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

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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 ± 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

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 the REDCap software began. The data are from the institution’s medical records, shown in Figure 1.

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)

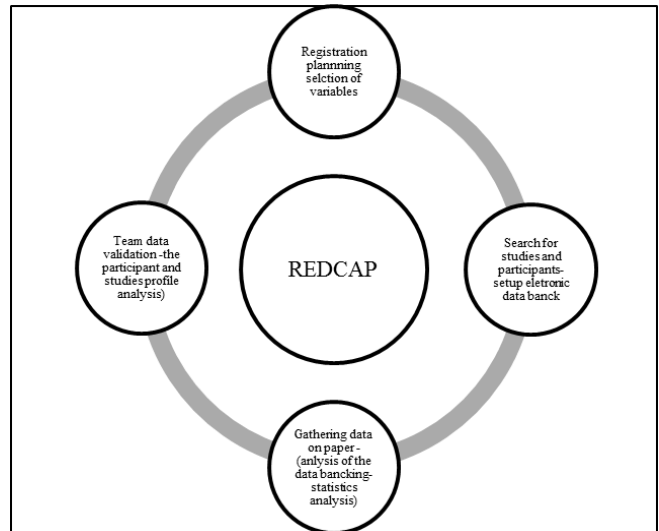


Figure 1. Logistic implementation flowchart of the software.

In the first and second sections, variables such as name, study stage, socio-demographic characteristics of the participants and the medical diagnosis were



Figure 2. Initial screen of the CEPEC database.

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 dislipidaemic (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%).

Conclusions

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 reproducible in clinical practice. It has shown that it is a low-cost tool and it is of great use to store and share multi-centric study information of a medium and large scale.

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

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