

A NATIONAL DEMENTIA REGISTRY FOR IRELAND

A Feasibility Study

Report prepared by
Louise Hopper, Suzanne Hughes,
Teresa Burke and Kate Irving



Ollscoil Chathair Bhaile Átha Cliath
Dublin City University



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Authors

Dr Louise Hopper, Post-doctoral Researcher, School of Nursing and Human Sciences,
Dublin City University, Dublin

Suzanne Hughes, Research Assistant, School of Nursing and Human Sciences,
Dublin City University, Dublin

Prof Teresa Burke, Chair of Psychology, School of Nursing and Human Sciences,
Dublin City University, Dublin

Dr Kate Irving, Senior Lecturer, School of Nursing and Human Sciences,
Dublin City University, Dublin

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Foreword

The Alzheimer Society of Ireland (ASI), as the leading advocacy and service organisation for people with dementia and their families, is concerned with the lack of accurate and available data about dementia in Ireland. Other jurisdictions have national data collection and storage structures which play a vital role in the development of many aspects of dementia health and social care. They help to improve and shape service planning and patient care, also informing policy and providing a research infrastructure.

With the publication of Ireland's first National Dementia Strategy in 2014, there was a governmental shift to take a strategic approach to address dementia. With this in mind, the ASI feels it is the right time to examine the potential for a framework to collect information on dementia in a reliable, accurate, valid, complete and timely way, specifically to explore what role a dementia registry can have in our national strategic approach to dementia.

This report, commissioned under the ASI's expert policy series, provides much needed information on the feasibility of developing a dementia registry within the Irish context. The authors proactively engaged with leading experts both in the field of dementia and in patient registries more generally. They also, very importantly, met and engaged with people living with dementia; those whose information would be collected, stored and used in any future registry. These expert opinions, combined with a review of national patient registries and a review of international dementia registries, identifies good practice as well as potential pitfalls in establishing and running such a registry.

We would like to sincerely thank the authors of the report, Dr Louise Hopper, Suzanne Hughes, Dr Kate Irving and Professor Teresa Burke from Dublin City University and all those who gave up their time to contribute to its contents. It provides an excellent evidence-base for a national discussion on this issue and to determine action on how we should move forward to make it a reality.

The ASI feels strongly that we need to continue to strengthen collaboration and partnership across disciplines and sectors to ensure that this report does not just collect dust but is used to bring real change to the growing number of people living with dementia.

Pat McLoughlin

CEO, The Alzheimer Society of Ireland

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Executive Summary

Purpose

Patient registries, it is argued, should be “central to the planning, delivery and review of health care in Ireland” (Medical Research Charities Group (MRCG) & Irish Platform for Patients’ Organisations, Science and Industry (IPPOSI), 2011, p. 1). The breadth, depth and longitudinal nature of patient registry data can inform clinical and policy decision making, support comprehensive health economic assessment, and facilitate health and policy research.

Unlike other jurisdictions that have national structures that play a vital role in the development of many aspects of healthcare services, including the provision of accurate and comprehensive data on dementia to facilitate clinical and policy decision-making, there is very poor recording and coding of dementia across all care settings (Cahill, O’Shea, & Pierce, 2012). The Alzheimer Society of Ireland (ASI) commissioned this study as part of their expert evidence-based policy series. The overall aim was to generate an evidence-based discussion document addressing the feasibility of a national dementia registry for Ireland. The specific objectives were to:

- 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.

Terminology

For the purposes of this report, the term 'register' refers to the patient records (i.e. the patient data) and the patient record database. Furthermore, a proper register is considered to be one that exists at a population level and is complete. The term 'registry' refers to the organisation and process that supports the register.

Methodology

A rapid review of published and grey literature examining the definition, function, operation and evaluation of patient registries, best-practice guidelines for their development, and the legal, ethical, clinical, technical and financial issues that need to be considered when establishing a patient registry was carried out. In addition, literature pertaining to existing international dementia registries and to existing patient registries in Ireland was reviewed. Semi-structured expert interviews were conducted with national and international experts ($n=21$) in areas relevant for this project. Two focus groups were held with representatives of the Irish Dementia Working Group (IDWG; $n=9$) in order to gain insight into the potential benefits and risks of a national dementia registry from the perspective of those with a diagnosis of dementia.

Findings: Literature review

Reliable, accurate, valid, comprehensive and timely data has a significant record of contributing to the effective and efficient planning, operation and evaluation of health and related social services. The breadth, depth and longitudinal nature of patient registry data can inform public health policy, improve patient care, support health research, and facilitate health technology assessment. Although the collection of these data is often expensive in terms of time and cost, requires ethical justification and flexibility to adapt to a changing legislative environment.

With the growth of patient registries worldwide, best practice guidelines have emerged in Australia, Sweden, the UK, the US and from the EU Cross-border Patient Registries Initiative. These guidelines provide guidance on registry purpose, the selection, collection, management and quality evaluation of registry data, ethics and data privacy, funding and resources, registry governance, registry quality and evaluation, registry outputs, the use of registry data and facilitating registry interoperability.

Several international dementia registries are currently operational and they provide useful epidemiological data for policy-making, resource planning and service provision. No one ideal model for a dementia registry has as yet been established, but the Swedish Dementia Registry (SveDem) is the most comprehensive and arguably the 'gold standard' of existing registries. It is a government funded web-based registry that operates with a national mandate and an opt-out consent process. Annual reports, registry evaluations and research publications illustrate how SveDem can contribute to the enhancement of expertise and how it supports the embedding of application of research findings in clinical practice. In contrast to the Swedish model, Denmark uses a continuous process of data collection as part of their National Clinical Quality Databases framework that in turn supports harmonisation and quality improvements in dementia services provided in each participating institution. In contrast, the Registry of Dementia of Griona offers a model that could be used as a starting point for any dementia registry that requires the potential to expand its scope over time.

The feasibility of any patient registry is influenced by the environment in which the registry operates. Previous Medical Research Charities Group reports have reviewed the national legislation and the international directives, conventions and codes relevant to patient registries. Such registries also need to be cognisant of the requirements of the recent European Data Protection Reform 2016 legislation, the Assisted Decision Making (Capacity) Act 2015, and the potential implications of the Health Information and Patient Safety Bill. Despite previous discussions regarding the strategic nature of patient registries and the publication of guiding principles for health and social care data collection, there is still a lack of strategic direction in Ireland. As a result Irish patient registries are characterised by significant heterogeneity with regard to size, function, disease, funding, cost and governance. Even when operating with a national mandate, the National Cancer Registry omits patients in private hospitals and still tends to be seen as external to the health service. That said, the review of existing Irish patient registries demonstrates that a lot can be achieved within the current limitations of the Irish health system.

Findings: Expert interviews and focus groups

A number of core themes emerged from the thematic analysis of the expert interviews and focus groups. These were:

- **Registry function** – experts agreed that a dementia registry would provide much needed data to enhance policy, enormous potential to improve care, and facilitate research within an Irish context.
- **Registry data** – expert consensus was that a formal diagnosis of dementia would be required for registry inclusion, but the complexity of this diagnosis and the lack of coding in primary care would be problematic. Data requirements and format should be driven by the primary purpose of the registry, opt-in patient consent is preferred, and data accuracy and completeness will be fundamental to registry success.
- **Data collection** – experts felt that data will be required from primary and secondary care. This will be challenging without electronic health records, but achievable with appropriate data matching processes. Data collection should not further stretch front-line resources and stakeholder buy-in will be essential to registry success.
- **Data management** – there was clear agreement that consumers of registry data should only have access to the data specific to their needs. Clear access rules, data privacy and data protection plans, and adequate technical support will also be required.
- **Registry governance** – experts agreed that a dementia registry should be independent, have formalised governance structures and undergo regular quality evaluations. They recognised challenges with regard to registry funding and the lack of national strategic planning.
- **Legislation** – privacy and data protection concerns were most prevalent. Experts also discussed the need for and the potential impact of individual health identifiers and the Health Information and Patient Safety Bill.

Three high level cross-cutting themes were also identified:

- **Benefits and risks** – improved policy-making, patient care and research potential were identified as key benefits. Risks would include securing funding to sustain the registry, privacy, confidentiality, data protection and data access, but experts felt each could be mitigated.
- **Barriers and facilitators** – the main barriers were thought to be a lack of strategic policy and sustainable funding, poor coding for dementia in primary care, consent procedures and the complexity of data collection. The changing legislative environment and the recognised need for better dementia-related information by policy makers were seen as key facilitators.
- **Dementia-specific challenges** – the complexity of a dementia diagnosis, the degenerative nature of dementia with regard to capacity, and the stigma associated with dementia were considered to be additional factors that would not be encountered in other patient registries.

Findings: Key considerations and recommendations

When taken together the findings indicate some clear direction for any potential registry in Ireland.

1. Clear aims and objectives are needed for the registry to be successful.
2. Legislative support is beneficial with regard to legitimacy and sustainability, however, the registry should remain independent.
3. Stable funding is crucial for the longevity of a registry.
4. Strong relationships and 'buy-in' are needed from all stakeholders.
5. Registry location can enable access to additional resources; independence must be preserved.
6. Patient consent needs to be carefully considered.
7. Patient recruitment is essential to the success of any registry.
8. Data collection is a complex process.
9. Data will never be truly comprehensive; this is a particular concern in the Irish health system.
10. Clear unambiguous and tangible outcome measures are required.
11. Registry governance must be formalised but not unwieldy.
12. Quality evaluations are vital in order to ensure that the registry is fit-for-purpose.
13. Standardisation of dementia diagnosis is needed to protect the credibility of the data.
14. Privacy and confidentiality needs to be assured for those registered.
15. Opportune timing can be instrumental in the setting up of a new registry.
16. A centralised ethical approval process is highly recommended.
17. Primary legislation is needed to establish a firm legal basis for data collection, research and data sharing with regard to patient registry data.

It is also clear that there are a number of key decisions that need to be made in order to develop a comprehensive proposal for a national dementia registry. Firstly, clear leadership and appropriate funding are required. Secondly, the scope, scale and main function(s) of the proposed registry need to be established as these will drive the design of the processes and procedures necessary to operate the registry effectively, efficiently and ultimately successfully. Subsequently, sustainability planning, governance structures and registry evaluation processes should be put in place. Finally, the registry team must advocate for a suitable policy and legislative environment conducive to the effective operation of any registry. To achieve this, they will need to increase awareness of the value of patient registries and the specific benefits of having a National Dementia Registry for Ireland.

Conclusions

This study assessed the feasibility of a National Dementia Registry for Ireland. The findings suggest that the benefits of developing such a registry make the required investment worthwhile as long as the registry has clear and focused aims and objectives, solid data management and data collection processes, produces credible results and is demonstrably fit-for-purpose. The funding for such a registry needs to be discussed in light of these key objectives (i.e. a definitive understanding of what the registry is for) as they will guide the identification of appropriate funding sources and the prioritisation of the dementia registry in comparison to other potential calls on this money.

Clear leadership will be required to win the 'hearts and minds' of the stakeholders that will be involved and the people with dementia who will provide their data to the registry. Ireland can and should learn from the development of dementia registries in other jurisdictions and the development of other patient registries in Ireland. Ideally, a national strategic policy on patient registries, adequate funding mechanisms, data sharing legislation and a robust eHealth system that includes unique health identifiers would be pre-requisites to the development of the registry, but one of the biggest challenges in Ireland is the length of time policy development and legislative and regulatory changes take and the long-awaited Health Information and Patient Safety Bill (HIPS) is a case in point. Were we to wait for each of these pre-requisites to arrive, it is likely that the national dementia registry would never be developed.

1.1 Introduction

It is argued that patient registries should be “central to the planning, delivery and review of health care in Ireland” (MRCG & IPPOSI, 2011, p. 1). Such registries provide data:

- that enable the trends and course of a disease to be observed,
- to identify differences and inequities in service provision and service use,
- to assess the efficacy of clinical outcomes,
- to explore the impact of the disease, treatment and care plans on patients’ quality of life and other patient-reported outcomes.

These findings, in turn, inform clinical and policy decision making and support comprehensive health economic assessment. Although Ireland does not as yet have a national strategy on patient registries, a variety of patient registries already exist and others are in the process of development.

The Alzheimer Society of Ireland (ASI), as a leading advocacy and service organization for people with dementia and their families, has concerns over the lack of data and information about dementia in Ireland. There is very poor recording and coding of dementia across all care settings (Cahill et al., 2012). This is unlike other jurisdictions that have national structures that play a vital role in the development of many aspects of healthcare services including the provision of accurate and comprehensive data on dementia to facilitate clinical and policy decision-making.

Given the strategic approach the Government is now taking to address dementia, with the publication of the Irish National Dementia Strategy (Department of Health (DoH), 2004), it is timely to examine the potential for a framework to collect dementia-related information in a reliable, accurate, valid, complete and timely way.

1.2 Terms of reference

The ASI has commissioned this study as part of their expert evidence-based policy series. The overall aim was to generate an evidence-based discussion document addressing the feasibility of a national dementia registry for Ireland. The specific objectives of this study were to:

- i Review patient registry models in Ireland and examine their function and operation.
- ii Review dementia registries that exist in other jurisdictions and examine their function and operation.
- iii Undertake a ‘landscape analysis’ identifying the impact of relevant legal, ethical, clinical, information technology (IT) systems and financial issues crucial to the development of a national dementia registry.
- iv Provide evidence-based policy recommendations that can progress this issue of improved recording structures for dementia in Ireland.

1.3 Definitions and Terminology

Inconsistent and confusing terminology has been used to refer to a wide variety of disease registries and to clinical and research databases (Gliklich & Dreyer, 2014; Newton & Garner, 2002), and the terms 'registry' and 'register' are often used interchangeably.

For the purposes of this study, Newton and Garner's (2002) terminology will be used.

- **Register** refers to the patient records (i.e. the personal health information of an individual kept over a long period of time) and the patient record database, and it is consistent with Last's (2001) description of a file of data concerning all cases of a particular disease or health condition in a defined population such that the cases can be related to a population base. An individual person (patient) is registered once as a unique entity that is not duplicated.
- **Registry** refers to the organisation and process that supports a register. One registry may support the operation of a number of individual registers.

Registers are subsequently classified according to the way in which their populations are defined (Gliklich & Dreyer, 2014). **Population registers**, alternatively referred to as disease, case and patient registers, are the most common and they specifically refer to databases that strive to identify systematically all cases of a particular disease in a specific population (Gliklich & Dreyer, 2014; Newton & Garner, 2002); for example national cancer registers. These registers are used for epidemiological research (e.g. prevalence, incidence and mortality rates), needs assessment, monitoring the effectiveness and improving the quality of clinical care, service provision and technology assessment. They are usually costly and it has been suggested that they are prone to over-estimating epidemiological variables by over-rating symptoms (González, 2015).

Population registers are distinct from **clinical registers** that collect data from those treated in a particular institution or group of institutions (e.g. hospital or primary care practice) and are focused on patient care, quality improvement and health technology assessment (Newton & Garner, 2002). They are also distinct from **patient databases** that are a simple collection of patients that share some characteristics (e.g. a diagnosis or treatment plan) and that are used to support the delivery of a particular service, clinical trial, or research study (MRCG & IPPOSI, 2011). Population registers should also be differentiated from **research registers** where people register their interest in participating in research; for example Join Dementia Research in the UK enables people with and without dementia to volunteer to take part in research projects (National Institute for Health Research, 2016).

Non-specific registers that identify all events of a particular type (e.g. GP Consultations, Hospital admissions, prescribed medications, population biomedical databases) also exist but they are not the focus of this study and are not included in this report.

Background and Methods

1.4 Methodology

Although several aspects of this research could be achieved through review of policy documents and published research, we interviewed expert stakeholders to garner a system view of the impact of any proposed approach to the generation of a national dementia registry, and held focus groups with representatives of the Irish Dementia Working Group (IDWG) to gain insight into the potential benefits and risks of a national dementia registry from the perspective of those with a diagnosis of dementia. The study ran for six months from January to July 2016.

1.4.1 Rapid literature review

Full systematic literature reviews are time-consuming and often take a minimum of six months to one year to complete (Ganann, Ciliska, & Thomas, 2010; Higgins & Green, 2008). Evidence suggests that more pragmatic searches focused on providing answers to a specific question can produce similar information more quickly (from one week to several months) and at less cost (Parkhill et al., 2011). As a result, there is an increasing move towards rapid literature reviews in order to synthesise high quality evidence for the purposes of policy development and planning while meeting the time constraints under which policy-makers often operate (Featherstone et al., 2015; Khangura, Konnyu, Cushman, Grimshaw, & Moher, 2012; Watt et al., 2008). The target audiences for these reviews typically include government policy-makers, healthcare institutions and health professionals, patient associations and patient advocacy groups (Ganann et al., 2010). A number of studies have examined the differences between the evidence produced by systematic and rapid reviews and generally rapid reviews that are fit-for-purpose are seen as positive and not inherently inferior to more comprehensive reviews (Khangura et al., 2012; Watt et al., 2008).

Given the time constraints of this study and the specific nature of the question asked, a rapid review of published and grey literature was deemed appropriate. The review concentrated on understanding what patient registries and registers are; the functions they fulfil; how they are developed, maintained and evaluated; and the legal, ethical, clinical, technical and financial issues that need to be considered when establishing a patient registry.

We also specifically examined literature pertaining to existing international dementia registries and to existing patient registries in Ireland. In accordance with Burls (2004) recommendations, authoritative guidance was provided in planning and reporting the rapid review by an advisory panel that included key stakeholders from primary care, health informatics and a representative from the ASI.

1.4.2 Expert Interviews

Expert interviews are about a person's special knowledge and experiences that result from the actions, responsibilities, or obligations of their specific functional status within an organisation or institution. They are not about the experts themselves, nor about the individual or single case, but about the expert as informant or source of information. With this in mind, we conducted systematising expert interviews with the objective of reconstructing the expert's special knowledge in one or more of the following areas: (1) Existing patient registries in Ireland; (2) Dementia registries in other jurisdictions; (3) Health policy; (4) Health Informatics; (5) Patient advocacy; (6) Clinical perspectives on dementia care. An initial list of potential experts was purposively developed from our knowledge of the health and dementia landscape in Ireland, from discussions with colleagues and the advisory panel, and from the literature review.

Following ethical approval from the DCU Research Ethics Committee, recommended experts were contacted and those who consented to participate were individually interviewed either face-to-face or by telephone/Skype. Interviews ($n=21$) were audio-recorded, transcribed intelligent verbatim and anonymised. The transcripts were analysed by applying an inductive qualitative content analysis; that is using open coding and deriving categories directly from the material (Elo & Kyngäs, 2008; Hsieh & Shannon, 2005). Some additional experts were suggested during the initial interviews and these were also invited to participate using the same process as described above. We additionally had personal communication with other experts ($n=13$) who were unavailable for formal interview. Every effort was made to anonymise the interview transcripts, but given the particular nature of the expertise required by this study and the limited range of suitable experts, it is possible that experts may be identified from the nature or context of their

TABLE 1 Question areas included in the expert interview protocol

Personal experience of registries	Data considerations	Legal aspects
Utility of patient registries	Data ownership and governance	Ethical considerations
Planning a registry	Cost, funding and sustainability	Technology requirements
Policy implications	Benefits and risks	

opinions. Experts were provided with a copy of the anonymised transcript for their review prior to data analysis and quotations used in this report were agreed with each expert prior to publication.

The semi-structured interview protocol was compiled following the rapid literature review and the protocol was reviewed by the advisory panel prior to commencing data collection. The interview protocol covered the topics presented in Table 1 above. Not all question areas were relevant for all experts; for example, a patient organisation may not have had the requisite knowledge to answer questions related to data storage costs, so a recommended interview path was identified for each expert prior to carrying out the interview. The protocol was flexible enough to allow for situations where additional areas of expertise were identified as the interview progressed.

1.4.3 Focus Groups

Two focus groups were conducted with representatives from the IDWG ($n=9$; Male = 5 and Female = 4; Mean age = 63.56 years; 1 person newly diagnosed, 4 diagnosed for 1-3 years and 4 for more than 3 years) to ascertain their opinions on the idea of a national dementia registry for Ireland. The focus groups took place after more than half of the expert interviews had been conducted and analysed so that potential registry models could be explored with the groups. This ensured that tangible examples could be used to illustrate the discussion questions.

The focus group setting encouraged free and open discussion among participants who were already familiar with working in that way. It allowed these participants to discuss their perceptions, opinions, beliefs and attitudes towards the idea of a national dementia registry for Ireland, and what the suggested model(s) would mean for them. A semi-structured format, similar to the expert interviews, was used and a sub-set of question areas were addressed:

- i Definition – what a ‘register’ means to you;
- ii Registry coverage;
- iii Content;
- iv Data ownership and governance;
- v Registry function;
- vi Benefits and risks.

Questions were simplified to suit the needs of these participants and the focus groups were carried out by researchers with previous experience of moderating discussions with people with dementia. The discussions were audio-recorded, transcribed intelligent verbatim, anonymised and analysed using the same procedures as detailed above for the expert interviews.

1.4.4 Limitations of this study

Given the scope and timeline available for this study, it was necessary to conduct a rapid rather than a systematic review of relevant literature. However, previous research suggests that rapid reviews are capable of reaching appropriate conclusions that do not differ extensively from those reached by a more systematic review (Featherstone et al., 2015; Watt et al., 2008). They are also particularly useful for contextualising the findings of previously published generalised findings, as was the objective here.

The selection of appropriate experts was guided by the advisory group but unfortunately, due to demanding work commitments, the expert from the Swedish Dementia Registry was unavailable for interview. Other members of the Swedish Registry team provided their input and comprehensive annual reports and published literature was used to extract other relevant information about the operation of that registry.

SUMMARY

The overall aim of this research was to generate an evidence-based discussion document addressing the feasibility of a national dementia registry for Ireland.

The specific objectives were to:

- 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.

A rapid literature review, semi-structured expert interviews ($n=21$), and two focus groups with the Irish Dementia Working Group ($n=9$) were carried out to analyse the feasibility of creating a national dementia registry for Ireland.

2.1 The functions of patient registries

Reliable, accurate, valid, comprehensive and timely information is essential to the effective and efficient planning, operation and evaluation of health and related social services (MRCG, 2015). Such data has a significant record of contributing to medical knowledge and health care in the UK (Newton & Garner, 2002) and it forms the backbone of current health (Department of Health, 2015; Department of Taoiseach, 2016), health information (Department of Health and Children, 2004) and disease-specific strategies in Ireland; for example the Irish National Dementia Strategy (Department of Health, 2014b).

A variety of different patient registries exist today and new registries are increasingly being developed to fulfil a variety of needs within health services. The breadth, depth and longitudinal nature of patient registry data enables a range of different health services and research objectives to be met, although the collection of these data is often expensive in terms of time and cost, requires ethical justification and flexibility to adapt to a changing legislative environment (MRCG, 2015; Newton & Garner, 2002). Chapter two of the MRCG and IPPOSI (2011) report on considerations for a national strategy on patient registries provides a detailed review of the range of functions supported by patient registries. In summary, the four main aims of a patient registry are:

Inform public health policy

The dynamic, ongoing and systematic process of collecting, analysing, interpreting and disseminating registry data correlated from a wide variety of sources is particularly suited to supporting public health decision-making. It is especially suitable for epidemiological surveillance, the monitoring of public health prevention and treatment strategies, the identification of disease-specific risk factors and at-risk populations, health and social care planning and resource allocation within these services (González, 2015; Morris, Mohs, Rogers, Fillenbaum, & Heyman, 1987). Longitudinal data facilitate analysis of disease trends and the examination of health service processes over time. Registry data can also be analysed to determine rapid responses to emerging research and policy questions (Gliklich & Dreyer, 2014). An improved understanding of disease progression, the monitoring of at-risk patient groups and the general ability to better determine the needs of patients and the likely burden of care, enables better planning and more equitable provisioning of health services (MRCG, 2015). As a result, patient registries enable public health policy makers to evaluate the aspects of the public health system that work well and those that are more problematic, and they provide an evidence base that can be used to drive continuous process quality improvements once there is an awareness of the data stored within the registry, that these data are accessible and that their accuracy and comprehensiveness has been evaluated (MRCG, 2015).

Improve patient care

Patient registries are increasingly seen as intrinsic components of a quality health service and important enablers of improvements in clinical care. The systematic collection of registry data can be used to standardise diagnostic and assessment processes, to manage demand and service provision and to monitor service access, thereby ensuring equitable and consistent delivery of health services that meet patient needs (Colias, 2005; Gliklich & Dreyer, 2014; Newton & Garner, 2002). When patient registries contain comprehensive medical records, this can facilitate the creation and monitoring of individualised care plans, the availability of co-ordinated patient data at the point of care and improved multidisciplinary collaboration. To successfully achieve care improvements, registries must collect data that can be used to modify health-related behaviours, processes or

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systems of care. This may necessitate integration with other data sources, which has ramifications for patient privacy and for data sharing processes and regulations. It may also require the use of specific quality improvement or benchmarking tools and the ability to compare quality across different aspects of the health service. Benchmarking has been found to introduce certain worries among health care providers and they may resist providing the necessary data to the registry unless they are clearly aware of the benefits that will accrue for themselves, their organisations and their patients (Trotter, 2002). Reporting can be blinded, but data can also be examined at local, regional and national levels (Gliklich & Dreyer, 2014); for example, patients who use a particular health service, or those with a specific disease or condition, can be tracked over time and across multiple health care providers. Finally, the registry must be able to adapt over time to new information, evidence and care processes that support the improvement of patient care.

Support health research

Patient registries can support research across all forms of disease and all manner of interventions, and a range of different research study methodologies can be supported by patient registry data; descriptive studies, research design improvements, process studies, intervention studies, hypothesis testing and randomised control trials (Gliklich & Dreyer, 2014; MRCG, 2012; Newton & Garner, 2002). In situations where research questions cannot be answered by registry data alone, the availability of patient identifiers within the registry can enable linking with other data sources (Gliklich & Dreyer, 2014), although processes for managing consent, data sharing, data transfer and data issues (e.g. patient matching, data duplication, patients in one source but not in the other) will be required. Patient registry data can also support the prioritisation of funding allocation to public health and health research priorities, as it helps to bridge the gap between research and practice and provides an evidence base from which to drive patient care and public health initiatives (González, 2015).

Facilitate health technology assessment

Health services face a growing need to be able to evaluate an ever-increasing range of new treatments and technologies. Although similar in some regards to research studies, these assessments typically precede government or health service approval for new treatments as they essentially use a cost-benefit analysis to establish the value of an intervention (Patrick et al., 2010). The completion of a health technology assessment has not as yet been carried out prior to the establishment of any of the existing Irish patient registries, although it has been suggested as something that should be considered for new registries.

While it is certainly possible to design registries that aim to address all of the above objectives, it is generally easier to establish patient registries that have public health needs and patient care as a primary objective as a registry built primarily to meet specific research objectives would require a substantially different design (Newton & Garner, 2002). In addition, rare disease registries are helped by clear diagnostic criteria and a limited number of care centres, each of which reduces the complexity of data collection, while the diagnostic criteria may be uncertain or more complex for other diseases or disease-specific outcome measures may be evolving. In these cases, the initial registry will need to be designed in a way that is more flexible and facilitates change so that it can adapt and grow as more information becomes available.

2.2 Review of existing best-practice guidelines

As more patient registries are established, operated and evaluated, it is becoming easier to identify the characteristics that drive success, those that can lead to problems and to be guided by the experiences of existing registries and the lessons they have learned. As a result, best practice guidelines have begun to emerge, initially in the UK (Newton & Garner, 2002), then in Sweden (EyeNet Sweden with support from the Decision Body for National Quality Registries, 2005), Australia (Australian Commission on Safety and Quality in Health Care, 2008) and most recently the US (Gliklich & Dreyer, 2014; Milken Institute, 2016) and from the EU Cross-border Patient Registries Initiative (Zaletel & Kralj, 2015). A comparative summary of these four guideline documents is provided in Annex 2 of the MRCG and IPPOSI (2011) strategic report. A brief summary of the recommended guidelines from across the four documents is also presented here.

2.2.1 Registry purpose

Each set of guidelines highlight the importance of formulating specific aims and objectives for the registry as these will enable the registry scope, target population and stakeholders to be clearly identified. Gliklich and Dreyer (2014) recommend designing the registry with respect to its primary purpose; this requires careful prioritisation of a range of objectives that are likely to be held by different stakeholders. Questions of clinical and epidemiological interest must be capable of being translated into specific, valid and measurable data items and clinical outcomes. Consideration will need to be given to where these data can be found, potential sources of bias and the feasibility of collecting these data accurately, comprehensively and in a timely fashion. A patient registry will not be successful or sustainable if it does not address the purpose for which it was intended.

2.2.2 Registry data

Best-practice guidelines illustrate that the core processes that must be supported by a patient registry are the selection of appropriate data and its collection, storage and processing.

Data selection: Required data items should be driven by the purpose of the registry, the target population (clearly identified with appropriate inclusion and exclusion criteria), the intended users and the specific outcomes of interest, including the quality characteristics that need to be measured. The collection of data with marginal value should be avoided (MRCG & IPPOSI, 2011). The comprehensiveness and validity of the registry data will largely depend on how well these data variables have been selected. Best practice guidelines recommend that a registry balances importance (data integrity and analysis of primary outcomes) and reliability with the ease or complexity of data collection, cost and the burden placed on data providers and patients. A registry should also focus on consistency across patients and across data collection sites, which influences the sources of data, the measures that are chosen and how data are collected by the registry. Not only is the importance of data standards stressed in each of the published guidelines documents, funding allocations are based on evidence of meeting these standards in the US (Gliklich & Dreyer, 2014) and in Australia (Australian Commission on Safety and Quality in Health Care, 2008).

Data collection: A single registry can collect data from a single source or it can integrate data from a variety of sources. An integrated system for collecting, cleaning, storing, monitoring, reviewing and reporting on registry data is recommended as this maximises the utility of the registry and more easily enables all registry goals to be met (Zurriaga et al., 2015). This does increase the complexity of the registry and sufficient personal identifiers will be required in order to match accurately patient data. Some see the use of shared patient identifiers as a tool to reduce administrative overheads and facilitate data exchange, but others see serious privacy and data protection concerns related to their use (MRCG, 2012; Newton & Garner, 2002). This debate is still unresolved in the US (Gliklich & Dreyer, 2014), but unique patient identifiers are widely used in the Scandinavian countries. The MRCG and IPPOSI (2011) argue that electronic patient records are the

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building blocks of effective and efficient registries and they can certainly streamline the data collection process, however, effective data collection procedures can be designed in situations where these are not available as long as robust data linking procedures ensure accuracy and effectiveness of registry data. The guidelines caution that data collection is costly and registry designers must be aware of the likely burden on data providers. Although it is recommended that data are collected as close as possible to the point of care, data collection during routine health-care procedures is often perceived as extra work 'imposed' on frontline healthcare professionals and can reduce their motivation to engage with the registry (EyeNet Sweden, 2005). Finally, data collection tools should be adequately pilot tested before being rolled out across the healthcare system to ensure ease of use, the collection of accurate and complete data and the robustness of the collection and issue resolution processes.

Data management: The ideal registry model would be a computerised system that imports data directly from electronic medical records in various locations and settings, with unique patient identifiers that facilitate data matching (Zurriaga et al., 2015). This ideal remains elusive but best practice dictates that a national registry should strive to create secure encrypted web-based data entry, data feedback and ad hoc reporting mechanisms and an online system for handling participant usernames, passwords, consent and other administrative functions (EyeNet Sweden, 2005). New registries are encouraged to consult with, or obtain the services of, an established technology firm with proven success in the creation and secure management of patient registries (Milken Institute, 2016). The precise level of data security required will be driven by the purpose of the registry and the nature of the data within. Each registry must establish the legal requirements that are specific to their collection, storage, processing and reporting of anonymised and personally identifiable health-care data, and the associated level of data security required given the available technical options, their cost and the likely risks to be mitigated.

Data quality: Monitoring data collection against an established data dictionary ensures that items are collected and stored in accordance with the correct procedures, that data meets predefined quality standards and that it is capable of meeting registry objectives. Potential missing data can be identified and the impact of data issues on results generation can be minimised. Best practice guidelines recommend the creation of a quality assurance plan that identifies and monitors the most likely and most critical sources of error and the issues that will have the greatest impact on the accuracy and the validity of the results.

2.2.3 Ethics and privacy

The purpose of the registry, the type of entity that creates and maintains the registry, those that contribute the data and use the reports and the extent to which data are anonymised or identifiable will drive the ethical, privacy and legislative implications of the registry. Public health and quality improvement initiatives can be driven by results based on fully anonymised data, but it is difficult to operate a registry with this type of data alone (Newton & Garner, 2002). There is the basic need to be able to match data from different sources to avoid double counting and to create complete longitudinal patient records as individuals move between different services and service providers. Registries may also wish to validate their data against other existing databases or to link with data in other unrelated datasets for research purposes. Although the consensus across best practice guidelines is the use of fully informed consent, it is possible to obtain different levels of consent for different registry functions, albeit that a more complex data management process will be required to support this. Where an individual is unable to give informed consent, proxy consent or assisted decision-making supports should be sought from a relevant other in accordance with legislative and research ethics requirements. If the use or availability of identifiable data changes, re-consent may be required. The form and documentation of initial and revised consent needs to be explicitly stated in the registry rules and a process put in place to manage the removal of data from the registry if consent is withdrawn.

2.2.4 Funding and resources

Funding is central to the sustainability of a registry and the final costs are generally determined by a combination of registry size, function, quality and the complexity of data collection and reporting processes. There are ethical implications if data are gathered without having a sustainable funding stream identified (MRCG & IPPOSI, 2011) yet, funding seems to be insecure for registries that do not have a national mandate (Newton & Garner, 2002). It is also rare that a single funding stream will be sufficient to ensure that sustainability of a registry in the longer term (Milken Institute, 2016).

Four guiding principles have been suggested to assist with funding allocations to patient registries:

- the relevance of the registry in terms of severity, volume, costs and needs, addressed at a national level;
- the potential of the proposed design to provide the information required;
- the competence of the registry governance structure to deliver;
- and the likely analysis and feedback that the registry can provide to enable clinical improvement (EyeNet Sweden, 2005).

Newton and Garner (2002) suggest that health authorities, specialist commissioning groups, national bodies and primary care centres should fund registers that inform public health policy and patient care improvements. Stakeholders are also likely to incur some costs and these are typically not borne by the registry itself, so funding packages may need to be structured in a way that enables stakeholders to claim for registry-related expenses to ensure their support. The consensus from best-practice guidelines is that although contributions from industry can be received, these must be evaluated carefully and appropriate consideration given to the continued independence and credibility of the registry.

2.2.5 Registry governance

Formal governance structures provide the overall direction for and facilitate the smooth operation of the registry (Wall, Irvine, & O'Brien, 2015). A governance plan should be prepared that clearly assigns responsibility for each registry function, data ownership and all aspects of data management. Swedish guidelines suggest that it can be particularly advantageous to invite key stakeholders essential to the overall success of the registry and any specialist associations or supporters to become members of the registry steering committee. This helps increase their motivation to support the successful operation of the registry (EyeNet Sweden, 2005). It also ensures that all stakeholders have a voice in the periodic evaluation of the registry and its ability to meet its objectives, to review potential changes to or expansion of any of the established registry processes and to plan and manage the range of issues that arise during the day-to-day operation of the registry. All guidelines also recommend the inclusion of members from established registries as they will be further along the natural lifecycle of a patient registry and their expertise can provide valuable guidance.

2.2.6 Registry quality and evaluation

The characteristics that describe quality healthcare in the US and Swedish health systems are “knowledge-based, suitable, safe, patient-oriented, effective, and unbiased” and ‘timely’, and the objective of any patient registry should be to facilitate the continuous strengthening and improvement of these attributes (Brkić, Pleše, Pajić, Pristaš, et al., 2015; EyeNet Sweden, 2005). Regular and transparent registry evaluations are essential in order to provide confidence that the registry design is fit-for-purpose, that registry processes are conducted ethically, legally and appropriately to meet these objectives, that data analyses are protected against bias and systematic error (Brkić, Pleše, Pajić, Pristaš, et al., 2015) and to encourage interoperability with other registries and research collaborations. Gliklich and Dreyer (2014) recommend that a registry evaluation differentiates between “research quality”, defined as the scientific process of the registry, and “evidence quality”, that which relates to the selection and collection of data items, and the analysis and interpretation of findings. A registry evaluation should also include an assessment of the cost of the resources needed to operate the registry, the effectiveness of

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the registry governance structures and suggest improvements where appropriate. Although comprehensive annual evaluations are recommended, there is a need to balance the scope of these evaluations with their feasibility and affordability. The responsibility for registry evaluations should be determined during initial planning.

2.2.7 Registry outputs and the use of registry data

Best-practice guidelines suggest that the registry's governing body should decide who accesses registry data and for what purpose, and the degree of transparency applied to registry findings and reports. The guidelines generally recommend considerable openness in the reporting of results, particularly with non-identifiable data, but they also acknowledge the need to balance openness and privacy requirements, and they caution that the registry may first need to reach a certain degree of maturity so that the validity and accuracy of reported results can be assured. It is likely that different levels of transparency will be agreed for different stakeholders so the guidelines recommend the development of an analysis and reporting framework that details the different types of reports that will be produced, report frequency, intended audience(s) and how data will be analysed and outcomes addressed. Frequent communication can be an effective tactic for keeping participants and stakeholders engaged (Milken Institute, 2016). At a minimum, the registry should meet with all stakeholders once a year and produce a publicly available annual report (see Gliklich and Dreyer (2014) for a detailed recommendation on the content of these reports). Guidelines suggest that local registry managers and data providers should also have the ability to perform ad hoc queries within the bounds of privacy and data access rules and consent limitations. At a minimum, this should include the ability to compare themselves to average data and see how all providers are distributed around the mean. All other requests for data access should be made formally to the registry and adjudicated on separately. Best practice guidelines also recommend that all publications that use registry data should be peer reviewed prior to publication.

2.2.8 Facilitating registry interoperability

Achieving interoperability with other national and international registries and databases is becoming increasingly important (Gliklich & Dreyer, 2014).

As a result, best practice guidelines highlight:

- the need for open standards that facilitate communication and data transfer without specific customisations at either end (syntactic interoperability);
- shared data dictionaries;
- standardised data definitions and measures (semantic interoperability);
- mutually agreed operating principles underpinned by the appropriate legal and ethical frameworks to govern data sharing and independent governance processes.

The PARENT framework (Brkić, Pleše, Pajić, Kostešić, et al., 2015) is an example of an objective-based framework that provides guidelines to and a shared infrastructure for the development of registry environments that support interoperability needs.

2.3 Review of international dementia registries

Since the 1980s, several dementia registries have been established internationally. No one ideal model for a dementia registry has as yet been established and it can be argued that design should be based on the objective of the proposed registry (González, 2015). Population registries are most common among international dementia registries and they provide useful epidemiological data for policy-making and planning resources and services for people with dementia and their families. A summary of the international dementia registries that are currently active is provided in Table 2 and a brief overview is presented of each.

2.3.1 Swedish Dementia Registry (SveDem)

SveDem was established in 2007 to monitor and improve the quality of diagnoses, treatment and care of patients with dementia. It is currently the most comprehensive dementia registry covering almost all of Sweden. Swedish National Guidelines for Care (Socialstyrelsen, 2016) identify seven indicators to evaluate the quality of dementia care:

- 1 proportion of patients diagnosed with dementia in last year;
- 2 proportion of patients undergoing basic dementia work-up;
- 3 proportion of Alzheimer Disease (AD) patients treated with cholinesterase-inhibitors and/or memantine;
- 4 proportion of patients treated with anti-psychotic drugs in nursing homes;
- 5 proportion of patients with day-care at diagnosis;
- 6 proportion of patients living in nursing homes;
- 7 proportion of patients followed-up at least once a year.

For each indicator, SveDem has established internal goals that they continually work towards achieving such as 90% of people receiving basic dementia work-up and reducing use of antipsychotic use in nursing homes to 10% (Religa et al., 2015).

People with dementia and their families have the right to 'Opt-Out' or have their data removed from the registry if they wish (Religa et al., 2015). The data are collected by physicians or nurses at affiliated SveDem units and entered into a web-based registry. A local co-ordinator for each unit can manage their own data and they can compare this to data from all units in Sweden. When the registry began, the majority of affiliated units were specialist settings (memory clinics) with data from primary care units gradually increasing from 25.6% (2007) to 48.2% (2012). By 2015, 93% of all specialist settings and 60% of all primary care centres were covered (Religa et al., 2015). Nursing homes were affiliated in 2012 and the registry continues to grow with 58,823 people registered as of 31st March 2016 (SveDem, 2016). The availability of unique health identifiers facilitates the use of multiple sources and supports increased accuracy and completeness. Furthermore,

TABLE 2 Active international population and clinical dementia registries

Registry	Country	Category	Year	Size	Inclusion	Assessment	Data sources	Data collected	Ownership	Consent	Funding
SveDem	Sweden	Population	2007	58,823	Dementia diagnosis	ICD-10	Specialist clinics, psychiatric primary care, nursing homes	Unique identifier, diagnosis, dementia sub-type, MMSE, diagnostic data, pharmacological and non-pharmacological treatment and support, BMI, demographic data, annual follow-up data	Karolinska University Hospital	Opt-out	State and Swedish Brain Power Network
DCDR	Denmark	Population	Est. in 2005 National 2016	30% of Danish population of PwD as of 2011*	Dementia and query dementia including MCI	ICD-10	Geriatric, psychiatric and neurology clinics	Data relating to eight quality indicators including diagnosis, sub-type, medication (see section 2.3.2)	Danish Clinical Registries	Mandatory	State
ReDeGi	Spain	Clinical	2007	70% Girona population to date*	Dementia diagnosis	DSM-IV-TR	Geriatric and neurology departments	Data source, diagnosis, diagnostic data, MMSE, CDR, BDRS,	Department of Health (Catalunya)	Opt-in	State
SCADR	USA	Population	1988	230,000	Dementia diagnosis	ICD-9	Federal databases, Revenue and Fiscal Affairs Offices	Case-identifying data, diagnosis, source, socio-demographic data, caregiver contact details, other medical diagnoses	Department of Health and South Carolina University (joint)	Mandatory HIPAA exemption	Partial state funding (not guaranteed)
WVADR	USA	Population	2011	28,000	Dementia diagnosis	ICD-9 ICD-10	Medicare Clinicians	As for SCADR	West Virginia University	Mandatory HIPAA exemption	Previous state funding, currently uncertain
GARDR	USA	Population	2014	112,430 (2013)	Dementia diagnosis	ICD-9 ICD-10	Medicare	As for SCADR plus diagnostic test results	Georgia Department of Health	Mandatory HIPAA exemption	State

*Where actual numbers of patients registered were unavailable, most recent published figures were used
 BDRS: Blessed Dementia Rating Scale; BMI: Body Mass Index; CDR: Clinical Dementia Rating Scale; DCDR: Danish Clinical Dementia Registry; DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders-Version 4-Text Revision; HIPAA: Health Insurance Portability and Accountability Act; ICD-9: International Classification of Diseases 9th Revision; ICD-10: International Classification of Diseases, 10th Revision; MMSE: Mini Mental State Examination; PwD: People with Dementia; ReDeGi: Registry of Dementia in Girona; SCADR: South Carolina Alzheimer’s Disease Registry; SveDem: Swedish Dementia Registry; WVADR: Washington Alzheimer’s Disease Registry.

a research nurse visits all SveDem units to verify that the data in the registry matches the original data in the person's medical records. Yet, despite the comprehensiveness of the registry, difficulties remain regarding the involvement of primary care centres. A significant part of the regional co-ordinators role relates to ongoing efforts to ensure primary care units are affiliated with SveDem to facilitate the completeness and accuracy of the data in the registry (Religa et al., 2015).

SveDem receives government funding (Swedish Association of Local Authorities and Regions) and funding from the Swedish Brain Power Network. It is governed by a steering committee made up of several healthcare professionals and headed by the registry holder who, along with the national co-ordinator, has responsibility for day-to-day registry function. There is also a full-time administrator employed by the registry and regional co-ordinators to ensure that SveDem is being implemented correctly in the units throughout the country. Uppsala Clinical Research Centre is responsible for developing the online database and its technical support and security, while Karolinska University Hospital has overall responsibility for the data. The organisational structure of SveDem, described in detail by Religa and colleagues (2015, p. 5), is an example of a comprehensive governance structure that can be adopted by any patient registry.

In addition to publishing an annual report of the quality of dementia diagnosis, treatment and care in Sweden, SveDem has published a variety of research studies using SveDem data that relate to prevalence (Religa et al., 2012), diagnostics (Falahati et al., 2014), costs (Wimo et al., 2013), medication (Fereshtehnejad, Johnell, & Eriksdotter, 2014), risk factors for dementia (Nilsson, Waldö, Nilsson, Santillo, & Vestberg, 2014) and clinical aspects of dementia (Eriksson et al., 2014). In a recent review, Religa and colleagues (2015) illustrate how SveDem can contribute to the enhancement of expertise and how it supports the embedding of application of research findings in clinical practice. They suggest that SveDem could also address some of the methodological problems currently experienced when researching dementia (e.g. research on individuals that do not reflect the population at risk) as it could function as a tool to identify and recruit patients that are suitable for specific studies. Given the possibility to observe the clinical course and progression

of dementia, they also suggest that SveDem could facilitate certain improvements in clinical trial design.

2.3.2 Danish Dementia Registry (DCDR)

DCDR, created in 2010, gathers dementia-related data from six geriatric, eight psychiatric and four neurology clinics relating to eight quality indicators that were chosen on the basis of meeting agreed minimum standards (Johannsen et al., 2011; Phung et al., 2007), namely:

- 1 percentage of patients with dementia proportional to number referred;
- 2 proportion of patients with dementia (including those with mild cognitive impairment) evaluated within 90 days;
- 3 proportion of patients assessed with the Mini Mental State Examination (MMSE);
- 4 proportion of patients assessed using Functional Activities Questionnaire (FAQ) scale;
- 5 proportion of patients with available results of all recommended blood tests;
- 6 proportion of patients with a CT or MRI scan;
- 7 proportion of patients where etiological diagnosis is determined;
- 8 proportion of patients with Alzheimer Disease, Dementia with Lewy Bodies and Parkinson's Disease Dementia treated with anti-dementia drugs.

Despite the use of mutually agreed guidelines, diagnostic variance still occurs.

The Danish Clinical Registries (RKKP) was subsequently established with responsibility for the infrastructure of all national clinical quality databases. With an annual budget of approximately €6.5m, RKKP manages 69 such clinical registries, now including the DCDR, which was rolled out on a national level in January 2016. As the purpose of clinical quality databases is to survey quality of health care services that are approved by the Danish National Board of Health, information can be collected without an individual's consent (Johannsen et al., 2011). RKKP consists of registry support centres, epidemiology and biostatistics that are affiliated with specialist universities and clinical quality and health informatics. Data are registered by clinical personnel and gathered through data-collection systems accessible from all computers within the hospital system. RKKP provides

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quality improvement feedback to clinicians and produces a yearly report with analysis and recommendations per database (Databasernes Faellessekretariat, 2016). Each registry has a professional board appointed by professional medical and nursing societies, representing the main clinical stakeholders, and each has to pass appraisal in the National Health Authority every three years, where it is assessed against national criteria for functionality, data safety and methodology.

Rather than following a typical dementia registry model such as that used in Sweden, the DCDR facilitates a continuous process of data collection that in turn supports harmonisation and quality improvements in services provided in each participating institution (Johannsen et al., 2011). Despite the use of different models, comparative studies with SveDem data demonstrate the potential value of using registries for comparing patient demographics, diagnostic procedures, diagnostic accuracy and the quality of dementia care in different countries (Fereshtehnejad et al., 2015).

2.3.3 The Registry of Dementia of Girona, Spain (ReDeGi)

ReDeGi is a clinical registry of newly diagnosed dementia cases established to gather epidemiological data to inform policy and planning services for dementia (Garre-Olmo et al., 2009) and to facilitate research. To date, these have predominately been drug studies (Àvila-Castells et al., 2013; Calvó-Perxas et al., 2012; Turró-Garriga et al., 2015). ReDeGi currently covers 70% of the Girona region and its limited scope (seven data collection sites) and size make it relatively easy to manage (ReDeGi, personal communication, April 2016). It offers an alternate approach to a comprehensive national registry model such as that implemented in SveDem and one that could be utilised as a starting point for any dementia registry that requires the potential to expand its scope over time. Patient consent is obtained following diagnosis and a registry technician reviews the patient's medical records, transcribes the required data into a paper data collection form and then enters the data into the registry database. While ReDeGi do not receive data directly from primary care sources, they do not consider this a significant factor because suspected cases of dementia in primary care are referred to memory clinics in one of the seven hospitals in the region (ReDeGi, personal communication, April 2016). Registry data can reliably be used to ascertain the incidence of new cases that contact specialised health services but caution is needed when estimating diagnostic coverage as the data are not representative of the real population incidence. The diagnosed cases consist of people referred to a specialised diagnostic clinic some of whom present with moderate to severe severity and a mean time of two years from onset of symptoms to time of diagnosis (Garre-Olmo et al., 2009). ReDeGi has a board and employs a director, a researcher and a technician. Annual reports containing data longevity statistics and quality evaluations are submitted to the regional government, and comparisons to MMSE scores validate the overall quality of the data in the registry.

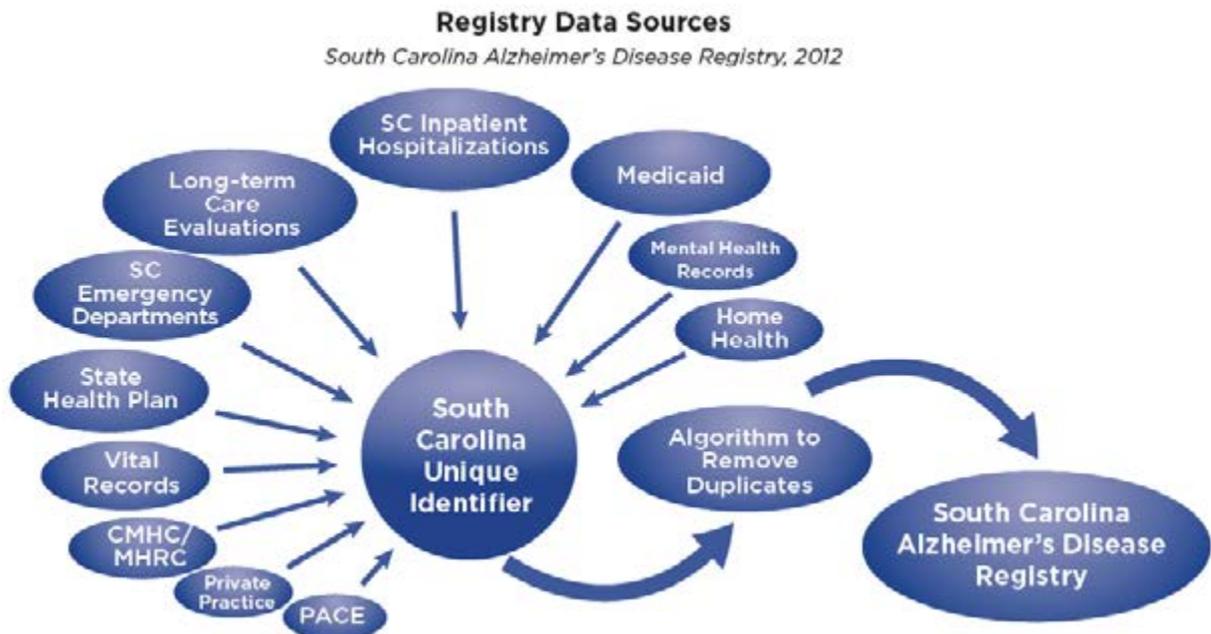


FIGURE 1 SCADR Data Sources (Arnold School of Public Health, 2014)

Reprinted with permission from South Carolina Alzheimer's Disease Registry Annual Report 2013-2014 (p. 4), by Arnold School of Public Health, 2014, Retrieved from http://www.asph.sc.edu/osa/OSA_annualreport_FINAL1.pdf. Copyright 2014 by Arnold School of Public Health.

2.3.4 South Carolina Alzheimer's Disease Registry (SCADR)

SCADR is a population registry of over 230,000 cases of Alzheimer's disease and related disorders (ADRD) in South Carolina (Arnold School of Public Health, 2014). It aims to provide disease prevalence estimates to support social and medical service planning, identify differences in disease prevalence among demographic groups, improve care for those with ADRD and to foster research into risk factors for ADRD. Numerous research studies have been carried out using registry data; for example, behavioural difficulties in long-term care (Dennehy, Kahle-Wroblewski, Sarsour, & Milton, 2013). Additionally, the registry facilitates many requests for information from grants projects with local hospitals and agencies (SCADR, 2016).

The SCADR can access multiple data sources, as outlined in Figure 1, yet the registry acknowledges that coverage issues remain, in particular data completeness as diagnosis and/or treatment can

take place in many different settings. Additionally, the registry misses data on those who do not seek medical treatment, a problem with all registries and the individuals who cross into border-states for diagnosis and/or treatment (SCADR, personal communication, May 2016).

In the United States, the collection of data that is deemed to be in the best interest of the public's health and well-being, is exempt from the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (U.S. Department of Health and Human Services, 2016). When a person goes to any medical facility they usually sign an agreement form that authorises the release of data for health statistics and health study purposes and acts as consent. As a result, SCADR does not need to obtain specific consent to collect and store registry data. Identifiable data are held by the registry but it can only be accessed by registry staff (SCADR, 2016). The registry itself is based in the Office of Aging in the Arnold School of Public Health in the University of South

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Carolina (USC) and USC has joint ownership of the registry data with the Department of Health and Human Services. SCADR is governed by a board and it employs a Registry Co-ordinator who is an epidemiologist and a PhD student who is a biostatistician, but USC is accountable for meeting quality standards as they are most involved with running the registry on a day-to-day basis. SCADR provides mandatory annual reports to its board, to legislators, to agencies they work closely with (e.g. The Alzheimer's Association) and to researchers in the university.

2.3.5 West Virginia Alzheimer's Disease Registry (WVADR)

WVADR is a population registry that collects data from healthcare providers on newly diagnosed cases of AD/DR in West Virginia to enable policy, planning and research (WVADR, 2016). Patient data are similar to that collected by SCADR and they can be submitted on paper or entered by clinicians through a web-based registry data entry screen (Schreurs, 2010). WVADR acknowledges there have been obstacles in obtaining 'buy-in' from healthcare providers to provide patient information; the 3,500 registered entries in 2013 fell considerably short of the estimated 36,000 people diagnosed with dementia in the state. Subsequent access to data from the Medicare database, the national social insurance program and medical provider for all over 65s in the United States, has led to an increase in the number of cases registered by early 2015 to almost 28,000 (Schreurs, 2010).

Under HIPAA exemption rules, the WVADR does not require consent to collect data, but patients are assigned a unique identifying number to protect their privacy. Access to identifiable data is restricted to the Registry Director and only summary statistical data are used in all reports (Schreurs, 2010). The registry is located in West Virginia University and is run by a board of governors and overseen by an advisory board that includes representatives from The Blanchette Rockefeller Neurosciences Institute, The Institute on Aging, Marshall University, West Virginia Department of Health and Human Resources and representatives of public and private entities and organizations and other individuals involved in AD/DR (WVADR, 2016). Previously funded by the state, recent deficit cuts have left the sustainability of the registry at a challenging crossroads, but it is hoped that the legal status of the registry

will facilitate its survival (WVADR, personal communication, June 2016).

2.3.5 Georgia Alzheimer's and Related Disorders Registry (GARDR)

GARDR is a population registry located within the Georgia Department of Public Health (GDPH) and based on the SCADR and WVADR models. It aims to collect sufficient data to identify epidemiological trends, inform programs and services for the ageing population, increase awareness at state level to the issues that affect healthy ageing and to plan and manage future registry needs (GDPH, 2016). Currently, Medicare is their only source of data but they plan more comprehensive data collection in the future and the registry has created a secure portal for physicians to report diagnoses of AD/DR. The registry acknowledges getting agreements in place for data sharing and 'buy-in' from clinicians is challenging (Georgia Department of Human Services, 2015).

2.3.5 Other dementia registries and databases

Within this review, we identified a number of international dementia registries that were successfully implemented but have since ceased to operate. Additional dementia registries whose definition does not meet the criteria for inclusion in this study and some proposed dementia registries that have not as yet progressed beyond the proposal or pilot stage were also identified. The additional registries and databases are summarised in Table 3.

TABLE 3 Other dementia registries and databases identified during the literature review

Registry	Country	Category	Year	Inclusion	Funding	Status and Description
CDCR (Camberwell Dementia Case Register)	UK	Case	1992–1997	Dementia diagnosis	Project grant and donations	Ceased – was specifically created to refine diagnostic criteria for dementia and develop predictive tests or risk factors for dementia subtypes (Cooper & Holmes, 1998); examine non-cognitive symptoms and clinical correlations of different subtypes (Holmes & Lovestone, 2003); and act as a framework for clinico-pathological studies (Russ et al., 2001) by the additional collection of biological material, ante- and post-mortem, from registry participants (Holmes, 1996).
CERAD (Consortium to Establish a Registry for Alzheimer’s Disease)	USA	Clinical-Epidemiological	1986	Alzheimer’s Disease diagnosis	National Institute on Aging (NIA)	Does not meet ‘Dementia Registry’ criteria – CERAD was established in 1986 to standardize procedures for the evaluation and diagnosis of patients with AD (Fillenbaum et al., 2008).
NYSDR (New York State Alzheimer’s Disease and other Dementias Registry)	USA	Population	1986	Dementia diagnosis (ICD-9)	State	Replaced – established in 1986 as a surveillance system to collect information necessary to “ <i>identify, locate and investigate the occurrence, frequency, incidence, cause, effect and prognosis of Alzheimer’s Disease</i> ” and maintain this information for research purposes (Lillquist, 2004). The New York State Coordinating Council for Services Related to AD/DR now produces reports every two years with general information about AD/DR that appears to have replaced the NYSDR (New York State Department of Health, 2016). Prevalence and epidemiological data are not reported.
ReDeCar (Centralised Registry of Cases with Cognitive Impairment in Argentina)	Argentina	Clinical-Epidemiological	2009	Cognitive Impairment diagnosis	National Health Research Committee	Does not meet ‘Dementia Registry’ criteria – Proposed development of a Cognitive Impairment Centralized Case Registry in Argentina based on the Epidemiological Surveillance Model. An observational prospective study was conducted in different healthcare centres and hospitals around Argentina (Melcon et al., 2010).
ReCeDemCu (Cuban National Dementia Registry)	Cuba	Clinical-Epidemiological	2015	Dementia diagnosis (DSM-IV or ICD-10)	State funding suggested	Does not meet ‘Dementia Registry’ criteria – Proposal for a centralised automated registry on cognitive deterioration and dementia in Cuba. A pilot study was scheduled to begin in 2015 to test the operational structure of hospitals, specialised clinics and several primary care facilities where registries will be compiled and later extended nationally (González Cáceres, 2013). No further information is available.
UCLA Alzheimer’s and Dementia Care Program	USA	Clinical-Epidemiological	2012	Dementia diagnosis	Assessment charge and multiple grants	Does not meet ‘Dementia Registry’ criteria – Patients are referred from physicians, usually general practitioners or geriatricians for the medical management of dementia-related issues by Nurse Practitioners (Reuben et al., 2013).
WADPR (Washington Alzheimer’s Disease Patient Registry)	USA	Population (post January 1987)	1987–1997	Dementia diagnosis	National Institute of Aging grant	Ceased – gathered epidemiological and genetic data for research purposes in a circumscribed area of Seattle with approximately 23,000 people over the age of sixty who were cared for by seven to nine primary care clinics (Larson et al., 1990). The registry did not intend to find ‘all’ cases of AD/DR but rather to find as many newly diagnosed cases as possible in the specified area (WADPR, 2016).

2.4 Review of existing patient registries in Ireland

The feasibility of any patient registry is influenced by the environment in which the registry operates. This section provides an overview of the policy and legal frameworks relevant to the creation of a national dementia registry in Ireland. The development of patient registries in Ireland is recent, but they continue to grow in number. The section concludes with a more detailed review of three examples representing the current spectrum of Irish patient registries. They demonstrate that a lot can be achieved within the current limitations of the Irish health system.

2.4.1 Strategic policy framework

Discussions regarding the strategic nature of patient registries have been taking place in Ireland over the last ten years. They have included a 2007 working group comprised of representatives from the HSE, Health Research Board (HRB), Health Information and Quality Authority (HIQA) and the research charities. A 2008 meeting on patient registries was attended by experts from science, industry, patient groups, medical charities and other key stakeholders. Despite this, there is still a lack of strategic direction in Ireland and the recommendations that were included in the Health Information and Patient Safety Bill (HIPS) consultation documents have had little response from government to date and the momentum has gradually ‘fizzled out’ (IPPOSI, 2015; MRCG & IPPOSI, 2011). Although HIQA have published guiding principles for health and social care data collection in Ireland (Health Information and Quality Authority, 2013), these do not go as far as setting national standards for databases such as patient registries and HIQA’s remit currently only extends to data collection within the HSE. They have identified that current data collections are often paper based, have limited data dictionaries and limited standardisation of coding, and are poorly integrated with other patient information systems (Donoghue, 2011). As a result Irish patient registries are characterised by significant heterogeneity with regard to size, function, disease, funding, cost and governance, and they still tend to be seen as external to the health service and somewhat of an ‘add-on’. According to

the MRCG and IPPOSI (2011), the fragmented nature and the absence of a strategic policy framework for the operation of patient registries has detrimental implications for future research in Ireland. For example, Irish institutions or researchers may be unable to participate in research at national or international levels because of a lack of accurate and comprehensive data or due to an inability to identify potential research participants, with subsequent impact on the profile of health research in Ireland and the potential to secure future international funding.

The MRCG and IPPOSI (2011) report advocates for incorporating the findings from high-quality patient registries into mainstream health service reports and decision-making while still ensuring that patient registries remain independent and in line with international best-practice. They see the Swedish registry support model as good practice that can inform policy development in Ireland. This model provides centralised allocation of resources, a national body for co-ordinating funding and the prioritisation of disease areas for investment (Swedish Association of Local Authorities and Regions (SALAR), 2005). Using this model, strong patient care and business cases can be made to support the creation of new patient registries that increase the effectiveness and efficiency of health services in Ireland. This is particularly the case for patients requiring chronic disease management that comes at a considerable cost to the state. The first step towards developing a strategic framework and appropriate funding mechanisms to support patient registries in Ireland is to raise awareness and understanding of the value of registries with all key stakeholders and demonstrate how the information gathered in existing patient registries can be integrated into decision-making processes (MRCG & IPPOSI, 2011). A potential Patient Registries Framework was suggested in the MRCG and IPPOSI (2011) report and this is reproduced with permission in Table 4.

TABLE 4 Patient Registries Framework*

Shared characteristics: The whole national population of the disease is covered. Each individual person (patient) is registered only once as a unique entity that is not duplicated.	
Patient Registry	The gold standard in the registries framework is the independent and well-resourced patient registry. A wide range of relevant data is collected and analysed. Compatibility with data collected by registries in other countries is a key concern. Registries strive to provide data and analysis that can shape the planning, delivery and review of services impacting on a particular disease, but not on the day to day treatment of individual patients. Depending on the level of resources, registries generally employ full and part-time staff with a range of data capture and analysis skills.
Patient / Electronic Health Register	Patient/Electronic Health Registers are an important development. They tend to be primarily developed and led by clinicians as an operational tool from which to support treatment and provide a relatively sophisticated level of data capture and analysis. Patient/Electronic Health Registers are less likely to have full or part-time staff. Resource issues are also likely to restrict the range of data collected and analysed and, concomitantly, they may have less of an impact on shaping overall policy in relation to a particular disease.
Patient Database	Patient Registries at their most basic are databases of patients who share some characteristics, such as a certain condition or medication regimen. They can be very useful in helping to deliver a defined service, including services provided by national patient advocacy bodies (mainly charities). Also developed in some instances by the pharmaceutical industry to support research.
Electronic Patient Records (hospital level)	Increasingly essential to the development of Patient Registries is the development of Electronic Patient Records (EPR). The EPR's contain relevant information captured by a hospital on all patients from one disease area attending that Hospital. Electronic Patient Records are, at present, an optional add-on to complement mandatory paper-based patient records. They are primarily developed for operational use in the treatment of a particular disease, including analysis of the key health indicators and treatment records of individual patients over a period of time. They also provide the most effective way for registries operating at a national level to capture the data they need, once the data capture template for Electronic Patient Records is consistent with that of the registry and data protection is observed.

*Reprinted with permission from South Carolina Alzheimer's Disease Registry Annual Report 2013-2014 (p. 4), by Arnold School of Public Health, 2014, Retrieved from http://www.asph.sc.edu/osa/OSA_annualreport_FINAL1.pdf. Copyright 2014 by Arnold School of Public Health.

One of the core assumptions of this framework is the standardisation of patient records within the HSE and the use of electronic patient records (EPR). Although there has been some movement with regard to electronic health records and investment in eHealth in Ireland since the publication of this report, huge disparities still exist with regard to the recording of patient data and there is also huge variance in the quality of data recorded by different hospitals and GPs (IPPOSI, 2015; MRCG & IPPOSI, 2011). This significantly compromises the current ability of patient registries to collect and manage

data effectively and efficiently; the matching of patient data is currently tedious and labour intensive, although possible in the current environment.

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2.4.2 Legal and regulatory environment

There are a number of international directives, conventions and codes relevant to patient registries and these are summarised in Appendix 1 of the MRCG (2012) report on patient registries in Ireland. The Irish legislation, directives and codes relevant to patient registries, relevant Law Reform Commission reports and an overview of the proposed Health Information Bill are also presented in that report in Appendices 2, 3 and 4 respectively (MRCG, 2012). This section will highlight relevant legislation that has been introduced since 2012 (specifically the European Data Protection Reform 2016 legislation (European Council, 2016) and the Assisted Decision Making (Capacity) Act 2015 (House of the Oireachtas, 2015)) and comment on the current status of the Health Information and Patient Safety Bill.

Data Protection Legislation

The newly enacted EU Data Protection 2016 (EUDP) regulation that came into force on the 25th of May 2016 covers the use of personal data in all sectors other than law enforcement. At a meeting of the Irish Health Research Forum (IHRF) in May 2016, Dr Beth Thompson (Wellcome Trust) argued that the EUDP essentially falls somewhere between an EU regulation and a directive; the guidelines are quite flexible and they provide individual member states with a lot of scope to be more flexible in their own legislation as a result (IHRF, 2016). It essentially preserves the status quo for health research in Europe, although there are some points that will require further confirmation with the EU (IHRF, 2016). We are now in the two-year period where each member state must determine how to introduce the changes required by EUDP and to clarify their position in legislative changes of their own. As policy, clinical care and research all depend on data it is incumbent on all stakeholders to engage with the debate to determine how best to make the EUDP work for them. As such, this is an opportune time for the Department of Health, the HSE and all patient registry stakeholders (including clinicians, policymakers, patient advocates and researchers) to engage in debate with the Data Protection Office and the Department of Justice to ensure that the resulting Irish legislation takes the needs of current and future patient registries into account.

The following are the key elements that directly influence the creation of patient registries:

- The regulation applies to personal data; it does not apply to fully anonymised data, but there are inconsistencies in how different member states define 'fully anonymised'. Dr Thompson highlighted the fact that 'Pseudonymisation' was defined in the EUDP but the definition differs from that typically used in research and it does not address the idea of coding where a key holder typically has the ability to identify the data (a method used by a number of existing patient registries). Further direction will be needed from the EU in this regard.
- The need to ensure that confidential data are collected carefully, securely and comprehensively, and with an individual's consent – **once**. It is no longer acceptable to duplicate data collection in many sites.
- Consent processes should be specific, explicit and informed – careful consideration at a national level is needed to determine how best to implement this guideline, understanding that there will be times when obtaining this type of informed consent is difficult; for example, in situations where bio-bank data are being collected and we are unsure how it might be used in the future, or situations where there is a question regarding the person's capacity to give consent. The EUDP board are expected to issue guidance to member states covering these types of situations. Dr Thompson also suggested that 'public interest' is poorly defined giving member states some flexibility in determining their own definitions.
- Data controllers (e.g. the 'owner' of a patient registry) are now required to demonstrate their compliance with the regulation. It is possible that the Privacy Impact Statements (PIAs) created by HIQA may play some role here although that has yet to be determined.
- New rules and requirements have been included specifically related to data breaches.

Assisted Decision Making (Capacity) Act 2015

The Assisted Decision Making (Capacity) Act 2015 is scheduled to be commenced by Ministerial Order during 2016 (House of the Oireachtas, 2015). It provides a statutory framework that enables an individual who lacks, or may lack capacity, to make a decision unaided to receive support and assistance when making decisions about their welfare, property, health care and other affairs. The Act provides for different levels of decision making support: Assisted decision-making, Co-decision making, Enduring Power of Attorney, Wards of Court and the introduction of a Decision Support Service within the Mental Health Commission to oversee, deliver and support each of these new functions. The Act also introduces the concept of Advanced Healthcare Directives into Irish law. The Act defines capacity as the ability to understand, at the time the decision is being made, the nature and consequences of the decision in the context of the choices that are available at the time (Citizens Information Bureau, 2015). A person lacks capacity if they are unable to understand the information pertinent to the decision, if they are unable to retain the information long enough to allow them to make an informed choice, if they are unable to evaluate the information as part of the decision-making process, or if they are unable to communicate their decision. However, a person does not lack capacity if they require the information to be explained to them in a way that is appropriate to their ability to understand and interpret it, if they can only retain the information for a short period of time, if they lacked capacity at one time but no longer do so, or if they lack capacity for decisions on some matters but retain capacity to make this particular decision.

The exact operation and impact of this new legislation is not yet clearly understood, but the position will become clearer over time and the consensus is that it will support better decision-making and consent processes. From the perspective of the person with dementia, the Act will enable them to appoint a co-decision maker to help them make informed consent decisions in a range of areas including whether to go on the dementia register, or what data can be held on the register (e.g. tiered consent). The Assisted Decision Making Agreement needs to be signed by both parties and two witnesses (one of which can be a family member) and registered with the Decision Support Service. Although this seems to be additional

work, it is likely to be needed for a range of health-care decisions required in day-to-day dementia care so it is not an additional step for the sole purpose of facilitating the collection of registry data.

Health Information and Patient Safety Bill (HIPS)

Legislative changes take a significant amount of time in Ireland and the long-awaited Health Information and Patient Safety Bill (HIPS) is a case in point. The proposed bill deals directly with issues related to patient registries (Department of Health, 2014a). It includes proposals on the definition of patient registries in Ireland, ethical approval processes, privacy impact statements, individual health identifiers, data matching, data sharing and regulations governing research other than clinical trials. However, the regulations contained within the bill are currently proposed as voluntarily guidelines for non-clinical-trial research whereas similar rules are mandatory in the EUDP. The most prominent area of conflict between the two pieces of legislation relates to consent. HIPS states that patient registries must operate with patient consent unless they are deemed exempt from needing this consent. There are currently situations where local ethics committees can waive the need for written consent under certain conditions (e.g. low-risk data collection or data collection that is in the national interest). HIPS proposes a change that would mean that this waiver can only be made by the Data Protection Commissioner following a privacy impact assessment made in conjunction with HIQA (Department of Health, 2014a). Concerns have already been raised that this is too restrictive and could inhibit research. Instead, a graduated system that has the Data Commissioner in an arbitration role has been suggested, but there is a need to ensure that whichever approach is adopted, it is EUDP compliant. It should be noted that the waiving of informed consent is a situation that currently exists for some of the patient registries that are operational in Ireland today and for many of the established international dementia registries.

The other key aspect of the HIPS legislation is that it authorises the Minister for Health to introduce health identifiers for individuals and health providers. The format and operation of the identifiers are not included in the bill; they will be established under the Health Identifiers Act (House of the Oireachtas, 2014). The aim is to allow for unique identification

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of individuals and of health service providers for all health-related purposes including patient registries, thus facilitating interconnection and interdependence of policies and practice in health information and health research, reduced duplication and better data linkages (multiple cases of care). However, it assumes that a data sharing and legislative framework can be agreed and implemented (IHRF, 2016). Moreover, HIPS includes a provision whereby an individual can refuse to provide their individual identifier to health services and that any data matching on the basis of this or any other identifier needs consent from the patient (MRCG, 2012). These provisions seem contradictory to the objectives of introducing unique health identifiers and it is unclear how the potential waiving of consent will apply in this instance.

2.4.3 Development and operation of existing patient registries

The creation of patient registries in Ireland has been a relatively recent development and their numbers are increasing; three developed between 1966 and 1991, and 16 between 2001 and 2009. The MRCG and IPPOSI (2011) report analysed 47 existing patient registries in Ireland and found that:

- The primary function for most of these registries in Ireland (48%) is to improve patient safety and quality of care. Disease surveillance and control is a secondary function, while research is considered to be an important tertiary function.
- Approximately 40% of registries had all of their target population enrolled on the register, 70% reached coverage levels of 60% and 30% had a coverage rate of less than 50%. Assessments ranged from one (60% of those assessed) to four years prior to publication.
- Some form of consent was used by 73% of those surveyed with just under half using written consent. Three quarters have an 'opt out' system of some kind; 55% of those registers without any form of consent also did not have an opt-out system).
- Case definitions were used by 58%, clinical coding systems by 24%, and disease classification systems by 70%. Half of all registries use data dictionaries.
- Most registries had access to clinical and to technology support either directly through the registry or through available resources at the location of the registry (e.g. university campus); one third of registries indicated that they had no access to any statistical support.
- A total of 21% of registries reported having web-enabled access to data but paper-based data transfer is active in 71% of registries.
- More than half of the registries carry out regular data validations, 70% carry out data duplication analyses and 77% perform missing data analyses.
- Only 58% of registries surveyed specified the amount of annual funding they receive. Excluding the funding of one very large registry, the average annual funding was €231,450.
- 68% of registries received start-up funding from the state, 12% from commerce and 20% from charities; 72% of registries have continued state funding, 4% commerce, 12% charities, but 12% had no funding when asked. Three registries had multiple funding sources.
- Staff were directly employed by 79% of the registries; 69% of those reported having two or less staff and 27% between three and ten staff.

The MRCG (2012) report also drew a number of conclusions about the operation of existing patient registries in Ireland. They also concluded that national policy and guidelines for patient registries are important to ensure standardisation and best practice and that these are urgently needed in Ireland.

- Fit-for-purpose registries that deliver tangible positive improvements in healthcare systems have an important and beneficial role in our health services.
- Consent based registries are best practice, but it is acceptable to waive consent in some circumstances to ensure that registry objectives can be met; for example, for large population-based registries where data collection is not directly linked to care provision.

- Good internal governance and external oversight is essential for registry success and to building and maintaining public trust in the registry.
- Confidentiality, privacy and security must be guaranteed in accordance with legislative and best-practice requirements.
- The ability to link and share registry data with other registries and databases, and with other data providers reduces duplication and maximises the potential utility of the registry. However, interoperability and the wider use of data increases the potential for misuse of these data and sanctions will be required both as a deterrent and to maintain public trust.
- Transparent and sustainable funding mechanisms will be essential to the successful and ethical operation of the registry.

More recently, HIQA (2016) have catalogued 109 national data collections including administrative sources, censuses, national routine surveys and national patient registries. They have also developed guiding principles for national data collections (HIQA, 2015) and they plan to translate these principles into standards that can be used to evaluate the quality of data within national data collections that fall within the remit of the HSE. In summary, HIQA's recommendations for the operation of patient registries in Ireland (IPPOSI, 2015) are as follows:

- A strategic framework needs to be developed for the oversight of national data collections.
- There is a need for standardising and improving data quality in data collections.
- Information use should be optimised rather than information being fragmented or siloed.
- Data protection compliance and frameworks for governance and data quality are needed.
- Existing health information should be optimised and more readily available to patients and the public.

2.4.3.1 National Cancer Registry of Ireland (NCRI)

The National Cancer Registry of Ireland (NCRI) is the largest patient registry in Ireland. It was established by the Minister for Health in 1991 to deliver four statutory functions and with a national mandate to commence data collection in January 1994 (National Cancer Registry Ireland, 2015):

- To identify, collect, classify, record, store and analyse information relating to the incidence and prevalence of cancer and related tumours in Ireland;
- To collect, classify, record and store information in relation to each newly diagnosed individual cancer patient and in relation to each tumour which occurs;
- To publish an annual report based on the activities of the Registry;
- To furnish advice, information and assistance in relation to any aspect of such service to the Minister.

The NCRI currently has 52 full-time and part-time staff. NCRI data are collected by trained Tumour Registration Officers (TROs) based in hospitals around the country, while the majority of the remaining staff are based at the Registry's headquarters. Hospital pathology reports are provided to NCRI for approximately 85% of all new cases (National Cancer Registry Ireland, 2016a). Most are registered manually by the TROs but data are also provided in electronic format for approximately 33% of all reports. A wide range of information is collected, including socio-demographic information, the type and location of the cancer, how advanced the cancer is, treatments received and if applicable the date and cause of death from death certificates. By December 2014, the NCRI database had approximately 500,000 registrations and over 38,000 cancers were being registered annually; an increase from 19,000 in 1994 (National Cancer Registry Ireland, 2015).

NCRI are exempt from needing patient consent to gather these data due to the nature of their statutory mandate. However, people do have the right to 'opt-out' of registering their information (National Cancer Registry Ireland, 2016a), although patients rarely exercise this right (NCRI, personal communication,

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May 2016). NCRI acknowledge their position of trust with healthcare professionals and the public alike and they observe the highest standards of data security, protection and confidentiality (National Cancer Registry Ireland, 2016b), including formal internal audits of registry functions (National Cancer Registry Ireland, 2015), the encryption and password protection of registry laptops and encoding of all data transmissions to and from the registry (National Cancer Registry Ireland, 2016b). NCRI has strict rules about who can have access to the data. Identifiable information is not released without the individual's written consent with one exception; the person's consultant can request information for the purposes of follow-up treatment. Published data are always anonymised. NCRI complies with international standards and criteria in recording of all major data items and has been consistent in its application of these since its inception.

NCRI operates under, and is funded by, the Department of Health, but it is independent of it. It has a board comprising seven members who meet four times each year (National Cancer Registry Ireland, 2016a). Board members come from professional backgrounds; National Cancer Control Programme, Northern Ireland Cancer Registry, Irish Cancer Society, HSE Public Health, Cork Cancer Research Centre, Department of Health and the Mater Misericordiae University Hospital. The Director of NCRI is responsible for the implementation of the Board's policies and oversight of all registry functions. Performance indicators are used to evaluate the success of the registry in attaining its strategic objectives and to compare performance to the four other cancer registries of the United Kingdom (National Cancer Registry Ireland, 2016a). NCRI report that their data quality and case ascertainment levels are high; completeness of case ascertainment of all invasive cancers (excluding non-melanoma skin cancer) is estimated to be 97%, although there is some heterogeneity between cancer sites (National Cancer Registry Ireland, 2012). NCRI publish detailed annual reports and related research findings on their website. To date, four research reports, 180 scientific papers and 125 presentations demonstrate the value of patient registry data to the research community. In addition, NCRI data has contributed significantly to the recent review of the National Cancer Strategy (National Cancer Registry Ireland, 2015). This review identified the need to make

NCRI more relevant to service planning and clinical practice illustrating the need to continually evaluate registry performance to ensure that it continues to fulfil its goals.

2.4.3.2 Cystic Fibrosis Registry of Ireland (CFRI)

The Cystic Fibrosis Registry of Ireland (CFRI) was established in 2001 by the Cystic Fibrosis Association of Ireland with funding from the Department of Health and Children and the HSE to keep the relevant medical records of all people with cystic fibrosis (CF). It became an independent legal entity in 2008. It is now financed solely by the HSE (Cystic Fibrosis Registry of Ireland, 2016d). By the end of 2014 there were 1,183 people registered, representing 90.7% coverage of the known population (Cystic Fibrosis Registry of Ireland, 2016a). A very clear set of goals in four main areas have been established for the CFRI as reproduced with permission in Table 5 overleaf.

The CFRI data sources include doctors, nurses, physiotherapists, dieticians and people with CF themselves (Cystic Fibrosis Registry of Ireland, 2016d). Every participating hospital that contributes patient data to CFRI must obtain ethical approval from their own research ethics committee. CFRI Clinical Research Associates take information directly from hospital medical charts and enter it into the CFRI database. It is envisioned that at some point in the future regionally-based staff will be trained to enter the required data. The CFRI collects a wide range of data including socio-demographics, diagnosis details and annual assessment details. Informed consent is required to collect data from all those registered with CFRI and each patient is assigned a unique identifier within the registry (Cystic Fibrosis Registry of Ireland, 2016c). The CFRI database is encrypted and password protected on two levels, meaning a user must log on to the operating system first and then again onto the database. Access to data is restricted to CFRI staff and hospital consultants, who only have access to the personal data of their own patients. Identifiable information is never published in research or annual reports. The CFRI has also redesigned their IT infrastructure in recent years to bring it in line with European infrastructure standards and to enable comparative studies with other European CF registries (CFRI, personal communication, April 2016).

Although located in University College Dublin, CFRI is administratively separate from the university. However, the academic setting provides benefits such as access to statistical support, potential funding opportunities and post-graduate researchers to carry out CFRI's own scientific research agenda (CFRI, personal communication, April 2016). The CFRI is structured into four sub-committees and an Executive Council of eleven members. Each subcommittee nominates a member to the Executive Council and others are representatives of the consultants who treat CF as well as number of representatives from the Patient Association. This structure is designed to accommodate the multi-disciplinary teams who treat and interact with people with CF (Cystic Fibrosis Registry of Ireland, 2016d). The CFRI also currently employs three full-time staff, a doctor and research nurse. The third member of staff has been funded for one-year only by European grant funding (CFRI, personal communication, April 2016). Further details are available in the CFRI Annual Reports which are available on their website (Cystic Fibrosis Registry of Ireland, 2016d). CFRI data has contributed to several research studies (Farrell et al., 2007; Jackson et al., 2011; McKiernan, Molloy, Cryan, McElvaney, & Greene, 2014; Somerville, Jackson, Zhou, Fletcher, & Fitzpatrick, 2013) and they are currently piloting an innovative research project where they will create a patient portal to allow patients and their Consultants access to real-time information regarding their condition. They hypothesise that this could positively influence clinical outcomes (CFRI, personal communication, April 2016).

TABLE 5

Main aims and objectives of the Cystic Fibrosis Registry of Ireland (2016b)*

1	Registry Process <ul style="list-style-type: none"> • To identify, record, analyse, and store information relating to the prevalence, incidence, and treatment of existing and newly diagnosed people with Cystic Fibrosis (CF) in the Republic of Ireland. • To register all Persons with Cystic Fibrosis (PWCF) whose usual residence is in the Republic of Ireland. • To provide data on long term prognosis for CF Patients in the Republic of Ireland and to compare this information with international data. • To compare CF management and treatment within Ireland and with best international practice standards. • To ensure that all information is complete, accurate, timely and confidential; in order to effectively use the data collected. • To develop and improve CF registry methodology.
2	Research <ul style="list-style-type: none"> • To promote and facilitate the use of clinical data in approved research projects. • To initiate research into the causes, distribution, treatment and outcome of PWCF, and to participate in similar research initiated by others; and to publish the findings. • To assist in the evaluation of novel treatments and screening programmes.
3	Planning and Management <ul style="list-style-type: none"> • To provide a Cystic Fibrosis information service for the Dept. of Health & Children, Health Boards, hospitals and clinicians.
4	Reporting <ul style="list-style-type: none"> • To publish an annual report based on the activities of the Registry. The Annual Report will cover the incidence, prevalence and treatment of patients registered, at a sufficient level of morbidity and geographical detail to make it useful for planning and delivering services to PWCF. • The Annual Report will also contain financial statements regarding expenditure. • To furnish information and assistance in relation to any aspect of Cystic Fibrosis to the HSE, CF Ireland, other service providers, and PWCF. • To provide specially requested reports for clinicians, the HSE, and hospitals. To provide individual consultants with trends and updated information in respect of their patient population.

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2.4.3.3 Idiopathic Pulmonary Fibrosis Registry (IPFR)

The Irish Thoracic Society (ITS) recently established the Idiopathic Pulmonary Fibrosis Registry (IPFR) to capture data related to Idiopathic Pulmonary Fibrosis (IPF) and Sarcoidosis; two relatively rare interstitial lung diseases (ILD). The IPFR is an example of a group of smaller Irish patient registries, many of which relate to specific rare diseases and benefit from clear diagnostic procedure and treatment settings and highly motivated patient populations who see huge benefit in providing consent to collect their data in an attempt to further the knowledge and understanding of their condition (IPFR, personal communication, April 2016). ITS developed the IPFR to address three main objectives:

- to establish prevalence and distribution to help influence policy and service provision;
- to facilitate improved clinical management of the disease;
- to facilitate research and the possible development of new therapies.

Initial funding came from an unrestricted grant from a pharmaceutical company, although additional funding will be needed to sustain the registry following the initial set-up period. A separate grant from another pharmaceutical company funds a specialist nurse who visits each centre to collect and input data and to provide some additional support to the clinics. This specialist nurse is seen as a vital asset as it had been difficult to get 'buy-in' from clinicians initially due to concerns about available time and resources in the clinics to support registry data entry. The IPFR is governed by a board comprising of a CEO, an external expert who has a pharma background and good technology expertise and two consultants.

The IPFR chose to consult closely with the already well-established CFRI and they engaged the services of a well-respected software company with expertise in setting up patient registries (including the CFRI) which enabled them to co-locate their registry data on the CFRI server and benefit from the data security protocols already in place in the CFRI (IPFR, personal communication, April 2016). The IPFR expect to register 100 individuals with ILD within the first year. Initially, information will be collected from six specialist respiratory clinics in Ireland (Cork, Galway,

Limerick, Mater, St. Vincent's and Tallaght), rather than in every hospital in Ireland. Each specialist clinic has obtained ethical approval from their respective research ethics committees and collection of data has begun in four of the six clinics (IPFR, personal communication, April 2016). The clinics have password protected web based access to the IPFR database. The data collected includes demographic information, how diagnosis was made and treatments with the aim of supporting the clinical management of registry patients.

IPFR are using an 'opt in' process for consent. Each person is provided with information regarding the registry and what their information will be used for but they have right to decline registration (IPFR, personal communication, April 2016). Due to potential benefits of establishing prevalence of ILD and the strong relationship that IPFR has built with the Irish Lung Fibrosis Association, there has been great support from people with ILD and to date everybody has given consent for their data to be stored. The data at each centre will be identifiable to assist with clinical care management, but data held centrally by the registry will be pseudo-anonymised. The board is developing data access guidelines and they expect to have restrictions on the type of data that can be made available to interested parties outside the registry. Care is also being taken to ensure that only anonymised data will be made available to companies who provided registry funding.

SUMMARY

The review of the literature demonstrates that patient registry data are essential for informing public health policy, improving patient care, supporting health research and facilitating health technology assessment.

Best practice guidelines have emerged in recent years that provide direction regarding registry purpose, data selection, collection and management, registry governance and registry quality.

Several international dementia registries are currently operational, but no one ideal model has as yet been established.

- The Swedish Dementia Registry (SveDem) is the 'gold standard' and most comprehensive dementia registry.
- The Registry of Dementia in Girona offers a simpler model that could be used as a starting point. It offers the potential to expand the scope of the registry over time.

The successful operation of a patient registry is influenced by the environment in which it operates. Unfortunately, there is a lack of strategic direction in Ireland with regard to patient registries. However, patient registries should be cognisant of national legislation and international directives relevant to patient registries. In addition, patient registries should be aware of the implications of recent and proposed legislation such as:

- The recent European Data Protection Reform 2016;
- The Assisted Decision Making (Capacity) Act 2015;
- The long-awaited Health Information and Patient Safety Bill.

Although existing Irish patient registries vary considerably with regard to size, function, disease, funding, cost and governance, they demonstrate that a lot can be achieved within the current limitations of the Irish health system.

This section presents the findings of the thematic analysis of the expert interviews and focus groups. This analysis revealed six themes:

- **Registry function**
- **Registry data**
- **Data collection**
- **Data management**
- **Registry governance**
- **Legislation.**

Three high level cross-cutting themes were also identified: (1) Benefits and risks, (2) Barriers and facilitators and (3) Dementia-specific challenges. Figure 2 presents a graphical representation of these themes.

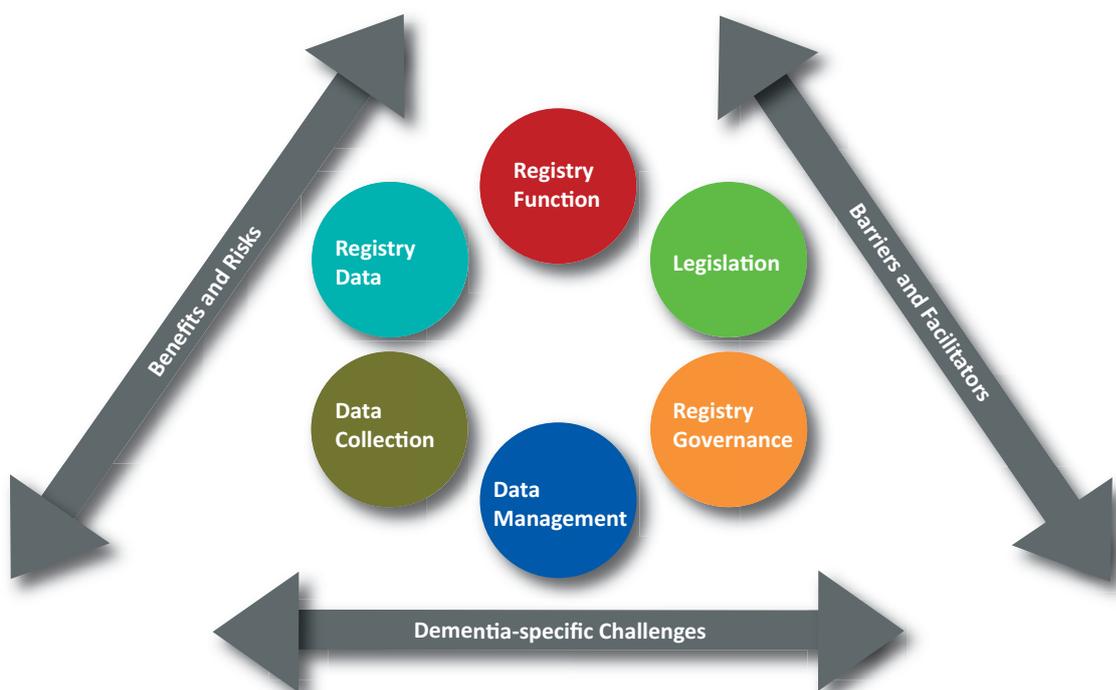
Anonymised direct quotations provide context and serve as anchor examples for the themes and sub-themes identified. The type of expertise in each case is included. Categories of expertise and their associated codes are presented in Table 6.

TABLE 6
Categories of expertise with associated codes.

Clinical Expert	CE
Health Informatics Expert	HI
Irish Dementia Working Group	IDWG
Legal Expert	LE
Policy Expert	PE
Registry Expert	RE
Research Expert	Res

Each of the six themes is presented below, with related sub-themes.

FIGURE 2 General and cross-cutting themes identified in the analysis of expert opinion



3.1 Theme 1: Registry function

“Patient registries are very valuable repositories of clinical information that can be used first and foremost to support patients and improve patient care. The information can also be used for research purposes and to drive policy decisions. So, yes, they are extremely worthwhile.” [HI]

3.1.1 Provide Information

The majority of experts agree that dementia registries provide very useful information. The fact that the number of cases of dementia in Ireland is estimated and that we currently rely on data extrapolated from other jurisdictions is problematic for policy-makers and service providers as they cannot adequately plan for the specific needs of Irish people with dementia and those of their families and carers. The general view was that information from a national dementia registry in Ireland would be more accurate and more comprehensive. It would enhance knowledge, understanding and awareness of dementia and better inform public health policy as well as equitable distribution of health and social care resources to support dementia care. Better diagnostic tracking would assist clinicians in implementing a mutually agreed and standardised diagnostic process. Clinicians would also benefit from information regarding dementia treatments and supports so they could monitor the quality of care being provided.

“The most important aspect of a registry is that it will provide a solid evidence-base on the population level burden of dementia. So we don’t have that in Ireland and we are very far from it. I think it’s one of the reasons that dementia isn’t attracting the type of funding that it really needs to in order to actually focus on the prevention aspect, but more importantly maybe, in the situation that we are in, is the diagnosis and care of dementia, it’s seriously under resourced and we do have a sense that there is this impending burden of dementia but we don’t have any quantification of that burden.” [PE]

People with dementia also generally agreed that more information would be helpful for a number

of reasons including knowledge production and public awareness.

“The more information there is the more learning and more understanding, and I think also the more presence of awareness, acceptance.” [IDWG]

That said, one expert questioned the need for a registry at all and felt that having really good age specific prevalence data on dementia would allow us to predict the likely numbers in certain areas. Other experts felt that this was a circular argument and questioned where this ‘really good’ data, taking into account local and national factors, would come from. A public health expert argued that examining dementia as an isolated condition was inappropriate, given high co-morbidity levels.

“And I think the one thing to remember is that dementia is not a clinical problem per se, it has clinical manifestations but it is a population level burden and problem, and it’s a public health issue and concern, and I think it has to be pitched at that level because I think the emphasis on the clinical burden of patients, it almost makes them into this sole population in and of themselves of older people with very kind of distinct care needs, and yes they are, but they are also part of an overall population in Ireland.” [PE]

Number of cases of dementia

A better understanding of the prevalence of dementia was seen as a critical objective for a dementia registry and information that would be beneficial to clinicians, policy-makers, researchers and to people with dementia.

“Then we know that there are quite a high proportion of people that never get a diagnosis of dementia or else a diagnosis very late in the disease... it would be very useful for providing information on that diagnostic gap”. [PE]

“I mean, as a researcher, God, it would be gold. It would be just great to have a dementia register... my early public health background was very much trying to establish a need for services in a population and you do need to have some idea of the numbers we are dealing with. So it’s really valuable as a health-planning tool and also I think for proactive case management.” [PE]

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People with dementia expressed concern that the number of cases of dementia around the country is not yet being adequately identified.

“I hear of so many people who would say, ‘But my parent isn’t sick.’ So there’s a group of people out there that actually aren’t even being recognised as having dementia. So when we talk of 48,000, that’s a rubbish number really.” [IDWG]

Diagnosis

The majority of experts agree that there are difficulties diagnosing dementia and there is a lack of consensus on how best to do this among clinicians. A national dementia registry could address some of these diagnostic issues by providing information with which to improve diagnostic accuracy and by establishing standardised assessment and coding procedures.

“I think part of the value of the registry also would be to actually try to improve the accuracy of the diagnosis... develop algorithms to try and understand pathways and also to develop services. So yes, it’s a challenge and it’s a problem but I think it’s also an opportunity.” [CE]

“The data from it would be really good for looking at differences between different GP practices or different memory clinics or different areas within the country and saying, well look, they seem to be doing really well in terms of diagnosis, but we might need to do a lot more education around case finding or recognition and assessment of dementia or around diagnosis itself.” [PE]

Day-to-Day living of people with dementia

In addition to difficulties diagnosing dementia, experts also recognise the complexity of the disease itself. Information on the day-to-day lives of those with dementia would enhance their knowledge and understanding and lead to better clinical care.

“No one case of dementia is the same as the next... the social aspect of management on a day-to-day level for people would be a very powerful set of data to collect... it may take a long time to actually get to a point where we can actually see some clear idea of what works for who and what circumstances”. [HI]

“Information about persons with dementia, can [help us] understand how the patient lives,

whether it’s alone or with families and [provide] information of cost of dementia treatments”. [RE]

Prevention

Some experts also suggested that we do not have enough information about prevention of dementia in an Irish context. This could be a potential objective for a national dementia registry.

“So we were very reliant on international data on dementia prevention... we don’t have sufficient data in an Irish context. So I would certainly be an advocate for developing a data resource.” [PE]

3.1.2 Enhance Policy

Most experts agreed that the integrated and co-ordinated nature of a national dementia registry would help inform dementia health and social policy and that it would provide an evidence-base to assist policy-makers in obtaining funding and in planning as well as providing dementia services.

“If we are then looking at the aim of the strategy, [it] is to enable people with dementia to live well at home, but we need to have the information to be able to plan appropriately.” [PE]

“I think there’s a huge piece around population health and knowing who, where, when and why so that we can actually do planning for the future by looking at data. What we’re not great at, at the moment in health in Ireland is turning data into information and I think registries actually give us one of the keys to... something that can actually facilitate changes to be made to health care.” [HI]

However, there was also a general feeling that the cost of creating and maintaining a dementia registry might be prohibitive and that funds could be better used in paying for care services.

“There is an impending burden... that’s a negative way to put it but I do think in terms of the health services itself that they [health service leaders] are struggling to know how to cope with it and I think they would very much welcome... an informed approach as to how to actually deal with dementia. I also think there is an awareness that we don’t have sufficient data to actually plan for service provision for dementia patients. So I do think there is an awareness there that something needs to be done. I think the gap is in

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finding something accessible and affordable that can actually be done to try and address it". [PE]

An expert from an Irish patient registry argued that the analysis of registry data can identify ways in which to remove cost from within the health system and thus provide obvious economic benefits.

"Tests were being duplicated on a centre-by-centre basis because there was no sharing of records... that's adding extra cost into the whole healthcare system... Registries are often seen just as a research tool and we are trying to make it much more... we want it to be a situation that it is of use to the medical staff." [RE]

Policy makers and people with dementia alike felt that the data from a dementia registry would enhance their ability to advocate for better dementia care.

"It's going to give us... a little bit of power in pushing for services and pushing for policy changes. So I think it might help us as opposed to hinder us." [IDWG]

"We can then use that information to lobby the Department of Health and kind of highlight the need for development of a registry. But the more information we have, the more evidence we have that having such a registry would benefit in the long-term, the benefits, I think that would be good." [PE]

3.1.3 Improve Care

All experts agreed that having a national dementia registry would provide enormous potential to improve the quality of clinical care. This was seen as another core objective of any patient registry. One expert from a well-established Irish patient registry went so far as to argue that the ability of patient registries in Ireland is best-suited towards quality improvement. Although their experience suggests that this has not been an easy sell in Ireland (Personal communication, April 2016).

"We've found over the years that being a relatively small country and a relatively short-term registry that you don't get a huge amount of epidemiological value out of a registry like that because most of the questions could be answered by people from bigger countries with registries that have been around for much longer, so a lot of it then comes down to health services research which is to look at what the disease burden is,

what sort of services that people avail of are, are there changes in disease burden over time, are there changes in the quality of outcomes, quality of life, that sort of thing?" [RE]

"It's the way that the Swedish system uses it, as well as having the kind of clinical data, they also have quality indicators for the system, so they are able to track changes over time and the kind of service provision and clinical care and [look] at differences between different areas in the country and differences between memory clinics and GP practice, so they are able to look at the quality of the care." [PE]

Formal dementia care

It was generally acknowledged that public health services may be unable to adequately provide comprehensive services and supports for people with dementia. In order to improve the overall quality of clinical care while successfully managing the cost of providing this care, more information is needed about the types of treatments and supports that work best in different scenarios.

"I do think it's basically down to... seeing how you can impact the quality of service looking at the sort of treatments that people have, the sort of supports that they get, what their quality of life is, trying to investigate what factors affect that quality of life, what can be done to improve it and so on." [RE]

"If you were to look at someone ... at the time of diagnosis and then you look at them two years on or four years on or six years on and then you look at ... what measures have been taken to support this person... if you looked at their social care supports, their family support, their quality of life... if you could somehow establish quality indicators around inclusion in the community you could maybe establish whether particular interventions or a level of intervention was going to maybe delay the worsening of dementia and reduce possibly the reliance on the hospital services or entry into nursing homes because I guess we've got to find cheaper ways of helping people with these needs... [it] would be really important for us to be able to compare our dementia data with those other countries and that in itself would be an impetus to improved services if we were found to be sorely lacking." [PE]

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Informal caregiving

Policy experts openly acknowledged that adequate services may be unavailable for people with dementia and that it will become increasingly important that families and carers have sufficient support in place. Again, an understanding of the burden of care on family carers is essential to providing the requisite support.

“I think there’s so little known about the issues and the problems that people face in their homes... If you have a partner who has dementia and you know that partner, then to some extent you can see why somebody would want to continue to keep that person at home indefinitely. However, if it’s a child and the father and the mother then that person has a different family potentially of their own and trying to manage that in the home is really, really tough.” [HI]

3.1.4 Support Research

The majority of experts agree that a national dementia registry could facilitate research into dementia within an Irish context. Experts associated with existing registries confirmed that having a registry has led to increased research involvement. Assuming that the national dementia registry included consent to be contacted regarding research studies, it would have the additional benefit of easily enabling people with dementia and/or their family caregivers to participate in research if they wished. The people with dementia in this study certainly wished to be involved in research. Other advantages could accrue such as attracting clinical trials to Ireland and the potential access to new treatments for people with dementia and comparative data to other jurisdictions.

“I have a strong leaning towards using it for the clinical research piece to be able to do and understand who has got what illnesses and potentially through consent allowing us to have a cohort of people that we can actually contact to take part in clinical research”. [HI]

“We are seeking to improve services but we also have it as a research database because it allows us to understand the disease and we’ve contributed quite substantially to the literature, by virtue of being able to have a population-based register with full ascertainment.” [RE]

“We don’t know what’s actually going to happen in the future as a group, and how you’re going to be in the years to come. So I suppose I’m very keen on looking at alternatives to what the consultants are looking at, and I’d be very much up to engaging with any tests that need to be done. That’s one of the things obviously. If you’ve got an illness you want to try and treat it. So I’d like to be involved in that, when it comes to it.” [IDWG]

“We see the potential of information collected for research purposes... around comparative analysis, looking at what’s happening in other countries. I think that’s important as well.” [HI]

An international dementia registry expert outlined some of the research studies that they have been involved in to date. This description is very similar to the expectations of how dementia research could be supported in the words of an Irish dementia policy expert.

“We have had various research studies. We partnered with a drug company and they were interested in looking at behavioural disturbances and nursing home placement. We used a sample of our registry... We have worked on different grant projects with hospitals in the area. And you know there is always new ideas and different things going on with research.” [RE]

“I think it would be useful for delving down into specific issues, so if you were interested in medication prescriptions you can see, well, this is the percentage of people who are prescribed antipsychotics and do we need to do something about that? So you don’t have to set up a whole new piece of research just to find out the proportion of people who have been prescribed antipsychotics, you know from the real live data coming in from people.” [PE]

3.2 Theme 2: Registry data

3.2.1 Inclusion criteria and diagnosing dementia

The discussion regarding whose data should be held on a national dementia registry was straight-forward. All experts agreed that the key inclusion criterion was having a formal diagnosis of dementia. The more interesting discussion centred on the diagnosis and coding of dementia and the added complexity of a dementia registry in comparison to a rare disease registry, for example.

Inclusion criteria

Most experts and people with dementia agreed that a formal diagnosis of dementia would be essential for inclusion on a dementia registry. In fact experts in the UK stressed that the entry point to the register must be a formal diagnosis of dementia, regardless of where that diagnosis comes from as the registry would be unmanageable otherwise. That said many worried that getting an accurate diagnosis is difficult given the complexity of diagnosing the condition and the hesitancy among GPs in particular at giving a definite diagnosis.

“It’s the accuracy of that [diagnosis] that’s key here. You could have somebody being labelled as having dementia when they may have MCI, or not getting into the registry because they’ve been diagnosed with MCI and they have in fact got dementia... I think if the diagnosis has been made in a memory clinic or other clinic... that’s probably okay. In my experience, very few GPs are making the diagnosis of dementia in their surgeries, they’ll put down cognitive impairment but they won’t necessarily put down dementia unless it’s been labelled so in the hospital by a specialist.” [CE]

There was evident need to have definite coding terms as expressed clearly by this policy expert. Yet, a person with dementia also clearly points out the inherent complexity of this with regard to dementia given the existing social stigma associated with the condition.

“The entry point should be a diagnosis of dementia or it becomes a register [of people with query dementia] which probably wouldn’t be much use so I think you need to define when the clock starts ticking and that’s when someone gets a diagnosis” [PE]

“So I know of and I’ve heard of and I’ve spoken to GPs who have said, ‘For older people, the family don’t want to call it ‘dementia’,’ so it’s not been entered. So that’s an area where we’re going to get not true and factual figures if that’s happening” [IDWG].

There was also a very clear direction that all forms of dementia should be included in the registry and that they should be sub-typed as accurately as possible. Similarly, there was an assumption that all sub-populations would be included. An expert regarding dementia and intellectual disability highlighted the specific difficulties with diagnosis in this population.

“There may be other sub-groups in the other dementias. It could be quite a tree of categories.” [IDWG]

“And the other big thing is the sub types. I mean, if you have a dementia register it might not tell you what the sub types diagnosis is and if you want to use that register for most instances you do want to know what kind of dementia they have. It’s still a huge problem” [Res]

“There are very few specialist memory clinics for people with intellectual disabilities. The generic memory system and memory clinic system is literally at a loss and at odds and many people are either...there’s huge diagnostic overshadowing and under-shadowing. But there’s a massive lack of skill in relation to diagnosing this population.” [PE]

Dementia diagnosis

A significant concern was therefore the difficulty diagnosing dementia and the possibility of getting the diagnosis wrong. Many experts stressed that a dementia diagnosis is much more difficult than other diseases (e.g. cancer and cystic fibrosis) and accurately sub-typing dementia is even harder. There was an acknowledgement that many of these issues have been successfully dealt with by existing international dementia registries (the Swedish registry was the most often cited example) and that we must not reinvent the wheel in Ireland but learn from what has been done elsewhere.

“My main concern would be how do you define dementia and how do you discover the people who are suffering from it? ... You come across GPs who underdiagnose, you come across over-

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diagnosis. And all of these so-called diagnostic tests have got quite a large margin of error. Again, it depends on what you call dementia... I think if you were to talk to GPs you'd find that there would be a wide divergence of opinion. The younger GPs tend to be more scientific and more numerate and to be more gone on things like the mini mental test score and so on. I think the older GPs are inclined to feel, well, there's no point in going looking for trouble; trouble will find you in its own good time." [RE]

People with dementia also expressed a concern about the accuracy of the diagnostic process and a lack of consistency among GPs and they felt that this could potentially lead to invalid data within the registry. Yet, if diagnostic processes are tracked and evaluated, this is one of the areas where a registry can be very beneficial as it allows clinicians to evaluate and improve diagnostic accuracy. Registry experts in Sweden and in the UK acknowledged that much of their day-to-day work revolves around addressing the issues with diagnosing and coding for dementia and collecting dementia-relevant data in primary care.

"It's a cluster of symptoms that delivers a diagnosis. So obviously that's not specific. It's not precise. It's a question of a valued judgment. One GP might say, 'That's the cluster,' and another would say, 'That's not the cluster.' So how tight is that focus?" [IDWG]

"So I would have to say I've heard some very strange tales of people who've been diagnosed. I've actually heard of a woman within four miles of me who was diagnosed and now they're telling her she doesn't have it." [IDWG]

"From what I understand from [GP], that doctors in Ireland, and I think that's probably the case in other countries, aren't always very good at coding for dementia, it's not an easy thing to code for". [PE]

There was a suggestion that the roll-out of the Single Assessment Tool (SAT) would be important in this context. It is a strategic priority for the HSE and it also results in an electronic record being established for everyone who is assessed. Although it will take some time to roll-out nationally (one expert suggested 5+ years), it provides an opportunity to support improved diagnosis and recording. It also provides a data source in its own right and one that could

easily be linked with and provide data to a national dementia registry. Experts advised against introducing new data collection systems for a dementia registry that would essentially duplicate information that will be available from another source. Although shortcomings of the system with regard to obtaining a specific dementia diagnosis were acknowledged.

"So while we probably still have the barrier of getting that definitive diagnosis, if you like, in the sense that this would be a way of diagnosing people with dementia but it would certainly flag those with diminished cognitive functioning. And while it wouldn't be a standalone dementia register, it would probably be much more valuable in the sense that you'd have a really comprehensive picture of older people and where that cognitive ability sits among other issues that they might have." [PE]

Coding systems

For a registry to be effective, there is also a need to identify proper coding systems and for these to be put in place across primary and secondary care so that there is consistent coding of dementia (and its subtypes). Coding systems should be carefully chosen and ideally the codes should also be consistent with (or be able to be mapped to) those in other countries so that comparative analysis can take place. Again experts mentioned that a lot of work has taken place in this area and that Ireland should learn from what has already been carried out.

"Well they've kind of grappled with that issue a little bit in the UK... one of the things they do is they have different kind of coding, so it might be if there's still uncertainty around the diagnosis you'd have a particular code which might be query dementia, something like that... but when there's a probable diagnosis and it's very clear that this is Alzheimer's disease or mixed dementia, whatever... depending on the code that's picked up in different ways for reporting. So there are ways around it." [PE]

The roll-out of the National Dementia Strategy for Ireland includes the objective to improve the coding of dementia in primary care using ICD-10 and ICPC codes. A tool is currently being developed to help 'clean' the codes that currently exist on patient records. A similar tool exists for atrial fibrillation but this will be the first of its kind within the gerontology

field (Clinician, personal communication, March 2016). Improved coding in primary care will facilitate the development of more accurate practice records that can in turn feed into a national dementia registry, but given the current difficulties in this area and the fact that there are no current links between GP systems and any patient registries in Ireland (including the NCRI) it may be better to take data directly from patients until these changes are operational.

3.2.2 Required data elements

All experts agreed that the amount and type of data to be collected should be driven by the primary purpose of the registry and the primary consumers of registry data. Healthcare professionals may benefit from information regarding treatment protocols, care management and certain medications. This information could also be of use to people with dementia and their families, along with data regarding diet and nutrition. So, the primary purpose of the registry needs to be established up front and this will dictate the minimum registry dataset; that is the collection of mandatory data items without which the registry cannot function effectively.

“You would need to set-up exactly what you think you want to look at first, and then you’d need to set-up what your core elements are that you want to include within the dataset, and then you need to set-up your structures by which you’re going to ascertain those. You have to be very careful with what you agree to put in the register and what you agree not to put in... So you have to decide what your criteria are, and if you don’t, if you’re woolly about your criteria, you’ll have a woolly register” [RE]

One health informatics expert warned against trying to be all things to all people.

“I don’t see that the registry data or all of the elements that you’d collect in a registry would be the same as what you’d be collecting in a personal health record, so again it comes back to who are we collecting the registry for? If the registry is being established for patients, for families and carers who have dementia that would be a very different looking registry to one that’s being collected in line with the current registries that are being used today.” [HI]

Once the minimum dataset has been established, the broader range of registry goals, the availability of data sources and practical concerns such as funding, storage and time should drive the maximum dataset that will be collected. While it is possible that some of this secondary data will be mandatory, it is often the case that these data items are optional. In some registries these are considered to be added-value data and providers can decide themselves if they would like to provide this information. Typically, the benefit to the provider is that it enables them to review clinical care for their own patients over time and performance against pre-defined registry standards, the average provider and others in their local area or district.

Some experts argued for the inclusion of data items from outside formal health and social care services. For example, capturing all of those voluntary and informal sources of support for people with dementia and their families in order to fully understand and evaluate their contribution. While it is certainly possible to gather and store this type of data, care is needed to ensure that data sources are valid, that it contributes to the goals of the registry and provides benefits that outweigh the additional cost of data collection.

“There is very little collected at the moment about the role of the voluntary agencies in the services, so I think again that’s another piece that needs to be collected in a registry... These people play a huge part, and maintaining people at their existing outcomes is very important... There’s the other part which is more maybe downstream going back to the family, the carer, the role of the carer and certainly sort of non-medical interventions that may be found useful as well for people with dementia and I think they should be looked at as well in a registry if it’s going to be in line with the new models of the care from the eHealth perspective.” [HI]

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3.2.3 Patient consent

Some policy experts strongly argued that to be effective, a patient registry needs to have mandatory data collection and the NCRI was cited as an example of an Irish patient registry with a national mandate. Many experts were concerned that requiring opt-in or opt-out consent would seriously reduce the effectiveness of the registry and this is explored as a separate sub-theme below. There was also a general sense that new legislation could make it easier to collect registry data without needing consent and that we are at an opportune moment to influence the government and the Department of Health in this regard.

“The fact that there is [a law] gives a totally different legitimacy to the registry than if [the registry] did not have this law.” [RE]

“I think the usefulness of a registry would be seriously reduced if it was an opt-in or opt-out system. I don’t think you can have a valid system that produces robust data unless it has a mandate.” [PE]

Experts also felt that issues around consent can be blown out of proportion and that we need to be careful not to make more of it than is needed. Consent processes should fit with legislation but they should also be pragmatic and not too restrictive.

“It’s easy to overplay it... you could probably sit three years considering and getting legal advice from anyone about it ... if I was starting afresh... something relatively light touch and putting sensible things in there and if patients and carers agree to have their information on a register then that takes away all the bureaucratic nonsense that’s out there.” [PE]

Tiered consent

The general consensus was that people should be asked for their consent before having their data included in a patient registry. Most experts felt that people will consent as long as they know what the registry is all about and how the data will be used. Opinions were more divided among people with dementia. Some felt that the need for comprehensive and accurate data far outweighed any risk involved in gathering this type of data and that participation should be mandatory, while some had no issue with mandatory provision of anonymised ‘statistical’ data but would like consent to be required for other types

of data. A few people were nervous about the implications of being on a dementia registry and wanted optional consent processes to be put in place for all types of data.

“I think the state has a right to say, ‘We need to know. We’re not saying we’re giving this information out... but we need to know how many people.’ So I certainly wouldn’t have a difficulty with that. I don’t know if anybody else would.” [IDWG]

“I mean the information in itself, we could have no complaint, I imagine, in my statistic as a male at a certain age having an onset diagnosis at a given time. That is of no consequence to me that anybody can have that information because they don’t know it’s me. So as long as it’s anonymised that’s the key thing. I do think the individual attribution of, ‘This set of statistics relates to this person ... lives in ... There’s his phone number. There’s his email.’ That’s a completely different situation. Anonymised data, to my mind, I can’t see any reason to object or be anxious.” [IDWG]

“I think anonymising the information is one phase. If there’s any move outside of that phase, for any reason, then I think the individual needs to be in charge.” [IDWG]

“There are some real difficulties that somebody might say it’s an infringement on our rights. The thing about it is I think you can sign-in or you can sign out, and you don’t have to. Nobody has to do it.” [IDWG]

This supports the idea of having a tiered consent policy (i.e. consent flags for different elements of data collection and/or data use). A number of the experts advocated for this approach as different types of registry data will fulfil different registry functions. Both 2-tier (anonymised, non-anonymised) and 3-tier consent models (anonymised, identifiable for health purposes and clinical care, identifiable for research) were suggested. Irish health informatics experts highlighted the fact that the Individual Health Identifiers (IHI) already have a two-tier consent flag built in; one for clinical care and one for research.

“It shouldn’t be a register that says ‘you can access my information or you can start using me in research’. It should be more about... ‘I am happy to be contacted to have a conversation about

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being a part of research'. So that we take away some of that 'consent for consent sake' which has tied a lot of countries up in knots as they try to work out how do I now use this information to contact the person." [HI]

"I think most people who would agree to this are doing it because they understand that this is really important in terms of service development, quality of care and also potentially for research. So as long as it's managed, operated and overseen correctly with respect to data protection and confidentiality, I think there shouldn't be any great risks. If you go to step 2 in terms of contacting them to see if they will participate in a research study, they still would have to give informed consent for any additional involvement in a research study or clinical trial." [CE]

Some experts suggested creating an online web page that would allow the person with dementia to change their levels of consent at different times. This proposal would need further investigation, however, as it would need to be able to manage situations where data had already been released under the previous consent options.

"If it was developed it would be some kind of online system, so you could have consent to be on the dementia register for clinical purposes, for the national registry and then for the research things. So you can opt in and out of different aspects of it... You'd have to consent for each level. I think it would be also important that people can ask for them to be taken off that registry at any time." [RE]

Opt-in or Opt-out consent?

The consensus in one of the focus groups with people with dementia was very much that people should have the option to opt-out of non-anonymised information but that basic statistical information should still be gathered even if consent is refused. This supports the Model of Consent in England where the patient can go to the GP and say that they don't want any personal data leaving the practice. This only applies to identifiable data and patients can't object where data has been anonymised. Only 5% of people currently opt-out (UK Health Informatics Expert, personal communication, May 2016). One person with dementia and one policy expert were also concerned that seeking any form

of consent would deter people from seeking a diagnosis.

"If you get a piece of paper that's signed, that says, 'I'm not happy to do that,' you still have a number. So if you have 50 of these forms saying, 'I don't want to be involved with it,' you know there are another 50 people, by default, who have actually got dementia of some kind." [IDWG]

"I suppose, on balance, I would think the opt-out route is probably the most open and practical approach. That's what I would feel, but it is a judgment call really. I think the nation would have a right to insist, if it felt it was necessary, to properly guide policy." [IDWG]

"So I think that's a challenge in and of itself in terms of the actual consent from patients themselves and their willingness to actually report it. So you don't want a registry to act as a deterrent for people to get a diagnosis." [PE]

Written consent is also preferred, although telephone consent has been used in some circumstances in Ireland, with specific agreement from the data protection commissioner. Some international registries also consider online consent (via a patient portal) to be equivalent to written consent.

Capacity to provide consent

Some experts were very worried about the competence and capacity of those with dementia to be able to provide consent. Yet, many others felt that this has already been dealt with in the research arena and that people with dementia shouldn't be further stigmatised by assuming that they would be unable to provide informed consent. It was acknowledged that those making the request would need to be skilled in communicating with people with dementia so that they can present the information about the registry in a way that is easily understood.

"I think in a situation where the person doesn't have the capacity to consent but does not object to participating in research, we should allow next of kin to be able to consent or give permission on their behalf. This is what we do in clinical research all the time." [CE]

"Unless somebody is extremely impaired it's often the case that they are competent to consent to their inclusion of very basic data onto a register. So I think there are theoretical concerns but in

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reality I think that those ethical concerns are more theoretical than reality.” [RE]

“People with dementia are no different to anyone else, they have the same rights as everybody else and that is that if any information on them is to be kept or retained or put on a register, they have to give full and free consent for that. So the question is how do you get consent for somebody who has dementia to go on a register? I think for anyone you’d have to explain what the register is for, what the information is going to be used for, who is going to have access to it, is it going to be public, all of that, and that applies equally to people with dementia. The difference is going to be that you may need to explain it in a different way because the person with dementia may need things explained more in terms of storytelling or using analogies in a different way and more simply explained than other people. So you need that skill, first of all.” [LE]

“I feel we are in danger of stigmatising dementia yet again by simply saying nobody has capacity... in the UK there’s a presumption people have capacity unless it’s sort of proven otherwise, and I think that’s a good way of dealing with it... because the kind of benefits of doing this really outweigh any potential problems that, there might be occasional cases where someone, their information goes up and they haven’t really given the... they don’t really have capacity to make that decision.” [Res]

Experts also felt that it was difficult to understand, as yet, exactly how the new Assisted Decision Making (Capacity) Act (2015) would influence informed consent. The consensus was that although the legislation has been well articulated, the decision support office has yet to be set up and it will take time to see how this Act translates into practice.

“In the new decision making capacity legislation, when it comes into force, will have a range of decision support mechanisms and it is possible that the person with dementia may have signed an advanced healthcare directive, for example, in which they say ‘I give consent in advance for my name to be put on a register and used for research purposes,’ or whatever. So, that may get them onto the register or they have appointed somebody who is a designated healthcare representative

to make all healthcare decisions for them now... Equally well, if they don’t have an advanced health care directive and they are in a hierarchy, they may have appointed a power of attorney with health care decisions... if the EPA is registered, [they] may have authority to give consent.” [LE]

The timing of the consent request

Many were concerned about how to identify the right moment to request consent especially if the intention is to do this at diagnosis. Registry experts stressed that there were often delays in obtaining consent and not to underestimate the impact this has on data collection.

“It’s a very difficult conversation and then you get into the difficulties around who is the person in the family who can admit or agree to that.” [HI]

“So I think if you go in and you have the diagnosis and it’s like, ‘Hey, here, now just sign this and you’re going on the register,’ I think I’d see that as not fair.” [IDWG]

“We find that doctors and nurses, having broken bad news to somebody, are not particularly keen on then asking them to sign a consent form to have their data handed over to a third party... For instance in Germany in the 1990s two of the registries were forced by their legal federal health authorities to seek consent and their registrations went down to about 10%. They reported back this wasn’t because patients were refusing consent but the doctors and nurses just wouldn’t ask for it because they felt it just wasn’t the right time.” [RE]

One suggestion was that anonymous coding for all people diagnosed with dementia should be made on GP and secondary care systems. This includes coding those that ultimately decline consent and this would facilitate the collection of basic anonymised prevalence data. Another was that consent for personal data use should be included in advance healthcare directives so that you could consent now for your data to be used at some point in the future if needed.

“I think the other issue then for me is about the ethics of advance use of data collected today with new technologies, like biotechnology in the future and trying to find what way we are going to get that consent... They were talking the other day about dynamic consent which means that the

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consent now to use the data in a dynamic way in the future as new knowledge comes through and we can sort of see things from a different advantage point. I don't think it's black and white." [HI]

People with dementia and legal experts also raised the point that additional consent should be sought for new uses of the information. Given the fact that dementia is a progressive disease, this can introduce complexities where someone who had previously had capacity, no longer does. Although the same process for gathering consent in the absence of capacity (e.g. assisted decision support) can be followed here.

"If something new comes up then it's brought to people again" [IDWG]

"The only difference is that you might be able to go back to somebody else at a later stage to say, 'We are now using this information for this reason,' but you might not be able to go back to the person with dementia because they may have lost full capacity at that stage. So I would think that when the person with dementia gives consent, the consent is only valid if they know very clearly what it's being used for and that use can't change later on." [LE]

3.2.4 Anonymised and identifiable data

In discussions about the use of anonymised and non-anonymised data, expert opinion varied, but all agreed that it really depended on the type of data that was going to be collected and the functions these data were to fulfil in the registry. Two different approaches are generally taken:

- where non-anonymised data are held at source (i.e. identifiable in data provision centres such as a specific primary care provider, hospital clinic, or memory clinic), but anonymised centrally and for all reporting.
- where non-anonymised data are held both at source and in the core registry, but data is still anonymised for reporting and data access unless specific consent exists to allow the transfer of some subset of available non-anonymised data.

The first approach makes data management and data access rules simpler for the registry, but it limits its function to reporting high level prevalence data and makes clinical care and research goals more difficult. Option two facilitates a broader range of uses albeit with more complex data management and access rules. Taking this position is a little easier for rare disease registries where the registry is often co-located in one of the main diagnostic or treatment centres, but it can and has been achieved for larger registries. Often, only a core group of registry staff have access to the key that identifies the person as that is needed to manage data matching and data issues. So, while the data are identifiable within the registry, data are pseudo-anonymised for most uses. Anonymised data are then made available to consumers of registry data including those using the data for research purposes.

"The information centre has a lot of information on dementia that's generally not held at the level of a person that you can identify." [PE]

"There's no identifiable information on an individual in the registry, but if you have to go back and contact the person for a particular reason, that information would be available and you would have permission to do so." [CE]

"Our research group has access to the codified data, but not to the individualised datasets

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through which people can be identified. So they're de-identified ... it's not [pseudo-anonymised] because we can track it back, because we have to track it back... So the person who has the codes is the data manager. So the person who has the codes can identify the patient's name through paper files... but you can't do it on the register." [RE]

"Obviously it's important that personal details aren't released to researchers, there's a balance there in terms of what can be released to ensure that there is quality research enabled and then also to protect the identity and security of the actual patients themselves." [PE]

Some countries have taken the additional caution of locating the registry within the health service such that any gaps in anonymisation are essentially managed by having identifiable data remain within the health service. While this may work for a co-ordinated health service such as the NHS in the UK, it would not provide additional protection in a fragmented service such as that in Ireland. There is also the valid question about maintaining the independence of the registry which seems to be the best-practice approach favoured by most experts (refer to Theme 5: Registry governance).

3.2.5 Accuracy and comprehensiveness of the data

The accuracy of the data in a registry was felt to be of paramount importance if the registry was going to be of any value. One registry expert argued that ensuring data accuracy and completeness was one of the biggest challenges for any patient registry.

"People get worried about things like data protection and ethics... but they're not the big problems in the registers. The big problems are the biases, the unknown biases or the poorly thought out registers with the biases that people should have known but didn't, and they're much more serious because they lead to erroneous conclusions which are dangerous." [RE]

Despite this challenge, public health experts clearly advocated for a population-based registry as they saw data accuracy as one of its greatest benefits. They argued for the widest range of data collection of any expert group so perhaps unsurprisingly they were also the most sceptical about the registry's ability to easily collect and ensure the accuracy of these data. This is where it may be easier for bigger countries to implement these kinds of registries, as highlighted earlier in section 3.1.3 by one of our registry experts.

"The most accurate registers are population-based... they give us the most accurate information. Nobody's too old, nobody's too sick. Nobody's too poor to go on a register. So that's the best type of register to have, but for dementia that's difficult because your ascertainment is going to be very difficult because dementia is fairly common, there isn't a single place that somebody with dementia goes." [RE]

"So background characteristics of patients would be incredibly important for us to try and establish any type of epidemiological evidence base on risk factors so that we could try to develop strategies for prevention... so things like socioeconomic status, lifestyle risk factor behaviours, such as smoking, alcohol consumption, exercise, obesity levels, those types of things, but also the more basic patient characteristics such as socioeconomic status, age, sex, those types of things and also it would have to take into account the other factors that are kind of emerging as really important in terms of developing risk which would be around

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early childhood trauma and mental health issues over the life course educational status.” [PE]

There is, however, more to public health than prevention although there is some overlap between data required for prevention and that needed for clinical care.

Experts expressed the view that the best data are generally available in primary care but those involved in existing registries also commented that this was the hardest data to get and that a lot of work is needed in order to ensure comprehensive data collection.

“In terms of health information, the data collected by GPs in primary care is one of the richest sources of clinical information, collected directly at the point of care.” [HI]

“A digital solution has been in GP practice for ten years or more in both the NHS and in Ireland and therefore the robustness of the data, the length of the data and the learning that’s been slowly undertaken across that dataset is huge compared to hospital datasets where it’s very siloed.” [HI]

“It took us I would say, five years to cross the 60% threshold. And really you need to have at least 60% of the total population covered in order to be really statistically relevant and now we are running at about 92%. We’ll never hit the 100% because there’s always the lag time between diagnosis and then getting the actual consent form signed.” [RE]

Experts also saw a link between standardisation of data and the accuracy and credibility of the registry, but those experienced with patient registries in Ireland highlighted the difficulties in achieving this.

“So trying to standardise that across the country I could see could be a major problem. Getting credibility of your data in the clinical community even for us is quite an uphill task... Because clinicians keep seeing patients over and over again, they tend to considerably overestimate the disease burden. So if you come along and say in this hospital 20 patients were diagnosed with dementia last year, they’ll say, ‘That’s ridiculous, that’s stupid. I see 20 every week in my clinic,’ and you have to say, ‘Yes, but they’re the same 20 people’. So if your credibility is undermined by sloppy methodology in the beginning or by

technical limitations or errors or whatever, it’s very, very difficult to retain it. It really took us I’d say 10 years before people were willing to accept our figures without arguing with them.” [RE]

In fact, the general consensus was that registry data will never be entirely comprehensive and many experts argued that you should never expect it to be given the local factors that can influence the data collection process. This was not considered to be problematic as health economic models are built to deal with incomplete data, although that is not a sufficient reason to be complacent about data collection. It would be essential to keep a close watch on data comprehensiveness rates and registry data cannot be expected to be immediately relied upon.

“You can’t really rely on a register for the first few years because it’s going to have all sorts of biases in it.” [RE]

3.3 Theme 3: Data collection

3.3.1 Data sources

Conflicting opinions emerged about the size of the task faced when setting up a registry. For some, particularly those with a public health and epidemiology background, the challenge is daunting. For others, often those who have experience with existing registries, it is possible and manageable once you are clear about what you want to do and pragmatic about what can be achieved. That said, a consensus emerged in that all experts found it hard to see a situation in the near term where data collection would be seamless and all acknowledged that some manual intervention would be likely.

Multiple data sources

Registries in the UK have an advantage where they can operate centrally to a large extent as they have the ability to see everything from referral letters to discharge letters online, but the process is more complex in Ireland.

“... so it means you don’t have to have people trailing round from hospital to hospital but it still means that you have to have a significant number of staff sitting in front of computer screens reading letters and going through medical records and trying to make sense of it and code it and all that. So it does cut down on work a bit.” [RE]

Policy and registry experts all spoke of the difficulties that were likely to be encountered collecting dementia-related data in Ireland and they felt that the challenge of obtaining comprehensive data should not be underestimated. There is no one natural source of data related to dementia as diagnosis happens in multiple settings. Although primary care data are seen as the ‘gold standard’, most formal diagnoses occur in secondary care. All registries, including international dementia registries, find primary care data the most difficult to manage and that which gives rise to the most data gaps. However, sourcing data from secondary care alone is also problematic as this will not give comprehensive coverage. As such, registries need to collect data from multiple settings and develop a process that accurately matches data across these settings.

“We’re not very good really at collecting information in primary care settings. In the hospital context

as people come through the door its part of the process. We need to look [at] sustaining that kind of data piece within primary care settings and I presume that’s where you would want people with dementia.” [HI]

“[The National Dementia Strategy contains] actions about recording in primary care and acute care. If you started work on that you might have the basis to build a register on at a later stage. That’s just a thought because to my knowledge there is very poor recording of dementia diagnoses in any of those sources, it’s very much hit and miss apparently and if dementia has not been diagnosed in primary care then you know it often doesn’t get put in the notes in the hospital.” [PE]

On the positive side, using multiple sources of information and cross-referencing the data for each patient does negate the potential bias of collecting data from a single data source.

“You can’t have a register drawing from just one dataset. It’s going to be biased...If you ascertain dementia through old-age psychiatry, for example, that would be a far different cohort from geriatricians, which would be a different cohort from neurologists, because each would be drawing from a slightly different segment of the population. If you draw from GPs, the diagnostic criteria for dementia are not very clear. So, dementia is quite a difficult one because it’s a heterogeneous condition.” [RE]

Many existing registries, such as the Swedish and US dementia registries have experience gathering data from multiple sources and demonstrate that it is achievable. That said, these registries typically have a legislative mandate that supports their data collection requests and they are also more advanced with regard to electronic records and unique patient identifiers.

“We pull from hospitalisation data, inpatient hospitalisation, Medicaid data, emergency room visits, long-term care evaluations... We have a State Health plan here that a lot of people belong too so we can search that for those ICD-9 codes. And there’s also community mental health facilities and we have one private practice that is giving us information and we are hoping to expand to get more private practices to provide their information as well... We try also to include free clinics... In the

sense of the providers furnishing us the data, it's voluntary. However the fact that there is this law gives a totally different legitimacy to the registry than if we did not have this law." [RE]

"If [data collection] is a challenge in Sweden where they have very good records and systems, it's going to be an incredible challenge for us here in Ireland... We don't have a joined-up system here, we don't have electronic records systems and there's difficulty in communicating from one hospital to another. There are going to be lots of practical issues in terms of accessing records but also in terms of data protection." [CE]

Yet, having a legislative mandate doesn't protect registries from the complexities of the Irish system. For example, the NCRI are still seen by the HSE as being 'outside the wall' and essentially 'not their problem', so they don't see the need to actively collaborate with them, nor do they see the need to have any direct role in terms of funding the registry, including contributing to the cost of data collection. Furthermore, having a national mandate would imply that all cancer-related data are captured by the NCRI and passed to the National Cancer Control Programme, but this is not the case as the registry does not include data from the private hospitals. Essentially they are missing the 30% of cancer patients that are not seen by the HSE. Experts concurred that it would be important that a dementia registry would be set up in such a way that data would be collected on a national basis and not just for the HSE. Given the lack of investment in dementia care in Ireland and the increasing privatisation of home care, it must be assumed that this will be a growth sector for private healthcare providers and any new dementia registry needs to be future-proofed to account for this.

Electronic health records (EHR) and electronic data entry

Irish registry experts describe data collection as a huge challenge when you don't have electronic health records (EHR) or any type of electronic data interface or data exchange with data providers. Registry staff are often required to go to data providers and to go through patient records and manually transcribe the data into electronic registry systems (personal communication, May 2016). There are obvious time and cost implications of this approach but experts agree that it is possible to get what you need in order to operate a patient registry successfully. Some experts feel that we are close to the adoption of EHR in the future, but despite clearly enthusiastic supporters, there was a general view that their rollout would realistically be in the order of 6-10 years given the significant issues with regard to legacy records, the necessity to run paper and electronic records in parallel for a period of time and data capture from paper to electronic records. One expert also recalled previously unsuccessful attempts to introduce EHRs in the mental health system. However, all agreed that all new registries must be designed with an eye to the future and the automatic uploading of required information from EHRs should be catered for. It should be noted that EHRs will not automatically result in all of their data transferring to a patient registry and appropriate consent and data collection processes will still be required. EHRs will just simplify the data collection process and reduce the time and cost involved.

"So we have some of the building blocks in place to really move towards what eHealth Ireland the strategy describes, having completed eReferrals, having put in place the individual health identifiers, having invested reasonably heavily in infrastructure over the last 12 months. We are setting ourselves up, as long as investment continues, to really deliver what we described we would by 2021 at the latest". [HI]

Many of the countries who have access to electronic data records have also built online data entry portals so that secondary data not present in the EHRs can be easily added.

"One of the other things, looking at other jurisdictions who are doing this now though is to get it out there and open it up so that you can actually have a portal to the citizen that says put yourself

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on this register and you consent to taking part in research or being part of population health studies and that has been very useful and very powerful certainly in the NHS in the dementia area in the past 12 months.” [HI]

Data matching and unique health identifiers

Experts felt that the practice and use of patient registries was probably best established in the Scandinavian countries where unique health identifiers are a prerequisite. Policy experts in particular saw the need for some form of IHI in Ireland to facilitate the accurate matching of patient data from different sources. Certainly the introduction of the Chi-number in Scotland (similar to the proposed health identifier in Ireland) facilitates data matching and helps avoid double-counting. Similarly, the NHS number enables patient data from a range of different centres to be linked and it is an important benefit for registries in the UK (Newton & Garner, 2002). It should be noted that if the registry holds the key to identifying patient data using the NHS number, that this is deemed to be identifiable data in legal terms. One expert expressed particular concern at the idea of attempting to set up a patient registry before IHIs were in place, although this view was not shared by the other experts interviewed.

“I just see a unique identifier is a prerequisite, so that would be another requirement here, because otherwise you can’t have people going to different GPs and, again, you know, the accuracy then of a kind of national register there becomes harder to manage if you don’t have unique identifiers.” [PE]

Registry experts highlighted the fact that while IHIs are ideal, existing patient registries are managing to effectively match data from different sources today and that ‘good enough’ workarounds (e.g. match on name and date of birth) can be used to link data with high accuracy (e.g. 95-98%). These can be put in place with appropriate controls and consent. Although a minority view was that data linking could threaten privacy, most felt that taking this approach is better than doing nothing and having no data with which to support clinical care and health policy planning.

“So a universal patient identifier makes life easier. It doesn’t completely avoid some of the difficulties that I mentioned, but it does make cross-referencing a bit less tedious”. [RE]

Recent progress has been made with the creation of IHIs in Ireland, although this progress has been slow and no clear roll-out plans are as yet available. Most experts expressed their frustration at the delays and suggested that there are more obstacles to be overcome before they will be fully in place.

“Well the unique health identifier has very much, I guess, progressed to a point where they are now looking at and have set up the infrastructure in the ICT department, albeit at an embryonic stage in terms of rollout... It is now established on a database and we have a unique... number set that is used...The health identifier will be in. It’s not a matter of if as much as when it will be in.” [HI]

“It [UHI] seems to have receded into the distance a small bit again. Nobody seems to know exactly what... some additional legal concerns now have been raised by the attorney general. Now what these could be, nobody has any idea, but it’s headed up for another little bit and I think there’s some consultation going on and usually consultation going on means that things are going to be put off for a long time.” [RE]

But the importance of having some kind of unique identifier on registry data records is important as it is what establishes the connectivity out to other databases.

“It’s the connectivity out to other databases and taking the impact on privacy and getting that right that’s actually the next challenge. So we’ve actually created the individual health identifier for every patient in Ireland, put that into a single place that we can reference out from. It’s the next stage is connecting those spokes to the hub basically.” [HI]

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3.3.2 Process of data collection

Registry data collection is not a once-off activity (i.e. at diagnosis); improving clinical care or supporting public health policy requires a registry process that supports longitudinal data collection. Unfortunately, Ireland does not have a health data infrastructure that easily supports this type of data collection. Many Irish patient registries have been set up as secondary data entry processes, which results in duplication of effort and an additional financial burden in terms of data collection and administration. Experts felt that it would be more beneficial for registries to be positioned at point of care, wherever that may be. As far as possible, data should be extracted from existing data sources where they are available. These data can then be transferred electronically to the registry in whatever format is required. Within the registry, data can be aggregated and combined with additional data from other sources as needed.

“I would say the most important thing and maybe the biggest obstacle is getting access to various data sources and then having continuity of the data. So what has been wonderful about our registry is that we’ve had these data sources for a very long period of time and we’re able to compare data over the years... I think that would be a very important thing to look at for Ireland.” [RE]

“I think you’d have to get the data in from clinicians’ clinics, but also from primary care. So anybody who actually has a diagnosis or where a diagnosis has been made; e.g. memory clinics, geriatric clinics, other specialist clinics... But as the dementia strategy gathers momentum, there should be more opportunities for the diagnosis to be made in primary care or to be confirmed over time in primary care, so it should link it back into primary care as well.” [CE]

“What it is does [automatic data collection process] is draw out the information from the electronic medical record and so you need to decide how often that happens. It could be on a monthly basis or a daily basis or whatever is needed, and when updated it will bring all the new cases in and it kind of uploads the records of existing cases.” [Res]

Although experts agreed that automatic data collection processes should be the long-term goal,

in the short term they felt that at least some manual intervention was inevitable. In particular, the need to collect data for an individual from a range of different sources requires the registry to be able to link and match data across these sources. IHIs will eventually make this easier but in the meantime resources are required to do this work or to resolve discrepancies that cannot be taken care of automatically. While experts felt that waiting for IHI and eHealth to be implemented in Ireland was impractical and would result in nothing moving forward with regard to registry creation, they recognised that now was an opportune time to engage with the eHealth debate in terms of looking at the data collection requirement for national datasets.

“To drive efficiencies and to have a more harmonised and integrated system, as much as possible we should be trying to make better use of our existing data sources. So, the ability to link and match registries with other sources of information is very important. This will also help to reduce duplication and fragmentation which currently exists.” [HI]

The need to link and match data must be built into funding and resourcing plans. In addition, it requires at least some identifiable data to be available in the core registry itself so that this matching process can occur. The availability of an IHI may remove the need for any identifiable data although there is an argument that says that the IHI itself becomes the key identifying piece of data. Registries should create a separate unique health identifier that cannot automatically be matched to the IHI.

Buy-in from data providers

Registry experts stressed the need for buy-in from the health professionals who would be providing the data, so it is important for these health professionals to see the benefits of providing these data.

“So I guess you would have to convince and... have on your side the medical professional that actually provides the diagnosis, you know the role players here... it’s key for the success of the registry.” [RE]

Registry experts were generally upbeat about the ability to collect the data.

“We had a few holdouts and from time to time... individual hospitals have withdrawn for short

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periods of time.... On one occasion they wrote to us and said that they couldn't supply [us] with the information because they didn't have the manpower to do this, and again we went and worked out a solution... These have all been transient problems, we've always managed to get over them really I suppose by saying, 'Well this is it, this is here. Everybody else in the world is cooperating with us, what's your problem?' So... there was no way that I was going to go round and try to get explicit consent from every doctor in the country. I'd be there for the next 200 years trying to manage that, you know." [RE]

But, collecting registry data is an onerous process and one which is likely to add to already burdened clinics.

"I think the worry is that while most of the registries are independently funded and they collect the data independent of any clinical care process... clinical people are battle weary, and we certainly don't want any data registries being developed with... additional workload for data entry". [HI]

"...now that they've started to input data I think people realise how onerous a task it is and busy clinical settings and busy clinics. I think that's one of the comments that has come back quite strongly." [RE]

Some experts suggested that incentives would be required and commented not only on the fact that monetary incentives were introduced in the UK, but also the fact that the need to provide data for patient registries has been built into their workload and into their contracts. A recent federal law in the US provides a type of tax benefit for those who provide data to a health registry. This has been described as helpful and some private practices now seek out the registry and look to join. Many felt that some form of incentivisation or acknowledgement of the additional workload required to provide registry data would be needed in Ireland, while others regard the system as being too complicated to introduce these effectively.

"What would be really important for that type of an approach is that the GPs have protected time to actually invest in that initiative... that there is training so they are very much on board with what is happening, but also that they actually

have time allocated to investing in this [initiative], because what will happen is that you will find that the feasibility study won't yield the type of effectiveness that it should because it's not getting the investment from the key actors that it should". [PE]

"In Ireland there are incentives for GPs for some of the, I'd say, diabetes, I think, and asthma, so that dementia will be included on that menu. I think if that happened then I think the introduction of a registry, it would be easier. I think it would be easier to get the GPs on board." [PE]

"I think there has to be some incentive to be able to get data out of different organisations... whether it's around payment for data, whether it's around clinical time, and additional processes to additional systems. There's different ways that incentives can be put in place but it's not something that's probably going to be done just for free just because it's a good thing to do unfortunately." [HI]

There was also a general view from experts, and not just those in primary care, that the workload of GPs has increased a lot in recent years and they are being asked to do a lot more documentation and provide a lot more information so it would be important to look for synergies with how GPs are coding dementia-related data in their own practices and develop automatic data transfer processes to reduce the workload for individual GPs. There was also a feeling that the timing was opportune as work is underway as part of the rollout of the National Dementia Strategy for Ireland regarding the collection and coding of dementia data in primary care.

"I know certainly in terms of GP burden you don't want to end up that this is a very burdensome process because obviously GPs don't have the time to dedicate towards that." [PE]

Skilled registry staff

In some registries the clinician makes the diagnosis and informs a technician who then takes the information required for the registry from the medical charts. In many cases they enter this information directly into a registry data collection system. In other cases a member of the registry staff inputs the data. Registry experts stressed the importance of having skilled staff involved in the data collection process and suggested three different approaches:

- front-line health professionals for each data provider;
- data managers or research nurses located at each data provider;
- separate personnel for data entry.

Having staff located within a data provider's organisation alleviates issues regarding access to patient charts but raises many more issues related to capacity to take on these additional tasks. As a result, hiring separate staff is often preferred. The advantage of looking for people with medical or nursing backgrounds is that they are easy to train but difficult to get and to retain. Alternatively, clerical staff can be recruited. They are much easier to get and typically easier to retain than nurses but a longer training period is required. Dedicated training resources will also be needed that cover a broad range of areas from anatomy to pharmacology. This in turn raises the need for adequate funding to support data collection.

"There's a lot of interpretation when you are capturing it as well... It's the skill levels. I'm just blessed that we have a very dedicated team who work at a very low salary level." [RE]

"And the critical thing which we have to emphasise to everybody all the time is that text is text and text has to be coded by somebody into some meaningful format before you can actually use it to register a disease." [RE]

In addition to data entry tasks, registry staff also provide their support and expertise to those inputting the data in provider sites, are involved in decision making and documentation of particular data sets, and have the ability to tweak data collection processes when problems emerge.

3.4 Theme 4: Data management

3.4.1 Access

There was consensus across policy, legal and registry experts that the registry data, first and foremost, should be available to those responsible for providing health care (e.g. the Department of Health and the HSE). It was also recognised that there would be many other stakeholders looking for access to registry data. There was clear agreement that the guiding principle for data access should be that consumers of registry data should only have access to the data specific to their needs; this is particularly relevant for identifiable data. A clear data access plan should be developed when the registry is being planned and this sits well with the idea of a tiered approach to patient consent.

"You've got to think about things like access controls to that information – should there be a hierarchy of access based on the sensitivity of the information concerned? Who has the right to amend the data at any point in time? Who will that data be shared with? And, ultimately, how long should that data be retained before it's either deleted completely or what's referred to as anonymising the data." [LE]

Some existing patient registries in Ireland have developed their online systems so that data providers can see their own information. This can be useful in terms of looking at performance over time and for improving cross-provider clinical care. It also gives the potential for data providers to compare their performance to the average and to other data providers. As no centralised ethics approval process exists in Ireland, each centre does need to apply to their own ethics board before access can be granted. Although time consuming, it has not been prohibitive to date, but the introduction of a National Ethics Committee would be advantageous here.

"We have now developed a system whereby each individual hospital can log into the system but they will only see their own patients. If the patient and the two hospitals have agreed on shared care ... then at least both [care centres] can see [this shared] patient data." [RE]

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This expert went on to elaborate on the economic benefits of this approach as it can remove cost from the healthcare system. As noted earlier in section 3.1.2 by one of our registry experts, duplicating tests in different settings could be avoided if relevant data was stored and shared across all those providing patient care.

In many cases, at least some registry staff have access to personal identifiers as they are needed to resolve duplication and data matching issues. Where registry staff don't have this option, data issues are necessarily harder to resolve. Given the absence of IHI to date, experts suggested that Irish registries need to give serious consideration to storing some form of identifiable data within the registry and including adequate data protection and data access policies for some sub-set of registry staff to have access to the key that links these identifiers to specific patients.

“Within the registry we ourselves are registered data administrators with the Data Protection Commissioner, so our patients have given permission for the staff within the registry to see the patient identifiers. In certain European countries the registry doesn't even see that and that creates problems with regard to a duplication... have I got this person before because now I can't identify them.” [RE]

Many experts felt that safeguards were needed against unacceptable or unethical use of registry data; for example, US patient registries are becoming an 'economic target' with patients treated as commodities where information gets collected primarily for clinical trials and industry purposes.

“... the risks that some will get the information from pharmaceutical companies or people like that might get the information and use it for their own benefit... be very clear in terms of how the data is going to be used and for what purpose.” [PE]

People with dementia were concerned about some of the ways in which registry data could be used and were worried about the potential impact for them. For some it was a generalised anxiety while others saw implications for their employment, finances, insurance and driving. This was particularly the case for younger people with dementia and a number of experts expressed similar concerns. Each was aware of instances where individuals were not disclosing

their diagnosis for fear of the ramifications of doing so.

“We need to be covering our tail ends as opposed to just doing this to get it done and then realising, 'Oh my God, we've opened up a vulnerable part of society where they can be...whatever. I don't know what the 'whatever' is, but....” [IDWG]

“So I think that that is a huge fear for people working... I'd love to say we were further along in the country with it, with dementia being treated like any other disability, but unfortunately as we all know around the table, that's not the case. So it's a difficult one, because if you are employed... They'll find ways of giving you the nudge out the door. So it's an issue.” [IDWG]

“I don't think it's black and white. It's not insignificant and then you also have the health insurance piece, the driving piece, the ability to work and be employable, getting a mortgage, all of those social elements come to play as well.” [HI]

“I think it's more about the fact that if I'm diagnosed in the very early stages... there are some important implications like they question me on my ability to drive, legal decisions and so on... I think it's more to do with the potential negative consequences that go with a diagnosis.” [PE]

Experts also highlighted the importance of having adequate security processes in place to safeguard all registry data regardless of the medium in which it is held. Avoiding unauthorised access to the registry data is key. There are also a range of legal implications that need to be considered if data access is given, even when it is appropriate, to organisations outside the EU as this creates problems with safe harbour. These concerns are significantly reduced when purely anonymised data are shared.

“There are controls that have to be applied depending on the medium to make sure that is safeguarded... But what you want to avoid is a data breach.” [LE]

3.4.2 Privacy

Although potential risks to privacy and confidentiality were discussed by all experts, they also acknowledged that once the registry has proper procedures and guidelines in place, there should be no real cause for concern.

“Well I guess the danger is that if the system isn’t robust and doesn’t work well that there will be problems with data protection and confidentiality. That’s if the system is not robust and isn’t set up correctly and monitored. So I think as long as it’s managed, operated and overseen correctly, from the data protection and confidentiality point of view, I think there shouldn’t be any great risks.” [CE]

Data protection

Experts agreed that a person’s right to privacy and confidentiality must be assured. They also highlighted the fact that data breaches can and do happen and that the ramifications vary depending on the type of data that was accessed and the response to the breach itself.

“The most important thing is that we have to respect a patient’s right to privacy and confidentiality, so whoever maintains the register must ensure that there are no data breaches ... Information will have to be very strictly controlled and under no circumstances should names or addresses or any identifiers be released to anyone outside of the business unit that is looking after that information.” [LE]

Some people with dementia were particularly worried about privacy because of breaches reported in the media and due to potential negative outcomes of being on a dementia registry.

“That’s something you would want to think of, the ramifications, is it going to impact? If somebody loses this hard-drive or steals the computer, we’ve all heard those tales of files getting out there, so I think that’s something people fundamentally should be given time to ponder on.” [IDWG]

“Couldn’t people get access to it? Will I forever be labelled ‘she’s no good she’s on the dementia register’, and I think people would have to be very assured of confidentiality and the use of a register beforehand and that could be quite difficult to explain to somebody who is in the earlier or

middle phases of dementia, especially when the whole illness itself makes it difficult to understand that you have an illness in the first place.” [IDWG]

Two elements need to be considered when thinking about data protection. The first relates to advance controls that are put in place by having adequate data security and risk management to prevent data breaches, or if one does occur, to lessen the impact. Secondly, there are other procedures and controls that can be put in place that are followed if a data breach does occur, depending on the nature of the breach and the nature of the data. This directs who needs to be informed. The type of controls depend on a range of factors including the data that is going to be stored, how it will be stored, amended, accessed and shared, how long data will be retained and how data will be removed from the registry.

A data protection framework has been in place in Ireland for some time, so establishing appropriate privacy and security procedures would not be a huge undertaking for a new registry as long as it is considered up front in the planning stages. A number of experts also referred to the fact that these challenges are not new and that they have already been addressed in other areas. For example, guidelines have already been developed for GP practices around patient information and how to share this data within a practice. The key for a new registry is not to reinvent the wheel but to build on what is already there.

“It doesn’t have to be overly complicated, it just means taking some time out at the start of the project to consider what we are going to collect, why we are collecting it and how we communicate the reasons and the nature of the studies... to the data subjects in advance, prior to actually receiving their information, and then considering once we have the information in our possession, what controls we are going to apply to ensure that it’s safeguarded and processed in a manner compliant to legislation, and ultimately how long we are going to use that information for and maybe how we’ll dispose of it at the end.” [LE]

One registry expert raised the need to ensure that privacy rights extend beyond death. This is one area where existing policies and guidelines may need to be enhanced.

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Privacy impact assessments (PIA)

HIQA and experts from existing patient registries in Ireland recommended undertaking PIA when planning the data needs of a new registry. A PIA requires a data controller to carry out an assessment prior to the collection of any personal information (including new categories of information for existing registries) to understand what the implications of collecting these data are for the data controller and for the individuals who provide the data. The PIA should also demonstrate compliance with the enhanced data protection regulations (Data Protection Commissioner, personal communication, May 2016). In essence, it formalises the work already being done by data controllers in existing registries. Indeed, if HIQA take over the quality evaluation of patient registries, it is likely PIAs will become mandatory, at least for HSE registries.

“If you are going to go to the department with a proposal, they would want you to adhere to the HIQA principles, they would want you to do a privacy impact statement because these are the sort of things that HIQA would insist on. So you wouldn’t have much of a day-to-day relationship with HIQA but you will be expected to conform to their standards.” [RE]

3.4.3 Technical requirements

Having a robust IT system was considered beneficial from a cost perspective and also for the ease with which it supports data management and facilitates data sharing. Some aspects that need to be considered are:

- data collection (how often, when and push or pull data transfer)
- data storage
- security
- implementing access rules (including password management)
- data transfer (including encryption).

Experts with existing patient registries also highlighted the importance of web-based access, not only for data entry and data reporting, but also in terms of improving security by allowing varying levels of access to one copy of the registry data.

“At the moment the system is not very good, it’s quite an old system, and each one of the people who enters the data has a copy of the database on their laptop because it’s not a web access, it’s a fixed database, so we have 21 copies of the data at any one time, which is not great from a security point of view but it’s encrypted and double-password protected and so on. But we are moving now to, at the end of this year, to a web-based one where there will only be a single copy of it.” [RE]

There was a clear recommendation to use an established technical partner in terms of providing technical support for any new registry. Many existing registries use the OpenApp company and they were considered to have significant expertise both in establishing and running registries in Ireland and elsewhere in the EU. Many of the policies, procedures and systems needed to manage data security, for example, have already been dealt with by this organisation as part of their work with some of the larger patient registries in Ireland.

“They’ve [OpenApp] got great expertise in this area... They also won the tender for the European [registry]. So they are very kind of embedded in this area... there’s a lot of expertise within that group... But I think also the fact that the [Irish registry] that we were consulting with them, and that a lot of the systems had already been established as part of the larger registry.” [RE]

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This same company has been involved in a major redesign of the CFRI technology infrastructure over the last two years and CFRI has now been brought in line with European infrastructure recommendations. This in turn allows for cross-Europe collaboration between registries (CFRI, personal communication, April 2016). Other Irish and international registries are keen to incorporate the CFRI model and IT infrastructure and the CFRI group currently host some smaller registries on their servers; for example IPFR and some test developments for the Irish Skin Foundation Registries. This enables smaller registries to benefit from a more substantial infrastructure than they are likely to be able to develop on their own.

“...that the people who are operating within the registries are at least thinking about it and going about it that sort of way of, you know, sharing core competencies.” [RE]

Despite long-term cost savings, significant funding is needed at the outset to develop an appropriate technology base. For example, the CFRI acquired lottery funding and contributions from the Pharma industry, but this still wasn't sufficient. They were fortunate that the European CF Registry were also looking at updating their technology and by getting onto the steering group for that project, and through a lot of hard work, they were able to benefit from the fact that the EU paid for the core of the technology and the CFRI could benefit from this (CFRI, personal communication, April 2016). It is also possible to co-locate the registry within a high-performance computing centre, most likely in a university, and this has additional benefits such as established data protection policies and structures within the university, access to expert data managers in these centres, specialist statistical analysis experience, natural research partners and collaborators for funding applications. If following this approach, it is recommended that the registry remain independent of the hosting institution.

Finally, some health informatics experts felt that we are at a point in Ireland where we need to think about our broader health information infrastructure. Although this is commendable, it is likely that it will take considerable time to debate, agree and implement any policy or guidelines in this area.

“I think you really need to have a way of linking it in with broader health information infrastructure that exists within the country... You know so there is a legislative infrastructure and then there's a kind of health standards infrastructure that sits alongside and also as part of that so I think they all need to be kind of thought of in the context of you know the feasibility around any new registries.” [HI]

3.5 Theme 5: Registry governance

3.5.1 Governance structures

Experts agreed that formalised governance arrangements should be established from the earliest planning stages as these ensure the creation of a registry that is fit-for-purpose. They set the standards for registry data collection thus ensuring the quality of the registry data. Assigning overall responsibility and accountability within this governance structure is crucial, as is ensuring that registry personnel map onto the specific domains and competencies required to support the effective running of the registry. An existing Irish patient registry described how they have a board that includes representatives from the registry itself, an external expert with a broad scientific, pharmacological and technological background, and two lead consultants from data provision centres. Health informatics experts agreed and added that a named individual, such as the CEO, needs to have overall responsibility and accountability while a management committee would be responsible for the day-to-day operation of the registry.

“You need a relatively small board and I think you need people who are actually going to turn up to board meetings and contribute rather than people who are just going to come and sit there... You need a good dynamic chair, somebody who is going to push things along, who is going to support your CEO. I think that’s a great asset as well because they have the authority on behalf of the board to say things which a CEO or a director might feel that they didn’t have, you know?” [RE]

However, the registry must avoid creating an unwieldy and bureaucratic governance structure. One international expert suggested that people with dementia and their carers should not only be involved in the registry governance but should lead it. This expert was particularly concerned that those with expertise in areas such as ethics and data protection could put onerous processes in place that would act as barriers to getting the registry up and running whereas those whose data is actually being captured and stored would be more pragmatic with regard to how this could be managed.

“You would spend more money governing it than you would you know actually doing it... But if it

was kind of light touch, led by patients and carers I’m sure you would get much more out of it.” [PE]

There was a general feeling that we have made some positive strides towards good governance of existing registries in Ireland. While this may have been very ad-hoc in the past and managed by specific patient organisations or universities, registries such as CFRI are seen as leaders in the field and people who have been through the process with a lot of learning that they can share. It is also very beneficial to have a broader scientific (or expert) advisory board that meets at least once a year. They can review policies and procedures, operations and quality evaluations and provide comments and guidance as required, but they should also have a strategic planning focus addressing the long-term sustainability of the registry.

“I think that was very, very helpful. We built up contacts with [another registry] at a very, very early stage and certainly for the first ten years that was hugely helpful to have somebody else to exchange ideas and problems with and all that sort of thing. Although they operate in a different way, at the same time it certainly was a great resource for us.” [RE]

It should also be noted that the organisation that sets up the registry also becomes the ‘data controller’ from the perspective of data protection legislation in Ireland. Experts highlight the importance, therefore, of clearly identifying the director or owner of the registry as they will be responsible for ensuring registry compliance.

3.5.2 Registry ownership and independence

Having an independent registry was considered paramount. Most Irish experts expected that the registry would be completely independent of HIQA. While some felt that HIQA would have a remit in terms of monitoring governance and quality assurance, this wasn't obvious to all; many argued that this function should be met by a quality assurance group with appropriate scientific and specific registry expertise. One expert also highlighted the importance of ensuring that registry governance was protected from political agendas, while experts in health informatics cautioned that the registry should not be unduly influenced by one particular organisation or type of data collection.

"Now, ours is a professional board which I would very, very strongly urge, because some bodies have really what you might call a political board where you have former TDs and people like that and many state agencies have boards which are quasi-political and really they are no use. You need a technical board. You need a board that you can actually go to for advice and steer and all that sort of thing." [RE]

"Who will own and be responsible for the database? If it's the Alzheimer's Society of Ireland versus a health policy group I think there might be very different data collected." [HI]

In fact, only one expert expressed a reservation with regard to independent registries but this was more in relation to the duplication of effort needed for data collection than the autonomy of the registry itself (as discussed in section 3.1.2 above; [HI]).

Expert opinion was less consistent regarding ownership of the registry although all agreed that a clear and independent owner was required. Some questioned the ability of patient organisations to successfully run national registers in the longer term. They also felt that establishing the registry in the Department of Health would just result in more of the same data already available. Others argued that the registry organisation must have the ability and the competence to run the registry.

"If it's going to be national... I think you'd have to have one body responsible for it." [PE]

"It certainly would be brave, I think, from the Alzheimer's Society's perspective to take ownership of a registry like this and to try and push it forward. I think putting it automatically into the Department of Health we'll probably get more of the same in terms of the data that you are collecting... there's nothing wrong with that, because that's very powerful data, but I don't think, looking at the models of care that are coming and the lack of funding that we have available for long-term care... I think it's worthwhile looking at it from a different angle." [HI]

Some experts felt that it was important to ensure that the registry would be embedded in a structure that links directly with policy and research. However, others felt that the overall ownership of the registry should sit with people who have a vested interest in the dementia agenda (e.g. practice and/or policy) rather than just a research focus. The exception to this would be if the registry was used to support clinical trials and particular research projects, in which case the data specific to this use would need to be managed by an appropriate clinical or research team.

"I'm not sure about a standalone company or an organisation managing this. For a dementia registry, you'd like it to be an organisation that has either an academic research or clinical connection." [CE]

"The tangible links that you can make from a registry so that the data can be used by research and that that research is part of a loop to feed back into policy making and service delivery planning." [PE]

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3.5.1 Registry quality

The formality of the quality assurance process differs across the range of national and international registries explored in this study. Some registries self-evaluate and this process is typically guided by their executive committees and advisory boards, while others operate within a framework that requires periodic external registry evaluations. Regardless of which process is currently in place in a given registry, all experts suggest that formal evaluation processes are required. Experts also felt that it would be really important for us to be able to compare our data with that of other countries and that this would facilitate improved dementia care.

“The fact that we looked at a lot of international experience and we looked for international standards and international coding and operating procedures... meant that from day one our data was internationally comparable and it also gave us a certain amount of clout locally, when people came up with alternative suggestions, then we were able to say, ‘Well that’s a great suggestion, but it actually doesn’t conform to international practice and this is what the international practice is.’” [RE]

In Ireland, HIQA currently have a remit under the Health Act (Department of Health, 2007) for the HSE and services funded by the HSE. This includes monitoring standards for national data collections, setting standards for health information and developing guidance in this area and identifying deficiencies in the national health information landscape. HIQA achieve this primarily through the setting of recommendations which are submitted to the Minister for Health. Based on the current draft of the HIPS (Department of Health, 2014a), HIQA is expected to have a stronger role across the broader health information landscape as the Minister for Health would have provision under this legislation to prescribe specific health information resources and bring them into the scope of HIQA monitoring. HIQA would then set the standards for those prescribed resources and broaden their remit beyond the HSE including monitoring compliance against standards and reporting to the Minister (HIQA, personal communication, April 2016). Irish experts generally recognise that HIQA’s role is continually expanding and that it could encompass this kind of compliance

monitoring but they question if HIQA has the competencies and capacity to provide true quality assurance for patient registries. They suggest that perhaps HIQA could be one link in a more comprehensive and registry-specific quality assurance process.

“There is a kind of a push to... harden up the approach... [to] apply standards as opposed to here’s some guidelines you might think of applying in any context... There’s an issue about capacity and how they [HIQA] would deliver on that.” [HI]

“So you would have an operations and a steering group. Now, you could have expert input on that steering group from quality assurance people like HIQA... but you would probably have to have your own quality assurance people on the operations side as well.” [CE]

3.5.1 Costs, funding and sustainability

Experts agreed that getting access to funding can be challenging. They also stressed that in addition to securing initial funding, it is important to be able to guarantee the sustainability of a dementia registry into the future.

“Registers are expensive. There’s no other way around it. You can’t run a register without spending money.” [RE]

“I think a challenge has been in terms of some smaller clinical registries which are set up on a more ad-hoc basis. In terms of the sustainability... funding, support and sustainability... would probably be the three biggest risks”. [HI]

Registry experts spoke of the difficulty of obtaining funding for the initial set-up and the day-to-day running of patient registries and the constant challenge to grow patient registries in the current environment.

“Five years ago I went to my board and I sort of said we are going to have to close down the registry. We just can’t keep going... We applied for an HRB grant about a year ago, we got to the final adjudication phase and we didn’t cross the actual line, and one of our challenges is because we are not seen as a research establishment, so we are not academic... if you had a centralised registry foundation then straight away you can align yourself with the academics but you still can be independent. [RE]

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“Funding registers is difficult because the health services are not really interested in registers... they don’t see them as valuable, though I disagree, with respect to delivery of service, and research agencies and funding agencies for research won’t fund registers because they’re not outputs of themselves. So funding registers falls between two stools”. [RE]

“The way the law is written it does not exactly determine where the financing for the registry comes from, which is a problem, however until up to this moment there’s been a gentleman’s agreement let say where the state cover part of the funding for the registry so it’s helpful in that sense.” [RE]

So, registries are not currently perceived by funding agencies as being of as much value as research output, nor are health services particularly interested as they also often don’t see their value. One of the difficulties raised by Irish experts is the lack of clarity around where the responsibility for national registries lies in Ireland. There is currently a distinction between care provision (remit of the HSE) and national health policy (remit of DOH) but there seems to be an ambiguity between the two organisations in terms of who actually manages the funds for service delivery. This may be changing, but for the moment the responsibility still resides with the health service. Yet many experts, including those within the Irish health service, felt that the DOH should take a leading role. Overall, there was little agreement regarding who should be responsible for a national dementia registry in Ireland. The consensus that did emerge was that it would be best for this registry to be independent and that a champion would be needed in order for it to progress.

“And I do honestly believe that you need that national mandate for that and that national mandate comes from the Department of Health and it has to be supported by the HSE, but I do believe that it has to be led by the Department of Health and fully supported at that level.” [PE]

“I would say that the Department of Health not the HSE because there’s lots of places outside of the HSE. So it is more Department of Health.” [PE]

If the registry was not to have a national mandate with appropriate funding streams in place, there

was a clear view that it should be linked to either an academic institution or to have research as one of its primary objectives in order to be able to access existing funding sources. Indeed, this is one of the reasons why using a registry to attract clinical trials is seen as beneficial.

“When something like a dementia registry has to be developed from a source of funding that isn’t coming directly from government it’s very difficult to get the mandate that you need to actually enforce it. So I think it’s really important that it does actually come directly from government funding”. [PE]

“One way to support a registry like this would be as a research activity. There may be opportunities in terms of linking with cohort studies, ongoing clinical trials or other types of research and ultimately you might be able to fund it that way. But the problem here is that’s all so project specific and once the project is over, you might not be able to continue to fund it”. [CE]

Irish experts echoed the call for appropriate funding mechanisms and suggested that a National Dementia Registry could be funded through a combination of Public-Private-Partnerships (PPP). These can comprise of some combination of public and private enterprise, government and academia (universities and university hospitals), health services, professional and patient associations and public payers. Other potential sources of funding were identified as the social care budget, the budget for older people and primary care. The argument being that if you were to look at the costs involved in supporting someone with dementia from diagnosis through home care (social needs, quality of life supports), formal care, acute care and palliative care, it is apparent that cheaper ways are needed to support people with these needs.

“You’ve got to have a balance between evidence generation and having money for underlying provision and it’s a difficult one... But I suppose the Dementia Strategy down the line is going to have to look at a version 2, and if we had better evidence base we could decide on what the policy priorities should be [and that they would be based on] peoples’ lived experience.” [PE]

Yet, given the costs associated with establishing and running a patient registry, some experts questioned

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the priority of funding national registries at a time when the health service is struggling for resources at every corner. Some experts seemed fearful of the gaps we might find if we went looking too closely at dementia care needs in Ireland. In some ways there was almost an argument against finding out about a demand that we already know we cannot meet.

“So we know the level of community-based supports is quite poor and then the pressure even on long-term care resource, Fair Deal and so on, is also immense ... we know we are not in a position to provide enough support at the moment... If it’s under primary care we know that there are lots of calls on that funding already... memory clinics will probably be based in secondary care and we know again the demands in that sector can’t be met either and increasing waiting lists for fairly standard and basic procedures... So should we divert that scarce resource towards something like a dementia register, probably not right now, you know, as a balance of the benefits that would flow from it.” [PE]

3.5.5 National strategic planning regarding patient registries

In addition to considering the governance of a registry itself, a number of Irish experts identified the need for a national strategic approach to the creation and sustainability of registries, which supports the findings of the MRCG and IPPOSI (2011) report. There was a suggestion that this should be part of the remit of the Assistant Secretary General with responsibility for research, development and health analytics in the Department of Health. They have responsibility for developing strategy and policies regarding national health information. They are also in a good position to be able to look at the viability, sustainability and funding of national registries, the need for and efficiencies related to the gathering of national health information, and how it can best support policy.

“I think there is a gap there in terms of oversight and governance of all of our national health information sources at a national level so ...

I think there is a move in that direction. I think people are identifying that there is this need for integration and oversight that’s missing at the moment” [HI]

Experts concur that national standards should specifically address robust governance arrangements. They also spoke about the need for a centralised resource to advise on issues of classification, coding and diagnostic standards. This does not need to be a permanent registry resource, although it can be. One registry has a pathologist and a haematologist on retainer for one session a week, for example, and they find this a great resource.

3.6 Theme 6: Legislation

3.6.1 Data protection legislation

Privacy and data protection were key concerns within the data management theme discussed in section 3.4.2 above. The legal data protection requirements are driven by the data that is being collected. If it is just the fact that a person has dementia, with some anonymised demographic characteristics, then this is of little impact, but if enhanced personal information is collected such as medical history, socioeconomic background, level of education and treatment plan, the more useful the data but the more data protection controls are required. That said, most experts felt that data protection legislation should not be seen as a barrier to collecting data, rather a framework that supports the confidentiality and privacy of the individual and facilitates data collection and sharing in a secure way. We should also learn from the various guidelines that have already been established in this area.

Some experts mentioned the recent (May 2016) amendment to EU data protection legislation and recognised that some work would be required before we could be certain of the data protection needs for different types of registries in Ireland and the processes related to mandatory data collection and consent exemptions under this new legislation.

“But data protection should not be seen as a barrier to obtaining this information. It’s a worthwhile goal and it will ensure that the way you treat the information is proper and correct... Ultimately, it is very beneficial to the organisation and to the patients themselves. So while this may seem like unnecessary red tape, the whole idea is to safeguard the rights and privacy rights of the people who are giving their information, but it also safeguards your own reputation, because if you are seen to be haphazard in the way you manage the information, your reputation will be damaged.” [LE]

Privacy Impact Assessments (PIAs) are also being introduced as part of this legislation. This means that data protection can no longer be bolted on to the end of a data collection process. It needs to be completed in advance. Current expert opinion suggests that this will not be very complicated, but that it will mean planning in advance to ensure that the registry complies with the eight basic data protection principles; the most important being consent from the data subject.

In addition, the Article 29 Working Group has been set up by the EU to interpret the eight principles and provide guidance to member states on how to put them into practice. Experts believe that this group will also provide guidance on how to obtain consent which would be beneficial to vulnerable populations such as those with dementia. This guidance would be welcomed by non-legal experts.

“What happens to other registries is that they do get tied up let’s say in the different understandings of what the data protection act means, and I think there needs to be an information for health type policy or piece of legislation around who can access what information, what information can be collected and the pieces around that.” [HI]

3.6.2 Other relevant Irish legislation

Experts only spoke about two other specific pieces of Irish legislation when asked to consider the legal requirements relevant to creating a national dementia registry:

- The forthcoming Health Information and Patient Safety Bill (HIPS) and the related legislation regarding individual health identifiers. The likely impact of this legislation has been discussed under the Data Collection theme above. There was definite frustration at the length of time this legislation was taking to come into force and a sense that the Department of Health was using the impending nature of this legislation to avoid answering specific questions regarding patient registries, data collection and consent exemptions.
- The Assisted Decision Making (Capacity) Act 2015. This has been discussed in relation to obtaining consent in the Registry Data theme above. People with dementia felt that the Act was working to protect their rights and all experts welcomed the idea of having an elected person to support decision making, including those related to patient registries.

“I suppose that act will provide a legal structure for us, which is very good that we have that structure and that for people to help us with our decisions, we can make our own decisions but also there’s a provision in there, as in the bill now, that we have somebody that will help us with our decisions.” [IDWG]

3.7 Cross-cutting theme 1: Benefits and risks

Overall the majority of experts agreed that dementia registries are worthwhile and have numerous benefits. These predominately relate to the range of different objectives that a dementia registry would have and they have been described in the Registry Function theme above. The consensus is that it is vital to collect better dementia-related data and that it will be difficult to progress policy or to improve the quality of clinical care without this information. In particular, the collection of longitudinal dementia data can support improved diagnostic accuracy and better sub-typing of dementia. Additionally, the establishment of a national dementia registry would bring Ireland in line with international best-practice.

“Oh absolutely, there’s no doubt. I mean... I would be surprised if anybody would say there isn’t a benefit in collecting this information because as it is we say that we have approximately 50,000 people with dementia but we actually really don’t know how many people we have in Ireland with dementia”. [PE]

The majority of experts agreed that there are numerous risks to establishing a dementia registry, but these risks can be mitigated. Experts felt that the biggest challenge would be securing appropriate funding to ensure the sustainability of the registry. A number of concerns were also raised regarding privacy, confidentiality, data protection and data access. There was a sense that a degree of stigma is still associated with dementia and that this could prevent people with dementia providing consent for their data to be included in the registry and that there would be a higher risk for these individuals if these data fell into the wrong or inappropriate hands. Ensuring the ethical use of dementia registry data was therefore an important objective for all. Finally, those experts who had hands-on experience with patient registries cautioned that there was a real risk of not having a clear understanding of the aims and objectives of the registry. Without this, it will be difficult to design and implement a registry that is fit-for-purpose and create appropriate data collection and data management processes. There would also be a very real danger of trying to attempt to do too much too quickly. Some experts felt that there was an over-emphasis on collecting registry

data that meets the medical model of the disease and that it would be more beneficial to collect additional psychosocial data to ensure that a bio-psychosocial model is facilitated by registry data collection.

“I think we just need to take the blinkers off. I mean, when people think of registries they just think of clinical trials, they think of treatment protocols... It’s a whole medical model... So we need to look at maybe further afield to see what other countries are doing and see how we can learn from those if there are more, I guess, socially orientated registries collected which include health and social care elements.” [HI]

Finally, health care organisations in Ireland were also seen as fundamentally not patient-centred and used to putting their own interests ahead of those of the patient. This was seen as a significant threat to achieving buy-in from data providers and the health service as whole.

3.8 Cross-cutting theme 2: Barriers and facilitators

Experts identified a number of barriers and facilitators to establishing a national dementia registry for Ireland, but interestingly there was a lack of consensus across the group; what were considered barriers for some, were facilitators for others. Registry experts argued that the main barrier was a lack of strategic policy and of a sustainable funding mechanism for patient registries. This view was shared by policy experts.

“I think the biggest challenge is money... the second biggest challenge is confidentiality and consent and trying to ensure that those don't interfere with your ability to register 100%... this is something you have to be very, very careful about, that once you set it up, that you are looking for 100% capture”. [RE]

The inherent difficulties and time-consuming nature of data collection, including the variety of locations in which a dementia diagnosis is made and the current poor state of eHealth and EHRs in Ireland, were also widely seen as detrimental to the creation of patient registries. Yet, while some felt that the unsuccessful implementation to date of IHI was further proof of this, other experts felt that the fact that IHI was in the pipeline could facilitate the data collection needs of a dementia registry. Similarly, some experts argued that the lengthy timeline that was likely to be needed for the national rollout of the SAT would be a barrier to the creation of a dementia registry, but others saw SATs as reducing the amount of new data collection that could be needed and providing an additional opportunity to convert to EHRs for those that were assessed in this way. Further barriers that were identified were the difficulties diagnosing and accurately coding dementia, a lack of clarity regarding the consent model to be used, a lack of a centralised ethical approval process and generally the length of time it takes to implement any policy or legislative changes in Ireland.

While many experts saw nothing but barriers associated with gathering dementia data from primary care providers, others felt that primary care was the best place to go for these data and that the forthcoming work to improve GP coding as part of the rollout of the National Dementia Strategy would facilitate the collection of these data. Many experts also felt that the recent Assisted Decision Making (Capacity) Act 2015 and the flexibility afforded by the latest EU Data Protection Directive create an environment more conducive to creating patient registries. There was a recognition that we can learn from dementia registry expertise in other jurisdictions. More importantly, we have significant patient registry expertise in Ireland not least with the CFRI and the OpenApp organisation that supports many of our registries. Finally, the positivity that people with dementia felt towards the idea of a dementia registry, particularly regarding the inclusion of anonymised data that could support policy and advocacy, is a clear facilitator to the creation of a registry albeit that there will be potential risks that the registry will need to mitigate. It would seem to be an opportune time to examine the feasibility of a national dementia registry given the current direction of Government strategy and the increasing focus on dementia. That said many experts were unsure if anyone would be willing to pay for it.

“I think in general the health service's leadership would welcome an informed approach as to how to actually deal with dementia. I also think there is an awareness that we don't have sufficient data to actually plan for service provision for dementia patients.” [HI]

“There isn't any national data register and that is something that was highlighted in the strategy, that there was a need for... if we are looking at kind of international best practice we do need a registry.” [PE]

3.9 Cross-cutting theme 3: Dementia-specific challenges

There were a number of areas that were seen as particularly challenging with regard to the creation of a dementia registry above and beyond those likely to be encountered if creating a registry for other diseases. Dementia is a cluster of symptoms that can be hard to diagnose and open to subjectivity bias. It is not as easy to diagnose as a disease with a specific test or within a specific clinic which is the case for many of the rare disease registries that are currently in operation in Ireland. People with a diagnosis of dementia also typically have a range of co-morbid conditions and there is an argument against tracking dementia without also monitoring these as clinical care and dementia policy are impacted by the combination of these items and not just dementia alone. The degenerative nature of dementia provides a further challenge with regard to capacity to provide informed consent, although there was recognition that this challenge has been addressed in the research arena. The recent Assisted Decision Making (Capacity) Act 2015 will provide more support and direction in this area.

It was clear that there is still a stigma associated with the diagnosis of dementia and to some extent, there is a stigma associated with the idea of 'being on a register'. Some experts worried that either or both of these would prevent people with dementia from seeking a diagnosis. In the former case there could be a concern about the ramifications of being placed on a dementia register with regard to who will see the data and the likely impact on an individual's welfare, employment and insurance, for example. In the latter case, the very idea of being placed on a register could prevent people from seeking advice if concerned about potential cognitive impairment. Furthermore, the stigma and fear associated with dementia makes the receipt of a diagnosis a very difficult time for individuals and their families. This deters clinicians from making informed consent requests at this time and people with dementia expressed the concern that they might not be in the best place to make an informed decision at that time.

SUMMARY

The analysis of the expert interviews and focus groups revealed six themes with related sub-themes:

1. Registry function

- Provide information
- Enhance policy
- Improve care
- Support research

2. Registry data

- Inclusion criteria and diagnosing dementia
- Required data elements
- Patient consent
- Anonymised and identifiable data
- Accuracy and comprehensiveness

3. Data collection

- Data sources
- Process of data collection

4. Data management

- Access
- Privacy
- Technical requirements

5. Registry governance

- Governance structures
- Registry ownership and independence
- Registry quality
- Costs, funding and sustainability
- National strategic planning regarding patient registries

6. Legislation

- Data protection legislation
- Other relevant Irish legislation

Three high-level cross-cutting themes were also identified:

- **Benefits and risks** – The majority of experts agreed that dementia registries are beneficial. Although there are associated risks, these can be mitigated.
- **Barriers and facilitators** – The main barriers to developing a national dementia registry were identified as a lack of strategic policy and of suitable funding mechanisms, and the complexity of data collection. However, recent legislation changes, the availability of registry expertise in Ireland and the acknowledged lack of dementia data were considered to be facilitators.
- **Dementia-specific challenges** – the complexity of a dementia diagnosis, the degenerative nature of dementia, and the stigma that is still associated with the diagnosis in Ireland, are challenges that a national dementia registry will need to overcome.

4.1 Learning from experience

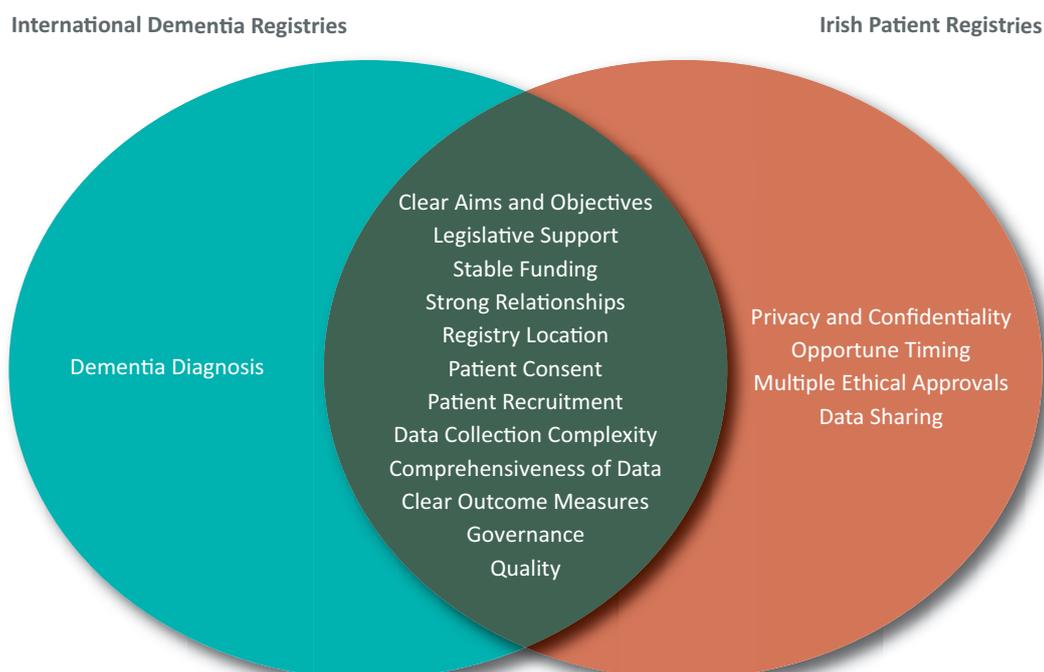
4.1.1 Lessons learned from existing patient registries

It is clear from the discussions with registry experts in Ireland and in other jurisdictions that there are a number of key lessons that can be learned from their experiences. Many of these lessons are common to all types of patient registries and some to dementia registries or to Irish patient registries in particular (see Figure 3).

Those lessons that are common across all patient registries are:

- **Clear aims and objectives** are needed for the registry to be successful. The most important starting point for any registry is asking ‘What is it that you want to know?’, ‘What is the value of knowing this information?’ and ‘Where do you want to get the data from?’ Experts also cautioned against trying to over-extend and recommended an initial focus on meeting the primary objectives of the registry.
- **Legislative support** is considered a beneficial facilitator when setting up and maintaining a registry. Registry experts reported that it gives legitimacy to the registry and that it is advantageous with regard to securing funding, the sustainability of the registry and to accessing data sources and obtaining buy-in from data providers. While legislative support can be advantageous it is important that the registry remains independent and is not subject to any undue political influence or pressure directly from the health service itself.
- **Stable funding** is crucial for the longevity of a registry. It should be noted that while legislative support may facilitate funding, some existing registries have found that it does not guarantee funding. In particular, budget deficits can lead to cuts in funding. All experts advised that the challenge of securing stable and sustainable funding should not be underestimated.

FIGURE 3 Lessons learned from international dementia registries and Irish patient registries.



- **Strong relationships** are needed with health-care professionals in order to capture accurate and comprehensive data, although getting their buy-in can be difficult due to time pressures, difficulties diagnosing dementia and the potential implications for the person with dementia. In particular, SveDem learned that in order to ensure adequate representation of data the involvement of primary care general practitioners was crucial (Religa et al., 2015). Building supportive relationships with other patient registries additionally benefits a new patient registry. Wider stakeholder (state, university, third sector and voluntary organisations, patient advocacy groups, informal caregivers and people with dementia) commitment and involvement is also crucial to the success of a registry. A close relationship with advocacy organisations is particularly advisable to ensure that the information provided by the registry positively impacts on patient care, and ‘passionate drivers’ need to be identified within the stakeholder group.
- **Registry location** also needs careful consideration. Locating it within existing structures can support security and continuity although again it is important that the independence of the registry is maintained. Location within a university can facilitate access to additional funding streams, to analytical expertise and it facilitates the research objectives of the registry.
- **Patient consent** needs to be carefully considered. The NCRI’s exemption from the need to obtain consent has been very beneficial, but this has only been possible due to their legislative mandate. Existing Irish patient registries have found that there can be a considerable delay in obtaining informed consent (e.g. up to six months) as diagnosis is an especially sensitive time for patients and it can be expected that this will be the case for people newly diagnosed with dementia. The difficulties of obtaining consent from this vulnerable population must also be considered. Many international dementia registries have not had to address this challenge as their mandate allows them to collect data without obtaining consent, but our experts felt that this challenge has been addressed in research context and a similar process could be adopted.
- **Patient recruitment** is essential to the success of any registry and explicit goals and strategies must be set during the planning of the registry and continually monitored and adjusted as needed during its operation.
- **Data collection is a complex process.** Skilled staff are required in order to interpret medical records accurately and registries should not assume that frontline clinical staff have sufficient availability to be able to complete this task without adequate incentives to do so. All existing dementia registries highlighted data collection challenges that they still face. For example, SveDem acknowledge that primary care data collection requires further improvement (Religa et al., 2015). SCADR are working hard to increase dementia coverage from private health care providers (SCADR, personal communication, May 2016) and ReDeGi highlight the importance of agreeing a minimum dataset for all patients from all providers (Garre-Olmo et al., 2009). UK experts commented on the fact that they really have no good data for routine epidemiology at the moment and that while linked data (across conditions, co-morbidities, clinicians) would be ideal, especially for vulnerable older people, they have been working on this for 10 years and they are still not there yet. So, they advise that you have to start with something that is ‘good enough’ and figure out how to continually improve it as you go along.
- **Data will never be truly comprehensive** and registry experts recognise that there will always be an unknown portion of incident cases due to individuals not coming into contact with medical services and where diagnostic processes have not yet begun. Other challenges are the number of ‘missed’ patients who are diagnosed but not reported and the lack of integrated data across public and private health care providers. This is a particular issue in the Irish health system.

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- **Clear unambiguous and tangible outcome measures** are required that facilitate accurate interpretation of registry findings and enable the registry to meet its objectives.
- **Registry governance** must be formalised but not unwieldy. Board members should comprise of representatives from the registry and external experts including someone with previous registry expertise. The selection of the right Chairperson is also vital. This should be someone who is strong, dynamic, enthusiastic and highly committed to achieving the aims of the registry.
- **Quality evaluations** are vital in order to ensure that all required data are entered and valid (e.g. the consistency of dementia diagnoses) and that it meets the purpose for which it was collected. There was a clear recommendation that the results of these evaluations should be published.

Only one area emerged that was specific to the creation and operation of dementia registries – **standardisation of dementia diagnoses**. Dementia registries are challenged by the subjectivity of a dementia diagnosis. It has been demonstrated that diagnosis is complex and differences are often seen between medical specialities (geriatrics, psychiatry and neurology); even when mutually agreed diagnostic criteria exist, clinicians may still differ in how the criteria are applied (Garre-Olmo et al., 2009; Johannsen et al., 2011). Standardisation of dementia diagnoses is needed to protect the credibility of the data, along with an emphasis on training physicians and other clinical personnel in achieving and coding accurate dementia diagnoses.

Lessons learned from patient registries in Ireland are:

- **Privacy and Confidentiality** needs to be assured for those registered and all Irish experts underlined the importance of having strict policies in place to protect individuals. Many experts highlighted confidentiality as being one of the key challenges faced when setting up a registry, in addition to funding and patient consent.
- **Opportune timing** can be instrumental in the setting up of a new registry. For example, the NCRI was established at a time where local pressure, a central government need for cancer-related data, cross-border collaboration and the establishment of cancer registries in other European countries came together. It can also be helpful if opportunities are available with other smaller countries/regions to pool resources, energy and momentum in order to make progress (e.g. Republic of Ireland, Northern Ireland and Scotland or other EU countries).
- **Multiple ethical approvals** are currently needed from the plethora of ethics committees relevant to different sectors of the health system in Ireland. All experts commented on the time-consuming nature of this approach and highly recommend the creation of a centralised process.
- **Legal difficulties** arise with regard to sharing data across different health institutions in Ireland as each is a separate legal entity. It was felt that this is something that needs to be dealt with as a matter of urgency and that primary legislation will be needed; governance or regulatory directives will not be sufficient to establish a firm legal basis for data collection, research and data sharing with regard to patient registry data.

4.1.2 Characteristics of successful registries

Registry success was succinctly defined as “careful planning + active upkeep” by the Milken Institute (2016). It is possible to determine the characteristics of successful patient registries by combining the findings from the rapid literature review and the existing patient registry guidelines (Australian Commission on Safety and Quality in Health Care, 2008; EyeNet Sweden, 2005; Gliklich & Dreyer, 2014; Milken Institute, 2016; Newton & Garner, 2002) with expert opinion and lessons learned in the creation and ongoing operation of existing patient registries. These characteristics are:

- Clear, focused and agreed aims and objectives.
- Tangible benefits from the outset.
- Stable funding.
- A registry designed with respect to its primary purpose.
- Clearly defined inclusion and exclusion criteria for registry participation.
- Clearly defined data sources.
- Clearly identified and agreed minimum data set.
- Minimal data collection – concise and relevant information is gathered and duplication is avoided.
- Data collection methods that match the specific needs and objectives of the registry.
- Data collection methods that are adaptable to local variation in how care is provided.
- Data providers are reimbursed for work required to provide data to the registry (e.g. GP practice software suppliers in the UK are reimbursed for the cost of extracting minimal data from their systems).
- Data and reports that are useful to front-line clinical staff.
- Web-access to registry reports (and in many cases data entry).
- Clear and transparent plans for governance with explicit roles and responsibilities for all stakeholders.
- Patients expect to and are treated as partners.
- Clear ownership of the registry (data and functions).
- Clear and visible leadership.
- The establishment of a multidisciplinary registry team – all disciplines involved in providing care to the target patient group are involved.
- A dedicated registry administrator with guaranteed funding.
- Formal procedures relating to consent, privacy and confidentiality and data protection adherence that are established at the outset.
- Formal procedures for data analysis, publication and data sharing – plans for managing potential conflicts of interest are advisable.
- Formal quality control and registry evaluation procedures.
- Flexibility to adapt to changing conditions.
- Registry functions include raising awareness of the value of and the need for the registry.
- Educational support is provided for all those interacting with the registry.

4.1.3 Characteristics of poorly performing registries

It is also easy to identify the characteristics of poorly performing registries, namely:

- Lack of funding.
- Lack of strategic policy direction and support for the registry.
- Registries that were driven by one person who subsequently retired or lost interest.
- Unclear or conflicting aims, objectives and outcome measures.
- Trying to do too much too quickly.
- Inability to mobilise registry data to inform clinical practice and public health policy.
- Overly inflated ambitions of how much data could be collected.
- Lack of recognition of the time required to collect data.
- Incomplete data.
- Out of date data.
- Inaccurate and poor quality data.
- Understaffed registries.
- Too high a data collection burden on front-line health professionals.
- Inability to attract participants.
- Poor stakeholder buy-in and/or lack of clarity regarding stakeholder roles and responsibilities.
- Disparate and non-standard data sources, or too many small databases, that are too difficult to bring together.
- Inadequate technical infrastructure (e.g. MS Excel spreadsheets, MS Access databases) that cannot adequately support governance and data security needs.

One concern regarding the suggested Patient Registries Framework in the MRCG and IPPOSI (2011) report, and presented in section 2.4.1 above, is that although not its intention, it may seem to support a move towards establishing less complex and less costly patient databases in individual clinical settings with the assumption that these databases can be brought together at some future point to form a national patient registry. As has been demonstrated with other diseases and in other jurisdictions, this is not as simple as it seems and it has often been unsuccessful. The most successful registries instead commence with a design that is suitable and scalable to a national level even if the first implementations are less ambitious.

4.2 The road to a National Dementia Registry for Ireland

This report brings together extensive evidence and analysis on the feasibility of establishing a National Dementia Registry for Ireland. It is clear that there are a number of key questions that need to be answered and key decisions that need to be made in order to develop a comprehensive proposal for a national dementia registry and these are discussed in this section. We also recommend actions that can be taken to advocate for a suitable policy and legislative environment conducive to the effective operation of any registry.

4.2.1 Getting started

The first questions that need to be addressed relate to establishing clear leadership to drive this debate forward, identifying all those interested parties that need to be involved in the discussion and decision-making with regard to its establishment, and identifying funding to support the creation of a comprehensive registry proposal.

Question 1: Who will take the lead in furthering the discussion regarding the feasibility of the National Dementia Registry of Ireland?

One individual (or one organisation) should have overall responsibility for driving these discussions forward, but they will not be able to do this alone. It is also important that this individual is someone who is enthusiastic about and committed to the aims and objectives that the national dementia registry is setting out to achieve.

Question 2: Who are the stakeholders that need to be involved in these discussions?

Relevant stakeholders need to be identified from all interested parties including those from government, health and social care services, patient organisations, people with dementia and their families, academia and industry. An expert group should then be established to guide the future development of the registry and to ensure that the proposed registry has a sound financial, clinical and scientific basis. The expert group will determine the primary aims of the registry and the initial data content and data collection processes. It will be very important that the expert group includes the voice of the person with dementia and that of their family carers.

Question 3: Is creating a national dementia registry the right thing to do (a) at all and (b) now?

A fundamental question that needs to be addressed is the value of creating a national dementia registry for Ireland. The need for a dementia registry needs to be formally debated and suggestions that our dementia data needs could be provided in another way need to be considered. Being able to answer these questions will be important in terms of arguing the need for a dementia registry and countering challenges to this position and to concerns that this is not the right time to consider establishing this registry given budgetary constraints and the current state of the Irish health and social care system. For example, the most proximal goal of a dementia registry for people with dementia is the improvement of patient care. Objectives such as public health and research, while still important, are typically more distal. So in this case if findings based on registry data can enable more parsimonious and equitable care for people with dementia, the idea of funding this registry from existing money within the health-care system needs to be discussed with this in mind.

Question 4: What funding is needed to support proposal development?

It will be necessary to secure funding for the development of a comprehensive registry proposal. The expert group will need to estimate the likely costs involved in this work, identify potential funding sources and secure the appropriate funding to progress to proposal development. It is difficult to determine where this funding can be sourced from. Government support will undoubtedly be required either directly to make funding available for the development of this proposal (e.g. through the National Dementia Strategy Office) or indirectly through the setting of research funding priorities with the HRB.

Associated issues:

lack of funding for patient registries.

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4.2.2 Determining the scope and design of the Registry

It is clear that a National Dementia Registry for Ireland should be designed with respect to the main function that it is being created to support. This primary objective will drive the registry model selected, the data that are required and all of the processes and procedures necessary to develop and operate the registry effectively, efficiently and ultimately successfully.

Question 5: What are the primary aims and objectives of an Irish national dementia registry?

A case can be made for establishing a dementia registry to provide better dementia-related data in Ireland to enhance policy, to improve patient care and to support research. Trying to address all of these objectives at the outset will be challenging. The costs and benefits of addressing each needs to be examined and a roadmap developed such that a focused set of objectives are initially delivered but that the registry is designed to enable further growth over time.

Question 6: What outcome measures should be included in the registry?

Policy and clinical requirements need to be translated into measurable items and outcomes that can be included in the registry database.

Question 7: What is the scope and who are the target population of the registry?

The inclusion and exclusion criteria regarding whose data will be captured and stored in the database will need to be established such that they facilitate unbiased data collection. Best-practice suggests that a formal diagnosis of dementia should be required, but issues such as inconsistencies in the assessment and coding of dementia need to be addressed as part of this process. Advances are being made to standardise and improve coding of dementia in GP practices as part of the rollout of the National Dementia Strategy and it would be opportune to capitalise on this work with regard to being able to use these data to populate a national dementia registry.

Associated issues:

lack of standardisation of dementia diagnoses, inconsistent coding of dementia and lack of adequate coding of dementia in primary care.

Question 8: What data will be collected?

The primary purpose of the registry will drive the data that needs to be collected. A minimum dataset will be required without which the registry cannot operate effectively. This minimum dataset should be mandatory for all data providers. Additional data items can then be mandatory or optional depending on their centrality to the primary aims and objectives of the registry, their general availability and the cost of their collection. Standardised data definitions will be required for all data items under consideration for the registry. These definitions must be clearly described in a well maintained data dictionary. Data sharing, data security and data confidentiality processes will be required in order to maximise the value of linking data from different sources and across different national and international registries.

Associated issues:

lack of standardised definitions for dementia-related data and the need to create and maintain a dementia data dictionary.

Question 9: Where will these data be sourced?

Dementia is not diagnosed in one place in Ireland and it would seem inevitable that data will need to be collected from primary and secondary data sources. This in turn requires the ability to match data from these sources for a given patient. It is unlikely that IHI's will be rolled out nationally in the near term, but it has been demonstrated that data matching is possible without the availability of unique patient identifiers although they do simplify the process greatly.

Associated issues:

method of determining unbiased case definition (inclusion and exclusion criteria); lack of standardisation of dementia diagnoses, inconsistent coding of dementia and lack of adequate coding of dementia in primary care; lack of readily available unique patient identifiers, lack of clarity regarding the operation of unique health identifiers and the final content and timing of the HIPS bill; the need to hold at least some identifiable data in the registry to facilitate data matching and the need for consent to collect and hold these data.

Question 10: What consent process is required to gain access to these data?

Given the increasing importance of privacy impact assessments in Ireland, a PIA should be carried out on the proposed dataset for a national dementia registry. The results of this PIA will drive data protection and security requirements and it will also inform the debate regarding the most appropriate consent mechanisms for the registry.

It will need to be established at the outset if a national dementia registry will have a legislative mandate to collect data (anonymised or otherwise). If this were unavailable or if it did not cover all required data items, appropriate consent mechanisms will need to be put in place. It will be important to achieve the right balance between privacy and the common good and to have a data protection process that is rigorous, robust and fair, but also facilitates the data collection and sharing needed to improve health policy and research in Ireland. A tiered consent process would seem the most pragmatic approach at this time.

Associated issues:

lack of strategic national policy regarding patient registries including the lack of clarity around patient consent; lack of clarity regarding the Irish legislation that will ratify the recent EU Data Protection Directive.

Question 11: How will the data be collected and stored?

Data collection procedures and the associated staffing requirements will need to be investigated. The lack of electronic records will be problematic and although the MRCG and IPPOSI (2011) are calling for the mandatory introduction of EHRs for certain disease categories, this is unlikely to occur in the near term. It is more likely that registry data will need to be captured by front-line staff, by registry staff located with front-line data providers, or by registry staff secondary to front-line dementia care. The ramifications of each of these options in terms of time, cost and likely incentives need to be evaluated. Options such as web entry, automatic data transfer where electronic records exist (e.g. GP practices) and the technical infrastructure needed to support data collection and storage need to be considered. Ultimately, a standardised implementation process will be required for all data providers to ensure consistency and reduce bias in the data collection process.

Associated issues:

lack of clarity regarding the operation of unique health identifiers and the final content and timing of the HIPS bill; poor electronic recording of patient data, lack of an agreed policy with regard to EHRs in Ireland and the lengthy timeframe that will be required even if EHRs became recommended policy.

Question 12: How will registry data be analysed and results disseminated?

The outcome measures established for the registry will determine the data analysis and reporting needs of the registry. In most cases the registry is responsible for carrying out this work but it often has support from academia or specialist statistical centres. There is some overlap here with the governance of the registry and strategic partnerships are likely to be required. In addition, arrangements need to be established to determine how outputs from the analysis of registry data will be disseminated. Secure data access procedures will be required to ensure that data protection legislation is adhered to. It may also be possible that the registry's strategic partner would be willing to house the dementia registry database within their I.T. infrastructure, therefore reaping the benefits of existing security protocols.

Associated issues:

lack of a legislative basis for data sharing across Irish health and social care institutions; need for strategic partnerships to provide the registry with the expertise needed to perform the necessary statistical analyses, data protection and data security.

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Question 13: What is the most appropriate and practical design for the registry?

It will be important to select the most appropriate and practical design for the registry with an eye to future growth potential. As already indicated in Section 2.3, no one ideal model for a dementia registry has as yet been established. It has been argued that design should be based on the objective of the proposed registry (González, 2015). The answers to the preceding questions will therefore be needed in order to select the most appropriate model for an Irish dementia registry.

The MRCG and IPPOSI (2011) argue that while patient registries remain the gold standard, patient databases have the potential to develop into registries as resources and time permit. Previous dementia registries that have tried to bring disparate patient databases together have found this very difficult and they typically have been unsuccessful. Re-consent processes are also needed where data are used for a purpose other than that for which it was originally collected. While a comprehensive model similar to that used in Sweden might be preferred, it is possible to adopt a phased approach to building a registry but the initial design of the registry must be pragmatic, sensitive to the challenges of the Irish health system and future-proofed to facilitate this growth. Typically the first phase of development is used to decide what data needs to be collected, who will collect it and how it will be collected. It includes a pilot implementation of these processes to determine the suitability of the data collection methods based on patient recruitment rates, data quality evaluations and feedback from the clinicians and patients providing the data. Subsequent phases involve national implementation of the core registry functions followed by expansion to include new data sources, secondary registry objectives and other potential updates required to adapt to a changing health care environment. It is vital that a strategic plan for a phased implementation exists from the outset. In many cases where this was expected to evolve from the first pilot, registries have failed to achieve their full set of objectives and have ceased to operate.

Pilot studies are very common in the Irish health system but few are implemented nationally. There is a significant danger that excessive pilot studies have now limited the buy-in needed from data providers to make a success of future studies. That said, Irish patient registries such as the CFRI and the IPFR have been successful with phased implementations and their models could be applied to setting up a national dementia registry in Ireland. The IPFR benefits from being kept on CFRI's server. In addition to the technical benefits, the close relationship with a pre-existing registry also affords IPFR the opportunity to benefit from CFRI's experience and expertise. This removes the need for a newly established registry like IPFR to 'reinvent the wheel' regarding the basic principles of operating a registry. The National Dementia Registry of Ireland should consider establishing close links with the CFRI and with the 'gold-standard' Swedish dementia registry when investigating the most appropriate and pragmatic model for an Irish registry. Consultation with a software company with expert knowledge of patient registries and the healthcare environment in Ireland would also be recommended.

Associated issues:

development of disparate sets of patient data and unstandardised data collection processes that cannot subsequently be amalgamated into a single working registry; potential need to re-consent for data uses not considered in the original consent process.

4.2.3 Ensuring the sustainability of the registry

Looking at the feasibility of a national dementia registry is just the first step and part of the work of the registry group will be to determine how to sustain the registry in the longer term.

Question 14: What are the potential long-term sources of funding for a national dementia registry?

While Question 4 above considered the relatively small amount of funding required to prepare a detailed proposal regarding the development of a national dementia registry for Ireland, significantly more funding will be required to develop and sustain the registry itself. Potential funding sources will need to be identified for the creation and the ongoing operation of the registry. It is not current practice for research funding to cover the establishment of patient registries, so existing funding structures will have to change to facilitate this need or a new national funding structure for registries will need to be established. It is not currently clear where this new funding is likely to come from and a range of options including government funding, PPPs and support from other stakeholder groups must be considered.

Associated issues:

lack of national strategic direction with regard to patient registries; lack of availability of national funding sources for patient registries; uncertainty regarding the likely costs of such a venture.

Question 15: What are the costs involved in initially developing the registry and what are the potential ongoing operational costs?

Experts in international dementia registries, Irish patient registries and the technical development and design of patient registries will need to be consulted in order to estimate the costs involved in creating and running a dementia registry in Ireland. A number of manual steps are likely to be required and therefore need to be included in the costs, at least in the short-term. It is likely that some of this cost can be reduced in the longer term if IHIs and EHRs become common place in the Irish healthcare system, but the lack of certainty regarding these proposals means that they should not be considered as a given when first developing the registry.

Associated issues:

consent requirements (and the potential for a national mandate to support the registry); registry scope and design; reporting and evaluation needs of the registry; potential to co-locate the registry with other existing patient registries and/or academic institutions that may provide shared value regarding technical infrastructure, data management, data validation support, statistical and analytical support and prior experience with similar datasets.

4.2.4 Delivering a quality dementia registry

The remaining questions relate to the governance and evaluation of the registry.

Question 16: Who will own the National Dementia Registry of Ireland?

A clear owner needs to be established for the National Dementia Registry of Ireland. All expert opinion recommends that the registry should be established as an independent entity. If this is not possible, giving responsibility to an existing HSE directorate or to an existing agency such as HIQA is suggested (MRCG & IPPOSI, 2011). The implications of the lack of independence in this instance needs careful consideration. While locating a registry within the Department of Health or the HSE might be additionally attractive from a funding and a data protection perspective, it presents real challenges in terms of the comprehensiveness of the data collected (e.g. omission of data from private providers), having the expertise to operate a registry successfully and ensuring that all objectives are met. It has also been demonstrated that this does not guarantee sustainable funding when budget cuts are being made.

Associated issues:

Lack of strategic policy with regard to the responsibility for patient registries in Ireland; potential conflict between funding providers and the goal of an independent registry.

Question 17: How will the National Dementia Registry of Ireland be governed?

Registry management and governance teams should be selected on the basis of their expertise and experience. The Swedish Dementia Registry and the CFRI have comprehensive governance structures that can be used as exemplars. They recommend setting up a steering group to ensure the registry is run according to its aims and objectives and patients' rights are respected. This group should also govern the use of registry data including all data access requests for research projects.

Question 18: How can the quality of the registry be assured and maintained?

Quality is not something that can be inspected into a registry at the end of the process and it therefore needs to be considered at the outset. Developing standardised data definitions and dementia codes, comprehensive and transparent data inclusion and data collection processes, reviewing all potential sources of bias and undertaking the appropriate practical steps to address these biases will be essential to ensure the quality of registry data. It will also ensure that biases inherent in the data are quantified and suggest how these systematic errors could impact on the use of registry data. Additionally, external periodic evaluation of the registry is recommended.

Associated issues:

lack of a national patient registry strategy and clarity of HIQA's role with regard to patient registries that encompass all healthcare providers (i.e. not just those within the HSE), and concern regarding HIQAs competence and expertise to comprehensively evaluate patient registries.

4.2.5 **Advocating for strategic policy and legislation to support patient registries**

There are a number of actions that will be required to support the successful development of patient registries in Ireland and this is an opportune time to advocate for patient registry needs. In terms of strategic policy, the registry team should be advocating for:

- A national strategic policy with regard to patient registries.
- Clear long-term funding streams for patient registries.
- The inclusion of dementia as a priority disease category.
- Categorisation of dementia as a chronic illness and review of dementia care as part of the upcoming renegotiation of GP contracts.
- Standardisation of dementia coding within primary care and across primary and secondary care.

With regard to legislation, the registry team should engage with the Departments of Health and Justice to advance and positively influence the following legislation:

- Irish implementation of the EU Data Protection Directive 2016.
- Nationwide implementation of IHIs.
- Clarification of the content and timeline for the outstanding HIPS bill.
- Data sharing across Irish health and social care providers.

To achieve this, it will be essential for the registry team to increase awareness of the value of patient registries and the specific benefits of having a National Dementia Registry for Ireland.

SUMMARY

This report brings together extensive evidence and analysis on the feasibility of establishing a National Dementia Registry for Ireland. It presents the lessons that can be learnt from international dementia registries and from existing patient registries in Ireland. The characteristics of successful patient registries demonstrate good practice. Those of poorly performing registries illustrate common pitfalls to be avoided.

It is also clear that a number of key questions need to be answered and key decisions need to be made in order to develop a comprehensive proposal for a national dementia registry. These are:

- Who will take the lead in furthering the discussion regarding the feasibility of the National Dementia Registry of Ireland?
- Who are the stakeholders that need to be involved in these discussions?
- Is creating a national dementia registry the right thing to do (a) at all and (b) now?
- What funding is needed to support proposal development?
- What are the primary aims and objectives of an Irish national dementia registry?
- What outcome measures should be included in the registry?
- What is the scope and who are the target population of the registry?
- What data will be collected?
- Where will these data be sourced?
- What consent process is required to gain access to these data?
- How will data be collected and stored?
- How will registry data be analysed and results disseminated?
- What is the most appropriate and practical design for the registry?
- What are the potential long-term sources of funding for a national dementia registry?
- What are the costs involved in initially developing the registry and what are the potential ongoing operational costs?
- Who will own the National Dementia Registry of Ireland?
- How will the National Dementia Registry of Ireland be governed?
- How can the quality of the registry be assured and maintained?

In addition, the registry team must advocate for a suitable policy and legislative environment conducive to the operation of any patient registry in Ireland.

There are many challenges facing health and social care systems in Ireland but these can be met with proper planning underpinned by comprehensive and accurate data. There is general agreement in the literature that patient registries have a role to play in national public health strategies and that they can facilitate improvements in policy and patient care as well as supporting related research endeavours. Successful registries aim to capture data from the patient's point of entry into the health system and across all interactions that they have with health and social care services once in. They also demonstrate a clear need for collaboration and data sharing to take place across health and social care services including public, private and voluntary providers. The creation of relatively effective and efficient patient registries in Ireland, such as the Cystic Fibrosis Registry of Ireland, demonstrates that a lot can be achieved within the limitations of the current Irish health system.

With regard to dementia, there is undoubtedly a need for more accurate and comprehensive data in Ireland and the development of a national dementia registry would certainly address this need. International evidence and expert opinion suggests that the construction and population of a dementia registry is feasible, but that the costs of such a solution cannot be underestimated. Initial development will be complex due to:

- a lack of funding mechanisms to support patient registries;
- a lack of awareness of the value of investing in these registries;
- difficulties and inconsistencies in making a dementia diagnosis;
- the lack of standardised coding structures and data definitions related to dementia;
- the fragmented nature of dementia care in Ireland and poor data recording structures in hospitals and within the broader health service.

Although a number of concerns will also need to be examined regarding privacy, confidentiality and data protection, robust legislation and guidelines exist to assist with this process, and many of these issues have already been addressed in other jurisdictions and in a research context.

The findings of this study suggest that the benefits of developing a national dementia registry make the required investment worthwhile as long as the registry has clear and focused aims and objectives, solid data management and data collection processes, produces credible results and is demonstrably fit-for-purpose. The funding for such a registry needs to be discussed in light of these key objectives (i.e. a definitive understanding of what the registry is for) as they will guide the identification of appropriate funding sources and the prioritisation of the dementia registry in comparison to other potential calls on this money. Clear leadership will be required to win the 'hearts and minds' of the stakeholders that will be involved and the people with dementia who will provide their data to the registry. Ireland can and should learn from the development of dementia registries in other jurisdictions and the development of other patient registries in Ireland. Ideally a national strategic policy on patient registries, adequate funding mechanisms, data sharing legislation and a robust eHealth system that includes unique health identifiers would be pre-requisites to the development of the registry, but one of the biggest challenges in Ireland is the length of time policy development and legislative and regulatory changes take and the long-awaited Health Information and Patient Safety Bill (HIPS) is a case in point. Were we to wait for each of these pre-requisites to arrive, it is likely that the National Dementia Registry would never be developed.

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Appendix:

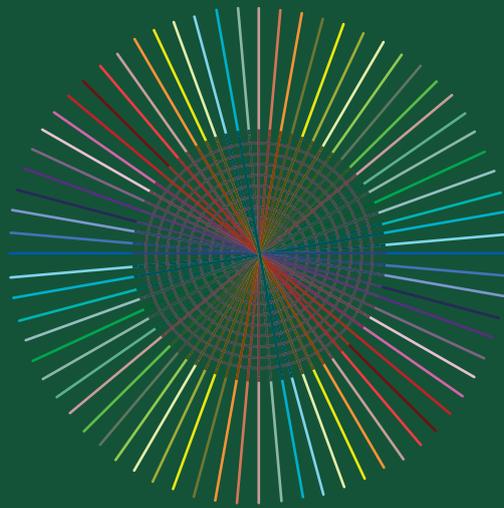
Acronyms and abbreviations

ACT	Adult Changes in Thought (programme)
AD	Alzheimer's Disease
ADRD	Alzheimer's disease and related disorders
ASI	The Alzheimer's Society of Ireland
BDRS	Blessed Dementia Rating Scale
BMI	Body Mass Index
CDCR	Camberwell Dementia Case Registry
CDR	Clinical Dementia Rating Scale
CE	Clinical Expert
CEO	Chief Executive Officer
CERAD	Consortium to Establish a Registry for Alzheimer's Disease
CF	Cystic Fibrosis
CFRI	Cystic Fibrosis Registry of Ireland
CRIS	Clinical Record Interactive Search (system)
CT	Computerised Tomography
DCDR	Danish Clinical Dementia Registry
DCU	Dublin City University
DoH	Department of Health
DPO	Data Protection Office
DSM-IV-TR	Diagnostic and Statistical Manual of Mental Disorders-Version 4-Text Revision
EHR	Electronic Health Record
EPR	Electronic Patient Record
EU	European Union
EUDP	European Union Data Protection Regulation 2016
FAQ	Functional Activities Questionnaire
GARDR	Georgia Alzheimer's and Related Disorders Registry
GDPH	Georgia Department of Public Health
GP	General Practitioner
HI	Health Informatics Expert
HIPAA	Health Insurance Portability and Accountability Act
HIPS	Health Information and Patient Safety Bill
HIQA	Health Information and Quality Authority
HRB	Health Research Board
HSE	Health Service Executive
ICD9	International Classification of Diseases Ninth Edition
ICD10	International Classification of Diseases Tenth Edition
ICPC	International Classification of Primary Care
IDWG	Irish Dementia Working Group
IHI	Individual Health Identifiers
IHRF	Irish Health Research Forum
ILD	Interstitial Lung Disease
IPF	Idiopathic Pulmonary Fibrosis

Appendix: Acronyms and abbreviations

IPFR	Idiopathic Pulmonary Fibrosis Registry
IPPOSI	Irish Platform for Patients' Organisations, Science and Industry
IT	Information Technology
ITS	Irish Thoracic Registry
LE	Legal Expert
MCI	Mild Cognitive Impairment
MMSE	Mini Mental State Examination
MRCG	Medical Research Charities Group
MRI	Magnetic Resonance Imaging
NCRI	National Cancer Registry of Ireland
NHS	National Health Service (UK)
NIA	National Institute on Aging
NYSDR	New York State Alzheimer's Disease and other Dementias Registry
PE	Policy Expert
PIA	Privacy Impact Assessment
PPP	Public-Private-Partnerships
PwD	Person with Dementia
RE	Registry Expert
ReDeCAr	Centralised Registry of Cases with Cognitive Impairment in Argentina
ReCeDemCu	Cuban National Dementia Registry
ReDeGi	Registry of Dementia in Girona
Res	Research Expert
RKKP	Danish Clinical Registries
RSG	The Health Region of Girona
SALAR	Swedish Association of Local Authorities and Regions
SAT	Single Assessment Tool
SCADR	South Carolina Alzheimer's Disease Registry
SveDem	Swedish Dementia Registry
TRO	Tumour Registration Officer
UCLA	University of California in Los Angeles
USC	University of South Carolina
WADPR	Washington Alzheimer's Disease Patient Registry
WVADR	West Virginia Alzheimer's Disease Registry

NOTES



For further information contact:

The Alzheimer Society of Ireland
Temple Road
Blackrock
Co Dublin
Phone: +353 (0) 1 2073800
Web: www.alzheimer.ie

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SOCIETY of IRELAND