Ollscoil Chathair
Bhaile Átha Cliath
Dublin City University

Development of a Model for the National Dementia Registry

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An Roinn Sláinte
Department of Health

HSE

National Dementia Office

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the dormant accounts fund

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Foreword

When we commissioned this two-year study to develop a Model for a National Dementia Registry in 2018, we had no idea that a global pandemic would strike and our lives would be changed so significantly. COVID-19 has shown us how important data can be to ensure that people are supported in times of crisis. The purpose of a dementia registry can support not only crisis management efforts but also enable the effective management of life limiting conditions such as dementia, by improving clinical outcomes, targeting the development of services and supports and importantly enabling the implementation of any future dementia models of care.

The information outlined in this report shows that a dementia registry is a feasible way to systematically collect and analyse data on dementia in Ireland; helping to shape a responsive and fit for purpose system. A timely output from the project is the identification of the dementia minimum data set. Through this project, consensus has been reached on what minimum data should be collected to inform standardisation of service across the country and enable comparisons across care setting nationally and internationally. Testing the minimum dataset prototype as part of the study also illustrated that the majority of data is already being collected in many care settings such as memory clinics; however a system to routinely collect additional data, the storage and management of the data, are issues that need to be addressed.

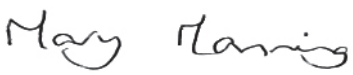
I would like to sincerely thank the authors of this report, Dr. Louise Hopper and Christina Bowen from Dublin City University for their concerted efforts in bringing the research elements together and compiling this comprehensive report.

I would also like to acknowledge the input of the expert advisory group and the special interest group of experts by experience, both groups were instrumental in shaping the direction of the work and determining the contents of the final model.

I would also like to acknowledge Dormant Accounts, who funded this project with the support of the Department of Health.

Finally I would like to sincerely thank Dr. Emer Begley who led the project on behalf of the NDO and the HSE.

Mary Manning



General Manager
National Dementia Office, Health Service Executive

Executive Summary

Purpose

Ireland currently lacks a systematic approach to the collection and analysis of dementia data. Many countries have recognised the vital role that dementia information systems have in the development of many aspects of dementia health and social care services, and in ensuring equitable access to these. COVID-19 has reinforced the importance of data for health service planning. The overall aim of this project was to develop a model for the national dementia registry for Ireland. A Steering Group and Special Interest Group (SIG) were established to provide expert input, lived experience, and oversight for the duration of the project. In addition to regular consultation with experts across all relevant domains, the wider environment within which the National Dementia Registry would operate was also explored. This comprised of:

— the National Dementia Strategy and the direction of dementia care in Ireland;
— legislation relating to data protection, health regulations and assisted decision making;
— current published recommendations for the creation of patient registries in Ireland;
— concept papers relating to new directions for integrated data within the health service;
— Interoperability initiatives globally and in an Irish context.

This project was initiated in support of Priority Action #8 of the National Dementia Strategy to develop an appropriate model for a registry or national database to support the roll-out of the National Dementia Strategy, with the potential to improve dementia care management and to inform and improve clinical outcomes for individuals living with dementia. The project was funded by Dormant Accounts through the Department of Health (DoH), commissioned by the National Dementia Office (NDO) and conducted by the School of Psychology, DCU.

The terms of reference and key objectives of the project were to:

— Identify all stakeholders that need to be involved and establish expert teams;
— Agree the primary aims and objectives for an Irish national dementia registry including reaching agreement on the outcome measures that should be included;
— Determine the scope and target population of the registry;
— Decide what data will be collected, identify the appropriate data sources and determine how this data will be managed and stored;
— Develop the consent process that will be required to gain access to this data;
— Decide how the registry data will be analysed and how results will be disseminated;
— Determine the most appropriate and practical design for the registry;
— Test the model for efficacy and effectiveness;
— Estimate the costs involved and develop a business case for a national model;
— Determine who will own the National Dementia Registry of Ireland
— Develop governance and quality procedures for the National Dementia Registry of Ireland.

Methodology

The study ran for 30 months from May 2018 to October 2020. A mixed methodology was selected for this project that comprised of:

— expert guidance and support (Steering Group, SIG);

— literature review of policy documents and published research;

— stakeholder and registry expert co-design of the recommended registry outcomes to be monitored and the data to be captured in the minimum dataset;

— the development of a National Dementia Registry Model; and

— a data and technical prototype to examine the efficiency of the recommended model.

Literature Review and Expert Consultation

Having examined different types of registries, the consensus that emerged from the stakeholder group was that the Irish National Dementia Registry would focus on quality and clinical improvement. With that comes a focus on guidelines, frameworks and referral pathways and the registry would support and enhance ongoing work in these areas. The agreed aims of the National Dementia Registry are to:

— Improve patient care and outcomes for the person with dementia

— Provide quality assurance and /quality indicators

— Assist with dementia planning/policy

— Assist in the long term with research.

By adopting this approach, evidence from other registries demonstrates that the Irish registry will able to provide valuable dementia data to a variety of stakeholders in health and social care and in government. The ability to improve care as a result of having access to these data will in turn benefit people living with dementia and their families, health and social care professionals providing and managing dementia care, and policymakers. It also has a strategic eHealth and interoperability programme. Although none of the existing dementia registries we spoke to have as yet undertaken a cost benefit analysis, our review of literature suggests that registries can be cost effective and lead to significant return on investment whether these savings are measured by rate of return or by the change in quality indicators over time; a benefit directly attributable to the registry. Most importantly, the Irish National Dementia Registry will capture dementia data that is not available from any other source.

Finally, best-practice governance recommendations were examined in conjunction with the governance structures implemented by existing dementia and Irish Patient Registries. Although best practice suggests that registries should be independent of the health service, legislation and health regulations often make this difficult, as is the case in Ireland. As a result, the consensus is that the registry will sit inside the health system, and more specifically ownership will reside with the HSE.

Determining Registry Outcome Measures

It is important that the National Dementia Registry tracks and reports on meaningful dementia indicators. As part of our quality indicator development process, we gathered indicators identified from literature review, key outcome measures relating to Alzheimer's disease, and those used by existing dementia registries. These were explored and extended during stakeholder workshops to identify the outcomes that matter most to people with dementia, their families, health and social care professionals, service providers and policy makers in Ireland. These priorities were then debated to determine the highest priority items that the Irish registry should be tracking, particularly in an initial implementation phase, so that it successfully addresses its aims and objectives and meets the need of a diverse stakeholder group. The following were prioritised as the Top 5 quality indicators:

— Proportion of patients undergoing basic dementia work up
— Overall quality of life of person with dementia
— Proportion of patients with dementia who receive a specific dementia diagnosis
— Overall Quality of Life and wellbeing of Carer
— Proportion of patients treated with antipsychotic drugs

Over time significant benefits may can realised from tracking quality indicators such as these; for example, improvement in the accuracy of dementia diagnosis, reduction in use of certain drug categories, and better support for both the person living with dementia and the carer through the journey of the disease.

Development of a Minimum Dataset

A key deliverable of this project was the development of a recommended minimum data set for the National Dementia Registry. The creation of this dataset was driven top-down by the agreed registry quality outcomes and it therefore retains a quality focus that is extensive across a number of domains. In addition, it is informed from the bottom-up by the data that is routinely collected by existing quality focused dementia registries. Having undertaken the detailed literature review and obtained examples of registry datasets, a combination of stakeholder workshops and expert guidance from the Steering Group facilitated the development process. The dataset contains the following four main categories of data:

— Personal Characteristics (often referred to in the literature as patient characteristics)
— Health Provider Details
— Diagnosis Data
— Treatment and Care Data

Throughout development of the dataset, there was a focus on future proofing and interoperability with a view to potential linkages to data sources over time.

Agreeing a minimum dataset for the registry, does itself support standardisation and will assist memory clinics, hospitals, and GPs to collect information and report dementia efficiently. In addition, having a minimum data will allow data comparison nationally and internationally, by centre, geographical location, service use, type of dementia and other variables within the dataset as needed.

Identification of Potential Data Sources

In Ireland, dementia-related data is collected and captured in multiple locations, in primary and secondary care settings, and in public and private parts of the health service. In the absence of an electronic health record there is no one obvious source of data from which to populate the National Dementia Registry. The table below summarises the potential data sources and the potential for future integration into the Dementia Registry.

Data held in	Potential registry data source	Indication of data quality	Potential for electronic integration
Memory clinics	High	Medium	Low
HIPE	Low	Medium	High
GP systems	Medium	Low	Medium
PCRS	Low	High	High
InterRAI (SAT)	High	Unknown	High
Patient Summary Record	Low	Unknown	Medium
Electronic Health Record	Low	Unknown	High (not available)

Memory clinics capture a rich source of data and are the most logical starting point for the registry. This is explored further in the data prototype chapter. The electronic mining of dementia registry data from other sources would presently be difficult but as these evolve through development (e.g. EHR), national roll-out (e.g. interRAI™), and data quality initiatives (e.g. recording of dementia in GP systems), so does the potential for integration.

Findings from the Data Prototype

A data prototype was conducted with five memory clinics and it commenced in mid to late February 2020, depending on the clinic in question. The clinics ranged from small to large and from urban to rural. Unfortunately the data collection in these clinics (e.g. people newly diagnosed with dementia) ceased as COVID-19 emerged. Clinics closed and in many cases, staff were relocated. Nevertheless, data for forty people with dementia was captured. Although this volume is small, the data prototype has validated that:

- dementia information can be gathered in a systematic way and having access to this type of health intelligence will support the implementation of strategic programmes, such as the National Dementia Strategy, the monitoring of dementia diagnosis and care pathways, and wider initiatives such as Sláintecare.
- the majority of the registry minimum dataset is available in memory clinics and it was relatively easily to gather and populate.
- the minimum dataset through use in clinics to ensure it is clear and understandable.
- a variety of reports can be created from the registry data;
- reports can be tailored to suit the needs of a variety of stakeholders the registry data can focus on particular cases to identify and explore divergences and outliers. Similarly, data can be combined to support multivariate analyses.
- it is possible to monitoring quality indicators over time with the aim of improving the quality of care for people with dementia and their families.

Some data gaps were identified during the prototype, mostly in relation to treatment and care. Very few memory clinics currently use disease progression or quality of life measures (for the person with dementia and their carer), nor do they capture data on the provision of home care support or the date of entry into long-term residential care. It may be possible that this data can be captured in the future if the registry is extended to cover GP and/or nursing home data. In the interim, work will be required in parallel with registry development and implementation to ensure that a common set of standard data is available for collection in all memory clinics. In time, integration to electronic data sources will also support the capture of this currently 'missing' information.

Technical Design and Findings from the Technical Prototype

The recommended National Dementia Registry Model is presented in Chapter 7 of this report. The model (see Figure 29) and associated registry functionality (see Figure 30) balance the urgent need to implement a solution for dementia data with the ability to integrate with electronic data sources as they become available, thus providing a means to reduce data replication over time. The model comprises of a database, a web-based user interface and modules to support data collection, data management, data analysis and reporting, system administration and ultimately data access.

The dementia registry system will be developed with a modular multi-tier architecture that will be extendable and platform independent. Functionality will be developed using a co-design approach to ensure that the system is fit-for-purpose and acceptable to stakeholders. End-user, programming and data interfaces will enable data to be captured, displayed and shared appropriately. Interoperability and data standardisation are core elements of the model, thus enabling the technical design of the registry to meet organisational, national and international data sharing requirements.

Successful data management will be fundamental to the success of the registry and accurate matching of participant data across potential data sources will be required until IHIs are rolled out nationally. Suitable data back-up processes and the creation of data management and data quality roles will be key. Data analysis and the provision of management information is also fundamental and the model is capable of supporting pre-defined and ad hoc analysis, reporting and data extract. System security and data privacy are managed by tiered access roles and segregation of identifiable and pseudonymised data respectively. Although not required for initial data collection, informed consent processes have been considered so that they can be incorporated into the registry model this ensuring that it is 'Research Ready'. Finally, data access processes and training requirements are presented.

Adopting a modular approach to the development of the registry model enables a phased implementation approach to be considered. We recommend that the first phase of implementation focus on data collection from Memory Clinics. It is likely that these data will be captured through the web interface in the short term, but provision has been made to plug in electronic data collection when this is available in the clinics. Subsequent phases can focus on new data collection environments (e.g. primary care; long-term care) and on increased integration with existing HSE datasets (e.g. PCRS, interRAI™) as dictated by health service priorities.

Funding, Sustainability and Cost

Funding is central to the development and sustainability of a registry. Although a variety of different funding models exist when you look across different types of registries, the predominant approach for existing dementia registries is that they are funded by the State (or region). Some existing registries commended as part of a programme of funding (e.g. Sweden), others started with whatever funding was available and built from there (e.g. Girona). Both approaches are still being followed by dementia registries that are currently in development (e.g. Australia and Greece respectively).

A set of cost estimates were developed for Phase 1 implementation of the National Dementia Registry (see Table 25). Estimated Phase 1 development costs are circa €356K (including VAT). These cost estimates are based on a number of assumptions including manual data collection in the memory clinics at the outset and the incorporation of data standards and interoperability requirements. The registry will therefore be 'Integration' and 'Research' ready. Suggested yearly operational costs were also presented and these included a small ongoing developmental budget to cover ad hoc requirements and potentially the replacement of manual data collection with automated data sources over time. Subsequent implementation phases will require separate cost estimates as the eHealth, data sharing and HSE Integration landscape is changing all the time.

High-level indicative costs for each integrated data source are also presented (range from €28.5K to €76K per dataset to be integrated depending on the HSE/Vendor allocation of days). These are currently difficult to produce with any certainty. They are potentially quite high, but we expect that they will reduce as an integrated infrastructure and associated components such as the National Data Dictionary are rolled out across the HSE. This makes data integration more suited to Phase 2 of the registry implementation.

Recommendations and Conclusion

It is recommended that the National Dementia Registry would be owned by and located in the HSE. This will allow the necessary data to be collected for the purpose of managing clinical care and measuring quality outcomes without the need for an individual's informed consent. Five high level recommendations are being made as a result of the work undertaken for this project. Each is broken down into constituent recommendations (see overleaf). The evidence to support all of these recommendations has been presented in the body of the report.

High-Level Recommendations

Funding and Long-term Commitment

- HSE ownership; Establish governance structures
- Stable funding stream; Dedicated Dementia Registry team

Infrastructure and Systems are developed

- Phase 1: Develop model and infrastructure to support implementation with memory clinics
- Complete procurement; engage software vendor with registry experience
- Work with stakeholders and developers to complete registry build and test

Adopt a phased implementation - Implement Phase 1

- Initial implementation with memory clinics; integration with electronic data (HSE datasets) in later phase (e.g. Phase 2 or 3)
- Continue to align with Chronic Disease Management System; Minimum dataset can evolve over time as needed

Continued and prioritized work on projects that assist the National Dementia Registry

- Standardisation of required data in memory clinics (includes quality of life and disease progression measures)
- In-depth review of the feasibility of bringing primary care into the registry in a future phase (e.g. Phase 2 or 3)
- Continued work on national guidelines, diagnostic and post-diagnostic care pathways; KPIs (PROMs) for dementia care
- National rollout of Individual Health Identifiers; and the InterRAI™ single assessment tool including care plans

Progress Strategic initiatives that would assist the National Dementia Registry

- Strategic direction with regard to patient registries urgently needed in Ireland; Standardised approach to registry development
- Consideration and clarity regarding legislation and health regulations

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- the Steering Group of national and international experts from various fields;
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  - Dr Conan Donnelly, National Cancer Registry of Ireland
  - Dr Neil Golden, GP, ICGP
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This Report reflects only the authors' views and listed organisations and individuals are not responsible for its content.

Table of Contents

List of Tables

List of Figures

1. Background, Context and Methodology

1.1 Introduction

Dementia is an important health issue nationally and internationally and a challenge for health and social services worldwide. It has a major impact on a person's life, not only on their cognition but also on their ability to manage activities of daily living. As the condition progresses, an increasing amount of care and support is needed from health and social care services (Kerpershoek et al., 2020). Traditionally, the primary focus of formal care has been on physical support (e.g. help with instrumental activities of daily living such as dressing and bathing). This is often not the support that the person with dementia needs and health and social services are increasingly required to integrate the care and support they provide to better meet the holistic needs of the person with dementia.

Approximately 64,000 people live with a diagnosis of dementia in Ireland and this is expected to increase to 150,000 by 2045 (Health Service Executive, 2020). High-quality clinical care has been shown to improve outcomes for people with dementia and for their family caregivers (O'Shea et al., 2017). However, there is a lack of consistency in the care that is available across the country and this variation results in inequities within the system. In addition, there is very poor recording and coding of dementia across all care settings in Ireland (Hopper et al., 2016). Many other countries have recognised the vital role that dementia information systems have in the development of dementia health and social care services, and in ensuring equitable access to these services. Ireland, in contrast, lacks a systematic approach to the collection and analysis of dementia data. In recognition of this fact, the Irish National Dementia Strategy (Priority Action 8) highlights the need to improve information systems on dementia (Department of Health, 2014).

1.2 Why have an Information System for Dementia?

The World Health Organisation (WHO, 2017) recognises the value of dementia data in order to improve dementia services and assist in the implementation of national dementia policies. It acknowledges that development of a dementia information system will require change to both the recording and sharing of health and social care data. The reward for collecting this data is great as it provides for the best available evidence for policy development and service delivery throughout the dementia journey from risk reduction measures to end of life.

"By building and/or strengthening information systems for dementia, the functional trajectories of people with dementia, their careers and families can be improved." (WHO, 2017, p. 30)

The COVID-19 crisis has also highlighted the importance of data to help inform decision- and policy-making. In the early days of the pandemic, interoperability issues emerged as countries adopted different approaches to data leading to a lack of alignment and difficultly making direct comparisons between countries. The impetus to resolve effectively and speedily these issues demonstrated what could be achieved when different people and systems work together with a clear purpose. In Ireland, for example, 50+ datasets were integrated to facilitate tracking and reporting and we now have the ability to analyse and compare cases in towns, cities, counties and the country as a whole (Health Intelligence Unit (HIU), personal communication, 25 August 2020). A National Dementia Registry would provide a similarly effective framework for the collection of reliable, accurate, valid, complete and timely dementia data. It therefore would provide benefits for people living with dementia, family carers, health and social care professionals and policymakers, while further supporting the delivery of integrated care.

1.3 Feasibility of a National Dementia Registry

The first step on the journey to systematic dementia data collection and the reporting of the quality of that data was to examine the feasibility of introducing a national dementia registry in Ireland. The Alzheimer Society of Ireland (ASI) commissioned Dublin City University (DCU) to conduct an evidence-based feasibility study. The resulting report brought together extensive evidence demonstrating that patient registries have a key role to play in national public health strategies and that they facilitate improvements in policy and patient care as well as supporting research endeavours (Hopper et al., 2016). International evidence and expert opinion suggested that the construction and population of a dementia registry in Ireland was feasible and that the benefits of developing a national registry make the required investment worthwhile. Initial development may be complex, so the registry must have clear and focused aims and objectives, solid data management and data collection processes, produce credible results and be fit for purpose. The report recommended the development of a National Dementia Registry Model to address the key questions and recommendations set out in the feasibility report and to determine the options, costs and implementation strategy for a national dementia registry in Ireland.

1.4 The Operating Environment of the National Dementia Registry

Before creating a model for a national dementia registry, it was important to understand the context in which this registry model would be built. An appreciation of the operating environment was essential, as we did not want to design the model in a vacuum. To assess the operating environment we carried out literature reviews and interviews to gather information and develop clear understanding of:

- The direction of dementia care in Ireland -
- Data protection, health regulations and the Assisted Decision Making (Capacity) Act (2015)
- Current thinking and framework for Irish health registries including
  - Ireland's strategy for the future direction of disease registries
  - the concept of the E-chart for enhanced care and
  - the work of the Chronic Disease Management System.
- Interoperability initiatives globally and in an Irish context

1.4.1 The direction of dementia care in Ireland

1.4.1.1 Strategic framework

The need for better data and the work to create a model for a National Dementia Registry was an outcome of the National Dementia Strategy aim to improve information systems on dementia (DoH, 2014). The Strategy identifies key principles to underpin and inform the full range of health and social care services provided to people with dementia, their families and carers. Six priority areas for action have been identified in the Strategy, as follows:

1. Better awareness and understanding
2. Timely diagnosis and intervention
3. Integrated services, supports and care for people with dementia and their carers
4. Training and education
5. Research and information systems
6. Leadership

The National Dementia Registry as a dementia information system will play an integral component in delivering this strategy. It will inform and assist in quality improvement through the provision of data around diagnosis, interventions and supports to those living with dementia.

1.4.1.2 Diagnostic and Post diagnostic Pathways

The Irish National Dementia Strategy (DoH, 2014) also identified the need for diagnostic and post-diagnostic pathways for dementia and a programme of work is ongoing under the guidance of the NDO to address both. Indeed there are a number of key areas that the NDO are focused on (see Figure 1), including these and the development of meaningful standard data collection forms, that are likely to have synergies with the National Dementia Registry project.

Timely Diagnosis	Right Care at Right Time	Planning for Future Service
— Standardised assessment and disclosure	— Post-Diagnostic supports	— Home care resource utilisation
— Enhanced diagnostic capacity	— Care pathways	— Community Health Networks
— National ID Service	— Models of care	
	— Psychotropic medication guidelines	

Figure 1 NDO Dementia Care Projects

1.4.2 Legal framework

1.4.2.1 Data Protection and its relevance for registry development

It is necessary to consider data protection legislation and its implications for the dementia registry in terms of data collection (i.e. the ability to enter people into the registry), ensuring the data is used properly and correctly, and the access of data for research purposes. The EU General Data Protection Regulation (GDPR; 2016/679) came into effect on 25th May 2018 (European Commission, 2016). This regulation governs the collection, use and storage of a living individual's personal data (personal data is defined as data relating to a living individual who is, or can be identified from, either the data itself or from the data in conjunction with other information) in any format. While GDPR is directly applicable as a law in all Member States, Ireland's national implementation, the Data Protection Act 2018/7 (House of the Oireachtas, 2018a) . This national legislation, in conjunction with related Health Research Regulations (S.I. No. 314 of 2018) (House of the Oireachtas, 2018b) and subsequent amendments (S.I. No. 188/2019) (House of the Oireachtas, 2019) dictate the legal basis for the processing of personal and health data (see Figure 2). For example, they require that explicit consent and ethical approval be obtained for the use of personal data for research purposes. However, data can be collected inside the health services for the purpose of clinical improvement without requiring an individual's consent.

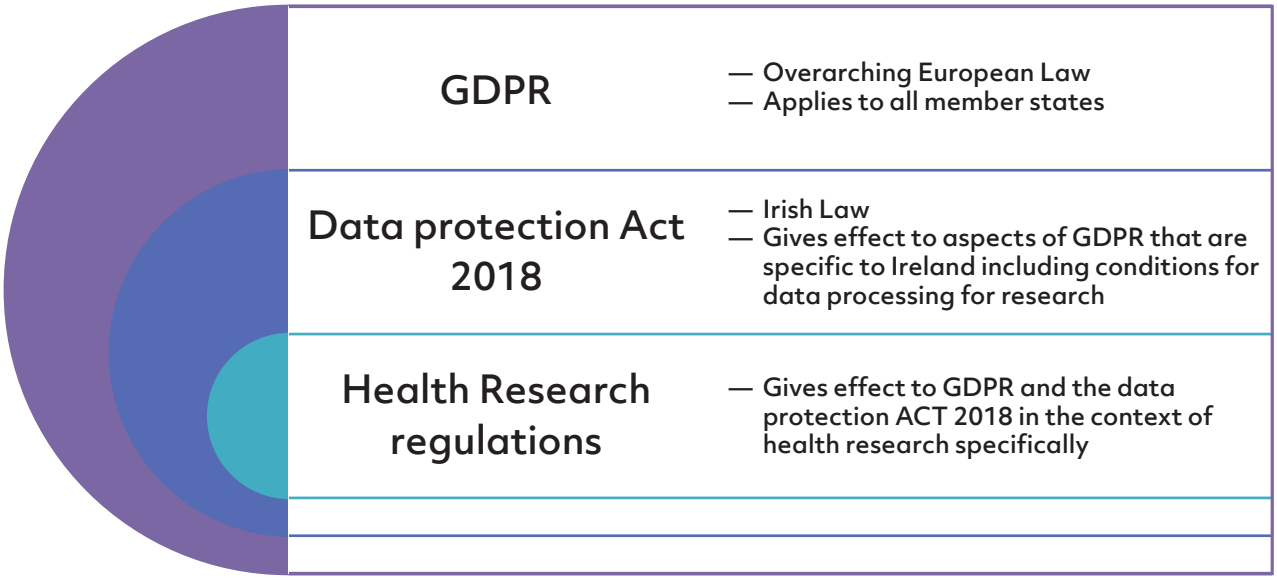

Figure 2 Data protection legislation relevant in the Irish context Clarke et al. (2019)

One of the most significant considerations for a registry is the consent process, which affects the recruitment procedure and rates of participation (Evans et al., 2013). We interviewed several existing dementia registries in other jurisdictions to identify the consent models typically used (see Table 1). Although the precise operation of registries differed, the majority did not require a person's consent in order to be able to enter their details into the registry.

Table 1 Consent models used by a sample of international dementia registries

Opt in	Opt Out	Not required
Norwegian Dementia Registry (NorCog)	Swedish Dementia Registry (SveDem)	Danish Quality Database for Dementia (DanDem)
		The French National Alzheimer Database (BNA)
		The Registry of Dementia of Girona (ReDeGi)

The Australian Dementia Registry Network (ADNet) is under development in Australia it will utilise two methods for recruitment to the register an:

1. opt out approach where the diagnosis has been communicated to the person (or a person identified as responsible for the person), they will receive information and consent is presumed if no active withdrawal

2. when the diagnosis has not been communicated to the person (or a person identified as responsible for the person) there will be a waiver of consent no information will be provided to the family and person is automatically included on the register

In Ireland, use of data by the National Dementia Registry for anything other than the management of health and social care would require opt-in informed consent from each person with dementia and potentially their primary caregiver unless the data remained within the Health Service and was not opened up for research access. The location, ownership and governance of the registry and its data are discussed further in Chapter 9.

1.4.2.2 Assisted Decision Making (Capacity) Act 2015

Informed consent is also central to the Assisted Decision Making (Capacity) Act 2015 (House of the Oireachtas, 2015), which provides a statutory framework for supported decision-making and enables formal agreements to be made by adults, who lack or may shortly lack capacity to appoint a trusted person to assist them. The aim is to maximise a person's right to make his or her own decisions, with legally recognised supports, whenever possible. This Act will be relevant for the National Dementia Registry Model should informed consent be required for data collection and/or data access. It should be noted, however, that the Act has yet to be implemented despite repeated calls to do so from organisations supporting the rights older adults (e.g. SAGE and Third Age).

1.4.2.3 Revision of the Health Information and Safety Bill

A government decision (29 January 2020) was made to remove the Health Information and Patient Safety Bill (known as HIPS) from consideration and it will instead be split into a number of distinct parts. The patient safety elements are being progressed in a new Patient Safety Bill (DoH, 2019d). The research ethics components are being wholly reformulated and they will be progressed as the National Research Ethics Committees Bill (DoH, 2019c). The information elements will not being proceeded with as a new Health Information Policy Framework is instead being developed in the Department (P. Lennon, personal communication, 31 January 2019). It is our understanding that this new framework will include a strategic view on registries and similar databases. Work on this strategy has been paused due to Covid-19 (A. Cahill, personal communication, 9 July 2020).

1.4.3 Strategic direction for patient registries in Ireland

1.4.3.1 Attempts to create a long-term vision

There are no standards in place for patient registries in Ireland and new registries continue to be set up as individual data collections that meet the specific needs of a single condition (or cluster of conditions) but pay little or no regard to data interoperability or to the standardised collection of common data fields (e.g. sociodemographic data). There have been a number of notable attempts to address this issue.

The Health Research Charities Ireland (HRCI) Group (formerly the Medical Research Charities Group) documented a long-term vision for registries in Ireland, central to which is the establishment of a National Federation of Registries (NFR; Gardner & Jackson, 2018). The NFR was intended to be independent of health and social care services. It was to bring all patient registries in Ireland together under one roof and act as a 'trusted third party' for patient-related health information. It could be argued that this suggestion is akin to an expansion of HIQA's current role managing a data catalogue of approximately 109 datasets.

At a more granular level, the HRCI report (Gardner & Jackson, 2018) and its predecessor (MRCG & IPPOSI, 2011) clearly articulate the need to reduce data duplication and increase potential for interoperability as much as possible in the development of new registries. They view electronic patient records (EHRs) as the building blocks of effective and efficient registries, but in their absence, accept that data can be linked with robust data matching processes. They clearly advocate for data collection that is driven by the purpose of the registry, and against the collection of data of marginal value. They acknowledge that the comprehensiveness and validity of the registry data will largely depend on how the variables comprising the minimum dataset are selected, hence the importance of focusing on primary outcomes and data integrity. They stress the importance of scalable software solutions that can grow over many years in order to facilitate the collection of new data, new therapies and related information as they become available. The HRCI also reiterated the need for clear policy in relation to patient registries in Ireland, prioritisation of the Health Information and Safety Bill (as it was at the time), and all other related legalisation required to support the collection, sharing and reporting of health and social care information. We agree with the call to action embedded in the HRCI report and we must stress that strategic direction is urgently required in relation to health information and interoperability.

1.4.3.2 An Integrated Approach: E-chart for enhanced care

It is clear from our discussions with the DoH and the HSE that current thinking has moved away from the idea of establishing an NFR and consequently the development of separate disease-specific registries even if they are to be managed by a single entity. The current approach is a move towards a conceptualisation of data integration that is essentially a 'virtual' electronic patient chart; A HSE concept paper entitled the E-Chart for Enhanced care sets out this proposed solution and the recommended approach to creating databases for clinical conditions (registries) by using and exploiting the potential of existing patient-centric data (H. Johnson, personal communication, 26 February 2019). By design, the scope of each database could expand iteratively depending on the availability of relevant routinely collected data across existing HSE systems data. These separate data streams would be successfully re-associated to become patient centric datasets. This integrated data would sit in a 'data hub' somewhere within the health system thereby availing of the legislative ability to gather data for clinical improvement within the health service without needing additional patient consent. The E-Chart concept operates under an umbrella framework covering governance, design, development and deployment, and it would be guided by subject-matter expert groups and Clinical Programmes as part of the overall eHealth agenda with a goal of delivering excellence in patient care, service planning and creating new knowledge, while ensuring compliance with GDPR and other relevant legislation. It will enable enhanced care for either rare or common diseases and it will be particularly beneficial in instances where a variety of data is needed in one place (e.g. management of co-morbidities and chronic disease).

The picture is as yet unclear in terms of how data from the private health sector would be managed and integrated in this model so as to support a full health (and social care) view of a person. There is a danger that the recurring delays in addressing the strategic direction of registries at a national level could lead to a situation where sections of the health service follow the published HRCI approach and continue creating new patient registries while others follow the E-chart 'Virtual Record' approach with integration and reuse of existing data at its core. All this will do is complicate the data and health information landscape further, thus reinforcing the need to agree a strategic directory for registries and patient databases as a matter of urgency.

1.4.3.3 Chronic Disease Management System

In 2020, as part of the Integrated Care Programme for the Prevention and Management of Chronic Disease, development of a Chronic Disease Management System is underway. This is the first Irish database to incorporate a number of conditions under a single umbrella and the first to examine issues such as integration across HSE data and interoperability with HSE systems as a core development objective (IIS, personal communication, 25 August 2020). Although dementia is not currently categorised as a chronic disease, the ASI argue in their manifesto that it should be considered as such as evidence from other jurisdictions shows that incentivisation and resourcing of chronic disease management can lead to health promotion, pro-active care and better outcome measures, There is also a particularly high degree of comorbidity between dementia and existing chronic diseases (ASI, 2019). The Canadian Chronic Disease Surveillance system (Government of Canada, 2018) collects data for over 20 chronic diseases and include within their neurological conditions dementia, including Alzheimer's disease, epilepsy, multiple sclerosis, Parkinsonism, including Parkinson's disease.

It is imperative that the Irish Dementia Registry is mindful of design decisions made in relation to the Chronic Disease Management System and potential alignment or integration at some point in the future. GP's commenced data collection for the Chronic Disease Management system in January 2020, the analysis and integration of this data has been delayed by the ongoing COVID-19 pandemic. The National Dementia Registry model will be developed based on our best available knowledge of the Chronic Disease Management System; two advisors to this programme are also members of our Steering Group.

1.4.4 Importance of Interoperability

1.4.4.1 Global initiatives

The Pew Charitable Trust (Pew Charitable Trusts, 2018) published a recent report that evaluated the state of healthcare data semantic interoperability. The report recognised that despite the general acknowledgement of the need for interoperability, the current state is quite distanced from the envisioned goal. In particular, they found that the registry community *"has not benefitted from, is not aligned with, and does not contribute to interoperability efforts."* They view registries as being in a unique position to influence dramatically and favourably the capture of real-world data to support clinical evaluation, quality and performance assessment and research – *"but only if fundamental changes are made to the healthcare ecosystem to enable and resource those efforts."* The predominant model for obtaining data for registries is still overwhelmingly forms-based manual chart abstraction and data re-entry. Few, if any, registries have electronic data capture at the point of care and transmission of that data by direct electronic mechanisms that would facilitate the 'capture once, use many times' mantra. Existing models of data capture essentially preclude the sharing of standardized data among registries, as there is no cross-registry standardisation at the data element level. To address the failings of current registry models, they have developed an interoperability framework (framework of frameworks) to identify how everything fits together (data, systems, clinical decision support, governance) and to standardise the use clinical concepts across healthcare. They recommended using 13 meta-data elements to define common data elements rather than full informatics modelling, although this is a long-term goal of the group. Their rational being that this supports an initial attempt at standardisation and the generation of cross-registry data elements and enables registries to show a willingness to collaboration to harmonise their data.

Interoperability is also promoted by the EU-funded European Platform for Rare Disease Registries (EPIRARE). They have established a standard for intra-country interoperability of registries (Taruscio et al., 2014) that aims to improve standardisation and data comparability among registries and support new data collections and registries. Similarly, EURODIS argues that *"interoperability and harmonisation between patient registries should be consistently pursued"* and have adopted this goal as one of the 10 major principles to consider when setting up a registry (EURODIS, 2013). They strongly advocate for the development of globally accepted definitions, classifications, data standards, and policies and resources relating to data sharing. They also recommend that standard operating procedures (SOPs), common resources or centralised platforms should be developed for new registries and that existing standalone registries should be migrated across to these platforms. Another key principle relates to the creation of a *"minimum set of common data elements (CDE)"* that should be consistently used by all registries. This supports the position set out in the Pew report (Pew Charitable Trusts, 2018). Use of standards, in combination with CDEs based on standard disease classification systems (e.g. ICD10, SNOMED CT), will enable registry data to become more useable for national and international collaboration and research.

The above literature review highlights attempts at harmonisation, but it also demonstrates that there is not one authoritative reference. Although we have not adopted any one of the proposed datasets completely, they have collectively assisted our design process and they supported the conduct of a completeness check.

1.4.4.2 Supporting International Dementia Informatics

There are a number of international organisations gathering country-level dementia data to facilitate cross-country monitoring and reporting. The WHO has established a Global Dementia Observatory (GDO), a knowledge and data exchange platform that assists member states with measuring progress against dementia strategies and actions, and gathers policy, service delivery, and information and research data to support monitoring and cross-country reporting (WHO, 2020b). In addition to monitoring dementia planning, risk reduction measures, awareness initiatives, infrastructure for providing care and treatment, health information capability, and research and innovation, the GDO is also interested in information on diagnosis, treatment, carer support and disease burden (WHO, 2018). To date, it has collected data from 21 countries and has plans to increase this to 50 countries. Ireland does not currently provide data to this repository, but the implementation of a national dementia registry would enable us to share anonymised data in this way.

The multi-disciplinary International Consortium for Health Outcomes Measurement (ICHOM) identifies health outcomes that matter for a particular health condition and provides practical tools and data sets to support these. ICHOM have produced a standard data set for Dementia (ICHOM, 2016) to encourage and promote worldwide standardised measurement of the condition. The dataset incorporates the following categories of data: demographic factors, baseline clinical status, clinical history, medication, symptoms, functioning and quality of life, carer quality of life, sustainability, full time care, safety and ongoing clinical status (disease progression overall survival). The full dataset is available in Appendix B. Ireland's policy, clinical and scientific communities will have access to wider potential collaborations with those who have similar data sets once we have a national dataset that supports a similar set of outcomes. This further emphases the need to design the registry in a manner that situates interoperability and standardisation at its core.

Finally, the Global Alzheimer's Association Interactive Network (GAAIN) was the first online integrated research platform to be developed that supports data sharing and analysis of large data sets with scientists and Alzheimer's disease study centres worldwide. Funded by the Alzheimer's Association (2020), it provides a mechanism for supporting data sharing of information relating to Alzheimer's disease, dementia and aging that remains fully controlled by the data owner but supported at low cost by GAAIN. Information from a variety of dementia databases have been made available to researchers in that way. While this may not be a primary objective of the Irish dementia registry, it demonstrates the possibilities that open up once data is collected in a systematic, standardised, valid and purposeful way.

1.4.4.3 Interoperability in Ireland

In Ireland, a National Data Dictionary and a National Release Centre for SNOMED CT have been established under the Enterprise Architecture function in the Office of the Chief Information Officer (OoCIO) in the HSE. To date in the HSE, the concept of the Standard Health Record (SHR) has formed a core part of their programme of work (M. Tully, personal communication, 16 October 2020). The approach of the SHR is to standardise the health record and the health data itself, rather than focusing on exchange standards. When the health record and data are standardised, exchange and aggregation of patient information becomes trivial (The Standard Health Record Collaborative, 2020). The group has been working towards this goal and they are currently looking at Phase 2 vision and requirements for the evolving Data Dictionary Toolkit (M. Tully, personal communication, 16 October 2020). The intention is to build on work to date with a formalised Meta Data Registry Framework (MDRF) programme.

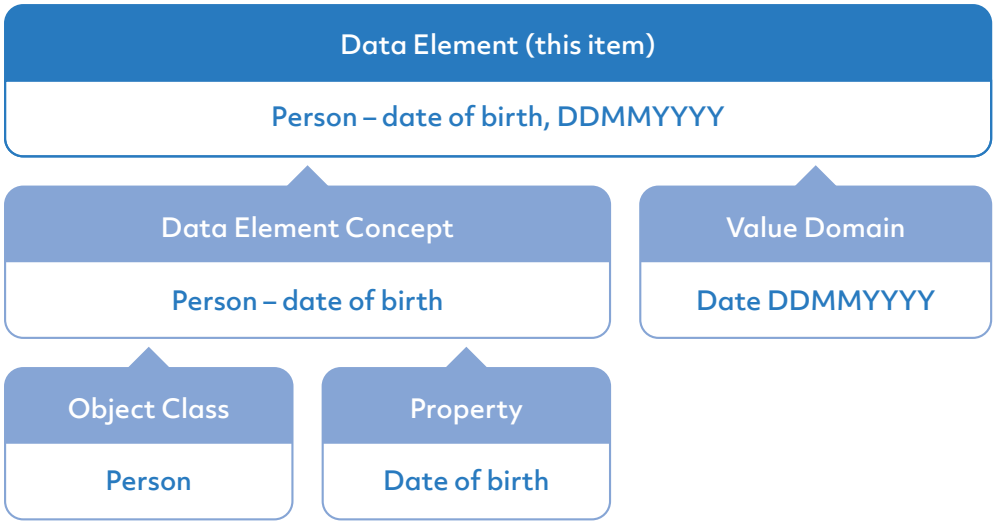

Figure 3 Example of components in the Registry metamodel

The basic components within the Registry metamodel are presented in Figure 3. Being able to identify each component uniquely enables the confident reuse of content and the avoidance of unnecessary duplication. A Data Dictionary can be produced from the content of the metadata registry as it is based on the data elements/singular terms with the correct definitions that have been endorsed by the Registration Authority.

A Dataset Specification Management Process (DSMP) has also been developed that brings Subject Matter Experts from core areas, within and external to the HSE, together to ensure a consistent approach to dataset specification management (H. Lambert, personal communication, 14 October 2019). The purpose of the process is to facilitate a quality assurance process for new and existing dataset specifications, thus recognising data as an important asset. This process aims to reduce re-work and costs due to errors and omissions in dataset specifications and data entry (duplication). There are a number of steps involved in the DSMP process namely Initiate, Dataset Specification Conference Call, Subject Matter Expert Engagement, and Dataset Specification Standardisation and Approval. These are presented in more detail in (Appendix C).

At the time of publication of this report, it is not a mandatory requirement for new software development in the HSE to engage with this group, however, we consider the evolving Data Dictionary Toolkit and the DSMP process to be essential to the standardisation of data across the HSE. For this reason, we have engaged with the National Release Centre as one of the stakeholders in this project. In our opinion, the DSMP process could be further extended within the HSE to build recognition of cross use of data and enforce use of common terminology. Furthermore, the clear and unambiguous adoption of the MDRF at a national level must also be considered.

The Health Research Board (HRB) have recently funded a project to identify the infrastructure and services needed to ensure safe Data Access, Storage, Sharing and Linkage (DASSL) for health-related data in Ireland (Health Research Board, 2019). It is hoped that the DASSL Model will *"stimulate discussion, inform decision-making and underpin action"* in relation to the safe management of data in Ireland. Recognition of the need to fund the development of this framework can be viewed as an acknowledgement of the stagnation in the progress in Ireland's eHealth strategy in this regard.

1.5 Developing a National Dementia Registry Model

This project was initiated to develop an appropriate model for a registry or national database to support the rollout of the National Dementia Strategy, with the potential to improve dementia care management and to inform and improve clinical outcomes for individuals living with dementia. The project was funded by Dormant Accounts through the Department of Health (DoH), commissioned by the National Dementia Office (NDO) and conducted by the School of Psychology, DCU.

1.5.1 Terms of Reference

The National Dementia Strategy (DoH, 2014) identifies key principles to underpin and inform the full range of health and social care services provided to people with dementia, their families and carers. A priority action area (PA8) of the strategy covers research and information systems. This project, the development of a model for a national dementia registry, was conducted in support of that action. The terms of reference and key objectives of the project were to:

— Identify all stakeholders that need to be involved and establish expert teams;

— Agree the primary aims and objectives for an Irish national dementia registry including reaching agreement on the outcome measures that should be included;

— Determine the scope and target population of the registry;

— Decide what data will be collected, identify the appropriate data sources and determine how this data will be managed and stored;

— Develop the consent process that will be required to gain access to this data;

— Decide how the registry data will be analysed and how results will be disseminated;
— Determine the most appropriate and practical design for the registry;
— Test the model for efficacy and effectiveness;
— Estimate the costs involved and develop a business case for a national model;
— Determine who will own the National Dementia Registry of Ireland
— Develop governance and quality procedures for the National Dementia Registry of Ireland.

These objectives are addressed in the subsequent chapters of this report.

1.5.2 Note about terminology

For the purposes of this report, the term '**register**' refers to the patient record database (i.e. the patient data). The term '**registry**' refers to the organisation and process that supports the register. A list of acronyms and abbreviations used in this report are provided in Appendix A.

1.6 Methodology

A combination of expert guidance and support, review of policy documents and published research, co-design of the registry outcomes and dataset, and a data and technical prototyping were required to address all aspects relevant to the creation of a dementia registry model. The study ran for 30 months from May 2018 to October 2020.

1.6.1 Stakeholder involvement and the establishment of expert teams

The inclusion and involvement of stakeholders is essential in order to develop a registry model that is fit for purpose and one that offers interoperability and long-term viability. It is also fundamental to the acceptability of the proposed design. It fosters a sense of ownership of the registry, lending weight to the advocacy needed to roll out the Registry, and improves the collection of dementia data in Ireland. Within a framework of user-centred co-creation, two working groups were established to guide the overall direction, and assist in the design of the registry model.

1.6.1.1 Special Interest Group

A Special Interest Group (SIG) comprising of people with dementia and their family caregivers was established with the assistance of the Irish Dementia Working Group, the Dementia Carers Campaign Network and the Alzheimer Society of Ireland (ASI). A SIG member, supported by the ASI Research and Policy Manager, attended the project Steering Group to bring the views, insights and perspectives of those with dementia and their carers to the group. They also reported the highlights of the Steering Group discussion, decisions made and action plans back to the SIG.

1.6.1.2 Steering Group

A Steering Group was also established with a broad range of expertise as reflected in

Figure 4 overleaf; see Acknowledgements for membership of both groups.

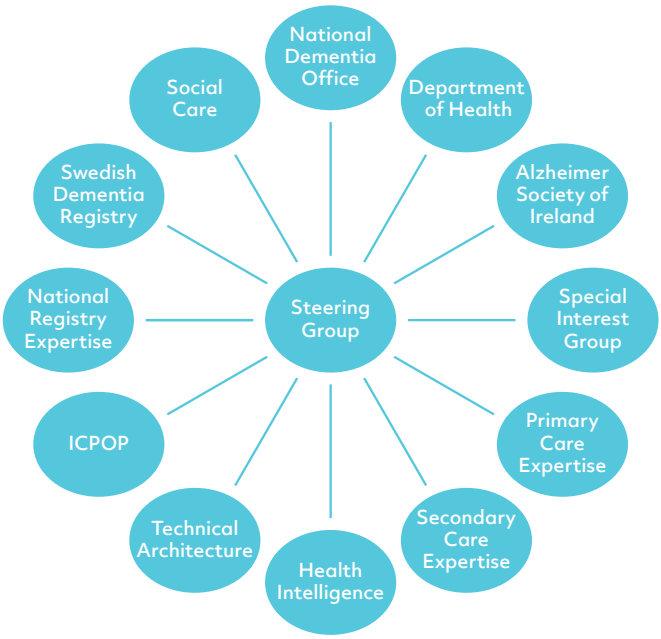

Figure 4 National Dementia Registry Steering Group Expertise

Together, the groups have provided expert guidance and opinion throughout the project, and met regularly to progress and deliver the specific aims of the registry project.

1.6.2 Literature Review

Given the number of objectives and the time allocated to this project, a rapid review of published and grey literature was conducted. It concentrated on examining existing international dementia registries and those in various stages of development. The purpose was to gain an understanding of the different types of registries, the broad categories of data collected; and the legal, technical and financial issues that need to be considered when establishing a dementia registry. This information was used to provide guidance to the Steering Group and SIG on general best practices.

1.6.3 Engagement with experts across all relevant domains

Throughout the project, we also engaged with and sought advice from numerous experts with whom we had built relationships during the feasibility study, from discussions with colleagues, existing networks and the steering group. We issued targeted questionnaires and conducted a number of systematic interviews, in addition to site visits, meetings and personal communications (via telephone/Skype/Zoom) with (1) Dementia registries in other jurisdictions (*n*= 11); (2) Dementia registry funders (3) Existing patient registries in Ireland; (4) Health policy; (5) Health Informatics; (6) Health systems; (7) Clinical perspectives on dementia . Where additional experts were suggested during the initial interviews, these were also contacted.

Several consultations and co-design workshops were also conducted with expert stakeholders and with members of the Steering Group and the SIG to ascertain their opinions and learn from their experience regarding several components of the dementia registry model.

1.6.3.1 Determining the primary aims of the registry

A combination of literature review, expert opinion and stakeholder workshops were used to determine the outcomes that were the highest priority for dementia care in Ireland. The output from these tasks were combined and a list of potential indicators were presented back to the workshops participants and to the SIG and Steering Group for review and feedback, leading to further refinement and prioritisation of these indicators. The final list of indicators are not set in stone; existing dementia registries have advised to start small and be realistic with what can be collected initially. Further indicators can be developed over time as data becomes available and in accordance with strategic focus and priority. The output from this study work stream are presented in detail in Chapter 2.

1.6.3.2 Determining the outcomes to be monitored by the registry

— The outcomes that matter most as regards dementia care and in the context of the Irish health and social care system, and the priorities associated with these outcomes (see Chapter 3).

— The minimum data set that would be required to measure these outcomes (see Chapter 4) and potential sources of these data (see Chapter 5).

— An exploration of the concept of being 'research ready' (see Chapter 7).

The co-design workshops took place after literature reviews and expert interviews had been conducted. This ensured that tangible examples could be used to illustrate and explore the discussion questions. The workshop setting encouraged free and open discussion. It encouraged participants to voice their perceptions, opinions, beliefs and attitudes towards the various components of the suggested model(s) and to identify what it would mean for them.

1.6.3.3 Determining the minimum dataset

A mixed methods approach was taken to the development and agreement of a minimum dataset for the National Dementia Registry. It comprised of:

— A literature review to examine published dementia registry datasets;

— A review of the datasets collected by existing international dementia registries;

— Collection of stakeholder input into the development of the minimum dataset driven by the need to collect the necessary data fields to report on the outcome measures identified in the previous chapter. Stakeholder feedback was gathered through workshops with the SIG and with other stakeholders, interviews and small group meetings as needed to resolve issues and/or inconsistencies. A briefing paper was also circulated to the Steering Group for review and feedback at a dedicated Steering Group meeting;

— Amalgamation of the all information gathered during these first three phases to identify core dementia fields and inform our approach to the development of the minimum dataset. Progress was also regularly cross referenced back to these individual sources to ensure that no major category of data had been overlooked;

— Initial review of potential data sources and data availability to support, but not to direct, conversations around appropriate data fields.

— Inclusion if the resulting minimum dataset in the prototype phase. Further refinement and prioritisation was conducted following the prototype in order to agree a final version of the dataset and to prioritise Phase 1 (initial implementation) and Phase 2+ data fields (i.e. those that would be held for subsequent enhancement phases).

1.6.4 Data Collection Prototype

The lack of a strategic framework and development plan for patient registries in Ireland means that there is no agreed 'blueprint' to follow when implementing a new registry, nor is there as yet a strategic approach to data integration that is available to a level of detail such that it can be incorporated into a proof of concept or registry prototyping exercise. As a result, the development of an end-to-end integrated Dementia Registry prototype was not possible. On advice from the Steering Group, which included representation from the Department of Health and the NDO, the decision was made to undertake separate data and technical prototypes.

A data collection prototype was carried out to enable us to identify and understand the effectiveness and efficiency of the recommended minimum data set for end users; highlight potential barriers to its implementation in routine practice; and guide implementation and planning. The prototype was also expected to inform the development of the estimated costs associated with implementing the registry model(s).

1.6.5 Developing the functional and technical model

A technical prototype was conducted in parallel with the data prototype to agree the functional and technical design of the registry and to combine this with the aforementioned components to form a National Dementia Registry Model. As with the previous components of the model, a mixed methods approach was taken to this task. It comprised of:

- A literature review of patient registry hardware and software designs;
- A review of the technical designs of existing international dementia registries;
- Technical workshops that has been anticipated with HSE clinical and technical staff could not take place due to COVID-19. This risk was mitigated by conducting a technical prototype workshop with OpenApp, a preferred supplier of patient registry software for the HSE and a group with extensive expertise in providing national and international patient registry systems, including the Chronic Disease Management System.

In addition to identifying best practice approaches and constraints of the Irish healthcare environment, the technical prototype was also expected to inform the development of the estimated costs associated with implementing the registry model(s).

SUMMARY

Ireland currently lacks a systematic approach to the collection and analysis of dementia data. Many countries have recognised the vital role that dementia information systems have in the development of many aspects of dementia health and social care services, and in ensuring equitable access to these. Covid 19 has reinforced the importance of data for health service planning.

The overall aim of this project was to develop a model for the national dementia registry for Ireland. A Steering Group and Special Interest Group (SIG) were established to provide expert input, lived experience, and oversight for the duration of the project.

In addition to regular consultation with experts across all relevant domains, the wider environment within which the National Dementia Registry would operate was also explored. This comprised of:

- the National Dementia Strategy and the direction of dementia care in Ireland;
- legislation relating to data protection, health regulations and assisted decision making;
- current published recommendations for the creation of patient registries in Ireland;
- concept papers relating to new directions for integrated data within the health service;
- Interoperability initiatives globally and in an Irish context

We agree with the view that "registries are in [a] unique position to dramatically and favourably impact the capture of real-world data that can enable clinical evaluation, research and discovery […] quality and performance assessment […] and clinical decision support – but only if fundamental changes are made to the healthcare ecosystem to enable and resource those efforts" (Pew Charitable Trusts, 2018, p. 4).

2 Literature Review and Expert Consultation

2.1 Types of Dementia Registries

The first main objective was to reach Steering Group agreement and consensus regarding the purpose and objectives of the National Dementia Registry and agreement on the main benefits of the registry. To assist the Steering Group in making an informed decision, the DCU project team undertook a review of dementia registries that extended the information available from recent systematic reviews and included projects that were in feasibility, design or start-up phases but are not as yet operational (Gliklich & Dreyer, 2014; Newton & Garner, 2002).

Three broad categories of dementia registries emerged from this literature review, characterised primarily by their aims and objectives. Most dementia registries fall into one of these categories (Krysinska et al., 2016) namely:

1. Epidemiological;
2. Quality of Care;
3. Research; which includes pre-clinical research and volunteer registers

2.1.1 Differentiating between an Epidemiological and a Quality focus

Essentially an epidemiological register would try to answer the question of how many people in Ireland have dementia and where they reside. In order to achieve this objective it would be essential to capture everyone with dementia in all care settings. Existing epidemiological registers acknowledge the difficulty in trying to achieve complete geographic coverage and gaps still remain due to cases of undiagnosed and undisclosed dementia. For example, the South Carolina Alzheimer's Disease Registry, which has been in operation for over 30 years, confirmed that people who have mild forms of dementia, but lack a diagnosis, do not appear in their Registry data (SCADR, 2019). Previous research also suggests that the number of individuals with Alzheimer's Disease Related Disorders may be nearly 50% greater than the number with diagnosed disorders (Hebert et al., 2003).

A quality registry differs in that it does not aspire to complete coverage of the population of people with dementia, but to follow the person with dementia over time to identify variation in 'best practice' and provide feedback on performance in an effort to stimulate quality improvement processes and to motivate change. Over time, the quality register provides a broad coverage representative of the population. Sweden, for example, has more than 100 National Quality Registries that provide the Swedish health care system with an opportunity to monitor quality and results (Nationella Kvalitetsregister, 2020). The stated primary purpose of each registry is to support learning and quality improvement. The Swedish Dementia Registry (SveDem) was established in 2007 and while coverage is good, SveDem focus on representativeness over coverage (SveDem, 2016). Registry data is used to discuss how care for people with dementia works and how well SveDem's database represents the situation for people with dementia in the country; this is considered more important than coverage (K. Vestling, personal communication, 3 September 2020).

Quality registries are often a piece of a bigger puzzle and part of a broader framework (Expert Group on Health Systems Performance Assessment, 2016). Several countries, including Sweden and Denmark, have adopted quality registries as an integral part of an overall strategic healthcare approach (see Table 2). In recent years, there appears to be a shift away from numbers towards quality improvement (Department of Health (Australia), 2019).

Table 2 Sample International approaches

Sweden	Denmark	The Netherlands
Sweden is a pioneer in quality registry development with 108 National Quality Registries, some of which have been in operation for more than 20 years (Nationella Kvalitetsregister, 2020).	Denmark has 69 National Clinical Quality Databases managed by the Danish Clinical Registries (RKKP) organisation, which also provides the infrastructure (Databasernes Faellessekretariat, 2016).	The Dutch Institute for Clinical Auditing (DICA), a clinician-led, independent, non-profit organisation funded by Dutch private health insurers, manages 22 registries (Dutch Institute for Clinical Auditing, 2020).
Two thirds of the National Quality Registries cover over 80 per cent of all eligible patients.	The registries are required to cover at least 90 per cent of eligible patients.	DICA was established to facilitate collaboration between insurers, hospitals and clinicians around clinical quality and outcomes data.
The registries are initiated and led by healthcare professionals with government support and funding.	Clinical registries are led by a board of healthcare professions, owned, and funded by the government.	

2.1.2 Examples of Epidemiological and Quality Dementia Registries

A selection of epidemiological and quality dementia registries is presented in Table 3 overleaf. These examples illustrate some of the key differences within and across each category.

Table 3 Examples of Epidemiological and Quality Dementia Registries

Registry Name	Type of Registry	Brief Description of Registry and its purpose
South Carolina Alzheimer's Disease Registry (SCADR)	Epidemiological	SCADR is a population registry of ADRD in South Carolina. It aims to provide disease prevalence estimates to support social and medical service planning, and identify differences in disease prevalence among demographic groups (Arnold School of Public Health, 2020).
Registry of Dementia of Girona (ReDeGi)	Epidemiological	The Registry of Dementia of Girona (ReDeGi) captures demographic and clinical data for all new dementia cases diagnosed at the specialist care level in Catalonia, Spain (Garre-Olmo et al., 2009).
French National Alzheimer Database System (BNA)	Epidemiological	The French National Alzheimer database (BNA) registers all medical acts performed by memory units and independent specialists throughout France (BNA, 2020).
The Danish Quality Database for Dementia (DANDEM)	Quality	The Danish Quality Database for Dementia (DANDEM) monitors and improves the quality of clinical investigations of patients referred for elective dementia examination in dementia units in the primary and secondary sectors (Copenhagen Healthtech Cluster, 2020).
Swedish Dementia Registry – (SveDem)	Quality	SveDem aims to improve the quality of dementia care in Sweden by compiling data to monitor changes in patient populations, diagnoses and treatments for dementia. The goal is to achieve equitable and optimal care for people with dementia (SveDem, 2016).
Norwegian Dementia Registry (NorCog)	Quality	Norwegian Register of Persons Assessed for Cognitive Symptoms in Specialist Health Care Services (NorCog) was established to improve the quality of assessment and treatment of dementia at hospital outpatient clinics in Norway and became a national registry for dementia in 2013 (M. Nåvik, personal communication, 4 February 2019).

2.2 Key benefits of a dementia registry

In addition to examining the different types of dementia registries, we also carried an analysis of the key benefits gained from the funding of a dementia registry from a variety of different perspectives; that is, registry funders, those who provide data to the registry and those who make use of the information derived from registry data collection. The following is a summary of findings from interviews held with dementia registry funders in France (Assistance Publique - Hôpitaux de Paris), Girona (Health Sector Director Catalan Health Service), Norway (Senior Advisor Norwegian Directorate of Health) and Sweden (Programme Manager Swedish National Board of Health and Welfare).

2.2.1 Provides valuable dementia data

Registry teams consistently responded to say that having a dementia registry provides valuable data on dementia. Most countries started out with limited dementia data and this lack of systematic collection of dementia data was a key driver in the formation of their national dementia registries. They typically started gathering data that answered key questions and was relatively easily available. Over time, they extended registry processes and functionality to address data quality, data comprehensiveness and new information requirements as they arose. Many registries now also facilitate the collection of patient-reported data alongside data reported by health and social care professionals (e.g. SveDem).

None of the registries we spoke to have as yet undertaken, or been asked by their funders to undertake, a cost benefit analysis and we were told that financial savings were not a key driver of the decision to create a dementia registry; rather it was a need to gather dementia data in a systematic way to fill a health information gap relating to dementia care.

> ***Norway:*** *"Cost benefit analyses have not been part of the critical review process for any of the Norwegian quality registries and it is not planned for any future registry applications either."*
>
> ***Sweden:*** *"As far as I know, no cost benefit analysis have been made."*
>
> ***Girona:*** *"No cost-benefit analysis has been carried out"*
>
> ***France:*** *"The assessment of the register does not include any cost benefit analysis"*

Funding continues to be made available to these registries primarily in recognition of the benefits derived from the information that the registry can provide. Countries with a dementia registry now feel they have better quality information in relation to dementia. Different people can use the registry data for different purposes.

> ***Norway:*** *"There are few or no other sources of information, which can deliver the information, needed like a quality registry. In Norway, the proportion of elderly people and thereby the number of dementia patients will increase. […] we believe that the registry over time will give us important medical information that will provide better understanding and lead to improvement in treatment to the benefit for patients and their families"*
>
> ***Sweden:*** *"SveDem is an important tool that can be used to provide quantitative data on size of populations and also on which methods are used for diagnosis, treatment, care and support of patients with dementia"*

Providing valuable data is the primary way in which benefit is derived from all existing dementia registries It was apparent from the discussions with the different Dementia Registries, and with experts in patient registries more generally, that a wide range of stakeholders benefit from the data gathered in the registry and from the outcomes that can be tracked as a result of having that data available.

2.2.2 Benefits for people living with dementia

In respect of persons with dementia and their family caregivers, a dementia registry can assist in timely diagnosis; improve treatment and care and ultimately quality of life.

> ***Norway:*** *"The goal is that the registry will provide for the patients to get examination for dementia more in accordance with the national guidelines and to use information from PREM [patient reported experience] data to improve the follow up of the patient and their families, the registry provides valuable information about how the patients and their families experience the examination".*

> ***Girona:*** *"We believe that they benefit from an improvement in the diagnostic process [in terms of time and quality]. We believe that, due to the greater degree of application of the clinical guides and protocols by the professionals that serve them [...] give the best possible service to citizens. This should be the ultimate goal of the best knowledge of dementia care".*

> ***Sweden:*** *"The aim of SveDem is to improve quality of diagnostics, treatment and care of patients with dementia disorders in all regions in Sweden and in different clinical settings. Patients newly diagnosed with one of the dementia diseases are registered and followed-up yearly".*

2.2.3 Benefits for health and social care professionals

In respect of healthcare professionals, a dementia registry would allow for benchmarking and setting of improvement targets, which in turn can lead to clinical improvement and to enhancement of knowledge and skills. The registry, as part of its reporting, can also provide a dashboard of data of interest to healthcare professionals and relevant to their locality.

> ***Norway:*** *"The registry provides the possibility for a department to compare its practice with other medical centres/ departments; e.g. how they define the audience, which diagnoses do they use and which methods they use for examination".*

> ***Sweden:*** *"Clinicians can use the registers to ensure that they use the recommended treatments. The quality registers also contribute to quality enhancement and an increased knowledge among staff working with people with dementia".*

2.2.4 Registry Benefits for policymakers

A dementia registry can assist and inform policymaking and the allocation of dementia services, and it can facilitate the monitoring and evaluation of these dementia services including their cost effectiveness.

> ***Sweden:*** *"Data from SveDem is important to policy makers, both on local, regional and national level, in order to identify quality gaps and regional differences as a basis for further actions. It would not be possible to evaluate the healthcare given to the group (people with dementia) without the existing quality registers mainly SveDem".*

> ***Girona:*** *"The register data should help to make decisions when it comes to adapting health care resources to a greater number of cases and increasing cases of older age. [Policymakers can] make decisions in relation to the provision of health and social services, based on validated epidemiological and clinical information. Knowledge of the evolution of the incidence of patients treated with dementia and their severity, should allow the estimation of the necessary resources, at short and long term".*

> ***Norway:*** *"The Norwegian dementia registry is primary a quality registry. That means the main reason for the establishment of the registry is to monitor the investigation of the patients in the medical departments in hospitals; to reveal if the medical investigation is in accordance with national guidelines and if there are any differences between departments".*

The national decision makers annually get information from all the quality registries in Norway and increasingly the registry data concerning dementia is used to answer questions from official agencies, boards and politicians.

2.2.5 Supports delivery of integrated care

South Korea is recognised by Alzheimer's Disease International (ADI) for its progress on implementation of its national dementia plans (Barbarino et al., 2019). The Korean government declared a 'war against dementia' and announced the first national dementia plan in 2008 (Lee & Seong, 2018). In 2012, the Dementia Management Act was enacted and the second national dementia plan was announced. This plan established basic infrastructure, such as a dementia management system at the national, regional, and municipal levels. The Republic of Korea's dementia management system K-Dreams aims to not only register and monitor people living with dementia in the country but also to connect them with all the healthcare services available in their area for their specific condition. In that way it all health, social care and administrative data from each encounter the person with dementia has with the system is shared across the system (OECD, 2018). This national monitoring helps to strengthen the dementia systems themselves. Korea's third national plan was designed to reduce effectively the burdensome aspects of dementia by establishing a user-based, continuous support system with wider community coverage.

2.2.6 Delivering economic value

Any investment in a registry should deliver value but it is important to give consideration to what value means. As no registry funders had carried out a detailed cost benefit analysis prior (or subsequent to) initial implementation, we undertook a literature review with two objectives: (i) to explore the concept of value further and (ii) to determine if an economic evaluation of registries has been previously carried out and the approach taken.

In 2018, The Value of Health Improving outcomes report was published (EFPIA, 2018). The report documented the discussions and findings of the Value of Health initiative over four years, which included seven multi-stakeholder roundtables, and working groups. Given that there is currently no universally accepted definition of value, the group provided an overview (see Figure 4) of the different dimensions of value in health systems

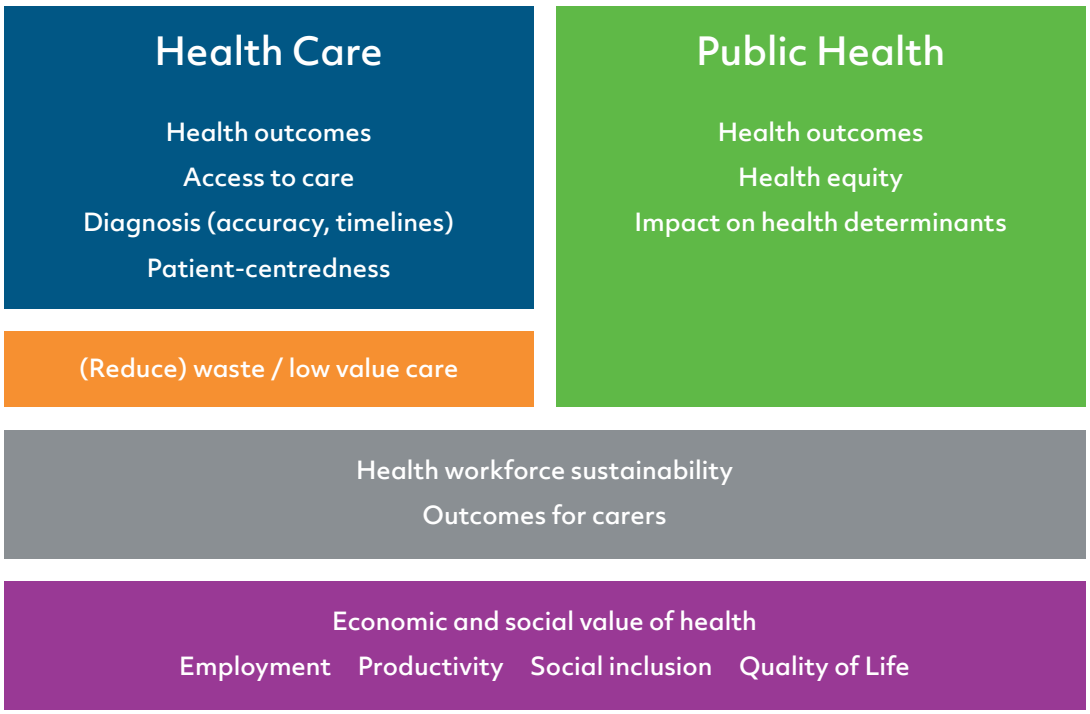

Figure 5 Value in health systems: a multi-stakeholder perspective (EFPIA. 2018, p. 2)

The report identified five main ways that data can be used to improve value for money in health systems by enabling improvements in health care quality namely:

1. Learning from health outcomes variation
2. Continuous improvement at clinicians level
3. Improving the effectiveness of public health interventions
4. Performance monitoring and transparency
5. Supporting the implementation of integrated care

Elements of what constitutes value was also discussed by Health Technology Assessment International (HTAI) at their policy forum (Henshall & Schuller, 2013) and depicted in Figure 6 below.

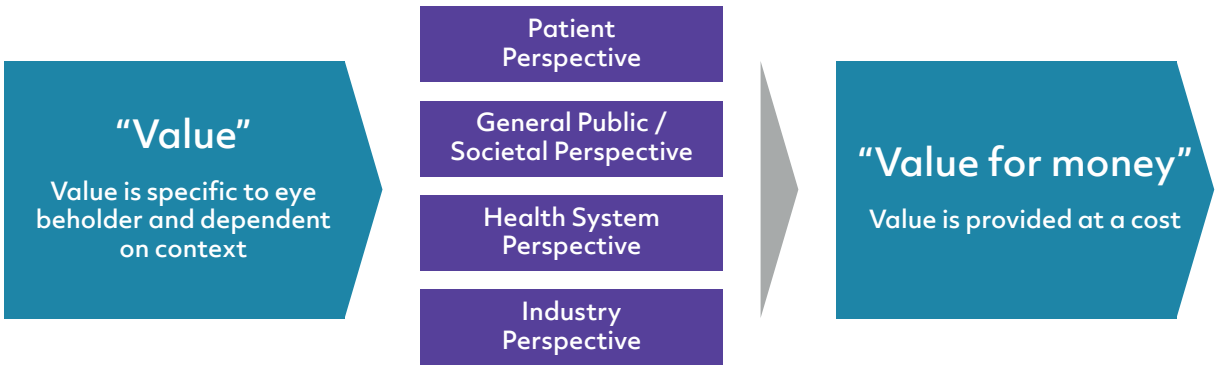

Figure 6 Definition of Value (HTAI Policy Forum; Henshall & Schuller, 2013)

There is also growing awareness of the value of diagnostic data not only to healthcare professionals in terms of patient management, but to healthcare providers (turn around time, operational costs, quality), healthcare systems (economic efficiencies) and to people (patients) themselves (clinical benefit, patient empowerment, satisfaction) (MedTech Europe, 2019). Diagnostic information is a component of all dementia registries, and underpins their ability to deliver thes types of benefits to stakeholders.

Cost effectiveness was also considered as part of a two year EBC research project on the Value of Treatment of Brain Disorders (VoT) in Europe (European Brain Council (EBC), 2017). The findings of the project resulted in the launch of a policy white paper, that included the data collected by nine expert working groups. The key findings from the project was that there was a:

— Low understanding of the diseases aetiology, risk and preventative factors
— Lack of disease awareness in the general public and lack of training for health care providers
— Lack of primary and secondary prevention programs
— Lack of timely and adequate diagnosis and treatment
— Fragmentation of health care services and lack of coordination between health and social services

The report acknowledges which there is still no cure therefore it is necessary to place focus on risk reduction. Taking a similar focus on monitoring risk factors of dementia would lead to similar cost avoidance by preventing disease and keeping the population in good health. In addition, capturing data at the point of diagnosis (ideally preclinical and early detection and diagnosis) allows for timely intervention. This would enable population to remain economically productive and socially active which in turn may reduce need for care.

There have also been a number of systematic reviews whose focus has been to perform an economic evaluation of registries. These have included a systematic review on the impact of clinical registries on quality of patient care by Hoque and colleagues (2017) that found despite the large number of published articles using data derived from CQRs, few have rigorously evaluated the impact of the registry as an intervention on improving health outcomes. Those that have evaluated this impact have mostly found a positive impact on healthcare processes and outcomes. The review found that registries play an important role in care management processes through:

— generating performance feedback reports to physicians,

— helping to identify patients who are not receiving treatment in accordance with guidelines,

— creating a trigger for action by physicians,

— creating a reminder for patients,

— identifying high-risk patients so they can be more closely monitored and

— reducing regional differences.

The value that registries therefore provide is demonstrable in the improvement of processes, care and clinical outcomes.

The Australian commission (2016) published an economic evaluation of clinical quality registries. The report concluded that Registries, when sufficiently funded and operated effectively, improve the value of healthcare delivery at a relatively low cost. By increasing the availability and use of process and outcomes data, investment in registries is likely to deliver strong economic returns on investment. Recent funding of the ADNet programme by the National Health and Medical Research Council's Boosting Dementia Research Initiative has secured $18 million over five years, commencing July 2018, to achieve its six core aims including development and maintainance of the ADNeT-Registry, that can track, benchmark and report on the quality of clinical care of people with dementia. Another economic evaluation of clinical quality registries concluded that CQRs can be cost-effective and can lead to significant returns on investment (Lee et al., 2019). This report suggested that cost savings can be considered in terms of rate of return or ICER, however cost effectiveness of a registry could also be measured by the change in quality indicators over time, a benefit which is directly attributable to the registry operation.

This sentiment of placing value in measuring quality indicators over time is echoed in a paper produced by MedtechEurope (2016). The report acknowledges that there is no shortage of evidence of the cost of health and care systems, but little is still known about the value, especially on the economic value offered by these investments. The report suggests that the way forward should be to focus on outputs/outcomes, including the socio-economic aspects of the outcomes, by identifying ways to measure and to compare indicators for outcomes. This will also make it possible to make a better judgement of the spending of health in relation to the cost versus investment discussion. More knowledge about the socioeconomic effects of health will help us to understand the value created by investing in health. The MedTech report is cognisant that, this will require a new way of thinking – changing from the traditional view of healthcare expenditure as a cost to viewing it as an investment – and an investment that will provide a return over a certain timespan.

This approach is operational in Sweden where they adopt the classical improvement cycle of Deming (2014) - : Plan-Do-Study Act. Their improvement methods are not specific to value based health care, but rather based on previous and present experiences and knowledge of improvement work. A 2011 health economics study in Sweden revealed that an annual investment of US$70m in registries could reduce the annual growth in health care spending by 0.6%, with the estimated cumulative return of more than US$7b over ten years – a $10 return on every dollar invested (Larsson et al., 2012).

2.3 Agreeing the aims and objectives of the National Dementia Registry

Following detailed discussion of the findings of the literature review and expert international consultations, the Steering Group were confident that the Irish National Dementia Registry would provide **valuable dementia data** that could be used by:

- Persons with dementia in Ireland, their carers, and advocacy groups to highlight inequitable service provision and strive for improvements in dementia care ;
- Healthcare professionals across Ireland to compare dementia data by centre, by county and by country;
- National Dementia Office to support the implementation of dementia policy and development of services;
- Department of Health as an input in policymaking and service provision in addition to addressing the need for improvement in information systems.

The SIG and Steering Group discussions included extensive consideration of the differences between epidemiological and quality registries and the approaches taken by other countries. An agreement was reached that the National Dementia Registry should be a quality registry that follows people with dementia along their journey with dementia. Over time, the national dementia registry will build up a picture of: (i) where people are, what services they are using and what services they need; and (ii) modify health behaviours, processes (e.g. standardisation of diagnosis) and systems of care.

This focus on quality is in line with a number of recent publications by the National Quality Improvement team that set out their strategic approach to improving quality to achieve better and safer care and vision for 2020-2024 (National Quality Improvement Team, 2020). In addition to the development of a registry, this quality focus requires associated guidelines, frameworks and referral pathways to support the key aims of the registry. These are to:

(1) Improve patient care and outcomes for the person with dementia
(2) Provide quality assurance and /quality indicators
(3) Assist with dementia planning/policy
(4) Assist in the long term with research.

While the initial focus of the National Dementia Registry model will be on quality, an important secondary goal is that the register would be capable of supporting research in the future ('Research Ready'). It was noted that this is a common secondary goal of existing dementia registries. In each case, dementia registry data is not automatically available for research purposes. Instead, a registry receives applications from researchers seeking data on an (pseudo) anonymised basis along with the rationale for, and intended use of, these data. On approval, the data are made available to the researchers in line with research, registry and data protection regulations (see Section 1.4.2).

It will also be important in the future to consider and identify synergies between the National Dementia Registry and the ASI Dementia Research Database (a separate project underway within the ASI to create a voluntary research registry similar in objective to Join Dementia Research in the UK). It will be important to ensure that each complements but does not overlap with the other.

2.4 Registry Ownership and governance

It is important that a formal governance structure and steering committee are established for the National Dementia Registry. Guidelines from United States (Gliklich and Dreyer, 2007), England (Newton & Garner, 2002) and Australia (McNeil et al., 2009) stress the need for good governance to ensure that the registry delivers on expected benefits. They recommend that all registries should have a management committee to assume responsibility for the day-to-day operational issues and a separate committee for oversight and policy issues, but for small registries, the functions of these committees can be incorporated into one structure. Registries should have access to appropriate expert advice including clinical, epidemiological and statistical expertise. Key principles of registry governance are shown in Figure 7:

Figure 7 Key principles of registry governance

Governance structures vary considerably across existing registries. As illustrated in Figure 8, SveDem has a governance structure that operates at a national, regional and unit level. As the registry is rolled out across more of the health and social care sectors, new units are added.

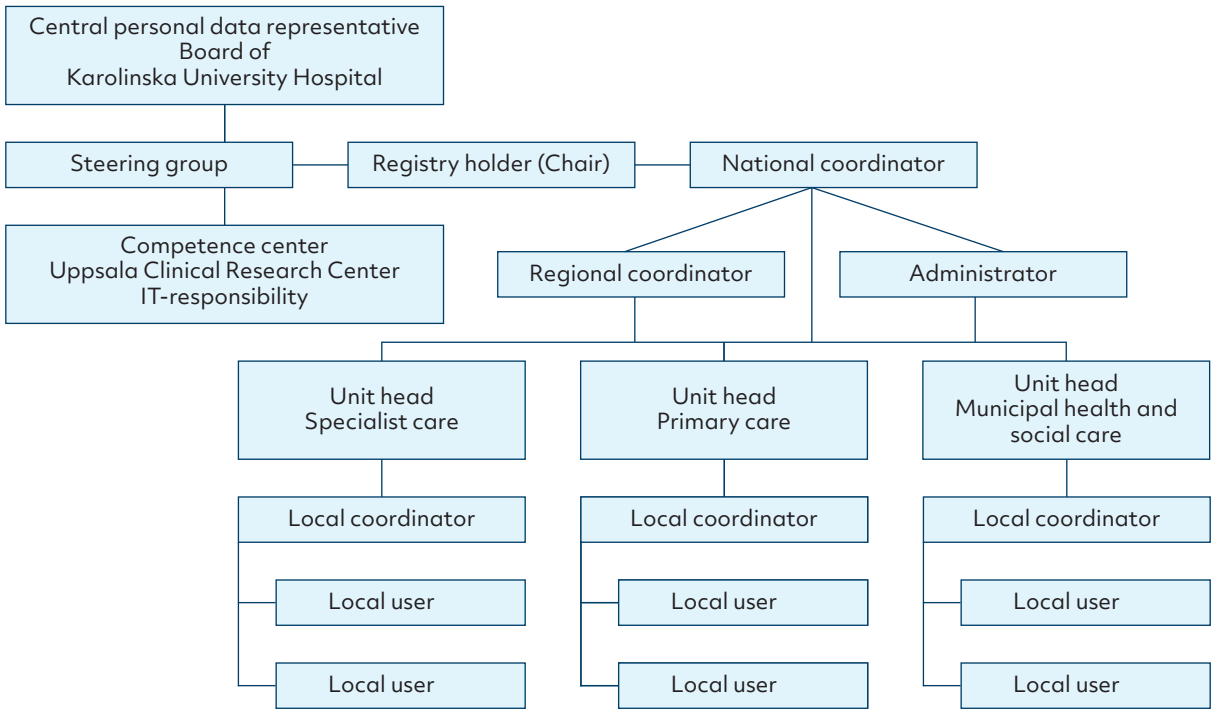

Figure 8 Swedish Dementia Registry Governance Structure

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 (Hopper et al., 2016).

In contrast, the National Cancer Registry of Ireland has a very simple structure (see Figure 9). Their Board has seven members who meet four times a year.

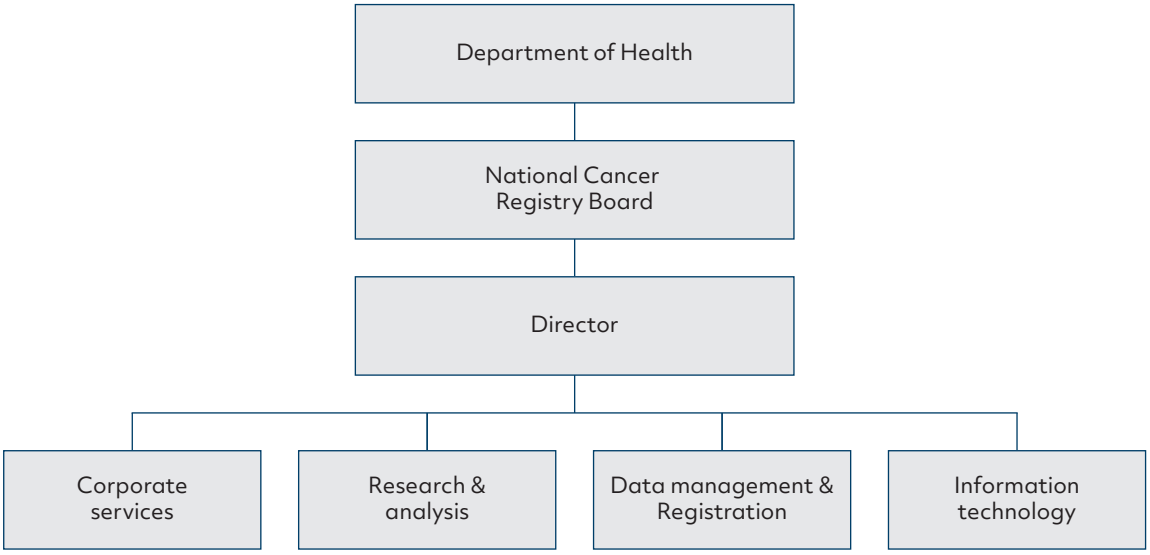

Figure 9 Structure of the National Cancer Registry of Ireland

Although not explicitly included in the examples of governance structures above, there is a common view that patient representation is important in the governance model in order to best represent the needs of the patient group, increase awareness of the registry among stakeholders and ultimately to improve the comprehensiveness and quality of the data collected (EURODIS, 2013). Many registries facilitate the collection of patient-reported data alongside data reported by health and social care professionals (e.g. SveDem, 2016). Further examples of dementia registry governance and funding can be found in Appendix D.

To date registries in Ireland have been set up somewhat organically and governed under different structures traditionally linked to their ownership and funding source. In the absence of a strategic approach, different types of health-related databases and registries sit with different owners. Applying the existing models to the ownership of the National Dementia Registry, would indicate that there are five potential options to choose from:

1. Ownership sits with the Department of Health within a 'Data Hub' or 'Health Intelligence Unit';
2. Ownership sits with the HSE in the OoCIO; perhaps in the Integrated Information Systems or in the Health Intelligence Unit;
3. Ownership sits with the NDO (HSE), which is under the remit of the National Social Care Division;
4. Ownership is given to HIQA as it is an independent authority established to drive high-end quality care. It has statutory responsibility for advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care and support services (HIQA, 2016).
5. As per best-practice guidelines, ownership resides with an independent body outside of health system. An existing example of this approach would be the Cystic Fibrosis registry (Cystic Fibrosis Registry of Ireland, 2016).

Although adhering to best-practice guidelines is important, the operational environment of the registry also needs to be considered. Choosing the most appropriate model will depend largely on the registry model and registry processes that will be implemented. We revisit the potential governance of the National Dementia Registry in Chapter 9, following the development and presentation of the proposed National Dementia Registry Model.

SUMMARY

The consensus from stakeholder group was the National Dementia Registry focus needs to be on quality and with that must come guidelines, frameworks and referral pathways.

The agreed aims of the National Dementia Registry are to:

(1) Improve patient care and outcomes for the person with dementia

(2) Provide quality assurance and /quality indicators

(3) Assist with dementia planning/policy

(4) Assist in the long term with research.

None of the existing dementia registries we contacted had undertaken a cost benefit analysis, our review of literature found that 'value' can mean different things to different stakeholders.

Evidence suggested registries can be cost effective and lead to significant return on investment these savings could be measures by rate of return or by the change in quality indicators over time a benefit directly attributable to the registry (Lee et al., 2019):

The registry will provide valuable dementia data that is not available from any other source.

Finally, best-practice governance recommendations were presented along with examples of the governance structures implemented by existing dementia and Irish Patient Registries. The selection of an appropriate governance model for the National Dementia Registry will be considered following the presentation of the registry Model.

3 Dementia registry outcome measures

Having established the aims and objectives of the National Dementia Registry, work began to identify, develop and reach agreement on the outcomes and quality indicators that should be monitored and tracked by the Registry. Quality indicators can take the form of process or outcome measures and primarily set out elements of a desired standard of care and a measurable goal for ongoing monitoring, benchmarking and improvement. Over time, significant benefits may be realised from tracking quality indicators including:

— Improvement in the rates of early and accurate dementia diagnosis;

— Reduction in variation in dementia services;

— Reduction in use of antipsychotic drugs;

— Better support for both the person living with dementia and the carer through the journey of the disease.

3.1 Methodology

As described in section 1.6.3.2, a combination of literature review, expert opinion and stakeholder workshops were used to determine the outcomes that were the highest priority for dementia care in Ireland. This chapter reports on the development of an agreed set of outcomes to be measured in the initial implementation of the National Dementia Registry. Further indicators can be developed over time as data becomes available and in accordance with strategic focus and priority. That said, existing registries caution against measuring too broad a set of outcomes at any point in time. SveDem, for example, aim to retire an outcome indicator that is no longer needed if a new indicator is being introduced (K. Vestling, personal communication, 11 March 2019).

3.2 Findings

Through our interactions with existing quality-focused dementia registries in Norway, Sweden, and Denmark, and with the team in Australia who are in the process of developing a dementia registry, we gathered a list of existing dementia-related quality indicators. From an analysis of this collective list, we identified that quality indicators broadly track the following categories:

1. Quality of Diagnosis
2. Quality of Treatment,
3. Quality of Support
4. Quality of Life (Patient Reported Outcome Measures; PROMS)

Adopting a similar set of quality indicators in the Irish registry would not only facilitate cross-country comparison of dementia data, but it would also take advantage of the considerable time invested by these countries in developing their indicators. Nevertheless, the quality indicators will need some adjustment to take account of Ireland's dementia care priorities. Clinical effectiveness as a key component of safe, quality care is a core principle of the Irish National Dementia Strategy and it underpins the other dementia care initiatives in progress within the NDO; for example, diagnostic and post-diagnostic care pathways. Adopting a clinical effectiveness approach that incorporates national and international best evidence will promote the delivery of integrated dementia care that is current, effective and consistent.

Table 4 Sample quality indicators from international quality-focused dementia registries

Swedish Dementia Registry	Norwegian registry of persons assessed for cognitive symptoms
Time from referral or contact date to work up start (spec)	the proportion of patients that have reported on Patient related outcome measures (PROM)
Time from work up start to diagnosis (spec o prim)	the proportion of patients where information is collected about neuropsychiatric symptoms
*Proportion of persons with dementia disease that received dementia diagnosis last year	the proportion of patients that have been assessed for depressive symptoms
Proportion of persons with dementia diagnosis undergoing basic dementia work up	the proportion among patients with dementia, that receive a specific etiologic diagnosis
Proportion of persons with Alzheimer's disease treated with dementia drugs	the proportion of patients with mild cognitive impairment or dementia that was referred to health service after the examination
Proportion of persons with dementia who have day care	
Proportion of persons with dementia in primary and specialist care, whose condition is followed up by health care at least once a year	
Proportion of persons with dementia for whom health care has initiated support for relatives in connection to dementia work up	
Proportion of persons with dementia in nursing home that lives in nursing home specialized for people with dementia	
Proportion of persons with dementia in nursing home are treated with antipsychotic drugs	
Proportion of persons with dementia in nursing home have undergone drug review last 12 months	
Proportion of persons with dementia in nursing home where the life story is the basis for care	
Proportion of persons with dementia in nursing home have individual environmental adjustments included in the "implementation plan"	
Proportion of persons with dementia in nursing home have strategies for treatment documented in the "implementation plan"	

Danish Quality Database for Dementia
Percentage of demented patients amongst numbers referred
Proportion of patients evaluated within 90 days
Proportion of demented patients assessed with MMSE
Proportion of demented patients assessed with IADL-FAQ scale
Proportion of demented patients with structural brain scan (CT/MRI)
Proportion of demented patients where the etiological diagnosis is determined
Proportion of patients with AD DLB and PSS treated with anti- dementia drugs

*proportion in each case refers to the proportion of people on the database/register rather than the proportion of people in the population

In addition to dementia outcome sets such as ICHOM (2016), a recent and robust systematic review of dementia-related outcomes was undertaken as part of the ROADMAP (Real world Outcomes across the Alzheimer's Disease spectrum for better care: Multi-modal data Access Platform) project. The aim of this study was to provide a foundation for integrated dementia-related data and it included the identification and further development of key outcome measures relating to Alzheimer's Disease (Janssen et al., 2020). ROADMAP ran from September 2016 to October 2018 and comprised of 26 partners led by the University of Oxford and Novartis. The advisory group for the project included a senior statistician, a number of medical doctors with expertise in Alzheimer's disease and psychiatry, and a pharmacoeconomic assessor, to ensure its outputs were of high scientific quality and meaningful applicability.

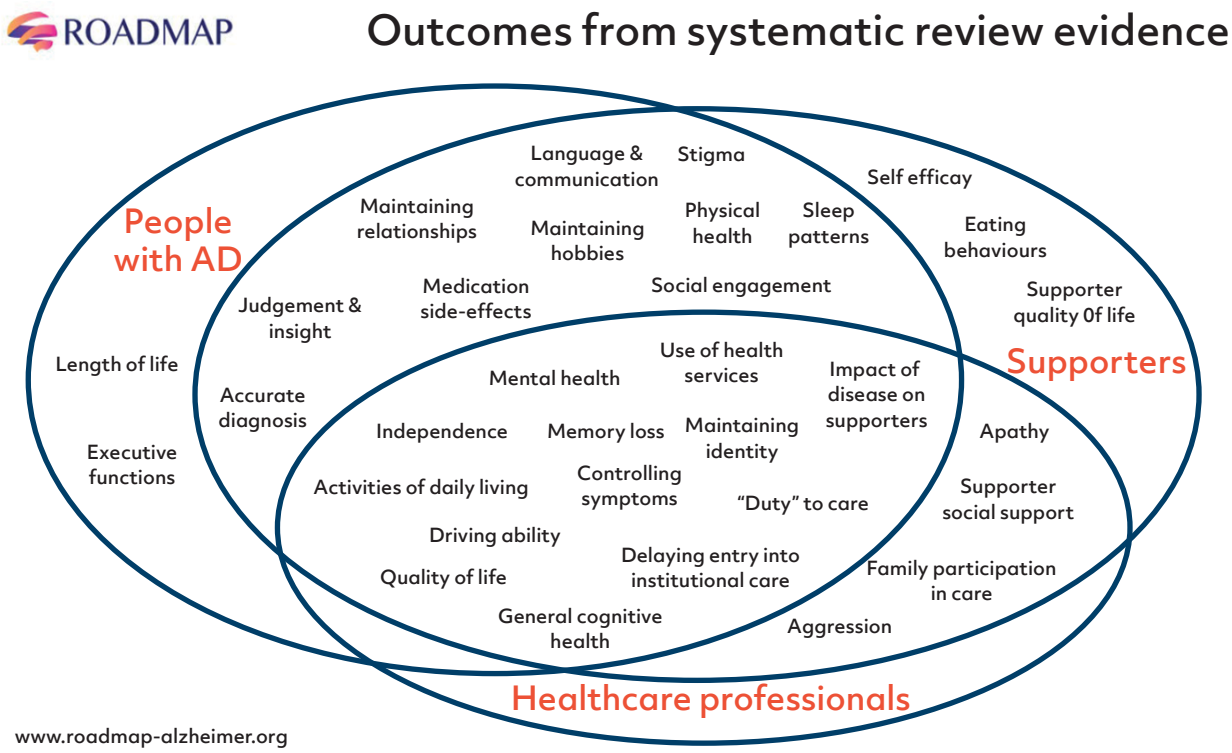

Figure 10 Summary of dementia-related outcomes from systematic review evidence by the ROADMAP study used in the outcome workshops (Smith, October 2018).

An updated version of this figure is now available (Tochel et al., 2019). ROAPMAP noted that coordinated national and regional efforts might be needed to change the reporting of outcomes in routine clinical care in order to ensure that missing outcomes are documented in EHRs and registries. They also identified the need for international collaboration to identify opportunities for harmonization (Janssen et al., 2020).

3.3 Applying the evidence to the Irish Context

The findings from our review were presented and discussed at two workshops held to seek views on the most important quality indicators from an Irish perspective. The first workshop comprised of 13 clinicians and other stakeholders and six participants from the SIG attended the second workshop. The specific objective of each was to discuss and brainstorm the outcomes that matter most to people with dementia, their families, health and social care professionals, service providers and policy makers. These priorities were then debated to determine the highest priority items that the Irish registry should be tracking so that it successfully addresses its aims and objectives and meets the need of a diverse stakeholder group.

3.3.1 Priority outcomes for health/social care professionals and policy makers

The first workshop compromising of clinicians, health and social care professionals, policy makers, public health and registry experts focused on reviewing outcomes from the literature review; primarily those from Roadmap and existing dementia registries. Outcome measures considered important in an Irish context were highlighted and new measures included as needed.

A detailed summary of each of the key discussion points and priorities are presented in Table 5 overleaf. It became clear that different groups of stakeholders (e.g. clinicians in comparison to policy makers; health information experts in comparison to service providers) might agree on a broad set of outcomes that should be monitored using dementia registry data, but they had very different priorities in relation to those outcomes. This is unsurprising given their different perspectives and the type of information that each would find particularly useful. Some stakeholders also found it very difficult to consider outcomes that did not have a currently obvious data source (e.g. individualised care plans). Consensus was difficult to achieve but it emerged as the workshop progressed and we identified a subset of outcomes that everyone saw as important. Once you moved beyond this set, it was a lot harder to get agreement and this demonstrates not only that a registry has many purposes but also that the registry cannot be '*all things to all people*'.

Table 5 Key outcomes and discussion points from Workshop 1

Pre-diagnosis	— No value seen in tracking indicators which monitor proportion of specific tests carried out (e.g. MRI) as test will change — Need to future proof — Support for broad tracking (neuroimaging, biomarkers cognitive testing) neuropsychiatric indicators and depressive symptoms — Currently, no defined diagnostic pathway; Could monitor adherence to a standardised process e.g. defined basic work up or guidelines such as NICE or Irish specific guidelines when developed
Diagnosis	— Importance of having an accurate diagnosis — Specific diagnosis should be recorded; e.g. dementia subtype — Need to capture where the diagnosis was made and by whom — Awareness of large numbers still going undiagnosed coupled with GP reluctance to diagnose, much of which is because of the uncertainty associated with making a dementia diagnosis. — Importance of adopting a standard operational definition of dementia
Lead times (waiting times)	— Measure how long it takes to get a diagnosis providing this measurement is meaningful — Should apply to all wait times from initial referral to diagnosis — Should cover all referrals (e.g. to a service in the community) — Diagnosis to Long Term Care (LTC)
Use of Health & Social Services	— 'Care Plan' - need for something meaningful rather than Yes/No tracking as there was a view that everyone would simply tick 'Yes' — Identify pockets of need — Measure patient experience of health service use — 'Psychosocial interventions' needs to be defined further; expect that it will be harder to source the data needed to track these — With move to supporting people longer in the community use of services would need to be tracked more broadly, could interRAI™ (SAT) be used as a potential data source? Note: important to recognise current challenges using SAT in practice — What is dementia costing society? – development of economic burden indicators
Support Network	— Measure the support network available to people with dementia — Measurement of the impact of the disease on the carer over time
Quality of Life Living Well	— Measuring ability to maintain hobbies, social engagement. — Not just living well, also living safe — Applicable to the person with dementia and to the carer
Medication	— Importance of measuring pharmacological data — Important to track antipsychotic medication in particular — There are known benefits to having a medication review process. Should this also be tracked?

3.3.2 Priority outcomes for the Special Interest Group (SIG)

The SIG were initially presented with the Roadmap diagram (see Figure 9). Each individual was asked to highlight his or her top five outcomes. Personal preferences were gathered, collated and presented back to the group. Together they discussed this feedback, identified common outcomes, reconsidered those not selected by anyone in the group and discussed if any outcomes were missing from the final list that they might have expected to see. The group considered the prioritisation of outcomes from their own perspective, but also from the perspective of other stakeholders and a lot of consistency was seen across the group. A summary of the final set of required outcomes is provided in Table 6.

Table 6 Key outcomes identified in Workshop 2

Diagnosis	— Age at Diagnosis — Type of Dementia diagnosed (sub-type very important)
Use of Health Services	— Track what people are accessing and where — Look at regional variations and gaps — Capture both public and private services — Track person and services over time
Support	— Capturing type of support being provided — Capture living circumstances — Capture support available for both carers and broader circle impacted by the diagnosis
Medication	— Track side effects vs benefits — Quantity and type of medication — Medication reviews to facilitate regular two way — Communication
Quality of Life	— Ability to continue to do what I want — Driving ability — Independence — Maintain relationships and social engagement

3.3.3 Achieving consensus regarding priority outcomes

The feedback from both workshops was collated and mapped to suitable quality indicators. At this point, outcome measures were not constrained by the data that was easily available, but this is an important consideration and it was acknowledged that the registry should start with a smaller number of outcomes that it could easily and reliably measure. These can be expanded over time as data sources become available.

Following analysis of the workshop discussions and a review of the priority outcomes identified within and across the groups, a list of potential indicators for the Irish Dementia Registry was developed (see Appendix E). The members of the Steering Group were then asked to prioritise these outcomes. The objective of this exercise was to examine further the outcomes that would be prioritised by all stakeholders. In other words, to identify those common to all stakeholder groups and those that could be omitted from the registry in the initial phase of development, thus ensuring that the initial registry model would focus on outcomes core to the main aim of the registry (i.e. outcomes that provide answers to the important questions, are meaningful and have purpose), while also being realistic about the number of outcomes that can be tracked in the initial development phase (Gliklich & Dreyer, 2014; MRCG, 2012). Twelve members of the Steering Group provided feedback (see Table 7) and again it was clear that different stakeholders have different perspectives, priorities and focus.

Table 7 Consolidated prioritisation of quality indicators (Top 5 items shaded)

Ranking	Top 15 Quality Indicators	Average Score
1	Proportion of patients undergoing basic dementia work up	9.08
2	Overall quality of life of person with dementia	8.58
3	Proportion of patients with dementia who receive a specific dementia diagnosis	8.50
4	Overall Quality of Life and wellbeing of Carer	8.42
5	Proportion of patients treated with antipsychotic drugs	8.25
6	Time waiting for home support services	7.92
7	Proportion of patients treated with anti-dementia drugs	7.75
8	Proportion of patients who have follow up or referral after the initial assessments	7.58
9	Time from start of investigation (1st contact with person) to diagnosis (number of days)	7.55
10	Disease progression	7.33
11	Proportion of patients who have a standard care plan	7.33
12	Proportion of patients in which the ability to continue driving has been assessed	7.17
13	Proportion of persons with dementia who have day-care	6.82
14	Proportion of patients who undergo an annual medications review	6.58
15	Time from diagnosis of dementia to permanent residential care	6.09

*basic dementia work-up refers to the agreed standard set of tests that should be run when dementia is suspected.

Table 8 Top three indicators per stakeholder group

	Clinical perspective	Policy perspective
1	Proportion of patients undergoing basic dementia work up*	Overall Quality of Life of Person with Dementia
2	Proportion of patients with dementia who receive a specific dementia diagnosis	Overall Quality of Life and wellbeing of Carer
3	Time waiting for home support services	Proportion of patients who have follow up or referral after the initial assessments

*basic dementia work-up refers to the agreed standard set of tests that should be run when dementia is suspected.

This prioritisation of quality indicators was subsequently presented to the SIG who confirmed that the prioritisation, particularly the top 5 outcomes as presented in Table 6, was in line with their priorities. They reiterated the view that timely proper diagnosis and quality of life are of paramount importance to those living with dementia. They felt that the other outcomes were linked in many ways to the key outcome measures. This exercise reinforced the importance of having a quality focus and the decision to adopt a quality model for the Irish National Dementia Registry.

Best practice dictates that target values should be agreed for all outcome indicators. These are typically based on clinical guidelines and national programme targets (Swedish National Board of Health and Welfare, 2020), but these do not exist, as yet, for dementia care in Ireland. Our recommendation at this point is that these target values are re-examined in light of forthcoming diagnostic and post-diagnostic path updates from the National Dementia Office.

SUMMARY

The National Dementia Registry should track and report on meaningful indicators. As part of our quality indicator development process, we gathered indicators identified from literature review key outcome measures relating to Alzheimer's Disease and those used by existing dementia registries. To explore and document what was important from an Irish context two workshops were held. The specific objective of each was to discuss and brainstorm the outcomes that matter most to people with dementia, their families, health and social care professionals, service providers and policy makers. These priorities were then debated to determine the highest priority items that the Irish registry should be tracking so that it successfully addresses its aims and objectives and meets the need of a diverse stakeholder group.

The following were prioritised as the Top 5 indicators

1. Proportion of patients undergoing basic dementia work up
2. Overall quality of life of person with dementia
3. Proportion of patients with dementia who receive a specific dementia diagnosis
4. Overall Quality of Life and wellbeing of Carer
5. Proportion of patients treated with antipsychotic drugs

Over time significant benefits may be realised from tracking quality indicators including:

— Improvement in the rates of early and accurate dementia diagnosis;
— Reduction in use of antipsychotic drugs;
— Better support for both the person living with dementia and the carer through the journey of the disease.

We recommend that target values be developed for each of the outcome indicators based on clinical guidelines for diagnostic and post-diagnostic care in Ireland.

4 Development of a Minimum Dataset

A key deliverable of this project was to develop and reach agreement on a minimum data set for the National Dementia Registry. The creation of this dataset was driven top-down by the agreed registry quality outcomes and it therefore retains a quality focus that is extensive across a number of domains. In addition, it is informed from the bottom-up by the data that is routinely collected by existing quality focused dementia registries. Data standardisation is a vital first step towards improved information (Rampisheh et al., 2019). Agreeing a minimum dataset for the registry will assist memory assessment centres, hospitals, and GPs to collect information and report dementia efficiently. In addition, having a minimum data will allow data comparison nationally and internationally, by centre, geographical location, service use, type of dementia and other variables within the dataset as needed.

4.1 Methodology

As described in section 1.6.3.3, a mixed methods approach was taken to the development and agreement of a minimum dataset for the National Dementia Registry. It comprised of literature review of published datasets, review of datasets in existing dementia registries and those that were in development at the time, collection of stakeholder input, review of all findings and creation of a recommended minimum dataset during stakeholder co-design workshops, review and feedback from our Steering Group, prototyping of the recommended dataset (this process is described in detail in Chapter 6) and finally update and prioritisation of data fields following the results of the data prototype. The final dataset, including the feedback from the prototype phase, is presented in this chapter. Data fields are discussed in relation to the domain in which they are categorised, for example, personal characteristics or diagnostic data. A complete data table including links to the quality outcomes that are supported by these data is presented in Appendix F.

4.2 Literature review findings

4.2.1 Dementia registry data

The literature review produced a number of publications relevant to devising a minimum dataset for a dementia registry. These included a review of 22 dementia and Alzheimer's disease registries that highlighted how existing registries, and those in development at the time of the review, differed in terms of their minimum datasets and data elements (Sarsarshahi et al., 2017). From their analysis, a minimum dementia registry dataset typically contained four main categories of data, namely:

— **Patient characteristics** (age, gender, marital status, educational status, residential status, insurance data, address, contact information)

— **Service provider characteristics** (centre, date of admission)

— **Diagnostic characteristics** (history, type dementia, BMI, MRI, blood test, clock test)

— **Treatment characteristics** (pharmacological treatment, psychosocial interventions)

However, they found that only eight of the 22 registries contained data for all four categories these registries included the Swedish Dementia Registry (SveDem); The French National Database (BNA) the Registry of Dementia Girona (ReDeGi) and The Danish Quality Database (DANDEM). The review concluded that there was an absence of international standards regarding the development of dementia registries. This claim is supported by our literature review as to the best of our knowledge; no standards have been published since the review.

A recent report detailing the case for an Australian dementia registry (Krysinska et al., 2016) also noted variation in the data elements across existing dementia registries. It found that the minimum datasets in dementia registries typically include data relating to:

— the service provider,
— the person with dementia and the informant/carer/caregiver including contact details and socio-demographic information,
— functional measure(s),
— cognitive measure(s),
— diagnostic work-up,
— diagnosis,
— medication and treatment.

4.2.2 Minimum datasets collected by existing dementia registries

Over the course of the Feasibility Study (Hopper et al., 2016) and this phase of model development, we have built good relationships with a number of international registries who kindly shared their dementia registry minimum datasets with us. These included:

— SveDem – the Swedish Dementia Registry (SveDem, 2016)
— NorCog – Norwegian Register for cognitive symptoms (NorKog, 2020)
— BNA - French Alzheimer's National Database (BNA, 2020)
— ReDeGi - Registry of Dementia of Girona (Garre-Olmo et al., 2009)

This registry sample was chosen for an in-depth examination of existing registry data partly given their willingness to share their datasets, but also because they represent four prominent dementia registries that together support a broad range of objectives and outcome measures relevant to the Irish context; that is the collection of a core set of dementia data that will support a quality focused registry. An overview of these datasets, broken down by category of data, is presented in Table 9.

Table 9 Overview of data collected by four existing dementia registries

	Sweden (SveDem)	Norway (NorCog)	France (BNA)	Girona, Spain (ReDeGi)
Personal Characteristics	Social Security Number Sex, Age, Living condition, Family history of Dementia (First degree second degree) BMI (Height Weight) Possession of driving license Possession of weapon license Death Time to Death	Sex Date of Birth/Age Marital status Children Formal schooling years Education profession Working Patient lives alone Contact with relatives Relation to patient Frequency of relative contact with patient Type of lodging Social activity Cultural activity Safety – Motoring –Weapons – Falls Tobacco Alcohol Use Drugs other than alcohol History from relatives related to mental function	Used name Birth name First name Date of Birth Birth place Birth municipality Geographic location in relation to the centre Accompanying person caregiver characteristics Current lifestyle living arrangements Last profession Date of death	ID, Sex, Town County, Date of birth Language, Ethnicity, Employee, Schooling, Civil status, Residence, Live alone, Familial history of degenerative disease (dementia, Parkinson, etc.) Personal comorbidity

Table 9 continued

	Sweden (SveDem)	Norway (NorCog)	France (BNA)	Girona, Spain (ReDeGi)
Service Provider Characteristics	Report date, Date of Investigation start, Follow up date	Referral receive date Date investigation first begins Reason for delay Type of outpatient clinic The patient has consented to be part of the register to be contacted again relatives have agreed to be contacted again	Year of first consultation New Patient Referred by Type of consultation Part of onward referral Part of research protocol	Centre Centre referring the patient Date of first visit
Diagnostic Characteristics	Diagnostic Work up (Blood test clock test, CT, MRI, LP, PET/ SPECT, EEG, Advance cognitive testing), MMSE-SR/MMT, MoCA, RUDAS-S Time needed for Diagnosis Type of Dementia	Diagnosis ICD-10	Primary diagnosis Symptom presentation Etiological MMSE IADL	Date of first symptoms Date of dementia diagnosis Speciality making the diagnosis (neurology, geriatric, internal medicine, psychiatry, other). Diagnostic criteria DSM-IV Research criteria MMSE Blessed Dementia Rating Scale Clinical Dementia Rating Global Deterioration scale Neuroimaging Laboratory Neuropsychologist interview Genetic test Date of MCI diagnostic (if) BPSD

Table 9 continued

	Sweden (SveDem)	Norway (NorCog)	France (BNA)	Girona, Spain (ReDeGi)
Treatment	Medication (ChEI, NMDA-Antagonist, Antidepressants, Antipsychotics, Anxiolytics, Hypnotics, Cardiovascular drugs, painkillers) Total number of drugs Day Care, Home care		Personal autonomy allowance ALD long term illness Pharmacological treatment Non pharmacological treatment Type of follow up Date of entry to residential care	Has the patient public help? Does the patient have help from anyone other than those who live with the patient?

While the registries differ in their purpose, SveDem and NorCog are quality registers while BNA and ReDeGi are epidemiology registers, there are common data fields across all four main categories; for example, date of birth, sex, living arrangements, diagnosis. Not all fields are the same, however. Quality registries follow the person with dementia over time and continue to record data for this individual. Epidemiology registries continue to add new people with a diagnosis of dementia to their registers; most do not remove or mark the person's record when they die. There are also culturally specific data in some existing registries that are not relevant in the Irish context e.g. possession of a weapon license

4.3 Development of a minimum dataset for Ireland

Having undertaken the detailed literature review and obtained examples of registry datasets, our next step was to determine the data that was considered important from an Irish perspective. A combination of stakeholder workshops and expert guidance from the Steering Group facilitated this process. Four main categories of data emerged (see Figure 11). The combined feedback on each of these categories is discussed below, along with a description of each of the proposed data-fields per category. This dataset has been approved by the project Steering Group, the SIG and it has been reviewed by the NDO.

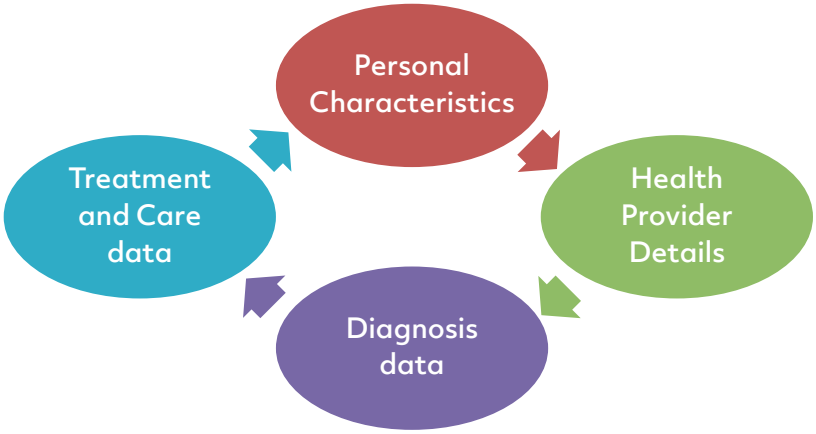

Figure 11 Dementia Registry Data Categories

The dataset should be kept open to review as informational needs change. The principle for considering data for the minimum dataset should be that they are directly linked to one or more registry outcomes and where possible, the data is gathered electronically from its original source.

4.3.1 Personal Characteristics

This category of data contains the personal and socio-demographic information pertaining to the person with dementia. In developing this data category, we were mindful of the data fields collected by the Individual Health Identifier (IHI) that was introduced through the Health Identifiers Act 2014. It requires that all healthcare providers to store the IHI for all their patients against each patient's record. The IHI is a unique number. The purpose of the IHI is to provide patient safety by identifying patients correctly and identifying their associated health records. The rollout of the IHI is key enabler of the delivery of eHealth as it provides the ability to identify multiple health records that may be associated with a patient. It will ensure ease of integration when this data is available for people with dementia. The rollout of the IHI number requires a once-off seeding for existing databases, the IHI Business Service using demographic details supplied by database will run this against the IHI database data fields (see Table 10) and find matches. It is important therefore that the dementia registry captures similar data to facilitate the matching process.

Personal characteristics also captures information relating to general health indicators, which is part of a wider public health message on disease risk factors and associated prevention measures. For these general health indicators we adopted the questions intended for use by the Chronic Disease Register at time of publication of this report.

Table 10 Interoperability considerations for personal data

IHI Data Fields		General Health Indicators (Chronic Disease Registry)
— Surname — Forename — Date of birth — Place of birth — All former surnames; for example, different names from different marriages — Mother's birth surname	— Address — Nationality — Personal public service number (if any) — Date of death (in the case of a deceased individual) — Signature — Photograph	— alcohol — smoking — weight, height, body mass index; and — physical activity

The SIG also felt it was important to capture living arrangements and family support networks available to person with dementia. Capturing the ability to maintain social engagement and if the person can drive, are associated with independence. Research demonstrates that both can have an impact on overall quality of life (Martyr et al., 2018; Sanford et al., 2018). The resulting personal characteristics component of the National Dementia Registry dataset is presented in Table 11 below.

Table 11 National Dementia Registry - Personal Characteristics dataset

Data Field	Type of Data field	Dropdown options if applicable
Registry ID	System generated	
Patient IHI number	Seeded	
Patient GMS⁺ (medical card number if known)	Alphanumeric	⁺*automated validation as per data rules*
Given name (First name)	Free Text	
Family name	Free Text	
Date of Birth	Date	
Sex at Birth	Dropdown	Male Female Unknown
Address	Free Text	
Eircode*⁺	Alphanumeric	**may be possible to link with an address finder if the eircode is provided* ⁺*automated validation as per data rules*
Marital Status	Dropdown	Single Married Separated Divorced Widowed Other
Living Status	Dropdown	Sheltered accommodation, Lives alone, no family, Lives alone, family/friends visit regularly, At home with partner, At home with family, At home no other information, In residential care centre, Other

Table 11 continued

Data Field	Type of Data field	Dropdown options if applicable
Socially active	Dropdown	Yes occasionally, Yes often, No
Physically active In a typical week how many days of physical activity 30+ mins	Dropdown	0 days 1-4 days 5-7 days Unable to be physical active No information available
If 4 days or less selected above in a typical week have you had either 150 mins of moderate or 75 mins of vigorous exercise	Dropdown	Yes No No information available
Hearing impairment	Dropdown	Yes long term deaf Yes acquired deaf No
Vision impairment	Dropdown	Yes long term Yes acquired No
Driving	Dropdown	Yes, Yes restricted license, Yes referred for assessment, No has stopped, No never drove
Education	Dropdown	No formal education/training Primary education Lower Secondary Upper Secondary Apprenticeship Degree Postgraduate degree/diploma PhD or higher
Employment status	Options	In full-time employment In part-time employment Not-working Retired
Employment What is /was the persons main employment	Free text	

Table 11 continued

Data Field	Type of Data field	Dropdown options if applicable
Intellectual Disability	Dropdown	Yes No
Aetiology of ID	Dropdown	Down Syndrome Yes Down Syndrome No
Weight recorded in Kg	Free text numeric	
Height in metres	Free Text numeric	
Body Mass Index	System generated BMI (Height, Weight)Numeric Kg/m^2	
How often do you have a drink containing alcohol	Dropdown	Never Monthly or less 2-4 times a month 2-3 times a week 4 or more times a week
How many drinks containing (10grams alcohol) do you have in a typical day when drinking	Dropdown	1-2 3-4 5-6 7-9 10 or more
How often do you have 6 or more drinks (10 grams each) on one occasion	Dropdown	Never Less than monthly Monthly Weekly Daily or almost daily
Smoking Status	Dropdown	Current (daily or occasional) Ex-smoker Never Unknown Not asked

4.3.2 Health Provider Details

It was agreed that this category of registry data should capture referral lead times but should not capture details about the clinic size, staffing and other organisational variables. These data are available elsewhere in the HSE and do not directly support the aims and objectives of the dementia registry. Referral lead times were considered important if the registry data would be meaningful and cognisant that there can be different avenues to a dementia diagnosis. Ideally measuring how long it takes from initial referral to diagnosis was felt to be most helpful, followed by the lead-time from referral to initial assessment. As referrals can be made from many locations, it is expected that the initial implementation of the National Dementia Registry (Phase 1) will focus on data that can be gathered in the location in which the entry is first made to the Registry; i.e. the diagnostic setting. In the longer term, the concept of 'clinic' as a data item will cater for alternative services or pathways to diagnosis and/or care.

Table 12 National Dementia Registry – Health Provider dataset

Data Field	Type of Data field	Dropdown options if applicable
Clinic ID	System generated through login	
Referral from	Dropdown	GP, Primary Care team member, Hospital inpatient, Hospital outpatient, Memory assessment service, Other
Date of receipt of referral	Free Text	
Date of Initial assessment for dementia	Free Text	
Date of Dementia Diagnosis	Free Text	

4.3.3 Diagnosis Data

There are currently no national clinical guidelines for the diagnosis of dementia in Ireland, but best-practice guidelines are available in other jurisdictions (e.g. National institute for Health and Care Excellence (NICE), 2018). The NDO is also currently working on diagnostic and post-diagnostic models of care. These models build on the work and outputs from the dementia diagnostic project with input from their National Expert Steering Group (Gibb & Begley, 2017; Gibb et al., 2019; NDO, 2019; Reves et al., 2018). In conjunction with international best-practice guidelines, they have supported the identification of appropriate diagnostic data to be included in the National Dementia Registry Model.

Stakeholder consultation highlighted that the registry, in addition to capturing the person who made the diagnosis, should also capture broad components of dementia testing. An important caveat was made during these discussions, namely the importance of not including specific test scores in the dataset. The rationale of the clinical experts in the group was that:

— tests will change over time; what is appropriate now may not be best practice in the future;

— different clinicians (and different specialities) will prefer different measures;

— different testing will be required for different kinds of people (i.e. the importance of individual context); for example, tests appropriate for someone with young onset dementia may not be appropriate for those with late onset dementia.

As can be seen from the diagnosis dataset presented in Table 13, the registry will capture the broad categories of testing that have been carried out for each registry participant. For this data to be meaningful, standardisation is required to ensure that clinically appropriate testing is conducted and that data is gathered in a way that comparisons can be drawn within and across diagnostic centres.

Future Action Point: There is a need for agreement (Irish guidelines) on the categories of diagnostic testing that should underpin these data fields (e.g., what constitutes a valid/acceptable cognitive test / functional test, etc.). The guidelines should align with the Irish dementia model of care in development, and with guidelines on the use of specific measures. It is unlikely that the model of care will recommend the use of specific tools (NDO, personal communication, August 23, 2020).

Table 13 National Dementia Registry – Diagnosis dataset

Data Field	Type of Data field	Dropdown options if applicable
Dementia Diagnosis	Data available	Vascular dementia Alzheimer's disease Mixed Alzheimer's/Vascular Frontotemporal dementia Dementia in Parkinson's disease Lewy body dementia Other (free text box) Unknown
Has the person been told about their diagnosis		Yes No – lack of capacity No – mental health issues No -other Not told
Translation to other disease classifications	System generated	Mapping above selection to ICD-10 and SNOMED

Table 13 continued

Data Field	Type of Data field	Dropdown options if applicable
Diagnosis made by	Dropdown	Geriatrician, Geriatrician led, MDT Psychiatrist, Psychiatrist led, MDT Neuropsychologist, Neuropsychologist, MDT Neurologist Neurologist led, MDT Nurse Nurse led, MDT GP
Brief cognitive test		Yes No
Comprehensive neuropsychological evaluation completed		Yes No
Neuroimaging testing completed (e.g. CT/MRI/MRI dementia protocol)	Data available	Yes No – person at the end of life No – imaging already available
Bio-markers completed	Dropdown	Yes No
Functional Evaluation	Dropdown	Yes No
Disease progression measure	Radio buttons choose only one measure to score	Clinical dementia rating (CDR) / Functional assessment staging test (FAST) / Global deterioration scale (GDS) CDR 0.5 / FAST 3 / GDS 2 CDR 1 / FAST 4 / GDS 3 CDR 2 / FAST 5 / GDS 4 CDR 3 / FAST 6 / GDS 5 FAST 7 / GDS 6
Disease stage (translation from disease progression measure)	System generated	Mild Moderate Severe

It was agreed, in discussion with the Steering Group that the dementia diagnosis should map to both ICD-10 and SNOMED data classifications. The suggested mapping is shown in Table 14. This mapping work was undertaken with the assistance of the HSE Clinical Terminology Architecture Lead, OoCIO (T. Barry, personal communication, 14 May 2020).

Table 14 Cross-classification mapping of dementia diagnosis

Irish Dementia Registry naming convention for dementia diagnosis dropdowns	SNOMED Fully Specified Name	ICD-10 Code	ICD term
Vascular dementia	429998004 |Vascular dementia (disorder)|	F019	Vascular dementia, unspecified
Alzheimer disease	26929004 |Alzheimer's disease (disorder)|	F009	Dementia in Alzheimer disease, unspecified
Mixed Alzheimer's/ Vascular	79341000119107 |Mixed dementia (disorder)|	F002	Dementia in Alzheimer disease, atypical or mixed type
Fronto-temporal dementia	230270009 |Frontotemporal dementia (disorder)	F020	Dementia in Pick disease/Frontotemporal dementia
Dementia in Parkinson's disease	101421000119107 |Dementia due to Parkinson's disease (disorder)|	F023	Dementia in Parkinson disease
Lewy body dementia	312991009 |Senile dementia of the Lewy body type (disorder)	331.82	Dementia with Lewy bodies
Other (free text box)			
Unknown			

Rather than selecting one disease progression measure to be used by all assessment clinics, it was also considered helpful if the registry could facilitate a range of measures and automatically translate the scores on these measures to a rating of the stage of dementia; namely mild, moderate or severe dementia. As a result, the Registry will accept scores from the three most commonly used disease progression scales: Clinical Dementia Rating scale (CDR; Morris, 1997); Functional Assessment Staging Test (Reisberg et al., 1984); and the Global Deterioration Scale (Reisberg et al., 1982). Each will be mapped to a single Registry data field, Disease Stage. The suggested mapping is presented in Table 15.

Table 15 Recommended mapping of dementia progression measures to registry disease stage

Disease State (Dementia Registry)	CDR	FAST	GDS
No Dementia (these options are not included in the registry)	CDR-0 No dementia	FAST Stage 1 Normal adult FAST Stage 2 Normal older adult	Stage 1 - No Cognitive Decline
Mild dementia	CDR-0.5 Very mild dementia	FAST Stage 3 Early Alzheimer's disease	GDS Stage 2 Very Mild Cognitive Decline
	CDR-1 Mild dementia	FAST Stage 4 Mild Alzheimer's	GDS Stage 3 – Mild Cognitive Decline
Moderate Dementia	CDR-2 Moderate dementia	FAST Stage 5 Moderate Alzheimer's	GDS Stage 4 - Moderate Cognitive Decline
Severe dementia	CDR-3 Severe dementia	FAST Stage 6 Moderately severe Alzheimer's FAST Stage 7 Severe Alzheimer's	GDS Stage 5 - Moderately-Severe Cognitive Decline GDS Stage 6 - Severe Cognitive Decline

4.3.4 Treatment and Care data

The Steering Group and the broader group of stakeholders acknowledged that we do not currently routinely capture this type of data, but that it is very important data from the perspective of a quality focused registry and steps should be made towards capturing these data even on a small scale. As a result, provision must be made within the minimum dataset for at least some relevant treatment and care data at implementation. Nevertheless, there is an understanding that the population of this data category is likely to build up over time and it will require better integration of health and social care data. The Steering Group identified the following treatment and care data that should be included in the registry minimum dataset:

— **Pharmacological treatment:** Medication often changes over time, so in order to future proof the dementia registry, it was felt that capturing drug category and the proportion of people treated with each category was most appropriate. Discussions illustrated a particular need to track the use of anti-psychotic drugs and it is clear that this is a salient concern given the prevalence of similar data in existing registry datasets. The data collected by the Irish registry will facilitate monitoring of the new national clinical guidelines on appropriate prescribing of psychotropic medication for non-cognitive symptoms in people with dementia (Department of Health, 2019a). These data are also in line with the WHO Global Dementia Observatory (World Health Organization, 2020b); a data and knowledge exchange platform that collects and provides access to key dementia data from member states. The WHO requests that member states confirm if medications/pharmaceutical treatment is monitored for people with dementia in their country, including the prescription of antipsychotics medication. It is possible that, at times, knowing which particular anti-dementia or anti-psychotic medication could be a helpful quality indicator. If this requirement arises, the potential to link to the Primary Care Reimbursement Scheme system will enable the registry to meet this requirement (see section 5.4).

— **Psychosocial treatment (intervention).** This type of data is largely absent in existing registries. Although related outcomes were prioritised by all stakeholder groups, it will be difficult to source this data for the Registry. Psychosocial interventions are not routinely offered in Ireland and data pertaining to these types of interventions is typically only captured as part of related research and evaluation studies. The NDO is currently conducting is developing dementia diagnostic and post-diagnostic models of care, which include guidance on core post-diagnostic support (functional; psychological/emotional; social and cognitive interventions). The progress of these projects have guided the data that has been recommended for inclusion in our minimum (NDO, personal communication, 2020).

— **Consideration of the carer.** Stakeholders emphasised the need to include the carer (or supporter) of the person with dementia as an embedded concept in the registry. Carer contact information will be captured as part of the personal characteristics dataset (see section 4.3.1). Here, a measure of carer quality of life was suggested. Recommended data for the treatment and care data category are presented in Table 16.

Table 16 National Dementia Registry – Treatment and care dataset

Data Field	Type of Data field	Dropdown options is applicable
Dementia medication	Dropdown	Yes - taking prior to this visit Yes - commenced at this visit No – as the dementia diagnosis is unclear No - previously intolerant
Anti-depressant medication	Dropdown	Yes No
Anti-Psychotic medication	Dropdown	Yes No
Benzodiazepines	Dropdown	Yes No
Total number of medications the person is taking	Free text	Number
Has a personalised care plan been created	Dropdown	Yes No person has no capacity No person wished not to participate No person was not given the opportunity No other specify …free text
Who created the care/support plan created by	Dropdown	Clinician Clinician + Family Clinician + Patient Clinician + Patient + Family Care Team (MDT) Care Team (MDT) + Family Care Team (MDT) + Patient Care Team (MDT) + Patient + Family Unknown
Current Supports	Radio buttons Multiple selection possible	Day care – current – planned In-home care – current - planned Residential respite in the last 12 months -Yes –No Not documented

Table 16 continued

Data Field	Type of Data field	Dropdown options is applicable
Psychosocial interventions Post-diagnostic Support	Radio buttons Yes No - Referred Not documented Multiple selection possible	Information and advice about their dementia Psychosocial supports to help stay connected (includes social activity and engagement)? Support to maintain a healthy lifestyle (includes nutrition, exercise, alcohol and smoking)? Cognitive support (includes cognitive rehabilitation, cognitive stimulation therapies)? Support to maintain emotional wellbeing (includes counselling, psychology, peer support)? Support for non-cognitive symptoms of dementia (includes occupational, environmental and psychosocial interventions such as music, play therapy, etc.). Assistive technology Other? (Please state…..)
Has there been a discussion on advanced care planning? If yes: Has an advanced care plan been developed?	Dropdown	Yes No Referred Not documented
Has this person a dedicated single point of contact within the health service	Dropdown	Yes If yes, please state No Unknown
Has this person a case manager	Dropdown	Yes (If yes please state…) No Unknown
QoL-AD Quality of Life measure carried out with the person who has dementia	Free text	Number
WHOQOL Quality of Life measure carried out with Carer	Free text	Number
Date of Death	Date	Valid Date

Future Action point: The NDO expects to publish the Diagnostic and Post Diagnostic Dementia Models of care in early 2021. The hope is that the next step will be to develop Key Performance Indicators (KPIs) for dementia in Ireland. These should incorporate relevant PROMS for diagnostic and post-diagnostic dementia care.

4.3.5 Measuring Quality of Life (QoL)

There is a lack of consensus regarding the most appropriate outcome measures to use with regard to QoL for people with dementia (Harrison et al., 2016). Each measure has its supporters and opponents, and it can be argued that a comprehensive holistic assessment of the person with dementia yields far more useful information with regard to QoL than a single scale ever could. This may at least partly account for a lack of traction in the use of standardised measures in clinical practice. Nevertheless, the measurement and of QoL and having the ability to monitor changes in QoL over time is essential to the person experiencing dementia and to their families and those who care for them. It was the highest priority outcome for almost all stakeholders involved in this project, and having a standardised way of measuring this construct would be beneficial as it would enable the registry to examine findings across dementia sub-types, settings, regions, countries and indeed any differentiating characteristics of people with dementia and/or care provision that are captured in the registry. In addition, it would enable the pooling of clinical and research data to identify the impact of potential treatments and interventions (Harrison et al., 2016; Ioannidis et al., 2014).

ICHOM (2020) recommend using the Quality of Life in Alzheimer's Disease (QoL-AD; Logsdon, 1999), the Quality of Well-Being Scale (QWB; Kaplan et al., 1993) or the EuroQol EQ-5D (1990)outcome measures. The QOL-AD is the most frequently used of these measures; the use of the other measures remains limited (Harrison et al., 2016; Moniz-Cook et al., 2008). For example, QOL-AD is currently captured by the Norwegian Dementia Registry. It is a brief measure (13-items) that has been found to be sensitive to the effects of psychosocial interventions (Spector et al., 2003) widely translated and correlated with health-utility measures (Moniz-Cook et al., 2008). As QoL is a subjective construct, the preference is to gather self-reported QoL from the person with dementia. In more advanced cases, this may not be possible and a proxy version of the QOL-AD can instead be completed by the primary caregiver.

Two distinct concepts exist in relation to carer QoL, one associated with general health and another that is disease-specific (Moniz-Cook et al., 2008). There is similarly a range of different measures available in each category that can be used to assess QoL among those caring for people with dementia. Again, there has been no consensus regarding the most suitable carer QoL measures and new dementia-related measures continue to be developed (e.g. C-DEMQOL; Brown et al., 2019). At this point in time, the WHO Quality of Life Assessment (WHOQOL-BREF) tool would appear to be the most suitable (The WHOQOL Group, 1998a). It is a cross-cultural internationally validated multi-dimensional measure that has been used successful in studies with dementia caregivers.

In conclusion, we are recommending the inclusion of standardised QoL measures in the National Dementia Registry in an attempt to meet a key priority of the Registry, while promoting the importance of PROMs and the attractiveness of the Irish data for inclusion in research reviews and meta-analyses. The inclusion of these measures does not preclude the determination of an alternate method of appraising QoL for people with dementia in a clinical context, nor does it prevent a further review of progress in relation to carer QoL dementia-specific measures at the point of development of the Registry. For example, there is a distinct PPI study underway in Norway to explore dementia-related PROMS and PREMS (G. Selbaek, personal communication, 21 August 2019), the output of would be important to take into consideration when available.

4.3.6 Capturing date of death

It is important that the registry remains current. If a person with dementia dies, they will be removed from the national dementia registry (the data would remain in registry archive). The Department Social Affairs, General Registrations Office maintains data relating to all Births, Deaths, and Marriages registered and are the owners of death certificate data. It may be possible for the registry to obtain electronic death certificates from this department and also to consider entering a memorandum of understanding with the central statistics office who could add value by analysing the underlying cause of death and pull this together extracting persons with dementia. In Quarter 1 2020 there were 539 deaths due to dementia of which 338 (or 62.7%) were female (Central Statistics Office, 2020). There were 176 deaths due to Alzheimer's, of which 110 (or 62.5%) were female. Rationale for specific exclusions from the minimum dataset

Our review of existing dementia registry datasets identified a small number of routinely collected data fields that, following discussion, we determined would not be included in the Irish National Dementia Registry. These data and the rationale for their exclusion are presented in Table 17.

Table 17 Potential data fields excluded from the minimum dataset.

Data Field	Rationale for exclusion
Ethnicity	The Steering Group highlighted data protection issues associated with the collection of this type of data. A decision was made to be guided by the IHI data fields; ethnicity is not captured in the IHI. As a result, it will not be captured here.
Number of hospital admissions	The WHO global dementia observatory asks countries if the number of hospital admissions for persons with dementia are monitored. The Steering Group view was that this data would be available in HIPE and data replication should be avoided where possible. Furthermore, automatic population in HIPE is likely to yield data that are more reliable in the longer term. There was also an acknowledgment that this information could be available from GP data. Linkages to primary care data could and should be the focus of a future phase of registry development. Methods of extraction of data from general practice and other sources would need to be modelled and agreed.
Comorbidities Clinical History Previous head injury Previous cardiovascular event	The overall view from the Steering Group and from the SIG was that clinical history was important data, but that this information is captured elsewhere and to avoid data replication, health information systems should be able to link dementia registry data to these data via the IHI and Electronic Health Record (EHR). Although there was a recognition that IHIs and EHRs have not yet been fully rolled out, it would be a huge challenge for Registry staff to find the appropriate data in paper records and to re-enter these into a Registry database when this is the purpose of the EHR.
If this is an existing client when did they last visit the clinic	Data will only be captured once a person has received a formal diagnosis of dementia. Over time, registry records will show the history of visits to a clinic. If the person was a client of a clinic (i.e. a person previously diagnosed with MCI) that data will not be tracked. Clinics will have their own records and the expectation is that registry data pertaining to a particular clinic can be made available to that clinic for their own analysis and reporting purposes.
Dependents	Removed as rarely collected by other dementia registries and no clear purpose for this data emerged from discussion. In addition, data is expected to be weak or unclear (e.g. use of a consistent definition of dependent). The omission of this data field will preserve the overall quality and accuracy of the registry.

4.4 Linking data to outcomes

Table 18 shows the linkage between the prioritised quality indicators for the National Dementia Registry and the corresponding data field in the minimum dataset. In addition, a recommendation has been made regarding the phase of development most suited to each data field. This decision was driven by the priority of the related outcome and the potential availability and likely source of the data, each of which is discussed in more detail in the next chapter. One outcome (O14) was excluded from the Registry (see Table 19).

Table 18 National Dementia Registry data fields mapped to prioritised outcomes

Rank	Top 15 Quality Indicators	Corresponding field from minimum dataset used to calculate outcome measure	Suggested Phase
O1	Proportion of patients undergoing basic dementia work up (i.e. an agreed standard of basic tests that should be run when dementia is suspected).	The registry will be able to provide the % of persons who had the following evaluations completed. — Brief cognitive test — Comprehensive neuropsychological evaluation completed — Neuroimaging testing completed (e.g. CT/ MRI/MRI dementia protocol) — Bio-markers completed — Functional Evaluation Further guidance will be needed to define basic dementia work up before this can be measured	Phase 1
O2	Overall quality of life of person with dementia	Quality of life measure carried out with the person who has dementia QoL-AD	Phase 1
O3	Proportion of patients with dementia who receive a specific dementia diagnosis	Dementia Diagnosis data field Vascular dementia Alzheimer's disease Mixed Alzheimer's/Vascular Frontotemporal dementia Parkinson's disease dementia Lewy body dementia Other (free text box) Unknown	Phase 1
O4	Overall Quality of Life and wellbeing of Carer	Quality of life measure carried out with the carer WHOQOL	Phase 1
O5	Proportion of patients treated with antipsychotic drugs	Anti-Psychotic medication data field	Phase 1
O6	Time waiting for home support services	No data capturing this electronically at the moment	Phase 2 (integration of care data)

Table 18 continued

Rank	Top 15 Quality Indicators	Corresponding field from minimum dataset used to calculate outcome measure	Suggested Phase
O7	Proportion of patients treated with anti-dementia drugs	Dementia medication data field	Phase 1
O8	Proportion of patients who have follow up or referral after the initial assessments	Care Plans Post-Diagnostic Support data field	Phase 1
O9	Time from start of investigation (1st contact with person) to diagnosis (number of days)	Data fields Date of referral – Date of initial assessment Date of initial assessment – date of dementia diagnosis Can show both lead times	Phase 1
O10	Disease progression	Disease progression measure – data field	Phase 1
O11	Proportion of patients who have a standard care plan	Has a personalised care plan been created – data field	Phase 1
O12	Proportion of patients in which the ability to continue driving has been assessed	Driving data field	Phase 1
O13	Proportion of persons with dementia who have day-care	Type of therapeutic interventions offered includes day care	Phase 2 (integration of care data)
O15	Time from diagnosis of dementia to permanent residential care	Registry data fields registry in Phase 1 will record the date of diagnosis and living status field	Further data fields will be required in Phase 3+ (extension of registry to LTC sector).

Table 19 Prioritised outcome excluded from the National Dementia Registry

Outcome	Rationale for exclusion
014 Proportion of patients who undergo an annual medications review	After extensive Steering Group discussion this outcome was removed as the view of the group was that it was more important for the person to be on the right medication rather than the timing of medications reviews which differ depending on the care setting

SUMMARY

A key deliverable of this project was to develop and reach agreement on a minimum data set for the National Dementia Registry. The creation of this dataset was driven top-down by the agreed registry quality outcomes and it therefore retains a quality focus that is extensive across a number of domains. In addition, it is informed from the bottom-up by the data that is routinely collected by existing quality focused dementia registries.

Having undertaken the detailed literature review and obtained examples of registry datasets, a combination of stakeholder workshops and expert guidance from the Steering Group facilitated the development process. The dataset contains all four main categories of data (see Table 27 for a summary of the full dataset):

1. Personal Characteristics
2. Health Provider Details
3. Diagnosis Data
4. Treatment and Care Data

Throughout development of the dataset, there was a focus on future proofing and interoperability with a view to potential linkages to data sources over time. Agreeing a minimum dataset for the registry will in itself bring standardisation and will assist memory clinics, hospitals, and GPs to collect information and report dementia efficiently. In addition, having a minimum data will allow data comparison nationally and internationally, by centre, geographical location, service use, type of dementia and other variables within the dataset as needed. The minimum dataset can be reviewed over time, as information needs change. At all time, the data gathered should be directly linked to an outcome variable and the principle of interoperability should be maintained (i.e. if the data is gathered elsewhere, try to use the data from the original source).

5 Identification of Potential Data Sources

In Ireland, dementia-related data is collected and captured in multiple locations; for example, in primary and secondary care settings, and in public and private parts of the health service. As a result, there is no one obvious source of data from which to populate the National Dementia Registry. In addition, many of the data fields required to support the desired outcomes of the Registry are not currently captured in any setting.

Given the spread of data across multiple settings, confirming a legislative basis for disease registries under GDPR, or an alternative statutory instrument, would be extremely helpful with regard to data collection and management. A more detailed consideration of the legislative framework within which the registry will operate is provided in Section 1.4.2.

For the purposes of analysing potential data sources for the National Dementia Registry, this chapter is agnostic to the public/private status of the diagnostic centre. It also makes the assumption, unless otherwise stated, that although data is not currently integrated within the health service, this is a goal of the existing health data strategy. At some point in the future, it will be possible to gather dementia data electronically and integrate these data easily. With this in mind, we examined a range of potential data sources and this chapter provides an overview of the type of dementia-related data currently collected in various settings and the suitability of this data as a data source for the registry.

5.1 Memory Clinic Data

There are c25 memory clinics spread across Ireland. Memory clinics make a formal diagnosis of dementia having carried out a number of different assessments.

Using Memory Clinic data to populate a Dementia Registry

A questionnaire was issued to all the memory clinics to gather the details of the data they collect and to understand whether this information was captured electronically or stored manually in paper files.

Ten memory clinics responded from counties:

- Dublin (4)
- Louth (1)
- Laois (1)
- Roscommon (1)
- Kilkenny (1)
- Wexford (1)
- Cork (1)

Figure 12 Memory Clinics in Ireland

The results of this exercise showed that memory clinics have a great amount of relevant data, but all clinics responded stating that these data are predominantly paper-based. A small number of clinics keep a spreadsheet but this is primarily to track the number of people seen and to assist with funding of certain resources such as memory technology rooms. In addition, memory clinic assessment forms are not standardised. This results in variation not only of the types of data currently being collected by clinics, but also of the measures used to collect these data and the way in which these data are recorded. Table 20 outlines the types of data collected by the clinics.

Table 20 Characteristics of Memory Clinic data based on survey responses

Personal Characteristics					
Name	10	Date of Birth	10	Patient Address	10
Sex	10	Language	9	Ethnicity	2
Living condition (patient current living arrangements; e.g. live alone, with someone)	10	Marital Status	9	Social Activity, hobbies	9
Education	9	Employment	8	BMI	5
Falls	10	Driving License	7	Date of Death	4
Health Provider Details					
Where patient was referred from	10	Date – of first visit	10	Time needed for Diagnosis	3
Visit Type (e.g. second opinion, informational visit)	7	Follow up status	7		
Diagnosis Data					
MoCA	9	MMSE	8	IADL	10
Dementia Rating Scale	2	Neuroimaging	6	Bio markers	3
Neuropsychologist interview	3	Date of dementia diagnosis	9	Diagnosis	9
Symptom Presentation	9				
Treatment and Care					
Pharmacological treatment –drugs	8	OT Physio Speech Therapist	6	Care – Is a Care plan activated?	7
Supports /Allowances	8				

Potential of using Memory Clinic data to populate the Dementia Registry

Memory Clinics capture a rich source of data for a dementia registry.

Data is mostly stored in paper records.

Potential data source rating: High **Indication of data quality:** Medium

Potential for electronic integration: Low at present. In the absence of electronic health records in the memory clinics, the introduction of the dementia registry would offer a mechanism and a potential inducement to move towards capturing data electronically.

Recommendation: We recommend that there is standardisation of data collection across memory assessment clinics. That is not to say that all memory clinics would be required to use the same measures to collect these data (e.g. the same cognitive tests), but that they all conduct a cognitive test(s) that meets the required diagnostic standards as defined in the forthcoming National Dementia Care Model (NDO).

5.2 Hospital In-Patient Enquiry (HIPE) System

The HIPE system is used in most (not all) hospital settings across Ireland (See Appendix G), HIPE collects data relating to inpatients, day patients and emergency admissions, and it is used to record an episode of care. HIPE does not record outpatient data, including memory assessment and dementia diagnoses made in outpatient clinics. The data record is populated when the patient is discharged from hospital. It contains primarily administrative and demographic data.

Using HIPE data to populate a Dementia Register

HIPE records a persons' date of birth, sex, area of residence, postal district/eircode, marital status, and medical card. The living arrangements of the patient will be captured in HIPE if they have an impact on patient care (code Z602 refers to living alone and it is inserted under the diagnosis code where relevant). HIPE also captures the Hospital code. In terms of a diagnosis, HIPE coders enter whatever has been written by the clinician in the patient file. Dementia may not be recorded anywhere by the clinician, particularly if it is a secondary condition. Moreover, clinicians do not always know the subset of dementia, which is a challenge for secondary coding. HIPE currently uses ICD-10 for disease classification. Diagnostic test information is also not recorded in HIPE. The National Integrated Medical Imaging System (NIMIS) does store neuroimaging information (HIPE staff have read only access to NIMIS_ and information relating to EEG is held in the Intellspace system. Blood test results are held in yet another separate system. If performed, MMSE and IADL data are found in the Hospital Patient paper file. HIPE records if the patient has seen a pharmacist, but the medication detail would only be available from examination of the physical patient file. Integration across all of these sources would be required to support the use of HIPE as a potential data source.

Potential of using HIPE to populate the Dementia Registry

HIPE holds a discreet pocket of registry data. Reports can be generated from the HIPE system to show the number of people with a dementia code who presented in a specified year and received an episode of care. It is unfortunate that HIPE does not contain outpatient hospital data from dementia clinics and consolidation of hospital data should be considered.

HIPE data is unlikely source for population of a dementia registry, however it holds an important wealth of information that could be combined with registry data in the longer term; for example, to provide additional statistics on falls and other injuries as they relate to people with dementia.

Potential data source rating: Low **Indication of data quality:** Medium

Potential for electronic integration: High (dependent on availability of IHI in both the Registry and HIPE).

5.3 GP Systems

There are four GP practice management software systems – Complete GP, Socrates, Health One and Helix Practice Manager, and the systems are quite different in structure. The software manufacturers are CompleteGP and Clanwilliam.GP systems will have the facility to record most but not all of the personal characteristics data needed by the registry. While most GPs operate electronic records, the tendency is to record what is needed for the purposes of providing primary care. GP interactions with other health services remain significantly paper based. Information that GPs receive from other care providers often arrives on paper that has to be scanned into the system. The lack of specific dementia data and the reliance on scanned information complicates potential data extraction.

Using GP systems to populate a dementia registry

Many GP's in Ireland operate as a sole trader or in a partnership making standardisation difficult. Extracting dementia data from GP systems may involve building on the systems' search functionality. If the GP is a member of the Irish Primary Care Research Network (IPCRN), the dementia uploader report could be used. This report contains the following information (McLoughlin et al., 2017):

- demographics of people coded with dementia
- the number of people prescribed antipsychotic medications in the last 12 months
- the number of people prescribed cholinesterase Inhibitors in the last 12 months
- smoking status
- flu vaccination in the last 12 months
- alcohol consumption
- consultation frequency and consultation visit code
- prescribed medications in the last 12 months

It is important to note that these data will only be available if they have been entered onto the GP's system. There is no requirement to capture these data as it currently stands. It may also be possible to build the functionality of this report into GP systems or rollout the report to all GPs regardless of their IPCRN membership status.

It may also be possible to detect people with suspected dementia through prescription of certain medication e.g. Cholinesterase Inhibitors. The Greek Registry team, for example, as part of their preparation towards developing a dementia registry, have added a template into their prescribing platform that GP s must fill in regarding dementia diagnosis (A. Politis, personal communication, 10 June 2019). This may be viewed as putting an additional burden on GP's, but it must be recognised that using primary care data as a source, even if that is one of many, for the Dementia Registry, will require better coding of dementia (and related data fields) by GPs.

Potential of using GP systems to populate the Dementia Registry.

While GPs use electronic systems, the use of free text boxes and scanned documents make data retrieval difficult. Dementia data can only be extracted from GP systems if it has been entered into the system. In addition, GPs seldom select specific disease classification codes. There is potential for data improvement in relation dementia risk factors with the introduction of the Chronic Disease Registry and the associated incentive to accurately capture data required by that system (e.g. BMI, smoking, alcohol, and exercise). Other registries have tried to improve the coding of dementia in primary care by including a pop-up alert where a GP prescribes dementia medication without having recorded a diagnosis for dementia. Further analysis of the merits of this approach would be required in conjunction with the Irish College of General Practitioners (ICGP).

Consequently, we view GP data as a potential long-term registry source. Indeed, a number of existing dementia registries (e.g., SveDem, ReDeGi) created their initial registry using secondary care data and in a later phase, extended the Registry to include primary care data.

Potential data source rating: Medium **Indication of data quality:** Low

Potential for electronic integration: Medium (dependent on data quality improvement)

5.4 Primary Care Reimbursement Scheme (PCRS)

The PCRS database is a comprehensive medications database that captures:

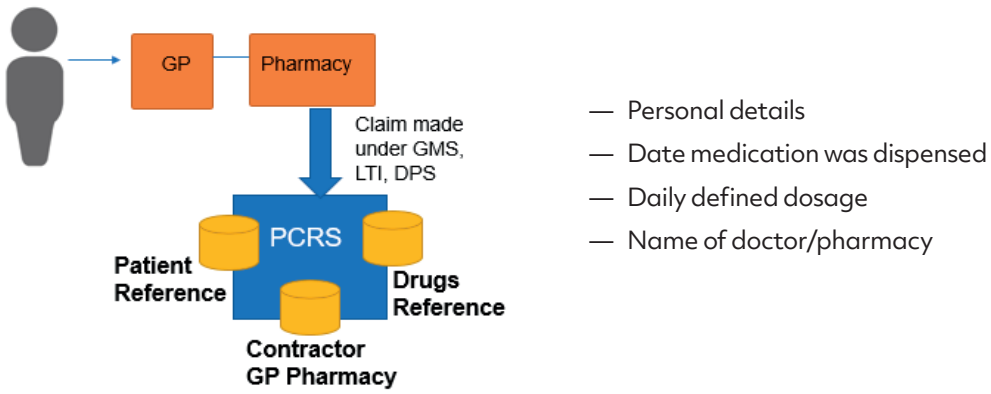

Figure 13 Overview of PCRS system

The Drugs Reference Database contains the Anatomical Therapeutic Chemical (ATC) code. This is a unique code assigned according to how it words on particular organs or systems. This medication classification would make it possible to extract information relating to all those individual's taking prescribed dementia medication and/or anti-depressant or anti-psychotic medication, or benzodiazepines.

Using PCRS to populate a Dementia Register

Using PCRS as a source for the Dementia Registry assumes that everyone taking dementia medication has a diagnosis of dementia. Given the rate of undiagnosed dementia in the country, this may not always be the case. It could be argued that PCRS would be a mechanism to identify these individuals, which delivers a benefit in its own right. As PCRS currently could only provide a subset of data for the registry relating to medication, it means that in the absence of integrated systems, it would be difficult to gather the other data that the registry needs for these individuals in a reliable and valid way.

Potential of using PCRS to populate the Dementia Registry

PCRS provides a discreet pocket of data with a narrow focus that could be valuable source of information for the registry. The database could be mined for the purposes of carrying out an annual audit to identify persons on dementia medication who possibly remain without a formal diagnosis. If medical records for an individual were integrated across the health system, or if IHIs were rolled out, even if that is limited to people with a diagnosis of dementia, PCRS would be a potential source of medication data.

Potential data source rating: Low **Indication of data quality:** High

Potential for electronic integration: High (dependent on availability of IHI in both the Registry and PCRS).

5.5 interRAI™ Ireland (formerly the Single Assessment Tool pilot project)

interRAI™ is a not-for-profit collaborative network of researchers and practitioners in over 35 countries who are committed to improving care for persons with disabilities and those whose care is classified as medically complex. The interRAI™ consortium strives to promote evidence-informed clinical practice and policy decision making through the collection and interpretation of high- quality data about the characteristics and outcomes of people served across a variety of health and social services settings. The HSE has selected interRAI™ as the standardised clinical care needs assessment of choice within Services for Older People. It is a key enabler for the programme of reform in Services for Older Persons supported by the strategic direction set out under Sláintecare, the HSE Corporate Planning processes and the National Clinical Programmes.

An interRAI™ detailed assessment is captured in electronic format and when fully complete, it provides a comprehensive picture of an older person (see Figure 13). All of the interRAI™ assessments have inbuilt software algorithms that stream assessment information into several different interRAI™ outputs and scales to support effective, outcome focused, individualised care planning (HSE,2020b). At an aggregated level, these outputs support service provision/ development, service prioritisation, quality monitoring, case-mix funding, and policy decision-making.

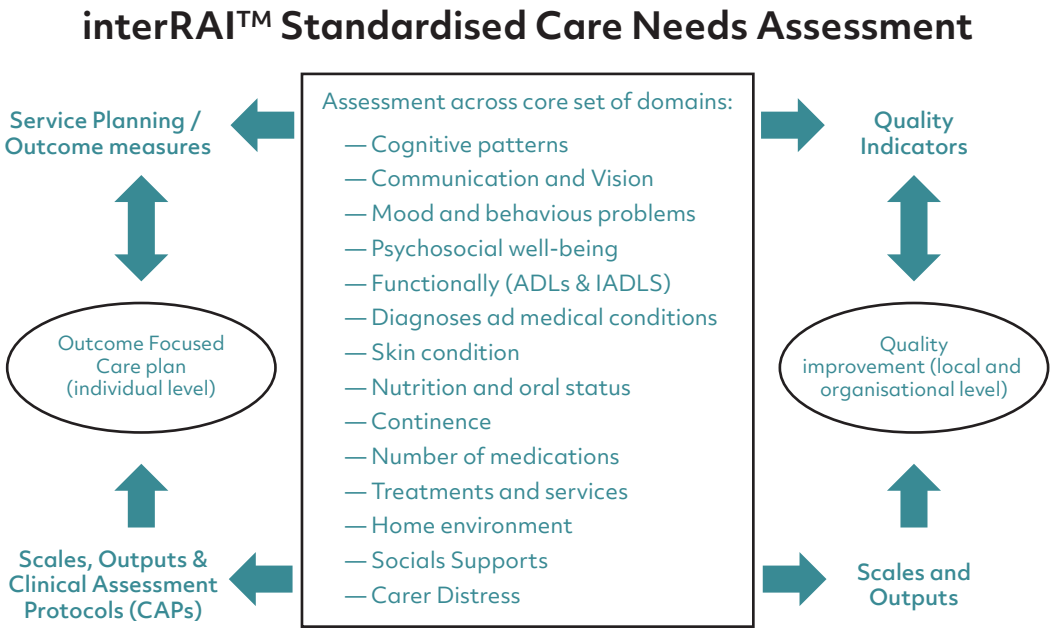

Figure 14 Overview of the interRAI™ Assessment

The implementation of interRAI™ is proceeding beyond the pilot sites and it is replacing CSAR assessments in a number of locations across CHOs as displayed in Figure 15. Remaining CHOs are in the process of training (HSE Inter-RAI Team, personal communication, October 23 2019. As of end of Q3 2020, over 8,000 older people have been assessed using interRAI™. An EU procurement exercise has concluded resulting in a new software vendor to progress and further develop the interRAI™ system across all areas in 2020/21. It is anticipated that interRAI™ will be tested for use as the standardised assessment for the Home Care legislative Scheme. (DoH, personal communication, December 4 2019).

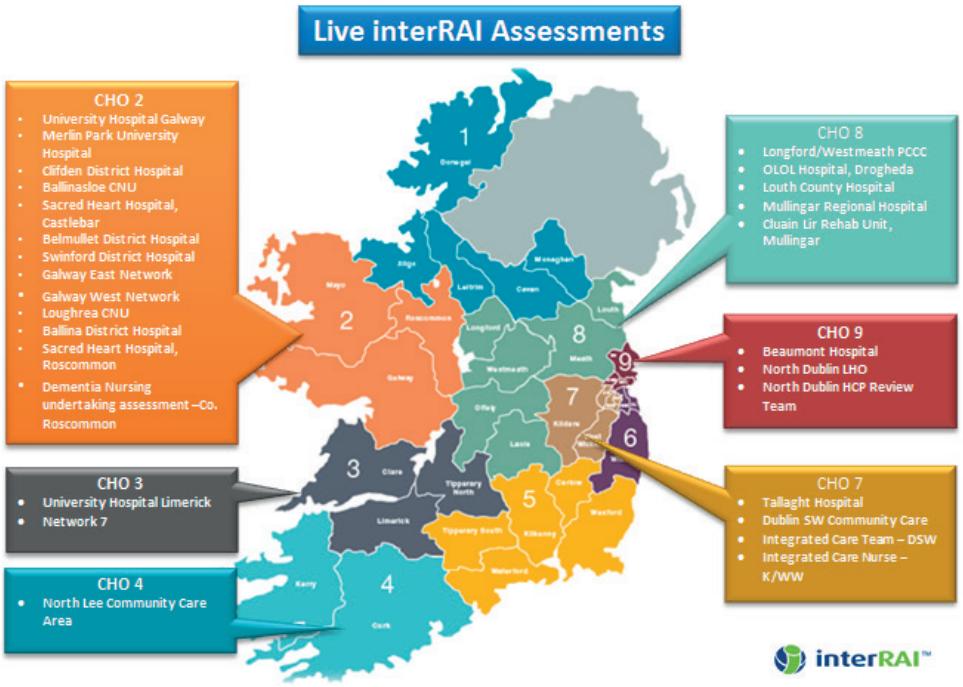

Figure 15 InterRAI™ rollout map

Using InterRAI™ data to populate a Dementia Register

Of the 36 countries who are members of the interRAI™, nine have an existing Dementia Registry and a further two are in the process of developing a registry. To the best of our knowledge, no country currently uses interRAI™ as a direct source of data for their registry.

Sub-sections of the interRAI™ assessment form (which cannot be included here, as interRAI™ does not permit publication of its assessment forms) would be useful from a dementia registry perspective as the assessment captures information including:

— **Patient characteristics** - including name (first middle last), title, gender (male/ female), marital status, postal code and the persons current living arrangements (whether living alone or with family).

— **Disease diagnosis** - 'Alzheimer's disease' and 'Dementia other than Alzheimer's disease' are available to be selected by the assessor. In addition, a separate window opens within the assessment linking to an ICD-10 disease classification table.

— **Psychosocial wellbeing** - the social relationships of the person including whether they are lonely, if that has changed in last 90 days, length of time alone and life stressors. An additional section documents the person's activity preferences and involvement, details about daily living activities and if the person has been driving in last 90 days.

— **Medications** - including the number of medications, adherence to medications, recent medication changes and if there is a need for a medication review.

interRAI™ also has a separate Carer Needs Assessment tool that is due to be piloted in 2021. This would be the first standardised attempt to capture data relating to the specific needs of Carers and includes the following sections: (a) Family Carer Identification Information; (b) Family Carer: Cognition, Comprehension, Vision; (c) Family Carer: Social Needs; (d) Family Carer: Function/Endurance/Stamina; (e) Family Carer: Self-Reported Mood; (f) Family Carer: Health/Clinical Conditions; (g) Client-Carer Relationship; (h) Family Carer Role; and (i) Life Satisfaction/ Contingency Planning.

Potential of using interRAI™ to populate the Dementia Registry

interRAI™ could potentially be a great source of data for the Dementia Registry in the mid to long term once it is has been rolled out across the country. It would be important to audit the dementia diagnosis data that has been captured to date, as there is a sense that not all dementia diagnoses have been appropriately captured (HSE interRAI™ team, personal communication, July 25 2018.)

Potential data source rating: High **Indication of data quality:** Unknown

Potential for electronic integration: High (dependent on national rollout and confirmation of data comprehensiveness and quality).

5.6 Patient Summary Record

HIQA is in the process of defining a minimum set of data for a national electronic patient summary record (Health Information and Quality Authority, 2018). This is being developed as part of an EU initiative to make electronic patient summaries (with opt-in patient consent) available across member states. The overall benefit of the patient summary record is to assist clinicians treating a patient in an emergency out-of-hours situation or if visiting a doctor in another country. Roll-out was initially expected to be in place by March 2020, but following delays connected with data protection, the 22 member states who are part of the eHealth Digital Service Infrastructure (including Ireland) are expected to exchange such data by 2021 (European Commission, , 2019).

Using the Patient Summary Record to populate a Dementia Registry

Relevant categories of information that are expected in the patient summary record, as outlined in National Standard on information requirements for a national electronic patient summary (HIQA, 2018), include:

— **Subject of Care** – Title (**o**ptional), Forename (**m**andatory), Surname (m), Address (m), DOB (m), Sex (m), Health Identifier (o), Next of Kin (m).

— **Health Condition** - Current Health Condition (m), Clinical Description (o) narrative, Date of Onset (o), Status (m), Date resolved deactivated (o), No health conditions identified (o).

— **Medication** - Medicinal Product (m), Dose Strength (m), Dose form type (m), Number of units intake (m), Frequency of intake (m), Duration of treatment (m), Date of start of treatment, No medication prescribed (o).

Potential of using the Patient Summary Record to populate the Dementia Registry

The Patient Summary Record contains limited data, not all of which is mandatory. A number of the data fields could be relevant to the Dementia Registry but these may also be available from other data sources (e.g. PCRS, IHI). On a positive note, the summary record is one of the few datasets that has been developed with standardisation and interoperability in mind, which would facilitate data sharing.

Potential data source rating: Low **Indication of data quality:** Unknown

Potential for electronic integration: Medium (alternative sources may have more data required by the Dementia Registry)

5.7 Electronic Health Record (EHR)

The National Electronic Health Record (EHR) has been identified as a cornerstone of Ireland's eHealth Strategy (DoH, 2019b) and it aims to develop an electronic record that captures all clinical information relating to an individual over time. This record will be available to health and social care professionals and, importantly, to the individual themselves. IHIs, as discussed in section 4.3.1> above, are a critical pre-requisite for EHRs (OoCIO HSE, 2016) as they provide the unique identifier needed to match individuals and their health records, and to track their touchpoints through health and social care services over time.

The implementation of EHRs is not just about linking people's data together. A vital element of this programme is the development of 'Integration Capability' that enables patients data to be shared across systems with appropriate consent. It is essentially "*the glue that binds the system together and ensures the security of the information being transmitted*" (OoCIO HSE, 2016, p. 16). With the advent of EHRs, patient data is no longer in a paper file tied to a physical location (for example, in a Memory Clinic). EHRs enable Health Information Exchange – the sharing of comprehensive and accurate health and social care data across services the individual comes in contact with, crossing geographical, sectoral and organisational boundaries as required (Fennelly, 2019). This in turn enables greater clinical collaboration and richer health intelligence on which to base decisions.

The importance of EHRs was further underlined in the Sláintecare Report (Houses of the Oireachtas Committee on the Future of Health care, 2017, p. 27), who clearly identified the need for "*continued strong support of the e-health strategy – particularly ensuring the necessary funding for the timely roll-out of the EHR system*". Ireland's eHealth Strategy (DoH, 2019b) presented plans to roll out a unique health identifier by 2018, and although the IHI has been rolled out in parts of the health system, neither people with dementia nor the services that support them are as yet using IHIs. There is currently no publically available date for the completion of IHI rollout.

Using the EHR to populate a Dementia Registry

The combination of EHRs and IHIs provide the ideal mechanism for gathering health and social care data, tracking people over time, identifying trends, informing and improving patient care and ensuring patient outcome measures are met. In other words, they provide a mechanism that links all of the data about a person together, thus providing the basis of a data hub whereby the EHR data can be mined to provide appropriate health and social care intelligence that in turn can drive better clinical and patient outcomes.

The availability of EHRs and the integration capabilities required for their creation would fundamentally change the approach to creating patient registries in Ireland. Data would no longer be disease-specific; instead, data can be extracted to suit the needs of a variety of stakeholders. From the perspective of the National Dementia Registry, for example, EHRs could be interrogated to determine the prevalence of people with dementia (in Ireland, by CHO, by health provider, etc.). The same set of EHR data can also be interrogated to examine all those with dementia and Type II diabetes, or all those with dementia who had a cardiovascular event in the past, and so on. EHRs would truly unleash the power of the data that is routinely collected within the health system while reducing the need for data replication. The Dementia Registry would identify the sub-set of data that is relevant to dementia and required in order to measure desired outcomes. It would gain access to these data with appropriate consent or under the provision of appropriate legislation and Registry, processes would become focused on how to interrogate and add value to these data to produce the health information needed by various stakeholders. The Registry would then curate this information over time.

Potential of using the Electronic Health Record to populate the Dementia Registry

Unfortunately, EHRs are not currently available in Ireland. When this project commenced, there was an expectation that EHRs would become available over the next five years. We did not expect EHRs to be available in the lifetime of this project, but there was an expectation that all new systems would need to conform to the HSE evolving Data Dictionary guidelines and that integration and interoperability standards would be available that could drive the technical design of the Registry. Unfortunately, the anticipated progress has not been made either in relation to IHIs or to EHRs. At this point, it is difficult to say when EHRs are likely to be available and when they are likely to be rolled out to dementia-related services. As a result, if we seek to develop a mechanism to gather dementia-related data to enable us to report on key dementia-related outcomes, an alternate model needs to be followed. It is still important to ensure that the National Dementia Registry Model is designed in a modular way so that electronic data provision can be integrated into the registry model as EHRs or indeed different data sources that underpin the EHRs (e.g. IHIs) become available.

Potential data source rating: Low **Indication of data quality:** Unknown

Potential for electronic integration: High but unlikely to be available in the short- to medium-term.

SUMMARY

In Ireland, dementia-related data is collected and captured in multiple locations, in primary and secondary care settings, and in public and private parts of the health service. In the absence of an electronic health record there is no one obvious source of data from which to populate the National Dementia Registry. The table below summarises the potential data sources and the potential for future integration into the Dementia Registry.

Data held in	Potential registry data source	Indication of data quality	Potential for electronic integration
Memory clinics	High	Medium	Low
HIPE	Low	Medium	High
GP systems	Medium	Low	Medium
PCRS	Low	High	High
InterRAI (SAT)	High	Unknown	High
Patient Summary Record	Low	Unknown	Medium
Electronic Health Record	Low	Unknown	High (not available)

Memory clinics capture a rich source of data and are the most logical starting point for the registry. This will be explored further during the data prototype. The electronic mining of dementia registry data from other sources would presently be difficult but as these evolve through development EHR),implementation (interRAI™), quality improvement initiatives GP systems) so does the potential for integration

6 National Dementia Registry Data Prototype

As discussed in section 1.6.4, a small-scale registry data proof of concept (prototype) was carried out to investigate the effectiveness and efficiency of the recommended data collection model for end users. The intention was also to highlight potential barriers to its implementation in routine practice and to guide implementation planning. Specific objectives were to: (a) explore the availability of dementia data in memory clinics; (b) the usefulness and clarity of the minimum dataset fields; and (c) the usability of the registry through the input of case data into the registry in memory clinics and a qualitative analysis of memory clinic feedback. This chapter presents the detailed methodology and findings of the data prototype.

6.1 Methodology and approach

6.1.1 Design

Following discussion with the project Steering Group and with memory clinics that had indicated their interest in taking part in the study, a mixed method 8-week multi-memory clinic prototype was designed. The prototype comprised of:

i. Data collection for people attending the memory clinics and were diagnosed with dementia during the prototype phase.

ii. Data collection for people who had been given a recent diagnosis of dementia. Where possible (subject to resource availability), memory clinics were asked to retrospectively examine the records for people recently diagnosed with dementia. The rationale for this request was that smaller clinics would be unlikely to diagnose a large number of people in an 8-week period.

Memory clinics were asked to determine how much of the Registry minimum dataset could be populated from the data that was routinely captured. For diagnoses made during the prototype period, memory clinics were asked to try to gather any additional registry data required to complete the minimum dataset; it was acknowledged this would not be possible for retrospective cases. Memory clinics were also asked to record the overall time taken to populate the registry record per person and to provide information in the notes section of discrepancies, difficulties or questions they had as they followed the process. If a piece of data could not be collected, memory clinics were asked to leave this blank or to note that the data was unavailable. Qualitative interviews were conducted at the end of the prototype to gather participant feedback.

6.1.2 Participating Memory Clinics

Memory Clinics, including those based in hospital settings had been approached in the earlier stages of this project to take part in co-design activities, site-visits and interviews. Each memory clinic was asked at that point if they would be willing to take part in the National Dementia Registry prototype. Five memory clinics were purposively sampled from those who had expressed interest in taking part in the prototype. Three were hospital-based outpatient memory clinics and two were non-hospital-based memory clinics. Of the five memory clinics, three were psychiatrist-led and two were geriatrician-led. They represented rural and Dublin-based memory clinics of different sizes.

6.1.3 Materials

An Excel spreadsheet was prepared to match the recommended minimum dataset and dropdown options were provided to match the allowable data in each field. A separate spreadsheet was sent to each participating clinic to be completed during the prototype. No personal patient details were collected as part of the prototype. Memory clinics were asked not to disclose patient's name, address, eircode, and date of birth.

6.1.4 Procedure

Four key stages were undertaken with each memory clinic to facilitate the systematic collection of the data.

— **Stage 1:** A registry data spreadsheet was sent to each participating clinic to review and the data protection protocol was agreed.

— **Stage 2:** A follow up 'training' call was held with each memory clinic to walk through the registry minimum data set and the corresponding dropdown options, which gave memory clinic personnel the opportunity to review the required data and to ask any questions they might have.

— **Stage 3:** Memory clinics commenced their 8-week data collection period on an agreed date; the majority of memory clinics commenced in February 2020. Each memory clinic was expected to send a copy of their completed spreadsheet at the mid-way 4-week point and again at the end of the eight weeks.

— **Stage 4:** At the completion of the data collection phase, a call was scheduled to gather feedback from each memory clinic, including identifying the aspects of data identification and collection that went well, those that could be improved and any thoughts and ideas the memory clinics had following their participation in the prototype.

Memory clinics were also free to contact the Registry team at any point during the prototype if they had any questions or if they encountered any issues.

6.1.5 Impact of Covid-19

Data collection for the dementia registry prototype commenced in memory clinics in February 2020. The first confirmed case of Covid-19 was on the 29th of February. As the number of cases of Covid-19 continued to grow, memory clinics began planning for cessation of service. The subsequent curtailment of memory clinics and redeployment of staff resulted in suspension of data collection for the prototype, which had a significant impact on the number of people seen and the subsequent cases registered. In order to supplement the dementia data collected by the memory clinics, we examined the possibility of mining existing data sources including PCRS and interRAI™, however this was not possible given the redeployment of staff to manage the pandemic.

6.2 Findings

Five memory clinics participated in the registry data protocol. Despite the arrival of COVID-19, clinics managed to collect some data and these yielded insight into the operational aspects of the registry prototype and showed the potential of the registry to provide data across a number of domains. Forty registry patient records were compiled in total.

Having collected the data from the participating memory clinics, the statistical results displayed on the following pages illustrate the type of information that would be available if the National Dementia Registry was implemented. We recognise that the prototype sample is small (*n*=40), so one anomaly (e.g. longer than average waiting time) will greatly distort the figures presented. It is not intended that these results should be in any way representative of current dementia incidence, diagnostic process or post-diagnostic care. The aim of the prototype was to show the enormous potential that can be derived from gathering registry data; in particular, how it can be mined for health intelligence to support dementia management and patient care.

6.2.1 Demographic details for people diagnosed with dementia

The following figures present examples of the type of demographic information that can be generated from the registry data. The data in Figure 16, for example, will facilitate reporting of the outcome measure proportion of patients in which the ability to continue driving has been assessed (O12).

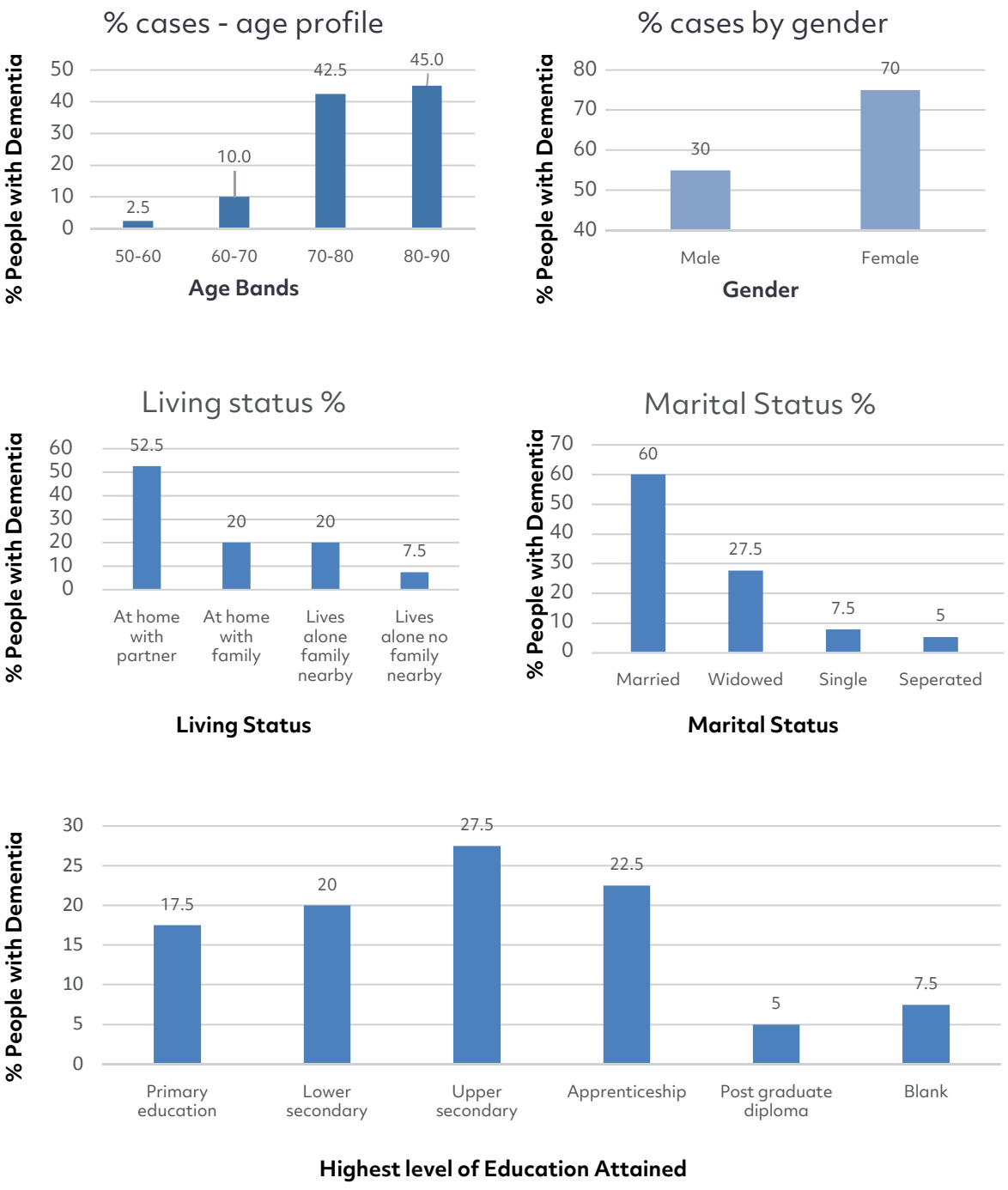

Figure 16 Sample Registry output showing basic demographic data

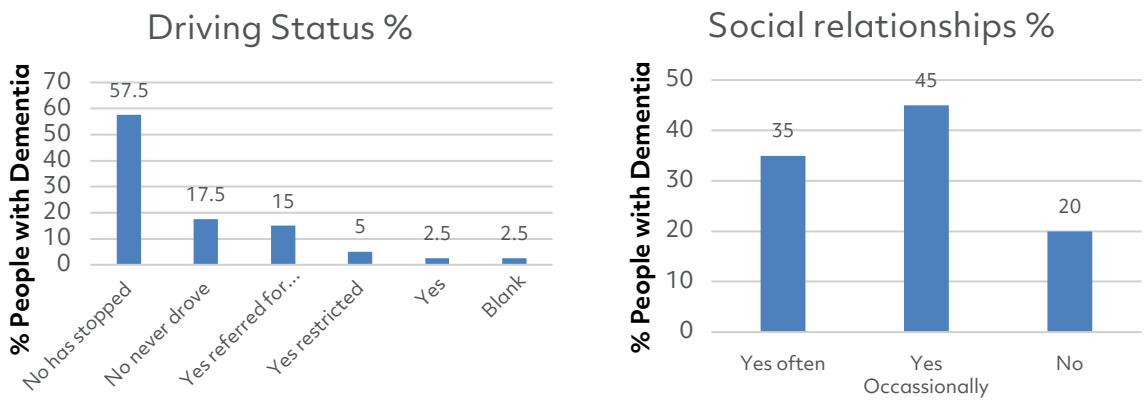

Figure 17 Sample Registry output showing extended demographic data

6.2.2 Waiting times and referrals

Capturing data on referral and assessment times facilitates the calculation and tracking of waiting times for each person on the register (see Table 21). These data will facilitate monitoring outcome O9 [time from start of investigation (receipt of referral) to diagnosis (number of days)]. They can also be used to report on sub-elements of O9, namely; time from referral receipt to initial assessment and from initial assessment to diagnosis, and input to the longer-term measurement of O15 [time from diagnosis of dementia to permanent residential change]. An error was made in the recording of referral information in one clinic and these data have been removed from the analysis.

Table 21 Average wait time (weeks) from referral to assessment to subsequent diagnosis

	Referral to Initial Assessment (weeks)	Initial Assessment to Diagnosis (weeks)
Clinic 1 2 cases	3	7
Clinic 2 10 cases	3	10
Clinic 3 11 cases	17	25
Clinic 4 2 cases	34	4
Average Wait Times per Clinic (weeks)	**14.25**	**11.5**

These data also allow for the monitoring of referrals to memory clinic, which in turn facilitates monitoring where referrals originate from and forecasting demand for each memory clinic (see Figure 18). Finally, the date of follow-up visits will also be captured thus contributing to the measurement of O8 [proportion of patients who have follow-up or referral after the initial assessments].

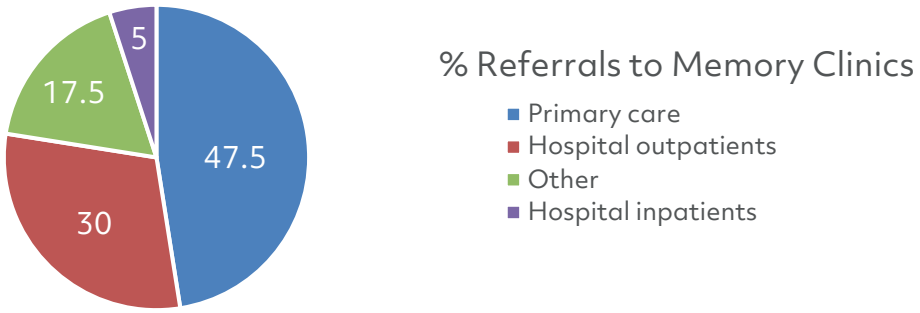

Figure 18 Breakdown of Memory Clinic Referrals by Source

6.2.3 Analysis of diagnostic data

The registry will be able to analyse the use of various diagnostic assessments simply (see Figure 19) and/or through the clustered analysis of combined data fields (e.g. percentage of people diagnosed with Lewy Body Dementia who underwent biomarker testing). These data will enable outcome O1 [proportion of patients undergoing basic dementia work-up] to be reported; subject to an agreed definition of what constitutes a basic work-up (e.g. national clinical guidelines). Planned diagnostic data capture will also facilitate measurement of outcome O3 [proportion of patients with dementia who receive a specific dementia diagnosis] as presented in Figure 20*, and the collection of smoking status and alcohol consumption facilitate the tracking of these dementia risk factors (see Figure 21). Finally, outcome O10 [disease progression] can be tracked by mapping any one of three eligible measures (CDR, FAST and GDS) The prototype data highlighted that only 25% memory clinics are currently gather this data using one of the eligible measures. The remaining memory clinics either infer disease progression using PMS, IADL or do not use any disease progression measure (see Figure 22). The recommended mapping was presented earlier in section 4.3.3.

**Note that there were no cases of people with intellectual disability in the prototype sample.*

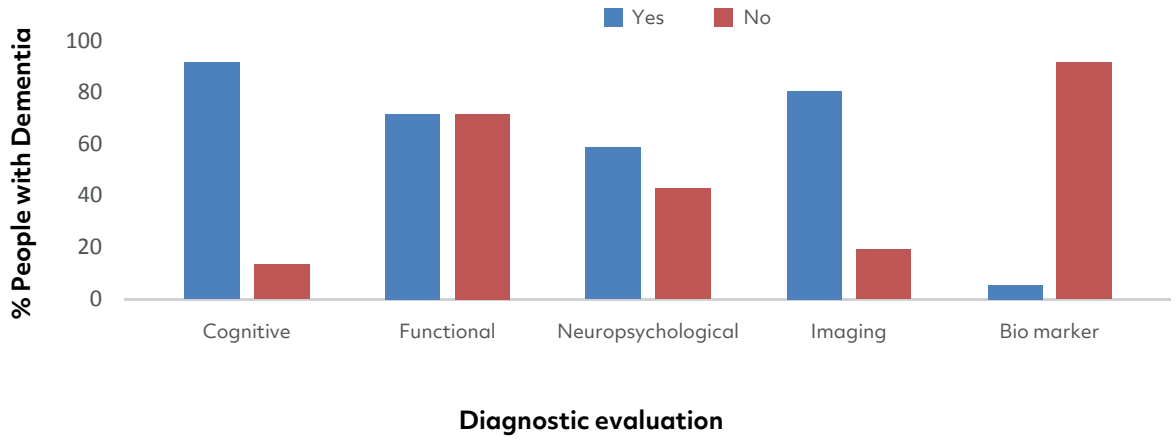

Figure 19 Breakdown of diagnostic evaluations

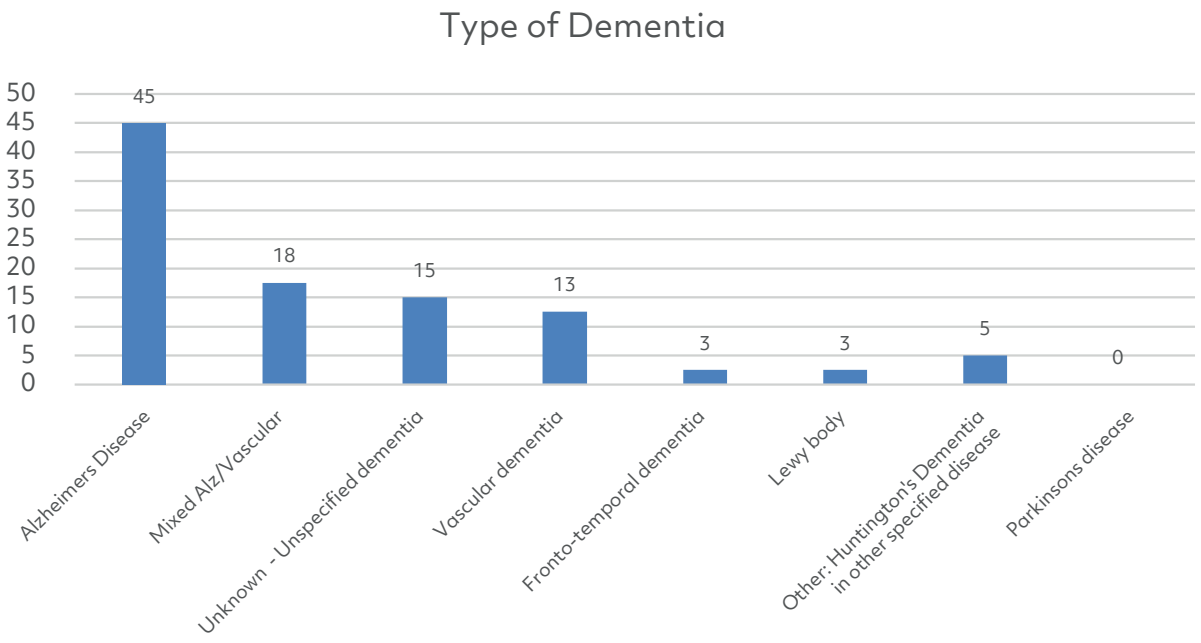

Figure 20 Breakdown of registry population by dementia subtype

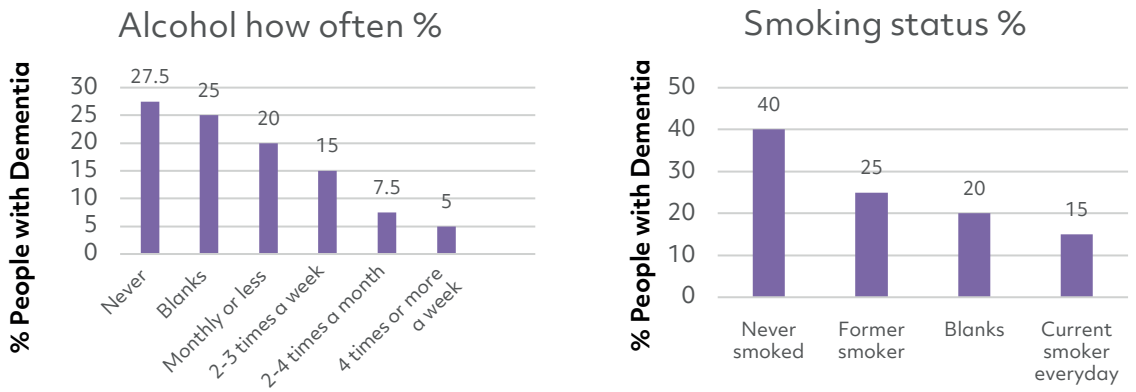

Figure 21 Dementia risk factors

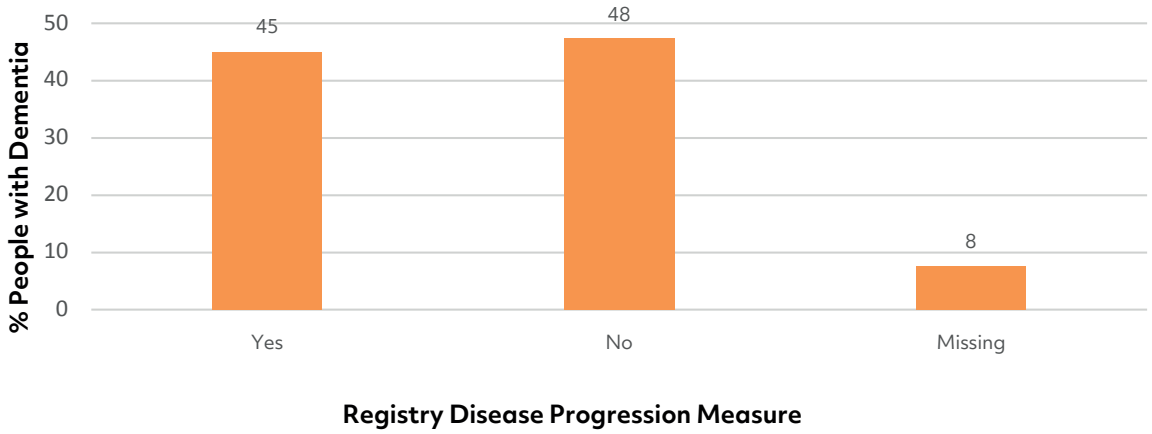

Figure 22 Disease progression

6.2.4 Analysis of treatment and care for people with dementia

As presented in Figure 23, the medication data captured in the minimum data set facilitates the measurement of outcomes O5 [proportion of patients treated with antipsychotic drugs] and O7 [proportion of patients treated with anti-dementia drugs]. These data are typically available in the memory clinics.

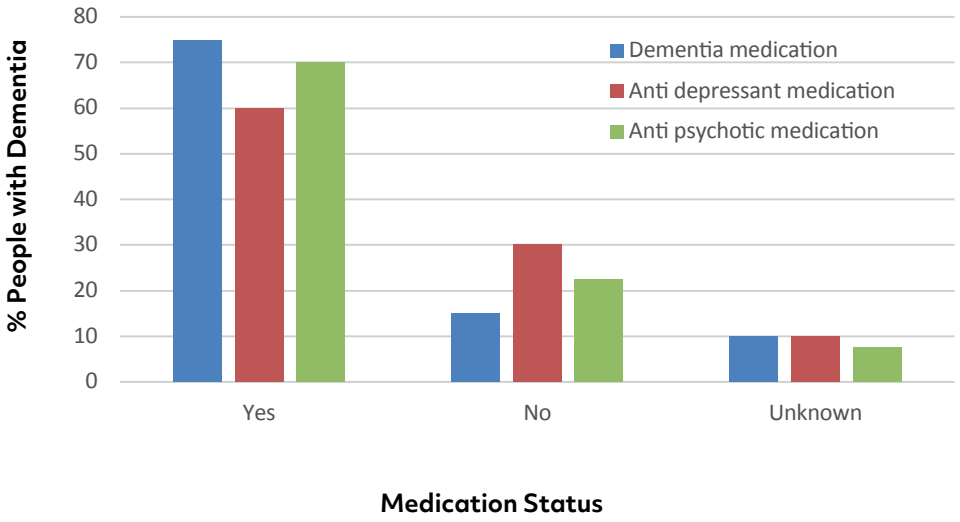

Figure 23 Analysis of medication prescribed to people with dementia

In contract, the measurement of O11 [proportion of patients who have a standard care plan] requires memory clinics to provide data relating to treatment and support planning, and this data is not available in many clinics (see Figure 24).

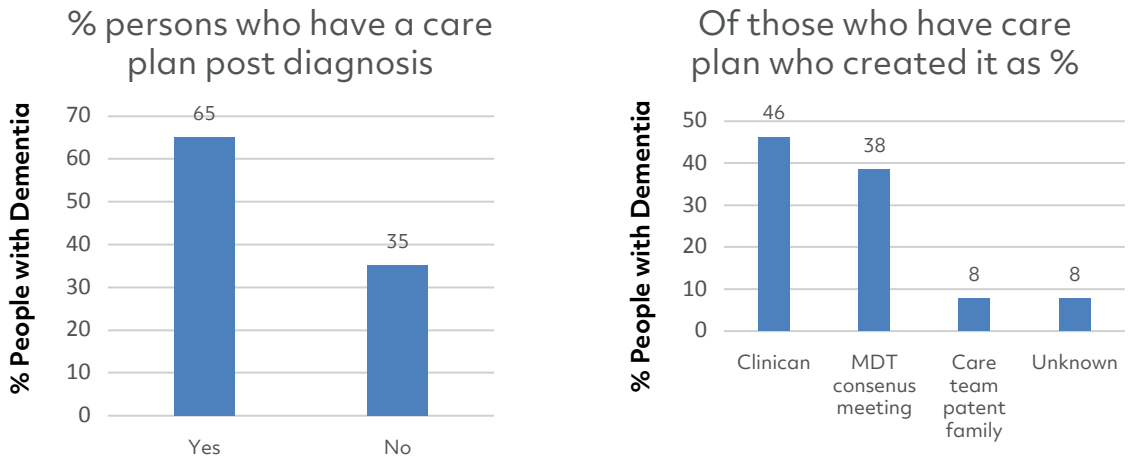

Figure 24 Analysis of care planning with people with dementia

The Dementia Post-Diagnostic Pathway project is ongoing and as the categories of psychosocial supports that the NDO wish to track were still in development, memory clinics were asked during the prototype to provide data relating to the use of post-diagnostic supports and a broad range of onward referrals to allied health professionals. The minimum dataset and subsequent registry reporting now reflect the psychosocial categories as defined by the completed Post-Diagnostic Pathway for Dementia.

These data will enable the registry to track outcomes O8 [proportion of patients who have follow up or referral after initial assessments] and O13 [proportion of persons with dementia who have day-care]; see Figure 25 and Table 22. Knowing the rate of referral to post-diagnostic supports would enable the NDO to monitor the rollout of the post-diagnostic pathways for people with dementia. In combination with the specific quality of life data fields, this referral data can also support the monitoring of person with dementia and carer wellbeing; outcomes O2 and O4 respectively.

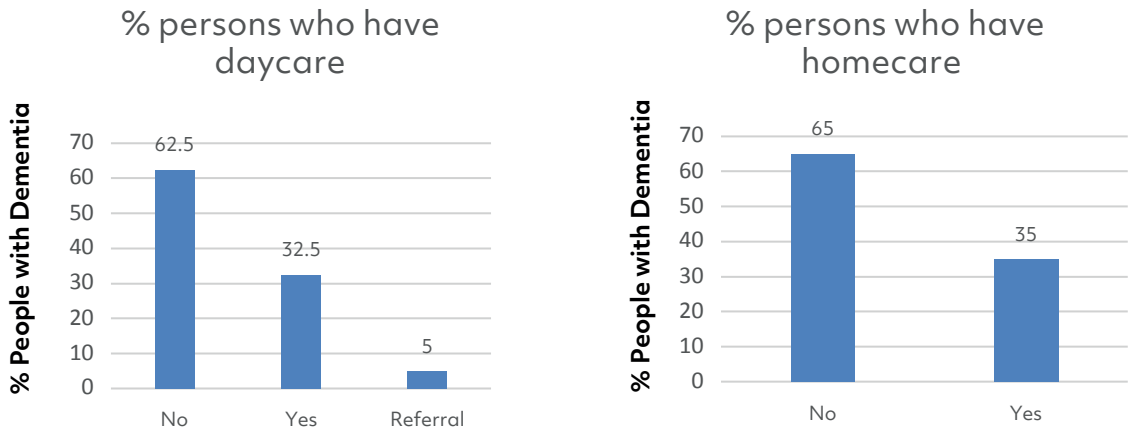

Figure 25 Analysis of post-diagnostic services for people with dementia

Table 22 Analysis of post-diagnostic supports

% persons offered any of the following post diagnostic supports	
Psychosocial	50%
Blank	35%
Assisted technology	5%
Sensory	5%
Other	3%
Non cognitive	3%

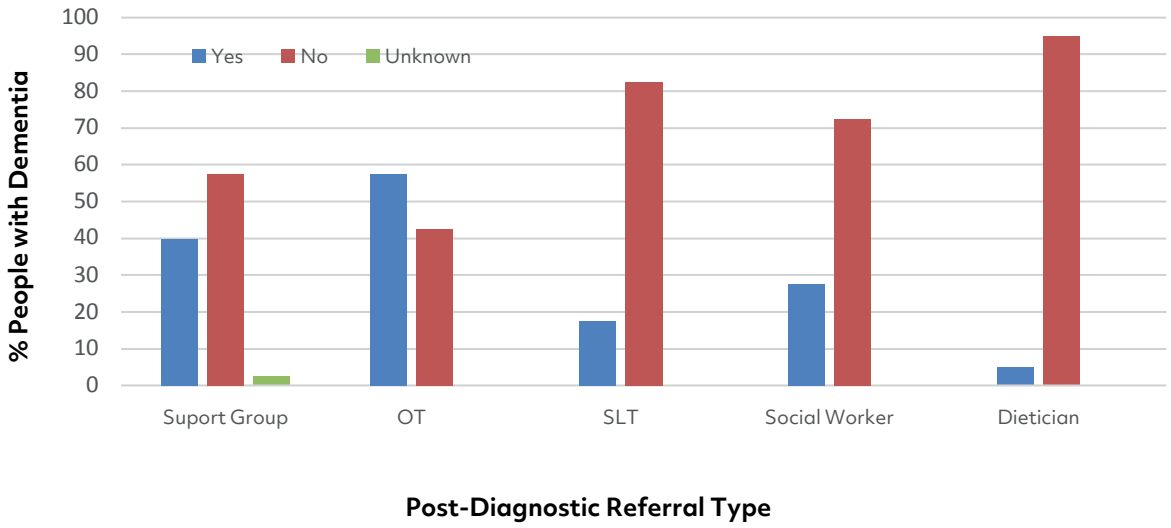

Figure 26 Breakdown of post-diagnostic referrals

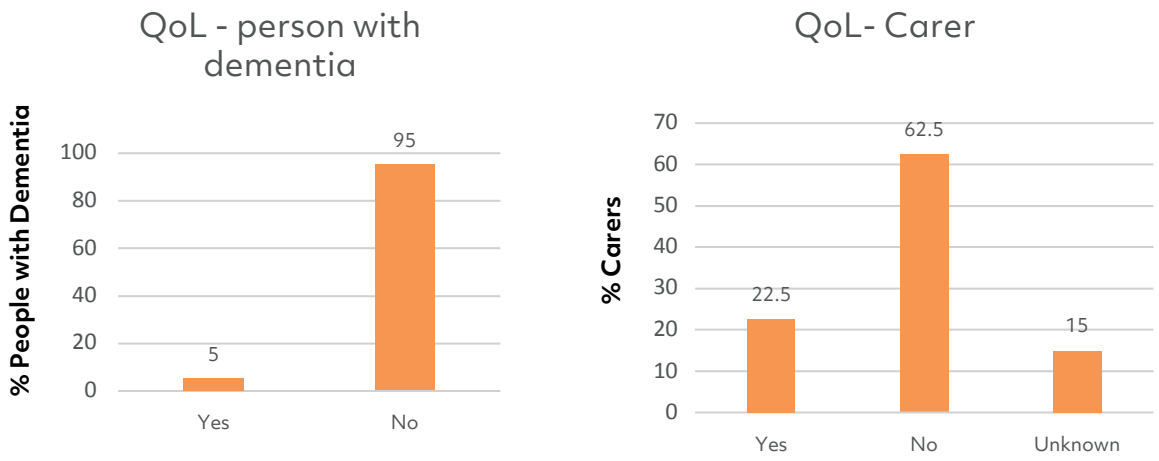

Figure 27 Quality of life of the person with dementia and the primary carer

It should be noted that the measures used in the memory clinics in the prototype, CASP-19 for people with dementia (Hyde et al., 2003) and NPI for carers (Cummings et al., 1994), differ from those recommended in this report; QoL-AD (Logsdon, 1999) and WHOQOL (The WHOQOL Group, 1998b) respectively.

6.2.5 Availability of data

The data prototype has demonstrated that the majority of the registry minimum dataset is available in clinics even if it is not always collated into a single 'form' in the patient chart. The most data gaps were found in the Treatment and Care category.

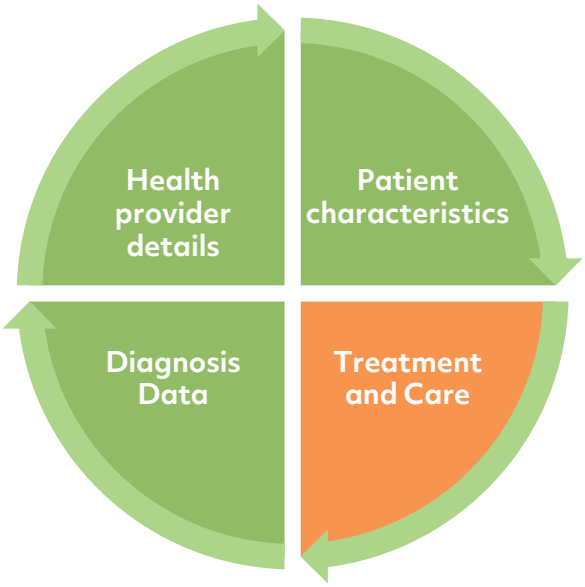

Figure 28 Status of available data across registry data categories

Data fields for which information was scarce included:

— Dementia risk factors including Height /Weight to allow calculation of BMI greater information around alcohol consumption

— Disease progression measure will need to be widely used in memory clinics

— Care plan, there needs to be further exploration of this to ensure consistency in approach and adoption of best practice

— Quality of life measures for both the person with dementia and their carer will need to be widely completed and recorded to facilitate data for the QoL outcome measure. Finally, no data was found during the prototype that can currently be used to track two of the priority outcomes, namely:

— O6 [time waiting for home support services] - there is no consistent way of reporting or tracking the provision of home care support across CHOs, as a result it is not currently possible to integrate this data into the National Dementia Registry. It may be possible to identify a suitable data source at a future point if these data are standardised and captured electronically or future data collection from primary care could provide this data as memory clinics tend to refer people back to their GP when access to home care is required; and

— O15 [time from diagnosis of dementia to permanent residential care] – although the date of diagnosis is available, memory clinics are not currently capturing date of entry into long-term residential care. It is likely that this data may be available at a future point if the registry is extended to cover GP and/or nursing home data.

6.2.6 Assessment centre feedback

We sought qualitative feedback from the clinics to explore the issues they had and to seek any suggested areas for improvement. All observations related to the clarity and usability of the prototype data sheet and to the availability of data. Below is a summary of the main observations from this feedback.

6.2.6.1 Usability

The memory clinics found the spreadsheet relatively straightforward and easy to complete. Thinking ahead to the implementation of the registry, a number of memory clinics noted that it would be beneficial if the patient assessment forms used in the memory clinics aligned to the fields on the dementia registry, albeit that the memory clinic form may want to collect additional data for their own purposes.

6.2.6.2 Data collection

Clarification was sought around medications and memory clinics queried if the dementia registry would capture only medications prescribed by that particular memory clinic or all medications for an individual. It was agreed that the registry should capture all medications the person with dementia is currently taking and any prescribed at that visit.

Memory clinics felt that it was useful to have a disease progression measure captured by the registry, but they pointed out that there is no existing standard regarding which measure to use. In addition, they pointed out that disease progression data may not currently be captured by all memory clinics.

For retrospective cases, the data was on occasion, buried in the manual file making it hard to locate. As a result, memory clinics found that it was quicker to complete the registry information for prospective clients. Average time to complete registration information per clinic was between 5-15 minutes. Overall average completion time of 15 minutes with approximately 20% missing data.

6.2.7 Further iteration of minimum dataset development

The findings from the data prototype resulted in modifications to the minimum dataset these included:

- Simplifying and shortening the number of dropdown options available in the following data-fields: dementia diagnosis subtype, living status and educational status.
- Aligning general health questions to that of the Chronic Disease Management System thus ensuring future interoperability. These data fields related to smoking, alcohol and physical activity.
- Tweaking of the naming conventions for the diagnostic tests to ensure it accurately reflected the terminology used by clinicians
- Allowing user the ability to select multiple responses when capturing data relating to psychosocial interventions.

The final dataset presented in the minimum dataset chapter has taken these refinements into account (see Section 4.3).

Recommendation:

- There needs to be further exploration into care plans to ensure consistency in approach and adoption of best practice
- To facilitate the monitoring of outcomes memory clinics need to adopt disease progression and quality of life measures (for the person with dementia and their carer)
- Memory clinics found the register relatively straightforward and easy to complete. A number of memory clinics recommended that it would be beneficial if the forms used in the memory clinics aligned to the fields on the dementia registry albeit clinics may also collect their own additional data,

SUMMARY

The data prototype although small scale has validated that:

- dementia information can be gathered in a systematic way and having access to this type of health intelligence will support the implementation of strategic programmes, such as the National Dementia Strategy (DoH, 2014), and other initiatives (e.g. forthcoming dementia model of care; Sláintecare (2017)).
- the majority of the registry minimum dataset is available in memory clinics and it was relatively easily to gather and populate
- the minimum dataset can be adopted for use in clinics. Standardisation of data would be helpful to ensure that it is clear and understandable by all.
- infographics and other useful outputs can be created from the registry data;
  - these can be tailored to suit the needs of a variety of stakeholders the registry data can focus on particular cases to identify and explore divergences and outliers. Similarly, data can be combined to support multivariate analyses.
  - to report on quality indicators, the monitoring of these over time will improve the quality of care for people with dementia and their families
- data gaps were mostly found in the Treatment and Care category. Very few memory clinics currently use disease progression or quality of life measures (for the person with dementia and their carer).
- memory clinics do not capture data on the provision of home care support or the date of entry into long-term residential care however this data may be available at a future point if the registry is extended to cover GP and/or nursing home data.

7 The National Dementia Registry Model

The objective of the National Dementia Registry is to follow the person with dementia's journey and capture key data to monitor and improve clinical care and quality of life for people with dementia and their carers. A person will be enrolled in the registry when they receive a formal diagnosis of dementia. Follow-up data will be captured for an individual at each subsequent dementia-related consultation. The initial focus of the registry will be on capturing data from memory clinics and hospital-based memory assessment centres. Over time, the expectation is that the registry scope will expand to include other dementia care settings, for example primary care and other outpatient clinics.

7.1 Introducing the Model

In tandem with the development and prototyping of the minimum dataset, a functional and technical design was produced for the registry. This design was based on recommended best practice from the literature, typical registry ecosystems (see Figure 29), the technical models of existing dementia registries, the objectives and primary outcomes of the proposed registry, and the agreed minimum data set and potential sources for these data.

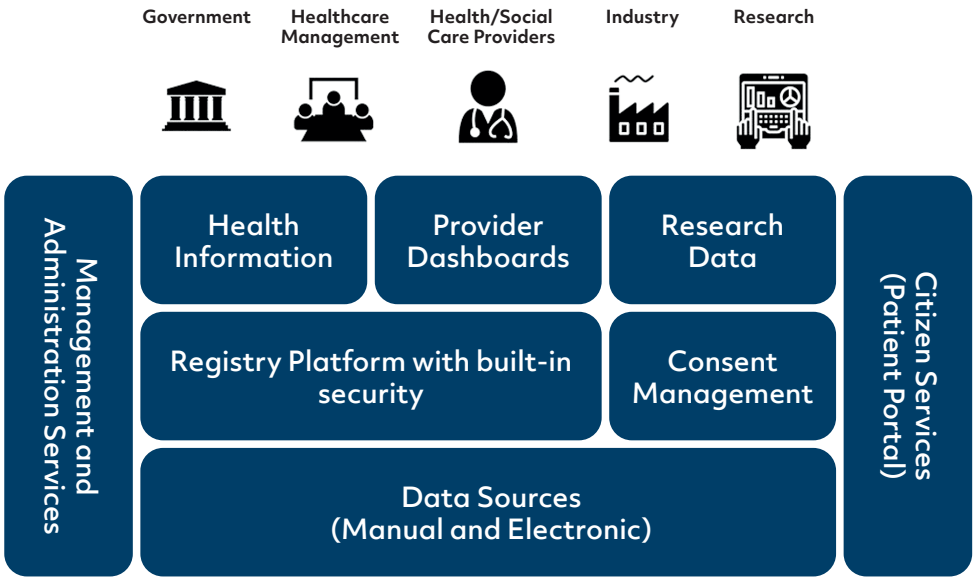

Figure 29 Typical Registry Ecosystem (The Norwegian Directorate of eHealth, 2019, p. 20)

The registry model that has been developed balances the desire to integrate with existing data sources and minimise replication of data collection, with the need to implement the registry and access the benefits that will it bring as a matter of urgency. As a result, the model has been designed in a modular fashion. Potential digital data sources have been identified even though they are not currently capable of providing data to the registry due to lack of standardisation, inadequate data sharing infrastructure, lack of national availability and other reasons (see Chapter 5). Initially, the intention is that data will be captured through a web-based interface when the person is diagnosed with dementia and at follow-up visits. Electronic data sources can be amalgamated into the model as they are available, comprehensive and valid, and once the required data-sharing infrastructure is in place. For example, when medication information can be gathered directly from PCRS system, these data will no longer need to be manually entered.

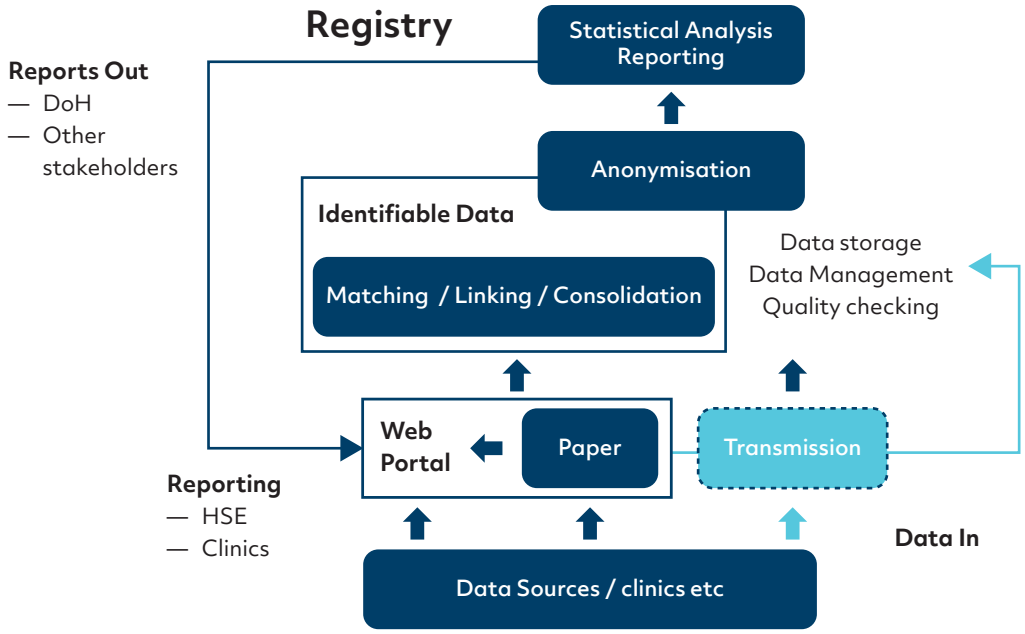

Figure 30 The recommended system design for the National Dementia Registry

As illustrated in Figure 30, the registry model includes the following components:

— A **database** where data is stored and from where it can be extracted and reported.

— A **web-based user interface** through which data can be entered and using which data can be reported and extracted.

— A **data collection module** that gathers data from whatever sources are available (for example, online through the user interface or pulled/pushed from electronic data sources).

— A **data management module** that matches data for a particular individual across sources, conducts data mapping (e.g. across disease classifications) and data calculation (e.g. BMI) as required, anonymises the data accessible within the registry and performs data completeness, accuracy and quality checks.

— A **data analysis and reporting module** that produces periodic pre-defined reports including annual reports and regular operational and stakeholder reports. This module in conjunction with the end user interface will also support ad hoc real time reporting and dashboard style reporting for providers (e.g. memory clinics).

— A **system administration module** that managers users and access permissions.

— A **data access module** that assesses and manages research applications for access to registry data and the informed consent data that would be required in that case.

Five core areas of functionality are required to support the primary aims and objectives of the registry (Gliklich & Dreyer, 2014; Lindoerfer & Mansmann, 2017b; McNeil et al., 2009; SveDem, 2016) and these are shaded in green in the functional overview diagram presented in Figure 31. It is important that the recommended registry model is future-proofed, in particular in relation to the provision of data for research purposes. Two additional processes (highlighted in yellow) are required to support the development of a registry that is 'Research Ready'.

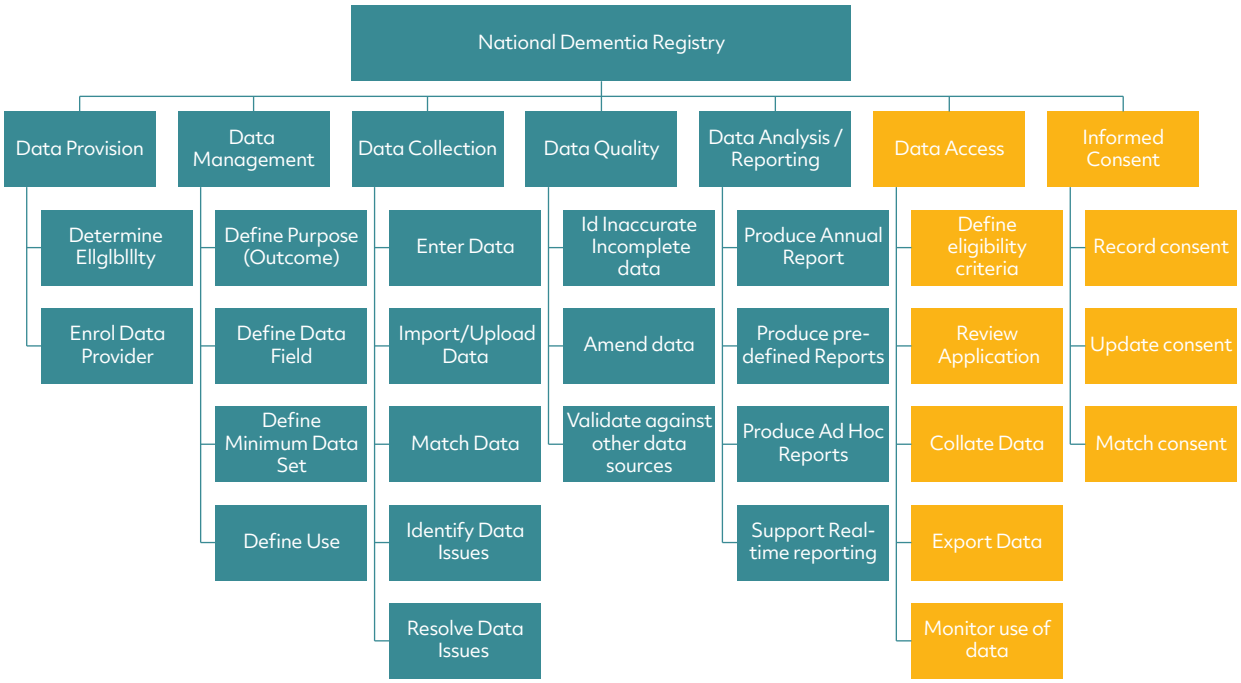

Figure 31 National Dementia Registry Functional Overview

The high-level design and the functional overview fed into the technical prototyping activities that culminated in the development of a more detailed set of requirements and technical design. These are presented in the following sections.

7.1.1 Patient Registry Software Development Framework

Lindoerfer and Mansmann (2014) developed a *Checklist for Patient Registry Software Systems* (CIPROS) following an extensive systematic review of the literature pertaining to the technical architecture of registry systems. CIPROS addresses 72 items that have been clustered into 12 logical sections (see Figure 32). These in turn address system components, functional aspects of the registry and design steps. CIPROS is not intended to replace a software requirement specification for the registry. Instead, it provides a framework that can be used when designing and creating standards for patient registry models that is built on a wealth of published experience of patient registry development. The CIPROS framework can also be used to standardise the reporting of registry models, which supports knowledge transfer and cross-registry comparisons.

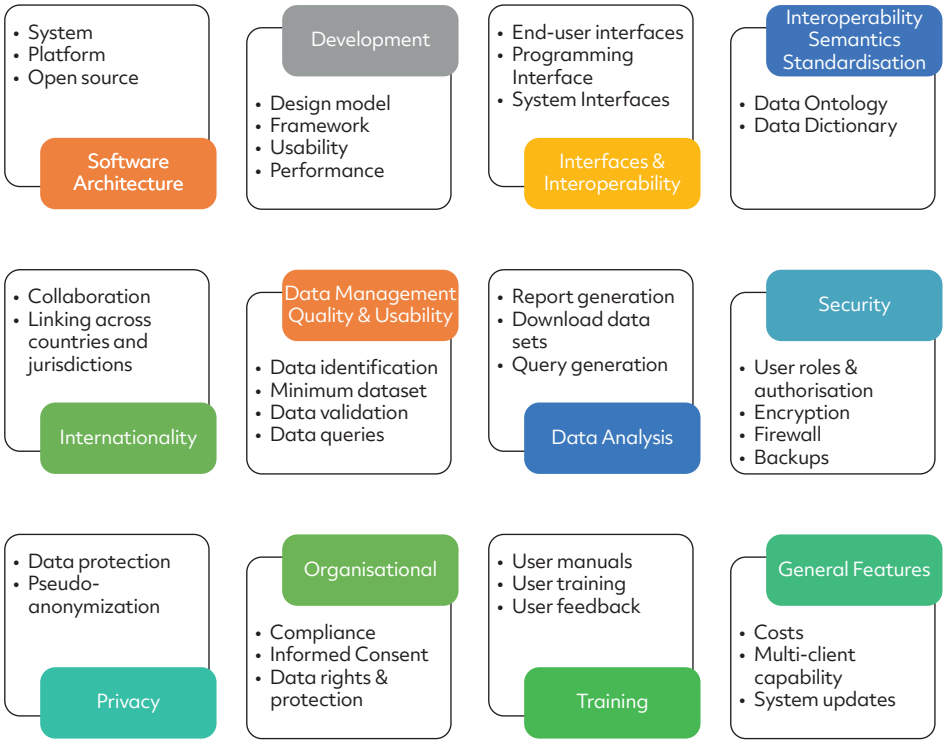

Figure 32 CIPROS checklist of items for patient registry development

The requirements, the registry processes where relevant, and the recommended technical design for the National Dementia Registry are presented in the next section using the CIPROS model as a framework (Lindoerfer & Mansmann, 2017a, 2017b).

7.2 The Dementia Registry Model in more detail

7.2.1 Software architecture

Best-practice recommends that a new registry system should have **a modular multi-tier architecture** capable of running on multiple platforms. With this in mind, the Registry will have at least a three-tier architecture that includes:

i. A web-based user interface
ii. A middle-tier that contains the application logic
iii. A resource manager that stores the data

The Registry system will be **extendable** so that additional components and further functionality can be easily developed and integrated. Periodic co-design, release and testing of software and the incorporation of the resulting feedback into the development process will facilitate an agile and phased approach to development that can evolve over time. This co-production approach requires the involvement of stakeholders throughout the process. For example, clinicians, key staff who may enter the data into the Registry (e.g. clinical nurse specialists), and representative of the various stakeholders who will consume registry data (e.g. via reports and/or data extracts). The involvement of key stakeholders in this way ensures that the Registry will develop in a way that is intuitive and usable in varied settings. Consequently, we are recommending a phased registry design, development and implementation approach that maximises acceptance of the Registry and its associated inputs, functionality and outputs in clinical practice and by the broader stakeholder group.

The registry system will be **platform independent**; that is, it must be able to run on different server operating systems. Any device with Internet access and a browser should be able to be used to interact with the Registry application assuming they have the requisite security access and permissions to do so. Any required data entry, data validation, data presentation, management information (MI) and data export functionality will be possible from any location and at any time. Ideally, no software will be required on the user's terminal, or if necessary, the software needed will be minimised. It will be important that the display and download times are within the acceptable range and the system can tolerate simultaneous users interacting the application.

7.2.2 Development

The basic requirement of the development phase of the National Dementia Registry is to implement the registry model; that is, the capture, storage, viewing and reporting of the required dementia-related data to address the prioritised registry outcomes. The registry system should be capable of **capturing data** (as dictated by the minimum data set) for people with dementia and their primary family carer at the point of diagnosis of dementia and in subsequent follow-up visits. The system should be capable of **storing that data securely** and **providing views of that data** to authorised users on-screen, in pre-defined reports and via data extracts. System usability and performance will also be assured during the development phase.

As recommended by the CIPROS model (Lindoerfer & Mansmann, 2014, 2017a), the registry system should be developed following an agile approach; for example Design Thinking (Ferreira et al., 2015). This framework then guides the development of all aspects of the registry system to ensure acceptance, usability and buy-in. A **co-design approach** was used when developing the model for the registry during this project and as such, development will be an extension of this model. Involving key registry stakeholders in this way will ensure that the registry is fit for purpose and acceptable to those for whom it is being designed. Key stakeholders include, but are not limited to: clinicians, health and social care professionals involved in the diagnosis and care of people with dementia, data experts (HSE), integration experts (HSE), HSE and DoH governance and policy makers in the area of dementia care; registry experts, family carers and people with dementia themselves.

7.2.3 Interfaces and interoperability

End-User Interface: We recommend that the Dementia Registry has **a web-based application** accessible by all centres who are members of the Registry. This approach has been shown to be very successful for existing registries (e.g. Cystic Fibrosis Registry of Ireland, 2016; SveDem, 2016). The Web interface will be accessible from a wide range of devices and operating systems, and it will be compatible with most common web browsers. It will enable memory clinic and/or registry personnel to enter data directly into the registry system, display these data and any automatically collected data fields subject to access permissions, and create ad hoc reports also based on user access rights.

Many registries also provide a **'patient' interface** to facilitate the collection of data from people with dementia and their primary family caregiver that would not otherwise be possible in the short-term; for example, self-reported quality of life and psychosocial interventions data not currently available from any other source in the health service. Given the lack of care data currently captured in memory clinics in Ireland, we recommend the inclusion of a patient interface in our model. In the longer term, the patient interface could be a suitable mechanism for managing informed consent for research activities, collecting optional registry data and potentially facilitating point-in-time surveys of registry participants.

It should also be possible for the application to send emails to system users. These emails could relate to administrative reminders or alerts, management of user passwords, the publication of periodic registry reports and point in time functions such as announcements and issuing online surveys. It must also be possible to extend the interface to include new data capture screens, if required, as new data providers and new functionality is rolled out; for example, informed consent entry and update for research use of data.

Programming Interface: It should be possible to exchange data with a third-part system securely and appropriately. The registry will be capable of sending requests to other systems (data sources) for data to populate the record of new registry participants (API for retrieving data). It will also have the facility to receive periodic data from other sources and extract data required to populate/update registry records (API for inserting data automatically into the system and an API for updating records when required). The registry will be capable of sending reports electronically, printing reports and exporting the data underpinning the report as required by different end users.

Data interface: The system should enable manual and automated (push/pull) data entry. Given the recommended phased implementation of the registry, extensibility should also be possible so that integration to new data sources can be added over time. This includes development to facilitate the inclusion of primary care, community care and long-term care dementia data as the need arises. The registry will also be developed such that it is 'research ready'. Although the primary objective of the registry is to support clinical care and the quality of life of the person with dementia and their carer, a mechanism will be developed to enable the registry to capture, store, track and amend registry participant informed consent. Subject to the appropriate legal and data access protocol, the registry will also be capable of extracting requested data for authorised research projects for only those persons who have given their consent for their data to be shared and subject to the basis on which the data can be shared (e.g. anonymised; pseudoanonymised).

7.2.4 Interoperability, semantics and standardisation

There is a requirement for the registry to build interoperability and standardisation into the design from the outset, even if data must be manually entered into the system in the short-term. The registry should be able to exchange and make use of information between different software systems, thus aligning with the Sláintecare implementation plan (Houses of the Oireachtas Committee on the Future of Health care, 2017). The registry must be capable of communicating with other healthcare systems in a standardised language using the evolving Data Dictionary Toolkit and standardised metadata. A range of standardised metadata models exist, such as the Common Data model (*The Book of OHDSI: Observational Health Data Sciences and Informatics*, 2020) and the Dementia Registry development team will require access to the appropriate technical, security and data standardisation infrastructure and support teams within the HSE to support these requirements. A robust methodology is also required for re-associating data (matching) from different sources.

As part of the model design for the dementia registry, we have already initiated the dataset specification process (DSMP) for the National Dementia Registry Minimum Data Set (MDS). While not mandatory, we believe it is important to engage with this group and to commence the design of the registry with standardisation in mind. We will continue to move the registry MDS through this process in preparation for the next phase of development.

7.2.5 Internationality

Registry data should be capable of being anonymised for research collaborations and for reporting to global observatories such as the WHO-GDO. Key data items, such as dementia diagnosis, should also be mapped to the common disease classification models (e.g. ICD-10 and SNOMED CT), as described in Table 14 (section 4.3.3) above.

The registry governance board will need to determine when it is the appropriate time to share data with organisations such as the WHO-GDO would be. For example, the registry would need to be able to articulate clearly the comprehensiveness and quality of the data. Based on the experience of existing registries this will develop over the initial years of operation. A Standard Operating Procedure (SOP) will need to be developed to support data sharing with organisations. It is possible that the HSE has existing data sharing processes that could be adopted or amended, for example with Health Atlas (Health Service Executive, 2020). This SOP will need to consider the data protection, health regulations and data sharing regulations that are applicable at the point in time. Input will be required from the registry's External Advisory Board, in particular representatives from the DoH, and the HSE HIU and IIS groups. Consideration should also be given to progress that has been made in the interim period with the HRB DASSL project as collaborative knowledge sharing partnership could be beneficial (see section 1.4.4.3).

The technical design required to meet internationality requirements will be closely related to those required to enable data access and data sharing at an organisational level; that is, a clearly defined data dictionary with standardised data definitions, measures and vocabularies that can be shared with potential collaborators (see section 7.2.10 below). Any additional design that is required is likely to focus on unique aspects of the internationality business process and changes to the legislative and data-sharing environment between now and then.

7.2.6 Data management

The management of data will be fundamental to the success of the registry. In this case, data management includes data collection, storage, data quality and usability and it includes the following requirements:

- Adhering to GDPR, there will be a requirement to store the personal information of patients, such as name, address, date of birth, IHI and MCN in the registry database, to facilitate matching patient data across data collection sources. These data will not be readily accessible within the system.
- A key will be required to identify each person in the data. A pseudonymous registry patient identifier (RPID) will be created by the system when a new patient is entered into the system for the first time.
- The RPID (patient key) will be used in the tables of the registry database to identify the corresponding patient data. This means that the personal information that could be used to identify an individual can be stored separately and securely to the rest of the registry data. The patient key will also be stored with the personal data so that a link can be made to the registry data if required (see Figure 33).
- Registry data should be divided into logical parts where associated variables should be stored together; that is structured into sub-sections relating to patient characteristics, service provider details, diagnostic assessment, and treatment and care data.
- An initial minimum set of data will be collected but in a way that ensures that the dataset can be extended (or reduced) over time following appropriate review.
- The majority of responses will be multiple choice and the system will facilitate the selection of one or multiple options. Free text fields must be avoided and used only if the data cannot be captured systematically. Some free text fields have been included in the minimum data set so that we were able to reach consensus on this data set. They generally fill a gap in the availability of dementia data, but they must be reviewed continually during implementation and removed as soon as possible in order to maintain the quality and integrity of the registry data.
- No data should be predefined in the data entry fields in order to avoid unwanted data entries.
- The system will have inbuilt data validation checks; for example, to ensure that dates have not been entered incorrectly or the wrong way around (MM/DD instead of DD/MM), referral date should be before date of diagnosis, which should be the same as or later than the date of initial assessment.
- All mandatory data fields should have a valid entry before submission of the record to the database.
- Data with unresolved queries (for example, as a result of the data matching process) will be marked with warning flags.
- It will be possible to perform manual data queries within the system. For example, identification of data with warning flags for review and correction. Note that when data is corrected, these warning flags will be removed.
- In addition to being able to report the results of these manual queries, it will also be possible to extract these data into a .csv file or excel spreadsheet.
- Provision will be made to capture informed consent data even though the initial implementation of the registry will not require this consent. This ensure that the database is research ready whenever the decision is made that the registry data is sufficiently comprehensive and of acceptable quality to make it available to external researchers, subject to application and review.
- Registry data, including consent data, will be updated when a person with dementia or a carer whose data has been captured by the registry dies. The data will not be removed from the registry.

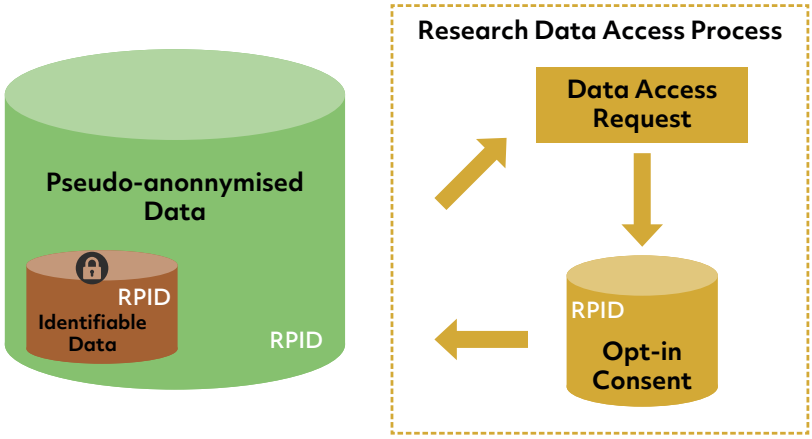

Figure 33 Secure Management of Identifiable Data

A systematic and robust data definition process will be followed that will take the Registry minimum dataset as defined in Chapter 4 and enhance the data field definitions, validation rules, and associated information (OpenApp, 2020a). Data definition will comprise of assigning each data field:

- A unique ID that can be used to reference the field within the registry software
- A data label – the text that will appear on the screen to identify the data item
- Conditional display rules; e.g. display if the person has an intellectual disability
- Field type – date, number, text, auto calculated, etc.
- Field options – dropdown or selection options
- Field Display – how the data should be formatted for input and display (e.g. dd-mm-yyyy)
- Repeating – if more than one entry can be added for this field, this hold the maximum number allowed.
- Ongoing – this data is shown on the screen for subsequent visits (e.g. address will be entered at enrolment but displayed and may be amended during follow-up visits).

Data Validation will comprise of presence checks (mandatory, expected, optional), business rules (date of diagnosis cannot be before date of assessment), validation messages (text to display if rule not met), and validity check (has a valid date been entered). Additional information such as 'Help Text' and 'Special Instructions' (e.g. auto-calculation rules) can also be defined where required.

Given the centrality of data management to the operation of the Registry, clear responsibility for Data Management within the National Dementia Registry and in the organisations that provide data to the Registry will be essential. Two key roles were identified following the prototyping of the required Registry Data Management process and functionality: a Data Monitor and a Data Manager.

The **"Data Monitor"** is a person responsible for ensuring data accuracy and quality at a data provider level. They will verify source data according to the registry's data validation plan. For example, the data validation plan might require data verification to be done in all documents of five randomly selected patients for each centre. The monitor will access and review each document saved for each of the five selected individuals. They can either verify each data element or raise a query with the investigator that recorded the data for further clarifications.

The **"Data Manager"** is the person responsible for the data accuracy and quality across the entire database, as well as ensuring the recruitment goals are being met according to the Data Management Plan. The Data Manager also has the ability to verify data and patient records, but also to lock data, which prevents any further action being performed with that data, with the aim of establishing a cohort of patients with verified data available for further data analysis. This can occur repeatedly over the lifetime of the registry project, with the data validation and management plans being reviewed as needed. The Data Manager can lock the entire database preventing from any editing or queries to be raised against the data.

The precise workflow will be developed in accordance with an established Registry protocol (SOP). It is possible for these two roles to be completed by the same individual, although for contingency and sustainability planning, it would be preferable for these roles to be filled by two individuals. The roles would ideally be situated in the Registry organisation, but in larger centres, it would be possible that the Data Monitor could be provider-based.

Data ownership is also an important consideration from a registry perspective. Patient-owned data (e.g. consent) will be separated from clinician owned data (e.g. diagnostic data elements). Each controls what the other can see in the web portal and on dashboard reports. Most importantly, the clinician is not responsible for monitoring data entered by patients.

7.2.7 Data analysis and reporting

The provision of reports, management information and data extraction are key strengths of a patient registry. The National Dementia Registry will be required to provide different subset of data and different management information reports to multiple stakeholders at different times and in different ways. The variety of different interests and reporting requirements were evident from the stakeholder outcome workshops and the prioritisation of registry outcomes task in particular. As a result, a flexible data analysis and reporting approach will be required. Registry software can be developed to support the following data analysis and reporting requirements:

- Produce predefined reports on a periodic basis without user intervention. These reports will also be able to be produced as needed using a manual trigger and subject to end user permissions. These reports can be sent automatically to the appropriate recipient(s), downloaded in report format, and downloaded as a dataset (.xls or .csv file).
- Generate reports for selected cohorts of patients (e.g. by diagnosis, by service provider, by geographical region, by treatment).
- Generate real-time reports using a query-builder subject to end user permissions (e.g., a service provider can produce real-time reports of their own data; or of their performance versus the average/best; the NDO can produce real-time reports based on anonymised aggregated data). These reports can be displayed on screen, printed, downloaded in report format, and downloaded as a dataset (.xls or .csv file).
- Produce and display results as tables and as coloured graphs.

There is a variety of options available from a software point of view when it comes to reporting. These range from simple, downloadable, pre-defined pdf reports to embedding a report writing tool to support data analysis within the system; for example:

Predefined reports that run periodically within the registry. These can be downloaded as PDFs and/or emailed to prescribed recipients. This type of reporting is best suited to standardised registry and stakeholder reports (e.g. patient feedback reports, monthly operational reports; annual reports). These reports can vary in scope (e.g. range of data included in the report), in detailed (e.g. aggregated summary statistics or detailed reports) and in complexity (e.g. simple reporting of data within the Registry or more complex hierarchical reporting with calculated fields). An example of this type of report is provided in Figure 34.

Figure 34 Sample predefined registry report

Interactive dynamic real-time reports (often referred to as Dashboards). These allow for real-time filtering of required data fields and graphical visualisation of data online or as printed reports. The data analysed in these reports can also be downloaded, subject to user permissions. This approach is particularly suited to service provider reports where, for example, memory clinics can review their own patient data over selected periods, or in comparison to average or 'best of class' results. Dashboard reporting could also suit the needs of the National Dementia Office who may want to be able to access aggregated data on an ad hoc basis based on different filters (e.g. geographical locations, condition, diagnostic pathway, etc.). An example of a registry dashboard from the Swedish Dementia Registry (SveDem) is presented in Figure 35 and a further example is presented in Figure 36.

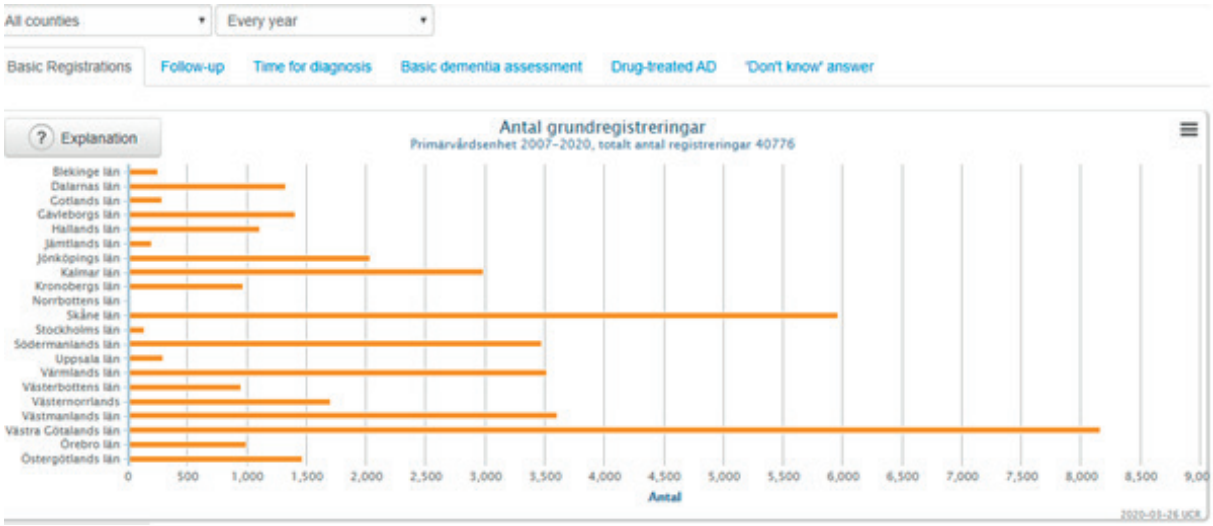

Figure 35 Sample Dashboard (SveDem) – Ad Hoc Reporting

For more **advanced reporting requirements**, including the ability to conduct complex statistical analysis within the registry system itself, it is recommended that a tool such as RStudio (or similar) can be embedded into the registry. These tools provide an integrated development environment for a programming language (e.g. R) that can be used to conduct statistical computing and graphics. This option requires registry staff who are competent with data analytics and statistical analysis using the programming language in question. Given that data can be extracted from the registry, if appropriate statistical expertise and software exists elsewhere within the organisation, this option is less likely to be required.

Based on the requirements of the National Dementia Registry, pre-defined PDF and real-time interactive dashboards will be sufficient to meet reporting needs. Furthermore, the data underpinning ad hoc real-time reports can be downloaded to a file (subject to user permissions), which can be analysed separately if required. Registry staff will have the ability to access pseudoanonymised data within the registry and more complex data analysis will be possible on an ad hoc basis provided that statistical and data analytic experience exists within the registry team. Functionality such as RStudio could be incorporated into future development of the Registry should the need arise.

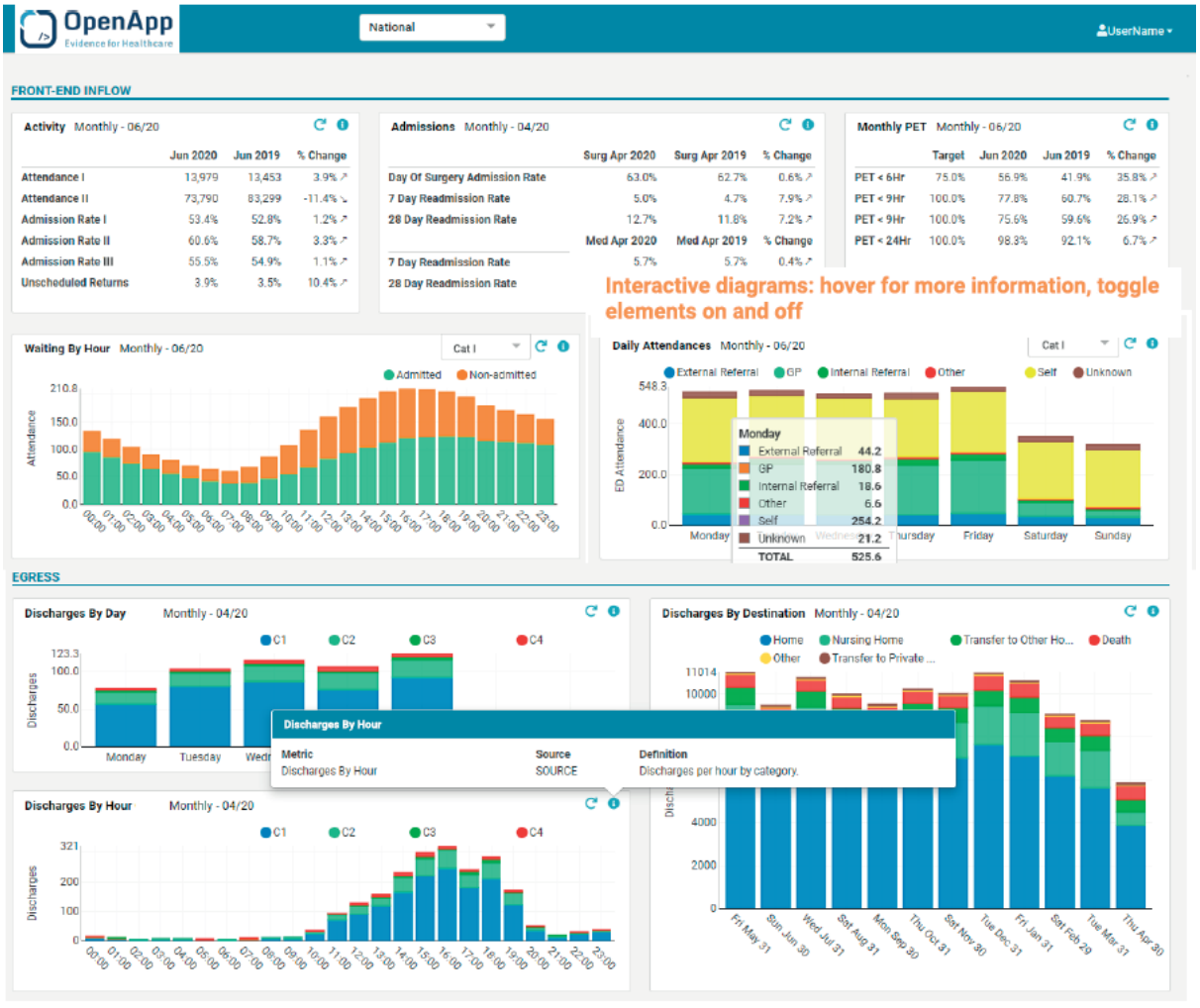

Figure 36 Sample Interactive Dashboard (real-time reporting)

7.2.8 Security aspects

Security has been considered from a registry software perspective and with regard to registry operating processes. Security-related items include:

- Only authorised users will be able to access data. Access control will consist of a username and password.
- Multiple users will be able to access the system at any time.
- There will be role-based user access; for example, there will be end-users (service providers, registry staff, other stakeholders) with different levels of access and with permission to access different cohorts of data. There will be registry administrators with superior levels of access to the Registry including the ability to add, amend and remove users.
- The system will ensure that data is encrypted at both rest and when data is in transit. This is particularly important as some of the data is categorised as sensitive health data and it is important that it is not readable by anyone other than the intended recipients of the data.
- Personal identifiable information (e.g. patient name, address, date of birth, IHI, MCN) will be encrypted in the database. They will also be stored separately to other registry data for an individual and linked only through the pseudoanonymised RPID (patient key).
- All data entries, changes and deletions will be captured and tracked in an audit trail in conjunction with data that identifies the end user who made the changes. These data will be accessible, subject to permissions, should an action need to be reversed.
- The system will be backed up on an agreed basis. If a system failure occurs, it will be possible to restore the system to the data status from the most recent backup (e.g. previous night) such that lost data is minimised. The registry system will also be incorporated into organisational disaster recovery plans.
- The system server(s) will be located behind a firewall to minimise the risk for cyberattacks.
- The system will be available on an agreed basis. For example, expected availability (e.g. 24/7, or at a minimum between the hours of 7am and 7pm Monday to Friday), percentage of availability within those times (e.g. 95%), and the ramifications of not meeting agreed availability. Agreements regarding scheduled downtime and system upgrade processes will also be documented.
- Those aspects of system access that will be managed centrally by the registry team and those that will be devolved to local centre system administration will be clearly defined.

Access to registry applications is typically based on the definition of user roles. Each user profile (role) will have a set of clearly defined permissions that will govern how they interact with the registry interfaces and with the registry data. In other words, the role assigned to an end-user will determine what they can do within the registry and what data they can see. Table 23 presents the standard roles typically available with a patient registry. Each is described in the context of how this role is likely to exist in the National Dementia Registry. It is possible for an individual to perform more than one role on the system. For example, an individual in a memory centre could be both the Local System Administrator and an Investigator. New roles can be defined as needed during registry implementation.

Table 23 Standard user roles in a patient registry

Role	Description (in the context of a dementia registry)
Investigator	Where data is captured real-time into the registry system, the Investigator is typically one of the health professionals involved in the care of the person with dementia; for example, one of the clinical team who meet with the person. It can also be a nurse, nurse-researcher or administrator in the team, or a specialist data entry person employed on the clinical site or by the Registry itself. The Investigator has permission to: — Enrol registry participants (patients) — Record and update patient details and other data required by the registry — View, respond to and answer queries on all registry data pertaining to the patient within that clinical setting.
Data Manager	The Registry Data Manager is responsible for all aspects of the data recorded within the registry, They have permission to: — View the data structure — Generate reports and export the data to data files. — Monitor data collection processes (e.g. view data collection statistics) — Lock (and unlock) patient records
Data Monitor	The Registry Data Monitor is responsible for the integrity of the data recorded within the Registry. They have the same permissions as the Data Manager, and they can also view the data recorded in the system.
Sponsor	An individual with a role of Sponsor is typically a key stakeholder for the Registry data (for example, a member of the National Dementia Office). A Sponsor has permission to: — View Registry data that has been anonymised for display. — Crate (real-time) view and export anonymised reports.
System Administrator	The System Administrator has access to all aspects of the Registry system needed to support the operation of the Registry. They can manage users, centres and general registry functions. They are typically the first port of call should any questions or issues arise. Some aspects of system administration can be devolved to participating service providers; for example, a role of Local System Administrator can be created which enables someone in the centre to manage their own users (e.g. create new users, amend user permissions, delete users). They would not typically have permission to perform non-user-related system administration tasks.

This table has been reproduced with minor amendments (OpenApp, 2020b)

Standard database infrastructure models comprise of a primary and a secondary machine (server). The database is replicated from the primary to the secondary, and the software application layer is installed on both. The secondary server acts as a 'warm standby' solution. Some manual intervention and minor configuration changes will make this secondary server active, should the primary fail. In addition, nightly backups are recommended for the database. A copy of the current application layer will also be kept should there be a need to deploy it again. The configuration of the two servers is presented in Figure 37. Key data is stored within the database layer while the end user interacts with the application layer.

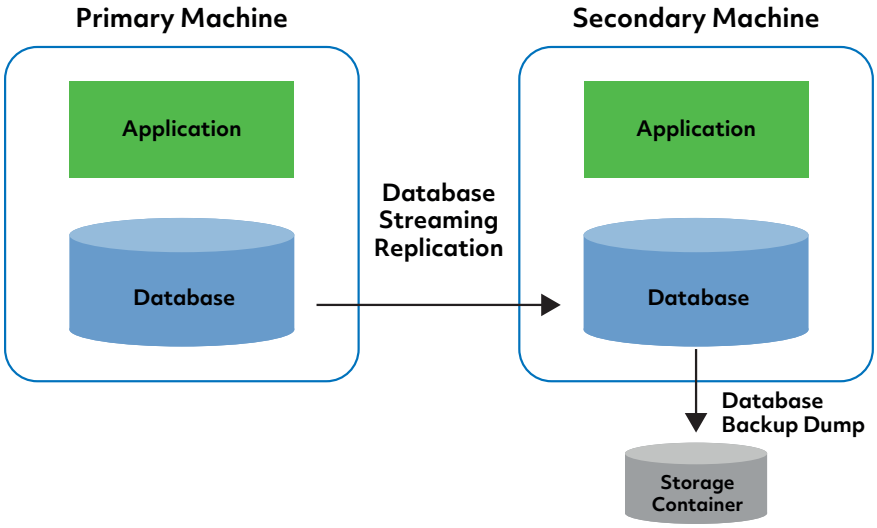

Figure 37 Suggested Database Infrastructure Model (OpenApp, 2020b)

The two servers will be hosted in the same data centre. The location of this will be determined by the registry technical architect. The servers may be hosted within an existing infrastructure or in an independent hosting provider. The servers should also be incorporated into existing disaster recovery plans. The management of the infrastructure, including data security, backups and contingency planning, is typically incorporated into the annual registry maintenance costs.

7.2.9 Privacy

Privacy is closely linked with data management (see section 7.2.6) and with data protection guidelines and registry governance (see section 7.2.10). The registry system should adhere to data protection guidelines throughout.

Although international registry guidelines recommend that data is anonymised before being stored in the database (Gliklich & Dreyer, 2014; MRCG, 2012; Newton & Garner, 2002), this is not possible for Irish data as identifiable information is required in order to match data coming from different sources. Identifiable data will also be required when the registry is opened up to research data requests, as the data owner (i.e. the person with dementia and/or the carer) will need the ability to provide and amend informed consent. It is possible that much of matching process can be removed in the longer term if an integrated data hub is established within the HSE, but there will still be a need to match consent information with registry data records. There may also be a need to match individuals in the HSE data hub with information provided by the private health sector, unless the intention is that the HSE data hub will also have responsibility for integrating these data. In the interim, it will be important that access to identifiable data is restricted in the registry database.

Where personal data is required for matching an individual's data across multiple data sources, these identifiable data should not be available for look-up or reporting. Only the person(s) with authority to manage the data matching process for the registry should have access to these data. Registry participants will be assigned a pseudoanonymised Registry ID for the purposes of linking data across tables in the registry database. Although it is not currently the intention to store biological, imaging or genomic data in the registry, the design will allow these data to be potentially stored at a future point. Double pseudoanonymisation is recommended for all such data. The key to re-identifying registry data must be kept separate to the rest of the clinical data.

A SOP will be required with each centre that provides data to the registry and with the management team who operate each of the electronic data sources input to the registry. The SOP will include a Memorandum of Understanding (MoU) that details when and how often data should be input to the system and the quality control parameters for that data (e.g. 95% of fields should be completed). A similar SOP and MoU will be required that details how the data matching process will take place and where within that process that manual intervention is possible to resolve data issues. These may form part of the original agreement with data providers or, for processes that take place within the registry itself, separate processes will be required. This will be determined on a case (organisation/system) by case basis depending on how data will be provided to the registry.

A Data Monitor(s) must be allocated at centre level (e.g. memory clinic, electronic data source). They will monitor the comprehensiveness and accuracy of the data provided to the registry from their organisation/system. They will have the authorisation to intervene to correct the data when issues arise. A Data Manager(s) role will be established within the Registry itself. This person(s) will have responsibility for data oversight across all centres and data sources. They will monitor data accuracy, comprehensiveness and compliance to data management procedures for the Registry. The MoU will also detail the scope of the data amendment that is permissible by these individuals to resolve data issues. For example, in the matching process or where missing or incorrect data is found. Data Management reporting should be included in the Registry oversight (e.g. governance and data quality).

A database management module will be created as part of the registry development and all data matching activities will happen within this module. There will be a facility to highlight issues that arise during the data matching process (e.g. error and warning reports). These reports and the underlying identifiable data will only be available to authorised Data Monitor(s) at a provider level and Data Manager(s) at a database level. All amendments to data, for example to resolve matching issues, will be documented in an audit trail along with details of the person making the change.

7.2.10 Organisational

The registry system will be designed to support and be complaint with all known data protection and health regulation legislation and guidelines. All data that is kept within the health system can be captured and used for clinical care and improvement without requiring patient consent. Any data that will or could be shared outside the registry, must comply with data protection regulations; that is, informed patient consent is required unless the data is to be aggregated and anonymised (e.g. annual report data), and only those data that are required by the external process should be made available to that process. Although supporting research activities is not the primary purpose of the National Dementia Registry, it will be designed so that it is 'research ready'. This requires the development of data access and informed consent processes and system functionality to manage each. In addition, the registry must be able to support Freedom of Information (FOI) requests (also known as Subject Access Requests - SAR), Privacy Impact Assessments (PIAs) and Data Protection Impact Assessments (DPIAs). SOPs will therefore need to be developed to support each of these requirements.

The registry roles with key responsibilities in this area will be the governance team, the Registry Data Manager and the Data Quality Manager. Ideally, the latter should be two separate roles, but they may be allocated to the same individual during development and initial implementation of the registry until data collection stabilises. As the registry grows, particularly as new data providers are added (e.g. primary care), two separate roles will be required based on workload alone. The following high-level process designs have been prepared during this project to provide a baseline from which the detailed business processes will be developed during the implementation phase.

7.2.10.1 Informed Consent

A workshop was held with the Special Interest Group to discuss and explore the idea of giving individuals and/or groups, access to registry data to support research projects. For the purpose of this discussion, research data access was defined as a request from a researcher or a research group to access **a set of registry data** for some or all persons on the dementia register, based on a clear set of inclusion and exclusion criteria, and approved by the registry team. It was noted that research did not involve giving access to people themselves (e.g. as in recruitment for research studies). In addition, the registry will require a research data access request to be made formally, and to contain sufficient detail to enable subsequent review and acceptance/rejection. The SIG members were made aware that current GDPR and Irish health regulation requirements require opt-in informed consent to be obtained from an individual to use data in this way. Notwithstanding the current legislative environment, the SIG group was asked to consider what level of consent they felt was important for four different levels of data access, namely: (i) identifiable data; (ii) pseudoanonymised data; (iii) anonymised data at a person level; and (iv) anonymised aggregated data.

We found that the nature of the informed consent recommended for each level of data disclosure was dependent on an individual's personal preferences regarding confidentiality and disclosure, and how the data was going to be used. Some SIG members felt that researchers should have access to as much data as possible, arguing that this information matters and by allowing researchers to access it you are, in many ways, leaving a "*good legacy*". Enabling researchers to learn more about the condition could help "*siblings, children and grandchildren*". Some view that the dementia registry should operate on a legislative basis (i.e. mandatory consent); some others agreed but wanted to see a formal opt-out facility; and the remainder preferred the idea of an opt-in approach but commented that it would be important to "*sell the positives, value and benefits*" of being involved in research to ensure that people would understand why they should opt-in. At the end of the discussion, a consensus had been reached that no consent should be required for fully anonymised data, but that informed consent would be the best option, as per current legislation, for pseudoanonymised and identifiable data. A caveat was added that the registry should only approve data access requests for research that will be of benefit to the person with dementia. The SIG was quite clear that no registry data should be made available to insurance companies, employers, driving authorities and other similar bodies. As a result, they recommended that the registry maintain a prohibited access list.

The SIG then considered where, when and how a person with dementia and their carer should be approached to give informed consent for their data to be accessible to research. There was clear agreement that it was definitely not appropriate to discuss research at the point of diagnosis as the person and their family have enough to take in and process at that time. In essence, this means that informed consent would not be addressed at the point at which the person with dementia is being enrolled into the registry database. The SIG recommended that the research and data access conversation should occur post-diagnosis. They also felt that the conversation should not only be raised at one point in time, but that it could be raised over a series of meetings so that a person has time to reach the point where they would respond "*Can I hear more about it?*". The rationale for this approach was that giving people whatever time they need to reach this stage would increase engagement (levels of informed consent) overall.

The SIG felt that the conversation should be managed by the main point of contact that the person with dementia has to accompany them on their dementia journey, for example, the Link Worker, Case Manager or Dementia Advisor. Ideally, this conversation would happen in the person's own home, but the group acknowledged the need to cater for a situation where the person with dementia was no longer living at home. The conversation should be in simple lay language and it should take place with the person himself or herself. They discussed the challenge of capacity and assisted decision making and acknowledged that the person with dementia should be able to nominate a proxy to make consent decisions on their behalf, if they are no longer able to, but that the avoidance of coercion and the importance of ethical conduct should be considered at all times.

At the time of the workshop, there had been an increase in the number of cases of Mumps and a corresponding increase in media information about the condition. The group cited this as a good example of giving different levels of detail about the condition to different interested parties. For example, similar simple and transparent paperwork (e.g. a visual pamphlet with easy to use tick boxes) could be developed and a person decides the level of data access they would be willing to consent to. A person should also have as much time as they want to make this decision and have the option of discussing it with others (e.g. family, their GP) before making the decision. One member of the group raised the point that they felt that their view on informed consent and/or access to different levels of data could change over time. This was discussed and the group suggested providing the ability to view and amend their preferences online. It was very important to SIG members that they remained in control of their preferences regarding informed consent at all times and that this information was always correct; in other words, preferences were updated real-time. The consent record of that individual will also be updated to record the death of a registry participant as appropriate.

An online mechanism for capturing, viewing and updating registry participants (person with dementia and carer) informed consent will be included in the registry design. It will be possible for the consent flag to be set for different levels of data access; for example, consent is given for pseudoanonymised data but not for identifiable data. It will also be possible for different consent responses to be given for the person with dementia and for the carer. If or when a person updates their consent information, this update will be captured and reflected across the system in real time. A link will be built between the registry and the CSO so that date of death can be recorded as appropriate on the registry database. GDPR no longer applies in the case where a person is deceased but it is important to be mindful of the fact that each registry record will hold information pertinent to two individuals - the person with dementia and the carer.

It will be possible for data management personnel within the registry team to extract the necessary data to fulfil approved data access requests. These data will be encrypted and a mechanism will be available to ensure that the data can be securely transferred to the data recipient. Finally, details of how to make an FOI will be made available to registry participants as part of the registry help system in the patient interface.

7.2.10.2 Data Access Requests

If a researcher or organisation wishes to gain access to registry data for research purposes, they will be required to make a formal request to the National Dementia Registry team. A data access application will be developed that will gather all of the information needed by the registry team in order to review and subsequently accept or reject the application. A review team will be required to assess the merits and risks associated with each data access request (e.g. Registry Advisory Board). The composition of this team has not been discussed in detail as it is not intended to include this process in the initial implementation of the National Dementia Registry, however, based on the approaches taken by existing dementia registries, it would be expected that the team will include the Registry Data Manager and representation from the Registry Governance Group, the Expert Advisory Board, the National Dementia Office, people with dementia and family caregivers.

Some patient registries provide data for research at no cost while others charge for this service. The Registry Governance Group should decide if there will be a cost of making a data access request and if so, how much that cost will be. It is possible that this decision and the associated cost could change over time. Given that registries find it difficult to identify long-term sustainable funding, our recommendation is that the provision of data exports to external researchers and organisations does incur a fee that covers at a minimum, the cost of processing the data access request, the cost of providing the data export for those requests that are approved, and the cost of overseeing the use of that data (e.g. data access audit).

7.2.10.3 Freedom of Information (FOI) Requests

The National Dementia Registry will be subject to FOI under the Freedom of Information Act (Houses of the Oireachtas, 2014). It will comply with existing processes within the DoH and the HSE for managing and processing an FOI; also known as a SAR (Government of Ireland, 2020; Health Service Exectutive, 2020a), but it is expected that the Registry will require a SOP that details the process of responding to an FOI. The Registry Data Manager will be responsible for managing this process. The person making the request will be signposted to the process they must follow.

7.2.11 Training

A training process will be required (a) for core registry staff and (b) for all centres providing data. This process should be developed in line with HSE training guidelines for the introduction of new systems. Ideally, a training programme will be developed that can be provided online and/or in-person, and is modular such that an individual need only train in the components relevant to their role, for example:

— an 'Investigator' will only train in how to enrol people from their clinic into the registry, how to view and enter data as (as required) and how to generate ad hoc queries (e.g. Dashboard reports) for their clinic.

— A centre-based 'System Administrator' will learn how to provide local support to the centre, manager users of the registry system and the support relationship with the central registry team.

These roles may be filled by different people in a centre, but they can also be filled by the same person, in which case that individual requires two training modules. In addition, registry development will incorporate the following:

— Training manuals and/or online manuals/videos should be available for registry end-users that explain how to use the system.

— Online support comprising of a general Help function and dynamic, intelligent hover assistance over fields and menu options.

— A mechanism to gather regular user feedback to support further improvements of the system. For example, periodic questionnaires on topics such as training, usability, usefulness and satisfaction. Periodicity can be set at different rates for different questionnaires (e.g. quarterly, half-yearly, and/or yearly).

7.2.12 General features

This final section covers those aspects of registry system development that are required, but do not fall under any of the sections above. During the design workshops, data providers, particularly smaller memory clinics, felt that they would lack the skills and resources to take on technical support tasks that might be required in relation to the registry; for example, software updates. As far as possible, software should be installed on the server and not on the client side. When a software update has taken place, the client will automatically get a new version when they next log in.

7.3 Phased Implementation Approach

Adopting a modular approach to the development of the Registry model, including the desired outcomes and minimum dataset enables a phased implementation approach to be taken (see Figure 38). All registry experts and best-practice guidelines caution against trying to implement everything at the one time and instead recommend a series of planned development phases that commence with the implementation of a registry model that is standardised, interoperable and scalable.

The first implementation phase will encompass the initial creation of the registry infrastructure and the core set of registry functionary. The intention is that people will be enrolled on the registry once they receive a formal diagnosis of dementia. They will also be followed up over time. As a result, the initial implementation of the registry will focus on memory clinics (standalone and hospital-based).

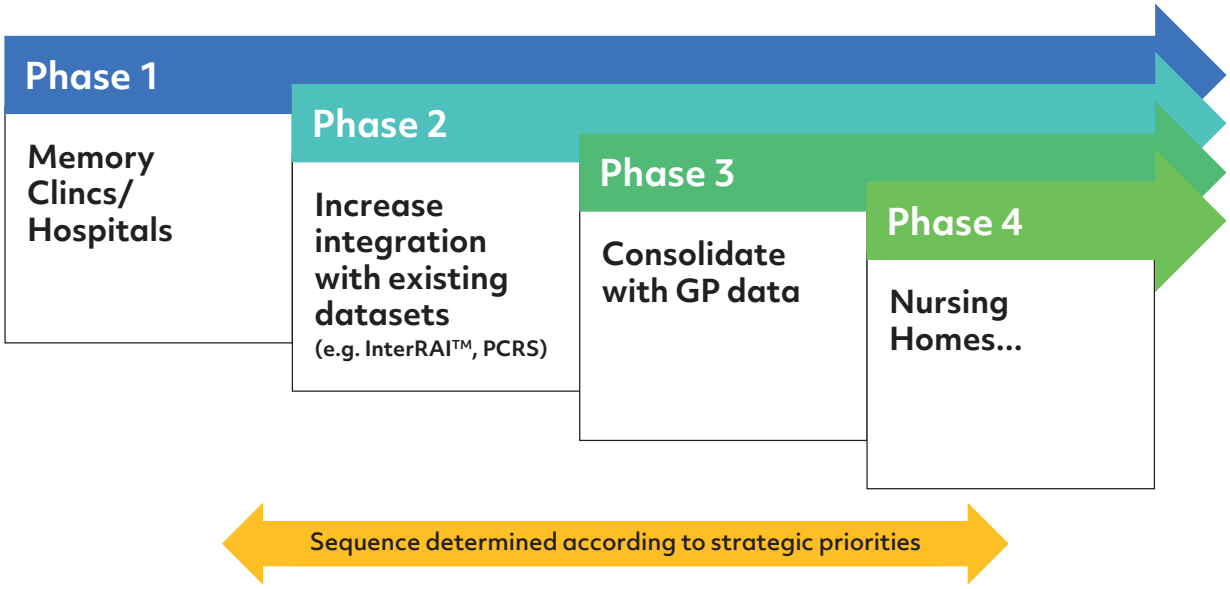

Figure 38 Phased Implementation of the National Dementia Registry

The typical implementation pathway for existing dementia registries is to complete the implementation of a core set of data, usually in a controlled diagnostic environment - in this case, memory clinics. In subsequent implementation phases, data collection is expanded to other diagnostic sites (e.g. primary care, long-term residential care). These expansions may introduce minor extensions to the minimum dataset in order to address outcomes that may be location-specific (typically, these are small number as core outcomes have already been captured). It may be, however, that future phases of development of the Irish registry can focus on increased integration with existing HSE datasets, and particularly IHIs become widespread. Ideally, subsequent implementation phases will be determined by the Registry Governance Group in alignment with strategic priorities.

SUMMARY

The National Dementia Registry Model presented in this Chapter balances the urgent need to implement a solution for dementia data with the ability to integrate with electronic data sources as they become available, thus providing a means to reduce data replication over time. The model comprises of a database, a web-based user interface and modules to support data collection, data management, data analysis and reporting, system administration and ultimately data access.

The dementia registry system will be developed with a modular multi-tier architecture that will be extendable and platform independent. Functionality will be developed using a co-design approach to ensure that the system is fit-for-purpose and acceptable to stakeholders. End-user, programming and data interfaces will enable data to be captured, displayed and shared appropriately. Interoperability and data standardisation are core elements of the model, thus enabling the technical design of the registry to meet organisational, national and international data sharing requirements.

Successful data management will be fundamental to the success of the registry and accurate matching of participant data across potential data sources will be required until IHIs are rolled out nationally. Suitable data back-up processes and the creation of data management and data quality roles will be key. Data analysis and the provision of management information is also fundamental and the model is capable of supporting pre-defined and ad hoc analysis, reporting and data extract. System security and data privacy are managed by tiered access roles and segregation of identifiable and pseudonymised data respectively. Although not required for initial data collection, informed consent processes have been considered so that they can be incorporated into the registry model this ensuring that it is 'Research Ready'. Finally, data access processes and training requirements are presented.

Adopting a modular approach to the development of the registry model enables a phased implementation approach to be considered. We recommend that the first phase of implementation focus on data collection from Memory Clinics. It is likely that these data will be captured through the web interface in the short term, but provision has been made to plug in electronic data collection when this is available in the clinics. Subsequent phases can focus on new data collection environments (e.g. primary care; long-term care) and on increased integration with existing HSE datasets (e.g. PCRS, interRAI™) as dictated by health service priorities.

8 Funding, Sustainability and Costs

Funding is central to the development and sustainability of a registry and the final costs are generally determined by a combination of registry size, function, quality and complexity of the data collection, data management, and reporting processes. Newton and Garner (2002) specify that registries that inform public health policy and improvements in patient care should be funded by the State. We argue that this statement can be extended to include those that also inform improvements in patient-related outcomes, as is the case with the proposed Irish National Dementia Registry.

8.1 Funding and Sustainability

As discussed in section 2.2.1, none of the existing dementia registries we spoke to have yet undertaken, or been asked by their funders to undertake, a cost benefit analysis. The need to gather dementia data in a systematic way to fill a health information gap relating to dementia care drove the creation of each of these registries. Each started out with a registry model (design and processes) that they could afford as outlined in Table 24. The ongoing funding of these registries continues primarily because of the benefits to the health system from the information that they provide.

When gathering funding information from existing dementia registries and their funders (predominately state and regional governments), it was stated clearly that most registries did not set out from the outset to cover the entire population of the country. Given the complexity of dementia registries, driven in large part by the subjectivity of the dementia diagnosis and the breadth of stakeholders required to input to registry specification and development, many dementia registries prioritised the quality of the information they collect. They did so by maintaining a clear focus on their core objectives, by collecting data manually or from validated sources, and by not trying to be all things to all people. As a result, they are fit for purpose and continue to be funded.

Table 24 Funding of a sample of existing dementia registries

Country	Allocation
France French National Alzheimer Database (BNA)	State funding €300k year + financing of some major updates (provisional) + funding of the memory centres in proportion to their BNA activity State funding allows the ministry to guide registry decisions: e.g., how the register will evolve; who can access the data… **Resources:** Staff consists of a statistician in charge of data management and a computer systems manager. A proportion of the funding allocated also goes towards memory centres in proportion to their registry activity.

Table 24 continued

Country	Allocation
Girona	Annual funding €130,700
Registry of Dementias of Girona (ReDeGi).	Financed by the *Catalan Health Service–Girona Health Region*, as part of a Territorial Alliances Program. It is paid to a public health service provider entity: the Institut d'Assistència Sanitària (IAS), which provides hospital care services (Santa Caterina Hospital). **Resources:** The provider entity (IAS) has a full-time senior technician and a part-time coordinator (40-50% part-time). IAS also supports the technical registry office (computer tools, secretarial support and documentation).
Sweden	Annual state funding of €300k per annum
Swedish Dementia Registry (SveDem)	**Resources:** Currently 3 full-time registry staff plus technical support. Separate statistical support is provided by the Karolinska Institute on an as-needed basis. *In the initial development phase, this figure would have been higher as the registry team started out at 12 people. Over time, this number has reduced to 3 people.

Examining two dementia registries at different but early stages of development further highlights the importance of state support either directly from the national or regional government or through state-sponsored funding schemes. Greece faces a similar challenge to Ireland in that dementia is treated in different places within the health system. While there is a strategic plan to build a dementia registry, they are reliant on state funding that is not currently available (A. Politis, personal communication, 10 June 2019). In Greece, they are fortunate to have a national patient file for all those who encounter the health service, so in the short term they have identified a clear patient-oriented outcome that they are prioritising; namely reducing the amount of over-prescribing that they believe is occurring in dementia care. GP systems have been updated to prompt a GP to respond with some diagnostic data if a dementia medication is prescribed.

In Australia, the funding for the dementia registry is part of a larger programme, the Australian Dementia Network (ADNeT), which is funded by the National Health and Medical Research Council. ADNeT is a multi-institutional consortium of researchers and clinicians who are taking a coordinated approach to dementia research and clinical improvement. As presented in Figure 39, there are three pillars to this programme, the first of which is the ADNeT registry and the second a memory clinics initiative to standardise practice and data collection. This is viewed as fundamental to support the other two pillars.

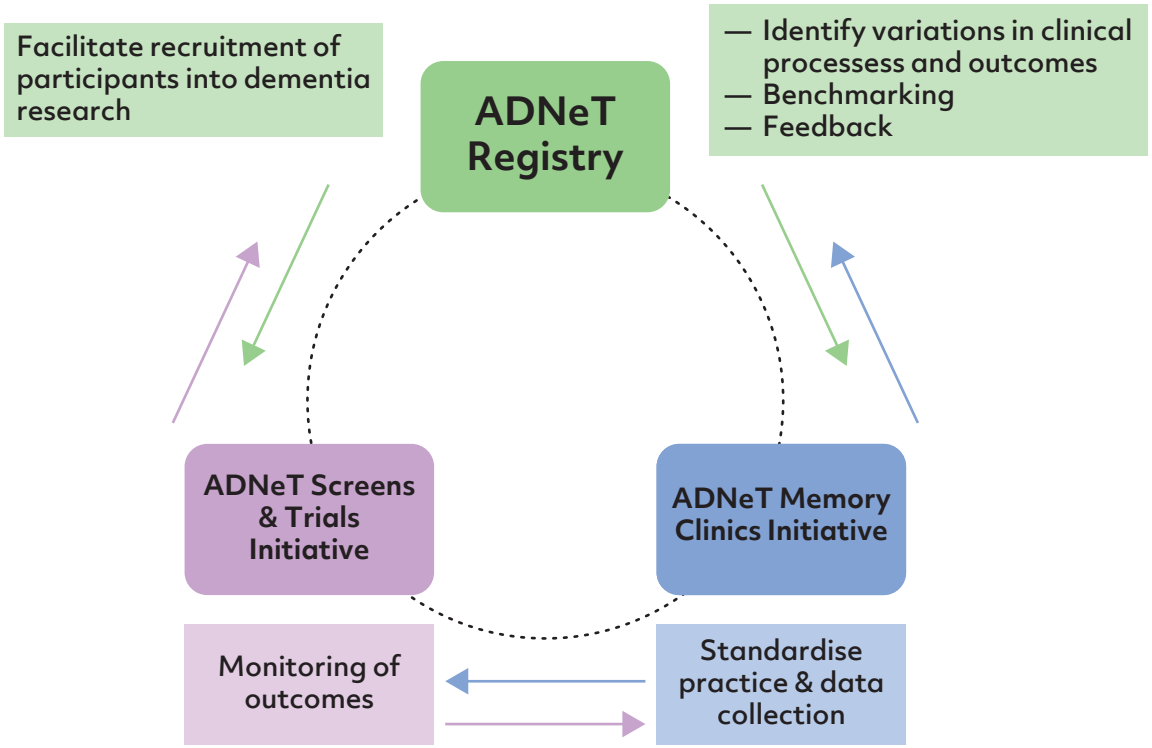

Figure 39 Three key pillars of ADNeT (Ahern et al., 2019)

In contrast to the state and regional funding typically found in the case of dementia registries, rare disease registries have a wider range of funding models. Registries that have the potential to benefit governments and private groups and involve collaborative development are often supported by Public-Private Partnerships and these have shown promise in some areas (EURODIS, 2013). This approach is also frequently reliant on incorporating support for clinical trials in order to attract industry funding, and the building and empowering patient communities to advocate for the development and maintenance of the registry. 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 (Newton & Garner, 2002).

Given the agreed aims and objectives of the Irish National Dementia Registry, state funding is really the only viable funding option in the short- to medium-term. Furthermore, direct DoH support is essential to ensure that data for the registry is gathered across the two-tiered health system resides. The legislative environment and collaborative data sharing arrangements must be pursued with this in mind.

8.2 Estimated Cost of the National Dementia Registry (Phase 1)

This section presents the cost estimates that have been developed for the development and implementation of the core registry system and the collection of memory clinic data, as described in this report (Phase 1). Data collection has been costed as a manual activity at the outset. Suggested yearly operational costs are also included. We have recommended the inclusion of a small ongoing developmental budget in the yearly operational costs to cover ad hoc requirements and potentially the replacement of manual data collection with automated data sources over time. Subsequent implementation phases will require separate cost estimates as the eHealth, data sharing and HSE Integration landscape is changing all the time. High-level indicative costs for each integrated data source are also presented, as they were provided to the authors. The expectation is that integration costs should reduce as an integrated infrastructure and associated components such as the National Data Dictionary are rolled out across the HSE.

8.2.1 Phase 1 and yearly operational costs

The main component costs of development of the registry include:

- **Creation of a dedicated dementia registry project team.** Staff recruitment will be on an as needed basis; e.g., registry data input staff will not be needed until preparation (training) for the initial rollout.
- **Information technology (hardware and software) build.** This includes finalisation of the IT requirements document for the registry build and ongoing work with successful software developer and key registry stakeholders to oversee all stages of the dementia registry software build and testing phases.
- **Costs associated with the support of the Registry Team during the phased rollout and implementation of the registry.** This includes training and engagement with memory clinics.

A justification is provided with each cost item and all resource costs are based on current market rates.

The estimates do not include costs associated with the tender process required to engage software developers to build the registry in line with requirements. Nor do they include any incentive that may be deemed appropriate for memory clinics to support their engagement with the registry (e.g. as was the case in Sweden and France). It is likely that stakeholders, particularly memory clinics, will incur some costs, but we are recommending that standardisation of memory clinic data is considered in tandem with the National Dementia Registry implementation such that a single approach can be taken to data provision (rather than potentially adopting a different approach in every clinic).

A number of assumptions were made in the preparation of these costs and a number of caveats are associated with these estimates. They are not intended to be exact costs, nor are they are response to any anticipated request for tender. Associated assumptions, dependencies and risks are detailed following the presentation of the costs (see section 8.2.2).

Table 25 Phase 1 (development) and post-development yearly registry running costs

	Phase 1 Development (1 year)	Post-Dev Yearly Running Cost
Direct Costs		
HSE Project Manager / Registry Manager (Grade VII)	49837	49837
Research Assistant / Registry Support (Grade IV - 9 mths)	21139	28185
Academic Project Advisor (24 x €850 pd)	20400	4250
HSE IT Development/Support (Technical Officer)	54277	0
Registry System Admin 50% FTE (Technical Officer)	0	27138.5
Registry Data Entry Personnel (3 x Grade IV)	0	84555
Estimated Hardware Costs*	9900	0
Estimated (non-registry) Software Costs (e.g. firewall)	33700	8700
Estimated Travel Costs**	3480	13170
Running & Other Costs	10000	10000
Total Direct Costs	**202733**	**225836**
Indirect Costs		
IT Development Base Model (Consultancy)	70000	0
IT Development Initial Customisation (Consultancy)	19000	0
IT Development Reporting (Consultancy)	35000	0
IT Yearly Support (limited development days)	0	40000
IT Yearly Development Days (20)	0	19000
Total Indirect Costs excluding VAT	**124000**	**59000**
VAT 23%	28520	13570
GRAND TOTAL (Including VAT)	**355253**	**298406**
GRAND TOTAL (Excluding VAT)	**326733**	**284836**

** Hardware costs could be considerably reduced if sharing server space with other HSE applications.*

*** Estimated 3,500 km for 1 return visit to each memory clinic from Dr Steeven's Hospital; €0.39 per km; distances calculated using Google MapsTM. A small additional allowance is included for local travel.*

8.2.2 Estimating the cost of integration with existing datasets

A separate exercise was undertaken to attempt to develop reliable costs for the integration of existing HSE datasets as part of the data collection module of the National Dementia Registry. Although there has been significant progress in the area in the HSE in recent months, the cost estimation framework is still quite rudimentary and it adopts a one-size-fits-all approach to estimating the development costs for each dataset to be integrated. In summary, any integration is assigned a complexity level of 'very complex' regardless of the location of the data set or any other parameter associated with the integration requirement (e.g. number of data fields to be gathered). This is not unexpected as the integration framework is in its infancy. It will become more robust with time and as the number of integrated datasets within the HSE increases.

The difficulty with using this framework in arriving at a cost estimate for Phase 1 of the registry project is that it significantly increases the overall cost of the project. A very complex development unit requires a large number of development days (e.g. 50 days). As other components of the overall cost are then estimated as percentages of the development effort (e.g. analysis @ 30%; testing @ 20%; project management @ 20%; contingency @ 20%) it results in an additional cost of anywhere from €28,500 (100% development by HSE resources) to €76,000 (100% vendor development) per dataset to be integrated. As a result, we recommend that Phase 1 concentrates on building the registry model, including interoperability capability, but that integrated to existing datasets is considered in a later phase. As the integration framework will develop in the interim, it is likely that these costs will be significantly reduced when Phase 2 registry development (and beyond) is reached.

8.2.3 Assumptions, dependencies and risks

8.2.3.1 Assumptions

A number of assumptions were made when developing these costs. The general assumptions relating to the approach, model and registry processes are listed first. Specific assumptions that underpin cost estimates are presented in Table 26 for each cost category.

General Assumptions:

— Costs are estimates for a model with integration capacity but no (or minimal) integration to electronic data sources. Costs will increase as the complexity of data collection (e.g. integration to HSE systems) increases.

— The management of the registry infrastructure (e.g. data security, regular backups, and contingency planning) is included in the annual maintenance fee.

— A Service Level Agreement (SLA) will establish the elements of the support structure that are the responsibility of the Registry team (owner organisation) and those that are the responsibility of the vendor. See Appendix I for an example of a typical SLA. Costs have been estimated based on such an agreement.

Table 26 Assumptions underpinning National Dementia Registry cost estimates

Cost Category	Assumptions
Resource costs	The Registry team will be set up within the HSE, although budget will be required to cover consultancy days from an academic collaborator with experience of the development of the National Dementia Registry model. This has been estimated at 24 days in total (2 days per month for 1 year) @ €850 per day. The Registry Manager will be appointed at Grade VII. Registry support staff (development phase) and registry data entry staff (implementation phase) will be appointed at Grade IV. HSE IT Development, support and system administration will be provided by a resource at Technical Officer level. Costs are based on Q2 2020 salary scales.
Hardware costs	An assumption has been made that new servers will be required to house the National Dementia Registry. Individual servers can cost anywhere from €6,000 once-off purchase cost plus €300 per month for maintenance and €300 per year warranty. If sharing servers with another part of the organisation, it is likely that these costs can be reduced.
(non-registry) Software costs	Costs should include software to support integration with HSE system. Per integration, this includes: A firewall €5,000 once-off cost plus €300 per month support and €600 per year warranty; A virtual private network (VPN) €4,000 once-off cost plus €300 per support and €600 per year warranty
Travel costs	2 people make 1 site visit per memory clinic during development. 1 person makes 3 data collection site visits
Running and other costs	Running costs are assumed to contain non-travel related costs incurred by the Registry team, costs associated with stakeholder involvement in the development of the registry, training costs associated with the Phase 1 role-out and other sundry project costs.
Consultancy costs	The base product cost (€70,000) includes development of two data entry forms, configured standard user roles, user administration, data verification workflow, data export, and the provision of audit trails; Any requirements beyond the base product require customised development. These costs are calculated using daily rates from €750 to €950 per day, depending on the skill level required. It is assumed that customised development will be needed for the interactive reporting dashboard (15 to 20 days) and 12-15 days for additional pre-defined reports. An additional €35,000 has been included for these customised developments.

Table 26 continued

Cost Category	Assumptions
Annual maintenance costs	Typical annual maintenance and support costs for small patient registries (up to 50,000 patients) are typically covered by a fixed price cost of €40,000. This includes infrastructure management, maintenance of software (bug fixing) of 20% of the development cost, and 2nd level support. This in turn assumes that the Registry team provide 1st level support to registry end users. It is assumed that this magnitude of cost will be sufficient for the initial years of the registry until most (or all) locations in which a dementia diagnosis is made have been incorporated into the registry (Phase 4 any beyond). At that point, a usage model may be more appropriate, whereby the annual maintenance fee will vary in accordance to agreed ranges of users.
Yearly development costs	Although the initial registry development will include some pre-defined reports, an assumption has been made that additional reporting will be required once registry data is available and stakeholders can see its value. This is based on the experience of other registries, particularly in the early years of the registry. Yearly operational costs assume the need to include a provision for annual development of 20 days @ €950 per day (€19,000).

8.2.3.2 Dependencies

The key dependency relating to the implementation of Phase 1 at the estimated costs is that the HSE accepts ownership of the National Dementia Registry project. Specifically, the project team will be located within the HSE this enabling them to access legally the data required to populate the registry without requiring patient consent. A related dependency is the availability, on a consultancy basis, of the academic partner involved in the feasibility study and in the preparation of the recommended model.

The other key dependency relates more specifically to the costing of a registry model that includes a higher level of integration with existing HSE datasets. Reliable integration costs can be developed once an integration estimation framework is available that can deal with differing levels of integration required across different datasets, rather than the one-size-fits-all framework that is currently available.

8.2.3.4 Risks

The following risks should be taken into account in relation to the costs estimates provided in this report:

— Salaries have been costed based on current market rates. If market rates change significantly in the period between publication of this report and the commencement of the National Dementia Registry Phase 1 development, this will affect the cost estimates.

— Typical hardware, software and vendor consulting costs have been used to develop the cost estimate. The final costs may need to be adjusted depending on which HSE pricing framework is applied in relation to the tender for this work; e.g. (i) Developing & Consulting Services HSE 7900; (ii) Infrastructure HSE 7901 – Infrastructure support; or (iii) Application Support HSE 8869 – Application support framework.

SUMMARY

Funding is central to the development and sustainability of a registry. Although a variety of different funding models exist when you look across different types of registries, the predominant approach for existing dementia registries is that they are funded by the State (or region). Some existing registries commended as part of a programme of funding (e.g. Sweden), others started with whatever funding was available and built from there (e.g. Girona). Both approaches are still being followed by dementia registries that are currently in development (e.g. Australia and Greece respectively).

A set of cost estimates were developed for Phase 1 implementation of the National Dementia Registry (see Table 25). These are based on a number of assumptions including manual data collection in the memory clinics at the outset and the incorporation of data standards and interoperability requirements. The registry will therefore be 'Integration' and 'Research' ready. Suggested yearly operational costs were also presented and these included a small ongoing developmental budget to cover ad hoc requirements and potentially the replacement of manual data collection with automated data sources over time. Subsequent implementation phases will require separate cost estimates as the eHealth, data sharing and HSE Integration landscape is changing all the time.

High-level indicative costs for each integrated data source are also presented. These are currently difficult to produce with any certainty and they are, as a result, quite high. We expect that these costs will reduce as an integrated infrastructure and associated components such as the National Data Dictionary are rolled out across the HSE, making data integration more suited to Phase 2 of the registry implementation.

9 Summary, Recommendations and Conclusions

In Ireland, we do not currently collect data about people living with dementia in a systematic way. A National Dementia Registry would help address this and we believe that now is the ideal time for it to be developed. This report brings together extensive evidence and outlines a viable model, which ultimately brings us a step closer to the establishment of a National Dementia Registry for Ireland.

The World Health Organisation recognises dementia as a public health priority. Worldwide, around 50 million people have dementia, and there are nearly 10 million new cases every year (WHO, 2020a). The WHO has noted the need for improvement of information systems on dementia in its global action plan (World Health Organization, 2017). Reliable dementia data is essential and would be extremely valuable to a variety of stakeholders including:

— **Department of Health** who can use registry data as an input in policy making, service provision and addressing the WHO targeted action area for improvement in dementia information systems;

— **National Dementia Office** to support the implementation of dementia pathways, dementia policy and development of services;

— **Persons with dementia in Ireland,** their carers, and advocacy groups to highlight their needs, inequitable service provision and to strive for improvements in dementia care;

— **Healthcare professionals across Ireland** can use registry data to support their delivery of improved clinical and social care; those in dementia assessment centres can use the data to compare their centre to others, and more broadly examine data by geographical area;

— **Researchers,** in a subsequent implementation phase of the registry, will be able to apply for anonymised data to support their research needs.

Throughout the development of this model, there was regular consultation with our Steering Group, the Special Interest Group and experts nationally and internationally across all relevant domains. The resulting dementia registry model has taken into consideration the wider operating environment in which it will be situated to ensure that it can be integrated with existing systems and in so far is possible, the model looks to the future mindful of:

— the priorities set out in the Irish National Dementia Strategy (DoH, 2014) and the direction of dementia care in Ireland;

— legislation relating to data protection, mindful that new regulations are anticipated in the area of health research;

— the absence of a strategy for patient registries in Ireland, with an anticipation that this may be covered in the new health information strategy in progress in the Department of Health;

— the progress of the Chronic Disease Management System; and

— interoperability initiatives within the health service.

The project has systematically addressed each of the specific key deliverables of the project as summarised below.

9.1 Summary of project activities

9.1.1 Agree the primary aims and objectives of the Irish National Dementia Registry

The consensus view was that National Dementia Registry would focus on **quality**. This is in line with the HSE framework for improving quality and the objectives of existing dementia registries including Sweden, Norway, Denmark and Australia. The primary aims and objectives of the dementia register are to:

— Improve patient care and outcomes for the person with dementia and their family

— Provide quality assurance and /quality indicators

— Assist with dementia planning/policy

— Assist in the long term with research.

The National Dementia Registry will provide an overview of existing dementia data that is not currently available. It will contribute to improvements in data quality and facilitate the more efficient collection, use and management of dementia-related health and social care data.

9.1.2 Consensus on the outcomes measures that should be monitored

After extensive research and discussion with stakeholders, quality indicators were identified and prioritised. The five most important indicators that will be monitored by the National Dementia Registry are noted below (see Chapter 3 Table 7 for a list of indicators):

1. Proportion of patients undergoing basic dementia work up
2. Overall quality of life of person with dementia
3. Proportion of patients with dementia who receive a specific dementia diagnosis
4. Overall quality of life and wellbeing of carer
5. Proportion of patients treated with antipsychotic drugs.

The Special Interest Group reaffirmed this prioritisation by the Steering Group noting that having a 'proper dementia diagnosis' (e.g. dementia subtype) and focussing on the overall wellbeing of the person are of the upmost importance. Over time, significant benefits may be realised from tracking quality indicators including improvement in the rates of early and accurate dementia diagnosis, to reduction in use of antipsychotic drugs and better support for both the person living with dementia and the carer through the journey of the disease.

9.1.3 Agree the scope and target population of the registry

After extensive discussion of the scope of existing dementia registries and best-practice recommendations, it was agreed that the registry population would be people with a **confirmed diagnosis of dementia.** Selecting this benchmark for participation delineates a clear scope for the initial registry implementation and avoids a common pit-fall of lessor performing registries (i.e. scope ambiguity; (Gliklich & Dreyer, 2014). The registry will **follow the journey of the person of dementia,** starting at initial diagnosis and subsequently through regular follow-ups.

9.1.4 Develop the minimum dataset

A minimum dataset for the dementia registry was co-developed across a number of stakeholder workshops with input from literature review findings and registry experts. The creation of the minimum dataset was driven top-down by the agreed registry quality outcomes, thus retaining a quality focus. In addition, it was informed from the bottom-up by the data that is routinely collected by existing quality focused dementia registries. There are no international standards and dementia registries data does vary. The most comprehensive dataset covers the four categories of data namely (1) personal details, (2) service provider details, (3) diagnostic characteristics and (4) treatment and care. Throughout development of the dataset, there was a focus on future proofing and interoperability with a view to potential linkages to data sources over time. Potential data fields and the final recommended version of the minimum dataset were reviewed by all members of the steering group.

The recommended minimum dataset (see Table 27) is comprehensive without being burdensome. The majority of data fields in the minimum data set will be multiple choice and the registry interface will facilitate the selection of one or multiple options as appropriate. The registry system will also build in as much data validation as possible at the data entry stage.

Table 27 National Dementia Registry Minimum Dataset

Patient Characteristics	Service Provider Characteristics	Diagnostic Characteristics	Treatment and Care Characteristics
Registry ID	Clinic ID	Dementia diagnosis	Dementia medication
Patient IHI number	Referral from	Has the person been told about their diagnosis	Anti-depressant medication
Patient GMS /MCN number	Date of receipt of referral	Translation to other disease classifications	Anti-Psychotic medication
First Name	Date of Initial Assessment for dementia	Diagnosis made by	Benzodiazepines
Family Name	Date of Dementia Diagnosis	Brief cognitive test	Total number of medications the person is taking
Date of Birth		Comprehensive neuro-psychological evaluation completed	Has a personalised care plan been created
Sex at Birth		Neuroimaging testing completed (e.g. CT/MRI/MRI dementia protocol)	Who created the care/ support plan
Address		Bio-markers completed	Current Supports
Eircode		Functional Evaluation	Psychosocial interventions Post-diagnostic Support
Marital Status		Disease progression measure	Advanced care planning
Living Status		Disease stage (translation from disease progression measure)	Has this person a dedicated single point of contact within the health service?
Socially active			Has this person a case manager?
Physically active			QoL-AD Quality of Life measure carried out with the person who has dementia
Hearing impairment			WHOQOL Quality of Life measure carried out with Carer
Vision impairment			Date of Death
Driving			
Education			
Employment status			
Employment position			
ID Aetiology of ID			
Weight in kg			
Height in M2			
Body Mass Index			
Alcohol Status			
Smoking Status			

Use of free text fields in the registry were kept to a minimum to ensure systematic collection of useful data; i.e. data that can easily be interrogated and reported.

Collection of the minimum dataset will bring standardisation. It will also allow data comparison nationally and internationally, by centre, geographical location, service use, type of dementia and other variables within the dataset as needed. We recommended that the registry dataset should not remain static and should, following appropriate review, be reduced or extended over time to meet the outcomes that are prioritised by the needs of people with dementia and dementia care provision and planning.

9.1.5 Identify appropriate data sources

In Ireland, dementia-related data is collected and captured in multiple locations, in primary and secondary care settings, and in public and private parts of the health service. As a result, there is no one obvious source of data from which to populate the dementia registry. Undoubtedly, our job would be easier if EHRs were available across health and social care services, but there is a consensus from both the steering group and among stakeholders that this is exactly the right time to be doing this work and things can be achieved in the short, medium and long-term.

Table 28 Potential data sources for integration into the National Dementia Registry

Data held in	Potential registry data source	Indication of data quality	Potential for electronic integration
Memory clinics	High	Medium	Low
HIPE	Low	Medium	High
GP systems	Medium	Low	Medium
PCRS	Low	High	High
InterRAI (SAT)	High	Unknown	High
Patient Summary Record	Low	Unknown	Medium
Electronic Health Record	Low	Unknown	High (not available)

While the initial implementation of the National Dementia Registry will involve manual data entry, Table 28 shows existing data sources and the potential for their integration into the registry. A more detailed Integration Matrix is provided in Appendix J.

In order to exploit the above dementia data sources, we recommend a phased implementation and rollout of the National Dementia Registry. **Phase 1** will comprise of **registry development and data collection from memory clinics**, including those based in hospital outpatient clinics. To ensure efficiency, we recommend that this first implementation phase run in parallel with the project to standardise documentation in the memory clinics. The next implementation phase should be strategically determined; we recommend that consideration is given either to (i) enhanced integration of data from existing sources (and the subsequent reduction in the need for manual data collection) or (ii) the further rollout of the registry to primary care.

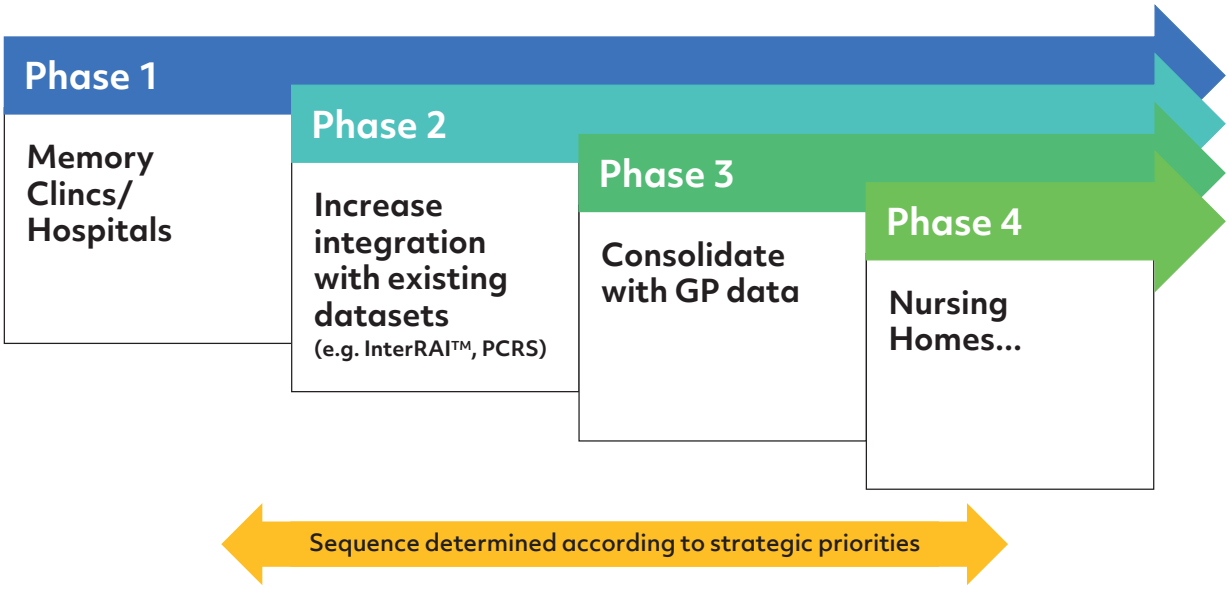

Figure 40 National Dementia Registry phased implementation approach

9.1.6 Develop data management and storage processes

The management of data will be fundamental to the success of the registry. Registry data will be stored securely on a database from where it can be interrogated, reported and extracted as needed. A patient identifier will be created by the system when a new person is entered into the registry for the first time. There will be a requirement to store personal information such as name, address, date of birth, IHI and MCN in the registry database. This is necessary in order to facilitate matching patient data across potentially multiple data collection sources. This personal data will adhere to data protection and health regulation legislation and will not be readily accessible within the system. A key will be required to identify and access this data and it will be stored separately to other data within the registry.

Regular and transparent registry data quality evaluations will be essential in order to provide confidence that the registry data is accurate, comprehensive and fit-for-purpose; that data is gathered and used ethically, legally and appropriately (i.e. to meet registry objectives), and that data analysis are protected against bias and systematic error. It is clear from the experiences of other patient registries that any new registry may have to reach a certain degree of maturity so that the validity and accuracy of reported results can be assured (EyeNet Sweden, 2005; Hopper et al., 2016). Keeping a close reign on the scope of the initial implementation – confirmed diagnoses of dementia in memory clinics – minimises the time that will be required to assure initial data quality and ensure that registry benefits are delivered early such that stakeholders remain engaged and supportive of the opportunities provided by the registry. Access to valid registry results will also help communicate the benefits of the registry ahead of any future registry implementations.

9.1.7 Allow for research and external access to registry data

Supporting research activities is not considered the primary purpose of the National Dementia Registry and research (or any external) access to registry data is not a goal of the initial implementation. Nevertheless, it is important that the registry model be designed so that it is 'research ready'. This need has been considered in the development of the registry model and data access and informed consent processes and system functionality have been included to manage it.

9.1.8 Decide approach to data analysis and dissemination

Frequent communication from the registry can be an effective tactic for keeping stakeholders and registry participants engaged (Milken Institute, 2016). In line with best practice, we recommend that results from the registry data should be integrated into mainstream health service reports and decision-making (Gardner & Jackson, 2018; MRCG & IPPOSI, 2011). At a minimum, the registry will provide a publically available annual report. The registry team and local data providers (e.g. memory clinics) will have the ability to perform ad hoc queries within the bounds of privacy and data access rules. We believe that a combination of pre-defined reports, available as pdfs and data extracts, and real-time interactive dashboards will be sufficient to meet reporting needs.

9.1.9 Determine the most appropriate and practical design for the Registry

The registry model that has been developed balances the data collection requirements and the desire to integrate with existing data sources, with the need to implement the registry and access the benefits that will it bring as a matter of urgency.

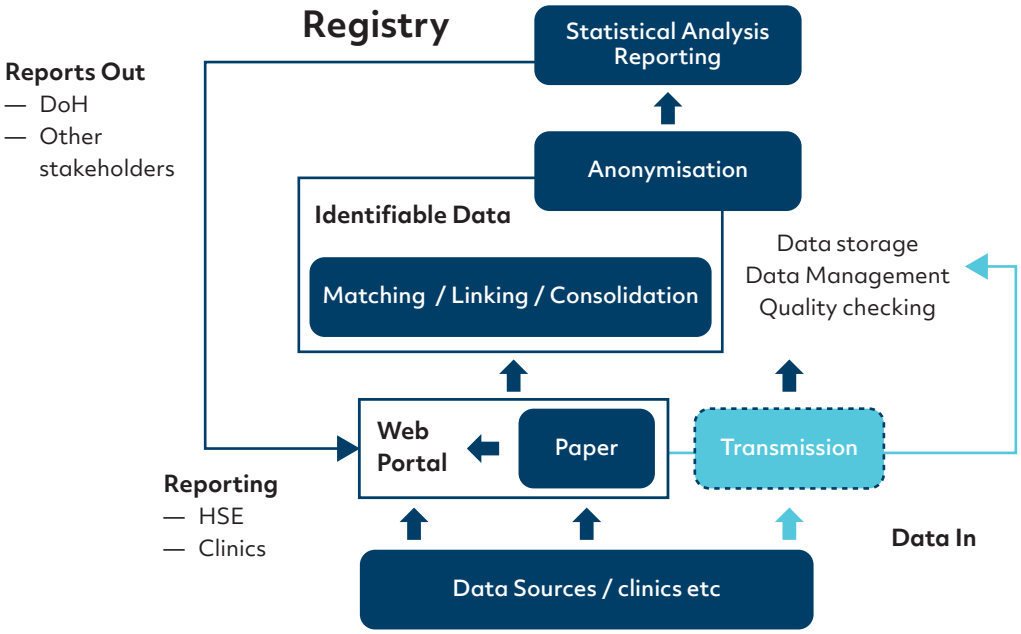

Figure 41 National Dementia Registry Model Design

Initially, the intention is that data will be captured through a web-based interface when the person is diagnosed with dementia and then again at each subsequent visit to the memory clinic. Electronic data sources can be amalgamated into the model as they are available, comprehensive and valid, and once the required data-sharing infrastructure is in place within the HSE.

9.1.10 Test the model for efficacy and effectiveness

The registry model was tested through a data prototype with five memory clinics and a technical prototyping workshop. The latter was conducted with the support of OpenApp, an existing HSE patient registry supplier who is also actively involved in the development of the Chronic Disease Management System. They have experience of integration and interoperability within the Irish context as a result. Unfortunately, this phase of the project was impacted by COVID-19. Data collection in the memory clinics had to be curtailed as clinics closed and personnel were reallocated to other duties. Similarly, stakeholders from the health/social services were not available to take part in the technical prototyping, but sufficient documentation was available from earlier stakeholder workshops to enable these to proceed.

The data prototype while small showed the enormous potential of the registry, facilitated the identification of dementia data availability in clinics and provided insight into the operational aspects of the registry and the infographics that can be produced. The majority (80%) of the recommended registry minimum dataset is available in memory clinics and it was relatively easily to gather and populate, albeit that it required someone to go back to the physical patient chart to access the data. A number of memory clinics fed back that it would be beneficial if the forms used in the memory clinics aligned with the fields on the dementia registry, while retaining the flexibility for clinics to capture additional clinical data if they wished to do so. The findings from the data prototype resulted in minor modifications to the minimum dataset and this final version is what has been included in the recommended model.

The registry objectives, outcomes, minimum dataset, required functionality and associated processes were fed into the technical prototype. The majority of the registry technical design is agnostic to the data collection approach, but an overarching principle of the prototype was a commitment to interoperability regardless of how data would be collected in the short-term. Similarly, a commitment was made to ensure that the model would be scalable and 'research ready' and the technical prototype demonstrated that these were achievable. The approaches to data collection were examined as follows:

— **Manual data collection** – the model was tested to ensure that data could be captured by the registry interface and a registry interface will be developed that allows some or all required data to be manually input into the registry. This element of the model supports immediate collection of dementia data without being dependent on IHIs, EHRs or HSE integration infrastructure projects, but it also allows for the volume of data collection to be reduced as electronic sources are incorporated into the registry model.

— **Integrated data collection** – discussions took place to explore the potential integration that could be incorporated into the registry model given recent strides in data integration in the HSE in response to COVID-19. This approach certainly seems more viable in the medium term than it did at the outset of the national dementia registry model project, but it is difficult to forecast when different data sources will be available and the cost of integrating them into the registry.

It should also be noted that even when a significant number of registry data fields are populated by existing data sources, there would still be some dementia data that can only be gathered in memory clinics, in primary care or in other outpatient clinics. Based on the findings of the technical prototype, we recommend that the registry is developed with interoperability in mind (e.g. establish a data dictionary for the registry minimum data set; ensure connectivity to the HSE systems) but that it commences with manual data entry in the short-term. A subsequent implementation phase(s) can integration to existing data sets when available (e.g. to IHI and/or interRAI™ when rolled out nationally) and when the quality of their data has been validated.

9.1.11 Provide cost estimates

A set of cost estimates were developed for Phase 1 implementation of the National Dementia Registry (see Table 25). Estimated Phase 1 development costs are circa €356K (including VAT). These estimates are based on a number of assumptions including manual data collection in the memory clinics at the outset and the incorporation of data standards and interoperability requirements. The registry will therefore be 'Integration' and 'Research' ready. Suggested yearly operational costs were also presented - just under €300K. These included a small ongoing developmental budget to cover ad hoc requirements and potentially the replacement of manual data collection with automated data sources over time. Subsequent implementation phases will require separate cost estimates as the eHealth, data sharing and HSE Integration landscape is changing all the time.

High-level indicative costs for each integrated data source are also presented (range from €28.5K to €76K per dataset to be integrated depending on the HSE/Vendor allocation of days). These are currently difficult to produce with any certainty and potentially quite high, as can be seen from the broad range. We expect that these costs will reduce as an integrated infrastructure and associated components such as the National Data Dictionary are rolled out across the HSE, making data integration more suited to Phase 2 of the registry implementation.

9.1.12 Determine registry ownership and governance

It is recommended is that the National Dementia Registry would be located within the HSE. This allows identifiable data to be collected for the purpose of the managing clinical care and measuring quality outcomes without requiring an individual's consent. However, it is important to stress that the registry must be a repository for dementia-related data for the entirety of the Irish health system. Effective engagement with the private health sector will be required in order to ensure a comprehensive registry. In the absence of finalised governance structures for two similar registries/data management systems (e.g. the Diabetes Registry and the Chronic Disease Management System), we recommend a governance structure for the National Dementia Registry similar to that presented in Figure 42.

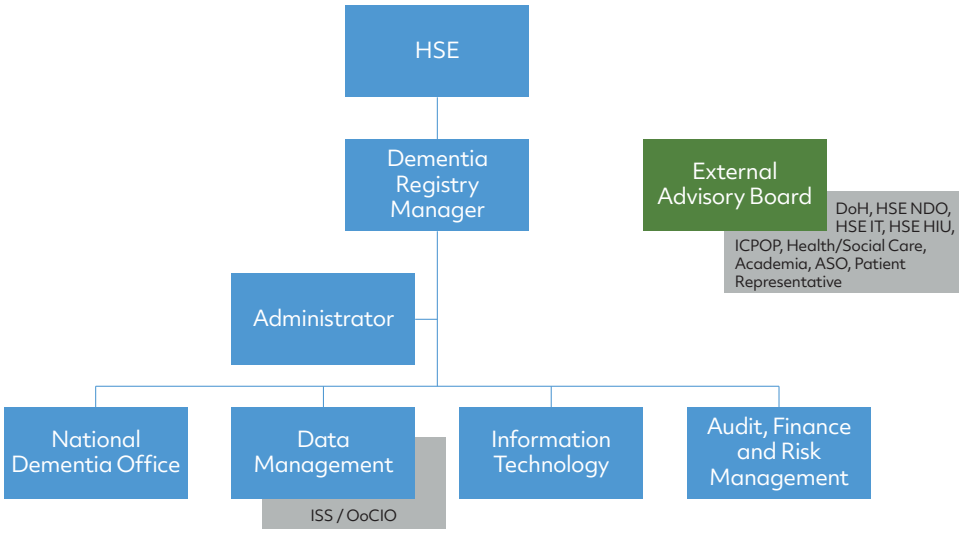

Figure 42 Recommended Dementia Registry Governance Structure

9.2 Recommendations

Five high level recommendations are being made because of the work undertaken for this project. Each is broken down into constituent recommendations. The evidence to support all of these recommendations has been presented in the body of the report.

The National Dementia Registry receives funding and long-term commitment
1.1 The national dementia registry is owned by the HSE and the required governance structures are put in place.
1.2 A guaranteed and stable funding stream is put in place to facilitate dedicated staff to work on and build the dementia registry.
1.3 Set-up the Registry team, including a full-time project manager, within the HSE. This team will manage all registry development and implementation.

National Dementia Registry infrastructure and systems are developed

2.1 The first implementation phase will encompass the initial creation of the registry infrastructure and the core set of registry functionary components.

2.2 Develop a tender document that includes a set of IT requirements for the registry build based on the recommendations in this report.

2.3 Tender and engage with software developers to build the registry in line with the requirements document.

2.4 Work with registry stakeholders and successful software developers to complete the registry build and testing phases.

The National Dementia Registry will be implemented in phases

3.1 We recommend a phased registry implementation approach that maximises acceptance of the Registry and its associated inputs, functionality and outputs in clinical practice and by the broader stakeholder groups.

3.2 We recommend initial implementation with memory clinics.

3.3 Future phases of registry development can focus on increased integration with existing HSE datasets and/or data collected across other dementia care settings as determined by the Registry Governance Group in alignment with strategic dementia care priorities.

3.4 We recommend continued alignment with the relevant data fields (e.g. alcohol and smoking) in the Chronic Disease Management System.

3.5 We recommend that the registry minimum dataset should not remain static and should evolve with appropriate review and be reducing or extending over time.

Continued and prioritised work on projects that would greatly assist the National Dementia Registry

4.1 It is essential that there is **standardisation of data collection across memory clinics.** Standardisation would still allow a degree of flexibility within clinics regarding the data they collect and the tests they perform but it would provide a harmonisation and ensure a core dataset is being collected, which would ensure efficacy and effectiveness in the process.

4.2 We strongly recommend that **memory clinics adopt disease progression and quality of life measures** (for the person with dementia and their carer) to facilitate adequate monitoring of registry quality indicators.

4.3 As primary care is heavily involved on the dementia diagnosis and care pathways, we recommend that an in-depth review is conducted on what would be involved in bringing primary care into the National Dementia Registry this would identify data improvement areas (e.g. coding of dementia; those who remain undiagnosed) and lead to an overall direction for the management of dementia within primary care.

4.4 We strongly recommend that work continues on developing **national standards and guidelines in dementia diagnosis** to provide clarity on the diagnostic testing that should underpin the registry data fields (e.g., what constitutes a valid/acceptable cognitive test / functional test). The guidelines should align with the Irish dementia model of care that is in development (NDO expected to publish in early 2021).

4.5 We strongly recommend that the DoH progress the development of **key performance indicators (KPIs) and associated targets for dementia care in Ireland.** These should incorporate relevant PROMS for diagnostic and post-diagnostic dementia care. The dementia registry will add value by aligning with and monitoring performance and delivery of these KPI's/PROMS.

4.6 We recommend further exploration into **the creation, delivery and tracking of care plans** to ensure consistency in approach and adoption of best practice.

4.7 We recommend continued national **Rollout of InterRAI**™ (Assessment and Care Planning for person with Dementia and Carer Assessment tool).

4.8 The universal rollout of **Individual Health Identifiers** is not only critical for this project, but for many other projects across the HSE. The slow rollout of IHIs perpetuates the retention of information in silos; the reverse is equally true. This particular recommendation is **fundamental to the successful development of an integrated registry model.**

Strategic initiatives that would assist the National Dementia Registry

5.1 We strongly recommend the provision of strategic direction from the DoH regarding disease registries in Ireland and their future vision and strategy.

5.2 We strongly recommend consideration of, and clarity with regard to, registries and to research data in current and future amendments to data and health regulations.

5.3 We recommend that the DoH and the HSE give priority to and engage with all Irish patient registries (existing and in development) to drive improvement in interoperability through agreed data standards, definitions, classifications and terminologies for use in Irish health and social care AND processes to ensure strict adherence to same.

5.4 We recommend that the DoH consider and reach a decision on whether all disease registries should operate under an overall Quality framework, which would provide a forum to standardise approach to registry development, share knowledge and benefit from cross-registry synergies.

9.3 Conclusions

Dementia is a condition with distributed care and high burden the National Dementia Registry will be an important tool to monitor practice and provide feedback to improve care. This project has demonstrated that a National Dementia Registry will provide an effective framework for the collection of reliable, accurate, valid, complete and timely dementia data. Commitment by all diagnostic centres (beginning with memory clinics) to gather the minimum data fields necessary to populate the registry, adoption of IHIs, data and interoperability standards, and comprehensive and secure data management are fundamental to the success of the Registry. Once these core components are achieved, the National Dementia Registry will provide benefits for people living with dementia, family carers, health and social care professionals and policymakers, while further supporting the delivery of integrated care. It is important to keep in mind the overall goal that "*By building and/or strengthening information systems for dementia, the functional trajectories of people with dementia, their careers and families can be improved.*" (WHO, 2017, p. 30).

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Appendix A. Acronyms and Abbreviations

AD	Alzheimer's Disease
ADI	Alzheimer's Disease International
ADL	Activities of Daily Living
ADNeT	Australian Dementia Network
ADRD	Alzheimer's Disease and Related Disorders
ALD	Affection de Longue Duree (French Health System) similar to the Irish Long-Term Illness Scheme (LTI)
ASI	The Alzheimer's Society of Ireland
ATC	Anatomical Therapeutic Chemical
BMI	Body Mass Index
BNA	The French National Alzheimer Database
BPSD	Behavioural and Psychological Symptoms of Dementia
CASP-19	Quality of life and beliefs about ageing scale
CDE	Common Data Element
C-DEMQOL	Carer-Dementia Quality of Life scale
CDR	Clinical Dementia Rating scale
ChEI	Cholinesterase Inhibitors (Alzheimer's Medication)
CHO	Community Healthcare Organisation
CQRs	Clinical Quality Registries
CSAR	Common Summary Assessment Report
CSO	Central Statistics Office
CT	Computerised Tomography
DANDEM	The Danish Quality Database for Dementia
DASSL	Data Access, Storage, Sharing and Linkage
DCU	Dublin City University
DICA	Dutch Institute for Clinical Auditing
DOB	Date of Birth
DoH	Department of Health
DPS	Drug Payment Scheme
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders – Ver. 4

DSMP	Dataset Specification Management Process
EBC	European Brain Council
EEG	Electroencephalogram
EFPIA	European Federation of Pharmaceutical Industries and Associations
EHR	Electronic Health Record
EPIRARE	European Platform for Rare Disease Registries
EQ-5D	EuroQoL
EU	European Union
EURODIS	Non-governmental rare disease patient organisation
FAST	Functional Assessment Staging Test
GAAIN	Global Alzheimer's Association Interactive Network
GDO	Global Dementia Observatory
GDPR	General Data Protection Regulation
GDS	Global Deterioration Scale
GMS	General Medical Services Scheme
GP	General Practitioner
HER	Health Economics Research
HIPE	Hospital In-Patient Enquiry system
HIPS	Health Information and Patient Safety Bill
HIQA	Health Information and Quality Authority
HIU	Health Intelligence Unit
HRB	Health Research Board
HRCI	Health Research Charities Ireland
HSE	Health Service Executive
IADL	Instrumental Activities of Daily Living
IAS	The Institut d'Assistència Sanitària, Girona, Spain
ICD10	International Classification of Diseases Tenth Edition
ICER	Incremental Cost-Effectiveness Ratio
ICGP	Irish College of General Practitioners
ICHOM	International Consortium for Health Outcomes Measurement

ICPOP	Integrated Care Programme for Older People
ID	Intellectual Disability
IHI	Individual Health Identifiers
IHI	Individual Health Identifier
IIS	Integrated Information Systems (HSE)
IPCRN	Irish Primary Care Research Network
IPPOSI	Irish Platform for Patients' Organisations, Science and Industry
LP	Lumbar Puncture
LTC	Long-Term Care
LTI	Long-Term Illness Scheme (HSE)
MCI	Mild Cognitive Impairment
MDRF	Meta Data Registry Framework
MDT	Multi-Disciplinary Team
MI	Management Information
MMSE (SR) / MMT	Mini Mental State Exam (self-report)
MoCA	Montreal Cognitive Assessment
MRCG	Medical Research Charities Group
MRI	Magnetic Resonance Imaging
NDO	National Dementia Office (HSE)
NFR	National Federation of Registries
NIMIS	National Integration Medical Imaging System
NMDA	NDMA receptor antagonists (Alzheimer's Medication)
NorCog	Norwegian register of persons assessed for cognitive symptoms
NPI	Neuropsychiatric Inventory
OoCIO	Office of the Chief Information Officer, HSE
OT	Occupational Therapist
PA8	Priority Action Area #8 (National Dementia Strategy)
PCRS	Primary Care Reimbursement Scheme
PET	Positron Emission Tomography
PREMS	Patient Reported Experience Measures

PROMs	Patient Reported Outcome Measures
QoL	Quality of Life
QoL-AD	Quality of Life in Alzheimer's Disease
QWB	Quality of Well-Being Scale
ReDeGi	Registry of Dementia in Girona
ROADMAP	Real world Outcomes across the Alzheimer's Disease spectrum for better care: Multi-modal data Access Platform
RUDAS	Rowland Universal Dementia Assessment Scale
SAT	Single Assessment Tool (interRAI™)
SAT	Single Assessment Tool
SCADR	South Carolina Alzheimer's Disease Registry
SHR	Shared Health Record
SIG	Special Interest Group
SLA	Service Level Agreement
SNOMED - CT	Systematised Nomenclature of Medicine – Clinical Terms
SOP	Standard Operating Procedure
SPECT	Single-Photon Emission Computed Tomography
SveDem	Swedish Dementia Registry
VPN	Virtual Private Network
WHO	World Health Organisation
WHOQOL	World Health Organisation Quality of Life scale
WHOQOL-BREF	World Health Organisation Quality of Life Brief scale

Appendix B. ICHOM Standard Dataset for Dementia

ICHOM Standard Set for Dementia

Case-Mix Variables

Patient Population	Measure	Supporting Information	Timing	Data Source
Demographic Factors				
All patients	Age	Date of birth	Baseline	Clinical, Administrative data or patient/caregiver reported
	Sex	Sex at birth		
	Level of education	Highest level of schooling completed		Administrative data or patient/caregiver reported
	Living status and location	Most recent living arrangements	Baseline and annually	Patient/caregiver reported
	Smoking status	Smoking status (of cigarettes, cigars or tobacco)		
	Alcohol use	How much alcohol is consumed regularly		
	Body mass index	Body mass index		Clinical
Baseline Clinical Status				
All patients	Type of dementia	Using ICD classification	Baseline	Clinical or administrative
	Level of dementia	Tracked via the Clinical Dementia Rating scale		
Associated Clinical History				
All patients	Previous head injury	Has the person with dementia sustained a traumatic brain injury prior to dementia diagnosis, classified as mild/minor, moderate or severe	Baseline	Clinical or administrative
	Cardiovascular event incidence	Incidence of a cardiovascular event	Baseline and annually	Patient/caregiver-reported, clinical or administrative
	Comorbidities	Comorbidities (these include high blood pressure, diabetes, depression, and high cholesterol)		
Medication Variables				
	Total number of medications prescribed	What is the total number of (non-topical, and not over-the-counter) medications (for dementia and/or other conditions) the person with dementia has been prescribed		
	Acetylcholinesterase inhibitors	Indicate if the person with dementia is currently prescribed an acetylcholinesterase inhibitor		
	NMDA receptor antagonists	Indicate if the person with dementia is currently prescribed a NMDA receptor antagonist		

All patients	Antipsychotic drugs (also known as neuroleptics or major tranquilizers)	Indicate if the person with dementia is currently prescribed any antipsychotic drugs (also known as neuroleptics or major tranquilizers)	Baseline and annually	Clinical or administrative data
	Antidepressants	Indicate if the person with dementia is currently prescribed an antidepressant		
	Anticonvulsant medications	Indicate if the person with dementia is currently prescribed an anticonvulsant medication		
	Hypnotics	Indicate if the person with dementia is currently prescribed a hypnotic		
Symptoms, Functioning & Quality of Life				
All patients	Neuropsychiatric	Includes anxiety, depression, behaviour, apathy and psychosis (tracked via the Neuropsychiatric Inventory)	Baseline and annually	Clinical
	Cognitive	Includes memory, orientation, verbal fluency and executive function (tracked via the Montreal Cognitive Assessment)		
	Social	Includes community affairs and relationships		
	Daily living	Includes activities of daily living such as sleeping, eating and financial resource. Tracked via the Bristol Activity Daily Living Scale		
	Overall quality of life and wellbeing	Patient reported dementia specific and general health-related QOL Includes enjoyment of activities, pain, financial resource and side effects of medications (tracked via the Quality of Life-AD and Quality of Wellbeing Scale-Self-Administered)	Baseline and 6-monthly	Patient/caregiver reported
Carer				
All patients	Carer quality of life	Carer-reported health related QOL (Tracked via the EuroQol-5D). Refer to Data Dictionary for alternative options.	Baseline and annually	Patient/caregiver reported
Sustainability				
All patients	Full-time care	Does the person with dementia require 24 hour care (delivered in any setting)	Baseline and annually	Patient/caregiver reported

Safety				
All patients	Falls	How many falls has the person with dementia sustained in the last 12 months	Baseline and annually	Caregiver-self-reported
Clinical Status				
All patients	Disease progression	Level of dementia (tracked via the Clinical Dementia Rating)	Baseline and annually	Patient/caregiver reported
	Hospital admissions	How many times has the person with dementia been admitted and readmitted to hospital in the last 12 months		Administrative data
	Overall survival	All-cause mortality		Administrative data (e.g.death registry)

Cognitive Outcomes

The Working Group recommend the Montreal Cognitive Assessment (MoCA) for measurement of cognitive outcomes, however the following limitations of this tool should be considered:

- There is emerging evidence of limitations of using the MoCA in sub-populations (Rossetti et al 2011).
- As with many cognitive tools, the MoCA is influenced by education bias of test (Zhou et al 2015, Rossetti et al 2011, http://www.mocatest.org/faq/).
- For some language translations of the MoCA, there are multiple versions of the test with unclear differences, and the subsequent validity and reliability of different versions.
- There is a strong need to ensure the tool is administered reliably in routine clinical settings.
- As with many cognitive tools, there may be increasing limitations of the MoCA in persons with very late stages of dementia.

Health-related Quality of Life

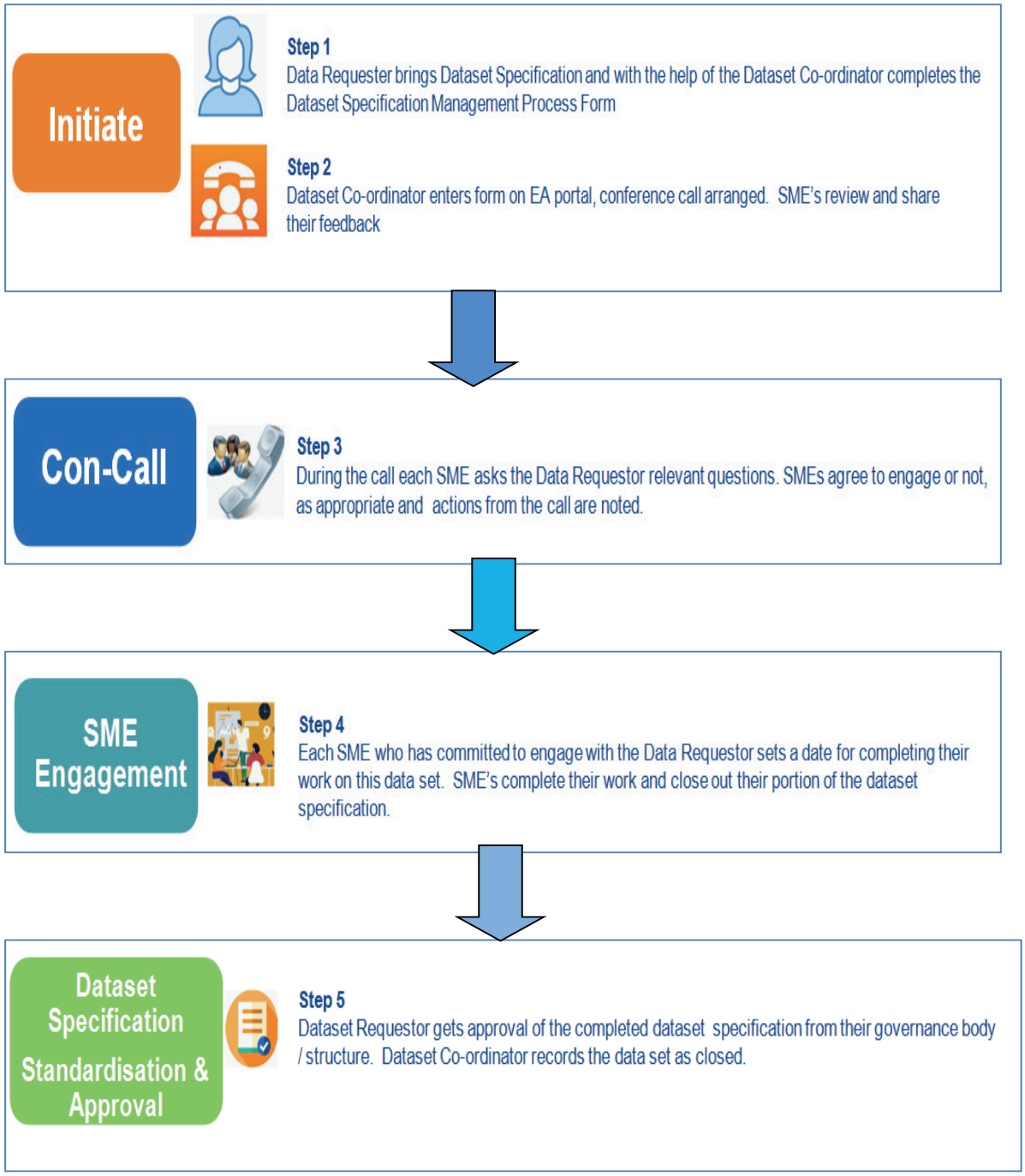
The international nature of this effort is reflected in our recommendation of instruments for measuring health-related quality of life. We recommend using the EQ-5D-5L/3L, SF-12, or VR-12. The EQ-5D-3L is more commonly used in European countries while the SF-12 and VR-12 are commonly used in the United States. As cross walks have been developed enabling translation between these instruments, we present them here as equally valid instruments (Le QA, 2014). EQ-5D scores can be predicted from PROMIS global items, the PROMIS-10 (Revicki et al 2009).

The Euro-Qol group has also published a 5 level version of the EQ-5D in addition to the 3 level version which demonstrates valid redistribution, reduced ceiling, and improved discriminatory power and convergent validity (Janssen et al 2012). Scores of the 5D version can be translated to the 3D version (van Hout et al 2012 and on the EuroWol website www.euroqol.org), and therefore the EQ-5D-3L could also be used as a measure of health-related quality of life in this Standard Set.

1. **Probabilistic mapping of the health status measure SF-12 onto the health utility measure EQ-5D using the US-population-based scoring models.** Le QA. Qual Life Res. 2014 Mar;23(2):459-66. doi: 10.1007/s11136-013-0517-3. Epub 2013 Sep 13.
2. **Measurement properties of the EQ-5D-5L compared to the EQ-5D-3L across eight patient groups: a multi-country study.** M. F. Janssen, A. S Pickard, D Golicki, C Gudex, M Niewada, L Scalone, P Swinburn, J Busschbach. Qual Life Res 2012 DOI 10.1007/s11136-012-0322-4
3. **Predicting EuroQol (EQ-5D) scores from the patient-reported outcomes measurement information system (PROMIS) global items and domain item banks in a United States sample.** Revicki DA1, Kawata AK, Harnam N, Chen WH, Hays RD, Cella D.Qual Life Res. 2009 Aug;18(6):783-91. doi: 10.1007/s11136-009-9489-8. Epub 2009 May 27.
4. **Interim scoring for the EQ-5D-5L: Mapping the EQ-5D-5L to EQ-5D-3L value sets.** van Hout B, Janssen MF, et al. Value in Health 2012 Jul-Aug;15(5):708-15."Neurology. 2011 Sep 27;77(13):1272-5. doi: 10.1212/WNL.0b013e318230208a. Epub 2011 Sep 14.
5. **Normative data for the Montreal Cognitive Assessment (MoCA) in a population-based sample**. Rossetti HC1, Lacritz LH, Cullum CM, Weiner MF.
6. **Use of the MoCA in Detecting Early Alzheimer's Disease in a Spanish-Speaking Population with Varied Levels of Education.** Yan Zhou,a,* Freddy Ortiz,a Christopher Nuñez,a,c,d David Elashoff,a,b Ellen Woo,a Liana G. Apostolova,a Sheldon Wolf,a Maria Casado,a Nenette Caceres,a Hemali Panchal,a and John M. Ringmana Dement Geriatr Cogn Dis Extra. 2015 Jan-Apr; 5(1): 85–95.

Appendix C. Dataset Specification Management Process (HSE)

DSMP Steps



Appendix D. Funding, Governance and Operations - Examples

	Funding, Governance and Operations
Danish Dementia Registry (Quality)	Danish Clinical Registries are founded as part of a national initiative to ensure continued clinical and research improvement through the utilisation of data (health informatics). Each database, including the Danish Dementia Registry, is mandated by law (consent not required for data collection) and regulated by national government, but is financed and owned by regional governments (currently covers memory clinics in the capital region of Denmark – Copenhagen and northeast Zealand; approximately 30% of the population). Each Registry has a professional board representing the main clinical stakeholders.
The French National Alzheimer Database (BNA) (Epidemiological)	The BNA captures every consolation or point of care in a memory unit, memory resource and research centre and by specialists (neurology, geriatrics, psychiatry) as a separate entry. Data is administered collaboratively through a partnership between the Public Health Department of Nice University Hospital, the French Institute for Public Health Surveillance and the Directorate General of Care Provision. The servers are hosted in Nice University Hospital and the BNA team has a permanent staff consisting of a statistician in charge of data management and a computer systems manager. Other staff is composed of clinicians working in the Nice CMRR and the Public Health Department. Patient consent is not required for data collection and data is fully anonymised for reporting purposes.
Registry of Dementias of Girona (ReDeGi) Epidemiological (but investigating a move to a quality focus)	ReDeGi is a local dementia registry funded by the Health Region of Girona, from the Department of Health of the Generalitat de Catalunya. Data is gathered from hospital diagnostic settings and a mixture of opt-in and opt-out consent is used for different aspects of the registry. Registry staff visit the clinics to perform data collection activities. Unlike many epidemiology registers, it includes annual follow-up.
Norwegian Dementia Registry (NorCog) (Quality)	NorCog is a national registry that captures data for all persons referred for dementia assessment in relevant outpatient clinics and its focus on quality improvements to diagnostic and post-diagnostic dementia care. It operates using opt-in consent, which is sought in the first visit. If a person is not able to give consent, they are not approached.
South Carolina Alzheimer's Disease Registry (Epidemiological)	Maintained by the University of South Carolina, in cooperation with the SC Department of Health and Human Services, the SC Department of Mental Health, the USC School of Medicine, and the SC Office of Budget and Control
Swedish Dementia Registry SveDem (Quality)	The Swedish Dementia registry is funded by the Swedish Association of Local Authorities and Regions and the Swedish Brain Power network. Karolinska University Hospital has the overall responsibility for the data (SveDem registry holder), and the registry is governed by a steering committee consisting of representatives from healthcare professions. A formal agreement between the registry holder and the head of the clinic is created for each clinic that provides data to the registry. The registry holder and the national coordinator have day-to-day responsibility for the registry. Staff include a fulltime administrator and regional coordinators, Consultancy in epidemiology and statistics is purchased if needed. SveDem followed a phased implementation approach starting with memory clinics, then primary care and now residential care. The aim is to follow the person along the full chain of care. Follow-up data is recorded annually. Consent is not required to collect data, but an opt-out option is available and if actioned, the person's data will be removed from the registry. **Note: Sweden has a separate BPSD registry that focuses on collection of data relating to NPI scores and treatment plans.**

The data for this table are taken from (Krysinska et al., 2016)

Appendix E. Summary Feedback - Outcomes and Quality Indicators Workshops

Category	Initial commentary and feedback received from two workshops	Proposed Quality Indicator	Corresponding Registry Data Field	Comments and feedback received back on the proposed quality indicator	Policy Impact
Quality of Diagnosis	Clinicians: Some sort of lead time measurement would be useful providing it is meaningful	Time from start of investigation (1st contact with person) to diagnosis (number of days)	Date of referral Date of Diagnosis	Needs to be clearer and possibly split out further; e.g. Time from referral to initial assessment - Time from assessment to diagnosis. Imaging can sometimes cause delays. Longer time to diagnosis may be better in for some patients. Focus should be to ensuring patients are not waiting too long for their initial appointment.	Dementia Diagnostic and Post Diagnostic Model of Care and Support – publication forthcoming - Outcome measure should reflect expected pathways
	Clinicians: Diagnostic outcome measures should be future proofed. Outcome measures should not be test specific (MMSE, IADL). Not all patients the same there is an element of discretion to the tests performed depending on the individual.	Proportion of patients undergoing basic dementia work up	Cognitive assessment undertaken Neuropsychological evaluation completed Neuroimaging testing completed Biomarkers completed Functional evaluation Validated set of functional test	Who will define basic dementia work up? acknowledging that certain tests will not be applicable in certain circumstances Agreement that we need some common understanding. NDO noted this should come with the diagnostic framework that will be published as part of the Diagnostic Pathways project.	Diagnostic guidelines outlining the list of valid tests in each broad assessment category Basic dementia work to be defined in the national guidelines

Category	Initial commentary and feedback received from two workshops	Proposed Quality Indicator	Corresponding Registry Data Field	Comments and feedback received back on the proposed quality indicator	Policy Impact
	SIG: Sub-type of dementia is important, as journey is different.	Proportion of patients with dementia who receive a specific dementia diagnosis	Dementia subtype	Consideration should be given to which disease classifications to map to HIPE uses ICD10 DSM-V not used outside psychiatry. HSE medium LT plan go to SNOMED.	Evidence to guide service and support response to address dementia subtypes and associated symptoms Registry will need a list that can map to various codes (as needed) in the background.
Quality of Treatment	Clinicians: Important to track antipsychotic medication Benefits of having medication review SIG: quantity and type of medication – important to have a medication review	Proportion of patients treated with antipsychotic drugs Proportion of patients treated with anti-dementia drugs Proportion of patients who undergo an annual medications review	Antipsychotic medication Dementia Medication	Driven by the national clinical guidelines Discussion noted the importance of covering both antipsychotic drugs and benzodiazepines. In terms of medication reviews HIQA recommendation 3 months /4 months but only residential care. Acute hospital setting different; so too is community care. Annual might be too long. Consensus reached that indicator should not be centred on time as it varies across clinical settings but focus on ensuring good medication in a meaningful way.	Guidelines on the prescribing of antipsychotic medication have been developed and are being published in December. No standard practice around medication reviews

Category	Initial commentary and feedback received from two workshops	Proposed Quality Indicator	Corresponding Registry Data Field	Comments and feedback received back on the proposed quality indicator	Policy Impact
Quality of Support	Clinicians: Care Plan need for something meaningful rather than yes /no	Proportion of patients who have a care plan		Discussion lead to 'What is a Care Plan?' Understanding amongst some in the group that this was a document that identifies a patient's issues and addresses each individually. In Mental Health, each member of the team inputs into the care plan The ICPOP is seen as a good example of integration of this Multi-Disciplinary Team approach. Difficulty flagged with sharing information between the different care providers.	If Care Planning is important there needs to be guidelines around what clinicians are expected to track here
	SIG: A lead time measurement should cover all referrals (e.g. to a service in the community)	Proportion of patients who have follow up after the initial assessments		This would be linked to the Care Plan there is obvious data source currently for this information	The NDO are developing a post-diagnostic framework, which will outline the foundations of post-diagnostic support.
	SIG: Track living circumstances	Time waiting for home support services		Some may already have home support; need to cover both new and additional supports	Support further service development

Category	Initial commentary and feedback received from two workshops	Proposed Quality Indicator	Corresponding Registry Data Field	Comments and feedback received back on the proposed quality indicator	Policy Impact
	SIG: Track living circumstances	Proportion of persons with dementia who have day care		Important to look at psychosocial interventions, but it should be noted that not everyone needs them. If person is receiving no supports, that is the group we need to focus on Younger onset – if in employment, what supports do you need to stay in employment?	
	SIG: Track living circumstances	Time from diagnosis of dementia to permanent residential care			To support further service development
Quality of Life	Special Interest Group: Discussion on Driving ability and the importance transport infrastructure for independence	Proportion of patients in which the ability to continue driving has been assessed		Driving can be considered part of quality of life.	Driving comes up in discussions is it something the Dementia Registry should track

Category	Initial commentary and feedback received from two workshops	Proposed Quality Indicator	Corresponding Registry Data Field	Comments and feedback received back on the proposed quality indicator	Policy Impact
	Workshop discussion Ability for the person to continue to do what they want. Patient Reported Outcome	Overall Quality of Life of Person with Dementia	Suggested Data QoL-AD score EQ-5D score ….	Options include: WHO standardised tool QoL-AD copyright issues Alternative EQ-5D, but this is very health oriented. If QoL-AD is the right tool, it might still be worth paying price.	Decision required regarding the appropriate PROM measure
	Carer Reported Outcomes	Overall quality of life and wellbeing of Carer	Suggested Data QoL-AD score EQ-5D score Carer Strain/Burden Index….	May want the carer equivalent to the dementia QoL measure but can also consider a carer-specific measure	Decision required regarding the appropriate PROM measure

Table 29 Initial set of Irish Dementia Registry outcome measures for prioritisation

Indicator Prioritisation Form

Please give an importance score on a scale from 0 to 10 for each indicator where:

— 0 is not important
— 1-4 indicates limited importance
— 5-7 indicates important but not critical
— 8-10 indicates critical

	Proposed Quality Indicator for the National Dementia Registry	Please indicate importance score using criteria above
1	Time from start of investigation (1st contact with person) to diagnosis (number of days)	
2	Proportion of patients undergoing basic dementia work up	
3	Proportion of patients with dementia who receive a specific dementia diagnosis	
4	Proportion of patients treated with antipsychotic drugs	
5	Proportion of patients treated with anti-dementia drugs	
6	Proportion of patients who undergo an annual medications review	
7	Disease progression	
8	Proportion of patients who have a standard care plan	
9	Proportion of patients who have follow up or referral after the initial assessments	
10	Time waiting for home support services	
11	Proportion of persons with dementia who have day care	
12	Time from diagnosis of dementia to permanent residential care	
13	Proportion of patients in which the ability to continue driving has been assessed	
14	Overall Quality of Life of Person with Dementia	
15	Overall Quality of Life and wellbeing of Carer	

Appendix F. National Dementia Registry Minimum Data Set

Table 30 Summary of initial feedback in relation to important outcomes and proposed quality indicators

	Data Field	Data Availability	Prototype	Development	How the data will be used
1	Registry ID	System generated		Phase 1	
2	Patient IHI number	System generated		Phase 1	
3	Patient GMS (medical card number if known)	Unknown	×	Phase 1	
4	Given name (First name)	Available	×	Phase 1	
5	Family name	Available	×	Phase 1	
6	Date of Birth	Available	✓	Phase 1	MI – age profile of persons with dementia
7	Sex at Birth	Available	✓	Phase 1	MI – number/% males vs females
8	Address	Available	×	Phase 1	MI – location of persons with dementia
9	Eircode	Available	×	Phase 1	MI – location of persons with dementia
10	Marital Status	Available	✓	Phase 1	MI – Living arrangements
11	Living Status	Available	✓	Phase 1	MI – Living arrangements possible care need
12	Socially active	Available	✓	Phase 1	MI – social relationships /indicator of QoL
13	Physically active In a typical week how many days of physical activity 30+ mins	Unknown	×	Phase 1	MI – risk factors
14	If 4 days or less selected above in a typical week have you had either 150 mins of moderate or 75 mins of vigorous exercise	Unknown	×	Phase 1	MI – risk factors
15	Hearing impairment	Unknown	×	Phase 1	MI risk factors

	Data Field	Data Availability	Prototype	Development	How the data will be used
16	Vision impairment	Unknown	×	Phase 1	M risk factors
17	Driving	Available	✓	Phase 1	Outcome measure: Proportion of patients for which the ability to continue driving has been assessed.
18	Education	Available	✓	Phase 1	MI: Socioeconomic status /dementia risk factor
19	Employment status	Unknown	×	Phase 1	MI: Socioeconomic data
20	Employment What is /was the persons main employment	Available	✓	Phase 1	
21	Intellectual Disability	Available	✓	Phase 1	Useful for ID research
22	Aetiology of ID	Available	✓	Phase 1	
23	Weight recorded in Kg	Not available	✓	Phase 1	Needed to calculate BMI
24	Height in metres2	Not available	✓	Phase 1	Needed to calculate BMI
25	Body Mass Index	System generated		Phase 1	MI: BMI data important as risk factors/risk modification prevention measures
26	How often do you have a drink containing alcohol	Available	✓	Phase 1	important as risk factors/risk modification prevention measures
27	How many drinks containing (10grams alcohol) do you have in a typical day when drinking	Not always available	✓	Phase 1	18/40 clinics had data important as risk factors/risk modification prevention measures
28	How often do you have 6 or more drinks (10 grams each) on one occasion	Unknown	×	Phase 1	important as risk factors/risk modification prevention measures

	Data Field	Data Availability	Prototype	Development	How the data will be used
29	Smoking Status	Available	✓	Phase 1	important as risk factors/risk modification prevention measures
30	Clinic ID	System generated from login details		Phase 1	
31	Referral from	Available	✓	Phase 1	
32	Date of receipt of referral	Available	✓	Phase 1	Outcome measure: (1) Time from referral to initial assessment (2) Time from referral to dementia diagnosis
33	Date of initial assessment for dementia	Available	✓	Phase 1	Outcome measure: Time from referral to initial assessment
34	Date of dementia diagnosis	Available	✓	Phase 1	Outcome measure: Time from referral to dementia diagnosis
35	Dementia Diagnosis	Available	✓	Phase 1	Outcome measure: Proportion of patients who receive a specific dementia diagnosis
36	Has the person been told about their diagnosis	Unknown	×	Phase 1	
37	Translation to other disease classifications	System generated			Mapping exercise undertaken with ICD-10/ SNOMED
38	Diagnosis made by	Available	✓	Phase 1	
39	Brief cognitive test	Available	✓	Phase 1	Outcome measure: Proportion of people undergoing basic dementia work up
40	Comprehensive neuropsychological evaluation completed	Available	✓	Phase 1	Outcome measure Proportion of people undergoing basic dementia work up
41	Neuroimaging testing completed (e.g. CT/MRI/ MRI dementia protocol)	Available	✓	Phase 1	Outcome measure Proportion of people undergoing basic dementia work up
42	Bio-markers completed	Available	✓	Phase 1	Outcome measure Proportion of people undergoing basic dementia work up
43	Functional Evaluation	Available	✓	Phase 1	Outcome measure Proportion of people undergoing basic dementia work up

	Data Field	Data Availability	Prototype	Development	How the data will be used
44	Disease progression measure	Not available	✓	Phase 1	Outcome: Disease Progression
45	Disease stage(translation from disease progression measure)	System generated			
46	Dementia medication	Available	✓	Phase 1	Outcome measure: Proportion of persons treated with dementia drugs
47	Anti-depressant medication	Available	✓	Phase 1	
48	Anti-Psychotic medication	Available	✓	Phase 1	Outcome measure Proportion of persons treated with anti-psychotic medication
49	Benzodiazepines	Available		Phase 1	
50	Total number of medications the person is taking	Available	✓	Phase 1	
51	Has a personalised care plan been created	Available	✓	Phase 1	Outcome Proportion of persons who have a care plan
52	Who created the care/support plan created by	Available	✓	Phase 1	
53	Current Supports At the time of the visit is the person availing of any of the following	Not available		TBD	
54	-Psychosocial Post-diagnostic Support	Not available		TBD	
55	Has there been a discussion on advanced care planning? If yes: Has an advanced care plan been developed?	Unknown		TBD	
56	Has this person a dedicated single point of contact within the health service	Unknown		TBD	
57	Has this person a case manager	Not available		TBD	

	Data Field	Data Availability	Prototype	Development	How the data will be used
58	QoL-AD Quality of Life measure carried out with the person who has dementia	Not available		Phase 1	
59	WHOQOL Quality of Life measure carried out with Carer	Not available		Phase 1	
60	Date of Death	Integrated field		TBD	Could move to Phase 2

Table 31 National Dementia Registry Minimum Dataset

Patient Characteristics	Service Provider Characteristics	Diagnostic Characteristics	Treatment and Care Characteristics
Registry ID	Clinic ID	Dementia diagnosis	Dementia medication
Patient IHI number	Referral from	Has the person been told about their diagnosis	Anti-depressant medication
Patient GMS /MCN number	Date of receipt of referral	Translation to other disease classifications	Anti-Psychotic medication
First Name	Date of Initial Assessment for dementia	Diagnosis made by	Benzodiazepines
Family Name	Date of Dementia Diagnosis	Brief cognitive test	Total number of medications the person is taking
Date of Birth		Comprehensive neuro-psychological evaluation completed	Has a personalised care plan been created
Sex at Birth		Neuroimaging testing completed (e.g. CT/MRI/MRI dementia protocol)	Who created the care/ support plan
Address		Bio-markers completed	Current Supports
Eircode		Functional Evaluation	Psychosocial interventions Post-diagnostic Support
Marital Status		Disease progression measure	Advanced care planning
Living Status		Disease stage (translation from disease progression measure)	Has this person a dedicated single point of contact within the health service?
Socially active			Has this person a case manager?
Physically active			QoL-AD Quality of Life measure carried out with the person who has dementia
Hearing impairment			WHOQOL Quality of Life measure carried out with Carer
Vision impairment			Date of Death
Driving			
Education			
Employment status			
Employment position			
ID Aetiology of ID			
Weight in kg			
Height in M2			
Body Mass Index			
Alcohol Status			
Smoking Status			

Appendix G. HIPE Summary Sheet

Hospital In-Patient Enquiry (HIPE) Summary Sheet

For use with HIPE on ALL DISCHARGES FROM 01.01.2019

Patient's Hospital of Discharge | | |

MRN | | | | | | |

Sex | | Date of Birth / /

Admission Date / /

Admission Time _ _ : _ _

Discharge Date / /

Discharge Time _ _ : _ _

Type (priority) of Admission

W/List If Type=1-2	Type of Elective Adm If Type=1-2	Mode If Type=4,5,7

IF TRANSFER IN:
Tick if this a transfer of a non-admitted patient

FOR LOCAL COLLECTION ONLY

*Name:_____

*Address:_____

_____

Affix Label

Admission Source

Discharge Code

Duration of continuous ventilatory support (hours) Cumulative | | |

Number of nights in a virtual ward | | |

Area of Residence | | |

*Eircode | | | | | |

Marital /Civil Status

Medical Card

Discharge Status

Health Insurer

Parity Still + Live

Admitting Ward | | | | |

Discharge Ward | | | | |

Transfer from | | |

Transfer to | | |

Temp Leave Days

Date of Transfer to rehab/PDU / /

Infant Admit Weight (grams) | | |

Days in a Critical Care Bed

Day Case

Day Ward

Day Ward ID | | | | |

	Total	Single	Multiple
Days in a Private Bed			
Days in a Semi-Private Bed			
Days in a Public Bed			
Days (or part there of) in ICU			

Admitting Consultant | | |

Primary Consultant | | |

Intensive Care Consultant | | |

Up to 10 **Intensive Care** consultants may be recorded

Discharge Consultant | | |

Specialty of **Discharge** Consultant | | |

Medical Discharge Date / /

PDX = *The diagnosis established after study to be chiefly responsible for occasioning the patient's episode of care in hospital (ACS 0001)*

	ICD-10-AM Code		Hospital Acquired Dx	Consultant #	Specialty
(1)	| | | |	Principal Diagnosis (PDX)	^	| | |	| | |
(2)	| | | |			| | |	
(3)	| | | |			| | |	
(4)	| | | |			| | |	
(5)	| | | |			| | |	
(6)	| | | |			| | |	
(7)	| | | |			| | |	
(8)	| | | |			| | |	
(9)	| | | |			| | |	
(10)	| | | |	Up to 30 diagnoses codes may be entered.		| | |	

For use on all discharges from 01.01.2019

	Procedure/Intervention Codes	Block No.		Consultant #	Consultant Anaesthetist #	Date of Procedure
(1)	| | | | – |	[ ]	Principal Procedure	| | |	| | |	/ /
(2)	| | | | – |	[ ]		| | |	| | |	/ /
(3)	| | | | – |	[ ]		| | |	| | |	/ /
(4)	| | | | – |	[ ]		| | |	| | |	/ /
(5)	| | | | – |	[ ]	Up to 20 procedure codes may be entered.	| | |	| | |	/ /

Case entered on HIPE: | | Hospital Ref No. For HPO Use: | | |

* Patient Name, Full Address, full DOB, and Full Eircode are currently not exported to the HPO. These are collected only at hospital level.

More than one consultant can be recorded.

^ HADx flag can be assigned for PDx in **Neonates on the birth episode only**.

Source: Healthcare Pricing Office

Appendix H. Examples of dissemination of registry data

SveDem
Svenska Demensregistret

Swedish Dementia Registry

A-K Edlund[1], K Spångberg[2], D Religa[1], S Eriksson[3], N Granqvist[4], T Hallén[5], L Kilander[6], K Kåwe[7], U-B Mattsson[8], C Mörk[9], A Nelvig[10], K Nägga[11], H Wijk[12], A Wimo[13], B Winblad[13], M Eriksdotter Jönhagen[1]

[1] Geriatric clinic, Karolinska University Hospital, Stockholm, [2] Uppsala Clinical Research Center (UCR), Uppsala, [3]Section of Geriatric Medicine, Dept of Community Medicine and Rehabilitation, Umeå University, Umeå, [4]Primary Health Care Center, Borensberg , [5]The municipality of Motala, [6] Dept. of Geriatrics, Uppsala University Hospital, Uppsala, [7]Memory clinic, Karlstad Central Hospital, [8] Neuropsychiatric clinic, Sahlgrenska University Hospital, Gothenburg, [9]Primary Health Care Center, Uppsala, [10] Geriatric clinic, Sundsvall Hospital, Sundsvall, [11]Neuropsychiatric clinic, Skåne University Hospital, Malmö, [12]The Sahlgrenska Academy, Gothenburg, [13] Alzheimers Disease Research Center, Karolinska Institutet

Introduction

The number of patients suffering from dementia is increasing. To achieve a dementia care of similar and high quality in the whole country the national quality registry for patients with dementia disorders, SveDem, was initiated by the Swedish Brain Power network in 2007.

The aim of SveDem is an equal, optimized care and treatment of patients with dementia disorders in Sweden. SveDem is financed by the Swedish Association of Local Authorities and Regions and Swedish Brain Power.

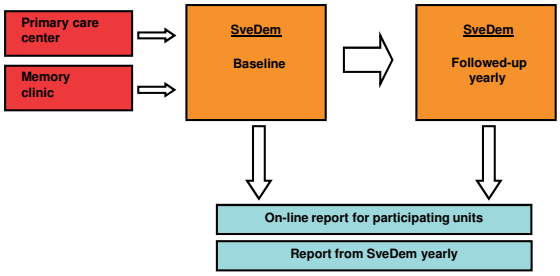
Method

Patients diagnosed with dementia disorders are registered and followed-up once a year. Memory clinics and primary care centers report to the webbased registry.

Exampels of parameters registered

- Time from referral to diagnosis
- Work up investigations
- Age, gender, BMI, level of care
- Diagnosis
- Medical treatment
- Support from Local Authority

All participating units have access to their own data, which also can be compared with data from their region and the whole country. A report from SveDem is published yearly.



Results

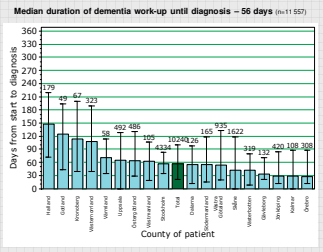
90% of all memory clinics in Sweden are currently participating in SveDem. At present 11 557 patients, newly diagnosed with dementia, are registered and 4 277 followed-up once a year.

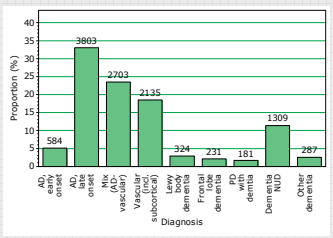
Demography (% alt. median, n=11 557):

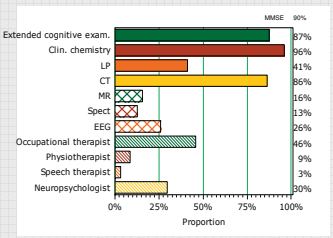
- Women 59%
- Age 79 yrs
- BMI 24
- MMSE 22/30
- Numbers of drugs at work-up start 4
- Living in own home 92%
- Living alone 48%
- Day Care 5%
- Home Care 32%

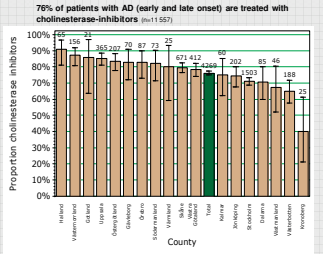
Quality parameters

- Time from referral to work-up start, aim 1 month – currently 40 days
- Time from work-up start to diagnosis, aim 1 month – currently 56 days
- >90% of patients undergoing basal dementia work-up according to national guidelines – currently 78%
- 90% of patients diagnosed with AD will be treated with cholinesterase-inhibitors – currently 76%
- 100% of patients followed-up once a year.
- No gender differences in care









Conclusion

SveDem will lead to

- improvement in diagnostics, work-up, support and treatment at local and national level
- memory clinics adhere well to national guidelines concerning basal dementia work-up, but primary care unknown
- a challenge is to implement registry in primary care centers

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SWEDISH brain POWER

KAROLINSKA Universitetssjukhuset

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Appendix I. Typical Support Infrastructure SLA

A typical Service Level Agreement will include the services provided and responsibilities as shown in the table below (OpenApp, 2020b).

Service Desk Services	Vendor	Customer
Provide front line support for all registry users		√
Provide front line support & access management for all registry users		√
Provide 2nd line Email & Telephone Support for nominated registry Super Users	√	
Provide 3rd level software maintenance "software bugs" resolution	√	
Solution Maintenance	**Vendor**	**Customer**
Manage one operating environment. OpenApp software will be deployed on one virtual machine on the Health Atlas infrastructure.	√	
Carry out 24/7 Event Management on Solution *(Intrusion Detection, Security, Storage, Swap, Network, Operating system and software modules)*	√	
Carry out Incident Management on Solution. Incidents are normally raised via the OpenApp Event Management process or notification from Super Users.	√	
Carry out daily backup of the database.	√	
Manage Network Services and infrastructure	√	
Manage OS operational environments	√	
System security administration	√	
Capacity planning and performance tuning	√	
Manage storage services	√	
Manage Disaster Recovery of the operating platform, database, DNS service, and cloud computer-hosting service.	√	
Standard database administration activities (Vacuum, reindexing and storage management)	√	
Troubleshoot and resolve OS-related problems	√	
Management of DNS alpha1registry.openapp.ie	√	
Management of cloud computing services provided by third party vendor (Vendor is HEAnet)	√	
Service Management	**Vendor**	**Customer**
Carry out Problem Management and Continual Service Improvements initiatives	√	√
Manage Solution Change Management & Release Management Activities	√	
Participate in Change Management & Release Management Activities (UAT Testing)	√	√
Provide Escalation contacts for Incident Escalation	√	√
Provide contact to authorize disaster recovery	√	√
Provide contact for security incident escalation	√	√
Participate in annual Service Reviews	√	√

Appendix J. Integration Matrix

	National Dementia Registry Data Field	Notes	HIPE Summary Sheet	Chronic Disease Management System	PCRS	interRAI™	Patient Summary Record
1	Registry ID	Generated by registry itself					
2	Patient IHI number	May be possible to introduce Find IHI functionality into the registry from outset		Yes (seeded)	Not seeded	Field for IHI not seeded	Captures Health identifier
3	Patient GMS (medical card number if known)		MRN	Yes		Medical scheme card number	
4	Given name (First name)		Name is part of address label local collection only	Yes	PCRS stores personal details	Yes	Yes
5	Family name		Name is part of address label local collection only	Yes		Yes	Yes
6	Date of Birth		Yes	Yes		Yes	Yes
7	Sex at Birth		Yes	Yes		Yes	
8	Address		Address label local collection System tracks Transfer from Transfer to	Yes			Yes
9	Eircode		Yes	Yes		Postcode	
10	Marital Status					Yes	

	National Dementia Registry Data Field	Notes	HIPE Summary Sheet	Chronic Disease Management System	PCRS	interRAI™	Patient Summary Record
11	Living Status					Yes	
12	Socially active					Social relationships	
13	Physically active In a typical week how many days of physical activity 30+ mins			Yes		Last 3 days	
14	If 4 days or less selected above in a typical week have you had either 150 mins of moderate or 75 mins of vigorous exercise			Yes			
15	Hearing impairment					Yes	
16	Vision impairment					Yes	
17	Driving					Unsure	
18	Education			Yes			
19	Employment status						
20	Employment What is / was the persons main employment						
21	Intellectual Disability						
22	Aetiology of ID						
23	Weight recorded in Kg			Yes		Yes	
24	Height in metres2			Yes		Yes	

	National Dementia Registry Data Field	Notes	HIPE Summary Sheet	Chronic Disease Management System	PCRS	interRAI™	Patient Summary Record
25	Body Mass Index			Yes			
26	How often do you have a drink containing alcohol			Yes			
27	How many drinks containing (10grams alcohol) do you have in a typical day when drinking			Yes		Yes different categorisation	
28	How often do you have 6 or more drinks (10 grams each) on one occasion			Yes			
29	Smoking Status			Yes		Yes different categorisation	
30	Clinic ID			Captures GP practice		Yes assessment CHO	
31	Referral from						
32	Date of receipt of referral						
33	Date of initial assessment for dementia						
34	Date of dementia diagnosis						

	National Dementia Registry Data Field	Notes	HIPE Summary Sheet	Chronic Disease Management System	PCRS	interRAI™	Patient Summary Record
35	Dementia Diagnosis			Dementia Listed as radio button of one of the Other Major Diagnoses (excl. CDM diagnoses)		'Alzheimer's disease' and 'Dementia other than Alzheimer's disease' are available to be selected by the assessor.	Current Health Condition (m), Clinical Description (o) narrative, Date of Onset (o), Status (m), Date resolved deactivated (o), No health conditions identified (o).
36	Has the person been told about their diagnosis						
37	Translation to other disease classifications		Yes ICD 10 code			Yes	
38	Diagnosis made by		Consultant code				
39	Brief cognitive test						
40	Comprehensive neuropsychological evaluation completed						
41	Neuroimaging testing completed (e.g. CT/ MRI/MRI dementia protocol)						
42	Bio-markers completed						
43	Functional Evaluation						
44	Disease progression measure						

	National Dementia Registry Data Field	Notes	HIPE Summary Sheet	Chronic Disease Management System	PCRS	interRAI™	Patient Summary Record
45	Disease stage(translation from disease progression measure)						
46	Dementia medication						Medicinal Product (m), Dose Strength (m), Dose form type (m), Number of units intake (m), Frequency of intake (m), Duration of treatment (m), Date of start of treatment, No medication prescribed (o).
47	Anti-depressant medication				Yes	Yes	
48	Anti-Psychotic medication				Yes	Yes	
49	Benzodiazepines				Yes		
50	Total number of medications the person is taking			Medication review Y/N	Yes	Yes	
51	Has a personalised care plan been created			Agreed written care plan Y/N/ Declined		Not yet implemented, but could be available	
52	Who created the care/ support plan created by						
53	Current Supports At the time of the visit is the person availing of any of the following						

	National Dementia Registry Data Field	Notes	HIPE Summary Sheet	Chronic Disease Management System	PCRS	interRAI™	Patient Summary Record
54	-Psychosocial Post-diagnostic Support			Education provided by GP / Practice team.		Yes different categorisation	
55	Has there been a discussion on advanced care planning? If yes: Has an advanced care plan been developed?					Advanced healthcare directives	
56	Has this person a dedicated single point of contact within the health service						
57	Has this person a case manager						
58	QoL-AD Quality of Life measure carried out with the person who has dementia						
59	WHOQOL Quality of Life measure carried out with Carer					Carer assessment being rolled out	
60	Date of Death						

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