JISfTeH

Journal of the International Society for Telemedicine and eHealth

IMPLEMENTATION OF A MANAGEMENT REGISTRY FOR STORING CLINICAL DATA IN A RESEARCH CENTRE

Suimara Santos MSc, Michelle Santarém MSc, Clarissa Rodrigues PhD, Maria Antonieta P de Moraes PhD

Instituto de Cardiologia do Rio Grande do Sul / Fundação Universitária de Cardiologia

Abstract

In clinical research, there is great concern about the storage and veracity of electronic data to ensure the accuracy of information. Objective: To implement a management registry for storing study data in the cardiovascular area, conducted in a clinical research centre. Methods: This is a retrospective registry and prospective joint study. An electronic database was developed using REDCap software. Data elements were standardised in accordance with the American College of Cardiology Foundation and American Heart Association. Data were extracted from research participants from the clinical studies conducted in our Institution with records of cardiovascular diagnosis that were monitored by the health team from 2009 to 2015. Results: The registry was composed of eight sections: demographic variables, diagnostic tests, laboratory tests, cardiovascular risk factors (CV), comorbidities and pharmacological treatment used, and outcome of patients. Each session consisted of sub-items, totalling 113 variables. Phase III (57.8%) and phase IV (36.8%) studies with mean follow-up of 2±4 years were predominant. We used data from 490 participants randomised to 25 studies, 63 percent men, aged 63 ą 10 years, hypertensive (81.4%), with dyslipidaemia (56.5%), and diabetes 48 (36.3%). Most had previous myocardial infarction (72.7%) and underwent coronary angioplasty (87.2%). Conclusion: The implementation of an electronic database of research on participants with cardiovascular disease was applicable and reproducible in clinical practice, being a low cost and very useful tool to store and share data from multicentre studies of medium and large scale.

Keywords: RedCap; cardiology; clinical research; registry

J Int Soc Telemed eHealth 2017;5(GKR):e48

Introduction

In Brazil, clinical studies designed in partnership with centres of excellence and regulatory agencies provide the most updated healthcare evidence.[1] There is a professionalisation of the research centres and the country is recognised for its participation in international multicentre studies.[2,3]

Considering this perspective, it is fundamental to implement software to optimise data gathering and dissemination among researchers and institutions.[4-6] In this context, the Research Electronic Data Capture (REDCap) is software used to collect and spread variables of clinical studies, provide access to data among institutions and academic departments, allowing real time validation, central data storage and management, backups and automated export of data.[7,8]

The creation of electronic databases through this software will give us the opportunity to identify, screen and enrol volunteers for research protocols, as well as will allow for a better management of the studies conducted in our institution. In view of this and the lack of similar tools at our institution, this study was designed to create and implement the electronic database through the REDCap software of clinical research participants who have been followed over the last six years in a Research Centre.

Methods

This is a retrospective and prospective registry implemented from September, 2014 to December, 2015. The information was taken from the patients' records of randomised clinical trials (RCT) in the cardiovascular area that were conducted from January, 2009 to December, 2015 in a clinical research centre (CEPEC - *Centro de Pesquisa Clínica*). For this purpose, all research protocols of CEPEC and IC/FUC that were in process or concluded in the above mentioned period, were included.

Logistics REDCap software implementation and variable standardisation

Vanderbilt University was contacted for registration and license application, in order to become a REDCap consortium customer. Concomitantly, variables were selected according to the international standard of the American College of Cardiology Foundation and the American Heart Association ACC/AHA.[9] Eight sections were created to compound the *software*. In the following step, all studies carried out in the CEPEC were sought out and the insertion of data in theREDCap software began. The data are from the institution's medical records, shown in Figure 1.

- By Author
- By Title
- Other Journals

ABOUT THE AUTHORS

Suimara dos Santos
Instituto de Cardiologia do Rio Grande do Sul / Fundação Universitária de Cardiologia
Brazil

Michelle Dornelles Santarém
Instituto de Cardiologia do Rio Grande do Sul / Fundação Universitária de Cardiologia
Brazil

Clarissa Garcia Rodrigues
Instituto de Cardiologia do Rio Grande do Sul / Fundação Universitária de Cardiologia
Brazil

Maria Antonieta Pereira de Moraes
Instituto de Cardiologia do Rio Grande do Sul / Fundação Universitária de Cardiologia
Brazil

ARTICLE TOOLS

Abstract
Print this article
Indexing metadata
How to cite item
Supplementary files

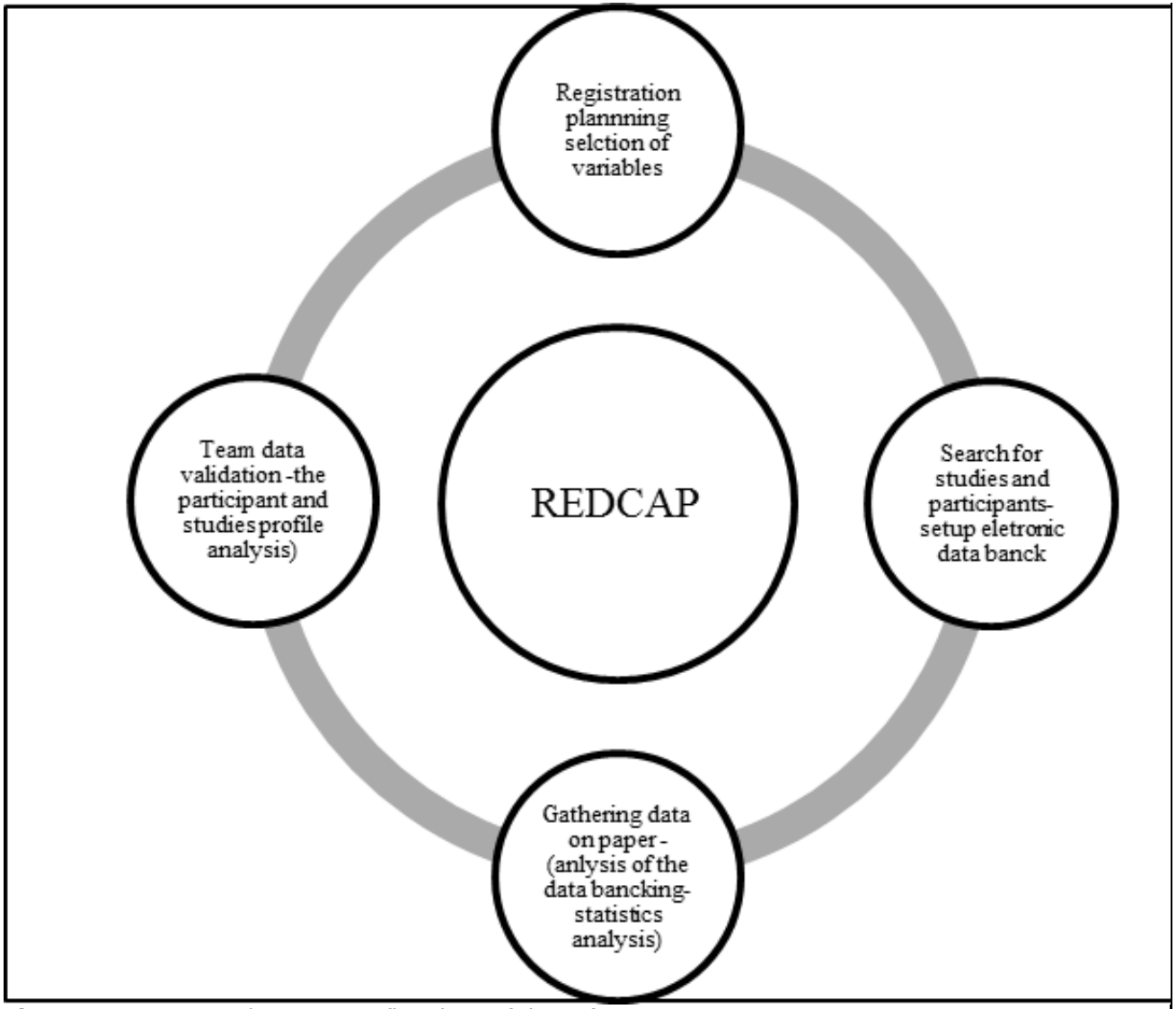

Figure 1. Logistic implementation flowchart of the software.

Results

Variables and REDCap software

Between September, 2014 and December, 2015, 240 variables were selected according to the international standard *ACC/AHA.* Out of these, 113 variables were inserted in eight sections. (Figure 2)

KEYWORDS

Brazil Telehealth Telemedicine eHealth eLearning healthcare informatics innovation mHealth medical education medical informatics mhealth nursing primary care primary healthcare security telecare teleconsultation telehealth telemedicine telemonitoring

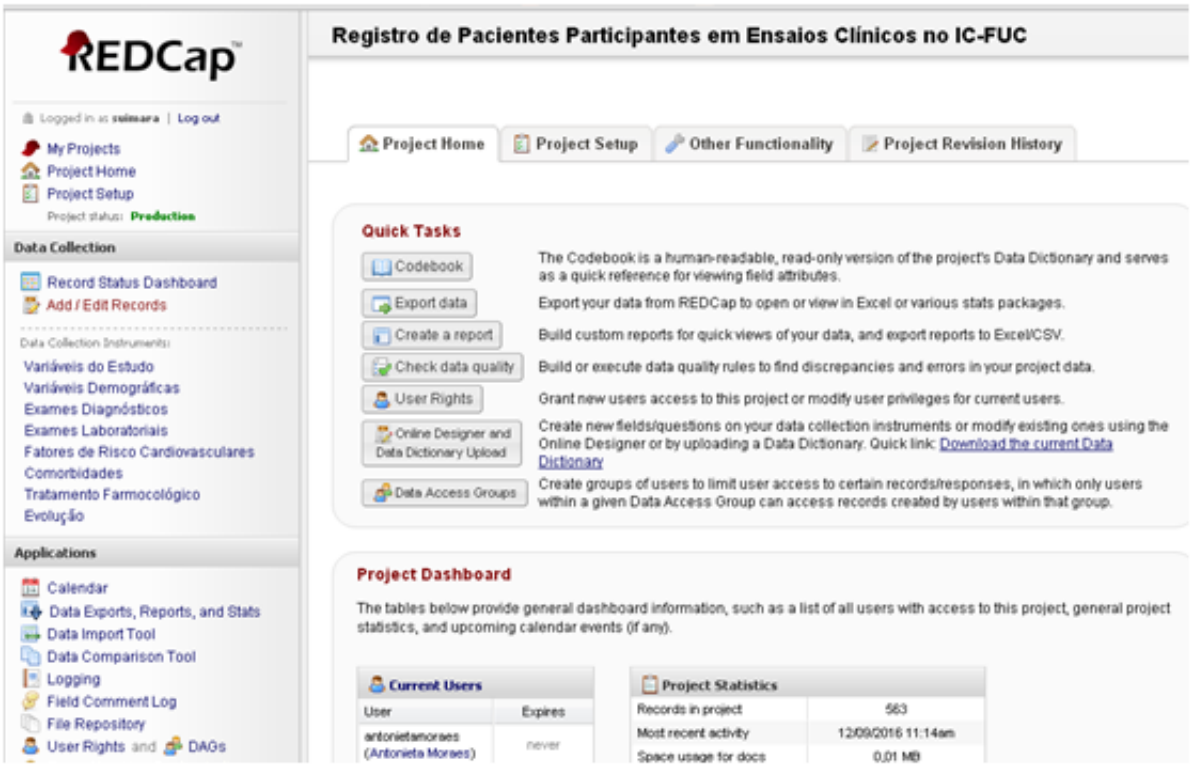

Figure 2. Initial screen of the CEPEC database.

In the first and second sections, variables such as name, study stage, socio-demographic characteristics of the participants and the medical diagnosis were entered. In the diagnostic and laboratory tests sections, those common to all of studies, used in the practice of cardiology, were prioritised.

The previous comorbidities section was represented by 27 variables with different pathologies, and the clinical evolution with 4 variables linked to the possible adverse events and death. Finally, the pharmacological therapy was rated in 14 types of medicines and 26 variables.

Population characterisation and studies conducted in the CEPEC

During the period between 2009 and 2015, 25 cardiovascular studies were conducted. From these, 19 were entered and analysed. Ten studies were concluded, nine were in progress and the other six were in their initial phase. The results highlighted that there was a predominance of studies in phases III and IV (57.8% and 36.8%), with a mean conduction time of 2±4 years.

Among the 490 participants included in the clinical trials, 59 presented screening failure, 14 died and 417 were being followed up. Among them, most were men (63%), around age 63±10 years, hypertensive and dislypidaemic (81.4% and 56.5%), with a IAM diagnosis (72.7%). The most prevalent therapeutic procedures in this population were percutaneous revascularisation (87.2%) and surgery (12.8%).

Diagnosis, laboratorial and pharmacologic therapeutic tests

The results showed that most of the population had undergone lab tests of creatinine (94.3%), cholesterol

(76%), triglycerides (72%) and glycosylated haemoglobin (49.4%). The most requested diagnostic tests were electrocardiogram (87.6%), cardiac catheterisation (79.4%) and echocardiogram (37.8%). In the pharmacological therapy prescribed, there was prevalence of the use of antiplatelet medication (91%), statins (86%) and angiotensin converting enzyme inhibitors (65.5%).

Conclusion

The database contributes information about innovate treatments with integrity and confidentiality, it allows the expansion with other databases, and generates automatic quality data reports through standardised variables.[10-13] The benefit of this project was the viability of the characterisation of the leading clinical studies in the CEPEC, as well as the cardiovascular clinical profile.

Our data allows us to conclude that the construction and implementation of an electronic database, with participants in cardiovascular disease research, through the REDcap software, was applicable and

share multi-centric study information of a medium and large scale.

Corresponding author:
Suimara Santos
Instituto de Cardiologia do Rio Grande do Sul / Fundação Universitária de Cardiologia
Porte Alegro
Brazil
eMail: suienf@gmail.com

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

References

1. Sung NS, Crowley WF Jr., Genel M, et al. Central challenges facing the national clinical research enterprise. *JAMA* 2003;289(10):1278-1287.
2. Usher RW. PhRMA BioResearch Monitoring Committee perspective on acceptable approaches for clinical trial monitoring. *Drug Inf J* 2010;44(4):477-483.
3. 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. *J Am Coll Cardiol* 2015;66(20):2230-2245.
4. Silva LR da, Laguardia J, Alves MRAB, et al. ReBEC in numbers: reflexos da política mandatória em pesquisa clínica na trajetória do Registro Brasileiro de Ensaios Clínicos.Notebooks BAD. 2014;2:1071-1114. Available at: http://www.ensaiosclinicos.gov.br accessed 18 June 2014.
5. Gasca-Hurtado GP, Losada BM. Taxonomía de riesgos de outsourcing de software. Ingeniare. *Rev Chil ing*. 2013;21(1):31-53. Available in http://dx.doi.org/10.4067/S0718-33052013000100005 accessed 29 July 2014.
6. McCourt et al. Data standards: at the intersection of sites, clinical research networks, and standards development initiatives. *Drug Inform J* 2007;41(3):393–404.
7. Contributors R-p. The R Project for Statistical Computing. 2014 Available in www.r-project.org accessed 18 June 2015.
8. Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42(2):377-381.
9. Cannon CP, Brindis RG, Chaitman BR, et al. 2013 ACCF/AHA Key data elements and definitions for

measuring the clinical management and outcomes of patients with acute coronary syndromes and coronary artery disease. *J Am.Coll. Cardiol* 2013;61(9):992-1025.
10. Klipin M, Mare I, Hazelhurst S, Kramer B. The process of installing REDCap, a web based database supporting biomedical research: the first year. *Appl Clin Inform* 2014;5(4):916-29.
11. Carvalho ECA de, Jayanti MK, Batilana AP, et al. (2010) Standardizing clinical trials workflow representation in UML for international site comparison. *Plos One* 2010;5(11):1-8.
12. Silva KR da, Costa R, Crevelari ES, et al. Glocal Clinical Registries: Pacemaker Registry Design and Implementation for Global and Local Integration – Methodology and Case Study. *Plos One.* 2018;8(7):e71090.
13. Anderson HV, Weintrub WS, Radford MJ, et al. Standardized cardiovascular data for clinical research, registries, and patient care: a report from the Data Standards Workgroup of the National Cardiovascular Research Infrastructure project. *J Am Coll Cardiol* 2013;61(18):1835-1846.

Santos S, et al, *J Int Soc Telemed eHealth* 2017;5(GKR):e48

Refbacks

- There are currently no refbacks.

Journal of the International Society for Telemedicine and eHealth. **ISSN 2308-0310**