Medical Device: Patient Safety

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INTRODUCTION

Numerous data and reports indicate a staggering scale of medical device-related incidents.[1,2] The Implant Files (2018) uncovered 80,000 deaths and 1.7 million injuries associated with medical devices from US alone.[3] In the EU, Poly Implant Prosthèse (PIP) was found to be utilizing industrial grade material for its silicone breast implants.[2] The scenario led the European Union to introduce new legislation on medical devices.[4]

AIMS

- To appreciate challenges with respect to the use of medical devices and patient safety within a hospital setting
- To classify medical devices involved in incidents
- To develop a structured approach to focus on patient safety in a central procurement unit for hospital systems

SETTING

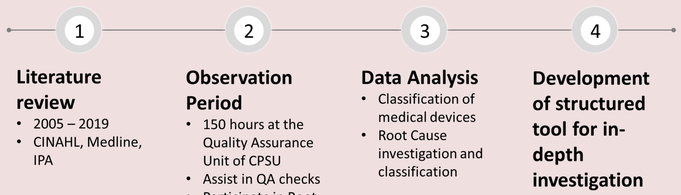
Central Procurement and Supplies Unit (CPSU) at the Ministry for Health which is responsible for the procurement and distribution of all medicines and medical devices for the National Healthcare System

Acknowledgments: Central Procurement and Supplies Unit at Ministry for Health, Malta particularly Ing. Karl Farrugia, CEO and Pharmacist Josette Sciberras, Quality Assurance manager and staff at the Quality Assurance unit as well as Logistics Unit of CPSU

METHOD

- Literature analysis was carried on medical device barriers to safety using Medline, International Pharmaceutical Abstracts and CINAHL databases covering 2005 to 2019.
- A total of 150 hours of fieldwork were undertaken in the Quality Assurance Unit of CPSU. Devices involved in incidents were classified using the Global Medical Device Nomenclature.
- An innovative tool for medical device incidents root cause analysis and classification was developed based on the Amoore tool.[4]
- Root cause investigation and classification for the incidents identified was carried out using the innovated Amoore tool.

Figure 1: Methodology flowchart



RESULTS

- Literature review based on 53 sources that satisfied the inclusion criteria revealed nine major themes of medical device challenges to safety with the major reported areas being healthcare setting, regulatory systems and incident reporting (Figure 2).
- A total of 333 medical device incidents that were investigated and closed from 2016 to July 2019 at the CPSU were analysed. The leading devices with incidents were sutures (10.5%), dressings (9.61%) and gloves (6%) (Figure 3). The causes of incidents as classified by the Quality Assurance Department of CPSU were defective devices (70%), wrong product (17%), European Council directive non-compliance (4%), unclassified reason (4%), recalls (3%) and complaints (3%).
- The innovated Amoore tool for medical device incidents root cause analysis consisted of two new major classification groups namely supplier and regulatory compliance (Figure 4,5).

Fig. 2 Distribution of barriers and challenges in medical device safety; Number of articles = 53

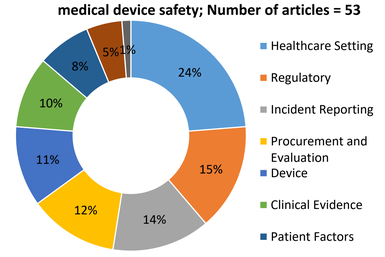


Fig. 3 Leading Medical Devices with Incidents at CPSU (2016-2019)

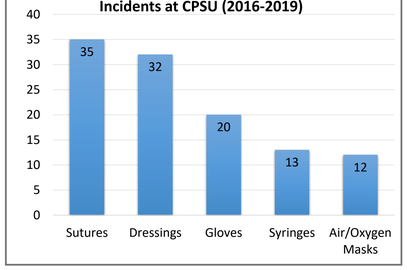


Fig. 4 Innovated Amoore Tool

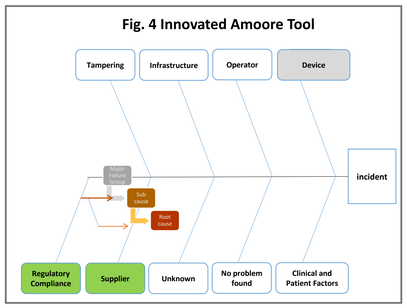
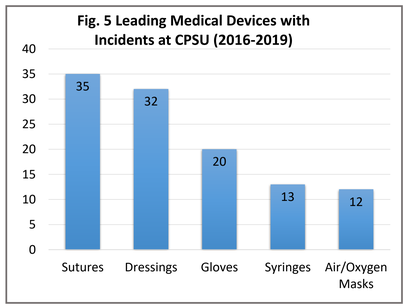


Fig. 5 Leading Medical Devices with Incidents at CPSU (2016-2019)



Using the developed tool, root cause analysis for the incidents reviewed was described as device (35%), infrastructure (14%), supplier (9%), regulatory compliance (8%), no problem found (6%), operator (2%), clinical and patient factors (1%). For 24%, the cause was unknown due to lack of data during the incident reporting, indicating a weakness in the reporting system adopted at CPSU.

CONCLUSION

The study led to a structured analysis of medical device-related incidents. An innovated tool for investigating causes of incidents was developed which could be implemented in quality assurance units handling incident reporting of medical devices.

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