

Study of Reporting System for Adverse Events Related to Common Medical Devices at a Tertiary Care Public Sector Hospital in India

S. Kurien, S. Satpathy, S. K. Gupta, S. K. Arya, D. K. Sharma

Abstract—Advances in the use of health care technology have resulted in increased adverse events (AEs) related to the use of medical devices. The study focused on the existing reporting systems. This study was conducted in a tertiary care public sector hospital. Devices included Syringe infusion pumps, Cardiac monitors, Pulse oximeters, Ventilators and Defibrillators. A total of 211 respondents were recruited. Interviews were held with 30 key informants. Medical records were scrutinized. Relevant statistical tests were used.

Resident doctors reported maximum frequency of AEs, followed by nurses; and least by consultants. A significant association was found between the cadre of health care personnel and awareness that the patients and bystanders have a risk of sustaining AE. Awareness regarding reporting of AEs was low, and it was generally done verbally. Other critical findings are discussed in the light of the barriers to reporting, reasons for non-compliance, recording system, and so on.

Keywords—Adverse events, health care technology, public sector hospital, reporting systems.

I. INTRODUCTION

THE system of healthcare delivery is continuously evolving, keeping pace with the advances and innovations in technology and the quest to reduce various patient safety issues including adverse events. Adverse events (AE) related to the use of medical devices are increasingly being recognized world over and now remain an area of considerable concern [1]-[3]. An adverse event is defined as a problem that can or does result in permanent impairment, injury or death to the patient or the user [4]. It can also be a discrete occurrence related to healthcare management that results in unintended injury, illness or death [5]. An adverse event related to medical device is defined as adverse event in which a medical device was considered to have been involved (caused or contributed) to the event.

Each year about 400 people are killed or seriously injured in adverse events involving medical devices as per study in NHS, UK [6]. UK National Patient Safety Agency revealed that a

total of 1021 cases were associated with medical devices and the most common among them were syringe pumps/infusion devices, ventilators, haemo-filters and monitoring equipment. The reasons for the adverse events included failure of the device per se, faulty equipment, inadequate training, incorrect use or setting and lack of/incorrect cleaning [1]. A study done in France reported 4,188 adverse events, of which 91% were minor, 7% severe and 2% were fatal. The cause was available for only 1,935 events (46%). Faulty manufacturing was the main cause of minor events. Inappropriate use was the cause in a significantly larger proportion of severe events than minor events and was usually considered preventable *via* improved knowledge or device verification before use [2]. In another study it was reported that equipment for ventilation and infusion, and monitors of all kinds, accounted for most of the AEs, representing 37%, 30% and 12%, respectively [3].

Hefflin et al. (2004) in USA, during a one year period, reports of 10,395 medical device-associated adverse events were accumulated using the National Electronic Injury Surveillance System (NEISS), which collects information on product-related injuries, from the Emergency Department records of a national stratified probability sample of hospitals. The study reported that adverse events associated with medical devices can be multifaceted and unconventional; the contribution of a device to an adverse event may be subtle and indirect, and therefore would go unrecognized and unreported, thus making medical device-associated adverse events as an under-recognized public health problem [7]. The study by Samore et al. (2004) revealed that in a tertiary care hospital in the United States, the overall incidence of adverse medical device events was 83.7 per 1000 discharges [8].

Adverse incidents with medical devices are caused by a variety of factors not simply either device or user errors [6]. Effective reporting system is the cornerstone of safe practice and within a hospital or other healthcare organisation, a measure of progress towards achieving a safety culture. Common barriers such as time constraints, unsatisfactory processes, deficiencies in knowledge, cultural norms, inadequate feedback, beliefs about risk, and a perceived lack of value in the process were identified by [9]. It was found out by Hynan et al. that exposing medical trainees to a patient safety educational programme for improving medical event reporting did have a positive impact on the attitude to reporting in Dallas [10]. Issues such as babies sustaining fatal burns in incubators are very often reported in India [11].

Lt Col (Dr) Sudhin Kurien is Medical Officer (Hospital Administration) at Command Hospital NC; C/o 56 APO

Prof Sidhartha Satpathy, is with Dept of Hospital Administration, All India Institute of Medical Sciences (AIIMS), Ansari Nagar, New Delhi-110029; India (Phone: 0091-11-26594708; Fax: 0091-11-26588641, 26588663; e-mail: dr.sidharthasatpathy@gmail.com).

Dr.Shakti Kumar Gupta is Medical Superintendent of Rajendra Prasad Center for Ophthalmic Sciences, at AIIMS, New Delhi, India.

Prof. Sanjay Kumar Arya is with Dept of Hospital Administration, All India Institute of Medical Sciences, Ansari Nagar, New Delhi, India.

Dr.D.K.Sharma is Medical Superintendent, AIIMS, New Delhi, India.

Unfortunately, scientific publications on this issue in the entire South Asian region including India are almost non-existent.

It is of paramount importance to focus on the patients' as well as caregivers' safety to enhance the quality of health care delivery in a more efficient manner. Again to highlight the urgent need of study, it is important to mention here that as per the 53rd Annual Report of the study hospital (a 2500 bedded premium tertiary care hospital located at New Delhi) for the year 2008-2009, the main hospital provided care to 1,50,7,786 outpatients and 65,687 in-patients and 108,486 patients with emergent conditions with an average length of stay of 5.9 days, the average bed occupancy of 79.9% and the net death rate of 2.7% which is at par with similar parameters in developed countries [12].

II. OBJECTIVE

The key objectives were i) to carry out a KAP survey on "Adverse Events related to Medical Device" among consultants, resident doctors, and nurses posted in different patient care areas, ii) and to study the existing system of reporting in this hospital.

III. METHODOLOGY

A. Ethical Clearance

After obtaining ethical clearance from the hospital Ethics Committee, the study was carried out from October 2011 to Jun 2012.

B. Study Design

This was a descriptive cross sectional design of study with 3 arms of cadres for comparison.

C. Study Area: Inclusion and Exclusion

The study area was limited to Operation Theatre, Intensive Care Units, Inpatient areas, & Emergency services only. The outpatient departments were excluded from the study, as the devices under consideration in the study are not used in this area.

D. Medical Devices: Inclusion and Exclusion

The study included the medical devices (electricity / battery operated), which were most commonly used by the healthcare personnel across all the areas under study viz-Infusion pumps, Defibrillators, Monitor based devices (ICU monitor, non-invasive blood pressure monitor, pulse-oximeter), and Ventilators.

The devices that are not electrically / battery operated and the consumables, in vitro reagent or calibrator, software were excluded from the purview of the study.

E. Sample Inclusion and Exclusion

The total universe of sample was a total number of 2244 (131 consultants/faculty, 572 resident doctors and 1541 nurses working in the study areas. After a requisite sample calculation by formula $n = \frac{4xPxQ(1-P)}{d^2}$ the required sample was 100. Considering the non-response, a total of 400 (30 consultants, 100 resident doctors, and 270 nurses) potential

respondents on a convenient sampling procedure (after taking their willingness and availability to participate in the study, and those who had earlier participated in the pilot study) were recruited. Out of these 400 recruited people, the final sample included 211 respondents (24-consultants, 45-resident doctors, and 142-nurses) who returned back the questionnaires. The overall response rate was 52.75%.

Tools Used:

Objective-1:

A semi-structured questionnaire containing a total of 26 items; demographic details (4 items), subject specific parameters (19 items) and open-ended questions (3 items) was developed. The subject specific questions included 3 dimensions of knowledge (7 items), attitude (4 items), and practice (8 items) about medical device and its operation, AEs related to medical devices, reporting, and prevention measures. The open-ended items focused on the common reasons for medical devices related adverse events, their frequency (during last year); and measures to prevent such events. The finalisation of questionnaire was done after a pilot study conducted on a subset of 30 persons drawn from the same study universe (later on excluded from the final sample) and relevant modifications were undertaken for the clarity and unambiguity of language, adequacy of items, and relevance of questions. Responses varied from yes/no type of answers to 3-4 point scale options and multiple answers to a particular item.

Objective-2:

- a) Unstructured interviews were carried out with key informants/stakeholders of the Medical Records, Stores Section, Medical Superintendent Office and the Chief Nursing Officers office, to study the present system for reporting of Adverse Events related to medical devices in the study hospital. The interview was carried out with 11 consultants, 10 resident doctors and 9 nurses (total of 30 key informants). The interview was done over a period of three months (February to May 2012). The average duration of the interview was 25 minutes.
- b) A retrospective study of records and documents in AIIMS Main Hospital pertaining to adverse events related to medical devices for last one year was done to understand the existing system. Files in the Hospital Stores, Establishment section, Nursing Office including complaint files were studied.

F. Procedure of Data Collection

The questionnaires were distributed at the faculty offices, resident rooms and nursing hubs. They were apprised that collection of the questionnaire will be done after 4 days from the same points. The respondents directly sent most of the questionnaires to the researcher. The remaining questionnaires were collected back from the same points of distribution over the succeeding week. The total number of returned questionnaires was 211, which constituted the final sample.

G. Data Analysis

All valid responses were then analyzed using the SPSS version 16. A bi-variate analysis of cadre against the various fields that pertained to the domains of knowledge, attitude and practice were done.

IV. RESULTS & DISCUSSION

The key findings of objective no 1 (KAP study) are first discussed in the light of supporting and contrasting studies reported in literature. The findings are presented in Table I.

Although three quarters of the total respondents had stated that they had acquired knowledge of operating these devices from informal sources i.e. from peers, and seniors, there were significant differences between cadres. Similar findings have been reported in a study from Australian nurses, where 87.1% had reported learning about devices from other staff nurses in

the unit, [13]; where-as in USA, trial and error method was most common, followed by user manual [14]. Less than a third of the consultants, and nurses; and only few resident doctors acquired this knowledge from the equipment supplier/vendor; while some resorted to self-learning. Awareness about availability of user manual in patient care areas was low amongst Consultants and Resident doctors; whereas it was high in case of nurses. This can be attributed to the fact that, it is the nursing staff that indent the devices from Stores, and hence have firsthand knowledge regarding user manuals. Where-as it is well known that patients can get injured due to device related adverse events, risk of injury to by-standers (attendants, other staff, visitors etc.); also occurs, albeit rarely. The awareness regarding this issue was significantly different amongst different cadres.

TABLE I
SIGNIFICANT FINDINGS ON KEY KNOWLEDGE, ATTITUDE, PRACTICE (KAP) ITEMS

Dimensions	Cadre of staff			Significance of difference
	Consultants (C)	Resident doctors (RD)	Nurses (N)	
Knowledge				
Sources of device information from formal sources (vender, manual, etc.)	8 (33.3%)	3 (6.5%)	44 (30.9%)	p<.01 (C vs RD and RD vs. N, both)
Awareness about existence of user manual for device	13 (54.2%)	18 (40%)	111(78%)	p<.05 (RD vs. N and C vs. N, both)
Awareness of risk to bystanders from AEs	12 (50%)	22 (48.8%)	36 (25.4%)	p<.05 (RD vs N) p<.01 (C vs.N)
Attitude				
Option of teaching about AEs & reporting at undergraduate level	5 (20.8%)	16 (35.5%)	37 (26.1%)	Not significant
Option for induction training and refreshers courses	24 (100%)	45 (100%)	97 (67.6%)	P<.05 (C & RD vs N)
Use of multiple options for reporting AEs	14 (58%)	33 (73.3%)	106 (74.6%)	Not significant
Practice				
Verbal reporting of AE to superiors	19 (80%)	41 (91%)	98 (69%)	Not significant
Verbal reporting of AE to vender	10 (41.6%)	19 (42.2%)	61 (43%)	Not significant
Written reporting of AE to stores	13 (54.1%)	5 (11.1%)	54 (38%)	Not significant

As regards items related to attitude are concerned, the only significant finding was pertained to willingness for inclusion of adverse events related to medical devices in induction training and refreshers courses. A study by Coyle in 2005 revealed that 28.5% opted for graduate level training where as 45.86% opted for regular reporting systems and 73.16% opted for multiple options [10].

Table II represents data on barriers to reporting.

The queries on the various barriers that prevented reporting had evoked very interesting findings. In this study, about one-fifth of the respondents reported lack of time as a barrier to report; whereas in another study conducted in 2005 in United States it was rated as a major barrier to event reporting [10]. A quarter of the sample population did not report due to fear of legal repercussion while US FDA found in its own study that legal liability concerns was the top most barrier to reporting [15]. In a similar study in Australia Evans et al also concluded that fear of litigation was a major barrier to reporting [9]. This difference could be due to the fact that in this current study non-existence of a convenient reporting system was

highlighted as the top most barriers. In addition, the difference could be attributed the difference in methodology and sample size. The fact that a limited group among respondents did not report on colleagues, is consistent with the general international feeling of unwillingness on the part of the healthcare professionals to report on others as brought out in a study by Parker in United States [16]. The lack of convenient system as expressed is indeed a cause for concern. The necessity for having a convenient system needs no further highlight and has been already argued for in the study at Harvard in 2000 [17].

Although there was no significant difference between any two cadre of staff on key practice items, it is relevant and important to mention here that verbal reporting is mostly prevalent at this hospital. This verbal reporting is informal and is usually made to colleagues and seniors in the department and in few cases to the vender/authorized representatives of suppliers. However, as no written records of this verbal intimation to the vender exist, the follow up actions and corrective measures get compromised.

TABLE II
BARRIERS TO REPORTING (PRACTICE DIMENSION)

Reasons for lack of reporting	Cadre of staff		
	Consultants (C)	Resident doctors (RD)	Nurses (N)
Lack of time	5 (20.8%)	12 (26.7%)	23 (16%)
Fear of legal repercussion	5 (20.8%)	11 (24.5%)	37 (26%)
Donot want to put colleague in trouble	5 (20.8%)	11 (24.5%)	37 (26%)
Non-existence of convenient reporting system	20 (83.3%)	39 (86.7%)	71 (50%)
AEs did not merit reporting	0	11 (24.5%)	30 (21.1%)
AEs could be identified by user	10 (41.6%)	8 (17.7%)	47 (33%)

Out of 4 items under attitude dimension, the consultants and the resident doctors significantly differed ($p < .01$) from the nurses in viewing proving entry level training and regular refresher courses which can reduce the number of adverse events in this hospital. This indicated that the nurses' preference for induction training and refreshers' course was significantly lower than the consultants and resident doctors. It could be attributed to the other related findings (which are not included in this present paper) such as the majority of the nurses were of the opinion that adverse events should be tackled by use of multiple methods which include teaching

about the same at graduation level, regular reporting of AEs and a combination of all three methods. Although the difference between cadre of staff was not reported in any study, this finding was in line of few other findings regarding intention to report AEs that have been reported from China and Australia [18], [19].

Table III represents data on number of adverse events occurring in last one year. Unexpectedly, it was found that more than 96% of consultant respondents were unaware of any adverse event happening.

TABLE III
NUMBER OF ADVERSE EVENTS OCCURRING IN LAST ONE YEAR

Cadre of staff	Frequency and % of occurrence of AEs per year		
	1-5	6-10	Unaware of any AE
Consultants N=24	0	1 (4.2%)	23 (95.8%)
Resident doctors N=45	27 (60%)	12 (26.7%)	6 (13.3%)
Nurses N=142	109 (76.8%)	0	33 (23.2%)

Table IV reveals data on common reasons for adverse events.

The study revealed the commonest reason for adverse events as the malfunctioning of devices, followed by lack of battery backup and user errors resulting in improper settings' of the devices resulting in non-function. Beydon et al. have also reported similar findings in 2010, which revealed that

faulty manufactured devices and inappropriate use caused severe adverse events [2]. While the reason for adverse events could be multifaceted and can remained under recognized [7], the study findings perhaps indicated a vicious cycle of incidents such as inappropriate use leading to inappropriate setting of devices again leading to malfunctioning in general and malfunctioning due to battery backup, in particular.

TABLE IV
COMMON REASONS FOR ADVERSE EVENTS

Common reasons	Frequency and % of Respondents		
	Consultants N=24	Resident doctors N=45	Nurses N=142
Malfunctions	12 (50%)	16 (35.6%)	51 (35.9%)
Lack of battery backup	5 (20.8%)	18 (40%)	53 (37.3%)
User errors leading improper setting and non-functioning of device	2 (8.3%)	3 (6.6%)	6 (4.2%)

Table V represents data on measures to prevent adverse events related to medical devices. The commonest preventive measure suggested was the need for proper training, which can be corroborated from the other studies [1]. This indicated that training is required at the time of joining of different cadres, and also at the time of introduction of upgraded/newer models of these devices. Similarly, requirement of device maintenance has also been suggested as the second most common requirement. Some of the respondents (from all cadres) have suggested that trained biomedical engineers should carry out the maintenance of such device. This finding seems to be in

the line of findings reported by [20] on ventilators, and by [21] which revealed that device maintenance including calibration by biomedical engineers was significantly better as compared to maintenance by users. At present, this is being carried out in an informal manner by nursing staff in liaison with store personnel. About one-fifth of the respondents have suggested having a user-friendly and confidential reporting system that provides a feedback to the person reporting. These suggestions seem to be feasible and would require organizational commitment for implementation.

TABLE V
MEASURES TO PREVENT ADVERSE EVENTS RELATED TO MEDICAL DEVICES

Suggested preventive measures	Frequency and % of Respondents		
	Consultants N=24	Resident doctors N=45	Nurses N=142
Insufficient awareness and need for regular training	11 (45.8%)	14 (31.1%)	63 (44.4%)
Device maintenance requirements	9 (37.5%)	17 (37.7%)	51 (36%)
Confidential and user-friendly reporting system	8 (33.3%)	14 (31.1%)	17 (12%)

Objective-2

- a) Study of existing reporting system in hospital: The interviews with the 30 key informants revealed that in the absence of a formal and structured reporting system of adverse events, the details of the events are not evaluated to its logical conclusion. The present system of reporting is very rudimentary and includes informal intimation of events or event related happenings, based on individual perception, preferences and attitudes as well as based on the receptiveness of the authority reported to. The result of the lack of appropriate reporting system has led to instances of informal verbal as well as formal written intimation of adverse events, but the course of actions taken to address the issue has often been not mentioned. Two third of the key informants expressed the need for guidelines/SOP for the personnel facing such events regarding the course of action to be taken by them, including reporting of the event in a suitable format to appropriate authority subsequent to the event, to prevent such adverse events. A study in USA has reported that underreporting of adverse events related to medical devices (50-96% annually) even with good reporting facility [17]. Thus, it is clear that underreporting of adverse events could be a more rampant and crucial problem where no formal reporting system is existent.
- b) A search for last one year's documents/circulars pertaining to adverse events related to medical devices was done in equipment stores, establishment section and nursing Office. The circular files and complaint files in the establishment office and nursing office were perused and so were the files in the Equipment stores. However, no documents were traceable pertaining to adverse events happened in the last one year.

It is evident from the above that there is no formal system for reporting of adverse events highlighting the significance of development and implementation of an effecting reporting system, Studies in developed countries [9], [17], [22] have already established the need for having effective reporting systems, as a method of capturing adverse events, and initiating remedial measures.

V. LIMITATIONS AND DIRECTIONS FOR FUTURE RESEARCH

Notwithstanding the current study had few limitations, however, on the basis of available literature, it is evident that this is perhaps the first ever study in this area of reporting of adverse events related to medical devices in a large scale tertiary care level hospital. The findings of this study cannot be generalized as it is done in a large-scale tertiary level

hospital with a smaller sample size. The researchers interested in this area may consider to opting for a comparative cross sectional study across various hospitals to which would provide a pattern of reporting systems practiced in a particular geographical location. In addition, the questionnaire may have failed to capture the full spectrum of the three domains of knowledge, attitude and practice regarding adverse events related to medical devices, which the future researchers may consider to improve upon by making it more quantifiable uniform response format for all three dimensions.

VI. CONCLUSION

The study concludes by stating that the existing system of reporting of adverse events related to medical devices in the studied hospital is informal, unstructured and rudimentary in nature. In order to capture these adverse events, the reporting system has to be completely revamped in consonance with the World Health Organisation (WHO) guidelines.

REFERENCES

- Thomas AN, Galvin I. Patient safety incidents associated with equipment in critical care: a review of reports to the UK National Patient Safety Agency. *Anaesthesia*. 2008 Nov; 63(11):1193-7.
- Beydon L, Conreux F, Le Gall R, Safran D, Cazalaa JB. Analysis of the French health ministry's national register of incidents involving medical devices in anaesthesia and intensive care. *Br J Anaesth*. 2001 Mar; 86(3): 382-7.
- Beydon L, Ledenmat PY, Soltner C, Lebreton F, Hardin V, Benhamou D, et al. Adverse events with medical devices in anaesthesia and intensive care unit patients recorded in the French safety database in 2005-2006. *Anesthesiology*. 2010 Feb; 112(2):364-72.
- Medical Device Regulations-Global review and guiding principles, Internet. cited 2011 May 11. Available from: http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf
- QualityandsafetyinhealthcareHS-227-PromotingPatientSafetyatHealth Care.pdf Internet. Cited 2011 Sep 11. Available from: <http://www.searo.who.int/LinkFiles/QualityandsafetyinhealthcareHS-227-PromotingPatientSafetyatHealthCare.pdf>
- Amoore J. Quality improvement report: Learning from adverse incidents involving medical devices. *BMJ*. 2002 Aug; 325(7358):272-5.
- Hefflin B. Estimates of medical device-associated adverse events from emergency departments*1. *American Journal of Preventive Medicine*. 2004 Oct; 27(3):246-53.
- Samore MH, Evans RS, Lassen A, Gould P, Lloyd J, Gardner RM, et al. Surveillance of medical device-related hazards and adverse events in hospitalized patients. *JAMA*. 2004 Jan 21;291(3):325-34.
- Kingston MJ, Evans SM, Smith BJ, Berry JG. Attitudes of doctors and nurses towards incident reporting: a qualitative analysis. *MEDICAL Journal of Australia*. 2004;181:36-9.
- Coyle YM. Effectiveness of a graduate medical education program for improving medical event reporting attitude and behavior. *Quality and Safety in Health Care*. 2005 Oct 1;14(5):383-8.
- Purnima. S. Tripathi. Death in the incubator. 2001 Dec 24 (cited 2011 May 9); 18(24). Available from: <http://www.hindunet.com/fline/fl1824/18240370.htm>
- AIIMS. 53rd Annual Report, AIIMS Publications, 2008-2009, New Delhi.

- [13] McConnell EA, Fletcher J. Agency registered nurse use of medical equipment: an Australian perspective. *Int J Nurs Stud.* 1995 Apr; 32(2):149–61.
- [14] McConnell EA. How and what staff nurses learn about the medical devices they use in direct patient care. *Res Nurs Health.* 1995 Apr; 18(2):165–72.
- [15] Gardner S, Flack M. Medical Device Provisions of FDA Modernization Act > Designing a Medical Device Surveillance Network (Internet). (cited 2012 Aug 21). Available from: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm168938.htm#4.1>
- [16] Lawton R, Parker D. Barriers to incident reporting in a healthcare system. *QualSaf Health Care.* 2002 Mar; 11(1):15–8.
- [17] Barach P. Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. *BMJ.* 2000 Mar 18; 320(7237): 759–63.
- [18] Liu A-P, Zhang L-M, Yan W, Zhang J-H, Zhu Y-P. (Analysis on evaluation of medical device adverse events monitoring and some factors influencing MDAE's reporting by medical personnels). *Zhongguo Yi Liao Qi XieZaZhi.* 2008 Jan; 32(1):47–9.
- [19] Evans SM, Berry JG, Smith BJ, Esterman AJ. Anonymity or transparency in reporting of medical error: a community-based survey in South Australia. *Med. J. Aust.* 2004 Jun 7; 180(11):577–80.
- [20] Garg R, Bhalotra A, Pruthi A, Bhalotra P, Anand R, Gupta N. Awareness among resident doctors with regards to cardiac defibrillators. *Saudi Journal of Anaesthesia.* 2010; 4(3):182.
- [21] Brown AS. To what extent does medical device maintenance pose clinical risk? *Clinical Risk.* 2008 Mar 1; 14(2):59–62.
- [22] Pittet D. Challenging the world: patient safety and health care-associated infection. *International Journal for Quality in Health Care.* 2006 Feb 1; 18(1):4–8.