RIAM – MULTICENTRE, INTEROPERABLE, CLINICAL REGISTRY OF ACUTE MYOCARDIAL INFARCTION

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Abstract

Introduction: Ischaemic heart disease is the leading cause of death in the world. In Brazil, in 2013, acute myocardial infarction (AMI) was the main cause of mortality due to heart disease. A better identification of the patients will serve as a tool to improve the treatment of this pathology. Objective: To expand the database of patients with ST elevation myocardial infarction (STEMI) of the Cardiology Institute (Porto Alegre-RS, Brazil). Methods and Results: The following steps were taken: (1) data elements standardisation in accordance with standard variables, including all applicable standardised data elements published by the American Heart Association / American College of Cardiology, and Brazilian national datasets standards; (2) Development of electronic case reports (CRF) using REDCap (Research Electronic Data Capture) and in accordance with the HIPAA (Health Insurance Portability and Accountability Act) privacy rule; and (3) expansion of registration to other referral centres. The participating institutions are distributed in the regions of Santa Maria, Passo Fundo, Caxias do Sul all of Rio Grande do Sul, as well as the regions of Santa Catarina and the Distrito Federal in Brasília. The data collected will be stored according to the Health Insurance Portability and Accountability Act. Conclusion: The enhancement and expansion of the RIAM Registry to other referral centres is generating data directly into the REDCap CRF, is a tool with results the treatment of AMI in our environment, which contributes to clinical practice, health services management and policies.

Keywords: acute myocardial infarction; REDCap; research

Introduction

Ischaemic heart disease (IHD) is one of the frequent causes of death in the world, corresponding to between 30 and 50% of the cases.[1] In Brazil, in 2013, acute myocardial infarction (AMI) was the main cause of death among cardiovascular diseases.[2]

In this context, accurate data representative of the real world situation is necessary to help define clinical practice guideline and health policies.[3,4] Because of this, the number of clinical registries, defined as observational datasets including data collected systematically for specified purpose,[5] has increased significantly over the past years.

The American College of Cardiology (ACC) implemented the National Cardiovascular Data Registry (NCDR) in order to measure and improve the quality of care provided to patients with cardiovascular disease, such as AMI.[6] In Brazil, high quality clinical registries are still scarce, especially when considering patients with AMI with ST- segment elevation (STEMI). At our institution, we have a well-established clinical registry (RIAM - *Registro de Infarto Agudo do Miocárdio*) with more the 2,000 thousand patients with STEMI assisted at our hospital. The aim of this project was to expand the database of patients with STEMI of the Cardiology Institute (Porto Alegre-RS, Brazil), within the national territory.

Method and Results

RIAM is a prospective clinical registry which includes patients with STEMI. The Registry RIAM is coordinated by Cardiology Institute of Rio Grande do Sul - University Foundation of Cardiology (IC-FUC) and was expanded to other referral centres in Brazil. The study was conducted between March, 2014 and June, 2016. The five stages of expansion are shown in Figure 1.

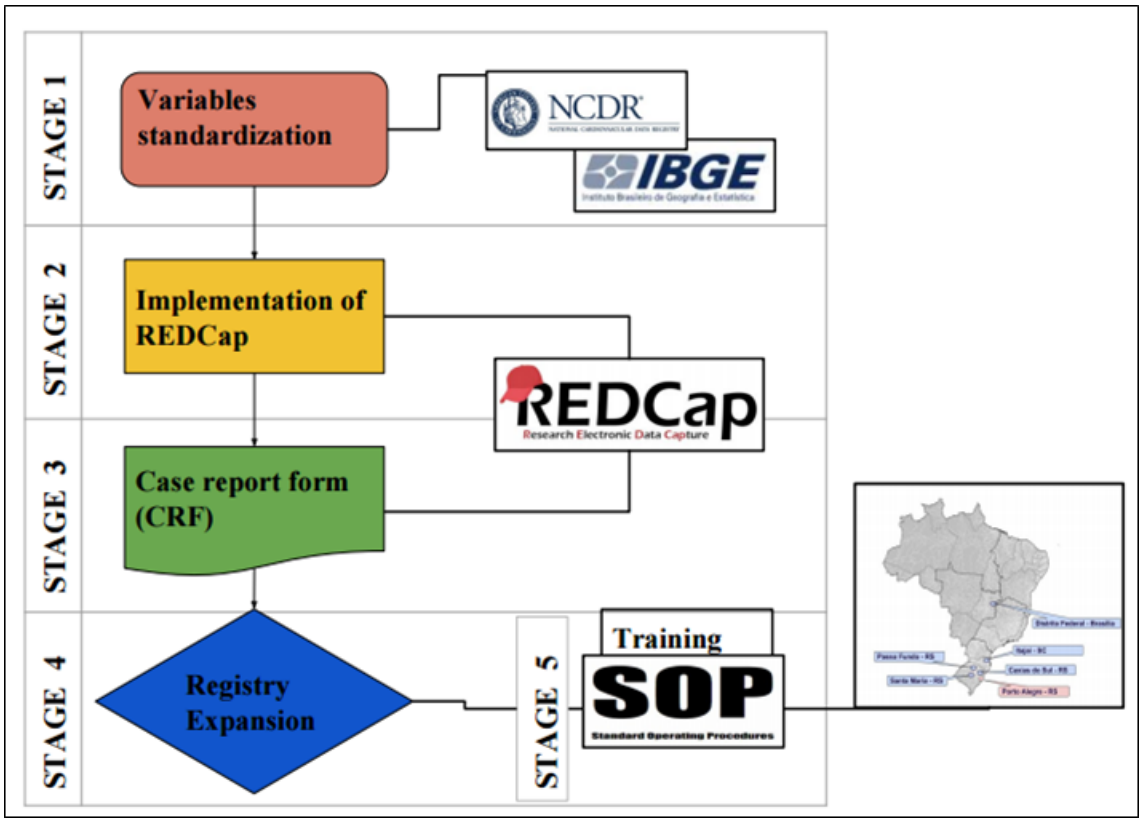

Figure 1. Flowchart of the RIAM Registry expansion.

Variables standardisation

We compared the RIAM variables with standard data elements proposed by the guidelines from the American College of Cardiology (ACC) and American Heart Association (AHA).[7] We evaluated the data elements from the ACTION Registry®-GWTG ™ (quality programme for patients with AMI) - from NCDR, and from the *Instituto Brasileiro de Geografia e Estatística* (IBGE).[8] Table 1 shows some of the variables extracted from the ACTION for comparison with the RIAM variables.

Most of the variables were similar between RIAM and the data elements proposed by the ACC/AHA. Table 2 represents the RIAM classes and number of variables defined.

REDCap implementation

REDCap[9] is available at our institution under a license provided by the Vanderbilt University.[10] The software is recognised for its safety and applicability for clinical data collection and storage and follows the guidelines from the Health Insurance Portability and Accountability Act (HIPAA).[11]

Table 1. Variables extracted from the ACTION for comparison with the RIAM variables.

A. Demographics	**Variable / Field Name**	**Field Label**
Patient ID	patient_ID	Patient identifier number
Birth Date	birth_date	Patient date of birth
Gender	sex	Patient gender
Race	race	Patient race
B. Admission		
Admission Date	admission_date	Patient admission date
Private Insurance Payer	insurance_payer_private	Patient insurance payer
C. Cardiac Status		
Symptom Onset Date	symptom_onset_date	Indicates the date of the first ischaemic symptoms
Heart Failure	heart_failure	Indicates the presence of heart failure
Cardiogenic Shock	cardiogenic_shock	Indicates the presented cardiogenic shock

Case Report Form - CRF

The electronic CRF were developed using REDCap. The steps of the creation of CRF follow the software orientation according to Table 3.

Expansion of the registry

RIAM was expanded and now includes six sites in Rio Grande do Sul, at Porto Alegra, Santa Maria (2), Passo Fundo, Caxias do Sul (1) and one site each at Itajaí in Santa Catarina and Distrito Federal in Brasília. (Figure 2)

Training - SOP (Standard Operating Procedure)

The principal investigator (PI) and their teams received an e-mail with the necessary information to access REDCap, including individual and non transferable username and password, together with an SOP describing the eight steps to access the system and use of the record status and event grid.

Data quality reports

In order to minimise missing data, we defined some variables such that it is not possible to move to the

Table 2. Classes of variables.

Name of the Instrument	Variables Classes	Variables
Demographic Data	Patient ID; date of birth; age; health insurance; level of schooling; race; sex.	6
Contacts	Main telephone number; Second telephone number; Family telephone number; e-mail.	4
Clinical Data - first 24 hours	Symptoms and first service; the beginning of the distress; Precedence; The ECG Data; AMI wall; Vital signs and physical test; Reperfusion and strategy.	18
Medication - first 24 hours	Medications administered.	23
Pre Clinical History	Height; Weight; DM; Smoker; Hypertension; Dyslipidemia; Angina; AMI; PCI; Heart failure; Family historic; Stroke; CABG; Currently on Dialysis; Cancer; Depression; Peripheral Artery Disease; Atrial Fibrillation or Flutter; Cardiac Dispositive.	22
Catetherism and intervention	Cardiac Catheterism and PCI; Angiographic discover; Angioplasty Data; Angiographic Aspects;	34
Lab Datas - hospitalisation	Collection for laboratorial tests; Myocardial lesion Markers.	20
Procedures and complications – Hospitalisation and Discharge	The kind of AMI; Procedures until discharge; Complication until discharge.	26
Discharge hospital data	Death until discharge; Date of the discharge; Period of hospitalization; Medicines in the date of discharge; MACE Hospitalization.	9
Endpoints and segments	Contact Data; Date; Death; The cause of Death; Hospitalization; AMI; Angina; Cardiac Arrest; Stroke; PCI; CABG; Re-stenosis; MACE.	24
ID: identification; ECG: Electrocardiogram; DM: Diabetes Mellitus; PCI: Percutaneous Coronary Intervention; AMI: Acute Myocardial Infarction; MACE: Major Adverse Cardiac Events.		

Table 3. The Steps of the creation of CRF.

Step	Orientations	Conclusion
1	Settings of the main project, setting of CRF respecting to the Project goals.	Concluded
2	The license of modules and CRF customisation with variable insertion.	Concluded
3	Pilot test of CRF with the inclusion of 30 patients; add data in each banking section. The test defined the variables and the time of the banking is fed. As well as the logics and counts. After that reports of quality of the test and the exportation of data to the other systems were generated: Microsoft Excel; SPSS - Statistical Package for the Social Sciences; SAS - Statistical Analysis System e o System R.	Concluded
4	Project status change. After the checking of the last items. The Project had its status changed about production development. The fields of the Project that needs to be approved by the manager of REDCap have not been able to be edited.	Concluded
5	Links to the project were optional. They are not necessary.	Optional
6	Rights and user permissions. Aimed to the user permissions in REDCap. All users were setting to the different permission level, which vary between visualisation and the edition of the project.	Concluded

next CRF page without completing them. We also defined ranges for numerical variables. Data quality reports are run weekly by the coordinating site and sent by email to the other sites.

Ethical Aspects

The study was conducted in accordance with the Brazilian law and the Good Clinical Practice (GCP) guidelines, and was approved by the Institutional Review Board (IRB) of the IC-FUC and was sent to be approved at the included data collection sites.

Conclusion

RIAM has provided important data for several publications, and also for quality of care improvements, education and health policies definitions. The registry has great potential enabling research in the area and development of new technologies and innovation in health.

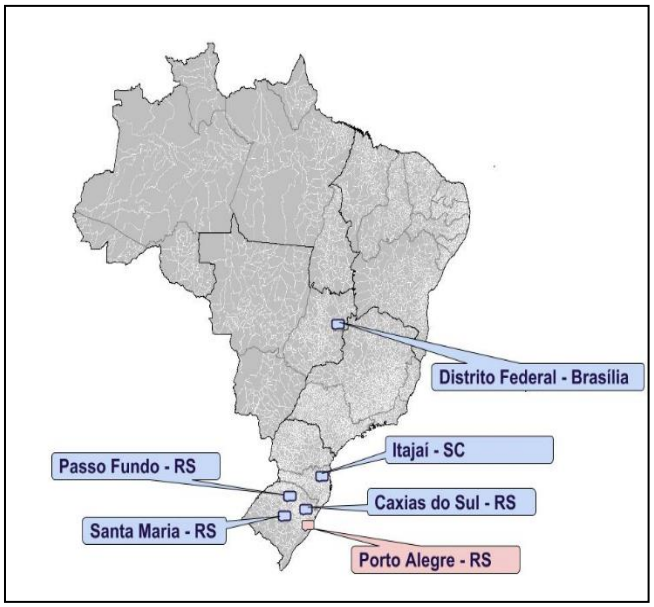

Figure 2. Location of the sites included in the Registry.

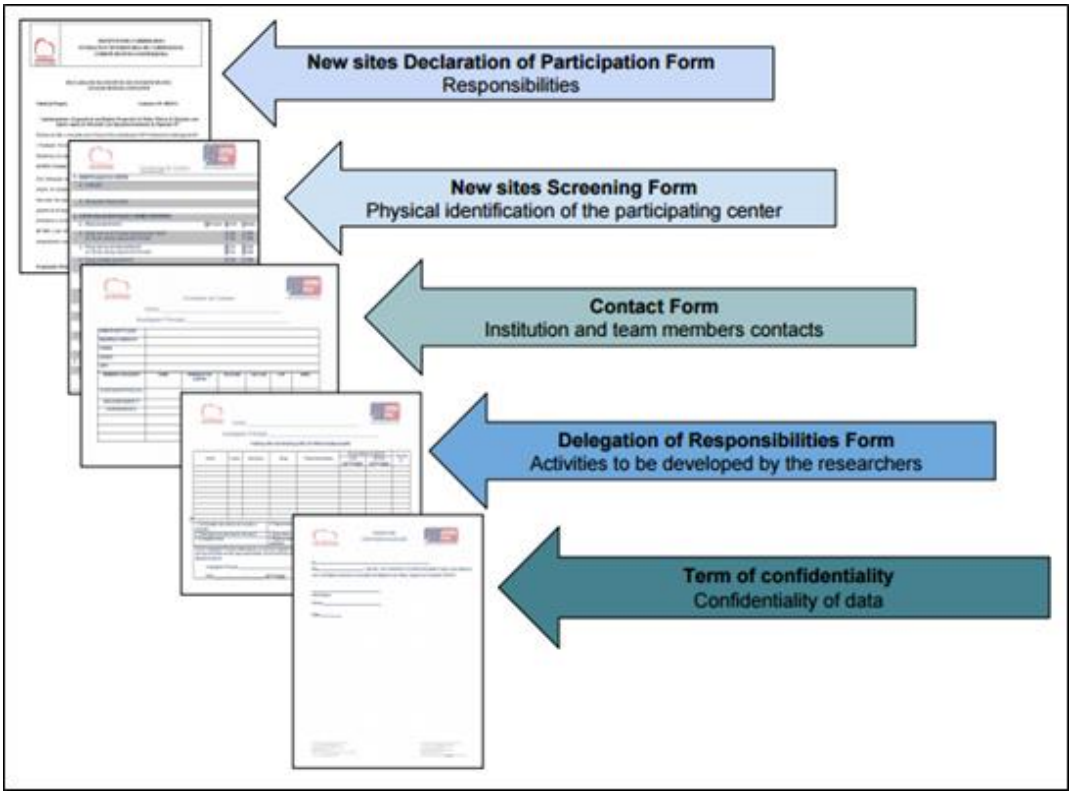

Figure 3. Protocol of RIAM Registry.

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Conflict of interest. The author declares no conflict of interest.

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