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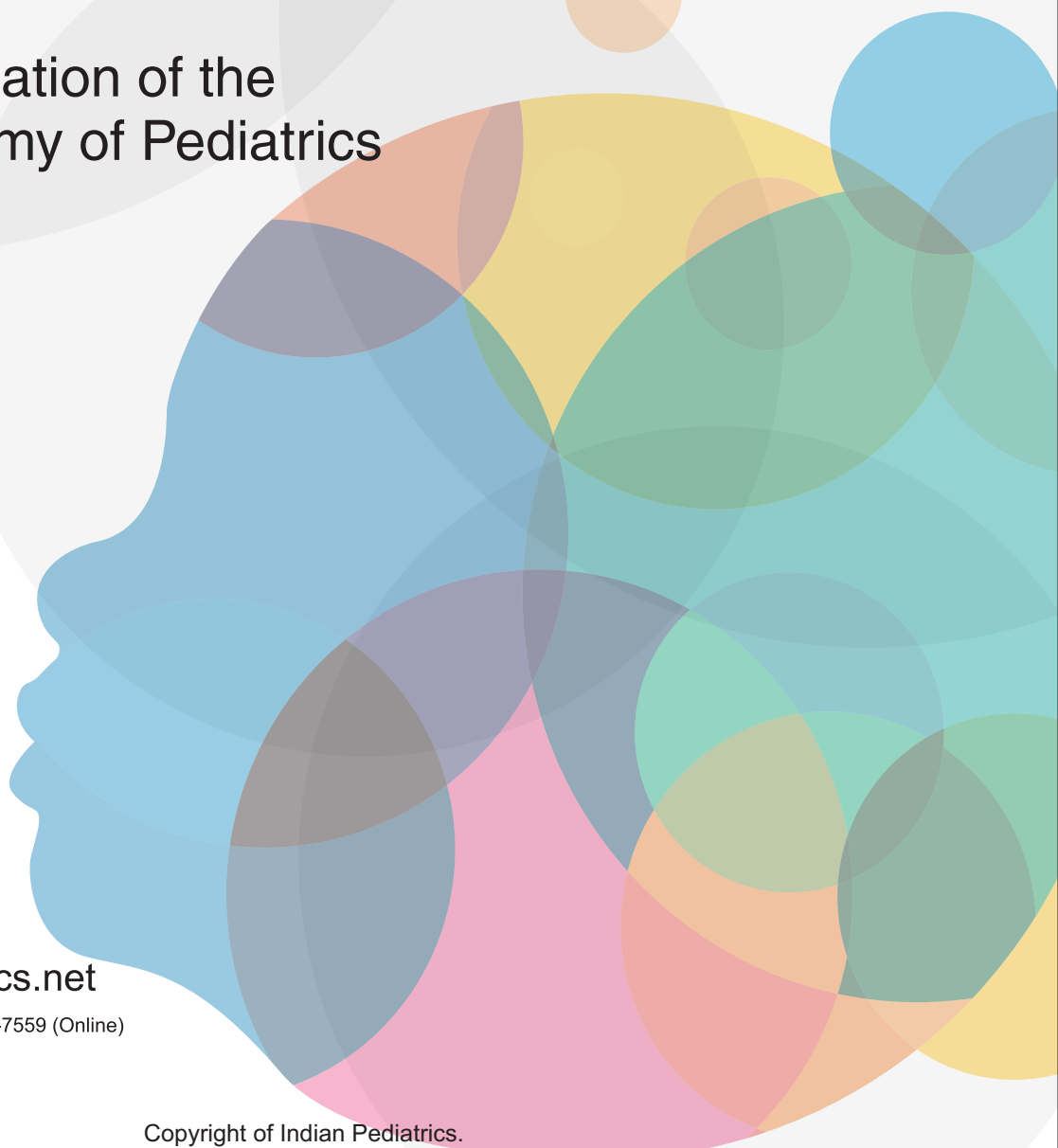

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Contents

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Prevention of Childhood Injuries

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The word 'injuries' has replaced the erstwhile terminology of 'accident'. Rightly so, as the term 'accident' denotes an event which has occurred suddenly and there was no way to anticipate or prevent it. On the other hand, injuries can both be anticipated and prevented.

Injuries in children are major health hazards. Childhood injuries are also considered to be the second most common cause of mortality in school age children [1].Other than stray data from localized or hospital-based studies, the exact magnitude of this major public health problem remains unexplored in a nation-wide survey, specifically in children. To prevent this major burden, it is imperative that we understand where injuries occur (at home, at school, at play or on road), which children are affected (age group, urban/rural, gender), what are the various types of injuries, and most importantly, what is the magnitude or burden of the problem.

Recognizing that injuries in children is a major public health problem and lack of data from both observational and interventional research in this arena, Indian Council of Medical Research (ICMR) issued a call for research proposals related to childhood injuries, a few years back. Individual proposals pertaining to descriptive research focusing on prevalence and risk-factors associated with unintentional childhood injuries were collated into a Taskforce and a multicentric cross-sectional, community-based study was envisaged, to cover 11 diverse geographical locations in India. The Taskforce ensured to have representation of urban and rural areas; and also plains and hills. The study commenced in 2018 and was completed in September, 2020. Detailed findings of this study are presented in this focused issue of *Indian Pediatrics* [2]. The study covered 31,000 children (6 mo-18y) in more than 25,000 households. WHO definitions and protocols were followed for collecting data through cloud-based software, and quality was ensured. Overall prevalence was 14%. Injuries were more common between 5-14 years age, in boys (2:1), and in rural areas. Falls were the most common type of injuries, followed by road traffic injuries. Authors also concluded that more than 50% injuries occurred in home environment. This is; however, perplexing, as the most common types of injuries noticed in this study are expected to occur outdoors! The study also identified poor housing conditions and lack of safety measures at home and play areas as the key factors in causation of injuries.

A randomized controlled trial, published in this issue [3] as part of the ICMR initiative, has shown reduction in home injuries following an appropriate home safety supervisory hazard reduction teaching program, aimed at caregivers of children below 5 years, residing in a rural area of Karnataka. These results assume importance since the main taskforce study concluded that most injuries occur at home. Another cluster randomized study [4] evaluated the effectiveness of school-based intervention program in 1100 children (studying in 5-7 standards) over 10 months. Children were trained on periodic and regular basis on inculcating safety and injuries prevention strategies. There was a marked decline in the incidence of injuries in the interventional arm compared to control (50% vs 13%). Another study from Ujjain [5] on educational school-based intervention in 1944 adolescents also demonstrated an increase in the knowledge of prevention of unintentional injuries and first aid significantly.

Other than these studies funded by ICMR, this issue has several other reports on diverse facets of injuries. The spectrum of injuries totally changes when we move from community-based or school-based studies to hospital-based studies. Road traffic injuries emerge as the predominant cause of pediatric injuries presenting to a trauma center [6].

Safety and security of children is an integral component of 'nurturing care' of children and is considered essential to ensure an optimal early childhood development (ECD). Indian Academy of Pediatrics has already declared Nurturing Care for ECD as the flagship program of the Academy in 2021 [7]. The efforts of the Academy in promotion of all the components have been

acclaimed by WHO, UNICEF, and Government of India. This issue of *Indian Pediatrics* is being released at a very apt moment when the emphasis on nurturing care is also being focused on safety and security of children.

It is also the need of the hour to formulate a comprehensive plan for prevention of childhood injuries on a national basis. This necessitates inclusion of prevention of injuries in both pre-service and in-service medical education programs. WHO has taken a lead in this aspect and already formulated guidelines on training of under-graduate students in prevention of injuries [8]. However, this needs to be re-emphasized and ingrained in medical curricula of health universities in India regulated by the National Medical Commission.

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Competing interest: PG was the chairman of the ICMR taskforce constituted to assess the burden of injuries in children.

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RESEARCH PAPER

Descriptive Epidemiology of Unintentional Childhood Injuries in India: An ICMR Taskforce Multisite Study

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Background: Children 0-14 years constitute about 31.4% of Indian population, among whom the magnitude and risk factors of childhood injuries have not been adequately studied.

Objective: To study the prevalence of and assess the factors associated with unintentional injuries among children aged 6 month - 18 years in various regions.

Methodology: This multi-centric, cross-sectional, community-based study was conducted at 11 sites across India. States included were Gujarat, Karnataka, Madhya Pradesh, Punjab, Sikkim, Tamil Nadu, Uttarakhand, and West Bengal between March, 2018 and September, 2020. A total of 2341 urban and rural households from each site were selected based on probability proportionate to size. The World Health Organization (WHO) child injury questionnaire adapted to the Indian settings was used after validation. Information on injuries was collected for previous 12 months. Definitions for types (road traffic accidents, falls, burns, poisoning, drowning, animal-related injuries) and severity of injuries was adapted from the WHO study. Information was elicited from parents/primary caregivers. Data were collected electronically, and handled with a management information system.

Results: In the 25751 households studied, there were 31020 children aged 6 months - 18 years. A total of 1452 children (66.1% males) had 1535 unintentional injuries (excluding minor injuries) had occurred in the preceding one year. The overall prevalence of unintentional injuries excluding minor injuries was 4.7% (95% CI: 4.4-4.9). The commonest type of injury was fall-related (842, 54.8%) and the least common was drowning (3, 0.2%). Injuries in the home environment accounted for more than 50% of cases.

Conclusions: The findings of the study provide inputs for developing a comprehensive child injury prevention policy in the country. Child safe school with age-appropriate measures, a safe home environment, and road safety measures for children should be a three-pronged approach in minimizing the number and the severity of child injuries both in urban and rural areas.

Keywords: *Animal-related injuries, Burns, Falls, Poisoning, Road traffic injuries*.

Globally, injuries and violence are major public health problems. Children are at a higher risk for injuries due to their physical and psychological attributes. Their small body size and the softness of tissues lead to greater vulnerability for severe impact. Children's risk perception is limited, making them more susceptible to involvement in road accidents, drowning, burns, and poisoning. Psychological characteristics of children like impulsiveness, curiosity, experimentation, an inadequate judgment of distance/speed, and low levels of concentration make them vulnerable to injuries [1].

The precise number of deaths and injuries due to specific causes or any reliable estimates of injury deaths in India are not available from a single source. The National Crime Records Bureau data and a study based on available data reveal that nearly 10-15% of India's injury deaths occur among children [2,3]. An examination of 'years of potential life lost' indicates that injuries are the second most common cause of death after 5 years of age in India [2]. While there are selected studies related to unintentional childhood injuries from hospital-based data, the true magnitude of the issue with population-level determinants is mostly lacking.

This study presents the results of a national level community-based multi-centric task force study of unintentional childhood injuries in India, commissioned by the Indian Council of Medical Research (ICMR).

METHODS

This multi-centric community-based cross-sectional study was conducted at 11 different sites across eight states in India between March, 2018 and September, 2020. A purposive selection of study sites was made, ensuring adequate geographical representation. The study population comprised children aged six months to <18 years from both rural and urban areas viz. Siddlaghatta, Bangalore, Karnataka; Pauri Garhwal, Srinagar, Uttarakhand; Vellore, Tamil Nadu; Perundurai, Erode, Tamil Nadu; Mangalore, Karnataka; Bardhman Sadar North, Bardhman, West Bengal; Dhoraji, Rajkot Gujarat; East Sikkim, Sikkim; Dholka, Ahmedabad, Gujarat; East Ludhiana, Ludhiana, Punjab; Huzur, Bhopal, Madhya Pradesh (**Fig. 1**).

Sample size and sampling strategy: The sample size was calculated considering the overall prevalence of childhood injuries to be 11.0% (including minor injuries) as per the guidelines for conducting community surveys on injuries and violence by WHO [4], with a relative precision of 13% and 95% desired confidence level, with increase in sample size by 10% to allow for non-responses, design effect of 2 to account for cluster sampling and relative precision of 13%. Hence, 2341 households from rural and urban areas (combined) were selected from each site proportionately based on the population's rural-urban distribution as per 2011 census [5]. In each site, the district predominantly served by the participating institution was selected. Subsequently, one taluk was selected through a simple random sampling technique. Applying probability proportionate to size (PPS) sampling, within each taluk, clusters of households in rural areas and urban areas were selected. Each cluster consisted of 16 houses (estimated based on the number of households to be covered by four field workers in a day) both in urban and rural areas.

Further, within the rural areas, all villages in the selected taluk were in the sampling frame. In each village, each cluster consisted of 16 households. The number of clusters to be surveyed to meet the required sample was arrived at.

In the case of urban areas, one town was selected using a simple random sampling technique from the total number of towns in the taluk. Like rural areas, 16 households made up one cluster. The required number of clusters were selected from a randomly chosen locality in the town.

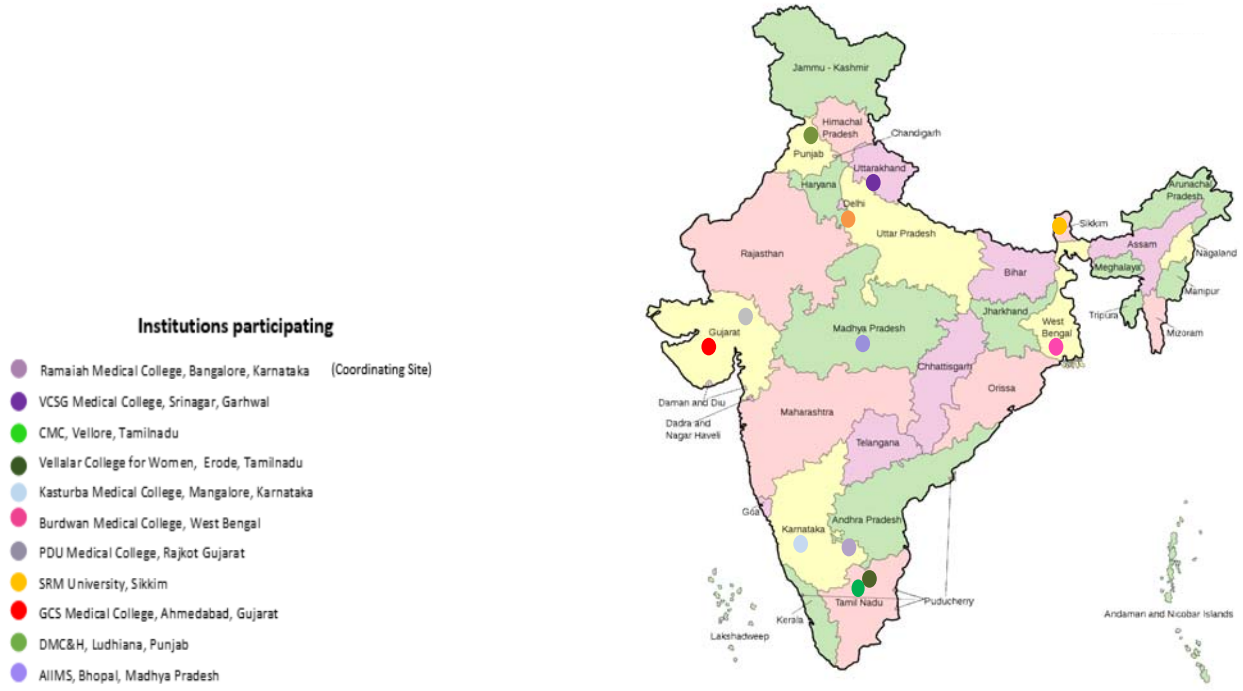


Fig. 1 Map of India with location of participating institutions and study sites.

The inclusion criterion was to have all six months to <18-year permanent resident children, and visiting children living in that area for a minimum duration of previous six months. Additionally, information pertaining to deaths in the above age group due to unintentional injuries was sought from the government sources. Birth injuries or injuries consequent to intra-natal complications, and disabilities due to other conditions were excluded.

After clearance from the institutional ethics committee (IEC), permissions were obtained from the district and taluk administrative authorities at all sites, the zilla panchayat CEO, and the Child Development Project Officer for accessing information of village panchayats and community health workers.

Data collection: Each site recruited four field workers (medico-social workers) who underwent standardized training of 5 days, through a workshop conducted at each site. The workshop oriented the field investigators to undertake an initial pilot study about child injuries, the tool, rapport building in the community, data collection procedures and hands-on instructions on using the electronic handheld device.

Subsequently, field investigators prepared a spot map of each selected village (rural area) or locality (urban area) and numbered the houses serially. After explaining the study's purpose in the local language, informed written consent was obtained from the respondent (parent/primary caregiver). Verbal assent was taken from children more than or equal to 7 years of age. In addition to interviewing the adult, children 7 years and above were also interviewed to substantiate parents' information. A history of previous three months was used to collect information relating to all injuries whereas information about fatal injuries was collected for the previous 12 months and verified in the register maintained in the panchayat office. At the end of every interview, the caregivers were verbally provided education regarding injury prevention among children.

Tool employed for data collection: The World Health Organization (WHO) child injury questionnaire adapted to the Indian settings was used [4]. Definitions for types (road traffic accidents, falls, burns, poisoning, drowning, animal-related injuries) and severity of injuries (mild, moderate and severe) was adapted from the WHO standard definitions [6]. Injuries other than these types were categorized as miscellaneous. A cloud-based software was developed through an external vendor and validated. Each center received four handheld devices for the field workers and one for the supervisor. Quality assurance of data was built into the software with features of valid entries, skip logic and consistency checks.

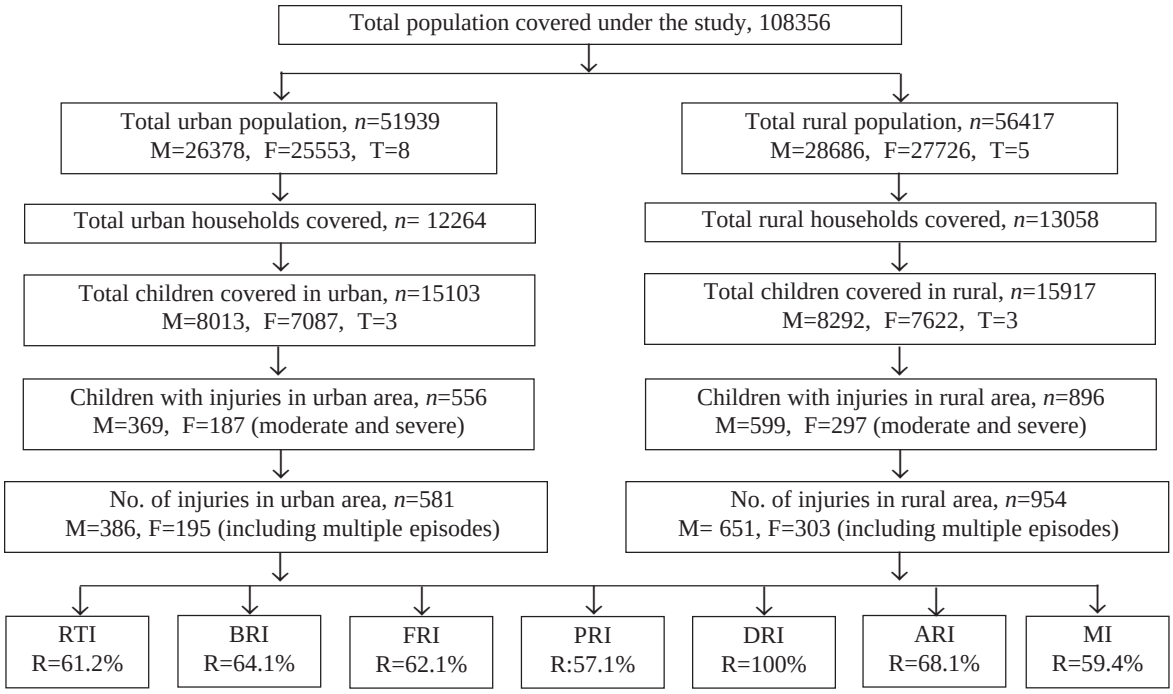
A robust management information system and dashboard was developed through which each site could visualize their respective electronic data on the web and download a copy of their data. Data were analyzed centrally based on the approved statistical analysis plan.

Quality assurance: An operation manual and a training manual for field workers were prepared by the coordinating team and shared with the participating sites to ensure uniformity. Online monthly meetings were organized by the central and national coordinating sites with other site investigators and field workers for centralized monitoring and supportive guidance to ensure regular interaction and quality of data collected. The coordinating center continuously monitored data through the dashboard. A team from the coordinating center and ICMR team visited each of the sites during data collection for supportive supervision. The investigators in each site revisited 5% of households randomly and collected information independently to check data quality and discrepancies if any, were resolved.

Statistical analyses: Data from all sites were analyzed by the coordinating team using Statistical Package for the Social Sciences 16.0 (SPSS Inc.). Data were coded according to severity of injuries. Minor injuries were excluded for subsequent estimates. The association between factors such as prevalence rate with age, gender, and other factors was tested for statistical significance by Chi-square test or Fisher's exact test. The difference in mean values between two groups was tested for statistical significance by Student's t-test. Probability value <0.05 was considered as cutoff for statistical significance. Prevalence rates (period prevalence for 3 months) with 95% confidence intervals were estimated.

RESULTS

The overall prevalence (95% CI) of unintentional childhood injuries, including minor and trivial was noted to be 14.5% (14.1-14.9). **Fig. 2** describes the samples selected and the distribution of the types of injuries in all sites combined. However, after excluding minor and trivial injuries, it was noted that 1452 children reported 1535 events of unintentional injuries. The prevalence rate of injuries in various sites ranged from 0.6-12.0% (rural areas) and 1.1-8.4% (urban areas) (**Fig. 3**). The prevalence was higher among males as compared to females (5.9% vs 3.3%, $P<0.001$). The differences in the prevalence rates between different age groups was found to be statistically significant ($P=0.01$), with the lowest prevalence rate among children below 1 year. The prevalence rate showed a decreasing trend with increasing socioeconomic status. The difference in prevalence based on the number of children in the family was minimal (**Table I**).



RTI-road traffic injuries, FRI-fall related injuries, BRI-burn related injuries, PRI-poison related injuries, DRI-drowning related injuries, ARI-animal related injuries, MI-miscellaneous injuries, T-transgender, M-males, F-females.

Fig. 2 Study flow and injury types at all participating sites (excluding mild/trivial injuries).

Among the different types of injuries, fall-related injuries had the highest prevalence rate of 2.7% (95% CI: 2.5-2.9) followed by road traffic accidents (RTA) (1%; 95% CI: 0.8-1.1). Drowning related injuries were the least (**Table II**). As per the World Health Organization severity grading, burn injuries (44.7%) followed by fall injuries (30.8%) reported a large number of severe type of injuries. A total of five fatal injuries were reported across the different sites (**Table III**).

Male children from rural areas in the age group of 5-9 years were commonly involved. The commonest location of injury for all categories was at home. Age was an important factor associated with different types of injuries.

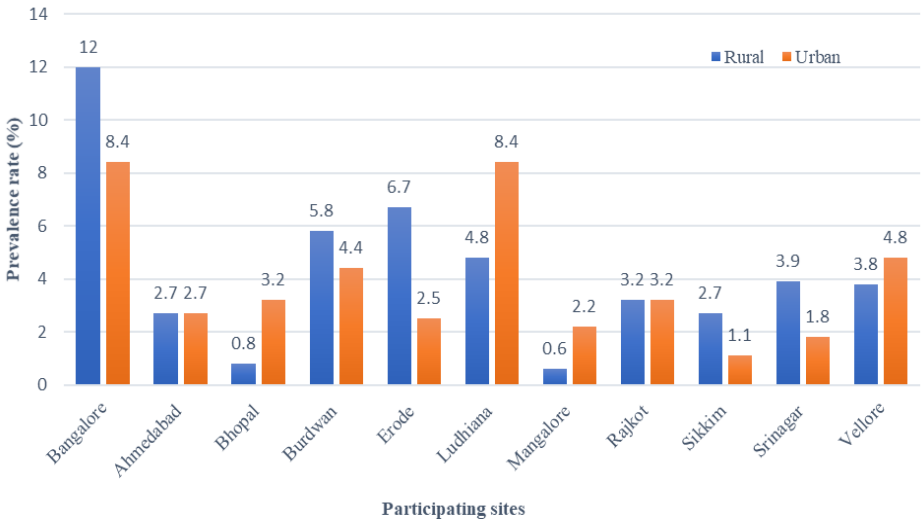


Fig. 3 Site-wise injury prevalence rate (%) by rural and urban areas.

Table I Socio/Demographic Characteristics and Prevalence of Injuries

	No. of children n=31020	*No. with injury n=1452*	*Prevalence (95% CI)*
Age group			
6 mo - < 1 y	768	2	0.3 (0.03-0.9)
1-4 y	6375	266	4.2 (3.7-4.7)
5-9 y	8682	449	5.2 (4.7-5.7)
10-14 y	9326	471	5.1 (4.6-5.5)
15-<18 y	5869	264	4.5 (3.9-5.1)
Gender[a]			
Male	16305	968	5.9 (5.5-6.3)
Female	14709	484	3.3 (3.0-3.6)
Area of residence			
Urban	15103	556	3.7 (3.3-4.0)
Rural	15917	896	5.6 (5.2-6.0)
Socioeconomic status			
Lower	3879	194	5.0 (4.3-5.7)
Lower middle and Upper lower	24323	1190	4.9 (4.8-5.5)
Upper middle and Upper	2818	6	2.4 (0.8-4.5)
Number of children in the family			
1-2	21313	1009	4.7 (4.2-5.2)
>2	9597	443	4.6 (4.0-5.1)
Type of family			
Nuclear	19323	921	4.8 (4.4-5.1)
Joint	6759	316	4.7 (4.2-5.2)
Three generation	4938	215	4.3 (3.8-4.9)

[a]*6 were transgenders and none of them had injuries. Comparisons of prevalence rates between different age group, gender, area of residence, socioeconomic status, number of children in the family, and type of family showed all P<0.001.*

While road traffic accidents, predominantly involved rural 10-14 year-old males (61.2%), fall-related injuries were common among the younger 5-9 year-old children resulting in considerable impairment (74.8%). However, in case of burn injuries, infants and toddlers had a higher proportion (45.6%) as compared to their older counterparts.

Table II Prevalence of Different Types of Injuries (*N*=31020)

Type of injury	*Prevalence rate (95% CI)*
Road traffic injuries, *n*=304	1.0 (0.8-1.1)
Falls, *n*=842	2.7 (2.5-2.9)
Burns, *n*=103	0.3 (0.2-0.4)
Poisoning, *n*=14	0.05 (0.02-0.08)
Drowning, *n*=3	0.01 (0-0.03)
Animal-related, *n*= 94	0.3 (0.2-0.4)
Miscellaneous, *n*=175	0.6 (0.4-0.7)

More than 80% of respondents with different types of moderate and higher grades of injuries sought care at private clinics initially. Most of the respondents reached the facility within one hour of the occurrence of major injuries. Although activities of daily living were affected among 88% of children with major injuries, more than 77% of the children returned to their usual level of activity in a short time. Less than a quarter of the respondents reported borrowing money for treatment related to injuries. Although a large proportion of children with injuries had some disability, most of them were temporary. Permanent disability was noted in 4.3% in road traffic accidents, 11.8% in falls, 16.5% in burns, 14.3% in poisoning, 11.7% in animal-related and 10.3% in miscellaneous injuries.

DISCUSSION

This study was undertaken to obtain the population estimates of unintentional childhood injures and major factors associated with them. The all-site prevalence of injury including minor and trivial was noted to be 14.5%. As per the reports from several studies done in various parts of India, the prevalence of injury ranges from 11% to 64% [7-9]. This wide range of prevalence may be attributed to the variation in the sources of data, definitions used, and selection criteria for assessing the burden of injuries.

Five deaths due to injuries were reported in one year of the study recall period (0.16 per 1000 children). According to the Bangalore Injury Surveillance Program (BISP), the ratio of fatal to nonfatal injury in children below 18 years was 1:27 and male to female ratio 3:1 [3]. Lower mortality rate reported in the present study may be attributed to the poor reporting systems as well as absence of validation of mortality reports for children below 18 years of age. An ontological analysis of national programs in India revealed lack of structured reporting mechanisms for childhood mortality [10].

Occurrence of injury was high among male children compared to female children (2:1). This could be attributed to the cultural practice of boys playing more outdoors as compared to girls, especially in the higher age-groups. Higher prevalence in males was reported by other studies as well [7, 8]. However, a study done in Agartala did not find any relation between gender and injury prevalence [9]. The confounding effect of the socio-cultural factors related to gender and different activities across various age groups is to be noted while interpreting the relationship between gender and injuries among children.

We observed that injuries were more common among children aged 5-14 years compared to children less than 5 years and 15 years and above, which has also been reported by Peden, et al. [11]. Children younger than

Table III Severity of Different Types of Injuries (*N*=1535)

Type of injury	*Fatal injury n=5*	*Severe injury n=444*	*Serious injury n=404*	*Major injury n=423*	*Moderate injury n=259*
RTI	1 (0.3)	76 (25.0)	81 (26.6)	95 (31.3)	51 (16.8)
Falls	1 (0.1)	259 (30.8)	224 (26.6)	20 (19.4)	151 (17.9)
Burns	1 (0.9)	46 (44.7)	32 (31.1)	20 (19.4)	4 (3.9)
Poisoning	1 (7.1)	1 (7.1)	3 (21.3)	7 (50.0)	2 (14.2)
Drowning	0	0	2 (66.7)	1 (33.3)	0
Animal-related	0	15 (15.9)	20 (21.3)	39 (41.5)	20 (21.3)
Miscellaneous	1 (0.6)	47 (26.9)	42 (24.0)	54 (30.9)	31 (17.7)

Values in no. (% of row total). RTI: road traffic injuries. Classification of injury severity as per World Health Organization [6].

5 years usually have close adult supervision and children older than 15 are relatively less playful. The age group 5-14 years are associated with independent locomotion with lack of appreciation of risk of getting injured. Similar results were reported by two other studies [1,12].

Falls contributed to 55% of injuries and most of them occurred in the domestic environment. WHO global disease burden report suggests that in most countries, falls are the most common type of childhood injury seen in emergency departments, accounting up to 52% of assessments. In Asia, falls are responsible for 43% of all injuries in children [13]. Other studies have also reported falls to be the most common injury which occurs in the home environment [2,7,11,14].

In Bangalore in 2007, 26% of injury deaths were due to road traffic injuries, 17% due to burns, 13% due to falls, 6% caused by drowning, and poisoning accounted for 5%. RTAs accounted for 40% of hospitalizations due to injury. Surveys show that road traffic injuries are one of the five leading causes of disability among children [2,3].

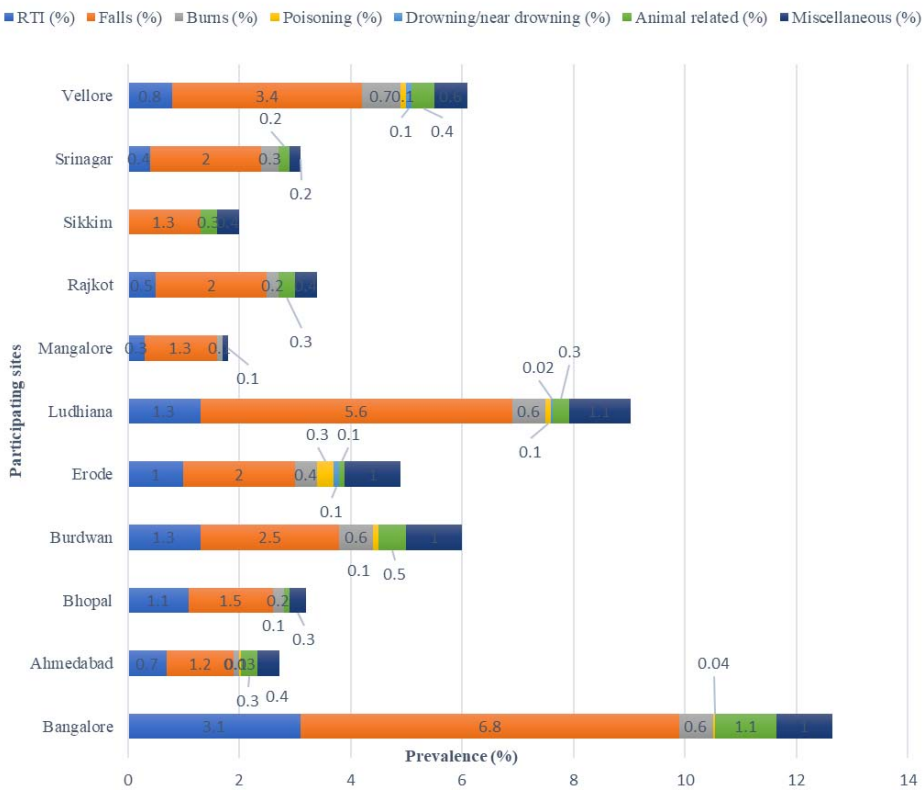


Fig. 4 Prevalence rate (%) of unintentional childhood injuries from different sites in India.

WHAT IS ALREADY KNOWN?

- Information on childhood injuries is largely available from hospital-based studies, with limited population-based data.

WHAT THIS STUDY ADDS?

- The all-site prevalence of injuries in children aged <18 years was 14.5% (including minor and trivial injuries).
- Fall-related injuries were most common (54.8%), and most injuries occurred in the domestic environment.

Burns (6.7% of injuries) were commonly reported due to electric shock or contact with hot liquids or steam. According to WHO, fire-related burns are the 11th leading cause of death for children between the ages of 1-9 years [15]. Children under the age of five years are at the highest risk of hospitalization from burns [12]. In India, cooking at floor level and wood fired stoves contribute significantly to burn injuries. Among older children, carelessness is an important contributor to burn injuries caused by fireworks [16].

Although this study reports only three cases of drowning in 5-9-year male children, it remains a health hazard. Fatal drowning is the 13th cause of death among children. Globally, rate of death due to drowning is 7.2 per 100000 population among children and the rate is 6 times higher in low- and middle-income countries compared to higher income countries [17]. Water storage sumps and ponds require special attention to make them safe for young children. Poisoning was reported more in rural areas. Kerosene poisoning is the most common accidental poisoning among children in India, especially in the age group of 1-3 years. Most injuries occur due to careless storage and use of pesticides, insect and mosquito killers, and naphthalene acids [18]. Animal-related injuries were also more common in rural areas and three-quarters of them were due to dog bites or scratches. The BISP has reported that 11% of injuries in children were due to animal bites [3,19]. A large portion of the Indian population live in rural communities, with likelihood of close contact with animals and hence a proclivity for animal-related injuries.

Domestic factors like inadequate living conditions, poor housing, no separate area for washing or cooking, use of smoke forming fuels, absence of cooking plat-forms, lack of safe storage area, absence of dedicated recreational area for children are key factors in the causation of injuries. Inadequate lighting would promote the chances of accidents at home. These factors are the major cause of falls, burns and accidental poisonings at home [7].

More than 50% of the children in the present study had cut injuries and lacerated wounds. In a study on unintentional injuries in the developing countries [20], cuts/bites and open wounds (23.9%) were the most common injuries. Bruise/superficial injury and burns accounted for 15% of all injuries while fracture was responsible for 19% of the injuries [7]. Another study reported that the most common physical nature of injury was bruise/superficial injuries (39.3%) and cut/bite or open wound injuries (35.3%) [12]. Abrasion and contusion contributed to around 1/3rd of injuries in our study, in contrast to another study done in Aligarh, which reported superficial injuries among under-five children and cut injuries among children aged more than 6 years [12].

A longitudinal study using verbal autopsy is helpful in collecting accurate information on fatal injuries. Logistic problems led to inability to collect data from all houses in hilly terrains and during winters and heavy rains. Clusters of 16 houses could not be found in sparsely populated areas/ hilly terrains and hence there is a need to develop newer approaches and smaller cluster size in such areas.

The findings of the study point to the facets that will be needed to formulate a comprehensive child injury prevention policy in the country. Implementation of the policy should be underscored at the level of the school and household. Child-safe schools with age-appropriate measures, a safe home environment and road safety measures for children should be a three-pronged approach in minimizing the number and the severity of child injuries. These measures must be reinforced through adolescent education, by articulating specific interventions to control risk taking behavior. Focused attention on 'injury-safe' rural environments will also curtail the burden of child injuries.

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ANNEXURE

List of Co-Investigators

Co-investigators from Participating Sites

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Web Table I Institution, Taluk and Urban:Rural Population Ratio of Each Site

Site	*Urban: Rural*[a]
Bangalore (Coordinating site)	24:76
Ahmedabad	37:63
Bhopal	89:11
Burdwan	26:74
Erode	46:54
Ludhiana	85:15
Mangaluru	79:21
Rajkot	45:55
Sikkim	53:47
Srinagar	37:63
Vellore	63:37

[a]*As per Census of India, 2011 [8].*

Web Table II Sociological Factors, Treatment and Outcome of Unintentional Injuries

Type of injury, n	*Commonest place where injury occurred*	*Commonest activity of the victim at the time of injury*	*Commonest physical nature of injury*	*Had impairment due to injury*	*Commonest nature of disability*	*Sought Medical attention for injury*	*Commonest Type of facility for medical care*	*Hospitalized at least for one day*	*Treatment received immediately*	*Reached health facility within 1 hrour*	*Affect daily activity*	*Return to usual level of activity*	*Did not borrow money for treatment*
RTI, *n*=304	260 (85.5) Road	140 (46.1) Travelling	160 52.6) Open wound	248 (81.6)	146 (48.0) Difficulty in walking	275 (90.5)	115 (37.8) Private clinic	57 (18.8)	206 (67.8)	217 (71.4)	281 (92.4)	246 (80.9)	223 (73.4)
Falls, *n*=842	427 (50.7) Home	479 (56.9) Leisure/play	259 (30.8) Open wound	630 (74.8)	254 (30.2) Difficulty or unable to use hand or arm	690 (81.9)	289 (34.3) Private clinic	74 (8.8)	603 (71.6)	557 (66.2)	737 (87.5)	652 (77.4)	706 (83.8)
Burn, *n*=103	93 (90.3) Home	52 (50.5) Leisure/play	62 (60.2) Scarring	80 (77.7)	46 (44.7) Difficulty or unable to use hand or arm	89 (86.4)	42 (40.8) Private clinic	12 (11.7)	79 (76.7)	69 (66.9)	89 (86.4)	74 (71.8)	86 (83.5)
Animal-related, *n*=94	47 (50.0) Home	36 (38.3) Leisure/play	47 (50.0) Other open wound	66 (70.2)	31 (32.9) Difficult to walk/walk with limp	86 (91.5)	34 (36.2) Government health center	12 (12.8)	68 (72.3)	75 (79.8)	80 (85.1)	76 (80.9)	82 87.2)
Miscellaneous, *n*=175	98 (56.0) Home	96 (54.9) Leisure/play	73 (41.7) Cut	139 (79.4)	61 (34.9) Difficulty or unable to use hand or arm	156 (89.1)	67 (38.3) Private clinic	20 (11.4)	128 (73.1)	129 (73.7)	155 (88.6)	132 (75.4)	141 (80.6)

All responses in no. (%).

RESEARCH PAPER

Outcomes of Neonates Born to Mothers With Coronavirus Disease 2019 (COVID-19) – National Neonatology Forum (NNF) India COVID-19 Registry

NATIONAL NEONATOLOGY FORUM (NNF) COVID-19 REGISTRY GROUP*

**List of group members provided as Annexure*

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Received: January 27, 2021; Initial review: February 25, 2021; Accepted: March 13, 2021.

Background: Limited evidence exists on perinatal transmission and outcomes of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection in neonates.

Objective: To describe clinical outcomes and risk factors for transmission in neonates born to mothers with perinatal SARS-CoV-2 infection.

Design: Prospective cohort of suspected and confirmed SARS-CoV-2 infected neonates entered in National Neonatology Forum (NNF) of India registry.

Subjects: Neonates born to women with SARS-CoV-2 infection within two weeks before or two days after birth and neonates with SARS-CoV-2 infection.

Outcomes: Incidence and risk factors of perinatal transmission.

Results: Among 1713 neonates, SARS-CoV-2 infection status was available for 1330 intramural and 104 extramural neonates. SARS-CoV-2 positivity was reported in 144 intramural and 39 extramural neonates. Perinatal transmission occurred in 106 (8%) and horizontal transmission in 21 (1.5%) intramural neonates. Neonates roomed-in with mother had higher transmission risk (RR1.16, 95% CI 1.1 to 2.4; *P*=0.01). No association was noted with the mode of delivery or type of feeding. The majority of neonates positive for SARS-CoV2 were asymptomatic. Intramural SARS-CoV-2 positive neonates were more likely to be symptomatic (RR 5, 95%CI 3.3 to 7.7; *P*<0.0001) and need resuscitation (RR 2, 95%CI 1.0 to 3.9; *P*=0.05) compared to SARS-CoV-2 negative neonates. Amongst symptomatic neonates, most morbidities were related to prematurity and perinatal events.

Conclusion: Data from a large cohort suggests perinatal transmission of SARS-CoV-2 infection and increased morbidity in infected infants.

Keywords: *Horizontal transmission*, *Outcome*, *Perinatal transmission, Risk*.

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The severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) has infected over 15 million individuals in India [1]. The SARS-CoV-2 infects both children and adults but has higher fatality in the elderly and individuals with co-morbidities [2]. SARS-CoV-2 infects pregnant women as much as other reproductive-age women [3]. The knowledge about the epidemiology, clinical characteri-stics, prevention, and treatment of SARS-CoV-2 infection is continually evolving. Currently available data on the consequences of SARS-CoV-2 infection in pregnancy, fetus, and the neonate is mostly from case reports, small case series, retrospective cohort or cross-sectional studies, compiled in a recent systematic review [4]. There is limited data on perinatal SARS-CoV-2 infection from the developing world. We report analysis from a large neonatal coronavirus disease 2019 (COVID-19) registry under the National Neonatology Forum (NNF) of India, on the incidence of perinatal transmission and the factors associated with it, and the clinical features of SARS-CoV-2 positive neonates.

METHODS

In this prospective cohort study, data were collected from various hospitals voluntarily enrolled in the NNF COVID-19 registry, which was initiated in April, 2020. Neonates born to women with SARS-CoV-2 infection within two weeks prior to or two days after delivery and neonates with confirmed SARS-CoV-2 infection within 28 days of life were eligible for enrolment in the study. COVID status of mothers and neonates was assessed by nasopharyngeal RT-PCR in all participating hospitals.

SARS-CoV-2 infected neonates were defined as those with a positive SARS-CoV-2 quantitative RT-PCR test in nasopharyngeal swab within 28 days of birth [5]. SARS-CoV-2 infected mothers were defined as those with a positive SARS-CoV-2 quantitative RT-PCR test in the

nasopharyngeal sample during the peripartum period [5]. Perinatal transmission was defined as positive nasopharyngeal RT-PCR in a neonate in the first 72 hours after birth [6,7]. This included intrauterine and intrapartum transmission. Testing was avoided in the first 12 hours to minimize false positives due to superficial colonization. Horizontal transmission was considered in a neonate with negative RT-PCR within the first 72 hours who subsequently tested positive any time after 72 hours of birth irrespective of the mother's SARS-CoV-2 status [6,7].

Mothers were either tested at admission or referred for admission because of the SARS-CoV-2 positive reports. Testing and management were as per the Indian Council for Medical Research (ICMR) and NNF guidelines, and local standard operating procedures [8,9]. SARS-CoV-2 status of the neonate was tested as per NNF guidelines and local institutional protocols, which in most centres was done within the first 72 hours after birth or when the neonate was symptomatic and admitted to the neonatal unit [8]. All neonates were monitored for clinical symptoms for the first seven days after birth and for as long as the mother was admitted to the hospital. Data on mothers and neonates was available till disposition from the hospital.

Data collection: Data was prospectively submitted to the registry by the participating hospitals in a web-based secure platform (*https://innc.org/covid*). All the registered hospitals received a short message alert every week on the number of enrolled cases and data completeness. Twenty percent of the enrolled cases from each participating centre were randomly cross-checked for data quality. A closed group of clinical leads from participating hospitals was formalized for secure, encrypted communication. This group managed the updates to the database, day-to-day problems in data management, the progress of the registry, and sharing of education and communication. Any inconsistency in data was highlighted to the respective hospital lead for verification.

The data included baseline characteristics of the mothers, mode of delivery, type of feeding, rooming-in with mother or isolation from mother, clinical features, diagnosis, and neonatal outcomes. The clinical status of patients was classified as per guidelines from the Ministry of Health and Family Welfare, Government of India [10].

The primary outcomes of the study were: (*i*) the incidence of perinatal transmission; (*ii*) the rates of SARS-CoV-2 virus positivity in the neonates in association with risk factors of transmission such as mode of delivery, type of feeding and care practices, and (*iii*) comparisons between intramural and extramural, SARS-CoV-2 positive and SARS-CoV-2 negative neonates born to SARS-CoV-2 positive mothers. The secondary outcomes were respiratory morbidities, the need for respiratory support, and mortality in these infants.

Statistical analyses: Descriptive statistics were used, and comparisons were made using the chi-square test for categorical variables and the Student t-test or Mann-Whitney U test as appropriate for continuous variables. A *P*-value of <0.05 was considered significant.

RESULTS

The web-based COVID-19 registry received a total of 1733 entries for mothers and their neonates. Almost all (1730/1733) of the enrolled mother-infant dyads were from tertiary care hospitals, 1649 (95%) from public sector hospitals, and 82 (5%) from private hospitals. We excluded 22 entries where both mothers and neonates were negative but were referred because of suspicion of SARS-CoV-2 infection, and 1711 mother-infant dyads were enrolled in this study. Most of the mothers (94.5%) were asymptomatic, and only 1% were critically ill. Cesarean section was the mode of delivery in 68%.

Of the 1711 enrolled neonates, 1589 were intramural, while 122 were extramural births. The extramural infants were referred to the participating hospitals for either symptomatic status or for SARS-CoV-2 positive status of the mother. Figure 1 gives a study flow for intramural neonates enrolled in the registry. Out of 1589 intramural infants, SARS-CoV-2 testing was either not done or not reported in 259, so we excluded them from the analysis. Amongst 1330 tested neonates, 143 (10.8%) were SARS-CoV-2 positive. Of these, 68 (5.1%) tested positive on day one (**Fig. 1** and **2**). Amongst the intramural newborn infants, 106 (8%) were positive for SARS-CoV-2 within 72 hours (perinatal transmission) and 21 (1.5%) beyond 72 hours (horizontal transmission) of birth. The risk of transmission was not associated with the mode of delivery or type of feeding. The risk of transmission of SARS-CoV-2 from mother to neonate was marginally higher if the baby was roomed-in with the mother (RR 1.16, 95% CI 1.1-2.4; *P*=0.01). **Tables I** and **II** compare the SARS-CoV-2 positive and negative infants born to SARS-CoV-2 positive mothers. The demographic para-meters in both the groups were not different except for the prematurity rate, which was higher in SARS-CoV-2 positive group. SARS-CoV-2 positive neonates were five times more likely to be symptomatic and twice more likely to need resuscitation. They had significantly higher probability of having sepsis and septic shock. SARS-CoV-2 positive neonates were more likely to have abnormal radiological findings and need respiratory support. They were also more likely to have received surfactant, steroids and inotropes. The risk of

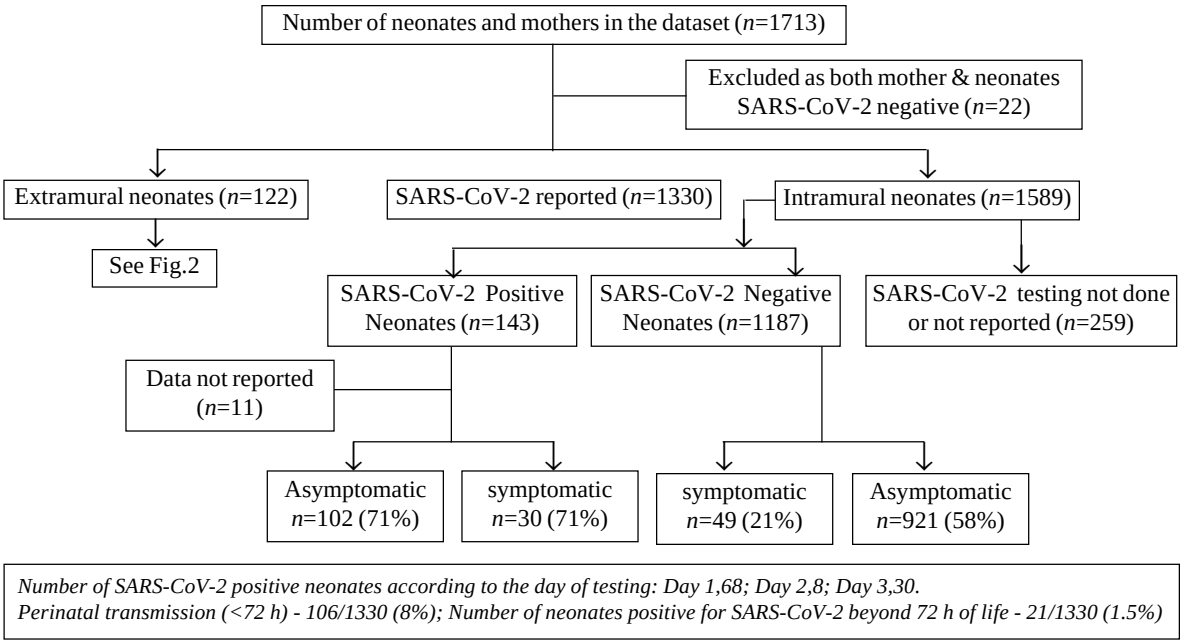

Fig. 1 Study population flow for intramural neonates.

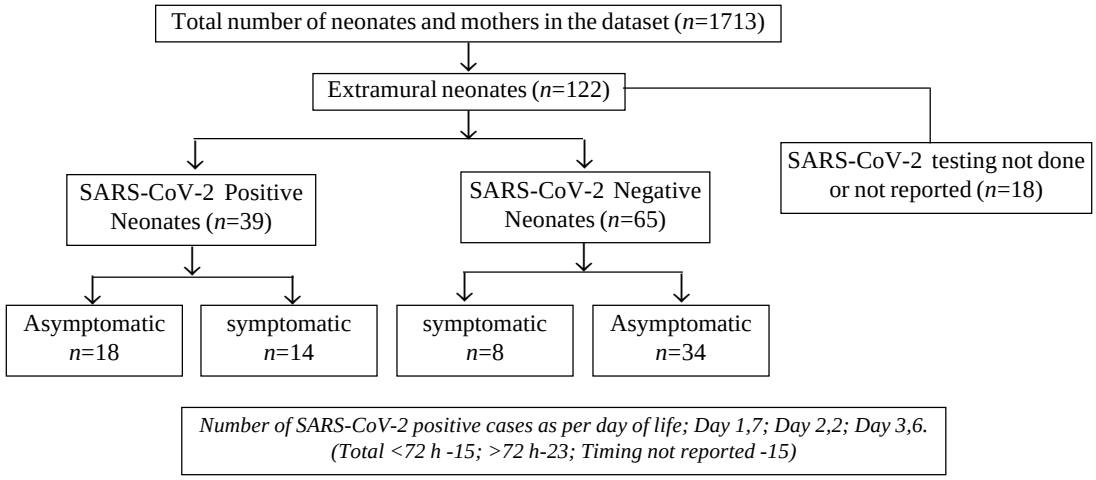

Fig. 2 Study population flow for extramural neonates.

mortality was however not significantly different between the two groups. No significant association was noted between mother's symptomatic status and baby's SARS-CoV-2 positivity, need for resuscitation, and symptoms.

Fig. 2 depicts the study flow for extramural neonates. Extramural SARS-CoV-2 infected neonates were more likely to present with pneumonia, seizures, and septic shock, and were more likely to present after the first 72 hours of birth (**Tables III** and **IV**). This cohort of neonates was generally symptomatic. Like intramural neonates, extramural SARS-CoV-2 infected neonates tended to have more respiratory symptoms, radiological abnormalities, and needed more respiratory support.

There were 17 neonates in the registry, who were positive for SARS-CoV-2, but their mothers were reported negative. Five of these neonates were positive within 72 hours of life, and the remaining tested positive beyond 72 hours of birth. In this sub-group, 3 (17.6%) needed resuscitation at birth, 3 (17.6%) had pneumonia, 5 (29%) had respiratory distress, and 4 (23.5%) had sepsis. One (5.9%) infant had encephalopathy, and 3 (17.6%) had seizures.

Table I Demographics and Risk Factors in SARS-CoV-2 Positive and Negative Intramural Neonates

Parameters	*SARS-CoV-2*		*RR (95% CI)*
	Positive (n=143)	*Negative (n=1187)*	
Male gender	81 (57)	581 (49.2)	1.1 (0.9 -1.3)
Weight, g[a]	2746 (618)	3024 (170)	
Gestation, wk[a]	37.5 (2.1)	37.7 (1.5)	
Prematurity	Reported in 130 (90.9)	Reported in 1142 (96.2)	
34-36 wk	21 (16.1)	106 (8.9)	1.6 (1-2.5)[c]
<34 wk	6 (4.6)	15 (1.3)	3.3 (1.3-8.4)[b]
<37 wk	27 (20.7)	121 (10.2)	1.8 (1.2-2.7)[b]
Caesarean delivery	88 (61.5)	821 (69.7)	0.8 (0.7-1)
Mother positive[d]	135 (94.4)	1167 (98.3)	0.1 (0.08-0.12)[b]
Roomed-in with mother	111 (77.6)	800 (67.4)	1.16 (1.1-2.4)[c]
Breastfeeding	119 (83.2)	998 (84.1)	0.97 (0.6-1.5)

Values in no. (%) or [a]mean (SD);[b]P<0.01; [c]P=0.01; [d]RT-PCR for SARS-CoV-2.

DISCUSSION

In this large registry of neonates born to SARS-CoV-2 positive mothers, we report the incidence of neonatal infection, type of symptoms, and neonatal outcomes. Neonates acquired infection most commonly in the first 72 h after birth. The 5.1% neonates who tested positive on day one may have acquired the infection intrauterine or intrapartum. Those neonates who tested positive on days two or three may also have been due to intrauterine transmission but could have acquired the infection postnatally from mother, other family members, or healthcare providers. In the absence of serial testing and testing of various body fluids from mother, it is not possible to pinpoint the timing of acquisition. It is also to be noted that many neonates were tested for the first time on day three as per the local protocols, and the absence of testing on the first day after birth could have led to misclassification of the type of infection. We found a significantly higher incidence of perinatal transmission than that reported in a recent review [10].

This study highlights that SARS-CoV-2 positive neonates are more likely to be symptomatic, more likely to have respiratory symptoms, and other neonatal morbidities. However, the mortality is not increased significantly. In a systematic review by Raschetti, et al. [4], the median age at diagnosis was five days, and 55% of neonates were symptomatic [4]. Common symptoms reported include respiratory distress, fever, and those related to gastrointestinal illness. Most of the infected

Table II Clinical Features and Management of SARS-CoV-2 Infection in Intramural Neonates at Birth

Parameters	*SARS-CoV-2*		*RR (95% CI)*
	Positive (n=143)	*Negative (n=1187)*	
Resuscitation[d]	15 (10.4)	26 (2.1)	4.4 (2.4-8.2)[a]
Symptomatic	30 (21)	49 (4.1)	5 (3.3-7.7) [a]
RDS	13 (9)	12 (1.1)	7.5 (3.4-16.8)[a]
Pneumonia	10 (7)	1 (0.08)	83 (10.7-643)[a]
Sepsis	5 (3.5)	1 (0.08)	41.5 (4.8-352)[a]
Seizures	5 (3.5)	6 (0.5)	6.9 (2.1-22.3)[b]
Septic Shock	6 (4.2)	6 (0.5)	8.3 (2.7-25.3)[a]
DIC	4 (2.8)	4 (0.3)	8.3 (2-32)[c]
Encephalopathy	3 (2.1)	7 (0.6)	3.5 (0.93-13.6)
Jaundice	6 (4.2)	6 (0.5)	8.3 (2.7-25.4)[a]
Other morbidities	28 (19)	43 (4.5)	5.4 (3.4-8.4)[a]
Abnormal CXR	16 (11.2)	7 (0.6)	18.9 (7.9-45.3)[a]
Oxygen therapy	11 (7.7)	27 (2.3)	3.3 (1.7-6.6)[a]
CPAP	7 (4.9)	13 (1)	4.5 (1.8-11)[a]
Ventilation	8 (5.6)	14 (1.2)	4.7 (2- 11.1)[a]
Surfactant	5 (3.5)	7 (0.6)	5.9 (1.9-18.4)[c]
Inotropes	8 (5.6)	10 (0.8)	6.6 (2.6-16.5)[a]
Corticosteroids	4 (2.8)	2 (0.2)	16.6 (3-89.8)[b]
IVIG	0	1 (0.08)	–
Oseltamivir	2 (1.4)	0	–
Mortality	2 (1.4)	4 (0.3)	4.1 (0.76-22.4)

[a]P<0.001; [b]P=0.001; [c]P<0.05; [d]at birth. CXR: chest X-ray; IVIG: intravenous immunoglobulin, CPAP: continuous positive airway pressure; RDS: respiratory distress syndrome; DIC: disseminated intravascular coagulation.

Table III Demographics and Risk Factors in SARS-CoV-2 Positive and Negative Extramural Neonates

Parameters	*SARS-CoV-2*	
	Positive (n=39)	*Negative (n=65)*
Male gender	22 (57)	32 (49.2)
Weight (g)[a]	2572 (600)	2822 (582)
Gestation (wk)[a]	36.9 (2.2)	37.3 (1.7)
Prematurity	27	35
34-36 weeks	4 (14.8)	2 (5.7)
<34 weeks	3 (4.6)	4 (1.3)
Total <37 wk	7 (19.4)	6 (7%)
Caesarean delivery	17 (43.6)	43 (66.1)
Mother positive[b,d]	26 (76.5)	62 (95.4)
Roomed-in	17 (43.6)	23 (35.9)
Breastfeeding[c]	18 (48.6)	45 (70.3)

Values in no. (%) or [a]mean (SD). [b]RR(95%CI)=0.7(0.6-0.9), P<0.001; [c]RR(95%CI)=0.7 (0.4-0.9); P=0.05; [d]RT-PCR for SARS-CoV-2.

Table IV Clinical Features and Management of SARS-CoV-2 Infection in Extramural Neonates

Parameters	*SARS-CoV-2*		*RR (95% CI)*
	Positive (n=39)	*Negative (n=65)*	
Symptomatic	13/27 (48)	6/36 (16.6)	2.9 (1.2-6.6)[d]
RDS	13 (33.3)	8 (12.2)	2.7 (1.2-5.9)[c]
Pneumonia	6 (15.4)	1 (1.5)	10.1 (1.2- 81)[c]
Seizures	4 (10.2)	1 (1.5)	6.6 (0.7-57)[d]
Septic Shock	6 (15.4)	1 (1.5)	10 (1.2-80)[d]
DIC	3 (7.7)	0	12.1 (0.6-229)[e]
Encephalopathy	1 (2.6)	1 (1.5)	1.6 (0.1-25.8)[e]
Diarrhoea	2 (5.1)	2 (3.1)	1.6 (0.2-11.3)[e]
Other morbidities	11 (28)	2 (3.1)	9.1 (2.1-39)[b]
Abnormal CXR	16 (11.2)	7 (0.6)	18.9 (7.9- 45.3)[a]
Oxygen therapy	10 (25.6)	4 (6.1)	4.1 (1.4-12.3)[c]
CPAP	3 (7.7)	3 (4.6)	1.7 (0.3-8.2)[e]
Ventilation	7 (17.9)	1 (1.5)	11.6 (1.5-91)[c]
Inotropes	5 (12.8)	1 (1.5)	7.7 (0.9-64)[e]
Corticosteroids	2 (5.1)	0	8.2 (0.4-167)[e]
IVIG	2 (5.1)	0	8.2 (0.4-167)[e]
Mortality	1 (2.6)	1 (1.5)	1.6 (0.1-25.8)[e]

CXR: chest X-ray; IVIG: intravenous immunoglobulin; CPAP: continuous positive airway pressure; RDS: respiratory distress syndrome; DIC: disseminated intravascular coagulation. [a]*P<0.001;* [b]*P=0.001;* [c]*P<0.01;* [d]*P<0.05;* [e]*Not significant.*

neonates were not reported to need any respiratory support and had a good outcome after a median duration of hospitalization of 10 days. In our study cohort, 21% (30/143) of SARS-CoV-2 positive intramural neonates were symptomatic, and the most common symptoms included respiratory distress and sepsis-like features. However, fever and gastrointestinal symptoms were not commonly reported. The prematurity rate of 20.7% in our cohort was significant and similar to what was reported by the UK registry [11]. This raises concerns about the possibility of increased risk of premature labor in SARS-CoV-2 positive pregnant women. The incidence of symptomatic infection reported by us is lower than that reported in the previous reviews [4,12-13] and an Indian case series [14], but similar to that reported by Anand, et al. [15]. This can be explained by possible selection bias inherent in the type of studies - case reports and case series- included in the systematic reviews.

Another important finding in our cohort is that SARS-CoV-2 infected neonates were significantly more likely to need resuscitation, be symptomatic, need NICU admission, have abnormal chest *X*-rays, and need respiratory support. Previous studies have reported a high incidence of NICU admissions in SARS-CoV-2 positive neonates or neonates born to SARS-CoV-2 infected mothers [4]. Some of the variations in NICU admission rates may be due to local protocols for admission and isolation rather than due to the illness per se. Prematurity is an obvious confounder for higher respiratory and other morbidities in the SARS-CoV-2 positive group, and we did not adjust for prematurity rates. However, the difference in prematurity rates is unlikely to explain the magnitude of differences in morbidities.

We found a marginally higher incidence of infection in neonates who were roomed-in with mother. However, we did not find any association with breastfeeding. Similar findings have been reported by Raschetti, et al. [4], wherein lack of mother–neonate separation from birth was associated with late SARS-CoV-2 infections, while breastfeeding was not associated with increased risk. Recent systematic reviews have found a very low rate of detection of SARS-CoV-2 RNA in breastmilk, with a much higher prevalence of antibodies to the virus in the breastmilk [16,17]. The World Health Organization recommends that neonates should be roomed-in with mother and exclusively breastfed while following precautions to limit the spread of SARS-CoV-2 infection to neonates [18]. A higher incidence of neonatal infection in infants roomed-in with mothers is likely due to incomplete adherence to the suggested precautions. Salvatore, et al. found no perinatal transmission in a cohort of 116 SARS-CoV-2 positive pregnant women from three New York hospitals with rooming-in and breastfeeding, if correct hygine precautions, maternal masking and parental education were undertaken [19]. Similarly, Anand, et al. [15] report a low risk of transmission of infection from mother to baby with rooming-in and breastfeeding. This is important information for families to be aware of, along with the finding that infection is asymptomatic in the majority of neonates, and the outcome is largely favorable. Meanwhile, more research is needed to evaluate measures to prevent postnatal transmission to neonates and improve adherence to currently prescribed precautions.

We also report on extramural neonates referred to tertiary care hospitals following contact with an infected adult in the family or for other morbidities. SARS-CoV-2 positivity was more likely if these neonates were symptomatic at admission. The repertoire of symptoms was similar to symptomatic intramural neonates. The high incidence of infection in neonates who are symptomatic at presentation underscores the need for universal testing guidelines for this category of neonates [20].

WHAT IS ALREADY KNOWN?

- Limited evidence exists on the perinatal transmission and the management of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection among newborns, especially from the developing world.

WHAT THIS STUDY ADDS?

- Our data confirms perinatal transmission of SARS-CoV-2 and suggests increased morbidity in infected infants. Breastfeeding and rooming-in seem to be safe but require compliance with additional precautions.

This large registry was created for the new COVID-19 disease within a short span of time after the WHO's announcement of the pandemic and data was contributed by 20 hospitals on a voluntary basis across the country. The most important limitation, as highlighted above, was non-uniformity in age at testing of neonates born to SARS-CoV-2 positive mothers. As this was a registry-based study, testing of other biological sources like amniotic fluid, placenta, blood, or breastmilk was not pursued. We also did not test for the presence of specific antibodies in the neonatal blood to look for intrauterine infection as suggested by a recent guideline to classify the type of neonatal infection [7]. We did not capture data for neonates with the possibility of multi-system inflammatory syndrome in children (MIS-C) following SARS-CoV-2 infection, which is recently being reported [21].

In conclusion, our study provides important data on neonatal infection, clinical features, and outcomes in neonates born to SARS-CoV-2 positive women. This information can be used to make informed decisions and policies on neonatal SARS-CoV-2 testing, healthcare organization for neonates born to SARS-CoV-2 positive women, and counseling of families regarding various management options.

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ANNEXURE

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RESEARCH PAPER

Effectiveness of an Educational School-Based Intervention on Knowledge of Unintentional Injury Prevention and First Aid Among Students in Ujjain, India

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Objective: To determine the effectiveness of an educational intervention on the knowledge of adolescents on prevention of unintentional injuries and first aid.

Methods: The study used one group pre-post intervention design, without external controls. A two-stage (at schools and classes) cluster sampling was used to enroll 1944 high school students in Ujjain district. The intervention consisted of educational intervention using lectures presented through Power Point presentations, pictures, and videos. Sixty sessions each wherein a questionnaire to assess knowledge of participants was administered before and after the educational intervention. The outcome was a change in knowledge score.

Results: The study included 1944 school students [1105 (57%) boys] with mean (SD) age of 15.9 (1.3) years. The analysis of variance revealed the difference between the sum total of pre- and post-intervention scores was statistically significant (P <0.001), with a large effect size of 3.7. Younger students outperformed older students, boys outperformed girls, students of urban schools outperformed their rural counterparts, students of public schools outperformed those of private schools and students of Hindi medium schools outperformed students of English medium schools.

Conclusions: This school-based educational intervention significantly increased the knowledge of students on the prevention of unintentional injuries and first aid.

Keywords: *Adolescent, Educational intervention, Prevention.*

Injury is a leading cause of mortality worldwide, more so in lower income countries and lower-middle-income countries [1-3]. The large burden of injury and the associated mortality and morbidity are preventable [4]. Delay in immediate and appropriate first aid increases the mortality and morbidity due to injuries.

Trauma services and pre-hospital care are inadequate in many parts of India [3]. Furthermore, the lack of guidelines for pre-hospital care, sparse skilled staff and ambulances, and the long distances to hospitals aggravates the severity of the of injuries and road traffic accidents [5,6]. First aid is the initial part of the continuum of injury and trauma care, which can protect the lives at homes, schools, workplaces, and public places. Therefore, first aid education to lay people is needed.

The target population of the intervention in the present study was adolescents because they are pivotal members of the community and can act as change agents [7]. Moreover, adolescents spend most of their time in schools, and their active participation in sports and other physical activities exposes them to various unintentional injuries [7]. Therefore, creating awareness among adolescents by imparting knowledge on injury prevention and first aid is essential.

A systematic review from Australia examined the breadth of first aid training delivered to adolescent school students and identified only two studies that focused on injury prevention and first aid measures [7]. The efficacy of educational interventions in creating awareness about the prevention of injuries and their first aid among students has been reported by both teachers and students [7]. First aid is not a part of the formal teaching curriculum in most schools in India; therefore, this study was planned to impart formal knowledge of first aid to adolescents and to determine the effectiveness of the school-based educational intervention for prevention of unintentional injuries in improving the knowledge of adolescents studying in schools located in a district in Madhya Pradesh (MP), India.

METHODS

The present pre-post intervention study without external controls was conducted on 1944 students aged 14-20

years and studying in classes 9 to 12, from 30 schools from both rural and urban areas of Ujjain district located in MP. The population of the district is approximately 1.9 million, with 61% of the population resides in rural areas having agricultural economy [8]. Children under 15 years of age constitute 28.9% of the total population [9].

A total of 50 students were enrolled in a pilot study to calculate sample size as there are no similar Indian studies. Of the total questions, administered to the participants, 48–56% were answered correctly. To maximize the sample size, the lower proportion 48% of the range was used. Assuming a two-sided alpha error of 0.05, margin of error of 0.04, and power of 90%, the sample size was 1640. An additional 10% was added to the above sample size to compensate for attrition or refusal, resulting in the final sample size of 1804.

The institutional ethics committee of RD Gardi Medical College, Ujjain approved the research protocol. Prior permission was taken from the District Education Officer and the District Magistrate. Invitations were sent to the principals or heads of the selected schools, who reviewed the study design and approved participation in the study. Informed written assent consent to participate in the study was obtained from students and their parents.

A two-stage (schools and classrooms) cluster sampling was used. Out of the total of 514 higher secondary schools in Ujjain, 93 schools had 40-50 students in class 9-12. We selected 30 schools using random numbers. During second stage sampling, we randomly selected 2002 students of class 9-12 from these schools. Of these, parents of 1944 children provided consent, and were enrolled for the study.

Data were collected for six months, duration from July, 2018 to December, 2018. A structured questionnaire was developed in English and was then translated to Hindi as per World Health Organization recommendations. Forward translation was performed by a bilingual professional health care worker, namely a pediatrician who had injury work experience, and an expert panel resolved any discrepancies in translation [10]. The questionnaire was back translated to English to ensure that the original meaning had been retained. Pilot testing of the questionnaire was performed on 10 school students (aged 15-18 years), and the final version was then produced.

A team of trained research assistants asked the students to fill-in a questionnaire following which the educational intervention was administered. Post-training assessment of students was conducted one-month later using the same structured questionnaire. Students took approximately 20 min to complete the questionnaire. The questionnaire consisted of 25 questions, of which 8 were on prevention and 17 were on first aid. A score of 1 was given to each correct answer and the minimum and the maximum score obtained was 0 and 25, respectively.

Educational intervention: A visit to each school was scheduled before starting the educational intervention. The training session used a training module based on the Red Cross Society first aid module [11]. The length of an intervention session was 40 min. A total of 120 sessions were conducted in 6 months which included 60 pre-intervention and equal number of post-intervention sessions. Apart from post-intervention sessions no other reinforcement was provided to the students. A minimum gap of one month was maintained between pre- and post-intervention sessions.

The educational intervention included lectures on different types of unintentional injuries, such as burns, poisoning, drowning, suffocation, and physical injuries (wounds, fractures, and road traffic accidents) and their first aid through PowerPoint presentations, pictures, and videos. Other lecture topics in the training included basic information on the 'Good Samaritan law' in India, importance of the golden hour, and importance and components of the first aid box. Participants were not informed in the beginning that they would be tested later.

Fidelity of the intervention: The intervention design was informed by the theoretical framework of the information-motivation-behavioural skills (IMB) model of health behavior [12]. Further, the research assistants were trained by the principal investigator to maintain the fidelity of the intervention. The intervention module consisted of a 3-hour training session involving a discussion on all pictures, videos, and each slide in the power point presentation regarding the content and the way of delivering the lecture. The concepts were reinforced by providing the research assistants an opportunity to engage in role-playing. The session was repeated once every fortnight during the study period. To ensure the implementation of the intervention, a training manual was used to articulate the contents and delivery of the educational interventions. The participants' receipts of intervention were assessed on the basis of their attendance and the acquired knowledge post-intervention.

The main outcome variable (dependent variable) was the change in pre- and post-intervention knowledge score. Age, gender, school location, school type, medium of education in the schools, and the class in which the students were studying were the main independent variables.

Statistical analysis: Data were collected in the schools

through paper-based questionnaires which were reviewed daily by the principal investigator and co-investigators for consistency and completion. The data were coded and entered in Epi Info (Version 7.2). Data analysis was performed using Stata (Version 16.0, Stata Corp). The data were analyzed to determine the proportion of correctly answered questions by students pre- and post-intervention. Pearson chi-square test was used as a test of significance. Sum total of knowledge scores before and after intervention were compared using repeated measures analysis of variance. To quantify the effectiveness of educational intervention, an effect size (Cohen's d) was derived. A multivariate quantile regression model was used to test the association between the dependent and independent variables.

Quantile regression model was chosen to capture the full distribution of the outcome – change in pre- and post-intervention knowledge scores. The coefficient (b), standard error, and 95% confidence interval (CI) were estimated for 10th, 25th, 50th, 75th, and 90th quantiles of the change in pre- and post-intervention knowledge scores based on 500 bootstrap samples. A *P* value <0.05 was considered significant.

RESULTS

Of the 1944 students, 1105 (57%) were boys and the remaining 839 (43%) were girls. The mean (SD) age of the participating students in the study was 15.99 (1.33) years. **Table I** illustrates the demographic characteristics of the study participants.

The mean (SD) pre- and post-intervention knowledge scores of students were 8.12 (3.59) and 21.31(3.46), respectively. **Suppl. Table I** shows the comparison of correct responses related to knowledge of unintentional injury and first aid. The difference between the sum total of pre- and post-intervention scores was statistically significant (*P*<0.001). For pre-post intervention knowledge scores, Cohen's d effect size was 3.7, with an effect size ≥0.8 defined as large.

Younger students outperformed older students with most significant association seen at quantiles q25 [b= -0.28], 95% CI (-0.53 to -0.03), *P*=0.026], q75 [b= -0.44, 95% CI (-0.64 to -0.24), *P*<0.001] and q90 [b= -0.53, 95% CI (-0.80 to -0.26), *P*<0.001]. Boys outperformed girls with most significant association seen at median quantile [b=1.57, 95% CI (0.85 to 2.30), *P*<0.001]. Students of urban schools outperformed their rural counterparts across all quantiles (q10, q25, median, q75 and q90). Students of public schools outperformed the students of private schools with most significant association seen at quantile q90 [b= -3.30 (-5.96 to -0.64), *P*=0.015]. Students of Hindi medium schools performed better than the students of English medium schools, with most significant association seen at quantile q10 [b= -4.81, CI (-7.22 to -2.41), *P*<0.001].

DISCUSSION

The study findings demonstrated that the school-based educational intervention significantly increased the knowledge on the prevention of unintentional injuries and first aid among adolescents, with a large effect size. The present study adds to the body of evidence generated by a systematic review on the effectiveness of a school-based educational intervention aimed at increasing the knowledge of adolescents on unintentional injury pre-vention and first aid [8]. Although knowledge of students improved, but this knowledge does not necessarily lead to motivational and behavioral changes [13]. The present study worked on the health promotion information side only.

The results of our study are consistent with previous first aid educational intervention studies on adolescents [14]. A study conducted in Australia also reported that the burn victims receive inadequate first aid due to inadequate knowledge of the recommended 10-20 minutes time for submerging the burned part in water [15].

In our study, the cardiopulmonary resuscitation (CPR) knowledge of students significantly increased following educational intervention. The finding is consistent with studies conducted in New Zealand and Australia [15,16]. The Australian study also revealed that a training program on first aid, CPR, and beach safety offered to school students enhanced their confidence level in providing first aid following drowning [16]. India

TABLE I Characteristics of School Children Enrolled in the Study (*N*=1944)

Characteristics	*No. (%)*
Age categories	
14-16 years	1059 (55)
16-18 years	760 (39)
18-20 years	125 (6)
Boys	1105 (57)
Urban location	1063 (55)
Public school	1165 (60)
English medium school	812 (42)
Grade	
9	690 (35)
10	513 (26)
11	438 (23)
12	303 (16)

WHAT IS ALREADY KNOWN?

- School-based intervention studies improve knowledge of first aid and injury prevention.

WHAT THIS STUDY ADDS?

- The study generates data on the effectiveness of school-based educational intervention in Indian adolescent children to improve knowledge about first aid and prevention of unintentional injuries.

instituted the 'Good Samaritan law' to support bystanders for helping trauma victims in 2016 [17], and therefore, students were also educated about the law.

In the present study, younger students outperformed the older ones. The finding is consistent with a study on first aid training of preschool children in Egypt, which reported that age is directly associated with the first aid knowledge of students [18]. However, another review from Australia suggests that first aid learning, and retention of knowledge and skills generally increase with age and practical training sessions [19].

In the present study, boys outperformed girls. The finding is contrary to a study in Saudi Arabia conducted on university students, which reported that females' knowledge on CPR and trauma management was superior to those of male students [20]. Moreover, the performance of urban school students was found superior to their rural counterparts in the present study. Another first aid educational intervention study on the knowledge assessment of adolescents also reported that the residence significantly affected the knowledge scores [21]. Furthermore, students of public schools outperformed those of private schools in our study. However, a study conducted in Ethiopia reported that government school teachers possess less knowledge and lack appropriate attitude on first aid compared with private school teachers [22]. In the present study, students of Hindi medium schools outperformed those of English medium schools. This might be due to the fact that students learn better when taught in their mother tongue [23].

The research team conducting educational intervention was same in all schools. Random selection of participants and a robust statistical analysis and multivariate quantile regression are also the other merits of our study. However, lack of external controls, poses a threat to generalizability of the results. Pre-post design using the same questionnaire might have allowed some students to memorize the questions (interaction effect). However, the students were not aware that a post-test would be done. The study design allowed the interpretation of results based on a temporal relationship of measurements with the educational intervention. Additionally, the study was not designed to follow-up students for the evaluation of long-term knowledge retention. We do not currently know the number of reinforcement sessions needed for long term knowledge retention among adolescent students, which needs to be studied in future studies.

We conclude that educational interventions in school curriculums can strengthen the knowledge of adolescents on unintentional injury prevention and first aid. Quality school-based educational trainings can help raise awareness among adolescents.

Note: Supplementary material related to this study is available with the online version at *www.indianpediatrics.net*

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Contributors: SM, AM, JJ, AP: contributed towards the conception and design of the work, analysis and interpretation of data for the work, drafting the work or revising it critically for important intellectual content, and final approval of the version to be published. All authors agreed to be accountable for all aspects of the work
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CLIPPINGS

Randomized clinical trial of 20% mannitol versus 3% hypertonic saline in children with raised intracranial pressure due to acute CNS infections

(*Pediatr Crit Care Med. 2020;21:1071-80*)

Mannitol is a commonly used osmotherapy agent in raised intracranial pressure but it has significant side effects. Hypertonic 3% saline shows varied results in traumatic brain injury as compared to 20% mannitol. This is an open label randomized controlled trial conducted on 1-12 years of children admitted to PICU with raised intracranial pressure and modified-Glasgow Coma Scale scores less than or equal to 8 to compare the effect of 3% hypertonic saline versus 20% mannitol on raised intracranial pressure in pediatric acute CNS infections. Fifty seven children were randomly assigned to 20% mannitol (*n*=28), 0.5 g/kg/dose versus 3% hypertonic saline (*n*=29), 10 mL/kg loading followed by 0.5–1 mL/kg/h infusion. An intra-parenchymal catheter was used to monitor the intracranial pressure. In children with CNS infection, raised ICP was significantly better controlled in 3% hypertonic saline group. Hypertonic saline group also had a significantly better fall in intracranial pressure, a rise in cerebral perfusion pressure, and this trend persisted over 72 hours. Since, this is a single-center open-label design, and blinding was not possible because of the nature of the study and also cerebral hemodynamics and metabolism could not be studied. Therefore, a multi-centric trial for an evidence-based recommendation of 3% hypertonic saline is suggested.

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SUPPLEMENTARY TABLE I Comparison of Correct Responses Related to Knowledge of Unintentional Injury Prevention and First-aid Pre- and Post-Educational Intervention Among School Students Aged 14-20 Years in Ujjain, India (*N*=1944)

Topics/items from pre-post questionnaires	*Pre intervention n (%)*	*Post intervention n (%)*
International Injury Prevention		
Correct precautions for burns	667 (34)	1565 (81)
Correct precautions for poisoning	779 (40)	1784 (92)
Correct precautions to avoid drowning	688 (35)	1634 (84)
Correct precautions to avoid suffocation	711 (37)	1656 (85)
Correct precautions to avoid physical injuries	623 (32)	1590 (82)
Helmet is necessary while driving	492 (25)	1726 (89)
Preferred side of the road for walking, in the event of no sidewalk	704 (36)	1768 (91)
First-aid		
Definition of first aid	719 (37)	1625 (84)
Correct time for submerging the burnt part in water	550 (28)	1702 (88)
Correct first aid for burns	697 (36)	1688 (87)
Abstain on ingestion of poisonous substance	675 (35)	1762 (91)
Correct first aid for snake bites	414 (21)	1670 (86)
Correct first aid for drowning	680 (35)	1587 (82)
Correct method of back blow	708 (36)	1576 (81)
Benefit of back blow	569 (29)	1705 (88)
Identification of suffocating person	679 (35)	1567 (81)
Correct first aid for cuts	633 (33)	1704 (88)
Correct abbreviation of CPR	401 (21)	1564 (80)
Correct ratio of CPR	669 (34)	1580 (81)
Items for splinting broken bone	599 (31)	1684 (87)
Symptoms of fracture identification	677 (35)	1604 (83)
Golden hour in context of injury	578 (30)	1704 (88)
Legal action on providing assistance to an injured person in an emergency	850 (44)	1784 (92)
Items in a first aid box	435 (22)	1657 (85)

Values in No. (%) CPR= cardiopulmonary resuscitation. P<0.001 for all comparisons.

RESEARCH PAPER

Effectiveness of School-Based Interventions in Reducing Unintentional Childhood Injuries: *A Cluster Randomized Trial*

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Objective: To evaluate the effectiveness of school-based interventions in promoting child safety and reducing unintentional childhood injuries.

Methods: This cluster randomized trial with 1:1 allocation of clusters to intervention and control arm was conducted in the public and private schools of Dakshina Kannada district, Karnataka, over a period of 10 months. Study participants included children from standard 5-7 in schools selected for the study**.** 10 schools that could accommodate 1100 students each, were randomly allocated to the interventional and control arm. A comprehensive child safety and injury prevention module was developed based on the opinions of school teachers through focus group discussions. This module was periodically taught to the students of intervention arm by the teachers. The children in control arm did not receive any intervention. Outcome was assessed by determining the incidence of unintentional injuries and type of injuries from the questionnaire used at the baseline, and at the end of three, six, and ten months.

Results: Unintentional injuries declined progressively from baseline until the end of the study in both the interventional arm (from 52.9% to 2.5%) and control arm (from 44.7% to 32%) [AOR (95% CI) 0.458 (0.405-0.518); *P* value <0.001]. The decline in incidence of injuries in the interventional arm was higher than that in the control arm (50.4% vs 12.7%; *P* <0.001).

Conclusion: School based educational intervention using child safety and injury prevention modules is effective in reducing unintentional injuries among school children over a 10-month period.

Keywords : *Education, Fall, Prevention, School health.*

Trial registration: CTRI/2018/02/011765 ***Published online:*** February 19, 2021; ***PII:*** S097475591600292

Unintentional injuries specifically cause up to 950,000 deaths among children under 18 years annually [1] and more than half of these deaths are reported from Sub-Saharan Africa and South Asia [2]. Aside from mortality, accidental injuries can also lead to long-lasting emotional, physical, behavioral and developmental disabilities in children, which in turn could adversely affect the health and socio economic aspects of a nation [3].

Prevention of injuries has been classified into three strata of primary, secondary and tertiary prevention, as per a model suggested by World Health Organization [4]. The above-suggested WHO model can be incorporated while designing an effective school-based injury-prevention program. This can be used to address the policies and procedures, capacity building of school teachers, the physical environment of the school, and the curriculum in a coordinated manner.

There is little existing evidence to prove that educational interventions alone are sufficient in reducing the incidence of unintentional injuries [5]. Further studies are required to evaluate the impact of school-based interventions on injury occurrence as current studies only show a weak association between the two [5]. Thus, this study was conducted to evaluate the effectiveness of school-based interventions in promoting child safety and reducing unintentional injuries.

METHODS

The study was conducted in the public and private schools of Dakshina Kannada district, Karnataka, over a period of 10 months from July, 2017 to March, 2018. It was a cluster randomized trial with 1:1 allocation of clusters into intervention arm and control arm, where schools are considered as clusters. After excluding schools based on their willingness to participate and existing participation in any child safety and injury prevention program, randomization of schools was done to accommodate 10 schools in the intervention arm and 10 schools in the control arm by simple random method. Due representation was provided to both public and private schools in both

arms. The study participants included 1100 children from standard 5-7 in the schools selected for the study**.** We assumed there would be 40 students in each section of these standards. By enrolling all the students of a particular section, we would be enrolling 120 students from each cluster for the study. Selection of a section for a particular class was done by adopting simple random technique.

The sample size for the study was calculated by considering a prevalence of 23% childhood injuries as per a previous study [6]. The proposed intervention was considered effective if it reduced the incidence of injury to 15%. Hence, to account for the 8% reduction as significant at 90% power, 5% level of significance and at two-sided test, the sample size was calculated to be 503 in each arm. As it was a cluster-randomized trial, we presumed a design effect of 2 and the sample size was 1006. As we anticipated a maximum of 10% loss during the follow-up period of 10 months; the final sample size was calculated to be 1107 in each arm.

A comprehensive child safety and injury prevention module was then developed based on the opinions of school teachers from both urban and rural settings through focus group discussions. Later, subject experts validated the contents of the module. This comprehensive pictorial module consisted of child safety and measures to be taken by the children for the prevention of unintentional childhood injuries due to road traffic accidents, fall, burns, drowning, poisoning, animal related and other domestic causes.

Two teachers (including one physical training/sports teacher) from each school of the interventional arm were trained using this module. The teachers then taught the children on a periodic and regular basis for the duration of the study, using an instruction manual for modular teaching (25-30 hours on an average was spent per school). The students in the control arm received the comprehensive modular training after the end of the final data collection. While imparting this modular training, emphasis was given for child safety and injury prevention strategies to be inculcated by the children.

The tool used for data collection was a semi-structured questionnaire developed based on World Health Organization guidelines for conducting community surveys on injuries and violence [7]. This captured the incidence of unintentional injuries and the type of injuries among schoolchildren of both arms in the preceding three months. The same questionnaire was administered for both the groups at baseline, and at three, six, and ten months of the study. Outcome was assessed by the same set of investigators at each point of time in both intervention and control arm students.

Clearance was obtained from the institutional ethics committee and permission was taken from the Block Education Office. Due clearance was also obtained from the school principals where the study was conducted. As the study participants were children younger than 18 years, a written informed consent was obtained from their parents before enrolment into the study. Assent from the students were also obtained. Confidentiality and anonymity was maintained throughout the study.

Statistical analysis: All the data collected in the field were managed at the central coordinating site. The variables were coded and entered into Statistical Package for Social Sciences Version 25.0 (IBM Corp). Descriptive statistics and inferential statistics (Z test for difference in two proportions, and generalized estimation equations (GEE) was used to test the overall effectiveness of the intervention across the groups with time) were used to express the results. $P<0.05$ was considered statistically significant.

RESULTS

Out of 2327 children who were enrolled into the study at baseline, 1177 children were in the interventional arm and 1150 were in the control arm (**Fig. 1**). The baseline data is provided in **Table I**.

Incidence of unintentional childhood injuries among schoolchildren of interventional and control group during the study period is shown in **Table II**. Nearly half of the study participants of the intervention (52.9%) and control (44.7%) group had injuries in the preceding 3 months at the baseline. The incidence of injuries declined progressively from baseline until the end of the study among children in both the groups [Adjusted OR (95% CI) 0.46 (0.40-0.52; P <0.001] (**Fig. 2**).

The extent of decline in incidence of injuries from the start of the study till the end in the interventional arm was higher than in the control arm (50.4% vs 12.7%; P<0.001).

Table I Baseline Characteristics of Study Participants (*N*=2327)

Characteristics	*Intervention group (n=1177)*	*Control group (n= 1150)*
Male sex	658 (55.9)	500 (43.5)
Class		
5th	367 (31.2)	362 (31.5)
6th	306 (26.0)	501 (43.5)
7th	504 (42.8)	287 (25.0)
Urban locality	656 (55.7)	314 (27.3)
Government school	507 (43.1)	408 (35.5)

Values in no.(%).

Table II Incidence of Unintentional Childhood Injuries

Unintentional injury	*Intervention group*	*Control group*
Baseline	623 (52.9)	514 (44.7)
3 mo	224 /1179 (19.0)	382/1123 (34.0)
6 mo	107/1184 (9.0)	442/1175 (37.6)
End line	29/1169 (2.5)	356/1113 (32.0)

Incidence based on generalized estimating equations (GEEs). Values in n/N (%). Adjusted OR (95% CI)=0.45 (0.40-0.52), P<0.001.

Various causes of unintentional childhood injuries across both groups throughout the duration of the study is depicted in **Suppl. Table I**. Fall was the most common cause of injury among children of interventional (56.8%) and control group (46.7%) at baseline. Decline in the incidence of unintentional injuries was observed in both the groups across all categories.

DISCUSSION

We found that the incidence of unintentional injuries among students in both the control arm and interventional arm decreased compared to baseline incidence. However, the extent of decrease was much greater in the interventional arm. While comparing incidences in both groups across specific categories, the number of children who sustained injuries from road traffic accidents, falls and others decreased to a larger extent in the interventional group compared to the control group with the biggest reduction noted in falls.

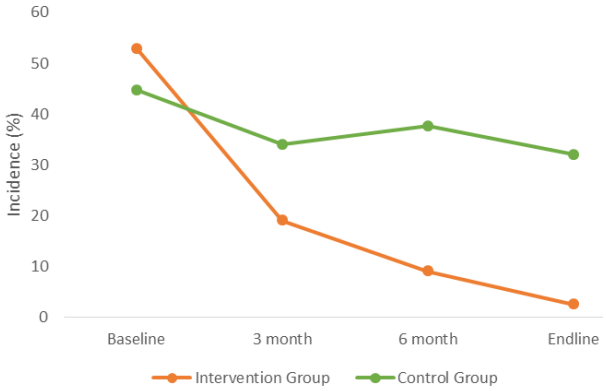

Fig. 2 Trends in incidence of unintentional childhood injuries over 10 months.

A randomized pre-test and post-test comparative design study, 'Think First for Kids' [8] conducted among grade 1, 2 and 3 students, evaluated the outcome of an injury prevention program. The results of this study showed that students in the interventional group had lesser self-

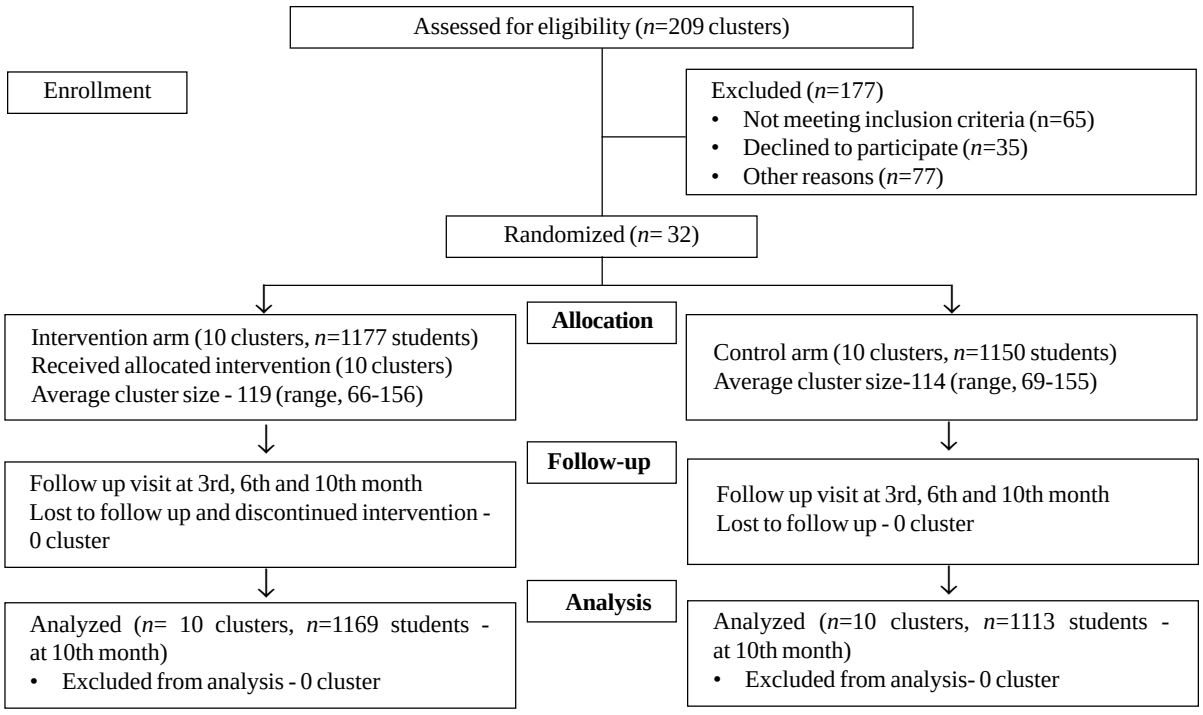

Fig. 1 Flow diagram of the study.

WHAT THIS STUDY ADDS?

- A school-based educational intervention is effective in reducing the incidence of unintentional childhood injuries among school children.

reported high-risk behaviors, and increased knowledge about 'safe' behaviors to avoid injuries as compared to students in the control arm. In another study in rural China [9], a multi-level educational interventional model (open letter about security instruction distributed to parents, children's injury-avoidance poster put up at schools, and multimedia resource-aids for health education) improved knowledge and safety attitudes among students in the intervention arm as compared to the control arm.

It is interesting to note that the incidence of unintentional injuries decreased among children in the control group as well. We hypothesize that this could be due to a combination of various factors. This includes the learning curve of the child after experiencing an unintentional injury and knowledge gained over time from other sources such as parents or public health awareness campaigns.

From our study we also noted that the biggest reduction in unintentional injuries was in the category of falls among children in the interventional arm. The educational module imparted knowledge on safe behaviors at home and while playing outdoors. There were pictorial representations of scenarios which most-likely lead to falls such as playing on escalator and climbing trees. Another study by Morrongiello and Matheis [10] used a similar educational intervention and it was shown to reduce falls, particularly in the playground, through the 'practice what you preach' project. Children had less risk-taking behavior and more safe practices after the intervention.

Unintentional injuries due to road traffic accidents also considerably reduced in the interventional group as compared to the control group. Pictorial representations of Dos and Don'ts related to Road safety was used to educate children every week. Another public school based educational intervention to improve attitudes, increase knowledge and change unsafe road practices was implemented in four schools in Mexico among 219 children and teenagers [11]. A significant improvement in the attitude, practices and knowledge of involved students were seen. The number of students suffering from burns decreased significantly in the interventional group while it remained constant in the control group, showing the effectiveness of the educational module in this area. A cluster randomized controlled trial evaluating an injury prevention program "Risk Watch' in 20 primary schools among 459 children aged 7-10 years in Nottingham, UK showed similar results [12]. At the end of this one-year injury prevention program, it was effective in increasing few aspects of children's knowledge of fire and burn prevention skills, although it had little effect on self-reported safety behaviors, unlike our study.

The main limitation of our study is that it is a single centric study and had a short duration of follow-up. The results obtained regarding the prevention of unintentional injuries among children using educational interventions cannot be extrapolated until further multi-centric studies show the same results. As this school based intervention using child safety and injury prevention module was found to be effective in reducing the incidence of unintentional injuries; this modular intervention can be considered for incorporating it in the school curriculum, after obtaining evidence from well-planned multi-centric studies incorporating a longer follow-up.

To conclude, the school based educational interventions using the child safety and injury prevention module have significantly reduced the incidence of unintentional injuries among children in the intervention arm when compared to students of control arm where such educational interventions were not given.

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Note: Supplementary material related to this study is available with the online version at *www.indianpediatrics.net*

Ethics clearance: Institutional Ethics Committee of Kasturba Medical College, Mangalore; No. IEC KMC MLR 12-14/285, dated 17 December, 2014.

Contributors: RH, DB: Concept and design, analysis, interpretation of data, drafting the article; BUK: Concept and design, interpretation of data, drafting the article, revising it critically; VK, NK: Interpretation of data, revising it critically for important intellectual content; RT, PM: Study design, interpretation of data, revising it critically for important intellectual content; AS: Revising the manuscript critically for important intellectual content and critical interpretation of the data captured; AG: Analysis of the data, drafting the manuscript and proof reading; HK: Data analysis and critical revision of the results. All authors approved the final version of manuscript, and are accountable for all aspects related to the study.

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Competing interests: None stated.

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CLIPPINGS

Efficacy of adjunctive zinc in improving the treatment outcomes in hospitalized children with pneumonia: A randomized controlled trial (*J Trop Pediatr. 2020;66:419-27*)

Pneumonia is still one of the largest contributors to under-five mortality in developing country like ours. Zinc is used by health professionals as an adjunct treatment in children with pneumonia. This is a randomized, double blind placebo controlled trial conducted on hospitalized children with pneumonia with the aim to assess the efficacy of adjunctive zinc supplementation on the treatment outcomes of pneumonia. Ninety one children (2-6 months) were randomly received either zinc bis-glycinate (15 mg elemental zinc) or placebo, twice daily. The time to resolution of clinical pneumonia was significantly shorter in the zinc group than the placebo, and the hospitalization period as well as time to resolution of fever were significantly shorter in the zinc group. Due to small number of enrolled participants, the generalizability of the study on a global scale might be affected. Therefore, larger randomized trials are recommended for future investigations, as well as various variables that may influence the outcomes should be considered in future trials.

Skin manifestations of COVID-19 in children: Part 1, Part 2, Part 3. (*Clin Exp Dermatol. 2021;46:444-72*)

The current COVID-19 pandemic is caused by SARS-CoV-2. The initial recognized symptoms were respiratory, sometimes culminating in severe respiratory distress requiring ventilation, as time has passed, other symptoms have also been recognized. The initial reports of cutaneous manifestations were from Italian dermatologists, probably because Italy was the first European country to be heavily affected by the pandemic. The overall clinical presentation, course and outcome of SARS-CoV-2 infection in children differ from those in adults as do the cutaneous manifestations of childhood. In this extensive review, divided into three parts, the current knowledge on the cutaneous manifestations of COVID-19 in children are summarized after thorough and critical review of articles published in the literature and from the personal experience of a large panel of paediatric dermatologists in Europe. In Part 1, first and most widespread cutaneous manifestation of COVID-19, chilblain-like lesions are discussed. In Part 2, other cutaneous manifestations are reviewed, including erythema multiforme, urticaria and Kawasaki disease-like inflammatory multisystemic syndrome; while in Part 3, the histological findings of COVID-19 manifestations are discussed, and the testing and management of infected children, for both COVID-19 and any other pre-existing conditions.

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Supplementary Table I Causes of Injuries Among Study Participants During the Study Period

Causes of injuries [a]	*Intervention group*				*Control group*			
	Baseline (n=623)	*3 mo (n=224)*	*6 mo (n=107)*	*End line (n=029)*	*Baseline (n=514)*	*3 mo (n=382)*	*6 mo (n=442)*	*End line (n=356)*
Fall	354 (56.8)	154 (68.7)	58 (54.2)	15 (51.8)	240(46.7)	222(58.1)	229(51.8)	192(53.9)
Road traffic injuries	135 (21.7)	25 (11.2)	13 (12.1)	2 (06.9)	111(21.6)	63 (16.5)	74 (16.7)	27 (07.6)
Burns	41 (06.6)	17 (07.6)	17 (15.9)	1(03.4)	25 (04.9)	21 (05.5)	29 (06.6)	25 (07.0)
Poisoning	-	-	-	-	-	-	1 (00.2)	-
Drowning	1 (00.2)	-	-	-	-	-	2 (00.5)	2 (00.6)
Animal related	11 (01.8)	06 (02.7)	3 (02.8)	-	11 (02.1)	10 (02.6)	10 (02.3)	7 (02.0)
Others[b]	93 (14.9)	24 (10.7)	18 (16.8)	11 (37.9)	132 (25.7)	71 (18.6)	102 (23.1)	103 (28.9)

[a]Values in no. (%). Multiple responses were received; [b]Cuts by sharp objects, thorn/nail pricks, collision with heavy/hard objects etc.

RESEARCH PAPER

Effectiveness of Child-To-Child Approach in Preventing Unintentional Childhood Injuries and Their Consequences: *A Non-Randomized Cluster-Controlled Trial*

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Background: Child-to-child approach is an innovative strategy for preventing and reducing the morbidity and mortality burden of unintentional childhood injuries.

Objectives: To test effectiveness of Child-to-child Approach in preventing unintentional childhood injuries and their consequences.

Study design: Community-based non-randomized cluster-controlled trial of parallel design.

Participants: 397 children and adolescents.

Intervention: Eldest literate adolescent of selected families of intervention area were trained on prevention of injuries. They were to implement the knowledge gained to prevent injuries in themselves and their younger siblings and also disseminate this knowledge to other members of their families.

Outcome: Data was collected from both intervention and control areas during pre- and post-intervention phases on the magnitude of injuries, time for recovery from injuries, place for seeking treatment, cost of treatment, knowledge and practice of participants and their families regarding injuries.

Results: During post-intervention phase, the intervention group experienced a significant reduction in incidence of injuries, increased preference for institutional treatment of injuries and increased knowledge and practice regarding injuries, in comparison to its pre-intervention data and data of the control group in post-intervention phase. Total time for recovery and cost of treatment for injuries also decreased in intervention group in post-intervention phase, though differences were not statistically significant.

Conclusion: Child-to-child approach is effective in reducing childhood injuries, improving choice of place for seeking treatment, increasing knowledge of participants, improving family practices regarding prevention of injuries and reducing expenditure on treatment of childhood injuries.

Key words: Accident, Educational intervention, Prevention, Trauma.

Trial registration: CTRI/2018/07/014872 ***Published online:*** February 19, 2021; ***PII:*** S097475591600291

With a change in epidemiological pattern of disease burden in the population, injuries are rising and contributing to a major part of morbidity and mortality in the entire population, including children. Childhood injury is currently an alarming problem in the world. Injuries constitute a large proportion of global burden of childhood death, particularly for older children in whom it accounts for almost half of the deaths. Analysis conducted using Global Burden of Diseases data revealed that unintentional injuries accounted for 18% of the estimated deaths among children between the ages of 1 and 19 years globally [1] and 11.2% of total DALY's lost in all age groups [2]. Cost incurred by families towards treatment of childhood injuries is also enormous around the world [3].

Strategies need to be worked out and implemented for prevention and control of the problem of unintentional childhood injuries. Child-to-child approach is one such innovative strategy [4], which has earlier been proved to be effective in health promotion among children [5-8]. However, this approach has not been tested for prevention and control of injuries in children.

The study was conducted with the objective of assessing the effectiveness of child-to-child approach in preventing unintentional childhood injuries and their consequences in terms of time taken for recovery and cost incurred on treatment.

METHODS

A community based non-randomized cluster-controlled trial of parallel design was conducted in rural area of Delhi. The study was approved by the Institutional Ethics Committee and written informed consent was taken from heads of the families and consent/assent was taken from all participants as applicable.

The study area comprised of one intervention and one control village in North-West Delhi, which were widely separated from each other with another habitation located in between, to prevent contamination. The villages for intervention and control groups were selected by purposive sampling considering logistic and operational feasi-bility. The main study was undertaken from August, 2017 to January, 2019 and comprised of 7 broad phases – recruitment, pre-intervention, intervention, reinforcement, washout, post-inter-vention and intervention in control group.

For operational purposes, injury was defined as physical damage to the child's body, caused unintentionally/accidentally. 'One injury' was defined as each injury of a different type or in different body part occurring in a child, even if occurring at the same time due to the same cause. 'One injury event' was defined as one child injured at one point of time, even if it resulted in multiple injuries.

Children and adolescents aged 0-19 years belonging to families having at least one adolescent and two younger siblings were included in the study. Mentally deranged or critically ill participants were excluded from the study. Consecutive families were selected for wide dissemination of the message which is the crux of child-to-child approach. Recruitment was done at the initiation of the study.

Sample size calculation was based on a pilot study which was conducted in a different part of the study area; 50 children aged 0-19 years with a recall period of 3 months were evaluated and the incidence of injury was observed as 15%. Expecting a 5% reduction in incidence of injury after the intervention and keeping alpha and beta errors at 5% and 20%, respectively, sample size was estimated as 90 as per the WHO guidelines [9] for a two-sided hypothesis test for an incidence rate, when the observations are censored at 4 months. As the study required more than one child from one family for implementing child-to-child approach, clustering effect was likely to occur due to similarity of participants within a family. Keeping this in view and to adjust for design effect, calculated sample size was multiplied by a factor of 2, making a size of 180 children. Since the study required follow-up of 20 months, possibility of non-response/attrition was considered and hence 10% was added to this and rounded off to final sample size of 200 participants each in intervention and control group.

Training was given to the eldest adolescents in the families of intervention area during intervention phase i.e., January-April, 2018. Eldest adolescents of the families of the control area were trained after the completion of data collection in post-intervention phase. Eligible adole-scents were trained on various aspects of injuries and their prevention. Training included three components: (*i*) First aid and cardio-pulmonary resuscitation (CPR) by St. John's Ambulance Services of Indian Red Cross Society, (*ii*) road safety and traffic rules as collaboration between Delhi Traffic Police and Hero MotoCorp, Hero Honda and (*iii*) injury prevention and immediate care by the research team. In addition, messages were given regularly to adolescents during home visits for data collection. At the end of training, the trained adolescents were each given a module highlighting salient points covered in the trainings regarding common injuries and their pre-vention, a first aid kit and a box with child lock for safe storage of items likely to cause injury. Trained adole-scents were told to be vigilant and thus prevent occurrence of injuries in themselves and their younger siblings. They were also encouraged to pass on the knowledge they had gained through trainings to their adolescent siblings and all adult women in their families including mothers, aunts, grandmothers, elder sisters or sisters-in-law. Subsequently, weekly visits were made and reinforcement of information was done for 2 months (May-June, 2018), followed by washout period of 2 months (July-August, 2018). Control group was also visited at similar frequency and interval, but only general health messages were given with no special mention regarding injuries.

Data was collected using a pre-tested semi-structured proforma, during pre- and post-intervention phases of four months each, in same months of the year, pre-intervention data being collected during September-December, 2017 and post-intervention data collected during September-December, 2018. Ongoing data collection regarding injury events continued during intervention, reinforcement and washout phases. Each family was visited once a week during data collection periods and details regarding injuries that had occurred in the previous week were enquired into. Families were also given a notebook each and were told to note down the relevant details which were assessed by the field investigators at their subsequent weekly visit and cross-checked by investigators. Data variables included details about injuries that occurred, time for recovery from the injury, health care facility availed for treatment and expenditure incurred for treatment. Expenditure incurred for treatment for all injury events included doctor's consultation fee, medicines, investigations, operations, bed charges, expenses for travel and expenses for accompanying person. Wage loss was also considered. For calculating cost of treatment in private sector, information was taken about amount actually paid for availing services, while that in government sector included the cost of medicines, investigations and procedures as calculated on the basis of rate contract of Delhi Government Central Procurement Agency for medicines and the amount prescribed for reimbursement for investigations and procedures

under Delhi Government Employees' Health Scheme. In addition, the field investigators during their weekly visits distributed medications for symptomatic treatment under guidance of investigators of this research.

Prior to the intervention, baseline knowledge of participants and practice of families as reported by participants was assessed by interview of adolescents eligible for training, all other adolescents and all women aged 20 years and above of the families. Family practice was assessed as reported by respondents, on two aspects i.e. measures taken for prevention of injuries and treatment seeking behavior in case of occurrence of injuries. Each response was scored and the total knowledge and practice (KAP) score was calculated. Maximum attainable score was 29 for knowledge, 60 for practice and 89 for total KAP score. Higher score implied better knowledge and safer practice.

Statistical analysis: Primary outcome measure was magnitude of injuries, while secondary outcome measures included time taken for recovery from injuries, choice of health facility for treatment of injuries, cost for treatment of injuries, knowledge of participants and practice of families regarding injuries and their prevention. Comparison was made between data of intervention and control groups during pre-intervention phase to establish matching, pre- and post-intervention phases of intervention group to assess changes following intervention, and intervention and control groups during the post-intervention phase to establish that changes occurred mainly due to the intervention. For all comparisons, *t* test for difference between means and *z* test for difference between proportions were used for quantitative and qualitative data, respectively. Chi-square test with Yates correction was done for comparison of health care facility availed. For comparison of mean and median cost, Mann Whitney U test and median test were done, respectively. *P* value of <0.05 was considered significant.

RESULTS

We included 197 and 200 participants each in the 59 and 57 families, respectively of the intervention and control groups. Recruitment of participants is shown in **Fig. 1**. Participants in both the areas were comparable in terms of sociodemographic profile.

Throughout the period of study there was no fatal injury and none of the injured participants required hospital admission. **Table I** shows the incidence of injuries in the two areas. Annual and monthly incidence of injury events were calculated as number of injury events occurring per 100 children per year or month as applicable. Annual incidence of injury events in the total participants was 32.24 per 100 children per year with average monthly incidence of 2.69% (2.62 in intervention group and 2.75 in control group), with no statistically significant difference between the two groups. In the intervention group, the monthly incidence dropped significantly in post-intervention phase. Though monthly incidence had dropped slightly in control area also in the post-intervention phase, it was still significantly higher than that in intervention group.

The mean time taken for recovery from injuries in total study participants, which included the total duration for the

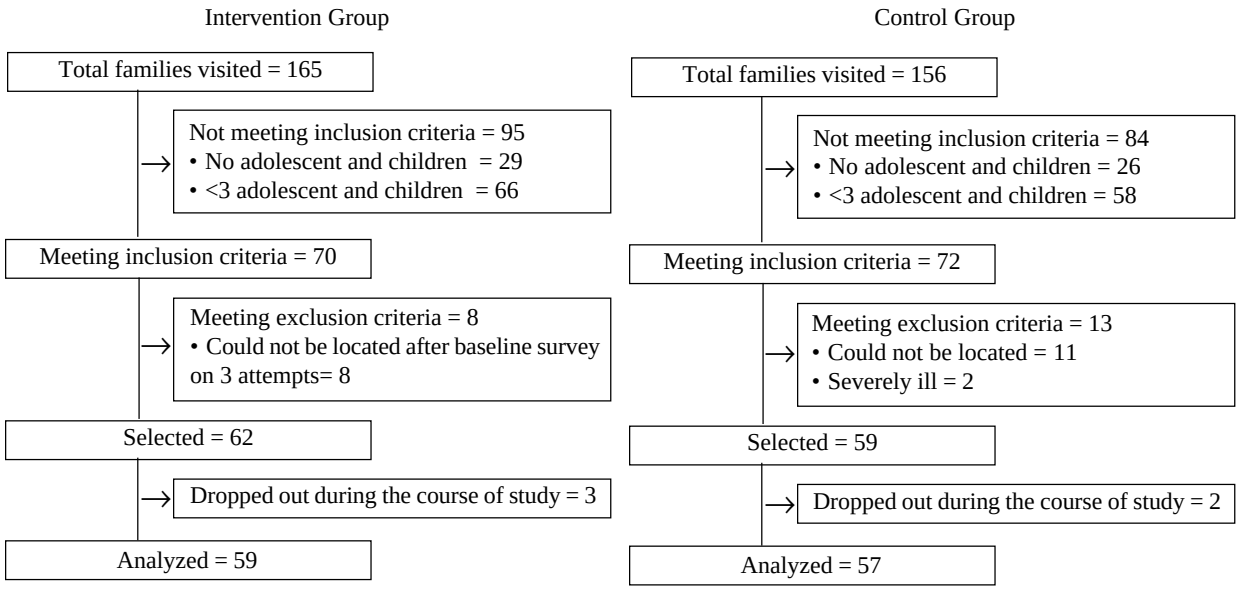

Fig. 1 Flow chart showing recruitment of participants based on eligibility criteria.

Table I Total Injury Events and Monthly Incidence in the Participants in the Intervention and Control Groups

Phase of study	*Intervention group (n=197)*	*Control group (n=200)*	*P value*	*Total (N=397)*
Pre-intervention	25, 3.17 (0.72-5.6)	26, 3.25 (0.79-5.7)	0.86	51, 3.21 (1.48-4.9)
Post-intervention	16, 2.03 (0.06-4.0)	29, 3.62 (1.03-6.2)	<0.001	45, 2.83 (1.2-4.46)
Annual incidents of injuries[a]	62, 31.47 (24.9-37.9)	66, 33.00 (26.5-39.5)	0.74	128, 32.24 (27.6-36.8)

Data expressed as total injury events, monthly incidence (95% CI). P=0.009 for pre- and post-intervention periods in intervention group and P=0.0002 for post-intervention period in intervention and control groups. [a]Includes injuries that occurred from September, 2017 to August, 2018.

wound to heal/ medicines to be stopped/ normal activities to be resumed (as applicable on a case-to-case basis), was similar in the two groups in the pre-intervention phase (*P*=0.58). Both the intervention group [5.7 (2.4) vs 5.9 (2.9); *P*=0.79] and control group [7.8 (19.0) vs 7.0 (4.5); *P*=0.82] did not show any significant differences in their respective pre- and post-intervention time for recovery. Total time for recovery from all injuries had reduced in post-intervention phase in intervention group (143 vs 95 days), while it remained same in control group in both phases (204 days).

Table II shows the choice of health care facility by the families for treatment of injuries. Families had taken treatment from government or private hospital/health center/clinic, registered medical practitioners (RMP), over-the-counter treatment by buying medicines from the pharmacy without consulting a doctor, and home treatment. In the pre-intervention phase, majority of injured participants in both groups (>75%) had taken treatment from unqualified providers, which decreased to 18.1% in the intervention group in post-intervention phase, in contrast to 86.2% participants in the control group (*P*<0.001) (**Table II**).

The total and the median (IQR) cost of treatment for injuries in the intervention group decreased from Rs. 5962.9 to Rs 4949.5, and Rs 90 (102.5) to Rs 19.8 (116.28), respectively (*P*=0.84). The corresponding values in control group were Rs 4734.5 and Rs 7013.4 and Rs. 46.5 (153.75) and Rs. 40 (135.31), respectively. These differences were statistically insignificant. The post-intervention median costs in intervention arm and control arm were comparable.

Table III depicts the KAP scores of all three groups of participants. These scores were similar for all participants during the pre-intervention phase. Mean scores in all aspects had improved considerably during post-intervention phase in all participants in the intervention area. Scores had improved slightly in all groups of control area also. KAP scores in all groups of participants between pre- and post-intervention phases in intervention area and between post-intervention phases in both areas showed statistically significant differences, indicating dissemination of safety messages.

DISCUSSION

This community based non-randomized cluster-controlled trial of parallel design was conducted in rural area of Delhi, to test the effectiveness of child-to-child approach by training the eldest adolescent members of the families for preventing unintentional childhood injuries in themselves and their younger siblings. During post-intervention phase, the intervention group experienced statistically significant reduction in incidence of injuries, improvement in preference for health facilities for seeking treatment, and increase in knowledge and practice regarding injuries, in comparison to its pre-intervention data and data of control group in post-intervention phase. Total time for recovery and cost of treatment for injuries including out-of-pocket expenditure also decreased in intervention group in post-intervention phase, though differences were not statistically significant.

However, the study had some limitations. Firstly, a randomized controlled trial could not be done as study design required consecutive families be included for

Table II Type of Health Facility Attended for Treatment of Injury Events

Type of facility	*Intervention group*		*Control group*	
	Pre-intervention (n=25)	*Post-intervention (n=16)*	*Pre-intervention (n=26)*	*Post-Intervention (n=29)*
Hospital/health centre/clinic	6 (24.0)	13 (81.3)	3 (11.5)	4 (13.8)
RMP/FI/OTC/ home/none	19 (76.0)	3 (18.7)	23 (88.5)	25 (86.2)

Data in no. (%). RMP: registered medical practitioner; OTC: over the counter.

Table III Knowledge and Practice Scores Regarding Injuries in the Study Groups

	Intervention group			*Control group*		
	No.	*Pre-intervention*	*Post-intervention*	*No.*	*Pre-intervention*	*Post-intervention*
Adolescents for training	59			57		
Knowledge		8.8 (1.9)	11.6 (2.6)		9.0 (1.9)	9.0 (1.6)
Practice		39.6 (4.9)	47.5 (4.8)		37.9 (5.7)	41.2 (3.7)
Total score		48.5 (5.3)	59.1 (6.4)		46.9 (6.6)	50.3 (4.2)
Other adolescents	93			81		
Knowledge		7.9 (2.2)	9.8 (2.3)		8.5 (1.7)	8.4 (1.4)
Practice		38.4 (3.9)	47.0 (5.2)		37.5 (4.3)	41.1 (3.8)
Total score		46.4 (4.8)	56.8 (6.5)		46.0 (5.0)	49.5 (4.2)
Adult women	93			86		
Knowledge		8.0 (1.7)	10.5 (2.3)		8.2 (1.6)	8.7 (1.5)
Practice		40.4 (4.7)	48.4 (4.1)		41.4 (4.6)	44.2 (4.1)
Total score		48.5 (5.4)	58.8 (5.3)		49.6 (5.2)	52.9 (4.6)

Scores expressed as mean (SD). Data were compared for knowledge scores, practice scores and total scores for all three groups viz., adolescent for training, other adolescents and adult women. For comparison of pre-intervention data of intervention and control groups, all P>0.05; for pre- and post-intervention data of intervention group, all P<0.001; for post-intervention data of intervention and control groups, all P<0.001.

dissemination of information and blinding also could not be done due to obvious reasons. Secondly, the pre- and post-intervention data collection periods were short due to operational feasibility. Since data regarding injury and treatment details was self-reported, these may have been under-reported although efforts to minimize the same were done by asking participants to record the events in notebooks which were assessed on a weekly basis by the research team. Strengths of the study included a good follow up with an attrition rate of only 4.6%. Frequent visits by field investigators also resulted in a good rapport-building and ensured cooperation from the community. A control group was used that resulted in drawing valid conclusions regarding outcome. The study groups of both areas at the time of recruitment were matching in all characteristics of the study participants and families. Extensive trainings could be given to the adolescents, two of those being formal trainings from professional organizations. Pre- and post-intervention data were collected during the same months of the year to rule out the chance of seasonal variation. Data regarding injuries was collec-ted by weekly house visits and hence recall period being very short ensured good quality of data.

Childhood injury is an area of concern in the entire world, including India. Studies conducted on childhood injuries in India and abroad have reported various levels of magnitude [10-20]. Higher annual incidence observed in the present study was due to weekly active surveillance undertaken that could capture even minor injuries which are usually attended at home and hence remain unreported to the health system. To prevent and control such an alarming problem, various researchers have reported success of implementing intervention measures as part of their research on home injury hazards [21], first aid [5,6], nutrition [7] and health education in general [8]. Intervention in some of these studies was by implementation of child-to-child approach [5-8]. Though two of these studies were on improving knowledge regarding injuries and first aid, there was no study using this approach on injury prevention or cost reduction. Slight decrease in incidence of injuries and increase in KAP score was obser-ved in the control area also, probably due to increased awareness through repeated visits and enquiry regarding injury occurrence.

The present study highlights the need for introduction of safety education in school curriculum to make children aware of injuries, their consequences and methods of prevention. Training on first aid and CPR may be made compulsory in all schools and colleges, with regular mock drills for injury management in educational institutions, occupational institutions and community. Child-to-child program needs to be implemented by training older adolescents in schools, encouraging them to take care of their younger siblings at home and disseminate the messages widely. It can also be implemented by integrating with other community based health programs and delivered through primary health care platforms, which will go a long way in combating the problem of unintentional childhood injuries in the country.

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WHAT IS ALREADY KNOWN?

- Implementation of child-to-child approach is an effective way to improve awareness of school children regarding unintentional childhood injury and first aid.

WHAT THIS STUDY ADDS?

- Child-to-child approach is effective in reducing number of injury events, total time for recovery from injuries, cost for treatment of injuries and out-of-pocket expenses of families, as well as in improving knowledge of participants and practice of families regarding injury prevention and control.

Ethical clearance: Institutional Ethics Committee, Maulana Azad Medical College; No. IEC/MAMC/(56)/2/2017/No 74, dated 17 May, 2017.
Contributors: BB contributed to designing the study, analyzing and interpreting the data, and drafting the manuscript; RB contributed to analyzing data, and drafting the manuscript; GKI contributed to designing the study and revising the manuscript; PM contributed to acquiring and analyzing data; NS contributed to analyzing data and revising the manuscript; SG contributed to analyzing data and revising the manuscript. All authors approved the final manuscript and agreed to be accountable for the work.
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RESEARCH PAPER

Effect of a Home Safety Supervisory Program on Occurrence of Childhood Injuries: *A Cluster Randomized Controlled Trial*

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Objectives: To evaluate the effect of home safety supervisory program on improvement in childhood safety, self-reported home hazard of caregivers, and caregivers' supervisory attitude.

Design: Randomized controlled trial.

Setting and Subject: Caregivers of children between 2 to 5 years of age residing in selected villages in Karnataka.

Intervention: Intervention group was administered Home safety supervisory program (HSSP), whereas the control group received teaching on child care.

Results: The intervention group had a significant reduction in the frequency of childhood injuries when compared with the control group [MD (95% CI) 8.96 vs 3.37], after the administration of Home safety supervisory program. There was a significant difference in the mean baseline scores of caregivers self-reported home hazard practices between the two groups (P<0.001), and improvement in the supervisory attitudes of caregivers in the intervention group (P<0.001).

Conclusion: Appropriate and effective home hazard reduction teaching reduces home injuries in children. The improved awareness of caregivers in child safety, and child supervision emphasizes the importance of this program.

Keywords: *Adult supervision, Home hazard, Injuries, Prevention*.

***Trial registration**:* CTRI/2018/04/019386

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Injuries at home constitute a significant number of childhood injuries, as children spend longer period of time in the home and also due to the many hazards that may be present [1,2]. The common injuries for younger children typically occurring at home are burns [3], falls [4] and poisoning [2,3,5,6].

Children those who are left unsupervised or inadequately supervised may come across with physical, mental, or social negative outcomes [7,8]. Lack of supervision has been associated with unintentional childhood injuries ranging from minor to ones with fatal severity. In cases of inadequate supervision, multiple factors interact with each other to either increase or decrease the risk of injury among children [8,9].

In India, unintentional injuries which are preventable, is a major public health problem that disproportionately affects children. The data on childhood injury in the hospital and emergency departments are very poorly maintained and the broader portion of iceberg of issues is not reported [10].

Unintentional injuries in children are a combined and interrelated product of human behavior, environment and other demographic factors. We planned to develop and implement an intervention and evaluate the effect of a home safety supervisory program (HSSP) on caregivers of children below 5 years of age, on childhood supervisory practices.

METHODS

After clearance from the institutional ethical committee, a cluster randomized controlled trial was conducted to assess the effectiveness of HSSP in 10 villages in Udupi district, Karnataka.

Cluster randomization technique was used, wherein villages were considered as clusters and houses in the village as cluster units. A random allocation was carried out at the level of selection of villages to the intervention and control group. Individual houses or selection of cluster units were done by an external person who was not involved in the study. Selection of the villages was done using probability proportional to size. In EPI methodology, which is carried out after creating a cumulative list of community population and selecting systematic sample of clusters with a random start [11]. After identifying the villages, a randomization process was done to select the villages to the experimental and control group. This was done using tossing of coin. The villages

were randomized into intervention group (5 cluster) and control group (5 cluster). From each cluster, 13 cluster units (houses) consisting of children between the age group of 2 to 5 years were selected. Home safety supervisory program was administered to intervention group cluster and the control group received teaching on child care. **Fig. 1** shows the CONSORT flow chart of participant selection.

The sample size in the RCT is based on comparison of means which was calculated on the basis of pilot study finding. A total of 130 families were included in the study (65 each in intervention and control group) who met the following inclusion criteria: Houses consisting of at least one child belonging to the age group of 2 to 5 years, caregivers' of children (2 to 5 years) who can read, write and understand English or Kannada (local language) and caregivers' who care for the children for at least 6-8 hours a day.

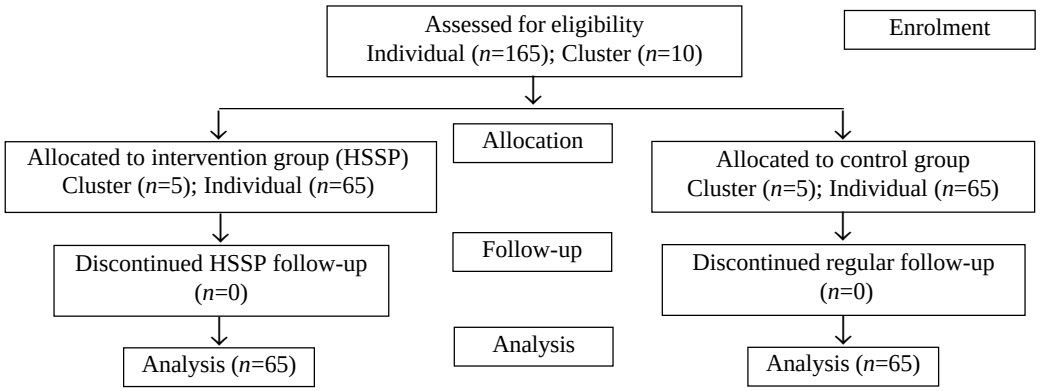
A demographic proforma was used to collect basic information about the child and caregiver, age and gender of the child, birth order, and type of family. Risk behavior assessment questionnaire is a self-prepared 20-item questionnaire to collect information from the caregivers regarding events of injury in the past three months among their children.

A home hazard assessment self-report questionnaire was in the local language used to assess the presence of home injury hazards as reported by caregivers during a personal interview. This questionnaire was prepared by the researcher and established validity and reliability. It consisted of 27 items categorized under following areas: burns, cut/injury, fall, drowning, suffocation/chocking and poisoning. A higher score indicates more hazards at home that can cause injury to the child. Observed home hazard (OHH) inventory was used by the researcher to personally observe the home hazards in the house which was researcher developed instrument based on the practices in the local area. Caregiver supervisory attitudes (CSA) is a five-point Likert scale 25-item questionnaire to assess the caregiver's child supervision practices. All the instruments underwent validity and reliability studies. The tools were later translated to local language and retranslation was done to make sure the accuracy. The schematic representation of the study is shown in **Fig. 2**.

The home safety supervisory program for caregivers (HSSP) is the intervention developed for caregivers of children aged 2 to 5 years in intervention group. The program consisted of a video on 'Safe home; Safe child,' a poster on 'Safe home; Safe child' and an individual home visit. Health teaching on care of children between 2 to 5 years of age was administered to the caregivers in the control group. The contents of the health teaching included nutritional needs, hygienic needs, safety needs and normal growth and development.

RESULTS

The sociodemographic characteristics of 130 enrolled children depicts that most (41.6%) of the children in intervention group were in the age group of 3 to <4 whereas 43.1% of children in the control group belonged to 2 to <3 years of age. Most of the children were first born in both the intervention and control groups (53.8% and 49.2%, respectively). In both the groups, the number of siblings for the indexed child was 1 to 3 (52.3% in intervention and 58.4% in control group). **Table I** shows the baseline characteristics of the children. **Table II** shows the distribution of childhood injuries in previous three months (baseline) and during one month follow-up in both the groups.



HSP-Home safety supervisory program

Fig. 1 CONSORT flow chart of the study.

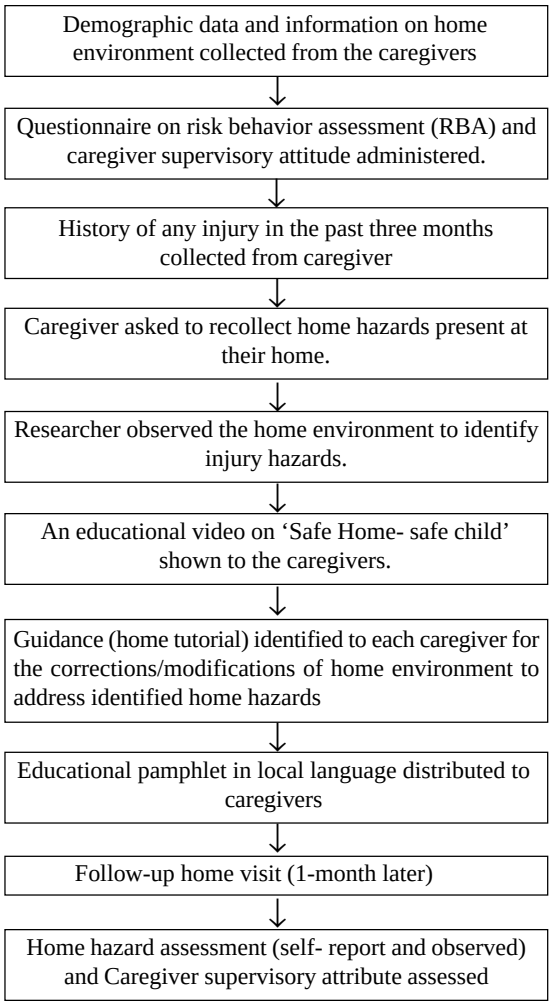


Fig. 2 Schematic representation of the study description.

Table I Baseline Sociodemographic Characteristics of Children and Caregivers in the Two Groups

Variables	*Intervention group (n=65)*	*Control group (n=65)*
Age (y)[a]	3.3 (0.89)	3.3 (0.97)
Male	36 (55)	31 (47)
Nuclear family	42 (64)	47 (72)
Caregiver mother	52 (83)	50 (76)
Caregiver age (y)[a]	33.5 (10.5)	34.2 (11.3)

Values no. (%) or [a]mean (SD).

The children in the intervention group showed a significant reduction in the injury pattern when compared with those that of control group (P=0.02). A significant change was observed in the mean scores of home safety practices of caregivers in the intervention group whereas only minimal change was seen in the mean scores of home safety practices of caregivers in the control group. A significant difference in the mean follow-up scores of caregivers self-reported home hazard practices between the intervention and control group was noted. At the same time, no significant difference was found in the mean baseline and follow-up comparison of control groups.

The intervention with HSSP was an effective method to reduce the home hazard practices as reported by the caregivers as the mean difference observed from the baseline to follow-up in the intervention group (6.48) was higher as compared to that in the control group (0.18). A significant improvement was found in the mean difference of caregivers' supervisory attitude scores within the intervention group from baseline to follow-up. At the same time, no significant difference was found in the mean baseline and follow-up comparison of control groups.

DISCUSSION

Many published studies reported that the majority of injures occurs for children between the age of one to four years [12,13]. In this study the mean age of children experiencing home injuries was 3.3 years.

Table II Injuries Among Children in Intervention and Control Groups at Baseline and Follow-up

Childhood injury	*Intervention group (n=65)*		*Control group (n=65)*	
	Baseline	*Follow-up*	*Baseline*	*Follow-up*
Childhood injuries[a,c]	43.2 (3.22)	34.2 (2.27)	44.4 (4.22)	41.1 (3.36)
Burns	3.1 (1.88, 4.32)	0	4.6 (3.38, 5.82)	1.5 (0.28, 2.72)
Fall	21.5 (20.3, 22.7)	9.2 (7.98, 10.4)	18.518.6 (17.3, 19.7)	15.4 (14.2, 16.6)
Cut/injury[b]	12.3 (11.1, 13.5)	4.6 (3.38, 5.82)	9.29.3 (7.98, 10.4)	10.8 (9.58, 12.0)
Suffocation/choking	1.5 (0.28, 2.72)	0	0	0
Poisoning	0	0	1.5 (0.28, 2.72)	0

Value in median (IQR) except [a]mean (SD). [b]Comparison of mean difference between the intervention and control groups, P=0.02; [c]For comparison of childhood injuries at baseline and follow-up in intervention group, P<0.001 and for control group, P=0.38.

WHAT IS ALREADY KNOWN?

- Children below five years are prone for injury. They spend maximum time at home. Caregivers are responsible for the supervision of children.

WHAT THIS STUDY ADDS?

- The present study evaluated the effectiveness of a home supervisory program. This study also identified the attitudes of caregivers after the intervention.

Interventions for caregivers are very effective in reducing the injuries among children [14]. There are two different strategies in interventions. They are active and passive. One of the active strategy is training [15-16]. Injuries among children at home can be maximally reduced by giving training or education for caregivers [17]. The results of the present study revealed that such an intervention had a significant reduction in the overall injury status of children.

An educational program in combination with the distribution of a barrier or playpen was found to have a significant decrease in burns injury among children post intervention [18]. There is evidence that caregiver supervision may reduce the risk and severity of childhood injuries [19] and protect children who have injury risk factors [9].

An educational intervention was found to have improved the home safety practices of families with young children with significant increase in the percentage of homes deemed 'safe' after the fall intervention counseling [16,20]. The findings of a systematic review reported that parenting interventions, provided within the home using multi-faceted interventions may be effective in reducing child injury [21,22].

As the injury history in the study was collected retrospectively, there might be varations while reporting by the caregivers. There could be observer bias in the present study as the observed home hazard safety practices was assessed by the researcher.

The external validity of the study can be improved by increasing the sample size and representation of sample. A follow up of one year will make sure the retention of practices.

The intervention in the study aimed at increasing the caregivers awareness about home injuries and various home safety practices, which inturn contributes to the overall health and wellbeing of the children. Further the study emphasizes that the intervention should be directed towards the caregivers to have the change in the behaviour of children and themselves and also to improve the home environment. Surveillance of childhood injury and caregiver awareness would help to bring down the unintentional injuries among children.

Ethics clearance: Institutional Ethics Committee of Kasturba Medical College and Kasturba Hospital, Manipal; No. IEC193/2018, dated March, 2018.
Contributors: AG: concept and design development, data collection, writing the first draft and consecutive revisions of the manuscript; RG: concept and design development, development of the instruments, preparation and consecutive revisions of the manuscript; SS: data collection, data analysis and preparation and consecutive revisions of the manuscript. All authors approved the final version of manuscript, and are accountable for all aspects related to the study.
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RESEARCH PAPER

Profile of Injuries in Children: Report From a Level I Trauma Center

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Objective: We present our experience of pediatric injuries over 5 years from a level I trauma centre. **Methods**: De-identified data from a prospectively maintained database of pediatric patients was analyzed for demography and injury-related parameters, and management provided. **Results**: There were 906 patients (698 male, median age 12 years). Predominant cause was road traffic injuries. The median injury severity score was 9. Abdomen and thorax were the commonest regions affected. There were 44 deaths. Sepsis and hemorrhage were the commonest causes of mortality. **Conclusions**: The magnitude of pediatric injuries is significant, and maintenance of dedicated trauma registries is the need of the hour.

Keywords: *Epidemiology, Injuries, Management, Unintentional.*

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Trauma is one of the leading causes of death and disability worldwide. More than 90% of injury related deaths occur in low and middle-income countries (LMICs) where preventive efforts are largely non-existent and the health care systems are poorly equipped [1]. Owing to poor registry, the epidemiology of pediatric injuries is difficult to estimate in LMICs [2].

We conducted this study to appraise various parameters of injured pediatric patients, so as to provide baseline information for further research, effective management and planning of preventive strategies for pediatric trauma patients in the country.

METHODS

The study was conducted at a high volume Level I trauma centre in India. All patients are managed using Advanced Trauma Life Support (ATLS) protocol [3]. Inpatient data from January, 2012 to September, 2017 was collected and de-identified using a unique health identification number, in a prospectively maintained computerized database. Patients aged 18 years or less were included. Age, gender, mechanism of injury, findings of primary and secondary survey, region-wise distribution of injuries, hospital stay and mortality was recorded. The data were entered in a pre-designed performa and analyzed using SPSS version 25. The data were summarized using percentage, median and mean.

RESULTS

There were 906 patients (77% males) with median (IQR) age of 12 (7-17) years. Majority (n=440; 48.6%) belonged to 13-18 y age group, followed by 7-12 y (n=216; 23.8%) and 4-6 y (n=120; 13.2%); toddlers constituted 11.7% of the cohort (n=106). Road traffic injury (RTI) was the commonest cause of trauma (47.4%) (**Table I**).

Airway was found threatened or compromised in 72 (7.9%) patients. Breathing was compromised in 92 (10.2%). Focused assessment sonography in trauma (FAST) was positive in 294 (32.5%) patients. Glasgow coma scale (GCS) score was subnormal at presentation in 149 (16.4%) patients. Isolated trauma, defined as injury to one abbreviated injury score (AIS) region only was found in 445 (49.1%) patients, whereas 461 (50.9%) had polytrauma. Median (IQR) Injury Severity Score (ISS) was 9 (4-13).

We had 63 patients with head injury, 14 with neck and 80 patients with maxillo-facial injuries (**Web Table I**). Two hundred thirteen (23.5%) patients had chest trauma, majority of them (196, 92%) were managed non-operatively; 90 patients required insertion of an ICD tube (**Web Table II**). Four patients presented with cardiac tamponade, requiring urgent thoracotomy.

There were 370 (40.8%) patients of abdominal trauma, with 351 (94.9%) having blunt trauma while rest had penetrating injuries. Ninety-three percent (188/202) liver and 71.1% (64/90) splenic injuries were successfully managed non-operatively. We had 78 patients of pelvic injuries, all but one due to blunt trauma; 37 (47.4%) of them required operative intervention for associated abdominal injuries and/or pelvic fixation (**Web Table III**).

TABLE I Mechanism of Trauma and Causes of Death in Pediatric Inpatients (<18y) With Trauma (*N*=906)

Characteristic	*n (%)*
Mechanism[a]	
Road traffic injurty	429 (47.4)
Railway track injury	13 (1.4)
Fall from height	81 (8.9)
Blunt assault	46 (5.1)
Gunshot	16 (1.8)
Stab injury	26 (2.9)
Unknown	59 (6.5)
Self-inflicted	15 (1.7)
Accidental/sports	192 (21.2)
Machine injury	14 (1.5)
Cause of death (n=44)	
Sepsis	21 (47.7)
Hemorrhagic shock	15 (34.1)
Head injury	5 (11.4)
Arrythmia	1 (2.3)
Cardiac arrest	1 (2.3)
Not known	1 (2.3)

[a]*Fall of object on patient (n=6), animal injury (n=4), foreign body ingestion and blast injury (2 each) and electrocution (n=1) were other causes of injury.*

There were nine children with vascular injuries in torso including one internal mammary artery (IMA), one inferior vena cava and one hepatic artery injury. All were repaired except IMA which was ligated. Six patients had pseudoaneurysm of various abdominal vessels that were coil embolized. In extremity vascular trauma, we had 63 arterial and 2 venous injuries in 53 patients. Mode of trauma was sharp in 15 (28.3%) and blunt in rest. All of them underwent various standard surgical procedures (**Web Table IV**). There was no amputation.

Soft tissue injuries were seen in 132 patients (**Web Table V**). There were 14 nerve and 15 tendon injuries, all were repaired primarily. There were 157 extremity fractures, 6 dislocations, 11 traumatic amputations, 14 mangled extremities, 33 crush injuries and 9 compartment syndromes in 158 patients. One hundred four (65.8%) patients required operative management and rest were managed non-operatively. There were 27 patients with spine injuries; 15 (55.6%) were managed with surgery.

Discharge to home care was possible in 862 patients (95.1%). There were 44 (4.9%) deaths. The commonest cause of mortality was sepsis followed by hemorrhagic shock and head injury (**Table I**).

DISCUSSION

Almost half of our patients were less than 12 years of age. It has been reported that the most common pediatric age group affected by injury is 6-12 years [4]. Male to female ratio in our study was 3.36:1, which is in agreement with the published literature [5]. Some investigators have found home to be the most frequent place of injury [6] whereas, similar to our findings, others report RTI as the most common cause [1,5]. Fall from height has been cited as the commonest mechanism of trauma in pediatric age group by various authors [7,8]. We did not find similar result; this could be due to exclusion of neurosurgical patients, as majority of children sustaining fall from height suffer head injuries and are therefore likely to be admitted under care of neurosurgeons.

Most of the children with chest injuries were successfully managed non-operatively with insertion of ICD in select patients. Similar findings have been reported by other authors too [9,10]. This supports that majority of such patients can be managed at centres having basic resources and a team who can care for an injured child. Our experience with traumatic cardiac injuries also reinforced the importance of trauma management protocols in place. We could identify all patients with cardiac tamponade based on mechanism of injury, vital signs and findings of FAST alone. All of them were operated by trauma surgeons without cardiopulmonary bypass with good results.

We could manage majority of solid visceral injuries with close monitoring alone, as also reported previously [9,10]. This can be accomplished with basic resources like a facility for close observation, blood bank and operation theatre, or a robust referral system to an equipped facility. Similarly, all our patients with extremity vascular injury were managed by trauma surgeons with good outcome. Good functional outcome of vascular injuries managed by general surgeons have been reported by others too [11]. Most of the patients with soft tissue injury were managed non-operatively. Early and aggressive treatment of soft tissue injuries in children have been emphasized by other authors as well [12,13].

The mortality rate in our cohort was 4.9%, which is lower than the Western data [14] and that from elsewhere in India [9]. One reason for the low mortality rate in our study may be the exclusion of neurosurgical patients as up to 85% of deaths have been reported due to head injuries in pediatric patients [15]. However, we believe that an organized approach by a committed team with appropriate resources is able to achieve better outcomes. Better outcome has been reported by many other authors following standard trauma protocols [1].

WHAT THIS STUDY ADDS?

- This study on 906 injured children gives a comprehensive account of demography, profile and outcome of pediatric inpatients with injuries.

Limitations of this study include exclusion of patients admitted under neurosurgery and orthopedics; including them could have brought our results closer to actual burden of pediatric trauma in our setting. The single-center data and inclusion of only inpatients also precludes generalization of these findings.

Results comparable to dedicated pediatric trauma centers can be achieved by adopting an organized and protocol-based approach to trauma care. Maintenance of dedicated trauma registries is the need of hour. However, the goal of all studies on pediatric trauma will be fulfilled only when injury prevention strategies are effectively implemented.

Contributors: AR: conceptualized the study, revised the draft critically for important intellectual content, MKJ:acquisition, analysis and interpretation of data for the work, drafted the work and revised it critically for important intellectual content, BM, SK, SS:substantially contributed to the design of the work, revised the manuscript critically for important intellectual content, AG:acquisition and interpretation of data, substantially contributed to the design of the work, revised the manuscript critically for important intellectual content. All authors approved the final version to be published and are accountable for all aspects of the work.

Ethical clearance: Institute Ethics Committee, AIIMS New Delhi; No. IEC-238, dated April 11, 2020.

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Web Table I Head, Neck, Face and Maxillofacial Injuries in Pediatric Inpatients With Trauma (*N*=157)

Anatomic region	*Breakup of Injuries*	*Operative*	*Non-operative*
Head (*n*=63)			
Parenchymal	25	0	63
Bony injury	24		
EDH	8		
SDH	7		
SAH	4		
Neck (*n*=14)			
Cervical trachea	10	5	5
Cervical esophagus	3	1	2
Cervical vascular injury	4	1	
Spinal/ vertebral/ bony	1		
Muscular	1	1 (muscle repair)	
Thyroid	1		
Face and maxillofacial (*n*=80)			
Mandibular injury	50	ORIF	54
Extra mandibular bony injury	57	Orbital floor repair	1
Eye/ear	6/1	FTP fasciocutaneous flap	1
		SSG	2
		Ex Fix	1

EDH:extradural hemorrhage; SDH: subdural hemorrhage; SAH: Subarachnoid hemorrhage; ORIF: open reduction and internal repair; SSG: split skin graft; FTP: frontotemporoparietal.

Web Table II Chest Injuries in Pediatric Inpatients With Trauma (*N*=213)

Finding/ organ injured	*No.*	*Operative*	*(n=17)*
Pneumomediastinum	6		
Subcutaneous emphysema	9		
Rib fracture	67		
Hemopnemothorax	32		
Pneumothorax	64	Thoracotomy[a]	2
Hemothorax	36	Thoracotomy[a]	4
		VATS[b]	1
		Thoracotomy[b]	2
Lung contusion	50		
Thoracic tracheal injury	12	Thoracotomy[c]	
	2		
Esophagus injury	2	Thoracotomy[c]	1
Chylothorax	1		
Blunt cardiac injury	2	Thoracotomy	2
Penetrating cardiac Injury	2	Thoracotomy	2
Great vessel injury (SVC)	1	Sternotomy (SVC)	1
Overall ICD use in chest trauma non operative management (n=196)			
Without ICD	106		
With ICD	90		

[a]massive or [b]retained hemothorax;[c]Posterolateral thoracotomy. ICD: intercostal drain; SVC: superior vena cava; VATS: video-assisted thoracoscopic surgery.

Web Table III Abdominal, Pelvic, and Genitourinary Trauma in Pediatric Inpatients (*N*=370)

Organ	*Break-up/AAST Grade*	*No.*	*Operative*	*No.*	*Non-operative, no.*
Diaphragm (*n*=7)			Primary repair	6	1 (right side)
Spleen (*n*=90)	1	11	Splenorrhaphy	2	64
	2	24			
	3	26			
	4	23	Splenectomy	24	
	5	6			
Liver (*n*=202)	1	21	Peri-hepatic packing	13	188 (1 AE)
	2	36			
	3	52	Packing + angioembolization (AE)	1	
	4	78			
	5	15			
Kidney (*n*=55)	1	2			51 (Pigtail for urinoma- 8)
	2	12			
	3	14			
	4	20	Nephrectomy	4	
	5	7			
Hollow viscus (*n*=26)	Stomach	0	Repair+RD+FJ	3	1 (mesenteric tear)
	Duodenum	1	Primary repair	11	
	Jejuno-ileal	10	Resection anastomosis	4	
	Large bowel	12	Stoma		17
	Mesenteric	3	Laprotomy	7	
Pancreas (*n*=3)	1	1			1
	2	0			
	3	0			
	4	2	Distal Pancreatectomy	2	
	5	0			
Biliary system (*n*=2)	Blunt trauma		1		1 (AE for hemobilia)
Perineum (*n*=11)[a]	Penetrating injury	3		10	1
	Blunt	8			
Genitourinary (*n*=14)	Ureter	1	Primary repair	1	0
	Urethra	4	Suprapubic cystostomy	4	0
	Male genitalia	2		2	0
	Female genitalia	7		3	4
	Urinary bladder				
	Extraperitoneal	2	Bladder neck repair	1	1
	Intraperitoneal	4	Primary repair	4	0
Pelvis (*n*=78)			Packing +/- ExFix	37	41
Great vessels (2)	IVC	2	Primary repair	1	1

[a]*Associated injuries: bowel-8, urethra-2. AAST-American Association for the Surgery of Trauma.*

Web Table IV Peripheral Vascular Injuries in Pediatric Inpatients With Trauma (*N*=65)

Vessel	*Embolectomy*	*Repair*	*End-to-End anastomosis*	*Interpostition vein graft*	*Ligation*
Brachial(*n*=25)	5	7	8	5	0
Ulnar (*n*=14)	2	5	4	1	2
Radial (*n*=12)	1	6	4	1	0
Femoral (*n*=7)	2	1	3	1	0
Popliteal (*n*=5)	1	0	3	1	0
External jugular veins (*n*=2)	0	0	0	0	2

Values in no.

Web Table V Soft Tissue Injuries in Pediatric Inpatients With Trauma (*N*=132)

Organ	*No.*	*Operative*	*No.*	*Non-operative, no.*
Peripheral nerves	14	Primary repair	14	0
Tendon	15	Primary repair	15	0
Skin and subdermal tissue trauma		*Procedures done*		
Abrasions	3	Debridement	95	8
Lacerations	53	Primary/delayed primary closure	57	
Degloving injuries	38	Split skin graft	41	
Incised wounds	4	Flap coverage	8	
		Vacuum assisted closure	2	
Region-wise location of soft tissue trauma				
Head and neck	20			
Orofacial	26			
Thorax	6			
Abdomen/perineum	11			
Extremity/shoulder/pelvic girdle	49			

RESEARCH PAPER

Interpersonal Violence Against Children and Adolescents: A Forensic Study From Greece

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Objective: To investigate differences in victimization of minors after allegations of domestic violence and community violence. **Methods:** This retrospective study was conducted by reviewing the archive of clinical examinations after allegations for interpersonal violence against minors that were performed at the Department of Forensic Medicine and Toxicology of our Medical School from 2012 to 2016. **Results:** 216 cases of allegations for victimization of minors' were referred to our department, representing 8.8% of all clinical forensic examinations. Boys community violence victims were affected mainly on the head, whilst girls mainly on the genital area. Upper limbs were the predominant site of injuries on domestic violence victims of both sexes. **Conclusions:** Adolescents were in greater danger of sustaining injuries than younger children. Upper limb injuries may prove to be a useful screening tool for domestic violence in school-age children and adolescents, while trunk injuries may indicate domestic violence in preschool children.

Keywords: *Child abuse, Clinical forensic examination, Community violence, Domestic violence, Greece, Minors' victimization.*

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World Health Organization (WHO) defines violence as the intentional use of physical force or power, threatened or actual, against oneself, another person, or against a group or community that either results in or has a high likelihood of resulting in injury, death, psychological harm, mal-development or deprivation [1]. Whilst the definition provided by the WHO about child abuse/ maltreatment includes mostly victimization by a parent or caregiver [1,2], minors may be also victimized in the community context by strangers or acquaintances (youth violence) [3].

According to a systematic analysis, 40-60% of boys and girls, aged between 2-14 years, have experienced physical abuse by a parent, another family member or caregiver, and approximately half of boys and girls, aged between 8-11 years, have experienced physical violence by a classmate [4]. Despite the amount of the existing literature on child abuse, very few studies have been published concerning the injuries in such cases. In Greece, studies concerning domestic abuse of children are extremely rare [5,6], whilst studies concerning minors' victimization in the community context are practically non-existent.

One of the main goals of the forensic clinical examination of injured minors is to evaluate whether injures are accidental or intentional [7-9]. Aim of this study was to investigate differences in minors' victimization in domestic (DV) and community violence (CV) incidents in Greek population, with emphasis on anatomic injury location, in an attempt to investigate its usefulness as a screening tool for identifying the perpetrators' relation to the victim.

METHODS

The archives of the Department of Forensic Medicine and Toxicology of Medical School of National and Kapodistrian University of Athens (NKUA) were reviewed concerning clinical examinations for non-lethal injuries conducted from 2012 to 2016, and cases of minors' victimization were included in our study. Allegations originated from areas that cover approximately one tenth of the Greek population. All data were collected anonymously, and the study was approved by the Ethics Committee of our Medical School (NKUA).

Allegations were categorized into two groups: *i*) domestic violence cases, subjected to Greek Law about Domestic Violence (GLDV), and *ii*) community violence

cases, subjected to the Greek Penal Code (GPC). Variables recorded for every case included victims' and perpetrators' demographic characteristics, clinician's examination findings before the forensic clinical exami-nation, mechanism of injuries (*a*) physical violence (when just a body part acted as a blunt force instrument), (*b*) use of a blunt force object only, (*c*) combination of a and b; (*d*) sharp force instrument; (*e*) sexual abuse; and (*f*) firearm injuries), type of injuries (*a*) external injuries affecting only soft tissue (*e.g*. bruises); (*b*) internal injuries (*e.g*. fractures); and (*c*) evidence of sexual abuse), affected body region (head, neck, trunk, upper and lower limbs), and characterization of injuries according to GLDV [10] and GPC [11].

Statistical analysis: Data are presented as proportions. Categorical data were analyzed using Pearson chi-square test. Data analyses were performed using the Statistical package for social sciences software (SPSS version 25.0, SPSS Inc. Chicago, Illinois). A $P<0.05$ was considered statistically significant.

RESULTS

Two hundred and sixteen cases of minors' victimization were referred to our department, representing approximately 8.8% of all clinical examinations [community violence (CV): 8.5%, domestic violence (DV): 9.4%]. Victimization of boys was less frequent in the domestic context ($P=0.01$) and concerned mainly adolescents (**Table I**). Victimization in the domestic context was more frequent for school-age boys ($P=0.01$). Most DV cases (91.0%) concerned allegations against a parent, whilst 6.4% concerned a grandparent and 2.6% a sibling. In 68.3% of the total cases, victims knew the perpetrator(s). There were no allegations for intimate partner violence in the adolescent age group, neither any allegation for physical violence by teachers.

In 48.5% of CV allegations, the perpetrators were strangers. Girls knew the perpetrator(s) more frequently than boys (81.4% vs 58.8% for boys). Allegations against females were more frequent in DV allegations ($P=0.016$ for boys, and 0.032 for girls), whilst allegations against males were more frequent in CV allegations ($P=0.001$). A clinician examined 77 victims (35.6%) before the forensic examination. DV victims were less frequently examined by a clinician than CV victims (DV: 21.8%, CV: 43.5%, $P=0.001$).

In 43 cases (19.9%), a single injury was assessed during the examination (CV: 18.8%, DV: 21.8%), whilst 144 victims (66.7%) sustained multiple injuries (CV: 55.1%, DV: 48.7%). Sexual assaults against girls comprised 52.8% of the CV and 25.0% of the DV cases, whilst allegations of sexual abuse in boys were rare (CV: 2.3%, DV: 11.8%). Signs of sexual abuse were more frequent in allegations about sexual victimization in the community context (CV: 33.3%, DV: 20.0%, $P=0.01$). In most boys' victimization, the perpetrator employed only physical force (CV: 68.2%, DV: 61.4%). Sharp force instruments were used by perpetrators only in CV (boys: 7.2%, girls: 3.8%). CV victims were more likely to sustain internal injuries, compared to DV victims (CV: 15.2%, DV: 3.8%, $P=0.04$). Anatomical distribution of injuries is depicted in **Table II** and **Web Table I**. Injuries inflicted in DV were more likely to be characterized as simple injuries ($P=0.01$)

DISCUSSION

According to our study, CV cases concern more frequently boys, especially adolescents, and DV affects equally both sexes. DV frequency was at comparable levels with a Netherlands study, whilst CV cases were significantly less [12]. This finding may suggest that CV,

Table I Demographic Characteristics of Victims and Perpetrators in Children With Interpersonal Violence (*N*=216)

	Community violence		*Domestic violence*	
	Boys (n=85)	*Girls (n=53)*	*Boys (n=34)*	*Girls (n=44)*
Victim's nationality				
Greek	76 (89.4)	42 (79.2)	29 (85.3)	39 (88.6)
Other	9 (10.6)	11 (20.8)	5 (14.7)	5 (11.4)
Victim's age				
Infant (<1 y)	0	0	1 (2.9)	1 (2.3)
Preschool age (1-5 y)	3 (3.5)	4 (7.6)	4 (11.8)	9 (20.4)
School age (6-12 y)	15 (17.7)	19 (35.8)	22 (64.7)	15 (34.1)
Adolescent (13-17 y)	67 (78.8)	30 (56.6)	7 (20.6)	19 (43.2)
Age (y)[a]	14.1 (3.6)	12.6 (3.5)	9.2 (3.9)	10.4 (5.1)
Perpetrator's sex				
Male	65 (76.5)	46 (86.8)	23 (65.6)	30 (68.2)
Male and female	0	2 (3.8)	0	0
Unknown	13 (15.3)	0	2 (7.9)[b]	3 (6.8)[b]
Perpetrator's sex				
Under 17 y	28 (32.9)	7 (13.2)	1 (2.9)	0
Over 18 y	30 (35.3)	22 (41.5)	33 (97.1)	44 (100)
Unknown	27 (31.8)	24 (45.3)	0	0
Perpetrator's nationality				
Greek	40 (47.1)	31 (58.5)	27 (79.4)	38 (86.4)
Other	5 (5.8)	10 (18.9)	4 (11.8)	3 (6.8)
Unknown	40 (47.1)	12 (22.6)	2 (8.8)	3 (6.8)

Data is presented as No. (%) except [a]mean (SD). [b]five allegations about domestic violence were against the parent but there was no information whether it was the father or the mother.

Table II Body Region Injured in Children With Interpersonal Violence (*N*=216)

	Community violence		*Domestic violence*		*P value*	*P value*
	Boys (n=85)	*Girls (n=53)*	*Boys (n=34)*	*Girls (n=44)*	*(for boys)*	*(for girls)*
None	10 (11.8)	16 (30.2)	10 (29.4)	13 (29.5)	0.02	0.05
Head	53 (62.3)	8 (15.1)	10 (29.4)	8 (18.2)	0.001	0.68
Face	52 (61.2)	8 (15.1)	9 (26.5)	7 (15.9)	0.001	0.91
Cranium	8 (9.4)	1 (1.9)	2 (5.9)	3 (6.8)	–	–
Neck	11 (12.9)	5 (9.4)	2 (5.9)	4 (9.1)	–	–
Trunk	19 (22.3)	15 (28.3)	9 (26.5)	13 (29.5)	0.62	0.89
Thorax	12 (14.1)	5 (9.4)	7 (20.6)	3 (6.8)	0.38	–
Abdomen	5 (5.9)	1 (1.9)	0	3 (6.8)	–	–
Back	12 (14.1)	9 (17.0)	5 (14.7)	7 (15.9)	–	0.89
Genitalia	0	10 (18.9)	0	2 (4.5)	–	0.03
Upper limbs	28 (32.9)	11 (20.7)	12 (35.3)	17 (38.6)	0.81	0.05
Arms	13 (15.3)	5 (9.4)	8 (23.5)	14 (31.8)	0.29	0.006
Forearms	21 (24.7)	8 (15.1)	5 (14.7)	9 (20.4)	0.23	0.49
Hands	11 (12.9)	1 (1.9)	5 (14.7)	8 (18.2)	–	–
Lower limbs	21 (24.7)	8 (15.1)	7 (20.6)	11 (25.0)	0.63	0.22
Thighs	15 (17.6)	8 (15.1)	4 (11.8)	10 (22.7)	0.43	0.33
Leg calves	16 (18.8)	4 (7.5)	6 (17.6)	5 (11.4)	0.88	0.52
Feet	1 (1.2)	0	0	2 (4.5)	–	–

Data is presented as no. (%).

especially youth violence, occur less frequently or is reported less frequently to the Police in Greece than in other countries.

Physical violence was the most common mechanism that perpetrator(s) employed, which is in accordance with other studies [5,12]. According to an American study, injuries inflicted by weapon(s) were less frequent in girls than boys and were recorded only in CV incidents [13]. This finding probably means that DV perpetrators (mostly parents) employ just physical violence (by use of body parts) as punishment and disciplinary measures.

Another finding of our study was the smaller frequency of prior examination by a clinician for DV inci-dents, compared to CV frequency. Clinicians, especially pediatricians, can and should play an important role in the early diagnosis of abuse and victimization, especially in the domestic context. According to Joseph, et al. [14], boys admitted at emergency departments (EDs) were more likely to be DV victims than their female counterparts. Our results do not confirm this finding. Furthermore, according to our results, head was the predominant site of injury, which is in accordance to another Greek study [5]. Nevertheless, the latter depicts only male victims of CV, in contrast to other studies that reported head injuries in child abuse incidents more frequently [5,14]. These findings could possibly suggest a selection bias, as our study included forensic population (after allegations for inter-personal violence), whilst the studied populations by Joseph, et al. [14] and Petridou, et al. [5] represented patients admitted at EDs.

According to a UK study 65.6% of assaults were recorded only on EDs, 23.6% were reported only to the Police, and only 10.8% were reported both to EDs and the Police. Furthermore only 1 or 2 out of 10 minors have reported their victimization to both a police officer and a clinician, as up to 60-70% had mentioned the incident only at EDs [15]. These findings suggest that future research should combine records from EDs, forensic departments and the police department, to ascertain the true extent of minors' victimization which seek medical care or judicial support.

Our study demonstrated that most DV and CV adolescent victims sustained injuries, suggesting that they are in greater danger of getting injured than younger children, especially than children at the preschool development stage. Furthermore, upper limbs injuries could possibly become a screening tool for domestic abuse in school-age children and adolescents, whilst trunk injuries could imply domestic abuse in preschool children, but these results should be verified by future large scale community studies.

WHAT THIS STUDY ADDS?

- In a Greek population, head injuries in boys and genital injuries in girls were associated with victimization in the community context, whereas arm injuries in girls were associated with domestic violence.
- Upper limb injuries in school-age children and adolescents, and trunk injuries in preschool children were associated with domestic abuse.

To the best of our knowledge, this is the first study in Greece that compared minors' victimization in the community and the domestic context. High incidence and prevalence of exposure to physical violence (both domestic and community) reported by Petroulaki, et al. [6] compared to allegation rates in our Department suggest that minors' victimization is underreported in Greece. Campaigns about child abuse and youth violence are needed, to eliminate or at least reduce these phenomena.

Ethics clearance: Ethics Committee of the Medical School of National and Kapodistrian University of Athens, Greece; No. 5836 dated February 2, 2015.

Contributors: KK: concept and design of the study, collection, and interpretation of the data, drafting the article and revised it critically for important intellectual content; ES: Interpretation of the data, drafting the article and revised it critically for important intellectual content; EZ*:* analysis and interpretation of the data, revising the article critically for important intellectual content; AT,NG,DV, SP: concept and design of the study, drafting the article and revised it critically for important intellectual content; CS: concept and design of the study, drafting the article and revised it critically for important intellectual content. All authors approved the final version of manuscript, and agreed to be accountable for all aspects related to the study.

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Web Table I Body Region Injured and Victim Age in Children With Interpersonal Violence (*N*=216)

	Community violence (n=138)			*Domestic violence (n=78)*		
	Preschool child (n=7)	*School-age child (n=34)*	*Adolescent (n=97)*	*Preschool child (n=13)*	*School-age child (n=37)*	*Adolescent (n=26)*
None	4 (57.1)	13 (38.2)	19 (19.6)	6 (46.1)	12 (32.4)	5 (19.2)
Head	1 (14.3)	4 (11.8)	56 (57.7)	3 (23.1)	6 (16.2)	8 (30.8)
Face	1 (14.3)	4 (11.8)	55 (56.7)	3 (23.1)	5 (13.5)	7 (26.9)
Cranium	0	0	9 (9.3)	1 (7.7)	1 (2.7)	2 (7.7)
Neck	0	4 (11.8)	12 (12.4)	0	4 (10.8)	2 (7.7)
Trunk	1 (14.3)	8 (23.5)	25 (25.8)	5 (38.5)	10 (27.0)	6 (23.1)
Thorax	0	2 (5.9)	15 (15.5)	2 (15.4)	5 (13.5)	2 (7.7)
Abdomen	1 (14.3)	0	5 (5.1)	0	2 (5.4)	1 (3.8)
Back	0	4 (11.8)	17 (17.5)	3 (23.1)	6 (16.2)	3 (11.5)
Genitalia	0	5 (14.7)	5 (5.1)	1 (7.7)	0	1 (3.8)
Upper limbs	2 (28.6)	10 (29.4)	27 (27.8)	3 (23.1)	15 (40.5)	11 (42.3)
Arms	1 (14.3)	4 (11.8)	13 (13.4)	2 (15.4)	12 (32.4)	8 (30.8)
Forearms	0	8 (23.5)	21 (21.6)	2 (15.4)	6 (16.2)	6 (23.1)
Hands	1 (14.3)	0	11 (11.3)	3 (23.1)	4 (10.8)	6 (23.1)
Lower limbs	1 (14.3)	8 (23.5)	20 (20.6)	0	10 (27.0)	7 (26.9)
Thighs	1 (14.3)	4 (11.8)	18 (18.6)	0	6 (16.2)	7 (26.9)
Leg calves	0	6 (17.6)	14 (14.4)	0	6 (16.2)	4 (15.4)
Feet	0		1 (1.0)	0	1 (2.7)	1 (3.8)

Data is presented as no. (%). Infant (<1 y); preschool age (1-5 y); school age (6-12 y); adolescent (13-17 y).

RESEARCH PAPER

Unintentional Injuries Among Under-five Children in a Rural Area in Delhi

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Objective: To determine the prevalence of unintentional injuries and its associated factors among under-five children in Rural Delhi. **Methods:** This community based cross-sectional study was conducted in Pooth Khurd village of Delhi during 2018 among under-five children and their care givers. Primary caregivers of the child in the randomly selected households were interviewed using a semi-structured pretested questionnaire. Data related to unintentional injuries in past 12 months and its associated factors were collected. **Results:** Unintentional injuries were prevalent in 29.3% (95% CI: 25.8-32.9) of the 650 under-five children included. Male children had 1.4 times increased prevalence of injuries (aPR=1.4, 95% CI: 1.1-1.7). As the age increases from 2 years to 5 years the prevalence of injuries increased constantly from 29% to 50%. The prevalence of unintentional injuries was significantly higher among children of working mothers (aPR=1.7, 95% CI: 1.4-2.1), family with more than 3 children (aPR=1.6, 95% CI:1.1-2.4), household without a separate kitchen (aPR=1.6, 95% CI:1.2-2.2) and household with inadequate lighting (aPR=1.8, 95% CI:1.4-2.3). **Conclusions:** The factors significantly associated with unintentional injuries were male gender, higher age of the children, maternal occupation, increased number of children in the family, not having a separate kitchen and inadequate lighting.

Keywords: *Accident, Epidemiology, Domestic injuries, Risk factors, Trauma*.

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World Health Organization has estimated that in 2017, 3% of the global under-five deaths were attributed to injuries [1-3]; with South-East Asia region contributing 31% [4]. Unintentional injuries are the sixth leading cause of under-five mortality in India [5], with 4% of the under-five deaths in India being attributed to injuries [6].

In rural India, drowning is the most common type of unintentional injuries whereas in urban India accidental falls are the most common type [7,8]. Injuries could be reduced by identifying the factors associated with unintentional injuries. Various factors associated with unintentional injuries can be classified as child-related factors like the softness of body parts, impulsiveness, experimentation, and lack of knowledge on the judgment of speed [7-9], environment-related factors like poor housing infrastructure, unsafe storage places for harmful substances, and lack of barriers to cooking/washing areas [8]. These living conditions are more common in low and middle-income countries like India. This study was conducted to determine the prevalence of unintentional injuries and its associated factors among under-five children in a rural area of Delhi.

METHODS

A community-based cross-sectional study was conducted in the Pooth Khurd village of North-West district of Delhi. As per census 2011, the total population of village was 10654 among which 14.12% belong to the age group of 0-6 years. The total number of houses in the village was 2030 out of which 1350 households had children. This study was conducted over a period of 12 months from January to December, 2018 in the service area catered to this hospital.

The parents/caregivers of the under-five children who were residing in the study setting for a minimum period of 6 months were included in the study. Primary caregivers included parents, other persons who are directly responsible for the child at home. The parents/ caregivers who were suffering from any debilitating illness or mental disorders were, not able to communicate in Hindi/English or who were not cooperative during the interview, were excluded from the study.

With the expected prevalence of unintentional household injuries in under-five children as 37.4%, with 10% relative precision and 95% confidence level, the

sample size was calculated to be 643 using OpenEpi, Version 3 [8]. The sample size was rounded to 650. There were 1350 households with children, out of which 650 households were selected by simple random sampling technique using computer-generated random number.

The selected households were visited by the investigator to check for the eligibility and availability of primary caregiver/parent. If the caregiver was available, participant information sheet was given after explaining the study procedure and informed written consent was obtained. If the caregiver was unavailable, two revisits to the household were made. If the caregiver was not available even with revisits, that household was excluded from the study. If there were more than one under-five children in the household, then injury details were collected for the eldest child to avoid the clustering effect of risk factors at household level. A pretested semi-structured questionnaire was used to interview the primary caregivers of under-five children. Data related to socio-demographic characteristics and details about unintentional injuries were collected.

Unintentional injury included all recallable bodily injury to the index child in the past 12 months, for which there was no evidence of predetermined intent at the time of the interview. It included road traffic accidents, falls, fires and burns, drowning, animal bites, poisonings and aspirations [1].

The variables included in the study were child's age, gender, primary caregiver's age and relation to the child, mother's and father's education and occupation, religion, family type, socio economic status, number of children in the household, presence of overcrowding, adequate lighting, separate kitchen and pets/animals in and around the households. Overcrowding was assessed using the criteria based on number of persons living per room in the household [10]. If the investigator was able to read news print in all the corners, the center of the room and also in the darkest portion of the room, then the lighting was considered adequate. The socio-economic status of the household was assessed using modified BG Prasad, 2019 classification [11].

The study was conducted after getting clearance from the Institutional Ethics Committee. Informed written consent was taken from the primary caregivers/parents. The children who were found to have injury related health issues during the visit were managed by the investigator based on the severity of the injury. Children with an injury which needed referral were referred to the nearby secondary health care center.

Statistical analysis: Data were entered using EpiData software version 3.1 (EpiData Association Odense) and analysis was done using STATA statistical software version 14 (StataCorp LCC). Association between various risk factors and unintentional injuries were analysed using univariate logistic regression models. Multivariate analysis was done using generalized linear models (GLM) with Poisson distribution and adjusted prevalence ratio was calculated. The independent variables which were significantly associated with unintentional injuries ($P<0.05$) were included in the model.

RESULTS

In total, the 650 under-five children were included in the study. The median (IQR) age of the children was 25 (10-40) months and 363 (56%) of the children were boys. Mother was the primary caregiver in 90% of the children and 87% of the primary care givers were in the age group 21-40 years. Sixty four percent of the mothers were educated above primary level (76.3% fathers) and only

Table I Socio-demographic Characteristics of Under-five Children With Unintentional Injuries (*N*=650)

Characteristics	*No. (%)*	*Children injured (n=191)*
Male	363 (55.8)	120 (33.1)
Age of child (mo)		
<12	200 (30.8)	17 (8.5)
13-24	115 (17.7)	34 (29.6)
25-36	131 (20.2)	48 (36.6)
37-48	98 (15.2)	39 (39.8)
49-60	106 (16.3)	52 (49.1)
Age of primary caregiver (y)		
<20	20 (3.1)	8 (40.0)
21-40	576 (88.6)	163 (28.3)
41-60	50 (7.7)	17 (34.0)
>60	4 (0.6)	2 (50.0)
Nuclear family	569 (87.5)	174 (30.6)
SES		
Class 5	339 (52.2)	110 (32.5)
Class 4	206 (31.7)	50 (24.3)
Class 3	70 (10.8)	15 (21.4)
Class 2	30 (4.6)	11 (36.7)
Class 1	5 (0.8)	4 (80.0)
Number of children		
1-2	490 (75.4)	115 (23.5)
3-4	137 (21.1)	60 (43.8)
5 and above	23 (3.5)	15 (65.2)

SES: socioeconomic status classified based on modified BG Prasad scale,2019.

16.6% of the mothers and 99.4% father were working. Eighty-four percent of the families belonged to socio-economic classes 4 and 5. Unintentional injuries occurred in 191 (29.3%) under-five children (95% CI: 25.8-32.9) (**Table I**). Seventy eight percent of the study participants were living in pucca house. Overcrowding was present in 31.6 percent of the households and adequate lighting was absent in 32% of the households. Separate kitchen was there in 59.7% of the households and pets were there in 54% of the households.

The results of univariate and multivariate analysis for the factors associated with unintentional injuries are given in **Table II**. Prevalence rate of unintentional injuries were higher in male children (aPR=1.4 95%CI: 1.1-1.7), children older than 12 month [aPR=3.0 (95% CI:1.8-4.9) for 2- year-old children; aPR=4.5 (95% CI:2.8-7.2) for 4-year-old children], and children of working mothers (aPR=1.7, 95% CI:1.4-2.1).

Among household-level characteristics, not having separate kitchen (aPR=1.6, 95% CI:1.2-2.2) and inadequate lighting (aPR=1.8, 95% CI:1.4-2.3) were significantly associated with unintentional injuries.

Table II Socio-demographic Characteristics Associated With Unintentional Injuries Among Under-five Children in a Rural Area, Delhi (*N*=650)

Characteristics	*Adjusted PR (95% CI)*	*P value*
Male gender	1.4 (1.1-1.7)	0.004
Age of children, mo		
<12	1	-
13-24	3.0 (1.8-4.9)	<0.01
25-36	3.5 (2.1-5.6)	<0.01
37-48	3.7 (2.3-6.1)	<0.01
49-60	4.5 (2.8-7.2)	<0.01
Education of mother below primary level	1.0 (0.7-1.4)	0.95
Working mother	1.7 (1.4-2.1)	<0.01
Education of father below primary level	1.0 (0.8-1.4)	0.76
Nuclear family	1.3 (0.8-2.2)	0.27
Socioeconomic status		
Class 5	0.7 (0.4-1.2)	0.17
Class 4	0.9 (0.6-1.1.6)	0.84
Class 3	1	–
Class 2	1.6 (0.8-3.1)	0.17
Class 1	2.0 (0.9-4.2)	0.06
Number of children in the family		
1-2	1	–
3-4	1.5 (1.1-1.9)	0.002
5 and more	1.6 (1.1-2.4)	0.008
Overcrowding	1.1 (0.7-1.7)	0.69
Kutcha or semi-pucca house	1.1 (0.8-1.3)	0.61
No separate kitchen	1.6 (1.2-2.2)	0.002
Inadequate lighting	1.8 (1.4-2.3)	<0.01
Pets/animals in or around house	1.2 (0.9-1.6)	0.08

PR-prevalence ratio

DISCUSSION

The prevalence of unintentional injuries was lower at 29.3% in our study compared to Indian studies [7,8,12]. This difference might be due to the differences in the study setting since the socio-demographic characteristics are widely variable in these regions. The operational definition for unintentional injuries and the duration of its assessment were also different in these studies which might have contributed to the difference in results.

Our study has found that male children are having 1.4 times higher prevalence injuries which is similar to the results from other studies and reports from all over the world [7,8,12,13]. This might be because of the socialization processes, which lead male children to engage in risky behavior than females, differences in aggressiveness, personality and infant care. The current study found that as the age of the child increases, the chance of getting injured increases. These results are also consistent with other studies [7,12]. As the age increases the child becomes more active and more ambulatory which increases the risk of getting injured. Our study found that children of working mothers had 1.7 times higher prevalence of injuries which is similar to other studies [8,12,13]. Lack of time and ability to implement injury prevention practices among working mothers might be the reason [14]. Among the household level risk factors, the prevalence rate of injuries were significantly higher among children living in households without separate kitchen which is similar to another Indian study [15]. In Indian setting, kitchen is the place where most of the hazardous materials are kept. The absence of a separate kitchen exposes the children to these hazardous materials and increases the risk of injury.

A well-known risk factor, children's risk-taking behavior was not assessed in the study. However other socio-demographic characteristics and household level risk factors were assessed. Our study considered the occurrence of injuries in the past 12 months which might involve recall bias, which could not be avoided. The temporality of the association cannot be inferred since it is a cross-sectional study. However, few socio-demo-

graphic risk factors did not change with time for which temporal association can be inferred.

A relatively large sample size and representative sampling technique increased the study's external validity. Standard definitions were used for the exposure and outcome variables which increased the internal validity of the study.

Almost one-third of the under-five children in this rural area had unintentional injuries in the past one year. Community-based interventions need to be done emphasizing the improvement of house type, overcrowding, lighting and having separate kitchen in the household. Injury prevention education may address care giver and household related factors to some extent. Studies from other settings may provide more comprehensive information for interventions at a national level for injury prevention in children.

Ethical clearance: Institutional Ethics Committee, MAMC, No.F.No.17/IEC/MAMC/2017/248 dated 4 May, 2018.
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RESEARCH PAPER

Spectrum of Self-Reported Childhood Sexual Abuse Among Medical Students: A Single Center Experience

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Objective: To study the prevalence and spectrum of self-reported childhood sexual abuse (CSA) in a sample of medical students from a medical college in Southern India. **Methods:** A self-administered questionnaire was distributed to consenting students of a medical college located at Puducherry. Those students who could not be contacted despite three attempts were excluded. **Results:** Of total 452 students, 148 (32.7%) students reported experiencing one or other form of CSA. Prevalence of CSA was almost equal in both the sexes. Most instances of CSA occurred either at own house (33.8%) or at a neighbor's house (22.9%). Majority (60.1%) did not inform anyone; due to fear of negative consequences (43.2%) and feelings of guilt (30.4%) most commonly. **Conclusion:** Approximately one third of medical students reported an incident of sexual abuse at least once in his/her life. Both girls and boys are equally likely to face CSA.

Keywords: *Outcome, POCSO, Protection, Psychological problems*.

Child sexual abuse (CSA) is a multidimensional problem having legal, social, medical and psychological implications with long term adverse effects on both physical and psychological health [1]. CSA is the indulging of a child in sexual act that he or she may not comprehend, not able to give informed consent to, or for which the kid is not developmentally prepared, or that violates the laws or social taboos of society [2].

CSA is grossly under-reported offence in our country [3,5]. Literature on the burden and pattern of sexual abuse among children in India is scanty. We studied the prevalence and spectrum of self-reported childhood sexual abuse in a sample of college students at a medical college in Southern India. An additional objective was to study the psychological problems associated with CSA.

METHODS

This descriptive study was conducted at the Department of Forensic Medicine, Indira Gandhi Medical College, Puducherry in July-September, 2018. The study population consisted of undergraduate medical students (MBBS) studying in the institution. At the time of study there were five batches of medical students, with 150 students. (total 700-750 students). All these students formed the study population. Those students who could not be contacted despite three attempts were excluded.

A pretested, structured, anonymous, self-administered English language questionnaire served as the study tool. The questionnaire was prepared using core components of child sexual study by Halpérin, et al. [6] and in consultation with the subject experts. It was pretested in a small group of students and modified accordingly. Questions were framed in various sections regarding loss of parents, parental care, abuse physical and/or sexual and support. Term sexual abuse was defined as a variety of acts like fondling genitals of a child, making the child fondle genitals of an adult, exhibitionism, pornography and sexual assult like intercourse, incest, rape and sodomy etc [7]. For the purpose of this study, lifetime experience of sexual abuse was considered if any subject has experienced of any kind of sexual abuse in his/her life till date.

The students were briefed about the study objectives and assured of complete confidentiality and privacy. Written informed consent was obtained. Consent forms were kept separate from the questionnaires to maintain anonymity. Questionnaires were handed out to the

students just after completion of classes and ensuring privacy at all times.

Study subjects were explained and informed about not writing their names or put any mark that can help in their identification neither on the questionnaires nor on the envelopes. Students were instructed to fill the questionnaire and leave it in the prepared collecting box. Of them, boys and girls were 15 each. On an average, it took 30-45 minutes to conduct interview with one subject. Permissions were obtained from the institutional ethics committee, respective colleges, and Child Welfare Committee of Puducherry.

Qualitative data collection was done by in depth interview with respondents willing to talk freely till point of exhaustion. The semi-structured interviews (*n*=30) were conducted by a trained interviewer.

Statistical analysis: All the questionnaires were manually checked for completeness and were then coded for computer entry. The collected data was entered in Excel and analyzed using SPSS version 22 (IBM). Chi square test was used to test statistical significance, wherever applicable.

RESULTS

Of the 452 respondents (57% girls), 148 (32.7%) reported experiencing one or other form of sexual abuse; 84 (56.8%) of these were girls.

Most instances of CSA occurred either at own house (*n*=50, 33.8%), a neighbour's house (*n*=34, 22.9%) or at any other unknown place (*n*=30, 20.3%). Sexual abuser was someone from friend (*n*=39, 26.4%), some unknown person (*n*=32, 21.6%), uncle (*n*=15, 10.1%), neighbor and some known person (*n*=14, 9.5% each) followed by cousin brother (*n*=10, 6.8%). Most (*n*=126, 85.1%) of the times the sexual abuser was male. As per respondants, abuser was below twenty years in 80 (54.1%) such instances whereas 21-30 years in 48 (32.4%) cases. Majority of sufferers (*n*=89, 60.1%) did not inform or share the instance of CSA to anyone. Fear of negative consequences (*n*=64, 43.2%), feelings of guilt (*n*=45, 30.4%), fear of not being believed by family (*n*=17, 11.5%), loyalty to the perpetrator (*n*=15, 10.1%) were few factots that made them not to inform such abuse to their family members. Most (*n*=41, 69.5%) of the times, instances of CSA was revealed to the friends followed by mother and sisters (*n*=7, 11.9% each).

Fondling (44.6%), making him/her look at pornographic pictures, films, videotapes or magazines (29.7%), and looking at his/her genitals (22.3%) were the three most common types of sexual abuse (**Table I**).

Table I Prevalence and Type of Self-Reported Sexual Abuse Among Medical Students (*N*=148)

Type of sexual abuse	*Boys, n=64*	*Girls, n=84*
Look at his/her genitals, *n*=33	17 (22.6)	16 (19.0)
Undress and show him/her genitals, *n*=17	11 (17.2)	6 (7.1)
Watch him/her masturbate,[a] *n*=22	16 (25.0)	6 (7.1)
Fondled (*touches, manipulate, kisses or any other way by which he/she on the whole body and/or your genitals)*, *n*=66	29 (45.3)	37 (44.0)
Fondle him/her (*touches, manipulate, kisses or any other way by which he/she on the whole body and/or his/her genitals)*, *n*=34	19 (29.7)	15 (17.9)
Made him/her look at pornographic material,[b] *n*=44	31 (48.4)	13 (15.5)
Made him/her to be naked and to exposed his/her genitals for taking picture or filming, *n*=5	3 (4.7)	2 (2.4)
Submit him/her for penetrative sexual assault,[b] *n*=28	20 (31.3)	6 (7.1)
Submit him/her to having his/her fingers or an object introduced into your body, *n*=32	12 (18.8)	20 (23.8)

Values in no. (%). [a]*P<0.01;* [b]*P<0.001.*

Table II Psychological Problems Associated With Self-Reported Sexual Abuse in the Study Participants (*N*=452)

Psychological problem	*Self-reported sexual abuse*	
	Present (n=148)	*Absent (n=304)*
Ever had sense of insecurity at home[a]	33 (22.3)	16 (5.3)
Ever had suicidal thoughts[a]	28 (18.9)	11 (3.6)
Ever feel that parents dislike them[a]	19 (12.8)	6 (2.0)
Ever had sense of depression[b]	15 (10.1)	6 (2.0)
Ever had sense of anxiety[b]	12 (8.1)	4 (1.3)
Ever diagnosed with PTSD	2 (1.4)	1 (0.3)

[a]*P<0.01,* [b]*P<0.05. PTSD-post-traumatic stress disorder.*

Psychological problems like sense of insecurity at home, suicidal thoughts, of being disliked by parents, sense of depression and anxiety were significantly more in subjects who had experienced CSA (**Table II**).

DISCUSSION

The current study among medical college students in Puducherry found that overall, 32.7% of them had a history of sexual abuse, and it was similar between the sexes. These results are in consonance with previous reports [8,9]. A meta-analysis of more than fifty studies

WHAT THIS STUDY ADDS?

- Nearly a third of medical students in this single-institution study reported childhood sexual abuse in the past.

across various countries reported that the burden of CSA was 8-31% among girls and 3-17% among boys aged less than eighteen years of age [8]. Another meta-analysis concluded that 7.9% of males and 19.7% of females experienced one or other form of sexual abuse before attaining the age of 18 years [9].

Another study from Southern India on childhood sexual abuse conducted among a sample of college students reported the prevalence of CSA as 2.6–14.3% [10]. Similar prevalence among boys and girls has also been reported previously [11]. As per UNICEF (2005–2013) report, 42% of Indian girls have faced trauma of sexual violence in their teenage life [12]. Another study from Kerala [13] on burden of sexual abuse among adolescents, reported that 36% boys and 35% girls suffered from one or more incidents of sexual abuse at least once.

In this study we observed that most instances of CSA occurred either at home or in the neighbourhood, in contrast to the study by Krishnakumar, et al. [13], that reported majority of such incidents took place while travelling in bus or train [13]. The commonest type of CSA acts in our study were similar to previous reports [10,13].

Not surprisingly our study shows that majority (60.1%) did not inform or share the instance of CSA to anyone. Probably it could be due to conservative nature of Indian society where conversation and discussion on topics related to sex and sexuality is considered a taboo.

We also observed that the psychological problems like sense of insecurity at home, suicidal thoughts, of being not liked by parents, sense of depression and anxiety were clearly more in subjects experiencing the CSA. Clear evidance is available in literature about a link between CSA and psychiatric symptoms [14-16].

We chose medical students for the purpose of this study as openness to talk on such issues and better recollection of past incidents were required. Children may not recognize the diverse aspects of CSA. This aspect motivated us to fetch the desired information from a sample of medical students, thus adding strength to the study. Regarding limitations, possibility of recall bias is definitely an evident limitation. The results of this investigation are from a single tertiary care centre which limits the generaliability of the findings. Multicentric studies with bigger sample size are warranted.

Approximately one-third of medical students reported an incident of sexual abuse at least once in his/her life in Puducherry thus roots of CSA are deep in the society in which we live. In contrast to the socially prevalent belief that girls are more sexually abused compared to boys, this investigation interestingly highlights that even boys are equally facing the burnt of this issue. Discussion on topics related to sex and sexuality is still considered a taboo. Therefore this is need of an hour to evolve methods of protecting our childen from CSA and it should cater need of both boys and girls.

Ethics clearance: Institutional ethics committee of Indira Gandhi Medical College and Research Institute; No. 17/IEC/IGMC/F-7/2017 dated 21 November, 2017.
Contributors: RDM: Conception and design, AS: Analysis and interpretation of the data, MC: Drafting of the article, Manuscript preparation, MB: Manuscript editing, Final approval of the article, PM: Literature search, YB: Statistical analysis, RR: Collection and assembly of data.
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RESEARCH PAPER

Characteristics and Transmission Dynamics of COVID-19 in Healthcare Workers in a Pediatric COVID-Care Hospital in Mumbai

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Objective: To evaluate if Healthcare workers (HCWs) at the frontline of COVID-19 response in a pediatric hospital are at an increased risk of acquiring SARS-CoV-2. **Methods**: The Hospital Infection Control Committee (HICC) and virology testing records were combined to identify SARS-CoV-2 positive HCWs and study the transmission dynamics of COVID-19 over 6 months. **Results**: COVID-19 cases in our HCWs cohort rose and declined parallel to community cases. Forty two out of 534 HCWs (8%) were SARS-CoV-2 positive with no fatalities. No clinical staff in the special COVID ward or ICU was positive. Significant proportion of non-clinical staff (30%) were SARS-CoV-2 positive. About 70% of SARS-CoV-2 positive staff had likely community acquisition, with a significant proportion having travelled by public transport or having a contact history with a positive case in the community. Twenty four percent of positive staff were asymptomatic and detected positive on re-joining test. **Conclusions**: Sustained transmission of SARS-CoV-2 did not occur in our cohort beyond community transmission. Appropriate PPE use, strict and constantly improving infection control measures and testing of both clinical and non-clinical staff were essential methods for restricting transmission amongst HCWs.

Keywords: *COVID-19, Healthcare workers, Testing, SARS-CoV-2*.

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The coronavirus disease 2019 (COVID-19) pandemic started in Wuhan, China in December, 2019. Nosocomial transmission has been a significant concern right from the start of the pandemic with one-third of the initial cohort of COVID-19 patients being healthcare workers (HCWs) and hospitalized patients [1]. In publications so far, healthcare workers (HCW) infection rates in China, Italy and USA have been reported as 3.8%, 10% and 19%, respectively with fatality up to 1.2% [2]. Union health ministry data shows that the positivity rate amongst HCWs in Maharashtra was 16%. Mumbai was one of the first cities significantly affected by the pandemic in India. Our hospital is a 200-bedded tertiary level pediatric centre. Healthcare workers showing any symptoms were tested for SARS-CoV-2 from late March, 2020. All routine work was suspended and only emergencies were managed from 20 March, 2020, when Mumbai had recorded 50 cases of COVID-19. Our center was designated as a pediatric COVID care centre from 6 April, 2020 onwards. The present study was aimed to analyze the characteristics and transmission dynamics of COVID-19 in HCWs over first 6 months of the pandemic at a tertiary pediatric COVID care setup in Mumbai.

METHODS

Any employee who was working in hospital premises with or without direct patient contact was included as a HCW. This included individuals employed directly by the hospital or via a company in contract with the hospital. All HCWs – both clinical and non-clinical, were tested if any of the following symptoms were present- fever, cough, sore throat, body ache, headache, vomiting and diarrhoea; or if re-joining work after a leave of more than 14 days. Testing was done with a nasopharyngeal swab for SARS-CoV-2 RT-PCR by an ICMR approved kit having 99% sensitivity and specificity. Healthcare workers were encouraged to self-test, if required under supervision to minimize exposure to other HCWs. Self-collection has been found to be an appropriate and reliable alternative to HCW collection [3,4]. Awaiting results, HCWs were sent for home isolation or quarantined in the hospital staff quarters. Healthcare workers that tested positive were evaluated by a member of the hospital infection control committee (HICC) for contact tracing. Those at high risk exposure (exposure >15 min without mask, less than a meter distance) were quarantined for 14 days with a repeat SARS-CoV-2

RTPCR done on day 12 or 13 before re-joining work [5]. All positive HCWs followed Municipal Corporation of Greater Mumbai (MCGM) guidelines for home or institutional quarantine and re-joined work after testing negative for SARS-CoV-2. Once travel restrictions were lifted, details of travel i.e.; self-driven vs public transport were documented at the time of contact tracing. The virology laboratory data of HCWs tested and HICC team data for category of staff and contact tracing from March, 2020 to August, 2020 was retrospectively analysed after approval. Exposure was defined as hospital exposure when there was contact with a SARS-CoV-2 positive patient or staff in hospital premises and for individuals working in areas of the hospital like Emergency room, radiology etc. where exposure to SARS-CoV-2 unknown status is high, and community exposure was defined as any HCW who was SARS-CoV-2 positive with history of exposure to SARS-CoV-2 in the community including family members and during travel. Exposure was considered likely community acquired if there was no exposure to SARS-CoV-2 positive or unknown status patient without breach in social distancing measures with colleagues. Home leave was defined as leave from work for more than 14 days and new employees. Hostel exposure included nurses who were residing in the hostel and also staff who preferred not going home during the pandemic and were residing in hospital quarters. Individuals exposed to positive staff residing in the same room/flat were considered as high risk exposure.

Personal protective equipment (PPE) donning and doffing training was carried out for HCWs. PPE use was decided based on location and risk category as per Ministry of Health and Family Welfare (MOHFW) guidelines [6]. As the pandemic progressed and we learnt more about the transmission dynamics, changes were made to infection control protocols and staff were briefed about it.

RESULTS

Five hundred and thirty four HCWs were tested during 6 months with 42 HCWs (8%) positive for SARS-CoV-2 without any fatalities. The monthly incidence of SARS-CoV-2 positivity in HCWs is depicted in **Fig. 1**. Peak incidence of cases in Mumbai was seen in June [7]. Cases in HCWs rose and fell parallel to community incidence.

Nurses had the highest incidence of SARS-CoV-2 positivity; 13 out of 42 (31%) although only 3 out of 13 (23%) had direct high risk patient exposure in the emergency room and day care unit (**Fig. 2**). Fourteen percent (6 out of 42) positive cases were seen in cafeteria and human resource personnel. Clustering of cases was seen in blood bank and amongst laboratory technicians. Doctors were least positive in our cohort (2 out of 42).

Almost 70% (29 out of 42) of the positive cases had no high risk exposure in the hospital and were classified as likely community acquired (**Fig. 3**). Amongst high risk exposure areas- day care area, suspected and positive COVID ward, and COVID ICU had the least SARS-CoV-2 positivity. No doctor or nursing staff working in COVID wards or ICU tested positive for SARS-CoV-2. After a nursing staff tested positive in day care area, PPE used while managing day care patients was modified with

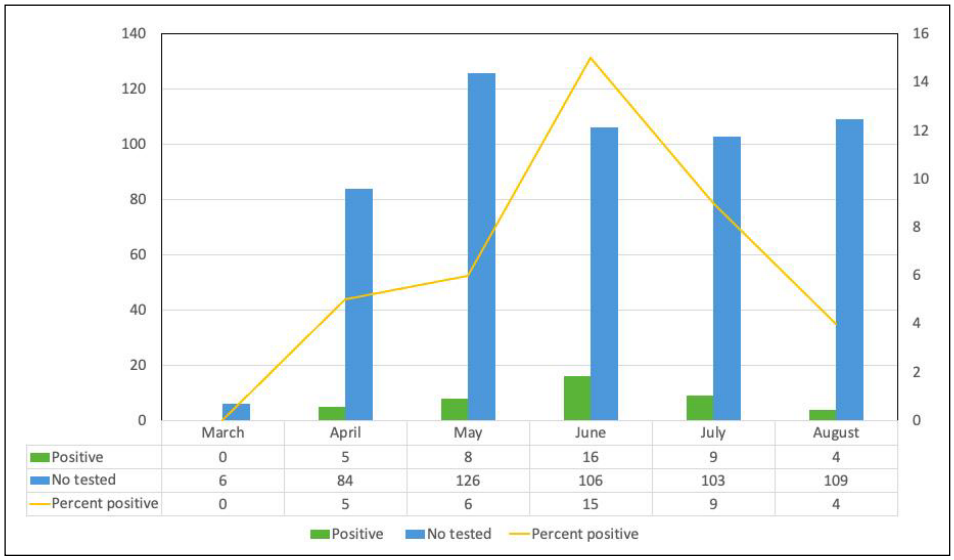
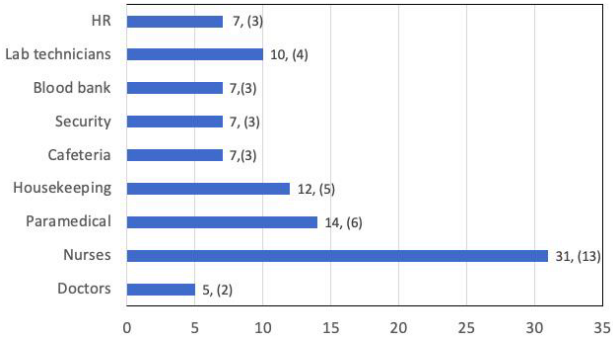


Fig. 1 Healthcare workers tested Monthly for SARS-CoV-2 in the first six months of the pandemic.



Number of staff positive in brackets. HR-Human resources personnel

Fig. 2 Percentage positivity in the category of staff tested.

no further cases noted. Two nursing staff working in the emergency room tested SARS-CoV-2 positive.

Amongst positive staff with likely community acquired transmission (**Fig. 3**), 21% (4 out of 19) had history of SARS-CoV-2 positive contact and 37% (7 out of 19) travelled by public transport. Nearly one fourth of SARS-CoV-2 positive staff were returning from home leave (10 out of 42) and almost all were asymptomatic at the time of testing (**Fig. 3**).

DISCUSSION

The present study analyses the transmission dynamics of the first HCW cohort from India. In a pediatric cohort, risk of asymptomatic SARS-CoV-2 carriage is compounded by presence of caregivers. Other risk factors for HCW exposure include inadequate social distancing between employees and non-compliance of mask wearing during breaks [8].

Contact tracing for a SARS-CoV-2 positive HCWs, showed that 2 staff had to be quarantined for having lunch together. Cafeteria tables were re-arranged to ensure not more than 2 people could sit at a table at a time at adequate distance and leaflets emphasising social distancing amongst HCWs were put up in the staff cafeteria. HCWs were encouraged to have meals on their own in their respective areas whenever possible, which was similar to Contejean, et al. [9]. This significantly reduced the incidence of high risk exposure amongst HCWs during meals. Clustering of cases seen in blood bank were considered hospital acquired as individuals were on same shift and hence in contact.

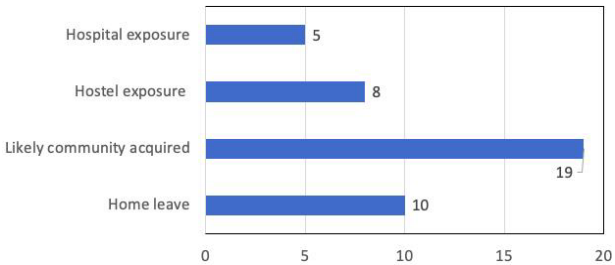


Fig. 3 Likely source of SARS-CoV-2 transmission to healthcare workers.

Zheng, et al. [2] had an incidence of 7.3% clinical HCWs being SARS-CoV-2 positive and 2.8% of non-clinical staff. In our cohort, we had similar findings with 2% non-clinical staff being SARS-CoV-2 positive emphasising the need of testing non-clinical symptomatic staff (**Fig. 2**). Non clinical staff access common areas and testing all staff groups has key infection control implications. Doctors were least positive in our cohort.

Twenty percent (8 out of 42) SARS-CoV-2 of HCWs were positive as a consequence of sharing rooms in the hostel with a SARS-CoV-2 positive staff despite immediate isolation of HCWs at symptom onset indicating transmission of the virus before onset of symptoms. Our findings were similar to He, et al. [10], who reported that 9% of transmission could occur 3 days prior to symptom onset and presymptomatic transmission to be 44%. Nearly one fourth of SARS-CoV-2 positive staff were returning from home leave and almost all were asymptomatic at the time of testing. Though highly debatable, we preferred testing HCWs returning from home leave in view of high incidence of community transmission during the first few months of the pandemic. Testing policy on re-joining work was modified as per community transmission dynamics. HCWs who preferred travelling by public transport to the hospital had increased community exposure. Almost 70% of SARS-CoV-2 positive staff had likely community acquisition with 7 out of 19 (37%) travelling by public transport and 4 out of 19 (21%) having a contact history with a positive case in the community.

Implementing infection prevention and control (IPC) policies can be challenging during a pandemic but in studies where reinforcement of IPC measures was done, the curve flattened in HCWs despite ongoing exposure to COVID-19 patients [8,9].

We improvised infection control measures and reinforced basic preventive measures throughout the pandemic. In presence of adequate PPE and good adherence to infection control practices, nosocomial acquisition or transmission was less likely, similar to previous reports [2,11]. HCWs face a significant risk of SARS-CoV-2 exposure while providing care to suspected or confirmed COVID-19 patients. It is though important to remember that transmission may occur in non-patient-care areas while having meals or talking or from the

WHAT THE STUDY ADDS?

- Most SARS-CoV-2 positive healthcare workers had likely community transmission with public transport being a possible high-risk exposure.
- Testing nonclinical symptomatic staff is essential to reduce transmission as they share common areas.

community. Lack of adequate PPE, inpatients caregivers, high risk departments, long duty hours and suboptimal hand hygiene have been linked to COVID-19 infections in HCWs in various studies [12]. Hand hygiene, inpatient caregivers and duty hours could have confounded our findings. Doctors tested least positive in our study which is similar to Zheng, et al. [2]. Doctors in highly specialized roles who cannot be replaced by other colleagues, may continue working with mild and non-specific symptoms, which is a limiting factor in our study too.

Ethics approval: IEC, SRCC-CH; R-202019, November, 2020.
Contributors: AP, SU: designed the retrospective study and wrote the manuscript; MB: wrote the contact tracing guidelines for HCWs; SS, SK: were involved in testing and tracing positive HCWs. All authors approved the final version of manuscript, and are accountable for all aspects related to the study.
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RESEARCH PAPER

Impact of Comorbidities on Outcome in Children With COVID-19 at a Tertiary Care Pediatric Hospital

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Objective: To study the various comorbidities and their impact on outcome of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infected children. **Methodology:** Review of medical records of 120 children (58.4% males), aged 1 month to 18 years, admitted between 1 March and 31 December, 2020 with at least one positive RT-PCR test for SARS-CoV-2. Clinical and demographic variables were compared between children with and without co-morbidities. **Results:** 62 (51.7%) children had comorbidities. The most common comorbidity was tuberculosis (32.3%) followed by other infections (27.4%) and hematological (19.4%) conditions. Fever (89.2%) was the most common clinical feature followed by respiratory (52.5%) and gastrointestinal (32.5%) manifestations. There was no significant difference in the severity of COVID illness, length of hospital stay and adverse outcomes (ventilation and mortality) among children with and without comorbidities. **Conclusion:** The presence of a comorbid illness in pediatric inpatients with COVID-19 did not impact the illness severity, length of hospitalization, ventilation requirement and mortality.

Keywords: *Mortality, Outcome, Tuberculosis, Ventilation*.

The Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) pandemic has evolved rapidly leading to a multitude of presentations and variable severity, with substantial information regarding clinical manifestations and outcomes of coronavirus disease (COVID-19) in adults. It has been observed that presence of comorbidities is associated with severe illness and worse outcomes in adults infected with SARS-CoV-2 [1,2], but our knowledge about clinical characteristics as well as outcomes of COVID-19 infected children with comorbidities is limited. Moreover, there is limited literature on the spectrum of pediatric comorbidities and their outcome in association with SARS-CoV-2 infection from our country, which tends to be entirely different from those observed in the children from developed countries [3]. This study was planned to examine the effect of comorbidities with regard to disease presentation, evolution and outcomes in children infected with SARS-CoV-2.

METHODS

This case record review was undertaken at a tertiary care pediatric teaching hospital in northern India. During the SARS-CoV-2 outbreak, any child brought with history of recent onset fever, cough and/or fast breathing or other suggestive symptoms like recent onset fever with diarrhea or contact with COVID-19 positive patient was tested with RT-PCR test for SARS-CoV-2. These children were also screened for presence of any comorbidity. Comorbidity was defined as any distinct additional acute or chronic condition that has existed or may occur during the clinical course of a patient who has the index disease under study, and might alter the course of disease or the outcome [4].

Based on the results of confirmatory RT-PCR and clinical assessment, cases were classified as asymptomatic, mild, moderate and severe as per standard guidelines [5]. The criteria for admission for suspected COVID-19 illness included any of the following: respiratory distress, SpO2 on room air <94, shock/poor peripheral perfusion, poor oral intake or lethargy, specifically in infants and young children and/ or presence of seizures or encephalopathy [6]. Based on the results of confirmatory RT-PCR and clinical assessment, hospital treatment or home isolation measures were instituted with contact tracing measures as applicable (in accordance with the local prevailing guidelines). The patients were managed as per the standard WHO protocol [5].

All children 1 month to 18 years of age, with at least one positive RT-PCR test for SARS-CoV-2 and requiring admission between 1 March and 31 December, 2020 were

included in the study. A special COVID ward was created during the ongoing pandemic for care of these children. Epidemiological, demographic, clinical, treatment, and outcome data of children with and without comorbidities was extracted from the case records and compared. The study was reviewed and approved by the institutional ethical committee with a waiver of consent for data collection.

Statistical analysis: Comparison of means between the two groups i.e., children with and without comorbidities was performed using the two-sample Student t-test. Categorical data were compared using Chi-square test. All tests were 2-tailed with the threshold level of significance at $P<0.05$. Statistical analysis was performed using STATA 14.2.

RESULTS

A total of 3180 suspected children were tested for SARS-CoV-2; 295 (9.27%) children tested positive. Amongst the latter, 120 SARS-CoV-2 positive children (70 boys) required admission in the COVID ward. Fever (89.2%) was the most common clinical feature at the time of presentation, and 64 (53.3%) had severe acute malnutrition or thinness. Comorbidities were seen in 62 (51.7%) children. The most common comorbidities were infections like tuberculosis (32.3%) followed by other infections (27.4%) (**Table I**).

The mortality rate in admitted patients was 24.2% (*n*=29). There was no difference in the clinical characteristics of admitted children with and without comorbidities with respect to baseline characteristics. There was no statistical difference in the severity of COVID illness, mean duration of hospital stay and adverse outcomes like ventilation and mortality among the two groups (**Table II**). However, severe anemia and thrombocytopenia were present in significantly higher number of children with comorbidities (**Table II**).

Table I Comorbidities in SAR-CoV-2 Positive Pediatric Inpatients

Comorbidity	*Disease n=62*	*Deaths n=12*
Hematological[a]	12 (19.4)	2 (16.7)
Aplastic anemia	2	1
Acute lymphoblastic leukemia	7	1
Tuberculosis[b]	20 (32.2)	4 (33.3)
Disseminated	9	3
Pulmonary	7	1
Abdominal	3	0
Renal	5 (8.1)	0
Nephrotic syndrome	4	0
Post-streptococcal glomerulonephritis	1	0
Neurological[c]	5 (8.1)	1 (8.3)
Spastic cerebral palsy with epilepsy	3	1
Insulin dependent diabetes mellitus	1 (1.6)	0
Rheumatological[d]	2 (3.2)	2 (16.7)
Surgical[e]	2 (3.2)	0
Non-tubercular co-infections	15 (24.2)	3 (25)
Disseminated staphylococcal sepsis	4	2
Liver abscess	7	0
Severe dengue	4	1

[a]one each with acute myeloid leukemia, Hodgkin disease and thalassemia; [b]one with lymph node tuberculosis; [c]one each with Tay Sachs disease and Gaucher disease; [d]one each with systemic lupus erythromatosis and systemic onset juvenile idiopathic arthritis; [e]one each with congenital cystic adenomatoid malformation and abdominal lump.

Table II Characteristics of Coronavirus Disease 2019 (COVID-19) Patients With and Without Comorbidities

Clinical parameter	*Comorbidity present, (n=62)*	*No comorbidity (n=58)*
Mean age, mo[a]	58 (34.6)	62 (28.4)
Male	38 (61.2)	32 (55.1)
Symptoms at admission	*n (%)*	*n (%)*
Fever	58 (93.5)	49 (84.5)
Respiratory	34 (54.9)	29 (50)
Gastrointestinal	22 (35.5)	17 (29.3)
Neurological	3 (4.8)	4 (6.9)
Cardiovascular	1 (1.6)	3 (5.2)
Others[b]	2 (3.2)	5 (8.6)
SAM/severe thinness	38 (61.3)	26 (44.8)
Hospital stay, (d)[a]	9.26 (6.68)	8.65 (7.72)
Severity of COVID illness		
Mild to moderate	46 (74.2)	38 (65.5)
Severe to critical	16 (25.8)	20 (34.5)
Ventilated	16 (25.8)	19 (32.7)
Deaths	12 (19.4)	17 (29.3)
Laboratory parameters		
Severe anemia[c]	21 (33.9)	9 (15.5)
Leucopenia (<4000/cu.mm)	17 (27.4)	12 (20.1)
Lymphopenia (<1500/cu.mm)	18/46 (39.1)	14/48 (29.2)
Thrombocytopenia[d]	29 (46.8)	13 (22.4)
Elevated CRP (>6 mg/L)	37 (59.7)	35 (60.3)
Elevated ESR (>10 mm/h)	29/39 (74.3)	16/23 (69.6)

Values in no. (%) or [a]mean (SD). [b]rash/myalgia/poor oral intake. SAM: severe acute malnutrition; CRP: C-reactive protein; ESR: erytherocyte sedimentation rate; [c]P=0.02; [d]P=0.005.

WHAT THIS STUDY ADDS?

- Presence of a comorbid illness was not associated with increase in the severity of COVID illness, length of hospital stay or adverse outcome in children.

DISCUSSION

The clinical presentation in our cohort is similar to that observed by previous studies [7]. There was no significant difference in the clinical symptomatology, severity of COVID illness, mean duration of hospital stay and adverse outcomes among the children with and without comorbidities.

Tsankov, et al. [5] in their meta-analysis observed that the most common comorbidity in children infected with COVID-19 infection was obesity; whereas, we observed that more than 50% of our patients were underweight for age. The other comorbidities observed in their study were chronic respiratory conditions, cardiovascular disorders and neuromuscular diseases [5], whereas in our study where other infections were the most common comorbidities. The mortality rate observed in our study is higher than that reported globally [7], presumably due to referral bias due to our center being one of the largest tertiary care pediatric hospital in the public sector in this region.

There is a dearth of published literature on outcome of SARS-CoV-2 infected children with various comorbidities [8-11]. Three children with disseminated tuberculosis developed acute respiratory distress syndrome (ARDS) and multi-organ failure syndrome (MODS), and one died due to raised intracranial tension with neurogenic shock. The children with hematological disorders died secondary to febrile neutropenia with associated septicemia and catecholamine refractory shock. One child with spastic cerebral palsy was admitted with severe pneumonia and status epilepticus and went on to develop ARDS. The patient with systemic lupus erythematosus developed severe pneumonia with ARDS and acute kidney injury, whereas the patient with systemic onset juvenile idiopathic arthritis died due to macrophage activation syndrome and MODS. Two children died due to disseminated staphylococcal infection with catecholamine refractory shock, and one due to severe dengue with disseminated intravascular coagulation. The mortality was not significantly different across groups, possibly because most of our patients with comorbidities were under regular follow-up in our hospital and were well versed with the system, they might have presented early or might had been diagnosed early with symptoms of COVID-19 infection. Alternatively, some of these children were on immunomodulatory and immunosuppressant drugs, which could also have modified the course of infection by interfering with the cytokine storm responsible for organ damage in COVID-19 [12]. Most of the SARS-CoV-2 infected children without comorbidities presented in advanced and decompensated clinical condition, presumably secondary to suboptimal management caused by delay in diagnosis, initiation of appropriate treatment, referral or transport during this unprecedented time of ongoing pandemic. However, this observation needs to be further evaluated in prospective studies with larger sample size.

Tsankov, et al. [5] in their meta-analysis also con-cluded that they could not determine whether comorbidities increase risk of severe COVID-19 in children. However, our observations are in contrast to those observed by Rao, et al. [13], who observed that presence of comorbidity increases the severity of COVID-19 disease.

Our study had limitations of having a retrospective design, small sample size and lack of follow-up. In spite of these shortcomings, this study provides preliminary data on the spectrum and outcome of comorbidities in children infected with SARS-CoV-2.

To conclude, the most common comorbidities observed in COVID infected children were infections like tuberculosis and other co-infections. There was no significant increase in the severity of COVID illness, duration of hospital stay or adverse outcome in these children. However, this observation does not understate the vulnerability of these children to develop severe illness and they should take all necessary precautions to avoid getting infected with SARS CoV-2. Further studies examining the effects of specific well-defined comorbidities are warranted to examine the effects that pediatric underlying conditions play in COVID-19 severity.

Ethical clearance: Institutional Ethical Committee, LH Medical College; No. LHMC/IEC/2020/97, dated November 6, 2020.
Contributors: DK: collected data and wrote the initial manuscript; VK, PK: critically analyzed the manuscript; PS: helped in data collection and revision of manuscript. All the authors read and approved the final manuscript.
Funding: None; *Competing interests*: None stated.

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SPECIAL ARTICLE

Integrating Child Protection and Mental Health Concerns in the Early Childhood Care and Development Program in India

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Adverse childhood experiences and protection risks such as neglect and abuse and family psychosocial and protection vulnerabilities, beginning in early childhood, are linked to negative development and mental health. Child protection is becoming an increasing concern in India, creating new imperatives to address it amongst all children, but particularly among children below the age of 6 years, who due to their age and developmental abilities, are rendered more vulnerable than older child populations. It is therefore imperative, particularly in developing contexts such as India, for early childhood development (ECCD) to integrate child protection and mental health services into their existing intervention package. Although early childhood programs work with multiple sectors, they have limited collaboration with child mental health and child protection systems. This article addresses the question of how to integrate child protection and mental health interventions into existing ECCD programs by describing the experience of a pilot project in the Indian context. It provides the rationale, methodology and content of service delivery for integrating child protection and mental health interventions into the existing ECCD program, the Integrated Child Development Scheme, highlighting emerging concerns and challenges and drawing from the interventions to show how some of these were addressed.

Keywords: *Adverse childhood experiences, Integrated child development services, Intervention, Mental health*.

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The term 'child protection' refers to preventing and responding to violence, exploitation, abuse and neglect of young children. Article 19 of the United Nations Convention of Children's Rights (UNCRC/CRC), 1989 provides children a specific right to protection [1]. About 13.5% of India's population, 16.45 crore children, are in the age group 0-6 years [2]. According to a national study conducted by Ministry of Women and Child Development (MoWCD), on child abuse in India, 66% are reported to be physically abused, 50% have faced one or more forms of sexual abuse and emotional abuse [2,3]. As per the National Crime Records Bureau's 2017 report on crime against children, a total of 129032 cases were recorded, including kidnapping and abduction, sexual offences and murder [4]. A total of 32,608 child sexual abuse cases were recorded in 2017 alone, including for children below 5 years of age [5] and a total of 78,000 orphan and vulnerable children are residing in child care institutions under the Integrated Child Protection Scheme (ICPS) [6]. Child protection is thus becoming an increasing concern in India, creating new imperatives to address it amongst all children, but particularly children below 6 years of age, who due to their age and developmental abilities are rendered more vulnerable than older child populations.

Due to paucity of age-specific data, it is unclear as to what proportion of abused children are between 0 to 6 years of age. Many behaviors such as defiance, anxiety to new situations, which are considered pathological in older children, constitute normal development in young children. Thus, it is difficult to differentiate between normal and pathological behaviors, making mental health diagnosis in young children difficult [7]. Due to their developmental age, and their lower verbal communication skills, they are also hindered from reporting experiences [8], consequently rendering them more vulnerable than older children, to traumatic death and injury caused due to abuse and neglect [9-11].

There is now considerable evidence to show that adverse experiences in early childhood also have a negative impact on young children's overall development and so, if not addressed, may lead to adverse outcomes in later years. For instance, children's exposure to frequent and prolonged abuse, neglect, violence, substance abuse in caregivers, family and economic stressors, and poor attachment relations negatively impacts their mental health, neurodevelopment, psychosocial development and academic functioning [14-17]. Mental health is impacted by increasing the risk of internalizing and externalizing

problems such as anxiety, depression and suicide [18,19], antisocial behavior and psychopathy [20], substance abuse, and legal problems in their adult life [21-23]. The risks of adverse childhood experiences also combine with the disciplinary strategies used with children, including all forms of corporal punishment, to result in increased risk of negative behavioral, cognitive, psychosocial, and emotional outcomes among children [24].

Since critical brain development occurs in the early years of life [25], it is important to note that child protection in early childhood critically involves, but is not restricted to, abuse and neglect. Child protection in early childhood also entails protection from the adverse influences of unmet developmental needs along with the other interventions. According to the Adverse childhood experiences studies, the relationship between adverse childhood experiences and negative health indicators begins early in childhood; child care service providers thus have an opportunity to provide interventions that prevent long-term negative health consequences [26]. Child protection, therefore involves addressing risks relating to neglect, (physical, sexual and emotional) abuse, and absence of opportunities (for learning and development).

INTEGRATING CHILD PROTECTION INTO EARLY CHILDHOOD CARE AND DEVELOPMENT PROGRAMS

Early Childhood Care and Development (ECCD) programs across the world majorly focus on nutrition and early stimulation along with other health interventions such as immunization, hygiene, educational and support measures for caregivers to ensure consistent care and support for children. Even though ECCD programs work with multiple departments, they have limited colla-boration with child mental health and child protection systems [27].

While there are child protection programs around the world, those working specifically in the context of early childhood, are relatively limited. For those that do work in the area of early childhood, there are very few that integrate ECCD issues with child protection. Examples of integrated programming include UNICEF's programme guidance for early childhood development [28] and Plan International's development of program models and tools to integrate child protection into ECCD, as reflected in their exploratory studies in Uganda, Bolivia and Timor-Leste [29]. Save the Children, has also attempted, in few of their programs, to integrate child protection into ECCD but while they focus on orphans and vulnerable children, they do not have a mental health component [30].

There are examples of child violence prevention programs, which have been successfully implemented both in developed and developing countries [29,31-35], through parents, nurses or community health worker in the primary health care system. These have focused, and legitimately so, mostly on positive parenting, monitoring for prevention child maltreatment (through home visits by community health care workers), mother–child therapy interventions, provision of primary health care services and safe spaces for children to grow and play. However, these programs have worked largely in family settings–an approach that India could draw upon but that would not be entirely applicable to its context, because the socio-economic situation of many vulnerable children often does not allow for family members to be present for the child. Therein lies the importance, in the Indian context, of the role of the ECCD workers and the need to integrate child protection into the government preschool system.

The key objectives of ECCD and child protection programs are to ensure age-appropriate development, early stimulation and primary prevention. The World Health Organization's Nurturing care framework also recommends providing for the children's physical and emotional needs, protection from harm along with learning and development opportunities as its central tenet [36]. Given that ECCD programs qualify as a universal intervention, their coverage tends to be wide, and ECCD workers and educators are ideally placed to implement protection strategies to assist children at risk of abuse and neglect [37]. Thus, ECCD programs may serve as effective vehicles to protect children from adversities.

Furthermore, as erstwhile described, exacerbated by poverty and other vulnerabilities, mental health needs of children from adverse circumstances are high – placing children at increased risk of continued child protection problems. Thus, it is imperative for integrated ECCD and child protection programs to include child mental health interventions. Effectively addressing emotional and behavioral problems that are consequences of protection issues, would be critical to the successful implementation of early childhood care and protection services and programs [9].

We, herein, address the question of how to integrate child protection and mental health interventions into existing ECCD programs by describing the experience of a pilot project in the Indian context. It provides the rationale, methodology and content of service delivery for integrating child protection and mental health interventions into the existing ECCD program, the Integrated Child Development Scheme (ICDS), highlighting emerging concerns and challenges and drawing from the interventions to show how some of these were addressed. We also discuss how child care service providers, particularly pediatricians, can play a pivotal role in this endeavor.

Experience With a Pilot Project

Prior to this pilot project a large community-based child and adolescent mental health service project, had been implemented by us. The community-based project had executed a resource mapping and needs assessment for community child and adolescent mental health services [4], prior to the start of its activities. With the objective of promoting early stimulation and optimum development in children, activities such as implementation of early stimulation, training and capacity of Anganwadi workers on early stimulation (child protection was not a prominent focus of the program at the time) were conducted. The observations and experiences of our work are available elsewhere (*www.nimhans childproject.in*).

Subsequently this experience was used to develop a pilot project that focused exclusively on ECCD interventions, to include child mental health and protection interventions. In order to obtain a more specific understanding of how ICDS staff view child protection issues, an additional assessment was done prior to this project, and the findings incorporated into the design and content of the interventions.

Context of Intervention

The potential of the integrated child development scheme: The ICDS provides a huge opportunity to incorporate protection components into ECCD because of its universal coverage agenda, particularly in socio-economically deprived communities where some of the most vulnerable children reside. Also, the anganwadi worker, the key worker in the ICDS scheme, conducts non-formal education and early stimulation activities for a given group of children, on a daily basis, over a relatively long time period (such as a year). This provides a perfect platform, not only for early screening and referral for developmental delays, emotional and beha-vioral and protection issues, but also to engage children in personal safety awareness programs.

Protection programs, policies and laws relevant to young children: As a signatory to the UNCRC, the Indian Government established a statutory body, the National Commission for Protection of Child Rights (NCPCR), in 2007, and more importantly, the Ministry of Women and Child Development, launched the Integrated Child Protection Scheme (ICPS) in 2009. The ICPS translates into programs, the vision of a secure environment for all children, as envisaged in the Juvenile Justice (Care and Protection of Children) Act, 2015, which in turn is based on principles of 'protection of child rights' and 'best interest of the child'. It aims at building a protective environment for children in difficult circumstances, as well as other vulnerable children, by bringing together various child protection schemes under one roof and integrating additional interventions for protecting children and preventing harm [39].

India has enacted another key law with regard to child protection – The Protection of Child Sexual Offences (POCSO) Act 2012 which aims to effectively address sexual abuse and sexual exploitation of children. The act defines various forms of sexual abuse, focuses on mandatory reporting issues, stringent punishment graded as per the gravity of the offence, and requisite child-friendly court processes [40].

Despite the existing range of ECCD programs and services, there are gaps and challenges, at knowledge, skill and policy levels, leading to inadequate realization of child protection laws and policies. Some of the challenges observed during the course of our child mental health and protection work in recent years include: limited understanding of child protection and psycho-social issues within child protection system, lack of focus on protection services for young children, inadequate knowledge and skills to identify and address protection concerns, especially in young children and paucity of systematic and standardized materials and protocols for child protection response.

ICDS staff knowledge and skills in child development and protection issues: Based on the needs assessment exercise conducted with anganwadi workers within the ICDS, for a deeper understanding on the staff 's perspectives on young child protection, various issues emerged (which also reflect the general lacunae in the child protection system in the country). Anganwadi workers have not been trained in the use of systematic assessments in child protection, nor in assessment of child mental health and development issues.

Young children in anganwadis: The children in the Anganwadi*s* are drawn from vulnerable homes and communities. Their families were characterized by low socio-economic status, residence in urban slums, substance abuse in caregivers, domestic violence, violence and conflict (extending through neighbor-hoods). The primary caregivers were frequently day laborers, so they were absent for most of the day i.e. as such children's interactions with primary caregivers were limited to a couple of hours a day. Consequently, they spent the maximum number of hours at the anganwadi, with the anganwadi worker serving as a key caregiver.

Conceptual framework: Based on the available literature, a comprehensive framework for integration would entail the following: *i*) early stimulation and development, including provision for learning opportunities; *ii*) providing alternative opportunities for developing healthy attachment, particularly for children who are from

compromised or dysfunctional families; *iii*) creating awareness in children regarding personal safety and abuse issues to enable early reporting of abuse experiences; and *iv*) equipping ECCD workers with knowledge, skills and methods to identify protection risks in young children. Including emotional and behavioural issues, and to address them, depending upon the severity.

The aim of the intervention was to integrate mental health and protection services for young children between the ages of 0 to 6 years into the existing the ICDS program.

Methodology

As shown in **Fig.1**, we used a multi-pronged approach to provide com-munity-based mental health and protection services for promotive, preventive and curative care through direct service delivery for children, and training and capacity-building of anganwadi workers.

The interventions were implemented in anganwadis in which the ICDS is implemented, in vulnerable urban communities the Bangalore. Anganwadis from the five (urban slums) near our center were selected. From amongst these, anganwadis were selected, which had greater number of children, and more than one center in the same location were selected – in order to ensure that a greater number of children would be reached through a single visit.

Results

In all, during the 7 months, the interventions were carried out in 31 Anganwadi centers (**Table I)**. Based on the context of intervention and the conceptual framework, two types of interventions were implemented to integrate child mental health and protection into the ICDS program, through i) direct services for children and ii) capacity building initiatives for ICDS staff.

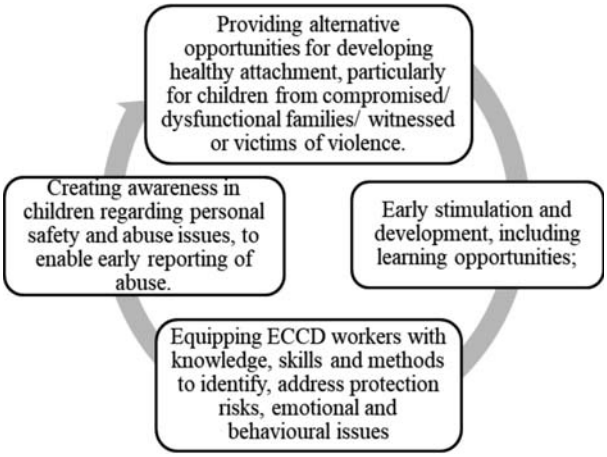

Fig. 1 Conceptual framework for integration of child protection and mental health with early childhood care and development.

Direct services for children: This was carried out in two distinct steps viz., individual assessment of development, mental health and protection issues in anganwadi children, and group activities for children in anganwadis.

An assessment proforma comprising of questions on child development, emotional and behavioral issues and protection concerns was developed (available at: *https://www.nimhanschildproject.in/anganwadis-phcs/).* It was based on existing clinical assessment proformas at the department of child and adolescent psychiatry in a tertiary care facility. The proforma has also drawn from the community-based programs previously executed by the authors, particularly in young child institutions, where children orphan and abandoned children, with serious child protection issues, reside. This assessment was not primarily aimed at arriving at a diagnosis, but mainly geared to help child care service providers to identify and understand children's problems and vulnerabilities, with a view to helping them to access appropriate inter-ventions. Due to the variation in developmental abilities and needs, the proforma was adapted to three sub-groups of children under the age of 6 years: 0 to 1 year, 1 to 3 years and 3 to 6 years.

The assessments were conducted in the anganwadi. An average of 20 minutes was spent engaging with the child and about 15 minutes with the anganwadi worker, for completion of an individual child's assessment. To ensure that the assessments were accurate i.e., that they truly reflected children's developmental abilities, allowing them to respond freely, ice-breakers and group activities were used to build rapport with children Developmental checklists were filled out by observing the child and asking him/her to perform simple tasks and activities that would allow for assessment of develop-mental skills and abilities. Information about the child's family context and related protection issues was gathered by interviewing anganwadi workers and helpers.

Following each assessment, for mild to moderate developmental, mental health and protection issues, the

Table I Interventions and Coverage

Outcomes	*Coverage*
Number of anganwadis and anganwadi workers reached	31
Number of individual assessments done for examining developmental, mental health and protection issues	237
Number of group sessions conducted with the anganwadi children	190
Number of children reached through group activities	276
One day training workshops for anganwadi workers	4
Number of weekly training sessions for anganwadi workers	89

anganwadi worker was provided with first level inputs including what the Anganwadi worker may do to help the child, and how she could counsel the parents. For complex issues (such as developmental disabilities) requiring specialized assistance, the anganwadi worker was assisted to refer the child to the dept. of child and adolescent psychiatry of a tertiary care facility and/or to the concerned child welfare committee.

Group activities were conducted with the anganwadi children along with anganwadi workers (also as part of their capacity building through demonstration and on-the-job training). These group sessions with children, focused on domains of development, mental health and protection, and comprised of the following: Activities for promotion of early stimulation and optimum develop-ment in the five key areas of child development (physical, social, speech and language, cognitive and emotional development). including fine motor activities to develop pre-writing skills; Activities for socio-emotional develop-ment, with a focus on helping children recognize and manage emotions, and develop empathy; and, Activities for child sexual abuse prevention and personal safety.

Capacity building of anganwadi workers: This was done using capacity building workshops and on-the-job training.

One of the key objectives of the intervention was to build the knowledge and skills of the anganwadi workers in the areas of child development, mental health and protection. The specific training objectives included enabling anganwadi workers to: Understand the context of child abuse and neglect, including physical, emotional and sexual abuse; Identify and provide first level and emergency responses and necessary referrals in the context of child abuse and neglect; Administer the assessment proforma to child developmental, protection and mental health needs and issues in individual children; Use personal safety and sexual abuse prevention module with preschoolers; and, identify and manage (including refer) emotional and behavioral problems, develop-mental and protection issues among young children.

The training content is detailed in **Box I**. It was delivered using creative participatory and experiential methods, such as role play, case discussions, simulation games, demonstrations, brain-storming, pile sorting/ listing – so that the learning was made fun and interesting, but also to enable workers to learn necessary methodologies for use with young children.

Over a 7-month period, training and capacity building activities were conducted through 4 one-day workshops, which were held once in two months, at the tertiary care facility that the project was based out of. Other times, weekly sessions were held on an on-going basis, for clusters of anganwadis (4 to 12 Anganwadi workers) located near each other. This enabled Anganwadi workers to avoid travelling long distances to attend training; and it allowed them to complete their morning tasks com-fortably in order to free up their time for the afternoon session. The training team ensured that a friendly, light-hearted learning environment was created in the Anganwadi and in workshops.

Alongside the training, daily field visits were used by the team, to provide on-the-job support to the anganwadi workers. This included demonstrations on conducting activities for early stimulation and development, and for

Box I Training Content for Integrated Child Development, Mental Health and Protection Programming

Children and childhood

Setting the tone: Re-connecting with childhood
Child development basics
Power and rights

Child development

Physical development
Speech and language development
Cognitive development
Social development
Emotional development (Including demonstration of early stimulation activities in five domains of developmentand development of low-cost early stimulation materials)

Identifying problems and contexts: the child's experience and inner voice

Understanding the child's experience and inner voice
Identifying and understanding child's behavior using the context, experience and inner voice framework

Understanding and responding to common emotional and behavior problems in early childhood

Different methods of responding to emotional and behavioral concerns
Managing the aggressive and oppositional child
Management of children with temper tantrums
Identifying and understanding an ADHD child

Conceptual understanding of child protection in early childhood

Introduction to child protection issues specific to early childhood
Introducing government systems and programs available for child protection

Understanding child sexual abuse in early childhood

Child sexual abuse basics
First level psychosocial responses for sexually abused children
Introduction to the child sexual abuse prevention module
Practicing the child sexual abuse prevention module

Assessing children for developmental, mental health and protection issues in early childhood

Assessment of child development issues in early childhood
Assessment of emotional and behavioral problems in early childhood
Assessment of child protection issues in early childhood

**The content is available as a training manual at: https://www.nimhanschildproject.in/training-and-capacity-building/training-manuals-materials-for-child-care-service-providers/*

personal safety and abuse prevention, administration of the assessment proforma and management of common emotional and behavioral problems in young children. Additionally, revision and recap of some of the training workshops/sessions were also done in one-on-one sessions with anganwadi teachers, to help them link theory and practice issues in the field.

Development of activities and materials for use with children: In order to provide Anganwadi workers with standardized methods in their direct work with children, several materials have been developed for intervention purposes. Some of these materials were also translated into the local language. The materials include the following: activity book for socio-emotional develop-ment in pre-school children; child sexual abuse and personal safety module - activity-based awareness and learning for preschoolers and children with developmental disabilities; early stimulation and development activity books and flip charts (for use with parents, teachers and caregivers); Stories for preschoolers on themes of loss and grief, separation anxiety and attachment, etc. (material available at: *https://www. nimhanschildproject. in/interventions/pre-school-0-to-6-years*/).

Given the contextual challenges of the anganwadi workers, the team developed and adopted several types of strategies, throughout its implementation processes, so as to provide for a more enabling learning and work culture and environment for the workers (**Box II**).

Process outcomes of interventions: Since our interventions were not part of a research study, no measures were used to examine the effectiveness of the interventions we provided. However, based on observations and feedback received from anganwadi workers, some critical qualitative process outcomes, mainly in terms of anganwadi workers' attitudes and learning were found. The anganwadi workers over come their initial reluctance, appreciated learning relevant skills and interventions, and became more aware of the child protections risks and interventions.

LESSONS LEARNT

As evidenced by the gaps in literature, there is little data on young child protection and mental health issues in developing contexts, including in India. It is critical therefore for research and intervention studies to be undertaken in non-clinical, community settings to better understand health, protection and developmental issues in some of the most vulnerable children in our country i.e. those who are least likely to access protection and mental health services. Whether for action research or programmatic interventions, the existing ECCD program, namely the ICDS, with its coverage and reach, provides the best chance that a low resource country such as India has, to protect its most vulnerable children.

Box II Specific Strategies Adopted for Capacity Building of Anganwadi Workers

Use of creative methods in training, also to understand importance of child-friendly methods

- Shorter and more focused learning with an element of continuity and follow up.
- Contents were tailored to the learning abilities of the Anganwadi workers.
- Minimal use of lecture methods; increased use of experiential, creative and participatory methods,
- Creation of a sense of anticipation and enthusiasm amongst the workers, and also gave them a sense of the importance of methodology in child work.

Connection, not correctional approaches

- Listening, recognizing and validating the Anganwadi workers' experiences and concerns.
- Assurance that the intent was to reduce, not increase their work burden.
- Assurance that the objectives were neither to criticize nor report but to understand and support their work, to enhance what they are already doing, so as to benefit children.

Helping workers with time management

- Helping with time management and enabling balance between administrative responsibilities and child work.
- Enabling daily schedules to allow time for direct work and non-formal education activities with children.

Motivational strategies

- Creation of WhatsApp group as a shared learning platform to allow for peer learning and appreciation of new techniques and creativity.
- Encouragement of posting of videos for visual (peer) learning.
- Creation of a book of children's songs for early stimulation (with the names of the Anganwadi workers who contributed).

Revision and review

- Encouragement to initiate new activities that help translate theory into concept.
- Competitions wherein Anganwadi workers were asked to create and share low cost aids for early stimulation (with prizes/rewards for some of the most creative efforts–but in a spirit of fun and friendship).
- No criticism or blame was laid on a worker who was unable to do 'homework' activities.
- Appreciation for workers who implemented 'homework' activities', with an emphasis on the positive aspects of the activity designed.

While a great many systemic measures and changes are required to enable the ICDS to gear itself to integrated programming that straddles child development, pro-tection and mental health, child health experts, who are already available within the secondary and tertiary levels of healthcare, can initiate transformations through the approaches they bring to child services. Pediatricians usually see children and families regularly and over a long period, thus having the advantage of trust and a personal relationship that allows them to gain a deeper knowledge of the child's background, including family systems and dynamics. The relationship pediatricians have with the children and parents is devoid of the stigma usually associated with mental health and child protection professionals, thus causing parents and caregivers to be more open and receptive to their suggestions and inputs [41]. Consequently, they are well-placed to pick up on child protection concerns and provide recommendations and/or referrals to child protection systems [42]. Pediatricians can also lead the way in child protection in India, including to provide capacity building support to the ICDS.

The training courses conducted by job training centers who provide capacity building programs to anganwadi workers require major re-examination and over-hauls, so that they develop integrated conceptual frameworks and interventions that cater to the critical domains of early childhood development, protection and mental health, and use pedagogies that are appropriate to those who work with young children–the use of creative and participatory methodologies in training programs are more likely to be translated into practice at field level, in direct work with children.

It is true that anganwadi workers experience a great many challenges and thus work under extraordinarily difficult conditions. It is understandable that high workloads, and lack of health insurance, to serve as demotivating factors for them. This is why methodology is as critical as the content – more so perhaps in this context. The challenge is not so much about the potential opportunities these programs and systems provide for the integration of protection services for young children, rather how best to plan an intervention through which the capacities of the service providers could be developed by navigating through their many challenges.

We have begun work with state departments on sharing the models and methods described in this paper. In conclusion, experiences from our pilot project suggest that an empathic approach, that acknowledges the anganwadi workers challenges and limitations, and takes them into consideration in program design, would be the way forward. The use of less conventional approaches that are built into local traditions and cultures, creating community-based forums that workers are keen to be a part of, is a key strategy for making space and time for their capacity building and for their work with children. We have begun work with state departments on sharing the models and methods described in this paper. In addition to the commitment of the ICDS scheme and its functionaries, further work, research and experiences across the country will determine the scalability of these methods.

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Formulation of Research Question and Composing Study Outcomes and Objectives

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Framing an appropriate research question is the most critical and fundamental part of a study. This helps in developing a hypothesis, formulating aims and objectives and methodological execution of the study. Research questions are usually generated by literature backed thorough analysis of the gaps in previous studies and funnelling it to a specific focussed issue. The research question should be framed using the PICO (Population, Intervention/Exposure, Comparator and Outcome) format and should fulfil the FINER (feasible, interesting, novel, ethically sound, and relevant) criteria for practical aspects. Objectives should always be framed in alignment of the research question using SMART (specific, measurable, achievable, realistic and time defined) approach. Outcomes are classified as primary and secondary. It is advisable to have only one primary objective while secondary objectives can be multiple (usually not exceeding five). This paper describes a cascade approach starting from framing the research question and then deciding on the outcomes and study objectives.

Keywords: *Aim, FINER, Hypothesis, PICO, Study design.*

Research question (RQ) is the question or the query which the researcher is trying to answer by conducting an investigation. The formulation of appropriate research question is the most fundamental and critical part of a study. All the further steps of the research i.e., developing a hypothesis, formulating objectives and methodological execution of the study depend upon the framing of the RQ. Composing the objectives and outcomes is the natural progression after framing the RQ in planning a study. Researchers often find it difficult to frame appropriate RQ and objectives from an inviting idea. This paper details the step-by-step systematic conversion of an idea to a valid RQ and translating it further to frame objectives and outcomes.

Getting Ideas for Research

Ideas are everywhere but they have to be converted to a valid RQ. The choice of RQ may be made from the evaluation of previous studies, one's own experiences, from topic of interest or by the need of the time [1]. Most of the ideas for research come from one's perceived gaps in the existing knowledge of a topic. These gaps could be the lack of clear conclusions or insufficient results from previous studies. Identification of such gaps could be taken up as a RQ which would then be used to build on the previous research. Ideas could also be developed from observations made on the previous work. Systematic analysis of this observation after brainstorming may also be one of the methods of finding the correct RQ. Unprecedented circumstances may also yield multiple RQs on a single topic.

Developing Research Question From an Idea

As a rule of thumb, the broad ideas themselves do not form a RQ. They should be chiselled to yield one. This is achieved by an exhaustive and critical analysis of the broad idea by a thorough literature research. The brainstorming would include searching for studies conducted in past on same topic, identifying the lacunae in the existing knowledge or need to replicate the question in different settings, thinking of a hypothesis, and then generating a RQ [2]. Although multiple RQs may stem from a broad idea, it is best to choose only one primary RQ for a particular project (choosing the best RQ is described later). The RQ is the interrogative form of the solution which we are looking. Simply put, it is the purpose of study written in a question format [3]. It has to be specific, focused and clearly defined in terms of population targeted, planned intervention, outcome etc.

For example, while working in pediatric neurology ward, a student observed that there were a large number of children coming with breakthrough seizures. He

brainstormed with peers to analyze the reasons for poor control of seizures in children with epilepsy. One of the RQ which was formed was 'What are the causes of non-compliance of treatment among children with epilepsy at a tertiary-care center?'

ESSENTIAL ELEMENTS OF A RESEARCH QUESTION

The RQs are broadly classified into descriptive and inferential questions based upon the purpose, objective, and clinical context of the study [4]. Various types of RQs along with examples are given in **Table I**.

A RQ has multiple components. The most common approach to address these is referred to as PICO approach, the acronym standing for Population, Intervention/Exposure, Comparator and Outcome [5]. Sometimes Timeframe, and Effect Size are also added to call it as PICOTES approach which makes it more comprehensive. Although most commonly used in the inferential RQ, some of the elements (P and O) are also mandatory in the descriptive RQ. The salient features of PICO elements are explained in **Box I**.

Attributes of a Good Research Question

Some of the framed RQs, although inviting and lucrative are not possible to do. A good RQ once framed, should be assessed using the FINER approach given by Hulley, et al. [6]. It should be feasible, interesting, novel, ethically sound, and relevant. It should be clearly stated and appropriately complex. This audit should be done before the start of the study to avoid wastage of manpower and resources. Doing a pilot study may also help in unearthing real time issues. These attributes are described in the **Table II**. The RQ should be chosen so that it addresses issues common to clinical setup of a particular area, builds upon previous gaps, ethically sound and is doable by the researcher in the given time limit.

Framing a Research Question

The RQ should be written in one's own wording, be appropriately complex and should not be very broad. It should be in question format and complete in itself [7]. One example of research question would be "How efficacious is intravenous phenobarbitone in comparison to intravenous levetiracetam, as a first line drug, in controlling neonatal seizures?" RQ should NOT be framed to provide answer in YES or NO. Binary outcome framing is not a correct approach as decisions in medicine are based on probabilities and cannot be absolute (0 or 100). Some examples of errors in framing RQ are shown below.

Table I Types of Research Questions and Their Characteristics [4]

Type	*Purpose*	*Example*
Descriptive	Intends to seek measurement of a phenomenon in a defined population. Usually covers only one variable and provides result in frequencies.	What is the prevalence of scabies in primary school children in village 'X'?
Inferential	Aims at drawing inference of an exposure, intervention, or laboratory test on a sample of defined population. It involves a minimum of two variables– Independent and Dependent (one each).	What is the effect of applying chlorhexidine on umbilical cord in decreasing neonatal mortality and neonatal sepsis?
Causal	Intends to seek the association of exposure of a causative factor in a defined population as compared to comparator.	What is the association of developing retinopathy of prematurity (ROP) in preterm neonates with receiving 100% oxygen therapy?
Diagnostic (descriptive)	Seeks to describe the measurement of a phenomenon related to the diagnostic test in a defined population.	What is the sensitivity of CRP in the diagnosis of late onset sepsis in neonates weighing less than 1500 grams at birth?
Diagnostic (analytical)	Seeks to analyze which out of the two diagnostic tests is better in picking a particular phenomenon in a sample of defined population.	What is the predictive value of procalcitonin compared to CRP for diagnosing late onset neonatal sepsis in VLBW neonates?
Prognostic	Intends to find the measure of the prognostic value of a marker in a defined population predisposed to a particular disease.	What is the risk of poor neurodevelopmental outcome in ELBW neonates having received intensive phototherapy for more than 72 hours?
Qualitative	Intends to find explanations of the defined phenomenon which are not possible to quantify in a specific population. The questions are usually broad and open-ended.	What are the perceptions of the mothers who have undergone preterm delivery regarding the usage of donor human milk in their offspring?

Box I PICO Elements in a Research Question

Population of Interest, **P**atient or **P**roblem to be discussed in the descriptive RQ

Description: The study population characteristics need to be clearly defined so that there is no ambiguity.

Example:

- Preterm neonates < 32 wk gestation
- Neonates requiring umbilical arterial catheter (UAC)
- VLBW Neonates having suspected early onset sepsis

Intervention or Exposure

The primary variable whose effect is investigated in the defined population. Could be an intervention (drug, treatment, procedure) or an exposure.

Example:

- Delayed cord clamping for 60s
- Positioning a high UAC
- Estimating use of CRP in first 24h

Comparator or **C**ontrol

An alternative condition to compare the primary variable. Could be the gold standard or placebo.

Example:

- Immediate cord clamping
- Positioning a low UAC
- Estimating procalcitonin in first 24h

Outcome

The expression that will be assessed at the end point of the study.

Example:

- Incidence of intraventricular hemorrhage
- Complications related to UAC
- Detection of culture proven neonatal sepsis

Table II Attributes of a Good Research Question - FINER

F	Feasible	Ensure the availability of appropriate and adequate • Participants to be enrolled • Adequate manpower • Time to complete the study • Funds • Equipment • Expertise in the investigator
I	Interesting	Getting the answer of the RQ should arouse interest in the investigator, colleagues, readers and community
N	Novel	RQ should address to the unexplored areas of a topic The answer to RQ should extend, annul or confirm the previous findings RQ of other studies should not simply be copy pasted because of ease of doing
E	Ethically sound	Mandatory to get ethical approval for the authorities for any study Should not pose harm to the subjects Should follow the principles of Declaration of Helsinki
R	Relevant	The RQ should arise from issues raised from local problems The research should contribute to: • Scientific knowledge • Clinical and health policy • Future research

Example 1

Incorrectly framed: In preterm neonates less than 30 weeks, does formula feeding predispose to necrotizing enterocolitis (NEC)?

Reason: RQ should not have a binary outcome.

Correct: What is the relationship of formula feeding with NEC in preterm neonate less than 30 weeks?

Example 2

Incorrectly framed: What measures are being taken to prevent postoperative wound infection undergoing emergency surgeries?

Reason: Too simple and broad, should be appropriately complex.

Correct: What are the risk factors associated with deep surgical site infection following laparotomy for acute perforation peritonitis?

FORMULATING THE OUTCOMES

The writing of RQ should be followed by the framing of study outcomes and objectives. Outcomes are the measurable endpoints of the objectives which are monitored during the study and occurrence (or absence) of these indicate that result has been achieved. They should originate and be in alignment with the study objectives. It is of utmost importance to *a priori* define an outcome as well as a standard validated method to measure it as a particular entity may be definable or measurable by variable methods. The outcomes should be clearly written such that anyone can easily understand the nature of what is being measured and replicate the measurements at their research settings. The ideal outcomes should be reproducible under same conditions and have minimum inter observer difference, and valid i.e. should measure what they intend to measure. The primary outcome is the most important measurable endpoint and should correspond to the primary objective.

Table III Examples of Research Questions (RQ) Integration With Objectives

Parameter	*Example 1 (descriptive study)*	*Example 2 (case-control study)*	*Example 3 (cross sectional)*
RQ	What is the magnitude of typhoid fever in under-five children in region A?	What is the impact of malnutrition on clinical recovery in under-five children with typhoid fever?	What is the diagnostic role of Typhidot-M test as compared to blood culture in the diagnosis of typhoid fever in under-five children in first week of illness?
Aim	To study the proportion of under-five children with confirmed diagnosis of typhoid fever in 'X' hospital.	To compare the outcome of typhoid fever in malnourished vs normal children	To ascertain the diagnostic accuracy of Typhidot-M against blood culture for early diagnosis of typhoid fever
Primary objective	To document the proportion of children with typhoid fever among total hospitalized children	To compare the duration of hospitalization between undernourished and normal children with typhoid fever	To estimate the predictive value of Typhidot M for diagnosis of typhoid fever as compared to blood culture
Secondary objectives	• Rate of complications • Mortality	• Rate of complication • Mortality	• Sensitivity • Specificity

The study design and sample size are also based upon the primary outcome of the study. The additional measurable endpoints pertaining to the secondary objectives are called as secondary outcomes. Usually outcomes are analyzed independently but 'composite outcomes' can be used when the individual occurrences are rare, correlate with each other or a combination is more informative as compared to an isolated outcome [12]. Mortality or bronchopulmonary dysplasia is a composite outcome used in RQs pertaining to respiratory support in neonates; death or presence of a severe neuro-development impairment (blindness, deafness, motor or cognitive disability) by two years of age is another example of composite outcome used in assessing long term impact of various interventions in extremely low birth weight neonates.

STUDY OBJECTIVES

The RQ tells us that what we are planning to do. The objectives of the study give us accurate description of the steps about how we are going to achieve what we had thought of in the RQ. The objectives serve as milestones for the ultimate goal [8,9]. The objectives are classified as primary and secondary. The primary objective is the most important endpoint and should reflect the RQ. The additional endpoints which we want to study are termed as secondary objectives. It is better to have only one primary objective for a particular RQ. Secondary objectives can be multiple; however, should not exceed five.

Framing the Objectives

Objectives are written in single infinitive sentence format starting with the word 'To' using SMART format. They should be specific, measurable, achievable, realistic and time defined [10]. The action verbs from Bloom's measurable verb list e.g. determine, compare, verify, establish etc. should be used in the framing of the objective [11]. The objectives dictate the type of study design and help in developing the methodology section of the protocol. We should avoid writing too many objectives and should have a clear flow between the RQ and objectives as shown in **Table III**. The relationship between the individual objectives should have a synergistic impact [8,9].

CONCLUSION

The formulation of RQ is most critical and fundamental part of a study which should be done carefully and scientifically. Framing of objectives is a natural corollary after finalizing the research questions. Defining the outcome (mostly in the form of a numerical measurable expression) is a necessary intermediary between the two processes. A summary of the process of developing a research question and translating it into outcomes and objectives is exemplified (**Table IV)**.

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Table IV Systematic Framing of the Research Question and Study Objective

Steps	*Example*
Choose an interesting general topic	Typhoid fever
Extend your knowledge on the topic by consulting several resources	Brief review of treatment of typhoid Fever The antibiotics currently used for treatment of typhoid infections include fluoroquinolones, cephalosporins and macrolides. All lead to therapeutic response, but with variable duration of achieving defervescence. Azithromycin is increasingly being used but recent data about its efficacy in early resolution of fever has not been tested.
Likely research questions	Q1. What is the efficacy of oral azithromycin in treatment of typhoid fever? Q2. What is the comparative rate of recovery following treatment with fluroquinolone and cephalosporins in children with proven typhoid fever? Q3. What is the advantage of polytherapy over monotherapy in typhoid fever?
Brainstorming of the research questions after discussing with mentors and experts	To compare the efficacy of azithromycin and fluoroquinolones for treating typhoid fever in children
Frame an appropriate research question/ hypothesis	What is the efficacy of azithromycin in treating typhoid fever in children compared to ciprofloxacin?
Check for PICO elements:	• Population: Children with typhoid fever • Intervention: Azithromycin • Comparator: Ciprofloxacin • Outcome: Efficacy
Test for practicality	The study is feasible, interesting, novel, ethically sound and relevant (FINER).
Study design	Randomized control trial
Outcomes	Efficacy can be measured in terms of duration of hospitalization, proportion of non-responders, or patient satisfaction.
Primary objective	To compare the duration of hospitalization in children receiving azithromycin or ciprofloxacin for treating uncomplicated typhoid fever
Secondary objectives	To study the proportion of non-responders in children receiving azithromycin vs ciprofloxacin. To compare the satisfaction of parents in two treatment groups

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Epidemiology of Ocular Trauma in a Pediatric Referral Unit, Sao Paulo, Brazil

We performed a retrospective study of hospital records of children younger than 14 years with ocular trauma seen at our center in Sao Paulo, Brazil, between 2011 and 2012. From the total number of cases, 224 (89.2%) could be easily avoided. Accidents occurred with 5 children under 1 year of age; with one baby as young as 2 months. Also, there was a higher prevalence of ocular trauma in 2-to-6-year-old male patients, mainly caused by accidents resulting from the patient's own actions and occurred at home, usually in the presence of an adult. The average time (range) between the accident and seeking medical care was 17.4 hours (10 minutes to 14 days). There is a need to educate parents for preventing ocular trauma.

Keywords: *Accident, Blindness, Injury, Outcome, Prevention.*

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Childhood ocular trauma mainly occurs within the family environment and is the major cause of unilateral blindness and amblyopia [1,2]. Two types of ocular trauma are described: open-globe injury (outermost tunica is disrupted) and closed-globe injury (corneoscleral wall of the globe remains intact) [3]. Of the registered OTs, 20-50% occur in children, most of them are male [1,3-5]. The assessment of children involved in accidents should be systematic in order to prevent a vision-threatening pathology from going unnoticed [6]. Epidemiological data on ocular trauma in countries like Brazil are scarce. We herein report on profile of ocular trauma from a single center in Brazil.

A retrospective study was performed by analyzing the medical records of patients under 14 years old presenting to a referral emergency unit (REU) in Sao Paulo, Brazil with ocular trauma between 2011 and 2012.

There were 251 cases (62.6% males) of ocular trauma being the most affected the pre-school (2-6 y) [105 (41.8%)] age (**Table I**). Accidents occurred with 5 children under 1 year of age; with one baby as young as 2 months. From the total number of cases, 224 (89.2%) could be easily avoided being 29% caused by patient (15.4% by super glue; 17% by furniture; 4.6% by wire; and 14% by toys); 22.8% by IFB; 12.9% by physical aggression [mainly, 24.1% by stone throwing; 34.5% by classmates; 27.5% by siblings]; 12.1% by burn; 5.3% by scratch/bite (75% dogs; 25% cats); 4.1% by fall. The average time (range) between the accident and seeking medical care was 17.4 hours (10 minutes to 14 days). An adult was present at the time of the accident in 56.8% of cases, mainly the mother (60.5%).

The most commonly affected age group was preschool children, and thus require more attention from parents and caregivers. We must also take into account that the younger the child, the faster and deeper amblyopia is likely to be, which will eventually lead to visual deprivation [7].

Table I Characteristics of Children With Ocular Trauma Treated at a Referral Emergency Unit, Brazil (*N*=251)

Characteristic	*No (%)*
Age	
Children (≤2 y)	28 (11.2)
Pre-school (2-6 y)	105 (41.8)
School age (7-10 y)	64 (25.5)
Teenagers (11-14 y)	54 (21.5)
Injured eye, n=230	
Right	104 (45.2)
Left	124 (54.0)
Both	2 (0.8)
Type of injury, n=218	
Open globe	18 (8.2)
Closed globe	158 (72.5)
Eyelid	42 (19.3)
Activity during the accident, n=97	
Playing[a]	49 (50.6)
Inappropriate activity[b]	24 (24.7)
Playing with the ball[c]	10 (10.3)
No activities[d]	14 (14.4)
Place of accident, n=133	
At home	99 (74.4)
On the street	25 (18.8)
At school	9 (6.8)
Trauma caused by, n=224	
Intraocular foreign bodies[f]	65 (29.0)
Physical aggression[h]	51 (22.8)
Accident[e]	31 (13.8)
Burn	29 (12.9)
Falls	27 (12.1)
Pets	12 (5.3)
Another person[g]	9 (4.1)
Interval between accident and medical care, n=184	
Less than 1 h	12 (6.5)
From 1 h to 4 h	80 (43.5)
From 5 h to 1 d	54 (29.3)
More than 1d	38 (20.7)

[a]*running, climbing furniture, making and flying a kite, riding a scooter or bike;* [b]*climbing up a bunk bed, playing with alcohol and fire, playing with an iron bar and wooden club, fixing a bicycle, fighting, jumping on the bed, jumping over a bonfire, running with scissors and playing with glue;* [c]*playing volleyball, soccer and basketball;* [d]*sitting, sleeping, crawling, cutting a nail, staying or sitting under a tree and brushing the teeth;* [e]*nail scratching, finger in the eye, hit by stone, hit by a ball, hook, stab, explosive, detergent and toothbrush;* [f]*hit something in the eye or hit an eye on furniture and super glue;* [f]*speck, sand, wood, glass, earth, sparks, dust, wood, marbles and vegetable;* [g]*brother, father or classmates;* [h]*caused by stone, toy, beans, stick and broom.*

A larger proportion of boys could be explained by their propensity for violent/dangerous games, and participation in inappropriate activities. Other authors also report similar sex predilection [8-11]. Most of the traumas were caused by the patients themselves and at home, which could be avoided with supervision of parents and caregivers during their activities. Furthermore, the high number of physical aggression against children reveals a social problem. Most of them occurred among classmates/neighbors (41%) and among siblings (17%).

The average time to seek medical care over 12 hours reveals the population´s lack of knowledge regarding ocular trauma, and this number is likely to decrease if awareness activities are undertaken among the population.

Our results contrast from a demographic data from ocular trauma in Indian children at a tertiary eye care center in central Maharashtra, where the children aged 6–10 years (39.3%) were most commonly affected followed by children from 11 to 15 years (36.1%) [12]. We described a higher number of cases with closed-globe injury contrasting with the Indian children where the most (63.9%) had open-globe injury which required immediate surgical intervention in 92.3% of the cases [12].

A standard protocol for data collection in pediatric ocular trauma epidemiological studies is of utmost importance and should include: incidence, demographic characteristics, causes/ mechanisms, places of the accident and sites of injury, clinical treatment and visual results of injured children [13]. In addition, special attention should be paid to the family environment, where the prevalence of pediatric ocular trauma is high [14].

In the literature, the most common causes of reduced visual acuity after ocular trauma in children are amblyopia and the presence of corneal opacity. The main risk factors associated with this reduction in visual acuity are younger age at the time of the trauma, presence of low initial visual acuity, location of the lesion in zone 3 (posterior region), extent of the lesion, lens involvement, vitreous hemorrhage, retinal displacement and endophthalmitis [15]. Standardized scores to classify ocular trauma in children [16] are available.

As study limitations, the authors were not able to perform a description for visual disability or loss of sight in our patients; also, a follow-up study was not done in our sample and an ocular trauma score was not evaluated.

There was a higher prevalence of trauma in 2-to-6-year-old male patients, mainly caused by accidents resulting from the patient's own actions. Most of the patients treated had closed-globe injuries and the accident occurred at home. In most cases, an adult was present at the time the trauma occurred. Prevention is vital and in order to be effective, needs more awareness activities and structured management.

Ethics clearance: Ethics Committee [CAAE - 92754318.7.0000. 5404].

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The Initial Steps in Neonatal Resuscitation

We read with interest the randomized control trial by Kumar, et al. [1] and would like to make some observations. Neonatal Resuscitation program as per the International Liaison Committee on Resuscitation (ILCOR) guidelines had made it clear that the initial steps should include, in order, positioning the baby under radiant warmer, then suctioning if there is a lot of secretions, and after that only drying and gentle stimulation, if needed. The process of rubbing the baby's back while drying, itself is a good stimulant for 90% of the babies to make a good cry and establish respiration. Certain points require consideration:

1. The reason this RCT did not pick up the difference is that the study was looking at composite outcome of admission temperature in the NICU and respiratory distress at 6 hours of age.
2. In the study only 5.2% in the first group (suctioning before drying) died, while 11.7% died in the second group (drying before suctioning) [RR (95% CI) 0.44 (0.14-0.38)]. This is an eye opener that depressed sick babies require suctioning first and then only drying.
3. The babies were transported to NICU without any additional source of heat which is not acceptable. Even years back, we have the consensus that the baby should be transported in a transport incubator, or a warmer or phase exchange material like Embrace or at least swaddling the baby well. Ideally babies temperature should have been recorded in the delivery room itself.

To bring uniformity and consistency among health professionals and to avoid confusion in implementation of NRP guidelines, let us follow a scientific and common sense approach which is in agreement with the standard guidelines. So in the initial steps of resuscitation of a depressed neonate (apneic/gasping/ decreased tone) let us follow the standard guidelines of NRP namely, positioning under the warmer, suctioning if needed, drying and removing the wet linen, followed by gentle stimulation or evaluation for respiration and heart rate [2].

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AUTHORS' REPLY

1. The sequence of performing suctioning and drying during initial steps of delivery room resuscitation is not evidence-based. The purpose of suctioning (clearing airway) is to prevent aspiration of secretions and respiratory distress while drying helps to prevent hypothermia. In our study, we compared the sequence of the two approaches (suctioning first versus drying first). We feel that without using the composite outcome of admission hypothermia or respiratory distress, we would have favored one group over the other, compromising the validity of the trial. Separate analysis of the incidences of admission hypothermia or respiratory distress did not show any significant difference between the two groups.
2. Relative risk should be interpreted in relation to the 95% confidence interval, which was quite wide (0.14-1.38). Based on our findings, there was no significant difference between the two approaches. We therefore differ with the reader that depressed newborns should always be suctioned first followed by drying. Interestingly, the upcoming eighth edition of NRP by the American Academy of Pediatrics has reordered the sequence of initial steps (drying first and suctioning later, if needed) to better reflect the common practice [2]. It appears that the proposed change is based on expert opinion rather than any evidence. In fact, our study provides evidence to this change of practice.
3. We agree to the concern of the authors. Our NICU is close to both labor room and maternity operation theatre. Babies are transported to NICU well swaddled. We do not have transport incubator. Currently we are using Embrace to maintain temperature during transportation. However, its use does not entirely eliminate the problem of admission hypothermia.

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Social and Emotional Learning Program Among Preschool Children

Social and emotional learning (SEL) is the process through which children and adults understand and manage emotions, set and achieve positive goals, feel and show empathy for others, establish and maintain positive relationships, and make responsible decisions [1]. Currently, in India, SEL is not being given importance due to changing lifestyle, urbanization, both parents working, single child, and non-availability of secure play areas etc. Children are sent to preschool early, with a focus on academics rather than on personal development. This makes them socially and emotionally detached [2]. We share our experience of a short duration SEL program at kindergarten level.

Children aged 5-6 years, studying in upper kindergarten were enrolled in the program, and data of those with attendance less than 80% in the SEL program was excluded. An introductory class was taken for the parents about SEL. School administrators, teachers and parents were actively involved throughout the sessions. Eleven hours of the program was conducted over 6 weeks (1 hour session, 2 per week, conducted by a trained psychologists). Children were given work sheets and fun activities as home project to ensure parental participation. Questionnaires based on the social skill improvement system were administered to the parents before and after the sessions to see the effect of the program. School was given inputs to integrate SEL into the curriculum. Teachers' comments were also taken into consideration to identify any problem behaviors. The SSIS (Social skill improvement system) parent form (social skills subdomain, 3-5 years) was used to provide a picture of child's behavior in multiple settings. However, due to the large number of students to teacher ratio (40:1), the teacher form was not included. The Kimochis Educator's Tool Kit was used. It is a universal, school-based, social emotional learning curriculum designed to give children the knowledge, skills and attitudes they need to recognize and manage their emotions.

113 children (58 boys; mean age, 5.3 years) were included in the study, and classified to two groups based on the behavior levels obtained from the pre-SEL questionnaire. Group 1 (n=23) had below average and well below average level on social skills sub scale, and children in group 2 (n=90) had an average, above average and well above average level of social skills. The mean score for each of the social skill sub-domain raw scores (communication, cooperation, assertion, responsibility, empathy, engagement and self-control) and total score was calculated for groups. Analysis of variance (ANOVA) was used to compare scores between the groups. Analysis was done using Microsoft Excel. A 5% level of significance was considered significant.

In Group 1, 15 (65.2%) children showed an improvement in the total social skills raw score following the intervention. There was a significant improvement in mean (SD) total social skills score after the intervention [64.7 (8.16) vs. 72.1 (10.74); P<0.01], indicating short term Kimochi training is effective for children. In Group B, 40 showed an improvement in the total social skill score and 47 (44.4%) children showed reduction in scores. No statistically significant difference was noted in the pre-and post-intervention mean (SD) total skill score in this group [91.3 (14.26) vs 90.8 (16.21); P=0.82].

However, follow-up is needed to see the impact of the skills learned, as children need time to practice and integrate the learned skills (sleeper effect) [3]. The CASEL meta-analysis [4] noted that though impact is maximum immediately, it still persists, though the impact of the program tends to fade.

At the closing session of our program, parents were advised how to promote SEL at home. Children with problem behaviors were guided appropriately. Preschool teachers' workshop was conducted to promote professional development and early identification of developmental problems. We feel that our experience shall promote more studies to establish healthy SEL at schools, especially in the Indian scenario, where there is a paucity of the same.

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Milking of Umbilical Cord vs Delayed Cord Clamping

We read the article by Mangla, et al. [1] which deserves appreciation for the novelty of the topic. We seek clarifications on following issues:

i) In the study outcome, hematocrit values differ by mere 1.8% and 0.8% at 48±6 hours and at 6 weeks, respectively. This seems to be clinically insignificant, consequently not requiring any interventions.

ii) In babies delivered by caesarean section, anesthesia and surgical interventions interferes with active uterine contraction leading to more blood volume remaining in placenta. Hence, cord will not be refilled after first milking maneuver [2], leading to inefficiency of umbilical cord milking.

iii) At high altitudes [3], infants born to mothers with anemia have higher hematocrits than those born to non-anemic mothers, these factors were not considered while interpreting secondary outcome at 6 weeks of life. Many other studies showed contradictory findings such as no difference on neonatal and maternal outcomes at the age of 48-72 hours in term neonates [4].

We feel that the findings of this study cannot be used to promote umbilical cord milking over delayed cord clamping due to the above noted gaps.

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AUTHORS' REPLY

We thank the readers for their thoughtful comments on our article [1]. Our response is as follows:

i) Our study demonstrated a statistically significant difference of 1.68% and 1.75% in the hematocrit values at 48 hours and 6 weeks, respectively, between the two groups. A difference in the hematocrit of 1.75% – roughly a difference of 6 g/L in hemoglobin – at six weeks does indeed look small. However, what constitutes a clinically meaningful difference in a continuous outcome variable is always a matter of debate. One cannot simply disregard the difference in the mean hematocrit without evaluating the risk of other related outcomes like the requirement of transfusion in the first few months of life, failure to thrive, and stunting. Interestingly, a systematic review on daily iron supplementation in children aged 4-23 months showed a mean difference in the hemoglobin values of only 7.2 g/L but a considerable reduction in the risk of anemia – by 39% – in the intervention group [2].

ii) The reference provided for the inefficiency of umbilical cord milking after the first milking maneuver refers to a study that does not include intact-umbilical cord milking but compares early vs. delayed cord clamping (DCC). On the contrary, intact umbilical cord milking has been shown to deliver a more significant placental transfusion than DCC in premature newborns delivered by cesarean section [3].

iii) The comment that infants born to mothers with anemia have higher hematocrits than those born to non-anemic mothers at high altitudes is again not relevant to our study [1] because firstly, the mean hemoglobin (117 vs. 114 g/L) and the proportion of women with anemia were comparable between the two groups, Secondly, the study was conducted in Delhi and not in a high-altitude site; most, if not all, mothers hailed from in and around Delhi. Moreover, the study was a randomized controlled trial, and the randomization process could have taken care of these confounders to a large extent.

Lastly, the study did not conclude that umbilical cord milking should be promoted over of DCC given the significant results; instead, it just stated that the intervention leads to higher venous hematocrit at 48 hours when compared with delayed cord clamping in late preterm and term neonates but the long-term effects of milking need to be further evaluated.

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Lactating mothers transfer SARS-CoV-2 antibodies to infants after vaccination

With COVID-19 cases skyrocketing, people have realized the importance of vaccines and are overcoming vaccine hesitancy. The Government of India has reduced the minimum age for vaccine eligibility to 18 years from May 1, 2021. A common query now is whether lactating mothers are candidates for the vaccine.

A study published recently in JAMA found robust secretion of SARS-CoV-2 specific IgA and IgG antibodies in breast milk for 6 weeks after vaccination. It was conducted on 84 lactating women, with 2 doses of the Pfizer-BioNTech vaccine administered 3 weeks apart. IgA secretion was evident as early as 2 weeks after vaccination and peaked at 4 weeks. A spike in IgG occurred at 4 weeks. These antibodies showed strong neutralizing effects, suggesting a potential protective effect in infants. No mother or infant had any serious adverse effect.

The World Health Organization (WHO) recommends use of Pfizer-BioNTech, Moderna, AstraZeneca, and Janssen vaccines in breastfeeding women. The Federation of Obstetricians and Gynaecologists Society of India (FOGSI) has also suggested use of these vaccines in breastfeeding women, as their benefits seem to far outweigh any theoretical and remote risks. Although, no data are available on the use of Indian vaccines in lactating women, the Ministry of Health and Family Welfare (MOHFW) has recently included this subgroup for vacination.

With COVID cases soaring and an impending third wave, this inclusion of lactating women for vaccination seems reasonable. Studies should be done to assess the protective effect imparted by the Indian vaccines in lactating women.
(JAMA, 12 April, 2021)

Does the double mutant B.1.617 SARS-CoV-2 variant evade vaccine-induced immunity?

The B.1.617 variant is termed the 'double mutant' as it simultaneously carries two important mutations in the receptor binding domain – L452R and E484Q. The L452R mutation was found in the Californian variant, which was highly transmissible. The E484Q mutation is similar to the E484K mutation found in the rapidly spreading South African (B.1.351) and the Brazilian (P.1) variants. The combination of these mutations created an apprehension that it could increase transmission and surpass immune defenses. It has recently been classified by the WHO as a 'variant of concern'.

Researchers screened 146 COVID-19 cases in Maharashtra using next generation sequencing and found the double mutant variant in 15 of them. The neutralization capacity against the prototype B1 (D614G) variant was compared with the B.1.617 variant using sera of Covaxin recipients. Although a drop in neutralization was detected with the B.1.617 variant, it was limited to 2-fold (GMT ratio1.95). When sera from COVID-19 recovered people (infected with other variants) were compared with sera from Covaxin recipients, the neutralizing capacity against B.1.617 was similar. Early results of another study have shown that both convalescent sera and Covishield-vaccinated sera offer protection against the B.1.617 variant.

Although further studies would be needed to confirm these findings, results of these studies assuring neutralization of B.1.617 variant with sera of Covaxin and Covishield vaccine recipients would provide the much-needed boost to the COVID-19 vaccination program in India.
(BioRxiv preprint, 23 April 2021)

Myopia in children post COVID-19 home confinement

Apart from the damage caused by the SARS-CoV-2 virus itself, there have been ill-effects due to public health measures taken to combat the virus. One among them is the impairment of visual health in school-aged children post COVID home confinement.

To prevent COVID-19 spread, nations across the world have closed their schools and begun online classes. This has reduced the time spent by children in outdoor activities and increased the screen time. A Chinese study found a significant myopic shift (approximately –0.3 diopters) in the 2020 school-based screen-ings compared with previous years (2015-2019) for children aged 6-8 years. The change was not significant in older children.

This suggests that younger children are in a critical period for the development of myopia and their eyes are more sensitive to environmental changes. While myopic children can see well through glasses or contact lenses, myopia increases the risk of high myopia later in life, which in turn can cause retinal detachment/tears, macular degeneration, glaucoma, and blindness.

With the pandemic far from over, public health authorities should take this into consideration and plan an intelligent lockdown. Parents should plan an appropriate indoor life for younger children and restrict their screen times.
(JAMA Ophthalmology, 14 January 2021)

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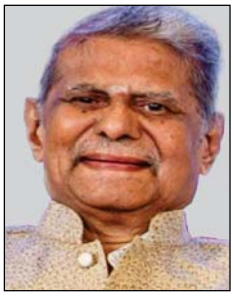
OBITUARY



Dr A Parthasarathy MD DCH DSc (Hon) FIAP
8 August, 1938 – 15 May, 2021

Dr A Parthasarathy, was fondly called "*Aa Pa Sa"* by pediatricians from Tamil Nadu and as "Partha" and "Partha Sir" by others, graduated from Madras Medical College and studied MD Pediatrics at the Institute of Child Health and Hospital for children, Madras Medical College. He retired as Deputy Superintendent of the same institution.

As an Assistant Professor, he was in-charge of the tuberculosis clinic and the vaccine preventable diseases ward (then known as isolation ward), and did a commendable job in caring for the sick children and teaching students. He was the key person in establishing an immunization clinic at ICH, and taking it further to the community through immunization camps. His contribution to polio eradication is unparalleled.

He was a key person in promoting the activities of Indian Academy of Pediatrics in Tamil Nadu along with Prof N Sundaravalli in the yester years. He constantly motivated young pediatricians to become members of IAP and was instrumental in getting them involved in the activities of IAP – Tamil Nadu Branch and central IAP. He served CIAP as Executive Board member, and then as President during the year 1997.

He was the founder Editor of the "IAP Text Book of Pediatrics." His contribution as editor of many other books is praiseworthy. He had contributed numerous articles to books and journals. His contribution to the field of vaccinology is laudable. His keen interest in bringing out books on various pediatric topics continued till his last days.

He was also the Founder Editor of *Indian Journal of Practical Pediatrics*, and served as its Editor-in-Chief from 1993 to 1995. He continued to be a guiding force for the journal as its Emeritus Editor.

He was pleasant and considerate towards his colleagues and juniors alike. His sudden demise is a great loss to the pediatric fraternity and the community, as a whole. He is survived by his wife, son, daughter and grandchildren.

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Iron Deficiency Anaemia