

PROSPECTIVE CLINICAL REGISTRY TO EVALUATE CLINICAL OUTCOMES OF HYPERTENSIVE PATIENTS IN A MULTIDISCIPLINARY CLINIC

Michelle Dornelles Santarem MSc^{1,2}, Patricia de Oliveira Dias MSc¹, Suimara Santos MSc^{1,2}, Clarissa Garcia Rodrigues PhD¹, Silvia Goldmeier PhD¹

¹Instituto de Cardiologia do Rio Grande do Sul / Fundação Universitária de Cardiologia, Porte Alegre, Brazil

²Hospital de Clínicas de Porto Alegre, Brazil

Abstract

Introduction: clinical registries are necessary to define public policies for treatment and prevention, by providing highly accurate and interoperable data. **Objective:** to describe the implementation of a prospective, computerised, interoperable and multidisciplinary clinical registry to evaluate the clinical practice and outcomes of hypertensive patients. **Methods:** prospective observational study designed as a clinical registry carried out in a multidisciplinary hypertension clinic, in Brazil. A multi-professional team attends the patients. The database included patients with primary hypertension, above 18 years of age. Patients who had undergone surgery, a stroke, myocardial infarction, or renal failure were excluded. Variables were defined in accordance with national and international variables to allow interoperability. **Results:** the RE-HYPER registry was implemented by following the steps: (1) Data standardisation. The dataset included all applicable standardised data elements published by the American Heart Association / American College of Cardiology, and Brazilian national datasets standards; (2) Development of an initial data collection and clinical research workflow; (3) 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; (4) Pilot testing and validation of the data collection and clinical research workflows and CRFs, and (5) Development of automated data quality report using REDCap. **Discussion:** Due to the magnitude of this disease in the world, this study becomes relevant to clinical practice. **Conclusion:** The study showed reproducible standards and solutions that can be applied in the implementation of health records, allowing data integration between health

and research services.

Keywords: software; hospital outpatient; hypertension; registry

Introduction

According to the 8th US National Guideline of 2014 it is estimated that about 28 million adults live with uncontrolled high blood pressure (HBP) in the world. Previous meta-analysis evaluating the risk of cardiovascular disease, ischemic cardiovascular disease and cerebrovascular accident in pre-hypertensive individuals showed that the risk was higher in those with levels between 130 and 139 or 85 and 89 mmHg than in those with levels between 120 and 129 or 80 and 84 mmHg. These results suggest that a significant proportion of those patients will develop hypertension and its complications.^{1,2}

HBP values, when combined with other risk factors such as smoking, diabetes and dyslipidaemia, are related to a higher incidence of morbidity. Hypertension treatment reduces fatal and non-fatal cardiovascular events and inadequate treatment adherence is related to poor BP control.^{3,4}

Since hypertension is a multifactorial disease, it is recommended that a multi-professional approach be taken to treat HBP patients^{4,5} to promote long term control of risk factors and promote drug and non-drug treatment adherence.^{4,6} Studies providing high quality data to evaluate the multi-professional approach to hypertensive patients in real practice are needed.⁷ In this context, well designed clinical registries may represent a possible solution.

The objective of this study was to develop and implement a clinical, prospective, computerised registry to evaluate the current clinical practice of patients with hypertension in a multidisciplinary outpatient clinic.

Methods and Results

Development and implementation of the RE-Hyper Registry

Research Electronic Data Capture (REDCap) software was available under a license provided by Vanderbilt University.⁸ This software is recognised for its safety and applicability for clinical data collection and storage, and follows Health Insurance Portability and Accountability Act (HIPAA) guidelines.⁹

The process for development and implementation of the RE-Hyper Registry is shown in Figure 1.

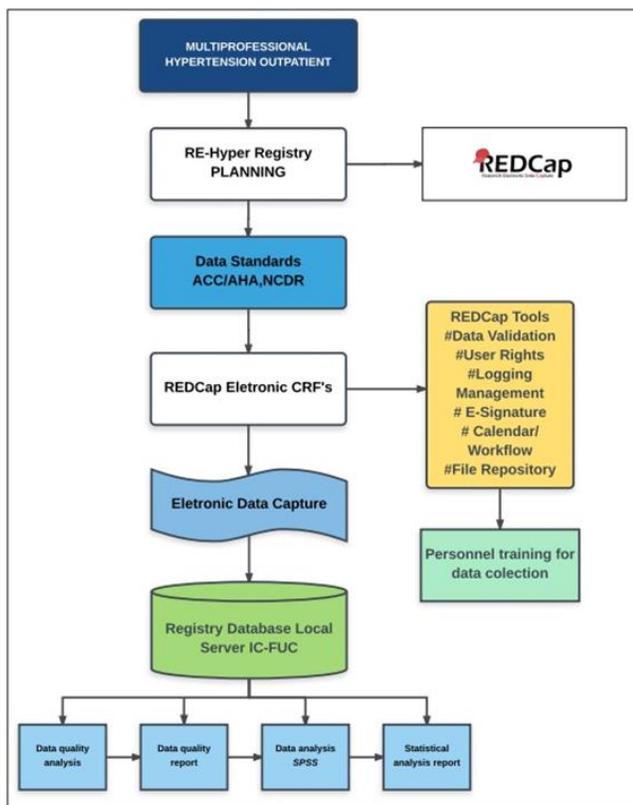


Figure 1. Development and implementation of the RE-Hyper Registry. Legend: ACC/AHA = American College of Cardiology/ American Heart Association; CRF = Case Report Form; NCDR = National Cardiovascular Data Registry; REDCap = Research Electronic Data Capture.

The study population

Patients older than 18 years old, with primary hypertension screened at the IC-FUC cardiology outpatient clinic, other outpatient clinics and basic health units were eligible for inclusion. Patients with secondary hypertension and with incomplete or missing data and / or no possibility of contact were excluded.

Patient follow-up

Patients were evaluated at the first appointment by the cardiologist and the multi-professional team using standardised protocols. Every two months, patients were contacted by telephone to confirm their appointment schedule. At one-year follow up all protocols were re-applied and biochemical tests rescheduled.

Variables standardisation

Definition and standardisation of variables was conducted in accordance with national and international guidelines for databases: Brazilian cardiovascular registries, and the National Cardiovascular Data Registry (NCDR)¹⁰ - PINNACLE (a registry of outpatients with coronary artery disease, hypertension, heart failure and atrial fibrillation). The quality of life questionnaire for hypertension (MINICAL), validated for Brazil, was used.¹¹ Standardisation was performed in English, with an interface in Portuguese to facilitate data collection in Brazil. The BECK depression scale, the Lipp adult stress scale, and the scale of problem-nursing modes were used to standardise the variables related to psychology assessment.¹²⁻¹⁴

The use of established data standards is crucial for the semantic interoperability between information systems, and will become increasingly important with the use of electronic health information systems as they become widely available worldwide.

Data management

The study was coordinated by the Clinical Registries Sector at IC-FUC. Electronic case report forms (CRF) were built using the Research Electronic Data Capture (REDCap) software (Figure 2).

REDCap has an interface with programs for analysing database data. The software also has tools that allow for central checking of data to correct and verify possible inconsistencies in the variable bank, and the software has a calendar where it signals and enables the researcher to schedule reassessments for patients.

Data integrity was facilitated by several steps. Prior to initiation of the study, the multi-professional team was trained to perform the appropriate completion of variables in the RE-Hyper database, reducing data entry errors in the software. Each member of the team had a differentiated level of security access to fill in the variables and to avoid modifying the variables in the original database.

To avoid systematic errors (bias), ranges were defined for numerical variables. The sample was consecutively included, the search was active for these patients to avoid and prevent loss, using partial reports of data quality by the software. REDCap provided a total number of discrepancies found for each rule and allowed the researcher to see these details.

In addition to these measures each user had an electronic signature to identify and allow tracking of all actions. After identifying failures and difficulties related to the insertion of registry data, corrective measures were adopted.

Tracking of the record was performed by means of completion indicators for each step, which indicated which forms were complete and checked, complete and unchecked, or which data were incomplete and empty.

Discussion

The logistics involved in the development and implementation of the Re-Hyper Registry was des-

cribed in this study, including database planning, standardisation of variables recommended by international organizations and adoption of standardised data elements, and automated data quality reports.

Several factors contributed to the successful implementation of the Re-Hyper Registry. Initially a training was offered to the multi-professional team that use the tool. This action ensured the proper use and completion of the database variables in question. At this stage the researchers responsible for the construction of the database assigned different levels of access for each member of the research team for security.

The use of standardised data elements is crucial for the semantic interoperability between information systems, which will become increasingly important with the use of electronic health information system as it is becoming widely available worldwide. Many strategies were used to avoid systematic errors (biases). Ranges for continuous variables were instituted, besides active search for eligible patients

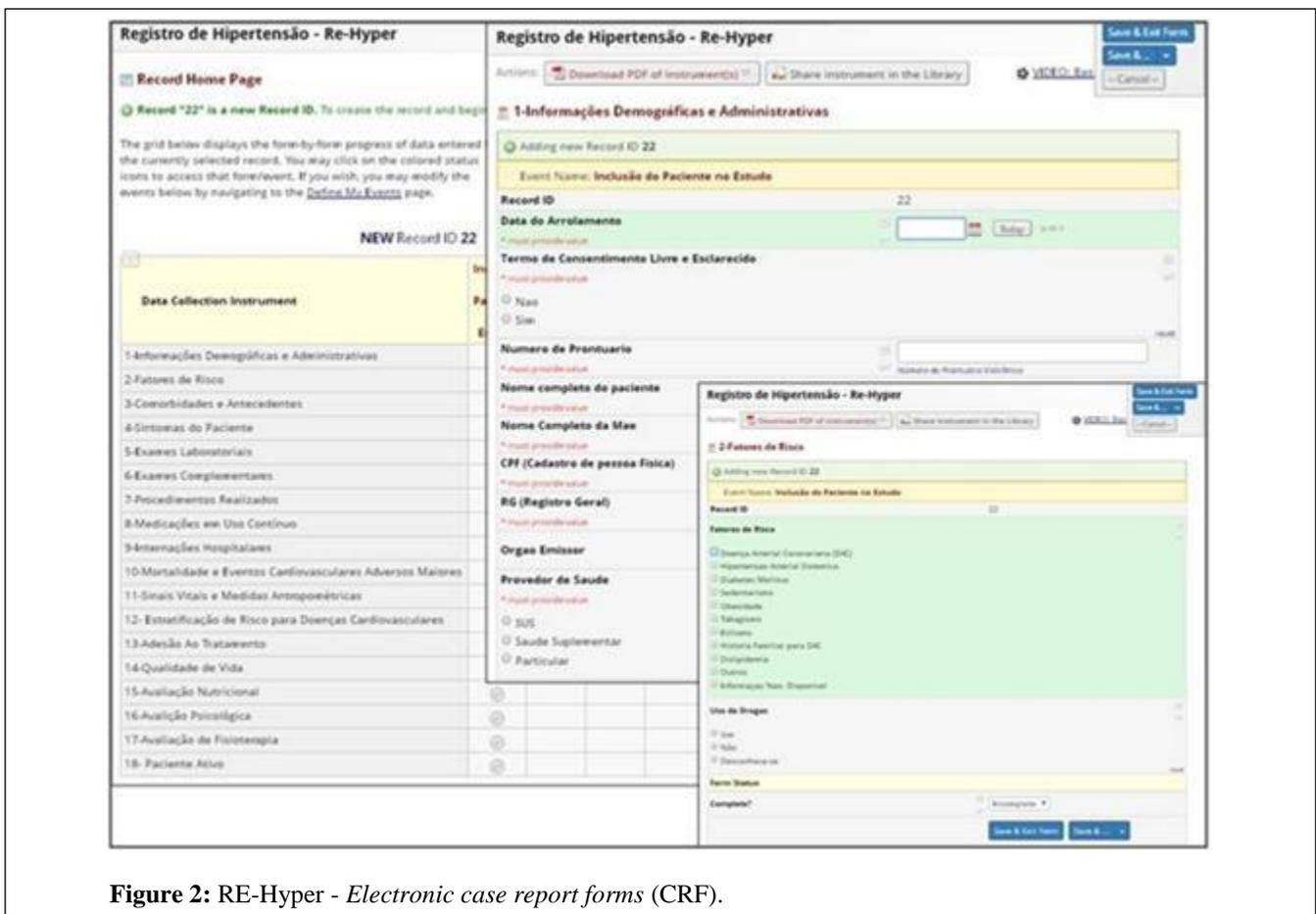


Figure 2: RE-Hyper - Electronic case report forms (CRF).

and consecutive sampling, and regular data quality reports. Our system provides a total number of discrepancies found for each rule and allows the researcher to see these details.

The segment tracking of the record is performed by means of completion indicators of each step, which indicates which forms are complete and checked, complete and unchecked, and which data are incomplete and empty.

Additionally, our system is able to export data in different formats such as Microsoft Excel programs, SPSS Statistical Software, SAS Statistical Software, R Statistical Software, and Stata Statistical Software. This tool enables the central data check to correct and verify possible inconsistencies in the variables. In addition to these tools, the software has a calendar where it signals and enables the researcher to schedule patient follow-ups.

Conclusion

The multidisciplinary team stands out and is distinguished by the development of interactive practices and care integrators, which have been acquiring a differentiated repercussion, both in education and health promotion, as well as in the promotion of policies aimed at the social well-being of families and communities. The recognition of clinical manifestations that may lead to unfavourable outcomes for these individuals is essential as well as the understanding of the pathological process, treatment, use of medications and their adverse effects. The encouragement of the patient's participation in self-care programs and changes in lifestyle favour the understanding of pathology by strengthening adherence to treatment.

Accurate data collection is essential for understanding diseases, as well as for the study of new diagnostic and treatment methods. In this context, the implementation of the RE-Hyper Registry has great potential for defining healthcare practices and policies, as well as enabling health research and development of new technologies and health innovation.

.....

Corresponding author:

Michelle D Santarem
 Avenida Princesa Isabel, 370 – Santana
 CEP: 9620-000 – Porto Alegre (RS), Brasil
 E-mail: michasantarem@cardiologia.org.br

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

References

1. Navar-Boggan AM, Pencina MJ, Williams K, Sniderman AD, Peterson ED. Proportion of US adults affected by the 2014 hypertension guideline. *JAMA* 2014;311(14):1424-1429.
2. James PA, Oparil S, Carter BL, et al. 2014 Evidence-based guideline for the management of high blood pressure in adults: report from the panel members appointed to the Eighth Joint National Committee (JNC 8). *JAMA* 2014; 311(5):507-520.
3. Linked Data. (2014). Connect distributed data across the web. Available at: <http://linkeddata.org> accessed 05 July 2014.
4. 7th Brazilian Guidelines on Hypertension. *Arq Bras Cardiol* 2016;107(3, Suppl 3):1-102.
5. Santos ZMSA, Frota MA, Cruz DM, Netherlands SDO. Adherence of the hypertensive client to the treatment: analysis with an interdisciplinary approach. *Texto Contexto Enferm* 2005;14(3):332-340.
6. Mendes EV. The care of chronic conditions in primary care: the imperative of consolidation of the Family Health Strategy. *Brasília (DF): Organização Pan-Americana da Saúde* (2012).
7. Brazilian Cardiovascular Registries. (2014). Available at: <http://socios.cardiol.br/iephcor/registros.asp> accessed 1 July 2014.
8. Vanderbilt University. (2017). Department of Biomedical Informatics Available at: <https://medschool.vanderbilt.edu/dbmi/redcap> accessed 6 January 2017.
9. Health Insurance Portability and Accountability Act (HIPAA). (2017). Available at: <https://www.hipaa.com/> accessed 6 January 2017.
10. National Cardiovascular Data Registry. (2014). Available at: <https://www.ncdr.com/webncdr/> accessed 1 July 2014.
11. Badia X, Roca-Cusachs A, Dalfó A, et al. MINICHAL Group. Validation of short form of the Spanish hypertension questionnaire (MINICHAL). *Clin Ther* 2002;24(12):2137-2154.
12. Cunha JA. *Manual of the Portuguese version of the Beck Scales*. São Paulo: Brazil: Casa do Psicólogo; 2001.

13. Lipp M. *Lipp Adult Stress Inventory. Inventory Application Manual*. São Paulo: Casa do Psicólogo; 2000.
14. Rodríguez SY, Spiendler, Carlotto MS, Barcinski M. Coping strategies used by psychologists: a gender analysis. *Salud & Sociedad* 2016;6(2):110-119.