

Stem Cell Transplant Registry Implementation: A Case Report

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ARTICLE INFO

Received: 📅 April 29, 2024

Published: 📅 May 07, 2024

Citation: Ftoon Kedwan. Stem Cell Transplant Registry Implementation: A Case Report. Biomed J Sci & Tech Res 56(3)-2024. BJSTR. MS.ID.008863.

ABSTRACT

In the digitized world, there is always a need to automate hectic processes for the purpose of saving time and ensuring better accuracy and efficiency. Similarly, King Abdulla International Medical Research Center at the National Guard Health Affairs in Riyadh sponsored a stem cell transplant registry project to automate the process of stem cell transplant data collection and analysis. This digitization project went through a series of administration processes and overcame a couple of implementation difficulties which are all reported and discussed in this case report.

Keywords: Registry Implementation; Stem Cell Transplant; Medical Information System

Abbreviations: NGHHA: The National Guard Health Affairs; KAIMRC: King Abdulla International Medical Research Center; LIS: Laboratory Information System; RIS: Radiology Information System; HIS: Hospital Information System; MNGHA: Medical Research Center at the National Guard Health Affairs; EMR: Electronic Medical Record; IRB: Institutional Review Board; GCP: Good Clinical Practice; CRF: Case Report Form; RD: Research Database; DR: Disease Registry; ITD: Information Technology Department; ISID: Information Systems And Informatics Department

Introduction

Nowadays, health-related research and studies has become very valuable to Saudi society. It can provide vital information about diseases; patterns of care, risk factors and outcomes (Nass [1]). Health-related research plays a significant role in the development of new medical treatments and finding new ways to prevent diseases (WHRI [2]). There are many types of health-related research such as: behavior studies, clinical trials, genetic studies, observation studies and prevention studies (WTHR [3]). However, all of these research types require data to support their outcomes. One of the most rapidly evolving health-related research fields around the world is the stem cell research. stem cells are very special, powerful cells, and so called the core of regenerative medicine. They have the ability to replicate themselves in order to replace and repair other cells, tissues, and organs damaged from injury, disease, or aging [4]. Many countries are establishing stem cells banks using registries in order to have the necessary detailed information for research. Such research helps so-

ciety to know the outcomes of the stem cells transplant. stem cells (blood or marrow) transplant is “the infusion, or injection, of healthy stem cells into your body to replace damaged or diseased stem cells” (Knowles [5]). This work will highlight the stem cell transplant project as implanted in the National Guard Health Affairs (NGHA), Riyadh, Saudi Arabia (MNGHA [6]).

The defects of the current collection process for the data needed for the research of such a project will be defined. A solution will be proposed by establishing a registry that will be sponsored by King Abdulla International Medical Research Center (KAIMRC), Riyadh, Saudi Arabia (KAIMRC [7]). KAIMRC is a research center under the umbrella of the NGHHA. NGHHA was established in 1982 (MNGHA, ‘History’). it is one of the largest healthcare organizations in the Kingdom of Saudi Arabia. NGHHA provides tertiary health care to National Guard employees and their families, as well as to Saudi Nationals with

tertiary health problems. It serves more than 2.5 million outpatients and around 60,000 in-patients yearly. NGHHA consists of five hospitals, sixty primary and secondary health centers scattered in five regions around the kingdom (Riyadh, Jeddah, Dammam, Al-Ahsa, and Al-Madina) ("Medical Cities", NGHHA). KAIMRC also has several offices all with the main goal of developing and supporting the scientific research. The supported research shall assist in understanding and solving medical and health-related problems, evaluate the results of the application of basic research, build capacity, and promote health research cooperation. In fact, KAIMRC is known with its remarkable primary research projects such as the Saudi Bio-Bank, Cord Blood Bank, and many other projects. These projects contribute in studying the most common diseases within Saudi Arabia, including cardiovascular diseases, diabetes, hypertension, trauma, and obesity [KAIMRC [7]].

Problem Statement

Stem cell transplant project started at the NGHHA by a team from the hematology department to study the outcomes of the transplant procedures that had been done on different patients. The purpose was to find out how do they response and what is the effectiveness of this transplant procedure. Also, does this procedure have side effects or positive affects in helping patients to recover faster from certain diseases, such as blood cancer. A general purpose is to provide better care for patients. Hence, for that reason, there is a highly need for a system that can provide all the needed data in an electronic, accurate, and protected way, such as a registry, to help researchers in conducting their studies about stem cell transplant. However, the process of data collection and analysis to extract knowledge had many defects. First of all, there was no electronic system to help collect data and there was no actual repository to store them. Instead, data and acquired information were being logged manually on an excel sheet, which is a time consuming and doesn't include any validation.

Nevertheless, some of these data are available from different resources in the hospital such as Hospital Information System (HIS), Laboratory Information System (LIS) and Radiology Information System (RIS) as well as the hard copies from patients' records. Having sparse data make it very hard to collect these data by accessing each system individually and get back to the paper records one by one, then manually entering them into the excel sheet as a code. In fact, this process of collecting data in a flat file such as an excel sheet requires some statistical techniques that may take days to generate needed reports for research.

Summary of Key Facts

There are some key factors surrounding the data collection process that is being used for stem cell transplant project, which are:

- Time consumption
- Data accuracy

- Data integrity
- Patient care
- Data availability
- Patient privacy and confidentiality
- Employees buy-in
- Hospital administration and regulation

Implications of the Problem

With regard to the process used currently in collecting data needed for research on stem cell transplant procedure in NGHHA, there are some limitations and defects that should be taken into consideration. Firstly, the time consumption is significantly high since there is no electronic system that has the power of interfacing with other systems in the hospital, such as HIS, LIS, RIS, for collecting and managing all needed data. Secondly, with the current process of entering the collected data manually into an excel sheet, there is a high risk in entering wrong data, which would affect the accuracy and integrity of data and that would lead to affect the research outcomes. In addition, these inaccurate data will affect patient care as the research results are mainly used for patient care such as finding out the effect of the treatment on patients considering different factors (age, gender, etc.). Thirdly, collecting data in a flat file format such as excel sheet stored in a single computer machine without having a backup copy where the computer could crash at any time leading to the loss of the collected data. Finally, storing data in an excel sheet is not providing the needed security where such data should be stored in a secured database to ensure patient privacy and confidentiality.

Proposed Solution

In recent years, there is an enormous improvement in the health-care sector in Saudi Arabia and more awareness in the importance of research as there was several research centers that have been established. KAIMRC is one of those research centers where there are various research studies and registries established. However, among all of these researches, there is a project about stem cell transplant conducted by a team from the hematology department within NGHHA. Their goal is to know the outcomes of such transplant to help assure better patient treatment. However, as mentioned earlier, there are limitations and defects behind the current process and the workflow used to collect the required data for such a project. Thus, KAIMRC will be the sponsor by providing a solution of having a repository that includes all data needed through the utilization of technology. Hence, from the concept of Electronic Medical Record (EMR), KAIMRC will establish a registry for stem cell transplants. This registry will be a web-based system of a special and secure database designed to collect specific data. It shall help the researchers and their teams to enter data through the use of electronic data capture forms with an easy user interface. In addition, as a web based system, the data entering

process can be conducted at anytime, anywhere and from various devices whether PC, laptops, tablet PC or even Smartphone devices (iPhone, iPad, etc.)

Moreover, the registry will be supported with special statistical techniques and queries to create reports and graphics in an easy and

rapid way. Since the data is collected from different sources of patients' records, there should be an integration between the registry and the hospital subsystems in NGHHA as shown in Figure 1. This registry implementation and integration shall save time and effort compared with the current way of manual data collection.

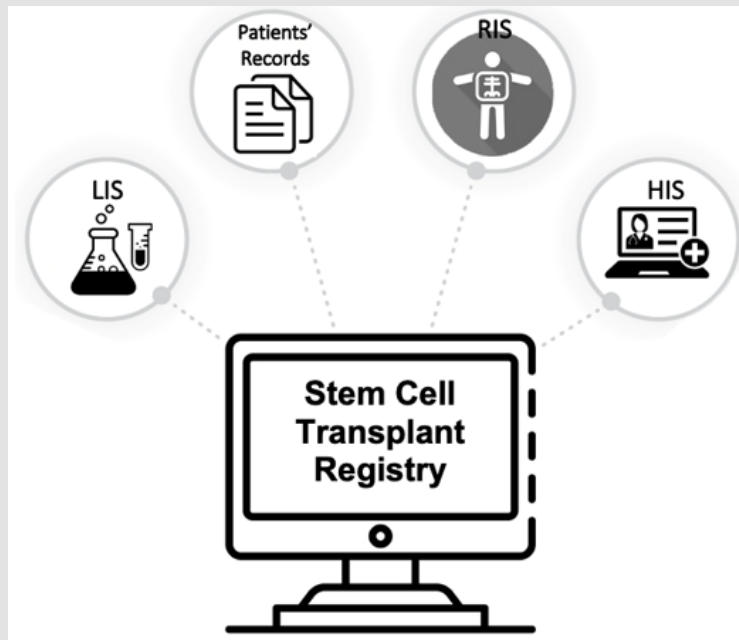


Figure 1: Registry Integration with MNGHA Subsystems.

Implementation Plan

In order to have an efficient and effective stem cell transplant registry that covers the needs and regulations of research, there is a need to have a clear requirements of such registry which includes research proposals approved by Institutional Review Board (IRB). There is also a need for a clear patient's consent form according to the Guidelines of Good Clinical Practice (GCP) needed for patient signature since there will be a transplant procedure done on them (World Health Organization [8]). In addition, there is a need for a Case Report Form (CRF), which is the form used to collect the required data needed for research such as laboratory/radiology tests, implication or adverse event and other required data. Indeed, all of these requirements will be provided to the Research Office Department at KAIMRC to ensure that everything is complete. After that, the Research Office will send the proposal along with the CRF to the department of Research Database And Disease Registry (RD&DR). Then, when RD&DR receives these documents, a consultation form will be sent to the researchers of the project. The consultation form is a form implemented by the RD&DR department and it includes the type of the research proposed, whether it is a survey, clinical trials, or a registry, as well as the type of services that the researcher needs. After the response is received

from the researchers, firstly, the manager of the department will assign a team for the project including clinical analysts, developers and a team leader where each team member has a role and responsibility.

In reality, the clinical analyst will provide assistance during the review of the registry implementation proposal and the CRF as there are medical terminology used and need to be clarified to the developer during the designing of the electronic CRF. The team leader will manage the overall project by creating the project plan; ensuring that everything under control and the delivery of the project will be on the specified period of time and within allocated budget. Secondly, a meeting will be conducted between the researchers; manager and the team members of the project to discuss the plan of the project and other required information related to the building of the registry, such as the validation requirements and analysis reports needed. Hence, if everything is clear and complete, the developer will start working on the building of e CRF. A team from the Information Technology Department (ITD) is also involved and responsible for the infrastructure of the registry (server, backup, maintenance, etc.) Moreover, this team along with the developer of the registry will collaborate with the Information Systems And Informatics Department (ISID) in NGHHA on the matter of integration between the registry and the hospital sys-

tems such as HIS, LIS, and RIS. Finally, after the implementation and testing of the registry is done, the RD&DR team will schedule a time for training the researchers with their teams along with providing them with a training manual.

Challenges

With regards to the establishment of a stem cell transplant registry, like any new system implemented, there are always some challenges and obstacles that might be encountered during the implementation process. Some of those challenges are as follows:

- Technical challenges: the high costs of hardware and software needed as well as the network availability since it must be always available.
- People challenges: like any other new technology, there was a resistance from the staff to adopt and use the registry.
- Integration challenges: The challenge of integration with hospital systems, as there were strict regulations from the ISID department.

Conclusion

A stem cell transplant registry implementation project started in NGHHA to study the outcomes and the complications of the transplant procedures at the hospital. The difficulties of the manual process used

to collect the needed data for research mandated the utilization of the technology by implementing stem cell transplant registry software, where KAIMRC was the main sponsor. The implemented registry included various features to help researchers save data collection and processing time and to ensure the accuracy of data collected and results reported.

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ISSN: 2574-1241

DOI: 10.26717/BJSTR.2024.56.008863

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