Available online at **www.ijmrhs.com**

ISSN No: 2319-5886

International Journal of Medical Research & Health Sciences, 2016, 5, 4:22-26

Good practices in the conduct of a patient registry

Manu Somanath, Anup Nair, Rituraj Mohanty, Uttam Barick, Arun Gowda and Anand Patil

Focus Scientific Research Centre (FSRC), part of phamax Analytic Resources Private Limited, #19 KMJ Ascend, 1st Cross, 17th C Main, 5th Block, Koramangala, Bangalore, Karnataka, India – 560095

Corresponding e-mail:manu.somanath@fs-researchcenter.com

ABSTRACT

A patient registry is defined as "a structured system that practices observational study methods to collect constant data (clinical and other) to evaluate detailed outcomes for a population defined by a particular disease, condition or exposure, and that serve one or more predetermined scientific, clinical, or policy purposes"[1]. The data derived from patient registries can provide a real-world view of clinical practice, patient outcomes, safety, and comparative effectiveness [2]. This article highlights the good practices that are essential to the design and conduct of patient registries. To provide a brief insight on the good practices to conduct patient registries. The key aspects to be considered when conducting a registry are accessibility, set up of the right research questions and maintaining the confidentiality and transparency of patient data. A patient registry must be conducted without affecting the ethical rights of the patients.

Keywords: Patient Registry, Case Control, Cohort, Cross- Sectional, Informed Consent Form (ICF), Case Report Form (CRF).

INTRODUCTION

A patient registry is defined 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 a predetermined scientific, clinical, or policy purpose(s)." In brief, a patient registry is a collection for one or more purposes—of standardized information about a group of patients who share a condition or experience[3]. Registries are observational in nature and provide a real-world view of clinical practice, patient outcomes, safety, and comparative effectiveness[2]. Effectiveness is measured in patient registry studies and efficacy is measured in clinical studies. Effectiveness refers to how well a device/drug performs in the general population. Thus, it is imperative that a patient registry is designed and conducted properly to achieve specific study outcome.

MATERIALS AND METHODS

The key factors that must be focused upon when planning, designing and conducting patient registries are[4]:

1.Increase accessibility to patient registries: A research is often designed by researchers, but the involvement of other stakeholders such as patients, providers or payers dictate need to ensure that the study design does not change the treatment patterns and patient outcomes. The eligibility criteria must be broad so that a large group of patients can be included to generalize the results.

2. Design the study with essential questions: The study should be designed with end-user of the product/research in mind. The research questions should be designed by identifying the gaps in the evidence available, as per the purpose of the registry, the target population and the standard treatment patterns.
3. Transparency of data: The data collected from a registry (either paper or electronic tools) must be transparent and reliable without affecting the confidentiality of the patient.

Stakeholder's requirement:
Each project has certain aims, expectations and requirements. Some of them are:

- Address data gaps
- Access feedback from payers and patients
- Provide maximum treatment safety and effectiveness
- Provide reduced treatment cost
- Understand the safety patterns
- Improve the quality of life of the patients

Adequate efforts should be made to safeguard the interest and concerns of the sponsor during the planning phase.

The processes in patient registry are:

Design of the protocol:
Patient registries are categorized under analytic study designs and are further sub-classified as observational or experimental study designs[5]. There are three types of observational studies, cohort, case-control, and cross-sectional studies[6]. Case-control and cohort studies offer specific advantages by measuring the occurrence of a disease and its association with an exposure by proposing a temporal dimension (i.e. prospective or retrospective study design). Cross-sectional studies, also known as prevalence studies, examine disease and the related exposure at a particular point of time. The conventional study models of case- control, cohort and cross sectional studies are commonly applied to data derived from registries to facilitate examination of questions that arise. It is also important to define the background that will be used to analyse the data to design the registry and collect registry data. Also crucial to the success of a registry is the identification of an ideal study design that answers the research question effectively and that can be used as evidence in decision making.

Identification and selection of sites/centers:
The quality of the hospital prescribed for the study is mandatory to ensure its efficacy. The hospital participating in the study gains recognition as a centre of excellence. The following must be considered when filtering a hospital for the study that adheres to all quality requirements[8]:

- Identify eligible hospitals from the available hospital database
- Utilize sponsor to identify potentially interested hospitals
- Register hospital through physicians who work there and are interested in registry
- Reach out to physician contacts or hospital administrators through relevant professional societies or hospital associations
- Check for the required facilities at the site
- Availability of support team
- Feasible travel facilities
- Availability of a registered Institutional Ethics Committee
- Relevant certifications (ISO, NABL accreditations etc.)

Identification and selection of physicians:
Identification and selection of well qualified physicians by education, training and experience is very essential for the successful completion of registry. The physician selection criteria include several factors which can also be provided by the sponsors based on their experience with the physicians[8].

The factors that can be considered to select physicians are[7, 8]:

- Qualification of the physician
- Experience in conducting registries
- Facilities available to conduct the registry
- Availability of support staff
- Previous experience with the sponsor
- Patient pool

Methods of physician selection:

- Partner with local site management organizations (SMO)
- Ask the physicians in the field to suggest interested colleagues
- Recruit and raise awareness at conferences or health check-up camps

Participating in registry studies often provide significant benefit to the practicing physician/patient, transparency and confidentiality of patient's record[8].

Patient recruitment:
Patient recruitment is a challenge if it is not planned accordingly during the planning stage. All technical and logistic problems must be forecasted during planning stage. A frequent re-evaluation may lead to a failure to maintain the desired goals. Patients can be recruited based on the judgement of the physician who provides care[9].

Recruitment of patients by a physician who provides their care is one of the most successful strategies. Physician participation and support in the patient registries encourages the patient to participate in the registry studies. Since registries should not modify the usual care that physician provide to their patients, there should be little or no conflict between the role of the physician in a research program.

Methods of patient recruitment:
- Recruit through the physician who is caring for the patient
- Communicate to the patient that registry participation may help to improve care for all future patients with the target condition
- Write all patient materials (brochures, consent forms) in a manner that is easily understandable by a layman
- Keep the survey forms short and simple
- Provide the status and progress of the study on monthly basis (such as newsletters, reports, leaflets etc.)

The procedural concerns mentioned in informed consent form (ICF) must be considered when developing a recruitment plan for a registry. These concerns should clarify on the risks and benefits, the study design and methods, the approval and confidentiality of data. The ICF should clearly explain the registry policy regarding any necessary approvals. Patient related documents must be offered to the participants for their assistance.

Lastly, confidentiality is a key requirement. Methods of ensuring institutional, physician and patient confidentiality needs to be clearly explained in all registry-related documentation.

Patient identification methods:
Site staff related to the study can simplify the process to identify and track patients for follow up. They can also help to design a process to identify lost to follow up patients[10].

There are also potential barriers to be considered. The intention of a registry is generally for all the patients to remain in the study until the planned follow up is completed. Planning for patients to leave the study before the completion of the full follow up may lead to analysis problems.

To retain the patient and to follow up with the patients throughout the study following parameters are to be collected during the process of the study[8, 10].

Pre-enrolment history: Collecting the patient enrolment history aids a good relationship with the patients with insights into their diseases and provide counselling when required. Information such as:
- Medical history
- Treatment history
- Medications
- Health care resources utilization
- Diagnostic tests and results
- Procedures and outcomes
- Emergency room visits, hospitalizations (including length of stay), long term care etc.

Patient details
- Functional status (including ability to perform tasks related to daily living), quality of life, systems etc.
- Health behaviours (alcohol, tobacco use, physical activity, diet etc.)
- Social history
- Economic status, income, living situation
- Address, telephone number, contact information of relatives and neighbours job location and address
- Individual understanding of medical conditions and the risks and benefits of interventions

Financial/economics information

- Health care utilization behaviour, including outpatient visits, hospitalizations (including length of stay) and visits to the emergency room or urgent care
- Patient assessments of the degree to which they avoid health care because of costs
- Patients insurance cover
- Destination when discharged from a hospitalization (home, skilled nursing facility, long term care etc.)[8]

Data collection:

It is important to consider the registry's purpose and the target population when designing a patient registry as it affect the type of data, source(s) of data, and the manner in which it is collected. A data dictionary defining the specific data elements to be collected is a key to ensure the quality of the registry[8]. The compliance of physicians and patients who provide the registry data is instrumental to data collection and should be addressed early[8].

The three sets of documents which constitute data collection are as follows[2,8].

1. Case report forms (either paper or electronic forms): Data is gathered and entered into coded fields and transmitted to a data management centre
2. Data dictionary: It contains a detailed explanation of how each variable is used in the registry. For example, the question may be "Do you smoke?" (which can be defined has period of tobacco smoked within the previous year)
3. Data validation rules: These are logical checks on the data for discrepancies e.g. males taking birth control pills

A data management manual should be developed to define the:

- Project objective
- Type of data entry
- Specifications of data processing
- Design attributes
- Types of query
- Methods to generate and answer the queries
- Responsibilities of people handling the data
- Quality assurance of data

Patient retention:

Once hospitals and physicians are recruited into registries and patients are enrolled in the study, retaining these patients becomes a key to success. By carefully pilot testing all aspects of the registry prior to the full recruitment, there is less possibility that there will be problems that threatens the reputation of the registry. Patient retention tools used to retain the patients include[8]:

- Newsletters/instruction manuals: For updates on the study
- Telephone help lines: To support the patients
- Site audit/retraining visits: To assure the quality of the data
- Customers satisfaction/opinion surveys: To get the feedback from the patients in the study
- Arrange presentations at conferences/training meetings with patients: To get the feedback from the patients in the study
- Publications of registry studies: For transparency of the data

DISCUSSION

Registries are an ideal way to collect the broad surveillance data required, because in certain circumstances FDA may require a post-approval study under Section 522 of the Food, Drug, and Cosmetic Act[11]. Generating patient registry requires the right data, the appropriate tools and the methods to structure and interrogate it, and grounded science to turn it into actionable insights and engage sponsors appropriately. This report outlines the good practices to conduct registries which can minimize and avoid the potential difficulties at different stages.

CONCLUSION

The key aspects to focus upon are accessibility, set up the right research question and maintain the confidentiality and transparency of the patient data while conducting a registry. A registry mostly focuses on a larger group of population without stringent eligibility criteria. This is to increase the accessibility of the patients towards the available treatments. The goals of minimal process involved are to minimize the initial drawbacks in registries and help to identify and select outcomes that are study specific. The process described in the article ensures the

transparency of data for all the stakeholders and end-users. If the design of the study is understood by all the stakeholders the use of registries will be assessable to large populations with better results.

Acknowledgment
The authors would like to acknowledge the efforts of Nidish Narayanan, Senior Editor at phamax and Anto Vijaykanth, Clinical Research Associate at focus scientific research center (FSRC) for supporting us to develop this article.

REFERENCES

[1] Gliklich R. Standards in the Conduct of Registry Studies for Patient-Centered Outcomes Research [Internet]. 1st ed. 2016 [cited 7 April 2016]. Available from:http://www.pcori.org/assets/Standards-in-the-Conduct-of-Registry-Studies-for-Patient-Centered-Outcomes-Research1.pdf
[2] Gliklich R, Dreyer N. User's guide to registries evaluating patient outcomes. Rockville, Md.: Agency for Healthcare Research and Quality; 2007
[3] Workman TA. Engaging Patients in Information Sharing and Data Collection: The Role of Patient-Powered Registries and Research Networks. AHRQ Community Forum White Paper. AHRQ Publication No. 13-EHC124-EF. Rockville, MD: Agency for Healthcare Research and Quality; September 2013
[4] Npcnow.org. Real-World Evidence | National Pharmaceutical Council [Internet]. 2015 [cited 4 December 2015]. Available from: http://www.npcnow.org/issue/real-world-evidence
[5] Song J, Chung K. Observational Studies: Cohort and Case-Control Studies. Plastic and Reconstructive Surgery. 2010;126(6):2234-2242
[6] Guidelines for good pharmacoepidemiology practice (GPP). Pharmacoepidemiology and Drug Safety. 2015
[7] Hutchinson D. ICH GCP guidelines
[8] Gliklich R, Dreyer N. User's guide to registries evaluating patient outcomes. Rockville, Md.: Agency for Healthcare Research and Quality; 2014 (3rd EDITION).
[9] Stark N. Registry Studies: Why and How - CDG Whitepapers [Internet]. Clinicaldevice.typepad.com. 2011 [cited 3 December 2015]. Available from: http://clinicaldevice.typepad.com/cdg_whitepapers/2011/07/registry-studies-why-and-how.html
[10] AchilleasThoma M. How to optimize patient recruitment. Canadian Journal of Surgery [Internet]. 2010 [cited 4 December 2015];53(3):205. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2878987/
[11] Food, Drug, and Cosmetic Act, Section 522 Postmarket Surveillance