Factors Influencing Reporting of Medical Device Related Incidents in the Maltese Healthcare System

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INTRODUCTION

Ranging from simple tongue depressors to heart valves and robotic surgery systems, medical devices are essential in healthcare sector providing numerous benefits to the patient. The use of medical devices (MD) is associated with adverse incidents which may lead to serious health implications [1].

Voluntary reporting by users and operators is a means of data sharing, adverse event trends and overall performance[2]. In Europe, MD manufacturers are obliged to report serious adverse events to regulatory authorities. Voluntary reporting, although encouraged by regulators, is not a requirement for healthcare professionals, users and facilities but should be done based on moral obligations in the interest of promoting public health[1].

Reporting of MD-related incidents by healthcare professionals (HCPs) is essential for successful post-market surveillance systems.

AIMS

The purpose of the study was to improve the current incident reporting system for MD in the national healthcare system.

The research objectives were:

- To investigate the MD incidents reports received within the National Healthcare System (NHS)
- To explore factors influencing reporting of incidents by healthcare professionals
- To improve the MD incident reporting form

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METHOD

Phase 1

Analysis of the MD incident reports submitted within the NHS by healthcare professionals in 2019 were collated in a database and analysed. The reports were categorised by device type, classification by medical speciality (as per FDA Classification Panel), type of injury, local distributor, site of incident.

Phase 2

A two-hour focus group session, consisting of a panel of 12 experts, was set up to (i) identify the challenges faced when reporting MD related incidents and (ii) to provide recommendations for the development of an improved incident reporting system. The participants are all involved in medical device incident reporting either as reporters or form part of the team handling the reports at the Central Procurement and Supplies Unit within the NHS.

Barriers related to MD incident reporting were identified. Findings from the focus group discussion were used to update the Medical Device Incident Reporting Form, used by the NHS. The objective was to (i) make the form more comprehensive and user friendly and (ii) capture more data. The new form was validated for face and content and underwent reliability testing.

RESULTS

A total of 107 MD related incidents were submitted in 2019. The most common departments to report incidents were operating theatres (n=49; 46%) followed by wards (n=18; 17%). Injury to patient was reported in 18 cases (17%). The most common type of devices reported were General and Plastic Surgery devices (n=48; 45%), General Hospital Devices (n=22; 21%) and Cardiovascular Devices (n=12; 11%).

Issues related to incident reporting identified during focus group session included (i) Reporting Issues, (ii) Confidentiality Issues, (iii) Training Needs (iv) Supplier Issues and (v) Others. The most common topics that were discussed were attitudes of HCPs towards reporting, blame culture, legal liability, deficiencies in the MD procurement process, lack of training and education, recognition of MD incidents, and deficiencies in the current reporting method.

Areas identified for improvement in the incident reporting form were (i) incident details, (ii) details of reporter, (iii) administrative information and (iv) checklist of procurement documentation. The new form includes a section on sample retention together with photographic evidence, a section of combination products (e.g. other MD or medicinal products used at the time of the incident), the functional use of the device and specification of the type of adverse event suffered by the patient/ user.

Figure 1: Barriers Towards Medical Device Incident Reporting Identified in the Study

CONCLUSION

The attitudes of HCPs towards incident reporting was found to play a major role. Six barriers related to filing a MD incident report form in a hospital setting were acknowledged by the participants. Participants perceived reporting as a necessary process to safeguard patient safety but were not motivated to report incidents by their superiors. Fear of blame, personal liability and punishment following incidents are recognised barriers to medical incident reporting and have been documented in various studies including studies on MD incident reporting carried out in Canada[2,3,4]. Educational programmes for HCPs regarding the MD surveillance systems are essential. HCPs should be trained to understand the scope of such systems and the benefit these systems bring to users and patients. Such training programmes are also beneficial in increasing the reporting rates of incidents.

The results indicate that there is under-reporting of MD incidents in the NHS. Changes to the current system are warranted to improve the reporting rates. Strengthening a safety culture based on lessons learnt and education needs of HCPs, in the context of MD incident reporting is proposed to improve patient and user safety.

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