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Building a cloud-based data sharing model for the Saudi national registry for implantable medical devices: Results of a readiness assessment

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ABSTRACT

Background: Implantable medical device registries are used as a medium to conduct post-marketing surveillance. Little information is available on the development and implementation of implantable biomedical device registries in general and specifically in Saudi Arabia and the Middle East.

Objectives: This study presents the experiences of building an implantable medical device registry in the Kingdom of Saudi Arabia. The work specifically addresses the early experiences of the Saudi Food and Drug Authority in the planning and development of a data sharing model for the implementation of a medical device registry at different hospital sites within the country.

Methods: A two-year case study in which 60 health professionals from 5 hospitals in Saudi Arabia participated in a readiness assessment survey. The readiness assessment examined system-level capacity, hospital workflow and operations, clinical staff-level engagement, and technological assessment as they relate to the implementation of the Implantable Medical Device Registry (IMDR). Both subjective and objective data were collected as part of the readiness assessment survey at each hospital site. Data was collected from participants either individually or as part of a group at each hospital site. Using Microsoft Excel, Microsoft Word, flip charts, and back-and-forth discussion, the data was descriptively summarized and synthesized to provide an overview of hospital readiness for IMDR implementation.

Results: Results show that there are large differences among Saudi hospitals in terms of their readiness for IMDR implementation due to a variety of factors relating to differences in hospital-wide organizational systems, clinical practice, technological infrastructure, and data sharing capabilities. Each of the hospitals surveyed in this study had differences in how clinical biomedical implantation policies and procedures were utilized. Manual entry into the cloud-based IMDR was recommended as the most optimal data sharing model that would mitigate the differences between hospital readiness for IMDR implementation.

Conclusion: Registries play a major role in monitoring the effectiveness of implantable biomedical devices. National standardized policies, enforced regulations, and information technology infrastructure are needed to achieve this goal. Furthermore, due to differences in hospital readiness, building a cloud-based registry system through manual data entry into the IMDR was found to be the most appropriate data sharing model that can be implemented at the national level.

Abbreviations: IBD, Implantable biomedical device; SFDA, Saudi Food and Drug Authority; IMDR, Implantable medical device registry; ICD, Implantable cardioverter defibrillator; EMR, Electronic Medical Record; CRF, Case report forms

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1. Introduction

The concept of a medical data registry is not new. A medical data registry is a place to store, extract, analyze, and share large amounts of clinical data and typically focuses on patients who share a common reason for needing health care [1]. There are many types of clinical data registries based on the type of data contained in them, including those that focus on a disease or condition, a procedure, or tracking the performance of a device [1]. Information from registries may also be used to compare the performance of healthcare providers with regard to their healthcare outcomes and resource use [2]. Medical registries also provide essential information to healthcare decision makers to address the knowledge gap regarding the safety and effectiveness of pharmaceuticals and medical devices [3]. Manufacturers in the pre-market approval phase for a device must provide clinical data to regulatory bodies to prove the safe and effective operation of their devices. If the data presented are sufficient and meet the regulations, regulators issue approval for the device to enter into the market. The level of depth of the clinical data depends on the risk class of the device: more clinical data are required for riskier devices. When it comes to implantable devices, it is hard to perform clinical trials on subjects that represent the world population. People have different anatomy, physiology, and genomic structure. The pre-market clinical data will not be representative of the population. Therefore, post-market monitoring through registries for implantable devices are a tool used to ensure the effective and safe operation of such devices after they have been implanted in a patient. Of particular interest is the recent emergence of implantable biomedical device (IBD) registries, which provide information to help food and drug authorities monitor the effectiveness of an IBD (e.g., a stent or joint replacement) immediately after surgery and during follow-up care.

Thus far, the literature has focused on different aspects of biomedical device registries. These include a user's guide to building medical device registries [4] evidence evaluation [5], stent registries [6], joint replacement registries [7], and registries for post-marketing surveillance [7]. However, there remains much to learn about the development of biomedical device registries, their impacts on healthcare outcomes, workflow, and use in different patient populations. For instance, what are the technological, political, and financial challenges faced by hospitals in implementing biomedical device registries? How ready are hospitals for implementing biomedical device registries? Moreover, how willing are the users of the biomedical device registries to enter, validate, and utilize implantable biomedical registry data?

The purpose of this paper is to describe the experiences of a two-year case study on the development of an IBD registry in Saudi Arabia. Specifically, this paper addresses the experiences of the Saudi Food and Drug Authority (SFDA) during the planning and development of a data-sharing model for an IBD registry at different host sites within the Kingdom of Saudi Arabia using a readiness assessment survey. In this paper, the term "IBD registry" refers to a registry that captures data relating to IBDs such as stents, pacemakers, and hip and joint replacements. In this work, the relevant literature is first reviewed. Second, the importance of an IBD registry for Saudi Arabia is described in the study background. Third, the study design is outlined in terms of the participants, staff and sites, research methodology, and data sources. Fourth, key findings are presented. Last, the implications of the findings are discussed.

1.1. Literature review

In today's world, along with the increases in life span, the number of age–related diseases has also increased. The need for new treatments, implants, prostheses, and long-term pharmaceutical usage as well as the need for prolonging the life span of the current techniques have also increased [8]. Implantable medical devices, as defined by the American Food and Drug Administration (FDA) are devices that are partly or completely inserted into the body using surgical or medical procedures and are expected to remain in the body or orifice permanently or for at least 30 days [9]. These devices can only be removed surgically or deactivated medically [9]. Medical devices are currently one of the fastest growing industries because of the innovation and rapid advancement of their technologies [10]. Jiang and Zhou [11] described that 5%–6% of people in industrialized countries and 8%–10% of the population in America alone have experienced an implantable medical device for rebuilding body functions, to achieve better quality of life, or to expand longevity. The wide range of medical devices plays a major role in various aspects of healthcare services such as diagnosis, treatment, prevention, and rehabilitation. Joint diseases represent one example of changing needs in medical treatment. According to statistics, 90% of the population over the age of 40 suffers from a degenerative joint disease [10]. Cardiovascular diseases are another example and are a major cause of death globally, accounting for 54 million deaths in 2013 [12].

Coronary stents have become a new standard in angioplasty procedures over the last five years [10]. For instance, over 500,000 patients were implanted with stents in the US in 2013 [13,14]. However, many countries lack access to high-quality devices and equipment appropriate for their specific epidemiological needs. Likewise, medical device registries and post-market medical device surveillance systems remain emergent in Saudi Arabia and the Middle East and North Africa region in general. Medical device product evaluation presents several unique challenges related to the diversity and complexity of medical devices and the rapid technological advances of medical device development [6]. Internationally, few systems currently exist for comprehensive medical device surveillance at the national level or even at a health-facility level [6]. Instead, most existing systems rely largely upon voluntary reporting from providers, healthcare facility networks, industry, claims-based companies, or other healthcare practice databases to characterize the risks and benefits of medical devices, leaving many shortcomings unnoticed. Moreover, the evidence gaps that exist regarding medical device-related incidents and potential risk concerning patient safety have been well documented in the literature [7,8]. In addition, to deliver safe and effective medical devices to market as quickly as possible, the U.S. FDA [15] currently requires a manufacturer to conduct post-market surveillance studies to avoid any failure of the device that could have serious adverse health consequences. However, the primary aim of a medical device registry and post-market surveillance system is to provide critical information about device quality and safety, short and long-term device performance, and the safety and effectiveness in improving patient outcomes.

1.2. Study background

Little information is known about the health and safety impacts of implantable medical devices on patients in Saudi Arabia and the Arab world in general. Most countries in the Arab world have regulated Food and Drug Authorities to register medical devices, however, the regulatory framework lacks a cohesive framework among countries in the region [4,16–19]. Recently, in Saudi Arabia, there has been a variety of work conducted on the development of registry and health surveillance systems. At a national level, there are three well-known national registries: the National Cancer Registry, Saudi Center for Organ Transplantation registry, and National Registry for Diabetes. For health surveillance systems, there are three well-known systems: the Notifiable Surveillance System on Infectious Disease housed at the Ministry of Health, the National Injury Surveillance System housed at King Saud University, and the Hajj Surveillance System, which is used to monitor and control the spread of infectious diseases for the millions of people who travel to Saudi Arabia for the Hajj pilgrimage. For IBD surveillance, there are no existing systems in Saudi Arabia or within the region. In 2007, a royal decree assigned the responsibility for regulating medical devices to the Saudi Food and Drug Authority (SFDA). Later in