



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

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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

Characteristic	Variable	Screening criteria positive		Screening criteria negative		p-value
		n	%	n	%	
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	

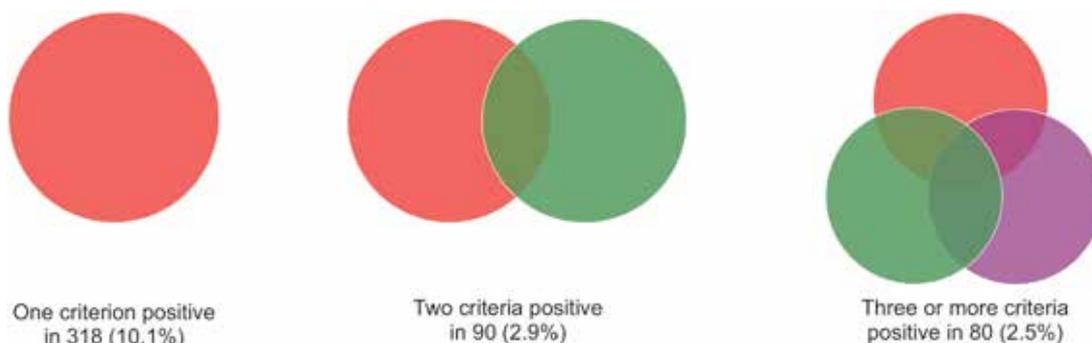


Fig. 1: Number of criteria screened positive in current record review



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

	Medical specialty		Surgical specialty		Total		
	n	%	n	%	Percentage with respect to positively screened patients		Percentage with respect to total screened patients
					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		

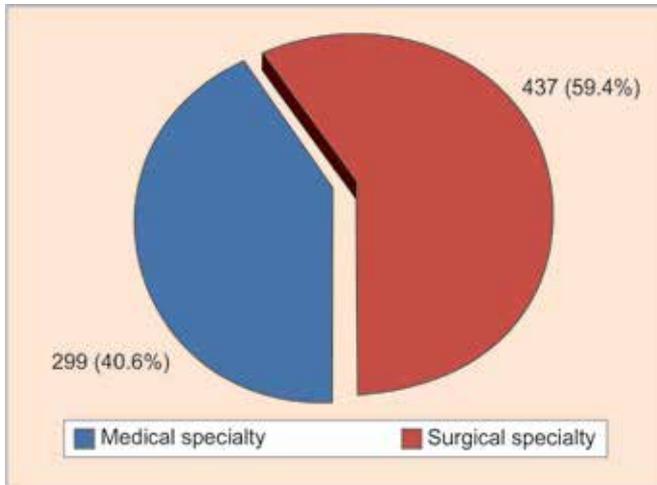
presented with visible untoward outcome. Out of 577 untoward outcomes 402 (92.0%) belonged to surgical specialties and 175 (58.5%) belonged to medical specialties ($p < 0.0001$) (Graph 2, Tables 3 and 4).

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).

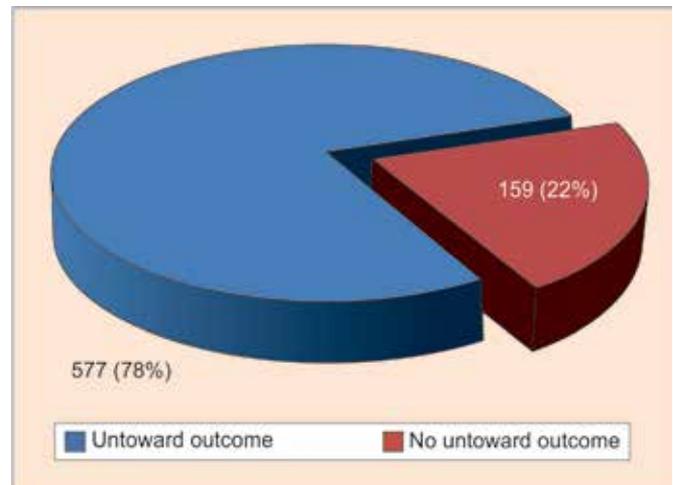
Three hundred and eighty-one (76.8%) of adverse event occurred before the index admission and only 115 (23.2%) of adverse events occurred after admission. Out

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).

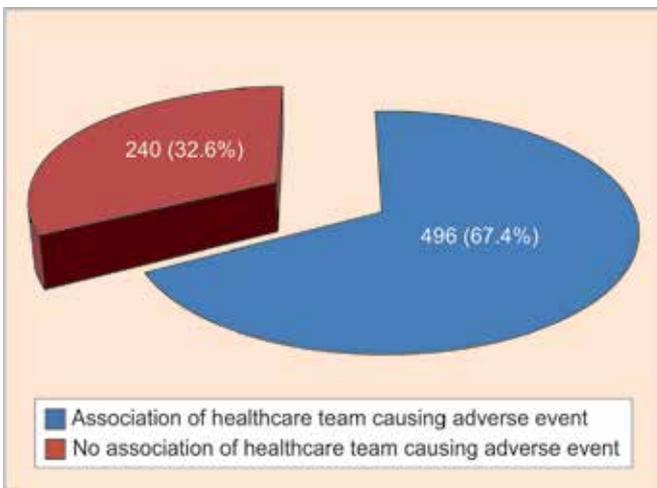
Preventability was calculated using a confidence score of 6 in which if the score came to be 3 or less, adverse event was said to be non-preventable. If the confidence score came to be 4 or more, adverse event was said to be preventable. 71.33% of studied adverse events were found to be preventable and 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).



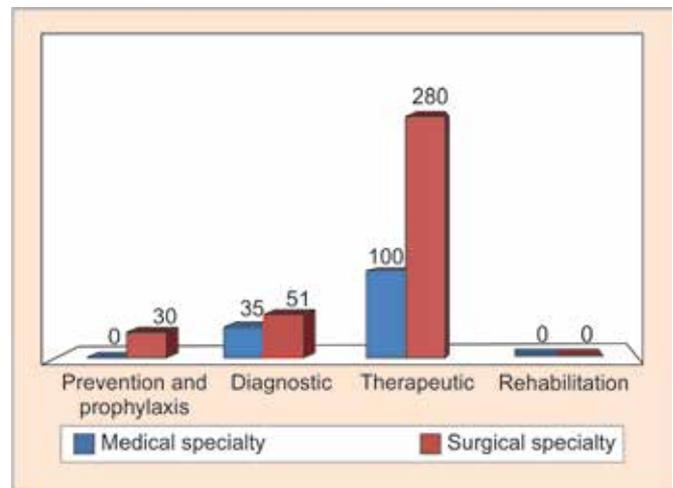
Graph 1: Specialty-wise adverse events studied through RF-2 form in current record review



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

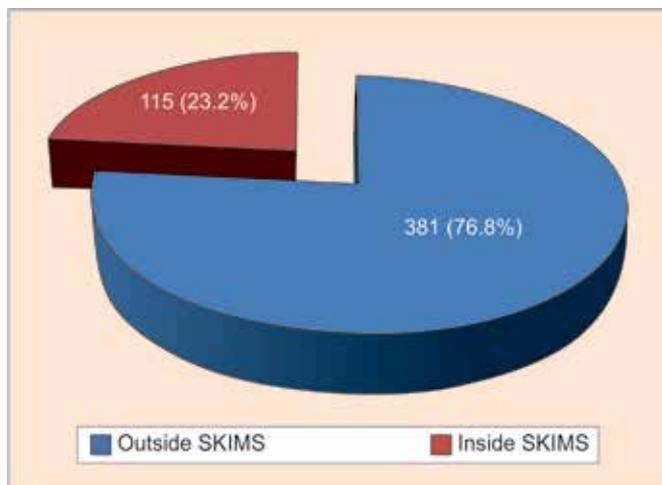
Outcome	Medical specialty	Surgical specialty	Total	p-value
Adverse event causing admission in ward	100 (21.19%)	372 (78.81%)	472 (81.8%)	<0.0001
Adverse event associated with death	20 (80%)	5 (20%)	25 (4.33%)	<0.0001
Adverse event associated with disability at discharge	45 (33.33%)	90 (66.67%)	135 (23.4%)	<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.

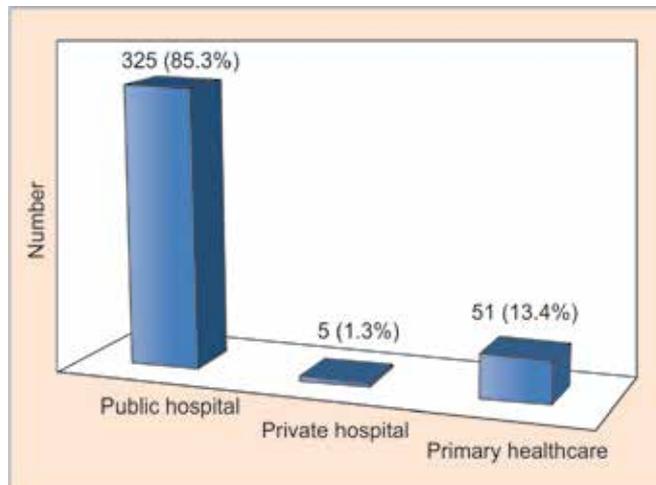
DISCUSSION

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.

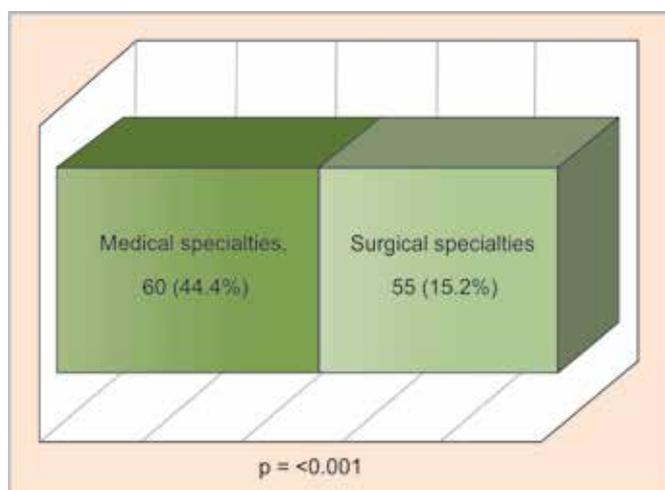




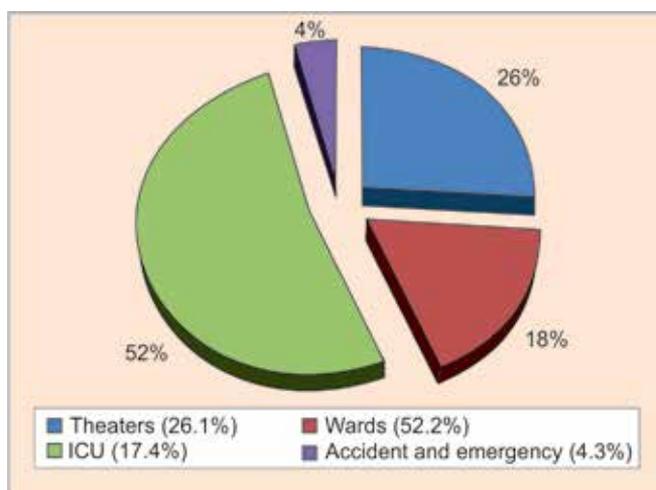
Graph 5: Location of adverse events in current record review



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}

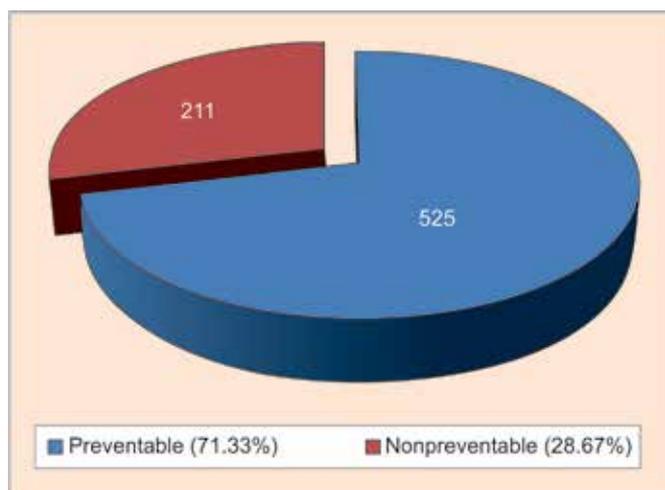
In the present study, most common indicator of adverse event having occurred was readmission during

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%)	< 0.0001
Inside SKIMS	60 (44.4%)	55 (15.2%)	115 (23.2%)	
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%)	<0.001
Private hospital	0 (0.0%)	5 (1.6%)	5 (1.3%)	
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%)

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

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



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 than 50%).^{4,17,21-23} Other studies showed preventability less than 50%.¹¹⁻¹⁵

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