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REVIEW ARTICLE

Challenges encountered by healthcare professionals in monitoring adverse events due to medical devices-A review

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Abstract

Medical devices can be hazardous despite their positive benefits. Reporting medical device adverse events are voluntary for all the health care professionals but the number of reporting adverse medical events are less when compared with all the available studies in India. Hence it is important to address the reasons and challenges that are faced by health care professionals in reporting the events so that safety and quality action can be taken in order to prevent them. Understanding the obstacles to and reasons for patient reporting is necessary and may help to increase the safety of medications. This review provides an insight into factors contributing to underreporting of MDAE such as Health care system capacity related, organizational related barriers, and Industry responsiveness. This review might offer helpful data for overcoming barriers in monitoring and support quality and safety management in hospitals.

Keywords: Lack of reporting, Materiovigilance program of india, Medical device adverse events, Poor awareness, Self-implementation of devices.

Introduction

According to WHO, any apparatus, instrument, appliance, substance, reagent for *in-vitro* usage, software or other medical related objects are considered as Medical devices. (Organization, 2019) Technology breakthroughs including drug-device combo products, automation and wireless innovations, and advanced clinical use of devices have allowed for a rapid increase in the usage of medical devices in medical facilities all over the world. (Fouretier & Bertram, 2014). Devices can be hazardous despite their positive aspects. (Muthuselvi *et al.,* 2022). The "Materiovigilance Programme of India" is a programme that has been started in India at Ghaziabad, on 2015 July 6th to monitor the negative events that result from the usage of medical devices and to take the required steps to address those negative events. (Hoda *et al.,* 2020). The workflow process of materiovigilance program of India is illustrated in Figure 1.

The reporting of adverse medical device reactions by health care professionals is very rare as per the available literatures. Understanding the obstacles to and reasons for patient reporting is necessary and may help to increase the safety of medications.

To increase the effectiveness of MDAE management, the promptness of MDAE response, and the effectiveness of multiparty coordination among medical institutions, dealers, and medical device manufacturers, a number of issues still need to be resolved. Reporting MDAE are voluntary for all the health care professionals but the number of reporting adverse medical events are less when compared with all the available studies in India. Hence it is important to address the reasons and challenges that are faced by health care professionals in reporting the events so that safety and quality action can be taken in order to prevent them. This review gives an insight of various challenges faced by health care professionals in reporting from the available literatures. The number of reporting centres year wise in medical India is displayed in Table 1.

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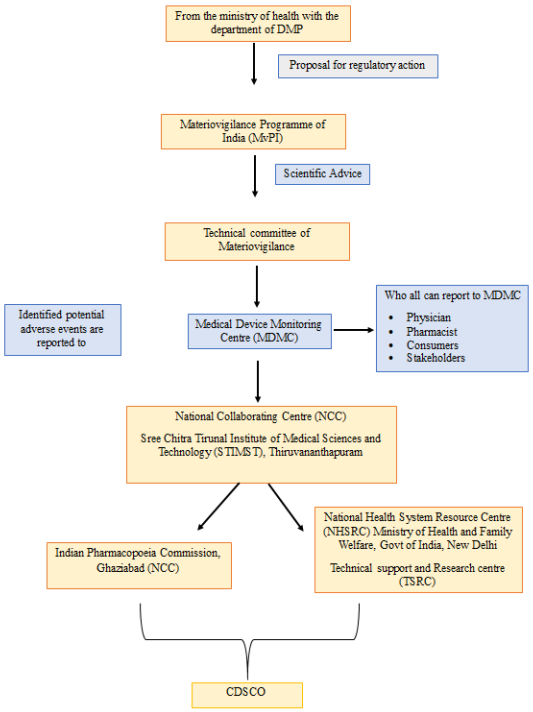

Figure 1: Systematic process in reporting medical device adverse events

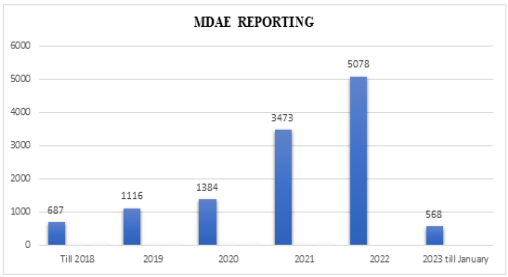

Figure 2: Yearwise medical device adverse events reporting trend

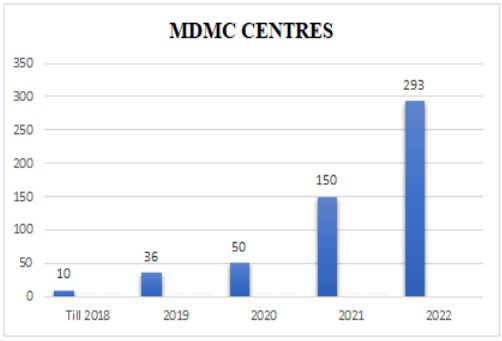

Figure 3: MDMCs centres across India year wise

Table 1: Difference between drug and medical device

Drug	*Medical device*
Chemistry and pharmacology	Biomedical engineering & compatibility
Safety and efficacy	Safety and performance
Good manufacturing practices	Quality management system
Local and systemic toxicity	Biocompatibility

Challenges in adverse event reporting owing to medical devices

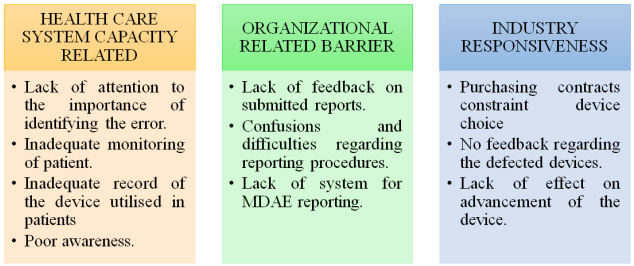

Figure 4: Overview of challenges associated with reporting Adverse events

Factors contributing to under reporting of MDAE

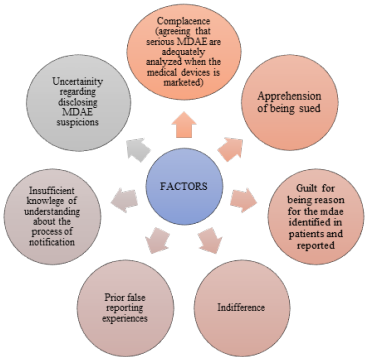

Figure 5: Factors contributing to under reporting of adverse events owing to Medical devices

Health care functioning related

Inadequate attention to the importance of identifying the event

Identifying adverse related to medical device was not consciously thought of as a duty and many MDAEs weren't identified which affects the patient safety and quality of life(Gagliardi *et al.,* 2018) (Figure 2). Thus the individual physicians and other healthcare professionals should broadly share the information regarding the identification, reporting and its significance to other healthcare professionals, patients and various stakeholders (Maisel, 2004).

Table 2: Number of reporting in medical device monitoring centres

Year	*No. of MDMCs*	*No. of reports*
Since 2015-2017 (From SCTIMST, Kerala)	10	347
IPC National Coordination Centre		
2018	10	687
2019	36	1116
2020	50	1384
2021	150	3473
2022	293	5078

Inadequate monitoring of patient

The majority of studies in which HCPs claimed that they did not keep track of negative outcomes for specific patients who had devices implanted after the first healing phase(Shuren & Califf, 2016). Identifying the of deficient monitoring from the doctor inserting devices and the incomplete of immediate monitoring and MDAE detection by another doctors(Maisel, 2006). MDAEs, that might occur for days and some months after the fixation of devices, might be not taken into account(AJ, 2012). The only real monitoring that occurs is when we administer something and then check in to see if it has healed and the issue has been resolved (Somberg *et al.,* 2014) (Table 2).

Inadequate record of the device utilised in patients

The patients in many studies had complaints regarding, the information concerning implanted devices or any other medical devices was missing from patient medical records (Samuel *et al.,* 2016). Thus, it would be challenging to replace a recalled devices and to determine which patient received the respective devices (Kingston *et al.,* 2004; Waring, 2005). Hence instead of reporting MDAEs, they continued using them and managing their own techniques to resolve AE rather than reporting it to the MDMCs (Hartnell *et al.,* 2012) (Figure 3).

Poor awareness

Many qualitative and quantitative studies shown that the underreporting is due to the poor awareness regarding the MDAE reporting system, such poor awareness is due to various challenges (Lawton *et al.,* 2012). It is mainly due to unaware about (Figure 4).

- The implementation program of Materiovigilance, inadequate knowledge about MDRs negative attitude towards the reporting of AE.
- Lack of time and interest.
- Considering adverse events as non-serious and unaware about the potential effects it could cause.(Ambika *et al.,* 2014)
- No education and training about Materiovigilance concept and their reporting system among various healthcare professionals, stakeholders and general public (Polisena *et al.,* 2015).

Hence, the above factors highlights the necessity for the HCPs and every personnel to have required education and regular training about the entire concept of reporting system with continual public enlightenment and awareness campaign on spontaneous reporting of MDAE and encourage them about the significance of reporting rates (Auerbach & Silverstein, 2003). (Sandelowski, 2000). There was a lack of the transition from adequate information and a supportive attitude to good MDAE reporting practises (Butterfield *et al.,* 2005).

Organizational Related Barrier

Lack of feedback on submitted reports

From two investigations performed by (Jung *et al.,* 2008) (Ivers *et al.,* 2012) , patients worries about the improper and lack of submitted MDAE report and 33% of subjects from a study conducted in UK said that they are expecting the comment from the reported MDR and 1.8% thought that receiving less-than-detailed feedback could make them reluctant to report and submit the reports in the future (Jung *et al.,* 2008). Individual opinions regarding the likelihood, prevalence, time interval, course and root cause of MDAE were not known due to the lack of impact and feedback on reporting (Ivers *et al.,* 2012). Feedback systems could improve patient reporting of MDRs by making patients more familiar with the system and by laying out clear reporting procedures (Ouriel *et al.,* 2014) (Figure 5).

Confusions and difficulties regarding reporting procedures

Four quantitative and qualitative analyses found issues with the system of reporting and their procedures. In the UK, the proportions citing difficulties ranged from 14.9% to 83%. (Vidi *et al.,* 2011) Subjects in the UK study, for instance, complained about the following:

- The formats of paper being laborious, inconsistent with online forms, and available only in English.
- Reporting by telephones, mails are being restricted to the working days, which was irksome and onerous.
- Issues with the technical systems and online reporting that frequently resulted in a loss of information (Vidi *et al.,* 2011).

Lack of system for MDAE reporting

A lack of reporting procedures was cited mostly by the medical professionals as a deterrent to interpret an MDAE (Rao *et al.,* 2008).The HCPs may be discouraged from determining whether an adverse event has occurred or not if they are unable to access the online system (Mandl *et al.,* 2014) (Figure 6).

Industry responsiveness

Purchasing contracts constraint device choice

Participants reported that even when a device was not the best option or produced less than ideal patient results, they were nevertheless forced to use it under the terms of hospital or health region purchasing agreements with producers (Wiig *et al.,* 2014). As a result, although it's a MD was due MDAEs, doctors working regarding the purchases which might be impossible to move to alternative equivalent instrument that was on the purchase (Gauld, 2016). Because of those restrictions, they might also be less reliable to interpret MDAEs. Due to tlarge purchases, the purchasing group was able to negotiate a lower price from the implant

Figure 6: Factors contributing to lack of system reporting

Figure 7: Challenges in reporting MDR

manufacturer (Amoore, 2014) The complication risk increases temporarily, according to thye authors experience, if surgeons are forced to switch implants as a result of a contract. Thus, cohere about the commercial sense to look the revised expanses for the following months to years with their follow up care (Ward & Clarkson, 2004).

Lack of effect on advancement of the device

The lack of feedback participants received after reporting MDAEs to physicians' that it is not their duty to interpret adverse events and that they must instead carry on to come up with remedy or, use different devices (Commission, 2005). When the manufacturer finally took notice, they modified the design of the product. However, that most likely took more than three years. They spent a lot of money developing the product, and now they have a lot of inventory on hand (Group *et al.,* 2009). There is far less pressure on the corporation to change if there is a significant cost to the change and consumers have found a solution (Desveaux & Gagliardi, 2018) (Figure 7).

Conclusion

This review emphasises the necessity for intervention studies that concentrate on teaching Health care professionals about MDAE. Challenges faced by healthcare professionals in reporting MDAE are administration, healthcare professionals, self-implementation of devices, counter-fit devices, and poor awareness Poor adverse event reporting practises were linked to a lack of training, inadequate expertise, and limited job experience. Healthcare professionals must be educated and trained on patient-centred aspects of medicine surveillance in order to deliver adequate care while maximising patient safety in order to meet these obstacles. This review might offer helpful data for overcoming barriers in monitoring and support quality and safety management in hospitals.

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Author Contributions

Mrs.Nithya Raju conceptualised and the title and content, Ms.Shruthi deivigarajan, and Ms.Sindhuja santhakumar drafted the manuscript. Mrs.Nithya Raju and Ms.Sneha done proof reading and approved the final manuscript.

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