

Research Article**National Registry of Specified Heart Diseases****Ftoon Kedwan*, PhD**

Assistant Professor, College of
Computer and Cyber Sciences

Head of Software Engineering
Program, University of Prince Muqrin,
Medina, SA

Abstract

Topic: This experience report discusses the implementation of a heart disease registry as a national database to be used by researchers and academics. The implementation started in King Abdulaziz Medical City For National Guard Hospital, Riyadh, Saudi Arabia. Then, and upon successful implementation, it shall be nationalized among all Ministry of Health hospitals and medical facilities. This report also answers questions like; what are the types of medical research? what is the meaning of medical registry? what are the defects of the specific heart disease registry as implemented?

Approach: This implementation included several other minor projects such as adding additional questions into the Electronic Case Report Form, automating and systemizing patients' data collection and medical diagnoses coding, building dedicated private places to handle patients' interviews, and finally, planning the use of smartphones as an initial means of patients' data collection.

Findings: This automation mechanism improved the way of documenting and collecting diagnosis, medical disorders, or operations' data. It also saved the data entry personnel time and effort, and eliminated a considerable amount of potential human errors.

Keywords: Heart Disease, Medical Registries, Health Informatics, Project Implementation, Technical Solutions.

Introduction

Nowadays, medical research has become extremely valuable in the Saudi society. It can provide vital information about diseases; patterns of care, risk factors and treatment outcomes [1]. Health-related researches play a significant role in the development of new medical treatments, or finding new precautions measures [2]. Some of health researches include, but not limited to, behavior analyses, clinical trials, genetic experiments, and observation and prevention studies [3]. However, health research require datasets and registries that support research experiments' findings and conclusions.

A medical registry is a central database that stores predefined health and demographic datasets for patients with specific diseases [4]. One of the registries in Saudi Arabia is related to a specific heart disease. The importance of this registry lies on: providing a national database for this illness, developing standards for effective information management, and supporting scientific researches to be used in assessing and improving treatment, prevention, intervention and overall administration of the disease anomalies.

With such a fast technology growth, medical registries should be supported with advanced hardware and software to get the ultimate benefit out of them. Therefore, this case study will spotlight this registry as implemented in the King Abdulaziz Medical City (KAMC) For National Guard Hospital, Riyadh, Saudi Arabia. System implementation challenges and faults will be defined to provide an eventual improved solution.

Background**Problem Statement**

Kingdom of Saudi Arabia is a big country, with around 251 hospitals in the ministry of health alone, not mentioning the private hospitals and sole practitioners' clinics [5]. Those hospitals are not connected with each other, which make it difficult to document all of the incidents and prevalence of a specific disease or health problem.

Heart diseases are one of the major health problems that have a direct impact on the patients' survival or disability in some cases [6]. Such a disease needs a long term of follow ups, which make it important for patients' medical records

***Corresponding Author:**

Ftoon Kedwan, Assistant Professor,
College of Computer and Cyber
Sciences, Head of Software
Engineering Program, University of
Prince Muqrin, Medina, SA
Email: ftoon.k19@gmail.com

Received Date: 25 Oct, 2022

Accepted Date: 29 Oct, 2022

Published Date: 12 Dec, 2022

and documentations to be available for any future interventions. For this reason, there is a need for a registry for heart diseases. In fact, there is already a registry for heart diseases implemented, but it has some issues. Currently, the data available in the registry is not a solid data, and as a national registry that will be used by many researchers around the Kingdom, it will be more useful if the registry covers most of the researchers' needs.

The data collection process is an important phase. However, there are some issues in the current method starting with interviewing the patient or his/her family. In reality, there is no private room for this purpose, and the patient is being interviewed in a public area which is ethically wrong and incompatible with Good Clinical Research Practice (GCP) guidelines [7].

First, the data is collected in a hard copy form. Then, Data Entry Personnel (DEP) enters data in the Electronic Case Report Form (e-CRF). Part of registering the data in the e-CRF is related to diagnosis coding. Currently, the diagnosis codes in the e-CRF is separated into several fields, and in order to register it in the e-CRF, DEP needs to search the diagnosis first from the e-CRF to find the code, then they write it again in the hardcopy. After that, they register it in the e-CRF. This process of diagnoses coding can lead to registering inaccurate data, as there are too many steps to go through before the data is finally saved in the registry. Furthermore, DEP keep hard copies in a storage room, which is very accessible and not safe. All these issues are confirming the main purpose of implementing the national disease registry in the first place, which is providing an accurate reference for researchers and statisticians.

Context/Organizational Setting

KAMC hospital is one of the hospitals in Saudi Arabia located in Riyadh city. It started with 40-beds capacity, and since then, the hospital kept growing and developing to be a qualified hospital in the healthcare sector in Saudi Arabia. Today, it contains 10 medical departments with 650-beds capacity, and it has a total of 2000 employees.

KAMC serves adults and pediatric patients following high standards in highly specialized clinics. It has a special cardiac center consisting of three clinical sections for Adult Cardiology, Pediatric Cardiology, and Cardiac Surgery. All wards and departments are committed to serve patients with all kinds of cardiovascular cases by using advanced information systems and evidence-based practices.

The heart disease registry system is one of those advanced information systems that serve both clinical and managerial staff with current evidence-based knowledge. The registry is designed as a database format, where it includes records of patients with heart or vessels (cardiovascular) illnesses, and columns of the registered features per patient [8]. The registered features include patients' specific diagnosis, prescribed treatments, and the health care services (X-Rays, Surgeries, Lab Tests, etc.) provided to them, and the results or consequences from those treatments or services.

The heart disease registry documents cases related to cardiovascular diseases for various reasons. Medical researchers may use this registry for trying to find a way of preventing or expecting a heart disease accident before it happens using common symptoms and life habits of previous patients' cases that were registered in the heart disease registry [9].

Medical managers may also use the knowledge extracted from this registry to analyse evident methods of improving medical

services quality, or to improve the treatments provided for cardiovascular patients.

Summary of Key Facts

There are certain key factors surrounding the Heart Disease Registry (HDR) implementation and should be taken in consideration including:

- Continuous internet network connection availability and quality between participated hospitals and the registry.
- Storage memory capacity needed for storing scanned hardcopies.
- Lack of dedicated locations in most of hospital cardiac clinics for interviewing patients.
- Data accuracy and integrity.
- Patient's privacy and confidentiality.
- Lack of patients' awareness about research purposes.

Implications of the Problem

The National HDR is used by various hospitals around the Kingdom of Saudi Arabia. Hence, in case of the persistence of the current issues, there will be long term, as well as short term, problems. First, the researchers may not reach their research goals with such inaccurate and limited information and datasets. Second, the current process of data collection in hard copies, and then registering them again as a soft copy in the e-CRF can affect the data quality (Accuracy and Soundness) by the possibility of entering wrong data, which could eventually affect patients' safety and research outcomes' validity.

Besides, usage of hard copies consumes additional resources (e.g. papers, storage space) unnecessarily, and has a higher risk of losing the forms than soft copies. This could lead to compromising patients' privacy and confidentiality. Additionally, when the patient is being interviewed in the clinic's waiting room or another public area, there will be no consideration for patient's privacy and will potentially affect patient's medical experience view and satisfaction. Likewise, patients may refuse to answer personal questions, or even give the interviewer wrong information.

Finally, in the partial electronic process of diagnosis coding, the DEP may enter wrong codes by mistake, which will affect the accuracy and validity of the collected datasets from the e-CRF system. Moreover, researchers' results may lead to threatening patients' safety since these results are based on low-quality datasets.

Implementation and Methodology

In order to have an efficient and effective national HDR registry for specific heart diseases, there is a need to have a clear and precise implementation plan approved by all concerned parties (stakeholders). KAMC hospital took the initiative to design a specified HDR to be implemented first in the KAMC facility, and upon successful implementation, consider it to be a national registry around the kingdom. This plan will take place in collaboration with various other Ministry of Health (MOH) hospitals.

However, during the implementation of the HDR in the KAMC facility, researchers and DEPs found some system limitations in this registry. For a national HDR solution, those limitations ought to be addressed. Therefore, this solution documentation will discuss the HDR registry enhancement from different perspectives.

During the comparison with other international HDR registries related to heart diseases, and according to the researchers' needs

of certain patient's information, it became clear that HDR needed more comprehensive patients' data to be collected. To include extra questions in the e-CRF, the researchers should communicate with the decision makers at the KAMC hospital for their approval by submitting a research proposal along with the data types that they are interested in to be collected from the patient, such as the type of medication, family medical history, or blood samples data, taking in consideration in case of blood samples and according to Good Clinical Practice (GCP) guidelines, there should be a written consent form signed by the patient. Consequently, additional questions were added into the e-CRF system, and DNA samples data were requested from patients to answer specific questions related to genetics.

The additional information collected is to help researchers in their experiments and investigations about the causes and treatments of heart diseases. This strategy shall have a positive impact on patients and the Saudi population in the future.

Alongside with the technology evolution, and for better utilization of the e-CRF system, data collection process has been redesigned. Instead of manually collecting patients' information on hard copies, and then decoding them into the system, capturing the data is now through the use of automated applications installed in smartphones (e.g. iPad, iPhone, or tablets). For such technology use, the e-CRF system developer needs to upgrade the system setting by upgrading the backend programming or adding personalised Java scripts that allows the smartphone devices to be compatible with the e-CRF system forms and interfaces.

To utilize the available technology that helps automated data coding, the registry backend developer needs to write some programming codes that enhances the e-CRF to be more user-friendly and flexible. Meaning, during the data collection, if the DEP selects the appropriate diagnosis, syndrome, or procedure, the code should be popped out automatically and the staff does not need to type the code in a paper and then re-enter it into the e-CRF system.

This change of data collection methodology is to improve the way of documenting and collecting diagnosis, medical disorders, or operations data. It will also save the DEP time and effort, and eliminate as much unnecessary human errors as possible.

Moreover, due to the ethical perspective behind collecting the data from patients in a public area, there should be a dedicated private place for this purpose. This place should be close to clinics to ensure patients' privacy and confidentiality during the data collection process, and to increase patients' awareness about their diseases. Also, patients should be advised with the concept of research registry, and how their participation is enriching the HDR registry development. This could be accomplished via providing the patients with informing brochures while they are sitting in the waiting area. Brochures should talk about heart diseases, what is HDR registry, what are the benefits from such a registry, what will researchers do with patients' data, and how confidential is this process, along with a poster about the HDR registry for essential patients' attention.

Finally, enhancing the HDR database accessibility and connectivity to participated facilities and hospitals is among the highest priorities in this project implementation.

Conclusion

This case study is about national HDR registry implementation for specified heart diseases that was applied in the Saudi KAMC hospital. It showed the e-CRF system improvement process challenges and implications, and how can health informatics solutions help in enhancing medical systems from different technical and practical perspectives.

As a national registry with collaboration between various hospitals around the kingdom, there were challenges and obstacles encountered during this implementation. The committee did not approve the whole data requested to be included in the e-CRF system, especially in case of patients' blood samples data. In addition, the accumulative cost of purchasing smartphone devices such as iPad/iPhone, along with the enhancement costs of the discussed systems, delayed the approval process of the solution proposal. Lastly, the lack of having private places to be dedicated for patients' interviews added additional costs for constructing partitioning walls and room sections to serve the cause. Conflict of Interest: None
Source of Funding: None

References

1. Gostin LO, Levit LA, Nass SJ (2009) Beyond the HIPAA privacy rule: enhancing privacy, improving health through research. National Academies Press.
2. Why is health research important?, Community Connect to Research, Retrieved from: <https://www.hcfama.org>, Last accessed July 5th, 2018.
3. What types of health research are there?, Community Connect to Research, Retrieved from: <https://www.hcfama.org>, Last accessed July 6th, 2018.
4. Arts DG, De Keizer NF, Scheffer GJ (2002) Defining and improving data quality in medical registries: a literature review, case study, and generic framework. *Journal of the American Medical Informatics Association* 9: 600-11.
5. MOH Vision of Statistics and Indicators, General Administration of Statistics and Information, Ministry of Health, Retrieved from: <https://www.moh.gov.sa/en/Ministry/Statistics/Pages/default.aspx>, Last accessed July 5th, 2018.
6. Moons P, Van Deyk K, Marquet K, Raes E, De Bleser L, et al. (2004) Individual quality of life in adults with congenital heart disease: a paradigm shift. *European Heart Journal* 26: 298-307.
7. Handbook for good clinical research practice (GCP): Guidance for implementation, World Health Organization, World Health Organization, Retrieved from: http://www.who.int/medicines/areas/quality_safety/safety_efficacy/gcp1.pdf, Last accessed July 4th, 2018.
8. Berul CI, Van Hare GF, Kertesz NJ, Dubin AM, Cecchin F, et al. (2008) Results of a multicenter retrospective implantable cardioverter-defibrillator registry of pediatric and congenital heart disease patients. *Journal of the American College of Cardiology* 51: 1685-91.
9. Zühlke L, Engel ME, Karthikeyan G, Rangarajan S, Mackie P, et al. (2014) Characteristics, complications, and gaps in evidence-based interventions in rheumatic heart disease: the Global Rheumatic Heart Disease Registry (the REMEDY study). *European heart journal*, 36: 1115-22.