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Development of trigger tool for identifying adverse events in surgery: Experience of a pilot study

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ABSTRACT

A trigger is defined as an "occurrence, prompt, or flag found on review of the medical record that 'triggers' further investigation to determine the presence or absence of an adverse event". Trigger tool method is a measure of hospital safety programme which helps to assess the level of harm. The present study was aimed to develop a list of triggers to identify adverse events in a surgery department of a tertiary care teaching hospital. The development of trigger tool was carried out in six stages including literature review, expert panel review, three rounds of Delphi panel review and consolidation. Delphi Panel review was found to be suitable for the development of trigger tools. A total of 120 case records were reviewed using the developed tools for a period of six months. The triggers were studied for their presence, frequency, ability to pick up adverse events. The developed trigger list was able to flag 75 case profiles out of 120 reviewed case reports with potential adverse events. AEs were identified in 35% of the reviewed cases. The triggers like transfusion/ use of blood products, repeated request lab assessment were able to identify AEs more frequently. The developed tool of the present study may be suitable for Indian settings if validated further in other centres and will be valuable in enhancing patient safety in surgical settings.

INTRODUCTION

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use defines Adverse Event (AE) as “Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment” [1,2]. AEs are considerable indicators of patient safety in health care management [3]. Different methods of identifying AEs are chart review, voluntary reporting by health care providers, patients' experiences of adverse events, assessment of a random sample of medical records and assessment of all deceased patients [4,5,6,7].

Surgery is one of the reasons for adverse events [8] and number of studies has quoted the incidence of adverse events in surgery as 3.7% to 6.2% % [9]. The Harvard Medical Practice study reported that the adverse events occurred in about 2% of hospitalized patients and most of the times (74%) these adverse events are preventable [10]. Number of studies has reported on the use of 'trigger tool' methodology to identify adverse events in surgical cases [11].

A trigger is defined as an "occurrence, prompt, or flag found on review of the medical record that 'triggers' further investigation to determine the presence or absence of an adverse event"[12]. Trigger tool method is a measure of hospital safety programme which helps to assess the level of harm. Studies have shown the superiority of trigger methodology over hospital based occurrence reporting strategy [13].

India is the world's second most populated country with varied disease prevalence patterns and different systems of medicines. Indian health care system is evolving and still need robust system for ensuring patient safety [14]. AEs are formidable challenge to health care institutions. Hence, there is a need for appropriate patient safety monitoring programme at the institutional level.

The present study was aimed to develop a list of triggers to identify adverse events in a surgery department of a tertiary care

teaching hospital. The list of triggers was planned based on published studies improvised with the help of a Delphi panel. The developed tool was used in a small sample of patients as a pilot study to assess its usefulness in detecting Aes.

METHODOLOGY

Development of Trigger tool:

This study was carried out at the surgery unit of Kasturba hospital which is a tertiary care teaching hospital. Institutional ethics committee's approval was obtained before the commencement of the study. The development of trigger tool was carried out in six stages. Triggers were identified from available resources and published studies and initial list of triggers were prepared [15,16,17]. This step was followed by review of expert panel consisting of surgeons and clinical pharmacists. This was followed by three rounds of Delphi panel review. A Delphi panel was formed with two surgeons and two clinical pharmacists. The panel members decided on each trigger item based on its relevance, validity and suitability. The members evaluated the items in the list with ratings on a Likert scale of 1 to 5. Collective opinion was taken before adding or deleting an item from the list. At the end of each review, the ratings of the members were summarized along with their own ratings and circulated to all the members of the team. During each subsequent review, each panel members re-assessed their ratings in the light of ratings given by others. An item which received a mean rating of 3 and above, out of 5, was considered for inclusion into the list. At the end of Delphi Panel review, the final trigger tool was compiled. The stages are presented in Fig.1.

The prepared list of triggers was used for reviewing case records for identifying AEs. Only closed and completed case records were reviewed for the presence of triggers. The review was in the following order: discharge summary, medications administered, prescribed, physician progress note, surgical records, nurses notes, laboratory results, history and physical examination, consultation notes and emergency department notes. The review findings were used for further analysis. The parameters assessed were the frequency of triggers in the records, total number of identified triggers, unused triggers.

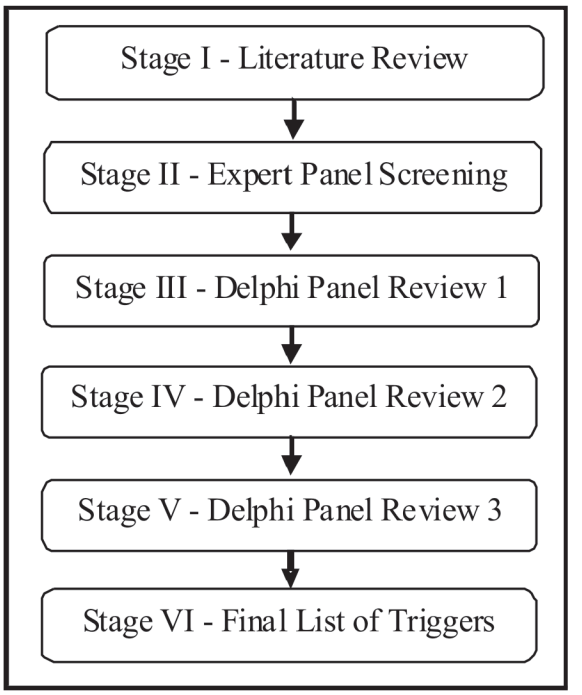

Fig. 1: Stages of development of trigger tool

Assessment of Adverse Events in the case records

Case record review was carried out for a period of six months with 20 randomly selected case records per month. A total of 120 records were reviewed for the presence of triggers at the end of the study period. The case records with triggers were scrutinized further to identify adverse events. Once the presence of adverse events is identified, the level of harm was categorized using NCC MERP Index [15]. The harm categories according this index were E (temporary harm requiring intervention), F (temporary harm requiring initial or prolonged hospitalisation), G (permanent patient harm), H (intervention for sustaining life) and I (death).

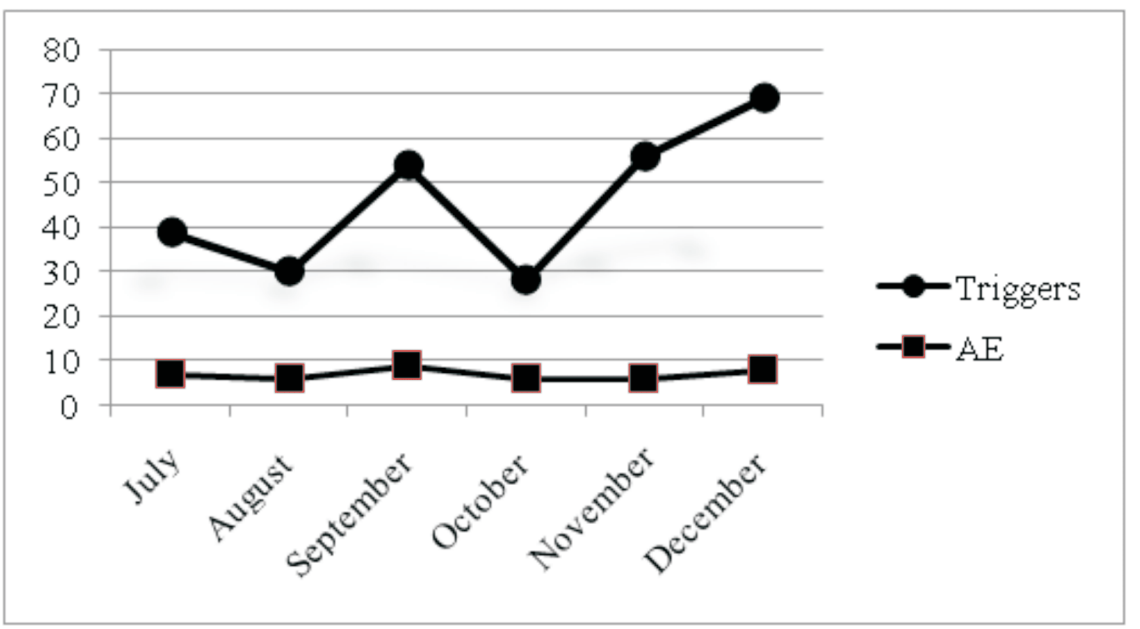

Fig. 2: Month wise data on identified triggers and AEs

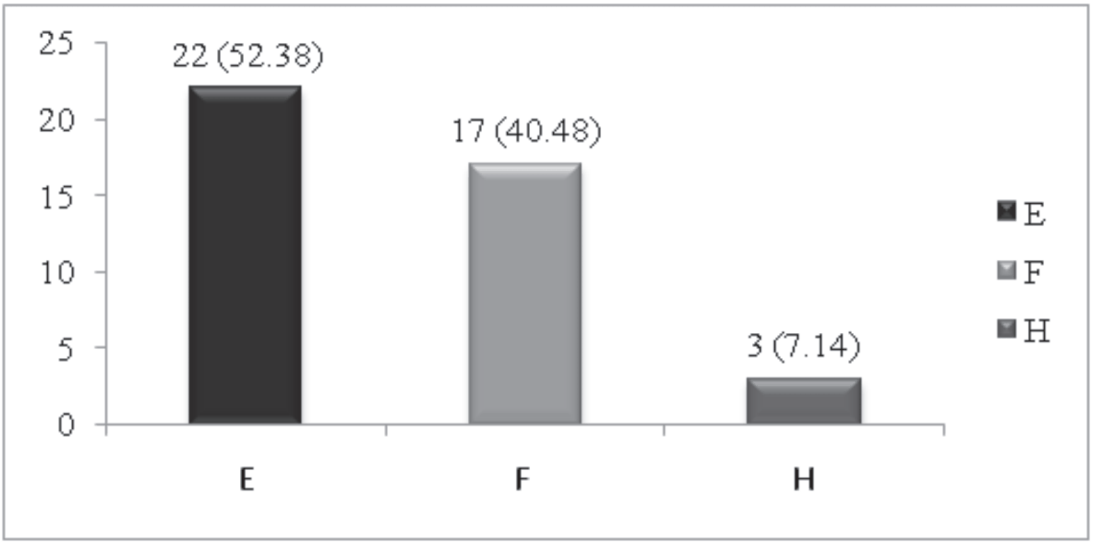

Fig. 3: Categories of Adverse Events

After the identification of AEs, the correlation between the number of triggers and the level of harm was assessed using Spearman's correlation coefficient. The number of AEs per month was found out. Statistical analysis was performed using SPSS version 19.0.

RESULTS

Expert panel and Delphi panel

Initial list of 76 triggers were prepared based on literature review. The trigger tool had three modules namely a) Critical care module, b) Surgical care module, c) Medical care module. These triggers were screened and approved by the expert panel for further review by the Delphi panel. Delphi panel conducted three rounds of review as per the set criteria. After the first review by Delphi panel, a total of five items were deleted (C8, S9, M1, M32, and M36) and seven new items (C15, S16, S17, M48, M49, M50, and M51) were added. After the second review of Delphi panel three items (C11, M20 and M28) were deleted and new three items (C16, S18, and S19) were added. In the third review of Delphi panel, one item (M50) which was added in the first review was deleted and there were no new additions to the list. (Table 1&2). The final trigger list consisted of 77 items and were categorized into three namely, critical care module (14), surgical care module (18) and medical module (45).

Screening of Case Records using trigger tools

A total of 120 case records were reviewed for the presence of triggers. 276 Triggers were present only in 75 case records and 45 case records did not have any trigger.

Critical care module

Out of the 14 triggers in critical care module, 4 items were identified more than five times in the reviewed case records. Transfusion/use of blood products were identified 35 times followed by Infection of any kind (10 times), re-admission within 30 days (9 times) and procedure (6 times). Four items like dialysis, pressure ulcers, readmission to emergency department (ED) within 48 hours and time in ED >6hrs were not identified in any of the records. Triggers of the critical care module and the frequency of their identification are presented in Table 3.

Table 1: List of Triggers added during reviews

Sl No	Mod No	Added Triggers	Stage of Review
01	C15	Readmission to ED within 48 hours	1
02	C16	Time in ED > 6 hours	2
03	S16	Removal/ injury or repair of organ	1
04	S17	Change of Anasthetic agent	1
05	S18	IV atropine	2
06	S19	Hypocalcemia after surgery	2
07	M48	Use of Nebuliser/steam inhalation	1
08	M49	Use of Mephenteramine	1
09	M50	Pseudomonas/ staphylococcus	1
10	M51	Use of steroids	1

Table 2: List of Triggers deleted during reviews

Sl No	Mod No	Deleted Triggers	Stage of Review
01	C8	Falls	1
02	C11	In hospital stroke	2
03	S9	Post-op Troponin level >1.5ng/ml	1
04	M1	Clostridium difficile positive culture	1
05	M20	Use of K-bind	2
06	M28	GI disturbance or GI Bleed	2
07	M32	ARF and/or renal insuffiency	1
08	M36	ER visit/hospitalization due to hyperthyroidism	1
09	M50	Pseudomonas/staphylococcus	3

Table 3: Presence of Critical care Module triggers in reviewed cases

Sl No	Mod No	Triggers	Frequency (%)
01	C1	Transfusion/ use of blood products	35 (29.2)
02	C2	Any code/ arrest	1 (0.8)
03	C3	Dialysis	0
04	C4	Positive blood culture	1 (0.8)
05	C5	X-ray or Doppler studies for emboli	2 (1.7)
06	C6	Abrupt drop of >25% in Hb or Hematocrit	3 (2.5)
07	C7	Re-admission within 30 days	9 (7.5)
08	C9	Pressure ulcers	0
09	C10	Infection of any kind	10 (8.3)
10	C12	Transfer to higher level of care (ICU)	3 (2.5)
11	C13	Procedure	6 (5.0)
12	C14	Pneumonia onset	1 (0.8)
13	C15	Readmission to ED within 48 hours	0
14	C16	Time in ED > 6 hours	0

Surgical care module

Out of the 18 triggers in surgical care module, 2 items were identified more than 5 times in the reviewed case records. Return to surgery was identified 13 times followed by the Occurrence of any post-operative complications (9 times). Items with module numbers S2, S6, S11, S15, S16, S17 and S19 were not identified during review. Triggers of surgical care module and the frequency of their identification are presented in Table. 4

Medical care module

Out of the 45 triggers in medical care module 10 triggers were identified more than five times in the reviewed case records. Repeated request for lab investigations identified for 29 times followed by pyrexia (24 times), use of laxatives (21 times), use of analgesics / pain (16 times), vomiting, nausea / antiemetic use (12 times), electrolyte imbalance K, Na, Cl, Ca (10 times), electrolyte / nutrient supplementation (8 times), diarrhoea / use of antidiarrheal (6 times) and acute urinary retention (6 times). A total of 16 triggers could not be identified in any of the reviewed case records. Medical module triggers and their frequency are presented in the Table 5.

The most commonly identified triggers were listed separately

Table 4: Presence of Surgical Care Module triggers in reviewed cases

Sl No	Mod No	Triggers	Frequency (%)
01	S1	Return to surgery	13 (10.8)
02	S2	Changing procedure	0
03	S3	Admission to intensive care post-operatively	3 (2.5)
04	S4	Intubation/ reintubation or use of BiPap in PACU	1 (0.8)
05	S5	X-Ray intra operatively or in post anesthesia care unit	1 (0.8)
06	S6	Intra or post-operative death	0
07	S7	Mechanical ventilation > 24hrs post operatively	1 (0.8)
08	S8	Intra-operative administration of epinephrine or norepinephrine	3 (2.5)
09	S10	Change of anesthetic during surgery	1 (0.8)
10	S11	Consult requested in post anesthesia care unit PACU	0
11	S12	Occurrence of any post operative complications	9 (7.5)
12	S13	Pathology report normal or identifying specimen unrelated to initial surgical diagnosis	1 (0.8)
13	S14	Insertion of arterial or central venous line during surgery (not starting surgery)	1 (0.8)
14	S15	Operative time > 6 hours	0
15	S16	Removal/ injury or repair of organ	0
16	S17	Change of Anasthetic agent	0
17	S18	IV Atropine	0
18	S19	Hypocalcemia after surgery	0

Table 5: Presence of Medical Module triggers in reviewed cases

Sl No	Mod No	Triggers	Frequency (%)
01	M2	Partial Thromboplastin Time (PTT) > 100 seconds	1 (0.8)
02	M3	International Normalized Ratio (INR) > 6	1
03	M4	Glucose less than 50 mg/dl	0
04	M5	Rising BUN or Serum Creatinine > 2 times baseline	0
05	M6	Vitamin K administration	2 (1.7)
06	M7	Antihistamine use	5 (4.2)
07	M8	Flumazenil (Romazicon) use	0
08	M9	Naloxone (Narcan) use	0
09	M10	Vomiting, nausea / Antiemetic use	12 (10)
10	M11	Over-sedation/ hypotension/lethargy	5 (4.2)
11	M12	Abrupt medication stop	4 (3.3)
12	M13	Repeated request lab assessment	29 (24.1)
13	M14	Skin rashes/angioedema/Steven Johnson syndrome/TEN	0
14	M15	Electrolyte imbalance K,Na,Cl,Ca	10 (8.3)

15	M16	Electrolyte/nutrient supplementation	8 (6.7)
16	M17	Dose reduction	2 (1.7)
17	M18	Frequent ECG request	3 (2.5)
18	M19	Use of laxative/constipation	21 (17.5)
19	M21	Aminoglycoside toxicity (ARF and/renal insufficiency and/ vestibular damage and/or auditory damage)	1 (0.8)
20	M22	Headache	4 (3.3)
21	M23	Immobility (emboli)	0
22	M24	Bleeding	0
23	M25	Diarrhea/use of antidiarrheal	6 (5)
24	M26	Cough/ use of antitussive	5 (4.2)
25	M27	Dyspepsia/Upp GI bleed/ perforation/ GI ulcer or anemia/ use of PPIs	0
26	M29	Melena	1 (0.8)
27	M30	Loss of seizure control or seizure activity	0
28	M31	Tremor	0
29	M33	Use of Analgesic/pain	16 (13.3)
30	M34	Acute urinary retention	6 (5)
31	M35	Acute respiratory failure	0
32	M37	Pyrexia (Fever)	24 (20)
33	M38	Intubation/re-intubation	1 (0.8)
34	M39	ER visit/hospitalization due to congestive heart failure	0
35	M40	ER visit/hospitalization due to extreme hypoglycaemia	1 (0.8)
36	M41	ER visit/hospitalization due to worsening renal impairment and/or acute renal failure and/or renal insufficiency	1 (0.8)
37	M42	Admission to dialysis unit	1 (0.8)
38	M43	Digoxin toxicity	1 (0.8)
39	M44	Blood dyscrasias	2
40	M45	Major and/or minor hemorrhagic event, INR 6, elevated APTT	0
41	M46	Abnormal LFT	1 (0.8)
42	M47	Raised serum creatinine	1 (0.8)
43	M48	Use of Nebuliser/steam inhalation	0
44	M49	Use of Mephenteramine	0
45	M51	Use of steroids	0

to assess the prominence of specific trigger and module. There were a total of 9 triggers from medical module followed by 4 triggers of critical care module. The prominent triggers in this study were tabulated in the Table 6.

When the triggers in each case record were analysed, it was found that the median number of trigger per case record was 1 with a range of 0 to 26.

Assessment of Adverse Events (AEs):

A total of 120 case records were reviewed for the presence of the triggers and in 75 case records triggers were identified and in the remaining 45 records, there were no triggers. The triggers list consists of 77 items and 46 of these items were present in 75 case records. Altogether 31 items were never identified in any of the case records. Totally 276 triggers were present in the 75 cases with an average of 3.68 triggers per case. Out of 75 case records with identified triggers, AEs were present in 42 (35%) case records and 33 case records the triggers were false positive without identification of AEs. The triggers and AEs were calculated per month (Fig.2). Certain triggers identified adverse

Table 6: Prominent triggers identified during the review

Sl No	Mod No	Triggers	Frequency (%)
01	C1	Transfusion/ use of blood products	35 (29.2)
02	M13	Repeated request lab assessment	29 (24.1)
03	M37	Pyrexia (Fever)	24 (20.0)
04	M19	Use of laxative/constipation	21 (17.5)
05	M33	Use of Analgesic/pain	16 (13.3)
06	S1	Return to surgery	13 (10.8)
07	M10	Vomiting, nausea / Antiemetic use	12 (10.0)
08	C10	Infection of any kind	10 (8.3)
09	M15	Electrolyte imbalance K,Na,Cl,Ca	10 (8.3)
10	C7	Re-admission within 30 days	9 (7.5)
11	S12	Occurrence of any post operative complications	9 (7.5)
12	M16	Electrolyte/nutrient supplementation	8 (6.7)
13	C13	Procedure	6 (5.0)
14	M25	Diarrhea/use of antidiarrheal	6 (5.0)
15	M34	Acute urinary retention	6 (5.0)

Table 6: Prominent triggers identified during the review

Sl No	Mod No	Name of Adverse Event	AEs Frequency (N)
1	M13	Repeated request for lab assessment	24
2	C1	Transfusion/ use of blood products	20
3	M37	Pyrexia (Fever)	15
4	M19	Use of laxative	13
5	S1	Unscheduled return to surgery	12
6	C10	Infection of any kind	10
7	M15	Electrolyte imbalance (K, Na, Cl, Ca)	10
8	S12	Post-operative complications	9
9	M10	Vomiting, nausea	9
10	M33	Pain	9
11	C7	Unscheduled re-admission within 30 days	8
12	M16	Nutritional imbalance	8
13	C13	Unscheduled procedure	6
14	M7	Allergy – Drug induced	5
15	M11	Over-sedation/ hypotension/lethargy	5
16	M25	Diarrhea – Drug induced	5
17	M34	Acute urinary retention	5

events in number of case records. When the frequency of adverse events identified by the triggers were compared, repeated request for lab tests was identified as a trigger which identified the most number of adverse events of drug induced lab abnormalities (24%) (Table 7). Many a times a particular AE was identified by multiple triggers. Correlation between the number of triggers and the harm level was assessed by spearman's correlation co-efficient. The correlation coefficient was 0.62 at 0.01 significant levels.

Adverse Events were categorised using NCCMERP Index. There were only three categories of harm (E, F&H). E was the most common category (52%) and H was the least (7%) (Fig 3).

DISCUSSION

The present study attempted to develop a trigger tool for surgery which is ideal for Indian conditions. There are number of reports are available on adverse events in surgery [18,8,19]. In an Australian Health care study, it has been reported that around 50% of the adverse events reported are associated with surgery. In a study reported by IHI, 16% of surgical patients experienced serious adverse events [8]. In India there was reported study on adverse events in surgery which reported around 32% of events in reviewed cases [20].

Trigger tools are prepared by various groups and used to assess adverse events in number of settings [18,8]. Trigger tool methodology offers a better approach to screen adverse events both in medical and surgical care settings [8,18,21]. In the present study although the study is carried out in surgical units, medical care module was also used since many patients were put on multiple drug therapy with potential to cause adverse events.

Delphi technique is the most widely used method for development of trigger tool. This method allows for reliable way of collating opinions of experts to arrive at consensus. Delphi method is considered reliable as it is more objective in exploring human judgements in a situation where subjective decisions are made [21]. Present study successfully utilized the methodology of Delphi technique for developing trigger tool with consensus among the panel members. Final trigger tool developed after three rounds of Delhi review had 77 items.

When the screened records were analysed for prominent triggers, transfusion of blood and blood products was the most commonly identified trigger. Since use of blood products is part of a regular surgical procedure, it has to be screened to identify in which case, the use was routine and which cases had additional use in complications. This item was present 35 times out which it identified AEs 20 times. Another trigger commonly identified was repeated request for lab and in this category request for electrolyte abnormality was identified (24) times. High presence of this trigger most often points to some serious issues in therapy as the patient's condition is unstable [18,19].

When the actual adverse events detected by trigger tools were assessed, a total of 42 adverse events were detected, many of them were of category E, according to NCC MERP Index for Categorizing Errors, was minor in nature. This was similar to available reports [13]. This shows that these AEs are manageable provided if identified at the right time. This underlines the role of trigger tools in clinical and surgical settings in enhancing patient safety.

The most common adverse event noted was abnormal values like alteration PT, Hb,etc. This might have been appeared as a result of surgeries or further drug therapy following surgery.

Traditionally adverse event detection primarily depends upon voluntary reporting. Since, this method needs less resource and easily implementable, it was normally used as a standard method to detect adverse events. But on the down slide this method resulted in very poor reporting and lack of co-operation from health care practitioners among number of other factors [22,17].

Trigger tool methodology offers an alternative way of screening for adverse events and this method does not need much time of the treating clinician since reviewer takes care of the burden of reviewing, verifying and reporting the event. This method has been reported to pick up more adverse events compared to voluntary reporting. In the present study AEs were identified in 35% of the reviewed cases showing the usefulness of this method in Indian settings. This method can be the basis not only for estimating the frequency of adverse events in an organisation, but also determining the impact of interventions that focus on reducing adverse events in surgical patients [8]. Since this method involves a random selection of cases, it becomes an unbiased method for case selection for screening.

Study limitations:

The number of case records is not adequate enough to generalize the results to other clinical settings in the country. Two reviewers reviewed cases and identified the triggers and the inter-rater reliability has not been assessed. Some reviewed case records were not complete in all the aspects.

CONCLUSION

The development of trigger list for AEs in surgery department is the first of its kind in India. The developed trigger list was able to flag 75 case profiles out of 120 reviewed case reports with potential adverse events. Delphi Panel review was found to be suitable for the development of trigger tools. The triggers like transfusion/ use of blood products, repeated request lab assessment were able to identify AEs more frequently. AEs were identified in 35% of the reviewed cases. Validating this trigger tool and implementation in practice will help to identify potential AEs effectively. The developed tool of the present study may be suitable for Indian settings if validated further in other centres and will be valuable in enhancing patient safety in surgical settings.

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