

The Need for a Multiple Sclerosis Patient Registry in Ireland – Briefing Document and Position Paper

Background

What are patient registries?

A patient registry is defined as a “framework for collecting and analysing data on a particular disease that aims to cover the whole national population of that disease” (MRCG & IPPOSI, 2011, p.5). Individual patients are recorded only once in a registry and are not duplicated.

Within the framework of the concept of registries, four different sub-types or categories have been identified as follows (MRCG & IPPOSI, 2011, p.5):

- **Patient Registry** – the ‘gold standard’ in the registries framework is a well-resourced national patient registry that captures a wide variety of high-quality data and interacts with registries in other countries to contribute to an international body of research on a particular disease. A properly resourced registry will generally employ dedicated staff to capture and analyse the data. Data from a registry is not generally used to influence the treatment of individual patients, but rather exists to inform research into treatments and therapies, and plan for current and future service delivery to meet the needs of a particular patient population
- **Patient/Electronic Health Register** – these are generally developed and operated primarily by clinicians as a means for monitoring and managing individual patients’ conditions. As such, whilst they can capture very high quality data, they tend to contribute less to overall policy and practice in relation to the management of particular diseases than a full registry. Patient/Electronic Health Registers can be important building blocks on which a full registry can be developed
- **Patient databases** – these are smaller data sets of particular patient groups, such as those held by patient organisations to inform the development and delivery of their services, and data sets held by pharmaceutical companies to monitor the efficacy and safety of particular medications

- **Electronic Patient Records (hospital level)** – these are records held by individual hospitals of particular patient populations attending their clinics. Currently in Ireland, Electronic Patient Records are optional add-ons to traditional paper-based recording and are not operated consistently between hospitals and disease groups. It is widely recognised that, if developed and implemented properly, Electronic Patient Records form the most useful basis from which to transfer data to a national Patient Registry.

Why are patient registries important?

The Medical Research Charities Group (MRCG) and the Irish Platform for Patient Organisations, Science and Industry (IPPOSI) released a report in 2011 entitled ‘Towards a National Strategy for Patient Registries in Ireland: Considerations for Government’. This report states that:

“Patient Registries should be central to the planning, delivery and review of health care in Ireland as they provide data and analysis to:

- Observe the trends and course of a disease
- Enable the more effective use of limited resources
- Inform clinical and policy decision-making at a national and institutional level
- Illuminate practice patterns and variations in practice patterns
- Assess clinical outcomes: effectiveness and safety
- Explore the impact of the disease and treatment on patients, including health-related quality of life and other patient-reported outcomes
- Assess health economic inputs, outcomes and impact”

(p.4).

A 2012 report from the MRCG identified the following benefits of patient registries (MRCG, 2012, pp.12-24):

- The facilitation of multi-disciplinary working and integrated care for patients with complex needs. Registries can also help with the development of funding models whereby ‘money follows the patient’
- Improvement of management of chronic diseases and reduction in unnecessary hospitalisations, thus allowing more efficient use of healthcare resources

- Improvement of relationships and communications between healthcare professionals, e.g. emergency department staff and consultants
- Improvement in patient outcomes – specific examples given in the report include two diabetes registries and two stroke registries in the US which recorded notable improvements in patient outcomes since the development of the registries
- Allowing physicians with a particular clinical interest to network with each other, share best practice and contribute to research
- Examining disease trends in populations over time including incidence rates and prognoses. This can be extremely important for research, including helping to generate hypotheses about possible causes of diseases like MS
- Supporting research into genetic susceptibility to diseases and helping to identify genetic markers that may increase or decrease the risk of developing diseases like MS
- Supporting surveillance of the efficacy and safety of medications
- Helping identify gaps in service provision, evaluate service delivery and plan for the future delivery of services
- Supporting the health technology assessment process by providing data on the cost effectiveness of treatments
- Providing a source of participants for clinical trials and data to calculate sample sizes for trials
- Examining the translation of information from randomised controlled trials into clinical practice

Additionally, patient education programmes such as EUPATI (European Patients' Academy for Therapeutic Innovation) report that registries can be a positive force in empowering patients to be involved in their disease management.

Patient registries in Ireland

Ireland currently lacks a strategic framework for patient registries. Registries for some disease groups exist (such as cancer and cystic fibrosis), and others are in the process of being established (such as a dementia registry), but there is no national oversight and no single body within the Health



Service Executive (HSE) that has responsibility for managing, funding or regulating registries (IPPOSI, 2015).

Current challenges to the development of patient registries in Ireland include a lack of a specific funding mechanism to set up and sustain registries, lack of necessary IT infrastructure, concerns regarding impact on clinicians' time for updating records, lack of standardisation of data captured in existing data sets, the lack of a single centralised body to which researchers and data collectors can apply to for ethical approval and a general lack of awareness of the importance of registries among key stakeholders including Government organisations and patient organisations (MRCG & IPPOSI, 2011; IPPOSI, 2015).

A recent report by IPPOSI highlighted that lack of registries is a major problem in terms of attracting clinical trials to Ireland (2015, p.12):

“Without good quality data available, Ireland is not on the map for industry-led clinical trials. If industry cannot identify and track patients and their outcomes, they simply will not conduct clinical trials in Ireland”.

There is currently no national registry for multiple sclerosis in Ireland. Electronic Patient Records for people with MS exist in some individual hospitals and pharmaceutical companies hold databases on particular MS medications. Multiple Sclerosis Ireland, as the only national MS patient organisation, holds a non-medical database on people with MS who interact with the organisation and use their services (MS Ireland, 2015).

The National Clinical Programme for Neurology Model of care, launched in September 2016, also references the need to establish an MS registry (HSE, 2016, p.177):

“To support the effective and efficient management of DMT's the Neurology Programme would support the development of a national treatment registry for all MS patients in Ireland. The aim of such a registry would be to encourage regular reviews of MS patients where their clinical progress is assessed”.

Multiple sclerosis registries internationally

Multiple sclerosis registries exist in a number of countries internationally and there are now some collaborative efforts underway to conduct cross-border data collection. For example, the European Multiple Sclerosis Platform's European Register for Multiple Sclerosis project ([EUREMS](#)) ran from 2011 to 2014 and collected data from MS registries in 12 European countries. Data collected from EUREMS fuelled four studies on incidence of MS, disease modifying treatment use and efficacy and the economic burden of MS (EMSP, 2014). Similarly, the Big Multiple Sclerosis Data network includes

MS registries from a number of countries and allows researchers to pool data and collaborate on research projects (European Medicines Agency, 2017).

MS Ireland position and recommendations

The lack of a national MS registry in Ireland creates a number of problems, including difficulty attracting clinical trials, lack of accurate data on disease prevalence and trends and lack of effective long-term monitoring of medication safety and efficacy.

MS Ireland will seek funding for the conduction of a feasibility study, similar to a recent study conducted by the Alzheimer Society of Ireland on establishment of a dementia registry. The purpose of the Alzheimer Society's study was as follows:

- Review patient registry models in Ireland and examine their function and operation
- Review dementia registries that exist in other jurisdictions and examine their function and operation
- Undertake a 'landscape analysis' identifying the impact of relevant legal, ethical, clinical, IT systems and financial issues crucial to the development of a national dementia registry
- Provide evidence-based policy recommendations that can progress the issue of improved recording structures for dementia in Ireland

(Hopper, Hughes, Burke & Irving, 2016, p.1)

As an important initial step to supporting future development of registries for MS and other diseases, the HSE should as a matter of priority introduce nationwide Electronic Health Records and Individual Health Identifiers. MS Ireland also supports the work of IPPOSI and the MRCG in calling on the HSE and the Department of Health to establish a national policy framework and strategy for the development of patient registries, which would include a funding mechanism for both the development and long-term maintenance of patient registries.

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References

European Medicines Agency [EMA] (2017). *Patient registries workshop, 28 October 2016. Observations and recommendations arising from the workshop*. London: EMA.

European Multiple Sclerosis Platform (2014). *Projects: EUREMS*. Retrieved August 10, 2017 from <http://www.emsp.org/projects/eurems/>

Health Service Executive (2016). *National clinical programme for neurology model of care*. Dublin: HSE, Royal College of Physicians & National Clinical and Integrated Care Programme.

Hopper, L., Hughes, S., Burke, T. & Irving, K. (2016). *A national dementia registry for Ireland. A feasibility study*. Dublin: Alzheimer's Society of Ireland.

Irish Platform for Patients Organisations, Science and Industry [IPPOSI]. (2015). *Outcome report: health information round table meeting: developments and next steps. September 2015*. Dublin: IPPOSI.

Medical Research Charities Group [MRCG] (2012). *MRCG report: patient registries in Ireland*. Dublin: MRCG.

MRCG & IPPOSI (2011). *Towards a national strategy for patient registries in Ireland: considerations for government*. Dublin: MRCG & IPPOSI.

Multiple Sclerosis Society of Ireland (2015). *Societal costs of multiple sclerosis in Ireland 2015*. Dublin: MS Ireland, UCD and Novartis.