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## Climate change: A global emergency, let's save our planet

"Earth provides enough to satisfy every man's need, but not every man's greed"

- Mahatma Gandhi

The certainty that earth has warmed up is unequivocal, and human influences are the major cause for global warming.[1] We all know that greenhouse gases: CO<sub>2</sub>, methane, chlorofluorocarbons, and nitrous oxide are like blanket around the earth, trapping energy and causing it to warm. Human activities are changing the natural greenhouse and have increased CO, concentration by more than a third since the industrial revolution began. This is the most important long-lived "force" for climate change. [2] The major part of this increase in core concentration is due to burning of fossil fuel and coal. Industrial activities have raised atmospheric concentration of carbon dioxide from 280 to 400 ppm in the past 150 years (Intergovernmental Panel on Climate Change [IPCC] Fifth Assessment Report, 2014).

The IPCC has warned of disastrous consequences if the current trend of global warming is not reversed immediately. Human activities are estimated to have caused about 1.0% of global warming above preindustrial levels; however, if it continues to increase at the current rate, global warming is likely to reach 1.5% between 2030 and 2052. This level of global warming increases the climate-related risks to health, food security, human security, water supply, and economic growth. Changes in the pattern of precipitation and temperature have led to a rise in sea level and consequently threat the availability of freshwater around the world.

Climate change is one of the largest and most complex problems affecting almost every individual globally. Apart from deleterious effect on weather, rainfall, higher temperature, etc., it affects the human health in many negative consequences. Till 1990s, there was a general lack of understanding as to how disruption of biophysical and ecosystems might affect the health of a population. However, late in 1996, the second assessment report of IPCC devoted a whole chapter to potential risk to health. Moreover, now, we have an abundance of literature and research, suggesting the effect of climate

change on health.<sup>[3]</sup> It is projected that human health will be affected with negative consequences with any increase in global warming. Lower risks are projected at 1.5°C than at 2°C for heat-related morbidity and mortality. Risks from some vector-borne diseases, such as malaria and dengue fever, are projected to increase with warming from 1.5°C to 2°C, including potential shifts in their geographic range.<sup>[4]</sup>

Climate change affects social and environmental determinants of health such as safe drinking water, availability of food, clean air, and secure shelter. Certain groups such as children, elderly, pregnant women, socially marginalized population, or people with other health conditions such as HIV are more susceptible to health impacts due to climate change. Climate change affects human health as can lead to emergence of new epidemiological pattern (e.g., malaria may move to areas where there have never been cases before), it also increases the transmission season and extend the geographical range of many diseases like malaria and dengue.[5] Global warming brings new and emerging health issues, which also covers heat waves and other extreme events. Heat stress increases the risk of cardiovascular, respiratory, and renal diseases. Many waterborne diseases and infectious diseases are highly sensitive to climatic conditions. [6,7]

Impacts of climate change on food security, particularly in relation to floods and drought, highlight concern for undernutrition and malnutrition. Considering the product life cycles, food consumption is a major polluting activity too, and plant-based diet can be a promising solution to it, as the production of plant protein requires less energy, water, and land in comparison to animal protein. Moreover, the life cycle inputs per kilogram of animal protein is significantly higher than plant protein.[8] The lives and livelihoods of millions have been affected by the impact of higher temperatures, extreme weather, ozone depletion, increased danger of wildland fires, loss of biodiversity, stress to food production, and the global spread of infectious diseases such as malaria, dengue, cholera, diarrheal diseases, and rodent-borne diseases.<sup>[9]</sup> Moreover, the WHO assessment concludes that climate change is expected to cause approximately

2.5 lakh additional deaths per year between 2030 and 2050: 95,000 due to childhood undernutrition, 48,000 due to diarrhea, 60,000 due to malaria, and 38,000 due to heat exposure in elderly people. [10]

Realizing the "pressing need," India has taken many clean and green development initiatives at both the state and national levels. A comprehensive publication titled-"India-spearheading climate solutions" was released on February 12, 2019, by the Union minister of Environment, Forest, and Climate change.[11] This document mentions key actions taken by India under various sectors to combat and adapt to climate change. Some of the major initiatives of India are India's National Action Plan on Climate Change which deals with eight major missions: Solar - to promote solar energy by competing fossil fuels; Enhanced Energy Efficiency - to improve energy efficiency of domestic, commercial, and industrial sectors; Sustainable Habitat - to encourage sustainable urban planning; Water - to conserve it, minimize waste, and ensure equitable distribution; Strategic knowledge on climate change; Sustainable agriculture; Green India – to promote, enhance, and restore forests, and Sustaining Himalayan ecosystem. However, there stand major challenges in the efficient implementation of the missions in terms of institutional, systemic and process barriers, and also the approach seems broad with lacking specificities.<sup>[12]</sup> Other initiatives are International Solar Alliances, State Action Plan on Climate Change is which obliges state to incorporate climate change concerns in decision-making process, Faster Adoption and Manufacturing of Electric Vehicles Scheme to boost e-mobility, Atal Mission for Rejuvenation and Urban Transformations for smart cities, Pradhan Mantri Ujjwala Yojana to provide access to clean cooking fuel and empower women and Swachh Bharat mission to bring behavioural change people with respect to toilet access and usage. However, no promising results in terms of climate change are evident and thus require a strong commitment at both individual and government levels to combat the need.

Recently, the author was in Australia where federal elections were held on May 18, 2019. Climate change was one of the major concerns, and the narrative is debated by political parties. Elsewhere, a lot of efforts are being made for a climate change. June 5 is celebrated as "World Environment Day" to draw attention to a particularly pressing concern and accordingly, "Air Pollution" was identified as an environmental concern for 2019. As per the World Air Quality Report, 2018, the Indian National Capital Region has emerged as the most polluted region in the world, with

an yearly average of particulate matter 2.5 concentration at  $11.3 \,\mu g/m^3$ .

Promotion of research and development for battery-run transports, increase in the vegetative cover, strict checking of Pollution Under Control certificates, restriction on number of vehicles owned per individual/family, adaption of best practices to minimize emissions from construction sites/activities, promoting renewable energy choices, and adapting plant-based diet can be some of the many commitments for a change toward healthier climate.

There is a need for extraordinary efforts by every human being to adapt to healthy climate-friendly practices. Environment, air, sky, water, etc., does not define political or national barriers. The entire global family has to move unitedly to ensure the planet is a healthy place for survival and existence of human race and biological life-forms. It is a dire need to save the mother earth from the devastation of climate change and thus require to make the clean renewable energy as the profitable kind of energy. It is a global emergency and every human being has to contribute for a healthier environment.

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## Fellowship in Public Health Nutrition Department of Community Medicine and Family Medicine AIIMS Bhubaneswar

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## **Prevalence of polypharmacy: Comparing the status of Indian** states

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#### **Abstract**

**Introduction:** The word "poly" is Greek and means many or much. However, the term polypharmacy has been given definitions connected both to the use of more than a certain number of drugs concomitantly and to the clinical appropriateness of drug use. Polypharmacy is the use of multiple medications by a patient, generally older adults (those aged 60 or over 65 years). More specifically, it is often defined as the use of 5 or more regular medications. It sometimes alternatively refers to purportedly excessive or unnecessary prescriptions. The term polypharmacy lacks a universally consistent definition with an increasing share of population in this age group, it is natural to expect an increase in the problems associated with them as well. Health problems are supposed to be the major concern of this section of the society, and it is reported that use of medications has increased significantly among the elderly in the last decade.

**Objective**: The objective of this study is to assess the prevalence of polypharmacy among elderly patients in different Indian states, to make a comparison, and also to study the patterns of polypharmacy and its associated aspects.

Materials and Methods: Literature review comprising of original articles, reviews, and case studies was studied to identify articles which correspond to research done on polypharmacy in various different ways published between the years 2010 and 2018. As the review focuses on the geriatric population, so considerable data were searched and collected for the use of medication in geriatrics to assess what makes them prone to polypharmacy, what pattern of polypharmacy they follow, and how they are affected by the consequences.

**Results:** Uttaranchal, Karnataka, and Telangana reported a higher level of polypharmacy with 93.14%, 84.6%, and 82.8%, respectively, whereas Andaman and Nicobar Islands (2%) and West Bengal (5.82%) showed the lowest polypharmacy.

**Conclusion:** Overall comparisons made show that there are more studies needed to assess the level of polypharmacy and ways and measures should be incorporated by the government in states showing high polypharmacy.

Keywords: Cascade, elderly, India, polytherapy, states

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#### **INTRODUCTION**

Elderly population is increasing worldwide. In India, the size of elderly population is fast growing; from 5.6% in 1961, it is projected to rise to 12.4% of the population by the year 2026.[1] India has witnessed a remarkable growth in the life expectancy in the last century. In the early 1930s, the average life expectancy of an Indian adult was only 32 years. Against a global average life expectancy of 75 years, currently, the life expectancy in India is about 67 years. The life expectancy in India is expected to reach 75 years by 2025. Further, the United Nations projections indicate that elderly Indian population will rise to 21.2% of the total by 2055 (from 7.2% estimated in 2005). This increase in life expectancy may be one of the most significant achievements of Indian health-care system. At the same time, it also poses a major public health issue. With the increase in the aging population, the drug-related problems have also increased. The health-care needs of this growing population are based on the presence of age-related diseases, increase in the chances of hospital admissions, longer hospital stays, and more extensive drug therapies.<sup>[2]</sup> In India, an estimated 50% of elderly people suffer from at least one chronic disease that requires lifelong medication.<sup>[3]</sup> The term "elderly" or "geriatrics" refers to a population with a chronological age of >65 years in most of the developed nations, while this does not adapt very well to the underdeveloped or developing nations. The United Nations thus recommends no standard numerical criterion but agreed a cutoff of >60 years as elderly population. In January 1999, the Government of India adopted the "National Policy on Older Persons" by which "senior citizen" or "elderly" is defined as persons who are of the chronological age of 60 years or above. Based on the 2011 census, the number of the elderly living in India is 103.8 million (10.38 crores), which corresponds to 8.6% of the total population. Polypharmacy as such has no standard definition but is generally referred as taking multiple medications together usually 5 or more per day and/or administration of more medications than that are clinically warranted, indicating unnecessary or unwanted drug use. High level of polypharmacy is defined as intake of 10 or more drugs.<sup>[4]</sup> Although polypharmacy is practiced quite often, there is a lack of consensus definition for polypharmacy. It is also not known as to the concurrent use of how many medications are considered as polypharmacy. Different thresholds have been used to assess polypharmacy. Some of the authors use thresholds of 3, 4, 5, or 10 medications to evaluate polypharmacy. This definition is solely based on the count of medications irrespective of clinical indications and conditions suffered by the patient.<sup>[5]</sup>

#### Rationale

Elderly population constitute nearly 8% of the total Indian population. However, this segment of population is neglected in almost all the aspects of life. They are social sufferers and are major victims of compromised health. With this review, we will be able to assess the level of polypharmacy that is prevalent among elderly population in different states as the comparison will help the respective states to improve their insights and focus on this segment of population. The generated data of this study can then be utilized in various programs to take adequate measures to reduce adverse effects of polypharmacy. There should be concern given to the optimal use of medication and to improve the good communication among elderly patients and health providers.

#### MATERIALS AND METHODS

Literature review comprising of original articles, reviews, and case studies was studied to identify articles which correspond to research done on polypharmacy in various different ways published between the years 2010 and 2018 to give priority to the freshness of the article as the most recent data will provide the best results. Furthermore, the focus was laid on the work and data pertaining to research done on this subject in the elderly. Effort was put in to at least have data of one study from each state, but some states were found to be having no work on polypharmacy. Literature review was also done to understand the general concept of polypharmacy and the associated causes. Reference lists of the most relevant articles were separated from the gray literature and were sorted to identify other relevant articles. The search strategy was developed in consultation with the coauthors with a predetermined protocol for methods to search and select relevant articles. The studies done specifically showing the prevalence of polypharmacy were chosen and analyzed, and useful material was then extracted from the collected material according to the need of this review.

#### Data extraction

Data items extracted included the definition of polypharmacy and associated causes and the prevalence of polypharmacy in different states. The studies conducted in different states were searched and compiled individually. Later, these articles were studied and screened, and then, the most similar articles were considered for final inclusion in the review. Once the primary data extraction was complete, all authors reviewed the content for each of the extracted studies, and later, the data were further summarized in Table 1.

Table 1: Comparison among the states in reference to polypharmacy prevalence

State	Region	Study done by	Prevalence (%)
Andhra Pradesh	Kadapa	Srikanth and Sireesha, 2012 <sup>[6]</sup>	40.77
Assam	Guwahati	Borah <i>et al.</i> , 2017 <sup>[7]</sup>	78
Goa	GMC, Goa	Khandeparkar and Rataboli, 2017 <sup>[8]</sup>	13.85
Gujarat	Anand	Shah et al., 2012 <sup>[9]</sup>	52
Himachal Pradesh	Kangra	Priya <i>et al.</i> , 2018 <sup>[10]</sup>	33.7
J&K	Jammu	Gupta <i>et al.</i> , 2018 <sup>[11]</sup>	53.13
Karnataka	Bangalore	Saldanha <i>et al.</i> , 2017 <sup>[12]</sup>	84.6
Kerala	Kochi	Rajeev <i>et al.</i> , 2018 <sup>[13]</sup>	22.9
Madhya Pradesh	Bhopal	Rambhade <i>et al.</i> , 2012 <sup>[14]</sup>	8.73
Maharashtra	Wardha	Agrawal and Nagpure, 2018 <sup>[15]</sup>	26
Punjab	SAS Nagar	Kashyap <i>et al.</i> , 2016 <sup>[16]</sup>	57.9
Tamil Nadu	Elayampalayam	Tamilselvan <i>et al.</i> , 2018 <sup>[17]</sup>	43
Telangana	Mahbubnagar	Radhika <i>et al.</i> , 2018 <sup>[18]</sup>	82.8
Tripura	Agartala	Chakraborty <i>et al.</i> , 2017 <sup>[19]</sup>	6.81
Uttaranchal	Dehradun	Singh et al., 2017[20]	93.14
Uttar Pradesh	Bareilly	Shalini and Joshi, 2012 <sup>[21]</sup>	25.20
West Bengal	Kolkata	Indu <i>et al.</i> , 2018 <sup>[22]</sup>	5.82
Andaman and Nicobar Islands	Andaman and Nicobar	Vardhan <i>et al.</i> , 2017 <sup>[23]</sup>	2
Pondicherry	Pondicherry	Kanagasanthosh et al., 2015[24]	16.5

#### Causes of polypharmacy

- An aging population with comorbidities requiring several different medications and an increasing availability of newer medications
- Patients self-medicating with over-the-counter medications and herbal preparations without a clear understanding of the adverse reactions and interactive effects
- A "prescribing cascade" which occurs when patients take a medication and exhibit side effects that are misinterpreted by the health-care practitioner as symptoms of a disease and requiring additional medication
- The patient sees several physicians and fills prescriptions at different pharmacies, but there is a failure to keep all parties informed about each other's actions
- Ineffective communication and coordination between health-care practitioners result in redundancy.<sup>[18]</sup>

#### **RESULTS**

The data above in the tabulation form shows the prevalence of polypharmacy in various Indian states. It reveals the range of medicines taken by the individuals mostly above four which further goes upto the range of ten and in some states even more than 10.

#### DISCUSSION

Although it is stated in literature that the use of even one medicine which is not indicated by a practitioner is also considered polypharmacy, most of the studies have taken the use of >5 medicines as polypharmacy. Thus, this review takes into account the use of 5 or more medications as the base for defining polypharmacy. However, the criteria for polypharmacy differed in all the studies with respect to demographic variables. There was a considerable amount of difference in prevalence rates depending on the type of study, institution-based study, or community-based study, but to maintain homogeneity of this review, the most matching relevant available material was included to understand the general prevalence and trend of polypharmacy in Indian states. It was understood from the literature that maximum studies related to the prevalence of polypharmacy were done in southern states of India. Thus, in states such as Bihar, Chhattisgarh, Haryana, Meghalaya, Mizoram, Nagaland, Orissa, Rajasthan, Sikkim, Jharkhand, Chandigarh, Dadra and Nagar Haveli, Daman and Diu, and Delhi, Lakshadweep showed no relevant data in relation to the prevalence of polypharmacy in the literature studied.

The study done by Pandey and Saharan shows that the prevalence of polypharmacy is 4.2% among the elderly in India. Saldanha *et al.* revealed that the prevalence of polypharmacy was 84.6% and the prevalence of high-level polypharmacy was 11.1%. [12,25]

The study done by Kumar et al., 2015, revealed that the prevalence of polypharmacy was 73.93%; among this, minor polypharmacy (2-4 drugs) accounted for 81.15% and major polypharmacy (≥5 drugs) for 18.85%. Mean (±standard deviation SD) number of medication taken was 2.57 (±1.47), while the study done by Dhanapal et al. revealed that out of 502 prescriptions, 61 (11.73%) prescriptions were minor polypharmacy and 457 (88.26%) prescriptions were major polypharmacy. Furthermore, Radhika et al. revealed that polypharmacy was observed in 82.8% and 5-8 drugs were prescribed for most of the patients (42.6), followed by >8drugs (40.2%). These studies showed dissimilarity to the study conducted by Mohammad et al. which shows that of 1003 prescriptions, 403 (40.18%) prescriptions were found to be of minor polypharmacy and 600 (59.82%) prescriptions were of major polypharmacy.[3,4,18,26]

The study done by Raut *et al.*, 2013, revealed that polypharmacy was observed in almost all cases, wherein 45% were prescribed 11–15 drugs and 32% patients were with 6–10 drugs per prescription. Romana *et al.* study showed that 18% of the patients received six drugs, 24% of the patients received seven drugs, 20% of the patients received eight drugs, and 38% of the patients received nine drugs or >9 drugs. [27,28]

Battula et al. concluded that polypharmacy was observed based on the number of drugs prescribed in each participant and found that the average number of drugs for prescription was found to be 9.92  $\pm$  0.53 (95% confidence interval). Polypharmacy was categorized into four types (no polypharmacy [0-2 drugs], minor polypharmacy [3-5 drugs], major polypharmacy [6-9 drugs], and excessive polypharmacy [≥10 days]). It was found that 48% (n = 101) of participants had excessive polypharmacy, 42% (n = 89%) had major polypharmacy, and 10% (n = 21) had minor polypharmacy. This showed similarity to the studies conducted by Harugeri et al. and Joy et al. which revealed that polypharmacy and high-level polypharmacy were prescribed in 366 (45.0%) and 370 (45.5%) patients and the prevalence of poly pharmacy and potentially inappropriate medication use was 41% (n = 51) and 51% (n = 63), respectively. Shah et al. revealed that polypharmacy and high polypharmacy were prevalent in 52% and 23.25% of patients, respectively. This showed similarity to the studies of Kashyap et al. and Gupta et al., with 57.9% and 53.13% of geriatrics, respectively. [9,11,16,29-31]

Another study done by Agrawal and Nagpure revealed that ≤4 number of drugs were prescribed to 74% population, 5–9 number of drugs were prescribed to 25% population, and 10–14 number of drugs were prescribed to 1% population.<sup>[15]</sup>

Manjaly *et al.* revealed that 73.3% of patients were subject to polypharmacy. The mean number of medications consumed per day by the patients in the study group was  $6.7 \pm 3.1$ . This showed similarity to the study conducted by Rathnakar *et al.* in which polypharmacy of 4 or more drugs was found in 71.77% of prescriptions. Rakesh *et al.* revealed that around 66.19% of patients were receiving polypharmacy. A significant number of patients were receiving drugs which are to be avoided as well as overprescribed and underprescribed. [32-34]

The study done by Kanagasanthosh *et al.* revealed that a total of 1769 drugs were prescribed, giving an average of 2.98 drugs per person (range: 1–9). Polypharmacy (≥5 drugs)

was observed in 99 patients. Sehgal et al. revealed that a total of 312 patients were on polypharmacy (5 or more medications at the time of admission). The study done by Khandeparkar and Rataboli revealed that the total number of drugs per prescription ranged from minimum of 5 to maximum of 16 drugs, with an average of  $7.96 \pm 1.75$ . A large number of 596 prescriptions contained 6-9 drugs per prescription. Chakraborty et al. revealed that 90.9% of patients were on <6 medications, while 6.81% and 2.27% of the patients were on 6-10 medications and >10 medications, respectively. Vardhan et al. revealed that the most number of prescriptions were containing 3 drugs accounting for 2360 (61%) prescriptions, followed by 1120 (29%) prescriptions with 4 drugs, followed by 300 (8%) prescriptions with 2 drugs and the least number were of prescriptions containing >4 drugs with 72 (2%) prescriptions, and all these prescriptions were containing at least 1,[8,18,23,24,35]

Nandagopal *et al.* revealed polypharmacy in geriatric patients, with an average number of drugs per prescription being 7.02. This deviates from the WHO standards of 1.6–4.8. Polypharmacy unfortunately is very common in India and some other countries. It results in increased cost of treatment, which may lead to nonadherence by patients as they have more medicines than they can cope with. It also increases the risk of significant adverse drug interaction.<sup>[36]</sup>

#### **CONCLUSION**

Polytherapy is often mandatory in the management of most of the common ailments affecting geriatric patients. Drug prescription in the elderly is a serious challenge as there is an increased possibility of drug interaction resulting in toxicity, treatment failure, or loss of drug effect. Duplicative prescribing within the same drug class often occurs, and unrecognized drug side effects are treated with more drugs. To minimize polytherapy, periodic evaluation of patients' drug regimen is necessary. Prescribers need to know what other prescriptions patient is taking including herbs and teas. The small number of drugs in low doses with a simple regimen is good for drug therapy in the elderly. A significant proportion of hospitalized geriatric patients are exposed to substantial polypharmacy. Further researches are required to identify the risk of adverse drug effects following multiple drug administration and specific potential drug-drug interaction. It would be pertinent to develop country-specific list of medications inappropriate for the elderly and include this list in national drug formularies so as to reduce their prescription and use in this age group.<sup>[37,38]</sup>

#### Recommendations

There are few studies in the predictors of polypharmacy among the elderly in India. With this review, the gross idea of the level of polypharmacy that is prevalent among the elderly population in India is assessed. The generated data of this review can be utilized in various programs to take adequate measures to reduce its adverse effects and misery to the elderly. There should be concern given to the optimal use of medication and to improve the good communication among elderly patients and health providers. Findings of the review will be helpful for the programs and policymakers, researchers, academician, and social workers who are working in the field of health and geriatrics.

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#### Conflicts of interest

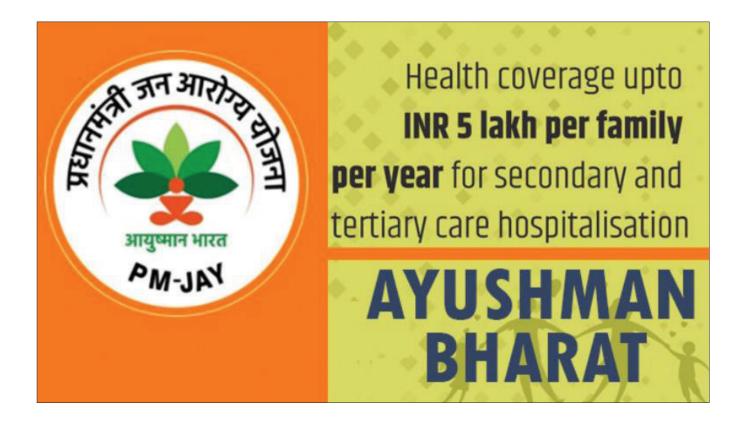
There are no conflicts of interest.

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## Operational issues and lessons learned during National Iron Plus Initiative documentation in Eastern India

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#### **Abstract**

Anaemia is a condition in which red blood cells have fewer haemoglobin molecules than normal, or fewer red blood cells overall, and thus less ability to carry oxygen to tissues in the body. Nutritional anaemia is a major public health problem in India and is primarily due to iron deficiency. Symptoms of iron deficiency anaemia are primarily non specific and become apparent when there is severe anaemia. The National Iron Plus Initiative (NIPI) is the most ambitious and comprehensive anaemia control programme in the world. The process documentation team conducted 170 interviews in March, April and May 2016 among officials and frontline workers at state, district, block, sector/cluster and field levels and among NIPI beneficiaries in Odisha. To achieve variation in responses and to get full set of information on how NIPI was being implemented, process documentation and survey data were collected in four districts of Odisha–Keonjhar, Jagatsinghpur, Bhadrak and Kalahandi. This review will give an overview about the operational issues encountered during the National Iron Plus Initiative documentation in Odisha.

Keywords: Anemia, iron and folic acid supplementation, National Iron Plus Initiative documentation

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#### **INTRODUCTION**

Anemia is a widely prevalent disorder affecting over half a billion women of reproductive age (WRA) and over quarter of a billion children under 5 years old worldwide. [11] It is a condition in which red blood cells have fewer hemoglobin (HB) molecules than normal, or fewer red blood cells overall, and thus have less ability to carry oxygen to tissues in the body. The word anemia derived from the ancient Greek word meaning "lack of blood." [2]

Iron deficiency, due to diets poor in iron, accounts for around 50% of anemia.<sup>[3]</sup> A study estimated that 25% of all anemia among children under 5 years and 37%

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among nonpregnant WRA were due to iron deficiency.<sup>[4,5]</sup> Others estimated that 42% of anemia in children would be amenable to iron supplementation and 50% anemia in women could be eliminated with iron supplementation.

Among the 24 countries in the global review, the prevalence of anemia in the mid-2000s among pregnant women was >50% in 13 developing countries, including India, was 30%—49% in 10 countries, and was <30% in only one country (Haiti).

India is one of the countries with a very high prevalence of anemia in the world. Nutritional anemia is a major public health problem in India and is primarily due to iron deficiency.

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The National Iron Plus Initiative (NIPI) is the most ambitious and comprehensive anemia control program in the world. Its beneficiaries are from adult women to infants - pregnant and lactating women, adolescent girls and boys in secondary school and adolescent girls out-of-school, preadolescent school-going girls and boys in primary school, and young children 6 months to 5 years. NIPI was inaugurated in 2013. After 2 years of program experience, the Government of Odisha wanted to investigate how the program was progressing and chose to conduct a process documentation in the state. Therefore, the Department of Health and Family Welfare, Government of Odisha, in partnership with the UNICEF aimed to review the current implementation status of childhood, adolescents, and pregnant and lactating mothers' anemia components of NIPI in the state, with the purpose of documenting the successes, challenges, bottlenecks, and lessons learned and making concrete recommendations for future actions.

#### **METHODOLOGY**

The process documentation team conducted 170 interviews in March, April, and May 2016 among officials and frontline workers at state, district, block, sector/cluster, and field levels and among NIPI beneficiaries. To achieve variation in responses and to get full set of information on how NIPI was being implemented, hence a process documentation and survey data were collected in four districts of Odisha–Keonjhar, Jagatsinghpur, Bhadrak and Kalahandi. The quantitative survey team conducted 4809 survey interviews from April to July 2016 in the same four districts.

#### Selection of districts

To understand the scenario of Odisha as a whole, it was decided to take one district from each revenue division. As per the Annual Health Survey (AHS) 2012–13, districts of Odisha were ranked by taking the average percentage of consumption of iron and folic acid (IFA) by mothers (who consumed IFA for 100 days or more) and children (aged 6–35 months, who received IFA tablets/syrup during the past 3 months). Taking above mentioned indicators the district having poorest performance from each revenue division was selected for the process documentation. To understand the variations among good-performing and poor-performing districts, the best-performing district as per the AHS 2012–13 was selected as the fourth district under the study. The four districts selected were Bhadrak, Keonjhar, Kalahandi, and Jagatsinghpur.

#### Selection of blocks

Within the selected districts, one good-performing block and one poor-performing block were purposively selected based on the inputs from district collectors, Chief District Medical Officer/Assistant District Medical Officer, and district officials from other line departments.

To achieve variations during the process documentation the data were collected from 2 blocks from each districts of keonjhar & jagatsinghpur district (Harichandanpur March 10–18, 2016, and Banspal April 26–29, 2016, in Keonjhar district and Raghunathpur April 7–12, 2016, and Kujang April 18–21, 2016, in Jagatsinghpur district). The documentation in Bhadrak and Kalahandi was limited to one block because no new information was being gleaned from interviews (Bhandari Pokhari Block in Bhadrak district and Lanjigarh Block in Kalahandi district).

Officials at state and district and many at block level were interviewed individually during in-depth interviews. Groups of sector/cluster officials, field workers, and beneficiaries were interviewed during focus group discussions. In addition, observations were made of records of IFA distribution at Village Health and Nutrition Day, Anganwadi Centre, and schools, as well as the actual distribution of IFA at VHNDs and schools.

#### **SAMPLING**

#### Qualitative survey

For the process documentation, respondents were purposively chosen to provide information on the planning and implementation of NIPI from a variety of perspectives – state, district, block and sector/cluster officials, field workers, other stakeholders such as fathers, and beneficiaries. There were 170 respondents – 12 state officials, 27 districts, 32 blocks, 16 sectors/cluster, 49 field workers, and 34 beneficiaries – with district officials chosen evenly across the four districts and with block and sector officials, field workers, and beneficiaries chosen evenly across the six blocks.

According to three departments jointly implementing NIPI, the most respondents were associated with the Health Department's implementation (70), the second largest group associated with the Education Department (55), and the smallest group from the Integrated Child Development Services (ICDS) Department (35), as well as 10 others.

#### Quantitative survey

A line list of all the subcenters from within the selected eight blocks in four districts was prepared. From this were selected 50 subcenters using probability proportionate to size sampling method. Figure 1 shows the process of sample selection and size for the quantitative survey.

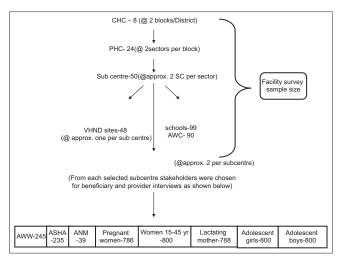


Figure 1: Sample selection and size for the quantitative study

#### Ethical approval and informed consent

The process documentation protocol was approved by the Ethical Committee of AIIMS Bhubaneswar. Informed consent was obtained from all the study participants. Confidentiality was maintained. All those detected with anemia were advised to visit the nearest health center or AIIMS for further management.

## OPERATIONAL ISSUES IN NATIONAL IRON PLUS INITIATIVE DOCUMENTATION IN ODISHA

#### Political commitment

There was lack of political commitment to increase coverage and strong service delivery of the NIPI.

Teachers are apprehensive and also have poor clarity regarding the program. Hence, the program is not running well in schools. Active involvement of teachers should be there for the smooth running of the programme. However, they do not want to take the risk.

## Coordination and convergence among government departments

- a. District level Leadership at the district level is less apparent and a number of issues have emerged
- Block level At the block level, there were lack of coordination between Education department and Health Department.

## Logistics management Indenting of iron and folic acid and albendazole For the health department

- Lady Health Visitor are not involved in the practice of indenting as per the guidelines, rather ANMs pass their indent to the MO I/C
- The block pharmacist assists the MO I/C to prepare the indent, and the district pharmacist assists the CDMO.

#### For the Integrated Child Development Services

The Child Development Project Officer (CDPO)
compiles the indent for the MO I/C in practice,
instead of the opposite, the CDPO should compile
it for the District Social Welfare Office as per the
guidelines.

#### For the education department

- The Block Education Officer (BEO) compiles the indent for the Border Personnel Meeting (BPM) in practice, instead of the opposite, the BEO should compile it for the Department of Economic Opportunity (DEO) as per the guidelines
- The indent is sent to the Health Department officials at the block level in practice, instead of passing from the BEOs to the DEOs to the State Nodal Officer for midday meals and being sent to the Health Department at the state Director of Family Welfare level as per the guidelines.

At field and sector levels, the indent is prepared by hand. Starting at the block level, the indent is entered online.

#### Warehouse maintenance

The conditions of the State Drug Management Unit warehouses were typically inadequate – not enough space, racks, ventilation, or refrigeration. Odisha State Medical Corporation Limited is gradually upgrading them, including a refrigerator for those drugs that require cold storage condition; however, currently, space is still severely limited.

#### Timeline in the flow of supply

At the district level, every new installment of supply takes a minimum of 2 months, in most cases 3–4 months, before it gets distributed to block community health centers. This was found to be the case for all formulations of IFA tablets and IFA syrup. The main reason for this time lag was the wait for quarantine clearance for new batches of supply.

At the block level, every new installment of supply takes a minimum of 10 days, in most cases 1–2 months, before it gets distributed to CDPO/CRCC/SC. This was found true even in situations where officials were aware of the low stock availability of a particular IFA formulation at field level.

#### **Training**

Most district, block, sector, and frontline workers described receiving training at the beginning of NIPI and getting updated NIPI information through regular meetings. For the most part, any gaps in information or shortfalls in performance could be filled through additional supportive supervision at all levels. A budget for refresher training should also be considered.

#### Administration of iron and folic acid supplements

- More clarity on guidelines and implementation of IFA consumption during the school holidays is recommended
- Teachers and others in the education sector in a few areas still fear that giving IFA tablets may cause ill effects among their students, draw media attention, or cause black stools or that the tablets may reach their expiry date and then may be dangerous.

#### Diagnosis, treatment, referral, and follow-up

HB concentration is not tested among young children, schoolchildren, or adolescents out-of-school. Instead, the visual pallor technique is used, which detects only severe anemia.

Without assessing HB concentration, it is difficult for RBSK teams and anganwadi workers (AWWs) to follow the GOI NIPI guidelines for the treatment of mild and moderate anemia.

#### Monitoring and supervision

Despite the number of visits and meetings for monitoring and supervision, little was mentioned about the actions taken during and after these occasions. A robust monitoring system is needed to assess further acceptance of IFA consumption, albendazole consumption, and behavior change related to hygiene and dietary diversity.

#### Recording and reporting mechanisms

Those who will be recording and reporting the data they should have knowledge regarding the purpose of collection and use of data. At minimum, data are recorded to show accountability for having distributed the IFA tablets and syrup. Ideally, the data recorded at all levels will be reported back to those who compiled it in a summary form so that it can inform the work at each level.

#### Inadequate reporting

Reporting IFA consumption was cited as inadequate for many units under the Education Department – numerous schools did not report to a CRCC, numerous CRCCs did not report to an BEO, and numerous BEOs did not report to the DEO.

## Social mobilization and community awareness for anemia and National Iron Plus Initiative

The NIPI Program has largely overcome initial resistance and is performing reasonably well, but to increase program participation further, the program needs ways of increasing relevance (NIPI beneficiaries except pregnant women do not understand that they are likely anemic) and enthusiasm (for example, giving awards, staging competitions, and initiating other information, education, and communication [IEC]).

#### Hard-to-reach National Iron Plus Initiative beneficiaries

"Hard-to-reach" had four components – remoteness in terms of residing a far distance from main roads and from government attention, language in terms of beneficiaries not speaking Odia, tribal issues and customs, and low education level of beneficiaries. Although all four might exist together, especially among tribal people, separating the components of being hard to reach is important for making recommendations to reduce programmatic constraints related to their geographic, cultural, and educational circumstances.

#### DISCUSSION

In the present study, the IFA and albendazole supply chain is managed well and consistently. The visual pallor technique is used, which detects only severe anemia in young children, schoolchildren, or adolescents out-of-school. In a qualitative study by Shet *et al.*, they found that at the health system level, lack of streamlining of Lady Health Worker duties, inability of LHWs to diagnose anemia, and temporary shortfalls in the availability of iron supplements constituted potentially modifiable barriers.<sup>[6]</sup>

Resistance to NIPI has decreased significantly due to social mobilization. Similarly, in a study by Chakma *et al.* regarding IFA supplementation among tribal adolescent girls of Bijadandi block, Mandla district, Madhya Pradesh, social mobilization, timely supply of tablets, quality of tablets (blister pack), and availability of teachers and AWWs were also associated with the compliance and feasibility.<sup>[7]</sup>

In this study, little emphasis was given to raise awareness among beneficiaries, community members, field-level workers, and so on to build demand for reducing anemia. However, a study by Vir *et al.* showed that counseling has very much positive effects on the regular weekly IFA intake that contributed to a high compliance rate. [8]

A study by Aguayo *et al.* found that knowledge-centered approach can successfully guide the scaling up of public health nutrition interventions and facilitate intersectoral convergence among different government departments and development partners to break the intergenerational cycle of undernutrition and deprivation.<sup>[9]</sup>

In a study by Kotecha et al. observed that supervised, once a week IFA supplementation to adolescent girls

through institutions, especially schools, was found to be an effective intervention to reduce anemia and was scalable within the system. The experience to educate the girls on dietary behavior has not been satisfactory, and covering all out-of-school girls is still a challenge to the success of anemia control.<sup>[10]</sup>

#### CONCLUSION AND RECOMMENDATIONS

There is a coordination among the Health, ICDS, and Education Departments for the provision of IFA supplements, successful biannual provision of deworming medicine to all beneficiaries, and a well-functioning supply chain of IFA supplements – but coverage of IFA supplementation lags behind. Other components such as to promote iron-rich diets and hygiene practices ultimately reduce the prevalence of anemia.

For further betterment of the program, some recommendations are needed at particular levels as mentioned below.

#### For enhanced social mobilization

To prioritize social mobilization and develop an enhanced NIPI communication (IEC) strategy, IFA should universally be referred to as a "supplement" to food, not as a tablet, to avoid fear of medicines and their side effects. IEC material should be translated into several of the major tribal languages. Leaflets should be developed with pictorial messages for nonliterate beneficiaries.

#### For administering the intervention

For pregnant and lactating women, frontline workers (ANMs, ASHAs, and AWWs) should ensure that they get 360 IFA tablets, if anemic, and 180 if not.

Pregnant women should be encouraged to take their Mother and Child Protection (MCP) Card with antenatal care records with them when they move to their natal home for the end of their pregnancy and 1<sup>st</sup> month or so postpartum. For administration of IFA syrup to children 6 months to 3 years, 3–5 years encourage the mother to give on Tuesdays and Fridays and self-record it in MCP card. For adolescent girls out-of-school, make the session more informative focusing on their health, behavior, and build in incentives for them to participate in Saturday sessions at the AWC.

#### For logistics management

For proper storage of IFA and albendazole along with other essential drugs more racks should be included in the pharmacies of district, block and primary health center level. Local storage conditions in AWCs, schools, and subcenters should be checked.

## Recommendations for increased diagnosis, treatment, referral, and follow-up

All health centers should have functioning hemoglobinometers. Hemoglobinometers should be available to RBSK teams to assess students' anemia status and should develop a strategy to monitor whether hemoglobin levels are improving over time.

## For monitoring and supervising the National Iron Plus Initiative Program

- Provide copies of supply and consumption reports to align reporting and supervision processes. The purpose of reporting should be clear, widely available, and summary of results comparing districts, blocks, even sectors, and clusters
- Review whether the purpose, participants, and frequency of meetings in which NIPI is discussed are adequate for its monitoring implementation review and problem-solving and for updating participants.

#### For strategic training

Audio-video training tools on anemia could be made widely available and shown at regular or project meetings, functioning as refresher training.

#### For reaching the hard-to-reach

Resources by state and district governments need to be increased for more remote hilly areas, including roads and health services. Involvement of local village tribal heads in the program should be encouraged to minimize local resistance and arrange for their sensitization, budgeting accordingly.

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#### **Conflicts of interest**

There are no conflicts of interest.

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# Decoding mystery disease "litchi as idiopathic triggering cause of hypoglycemia-induced (LITCHI) encephalitic syndrome" – Are the evidence of association adequate?

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#### **Abstract**

There has been an increase in reports of outbreak of encephalopathy in children presenting with a syndrome of sudden onset of high fever and altered sensorium in and around the peak of Indian summer months in geographical regions that flourish in Litchi plantation. In the light of the increased mortality and morbidity due to the mystery disease and the speculations surrounding litchi consumptions, a study was conducted in the litchi production hub of Muzaffarpur district Bihar in India by the NCDC in technical collaboration with US CDC. The variables that were significantly associated were litchi consumption (OR: 9.6 [3.8–24.1]), visiting a fruit orchard (OR: 6 [2.7-13.4]), and absence of an evening meal (OR: 2.2 [1.2–4.3]) in the 24-h preceding illness onset. The recommendations that have been advocated are to avoid eating unripe litchi or its seed and always preferring fresh and ripe ones, children should not to go to sleep without a proper dinner meal during the litchi season and cases of altered sensorium should be always be checked for blood glucose levels and prompt correction should be done if levels suggest hypoglycemia in hospitals.

Keywords: Acute encephalitis, children, hypoglycemia, litchi

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#### **SUMMARY**

There has been an increase in reports of outbreak of encephalopathy in children recently from the eastern part of India, where it is characterized by a syndrome of sudden onset of fever of high grade and associated with altered sensorium. The reporting of such incidences increases in and around the peak of Indian summer months confined to the geographical regions that flourish in litchi plantation for the past couple of decades.

Etiology of disease was many a times proposed to be of viral (non-Japanese encephalitis [JE] virus) origin, [1] sequelae

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to heat stroke, [2] emerging bat virus, [3] or the residual after-effects of pesticides. [4] These speculated etiologies are yet to be proven for causality for the outbreak of encephalopathy. These unexplained cases of encephalopathy have been conveniently labeled as "mystery disease" as no definitive clinical diagnosis consistent with the International Classification of Diseases has been made for two decades.

Recent evidence put forwarded by various studies show an association with the litchi fruits belonging to the Sapindaceae family of plants that bear

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methylenecyclopropylglycine (MCPG) which is an analog of hypoglycin A in the seeds<sup>[5-7]</sup> which have the potential to cause hypoglycemia leading to consequent encephalopathy in laboratory animals.<sup>[8,9]</sup>

In the light of the increased mortality and morbidity of children due to the mystery disease and the widely believed speculations surrounding litchi consumptions, this study was conducted in the litchi agricultural/harvesting hub of Muzaffarpur district in Bihar, India, by the National Centre for Disease Control in technical collaboration with US Centre for Disease Control. [10] Factors such as presence of infectious pathogen (JE virus, West Nile virus, etc.), pesticides, and heavy metal content were analyzed by collection of samples (blood, urine, and cerebrospinal fluid [CSF]) from cases presenting with the symptoms over a period of 2 consecutive years from 2013 to 2014 and controls over the same period with similar conditions from hospital and community from the surrounding areas.

This was a case—control study in which they have recruited cases and controls from two different hospitals which were the only known hospitals to provide treatment to such mystery disease cases presenting with or referred with acute neurological symptoms in the region. As per protocol of the study design, the cases and controls were matched, with the only differentiating factor that, the controls were without any history of neurological symptoms in present or in their lifetime.

The treating physicians were communicated about the recruitment criteria of "patients aged ≤15 years presenting with new-onset seizures or altered sensorium in the past 7 days," and the management of each case was guided as per the physicians' discretion which led to the nonuniformity of diagnostic tests in the participants.

Finally, in the summer of 2014 during the months of May–July, 104 cases were selected with 104 matched controls for the study. Probing questionnaire also covered the practices followed by the participants such as consumption of food items, cleaning of food prior consumption, time spent in agricultural fields or litchi orchards, and consumption of a regular dinner meal or litchi.

Blood, CSF, and urine samples were collected for the evaluation of infectious pathogens, pesticides, and heavy metal toxicology along with investigation for hypoglycin A and MCPG in urine samples of the enrolled cases and controls. 64% and 45% of the samples from cases demonstrated the presence of hypoglycin A and its

metabolite MCPG in urine samples versus 0 levels in the controls. The independent variables that were significantly associated with the illness on matched bivariate analysis were litchi consumption (matched odds ratio [mOR]: 9.6 [95% confidence interval (CI): 3.8–24.1]), visiting a fruit orchard (mOR: 6 [95% CI: 2.7-13.4]), and absence of an evening meal (mOR: 2.2 [95% CI: 1.2–4.3]) in the 24-h preceding illness onset. Stratified analysis controlled for age and absence of an evening meal in the previous 24 h significantly modified the relation between litchi consumption and illness (OR: 7 8 [95% CI: 3.3–18.8], without evening meal; OR: 3.6 [95% CI: 1.1–11.1] with evening meal).

#### **COMMENTS**

A maximum number of cases (37%) were reported during June 8-14 which coincided with the harvesting season where there is abundant litchi on trees. Children often consume them irrespective of ripen or unripen state due to its delicacy. Small children might not be able to distinguish between rotten and ripen litchi fallen on the ground. Parents/guardians of the cases have reported that most of the children had spent their playtime in the litchi orchards prior to presentation in the hospitals with the symptoms of encephalopathy which had a strong association of having a large amount of litchi consumed during the previous day which led to skipping of a regular meal later in the evening and subsequent development of hypoglycemia following early morning due to the high levels of hypoglycin A and its metabolites. This event might have triggered the development of acute neurological syndrome between 3:00 AM and 8:00 AM in the morning precipitating in the form of seizures or altered sensorium in a participant without any previous history of febrile seizures or altered sensorium.

The results of the study may hamper the economy of Indian agriculturists and farmers by labeling the tropical fruit litchi as a precursor agent prone to cause seizure episode in small children consequently reducing the demand of the fruit in the international market by negative publicity and at the same time depriving an agricultural community that have an opportunity to harvest and earn from the ephemeral yields of litchi only for a single season in a year. Now that we are aware of clues and conditions that mediate to cause this "mystery disease," further studies can be planned to investigate and establish conclusive evidences before labeling litchi to be the seed of the disease.

Thus, litchi consumption by children should be controlled by parents/guardians, especially residing in the vicinity of litchi cultivation areas; they must avoid eating unripe litchi or its seed (as toxins are found in greater amounts in unripe fruits than in fully ripe ones) and should always prefer eating fresh and ripe ones. Furthermore, children should never miss a meal, particularly dinner. In case of any illness during the "season," the blood glucose levels should be checked "first/soon after admission" to gain a healthy lead time improving the prognosis of the "mystery disease," and if required, glucose can be administered promptly to correct low levels during the course of treatment.

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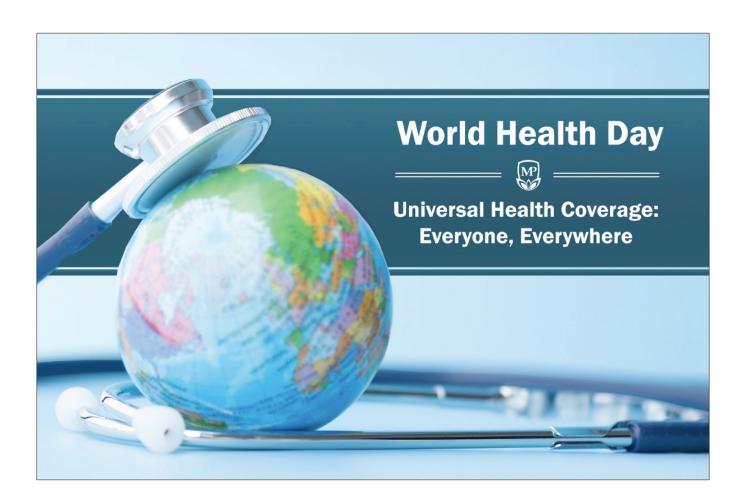
#### Conflicts of interest

There are no conflicts of interest.

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## Oral leukoplakia: Management protocol for primary health-care providers and family physicians

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#### **Abstract**

Oral cancer is very common in India. Most of the oral cancers develop on a potentially malignant (precancerous) lesion. Leukoplakia is the most common precancerous lesion in the oral cavity. The malignant transformation rate of oral leukoplakia is very high. There is no marker to distinguish those lesions that may transform to frank cancer from those that may not. Thus, early identification of oral leukoplakia and its proper treatment is important for best prognosis. This article highlights on the diagnosis and treatment protocol for oral leukoplakia.

**Keywords:** Family physicians, management protocol, oral cancer, oral leukoplakia, primary health-care providers

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#### INTRODUCTION

Majority of the oral cancers are preceded by asymptomatic clinical lesions together called oral potentially malignant disorders or a precancerous lesion. The prevalence of precancerous lesions in the oral cavity is about 2.5% in the general population. About 15%–48% of the squamous cell carcinomas of the oral cavity are developed from innocent-appearing precancerous lesions, 2,3 and approximately 60% are present as white keratotic lesions. However, most of the precancerous lesions are diagnosed at a late stage. Early identification of the oral precancerous lesions, particularly in high-risk individuals, is important to prevent further morbidity and to improve the oral health-related quality of life. Although dentists screen their patients' oral mucosa for any early sign of oral cancer, the identification of any suspicious lesions by a primary

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health-care provider is paramount for their early treatment. Of all oral precancerous lesions, leukoplakia has a very high malignant transformation rate. This article highlights the oral leukoplakia management protocol for a primary health-care provider and family physician.

## WHICH LESIONS SHOULD BE DEFINED AS ORAL LEUKOPLAKIA?

The term "leukoplakia" was first described in 1877 by Schwimmer.<sup>[5]</sup> In 1978, the World Health Organization (WHO) defined leukoplakia as a white patch that does not rub off and cannot be characterized clinically or histopathologically as any other disorder.<sup>[6]</sup> In 1994, the WHO has modified the definition by adding "oral leukoplakia is not associated with any physical or chemical cause, except smoking and it can cause cancer" to the previous WHO definition.<sup>[7]</sup> However, in 2007, it was

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decided that the term leukoplakia should only be used for clinical diagnosis. However, any white patch in the oral cavity can be identified clinically as any other diseases such as candidiasis, white sponge nevus, lichen planus, or leukoedema. Then, the disorder cannot be called as leukoplakia. In certain clinical situation, a white patch may be diagnosed clinically as leukoplakia, but when histopathology reveals it as another specific diagnosis, the lesion should not be specified as a leukoplakia. Furthermore, white patches in the oral cavity due to chronic irritation by denture or cheek bite should not be categorized as leukoplakia, as these lesions are not premalignant and are reversible in nature if the irritation is withdrawn. Similarly, the nicotine stomatitis and tobacco pouch keratosis also should not be called as leukoplakia. In 2012, the latest definition of leukoplakia defines it as" a predominantly white lesion or plaque of questionable behavior having excluded clinically and histopathologically, any other definable white disease or disorder.[8]

### WHAT ARE THE RISK FACTORS OF ORAL LEUKOPLAKIA?

The exact etiology of oral leukoplakia is unknown and considered as multifactorial. Most important etiological factors are tobacco and alcohol, either separately or synergically. However, tobacco smoking is considered as the most accepted risk factor of oral leukoplakia. Other physical agents such as chronic irritation, electro-galvanic reaction between unlike restorative metals, and ultraviolet radiation are also considered as risk factors for oral leukoplakia. <sup>[10,11]</sup> There is a possible role of human papilloma virus infection in the origin of leukoplakia. <sup>[12]</sup> Further oral hairy leukoplakia has been considered as an early sign of HIV infections. <sup>[13]</sup>

### WHAT ARE THE CLINICAL CHARACTERISTICS OF ORAL LEUKOPLAKIAS?

Leukoplakia is common in the middle- and older-age group individuals and is more common in males. Buccal mucosa, alveolar mucosa, and lower lip are the most common sites for leukoplakia. [14] In the beginning stage, the lesions appear as slightly elevated grayish-white plaque [Figure 1]. Its margin may be either well defined or gradually blend into the surrounding normal mucosa. [15] Then, slowly, early lesions become thicker and whiter and leathery appearance with surface fissures [Figure 2]. Few lesions may develop surface irregularities and are called as granular or nodular leukoplakia [Figure 3]. Furthermore, few lesions develop a papillary surface and are called as verrucous leukoplakia. One occasional variety of leukoplakia is called as proliferative verrucous leukoplakia, [Figure 4]



Figure 1: Early-stage leukoplakia on the left buccal mucosa which appears as slightly elevated grayish-white plaque



Figure 2: A mature leukoplakia on the left lateral border of the tongue which is thicker and whiter and having leathery appearance with surface fissures



Figure 3: Nodular leukoplakia on the left buccal mucosa

characterized by the widespread multiple sites of involvement and is developed without any known risk



Figure 4: Proliferative verrucous leukoplakia on the dorsum of the tongue

factors.<sup>[16]</sup> This proliferative verrucous leukoplakia has a high recurrence rate and very often transform into oral squamous cell carcinoma. In many patients, white patches are developed on the alveolar mucosa and buccal vestibule secondary to the use of mouthrinses containing herbal extract Sanguinaria.<sup>[17]</sup> However, Sanguinaria associated white patches are usually multifocal and should not be confused with early proliferative verrucous leukoplakia. Few leukoplakias develop in combination with red patches, i.e., erythroplakia. When both red and white patches are interproxed, the lesion is called speckled leukoplakia or speckled erythroplakia [Figure 5].

As the risk level of oral leukoplakia is difficult to measure clinically, few noninvasive methods that eliminate the need for surgical procedure can be used to detect the risk level. Brush biopsy can be done to collect the basal layer cells for microscopic evaluation. Toluidine blue which stains the nucleic acids and dysplastic cells can be applied clinically over the lesion to detect the level of risk. It is also used to select the best site for biopsy. These two methods are adjunctive diagnostic methods only and are not substitute to traditional scalpel biopsy.

## WHAT IS THE MALIGNANT TRANSFORMATION RATE OF ORAL LEUKOPLAKIAS?

The overall frequency of malignant transformation rate of oral leukoplakia varies between 15.6% and 39.2%. [18,19] A speckled leukoplakia has maximum malignant transformation rate. [20] The annual average of malignant transformation rate of oral leukoplakia is 1% in various populations with the highest reported rate of 43%. [21] The location of the lesion has a significant correlation with the malignant transformation rate. Lesions on the floor of the mouth have the highest malignant transformation



Figure 5: Erythroleukoplakia on the right buccal mucosa having alternate white and red patches

rate of 42.9% followed by 24.2% on the tongue and 24% on the lip.<sup>[18]</sup> The clinical appearance of the leukoplakia also has a correlation with their malignant transformation rate. In general, the thicker the lesion the greater the chance of having dysplastic changes.<sup>[15]</sup> The dysplastic changes are thus more with verrucous leukoplakia than a thick homogeneous lesion and which, in turn, is more than a thin homogeneous leukoplakia.<sup>[15]</sup> The malignant transformation rate of homogeneous leukoplakia is 6.5% and speckled leukoplakia is 23.4%. [22] Furthermore, 36.4% of the leukoplakia with microscopic evidence of dysplastic changes transformed into frank oral squamous cell carcinoma. [22] Almost 70.3% of the patients with proliferative verrucous leukoplakia change into oral squamous cell carcinoma.[16] In females, the malignant transformation rate is more compared to males.[11] Furthermore, the malignant transformation rate of leukoplakia among nonsmokers is more compared to smokers.[11,22] The malignant transformation rate of oral leukoplakia is more when the size of the lesion is >200 mm<sup>2</sup>.<sup>[23]</sup> Furthermore, when there is the presence of invasive Candida albicans, the malignant transformation rate is more.[23]

### WHAT ARE MICROSCOPIC CHARACTERISTICS OF ORAL LEUKOPLAKIA?

Microscopic characteristics of oral leukoplakia vary between normal epithelial cellular architecture to dysplasia and carcinoma. The dysplasia may be mild, moderate, and severe types. The severity of the dysplasia can be assessed based on architectural disturbance accompanied by cytological atypia. According to the WHO, irregular epithelial stratification, loss of polarity of the basal cells, drop-shaped rete ridges, increased number of mitotic cells, dyskeratosis, and keratin pearls within rete ridges are the characteristics of epithelial dysplasia. There are no precise

criteria to divide the dysplasia into mild, moderate, and severe categories. [24] In mild dysplasia, the cytological and architectural changes are confined to lower third of the epithelium thickness; in moderate dysplasia, the changes are up to the middle third of the epithelial thickness; and in severe dysplasia, the changes are more than middle two-third of the whole epithelium thickness. [24]

#### HOW TO DIAGNOSE AN ORAL LEUKOPLAKIA?

A white lesion cannot be diagnosed clinically as any other disease of the oral mucosa (such as white sponge nevus, frictional lesions, candidiasis, chemical injury, leukoedema, hairy and leukoplakia) is a provisional diagnosis of leukoplakia. When any etiology such as tobacco, C. albicans and mechanical irritation, etc., is excluded and histopathologic examination cannot reveal that lesion as any other specific disease, then it is diagnosed as a definite leukoplakia. The tissue for the biopsy must be taken from most suspicious area. Toludine blue may be applied to select a suitable biopsy site. For a smaller size leukoplakia (<2-3 cm), excisional biopsy should be considered. For wide spread or multifocal leukoplakia, multiple incisional biopsies should be considered. Histopathology is considered to be the gold standard for the diagnosis of leukoplakia. When histopathology reveals typical characteristics, the lesion is confirmed as leukoplakia.

## WHAT ARE THE TREATMENT OPTIONS FOR ORAL LEUKOPLAKIA?

The goal of leukoplakia treatment is to prevent its malignant transformation. Cessation of the smoking and alcohol habits is the first step in leukoplakia treatment. Usually, the degree of epithelial dysplasia and the location of the leukoplakia decide the choice of the treatment.[8] The ideal treatment for a leukoplakia is surgical excision. The commonly used surgical options for the excision are conventional scalpel surgery, carbon dioxide laser ablation, electrocauterization, and cryosurgery. However, there is no mention of the width of the margin that should be considered while excision. The recurrence rate following excision of the lesion varies between 0% and 30%.[8] Apart from surgical treatment, many chemoprevention treatment options such as topical or systemic use of antioxidant such as carotenoids (retinoids, beta-carotene, and lycopene); vitamins such as Vitamin A, C, and E; mouthwash containing an attenuated adenovirus; ketorolac mouthwash; local bleomycin; and mixture of tea are available in the literature. [25] However, the success of these chemoprevention treatments is not well documented.

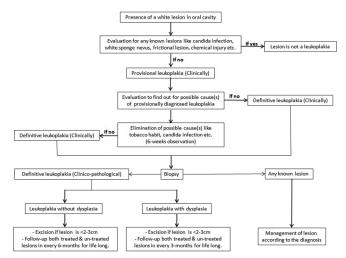


Figure 6: Oral leukoplakia management flowchart

## WHAT IS THE MANAGEMENT PROTOCOL FOR ORAL LEUKOPLAKIA?

An outline for the management of oral leukoplakia is mentioned in Figure 6. The level of competency of a clinician to diagnose white lesions clinically is important. It is very critical to distinguish leukoplakia-like lesions from a true leukoplakia. Elimination of associated risk factors such as tobacco habit might need professional habit intervention, and 6–8 weeks are acceptable to observe a possible regression of the lesion. If the lesion does not regress within 6–8 weeks, a biopsy must be taken from the lesion. There is no quality scientific evidence showing that treatment of leukoplakia can prevent recurrence or further development of squamous cell carcinoma. It is always safe to treat a leukoplakia irrespective of the presence or absence of epithelial dysplasia. [26]

#### **CONCLUSION**

An oral leukoplakia if left untreated may lead to frank oral cancer. The role of a primary health-care provider or a family physician is very important and crucial in the early identification of the leukoplakia. Elimination of associated habits can reduce the malignant transformation of a leukoplakia. There is no universally accepted standard treatment for the leukoplakia, but surgical excision of the total lesion is widely accepted treatment. These patients need lifelong follow-up at regular intervals.

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#### Conflicts of interest

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# Understanding the patterns of technology and internet use for academics by undergraduate medical students in a teaching hospital of North India

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#### **Abstract**

**Background:** E-learning or computer-based learning has been incorporated into medical education in many countries. Readiness to utilize this medium merits exploration in the Indian context. Therefore, we aimed at assessing the current patterns of technology and internet use by undergraduate medical students in a tertiary care teaching hospital, focusing on their use for academics and their views on e-learning.

**Materials and Methods:** This cross-sectional study was conducted using a self-administered questionnaire among undergraduate medical students in the first 4 years of the study. The data generated were entered into Microsoft Excel and analyzed using SPSS version 22. Descriptive analysis and comparison of proportions were done using Chi-square test.

**Results:** A total of 212 students responded, with a mean ( $\pm$ standard deviation) age of 20 years ( $\pm$ 1.54) and 70.3% of males. There was universal access to technological devices with complete internet access. Internet was used primarily for entertainment (99.1%) and WhatsApp (97.2%), with 86.8% use in academics. Most students accessed the internet multiple times each day. Majority of the students (90.6%) used social networking sites and were open to using it for academics. Reliability of the material found online was a concern (83.5%), and most (63.2%) were interested in further training. Only a quarter of the students had utilized medical e-learning material online, and a majority (77.4%) were willing to incorporate it into the curriculum feeling that it would benefit them (64.6%).

**Conclusions:** Incorporating e-learning tools into the medical curriculum needs to be considered for undergraduate medical studies, owing to its availability and readiness for utilization.

Keywords: E-learning, internet, medical education, technology, undergraduate students

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#### **INTRODUCTION**

Technological advancement has brought forth a new generation of medical students, who are adept at using computers for various different activities and are in need of structured training in its most effective use in medical care. The landscape of medical education

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has been evolving rapidly to include new modalities of instruction, such as e-learning or computer-based learning to cater to these young minds. Such tools have been incorporated into the medical curriculum in many countries.<sup>[1,2]</sup>

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E-learning refers to any form of web-based or computer-assisted learning with the use of videos and multimedia to convey nuances in the subject matter easily. [3] Currently, many formal courses can be accessed online referred to as Massive Open Online Courses, available free of cost, offering training in diverse subjects including medicine. [4] Such courses can be incorporated into the curriculum or emulated to specially target the Indian medical student.

Multiple studies have been done to assess the usage of computers and the internet by medical students around the world<sup>[1,2,5-9]</sup> and in India.<sup>[10-14]</sup> The studies have varied results. Some studies show a low level of access to internet,<sup>[1,5,10]</sup> while a few showed that academic use of Internet was low.<sup>[1,10,12]</sup> Some have looked into the students' interest in incorporating e-learning into the medical curriculum, showing mainly positive attitudes.<sup>[1,5,12]</sup> Only one study looked at the accessibility of mobile internet by Indian medical students.<sup>[11]</sup>

Against this background, we aimed at assessing the current patterns of technology and internet use by undergraduate medical students in a tertiary care teaching hospital, focusing on their use for academics. In addition, their views on e-learning were assessed to explore the possibility of introducing such novel teaching methods to complement the existing system.

#### MATERIALS AND METHODS

This cross-sectional study was conducted during May and June 2016, after acquiring ethics clearance from the institutional review board of the All India Institute of Medical Sciences (AIIMS), New Delhi (Ref. No. IECPG/285-27.04.2016).

Consent was taken before participation, and data were collected using a pretested, self-administered questionnaire in English, prepared specifically for the purpose of the study by the authors. All undergraduate medical students in the first 4 years of study (approximately 288) enrolled at AIIMS, New Delhi, were approached to participate. The questions covered student demographics, their access to technology, knowledge and use of online academic resources, awareness of e-learning modalities, and receptivity to incorporate the same into the curriculum. The data were entered into Microsoft Office Excel 2007 and analyzed using SPSS version 22 (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). Relevant proportions were compared using the

Chi-square test. Students in the first 2 years of MBBS were taken as one group of "juniors in preclinical years," and the  $3^{\text{rd}}$ - and  $4^{\text{th}}$ -year students were taken to be in the "senior group in their clinical years." A significant difference was judged from a P < 0.05.

#### RESULTS

A total of 212 of 288 students responded (73.6%), with an average age of 20 years (±1.5 years, range: 17–27) and 70.3% were males. There were 58 1st-year (27.3%), 55 2nd-year (26%), 36 3rd-year (17%), and 63 4th-year (29.7%) students. There was universal access to technological devices, with most students owning a smart phone (98.6%) and a laptop (93.4%). All the students had access to the internet. It was used primarily for entertainment (99.1%) and WhatsApp messaging (97.2%), with 86.8% use in academics. Most students (96.2%) accessed the internet multiple times each day. Majority of the students (90.6%) used social networking sites and 74.5% were open to using it for academics.

The perceived advantages of using the internet for academics were for its quick access (93.4%), ease of search (84.4%), material being up to date (50.9%), and accuracy of information (20.3%), with only 1.4% stating that they saw no advantages. The major limitation to using the internet was due to doubts regarding authenticity of information (83.5%), with others being slow speed (25%), lack of resources (18.4%), ineffective use of the internet by students (18.4%), and lack of time (9.9%). 5.2% stated that they saw no limitations.

Only one half of the students believed that they had adequate skills to search for reliable academic material online. The students in the clinical years were more comfortable with a significant difference noted (60.6% vs. 44.2% P = 0.02). Only a quarter of the students stated that they were aware of how to access academic articles using the institute library's database, with seniors being significantly more capable (32.3% vs. 20.4%, P = 0.047). Wikipedia was the most visited website (92.5%) for reference, with two-thirds students visiting PubMed or Medscape. There was a significant difference noted for the utilization of Medscape by students in the clinical years (3<sup>rd</sup>- and 4<sup>th</sup>-year students) as compared to students in the basic science years (1st- and  $2^{\text{nd}}$ -year students) (94.9% vs. 46.9%, P = 0.000). Only 16.5% of students used up to date (an evidence-based, physician-authored online clinical decision support resource), with seniors using it more than juniors (26.3% vs. 9%, P < 0.001).

Training in the usage of statistical software in research was demanded by 74.1%, with seniors feeling the need significantly more than juniors (85.9% vs. 63.7%, P < 0.001), and two-thirds of students felt the need for training to access reliable academic content online.

Only a quarter of the students had utilized medical e-learning material online although a majority (77.4%) were willing to incorporate it into the curriculum feeling it would benefit them (64.6%). Figure 1 depicts the perceived advantages of e-learning with easy access to materials (86.3%) and interactive learning modes (72.6%) being quoted the most. Figure 2 shows the perceived disadvantages to e-learning, with two-thirds showing concern over the loss of the personal student–teacher interaction.

#### **DISCUSSION**

This was a rapid assessment undertaken to explore technological mediums for undergraduate medical teaching in the North Indian setting. There was universal access to internet-enabled devices among our participants. Only the studies conducted in Akola, Maharashtra, India,<sup>[11]</sup> and in Iran<sup>[9]</sup> showed over 95% use of computers and the internet. The older studies in India generally showed about two-thirds students having access to computers and the internet.<sup>[10-14]</sup>

Interestingly, our students reported accessing the internet multiple times daily; however, internet was accessed <3 h/week in the studies from Mangalore in 2008, (80%), [12] Meerut in 2012 (77.2%), [10] and Sri Lanka in 2012 (40.2%), [7] while a third of students from Iran [9] in 2014 reported accessing the internet daily. This probably reflects the rising trends

in internet use by students over the years and newer studies from other regions need to be done to support this.

Almost all students in our study use the internet for entertainment and for WhatsApp messenger, which differs largely from previous studies where there was a majority but more modest use of the internet for entertainment in Puducherry (76.6%), [13] Akola (66.67%), [11] and Iran (62%), [9] with only a quarter doing so in Mangalore. [10] WhatsApp, being a recent invention, does not feature in any of the studies. Social networking was also popular among students here similar to those in Akola (80%), [11] Turkey (93.4%), [15] and Kenya (99%). [16] A majority of our students were also in favor of using social media platforms for academics, which has already been done in Turkey [15] where 89.3% used it professionally.

The internet was used for academics by a large proportion of our students (86.8%), which has been the findings of India in Puducherry (75.9%)<sup>[13]</sup> and Akola (76.79%),<sup>[11]</sup> though lesser in Mangalore (15%)<sup>[12]</sup> and Meerut (21.6%).<sup>[10]</sup> Abroad, Iran had a high usage (95.50%)[9] with the modest levels of use in Lahore (61%)[6] and Cameroon (41%).[1] However, despite the high proportion of internet usage in academics, our students expressed doubts regarding the authenticity of academic material found online. Further, only a quarter of the students knew how to use the institutes' library resources to look up journals. This reveals a lacuna in the students' ability to effectively find academic material, despite having the resources for the same. This is also reflected in their desire to learn more efficient ways of accessing reliable academic material online. A majority of students in our study were also interested to have training in statistical methods in research, which is a favorable finding

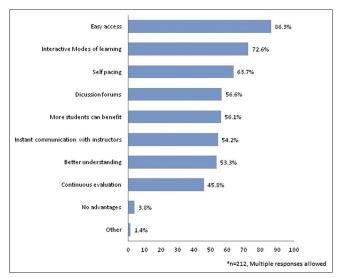


Figure 1: Advantages of e-learning

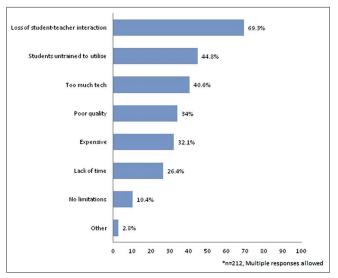


Figure 2: Limitations of e-learning

indicating a growing interest among undergraduates toward research. Our results were indicative that senior students would be more receptive to additional training and the introduction of newer methods of learning.

In addition, majority favored e-learning as a novel and interesting learning tool. Previous studies that have looked into the students' interest in incorporating e-learning into the medical curriculum had also shown mainly positive attitudes. [1,5,12] Students cited loss of interaction with teachers as the most common limitation indicating that e-learning should be a complementary to traditional teaching methods. Options for blended learning models seem viable for incorporation into medical teaching for undergraduates.

Many smart phone applications (app.) are already available on standard operating systems. Of note, the AIIMS-WHO Collaborating Centre Standard Treatment Protocols app. for the management of sick newborns was created by neonatologists to aid physicians and nurses in remote settings. Studies have demonstrated the efficacy of this novel tool among pediatricians. [17] Similar applications would be welcome, with further studies done to explore their effect on enhancing knowledge among MBBS students.

#### **CONCLUSION**

India is currently experiencing exponential technological growth with the central government's new Digital India movement through which it aims to bring technological connectivity to every citizen in the country. As this vision transforms into a reality, medical students across the country would be able to access diverse academic content even from remote areas for study and work. This has wide public health implications wherein the diverse population of our country has the opportunity to be cared for by health providers who are connected across the internet and have access to the best resources and training.

Further interventional studies are needed to evaluate the e-learning options available within medical teaching methodology. Feasibility along with its comparison to traditional teaching methods will be key for making a case for its incorporation in the future.

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#### **Conflicts of interest**

There are no conflicts of interest.

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# Effect of information, education, and communication activity on health literacy of smoking and alcohol among school-going adolescents in Delhi

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#### **Abstract**

**Background:** Noncommunicable diseases (NCDs)/lifestyle diseases account for a major cause of deaths every year. Risk factors such as smoking and alcohol consumption contributing to the development of lifestyle diseases were more prevalent in the developed countries decades back, but millions of productive years of life are lost due to NCDs in India too.

**Objective:** This study was conducted to assess the health literacy of school-going adolescents regarding harmful effects of smoking and alcohol consumption and assess the improvement in their knowledge after different information, education, and communication (IEC) activities.

**Methods**: It was a school-based interventional study conducted among students of class 6, 7, and 8. Assessment of health literacy of risk factors – smoking and alcohol use in lifestyle diseases was done by self-administered questionnaire among school-going adolescents. Intervention in the form of IEC was done three times, and the postintervention data were collected 2 weeks after the first and 3 months after the last intervention. Responses were scored and categorized as satisfactory and unsatisfactory.

**Results:** There were a higher proportion of students with satisfactory level of knowledge of smoking and alcohol use effects in both the schools after 3 months of educational intervention, although the result was statistically significant for School 2 only where intervention was given by didactic lectures (P < 0.05). **Conclusions:** There was an improvement in scores of students in both the schools after 2 weeks and 3 months of educational intervention, though the results were statistically significant for 3 months only (P < 0.05).

**Keywords:** Adolescents, alcohol, health literacy, information education communication, smoking

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#### INTRODUCTION

Globally, noncommunicable diseases (NCDs) account for approximately 17 million deaths a year, which is nearly one-third of the total number of deaths occurring globally in a year. [1] Risk factors such as smoking and alcohol consumption contributing to the development of lifestyle diseases were more prevalent in the developed countries

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earlier, but millions of productive years of life were lost due to the NCDs in India too.<sup>[2]</sup>

Risk-taking behaviors that can have lifelong implications are often begun in adolescence. Two common health-risk behaviors that are frequently initiated are cigarette smoking and alcohol consumption.<sup>[3]</sup> Thus, intervention should

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start at an early age as it takes time for healthy practices to blend into behavior. To address the vast magnitude of this problem, health literacy may play an important role in prevention.

A school is a key location for educating children about health, hygiene, and nutrition and for putting in place the interventions to promote the health of children.<sup>[4]</sup>

Health literacy is defined as the ability to obtain, read, understand, and use health-care information to make appropriate health decisions for one's own health and family and community health and follow instructions for treatment. <sup>[5]</sup> An adequately health literate individual can communicate with health professionals, understand and use health materials (in a variety of formats) that they need to stay healthy, apply health-related knowledge to health care, and decision-making so that they are able to make healthy choices and have more control over the things that make them healthy. <sup>[6]</sup>

This study was done with the objective of assessing the health literacy of risk factors of NCDs such as smoking and alcohol among school-going adolescents; conducting intervention by information, education, and communication (IEC) activity among school-going adolescents; and assessing the effect of the different IEC activities among them.

#### **METHODS**

It was a school-based interventional study conducted in Najafgarh in the year 2016. Prior permission was obtained from the Deputy Directorate of Education and Institutional Ethical Committee to conduct the study. From 13 schools in Najafgarh, two schools were selected by simple random method of sampling and the Principals of these schools were explained about the objectives and methodology of the study and consent was obtained from them. A total of 120 students were selected from each school using a list of all students enrolled in class 6<sup>th</sup>, 7<sup>th</sup>, and 8<sup>th</sup> obtained from both the schools. One section of each standard was selected by simple random method from both the schools and assent was obtained from the students. Students who were absent during the baseline evaluation were excluded from the study.

Since this study is a part of the bigger study in which all risk factors of NCDs are studied, thus sample size calculation is not based on these two risk factors. For the main study, sample size was calculated based on the study conducted by George *et al.* in 2014 in two government and one private school in Central Delhi in which they found that among the

various risk factors of lifestyle diseases listed in the study; 34.6% ( $P_1$ ) students (the least) had the knowledge that by exercising for at least 1 h a day cardiovascular diseases can be prevented. In the main study, the knowledge was expected to increase to up to 60% ( $P_2$ ) among the students after the intervention. Taking an alpha error ( $\alpha$ ) and beta error ( $\beta$ ) of 5% and 20%, the sample size calculation was as follows:

$$n_{1} = n_{2} = \frac{\begin{cases} z_{1} - \left(\frac{\alpha}{2}\right) \sqrt{2 \times P_{m} (1 - P_{m})} + z_{1} - \frac{2}{2} \\ \beta \sqrt{P_{1} (1 - P_{1}) + P_{2} (1 - P_{2})} \end{cases}}{(P_{1} - P_{2})^{2}}$$

Where 
$$z_1 - \left(\frac{\alpha}{2}\right) = 1.96$$
,  $z_1 - b = 0.84$   
 $P_1 = 0.34$ ,  $P_2 = 0.60$ ,  $P_m = P_1 + P_2/2 = 47.3\%$  (0.473)  
 $n = 51$ ,

Considering design effect = 2,  $n \times 2 = 51 \times 2 = 102$ 

Loss to follow-up or nonresponse of up to 10%

Sample size came out to be 120.

Thus, a total of 120 students from class 6<sup>th</sup>, 7<sup>th</sup>, and 8<sup>th</sup> in each school were taken.

A pretested, semi-structured, self-administered questionnaire based on the materials to be used for intervention was used for baseline and postintervention data. The questions were based on the IEC material taken from the World Health Organization (WHO) and Central Health Education Bureau (CHEB) which were to be used for the intervention. The response options were Yes/ No/Don't know. Each right answer was awarded score 1 and wrong answer as 0. No response was considered as incorrect response and scored 0. The responses were scored and categorized as unsatisfactory (<50% score) and satisfactory (>50% score) knowledge. The maximum scores for questions on smoking and alcohol were 12 and 7 respectively and the minimum score was 0. Intervention was given in the form of IEC activity on harmful effects of smoking and alcohol use with the help of posters and pamphlets taken from the WHO office and CHEB, New Delhi, for School 1 and lecture from the same reference material was prepared in PowerPoint Presentation for School 2.

After the baseline evaluation in June in both the schools, the intervention was done on the next visit in July by giving the pamphlets to the students and displaying posters in their classes and common areas. The postintervention data were obtained after 2 weeks from both the schools by administering the same questionnaire. After that respective interventions were repeated two more times monthly among the students of both the schools in August and September for reinforcing knowledge. Thus, interventions were given a total of three times in the span of 3 months, and postintervention data were also obtained at 3 months from the last intervention, i.e., in January. Thus, postintervention data were obtained two times — first at 2 weeks after the first intervention and the other after 3 months from the last intervention.

There was a loss to follow-up in both the schools during interventions. At 2 weeks, there was attrition rate of 7.5% in School 1 and 4% in School 2 and at 3 months follow-up, there was attrition of 21% in both the schools.

Data analysis was done using Statistical Package for the Social Sciences software SPSS for windows version 17.0. Released 2008 (SPSS Inc., Chicago, IL, USA). All the values were analyzed using descriptive statistics to calculate frequencies, mean, range, and standard deviation. Chi-square test was applied to compare the proportion of scores (satisfactory and unsatisfactory) at baseline, 2 weeks, and 3 months and P < 0.05 was considered to be statistically significant.

#### RESULTS

There were a total of 120 students each in both the schools. The mean age of students of both the schools was 12.2 years. Majority of students of both the schools belonged to nuclear family and socioeconomic Class IV according to the Modified BG Prasad scale, 2017. Majority of the students' parents were educated till primary as shown in Table 1.

Cancer and premature death were the maximally known harm of smoking among the students and the least known harm was "atherosclerosis" and "osteoporosis" as shown in Table 2.

"Liver damage" was the maximally known harm of alcohol consumption and the least known harm was "diabetes" as shown in Table 3.

There were a higher proportion of students with satisfactory level of knowledge about smoking after 2 weeks of intervention in School 1, while there was a lower proportion of students with satisfactory level of knowledge about smoking after 2 weeks of intervention in school 2 compared to baseline though these differences were not

Table 1: Distribution of the study participants according to sociodemographic characteristics (*n*=120)

Demographic variables	<b>School 1, n (%)</b>	School 2, n (%)
Age (years)		
Mean	12.2±1.2	12.2±0.9
Range	6 (10-16)	6 (10-16)
Sex		
Boys	32 (26.7)	66 (55.0)
Girls	88 (73.3)	54 (45.0)
Religion		
Hindu	111 (92.5)	115 (95.8)
Others	9 (7.5)	5 (4.2)
Class		
6 <sup>th</sup>	25 (20.8)	32 (26.7)
7 <sup>th</sup>	30 (25.0)	42 (35.0)
8 <sup>th</sup>	65 (54.2)	46 (38.3)
Type of family		
Nuclear	82 (68.3)	65 (54.2)
Joint	38 (31.7)	55 (45.8)
Father's education		
Illiterate	13 (10.8)	4 (03.3)
Primary	39 (32.5)	12 (10.0)
Middle	22 (18.4)	40 (33.3)
High	24 (20.0)	22 (18.3)
Senior secondary	13 (10.8)	24 (20.0)
Graduate	8 (6.7)	17 (14.3)
Postgraduate	1 (0.8)	1 (0.8)
SES class*		
I	3 (2.5)	12 (10.0)
II	13 (10.8)	21 (17.5)
III	30 (25.0)	31 (25.8)
IV	55 (45.9)	36 (30.0)
V	19 (15.8)	20 (16.7)

<sup>\*</sup>Socioeconomic class according to Modified BG Prasad Scale, 2017. SES: Socioeconomic status

statistically significant (P > 0.05). There were a higher proportion of students with satisfactory level of knowledge about alcohol after 2 weeks of intervention in both the schools compared to baseline, but this difference was not statistically significant (P > 0.05) as shown in Table 4.

There were a higher proportion of students with satisfactory level of knowledge about smoking after 3 months of intervention in both the schools compared to baseline, and this difference was statistically significant (P < 0.05). There were a higher proportion of students with satisfactory level of knowledge about alcohol after 3 months of intervention in both the schools compared to baseline, though this difference was statistically significant (P > 0.05) for School 2 as shown in Table 5.

#### **DISCUSSION**

In the present study, cancer as the harm caused by smoking was known to the maximum students of School 1 and premature death as the harm caused by smoking was known to the maximum students of School 2. The least known harm caused by smoking in School 1 was atherosclerosis, while in School 2 osteoporosis was the least known harm

Table 2: Distribution of the study participants according to awareness of harmful effects of smoking before the intervention (n=120)

Response*		School	1	Total	School 2			Total
	Yes, n (%)	No, n (%)	Don't know, n (%)		Yes, n (%)	No, n (%)	Don't know, n (%)	
Premature death	78 (65.0)	11 (9.2)	31 (25.8)	120 (100)	95 (79.2)	7 (5.8)	18 (15.0)	120 (100)
Stroke	34 (28.3)	23 (19.2)	63 (52.5)	120 (100)	59 (49.2)	25 (20.8)	36 (30.0)	120 (100)
Cancer	96 (80.0)	7 (5.8)	17 (14.2)	120 (100)	69 (57.5)	12 (10.0)	39 (32.5)	120 (100)
Inflammation of respiratory tract	56 (46.7)	18 (15.0)	46 (38.3)	120 (100)	76 (63.3)	14 (11.7)	30 (25.0)	120 (100)
Heart attack	47 (39.2)	10 (8.3)	63 (52.5)	120 (100)	82 (68.3)	5 (4.2)	33 (27.5)	120 (100)
Premature birth	36 (30.0)	16 (13.3)	68 (56.7)	120 (100)	45 (37.5)	26 (21.7)	49 (40.8)	120 (100)
Infertility	30 (25.0)	18 (15.0)	72 (60.0)	120 (100)	39 (32.5)	27 (22.5)	54 (45.0)	120 (100)
Atherosclerosis	15 (12.5)	24 (20.0)	81 (67.5)	120 (100)	40 (33.3)	19 (15.8)	61 (50.9)	120 (100)
Osteoporosis	21 (17.5)	14 (11.7)	85 (70.8)	120 (100)	33 (27.5)	18 (15.0)	69 (57.5)	120 (100)

<sup>\*</sup>Multiple responses are possible

Table 3: Distribution of the study participants according to awareness of harmful effects of alcohol before the intervention (n=120)

Response*		Schoo	l 1	Total School 2		School 2		
	Yes, n (%)	No, n (%)	Don't know, n (%)		Yes, n (%)	No, n (%)	Don't know, n (%)	
Brain damage	70 (58.3)	19 (15.8)	31 (25.9)	120 (100)	73 (60.8)	18 (15.0)	29 (24.2)	120 (100)
Congenital malformations	49 (40.8)	27 (22.5)	44 (36.7)	120 (100)	45 (37.5)	42 (35.0)	33 (27.5)	120 (100)
Depression	33 (27.5)	29 (24.2)	58 (48.3)	120 (100)	42 (35.0)	25 (20.8)	53 (44.2)	120 (100)
Road traffic accidents	69 (57.5)	16 (13.3)	35 (29.2)	120 (100)	76 (63.3)	15 (12.5)	29 (24.2)	120 (100)
Cancer	76 (63.3)	6 (5.0)	38 (31.7)	120 (100)	85 (70.8)	9 (7.5)	26 (21.7)	120 (100)
Diabetes	26 (21.7)	24 (20.0)	70 (58.3)	120 (100)	28 (23.3)	35 (29.2)	57 (47.5)	120 (100)
Liver damage	82 (68.3)	6 (5.0)	32 (26.7)	120 (100)	89 (74.2)	3 (2.5)	28 (23.3)	120 (100)

<sup>\*</sup>Multiple responses are possible

Table 4: Comparison between level of knowledge of smoking and baseline at baseline and 2 weeks after intervention in School 1 and 2

	Level of knowledge	e of smoking at bas	seline and 2 weeks after	the intervention	
School 1	Before intervention	2 weeks	School 2	Before intervention	2 weeks
Satisfactory	54 (45.0)	53 (47.7)	Satisfactory	atisfactory 89 (74.2)	
Unsatisfactory	66 (55.0)	58 (52.3)	Unsatisfactory	31 (25.8)	32 (27.8)
Total	120 (100)	111 (100)	Total	120 (100)	115 (100)
Р	>0.05	>0.05		>0.05	
	Level of knowle	dge of alcohol at b	aseline and 2 weeks afte	er intervention	
Satisfactory	58 (48.3)	58 (52.3)	Satisfactory	65 (54.2)	69 (60.0)
Unsatisfactory	62 (51.7)	53 (47.7)	Unsatisfactory	55 (45.8)	46 (40.0)
Total	120 (100)	111 (100)	Total	120 (100)	115 (100)
Р	>0.05		Р	>0.05	

Table 5: Comparison between level of knowledge of smoking and alcohol at baseline and 3 months after intervention in School 1 and 2

Level of knowledge of smoking at baseline and 3 months after intervention					
School 1	Before intervention	3 months	School 2	Before intervention	3 months
Satisfactory	54 (45.0)	68 (72.3)	Satisfactory	89 (74.2)	82 (86.3)
Unsatisfactory	66 (55.0)	26 (27.7)	Unsatisfactory	31 (25.8)	13 (13.7)
Total	120 (100)	94 (100)	Total	120 (100)	95 (100)
Ρ	<0.05		Р	<0.05	
	Level of knowled	ge of alcohol at base	eline and 3 months afte	r intervention	
Satisfactory	58 (48.3)	52 (55.3)	Satisfactory	65 (54.2)	74 (77.9)
Unsatisfactory	62 (51.7)	42 (44.7)	Unsatisfactory	55 (45.8)	21 (22.1)
Total	120 (100)	94 (100)	Total	120 (100)	95 (100)
Р	>0.05		Р	<0.05	` '

of smoking. In a study conducted by Sogarwal *et al.* in 2011 among students of both private and government school of Nainital, Wardha, Thrissur, Ratlam, and Nellore, cancer was the most commonly known harm of smoking and the least known was diabetes.<sup>[8]</sup> In another study conducted by Matapathi *et al.* in 2014 in Bengaluru, majority of the

students knew bad odor and staining of teeth followed by oral cancer and lung cancer as harmful effects of smoking.<sup>[9]</sup> In another study conducted by Sreedhar *et al.* in 2013 among high school students in Hyderabad, most commonly known of harmful effects of smoking were lung cancer followed by oral cancer and oral diseases.<sup>[10]</sup> In another

study conducted by Singh and Gupta in 2006 among students of class 9–12 in Jaipur, >90% students were aware of its importance (smoking) in causing respiratory diseases followed by cause general debility, heart disease, cancer, impotence, ulcer of stomach, and death.<sup>[11]</sup>

In another study conducted by George *et al.* in 2012 in Delhi in both government and private schools, majority of the students in government school knew smoking causes heart diseases.<sup>[7]</sup> In another study conducted by Chaudhari *et al.* in 2016 among high school children of Patan city, Gujarat, knowledge regarding hazards of smoking was maximum for lung cancer followed by for oral cancer.<sup>[12]</sup> In another study conducted by Jayakrishnan *et al.* in 2016 among students of rural government school of Kerala, 41.5% students were aware of the relationship between oral cancer and tobacco and 4.5% students mentioned CVD as tobacco related.<sup>[13]</sup>

In the present study, there were a statistically significant higher proportion of students with satisfactory level of knowledge about smoking after 3 months of educational intervention (through posters and pamphlets) compared to baseline in School 1. In another study conducted by Chaudhari et al. in 2015 in Gujarat, baseline knowledge of the students regarding the hazards of smoking was increased after the intervention and the difference was significant<sup>[12]</sup> similar to the present study. In an interventional study conducted by Matapathi et al. in 2014 among students of class 9th and 10th in Bengaluru, mean score of knowledge of harmful effects of smoking increased from baseline to posthealth education irrespective of the method used (lectures with PPT in one school and only lecture in other school), and the difference was statistically significant.<sup>[9]</sup> In another study conducted by Kumar B et al. in 2013 in Dehradun among students of class 11th and 12th. There was a significant improvement in knowledge regarding harmful effects of tobacco 7 days after teaching session along with exhibition on harmful effects of tobacco.<sup>[14]</sup> In a study conducted by Jayakrishnan et al. in 2016, similar significant increase in mean knowledge scores was found after educational intervention in the form of audio-visual aids among higher secondary students.[13] In a study conducted by Saraf et al. in 2015 in middle schools of rural Ballabgarh, postintervention, knowledge about tobacco increased significantly in the intervention group where intervention consisted of school component (policies), classroom (activities), and family component (IEC) as compared to the control school. [15] In a study conducted by Chaudhari et al. in 2016 in Gujarat, they found that baseline knowledge regarding harmful effects of smoking and/or chewing tobacco increased significantly

after the educational intervention in the form of lectures, demonstrations, and charts.<sup>[12]</sup>

In the present study, liver damage as the harmful effect of alcohol was known to the majority of students and the least known harmful effect of alcohol was diabetes. Similar results have been observed by Sogarwal *et al.* in 2011 among students of both private and government school of class 8<sup>th</sup> to 10<sup>th</sup> of five districts of India, Nainital, Wardha, Thrissur, Ratlam, and Nellore where liver diseases were the most commonly known harm of alcohol and diabetes was the least known harm. <sup>[8]</sup> In another study conducted by Nebhinani *et al.* in 2011 among school (class 8<sup>th</sup> to 10<sup>th</sup>) and college students in Chandigarh majority of the school students knew that substance causes liver damage if used for longer duration. <sup>[16]</sup> The present study has found lower awareness which may be because they included higher class students in their study.

In the present study, there were a higher proportion of students with satisfactory level of knowledge about alcohol 3 months after intervention in school 2 where the intervention was given in the form of didactic lecture, and the difference was statistically significant (P > 0.05). In a study conducted by Chaudhari et al. in 2015 in Gujarat among high class students, knowledge of the students regarding the hazards of alcohol increased significantly after educational training.<sup>[12]</sup> In another study conducted by Kumar B et al.[14] in 2013 in Dehradun among senior secondary class students, they found a significant improvement in knowledge regarding harmful effects of alcohol 7 days after teaching session along with exhibition on harmful effects of alcohol.[8] In another interventional study conducted by Jani et al. in 2013 among secondary school students in Vadodara knowledge regarding ill effects of alcohol consumption the mean score improved from baseline after educational training, and the difference was statistically significant.<sup>[17]</sup> This improvement after intervention is similar to the result of the present study.

#### **CONCLUSIONS**

There was a significant improvement in the knowledge regarding smoking and alcohol use among school-going adolescents after IEC activities in the form of didactic lectures, pamphlets distribution and poster display. Thus IEC activity may be one of the tools to improve health literacy regarding harmful effects of smoking and alcohol use among school going adolescents.

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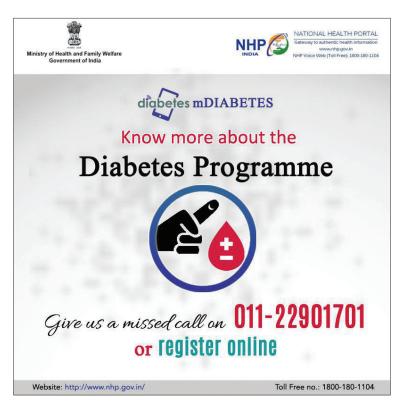
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#### Conflicts of interest

There are no conflicts of interest.

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## They do not just drive when they are driving: Distracted driving practices among professional vehicle drivers in South India

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#### **Abstract**

**Background:** Driving is a complex task, requiring coordination between multiple mental and physical faculties. Distractions lead to delayed recognition of information needed to drive safely. It is essential to understand distracted driving practices to regulate them and reduce crash risk. This study aims to identify common distractors among professional vehicle drivers in South India.

**Methodology**: A questionnaire-based cross-sectional study was conducted on professional drivers of three-and four-wheeled vehicles. Epicollect 5, a mobile-based data collection tool, was used for data collection and entry.

**Results:** Among 82 male professional drivers (57.3% car, 35.4% bus/lorry), with a mean (standard deviation) age of 38.4 (10.6) years, all reported being distracted by at least one of the listed distractors. Mobile phone usage and cognitive distractions were reported by 75.6% and 79.3%, respectively. Younger drivers (P = 0.005) and those with less than a decade of driving experience (P = 0.038) were more likely to use mobiles while driving. Drivers reporting cognitive distractions were more likely to have met with an accident than those who did not (44.6% vs. 23.5%).

**Conclusions:** Distracted driving is common among professional drivers. Cognitive distractions are as common as distractions due to mobile phones. Sensitization of drivers and strict enforcement of legislation are recommended.

Keywords: Cognitive distraction, distracted driving, mobile phone use, road traffic accident, safe driving

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#### INTRODUCTION

Driving a vehicle is a complex task, requiring the concurrent execution of various cognitive, physical, sensory, and psychomotor skills. Distraction occurs when a driver "is delayed in the recognition of information needed to safely accomplish the driving task because some event, activity,

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object, or person within or outside the vehicle compels or induces the driver's shifting attention away from the driving task." While the exact proportion of drivers who are distracted while driving is quite variable across countries, tudies suggest that this proportion has been increasing over the past decade.

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Distractions can be classified based on their source is internal to the vehicle like in-vehicle gadgets or mobile phones or external to the vehicle such as flashboards or pedestrians. Distractions could make the driver take his eyes off the road and/or hands off the steering wheel. Cognitive distractions, causing the driver's concentration to drift away from the driving activities, such as conversing, using voice-controlled gadgets, thinking, calculating, and listening to audio are also observed.

Mobile phones alone have been known to increase the crash risk by three to four times.<sup>[3,4]</sup> According to an estimation, restricting cell phone use while driving could have prevented 22% of the road traffic accidents in the US in 2008.<sup>[5]</sup> In India, around 31% of the road traffic accidents could be attributed to the use of mobile phone while driving leading to an estimated loss of 3% of the gross domestic product.<sup>[6]</sup> Besides these, the increasing use of gadgets that are incorporated into the vehicle's design has increased the in-vehicle distractions that a driver is exposed to.<sup>[7]</sup>

It is necessary to understand the distracted driving practices within a given social milieu to be able to plan appropriate and effective interventions to prevent and tackle them. <sup>[8]</sup> This study aimed to identify the common distracters while driving among professional vehicle drivers in a city in South India.

#### **METHODOLOGY**

This cross-sectional study recruited participants aged 18 years and above who drive vehicles for a livelihood in Madurai city, India. Although both males and females were proposed to be included, we could recruit only male participants, as it is uncommon for women in India to choose driving as an occupation. Vehicles were defined to include cars, buses, lorries, and auto rickshaws. Assuming 45% use mobile phones while driving, desiring an absolute precision of 12, allowing an alpha error of 5%, the desired sample size was 67. Accounting for nonresponse and missing data, a target sample size of 80 was calculated and a final sample size of 82 was achieved. The drivers were contacted at places where they were most likely to gather namely bus stands/terminals, parking lots in public places, and auto-rickshaw stands. Informed consent was obtained and after assurance of anonymity and confidentiality, a questionnaire prepared and pretested for this purpose was administered. The questionnaire was designed to collect data on the driver's practices while driving and their responses to the different distracters: physical and cognitive. The questionnaire also elicited the drivers' perceived severity of distraction caused by each of the listed distracters. Since being distracted while driving is undesirable behavior, some social desirability bias was anticipated. Repeating questions in a different context, presenting real-life scenarios, and requesting to respond as a third person were the techniques used to overcome this bias. For cognitive distractions, we had questions on "family stress," "workplace stress," "ruminating over events while driving," and "engaging in serious conversations with co-occupants." A positive response to any of these questions was meant to indicate cognitive distraction.

Epicollect 5, a mobile-based data collection tool designed by Imperial College, London, was used for data collection to ensure efficient and quality-assured data collection and entry. Data were exported to Microsoft Excel and analyzed using SPSS v21.0 (IBM Corp., Armonk, NY). The study was approved by the Institute Ethical Committee of Velammal Medical College Hospital and Research Institute, Madurai.

#### **RESULTS**

All the 82 drivers who participated in the study were male, with a mean (standard deviation [SD]) age of 34.8 (10.4) years. Most (93%) had attended some level of school or college. The median (interquartile range) duration of being a professional driver was 13 (7, 20) years [Table 1].

When asked to rate various distracters on a scale of 0–5, the mean  $\pm$  SD scores were highest for mobile phones (4.5  $\pm$  0.8), family (4.4  $\pm$  0.9), and workplace stress (4.4  $\pm$  0.8).

Drivers aged <35 years (P = 0.005) and those with less than a decade of driving experience (P = 0.038) were more likely

Table 1: Profile of professional vehicle drivers in Madurai, India (*n*=82)

Characteristic	n (%)
Education	
Illiterate	3 (3.0)
No formal schooling	3 (3.7)
Any schooling	38 (46.3)
Any college education	38 (46.3)
Frequency of driving	
Daily	59 (72.0)
3-5 days a week	17 (20.7)
Twice a week/only weekends	5 (6.1)
Missing	1 (1.2)
Vehicle usually driven	
Car	47 (57.3)
Bus/minibus/lorry, and other heavy vehicles	29 (35.4)
Auto/share auto	6 (7.3)
Age (years), mean±SD	34.8±10.4
Duration of driving (years), median (IQR)	13 (7-20)
Hours spent driving in a typical working day, median (IQR)	3 (2-7)
SD: Standard deviation IOP: Interquartile range	

to use mobile phones during driving compared to their older and more experienced counterparts. Younger drivers also reported to be significantly (P = 0.004) more distracted than older drivers by other distracters inside and outside the vehicle such as co-passengers, flashboards, eating or drinking within the vehicle, wearing on or taking off the seat belt, handling the music player or global positioning system, and smoking [Table 2].

Although not statistically significant, those who had ever met with an accident, were more likely to report cognitive distractions compared to those who had never met with an accident (44.6% vs. 23.5%, P = 0.114). There was no statistically significant association between having met with a road traffic accident and mobile phone usage or other distractions [Table 3]. Only 24 (29.2%) drivers had never been penalized for a traffic offense. Not using seat belt was the most common offense (63.4%), for which the drivers report having been penalized (data not shown).

#### **DISCUSSION**

Our questionnaire-based cross-sectional study on professional vehicle drivers revealed that all of them reported being distracted by one or the other of the listed distracters. Mobile phone usage and cognitive distractions were reported by almost three-fourths of the study participants. Drivers perceived mobile phones and mental stress as top distractions while driving. Drivers who reported cognitive distractions were more likely to have met with an accident than those who did not.

This prevalence of distracted driving practices was as high as 75.6% for mobile phone use, 79.3% for cognitive distraction, and 62.2% for other distractions. Shabeer and Banu estimated mobile phone usage among a sample of vehicle drivers in India at about 82%. [6] Farmer *et al.* have found that drivers in the US spend an average of 7% of the driving time talking on their phones. [5]

We found that younger and relatively inexperienced drivers (≤10 years of experience in driving) were more distracted while driving, especially using mobile phones while driving. Klauer *et al.* reported the same and in addition, reported that for the same distraction, the novice had higher odds of a crash compared to the experienced drivers in the USA. [10] Younger drivers are more technology savvy as compared to the older ones. Further, with experience, some of the tasks in driving become automatic and the experienced drivers are more capable of dividing attention to secondary tasks while driving.

Engaging in secondary tasks have been proved to increase crash or near-crash risk.<sup>[10]</sup> Using mobile phones restricts head movements, narrows the peripheral vision field, and can lead to poor velocity control and lane management.<sup>[11,12]</sup> Drivers resort to compensatory measures such as slowing down or frequent braking when distracted in an attempt to reduce crash risk. Despite these, distraction has been reported to account for 10% and 17% of fatal and injury crashes, respectively.<sup>[12]</sup>

In our study, we could not find an association between mobile phone usage and history of having met with a major accident probably because of the small sample size. However, a substantial proportion of the interviewed drivers were using mobile phones while driving. Although not popular yet among our study population, hands-free phones are not recommended as a safer alternative to handheld phones.<sup>[13]</sup>

People with cognitive distractions were more likely to have met with a major accident compared to those who did not report cognitive distractions. A preoccupied mind as measured by questions on rumination, or an agitated state of mind as measured using questions on engaging in serious conversations, resolving conflicts or feeling workplace or family stress while driving were reported by almost 80% of the drivers studied. Emotional distractions

Table 2: Association of age of the driver and duration of driving experience with self-reported distraction (n=82)

Distraction	Dri	ving experience			Age	
	≤10 years, <i>n</i> (%)	>10 years, n (%)	P	≤35 years, <i>n</i> (%)	>35 years, n (%)	P
Mobile phone						
No	5 (13.5)	15 (33.3)	0.038	5 (11.6)	15 (38.5)	0.005
Yes	32 (86.5)	30 (66.7)		38 (88.4)	24 (61.5)	
Cognitive distracters	, ,	, ,		, ,	, ,	
No	4 (10.8)	13 (28.9)	0.240	6 (14.0)	11 (28.2)	0.310
Yes	33 (89.2)	32 (71.1)		37 (86.0)	28 (71.8)	
Other distracters	, ,	, ,		, ,	, ,	
No	11 (29.7)	20 (44.4)	0.171	10 (23.3)	21 (53.8)	0.004
Yes	26 (70.3)	25 (55.6)		33 (76.7)	18 (46.2)	
Accident	, ,	, ,		· · ·	, ,	
No	22 (59.5)	27 (60.0)	0.960	25 (58.1)	24 (61.5)	0.754
Yes	15 (40.5)	18 (40.0)		18 (41.9)	15 (38.5)	

Table 3: Association between self reported distraction and having met with a road traffic accident (n=82)

Distraction	Ever met with a major road traffic accident while driving, n (%)	P
Mobile phone		
Never	11 (55.0)	0.122
Ever	22 (35.5)	
Cognitive distracters		
No	4 (23.5)	0.114
Yes	29 (44.6)	
Other distracters		
No	13 (41.9)	0.808
Yes	20 (39.2)	

may have adverse effects on the driver's behavior and compromise safe driving. [14] The emotional content of the distraction differentially influenced driving speed and response times depending on whether they were positive or negative. [15] Although visual distraction is expected to impair driving skill more than cognitive distraction, the latter made steering less smooth, affected vehicle control, and led to more episodes of hard braking. [16,17] These distractions are relevant in the context of the increasing use of in-vehicle information systems which are intended to reduce the distraction by manual operation and handling of the in-vehicle devices. The possibility of cognitive distraction and its effects on driving is to be kept in mind while designing these devices. [18]

People rated mobile phones and mental stress high up as distracters in our study. Despite that, the prevalence of these distracted driving practices is high.<sup>[19]</sup> A recurring question is that why, despite the awareness about these distracters, do people continue yielding to them. While the risk has been communicated and is perceived, it does not reflect in the behavior.

#### Strengths and limitations

This is the first study focusing on distracted driving practices among professional vehicle drivers in India. There are a few limitations in this study. Our study interviewed a convenient sample of professional vehicle drivers. We could only collect self-reported data on distractions while driving and involvement in accidents due to distraction. A more preferred method of study using objective measures of the distraction based on surveillance camera recordings, in-vehicle devices, or official records of road traffic accidents would have yielded more robust data. Participants could have underreported the mobile phone usage as it is against law and perceived widely an undesirable practice. Cognitive distractions, on the other hand, are not generally perceived as undesirable behaviour. Further, since they are not easily detectable or punishable by law enforcers, they could have been reported accurately. The study's inability

to detect an association between mobile phone use and having met with an accident could be because people who had met with accidents might have reduced their tendency to get distracted posttrauma.

#### CONCLUSIONS AND RECOMMENDATIONS

Distracted driving is common among professional drivers in Madurai, India. Cognitive distractions are as common as distractions due to mobile phones or other distracters within and outside the vehicle. Sensitization of the drivers to the hazards of distracted driving and its association with increased crash risk has to be undertaken. The in-vehicle gadgets need to be tested for their impact on driving skills before their becoming a part of the make of the vehicle. Strict enforcement of legislations governing distracted driving practices are needed to reduce distracted driving.

#### Financial support and sponsorship

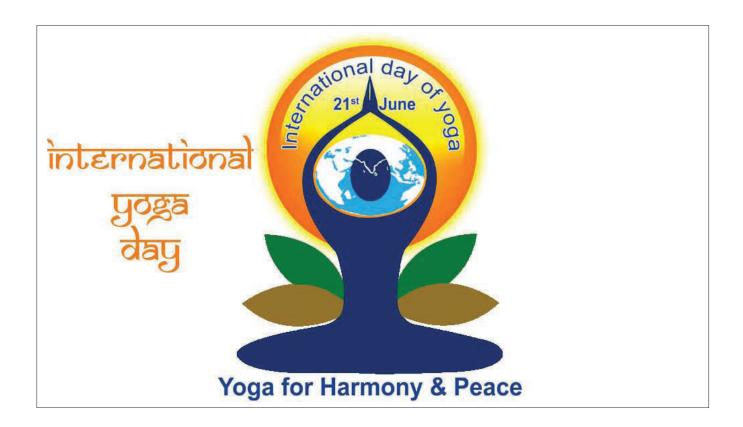
Nil

#### Conflicts of interest

There are no conflicts of interest.

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## Nutritional assessment among children (1–5 years of age) using various anthropometric indices in a rural area of Haryana, India

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#### **Abstract**

**Background:** Global Nutrition Targets 2025 specified a set of six global nutrition targets, and one aim is to achieve a 40% reduction in the number of children under 5 years of age who are stunted. National data on underweight provided under National Family Health Survey-4 (NFHS-4) (2015–2016) revealed an underweight prevalence rate around 35.7% as compared to NFHS-3 where it was 42.5%, which reflects only 6.8% reduction in underweight over a decade.

**Methods**: This cross-sectional study was conducted in the rural area of Rohtak district during October 2014 to September 2015 among children who were 1–5 years of age. The anthropometric measurement and nutritional status categorization among children were done using the WHO guidelines.

**Results:** A total of 600 children participated in the study. Around 41.3% of the study participants had stunting as their nutritional status, while taking composite index of anthropometric failure (CIAF) for nutritional status into consideration, nearly 54.4% of the participants were undernourished. Stunting and underweight were more prevalent among girls.

**Conclusions:** Composite anthropometric index provides the actual prevalence or proportion of undernourished children in a community, so the policies should be based on the basis of CIAF so to reduce the prevalence of undernutrition in the community more effectively.

Keywords: Composite index of anthropometric failure, stunting, underweight, wasting

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#### INTRODUCTION

Global Nutrition Targets 2025 specified a set of six global nutrition targets, and one aim is to achieve a 40% reduction in the number of children under 5 years of age who are stunted. Child malnutrition significantly increases the risk of infant and child death, with some estimates suggesting that child malnutrition is responsible for half or more of child deaths in the developing world. [1] The National Family

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Health Survey-4 (NFHS-4) data analysis showed a strong relationship between under-five child mortality rates and child underweight rates.<sup>[2]</sup> There is also a large body of evidence from around the world relating undernutrition in childhood to lower levels of school performance, cognitive development, and health and ultimately in adulthood to lower levels of labor productivity. Thus, the economic

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and human costs of child malnutrition in India are likely to be very high. [3] NFHS-4 data revealed the prevalence of underweight, stunting, and wasting as 35.7%, 38.4%, and 21% when compared to NFHS-3 42.5%, 48%, and 19.8% in India, which reflects slow reduction in the prevalence of malnutrition. [2,4] It also suggests that Indian children suffer from both aspects of undernutrition which means short-term, acute food deficits (as reflected in low weight-for-age) as well as from long-term, chronic undernutrition (as manifested in high rates of stunting).

The undernutrition is due to multidimensional aspects such as poverty and diseases. Keeping that in mind, the rate of decline in undernutrition is lacking behind, and to achieve the pace in the reduction of undernutrition prevalence, Svedberg suggested new classification of undernutrition known as composite index of anthropometric failure (CIAF).<sup>[5]</sup> It was revised by Nandy et al. by addition of one more subgroup "Y" (underweight only) to existing one. The anthropometric subgroups of the children are as follows: A – no failure, B – wasting only, C – wasting + underweight, D - wasting + stunting + underweight, E – stunting + underweight, F – stunting only, and finally, Y – underweight only. [6] The sum of the children in groups B-F provides the CIAF. As a single indicator, CIAF provides a single number to the overall estimate of undernourished children in a population, which none of the current indicators do. This classification gave concern that children can have multiple growth failure and need special attention. Global Nutrition Targets 2025 are yet to be achieved at both national and state level (Haryana). [2] As in Haryana there is a paucity of studies based on CIAF, this was conducted to measure the undernutrition prevalence by both conventional methods and CIAF and to observe the reliability of CIAF.

#### **METHODS**

#### Study design and the participants

This cross-sectional study was conducted in rural field practice area attached to the Department of Community Medicine, PGIMS, Rohtak, Haryana, India, during October 2014 to September 2015. The sample size was calculated (n = 550) considering the prevalence of underweight among under-five children as 41% (approximate) in rural areas of Haryana (NFHS-3) with confidence level of 95% and 10% relative allowable error by applying the following formula:  $n = (Z1 - a/2)^2 \times p (1 - p)/d^2$ , where Z = Standard normal variate for level of significance (at 5% type I error [P < 0.05], Z = 1.96 for two-sided test), a = Level of significance (0.05), P = Prevalence (proportion = 41%), d = Relative Allowable error (10%), and n = Sample size. [4]

Although the calculated sample size came out to be 550, a sample of 600 study participants was included for the study. The participant involved were children, 1-5 years of age along with their parents/guardians. A total of 112 anganwadi centers (Integrated Child Development Scheme Centers [ICDS centers]) were there under the rural field practice area, of which 30 anganwadi centers were selected by adopting systematic random sampling procedure. From each selected anganwadi center, 20 children were selected by simple random sampling. Thus, a sample of 600 children was included in the study. This study was approved by the ethical committee, and prior consent was taken by parents/guardian of the children before the interview and examination of the child. The children who were unavailable at three consecutive visits or whose birth records at present not available were excluded from the study.

#### Study tools

A pretested, predesigned questionnaire was used by an investigator to interview the study participants and house-to-house visit was also done. The age of children was recorded using birth/delivery records or anganwadi center (ICDS centers) records and was estimated to the most recently attained month. The anthropometric measurements of children were done using the WHO guidelines.<sup>[7]</sup> To measure weight and height, parents/guardians were suggested to bring their children to respective anganwadi center (ICDS centers) to increase the accuracy level of respective measuring parameters. The weight of child was measured using a Salter's weighting apparatus developed by the UNICEF in collaboration with the WHO. The height of children who were more than 2 years and were able to stand without support was measured using a stadiometer; and for those below 2 years or were unable to stand or child length < 85 cm, recumbent length was measured using an infant meter.

The participants were classified as stunted, wasted, and underweight as their undernutritional status depending upon the Z-score value which was calculated using WHO Anthro Software (version 3.2.2, 2011, Department of Nutrition, World Health Organization, Avenue Appia 20, 1211 Geneva 27, Switzerland). If Z-score <-2 = moderately undernourished, and if Z-score <-3 = severely undernourished. The undernutritional status of children was also classified on the basis of CIAF using Nandy *et al.* model of 6 groups (stunted only, underweight only, wasted only, wasting and underweight, stunted and underweight, and finally, stunted, wasted, and underweight) of children was used. If Three new indices proposed by Bose and Mandal were also used to asses

with the problem of stunting, underweight, and wasting relative to the total prevalence of under nutrition. [9] These three indices are stunting index (SI) = stunting/CIAF; underweight index (UI) = underweight/CIAF; wasting index (WI) = wasting/CIAF.

#### Statistical methods

The responses to schedule by each participant were entered into excel sheet and data were tabulated and statistical analysis was done using SPSS 20.0 (Statistical Package for the Social Sciences, IBM SPSS Inc., Chicago, Illinois, USA). Categorical data were presented as percentages (%) and Pearson's Chi square test was used to evaluate differences between groups for categorized variables.

#### RESULTS

A total of 600 children participated in the study. In the study, boys and girls frequency (%) accounted as 337 (56.2%) and 263 (43.8%). The age-wise of distribution among boys and girls of children can be well observed in Table 1, as maximum participants (23.8%) belonged to 12–23 months of age whether the participant was girl (30.8%) or boy (35.6%). The wasting (severe and moderate) was observed among 18.4% of participants; while 41.3% participants were stunted (severe and moderate), 38.3% were underweight (severe and moderate) [Table 2].

The proportion of wasting and underweight were highly statistically significant (P < 0.05) when compared in terms of age-wise distribution of the study participants [Table 3]. The proportion of wasting was higher among boys, whereas proportion of stunting and underweight was higher among girls. CIAF rate (54.4%) as recently suggested one of indicators of undernutrition was higher than wasting, underweight, and stunting rates [Table 4].

Using Nandy et al.'s CIAF classification for participants [Table 4], it was observed that the frequency of subgroup "E" among growth failure (B–Y) subgroups was the highest (22.1%), which accounted for 20.1% and 24.7% in respective proportion of boys and girls participants. The SI (0.783) and UI (0.587) were higher among girls and WI was higher among boys (0.359) [Table 5].

#### DISCUSSION

The time trend of undernourished children in India is showing declining pattern, but the pace of reduction is not matching the criteria set by United Nation

Table 1: Distribution of children by age and sex

Age (months)	Frequency (%)		
	Boys	Girls	Total
12-23	120 (35.6)	81 (30.8)	201 (33.5)
24-35	87 (25.8)	76 (28.9)	163 (27.2)
36-47	58 (17.2)	55 (20.9)	113 (18.8)
48-59	72 (21.4)	51 (19.4)	123 (20.5)
Total	337 (56.2)	263 (43.8)	600 (100)

Table 2: Prevalence of undernutrition among children using the WHO child growth standards

Characteristics	Frequency (%)		
	Boys (n=337)	Girls ( <i>n</i> =263)	Total (n=600)
Weight-for-height (Z-score)			
No wasting (>-2 SD)	273 (81.0)	217 (82.5)	490 (81.6)
Moderate wasting (<-2 SD)	41 (12.2)	35 (13.3)	76 (12.7)
Severe wasting (<-3 SD)	23 (6.8)	11 (4.2)	34 (5.7)
$\chi^2$ , df, P		2.01, 2, 0.366	5
Weight-for-age (Z-score)			
No underweight (>-2 SD)	213 (63.2)	157 (59.7)	37061.7)
Moderate underweight (<-2 SD)	85 (25.2)	78 (29.7)	163 (27.1)
Severe underweight (<-3 SD)	39 (11.6)	28 (10.6)	67 (11.2)
$\chi^2$ , df, P		1.48, 2, 0.478	3
Height-for-age (Z-score)			
No stunting (>-2 SD)	205 (60.8)	147 (55.8)	352 (58.7)
Moderate stunting (<-2 SD)	68 (20.2)	58 (22.1)	126 (21.0)
Severe stunting (<-3 SD)	64 (19.0)	58 (22.1)	122 (20.3)
$\chi^2$ , df, P		1.54, 2, 0.462	2

Development Project under millennium developmental goals for India. This is matter of concern as undernutrition causes a significant contribution in under-5 year children mortality.[10] The present study conducted in rural area showed the prevalence of stunting, underweight, and wasting among the study participants as 41.3%, 38.3%, and 18.4%, respectively, which when compared to latest available data of NHFS-4 (Haryana), the prevalence for stunting (39.6%) and wasting (19.0%) was similar, but it differed underweight (45.7%) rate.[11] As the prevalence of undernutrition is declining and NFHS-3 (Haryana) provides a decade back scenario, the prevalence rate of stunting, underweight, and wasting calculated in it was of higher range when compared with our study.[12] The prevalence of stunting and underweight was coming out to be on lower side in our study in comparison to other studies.[9,13]

The present study showed the highest prevalence for stunting (41.3%), followed by underweight (38.3%) and least for wasting (18.4%). Similar trends for prevalence were noticed in NFHS-4 (Haryana, stunting 45.7%, underweight 39.6%, and wasting 19.0%) and other studies but differed from Bose and Mandal's observation. [11,13-16] In our study, the prevalence of stunting (44.2%) and underweight (40.3%) was higher among girls than boys (stunting 39.2%;

Table 3: Association between nutritional status and age of children

Age (months) ( <i>n</i> =600)	Frequency (%)			
	No wasting (n=502)	Moderate wasting (n=75)	Severe wasting (n=23)	
12-23 ( <i>n</i> =201)	160 (79.6)	23 (11.4)	18 (9.0)	
24-35 ( <i>n</i> =163)	132 (81.0)	28 (17.2)	3 (1.8)	
36-47 (n=113)	101 (89.4)	6 (5.3)	6 (5.3)	
48-59 (n=123)	97 (78.9)	19 (15.4)	7 (5.7)	
$\chi^2$ , df, $\stackrel{\frown}{P}$		17.56, 6, 0.007		
Age (months) ( <i>n</i> =600)	No stunting (n=352)	Moderate stunting (n=126)	Severe stunting (n=122)	
12-23 ( <i>n</i> =201)	124 (61.7)	36 (17.9)	41 (20.4)	
24-35 (n=163)	96 (58.9)	40 (24.5)	27 (16.6)	
36-47 (n=113)	65 (57.5)	22 (19.5)	26 (23.0)	
48-59 (n=123)	67 (54.5)	28 (22.8)	28 (22.8)	
$\chi^2$ , df, $\dot{P}$	` ,	4.798, 6, 0.570	· ,	
Age (months) ( <i>n</i> =600)	No underweight (n=370)	Moderate underweight (n=163)	Severe underweight (n=67)	
12-23 ( <i>n</i> =201)	137 (68.2)	40 (19.9)	24 (11.9)	
24-35 (n=163)	97 (59.5)	55 (33.7)	11 (6.7)	
36-47 (n=113)	66 (58.4)	34 (30.1)	13 (11.5)	
48-59 (n=123)	70 (56.9)	34 (27.6)	19 (15.4)	
$\chi^2$ , df, $\stackrel{ ightharpoonup}{P}$	. ,	13.996, 6, 0.030	,	

Table 4: Distribution of children into subgroup of anthropometric failure using composite index of anthropometric failure

Group name	Frequency (%)			
	Boys ( <i>n</i> =337)	Girls ( <i>n</i> =263)	Total (n=600)	
A	159 (47.1)	115 (43.7)	274 (45.6)	
В	15 (4.4)	9 (3.4)	24 (4.0)	
С	24 (7.1)	19 (7.2)	43 (7.1)	
D	25 (7.4)	18 (6.8)	43 (7.1)	
E	68 (20.1)	65 (24.7)	133 (22.1)	
F	39 (11.5)	33 (12.5)	72 (12.0)	
Υ	7 (2.1)	4 (1.5)	11 (1.8)	

Table 5: Comparison of composite index of anthropometric failure indices among children

CIAF index	Boys	Girls	Overall
Wasting index	0.359	0.310	0.337
Stunting index	0.741	0.783	0.760
Underweight index	0.561	0.587	0.573

CIAF: Composite index of anthropometric failure

underweight, 36.8%), which again followed similar pattern of NFHS-4 (Haryana) data and Berger *et al.*'s study but not in agreement with other studies.<sup>[11,16-18]</sup>

When taking CIAF into consideration for calculating prevalence of undernourished children, it was coming out to be 54.4%, which tends to be higher than the overall prevalence rates of stunting, wasting, and underweight calculated using conventional methods and this tendency was in agreement with the observations of other studies. [13,17,19,20] CIAF prevalence calculated in other studies was elevated than the prevalence calculated in the present study; on the other hand, CIAF prevalence estimation concerned with Dasgupta *et al.*'s study was lower than the present study. [13,16,18,19] Underweight as the only criterion for identifying undernourished children may underestimate the

true prevalence of underutrition, by as much as 16.1% in the present study. As far as SI, UI, and WI are concerned, studies of Nandy *et al.* and Anwar *et al.* found lower value for SI, WI, and UI than the present study. [6,19] From above discussion, CIAF classification seems to being welcomed by various authors, but Bhattacharyya has criticized it and raised issues regarding its usefulness. [21] As the main objective of study was to calculate undernutrition burden using current conventional indicators and CIAF classification, the information regarding calorie and protein intake, morbidity history, and socioeconomic status of the participants was not gathered in the present study which can be considered as its limitation.

#### **CONCLUSIONS**

In speeding up to decline the rate of undernutrition in community, additional steps have to be taken. CIAF must be included under routine growth monitoring at the community level as it requires inclusion of measurement of height at anganwadi centers (ICDS centers) in addition to weight measurement. Underestimating this proportion might prevent undernourished children from receiving the benefit of the extra supplementation they deserve. It must be emphasized, however, that conventional indices reflect distinct biological processes and cannot be disregarded, but this issue has been addressed with the construct of the new indicator CIAF and its merits further consideration as a policy and monitoring tool for planning purposes. The disaggregation of undernourished children into different subgroups as done in CIAF allows the researchers to further examine the relationship between particular combinations of undernutrition and poverty or morbidity/mortality data. This is a very serious problem, by any scale. Under such conditions, our intervention efforts need to be broader than providing supplementary nutrition alone.

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#### Conflicts of interest

There are no conflicts of interest.

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## Mental health, functional ability, and health-related quality of life in elderly patients attending a tertiary hospital of Patna

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#### **Abstract**

**Background:** With changing socioeconomic, demographic, and development scenario, there is a cultural shift in looking after the elderly population which may lead to depression in this age group.

Materials and Methods: The study was a hospital-based cross-sectional study conducted in the orthopedic department of a tertiary care setting on 157 elderly individuals. This study was conducted with objectives to estimate the proportion of depression using the Geriatric Depression Scale Short Form (GDS-SF) questionnaire along with its associated factors in geriatric population coming to the orthopedic department of the institute. The study tools were GDS-SF, Katz Index of Independence in activities of daily living (ADL), the Lawton instrumental ADL, and health-related quality of life by the Centers for Disease Control.

**Results:** The proportion of depressed individuals was 70/157 (44.6%) using GDS as a tool. The maximum number was in the age group of 60–74 years. Women outnumbered men (51.3% vs. 38.31%) for depression. The depression using GDS score was more prevalent in rural elderly, illiterate, and elderly who were economically dependent on their children and who belonged to lower middle socioeconomic status. Approximately 98% of the study participants were found to be independent using ADL. Approximately 60% males and 68% females were dependent for the instrumental ADL using Lawton score. Most of the study participants had arthritis as a major impairment sharing almost equal proportion among males and females. **Conclusion:** The current study concludes that there is a very high proportion of elderly subjects who are experiencing depression using the GDS-SF tool. There should be regular screening for this disease in this age group even in a tertiary care setting.

**Keywords:** Activities of daily living, geriatric depression, geriatric depression scale short form, health-related quality of life, instrumental activities of daily living

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#### INTRODUCTION

The increase in life expectancy has resulted in an increase in the population of elderly, and in India, the share of the population over the age of 60 years is projected to increase from 8.3% in 2011<sup>[1]</sup> to 19% in 2050. By the end

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of the century, the elderly will constitute nearly 34% of the total population in the country.<sup>[2]</sup> In India, it is a cultural practice for families to take care of the needs of older persons, including economic and social needs. With the changing socioeconomic, demographic, and development

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scenario, now, there is a cultural shift in this practice which is leading to some form of psychological stress among elderly.<sup>[2]</sup> According to the WHO, mental health disorders account for 13% of the global burden of diseases and are particularly common among older adults.

Vulnerability among older persons increases with declining functional abilities. Activities of daily living (ADL) are the basic tasks of everyday life such as feeding, bathing, dressing, mobility, use of the toilet, and continence and when older persons are not able to perform these activities, they require assistance. ADL limitations are indicative of the care burden in any society. ADL limitations are more for older women than men with 9% of the older women and 6% of the older men needing assistance with at least one activity. This indicates a high care burden considering the sheer number of older persons in the country. [3] Therefore, this study was conducted with objectives to estimate the proportion of depression using Geriatric Depression Scale Short Form (GDS-SF) questionnaire along with its associated factors in geriatric population coming to the orthopedic department of the institute and to assess the functional ability and health-related quality of life (HRQOL) in the same population.

#### MATERIALS AND METHODS

#### Study design, area, and study group

The study was a hospital-based cross-sectional study conducted in the Orthopaedic Department of AIIMS Patna, for 1 year (from October 2016 to September 2017).

## Sample size, sampling method, and recruitment of study participants

The sample size for this study was calculated using Taro Yamane formula with a 95% confidence level. According to hospital record, 9800 patients consulted in the orthopedic outpatient department (OPD) during the year 2016. The calculation formula for Yamane is as follow  $n = \frac{N}{1 + N(e^2)}$ 

where n = sample size required. N = Population size, e = Allowable error (%). We took allowable error to be 10%; the required minimal sample size was calculated to be 99. Finally, 157 participants were included over the study period. The final precision of this study was 8%. The power of this study was calculated using G\*Power Version 3.1.9.4, (Fraz Faul Universitat Kiel, Germany) statistical software. A post hoc power analysis was applied using an exact test for proportion difference from constant. A similar study by Prakash et al., [4] using GDS-15 tool in geriatrics patients in

the hospital reported a proportion of 22%. We assumed an effect size of +10% in our study setup. The power of study thus calculated to be 87%.

#### Sampling technique

All the elderly study participants visiting the OPD were included who met the following inclusion criteria: age ≥60 years, not having a current history of fracture of any part (nontraumatic), no history of tumor/cancer, and free from debilitating conditions.

#### Conduction of interview

The interview was conducted in Hindi. The semi-structured questionnaire was translated in Hindi and pilot tested in 20 patients. It was back translated by an independent person well versed with both languages to ensure the validity of the translation. The interview was conducted in a separate room, by one orthopedic senior resident after the training by the principal investigator. It was a half day training which was subsequently reinforced periodically.

#### Ethical approval

Ethics approval of the institutional ethics committee was obtained before the commencement of the study. The purpose of the study was explained to the study individuals and their signed consent was obtained. All the study participants who were depressed using the GDS were referred to the psychiatry department for further assessment and treatment.

#### Study tool

A predesigned and pretested semi-structured questionnaire containing various sociodemographic parameters and other assessment tools was used. The Whisper test was performed to assess hearing impairment.<sup>[5]</sup> Standard methods were used for anthropometric measurement. The mental health status, functional ability, and HRQOL were measured using the following tools.

#### Mental health status

GDS-SF was used to estimate the depression in the study participants. [6] The GDS: SF consists of 15 questions requiring "yes" or "no" answers and can be completed quickly. The depression was assessed using the 15-item GDS, [7] which is a 15-item self-report assessment used as a basic screening measure of depression in the elderly. The accuracy of the GDS-15 is not influenced by the severity of medical burden, age, or other sociodemographic characteristics and even the "very old" and ill can be screened appropriately. [8] Moreover, the presence of a major depressive episode among elderly home-bound adults can be reliably detected. In a validation study,

comparing the long and SFs of the GDS for self-rating of symptoms of depression, both were successful in differentiating depressed from nondepressed adults with a high correlation (r = 0.84, P < 0.001). Hence, this scale is better suited for identifying depression in the elderly. Those with a GDS score >5 were categorized as depressed. Using this cutoff, high sensitivity and specificity of the 15-item GDS have been reported.<sup>[9]</sup>

#### Functional ability

The ADL was assessed using the Katz Index of Independence in ADL (Katz, 1970). [10] The Index ranks adequacy of performance in the six functions of bathing, dressing, toileting, transferring, continence, and feeding. Client's responses were scored yes/no for independence in each of the six functions. A score of 6 indicates full function, 4 indicate moderate impairment, and 2 or less indicates severe functional impairment. [11]

The Lawton Instrumental ADL (IADL) (Lawton, 1969) Scale assesses a person's ability to perform tasks such as using a telephone, doing laundry, and handling finances. [12] Measuring eight domains, it can be administered in 10–15 min. The scale may provide an early warning of functional decline or signal the need for further assessment. These skills are considered more complex than the basic ADL as measured by the Katz Index of ADLs. The instrument is most useful for identifying how a person is functioning at present, and to identify improvement or deterioration over time. There are eight domains of function measured with the Lawton IADL scale. Women are scored on all eight areas of function. For men, the areas of food preparation, housekeeping, and laundering are excluded. Clients are scored according to their highest level of functioning in that category. A summary score ranges from 0 (low function, dependent) to 8 (high function, independent) for women and 0 to 5 for men.

#### Health-related quality of life

This includes a total of 14 questions. It has three parts – healthy days core module (4 questions), activity limitation module (5 questions), and healthy days symptoms modules (5 questions). It enquires regarding the health in general, about the physical health, which includes physical illness and injury in the past 30 days, about the mental health, which includes stress, depression, and problems with emotions in the past 30 days and whether this physical or mental health prevented them from doing the usual activities. These questions also ask about recent pain, depression, anxiety, sleeplessness, vitality, and the cause, duration, and severity of a current activity limitation an individual may have in his/her life.<sup>[13]</sup>

Unhealthy days are an estimate of the overall number of days during the previous 30 days when the respondent felt that either his or her physical or mental health was not good. To obtain this estimate, responses to questions 2 and 3 are combined to calculate a summary index of overall unhealthy days, with a logical maximum of 30 unhealthy days.<sup>[14]</sup>

#### Statistical analysis

The data were entered and analyzed into IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. (IBM Corp., Armonk, NY). To test the significance in the difference of proportion, a Chi-square test was performed. The ANOVA was applied to test the difference in the mean score across various groups. The P < 0.05 was considered statistically significant. The reliability of the GDS tool was tested using Cronbach's alpha.

#### **RESULTS**

The proportion of depressed individuals was 44.6% (36.7–52.7) using GDS as a tool. The maximum number was in the age group of 60–74 years. Women outnumbered men (51.3% vs. 38.31%) for depression. The depression (using GDS score) was more prevalent in elderly who inhabited the rural area, illiterate, were economically dependent on their children and belonged to lower middle socioeconomic status [Table 1]. Cronbach's alpha of GDS tool in the current study is 0.69.

The distribution of the mean GDS score among nondepressed and depressed groups across sociodemographic parameters is presented in Table 2. Among the nondepressed group, the mean GDS score was below 2, across the majority of variable categories except for secondary education level, widow/widower, those living alone, partially dependent, and those belonged to lower strata. Among the depressed group, the mean GDS score ranged from 8.2 to 11.6 for all variable categories. The statistical analysis using *F*-test showed that there was no significant difference in mean GDS score across sociodemographic parameters in nondepressed as well as depressed group, except across socioeconomic levels in the depressed group (<0.002) [Table 2].

The proportion of depressed individuals were more in the obese category as compared to their normal counterparts. [Table 3]. The distribution of study participants taking the waist circumference as risk criteria was almost similar in both the categories. The prehypertension category of people was more depressed than Stage I and II hypertension. The maximum proportion of nondepressed individual belonged to a normal category.

Table 1: Geriatric Depression Scale score-category according to sociodemographic parameters of study individuals (n=157)

	Nondepressed, n (percentage with 95% CI)	Depressed, n (percentage with 95% CI)	P
Age category (years)			
60-74	84 (55.6, 47.8-63.4)	67 (44.4, 36.6-52.2)	>0.05
75-84	3 (50, 42.2-57.8)	3 (50, 42.2-57.8)	
≥85	NA	NA	
Gender			
Male	49 (62, 54.4-69.6)	30 (38, 30.4-45.6)	>0.05
Female	38 (48.7, 40.9-56.5)	40 (51.3, 43.5-59.1)	
Residence		,	
Rural	51 (53.1, 45.3-60.9)	45 (46.9, 39.1-54.7)	>0.05
Urban	36 (59, 51.3-66.7)	25 (41, 33.3-48.7)	
Education	, ,		
Illiterate	28 (48.3, 40.5-56.1)	30 (51.7, 43.9-59.5)	>0.05
Primary	7 (38.9, 31.3-46.5)	11 (61.1, 53.5-68.7)	
Middle	17 (70.8, 63.7-77.9)	7 (29.2, 22.1-36.3)	
Secondary	14 (53.8, 46-61.6)	12 (46.2, 38.4-54)	
Graduate and above	14 (60.9, 53.3-68.5)	9 (39.1, 31.5-46.7)	
Marital status	,	, , ,	
Married	85 (56.3, 48.5-64.1)	66 (43.7, 35.9-51.5)	>0.05
Widow/widower	2 (33.3, 25.9-40.7)	4 (66.7, 59.3-74.1)	
Religion	, ,	, ,	
Hindu	78 (54.9, 47.1-62.7)	64 (45.1, 37.3-52.9)	>0.05
Muslim	8 (61.5, 53.9-69.1)	5 (38.5, 30.9-46.1)	
Others	1 (50, 42.2-57.8)	1 (50, 42.2-57.8)	
Living arrangement	, ,	,	
With spouse	7 (43.8, 36-51.6)	9 (56.2, 48.4-64)	>0.05
With spouse and children	71 (56.3, 48.5-64.1)	55 (43.7, 35.9-51.5)	
With children	5 (45.5, 37.7-53.3)	6 (54.5, 46.7-62.3)	
Alone	4 (100, 100-100)	NA	
Economic dependence			
Independent	31 (63.3, 55.8-70.8)	18 (36.7, 29.2-44.2)	>0.05
Partially dependent	4 (23.5, 16.9-30.1)	13 (76.5, 69.9-83.1)	
Dependent	52 (57.1, 49.4-64.8)	39 (42.9, 35.2-50.6)	
Socioeconomic status		,	
Upper	9 (37.5, 29.9-45.1)	15 (62.5, 54.9-70.1)	>0.05
Upper middle	21 (67.7, 60.4-75)	10 (32.3, 25.1-39.6)	
Middle	22 (66.7, 59.3-74.1)	11 (33.3, 25.9-40.7)	
Lower middle	16 (44.4, 36.6-52.2)	20 (55.6, 47.8-63.4)	
Lower	19 (57.6, 49.9-65.3)	14 (42.4, 34.7-50.1)	

CI: Confidence interval, NA: Not available

Although the proportion of individuals who reported hearing impairment was very low (4.4%) the majority of them were depressed [Table 2].

The mean GDS score among the nondepressed group for various categories of body mass index, waist circumference, blood pressure, and hearing assessment was reported to be <2 except for Stage II hypertension (3.55  $\pm$  2.16) whereas among the depressed group, it was between 9.2 and 11.6 [Table 4].

The unhealthy days were ranging from 15.9 days to 22.6 days. The maximum unhealthy days were due to sleeplessness (22.6 days) which was statistically significant, followed by anxiety (22.3 days) in men. The women had a smaller number of unhealthy days as compared to their male counterparts [Table 5].

Approximately 98% of the study participants were found to be independent using ADL. Approximately 60% males

and 68% females were dependent for the instrumental ADL using Lawton score [Table 6].

The study participants were interviewed regarding one major impairment or health problem that limited their activities. Most study participants had arthritis as a major impairment sharing almost equal proportion among males and females. The same pattern was observed across other health conditions also [Figure 1].

#### **DISCUSSION**

It is a myth in the community that depression in the elderly is due to normal aging phenomenon. This leads to the under diagnosis and treatment of the disease.

The proportion of elderly suffering depression in the current study is 44.6%. This was relatively high as compared to other studies<sup>[15-18]</sup> which reported the proportion ranging from 10.4% to 16%. The shorter version GDS-15 tool was

used in the current study. The use of this shorter version tool for screening depression in geriatric population was

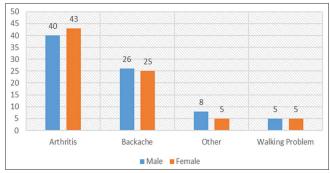
Table 2: Mean Geriatric Depression Scale score according to sociodemographic parameters of study individuals (n=157)

	Nondepressed	F-test,	Depressed	F-test, P
Age category (years)				
60-74	1.64 (2.0)	0.98	10.1 (2.8)	0.38
75-84	1.67 (2.8)		8.6 (0.57)	
≥85				
Gender				
Male	1.92 (2.2)	0.15	10.1 (2.8)	0.94
Female	1.29 (1.7)		10.0 (2.8)	
Residence				
Rural	1.59 (2.1)	0.76	10.7 (1.9)	0.22
Urban	1.72 (1.9)		9.1 (2.1)	
Education				
Illiterate	1.32 (1.9)	0.06	11.1 (3.0)	0.64
Primary	0.86 (1.5)		9.9 (2.8)	
Middle	1.65 (2.1)		10.4 (1.9)	
Secondary	3.43 (1.3)		8.5 (2.2)	
Graduate and above	1.14 (2.0)		9.0 (2.4)	
Marital status				
Married	1.61 (2.0)	0.34	10.1 (2.8)	0.18
Widow/widower	3.00 (1.1)		8.2 (1.7)	
Religion				
Hindu	1.69 (2.0)	0.80	10.1 (2.7)	0.37
Muslim	1.25 (1.8)		11.2 (3.8)	
Others	1		7	
Living arrangement				
With spouse	2 (2)	0.42	9.2 (2.5)	0.6
With spouse and	1.65 (2.0)		10.2 (2.8)	
children				
With children	0.4 (2.3)		9.8 (3.0)	
Alone	2.5 (2.3)			
Economic dependence				
Independent	1.29 (1.9)	0.11	9.11 (2.5)	0.39
Partially dependent	3.5 (2.3)		10.7 (3.4)	
Dependent	1.71 (1.9)		10.3 (2.7)	
Socioeconomic status				
Upper	1.11 (1.9)	0.82	10.2 (2.9)	0.02
Upper middle	1.76 (2.2)		8.8 (2.6)	
Middle	1.55 (2.1)		8.7 (2.4)	
Lower middle	1.44 (1.6)		11.6 (2.4)	
Lower	2.05 (2.1)		9.6 (2.8)	

found to report high prevalence.<sup>[15]</sup> Such a high prevalence was reported earlier by Sanghamitra Maulik<sup>[19]</sup> among 82 elderly in a rural area of Hooghly district of West Bengal as 53.7%, by Reddy *et al.* from the rural area of Valadi, Tamil Nadu, as 47%,<sup>[20]</sup> and by Ghimire *et al.* in 289 elderly as 57.4%.<sup>[21]</sup>

Boyanagari *et al.* used the GDS-15 scale in their study and reported a Cronbach's alpha reliability of this tool as 0.81.<sup>[22]</sup> In the current study, it is 0.69. A value of Cronbach's α between 0.6 and 0.7 indicates acceptable reliability and a moderate degree of correlation between items. An item-total statistics table showed a very high degree of a positive correlation between all items.

Respondent's age, sex, marital status, educational status, living status, and economic dependency were not found to be associated with depression in earlier studies.<sup>[14,15]</sup> In another study, female preponderance, illiteracy, and staying alone were significant risk factors for depression,<sup>[19]</sup> whereas in the current study, no such significant association of depression with various sociodemographic profile was reported.



**Figure 1:** Gender-wise distribution of major health problems in the study participants (n = 157)

Table 3: Geriatric Depression Scale score category across various clinical parameters of study participants (n=157)

	Nondepressed, n (% with 95% CI)	Depressed, n (% with 95% CI)	P
BMI category			'
Underweight	3 (42.8, 35.1-50.5)	4 (57.2, 49.5-64.9)	>0.05
Normal	49 (60.5, 52.9-68.1)	32 (39.5, 31.9-47.1)	
Overweight	28 (51.9, 44.1-59.7)	26 (48.1, 40.3-55.9)	
Obese	7 (46.7, 38.9-54.5)	8 (53.3, 45.5-61.1)	
Waist circumference (cm)			
Low risk	44 (56.4, 48.6-64.2)	34 (43.6, 35.8-51.4)	>0.05
High risk	43 (54.4, 46.6-62.2)	36 (45.6, 37.8-53.4)	
Blood pressure (category)			
Normal	17 (73.9, 67-80.8)	6 (26.1, 19.2-33)	>0.05
Prehypertensive	57 (50.4, 42.6-58.2)	56 (49.6, 41.8-57.4)	
Stage I hypertension	11 (61.1, 53.5-68.7)	7 (38.9, 31.3-46.5)	
Stage II hypertension	2 (66.7, 59.3-74.1)	1 (33.3, 25.9-40.7)	
Hearing assessment			
Impaired	2 (28.6, 21.5-35.7)	5 (71.4, 64.3-78.5)	>0.05
Normal	85 (56.7, 48.9-64.5)	65 (43.3, 35.5-51.1)	

BMI: Body mass index, CI: Confidence interval

Table 4: Mean Geriatric Depression Scale score category across various clinical parameters of study participants (*n*=157)

	Nondepressed	F-test,	Depressed	F-test,
		Р		Р
BMI category				
Underweight	0.67 (1.15)	0.87	10.5 (3.0)	0.60
Normal	1.6 (2.06)		11.0 (3.06)	
Overweight	1.6 (2.02)		9.0 (2.44)	
Obese	1.7 (2.3)		9.5 (2.07)	
Waist circumference				
(cm)				
Low risk	1.5 (2.01)	0.78	9.9 (2.69)	0.70
High risk	1.7 (2.07)		11.5 (2.0)	
Blood pressure				
(category)				
Normal	1.2 (1.81)	0.01	12 (3.5)	0.23
Prehypertensive	1.4 (1.9)		9.8 (2.6)	
Stage I hypertension	3.5 (2.16)		9.5 (3.2)	
Stage II				
hypertension				
Hearing assessment				
Impaired	1.5 (1.87)	0.25	9.2 (1.78)	0.48
Normal	1.6 (2.01)		10.5 (2.2)	

BMI: Body mass index

Table 5: Average unhealthy and activity limitation days across gender (n=157)

Category	Mean	Test of	
	Female ( <i>n</i> =78)	Male (n=79)	significance t, P
Physical	19.6±10.6	18.9±10.3	0.419, 0.67
Mental	17.7±11.6	16.6±10.5	0.622, 0.53
Painful	22.2±9.9	17.0±11.6	0.419, 0.67
Sleeplessness	22.6±10.2	15.9±9.6	4.23, 0.001
Anxiety	22.3±9.9	20.3±9.4	1.29, 0.193
Activity limitation	$20.4 \pm 12.3$	$20 \pm 10.3$	0.220, 0.82

SD: Standard deviation

Table 6: Distribution of Instrumental Activities of Daily Living dependency by sex (n=157)

IADL dependency	Male, n (%)	Female, n (%)	Test of significance $\chi^2$ , $P$
Independent	32 (40.5)	25 (32.1)	1.21, 0.13
Dependent	47 (59.5)	53 (67.9)	

IADL: Instrumental Activities of Daily Living

The current study observed no relationship between blood pressure level and depressed state which is in line with the findings of Rajkumar *et al.*<sup>[16]</sup> The normotensives have a low proportion of depression, but this association was not significant. A very low proportion, 4.6% of study individuals were undernourished in our study whereas other authors reported much higher proportion. <sup>[18,21,22]</sup> Unilateral hearing impairment showed higher odd for the presence of depression in bivariate analysis. <sup>[16]</sup> While another study reported higher odd for depression in bilateral hearing impairment, <sup>[15]</sup> the current study reported 4.6% hearing impairment in elderly, which is in contrast to the finding of Boyanagari *et al.*<sup>[22]</sup> where hearing impairment was more than 30%.

The current study reported mean GDS score above 8.2 across various categories of sociodemographic variables without any significant association. Whereas in another study, the mean score for GDS was more in literate people and high score was associated with older age.<sup>[7]</sup>

The current study reported only 2% of the respondents to be fully dependent using the ADL tool. The UNFPA report documented<sup>[2]</sup> that ADL limitation was more for older women than men with 9% of the older women and 6% of the older men, needing assistance with at least one activity. Among the activities, the highest proportion of the elderly faced some difficulty in bathing followed by going to the toilet. [2] Disability status was not associated with depression.<sup>[16]</sup> Shanbhag et al. assessed the functional ability of 181 elderly and found out that 97% were partially dependent for ADL and 45% were not freely mobile.[18] Kavya et al.[23] in her study on 91 elderly found out that 25% of the elderly had decrease ability in performing ADL. Boyanagari et al. in their study observed that 98% of the elderly were dependent for ADL.[22] Ohri et al. assessed ADL and IADL on 215 elderly people and reported maximum inability in breathing and dressing, and female elderly being more dependent than male.[24]

The current study observed that the maximum unhealthy days were due to sleeplessness (22.6 days) followed by anxiety (22.3 days) in men. The women reported less number of unhealthy days.

#### CONCLUSION

The current study concludes that there is a very high proportion of elderly participants who are experiencing depression using the GDS-SF tool, and this depression was not associated with sociodemographic factors or their clinical parameters. The ADL limitation was very low and the majority of them were independent in their activity of daily living. Hence, there should be regular screening and treatment for depression in this age group even in a tertiary care setting.

#### Limitations

- It was a hospital based study. Therefore the external validity of the the findings are limited
- The majority of the study participants were in the age group of 60–74 years and the proportion of the oldest old was very low
- The other clinical departments were not included in the study setting.

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#### Conflicts of interest

There are no conflicts of interest.

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## Anemia among pregnant women attending antenatal clinic at a secondary health care facility in district Faridabad, Haryana

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#### **Abstract**

**Background:** India confronts a high burden of anemia among pregnant women, that contributes to significant morbidity and mortality for mother and child. Anemia Mukt Bharat strategy launched by Government of India envisages provision of variety of facility-based interventions for management of anemia in pregnancy. Secondary care hospitals prescribe injectable iron treatment for moderate anemia and blood transfusion services for severe anemia.

**Objective:** To estimate the magnitude and severity of anemia among pregnant women when they presented themselves for the first time at the antenatal care clinic of a secondary care hospital so as to forecast adequate supplies of medicines for managing anemia.

Materials and Methods: This was a descriptive study using routinely maintained hospital clinical records during the years 2013–2015. It was conducted in a subdistrict hospital, Ballabhgarh in Faridabad district of Haryana state. Hemoglobin (Hb) level was routinely measured at first visit for all pregnant women using BC-3000 plus autohematology analyzer. Anemia in pregnancy was considered when Hb concentration was <11.0 g/dL.

**Results:** The Hb level at first visit was available for 13,467 women during the study period. The mean Hb level (standard deviation) was 9.3 g/dL (1.3). The proportion of anemic pregnant women was 91.3% (95% confidence interval [CI]: 90.8, 91.7). The most common category of anemia was moderate anemia 62.5% (95% CI: 61.6, 63.2).

**Conclusion:** We found a very high prevalence of anemia in pregnant women presenting to a secondary care setting of a North Indian hospital during their first visit to the facility during the antenatal period.

Keywords: Anemia, Ballabhgarh, pregnancy, secondary care

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#### INTRODUCTION

Anemia is one of the most common prevalent nutritional public health problems globally and in India. Anemia has significant adverse health consequences affecting social and economic development. The World Health

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Organization (WHO) estimates anemia to affect 800 million children and women in year 2011. The global prevalence of anemia for pregnant women was 38.2% (95% confidence interval [CI] 33.5–42.6)<sup>[1]</sup> during the year 2011. According to recent round of National Family Health

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Survey-4 (NFHS-4) (2015–2016), 50% pregnant women in India were anemic,<sup>[2]</sup> indicative that the condition is of severe public health significance.<sup>[3]</sup>

Approximately 50% of anemia among women is due to iron deficiency. <sup>[4]</sup> Iron deficiency anemia during pregnancy is associated with higher morbidity and mortality among both mother and child. <sup>[5]</sup> In year 2012, the World Health Assembly Resolution 65.6 endorsed a comprehensive implementation plan on maternal, infant, and young child nutrition <sup>[6]</sup> that targeted 50% reduction of anemia in women of reproductive age group. <sup>[7]</sup>

The Indian Public Health Service Standards and quality benchmarks for secondary care hospitals prescribes injectable iron treatment for moderate anemia and blood transfusion services for severe anemia. [8,9] Early identification of pregnant women with moderate and severe anemia is of particular importance. It would give us sufficient time to correct their anemic status; and thus, the mother—child pair could expect to reap benefit from the intervention.

Therefore, we tried to estimate the magnitude and severity of anemia among pregnant women when they presented themselves for the first time at the antenatal care clinic of a secondary care hospital. For provision of efficient services and inventory management of supplies, such an information is a necessity.

#### MATERIALS AND METHODS

#### Design

This was a descriptive study using routinely maintained hospital clinical records.

#### Study setting

The study was conducted in a subdistrict hospital (SDH), Ballabhgarh in Faridabad district of Haryana state. This was a secondary care hospital, with outpatient and inpatient services. Antenatal care clinic was held thrice in a week. The hospital also provided delivery services that included normal, assisted deliveries, and cesarean sections. Both basic and emergency obstetric care services were available for pregnant women at SDH Ballabhgarh.

#### Study population

The study population comprised of pregnant women attending antenatal outpatient department at SDH Ballabhgarh during the years 2013–2015 (January–December). The hospital is located in Ballabhgarh town with a population around 187,000. Pregnant women who registered themselves for the first time for antenatal care

were included. These pregnant women mostly resided in area adjoining SDH Ballabhgarh and surrounding areas from Faridabad and Palwal districts. Largely, the population belonged to urban and peri-urban area and represented lower to middle socioeconomic strata. More details about our hospital and other services are mentioned elsewhere. [10] Hemoglobin (Hb) level was routinely measured at first visit for all pregnant women.

#### **Tools**

Hb was measured using BC-3000 plus autohematology analyzer (Mindray bio-medical electronics Co., Ltd.; Shenzen, Guangdong, China). This was a quantitative, automated hematology analyzer for *in vitro* diagnostic use in clinical laboratories. Two milliliters of blood was obtained by venepuncture following aseptic conditions by a trained laboratory technician within SDH, Ballabhgarh, and collected in a salt of dipotassium ethylenediaminetetraacetic acid. The sample was then subjected to analyzer, and hemoglobin was estimated using colorimetric method. Well-qualified laboratory technician performed the testing procedure. For each batch of test, simultaneous running control panels as recommended by the manufacturer of the machine were also included as a quality control measure.

#### Data collection, entry, and analysis

Data were retrieved through records and registers maintained within the laboratory of SDH, Ballabhgarh. The relevant details pertaining to registered pregnant women including registration number, age, and Hb level at the time of first visit were entered in Microsoft Office Excel spreadsheet database. Women, whose Hb measurement was missing, were excluded from the analysis. The analysis was done by STATA software version 12.0 (StataCorp., College Station, Texas, USA). The data are descriptively summarized.

Operational definitions for the study: The WHO recommendations for Hb concentrations were used for reporting anemia in this study. Anemia in pregnancy was considered when Hb concentration was <11.0 g/dL. Mild anemia was considered when Hb concentration range was between 10.0 and 10.9 g/dL. Moderate anemia was considered when Hb concentration was between 7.0 and 9.9 g/dL and severe anemia was taken as Hb concentration less <7.0 g/dL.

#### RESULTS

A total of 17,428 pregnant women were registered during 2013–2015. Of these, measurement of Hb level at first visit was available for 13,467 women. The remaining 3961 (23%)

pregnant women whose Hb level was not available were excluded from further analysis. The mean age (standard deviation [SD]) of the pregnant women was 23.8 (3.6) years.

The range of Hb level was from 2.5 g/dL to 15.2 g/dL. The distribution of Hb level is shown in Figure 1. The mean Hb level (SD) was 9.3 g/dL (1.3).

The proportion of anemic pregnant women was 91.3% (95% CI: 90.8, 91.7) [Table 1]. The proportion of mild anemia was 23.9% (95% CI: 23.2, 24.6). The most common category of anemia was moderate anemia 62.5% (95% CI: 61.6, 63.2). The proportion of severe anemia was 4.9% (95% CI: 4.6, 5.3). Mean Hb concentrations in these categories are represented in Table 1.

#### **DISCUSSION**

The WHO defines anemia to be of severe public health significance when it is present in >50% of the concerned population group. [3] The reported prevalence of anemia among antenatal women ranges from 50% to 96%. [11-15] The wide range in the reported prevalence in these studies could be due to variation in demographic profile, place of residence, sociocultural reasons, dietary differences, study methodology, sample size, Hb testing procedures, etc., The most recent round of NFHS-4 (2015–2016) reported overall 50% of pregnant women in urban Haryana to be anemic. [16] The Hb level in NFHS-4 was measured by

Table 1: Distribution of first-time antenatal care clinic attendees at subdistrict hospital, Ballabhgarh by their anemia status, 2013–2015

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Anemia status (Hb in g/dL)	n	Percentage (95% CI)	Mean Hb (SD)
Normal (11.0 or higher)	1,176	8.7 (8.3-9.2)	11.6 (0.6)
Mild (10.0-10.9)	3,215	23.9 (23.2-24.6)	10.2 (0.3)
Moderate (7-9.9)	8,410	62.5 (61.6-63.2)	8.9 (0.8)
Severe (<7.0)	666	4.9 (4.6-5.3)	5.9 (0.8)
Total		1,467	

Hb: Hemoglobin, CI: Confidence interval, SD: Standard deviation

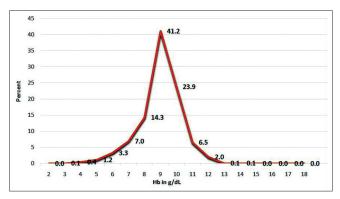


Figure 1: Distribution of pregnant women at subdivisional hospital, Ballabhgarh by their hemoglobin level

HemoCue method. We had used automated hematology analyzer for measuring Hb. Automated analyzers have higher precision for detecting anemia over HemoCue method. [17] Despite the decline noted over different rounds of NFHS, the prevalence of anemia had remained >50%, indicating that anemia was of severe public health significance. [18] Our finding of 91.3% of pregnant women reporting to SDH being anemic was much higher than the 55% (overall) reported for pregnant women in Haryana in NFHS-4. One possible reason could be due to our antenatal services being free, had attracted urban poor in greater proportion. Urban poor are more likely to be anemic. [19,20]

A study conducted in two villages of Delhi among women in early pregnancy (12-20 weeks of gestation) reported similar high proportions of pregnant women to be anemic (96.5%) as found in our study. [21] A multicentric study conducted in seven states of India reported anemia in 84% of pregnant women. The study found maximum women having moderate degree of anemia (51%), [22] which was similar to our findings. A previous community-based study in our study area had reported 73.4% of pregnant women deficient in iron and 75% were consuming <50% of the recommended iron.<sup>[23]</sup> However, we had not ascertained factors associated with anemia in our study. Urban poor are likely to be underweight with low education and higher number of births. These factors have been found to be associated with higher odds for moderate and severe anemia.<sup>[21]</sup> We had not collected information on socioeconomic status and residential address. However, if our assumption that large proportion of pregnant women reporting to SDH were urban poor is correct, then it would explain the high rate of prevalence observed.

The proportion of pregnant women with moderate anemia was largest. Correction of their anemic status or even shifting them to milder status of anemia through appropriate therapeutic interventions will be beneficial to the women themselves as well as the unborn baby. The Indian Obstetric Surveillance System in Assam reported women with severe anemia had higher odds of Post-Partum Hemorrhage (PPH) (adjusted odds ratio [aOR] 9.5, 95% CI:2.6, 34.0); low birth weight babies (aOR 6.2, 95% CI: 1.4, 26.7) and small for gestational age babies (aOR 8.7, 95% CI: 4.4, 61.5). Odds of PPH increased seventeen fold among women with moderate-to-severe anemia who underwent induction of labor and nineteen fold among women who had infection and moderate-to-severe anemia. [24] We found that the proportion of severely anemic pregnant women were 5%. Such women were thus at a higher risk of adverse pregnancy outcome.

In year 2016, the hospital took a policy decision to implement recommendations of Indian Public Health Services Standards for treatment of moderately anemic pregnant women by injectable iron. We had chosen to administer intravenous iron-sucrose (IVIS) which came as vial each containing 100 mg of elemental iron. The management was faced with the question regarding numbers of vials of IVIS to be procured to implement the program. To answer this question, two information were crucial, i.e., total number of moderately anemic women and their mean Hb level. The current study findings provided both the information. Thus, based on these information, we could use Ganzoni formula<sup>[25]</sup> to calculate average amount of elemental iron required for each moderately anemic pregnant women. This formula considers weight of woman and current Hb level to calculate dose for computing iron deficit. The recently initiated test and treat strategy under Anemia Mukt Bharat strategy as part of Intensified National Iron plus Initiative recommends point-of-care treatment for anemic individuals including oral and injectable preparations. It requires planning and maintaining adequate supplies at the facility level for providing appropriate care to anemic women. We were therefore able to take informed decision regarding the number of IVIS vials to be procured for efficient service provision. Our findings are of great relevance to similar settings and facilities that are managing anemia in pregnancy. Our study found that moderate anemia is the most common presentation among pregnancy, and thus, if these women be managed adequately during the pregnancy period, the iron reserves can sufficiently be increased to mitigate the risks posed during pregnancy and childbirth both for mother and baby.

The data were retrieved from records/registers and therefore likely to be unbiased. Tool used for measurement of Hb was appropriate. The staff was well qualified, and quality control measures were in place. Hence, the Hb measurement was valid. The analysis included large numbers of pregnant women who reported to ANC clinic of a secondary care hospital. This yielded a more precise estimate of prevalence of anemia with narrow CIs. We did not have Hb level of 3961 women and were excluded from this analysis. Missing data is a usual limitation of retrospective reviews conducted with routine clinical records. We could not identify any particular reason which could cause those included to be systematically different from those excluded. Therefore, though a large proportion (23%) of pregnant women were excluded from the analysis, we believe it would not adversely affect the validity of the findings. Based on our personal experience, we had assumed that the pregnant women came from area adjoining SDH. However, we do not have firm data to validate this assumption. In the absence of residential address of the pregnant women attending this hospital, the findings of this study may not be extrapolated to any specific population group. Hence, severity in public health terms cannot be directly deemed. Furthermore, we did not have details of women regarding their period of gestation, past obstetric history, etc., that could affect their Hb concentration. This was because Hb level of women were retrieved from laboratory registers that did not capture these additional information. Furthermore, our primary objective was to see the distribution of Hb concentrations among the pregnant women and not ascertain the determinants of anemia in these women. To examine them, additional details would be required including the dietary intake of the women and can be captured in future by conducting further cross-sectional and prospective studies in our setting.

#### **CONCLUSION**

We found a very high prevalence of anemia in pregnant women (91%) with moderate degree of anemia the most common (62.5%) among all categories of anemia. Based on the magnitude and proportion of different categories of anemia, we were able to forecast the requirement of iron-sucrose vial for managing pregnant women reporting to SDH Ballabhgarh.

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#### **Conflicts of interest**

There are no conflicts of interest.

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# Effectiveness of daily directly observed treatment, short-course regimen among patients registered for treatment at an urban primary health center in Bengaluru

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#### **Abstract**

**Background:** Tuberculosis (TB) is a major public health problem in India with high morbidity and mortality. As per the World Health Organization guidelines, the Revised National Tuberculosis Control Program introduced daily directly observed treatment, short-course (DOTS) regimen with a fixed-dose combination with weight bands. This study was undertaken to compare the effectiveness of daily DOTS regimen with intermittent regimen and to assess the proportion of adverse drug reactions in both groups.

**Materials and Methods:** A descriptive study was conducted at a peripheral health institute under one of the TB Units in South Bengaluru. Participants registered for treatment during the third and fourth quarter of 2017 were selected using continuous sampling. Data were collected by case record analysis, structured interviews, and telephonic follow-up.

**Results:** The study included 81 participants, with the mean age of  $40 \pm 16.1$  years. Majority of the study participants 55 (67.9%) were male, and majority (38 [46.9%]) belonged to the upper-lower class. Forty-two (51.8%) of the study participants were on intermittent regimen, and 39 (48.1%) were on daily DOTS regimen. There was 100% sputum conversion at the end of treatment under both treatment regimens. A total of 36 (85.7%) participants under intermittent regimen and nine (23%) under daily regimen developed one or the other adverse drug reactions. The treatment success for participants under intermittent regimen was 38 (90.47%) and that for daily regimen was 35 (89.74%). However, there was no statistically significant difference between the two groups. **Conclusion**: Both daily and intermittent DOTS regimens are equally effective in TB treatment, but adverse drug reactions were more common with the intermittent regimen.

Keywords: Daily regimen, directly observed treatment, intermittent regimen, short-course, treatment outcome

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#### INTRODUCTION

Tuberculosis (TB) is an ancient disease known to humankind, which continues to cause significant morbidity

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and mortality despite the availability of highly efficient diagnostic tests and effective treatment. India accounts for one-fourth of the global TB burden with an incidence of

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28 lakh and mortality of 4.8 lakh, which amounts for the highest number of TB and multidrug-resistant TB cases in the country according to the global TB report published by the World Health Organization (WHO).<sup>[1,2]</sup>

The National Tuberculosis Program was initiated in India during 1962 which was revised in 1997 as the Revised National Tuberculosis Control Program (RNTCP) that used WHO recommended (directly observed treatment, short-course [DOTS] chemotherapy) strategy. Although DOTS was implemented throughout the country by the year 2006, the number of cases of TB continued to raise simultaneously with increased number of relapses and drug-resistant TB cases.<sup>[3]</sup>

In this regard, in March 2016, RNTCP introduced daily DOTS regimen with fixed-dose combination in a phased manner for the treatment of TB patients; to make the treatment more effective, reduce the relapses, and the incidence of drug resistance in TB patients.<sup>[4]</sup>

There are very few studies comparing the effectiveness of intermittent with daily DOTS regimens. In the district where the study site is located, the daily DOTS regimen was started from October 2017. Since it is the transition period between the switch over from intermittent to daily DOTS regimen, this study was taken up to compare the effectiveness of daily and intermittent DOTS regimens and to find out the proportion of adverse drug reactions in both the regimens.

#### MATERIALS AND METHODS

#### Study design

The study design was a descriptive study.

#### Study site

The descriptive study was conducted at the peripheral health institute under one of the TB units in Bengaluru.

#### Sampling

The sampling used was continuous sampling.

#### Sample size

All cases registered for the treatment during the last quarter of 2017 for daily regimen, and cases registered for the treatment during the third quarter of 2017 for intermittent regimen.

#### Inclusion criteria

The inclusion criteria are as follows:

- Patients registered for TB treatment during the third and fourth quarter of 2017 at a peripheral health institute attached to a TB unit in Bengaluru
- Patients consenting for the study.

#### **Exclusion criteria**

• Seriously ill patients were excluded from the study.

The data collection was started after obtaining permission from the Institutional Ethics Committee of the medical college and the District Tuberculosis Officer, Bengaluru.

The sociodemographic profile of all the participants was collected from the treatment cards and structured interviews. Details regarding the profile of TB, which included the type of TB, the patients were suffering from, prior treatment for TB, test used for diagnosis, and category of DOTS regimen were collected through treatment cards. The socioeconomic status classification was done using the modified Kuppuswamy's classification with updated income ranges for 2018.<sup>[5]</sup>

Information regarding the comorbidities that patients were suffering from, including HIV status and diabetes, were collected from the treatment cards.

A case record analysis of the participants registered for the treatment from July 2017 to September 2017 was done for assessing the treatment outcome at the end of the intensive phase and at the end of treatment in terms of sputum conversion and weight gain (only for bacteriologically confirmed cases of pulmonary TB).

Similarly, assessment of the cases registered for the treatment from October 2017 to December 2017 was done for the treatment outcome at the end of the intensive phase and at the end of treatment in terms of weight gain, sputum conversion (only for bacteriologically confirmed cases of pulmonary TB), and adverse drug reactions during the treatment were collected by the personal and telephonic follow-up.<sup>[6,7]</sup>

Data were entered in Microsoft Excel 2010 and analyzed using openEpi software (Open Source Epidemiologic Statistics for Public Health). Descriptive statistics such as mean and standard deviation were used. Inferential statistics such as Chi-square test was used to test the association between treatment success and different treatment regimens.

#### **RESULTS**

The present study included 81 participants fulfilling the inclusion and exclusion criteria. The mean age of the study participants was  $40 \pm 16.1$  years. Majority of the study participants were male 55 (67.9%). Sixty-four (79.1%) of the study participants were Hindus and 17 (20.9%) were Muslims by religion. Majority of the participants,

38 (46.9%) belonged to the upper-lower class followed by the lower class 20 (24.7%), lower middle 18 (22.2%), and rest belonged to the upper class. A total of 75 (92.6%) participants were married and 73 (90.1%) of the participants lived in a nuclear family [Table 1].

The profile of TB was as follows: majority (56 [69.1%]) of the participants were suffering from pulmonary TB and 25 (30.9%) from extrapulmonary TB. Sixty-six (81.5%) were treated with Category I DOTS therapy and 15 (18.5%) on Category II. The number of participants started on treatment during the third quarter of 2017 (i.e., intermittent regimen) was 42 (51.8%), and the number of participants started on treatment during the last quarter (i.e., daily DOTS regimen) was 39 (48.1%). Sixty-two (76.5%) participants were microbiologically confirmed which included sputum microscopy/CBNAAT and 19 (23.4%) were clinically diagnosed [Table 2].

None of the study participants were HIV-positive, and 24 (29.6%) participants were suffering from diabetes. A total of 15 (18.5%) participants were smokers, and 13 (16%) of the participants were alcoholics. The mean weight gain among participants on daily regimen was  $2.7 \pm 2.2$  kg and that among patients on intermittent regimen was  $2.4 \pm 2.3$  kg at the end of the intensive phase. Similarly, the mean weight gain at the end of treatment was  $3.2 \pm 2.6$  Kg for daily regimen and  $3.6 \pm 2.9$  Kg for intermittent regimen. However, on applying *t*-test, there was no statistically significant difference in the weight gain between the two groups both at the end of the intensive phase and at the end of the treatment.

All the 28 (66.7%) participants under intermittent regimen with smear-positive status at the beginning of treatment had sputum conversion at the end of the intensive phase, i.e., no TB bacilli was detected at the end of the intensive phase; hence, it was 100% conversion. However, of the 28 (71.8%) participants under daily regimen having initial sputum-positive status, four (14.3%) participants continued to have the sputum-positive status even at the end of the intensive phase; hence, the conversion rate was 85.7% for the daily regimen. At the end of the treatment, the sputum conversion was 100% for both the regimens; however, on applying the Chi-square test, there was no statistically significant association between the groups [Table 3].

On assessing the final treatment outcome of the 39 participants under daily DOTS regimen, 26 (66.7%) participants were labeled cured, 9 (23%) treatment completed, 3 (7.7%) participants died during the treatment, and 1 (2.6%) participant was diagnosed with extensively

Table 1: Distribution of the study participants based on sociodemographic profile

	Intermittent regimen (n=42)	Daily regimen (n=39)
Sex		
Male	28 (66.7)	27 (69.2)
Female	14 (33.3)	12 (30.8)
Religion		
Hindu	27 (64.3)	37 (94.8)
Muslim	15 (35.7)	2 (5.1)
Socioeconomic class		
Upper	2 (4.8)	2 (5.1)
Upper middle	-	1 (2.6)
Lower middle	15 (35.7)	3 (7.7)
Upper lower	17 (40.5)	21 (53.8)
Lower	8 (19.0)	12 (30.8)

<sup>\*</sup>Figures in parenthesis indicate percentage

Table 2: Distribution of the study participants based on the profile of tuberculosis

	Intermittent regimen (n=42)	Daily regimen (n=39)
Disease classification		
Pulmonary	28 (66.7)	28 (71.8)
Extrapulmonary	14 (33.3)	11 (28.2)
Basis of diagnosis		
Microbiologically confirmed	31 (73.8)	31 (79.5)
Clinically diagnosed	11 (26.2)	8 (20.5)
Category of DOTS treatment		
Category I	35 (83.3)	31 (79.5)
Category II	7 (16.6)	8 (20.5)

<sup>\*</sup>Figures in parenthesis indicate percentage. DOTS: Directly observed treatment, short-course chemotherapy

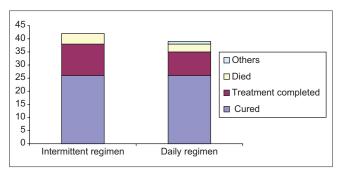
Table 3: Distribution of study participants based on treatment outcome at the end of the intensive phase

	Intermittent regimen (n=28)	Daily regimen (n=28)
Sputum conversion Yes No	28 (100) -	24 (85.7) 4 (14.28)
	Intermittent regimen (n=42)	Daily regimen (n=39)
Weight gain (in kg) Mean±SD Range	2.4±2.3 0-10	2.7±2.2 0-14

<sup>\*</sup>Figures in parenthesis indicate percentage. SD: Standard deviation

drug-resistant TB [Table 4]. Similarly, of the 42 participants on intermittent DOTS regimen, 26 (61.9%) were labeled cured, 12 (28.6%) treatment completed, and 4 (9.5%) participants died during the course of treatment. No participants were lost to follow-up during the course of treatment [Table 4 and Graph 1].

Just 9 (23%) participants on daily regimen developed some sort of adverse drug reactions with the most common one being generalized itching, and 36 (85.7%) participants on intermittent regimen had one or the other adverse drug reactions with fatigue being most common [Table 5].



**Graph 1:** Distribution of the study participants based on the treatment outcome

Thirty-five (89.7%) participants had overall treatment success (participants with treatment outcome as cured and treatment completed) under daily DOTS regimen and 38 (90.4%) participants under intermittent regimen. However, there was no statistically significant difference between the two treatment regimens in terms of treatment success [Table 6].

#### **DISCUSSION**

The Government of India has made tremendous efforts to control TB and ultimately eliminate TB by 2025. A strong commitment toward TB control is seen since the inception of National Tuberculosis Control Program in 1962, and subsequently, RNTCP was implemented as pilot project from 1993 and implemented throughout India by the year 2006. Accordingly, the treatment regimens were more standardized and adequate treatment supply was ensured. Despite efforts, even after the pan India implementation of RNTCP, the burden of the disease continued to be high, and hence, the government revised the treatment and operational guidelines in 2016 based on the revised guidelines published by the WHO, and accordingly, daily regimen was one of the strategies. [1,3,4,8]

Majority of the study participants in the present study were in the age group of 30–40 years, but in a study conducted in Kolkata in 2011 revealed that majority of the study participants were in the age group of 21–40 years.<sup>[9]</sup>

At the end of the intensive phase, the sputum conversion rate was 100% for participants taking intermittent regimen and 85.7% for participants taking daily regimen. However, in a clinical trial conducted at the National Institute of Research in Tuberculosis, Chennai, it was observed that daily treatment was better than the intermittent regimen which may be attributed to different study settings. [10]

The cure rate in the current study was 61.9% for participants under intermittent regimen and 66.7% for those under daily

Table 4: Distribution of study participants based on treatment outcome at treatment completion

Distribution	Intermittent regimen (n=28)	Daily regimen (n=28)
Sputum conversion Yes No	28 (100) -	28 (100) -
Distribution	Intermittent regimen (n=42)	Daily regimen (n=39)
Weight gain (in kg)		
Mean±SD	3.6±2.9	3.2±2.6
Range	0-14	0-15
Treatment outcome		
Cured	26 (61.9)	26 (66.7)
Treatment completed	12 (28.6)	9 (23)
Treatment success	38 (90.47)	35 (89.74)
Died	4 (9.5)	3 (7.7)
XDR	- '	1 (2.6)

<sup>\*</sup>Figures in parenthesis indicate percentage. SD: Standard deviation, XDR: Extensively drug resistant

Table 5: Distribution of study participants based on adverse reactions following treatment

Adverse reactions#	Intermittent regimen (n=42)	Daily regimen (n=39)		
Abdominal pain	7 (16.6)	2 (5.1)		
Generalized itching	7 (16.6)	9 (23)		
Fatigue	19 (45.2)	4 (10.3)		
Chest pain	6 (14.3)	2 (5.1)		
Sleep disturbances	4 (9.5)	1 (2.6)		
Joint pain	12 (28.6)	5 (12.8)		
Vomiting	14 (33.4)	7 (17.9)		
Reduced appetite	4 (9.5)	2 (5.1)		

<sup>\*</sup>Figures in parenthesis indicate percentage, #Indicates >1 response

Table 6: Comparison of treatment success of daily and intermittent regimens

Treatment success	Intermittent regimen (n=42)	Daily regimen (n=39)	χ², <b>P</b>	
Yes	38 (90.5)	35 (89.7)	0.002,	
No	4 (9.5)	4 (10.3)	>0.05	

<sup>\*</sup>Figures in parenthesis indicate percentage

regimen, but according to a study done in South India, the cure rate for participants taking intermittent regimen was 84% which may be attributed to the differences in the sociodemographic characteristics of the participants. Similarly, a study conducted by us at a TB unit, Bengaluru, the treatment success rate was 80.9% which is again less than the objective of 85% set by RNTCP. Similarly, a study done at a tertiary hospital in Kolkata concluded that sputum conversion rate and treatment success rate at the end of intensive phase were almost similar in both regimens. [9-12]

On assessing the adverse drug reactions, the intermittent regimen had more adverse reactions compared to daily regimen, which may be attributed to the lack of weight bands in the participants receiving intermittent regimen. However, a study done at a tertiary hospital in Kolkata, India, observed that the incidence of adverse drug reactions was more among the patients taking treatment under daily DOTS regimen. [9]

#### CONCLUSION

The treatment success rates for the daily and intermittent regimens were almost the same with no statistically significant difference between them. The weight gain in participants under both the regimens was also the same. The participants under intermittent regimen had better sputum conversion at the end of the intensive phase compared to those taking daily regimen, but the sputum conversion rate was the same at the end of treatment for both the regimens. The adverse drug reactions were more among the participants who took treatment under intermittent regimen compared to daily DOTS regimen; this can be attributed to treatment under daily DOTS regimen based on weight bands. There is a need for similar studies with a larger sample size to confirm the results of the study.

#### Limitation of the study

The study is done on a small sample size in only one peripheral health institute, hence the study findings cannot be generalized.

#### Recommendations

Similar studies at multiple sites in different geographical areas and different clinical settings have to be conducted with a larger sample size to arrive at a better conclusion and to generalize the results.

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#### **Conflicts of interest**

There are no conflicts of interest.

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## A community-based study on awareness of cancer and anticipated barriers in seeking help

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#### **Abstract**

**Introduction:** Cancer is a leading public health problem worldwide. Contributing factors include lack of awareness regarding cancer and improper help seeking behavior.

**Objective**: To assess the awareness regarding early warning signs of cancer, its risk factors and anticipated barriers in seeking help.

**Methodology**: A community-based cross-sectional study was conducted among 470 study participants. Trained workers administered a standardized tool to respondents after obtaining their informed consent. Epi Info software for windows version 7.2 was used for the analysis.

**Results:** Overall, merely 7.7% (36/470) of the study respondents were aware of all the nine warning signs of cancer. The most commonly known early warning sign of cancer was "unexplained swelling" (58.3%). Further, although majority knew that cigarette smoking is a risk factor for cancer (90.4%), very few were aware about the role of inadequate physical activity (9.3%) and diet devoid of adequate amounts of fruits and vegetables (11.9%). There were few anticipated barriers in seeking help such as embarrassment (13.2%) and difficult to interact with a doctor (7.9%).

**Conclusion:** There was inadequate awareness about cancer but a favorable help-seeking behavior. It is, therefore, recommended that health-care professionals should scale up efforts for disseminating information regarding cancer among the people.

Keywords: Cancer, early warning sign, risk factors

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#### **INTRODUCTION**

Cancer is a global public health issue. Its incidence and mortality are rapidly increasing. According to the World Health Organization, worldwide every year, around 10 million people are newly-diagnosed with cancer. There are approximately 7.5 million deaths, of which two-thirds are from developing countries. [1] In India, cancer is a leading cause of death next to cardiovascular disease. [2] The age-standardized cancer incidence rate of

India, according to GLOBOCAN 2018 report, is 89.4/lakh population (females 90.0/lakh; males 89.8/lakh).<sup>[3]</sup> The cancer incidence is comparatively higher in Chandigarh; according to the Population-Based Cancer Registry report (105/lakh in women; 93.4/lakh men).<sup>[4]</sup>

Cancer is caused by both inherited mutations and lifestyle factors such as smoking,<sup>[5]</sup> obesity,<sup>[6]</sup> lack of exercise,<sup>[7]</sup> and poor diet.<sup>[8]</sup> Certain infections such as human papilloma virus (HPV) increase the risk of cervical cancer.<sup>[9]</sup> Cancers

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are preventable if people are aware of their early warning signs and associated risk factors. [10] Research has shown that people lack awareness regarding cancer. Feizi *et al.* in a study conducted in Iran reported that a few respondents had adequate level of knowledge about cancer. [11] Ryan *et al.* in their study among Irish adults documented poor awareness of risk factors for cancer. [12] Babu and Thomas observed a low level of awareness of cancer warning signs among the rural population of Kerala, India. [13] There is a need to document public awareness about the early warning signs of cancer, its risk factors, and anticipated barriers in seeking help. The objective of the current study was, therefore, to find this in a selected area of Chandigarh.

#### **METHODOLOGY**

A community-based cross-sectional study was conducted among individuals aged between 20 and 50 years residing in the rural field practice area of the Department of Community Medicine. A sample size of 480 study participants was calculated using the formula 4pq/P; considering 50% awareness of cancer, 0.05 desired precision, 95% confidence interval, and a non-response rate of 20%. A random selection of houses was done; and in each house one eligible person was interviewed by workers who were trained in administering the questionnaire. Before starting the interview, the study participants were apprised about the objective of the study, and informed consent was obtained. "Cancer Awareness Measure", a validated tool, was used to measure the awareness of warning signs of cancer, anticipated barriers in seeking help, and risk factors of cancer. [14,15] The nine early warning signs included: "unexplained swelling," "persistent unexplained pain," "unexplained bleeding," "persistent cough or hoarseness," "persistent change in bowel habits," "persistent difficulty swallowing," "change in appearance of mole," "sore that does not heal," and "unexplained weight loss." The anticipated barriers in seeking help included "embarrassment," "scared," "worried about wasting the doctor's time," "difficult to talk with doctor," "difficult to make an appointment with doctor," "busy to make time to go to the doctor," etc., The risk factors for cancer included "smoking any cigarettes," "exposure to second-hand cigarette smoke," "alcohol drinking," "eating <5 portion fruit and vegetables a day," etc., moderate physical activity <30 min five times a week, etc.

Epi Info software for windows version 7.2 (Centre for Disease Control, Atlanta, USA) was used for the statistical analysis. Sociodemographic variables were dichotomized (i.e., age [20–35 years and 36 years and above]) and education [illiterate/literate]. The Chi-square test was used to test for testing the relationship between sociodemographic

variables and participants' responses. A value of P < 0.05 was considered statistically significant. The study was approved by the Ethical Committee of the Medical College.

#### **RESULTS**

The study included 470 participants with a response rate of 97.9%. The mean age of the study participants was 30.4 years (SD = 12.6). Of the 470 interviewed study participants, 190 (40.4%) were male. The majority of the study participants were literate (85.3%). Overall, merely 7.7% (36/470) of the study respondents were aware of all the nine warning signs of cancer. Around half of the respondents thought that unexplained lump (58.3%), unexplained bleeding (50.4%), persistent difficulty in swallowing (52.1%), persistent cough or hoarseness of voice (48.5%), and persistent unexplained pain (40.2%) could be early warning signs of cancer. Around one-third felt that sore that does not heal (34.5%) and unexplained weight losses (32.1%) are the early warning signs of cancer. A few respondents opined that persistent change in bowel habits (24.7%) and change in the appearance of mole (22.8%) could also be indicative of cancer.

Among the risk factors, the most frequently recognized risk factors were smoking tobacco (90.4%; [agree 8.7% and strongly agree 81.7%]) followed by exposure to second-hand cigarette smoke (82.7%; [agree 17.0% and strongly agree 65.7%]), and drinking alcohol (70.4%; [agree 33.2% and strongly agree 37.2%]). Around one-fifth knew that being overweight (23.6%) and age >70 can lead to cancer (28.3%). The least recognized risk factors were inadequate physical activity (9.3%; [agree 7.4% and strongly agree 1.9%]) and having an unhealthy diet with <five portions of fruits and vegetables (11.9%; [agree 9.8% and strongly agree 2.1%]). Only 14.7% (agree 10.9% and strongly agree 3.8%) agreed that infection with HPV can lead to cancer. When asked about the anticipated barriers in seeking help; most respondents did not believe that they would be embarrassed (84.7%) or scared (84.3%). Most of them opined that it would not be difficult to talk with a doctor (90.9%), take appointment (84.5%), or arrange transport for going to him/her (87.7%) [Table 1].

The sociodemographic break up shows that female respondents were significantly more likely than males to be aware of warning signs (significant for persistent cough [female 79.1% vs. male 67.7%], persistent change in bowel habits [female 61.0% vs. male 47.4%], change in appearance of mole [female 62.1% vs. male 42.4%], and sore that does not heal [female 72.7% vs. male 59.6%]). Females had significantly higher awareness of all the risk factors of cancer as compared to males such as

Table 1: Awareness of early warning sign, risk factors, and help-seeking behavior of the study population

Serial number	Warning signs of cancer	Yes	No	Don't know			
1a	Unexplained lump or swelling	274 (58.3)	57 (12.1)	139 (29.6)			
1b	Persistent unexplained pain	189 (40.2)	78 (16.6)	203 (43.2)			
1c	Unexplained bleeding	237 (50.4)	72 (15.3)	161 (34.3)			
1d	Persistent cough or hoarseness	228 (48.5)	84 (17.9)	158 (33.6)			
1e	Persistent change in bowel habits	116 (24.7)	100 (21.3)		254 (54)		
1f	Persistent difficulty swallowing	245 (52.1)	56 (11.9)		169 (36)		
1g	Change in appearance of mole	107 (22.8)	105 (22.3)		258 (54	.9)	
1h	Sore that does not heal	162 (34.5)	88 (18.7)		220 (46	.8)	
1i	Unexplained weight loss	151 (32.1)	90 (19.1)		229 (48.	.7)	
-	Awareness of all signs of cancer		3	36 (7.7)			
Serial number	Anticipated barriers in seeking help	Yes often	Yes sometimes	No	Do	n't know	
2a	Too embarrassed	21 (4.5)	41 (8.7)	398 (84.7)		10 (2.1)	
2b	Too scared	25 (5.3)	42 (8.9)	396 (84.3)	7 (1.5)		
2c	Worried about wasting the doctor's time	8 (1.7)	18 (3.8)	436 (92.8)	92.8) 8 (1.7)		
2d	Doctor would be difficult to talk to	12 (2.6)	25 (5.3)	427 (90.9)			
2e	Difficult to make an appointment with doctor	16 (3.4)	50 (10.6)	397 (84.5)			
2f	Busy to make time to go to the doctor	35 (7.4)	44 (9.4)	381 (81.1)			
2g	Many other things to worry about	31 (6.6)	38 (8.1)	390 (83)			
2h	Difficult to arrange transport to the doctor's surgery	16 (3.4)	33 (7)	412 (87.7)	412 (87.7) 9 (1.9)		
2i	Worried about what the doctor might find	23 (4.9)	30 (6.4)	409 (87)	109 (87) 8 (1.7)		
2j	No confidence talking about my symptom with the doctor	8 (1.7)	34 (7.2)	417 (88.7)		11 (2.3)	
Serial number	Awareness of risk factors for cancer	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	
3a	Smoking cigarette	6 (1.3)	1 (0.2)	38 (8.1)	41 (8.7)	384 (81.7)	
3b	Exposure to second-hand cigarette smoke	7 (1.5)	19 (4)	55 (11.7)	80 (17)	309 (65.7)	
3c	Drinking alcohol >1 unit a day	10 (2.1)	33 (7)	96 (20.4)	156 (33.2)	175 (37.2)	
3d	Eating <5 portion fruit and vegetables/day	31 (6.6)	89 (18.9)	294 (62.6)	46 (9.8)	10 (2.1)	
3 e	Eating processed meat once a day or more	22 (4.7)	49 (10.4)	336 (71.5)	53 (11.3)	10 (2.1)	
3f	Being overweight	15 (3.2)	52 (11.1)	292 (62.1)	96 (20.4) 15 (3.2)		
3g	Being over 70 years old	12 (2.6)	64 (13.6)	261 (55.5)	112 (23.8) 21 (4.5)		
3h	Getting sunburnt more than once as a child	15 (3.2)	64 (13.6)	322 (68.5)	, , , , ,		
3i	Having a close relative with cancer	17 (3.6)	62 (13.2)	258 (54.9)	, , , , , , , , , , , , , , , , , , , ,		
3j	Infection with human papilloma virus	9 (1.9)	37 (7.9)	355 (75.5)	51 (10.9)	18 (3.8)	
3k	Doing <30 min of moderate physical activity five times a week	22 (4.7)	67 (14.3)	337 (71.7)	35 (7.4)	9 (1.9)	

Numbers in brackets denote the percentage

smoking (99.6% vs 96.8%) and drinking alcohol (96.6% vs 78.3%). Further, respondents <35 years were significantly less likely than those aged >35 years to be embarrassed (11.6% vs. 19.8%) and scared (12.3% vs. 21.7%). Furthermore, younger participants were less likely to find it difficult to arrange transport for doctor's surgery (9.0% vs. 15.9%) as compared to their counterparts. There was gender variation, in which females were less likely than male counterparts to be embarrassed (4.4% vs. 26.6%) or scared (3.3% vs. 30.5%) and worry about wasting doctors time (1.1% vs. 12.2%) [Table 2].

#### **DISCUSSION**

In the current study, merely 7.7% of the study respondents were aware of all the nine warning signs of cancer. Low awareness of cancer warning signs has been reported in studies conducted in India<sup>[13,16]</sup> and abroad.<sup>[17,18]</sup> Further, in the present study, we found that the most common known warning signs of cancer were "unexplained lump" and the least was "change in the appearance of mole." A study conducted among the adult population in a Puducherry,

India, reported that "unexplained bleeding" was the most common known warning sign and least known was "change in wart/mole." [16]

In our study, cigarette smoking was the most known risk factor followed by second-hand smoke and alcohol intake. Only few were aware of the role of inadequate physical activity and having a diet devoid of adequate amounts of fruits and vegetables in cancer prevention. Veerakumar et al. in their study reported that most of the respondents attributed smoking to be a risk factor of cancer with very few knowing the fact that unhealth diet can be a predisposing factor.<sup>[16]</sup> Poudel et al. in their study among Nepalese adults reported that half of the study respondents were aware that inadequate physical exercise can be risk factor for cancer (51%). Further, around one fourth (23%) knew that unhealthy diet is a risk factor for cancer. [19] In our study, only 15% of the study participants were aware that infection with HPV can lead to cancer. Improper awareness about HPV as a risk factor for cancer has been reported

Table 2: Sociodemographic predictors of cancer early warning signs, its risk factors, and anticipated barriers in seeking help

Aware of warning signs	1a	1b	1c	1d	1e	1f	1g	1h		1i		
Age group ≤35 years	200 (81.6)	145 (70.7)	181 (77.7)	176 (74.9)	88 (54)	177 (79)	80 (49.7)	119 (63.3)		112 (61.5)		
36 and above	74 (86)	44 (71)	56 (73.7)	, ,	28 (52.8)	68 (88.3)	,	43 (69.4)		39 (66.1)		
Gender	( )	,	, ,	( , , , ,	( , , , ,	( ,	(* )	( ,		( , , ,		
Male	131 (79.4)	94 (65.7)	119 (72.6)	111 (67.7)	55 (47.4)	131 (80.4)	53 (42.4)	90 (59.6)		82 (58.6)		
Female	143 (86.1)	95 (76.6)	118 (81.4)	117 (79.1)*	61 (61)*	114 (82.6)	54 (62.1)*	72 (72.7)*		69 (68.3)		
Education												
Literate	245 (84.2)	171 (71.5)	215 (78.5)	207 (73.4)	103 (53.4)	220 (81.2)	95 (50.3)	147 (64.2)		139 (62.6)		
Illiterate	29 (72.5)	18 (64.3)	22 (62.9)	21 (70)	13 (56.5)	25 (83.3)	12 (52.2)	15 (71.4)		12 (63.2)		
Anticipated barriers in seeking help	2a	2b	2c	2d	2e	2f	2g	2h	2i		2j	
Age group	44 (44 ()	4.4.440.00	10 (5.1)	0 ( (7.0)	40 (40 0)	F7 (4 ( 4)	40 (40 0)	00 (0.0)	07 (10 4)	0.5	(7.4)	
≤35 years	41 (11.6)	44 (12.3)	18 (5.1)	26 (7.3)	49 (13.8)	57 (16.1)	49 (13.8)	32 (9.0)	37 (10.4)		25 (7.1)	
36 and above	21 (19.8)*	23 (21.7)*	8 (7.5)	11 (10.3)	17 (15.9)	22 (20.8)*	20 (19.0)*	1/ (15.9)*	16 (15.0)	17 (	15.9)*	
Gender	FO (O( ()	FO (20 F)	00 (10 0)	21 (1/ 4)	(0 (01 0)	74 (20 ()	(2 (24 0)	44 (00 5)	45 (04.1)	27	(00.4)	
Male	50 (26.6)	58 (30.5)	23 (12.2)	31 (16.4)	60 (31.9)	74 (39.6)	63 (34.2)	44 (23.5)	45 (24.1)		(20.1)	
Female Education	12 (4.4)*	9 (3.3)*	3 (1.1)*	6 (2.2)*	6 (2.2)*	5 (1.8)*	6 (2.2)*	5 (1.8)*	8 (2.9)*	5 (	1.8)*	
Literate	57 (14.5)	62 (15.7)	22 (5.6)	34 (8.6)	58 (14.6)	70 (17.8)	62 (15.8)	42 (10.6)	47 (11.9)	27	(9.4)	
Illiterate	5 (7.5)	5 (7.4)	4 (5.9)	34 (6.0)	8 (11.9)	9 (13.4)	7 (10.6)	7 (10.6)	6 (9.0)		(9.4) (7.6)	
	. ,	3 (7.4)	· /			3f		· /	3i		`	
Awareness of risk	3a	30	3c	3d	3e	31	3g	3h	31	Зј	3k	
factors												
Age group												
≤35 years	326 (98.2)	, ,	, ,	, ,	44 (45.8)	, ,	51 (48.6)	, ,	, ,	48 (58.5)	30 (33.3)	
36 and above	99 (99)	92 (93.9)	78 (86.7)	12 (25)	19 (50)	25 (53.2)	18 (41.9)	30 (56.6)	37 (62.7)	21 (63.6)	14 (32.6)	
Gender												
Male	179 (96.8)	, ,	130 (78.3)	,	37 (40.2)	61 (53)	39 (39.4)	69 (53.1)	, ,	50 (60.2)	27 (26.7)	
Female	246 (99.6)*	231 (97.5)*	201 (96.6)*	28 (56)*	26 (61.9)*	50 (79.4)*	30 (61.2)*	64 (81)*	68 (77.3)*	19 (59.4)*	17 (53.1)*	
Education	074 (00 *)	0.44 (0.0 1)	000 (00)	E0 (04 ()	50 (40 T)	100 ((1 5)	(0 (1 ( ))	100 ((0 =)	101 ((0 =)	( 4 ( / 4 = `	44 (00 1)	
Literate		341 (93.4)	293 (88)	50 (31.6)	58 (48.7)		62 (46.6)		121 (62.7)		41 (33.6)	
Illiterate	51 (98.1)	48 (96)	38 (92.7)	6 (33.3)	5 (33.3)	9 (69.2)	7 (46.7)	10 (62.5)	12 (63.2)	5 (45.5)	3 (27.3)	

<sup>\*</sup>Significant a P<0.05. Numbers in brackets denote percentage

in other studies. [20,21] In our study, around one-fifth were aware that overweight is a risk factor for cancer. Similar to this finding, Ryan *et al.* studied Irish adults and reported that only 32% of the public were aware that obesity is a risk factor of cancer. [12]

Encouraging individuals to seek help for the suspected sign is the hallmark for early diagnosis and treatment of cancer. In the present study, only a few respondents anticipated barriers in seeking help. Contrary to this finding, a study conducted by Al-Azri et al. reported a comparatively higher proportion of respondents (one half) having barriers in seeking help for the cancer symptoms. [22] This difference can be attributed to the difference in the study area and its population. In the present study, it was found that females were significantly more likely than males to be aware of the warning signs of cancer. This can probably be explained by another finding of this study; wherein females had comparatively better help-seeking behavior than the male counterparts. Thus, they are more likely to report symptoms to a healthcare provider and get information on diseases. Feizi et al. in their study reported that females had a better knowledge of warning signs as compared to that of males.<sup>[11]</sup>

#### **CONCLUSION**

In conclusion, the results of the present study revealed that respondents had inadequate awareness of early warning signs and risk factors of cancer. There were however few anticipated barriers in seeking help. It is, therefore, recommended that healthcare professionals should regularly hold community-based activities to make people aware about cancer.

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#### **Conflicts of interest**

There are no conflicts of interest.

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### **Eagle syndrome or foreign body throat?**

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#### **Abstract**

Eagle syndrome is a rare condition caused by an elongated styloid process or abnormal calcification of the stylohyoid ligament complex. Patients typically present with recurrent throat pain, neck or facial pain, sensation of foreign body in the throat, or even dysphagia. The finding of an elongated styloid process is usually incidental, with patients having no related symptoms. Only patients with symptoms are diagnosed with Eagle syndrome. This condition may be difficult to diagnose due to its rarity and the nonspecific nature of signs and symptoms. Diagnosis is mainly by clinical assessment and confirmation with radiological evidence. We present a unique case of eagle syndrome in a patient who complained of acute neck pain after eating fish.

Keywords: Eagle syndrome, swallowed fish bone, stylalgia

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#### **INTRODUCTION**

Eagle syndrome was first described in 1937 as "stylalgia" – a condition caused by abnormal length of the styloid process or mineralization of the stylohyoid ligament complex. [1] The stylohyoid complex consists of the styloid process, the stylohyoid ligament, and the lesser cornu of the hyoid bone. The styloid process is a cylindrical bony projection from the temporal bone. It extends downward, forward, and medially, and is immediately anterior to the stylomastoid foramen. The adjacent structures around the stylohyoid complex include the internal and external carotid artery; internal jugular vein; and the facial, glossopharyngeal, vagus, and hypoglossal nerves.

Usual complaints from patients with stylalgia are recurrent throat pain and foreign body sensation. Occasionally, a palpable hardness can be felt in the tonsillar fossa which could be indicative of this condition. The incidence of this condition is only about 4% of the general population and occurs in adults aged 30–50 years.<sup>[2]</sup>

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#### **CASE REPORT**

A 43-year-old woman presented with throat pain after a fish meal. She claimed to be eating fish when she felt a sudden prickling sensation at her throat and tried to remove the bone with her fingers but was unsuccessful. She consulted a general practitioner who duly referred her to a specialist center, where a flexible nasopharyngolaryngoscopy was done with no significant findings. A computed tomography (CT) scan was done which was reported as normal. She was discharged home with reassurance.

However, her symptoms persisted, and thus she went to seek another consultation 3 weeks later and underwent an examination under anesthesia and direct laryngoscopy and esophagoscopy. There were no significant findings as well.

Post procedure, she claimed her symptoms to be still present. The doctor-in-charge promptly ordered another CT neck which showed a radiopaque foreign body in the soft tissue of

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the neck [Figure 1]. This led us to believe that the foreign body may have migrated from the cervical esophagus into the neck.

The patient underwent neck exploration, and the suspected foreign body was found deep into the submandibular gland just above the hyoid bone [Figures 2 and 3].

After the operation, the patient's symptoms completely resolved.

Histopathological examination of the "foreign body" removed showed benign lamellar bony tissue with adjacent fibrous and cartilage tissues, suggestive of ligament tissue [Figure 4].

#### **DISCUSSION**

Classical symptoms of eagle syndrome are pain or foreign body sensation in the throat, odynophagia, and dysphagia. This is usually precipitated by tonsillectomy operation.

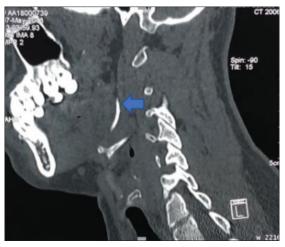


Figure 1: Sagittal view of computed tomography scan. Blue arrow showing the suspected foreign body



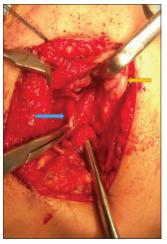
Figure 3: Specimen of the suspected foreign body removed. It appeared to be soft with a cartilaginous feel and smooth edges

Clinically, hardness can occasionally be palpated in the tonsillar fossa. Rarely, the styloid process causes pressure to the surrounding carotid arteries, leading to symptoms such as neck pain on head movement, buzzing in the ear, and headaches.<sup>[2]</sup>

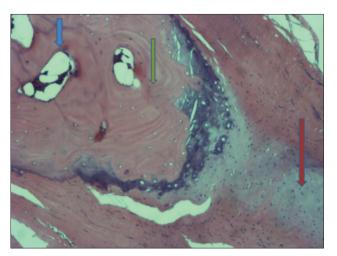
Theories on the cause of this condition include congenital (persistence of cartilaginous elements of precursors of styloid process) or acquired (proliferation of osseous tissue of the stylohyoid complex).<sup>[3]</sup>

There are several explanations for the symptoms, based on anatomical understanding namely:

- Fracture of the styloid process leading to granulation tissue and pressure of the surrounding tissue
- 2. Compression of adjacent nerve (glossopharyngeal, chorda tympani, and lower branch of trigeminal)
- Degenerative and inflammatory changes at the tendinous portion of stylohyoid insertion



**Figure 2:** Intraoperative findings from right transcervical approach showing the suspected foreign body in blue arrow. Yellow arrow marks the right submandibular gland



**Figure 4:** Histology picture of the suspected foreign body showing bone marrow (blue), bone (green), and cartilage (red)

- 4. Irritation of pharyngeal mucosa from direct compression or post tonsillectomy scarring
- 5. Impingement to carotid vessels with irritation of sympathetic nerves in the arterial sheath.

Skull X-ray with lateral and frontal view would usually suffice for diagnosis. However, with the availability of CT scan, images are clearer and easier to delineate the surrounding anatomy and would aid if surgical excision is required.<sup>[4]</sup>

In our particular case, the presenting complaint of the patient led us toward a diagnosis of foreign body ingestion. She came with a clear history of throat discomfort after eating a fish meal. Her first CT scan does not reveal any foreign body or any abnormality. Only 3 weeks after her initial presentation did a repeat CT showed a "foreign body" in her right neck.

This presentation would lead to an assumption of a migrated fish bone into the neck. However, this diagnosis was challenged when the intraoperative neck exploration showed the suspected foreign body found deep into the submandibular gland and above the hyoid bone with no inflammation surrounding it. The gross appearance and tactile sensation of the suspected foreign body as well was not suggestive of a migrated fish bone. The histopathological examination report was also suggestive of a calcified stylohyoid ligament.

These findings prompted us to reconsider our initial diagnosis. The challenge is how to explain her very suggestive and clear history of her complaint to her diagnosis. The possible explanation could be that she did swallow a fish bone, albeit a small and clinically insignificant one. The irritation might have alerted her to the foreign body sensation and made her more aware of it. Another explanation could be that the irritation of the pharyngeal mucosa due to the fish meal (fish bone) or due to her manual attempts to remove the bone might have exacerbated the symptoms on a preexisting elongated styloid process.

There have been other cases reported in which eagle syndrome was diagnosed incidentally.<sup>[2-5]</sup>

Surgical management is the treatment of choice for eagle syndrome. The approach can be intraoral or transcervical. Either approach has its own advantages and limitations; hence, the choice of approach should depend on individual surgeon's experience and preference.

Medical management has also been described in the form of local injection with steroid or anesthetic agents. Other medications that can be used are analgesics, anticonvulsants, and antidepressants.<sup>[6]</sup>

#### **CONCLUSION**

This case has been a unique experience to us in the otorhinolaryngology field in the way of its presentation. While it is good that the underlying condition has been treated for this patient, it is unfortunate that she had to suffer the discomfort for a whole month before treatment. This would be a lesson to others in the otorhinolaryngology field as well as primary caregivers to whom patients would seek treatment for similar complaints. Eagle syndrome is rare, and a high level of awareness is needed to not miss this benign but debilitating condition.

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### **Conflicts of interest**

There are no conflicts of interest.

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# Clinical correlates and profile of patients on antiretroviral therapy: A hospital-based cross-sectional study from a tertiary care institution of North India

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# **Abstract**

**Introduction:** HIV/AIDS as a global pandemic has affected each and every region of the world. The HIV epidemic is dynamic in nature with relation to temporal changes, geographic distribution, and modes of transmission. India, though in the declining phase, is still confronting with the varied nature of the spread of the disease.

Materials and Methods: This hospital-based cross-sectional study was conducted among four hundred people living with HIV/AIDS (PLHIV) attending the antiretroviral therapy (ART) center of a tertiary care institute of North India. Data were collected from the patients using a predesigned pretested questionnaire maintaining confidentiality. The data were analyzed using simple proportion and percentages.

**Results:** The mean age of the study participants was  $32.8 \pm 7.4$  years. The mean duration of ART intake was  $24.5 \pm 14.4$  months. There was a significant improvement in clinical staging and CD4 count with ART intake among PLHIV. The most prevalent possible route of transmission was found to be heterosexual (85.5%) route. **Conclusion:** The spread among the population, particularly in the younger age group, reinforces the fact that preventive strategies need to be initiated within the target population at an early stage. Health education and social campaigns are the mainstays for "getting to zero" target.

Keywords: Antiretroviral therapy, HIV/AIDS, people living with HIV, transmission

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#### INTRODUCTION

HIV/AIDS has rapidly established itself as one of the fastest growing epidemics since its inception. It has become, in the truest sense, the first international epidemic crossing oceans and borders. In about three decades since AIDS emerged as a major health concern, the epidemic has had a serious and in many places, a devastating effect on human development. HIV continues unabated as a major

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public health issue, with about 35 million deaths so far. Globally, one million people died from HIV-related causes in 2016. In absolute terms, globally, there were 36.7 million people living with HIV (PLHIV) at the end of 2016 with 1.8 million newly infected cases.<sup>[1]</sup> Every day, 4900 people die from HIV/AIDS and another 7300 people get infected with HIV.<sup>[2]</sup> It is one of the ten leading causes of global disease burden in low- and middle-income countries.<sup>[3]</sup>

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India, albeit some recent gains, is still plagued by this epidemic, housing the third largest PLHIV, only after Nigeria and South Africa. The Indian epidemic is centered amid vulnerable populations at high risk for HIV. The concentrated epidemics are driven by unprotected sex between sex workers and their clients and by injecting drug use (IDU) with contaminated syringes. The HIV prevalence according to the HIV Sentinel Surveillance 2016-17 was female sex workers (FSW, 1.56%), men having sex with men (MSM, 2.69%), IDUs (6.26%), hijra/transgender (3.14%), long-distance trucker (0.86%), and single male migrant (0.51%).[4] The hallmark of the HIV/AIDS epidemic in India is heterogeneity; it follows the Type 4 pattern, where the epidemic shifts from the most vulnerable populations (such as FSW, IDU, and MSM) to bridge populations (clients of sex workers, STI patients, and partners of drug users) and then to the general population. The shift usually occurs when the prevalence in the first group exceeds 5%, with a 2-3 years' time lag between shifts from one group to another. [5] However, the introduction and implementation of antiretroviral therapy (ART) has been able to reduce mortality and morbidity, improve quality of life, and increase the life expectancy of HIV-infected individuals.

ART has changed the face of HIV/AIDS by leading to a decisive decrease in HIV-related morbidity and mortality among those with access to therapy. This has made the once "imminent killer" to a chronic manageable condition. Early diagnosis, ART, and treatment of opportunistic infections remain the pillars for the control of HIV replication, disease progression, and ultimately, the containment of the epidemic. The sociodemographic profile greatly affects the health-care-seeking behavior and practices of the infected population. Keeping these facts in mind, this study was undertaken to elucidate the epidemiological and clinical profile of HIV-positive patients on ART attending a tertiary care institute of Haryana.

#### MATERIALS AND METHODS

This cross-sectional descriptive hospital-based study was carried out from January 2014 to September 2014 at the ART center of a tertiary care institute of Haryana. This ART center serves not only the population of Haryana but also caters population of adjoining states of Punjab, Uttar Pradesh, and Delhi. A convenient sample of four hundred HIV-positive patients aged above 18 years and taking ART for at least 6 months were enrolled for the study. Informed written consent

was obtained from the study participants before the start of the interview. The interview was conducted by the interviewer himself, and the responses were recorded using a predesigned and pretested semi-structured questionnaire. The questionnaire consisted of questions regarding sociodemographic characteristics such as age, sex, literacy status, marital status, occupation, and clinical presentation. Confidentiality and absolute anonymity of the individuals were maintained. Data were also obtained from the ART cards (white card) of the patients that were maintained at the ART center regarding the possible mode of transmission, functional status, and CD4 count of recruited individuals both at the start of ART and at the time of interview.

#### **Ethics**

Participation in this study was voluntary, and written informed consent was obtained from each study participant after a detailed description of study objectives and procedures. Moreover, the study participants had an opportunity to refuse or to discontinue participation at any time. Privacy was strictly protected by conducting the interviews at a private place, and we ensured the confidentiality of the respondents by removing all personal identifiers from the survey questionnaires. The permission for the study was obtained from the institutional ethics committee.

### **Statistics**

Data were processed and analyzed using the Statistical Package for Social Sciences version 17.0 version (SPSS Inc., Chicago, IL, USA). The data were expressed in proportion and percentages; Chi-square test was used for categorical data. P < 0.05 was considered statistically significant at 95% confidence interval.

#### **RESULTS**

A total of four hundred patients were included in the study attending the ART center from January 2014 to September 2014. Male patients (247, 61.8%) outnumbered the female patients (153, 38.2%). The mean age of the study participants was  $32.8 \pm 7.4$  years.

Nearly half (48.8%) of the study participants were in the 26–35 years' age group, whereas the age group of 45 years and more constituted the least (3.7%). More than two-thirds (69.8%) of the study participants were living with spouses, whereas rest (31.2%) were single (unmarried/separated/widowed). Among the female respondents, nearly one-fifth (18.3%) were widowed. Most (81.67%) unmarried individuals were males.

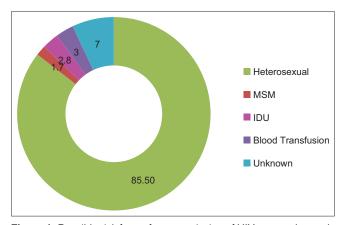
Nearly one-fifth (19.3%) of the study participants were illiterate, whereas few (6.2%) had completed graduation. Majority of patients were homemakers (27.8%) and farmers and laborers (36.8%) by occupation. Among males, farmers (143, 26.24%), businessmen (65, 11.93%), and drivers (53, 9.72%) constituted other occupations [Table 1].

The mean duration of ART intake was  $24.5 \pm 14.4$  months. Most (31%) of the study participants had taken ART for 13–24 months and only 76 (19%) for >36 months [Table 2].

On the basis of WHO clinical staging of AIDS, half of the individuals (50%) were in Stage II, 33.8% in Stage III while only 13% in Stage I at the start of ART, whereas at the time of interview, majority (54.5%) were in Stage I followed by Stage II (31.7%). This shows that there was a substantial reduction in stage of disease with the intake of ART. The association was also found to be statistically significant [Table 3].

At the start of ART, majority (58.3%) of the study participants had CD4 count of <200/mm³, whereas only 13% had >500/mm³. The mean CD4 count at the start of ART was found to be 189 cells/mm³. However, at the time of interview, more than three-fourths (76.7%) had CD4 count of >200 cells/mm³, with the mean CD4 count at the time of interview being 313 cells/mm³. This change in CD4 count was found to be statistically significant [Table 4].

The most common possible route of transmission was heterosexual (85.5%), whereas in 7.0% of the study participants, it was unknown. In a small group of patients, the possible mode of transmission was through blood transfusion (3.0%), intravenous drug use (2.8%), and homosexual (1.8%) [Figure 1].



**Figure 1:** Possible risk factor for transmission of HIV among the study participants (n = 400)

### **DISCUSSION**

The revamped roadmap aims at embarking on a strategy for ending the AIDS epidemic by 2030. Combined with a stronger focus on HIV prevention, reaching the 90–90–90 target – i.e., by 2020, 90% of all PLHIV know their HIV status, 90% of people diagnosed with HIV receive ART, and 90% of all people on HIV treatment achieve viral suppression – will enable to lay the groundwork to end the AIDS epidemic by 2030. [6] ART scale-up is the mainstay

Table 1: Sociodemographic characteristics of the study participants

Characteristics	Group	Male	Female	Total
Age group (years)	18-25	44 (17.8)	36 (23.5)	80 (20.0)
	26-35	130 (52.6)	65 (42.5)	195 (48.8)
	36-45	68 (27.5)	42 (27.5)	110 (27.5)
	>45	5 (2.0)	10 (6.5)	15 (3.7)
Marital status	Married	169 (68.4)	110 (71.9)	279 (69.8)
	Separated	9 (3.6)	4 (2.6)	13 (3.2)
	Unmarried	49 (19.8)	11 (7.2)	60 (15.0)
	Widow/widower	20 (8.1)	28 (18.3)	48 (12.0)
Place of residence	Rural	126 (51)	102 (66.7)	228 (57)
	Urban	121 (49)	51 (33.3)	172 (43)
Education level	Illiterate	19 (7.7)	58 (37.9)	77 (19.3)
	Primary	68 (27.5)	35 (22.9)	103 (25.8)
	Secondary	115 (46.6)	35 (22.9)	150 (37.5)
	Higher	30 (12.1)	15 (9.8)	45 (11.2)
	secondary Graduate and above	15 (6.1)	10 (6.5)	25 (6.2)

Table 2: Duration of antiretroviral therapy taken by the study participants at the time of interview (n=400)

<b>Duration of ART intake (months)</b>	Male	Female	Total
6-12	58 (23.5)	48 (31.4)	106 (26.5)
13-24	84 (34.0)	40 (26.1)	124 (31.0)
25-36	64 (25.9)	30 (19.6)	94 (23.5)
>36	41 (16.6)	35 (22.9)	76 (19.0)
Total	247 (100)	153 (100)	400 (100)

Figures in parentheses indicate percentages. ART: Antiretroviral therapy

Table 3: WHO clinical staging of AIDS of the study participants (*n*=400)

WHO staging	At the start	At the time	$P; \chi^2; df$
	of ART	of interview	
I	52 (13.0)	218 (54.5)	0.000; 162; 3
II	200 (50.0)	127 (31.7)	
III	135 (33.8)	47 (11.8)	
IV	13 (3.2)	8 (2.0)	
Total	400 (100)	400 (100)	

ART: Antiretroviral therapy

Table 4: CD4 count of the study participants (n=400)

CD4 count (per mm³)	At the time of the start of ART	At the time of interview	$P; \chi^2; df$
<200	233 (58.3)	93 (23.2)	0.000; 104; 2
200-500	115 (28.7)	229 (57.3)	
>500	52 (13.0)	78 (19.5)	
Total	400 (100.0)	400 (100.0)	

Figures in parentheses indicate percentages. ART: Antiretroviral therapy

of effective HIV prevention, as experience in different parts of the world has demonstrated that expanding the use of ART is directly correlated with declines in new HIV infections.<sup>[7,8]</sup>

HIV/AIDS strikes the root of every aspect of the society involving individuals, families, sectors, and institutions. It has ruined the social framework of many communities and countries, especially in those countries with a high burden of disease. A preponderance of males in this study may be due to the fact that they practice more high-risk sexual behavior than females. This is especially conspicuous in occupations such as drivers and army personnel where the job demands being away from home for long periods. Sexually active unmarried men, in general, are engaged in sexual risk behavior to meet physical needs and to relieve the loneliness and anxieties of home. Furthermore, nearly half of the participants were in the 26-35 year age group. HIV/AIDS generally affects the economically productive and younger age group, which forms the most important threat to the community. Adekeye outlined in their study that adolescents and youth remain the major propellers as well as victim of this pandemic. [9] Gallagher reported that the HIV infection rate is highest in the age group of 19-35 years. According to him, this portends danger for population structure as the younger people will die, leaving behind orphans who are usually cared for by older ones who are themselves dependents.[10] This situation has been viewed by Barnett and Blaikie as an impending disaster with serious implications for developmental issues and agricultural production.[11]

The distribution according to the educational status showed that the seropositivity was higher among the individuals with lesser education (primary and illiterate individuals). Low education and relative ignorance about safe sex practices contribute to a sizeable proportion of it. In terms of genderwise distribution of occupation, majority of male respondents were farmers, followed by laborers and drivers. Similarly, a higher proportion of laborers and drivers among PLHIV were reported in a study conducted by Subramanian et al. in South India.[12] The occupation of these two groups makes them vulnerable to practice high-risk behavior, which in turn leads to higher rates of HIV positivity among them. Most of the laborers being migrants act as a bridge population spreading HIV between urban and rural areas and between high-risk and low-risk groups. Among females, the higher proportion of HIV positivity among homemakers suggests that most of them had contracted the disease from their seropositive husbands. In our country, the female gender are particularly vulnerable to being exposed to HIV where inequalities, embodied in cultural or religious practices, make them increasingly economically and socially dependent on men.

Duration of ART along with proper adherence is crucial because PLHIV needs to take medications lifelong. According to the National AIDS Control Organization (NACO), timely intake of ART with a minimum of 95% adherence is required to avoid viral resistance and treatment failure. Duration of ART intake is influenced by many factors such as patient characteristics, location of health facilities, attitude of family members, and societal behaviors. The association between the ART and WHO clinical staging was found to be statistically significant. This manifests the effectiveness of ART as a modality of treatment in halting the progression and ameliorating the clinical course of the disease. As per the WHO recommendations, HIV/AIDS patients placed on ART show a definitive improvement in staging. [13]

Moreover, the WHO clinical staging system has been shown to be a practical and accurate way to manage HIV-infected patients, with international studies showing agreement between clinical manifestations included in the WHO staging system and laboratory markers including CD4 cell count and total lymphocyte count.[14-17] In the present study, it was found that at the start of ART, majority (58.3%) of the study participants had CD4 count of <200/mm<sup>3</sup>, whereas only 13% had >500/mm<sup>3</sup>. The mean CD4 count at the start was 189 cells/mm<sup>3</sup>. At the time of interview, 76.7% of the individuals had CD4 count >200 cells/mm3, and the mean CD4 count was found to be 313 cells/mm<sup>3</sup>. This relationship was found to be statistically significant. These findings were comparable to the study conducted by Xiaoyan and Sato in China where they reported a significant improvement in CD4 count at the time interview, i.e., 48.9% of the study participants had count between 200 and 500 cells/mm<sup>3</sup> and 20.2% of the patients had CD4 count >500 cells/mm<sup>3</sup>.[18] These data substantiate the fact that there is a marked and sustained CD4 response to ART among patients remaining on therapy.

According to the report – India HIV estimates released by the NACO, [19] heterosexual (88.2%) is the most common route of HIV transmission, followed by vertical transmission (5.4%), IDU (1.6%), and use of infected blood and blood products (1.0%). This emphasizes the fact that sexual, especially heterosexual transmission is the main propeller of the epidemic in most of India. Because of stigma associated with sexual route, a PLHIV (infected through sexual route) finds it difficult to share HIV status with his/her spouse/family. This leads to severe

repercussions and in many cases unfortunately propagates the spread of the epidemic.

There are some limitations to our study. The reason "vertical transmission" does not figure in our study is may be because only those individuals who were above 18 years of age were selected. The cross-sectional nature of our study does not allow a causal relationship. The respondents were those who were actively seeking routine medical care. The degree to which the study is representative of the larger HIV-infected population is influenced by the potential selective factors associated with recruiting from HIV treatment settings.

### **CONCLUSION**

The study reinforces the fact that HIV is particularly prevalent in the younger age groups threatening the economically productive age group and the social thread of many families. An integrated approach emphasizing on its preventive aspect and spreading more awareness by educating people regarding the dreadful effects of this disease is mandated. Nevertheless, the role of ART as a definitive mode of therapy cannot be undermined. This study clearly demonstrates the improvement in clinical profile of patients, both in terms of clinical staging and CD4 count in the patients. This information can guide us on approaching the epidemic through a holistic population lens, for a more disseminated impact.

# Financial support and sponsorship Nil.

# Conflicts of interest

There are no conflicts of interest.

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- 3. Roddy P, Goiri J, Flevaud L, Palma PP, Morote S, Lima N. *et al.*, Field Evaluation of a Rapid Immunochromatographic Assay for Detection of *Trypanosoma cruzi* Infection by Use of Whole Blood. J. Clin. Microbiol. 2008; 46: 2022-2027.
- 4. Volume with supplement: Otranto D, Capelli G, Genchi C: Changing distribution patterns of canine vector borne diseases in Italy: leishmaniosis vs. dirofilariosis. *Parasites & Vectors* 2009; Suppl 1:S2.

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# **Forthcoming Events**

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- 2. **World Rural Health Conference**. 11 Oct 15 Oct, 2019. Albuquerque, New Mexico, USA Details can be accessed from https://www.ruralhealthweb.org/wrhc
- 3. Workshop on Clinical Trials and Case Control Study Designs. CMC Vellore. 18-30 Nov 2019. Details can be accessed from https://www.cmch-vellore.edu/Events.aspx?etype=INSTITUTION
- 4. 47<sup>th</sup> Annual National Conference of Indian Association of Preventive & Social Medicine (IAPSM) 2020. Chennai
- 5. 64<sup>th</sup> Annual National Conference of Indian Public Health Association (IPHA) 29<sup>th</sup> Feb-2<sup>nd</sup> March 2020. AIIMS New Delhi
- 6. **World Public Health Nutrition Congress**. Brisbane, Australia. 31 March-3 April 2020. Details can be accessed from https://10times.com/wphn
- 7. **WONCA Asia Pacific Regional Conference** 23-26 April 2020, Aotearoa, New Zealand. Details can be accessed from https://www.globalfamilydoctor.com/News/AsiaPacificregionconference inNewZealandin2020.aspx
- 8. WCE 2020. **World Congress of Epidemiology**. 13-16 September 2020. Melbourne, Australia. Details can be accessed from http://wce2020.org/
- 9. **16**<sup>th</sup> **World Congress on Public Health 2020**. Public health for the future of humanity: analysis, advocacy and action. Rome, Italy, 12 17 October 2020 Details can be accessed from https://wcph2020.com/
- 10. **15**<sup>th</sup> **Global Conference on Ageing**. Niagara, Canada. 1-3 November 2020. Details can be accessed from https://www.ifa-fiv.org/

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