Research Article

Portuguese Journal of PUBLIC HEALTH

Port J Public Health 2017;35:126–131
DOI: 10.1159/000479778

Received: November 15, 2016
Accepted: July 6, 2017
Published online: December 18, 2017

RegisPt: Registry of Registries in Portugal – Design, Data Model, and Functionalities

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Keywords
Patient registries · Databases · Epidemiologic studies · Health technology assessment

Abstract
Introduction: The number and quality of existing patient registries are not known in Portugal. In order to improve the knowledge regarding this issue, an interactive tool (RegisPt) was developed to identify and characterize all available patient registries in our country. This article aims to describe the RegisPt design, data model, and due functionalities. ***Methods:*** RegisPt was developed in Microsoft Office Access 2010 and all variables definitions were done according to standardized international classifications. A review of the available literature and web resources was performed in order to identify all relevant patient registries. ***Results:*** The RegisPt platform is divided into 5 core modules containing comprehensive information from each patient registry (general data, registry design, characterization, effectiveness, and publications). Effectiveness is of utmost importance for health technology assessment and is divided into 2 sections: the exposure (health care service, pharmaceutical drugs, and medical devices) and the outcomes (safety, clinical, and economic). The RegisPt platform allows adding and editing registries as well as consulting all available registries in an interactive and user-friendly way, using a preferred query (e.g., registry name, institution, and therapeutic area). About 50 patient registries were identified and characterized in Portugal in accordance with the patient registry definition of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). ***Discussion:*** The RegisPt is a first step to better understand and use the available resources for health research in Portugal. RegisPt can promote collaboration between researchers and registry owners and encourage the efficient use of resources and may improve the access to registries. This project may also be useful to identify therapeutic areas still lacking patient registries and to optimize existing ones in the country, by comparing registry design, quality, and functional strategies. In the future, this valuable platform may be particularly relevant for researchers and authorities aiming to carry out health technology assessment.

RegisPt: registo de registos em Portugal: desenho, modelo de dados e respetivas funcionalidades

Palavras chave
Registo de doentes · Bases de dados · Estudos epidemiológicos · Avaliação de tecnologias da saúde

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Resumo

Introdução: O número e a qualidade dos registos de doentes existentes em Portugal não são inteiramente conhecidos. Com o objetivo de melhorar o conhecimento nesta área, foi desenvolvida uma ferramenta interativa (RegisPt) para identificar e caracterizar todos os registos de doentes disponíveis no nosso país. Este artigo descreve a estrutura e o desenho do RegisPt, o modelo de dados recolhidos e as respetivas funcionalidades. ***Métodos:*** O RegisPt foi desenvolvido em Microsoft Office Access 2010 e todas as definições de variáveis basearam-se em classificações internacionais. Foi realizada uma revisão de literatura para identificar e caracterizar todos os registos de doentes relevantes. ***Resultados:*** A plataforma RegisPt está dividida em cinco módulos principais que contêm informações abrangentes de cada registo de doentes (Dados Gerais, Desenho do Registo, Caracterização, Efetividade e Publicações). Em particular, o módulo de Efetividade é de extrema importância para a Avaliação de Tecnologias em Saúde e está dividido em duas seções principais: Exposição (Serviço de Saúde, Medicamentos e Dispositivos Médicos) e Resultados (Segurança, Outcomes Clínicos e Económicos). A plataforma RegisPt permite adicionar e editar registos, bem como consultar todos os registos disponíveis de forma simples e interativa, através de pesquisas específicas (por exemplo, nome do registo, instituição e área terapêutica). Cerca de 50 registos de doentes foram identificados e caracterizados de acordo com a definição adotada pela International Society for Pharmacoeconomics and Outcomes Research (ISPOR). ***Discussão:*** O RegisPt é um primeiro passo para melhor entender e utilizar os recursos disponíveis para investigação em saúde realizada em Portugal. O RegisPt poderá promover a colaboração entre investigadores e responsáveis de registos, bem como incentivar a utilização eficiente de recursos e melhorar o acesso aos registos já existentes. Este projeto poderá ainda ser útil para identificar áreas terapêuticas com lacuna de registos de doentes e para otimizar aqueles já existentes. No futuro, esta plataforma poderá ser particularmente relevante para investigadores e Autoridades para a eficiente implementação da Avaliação de Tecnologias em Saúde em Portugal.

Introduction

The Portuguese National Health Service (NHS) is currently under high pressure to become more efficient, by treating better with fewer resources. This reality influences policy makers, researchers, and healthcare professionals. It affects the whole decision-making process in the healthcare area and all due allocation of needed resources. Good quality knowledge about disease patterns and potential interventions, such as healthcare technologies, is needed in order to help deciders making reasoned and sustainable decisions about the future of the NHS. Although clinical guidelines and support for decision-making mainly comes from clinical trials and evidence from abroad, the need for knowing our own reality, namely the epidemiologic patterns, and the effectiveness of available policies and interventions is increasing. Moreover, a consensus exists on the general need for greater availability of real world data (RWD) [1].

Registries represent one of the main sources of RWD. The use of registries was initiated in the 1930s in the UK and USA as a means to systematically collect data on cancer patients [2]. In 1949, the term "registry" was defined as a "system of recording frequently used in the general field of public health which serves as a device for the administration of programs concerned with the long-term care, follow-up or observation of individual cases" [3]. Over the last decades, several definitions have been proposed by the World Health Organization and US National Committee on Vital and Health Statistics among other entities [4]. Despite variations in definition, it is clear that a registry involves a long-term, systematic, and organized process of collecting data, which is driven by specific, predefined aims [1]. Nowadays, the US Agency for Healthcare Research and Quality (AHRQ) defines "patient registry" as "an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes" [4]. In line with this definition, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) also has its own definition of "patient registry" [5].

As a direct response to the objective set in Article 14(2) b of the healthcare Directive 2011/24/EU, the Member States and the European Commission created the "PARENT Joint Action", cross-border PAtient REgistries iNiTiative to improve secondary use of data from patient registries in a cross-border setting for both public health

and research needs. To achieve one of their objectives, the PARENT launched an online tool "Registry of Registries (RoR)" available at http://www.parent-ror.eu with the aim of mapping patient registries in the European Union with the purpose of supporting search and identification of available data sources, and exchanging information about national best practices and lessons learnt on patient registries [1].

Other initiatives are also known, including Registry of Patient Registries (RoPR) in the USA. In addition, there are also several other examples such as DoCDat – Directory of clinical databases in the UK [6], Monash Clinical Registries in Australia [7], Health Information and Quality Authority (HIQA) in Ireland, and Sweden Quality Registries in Sweden. Although these international organizations contain comprehensive lists of patient registries, the level of registry characterization varies significantly across the several lists of patient registries.

In Portugal, despite the growing need of RWD, we still do not know exactly the current situation in our country when it comes to patient registries, namely regarding the number, the quality, and the clinical areas already covered. The existence of a searchable public website (or database) designed specifically to provide information about patient registries in Portugal would result in a significant resource for improving the efficiency for our NHS. Essentially, such a database would prevent unnecessary duplication of registries, reduce redundancies, identify gaps in research and epidemiologic data, enable researchers to understand the quality of data within registries, support research collaborations, encourage the efficient use of resources, and improve quality and transparency in observational research. Thus, in an attempt to improve the knowledge of existing patient registries in Portugal, we developed an interactive tool (RegisPt) that identifies and characterizes all available patient registries in Portugal. Ultimately, a registry of registries may be a major contribution to boost evidence-based decisions in our healthcare sector. This article aims to describe the RegisPt design, data model, and due functionalities.

Methods

The RegisPt was developed in several phases.

Phase I

Identification of variables to be included in RegisPt using 2 main guiding documents: "Registries for Evaluating Patient Outcomes: A User's Guide" [4] and "ISPOR Taxonomy of Patient Registries: Classification, Characteristics and Terms" [5].

Phase II

Five core modules were built in order to group all the previously selected variables:

General Data

This module includes the description of the registry, relevant administrative information (e.g., ownership, main scientific contact, website, and institutional address), registry classification (i.e., disease, health technology, health management/health services), and due clinical and therapeutic area. Additionally, this module describes the type of investigators (e.g., physicians, pharmacists, and other healthcare professionals), the type and number of sites involved in the registry, the number of enrolled patients, and relevant milestones, such as the year when the registry started.

Registry Design

This module identifies the data sources used to collect data in the registry (e.g., clinician- and/or patient-reported data), the main purpose (e.g., effectiveness and safety monitoring), and the patients' eligibility criteria. This module also contains information about the frequency and description of the assessments and the type of outcomes that are collected in the registry and identifies the potential research outputs that may be achieved using its data (e.g., persistence studies, burden of illness, and cost-effectiveness analysis).

Characterization

This module is divided into 6 sections. The first section aims to list the socio-demographic variables collected by the registry. The following sections aggregate variables related with quality of life and functional measures, occupational data, lifestyle, healthcare access, and clinical data. All variables may be characterized in accordance with the moment of data collection (i.e., baseline and follow-up).

Effectiveness

This module is divided into 2 sections. The exposure section aims to characterize the variables related with the healthcare intervention (i.e., healthcare service, pharmaceutical drugs, and medical devices). Pharmaceutical drugs and medical devices may be selected from predefined lists imported from INFARMED's databases (https://www.infarmed.pt/infomed/inicio.php and https://app.infarmed.pt/dec_hosp/pages/cdmpublic.aspx), which contain relevant information already filled in line with standardized classifications (e.g., drug substance, brand name, dosage form, strength, marketing authorization holder, medical device code, and manufacturer). The outcomes section aims to characterize the variables related with the potential outcomes that might be analyzed following an intervention collected in a given registry, encompassing safety, effectiveness (e.g., surrogate markers and prespecified hard clinical endpoints), and economic outcomes (e.g., healthcare resource utilization and productivity losses).

Publications

This module aims to list all scientific publications related with information retrieved from the registry.

Phase III

Development and testing of the RegisPt IT platform using Microsoft Office Access 2010.

Phase IV

Identification and characterization of all available Portuguese patient registries. A review of available literature and web resources was performed in order to identify and characterize all patient registries taking into consideration the variables selected in RegisPt. The adopted criteria used for the inclusion of registries in the RegisPt was the patient registry definition of ISPOR, which defines a "patient registry" as "a prospective observational study of patients, sharing some common characteristics over time, which collects ongoing and supporting data on well-defined outcomes of interest for analysis and reporting" [5]. There were no further criteria applied in the selection of patient registries.

Phase V

In order to gather sustainable support from other relevant entities, important partnerships were created with the following institutions: Fundação Calouste Gulbenkian, Escola Nacional de Saúde Pública, Instituto Nacional Ricardo Jorge and Capítulo Português do ISPOR. A Scientific Committee was established with representatives of each partner, which will be responsible for the overall strategy, oversight, and governance of the RegisPt.

Phase VI

Systematic contact, validation, and further data input by the respective registries' owners in order to complete and validate the RegisPt database (this phase is still ongoing).

Results

Over 50 patient registries were identified in Portugal according with the above-mentioned definition of ISPOR. Furthermore, during the development and early implementation of RegisPt, about 60 other epidemiological databases were found, which fell outside this definition. These databases were also listed and characterized in their own repository, labeled "other databases" defined as "other records/databases not fulfilling the patient registry definition of ISPOR."

The RegisPt platform allows the addition of new registries and the edition of any already listed, without any access to specific patient's data. It also allows an interactive and user-friendly search, using a preferred query (e.g., registry name, institution, and therapeutic area). Navigation through each of the selected registries is simple and straightforward. Editing of the RegisPt platform is restricted to register users with due privileges previously granted by the RegisPt Scientific Committee. The system is prepared to set different levels of user privileges (from read-only to administrator rights). All addition or editing actions done in the RegisPt platform are subject to prior approval and are automatically notified to the Scientific Committee through an e-mail with the details of performed additions/edits. This Committee is responsible for approving or declining any proposed addition/editing done in the system.

RegisPt has a track record system in place allowing the Scientific Committee and the system's administrators to have access to the database administration module, where they can view all past editing performed in the RegisPt and all decisions that were performed since the beginning of the RegisPt (see online suppl. Fig. 1; see www.karger.com/doi/10.1159/000479778 for all online suppl. material).

Discussion

The number of existing patient registries and their area of intervention are not known in Portugal. RegisPt consist in an interactive platform that aims to identify and characterize all available patient registries in the country. This initiative is an ongoing project and until now, we have identified and characterized about 50 patient registries and 60 other databases.

RegisPt may promote collaboration between researchers and registry owners, encourage the efficient use of resources, reduce redundancy, improve the transparency in registry-based research, and facilitate the access to information about registries as well as the overall quality of clinical records in Portugal. This project may also be useful to identify therapeutic areas still lacking patient registries, to discourage initiatives aiming to collect evidence already covered by other registries, and to optimize existing ones, while making a critical contribution in making better decisions in public health.

The importance of projects like RegisPt and others at the European level have already been recognized by researchers, policy makers, and other stakeholders, namely to support health technology assessment (HTA) [1, 8]. HTA and particularly health economic evaluations can be useful tools to help prioritizing new interventions, because they illustrate the costs and health outcomes associated with the different interventions [9]. In a time of economic constraints, not all new interventions that are effective may be introduced and/or maintained in the healthcare systems. Therefore, reliable tools that help this sort of analytical methods and decisions are of paramount importance.

Traditionally, the HTA depends on data generated by randomized controlled trials and literature reviews on the subject. Although they are considered as a "gold standard" in clinical efficacy, these studies have some limitations. Typically, they are conducted during a short peri-

od of time, in a well-defined population with the aim of establishing clinical efficacy and safety, with specific inclusion and exclusion criteria, and under almost "laboratory-like" conditions [10]. Due to these methodological characteristics, their results cannot be extrapolated to uncontrolled environments as the real clinical practice [10].

In HTA, data from registries may serve as a source of real-world evidence about the "effectiveness" of treatments. Hence, it is clear that data from patient registries can supplement the data from randomized controlled trials, because it allows having a more realistic view of the true impact of a given treatment in the population (i.e., real-world treatment effect) [10]. The use of patient registries has several potentialities, such as to observe the clinical course of a disease, to illustrate practice patterns and variations of them, to determine clinical effectiveness and/or cost-effectiveness, to assess safety or harm, to explore humanistic outcomes, including health-related quality of life and other patient-reported outcomes, and to track economic data, namely resource utilization [8].

Portugal is no exception to the global resources scarcity scenario and the reinforced need to take into account the sustainability of the NHS. This situation has led to the new HTA system implemented in our country, called "Sistema Nacional de Avaliação de Tecnologias de Saúde" (SiNATS), which introduced substantial changes in the previous model of technology assessment in health. The SiNATS main objectives are to maximize health gains and the quality of life of the citizens, to contribute to sustainability of the NHS, to guarantee efficient use of public resources in health, to monitor the use and technologies, to reduce waste and inefficiencies, to promote and reward relevant innovation development, and to promote equitable access to technologies [11].

Among several important changes to the old model, this new system introduces a reassessment of technologies (ex post evaluation), based on effectiveness monitoring on patient registries, showing a paradigm change in the HTA setting in Portugal. Within this new system, an information system for HTA (SiATS – Sistema de Informação para a Avaliação das Tecnologias de Saúde) was initiated that aims to monitor all data sources and existing patient registries that may support the assessments of new products in the future. SiATS will prioritize the following patient registries at a national level: (1) oncology (national oncologic registry), (2) HIV/AIDS, (3) rare diseases/orphan products, (4) medical devices (cardiology), and (5) hepatitis C (already in use) [11].

In Portugal, the current situation about existing patient registries is unknown. Within the framework of this new national HTA system and taking into account the need of patient registries as data source for reassessment of new technologies in the market, the RegisPt can be viewed as an useful tool for the activity of SiNATS and be used as a starting point for the much needed discussion regarding the availability of data sources for the execution of their aims. Arguably, RegisPt might be a valuable resource for SiNATS. Overall, by increasing the public knowledge of patient registries, RegisPt may contribute to accelerating the most needed evidence-based decisions in our healthcare sector.

Future Perspectives

Despite the potential benefits of patient registries, there are some limitations that need to be highlighted, which in turn influence its utilization as a primary data source for reassessment of technologies, clinical research, clinical audit, or planning and management of clinical services. The use of registries is not only conditioned by the lack of knowledge about their existence/availability and by the coverage they have, but also by the quality of data included in the registry. To our knowledge, there are no established guidelines at the international level setting criteria and quality measures of patient registries. Nevertheless, some quality assessment checklists have already been developed, for instance in the UK [6], by other initiatives similar to RegisPt based on the approach used to develop CONSORT [12], the checklist assessing the quality of randomized trials. Due to the need of high-quality registries, governmental agencies such as the Agency for Healthcare Research and Quality [4] or international societies such as ISPOR [5] among others have prepared and published dossiers to guide healthcare organizations towards planning and implementation of new registries. On this regard, the RegisPt Scientific Committee will try to develop a quality assessment checklist based on the available literature and in the experience of similar projects. This checklist might then be applied to all registries included in our database. Finally, RegisPt will be soon accessible to the scientific community and the general public through a public website that will allow any user to consult all patient registries identified in Portugal and to view all variables collected by each registry. This may highlight the therapeutic areas still needing to be covered by a patient registry and might also help to raise the current quality standards for the ongoing registries, not only

in terms of the quality of data being collected and registered, but also regarding the interconnectivity within the established registries and with other databases, such as the hospital and death records, which is undoubtedly an area to improve in our country.

Acknowledgements

We would like to acknowledge Paulo Nicola for the critical revision of this article.

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