Developing a Patient Registry: **A Practical Guide**

Dr Michelle Gardner
Research Manager
Medical Research Charities Group, Ireland

Dr Abaigeal Jackson
Research Lead,
Cystic Fibrosis Registry of Ireland

medical research charities group
Unity is our Strength

Published 2018

Acknowledgements

We are deeply grateful to the experts who so generously gave their time and shared their knowledge at our registries workshop. They are:

Dr Abaigeal Jackson, Cystic Fibrosis Registry of Ireland

Godfrey Fletcher, Cystic Fibrosis Registry of Ireland

Dr Conan Donnelly, National Cancer Registry Ireland

Professor Anthony O'Regan, Interstitual Lung Disease Registry

Harriet Doig, MS Ireland

Dr Laura Brady, Fighting Blindness

Dr Sinead Hickey, DEBRA Ireland

A particular note of thanks to Godfrey Fletcher whose vision for the future of registries we have borrowed heavily from.

We would also like to thank the Directors of the MRCG, especially our very committed Chairperson and strong advocate of patient registries, Philip Watt.

Published by:
The Medical Research Charities Group (MRCG)
Digital Office Centre, 12 Camden Row, Dublin 8
Telephone: 353 1 479 3234

Company Number: 377794
Charity Number: CHY 15386

THE MRCG IS SUPPORTED BY

pobal
government supporting communities

An Roinn Tithíochta, Pleanála, Pobail agus Rialtais Áitiúil
Department of Housing, Planning, Community and Local Government

HRB Health Research Board

Contents

Foreword

Patient registries are broadly recognised as a critical underpinning for improving healthcare through research. As an umbrella organisation for many medical research charities intimately involved in this pursuit, registries are a reoccurring theme. Despite their importance however, in too many cases, registries remain a thing of the future.

The challenges to developing registries are large but getting less, as technology develops and expertise is shared. However, practical and simple guidance on registry development is still very limited. With this in mind, we organised a workshop, entitled 'The Nuts and Bolts of Patient Registries', for our member charities and other guests in April 2018. The aim of the workshop was to facilitate jargon-free, practical discussion on all aspects of registry development and management. Emerging from the workshop and our work in the area of registries is this guide. It has been written with patient organisations foremost in mind but should be much more widely useful.

We have brought together the views of those at the workshop to shape a vision for registries in Ireland, central to which is to establish a National Federation of Registries. The final section outlines this vision in more detail.

We are delighted that Dr Abaigeal Jackson, of the Cystic Fibrosis Registry of Ireland, has partnered with us in writing the guide. Abaigeal brings a rich experience of registries that is evident throughout. We are also extremely grateful to the other presenters at the workshop, whose expertise we have drawn heavily on. Please see the acknowledgements section for their details.

Embarking on the development of a new registry can be overwhelming but, remember, no-one person can hold all the knowledge and expertise required. Reach out to others who have done it before, involve the range of experts you need and take it step-by-step. The enormous value that a registry can add to patients' lives will make it all worthwhile.

Dr Avril Kennan
CEO, Medical Research Charities Group (MRCG)


Dr Avril Kennan


Dr Michelle Gardner


Dr Abaigeal Jackson

Introduction

Information from people's health records or 'patient data' is vital for individual care, but also for improving the health, care and services of the population. The need for patient registries arises from a desire to have accurate, valid, reliable and timely information about a particular patient group or condition. Although examples of good practice exist, the current health information technology infrastructure in Ireland is highly fragmented with major gaps and silos of data. Difficulties associated with bringing data together from different sources makes informed decision-making a challenge for those planning health and social services.[1]

A patient registry is defined as "an organised system that uses an observational study method 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."[2] Information captured by patient registries can facilitate research, accurate reporting for health service planning and management, and monitoring and improvement of treatment and care of affected individuals.

Despite patient registries being recognised as a valuable approach to capturing patient data and a way of contributing to improvement in health and social care, there were just 75 national data collections recorded in Ireland in 2017[1]. The complexity of establishing and sustaining a patient registry, as well as the voluntary nature of operating an independently owned and governed not-for-profit organisation, renders registry development a challenging pursuit. Considerable time, effort and resources are invested into establishing and operating high-quality patient registries. There is no one size fits all solution to many of the common questions and concerns faced by those embarking on their journey to develop a patient registry. Experts in this area are few and far between, and underfunding of health information solutions can be a problem.

On April 9th 2018, a group of experts and parties interested in patient registries were invited to an MRCG workshop, entitled 'The Nuts and Bolts of Patient Registries'. This report outlines the key themes and issues identified during the workshop as being pertinent to the establishment and development of patient registries in Ireland. Topics covered in this brief guide to patient registries include; getting started with registry development, data collection, registry software considerations, data management, storage and security, funding, governance and sustainability.

1. Health and Information Quality Authority, 2017 'Catalogue of National Health and Social Care Data Collections' https://www.hiqa.ie/reports-and-publications/health-information/catalogue-national-health-and-social-care-data

2. Gliklich, RE & Dreyer NA, 3rd edition 2014 'Registries for Evaluating Patient Outcomes' https://www.ncbi.nlm.nih.gov/books/NBK208616/

Identifying your registry's aim and objectives

Establishing a registry requires clarity of thought around the specific aims & objectives of the registry. This information will guide the selection of data elements you will seek to collect. Examples of ways in which patient data can be used to improve health and care of the population include:[3]

- improving diagnosis (examine effectiveness of screening).
- treatment and prevention (identifying patients for clinical trials, real world evidence of treatment).
- patient safety (monitoring safety of vaccines, devices).
- planning health services (prevalence estimation).
- evaluating policy (international rate comparison, showing impact of health promotion activities).
- understanding disease (identify risk groups).
- individual care (all team have up to date information, help people manage their condition).

Defining your registry dataset

The selection of registry data should be confined to routinely recorded, reproducible, objective data. Gathering data is time consuming and labour intensive, so avoid the collection of superfluous data. Select defined health outcomes that are systematically measured at predefined intervals. Aim to capture measures that are standardised among national hospitals and/or comparable with other relevant datasets and/or international registries if possible, to facilitate potential future integration or comparison. A useful approach can be identifying data elements that are mandatory (a core dataset) and data elements that are optional (nice to have, but not essential). It is always better to have a minimal, well completed dataset than one with lots of gaps, or with questionable data quality. Expansion of the registry dataset can always occur later.

Define your data collection interval – do you want to record measures from every hospital encounter or do you want one measure per year. Patients with certain chronic conditions, for example, may require annual assessment, which provides an opportunity to capture variables at yearly intervals.

In a registry database containing hundreds or thousands patient records, having patient identifiable information linked to each health outcome is important. It allows an individual's outcomes to be followed over the course of their lifetime. The development of registry patient portals, providing the opportunity for patients to view their own registry records, also requires the ability to distinguish an individual's registry record from all other participants' records.

3. www.understandingpatientdata.org.uk

Registry data should adequately describe the patient's condition & major co-morbidities, using clinical outcome measures captured by healthcare professionals. Prognostic information, such as date of death, should also be collected. Health interventions and other patient interactions with health and social care services should be recorded as needed e.g. hospitalisation, medication. Knowing why health outcomes vary across a defined patient population can be difficult, but it might be important to capture genetic, environmental, social, economic and other relevant factors that may have a bearing on patient outcome.

Patient involvement is valuable. Patients and their representatives should be engaged from the beginning of the process of defining a registry dataset, to ensure that the registry addresses patient needs. Patients are uniquely positioned to provide insights about the impact of the condition/disease on their life, and identify the factors which are most pertinent, such as quality of life or socio-economic status. The capture of such patient-centred outcome measures (PCOMs) by registries can be challenging, as this information is not typically documented in records traditionally examined for registry data capture i.e. hospital charts. In registries for life-limiting conditions, markers of patient-reported quality of life are occasionally captured, such as educational attainment, independent living, and pregnancy. Registries of the future may provide innovative opportunities for patients to submit such data directly to the registry database.

Establishing registry data collection

Data collection needs to be both reliable and sustainable. First, sites attended by your patient population should be identified, to aid the planning of resources for data collection at those sites. This may have been previously established if there are designated centres of excellence or a relevant national clinical care programme. However, this is not always the case. A useful way to establish the distribution of your patient population is a survey or census of all hospitals and/or other relevant institutions. This can determine the number of hospital attendees with the specific condition/disease in a given time period.

In most cases, patients and/or their parents/guardians will need to be invited to participate in the registry. To this end, patient information sheets, informed consent forms and a list of data elements to be captured should be prepared and submitted for research ethics committee consideration at each intended data collection site. Research Ethics Committee (REC) applications can be time consuming, taking a number of months from the time of submission, provided no major ethical issues are encountered. In Ireland, a common REC application form is used by most hospitals to help expedite this process.

Registry coverage of the patient population is important, that is, the proportion of the population on the registry. Given the reality of restrictions on staff time and resources, there is a balance to be achieved between the attainment of close to complete coverage of the patient population and the depth of information collected on registry participants. The depth of the data is crucial for future research purposes; however, the credibility of the registry's population-level statistics is linked to its coverage of the population. In most instances, it is preferable to have limited, high quality data on nearly all of the affected population, rather than very detailed information on a small proportion of the population. The latter is unlikely to

reflect the true pattern of disease among the entire population, due to the under- or over-estimation of patient outcomes and health service utilisation. It also limits opportunities to perform comparative population analyses with international peers.

Utilising previously collected data as the foundation for a new registry is unlikely to be suitable. Beginning a registry from scratch has the advantage of having explicit patient consent for registry participation, a clear protocol for data collection, governance practices and clear intent for registry research.

Sustaining registry data collection

Sustainability of data collection is key to a registry's success. Aim for sustainable long-term data collection from data sources that are ongoing. There should be no reliance on ad hoc research studies for data collection. The use of common standards and definitions will greatly enhance the utility of registry data over long time periods and is especially important for studies examining epidemiological changes over time. Having clear guidelines on consent and data storage is important for sustaining long term data collection from data sources and safeguards the use of registry data in years to come. Audit structures should be also developed, to ensure that the data collected is in accordance with agreed procedures, the data collected meets the required standards of quality, and that the registry is operating according to its intended purpose.

The issue of who is best placed to collect the data on an ongoing basis needs to be examined carefully. This could be a range of individuals from within the hospital environment or a registry research nurse/assistant who travels to all relevant hospital sites. The decision is dependent on a number of factors, including the size of the patient population and the distribution of patients across the country along with funding and resources. There is no single optimal solution, rather each situation needs to be judged on its own merits and in its own context. However, necessary skills for anyone collecting data needs to be both the ability to invite patient consent, interpret medical notes and basic IT skills at a minimum.

Simplify the data collection process wherever possible. When collecting data, have a clear protocol to ensure consistency across data collection sites and data entry personnel. Guidance for the registry team on how to invite consent and data storage should be provided. Providing regular refresher training on the protocol for those doing the collecting is important. Avoid duplication of data wherever possible - this can arise where data is handwritten onto data proformas, then data entry into the registry database occurs at a later time. Technological solutions can provide opportunities to avoid duplication, such as direct data entry at the data collection site on a secure web-based registry system.

Registry software selection

Choose an electronic web-based software. The software should have the capacity to collect longitudinal data – that is, follow the patient over the course of their lifetime. It should have a user-friendly interface for multiple users with different backgrounds, and allow differing levels of access rights. At the same time it should have the appropriate data security/protection measures. The use of an open source technology is a very valuable approach as it facilitates

interoperability with other data collections and ensures that you can gain access to the software source code, if the company ever stops operating. Alternatively, a suitable agreement should be put in place with the vendor.

Your software will need to be able to grow with your organisation over many years. Ideally opt for scalable software with integration capabilities to other data sets and patient records. Cutting-edge registries are interoperable, meaning they can talk to other datasets, such as other national data collections, European or international registries for the patient population/disease/condition or a bio-banking databases.

Having the ability to scale up your registry means that you can collect additional data that may become important in the future. For example, if a screening programme is introduced or a new therapy becomes available, you may be interested to capture related information. At a later date in your registry's development you may wish to consider additional functionality, such as providing a patient portal for individuals to access their own registry records. This could also provide opportunities for inputting of relevant socio-economic and quality of life data (or other PCOMs) by patients, that are not captured by clinical records.

When establishing a registry, the focus is typically on the collection and input of data. The reporting interface or engine should also be carefully considered when selecting registry software. Consider the 'output' you would like: whether you want defined routine reports, access to raw data files for in-depth statistical analysis and modelling, or both. Having access to raw data files requires having appropriately skilled registry staff to manage, analyse and report on the data. This is preferable, however, as the data can be 'cut' for use in multiple research projects, thus providing opportunities to acquire future funding for your registry (see section on funding-page 10).

Agree service fees/service level agreement for ongoing support of your software with the provider, bearing in mind that changes may need to be made down the road, as the registry grows. Changes to software required after the product is delivered for use can be costly, depending on the agreement.

Governance

Patient registries should be independent organisations. Registries should ideally be viewed as trusted third parties holding personal information, and so need to be governed in a way that maintains patient confidentiality and operates ethically/responsibly. The ownership of the registry is not by any one individual, but rather by collective membership of the organisation and the governing board. Each registry participant owns his/her own information and can control whether or not that is entered into the database, through a consent process. Equally, each participant has the right to refuse and or withdraw consent.

Having the right governance structures in place will allow you to retain independence as a trusted third party. It is important, at the outset, to establish the correct legal structure, such as a company limited by guarantee. In Ireland, the Charities Regulator has agreed a Model Constitution for Companies Limited by Guarantee, to encourage improved drafting of constitutions (www.charitiesregulatorauthority.ie).

Identify your stakeholders and involve them from the beginning. Recognise that registry governance requires expertise in issues not solely related to medical care of your patient group, but also research ethics, legislation, business, finance etc.

This should be reflected in the skillset of your governance board. As with all aspects of registry development, ensure patient representatives are included on the governance board. Finally, define terms of reference for the board of governance, including their term of office, to allow the leadership to be refreshed. Develop a Memorandum and Articles / Constitution for your registry, as this establishes your governance structure. Set up advisory / steering groups and committees and protocols for data governance and other routine registry functions, as needed.

Consider the independence of your patient registry. Separation from the patient association that may have initially driven the setup of the registry may be a good idea in some situations to ensure the privacy of patients' records. Separation from Health Institutions, Health Bodies and Industry can also be important. Remove any threat of bias while working in partnership with all stakeholders. This will guarantee that the analysed output is respected and trusted by all.

Data protection

Data security is critical and can be ensured by addressing electronic and physical security measures, in addition to governance issues. A data protection officer should be nominated who is accountable for ensuring best practice is adhered to. If possible, have legal services involved in the development of data protection practices.

After the deployment of your registry, data sharing with external parties for research projects will become possible e.g. linking registry data with biobank data. Decide who has the authority to share data. In a company limited by guarantee, the governing board hold this responsibility. Any conflict of interest among board members should be identified. Data governance protocols are needed to structure a process for external researchers and organisations to request the registry data. Prepare an application form template and identify a scientific board that will review and decide whether to approve the data request. Having a data access agreement will ensure all parties abide by the terms of the data sharing arrangement. Finally, consider carefully instances in which analysed or anonymised raw data will be shared with approved requesters. Identifiable patient information should never be shared.

Resourcing & funding

The majority of patient registries operate on limited funding. An MRCG report in 2012 identified 47 patient registries in Ireland. More than two-thirds had less than 3 staff members. Sources of funding identified included the Irish State, charitable organisations, commercial sources, and no funding was reported by some.[4]

There is a high likelihood that building a registry will take longer and cost more than expected. Capital and operational expenditure will vary according to the phase of registry development. Budgeting and resourcing of patient registries should take account of whether the registry is in a planning (design), implementation, operation or growth phase. Acquiring funding requires building strategic alliances and building a stakeholder base external to the registry organisation.

4.Donohue, F. 2012, Medical Research Charities Group Report: Patient Registries in Ireland.

An approach used by some Irish patient registries is to operate the registry as a business, with core funding that is topped up with additional external contracts. For example, by participating in research studies, a ring-fenced budget for registry participation in the study can be factored into research grant applications. Sharing of analysed, anonymised data reports with approved researchers can also generate additional revenue, provided the relevant ethics and governance of such a practice is in place.

Sustaining a registry

Patient registries are often dependent upon a single visionary to establish, develop and maintain the organisation. In reality this is unsustainable. Ensure the continuity of the registry by selecting a board of governors that are both interested and engaged.

Build a skilled management and operations team. The person to lead the operation should be someone whose interests are invested in the registry, and who understands the value of gathering data for health research purposes. Due to the time constraints associated with their patient-facing role, this person is not always a practicing clinician. The person specification required for each phase of registry development may change. The skillset and competencies required to set up the registry may not be the same for the long term management of the registry.

In Ireland, given that data extraction generally involves accessing, reading and interpreting written notes in paper hospital records, a registry research nurse, clinical research nurse or registry co-ordinator is needed. The person specification for this role would be someone with familiarity with hospital data systems, reading clinical charts, building relationships and communication with health care staff and patients.

Another approach to sustaining your registry, is to ensure the on-going need for the registry data. It is important to capture enough clinical outcomes so that the requirement for registry data is ongoing, and therefore requires long-term support from funding bodies. One way to do this is to become part of an international community e.g. a European registry. Secondly, the European Medicines Agency recently issued a 'Qualification Opinion' statement, strengthening the role of registries in providing real world evidence for newly marketed therapies in Europe[5]. Typically these long-term safety and effectiveness studies last 4-5 years. This statement changes the perception of registries from being nice to have, to being qualified as an appropriate data source for post-authorisation studies, which support regulatory decision-making on medicines.

Patient engagement and support is very important to sustain your registry. While routine registry reports are typically prepared for clinical and scientific audiences, equal investment should be made in developing patient-friendly infographics and reports. Participation in patient conferences and dissemination of reports though patient organisations and relevant hospital clinics is a way of showing patients how their data is used. Patient involvement in planning all aspects of the registry is also highly recommended. It is important not to lose the support and engagement of the individuals, without whom, the data would not be available for registry use.

5. http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline /2018/02/WC500243542.pdf

Long term vision for registries in Ireland

Central to our vision for the future of registries in Ireland is increased collaboration and the sharing of resources between registries. This could be achieved through an independent **National Federation of Registries**, that acts as a trusted third party for patient health information. The coming together of patient registries under one umbrella could offer enormous benefits, while at the same time allowing for individual registries to maintain their own independence and drive their own agenda.

An appropriately funded and supported Federation of Registries could support:

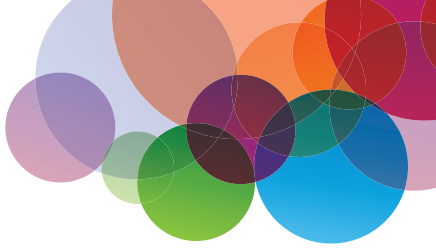
- Registries being operated in a cost-efficient manner, through the sharing of common resources (research nurses/co-ordinators, statisticians) and expertise.
- A coordinated and informed approach to tackling of pertinent registry issues, from research ethics committee approval challenges to a lack of registry funding.
- The development of guidelines for new and emerging registries, focused on topics such as ethics and privacy, data standards and quality, evaluation, governance structures and processes etc.
- Steps to bring Ireland into line with established European and US standards for patient registries.
- An overall improvement in standards within registries, so as to enhance their role within health services.
- Steps towards the adequate resourcing of registries.

We note that the Programme for Government (2016) states "We will develop National Patient Disease Registries and prioritise the passage of the Human Tissue Bill and the Health Information and Safety Bill"[6]. It is essential that a clear policy on patient registries is developed by the Irish Government as soon as possible. Such a policy should include an acknowledgement of both the importance of patient registries and consideration of an improved model to fund registries, that would include increased support from government.

Patient and Public Involvement (PPI), is now widely recognised as an essential component of undertaking health research and developing effective health policy and services. All future patient registry activities should include the meaningful involvement of patients, from the earliest planning phases, wherever possible. Patient registries provide an important example of 'PPI in practice' to make a significant impact on patient health outcomes through working in partnership with key stakeholders. Indeed, patient groups have often provided the initial spark for patient registries in Ireland and continue to be involved in their on-going governance.

Currently, health Information in Ireland is fragmented and isolated in data silos, only worsened by the fact that electronic health records are not commonplace. Patient registries are under-resourced, from the perspective of funding, time and know-how. We must find a way to overcome these challenges, in order to meet an urgent demand for quality patient information that only registries can provide. Perhaps it is time for a new model – one that is based on strength in numbers, sharing of resources and appropriate funding. We look to a future where it is commonplace for health data to be used effectively, in order to improve patients' lives.

6. A Programme for a Partnership Government (2016) p57. (https://www.taoiseach.gov.ie/DOT/eng/Work_Of_The_Department/Programme_for_Government/Programme_for_Government.html)



Glossary of terms as used throughout the guide

Anonymised data	Data that has had identifying details removed. Data can be considered anonymised when the individual it relates to cannot be identified through interrogating it.
Clinical outcome	The impact of a healthcare intervention on a patient.
Co-morbidities	The presence of one or more additional diseases or conditions co-occurring with a primary disease or condition.
Data collection interval	The frequency with which you collect data e.g. annually.
Data element	A single unit of data which has a unique meaning and is recorded through distinct units or values e.g. patient identifier, gender or diagnosis.
Data set	A collection of data elements that a registry collects information on.
Data silos	Repositories of data that remains under the control of one organisation or department and are isolated from other data repositories.
Epidemiological	Relating to the branch of medicine which deals with the incidence, distribution and control of diseases.
Informed consent	Permission granted in full knowledge of the potential consequences, i.e. knowledge of the possible risks and benefits.
Longitudinal data	Data captured through repeated observations of the same variables over time.
Open source technology	Any software program whose source code is made available for use or modification by users or other developers. Open source software is usually developed as a public collaboration and made freely available.
Outcome measures	Measures of the impact of healthcare activities on patients e.g. whether symptoms improve or worsen or whether patients live or die.
Patient-centred outcome measures	Measures that capture outcomes that are relevant to patients e.g. the impact of a healthcare intervention on their ability to sleep or to socialise.
Post-authorisation studies	Studies carried out after a medicine has been authorised for widespread use e.g. to obtain more information on a medicine's safety, or to measure its effectiveness over time.
Prognostic information	Information that will need to be collected at a future point e.g. date of death.

medical research charities group

Unity is our Strength

The Medical Research Charities Group (MRCG)
Digital Office Centre, 12 Camden Row, Dublin 8
Telephone: 353 1 479 3234

Email: info@mrcg.ie Web: www.mrcg.ie