L-Università ta' Malta
Faculty of Medicine & Surgery
Department of Pharmacy

MALTA MEDICINES AUTHORITY

Developing a Patient Centred Incident Reporting Medical Device Framework

Julian Fearne, Julia Catania, Louise Grech, Anthony Serracino Inglott

Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta
Medical Devices and Pharmaceutical Collaboration Directorate, Malta Medicines Authority, San Gwann, Malta

BACKGROUND

In Malta, there is a significant rate of under-reporting of medical device related incidents. Implementing an incident reporting (IR) framework that encourages communication and transparency with stakeholders will reduce risk to users and improve the quality of medical devices on the market.

PURPOSE

To develop a patient-centred IR framework that allows for communication and transparency with stakeholders in concluding IR for the benefit of patient safety.

METHOD

The methodology was divided into three phases:

- **Phase 1: *Needs assessment*, IR systems of European Member States available on the respective National Competent Authority (NCA) websites were reviewed. Common themes and data fields used were identified and discussed through an expert panel. An IR Form for healthcare professionals and another for patients were developed and validated by the same expert panel.**
- **Phase 2: *Development of quality management system supporting the IR framework,* focused on the development of SOPs that related to the receipt and processing of IRs, the liaison with other NCA and notified bodies as necessary. As well as the procedure for discussion through an Incident Action Group consisting of representatives from the national procurement unit of medical devices, the clinicians as end users and the NCA. Economic operators were invited accordingly for their input. The SOPs compiled were reviewed by the same expert panel.**
- **Phase 3: *Implementation of the IR framework* focused on the pilot implementation of the structure.**

Table 1: Expert Panel Members*		
Clinicians	**Pharmacists**	**Stakeholders****
* 2 members of each group **representatives from medical device sector		

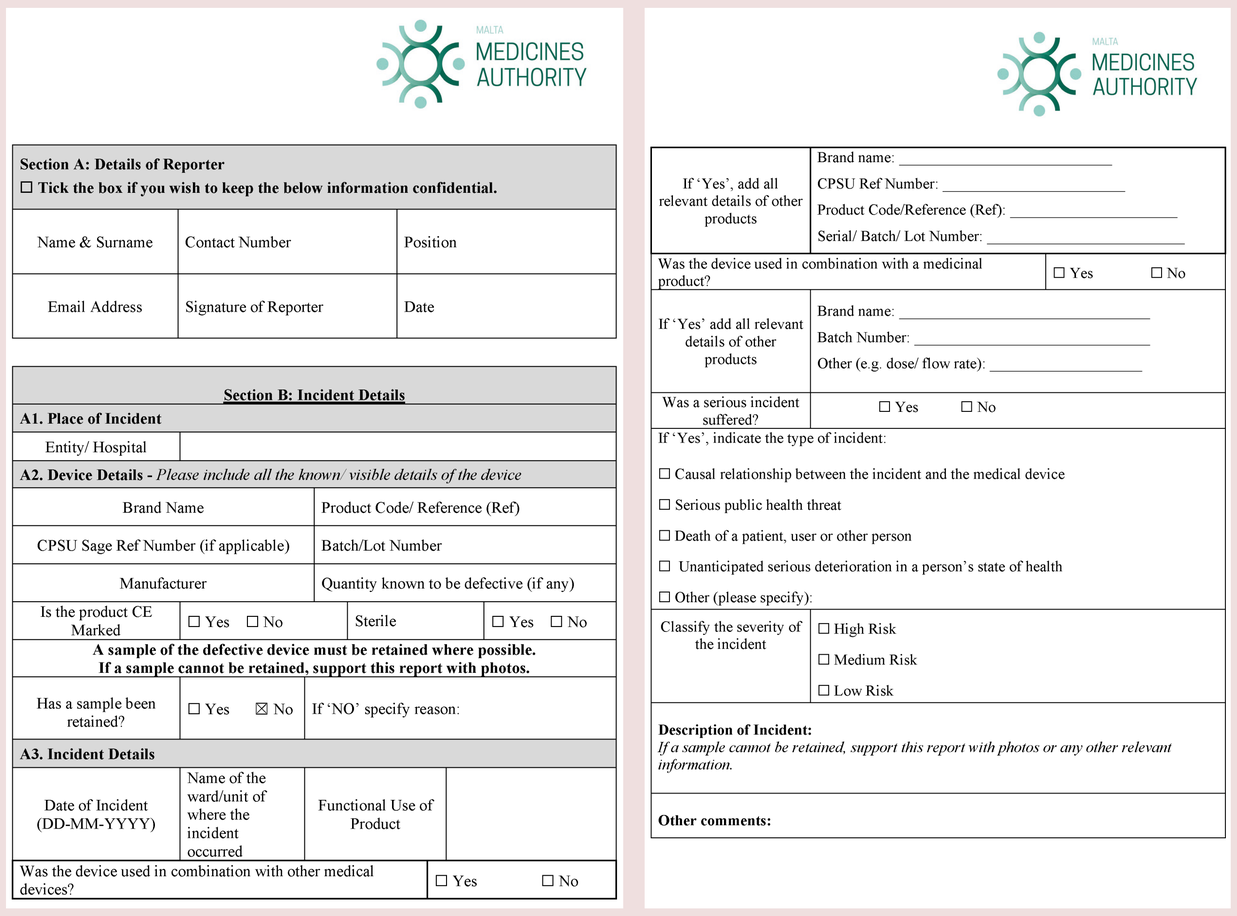
RESULTS

Phase 1: Eight themes were included in the IR forms as identified through the expert panel (Table 2). The validated Incident Report Form is shown in Fig 1.

Table 2: Themes included in IR forms	
Device and patient data	**Device performance and malfunction**
Incident details	**User error**
Adverse events	**Follow up actions**
Suspected cause	**Reporter details**

Phase 2: Three SOPs were compiled. All the expert panel agreed that the SOPs were clear, concise, robust and served their intended purpose.

Phase 3: The IRs reported between 2022 and March 2023 were 216, 207 of which were received from Healthcare Professionals with the National Health Service. The IRs were classified during 14 2-hour incident group action meetings, 186 IRs were successfully classified and concluded.



MALTA MEDICINES AUTHORITY

Section A: Details of Reporter ☐ Tick the box if you wish to keep the below information confidential.		
Name & Surname	Contact Number	Position
Email Address	Signature of Reporter	Date

Section B: Incident Details			
A1. Place of Incident			
Entity/ Hospital			
A2. Device Details - *Please include all the known/ visible details of the device*			
Brand Name		Product Code/ Reference (Ref)	
CPSU Sage Ref Number (if applicable)		Batch/Lot Number	
Manufacturer		Quantity known to be defective (if any)	
Is the product CE Marked	☐ Yes ☐ No	Sterile	☐ Yes ☐ No
A sample of the defective device must be retained where possible. If a sample cannot be retained, support this report with photos.			
Has a sample been retained?	☐ Yes ☒ No	If 'NO' specify reason:	
A3. Incident Details			
Date of Incident (DD-MM-YYYY)	Name of the ward/unit of where the incident occurred	Functional Use of Product	
Was the device used in combination with other medical devices?	☐ Yes ☐ No		

MALTA MEDICINES AUTHORITY

If 'Yes', add all relevant details of other products	Brand name: _____ CPSU Ref Number: _____ Product Code/Reference (Ref): _____ Serial/ Batch/ Lot Number: _____
Was the device used in combination with a medicinal product?	☐ Yes ☐ No
If 'Yes' add all relevant details of other products	Brand name: _____ Batch Number: _____ Other (e.g. dose/ flow rate): _____
Was a serious incident suffered?	☐ Yes ☐ No
If 'Yes', indicate the type of incident: ☐ Causal relationship between the incident and the medical device ☐ Serious public health threat ☐ Death of a patient, user or other person ☐ Unanticipated serious deterioration in a person's state of health ☐ Other (please specify):	
Classify the severity of the incident	☐ High Risk ☐ Medium Risk ☐ Low Risk
Description of Incident: *If a sample cannot be retained, support this report with photos or any other relevant information.*	
Other comments:	

Figure 1: Adaptation of the Incident Report form developed for Healthcare Professionals

CONCLUSION

The pilot implementation of the framework showed positive results, with a significant number of healthcare professionals reporting incidents, and the Incident Action Group successfully closing most of the reported incidents. The implementation of the patient-centred IR framework can contribute significantly to reducing adverse events, promoting patient safety, and enhancing the quality of healthcare services. Future research should aim to assess the long-term impact of the framework on patient outcomes and its effectiveness in different healthcare settings.