for many years now [2].

6

The lessons and examples from other industries show that by using human factors principles we can also improve work processes in health care. For example, the underlying causes of many adverse events relate to the miscommunications and actions of the people in the system. Many people think that communication difficulties among the health-care team relate to the fact that each person has a number of tasks that have to be performed at one time. Human factors engineering research shows that what is important is not the number of tasks but the nature of the tasks being attempted. A doctor may be able to tell a student the steps in a simple operation while he is doing one but if it was a complicated case he may not be able to do that because he has to concentrate. An understanding of human factors and adherence to human factors principles is now fundamental to the discipline of patient safety [3].

7

Human factors experts help make it easier for the widest range of health-care providers to perform at their best while caring for patients. This is important because the goal of good human factors design is to accommodate all the users in the system. This means not just thinking about design issues as though the task was to be accomplished not only by a calm, rested experienced clinician, but also for an inexperienced health-care worker who might be stressed, fatigued and rushing.

8

9

Human factors experts use evidence-based guidelines and principles to design ways to make it easier to safely and efficiently do things such as: (i) order medications; (ii) hand off (hand over) information; (iii) move patients; and (iv) chart medications and other orders electronically. If

these tasks were made easier for the health-care practitioner, then they would be able to provide safer health care. These tasks require design solutions that include software (computer order entry systems), hardware (IV pumps), tools (scalpels, syringes, patient beds) and the physical layout, including lighting of work environments.

10

11

The technological revolution in health care has increased the relevance of human factors in errors because the potential for harm is great when technology is mishandled [3].

12

In its broadest sense human factors incorporates the human-machine interactions (including equipment design) and human-human interactions such as communication, teamwork and organizational culture. Human factors engineering seeks to identify and promote the best fit between people and the world within which they live and work, especially in relation to the technology and physical design features in their work environment.

13

Human factors recognize that the workplace needs to be designed and organized to minimize the likelihood of errors occurring and the impact of errors when they do occur. While we cannot eliminate human fallibility, we can act to moderate and limit the risks.

14

15

Note that human factors is not as *directly* about “humans” as the name might suggest. But it is about understanding human limitations and designing the workplace and the equipment we use to allow for variability in humans and human performance.

Knowing how fatigue, stress, poor communication and inadequate knowledge and skill affect health professionals is important because it helps us understand predisposing characteristics that may

be associated with adverse events and errors. The fundamental basis of human factors relates to the issue of how human beings process information. We acquire information from the world around us, interpret and make sense of it and then respond to it. Errors can occur at each step in this process (see topic 5 on understanding and learning from errors).

Human beings are not machines; machines, when maintained, are on the whole very predictable and reliable. In fact, compared to machines, humans are unpredictable and unreliable, and our ability to process information is limited due to the capacity of our (working) memory. However, human beings are very creative, self-aware, imaginative and flexible in their thinking [4].

16 17

Human beings are also distractible, which is both a strength and a weakness. Distractibility helps us notice when something unusual is happening. We are very good at recognizing and responding to situations rapidly and adapting to new situations and new information. However, our ability to be distracted also predisposes us to error, because by being distracted we may not pay attention to the most important aspects of a task or situation. Consider a medical student taking blood from a patient. As the student is in the process of cleaning up after taking the blood, a patient in a neighbouring bed calls out for assistance. The student stops what she is doing and goes to help and forgets that the blood tubes are not labelled, which the student forgets when she returns to collect the tubes. Or consider a nurse who is taking a medication order over the telephone and is interrupted by a colleague asking a question; the nurse may mishear or fail to check the medication or dosage as a result of the distraction.

Our brain can also play “tricks” on us by misperceiving the situation and thereby contribute

to errors occurring.

18 19 20

The fact that we can misperceive situations despite the best of intentions is one of the main reasons that our decisions and actions can be flawed, resulting in making “silly” mistakes—regardless of experience level, intelligence, motivation or vigilance. In the health-care setting, we describe these situations as errors, which may have consequences for patients.

21 22 23

These are important considerations to recognize because they are reminders that making errors is not so much bad as *inevitable*. In simple terms, error is the downside of having a brain. Reason [4] described “error” as the failure of a planned action to achieve its intended outcome or a deviation between what was actually done and what should have been done.

24 25

The relationship between human factors and patient safety

It is important for all health-care workers to be mindful of situations that increase the likelihood of error for human beings in any situation [5]. This is especially important for medical students and other inexperienced junior staff to be aware of.

26

A number of individual factors impact on human performance thereby predisposing a person to error.

27

Two factors with the most impact are fatigue and stress. There is strong scientific evidence linking fatigue and performance decrement making it a known risk factor in patient safety [6]. Prolonged work has been shown to produce the same deterioration in performance as a person with a blood alcohol level of 0.05 mmol/l, which would make it illegal to drive a car in many countries [7].

28

The relationship between stress levels and performance has also been confirmed through research. While high stress is something that everyone can relate to, it is important to recognize that low levels of stress are also counterproductive, as this can lead to boredom and failure to attend to a task with appropriate vigilance.

29

The aviation industry requires individual pilots to use a number of personal checklists to monitor their performance—an approach that health-care workers could easily emulate. All health-care workers should consider using a series of personal error reduction strategies to ensure that they perform optimally at work.

30

The acronym IM SAFE (illness, medication, stress, alcohol, fatigue, emotion) that was developed in the aviation industry is useful as a self-assessment technique to determine when entering the workplace each day whether a person is safe for work.

31

WHAT STUDENTS NEED TO DO (PERFORMANCE REQUIREMENTS)

Apply human factors thinking to your work environment [8]

Medical students are able to apply human factors thinking as soon as they enter a hospital or clinic environment. In addition, the following tips are known to limit the potential errors caused by humans.

Avoid reliance on memory

Success in examinations requires students to remember lots of facts and information. This is fine for exams but when it comes to treating patients, relying solely on memory is dangerous, particularly when the result may be a patient

receiving a wrong dosage or drug. Students should look for pictures and diagrams of the steps involved in a treatment process or procedure. Checking one's actions against a picture diagram can reduce the load on the working memory and this frees the student to focus on the tasks in real time such as taking a history or ordering the drugs from the hospital pharmacy.

This is a major reason that protocols are so important in health care—they reduce reliance on memory. On the other hand, having too many protocols is unhelpful, especially if they are not updated in a timely manner. Students should ask about the main protocols used by a ward or clinic so that they are familiar with them. It is important to check when the protocols were last reviewed—finding out more about the process by which protocols are updated reinforces the important point that to be effective, protocol must be a living document.

Make things visible

Students will observe that many wards and clinics have equipment that is necessary in patient treatments—e.g. infusion pumps. Many students will be required to use such equipment. Again, the use of pictures and notices about the steps involved in switching the machine on and off and reading the displays will help the student master the skill. Another good example of making the right thing to do more visible is the use of pictorial reminders to staff and patients about handwashing—this has proven to be effective in improving handwashing compliance and technique.

Review and simplify processes

Simple is better. This statement applies to all walks of life, including health care. Some health-care tasks have become so complicated that they are a recipe for errors—examples include hand-off (or hand-over) and discharge processes. Making

handoff simpler by implementing communication strategies that are fewer in number, but more clear in purpose, will reduce errors. Students can help simplify communication processes by repeating back instructions and ensuring they understand any protocols being instituted. If there is no protocol for handoffs, for example, the student could ask how the health-care professionals ensure their communications are heard correctly and how they are confident the patient has been treated correctly.

Other examples of processes that could be simplified include: (i) limiting the range of drugs available for prescribing; (ii) restricting the number of different dosage preparations of the drugs that are available; and (iii) having inventories of frequently administered drugs.

Standardize common processes and procedures

Even though students will be working in one place (clinic or hospital), they may observe that each department or ward does common things differently. This means that they have to relearn how things are done when moving to each new area. Hospitals that have standardized the way they do things (where appropriate) help staff by reducing their reliance on memory—this also improves efficiency and saves time. Drug order forms, discharge forms, prescribing conventions and types of equipment can all be standardized within a hospital, region or even a whole country.

Routinely use checklists

The use of checklists has been successfully applied in many areas of human endeavour—studying for exams, travelling, shopping and in health care. Checklists are now routine in surgery. Students should get into the habit of using checklists in their practice, particularly when there is an evidenced-based way of implementing a treatment.

Decrease reliance on vigilance

Humans quickly become distracted and bored if there is not much going on. Students should be alert to possible errors when they are involved in lengthy repetitive activities. In such situations, most of us will have decreased attention to the task at hand, particularly if we become tired. Our efforts to stay focused will fail at some point.

Summary

In summary, the lessons from human factors in other industries are relevant to patient safety in all health-care environments—this includes understanding the interaction and interrelationships between humans and the tools and machines they use. Understanding the inevitability of error and the range of human capabilities and responses in any given situation is essential to knowing how application of human factors engineering principles can improve health care.



HOW TO TEACH THIS TOPIC

Teaching strategies/formats

This topic is likely to be very new for most people so it is probably a good idea to teach this as a stand alone topic *in the first instance*. But this topic provides an opportunity for imaginative and creative teaching in the clinical environment and is ideally taught using practical exercises rather than didactic lectures.



Lecture for general introduction



Individual and small group activities:

- practical exercises that explore the human factors considerations of common clinical equipment;
- often good and poor examples of human factors principles can be found in any and every clinical environment.

Examples:

1. Students should be asked to examine medical equipment in various parts of the hospital, e.g. operating theatre, ICU, emergency department. Which environment has the most equipment? What are the hazards associated with having multiple pieces of equipment applied to a patient?

For the various pieces of equipment they discover they should consider:

- How easy is it to find the on/off switch?
 - How easy is it for the students to work out how the equipment works?
 - Do they observe doctors and nurses struggling to work out how to use the equipment?
2. In terms of alarms:
 - How often do different sorts of equipment alarm?
 - How often are alarms ignored?
 - What happens when the alarm is suspended and is it clear how long it is suspended for?
 - Is silencing the alarm an “automatic” response or is there a systematic approach to finding the cause?
 3. Students should consider how the design of infusion pumps is related to safety
 - How easy is it to programme the pump correctly?
 - How many different types of infusion pumps can the students find
 - In the one ward?
 - In the hospital?
 - What hazards are associated with having more than one such device?
 4. Design a checklist for undertaking a clinical procedure, e.g. IV cannulation.
 5. Use the investigation of an adverse event to review human factors issues (see topic 5 on understanding and learning from errors).

CASE STUDIES

A swab left behind after episiotomy

This case illustrates a failure in checking protocols in theatres.

Sandra, a 28-year-old woman, goes to see her obstetrician complaining of a three-day history of foul-smelling vaginal discharge. Sandra gave birth to a baby boy 10 days earlier. She required an episiotomy during the delivery process. The obstetrician suspects a urine infection and prescribes a five-day course of antibiotics.

Sandra returns to see the obstetrician a week later with the same symptoms. She has completed the course of antibiotics. Vaginal examination reveals tenderness at the episiotomy site and some swelling. The obstetrician goes through Sandra’s case notes in detail, looking particularly at the notes relating to the delivery and at the swab count. The count has been documented in the case notes, and verified by a second nurse. A further course of antibiotics is prescribed.

As the symptoms persist, Sandra decides to seek a second opinion and goes to see a different obstetrician. The second obstetrician admits her for an examination under anaesthesia and dilation and curettage (D&C). The obstetrician telephones the first obstetrician of finding a swab left behind during packing of the episiotomy wound and to advise him to inform his professional indemnity insurer.

Reference

Case from the WHO Patient Safety Curriculum Guide for Medical Schools expert consensus group.

Supplied by Ranjit De Alwis, International Medical University, Kuala Lumpur, Malaysia

An unaccounted retractor

This case illustrates the importance of using checklists and listening to patients.

Suzanne's medical history included four caesarean sections in a 10-year period. The second and third operations were held at hospital B and the fourth at hospital C. Two months after her fourth caesarean, Suzanne presented to hospital C suffering from severe anal pain.

A doctor performed an anal dilation under general anaesthesia and retrieved a surgical retractor from the rectum that was 15 cm long by 2 cm wide, with curved ends. It was of a type commonly used by New South Wales hospitals and the engraved initials indicated it came from hospital B. The doctor thought that the retractor had been left inside Suzanne after one of her caesareans and it had worked its way gradually through the peritoneum into the rectum.

During her fourth caesarean, the surgeon noted the presence of gross adhesions, or scarring, to the peritoneum; whereas, no scarring had been seen by the doctor who had performed the third caesarean two years earlier. While it is not known for certain what had occurred, the instrument was most likely to have been left inside Suzanne during her third caesarean and remained there for more than two years.

Reference

Case studies—investigations. Health Care Complaints Commission, New South Wales. *Annual Report 1999–2000*, p. 58.

Tools and resources

Patient safety

National Patient Safety Education Framework, sections 4.2 and 4.5
(<http://www.health.gov.au/internet/safety/publishin>

[g.nsf/Content/C06811AD746228E9CA2571C600835DBB/\\$File/framework0705.pdf](http://www.health.gov.au/internet/safety/publishing.nsf/Content/C06811AD746228E9CA2571C600835DBB/$File/framework0705.pdf), accessed May 2008).

Clinical human factors group

(<http://www.chfg.org>, accessed May 2008).

Medical Simulation Center Rhode Island Hospital

(<http://www.lifespan.org/rih/services/simctr/training/materials/>, accessed May 2008).

US Department of Veteran affairs

(<http://www.va.gov/NCPS/curriculum/HFE/index.html>, accessed May 2008).

Toolkit for redesign

Toolkit for Redesign in Health Care. AHRQ Publication No. 05-0108-EF. Rockville, MD, Agency for Healthcare Research and Quality, September 2002
(<http://www.ahrq.gov/qual/toolkit/>, accessed May 2008).

Device use

Safety Briefing Model, Institute for Healthcare Improvement, Iowa Health System
(<http://www.ihl.org/IHI/Topics/PatientSafety/MedicationSystems/Tools/DeviceUseSafetyBriefingModelIHS.htm>, accessed May 2008).

Mistake-proofing design

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(<http://www.ahrq.gov/qual/mistakeproof/mistakeproofing.pdf>, accessed May 2008).

Inspectors toolkit

Inspectors toolkit: human factors in the management of major accident hazards. Health and Safety Executive, October 2005
(<http://www.hse.gov.uk/humanfactors/comah/toolkitintro.pdf>, accessed June 2008).

HOW TO ASSESS THIS TOPIC

A range of assessment strategies are suitable for this topic including MCQs, essays, SBA, case-based discussion and self-assessment. Having a student, or a group of students, lead a small group discussion on a human factors issue in the clinical area is a useful way to elicit understanding.

HOW TO EVALUATE THIS TOPIC

Evaluation is important in reviewing how a teaching session went and how improvements can be made. See the Teacher's Guide (Part A) for a summary of important evaluation principles.

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- 1 Kohn LT, Corrigan JM, Donaldson MS, eds. *To err is human - building a safer health system*. Washington, DC, Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, 1999.
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- 5 Vincent C. *Clinical risk management—enhancing patient safety*, London, British Medical Journal books, 2001.
- 6 Flin R, O'Connor P, Crichton M. *Safety at the sharp end: a guide to non-technical skills*. Aldershot, UK, Ashgate Publishing Ltd, 2008.
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SLIDES FOR TOPIC 2: WHAT IS HUMAN FACTORS AND WHY IS IT IMPORTANT TO PATIENT SAFETY?

Didactic lectures are not usually the best way to teach students about patient safety. If a lecture is being considered, it is a good idea to plan for student interaction and discussion during the lecture. Using a case study is one way to generate group discussion. Another way is to ask the students questions about different aspects of health care that will bring out the issues contained in this topic.

The slides for topic 2 are designed to assist the teacher deliver the content of this topic. The slides can be changed to fit the local environment and culture. Teachers do not have to use all of the slides and it is best to tailor the slides to the areas being covered in the teaching session.

Topic 3: Understanding systems and the impact of complexity on patient care

Why systems thinking underpins patient safety

1

Health care provision is rarely carried out by single individuals. Safe and effective patient care is, therefore, dependent not only on the knowledge, skills and behaviours of the front line workers, but also how the workers work together in the particular work environment, which itself is usually part of a larger organization. In other words, patients depend on many people doing the right thing at the right time for them: that is, they depend on a “system” of care [1].

Keywords:

System, complex system, high reliability organization (HRO).

Learning objective

2

Understand how systems thinking can improve health care and minimize patient adverse events.

Learning outcomes: performance and knowledge

What a student needs to know (knowledge requirements)

3

- explain what is meant by the terms “system” and “complex system” as they relate to health care;
- explain why a systems approach to patient safety is superior to the traditional approach.

What a student needs to do (performance requirements)

4

Describe the term HRO and the elements of a safe health-care delivery system.

WHAT STUDENTS NEED TO KNOW (KNOWLEDGE REQUIREMENTS)

Explain what is meant by the words “systems” and “complex system” as they relate to health care

What is a system

5 6 7

The word system is a broad term that is used to describe any collection of two or more interacting parts, or “an interdependent group of items forming a unified whole” [2].

Medical students will be familiar with the concept of systems usually in the context of biological and organic systems. Organic systems cover something as small as a single cell to more complex organisms or whole populations. These systems are in a continuous state of information exchange both internally and externally. The continuous process of inputs, internal transformation, output and feedback is characteristic of these systems. These same characteristics apply to the health system and the multiple systems that make up health care.

When medical students first enter a large hospital they are often overwhelmed by the complexity—the large number of health professionals, the diversity of patients, the different departments, the different smells, the geography and so on. What they are seeing and reacting to is the hospital as a system. It appears chaotic and unpredictable and they wonder how they will ever adapt to the environment. Eventually, they are assigned to different wards and departments and they become familiar with the workings of that particular area or discipline. They forget about the rest of the system.

A *complex* system is one in which there are so many interacting parts that it is difficult, if not impossible, to predict the behaviour of the system based on a knowledge of its component parts [3]. The delivery of health care fits this definition of a complex system, especially in a hospital setting. Hospitals are made up of many interacting parts, including humans (patients and staff), infrastructure, technology and therapeutic agents—the various ways they interact with one another and how they collectively act is highly complex and variable [3].

Health-care professionals need to have an understanding of the nature of complexity in health care, as it is important in preventing hazards from occurring and helpful in terms of analysing when things go wrong. Otherwise, there can be a tendency to blame only the individuals directly involved in a situation, without realizing there are usually many other contributory factors. Health care is complex because of:[3]

- the diversity of tasks involved in the delivery of patient care;
- the diversity of patients, clinicians and other staff;
- the huge number of relationships between patients, carers, health-care providers, support staff, administrators and community members;
- the vulnerability of patients;
- variations in physical layout of clinical environments;
- variability or lack of regulations;
- implementation of new technology;
- increased specialization of health-care professionals—while specialization allows a wider range of patient treatments and services, it also provides more opportunity for things to go wrong and errors to be made.

Students visiting patients on the wards quickly understand that each individual patient requires care and treatment tailored to their specific conditions and circumstances. A student can quickly see that when all the individualized health services are combined they form a system of care.

Many health services present as a system—buildings, people, processes, desks, equipment telephones—yet unless the people understand its purpose and aim it will not operate as a whole unified system. People are the glue that binds and maintains the system.

An understanding of the health system requires students to think beyond the individualized service. For the health system to work effectively, the doctors, nurses and other health professionals need to understand each other's roles and responsibilities. It also requires their understanding about the impact of complexity on patient care and that complex organizations such as health care are prone to errors. Until relatively recently, we viewed the hundreds of services provided to patients as separate distinct services. The work of doctors was separate from the tasks of nurses or physiotherapists. Units and departments were also seen as distinct entities.

If the emergency department was not able to see urgent patients quickly enough, we thought that by fixing the broken bit—the emergency department—without any attention to other services that relate to it then we could solve the problem. Perhaps the emergency department was not able to transfer the patients to the wards in a timely manner because there were no beds to put the patients in. The staff may have had too many conflicting priorities that impeded their abilities to be responsive to patient needs.

Even though health professionals daily confront many challenges in their workplaces and may

even understand the multiple components and relationships that are prone to dysfunctionality, they have difficulty in thinking in terms of systems because, typically, they are not trained to think in the concepts or language of systems theory, nor do they use its tools to make sense of the systems in which they work.

Knowledge about the complexity of health care will enable health-care professionals to understand how the organizational structure and the work processes can contribute to the overall quality of patient care. Much of the knowledge about complex organizations comes from other disciplines such as organizational psychology. The Institute of Medicine report *To err is human* highlighted that organizational processes such as simplification and standardization are recognized safety principles, yet were rarely applied to health-care delivery systems.

Systems thinking helps us make sense of complex organizations by enabling us to look at health care as a whole system with all its complexity and interdependence. It removes the focus from the individual to the organization. It forces us to move away from a blame culture towards a systems approach. Using a system approach, a nurse will be able to tell a doctor that there may be a problem with fulfilling an order immediately because of other competing demands. The doctor and the nurse can then work out a solution to the problem together, thus foreseeing and avoiding a problem later on.

In summary, a systems approach enables us to:

- examine organizational factors that underpin dysfunctional health care and accidents/errors (poor processes, poor designs, poor teamwork, financial restraints and institutional factors) rather than focus on the people who are associated with or blamed for the blunders or negligence;

- move away from blaming to understanding;
- improve the transparency of the processes of care rather than focus solely on the single act of care.

The traditional approach when things go wrong in health care—blame and shame

8 9

In such a complex environment it is no surprise that many things go wrong on a regular basis. When something does go wrong, the traditional approach is to blame the health-care worker most directly involved in the patient care at the time—often the nurse or junior doctor—example, a wrong drug has been administered by a junior nurse or medical student. While the tendency to blame an individual (the “person approach”) [4] is a strong one—and a very natural one—it is unhelpful, and actually counterproductive for a number of reasons. Whatever role that the “blamed” health-care worker may have had in the evolution of the incident, it is very unlikely that their course of action was deliberate in terms of patient harm (if the action was deliberate this is termed a *violation*—see topic 5 “Understanding and learning from errors” and topic 6 “Understanding and managing clinical risk”).

T5 T6

Most health-care workers involved in an adverse event are very upset by the prospect that their action (or inaction) may have been in some way a contributory episode. The last thing they need is punishment—Wu described the health-care worker as the “second victim” in such circumstances [5]. The natural tendency in such situations is to limit reporting because no one would report future incidents for fear that they would be blamed if anything untoward ever happened. If such a blame “culture” is allowed to persist a health-care organization will have great

difficulty in decreasing the rate of adverse incidents of a similar nature occurring in the future (see topic 5 “Understanding and learning from errors”).

Unfortunately many health-care professionals including senior doctors, nurses and managers share with many in the wider community a different view, one that supports the idea that an individual *should* be “blamed”. This represents a major challenge, especially for junior staff (see introduction to topics).

Introduction

Adopting a system approach to errors and adverse events does not mean that students and health professionals are not professionally responsible for their actions. If a medical student administers the wrong medication to a patient because they failed to follow the protocol for checking medications should they be held accountable? An analysis of this case using a systems approach would examine the factors that contributed to the student not checking the medication. What if the student was new to the ward and was not being supervised, if they did not know the steps involved or that a policy existed to help make sure the correct medication is given to the correct patient, if they were unsure but there was no one around to check and they feared getting into trouble for delaying the administration? Systems thinking would suggest that this student was not prepared for such duties. But if the student was prepared, was being supervised and was aware of the protocols but he did not check the medication because he was lazy or sloppy or wanted to finish work early then he would be responsible for the error. Most circumstances surrounding adverse events are complicated so it is best to use a system approach to understand what happened and why and then make decisions about personal accountability.

Accountability is a professional obligation, and no one thinks that individuals should not be held accountable. However, in addition to personal accountability there is also system accountability. System accountability requires that the system look at itself; for too long the system has passed on mistakes and errors in the system of health care to the individual health-care workers.

10 11

The new approach

Safety experts believe that although it is hard to change aspects of complex systems, it is harder to change the behaviour and thinking processes of human beings in terms of their contributions to errors [4]. Therefore, the main response to an error should be to try to change the system through a “systems approach” [4]. A systems approach to errors in health care, therefore, requires an understanding of the multiple factors that are involved in each of the areas that make up the health-care system. Health-care workers are part of the system, and provide the context in which the humans contribute to a situation. Analyses of accidents in other industries indicate that there is rarely ever one cause of an accident; rather, system failures come from a diffuse range of factors. The intention of a systems approach to incident investigation is to improve the design of the system so as to prevent errors from occurring or to minimize their consequences.

12

Reason outlined the many elements of the system that should be considered as part of a “systems-thinking” approach to accident investigation in the following categories [6].

13

Patient and provider factors

These are the characteristics of the individuals involved, including the patient. It is important to remember that health-care providers, including

medical students and patients are part of the system. This demonstrates that “systems thinking” does not exclude individual contributions to safety, or a lack thereof.

Task factors

These are characteristics of the tasks or jobs health-care providers perform, including the tasks themselves, as well as characteristics such as workflow, time pressure, job control and workload.

Technology and tool factors

Technology factors refer to quantities and qualities of technologies in the organization. Such factors include the number and types of technologies and their availability, usability, accessibility and location. The design of tools and technologies, including their integration with other technologies, the training of the users, propensity to breakdown or crash, responsiveness and other design characteristics would also be included (see topic 2 “What is human factors and why is it important to patient safety?”).

Team factors

Much of health care is provided by multidisciplinary teams. Factors such as team communication, role clarity and team management have been shown to be important in other industries and are now increasingly being recognized as important in health care [7].

Environmental factors

These are the features of the environment in which health-care providers work. These features include lighting, noise and physical space and layout.

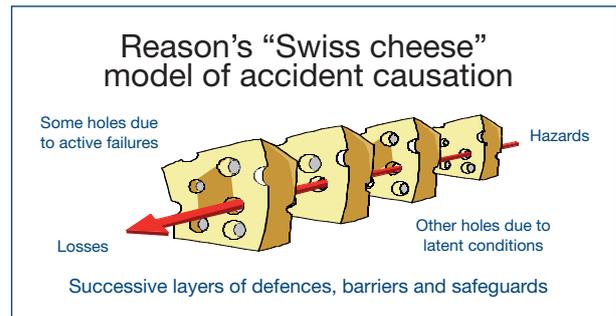
Organizational factors

These are the structural, cultural, and policy-related characteristics of the organization. Examples include leadership characteristics,

culture, regulations and policies, levels of hierarchy and supervisor span of control.

The Swiss cheese model

14



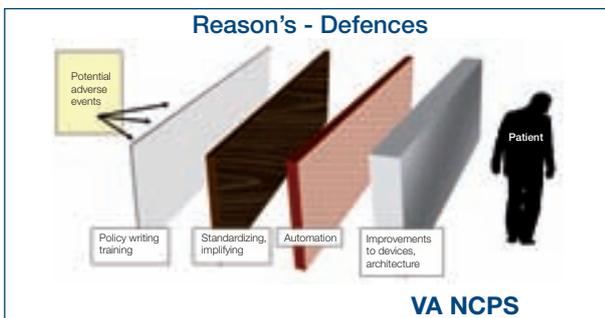
Looking at health care from this broad series of perspectives highlights the multifactorial nature of any single patient safety incident or event. This is why students must carefully guard against jumping to blame someone, and instead consider the systems issues associated with the unwanted event. Usually there are both systems and human issues involved. Reason applied the term “active failures” to any errors made by the workers that have an immediate adverse effect. But he described a second essential precondition for an adverse event to occur, namely the presence of one or more “latent conditions”. Latent conditions are usually the result of poor decision-making, poor design and poor protocols by other humans who do not work at the front line. These conditions are often set in place long before the event in question. Examples of latent conditions for junior medical staff include: fatigue, inadequate staffing levels, faulty equipment and inadequate training and supervision [8].

Reason created the Swiss cheese model to explain how faults in the different layers of the system lead to incidents [4]. The model shows that a fault in one layer of the system of care is usually not enough to cause an accident. Adverse events usually occur when a number of faults occur in a number of layers (for example, fatigued

workers plus inadequate procedures plus faulty equipment) and momentarily line up to permit a “trajectory” of accident opportunity (indicated by the arrow).

To prevent these adverse events occurring, Reason proposed the need for multiple “defences” in the form of successive layers of “protection” (understanding, awareness, alarms and warnings, restoration of systems, safety barriers, containment, elimination, evacuation, escape and rescue) designed to guard against the failure of the underlying layer. The advantage of the systems approach to investigating situations is that this approach considers all the layers to see if there are ways that any of them can be improved.

15



WHAT STUDENTS NEED TO DO (PERFORMANCE REQUIREMENTS)

16 17 18

Describe the term high reliability organization (HRO) and understand the elements of a safe health-care system

The term HRO [9] refers to organizations that operate in hazardous conditions but manage to function at a level of hazard that is almost completely “failure free”—that is they have very few adverse events. These are industries such as air traffic control systems, nuclear power plants and naval aircraft carriers. While there are many differences between these industries and health care, the message for health care is that it is

possible to achieve consistently safe and effective performance despite high levels of complexity and unpredictability in the work environment. HROs demonstrate to health-care organizations that they too can improve safety by focusing on the system.

The differences between HROs and health-care organizations are significant and go to the very heart of the existing problems we have. In health care, we do not routinely think that health care will fail. It is not part of the way of thinking unless it is to do with specific treatments. We do not provide health care being mindful that health professionals might miscommunicate, or that the surgeon may be extremely tired having worked all night or that the doctor’s handwriting was illegible so the student gave the wrong dose. Any one of these may be a factor in an adverse event. Doctors are used to talking about risks to individual patients in relation to knowing side-effects and complications, but they do not apply the same reasoning to the treatment being provided by the people and the system. Systems thinking require that health professionals think about both potential risks: treatment risks and system risks.

HROs are also known for their resilience—they try to pre-empt failures and take steps to prevent them. Patients are the most resilient in our health system and many adverse events are avoided because of the resilience of the patients themselves. They get better not withstanding being given the wrong medication or having the wrong treatment.

We do not yet have a culture of safety in health care. HROs spend a lot of effort, providing incentives and rewards for the workers. People are rewarded in a HRO if they admit a mistake because the admission and the resulting actions to prevent future similar errors save the organization time and money. Imagine a health system where staff could freely admit their

mistakes and we had capacity to put in features and resources that would mean a similar mistake would be prevented or minimized. The adverse event rate would significantly decrease thus saving many lives, reduce suffering and improve staff morale.

19

Characteristics of high reliability organizations [9]

High reliability organizations share the following characteristics:

- *preoccupation with failure*: acknowledge and plan for the possibility of “failure” because of the high-risk, error-prone nature of their activities;
- *commitment to resilience*: proactively seek out unexpected threats and contain them before they cause harm;
- *sensitivity to operations*: pay close attention to the issues facing the workers at the frontline;
- *a culture of safety* in which individuals feel comfortable drawing attention to potential hazards or actual failures without fear of criticism from their seniors if they speak up when they uncover a hazard—or even a potential hazard.

Health-care organizations can learn from HROs even though they are different from health care. We can examine their successes and study what factors made them work. We can also learn from their failures—how do disasters occur and what factors are typically present.

Summary

Analysis of adverse events demonstrates that multiple factors are usually involved in their causation. Therefore, a systems approach to considering the situation—as distinct from a person approach—will have a greater chance of setting in place strategies to decrease the likelihood of recurrence.

20

CASE STUDIES

A failure to administer preoperative antibiotic prophylaxis in a timely manner according to protocol

This example highlights how system complexities cannot accommodate last minute changes and requests.

The anaesthetist and the surgeon discussed the preoperative antibiotics required for the laparoscopic cholecystectomy that was about to begin. The anaesthetist informed the surgeon of the patient’s allergy to penicillin and the surgeon suggested clindamycin as an alternative preoperative antibiotic. The anaesthetist went into the sterile corridor to retrieve the antibiotics but returned and explained to the circulating nurse that he could not find any suitable antibiotics in the sterile corridor. The circulating nurse got on the phone to request the preoperative antibiotics. The anaesthetist explained that he could not order them because there were no order forms (he looked through a file folder of forms). The circulating nurse confirmed that the requested antibiotics “are coming”.

The surgical incision was performed. Six minutes later the antibiotics were delivered to the OR and immediately injected into the patient. This injection happened after the time of incision, which was counter to protocol that requires antibiotics to be administered prior to the surgical incision in order to avoid surgical site infections.

Case from the WHO Patient Safety Curriculum Guide for Medical Schools working group. Supplied by Lorelei Lingard, University of Toronto, Toronto, Canada.

Wrong substances used in exploratory surgery

This case shows the importance of checking substances at every care episode. The way medications are ordered, stored and delivered to theatres and the method for ensuring correct medications are given to patients involve multiple steps with many opportunities for errors.

Jacqui had an exploratory procedure called an endoscopic retrograde cholangiopancreatography at a large teaching hospital for a suspected disorder of her gallbladder. Under general anaesthetic, an endoscope was inserted into her mouth and was guided through the oesophagus to the duodenum. Cannulas were inserted through the endoscope into the common bile duct and a contrast medium injected so an X-ray could be taken.

Two months later, Jacqui was told she was one of 28 patients who had been injected with contrast medium containing a corrosive substance, phenol. Normally, the pharmacy department ordered 20 ml vials of “Conray 280”. However, for a period of approximately five months they incorrectly ordered and supplied to theatre 5 ml vials of 60% “Conray 280” with 10% phenol in which the label clearly stated “use under strict supervision—caustic substance” and “single dose vial”. A nurse finally picked up the mistake, which had been missed by the pharmacy department and many teams of theatre and surgical staff.

Report on an investigation of incidents in the operating theatre at Canterbury Hospital 8 february-7June 1999.
<http://www.hccc.nsw.gov.au/downloads/canterbu.pdf>, accessed April 2008.

Chain of errors leading to wrong site surgery

This case raises the latent problems that exist in the system and can result in errors at the sharp end of care.

Neurosurgeon A was performing a craniotomy on a child called Jim. The flap was made on the right side in preparation for the removal of a suspected meningioma. The surgeon paused to recalled the history of the patient. He is puzzled, as he recalls that the meningioma was on the left side, not the right.

The neurosurgeon re-checked the computed axial tomography (CT) scans. The scans showed that the lesion was in the right frontal lobe. The neurosurgeon checked his own notes on Jim, and saw that he has written a diagnosis of a left-sided cerebral lesion. Seeing, however, that the CT scan shows the lesion to be on the right side, he went ahead with the surgery.

To his surprise, there is no evidence of any tumour. The neurosurgeon closed up the flap and sent the boy to recovery. The next day, Jim was sent for a second CT scan. The second set of scans showed that the lesion was indeed on the left, as he had remembered.

The following errors had occurred:

- CT scan had been mislabelled; the marker for “R” (right) had been placed incorrectly;
- mistake made in the booking of the operating theatre, which should have stated the site of the procedure;
- neurosurgeon did not double-check CAT scan and notes prior to surgery.

Reference

Case from the WHO Patient Safety Curriculum Guide for Medical Schools working group.
Supplied by Ranjit De Alwis, International Medical University, Kuala Lumpur, Malaysia.

Miscommunication to a patient about the type of anaesthesia to expect for surgery

This example highlights system complexities that reach outside of the immediate operating room setting and includes communication between individuals not immediately involved in the current surgical procedure, both between and across professions.

A patient arrived in the operating room for an inguinal hernia repair. Although the procedure had been booked as a general anaesthesia case, the anaesthetist discussed a local anaesthetic with the patient. During his pre-operative anaesthesia consultation, it had been established that the patient would receive a local anaesthetic.

When the surgeon entered the room several minutes later, the patient told him that he wanted to have a local anaesthetic. The surgeon examined the hernia and reported that the hernia was too big for a local anaesthetic and would require either a spinal or general anaesthesia. The surgeon was irritated and said that, "if (the anaesthetist who did the pre-op consult) wants to do the procedure under a local that's fine, but I do not". The patient and the anaesthetist discussed the side-effects of a spinal and the patient asked the surgeon which one he would recommend. The surgeon suggested general anaesthesia and the patient agreed to this.

After the patient had been induced and intubated the surgeon asked the anaesthetist to tell the other anaesthetists that they should not speak to patients in pre-admit about local versus general anaesthesia because they had not examined the patient. It has happened three or four times that the pre-admit anaesthetists have told patients something different in their pre-op consult than what the surgeon has recommended. The anaesthetist agreed to speak to his colleagues and the chief of anaesthesia.

Case from the WHO Patient Safety Curriculum Guide for Medical Schools working group. Supplied by Lorelei Lingard, University of Toronto, Toronto, Canada.

TOOLS AND RESOURCES

IHI clinical microsystem assessment tool

Batalden PB et al. *Microsystems in health care: Part 9. Developing small clinical units to attain peak performance*. Joint Commission Journal on Quality and Safety, 29 November 2003, 29(11):575–585 (<http://www.ihl.org/IHI/Topics/Improvement/ImprovementMethods/Tools/ClinicalMicrosystemAssessmentTool.htm>).

Learning to improve complex systems of care

Headrick LA. Learning to improve complex systems of care. In: *Collaborative education to ensure patient safety*. Washington, DC, HRSA/Bureau of Health Professions, 2000, 75–88 (<http://www.ihl.org/NR/rdonlyres/15FB8A41-D6B0-4804-A588-6EC429D326E9/0/final11700version.pdf>).

Organization strategy

Runciman B, Merry A, Walton M. *Safety and ethics in health care: a guide to getting it right*, 1st ed. Aldershot, UK, Ashgate Publishing Ltd, 2007.

Kohn LT, Corrigan JM, Donaldson MS, eds. *To err is human: building a safer health system*. Washington, DC, Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, 1999 (<http://psnet.ahrq.gov/resource.aspx?resourceID=1579>).

HOW TO TEACH THIS TOPIC

Teaching strategies



Interactive DVD

WHO *Learning from error* workshop, including intrathecal vincristine DVD, which depicts a case of intrathecal vincristine administration and the systems issues that contributed to the evolution of this incident. The aims of the workshop are: to enhance awareness of the risks of vincristine administration; to develop understanding of the need for a new emphasis on patient safety in hospitals; to equip participants with the skills to contribute to patient safety; and to identify local policies and procedures to make the workplace safer. (This workshop could apply to most of the topics in this Curriculum Guide.)



Lecture on systems and complexity



Small group discussion about the various levels of the “system” in own workplace

- The group could discuss *The wrong patient* article [10] with a tutor.
- Select one of the cases above and discuss using a systems perspective.

Teaching activities

- Follow a patient from the time they enter the service to the time they are discharged and discuss all the steps and types of health-care workers involved.
- Keep a track of the people from the different parts of the health system and discuss their roles and functions in health care.
- Visit unfamiliar parts of the organization.
- Participate or observe a root cause analysis process.

HOW TO ASSESS THIS TOPIC

- Write an account of a patient tracking experience in which a student follows a patient throughout their entire hospital stay.

A range of assessment strategies are suitable for this topic including MCQs, essays, SBA, case-based discussion and self-assessment. Having a student, or a group of students, lead a small group discussion on the various levels of the system in their own workplace is a useful way to elicit understanding.

HOW TO EVALUATE THIS TOPIC

Evaluation is important in reviewing how a teaching session went and how improvements can be made.

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Slides for topic 3: Understanding systems and the impact of complexity on patient care

Didactic lectures are not usually the best way to teach students about patient safety. If a lecture is being considered it is a good idea to plan for student interaction and discussion during the lecture. Using a case study is one way to generate group discussion. Another way is to ask the students questions about different aspects of health care that will bring out the issues contained in this topic such as the blame culture, nature of error and how errors are managed in other industries.

The slides for topic 3 are designed to assist the teacher deliver the content of this topic. The slides can be changed to fit the local environment and culture. Teachers do not have to use all of the slides and it is best to tailor the slides to the areas being covered in the teaching session.

Topic 4: Being an effective team player

Why teamwork is an essential element of patient safety

1

Effective teamwork in health-care delivery can have an immediate and positive impact on patient safety [1]. The importance of effective teams in health care is increasing due to factors such as: (i) the increasing complexity and specialization of care; (ii) increasing co-morbidities; (iii) increasing chronic disease; (iv) global workforce shortages; and (v) safe working hours initiatives. Paul M. Schyve, MD, senior vice president of the Joint Commission has observed, “Our challenge ... is not whether we will deliver care in teams but rather how well we will deliver care in teams.”[2]

A typical example of complex care involving multiple teams would be a pregnant woman with diabetes who develops a pulmonary embolus—her medical care team includes: an obstetrician, an endocrinologist and a respiratory physician. The doctors and nurses looking after her will be different during the day compared to at night and on the weekend. In a teaching hospital, there will be teams of doctors for each specialty area, all of whom need to coordinate care with each other, the nursing staff, allied health providers and the patient’s primary care team.

This topic acknowledges that medical students are unlikely in their early years to have participated as a member of health-care team themselves and often have little understanding of how teams are constructed and operate effectively. We aim in this topic to draw on students' past experiences of teamwork as well as look forward to the teams they will increasingly participate in as later year students and practising clinicians.

Keywords:

2

Team, values, assumptions, roles and responsibilities, learning styles, listening skills, conflict resolution, leadership, effective communication.

Learning objectives:

- understand the importance of teamwork in health-care;
- know how to be an effective team player;
- recognize you will be a member of a number of health-care teams as a medical students.

Learning outcomes: knowledge and performance

What students need to know (knowledge requirements)

3

4

Knowledge requirements in this module include a general understanding of:

- the different types of teams in health care;
- the characteristics of effective teams;
- the role of the patient in the team.

What students need to do (performance requirements)

5

Use the following teamwork principles to promote effective health care including:

- mindful of how one’s values and assumptions affect interactions with others;
- mindful of the of team members and how psychological factors affect team interactions;
- aware of the impact of change on teams;
- include the patient in the team;
- use communication techniques;
- resolve conflicts;
- use mutual support techniques;
- change and observe behaviours.

WHAT STUDENTS NEED TO KNOW (KNOWLEDGE REQUIREMENTS)

The different types of teams in health care

What is a team?

6

The nature of teams is varied and complex, they include: (i) teams that draw from a single professional group; (ii) multiprofessional teams; (iii)

teams that work closely together in one place; (iv) teams that are geographically distributed; (v) teams with constant membership; and (vi) teams with constantly changing membership.

Regardless of the type and nature of the team they can be said to share certain characteristics.

These include:

- team members have specific roles and interact together to achieve a common goal; [3]
- teams make decisions; [4]
- teams possess specialized knowledge and skills and often function under conditions of high workloads; [5,6]
- teams differ from small groups in as much as they embody a collective action arising out of task interdependency [7].

Salas defines teams as a “distinguishable set of two or more people who interact dynamically, interdependently, and adaptively towards a common and valued goal/objective/mission, who have been each assigned specific roles or functions to perform, and who have a limited lifespan of membership” [8].

Examples of teams include choirs, sporting teams, military units, aircraft crew and emergency response teams.

What different types of teams are found in health care?

7

There are many types of teams in health care. They include labour and delivery units, ICUs, medical wards, primary care teams in the community, teams assembled for a specific task such as an emergency response team or multiprofessional teams such as multidisciplinary cancer care teams that come together to plan and coordinate a patient’s care.

Teams in health care can be geographically co-located, as in an ICU or surgical unit, or

distributed as in a multidisciplinary cancer team or primary health-care team.

Teams can include a single discipline or involve the input from multiple practitioner types including doctors, nurses, pharmacists, physiotherapists, social workers, psychologists and potentially administrative staff. The role these practitioners play will vary between teams and within teams at different times. Roles of individuals on the team are often flexible and opportunistic such as the leadership changing depending on the required expertise or the nurse taking on the patient education role as they are the ones that have the most patient contact.

In support of patient-centred care and patient safety, the patient and their carers are increasingly being considered as active members of the health-care team. As well as being important in terms of issues such as shared decision making and informed consent, engaging the patient as a team member can improve the safety and quality of their care as they are a value information source being the only member of the team who is present at all times during their care.

8

9

The TeamSTEPS™ [9] programme developed in the United States identifies a number of different but interrelated team types that support and deliver health care:

1. Core teams

Core teams consist of team leaders and members who are involved in the direct care of the patient. Core team members include direct care providers (from the home base of operation for each unit) and continuity providers (those who manage the patient from assessment to disposition, for example, case managers). The core team, such as a unit-based team (physician, nurses,

physiotherapist, and pharmacist) is generally based where the patient receives care.

2. *Coordinating teams*

The coordinating team is the group responsible for:

- day-to-day operational management;
- coordination functions;
- resource management for core teams.

3. *Contingency teams*

Contingency teams are:

- formed for emergent or specific events;
- time-limited events (e.g. cardiac arrest team, disaster response teams, rapid response teams);
- composed of team members drawn from a variety of core teams.

4. *Ancillary services*

Ancillary services consist of individuals such as cleaners or domestic staff who:

- provide direct, task-specific, time-limited care to patients;
- support services that facilitate care of patients;
- are often not located where patients receive routine care.

Ancillary services are primarily a service delivery team whose mission is to support the core team. This does not mean that they should not share the same goals. The successful outcome of a patient undergoing surgery requires accurate information on catering and instructions in relation to “nil by mouth” orders so that a patient does not inadvertently receive a meal that may place them at risk of choking. In general, an ancillary services team functions independently, however, there may be times when they should be considered as part of the core team.

5. *Support services*

Support services consist of individuals who:

- provide indirect, task-specific services in a health-care facility,
- are service-focused, integral members of the team, helping to facilitate the optimal health-care experience for patients and their families.

Their roles are integrated in that they manage the environment, assets and logistics within a facility. Support services consist primarily of a service-focused team whose mission is to create efficient, safe, comfortable and clean health-care environments, which impact the patient care team, market perception, operational efficiency and patient safety.

6. *Administration*

Administration includes the executive leadership of a unit or facility, and has 24-hour accountability for the overall function and management of the organization. Administration shapes the climate and culture for a teamwork system to flourish by:

- establishing and communicating vision;
- developing and enforcing policies;
- setting expectations for staff;
- providing necessary resources for successful implementation;
- holding teams accountable for team performance;
- defining the culture of the organization.

How do teams improve patient care?

10

Medical practice has traditionally focused on the individual physician as solely responsible for a patient's care. However, patients today are rarely looked after by just one health professional. Patient safety, in the context of a complex medical system, recognizes that effective teamwork is essential for minimizing adverse events caused by miscommunication with others caring for the patient and misunderstandings of their roles and responsibilities.

The link between non-technical skills such as teamwork and adverse events is now well established [10,11], as is the increasing burden of chronic disease, co-morbidities and ageing populations that require a coordinated and multidisciplinary approach to care [12].

Baker et al. [1], in a major review of team training, contended that the training of health professionals as teams “constitutes a pragmatic, effective strategy for enhancing patient safety and reducing medical errors”.

Teamwork has been associated with improved outcomes in areas such as primary care [13] and

cancer care [14]. Teamwork has also been associated with reduced medical errors [15,16]. As summarized in Table 12, improving teamwork can have benefits beyond improving patient outcomes and safety that include benefits for the individual practitioners in the team, the team as a whole as well as the organization in which the team resides (adapted from Mickan, 2005) [12].

How do teams form and develop?

11

Considerable research into how teams form and develop has been conducted in other high stakes industries. As detailed in Table 13, Tuckmann [17] identified four stages of team development: forming, storming, norming and

Table 12: Measures of effective teamwork (adapted from Mickan, 2005)

Outcome measures of effective teamwork			
		Individual benefits	
<i>Organizational benefits</i>	<i>Team benefits</i>	<i>Patients</i>	<i>Team members</i>
Reduced hospitalization time and costs	Improved coordination of care	Enhanced satisfaction	Enhanced job satisfaction Reduced unanticipated admissions
Efficient use of health-care services	Acceptance of treatment	Greater role clarity	Better accessibility for patients
Enhanced communication and professional diversity	Improved health outcomes and quality of care	Reduced medical errors	Enhanced well-being

Table 13: Stages of team development (modified from Flin [18])

Stage	Definition
Forming	Typically characterized by ambiguity and confusion when the team first forms. Team members may not have chosen to work together and may be guarded, superficial and impersonal in communication, as well as unclear about the task.
Storming	A difficult stage when there may be conflict between team members and some rebellion against the tasks assigned. Team members may jockey for positions of power and frustration at a lack of progress in the task.
Norming	Open communication between team members is established and the team starts to confront the task at hand. Generally accepted procedures and communication patterns are established.
Performing	The team focuses all of its attention on achieving the goals. The team is now close and supportive, open and trusting, resourceful and effective

performing.

Similar to other industries, many health-care teams (such as surgical teams) are required to work together and need to be fully functioning without any time to establish interpersonal relationships and go through the forming or norming phases described above [18]. This makes team training essential for all members of the team prior to joining the team.

The characteristics of successful teams

What makes for a successful team? 12

There are many models describing effective teamwork. Historically these come from other industries such as aviation's Crew Resource Management. Extensive studies have been conducted into health-care teams and this has led to the development of a number of models and toolkits specific to health care.

Mickan and Roger [19] offer the following six simple characteristics that underpin effective health-care teams:

1. *Common purpose*
Team members generate a common and clearly defined purpose that includes collective interests and demonstrates shared ownership.
2. *Measurable goals*
Teams set goals that are measurable and focused on the team's task.
3. *Effective leadership*
Teams require effective leadership that set and maintain structures, manage conflict, listen to members and trust and support members. The authors also highlighted the importance of teams to agree and share leadership functions.

4. *Effective communication*

Good teams share ideas and information quickly and regularly, keep written records as well as allow time for team reflection. Some of the most in-depth analysis of interprofessional team communication has occurred in high stakes teams such as are found in surgery [20,21].

5. *Good cohesion*

Cohesive teams have a unique and identifiable team spirit and commitment and have greater longevity as teams members want to continue working together.

6. *Mutual respect*

Effective teams have members who respect the talents and beliefs of each person in addition to their professional contributions. In addition, effective teams accept and encourage a diversity of opinion among members.

Additional requirements for effective teams include: [9,18,22]

- demonstrating individual task proficiency (both in terms of personal technical skills and teamwork skills);
- having task motivation;
- being flexible;
- monitoring their own performance;
- effectively resolving and learning from conflict;
- demonstrating situation monitoring.

Leadership 13 14

Effective leadership is a key characteristic of an effective team. Effective team leaders facilitate and coordinate the activities of other team members by:

- accepting the leadership role;
- calling for help appropriately;
- constantly monitoring the situation;
- setting priorities and making decisions;

- utilizing resources to maximize performance;
- resolving team conflicts;
- balancing the workload within a team;
- delegating tasks or assignments;
- conducting briefs, huddles, debriefs;
- empowering team members to speak freely and ask questions;
- organize improvement activities and training for the team;
- inspire “followers” and maintain a positive group culture.

Including the patient as a member of the health-care team is a new concept in health care. Traditionally the role of the patient has been more passive as being a receiver of health care. But we know that patients bring their own skills and knowledge about their condition and illness. Medical student can begin showing leadership in this area by trying to include the patient or their family as much as possible. Establishing eye contact with patients, checking and confirming information and seeking additional information can all be done in the context of a ward round. Including the patient is a safety check to ensure the correct information and complete information is available to everyone on the team.

Communication techniques for health-care teams

15

George Bernard Shaw said, “The greatest problem with communication is the illusion that it has been accomplished.” Good communication skills are at the core of patient safety and effective teamwork. The following strategies can assist team members in accurately sharing information and ensuring that the focus is on the information being communicated. Use of a modified version of the “SBAR” called the “ISABAR” has recently been demonstrated to improve telephone referrals by medical students in an immersive simulated environment [23].

The following description of tools and case examples have been taken from The

TeamSTEPPS™ [9] programme and can be found at <http://www.ahrq.gov/qual/teamstepps/>.

SBAR

SBAR is a technique for communicating critical information about a patient’s concern that requires immediate attention and action. The technique is intended to ensure the correct information and level of concern is communicated in an exchange between health professionals.

Situation

What is going on with the patient?

“I am calling about Mrs Joseph in room 251. Chief complaint is shortness of breath of new onset.”

Background

What is the clinical background or context?

“Patient is a 62-year-old female post-op day one from abdominal surgery. No prior history of cardiac or lung disease.”

Assessment

What do I think the problem is?

“Breath sounds are decreased on the right side with acknowledgement of pain. Would like to rule out pneumothorax.”

Recommendation

What would I do to correct it?

“I feel strongly the patient should be assessed now. Are you available to come in?”

Call-out

Call-out is a strategy to communicate important or critical information that:

- informs all team members simultaneously during emergent situations;
- helps team members anticipate the next steps;
- directs responsibility to a specific individual responsible for carrying out the task.

An example of a call-out exchange between a team leader and a resident would be:

Leader: *Airway status?*

Resident: *Airway clear.*

Leader: *Breath sounds?*

Resident: *Breath sounds decreased on right.*

Leader: *Blood pressure?*

Resident: *BP is 96/92.*

- receiver accepts message and provides feedback;
- sender double-checks, to ensure the message is understood.

Doctor: *Give 25 mg Benadryl IV push.*

Nurse: *25 mg Benadryl IV push?*

Doctor: *That's correct.*

Check-back

This is a simple technique for ensuring information conveyed by the sender is understood by the receiver, as intended:

- sender initiates message;

Handover or handoff

Handover or handoff are crucial times where errors in communication can result in adverse outcomes. "*I pass the baton*" is a strategy to assist timely and accurate handoff.

I	Introduction	Introduce yourself, your role and job and the name of the patient.
P	Patient	Name, identifiers, age, sex, location.
A	Assessment	Present chief complaint, vital signs, symptoms and diagnosis.
S	Situation	Current status/circumstances, including code status, level of (un)certainly, recent changes and response to treatment.
S	Safety concerns	Critical lab values/reports, socioeconomic factors, allergies and alerts(falls, isolation and so on).
The		
B	Background	Co-morbidities, previous episodes, current medications and family history.
A	Actions	What actions were taken or are required? Provide brief rationale.
T	Timing	Level of urgency and explicit timing and prioritization of actions.
O	Ownership	Who is responsible (person/team), including patient/family.
N	Next	What will happen next? Anticipated changes? What is the plan? Are there contingency plans?

Resolving disagreement and conflict



Key to successful teamwork is the ability to resolve conflict or disagreement in the team. This can be especially challenging for junior members of the team, such as medical students, or in teams that are highly hierarchical in nature.

However, it is important for all members of the team to feel they can comment when they see something that they feel will impact on the safety of a patient.

The following protocols have been developed to help members of a team express their concern in a graded manner.

Two-challenge rule

The two-challenge rule is designed to empower all team members to “stop” an activity if they sense or discover an essential safety breach. There may be times when an approach is made to a team member but is ignored or dismissed without consideration. This will require a person to voice his or her concerns by restating their concerns at least twice, if the initial assertion is ignored (thus the name “two-challenge rule”). These two attempts may come from the same person or two different team members:

- the first challenge should be in the form of a question;
- the second challenge should provide some support for the team members’ concern;
- remember this is about advocating for the patient—the “two-challenge” tactic ensures that an expressed concern has been heard, understood, and acknowledged;
- the team member being challenged must acknowledge the concerns;
- if this does not result in a change or is still unacceptable, then the person with the concern should take stronger action by talking to a supervisor or the next person up the chain of command.

CUS

CUS is shorthand for a three-step process in assisting people in stopping the activity.

I am **C**oncerned

I am **U**ncomfortable

This is a **S**afety issue

DESC Script

DESC describes a constructive process for resolving conflicts.

Describe the specific situation or behaviour and provide concrete evidence or data.

Express how the situation makes you feel and what your concerns are.

Suggest other alternatives and seek agreement.

Consequences should be stated in terms of impact on established team goals or patient safety. The goal is to reach consensus.

Barriers to effective teamwork

17

A number of specific barriers exist to establishing and maintaining effective teamwork in health care. These include:

Changing roles

There are currently considerable change and overlap in the roles played by different health-care professionals. Examples include radiographers reading plain film X-rays, nurses performing colonoscopies and nurse practitioners having prescribing rights. These changing roles can present challenges to teams in terms of role allocation and acknowledgement.

Changing settings

The nature of health care is changing including increased delivery of care for chronic conditions into community care and many surgical procedures to day-care centres. These changes require the development of new teams and the modification of existing teams.

Medical hierarchies

Medicine is strongly hierarchical in nature and this is counterproductive in terms of establishing and effectively running teams where all members’

views are accepted and the team leader is not always the doctor. While there has been a growing acknowledgement that teamwork is important in health care this has not necessarily been translated into changed practices, especially in emerging and developing nations where cultural norms of communication may mitigate against teamwork.

Individualistic nature of medicine

The practice of medicine is based on the autonomous one-on-one relation between the doctor and patient. While this relationship remains a core value, it is challenged by many concepts of teamwork and shared care. This can be at many levels including doctors being unwilling to share the care of their patients through to medico-legal implications of team-based care.

Instability of teams

As already discussed, health-care teams are often transitory in nature, coming together for a specific task or event (such as cardiac arrest teams). The transitory nature of these teams places great emphasis on the quality of training for team members, which raises particular challenges in medicine where education and training is often relegated at the expense of service delivery.

Accidents in other industries

18

Reviews of high-profile incidents such as the crash of Pan Am flight 401 have identified three main teamwork failings as contributing to accidents, namely: [18,24]

- roles not being clearly defined;
- lack of explicit co-ordination;
- miscommunication/communication.

Assessing team performance

19

Assessing the performance of a team is an important step in improving team performance.

A number of teamwork assessment measures are available [18,25, 26]. Assessment of teams can be carried out in a simulated environment, by direct observation of their actual practice or through the use of teamwork exercises such as described in the section below on teaching teamwork.

Assessment of teams can either be done at the level of individual performance within the team or at the level of the team itself. Assessment can be performed by an expert or through peer rating of performance.

An analysis of the learning styles or problem solving skills individuals bring to teamwork can be useful following the assessment of team performance [27].

Summary

20

Teamwork does not just happen. It requires an understanding of the characteristics of successful teams, knowledge of how teams function and ways to maintain effective team functioning. There are a variety of team tools that have been developed to promote team communication and performance and these include SBAR, call-out, check-back and I Pass the Baton.

WHAT STUDENTS NEED TO DO (PERFORMANCE REQUIREMENTS)

Using teamwork principles

21

Medical students can use teamwork principles as soon as they start their medical courses. Many medical degrees are based on a problem based learning (PBL) format and require

students to work together in teams to build knowledge and solve clinical problems. They can begin to understand how those teams function and what makes an effective PBL group. Learning to share information, textbooks and lecture notes is a forerunner to sharing information about patients.

Be mindful of how one's values and assumptions affect interactions with other team members

Students learn by observing how different health professionals interact with each other. They will realize that even though a team can be made up of many personalities and practice styles, this does not necessarily make the team less effective. Rather, it can show how the strengths and weaknesses of different members of the team can assist deliver quality and safe care.

Be mindful of the role of team members and how psychosocial factors affect team interactions, recognize the impact of change on team members

It can often be difficult for medical students (and indeed practising clinicians) to appreciate the different roles that health-care professionals play in teams, or how teams respond to change or psychosocial factors. Students can be encouraged to make structured observations of teams to observe what roles are played by different individuals and how this relates to factors such as their personal characteristics as well as their profession. Students can be encouraged to talk to different team members around their experience of working in a team. Faculty can themselves ensure that students are included in teams and assigned roles so they can observe these processes from the inside.

Include the patient as a member of the team

Medical students can ensure that when they are taking histories or performing procedures on

patients that they take the time to engage with the patient. This can include discussing with the patient the procedure they are undergoing or any anxieties or concerns the patient or their carers may have. They can actively include patients in ward rounds by either inviting them at the time to participate or by discussing with the team how patients might be included in ward round discussions.

Using mutual support techniques and resolving conflicts, using communication techniques and changing and observing behaviours

22 23

Medical students can practise all of these competencies either in their work with their peers in study groups or within health-care teams as they move through their programme and are increasingly involved. As detailed below, many teamwork activities can be used with groups of students and practitioners to explore leadership styles, conflict resolution and communication skills.

A number of practical tips exist to help medical students improve their team communication skills. They can start practising good teamwork at the very beginning of their medical course. The following activities and steps will promote good teamwork in any situation whether as a medical student or a hospital senior doctor.

- Always introduce yourself to the team or those you are working with even if it is for a few minutes.
- Reading back and closing the communication loop in relation to patient care information.
- Stating the obvious to avoid confusion.

Nurse: *Mr Brown is going to have an X-ray.*

Student: *So, we are taking Mr Brown to have an X-ray now.*

- Asking questions and continually clarifying.
- Delegating tasks to people—look at them and check they have the information to enable them to do the task. Talking into the air is an unsafe practice because the person may not think that it is they who have the responsibility of the task.
- Clarifying your role in different situations.

Nurse: *Mr Brown is going to have an X-ray.*

Student: *So, we are taking Mr Brown to have an X-ray now.*

Nurse: *Yes.*

Student: *Who is taking Mr Brown for his X-ray?*

- Using objective language not subjective language.
- Learning the names of people who are in the team and using them. Some doctors do not bother to learn the names of the nurses and other allied health-care workers thinking they are not as important. However, doctor better relationships with other team members if they use people's names rather than referring to them by their profession, such as "nurse".
- Being assertive when required. This is universally difficult, yet if a patient is at risk of serious injury then the health professionals, including students, must speak up. Senior clinicians will be grateful in the longer term if one of their patients avoids a serious adverse event.
- If something does not make sense, ask for clarification.
- Briefing the team before undertaking a team activity and performing a debriefing afterwards.

This encourages every member of the team to contribute to discussions about how it went and what can be done differently or better next time.

- When conflict occurs, concentrate on "what" is right for the patient not on establishing "who" is right or wrong.

CASE STUDIES

Right action, wrong result

A doctor was coming to the end of his first week in the emergency department. His shift had ended an hour before, but the department was busy and his registrar asked if he'd see one last patient. The patient was an 18-year-old man. He was with his parents who were sure he'd taken an overdose. His mother had found an empty bottle of paracetamol that had been full the day before. He had taken overdoses before and was under the care of a psychiatrist. He was adamant he'd only taken a couple of tablets for a headache. He said he'd dropped the remaining tablets on the floor so had thrown them away. The parents said they'd found the empty bottle six hours ago and felt sure that he couldn't have taken the paracetamol more than ten hours ago. The doctor explained that a gastric lavage would be of no benefit. He took a blood test instead to establish paracetamol and salicylate levels. He asked the lab to phone the emergency department with the results as soon as possible. A student nurse was at the desk when the lab technician phoned. She wrote the results in the message book. The salicylate level was negative. When it came to the paracetamol result, the technician said, "two" paused, and then, "one three", "two point one three" repeated the nurse, and put down the phone. She wrote "2.13" in the book. The technician didn't say whether this level was toxic and he didn't check whether the nurse had understood. When the doctor appeared at the desk, the nurse read out the results. The doctor checked a graph he'd spotted earlier on the notice board. It showed when to treat overdoses.

There was also a protocol for managing paracetamol overdoses on the notice board, but it was covered by a memo. The graph showed that 2.13 was way below treatment level. The doctor thought briefly about checking with the registrar, but she looked busy. Instead, he told the student nurse that the patient would need admitting overnight so that the psychiatrist could review him the next day. The doctor went off duty before the printout came back from the lab. It read “paracetamol level: 213”. The mistake wasn’t discovered for two days, by which time the patient was starting to experience the symptoms of irreversible liver failure. It wasn’t possible to find a donor liver for transplant and the patient died a week later. If he’d been treated when he arrived at the emergency department, he might not have died.

The doctor was told what had happened by his consultant on Monday when he started his next shift and, while still in a state of shock, explained that he had acted on what he thought was the correct result. He had not realised, he admitted, that paracetamol levels are never reported with a decimal point. Because he had not seen the protocol he had also not appreciated that it might have been appropriate to start treatment before the paracetamol level had come back anyway, bearing in mind that the history, although contradictory, suggested the patient might well have taken a considerable number of tablets. It would be unfair to blame the doctor or the student nurse individually. The real weakness is the lack of safety checks in the system of communicating test results. In fact, no-one made a really big mistake. At least three people made a series of small ones, and the system failed to pick these up.

Reference

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A failure to relay information between staff and to confirm assumptions, resulting in adverse patient outcome

This example highlights how the dynamics between surgical trainees and staff and the flow of staff in and out of the operating room can allow adverse events to happen.

Before a roux-en-y gastric bypass patient was brought into the operating room, a nurse reported to a second nurse that the patient was allergic to “morphine and surgical staples”. This information was repeated again to the staff surgeon and the anaesthetist before the start of the procedure.

As the surgery was coming to an end, the staff surgeon left the operating room, leaving a surgical fellow and two surgical residents to complete the procedure. The surgical fellow then also left the operating room, leaving the two residents to close the incision. The two surgical residents stapled a long incision closed along the length of the patient’s abdomen. They stapled the three laparoscopic incisions closed as well. When the residents began the stapling, a medical student removed a sheet of paper from the patient chart and took it over to the residents. The medical student tapped one of the residents on the shoulder, held the paper up for her to read and told her that the patient was allergic to staples. The resident looked at it and said “you cannot be allergic to staples.”

The staff surgeon returned to the operating room as the residents were completing the stapling. He saw that the residents had stapled the incisions and informed them that the patient did not want staples. He told them that they would have to

take all the staples out and suture the incision. He apologized for neglecting to inform them of this allergy. One of the residents asked whether you could be allergic to staples and the staff surgeon said: “It does not matter. The patient is convinced that she is.” The staff surgeon told the residents they would have to remove all the staples and sew the incisions. This took an additional 30 minutes.

Case from the WHO Patient Safety Curriculum Guide for Medical Schools working group. Supplied by Lorelei Lingard, University of Toronto, Toronto, Canada.

Emergency resuscitation requires teamwork

This case illustrates the importance of the team being prepared to carry out an effective code blue or emergency resuscitation.

Medical officer Simon was in the cafeteria eating a late lunch. Halfway through his meal, a cardiac arrest announcement was made over the public address system. He ran to get the lift up to the fifth floor ward where the emergency was. It was peak hour and the lifts were busy. By the time he reached the patient, a nurse had wheeled in the cardiac arrest trolley and another nurse had an oxygen mask on the patient.

“Blood pressure, pulse, heart rate?” yelled the doctor. A nurse grabbed a blood pressure cuff and began to inflate it. The nurse holding the oxygen mask tried to find a pulse on the patient’s wrist. The medical officer shouted for an ECG monitor to be placed on the patient and for the of the bed head to be lowered. The nurses tried to obey his orders; one stopped trying to get the blood pressure and lowered the bed. This made the oxygen mask fall off as the tubing gets caught in the side panels of the bed.

Simon became agitated. He had no idea of the

heart rate or rhythm. The patient did not seem to be breathing. The heart monitor came on and showed ventricular fibrillation.

“Pads and 50 joules”, called Simon. The nurses look at him and say, “What?” “Pads and 50 joules, stat!” Simon replied. “Call a doctor, any doctor, to come and assist me *now!*” he yelled. They could not revive the patient.

Reference

Case from the WHO Patient Safety Curriculum Guide for Medical Schools working group.

Supplied by Ranjit De Alwis, International Medical University, Kuala Lumpur, Malaysia.

Everyone on the team counts

This is an example of how an initiative such as a preoperative team briefing can provide an opportunity for individual members of the operative team to provide information that impacts patient outcome. A preoperative team briefing is a short gathering including nurses, surgeons and anaesthetists held before the surgery with the goal of discussing important patient and procedure relevant issues.

In preparation for a low anterior resection and ileostomy, the interprofessional team met to have a briefing. The surgeon asked a nurse whether she had anything to contribute. The nurse reported that the patient was worried about her hernia. In response to this the surgeon questioned the patient (who was still awake) about the hernia. The surgeon then explains to the operating room team how he will proceed around the hernia and that he might use mesh.

Case from the WHO Patient Safety Curriculum Guide for Medical Schools working group. Supplied by Lorelei Lingard, University of Toronto, Toronto, Canada.

HOW TO TEACH THIS TOPIC

Teaching strategies and formats

This module recommends a number of strategies to build education and experience around teamwork.

Effective teams do not just happen and there is substantial body of underpinning theory that can be appropriately delivered in a didactic manner. The knowledge requirements listed above can form the basis for didactic presentations.

Given that one of the most effective ways of learning about teamwork is to participate in a team, we include a number of team-based activities that can easily be run with small groups of students with limited resources. Given that medical students will often have little experience of participating in health-care teams, we include activities where students reflect on their experiences of teamwork outside of medicine.

To familiarize students with actual health-care teams we then include activities that anticipate the types of teams that students will increasingly encounter as they move forward in their training and on to practice.

We conclude this section with a discussion of interprofessional education that may or may not be an option for consideration within your medical curriculum.

A recent systematic review of teamwork training developed for medical students and junior doctors found that teaching teamwork skills to students and young doctors was moderately effective over the short term and appeared to be more effective when more teamwork principles were addressed within the training [28].

Any team education and training programme developed must consider local culturally

acceptable behaviour in regard to speaking out in a team and the nature of hierarchies in a given country.

Building teamwork education over the course of a programme

Over a four- or six-year medical programme there is an opportunity to stratify teaching and learning around teamwork. For instance, a programme could be structured in the following ways.

Early years:



Didactic presentations around

- basics of teamwork and learning styles;
- different types of teams in health care;
- different learning styles.



Small group activities that focus on:

- building fundamental team-based skills;
- appreciating different learning and problem solving styles;
- reflecting on experience of participating in teams outside of health care;
- the roles of various health-care teams.

Middle and later years:



Didactic presentations around

- the roles and responsibilities of different health professionals in teams;
- characteristics of effective teams;
- strategies to overcome barriers to effective teams.



Small group activities that include

- interprofessional participation;
- reflection on the experience of participating as a medical student in health-care teams;
- teamwork simulation in health-care context (high or low fidelity).

Teaching activities

Engaging role models

Given that teamwork is not always recognized or valued in the health-care delivery environments encountered by students, it is important to engage clinical role models the delivery of teamwork education. If possible, identify clinicians with good reputations for working in multidisciplinary teams. Ideally, these role models would present different aspects of the theory behind teamwork and give examples from their own experiences. Wherever possible, role models should be drawn from multiple health-care professions.

Reflective activities around experiences of teamwork

A simple way to introduce teamwork concepts to medical students is to get them to reflect on teams they may have participated in during school or university. This may include sporting teams, work teams, choirs and so on. Reflective exercises can include the creation of simple surveys that can be used to draw out questions around teamwork.

Reflective exercises can also be built around examples of teamwork failures or successes that may be topical and/or current within the local community. This may include the development of quizzes or group discussions about newspaper articles describing failures in sporting teams associated with teamwork failures or high-profile examples of medical errors due to failures in teamwork. The case studies provided within the framework could also be used to reflect on failures in teamwork.

High-profile examples of teamwork failures and successes outside of health care such as plane crashes or nuclear power station failures are often used in the teaching of teamwork principles. A

number of these are described in detail by Flin et al. [18] and include the crashes of in the Pan Am and KLM 747s in Tenerife and the rescue of the Apollo 13 mission.

Team building exercises

There are a wide range of activities that can help promote an understanding of team dynamics and different learning styles. A simple search of the internet will provide access to many examples. These can be useful for any level of team participant and require no prior knowledge of health care or teamwork. The intention is that they are fun to take part in and often have a positive side-effect of bonding student groups together.

Remember, one of the most important parts of any team building exercise is the debrief at the end of the exercise. The purpose of the debrief is to

- reflect on what worked well for the team so that effective team behaviours are reinforced;
- reflect on what was difficult and what challenges the team face—strategies to manage the challenges should be explored and then practised in subsequent sessions.

Free team building games can be found on the following web site.

<http://www.businessballs.com/teambuildinggames.htm>

Building newspaper towers: an example of a team building exercise (taken from the web site above)

An interactive exercise that requires no physical contact that can be varied depending on the group size, dynamics and available time.

Basic exercise:

Split the group into smaller groups of 2–6 people. Issue each group with an equal number of newspaper sheets (the fewer the more difficult, 20–30 sheets is fine for a 10–15 minute exercise),

and a roll of sticky tape. The task is to construct the tallest free-standing tower made only of newspaper and sticky tape in the allotted time. The point of the exercise is to demonstrate importance of planning (time, method of construction, creativity) and the motivational effect of a team task. The facilitator will need a tape measure.

Instructions need to be very clear. For instance, does the tower have to be free standing or can it be braced? It does not matter which, it matters only that any issues affecting a clear result are clarified.

Tips for newspaper constructions exercises

You can allocate as many sheets as you wish, depending on the main purpose of the exercise, and to an extent the duration and how many team members per team. As a general rule, the fewer the sheets the smaller the teams and the shorter the exercise. Short timescales, big teams, lots of sheets = lots of chaos. This may be ideal for demonstrating the need for leadership and management. Unless the primary purpose is leadership and managing the planning stage, avoid small numbers of sheets with large teams. Small teams do not need lots of sheets unless you make a rule to use all materials in order to put pressure on the planning and design stage.

Examples of main purposes and numbers of sheets:

- very strong emphasis on preparation and design;
- 1-5 sheets in pairs or threes;
- design, planning, preparation, teamworking: 5-10 sheets in team of three or four;
- team building, time management, warm up, ice-breaker, with some chaos management: 20 sheets in teams of four, five or six;
- managing a lot of chaos: 30 sheets and upwards in teams of six or more.

Newspaper construction exercises are terrifically flexible and useful. Once you decide the activity purpose and rules, the important thing is to issue the same quantity of materials to each team.

Other tips for newspaper construction activities:

- Building tips: it does not matter how big the sheets are, but large double pages offer the greatest scope for the towers.
- Think about how much paper is issued as it changes the type of challenge: lots of paper makes it much easier and places less emphasis on planning. Very few sheets, or even just one sheet, increases the requirement for planning.
- The main trick (do not tell the participants before the exercise) is to make long thin round-section struts by rolling the sheets and fixing with sticky tape—Sellotape or Scotch tape, or narrow masking tape instead. The struts can then be connected using various techniques, rather like girders.
- Round struts (tubes), and any other design of struts or sections, lose virtually all their strength if flattened or bent. Very few newspaper exercise builders understand this fundamental point, and some fail to realize it even after completing the exercise, so it is worth pointing out during the review.
- Square sections are not very strong. Triangular or circular sections work best, although the former are difficult to make.
- It is possible to make a very tall tower (8-10 feet) using a telescopic design, which requires many sheets to be stuck together end-to-end, rolling together and then pulling out from the centre.
- Most people make the mistake of forming big square section lengths or spans, which are inherently very weak and unstable. This is why the newspaper constructions are such good exercises—each one needs thinking about and planning and testing or people fall

into traps and make simple mistakes.

- The best way of finding answers is to try it—you should be doing that anyway if you are facilitating and running the session. You will be amazed at how strong paper can be if it is folded and/or rolled and assembled with a bit of thought.

Simulated health-care environments

Simulation is being increasingly used to learn and practise teamwork in health care. This is an ideal learning environment for medical students, as it combines safety—there is no “real” patient—and the ability to increase or decrease the speed of evolution of the scenarios to optimize learning, especially if using mannequin-based simulation techniques. This is ideal for teamwork exercises as the importance of sound teamwork behaviours is particularly manifest in “emergency”, time-critical situations. In addition, students get a chance to experience what it is like to manage a situation in “real” time.

Ideally, simulated environments may be used to explore teamwork using mixed groups of health-care professionals. When exploring teamwork the focus should not be on the technical skills of the students but rather their interactions and communication with one another. The best way to ensure this remains the focus of the exercise is to allow the students to learn and practise the technical aspects of the scenario together prior to the actual scenario, usually through an initial procedural workshop. If the team struggle with basic knowledge and skills then the opportunity to discuss teamwork may be lost as there may be so many important medical and technical issues to discuss. However, if the students are well drilled on the technical aspects of the scenario beforehand, the challenge for them is to put what they know into action as a team. The simulation then becomes a powerful opportunity to explore the “non-technical” aspects of the scenario,

namely the teamwork, leadership and communication issues that emerge as the scenario unfolds [18].

As with the non-health-care team building exercises discussed above, it is vital that a structured debriefing is conducted that explores the way the teams performed in the exercise: what worked well and why, what was difficult and why, and what could be done to improve performance on subsequent occasions. If different health-care students are working together in the simulation, the different roles, perspectives and challenges of each profession can be discussed during the debriefing as well.

The major constraint with simulation exercises is that they can be resource intensive, especially if using a computerized mannequin and attempting to make a teaching setting look like a clinical environment.

Participating in health-care teams

Students, particularly in their later years, should be encouraged to participate in a number of different types of health-care teams at every opportunity. Just because the doctors and nurses from a particular ward or clinic maintain the traditional silo approach to health care does not prevent medical students working with other health professionals as part of a team.

The faculty should identify teams where students will be welcomed and ideally given some form of participatory role. These teams may include well-established multidisciplinary care planning teams such as found in mental health or oncology or more fluid teams as found in emergency departments. They should also include primary health-care teams in the community.

It is important to get students to reflect on team-based experiences in health care and share these

experiences with other students and faculty staff. This will allow them to discuss both the positive and negative aspects of their experience. Students should be asked to identify model teams and why they believe they can be identified as such. They should be encouraged to ask questions such as:

- What were the strengths of the team?
- What professions were represented on the team and what was their role?
- Did the team have clear goals?
- Was there a clear leader?
- Were all team members permitted to participate?
- How did members of the team communicate with one another?
- How could the student see the team being improved?
- Was the patient part of the team?

Students should be asked to explore and reflect on areas of teamwork where errors are known to occur such as communication between primary and secondary care or during handover/hand off.

It may also be possible for students to take part in a panel discussion with an effective multidisciplinary team to discuss how the team functions and works together.

Interprofessional education

While the focus of this Curriculum Guide is on medical schools, teamwork in health care cannot be discussed without discussing the important role of interprofessional education (IPE) in undergraduate health education.

At the heart of IPE is the preparation of future practitioners for effective team-based practice through bringing students from different disciplines together during undergraduate education to learn from and with each other. Undergraduate education is a good time to bring

different groups of students together to appreciate and respect the different roles of health professionals before they have joined a professional group themselves.

While there is a compelling argument that undergraduate IPE should improve subsequent teamwork in practice, the research to support this argument is not yet conclusive.

Universities have taken different approaches to introducing IPE depending on available resources, the available undergraduate programmes and the degree of support for the concept at a senior level. Approaches have ranged from a full re-engineering and alignment of all health curricula through to inserting IPE modules and activities into existing curricula on a relatively opportunistic basis.

The resources and activities included in this guide are intended to be useful either for programmes teaching only medical students or for those teaching multiprofessional student groups.

Below we include further reading on IPE and links to universities that have introduced IPE into their curricula.

Resources

Institute for Healthcare Improvement. *Health profession education: a bridge to quality*. Washington DC, National Academies Press, 2003.

Almgren, G et al. *Best practices in patient safety education: module handbook*. University of Washington, Seattle, Center for Health Sciences Interprofessional Education, 2004.

Universities that have introduced major initiatives in IPE include:

- Health Care Innovation Unit, University of Southampton, UK
<http://www.hciu.soton.ac.uk/>
- Faculty of Health Sciences, Linköping University, Sweden.
<http://www.hu.liu.se/?l=en>
- College of Health Disciplines, University of British Columbia, Canada.
<http://www.chd.ubc.ca/>
- Faculties of Health, The University of Sydney, Australia
<http://www.foh.usyd.edu.au/ipl/about/index.php>

Summary

In summary, team training for medical students can be effective using a variety of techniques, many of which can be delivered in the classroom or low-fidelity simulated environment.

Ideally, medical students should take part in real teams and learn through experience and guided reflection.

As far as possible, team training should focus on as many principles of effective teamwork as possible.

TOOLS AND RESOURCES

TeamSTEPPS™: Strategies and tools to enhance performance and patient safety

Department of Defense in collaboration with the Agency for Healthcare Research and Quality (AHRQ)
(<http://teamstepps.ahrq.gov/abouttoolsmaterials.htm>).

TeamSTEPPS™ also includes free access to a number of trigger tapes and videos.

SBAR Toolkit

Institute for Healthcare Improvement (IHI), Oakland, CA Kaiser Permanente
(<http://www.ihl.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/SBARToolkit.htm>).

Teamwork in health care: promoting effective teamwork in health care in Canada

Canadian Health Services Research Foundation (CHSRF), 2006
(http://www.chsrf.ca/research_themes/pdf/teamwork-synthesis-report_e.pdf).

How to assess this topic

Many different modalities can be used to assess teamwork.

MCQs and MEQs can be used to explore knowledge components.

A portfolio to be maintained over the entire curriculum can be used to record and reflect on team activities encountered at medical school.

Assignments can be specifically designed to require teamwork among students. This may include students self-selecting a health- or non-health-related project to complete or faculty suggesting a project such as planning the development of an apartment for a person who uses a wheelchair or planning the development of a rural outreach programme for oral health. In developing the assignment, the emphasis is not so much on the outcome of the project but rather the manner in which the students approach the teamwork aspects of working together.

Later assessments can be more complex and require items such as a review of a team with which the student is working and the development of recommendations for how that team could be improved.

A writing assignment could include tracking team functions by following either a patient stay for a defined period of time or tracking a health-care provider and reviewing how many teams they intersect with and what their roles are on each team.

Depending on available resources, simulation can also be used as an effective formative and summative assessment of health-care teamwork.

Ideally, some assessments would require students from different health professions to work together.

HOW TO EVALUATE THIS TOPIC

- As with any evaluation exercise, a number of evaluation phases need to be considered. These would include
- a needs analysis (or prospective evaluation) to judge how much teaching in teamwork currently exists and how much is needed;
- a process evaluation during the delivery of any programmes to maximize its effectiveness;
- an impact evaluation to track the impact of the programme on knowledge and competencies gained during the delivery of the programme.

See the Teacher's Guide (Part A) for more information on evaluation.

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Slides for topic 4: Being an effective team player

Didactic lectures are not usually the best way to teach students about patient safety. If a lecture is being considered, it is a good idea to plan for student interaction and discussion during the lecture. Using a case study is one way to generate group discussion. Another way is to ask the students questions about different aspects of health care that will bring out the issues contained in this topic.

The slides for topic 4 are designed to assist the teacher deliver the content of this topic. The slides can be changed to fit the local environment and culture. Teachers do not have to use all of the slides and it is best to tailor the slides to the areas being covered in the teaching session.

Topic 5: Understanding and learning from errors

Coming to terms with health-care errors

1

It is important that medical students have a basic understanding of the nature of error. All health-care workers need to understand the different types of errors and how they come about. This is essential for devising strategies to prevent them from happening or intercept them before they can cause harm to patients.

An equally important consideration is the issue of learning from errors—one’s own as well as those of others. It is through investigation of errors and error-causing conditions that improvements in system design can be implemented in the hope of decreasing the frequency and impact of errors. See topic 3 “Understanding systems and the impact of complexity on patient care” for further information.

T3

Keywords

Error, violation, near miss, hindsight bias, root cause analysis.

Learning objective

2

Understand the nature of error and how health care can learn from error to improve patient safety.

Learning outcomes: knowledge and performance

What a student needs to know (knowledge requirement):

3

explain the terms error, violation, near miss, hindsight bias.

What a student needs to do (performance requirements):

4

know the ways to learn from errors;
participate in an analysis of an adverse event;
practise strategies to reduce errors.

WHAT STUDENTS NEED TO KNOW (KNOWLEDGE REQUIREMENTS)

Errors

5

In simple terms, an error occurs “when someone is trying to do the right thing, but actually does the wrong thing (p.112).” [1] In other words, there is a non-deliberate deviation from what was intended. Reason stated this fact of life more formally by defining errors as “planned sequences of mental or physical activities that fail to achieve their intended outcomes, when these failures cannot be attributed to the intervention of some chance agency” [2]. Errors may occur by doing the wrong thing (commission) or by failing to do the right thing (omission).

A violation is different from errors caused by the system. Violations are errors caused by a deliberate deviation from an accepted protocol or standard of care.

6

Errors and outcomes are not inextricably linked. Students will often observe patients who have a bad outcome where no human error was made. Some treatments have well-recognized complications that can occur even in the best of hands and health care. Other numerous errors that are made do not lead to a bad outcome because the error was recognized in time and the appropriate steps or treatment taken to counteract the wrong treatment caused by the error. Sometimes, as mentioned in topic 3 in the section on HRO, patients themselves are resilient and even though an error was made the patient does not suffer because their own body or immune system has withstood the incorrect treatment.

7

It is important to point out that there is no reference to outcome in the definition of error, though the fact of the (usually untoward) outcome often is what draws our attention to the fact that

an error has occurred. Indeed, most errors in health care do not lead to harm for patients because they are recognized before harm occurs and the situation is retrieved. There is no doubt that the nature of the outcome usually influences our perception of the error, often due to phenomenon of “hindsight bias” in which knowledge of the outcome of a situation influences our perception (usually unfavourably) of the standard of care before and during the incident in question [2].

One only has to consider one’s last “silly mistake” in everyday life to be reminded of the inevitability of error as a fundamental facet of the “human condition” (see topic 2 “What is human factors and why is it important to patient safety?”). T2

The challenging reality for health-care workers is that the same mental processes that lead us to make “silly mistakes” away from the workplace are also in play when we are at work. However, the work context makes the consequences vastly different.

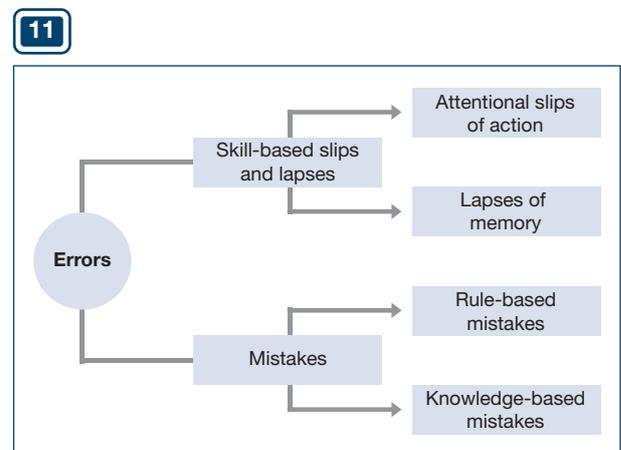
The term “medical error” is slightly misleading as it may give the impression that the kinds of errors that can occur in health care are unique to health care. This is not the case: the patterns of errors are no different from the sorts of problems and situations that exist in other settings. What is different about health care is that there remains an element of a culture of infallibility that denies the prevalence of error. 8 9 10

The unique feature in health care-associated errors is that when failure occurs (omission or commission) it is the patient or patients who suffer.

Errors occur because of one of two main types of failures: either actions do not go as intended or the intended action is the wrong one [3]. The

former situation is a so-called error of execution and may be further described as being either a “slip” –if the action is observable– or a “lapse” if it is not. An example of a slip is accidentally pushing the wrong button on a piece of equipment; an example of a lapse is some form of memory failure such as failing to administer a medication (see Figure 6).

Figure 6. Summary of the principal error types



Source: Reason JT. Human error: models and management. British Medical Journal, 2000, 320:768–770.

A mistake is a failure of planning, i.e. the plan is wrong. This can be either rule based, because a “wrong” rule is applied, or knowledge based, because the clinician does not take the correct course of action. An example of a rule-based mistake would be getting the diagnosis wrong and so embarking on an inappropriate treatment plan. Knowledge-based mistakes tend to occur when clinicians are confronted with what is for them a “new” clinical situation.

Slips, lapses and mistakes are all serious and can potentially harm patients, though again it all depends on the context in which the error occurs.

Situations that increase the likelihood of error as well as personal error reduction strategies are described in topic 2 “What is human factors and why is it important to patient safety?” Some other

general error reduction principles are outlined below. Reason has also promoted the concept of “error wisdom” [4] for frontline workers as a means to assess the risk in different contexts depending on the current state of the individual involved, the nature of the context and the error potential of the task at hand.



Situations associated with an increased risk of error



We now know from various studies that students and junior doctors in particular are vulnerable to errors in particular circumstances.

When they are unfamiliar with a task

It is very important that students do not perform a procedure for their very first time on a patient. They need to first understand what they are doing and to practise on a mannequin or other prop in a simulated environment. If it is the first time, the student should be properly supervised and watched while they perform the procedure.

Inexperience

Students are in a privileged position because patients do not expect students to know much they appreciate they are learning. This is why it is very important they do not pretend or let others present them as having more experience than they do.

Shortage of time

Time pressures make people cut corners and take shortcuts when they should not. Not washing hands properly is an example.

Inadequate checking

The simple act of checking has saved thousands of patients receiving the wrong medications. Pharmacists routinely check drugs and assist the health team in making sure the patient receives the correct drug, dose and by the correct route. Students should establish good relationships with

pharmacists and nurses who have habitual checking routines built into their discipline. Medicine has not had such a long tradition of using techniques to help minimize errors. Checking is a simple thing that students can start practising immediately when they are placed into the clinical environment.

Poor procedures

This can relate to a number of factors— inadequate preparation, inadequate staffing and inadequate attention to the particular patient. Students may be required to use a piece of equipment without fully understand what it is for or how to use it. Before using any equipment students should familiarize themselves with it. Watching someone use it and then discussing with them the procedure for which it is used is very instructive.

Individual factors that predispose students (and other health-care workers) to errors



In addition to recognized situations prone to errors, there are also individual factors that predispose errors:

Limited memory capacity

How medical students perceive themselves in the medical and hospital hierarchy may relate to how confident and willing they are to ask for help. Asking for help is expected of students yet it still remains a challenge for many students. This in turn may affect their ability to recognize their limitations. Lack of confidence could be a significant factor in whether a student asks for help in mastering a new skill. If they are unwilling or lack confidence to ask for help with simple tasks, will they have the confidence to ask for help when they are in trouble?

Learning to ask for help is an essential skill for all medical students and junior doctors. The

preparedness of medical students for clinical practice has been studied. Most reveal that many graduating medical students in their early intern year have deficiencies in basic clinical skills. This may be because of a reluctance to ask for help as students. Inadequate understanding of the crucial signs of acute illness, airway obstruction and basic life support were examples of specific areas where new doctors had inadequate knowledge and skills.

Many students think that if they can regurgitate the medical information stored in textbooks they will be good doctors. However, this is not the case. The amount of information that a doctor is required to know today is far beyond that which is capable of being memorized. Today, educational outcomes are more about performance than retention of information. This is because educationalists recognize that the human brain is a limited organ that is only capable of remembering a finite amount of information. Students should not rely on memory, particularly when there are a number of steps involved. Guidelines and protocols were developed to assist clinicians to provide care following the best available evidence. Students should get into the habit of using checklists and not relying on their memory. Topic 7 has a section on guidelines. 

Fatigue

Memory is affected by fatigue. Fatigue is a known factor in errors involving junior doctors. In recognition of the problems caused by fatigue many countries have or are reforming the excessive hours worked by doctors. The connection between sleep deprivation of interns due to long hours and circadian interruption and well-being was made three decades ago, yet it is only recently that governments and regulators have been serious about limiting hours. A 2004, study by Landrigan et al. [5] was one of

the first to measure the effects of sleep deprivation on medical errors. They found that interns working in the medical intensive unit and coronary care unit of Brigham and Women's Hospital (Boston, United States) made substantially more serious mistakes when they worked frequent shifts of 24 hours or more than when they worked shorter shifts. Other studies show that sleep deprivation can have similar symptoms to alcohol intoxication [6].

Stress, hunger, illness

When students feel stressed, hungry or ill they will not function as well as when they have none of these issues. It is very important for students to begin to monitor their own status and well being, being mindful that if they are feeling unwell or stressed that they are more likely to make errors.

Language or cultural factors

The potential for communication errors caused by language and cultural factors is obvious but there are many patient–doctor interactions that occur without an interpreter or understanding of the language. Students should appreciate the problems caused by language barriers and misunderstanding of cultural norms.

Hazardous attitudes

Medical students who perform procedures on patients without supervision might be said to display a hazardous attitude. The student may be more interested in practising or getting experience rather than any concern for the well-being of the patient. Students should always appreciate that accessing patients is a privilege and one that should not be taken for granted.

There are many easy to remember mnemonics to assist students monitor themselves. HALT is one such aid.

14 15

Do not forget if you are

H Hungry

A Angry

L Late

or

T Tired

Another tool is IM SAFE

I Illness

M Medication (prescription alcohol and others)

S Stress

A Alcohol

F Fatigue

E Emotion

WHAT STUDENTS NEED TO DO (PERFORMANCE REQUIREMENTS)

Know the ways to learn from errors

Incident reporting

16

Incident reporting and monitoring involves collecting and analysing information about any event that could have harmed or did harm a patient in the hospital, clinic or health-care organization. An incident-reporting system is a fundamental component of an organization's ability to learn from error. The lessons allow the organization to identify and eliminate the "error traps". Topic 6 "Understanding and managing clinical risk" provides more information on organizational responsibility for incident monitoring.

17

Incidents are traditionally under-reported, often because the person approach to incident analysis is still pervasive in health care, whereby the frontline workers—often the ones who report the

incident—are criticized for their role in the evolution of the incident. As mentioned above, this situation is often exacerbated by the phenomenon of hindsight bias. The person approach is counterproductive at several levels (see topic 3 "Understanding systems and the impact of complexity on patient care").

T3 18

The frequency of reporting and the manner in which incidents are analysed—using a systems approach rather than a person approach—are heavily dependent on the leadership and "culture" within an organization. More attention is being paid to the importance of organizational culture in health care in recent years [7], reflecting lessons learnt in other industries in relation to system safety. It is likely that there is a correlation in health care between organizational culture in a health service and patient safety.

An organization's culture reflects the shared values and beliefs that interact with an organization's structure and control systems to produce behavioural norms [8]. Organizations with a strong reporting culture are well placed to learn from errors because the staff feel free to report actual or potential problems without fear of ridicule or reprimand. Medical students and junior doctors are part of the work culture. They may feel that it is too hard and they have no power to change of effect anything in the hospital or clinic. However, they can look out for ways to improve the system. It can be as simple as being respectful to the health-care team, including patients in discussions about their care or asking if the nurses would like a coffee if the student is making coffee.

19 20

Other successful strategies in terms of incident reporting and monitoring include: [6]

21

- anonymous reporting;
- timely feedback;
- open acknowledgement of successes resulting from incident reporting;
- reporting of near misses is useful in that “free lessons” can be learnt, i.e. system improvements can be instituted as a result of the investigation but at no cost to a patient.

Root cause analysis

See also topic 7 “Introduction to quality improvement methods”.

22

T7

The Veterans Affairs National Center for Patient Safety of the US Department of Veterans Affairs has developed a structured approach called root cause analysis to evaluate, analyse and develop system improvements for the most serious adverse events [9].

Reporting an incident requires the following basic information: [1]

23

- What happened?
- Who was involved?
- When did it happen?
- Where did it happen?
- The severity of the actual or potential harm.
- The likelihood of recurrence.
- The consequences.

Root cause analysis focuses on the system and not the individual worker and assumes that the adverse event causing harm to a patient is a system failure. The VA system uses a severity assessment code to help triage the reported incidents to ensure those indicating the most serious risk to the organization are dealt with first.

The root cause analysis model is a tested model

that focuses on prevention not blame or punishment. Other processes are used when people are required to be accountable for their actions. The focus is on systems level vulnerabilities and not individual performance. The model examines multiple factors such as communication, training, fatigue, scheduling, rostering, environment, equipment, rules, policies and barriers.

24

The defining characteristics of root cause analysis include: [10]

- review by an interprofessional team knowledgeable about the processes involved in the event;
- analysis of systems and processes rather than individual performance;
- deep analysis using “what” and “why” probes until all aspects of the process are reviewed and contributing factors are considered;
- identification of potential improvements that could be made in systems or processes to improve performance and reduce the likelihood of such adverse events or close calls in the future.

Practise strategies to reduce errors

25

Medical students can immediately start practising error reduction behaviours by looking after their own health. Being aware when they are tired, becoming familiar with the environment they work in, and being prepared for the usual knowing that unusual things can happen. We know that it is impossible for any one individual to know everything so it is important that medical students get used to asking questions if they do not know something relevant and important to the patients.

Some personal error reduction strategies for students are to

- know yourself (eat well, sleep well and look after yourself);
- know your environment;

- know your task(s);
- preparation and planning (What if...);
- build checks into the routine;
- ask if you do not know.

Medical students should assume that errors will occur. This will be a change for many because in some cultures there is still the belief that only bad or incompetent doctors make mistakes. Students should

- assume that errors will be made and that they should prepare for them;
- identify those circumstances most likely to lead to errors;
- have contingencies in place to cope with problems, interruptions and distractions;
- always mentally rehearse complex procedures or if it is the first time you are doing an activity involving a patient.

26

Summary

Medical error is a complex issue, but error itself is an inevitable part of the human condition.

27

These tips are known to limit the potential errors caused by humans (see also topic 2 on human factors engineering). [11]

- avoid reliance on memory;
- simplify processes;
- standardize common processes and procedures;
- routinely use checklists;
- decrease the reliance on vigilance.

Learning from error can occur at both an individual and organizational level through incident reporting and analysis. Barriers to learning from error include a blame culture that institutes a person approach to investigation and the phenomenon of hindsight bias. A broadly based system approach is required for organizational learning and the possibility of system change to occur.

Root cause analysis is a highly structured system approach to incident analysis that is generally reserved for the most serious patient harm episodes.

CASE STUDIES

Vincristine administration alert

The following alert No. 115 was published by WHO on 18 July 2007. It relates to the administration of the drug vincristine.

Hong Kong, 7 July 2007

A 21-year-old female has died after being administered vincristine accidentally via a spinal route in error. An inquiry is under way. Vincristine (and other vinca alkaloids) should only be given intravenously via a minibag. Vincristine, a widely used chemotherapeutic agent, should only be administered intravenously, and never by any other route. Many patients receiving IV vincristine also receive other medication via a spinal route as part of their treatment protocol. This has led to errors where vincristine has been administered via a spinal route. Since 1968, this error has been reported in a variety of international settings 55 times. There have been repeated warnings over time and extensive labelling requirements and standards. However, errors related to the accidental administration of vincristine via a spinal route continue to occur.

Other recent deaths and near misses:

United States, November 2005

A 21-year-old male was being treated for non-Hodgkin's lymphoma. A syringe containing vincristine for another patient had been accidentally delivered to the patient's bedside. A physician administered vincristine via a spinal route, believing it was a different medication. The error was not recognized and the patient died three days later.

Spain, October 2005

A 58-year-old female was being treated for non-Hodgkin's lymphoma. Vincristine was prepared in a 20 ml syringe and delivered in a package containing two other drugs, including methotrexate. Route of administration was not indicated on the solutions. The intrathecal treatment was administered at noon. The haematologist was particularly busy and requested help from another doctor who had not recently participated in intrathecal procedures. The medication was delivered in the patient's room. The nurse who assists was not familiar with the intrathecal procedures. The 20 ml syringe with vincristine was passed to the doctor who started to inject it. After administering approximately 2 ml, he noticed the size of the syringe and ceased administration realizing the error. The patient died approximately 100 days later.

Australia, 2004

A 28-year-old male with Burkitt's lymphoma was receiving methotrexate via a spinal route. The doctor documented that "vincristine and methotrexate [were] given intrathecally as requested". The warning label on the vincristine was incomplete, and in small print, being read in a darkened room. The error was not recognized until five days later, after paralysis of the lower limbs had occurred. The patient died after 28 days.

Reference

World Health Organization, SM/MC/IEA.115 (http://www.who.int/patientsafety/highlights/PS_alert_115_vincristine.pdf).

A nurse speaks up to avoid further error preventing the patient from an adverse outcome

This case illustrates the importance of speaking up if there are concerns for the safety of patients.

As the preoperative team briefing (team discussion before surgical procedure) was coming to an end, a nurse spoke up and reported that "the patient has a left contact lens in his eye". The anaesthetist asked whether it was permanent and the nurse verified that it was disposable. The anaesthetist asked the patient why the contact was being worn, but the patient was sedated and not very coherent when he attempted to respond. The nurse explained that the patient was unable to see without the contact. The anaesthetist explained to the operating room team that the patient could not have the contact lens with anaesthetic and that the patient should not have been sedated with it. One of the team members asked the anaesthetist if he wanted the contact lens to be taken out and the anaesthetist replied, "Well, he cannot have anaesthesia with it". The surgical resident helped the patient remove the contact lens from his eye. The patient asked for something to put it in so saline was located and the contact lens was stored in a small container of saline.

Case from the WHO Patient Safety Curriculum Guide for Medical Schools working group. Supplied by Lorelei Lingard, University of Toronto, Toronto, Canada.

HOW TO TEACH THIS TOPIC

Teaching strategies/formats



Simulation exercises:

- different scenarios could be developed about adverse events and the need to report and analyse errors;
- practical exercises that show how errors are avoided;
- rehearse strategies for managing errors.



An interactive/didactic lecture

Use the accompanying slides as a guide, covering the whole topic. The slides can be PowerPoint or converted to overhead slides for a projector. Start the session with a case study from the Case Study Bank or get the students to identify some errors they have recently made.



A small group discussion session

- Small group discussion about common errors made in the workplace.
- One or more students could be presented with the topic and be asked to lead a discussion about the areas covered in the topic. The students could follow the headings as outlined above and present the material. The tutor facilitating this session should also be familiar with the content so information can be added about the local health system and clinical environment.

Teaching activities

Different methods for generating discussion about the areas in this topic include:

- asking the students to keep a journal in which they write about an observed error or near miss (what happened, categorize the type of error, make recommendations as to what might be done to prevent a similar thing happening again);
- selecting a case study from above that sets the scene for a discussion about the most common errors in health care;
- using examples from the media (newspapers and television) that have been published/broadcasted;
- using de-identified case examples from your own hospitals and clinics;
- using a case study get the students to brainstorm the possible errors and the associated factors;

- getting examples of lessons about error and system failure from other industries;
- inviting a staff member from another discipline such as engineering or psychology to talk error causation theory, cultures of safety and role of error reporting in safety;
- inviting a senior respected clinician to talk about their errors;
- inviting a quality and safety officer to talk about system in place to minimize errors and manage adverse events;
- discussing the difference between system failures, violations and errors;
- using a case study to analyse the different avenues for managing an adverse event;
- participating or be an observer in a root cause analysis.

Activities for students in their clinical placements:

- attend a root cause analysis investigation;
- ask students to find out if the hospital conducts mortality and morbidity meetings or other peer review forums where adverse events are reviewed;
- require the students to talk among themselves errors they have observed in the hospital using a non-blame approach;
- ask the students to select a ward or clinic where they are placed and inquire about the main types of errors in their area and the steps they take to minimize them and learn from them.

TOOLS AND RESOURCES

Medical error and patient safety

(<http://www.ahrq.gov/qual/errorsix.htm>, accessed May 2008).

A vast array of resources on medical error and related topics from the Agency for Healthcare Research and Quality
New York Medical College. *Medical errors and*

patient safety: a curriculum guide for teaching medical students and family practice residents, (<http://www.nymc.edu/fammed/medicalerrors.pdf>, accessed May 2008).

HOW TO ASSESS THIS TOPIC

Assessment strategies/formats

A range of assessment strategies are suitable for this topic including MCQs, essays, SBA, case-based discussion and self-assessment. Having a student, or a group of students, lead an adverse event investigation or even a “mock” root cause analysis is a highly engaging way to elicit understanding.

HOW TO EVALUATE THIS TOPIC

Evaluation is important to review how a teaching session went and how improvements can be made.

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Slides for topic 5: Understanding and learning from errors

Didactic lectures are not usually the best way to teach students about patient safety. If a lecture is being considered, it is a good idea to plan for student interaction and discussion during the lecture. Using a case study is one way to generate group discussion. Another way is to ask the students questions about different aspects of health care that will bring out the issues contained in this topic such as the blame culture, nature of error and how errors are managed in other industries.

The slides for topic 5 are designed to assist the teacher deliver the content of this topic. The slides can be changed to fit the local environment and culture. Teachers do not have to use all of the slides and it is best to tailor the slides to the areas being covered in the teaching session.

Topic 6: Understanding and managing clinical risk

Why clinical risk is relevant to patient safety

1 2

Risk management is routine in most industries and has traditionally been associated with limiting litigation costs. Many corporations try to avoid financial loss, fraud or a failure to meet production expectations by implementing strategies to avoid such events. Hospitals and health organizations use a variety of methods for managing risks. The success of a risk management programme, however, depends on the creating and maintaining safe systems of care, designed to reduce adverse events and improve human performance [1]. Many hospitals have well-established systems in place for reporting patient falls, medication errors, retained swabs and misidentification of patients. Nevertheless, they are only beginning to focus on all aspects of clinical care to see opportunities for reducing risks to patients.

A medical student, along with everyone else who works in a hospital or clinic has a responsibility to take the correct action when they see an unsafe situation or environment. Taking steps to ensure a slippery floor is dry and preventing a patient from falling over is as important as ensuring that the medication a patient is taking is the correct one. In the event of a patient falling on a slippery floor or receiving the wrong medication, it is equally important for a student to report these events so that steps can be taken to avoid future incidents.

Effective risk management involves every level of the health service, so it is essential that all health-care workers understand the objectives and relevance of the risk management strategies and their relevance to their own workplace. Unfortunately, even though a hospital may have a policy of reporting incidents such as medication errors, the actual reporting of them is often sporadic. Students can begin to practise reporting by talking with the health-care team about

medication errors and the strategies in place to manage and avoid them.

Research shows that nurses are more likely to report an incident than other health professionals, certainly more so than doctors. This may be because the blame culture in medicine is a strong deterrent to reporting. Today, most risk management programmes aim to improve safety and quality in addition to minimizing the risk of litigation and other losses (staff morale, loss of staff, diminished reputation), but the degree of their success depends on many factors.

3

Clinical risk management specifically is concerned with improving the quality and safety of health-care services by identifying the circumstances and opportunities that put patients at risk of harm and then acting to prevent or control those risks. The following simple four-step process is commonly used to manage clinical risks:

1. identify the risk;
2. assess the frequency and severity of the risk;
3. reduce or eliminate the risk;
4. assess the costs saved by reducing the risk or the costs if the risk eventuates.

Medical students, along with all other health professionals will be mainly concerned about the risk to patients. The first topic in this Curriculum Guide outlines the extent of the harm done by health care. It is against this backdrop that organizations are concerned about managing clinical risks. Clinical risk management allows identification potential errors. Health care itself is inherently risky and although it would be impossible to eradicate all harm, there are many activities and actions that can be introduced that will minimize opportunities for errors. Clinical risk is relevant to medical students because it recognizes that clinical care and treatment are risky and incidents may occur during clinical care and treatment. Students (as well as all other

health-care professionals) must actively weigh up the anticipated risks and the benefits of each clinical situation and only then take action. Students should seek out information about past risks and actively participate in efforts to prevent them recurring. For example, compliance with a handwashing protocol so that the spread of infection is minimized. In this sense students are acting proactively to avoid problems and not merely reacting to a current problem.

Keywords

Clinical risk, reporting near misses, reporting errors, risk assessment, incident, incident monitoring.

Learning objective

Know how to apply risk management principles by identifying, assessing and reporting hazards and potential risks in the workplace. 4

Learning outcomes: knowledge and performance

What students need to know (knowledge requirements):

- the activities for gathering information about risk;
- fitness-to-practice requirements;
- personal accountability for managing clinical risk. 5

What students need to do (performance requirements):

- know how to report known risks or hazards in the workplace;
- keep accurate and complete medical records;
- know when and how to ask for help from a supervisor, senior clinician and other health-care professionals;
- participate in meetings that discuss risk management and patient safety; 6

- respond appropriately to patients and families after an adverse event;
- respond appropriately to complaints.

WHAT STUDENTS NEED TO KNOW (KNOWLEDGE REQUIREMENTS)

What are the activities for gathering information about risk? 7

Medical students working in hospitals may not be immediately aware of a risk management programme in their hospital or clinic. Nevertheless, most countries today will have a range of mechanisms to measure the harm to patients and staff as well as avoid known problems. Some countries have well-developed state and national data sets of incidents. In Australia, the Advanced Incident Management System is a comprehensive approach to reporting incidents and analysing the various types of incidents. The Veterans Affairs Administration of the US Department of Veterans Affairs has established a National Center for Patient Safety that uses a structured approach called root cause analysis to evaluate, analyse and treat the problems. See topics 5 and 7 for more information about the root cause analysis methodology. T5 T7

The principle underpinning root cause analysis is that the actual (root) cause of a particular problem is rarely (immediately) recognizable at the time of the mistake or incident. A superficial and biased assessment of any problem usually does not fix the problem and more incidents will occur involving others in similar situations. An essential part of any root cause analysis is the implementation of the findings of the root cause analysis process. Many hospitals and organizations fail to complete the process because either the recommendations involve resources that are not available or there is no commitment by the senior hospital management to

carry through the recommendations. Some health-care organizations that mandate reporting of incidents can become so overloaded with reported incidents with the consequence that many remain unanalysed due to inadequate resources. Even the introduction of a triage system to distinguish serious incidents from others has not resolved this dilemma in some systems. Many systems now have borrowed from the Veteran Administration and introduced a severity assessment code to help identify those incidents that indicate the most serious risk to the organization.

Below are some common activities used to manage clinical risk.

Incident monitoring

Incident reporting has existed for decades. Many countries now have national databases of adverse events pertaining to different specialties such as surgery, anaesthesia, maternal and child health. WHO defines an incident as an event or circumstance that could have or did lead to unintended and/or unnecessary harm to a person and/or a complaint, loss or damage. The main benefit of incident reporting lies in the information about prevention rather than the frequency of the incident; other quantitative methods are required for that.

Facilitated incident monitoring refers to the mechanisms for identifying, processing, analysing and reporting incidents with a view to preventing their recurrence [2]. The key to an effective reporting system is to have staff routinely reporting incidents or near misses. However, unless staff trust that the organization will use the information for improvement and not to blame individuals, they will not report. Trust includes the belief that the organization will also act upon the information. If a medical student reported an incident to a senior nurse or doctor who dismissed their effort and told them not to bother, then the student is less likely to

make a report again. Even when this happens, students should be encouraged by faculty staff to continue to report. One day the student will be a senior doctor and their actions will be highly influential on younger doctors and students. Facilitated monitoring is designed to identify a greater proportion of incidents and to produce reports that are aimed at improving care. This type of monitoring is a continuous activity of the clinical team involving the following actions:

- discussion about incidents is a standing item in the weekly clinical meetings;
- there is a weekly review of areas where errors are known to occur;
- a detailed discussion about the facts of an incident and follow-up action required is done with the team;
- the discussion is always educational rather than attributing blame;
- identifies the system issues so they can be addressed and other staff made aware of the potential difficulties.

As well as reporting actual incidents, some organizations encourage the reporting of “near misses” because of the value they bring about new problems and the factors that contribute to them, and how they may be prevented, before serious harm is done to a patient. A near miss is an incident that did not cause harm. Some people call “near misses” “near hits” because the actions may have caused an adverse event, but corrective action was taken just in time or the patient had no adverse reaction to the incorrect treatment. Talking about “near misses” may be easier in some environments where there is a strong blame culture because no one will be able to be blamed because there was no adverse outcome to the patient. See Table 14 for more analysis of incident monitoring.

Sentinel events

A sentinel event is an unexpected occurrence involving death or serious physical or

Table 14. Types of issues identified by incident monitoring

Type of incident	% of reports ^a
Falls	29
Injuries other than falls (e.g. burns, pressure injuries, physical assault, self-harm)	13
Medication errors (e.g. omission, overdose, underdose, wrong route, wrong medication)	12
Clinical process problems (e.g. wrong diagnosis, inappropriate treatment, poor care)	10
Equipment problems (e.g. unavailable, inappropriate, poor design, misuse, failure, malfunction)	8
Documentation problems (e.g. inadequate, incorrect, not completed, out of date, unclear)	8
Hazardous environment (e.g. contamination, inadequate cleaning or sterilization)	7
Inadequate resources (e.g. staff absent, unavailable, inexperienced, poor orientation)	5
Logistic problems (e.g. problems with admission, treatment, transport, response to emergency)	4
Administrative problems (e.g. inadequate supervision, lack of resource, poor management decisions)	2
Infusion problems (e.g. omission, wrong rate)	1
Infrastructure problems (e.g. power failure, insufficient beds)	1
Nutrition problems (e.g. fed when fasting, wrong food, food contaminated, problems when ordering)	1
Colloid or blood product problems (e.g. omission, underdose, overdose, storage problems)	1
Oxygen problems (e.g. omission, overdose, underdose, premature cessation, failure of supply)	1

^a More than one type of incident may be assigned to a report.

Source: Runciman B et al. [3]

psychological injury to a patient and includes any process variation for which a recurrence would carry a significant chance of serious adverse outcome [4]. The current trend in many countries in analysing adverse events is to rank the seriousness of the event. A sentinel event is reserved for the most serious ones.

Many hospitals and clinics have mandated the reporting of these types of events or events because of the risk of a repeat. These are often called “never events” that *should never be allowed to happen* because of the potential for death or significant harm. Catastrophic event is another term used and these make up half of all the sentinel events reported in the United States and over two thirds of those reported in Australia [3].

The role of complaints in improving care 9

A complaint is defined as an expression of dissatisfaction with their health care by a patient or a family member. Because medical students will be treating patients under supervision they may be named in a complaint from a patient or family member. Students may feel exposed when this happens and may feel that they will be blamed for their actions. Students and all health professionals may feel embarrassed, remorseful, angry or defensive if they are the subject of a complaint. While complaints from patients or their families may be uncomfortable to deal with, they are a very good opportunity for improving clinical practice [5] and restoring a trusting relationship between the patient, their family and the health-care team. Complaints often highlight problems that need addressing such

as the common problems of poor communication or suboptimal clinical decision-making. Communication problems are common causes of complaints as are problems with treatment and diagnosis. Students are learning about clinical decision-making and patient management and are seeing just how complex these tasks can be. So it is not surprising that miscommunication or suboptimal care may sometimes occur. Patient complaints help to identify areas in the processes of care that could be improved. The information from complaints can also be used to educate and inform health professionals about problem areas.

Other benefits of complaints include that they: [5]

- assist to maintain standards;
- reduce the frequency of litigation;
- help maintain trust in the profession;
- encourage self-assessment;
- protect the public.

Students should be aware that most doctors will receive complaints in their careers and that it is not an indication of incompetence—even the most conscientious and skilful clinicians can and do make mistakes. Medical error is a subset of human error; all humans make mistakes. Legal and ethical obligations are reinforced when a complaint is in the hand.

If a student is involved in a complaint, or if they receive one when they are doctors, they should be open to discussing the complaint with the patient or family. It is a good idea to have a more senior person present during these discussions. If a student is required to provide a written statement about their actions, it is important that the statement is factual and relates directly to the student's or doctor's involvement. It is important to always check with a supervisor if a written complaint is received and a statement required. The hospital or clinic will most likely have in place a policy for managing complaints.

Complaints and concerns where the individual is responsible

From a patient's perspective individual patients should be able to have their concerns examined to see if there has been a departure from professional standards. After examination or investigation it may be that system issues are at the heart of the problem but the treating doctor or health-care team may also have been at fault—for example by cutting corners and breaching accepted protocols. The standard of care may be low resulting in suboptimal care. Guidelines may not have been followed or hospital rules broken.

An example is failure of a staff member to wash their hands, resulting in transmission of infection from one patient to another. While the initial approach to the investigation should adopt a systems-based view, individuals are also required to meet their professional responsibilities—it may be that the staff member was indeed directly at fault through failing to adhere to accepted standards of care. Reason [6] defined a violation as a deviation from safe operating procedures, standards or rules.

Coronial Investigations

Most countries have some system for establishing cause of death. Specifically appointed people, often called coroners, are responsible for investigating deaths in situations where the cause of death is uncertain, or thought to be due to unethical or illegal activity. Coroners often have broader powers than a court of law and after reporting the facts will make recommendations for addressing any system-wide problems.

Fitness-to-practise requirements

Medical students and all health professionals are accountable for their actions and conduct in the clinical environment. They are responsible for their actions according to the circumstances in which they find themselves. Related to

10

accountability is the concept of “fitness to practise”. Why is fitness to practise an important component of patient safety?

Of the many factors underpinning adverse events one factor relates to the competence of clinicians. Many mistakes leading to adverse events are associated with the fitness of a doctor to practise. Are they competent? Are they practising beyond their level of experience and skill? Are they unwell, suffering from a stress or a mental illness? Most countries will have a system for registering doctors, dealing with complaints and maintaining standards. It is important that medical students understand why it is important to be vigilant about their own fitness and that of their colleagues. Medicine as a profession places duties and obligation upon doctors with the aim of keeping patients safe.

Selecting the right students to study medicine is the first step in making sure that the people who are choosing medicine as a career have the professional attributes for safe and ethical practice. Many medical schools now have OSCE-type (Objective Structured Clinical Examination) processes to help identify those students who in addition to their examination results also have the attitudes and behaviours best suited to medicine and patient safety. Doing medicine because of family expectations or a desire for high status or money is often insufficient to sustain a career in medicine. Attributes such as compassion, empathy, a vocational aspiration to do good and to provide benefits to society are the sustaining qualities.

The duties of a doctor (and medical student) extend to reporting a peer or colleague who is unsafe because of either incompetence or unprofessional or unethical behaviour. Some countries require mandatory reporting of practitioners if they are unfit, while others rely on individuals to use their conscience in this regard.

Hospitals and health-care organizations also have responsibilities to ensure that only competent and qualified doctors treat patients. They are required to check that a doctor has the right qualifications and experience to practise in the area they nominate. The processes for doing this follow.

Credentialling

Credentialling is the process of assessing and conferring approval on a person’s suitability to provide specific consumer/patient care and treatment services, within defined limits, based on an individual’s licence, education, training, experience and competence (Australian Council on Healthcare Standards). Many hospitals have credentialling processes in place to check whether a doctor has the required skills and knowledge to undertake specific procedures or treatments. Hospitals will restrict the type of procedures offered at a hospital if there are no qualified personnel or if the resources are not available or appropriate for the particular condition or treatment.

Accreditation

Accreditation is a formal process to ensure delivery of safe, high-quality health care based on standards and processes devised and developed by health-care professionals for health-care services. It can also refer to public recognition of achievement by a health-care organization of requirements of national health care standards.

Registration

Most countries require medical practitioners to be registered with a government authority or under a government instrument. The principal purpose of a registration authority is to protect the health and safety of the public by providing mechanisms designed to ensure that medical practitioners are fit to practise medicine. It achieves this by ensuring that only properly trained doctors are registered, and that registered doctors maintain proper standards of conduct and competence.

Personal accountability for managing risk

11

More senior medical students will begin to establish clear roles and responsibilities as members of health-care teams when they spend more time on the wards, clinics and in the hospitals. Close to the completion of their medical training they will be required to demonstrate competence in a number of basic clinical tasks. The following activities are not exhaustive or indeed prescriptive. They are offered to give some idea of the competencies students require when they complete their medical degrees and start working in a hospital or clinical environment.

- Know how to organize a request for consultation from another doctor or health-care team. These skills include using correct identification procedures, accurate summary of the patient's background and the reason for admission, current clinical problem and the results of any investigations. Only include relevant and necessary information and write legibly.
- Know how to make a telephone call to a primary care doctor. The student should make sure they are supervised during this activity. Practising providing accurate information about the patient, correctly pronouncing medical terminology, using techniques to ensure the person on the telephone has understood what the student was saying, seeking information about concerns and writing a summary of the telephone conversation for the medical record.
- Know how to write a prescription accurately and following the hospital policy. It is a good idea to routinely check with pharmacists who may be working in the hospital.
- Know how to write a letter when a patient's care is being transferred to another health provider or team. The letter should contain

the relevant patient identifying information, dates of admission and discharge, and the name of the doctors responsible for the care of the patient while they were in hospital, accurate summary of the patient's stay in hospital, the final diagnosis, key investigations, reason for admission, and the status of the patient's clinical problems, describe the therapeutic interventions undertaken, the outcome, follow-up arrangements and outstanding investigations. An accurate and complete list of medications including dose, route, and planned duration of therapy and be completely legible.

The role of fatigue and fitness to practise

There is strong scientific evidence linking fatigue and performance. Students should be aware that when they are fatigued they will be less alert, and not be able to perform as normal in a variety of psychomotor tasks because of poor quality sleep and inadequate time for them to recover.

- Studies in the Ireland and the United Kingdom also show that fatigue can impact on the well-being of residents affecting their mood (depression, anxiety, anger and confusion) [7];
- Recent controlled studies have confirmed the findings that sleep deprivation can negatively impact on clinical performance [8];
- Fatigue has also been linked to increased risk of medical errors [9] and motor vehicle accidents;
- A 2004 study by Landrigan et al. [10] was one of the first to measure the effects of sleep deprivation on medical errors. They found that interns working in the medical intensive unit and coronary care unit of Brigham and Women's Hospital (Boston, United States) made substantially more serious mistakes when they worked frequent shifts of 24 hours or more than when they worked shorter

shifts. Other studies show that sleep deprivation can have similar symptoms to alcohol intoxication [11].

Stress and mental health problems

Students are also prone to stress caused by examinations, part-time work, family and workplace concerns.

- Strong evidence suggests physicians are prone to mental health problems [12], particularly depression, in their first postgraduate years as well as in later years. Students also suffer from stress and associated health problems that they carry with them when they start practising as doctors;
- While rates of depression and mental health problems among doctors are higher than those experienced by the general population, the literature shows that when interns and residents are supported by fellow house officers and senior clinicians, and are members of well-functioning teams, they are less likely to feel isolated and suffer stress;
- Performance is also affected by stress;
- There is strong evidence indicating that inadequate sleep contributes to stress and depression, rather than the number of hours worked;
- Other stressors identified in the literature include financial status, educational debt and term allocation and emotional pressures caused by demands from patients, time pressures and interference with social life.

Work environment and organization

Hospitals and clinics can be very stressful places to the newcomer. Unfamiliar work practices and rosters can make it very difficult in the early phase of a new workplace. In addition, long hours cause fatigue.

There are well-known situations such as change-overs of shift, shift work, nights, week ends and

overtime that have been noted to have an association with increased errors. The factors underpinning these errors can range from lack of supervision to tiredness. Students should be extra vigilant during these times.

Supervision

Good supervision is essential for every student and the quality of the supervision will determine to a large extent how successfully a student integrates and adjusts to the hospital or clinical environment.

- The failure of senior clinicians to supervise or arrange adequate supervision for medical students and interns and residents makes them more vulnerable to making mistakes either by omission (failing to do something) or commission (doing the wrong thing).
- Students should always request supervision if it is the first time they are attempting a skill or procedure on a patient. They should also advise the patient that they are students and request their permission to proceed to treat them or perform the procedure.
- Poor interpersonal relationships between students, other health-care professionals, interns, residents and supervisors have also been identified as factors in errors. If a student is having a problem with a supervisor, they should seek help from another faculty member who may be able to mediate or help the student with techniques to improve the relationship.
- The literature also shows that students who have problems with inadequate skills acquisition also have poor supervision. Many health professionals have learnt a procedure while unsupervised and were judged by supervisors to have poor technique and inadequate mastering of procedures. Students should never perform a procedure on a patient without sufficient preparation and supervision.

Communication Topics



Communicating accurate information in a timely way between the multiple health workers (consultants, registrars, nurses, pharmacists, radiologists, medical records and laboratory personnel) is not easy, nor are there standard ways for communicating within hospitals. The role of good communication in the provision of quality health care and the role poor communication plays in substandard care are both well documented. How successfully patients are treated will often depend on informal communications among staff and their understanding of the workplace [13]. Treatment errors caused by miscommunication, absent or inadequate communication are well known and occur daily in hospitals. The quality of the communication between patients and other health professionals strongly correlates with treatment outcomes. Checklists, protocols and “care pathways” are effective for communicating patient care orders.

WHAT STUDENTS NEED TO DO (PERFORMANCE REQUIREMENTS)

12

Know how to report known risks or hazards in the workplace

Students should seek information on the incident reporting system used in the hospital where they are practising or placed. There will usually be a specific method for reporting—either an electronic or paper form. Students should be familiar with the system in place and seek information about how to report an incident.

Keep accurate and complete medical records

A medical record is a term used for a document that stores the different kind and types of information about a patient. Students should be aware that good quality medical records are essential to the medical care and treatment of patients. Medical records will be subject to a number of government and hospital requirements in relation to who can have access to them, who can write in them and where they are stored and for how long.

Medical students have an ethical and legal obligation to accurately record their observations and findings to ensure good patient care. When writing in the records, students should

- provide sufficient information to identify the patient to whom the record relates so that other members of the health-care team can continue caring for the patient;
- keep note down any information relevant to the patient’s diagnosis or treatment;
- notes about information or advice given to the patient by the student.

Know when and how to ask for help from a supervisor, senior clinician or other health professional

Many medical students fear that if they admit to not knowing something that their teachers will think less of them. It is important for students to recognize the limitations caused by their lack of knowledge and the importance of seeking help or asking for information. Students should be clear about who they report to in the hospital or in the clinic. This person will be able to assist them if they get into a situation beyond their current knowledge and skills. It is essential that students ask for help even if they feel uncomfortable about doing so. Supervisors and senior clinicians do not expect medical students or junior doctors to have the depth of learning required to independently treat

patients. They expect students to ask for help. Asking for help in unfamiliar environments can be a bit daunting for students, nonetheless they should still ask a senior health professional. Students need to be clear about who their supervisor is and when they are available. It is very difficult having a supervisor who is rarely in the hospital. If this is the case the student should seek out another appropriate person who is on the wards or in the clinic. This can be discussed with the supervisor so they are aware of the local arrangement.

Participate in meetings that discuss risk management and patient safety

It will not be obvious at first which risk management programmes exist in a particular hospital. Students can request from senior hospital management the risk management programmes in place and whether it is possible to attend a meeting to see how the system works to protect patients.

Respond appropriately to patients and families after an adverse event

Students will not be expected to accept responsibility for disclosing adverse events to patients or their families. If they are asked to do this they should immediately seek assistance from a faculty member or senior supervisor. Many places are now introducing open disclosure guidelines. It is vital that any open disclosure process is not rushed, is transparent and involves taking steps to make sure the same mistake does not happen again.

Respond appropriately to complaints

All students who are involved in a complaint should write a complete and factual statement about what happened. They should be honest about their role or actions but it is important to also minimize subjective or emotional statements.

Summary

Doctors are responsible for the clinical outcomes of their patients. One way for doctors to manage this is to identify areas prone to errors and adverse events. The proactive intervention of a systems approach to minimizing the opportunities for errors can prevent adverse events. Individuals can also maintain a safe clinical working environment by looking after their own health and responding appropriately to concerns from patients and colleagues.

HOW TO TEACH THIS TOPIC

Teaching strategies/formats



An interactive/didactic lecture

Use the accompanying slides as a guide, covering the whole topic. The slides can be PowerPoint or converted to overhead slides for a projector. Start the session with the case study and get the students to identify some of the issues presented in the story.

Panel discussions

Invite a panel of respected clinicians to give a summary of their efforts to improve patient safety. Students could also have a list of questions about adverse event prevention and management and have time scheduled for their questions. Experts on risk management outside health care may also be invited to talk generally about the principles.



A small group discussion session

The class can be divided up into small groups and three students in each group be asked to lead a discussion about one of the types of incidents described in Table 14. Another student can focus on the tools and techniques available to minimize opportunities for errors and another could look at the role of mortality and morbidity meetings.

The tutor facilitating this session should also be familiar with the content so information can be added about the local health system and clinical environment.



Simulation exercises

Different scenarios could be developed about adverse events and the techniques for minimizing the opportunities for errors such as

- practising the techniques of briefings, debriefings, and assertiveness to improve communication;
- role play using a “person approach” and then a “system approach” in a mortality and morbidity meetings;
- role play a situation in theatre where a medical student notices something is wrong and needs to speak up.

Teaching activities

Administration, theatre and ward activities:

- students can observe a risk management meeting;
- students could meet with the people who manage complaints for the hospital or clinic—part of the exercise would be to ask the hospital policy on complaints and what usually happens if a complaint is made;
- students could take part in an open disclosure process.

After these activities students should be asked to meet in pairs or small groups and discuss with a tutor or clinician what they observed and whether the features or techniques being observed were present or absent, and whether they were effective.

CASE STUDIES

Inadequacy in orthopaedic surgeon’s practice management systems

Accurate and legible records are essential for

maintaining continuity of care.

Brian was being treated by a new specialist and needed his records from the orthopaedic surgeon who operated on his knee two years earlier. When the records finally arrived, Brian’s new doctor informed him that they were not “up to scratch”.

The records were poorly documented with no meaningful notes concerning the consent discussion for Brian’s operation. There were also gaps in the information recorded in the operation report and there was no documentation of the orthopaedic surgeon’s verbal advice about the risks and complications of the operation. Brian was dismayed to discover that the surgeon had not followed up on a missed postoperative review.

Reference

Case adapted from Payne S. case study: managing risk in practice. United Journal, 2003, Spring, p. 19.

Acknowledgment of medical error

This case shows the value of open disclosure.

Frank is a resident of an aged care facility. One night, a nurse mistakenly gave Frank insulin, even though he does not have diabetes. The nurse immediately recognised his error and brought it to the attention of the other staff, who in turn informed Frank and his family. The facility took immediate action to help Frank and arranged his transfer to a hospital where he was admitted and observed before being returned to the aged care facility. The nurse was commended for fully and immediately disclosing the incorrect administration of the insulin. Following this incident, the nurse undertook further training in medications to minimise the possibility of a similar error occurring.

Reference

Open Disclosure. Case Studies—Volume 1. Sydney: Health Care Complaints Commission, 2003: 16–18.

General practice rooms not up to standard

This case shows the importance of complaints to improving health care.

When Denise visited her local medical practice, she was shocked to see that the practice was not as hygienic as she expected. It was so bad that she complained to the New South Wales Department of Health. A health inspector noted that Dettol was stored in a drink container, drugs were stored beyond their use-by date, there was no adrenaline in the surgery to treat a heart attack, patients at times had unsupervised access to the doctor's medical bag containing injectable narcotics and a prescription pad, paper sheets on the examination table were not changed between patients and the doctor did not wash his hands following examinations. There were also no sinks in the consulting rooms.

The Health Care Complaints Commission recommended counselling by the New South Wales Medical Board and an on-site visit to advise the staff on Department of Health guidelines on infection control and make sure the appropriate steps had been taken to protect public health. Denise was glad to learn that the centre made improvements as a result of her complaint.

Reference

Review of investigation outcomes. Health Care Complaints Commission, New South Wales. *Annual Report 1998–1999*, p. 39–40.

Inadequate complaints management

This case shows the importance of timely attention to complaints.

Alexandra had been seeing a psychologist who was practising in a private hospital. On both her first and second consultations, the psychologist breached patient confidentiality by discussing personal details about his other patients. Alexandra decided she should raise her concerns with someone at the hospital. She attended one meeting with hospital representatives about a number of concerns she had with the hospital, including those with the psychologist. Many months passed with no written response from the hospital detailing the actions they had promised to take. With the help of the Patient Support Office, Alexandra attended a meeting with an official of the office and the chief executive officer and deputy chief executive officer of the hospital. The hospital made an apology to Alexandra and a commitment to ongoing staff training in complaints management. They also encouraged Alexandra to lodge a formal complaint with the Psychologists Registration Board regarding the psychologist's behaviour.

Reference

Patient Support Service, Health Care Complaints Commission, New South Wales. *Annual report 1999–2000*, p. 37–46.

An impaired nurse

This case shows how health professionals need to maintain their fitness to practise.

During Alan's operation, a nurse knowingly replaced the painkiller fentanyl, which was ordered to treat Alan, with water. This nurse placed Alan in physical jeopardy because of the nurse's desperate need to obtain an opiate drug to satisfy his drug addiction.

This was not the first time that the nurse had stolen Schedule 8 drugs for the purposes of self-administering them. A number of complaints had been made about the nurse while working at a

private hospital including professional misconduct, impairment for drug addiction, lack of good character and that which rendered the nurse unfit to practice.

Reference

Swain D. The difficulties and dangers of drug prescribing by health practitioners. *Health Investigator*, 1998, 1(3):14–18.

A junior doctor with bipolar disorder

The case shows how important it is to refer colleagues who are unwell and to protect patients from clinicians who behave unethically.

Irene was upset because her new doctor verbally abused her during the consultation at the hospital clinic. She asked for another doctor and made a complaint to the hospital administration. Irene's complaint was just one of a number of complaints against the doctor including others concerning a refusal to treat a patient, making sexual advances to staff and patients and neglecting his own diabetes condition. He also refused to comply with psychiatric treatment suggestions. One year earlier, the doctor had been investigated for prescribing errors and sexual advances to patients. At that time, the doctor was reviewed and diagnosed with a long-standing bipolar (manic depressive) disorder. He had made undertakings in relation to treatment of his mental illness, which he was obviously not observing now.

Reference

Case studies—investigations. Health Care Complaints Commission, New South Wales. *Annual Report 1995–1996*, p. 35.

TOOLS AND RESOURCES

Better practice guidelines on complaints management for health care services. Australian

Commission for Safety and Quality, 2006. [http://www.health.gov.au/internet/safety/publishing.nsf/Content/2D41579F246E93E3CA2571C5002358A0/\\$File/guidecomplnts.pdf](http://www.health.gov.au/internet/safety/publishing.nsf/Content/2D41579F246E93E3CA2571C5002358A0/$File/guidecomplnts.pdf).

Complaint or concern about a clinician - principles for action. Department of Health, New South Wales, 2006 (http://www.health.nsw.gov.au/policies/pd/2006/pdf/PD2006_007.pdf).

HOW TO ASSESS THIS TOPIC

A range of assessment methods are suitable for this topic including observational reports, reflective statements about surgical errors, essays, MCQ paper, SBA, case-based discussion and self-assessment. Students can be encouraged to develop a portfolio approach to patient safety learning. The benefit of a portfolio approach is that at the end of the student's medical training they will have a collection of all their patient safety activities. Students will be able to use this to assist job applications and their future careers.

The assessment of knowledge about clinical risk management is assessable using any of the following methods

- portfolio;
- case-based discussion;
- written observations about a risk management activity, such as an pen disclosure process or incident monitoring system;
- reflective statements (in particular) about
 - how complaints are managed at the hospital or clinic;
 - the systems in place for reporting health-care errors;
 - how clinicians learn from errors.

The assessment can be either formative or

summative; rankings can range from unsatisfactory to giving a mark. See the forms in Appendix 2 for assessment examples.

HOW TO EVALUATE THIS TOPIC

Evaluation is important in reviewing how a teaching session went and how improvements can be made. See the Teacher's Guide (Part A) for a summary of important evaluation principles.

References

1. Reason JT. Understanding adverse events: the human factor. In: Vincent C, ed. *Clinical risk management*: British Medical Journal Books, 2001, 9–14.
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4. Joint Commission on Accreditation of Healthcare Organizations. *Sentinel event policy and procedures*. In: JCAHO, ed. Chicago, JCAHO, 1999.
5. Walton M. Why complaining is good for medicine. *Journal of Internal Medicine*, 2001, 31(2):75–76.
6. Reason JT. *Human error*: Cambridge, Cambridge University Press, 1999.
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11. Dawson D, Reid K. Fatigue, alcohol and performance impairment. *Nature* 1997:388–335.
12. Tyssen R, Vaglum P. Mental health problems among young doctors: an updated review of prospective studies. *Harvard Review of Psychiatry*, 2002, 10:154–165.
13. Spath PL, ed. *Error reduction in health care: systems approach to improving patient safety*. San Francisco, Jossey-Bass, 1999.

SLIDES FOR TOPIC 6: UNDERSTANDING AND MANAGING CLINICAL RISK

Didactic lectures are not usually the best way to teach students about patient safety. If a lecture is being considered, it is a good idea to plan for student interaction and discussion during the lecture. Using a case study is one way to generate group discussion. Another way is to ask the students questions about different aspects of health care that will bring out the issues contained in this topic such as the blame culture, nature of error and how errors are managed in other industries.

The slides for topic 6 are designed to assist the teacher deliver the content of this topic. The slides can be changed to fit the local environment and culture. Teachers do not have to use all of the slides and it is best to tailor the slides to the areas being covered in the teaching session.

Topic 7: Introduction to quality improvement methods

Why students need to know about quality improvement methods

1

Students will be familiar with the term evidence-based medicine and the randomized controlled trial, which has enabled medicine to establish if a particular treatment is validated by evidence or merely one that rests on belief of the practitioners. Research methods such as the randomized controlled trial measure clinical effectiveness. But such methods do not measure contextual components or the process of care. The problems in health systems are significantly affected by the processes of care and a randomized controlled trial will not measure the problems nor fix them. Students need to be aware that process measures require different methods. The science of improvement is new to medicine and as a result there has been debate about whether the measures of quality improvement are rigorous enough. Berwick has captured this debate in a paper published in 2008 where he argued that both research methods are necessary to improve health-care research for improving clinical evidence and research for improving processes of care [1].

Quality improvement methods are designed to study processes and have been successfully used for decades in other industries. In health care, students will be familiar with the goal of scientific research, which is to discover new knowledge but they will be less familiar with quality improvement, which is to change performance [2]. Students are encouraged to observe or join a team undertaking an improvement activity. Medical students can begin to understand the role of quality improvement methods by:

- asking about measures that improve quality and safety;
- recognizing that good ideas can come from anyone;
- being aware that the situation in the local environment is a key factor in trying to

make improvements;

- being aware that the way people think and react is as important as the structures and processes in place;
- realizing that the spread of innovative practices is a result of people adopting new processes and not the other way around.

Most quality improvement methods are based on the application of continuous quality improvement theory developed by the manufacturing industry. The principle underpinning quality improvement was that quality was not something controlled at the end of the line, but rather throughout the entire work process. This topic explains some of the underlying theory.

Traditional attempts to persuade and influence clinicians to change behaviour, such as compliance with a protocol or vigilance in regard to drug interactions in the interest of improving the quality of patient care, have by and large failed. There have been thousands of recommendations by hundreds of committees and peer groups for improving the safety and quality of patient care over decades, yet there is little evidence that clinicians have changed their practice because of them. The publication of evidence in peer reviewed journals, does not necessarily lead in of itself, to clinicians' changing their practice. Many articles outline best practice and make urgent recommendations for changes as a result of new information [3].

Quality improvement methods have successfully addressed this gap and provide clinicians with the tools to: (i) identify a problem; (ii) measure the problem; (iii) develop a range of interventions designed to fix the problem; and (iv) test whether the interventions worked.

Tom Nolan, Brent James, Don Berwick and others have applied quality improvement principles in

developing quality improvement methods for health clinicians and managers. The identification and examination of each step in the process of health-care delivery is the bedrock of this methodology. When students examine each step in the process of care they begin to see how the pieces of care are connected and measurable. Measurement is critical for safety improvement.

A range of quality improvement methods have been designed. Below are some more common examples:

- clinical practice improvement (CPI);
- root cause analysis to retrospectively examine what went wrong;
- failure modes and effects analysis to prospectively consider what might go wrong.

Keywords

Quality improvement methods, PDSA cycle, change concepts, continuous improvement methods, variation, CPI, root cause analysis, flowcharts, Cause and effect diagrams (Ishikawa/fishbone), Pareto charts, histograms, run charts.

Learning objective

2

The objectives of this topic are to describe the principles of quality improvement and to introduce students to the basic methods and tools for improving the quality of health care.

Learning outcomes: knowledge and performance

This topic is an important one for students to understand because improvement will only be achieved and sustained through continuous measurement. However, it will also be one of the most difficult because many hospitals and clinics do not measure the processes of their care. An effective way for students to understand the benefits of using quality improvement methods is

to apply the principles and use the tools to undertake their own improvement project.

What students need to know (knowledge requirements):

3

- the science of improvement;
- the quality improvement model;
- change concepts;
- two examples of continuous improvement methods;
- methods for providing information on clinical care.

What students need to do (performance requirement):

4

- know how to perform a range of improvement activities and tools.

WHAT STUDENTS NEED TO KNOW (KNOWLEDGE REQUIREMENTS)

The science of improvement

5

W Edwards Deming, the father of improvement theory, described the following four components of knowledge that underpin improvement: [4]

- appreciation of a system;
- understanding of variation;
- theory of knowledge;
- psychology.

Deming stated that we do not need to understand these components in depth to apply the knowledge. An analogy used by improvement leaders (e.g. Langlely; Nolan [4,5]) is that we can drive a car without understanding how it works. Students beginning their medical careers only need a basic understanding of the science of improvement. It is more important to be familiar with the methods used to improve the processes of care.

Appreciation of a system

In applying Deming's concepts to the health care, we need to remember that most patient care outcomes or services result from a complex system of interaction between health-care professionals, treatment procedures and medical equipment. Therefore, it is important that medical students understand the interdependencies and relationships among all of these components (doctors, nurses, patients, treatments, equipment, procedures, theatres and so on) thereby increasing the accuracy of predictions about any impact that changes may have on the system.

Understanding of variation

Variation is the differences between two or more similar things such as different rates of success for appendectomies in two different parts of the country. There is extensive variation in health care and patient outcomes can differ from one ward to another, from one hospital to another and one region to another. Variation, though, is a feature of most systems. Shortages of personnel, drugs or beds can lead to variations of care. Deming urges people to ask questions about variation. Students can get into the habit of asking their clinical supervisors what their outcomes are for a particular treatment or procedure. Do the three patients returned to theatres after surgery indicate a problem with surgery? Did the extra nurse on duty make a difference with patient care or was it a coincidence? The ability to answer such questions and others like them is part of the reason for undertaking improvement activities.

Theory of knowledge

Deming says that the theory of knowledge requires us to make predictions that any changes we make will lead to an improvement. Predicting the results of a change is a necessary step to enable a plan to be made even though the future is certain. Many students will have experience of such predictions, having written study plans

predicting what is necessary to pass exams. Those with specific experiences may be better at focused predictions. For example, health professionals who work in particular health-care settings such as a rural clinic may be better at predicting the results of a change in this environment. Because they have more knowledge about these clinics and the way they function or should function and the way the change will impact on the patients and their families. When health professionals have experience and knowledge of the area they wish to change it is more likely that the change will result in an improvement. Comparing the results with the predictions is important learning. Deming says that building knowledge by making changes and measuring the results or observing the differences is the foundation of the science of improvement.

Psychology

The last component is the importance of understanding the psychology of how people interact with each other and the system. Making a change whether it is small or large will have an impact and knowledge of psychology helps to understand how people might react, and why they might resist change. A medical ward, for example, includes a number of people who will vary enormously in their reactions to a similar event such as introducing an incident monitoring system. The potential different reactions must be factored in when making an improvement change.

Deming stresses that successful improvements can only be achieved when all four components are addressed; he calls this the system of knowledge underpinning improvement. Deming says it is impossible for improvement to occur without the following action: developing, testing and implementing changes.

The role of measurement in improvement

Quality improvement activities require health professionals to collect and analyse data generated by the processes of health care. For example, a student cannot study the change in his study habits without obtaining some information about his current study habits and the environment in which he lives and studies. He first needs the data to see if he has a problem with study habits and, second, he needs to decide what information he requires to measure whether he has made any improvements.

In this analogy, the aim of the improvement project is to make a change in the study habits of the student leading to improved success in leading to improved success his examinations, rather than simply identifying students with poor study habits.

Measurement is an essential component of quality improvement because it forces people to look at what they do and how they do it. Most activities in health care can be measured, yet currently they are not. There is strong evidence to show that when people use the appropriate measures to measure change, significant improvements can be made. All quality improvement methods rely on measurement. The medical student will only know he has improved his study habits by measuring the before and after situation.

Medical students will be familiar with measurement in the basic sciences; the measures in quality improvement are different from those used in formal medical research. The IHI has produced the following chart (see Table 15) to distinguish between the two measures.

6

Table 15. Institute for Healthcare Improvement: different measures

	Measurement for research	Measurement for learning and process improvement
Purpose	To discover new knowledge	To bring new knowledge into daily practice
Tests	One large “blind” test	Many sequential, observable tests
Biases	Control for as many biases as possible	Stabilize the biases from test to test
Data	Gather as much data as possible, “just in case”	Gather “just enough” data to learn and complete another cycle
Duration	Can take long periods of time to obtain results	“Small tests of significant changes” accelerates the rate of improvement

Three main types of measures

7

Outcome measures

Examples of outcome measures include patient satisfaction surveys and other processes that capture the patients' and their families' views about their health care. This includes surveys and other methods such as interviews that seek to ascertain peoples' perceptions or attitudes to the service and their level of satisfaction with the hospital or clinic.

Some specific examples include:

- access: time waiting for surgery
- critical care: number of deaths in the emergency department;
- medication systems: the number of medication dosing or administration errors.

Process measures

Process measures refer to measurements about the workings of the system. These measures are usually used when a clinician or manager wants to find out how well a part or aspect of a health service or system is working or being performed.

Some specific examples:

- access: number of days the ICU is full and has no spare beds;
- surgical care: number of times swab count completed.

Balancing measures

This measure is used to ensure that any change does not create additional problems. It seeks to examine the service or organization from a different perspective. If a medical student makes a change to his study habits that leaves no time for him to see his friends that may have an impact on his well-being.

A specific example is:

- reducing the length of stay in hospital: ensure readmission rates are not increasing.

The quality improvement model

8

The quality improvement model is a combination of building and applying knowledge to make an improvement by asking three questions and using the PDSA (plan, do, study,act) cycle developed by Deming.

The questions are:

1. What are we trying to accomplish?
2. How will we know whether a change is an improvement?
3. What changes can we make that will result in an improvement?

Deming stresses that the questions can be asked and answered in any order. This model takes the simple concept "trial and error" and transforms it into the PDSA model that can be used to make improvements for all sorts of problems, both big and small.

What are we trying to accomplish?

The idea behind this question is to guide and focus the efforts of the health-care team doing the improvement. It is important that the team agrees that a problem exists and that it is worthwhile fixing.

Does everyone agree that the infection rate in patients who have had a knee operation is too high?

Confirmation that there is a problem requires that supporting evidence (qualitative or quantitative) exists indicating the extent of the problem.

Do we have the figures indicating the high infection rate?

It is not a good idea to put a lot of effort into something that only one person thinks is a problem.

The person who said the infection rate was high had only worked one shift in three and had a patient who had an infection-is this a significant problem?

Many countries will have national and international databases for specific disease indicators that are

useful, particularly for benchmarking. These data are important because it allows the team to focus on the right area. In some cases, there might not be much available to help answer the question; however, irrespective of the extent of information, the simple rule is to keep the answer short and concise.

How will we know that a change is an improvement?

An improvement can only be confirmed when the measures show things were improved over time.

What changes can we make that will result in an improvement?

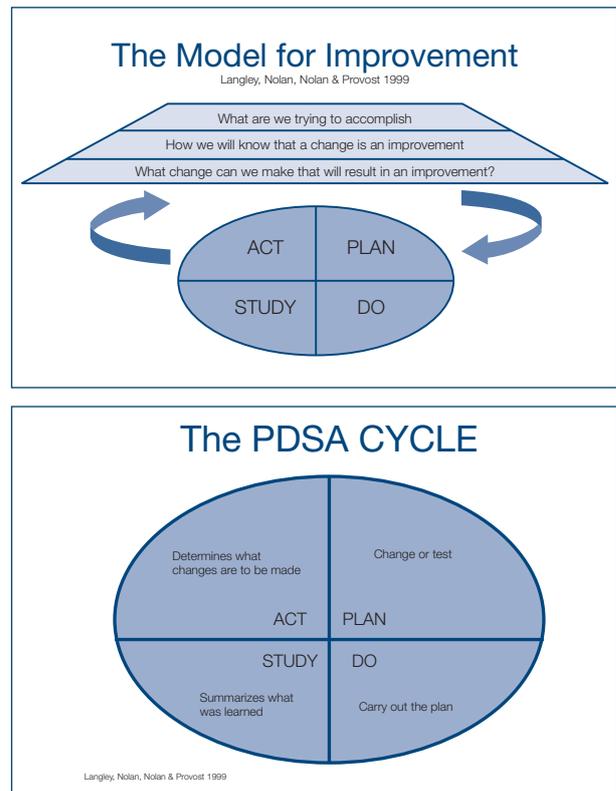
This last question involves the team testing the different interventions used to make the improvements. PDSA is a method designed to assist testing a range of ways to see if an intervention worked.

Using the improvement model developed by Langley, Nolan and others, the IHI has created a PDSA template to assist health-care practitioners implement PDSA cycles to improve health-care services or processes (see Figure 4). The model for improvement, promoted by the IHI was developed by Associates in Process Improvement. Their version of quality improvement is different from other change models in that it seeks to accelerate improvement. Hundreds of health-care organizations have successfully used the model to improve health-care processes and outcomes.

Plan-do-study-act cycle

9 10

Figure 4 Model for improvement



IHI has summarized a range of quality improvement methods, which can be accessed on their web site at <http://www.ihl.org/IHI/Topics/Improvement/ImprovementMethods/Tools/> accessed May 2008.

One of the rules of quality improvement is regular testing of any changes introduced because unexpected things may happen. The cycle begins with a plan and ends with an action. The study section is designed to build new knowledge. This is an important step in improvement science because the new knowledge allows better predictions about the impact of changes. The application of the model can be simple or complex, formal or informal. It can be used to improve waiting times in the clinic or decrease surgical infection rates in theatres. A formal improvement activity may require detailed

documentation, more complex tools for data analysis or more time for discussion and team meetings. The PDSA model depends on a format that repeats steps over and over until an improvement has been effected and sustained.

The IHI model has two parts:

- three fundamental questions, which can be addressed in any order (as set out by Deming);
- the PDSA cycle to test and implement changes in real work settings—the PDSA cycle guides the test of a change to determine if the change is an improvement.

Forming the team

Including the right people on a process improvement team is critical to a successful improvement effort. Teams vary in size and composition. Each organization builds teams to suit its own needs. For example, if the improvement project is to improve discharge planning then the team should have people who know about discharge-nurses, doctors, patients, primary care physicians and nurses.

Setting aims and objectives

Improvement requires setting aims and objectives. Objectives should be time-specific and measurable and should also define the specific population of patients that will be affected. This helps keep the team focused on the project.

Establishing measures

Teams use quantitative measures to determine if a specific change actually leads to an improvement.

Selecting changes

All improvement requires making changes, but not all changes result in improvement. Organizations, therefore, must identify the changes that are most likely to result in improvement.

Testing changes

The PDSA cycle is shorthand for testing a change in the real work setting—by planning it, trying it, observing the results and acting on what is learnt. This is the scientific method used for action-oriented learning.

Implementing changes

After testing a change on a small scale, learning from each test and refining the change through several PDSA cycles, the team can implement the change on a broader scale—for example, for an entire pilot population or on an entire unit.

Spreading changes

Successful implementation of a change or package of changes for a pilot population or an entire unit can permit the team or managers to spread the changes to other parts of the organization or in other organizations.

Change concepts

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Many people intuitively use change concepts in their daily lives such as asking what changes can be made to improve a particular situation—improved study habits, tension with a family member, a teacher or difficulties at work. They ask: “What can I do to make the situation better—to make an improvement?” A change concept in quality improvement is a general notion (a good idea, an approach) that has been found useful in developing specific ideas for change that will result in improvement.

Nolan and Schall [5] defined a change concept as a general idea, with proven merit and sound scientific or logical foundation, that can stimulate specific ideas for changes that lead to improvement.

They identify a number of sources for thinking about possible changes: critical thinking about the current system, creative thinking, observing the

process, a hunch, an idea from the literature, a patient suggestion or an insight gained from a completely different area or situation. A health-care team that wants to improve patient care takes a concept and moulds it to fit their local environment, situation or the task they are trying to improve. This is an important step because it engages the local team in the process. Team members will be more committed to the improvement project and it caters for the particular variations that can occur in different settings. Langley and his colleagues have developed 70 change concepts that have been grouped into the following nine general categories listed in their 1996 landmark book on improvement, *The improvement guide: a practical approach to enhancing organizational performance*.

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1. *Eliminate waste*

Look for ways of eliminating any activity or resource in the hospital or clinic that does not add value to patient care.

2. *Improve workflow*

Improving the flow of work in processes is an important way to improve the quality of patient care delivered by those processes.

3. *Optimize inventory*

Inventory of all types is a possible source of waste in organizations; understanding where inventory is stored in a system is the first step in finding opportunities for improvement.

4. *Change the work environment*

Changing the work environment itself can be a high-leverage opportunity for making all other process changes more effective.

5. *Enhance the health provider/patient relationship*

To benefit from improvements in quality and safety of health care, the health-care professionals and patients must recognize and appreciate the

improvements.

6. *Manage time*

An organization can get more achieved by reducing the time to deliver health care, develop new ways of delivering health care, reducing waiting times for services and cycle times for all services and functions in the organization.

7. *Manage variation*

Reducing variation improves the predictability of outcomes and helps reduce the frequency of adverse outcomes for patients.

8. *Design systems to avoid mistakes*

Organizations can reduce errors by redesigning the system to ensure that there is redundancy i.e. multiple checks and balances to combat human error.

9. *Focus on the product or service*

Although many organizations focus on ways to improve processes, it is also important to address improvement of products and services.

Example: change concept

A health-care team may want to adhere to the WHO protocol *Clean hands are safer hands*. Infection control is a good idea and the WHO guidelines are based on evidence, expert opinion and the literature. One could predict that if the guidelines were implemented then an improvement would be made, i.e. a decrease in the transmission of infection via hands. Implementing a guideline is an example of an abstract concept.

The team is required to then make more specific statements about implementing the guideline in their workplace. This process will move the abstract change concept to a practical aim. If the

change concept is abstract as opposed to practical then it should be backed by literature and evidence-based medicine.

As the concept becomes more local and practical it should be increasingly concrete, logically connected and sensitive to the local situation. One of the benefits of lists such as the 70 change concepts described by Langley et al. is that they can speed up the process by not having to duplicate long searches for ideas to test using the PDSA cycle.

A number of catalogues have been published covering topics such as medical errors, waiting time, delays, intensive care and asthma.

Two continuous improvement methods

There are a number of examples of quality improvement methods in health care but the two most relevant to medical students are:

- CPI (Clinical practice improvement) methodology;
- root cause analysis.

Clinical practice improvement Slides 13 14

CPI methodology is used by health-care professionals to improve the quality and safety of health care. It does this through a detailed examination of the processes and outcomes in clinical care. The success of a CPI project depends on the team covering each of the following five phases. An example of a completed CPI project is provided in the second part of this topic and in the Case Study Bank in Appendix 1.

Project phase: The team needs to ask themselves what it is they wish to fix or achieve. They do this by developing a mission statement or objective that describes what it is they wish to do in a few sentences. This is the time to select the team members who should be selected on the basis of their knowledge about the problem.

Patients should always be considered as appropriate members of the team rather than as an after thought. At this stage the team should consider the type of measures they may use.

Diagnostic phase: Some problems are annoying yet may not be worth fixing because of the little benefit they add. Therefore, the team needs to ask if the problem they have identified is worth solving. The team should establish the full extent of the problem by gathering as much information about the problem as possible. A brainstorming exercise by the team will generate possible changes that could lead to an improvement. A decision about how to measure the improvement needs to be resolved during this phase.

The following activities will assist the team to complete the diagnostic phase.

1. Team members collect and analyse quantitative and qualitative data of the process being investigated to establish causes of and potential solutions.
2. Members discuss the different causes interact to produce the problems.
3. Members identify solutions using the following activities.
 - process flowchart;
 - brainstorming;
 - consumer focus groups;
 - nominal group technique;
 - tally chart.

Members organize and prioritize information by using the following tools.

- cause and effect diagram;
- affinity diagram;
- Pareto chart.

Members prepare graphs of current data-run chart, statistical process control chart.

Intervention phase: By now, the team will have worked out what the problems are and their

possible solutions. Each of the solutions have to be tested through a trial and error process by using the PDSA cycles to test changes, observe them and keep the bits that work.

15 16 17 18

Impact and implementation phase: This is the time to measure and record the results of the trials of the interventions. Did they make any difference?

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All changes are required to be measured for impact so that the change can be said to truly have made a difference rather than a coincidence or a one-off effect. The goal is to introduce a change that has sustained improvement. The data showing the evidence of the change are displayed using run charts and statistical process control. Using the study habits of a student as an example, we can say that the student has improved his study habits if he has maintained his improved study habits for a period of months and not returned to the old habits.

Sustaining and Improvement phase: The final phase requires the team to develop and agree upon a monitoring process and plans for continuous improvement. Improvements made now will become failures in the future if there are no plans to sustain the improvements.

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This may involve:

- standardization of existing processes and systems for undertaking work activities;
- documentation of relevant policies procedures protocols and guidelines;
- measurement and review to enable the change to become routine;
- training and education of staff.

Root cause analysis

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Many hospitals and health services are now using a process called root cause analysis to determine the underlying causes of adverse events or incidents. A root cause analysis is used after an incident has occurred to uncover the primary possible causes. As such, it focuses on the particular incident and the circumstances surrounding it. However, there are many lessons to be gained from this retrospective process that may prevent similar incidents in the future.

A root cause analysis is a defined process that seeks to explore all of the possible factors associated with an incident by asking what happened, why it occurred and what can be done to prevent it from happening again.

Health-care workers require training in this method as they do in CPI methodology. Many countries have introduced training programmes for staff to develop skills in conducting root cause analyses. The Veteran Administration in the United States has adapted root cause analysis to investigate adverse events; their model has become a prototype for health-care organizations the worldwide.

It will be very difficult for a team of health-care professionals to conduct a root cause analysis without the support of the organization because the process requires resources to be effective—people, time, support from the managers and clinicians and the chief executive. Yet, the benefits are real and can lead to improvements of the system as a whole. An effective root cause analysis requires the following components.

- multidisciplinary team:
 - of no more than six people;
 - including lay people, particularly those that may bring a patient's perspective;
 - in which no one on the team has had an actual involvement in the event under review;

- composed of people who can add value because of their knowledge, position in the organization or unique perspective they bring;
- made up of some members who have been trained in root cause analysis, who can guide the rest of the team with just-in-time training about the root cause analysis process, wider system issues and factors that may be associated with the event;
- who will be committed to meeting weekly for two to four hours at a time over a period of five to six weeks;
- root cause analysis effort is directed towards finding out what happened:
 - documentation and review (medical records, incident forms, hospital guidelines, literature review, letters from the patient or their family or carer);
 - site visit—the team will benefit from visiting the environment in which the event occurred to examine the equipment, the surroundings and observe the relationships of the relevant staff;
- event flowchart is a key part of the investigation as it:
 - helps to form a common understanding of what happened;
 - allows the team to develop problem statements to enable a cause and effect diagram to be developed;
 - outlines the story and defines what happened chronologically;
- the team develops a problem statement that:
 - clearly states the problem to be addressed;
 - focuses deeply about the problem(s) and not the solutions;
- establishing the contributing factors or root causes are accomplished through:
 - a brainstorming process of all possible factors;
 - the development of an event flowchart of

the events including documenting the process of questions about each event and expanding the chart on the basis of the information:

- *environmental factors*: e.g. the work environment and its attention to safety; the type of culture in the unit or locality; medico-legal issues;
- *organizational factors*: e.g. staffing levels; quality and attention to policies; morale of staff; workload and fatigue; access to essential equipment; administrative support, attitudes to patients and their families;
- *team staff factors*: e.g. supervision of junior staff; quality and effectiveness of communication between professional groups; availability of senior doctors;
- *individual staff factors*: e.g. level of knowledge or experience; fatigue and stress; expectations of staff;
- *task factors*: e.g. existence of clear protocols and guidelines; system in place for obtaining test results; definition and description of tasks;
- *patient factors*: e.g. distressed patients; communication and cultural barriers between patients and staff; multiple co-morbidities.

The VA root cause analysis process has developed a guide to staff about the possible areas and questions they might ask to uncover the possible factors involved in an incident.

- *communication*: Was the patient correctly identified? Was information from patient assessments shared by members of the treatment team on a timely basis?
- *environment*: Was the work environment designed for its function? Had there been an environmental risk assessment?
- *equipment*: Was equipment designed for its

intended purpose? Had a documented safety review been performed on the equipment?

- *barriers*: What barriers and controls were involved in this? Were they designed to protect patients, staff, equipment or environment?
- *rules, policies and procedures*: Was there an overall management plan for addressing risk and assigning responsibility for risk? Had a previous audit been done for a similar event, were the causes identified and were effective interventions developed and implemented on a timely basis?
- *fatigue/scheduling*: Were the levels of vibration, noise and other environmental conditions appropriate? Did personnel have adequate sleep?

Other activities involved in the root cause analysis process include:

- cause and effect diagrams:
 - a cause and effect diagram helps the team to stay focused on all of the possible causes rather than fixate on the one cause. The cause and effect diagram or fishbone diagram begins with a few problem statements and shows how these may have been caused by a few actions and many latent (underlying) conditions;
- root cause statements:
 - root cause statements should only be made at the end of the process—the VA process provides the following guidance to staff in writing root cause statements;
- the cause and effect relationship must be explicit and:
 - avoid negative value statements;
 - identify a preceding cause in each human error;
 - each procedural deviation must have a preceding cause;
 - failure to act is only causal when there

was a pre-existing duty to act;

- preventing a reoccurrence:
 - many root cause analyses fail at this stage because they have not paid sufficient attention to the feasibility and practicality of the recommendations—if there is no senior engagement and commitment to implementing the recommendations then a root cause analysis process can wither before it blooms;
 - once the root cause analysis is completed the team should come up with recommendations that aim to either eliminate it (requires action), control it (requires action) or accept. They should be very focused and not too general and certainly not only about more resources.

All recommendations should be realistic and:

- address the root cause of a problem;
- be specific and concrete;
- be easily understood;
- be possible to implement;
- define roles and responsibilities for implementation;
- define a timeframe for implementation.

WHAT STUDENTS NEED TO DO (PERFORMANCE REQUIREMENTS)

Know how to use a range of improvement activities and tools.

Quality improvement tools

22

The following tools are commonly used in quality improvement efforts to improve health care. They are simple to use and can be used by everyone in the organization. Most hospitals and clinics routinely collect and use data about the health services being delivered and many will statistically analyse the data to report to the health authorities or head of the health service. The following tools are commonly known as the seven

tools of TQM (total quality management). Four of these are listed below.

- flowcharts;
- cause and effect diagrams (Ishikawa/fishbone);
- Pareto charts;
- run charts.

Experience from other industries and quality improvement experts such as Ishikawa demonstrate that 9 out of 10 operational problems may be solved by one of the tools described in this section. In health care that means a health service problem can usually be solved by applying some or all of these tools.

The following case example of a CPI project will assist students to understand the tool and how it is used in the improvement process. The case used below is a real case and was undertaken during the CPI programme conducted by the Northern Centre for Healthcare Improvement (Sydney, New South Wales, Australia). The name of the hospital and the participants are de-identified, the title of the project is accelerated recovery colectomy surgery (ARCS).

The first thing that needs to be done is to identify exactly what it is that needs fixing. Is the length of stay for patients having colectomy surgery too long and outside best practice? A mission statement is developed that captures the aim of the project. Participants are encouraged to aim high, to develop stretch goals. The following mission statement was agreed upon.

The mission statement:

To reduce the length of stay for patients having colectomy surgery from 13 days to 4 days within 6 months at the base hospital.

The next thing to do is to make sure that the right team has been selected to undertake this project. The team members must have the fundamental knowledge.

Guidance team members:

- Health service manager;
- Executive officer for the hospital;
- Director of nursing for the hospital;
- Area clinical nurse consultant pain management;
- Visiting medical officer surgeon.

Project team members:

- Area clinical nurse consultant pain management (team leader);
- General surgeon;
- Anaesthetist;
- Acute pain nurse;
- Peri-operative clinic;
- Surgical ward registered nurses;
- Physiotherapist;
- Dietician;
- Patient.

Is this a problem?

This group of health-care workers decided that there was a problem with the length of stay and wanted to reduce the time patients were in hospital

23

Flowcharts

24

The next step is to understand the steps involved for patients having colectomy surgery. A flowchart is a pictorial method for showing all the steps or parts of a process that makes up the system. Health care is so complex and before we can fix a problem we need to understand how the parts fit together and how they function. A range of people construct and contribute to a flowchart. It would be very difficult to only have a doctor draw a flowchart because he may not know the wide range of actions that occur in a particular situation or have access to the documentation of the service. Flowcharts are good for setting out what people actually do at work rather than what others think they do.

Even though the actions described may differ from the organization's view, it is important to draw in the flowchart what actually happens because this provides a common reference point and shared language that all members of the team can share. Constructing a flowchart enables a "real" and actual portrayal of the process.

The IHI has assembled a range of tools on the Institute's web page that is available to help people with improvement projects.

There are two levels of flowcharts:

- high-level flowchart:
 - there are only 6-12 steps described that gives an overview of a process;
 - these show any major blocks of activity, or the major system components, in a process;
 - they are especially useful in the early phases of a project.
- detailed flowchart:
 - there are many steps described and is a close-up view of the process;
 - it can identify loops and allows complex causes of errors to be identified;
 - these are often shown using the cloud symbol as shown in the slide below (flowchart of process);
 - detailed flowcharts are useful after teams have pinpointed issues or when they are making changes in the process.

Using a flowchart has a variety of benefits:

- it explains the processes involved in health-care delivery;
- it identifies the steps that do not add value to the health-care service including delays; needless storage and transportation; unnecessary work, duplication and added expense; breakdowns in communication;
- it helps health-care workers get a shared

understanding of the process and use this knowledge to collect data, identify problems, focus discussions and identify resources;

- it serves as a basis for designing new ways to deliver health care;
- health-care workers who document the process also gain a better understanding of each other's role and functions.

Not all flowcharts look the same. Slide 24 shows the flowchart developed by the team who want to reduce colectomy patient length of stay from 13 days to 4 days within 6 months.

The team also wants to understand the expectations of the participants.

25

A cause and effect diagram is a tool for solving problems. This diagram is also called an Ishikawa or fishbone diagram. The diagram is used to explore and display the possible causes of a certain effect. The content on each arm of the diagram is generated by members of the team in a brainstorm about possible causes. The fishbone diagram in slide 26 is the result of a brainstorm by a team of health-care professionals working on reducing length of stay post-colectomy.

26

A cause and effect diagram has a variety of benefits:

- it identifies multiple causes that may contribute to an effect;
- it graphically displays the relationship of the causes to the effect and to each other;
- it focuses the team to the areas for improvement.

Continuing with the CPI project conducted by the team at the base hospital who were trying to reduce length of stay post colectomy, the Pareto chart identifies the factors that they saw as contributing to the current time patients stayed in hospital.

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Pareto charts

In the 1950s, Dr Joseph Juan used the words “Pareto principle” to describe a large proportion of quality problems being caused by a small number of causes. The principle that a few contributions account for the majority of the effect is employed to determine where to focus the effort in attempting to fix a problem. This is done by prioritizing problems, highlighting the fact that most problems are affected by a few causes and indicating which problems to solve and in what order.

A Pareto diagram is a bar chart in which the multiple factors that contribute to the overall effect are arranged in descending order according to the magnitude of their effect. The ordering is an important step because it helps the team concentrate its efforts on the factors that have the greatest impact. It also assists them to explain the rationale for concentrating on particular areas.

Slides 26 and 27 come from the IHI tool Pareto diagram. Slide 26 describes a sample data table setting out the types of errors discovered during surgical setup and Slide 27 is a bar chart depicting in descending order the magnitude of the contributing factors.

Implementation of plan-do-study-act cycles

28

A team can brainstorm a number of possible interventions.

Run chart example

29

Slide 29 is a run chart produced by the base hospital team that tracks over time the improvements. Run charts or time plots are graphs of data over time. A run chart helps the team know if a change is an improvement over time or just a random fluctuation wrongly interpreted as significant improvement. Run charts help identify if there is a trend. A trend is formed when a series of seven consecutive points

continually fall or rise.

The benefits of using run charts include:

- helping the team judge how a particular process is performing;
- helping the team to identify when a change is truly an improvement by plotting a pattern of data that one can observe as the changes are made.

Strategies for sustaining improvements

30

Making the improvement is not the end; the improvement needs to be sustained over time. This means continuous measuring and making adjustments through PDSA cycles. Slide 30 describes the strategies for sustaining improvement and this is where we leave our team. They have successfully reduced the length of stay for patients having colectomy surgery at their hospital. In doing so they have saved the hospital a significant amount of money as well as decreased the chance of a patient receiving an infection. Even so, they need to sustain these improvements. The above strategies were identified by the team to monitor and measure the length of stay on a monthly basis.

Summary

There is overwhelming evidence that patient care improves and errors are minimized when clinicians use quality improvement methods and tools. Only then will the efforts of the team be rewarded by real sustained improvements to health care. This topic set out the methods for quality improvement and described a range of tools that are used in quality improvement.

HOW TO TEACH THIS TOPIC

Teaching strategies/formats

Teaching quality improvement methods to students can be challenging because it requires clinicians who have had real experience with the tools and know the benefits. The best way to

teach this topic is to get the students to use the quality improvement tools and arrange for individualized coaching in quality improvement methods. Students should be encouraged to join existing projects to experience the team approaches and how patient outcomes are significantly improved with such methods.

This topic can be delivered in a number of ways.

An interactive/didactic lecture

This topic contains a lot of underpinning and applied knowledge that is suitable for an interactive didactic lecture. Use the accompanying slides as a guide, covering the whole topic. The slides can be PowerPoint or converted to overhead slides for a projector.

Panel discussions

Invite a panel of health professionals who have done a root cause analysis or a CPI project to talk about the process and whether the methods gave them insights they would not have had except for the root cause analysis or CPI.

Small group discussion session

The class can be divided up into small groups with three students in each group asked to lead a discussion about the benefits of quality improvement methods—root cause analysis and CPI and when they might be used.

Simulation exercises

Different scenarios could be developed for the students: practising the techniques of brainstorming; designing a run chart, cause and effect diagram or histogram.

Teaching and learning activities

This topic is best taught by getting the students to practise the tools and techniques used in quality improvement methods by undertaking their own personal quality improvement project.

Examples of self-improvement projects:

- develop better study habits;
- spend more time with family;
- give up smoking;
- lose or put on weight;
- perform more housework.

Students can implement the PDSA cycle to suit their own personal circumstances and obtain a better understanding of the process so they can apply it in their professional work as medical students or members of a health-care team. Following the steps set out above in the case example, students can begin to experiment with the tools and see how to use them and whether they helped them in their project.

Another activity, if available, is for students to ask their clinical supervisors or other health professionals if the hospital undertakes quality improvement. If so, they could ask to observe a root cause analysis process of a CPI project.

After these activities students should be asked to meet in pairs or small groups and discuss with a tutor or clinician what they observed and whether the features or techniques being observed were present or absent, and whether they were effective.

TOOLS AND RESOURCES

WWW Web-based resources

Root cause: *Root cause analysis*. US Department of Veteran Affairs National Center for Patient Safety, 2007 (<http://www.va.gov/NCPS/rca.html>, accessed May 2008).

Flowchart: *Flowchart*. Institute for Healthcare Improvement Boston, 2004 (<http://www.ihl.org/NR/rdonlyres/9844A3FD-9F2F-44D7-A423-81F81891F19E/651/Flowcharts1.pdf>, accessed May 2008).

Improvement methods: *Improvement Methods*. Institute for Healthcare Improvement, Boston (<http://www.ihl.org/IHI/Topics/Improvement/ImprovementMethods/Tools/>, accessed May 2008).

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Clinical improvement guide: *Easy guide to clinical practice improvement: a guide for health professionals*. New South Wales Health Department, 2002 (http://www.health.nsw.gov.au/quality/pdf/cpi_easyguide.pdf, accessed May 2008).

Health care improvement: Northern Centre for Healthcare Improvement (<http://www.nchi.org.au/www/html/443-documentation.asp>, accessed May 2008).

There are many good examples of completed CPI projects.



Resources

Langley GL et al. *The improvement guide: a practical approach to enhancing organizational performance*. Institute for Healthcare Improvement. San Francisco, Jossey-Bass

Publishers, 1996.

Mozena JP, Anderson A. *Quality improvement handbook for healthcare professionals*. Milwaukee, ASQC Quality Press, 1993.

HOW TO ASSESS THIS TOPIC

A range of assessment methods are suitable for this topic including:

- complete and write up a self-improvement project;
- write a reflective statement about an observation of the root cause analysis or CPI process;
- participate in a root cause analysis or CPI project.

HOW TO EVALUATE THIS TOPIC

Evaluation is important in reviewing how a teaching session went and how improvements can be made. See the Teacher’s Guide (Part A) for a summary of important evaluation principles.

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4. Langlely GL et al. *The improvement guide: a practical approach to enhancing organizational performance*. San Francisco, Jossey-Bass Publishers, 1996.
5. Nolan TW et al. *Reducing delays and waiting times throughout the healthcare system*, 1st ed. Boston, Institute for Healthcare Improvement, 1996.

SLIDES FOR TOPIC 7: INTRODUCTION TO QUALITY IMPROVEMENT METHODS

Didactic lectures are not usually the best way to teach students about patient safety. If a lecture is being considered, it is a good idea to plan for student interaction and discussion during the lecture. Using a case study is one way to generate group discussion. Another way is to ask the students questions about different aspects of health care that will bring out the issues contained in this topic such as the blame culture, nature of error and how errors are managed in other industries.

The slides for topic 7 are designed to assist the teacher deliver the content of this topic. The slides can be changed to fit the local environment and culture. Teachers do not have to use all of the slides and it is best to tailor the slides to the areas being covered in the teaching session.

Topic 8: Engaging with patients and carers

Why engaging with patients and families is important

1

The claim of modern health care is that it is patient centred. Yet, the reality for many patients and consumers is that they have had a long-standing battle to overturn entrenched views about the level of involvement patients should have in their own care. The tide is turning and in many nations around the world the consumer's voice in health care is not only being heard but is being recognized by government, the professions and health-care providers.

Any health-care intervention has an element of uncertainty as to whether it will improve the health of the patient. Every consumer has the right to know what it means being a patient, and to receive helpful information about the quality of the care they will receive especially if they are to have any type of medical or surgical intervention. Informed consent allows them, in collaboration with health-care professionals, to make decisions about having the intervention and the recognized risks associated with that intervention. Such interventions may include, for example, a course of medication or an invasive procedure.

While most health-care interventions have good results or at least do no harm, poor outcomes do happen that can include errors, both random and systemic. The quality of a health-care system can be judged by the way it handles those errors. When health-care organizations fail to integrate consumer involvement in managing systemic risk, they lose access to important knowledge that cannot be gained from any other source.

The inclusion of open disclosure processes in many hospitals today reflects the increasing importance of professionalism and honesty with patients and their carers. This in turn is increasing opportunities for partnerships with patients.

Many consumer organizations are now turning their attention to organizational activities. The WHO initiative Patients for patient safety [1] is for consumers and focuses on education about patient safety and the system of health care as a contributing factor to adverse events.

Many patients having medical treatments, particularly when hospitalized, are in a vulnerable psychological state even when treatment goes according to plan. Symptoms akin to post-traumatic stress disorder can occur even following procedures that strike providers as routine. When a patient experiences a preventable adverse event, may be that the for emotional trauma is particularly severe.

This topic will provide an overview of consumer engagement activities that naturally divides into two dimensions: (i) learning and healing opportunities after an adverse event has occurred; and (ii) engagement of patients in preventing harm.

Keywords

Adverse event, advisory council, apology, communication, complaints, cultural norms, disclosure, education, error, fear, informed decisions, liability, mediation, patient and family, patient-centred, patient empowerment, patient engagement, patient rights, partnership, partnership councils, proactive, rapid response team, reporting, questions, *Speak up* campaign, stories, victims.

Learning objective:

2

The objective of this topic is to understand the ways in which patients and carers can be involved as partners in health care, both in preventing harm and learning and healing from an adverse event.

Learning outcome: knowledge and performance

What students need to know (knowledge requirements)

3

Students need to know:

- basic communication techniques;
- informed consent procedures;
- the basics of open disclosure.

What students need to do (performance requirements)

4

Students need to:

- actively encourage patients and carers to share information;
- show empathy, honesty and respect for patients and carers;
- communicate effectively;
- obtain informed consent;
- show respect for each patient's differences, religious and cultural beliefs, and individual needs;
- describe and understand the basic steps in an open disclosure process;
- apply patient engagement thinking in all clinical activities;
- demonstrate ability to recognize the place of patient and carer engagement in good clinical management.

WHAT STUDENTS NEED TO KNOW (KNOWLEDGE REQUIREMENTS)

Basic communication techniques

Reviewing good communication

Before getting into the detail of open disclosure, it is useful to quickly review the principles of good communication and obtaining informed consent if these have not already been covered in the course.

Gaining informed consent

The consent process is a good barometer to judge how involved and engaged a patient is with their treatment. Some students think that consent requirements are fulfilled when the patient signs a consent form, but consent is much more than a signature on a form. The consent process enables the patient (or their carer) to consider all the options they have in relation to their treatment. Because this is such an important process, guidelines have been developed to assist health care professionals competently complete this task. Unfortunately time pressures and sometimes attitudes to patients shorten this process. The consent process has been developed over time paying attention to the statutory laws and statute laws in a particular country. Essentially consent has two main phases [2]:

1. The elements which inform the patient:
 - disclosure of information by the health-care practitioner;
 - an understanding or comprehension of the information by the patient.
2. Elements that enable the patient to make a decision:
 - a free and voluntary choice by the patient;
 - competence.

Medical students will usually observe the consent process when they are assigned to hospitals or clinics. Some will observe excellent examples of doctors and patients discussing treatments and the patients consenting or declining the treatment, but many will see patients giving consent with minimal information about their treatments.

Many students might be concerned about how much and what type of information should be disclosed and how well it must be understood before it can be said that the patient has been appropriately informed. How can the practitioner know that a patient's decision is intellectually

unimpaired and voluntary? Is it free of intrinsic (stress, grief) and extrinsic (money, threat) pressures?

What a patient should know

5

Doctors are widely encouraged to use evidence-based medicine. For many treatments, there is a body of evidence on the likelihood of success and the likelihood of harm. It is important that such information is communicated to patients in a way that they can understand. Where there are printed resources to aid decision-making these should be used. Before a patient can decide whether to have the treatment or not they need to have information about the following issues.

The diagnosis

This includes test results and procedures. Without a diagnosis it is difficult for a patient to come to a decision about whether the treatment will be beneficial. If a treatment is exploratory, then this should be disclosed.

The degree of uncertainty in the diagnosis

Medicine is an error ridden profession; as more symptoms appear, the diagnosis can either be confirmed or changed. Disclosing uncertainty is essential.

Risks involved in the treatment

To enable patients to make a decision that suits them, they need to know:

- any side-effects;
- complications associated with the treatment or procedure;
- any outcome that may affect the patient's physical/mental well-being;
- nature of risks;
- consequences of not having the treatment.

One way to communicate the risks and benefits to patients is to move from the general information about the treatment or procedure to specific

information about the known risks and benefits (and uncertainties) associated with the specific treatment or procedure to the particular concerns and information needs of the patient or caregiver.

Patients need to know the range of options, not just the one favoured by the practitioner. In particular, they need to know:

- the proposed treatment;
- expected benefits;
- when treatment would start;
- length of treatment;
- costs involved.

The benefits of the treatment and the risks of not having the treatment

Some treatments, notwithstanding the risks, are better than no treatment because of the very poor prognosis.

Information on recovery time

The type of treatment or the decision to go ahead with a treatment or procedure may be influenced by other factors in the patient's life: employment, family responsibilities, money, location of the treatment.

Name, position, qualifications and experience of health workers who are providing the care and treatment

Patients are entitled to know the level of training and experience of health-care professionals. If a practitioner is inexperienced, then supervision becomes more important and information about supervision may become part of the information exchanged.

Availability and costs of any service required after the transfer of care (discharge) from hospital

Patients may require the services of the community nurse or the general practitioner.

Aiding good communication

6

There are several tools to enhance good communication, e.g. the SEGUE framework developed by Northwestern University in the United States [3]:

- **S**et the stage
- **E**licit information
- **G**ive information
- **U**nderstand the patient perspective
- **E**nd the encounter.

Cultural competence

7

According to APSEF (Australian Patient Safety Education Framework), cultural competence is a term used to describe the knowledge, skills and attitudes that a health-care worker needs in order to provide adequate and appropriate health-care services to all people in a way that respects and honours their particular culturally based understandings and approaches to health and illness [4].

Cultural competence [5] in providing health services requires medical students to:

- be aware and accept cultural differences;
- be aware of one's own cultural values;
- recognize that people from different cultural backgrounds have different ways of communicating, behaving, interpreting and problem-solving;
- recognize that cultural beliefs impact on how patients perceive their health, how they seek help, how they interact with health practitioners and how they adhere to the treatments prescribed;
- have an ability and willingness to change the way one works to fit in with the patient's cultural or ethnic background so that they can be provided with optimal care.

Culture is a broad term that includes more than language and custom but also values, beliefs, behaviours, practices, institutions and the way people communicate. Students will observe that

among their classmates there are different approaches to dress and food habits that may be related to culture or religion. Less obvious to them will be the underlying belief systems that their class mates adhere to.

It needs to be recognized that in many countries around the world, doctors and patients are only just beginning to think about patient safety and patient engagement. There are many debates to be had about how this transformation will affect the health-care service in those countries. While doctors should be culturally competent, it should also be recognized that for many countries around the world the patient safety movement is about a cultural change in the health-care system.

Benefits of patient and carer engagement

Compared with the medical profession and other health-care providers, health-care consumers have been the least represented stakeholder perspective in health-care safety and quality improvement efforts.

Because patients and their families are not as organized as other stakeholder groups, their interests and needs have not been well captured or well integrated into research activities, policy development, patient safety educational curricula, patient education or error/near miss reporting systems. Recently, patient safety leaders have observed that lack of progress may be due, at least in part, to our failure to effectively engage consumers of care as partners in ensuring the safety of care.

Is there evidence that patient engagement is effective?

8

While there are many ethical statements about the importance of partnerships with patients, there is little research about the extent to which partnerships with patients reduces medical error. A study by Gallagher, Waterman et al. [6]

indicated a strong willingness by hospitalized patients (91%) to be involved in error prevention activities. Their comfort level differed for different tasks. Patients were comfortable (85%) asking about a medication's purpose, though nearly half (46%) were very uncomfortable about asking healthcare workers whether they had washed their hands.

In a 2005 article by Gallagher and Lucas [7] about disclosing medical errors to patients, the authors noted that seven studies had assessed patients' attitudes to disclosure. These studies reported a gap between patients preferences and the fear by clinicians that sharing information with patients will expose them to medico-legal actions. Fortunately there has been a lot of effort put into developing Open Disclosure policies and since 2005 many hospitals have instituted an open disclosure policy without any obvious negative effects. A literature review on open disclosure is available on the web and can be found at [http://www.health.gov.au/internet/safety/publishing.nsf/Content/703C98BF37524DFDCA25729600128BD2/\\$File/Open%20Disclosure%20literature%20review.pdf](http://www.health.gov.au/internet/safety/publishing.nsf/Content/703C98BF37524DFDCA25729600128BD2/$File/Open%20Disclosure%20literature%20review.pdf) (accessed May 2008)

How patients can be engaged in their care

Patient stories are inspiring

Human factors experts have expressed considerable caution about assigning responsibilities to the patient or family without a clearer understanding of what their role is in preventing harm. We are yet to seriously research what role (or indeed whether there is a role) for patients in minimizing errors. Nevertheless, there are many stories told by patients who have suffered adverse events that have a powerful message for health providers. Students cannot fail to engage with these stories, reflect on the experiences of these patients and incorporate new understandings into their own professional practice.

Patients' experiences can teach us

We have not traditionally viewed the patient experience as particularly helpful in teaching, yet we are learning that patient stories and experiences of their illnesses can teach medical students and others a lot including: (i) the key role they can play in helping with the diagnosis; (ii) in deciding about appropriate treatments; (iii) in choosing an experienced and safe provider; (iv) in ensuring that treatments are appropriately administered; and (v) as identifying adverse events and letting people know about it as soon as possible [8].

Currently, the health-care system under-utilizes the expertise patients can bring to the health-care partnership. In addition to knowledge about their symptoms, preferences and attitudes to risk, they are a second pair of eyes if something unexpected happens [9].

What is disclosure? What must be disclosed?

9

Open disclosure refers generally to informing patients and their families of bad outcomes of medical treatment, as distinguished from bad outcomes that are expected from the disease or injury being treated. A number of definitions exist reflecting the uptake on open disclosure guidelines being developed and implemented in many countries. In Australia, open disclosure [10] is defined as:

the process of providing an open, consistent approach to communicating with the patient and their support person following a patient-related incident. This includes expressing regret for what has happened, keeping the patient informed and providing feedback on investigations, including the steps taken to prevent a similar incident occurring in the future. It is also about providing any information arising from the incident or its investigation relevant to changing systems of care in order to improve patient safety.

Open disclosure is the honest communications with patients and/or their families after an adverse event. The requirement to be honest is an ethical obligation and is documented in most medical ethical codes of practice. Basic questions would include: “What is the right thing to do in this situation?”, “What would I want in a similar situation?”, “What would I want if my loved one suffered an adverse event?” Many countries are yet to develop open disclosure guidelines for health-care professionals.

Do patients want disclosure of adverse events or errors that produce near misses?

A landmark study by Charles Vincent et al. [10] which examined the impact of medical injury on patients and their relatives and the reasons for taking legal action after such incidents gave impetus to consideration of the role and experience of patients. They interviewed 227 (out of a sample population of 466 or 48.7%) patients and relatives who were taking legal action in 1992 through five firms of plaintiff medical negligence solicitors. They found that over 70% of respondents were seriously affected by incidents that caused them to sue with long term effects on work, social life, and family relationships.

The survey results showed:

- intense emotions were aroused and continued for a long time;
- decision to take legal action was determined by original injury and by insensitive handling poor communication after the original event;
- where explanations were given less than 15% were considered satisfactory.

Four main themes emerged from the analysis of reasons for litigation [11]:

- concern with standards of care—both patients and relatives wanted to prevent similar incidents in the future;
- they needed an explanation—to know how the injury happened and why;

- compensation—for actual losses, pain and suffering or to provide care in the future for an injured person;
- accountability—a belief that the staff or organization should have to account for their actions; patients wanted greater honesty an appreciation of the severity of the trauma they had suffered and assurances that lessons had been learnt from their experiences.

After an adverse event, patients want disclosure of an event that including:

- an explanation of what happened;
- an admission of responsibility;
- an apology;
- the assurance of prevention of similar events to others in the future;
- in some cases, punishment and compensation.

Common barriers to honesty with patients after an adverse event

Doctors and nurses may want to provide accurate and timely information to patients about an adverse event, yet fear that such communications may result in legal action or, at a minimum, confronting an angry patient or family member. Targeted education about the disclosure process may better prepare doctors for such an event. Doctors may also fear causing more distress to patients, loss of reputation, job, insurance cover or shame.

Open disclosure principles

There are now many guidelines available to assist clinicians through the open disclosure process:

- crafting an effective apology (Joint Commission Resources);
- open disclosure (Australian Commission for Safety and Quality);
- open disclosure guidelines (New South Wales, Health Australia);
- disclosure of adverse event (Department of Veteran Affairs);

- When things go wrong: responding to adverse events (consensus statement of the Harvard hospitals).

We use the New South Wales open disclosure guidelines as an example, which is freely available at http://www.health.nsw.gov.au/policies/gl/2007/pdf/GL2007_007.pdf (accessed May 2008)

Key principles of open disclosure [12] (New South Wales, Australia)

10

- openness and timeliness of communication;
- acknowledgement of the incident;
- expression of regret/apology;
- recognition of the reasonable expectations of the patient and their support person;
- support for staff;
- confidentiality.

11

12

The open disclosure process has many steps that should be taken. Senior clinicians are responsible for this process and medical students should never be left with responsibility for telling patients and families about an adverse event. They should try to observe and sit in on the interviews with patients so they can learn about the process and the value to patients and their families. Slide 13 is a flowchart of the open disclosure process used in New South Wales, Australia, that commenced in 2007.

The 2006 consensus statement of the Harvard hospitals *When things go wrong* [13]: *responding to adverse events*, places a much stronger emphasis on the need for emotional trauma support for both patient/family and health-care professionals involved. The importance of documentation to facilitate transparent communication with the patient and family and safety improvement initiatives that follow an event is emphasized in the Harvard framework for disclosing adverse events to patients and families.

The Harvard framework for disclosure [13]:

13

1. preparing:
 - review the facts;
 - identify and involve the appropriate participants;
 - use an appropriate setting.
2. initiating conversation:
 - determine patient and family readiness to participate;
 - assess the patient and family's medical literacy and ability to understand;
 - determine the patient and family's level of medical understanding in general.
3. presenting the facts:
 - simple description of what happened:
 - no medical jargon;
 - speak slowly;
 - be aware of body language;
 - do not overwhelm with information or oversimplify;
 - explain what is known of the outcome at that point;
 - describe the next steps;
 - sincerely acknowledge the patient's and family's suffering.
4. actively listening:
 - allow ample time for questions;
 - do not monopolize the conversation;
5. acknowledging what you have heard.
6. responding to any questions.
7. concluding the conversation:
 - summarize;
 - repeat key questions raised;
 - establish the follow-up.
8. documentation:
 - describe the event;
 - describe the discussion.

Advanced communications techniques and open disclosure

It is important to note that there is a strong emotional context to adverse events. Patients may be frightened, feeling vulnerable, angry or frustrated. Students will need to build on their basic communication skills to be confident in dealing with emotionally charged situations. There are many tools to assist communicating with patients and carers. Typical examples asking patients to describe their feelings might include:

- *I imagine this is difficult news.*
- *You appear to be angry. Can you tell me what you are feeling?*
- *Does this news frighten you?*
- *Tell me more about what you are feeling about what I have just said.*
- *I'll try and help you.*
- *Is there anyone you would like me to call?*

Many medical schools have implemented communications training for students in recognition that good communication is a skill and requires teaching. Communication teaching sessions usually include teaching students how to ask the right questions, how to avoid being seen as “too defensive”, and how to show the patient that their concerns have been listened to and understood.

WHAT STUDENTS NEED TO DO (PERFORMANCE REQUIREMENTS):

- actively encourage patients and carers to share information;
- show empathy, honesty and respect for patients and carers;
- communicate effectively;
- obtain informed consent in an appropriate manner;
- show respect for each patient's differences, religious and cultural beliefs and individual needs;
- describe and understands the basic steps in an open disclosure process;
- apply patient engagement thinking in all clinical activities;
- demonstrate ability to recognize the place of patient and carer engagement in good clinical management.

The communication tool SPIKES [14] is used to assist health professionals to communicate bad news in “end-of-life” situations. SPIKES can be used more generally to assist communicating with patients and their caregivers in a wide range of situations—managing conflict, the elderly patient, difficult patients or those from different sociocultural backgrounds. Medical students can start practising some or all of the attributes listed below.

Examples of clinical situations where this structure could be useful include:

Practising SPIKES

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Step 1: setting (S)

Privacy

Students will observe in hospitals and clinics that sometimes privacy aspects of a patient's care and treatment is not optimal. The setting is important if sensitive material will be discussed. The patient

must be able to listen and ask questions with minimal disruptions. It is very important that the health professional and the patient are fully engaged with each other. For example, if a television is on, politely ask the patient to turn it off—this helps focus the patient on what you are going to be discussing.

Involve significant others

Patients should always be asked if they want to have a family member present to support them and help with information. Some patients, particularly the frail and vulnerable may need a person to help them make sense of the information. It is particularly important to let patients know that they can have someone with them if they wish.

Sit down

Medical students are often alert to the problems caused by doctors standing over a patient and will often comment on it in their early student years. However, with time they come to accept that this is normal and how things are done. Students should practise asking the patient's permission to sit down before doing so. Patients appreciate a doctor sitting down because it allows for direct communication and conveys to the patient that the doctor is not going to rush off.

It is important to always appear calm and maintain eye contact if this is culturally appropriate. Sometimes if a patient is crying it is best to look away and allow the patient some privacy and time to compose themselves.

Listening mode

An important role of a doctor is listening to the patient and not interrupting them when they are talking. Maintaining good eye contact and remaining quiet is a good way to show the patient your concern and interest.

Step 2: perception (P)

A good technique to understanding a patient is to first ask the patient what they think is going on. Then after they have talked it may be appropriate to obtain the relevant clinical information. This will enable the clinician and you the student to understand where the patient is in relation to their understanding of their situation.

Step 3: invitation (I)

Many students worry about how much information they should disclose to the patient. Different countries will have different rules for this process. A general rule that probably applies to most countries and cultures is to focus on each individual patient's informational needs. Patients are as varied as humanity and will differ in how much information they want or can cope with. Students should be guided by their supervisors in this area. Different clinicians will provide more or less; it is a good opportunity for the student to observe what works for the patient, and what works for different sorts of patients.

The informational needs of patients differ. If a patient has a family history of heart failure, the doctor may spend more time talking about the risks and paying attention to any anxieties the patient may have.

A simple rule to remember about risks is that all patients should be given information about treatments when there is potential for significant harm even if the risk is tiny and when side-effects, although minor, occur frequently. The application of this rule will help most clinicians to match patient informational needs. This approach enhances communication between the patient and the health provider by encouraging discussion.

Students will also observe that too much information at once can confuse patients.

Information overload can be avoided by asking some simple questions at the beginning of the consultation, for example:

How much information would you like me to give you about your diagnosis and treatment?

Medical students will quickly learn that patients will not retain important information given at a time of high anxiety, particularly if a difficult (for the patient) diagnosis is made. Some patients may not want a lot of information or make the decision about their treatment. However, discussion, explanations and answering questions are still necessary to maintain respect for autonomy.

Step 4: knowledge (K)

Effective communicators will always foreshadow to the patient that they will be covering some disturbing information. This gives the patient time to prepare, even if it is only a few minutes, for example: *Mr. Smith unfortunately I have some bad news for you...*

Step 5: empathy (E)

The following three steps will help students pay attention to the emotional needs of their patient:

- listen for and identify the emotion(s) and ask questions such as “*How does that make you feel?*” if you are unsure of the emotions being expressed or experienced;
- identify the source of the emotion;
- show the patient that you have identified their emotion and the origins of it.

It is inevitable that there will be some patients who are more difficult to treat than others. This could be because they have had previous bad health experiences and are angry, they could be frustrated because they have had to wait for treatment, they may be affected by drugs and alcohol, or have a mental illness. When a student comes across such a patient they should try to remember the dangers of stereotyping. It is not

uncommon for specific groups to be discriminated against in a busy hospital. When a patient or patient group (for example, injecting drug users) is stereotyped by the health-care team it is crucial that students are aware of how their own prejudices or preferences may interfere with their objectivity and decision-making. Indeed more care is required in these cases, not least because personal opinions and attitudes may cloud objective clinical judgement which may result in the wrong treatment or misdiagnosis.

Step 6: strategy and summary (S)

Summarizing the information at the end of the consultation is always a good idea. Patients may ask more questions or remember something important. If new issues come up at this last minute, make a time for another meeting.

Students should be encouraged to practise these activities as soon as they enter hospitals and clinics and are seeing patients. Taking a history from a patient is a prime opportunity to actively engage with a patient by listening, asking closed and open-ended questions and asking the patient if they understand their condition. Encouraging them to ask questions is a first step.

Promoting patients' involvement in their own care

It is known that patients who play active roles in the management of chronic health conditions seem to enjoy better outcomes over patients who play a more passive role in care [15-17].

Patients and their families can be made aware of opportunities to engage in adverse event prevention by:

- awareness raising/education about the risks of preventable harm;
- encouragement to speak up to providers about safety concerns.

HOW TO TEACH THIS TOPIC

Teaching strategies/formats

This topic can be broken up into sections to be included in existing curricula or can be taught as a stand alone learning activity. If the topic is being taught as a stand alone session, it can be delivered in a number of ways as listed below.

An interactive/didactic lecture

Use the accompanying slides as a guide covering the whole topic. The slides can be PowerPoint or converted to overhead slides for a projector. Start the session with the case study and get the students to identify some of the issues presented in the story.

A small group discussion session

One or more students could be presented with the topic and asked to lead a discussion about the areas covered in the topic. The students could follow the headings as outlined above and present the material. The tutor facilitating this session should also be familiar with the content so information can be added about the local health system and clinical environment.

Simulation exercises

Different scenarios could be developed about adverse events and the need to report and analyse errors.

Role plays involving discussions between patients and medical student in different situations could include:

- where there is a conflict in information;
- where the student does not know the information the patient wants;
- when a patient is complaining about a student;
- debriefing a student who has received a complaint.

Teaching activities

There are a number of different methods for generating discussion about the areas in this topic.

Law and ethics associated with disclosure following adverse events

The examples in this Curriculum Guide largely stem from Australia, the United Kingdom and the United States.

- Have a look at the ethics statements of your peak national medical association. What does it say about disclosure? Compare this with the position of your professional colleges.
- Find out about consumer representation bodies in your country.
- Have a look at your local media for stories of patients championing their rights.
- Invite a member of a doctor's insurance agency to take about common errors and advice to reduce them.

Patient complaints procedures



Invite a senior respected clinician to talk about how complaints are handled in their clinical practice.

- In relation to either of the case studies in this module or to real cases that have happened in your area, get the students to write a letter of apology using, for example, the Harvard tools.
- Have a look at one of the case histories. Work out what might be the costs that one of the patients subjected to error would need to recover from an insurer or be placed upon family. For example, loss of a job and ongoing treatments or even death
- Informally ask doctors what they think about patients being helped to make complaints. Rehearse the arguments with a fellow student as to why listening to the consumer voice can be a good thing.

Communication and disclosure

- Either in pairs or small groups get one student to take the part of one of the patients in the cases where a serious error has happened. Let the other student take the part of the doctor communicating the error. Debrief the students to see how they felt and what they learnt.
- Ask the students for examples of patient and carer engagement that they have lived through or their family have lived through.

Patient empowerment

- Ask students in pairs or small groups to gather information from patients about what makes them feel safe and conversely what things make them feel unsafe about their care.
- In pairs, get the students to talk to patients about ways they feel they could contribute to their own safety, e.g. checking medication. Let the students come back as a group and present their findings.

Cultural competence

- In small groups ask the students to consider the case study about cultural differences and get them to reflect on any differences in how doctors should communicate with patients from different cultural groups.
- Take an example where a patient has a life-threatening illness, e.g. cancer. Discuss with students any differences there might be between cultures as to what the patient should be told.
- Repeat the exercise where a patient has had an adverse event. Discuss with the students whether there are cultural differences in the way patients might react.

Activities for students in their clinical placements

- Follow a patient on their journey through the

health-care service.

- Follow the doctor who is consenting patients for a surgical list and reflect on that practice in relation to the framework for informed consent.
- Ask students to spend a day with another health professional (nurse, physiotherapist, social worker, pharmacist, dietician, interpreter) and explore some of the ways those particular professions engage with patients and carers.
- Ask students when they have patient encounters routinely seek to information about the illness or condition from the patient's perspective.
- Ask students to make inquiries of their hospital or health service about whether there are processes or teams to investigate and report on adverse events. Where possible, ask the students to seek permission from the relevant supervisor for them to observe or take part.
- Ask students to find out if the hospital conducts mortality and morbidity meetings or other peer review forums where adverse events are reviewed.
- Require the students to talk among themselves about errors they have observed in the hospital using a no-blame approach.
- Ask the students to select a ward or clinic where they are placed and inquire about a main protocol used by the staff. Get the students to ask how the guideline was written and how staff know about it and how to use it and when to deviate from it.

CASE STUDIES

Acknowledgment of medical error

Frank is a resident of an aged care facility. One night, a nurse mistakenly gave Frank insulin, even though he does not have diabetes. The nurse immediately recognised his error and brought it

the attention of the other staff, who in turn informed Frank and his family. The facility took immediate action to help Frank and arranged his transfer to a hospital where he was admitted and observed before being returned to the aged care facility. The nurse was commended for fully and immediately disclosing the incorrect administration of the insulin. Following this incident, the nurse undertook further training in medications to minimise the possibility of a similar error occurring.

Reference

Open Disclosure. *Case Studies—Volume 1*. Sydney: Health Care Complaints Commission, 2003: 16–18.

The importance of listening to a mother

This case illustrates the importance of examining each patient as individual and not blindly following rules.

Rachael, a single mother, gave birth to her first child. He was a healthy newborn of 37 weeks gestation, weighing 2700 grams. The birth was normal and mother and baby were stable one hour after delivery. She was informed by the nurse that everything was OK with both of them.

Breastfeeding started six hours after delivery. The nurse verbally told the doctor about some difficulties with the mother's breast and that the baby looked too sleepy. The hospital rules stated that that mothers were to be discharged 36 hours after birth, so the mother was prepared for early discharge.

Rachael was told by doctor A that everything was OK, that the baby has mild jaundice but that it will disappear in a couple of days because there was no incompatibility between the baby and mothers blood group, and breastfeeding should improve the next few days in this "healthy baby".

Another doctor (B) told her to return in a week to the hospital. While staying at home breastfeeding difficulties continued and the baby's jaundice increased. Rachael was afraid, and took the baby to the emergency room when he was 72 hours old. The doctor did not check the baby's weight but requested a bilirubin test. The result was 13.5 mg; he said that it was a low level for a 3-day-old baby and that everything was OK, so she should not have to come to the hospital when the baby was a week old. He advised Rachael to return in a week from that day and said, laughing, "Your baby is OK, do not be fearful. I know what I'm saying, I'm the doctor".

Over the next few days the baby required breastfeeding every hour and a half, and Rachael's breasts looked empty. She remembered having been told by the nurse while she was at the hospital not to take any supplements in order to stimulate milk production. Rachael's friends do not have children, so they said, "I do not know, but if the doctor said everything is OK, do not be paranoid, everything is OK".

Rachael took the baby to the hospital according to doctor B's advice, the baby was 10 days old, his weight had decreased 20% and his bilirubin test was 35 mg; during clinical examination the baby presented clear signs of bilirubin encephalopathy.

The hospital Advisory Board tried to understand why a healthy baby born from a healthy mother with a normal delivery developed this terrible and preventable situation.

Case from the WHO Patient Safety Curriculum Guide for Medical Schools working group. Supplied by Jorge Martinez, Universidad Del Salvador, Buenos Aires, Argentina.

Unpicking the concerns of patients / carers even when not fully expressed verbally is a key skill that needs to be mastered.

- We should never not take the mother's concerns into consideration, and should always take them seriously.
- We should never make them feel that they are having inappropriate concerns.

A letter from a patient

This letter presents a patient's perspective of her experience with her hospital.

I'm Alice, 25 years old. I had abdominal pain for six days and I was really frightened because my sister started a year ago with similar symptoms and now has intestinal cancer and is under a very aggressive treatment.

I decided to go alone to the hospital in order not to scare the whole family. I arrived at the hospital early in the morning. I didn't know exactly what to do or who to see; it was my first time at the hospital. Everybody looked in a hurry and they did not look very friendly. Some of them looked as frightened as I was.

I took a deep breath and asked a young lady who looked at me and smiled as if she knew where the gastrointestinal department was located. She laughed a little and said, "I'm a medical student and I'm lost too. Lets try together to find it, I have to go to the same place too". She said, "Why don't we go to the information office?" I thought it was a good idea, and all of sudden I started to feel in some way protected. A person I considered to be a health-care professional was with me.

We arrived at the information office to find it was crowded with a lot of people shouting, some of them angry. There was only one person providing information. Lucy, the medical student said, "I do not think we will get anywhere if we try to get information here". I thought we could follow the signals I had seen at the main entrance. I said, "Let's go".

After walking through the crowd, we arrived at the main entrance. We finally arrived at the gastrointestinal department. Lucy said, "Oh, yes, this is the place, ask the nurse over there; I should go to take my class, good luck".

The nurse told me that I shouldn't come directly to the gastrointestinal department, that I should go to the emergency department and they would decide about my condition. So, I had to return to the emergency room. When I arrived, plenty of people were waiting; they told me I would have to wait. "You should have come earlier", the nurse said (I arrived early!!).

A general practitioner eventually saw me and ordered X-rays and lab examinations. Nobody said anything and no explanations were provided to me. At that moment I was more scared than when I woke up with the pain.

I was at the hospital all day going from one place to another. At the end of the day, a doctor came and told me in few words you are OK, there is nothing to worry about, and I started "breathing" again.

I would like to say to the hospital authorities that they should realize that every person coming to the hospital, even if they do not have any important disease, is feeling stressed and often unwell. We need friendly people taking care of us, ones who try to understand our story and why we feel so bad. We need clear communication between health-care workers and patients. We need clear information on how we should use the hospital facilities in order to make best use of them. I understand that you cannot cure everybody--unfortunately you are not Gods--but I am sure that you could be friendlier to patients. Doctors and nurses have the incredible power that only with his/her words, gestures and comprehension of the patient situation, they can make a patient feel secure and relieved.

Please do not forget this power so incredibly useful for those human beings who enter your hospital.

With all my respect,

Alice

Case from the WHO Patient Safety Curriculum Guide for Medical Schools working group.
Supplied by Jorge Martinez, Universidad Del Salvador, Buenos Aires, Argentina.

TOOLS AND RESOURCES

WWW Key textbooks and references

Workshop: *Building the future for patient safety: developing consumer champions—a workshop and resource guide*. Chicago, Consumers Advancing Patient Safety. Funded by Agency for Healthcare Research and Quality (AHRQ) (<http://patientsafety.org/page/102503/>).

Patient-centred care: *Expanding Patient-Centred Care To Empower Patients and Assist Providers*. Research In Action, AHRQ, Issue 5, 2002 (<http://www.ahrq.gov/qual/ptcareria.pdf>).

Medical errors: *Talking about Harmful Medical Errors with Patients*. Seattle, University of Washington School of Medicine (<http://www.ihi.org/IHI/Topics/PatientCenteredCare/PatientCenteredCareGeneral/Tools/TalkingaboutHarmfulMedicalErrorswithPatients.htm>).

Open disclosure: *Open Disclosure Education and Organisational Support Package*. Open Disclosure Project 2002–2003, Australian Council for Safety and Quality in Healthcare <http://www.health.gov.au/internet/safety/publishing.nsf/Content/PriorityProgram-02>

Open disclosure guidelines: New South Wales Health Australia Quality and Safety Branch Open Disclosure Guidelines, May 2007 (http://www.health.nsw.gov.au/policies/gl/2007/pdf/GL2007_007.pdf).

Open disclosure: *A review of the literature*. Centre for Health Communication, February 2008 (<http://www.health.gov.au/internet/safety/publishing.nsf/Content/PriorityProgram-02>)

Disclosure of adverse events: *Disclosure of adverse events to patients*. VHA Directive 2005-049, Veterans Health Administration, US Department of Veterans Affairs, Washington, DC, October 2005 (http://www.sorryworks.net/pdf/VA_Link.pdf).

HOW TO ASSESS THIS TOPIC

Details of patient safety assessment are given in the Teacher's Guide (Part A). However, a range of assessment methods are suitable for this topic including essay, MCQ, SBA, case-based discussion and self-assessment. Students can be encouraged to develop a portfolio approach to patient safety learning. The benefit of a portfolio approach is that at the end of the students' medical training they will have a collection of all their patient safety activities. Students will be able to use this to assist job applications and their future careers.

The assessment of knowledge about patient engagement and open disclosure can include:

- portfolio;
- case-based discussion;
- OSCE station;
- written observations about the health system (in general) and the potential for error;
- reflective statements (in particular) about the
 - role patients play in hospitals or clinics;
 - consequences of paternalism;
 - role of senior clinicians in open disclosure process;
 - role of patients as teachers.

The assessment can be either formative or summative; rankings can range from unsatisfactory to giving a mark. See the forms in Appendix 2.

HOW TO EVALUATE THIS TOPIC

Evaluation is important in reviewing how a teaching session went and how improvements can be made. See the Teacher's Guide (Part A) for a summary of important evaluation principles.

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SLIDES FOR TOPIC 8: ENGAGING WITH PATIENTS AND CARERS

Didactic lectures are not usually the best way to teach students about patient safety. If a lecture is being considered, it is a good idea to plan for student interaction and discussion during the lecture. Using a case study is one way to generate group discussion. Another way is to ask the students questions about different aspects of health care that will bring out the issues contained in this topic such as the blame culture, nature of error and how errors are managed in other industries.

The slides for topic 8 are designed to assist the teacher deliver the content of this topic. The slides can be changed to fit the local environment and culture. Teachers do not have to use all of the slides and it is best to tailor the slides to the areas being covered in the teaching session.

Introduction to cluster topics 9–11

Putting knowledge into practice: infection control, medication safety and invasive procedures.

The following three cluster topics are best taught when the students are on placement and allocated to a clinical environment—ward or clinic.

Much of this Curriculum Guide will be new knowledge for the students. However, unless they apply this new knowledge in the workplace, beside the bed or in the operating rooms or clinics, there will be little change to the quality of the health care being provided by students and doctors or received by the patients. Students need to practise the techniques and behaviours described in this Curriculum Guide. The following three topics of infection control, medication safety and surgery and invasive procedures have been developed from a patient safety perspective. They are designed to maximize the student's ability to practise patient safety concepts and principles while on placements in the hospitals and clinics. Before teaching one or more of these topics it would be helpful to have some exposure to the concepts in the earlier topics, particularly the topics on teamwork, system thinking and errors.

Topic 4 “Being an effective team player” is essential prior learning for each of these cluster topics. Each of the following topics depends on every member of the health-care team (including the medical student) knowing the relevance and importance of accurate and complete communications with others including the patients and their families. Students should become familiar with the many techniques such as checking, checklists, briefings, de-briefings, feedback and timely handover during their time on the wards. When students see the relevance of such techniques they are more likely to be early adopters of such techniques.

The following three topics heavily rely upon the implementation of appropriate and authorised guidelines. Understanding the role of guidelines and why they are important to health care will show students that good patient outcomes are dependent on all the members of the health care team following the same treatment plans. Guidelines are designed to assist patient management using the best evidence available. Evidenced based practice uses the best evidence available to lessen variation and reduce risks to patients. There is plenty of evidence to show that the appropriate use of clinical guidelines can minimize adverse events caused by overuse, under use, and misuse of medical care [1,2].

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Topic 9: Minimizing infection through improved infection control

This topic acknowledges the work of the WHO Global Patient Safety Challenge: Clean Care is Safer Care and the Hôpitaux Universitaires de Genève.

Why infection control is relevant to patient safety

1

The spread of infection in health-care settings today affects hundreds of millions of people worldwide. In a WHO sponsored prevalence survey study [1] conducted in 55 hospitals of 14 countries representing four WHO regions (South-East Asia, Europe, the Eastern Mediterranean and the Western Pacific) it was found that, on average, 8.7% of hospital patients suffer health care-associated infections. At any time, over 1.4 million people worldwide suffer from infectious complications acquired while in hospital being treated for a medical condition. In the United States, about 90 000 patients die each year. Health care-associated increase suffering for the patients and keep them in hospital longer. Many suffer permanent disability and a significant number die. This alarming rate has led to increased attention by clinicians, managers, institutions and governments to preventing infection.

Box 6 lists some of the WHO statistics about the high rate of infection throughout the world. Everybody, health professionals and patients alike, has a responsibility to decrease the opportunities for contamination of clothing, hands and equipment that have been associated with transmission routes. This topic sets out the main areas where cross-infection occurs and identifies the activities and behaviours, which if routinely practised by everyone, would lead to reduced health care-associated infections.

Box 6. WHO: health care-associated infection: scale and cost

- Between 5% and 10% of patients admitted to modern hospitals in the developed world acquire one or more infections.
- The risk of health care-associated infection in developing countries is from 2 to 20 times higher than in developed countries. In some developing countries, the proportion of patients affected by a health care-acquired infection can exceed 25%.
- In the United States, 1 out of every 136 hospital patients becomes seriously ill as a result of acquiring an infection in hospital; this is equivalent to two million cases and about 80 000 deaths a year.
- In England, more than 100 000 cases of health care-associated infection lead to over 5000 deaths directly attributed to infection each year.
- In Mexico, an estimated 450 000 cases of health care-associated infection cause 32 deaths per 100 000 inhabitants each year.
- Health care-associated infections in England are estimated to cost £1 billion a year. In the United States, the estimate is between US\$ 4.5 billion and US\$ 5.7 billion per year. In Mexico, the annual cost approaches US\$ 1.5 billion.

Keywords

Infection control, hand hygiene, transmission, cross-infection, health-acquired infections, drug resistant, multidrug-resistant organisms, MRSA (methicillin-resistant staphylococcus aureus) infection, antiseptic handwashing agents, bloodborne virus infections.

Learning objective

The objective of this topic is to demonstrate the devastating effects of inadequate infection control and to show students know they can minimize the risks of contamination.

2

Learning outcomes: knowledge and performance

What students need to know (knowledge requirements):

- know the extent of the problem;
- know the main causes and types of infections.

3

What students need to do (performance requirements):

- apply universal precautions;
- be immunized against Hepatitis B;
- use personal protection methods;
- know what to do if exposed;
- encourage others to use universal precautions.

4

WHAT STUDENTS NEED TO KNOW (KNOWLEDGE REQUIREMENTS)

Know the extent of the problem

The urgency

The link between handwashing and the spread of disease was established about 200 years ago and until relatively recently, infection control was managed through the administration of antibiotics and the efforts of infection control nurses who generally considered infections an inevitable problem associated with an older and sicker population [2]. This is no longer the case, given the extent of the infected population, the different routes of transmission and the costs associated with it. Today, more than two billion people are infected with the airborne tuberculosis (TB) bacilli (the microbes which cause TB).

5

Multidrug-resistant TB remains a significant problem because the standard drugs are no longer working [3]. A number of antimicrobial-resistant organisms found in hospital settings such as MRSA, (methicillin-resistant staphylococcus aureus) and VRE (vancomycin-resistant enterococcus) also make treatment extremely difficult.

Each year, 490 000 new multidrug-resistant TB cases are diagnosed [4]. Over one million people died from TB in 2006, equating to 4500 deaths per day. TB is contagious and spreads through the air. One infected person can infect on average 10–15 people every year.

The increased rate of health care-associated infections in just the last 20 years in developing and developed countries has thrown up new challenges for modern health care. Today, antibiotics are often ineffective and more than 70% of hospital acquired bacterial infections are resistant to at least one of the drugs commonly used to treat them [5]. This means that this large group of infected patients stay longer in hospitals and are treated with less effective drugs that are more toxic, and/or more expensive. Among health care-associated infections, surgical site infections are a major source of infection. One study published nearly 20 years ago showed that in certain hospitals in sub-Saharan Africa [6] surgical site infections were the leading causes of illness and death. Health care-associated infections are also a problem in primary and community settings.

Country responses

Recognizing this worldwide crisis, WHO established the campaign *Clean hands are safer hands* and joins other campaigns by addressing the high infection rates through the implementation of endorsed guidelines aimed at reducing death from transmission of health care-associated infections [7,8].

6

The CDC's campaign to *Prevent antimicrobial resistance* aims to prevent antimicrobial resistance in health-care settings by a range of strategies aimed at preventing infection, diagnosing and treating infection, using antimicrobials wisely and preventing infection transmission. The campaign is targeting clinicians who treat particular patient groups such as hospitalized adults, dialysis patients, surgical patients, hospitalized children and long-term care patients [9].

The IHI campaign called the *5 million lives* aims to reduce MRSA infections through the implementation of five key interventions:

1. hand hygiene;
2. decontamination of environment, equipment;
3. active surveillance cultures;
4. contact precautions for infected and colonized patients;
5. compliance with central venous catheter and ventilator bundles.

Today, health-care professionals have to be vigilant in applying a range of prevention methods designed to control a variety of pathogens in all health-care environments, not just hospitals. When a student works on the wards, visits a clinic or does a home visit they are as capable of transmitting an infection as are all health-care workers. Multidrug-resistant organisms do not discriminate and while they are mainly found in acute care settings, any setting where patients are treated provides an opportunity for the emergence and transmission of antimicrobial-resistant microbes.

Student knowledge of universal precautions

The CDC [10] defines universal precautions as a set of precautions designed to prevent transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV) and other bloodborne pathogens when providing first aid or health care. Under universal precautions, blood and certain body fluids of all patients are

considered potentially infectious for HIV, HBV and other bloodborne pathogens. The precautions require students to apply infection control principles as set out above—correct handwashing, using gloves, a mask, a gown and eyewear and handle needles safely as well as safe disposal.

A 2006 cross-sectional study of medical staff and medical students at two hospitals in Iran showed that only 54% of students had heard about universal precautions [11]. Students should be habitually applying universal precautions as soon as they enter the hospital environment. It is easier to learn how to do something right the first time than trying to undo bad habits.

The economic burden

The costs associated with caring and treating patients suffering from infections are significant and have added a substantial economic burden to the health-care budgets of all countries. Estimates of the cost of infections range from US\$ 4500–5700 million a year in the United States, £1000 million a year in the United Kingdom, 5% of the annual budget of a county hospital in Trinidad and Tobago and up to 10% of Thailand hospital budgets and 70% of the entire health budget for Mexico [1].

The main causes and types of infections

Main types of infections

Infectious diseases are caused by pathogenic micro-organisms such as bacteria, viruses, parasites or fungi; the diseases can be spread, directly or indirectly, from one person to another. Zoonotic diseases are infectious diseases of animals that can cause disease when transmitted to humans.

Health care-associated infections

Infections are caused by bacteria, fungi or viruses entering the body through one or more of the following routes.

7

- person–person via hands of health-care providers patients and visitors;
- personal equipment (e.g. stethoscopes, computers) and clothing;
- environmental contamination;
- airborne transmission;
- carriers on the hospital staff;
- rare common-source outbreaks.

Patients vulnerable to colonization and infection include those with severe disease, recent surgery or implanted medical devices such as urinary catheters or endotracheal tubes. Epidemiological evidence suggests that multidrug-resistant organisms are carried from person-to-person by health-care professionals.

WHO [12] defines a health care-associated infection (also called “nosocomial”) as:

An infection acquired in hospital by a patient who was admitted for a reason other than that infection [1]. An infection occurring in a patient in a hospital or other health-care facility in whom the infection was not present or incubating at the time of admission. This includes infections acquired in the hospital but appearing after discharge, and also occupational infections among staff of the facility [4].

The following four types of infections [13] account for more than 80% of all health care-associated infections:

8

- urinary tract infections usually associated with catheters:
 - catheter-associated urinary tract infections are the most frequent, accounting for about 35% health care-associated infections;
- surgical infections:
 - these are second in frequency, about 20%;

- bloodstream infections associated with the use of an intravascular device:
 - about 15%;
- pneumonia associated with ventilators:
 - about 15%.

The evidence shows that infections rates in the first two categories can be reduced when health-care workers comply with infection control guidelines and patients leave hospital as soon as possible. Many infected patients (about 25%) are in an ICU with more than 70% of the patients having micro-organisms resistant to one or more antibiotics [13].

9

Preventing health care-associated infections in four areas

Over the course of training, medical students will experience many environments where there is a risk of transmission of infection. Students should approach every situation as having the potential to infect a patient or a health-care worker or themselves. This means that students will need to routinely undertake activities to prevent infection such as correct handwashing, effective sterilization procedures and correct gloving and gowning.

Infections are preventable when health-care workers use the right techniques and remain on the look out for unclean and unsafe situations.

1. *In the hospital*

10

Studies show infections are minimized when hospitals are:

- are visibly clean;
- use increased levels of cleaning during outbreaks;
- use hypochlorite and detergents during outbreaks.

2. *Personal attention to handwashing*

Everyone working in health care, whether it is a hospital or a clinic, needs to be aware of hand

hygiene. Applying correct hand hygiene procedures requires medical students to understand why hands need to be decontaminated.

Decontamination refers to the process for physical removal of blood, bodily fluids and the removal or destruction of micro-organisms from the hands. WHO has developed easy-to-follow brochures and diagrams to help health-care workers follow correct handwashing procedures, available on the WHO web pages at http://www.who.int/gpsc/tools/Five_moments/en/index.html

In addition, students need to:

- know how to clean hands;
- the rationale for choice of clean hand practice;
- techniques for hand hygiene;
- how to protect hands from decontaminants;
- promote adherence to hand hygiene guidelines.

11

Handwashing today is the single most important intervention *before and after* patient contact. Every health-care worker is required to act responsibly and without fail to apply the techniques for handwashing at every patient encounter. They also should advise patients and families of the importance of handwashing and give them permission to remind the staff.

Hospitals can make it easier for staff by providing alcohol hand rubs beside the beds. Alcohol rubs rapidly kill bacteria and have few side-effects for the staff. However, when hands are heavily soiled, alcohol rubs are not a substitute for soap.

Factors to consider to maintain clean hands:

- the level of contact with the patient or objects;
- the extent of the contamination that may occur with the contact;

- the activities being performed;
- the susceptibility of the patient.

How to clean hands:

- limited studies available to test the technique of hand decontamination;
- methods based on expert opinion:
 - before clinical shift begins remove all wrist and hand jewelry;
 - cuts and abrasions covered with waterproof dressings;
 - fingernails kept short clean and free from nail polish.

Effective handwashing technique:

- preparation:
 - wetting hands under tepid running water;
 - washing and rinsing.
- then apply liquid soap or antimicrobial preparation:
 - solution must have contact with whole surface area of hands—vigorous rubbing of hands for 10–15 seconds (especially tips of fingers, thumbs and areas between fingers).
- drying:
 - use good quality paper towel.

See a handwashing technique described in a leaflet developed by WHO to assist health-care workers at <http://www.who.int/gpsc/tools/GPSC-HandRub-Wash.pdf>, accessed April 2008

Promoting the use of hand hygiene guidelines

- The use of protective equipment:
 - assess the risks to patients, carers and self;
 - everyone should be educated about standard principles and trained in the use of protective equipment;
 - adequate supplies of disposable aprons, single use gloves and face protections are easily available wherever care is delivered;
 - gowns should be available on the advice of the infection control team.

3. *The use of personal protective equipment*

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Personal protective equipment includes the use of gowns, gloves, aprons, eye protection and face masks. Students will usually be told by a supervisor or tutor the type of protective equipment that should be used for each procedure. This is usually based on assessment of the risk of micro-organism transmission to the patient or to the carer as well as the risk of contamination of the health-care practitioner's clothing and skin by the patient's blood, bodily fluids, secretions or excretions.

Gloves

Gloves are now an everyday part of clinical practice. There are two main indicators for wearing gloves in the clinical setting:

- to protect the hands from contamination with organic matter and micro-organisms;
- to reduce the risk of transmitting micro-organisms to both patients and staff.

Even if a student is required to wear gloves this does not replace the need for cleaning one's hands. Gloves are not free from defects and sometimes leak. If a glove tears, is damaged in any way or leaks, the student should remove the gloves to perform hand hygiene and replace with new gloves. Every time a glove is worn it must be discarded appropriately after each task and the hands cleaned. This is because gloves are made for single use because they can carry micro-organisms.

However, health-care professionals still need to assess whether gloves are needed because overuse can lead to skin sensitivity and adverse reactions. Although standards exist for the quality of medical gloves, studies show that even when gloves are worn there is the possibility of contamination. The use of gloves as a barrier method cannot be relied upon to remove all of the risks associated with contaminated hands. The

following principles apply.

- gloves must be worn for:
 - all invasive procedures;
 - contact with sterile sites;
 - contact with non-intact skin or mucous membranes;
 - all activities assessed as having a risk of exposure to blood, bodily fluids, secretions and excretions, and handling sharps or contaminated instruments.
- gloves should be worn only once and should be put on immediately before the care activity, removed immediately afterwards and changed between patients and episodes of care;
- gloves must be disposed of as clinical waste and hands must be decontaminated by washing appropriately.

Aprons (gowns) and face masks

A few studies show high levels of vancomycin-resistant enterococci contamination of gowns, gloves and stethoscopes immediately after contact with infected patients. International guidelines recommend that protective clothing be worn by all health-care workers who have close contact with the patient and the patient's equipment or materials. Students should be guided by their clinical teachers as to the type of clothing to be worn.

Guidelines suggest that health-care professionals:

- wear disposable plastic aprons when in close contact with the patient, material or equipment or when there is a risk that clothing may become contaminated;
- dispose of plastic aprons after each episode of care or procedure. Non-disposable protective clothing should be sent for laundering;
- wear full-body, fluid-repellent gowns when there is a risk of extensive splashing of blood, bodily fluids, secretions or excretions with the exception of perspiration.

Face masks and eye protection should be worn when there is a risk of blood, bodily fluids, secretions and excretions splashing into the face and eyes. Respiratory protective equipment is to be worn when caring for patients with respiratory infections transmitted by airborne particles.

4. *The safe use and disposal of sharps*

13

Students should be aware of the significant problem for health-care workers caused by needle stick injuries, which are as prevalent as injuries from falls and handling and exposure to hazardous substances. Many health-care workers continue to be infected by bloodborne viruses even though they are largely preventable:

- keep handling to a minimum;
- do not recap needles, bend or break after use;
- discard each needle into a sharps container at the point of use;
- do not overload a bin if it is full;
- do not leave a sharp bin where children can reach it.

These safety measures are repeated below in the checklist for universal precautions.

Tuberculosis (TB)

The WHO web site demonstrates through its numerous reports that describe the prevalence and the devastating effects and suffering caused by TB. In response to rising rates of TB, a major campaign to stop the increase has been initiated in many countries with some small success. Students need to be aware of their own role in minimizing the spread of TB. TB is spread via the air from people who have TB affecting the lungs. It is contagious. The disease is spread by coughing, sneezing, talking or spitting that send the TB germs (bacilli) into the air. People then breathe in the bacilli. Some people will not develop an infection because their immune system keeps it dormant. When the immune system fails a person

the disease will become active and the person becomes infectious. Students should apply universal precautions at all times. Universal precautions are described later in this topic. If TB is a major problem in your country then additional information about the prevalence of TB in your country and strategies for containing the spread of TB would be appropriate to cover.

WHAT STUDENTS NEED TO DO (PERFORMANCE REQUIREMENTS)

Medical students have a responsibility to make every effort to minimize the spread of infection and to encourage patients and other health-care workers to actively engage in practices that minimize the spread of infection both in the community and in the hospitals and clinics.

Students need to

14

- practise universal precautions;
- be immunized against Hepatitis B;
- use personal protection methods;
- know what to do if exposed;
- encourage others to use universal precautions.

Apply universal precautions

15

WHO has developed the following checklist for health-care workers.

Practise universal precautions [8]

Students must handwash after any direct contact with patients.

The WHO campaign has published techniques for correct handwashing and safe health care. The following strategies can be found on the web pages of the WHO *Clean hands are safer hands* campaign at

http://www.who.int/gpsc/tools/Five_moments/en/index.html, accessed April 2008

Before contact with each and every patient a student should clean their hands before touching a patient.

This is important to protect the patient against harmful micro-organisms carried on the hands. Students may have been travelling on a bus immediately before entering the hospital and the ward where they intend to take a history from a patient. In doing so they may shake the hand of the patient or comfort the patient as a humane gesture. They may also be requested to assist a patient to move from the bed to a chair, or to a sitting area for more privacy. They might be required to perform a physical examination, take the pulse of the patient or blood pressure and abdominal palpation.

A student should clean hands before an aseptic task.

It is essential that students clean their hands immediately before any aseptic task. This is necessary to protect the patient against harmful micro-organisms, including the patient's own micro-organisms, entering his or her body. Students must protect against transmission through contact with mucous membrane: oral/dental care, giving eye drops, secretion aspiration. Often students will be treating patients who have open wounds and any contact with non-intact skin: skin lesion care, wound dressing, any type of injection is an opportunity for transmission. Medical devices are well known for harbouring potentially harmful micro-organisms and contact with devices such as catheter insertion, opening a vascular access system or a draining system must be done with careful preparation. Students should also be diligent in preparation of food, medications and dressing sets.

After contact with each and every patient a student should clean hands after any risk of exposure to body fluids.

Students should habitually clean their hands

immediately after an exposure risk to body fluids and after glove removal. Cases of transmission have been known to occur even with gloving. This is essential to limit the opportunity of the student receiving an infection. It is also necessary to maintain a safe health-care environment.

Medical students will inevitably come into contact with mucous membrane and with non-intact skin, as detailed in the indication "before aseptic task". Understanding the risks will help the student practise safe health care. They will also have contact with medical devices or clinical samples such as drawing and manipulating any fluid sample, opening a draining system, endotracheal tube insertion and removal.

At times they will be required to clean up a patient's urine, faeces or vomit. Students often help out in the hospital and clinic and may find themselves handling waste (bandages, napkin, incontinence pads), cleaning of contaminated and visibly soiled material or areas (lavatories, medical instruments). They need to be particularly aware of the importance of clean hands after such activities.

Students should wash hands after actual patient contact.

All students should clean their hands after touching a patient and his or her immediate surroundings. This should be done using one of the methods available to the clinic or hospital immediately after the patient contact is over. This is because in busy environments there are many distractions and busy people tend to rush onto the next job or patient. Many people forget in the rush to wash their hands. Forgetting to wash hands can lead to the student getting an infection and increasing the chances of the micro-organisms spreading throughout the environment. Saying goodbye to the patient by shaking a hand or touching a shoulder provides opportunities for micro-organisms to be transferred to the student

and vice versa. Activities in addition to those mentioned above that involve direct physical contact include helping a patient to move around, to get washed or to give a massage, which are known routes for micro-organisms spreading to others. Students performing clinical examination such as taking pulse, blood pressure, chest auscultation and abdominal palpation are all opportunities for cross-infection.

Students must handwash after contact with patient surroundings

Micro-organisms are also known to survive on inanimate objects. So it is important to clean one's hands after touching any object or furniture in the patient's immediate surroundings when leaving them, even without touching the patient. Students may find themselves helping other staff and change bed linen, adjust perfusion speed, monitor an alarm, hold a bed rail or make room on a side bed table for a patient.

In addition:

- Needles should never be recapped;
- All sharps should be collected and safely disposed;
- Students should use gloves when in contact with bodily fluids, non-intact skin and mucous (see more about this below);
- Students should wear a face mask, eye protection and a gown if there is the potential for blood or other bodily fluids to splash;
- Students should cover all cuts and abrasions including their own;
- Students should always clean up spills of blood and other bodily fluids;
- Students should make themselves aware of how the hospital waste management system works.

Students should be immunized against Hepatitis B [14]

Students, like all health-care workers, are at risk

of infection with bloodborne viruses. The risk of infection to both staff and patients depends on the prevalence of disease in the patient population and the nature of the frequencies of exposures. Students should:

- be immunized as soon as they start seeing patients in hospitals, clinics and the community or in the homes of patients;
- if possible conduct a post-vaccination test.

Students should use personal protection methods [14]

- use needle stick prevention devices where possible;
- let people know if supplies of personal protection are running low;
- provide feedback to the health-care team about the personal protective equipment;
- seek training in use of the equipment;
- model practice on respected and safe senior clinician;
- regularly perform a self-assessment of one's use of personal protective equipment and whether there has been any inappropriate use.

Students should know what to do if exposed [14]

If a student is inadvertently exposed or becomes infected they should immediately:

- notify the appropriate staff in the hospital or clinic as well as a supervisor. It is important that students receive appropriate medical attention as soon as possible.

Students should encourage others to participate in infection control

16

Be a role model:

- Students can encourage each other to use correct handwashing techniques by doing so themselves. Students can be leaders in this respect. If another health-care provider has poor technique and finishes much sooner than the student and does not wash his

hands but the student does, it may remind the health-care worker of the correct procedure. Sometimes people only need to be reminded to jolt them out of a false sense of security.

- Students can teach patients about the importance of handwashing: They will often have more time with patients than fully-qualified colleagues. It is also a good time to practise their skills on educating patient about health care and prevention.

Interacting with health-care professionals:

- Students may find themselves working in a clinic or hospital where the health-care professionals including doctors do not follow the institutional or professional guidelines for infection control. They may even observe senior doctors not washing hands or failing to maintain sterile environments. It can be very difficult for students to speak up on such occasions. Culturally, it may not be conceivable that a junior member of staff would challenge a more senior member. Safe health care requires students to maintain the correct techniques even if there is pressure on them to skip some steps. If a student is being pressured to cut corners they should still try to maintain the proper technique. .

Students may routinely observe staff who apply inadequate technique in handwashing.

- When this occurs students should maintain correct handwashing techniques and if appropriate have a discussion about the techniques used in the hospital or clinic and the reasons for the variation. However, in many cultures this may not be appropriate.

Students may routinely observe staff who fail to wash hands.

- How a student deals with this situation will depend on the relationship of the student to

the person who fails to wash their hands, the culture of the hospital and the culture of the society. It could be that a health-care worker was so busy that they inadvertently forgot to wash their hands. The student will have to make a judgement about this based on their knowledge of the doctor's or nurse's habits. If the student knows the person to be very attentive then it may be appropriate to raise it with the person or assist them by handing the alcohol rub or substances in use. In some circumstances such as gatherings of students it may be appropriate to reinforce the importance of correct handwashing technique.

Students may routinely observe staff who ignore correct infection control procedures.

Students may wish to ask the supervisor or team leader to put the issue of handwashing and infection control on the agenda for discussion. Alternatively, they could ask the department head if an expert can come and talk to the staff so that everyone is aware of the infection control guidelines.

Summary

17

- know the main guidelines in each of the clinical environments you are assigned;
- accept responsibility for minimizing opportunities for infection transmission;
- apply universal precautions;
- let staff know if supplies are inadequate or depleted;
- educate patients and families/visitors about clean hands and infection transmission;
- ensure patients on precautions have same standard of care as others:
 - frequency of entering the room;
 - monitoring vital signs.

HOW TO TEACH THIS TOPIC

Teaching strategies/formats

This topic can be delivered in a number of ways but the best way for this topic is to have the students practising infection control techniques in a simulated environment.



Simulation exercises

Different scenarios could be developed that are written to emphasize the educational components of infection control. Students attending the Israel Center for Medical Simulation (<http://www.msr.org.il>) practise washing their hands and then the hands are covered with a “blue gel” and put under a ultraviolet light to reveal the areas that were missed in washing hands. Students are surprised at how much they miss.

Different scenarios could be developed that are written to emphasize the educational components of infection control, for example:

- practising the techniques of assertiveness in different situations:
 - patient–doctor interactions in which the doctor fails to wash their hands;
 - student–patient interactions in which the student fails to wash their hands;
 - student–supervisor interactions in which the supervisor fails to wash their hands;
- role play using a “person approach” and then a “system approach” to a breach of infection protocols.



An interactive/didactic lecture

Use the accompanying slides as a guide covering the whole topic. The slides can be PowerPoint or converted to overhead slides for a projector. Start the session with a case study selected from the Case Study Bank and get the students to identify some of the issues presented in the story.

Panel discussions

Invite a panel of respected clinicians to give a summary of their efforts to minimize the transmission of infection. Students could have a pre-prepared list of questions about the prevention and management of infections.



Small group discussion session

The class can be divided up into small groups and three students in each group be asked to lead a discussion about the causes and types of infection. Another student could focus on the reasons why some hospitals either support correct handwashing techniques or ignore them.

The tutor facilitating this session should also be familiar with the content so information can be added about the local health system and clinical environment.

Teaching activities

This topic offers many opportunities for integrated activities during the time when students are assigned to any of the wards or clinics. These activities can start from the very first years in the hospital and clinic environments.

Operating room and ward activities

Students could also visit a patient who has an infection as a result of their health care. They could discuss with the patient the impact of the infection on their health and well-being. The meeting is not to discuss how or why the patient was infected but rather to discuss the impact of the infection

Students attend an infection control meeting observe and record what activities are undertaken by the team to ensure that everyone complies with the infection control guidelines

Students could observe a team who is treating patients who are known to have infections. They

should observe if they do anything differently to other health-care workers.

Students could follow a patient through the peri-operative process and observe the activities aimed at minimizing transmission of infection.

Students should examine and critique the protocol used for infection control including observations of the team's knowledge and adherence of it.

After these activities students should be asked to meet in pairs or small groups and discuss with a tutor or clinician what they observed and whether the features or techniques being observed were present or absent, and whether they were effective.

CASE STUDIES

Hepatitis C: reusing needles

This case shows how easy it is to inadvertently reuse a syringe.

Sam, a 42-year-old man, was booked for an endoscopy at a local clinic. Prior to the procedure he was injected with sedatives, but after several minutes the nurse noticed Sam seemed uncomfortable and required additional sedation. She used the same syringe, dipped it in the open sedative vial and re-injected him. The procedure continued as normal.

Several months later, Sam, suffering from swelling of the liver, stomach pain, fatigue and jaundice, was diagnosed with Hepatitis C. The Centers for Disease Control was contacted, as 84 other cases of liver disease were linked to the clinic. It was believed that the sedative vial may have been contaminated from the backflow into the syringe and that the virus may have been passed on from the contaminated vial. Several health-care workers

commented that reusing the syringe on the same patient (and thus dipping a used syringe into a common vial) was common practice.

Reference

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Bloody cuffs

This case illustrates the importance of adhering to infection control guidelines. It also illustrates why people should always adopt procedures that assume a possible transmission.

Jack, a 28-year-old male, and Sarah, a 24-year-old woman, were involved in a severe motor vehicle collision when Jack's car slammed into a cement pillar. They were brought into the emergency department with Jack suffering massive injuries and Sarah with severe cuts to her upper body from the shattered glass of the car. Jack was bleeding profusely when he was placed in the trauma bay. His blood pressure was taken and the cuff (made of nylon and fabric) became completely saturated with blood, so much that it could be wrung out. He was taken to surgery but later died.

Sarah, with cuts to her upper body, was placed in the same trauma bay where Jack had been treated. The same, unwashed, blood saturated cuff that was used on Jack was placed on her arm.

One nurse noted that the blood soaked cuff had been used on both patients; however, other staff members shrugged off the incident.

A letter from the medical examiner weeks later revealed that Jack was HIV and HBV positive and that the motor vehicle collision had been a suicide.

Reference

AHRQ – Agency for Healthcare, Research and Quality Web mortality and morbidity
<http://www.webmm.ahrq.gov/case.aspx?caseID=12&searchStr=bloody+blood+pressure+cuff>

A failure to check a child's intravenous drip site

A father brought his 2-year-old daughter Chloe into the emergency department of a regional hospital on a Friday evening. Chloe had a recent history of a 'chesty cold' and had already been seen as an outpatient. The medical officer admitted Chloe for treatment of pneumonia. An intravenous (IV) cannula was inserted in her left upper foot and a bandage applied. Chloe was admitted to the ward and was under the care of nursing staff, a general practitioner and visiting medical officer over the weekend.

The intravenous cannula site was not inspected until early on Sunday evening (nearly 48 hours later), despite the fact that damage to the skin is a known risk factor in infants that can occur within 8 to 12 hours. There was an area of necrosis noted on the left heel and ulcers developed later on the left upper foot. After discharge and outpatient treatment locally, Chloe was eventually admitted to a major children's hospital where she required ongoing treatment. She also developed behavioural problems as a result of her experience.

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TOOLS AND RESOURCES

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HOW TO ASSESS THIS TOPIC

A range of assessment methods are suitable for this topic including observational reports, reflective statements about surgical errors, essays, MCQ paper, SBA, case-based discussion and self-assessment. Students can be

encouraged to develop a portfolio approach to patient safety learning. The benefit of a portfolio approach is that at the end of the student's medical training they will have a collection of all their patient safety activities. Students will be able to use this to assist job applications and their future careers.

The assessment of knowledge about infection control is assessable using any of the following methods.

- portfolio;
- case-based discussion;
- OSCE station;
- written observations about how a hospital or clinic practises infection control;
- reflective statements (in particular) about:
 - how a hospital or clinic educates staff about infection control;
 - the role of hierarchy in the hospital influences infection control practices;
 - the systems in place for reporting breaches of infection control;
 - the role of patients in minimizing the transmission of infection;
 - the effectiveness or the infection control guidelines.

The assessment can be either formative or summative; rankings can range from unsatisfactory to giving a mark. See the forms in Appendix 2.

HOW TO EVALUATE THIS TOPIC

Evaluation is important in reviewing how a teaching session went and how improvements can be made. See the Teacher's Guide (Part A) for a summary of important evaluation principles.

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SLIDES FOR TOPIC 9: MINIMIZING INFECTION THROUGH IMPROVED INFECTION CONTROL

Didactic lectures are not usually the best way to teach students about patient safety. If a lecture is being considered, it is a good idea to plan for student interaction and discussion during the lecture. Using a case study is one way to generate group discussion. Another way is to ask the students questions about different aspects of health care that will bring out the issues contained in this topic such as the blame culture, nature of error how errors are managed in other industries.

The slides for topic 9 are designed to assist the teacher deliver the content of this topic. The slides can be changed to fit the local environment and culture. Teachers do not have to use all of the slides and it is best to tailor the slides to the areas being covered in the teaching session.

Topic 10: Patient safety and invasive procedures

Why patient safety is relevant to surgery and invasive procedures

1

There is now plenty of evidence to show that patients who undergo a surgical or an invasive procedure are at increased risk of suffering an adverse event [1-3]. This is not because the surgeons and proceduralists are careless or incompetent, rather it is because we now know about the many opportunities for things to go wrong because of the many steps involved in surgical procedures. In addition, there are the problems caused by surgical site infections that account for a significant proportion of all health care-associated infections. This topic will assist students to understand how patient safety principles can assist in minimizing adverse events associated with invasive procedures. There are many validated guidelines now available to assist the health-care team deliver safe surgical care. There may not be many opportunities for students to implement many of these steps to improve surgical outcomes. Nonetheless they can observe how the health professionals communicate with one another and what techniques they use to make sure they are operating on the correct person or doing the procedure on the correct body part. They can also observe what happens when health-care professionals appear not to follow a protocol. Does this make their job harder or easier?

Keywords

Surgical and procedural site infections, surgical/procedural errors, guidelines, communication failures, verification processes, teamwork.

Learning objective

2

The objective of this topic is to understand the main causes of adverse events in surgical and invasive procedural care and how the use of guidelines and verification processes can facilitate the correct patient receiving the correct procedure at the appropriate time and place.

Although the principles described in this topic are important for both surgical and invasive procedures, most of the evidence in the literature relates to surgical care.

Learning outcomes: knowledge and performance

What does a student need to know (knowledge requirements):

3

- the main types of adverse events associated with surgical and invasive procedures care;
- the verification processes for improving surgical and invasive procedures care.

What a student needs to do (performance requirements):

4

- follow a verification process to eliminate wrong patient, wrong side and wrong procedure;
- practise operating room techniques that reduce risks and errors (time-out, briefings, debriefings, stating concerns);
- participate in an educational process for reviewing surgical and invasive procedures mortality and morbidity.

WHAT STUDENTS NEED TO KNOW (KNOWLEDGE REQUIREMENTS)

The main types of adverse events associated with surgical and invasive procedural care

5

The traditional way of explaining adverse events associated with surgery and invasive procedures is usually related to the skills of the surgeons and the age and physical conditions of the patients. Vincent and colleagues [1] believed that adverse surgical (and other procedural) outcomes are associated with many other factors such as quality of the design-interface, teamwork and organizational culture. Students should have

learnt about a system approach in topic 3 as well as the topics on teamwork and infection control all of which is particularly relevant to this topic.

A systems approach to surgical and procedural adverse events requires us to examine both latent factors such as teamwork and inadequate leadership and sharp end factors such as communication during handoffs and poor history taking.



The three main causes of adverse events in surgical care are:  (Infection control)

1. Poor infection control methods

The Harvard Medical Practice Study II [2] found that surgical-wound infections constituted the second-largest category of adverse events and confirmed the long-held belief that hospital-based staphylococcal infections constituted a great risk for hospitalized patients, particularly those receiving surgical care. The implementation of safer infection control practices such as the appropriate administration of prophylactic antibiotics has reduced postoperative infections. In addition, increased attention to the risks of transmission show health-care workers how they as individuals and members of teams can minimize the risks of cross-infection.

Everyone has a responsibility to decrease the opportunities for contamination of clothing, hands and equipment that have been associated with transmission routes. Infection control is studied in more detail in topic 9. Students during their training will be present during an operation or invasive procedure. They must at all times comply with the infection control guidelines and practise universal precautions.

2. Inadequate patient management

The operating room and environment involves intensely complex activities that may explain why

there are more adverse events associated with surgery when compared to other hospital departments.

The main adverse events associated with surgical care include:

- infections and postoperative sepsis;
- cardiovascular complications;
- respiratory complications;
- thromboembolic complications.

When these events have been analysed, a range of pre-existing conditions (latent factors) have been identified. Some of these are:

- inadequate implementation of protocols or guidelines;
- poor leadership;
- poor teamwork;
- conflict between the different departments and the organization;
- inadequate training and preparation of staff;
- inadequate resources;
- lack of evidenced-based practice;
- poor work culture;
- overwork;
- lack of a system for managing performance.

In addition to latent factors, individuals working at the sharp end of peri-operative care are prone to the following types of errors known to cause adverse events, including:

- communication failures:
 - information is provided too late to be effective;
 - information is inconsistent or inaccurate;
 - key people are excluded from the information;
 - there are unresolved issues in the team;
- failure to take precautions to prevent accidental injury;
- wound infections, other wound problems, technical problems and bleeding;

- avoidable delays in treatment;
- failure to take adequate history or physical examination;
- failure to employ indicated tests;
- failure to act upon the results of findings or tests;
- practising outside an area of expertise (failure to consult, refer, seek assistance, transfer).

3. Failure by health-care providers to communicate effectively before, during and after operative procedures.

One of the biggest problems in the operating environment is miscommunication.

Miscommunication has been responsible for the wrong patients having surgery, patients having operations on the wrong side or site and having the wrong procedure performed. Failure to communicate changes in the patient's condition and failure to administer prophylactic antibiotics have also resulted in adverse events. In addition, disagreements about stopping procedures or failing to report errors have been documented.

Health professionals are often required to deal with many competing tasks in the operating room. A surgical term is viewed by most trainees and students as a very busy term. In addition to high workloads, the peri-operative environment is characterized by staff with varying levels of experience and abilities. This combination of factors can seriously impact on the team's ability to communicate accurately and timely. Communication problems occur at all stages—but particularly when patients are transferred from one phase of care to another.

The extent of adverse surgical events involving wrong site surgery [3] led The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) [4] to include wrong site surgery in its national database of "sentinel events". Many countries now collect data about wrong

patient/invasive procedures because it is recognized that one of the best ways to reduce errors caused by misidentification involves implementing best-practice guidelines for ensuring the correct patient receives the correct treatment. The evidence convincingly demonstrates that when health-care professionals follow endorsed guidelines and are familiar with the underlying principles supporting a uniform approach to treating and caring for patients, patient outcomes significantly improve.

The complexity of the surgical environment is a major factor underpinning communication errors and they occur at all levels. A study by Lingard and colleagues [5] described the types of communication failures that are set out in Table 17.

For a real example of how errors can occur in surgical procedures see <http://www.gapscenter.va.gov/stories/WillieDesc.asp> (accessed January 2009).

In the Lingard study [5], 36% of communication failures resulted in a visible effect such as team tension, inefficiency, waste of resources and inconvenience to patients or procedural error.

Table 17. Types of communication failure with illustrative examples and notes

Type of Failure	Definition	Illustrative example and analytical note (in italics)
Occasion	Problems in the situation or context of the communication event	The staff surgeon asks the anaesthetist whether the antibiotics have been administered. At this point, the procedure has been under way for over an hour. <i>Since antibiotics are optimally given within 30 minutes of incision, the timing of this inquiry is ineffective both as a prompt and as a safety redundancy measure.</i>
Content	Insufficiency or inaccuracy apparent in the information being transferred	As the case is set up, the anaesthesia fellow asks the staff surgeon if the patient has an ICU bed reserved. The staff surgeon replies that the “bed is probably not needed, and there is not likely one available anyway, so we’ll just go ahead”. <i>Relevant information is missing and questions are left unresolved: Has an ICU bed been requested, and what will the plan be if the patient does need critical care and an ICU bed is not available? (Note: this example was classified as both a content and a purpose failure.)</i>
Audience	Gaps in the composition of the group engaged in the communication	The nurses and the anaesthetist discuss how the patient should be positioned for surgery without the participation of a surgical representative. <i>Surgeons have particular positioning needs so they should be participants in this discussion. Decisions made in the absence of the surgeon may lead to the need for re-positioning.</i>
Purpose	Communication events in which purpose is unclear, not achieved or inappropriate	During a living donor liver resection, the nurses discuss whether ice is needed in the basin they are preparing for the liver. Neither knows. No further discussion ensues. <i>The purpose of this communication—to find out if ice is required—is not achieved. No plan to achieve it is articulated.</i>

The verification processes for improving surgical care



Guidelines

One of the most effective methods for improving patient care is to implement an evidenced-based guideline especially developed to manage a particular condition or situation. Many terms are used to describe a medical guideline such as protocol, clinical guideline, clinical protocol and clinical practice guideline. They all mean the same thing. A guideline is usually an electronic or written

document designed to guide decision-making in a specific area of health care. Guidelines are usually developed by a group of experts using the latest evidence. Evidence-based practice guidelines are normally endorsed at a national or international level by the relevant professional body and include summarized statements about the latest knowledge and preferred ways to treat.

Good guidelines are easily disseminated and designed to influence clinical practice on a broad scale.

Good guidelines share the following characteristics:

- they define the most important questions relating to clinical practice in a particular field;
- they attempt to identify all possible decision options and the known consequences of those decisions;
- they identify each decision point followed by the respective courses of action according to the clinical judgement and experience of the health professionals.

The extent of variation of practice in health care has been identified as a major problem. Institute of Medicine [6]. Variation caused by overuse, underuse and misuse of medical care can be addressed by evidence-based practice, which uses the best evidence available with the goal of lessening variation and reducing risks to patients. Health professionals working in hospitals and clinics do not have the time, resources or the available experts to each produce their own set of guidelines. Instead, clinicians are encouraged to adapt already established guidelines and then modify them to suit their local practice and environment.

Guidelines are necessary because the complexity of health care plus the level of specialization has made personal opinion or professional and organizational subjective preferences redundant and unsafe. There are now hundreds of validated guidelines to assist clinicians practise safe surgery such as preventing wrong site, wrong procedure, wrong person surgery and prevention of surgical site infections.

Medical students are not always told about the guidelines that are used in a particular area of medicine. Nonetheless, they should be aware that in many areas of clinical practice, particularly that associated with the management of chronic illness, there are established guidelines that

identify the best way to treat patients. Often guidelines may not be accessible to the team who is required to use them; they may not even be aware of them. It is not unusual for a health-care organization to publish a guideline but then not make sure that everyone knows about it. Sometimes there are so many guidelines to follow that people turn off and do not see the relevance or importance of them. Being aware of the importance of using appropriate guidelines is a first step to students asking about them and then using them.

Safe care requires that all the staff know what is expected of them in relation to implementing a guideline. The guidelines need to be accessible (are they in a written form or are they online?) and applicable to the workplace where they are to be used. (Do the guidelines acknowledge the differences in resources and the readily available health professionals?) For a guideline to be effective the staff must know about it, trust it, be able to access it easily and be able to implement it.

For various reasons to do with resources, locality and type of patients it may be that some steps in a guideline are impractical or inappropriate. In such cases, the team may need to change the guideline to fit the environment or circumstances. When this occurs everyone needs to know about the changes so they can apply them.

If a guideline is not followed consistently by all the team, if people routinely skip steps, the guideline will not be effective in protecting patients from adverse events. It is important that everybody, including medical students, abides by the protocol. Commitment of the whole team is necessary for successful implementation of guidelines or protocols.

Some physicians may question the value of a guideline particularly when they think their

autonomy is being compromised and questioned. They may feel their clinical discretion is being removed with a team approach. Sharing knowledge and information with others in the team is absolutely necessary for continuity of care and achieving the best outcomes for the patients.

Guidelines in surgical care

The main protocols in surgical care are about improved communication to ensure that the right person is having the right procedure in the right place and by the right health-care team. A quick review of the processes involved in surgery show the many steps requiring active face-to-face conversations particularly for consent, marking and or identifying the appropriate drugs and equipment to be used. The operating team—surgeons, assistants, anaesthetists, scrub nurses, circulating nurses (scout nurses) and others in the operating room—all have to know the nature of the planned procedure, so that everyone is aware of the management plans, expectations of the different staff and anticipated outcomes for the patients. For this reason, many sites now schedule “time out” that takes place in the operating room where the procedure will be performed, just before the procedure is to commence.

Safe surgery requires that every member of the surgical team knows the main protocols used in an area of practice. It would be very unusual for no protocols to be in place. If this is the case, then a member of the team should request discussion about whether a protocol is required at a team meeting.

There is universal agreement that the best approach to minimizing errors caused by misidentification of patients is the implementation of best-practice guidelines for ensuring the correct patient receives the correct treatment. There are many guidelines addressing this issue.

The JCAHO Universal Protocol™ for preventing wrong site, wrong procedure, wrong person surgery in 2003 is one example and sets out the process and approach for including every member of the team as well as the patient. The WHO recently released guidelines for surgical care advocating the use of a checklist to enhance safety [7].

WHAT STUDENTS NEED TO DO (PERFORMANCE REQUIREMENTS)

Follow a verification process to eliminate wrong patient, wrong side and wrong procedure

Most medical students will have an opportunity to visit operating rooms and observe how surgical teams work together. They will also observe how the team manages the processes involved—before, during and after the surgery. During a surgical rotation students should:

- locate the main protocols used in a particular surgical unit;
- understand how the guideline was developed and whether the processes align with evidenced-based practice;
- read and understand why the guideline is necessary;
- be able to identify the steps in the verification process including selection of the right patient, right site and right procedure;
- identify how conflicts are resolved in the team.

T4

Practise operating room techniques that reduce risks and errors (time-out, briefings, debriefings, stating concerns)

7

Topic 4 on teamwork provides a detailed analysis of how effective teams work and the actions that team members can take to effectively contribute to improved performance and safety. In the surgical environment there are particular

attributes and actions known to improve surgical care teamwork. If students are not able to participate on the team, then they can observe how the team functions. Students should actively try to become part of the team. They can respectfully ask the leader of the team if they can be a part of the team even if they do not have any specific function or role. Being included allows the students to better see and hear how the team members communicate with one another. If possible students should practise:

- participating in team briefings and debriefings:
 - students should observe and record how health-care professionals participate in the processes designed to keep the patient safe—do they use checklists, briefs, debriefs?
 - students should evaluate their own contributions to the team discussions about the status of the patient, including identity, site of surgery, condition of the patient and plans for recovery;
- how to appropriately share information:
 - students should verbally share information with all health-care members of the team that relates to the assessment and treatment of the patient;
 - students should know the main characteristics of the procedure and plans for managing the patient, including knowing relevant protocols and their role in implementation;
- asking questions:
 - students should actively question members of the team in an appropriate and respectful manner;
 - students should assess when it is appropriate to ask questions;
 - students should participate in and take the opportunity to ask questions during the period in which the team meets to go over the planned procedure;
- asserting oneself appropriately:
 - students should be able to express an opinion or ask for an opinion from any member of the team through questions or statements of opinion during *critical times*;
 - students should understand that assertion *does not* include routine statements or questions about a patient’s heart rate, tone, colour and respirations (these form part of information sharing or inquiry);
- stating or sharing intentions:
 - students should practise sharing information about intentions with team members and seek feedback before deviating from the norm—this is important because it alerts the rest of the team about planned actions that are not routine;
- teaching:
 - students should be aware that teaching is an integral part of surgical care;
 - teaching can be in a variety of formats—short or informal information exchanges as well as guided hands-on learning by doing;
 - students should be receptive to learning from any of the providers (for example, nurses can teach medical students);
- managing workload:
 - students should appreciate that workload is distributed among those according to level of knowledge and skill.

Participate in an educational process for reviewing surgical mortality and morbidity

8

Most hospitals where surgery is performed will have a peer review system for discussing cases so that lessons can be learnt and shared among the group. Many hospitals call surgical review meetings a “mortality and morbidity meeting”. These are well-established forums for discussing incidents and difficult cases and are the main peer review method for improving future patient care. Such meetings usually provide a

confidential forum for auditing surgical complications and are necessary for improving practice in a surgical department. The meetings may be held weekly, fortnightly or monthly and provide a good opportunity for learning about errors in surgery. Because patient safety is a relatively new discipline, many of these meetings are yet to adopt a systems approach (blame free) for discussions about errors. Instead, some remain focused on the person who made an error and use a punitive approach to discussing adverse events. When meetings adopt a “person approach” to discussions about errors they are often closed to other members of the operating team, junior doctors and medical students and only include the surgeons.

Notwithstanding some of the problems associated with the past, mortality and morbidity meetings are excellent places to learn about errors and discuss ways to prevent them in the future. Medical students should find out if the hospital has such meetings and ask the appropriate senior surgeon if they can attend. If this is possible, students should observe to see if the following basic patient safety principles are demonstrated:

- Is the meeting structured so that the underlying issues and factors associated with the adverse event are the focus, rather than the individuals involved?
- Is there an emphasis on education and understanding, rather than apportioning blame to individuals?
- Is the goal of the discussion prevention of similar things occurring again? This requires a timely discussion of the event when memories are still fresh.
- Are these meetings considered a core activity for the entire surgical team, including the technicians and managers as well as the clinicians (medical, nursing, pharmacy, allied health)?
- Does everyone who had any involvement with

the incident/area have the ability to report?

- Are juniors, including students, encouraged to attend and participate in mortality and morbidity meetings? These sessions provide an excellent opportunity for students to learn about errors and the processes for improving particular treatments and procedures.
- Are all deaths involving a surgical procedure at the site identified and discussed?
- Is a written summary of the discussions kept, including any recommendations made for improvement or review?

Summary

9

This topic outlines the value of guidelines in reducing errors and minimizing adverse events. But a guideline is only useful if the people using the guideline trust them and understand why using a guideline is better for patient care. Protocols can prevent the wrong patient receiving the wrong treatment as well as facilitate better communication among the team.

HOW TO TEACH THIS TOPIC

Teaching strategies/formats



An interactive/didactic lecture

Use the accompanying slides as a guide covering the whole topic. The slides can be PowerPoint or converted to overhead slides for a projector. Start the session with the case study and get the students to identify some of the issues presented in the story.

Panel discussions:

Invite a panel of surgeons and theatre nurses to give a summary of their efforts to improve patient safety and to talk about their roles and responsibilities. This can help students appreciate the role of teamwork in surgery and invasive procedures. Students could also have a pre-prepared list questions about adverse event

prevention and management and have time scheduled for their questions.



A small group discussion session

The class can be divided up into small groups and three students in each group be asked to lead a discussion about one category of adverse events associated with surgery. Another student can focus on the tools and techniques available to minimize opportunities for errors and another could look at the role of mortality and morbidity meetings.

The tutor facilitating this session should also be familiar with the content so information can be added about the local health system and clinical environment.



Simulation exercises

Different scenarios could be developed about adverse events in surgery and the techniques for minimizing the opportunities for errors. These could mainly involve junior staff having to speak up to more senior staff to avert an incident such as the wrong patient being operated on or the wrong limb being prepared.

Different scenarios could be developed for the students:

- practising the techniques of briefs, debriefs and assertiveness to improve communication in theatres;
- role play using a “person approach” and then a “system approach” in a mortality and morbidity meetings;
- role play a situation in theatre where a medical student notices something is wrong and needs to speak up.

Operating room and ward activities

This topic offers many opportunities for integrated activities during the time when students are assigned to a surgical ward. This will often be in

the later years of the programme. Nevertheless there is no reason why students could not be exposed to them from the very first year of study.

- Students could attend a surgical procedure and observe and record the activities undertaken by the team to ensure that the patient being operated on is the right patient, that they are having the right procedure and at the right time.
- Students could observe a surgical team, identifying who is on the team, how they functioned and how they interacted with the patient.
- Students can attend a mortality and morbidity meeting and write a brief report as to whether the basic patient safety principles were applied during the meeting.
- Students could follow a patient through the peri-operative process and observe the activities or tasks that focused on the patient’s safety.
- Students should examine and critique the protocol used for the patient verification process including observations of the team’s knowledge and adherence of it.
- Students should observe how patient information is communicated from the wards to the operating rooms and back to the wards.

After these activities, students should be asked to meet in pairs or small groups and discuss with a tutor or clinician what they observed and whether the features or techniques being observed were present or absent, and whether they were effective.

CASE STUDIES

Arthroscopy performed on wrong knee

This demonstrates the role of the team in ensuring the correct procedure is performed and how

hierarchies are a barrier to safe care.

Brian injured his left knee while exercising and was referred by his general practitioner to an orthopaedic surgeon. The orthopaedic surgeon obtained consent to perform an examination of the left knee under anaesthetic as a day surgery procedure. Two registered nurses confirmed as part of the ordinary preoperative processes that his signature appeared on the consent form for his left knee.

The surgeon talked to Brian before he entered the operating theatre, but did not confirm which knee was to be operated on. Brian was taken into the operating theatre and anaesthetized. The anaesthetic nurse saw a tourniquet draped over his right leg and applied it. The enrolled nurse checked the intended side on the operating list so she could set up and when she saw the orthopaedic surgeon preparing the right leg, she told him that she thought the other leg was the intended operative site. The doctor was heard by both the enrolled nurse and scrub nurse to disagree and the right (incorrect) knee was operated on.

Reference

Case studies. Professional Standards Committees, Health Care Complaints Commission, New South Wales, *Annual Report 1999–2000*, p. 64.

A routine operation.

The case illustrates the risks of anaesthetics.

A 37-year-old woman in good health was scheduled for non-emergency sinus surgery under general anaesthesia. The consultant anaesthetist had 16 years of experience; the ear, nose and throat surgeon had 30 years experience, and three of the four nurses in theatre were also very experienced. The operating room

was very well equipped.

Anaesthesia was induced at 08:35 but it was not possible to insert the laryngeal mask airway. Two minutes later, the patient's oxygenation began to deteriorate and she looked cyanosed (turning blue). Her oxygen saturation at this time was 75% (anything less than 90% is significantly low) and her heart rate was raised.

At 08:39, her oxygen saturation continued to deteriorate to a very low level (40%). Attempts to ventilate the lungs with 100% oxygen using a face mask and oral airway proved extremely difficult. The anaesthetist, who was joined by a consultant colleague tried unsuccessfully to achieve tracheal intubation to overcome the problems with the airway. By 08:45, there was still no airway access and the situation had become "cannot intubate, cannot ventilate", a recognized emergency in anaesthetic practice for which guidelines are available. The nurses present appear to have recognized the severity of the situation, one fetching a tracheotomy tray, another going to arrange a bed in ICU.

The doctors' intubation attempts continued using different laryngoscopes, but these were also unsuccessful and the procedure was abandoned with the patient transferred to the recovery room. Her oxygen saturation had remained at less than 40% for 20 minutes. Despite being subsequently transferred to ICU, she never regained consciousness and died 13 days later as a result of severe brain damage.

Reference

Bromiley, M. *Have you ever made a mistake?* Bulletin of the Royal College of Anaesthetists, March. Just a Routine Operation. 2008. DVD available from the Clinical Human Factors Group web site at www.chfg.org.

Wrong kidney removed despite a student's warning

This case demonstrates the relevance of using a protocol to ensure correct patient correct site correct procedure.

A male patient aged 69 was admitted for removal of his chronically diseased right kidney (nephrectomy). Due to a clerical error, the admission slip stated “left”. The operating list was transcribed from the admission slips. The patient was not woken from sleep to check the correct side on the preoperative ward round. The side was not checked in from the notes or the consent form. The error was compounded in the operating theatre when the patient was positioned for a left nephrectomy and the consultant surgeon put the correctly labelled X-rays on the viewing box back to front. The senior registrar surgeon began to remove the left kidney.

A medical student observing the operation suggested to the surgeon that he was removing the wrong kidney but was ignored. The mistake was not discovered until two hours after the operation when the patient had not produced any urine. He later died.

Reference

British Medical Journal, 31 January 2002, p. 246;
Telegraph, 13 June 2002.

A failure to administer preoperative antibiotic prophylaxis in a timely manner according to protocol

This case illustrates the importance of preplanning and checking prior to a procedure and how protocols can minimize the risk of infection.

The anaesthetist and the surgeon discussed the preoperative antibiotics required for the laparoscopic cholecystectomy that was about to begin. The anaesthetist informed the surgeon of

the patient’s allergy to penicillin and the surgeon suggested clindamycin as an alternative preoperative antibiotic. The anaesthetist went into the sterile corridor to retrieve the antibiotics but returned and explained to the circulating nurse that he could not find any suitable antibiotics in the sterile corridor. The circulating nurse got on the phone to request the preoperative antibiotics. The anaesthetist explained that he could not order them because there were no order forms (he looked through a file folder of forms). The circulating nurse confirmed that the requested antibiotics “were coming”

The surgical incision was performed. Six minutes later the antibiotics were delivered to the operating room and immediately injected into the patient. This injection happened after the time of incision, which was counter to protocol that requires antibiotics to be administered prior to the surgical incision in order to avoid surgical site infections. Subsequently a nurse raised a patient concern and effected a change in operative planning.

Case from the WHO Patient Safety Curriculum Guide for Medical Schools working group. Supplied by Lorelei Lingard, University of Toronto, Toronto, Canada.

TOOLS AND RESOURCES

Universal protocol for preventing wrong site, wrong procedure, wrong person surgery™: Carayon P. Schultz K. Hundt AS. Righting wrong site surgery. [Case Reports. Journal Article. Research Support, Non-U.S. Government. Research Support, US Government, P.H.S.] Joint Commission. *Journal on Quality & Safety*, 2004, 30(7):405–10 (http://www.jointcommission.org/NR/rdonlyres/E3C600EB-043B-4E86-B04E-CA4A89AD5433/0/universal_protocol.pdf, accessed May 2008).

5 step correct patient, correct site, correct procedure:

ACT Health (Australia), issued September 2005 (<http://www.health.act.gov.au/c/health?a=sendfile&ft=p&fid=1127862008&sid>, accessed 29 April 2008).

Surgical events toolkit: Joint Commission International Center for Patient Safety, 2007 <http://www.ccforspatientsafety.org/> accessed 29 April 2008).

Correct site surgery toolkit: Association of peri operative Registered Nurses (AORN) (<http://www.aorn.org/PracticeResources/ToolKits/CorrectSiteSurgeryToolkit/>, accessed 29 April 2008).

Perioperative patient “hand-off” toolkit: Association of Perioperative Registered Nurses (AORN) and the U.S. Department of Defense Patient Safety Program (<http://www.aorn.org/PracticeResources/ToolKits/PatientHandOffToolkit/>, accessed 29 April 2008).

Ensuring correct surgery and invasive procedures: Veterans Health Administration, US Department of Veterans Affairs, Washington, DC (http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1106, accessed 29 April 2008).

WHO safe surgery saves lives: The Second Global Patient Safety Challenge. (<http://www.who.int/patientsafety/safesurgery/en/index.html>).

Resources

Calland JF et al. Systems approach to surgical safety. *Surgical Endoscopy*, 2002, 16:1005–1014 (<http://www.springerlink.com/content/wfb947ub7ut3re9n/fulltext.pdf>, accessed 29 April 2008).

Vincent C et al. Systems approaches to surgical quality and safety: from concept to measurement. *Annals of Surgery*, 2004, 239:475–482

Cuschieri A. Nature of human error: Implications for surgical practice. *Annals of Surgery* 2006, 244:642–648 (<http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1856596>, accessed 29 April 2008).

HOW TO ASSESS THIS TOPIC

A range of assessment methods are suitable for this topic including observational reports, reflective statements about surgical errors, essays, MCQ, SBA, case-based discussion and self-assessment. Students can be encouraged to develop a portfolio approach to patient safety learning. The benefit of a portfolio approach is that at the end of the student’s medical training they will have a collection of all their patient safety activities. Students will be able to use this to assist job applications and their future careers.

The assessment of knowledge about surgical care and the potential harm to patients, about system approach to improving surgical outcomes and the techniques for minimizing opportunities for surgical errors are all assessable using any of the following methods:

- portfolio;
- case-based in discussion;
- OSCE station;
- written observations about the perioperative environment (in general) and the potential for error;
- reflective statements (in particular) about:
 - theatres and the role of teamwork in minimizing errors;
 - the role of hierarchy in the theatre and the impact on patient safety;
 - the systems in place for reporting surgical errors;
 - the role of surgeons in learning from errors and making improvements;
 - role of patients in the surgical process;
 - the effectiveness or otherwise of mortality and morbidity meetings.

The assessment can be either formative or summative; rankings can range from unsatisfactory to giving a mark. See the forms in Appendix 2

HOW TO EVALUATE THIS TOPIC

Evaluation is important in reviewing how a teaching session went and how improvements can be made. See the Teacher's Guide (Part A) for a summary of important evaluation principles.



References

1. Vincent C et al. Systems approaches to surgical quality and safety: from concept to measurement. *Annals of Surgery*, 2004, 239:475–482.
2. Leape L et al. The nature of adverse events in hospitalized patients: results of the Harvard Medical Practice Study II. *New England Journal of Medicine*, 1991, 323:377–384.
3. Kable AK, Gibberd RW, Spigelman AD. Adverse events in surgical patients in Australia. *International Journal for Quality in Health Care*, 2002, 269–276.
4. Joint Commission on Accreditation of Healthcare Organizations. *Guidelines for implementing the universal protocol for preventing wrong site, wrong procedure and wrong person surgery*: Chicago, JCAHO, 2003.
5. Lingard L et al. Communication failures in the operating room: an observational classification of recurrent types and effects. *Quality & Safety in Health Care*, 2004, 13:330–334.
6. *Crossing the Quality Chasm: a New Health System for the 21st Century*. Washington DC: National Academy Press, 2001.
7. WHO safe surgery saves lives: The Second Global Patient Safety Challenge. (<http://www.who.int/patientsafety/safesurgery/en/index.html>) accessed January 2009.

SLIDES FOR TOPIC 10: PATIENT SAFETY AND INVASIVE PROCEDURES

Didactic lectures are not usually the best way to teach students about patient safety. If a lecture is being considered, it is a good idea to plan for student interaction and discussion during the lecture. Using a case study is one way to generate group discussion. Another way is to ask the students questions about different aspects of health care that will bring out the issues contained in this topic such as the blame culture, nature of error and how errors are managed in other industries.

The slides for topic 10 are designed to assist the teacher deliver the content of this topic. The slides can be changed to fit the local environment and culture. Teachers do not have to use all of the slides and it is best to tailor the slides to the areas being covered in the teaching session.

Topic 11: Improving medication safety

Why focus on medications?

1 2

Medicines have proven to be very beneficial for treating illness and preventing disease. This success has resulted in a dramatic increase in medication use in recent times. Unfortunately, this increase in use and expansion of the pharmaceutical industry has also brought with it an increase in hazards, error and adverse events associated with medication use.

Medication has also become increasingly complex:

- There has been a massive increase in the number and variety of medications available. These may have different routes of delivery, variable actions (long acting, short acting) and there are drugs with the same action and formulation but with different trade names.
- Although there are better treatments for chronic disease, more patients take multiple medications and there are more patients with multiple co-morbidities. This increases the likelihood of drug interactions, side-effects and mistakes in administration.
- The process of delivering medications to patients is often shared by a number of health-care professionals. Communication failures can lead to gaps in the continuity of the process.
- Doctors are prescribing a larger range of medications so there are more medicines they need to be familiar with. There is just too much information for a doctor to be able to remember in a reliable way.
- Doctors look after patients who are taking medications prescribed by other doctors (often specialized doctors) and hence may not be familiar with the effects of all the medications a patient is taking.

Doctors have a major role in the use of medicine. Their role includes prescribing, administration, monitoring for side-effects, working in a team

and potentially a leadership role in the workplace in relation to medication use and improving patient care.

As future doctors, medical students need to understand the nature of medication error, learn what the hazards are in relation to using medication and what can be done to make medication use safer. All staff involved in the use of medication have a responsibility to work together to minimize patient harm caused by medication use.

Keywords

Side-effect, adverse reaction, error, adverse event, adverse drug event, medication error, prescribing, administration and monitoring.

Learning objectives:

3

- to provide an overview of medication safety;
- to encourage students to continue to learn and practise ways to improve the safety of medication use.

Learning outcomes: knowledge and performance

What a student needs to know (knowledge requirements):

4

- understand the scale of medication error;
- understand that using medications has associated risks;
- understand common sources of error;
- understand where in the process errors can occur;
- understand a doctors' responsibilities when prescribing and administering medication;
- recognize common hazardous situations;
- learn ways to make medication use safer;
- understand the benefits of a multidisciplinary approach to medication safety.

What a student needs to do (performance requirements)

5

Acknowledge that medication safety is a vast topic and an understanding of the area will affect how a clinician performs in the following tasks:

- use generic names;
- tailor prescribing for each patient;
- learn and practise thorough medication history taking;
- know the high-risk medications;
- be very familiar with the medications you prescribe;
- use memory aids;
- communicate clearly;
- develop checking habits;
- encourage patients to be actively involved in the medication process;
- report and learn from errors;
- learn and practise drug calculations.

WHAT STUDENTS NEED TO KNOW (KNOWLEDGE REQUIREMENTS)

Definitions:

6

7

Side-effect

A known effect, other than that primarily intended, relating to the pharmacological properties of the medication [1]. For example, a common side effect of opiate analgesia is nausea.

Adverse reaction

Unexpected harm arising from a justified action where the correct process was followed for the context in which the process occurred [1]. For example, an unexpected allergic reaction in a patient taking a medication for the first time.

Error

Failure to carry out a planned action as intended or application of an incorrect plan.[1]

Adverse event

An incident that results in harm to a patient.[1]

Adverse drug event

An incident that may be preventable (usually the result of an error) or not preventable.

Medication error

May result in:

- an adverse event if a patient is harmed;
- a near miss if a patient is nearly harmed;
- neither harm nor potential for harm.

Understand the scale of medication error

8

Medication error is a common cause of preventable patient harm.

The Institute of Medicine in the United States estimates:

- 1 medication error per hospitalized patient per day in the United States; [2]
- 1.5 million preventable adverse drug events per year in the United States; [2]
- 7000 deaths per year from medication error in US hospitals. [3]

Other countries around the world that have researched the incidence of medication error and adverse drug events have similarly worrying statistics [4].

Steps in using medication

9

There are a number of discrete steps in using medication: prescribing, administration and monitoring are the main three. Doctors, patients and other health professionals can all have a role in these steps. For example, a patient may self-prescribe over-the-counter medication, administer their own medication and monitor themselves to see if there has been any therapeutic effect. Alternatively, for example, in the hospital setting,

one doctor may prescribe a medication, a nurse will administer the medication and a different doctor may end up monitoring the patient's progress and make decisions about the ongoing drug regimen.

The main components of each step are outlined below.

Prescribing:

- choosing an appropriate medication for a given clinical situation, taking individual patient factors into account such as allergies;
- selecting an administration route, dose, time and regimen;
- communicating the plan with whoever will administer the medication. This communication may be written, verbal or both;
- documentation.

Administration:

- obtaining the medication and having it in a ready-to-use form. This may involve counting, calculating, mixing, labelling or preparing in some way;
- checking for allergies;
- giving the right medication to the right patient, in the right dose, via the right route, at the right time;
- documentation.

Monitoring:

- observing the patient to determine if the medication is working, being used correctly and not harming the patient;
- documentation.

There is potential for error at every step of the process. There are a variety of ways that error can occur at each step.

Understand that using medications has associated risks

Prescribing



Sources of error in prescribing:

- Inadequate knowledge about drug indications, contraindications and drug interactions. This has become an increasing problem as the number of medicines in use has increased. It is not possible for a doctor to remember all the relevant details necessary for safe prescribing. Alternative ways of accessing drug information are required.
- Not considering individual patient factors that would alter prescribing such as allergies, pregnancy, co-morbidities like renal impairment and other medications the patient may be taking.
- Prescribing for the wrong patient, prescribing the wrong dose, prescribing the wrong drug, prescribing the wrong route or the wrong time. These errors can sometimes occur due to lack of knowledge, but more commonly are a result of a “silly mistake” or “simple mistake”, referred to as a slip or a lapse. These are the sorts of errors that are more likely to occur at 04:00, or if the doctor is rushing or bored and not concentrating on the task at hand.
- Inadequate communication can result in prescribing errors. Communication that is ambiguous can be misinterpreted. This may be a result of illegible writing or simple misunderstanding in verbal communication.
- Mathematical error when calculating doses can cause errors. This can be a result of carelessness, but could also be due to lack of training and unfamiliarity with how to manipulate volumes, amounts, concentrations and units. Calculation errors involving medications with narrow therapeutic window can cause major adverse events. Not

uncommonly, a calculation error can occur when transposing units (e.g. from micrograms to milligrams) and may result in a 1000 times error. Competence with dose calculations is particularly important in paediatrics where most doses are determined according to the weight of the child.

Administration

15 16 17

Types of administration errors:

- Classic administration errors are a drug being given to the wrong patient, by the wrong route, at the wrong time, in the wrong dose or the wrong drug used. Not giving a prescribed drug is another form of administration error. These errors can result from inadequate communication, slips or lapses, lack of checking procedures, lack of vigilance, calculation errors and suboptimal workplace and medication packaging design. There is often a combination of contributory factors.
- Inadequate documentation. For example, if a medication is administered but has not been recorded as being given, another staff member may also give the patient the medication thinking that it had not yet been administered.

Monitoring

18 19 20 21

Types of errors in monitoring:

- inadequate monitoring for side-effects;
- medication not ceased once course is complete or clearly not helping the patient;
- course of prescribed medication not completed;
- drug levels not measured, or measured but not checked or acted upon;
- communication failures—this is a risk if the care provider changes, for example, if the patient moves from the hospital setting to the community setting or vice versa.

Contributory factors for medication errors

22 23 24 25

Adverse medication events are frequently multifactorial in nature. Often there is a combination of events that together result in patient harm. This is important to understand for a number of reasons. In trying to understand why an error occurred, it is important to look for *all* the contributing factors, rather than the most obvious reason or the final point of the process. Strategies to improve medication safety also need to be targeted at multiple points.

Patient factors:

- patient on multiple medications;
- patients with a number of medical problems;
- patients who cannot communicate well, e.g. unconscious, babies and young children, people who do not speak the same language as the staff;
- patients who have more than one doctor `prescribing medication;
- patients who do not take an active interest in being informed about their own health and medicines;
- children and babies (drug dose calculations required).

Staff factors:

- inexperience;
- rushing, emergency situations;
- multitasking;
- being interrupted mid-task;
- fatigue, boredom, lack of vigilance;
- lack of checking and double-checking habits;
- poor teamwork, poor communication between colleagues;
- reluctance to use memory aids.

Workplace design factors:

- absence of safety culture in the workplace. This may be evidenced by a lack of reporting systems and failure to learn from past near

- misses and adverse events;
- absence of readily available memory aids for staff;
- inadequate staff numbers;
- medicines not stored in an easy to use form.

Medication design factors:

- look-a-like, sound-a-like medication. For example, Celebrex (an anti-inflammatory), Cerebryx (an anticonvulsant) and Celexa (an antidepressant);
- ambiguous labelling—different preparations or dosages of similar medication may have similar names or packaging. For example, some slow release medications may differentiate themselves from the usual release form with a suffix. Unfortunately, there are many different suffixes in use to imply similar properties such as slow release, delayed release or long acting, e.g. LA, XL, XR, CC, CD, ER, SA, CR, XT,SR.

WHAT STUDENTS NEED TO DO (PERFORMANCE REQUIREMENTS)

What are some of the ways to make medication use safer?

Use generic names

26

Medications have both a trade name (brand name) and a generic name (active ingredient). The same drug formulation can be produced by different companies and given multiple different trade names. Usually the trade name appears in large letters on the box/bottle and the generic name is in small print. It is difficult enough familiarizing oneself with all the generic medications in use and can be almost impossible to remember all the related trade names. To minimize confusion and simplify communication it is helpful if staff only use generic names. However, it is important to be aware that patients will often use trade names as this is what appears in large print on the packaging. This can be confusing for both staff and patients. For example, consider a patient being discharged from hospital on their usual medication but with a different trade name. The patient may not realize that the discharge medication is the same as their pre-admission medication and hence continue with this as well, since no one has told them to cease it or that it is the same as the “new” medication. It is important to explain to patients that some medications many have two names.

Commercial pharmacies will sell the brand of medication prescribed by the doctor. Often a doctor will prescribe using a trade name as a way of ensuring the patient is dispensed the cheapest version of the medication available. In this situation, patients can still be made aware of the generic name of the medication. Patients should be encouraged to keep a list of their medications including both the trade and generic name of each drug.

Tailor prescribing to individual patients

27

Before prescribing a medication, always stop and think, “Is there anything about this patient that should alter my usual choice of medication?”

The sorts of factors to consider are allergies, pregnancy, breastfeeding, co-morbidities, other medications the patient may be taking and size of the patient.

Learn and practise thorough medication history taking:

28

- Include name, dose, route, frequency and duration of every drug the patient is taking;
- Enquire about recently ceased medications;
- Ask about over-the-counter medications, dietary supplements and complimentary medicines;
- Enquire if there are any medications they have been advised to take but do not actually take;
- Make sure what the patient actually takes matches your list. Be particularly careful about this across transitions of care. Practise medication reconciliation on admission to and on discharge from hospital, as these are high-risk times for errors [5] due to misunderstandings, inadequate history taking and poor communication systems;
- Look up any medications you are unfamiliar with;
- Consider drug interactions, medications that can be ceased and medications that may be causing side-effects;
- Always include a thorough allergy history. Remember, when taking an allergy history, if a patient has a potentially serious allergy *and* they have a condition where staff may want to prescribe that medication, this is a high-risk situation. Alert the patient and alert other staff.

Know which medications are high risk in your area and take precautions

29

Some medications have a reputation for causing adverse drug events. This may be due to a narrow therapeutic window, particular pharmacodynamics or pharmacokinetics or the complexity of dosing and monitoring.

Examples include insulin, oral anticoagulants, neuromuscular blocking agents, digoxin, chemotherapeutic agents, IV potassium and aminoglycoside antibiotics. It may be useful finding out from the pharmacist or other relevant staff in your area what medications tend to be most often implicated in adverse medication events and invest time teaching about these agents.

Know the medications you prescribe well

30

Never prescribe a medication you do not know much about. Encourage students to do homework on medications they are likely to use frequently in their practice. They should be familiar with the pharmacology, indications, contraindications, side-effects, special precautions, dosage and recommended regimen. If they have a need to prescribe a medication they are not familiar with they need to read up on the medication before prescribing. This will require having ready reference material available in the clinical setting. It is better to know a few drugs well than many superficially. For example, rather than learning about five different non-steroidal anti-inflammatory drugs, just know one in detail and prescribe this one.

Use memory aids

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Perhaps in the past it was possible to remember most of the required knowledge regarding the main medications in use. However, with the rapid growth in available medications and the increasing complexity of prescribing, relying on memory alone has become inadequate.

Students need to be encouraged to have a low threshold to look things up, they need to become familiar with using memory aids and they need to view relying on memory aids as a marker of safe practice rather than a sign that their knowledge level is inadequate. Examples of memory aids are textbooks, pocket sized pharmacopoeias and information technology such as computer software (decision support) packages and personal digital assistants. A simple example of a memory aid is a card with all the names and doses of medication that may be needed in the situation of a cardiac arrest. This card can be kept in the doctor's pocket and referred to in the event of an emergency when there may not be time to get to a textbook or computer to check the dose of a medication. Note that memory aids are also referred to as cognitive aids.

Remember the five Rs when prescribing and administering medication

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In many parts of the world, nursing education has emphasized the importance of checking the "five Rs" before administering a medication. The five Rs are: right drug, right route, right time, right dose and right patient. This is just as relevant for doctors, both when prescribing and administering medication. Two additions to the five Rs in use are right documentation and the right of a staff member, patient or carer to question the medication order.

Communicate clearly

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It is important to remember that safe medication use is a team activity that also includes the patient. Clear unambiguous communication will help to minimize assumptions that can lead to error. A useful maxim to remember when communicating about medications is to "state the obvious" as often what is obvious to the doctor is not obvious to the patient or the nurse.

Remembering the 5 Rs is a useful way of remembering the important points about a medication that need to be communicated. For example, in an emergency situation a doctor may need to give a verbal drug order to a nurse, "Can you please give this patient 0.3mls of 1:1000 epinephrine intramuscularly as soon as possible?" is much better than saying, "Quick, get some adrenaline".

Another useful communication strategy is to "close the loop". This decreases the likelihood of misunderstanding. In our example, the nurse would close the loop by saying, "Okay, so I will give the patient 0.3mls of 1:1000 epinephrine intramuscularly as soon as possible".

Develop checking habits

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It is helpful to develop checking habits early. To do this they need to be taught at undergraduate level. An example of a checking habit is to always read the label on the ampoule before drawing up a medication. If checking becomes a habit, then it is more likely to occur even if the clinician is not actively thinking about being vigilant.

Checking needs to be part of prescribing and administration. You are responsible for every prescription you write and drug you administer. Check the 5 Rs for allergies. High-risk medications and situations require extra vigilance with checking and double-checking, for example, using very potent emergency drugs in a critically ill patient. Checking on colleagues' actions as well as your own actions contributes to effective teamwork and provides another safeguard.

Remember that computerized prescribing does not remove the need for checking. Computerized systems solve some problems (e.g. illegible handwriting, confusion around generic and trade names, recognizing drug interactions), but present

a new set of challenges. [6]

Some useful maxims regarding checking:

- Unlabelled medications belong in the bin.
- Never administer a medication unless you are 100% sure you know what it is.

Encourage patients to be actively involved in their own care and the medication use process:

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- Educate your patients about their medication and any associated hazards;
- Communicate plans clearly with patients. Remember that the patient and their family are highly motivated to avoid problems, so if they are made aware that they have an important role to play in the process, they can contribute significantly to improving the safety of medication use;
- Information can be both verbal and written and should cover the following aspects:
 - name;
 - purpose and action of the medication;
 - dose, route and administration schedule;
 - special instructions, directions and precautions;
 - common side-effects and interactions;
 - how the medication will be monitored.
- Encourage patients to keep a written record of the medications that they take and details of any allergies or problems with medications in the past. This list should be presented whenever they interact with the health-care system.

Report and learn from medication errors

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Discovering more about how and why medication errors occur is fundamental to improving medication safety. Whenever an adverse drug event or near miss occurs there is an opportunity for learning and improving care. It will be helpful for your students if they understand the importance of talking openly about errors and

are aware of what processes are in place in your area to maximize learning from error and progress in medication safety.

Safe practice skills for medical students to develop practice

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Although medical students are generally not permitted to prescribe or administer medication until after graduation, there are many aspects of medication safety that students can start practising and preparing for. It is hoped that the following list of activities can be expanded upon at multiple stages throughout a medical student's training. Each task on its own could form the basis of an important educational session (lecture, workshop, tutorial). Thorough coverage of these topics is beyond the scope of an introductory session to medication safety.

An understanding of the inherent hazards of using medicines will affect how a clinician performs many daily tasks. Below are examples of what a safety conscious clinician will do.

- **Prescribing:** Consider the 5 Rs, know the drugs you prescribe well, tailor your treatment decisions to individual patients, consider individual patient factors that may affect choice or dose of medication, avoid unnecessary use of medicines and consider risk benefit ratios;
- **Documentation :** Clear, legible, unambiguous documentation. Those who struggle to write neatly should print. Consider the use of electronic prescribing if available. Include patient, dose, drug, route, time and schedule as part of documentation;
- **Use of memory aids:** Have a low threshold to look things up, be familiar with available memory aids, look for and use technological solutions if available and effective;

- **Teamwork and communication surrounding medication use:** Remember that drug use is a team activity, communicate with the other people involved in the process and make sure that false assumptions are not being made. Be on the look out for errors and encourage the rest of the team to be vigilant of their own and others actions;
- **Medication administration:** Be familiar with the hazards and the safety precautions of administering medication by different routes—oral, sublingual, buccal, inhaled, nebulized, transdermal, subcutaneous, intramuscular, intravenous, intrathecal, per rectum and per vaginam. Check the 5 Rs whenever administering a medication;
- **Involve and educate patients about their medications:** Look for opportunities and ways to help patients and carers help themselves to minimize errors;
- **Learn and practise drug calculations:** Be familiar with how to manipulate units, adjust volumes, concentrations and doses. In high-stress and or high-risk situations consider ways to decrease the chance of a calculation error such as using a calculator, avoiding doing sums in your head (use pen and paper), asking a colleague to also perform the calculation and see if you concur and use available technology;
- **Performing a medication history:** Always take a thorough medication history before prescribing and regularly review patients' medication lists, especially patients on multiple medications. Cease all unnecessary medications. Always consider medication as a possible cause of symptoms during the diagnostic process;
- **Performing an allergy history:** Always ask about allergies before prescribing a medication. If a patient has a serious allergy, stop and think if the patient is at risk of someone wanting to prescribe the medication

they are allergic to. For example, if a community doctor sends a patient to hospital with suspected appendicitis and the patient has a serious penicillin allergy, it is possible that there will be some momentum within the hospital to give the patient penicillin. In this situation, it is important to emphasize the allergy in communication with the hospital staff, warn the patient that the usual treatment for appendicitis involves penicillin-based antibiotics and encourage the patient to be alert to what medication they are being given and to speak up if someone tries to give them a penicillin;

- **Monitoring patients for side-effects:** Be familiar with the side-effects of the medications you prescribe and be proactive in looking for them. Educate patients about potential side-effects, how to recognize them and appropriate actions should they occur. Always consider medication side-effects as part of the differential diagnosis when assessing patients with undifferentiated clinical problems;
- **Learn from medication errors and near misses:** Learn from errors through investigation and problem solving. If an error can occur once it could occur again. Consider strategies to prevent recurrence of error at both an individual practitioner level and an organizational level. Be familiar with how to report errors, adverse reactions and adverse events involving medication.

Summary Slide

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Medications can greatly improve health when used wisely and correctly. Nevertheless, medication error is common and is causing preventable human suffering and financial cost. Remember that using medications to help patients is not a risk-free activity. Know your responsibilities and work hard to make medication use safe for your patients.

HOW TO TEACH THIS TOPIC

Teaching strategies/format

There are a variety of ways to teach medical students about medication safety and a combination of approaches is likely to be most effective.

Options include: interactive lectures, small group discussions, PBL, practical workshops, tutorials, project work including tasks to be undertaken in the clinical environment and at the bedside, online learning packages, reading and case analysis.

Lecture presentation and/or group discussion

The PowerPoint presentation included in this package is designed for use as an interactive introductory lecture to medication safety or a teacher-led small group discussion. It can be readily adjusted to be more or less interactive, and can potentially be adapted to your clinical setting if you include local examples, local issues and local systems. There are a series of questions interspersed throughout the presentation to encourage students to actively engage with the topic and also short cases with questions and answers that could be embedded in the lecture or provided for the students as a separate exercise.

Below are listed some other educational methods and ideas to consider using for teaching on medication safety.



Problem-based learning

Use cases that raise issues relevant to medication safety.

Online activities

Suggested activities include:

- responding to reflective questions after reading through a case;

- learning about high-risk medications;
- working through a drug calculations training package.

Teaching and learning activities

Practical workshops

Suggested topics include:

- drug administration;
- prescribing;
- drug calculations.



Project work:

Suggested topics include:

- interview a pharmacist to find out what errors they commonly see;
- accompany a nurse on a drug round;
- interview a nurse or doctor who administers a lot of medication (e.g. an anaesthetist) about their experience and knowledge of medication error and what strategies they use to minimize the chance of making a mistake;
- research a medication that has a reputation for being a common cause of adverse events and presenting what has been learnt to fellow students;
- prepare a personal formulary of medications likely to be commonly prescribed in the early postgraduate years;
- perform a thorough medication history on a patient on multiple medications—do some homework to learn more about each of the medications, then consider potential side-effects, drug interactions and if there are any medications that could be ceased for your patient; discuss your thoughts with a pharmacist or doctor and share what you have learnt with fellow students;
- find out what is meant by the term “medication reconciliation” and talk to hospital staff to find out how this is achieved at your hospital; observe and, if possible, participate in the process during admission

and discharge of a patient and consider how the process may prevent errors and also whether there are any gaps or problems with the process.

Role plays

Supplied by Amitai Ziv, The Israel Centre for Medical Simulation, Sheba Medical Centre, Tel Hashomer, Israel.

Scenario I

Erroneous administration of drugs

Description of event

During the early hours of the morning shift, the morning shift nurse administered subcutaneous regular insulin 100 units, instead of 10 units as was written in the physician's order. The error stemmed from the physician's illegible handwriting.

The patient suffered from dementia, was uncooperative and seemed to be asleep. During the nurse's regular checkup, she discovered the patient to be completely unresponsive. A blood test confirmed that the patient was in a state of hypoglycemic shock. The on-call physician was called, and the error was discovered.

The patient was treated with an infusion of glucose 50% IV. A crash cart was brought to the patient's room to be on hand. The patient recovered within a few minutes, woke up and began behaving normally.

Role playing actor

Later on in the morning shift, the patient's son, a lawyer, comes to visit his father. Looking agitated, he turns to the nurse asking, "What happened to my father?" His father's room-mate told him there was a problem and there were many people at his father's bedside at the beginning of the morning shift. The nurse responsible for the error and care

of the patient is called to speak with the patient's son.

If the nurse explains the chain of events, takes responsibility for and admits her error, the patient's son is not placated and retorts, "Is that the level of care my father has been receiving?", "What kind of nurses work in this ward?", "I won't have it, I will take action!", "I demand to speak to the chief or head physician immediately!", "I demand to see this event's report!". Needless to say, if the nurse does not explain the error and its details, the patient's son is upset and unwilling to accept any kind of explanation.

A physician passing by overhears the conversation and enters the room.

The physician will enter the room if the actor asks him to. If the actor does not request the physician, the physician will enter the room after approximately 8 minutes (12-minute scenario). The physician will enter the room and ask about last night. The nurse will update him as to this morning's events and her conversation with the patient's son (either in his presence or not, depending on the physician and nurse).

Role playing actor: description

RY, 45 years old, is a well-dressed lawyer. He visits with his father whenever possible. He does not attend to his father; rather, he hovers over him with unrest. He is interested in everything going on around him, but is having difficulty accepting his father's new medical state: confused, neglected and a bit sunken. He really wants to help, but does not know with what. A conversation with the social worker reveals that previously there was never a need for him to care for his father, but ever since his mother fell and broke her leg and his father's situation has deteriorated, the burden of their care rests on his shoulders alone.

Actor tips

The actor must intervene; complain to the head physician of a cover-up and omission of facts; threaten with negative publicity (going to the press) (i.e. “You almost killed him! You’re lucky it didn’t end that way!”)

Scenario II

Death due to erroneous medical care

Description of event

ST, 42 years old, was admitted for the re-section of a localized, non-metastatic malignant duodenal tumour.

ST was otherwise healthy, without any family history of malignancy. The patient had consented to surgery and any other treatment deemed necessary afterwards, according to pathology results.

On the morning of surgery, the patient said goodbye to her husband and two young children (ages 13 and 8). A small localized mass was resected in its entirety. The mass was sent to pathology for diagnosis. Two hours into surgery, the patient showed signs of decreased saturation, tachycardia and hypotension. The patient received IV fluids and oxygen, while the surgeon re-checked the re-section site for signs of haemorrhage, a tear or an embolism. After finding nothing, the surgeon sutured the site according to protocol.

Upon return to the ward, the patient quickly developed a high fever, which remained unchanged for a week. A medical order for antibiotics was written:

IV. GARAMYCIN 80 MGR X 3 P/D

The nurse copied the following order:

IV. GARAMYCIN 80 MGR X 3 P/DOSE

The nurse who copied the order mistook the letter “D” to mean “dose”, while the physician who wrote the order actually meant “day”. Over the next 10 days, the patient received 240 mg of Garamycin, three times daily.

During that time, the patient began showing signs of renal failure and hearing impairment. On the tenth day of treatment, as the head nurse was taking stock of the drugs administered, the error was discovered. The treatment was stopped, but the patient’s general status deteriorated due to acute renal failure progression; 10 days later, the patient died of generalized organ failure.

The patient’s family was critical of the nursing staff throughout the hospitalization, blaming them for malpractice. They expressed their anger to the head nurse and the department chief.

After the patient died, her husband asks to speak to the head nurse. He blames the nurses for the error and malpractice that culminated in his wife’s death. He claims to have already discovered which nurse copied the order, and threatens to sue her.

Role playing actor: description

The patient’s husband is a hard-working man, working in a store. He has difficulty providing for his family and is struggling to make ends meet. He is an angry and restless man who has not yet come to terms with his wife’s cancer diagnosis. He is angry with everyone and especially with the nursing staff, after his wife told him she received too many antibiotics because “the nurse couldn’t do math”. He wants to know what killed his wife, who is at fault and who is going to pay for it. He wants top hospital management involved, and wants help for his children. He is very upset, and shouts a lot.

Scenario III

Patient–caregiver communication

Description of event

KL, 54 years old, has been admitted due to transient chest pain complaints. He has been previously hospitalized in the ICU due to acute coronary events. This time, preliminary test results have been inconclusive, and his pain is not as severe. The physician has ordered complete rest and continuous 48 hour cardiac monitoring. KL is a heavy smoker, and is overweight. He has not been taking his prescribed medication for high blood pressure and high cholesterol.

The patient demands to be released immediately. He is afraid his hospitalization may cause him to lose his job at an automobile factory.

His anger is directed at the nurse-in-charge of the evening shift. He claims he was promised he would be discharged and that there is no need for him to be monitored or for complete rest. He is uncooperative. He has already convinced a young nurse that he is right, and she has let him leave the ward. Now, he demands to leave the ward again and refuses to remain in his room. He demands to smoke and wants to be discharged. He is angry and shouting by the nurses' station.

Assuming the nurse-in-charge insists he stay in the ward, the patient will accuse her of being insensitive, and will claim the younger nurse was nicer, more empathetic and understanding compared to the older nurse, who is more conservative and strictly adheres to protocol and bureaucracy.

The on-call physician is in the vicinity, but does not intervene and continues caring for other patients (some of which are near the nurses' station where the event is taking place).

Role playing actor: description

Irresponsible man, overweight, heavy smoker, shouts. Enjoys getting attention by shouting. He is very concerned that he will not be able to work as much and may be fired. He is very afraid of surgery, as his best friend died on the operating table two years ago at the same hospital.

Scenario IV

In-patient fall

Description of event

ED, 76 years old, was admitted to the ward due to recurrent falls, reporting continuous dizziness and instability. During his first night, he was helped out of bed several times in order to use the restroom. At 07:30, the patient's wife found him lying on the floor, with facial contusions and in pain. The patient does not remember what happened.

The nurses helped the patient back into his bed and treated his lacerations. Three hours later, he was examined by a physician, who ordered X-rays of the head, spine and limbs. The X-rays showed a fracture of the neck of the femur, as well as fractures in both hands. The patient underwent surgery. During his recovery, the patient was diagnosed with right-side hemiplegia and slight aphasia.

The patient is in pain, angry and suffering. His entire family has been called in. Most of the patient's anger is directed towards the nursing staff, which "didn't watch over him" and "didn't supervise" him. The family attributes the patient's further complications to the surgery.

In a heated discussion, the patient's son accuses the nurses of malpractice, "You're killing my father. You do not care about him because he's old. You were drinking coffee and didn't answer my father's calls..." His anger is directed towards the nurse-

in-charge of the shift and the nurse in charge of ED's care.

Role playing actor: description

GD, the patient's son, is a 34-year-old taxi driver living with his parents. He was not close to home when he learnt what had happened and, therefore, was only able to reach the hospital five to six hours after the event. He enters the ward and immediately asks to see his father and the nurse responsible for his fall. He has already been updated by other members of his family as to his father's complications after surgery.

Actor tips

You and your father are very close. You are a very uptight man. Your taxi driver friends usually think that medicine is not to be trusted.

TOOLS AND RESOURCES

Activities that can be included as part of the PowerPoint presentation, to help make the presentation more interesting, engaging and effective.



Case 1 with questions for discussion: a prescribing error

A 74-year-old man sees a community doctor for treatment of new onset stable angina. The doctor has not met this patient before and takes a full past history and medication history. He discovers the patient has been healthy and only takes medication for headaches. The patient cannot recall the name of the headache medication. The doctor assumes it is an analgesic that the patient takes whenever he develops a headache. But the medication is actually a beta-blocker which he takes every day for migraine. A different doctor prescribed this medication. The doctor commences the patient on aspirin and another

beta-blocker for the angina. After commencing the new medication, the patient develops bradycardia and postural hypotension. Unfortunately, the patient has a fall three days later due to dizziness on standing. He fractures his hip in the fall.

Case 2 with questions for discussion: an administration error

A 38-year-old woman comes to the hospital with 20 minutes of itchy red rash and facial swelling. She has a history of serious allergic reactions. A nurse draws up 10 mls of 1:10,000 adrenaline (epinephrine) into a 10 ml syringe and leaves it at the bedside ready to use (1 mg in total) just in case the doctor requests it. Meanwhile, the doctor inserts an IV cannula. The doctor sees the 10 ml syringe of clear fluid that the nurse has drawn up and assumes it is normal saline. There is no communication between the doctor and the nurse at this time.

The doctor gives all 10 mls of adrenaline (epinephrine) through the IV cannula thinking he is using saline to flush the line. The patient suddenly feels terrible, anxious, becomes tachycardic and then becomes unconscious with no pulse. She is discovered to be in ventricular tachycardia, is resuscitated and fortunately makes a good recovery. Recommended dose of adrenaline (epinephrine) in anaphylaxis is 0.3–0.5 mg IM. This woman received 1 mg IV.

Case 3 with questions for discussion: a monitoring error

A patient is commenced on oral anticoagulants in hospital for treatment of a deep venous thrombosis following an ankle fracture. The intended treatment course is three to six months. However, neither patient nor community doctor are aware of the planned duration of treatment. Patient continues medication for several years, being unnecessarily exposed to the increased risk

of bleeding associated with this medication. The patient is prescribed a course of antibiotics for a dental infection. Nine days later the patient becomes unwell with back pain and hypotension, a result of a spontaneous retroperitoneal haemorrhage, requiring hospitalization and a blood transfusion. Blood coagulation test reveals a grossly elevated result; the antibiotics have potentiated the therapeutic anticoagulant effect.

WWW TOOLS AND RESOURCES

WHO patient safety solutions

These are summary documents detailing solutions for patient safety problems. A number of them concern medication issues:

Solution 1 – look-alike, sound-alike medication names

Solution 5 – control of concentrated electrolyte solution

Solution 6 – assuring medication accuracy at transitions in care

Solution 7 – avoiding catheter and tubing misconnection

Solution 8 – single use of injection devices

These documents can be found at www.who.int/patientsafety/solutions/en/.

The web site www.webmm.ahrq.gov has case archives that can be used for potential case studies that may be helpful in your teaching.

Institute for Safe Medication Practices at www.ismp.org.

National Patient Safety Agency at www.npsa.nhs.uk.



Educational DVDs

Beyond Blame documentary. This DVD runs for 10 minutes and is a powerful way to engage students in the issue of medication safety.

It consists of a doctor, a nurse and a pharmacist talking about serious medication errors they have been involved in. This DVD is available for purchase through the Institute for Safe Medication Practices—Preventing Medication Errors at www.ismp.org

WHO *Learning from error* workshop includes a DVD depiction of a medication error – the administration of intrathecal vincristine. The DVD illustrates the multifactorial nature of error.



Books

Vicente K. *The human factor*. London, Routledge, 2004:195–229.

Cooper N, Forrest K, Cramp P. *Essential guide to generic skills*. Blackwell Publishing, 2006.

Institute of Medicine. *Preventing medication errors: quality chasm series*. Washington, DC, National Academy Press, 2006 (<http://www.iom.edu/?id=35961>).

HOW TO ASSESS THIS TOPIC

Assessment strategies/formats

A variety of assessment methods can be used to assess medication safety knowledge and performance elements including:

- MCQs;
- drug calculation quiz;
- short answer questions;
- written reflection on a case study involving a medication error, identifying the contributing factors and considering strategies to prevent recurrence;
- project work with accompanying reflection on learning outcomes of the activity;
- OSCE—potential stations include:
 - perform a medication and allergy history;
 - administer a medication checking the 5 Rs

- and for allergies;
- prescribing exercises;
- educate a patient about a new medication.

Note that several of these potential assessment topics are not covered in detail in the accompanying PowerPoint presentation on introduction to medication safety. They are included here as ideas for assessment in the area of medication safety on the assumption that students would have additional teaching on these particular aspects of medication safety.

HOW TO EVALUATE THIS TOPIC

Evaluation is important in reviewing how a teaching session went and how improvements can be made. See the Teacher's Guide (Part A) for a summary of important evaluation principles.

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SLIDES FOR TOPIC 11: IMPROVING MEDICATION SAFETY

Didactic lectures are not usually the best way to teach students about patient safety. If a lecture is being considered, it is a good idea to plan for student interaction and discussion during the lecture. Using a case study is one way to generate group discussion. Another way is to ask the students questions about different aspects of health care that will bring out the issues contained in this topic such as the blame culture, nature of error and how errors are managed in other industries.

The slides for topic 11 are designed to assist the teacher deliver the content of this topic. The slides can be changed to fit the local environment and culture. Teachers do not have to use all of the slides and it is best to tailor the slides to the areas being covered in the teaching session.

APPENDICES

WHO Patient Safety Curriculum Guide for Medical Schools

APPENDIX 1: Assessment method examples

Modified essay question example

An accident

Instructions to the student

A 20-year-old man lost control of his bicycle and fell heavily to the road having been clipped by a car that did not stop. He is conscious but mumbling and not able to speak coherently. He may be in shock. You (as a medical student) slow down as you approach the scene of the accident and a passerby flags you down and asks you to help.

What three important ethical issues are associated with treating patients in emergencies:

Outline the legal/professional responsibilities in relation to providing assistance in an emergency:

Outline the components of consent for the unconscious patient and conscious patient:

Summarize the challenges of providing leadership in this clinical situation?

Multiple choice question example

Question

As a medical student, you have been invited to observe a knee replacement in an elderly female. The day before the operation the student talked to the patient and remembered being told that her left knee had made it impossible for her to walk and she was looking forward to having it fixed. In the operating theatre the student hears the surgeon say to his assistant that they were going to be operating on her right knee.

What should you, as a medical student, do next?

- a) Do nothing because you may have confused this patient with another patient.
- b) Locate and review the medical records to confirm the side for the knee replacement.
- c) Say nothing because you have not asked permission to speak to others about her situation.
- d) Say nothing because hospitals never make mistakes and the student probably misheard.
- e) Tell the surgeon that you thought that the patient was having her left knee replaced.
- f) Keep silent because the surgeon is likely to know what he is doing.

Comments: Everybody has a role in patient safety. Every individual has an obligation to speak up when they think a potential error may be made that has the potential to harm a patient. Junior members of health-care teams are important eyes and ears for the team and their contributions can minimize the number of errors in the system. Wrong site surgery is a major cause of adverse events. Most countries have access to clinically endorsed guidelines to assist the correct identification of patients and site of surgery. These guidelines include that junior members of the team should be appropriately assertive.

OSCE station in patient safety examples

Station No.

Patient communication: an adverse event

Instructions to the student

The patient has just come out of routine surgery for the repair of an inguinal hernia. During the operation, the trainee surgeon had had difficulty in undertaking the procedure. The supervising surgeon had taken over and the operation was reported as being successful. However, there was extensive bruising around the scar site. You have been asked to discuss the patient's concerns with him.

NB: Please remember to hand your identity label to the examiner.

Station No.

Patient communication: an adverse event

Instructions to the student

Please carefully read the instructions to the student and to the examiner prior to the start of the examination.

You have come into hospital for the emergency removal of your appendix .
You were previously fit and well and work as a plumber.

As you were coming around from the operation, the theatre nurse explained that the training doctor found that the operation through a small incision was more difficult than expected. The consultant surgeon took over and things went smoothly during a laparotomy.

The scar site is bigger than you expected and is painful but you have had some painkillers that are helping. You are keen to discuss what happened to you in more detail.

Early on, you indicated that you are going to make an official complaint about the care you have had.

Station No.

Patient communication: an adverse event

Instructions to the examiner

Please carefully read the instructions to the student and the simulated patient.

Greet the student and give the written instructions to the student.

Observe the interaction between the student and the simulated patient and complete the mark sheet.

Please do not interact with the student or the simulated patient during or after completion of the task.

The purpose of this station is to assess the student's ability to discuss an adverse event with a patient

Station No.

Patient communication: an adverse event

Student name:

Examiner's name:(block capitals)

Greet the student and give the written instructions to the student.

Remember to ask the student for the identity label and affix it to the top of the mark sheet.

Please circle the appropriate mark for each criterion. The standard expected is that of a new pre-registration house officer (PRHO).

Criteria	Performed competently	Performed but not fully competent	Not performed or incompetent
Initial approach to the patient (introduction by the student to the patient and an explanation of what will be done)	2	1	0
Communicates with patients and carers in ways they understand	2	1	0
Demonstrates the principles of open disclosure	2	1	0
Ensures patients are supported and cared for after an adverse event	2	1	0
Shows understanding to patients following adverse events	2	1	1
Manages the factors likely to lead to complaints	2	1	0
Total (maximum 10)			

Overall rating on station

Clear fail	Borderline	Clear pass
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APPENDIX 2: Link to the Australian Patient Safety Education Framework

The Australian Patient Safety Education Framework (APSEF) has a separate volume containing the literature relied upon to build the framework. A Campbell Collaboration style for reporting the literature was used for the literature review. The bibliography is freely available and will assist teachers developing curriculum and conducting patient safety research.

The accompanying bibliography can also be accessed online at [http://www.health.gov.au/internet/safety/publishing.nsf/Content/C06811AD746228E9CA2571C600835DBB/\\$File/framewkbibli0705](http://www.health.gov.au/internet/safety/publishing.nsf/Content/C06811AD746228E9CA2571C600835DBB/$File/framewkbibli0705).

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Medication Without Harm



WHO Global Patient Safety Challenge



**World Health
Organization**

WHO/HIS/SDS/2017.6

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Foreword



More than 10 years ago, with colleagues in the World Health Organization (WHO), I was involved in establishing the foundation programme of a global patient safety initiative that was the first of its kind. It was wide-ranging and led to the launching of two Global Patient Safety Challenges. It also created a programme led by patients and families who had suffered avoidable harm from health care, and it set a clear agenda for research and development, among many other areas of work aimed at improving safety globally.

In the last decade, the WHO Patient Safety Programme has raised awareness across the world of the key concepts and strategies in patient safety. It has inspired passion for the universal cause of making health care safer. It has secured commitment at the highest level among health ministers and health leaders in Member States of WHO. It has provided standards, evidence-based guidance and practical tools to support those involved in the design of patient safety programmes within countries' health care systems. It has championed the use of the stories of patients and families who have been the victims of unsafe care.

Significant portions of the Programme's initial work have been delivered and a new direction and new priorities are now required for the next phase in this programme. Moreover, the global context of patient safety as a science has evolved considerably since the creation of the Programme. At the time, there were few, if any, national agencies with a recognized mandate to work on patient safety and virtually no training and education programmes in patient safety globally. Currently, many Member States have active safety and quality programmes, campaigns and agencies, although some still ask the World Health Organization to provide implementation assistance.

The WHO Patient Safety Team has received strong feedback from major stakeholders and

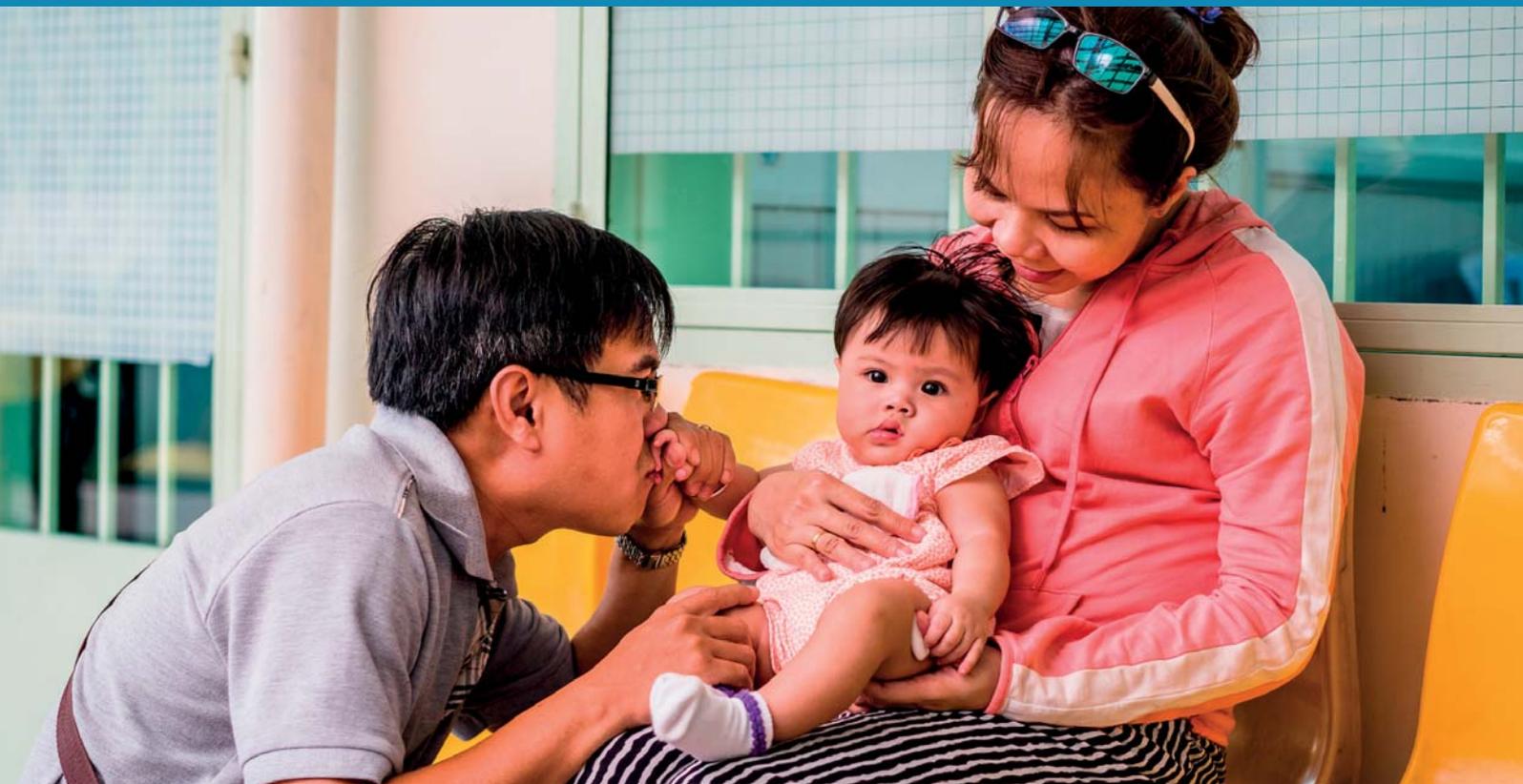
experts that a third global patient safety challenge should be the first of these new priorities and would be greatly welcomed. The Global Patient Safety Challenge is essentially a programme of change aimed at improvement and risk reduction. The programme blends evidence-based interventions with multi-modal implementation strategies. They seek to achieve widespread engagement and commitment. They span the needs of all countries. They are most impressive when they develop the features of a social movement, as the first and second challenges managed to do.

I was delighted and honoured, two years ago, when Assistant Director-General, Dr Marie-Paule Kieny, asked me to advise on the design of a third Global Patient Safety Challenge on medication safety. Dr Kieny and WHO's Director-General, Dr Margaret Chan have given me, as well as the world's patient safety community, unfailing support in continuing to pursue the goal of safer care as a core component of universal health coverage. In the hard work of bringing this historic Challenge to life, the WHO Secretariat

and leading world experts and stakeholders have given invaluable advice and support. In participating in the work to create this third Global Patient Safety Challenge, I have been driven and inspired by three things. Firstly, an awareness of studies in the 1960s that identified sources of medication error that can, and do, kill and harm patients in hospitals around the world today, nearly sixty years on. Secondly, that there are many individuals and groups in the fields of pharmacy, medicine, nursing, and other professions, who have been fighting for decades to see the day when medication safety would become a global priority; their passion has always been to save lives from this long-standing intractable type of avoidable harm. Thirdly, over the years, I have spoken to many people who have lost loved ones to medication-related harm; their stories, their quiet dignity and their acceptance of situations that should never have arisen have moved me deeply. It is to the memories of all those who have died due to incidents of unsafe care that this Challenge should be dedicated.

Sir Liam Donaldson

WHO Envoy for Patient Safety



Global Patient Safety Challenges

Global Patient Safety Challenges identify a patient safety burden that poses a significant risk to health, then develop frontline interventions and partner with countries to disseminate and implement the interventions. Each Challenge focuses on a topic that poses a major and significant risk to patient health and safety. WHO provides leadership and guidance in collaboration with Member States, stakeholders and experts, to develop and implement interventions and tools to reduce risk, improve safety and facilitate beneficial change.

Previous Global Patient Safety Challenges

Beginning in 2004, the World Health Organization (WHO) working in partnership with the (then) World Alliance for Patient Safety, initiated the two previous Global Patient Safety Challenges: *Clean Care is Safer Care*, followed a few years later by *Safe Surgery Saves Lives*. Both aimed to gain worldwide commitment and spark action to reduce health care infection and risk associated with surgery, respectively.

The scale and speed of implementation of these Challenges remains unprecedented. They secured strong and rapid commitment from health ministers, professional bodies, regulators, health system leaders, civil society and health care practitioners. Their success resulted from the following solid basis and achievements:

- an evidence-based analysis of the key problems and proposed solutions;
- an invitation to Member States and other relevant parties to pledge, or sign up, to address the aims of the Challenge;
- high-profile actions to generate passion and enthusiasm;
- facilitation of implementation by the WHO Secretariat and associated experts and advisers;
- strong leadership and extensive internal and external communication.

The third Global Patient Safety Challenge

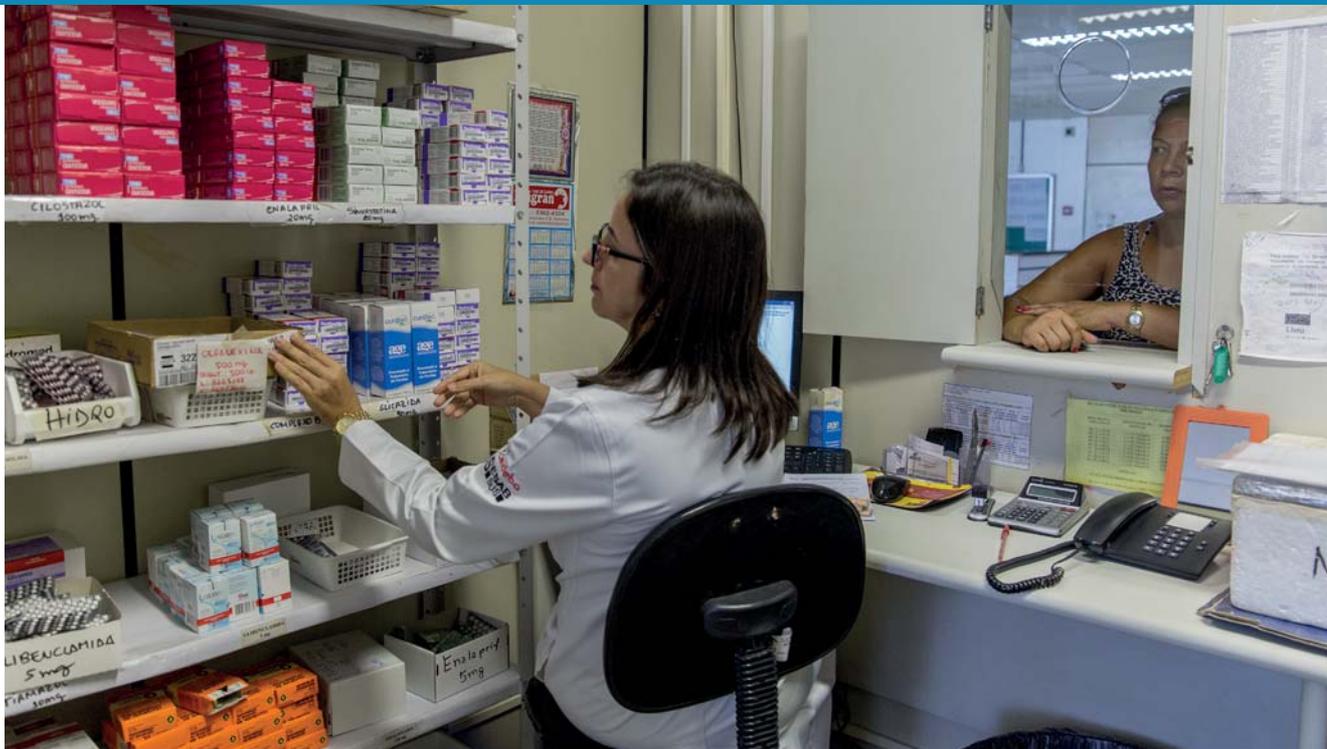
Medication Without Harm

WHO is initiating the third Global Patient Safety Challenge with the theme of medication safety. It is set within the philosophy of patient safety previously developed by WHO, namely that errors are inevitable and provoked in large part by weak health systems, and so the challenge is to reduce their frequency and impact. The Challenge was launched in March 2017, at the Global Ministerial Summit on Patient Safety in Bonn, Germany. By seeking the commitment of high-level delegates, ministers of health and experts, the launch created an opportunity for leaders to drive change and work together to make real difference to the lives of patients, families and health workers at the frontline. This Challenge will draw on the experience accumulated during the previous Challenges and will drive a process of change to reduce patient harm generated by unsafe medication practices and medication errors.

Every person around the world will, at some point in their life, take medicines to prevent or treat illness. Medicine has forever altered our ability to live with disease and generally increased the duration of our lives. However, medicines do sometimes cause serious harm if taken incorrectly, monitored insufficiently or as the result of an error, accident or communication problem.

Experience from other high-risk industries, and WHO's longstanding work with experts in health care safety, demonstrate that human beings make mistakes rarely through neglect, but instead because the systems, processes and procedures that they work with are often flawed or dysfunctional. This inevitably gives rise to errors and medication harm is no exception to this rule. All medication errors are potentially avoidable. They can thus be greatly reduced or even prevented by





improving the systems and practices of medication, including ordering, prescription, preparation, dispensing, administration and monitoring. Given that the subject is so vast, the approach of this third Challenge aims to save lives and reduce the medication-related harm caused by unsafe practices and errors, by specifically addressing the weaknesses of service delivery and developing more effective health care systems.

Severity of the problem

- Unsafe medication practices and medication errors are a leading cause of avoidable harm in health care systems across the world.
- The scale and nature of this harm differs between low-, middle- and high-income countries. Globally, the cost associated with medication errors has been estimated at US\$ 42 billion annually.
- Patients living in low-income countries experience twice as many disability-adjusted life years lost due to medication-related harm than those in high-income countries.
- Medication errors occur when weak medication systems and/or human factors such as fatigue, poor environmental conditions or staff shortages affect prescribing, transcribing, dispensing, administration and monitoring practices,

which can then result in severe harm, disability and even death.

- Errors occur most frequently during administration, however there are risks at different stages of the medication process.

Overall goal

The Global Patient Safety Challenge on Medication Safety focuses on improving medication safety by strengthening the systems for reducing medication errors and avoidable medication-related harm.

Reduce the level of severe, avoidable harm related to medications by 50% over 5 years, globally

The goal of the third Global Patient Safety Challenge on Medication Safety is to gain worldwide commitment and action to reduce severe, avoidable medication-related harm by 50% in the next five years, specifically by addressing harm resulting from errors or unsafe practices due to weaknesses in health systems. The Challenge aims to make improvements at each stage of the medication process, including prescribing, dispensing, administering, monitoring and use.



Objectives of the Global Challenge on Medication Safety

The Global Patient Safety Challenge on Medication Safety will facilitate a strengthening of systems and practices that can initiate corrective action within countries to improve patient safety and decrease avoidable harm related to medications.

In order to achieve this, the Challenge will adopt five specific objectives.

- 1. ASSESS** the scope and nature of avoidable harm and strengthen the monitoring systems to detect and track this harm.
- 2. CREATE** a framework for action aimed at patients, health professionals and Member States, to facilitate improvements in ordering, prescribing, preparation,

dispensing, administration and monitoring practices, which can be adopted and adapted by Member States.

- 3. DEVELOP** guidance, materials, technologies and tools to support the setting up of safer medication use systems for reducing medication errors.
- 4. ENGAGE** key stakeholders, partners and industry to raise awareness of the problem and actively pursue efforts to improve medication safety.
- 5. EMPOWER** patients, families and their carers to become actively involved and engaged in treatment or care decisions, ask questions, spot errors and effectively manage their medications.

Shaping the Challenge – the Strategic Framework

The lessons for success drawn from earlier Global Patient Safety Challenges include high visibility, political and professional commitment, multileveled ‘spearheading’ interventions and WHO’s ability to lead and mobilize the global community to reach the proposed goals. The Strategic Framework for this Challenge should galvanize commitment to reduce medication errors and medication-related harm and strengthen measurement and safety monitoring systems.

Four fundamental problems lay the ground for the strategic framework:

- **Patients and the public** are not always medication-wise. They are too often made to be passive recipients of medicines and not informed and empowered to play their part in making the process of medication safer.
- **Medicines** are sometimes complex and can be puzzling in their names, or packaging and sometimes lack sufficient or clear

information. Confusing ‘look-alike sound-alike’ medicines names and/or labelling and packaging are frequent sources of error and medication-related harm that can be addressed.

- **Health care professionals** sometimes prescribe and administer medicines in ways and circumstances that increase the risk of harm to patients.
- **Systems and practices of medication** are complex and often dysfunctional, and can be made more resilient to risk and harm if they are well understood and designed.

The actions planned in this Challenge are based on four domains of work, one for each fundamental problem identified. These are:

- patients and the public
- medicines
- health care professionals
- systems and practices of medication.

In each of these domains, there are many ways in which using medications can cause avoidable harm. There are many ways, too, in which care could be made safer.





Key action areas

The actions embraced by the Challenge fall into three categories:

Early priority actions. Ask countries and key stakeholders to make strong commitments, prioritize and take early action, and effectively manage three key areas to protect patients from harm, namely:

- high-risk situations
- polypharmacy
- transitions of care

Developmental programmes. Ask countries to convene experts, health care professionals and leaders, key stakeholders and patient representatives to design targeted programmes of change and take action to improve safety in each of the four domains of the Challenge framework: 1) patients and the public; 2) medicines; 3) health care professionals; and 4) systems and practices of medication.

Global action. WHO aims:

- a) to provide guidance and develop strategies, plans and tools to ensure that the medication process has the safety of patients at its core, in all health care settings;
- b) to strengthen human resource capacity through leadership development and skill-building;
- c) to strengthen the quality of monitoring data;
- d) to promote and support research in this area as part of the overall agenda of patient safety research;
- e) to continue engaging with regulatory agencies and international actors and continuously improve medication safety through improved packaging and labelling; and
- f) to develop mechanisms for the engagement and empowerment of patients to safely manage their own medications.



A mother's call for medication without harm

My oldest daughter, Martha went to study nursing with a strong desire of caring for the sick. But she had some health concerns of her own. She had chronic hypokalemia or low potassium that required supplementation from time to time and her EKG's were always abnormal. Even when further cardiac tests were done, the abnormal results were seen as normal for her and the results were simply filed away, and Martha and I remained unaware of her heart condition. Later, she developed mood swings that were seen as symptoms of bipolar affective disorder and she was prescribed lithium which helped to regulate her moods. We read the information sheet together and looked up the drug online, but we were not aware of a warning in her medical file specifically advising against prescribing lithium and we were not told of severe adverse reactions to look for. Even though her heart began to race at times, the lithium dosage was increased. Then 13 days later, her father went to wake her up one morning, and found Martha on her bedroom floor where she had died. She had not been able to get to the door to call for help. At just twenty-two years old,

our daughter had suffered a fatal cardiac arrhythmia.

Although a tragic series of medical errors and the adverse medication reaction took Martha's life, no reporting took place and her death was simply identified as 'natural'. It took six years of great effort, extensive media coverage, and two further death reviews to finalize Martha's death investigation and create meaningful changes to help prevent similar fatalities. So as patients and families, what can we do to help avoid medication-related harm? There are two things that stand out: 1) We can encourage reporting and can even report an adverse medication event ourselves; and 2) We can take an active role in the patient's own medical care and medication management.

Let's honour those like Martha who have been harmed, not by covering up what happened, but by demanding transparency and centralized reporting so these tragic events can lead to improved medication safety for everyone.

High-risk situations

The impact of medication errors is greater in certain clinical circumstances, such as with inpatients in hospital, rather than in ambulatory care. This may be related to the more acute or serious clinical situations in these settings and the use of more complex medication regimes. Young children and the elderly are more susceptible to adverse outcomes, as well as those with concomitant kidney or liver disease. Medication errors in these circumstances often involve the administration of the wrong dose, use of the wrong route, and a failure to follow treatment regimens.

Understanding the situations where the evidence shows there is higher risk of harm from particular medicines, is key to this Challenge. Tools and technologies may help health care professionals using high-alert medications (those that are associated with a high risk of severe harm if used improperly), and also enhance patient knowledge and understanding of these medications.

Polypharmacy

Polypharmacy is the routine use of four or more over-the-counter, prescription and/or traditional medications at the same time by a patient. Polypharmacy has increased dramatically with greater life expectancy and as older people live with several chronic diseases. Polypharmacy increases the likelihood of side effects, as well as the risk of interactions between medications, and may make adherence more difficult. If a patient requires many medicines, they must be utilized in an optimal manner, so that

the medicines are appropriately prescribed and administered, to ensure that they produce direct and measurable benefits with minimal side effects. The standardization of policies, procedures and protocols is critical to polypharmacy. This applies from initial prescribing practices, to regular medication reviews.

Patients can play a vital part if provided with the right information, tools and resources to make informed decisions about their medicines. Technology can also serve as a useful aid.

Transitions of care

Transitions of care occur when a patient moves between facilities, sectors and staff members; for example: a transfer from the emergency room to the intensive care unit, from a nursing home to a hospital, from a primary care doctor to a specialist, or from one nurse to another during a shift change. Transitions of care increase the possibility of communication errors, which can lead to serious medication errors. Patients are at increased risk during transitions of care and so serious mistakes can and do occur at these times, in particular.

Good communication is vital, including a formal comparison of medicines pre- and post-care, so-called medication reconciliation. Patients can be valuable and active participants in this process by maintaining a current medicine list that is updated when any medicine changes occur.



Political leadership, commitment and support

The third Global Patient Safety Challenge on Medication Safety invites WHO Member States to prioritize medication safety at the national level. Demonstrable commitment and leadership are needed to significantly reduce the level of severe, avoidable harm related to medications in their countries over a period of five years. The emphasis is on countries working out their own priorities and action programmes using the Challenge framework to support their work.

A five-point plan has been developed to facilitate adoption:

1. Take early action to protect patients from harm arising from: high-risk situations; polypharmacy; and transitions of care.
2. Convene national experts, health system leaders and practitioners to produce guidance and action plans for each of the targeted domains.
3. Put mechanisms in place, including the use of tools and technologies, to enhance patient awareness and knowledge about medicines and medication use process, and patients' role in managing their own medications safely.
4. Designate a national coordinator to spearhead the Global Patient Safety Challenge on Medication Safety.
5. Assess progress regularly.

The success of the Challenge will depend on the high prioritization of medication safety within health care systems, achieving widespread buy-in by stakeholders, a shift to the mainstream of care provision activities and taking concrete action to prevent harm.





WHO action

In driving forward the Global Patient Safety Challenge on Medication Safety, WHO will provide support in 10 key areas:

1. Lead the process of change and take global action to make progress on the domains of the Challenge framework.
2. Facilitate the development and implementation of country programmes.
3. Commission expert reports to provide a starting point for in-country work to develop guidance and action plans in each of the domains of the Challenge.
4. Develop strategies, guidelines, plans and tools to ensure safety of medication practices.
5. Publish a strategy setting out research priorities and mobilize resources for an international research study on hospital admissions due to medication effects.
6. Hold regional launch events in each WHO region following on from the global launch.
7. Create and implement a communications and advocacy strategy and a global campaign, and produce promotional and educational materials.
8. As part of the WHO Patients for Patient Safety programme, ensure that patients and families are closely involved in all aspects of the Challenge and develop a tool to help patients protect themselves from harm.
9. Monitor and evaluate impact of the Challenge.
10. Mobilize resources to enable full and successful implementation of the Challenge.

Throughout the implementation process, WHO will also seek to develop a much greater understanding of the special problems of medication-related harm in low- and middle-income countries and to reshape the Challenge to meet needs in diverse settings.

Collaboration and partnerships

Working with international experts, partners and interested stakeholders, WHO will develop the guidelines, tools, technologies and materials needed, and work in close collaboration with countries to implement the Challenge.

Who should act as a catalyst for change?

Ministries of health and health system leaders
 Educational and research institutions
 Regulatory authorities
 Health care professional societies
 Patient advocacy groups
 Donors and development partners
 Pharmaceutical industry

In addressing the overall goal and action areas of the Challenge, WHO will work with a wide range of stakeholders including: ministries of health, national coordinators or programme managers for medication safety, health system leaders, experts, educational institutions, researchers, safe medication practice centres, regulatory agencies, patient representative bodies and professional societies and industry.





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Patient Safety

Making health care safer



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Patient safety – a global concern

Patient safety is a fundamental principle of health care. A number of high-income countries have published studies showing that significant numbers of patients are harmed during health care, either resulting in permanent injury, increased length of stay in health care facilities, or even death. According to a new study, medical errors are the third leading cause of death in the United States. In the United Kingdom, recent estimations show that on average, one incident of patient harm is reported every 35 seconds. Similarly, in low- and middle-income countries, a combination of numerous unfavourable factors such as understaffing, inadequate structures and overcrowding, lack of health care commodities and shortage of basic equipment, and poor hygiene and sanitation, contribute to unsafe patient care. A weak safety and quality culture, flawed processes of care, and disinterested leadership teams further weaken the ability of health care systems and organizations to ensure provision of safe health care.

Ensuring the safety of patients is a high visibility issue for those delivering health care - not just in any single country, but

worldwide. The safety of health care is now a major global concern. Services that are unsafe and of low quality lead to diminished health outcomes and even to harm. The experience of countries that are heavily engaged in national efforts clearly demonstrates that, although health systems differ from country to country, many threats to patient safety have similar causes and often similar solutions. Treating and caring for people in a safe environment and protecting them from health care-related avoidable harm should be a national and international priority, calling for concerted international efforts.

Delivering safer care in complex, pressurized and fast-moving environments is one of the greatest challenges facing health care today. In such environments, things can often go wrong. The most important challenge in the field of patient safety must be how to prevent harm, particularly 'avoidable harm', to patients during treatment and care. All preventable errors can, and should be, avoided. But in order to provide high quality health services, the safety of each and every patient deserves to be given the highest priority.



The burden and impact of unsafe care



Every year, an inadmissible number of patients suffer injuries or die because of unsafe and poor quality health care. Most of these injuries are avoidable. The burden of unsafe care broadly highlights the magnitude and scale of the problem.

- It is commonly reported that around 1 in 10 hospitalized patients experience harm, with at least 50% preventability.
- In a study on frequency and preventability of adverse events, across 26 low- and middle-income countries, the rate of adverse events was around 8%, of which 83% could have been prevented and 30% led to death.
- It is estimated that 421 million hospitalizations take place in the world annually, and approximately 42.7 million adverse events occur in patients during those hospitalizations.
- Approximately two-thirds of all adverse events happen in low- and middle-income countries.

It is estimated that the cost of harm associated with the loss of life or permanent disability, which results in lost capacity and productivity of the affected patients and families, amounts to trillions of US dollars every year. Furthermore, the psychological cost to the patient and their family, associated with the losing a loved one or coping with permanent disability, is significant though more difficult to measure. Studies on direct

medical costs associated with poor care show that additional hospitalization, litigation costs, infections acquired in hospitals, lost income, disability and medical expenses have cost some countries between US\$ 6 billion and US\$ 29 billion per year. Loss of trust in the system and loss of reputation and credibility in health services are additional forms of collateral damage caused by unsafe health care.

The evidence currently available shows that 15% of hospital expenditure in Europe can be attributed to treating safety accidents. It is estimated that the aggregate cost of harm, in terms of lost capacity and productivity of the affected patients and families, comes to trillions of US dollars every year. The cost of preventing these errors is insignificant in comparison. In the United States alone, focused safety improvements led to an estimated US\$ 28 billion in savings in Medicare hospitals alone, between 2010-15.

Medical errors occur right across the spectrum, and can be attributed to both system and human factors. The most common adverse safety incidents are related to surgical procedures (27%), medication errors (18.3%) and health care-associated infections (12.2%). Yet, in many places, fear around the reporting of errors is manifested within health care cultures, impeding progress and learning for improvement and error prevention.



The World Health Organization's work on patient safety

The global need for quality of care and patient safety was first discussed during the World Health Assembly in 2002, and resolution WHA55.18 on 'Quality of care: patient safety' at the Fifty-fifth World Health Assembly urged Member States to "pay the closest possible attention to the problem of patient safety". Since then, there have been several international initiatives, which have brought the importance of the matter to the attention of policy-makers in many countries.

However, there have been limited systemic improvements in the safety of health care globally, and in some situations efforts made have been unsustainable and uncoordinated. In many countries, health services, where they are available, are of poor quality, thus endangering the safety of patients, compromising health outcomes, and this leads to lack of trust of the population in health

services. Clear policies, organizational leadership capacity, data to drive safety improvements, skilled health care professionals and effective involvement of patients in their care, are all needed to ensure sustainable and significant improvements in the safety of health care.

The World Health Organization's (WHO) strategic objectives in the area of patient safety are to provide global leadership for patient safety and to harness knowledge, expertise and innovation to improve patient safety in health care settings. WHO's unique convening role at the global level provides a vehicle for improving patient safety and managing risk in health care through international collaboration, engagement and coordinated action between Member States, institutions, technical experts, patients, civil society, industry, as well as development partners and other stakeholders.



Our vision

A world where every patient receives safe health care, without risks and harm, every time, everywhere.

Our mission

To facilitate sustainable improvements in patient safety and managing risks to prevent patient harm.

Our approach

WHO's work on patient safety began with the launch of the World Alliance for Patient Safety, in 2004, and has evolved over time. The WHO Patient Safety and Risk Management unit has been created to coordinate, disseminate and accelerate improvements in patient safety and managing risks in health care to prevent patient harm worldwide.

Our approach to driving improvements



Expected outcomes

- **Improved patient safety**
- **Reduced risks and harm**
- **Better health outcomes**
- **Enhanced patient experience**
- **Lower costs**

4

Since 2002, improving patient safety has been mandated by successive global and regional resolutions. WHO has been instrumental in shaping the patient safety agenda worldwide by providing leadership, setting priorities, convening experts, fostering collaboration and creating networks, issuing guidance, facilitating change and building capacity, and monitoring trends. Placing the patient at the centre of improvement strategies for safer health care, WHO's work on

patient safety is driving improvements through the following key strategic areas:

- Providing global leadership and fostering collaboration
- Developing guidelines and tools, and building capacity
- Engaging patients and families for safer health care
- Monitoring improvements in patient safety.



Medication Without Harm WHO's third Global Patient Safety Challenge

One of the concrete ways in which WHO facilitates improvements on the ground is through a 'Global Patient Safety Challenge'. The Challenge identifies a patient safety burden that poses a major and significant risk to patient health and safety, and then develops front-line interventions to tackle the issue. WHO provides leadership and guidance, in collaboration with Member States, stakeholders and experts, to develop and implement interventions and tools to reduce risk, improve safety and facilitate beneficial change. The two previous challenges, *Clean Care is Safer Care* and *Safe Surgery Saves Lives*, sparked action to reduce health care infection and risks associated with surgery, respectively.

Globally, the cost associated with medication errors is US\$ 42 billion each year, almost 1% of global expenditure on health.

WHO has initiated its third Global Patient Safety Challenge: *Medication Without Harm*, to address a number of issues related to medication safety.

This Challenge aims to reduce medication-related harm caused by unsafe medication practices and errors. The Challenge focuses on improving medication safety by strengthening the systems for reducing medication errors and avoidable medication-related harm, with the goal to

Reduce the level of severe, avoidable harm related to medications by 50% over 5 years, globally.

The Challenge was launched in March 2017 during the Second Global Ministerial Summit on Patient Safety in Bonn, Germany, in the presence of global health leaders and policy-makers. This event secured political support with commitments from health ministers to act as catalysts for change.

Countries are requested to prioritize taking action on medication safety, designate leaders to drive action and devise their own tailored programmes centred on local priorities. WHO will lead the process of change by providing support to countries for developing national programmes, instigating large-scale international research, providing guidance and developing practical tools for front-line health workers and for patients.

In driving forward the third Global Patient Safety Challenge, WHO will provide support with action in 10 key areas:

1. to lead action to progress the key components of the Challenge;
2. to facilitate country programmes;
3. to commission expert reports for planning and guiding actions to be taken;
4. to develop strategies, guidelines, plans and tools on safe medication practices;
5. to publish a strategy setting out research priorities and mobilize resources for international research on hospital admissions resulting from medication-related adverse events;
6. to hold regional launches to secure political commitment, as a follow-up from the global launch;
7. to create communication and advocacy strategies, alongside a global campaign with promotional and educational materials for in-country use;
8. to ensure patients and families are closely involved in all aspects of the Challenge, including in the development of patient tools;
9. to monitor and evaluate impact of the Challenge;
10. to mobilize resources to enable successful implementation of the Challenge.



WHO will also seek to develop a greater understanding of medication-related harm in low- and middle-income countries and adapt the Challenge to the varying needs of diverse settings.

A real story of harm from a medication error

6

A couple took their two-week-old baby girl for a routine check-up. The paediatrician ordered two injections of vitamin K. The nurse gave the baby one injection and passed the second vial to the parents. On their way home, the baby cried continuously. When she suddenly stopped crying, her parents realized she was no longer breathing. They rushed her back to the clinic, where the staff immediately began to resuscitate. The baby girl died later that afternoon.

As the grieving parents tried to understand what had happened, they looked at the vial of medicine they had remaining. It said EPINEPHRINE. They realized their baby had not been given vitamin K as they had thought. Clinic staff told them that the vitamin K and epinephrine bottles were similar in size and colour and were easy to confuse. "Look-alike" packaging is an ever-present challenge in dispensing of medications.





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Global Ministerial Summits on Patient Safety

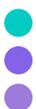
Since 2016, the Governments of the United Kingdom and of Germany have co-led an initiative, in collaboration with WHO, to organize annual global ministerial summits on patient safety for seeking political commitment and leadership to prioritize patient safety globally. As part of this, health ministers, high-level delegates, experts and representatives from international organizations meet once a year to progress the agenda at the political level, with different countries

invited to host the Summit each year. WHO is committed to sustaining and taking forward this global initiative and work with countries to develop systems for improving the safety of patients and managing the risks to prevent patient harm.

7

"I have full confidence that this summit will further invigorate a movement that makes patient safety a burning issue that no one can ignore".

Dr Margaret Chan, WHO Director-General at the Second Global Ministerial Summit on Patient Safety in Bonn, March 2017





Global Patient Safety (GPS) Network

Multiple stakeholders are active in the field of patient safety and a wealth of experience, best practices and lessons learned are available. With the support of the Governments of Japan and Oman, WHO has created a network to connect actors and stakeholders from national and international patient safety and quality agencies and institutions; ministries of health; national/regional/zonal focal points from countries across all six WHO regions; WHO country, regional and global focal points for patient safety and quality of care; international professional bodies and other key stakeholders. The primary aims of the network are to:

- encourage leadership commitment;
- collect evidence from a variety of standpoints, to inform future policies and practice;
- strengthen knowledge transfer and technical capacity across borders;
- institutionalize patient safety for sustainability;
- encourage the sharing and application of best practices.

Global Knowledge Sharing Platform for Patient Safety (GKPS)

Health care systems are still missing a timely and systematic way for sharing the lessons learned on patient safety incidents, as well as an effective approach to disseminating and facilitating the implementation of good patient safety practices.

The web platform addresses these gaps by providing space to systematically share the lessons learned from the systemic analysis of incidents and the implementation of safety practices, with a structured and sustainable process for enhancing linkages among authorities who manage reporting and learning systems, clinicians, safety managers and patient advocates.

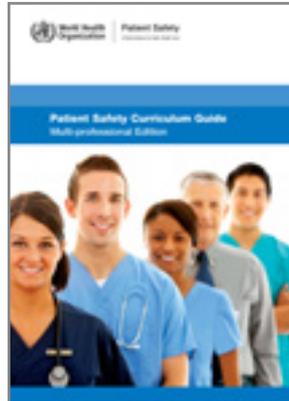
The platform connects key stakeholders involved in reporting and learning systems and the implementation of safety practices by sharing methods, tools and experiences of safety managers and local users, to speed up effective dissemination of patient safety and quality improvement strategies. WHO is developing GKPS together with the Centre for Clinical Risk Management and Patient Safety in Florence, the WHO Collaborating Centre for Human Factors and Communication for the Delivery of Safe and Quality Care.



Developing guidelines and tools, and building capacity

Patient safety education and training Multi-professional Patient Safety Curriculum Guide

WHO has published the *Multi-professional Patient Safety Curriculum Guide* to assist in patient safety education in universities, schools and professional institutions in the fields of dentistry, medicine, midwifery, nursing and pharmacy. Its implementation, adaptation, incorporation and related educational tools have been widely accepted as a core strategy to improve safety at the sharp end. Locally adapting the Guide can help encourage its uptake, and there are a variety of tools available to support its adaptation and implementation in countries.



WHO is currently in the process of developing an international patient safety e-academy based on the *Multi-professional Patient Safety Curriculum Guide* for building the capacity of health care professionals in patient safety.

Educational Councils Network

Educational councils act as a key mechanism for incorporating patient safety into the curricula for the education and training of health care professionals, including doctors, nurses, pharmacists and dentists through on-going training programmes. A WHO network of educational councils from around the world is now being created, which will foster information sharing and facilitate the implementation of patient safety curricula in educational institutions globally for improving patient safety.



Competencies for leadership, teamwork and communication for patient safety

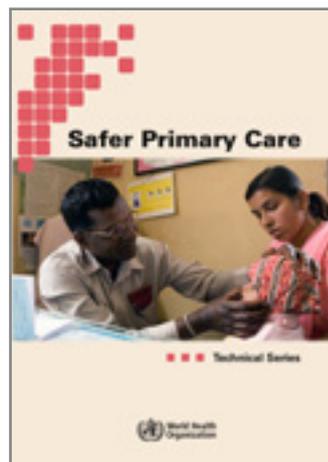
A competency framework, assessment tool and guide for leadership in patient safety are currently in development for building leadership capacity in patient safety at the organizational level. Recognizing the multidisciplinary nature of safe health care provision, a framework for competencies will also be developed for inter-professional teamwork and communication for patient safety.

Safer primary care

Primary health care strives to keep communities healthy. It has been heralded by some experts as the principal vehicle for achieving sustainable, universal health coverage and for ensuring no one is left behind. However to date, most patient safety research has focused on the hospital setting, and not on primary care where the majority of health care is actually delivered. Recognizing the scarcity of accessible information on safer

primary care, WHO recently developed a technical series on safer primary care to provide a compendium of information on key issues that can affect safety in primary care, to contribute to building national capacity in designing and delivering safer primary care services.

The *WHO Technical Series on Safer Primary Care* is a series of nine monographs related to patients, the health workforce, care processes, and tools and technology, which explore the magnitude and nature of harm and provide some possible solutions and practical steps for improving safety in primary care. The topics covered in the series are:



- Patient engagement
- Education and training
- Human factors
- Administrative errors
- Diagnostic errors
- Medication errors
- Multimorbidity
- Transitions of care
- Electronic tools.

Case study: Thailand

10

Building a safety competent workforce in Thailand

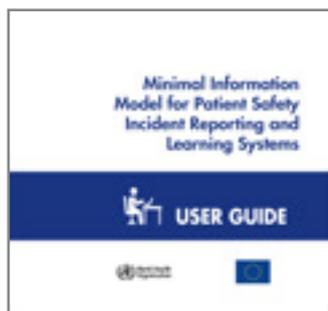
The Healthcare Accreditation Institute of Thailand successfully incorporated safety and quality topics into the Thai medical curriculum in 133 institutions, using a locally adapted version of the *WHO Multi-professional Patient Safety Curriculum Guide*. A collaborative approach was used, engaging key patient safety leaders, education institutions and training 120 trainers for a successful scale-up. Some key learning opportunities from this experience included:

- start with an interest group to lead advocacy and implementation;
- set up a central organization to coordinate and provide support; and
- devise a long-term evaluation plan for assessing improvements in professional competency.

Patient safety incident reporting and learning systems

Minimum Information Model

The *Minimal Information Model for Patient Safety* is a simple tool to facilitate the collection, analysis, comparison, sharing, and global learning derived from adverse events, and can be used by countries or institutions looking to set up or improve their current reporting and learning system. It was developed through the analysis of real adverse event data provided by multiple institutions and countries. The User Guide for the *Minimal Information Model for Patient Safety* has been developed to provide guidance for incorporating the information model while establishing patient safety incident reporting and learning systems.



Patient Safety Incident Reporting and Learning Guidelines

At the heart of most patient safety programmes in health care systems is a process for gathering and analysing data on errors and incidents that happen during the delivery of care. The *WHO Guidelines on Patient Safety Incident Reporting and Learning Systems* are scheduled to be released towards the end of 2017. This guidance will include key lessons learned from experiences within and outside health care, guidance on enhancing the reporting of incidents, including adverse events, near misses and errors in health care, capturing and aggregating data, assessing progress, engaging patients in reporting and learning, and translating data into meaningful action for better quality and safer care.



The WHO Safe Childbirth Checklist

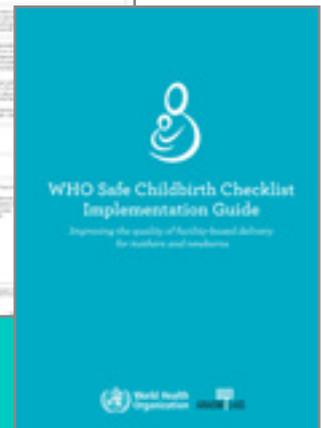
Estimates from 2015 suggest that, every year, 303 000 women die during pregnancy and childbirth worldwide, while 2.7 million babies die during the first 28 days of life and 2.6 million babies are stillborn. In addressing the major causes of maternal and neonatal death, the *WHO Safe Childbirth Checklist* synthesizes existing WHO evidence-based recommendations for safe childbirth into a simple and practical tool that helps health care workers adhere to the essential care standards needed during every child's birth.

The *WHO Safe Childbirth Checklist* is designed to improve the delivery of safe and essential practices around the time of birth, and the *WHO Safe Childbirth Checklist Implementation Guide* is to support health facilities which are planning to use and implement the Checklist.

Case study: Sudan

Piloting the WHO Safe Childbirth Checklist

The Sudanese Ministry of Health conducted a study in one of its largest hospitals to explore attitudes towards and compliance with the WHO Safe Childbirth Checklist. The Checklist improved the spirit of teamwork and communication, and revealed broader weaknesses in the system for complying with essential safety practices, such as the importance of hand hygiene. Support from nursing matrons was by far the most enabling factor revealing the central role of an actively engaged leadership in implementing new safety initiatives.





The WHO Surgical Safety Checklist

Globally, one in 25 patients has a surgical operation every year. Complications resulting from an operation occur for a quarter of all these patients. At least half of the cases in which surgery leads to harm are considered preventable. In 2008, the Second Global Patient Safety Challenge: Safe Surgery Saves Lives was launched. Extensive consultation with experts resulted in the development of the *WHO Surgical Safety Checklist*. The 19-item, three-phase checklist aims to decrease the potential for errors and adverse events, in part by increasing teamwork and communication in surgery. The Checklist's implementation has resulted in significant reductions in morbidity and mortality (around 36% on average) and has been implemented both at institutional and national levels. The Checklist is now used by a majority of surgical service providers around the world.

Surgical Safety Checklist		World Health Organization	Patient Safety
<p>Before induction of anesthesia</p> <p>Identify patient and procedure</p> <p>Has the patient confirmed by the identity, sex, age, date of birth, and weight?</p> <p>Has the patient been identified by the surgeon and the anesthesiologist?</p> <p>Has the patient been identified by the patient and the anesthesiologist?</p> <p>Has the patient been identified by the patient and the surgeon?</p> <p>Has the patient been identified by the patient and the anesthesiologist and the surgeon?</p> <p>Has the patient been identified by the patient and the anesthesiologist and the surgeon and the patient?</p> <p>Has the patient been identified by the patient and the anesthesiologist and the surgeon and the patient and the anesthesiologist?</p> <p>Has the patient been identified by the patient and the anesthesiologist and the surgeon and the patient and the anesthesiologist and the patient?</p>	<p>Before skin incision</p> <p>Confirm all team members have donned sterile gloves</p> <p>Confirm the site, side, and extent of surgery</p> <p>Has the patient been identified by the surgeon and the anesthesiologist?</p> <p>Has the patient been identified by the patient and the anesthesiologist?</p> <p>Has the patient been identified by the patient and the anesthesiologist and the surgeon?</p> <p>Has the patient been identified by the patient and the anesthesiologist and the surgeon and the patient?</p> <p>Has the patient been identified by the patient and the anesthesiologist and the surgeon and the patient and the anesthesiologist?</p> <p>Has the patient been identified by the patient and the anesthesiologist and the surgeon and the patient and the anesthesiologist and the patient?</p>	<p>Before patient leaves operating room</p> <p>Identify verbally</p> <p>Has the patient been identified by the surgeon and the anesthesiologist?</p> <p>Has the patient been identified by the patient and the anesthesiologist?</p> <p>Has the patient been identified by the patient and the anesthesiologist and the surgeon?</p> <p>Has the patient been identified by the patient and the anesthesiologist and the surgeon and the patient?</p> <p>Has the patient been identified by the patient and the anesthesiologist and the surgeon and the patient and the anesthesiologist?</p> <p>Has the patient been identified by the patient and the anesthesiologist and the surgeon and the patient and the anesthesiologist and the patient?</p>	

Engaging patients and families for safer health care

Patients for Patient Safety

WHO's Patients for Patient Safety (PFPS) programme relates to engaging patients and families in improving the safety of health care and enhancing and building their capacity to become informed and knowledgeable partners in their own care.

As part of this programme, a network of PFPS advocates was created a number of years ago for patients and families who have experienced harm as a result of unsafe health care. The motivation for joining the network is often to give meaning to their personal tragedy and honour their loved ones' lives by sharing their experience and expertise, but also to raise public awareness and stimulate change in the system. PFPS advocates call for greater patient engagement and empowerment in direct care, as well as at the organizational and policy level. They take this advocacy role on an individual way, reflecting their own personal experience of harm.

PFPS national workshops have been able to bring together PFPS advocates, health care professionals, local leaders, health care organizations and policy-makers to share knowledge about the national health system and explore mechanisms to improve patient engagement for safety. Through the workshops and ongoing technical support, PFPS aims:

- to advocate to the health care providers and policy-makers so they can more meaningfully engage with patients, families and communities;
- to foster collaboration between patients, families, communities, health care providers and policy-makers with the aim of co-producing improvement strategies, tools and initiatives;
- to raise awareness of the need for a more active role of patients and families in managing their own care;
- to engage partners and organizations to promote local leadership and ownership.

Case study: Uganda

Engaging patients and the wider community – the Community Health and Information Network initiative

In many low- and middle-income settings, the “doctor knows best” complex remains unchallenged, and a high proportion of patients are passive recipients of health care. The aim of Community Health and Information Network (CHAIN) Uganda's work is to improve safety by empowering patients to become active participants and partners in their care. Numerous community and patient engagement methods have been deployed. Community dance, sport and drama events, SMS text messaging services, as well as media campaigns, have been effective engagement techniques in low-resource settings. The engagement technique considered most effective was the open discussions held between community members and health professionals. These informal discussions about what patient safety is, and what patients can do to help, contribute to increased awareness, health literacy and knowledge, and empower patients to reduce the risk of harm.

Moving forward, engagement has been realized as a core strategy for advancing universal health coverage, safe and quality health care, service coordination and people-centredness. WHO is developing a comprehensive guide to engaging patients and families as part of the efforts to build country capacity in developing safe health systems which embed the concepts of patient and family engagement and people-centredness. This guide will provide practical suggestions on how to meaningfully engage patients and families, in direct care and

organizational and policy levels for improved access, integration, safety and quality of health service delivery. It contains tips for patients, health care professionals, policy-makers and other key stakeholders, to advance patient and family engagement along the whole continuum of care, from health promotion to palliation. To complement the guide, several educational, informational and communication tools are being developed for use by patients and families.

WHO is working with the Canadian Patient Safety Institute, the WHO Collaborating Centre for Patient Safety and Patient Engagement, to strengthen patient and family engagement for safer health care.



Monitoring improvements in patient safety

Measurement of patient safety

It is important to measure and monitor patient safety improvements over time. This may include having clear definitions of patient safety incidents, defining global, national and subnational indicators and measurement methodologies, setting up national or local incident reporting systems where data is compiled regularly or using tools to assess patient experiences and measure improvements. Good quality data is fundamental to this. WHO is, therefore, developing patient safety measurement tools and country guidance on measurement for responding

to growing country needs to monitor patient safety improvements.

In order to develop efficient patient safety metrics, WHO is collaborating with the Organization for Economic Cooperation and Development, the World Bank Group, Health Data Collaborative and other international partners to align this work with other global monitoring and evaluation initiatives. The main objectives of WHO's work on patient safety measurement are to develop sound methodologies, to work with countries to assess and build good information infrastructure, and to closely monitor the global patient safety situation as it improves.





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**World Health
Organization**



सत्यमेव जयते

National PATIENT SAFETY IMPLEMENTATION

Framework (2018-2025)

INDIA



MINISTRY OF HEALTH & FAMILY WELFARE
Government of India

National
PATIENT SAFETY IMPLEMENTATION
FRAMEWORK (2018-2025)

INDIA



सत्यमेव जयते

Ministry of Health & Family Welfare
Government of India



जगत प्रकाश नड्डा
Jagat Prakash Nadda



स्वास्थ्य एवं परिवार कल्याण मंत्री
भारत सरकार
Minister of Health & Family Welfare
Government of India



MESSAGE

Patient safety is being increasingly recognized as an issue of global importance in health care which is a function of Universal Health Coverage (UHC). In India a multitude of initiatives are underway in the health sector which address different patient safety aspects independently. Swachha Bharat Abhiyan, Kayakalp Hospital Awards, health systems strengthening through National Health Mission, National Quality Assurance Standards for public health facilities, National Action Plan on Antimicrobial Resistance are some of these initiatives.

It was realized that much is being done for patient safety in India but in a fragmented manner. The strategies and interventions should not be regarded as stand-alone initiatives that are working in silos but as part of a whole exercise and it is vital to bring them together under one umbrella. Therefore, the development of National Patient Safety Implementation Framework to synergize multitude of initiatives for additive and summative effects on the overall patient safety scenario has become imperative for our nation.

I envisage that all stakeholders in health care have an important role to play in the successful implementation of this National Patient Safety Implementation Framework and I urge them to come forward to ensure quality assured patient centric care that gives paramount importance to patient safety outcomes in service delivery. I wish that the National Patient Safety Implementation Framework (NPSIF) will help attain patient safety goals in a coordinated manner and contribute to overall agenda of improvement of quality of care within the context of Universal Health Care in India.

(Jagat Prakash Nadda)

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प्रीति सूदन

सचिव

PREETI SUDAN

Secretary



सत्यमेव जयते

भारत सरकार

स्वास्थ्य एवं परिवार कल्याण विभाग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

Government of India

Department of Health and Family Welfare

Ministry of Health & Family Welfare

Dated : 14th April, 2018



Message

Patient safety is a fundamental element of health care. It represents one dimension of quality of care alongside accessibility, acceptability, effectiveness, efficiency and people-centeredness. It encompasses both medical and non medical domains and patient safety problems due to communication errors, patient management errors and Clinical performance errors.

Patient safety errors can be avoided by adopting quality assurance practices applied in other industries, adopting new technology, health care staffs' continuing education and error reporting systems. It requires a multi-pronged approach directed towards laying SOPs for patient handling, diagnosis, treatment etc, adoption of hand hygiene and other universal precautions, availability of checklists, rational use of medicine, training of health care professionals, strengthening health care infrastructure, a hospital accreditation programme, awareness generation among patients. All these concepts should be an integral part of all national programmes and health care initiatives.

National Patient Safety Framework is a unifying framework that brings together the diverse programmes being implemented, to give better expression to patient safety elements. This framework document is intended for adoption by both public and private sector. I hope that with further technical guidelines on the subject safety of patients will be ingrained in health care delivery across public and private sectors.

(Preeti Sudan)

14-4-18



Sanjeeva Kumar

Additional Secretary

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Dated the 16th April, 2018



MESSAGE

In health care settings harm can be caused by a range of errors or adverse events. Over the past ten years patient safety has emerged as an important discipline which entails coordinated efforts to prevent harm caused by the process of health care itself. The concept of "Quality" that originated in industry and manufacturing slowly percolated into health care and now patient safety and quality of care are seen as closely intertwined.

Even though many data management systems exist there is little documentation on errors, negligence, HCAI, adverse events etc., newer challenges are also emerging in the health sector space such as online pharmacies and the need for their regulation. In response of these challenges a wide range of initiatives on patient safety are being implemented at different levels of health care by central and state governments and in both public and private sectors to address the diverse issues of patient safety and there is a multiplicity of national and international stakeholders working in this area.

Taking cognizance of the patient safety challenges and to harmonise the many initiatives, Ministry of Health & Family Welfare has developed an overarching framework on Patient Safety in India with the aim to improve patient safety at all levels of health care across all modalities of health care provision, including prevention, diagnosis, treatment and follow up within overall context of improving quality of care and progressing towards Universal Health Care in coming decade. I call upon the states, the private sector and other stakeholders to adopt the framework with zeal and enthusiasm.


(Sanjeeva Kumar)

Dr. Promila Gupta
Director General of Health Services



भारत सरकार
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GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF HEALTH SERVICES
NIRMAN BHAWAN, NEW DELHI-110 108



MESSAGE

दिनांक/Dated.....13.4.18..

The first idea of patient safety is enshrined in the Hippocratic Oath itself, which emphasises upon the concept of 'do no harm'. Though the concept of 'do no harm' is old but it is as relevant today with the advent of modern medicine and ever more complicated procedures. Estimates show that in developed countries 1 in 10 patients are harmed while receiving hospital care and out of 100 patients, 7 in developed and 10 in developing countries will acquire health care-associated infections (HAIs). However, availability of concrete data has been a limitation in India.

The different aspects of patient safety include error in diagnosis, adverse events following drugs & devices, surgical errors & hospital acquired infections, unsafe injections & blood products and bio-medical waste management. Simple things like - hand hygiene, personal protection, hospital environment, bio-medical waste disposal, serviced patient care equipment, proper disposal of waste, patient etiquettes are low cost interventions that help reduce additional health care cost. Universal Precautions help reducing the risk of hospital acquired infections.

Many of the above aspects are addressed in different strategies and programmes of Ministry of Health & Family Welfare. To name a few the National Health Mission builds on the health systems in the country, Clinical Establishment Act (2010) emphasises upon rights of the patients, Mother & Child Tracking System, Adverse Event Following Immunization, pharmacovigilance programme are adverse event surveillance systems. Then there are many nascent programmes such as surveillance of antimicrobial resistance and health care associated infections which need to be scaled up. In order to bring all the patient safety initiatives under one umbrella, the National Patient Safety Framework has been developed for India which lays down six pillars for patient safety in India and aspires quality assured safe care to patients across the health sector in the country.

13/4/18
(Dr. Promila Gupta)



Preface

Patient safety is the reduction of unnecessary harm associated with health care to an acceptable minimum. It is a fundamental element of health care and is intended for freedom for a patient from unnecessary harm or potential harm associated with provision of health care. Over past ten years patient safety has been recognized as an issue of global importance, but much work remains to be done.

The estimated burden of unsafe care is 1 in 10 patients receiving health care. It is estimated that globally of the 421 million patients hospitalized annually, 42.7 million patients suffer from adverse events. Major areas of concern are hospital associated infections (HAI), unsafe surgeries, unsafe injections, safe births, medication safety, blood safety and faulty medical devices. In 2013, the unsafe care is third in rank of causes of death globally after heart disease and cancer. Considering the magnitude of the problem, unsafe care is one of the major public health problems.

Managing medical errors is more complex, it has been based on the “personal approach”, the individual involved in the care at the time of incident are held responsible, which is referred to as blaming. Systematic improvements cannot be made as long as we focus on blaming individuals. At hospital setting patient safety consists of four domains, i.e. (i) health care providers, (ii) recipients of health care, (iii) health care infrastructure and (iv) reporting and feedback on performance. If these issues are addressed appropriately, there appears to have a wide scope for improvement.

The process of development of nation patient safety implementation framework consisted of approval of ministry to develop framework, constitution of an expert group, convening of group consultations, developing draft framework, seeking comments of the partners and designing final draft. The framework covers legal & regulatory aspects, external quality assessment, nature and scale of adverse events, competent & capable workforce, prevention & control of hospital associated infections, building patient safety campaign and building capacity in patient safety research. The plan is to implement the programme over 2018-2025.

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Abbreviations

AD	Auto Disable (syringe)
AEFI	Adverse Events Following Immunisation
AIIMS	All India Institute of Medical Sciences, New Delhi, India
AMR	Anti-Microbial Resistance
ASQua	Asian Society for Quality in Healthcare
BMW	Biomedical Waste
CEA	Clinical Establishment Act
CEO	Chief Executive Officer
CHC	Community Health Centre
CSR	Corporate Social Responsibility
DGHS	Directorate General of Health Services
FEMA	Failure Effect Mode Analysis
FRU	First Referral Unit
GMP	Good Manufacturing Practices
GoI	Government of India
HAI	Healthcare Associated Infections
HCF	Healthcare Facilities
HIC	Hospital Infection Control
HRH	Human Resources for Health
IAPO	International Alliance of Patients' Organizations
ICMR	Indian Council of Medical Research
IDSP	Integrated Disease Surveillance Program
IEC	Information, Education and Communication
IHR	International Health Regulations
IPC	Infection Prevention and Control
IPHS	Indian Public Health Standards
IPD	In-patient Department
ISQua	International Society for Quality in Healthcare

MCI	Medical Council of India
NABH	National Accreditation Board for Hospitals & Healthcare Providers
NACA	National Authority for Containment of Antibiotic resistance
NABL	National Accreditation Board for Testing and Calibration Laboratories
NCI	Nursing Council of India
NHSRC	National Health System Resource Centre
NHP	National Health Policy
NHM	National Health Mission
NOTP	National Organ Transplant Program
NOTTO	National Organ and Tissue Transplant Organization
NPSIF	National Patient Safety Implementation Framework
NQAS	National Quality Assurance Standards
MoHFW	Ministry of Health and Family Welfare
MS	Member States
PHC	Primary Health Centre
PEP	Post-Exposure Prophylaxis
QCI	Quality Council of India
OPD	Out-Patient Department
PHC	Primary Healthcare Centre
PIP	Program Implementation Plan
PVPI	Pharmacovigilance Program for India
RMNCH	Reproductive, Maternal, Neonatal and Child Health
RUP	Reuse Prevention (syringe)
SEAR	South-East Asia Region
SEARO	South-East Asia Regional Office
SIP	Sharps Injury Prevention (syringe)
SOP	Standard Operational Procedure
THOA	Transplant of Human Organs Act
UHC	Universal Health Coverage
UT	Union Territory
WHA	World Health Assembly
WHO	World Health Organization



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Structure and Purpose of the Document

This document is an endeavor to integrate the discrete patient safety concepts and activities into a single national level policy framework, so that patient safety issues can be addressed in a holistic way with commitment and contribution from all stakeholders – central and state governments, patient rights groups, professional associations, medical education institutions, agencies for quality and accreditation and of course healthcare providers at millions of public and private healthcare facilities of all sizes and functions. This document provides a formal institutional framework for patient safety in the country as well as mandates for establishing the process for adverse event reporting system, capacity building, infection control and patient safety research.

This document is structured in three broad sections:

Section one provides Introduction to the subject, rationale and current situation of patient safety in India.

Section Two is the main body of the document which states the goal and guiding principles for National Patient Safety Implementation Framework and six strategic objectives to achieve the stated goal. Each strategic objective has been further elaborated into key priorities and specific actions.

Section three gives a strategic action plan on defined priorities and activities along with responsible institutions and timelines.

Though this framework is a policy level document, it is relevant for all stakeholders.

Health Ministries and Directorates at state level should incorporate the key strategies from this document into their state specific policies to provide enabling institutional structure and processes for patient safety.

Program managers for various programs should understand the planned activities in this framework, so that specific activities can be integrated and there is no duplication or redundancy in execution.

Managers at health care facilities should undertake the preparatory work at their hospital / department level to ensure assessment, reporting and mitigation of patient safety risks.

This document is also useful for patient and consumer rights groups, patients, their relatives and community at large so they should understand their rights and responsibilities for enabling safe care.

'Patient Safety is Everyone's Responsibility'

Introduction, Rationale and Current Scenario



1. Introduction

Patient safety is a fundamental element of health care and is defined as a freedom for a patient from unnecessary harm or potential harm associated with provision of health care. Patient safety represents one of quality of care dimensions alongside accessibility, acceptability, effectiveness, efficiency and people-centeredness. It encompasses different aspects that are crucial to delivering quality health services. It is about safe surgical care and safe childbirth, it is about injection safety, blood safety, medication safety, medical device safety, safe organ, tissue and cell transportation and donation. It is also about bio-medical waste management, prevention of healthcare associated infections and much more. Failure to deliver safe care is attributed to unsafe clinical practices, unsafe processes and poor systems and processes.

Estimates show that in developed countries as many as 1 in 10 patients is harmed while receiving hospital care. The harm can be caused by a range of errors or adverse events. Of every 100 hospitalized patients at any given time, 7 in developed and 10 in developing countries will acquire Health Care-Associated Infections (HAIs). Hundreds of millions of patients are affected worldwide each year. Simple and low-cost infection prevention and control measures, such as appropriate hand hygiene, can reduce the frequency of HAIs by more than 50%. There are an estimated 1.5 million different medical devices and over 10,000 types of devices available worldwide. The majority of the world's population is denied adequate access to safe and appropriate medical devices within their health systems. More than half of low- and lower middle-income countries do not have a national health technology policy which could ensure the effective use of resources through proper planning, assessment, acquisition and management of medical devices. Key injection safety indicators measured in 2010 show that important progress has been made in the reuse rate of injection devices (5.5% in 2010), while modest gains were made through the reduction of the number of injections per person per year (2.88 in 2010). An estimated 234 million surgical operations are performed globally every year. Surgical care is associated with a considerable risk of complications. Surgical care errors contribute to a significant burden of disease even though 50% of complications associated with surgical care are avoidable. Safety studies show that additional hospitalization, litigation costs, infections acquired in hospitals, disability, lost productivity and medical expenses cost some countries as much as US\$ 19 billion annually. The economic benefits of improving patient safety are therefore compelling. Industries with a perceived higher risk such as the aviation and nuclear industries have a much better safety record than health care. There is a 1 in 1,000,000 chance of a traveler being harmed while in an aircraft. In comparison, there is a 1 in 300 chance of a patient being harmed during health care.

Patient safety has been increasingly recognized as an issue of global importance and in 2002, WHO Member States agreed on a World Health Assembly resolution on patient safety. In recent years, there is growing recognition that patient safety and quality of care are critical dimensions of Universal Health Coverage (UHC).

That is why Patient Safety strategies and interventions cannot be regarded as stand-alone initiatives, they cannot be in silos. They must be aligned with the overall health goals and embedded into broader strategies and incorporated into the existing programs.

2. Background and Rationale

In recent years there has been an increasing attention on improving quality of healthcare in India within broader Universal Health Coverage (UHC) context. Patient safety has been recognised as one of the key important components of quality of care and many initiatives have been taking place at central and state levels to address diverse issues of patient safety. Challenges in patient safety in India are various, ranging from unsafe injections and biological waste management to medication and medical device safety, high rates of health care associated infections, anti-microbial resistance etc. There is a wide range of initiatives in patient safety being implemented in India at different levels of care in both public and private sectors, and there is a multiplicity of national and international stakeholders working in this area.

In 2015 during the 68th WHO Regional Committee for South-East Asia all Member States of the Region, including India, endorsed the “Regional Strategy for Patient Safety in the WHO South-East Asia Region (2016-2025)” aiming to support the development of national quality of care and patient safety strategies, policies and plans and committed to translate six objectives of the Regional Strategy into actionable strategies at country level. In this context, Ministry of Health and Family Welfare (MoHFW), Government of India (GoI) constituted a multi-stakeholder Patient Safety Expert Group in August 2016. The Group was given a task to operationalize patient safety agenda at country level and develop a National Patient Safety Implementation Framework (NPSIF).

Development of a NPSIF is imperative for India because even though a range of initiatives for patient safety are implemented in the country, they are implemented in a fragmented manner by multiple stakeholders and sometimes overlap. It is vital to bring everything together under one umbrella. The NPSIF will ensure implementation of patient safety activities in a coordinated manner and contribute to overall agenda of improvement of quality of care within UHC context in India.

3. Current Situation of Patient Safety in India

3.1 National policies and strategies, institutional mechanisms, legal and regulatory framework, stakeholders' involvement

- ◆ Laws, regulations, policies and strategies on the quality of care do exist in the country, however they are largely fragmented.
- ◆ Consumer protection act deals with medical negligence and deficiency of services but has failed to define the rights of the patients. Legal rights of the patients are set out in the Clinical Establishment Act (CEA), but the CEA is not being implemented across India.
- ◆ National Pharmaceutical Pricing Authority (NPPA) and Drugs Controller General of India (DCGI) have mechanisms to see that patients' rights in terms of medication and device are protected and they are not overcharged.
- ◆ National Health System Resource Centre (NHSRC) has been designated as nodal agency at national level for implementing Quality Assurance program in public health facilities. National Quality Assurance Standards have been developed by NHSRC for specific quality and patient safety needs of public health institutions. These standards specifically cover requirements of RMNCHA and Disease control programs.

- ◆ The Ministry of Health and Family Welfare (MoHFW) publishes a regular national report on the performance of the health care system; however, it is limited to indicators for quality of care that in turn are designed around Reproductive, Maternal, Neonatal and Child Health (RMNCH).
- ◆ Under the Right to Information Act, all public facilities must report all information available at institutional level. In doing so, it is assumed that the quality of care is perceived as inadequate in quality, the facility might face the risk of media scrutiny and trials in case of honest reporting.
- ◆ Selected Private sector chain hospitals and individual institutions have implemented substantial measures to implement patient safety. As these hospitals constitute very small proportion of overall care providers these measures remain isolated and has limited in effect.
- ◆ Public reporting on quality of care to some extent exists in the country, but needs adjustment and improvement. Demand from population side is not adequate enough to influence policy directions.
- ◆ Accreditation mechanisms for healthcare facilities (including accreditation of laboratories and diagnostic facilities) are in place. Existing Accreditation system of hospitals; the National Accreditation Board for Hospitals and Healthcare Providers (NABH) is pertinent and provides enough flexibility. Insurance Regulatory Development Authority (IRDA) has issued a notification for the health entities to consider NABH Entry level accreditation for availing reimbursement benefits from the insurance providers.
- ◆ The public institutions are not currently actively involved in NABH Accreditation. Many of the public institutions which have enrolled into NABH/NABH Safe I/NABH Entry level have challenges to upgrade themselves to the desired standards. Public Hospitals are undertaking accreditation against National Quality Assurance Standards (NQAS) developed by MoHFW. Both NABH and NQAS standards are accredited by ISQUA.
- ◆ MoHFW, The Central Pollution Control Board (CPCB), Atomic Energy Regulatory Board (AERB), Professional Councils, regulatory bodies, NHSRC, NABH, ESI, Public Sector Units (PSUs) providing health care in other relevant ministries/departments like Defence, Railways, Environment, etc. are the key government departments and bodies responsible for execution.

3.2 Nature and scale of adverse events and surveillance systems

- ◆ Mechanisms of assessing the overall burden of unsafe care in the country exist for some programmes, such as Adverse Events Following Immunization (AEFI), Pharmacovigilance Program of India (PVPI), etc. but not for all.
- ◆ A patient safety incident surveillance and a system of reporting and learning from all adverse events and “near misses” at national and sub-national levels exist for certain events like needle-stick injuries, AEFI, Pharmacovigilance, Haemovigilance, Death audits etc. but not for all. Root cause analysis done for Maternal deaths, neonatal deaths, AEFI, etc. but not for all diseases/conditions. But not all Institutes follow the same standards all the time as no regulatory mechanisms exist.

3.3 Health workforce: education, training and performance

- ◆ Registration and re-registration, certification, and re-certification as well as continuous professional education of health care professionals are available for three different categories of health care workers.
- ◆ It is difficult to estimate the adequate number of appropriately trained and skilled staff in patient safety currently in position. Multiple trainings take place within the frames of different programs and projects, at different levels of governance (central and state) and health care (from primary through tertiary) and in many cases they are not well documented.

- ◆ Periodic assessments of awareness and understanding of basic patient safety principles and practices among different categories of healthcare workers is not done in public sector hospitals. Information about the same from the private sector is also not available.
- ◆ Whereas patient safety as a separate topic may not be available in different curricula, overall concept as well as many elements of patient safety are reflected across different syllabuses, including undergraduate, postgraduate and continuous medical education.
- ◆ STGs and protocols are available within the most important vertical national programs (TB, Vector Borne Diseases (VBD), HIV/AIDS, Maternal and Child Health (MCH), etc.). Under CEA, the STGs for 215 medical conditions under 21 specialties have been prescribed (reference <http://clinicaestablishments.nic.in/>).
- ◆ Under IPHS, there are elements of patient safety in general and infection control in particular. Even though it is not mandatory, there are some budgetary provisions to adopt and implement these standards. The standards run from sub-centre to district levels.
- ◆ Important elements, such as fire safety, seismic safety, device safety, the physical safety of health care facilities are also important in the Indian context though usually not included in patient safety paradigm most of the time.

3.4 Prevention and control of HAI

- ◆ Institute based systems for infection controls have been developed, but there is lack of integrated national level program, policy or guidelines which cover health care institution at all levels.
- ◆ There is no system of reporting HAI at any level and there is no authority in place to collect, analyse and report HAI at country level.
- ◆ Biomedical Waste Management Rules were first notified in 1998. These rules have been revised comprehensively recently in 2016 & 2018 (Amendment). These rules have helped in regulating management of biomedical waste by health care institutions.
- ◆ National Guidelines on Clean Hospitals (Swacchta Guidelines) were released in 2014. Government of India (GoI) has launched Kayakalp programme to improve general cleanliness and hygiene, infection control and waste management practices in public hospitals.
- ◆ NCDC and ICMR have created a network of laboratories for Antimicrobial Resistance surveillance in the country. Many private sector chain hospitals and autonomous institutes also have their own Infection control systems. 10 Network laboratories have been identified in the first phase to initiate antimicrobial resistance surveillance of four common bacterial pathogens of public health importance to determine the magnitude and trends of AMR in different geographical regions of the country.
- ◆ A concise interim guideline on infection control has been uploaded on NCDC website as a ready reference for the hospitals to start implementing infection control practices in their setting. National infection control programme has been drafted and is in the process of finalization. ICMR has also issued Infection Control Guidelines. There are other guidelines available, developed by institutions/ under various programs, e.g. RMNCH, Hospital Manual by DGHS, NACO manual.
- ◆ NABH has a system of surveillance for HAI but limited to NABH accredited hospitals only. There is also software to track hospital associated infection reports by the All India Institute of Medical Sciences (AIIMS) Trauma Centre.
- ◆ An expert group by the PMO office had given national recommendations which have been discussed at a high level in the Ministry of Health with all the central government hospitals for the implementation of sterilization practices.

- ◆ In the RMNCH programme, infection management and environmental plan was introduced in 2007 and implemented countrywide. Similarly, in the event of outbreaks, the respective guidelines for infection prevention and control are being issued. At the DGHS level, a hospital manual with elements of infection control has been implemented in the central public hospitals. NACO manual for infection control developed in 2006 is available in the public domain.
- ◆ It was observed that sporadic institute based system does exist in the country, but not at the national level, and a lot of activities are happening that have not been institutionalized.
- ◆ Hospital Infection Control Committee are mandatory in accreditation programme/s. The key stakeholders involved in the Committee could be the head of facility (administrator/manager), representative of a nursing staff, key clinicians, lab specialist/microbiologist, biomedical engineer with clear roles and responsibilities (e.g., biomedical engineer is responsible for building construction and maintenance, which is also key element in infection prevention and control).
- ◆ Currently only 192 combined Biomedical Waste Treatment Facilities (CBMWTF) exist in the country against 500 to 600 needed.

3.5 Patient safety in different programs

- ◆ A national policy and plan for surgical services at various levels of care have not been thought of until now. Surgical checklist is not uniformly implemented.
- ◆ 24x7 Basic Emergency Obstetric and Newborn Care (BEmONC) and Comprehensive Emergency Obstetric and Newborn Care (CEmONC) services up to Community Health Centre (CHC) level are available in most of the states.
- ◆ Multiple guidelines for even up to Primary Health Centre (PHC) level are available; Janani Suraksha Yojana, Janani Shishu Suraksha Karyakaram, Integrated Management Neonatal Childhood Illnesses, Sick Newborn Care Units, Indian Public Health Standards, BEmONC, CEmONC, SBA. However in private sector provision of desired services is not standardized.
- ◆ Safe Injection Guidelines by Indian Academy of Paediatrics and National Centre for Disease Control were released and are available online. The new Policy Guidance by WHO, issued in 2015, on Safe Injections is also available.
- ◆ An excellent surveillance of Needle Stick Injuries (NSIs) in all accredited hospitals is being conducted. Enhanced compliance with Biomedical Waste Management (BWM) rules in both public and private institutions are envisaged. But the data is more internal and larger picture of the issue of NSIs is not available. This is a major occupational hazard and many of the episodes are not getting reported.
- ◆ Variable implementation of the guidelines on infection prevention and controls are available especially in private sector, is important to address.
- ◆ Ensuring all health care providers are vaccinated against Hepatitis B (National Health Policy Recommendation) and waste handlers against tetanus is crucial to ensure safety from occupational hazards of health care providers. Availability of Post-Exposure Prophylaxis (PEP) for needle stick injuries at all casualities or emergency rooms/Operation Theatres (OTs) and other intervention sites are a big missing area.
- ◆ Since frontline health workers such as ASHAs and other village level volunteers are actively involved diagnostic practices such as conducting rapid diagnostic tests (e.g. for malaria) through finger pricking etc. therefore, BWM practices should reach the frontline health workers to ensure their safety as well as patient safety.
- ◆ Essential Drug List is available and is being used by the government institutions. High-Quality control by DCGI at manufacturing level is available.

- ◆ National STGs for common health conditions are available (issues discussed earlier).
- ◆ Medical colleges collect data related to adverse drug reactions. National Portal to register instances of spurious drugs is available.
- ◆ In the decentralized mechanism of drug storage, at the sub-district level, safety norms are not adequately followed.
- ◆ Blood is defined as a “drug” under the Drugs and Cosmetics Act and Rules thereof, and therefore blood banks are considered manufacturing units and can only function under a license issued by the State Food and Drug Administration (FDA) with approval of DCGI.
- ◆ All units of blood collected in the licensed Blood Banks undergo mandatory screening for human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), Malaria and Syphilis before being issued for transfusion.
- ◆ National Blood Transfusion Council provides policy directions to all the licensed Blood Banks through respective State Blood Transfusion Councils.
- ◆ All blood banks report to NACO/National Blood Transfusion Council (NBTC) through a Strategic Information Management System (SIMS) Also, a web- cum-mobile application had been created on the National Health Portal, which helps to locate the nearby blood banks, available blood groups, and units of blood available.
- ◆ NACO/ NBTC has recently published a baseline Assessment Report of 2626 Blood Banks of India and gaps in quality of Blood Transfusion Services have been identified.
- ◆ DGCI has a few national medical device regulatory and monitoring programmes, but to a very limited extent.
- ◆ Medical devices are well covered under Clinical Trials Services Unit (CTSU). A draft bill is in the public domain. A separate legislation is in the offering. Also, product liability is coming up strongly as part of the new consumer protection act which is supposed to go to the parliament end of 2016-beginning of 2017.
- ◆ Though much has not been done on medical device safety in India, a Health Technology Assessment Division exists in NHRDC and was recently designated as a WHO Collaborating Centre.
- ◆ Safer medical devices as per Good Manufacturing Practices (GMP) and WHO standards for infection control and patient safety exist.
- ◆ The deceased organ donor programme is quite robust; developing regional centres, state centres even individual numbers are being given to the hospitals that are doing transplantation. But it is also true that states do not wish to respond accordingly. Legal conditions regarding foreign trafficking have also been covered.
- ◆ Comprehensive legislation in the form of the Transplant of Human Organs Act (THOA), National Organ Transplant Program (NOTP), National Organ and Tissue Transplant Organization (NOTTO), different SOPs, including for selection and safety of donors; allocation policies, IEC, national registries are available.

3.6 Patient Safety Research

- ◆ There are research activities going on in this area, but they are very fragmented and not widely shared and utilized for decision making purposes.
- ◆ There is Minimal funding on patient safety research.
- ◆ Research institutions have limited capacity and academic foundation for patient safety research.
- ◆ Facilities both private and public hesitate to publish research on patient safety as this may tarnish the image of the hospital.
- ◆ The global burden disease study collect data on adverse effect of medical treatment.

Goal, Guiding Principles and Strategic Objectives



1. Goal and Overall Scope

The goal of the NPSIF is to improve patient safety at all levels of health care across all modalities of health care provision, including prevention, diagnosis, treatment and follow up within overall context of improving quality of care and progressing towards UHC in coming decade.

NPSIF applies to national and sub-national levels as well as to public and private sectors. Being a cross-cutting concept by nature, the scope of patient safety applies to all national programmes and envisages collaboration of wide range of national international stakeholders both within and outside health sector.

2. Guiding Principles

- ▶ **Articulating health system approach:** Invest more in strengthening health system across its core elements:
 - ◆ Ensure **health services** which deliver effective, safe, quality personal and non-personal health interventions to those that need them, when and where needed, with minimum waste of resources.
 - ◆ Invest in well-performing **health workforce** that works in ways that are responsive, fair and efficient to achieve the best health outcomes possible, given available resources and circumstances (i.e. there are sufficient staff, fairly distributed; they are competent, responsive and productive).
 - ◆ “Establish and maintain well-functioning health information system that ensures the production, analysis, dissemination and use of reliable and timely information on health determinants, health system performance including those related to medication errors, hospital acquired infections and other patient safety related aspects.
 - ◆ Ensure **equitable access to essential medical products, vaccines and technologies** of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use.
 - ◆ Design effective and efficient **health financing system** that raises adequate funds for health, in ways that ensure people can use needed services, and are protected from financial catastrophe or impoverishment associated with having to pay for them.
 - ◆ Strengthen **leadership and governance** to ensure strategic policy frameworks exist and are combined with effective oversight, coalition building, regulation, attention to system-design and accountability.

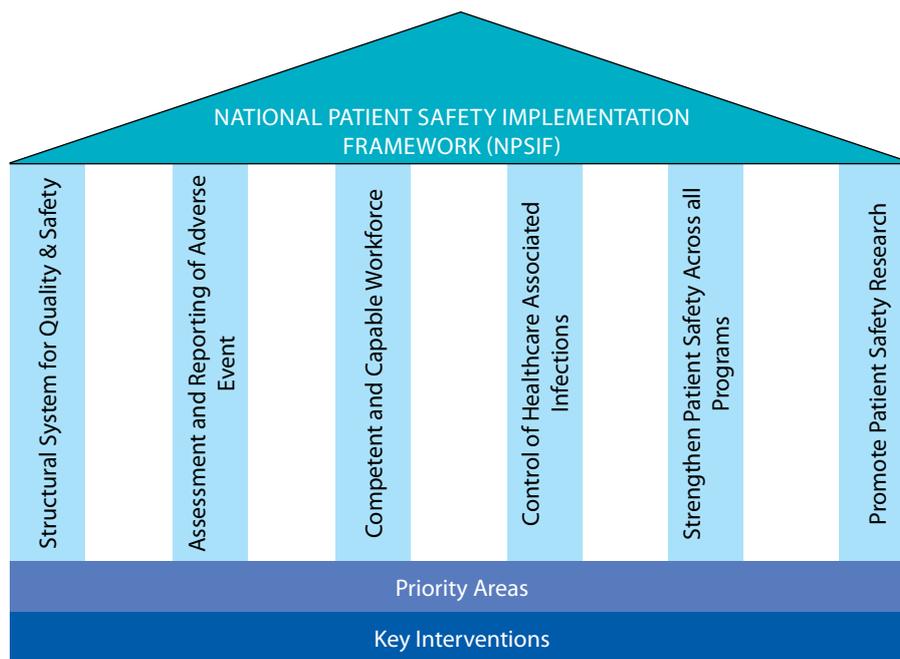
- ▶ **Defining evidence-based interventions:** Prioritize and implement those interventions that proved to be effective and efficient in improving patient safety at global, regional and country levels. Continuously invest in evidence generation to ensure the required adjustments throughout implementation.
- ▶ **Targeting all levels of care:** Bring patient safety to the core of healthcare provision given its cross-cutting nature and applicability to all modalities of healthcare provision, including prevention, diagnosis, treatment and follow up.
- ▶ **Adopting patient-centred approach:** Put the patients in the centre and involve and empower them to become equal partners in ensuring provision of healthcare that is respectful of, and responsive to, individual preferences, needs and values, and ensures that patient values guide all clinical decisions.
- ▶ **Promoting collaborative action:** Engage all stakeholders to improve patient safety - not only within, but also outside the health sector. There should be not only healthcare workers, health managers and decision-makers but also patients and their families, professional organizations, civil society and media. Everybody has different, but crucial role to play in patient safety. While it is important to recognize these differences in roles and responsibilities, it is equally important to recognize the connections between them.
- ▶ **Ensuring sustainability and monitoring progress:** Make interventions sustainable through addressing patient safety as policy objective with strong political commitment and respective institutionalization efforts and monitor implementation of interventions at different levels: national, sub-national and institutional levels with collectively agreed key performance indicators.

3. Strategic Objectives

Implementing patient safety framework would require a holistic and pragmatic approach. Patient safety concepts should be interlaced with building blocks of health system so safety culture becomes integral part of healthcare delivery. Six strategic objectives have been identified for this purpose after due consultation with stakeholders and reviewing global and regional frameworks for patients safety. Each strategic objective has been further explained in terms of key priorities and specific interventions. Following are the strategic objectives :

- Strategic Objective 1:** To improve structural systems to support quality and efficiency of healthcare and place patient safety at the core at national, subnational and healthcare facility levels.
- Strategic Objective 2:** To assess the nature and scale of adverse events in healthcare and establish a system of reporting and learning.
- Strategic Objective 3:** To ensure a competent and capable workforce that is aware and sensitive to patient safety.
- Strategic Objective 4:** To prevent and control health-care associated infections.
- Strategic Objective 5:** To implement global patient safety campaigns and strengthening Patient Safety across all programmes.
- Strategic Objective 6:** To strengthen capacity for and promote patient safety research.

Figure 1. Building Blocks of National Patient Safety Implementation Framework



Strategic Objective 1: To improve structural systems to support quality and efficiency of healthcare and place patient safety at the core at national, subnational and healthcare facility levels.

Developing quality and safety culture is a long term endeavor and requires enabling environment at policy, administrative and service provision level. This requires investments for creating structures for quality and safety and having credible quality accreditation system and regulatory mechanism to ensure compliance to minimum safety standards. India has a vibrant and growing health sector with mix of public and private providers. Further health is a state subject and each state government sets its own legislative, administrative, financing and healthcare delivery models as per priorities and context. This makes developing a pan-India institutional structure a challenging task. A rational approach would be to have an overarching national framework under which states are given flexibility to design their own institutional mechanism and modalities for quality & safety in public and private sector.

Framework should provide options of quality assurance and accreditation system that private and public healthcare providers can adapt as per requirements and preference. The institutional framework should be more a facilitator than regulator so as to let flourish a self-sustainable quality and safety culture. There is also need for developing culture for safe healthcare communication and involving patients in their treatment and welfare. Following are key priority areas improving structural systems for quality and safety.

Key Priority 1.1: Institutionalize patient safety and strengthen legislative and regulatory framework

Patient’s safety should become integral part of healthcare delivery system through institutionalisation within the existing policy, regulatory and program management framework. Following is the proposed institutional framework for patient safety India.

- i. National Level: National Patient Safety Steering Committee will be constituted under aegis of Ministry of Health & Family Welfare. This committee will have representation from all relevant governmental and non-governmental stakeholders. Quality Assurance mechanism under National Health Mission

(NHM) will also be utilized. This committee will work to implement a robust patient safety framework in country and coordinate with different stakeholders. Committee will be supported by a dedicated patient safety secretariat in Directorate General of Health Services, MoHFW. This secretariat will provide technical support for implementing patient safety including drafting technical guidelines & developing training material. The detailed TORs for National Patient Safety steering committee are given in Annexure.

- ii. State Level: at the state level there will be a designated nodal officer for implementing patient safety framework. State quality assurance committees have been constituted in all the states chaired by Principal Secretary (Health). As quality and patient safety are related concepts, it is therefore natural to use existing quality assurance committees for monitoring and implementation of patient safety framework too. A sub-committee on patient safety will be constituted under the state quality assurance committee. If required large states may engage a dedicated technical staff to support patient safety activities through National Health Mission. Though designated state nodal officers for quality assurance should be over all responsible for patient Safety activities also. TORs and functions of quality assurance committees and officers can be revised to include the patient safety components explicitly. Similarly, district quality assurance committees will be responsible for implementing the patient safety framework at district level through their existing mechanism.
- iii. Integration of patient safety Programs & Schemes: Patients safety concepts should also be strengthened in all vertical disease control program considering safety of both provider and patients/ beneficiary. Some important aspects are injection safety and reporting of AEFI in immunization programs, infection control in DMCs under RNTCP program, Blood Safety under National AIDS control program etc.
- iv. Clinical Establishment Act includes patient safety requirements for registration of clinical establishment. Patient safety concept should also be incorporated in draft Public Health Act or any such legislation which will contribute regulatory framework in health sector.
- v. Publicly funded health insurance schemes should incorporate provision for payment based on patient safety performance/ safety indicators such as hospital acquired infection rates, medication errors and use of safe surgery checklist.

Key Priority 1.2: Strengthen quality assurance mechanisms, including accreditation system

Quality assurance and accreditation mechanism for public and private healthcare facilities needs to strengthen so patient safety can be assured at point of delivery. While efforts will be made to increase the coverage of quality certification/ accreditation, there also need to strengthen the existing quality standards by incorporating the patient safety requirements more adequately in their assessment criteria. Following are the measures proposed:

- i. At national level a set of minimum patient safety indicator will be defined by Ministry of Health and Family Welfare. These indicators will be reported by all healthcare facilities both in public and private sector. Framework recommends leveraging the reporting mechanism instituted under existing quality assurance programs and accreditation systems.
- ii. Ministry of Health & Family Welfare will also define minimum patient safety standards to be incorporated by accreditation agencies in their respective assessment criteria for quality accreditation.
- iii. National Quality Assurance Program for public health facilities has defined a set Key performance indicators for each level of facilities to be reported on monthly basis. These KPIs will be revised to include minimum patient safety indicators defined at national level.
- iv. For private sector NABH will be required to include the minimum patient safety indicators in their accreditation programs including entry level certification. Selected indicators applicable to clinical laboratories will also be included in NABL accreditation program.

- v. A ranking/grading system for healthcare facilities based on patient safety indicators will be introduced.
- vi. Provision for “Patient Safe Healthcare Institutions” certification will be instituted. The criteria will be based on existing quality standards such as NQAS and NABH. Ministry of Health & Family Welfare may institute a special body for issuing patient safety certification.
- vii. Healthcare facilities will be encouraged to achieve quality accreditation through existing quality certification/ accreditation systems available for public and private healthcare facilities. Provision for financial incentives in reimbursement from insurance providers will be made for certified/ accredited hospitals.
- viii. To ensure that quality standards measure patient safety issues adequately, patient safety concerns such as fire safety, seismic safety, medical device safety and structural safety will be included in existing quality standards and norms.

Key Priority 1.3: Establishing a culture of safety and improving communication, patient identification, handing over transfer protocols in healthcare facilities

Patient safety concepts need to be incorporated in the work culture of healthcare providers and the way they communicate to each other while delivering the care. Apart from service providers, patients and community at large also need to be sensitized on patient safety related issues. For this purpose, following activities are suggested:

- i. A comprehensive communication strategy for patient safety will be developed involving all stakeholders. The communication strategy will be developed targeting both patient/ community as well as care providers.
- ii. For ensuring safe communication amongst care providers for delivery of healthcare services, standard operating procedures and checklist will be developed for error prone processes such as handover, verbal orders and transfer of patients.

Key Priority 1.4: Establishing patient-centered care and involving patients as partners in their own care

The objective of patient safety framework cannot be achieved without considering perspective of patients. In-fact patient is the most important stakeholder and should be at centre of healthcare design and delivery process. Following activities are suggested for achieving patient involvement for safe care:

- i. Developing educational and information material on patient safety such as audio-visual material, Posters, Brochures and IT based aids. Information on patient safety will be disseminated to both patient as well as care providers using communication channels such Mass Media, Print Media and Social Media.
- ii. Integrate web based grievance redressal system and toll-free helplines on patient safety within the existing ICT system of MoHFW (including toll free number and IT based solutions). This system will also enable anonymous reporting of incidents and practices compromising the safety of patients. The incidents reported will be examined by an independent agency.
- iii. Promoting establishment of patient right groups and facilitating their involvement in policy discourse and monitoring of patient safety outcome.

Strategic Objectives 2: To assess the nature and scale of adverse events in health care and establish a system of reporting and learning

A universal error and adverse events reporting system is crucial to know the extent of harm caused by unsafe care. Although just having reporting system does not mitigate the risk of getting harm, it does serve as the catalyst for improvement, regardless of the level of care. Following actions are proposed for establishing a credible system for reporting of adverse events:

Key Priority 2.1: Generating evidence for policy making

Since limited information is available about overall burden of unsafe care in India, it would be prudent to estimate the baseline quantum of unsafe care in Indian health care system. For this purpose following activities are proposed:

- i. Scope of errors and adverse events will be defined for Indian context based on internationally agreed benchmarks and best practices.
- ii. A baseline assessment of public and private healthcare facilities will be conducted for estimating the extent of errors and adverse events for defined scope. The survey can be conducted by a designated autonomous national level institution.

Key 2.2: Establishing robust surveillance systems for monitoring patient safety

A universal reporting and feedback system for reporting of errors and adverse events needs to be established for the country. This system should be non-punitive, confidential, independent, timely, system oriented and responsive in nature. Following are the specific activities:

- i. Developing system of reporting of errors, near miss and adverse events from facilities to state and national level. This will include standardization of adverse event definitions, reporting formats and establishing a web-based reporting system across public and private healthcare facilities.
- ii. Public Health programs such as Immunization and NACP already have some system of reporting of adverse event specific to their activities. Accreditation programs such as NQAS & NABH also mandate for reporting adverse events. There are national programs for pharmacovigilance and materiovigilance. All these reporting systems will be streamlined and integrated to establish a comprehensive patient safety surveillance system.
- iii. Guidelines for errors and adverse events reporting will be developed by Ministry of Health & Family welfare. This will include definitions, categorization and directory for errors, near miss and adverse events as well as process, codes and protocols to be followed by public and private healthcare institutions for patient safety reporting.
- iv. Annual reports on quality of care and patient safety will be released by Ministry of Health & Family Welfare based on the data available from patient safety surveillance system and quality assurance program/ accreditation system. A national level Resource Centre/Technical Institute will be designated to analyse patient safety data and prepare report on behalf of MoHFW.
- v. Patient safety risk assessment checklists will be developed for primary, secondary and tertiary care facilities for identifying and mitigating risks through internal assessment and quality improvement approach.
- vi. Health Workers' safety is as important as patient safety. Minimum healthcare workers' safety requirements will be issued by MoHFW, which needs to be incorporated in all licensing and accreditation programs.

Key Priority 2.3: Ensuring supportive legislative mechanisms for effective functioning of patient safety surveillance systems

Adequate legal and policy level provisions will be required to create an enabling environment for non-punitive and system oriented surveillance system:

- i. A system for analyzing the patient safety reports and feedback mechanism for taking corrective actions will be established with support of NHSRC & Patient Safety Secretariat.
- ii. The proposed Public Health Act will make provision for mandatory reporting of adverse events by healthcare facilities.

- iii. Adequate legal provisions will be made to keep sensitive patient safety reporting confidential and exempted from public access and litigation.

Strategic Objective 3: To ensure a competent and capable workforce that is aware and sensitive to patient safety

To sustain patient safety efforts it would need to be made part of the work culture at healthcare facilities. This would require a workforce that is sensitive, well trained and competent on patient safety issues. Though adverse events can be mainly attributed to failure of the system rather an individual, however, trained and sensitised care providers can prevent the harm and help in building an error free work environment. The Patient safety framework emphasises upon a “catch them young” approach, whereby patient safety principles are incorporated in medical and nursing education, and then sustain the accumulated skills through continual medical/ nursing education and on the job trainings. Following are the priorities:

Key Priority 3.1: Strengthening education, training and professional performance inclusive of skills, competence, and ethics of health-care personnel

To ensure health workers competence on patient safety multipronged approach is recommended which include making it part of professional licensing requirements as well creating institutional capacity for trainings. Following are the specific actions:

- i. Knowledge of basic patient safety concepts will be incorporated as part of evaluation criteria for medical, nursing and paramedical licensing exams. Certain credit hours of attending the online-courses/CMEs on patient safety will be made mandatory as criteria for renewal of professional licenses.
- ii. Academic and technical support intuitions at national and state level will be identified to develop training courses and deliver onsite/online trainings on patient safety.
- iii. An institutional framework will be prepared for developing and updating evidence based standard treatment guidelines in Indian context.
- iv. National Standard Treatment Guidelines for all disease conditions will be developed in phased manner and will be made available for healthcare providers through user-friendly applications and implementation tools.

Key Priority 3.2: Improving the understanding and application of patient safety and risk management in health care

The understanding of patient safety should start from the medical and nursing education and should be extended to healthcare facilities through safe work culture and positive learning environment that enables care providers to apply their learning and strengthen their skills. Following specific actions are planned to achieve this objective:

- i. Medical, Nursing and paramedical educational curricula will be mapped for existing components of patient safety. The syllabus for undergraduate and postgraduate level courses will be revised to incorporate adequate learning objectives for patient safety based on WHO patient safety curriculum guide.
- ii. Patient safety principles will also be incorporated into in-service education programs and on job trainings organised by employers in public and private health sectors.
- iii. Practical guidelines for implanting patient safety at health care facilities will be developed. These guidelines will guide hospital administrators and care providers for implementing patient safety program at facility level.
- iv. Patients Safety components will also be incorporated in job description of different cadres of workforces and their performance appraisal criteria. Financial and non-financial incentives such as awards can enhance adherence to safe care practices.

- v. A National Patient Safety day/ week will be observed across the country. Notification on desirable activities for this occasion will be issued by MoHFW.
- vi. Further to facilitate learning on patient safety, a web based/ Mobile based learning platform will be developed.

Strategic Objective 4: To prevent and control health-care associated infections

Healthcare Associated Infections are a major challenge in ensuring patient safety. This situation is further aggravated in public hospitals due patient overload and inadequate workforce. There is no credible data on burden of Health Care Associated Infection in India (HCAI). HCAI is a multidisciplinary challenge and requires multipronged approach to contain it. Following are key priorities –

Key Priority 4.1: Strengthening infection prevention and control structure and programmes across all healthcare services and all levels of care

The risk of health care associated infections can be mitigated through establishing a sustainable infection control program at health care facilities. A systems improvisation to this practice would be to connect these facility level programmes & committees with policy level objectives and interventions. Following key actions are proposed:

- i. A national level strategic plan for infection prevention and control will be prepared by Ministry of Health & Family Welfare. This will have close linkage with related programs such as Antimicrobial Resistance Program and National Action Plan on Viral Hepatitis.
- ii. Institutions which have successfully implemented infection prevention and control programs, will be identified and their best practices will be disseminated for evidence based learning and scaling up.
- iii. Functioning of infection control committees at facility level be strengthened and development of standard operating procedures to be undertaken along with regular reporting of indicators.
- iv. Infection Control activities in various national health programs will be integrated.
- v. A system for surveillance of Healthcare Associated Infections will be established in phased manner. Data of HCAI will be collected and analysed by the agencies responsible for patient safety reporting.

Key Priority 4.2: Providing appropriately cleaned, disinfected or sterilized equipment for patient care as required

Adequate financial resources will be made available to ensure availability of equipment and consumables for disinfection and sterilization of equipment. This will be taken under the overall umbrella of NHM for public health systems and through specific hospital levels budgets for other hospitals.

Key Priority 4.3: Providing a safe and clean environment by improving the general hygiene sanitation and management of healthcare waste in healthcare facilities

Hygiene, Sanitation and waste management are closely linked with infection control outcomes. Swacha Bharat Abhiyan has given an impetus for improving cleanliness in hospitals and surroundings. Following actions are suggested to further promote sanitation and hygiene in healthcare facilities:

- i. Hand Hygiene program will be further reinforced in medical and nursing curriculum and in service training at health care facilities.
- ii. Implementation of Kayakalp – clean hospital scheme will be further reinforced by disseminating good practices and replicating role models across countries.

Strategic Objective 5: To implement global patient safety campaigns and strengthening Patient Safety across all programs

Key Priority 5.1: Safe surgical care

- i. Safe surgery checklist will be adopted for secondary and tertiary care level hospitals to make sure that all elective and emergency surgeries are performed using safe surgery checklist.
- ii. WHO 24X7 Emergency and essential surgical norms will be adopted in all healthcare facilities providing surgical care.
- iii. Appropriate sterilization practices will be adopted within National Trauma Care and National Burns program.
- iv. Guidelines for surveillance and prevention on venous thromboembolism will be developed and implemented.

Key Priority 5.2: Safe childbirth

- i. Quality Assurance standards for maternal health care and assessment tools for labor rooms and maternity operation theater will be reviewed and updated based on latest evidences including respectful maternal care and natural birthing process
- ii. Quality standards for labour room and OT will be expanded and reinforced at private health care facilities to ensure quality of intrapartum and post-partum care

Key Priority 5.3: Safe injections

- i. Vaccination of all healthcare providers against Hepatitis B in addition to waste handlers against tetanus to ensure occupational safety concerns among healthcare providers
- ii. Strengthen the post-exposure prophylaxis (PEP) for needle stick injuries at all casualities/OTs and other intervention sites

Key Priority 5.4: Medication Safety

- i. Standard operating procedures for disposal of discarded/ expired drugs as per BMW rules 2016 will be developed.
- ii. Adverse drug reaction surveillance will be strengthened and implemented across all public and private health care facilities with close coordination between state health departments, pharmacovigilance agencies, professional associations drug manufacturers and national vertical programs.

Key Priority 5.5: Blood Safety

- i. Voluntary Non Remunerated Blood Donation will be promoted through improved donor selection, recruitment, retention and referral through an effective communication strategy and capacity building.
- ii. Adverse donor and transfusion reactions surveillance will be implemented at all levels of care.
- iii. Hospital transfusion committee will be constituted with standard composition and terms of reference and rational use of blood and blood products will be promoted.

Key Priority 5.6: Medical device safety

- i. Usage of non- mercury devices and equipment will be promoted.
- ii. Availability of biomedical engineers will be ensured at health care facilities.

- iii. SOPs for utility; breakdown; monitoring of medical devices, restricting reuse of single-use purpose devices, clear policy on condemnation of equipment and SOPs of calibration for electronically operated medical devices will be developed and made available to health care facilities.

Key Priority 5.7: Safe organ, tissue and cell transplantation and donation

- i. Deceased donor programme will be reinforced and modified as necessary.
- ii. Scale-up IEC for organ donation, training of personnel in addition to registration of organ retrieval centers.
- iii. Dissemination of relevant information and ensure uniform implementation across region/state/institutions/hospital/tissue banks on legislation (THOA), National Organ Transplant Programme (NOTP), National Organ and Tissue Transplant Organization (NOTTO), different SOPs, including for selection and safety of donors; allocation policies, and national registries.

Strategic Objective 6: To strengthen capacity for and improve patient safety research

Key Priority 6.1: Consolidation of patient safety research and utilization for decision-making

A repository of good quality research on patient safety and allied themes will be created at national level. This will be pursued through Indian Council of Medical research (ICMR) which is the nodal medical agency for research in the country.

Key Priority 6.2: Reinforcing research for patient safety

- i. Studies will be conducted for estimation of the overall burden of unsafe care including point prevalent survey of hospital acquired infections.
- ii. Research on different aspects of patient safety at country and state level will be prioritized.

SECTION 3

Action Plan & Monitoring Framework

1. Action Plan

Key: S= Short Term (Six Month) ; M= Mid Term (six months to one year) L= Long Term (More than one year)

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short-term M/Medium-term L/Long-term	Expected Output
Strategic Objective 1: To improve structural systems to support quality and efficiency of healthcare and place patient safety at the core at national, subnational and healthcare facility levels					
1.1 Institutionalize patient safety and strengthen legislative and regulatory framework	1.1.1 Constitute national level steering committee as a central coordinating mechanism for Patient Safety (on the basis of Patient Safety Expert Group)	MoHFW /DGHS/ DDG /NODAL OFFICER/ TAG TAG= Regional state person, NHP, Research based organization, pharmacovigilance, patient organization, private bodies (CII, FICCI, AHPI)	March 2018	S	Steering Committee is established at central level and functional
	1.1.2 Designate Patient Safety focal points at State level (on the basis of Quality Assurance Committees)	State Governments/ State Director General Health services/ Medical Services & State QA Officer	July 2018	M	Focal points for patient safety are designated in all states
	1.1.3 Establish nodal division/ sub committee for patient safety/quality of care at central and state levels	MOHFW/ SQAC	July 2018	M	Patient Safety Department is established and functional
	1.1.4 Incorporate Patient Safety principles and concepts in vertical programs	MoHFW/DGHS/ ALL PROGRAMME OFFICERS	October 2018	L	Vertical disease programmes address Patient Safety
	1.1.5 Incorporate Patient Safety principles and concepts in Public Health Act	MoHFW/NHSRC	July 2018	M	Public Health Act includes the clause on Patient Safety
	1.1.6 Streamline patient safety in different insurance schemes and link patient safety with pay for performance	MoHFW & IRDA	December 2018	L	Insurance schemes at central and state levels consider payment for better performance based on Patient Safety indicators

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short-term M/Medium-term L/Long-term	Expected Output
1.2 Strengthen quality assurance mechanisms, including accreditation system	1.2.1 Development and commissioning of minimum patient safety standards and Indicators	MoHFW/ National Patient Safety Secretariat	July 2018	M	
	1.2.2 Incorporate selected Patient Safety indicators as key performance indicators within the Quality Assurance Program	NHSRC	July 2018	M	Patient Safety indicators incorporated in key performance indicators within the Quality Assurance Programme
	1.2.3 Incorporate selected Patient Safety indicators within the accreditation system for hospitals and laboratories, including entry level accreditation	NHSRC NABH/ NABL	July 2018	M	Selected Patient Safety indicators incorporated into accreditation system for hospitals and laboratories, including entry level accreditation
	1.2.4 Introduce hospital performance monitoring/ ranking system based on number of indicators, including patient safety indicators	HMIS & NHSRC	December 2018	L	Hospital performance monitoring/ ranking system is introduced and incorporates Patient Safety indicators
	1.2.5 Establish Special Commission to declare "Patient Safe Healthcare Institution" based on adherence to defined standards (Quality Assurance, NABH, etc.)	MOHFW/DGHS	March 2019	L	Special Commission is established by order and functional
	1.2.6 Streamline accreditation programs for availing incentives in reimbursement benefits the insurance providers	NABH/NQAS/STATE STANDARD/ BIS/ IRDA/ RSBY	July 2018	M	Provision of incentives for Accreditation from any organization like NABH/NQAS/ISO/state govt. accreditation
1.3 Establishing a culture of safety and improving communication, patient identification, handing over transfer protocols in healthcare facilities	1.2.7 Incorporate fire safety, seismic safety, device safety, structural safety of healthcare facilities into the existing Quality Assurance and Accreditation standards	NABH/NQAS/NATIONAL BUILDING CODE/state govt.	July 2018	M	Quality Assurance and accreditation Standards incorporate fire safety, seismic safety, device safety, structural safety of healthcare facilities
	1.3.1 Develop comprehensive communication strategy for Patient Safety, targeting different stakeholders 1.3.2 Streamline standardization of Patient Safety initiatives at different levels of care through SOPs, algorithms, checklists, etc. (link to Strategic Objective 5)	MOHFW/DGHS MOHFW/DGHS /NHSRC	July 2018 December 2018	M L	Communication strategy is in place Number of SOPs, algorithms, checklists are developed and introduced into the system (link strategic objective 5)

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short-term M/Medium-term L/Long-term	Expected Output
1.4 Establishing patient-centred care and involving patients as partners in their own care	1.4.1 Ensure Patient Safety processes are clearly communicated to patients and caregivers prior, during and after intervention (using different communication means: videos, mobile apps, leaflets, brochures, etc.) through existing Quality Assurance and accreditation programmes	National Patient Safety Secretariat	March 2019	L	Patient Safety processes are clearly communicated to patients through different communication means
	1.4.2 Integrate web-based grievance system and toll-free helpline for Patient Safety within the existing ICT system of MoHFW	MOHFW/DGHS/NHM	2018-2019	M	Web-based grievance system and toll-free helpline for Patient Safety in all healthcare facilities established
	1.4.3 Introduce anonymous reporting system in healthcare facilities to be used by healthcare facility staff, students, residents, patients and families. Ensure analysis of the inputs to the system is done by third independent party	National Patient Safety Secretariat/ Nodal officers state level	December 2019	L	Anonymous reporting system established in healthcare facilities and is analyzed by third party
	1.4.4 Promote establishment of patient groups	MoHFW/ State Health Departments/ Rogi Kalyan Samities / NGOs/ Consumer Right Groups	March 2019	L	Patient groups registered and functional
	1.4.5 Facilitate involvement of patient groups in policy development and implementation processes	MoHFW/ State Health Departments/ Rogi Kalyan Samities / NGOs/ Consumer Right Groups	Ongoing	M	Patient groups involved in the development of ... policies, strategies and plans
Strategic Objective 2: To assess the nature and scale of adverse events in healthcare and establish a system of reporting and learning					
2.1 Generating evidence for policy making	2.1.1 Conduct baseline assessment of the overall burden of unsafe care in the country, including public and private sector	Any institution as designated by Dte.GHS	December 2018	L	Baseline assessment of the overall burden of unsafe care conducted
2.2 Establishing robust surveillance systems for monitoring patient safety	2.2.1 Develop Patient Safety incident surveillance system and system of reporting and learning from all adverse events and near-misses at national, subnational and healthcare facility levels (web-based). Surveillance system to consider environmental safety elements.	MOHFW/National Patient Safety Secretariat	December 2018	L	Web-based Patient Safety incident surveillance system and system of reporting and learning from all adverse events and near-misses is established at national, subnational and healthcare facility levels
	2.2.2 Streamline reporting on Patient Safety initiatives within the existing programmes and reporting mechanisms and introduce new ones as per need	MoHFW/ National Programmes/ NHM	March 2019	L	Periodic reports on patient safety initiatives are available on annual basis

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short-term M/Medium-term L/Long-term	Expected Output
2.3 Ensuring supportive legislative mechanisms for effective functioning of patient safety surveillance systems	2.3.3 Develop and reinforce error reporting guidelines and codes in public and private institutions	MoHFW/ National Patient Safety Secretariat NHM	July 2018	S	Error reporting guidelines are developed and reinforced in public and private facilities
	2.2.4 Strengthen public reporting on quality of care	NHM/ NHRSC	March 2019	L	Annual reports on quality of care are publicly available
	2.2.5 Develop checklist for patient safety risk assessment at healthcare facility level along with provision for voluntary disclosure of information	National Patient Safety Secretariat	6 months	M	Checklist for patient safety risk assessment at healthcare facility level is developed
	2.2.6 Develop a system for ensuring healthcare workers safety and link it to existing Quality Assurance and accreditation programmes	MoHFW	2018	S-M	System for healthcare workers safety established
	2.3.1 Establish a system of analysis all reported incidents to guide appropriate interventions at national, state and institutional levels	National/State Level Patient Safety Officer/Qa Officer of NHRSC	2018	M	System of analysis of all reported incidents established
	2.3.2 Incorporate the special clause in existing legal documents on mandatory reporting of adverse events and near-misses	PUBLIC HEALTH ACT	2019	M	Special clause on mandatory reporting of adverse events and near-misses is incorporated in ...
3.1 Strengthening education, training and professional performance inclusive of skills, competence, and ethics of health-care personnel	2.3.3 Enact special Law or Act for making sensitive healthcare data exempt from public domain	MoHFW/State Government	2020	L	Special Law or Act for making sensitive healthcare data exempt from public domain is enacted
	Strategic Objective 3: To ensure a competent and capable workforce that is aware and sensitive to patient safety				
	3.1.1 Revise licensing/certification and re-certification standards of all categories of health workforce, ensuring the requirement for a specific number of credit hours on Patient Safety	Professional Councils/ MoHFW	2019	S	licensing/certification and re-certification standards of all categories of health workforce revised
		central/state govt. Professional councils and bodies, medical and nursing colleges, district hospitals & training institutions like SIHFV	Ongoing process	S	Frame work developed and institutions identified
Professional bodies MoHFW/DGHS NHRSC		2018	S	Guide on STG development is endorsed	
3.1.2 Identify institutions by central/state govt. and develop a sustainable framework for ongoing education and capacity building of Health care workers both in public and private sectors	MoHFW/DGHS (vertical programmes) Professional bodies NHRSC	Ongoing process	M-L	Unified national STGs are available for all diseases/conditions	
3.1.3 Establishing national institutional framework and methodology for collating, developing and commissioning evidence based STG's in Indian context.					
3.1.4 Developing and implementing unified national STGs for each disease/condition (through collation/revision of existing and development of new ones)					

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short-term M/Medium-term L/Long-term	Expected Output
3.2 Improving the understanding and application of patient safety and risk management in health care	3.2.1 Develop/adjust the Patient Safety pre-service educational curricula/training modules through mapping and converging the available materials with their further institutionalization at undergraduate and postgraduate level (reference to WHO Patient Safety Curriculum Guide)	Leading agency: Professional councils Contributing agency: Academic institutions NIHFW	2018	S	Patient Safety pre-service educational curricula/training modules developed/adjusted
	3.2.2 Incorporate patient safety basic principles and practice in all in-service education/on job training for all categories of health workforce	Lead agency: Employer Contributing agency: NIHFW DGHS/vertical programmes Accreditation agencies	Ongoing process	S	Patient safety basic principles and practice are incorporated in all in-service education/on job training for all categories of health workforce
	3.2.3 Developing the practice guidelines on Patient Safety targeting healthcare providers	MoHFW/ Patient Safety Secretariat	December 2018	L	Practical Implementation guidelines on patient safety are developed and issued.
	3.2.3 Introduce elements of Patient Safety in job descriptions of different categories of health workforce and ensure their usage for monitoring performance at different levels, and linking that to promotion and financial incentives	Health Directorates Employer	2019-20	M	Elements of Patient Safety incorporated in job descriptions of different categories of health workforce
	3.2.4 Organize Patient Safety weeks/days across the country to promote different components of patient safety.	MoHFW/DGHS	July 2018	S	Patient Safety weeks/days organized
	3.2.5 Develop a IT based learning solutions for disseminating information on patient safety	MoHFW NHSRC	March 2019	M	IT based learning solutions developed for patient safety
Strategic Objective 4: To prevent and control health-care associated infections					
4.1 Strengthening infection prevention and control structure and programmes across all healthcare services and all levels of care	4.1.1 Develop national level IPC strategy/plan/ programme (link to National Action Plan on AMR NAP-AMR)	MoHFW (NACA/ National Patient Safety Secretariat)	2018	S	National IPC strategy/plan/ programme available
	4.1.2 Review existing frameworks, programmes and best practices, identify existing key hospitals which have successful IPC programmes and replicate and scale up their experience	National Conference for good practice conducted by NHM in collaboration with NHSRC/ NABH	2018-19	S	Existing IPC frameworks, programmes and best practices in selected hospitals reviewed and scaled up (through the national IPC programme)

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short-term M/Medium-term L/Long-term	Expected Output	
	4.1.3 Establish special Committees for the IPC programme at institutional levels, that must have Standard Operating Procedures (SOP) and indicators for monitoring implementation of IPC programmes in healthcare facilities	Central government, Quality assurance cell/Infection control committee at district and state level and individual hospitals	2019-20	M	Special Committees for the IPC programme at institutional levels established, operate and monitored based on SOPs (through the national IPC programme)	
	4.1.4 Improve effectiveness of the Hospital Infection Control Committees that is presently mandatory in accreditation programme/s	MoHFW in collaboration with NABH/ NHSRC	2018	S-M	Standardized forms	
	4.1.5 Explore the regulatory framework for integration of IPC within the national health programmes and in the overall national health system	MoHFW & CEA	2018-20	M	Amendment of act	
	4.1.6 Raise awareness about IPC having much broader scope than what is currently practiced and propagated	NACA/ Patient Safety Unit	2020	S-M	Awareness raising activities implemented	
	4.1.7 Promote the concept of hospital safety with proper incorporation of IPC elements in it	NACA/ Patient Safety Unit	2019-20	S-M	Hospital safety programme available national, or through quality assurance or accreditation programmes)	
	4.1.8 Establish a system for HAI surveillance and consider its phased introduction and implementation	ICMR	2022	Long Term	Surveillance system of HAI established and implemented	
	4.1.9 Designate authority to collect, analyze and report HAI at national level	NCU/NACA	2017-18	S	Authority to collect, analyze and report HAI at national level is designated	
	4.2 Providing appropriately cleaned, disinfected or sterilized equipment for patient care as required	4.2.1 Ensure incorporation of budget for implementation of IPC programmes in all relevant national programmes and institutional budgets with the comprehensive and precise elements, including consumables	MoHFW & State Government	March 2018	S	Proposals can be incorporated in PIPs of NHM.

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short-term M/Medium-term L/Long-term	Expected Output
4.3 Providing a safe and clean environment by improving the general hygiene sanitation and management of healthcare waste in healthcare facilities	4.3.1 Reinforce the hand hygiene programme in medical and nursing curriculum and in service training at all levels of health care with strong awareness raising and training component	MCI, NCI, HISI	2019-20	M	Hand-Hygiene programme scaled up at all levels of care (through IPC national programme or separately)
	4.3.2 Put in place mechanisms to ensure uniform adherence to and compliance with the available guidelines and standards, including BWM rules, in both public and private health care facilities across the country	Ministry of Health and Ministry of Environment & CC (CPCB)	2022	L	Mechanisms for uniform adherence to and compliance with the available injection safety guidelines and standards, including BWM rules, in place
	4.3.3 Reinforce implementation of Kayakalp by getting good practices, replicating and scaling-up across the country	NHSRC	Ongoing	S	Best practices of Kayakalp implementation documented and scaled up
	Strategic Objective 5: To implement global patient safety campaigns and strengthening Patient Safety across all programmes				
5.1 Safe surgical care	5.1.1 Uniformly adopt surgical safety checklist that cover elective and emergency surgeries	DGHS/State dte. Of Health services/ SQACs	2020	L	Surgical checklist adopted uniformly across the country
	5.1.2 Uniformly adopt WHO 24X7 Emergency and Essential surgical norms in all institute which provide surgical care	DGHS/State Dte. Of Health services	2020	L	Essential and emergency surgical norms
	5.1.3 Adopt the appropriate anesthetic and sterilization practices within National Trauma Care and National Burns Programme				
	5.1.4 Improve public awareness across diverse groups on what constitutes safe surgery	Directorate Central /state/SQAC	2022	L	Awareness raising activities implemented
	5.1.5 Carry out regular monitoring and surveillance of SSI	MoHFW/ NHM/ SQAC	2020	M	Surveillance system of SSI in place
	5.1.6 Carry out regular monitoring and surveillance of Venous Thromboembolism (VTE). Develop and introduce guidelines on prevention of VTE.	DGHS	2020	S-M	Guidelines on prevention of Venous Thromboembolism (VTE) in place
5.2 Safe childbirth	5.2.1 Review and update available standards regularly for greater efficiency	DGHS/ Programme Divisions	July 2018		Revised QA standards and assessment tools for Maternity Care
	5.2.2 Expand and reinforce the available standards to private sector as well as to all levels of care	DGHS & State Governments	March 2020	L	At least 80% of the MNH care providers are included under the scope
5.3 Safe injections	5.3.1 Ensure all healthcare providers are vaccinated against Hepatitis B in addition waste handlers against tetanus to ensure occupational safety concerns among healthcare providers	MoHFW (& State Governments	December 2018	M	Mechanisms established for mandatory vaccination of health care providers
	5.3.2 Mandate post-exposure prophylaxis (PEP) for needle stick injuries at all causalities/OTs and other intervention sites	NACO/ MoHFW/ Hospitals	July 2018	M	Mechanisms established for post-exposure prophylaxis for needle stick injuries
	5.3.3 Facilitate inclusion of the injection safety module in the MBBS course.	MCI	2022	L	MBBS course contains injection safety module

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short-term M/Medium-term L/Long-term	Expected Output
5.4 Medication Safety	5.4.1 Develop SOPs for disposal of discarded/expired drugs as per standard guidelines.	Hospital management & State Government	2020	S-M	SOPs for disposal of discarded/expired drugs developed
	5.4.2 Ensure implementation of surveillance of adverse drug reactions universally	Pharmacology Departments, CMSS, State Health Departments, National Pharmacovigilance Cell, Patient Groups, Private Hospital Chains IMA Drug Controllers Drug Manufacturers Development Partners	2019		Surveillance system of adverse drug reactions in place and operational
	5.4.3 Incorporate pharmacovigilance within all national vertical programme	National Pharmacovigilance Programme/ National Programmes	2019	S-M	All national vertical programmes include pharmacovigilance component
5.5 Blood Safety	5.5.1 Promote Voluntary Non Remunerated Blood Donation with improved donor selection, recruitment, retention and referral through an effective communication strategy and capacity building	MoHFW/ NACO/NBTC/CDSCO	2019	S/M	90% voluntary blood donation
	5.5.2 Ensure implementation of surveillance of adverse donor and transfusion reactions universally	MoHFW/ NIB/ HVPI/ CDSCO	2019	S/M	All licensed blood banks and blood donors report adverse reactions
	5.5.3 Develop/revise SOPs for ensuring healthcare workers' safety and disposal of discarded blood in accordance with BMW Rules	MoHFW/ NACO/ NBTC/ NHSRC	2022	S/M	SOPs for ensuring healthcare workers' safety and disposal of discarded blood and consumables developed/ revised
	5.5.4 Constitution of Hospital Transfusion Committees as per standard composition and terms of reference in every hospital transfusing blood/ blood components	MoHFW/ NACO/ NBTC/ State Government	2022	S/M	Standard norms prepared and disseminated Hospital Transfusion Committees created
	5.5.5 Promote appropriate clinical use of blood and blood products and ensure adherence to safe transfusion practices	MoHFW/ NBTC/ HVPI/ CDSCO	2022	S/M	
5.6 Medical Device safety	5.6.1 Bring medical devices other than syringes and plastic waste under the BMW rules	Dte.GHS (Env Cell), CDSCO, MoEF&CC	2022	S/M	BMW rules include diverse medical devices (beyond plastic waste)
	5.6.2 Promote usage of Non-Mercury devices and equipment	Dte.GHS (Env Cell), CDSCO, MoEF&CC	2018	M-L	Non-Mercury devices and equipment are in use across India

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short-term M/Medium-term L/Long-term	Expected Output
	5.6.3 Ensure services of the biomedical engineering in all healthcare facilities for continued maintenance of medical equipment from installation till the equipment is used. NS HICC should monitor the same wherever relevant	Dte. GHS (Env Cell)/ DSHS guidelines	2020	S/M	Position of biomedical engineer is established at ...HICC and filled
	5.6.4 Make available updated SOPs for utility; breakdown; monitoring of medical devices, restricting access of single-use devices for reuse purposes, clear policy on condemnation of equipment and SOPs of calibration for electronically operated medical devices	Hospitals as per DGHS/ DSHS guidelines	2020	S/M	Updated SOPs for utility; breakdown; monitoring of medical devices, restricting access of single-use devices for reuse purposes available SOPs of calibration for electronically operated medical devices available Policy on condemnation of equipment in place
5.7 Safe organ, tissue and cell transplantation and donation	5.7.1 Reinforce the deceased donor programme and modify as necessary	MoHFW/DGHS/NOTP	2022	S/M	Deceased donor programme modified and reinforced
	5.7.2 Scale-up IEC for organ donation, training of personnel in addition to registration of organ retrieval centers	MoHFW/DGHS/NOTTO	2022	S/M	IEC for organ donation, training of personnel in addition to registration of organ retrieval centres scaled up
	5.7.3 Disseminate relevant information and ensure uniform implementation across region/state/ institutions/hospital/tissue banks on legislation (THOA), National Organ Transplant Programme (NOTP), National Organ and Tissue Transplant Organization (NOTTO), different SOPs, including for selection and safety of donors; allocation policies, and national registries	MoHFW/DGHS/NOTP	2022	S/M	
Strategic Objective 6: To strengthen capacity for and promote patient safety research					
6.1 Consolidation of patient safety research and utilization for decision-making	6.1.1 Establish a repository of all good quality research on patient safety and allied themes.	Lead agencies: ICMR, NML, Department of Health Research, National Patient Safety Secretariat	December 2018	M	Repository on good quality research on patient safety and allied themes established
6.2 Reinforcing research for patient safety	6.2.1 Initiate research on estimation of the overall burden of unsafe care including point prevalent survey of hospital acquired infections.	Academic Institutions ICMR NIHFW NHSRC	2017-19	L	Study/ies on burden of unsafe care available
	6.2.2 Prioritize research on different aspects of patient safety at country and state level	Academic Institutions ICMR NIHFW NHSRC	2017-22	M-L	Study/ies on different aspect of patient safety at country and state level available

2. Human Resources

Implementation of the patient safety framework will require additional dedicated resources. Most of the interventions will be implemented within the existing programmes and by well-established organizations and institutions. Existing Institutional support structures for Hospital Administration & Quality Assurance will be utilized for implementation for patient safety initiatives. Additional trainings as per thematic areas will be undertaken for the health workforce for taking forward patient safety initiatives. Health Care Associated Infection prevention and control would be an area needing major strengthening through funds, availability of Hospital Infection Control Nurses and establishment of surveillance systems. Beside , technical support from international partners can also be envisaged as per mutual agreement and based on organizational mandates and priorities.

3. Budget and Potential Source of Funding

It will be important to ensure the specific budget lines for patient safety in general or for different elements of the same (capacity building, surveillance systems, infectious prevention and control, hand-hygiene, etc.) are included in all vertical national programmes. In case of the establishment of national programmes on IPC, for example, the central and state budget has to consider the same. In addition to that, technical support from international partners can also be envisaged as per the mutual agreement and based on organizational mandates and priorities. Budget can be earmarked under institutional budgets of hospitals.

4. Monitoring and Evaluation

Strategic Objective	Intervention	Indicator	Target
Strategic Objective 1			
Priority area 1	Establishment of patient safety cell/ divisions at central and state level	Operationalization of Patient Safety Secretariat/ Cells at national and state level	National Patient Safety Secretariat Operationalized 80% of states have instituted patient safety sub committee under state quality assurance committee .
Priority area 2	Patient Safety Certification	Proportion of facility achieved patient safety certification	80% Public Hospitals 80% Private Hospitals
Priority area 3	Patient Safety SOPs and Checklist safe communication	Proportion of healthcare facilities using SOPs and Checklist	80%
Priority area 4	Grievance redressal system	Proportion of states established grievance redressal system for patient safety	80%
Strategic Objective 2			
Priority area 1	Base line assessment of estimating burden of unsafe care	Proportion of states where baseline assessment conducted	100%
Priority area 2	Patient Safety Surveillance System	Proportion of healthcare facilities participating in surveillance system	60%
Priority area 3	Legal provision for safe guarding surveillance information	Incorporation of mandatory reporting in Legal Framework/ instrument	Provision incorporated
Strategic Objective 3			
Priority area 1	Training of healthcare workers on patient safety	Proportion of states with state level trainers on patient safety	80%

Strategic Objective	Intervention	Indicator	Target
Priority area 2	Practice guidelines and Training Manual on Patient Safety	Proportion of facilities where practice guideline/ SOPs are available	80%
Strategic Objective 4			
Priority area 1	Surveillance of HCAI	Proportion of facilities reporting HCAI monthly	80%
Priority area 2	Budgetary Provision sterilized equipment	Proportion of district hospitals are having dedicated CSSD	60%
Priority area 3	Adherence to BMW rules	Proportion of facilities linked with common treatment facilities.	90%
Strategic Objective 5			
Priority area 1	Adoption of Surgical Safety Checklist	Proportion of health care facilities implementing safe surgical checklist	80%
Priority area 2	Safe Child Birth facilities	Proportion of Labour Rooms quality certified	70%
Priority area 3	Vaccination of Healthcare providers	Proportion of vaccinated staff for Hepatitis B	80%
Priority area 4	Adverse Drug Reaction Reporting	Proportion of facilities reporting adverse drug reactions	90%
Priority area 5	Establishing hospital transfusion committee	Proportion of secondary and tertiary care hospitals established transfusion committee	90%
Priority area 6	Availability of Bio Medical Engineers	Proportion of secondary and tertiary care facilities appointed a dedicated biomedical engineer	60%
Priority area 7	IEC for organ donation	Percentage increase in persons registered for organ donation	50%
Strategic Objective 6			
Priority area 1	Repository for good quality research on patient safety	Number of research papers collated for Indian context	100%
Priority area 2	Funding for patient safety research	Percentage increase in funding for patient safety research	100%

5. Communication Strategy

Communication strategy for patient safety will consider the following aspects:

- i. Overall purpose and key issue:** Patient safety related issues have to be linked to the behavior change that needs to occur to improve patient safety in the country.
- ii. Context:** Strengths, Weaknesses, Opportunities, and Threats (SWOT) that affect the situation have to be analyzed in details.
- iii. Gaps in information** available to the program planners and to the audience that limit the program's ability to develop sound strategy. These gaps will be addressed through research in preparation for executing the strategy.
- iv. Audiences** (Primary, secondary and/or influencing audiences): Communication strategy for patient safety will clearly define target audience that will include policy makers at national and state levels; health managers and public health professionals at national state, district and institutional levels; general population, including patients, caregivers and families; different categories of healthcare workers and support staff employed by healthcare organizations; volunteers, involved in provision of healthcare to the population; media and international organizations and stakeholders. It is critical to define the groups of primary, secondary and influencing audiences).

- v. **Objectives and positioning** in the broader health system context: Communication strategy for patient safety will consider availability of similar strategies (or communication elements) on either covering broader health system issues or specific thematic issues.
- vi. **Key Message Points:** Development of key messages for IEC materials will be based on the materials already available within different vertical programmes across the country. Materials periodically released by WHO will be utilized as a basis for further development/adjustment/revision of the local materials. IEC materials will be translated into local languages and pre-tested before finalization with all defined target groups. Prioritization of key messages.
- vii. **Channels and Tools:** The communication tools and channels will be defined for each target audience accordingly. It is important to ensure that the following key principles are at the core of all communication activities and are reflected in the full range of IEC materials: accessibility, feasibility, credibility and trust, relevance, timeliness, clarity and comprehensiveness.
- viii. **Management Considerations and Partner Roles and Responsibilities:** Successful management requires leadership, clearly defined roles and responsibilities, close coordination and teamwork between all the participants, and adherence to a timeline and budget. It is important to distinguish the lead organization from collaborating partners, by identifying the key functional areas and skills that need to be in place to carry out the strategy. Typically, these roles include management coordination, policy, research, advertising, media planning and placement, PR, community-based activities, training, monitoring and evaluation.
- ix. **Timeline for Strategy Implementation:** If the communication strategy will be implemented in phases, it will be important to establish a timeline that shows when the major activities of each phase will take place and where the key decision points are. Since communication efforts are usually tied to service delivery, training, and other areas, it is important to create a timetable with appropriate linkages to all these respective interventions.
- x. **Budget:** Developing a detailed budget will ensure that financial resources will be available to carry out communication strategy in all its parts. The budget for communication strategy on patient safety will be either linked to the overall budget for patient safety framework and be reflected in PIPs or separate budget will have to be established for communication strategy.

National Patient Safety Steering Committee



This committee will have the overall responsibility for implementing patient safety framework in the country under the aegis of Ministry of Health & Family Welfare, Government of India. This committee will have a technical advisory and supervisory role. Administrative and regulatory functions will be vested with existing authorities under Clinical Establishment Act, professional councils, consumer protection acts, pollution control board. The committee will comprise Ministry of Health officials as well as representation from technical support institutions, NHM, NHSRC, Programme Division state quality assurance committees, Directorate of Health, professional associations, WHO, private sector associations, Medical Colleges, accreditation agencies, consumer protection groups, pharmacovigilance agencies. For the first tenure, the members of committee can be pooled from the expert group constituted for developing National Patient Safety Implementation Framework. Later additional members can be co-opted as per requirement. The committee will be chaired by Director General of Health Services (DGHS) and Deputy Director General (DDG) Public Health will be the member secretary of this steering committee. Steering committee will meet once in a quarter.

The steering committee will be supported by a National Patient Safety Secretariat staffed with fulltime technical and support staff. Secretariat can be located at Ministry of Health of Welfare or one of its technical support institutions. This secretariat will report Member Secretary (DDG Public Health) of National Patient Safety Steering Committee. The secretariat will work in close coordination with existing quality assurance institutional framework at national and state level.

Following are the functions of National Patient Safety Steering Committee:

1. Preparing the detailed action plan for implementation of national patient safety framework.
2. Operationalize the patient safety framework in the state health departments.
3. Defining the minimum set of reportable patient safety indicators for different level of hospitals.
4. Establishing reporting mechanism for reporting of patient safety indicators and adverse events from public and private sector hospitals.
5. Establishing system for grievance redressal on patient safety issues.
6. Periodic monitoring and feedback on reported patient safety indicators and grievance received.
7. Publishing periodic reports on status of patient safety practices and outcomes.
8. Promote research on patient safety related themes.
9. Develop the technical guidelines and implementation aids patient safety related topic.
10. Evolve and implement the communication strategy for patient safety including communication material for public and patients.
11. Design and disseminate the training packages for different healthcare cadres.

12. Facilitate / Provide master trainings on patient safety related themes.
13. Facilitating the participation and regular reporting from private sector.
14. Coordination and sharing of information with regulatory bodies, quality assurance committees and accreditation and certification agencies.
15. Channelizing technical assistance for the states & Health Facilities.



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MINISTRY OF HEALTH AND FAMILY WELFARE
Government of India
Nirman Bhavan, New Delhi