MANAGEMENT OF STANDARDISED, INTEROPERABLE CLINICAL REGISTRIES: VISIONING QUALITY OF CARE AND CLINICAL RESEARCH

Clarissa Rodrigues PhD, Jacqueline Vaz MSc, Patrícia Aristimunho MSc, Cristiane Vacca MSc, Bianca Verboski MSc, Renato Kalil MD, PhD

Instituto de Cardiologia do RS - Fundação Universitária de Cardiologia, Porto Allegre, Brazil

Abstract

Objective: To describe the implementation of a hospital sector dedicated to conduct clinical registries. Methods and Results: In 2014 a Sector was founded in the Clinical Research Centre specifically to design and manage clinical registries. Over the past two years we have participated in many adult and paediatric multicentre studies as a site collecting data, and have designed and implemented 14 clinical registries, including local and multicentre studies. The clinical registries include in-hospital and outpatient studies on acute myocardial infarction, cardiovascular rehabilitation, systemic hypertension, pacemaker and implantable cardioverter defibrillator, electrophysiology and ablation procedures, heart failure, cardiac transplantation, percutaneous cardiac intervention for left main coronary artery stenosis, percutaneous cardiac intervention with drug eluting stents, paediatric systemic hypertension, infectious endocarditis, clinical trials patients, paediatric cardiovascular prevention and adult cardiovascular surgery. The databases were built taking into consideration national and international standardised data elements to allow for interoperability among datasets, clinical and research workflows, and are in accordance with the HIPAA (Health Insurance Portability and Accountability Act) privacy rule. Currently, these registries hold data on more than five thousand patients. Integration with other clinical and costs datasets within institutions are underway. Data are used for quality assistance control and research. Conclusion: The Clinical Registry Sector has provided data for measuring quality of care and effectiveness. Additionally, the methodology used for building the clinical registries allow for interoperability among systems maximising the potential of its use.

Keywords: clinical registries, interoperability, cardiology

Introduction

The use of clinical registries in healthcare has been increasing every year. Clinical registries represent a powerful tool for assisting quality improvement, healthcare services management, technology assessment, health policies and clinical research.[1] There is general consensus of the value of clinical registries for healthcare, however, it is only possible if high quality data is available.[2]

In Brazil, although there are some important initiatives using clinical registries and their potential is recognised, there are still face several challenges in relation to data quality and integration. Our Institution, Instituto de Cardiologia do RS - Fundação Universitária de Cardiologia (IC-FUC), has a Clinical Research Centre (CRC) which has conducted several national and international multicentre clinical studies. In addition to conducting randomised clinical trials, a Sector inside the CRC was founded in 2014, specifically to design and manage clinical registries. The aim of this paper is to describe the implementation of a hospital sector dedicated to developing and managing clinical registries.

Methods and Results

Institutional Organisation Chart and Team

The Clinical Registries Sector belongs to the CRC. The regulatory and legal aspects of the clinical registries are managed by the CRC. The CRC team consists of a director, a general coordinator of the centre, two administrative employees, three study coordinators and physicians. The Clinical Registries Sector is responsible for creating and managing clinical registries, including centralised data

management of all studies as well as management of sites. (Figure 1)

The Sector was founded and run by Dr Clarissa Rodrigues working with a network of about 40 researchers working on the studies. Each clinical registry has a specific Principal Investigator (PI), who is always a clinician researcher from the IC-FUC with expertise in the clinical area of the respective clinical registry. Each PI brings together their teams who are trained for data collection by us. One of the Sector team members is assigned to work on the registry with the PI and his/her group.

Clinical Registries conducted at our Sector

Over the past two years we have participated in many adult and paediatric multicentre studies as a site collecting data (atrial fibrillation, pacemaker and implantable cardiac defibrillator, cardiac surgery, among others), and have designed and implemented 14 clinical registries, for local and multicentre studies, and three institutional medical logbooks. Logbooks are a specific type of dataset to document the activities of the medical residents. Logbooks are very useful not only to access the training undertaken by each medical resident, but also to assess the quality of the programmes offered by the Institutions. The clinical registries and logbooks that have implemented are summarised in Table 1.

Designing our Clinical Registries

The Sector serves researchers and managers at our Institution. When a need for data is identified to address a clinical or operational issue, the Clinical Registry Sector is contacted to evaluate the possibility of designing a clinical registry. This evaluation includes the assessment of originality, relevance, institutional priority, and appropriate team and resources required to allow collecting and managing high quality data. Following the evaluation a new registry is designed. Researchers are provided with templates to facilitate writing the study protocol which is then reviewed.

Table 1. Clinical registries and logbooks implemented.

Outpatient Registries
Adult systemic hypertension (RE-Hyper)
Cardiovascular rehabilitation (ReHab Heart Data)
Heart failure (RE-Heart)
Paediatric systemic hypertension (HASCA)
Paediatric cardiovascular disease prevention (PREVINA)
Hospital Registries
Adult cardiovascular surgery
Pacemaker and implantable cardioverter defibrillator
Electrophysiology and ablation procedures
Cardiac transplantation
Acute myocardial infarction
Percutaneous cardiac intervention for left main coronary artery
Percutaneous cardiac intervention with drug eluting stents
Infectious endocarditis (RE-Endo)
Patients included in clinical trials
Medical Logbooks
Residency in cardiology
Residency in cardiac catheterisation
Residency in echocardiography

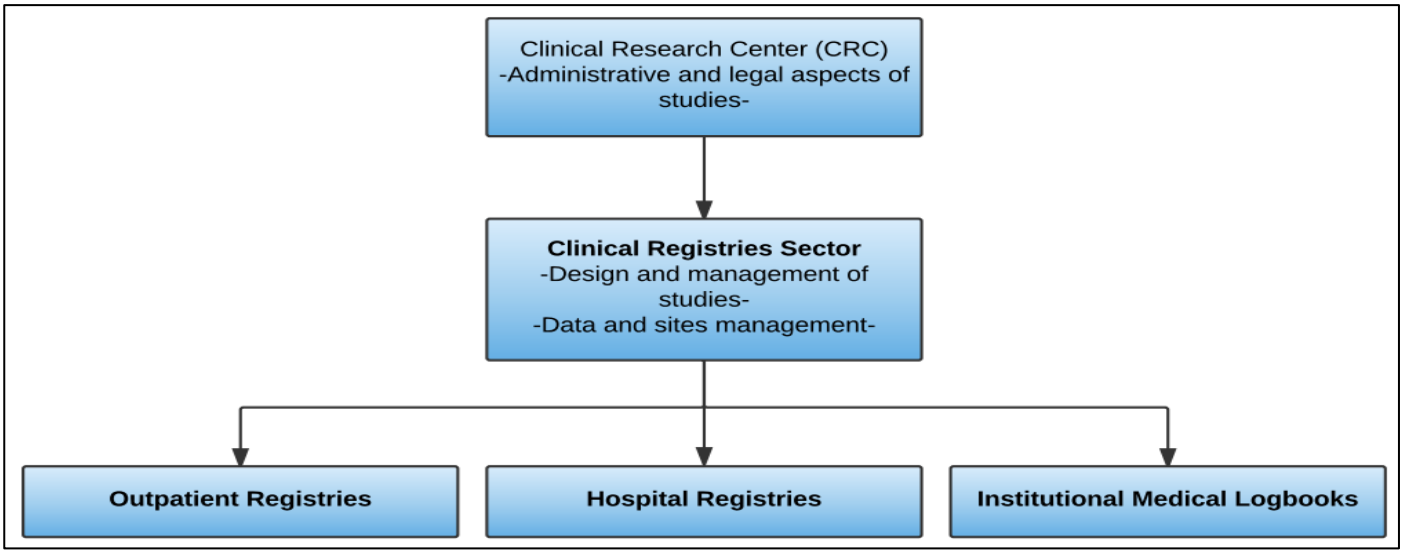

Figure 1. Institutional organisation chart.

Adaptations are carried out by both teams as needed. The study protocol is then submitted for Institution Review Board (IRB) approval.

The databases are built taking into consideration national and international standardised data elements and are in accordance with the HIPAA (Health Insurance Portability and Accountability Act) privacy rule. Use is made of standards such as the ones provided by the American Heart Association/American College of Cardiology (AHA/ACC), and Brazilian national clinical and demographic datasets, among others and are used to address the registry's aims, and allowing interoperability among datasets.

The registries make use of electronic case report forms (CRFs) which are created using Research Electronic Data Capture (REDCap) software. The Clinical Registries Sector suggests a first version of a data collection workflow based on the assessment of the registry's aims and institutional routines, and provides training for data collection. CRFs and data collection workflow are then piloted by the PI team and adaptations are implemented as needed. Lastly, the research workflow which includes strategies and routines for data management and team communication is defined. An example of the creation of a local clinical registry is shown in Figure 2.

The creation of registry workflow can vary slightly depending on the study aims and methodological characteristics such as being clinical or operational datasets, or local or multicentre studies.

Project and data management

Project and data management is conducted using REDCap Software. REDCap is a secure application for building and managing electronic online datasets, and can be used to collect any type of data (including 21 CRF Part 11, FISMA, and HIPAA-compliant environments). Recently, the REDCap Consortium launched an offline version of REDCap which synchronises with the respective online datasets once Internet connection is available. Offline data collection is already available at our Institution and is been used in some pilot projects.

Ensuring high quality data management is a challenge when managing a considerable number of clinical registries and working with different teams at the same time. A comprehensive set of tools to facilitate and guarantee quality is used. Automatic system statistics are generated weekly, including information on projects status, types and purposes.

Most of the studies are longitudinal. In these cases, automated calendars are used which presents the exact follow up schedule and the information that needs to be filled at each respective moment, for each patient. Additionally, the system allows tracking of

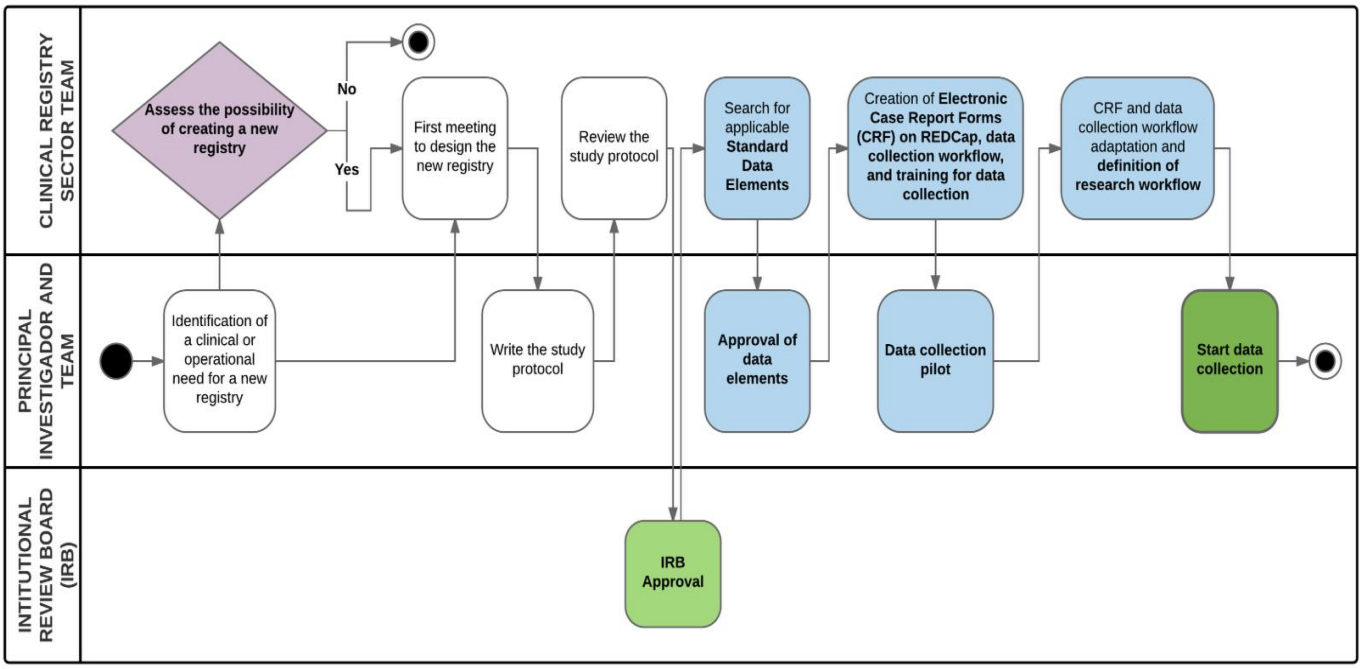

Figure 2. Example of the creation of a local clinical registry.

every single action inside each project, identifying the user, date and specific time of the action.

General reports of all variables are also automatically available in real time and it is also possible to customise reports of interest of each study or researcher. Reports of data quality including missing data, fields' validation errors, outliers for numerical fields (ranges are defined by us when creating the CRFs), hidden fields that contain values, multiple choice fields with invalid values and incorrect values for calculated fields. Other rules are created and added to the quality reports as necessary and appropriate for each project.

Lastly, the system exports the datasets in different file formats including all the main statistical software such as SPSS, SAS, R, STATA, etc. At our institution, there are two statistician available to all researchers, as well as training for data analysis for researchers and students. Figure 3 demonstrates some of the tools used for project and data management.

Within a registry there are different levels of user access to the system, depending on the role and activities of the user in the project. Figure 4 shows the aspects that can be customised for each project. User access to the system is provided only by one person at each study and is supervised by the coordinator of the Sector. In order to define the level of access of each person, the details are discussed with the respective PI and follow a standard operational procedure (SOP). All users are required to sign confidentiality and responsibility forms before receiving access to the datasets.

Management of sites

The Sector also manages sites and the routines are

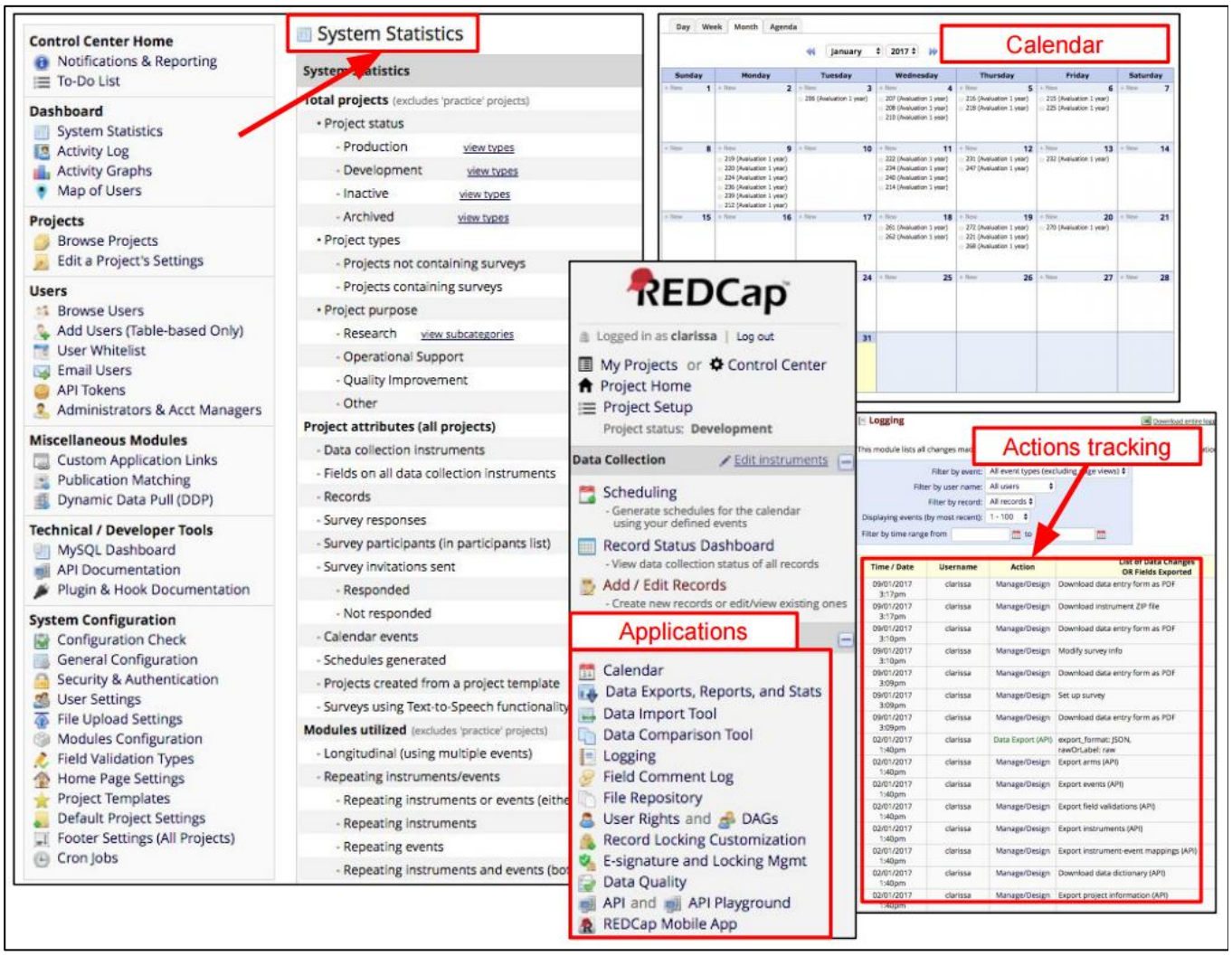

Figure 3. Tools for project and data management

defined considering the needs of each study. Each study has a Sector team member responsible for management of sites and communication.

Conclusion

The Clinical Registries Sector has been responsible for the creation and management of several clinical registries over the past two years, including local and multicentre studies. Data has been used for research and service management. The use of standardised and high quality methodologies for building the clinical registries allow for interoperability among systems maximising the potential of its use.

Corresponding author:
Clarissa Rodrigues
Instituto de Cardiologia do RS
Fundação Universitária de Cardiologia
Porto Allegre
Brazil
eMail: clarissagarciarodrigues@gmail.com

Conflict of interest. The authors declare no conflicts of interest.

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