Editorial

Need for Managing Variability of Healthcare Processes

Hospitals have scarce capacity. Almost always the demand for care is higher than the supply provided. Managing a hospital organization in an efficient, patient-centered, and timely way is easier said than done.

Let us try to understand the fundamentals of this problem. Imagine an 'ideal' world where a typical hospital provides services to patients. This hospital has 800 beds, 25 operating rooms (ORs), 50 intensive care unit (ICU) beds. Everyday exactly 80 patients are admitted and the length of stay (LOS) is exactly 10 days. All patients admitted are equal and all patients undergo the same procedure in the ORs. This procedure will be performed every time by the same surgical team. The procedure time is exactly 155 minutes and, after admission, every patient spends exactly 2 hours in the ICU and is discharged after exactly 10 days. In this world, hospital management can offer a perfect, efficient, patient-centered and timely service to the patient. Number of beds in uses will be, in the long-term, exactly 800 beds. There is no overtime in the ORs because all the procedures have the same duration, and the professionals in the ICU should not only know exactly when they can expect the next patient but also when this very same patient will be transported to the ward.

This ideal world is utopia. In healthcare, the word 'exactly' does not exist. To compare a hospital with a wine factory, there is known exactly how many bottles are filled with wine every minute and how many bottles are produced at the end of a working day. And at 5 pm, machines stop working. In healthcare, working days stop technically at 5 pm. But at 5 pm, we do not close the ORs when still patients are being operated.

In our example, remove the word 'exactly', and replace it by 'mean'. Now, in our real daily business, we call it a hospital where all patients are coming for the same or different procedures and surgical teams differ everyday and every week. From the fundamental point of view, we introduced the concept of 'variability'. Variability in health processes means that patients have to wait in queues for their appointment in the outpatient department, surgical procedures take more time than expected, patients stay shorter or longer in the ICU and the LOS may be shorter or longer. The latter results sometimes in that new patients cannot be admitted because of overloaded wards, where professionals work under stress. And, this may subsequently cause idle time in the ORs resulting in revenue loss for the hospital.

Managing variability can be a nightmare for many hospital managers. But, it should not be this way. Of course, everybody will understand that it is not possible to eliminate all the variability and, hence, create our ideal world (which is still utopia). But, we can use common sense and apply scientifically proven tools to at least diminish variability in healthcare processes and, hence, approach more toward a situation where efficient, patient-centered and timely care are more or less in an equilibrium.

Why should we do this at all, managing variability? Firstly, we want to use our scarce and costly hospital resources in an optimal way by knowing what is in the system and what can be expected. And secondly, we want to make sure that the service to our patient is timely by reducing the chance that a patient is rejected for admission or that a scheduled surgery is canceled. It is amazing to see that air traffic control knows from every plane where it is and when it is expected to take off and land. Ask yourself: do you know at this very moment (or within 5 minutes) how many elective patients are admitted to your hospital today and will be admitted for next Tuesday? And, how many patients you might expect tomorrow at 8 pm in the emergency room? Amazing, no!

Healthcare operation management is a medicine to handle to a certain extent the variability within healthcare processes. Basically, healthcare operations management focuses on the delivery of safe care to our patients. This is performed by analyzing the underlying operations and processes, thereby taking into account the potential links with resources (wards, ICUs, ORs, labs) needed.

Next we describe some examples. Concerning the OR, start the first case on time. A delay on the first case means that there is a higher probability that the last case will be cancelled because of overtime. Check your OR schedule per room. Try to schedule cases in one OR such that the sum of the variance for that OR is minimal. This gives a higher probability that all scheduled cases can be finished.

A simple example to illustrate this point. Assume block time OR number one is 10 hours (600 minutes). We have the option to schedule a combination of the following surgeries (mean procedure time and standard deviation (SD) calculated per surgeon-procedure combination): knee replacement (120 minutes, SD 30 minutes), pancreatectomy (300 minutes, SD 70 minutes), laparoscopic cholecystectomy (60 minutes, SD 15). Assume further that the mean turn over time between cases is 15 minutes.

For OR number 15 we can create two possible schedules:

Schedule A: Two patients for knee replacement followed by a pancreatectomy. Total time needed: procedure time 540 minutes plus 30 minutes turn over time equal 570 minutes. The sum of variances (square of standard deviation) of the included procedures equals 6,700.

Schedule B: Three patients for a knee replacement, followed by three patients for a laparoscopic cholecystectomy. Total time needed 615 minutes. Total variance: 3,3750.

Expected variance schedule B is smaller than schedule A, hence we prefer schedule A.

Another interesting but sometimes hard to answer question is, how many beds needed in the ward? A very useful tool can be found here http://www.vumc.nl/afdelingen/pica/Software/erlang_b/ Here we use the Erlang B loss mode. The Erlang B is also used in call centers to calculate how many operators are needed to let the caller not to wait more than let us say 3 minutes (with a probability of 95%). Input variables are: Arrivals, Average Stay, Operational/Staffed beds in the ward. Output data are: rejection rate, occupancy rate. Arrivals and average length of stay can be calculated using historical data of a specific ward. Suppose the number of arrivals per day is 5 patients, staying on average 4.5 days and that the ward has 30 beds. Then the percentage of refused admissions is 2.47% while the occupancy rate is 73.15%. More beds reduces the percentage of refused admissions but decreases the occupancy rate. Reducing beds increases the occupancy rate but may also create increased workload for the staff.

In these examples health operations management can help. Because of the mathematics and statistics involved it is sometimes hard to follow. But trying to understand this and applying it subsequently in your hospital brings your hospital more in control and hence will answer the previous questions in an affirmative way.

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ORIGINAL ARTICLE

Impact of Nutritional Services of Anganwadi Workers in Improving Nutritional Status of Infants in Delhi: A Study by Mixed Method Technique

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ABSTRACT

Background: Despite the presence of integrated child development services (ICDS) program in rural area of Delhi, the real impact of nutritional services of ICDS program on nutritional status of infants is not very clear, therefore, studying this area may provide new insights in this field.

Materials and methods: This study was carried out from 1st January 2015 to 31st March 2015 (3 months). All children up to 1 year of age (in AWC 1 and 2 area of a one rural ICDS block) were examined for their nutritional status by weight for age criteria. The registered infants of both these Anganwadi centers (AWCs) and their mothers were simultaneously observed for all kind of nutritional services they received from Anganwadi workers (AWWs) by way of key informants interviews and this was further confirmed by applying secret customer technique.

Results: The prevalence of mild to moderate malnutrition among infants in both the AWC area (AWC 1 area—6 months to 1 year category—52.9%, AWC 2 area (from 0–6 months and 6 months–1 year—69.3%) was higher. The key feeding factors identified for such scenario were: Improper colostrums feeding, wrong age of initiation of semisolid feeding, exclusive breastfeeding not done for 6 months, etc. [especially for AWC 2 area ($p < 0.05$) and AWC 1 area ($p > 0.05$)] among the AWCs. These factors were further confirmed by poor efforts of both AWWs in providing nutritional services toward mother and infants.

Conclusion: Anganwadi workers need to focus on quality of nutritional services provided toward mothers of infants and this area needs regular monitoring and supervision from ICDS and health system meticulously.

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INTRODUCTION

It has been found that undernourished rural pregnant women can be benefited by nutrition supplement in integrated child development service (ICDS) blocks,[1] but does this ICDS effort percolate down the generation in terms of augmented nutritional infants is a questionable issue. As per the recent UNICEF report (2015) in India, 25% newborns are underweight, 33% are exclusively breastfed for the first 6 months and nearly 50% children under 5 years of age suffer from moderate or severe malnutrition.[2] Against this gap, the Government of India efforts are also significant, in terms of improving the life chances of children by way of ICDS program.[2] Integrated Child Development Services in India is the world's largest integrated early childhood program, with over 40,000 centers nationwide.[2] The purpose of ICDS is to improve the health, nutrition and development of children. The program offers package of nutrition services, such as: (a) health, nutrition and hygiene education to mothers, (b) supplementary feeding for all children and pregnant and nursing mothers, (c) growth monitoring and promotion.[2] The changes in the ICDS program are also improving its impact. Greater emphasis is now placed on children less than 3 years of age and the percentage of severely malnourished children have declined due to these services.[2] Over the last two and a half decades, ICDS has also demonstrated its effectiveness in providing nutritional services.[2]

Although the ICDS program, is well-conceived and well-placed to address the major causes of child under nutrition in India. But issues, such as: (a) increasing

coverage than to improving the quality of service delivery and (b) to distributing food rather than changing family-based feeding and caring behavior has resulted in limited impact in area of nutritional services have also been enumerated by World Bank (2015).[3]

Many problems in ICDS programs nutritional services have been cited in literature, such as: (a) Enough attention is not given to improving infants nutrition, and (b) on educating parents how to improve nutrition using the family food budget, (c) older children (between 3 and 6 years) participate much more than younger ones (0–3 years) and (d) children from wealthier households participate much more than poorer ones.[3] In Infant feeding practices, which have been found to have a significant effect on children nutritional status, in which role of women literacy in child feeding practices and Anganwadi workers (AWWs) role in imparting nutrition and health education to mothers for managing nutrition of infants can also be a significant issue.[4] The role of father have[5] also been cited in the literature apart from other factors such sociocultural and economic factors of mothers and perceptions of community level stake holders and ICDS—health functionaries in nutritional status of under 5 years rural children of Delhi.[5-7] So, the real focus is poor on root of tackling undernourishment from birth till infancy, when the targets are most vulnerable.

For this above scenario, many reasons may exist, such as AWWs are overburdened due to few factors, e.g. they are expected to provide preschool education to 4 to 6 years old as well as nutrition services to all children under 6, with the consequence that most children under 3—the group that suffers most from malnutrition—do not get micronutrient supplements, and most of their parents are not reached with counseling on better feeding and childcare practices. Moreover, more reliance on AWW in National Rural Health Mission (NRHM) program had also caused AWWs to pay little attention to nutritional services toward infants.[3] Although AWWs are active in rendering their services to the beneficiaries but the ever increasing responsibilities of AWWs these days, moreover, they have also certain prescribed responsibilities other than the above mentioned services in the Anganwadi because of which focus of nutrition services toward infants are also getting affected.[8]

Anganwadi workers have a key role in growth monitoring and promotion of use of mother child protection card (MCPC) and all eligible infants (0–1 years) on monthly basis are supposed to be weighed at the Anganwadi center (AWC).[9] Reasons for faltering also needs to be identified and appropriate role delineation for frontline workers, convergence of health and ICDS guidance and counseling needs to be given to care givers.[9] But, this work of AWWs are also not up to that quality, which can give a sustained positive impact on infants. In view of the above uncertain scenario in this field, this study was, therefore, planned to found out the impact of nutritional services of AWWs on nutritional status of infants in rural area of Delhi, as literature lacks specific studies exploring the role and importance of ICDS functionaries specifically toward infants. That is why authors selected this research area.

MATERIALS AND METHODS

Research Question

What are the impacts of nutritional services given by AWWs on nutritional status of infants in rural area of Delhi?

Ethical Approval

First approval of Ethical Committee of the Institution was sought, followed by ICDS department's approval and consent for participation of their AWWs and mothers consent as well was taken for their participation in this study.

Duration of Study

1st January 2015 to 31st March 2015 (3 months).

Sampling Technique

Study Area Selection

Total 28 ICDS projects are running in nine districts of Delhi. From which one rural ICDS project was selected randomly from 28 ICDS projects. The study was done in the area of two AWCs of a one rural ICDS project in the community development block of Delhi. The Anganwadi (1) and Anganwadi (2) were selected randomly from this.

Study Unit Selection

Area of two AWCs in a Rural ICDS block as follows:

- AWC 1
- AWC 2

Selection of Beneficiaries (Mothers and Infants)

All the eligible children between the age group 0 to 1 years (infants) and mothers of these infants, who attended the AWCs in the survey register of each AWC at the time of data collection were included in the study. This constituted the survey of all infants in area of two AWCs. All the infants and their mothers from registered category of infants from both AWC 1 and AWC 2 each were studied

for nutritional services from AWWs by key informants interview and secret customer technique.

Selection of the Infants for Nutritional Status in Anganwadi's Area

All children under 1 year of age (in AWC 1 and 2 area) respectively were examined for their nutritional status by weight for age criteria. The registered children of both AWCs were also observed for the nutritional services they received from AWWs at both the AWCs. The mothers were observed by secret customer technique for nutrition and health education services they received from AWW.

Calculation of Prevalence of Malnutrition in Infants

The infants were classified into malnutrition grades by weight for age criteria used under ICDS scheme was employed to find their nutritional grades. For calculating the prevalence of malnutrition of each AWC area, the infant found malnourished by weight for age criteria were taken. The total population of infants of both the AWCs was used in calculation of prevalence. The prevalence of malnutrition in area of both AWCs was then compared.

Study Design

The present study involved collection of information pertaining to all the nutritional services rendered under ICDS scheme via key informant—interview of stake holders, such as AWWs and mothers who were directly or indirectly involved in malnutrition prevention and management among infants in a rural ICDS block of Delhi. This was followed by use of secret customer techniques used by authors for evaluating nutritional services given under ICDS scheme. Therefore, the study design was descriptive-mixed analytical study.

Data Collection Tools and Technique

Both primary and secondary data were collected as per the objectives of the study. Primary data were collected by the interview schedules and checklist after visiting the two AWCs. Secondary data were collected through study of records and reports maintained at AWC level in the ICDS scheme.

Data Analysis

As per the objectives of the study, the collected data were analyzed with using appropriate statistical package—Epi-info and ATLAS.Ti software.

RESULTS

Age, Sex and Birth Order of Infants in AWCs Area

There were 36 infants in the AWC 1 area and 65 infants in the AWC 2 area (total 101 infants in the study area) (Table 1).

In the infants subcategories of 6 months, 1 year population were 47.3% in AWC 1 and 60% in AWC 2. The sexes of children were evenly distributed, though boys were slightly higher than girls (52.7 and 52.3% males *vs* 47.3 and 47.7% females in AWC 1 and AWC 2 areas respectively). The majority of infants were first order births (36.1% in AWC 1 and 38.4% in AWC 2 area) (Table 1).

Distribution of Age Groups as per Nutritional Status of Infants

Normal nutritional status infants were higher among children in 0 to 6 month's age category in both AWC 1 and AWC 2 (52.7 *vs* 42.3%). The malnourished children in mild

Table 1: Distribution of infants according to age, sex and birth orders

	Anganwadi 1		*Anganwadi 2*		*Total*	
Variables	*No.*	*Percentage*	*No.*	*Percentage*	*No.*	*Percentage*
Age						
0–6 months	19	52.7	26	40	45	44.6
6 months–1 year	17	47.3	39	60	56	55.4
Total	36	100	65	100	101	100
Sex						
Male	19	52.7	34	52.3	53	52.4
Female	17	47.3	31	47.7	48	47.6
Total	36	100	65	100	101	100
Birth order						
First	13	36.1	25	38.4	38	47.5
Second	9	25	20	30.8	29	28.8
Third	8	22.2	17	26.1	25	24.8
Fourth	6	16.7	3	4.7	9	8.9
Total	36	100	65	100	101	100

to moderate category (grades 1 and 2) were present in 6 months 1 year age category in both AWC areas (AWC 1 52.9%, AWC 2 79.5%) with majority of infants in grade 1 undernourishment AWC 1 36.1% and AWC 2 41.5% in total. The severe malnourishment was not found in AWC 1 area (Table 2).

The severe malnutrition (grade 3) was present in infants in both below and above 6 months to 1 years of age in AWC 2 (3.9 *vs* 2.6%—total 3.1%). No infant was found in grade 4 undernourishment (Table 2).

Distribution of Sex as Per Nutritional Status of Infants

Although male infants of AWC 2 were more malnourished (67.7%) as compared to female infants of AWC 2 (64.5%) but the difference in malnourishment rate among AWC 1 and AWC 2 were not significant ($p > 0.05$) when males and females infants were individually seen (Table 3).

Distribution of Colostrum Feeding as Per Nutritional Status of Infants

All the children who had received the colostrums feeding were normal in nutritional status in both the AWCs (52.7% in AWC 1 and 42.3% in AWC 2) (Table 4).

The infants who did not receive colostrums feeding had higher % of malnourished children as seen in AWC 2 area (82.1%) as compared to AWC 1 area (52.9%). The colostrums feeding was significantly associated with nutritional status of children in the AWC 2 area ($p < 0.05$) but not in AWC 1 area (Table 4).

Distribution of Exclusive Breastfeeding for 6 Months

The majority of infants (52.6% in AWC 1 and 42.3% in AWC 2) who had received exclusive breastfeeding for 6 months were in normal nutritional status (Table 5).

The majority of infants who were malnourished (52.9% in AWC 1 and 82.1% in AWC 2) were found among those who did not received exclusive breastfeeding for 6 months. The exclusive breastfeeding for 6 months was significantly associated with the nutritional status of children in AWC 2 ($p < 0.05$) but not in AWC 1 area (Table 5).

Age of Initiation of Semisolid Feeding at 6 Months

The majority of children in whom semi-solid feeding was initiated at 6 months were normal (52.7% in AWC 1 and 42.3% in AWC 2). But those children who received semisolid feed after 6 month, onward were

Table 2: Distribution of infants according to age groups in AWC 1 and 2

	Age groups					
	0–6 months		*6 months–1year*		*Total*	
Nutritional status of infants	*No.*	*Percentage*	*No.*	*Percentage*	*No.*	*Percentage*
AWC 1 area						
Normal	10	52.7	8	47.1	18	50
Grade I	7	36.8	6	35.3	13	36.1
Grade II	2	10.5	3	17.6	5	13.9
Grade III	0	0	0	0	0	0
Grade IV	0	0	0	0	0	0
Total	19	100	17	100	36	100
AWC 2 area						
Normal	11	42.3	7	17.9	18	27.7
Grade I	8	30.7	17	43.6	25	41.5
Grade II	6	23.1	14	35.9	20	30.7
Grade III	1	3.9	1	2.6	2	3.1
Grade IV	0	0	0	0	0	0
Total	26	100	39	100	65	100

Table 3: Sex-wise distribution of nutritional status of infants in area of 2 AWCs

	AWC 1		*AWC 2*		*Total*	
	No.	*Percentage*	*No.*	*Percentage*	*No.*	*Percentage*
Male						
Normal	10	52.7	11	32.3	21	39.6
Malnourished	9	47.3	23	67.7	32	61.4
Total	19	100	34	100	53	100
Chi-square test = 2.0, df = 1, $p > 0.05$						
Female						
Normal	10	58.8	11	35.4	21	43.7
Malnourished	7	41.2	20	64.5	27	57.3
Total	17	100	31	100	48	47.6
Chi-square test = 2.4, df = 1, $p > 0.05$						

more malnourished more in AWC 2 area (82.1 *vs* 57.7%) (Table 6).

The age of initiation of semisolid feeding at 6 months was significantly associated with nutritional status of children in the AWC 2 ($p < 0.05$) but not in AWC 1 area (Table 6).

Distribution of Infants identified from Key Informants Interview and Secret Customer Technique who received Nutritional Services, from AWWs

Total 32.6% of mothers of infants received nutrition and health education (NHE) for nutritional care of infants in both AWCs combined and only 14.8% of mothers of infants received information on avoiding ceremonial feeding from AWWs. In both AWC areas—the 'colostrum feeding' was emphasized most to mothers of infants in 0 to 6 months category AWC 1 (68.4%) and AWC 2 (73.1%) by AWWs, whereas maximum mothers of infants in 6 months to 1 year category—received NHE for nutritional care of infants (41.1% in AWC 1 and AWC 2 (48.8%). But, all these differences were not statistically significant ($p > 0.05$) (Table 7).

Key Qualitative Findings after using Secret Customer Technique and Key Informants' Interviews

- AWW-2 was not approaching mothers for proper enrolment for nutritional counseling sessions.
- Nutrition and health education was not in main focus of both AWWs.
- Concept of avoiding ceremonial feeding was even not well understood by both AWWs.
- Main focus of AWW-2 was only to give supplementary nutrition to beneficiaries above 1 year.
- Both AWWs did not feel the real importance of starting of weaning at 6 months/exclusive breastfeeding (EBF) at least till 6 months.
- Mothers of infants had little idea about concept of avoiding ceremonial feeding.
- Concept of benefits of colostrums feeding was not popular in both AWCs area.
- All the mothers in AWC 1 area (n = 36, i.e. 100%) felt that AWW-1 was taking few efforts for better nutritional care of their infants.

Table 4: Distribution of infants according to start of colostrum feeding in area of AWC 1 and 2

	Colostrum feeding					
	Yes		*No*		*Total*	
Nutritional status of infants	*No.*	*Percentage*	*No.*	*Percentage*	*No.*	*Percentage*
AWC 1 area						
Normal	10	52.7	8	47.1	18	50
Malnourished	9	47.3	9	52.9	18	50
Total	19	100	17	100	36	100
Chi-square test = 0.11, df = 1, p > 0.05						
AWC 2 area						
Normal	11	42.3	7	17.9	18	27.7
Malnourished	15	57.7	32	82.1	47	72.3
Total	26	100	39	100	65	100
Chi-square test = 4.62, df = 1, p < 0.05						

Table 5: Distribution of infants according to exclusive breastfeeding received for 6 months in area of AWC 1 and 2

	Exclusive breastfeeding received for 6 months					
	Yes		*No*		*Total*	
Nutritional status	*No.*	*Percentage*	*No.*	*Percentage*	*No.*	*Percentage*
AWC 1						
Normal	10	52.6	8	47.1	18	50
Malnourished	9	47.4	9	52.9	18	50
Total	19	100	17	100	36	100
Chi-square test = 0.11, df = 1, p > 0.05						
AWC 2						
Normal	11	42.3	7	17.9	18	27.7
Malnourished	15	57.7	32	82.1	47	72.3
Total	26	100	39	100	65	100
Chi-square test = 4.62, df = 1, p < 0.05						

Table 6: Distribution of infants according to age of initiation of semisolid feeding (SSF) in area of AWC 1 and 2

	Age of initiation of SSF					
	At 6 months		*Between 6 months and 1 year*		*Total*	
Nutritional status of infants	*No.*	*Percentage*	*No.*	*Percentage*	*No.*	*Percentage*
AWC 1 area						
Normal	10	52.7	8	47.1	18	50
Malnourished	9	47.3	9	52.9	18	50
Total	19	100	17	100	36	100
Chi-square test = 0.11, df = 1, p > 0.05						
AWC 2 area						
Normal	11	42.3	7	17.9	18	27.7
Malnourished	15	57.7	32	82.1	47	72.3
Total	26	100	39	100	65	100
Chi-square test = 4.62, df = 1, p < 0.05						

Table 7: Distribution of infants identified from key informants interview and secret customer technique who received nutritional services from AWWs

	Anganwadi center						
	AWC 1 (n = 36)			*AWC 2 (n = 65)*			
Variables	*0–6 months*	*6 months–1 year*	*Total*	*0–6 months*	*6 months–1 year*	*Total*	*Total (n = 101)*
NHE received-by mothers on complete nutritional care of infants	3 (15.8%)	7 (41.1%)	10 (27.7%)	4 (15.4%)	19 (48.8%)	23 (35.3%)	33 (32.6%)
Chi-square test = 0.12, df = 1, p > 0.05							
Avoid ceremonial feeding	1 (5.3%)	6 (35.3%)	7 (19.4%)	1 (3.8%)	7 (17.9%)	8 (12.3%)	15 (14.8%)
Chi-square test = 0.43, df = 1, p > 0.05							
Provide colostrum feeding	13 (68.4%)	0	13 (36.1%)	19 (73.1%)	0	19 (29.2%)	32 (31.7%)
Chi-square test = 0.11, df = 1, p > 0.05							
On starting of weaning at 6 months/EBF at least till 6 months	2 (10.5%)	4 (23.6%)	6 (16.7%)	2 (7.7%)	13 (33.3%)	15 (23.2%)	21 (20.8%)
Total	19 (100%)	17 (100%)	36 (100%)	26 (100%)	39 (100%)	65 (100%)	101 (100%)
Chi-square test = 0.19, df = 1, p > 0.05							

- Majority of mothers in AWC 2 area (n = 35/65, i.e. >50%) felt that AWW-2 was not taking sufficient steps for better nutritional care of their infants.
- Nutritional and health education sessions were conducted only once in 3 months in AWC 2 area, whereas AWW-1 was doing it at least on monthly basis.

DISCUSSION

In India and average infant gets a poor start in their life by provision of poor nutritional efforts from all angles. According to Delhi Government data (2013), where 3.2 lac births take place in state of Delhi, with the birthrate figure of 21.07 and IMR of Delhi as 22.37, an area of a AWC with a population coverage of 1000, is expected to have live infants up to 83/AWC hence, for 2 AWCs it comes around 166 for both. However, when compared with our present study, total 101 infants were found in our study area, which indicates both AWWs might have missed some of the infants for enrolment for nutritional services. The higher proportion of infants (65) in AWC 2 also suggests that the AWW-2 had enumerated all the infants but perhaps she may have missed out some older children during the survey and whereas AWW-1 might have missed the number of infants in her survey area. Both of these issues imply that quality of AWWs survey for enrolment in nutritional services may not be adequate in the rural ICDS block of Delhi.

In our present study, the malnourished children in mild to moderate category (grades 1 and 2) were present in greater than 52% of infants 6 months 1 year age category in both AWC areas and also the majority of infants were in grade 1 undernourishment. The higher % of infants in grade 1 undernourishment in our study suggests that, although the work of AWW-1 is on track as compared to AWW-2, but the Intergenerational effect of malnutrition might be existing from years, for which AWWs are less sensitized and their efforts were not of desired standard.

Our study findings are, therefore, in line with study by Tandon et al (1981)[10] on under 3 years children in which grade 1 nutritional status got increased from

61.3%, whereas severe malnutrition got declined due to ICDS Services which was found also in study by Avsm et al[11] and Kapil et al.[12] Study of Pandey et al[13] also indicate that the mean weight of ICDS beneficiaries in general is more than that of non ICDS utilizers; but despite the ICDS Scheme being attractive but beneficiaries do not realize its actual importance, which is probably responsible for a higher figure of undernourishment among infants in Delhi, as found also in our study. The higher prevalence of malnutrition till 3rd year even among ICDS beneficiaries was also reported by Swami et al[14] as similar to findings of our present study. The study of Gupta et al[15] had also reported that weight for age was significantly higher in ICDS group males aged 6 months to 3 years and female children aged 2 to 4 years, as similar to our study findings. The lack of coordination might also be responsible for higher prevalence of under nutrition in our study; as literature also reveals inadequate, ineffective and defective perceptions and uncoordinated efforts of PRIs, ICDS, and Health department reducing undernourishment in rural area of Delhi by Davey et al.[6]

Weight recording, plotting and identification of growth faltering of infants are a crucial activity of AWWs. Care of infants who are underweight is their one of the key job responsibilities. Anganwadi workers normally weigh all infants and they are responsible for follow-up of all children who have rehabilitated at nutritional rehabilitation centers. Anganwadi worker also assigns special days prior to village health nutrition day (VHND) for growth monitoring and promotion; those unable to come for weighment at the AW center are followed up and weighed during home visit by the AWW. Anganwadi workers normally also focus on caregivers of children with growth faltering which require attention and counseling. All of these activities, however, were not done properly and seriously by both AWWs (although AWW-2 was more poor in her efforts) in our study area as mothers were also less sensitized on importance of growth monitoring by AWWs as per our observations by secret customer technique. Our these findings are in consonance with study by Prinja et al (2007)[16] which had also enumerated the problem of under-nutrition persistence with low involvement of mother and Nutritional counseling of mothers of children aged 0 to 1 year is found to be an effective tool in positive behavioral modification and should be actively incorporated and emphasized. This aspect of AWWs services was also found a weaker aspect in our study area as only 32.6% of total mothers of infants received NHE for nutritional care of infants in both AWCs. Moreover, the key feeding factors, such as colostrum feeding, exclusive breastfeeding and introduction of semisolid feeding at 6 months of age; all of them were significantly associated with nutritional status of children in the AWC 2 area ($p < 0.05$) but not in AWC 1 area. The infants who did not receive colostrum feeding, who did not receive exclusive breastfeeding for 6 months as well as those who were not given semisolid feeding at the age of 6 months had higher % of malnourished children as seen in AWC 2 area as compared to AWC 1 area. This finding indicates that the impact of nutritional counseling AWW-2 on mothers might not be significant in augmenting nutritional literacy of mothers for nutritional care of their infants. This aspect has been emphasized in many studies by Taksande et al[17] Bhasin et al[18] and Kapil et al.[19]

Many reasons for this aspect have been found in our study as also found from previous studies in literature; such as the role of AWWs and in imparting breast-feeding and complementary feeding messages to family members (e.g. mother), which may also be responsible for poor nutritional services of ICDS scheme Taksande et al.[17] Bhasin et al[118] in their ICDS project study in Alipur area of the north Delhi on 83 AWWs found that 98.7% AWWs knew that breastfeeding should be begun immediately after birth; 92.7% knew that new borne should receive colostrums and only 56.6% knew that top milk should not be diluted. On child feeding—the incomplete knowledge of AWWs in child feeding and diseases was also found among AWWs by Kapil et al.[19]

It also appeared from our study that both AWWs had incomplete knowledge, poor nutritional education practices and their perceptions to improve this weak area was also not so positive and this finding is similar to study in Gujarat, India, by Parikh et al[20] where it was also found that the AWWs perceptions and knowledge with regard to the rationale for appropriate recommended child feeding practices promotion was also found to be poor.

However, study by Joshi et al[21] found that knowledge of urban AWWs to be significantly higher than their mothers and also in other groups of AWWs, this was in contrast to our present study. Although previous studies also reveal ineffectiveness and inefficiency of AWC services as similar to findings of our study, but some study, however, show a statistically significant, positive association between those receiving supplementary nutrition from AWCs and infant survival rate and there is variable effectiveness of AWCs nutritional services on infant survival in India, in contrast to our study.[22]

In urban ICDS blocks of Delhi, the similar kind of issue was also identified in study by Davey et al[23] and these authors; in their another study also suggested to focus on repeated practical reorientation training to strengthen the correct knowledge of the AWWs, which can increases their capabilities to take corrective and preven-

tive action at appropriate time for optimum development of nutritional status of the children.[24] So, AWWs need constant upgradation of their knowledge in nutritional care of infants in their area for a better positive impact.

LIMITATIONS OF STUDY

In our study, we carried out only survey on two AWCs area on small sample of infants (101) for nutritional services they received, so this may not be a complete and true picture for generalization of findings to the whole population due to constraints for set up in this study.

CONCLUSION

The widespread poor feeding practices and ignored aspect of nutrition education to mothers in India, especially in the 1000-day window of opportunity from conception until the child's second birthday needs urgent attention from ICDS program. Anganwadi workers needs to provide quality health and nutritional educational services toward mothers of infants on at least monthly basis; in which focus on types, quantity and quality of feeding of infants needs more focus, and this area also needs regular attention from healthcare system and ICDS properly. Older children up to 6 years can be studied further in future in detail on this aspect by mixed methods for better elucidation of this picture.

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ORIGINAL ARTICLE

Employee Satisfaction and the Role of Motivation: A Study of a Super-specialty Hospital

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ABSTRACT

Employee satisfaction plays a role in motivation and ultimately, overall productivity and bottomline results. Employees who are more satisfied in their positions have more reasons to work hard and contribute to a shared work ethic that encourages others to do the same. Likewise, drops in productivity may stem from low levels of worker satisfaction. This paper throws light on the role of motivation and employee satisfaction in a super specialty hospital. A questionnaire pertaining to various motivations related questions was distributed to various employees. The sample size was 118 and a combination of descriptive and exploratory research methodology was used. Nominal scale and likert five points scaling was used for measuring the satisfaction level. Data were analyzed using the Statistical Package for the Social Science (SPSS) software program version-16 and conclusions were drawn. Approximately 53% of the employees were satisfied with the promotion policy. Sixty percent of respondents were satisfied with the working atmosphere of the organization and 32% were satisfied with the remuneration they are receiving. This paper discusses such more aspects which play a role in motivation and suggest solutions to make employees satisfied with their job.

Keywords: Employee satisfaction, Hospital, Human resource management, Job satisfaction, Motivation.

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INTRODUCTION

Human resources are the most important among all the resources an organization owns that can lead the organization to long-lasting success. Retention of efficient and experienced workforce in an organization is very crucial in overall performance of an organization. Motivated employees can help to make an organization competitively more value added and profitable,[1] whereas dissatisfied employees tend to perform below their capabilities, result in high turnover of staff and leave their jobs relatively quickly, and are not very likely to recommend your organization as an employer.[2] Motivational factors play an important role in increasing employee job satisfaction which results in improving organizational performance.

This study throws light on the level of employee satisfaction and the role of motivation in the less satisfied ones of a super specialty hospital.

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MATERIALS AND METHODS

Research Methodology

The present study was conducted among employees of a super specialty hospital. The period of this study was 2 months (August to October 2014). The total number of questionnaires distributed was 150, out of which, 118 found to be completely filled. The response rate was 78.6%.

Tools and Techniques

Respondents were selected by 'convenient sampling' technique. The researcher has used combination of exploratory and descriptive research. The research tool was a structured, self-administered bilingual questionnaire. The instrument is validated and reliable as it is taken from standard survey resource of employee satisfaction. The questions are about the appreciation and the feeling of self-fulfillment they get or do not get from their work. Questions are on money, benefits, compensation, communication, job security, appreciation from managers, recognition, training and development and promotion. Nominal scale and likert five points scaling was used for measuring the satisfaction level. The rating was done as following: 5 = Highly satisfied, 4 = satisfied, 3 = neutral, 2 = unsatisfied, 1 = highly unsatisfied.

Ethical Considerations

The institutional ethical committee approved methodology and data collection procedure of the study. Participation was purely voluntary for the respondents. An employee having age above 18 years was included in

the study. No pressure or inducement of any kind was applied to encourage an individual to become included in the study. Before participation, all employees were notified about the study's aim, objectives and methods. Any employee had the right to abstain from participation or to terminate participation at any time. The identity of employees from whom information is obtained in the course of the study was kept strictly confidential. No information revealing the identity of any individual was included in the final report or in any other communication prepared in the course of the study.

STATISTICAL METHODS

Data were analyzed using the Statistical Package for the Social Science (SPSS) software program version-16. First, the mean, median, mode, standard deviation was calculated, and then test of significance applied to calculate the p-value at the 95% confidence interval.

RESULTS

Fifty-five percent of the employees were males and the rest were females. Approximately, 34% of the employees fall in the age group 40 to 49. Thirty-six percent of the respondents have a work experience greater than 10 years (Table 1). The employees who participated in this study comprises of 59 respondents from Nursing staff, 18 respondents from technical staff and 41 respondents from administrative staff (Table 2). Fifty-three percent of the respondents were satisfied with the promotion polices. Sixty percent of respondents were satisfied with the working atmosphere of the organization. Approximately 62% employees were highly satisfied with the decision making authority given to them. Fourteen percent employees were unsatisfied with the communication from management related to hospital updates. Seventy-seven percent employees were satisfied with the trainings provided by the hospital and 65% employees were satisfied with the facilities given by the organization (Table 3). Fifty-eight percent of the employees were not satisfied in terms of receiving personal satisfaction from their job. Seventy-one percent employees agreed upon recognizing and acknowledging their work by the organization (Table 4). Cross tables were made and test of significance was applied to various determinants. It showed borderline statistical significant association between training provided by the organization and respondents of age 20 to 29 ($p < 0.05$). There occurred a statistical significant association between the administrative staff and facilities given by the organization ($p < 0.01$). The employees who have spent more than 10 years in this organization showed a statistical significant relationship with the overall job security ($p < 0.05$).

Table 1: Sociodemographic distribution of respondents in a Super-specialty Hospital (n = 118)

Variables	*Frequency*	*Percentage*
Gender		
Males	65	55.08
Females	53	44.92
Age		
20–29	18	15.25
30–39	26	22.03
40–49	40	33.90
50 and above	34	28.81
Work experience		
0–2 years	20	16.95
2–5 years	23	19.49
5–10 years	33	27.97
More than 10 years	42	35.59

Table 2: Percentage of the type of staff who participated in this study (n = 118)

Type of staff	*Percentage*
Nursing	50
Technical	15
Administrative	35

Table 3: Frequency of responses to various parameters of motivation part (n = 118)

Sl. no.	*Parameter*	*Highly satisfied*	*Satisfied*	*Neutral*	*Unsatisfied*	*Highly unsatisfied*
1.	Team spirit of your team members	28	44	14	30	2
2.	Your direct supervisor as a positive role model	21	32	18	41	6
3.	With your overall job security	39	55	2	14	8
4.	With the work environment	25	46	17	24	6
5.	With the salary provided by the organization	17	21	7	48	25
6.	With decision-making authority	44	30	6	21	17
7.	With promotion policy	39	24	3	42	10
8.	With opportunity to utilize your skills and talents	19	20	12	43	24
9.	With communication from management related to hospital updates	40	46	15	11	6
10.	With the training provided by the hospital	38	53	8	14	5
11.	With the facilities given by organization	34	43	14	15	12

Table 4: Percentage of responses to various parameters of motivation part (n = 118)

Sl. no.	*Parameter*	*Yes (%)*	*No (%)*
1.	Does your job give you a sense of personal satisfaction?	42	58
2.	Organization recognizes and acknowledges your work	71	39

DISCUSSION

Motivation is going to work if the right person with suitable skills is made responsible for the job or otherwise it will be the wastage of resources and time, and lead to job dissatisfaction.[3] Employee job satisfaction (EJS) is the feelings and thoughts of employees about their work and place of work. In result, job satisfaction is all about to satisfy one's needs in working place.[4] Job satisfaction can be typically defined as the emotional reaction of an employee toward work, on the basis of comparing the actual results and the expected ones.[5] The process of motivation usually starts with someone recognizing an unsatisfied need. Then, a goal is established to be reached and that way to satisfy the need. Motivation is the driving force in any individual which moves him (or her) to act in a certain way. It is what drives your employees to give their best for your business.[6] Find out what motivates man, touch that button to turn the key that makes men achieve.[7] Every organization's work culture is different, the needs of the employees should be understood and they should be imparted with different trainings, personal development and an atmosphere for freely expression of ideas which could be adopted for the betterment of the organization which in turn enhances productivity. Incentives, rewards and recognitions are the prime factors that impact on employee motivation. According to Baum (1995), HR progress through education, training, and development of employees at all levels which is a vital component in sustaining the industry's competitiveness in the international arena.[8] According to Herzberg, money is listed as a hygiene factor which is likely to cause job dissatisfaction. Salary is a thing that is expected to be at a certain level and comparable to the amount of work the employee does. Only 32% employees were satisfied in terms of remuneration they are receiving which means that the salary is not meeting the expectations of the employees which could hamper productivity in the long run. The management should take into account this factor, because when it is improved, it can raise the motivation of the employees which in turn enhances the productivity. Seventy-one percent employees agreed upon recognizing and acknowledging their work by the organization. This is in consistent with the study conducted by Gupta and Garg.[9] Fifty-eight percent of the employees were unsatisfied from their job in terms of personal satisfaction. Seventy-one percent employees agreed upon recognizing and acknowledging their work by the organization. Fifty-three percent of the respondents were satisfied with the promotion polices. Administration should take steps to gain more satisfaction of the employees in terms of promotion. Star employee of the month for nursing, technical and administrative staff could be a solution and these recognitions shall be attached in the employees' personal files, and, hence, promotions shall be given by keeping in mind these recognitions. Eighty percent of respondents were satisfied with their overall job security which is in contrast to the study conducted by Parvin and Kabir, who found 61% satisfaction.[10] Employees who feel their future is successful in the organization work better than those who are insecure about it. Job security plays a factor of intrinsic motivation. Approximately 45% of respondents were satisfied with their direct supervisor as a positive role model. Herzberg listed this factor as hygiene factor which could cause job dissatisfaction. Relationship with the immediate supervisor and their outlook toward him/ her plays an important factor in job satisfaction because if the relationship between the immediate supervisor and the employee is cordial, lot of misunderstandings could be sorted out which in turn results in a positive atmosphere which ultimately motivates the employee. Communication is essential among peers and at different hierarchical level. The employees feel that someone is listening to their concerns, suggestions. The employees in this hospital are fairly satisfied with the communication inside the company. Only 33% employees were highly satisfied with the opportunity to utilize their skills and talents. The management should take enough steps to provide them with a platform where the employees can express their views come up with recommendations and suggestions for improvement. Not many studies have been conducted in a hospital to measure the satisfaction levels of its employees. Research on the role of motivation in heathcare industry is still in infant stage. Future work to discover more such aspects may pave ways for many new ideas to gain productivity from the employees.

Questionnaire

Sociodemographic details					
• Name (optional)					
• Gender	• Male	• Female			
• Age (years)	• 20–29 years	• 30–39 years	• 40–49 years	• 50 and above	
• Work experience	• 0–2 years	• 2–5 years	• 5–10 years	• More than 10 years	
• Type of staff	• Technical	• Administration	• Nursing staff		
Parameters					
• Team spirit of your team members	1	2	3	4	5
• Your direct supervisor as a positive role model	1	2	3	4	5
• With your overall job security	1	2	3	4	5
• With the work environment	1	2	3	4	5
• With the salary provided by the organization	1	2	3	4	5
• With decision-making authority	1	2	3	4	5
• With promotion policy	1	2	3	4	5
• With opportunity to utilize your skills and talents	1	2	3	4	5
• With communication from management related to hospital updates	1	2	3	4	5
• With the training provided by the hospital	1	2	3	4	5
• With the facilities given by organization	1	2	3	4	5
• Does your job give you a sense of personal satisfaction?	Yes	No			
• Organization recognizes and acknowledges your work	Yes	No			

This questionnaire is prepared for assessing the satisfaction of employees in our hospital. Your cooperation will be highly appreciated. Your reply will be kept confidential. Therefore, please feel free to answer the questions. Please mark tick (√) on the suitable response. Scale to measure satisfaction: 5 = Highly satisfied; 4 = Satisfied; 3 = Neutral; 2 = Unsatisfied and 1 = Highly unsatisfied

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ORIGINAL ARTICLE

Transfusion Reaction Reporting Culture in Hemovigilance Program of India since Its Inception

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ABSTRACT

Hemovigilance Program of India (HvPI) at the national level was launched on 10th December 2012 by National Institute of Biologicals (NIB), Noida, Ministry of Health and Family Welfare, Government of India as the National Coordinating Centre (NCC). Awareness about the program, its objectives and its nonpunitive implications are being generated through organizing continuing medical educations (CMEs) on HvPI in different regions of the country from time to time. A total of 24 CMEs on HvPI have been organized all across the country. The study shows that creating awareness about this progam among healthcare professionals has resulted in substantial increase in number of center enrolled under HvPI as well as number of reporting of transfusion reactions under HvPI since the inception of this program.

Keywords: Clinicians and nurses, Continuing medical education, Hemovigilance, Reporting culture, Transfusion reactions.

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INTRODUCTION

Although blood transfusions can be life-saving, they are not without risks. Blood is being tested using advance technologies which has resulted in decrease risk of transfusion transmitted viral disease. However, there are variety of transfusion risks involved which cannot be entirely eliminated, several of which are noninfectious in nature.[1-4]

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Hemovigilance is an important tool for improving blood safety. Hemovigilance data provides valuable information wrt transfusion reactions in recipient of blood transfusion as well as complications in donors. It is defined as a set of surveillance procedures covering the whole blood transfusion chain from the collection of the blood and its components to the follow-up of its recipients, intended to collect and access information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent its occurrence and reoccurrence.[5] A centralized hemovigilance program to assure patient safety and to promote public health was launched for the first time in India on December 10, 2012, in 60 medical colleges in the first phase along with a well-structured program for monitoring adverse reactions associated with blood transfusion and blood product administration. National Institute of Biologicals (NIB) is the National Coordinating Center (NCC) for Hemovigilance Program of India (HvPI).[6]

MATERIALS AND METHODS

A total of 2737 transfusion reactions have been reported to HvPI since the inception of this program, i.e. from 10th December 2012 till 31st August 2015 and were analyzed. These reports are being forwarded through a hemovigil software which facilitate collection and collation of data in transfusion reaction reporting form (TRRF) from various centers across the country and transmit this data to NCC at NIB.[7]

A total of 24 continuing medical educations (CMEs) on HvPI have been organized all across the country. During the year 2012 to 2013, CMEs on hemovigilance were organized mainly for the personnel involved in blood banks and transfusion medicines departments. However, it was felt that, since the clinicians and nurses are important link to success of this program, dissemination information about the importance and need of the program may boost up the reporting to HvPI. The first CME on hemovigilance for clinicians was organized on 26th April 2014 at Government Medical College, Chandigarh. Thereafter, in every CME on hemovigilance organized by NIB, clinicians and nurses were actively involved as participants, panelists and speakers.

OBSERVATIONS

On analyzing the transfusion reaction, data reported to HvPI, it was observed that, out of 226 centers enrolled under hemovigilance program, 76 centers are actively reporting. The reporting centers included blood banks of medical institute (government/private), hospitals (government/private/charitable) and standalone blood banks. A total of 31 centers out of 76 centers reporting centers were from government medical colleges/hospitals, i.e. 40.78%, and rest 45 centers were from private/charitable/standalone blood banks, i.e. 59.22% (Fig. 1).

This study revealed that the number of centers enrolled during 1st year after the inception of the program were 117 (2012–2013), which increased to 184 for the second year (2013–2014) and till date 226 centers are enrolled under this program. Also number of transfusion reactions reported to hemovigilance program of India were 477 during 1st year after the inception of the program, which increased to 1665 for the second year (2013–2014) and till date 2737 transfusion reactions have been reported to this program.

It was observed that there was an increase in number of centers being enrolled under HvPI and the rate of reporting were also consistently increasing after dissemination information through HvPI newsletter, pamphlets, awareness programs and circulating updates to the center via e-mails (Graph 1). Also, involving clinicians and nurses in the awareness programs resulted in more number of centers being enrolled, and hence increased the frequency of reporting of transfusion reactions.

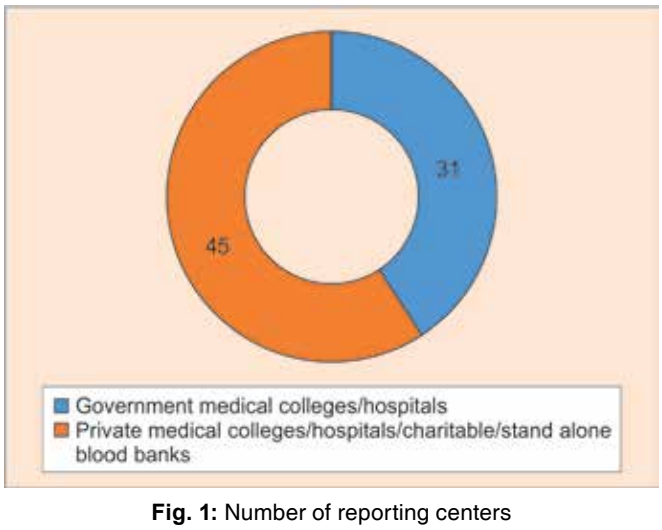
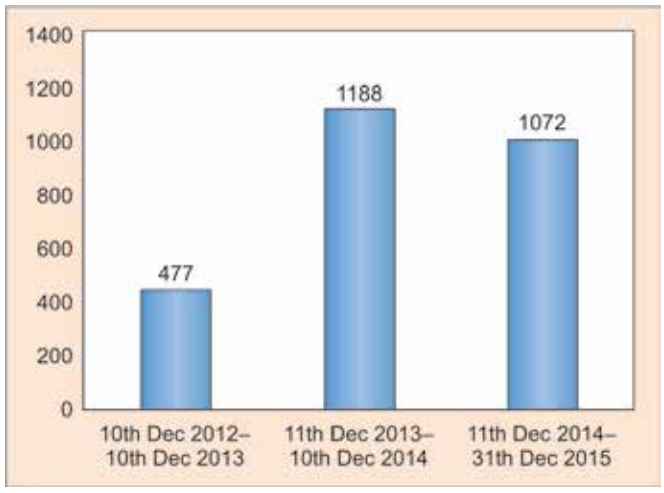


Fig. 1: Number of reporting centers



Graph 1: Number of transfusion reaction reported under HvPI

CONCLUSION

This study may be useful in devising strategies to create awareness about the program among healthcare professional and devising format to assess the problems wrt reporting of transfusion reaction by the enrolled centers under the hemovigilance program. Further, when compared the progress of this programs since its inception, i.e. from 10th December 2015, it is evident that awareness programs to sensitize the healthcare professionals is an essential tool to improve and strengthen the hemovigilance.

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ORIGINAL ARTICLE

A Study of Patient-Physician Communication and Barriers in Communication

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ABSTRACT

Context: Effective doctor-patient communication is the basic requirement in building a good doctor-patient relationship. Safe practices and effective, patient-centered communication is key to quality care. Good doctor-patient communication has the potential to help regulate patients' emotions, facilitate comprehension of medical information and allow for better identification of patients' needs, perceptions and expectations. Doctors with better communication and interpersonal skills are able to detect problems earlier, can prevent medical crisis and expensive intervention, and provide better support to their patients.

Current research indicates that ineffective communication among healthcare professionals is one of the leading causes of medical errors and patient harm. There are many barriers to good communication in the doctor-patient relationship, including patients' anxiety and fear, doctors' burden of work, fear of litigation, fear of physical or verbal abuse, and unrealistic patient expectations. National accreditation board for hospitals and healthcare providers (NABH) standards and international patient safety goals focus on the importance of effective communication in healthcare settings and how it leads to patient safety.

This study is an attempt to identify gaps in patient physician communication in the current healthcare settings, find the barriers in communication and give recommendation to enhance good practices in the future.

Aims: The aim of the study is to analyze the current levels of effective patient communication in a tertiary care hospital in Delhi-NCR with help of a self-administered questionnaire. The study will assess the level of information shared with the patient.

Settings and design: The design of our proposed study is a descriptive study where we will use a self-administered questionnaire to assess the level of patient-physician communication in the selected study setting.

Materials and methods: The NABH standard were used as a guideline for preparing the self-administered questionnaire. All admitted vulnerable patients of the selected study area will consist of the population for the study. Simple random sampling technique will be used to derive the sample out of the population.

Statistical analysis used: Correlation and analysis of variance (ANOVA) were used to establish associations between the independent and dependent variables.

Results: The study shows that 48% of the respondents were of opinion that they were given partial information, while 20% of the respondents alleged that they were not given any information about the explanation of their disease, its prognosis and the treatment option that were available, i.e. a total of 62% of the patients said that they had partial information to complete lack of information that would have made them aware of their diseases, its prognosis and the treatments options available to cure it, while only 32% of the patients agreed that they were supplied with thorough information during their interaction with the physicians.

Conclusion: The majority of the patients were not well-informed about their disease, its prognosis, treatment plan and continuity of care. There was a significant positive correlation between the communication made at initial stages of hospital stay and during the end stages of stay of patient. The main barrier to patient physician communication was time.

Keywords: Barriers in communication, IPSG, NABH, Patient-physician communication.

Key message: To ensure patient safety, it is imperative to inform patients about all the important aspects starting from admission till discharge.

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INTRODUCTION

Successful medical encounters require effective communication between the patient and the physician. 'Success' implies that the patient and physician have developed a 'partnership' and the patient has been fully educated in the nature of his or her condition and the different methods to address the problem. This allows the patient to be actively involved in the decision-making process and

establishes agreed upon expectations and goals.[1] Effective doctor-patient communication is the basic requirement in building a good doctor-patient relationship and to get better clinical outcomes. Safe practices and effective, patient-centered communication is key to quality care. Good communication is both an ethical imperative, necessary for informed consent and effective patient engagement, and a means to avoid errors, improve quality and achieve better and safer health outcomes. The ultimate objective of any doctor-patient communication is to improve the patient's health and medical care.

Good doctor-patient communication has the potential to help regulate patients' emotions, facilitate comprehension of medical information, and allow for better identification of patients' needs, perceptions and expectations. Doctors with better communication and interpersonal skills are able to detect problems earlier, can prevent medical crisis and expensive intervention, and provide better support to their patients. Effective patient physician communication leads to patient satisfaction. According to Shukla,[10] doctor-patient communication is important since it leads to improved compliance with medical treatment, better health and functional status, enhanced clinician and patient satisfaction and also reduces risk of medical malpractices. It is observed in hospitals that when patient physician appointments are of longer durations, doctors ask significantly more questions and make more statements explaining the problem and its management, while patients ask significantly more questions and make more statements of their own ideas about the problem. The entire process from entry to discharge has to be completed within a stipulated time frame and hence it becomes imperative for all the crucial communications to be made within that time with regard to treatment plan, possible complications, medication, prevention techniques, etc.

Kirstein Weir comments on how effective communication is linked to many positive medical outcomes. Research shows 'good communication is associated with patient adherence to treatment, control of symptoms, control of pain and patient satisfaction.' Informed patients are also more likely to decline elective surgeries and disease screenings that could lead to risks from false positives and unnecessary interventions (Weir 2012).[11] has pointed out that most of the studies reviewed demonstrated a correlation between effective physician-patient communication and improved patient health outcomes. The components of effective communication identified by these studies can be used as the basis both for curriculum development in medical education and for patient education programs. Future research should focus on evaluating such educational programs.[11]

Current research indicates that ineffective communication among healthcare professionals is one of the leading causes of medical errors and patient harm. Research conducted during the 10 years period of 1995 to 2005 has demonstrated that ineffective team communication is the root cause for nearly 66% of all medical errors during that period. This means that when healthcare team members do not communicate effectively, patient care often suffers. In his work, '5 side-effects of Ineffective Communication', Hicks[5] said that incomplete or inaccurate patient records and communication breakdowns can have serious consequences for the medical office and its patients. One vital piece of information not communicated can have disastrous results. Although some mishaps are unavoidable, effective communication can result in better outcomes for patients and the overall success of the medical office. Further, medical error vulnerability is increased when healthcare team members are under stress, are in high-task situations, and when they are not communicating clearly or effectively.[4] A review of reports from the Joint Commission reveals that communication failures were implicated at the root of over 70% of sentinel events (Joint Commission on Accreditation of Healthcare Organizations, 2005). In another study, conducted to examine factors that prompted families to file malpractice claims against doctors following perinatal injuries, it was shown that communication was an important factor that was related to these malpractice claims. The same authors also found that physicians who had been sued frequently were also the ones who received frequent complaints regarding the interpersonal care that they provided for patients, even by patients that never sued. The complaints from these patients included 'a feeling of being rushed', 'being neglected' and a lack of explanations for tests performed.[10] Other barriers to good communication in the doctor-patient relationship, include patients' anxiety and fear, doctors' burden of work, fear of litigation, fear of physical or verbal abuse, and unrealistic patient expectations.

According to Huntington and Kuhn,[6] the 'root cause' of malpractice claims is a breakdown in communication between physician and patient. Previous researches that examined plaintiff depositions found that 71% of the malpractice claims were initiated as a result of a physician-patient relationship problem. Closer inspection found that most litigious patients perceived their physician as uncaring. The same researchers found that one out of four plaintiffs in malpractice cases reported poor delivery of medical information, with 13% citing poor listening on the part of the physician.[3,6] Interviews with patients who have filed malpractice suits against their physicians often site poor communication and lack of empathy as a factor in pursuing legal action.[2]

National Accreditation Board for Hospitals and Healthcare providers (NABH) standards provide framework for ensuring patient safety and quality of patient care. The international patient safety goals also emphasizes the importance of effective communication in delivery of safe and effective patient care. This study aims to analyze the current levels of effective patient communication in a tertiary care hospital in Delhi-NCR with help of a self-administered questionnaire. The study will assess the level of information shared with the patient. Many models have been developed to assist healthcare providers in developing approaches to improve their ability to communicate with their patients. These models focus on improvement in the quality of the encounter and do not necessarily require any significant increased investment in the length of the encounter. These approaches have been demonstrated to improve patient satisfaction and also allow the provider to demonstrate empathy, concern and humanism.[3] It is clear from the study done by Kurtz et al[9] that better physician communication skills improve patient satisfaction and clinical outcomes and that good communication skill can be taught and learned. It is important that physicians learn the principles of good physician-patient communication and apply them in clinical practice. Medical education programs at all levels should include teaching of physician-patient communication.[9]

The reference for designing the questionnaire of this study is taken from patient rights and education (PRE). The chapter PRE specially emphasizes on the importance of communication and also has identified key areas of communication which are important for patients.

RESEARCH DESIGN

The current study was conducted at a super-specialty hospital. A descriptive research design was utilized in the current study. This design is concerned with description of a phenomenon of interest and focused on a single group or population characteristics without trying to make interference. A sample of convenience including 70 patients, representing all those who are admitted in the IPD units of the selected study setting was taken. A structured questionnaire was developed, tested for clarity and feasibility, and then used to collect data. Development of this questionnaire was guided by NABH Standards (Patient Rights and Education Chapter). Designed tools were examined for content validity by a panel of five experts.

Ethical Clearance and Confidentiality

The current study was approved by ethical committee of the selected Hospital. Confidentiality and anonymity of each subject were assured through coding of all data.

METHODOLOGY

The current study was conducted in two phases: the preparation phase and implementation phase. As regards to the preparation phase, it was concerned with construction and preparation of data collection tools, in addition to obtaining managerial agreement to carry out the study. This phase lasted for about 4 months. Concerning the implementation phase, it was carried out after obtaining official permissions to carry out the study. Data of the current study were collected over a period of 4 months starting from Oct 2014 to Jan 2015. The researcher/research associate was available during the time of filling the data collection sheet to answer any question, and to provide the needed explanations. Filling the questionnaire required about 15 minutes from each patient. Obtained data were fed into Microsoft Excel for further analysis.

The questionnaire had two parts: Part 1 was aimed to record the demographic details, i.e. gender and age of the respondents, while part 2 of the questionnaire had 14 questions pertaining to patient-physician communication. Fourteen questions were categorized into four categories: Patient-awareness communication (3 questions), patient-care communication (4 questions) which included patient-physician question pertaining to initial and regular assessment and treatment-related communication between patients and physician, patient-discharge communication (4 questions) and patient-rights communication (2 questions) which included education about patient and family rights.

RESULTS AND DISCUSSION

Table 1 presents the descriptive statistics for patient communication. There were 14 questions pertaining to patient communication and 70 respondents were picked up for the survey. Maximum score for each question was 3, i.e. maximum possible score that could be scored from 14 questions was 42. However, the mean score was 29.80 which indicated a gap in the patient communication. Low standard error of 0.89 along with low skewness of –0.14 further indicated low variance among the responses, i.e. there was uniformity among the patients' responses.

Patient Communication

Graph 1 shows that 62% of the patients said that they had partial information to complete lack of information that would have made them aware of their diseases, its prognosis and the treatments options those were available to cure it, while only 32% of the patients agreed that they were supplied with thorough information during their interaction with the physicians. As many as 48% of the respondents were of opinion that they were

Table 1: Descriptive statistics for patient communication

N = Number of questions	14.00
Maximum possible score	42.00
Mean	29.80
Standard error	0.89
Skewness	–0.14
Range	23.00
Minimum	18.00
Maximum	41.00
Count = Number of respondents	70.00

given partial information, while 20% of the respondents alleged that they were not given any information about the explanation of their disease, its prognosis and the treatment option those were available.

The above pie diagram depicts the overall scenario of patient communication while the below subsections are dedicated for more in-depth analysis of patient communication.

Patient-awareness Communication

Graph 2 shows that as high as 60% of the patients accepted that they received partial information which could make them aware of their diseases and treatment options and 17% of the respondents alleged that they were not given information. Only 23% of the patients agreed that they were supplied with thorough information during their interaction with the physicians. Thus out of every 100 patients, 77 patients remain unaware of their diseases and treatment options, which is a matter of concern for the patients' well-being.

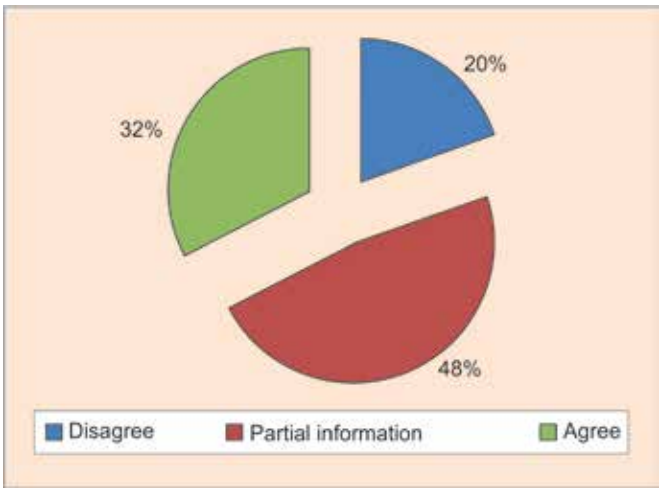
Graph 3 gives a more detailed scenario of the patient awareness communication. Majority of the patients accepted that they were given only partial information for all the questions related to 'patient awareness regarding medical conditions' (That is AW1 'Have you been explained about your medical condition?', AW2, 'Have you been explained about the prognosis of your medical condition?' and AW3 'Have you been told about the treatment options available?'). For the question, 'Have you been explained about your medical condition?', 56% of the patients said that the physician did not explain their disease fully to them, while as many as 50% said they were not being explained clearly about the prognosis of their disease. A staggering 74% of the patients said that they were not given complete information about the treatment options that were available. For each case, 23, 27 and 20% of the patients agreed that they received complete information. Hence, 77, 73 and 80% patients had partial to no information about their disease, prognosis of their disease and the treatment options available.

Patient-care Communication

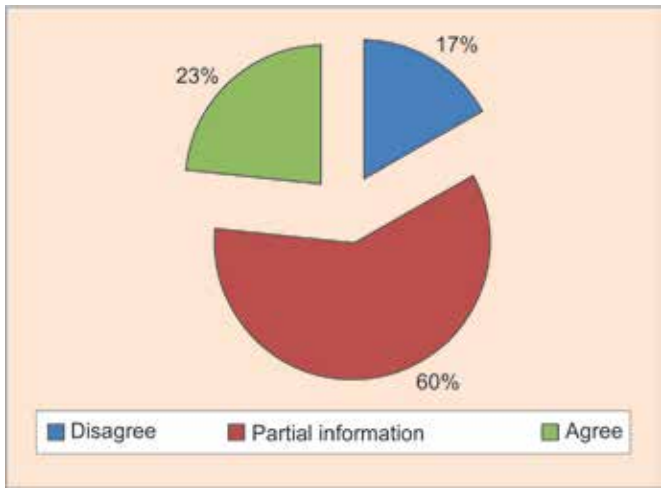
From Graph 4, it can be found that 62% of the patients proceed with the treatment without having complete knowledge of the aspects that are related to the treatment procedure.

Graph 4 shows that 38% of the patients agreed that they were supplied with thorough information during their interaction with the physicians regarding the treatment procedure and the aspects related to it, while 36% of the patients said that they received partial information related to treatment procedure, associated risks of the treatment, the duration of the treatment and the part/pre-preparation that needs to be done for the treatment while 26% of the respondents alleged that they were not given any information.

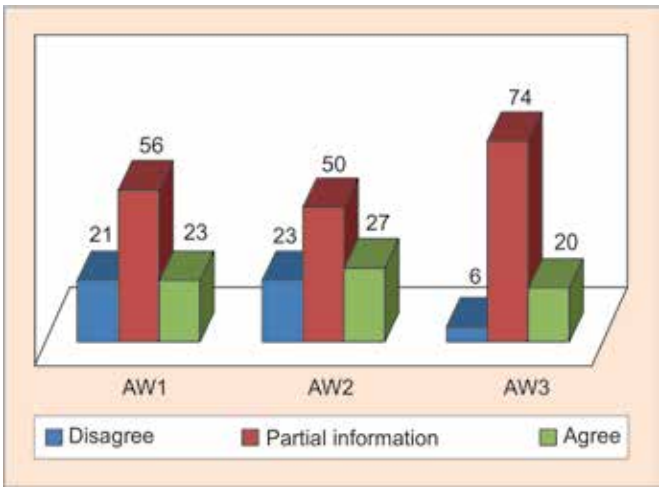
Graph 5 gives a more detailed scenario of the patient-care communication. While 43 and 44% of the patients agreed to that they were given complete explanation of their treatment procedure and the duration of it, only 25% of the patients accepted that they were given complete



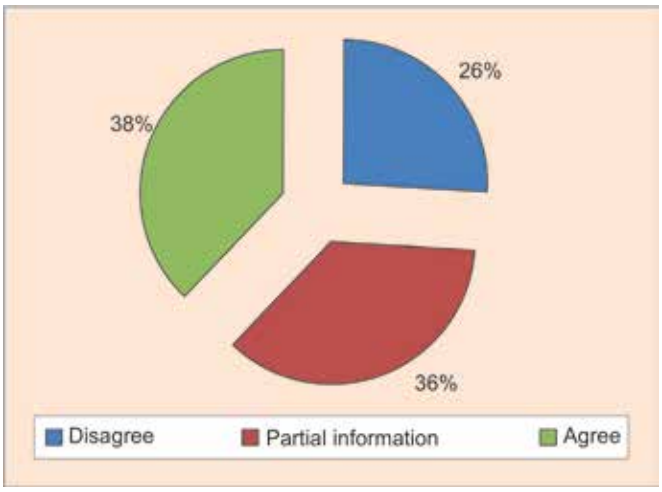
Graph 1: Patients' responses on patient communication



Graph 2: Patients' responses on patient awareness communication



Graph 3: Percentage distribution of responses on patient awareness communication



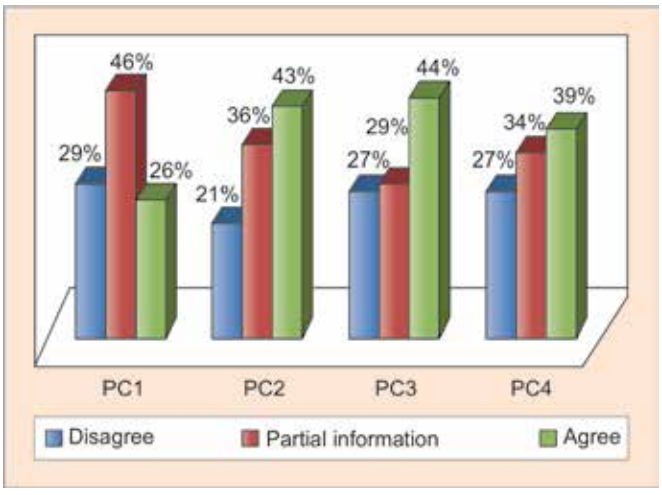
Graph 4: Patients' responses on patient care communication

knowledge of the associated risks of their treatment procedure, i.e. as high as 75% of the patients went ahead with the treatment procedure without having adequate information of the associated risks and hazards of their treatment procedure, of which 29% of the patients were not given any information and 46% of them were given superficial information. Thirty-nine percent of the patients accepted that they knew about the part/pre-preparations that should be done before the treatment while 27% of them said they had no information at all and 34% said that they had partial knowledge. Hence, 61% patients were without proper information about the part/pre-preparation that needed to be done before treatment.

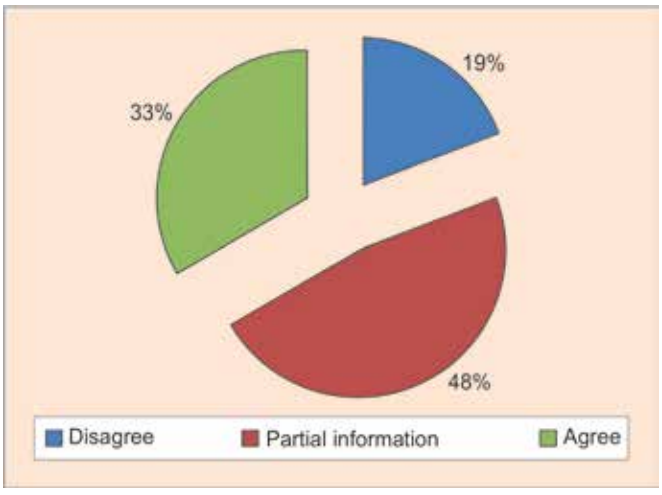
Patient-discharge Communication

Graph 6 shows that 33% of the patients accepted that they were given complete information about the lifestyle they should follow, the diet they should follow and the medicines they should take along with their timings, i.e. 67% of the patients admitted they left the healthcare unit without complete information of which, 19% said they were not given any advice while 48% of the patients said they were given partial information about the lifestyle and diet after discharge, along with the medicines that they must have with the timings of the medicines as well.

Graph 7 gives a more detailed scenario of the patient-discharge communication. A total of 44% of the patients agreed that they had complete information about the precautions that they should follow after discharge, 47% of the patients said that they had only partial information about it, while 9% said that they had no information at all. A total of 66% of the patients had partial information about the medicines that should follow and about the interaction of the drugs with the patients, while 34% agreed that they had complete information. The 33 and 32% of the patients had complete knowledge about the possible side effects of the medicines and the diet that they should follow, i.e. 67% of the patients were



Graph 5: Percentage distribution of responses on patient care communication



Graph 6: Patients' responses on patient discharge communication

not completely aware of the possible side effects of the medicines, of which 11% had no information at all while 56% of the patients accepted that they were given partial information about it.

Patient-rights Communication

Graph 8 shows that 33% of the patients accepted that they were given complete information about their rights as the patients which implies that. A total of 67% of the patients admitted they left the healthcare unit without complete information of which, 12% said they did not receive any education on patient rights while 55% of the patients said they were given partial information about their rights and claims as the patients.

Graph 9 gives a more detailed scenario of the patient rights communication. A total of 37% of the patients agreed that they had complete information about the procedure to obtain urgent follow-up. A total of 49% of the patients said that they had only partial information about it, while 14% said that they had no information at all. A total of 61% of the patients had partial information about their rights and responsibilities, while 29% agreed that they were completely aware of it. However, 10% of the patients said that they had no information about their rights and responsibilities.

Hypothesis 1 (H1): There is an association among patient awareness communication, patient care communication, patient discharge communication and patient rights communication.

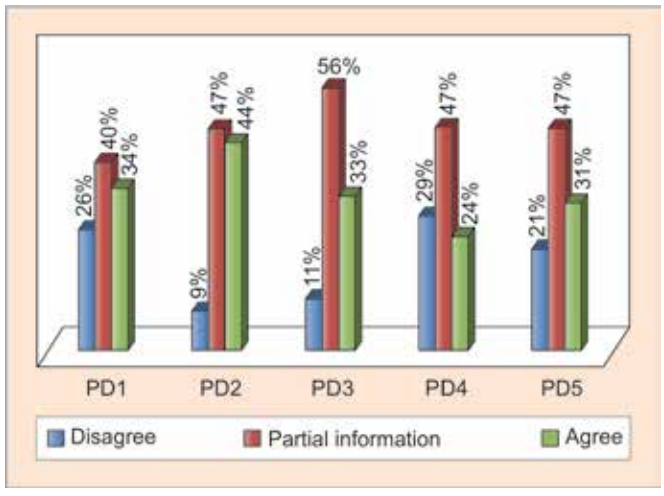
Table 2 suggested that there were moderate to high degree of positive linear association among patient awareness communication, patient care communication, patient discharge communication and patient rights communication.

Hypothesis 2 (H2): Age of the patients has an impact on patient communication.

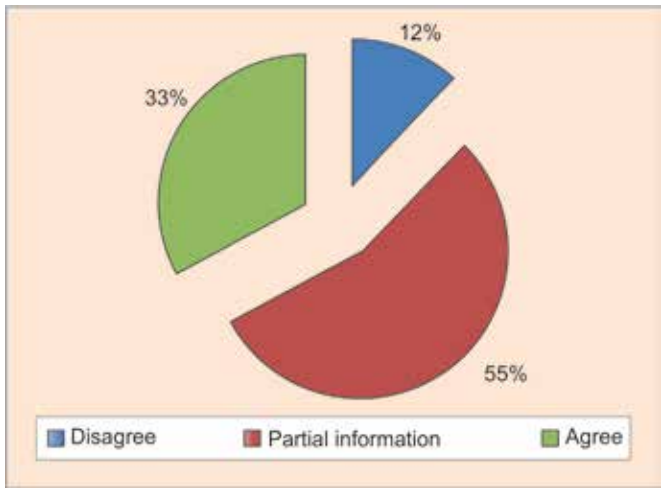
Table 3 suggests that age of the patients impacted their communication with the physician. The Table 3 suggested that the scores of the patients with in the age groups 20 to 30 years and 30 to 40 years were higher than the patients between the age groups below 20 years and above 40 years. This could be due to the reason that

Table 2: Correlation among patient awareness communication, patient care communication, patient-discharge communication and patient-rights communication

	Patient awareness	*Patient care*	*Patient discharge*	*Patient-rights*
Patient awareness	1.00	—	—	—
Patient care	0.78	1.00	—	—
Patient-discharge	0.71	0.89	1.00	—
Patient-rights	0.56	0.76	0.77	1.00



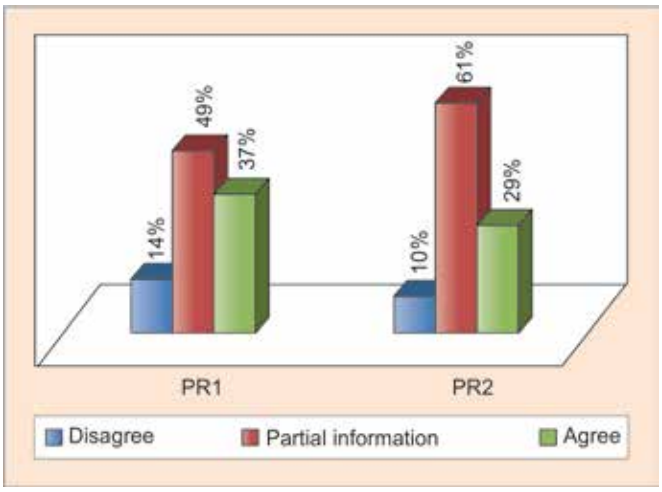
Graph 7: Percentage distribution of responses on patient-discharge communication



Graph 8: Patients' responses on patient-rights communication

Table 3: ANOVA results—impact of age on patient awareness communication, patient care communication, patient discharge communication and patient rights communication

Groups	*Count*	*PA mean*	*PC mean*	*PD mean*	*PR mean*	*Allover*
Below 20	7	4.86	5.71	7.00	3.14	20.71
20–30	15	7.40	9.73	12.73	5.07	34.93
30–40	23	7.22	11.48	13.30	5.30	37.30
Above 40	25	4.92	5.72	8.16	3.56	22.36
F-statistics		38.74	182.62	139.07	44.43	388.17
p-values		0.000	0.000	0.000	0.000	0.000



Graph 9: Percentage distribution of responses on patient-rights communication

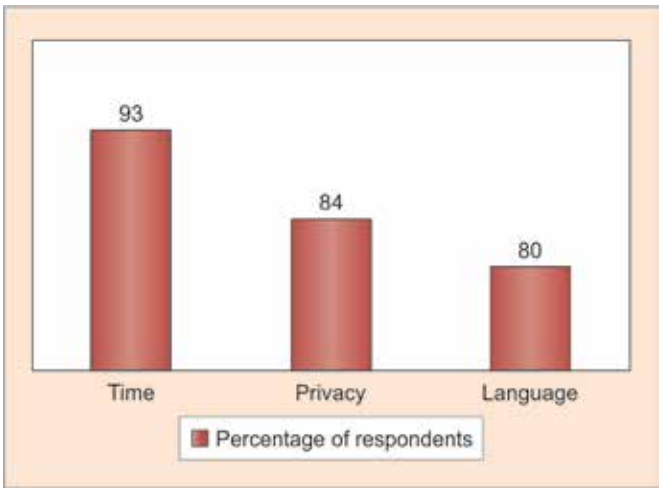
patients who were between 20 and 30 years and 30 to 40 years were young and they were more aware of the everything around them, and hence could understand things from a better perspective and might have asked questions to clear their doubts, while the patients who were above 40 years were relatively elder and they might not have asked questions to clear doubts.

Hypothesis 3 (H3): Gender has an impact on patient communication.

Table 4 depicts the impact of gender of the patient upon their communication with the physician. The Table 4 indicates that though gender has no role for the majority of patient-physician communication; however, it has an impact upon patient awareness communication, where the scores of the male patients were significantly higher than the female counterparts.

BARRIERS IN COMMUNICATION

Table 5 and Graph 10 depict the patients' responses on factors those were possible barriers in effective communication with the physician. When the patients were being asked about the barriers in their interaction with the physician, most of the patients chose more than one option out of the three options they were given. A total of 93% of the patients (65 out of 70) said that the physician did not give them enough time to interact and was in a hurry to get over with the session, while 84% of the patients (59 out of 70) said that they could not discuss their matter at length with the physician since they felt too shy to talk about it and felt that their privacy might be breached. A total of 80% of the patients (56 out of 70) said language was the barrier in their interaction with the physician.



Graph 10: Percentage of responses on barriers in communication

Table 4: Independent t-test results—impact of gender on patient awareness communication, patient care communication, patient discharge communication and patient rights communication

Impact of gender on patient communication: t-test					
	Mean score				
	Male	*Female*	*Difference*	*t-statistics*	*p-value*
Patient awareness communication	6.179	4.024	2.155	6.674	0.000
Patient care communication	8.429	8.500	–0.071	–0.105	0.917
Patient discharge communication	10.679	10.738	–0.060	–0.086	0.932
Patient rights communication	4.571	4.310	0.262	0.991	0.325
All over patient communication	29.857	29.762	0.095	0.052	0.959

Table 5: Barriers in communication

No. of respondents	*Time*	*Privacy*	*Language*
	65	59	56

CONCLUSION

Hence, the findings of the study reveal that majority of the patients were not informed about the crucial information required at different stages of patient care process. As supported by various studies[7-9] an effective patient physician communication leads to better patient care while lack of physician-patient communication can compromise with the safety of patients.

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ORIGINAL ARTICLE

An Analysis of Knowledge, Attitude and Practices regarding Standard Precautions of Infection Control and Impact of Knowledge and Attitude of ICU Nurses on Self-reported Practices of Infection Control

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ABSTRACT

Context: World Health Organization (WHO) defines healthcare-associated infection (HCAI) as infection acquired in hospital or a healthcare setting by a patient who was admitted for a reason other than that infection. The healthcare associated infections are one of the leading causes of mortality, morbidity and increase cost. Adherence to standard precautions for infection control and simple techniques like effective hand hygiene is essential for reducing healthcare associated infections. However, compliance of healthcare workers to hand hygiene (HH) guidelines are reportedly poor. It is important, therefore, to instill adequate knowledge and good attitudes and practices at the time of primary training of the healthcare workers. This study is an attempt to identify gaps in knowledge, attitudes and practices (KAP) to improve existing training programs and give recommendation to enhance good practices in the future.

Aims: The aim of the study is to analyze KAP of nursing professionals of intensive care units (ICUs) in a tertiary care hospital and to find the impact of knowledge and attitude of the ICU nurses on self-reported practices.

Settings and design: The study design is a survey research which has used a self-administered questionnaire to compare the KAP of nursing professionals of an ICU in a tertiary care hospital.

Materials and methods: The WHO standard precautions for infection control were used as a guideline for preparing the self-administered questionnaire. The scoring system was based on a study done by Uba et al (2015).

Statistical analysis: Correlation and analysis of variance (ANOVA) were used to establish associations between the independent and dependent variables.

Results: Participants had an average level of knowledge (79%), good attitude (89%) toward infection control guidelines and very good self-reported practices (91%). The collective KAP score of all the participants is good (85%) which indicates that average levels of knowledge are balanced by good attitude and very good practices. However, good knowledge is crucial for ensuring expected levels of infection control practices, and hence ensures patient safety.

Conclusion: To achieve an environment of patient safety, it is essential that the healthcare staff should have sound knowledge and positive attitude. The study shows the need for further improvement of the existing infection control training programs to address the gaps in KAP.

Keywords: Attitude, Healthcare-associated infections Infection control, Knowledge, Practice, Standard precautions.

Key message: Good knowledge and positive attitude are essential for attaining expected levels of infection control practices among critical care nurses.

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INTRODUCTION

A nosocomial infection also called 'hospital acquired infection' can be defined as: An infection acquired in hospital by a patient who was admitted for a reason other than that infection.[1-3] The infection might not be necessarily acquired in a hospital, they may occur in any other healthcare facility as well, therefore, they are more appropriately known as healthcare-associated infection (HCAI). A healthcare associated infection is that infection which was not present or incubating at the time of admission and includes infections acquired in the hospital but appearing after discharge, including occupational infections among healthcare staff of the facility.[4]

A survey conducted under the support of World Health Organization (WHO) in 55 hospitals of 14 countries representing four WHO regions (Europe, Eastern Mediterranean, South-East Asia and Western Pacific) showed an average of 8.7% of hospital patients had healthcare associated infections. At any time, over 1.4 million people worldwide suffer from infectious complications acquired in hospital.[5] The most commonly occurring healthcare acquired infections were pneumonia and lower respiratory tract infections, surgical site infections, urinary tract infections and bloodstream infections. Approximately 51% of ICU patients are infected with some or the other infection; the majority of these are healthcare associated infections and the risk of acquiring an infection increases with duration of stay in intensive care. Device-associated infections, like catheter-associated-urinary tract infections, catheter associated bloodstream infections and ventilator associated pneumonia accounted for 25.6% of all healthcare associated infections according to CDC survey reports.[6]

A situation as grave as it appears has a contrasting and ironically a simple solution. Adherence to infection control guidelines, sound knowledge of the healthcare workers (HCWs) and simple practices like hand hygiene (HH) have shown drastic effects on reduction of rates of healthcare associated infections. Improvement in HH compliance has been associated with a decrease in the incidence of healthcare associated infection.[7] Previous studies have shown that HH compliance among HCWs is generally low. As indicated by Louis,[8] a huge number of immune compromised patients are admitted to ICUs. Approximately 30% of ICU patients are affected by one or more episodes of HCAI[9] and nurses are likely to be exposed to microorganisms during their daily practice due to their close and frequent direct contact with patients.[10] Therefore, critical care nurses should have sound knowledge and strict adherence to infection control standard precautions.[11] Studies indicate that inadequate workers' knowledge and environment related problems, including the lack of protective materials and other equipment and utilities required to ensure safety of HCWs is a crucial issue that need urgent attention[12] and the current scenario shows that compliance with HH protocols by HCW is poor.[13]

The tool developed for the study was guided by the standard precautions defined by the WHO. World Health Organization has compiled guidelines in 2006 to provide evidence and recommendations for improvement of HH. These guidelines were based on successful experiences showing a consequent reduction in healthcare associated.

This justifies our need to study the current level of knowledge, attitude and practices (KAP) among the critical care nurses with regards to the standard precautions for healthcare associated infection, and hence give recommendations for further reducing the rate of healthcare associated infections. The aim of the study was to assess nurses' knowledge, attitude and evaluate their self-reported practices regarding infection control standard precautions at the ICU of a selected super speciality hospital. The specific objectives were as follows:

a. To assess the KAD scores of ICU nurses regarding standard precautions of infection control
b. To study the impact of professional experience on KAP scores
c. To analyze the impact of knowledge and attitude scores on self-reported practice score.

SUBJECTS AND METHODS

Research Design

The current study was conducted at two intensive care units (ICUs) (Medical ICU and Stoke Unit) of a super-specialty hospital. A sample of convenience including 47 nurses, representing all those who work in two ICUs of the selected study setting. A structured questionnaire was developed, tested for clarity and feasibility, and then used to collect data. Development of this questionnaire was guided by WHO standard precaution of infection control. This questionnaire consisted of two parts: (a) demographic characteristics, such as gender, age, department, years of experience, and (b) a list of infection control standard precautions (31 items). The tool's items were categorized under 8 main domains which were related to knowledge about HH, use of personal protective equipment (PPE); sharp devices & needle stick injuries; respiratory hygiene, environmental cleaning, linen management, waste disposal and patient care equipment. One score was allocated to each right answer and zero to the wrong answer. Scores of 70% or less were considered below average, scores between 71 and 80% average, 81 to 90% good and above 90% were very good. The scoring system is based on a study done by Uba et al (2015).[14] Designed tools were examined for content validity by a panel of five experts in the field of critical care medicine, and critical care and emergency nursing to test their clarity and objectivity and if they are suitable to achieve the aim of the study.

Ethical Clearance and Confidentiality

The current study was approved by ethical committee of the concerned University and permissions were obtained from scientific committee, ethics committee, quality heads and nursing directors of the ICU at the selected hospital. As well written consents were obtained

from critical care nurses after explaining the purpose and nature of the study. Each nurse was free to either participate or not in the current study and had the right to withdraw from the study at any time without any rational. Also, nurses were informed that obtained data will be used only for research purpose and not for their evaluation. Confidentiality and anonymity of each subject were assured through coding of all data.

Methodology

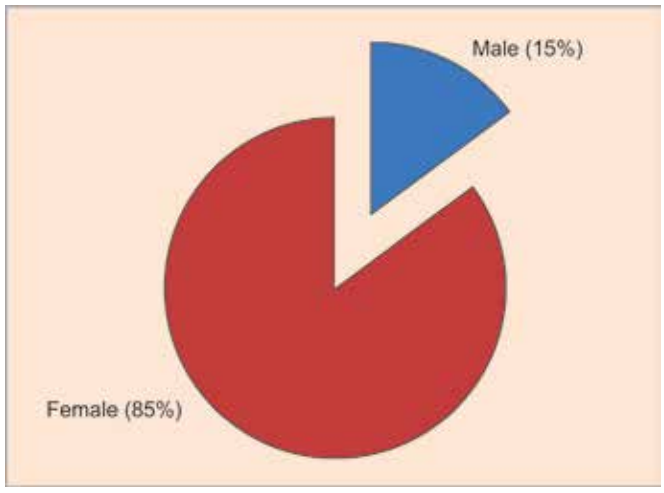
The current study started with the preparation and validation of data collection tool and followed by administrative permissions to carry out the study. This phase lasted for about 4 months. Actual study was carried out after obtaining official permissions. Data of the current study were collected over a period of 6 months starting from August 2014 to January 2015. The selected ICUs were visited on twice a week basis, and nurses were approached during two shifts (morning and afternoon) to ensure that all the nurses were included in the study. Their rotational duty cycle confirmed postings in these shifts during study period. They were explained the purpose and nature of the study and written consents were obtained from those who accepted to share in the study. Then involved nurses were given the structured questionnaire. The researcher/research associate was available at the ICU during the time of filling the data collection sheet to answer any question, and to provide the needed explanations. Filling the questionnaire required about 20 minutes from each nurse. Obtained data was fed into Microsoft Excel for further analysis.

RESULTS AND DISCUSSION

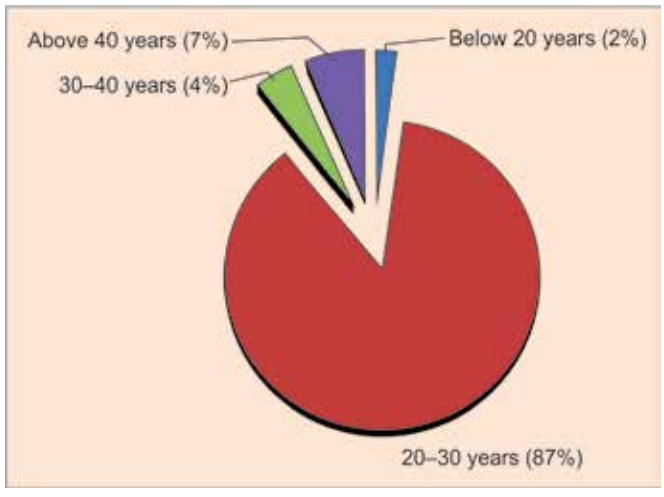
The study reflects the current levels of the knowledge and attitudes and the self-reported practices of the critical care nurses. A total of 47 nurses responded giving information in the structured format. In spite of repeated contacts we could illicit response from about 85% nurses due to very busy schedules in ICUs. Details few demographic characteristics like sex, age and work experience are given in Graphs 1 to 3 respectively.

As revealed from the current study and depicted in Graphs 1 and 2, majority of the participant nurses sample were female (85%), and largely (87%) between 20 and 30 years old. About 15% were males and a small percentage (7%) were aged between 30 to 40 years and 4% of the nurses were aged 40 years or more. A very small percentage (2%) was below 20 years of age. Graph 3 illustrates that the maximum number (41%) of respondents had 2 to 5 years of work experience, 23% of the nurses had more than 5 years of work experience and 19% of the staff was with 1 to 2 years of work experience. A small percentage of nurses (17%) were fresher or had work experience of below 1 year.

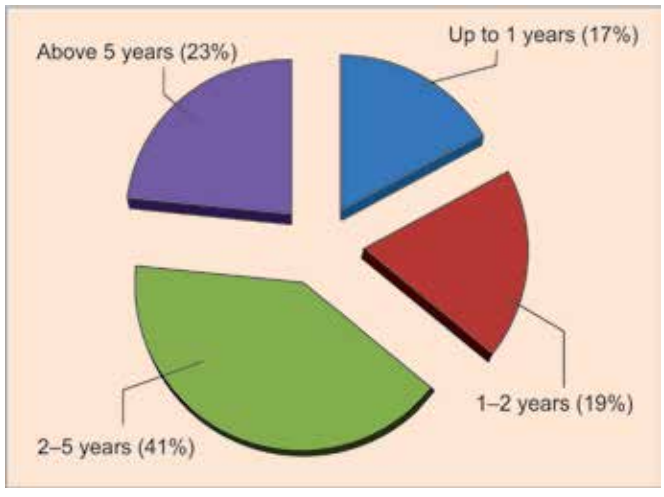
The segregated and total score obtained by nurses is given in Table 1. All the aspects were not given equal



Graph 1: Sex distribution of ICU nurses of a tertiary care hospital in Delhi NCR, 2014



Graph 2: Age distribution of ICU nurses of a tertiary care hospital in Delhi NCR, 2014



Graph 3: Work experience distribution of the ICU nurses of a tertiary care hospital in Delhi NCR, 2014

Table 1: Knowledge, attitude and practice scores of ICU nurses of a tertiary care hospital in Delhi NCR, 2014

	Knowledge	*Attitude*	*Practice*	*Cumulative KAP score*
No. of questions	13	9	9	31
Mean score for the respondents	10.23	8.00	8.17	26.40
Percentage	78.69	88.89	90.78	85.16
Standard deviation	2.22	1.20	1.02	3.75
Maximum	13	9	9	31
Minimum	3	4	4	12

weightage. Questions pertaining to knowledge were more and attitude and practices had equal weightage. The total number of questions were 31 out of which 13 were specifically asked to check the knowledge of the staff, 9 questions were asked to test their attitude and remaining 9 were asked to test their self-reported practices. Table 2 gives per cent distribution of the scores obtained.

The mean cumulative KAP score of the entire sample of the study was good, i.e. 26 correct responses out of 31 questions (85%). Specifically, the sample scored average, i.e. 10 correct responses out of 13 questions (79%) in knowledge, 8 correct responses out of 9 (89%), i.e. good in attitude and, 8 out of 9 (91%), i.e. very good in self-reported practices. Table 3 shows that nearly half the respondents (45%) have a good KAP score, about one-third (30%) of the respondents fall in very good KAP score category. One-tenth (10%) of the nurses have an average KAP score and a small percentage (15%) of the staff have a below average KAP score.

It is evident that around 75% (35 out of 47) of nurses scored 80% or more in KAP which indicate that most of the nurses are well aware of the infection control standard precautions. However, around 25% of the nurses (12 out of 47) scored not up to the mark who might require to undergo a training program to improve their, KAP scores related to infection control standard precautions. Another observation from the result is that the mean knowledge score is average (71–80%) but mean attitude score is good (81–90%) and mean practice score is very good (>90%) hence, the cumulative KAP score becomes good, i.e. the average knowledge is balanced by good attitude and very good practices.

Table 2: Cumulative KAP scores of ICU nurses of a tertiary care hospital in Delhi NCR, 2014

Category	*Number of nurses*	*%*
Below average (KAP <70%)	7	14.89
Average (KAP 71–80%)	5	10.64
Good (KAP 81–90%)	21	44.68
Very good (KAP > 90%)	14	29.79

The questionnaire designed for the study was based on the standard precautions defined by WHO. The standard precautions for infection control were divided into eight categories. While collecting the data, the respondents were asked specific questions to test their knowledge, attitude and practices with reference to each category. The eight subcategories of standard precautions for infection control were as follows:

- Hand hygiene (Ques. K1, K2, K3, A1, A2, P1, P2, P3)
- PPE: Gloves, facial protection, gown (Ques. K2, K3, K4, K5, K6, K7, A3, A4, A5, P4, P5, P6).
- Needle stick injury (NSI) (Ques. K8, A6, P7)
- Respiratory hygiene (RH) (Ques. K9, K10, A7, A8)
- Environment cleaning (EC) (Ques. K11, A9)
- Linen (Ques. K12)
- Waste disposal (WD) (Ques. K13, P8)
- Patient care equipment (Ques. P9)

Table 3 presents us with the frequency distribution of the correct responses for the nurses (N = 47) as regards to KAP for different facets of standard precautions for infection control. From Table 3, it is apparent that for most of the subtotals, majority of the nurses gave the correct responses. The findings show that the knowledge levels of nurses was maximum for use of PPE, HH and environmental cleaning and minimum for standard precautions for linen handling.

Detailed analysis of KAP scores in individual sub categories has been done only for two sub categories, i.e. HH and PPE. Other categories have not been analyzed individually as they did not have sufficient number of questions pertaining to KAP.

Table 3: Correct responses in each category of standard precautions for infection control

Categories	*Knowledge*	*Attitude*	*Practice*	*K (%)*	*A (%)*	*P (%)*
Hand hygiene	40	47	42	85.11	100	89.36
PPE: Gloves, facial protection, gown	42	42	41	89.36	89.36	87.23
Needle stick injury (NSI)	37	45	45	78.72	95.74	95.74
Respiratory hygiene (RH)	34	31	NA	72.34	65.96	NA
Environment cleaning (EC)	42	44	NA	89.36	93.62	NA
Linen	18	NA	NA	38.30	NA	NA
Waste disposal (WD)	16	NA	34	34.04	NA	72.34
Patient care equipment	NA	NA	41	NA	NA	87.23

NA: Not available

Hand Hygiene

Table 4 reveals that majority 27 out of 47 (57%) of the nurses had above average (i.e. good and very good) KAP score for HH. One fourth (25%) of the respondents had an average KAP score for HH. A very small percentage (14%) had a below average KAP score for HH. The overall knowledge score for HH was good (85%), the attitude for HH was very good (100%), i.e. all the nurses gave correct responses for questions related to attitude toward HH; and the practice score for HH was very good (89%).

Personal Protective Equipment

Table 5 represents that majority 22 out of 47 (47%) of the nurses had very good KAP score for PPE. A total of 19% of the respondents had a good score and 21% of the nurses had average KAP score for PPE. A very small percentage (13%) had a below average KAP score for PPE. The overall KAP score for PPE was good, i.e. 89, 89 and 87% respectively. The correlation coefficients among the three variables with 95% confidence limits are given in Table 6.

Table 6 indicates that correlation coefficient of knowledge with attitude and practice is 0.53 and 0.59 which indicates moderately strong positive linear relationship that knowledge shares with attitude and practice. However, the correlation between attitude and practice is very high (0.81) which indicates a high positive linear relationship between attitude and practice. The results indicates that knowledge, attitude and practice will move in the same direction, i.e. if one of them increase then the others will also increase.

Table 4: Cumulative KAP scores related to hand hygiene of ICU nurses of a tertiary care hospital in Delhi NCR, 2014

Criteria	*No. of nurses*	*%*
Below average (KAP <70%)	10	22
Average (KAP 70–79%)	17	37
Good (KAP 80–89%)	12	26
Very good (KAP > 89%)	7	15

Table 5: Cumulative KAP scores related to PPE of ICU nurses of a tertiary care hospital in Delhi NCR, 2014

Criteria	*No. of nurses*	*%*
Very good	22	46.81
Good	9	19.15
Average	10	21.28
Below average	6	12.77

Table 6: Correlation between knowledge, attitude and practice scores of the nurses

	Knowledge	*Attitude*	*Practice*
Knowledge	1.00	0.53 (0.28–0.71)	0.59 (0.37–0.75)
Attitude	0.53 (0.28–0.71)	1.00	0.81 (0.68–0.89)
Practice	0.59 (0.37–0.75)	0.81 (0.68–0.89)	1.00

However, the results for correlation (Table 6) should not be mistaken as a causal relation and to find the impact of knowledge and attitude on practice, multiple regression analysis is being conducted. The results are given in Tables 7 and 8.

Table 9 represents the regression statistics. From the value of R-square (0.69), it can be said that 69% of the variance in practice scores can be explained by the knowledge and attitude scores for the nurses. The value of adjusted R-square (0.67) indicates that when this model is applied for the population of nurses (generalize the result), then their knowledge and attitude scores can explain 67% of the variances in their practice scores.

The moderately high value of R-square along with a very small gap between R-square value and adjusted R- square value indicate that the model is fairly successful to explain the impact of knowledge and attitude on practice scores. However, whether the model along with the parameters (knowledge and attitude) is significant or not, will be revealed by analysis of variance (ANOVA) (Table 10) and the regression coefficients (Table 11).

The ANOVA results in Table 10 indicate that since the p-value is less than 0.05, we conclude that the overall regression analysis is significant, i.e. there is an impact of knowledge and attitude on practice.

However, whether both the explanatory variables, knowledge and attitude are significant or not will be revealed by regression coefficients (Table 11).

Table 7: ANOVA—impact of work experience on cumulative KAP scores for the nurses (summary)

	ANOVA: single factor summary			
Groups	*Count*	*Sum*	*Average*	*Variance*
0–1 year	8.00	188.00	23.50	36.86
1–2 years	10.00	237.00	23.70	38.01
2–5 years	19.00	489.00	25.74	11.32
>5 years	11.00	291.00	26.45	7.07

Table 8: ANOVA—impact of work experience on cumulative KAP scores for the nurses (F statistics and p-value)

	ANOVA				
Source of variation	*SS*	*df*	*MS*	*F*	*p-value*
Between groups	67.97	3.00	22.66	1.14	0.34
Within groups	874.51	44.00	19.88		
Total	942.48	47.00			

Table 9: Regression analysis: impact of knowledge and attitude on practice (regression statistics)

Regression statistics	
Multiple R	0.83
R-square	0.69
Adjusted R-square	0.67
Standard error	0.87
Observations	47.00

Table 10: Regression analysis: impact of knowledge and attitude on practice (ANOVA)

	ANOVA				
	df	*SS*	*MS*	*F*	*Significance F*
Regression	2.00	73.49	36.74	48.27	0.00
Residual	44.00	33.49	0.76		
Total	46.00	106.98			

Table 11: Regression analysis: impact of knowledge and attitude on practice (coefficients)

	Coefficients	*Standard error*	*t-test*	*p-value*
K	0.16	0.07	2.24	0.03
A	0.93	0.14	6.89	0.00

As this study is not focusing on forecasting the incremental change in practice scores due to the increase in knowledge and attitude scores hence the regression coefficients are not taken into considerations. Intercept is defined as the value of the dependent variable in absence of the independent variables. The model in our study is a model without intercept, which denotes that a certain level of knowledge and attitude are mandatory for the nurses to practice the infection control standard precaution measures. Table 11 denotes that the p-values for knowledge (0.03) and attitude (0.00) are below 0.05. Hence, we conclude that the regression model parameters are significant, i.e. there is a significant impact of knowledge and attitude score on practice scores.

Moving toward the next objective of the study: to gauge the impact of the work experience of the nurses on their total KAP scores.

Table 7 indicates that the mean KAP scores for the nurses increases with the increase in work experience of the nurses. However, ANOVA is conducted to statistically test the significance of these differences in mean KAP scores.

Table 8 presents with ANOVA results for impact of work experience on cumulative KAP scores for infection control standard precautions. Table 8 suggests that the results are not significant since p-value is above 0.05 (CI = 95%), the set value for level of significance. Thus, we conclude there is no impact of work experience on cumulative KAP scores. This contradicts the findings of various studies where there is a positive correlation between work experience and KAP scores (Eskander 2013, Taha 2014).[15]

The last objective of the study is to measure the impact of work experience of the nurses on individual KAP scores related to two sub categories, i.e. HH and PPE.

Table 12 presents with ANOVA results for impact of work experience on knowledge, attitude and experience KAP scores for HH and PPE. The table suggests that results are nonsignificant for all the findings since p-values for all the results are above 0.05. Thus, we conclude there is no impact of work experience on subtotal KAP scores related to two categories of standard precaution for infection control, i.e. HH and PPE.

Table 12: ANOVA—impact of work experience on KAP scores for the nurses (HH and PPE)

		f-value	*p-value*	*Remarks*
Hand hygiene	Knowledge	0.832	0.484	Not significant
	Attitude	0.739	0.535	Not significant
	Practice	1.826	0.157	Not significant
	Cumulative KAP	1.599	0.204	Not significant
PPE	Knowledge	1.381	0.261	Not significant
	Attitude	0.283	0.838	Not significant
	Practice	0.541	0.657	Not significant
	Cumulative KAP	0.257	0.856	Not significant

SUMMARY

The study was done to analyse the knowledge, attitude and self-reported practices KAP of two ICU of a tertiary care hospital in Delhi. The findings of the study show that majority of the nurses were females in the age group of 20 to 30 and had Good (KAP 81 to 90%) knowledge, attitude and practice related to standard precautions for infection control.

The results also show that there is a significant impact of knowledge and attitudes of critical care nurses on their self-reported practices. Demographic factors like work experience have no impact on KAP related to standard precautions for infection control according to this study.

CONCLUSION AND RECOMMENDATIONS

The study thus concludes that as knowledge and attitude of the critical care nurses significantly affects their practices for infection control, it becomes imperative for the hospitals to ensure that the nurses have a good level of knowledge and positive attitude for infection control.

The following recommendations can be made for future research work:

- As studies[15] show that training programs have an impact on knowledge hence training programs can be done to increase the knowledge of the nurses so as to increase their practices for infection control.
- Healthcare organizations can evaluate post training impact on knowledge, attitude and practices of nurses and improvement in infection rates.
- Only two ICUs were taken into the study, the model can be applied to other critical units and inpatient areas.
- The survey was done only for nursing staff, hence future studies can include other HCWs like doctors, paramedics, etc.

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ORIGINAL ARTICLE

Incidence Rates of Healthcare-associated Infections in Hospitals: A Multicenter, Pooled Patient Data Analysis in India

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ABSTRACT

Aim: The aim of this study was to collect the multicenter data of healthcare-associated infections (HAIs) to assess the infection control scenario in India in context with CDC/NHSN and INICC database.

Materials and methods: Four National Accreditation Board for Hospitals and Health Care Providers (NABH) accredited hospitals were selected on random basis and raw data on healthcare-associated infections—number of days and number of infections in all intensive care patients was obtained as per the CDC-NHSN definitions and formula. Three major device related infections were considered for analysis based on the prevalence of HAIs and discussions with subject matter experts. All nodal champions from each hospital were trained and common data collection sheet for surveillance in accordance to CDC-NHSN was formed. The pooled means for HAI rates and average of the pooled means for all were calculated using data from four hospitals and were compared with CDC/NHSN and international nosocomial infection control consortium (INICC) percentiles of HAIs rates.

Results: The Indian pooled mean HAI rates for all infections were above CDC/NHSN percentile threshold but below INICC percentile. Ventilator-associated pneumonia (VAP) was considered as matter of prime concern, crossing P90 line of CDC/NHSN threshold. However, no HAI rate was in limit of P25.

Conclusion: Indian HAI rates were higher when mapped with CDC threshold. This promotes the need for more standardized and evidence-based protocols been adhered to so as to bring HAI within CDC/NHSN thresholds. However, the four hospitals have better HAI rates as compared to pooled INICC database.

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Conflict of interest: None

INTRODUCTION

Healthcare-associated infections (HAIs) are recognized as a major burden for patients, society and healthcare management. In 2008, European Center for Disease Prevention and Control (ECDC) estimated that more than 4 million people acquire a HAIs each year in European Union (EU) of which approximately 37,000 die as the direct consequence of the infection.[1] In the USA alone, the incidence of HAIs has been estimated to be approximately 2 million cases annually with approx 99,000 HAI attributable deaths, making it as fifth leading cause of death in acute care hospitals.[2] The prevalence of HAI in developing countries can become as high as 30 to 50%.[3] In developing countries, in spite of effectiveness of these infection control practices, studies have shown a very low compliance by healthcare professionals.[4]

There is an updated report of data on device associated HAIs within intensive care units (ICUs) collected by hospitals participating in the International Nosocomial Infection Control Consortium (INICC).[5,6] In US, Centre for Disease Control and Prevention (CDC) runs a multicentric, HAI control program with a surveillance system which is known as US National Healthcare Safety Network (NHSN)[7] formerly the National Nosocomial Infection Surveillance system (NNIS).[8]

Quality and patient safety are integral components for the effective healthcare delivery system. Healthcare-associated infections are a major issue jeopardizing patient safety with substantial impact on morbidity, mortality and use of additional resources. At hospitals with low- and middle-income countries (LMICs), it is important to understand the primary needs and obstacles for prevention and control of HAIs. The main issues in

resource limited settings are lack of specific priorities, absence of data, healthcare safety both for the cared and the care-giver are low on priority and failure to implement the standardized practices. Collecting, collating and analysis of surveillance data in accordance to NHSN format and comparing them with benchmarked INICC or NHSN data will help us comprehend the gaps, thereby strategizing and operationalizing good prevention infection prevention and control (IPC) practices.

In this study, our aim was to prospectively analyze the patient data on HAI from four participating hospitals and comparing it with CDC/NHSN and INICC data. This helps to assess the Indian HAI scenario and explore need for evidence based HAI control policy at institutional and national level.

MATERIALS AND METHODS

Institutional Permission and Study Settings

This study was conducted with permission from institutional review board. As no direct patient data were utilized in the study, ethical clearance was waived.

Confidentiality Considerations

Being data of national importance, the participant institutions had requested to maintain anonymity for their names. Thus, in this study, the institutes were coded as 'Institute A', 'Institute B', 'Institute C' and so on throughout the project.

Study Design

This was prospective, multicenter, observational analytical study. Our primary objectives included calculation of proportion rates for HAIs (device related) from January 2010 to December 2012 and conduct comparative analysis of HAIs with CDC-NHSN[7,8] and INICC[5,6] HAI database.

Sampling Method and Data Collection

On preliminary approval of study synopsis, random selection of accredited hospitals was done. Nodal Officers from each healthcare organization were called and trained in accordance with CDC-NHSN definitions and formula (numerator and denominator). The nodal officers in turn went back and trained their IC team on surveillance methodology. Each participating hospital submitted their Intensive Care Device associated healthcare-associated infections (DA-HAI) data. Three device related HAIs *viz* Ventilator-associated pneumonia (VAP),[9] Central line-associated blood stream infections (CLABSIs)[10] and catheter-associated urinary tract infections (CAUTIs)[11] were agreed upon, their data were collected and analyzed. It is to be noted that prior to information retrieval, Non-disclosure agreement (NDA) was signed so as to maintain confidentiality. Before analysis, the hospital names were coded as 'A', 'B', 'C' and 'D'.

DATA ANALYSIS

Calculation of Pooled Means

Calculation of pooled means for each of three types of HAI rates—VAP, CLABSI and CAUTI was performed using the following formulas as mentioned in NABH 3rd edition.

Percentile Calculation

To explore the threshold value for HAIs to understand and improve hospital infection control measures' quality, 25, 50, 75 and 90% percentile ranges were calculated for all three types of device related infections based on the hospital infections data using 'percentile' built-in function in MS-EXCEL software.

COMPARATIVE ANALYSIS IN CONTEXT WITH CDC/NHSN AND INICC THRESHOLD

Tabular Method

Similar table was prepared to that reflected in CDC/NHSN guidelines to investigate and understand the difference between pooled means and percentiles of Indian HAI rates and CDC/NHSN and INICC based HAI rates.

Graphical Method

Hospital-wise pooled means of HAI rates were plotted against CDC/NHSN and INICC thresholds based on percentiles for each type of HAI to investigate whether infection control rates in study hospitals are within CDC/NHSN and INICC recommended limits. For ease of interpretation, hospital-wise means were further averaged and plotted together.

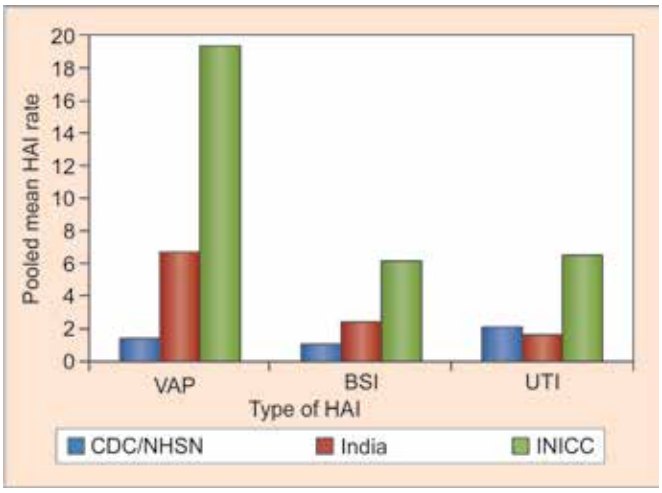
RESULTS

Four NABH-accredited hospitals pooled device associated HAIs data from their ICU measured 57807 ventilator days, 155614 central line days and 376585 urinary catheter days for the period of 2 years (Table 1). Pooled mean HAI rates emerged highest with VAP as 6.74/1000 ventilator days, next was 2.42/1000 central line days followed by 1.63/1000 urinary catheter days (Table 1 and Graph 1).

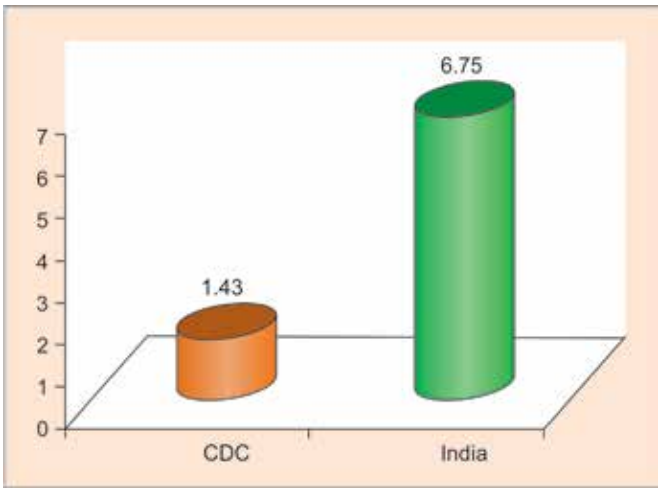
Pooled Indian ICUs data reveal VAP rate at 6.74/1000 ventilator days, which as compared to CDC-NHSN is 1.43 and INICC is 19.5. Pooled Indian CLABSI is at 2.40/1000 central line days which as compared to CDC-NHSN is at 1.02 and INICC is at 6.12, whereas pooled Indian CAUTI

Table 1: Pooled means of device-associated infections (pooled data from all four hospitals)

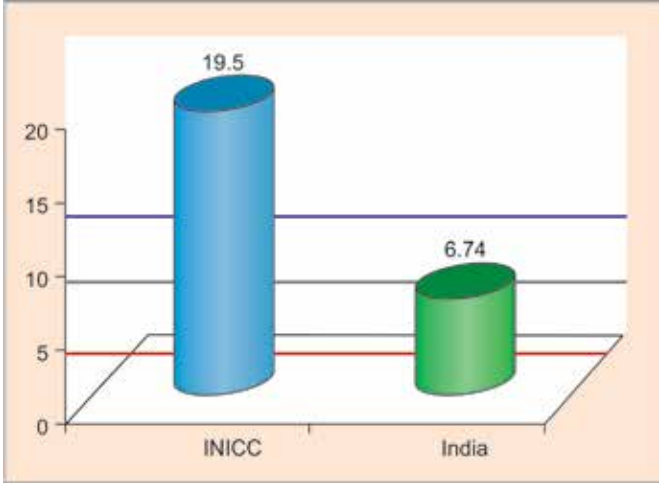
Type of infection	*Number of infections (N_I)*	*Number of infection days (N_{ID})*	*Pooled mean HAI rate [R = (N_I / N_{ID}) × 1000]*
Ventilator-associated pneumonia (VAP)	390	57807	6.74
Central line-associated bloodstream infections (CLABSI)	378	155614	2.40
Catheter-associated urinary tract infections (CAUTI)	615	376585	1.63



Graph 1: Comparison of pooled means of HAI rates for India, CDC/NHSN and INICC

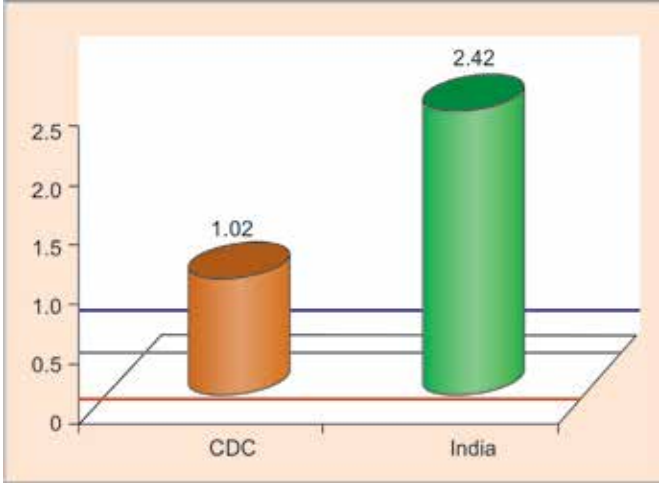


Graph 2: Mapping of pooled VAP incidence rates of study hospitals with CDC/NHSN thresholds



Percentile (VAP)	*CDC*	*INICC*
25%	0.36	4.88
50%	0.71	9.75
75%	1.07	14.62

Graph 3: Mapping of pooled VAP incidence rates of study hospitals with INICC thresholds



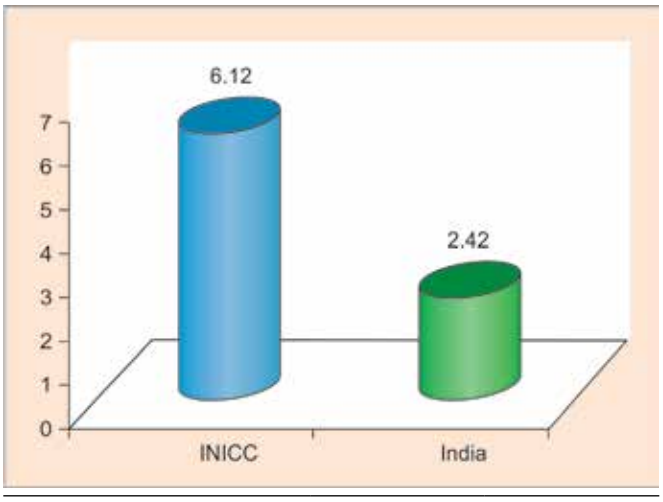
Graph 4: Mapping of pooled CLABSI incidence rates of study hospitals with CDC/NHSN thresholds

data is significantly better than the benchmark figure of CDC-NHSN at 2.09 and INICC at 6.5 (Graph 1).

Ventilator-associated pneumonia rate appears to be close to P75 (75th percentile) for CDC-NHSN data and close to P50 (50th percentile) for INICC (Graphs 2 and 3). Central line associated blood stream infections rates at 2.40 appears to be close to P90 (90th percentile) for CDC-NHSN and P25 (25th percentile) for INICC database (Graphs 4 and 5). Pooled Indian CAUTI rates at 1.63 appears to be close to between P50 and P25 (25th percentile) for CDC-NHSN and P75 (75th percentile) for INICC database (Graphs 6 and 7).

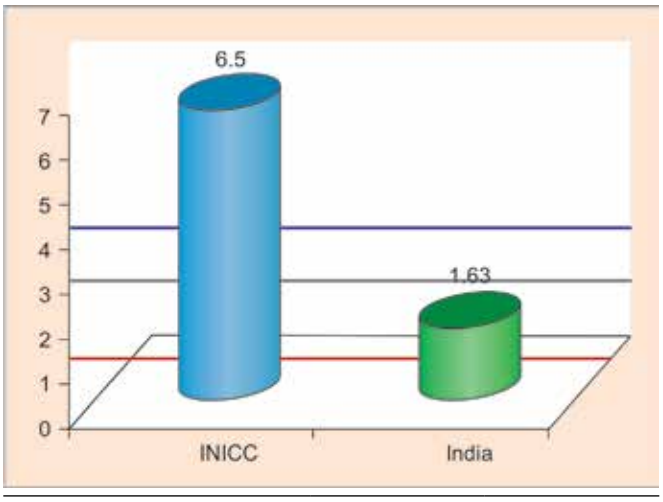
DISCUSSION

Centre for disease control/NHSN[8] HAI rates are considered to be a bench mark in hospital infection control. Evidence of which is utilized in developing HAI prevention policies for effective implementation across the world. Therefore, this was considered as baseline for comparative analysis in the study. International nosocomial infection control consortium[5] data for HAI rates were also used for comparison, as the data represents the developing countries across the world, and helps in determining the current status of HAI in



Percentile (BSI)	*CDC*	*INICC*
25%	0.25	1.53
50%	0.51	3.06
75%	0.76	4.59

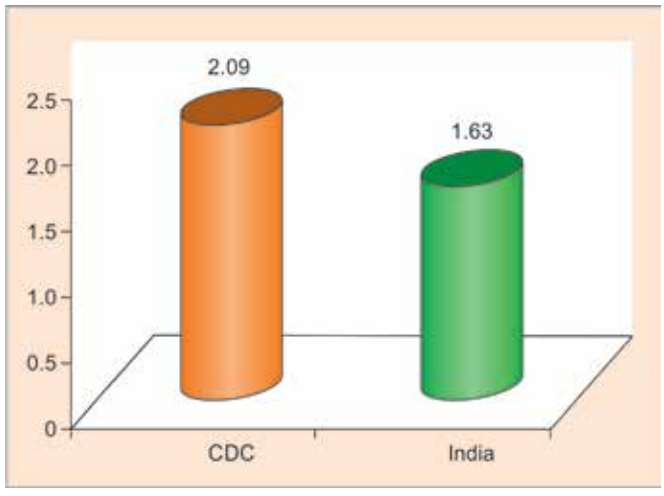
Graph 5: Mapping of pooled CLABSI incidence rates of study hospitals with INICC thresholds



Percentile (UTI)	*CDC*	*INICC*
25%	0.52	1.62
50%	1.04	3.25
75%	1.57	4.65

Graph 7: Mapping of pooled CAUTI incidence rates of study hospitals with INICC thresholds

India in relation to other developing nations. In current era of evidence-based guidelines, it is also necessary to incorporate real world evidence to explore solutions which are implementable in the Indian context of healthcare. Primary data were collected using vetted data extraction proforma from the hospitals which were NABH accredited. There is no standard guidelines/ policy on HAI prevention and control available in India. Although it is fact that INICC guidelines are evidence-based and could be utilized by developing countries for better care delivery, the contextualized implementation remains the biggest challenge.



Graph 6: Mapping of pooled CAUTI incidence rates of study hospitals with CDC/NHSN thresholds

As evident from the study findings, pooled incidence rates for VAP in India are beyond 90th percentile (P90) threshold as compared to CDC/NHSN VAP rates and were clearly identified as matter of prime concern. The lower threshold limit for CAUTI was because of lower rates compared to CLABSI and VAP. Nevertheless, holistically, there is an urgent need for evidence based HAI control policy similar to CDC/NHSN and strategies to effectively implement them. However, when the threshold values were replaced with INICC thresholds values, study hospitals showed remarkably better performance with pooled means of HAI rates lying below threshold lines of 25th percentile (P25). Surprisingly, VAP control was significantly evident in our study findings in context with INICC[6] thresholds with even 25th percentile limit (P25) unlike the CDC threshold with pooled rate crossing set limit. There could be an assumption that demography and prevalent hospital care delivery system in developed countries are different than those of developing countries, which results in better infection control policies and implementation measures in US as compared to the developing countries. Therefore, it is recommended to cautiously interpret the evidence, especially when mapping national quality indicators with established threshold of developed nations likewise in the present study, before any priority-setting and policy decisions.

The main limitation of our study was small number of study hospitals, though adequate regional representation across the country was fulfilled with hospital selection. Therefore, the average data could not be considered robust enough for informed decision-making. The causative factors tend to change according to regions in the country. As our study sites does not represent a comprehensive data taking into account of all the variability, this could be foreseen as a future scope of such projects with larger

sample size and more realistic population representation. The data represented in CDC/NHSN guidelines is categorized by speciality care area and their infection rates.

Being an exploratory research design, the Indian percentile values at this point of time cannot be considered as national threshold, for formulating guidelines of HAI prevention and control policies. However, the findings of this study does prove that existence of evidence-based guidelines results in better infection control. Thus, they could be essentially utilized to effectively inform the decision makers for structuring a stronger environment for HAI control in India. The study can be considered as a pilot project for designing larger epidemiologic studies including more quality indicators, and participation of wider range of healthcare setups from across the country. This will not only be more representative but also help in enhancing regional HAI trends leading to development of stronger and up-to-date database, which in turn would become a guide to formulate public health policies for effective prevention and containment of HAIs and rising antimicrobial resistance.

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ORIGINAL ARTICLE

A Study of Patient Safety with Special Reference to Incidence of Adverse Events taking Place in Patients in a Tertiary Care Hospital in North India

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ABSTRACT

Background: Adverse events in hospitals are now widely agreed to be a serious problem, annually killing more people than breast cancer or AIDS.

Aims: To study incidence of adverse events in admitted patients by current record review.

Materials and methods: A two-staged prospective study for a period of 1 year was carried out. Current records of inpatients were screened for adverse events. The adverse event was categorized as preventable or nonpreventable on the basis of World Health Organization (WHO) set confidence score of preventability.

Results: A total of 3150 patients were screened, among which 488 (15.5%) patients were screened positive for having adverse event. Readmission during last 12 months to any given healthcare for the same health condition (32.79%) was the most common adverse event seen. Hospital acquired infection/sepsis (26.64%) was the second most common adverse event seen. The 78% of adverse events presented with untoward outcome among which 81.8% of adverse events resulted in admission in wards, 4.33% adverse events were associated with death, 23.4% adverse events were associated with disability at discharge and 35.5% adverse events were associated with prolonged stay. A total of 67.4% of studied adverse events showed signs of healthcare team responsible for causing adverse events, among which 76.8% of adverse events occurred outside SKIMS before the index admission. A total of 71.3% of adverse events were categorized preventable.

Conclusion: Hospital acquired infection was found responsible for prolonged stay of the patients. Proper referral policy must be followed by the department of health services.

Keywords: Adverse events, Current record review, Patient safety.

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INTRODUCTION

Patient safety is central to quality healthcare. Medical errors can go unseen and unrecognized if there is a prevailing traditional culture of blame, a hierarchical environment rooted in medical education and traditions, tolerance, and denial and complacency in handling problems and errors.[1]

Adverse events are defined as an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge or both. Negligence is defined as care that fell below the standard expected of physicians in their community.[2]

Current record review estimates the point prevalence of adverse events. This method has the advantage of being more efficient, less time-consuming and easier to perform than the retrospective record review and of being able to identify current trends and problems in care rather than problems from the past calendar year.[3]

OBJECTIVE

To study incidence of adverse events in admitted patients by current record review.

MATERIALS AND METHODS

A study for a period of 1 year in 2013 was carried out in General Surgery and General Medicine of Sher-i-Kashmir

Institute of Medical Sciences (SKIMS). All the patients admitted in the concerned wards were subjected to the study. It was a two stage study. The researcher visited the wards on daily basis. To study the adverse events, a WHO structured questionnaire on patient safety consisting of Review Form-1 (RF-1) and Review Form-2 (RF-2) was used. Current records of all inpatients in these wards were screened for adverse events using RF-1 form. RF-2 form was filled only for those patients who were screened positive by RF-1 form for having an adverse event. A separate RF-2 form was filled for each adverse event screened positive by RF-1 form. Interaction was also made with patient and staff on duty. Statistical Package for the Social Sciences (SPSS) V20 has been used to analyze the data.

OBSERVATIONS AND RESULTS

In the current record review of in-patients, 3150 patients were screened. There were 488 (15.5%) patients screened positive for adverse events. It was observed that most patients were in the age group of 21 to 40 years (35.0%) (p = 0.006). It was also revealed that surgical specialty was having more adverse events (57.6%) which mainly occurred in emergency admissions (60.9%) (p = 0.05). Most commonly affected duration of stay was 11 to 20 days (p = 0.0001) (Table 1).

Among 488 patients screened positive, most common indicator of adverse event having occurred was readmission during last 12 months related to any given healthcare for the same health condition 160 (32.79%) (when calculated with respect to total screened 3150 patients, it comes out as 5.08%), followed by hospital acquired infection/sepsis 130 (26.64%) (when calculated with respect to total screened 3150 patients, it comes out as 4.17%) and patient/family dissatisfaction with care received documented or expressed during the current admission 120 (24.59%) (when calculated with respect to total screened 3150 patients, it comes out as 3.81%). Forty (8.19%) (when calculated with respect to total screened 3150 patients, it comes out as 1.27%) patients were screened positive for unexpected deaths due to adverse events (Table 2).

Among the 488 (15.5%) screened positive for adverse events, one, two and three or more screening criteria for adverse events in RF-1 form was positive in 318 (10.1%), 90 (2.9%) and 80 (2.5%) patients respectively. Total of 736 RF-2 forms were filled (Fig. 1, Graph 1 and Table 2).

Not all adverse events present with an untoward outcome. Out of 736 adverse events studied, 577 (78%)

Table 1: Profile of cases screened for adverse events by current record review

		Screening criteria positive		*Screening criteria negative*		
Characteristic	*Variable*	*n*	*%*	*n*	*%*	*p-value*
Age (in years)	0–20 years	41	8.4	169	6.3	0.006
	21–40 years	171	35.0	859	32.3	
	41–60 years	147	30.1	1013	38.1	
	61–above years	129	26.4	621	23.3	
Gender	Male	237	48.6	1393	52.3	0.126
	Female	251	51.4	1269	47.7	
Specialty	Medical specialty	207	42.4	1053	39.6	0.236
	Surgical specialty	281	57.6	1609	60.4	
Type of admission	Elective admission	191	39.1	1169	43.9	0.05
	Emergency admission	297	60.9	1493	56.1	
Duration of stay	0–10 days	222	45.49	1698	63.79	< 0.001
	11–20 days	226	46.31	804	30.20	
	21 and above days	40	8.20	160	6.01	
Total screened positive		488 (15.5%)		2662		3150

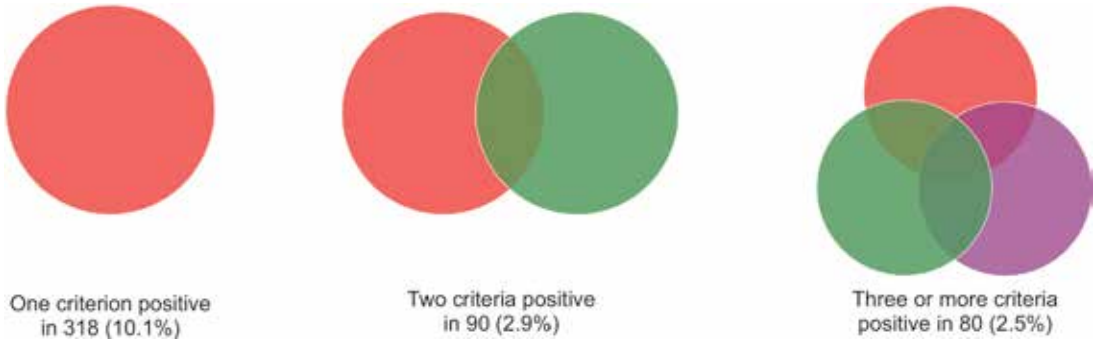


Fig. 1: Number of criteria screened positive in current record review

Table 2: Specialty-wise spectrum of adverse events screened through RF-1 in current record review

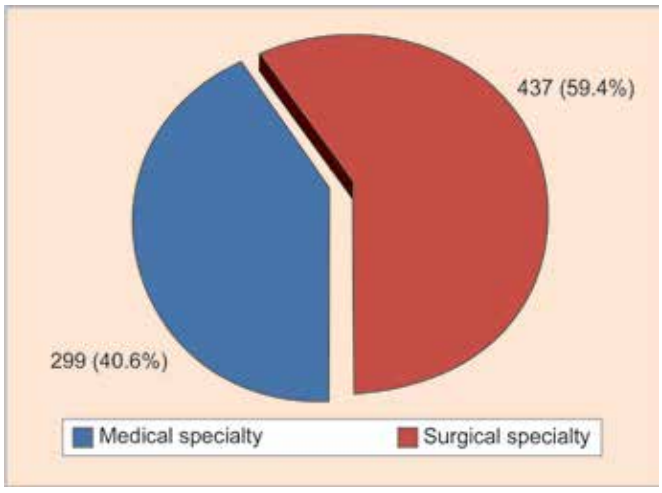
	Medical specialty		*Surgical specialty*		*Total*		
					Percentage with respect to positively screened patients		*Percentage with respect to total screened patients*
	n	*%*	*n*	*%*	*n*	*%*	*%*
Q1. During the last 12 months, any unplanned ward admission related to any given healthcare for the same health condition?	69	14.14	91	18.65	160	32.79	5.08
Q2. Hospital-incurred patient accident or injury?	0	0	50	10.25	50	10.24	1.59
Q3. Adverse drug reaction/drug error or related to administration of fluids or blood?	30	6.14	40	8.19	70	14.34	2.22
Q4. Hospital acquired infection/sepsis?	50	10.24	80	16.39	130	26.64	4.17
Q5. Unplanned removal, injury or repair of organ or structure during surgery, invasive procedure or vaginal delivery?	0	0	20	4.09	20	4.09	0.63
Q6. Unplanned return or visit to the operating theater during this admission?	0	0	20	4.09	20	4.09	0.63
Q7. Unplanned open surgery following closed or laparoscopic surgery?	0	0	10	2.05	10	2.05	0.32
Q8. Cardiac/respiratory arrest, low Apgar score?	50	10.24	10	2.05	60	12.29	1.90
Q9. Development of neurological deficit not present on admission?	0	0	0	0	0	0	0
Q10. Injury or complications related to termination of pregnancy or labor and delivery including neonatal complications?	0	0	0	0	0	0	0
Q11. Other patient complications including MI, DVT, PE, CVA, etc.?	20	4.09	20	4.09	40	8.19	1.27
Q12. Patient/family dissatisfaction with care received documented or expressed during the current admission?	50	10.24	70	14.34	120	24.59	3.81
Q13. Unplanned transfer from general care to intensive care higher dependency?	10	2.05	10	2.05	20	4.09	0.63
Q14. Unplanned transfer to another acute care hospital?	0	0	0	0	0	0	0
Q15. Unexpected death (i.e. not an expected outcome of the disease during hospitalization)?	20	4.09	20	4.09	40	8.19	1.27
Q16. Patients care delayed or lesser treatment given because the patient was unable to pay?	0	0	0	0	0	0	0
Q17. Admission significantly prolonged compared to the expected length for this clinical condition?	10	2.05	10	2.05	20	4.09	0.63
Q18. Any other undesirable outcomes (not covered by any of the above)?	20	4.09	10	2.05	30	6.15	0.95
Total patients screened positive for adverse events				488			

presented with visible untoward outcome. Out of 577 untoward outcomes 402 (92.0%) belonged to surgical specialties and 175 (58.5%) belonged to medical specialties ($p < 0.0001$) (Graph 2, Tables 3 and 4).

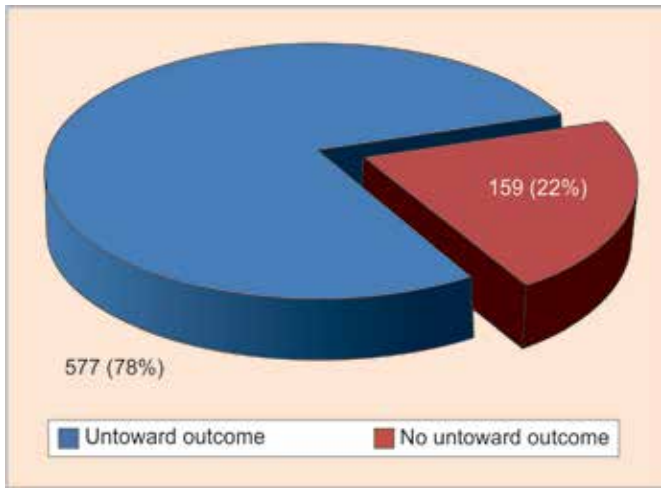
Four hundred and ninety (67.4%) of studied adverse events showed signs of healthcare team responsible for causing adverse events. Out of which 380 (76.6%) of adverse events were related to therapeutic care, 86 (17.3%) occurred during diagnosis ($p \leq 0.001$) (Graphs 3 and 4 and Tables 5 and 6).

Three hundred and eighty-one (76.8%) of adverse event occurred before the index admission and only 115 (23.2%) of adverse events occurred after admission. Out of 381 adverse event which took place outside SKIMS, 325 (85.3%) took place in public hospitals (Graphs 5 to 8, Tables 7 and 8).

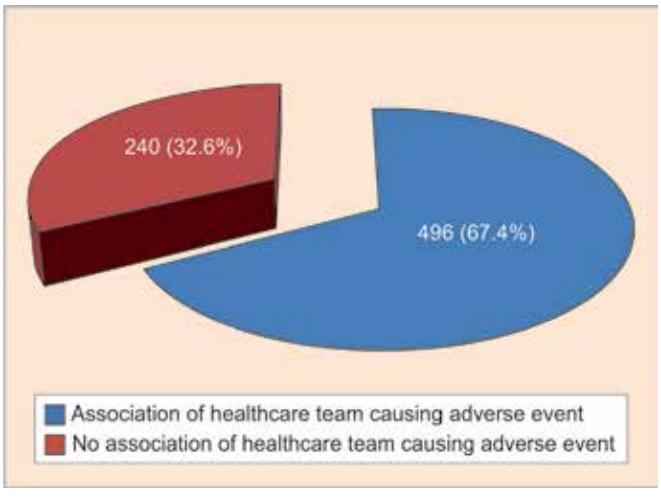
Preventability was calculated using a confidence score of 6 in which if the score came to be 3 or less, adverse event was said to be non-preventable. If the confidence score came to be 4 or more, adverse event was said to be preventable. 71.33% of studied adverse events were found to be preventable and 28.67% of adverse events were found nonpreventable. Definite certain evidence for preventability was seen in 4.1% of adverse events and virtually no evidence for preventability was seen in 6.7% of adverse events (Graph 9 and Table 9).



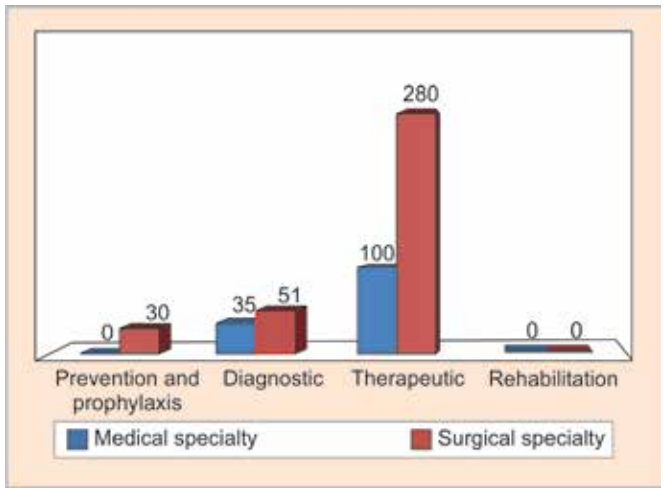
Graph 1: Specialty-wise adverse events studied through RF-2 form in current record review



Graph 2: Outcomes of adverse events in current record review



Graph 3: Cases having evidence that healthcare team caused adverse event



Graph 4: Type of care related to adverse event in current record review

Table 3: Specialty-wise untoward outcome in current record review

	Medical specialty	*Surgical specialty*	*Total*	*p-value*
Untoward outcome	175 (58.5%)	402 (92.0%)	577 (78.4%)	<0.0001
No untoward outcome	124 (41.5%)	35 (8.0%)	159 (21.6%)	—
Total	299 (100%)	437 (100%)	736 (100%)	

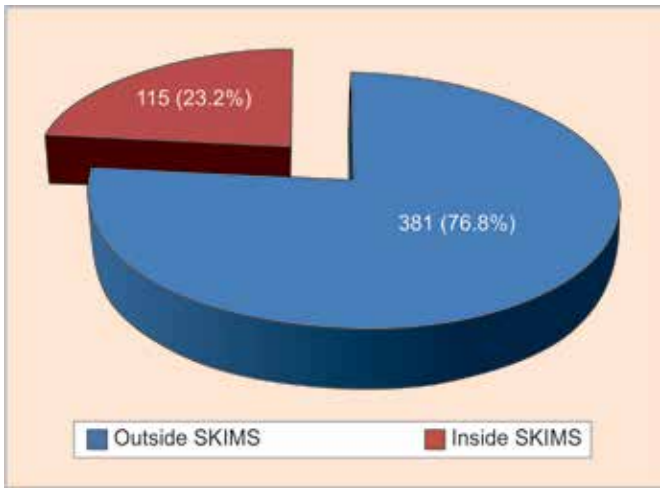
Table 4: Specialty-wise implication of adverse events on untoward outcome in current record review

Outcome	*Medical specialty*	*Surgical specialty*	*Total*	*p-value*
Adverse event causing admission in ward	100 (21.19%)	372 (78.81%)	472 (81.8%)	<0.0001
Adverse event associated with death	20 (80%)	5 (20%)	25 (4.33%)	<0.0001
Adverse event associated with disability at discharge	45 (33.33%)	90 (66.67%)	135 (23.4%)	<0.056
Adverse event associated with prolonged stay	50 (24.39%)	155 (75.61%)	205 (35.5%)	<0.0001
Total adverse events with untoward outcome	577			

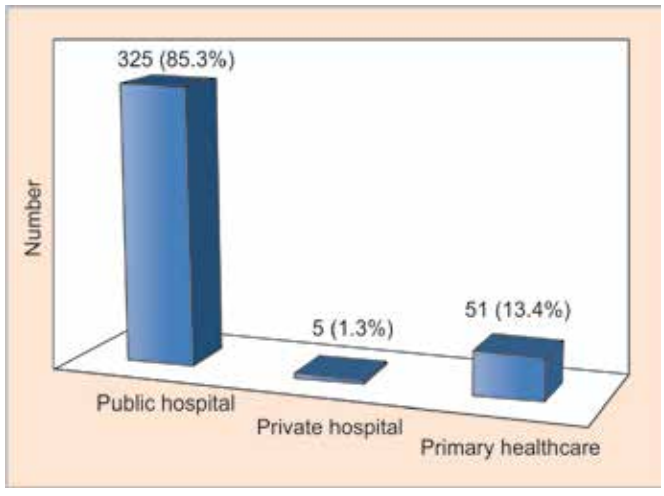
Thus, out of 488 patients having adverse events, 348 (71.33%) patients were found to have preventable adverse events. When calculated with respect to total patients screened (3150), it was found that 11.05% patients had preventable adverse events.

DISCUSSION

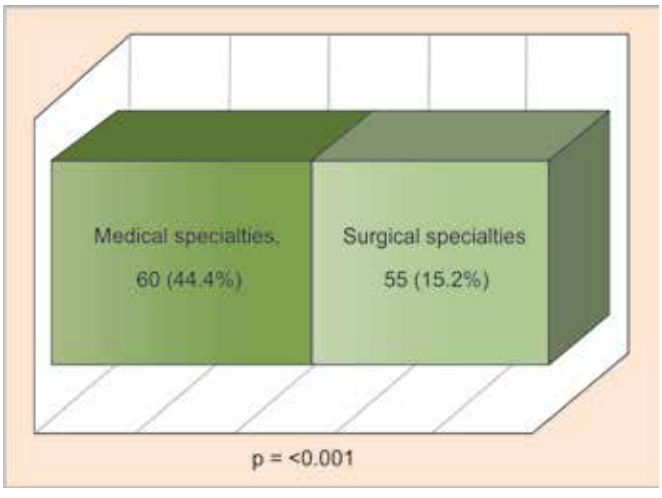
Analysis of adverse events studied by current record review using World Health Organization (WHO) standardized RF-1 and RF-2 format supplemented by patient and staff interview.



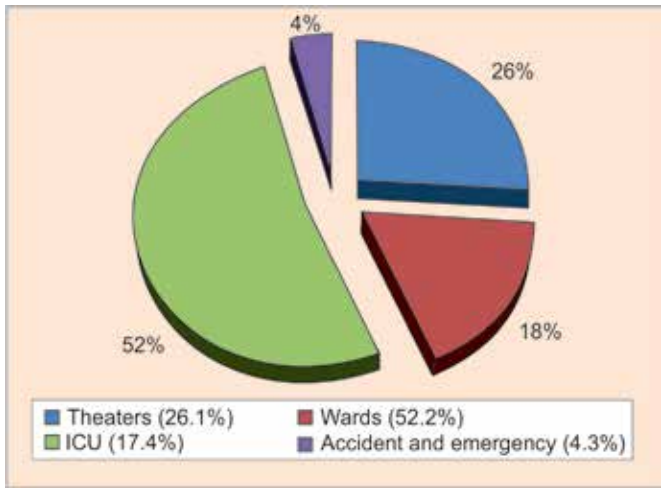
Graph 5: Location of adverse events in current record review



Graph 6: Location of adverse event taking place outside SKIMS in current record review



Graph 7: Specialty wise adverse events taking place at SKIMS in current record review



Graph 8: Location of adverse events which taking place at SKIMS in current record review

Table 5: Specialty-wise cases having evidence that healthcare team caused adverse event

	Medical specialty	*Surgical specialty*	*Total*	*p-value*
Association of healthcare team causing adverse event	135 (45.2%)	361 (82.6%)	496 (67.4%)	<0.0001
No association of healthcare team causing adverse event	164 (54.8%)	76 (17.4%)	240 (32.6%)	—
Total	299 (100%)	437 (100%)	736 (100%)	

Table 6: Specialty-wise type of care related to adverse event in current record review

	Medical specialty	*Surgical specialty*	*Total*	*p-value*
Prevention and prophylaxis	0 (0.0%)	30 (8.3%)	30 (6.0%)	<0.001
Diagnostic	35 (25.9%)	51 (14.1%)	86 (17.3%)	
Therapeutic	100 (74.1%)	280 (77.6%)	380 (76.6%)	
Rehabilitation	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Total	135 (100%)	361 (100%)	496 (100%)	

In the current study, 15.5% patients were found to have adverse events. This is comparable with rates found in various studies.[4-9] In contrary to these finding other studies showed lower rates of adverse events.[10-12]

In our study, surgical patients were screened to have more adverse events as compared to medical, mainly involving females in the age group of 21 to 40 years (35.0%) having emergency admission with the duration of stay of 11 to 20 days (Table 1). Finding of our study comes in line with many studies.[10,12-14]

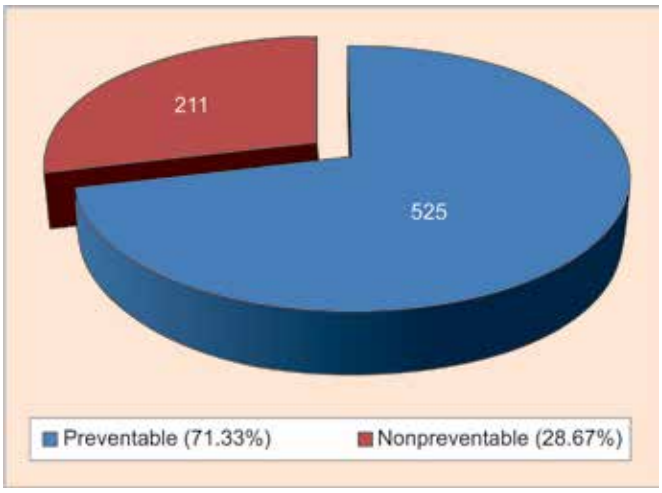
In the present study, most common indicator of adverse event having occurred was readmission during

Table 7: Specialty-wise location of adverse events in current record review

	Medical specialty	*Surgical specialty*	*Total*	*p-value*
Outside SKIMS	75 (55.6%)	306 (84.8%)	381 (76.8%)	
Inside SKIMS	60 (44.4%)	55 (15.2%)	115 (23.2%)	< 0.0001
Total	135 (100%)	361 (100%)	496 (100%)	

Table 8: Specialty-wise location of adverse event taking place outside SKIMS

	Medical specialty	*Surgical specialty*	*Total*	*p-value*
Public hospital	75 (100%)	250 (81.7%)	325 (85.3%)	
Private hospital	0 (0.0%)	5 (1.6%)	5 (1.3%)	<0.001
Primary healthcare	0 (0.0%)	51 (16.7%)	51 (13.4%)	
Total	75 (100%)	306 (100%)	381 (100%)	



Graph 9: Overall preventability of adverse events in current record review

Table 9: Confidence score of preventability of adverse event in current record review

Confidence score		*Frequency*
Virtually no evidence for preventability	1	49 (6.7%)
Slight to modest evidence for preventability	2	96 (13.0%)
Preventability not really likely; less than 50–50	3	66 (9.0%)
Preventability more likely than not; more than 50–50	4	299 (40.6%)
Strong evidence for preventability	5	196 (26.6%)
Definite certain evidence for preventability	6	30 (4.1%)

last 12 months related to any given healthcare for the same health condition (Table 2). Findings of our study almost comes in line with various other studies.[4,11,12,14,15]

Hospital acquired infection/sepsis was the second most common adverse event present in our study (Table 2). Many studies were found to have results in line to our study.[4,11,12,15]

In current study, unexpected deaths due to adverse events was seen in 1.27% of inpatients by current record review. Several study results were in line to our study.[4,11,12,15]

An adverse event does not always present with an untoward outcome. Some adverse events either have no untoward outcome or the untoward outcome is so minor that it goes unnoticed. In the current study, 736 adverse events were studied by RF-2 format, out of which 577 (78%) presented with untoward outcome for adverse events (Graph 2 and Table 3) mainly occurring in surgical specialties ($p < 0.0001$). Several studies were found in line with our study.[2,4,11,12,14,15,17]

Out of the total adverse events presenting with untoward outcome 81.8% adverse events caused admissions in wards, 4.33% of adverse events were associated with deaths, 23.4% of adverse events caused disability at the time of discharge and 35.5% of adverse events causing prolonged hospital stay (Table 4). Similar results were seen in line with our study.[11-15] There were some studies which were in contrast to the current study.[4,10,14,16-18]

Four hundred and ninety-six (67.4%) of studied adverse events through RF-2 form showed signs of healthcare team responsible for causing adverse events which could have been prevented. Out of 496 adverse events having evidence that Healthcare team has association with the causation of adverse event, 76.6% adverse events were related to therapeutic care, 17.3% adverse events occurred during diagnosis (Graphs 3 and 4, Tables 5 and 6). Finding of a study were found in line with other studies.[1,19] In contrast to our study, few studies showed adverse events related to diagnosis were more than therapeutic adverse events.[12]

It is pertinent to mention that not all adverse events seen in admitted patients occurred in the current admitting hospital. Sometimes an adverse event had already been taken place before index admission in a public or private hospital, nursing home or a primary healthcare center which was later on referred to the current admitting hospital. Sometimes an adverse event had taken place in previous admissions and got unnoticed.

In our study, 76.8% of adverse event occurred before the index admission and only 23.2% of adverse events occurred after index admission (Graphs 5 to 8, Tables 7 and 8).

Findings of current study are almost in line to other studies.[13] In contrast to our study, some studies showed

that index admission was mainly responsible for adverse events.[2,4,14-16,20]

In our study by current record review among inpatients, 71.33% of studied adverse events were found to be preventable and 28.67% of adverse events were found nonpreventable. Thus, out of 488 patients having adverse events, 348 (71.33%) patients were found to have preventable adverse events. When calculated with respect to total patients screened (3150), it was found that 11.05% patients had preventable adverse events (Graph 9 and Table 9).

Various studies in line to current study showed higher rates of preventability (greater that 50%).[4,17,21-23] Other studies showed preventability less that 50%.[11-15]

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ORIGINAL ARTICLE

A Study of the Awareness Levels of Universal Precautions in High-risk Areas of a Super-specialty Tertiary Care Hospital

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ABSTRACT

Centers for disease control and prevention (CDC), Atlanta, in 1987, defined universal precautions and recommended that blood and body fluid precautions be consistently used for all patients. Although universal precautions have been in existence for a long period of time and the risk of transmission of blood borne infections to healthcare workers (HCWs) is very real, the awareness levels among HCWs to these precautions is still far from satisfactory.

This study was conceived to study the knowledge of universal precautions in high-risk areas of a super-specialty tertiary care hospital in India among different categories of HCWs.

A pretested structured questionnaire common to all the categories of HCWs was used to study the awareness levels of universal precautions. Each question was assigned a unit score. Seventy-five percent score in the questionnaire was taken as cut-off for adequate knowledge.

The findings of the study reveal that the HCWs who had adequate knowledge of universal precautions were 29 (30%) out of 96 HCWs. These included 17 (53%) doctors, 8 (36%) nurses, 3 (31%) technical staffs and 1 (5%) housekeeping staff.

Keywords: Blood-borne infections, Healthcare workers, Tertiary care hospital, Universal precautions.

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INTRODUCTION

All healthcare workers (HCWs) and patients in healthcare settings are at a considerable risk to acquire various blood-borne infections, especially human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). These patients can neither be recognized on physical appearance nor on physical examination. These potentially fatal infections have no cure and no vaccine (except hepatitis B) and the cornerstone of prevention in healthcare settings is the simple practice of universal precautions. Universal precautions have been defined by centers for disease control and prevention (CDC) Atlanta,[1] and these are basic protective measures to prevent parentral, mucous membrane and non-intact skin exposure of HCW to blood borne pathogens. Implementation of universal precautions will reassure both HCWs and patients attending hospitals regarding reduced risk of accidental transmission of blood-borne pathogens.

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AIM

The aim of the study was to study the awareness levels of universal precautions in high-risk areas of a super-specialty tertiary care hospital at New Delhi in India.

METHODOLOGY

This study was conceived to study the awareness levels of universal precautions in high-risk areas of a super-specialty tertiary care hospital in India among four categories of HCWs *viz* doctors, nurses, technical staffs and housekeeping staffs. The study is descriptive and cross-sectional in nature. High-risk areas were those departments or wards where probability of exposure to blood and body fluids is higher due to either increased handling or large number of interventions performed and thus, six areas were selected which were blood bank, main laboratory, main operation theatre (OT), main intensive care unit (ICU), emergency services and dialysis unit.

Questionnaire was used to study the awareness level of universal precautions among the different categories of HCWs. A common questionnaire was prepared in bilingual language for all categories of HCWs. The questionnaire was prepared after extensive review of literature and discussions with hospital administrators. The questionnaire consisted of three segments:

Part I consisted of questions 1 to 6 and these were related to demographic data.

Part II consisted of questions 7 to 15 and these were used to assess the knowledge of various components of universal precautions.

Part III consisted of questions 16 to 25 which were related to practice of various components of universal precautions.

ANALYSIS OF QUESTIONNAIRE

Questions from 7 to 25, which pertained to knowledge and practice of universal precautions, were included in the scoring system. Each of these questions was assigned a unit score. Thus, the score could vary from 0 to 19. Maximum score of 19 would mean that responses for all 19 questions were correct representing the level of awareness as 100%. Seventy-five percent was taken as a cut-off for adequate knowledge, i.e. those HCWs who answered 75% or more questions correctly were considered to have adequate knowledge[2] of universal precautions and others (i.e. those with less than 75% correct responses) were considered to be having inadequate knowledge. The questionnaire was pretested through a pilot study done on 12 HCWs, three from each category. The questionnaires were distributed to each HCW personally. The requisite information and explanations were also provided wherever required. The participants were expected to complete the questionnaires according to their convenience and return them back within 7 days. If they were not returned within 7 days, the participants were reminded to complete the questionnaire and return it. The study population of different categories of HCWs in the six areas of the study was 255 + 126 + 101 + 87 = 569. Out of these 32 + 22 + 21 + 21 = 96 (16.87%) HCWs were selected by simple random sampling to assess the awareness levels of universal precautions through the questionnaire.

RESULTS AND DISCUSSION

There were a total of 96 HCWs who participated in the study to assess the awareness levels of universal precautions. These comprised of 32 doctors, 22 nurses, 21 technical staffs and 21 housekeeping staffs. Out of the 96 HCWs, 67 (69.79%) were males and 29 (30.21%) females. The reason for male preponderance is that majority of HCWs in technical staff and housekeeping staff working are males. Eighty-one (84.38%) of HCWs were in the age group of 20 to 40 years and 15 (15.63%) were in the age group of 41 to 60 years. Fifty-eight (60.42%) had 0 to 10 years of service and 38 (39.58%) had more than 10 years of service. Out of 32 doctors, 9 were graduates and 23 were postgraduates; of the 22 nurses, 1 was MSc, 5 were BSc and the remaining 16 were diploma holders; of the 21 technical staffs, 10 were graduates, 6 were senior secondary and the remaining 5 were matriculates; of the 21 housekeeping staffs, 3 were postgraduates, 2 were senior secondary, 11 were matriculates and the remaining 5 were below matriculates. Of the 96 HCWs, 12 (12.5%) were from the blood bank which included 2 doctors, 2 nurses, 5 technical staffs and 3 housekeeping staffs, 14 (14.6%) were from the main lab which include 3 doctors, 7 technical staffs and 4 housekeeping staffs, 20 (20.8%) were from the main OT which included 9 doctors, 4 nurses, 3 technical staffs and 4 housekeeping staffs, 17 (17.7%) were from the main ICU which included 8 doctors, 4 nurses, 2 technical staffs and 3 housekeeping staffs, 25 (26.1%) were from the emergency services which include 8 doctors, 10 nurses, 2 technical staffs and 5 housekeeping staffs, 8 (8.3%) were from the dialysis unit which included 2 doctors, 2 nurses, 2 technical staffs and 2 housekeeping staffs. The findings of the study are as under.

The study population of different categories of HCWs was 255 + 126 + 101 + 87 = 569, and out of these 32 + 22 + 21 + 21 = 96 (16.87%) HCWs were selected to assess the awareness levels of universal precautions through the questionnaire.

The awareness level of universal precautions was determined by a questionnaire consisting of 25 questions out of which first six related to demographic profile and the remaining 19 (7th to 25th) questions were used to check awareness levels. One hundred and four questionnaires were distributed out of which 96 were returned, thus leading to a response rate of 92.31%.

There were 6 questions out of 19 in which overall (combination of all the 4 groups of HCWs) more than 40% of HCWs answered these wrongly. These being question no. 13, 16, 17, 18, 21, and 22. For question no. 13th which was 'universal precautions apply to which body fluids?', only a dismal 10 (10.42%) respondents gave correct answers. For question no. 16th which was 'when should hand washing be performed by HCWs?' only 57 (59.38%) respondents gave correct answers. For question no. 17th which was 'what should be done if hands are soiled with blood or body fluids?' only 45 (46.88%) respondents gave correct answers. For question no. 21st which was that 'in which conditions should HCWs refrain from all direct patient care activities?' only 37 (38.54%) respondents gave corrects answers. For question no. 22nd which was 'what precautions should be taken during the management of HIV patient?' only 47 (48.96%) respondents gave correct answer. From the above observation, it is clear that in some areas of the universal precautions the awareness levels among the HCWs was low. These being as under:

- To which blood and body fluids universal precautions apply?
- When should HCWs perform hand washing?

- When should gloves be worn by the HCWs?
- What should HCWs do if their hands are soiled with blood or body fluids?
- In which conditions should HCWs refrain from all direct patient care activities?
- What precautions should be taken during the management of HIV patient?

Some of the above mentioned are key components of Universal precautions, thus it can be concluded that knowledge gaps exist among the HCWs and awareness levels among them needs to be improved.

Tables 1 to 3 reveal that the overall mean correct answer score by all the 4 categories of HCWs was 13.1 (68.9%) out of the 19 questions or 100% score. The correct answer score among the doctors was 14.5 (76.3%), among the nurse was 13.5 (71.1%), among the technical staff was 12.2 (64.2%) and among the housekeeping staff was 11.3 (59.5%). The difference among the four groups of HCWs was statistically significant ($p < 0.001$) (Graph 1).

The study findings reveal that the highest awareness levels were among the doctors as compared to nurses, technical staff and housekeeping staff suggesting that higher qualification has a positive impact on awareness of Universal precautions.

Vij et al[3] in a study in 1999 at Main Hospital of All India Institute of Medical Sciences, New Delhi to assess the knowledge of staff nurses on infection control measures concluded that the mean knowledge of staff nurses regarding infection control measures was 73.1%. The findings in the present study are comparable to these.

Another study by Clement et al[4] conducted on all surgical trainees in Nigeria in 1997 to determine the knowledge, attitude and risk perception of Nigerian surgery residents to HIV infection and AIDS showed

Table 1: Existing and the selected population of health care workers from each study unit

	Doctors		*Nurses*		*Technical staffs*		*Housekeeping staffs*	
Study unit	*E (N)*	*S (n)*	*E (N)*	*S (n)*	*E (N)*	*S (n)*	*E (N)*	*S (n)*
Blood bank	4	2	2	2	22	5	7	3
Main laboratory	12	3	0	0	46	7	17	4
Gyne OT	48	5	5	2	2	2	6	2
Surgery OT	38	4	8	2	2	1	4	2
Total main OT	86	9	13	4	4	3	10	4
Main ICU	60	8	35	4	12	2	12	3
Emergency services	77	8	69	10	10	2	35	5
Dialysis unit	16	2	7	2	7	2	6	2
Total	255	32	126	22	101	21	87	21

E: Existing population in the study units; S: selected sample of HCWs for the study

Table 2: Correct responses of questions 7 to 25 by different categories of HCWs

	Doctors (N = 32)		*Nurses (N = 22)*		*Technical staff (N = 21)*		*Housekeeping staff (N = 21)*		
Q. No.	*N*	*%*	*N*	*%*	*N*	*%*	*N*	*%*	*p-value*
7	30	93.75	22	100	21	100	21	100	0.25
8	32	100	22	100	14	66.67	16	76.19	**0.001**
9	32	100	17	77.27	17	80.95	11	52.38	**0.001**
10	25	78.13	17	77.27	11	52.38	7	33.33	**0.003**
11	30	93.75	19	86.36	21	100	19	90.48	0.36
12	29	90.63	18	81.82	14	66.67	16	76.19	0.18
13	6	18.75	4	18.18	0	0	0	0	**0.03**
14	32	100	21	95.5	21	100	21	100	0.33
15	26	81.25	13	59.09	17	80.95	15	71.43	0.26
16	18	56.25	11	50	11	52.38	17	80.95	0.14
17	17	53.13	19	86.36	8	38.10	10	47.62	**0.009**
18	21	63.63	11	50	7	33.33	6	28.57	**0.03**
19	31	96.88	18	81.82	14	66.67	17	80.95	**0.03**
20	22	68.75	17	77.27	12	57.14	9	42.86	0.09
21	17	53.13	8	36.36	7	33.33	5	23.81	0.16
22	23	71.88	13	59.09	8	38.10	3	14.29	**0.001**
23	27	84.38	16	72.73	17	80.95	16	76.19	0.74
24	25	78.13	16	72.73	15	71.43	17	80.95	0.86
25	21	65.63	15	68.18	21	100	11	52.38	**0.006**

N: Total no. of HCWs in the category selected for the study; n: Number of HCWs whose responses were correct; $p < 0.05$: Significant and is depicted in bold

Table 3: Mean scores of correct answers by HCWs in different study units

	Mean score of HCWs (0–19)					
Study unit	*Doctors*	*Nurses*	*Technical staff*	*Housekeeping staff*	*Total*	*p-value*
Blood bank	16 (84.2)	15.5 (81.6)	12 (63.2)	9.7 (51.1)	12.7 (66.8)	0.01
Main laboratory	15 (78.9)	—	11.7 (61.6)	9.5 (50)	11.8 (62.1)	0.14
Main OT	13.7 (72.1)	12 (63.2)	11.7 (61.6)	11.5 (60.5)	12.6 (66.3)	0.16
Main ICU	14.5 (76.3)	13 (68.4)	13.5 (71.1)	13.3 (70)	13.8 (72.6)	0.31
Emergency services	14.8 (77.9)	14.1 (74.2)	10.5 (55.3)	12.2 (64.2)	13.6 (71.6)	0.09
Dialysis unit	15 (78.9)	12.5 (65.8)	15.5 (81.6)	11.5 (60.5)	13.6 (71.6)	0.38
Total	14.5 (76.3)	13.5 (71.1)	12.2 (64.2)	11.3 (59.5)	13.1 (68.9)	**0.001**
p-value	0.28	0.41	0.07	0.09	0.19	

Mean score range from 0 to 19; Figures in parenthesis indicate percentage; p < 0.05: Significant and is depicted in bold

that 44.2% of the respondents knew the CDC guidelines for universal precautions well, 44.0% had an idea of these guidelines, i.e. knew them partially and 13.8% had no idea about them.

Among the different study units, the mean correct answer scores were 12.7 (66.8%) in the blood bank, 11.8 (62.1%) in the main laboratory, 12.6 (66.3%) in the main OT, 13.8 (72.6%) in the main ICU and 13.6 (71.6%) in the emergency services and the dialysis unit (Graph 2).

The above findings reveal that the awareness levels in the main ICU, emergency services and the dialysis unit were better in comparison to blood bank, main lab and the main OT, thus indicating that these areas need greater educational and training interventions.

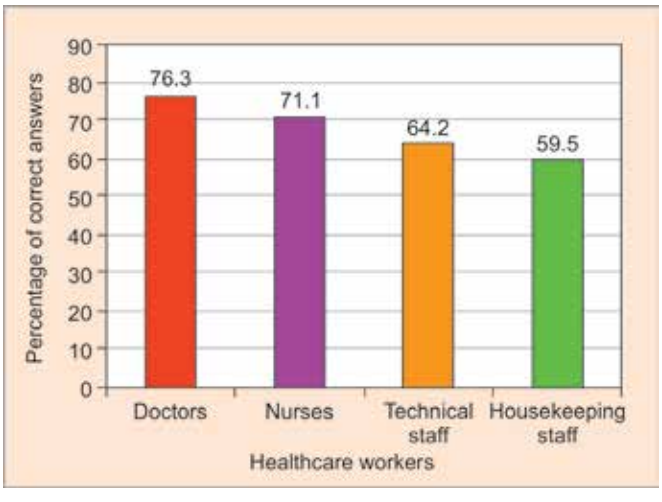
Table 4 reveals the number and percentages of HCWs who answered more than 75% questions in the questionnaire correctly, i.e. those who can be considered as having adequate knowledge (75% score was taken as cut-off score for adequate knowledge of universal precautions).[2]

Overall 29 HCWs out of 96, i.e. 30% answered more than 75% questions in the questionnaire correctly. Those

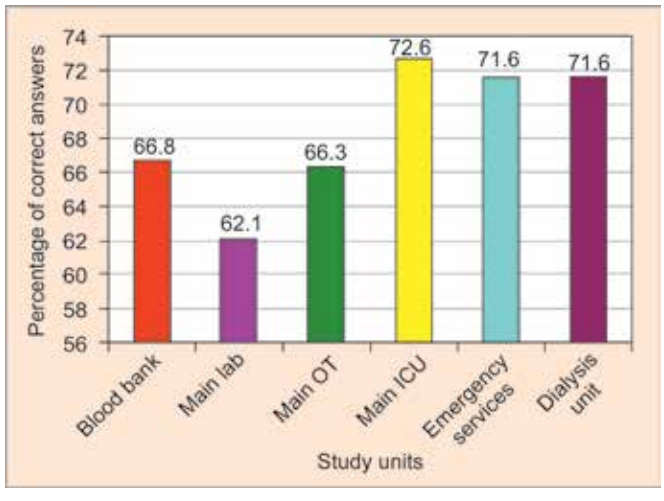
Table 4: Healthcare workers in different study units who scored 75% or more questions correctly, i.e. who had adequate knowledge

	Healthcare workers					
Study unit	*Doctors (N = 32) n/N (%)*	*Nurses (N = 22) n/N (%)*	*Technical staff (N = 21) n/N (%)*	*Housekeeping staff (N = 21) n/N (%)*	*Total (N = 96) n/N (%)*	*p-value*
Blood bank	2/2 (100)	1/2 (50)	0/5 (0)	0/3 (0)	3/12 (25)	**0.02**
Main laboratory	2/3 (67)	—	0/7 (0)	0/4 (0)	2/14 (14)	**0.01**
Main OT	2/9 (22)	1/4 (25)	0/3 (0)	0/4 (0)	3/20 (15)	0.59
Main ICU	5/8 (63)	1/4 (25)	1/2 (50)	0/3 (0)	7/17 (41)	0.25
Emergency services	5/8 (63)	5/10 (50)	0/2 (0)	0/5 (0)	10/25 (40)	0.08
Dialysis unit	1/2 (50)	0/2 (0)	2/2 (100)	1/2 (50)	4/8 (50)	0.26
Total	17/32 (53)	8/22 (36)	3/21 (14)	1/21 (5)	29/96 (30)	**0.001**

N: Total number of HCWs; n: HCWs who have scored 75% or more questions correctly; Figures in parenthesis indicate percentage; p < 0.05: Significant and is depicted in bold



Graph 1: Mean percentage of correct answers by the four categories of HCWs



Graph 2: Mean percentage of correct answers by HCWs in the six study units

who answered more 75% questions correctly were 17 (53%) among the doctors, 8 (36%) among the nurses, 3 (31%) among the technical staff and 1 (5%) in the housekeeping staff. The difference among the four groups was statistically significant ($p < 0.001$).

The study findings again reveal that the highest awareness levels were among the doctors as compared to nurses, technical staff and housekeeping staff suggesting that higher qualification has a positive impact on awareness of universal precautions.

Among the different study units, the percentage of HCWs who answered more than 75% questions correctly were 25% in the blood bank, 14% in the main laboratory, 15% in the main OT, 41% in the main ICU, 40% in the emergency services and 50% in the dialysis unit.

The above findings reveal that the awareness levels in the dialysis unit were satisfactory but were very low in blood bank, main lab and the main OT, thus indicating that these areas need educational and training interventions.

The findings also reveal that educational and training interventions are required for doctors of main OT and dialysis unit, nurses of all the six study units, technical staff of all the units except dialysis unit and housekeeping staff of all the six study units.

In a study by Gumodoko et al[2] conducted in nine hospitals in Mwanza region of Tanzania in 1997 showed that 65% of the HCWs had inadequate knowledge of the occupational risks of HIV transmission. Half of the medical staff and over 90% of the nursing attendants had inadequate knowledge. The findings are comparable with the present study which shows that 70% of HCWs had inadequate knowledge.

CONCLUSION

Although universal precautions have been in existence for a long time and the risk of transmission of blood-borne infections to HCWs is very real, the awareness levels to universal precautions are far from satisfactory and need improvements particularly among nurses, technical staff and housekeeping staff. The awareness levels among doctors though satisfactory but still needs some improvements. It is the responsibility of the hospital authorities and administrators toward the hospital, through trainings, supervision and stricter enforcement and of the HCWs toward themselves and their patients, through awareness and compliance to ensure that these precautions are actually implemented.

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ORIGINAL ARTICLE

Hand Hygiene Policy for a Tertiary Care Hospital

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ABSTRACT

Hand hygiene diminishes the carriage of potential pathogens on the hands. It results in reduction in patient morbidity and mortality from nosocomial infection. Eighty percent of nosocomial disease transmission is thought to be via hands. The purpose of this study is to provide policy with regard to hand hygiene which can be followed in tertiary care hospitals. It was a descriptive cross-sectional study carried out between April and August 2013. The study population included doctors, nursing personnel, paramedical staff and quality managers of tertiary care hospital from public and private hospitals. Checklist was made after an exhaustive review of literature which was then improvised. Validation of the checklist was done by experts in infection control in various private and public hospitals. Subsequently, interaction was done with study population against the back drop of the checklist and hand hygiene policy was formulated.

Keywords: Hand hygiene agents, Hand hygiene practices, Hand washing Techniques.

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INTRODUCTION

Most healthcare-associated infections (HAI) are thought to be transmitted by the hands of healthcare providers (HCPs) through direct contact, mainly when the hands of HCPs transfer microorganisms between individuals or between individuals and the environmental reservoir.

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It has long been known that hand hygiene among HCPs plays a central role in preventing the transmission of infectious agents.[1]

In developed countries, HAI affects about 5 to 15% of hospitalized patients.[6] The rate is higher among those in intensive care units (ICUs) between 9 and 37%.[6,7] The incriminating organisms are often microbial isolates of resistant organisms.[8] Hospitals in Europe Link for Infection Control through Surveillance (HELICS) estimate millions of extra days of hospital stay and huge economic burden.[9,10] In USA, the estimated HAI incidence rate in the year 2004 was 4.5% with a fatality rate of 5% and a huge economic impact.[11,12] Poor hand hygiene among healthcare workers was identified as one of the major causes of the infections.[1]

Hands often act as vectors that carry disease-causing pathogens from person to person, either through direct contact or indirectly via surfaces. Humans can spread bacteria by touching other people's hand, hair, nose, and face, hands that have been in contact with human or animal feces, bodily fluids like nasal excretions, and contaminated foods or water can transport bacteria, viruses and parasites to unwitting hosts.

The value of hand washing for the prevention of cross infection was first observed in the middle of the 19 century. This practice especially when done with soap can remove agents of infection both at the time they were emitted from the primary host and prevent them from reaching the secondary host. Regular hand washing is, thus, an excellent way of preventing the transmission of microbes from one person to another and has been described as a modest measure with big effects. Hand washing is especially important where people congregate (schools, offices), where ill or vulnerable people are concentrated (hospitals, nursing homes), where food is prepared and shared and in homes, especially where there are young children and vulnerable adults.[2]

HAND HYGIENE POLICY FOR A TERTIARY CARE HOSPITAL

Hand hygiene is recognized as the leading measure to prevent cross-transmission of microorganisms. Regarding hospital acquired infections, the compliance of nurses with hand washing guidelines seems to be vital in preventing the disease transmission among patients. There is a paucity of studies exploring this subject in Asia. Especially medical and nursing student's knowledge of

standard hand hygiene precautions is rarely compared. In one of the study in 2014 by Nair et al revealed that only 9% of participants (13 out of 144) had good knowledge regarding hand hygiene. Nursing students knowledge ($p = 0.023$), attitude ($p = 0.023$), and practices ($p < 0.05$) were significantly better than medical students.

NEED OF THE STUDY

Hand hygiene is recognized as the leading measure to prevent cross-transmission of microorganisms and to reduce the incidence of healthcare associated infections. Despite the relative simplicity of this procedure, compliance with hand hygiene among healthcare providers is as low as 40%.[4] To address this problem, continuous efforts are being made to identify effective and sustainable strategies. Nurses constitute the largest percentage of the healthcare workers (HCWs) and they are the 'nucleus of the healthcare system'. The importance of hands in the transmission of hospital because they spend more time with patients than any other HCWs, their compliance with hand washing guidelines seems to be more vital in preventing the disease transmission among patients. Infections has been well-demonstrated, and can be minimized with appropriate hand hygiene. However, compliance with hand washing is frequently suboptimal. In the Sri Lankan theater settings a study demonstrated that only 60% of the doctors performed appropriate hand washing before entering the theater.[3] Noncompliance with hand washing may be due to a variety of reasons, including lack of appropriate facilities for hand washing, high staff to patient ratios, insufficient knowledge and attitudes of the staff, and allergies to hand washing products. Therefore, it is important to address these issues.

METHODOLOGY

It was a descriptive cross-sectional study carried out between April and August 2013. The study population included Doctors, Nursing personnel, Paramedical staff and quality managers of tertiary care hospital from public and private hospitals. Checklist was made after an exhaustive review of literature which was then improvised. Validation of the checklist was done by experts in infection control in various private and public hospitals. Subsequently, interaction was done with study population against the back drop of the checklist and hand hygiene policy was formulated.

ANALYSIS AND RESULTS

One hundred people which included doctors, nurses, paramedical staff, pharmacists and quality managers of tertiary care public and private hospitals were approached for interaction against the back drop of the checklist. Total response rate is 56%. Twelve doctors responded out of 20 doctors approached, 18 nurses responded out of 20, 12 quality managers interacted out of 20 and 4 doctors, expertize in infection control practices responded out of 20 approached and 10 nurses, expertize in infection control practices out of 20 approached. Policy was framed after incorporating inputs from responses received against the back drop of the checklist.

HAND HYGIENE POLICY FOR A TERTIARY CARE HOSPITAL

Aim of the Policy

To make clear to all the staff about hand hygiene and to make available to the point information and guidance regarding hand hygiene. This document summarizes the information to patients and the public about hand hygiene. It sets out how the institute will meet its training prerequisites to ensure that staff receives adequate training in relation to hand hygiene, thus, reducing the risk of healthcare-associated infection.

GOALS AND PURPOSE

The goals and purpose of this policy is to ensure that staff pursues proper evidence-based hand washing techniques for the prevention and control of infections. This policy has been developed to lessen the risk of disease transmission to patients via the hands of staff.

SCOPE

It includes all procedures that require hand hygiene to be maintained.

INTRODUCTION

Hand hygiene:[4] Performing hand washing, antiseptic hand wash, alcohol-based hand rub, surgical hand hygiene/antisepsis.

Hand washing: Washing hands with plain soap and water.

Antiseptic hand wash: Washing hands with water and soap or other detergents containing an antiseptic agent.

Alcohol-based hand rub:[4] Rubbing hands with an alcohol-containing preparation.

Surgical hand hygiene/antisepsis: Hand washing or using an alcohol-based hand rub before operations by surgical personnel.

Improper hand hygiene by HCWs is responsible for about 40% of nosocomial infections. Lack of knowledge and lack of recognition of hand hygiene opportunities during patient care are mainly responsible for poor

hand hygiene among HCWs. Although many countries have guidelines regarding hand hygiene for healthcare settings, overall compliance among HCWs remains poor despite hand hygiene being regarded as one of the most important elements of infection control activities. World Health Organization (WHO), in 2005 issued guidelines regarding specific steps and procedures to be followed during hand washing.[5] The spread of infections in developing countries remains a serious problem, especially in high-risk settings, such as healthcare facilities due to lack of awareness in HCWs and compounded by 'omo syndrome' (a belief that they are super clean and sterile).[8] Present study attempts to formulate policy for tertiary care hospitals.

RESPONSIBILITIES

Responsibility of a hospital/institute are:

- To promote compliance with best practice in hand hygiene
- To embed hand hygiene as an integral part of the organization culture as a matter of clinical governance
- To view any drift in hand hygiene practices as a serious clinical issue
- To ensure all new employees receive the hand hygiene policy
- To make available sufficient resources to facilitate compliance with the hand hygiene policy
- To actively encourage compliance with the hand hygiene policy
- To ensure that audits of hand hygiene compliance are undertaken according to the infection prevention and control team audit calendar within their sphere of management
- To ensure that the amenities and equipment for hand hygiene are in place so that staff have appropriate and convenient access.

Responsibility of Infection Control Committee and Infection Control Team are:

- To counsel on current best practice in hand hygiene policy
- Advise on best practice in planning hand hygiene facilities for new construction and refurbishment work
- Plan and deliver a program of hand hygiene education
- Monitor compliance with the hand hygiene policy through infection control audit and routine observation of practice.

To use routine observation of hand hygiene practices as clinical indicator and feedback via the infection prevention and control link team and the infection control committee.

Responsibility of Infection Control Nurse

Act as a role model promoting good hygiene practice within the institute. Monitors the progress of hand hygiene assessments undertaken within their clinical areas and put forward support as required.

Responsibility of Nurses' In-Charge

Make sure that all facilities and equipment are in place to facilitate hand washing.

Any concerns to be highlighted to the member of the infection prevention and control team.

Ensures that all staff within their designated area of responsibility is aware of the hand hygiene policy and have had appropriate hand hygiene training.

Nominate a designated member of the ward staff who ensures that alcohol hand rubs are in place and that dispensers are full and functional.

Make sure that information and posters are available and placed in positions of prominence for all visitors to the ward area to see.

Monitor hand hygiene is taken seriously by all members of the healthcare team and any breaches are dealt with effectively and if necessary as a clinical incident.

Ensure that staff actively participate in all aspects of the Clean Your Hands Campaign.

Individual Responsibility

Timely effective hand hygiene is the personal responsibility of all individuals involved in the provision of healthcare.

All HCWs have a personal responsibility to comply with all aspects of the hand hygiene policy.

RECOMMENDATIONS

Indications for Hand Washing and Hand Antisepsis

- When hands are visibly dirty or contaminated with proteinaceous material or are visibly soiled with body fluids, wash hands with either a non-antiseptic soap and water, or an antiseptic soap and water.[6]
- If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands in following situations.
- Before having direct contact with patients.
- Before inserting indwelling urinary catheters, peripheral vascular catheters, or other invasive devices that do not require a surgical procedure.
- After contact with a patient's intact skin (e.g. when taking a pulse or blood pressure, and lifting a patient).

- After contact with body fluids or excretions, mucous membranes, nonintact skin, and wound dressings if hands are not visibly soiled.
- After removing gloves.
- Wash hands with nonantimicrobial soap and water or with antimicrobial soap and water if exposure to Bacillus anthracis is suspected or proven. The physical action of washing and rinsing hands under such circumstances is recommended because alcohols, chlorhexidine, iodophors, and other antiseptic agents have poor activity against spores.
  - After using the toilet
  - After cleaning up any spillage
  - Before handling food
  - Before and after aseptic procedures
  - After handling laundry and waste
  - Before and after administering medication
  - Before and after emptying urinary drainage bags

Types of Hand Hygiene[6]

Routine Hand Wash

Agent: Used is soap and water

Purpose: Remove soil, remove transient flora

Indication: Before significant contact with a patient like before emptying a catheter bag, injection, venipuncture, changing a nappy, assisting to eat, between performing procedures on the same patient, after activities likely to cause significant contamination, e.g. direct contact with body secretions, mucous membranes, wounds, removing gloves.

Technique

- Remove hand and wrist jewellery
- Wet hands first with water
- Apply product as recommended to hands
- Rub hands together vigorously for at least 15 seconds
- Cover all surfaces of the hands and fingers
- Rinse hands with water
- Dry thoroughly with a towel
- Use towel to turn off the faucetor elbow taps if available.

Antiseptic Hand Rubs

Agent: Used alcohol-based hand rub (alcohol 70% or alcohol 70% and triclosan).

Purpose: To destroy transient flora, reduce resident flora.

Note: This type of hand washing will not remove or denature soil.

Indication

- As for routine hand wash
- May be performed in lieu of routine hand wash, but only if hands are free of visible soil.
- May be performed in emergency situations where there is insufficient time/facilities (water).

Technique

- Remove hand and wrist jewellery
- Apply product as recommended to hands
- Rub hands together vigorously for at least 15 seconds
- Thoroughly rub all surfaces of the hands and fingers until hands are dry.

Antiseptic Hand Wash

Agent: Antiseptic soap, water friction.

Purpose: Remove soil, remove transient rlora, reduce resident flora.

Indication: Routine hand wash may be the preferred type of hand decontamination when attending high risk patient, e.g. neonatal intensive care unit (NICU), pediatric intensive-care unit (PICU), oncology, central lines but this type of hand hygiene can also be used.

Technique

- Remove hand and wrist jewellery
- Wet hands first with water
- Apply product as recommended to hands
- Rub hands together vigorously for at least 15 seconds
- Cover all surfaces of the hands and fingers
- Rinse hands with water
- Dry thoroughly with a towel.

Note: Hand antisepsis occurs simultaneously with hand washing when soaps for detergents which contain antiseptics are used.

Clinical Hand Wash

Agent: Used antiseptic soap, water friction

Purpose: To remove soil, remove transient flora, reduce resident flora.

Indication: Nonsurgical procedures which require aseptic technique, e.g. peripheral venous cannulation, insertion of a urinary catheter, wound dressings.

Technique

- Remove hand and wrist jewellery
- Wet hands first with water
- Apply product as recommended to hands
- Rub hands together vigorously for at least 60 seconds
- Cover all surfaces of the hands and fingers

- Rinse hands with water
- Dry thoroughly with a towel.

Surgical Hand Antisepsis

Agents used: Antiseptic soap only or soap and then alcohol based hand rub with persistent activity.

Purpose: To remove soil, transient flora reduce resident flora for duration of surgery in care of glove tear.

Indication: All surgical procedures including insertion of all CVC lines.

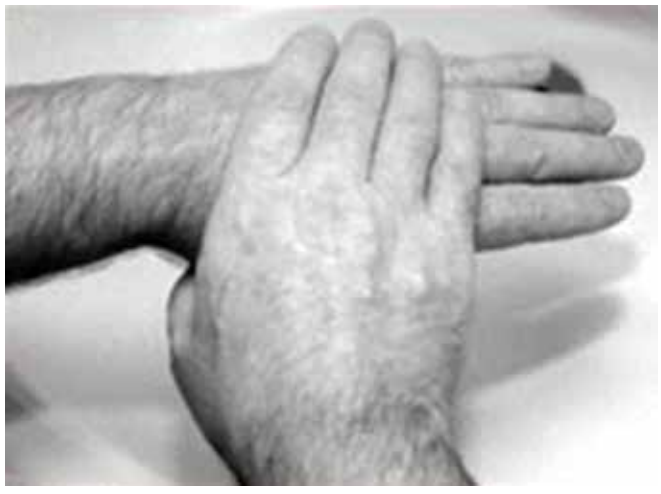
Technique

- Remove rings, watches, and bracelets before beginning the surgical hand scrub
- Fingernails should be kept short and well maintained
- Hands and forearms must be free of open lesions and breaks in skin integrity
- Be wearing complete operating room attire including mask, cap, and goggles if they are to be worn
- Keep clothing away from sink and splashes
- Turn on water and adjust temperature for your comfort
- Keep arms level well away from body and hands up above elbows for duration of scrub
- Wet hands and forearms
- Apply antiseptic hand wash solutions
- Lather hands and forearms for at least one minute from fingertips to three inches above elbows starting with hands to forearm, forearm to elbow
- Wash hands thoroughly, using the following steps to facilitate eradication of all bacteria and 10 seconds/ step.

Seven-step hand washing technique is being followed are:

1. *Step 1*: Palm to palm

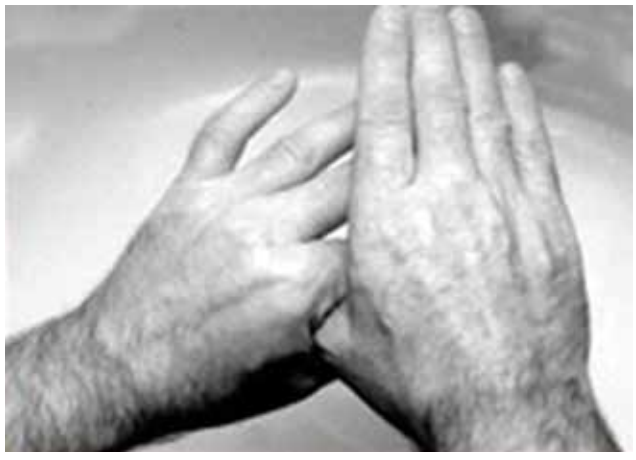
2. *Step 2*: Right palm over back of left hand. Change hands and repeat.



3. *Step 3*: Interlace fingers of right hand over left. Change hands and repeat.

4. *Step 4*: Rotational rubbing backward and forward with clasped fingers of right hand in left palm. Change hands and repeat.

5. *Step 5*: Rotational rubbing of right thumb clasped in left palm. Change hands and repeat.



6. *Step 6*: Grasp left wrist with right hand and work cleanser into skin. Change hands and repeat.

7. *Step 7*: Rub hands and wrists for 30 seconds, then rinse and dry thoroughly.

- Apply antiseptic hand wash solution a second time
- Lather hands and forearms for at least 2 minutes in the same manner
- Recommended scrub time is between 2 and 6 minutes, longer times are not necessary
- Prolonged and abrasive scrubbing may damage the skin
- Pay attention to all areas of the hands and forearms
- Rinse hands and forearms under running water keep hands higher than the elbow at all times
- Thoroughly dry hands and forearms with a sterile towel keeping hands raised.

Proceed to OT keeping hands above the elbow and out from scrub clothes.

- Allow hands and forearms to dry thoroughly before donning sterile gloves.
- Between short cases only, hands may be disinfected by using two or more applications of an alcohol hand rub.

Before applying the alcohol solution, pre wash hands and forearms with a nonantiseptic soap and dry hands and forearms completely.

Selection of Hand Hygiene Agent[4]

- To provide with hand-hygiene products that have low irritancy potential, mainly when these products are used numerous times per shift.
- When selecting nonantimicrobial soaps, antimicrobial soaps, or alcohol-based hand rubs, solicit information from manufacturers regarding any known interactions between products used to clean hands, skin care products, and the types of gloves used in the institution.
- Before making purchasing decisions, evaluate the dispenser systems of various product manufacturers or distributors to ensure that dispensers function adequately and deliver an appropriate volume of product.
- Central infection control council recommends that either Micro shield or Sterillium can be used as an alcohol-based hand rub. In OTs, only micro shield should be used because of greater residual activity.
- Do not add soap to a partially empty soap dispenser. This practice of 'topping off' dispensers can lead to bacterial contamination of soap'.

Other Important Aspects of Hand Hygiene[4]

Avoid wearing artificial fingernails or extenders when in direct contact with patients at high risk (e.g. those in intensive-care units or operating rooms).

- Keep natural nails tips less than 1/4" long
- To wear gloves when contact with blood or other potentially infectious materials, mucous membranes, and non intact skin could occur.
- To remove gloves after caring for a patient. Do not wear the same pair of gloves for the care of more than one patient, and do not wash gloves between uses with different patients.
- To change gloves during patient care if moving from a contaminated body site to a clean body site.

Facilities

All clinical areas *viz.* consultation chambers, nursing stations and critical care areas should have:

- Hand washing facilities appropriate to the area
- Clear unobstructed access to the hand washing sink
- Hand washing sinks for that purpose only and clear of inappropriate items
- Liquid soap and alcohol hand rubs available at every sink

- Hand drying facilities with disposable paper towels must be readily available at every sink
- Hand washing posters should be placed by each sink
- All critical areas should have alcohol-based hand rubs installed at entry points for use by visitors
- All critical areas should have alcohol-based hand rubs by each patient bedside
- The infection control committee should be consulted before any new construction or refurbishment work is planned to advice on sink type, number and placement of hand washing facilities.

Hand Washing Agents[6]

There are three types of agent, which can be used to remove microorganisms from hands: soap, alcohol-based, hand rubs and antimicrobial agents.

Soap

Will mechanically remove transient microorganisms but has little effect on resident microorganisms.

Alcohol-based Hand Rubs

Can be applied quickly without access to water. However, they are not effective in removing soiling and should only be used if hands are visibly clean.

Recent studies advocate the use of alcoholic hand rubs between each patient contact as a measure, which reduces the rate of hospital-acquired infection.

Antiseptic Agents

Are designed to remove transient and reduce resident skin microorganisms. Chlorhexidine-based preparations have been found to be more effective than iodine-based solutions as they have a residual effect, which influences the survival times of many organisms on hand surfaces.

Antimicrobial agents should be used in situations when there is a need to reduce resident microbial flora, e.g. in operating theaters or similar departments or when dealing with patients in isolation and before performing an invasive procedure.

Hand Drying Agents

Drying hands with paper products is preferable to using hot air or linen towels. The use of hot air dryers should not be used in clinical areas as these spread airborne bacteria by recirculating the surrounding environmental air.

Drying with a high absorbency paper towel will remove some of the transient organisms that remain after hand washing. Paper towels should be wall mounted.

Patient Hand Hygiene

Hand hygiene for patients must be encouraged as it is equally as important in the prevention and control of infection. Staff must ensure that patients are afforded an opportunity to hand wash prior to meals, after having used a bedpan/urinal or toilet or when hands are otherwise soiled.

Quality Assurance

- Training to be made mandatory for newly joined staff on hand hygiene
- Continuous monitoring and record keeping of adherence to hand hygiene practices
- Mechanism to provide feedback to healthcare workers about their performance
- To monitor the quantity of alcohol-based hand rub used per 1,000 patient days
- To monitor hospital acquired infection rates.

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ORIGINAL ARTICLE

Study of the Traffic Management System at an Apex Tertiary Care Teaching Hospital and Recommendations for Improvement

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ABSTRACT

Introduction: Hospital parking services often represent the very first contact patients and visitors have with our hospital and to make a positive perception of our hospital, we need ample patient and visitor parking. Over last decade, there has been a quantum increase in workload by 6 to 7 times and a corresponding increase in the number of vehicles entering the tertiary care teaching hospital premises. Aim of traffic management at tertiary care hospital is to decongest, improve and smoothen traffic by advocating lane discipline, platooning, signal lights, parking, footpaths, reducing the number of private vehicles, efficient public transport, car pooling, etc.

Aims and objective: To study vehicular traffic management system at a Apex Tertiary Care Teaching Hospital.

Methodology: This was done by survey of the area and observation of traffic flow and its measurement. The data, thus, collected were analyzed and based on the analysis an action plan was drawn.

Conclusion: As regards parking arrangements at the tertiary care teaching hospital are concerned, there is a need to create integrated parking lots on surface as well as basement of the buildings for parking of approximately 7600 vehicles which will also take into account the future needs. These parking lots should also include multilevel intelligent parking system with a computerized system of lifts stacking each car in a berth, and thus reducing the need for parking and service personnel.

Keywords: Intelligent parking, Parking lots, Traffic management, Valet system, Vehicles.

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INTRODUCTION

Traffic management is designed to improve the local environment and safety, by reducing accidents, injuries, congestion and pollution, achieved by slowing traffic speeds or redirecting traffic to more suitable transport routes through various means.[1] Traffic management entails influencing the traffic supply and demand in terms of time and place, in order to achieve a functionally effective system. Hospital parking services often represent the very first contact patients and visitors have with the hospital. Like heart attacks, traffic congestions are a lifestyle problem. When arteries get clogged, we get heart attacks and when roads get clogged we get gridlocks.[2]

If we really think about it, traffic management boils down to efficient 'space' management. It is to manage the utilization of a finite commodity like space on the streets. All measures taken or discussed to decongest, improve, smoothen traffic by advocating lane discipline, platooning, signal lights, parking, footpaths, lesser private vehicles, efficient public transport, car pooling, etc. boils down to the management of the available road space. All these need fail proof, nondiscriminatory, permanent, long-term solutions which have to be followed by one and all.

AN OVERVIEW OF EXISTING TRAFFIC SYSTEM AT THE TERTIARY CARE HOSPITAL

Background: The Apex Tertiary Care Hospital was planned as an 866 bedded hospital which has over a period of time increased to approximately 2424 beds. Over the last decade, there has been a quantum increase in workload by 6 to 7 times. This astronomical increase in workload has been far more than what was envisaged. To cater to this increased workload in the tertiary care hospital campus has undergone hazardous growth due to lack of prospective planning. The expansion of various buildings and facilities has taken place in an adhoc manner due to lack of proper planning. This has manifested in scattered structures, services, chaotic traffic and lack of parking spaces besides under utilization of land resulting in paucity of space for future expansion. Over 40,000 to 50,000 patients and visitors come to the Institute every day. A study conducted by tertiary care teaching hospital in 2003 concluded that 26,500 vehicles are parked in the Institute everyday.[3]

Existing Layout of the Tertiary Care Hospital

There are two types of traffic system in the hospital: (a) External traffic and (b) internal traffic.

External Traffic

- It is necessary to identify different types of traffic that traverses and sometimes crisscrosses the hospital.
- It is also essential to segregate the traffic at the perimeter so that it can be regulated inside.

Internal Traffic

- This relates to movement of staff, patients, attendants and goods within the hospital building.

AIMS AND OBJECTIVES

- To study the existing external vehicular traffic management system at an Apex Tertiary Care Hospital.
- To estimate the number of vehicles entering the campus and residual number of vehicles in the parking lots on different days of the week.
- To identify the problems pertaining to traffic management system at that Apex Tertiary Care Hospital.
- To suggest measures for improvement of the traffic management system at same Apex Tertiary Care Hospital.

METHODOLOGY

Study area: At the Apex tertiary care hospital.

Type of study: Descriptive observational study.

Methodology: Parking spaces in the tertiary care hospital campus were studied with the help of drawings of the campus and discussions with the officials. Traffic flow and traffic measurement was done by observation of the vehicles entering the campus, the routes followed and the parking spaces (Flow Chart 1).

A 4 days observational study (both full working day and Sunday/Holiday) was conducted in the month of October to count the vehicles (both four wheelers and two wheelers) entering the campus from all four gates of tertiary care hospital campus (Table 1).

OBSERVATIONS

Existing Conditions

Entrance gates

At present, there are four entrance and exit gates in the Apex Tertiary Care Hospital.

Gate 1: Main Hospital Gate (Aurobindo Marg)

Gate 2: Ring Road Gate (South Extension)

Gate 3: Yusuf Sarai Side, Campus Gate

Gate 4: Masjid Moth Gate

Flow Chart 1: Methodology used for conducting the study

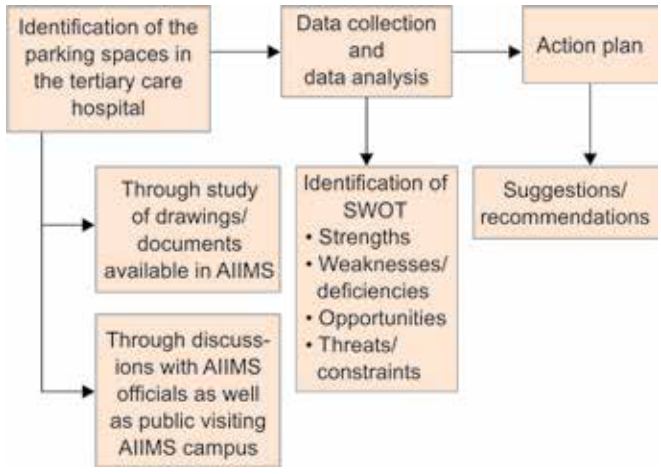

Table 1: Entry of vehicles into tertiary care hospital campus on full working day and Sunday

Sl. no.	*Study conducted*	*Four wheelers*	*Two wheelers*
1	Full working day	6006	5126
2	Sunday	3408	2799
3	Full working day	4716	2814
4	Sunday	2895	2805

Existing Parking at Tertiary Care Teaching Hospital

There are two types of parking space at the Apex Tertiary Care Hospital:

1. Parking Lot no: 'A' for faculty/staff:
   - Faculty/staff car/scooter parking behind RPC which is operational from 7 am to 8 am.
   - Faculty car/scooter parking in front of PC block, near examination section which is operational for 24 hours.
   - Staff car/scooter parking near gate no. 2 in front of garage which is operational from 7 am to 8 pm.
   - Staff scooter parking near Administration block which is operational from 7 am to 8 pm.
2. Parking Lot no: 'B' general public parking area
   - Adjacent to mortuary operational for 24 hours.
   - Masjid Moth land across Nallah operational from 7 am to 9 pm.
   - Scooter parking on both sides of subway near exit gate operational for 24 hours.

To manage and control the scooter and car parking areas in the institute campus, there is a rate contract with an outside agency to ensure orderly parking of vehicles along with organizing the smooth flow of traffic.

The duties and responsibilities of the contractor are as follows:

- To manage the scooter/car parking areas for the general public, which have been earmarked for this purpose within the institute campus on charge of requisite fee from the public.

- To manage the areas earmarked for parking of the vehicles of the Institute's staff/faculty free of cost.
- To manage the flow of traffic within the institutional areas of the main campus.
- To ensure that vehicles are not parked in 'No Parking' areas and to make arrangement for towing away the vehicles which have been parked in the unauthorized areas.
- To ensure that the flow of traffic is smoothly maintained without any hindrance and the roads meant for one way traffic are manned and ensuring that the vehicles are not allowed to violate traffic instructions issued from time to time.
- To provide adequate manpower to effectively run the services as mentioned earlier.

Control of Traffic

The traffic flow of vehicles is managed by the contractor by deploying traffic marshals/guides at the following locations for the durations as indicated against each:

- Ring Road Gate (South Extension) (6.00 am to 8.00 pm)
- Main hospital entrance gate (Aurobindo Marg) -do-
- Entrance gate near SBI -do-
- Gate near director's bungalow -do-
- In front of OPD -do-
- The intersection between the boys hostels and administration block -do-
- Entrance to IRCH/CN center -do-
- In front of Dr RP Center -do-
- Faculty car parking -do-
- RPC Gents Hostel scooter parking -do-

The contractor ensures that various instructions issued from time to time regarding movement of different kinds of vehicles, etc. are strictly enforced. The Deputy Chief Security Officer (Tertiary Care Hospital) of the institute issues detailed instructions regarding one way traffic, speed limit and timing, etc. The contractor is to ensure

- Proper maintenance of various traffic signboards installed in the institutional areas.
- Restrictions on the movement of such vehicles as are notified from time to time.
- Vehicles wrongly parked in various areas are towed away to a predesignated place within reasonable time at his own expenses without damage to the vehicles.

Average number of vehicles (four wheelers) entering to tertiary care hospital campus on a full working day from four entrances = 6006 + 4716/2 = 10722/2 = 5361.

Average number of vehicles (two wheelers) entering to tertiary care hospital on full working day campus from four entrances = 5126 + 2814/2 = 7940/2 = 3970.

Average number of vehicles (four wheelers) entering to tertiary care hospital campus on a Sunday/Holiday from four entrances = 3408 + 2895/2 = 6303/2 = 3151.

Average number of vehicles (two wheelers) entering to tertiary care hospital campus on a Sunday/Holiday from four entrances = 2799 + 2805/2 = 5604/2 = 2802.

In addition to the above-mentioned parking areas (Table 2) vehicles are also parked in:

- Old nurses hostel, behind new private wards (cars)—40
- Center for community medicine—10 cars + 20 two wheelers
- Gents hostel—100 cars + 100 two wheelers.

Road Side Parking

PMR department area—120 cars + 100 two wheelers

- Faculty parking (cars)—45
- VIP parking (cars)—20
- New private ward (cars)—20
- RPC hostel (two wheelers)—50

It was also observed that there are many vehicles parked in 'No parking areas' like in front of guest house, examination block, Amrit Kaur OPD, SBI Bank/Mother dairy, in-between IRCH and CN center, old private and new private wards. At any point of time approximate number of four wheelers and two wheelers parked in these areas were 1275 and 1350 respectively.

Existing Methods of Traffic Control at the Tertiary Care Hospital

- The contractor along with the security manages the traffic flow in one direction.
- Checks on unauthorized parking of vehicles.
- Cranes for towing away the vehicles parked in the unauthorized areas.

Table 2: Staff parking areas on Sunday

Sl. no.	*Parking area*	*Capacity*	*No. of vehicles from Monday to Saturday*	*No. of vehicles*
1	In front of examination section (cars)	130	130	10–15
2	In front of examination section (two wheelers)	130	130	30–35
3	Near administrative block (two wheelers)	400	400	50–60
4	Near ring road gate	65	65	5–10
5	Parking behind RPC (cars)	25	25	10–15
6	Parking behind RPC (two wheelers)	50	50	10–50

Problems Identified

Following observations were made:

- Parking area is far from OPD and in-patient areas, a distance of about 600 meters.
- Parking lots are inadequate to accommodate the vehicles entering into the hospital.
- Parikrama Sewa (free battery operated vans) available for transporting patients and attendants within the campus is not sufficient during the morning hours to cater to the load of patients and attendants who need transportation from parking lots to the patient care areas as a large number of patients and attendants arrive within a short time span during morning hours.
- The roads are not pedestrian friendly. There are hardly any signs and directions for the convenience of patients.
- There is no parking area demarcated for the visitors of patients admitted in the paying wards.

SWOT Analysis

Strengths	*Weakness*
• Land available	• Common entrance to OPD and emergency
• Funds available	• Distance from parking area to patient care area
• Roads and traffic system already existing	• Inadequate parking space
	• Insufficient shuttle/ parikrama sewa vehicles
	• The tertiary care hospital employees using vehicles for commuting from residential areas to the institute
Opportunities	*Threats*
• Parking space at the tertiary care hospital metro rail	• Chaotic traffic
	• Public dissatisfaction

RECOMMENDATIONS

The main objectives of the Traffic Management System is to provide a quality parking service facility to customers, facilitation of quick entry and exit from the parking points and reduction of travel time, streamline the entire traffic movement around the car parking area.

The following are the recommendations to augment the parking space which has been found to be inadequate in the present study:

Underground parking system: The most unique feature of such systems is that they can be planned under the new upcoming buildings.

Multilevel vertical parking system: These parking systems can be planned near the entrance gates of the tertiary care hospital.

Valet system: This service can be provided so that the need of the customer to park their own vehicle is eliminated. In contrast to 'self-parking', where customers find parking on their own, in the valet system customers' vehicles are parked for them by another person.

Multilevel intelligent parking system: Driver intervention is not required as the system estimates the size of the lot and maneuvers the vehicle appropriately. A computerized system of lifts stacks each car in a berth, reducing the need for parking and service personnel. They require no ramps and can house twice the number of cars in half the space.

There is clearly a need for the planners to balance convenience with practicality within the given space constraints.

CONCLUSION

As regards parking arrangements at the tertiary care hospital are concerned, it was observed that all over the Institute, there is a parking space available for approximately 1200 cars and keeping in view the number of patients/visitors, this parking space is inadequate.

A large number of patients coming to the tertiary care hospital are from other states and due to their morbid conditions use vehicles to come to the tertiary care hospital. Most of the patients coming to emergency department come on vehicles out of which a large number are personal vehicles. Further a lot of expansion in terms of increasing the bed complement is planned in the future. This will help increase the pressure on the existing space. It is, hence, recommended that multiple parking areas in different parts of the institute be created keeping in mind their proximity with the patient care and office areas. Besides in all the upcoming buildings two to three basement levels should be earmarked for parking space. Based on the present, study there is an immediate parking space requirement of approximately 7600 vehicles which needs to be planned on the surface and basement. In light of above highlighted measures, it is hoped that this problem can be addressed in future.[4]

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ORIGINAL ARTICLE

Code Blue Policy for a Tertiary Care Trauma Hospital in India

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ABSTRACT

"Code Blue" is generally used to indicate a patient requiring resuscitation or in need of immediate medical attention, most often as the result of a respiratory arrest or cardiac arrest. When called overhead, the page takes the form of "Code Blue, (floor), (room)" to alert the resuscitation team where to respond. Every hospital, as a part of its disaster plans, sets a policy to determine which units provide personnel for code coverage. In theory, any emergency medical professional may respond to a code, but in practice the team makeup is limited to those with advanced cardiac life support or other equivalent resuscitation training. Frequently, these teams are staffed by physicians (from anesthesia and internal medicine in larger medical centers or the emergency physician in smaller ones), respiratory therapists, pharmacists, and nurses. A code team leader will be a physician in attendance on any code team; this individual is responsible for directing the resuscitation effort and is said to "run the code". This phrase was coined at Bethany Medical Center in Kansas City, Kansas. The term "code" by itself is commonly used by medical professionals as a slang term for this type of emergency, as in "calling a code" or describing a patient in arrest as "coding".[1]

The purpose of this study is to make available policy with regard to Code Blue which can be followed in a tertiary care hospitals. It was a descriptive cross-sectional study carried out between January and June 2015. The study population included doctors, nursing personnel, paramedical staff and quality managers of tertiary care hospital from public and private hospitals. Checklist was made after an exhaustive review of literature which was then improvised. The checklist was discussed in focused group discussion held on 1 June 2015, and suggestions were incorporated. Validation of the checklist was also done by experts in various private and public hospitals. Subsequently, interaction was done with study population against the backdrop of the checklist and Code Blue policy was formulated.

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REVIEW OF LITERATURE

Hospital emergency codes are used worldwide to alert staff for various emergency situations in hospitals. The use of codes is intended to convey essential information quickly with a minimum of misunderstanding to the hospital staff, while preventing stress or panic among visitors of the hospital.

"Code Blue" is generally used to indicate a patient requiring resuscitation or otherwise in need of immediate medical attention, most often as the result of a respiratory or cardiac arrest. Each hospital, as a part of a disaster plan, sets a policy to determine which units provide personnel for code coverage. In theory, any medical professional may respond to a code, but in practice the team makeup is limited to those who had advanced cardiac life support or other equivalent resuscitation training. Frequently, physicians from anesthesia, emergency medicine and internal medicine are charged in the team. A rapid response team leader or a physician is responsible for directing the resuscitation effort and is said to "run the code".[2]

General Principles of Code Blue[3]

After ensuring the safety of the patient, staff and bystanders, the management of the collapsed patient involves as follows:

- Prevention of further injury
- Checking response to verbal and tactile stimuli
- Care of airway, breathing and circulation
- Calling for help
- Control of bleeding
- Protection from the environment
- Maintenance of normal body temperature
- Protection of skin and nerves by protection of bony prominences from hard objects

- Reassurance and continued observation of the collapsed patient.

Each member of the multidisciplinary team is to know and understand the skills and roles of each person involved in the Code Blue response. During a Code Blue response, the multidisciplinary team recognizes the resuscitation team leader for possessing broad skills of organization and performance related to the Code Blue response.

All active members should be performing as a well-constructed team, polished by practice and experience. This will assist in preventing a disorganized and frantic code scene (Flow Chart 1).[3] The incidence of out-of-hospital cardiac arrest is estimated between 36 and 128 per 100,000 subjects per year. In these victims, cardiopulmonary resuscitation efforts are made in as many as 86%, and return of spontaneous circulation (ROSC) can be achieved in 17 to 49%.[4]

Cardiac arrest is a medical emergency that, in certain situations, is potentially reversible if treated early. Unexpected cardiac arrest can lead to death within minutes: this is called sudden cardiac death (SCD). The treatment for cardiac arrest is immediate defibrillation if a "shockable" rhythm is present, while cardiopulmonary resuscitation (CPR) is used to provide circulatory support and/or to induce a "shockable" rhythm.

A number of heart conditions and non-heart-related events can cause cardiac arrest; the most common cause is coronary artery disease.[5]

Cardiopulmonary resuscitation is an important part of the management of cardiac arrest. It is recommended that it be started as soon as possible and interrupted as little as possible. The component of CPR that seems to make the greatest difference in most cases is the chest compressions. Correctly performed bystander CPR has been shown to increase survival; however, it is performed in less than 30% of out of hospital arrests as of 2007. If high-quality CPR has not resulted in ROSC and the person's heart rhythm is in asystole, discontinuing CPR and pronouncing the person's death is reasonable after 20 minutes.[5]

For decades, conventional wisdom in treating patients with cardiac arrest was that if the heart stopped beating for longer than 6 to 10 minutes, the brain would be dead. Now a new treatment being embraced by a growing number of US hospitals suggests that patients can be brought back to a healthy life even if their heart is stopped for 20 minutes, perhaps longer. In recent months around the US, doctors and nurses say, cardiac-arrest patients who would previously have been given up for dead have been revived and discharged to return to their families and jobs with all or nearly all of their cognitive abilities intact.[6] Each year in the US, 400,000–460,000 persons die of unexpected SCD in an emergency department (ED) or before reaching a hospital.[7]

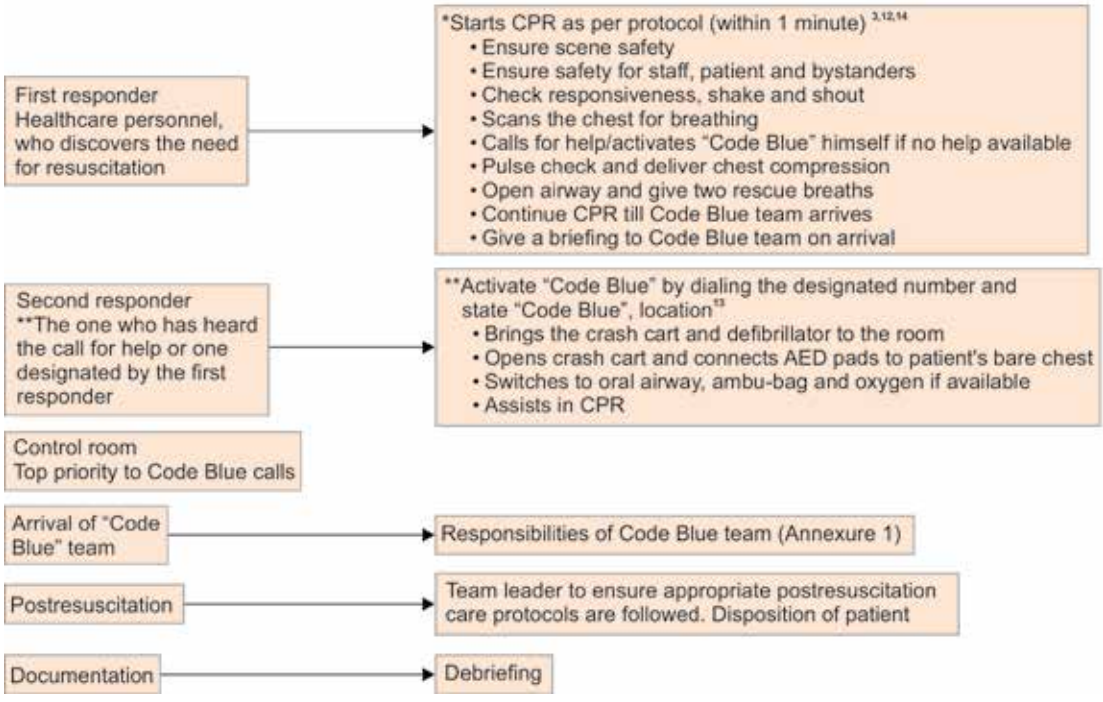
The proportion of SCD that occur out-of-hospital has increased since 1989. Death and disability from a heart attack can be reduced if persons having a heart attack can immediately recognize its symptoms and call for emergency care. Prehospital emergency medical service systems can assist in reducing SCD rates by dispatching appropriately trained and properly equipped response personnel as rapidly as possible in the event of cardiac emergencies. However, national efforts are needed to increase the proportion of the public that can recognize and respond to symptoms and can intervene when someone is having a heart attack, including calling the designated number, attempting cardiac resuscitation, and using automated external defibrillators until emergency personnel arrive.[7]

Survival rates for cardiac arrests that occur in hospitals and outside them continue to be low (17 and 6%, respectively), and fewer than one-third of patients who have an out-of-hospital cardiac arrest receive CPR. Consequently, a number of changes were made to the 2005 American Heart Association Guidelines for CPR and emergency cardiovascular care. The changes were intended to simplify CPR in order to increase its use and effectiveness by both clinicians and nonprofessionals.[8]

In one of the study by Stundek et al, it was found that there were 1,142 cardiac arrests which were included in the analytic data set. Prehospital ROSC occurred in 299 individuals (26.2%). When controlling for initial arrest rhythm and other confounding variables, individuals with no endotracheal intubation (ETI) attempted were 2.33 (95% confidence interval [CI] = 1.63–3.33) times more likely to have ROSC compared to those with one successful ETI attempt. Of the 299 individuals with prehospital ROSC, 118 (39.5%) were subsequently discharged alive from the hospital. Individuals having no ETI were 5.46 (95% CI = 3.36–8.90) times more likely to be discharged from the hospital alive compared to individuals with one successful ETI attempt.[9]

A study was conducted in the year 1996, by Cobbe et al to determine the short and long-term outcome of patients admitted to hospital after initially successful resuscitation from cardiac arrest out of hospital. From the study, it was found that about 40% of initial survivors of resuscitation out of hospital are discharged home without major neurological disability. Patients at high risk of subsequent cardiac death.[10]

Flow Chart 1: Process flow during "Code Blue"



Annexure 1: Responsibilities of Code Blue team

Team Leader

Doctor from department of anesthesiology will be the team leader

- Designates roles to team members and directs their actions
- Decides appropriate treatment as per ACLS guidelines and gives orders to team members
- Decides appropriate disposition of patient once stabilized
- Brief the patient's attendant after resuscitation and will make sure that information has been passed to patient's family members
- Ensures that one member (nursing) is designated to record events in the Code Blue flow sheet (Annexure-3) and get it verified from the team leader
- Fill Code Blue report (Annexure 2) and submit to the Code Blue committee.

Physician or Anesthesiologist

Manages the airway and circulation.

One Nurse

- Assists doctor in managing the airway
- Assists in obtaining intravenous access and drug administration as per team leader's instructions
- Assists in managing code as requested
- Will remain with the patient until the transfer occurs?

Other Nurse

- Automated external defibrillator (AED)/defibrillator switched on
- Monitor rhythms through AED pads /ECG leads/paddles
- Rhythm analysis and shock delivery as advised by Code Blue team leader
- Fill Code Blue flowsheet and attach to the patient's medical record after showing the same to team leader.

Security Personnel

- Directs team members toward code location
- He must ensure the area/scene is safe before proceeding with their response
- Ensures that no crowding of Code Blue site takes place.

Hospital Attendant

- Help nursing staff in pushing crash card near the patient
- Assists in various other activities.

Need of the Study

Cardiac arrest is a medical emergency that, in certain situations, is potentially reversible if treated early. Unexpected cardiac arrest can lead to death within minutes: this is called SCD.[5]

Despite advances in the prevention and treatment of heart disease and improvements in emergency transport, the proportion of cardiac deaths classified as "sudden" remains high, probably because of the unexpected nature of SCD and the failure to recognize early warning symptoms and signs of heart disease. The age-adjusted SCD rates and the state-specific variation in the proportion of SCDs suggest a need for increased public awareness of heart attack symptoms and signs.[7]

Death and disability from a heart attack can be reduced if persons having a heart attack can immediately recognize its symptoms and call for emergency care. Prehospital emergency medical service systems can assist in reducing SCD rates by dispatching appropriately trained and properly equipped response personnel as rapidly as possible in the event of cardiac emergencies. However, national efforts are needed to increase the proportion of the public that can recognize and respond to symptoms and can intervene when someone is having a heart attack, including calling a designated number, attempting cardiac resuscitation, and using automated external defibrillators until emergency personnel arrive.[7]

METHODOLOGY

It was a descriptive cross-sectional study carried out between January to June 2015. The study population included doctors, nursing personnel, paramedical staff and quality managers of tertiary care trauma hospital from public and private hospitals. Checklist was made after an exhaustive review of literature which was then improvised. The checklist was discussed in focused group discussion held on 1 June 2015, and suggestions were incorporated. Validation of the checklist was also done by experts from various private and public hospitals. Subsequently, interaction was done with study population against the backdrop of the checklist and Code Blue policy was formulated.

ANALYSIS AND RESULTS

A total of 200 people which included doctors, nurses, paramedical staff, and quality managers of tertiary care public and private hospitals were approached for interaction against the backdrop of the checklist. Total response rate was 62%. Forty-one doctors responded out of 50 doctors approached, 34 nurses responded out of 50, 20 quality managers interacted out of 50 and 16 doctors, expertize in handling Code Blue responded out of 25 approached and 14 nurses, expertize in infection control practices out of 25 approached. Policy was framed after incorporating inputs from responses received against the backdrop of the checklist.

CODE BLUE POLICY FOR A TERTIARY CARE TRAUMA HOSPITAL IN INDIA

Aim of the Policy

To make clear to all the staff about Code Blue and to inform and guidance regarding the same. This document summarizes the information to patients and the staff about Code Blue policy. It put in the picture how the institute will meet its training requisites to ensure that staffs receives adequate training in relation to Code Blue policy.

Goals and Purpose

The goals and purpose of this policy is to ensure that skilled medical team response for emergency resuscitation is provided.

Scope

Provide skilled medical team response for emergency resuscitation.

Responsibility

All employees of the hospital, Cardiac Arrest Review Committee for monitoring.

What is Code Blue?[1]

Code Blue is one of the emergency procedure codes for cardiopulmonary arrests and life-threatening emergencies in areas of the hospital. A Code Blue is the term used to alert the Code Blue team (resuscitation team) to an area where a person has had a cardiac/respiratory arrest.

Any attempt at resuscitation is better than no attempt.

Purpose

To provide immediate life saving measures in cases of life threatening emergencies.

When to Activate Code Blue?

A Code Blue will be initiated on all patients, visitors and staff suffering a cardiac/respiratory arrest showing following symptoms:

- Not responsive
- No breathing

- No neck pulse (to be witnessed by healthcare provider).

Who can Activate Code Blue?

Any individual may call a Code Blue and certified staff will initiate basic life support (BLS) and automated external defibrillator (AED) if available, until relieved by the Code Blue team.

How to Activate Code Blue?[11]

- The Code Blue team has to be notified by the control room (room designated to notify the message to the response team).
- The individual calling the Code Blue must dial the designated number to call a Code Blue.
- Identify yourself to the call center staff who responds to the call.
- Give the exact location (i.e., unit, floor, wing, building)
- Tell him/her that there is a adult/pediatric Code Blue
- Code Blue team will be notified using public address system.

What Happens when Code Blue is Announced? (Flow Chart 1)[12]

- When Code Blue is announced the message is sent to the Code Blue team (Annexure 1), who are expected to arrive at the scene as soon as they get the message

Affix patient label

Annexure 2: Code Blue report

This form has to be filled by the team leader of the Code Blue team who is the in-charge of the patient after evaluating the event.
This is to be submitted to the **Code Blue review committee** within 24 hours of occurrence of the event.

This form is for quality assurance purpose.

Date and time of Code Blue _____

Location of the Code Blue _____

Patient's description in brief

_____

_____

Conditions which led to Code Blue

_____

_____

Was the Code Blue managed appropriately?

_____

_____

Gaps in following the Code Blue protocol

_____

_____

Anything important needs to be mentioned

_____

_____

Name and sign of the doctor Date

Annexure 3: Code Blue flowsheet (adult and pediatric)

	Name _____, Age _____ Sex _____ UHID of the Patient _____ Date _____ Time of Code Blue announcement _____, Time of arrest _____, Witnessed _____, Unwitnessed _____ Cardiac arrest ☐ Respiratory arrest ☐	Circumstances prior to arrest Diagnosis	Treatment given to the patient prior to code team arrival Time of starting CPR _____ CPR given by _____

	Airway/Ventilation Breathing at onset ☐ Spontaneous: Aponic: Agonal: Assisted Time of first assisted ventilation: Ventilation: BVM ET Tracheotomy others Intubation: Time _____ Size: _____ By whom _____

	Defibrillation (Joules)	Epinephrine	Atropine	Amiodranone	Lidocaine	Magnesium	Code Blue team members

TIME	BP	PR	RR	SAO2	RHY		Comments:	

Monitor strips to be pasted here	Nursing notes
Monitor strips to be pasted here	Outcome Time resuscitation ended _____ Status: Alive ☐ Dead ☐ Reason of ending resuscitation_____ Return of circulation_____ Medical futility_____ Time deathdeclared _____ Death declared by whom _____ Family present at that time_____ _____ Name of the family member contacted _____ Recorder's signature _____

Cause
Other remarks if any Auditor's report Signature of the staff Signature of the team leader

(Code Blue response time is expected to be < 3 minutes).

- The members of the Code Blue team must ensure that the area/scene is safe before proceeding with their response. This requires rapid assessment of the location and circumstances associated with the Code Blue call.
- The members of the Code Blue team will not respond to areas where unpredictable and variable environmental conditions exist. When a Code Blue is called, all members of the Code team will respond immediately.
- Refer to appendices for site-specific information regarding members of the Code Blue team (Annexure 1).
- Code team members function collaboratively during the code with one person identified as the code team leader.
- The Code Blue will follow the advanced cardiovascular life support (ACLS) guidelines. It is recommended all members have current ACLS training and certification.
- The individual assigned as recorder will document all treatments, medications, electrocardiogram (ECG) data etc., on the Code Blue record (Annexure 3). The Code record remains in the patient's medical record after designated individual show it to the team leader.
- The Code Blue report (Annexure 2) is filled by the team leader at the end of the Code Blue and submit to Code Blue Committee completes the monthly statistics for Code Committee.
- Resuscitation equipment will be immediately available for all Code Blue calls.
- Following a successful resuscitation of in-patient, and planned transfer to a critical care unit, a Code Blue team nurse will remain with the patient until the transfer occurs.
- Following successful codes on other than registered in-patients (admitted patients) the patient should be transferred to ED for further assessment and treatment. Exceptions to the above may occur.

Means of announcing Code Blue differs from hospital to hospital depending on the resources available.

Number of Code Blue teams is not fixed and vary from hospital to hospital.

Annexure 4: Code Blue mock drill audit sheet (adult and pediatric)[15-19]

Assessment and activating help	**Yes**	**No**	**Comments**
Did the first responder assessed the patient appropriately?			
Did the first responder verbally summoned the help?			
Did he/she instructed someone to call on the designated number?			
Was there proper delegation of tasks to 2nd and 3rd responder by first responder?			
The victim was moved from the site of code only if absolutely essential to perform CPR effectively or safely			
Did the 1st responder performed appropriate ABC assessment and intervention?			
Alerting Code Blue			
Was there any delay in alerting Code Blue?			
Was Code Blue announced thrice (loud and distinct)?			
"Adult" of pediatric code announced			
Exact location specified when announced			
Any Pager/phone issue(s)/or any other means of communication			
Any other issue related			
Did Code Blue team responded in time (<3 minutes)			
Role of 2nd and 3rd responders			
Did the crash cart arrive/Kit Bag within 2 minutes?			
Did the 2nd responder did the assigned job appropriately? (opened the crash cart, provided ambu, attached defibrillator, attached oxygen, helped with CPR)			
Did the 3rd responder did the job as assigned (ensure/secure IV access)			
CPR quality			
Delivered compressions × 2 minutes, per AHA guidelines, then commenced with usual CPR methodology as follows:			
Opened airway/checked breathing			
Delivered two breaths			
Checked pulse (location appropriate to age of victim)			
Positioned proper hand position for compressions			

Contd...

Contd...

Performed correct depth for compressions			
Used correct rate/ratio for one-man CPR			
Applied and/or used ambu bag correctly			
Reported events information to second responders clearly			
Vascular access			
Delay			
Inadvertent arterial cannulation			
Infiltration/disconnection			
Other (specify in comments section)			
Defibrillation(s):			
Once AED available, turn on machine, applied pads and activated AED			
Followed directives per AED			
Crash cart			
Located drugs and equipment easily			
Located/assembled laryngoscope correctly and identified correct endotracheal (ET) tube			
Prepared IV equipment			
Correctly assembled suction			
Universal precautions			
Followed by all team members (gloves, face mask)			
Documentation			
Signature of Code team leader on code sheet			
Incomplete record			
Other			
Team behavior			
Was handover proper from 1st responder?			
Were team members aware of their roles and responsibilities?			
Was there any delay in identifying leader?			
Was knowledge of equipment appropriate?			
Was knowledge of medications/protocols appropriate?			
Was communication among team members appropriate?			
Any other issue			
Any protocol deviation			
With regard basic life support (BLS)			
With regard to ACLS			
Others			
Equipment			
Were equipment available?			
Was there any problem in the functionality of the equipment?			
Any other issue			
Miscellaneous points			
Did security personnel respond as per role?			
Did hospital attendants respond as per role?			

*Code Blue mock drill assessment team will assess any deviation from the protocol and report to Code Blue committee

Training

Continuous training is required for all the staff of the hospital (doctor, nurses, paramedics, grade IV, security) for the implementation of Code Blue policy for all. Training would be conducted through regular classes and Mock Drills (Annexure 4).

Awareness will be created by displaying poster both in Hindi, English and a local language showing the number clearly all around.

How Code Blue Teams may be Required for a Hospital?

There is no fixed number. Availability and accessibility of resources (manpower, equipment), size of the hospital, design of the hospital and many other factors specific to the hospital should be taken into account while deciding upon the number of Code Blue teams.

Limitation of the Policy

This policy is specially designed for a trauma care hospital.

Means of announcing Code Blue differs from hospital to hospital depending on the resources available.

Number of Code Blue teams is not fixed and vary from hospital to hospital.

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REVIEW ARTICLE

Integration in Operation Theater: Need of the Hour

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ABSTRACT

Integration in operation theater (OT) usually refers to systems integration, which means functionally connecting the OT environment. It includes integration of patient information system, audio, video, surgical lights and room lights, building automation (HVAC), medical equipment, telemedicine, video-conferencing, etc. When integrated, all technology can be manipulated from a central command console by single operator. Integration in OT holds the key for effective application of minimally invasive surgery, robotic surgery and functioning of hybrid OT. Apart from the conventional planning team for an OT, bringing on board an IT professional is a must for planning IT requirements. Integration in OT requires 15% more space than the conventional OT in order to accommodate the IT gadgets, i.e. walk-in technology room that would house teleconferencing and A/V equipment, blade-server computers, fiberoptic network electronics, teleconferencing and video conferencing equipment, audio-visual racks, etc. the level of integration can vary within an OT depending upon the user requirement. Space requirement for a general I-OT is about 60 m^2, a cardiovascular I-OT or one that includes robotics may come up to 80 m^2 or more, and I-OT with in-room imaging equipment requires at least 100 m^2. Integration in OT not only increases the efficiency and patient safety in delivery of healthcare but can significantly increase efficiency and effectiveness both in teaching and research.

Keywords: Integrated OT, Operation theater, Planning and designing, Surgery.

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INTRODUCTION

An operation theater (OT) complex is the 'heart' of any hospital/surgical center. All the skills of surgical professional and new scientific developments will be of little value unless the operating suite is properly planned and works efficiently.[1] The rapid growth of minimally invasive surgery (MIS) and also because of the ergonomically poor design of traditional operating rooms which involved a number of carts to be mobilized at the time of surgery has compeled significant developments in OT planning and designing. Not only this, digital information has become the standard format and universal way of accessing patient information and communicating with healthcare personnel. The OT requires easy real time access to these digital data and a way of managing the digital information acquired within the OT. More complex procedures in the interventional suite mean patients will require more clinical supervision and possibly a more intense level of care. This has been an important factor in shift from conventional OT toward integrated OTs. There is immense requirement for renovation of traditionally designed OTs in hospitals to facilitate the practice of MIS.[2]

WHAT DO WE MEAN BY INTEGRATION IN OT?

Integration in planning and design of OT can be seen from perspective of service integration and systems integration. In service integration, single authorized vendor is responsible for getting all kinds of the work done along with coordination with all other service providers. But, conventionally integration in OT is referred to systems integration, which means functionally connecting the OT environment. It includes integration of patient information system, audio, video, surgical lights and room lights, building automation (HVAC), medical equipment, etc. (Fig. 1). Healthcare personnel can easily route audio visual sources and effectively control surgical equipment. When integrated, all technology can be manipulated from a central command console by single operator.

When compared against a nonintegrated OT, where an assortment of equipment is arranged around the surgical table and individual pieces are pulled up or pushed back as and when needed. A circulating nurse works amidst the equipment to change settings during the surgery/procedure. Cables and cords from the equipment lie in

Fig. 1: Integrated OT

the path of the nurse, the patient gurney, even under the feet of the anesthesiologist and the surgical team. There is an inherent risk of tripping and disturbing the surgery, of pulling out wires, and of damaging equipment in such kind of setting. Figure 2 clearly portrays the difference that is brought to OT once it has been converted into an integrated OT.

In an integrated OT, cords and cables run inside the articulating arms of ceiling-mounted lights and booms through conduits in the ceiling. Ideally, there are no cords or cables on the floor. The circulating nurse works from a console at a control station, where she has access via a computer to numerous devices in the OT and no longer keeps navigating during the surgery. In fact, she is not even accessing the sterile area. All controls are on a touch screen, and the nurse can carry out the surgeon's requests from this common control station for all equipment. A surgeon may also have a command console within reach in the surgical field. Some systems are capable of even offering voice recognition, so that the surgeon wearing a wireless headset with a microphone can control the system directly. This not only results in lesser chaos inside a stressful setting but also reduces the movement and number of personnel entering the sterile area. In teaching hospitals where the surgical procedures are to be demonstrated to the medical graduates and postgraduates, an integration of IT technology not only provides better understanding and visibility through high definition displays but also reduces the number of personnel within the OT. This indirectly have an impact on infection control within the OT.

BENEFITS OF INTEGRATED OT[3]

An integrated OT means saving time and personnel because more procedures can be completed in the same room by the existing staff without increasing the strain on the team and without relocating equipment or personnel from another OT.[4]

- Hospitals are increasingly seeking to build state-of-the-art OTs so as to attract and retain healthcare personnel by offering them the advanced facility.
- There is overall improvement in the efficiency and patient safety inside the OT, having integrated technology, e.g. knowledge or bulletin board systems are now available that integrate patient and staff information as well as equipment and process documentation, and post them on a wide screen in the room. A preincision screen, intraoperative screen, closing screen, and case-summary screen bring together an arrangement of real-time data, such as the patient's vital signs, blood loss, and fluid levels. And because simple human errors, such as misidentification of a patient, can lead to life-threatening medical errors, the knowledge/bulletin board displays the procedure name, patient name, gender, age, weight, and critical information, such as allergies and special needs. In addition, the names of all staff in the OT are listed. The goal is to manage and coordinate details in order to reduce medical errors.
- Design for technology integration improves the quality of data captured and workflow. The surgeon looks comfortably at his or her screens as opposed to

Fig. 2: Operation theater before and after integration

looking to the side or behind to a system-on-a-cart solution. This has not only improved patient safety but also added to safety of staff by having better ergonomics of OT.

- Repetitive suturing and other surgical tasks can cause hand, back and leg fatigue. This requires frequent resting, extended surgery time, and varying degrees of precision. Integrated systems coupled with MIS minimize surgeon fatigue and improve patient outcomes. Many surgeons have a calming and mood-setting music playlist designed for their process. Not unusual are music selections chosen for opening, focus, and a closing celebration.
- With increased control of OT environment, the surgical team can work more efficiently and reduce operating time.
- Integrating various OT components into one centrally controlled system results in optimized processes.
- Setup and clean-up are faster and easier because equipment does not have to be connected and disconnected between procedures. The appropriate equipment swings into place via overhead booms, and monitors are easily positioned for optimal viewing by each surgical team.
- Unprecedented operating efficiency correlates with increased productivity and better utilization of every OT every day.
- The ability to reconfigure a room by using the control console to select the case type or surgeon setup makes the rooms flexible. The intent is to enable the facility to adapt to future additions, changes, and use/practice of technology.
- It also brings effectiveness and efficiency in training and research.

PLANNING FOR INTEGRATED OT

When an OT is being built or renovated, incorporating I-OT has a significant impact on planning and design. In this article, only the additional planning and design parameters of integration required in a conventional OT are discussed. The other planning and design parameters for, e.g. HVAC, lighting, infection control, space requirements for ancillary areas, etc. will be same like any other OT. It is important not only to consider what is needed now but also to plan ahead for what will be needed in the foreseeable future. Some picture archival and communication system (PACS) are centrally located miles away from the hospital. File sizes of the images to support intervention may be extremely large—from 50 to 900 MB. Over conventional networks, it might take half an hour for a server to get these images to the I-OT. Therefore, the IT process flow for PACS and the network need early evaluation and planning.

Planning Team

A qualified medical technology planning firm should be brought on board at the earliest planning stage to coordinate with all stakeholders. Planning team should consist of following members:[5]

- Hospital administrator
- Anesthetist
- Surgeons
- Clinicians
- Hospital infection control personnel
- IT department
- Radiology
- Biomedical engineering
- Architects
- Contractor
- Other stakeholders.

To help the clinical/physician staff reach decisions on the technology, the technology planner should coordinate with a variety of vendors to conduct on-site equipment evaluations. Also, the planner should provide a detailed work plan and guidance on integrating radiology, cardiology, gastroenterology, orthopedics, anesthesiology, and nursing and physicians.

Design Considerations

Integrated OT, when optimally designed, can lessen the complexity of the most complicated environment in the hospital—the surgery suite. User-friendly, integrated technologies augment surgeons' skills and help the entire surgical teamwork more safely and efficiently. The development and growth of MIS has spurred the creation of I-ORs. Today, more than half the surgery cases in the United States are performed with minimally invasive techniques.

A high-quality, magnified video, projected on a flat-screen monitor, gives the surgeon an optimal view of the surgical field. As minimally invasive surgery continues to grow and robotic surgery and telemedicine become more common, I-OTs will become an industry standard.[5]

Levels of Integration[5]

There are various levels to which an integrated OT can be made according to user requirement. The following classification of integrated OT is based on the basis of communication of I-OT with internal and external environment of the OT complex/department:

Level 1 integration: Level 1 integration, refers to where only internal environment of the OT is integrated, i.e. where audio, video, lighting, HVAC, music, within the OT is integrated.

Level 2 integration: In level 2 integration, OT is connected/integrated with other OT within the OT complex. By getting this level of integration, it is possible to video conference with other OT and take expert opinion while operating in other room. This brings in effectiveness and improves the quality of care rendered to patients. In this way, it also helps in capacity development of staff and on the job training.

Level 3 integration: In integrated OT of level 3, OT is not only capable of communicating within the OT complex, seminar room or classroom within the same hospital but can communicate with facilities located across the countries, continents with the help of ISDN line.

Another classification which is being followed depending upon the integration of different technologies and level of system integration:

VE level: At the minimal, or VE level, video from medical equipment is fixed in the room. The video sources are images from the arthroscopic, laparoscopic, and endoscopic cameras. These video images are displayed on specific flat-panel monitors hung from the ceiling boom or on a cart near the surgeon.

AVT level: Classic A/V and teleconferencing systems are at the AVT level of integration. These systems are used for conference room and auditorium presentations and may have music, television, and projection systems.

AVER level: The next level of integration is the AVER level (audio, video, medical equipment, room environment), which enables easy access and control of all equipment and video switching. Video switching, or routing, allows for video images to be redirected to two or more displays. These audio systems, surgical video systems, and room environment controls are interlinked so that the surgeon (via a nurse at the central control unit or via voice activation) can manipulate a multitude of devices—for example, an in-surgical-light camera, a surgical instrument light source, a vacuum pump, room lights and temperature, and video conferencing. All equipment is integrated and working together.

AVERPI level: In general, when we speak of I-OTs, we are referring to at least an AVERPI level of integration (audio, video, medical equipment, room environment, Picture Archive and Communications System (PACS), and information system). At this level, the I-OT is connected to other areas of the facility, such as radiology and laboratories. PACS images—computer desktop images with data images, such as lab results—can be routed to displays within the I-OT suite and digital picture images taken earlier can be accessed and viewed on monitors. A specialized information system may collect information specific to the case and present it on a large display at the wall to organize the surgery and its functional progress. This display of case knowledge improves safety while documenting the progress and maintaining staff orientation. When the surgeon takes a biopsy and sends it to the lab for analysis, images from the lab microscope can be sent back to the I-OT so that the surgeon and the pathologist can consult via phone while the surgery is in progress, avoiding delays that in the past would have meant a second surgery.

AVERPIT level: The most fully integrated systems, at the AVERPIT level, add telemedicine, which connects the I-OT to the outside world. Audio/video conferencing extends communication abilities to conference rooms and classrooms across the street or around the world, so that surgeons can consult and teach remotely. In fact, this level extends the skill set of a specialty surgeon, thus helping to expand a scarce resource.

At the AVERPIT, or highest, level of integration, audio, video, medical equipment, room environment, PACS, information systems and telecommunications all work together in the OT. Images and data can be resourced or shared with other areas of the hospital, and tele/videoconferencing capabilities extend to the outside world (Fig. 3).

The AVERPI and AVERPIT levels of integration provide the flexibility to utilize the surgical suite for many types of cases, which is advantageous for the hospital. However, large capital allocations are required for these levels of OT integration. Therefore, it is recommended to design and build all OTs to be adaptable for accommodating these levels of technology integration in the future. Otherwise, the OT would have to be shut down for wall and ceiling work, creating infection-control issues and lost revenue during construction. The 'adaptable' approach may be compared to the 'universal' approach which requires all OTs to be constructed for all levels and be fully fitted-out with equipment.

Design Features for Integrated OT

In addition to housing a large amount of technology, I-OTs impact work flow. Factors that must be considered in the design of an I-OT include:

- Total room size
- Best placement of lights, cameras, monitors, and the AV equipment
- Ceiling structures
- Articulating display arms
- Equipment booms should be designed to allow for added capabilities in the future.

Additional space is required for the infrastructure and electronics to support the components outside the OT.

Fig. 3: Integrated training OT in Melville, New York[3]

Room Size

In general, I-OTs are 15% larger than their non-integrated counterparts. It is true that some equipment is smaller than ever before, but an in-room control or documentation center adds about 10 m^2 to an OT. With integrated technology, a general I-OT is about 60 m^2, a cardiovascular I-OT or one that includes robotics may approach 80 m^2 or more, and I-OT with in-room imaging equipment requires at least 100 m^2.

Media Bridge

Media bridge maximizes the quality of surgical interventions providing surgeons, anesthetists and OT team's easy access to power supplies, manifold supplies, communication technologies and data transfers that can be easily positioned and customized or moved as per the requirement for different surgical procedures. They can be customized as per user specifications in a configuration, with one, two or four corners in order to match the size and organization of space (Fig. 4).

They are compatible with systems of ceiling laminar airflow, the beams are suspended in such a manner so that they do not disturb the laminar flow and generate turbulence, thereby aiding in maintaining the aseptic environment of the OT. It also allows the positioning of the equipment trolleys as per the need and can be moved from one end to the other. Support trolleys may be positioned on the entire periphery of the beam through swivelling angles.

Technology Room

The I-OT support hardware has invaded the telecommunications closet. This closet should be of atleast 10′ × 15′ walk-in technology room that would house teleconferencing and A/V equipment, blade-server computers in racks, fiberoptic network electronics, and fiberoptic cables to the work area. This has challenged the traditional structured cable system (SCS) design, in which fiber is used to move data vertically in a building and copper is used to move data horizontally. Fiber to the desktop is a reality for the interventional I-OT. Data transport via a T1 line, an integrated services digital network (ISDN), and a digital subscriber line (DSL) are common requirements for telemedicine data communications to the world.

The I-OT's video-integration technology often requires 3′ × 3′ × 6′ rack. In addition, there may be three or more additional computers to support PACS, hospital information data, electronic medical records, and/or care plan documentation. There is always a concern on where to place the rack, A/V electronics, and computers so they are not in the way during procedures or cleaning. One innovative solution is to create a dedicated closet for the rack. The closet has a door from the corridor and a door at the inside of the room. If the video equipment needs to be updated, changed, or serviced, it can be accessed from the corridor. The inside remains closed off so the I-OT can be used for procedures not requiring integration. Servicing the technology does not shut down the OT, and cleaning the OT does not disturb the equipment. The closet can be locked to secure the expensive commercial equipment.

In the surgery department outside the I-OTs, a department control desk with closed circuit TV technology and a large screen can facilitate efficiency in the suites. An image of every I-OT appears on the screen so that the viewer instantly knows the room status—whether or not a procedure is in progress, if the room is vacant, clean or in need of cleaning, or if it is ready for the next procedure. Providing this feature is a great aid in efficient scheduling.

CONCLUSION

The integration in OT is a technology to reckon considering the rapid development of minimally invasive

Fig. 4: Media bridge of an integrated OT (showing its various components)

surgery and robotic surgery. Also, the development of hybrid OT in hospitals has necessitated the integration in OT for its smooth functioning. In fact to the extent that all the OTs in a new or upcoming facility irrespective of the fact whether they are traditional/hybrid OT should be planned keeping the integration in mind. Integration in OT not only brings efficiency and patient safety in delivery of healthcare but can significantly increase efficiency and effectiveness both in teaching and research.

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REVIEW ARTICLE

Planning and Designing of Clinical Engineering Department in a Hospital

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ABSTRACT

Biomedical/clinical engineering departments (CED) with expertise in engineering and technology management have a vital role to play in determining the potential for implementation and cost-effectiveness of new medical technologies through technology assessment. It provides planned preventive maintenance and repair facility in a state of optimum operational efficiency along with conducts training and research in clinical engineering. For a successful design, the workflow should be kept in mind in terms of its functional needs that are related to space. The clinical engineering and maintenance unit may consist of functional areas dependent on the operational policy and service demand. Heating, ventilation and air-conditioning (HVAC), lighting and acoustic, electrical, fire planning should be done with deliberation and as per specification.

Keywords: Biomedical/clinical engineering, Planned preventive maintenance, Repair facility.

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INTRODUCTION

The American College of Clinical Engineering defines a clinical engineer (CE) as: 'a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology.' Clinical engineering is a subset of biomedical engineering. Whereas biomedical engineering is practiced primarily in academic institutions, the research laboratory, and manufacturing, clinical engineering is practiced in hospitals and other environments where medical device technologies are utilized.[1]

Clinical engineering emerged as a discipline in the latter half of the twentieth century as increasing numbers of complex electronic and mechanical medical devices entered the healthcare environment for preventive, therapeutic, diagnostic and restorative applications. Within the complex environment of the modern hospital, clinical engineering is concerned primarily with devices but recognizes that interactions between drugs, procedures, and devices commonly occur and must be understood and managed to ensure safe and effective patient care.

Objective of Clinical Engineering Department

- To plan and implement planned preventive maintenance and repair facility to hospitals, medical institutions.
- To ensure all the facilities, systems and services under the scope of engineering services are in a state of optimum operational efficiency.
- To provide consultancy service to various department on electromedical equipment in the area of pre installation and operation of equipment; and
- To conduct training and research in clinical engineering.[2]

Function of Clinical Engineering Department[3]

- Supervision of a hospital clinical engineering department that includes clinical engineers and biomedical equipment technicians (BMETs)
- Pre-purchase evaluation and planning for new medical technology
- Design, modification, or repair of sophisticated medical instruments or systems
- Cost-effective management of a medical equipment calibration and repair service
- Safety and performance testing of medical equipment by BMETs
- Inspection of all incoming equipment (new and returning repairs)
- Establishment of performance benchmarks for all equipment

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- Medical equipment inventory control
- Coordination of outside services and vendors
- Training of medical personnel in the safe and effective use of medical devices and systems
- Clinical applications engineering, such as custom modification of medical devices for clinical research or evaluation of new noninvasive monitoring systems
- Biomedical computer support
- Input to the design of clinical facilities where medical technology is used [e.g. operating rooms (ORs) or intensive-care units]
- Development and implementation of documentation protocols required by external accreditation and licensing agencies
- Equipment audit
- Academic affiliation/teaching
- Applications research and design
- Consulting
- Information systems support
- In-service training
- Technical/clinical investigation—clinical trials support
- Technology management
- Technology assessment.

Planning Premises of Clinical Engineering Department Location[4]

The clinical engineering and maintenance unit should be located on the ground floor to facilitate delivery and despatch of heavy items of equipment. Access to a loading dock is desirable. The unit will require ready access to all areas of the hospital and in particular, to plant rooms and areas. Depending on the size of the unit and the operational policy, considerable noise and fumes may be generated by the unit and care should be taken in locating the unit relative to other units, such as inpatient accommodation units as shown in Figure 1. The dept should be located at the rear of the building where all engineering services are clubbed together. It should have safe access for maintenance and when components have a service life less than the planned life of the principal asset, e.g. the building they serve, be installed with provision for replacement. Access points shall be following:

- Be positioned to avoid interference with healthcare delivery
- Be provided with appropriate access control for safety and security
- Provide for safe handling of any goods requiring access
- Access for fire fighting on all sides of all buildings and for truck and crane access to install and remove any items of equipment requiring truck transportation or crane placement
- Nondisruptive impact on the neighborhood.

General Planning Consideration[6]

For a successful design, the workflow should be kept in mind in terms of its functional needs that are related to space. This will include an exhaustive listing of physical resources, such as gas and water, that are needed for

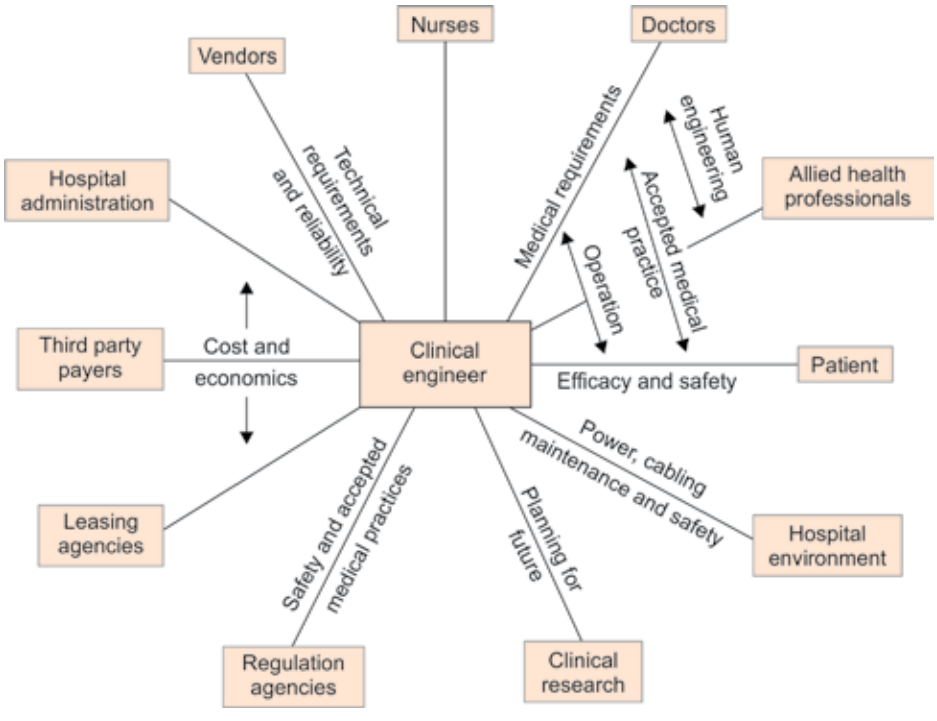


Fig. 1: Diagram illustrating the range of interactions in which a clinical engineer might be required to engage in a hospital setting

various tasks, as well as quantification of space needed, such as the number of linear feet required for storage of equipment manuals and equipment files. Using this approach, the space can be designed in a methodical manner to match the needs while fulfilling all applicable codes. For example, if there is only one water source in the department, that is the location where servicing of dialysis machines will take place unless funding is available for additional plumbing. Other equipment requiring a water source, such as humidifiers or lasers, will also be serviced in that location.

Functional Areas

The clinical engineering and maintenance unit may consist of the following functional areas dependent on the operational policy and service demand as shown in Figure 2:

- *Reception area*: The needs of a reception area are distinctly different from the equipment service area. The reception area will be used to receive the customers and business partners of the clinical engineering department. Comfortable seating in good repair is needed to accommodate these guests. The design of the reception area typically supports the administrative work processes of the department and hence typically includes such things as computers, printers, fax machines, copiers, filing cabinets, and desk furniture. Much of the office equipment can be hidden in well designed closets that are opened as needed for access. In this manner, the clutter of the workspace is minimized while accommodating convenient access.
- Workshop areas which may include separate areas for mechanical, sophisticated medical equipment and electrical services. There should be a separate space for the biomedical/electronic engineering section with a dust proof enclosure.
- Storage areas for all specialty services/trades including paint, gardening and flammable liquids
- Office area for administrative and clerical activities
- Training area
- A mechanical and electrical equipment room
- A maintenance shop

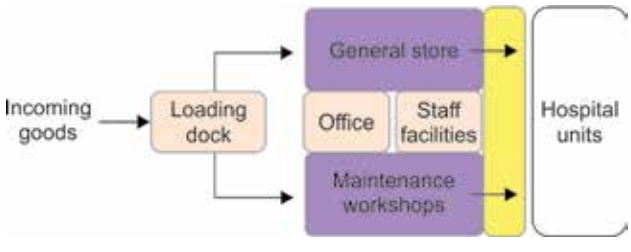


Fig. 2: Functional layout of clinical engineering department

- Staff amenities which may be shared
- A refuse room for trash storage located conveniently to a service entrance; and one janitor's closet on each floor.

Electronics Workshop

A separate workshop may be provided specifically for the storage, repair and testing of electronic and other medical equipment. The amount of space and type of utilities will vary with the type of equipment involved and types of service and maintenance contracts used.

Engineer's Office

If on-staff, an engineer's office shall be provided with file space and provision for protected storage of facility drawings, records and manuals. Provision of daylight shall be maximized throughout the unit especially for those who spend most of their working hours in a single confined space. Offices should be provided with external windows, where possible.

Storage Areas

A storage room shall be provided for the storage of building maintenance supplies. Storage for solvents and flammable liquids shall comply with relevant statutory requirements. Storage space must be designed to accommodate storage of chemicals and test gases, parts, equipment, office supplies, and service documentation. Also consider the items, such as office supplies, that essentially are utilized throughout the workspace. These items might be stored in a central storage depot or interspersed throughout the workspace. Some storage areas may need to be secured. For example, the department's practice may be to restrict access to service documentation. Storage space for staging equipment is necessary.

Infrastructure resource considerations for clinical engineering department are as below:[7]

- Anesthesia/respiratory therapy repair counter should include phone and data outlet, ample power outlets, gas outlets (nitrous oxide, oxygen, air, vacuum), large sink and cup sinks, parts storage.
- Dialysis machine repair counter should include phone and data outlet, GFI outlets, compressed air, recessed water spigots with raised drains, parts storage, sealed-membrane floor with floor drain.
- Radiology machine repair counter should include phone and data outlet, 50A, 220V single-phase power, portable lead shield, lead-lined doors, 10′ ceiling, wide-access door (48"), incandescent light on dimmer

switch, beam and hoist with 1-ton load capacity, deep-utility sink, 'room in use' light, power for wall-mounted view box.

- General workbench should include ample power outlets, static mat, electrostatic-free outlet, durable countertop, lockable drawers, manometer mount, vacuum, air, and phone and data outlet. Since the core work of the clinical engineering department takes place at the workbench, this area deserves the most investment of attention and resources. The workbench design optimally will incorporate sufficient countertop space, adequate storage space for test equipment and tools, and appropriate resources, such as vacuum, grounding mats, and access to sufficient quantities of electrical outlets. To make efficient use of the workbench space, shared resources can be mobilized by mounting on a cart. For example, a mobile solder station can be conveniently brought to the workbench, where a device is already disassembled, instead of bringing printed circuit boards to the stationary solder station.
- Lighting is a critical factor in creating a desirable ambience, as it is a essential requirement for engineering to work.
- An artwork can be very effective in humanizing a technical environment. Mounting of personalized name plates on the workbenches of employees is an example of an inexpensive approach to creating an environment of mutual respect. Personalization of workspace is also a work satisfaction issue that can be accommodated easily.
- Provision of small bulletin boards for the posting of family pictures allows for this personalization while avoiding the taping and tacking of things, such as pictures and calendars to the walls.
- The basin should be a medium wall mounted basin. The taps are either wall mounted or basin mounted with hands-free operation (elbow or wrist). This basin is used in areas requiring general staff hand-washing.
- Vinyl flooring is to be located under all hand wash basins. The flooring should be easily cleanable and in good condition. Floor surfaces, including joints in tiles in such areas, shall be resistant to food acids (epoxy grout). In all areas subject to frequent wet cleaning methods, floor materials shall not be physically affected by germicidal cleaning solutions.
- Clinical engineering department requires the following security considerations:
  - Doors to all offices shall be lockable
  - Rooms located on the perimeter of the unit shall be locked at any time when they are not occupied by staff.
  - Rooms used for storing equipment and files must be lockable.
  - Provision of after-hours access and security for staff.

HVAC System in CED

Heating systems shall be capable of maintaining all rooms at a minimum temperature of 70 to 76° Fahrenheit. Air conditioning systems shall be provided, capable of maintaining temperature and relative humidity at or between the following ranges:

Temperature (°Fahrenheit)	Relative humidity (%)
70–76	50–60

Acoustic performance: Noise levels shall not exceed those defined in the BCA and AS/NZS 2107: Acoustics—recommended design sound levels and reverberation times for building interiors. Acoustic isolation between spaces shall prevent the noise level in one space transmitting to an adjacent space and exceeding the allowable level in that space.

Acoustic Guidelines for CED

Room/space	*(dBA)**	*RT(sec)***
Assembly/preparation, reception/ clerical lounge/activity room	40–50	< 0.5
Staff room, staff station	40–45	< 0.7
Office staff and technical support	35–45	< 0.7

*A-weighted decibels; **Reverberation time

Vibration: Vibration in occupied spaces shall not exceed the just perceptible level defined by AS 2670.1. Vibration precautions shall include as follows:

- Dynamic balancing of machines
- Isolation of sources of vibration from vibration transmission paths (e.g. machines from pipes, ducts, support structures, etc.).
- Piping being designed to avoid pressure pulse noise or being fitted with effective pulse dampers.
- Structures being isolated from ground transmitted vibrations.
- Equipment being selected and supported to avoid operation at resonant frequencies.

Data Communications[8]

There shall be a data network linking information and computing workstations.

The data network shall at least the following:

- Provide a locked accommodation allocated exclusively to network servers and a main cable distribution hub
- Have cabling from main to sub distribution hubs run in dedicated channels in ducts or on tray

- Have sub distribution hubs located in locked cupboards where required
- With the exception of sub compartments within compartments required by the building code of Australia (BCA), a hub shall not serve more than one fire compartment
- Have cabling between sub hubs and data workstations terminating in wall sockets within 2000 mm of the computing equipment to be connected.

Cabling

It is important that cabling be labelled at each connection to servers, hubs and wall outlets. It should be neatly installed and supported and not run across floors. It should be routed away from electromagnetic interference and vulnerability to mechanical damage.

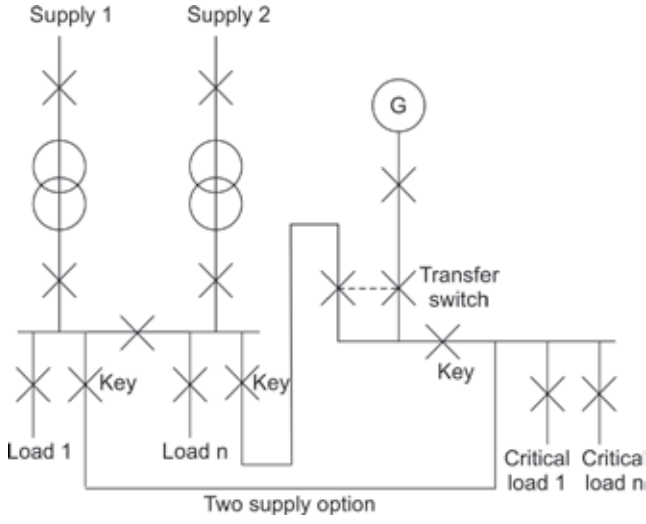
Servers and hubs shall be securely supported. Servers shall have an uninterruptible electricity supply connected to a delayed vital (30 seconds) circuit providing at least a 4 hours capacity at full load. Server rooms shall provide environments complying with server maker's specifications. The facility data network shall not be a limiting factor in the delivery of timely and competent healthcare outcomes.

There shall be emergency assistance call facilities, for use by staff, in every patient room, patient bathroom, treatment room and anywhere else where staff may be alone with a patient and need help to deal with a patient emergency. Requirements for system operation shall meet requirements of the facility risk management plan.

Electrical Services for CED shall Include[9-11]

- Provision of normal, vital (30 seconds), instantaneous (1 second), and uninterruptible (no break) electricity supplies
- Switchgear and circuit protection to safely operate and control the supplies
- Distribution arrangements to supply electricity to each end use
- Equipment to transform and condition voltages from supply voltage to end use voltage and within voltage and frequency tolerances
- Equipment to use the electricity for lighting, heating and motive power
- Where an electrical supply is denoted as being on an 'essential supply' then this shall be arranged as a vital (30 seconds) supply.

The following diagram illustrates the principles of the required supply configurations but will require adaptation to suit particular site distribution requirements:



Lighting Design[12]

It shall take into account for lux requirement of clinical engineering department. Special precaution for security requirements; entry points, car park and unattended areas shall be given.

Lightning Protection in CED

Its risk assessments shall be carried out on all facilities to comply with AS/NZS 1768 a presented to the proprietor. Risk assessment outcomes and mitigation strategies shall be agreed and recorded. Risks shall be mitigated, and as a minimum be in accordance with the recommendations of AS/NZS 1768.[13,14]

Fire Services in CED

It shall be provided to comply with requirements of the NBC 2005 and the proprietor's risk management plan and may include but not be limited to:

- Provision of materials and methods of construction complying with codes and regulations
- Compartmentation of the building(s) into fire and smoke control compartments
- Provision of complying fire egress arrangements
- Provision of fire and smoke alarms
- Storage arrangements for fire fighting water
- Fire fighting water pressure boosting arrangements
- Provision of smoke clearing ventilation
- Smoke mode controls for ventilation plant
- Provision of escape route air pressurization
- Provision of emergency warning and information equipment
- Provision of hose reel and hydrant fire extinguishing equipment
- Provision of automatic fire extinguishing systems
- Provision of portable fire extinguishers and fire blankets

- Provision of equipment to aid transportation of disabled persons
- Provision of escape diagrams.

Schedule of Accommodation

Area	*Area (m^2)*
Reception/clerical	1 × 12
Equipment collection bay	2 × 9
Bay-mobile equipment	1 × 4
Flammable liquid store	1 × 2
Bay-clean-up	1 × 3
Staff room	1 × 30
Workshop for equipment repair	1 × 25
Toilet-staff	2 × 2
Office—single person	1 × 12
Office—4 person shared	1 × 20
Office—workstation	2 × 6
Discounted circulation	Circulation will depend on size of unit (25–30%)

CONCLUSION

Biomedical/clinical engineering departments with expertise in engineering and technology management have a vital role to play in determining the potential for implementation and cost-effectiveness of new medical technologies through technology assessment. Each clinical engineering department will require some customization based on the services that it will provide and the resources that will be provided to it. However, every clinical engineering manager will need to consider and incorporate staffing, space, test equipment, tools, communications equipment, training, and a computerized maintenance management system into the department's plan.

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EXPERT VIEW

Regulation of Biologicals: Indian Perspective

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INTRODUCTION

The annual turnover of the Indian pharmaceutical industry is estimated to be about ₹ 128,044.291 crores during the year 2013 to 2014. The Indian biotech industry as per the data available is of the size of ₹ 25,165 crore approximately, of which 63% of the revenue is contributed by the biopharma sector, i.e. ₹ 15,853 crore. The strength of biopharma sector is evident from the fact that Indian biopharma companies are not only meeting the domestic requirement of the vaccines but also exporting these to more than 150 countries across the globe. Indian vaccine industry has occupied an important niche in the manufacturing of EPI vaccines in the last decade and is one of the major suppliers to United Nations (UN) agencies of pre-qualified vaccines.

This is a testament of impeccable credentials with respect to safety, quality and efficacy of the vaccines produced by Indian companies. Now, the Indian bio-pharma companies are venturing into the areas of development of tetravalent dengue vaccine, oral cervical cancer vaccine including vaccines for neglected tropical diseases, such as chikungunya and kala-azar. The regulations play a very vital role in the growth of this sector.

REGULATION OF BIOLOGICALS

The import and manufacture of drugs including biologicals are regulated under the provisions of drugs and cosmetic act 1940 and drugs and cosmetic rules 1945.

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The import and manufacture of biologicals without a license is an offence under the act. As such there is no separate definition of biosimilar in the act and rules, however, CDSCO and department of biotechnology published guidelines on regulation of similar biologic in 2012 which gives detailed account of regulatory expectations for the licensing of recombinant DNA products.

Biologicals in India include both vaccines as well as recombinant DNA products which are considered as new drugs as per the Drugs and Cosmetic Rules 1945. These products require new drug approval from central licensing authority popularly known as Drugs Controller General of India (DCGI) before grant of license to manufacture in the country by State Licensing Authorities (SLAs).

The drugs and cosmetic rules provide specific information to be furnished by the applicant for approval of new drug as specified in Form 44 read with schedule Y. The Schedule Y gives detailed guidelines on conduct of preclinical and clinical studies and data required in respect of manufacture and quality control.

As per Indian guideline, one repeat dose toxicity study is sufficient to demonstrate comparability in relevant animal model. In case of *in vivo* toxicity studies, at least one repeat dose toxicity study in a relevant species is required to be conducted for appropriate duration generally not less than 28 days with 14 days recovery period. Clinical studies usually phase 3 is also required as per Indian guidelines for approval of biologicals. Generally for vaccine, comparative phase 3 clinical trial in healthy volunteers is required. In cases where vaccines are meant for infants descending trial is needed to prove safety as well as efficacy. In case of biopharmaceuticals, the pharmacokinetics studies/pharmacodynamics studies, confirmatory safety and efficacy studies and safety and immunogenic data may be required for new drugs approval. For novel biologics, the firm is required to do a phase I, II and III clinical trial before marketing authorization is granted to the firm.

The similar biologics/novel biologics project work starts with either 'clone/strain development or clone/strain import', for which permission is needed from RCGM or DCG (I) as the case be. In case of recombinant product, the firm starts by submitting either clone development strategy or existing data for the clone to be

imported for IBSC approval. All applications submitted to RCGM need to be accompanied with an IBSC approval for the same. The clone development or import application is reviewed in RCGM meeting after which the clone development or clone import approval is granted to the firm. Similarly, application for 'carry-out-research' is made to RCGM after IBSC approval. The 'carry-out-research' application is reviewed in RCGM meeting after which the 'carry-out-research' approval is granted to the firm. The above two applications ('clone development or clone import' and 'carry-out-research') can be made to RCGM at the same time.

The firm also applies for NOC for Form 29 to DCGI. Prior to granting NOC for Form 29 approval, DCGI requests for joint inspection of the facilities to state FDA and CDSCO. On successful completion of joint inspection DCGI grants NOC for Form 29 approval, based on which Form 29 is granted by state FDA.

After receiving above referred approvals from RCGM, DCGI and state FDA, the firm develops/ imports the clone/strain and initiates the analytical and process development activities. Once the process is frozen, three consistency batches are taken and product characterization is completed, the firm applies for approval to conduct preclinical toxicity studies to IBSC in case of recombinant products, however, in case of vaccine no such approval in required.

Once the preclinical studies are completed the firm applies to DCG (I) for grant of approval of clinical trial proposal in Form 44 as per CDSCO format for clinical trial application along with CT protocol. Drugs controller general of India reviews the CT application for CMC and nonclinical and the CT protocol. Drugs controller general of India forward the CT protocol to subject expert committee (SEC) for review and comments. Subject expert committee meeting is conducted where the firm does a presentation on the CT protocol and design to obtain CT Protocol approval from SEC. Once the SEC gives favorable comments, the file is forwarded to technical committee as well as apex committee. Once technical committee and apex committee approves the CT protocol, DCGI grants CT permission to the firm.

After receiving CT permission from DCGI, the firm initiates the clinical trial. Once the clinical trial is completed, the firm applies for marketing approval to DCGI in Form 44 as per CDSCO application format for marketing authorization along with CT report. Drugs controller general of India reviews the marketing application for CMC and non-clinical and clinical sections, i.e. CT report, and forwards the CT report to SEC for review and comments. Subject expert committee meeting is conducted where the firm has to defend the CT report and results to obtain approval/favorable comments from SEC. Once the SEC gives favorable comments, DCGI grants marketing approval [Form 46A (for drug substance) and Form 46 (for drug product)] to the firm.

After obtaining Form 46A (for drug substance) and Form 46 (for drug product), the firm applies in Form 27D for Form 28D (manufacturing license) for both drug substance and drug product to SLA. In case the site has not been inspected with experts, joint inspection involving officers of Central Drugs Standard Control Organization, expert and officers of SLA is carried out to verify the firms compliance to GMP and product specific requirements. The report of the inspection is reviewed by the SLA and if satisfied, SLA sends the Form 28D to DCGI for approval. Once the approval is granted by DCGI on Form 28D, SLA grants Form 28D to the firm.

Once Form 28D is granted the firm manufactures commercial batches, ensure consistency of the batches produced and then launches the product in Indian market.

QUALITY CONTROL OF BIOLOGICALS

Biologicals are complex molecules difficult to characterize and standardize given to inherent variability from batch to batch and their test/analysis requires highly specialized facilities and domain expertise supported by an animal facility.

There are two laboratories at the national level, i.e. (i) central drugs laboratory, Kasauli, Himachal Pradesh; (2) National Institute of Biologicals, Noida, Uttar Pradesh, which are involved in quality control of biologicals.

The central drugs laboratory kasauli does the quality control testing and lot release for vaccines whereas National Institute of Biologicals is notified as Central Drugs Laboratory under Drugs and Cosmetic Act and Rules for various biologicals, i.e. (a) blood grouping reagents, (b) diagnostic kits–HIV/HBsAg/HCV, (c) blood products–human albumin, human norman immunoglobulin—IV/IM, human coagulation factor VIII, human coagulation factor IX, plasma protein factor, fibrin sealant kit, anti-inhibitor coagulation complex, (d) recombinant DNA products—r-insulin and insulin analogs, r-erythropoietin (EPO), r-granulocyte colony stimulating factor (G-CSF) and (e) glucose test strips and fully automated analyzer based glucose reagents.

Thus, the Indian regulatory system is robust and dynamic to meet the challenges thrown up by newer biologicals being launched or developed in the country from time to time.