

# Developing a Policy and Procedure Framework and Manual for a National Comprehensive Implantable Medical Device Registry in Saudi Arabia

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**Abstract.** Policy and procedure manuals provide guidance on the operation and governance of medical device registries. In Saudi Arabia, the Saudi Food and Drug Authority (SFDA) has been developing and implementing a comprehensive national registry for implantable medical devices to facilitate the monitoring of device outcomes through post-market surveillance studies. To help guide the operations of this registry, the SFDA developed a policy and procedure manual. This paper reports on the design of the framework used to develop that manual over the course of one year (2015–2016), using a variety of literature sources, and working with medical device registry and health systems experts. The policy and procedure manual included five key principal level categories, which led to the subsequent creation of seven policies and 28 relevant procedures. The five principal categories were: Staff Engagement, Information Governance, Quality and Auditing, Research, and Reporting. The results of this work could be used to guide the development of policies and procedures for other implantable medical device registries.

**Keywords.** Health Informatics, Medical Registries, Policy and Procedures

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## **1. Introduction**

The primary purpose of an implantable medical device registry is to monitor device outcomes for the purposes of surveillance, post-market observational studies, and evaluations of safety and effectiveness [1]. Overall, there is a lack of surveillance data on implantable medical devices, and only limited information is available on surveillance and the types of registries currently deployed worldwide [2]. In Saudi Arabia, where there have been no implantable medical device registries, the Saudi Food Drug Authority (SFDA) has only recently begun to develop a Comprehensive Implantable Medical Device Registry (CIMDR) to monitor the outcomes of orthopedic, cardiac, and breast implants, neurostimulators, and other implantable medical devices. The SFDA anticipates that the CIMDR will help improve outcome-based research related to implantable medical devices, and patient safety within the country [3-5].

A fundamental step in creating the CIMDR is the development of clear policies and procedures that govern its operations. To do so, major issues to be addressed involve studying hospitals' readiness, staff engagement, confidentiality and privacy of patient information, data entry and validation, auditing, and reporting. The present article aims to describe the CIMDR policies and procedures that have been developed by the SFDA. The work reported in this paper is part of a larger study, funded by the SFDA, to build and deploy the CIMDR.

## **2. Methods**

An iterative approach was employed in the planning, development and refinement of the CIMDR policy and procedures manual. In the planning phase, a PubMed and Google Scholar search was conducted, identifying approximately 50 research articles, five books, and six government-related works on the topic of medical device registries. These publications included a wide range of topics relating to cardiology, orthopedics, clinical trial registries, and others. The literature was reviewed and examined by a health systems and quality expert, a medical device expert, an information technology specialist, a medical physician, and a policy and procedures expert. Once the review was complete, the experts developed a policy and procedure framework based on multiple sessions and feedback over a four-month period (February to May 2016).

## **3. Results**

The research identified over 100 relevant policies and procedures. Based on feedback from and consultation with the content experts, 28 procedures and seven policies were found, organized around the five key principal level categories: Staff Engagement, Information Governance, Quality and Auditing, Research, and Reporting. Procedures relevant to the SFDA were labeled as 'internal procedures', and those related to hospitals were labeled as 'external procedures'. The five key principal level categories were dependent on one another. For example, without staff being engaged in entering data into the CIMDR (Staff Engagement), it would not be possible to have an Information Governance framework guiding the ways in which data is entered, validated, and archived. The principal level category relating to data Quality and Auditing relies on the Information Governance principal level category because, for

example, if there is no data in the CIMDR, Quality and Auditing checks cannot be conducted. Furthermore, without Quality and Auditing of the data, it would be difficult to conduct valid and reliable research, or to report on the research produced (Reporting) (See Figure 1).

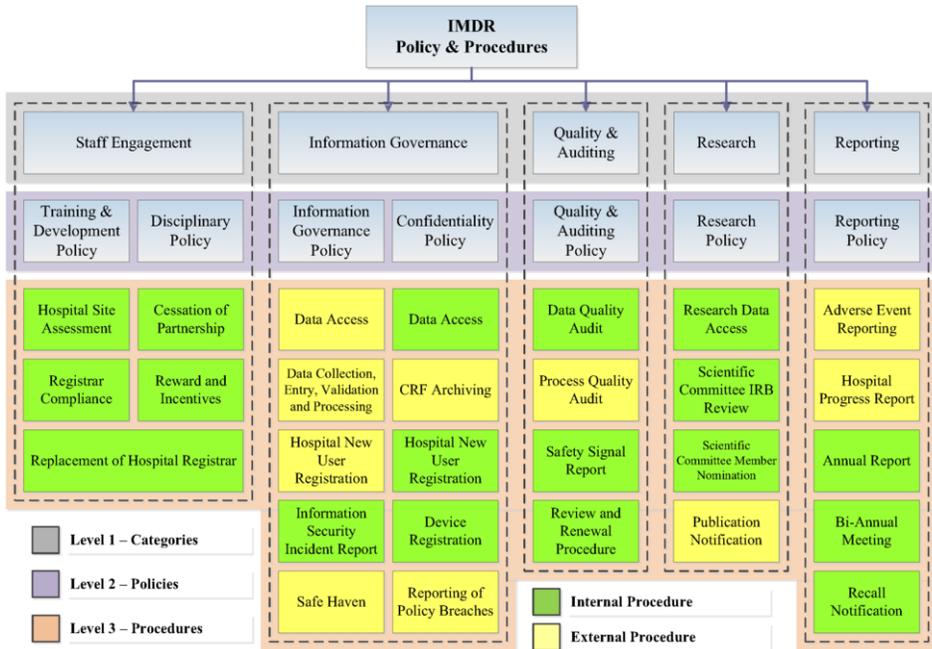


Figure 1. CIMDR Policy and Procedure Framework

### 3.1. Staff Engagement

Staff Engagement includes two policies and five SFDA-related internal procedures. Their purpose is to ensure that only hospitals that are ready to adopt the registry are included as CIMDR participants, and to follow up on research registry compliance.

### 3.2. Information Governance

For Information Governance, a total of two policies, four SFDA and six hospital related procedures were developed. The policies and procedures provided guidance on confidentiality of patient information and how to protect it and other procedures relating to data collection, data entry, data validation. Other procedures providing secure access, reporting of confidentiality breaches, and the registration of new users to access the CIMDR were also included.

### 3.3. Quality and Auditing

One policy, three SFDA-related procedures and one hospital-related procedure were developed for Quality and Auditing. Their primary purpose is to ensure that quality standards and requirements for data collection, entry and validation for the CIMDR were established regularly met.

### 3.4. Research

For Research, one policy, three SFDA-related procedures and one hospital-related procedure were developed. The research policy offers guidance on how to provide data to research projects, conduct an ethical review, take part in membership of scientific committees, and notification of research publications of studies conducted using CIMDR data.

### 3.5. Reporting

For Reporting, one policy, three SFDA-related procedures and two hospital-related procedures were developed. The reporting policy offers guidance for hospitals on how to report adverse events and how to develop progress reports for the SFDA. The SFDA-related procedures provide guidance on how the SFDA should conduct annual reports, host biannual meetings, and provide recall notifications to hospitals.

## 4. Discussion and Conclusion

The failure of implantable medical devices, although rare, can carry a substantial risk of serious patient injury. Since it is impossible to design an implantable medical device with no risk of failure, effective systems for monitoring outcomes and safety after a device is put on the market are essential to protect the health of members of the public.[6] Accordingly, implementing a national CIMDR and the prospective, active surveillance of this registry is crucial for monitoring the outcomes and safety of implantable medical devices. Having a policy and procedure framework and a manual can help guide the operations of such a registry to achieve its objectives.

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