JOURNAL OF THE INTERNATIONAL SOCIETY FOR TELEMEDICINE AND EHEALTH

IMPLEMENTATION AND PRELIMINARY RESULTS OF AN INTEROPERABLE, STANDARDISED CLINICAL REGISTRY ON CARDIOVASCULAR SURGERY

Bianca Milena Verboski RN MSc, Sofia Giusti Alves MD, Leonardo Bridi MD, Renato Kalil MD PhD, Clarissa Garcia Rodrigues PhD MBA

Instituto de Cardiologia do Rio Grande do Sul – Fundação Universitária de Cardiologia (IC-FUC), Porto Alegre, Rio Grande do Sul, Brazil

Abstract

The implementation of a Clinical Registry in a hospital environment becomes a challenge in the face of different types of treatment, care culture and non-standardized records. Objective: To describe the implementation and preliminary results of the Clinical Registry of Cardiovascular Surgery. Methods: The Registry was designed using REDCap, with remote access via a web interface. The registry included patients older than 18 years undergoing coronary artery bypass grafting, valve repair or replacement, aortic surgery, congenital heart disease and cardiac transplants, at the Cardiology Institute of RS - Brazil. Data elements were nationally and internationally standardised (STS Adult Cardiac Database and Bypass - Brazilian Registry of Cardiovascular Surgery in Adults). Results: Data were collected at pre, trans and immediate postoperative periods, in the intensive care unit, at hospital discharge, at 1 and 6 months, and annually after surgery. The dataset included 650 variables. A team of approx. 18 professionals were involved in data collection and management. The first year of data collection was completed in November 2016, reaching 1,000 patients. Male prevalence was 66.4%, mean age 62 years, use of the Public Health System 67.8%, procedures were myocardial revascularization surgery 60.9%, valve surgery 39.6%, aortic surgeries 10.5%), congenital heart disease 1.8%, and heart transplantation 0.2%. Conclusion: The registry allowed the identification of measures to evaluate care quality and cost efficiency. Successful interoperability with other registries in cardiology, will contribute to new discoveries and quality care improvements.

Keywords: clinical registry; cardiovascular surgery; database

Introduction

Clinical registries are defined as observational databases focused on a clinical condition, procedure, therapy, or population.[1,2] Data collection is systematic, there is no intervention and few exclusion criteria are considered, thus, it reflects reality in large populations. Cardiovascular registries have been associated with clinical improvement from the adoption of measures of performance and quality in cardiovascular diseases.[1]

However implementing clinical registries becomes a challenge when considering issues such as non-standard terminology, undefined care standards, etc. In view of this, the objective was to describe the process for implementation of the Clinical Registry on Cardiovascular Surgery of the Institute of Cardiology of Rio Grande do Sul - Fundação Universitária de Cardiologia (IC-FUC).

Methods

This was a prospective study, that documented the characteristics of cardiovascular disease patients who underwent cardiovascular surgery during their hospitalization, with routine pre, intra, post, and discharge evaluation during hospitalization, plus regular post-discharge follow-up (Figure 1).

The inclusion criteria were: patients of either gender, over 18 years old, and undergoing cardiovascular surgery (coronary artery bypass grafting, heart valve repair and replacement, aortic surgery, congenital heart defects, or heart transplant). Data collection included variables selected from the Brazilian Society Cardiovascular Surgery (SBCCV) registry,[3] and the Society of Thoracic Surgery (STS) registry,[4] to support interoperability with other national and international registries. In addition, adoption of common terms and definitions facilitated comparison of results and enhanced quality of care. The standardization process was performed in English, with an interface in Portuguese to facilitate data collection in Brazil. The registry incorporates the steps outlined in Table 1.

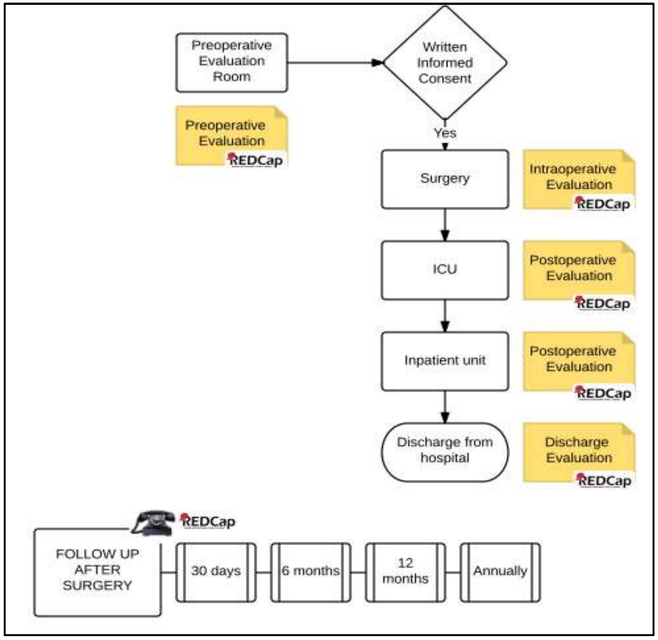

Figure 1. Flow of data collection for the Cardiovascular Surgery Registry. (ICU: Intensive Care Unit.)

The software chosen for development of the Clinical Registry on Cardiovascular Surgery was the Research Electronic Data Capture (REDCap) software package.[5] REDCap is recognized as the most used software package for data collection and management of clinical studies, with features such as security, intuitive interfaces, easy application, and Health Insurance Portability and Accountability Act (HIPAA) compliance.[6]

Access by IC-FUC to REDCap was granted by the REDCap Consortium, Vanderbilt University.[7] The server was local and protected by the IC-FUC network firewall. Each user had an electronic signature and non-transferable password, and each member of the team had different levels of access for insertion, query and exportation of data. Access to the software could be performed from any computer, tablet or smartphone connected to the Internet or using the offline version of REDCap. Training of the data collection team was performed using a basic manual to explain the user's registration in the system, and the patient's registration / location in the registry in order to complete the appropriate follow-up.

To meet the institutional demand, biweekly

Table 1. Site of data collection, data collection interval, and data to be collected.

Site	Data Collection Interval	Information to be collected
Preoperative Evaluation Room	Admission	• Inclusion / exclusion criteria • Demographic data
	Preoperative Evaluation	• Patient clinical profile • Preoperative history • Preoperative examinations
Postoperative ICU	Intraoperative Evaluation	• Transcription of the operative notes and anaesthetic record by the medical team after ICU admission
	Postoperative	• Clinical data of immediate patient assessment • Description of the surgical, trans-operative procedure, neurological evaluation, cardiovascular, exams and other complications
	Postoperative ICU discharge or 7 days	• At the discharge from ICU postoperatively, an occurrence of cardiovascular or non-cardiovascular complications that justify an increase in hospitalization time is evaluated
Inpatient Unit	Discharge from hospital	• Cardiac evaluation, pulmonary, renal, vascular and other complications following ICU discharge • Total mortality • Medications in use
Clinical Registries Sector	Follow-up at 30 days, 6 months, 12 months, and annually thereafter	• Total mortality • Larger cardiovascular events • Medications in use

registration of new medical collaborators has taken place. The training was performed at the hospital units where data were collected so that the users understood how data collection was performed together with the patient care workflow, and did not compromise the quality of care. Data collection and training took place in four sectors: preoperative evaluation room, post-operative ICU, inpatient unit, and the clinical registries sector.

As the registry encompassed several sectors and a vast team, standard operating procedures (SOPs) were developed, describing the process of data collection, step-by-step. This SOP provided a description of all procedures that should be conducted throughout the data collection process.

After the training, data insertion was initially supervised face-to-face or remotely by the study coordinator in order to guarantee adherence to the study protocol. The use of the Logging tool provided by REDCap allowed the monitoring and audit of who entered the data, which data, and at what time. When problems and difficulties related to data insertion were identified, measures such as exploration of concepts and reorganisation of the flow were introduced to resolve the problem.

Data management for the registry is performed by the IC-FUC, using the REDCap system. Clinical records transcribed from medical records were incorporated into a validation database. Data entry could be performed anywhere in the world. Since researchers and institutions can access secure web authentication simultaneously, data quality and integrity is maintained when transferring the record, and integration between the collection, storage, management and applicability of data is facilitated.

One of the great enablers for data collection is the automatic scheduling facility. At predetermined intervals, this indicates in a calendar format those patients requiring follow-up.

Quality assurance steps were carried out since the implementation of the registry, and included in the training for data collection. Electronic forms prevented incomplete data entry, especially for those elements that were mandatory, or where inconsistent data might be entered (e.g., values outside the biological range). Quality assurance reports were created quarterly, and included reports on screening, recruitment, data quality, adherence to protocol, plus consistency and completeness of forms.

Results

As of 1 November 2016, 12 months of operation had been completed, with 1000 registered patients. Demographics were: men (66.4%), average age 62 years, Public Health System users (67.8%), myocardial revascularization surgery (60.9%), valve surgery (39.2%), aortic surgeries (10.5%), congenital heart disease (1.8%), and heart transplants (0.2%). Combined surgeries occurred in 12.6% of cases.

Ethical Considerations

The Institutional Review Board (IRB) of IC-FUC approved the study, which was in accordance with Resolution Nº 466 of 2012 of the National Health Council, the Declaration of Helsinki and the Guidelines for Good Clinical Practices, as well as the regulatory requirements demanded in Brazil. All protocols, forms and Informed Consent were submitted and approved by the IRB.

Conclusion

A supportive institutional culture and the involvement of medical and surgical team coordinators was essential for the prospective, continuous and reliable collection of data. The registry identified opportunities for quality improvement, delivered valuable results, and provided performance measures that help qualify the Institution during accreditation processes.

……

Corresponding author:
Kuriko Kudo
Bianca Milena Verboski
Instituto de Cardiologia do Rio Grande do Sul
Fundação Universitária de Cardiologia (IC-FUC)
Porto Alegre
Rio Grande do Sul
Brazil
*eMail:*bianca.milenavb@gmail.com

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

References

1. Bhatt DL, Drozda JP Jr, Shahian DM, et al. ACC/AHA/STS Statement on the Future of

Registries and the Performance Measurement Enterprise: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and The Society of Thoracic Surgeons. *Circ Cardiovasc Qual Outcomes* 2015;8(6):634-648.

2. Tavazzi L. Do we need clinical registries? *Eur Heart J* 2014;35:7-9.
3. Brazilian Registry of Cardiovascular Surgery in Adults. Brazilian Society Cardiovascular Surgery. Available at: http://www.sbccv.org.br/medica/imageBank/informativo_09_rebccv.pdf accessed 14 January 2017.
4. Adult Cardiac Surgery Database. The Society of Thoracic Surgeons. Available at: http://www.sts.org/sts-national-database/database-managers/adult-cardiac-surgery-database accessed 14 January 2017.
5. Research Electronic Data Capture (REDCap). 2017. Available at: https://www.project-redcap.org/ accessed 14 January 2017.
6. Health Insurance Portability and Accountability Act (HIPAA). 2017. Available at: https://www.hipaa.com/ accessed 14 January 2017.
7. Vanderbilt University. 2017. Department of Biomedical Informatics. Available at: https://medschool.vanderbilt.edu/dbmi/redcap accessed 14 January 2017.