Towards a National Strategy for Patient Registries in Ireland

Considerations for Government

From
The Medical Research Charities Group (MRCG) &
Irish Platform for Patients’ Organisations Science and Industry (IPPOSI)
October 2011
Preface

This report arose from a concern that the role and potential of patient registries in Ireland could be considerably strengthened if a clear national strategy is developed by the Department of Health and Children and the Health Service Executive.

The report is published by the Irish Platform for Patients' Organisations, Science and Industry (IPPOSI) and the Medical Research Charities Group (MRCG) and builds on previous work on this issue.

There is a concern that the full potential of Patient Registries in developing cost effective and quality health services in Ireland is presently undervalued. The report calls for an urgent national strategy to further develop and indeed in some cases to sustain existing patient registries in Ireland as an invaluable tool for quality and cost effective patient services.

Acknowledgements

The MRCG and IPPOSI wish to thank the working group that organised the conference that led to this publication which includes Denise Cremins, Marie Downes, Eibhlin Mulroe and Philip Watt with further support from Karen Munnelly in IPPOSI and Alica May in the Cystic Fibrosis Association of Ireland (CFAI). With thanks to the ongoing support and encouragement of John McCormack, Chair of the MRCG and Margaret Webb, Chair of IPPOSI.

We wish to thank Dr Fionnuala Donohue, Public Health Doctor, Department of Health and Children who presented her emerging findings from a forthcoming report on patient registries. Further thanks to all those who participated in the seminar (annex one).

The report was written and edited on behalf of MRCG and IPPOSI by Philip Watt, Alica May (CFAI) and Eibhlin Mulroe (IPPOSI).
Section 1: Introduction

This report aims to provide an evidence based rationale for the development of a national strategy for Patient Registries in Ireland. The findings in this report are primarily drawn from a seminar that brought together experts and key stakeholders in the European Commission Office in Dublin in May 2011. This seminar was organised by Irish Platform for Patients’ Organisations, Science and Industry (IPPOSI) and the Medical Research Charities Group (MRCG). The participants included experts involved in health policy and information, patient organisations, health care professionals, including clinicians and those directly involved in Patient Registries (See Annex 1: Participants at the seminar). The findings and considerations for government in this report build upon both previous and emerging research and experience in this important, but consistently undervalued, area of health policy in Ireland.

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

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

The absence of a national strategy on Patient Registries in Ireland has meant that registries are sometimes viewed as an ‘add-on’ or something that is external to the health service. This report advocates the greater mainstreaming of the analysis arising from registries into the Irish health system, while maintaining the independence and quality of registries in line with international guidelines (Annex 2).

The report is made in the context of the growing recognition at both a national and international level of the contribution that Patient Registries can make to improving health care, including in times of economic recession when efficiency and concerns about value for money inevitably became a heightened public policy priority.

The approach of the report seeks to be pragmatic and sensitive to the challenges within the present health system in Ireland. The report is not about pushing forward an unattainable ‘wish list’, but to develop a strategic approach to registries of which resources is but one element. It seeks to build upon good practice that is already emerging within registries and, in particular, in the emergence of Electronic Patient Records, which are the building blocks for the development of effective and efficient registries.

In short, there is both a strong patient care and business case that can be made for development of a national strategy for the Patient Registries in Ireland.

Among the key findings outlined in section 6 of this report are:

- The data, information and analysis provided by Patient Registries should play an enhanced role in shaping the planning, delivery and review of health services in Ireland.
- The development of a national strategy for Patient Registries will significantly increase the effectiveness and efficiency of health services in Ireland, particularly for clearly definable groups of patients with an acute or long-term medical condition, which requires considerable expenditure by the State.
- Conversely, without clear policy direction and support, the potential of Patient Registries will be blunted. Some existing registries may become unsustainable or will have to significantly scale back their operations, resulting in the loss of years of research and analysis and concomitant negative impact on patient care. This will have major implications for the potential of registries to inform efficiencies and targeting within the health service.
- The national strategy for Patient Registries should usefully consider a framework approach that includes Patient Registries, Patient/Electronic Health Registers and patient databases.

Patient Registries remain the gold standard, but national Patient/Electronic Health Registers and to a lesser degree patient databases both have the potential of developing into registries over time and as resources permit. Registers and databases are also very useful in their own right. A key part of a national strategy for Patient Registries is the crucial role that Electronic Patient Records can contribute.

Part of a national strategy on Patient Registries in Ireland is the mainstreaming of the role and work of registries into existing and forthcoming policy. For example, of immediate priority is the inclusion of a stronger focus on Patient Registries in:

- The programme of work of the Quality and Clinical Care Directorate of the HSE, including the development of clinical standards in specific areas of policy and the appointment of clinical leads in particular areas of policy
- The work of the Health Information and Quality Authority (HIQA)
- The Health Information Bill

Section 2: Definitions and background

The Medical Research Charities Group (MRCG) in conjunction with the Irish Platform for Patients’ Organisations, Science and Industry (IPPOSI) hosted the seminar “Towards a National Strategy for Patient Registries” in Dublin on 10th May 2011. The aim of the roundtable was to:

- Highlight the contribution and cost effectiveness of Patient Registries
- Focus on developing and sustaining Patient Registries
- Consider emerging research findings on Patient Registries in Ireland
- Make recommendations to Government based on consensus among participants.

The meeting was well attended by representatives from patient organisations, healthcare staff including clinicians, the Department of Health and Children, the HSE, HIQA and Industry.

Defining a patient registry framework

The definition of Patient Registries for the purpose of the seminar and this report is a ‘framework for collecting and analysing data on a particular disease that aims to cover the whole national population of that disease’.

During the course of the discussion at the seminar, it became clear that it was useful to consider at least four levels to such a framework, of which resourced and independent Patient Registries are the ‘gold standard’. However, Patient/Electronic Health Registers and patient databases have an important and complementary role to play as part of this framework.

The following table provides a working definition and main characteristics of a patient registry framework in Ireland, while acknowledging that not all registry-type entities will fall neatly into one category or another. The framework is inclusive of Electronic Patient Records, not because they are registries in their own right but because they have the potential to be the building blocks on which registries are built. The development of Electronic Patient Records will significantly reduce the costs and improve the efficiency and impact of Patient Registries in Ireland.

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<th>Table 1: Patient Registries Framework</th>
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<td><strong>Shared characteristics:</strong> The whole national population of the disease is covered. Each individual person (patient) is registered only once as a unique entity that is not duplicated.</td>
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<tr>
<td><strong>Patient Registry</strong></td>
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<td><strong>Patient/Electronic Health Register</strong></td>
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<td><strong>Patient database</strong></td>
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<td><strong>Electronic Patient Records (hospital level)</strong></td>
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Background: Building on Previous Research and Discussion

The approach of the MRCG and IPPOSI to developing a national strategy for a patient registry framework is to build on previous work and discussion in this important policy area. In 2007, the MRCG brought together representatives from the HSE (Population Health Directorate), HRB, HIQA and research charities and established a Registries Working Group to see how each of these organisations with an interest in Patient Registries could work collaboratively. As an initial task, the group identified the need to develop a map of baseline information on what registries exist in Ireland and how they are managed. This work was commissioned by the Registries Working Group of the MRCG and undertaken by Dr Fionnuala Donohue in 2009/10. The research will be published in 2011. In 2008, IPPOSI organised a meeting on Patient Registries that was attended by experts from science, industry, patient groups/medical charities and other key stakeholders. The meeting focussed on the necessary supports for registries to identify the existing challenges and difficulties, and finally to get consensus on what needed to happen next. The findings of this report can be found in ‘Patient Registries in Ireland – Where we go from here’.

These recommendations were subsequently included in a submission to the DOHC Health Information Bill Consultation in 2008, which is to be enacted this year. Since 2008 there has been a very limited response from Government to promote and encourage a national approach to registries in Ireland. The relevant sections of the draft Health Information Bill, while of importance, largely focus on issues related to data protection issues for registries and does not provide substantive direction to encourage and support the development of Patient Registries in Ireland.

Section 3: Patient Registries in Ireland today: Emerging findings

This section of the report summarises the emerging findings of the research undertaken by Dr Fionnuala Donohue, Public Health Doctor, DOHC presented at the MRCG/IPPOSI seminar.

The research aims and methodology can be summarised as follows:
- Review international guidelines for Patient Registries
- Ascertain what Patient Registries are currently active in Ireland
- Draw up a survey to use with these Patient Registries, conduct interviews with relevant stakeholders
- Arrange focus groups with patients to establish their views on Patient Registries

Research Findings

International Guidelines for Registries

Four sets of international guidelines (UK1, US2, Australia3 and Sweden4) on Patient Registries were identified in the research. Best practice drawn from these guidelines encourages fully informed consent. Most of the guidelines required ethical committee approval before the registry commenced. With respect to data standards areas, all of the guidelines supported the use of a defined target population with inclusion/exclusion criteria, development of data dictionaries and data validation. In addition, evaluation of data standards was also recommended. In Australia and Sweden the ongoing attainment of funding is linked to the outcome of such evaluations. (Annex 2 provides an extended summary of international guidelines for Patient Registries).

Survey results from Existing Patient Registries in Ireland

There was 70.2% response rate from registries surveyed as part of the research. Most registries (73%) were found to operate on a National/Regional basis with just under half of these recording approximately 100 new cases each year. The establishment of registries in Ireland has been a relatively recent development, with only three set up from 1966-1991, and 16 opening over the period spanning 2001-2009. A total of 21% registries reported having web-enabled access but paper-based data transfer is active in 71%.

The primary function (48%) for most of these registries is to improve patient safety and/or quality of care. Disease surveillance/disease control rated highly as a secondary function, and research is regarded as an important tertiary function.

A total of 21% of registers had no staff directly employed. For those with staff (79%), 69% reported having two or less staff members, and 27% between three and ten staff members. Some 88% of registers (including 71% of those with no staff) had a named administrator.

Only 11 registries (2010/11) surveyed (58%) specified the amount of funding that they received on an annual basis. Excluding the funding of one very large register, the average amount received by the other ten registers was €231,450 per year. With regards to the start-up funding: 68% of registries reported funding was provided by the state, 12% received funding from commercial resources, and 20% received funding through a charity. In respect of ongoing funding required to sustain existing registers, 72% continue to receive state funding, 12% are funded through a charity, 4% receive commercial funding, 12% have no funding and three registries have dual funding.

Most registries reported having access to IT and clinical support directly through the registry or through available resources on campus; however, one third of registries responded to having no access to statistical support.

Three quarters of registers reported using some form of consent, with just under half using written consent and 75% have some degree of an “opt out” system (of the 27% with no consent 55% also did not have an opt out system). Register size and personnel employed appears to influence the type of consent used. Larger registers and those who have no staff directly employed are less likely to obtain consent. 61.1% of registers with less than three staff members obtained written or verbal consent compared to 28.6% of registers with no staff employed. Registers that had no staff were less likely to get written consent than registers that had staff employed. Large registers were also less likely to have written consent due to size and practicalities of gaining consent due to a large number of cases in the population.

In terms of coverage levels, approximately 40% of registers had all of their target population enrolled on the register, 70% had a

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1IPPOSI (2008). Patient Registries in Ireland – Where we go from here?


Registries were also asked about their use of case definitions, clinical coding systems, disease classification systems and data dictionaries. A total of 58% reported using case definitions, 24% clinical coding systems, 70% disease classification systems and half use data dictionaries. Over half of the registries reported carrying out regular data validations, 70% carry out data duplications and 77% follow up on missing data.

Lessons Learned and Way Forward
Registries were finally asked about the lessons they had learned in developing the registries and what their views were on the way forward for registries in Ireland. The most commonly cited lesson conveyed was the need for good quality consistent data followed by stakeholder involvement in improving data quality and utility of the registries. Continuity of adequate resources for staff training to ensure quality data is being produced was also a repetitive theme and to be conscious of not underestimating the time and resources required at the planning phase (e.g., resources for data collection, analysis and research) of the registry.

Continuity of funding and staffing was cited as being instrumental for the way forward. The development of improved IT systems through web-based data access would facilitate data linkage and sharing of information between hospitals. Improved access would also serve to make the data more relevant to end-users as they would have a more tangible and immediate benefit to participating in the register.

The establishment of national standards for registries to support the operation of those that serve to improve patient care, research and public health were also encouraged. The establishment of appropriate legislation to protect existing registries was also cited as being important.

Feedback from Focus Groups
The focus groups were carried out with patients or parents of patients. The main issues arising from the focus groups are that patients are generally very supportive of the existence of Patient Registries and are aware of their potential benefits to improving quality of care, service planning or facilitating research for the development of new treatments. Patients are also very supportive of data linkage and expressed support for registries that are properly regulated.

Factors affecting their support for registries include situations whereby the data that was being collected was not used purposefully or appropriately, or if it was not updated regularly. The group also raised concerns about the current health services ability to integrate registries into the existing system, given its current limitations and inefficiencies. The buy-in of health service providers was also cited as being important.

Opinions from the focus groups were mixed on the issue of consent, and indeed some questioned whether it was even necessary. They were supportive of legislation and regulation to ensure adequate standards are used for maximum benefit of the registries, to ensure data was actually provided to registries and to safeguard confidentiality. The group expressed concerns about health insurance companies or banks having access to their information, and how this could be used against them for mortgage or bank loan applications. In addition, the group supported some form of sanction or accountability on those who used data inappropriately. (see pg 14 for DPO opinion)

Patients felt that it was their right to have their data linked. The groups were very supportive of the linkage of health-based databases or registries, but questioned the duplication of resources if enrolled in multiple registries, for example, if they presented with several conditions or received care in several hospitals that was not ‘joined up care’. Different registers and different silos of information would just perpetuate this, whereas if they were just joined up it would support integrated care. In summary, the group supported the establishment of a ‘national register’ to avoid duplication of data entry, support integrated care, increase the value and reduce the costs of registries.

It is hoped that the outputs of this research will inform recommendations and guidelines for the development of an overall strategy for Patient Registries in Ireland.

Section 4: The Emergence of Electronic Patient Records
This section focuses on the emergence of Electronic Patient Records at hospital level and the increasing potential of synergies with Patient Registries and Registers.

Cystic Fibrosis
The first perspective was provided by Dr Cedric Gunaratnam, Respiratory Cystic Fibrosis (CF) Physician at Beaumont Hospital, Dublin who outlined the approach adopted by the CF team in Beaumont Hospital Dublin to collecting and utilising patient data effectively. His approach shows that hospital-based Electronic Patient Records can provide crucial data at a day-to-day operational level within the hospital in respect of the treatment of patients, but can also be complementary to the data requirements of a national patient registry.

In conjunction with the IT Department at Beaumont Hospital, Dr Gunaratnam came up with a cost neutral way of developing a modified electronic patient record. This allows him to capture and monitor important clinical data from cystic fibrosis patients including information on lung function (marker of health with CF), body mass index, types of bacterial infections, medications and record notes from other members of the multidisciplinary team. This is extremely useful as it allows the team to monitor the main markers of mortality for patients with CF on a ‘live record’ (See Annex 4 for a snapshot of this live record). This system does not replace the traditional medical chart required by hospital policy, but the work it in tandem.

These cystic fibrosis Electronic Patient Records are completely separate and independent to the Cystic Fibrosis Registry of Ireland (CFRD) and there is, at present, no way of transferring data electronically between the two. However, Electronic Patient Records do allow staff from the CFRI to retrieve data electronically by just a few clicks of the mouse. Clinicians can also pull information from patient records electronically into a letter format and then send this information to the referral GP via Healthlink – an electronics communications project which facilitates the transfer of information between primary and secondary care in Ireland. This is a process that can take weeks or even months with a paper system and re-emphasises the efficiencies of this system in terms of enhanced communication between healthcare professionals.

In addition to improved interrogation of records, the retrieval of information pertinent for research purposes is accelerated. The system also permits clinicians to monitor the performance of medications in patients and facilitates better services planning in the longer term.

For the next stage of development, the HSE are going to adopt the epilepsy electronic patient record in Beaumont Hospital to support a national programme of care for epilepsy in Ireland.
Section 5: Discussion

This section summarises in thematic form the discussion from the IPPOSI/MRCG seminar on Patient Registries that informs this report.

Definitions

The distinction between Electronic Patient Records, Patient Registries, Patient/Electronic Health Registers and Patient Databases was highlighted. It was proposed that a typology or framework could be usefully developed to provide a clearer picture of how these elements relate to each other (see section 2 of this report). While independent Patient Registries remain the gold standard, the emergence of Patient/Electronic Health Registers are an important and potentially complementary development. Furthermore, the greater use of Electronic Patient Records at hospital/institutional level while being a very useful tool in their own right also creates the potential for synergies with registries and registers with appropriate data protection measures in place.

Coverage of Registries

The absence of registries in Ireland on particular diseases (e.g., Huntington Disease), or fragmented databases or registers held by individual organisations and individuals, has a direct impact on the potential research activity. Poor data can prevent researchers in Ireland participating in longitudinal and cohort studies at a national level and comparative studies at an international level. This can lead to exclusion from both the studies themselves and concomitantly the opportunity to compete and raise research funds.

Funding and Sustainability

There is currently no specific funding mechanism in place to set up or sustain Patient Registries in Ireland. Despite this, 476 registries are currently known to be in operation in this country. There is currently no specific funding mechanism in place to set up or sustain Patient Registries in Ireland. Despite this, 476 registries are currently known to be in operation in this country. There is clearly a need for cross-reference with the IPPOSI/MRCG seminar on Patient Registries that informs this report. The Health Information and Quality Authority (HIQA) are currently working towards developing a national strategy for registries in Ireland that is consistent with existing policy and legislation in Ireland. Every patient registry was recommended to have a quality central programme and peer review or audit trail – this is reassuring for international scrutiny. There is a wealth of potentially useful information within the HSE and the difficulties in accessing it are a reflection of the data being collected and the concern about potential weaknesses. Potentially useful information is also relevant to the treatment of particular diseases, but often this is not compatible with data captured by registries/registers. Standardisation of information technology systems and processes must take place before the information from these resources can be interfaced.

The Role of Patient Registries in the Development of Clinical Guidelines

Consistent with current government policy, in particular the work of the Health and Care Information Board (HCIB) and the National Hospital Information System (NHIS), the Health Information and Quality Authority (HIQA) also highlighted that with the publication of the forthcoming Health Information Bill and the proposed introduction of an Individual Health Identifier (IHI) the quality of health information in Ireland should improve with better data linkages and reduced duplication of effort. The IHI will also enable patients to be linked across multiple episodes of care.

Clinical effectiveness is the marrying of evidence based guidelines to transparent governance structure, continuous audit and improvement, and the practical connections to implementing the guideline.

The Synergy between Electronic Patient Records and Registries

In the absence/limited availability of Electronic Patient Records, the labour and time associated with the collection of data is a huge issue for existing Patient Registries, such as the CPRD. Until patient information is readily available and accessible through standardised Electronic Patient Records, its collection and interrogation will remain a very tedious and labour intensive process. The establishment of Electronic Patient Records for patients with cystic fibrosis in Beaumont Hospital provides a new way forward with the potential to translate this approach into a health economics perspective to justify further state investment into Patient Registries in Ireland – ‘if you invest money now, you will save money later’ approach.

Value for money ‘investing now will save money later’

The value for money of Patient Registries was consistently highlighted during the seminar. This message must also be translated into a health economics perspective to justify further state investment into Patient Registries in Ireland – ‘if you invest money now, you will save money later’ approach.

Governing Standards and Data Capture

There are a range of diverse approaches to governance within Patient Registries and the linked issue of data capture and analysis. The establishment of a national strategy for registries in Ireland needs to include a focus on standards and good practice consistent with existing policy and legislation in Ireland. Every patient registry was recommended to have a quality central programme and peer review or audit trail – this is reassuring for international scrutiny. Builds confidence in the integrity of the data being collected and may facilitate research collaboration both nationally and internationally as a result.

There is a need for standardisation of patient records at HSE level, particularly through the use of Electronic Patient Records. There are currently numerous disparities in the structure of paper records and variability in terms of the quality of information that is being recorded in different hospitals and by GPs. These weaknesses potentially compromise the integrity of the data being collected and the consequent ability to analyse such data.

A significant number of small Patient Registries are currently in operation in Ireland. The potential value in shared resources in terms of IT, data management, and access to statistical and analysis support was highlighted. A shared central resource with standardised Electronic Patient Records, its collection and interrogation will remain a very tedious and labour intensive process. The establishment of Electronic Patient Records for patients with cystic fibrosis in Beaumont Hospital provides a new approach to this end.

The proposed standards for health information sources will address these issues and hope to cover themes such as:

- Efficiency and effectiveness - looking at data quality, usability and accessibility of the data sources
- Workforce and skills of personnel with an emphasis on training governance and management
- Patient-centred approach - looking at issues such as information governance, consent and confidentiality

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Consistent with current government policy, in particular the work of the Quality and Clinical Care Directorate of the HSE and the ongoing appointment of clinical leads and linked clinical care groups for diseases and health policy areas in Ireland, Patient Registries should be crucial building blocks to this process.

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Linkages with Forthcoming Policy Developments

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Section 6: Key Considerations for a National Strategy on Patient Registries

High Level Considerations

Priorities to be included in a National Strategy for Patient Registries

The following are the high level considerations for the Irish Government and relevant health agencies and for registries themselves arising out of this report.

- The data, information and analysis provided by Patient Registries should play an enhanced role in shaping the planning, delivery and review of health services in Ireland.
- The development of a national strategy for Patient Registries will significantly increase the effectiveness and efficiency of health services in Ireland, particularly for clearly definable groups of patients with an acute or long-term medical condition which requires considerable expenditure by the State.
- Conversely, without clear policy direction and support, the potential of Patient Registries will be blunted. Some existing registries may become unsustainable or will have to significantly scale back their operations, resulting in the loss of years of research and analysis and concomitant negative impact on patient care. This will have major implications for the potential of registries to inform efficiencies and targeting within the health service.
- The national strategy for Patient Registries should usefully consider a framework approach which includes Patient Registries, Patient/Electronic Health Registers and Patient Databases. Patient Registries remain the gold standard, but national Patient/Electronic Health Registers and to a lesser degree, patient databases have both the potential of developing into registries over time and as resources permit. Registers and databases are also very useful in their own right.
- A key part of a national strategy for Patient Registries is the crucial role that Electronic Patient Records can contribute.
- Part of a national strategy on Patient Registries in Ireland is the mainstreaming of the role and work of registries into existing and forthcoming policy. For example, of immediate priority is the inclusion of a stronger focus on Patient Registries in:
  - The programme of work of the Quality and Clinical Care Directorate of the HSE, including the development of clinical standards in specific areas of policy and the appointment of clinical leads in particular areas of policy
  - The work of the Health Information Quality Authority
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Some of the key issues to be included in a national strategy for Patient Registries

1. Adequate funding, support and sustain existing registries

A national strategy for registries should ensure adequacy and continuity of funding to existing registries. At present there can be significant uncertainty for many registries in relation to their budget from year to year.

2. The assignment of responsibility for policy development for registries to a Directorate within the HSE/DOHC

To date the responsibility for patient registry support and policy direction has been ad hoc and inconsistent. The model in Sweden where a dedicated agency acts as a resource to developing and shaping registries should be considered by the Irish Government. If a dedicated agency is not possible at this stage, an existing HSE Directorate or agency should be given responsibility for shaping registry policy direction and maximising the impact of registries.

3. Governance of registries consistent with international good practice

Included in the national strategy should be a focus on the governance of Patient Registries consistent with good practice informed by other countries but tailored to the Irish context (see Annex 2). As part of this good governance is the key issue of data protection.

4. The mandatory development of Electronic Patient Records

A key recommendation arising from this report is the mandatory development of Electronic Patient Records focusing on particular disease populations within the specialised centres treating that disease. This should be brought in on a phased basis. Clinicians, including those in Epilepsy and Cystic Fibrosis highlighted in this report, have already developed their own templates and software for Electronic Patient Records. A standardised approach to collecting data (Electronic Patient Records) would be invaluable for the development of registries.

Key considerations for Electronic Patient Records include:

- Identification of priority disease populations
- Developing standardised templates that can be tailored for a disease population
- Ensuring compatibility with data capture templates of registries
- Ensuring compatibility with software
- Building on existing good practice

5. Data Standardisation and linkage

There is often a considerable amount of data held in different data silos. There is a considerable value to be gained by linking data from different sources. However, with linkage come challenges such as security and confidentiality constraints, the lack of standardised definitions across databases, and the cost associated with undertaking data linkage.

The standardisation of definitions and database terminology would enable meaningful comparisons to be made from linking with other registries or databases. A data dictionary is necessary for this purpose to formalise a systematic approach for data collection and entry. Registries would essentially enhance their value through the capability of linking with other registries or databases.

6. Visibility of Patient Registries needs to increase

Key stakeholder and public perception and understanding of Patient Registries is important. Research suggests that the public are in favour of registries providing they are properly regulated and the data being stored is actually used for a particular purpose (e.g., health service planning, delivery and review). The visibility and external communication between registries and key stakeholders can vary considerably, but can often be limited.

The potential benefits of registries for the individual and overall patient care should be a greater priority for registries than at present, while recognising the constraints on this process from a resources perspective.

Next steps

It is proposed that a high level working group on Patient Registries is established by the DOHC/HSE which would be inclusive of representatives from IPPOSI and MRCG. The key role of this high level working group would be to develop a national strategy on Patient Registries.
Annex 1: Participants at the Seminar

Abbott ........................... ........................... Caoimhe Brady
Abbott .............................................. Carmel Donoghue
Abbott .............................................. Maurice Leonard
Alexion .............................................. Nicola Watt
Alpha One Foundation ......................... Geraldine O’Brien
Alpha One Foundation ......................... Kitty O’Connor
Alzheimer Society of Ireland ................. Sarah O’Callaghan
Asthma Society of Ireland .................. Louis Coyne
Beaumont Hospital ......................... Dr. Cedric Gunaratnam
Beaumont Hospital ......................... Mary Fitzsimons
CF Ireland .............................. Alica May
CF Ireland .............................. Philip Watt
Chronic Pain Ireland ...................... Gina Plunkett
Data Protection Office ................. Donna Tedstone Doherty PhD
Debra Ireland .......................... Dr. Avril Kennan
Debra Ireland .......................... Jimmy Fearon
DoHC ......................................... Peter Lennon
Dublin Dental School & Hospital .......... Michael O’Sullivan
EUROCAT Dublin registry .............. Ms. Virginia Delaney
EUROCAT Dublin registry .............. Dr. Bob McDonnell
EUROCAT South East Ireland registry .. Dr. Carmel Mulaney
Fabry Ireland .......................... Dr. Colin O’Reilly
Genzyme ....................................... Fred Doherty
GRDO /22q11 Syndrome ................ Ann Lawlor
GSK ........................................ Jenny Hughes
HIQA ........................................ Dr. Barbara Foley
HRB ........................................ Sarah Craig
HRB ........................................ Teresa Maguire PhD
HSE - Midland Regional Hospital Tullamore .. Dr. Gerard Crotty
HSE ........................................ Dr. Colin Doherty
HSE ........................................ Dr. Fionnuala Donahue
Huntington’s Disease Association of Ireland .. Catherine Paradise
Institute of Public Health in Ireland .... Dr. Helen McAvoy
IPPOSI Chair ....................................... Margaret Webb
IPPOSI & CFRI ......................... Gadhfrey Fletcher
IPPOSI CEO ..................................... Eibhlin Mulrue
Irish Cancer Society ................... John McCormack
Irish Cancer Society ................... Una Philan
Irish Epilepsy & Pregnancy Register, Clinical Research Beaumont Hospital ... Brenda Liggan
Irish Heart Foundation .................. Siobhan O’Daly
Janssen Cilag ................................... Fiona Lynch

Janssen Cilag ................................... Siobhán Mulhern Haughey
MMI ........................................ Aoife Connell
Motor Neuron Disease Register, Clinical Research Center, Beaumont Hospital .. Catherine Lynch
MRCG ........................................ Denise Dunne
MSD ........................................ Ciara O’Rourke
National Cancer Registry .............. Dr. Harry Camber
Novartis ....................................... Giles Ducarrey
Novartis ....................................... Oliver McCrohan
OHCAR - the National Out-of-Hospital Cardiac Arrest Register .. Siobhan Masterson
Shire ........................................ Briona O’Neill
Shire ........................................ Sian O’Neill
SJH Biobank ...................................... Blanaid Mee
TCD School of Nursing & Midwifery Studies ... Dr. Honor Nicholl
UCD School of Medicine & Medical Science ... Dr. Peter Doran
### Annex 2: Summary of International Guidelines on Patient Registries

<table>
<thead>
<tr>
<th>Country</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ethics &amp; Privacy</strong></td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>Freely given fully informed consent can be waived disproportionate effort/methodological problems involved Separate storage for identifiable &amp; csi data, or anonymised data Research Ethics approval if register involved in research</td>
</tr>
<tr>
<td>US</td>
<td>Freely given fully informed consent unless the register has been given a waiver Anonymisation or separation of identifiable data and use of crosswalk files to link to clinical file with access restricted to management Must have ethical approval</td>
</tr>
<tr>
<td>Australia</td>
<td>Consent best practice, but can be waived under certain circumstances Require ethical approval for data collection at each site unless covered by legislation</td>
</tr>
<tr>
<td>Sweden</td>
<td>Generally consent required for data processing, but the quality registers are exempt from this obligation (section 18 Personal Data Act) Must have ethical approval</td>
</tr>
<tr>
<td><strong>Standards</strong></td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>Written data standards Multiple sources case ascertainment Validation to ensure correctness of data Case definition essentialuseppe data stds, or develop stds &amp; use data dictionary and data map Documented data validation/cleaning Staff training &amp; supervision Defined target pop clear inclusion &amp; exclusion criteria</td>
</tr>
<tr>
<td>US</td>
<td>Use existing standards or develop stds &amp; use data dictionary Use data validation Training &amp; supervision of staff Published Eligibility criteria</td>
</tr>
<tr>
<td>Australia</td>
<td>Written agreed data elements In-built data validation Meet end users to ensure data validity &amp; completeness Defined system cases lost to follow up</td>
</tr>
<tr>
<td><strong>Evaluation</strong></td>
<td>Regular evaluation to ensure aims &amp; objectives still valid &amp; being met. If this is not the case, close/revamp register Regular evaluation to ensure it is meeting key functions in order to receive funding Registers must complete evaluation when applying for continued funding</td>
</tr>
<tr>
<td><strong>Governance</strong></td>
<td>Compliance with data protection, security &amp; ethical requirements Oversight &amp; accountability of staff Publication &amp; wide use of register data Governance functions incl executive, scientific, liaison, adjudication, data access, use &amp; publication should be established Formal governance structure which must be legal entity to incl executive and management functions Compliance with data protection, public record regulations &amp; encryption stds Accountability of staff &amp; management</td>
</tr>
<tr>
<td><strong>Resources &amp; Funding</strong></td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>Appropriate multidisciplinary team Robust and secure funding allocation system, with 3-5 yearly funding, for approved registers Multidisciplinary team incl clinical, registry, scie, data collection &amp; database management, legal, QA, project management Mixed funding methods</td>
</tr>
<tr>
<td>US</td>
<td>Mix of disciplines incl Clinical, epidemiologists &amp; health informaticists Secure funding subject to review of relevance and quality Central allocation of funding based on transparent criteria with deadline for applications in October &amp; decisions in December</td>
</tr>
<tr>
<td>Australia</td>
<td>National body for funding registers &amp; providing support to registers</td>
</tr>
</tbody>
</table>

*Excerpt from Dr Fionnuala Donohue’s presentation at the meeting ‘Towards a National Strategy for Patient Registries in Ireland’ in May 2011.

### Annex 3: Select Bibliography

1. IPPOSI submission to the Department of Health and Children’s Discussion Paper on the Proposed Health Information Bill:

2. Outcome report from based on input and discussion at the IPPOSI ‘Patient Registries in Ireland - Where we go from here meeting’, which was held in September 2008:

3. Handbook for establishing quality registers

4. Disease Registers in England (Newton & Garner)

5. Operating Principles and Technical Standards for Australian Clinical Quality Registries


7. Presentation by Dr Fionnuala Donohue, Public Health Doctor, DOHC at the meeting ‘Towards a National Strategy for Patient Registries in Ireland’ in May 2011:
Annex 5: Patient Registries and Registers in Ireland

Dr Fionnuala Donohue, Public Health Doctor, DOHC provided the following list of patient registries and registers in Ireland that were invited to participate in the MRCG commissioned research on Patient Registries in Ireland:

- Coronary Heart Attack Ireland Register
- Badger Neonatal Clinical Data Management System
- ALPHA ONE Registry
- Macbase Neurosurgical Database
- Beaumont Hospital Renal Database
- Cystic Fibrosis Registry of Ireland
- Eastern Area Confidential Cerebral Palsy Study
- Connolly Hospital Diabetes Register
- HSE West Diabetes Register
- Irish Epilepsy and Pregnancy Register
- EUROCAT (EAST)
- Heartwatch Programme
- Hepatitis C Database
- Liver Disease/Endoscopy Register
- Irish Hip Fracture Register
- Irish Motor Neurone Research Register
- Midlands Diabetes Structured Care Programme
- National Cancer Registry Ireland
- National Sudden Infant Death Register
- OHCAR
- Pulmonary Hypertension Ireland
- National Perinatal Epidemiology Centre
- Southern Ireland Cerebral Palsy Register
- Diabetes Register
- National Hepatitis C Database
- WISDOM Mental Health Information System
- NTBSS
- Irish Childhood Diabetes National Register
- Gynae CIS Database
- National Registry of Deliberate Self Harm
- Bleeding Disorder Database/Haemophilia Registry
- Irish Renal Transplant Registry
- Central Treatment List
- Register of Patients on Biologic Therapies
- Cardiac Rehabilitation Register
- Cardiac Rehabilitation Information System
- EUROCAT (Southeast)
- EUROCAT (South)
- Irish Diabetic Retinopathy Register
- Irish Heart and Lung Transplant Register
- National Cleft Database
- National Registry for Patients with Primary Immunodeficiency
- Southern Register for Adult CF Patients
- Scoliosis Database
- Southern Renal Register
- Stroke Registry (AMNCH)
- West Of Ireland Cerebral Palsy Register

Source: ‘An approach to collecting and utilising CF data effectively’, presentation by Dr. Cedric Gunaratnam, Respiratory Consultant at Beaumont Hospital, Dublin, at the meeting ‘Towards a National Strategy for Patient Registries in Ireland’ in May 2011.