Summary

As in other countries, increasing numbers of registries have been developed in Ireland in recent years. Registries contain large volumes of personal health information on individuals which are maintained over long time periods. Registries have the potential to play a vital role in many aspects of the healthcare services provided certain criteria are met.

This report provides recommended standards for registries from international guideline documents sourced through a comprehensive review of the literature. The results of a questionnaire of registries operating in Ireland assessing how they meet these standards are detailed in chapter along with the results from the qualitative research. The opinions of key informants were elicited through semi-structured interviews and patient opinion was obtained through focus groups. The qualitative research looked at a number of specific issues identified in the guidelines including data standards, consent, confidentiality and governance within the Irish context that impact on registries.

The international registry guideline documents contained common recommendations in a number of areas including data standards and governance structures and processes for registries. These key concepts were largely supported by the views of the informants including patients. The registry survey demonstrated that many registries operated with very limited resources. However a failure to employ the data standards or governance processes recommended in the guidelines was identified for some registries. The absence of data standards limits the value that can be obtained from registries and the lack of appropriate governance structures poses a potential threat to the privacy, security and confidentiality of personal patient information.

Other countries have moved to develop guidelines for registries and to introduce frameworks to allow greater co-ordination of registries and structured funding processes. The findings in this report indicate that such an approach is required in Ireland to support registries in improving standards thereby enhancing their role within the health services and providing greater security for patient confidentiality and privacy.
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Chapter 1 Introduction

Health registries or registers of which patient registries are one form have a long history and serve many functions within healthcare. It has been said (Weddell, 1973) that the development of “registers” dates back to the preparation of the doomsday book in 1086 but more specific patient registries probably date to the establishment of “registers of patients with leprosy” (Newton and Garner, 2002).

There is no universal agreement on what constitutes a registry (Solomon et al., 1991). An early definition used by Bellows (1949) (as cited by Solomon et al., 1991) was “a system of recording, frequently used in the general field of public health, which serves as a device for the administration of programs concerned with the long-term care, follow-up or observation of individual cases”.

There have been a number of definitions used since then including those of Brooke, (1974), Colias (2005, Solomon et al. (1991), Arts et al. (2002). In 2007, the Association for Healthcare Quality and Research in America (AHRQ, 2007) provided a definition of registries which are used to evaluate patient outcomes that incorporates a number of the concepts of earlier definitions:

“an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition or exposure, and that serves one or more predetermined scientific, clinical or policy purposes.”

Solomon et al. (1991) noted a rapid proliferation in registries in the previous 20 years in the United States which they relate to a number of public health trends:
- The co-ordinating role adapted by the Centres for Disease Control in ensuring that data sets are created in a standardised format for surveillance and research purposes.
- The demands of programmes developed within the department of public health for standardised information.
- Development of disease specific registries by health related interest groups.

Arts et al. (2002) link the recent rise in registries with the advances in information technology and the increasing demand for accountability within the health services.

**Terminology**

Some authors differentiate between the terms register and registry. “The registry is the organisation and process that supports a register and should be distinguished from the register itself” (Newton and Garner, 2002). Others define the term registry “both as the act of recording or registering and as the record or entry itself” (AHRQ, 2007). Thus in the literature both terms are present with the same and different meanings. The term register is used in this document to refer to the set of patient records and the term registry to refer to the organisation and process that supports a register except where quotations or titles are used.

**Importance of registries**

The use of reliable, accurate, valid, complete and timely information in the planning, operation and evaluation of the health services is a key feature of a modern health service referred to by both the Health Strategy (Department of Health and Children (DoHC), 2001) and the National Health Information Strategy (DoHC, 2004).

The use of information in the delivery of health services requires that:

- There is an awareness of the information sources that are available and their strengths and weaknesses.
- The information sources are accessible.
Patient registries differ from other data sources in the richness and complexity of data that they collect and the longitudinal observational cohort methodology that they use (Gladman and Menter, 2005). Another basic tenant of a “register” is that it follows patients without intervening in any way in their treatment (Garcia and Wolfe, 2007).

The collection of such extensive longitudinal data enhances the value that can be obtained from the analysis of patient registry data allowing them to serve a number of key roles within the health services. However the costs associated with the development and maintenance of such registries are not inconsiderable and there can be ethical concerns regarding the collection, analysis and storage of large volumes of personal health information.

Given the long-term commitment of resources associated with the development and operation of registries and the constraints on the healthcare budget Solomon (Solomon et al., 1991) states that it is important that registries are evaluated to ensure that they meet their objectives in an efficient manner and that there is no alternative source of information that could be used. It is also important that there is an awareness of the registries that are operating and the functions that they fulfil in order to avoid duplication of resources (Solomon et al., 1991).

If registry data is not being used to drive action within the health services then the consumption of resources by registries cannot be justified. Registry data cannot be used within the health services unless there is an awareness of them, they are accessible and their data are used.

The number of registries is increasing particularly in the last decades. While appropriately designed and operated registries have the potential to make an important contribution to the health services they can incur substantial costs and are not the solution to all the information deficits within the health services. In order for registries to impact on the health
services, there must be an awareness of their existence, the standards they employ and the outputs they produce.

To date in Ireland this information has not been readily available and therefore registry data has been underutilised. This report aims to address this deficit by identifying registries in Ireland, the standards they utilise and wider opinion of key stakeholders including patients on issues that affect registries.

This information will be combined with evidence from international guideline documents to make recommendations for future development of registries in Ireland.
Chapter 2 Uses of patient registries

Patient registries have existed for many years and their number has increased particularly in recent decades. Registries can contribute to the health services in a number of ways which will be discussed below.

Patient care

Registries can have a meaningful positive impact in patient care through a variety of roles as outlined in Table 1. Chronic diseases have increased dramatically, in what is referred to as the “epidemiological transition”, and there is a growing recognition of the need to have systems in place to facilitate better management of these and other diseases.

Table 1 Use of registries: Patient care

<table>
<thead>
<tr>
<th>Function</th>
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<tbody>
<tr>
<td>Enabling ready access to accurate, complete patient information at the point-of-care</td>
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<tr>
<td>Incorporation of evidence-based guidelines and / or computer-assisted diagnosis</td>
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<tr>
<td>Improving physician adherence to treatment guidelines</td>
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<tr>
<td>Risk stratification and monitoring of high risk groups</td>
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<tr>
<td>Flagging patients requiring follow-up care or patients with apparent gaps in care</td>
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<tr>
<td>Facilitating individual care planning</td>
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<tr>
<td>Facilitating structured care programmes and standardisation of practice</td>
</tr>
<tr>
<td>Integrating different levels and disciplines of care</td>
</tr>
<tr>
<td>Regulating access to services according to specified criteria</td>
</tr>
<tr>
<td>Providing feedback to clinicians on their management of patients</td>
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</table>

A clear benefit of patient registries is the facilitation of multidisciplinary working and the co-ordination of care. Poor care co-ordination has negative impacts especially for those patients who have multiple or complex chronic conditions. These patients now account for a major proportion of health care expenditure.

Patient registries that are embedded in the care transaction process can facilitate co-ordination by making information electronically available at the point of care. This allows clinical care processes to become more efficient and effective. In many conditions patients can attend a number of
specialists and a registry allows for close collaboration between specialities (Goldman and Menter, 2005).

The use of patient registries allows better management of chronic diseases by improving and streamlining patient care thus avoiding expensive hospitalisations and freeing up physician time for other tasks (White, 1999; Colias, 2005).

Research by Finlay et al. (2000) found that patient registries improved working relationships between ED physicians and cardiologists in the treatment of patients with acute myocardial infarction. Registries supported multidisciplinary working and allowed for the realignment of roles within the multidisciplinary team by making explicit the barriers to achieving optimal care.

Patient registries can be used to improve patient outcomes as demonstrated by the diabetes initiative at PeaceHealth where the introduction of a registry resulted in an increase in patients with HbA1C below target from 44% to 60% in a three year period (Colias, 2005). Similar improvements in patient outcomes were seen from the diabetes registry implemented at the Caritas Christi Health Care system in New England, (Campion et al., 2005) and the Californian Humbolt Diabetes Project (Hudson Center for Health Equity and Quality, 2006).

Hills and Johnston (2006) reviewed the impact of a stroke register in 86 US hospitals and found that patient management improved after the initiation of the registry with the greatest improvements seen in the first year. Greater proportions received anti-thrombotic medication within 48hrs and at discharge and greater proportions received DVT prophylaxis.

Evidence from the implementation of the Paul Coverdell National Acute Stroke Registry (PCNASR) in seven states in the United States over a five year period (2005-2009) showed an annual increase in adherence to stroke care guidelines and in quality of care provided (CDC, 2011). The prototype
phase (2001-2004) had demonstrated large gaps between recommended treatment guidelines and actual care provided in hospitals.

The use of registries can also identify those patients whose care does not meet the standards recommended in guidelines. A study of the treatment received by patients with heart failure identified that older people and particularly older women were less likely to receive recommended treatment (Yancy et al., 2009).

Where a disease has a relatively low incidence rate, the pooling of data from cases can provide evidence in support of treatment options that might not otherwise be available. Influenza A (H5N1) continues to cause sporadic cases with high mortality rates. Analysis of data using the global registry of patients with influenza A (H5N1) has indicated that the use of oseltamivir up to 6-8 days after symptom onset can reduce mortality by up to 49% (Adisasmito et al., 2010).

For physicians, there are a number of benefits to participating in patient registries (Trotter, 2002) including:

- Being able to contribute to the knowledge on a particular disease and its treatment.
- To be involved with a network of like-minded physicians and to benchmark outcomes with other similar practices.
- To be involved in research and contribute to publications based on the research outcomes.
- To access information on and contribute to best practice in certain disease areas.

Public health

The richness of data, the population coverage and the longitudinal follow-up ensure that patient registries are good sources of data for both surveillance of diseases/conditions over time and for the planning and evaluation of health services.
Public health, Surveillance

Registries collect data on a large number of people usually over a prolonged time period which makes them an ideal source of information for surveillance of different diseases, conditions or exposures as outlined in Table 2. The pooling of patient information and the length of follow up in registries increases knowledge with regard to aetiology, natural history, prognosis, survival rates and other trends over time.

Table 2 Use of registries: Surveillance

| Determining the incidence or prevalence of disease |
| Determining the natural history of disease |
| Providing prognostic information |
| Examining trends of disease over time |
| Generating causal hypotheses |
| Exploring aetiologies |
| Sharing of information |
| Providing early warning of changes in disease trends |

Increasingly registries are being used in collaborative efforts nationally and on a wider scale internationally including Europe. This sharing of standardised information enables even larger amounts of data to be analysed allowing for greater scientific progress and is particularly useful in identifying trends in the area of rare diseases.

The Automated Childhood Cancer Information System (ACCIS) project which looks at data from 63 comparable high quality cancer registries has provided clear evidence of an increase in cancer incidence in childhood and adolescence since 1979 with an acceleration of this trend. This would not have been possible without the use of combined registry data due to the low incidence of malignancy before the age of 20 years. (Steliarova-Foucher et al., 2004).

Paediatric cardiomyopathy is a rare condition but still the commonest cause of heart failure in children over one year. Despite this little was
known about the incidence, prevalence, risk factors, causes and natural history of this disease prior to the establishment of the “Pediatric Cardiomyopathy Registry” (PCMR) in the United States. Fifteen years on the PCMR provides invaluable information on the epidemiology and treatment options for patients, their families and clinicians (Wilkinson et al., 2010).

Patient registries are ideally suited to the uncontrolled world of post marketing surveillance due to their large and typically heterogeneous populations (Trotter, 2002). James et al. (2011) recommend that where post-marketing surveillance is mandated by regulatory authorities, manufacturers should provide financial assistance to existing registries to allow them to carry out the surveillance. This avoids the expense of establishing expensive stand-alone surveillance systems and provides valuable support to registries.

The surveillance of diseases using registry data can identify changes in disease trends which may be an indication of an emerging threat from a previously established disease or the emergence of a new or previously unidentified disease process. The longitudinal follow-up with registries allows the late unforeseen complications of a treatment to be detected.

The development of breast cancer in patients treated with supradiaphragmatic radiotherapy for hodgkins lymphoma was detected using registry data. In addition the existence of the cancer registry allowed for the establishment of a patient notification exercise (Horwich and Swerdlow, 2004).

**Public health, service planning**

By quantifying disease in terms of incidence and prevalence, registries can be used to estimate the burden of disease in a particular population. This allows future and current service needs to be identified and allows service providers to respond to these needs and plan for future service provision (see Table 3).
Table 3 Use of registries: Service planning

<table>
<thead>
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<th>Use of registries: Service planning</th>
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<tbody>
<tr>
<td>Estimating the magnitude of a problem</td>
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<td>Estimating relative burden of morbidity attributable to different diseases</td>
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<td>Assessing needs</td>
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<td>Predicting demand for services</td>
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<td>Identifying gaps in service provision</td>
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<td>Highlighting small area variation</td>
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<tr>
<td>Identifying groups at high risk</td>
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<tr>
<td>Targeting resources – capital planning, workforce planning, service configuration</td>
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<tr>
<td>Ensuring consistency and completeness of coverage</td>
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<td>Evaluating service delivery</td>
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The use of pulmonary arterial hypertension registry data by Mukerjee et al. (2003) allowed an accurate determination of prevalence and outcome. The authors state that these data are essential in planning services for this relatively rare condition with considerable impacts on morbidity, mortality and health service utilisation.

Kolominsky-Rabas et al. (2006) used the data from a stroke registry to estimate the number of first ischaemic strokes and the cost to the health service over the period 2006-2025. Their results showed that both stroke and healthcare costs would increase during that time frame and therefore they recommended that increased resources be directed to prevention and rehabilitation services for stroke.

Registries can highlight variation in outcome measures and this can be used to identify subgroups within a population that are vulnerable to particular diseases or that the services are failing to reach. Peterson et al. (2008) used data from the National Registry of Myocardial Infarction to show that although adherence to guidelines for the treatment of myocardial infarction improved over the period July 1990 and December 2006, women, blacks and those over 75 years of age were less likely to receive
revascularisation in hospital or lipid-lowering therapy on discharge relative to their counterparts.

A study in New Zealand utilising cancer registry data identified lower survival rates for Maori compared to non-Maori patients. The research indicated that one third of this was due to poor access to health services and a third to patient co-morbidity (Hill et al., 2010).

**Public health, service evaluation**

Registries can be a valuable tool for health service evaluation as delineated in Table 4. Registries can be designed to capture patient outcomes, healthcare costs and measures related to quality, safety and performance. Data can be provided locally and nationally, comparisons can be made and the resultant information can be used in audits and league tables. This benchmarking of data between different healthcare providers is an important tool in the quality improvement agenda. Data gathered can also assist in accreditation of services, facilities or institutions.

**Table 4 Use of registries: Health service evaluation**

<table>
<thead>
<tr>
<th>Documenting types of patients served by health providers</th>
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<tbody>
<tr>
<td>Evaluating patient outcomes</td>
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<tr>
<td>Assessing clinical and cost effectiveness</td>
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<tr>
<td>Measuring or monitoring safety or harm</td>
</tr>
<tr>
<td>Measuring quality</td>
</tr>
<tr>
<td>Measuring performance of teams and/or systems</td>
</tr>
<tr>
<td>Assisting in audits</td>
</tr>
<tr>
<td>Accreditation tool</td>
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<tr>
<td>Evaluating evolution and implementation of health policy</td>
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Involvement in the “Have a Heart Paisley” cardiac register has allowed practices to look at their own professional performance in a number of dimensions and to evaluate their performance against others. This ability to benchmark a practice’s performance against similar practices is essential to drive the quality improvement agenda (Clark et al., 2005).
White (1999) refers to the use of patient registries to measure a practices performance on a number of key outcomes and to examine trends in patient care and outcomes over time.

Stiller (1993) discusses the use of cancer registry data to evaluate the effectiveness and quality assurance of cancer screening programmes through linking screening data with cancer registry data.

**Health technology assessment and cost effectiveness**

The development of new treatments and technologies combined with increasing awareness and expectations from patients has resulted in a requirement for rigorous assessment techniques before new treatments and technologies receive governmental approval or funding. The availability of complex data and longitudinal follow up inherent with patient registries means they can facilitate the health technology assessment (HTA) process in a number of ways as shown in Table 5.

<table>
<thead>
<tr>
<th>Table 5 Use of registries: Health technology assessment</th>
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<tr>
<td>Evaluating patient outcomes including patient reported outcome measures (PROM)</td>
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<tr>
<td>Providing cost effectiveness data</td>
</tr>
<tr>
<td>Providing safety information e.g. side effects and adverse events</td>
</tr>
<tr>
<td>Providing data on the natural history of a disease or outcomes using current best available treatment</td>
</tr>
<tr>
<td>Facilitating the recruitment of an adequate sample size</td>
</tr>
<tr>
<td>Facilitating the use of case control methodologies</td>
</tr>
<tr>
<td>Providing the infrastructure for post licencing studies</td>
</tr>
<tr>
<td>Assessing the dissemination of outcomes from the HTA process</td>
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</table>

Drug treatments require an extensive amount of testing and evaluation before licensing which generates data on safety and efficacy. In contrast new procedures (surgical operations or techniques preformed in the assessment or treatment of patients) do not undergo a similar process leaving a gap in information on efficacy and safety. In addition randomised controlled trials (RCTs) are uncommon for new procedures due to issues
including blinding and variation in operators’ competencies. Therefore registry data are particularly useful in facilitating HTAs for procedures.

In 2003 the National Institute for Health and Clinical Excellence (NICE) issued guidance on the use of the Nuss procedure for correction of pectus excavatum, which specifically recommended that a “register” be established due to the deficiency in evidence to establish the safety and efficacy of the procedure (Patrick et al., 2010). Lyratzopoulos et al. (2008) have also called for the submission of data to registries to be routine for most new interventional procedures.

It has been recommended that registries be established for use in the HTA process of orphan drugs. McCabe et al. (2006) suggest that a registry of all patients with a rare disease is required, before a therapy is given orphan designation to ensure that data is available on the natural history of the disease prior to the introduction of a new therapy. This they state is the only way of determining the effectiveness of what are expensive therapies. There is also the added benefit that pre-existing registries will be able to provide samples of sufficient size that can be used for case control studies if there are patients on the registry who are not using the new therapy.

**Cost effectiveness**

Registry data is very useful in studies examining the cost effectiveness of treatments. Registries can facilitate the evaluation of cost effectiveness of medical treatments in several ways

- Registry data (cost, outcomes) can be used when developing a model for cost effectiveness analysis (Kobelt et al, 2009, Lindgren et al., 2009, Brennan et al., 2007)
- Registries can be used to identify or follow up patient cohorts in a cost effectiveness analysis (Roberts et al., 2012)
- Patients on a registry in receipt of different treatments can be compared on the basis of costs and outcomes. (Koskinen et al, 2008)
Many studies have identified that registries by improving quality of care contribute to reduced costs. In the Sierra Nevada Memorial Hospital the implementation of the National Registry for Myocardial Infarction was found to not only improve the quality of care but to reduce the cost of care and improve resource management (Finlay et al 2000). These cost savings were identified and measured. In Sweden the use of national arthroplasty registries to inform evidence based surgical practice has reduced the rate of revision of total hip arthroplasty to 7%, the lowest rate worldwide with subsequent cost savings for the healthcare system (Burns and Bourne, 2006).

However evidence of actual cost effectiveness of the implementation of a registry has been demonstrated in relatively few studies. Woolley et al (2006) demonstrated the cost effectiveness of a post splenectomy registry in preventing overwhelming post-splenectomy infection (OPSI) and death. They found that over the cohort lifetime the cost of the registry to be Aust $16,311 per life year gained and or Aust $105,159 per case of OPSI avoided compared to no registry.

An economic model was developed by the National Heart Foundation of Australia to look at the cost effectiveness of establishing coronary heart disease (CHD) registries in general practice. The model demonstrated that even with an effectiveness of 10% and a low reach, the net cost per DALY prevented was Aust $17,062 (Tonkin and Chen, 2010).

The design and utilisation of a registry can contribute to its overall cost effectiveness. The American Heart Association (AHA) recommends that data collection and entry costs should be minimised by integrating these process into the work flow of patient care and that registry data should be utilised to avoid the creation of additional pay-for-performance systems (Bufalino et al., 2011). This later point is relevant to the mooted reorientation of funding within the Irish healthcare system to a system whereby “money follows the patient”. 
Research

Although randomised controlled trials are considered the gold standard for demonstrating the efficacy of an intervention, there is increasing recognition of the role of registry or “real world” data in providing an evidence base on the safety and effectiveness of interventions in heterogeneous populations and across diverse healthcare settings (Dreyer and Garner, 2009). In addition, registries can be used to examine the translation of information from RCTs into clinical practice (McNamara, 2010). Patient registries can be used to support research in many other ways due to the large numbers enrolled, the relatively long follow-up and the generalisability as shown in Table 6.

Table 6 Use of registries: Research

<table>
<thead>
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<th>Use of registries: Research</th>
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<tr>
<td>Investigating aetiological causes</td>
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<td>Testing hypotheses where RCTs are not feasible or are unethical</td>
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<tr>
<td>Evaluating health effects of specific exposures</td>
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<tr>
<td>Facilitating cluster investigations</td>
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<tr>
<td>Providing detailed information on prognosis and prognostic factors over a long time period</td>
</tr>
<tr>
<td>Estimating survival analysis</td>
</tr>
<tr>
<td>Reflecting actual practice conditions in research</td>
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<tr>
<td>Providing pharmaceutical/medical device companies with post-approval data on utilisation and outcomes</td>
</tr>
<tr>
<td>Providing a source of potential participants for clinical trials</td>
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<tr>
<td>Conducting case-control studies, identifying suitable cases +/- controls</td>
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<tr>
<td>Providing data to calculate sample sizes</td>
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<tr>
<td>Identifying and quantifying of the effect of potential confounders</td>
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<tr>
<td>Investigating interactions between variables of interest</td>
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<tr>
<td>Developing reliable methods for making observations</td>
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<td>Developing and testing of analytical techniques</td>
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One of the advantages of using patient registries for research is that they aim to include all patients with a particular condition. This whole population based approach is known as population adjusted clinical epidemiology (PACE). The advantage of this approach is that it can improve the standards and consistency of treatment for all patients and not just those
suitable for clinical trials (Proctor, 1997). The SORT OUT III study compared the safety and efficacy of different drug eluting stents for the routine treatment of patients with coronary artery disease by obtaining follow up data from national healthcare registries in Denmark (Rasmussen et al., 2010).

Randomised controlled trials (RCTs) by their nature must include a highly selected population and therefore work well on simple treatments that are used in homogenous populations. Often medical practice does not operate under such conditions and research based on patient registries allows for reality based medicine (Proctor, 1997). Bravata et al., 2007 carried out a comparative effectiveness of percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) for coronary heart disease (CHD). They found that evidence from RCTs had indicated that myocardial infarction and mortality were similar for patients with the same level of disease treated with either PCI or CABG. However this data was based largely on patients with single or two vessel disease and did not account for other available treatment options. When observational data was examined it demonstrated a strong gradient of benefit for CABG by disease severity. The inclusion of patients with more advanced disease in the observational data proved additional evidence to support therapeutic decisions. (Bravata et al., 2007)

Registries have the potential to overcome the limitations observed in randomised controlled trials and retrospective cross sectional studies as well as those associated with observational studies which are conducted at a specific time point. (Garcia and Wolfe, 2007).

Trotter (2002) states that the very controls required to support the conduct of the research in clinical trials create artificial conditions which are not replicated in real life. This is especially true for those patients who have a number of different co-morbidities. For example, the average age for most patients in heart failure trials is under 60 years whereas most patients who have heart failure are over 60 years of age (Gliklich and Bertagna, 2006).
The number of recent drug withdrawals is further evidence of the disconnect between the clinical trial environment and that of the real world. Trotter (2002) asks why there is no formal requirement for more real world data to be submitted before widespread utilisation of new products since the actual effectiveness of a drug as opposed to its efficacy can only be seen under real world conditions. These real world conditions can be provided through patient registries.

Work by Leurs et al. (2007) compared outcomes in patients undergoing endovascular aneurysm repair recorded in a registry (EUROSTAR registry) and in a randomised trial (DREAM trial). They found the results were very similar, demonstrating that observational study outcomes can be as valid as randomised controlled trials as long as the methodological weaknesses of the observational methods are identified and limited either by design or analysis. Similar findings have been made by Benson and Hartz (2000), Concato et al. (2000) and McKee et al. (1999).

Gladman and Menter (2005) describe the use of registry data in research into the genetic susceptibility to psoriasis which led to the identification of multiple susceptibility genes. Research into genetic susceptibility to disease and genetically determined treatment responses requires very large numbers of patients. This area of research can be considerably advanced by the utilisation of the large volumes of data contained on patient registries.

In certain situations where it may not be appropriate or feasible to conduct a RCT, registry data can be used to provide the evidence. Data from the CRUSADE registry was used to determine the optimal timing of intervention for patients with unstable angina or non-ST segment elevation myocardial infarction (Ryan et al., 2005).
Chapter 3 International Guidelines for patient registries

This chapter describes international guidelines for patient registries developed in other countries. In addition to guidelines that have been developed specifically for patient registries, there are a number of Irish and International laws, directives and codes of practice covering legal and ethical standards that registries should observe which are outlined in Table seven.

Table 7 International, European and Irish legal and ethical standards

<table>
<thead>
<tr>
<th>International</th>
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<tr>
<td>- Nuremberg Code (1947)</td>
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<tr>
<td>- Universal Declaration of Human Rights (1948)</td>
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<td>- World Medical Association Declaration of Helsinki (1964 and subsequent</td>
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<td>amendments)</td>
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<td>- International Covenant on Civil and Political Rights (1966)</td>
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<td>- CIOMS International Ethical Guidelines for Epidemiological Studies (2009)</td>
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<td>- CIOMS International Ethical Guidelines for Biomedical Research Involving</td>
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<td>Human Subjects (2002)</td>
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<td>- UN Declaration on Bioethics and Human Rights (2005)</td>
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<td>- Council of Europe ‘Convention for the Protection of Individuals with regard</td>
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<td>to automatic processing of personal data’ (No 108) (1981)</td>
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<td>- Additional Protocol to the Convention on Human Rights and Biomedicine,</td>
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<td>- Medical Council Guide to Ethical Conduct and Behaviour (2009)</td>
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A brief summary of the main points that apply to registries in these documents are contained in appendices 1 and 2.

In addition there are a number of recommended changes to Irish legislation that would impact on patient registries, namely the proposed Health
Information Bill (DoHC, 2008) and the recommendations of the Law Reform Commission in the area of children and medical treatment (Law Reform Commission, 2011) and the area of vulnerable adults and the law (Law Reform Commission, 2006). The main points of relevance are summarised in appendices 3 (Law Reform Commission Reports) and 4 (proposed Health Information Bill).

**International guidelines for patient registries**

The established databases of medical literature and the grey literature were searched to identify guidelines available in English which provided generic guidance to registries.

This search identified guidance documents for registries from the following countries; England, United States of America, Australia and Sweden. The contents of each document will be summarised under the following headings:

1. Uses.
2. Ethics and privacy.
3. Data standards and quality.
4. Evaluation.
5. Governance structures and processes.
6. Resources and funding.
7. Central co-ordination of registries.

The guideline documents are also summarised under headings 2-7 in Table 8 at the end of this chapter.

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) are due to publish a report in Summer 2012 “ISPOR Taxonomy of Patient Registries: Classification, Characteristics and Terms” (see [http://www.ispor.org/publications/BooksIndex.asp](http://www.ispor.org/publications/BooksIndex.asp)) which will provide additional valuable information.
International guideline documents key findings


Ethics and privacy

All of the guideline documents recognise that best practice is fully informed and freely given consent, it is accepted that in certain circumstances this could invalidate the work of registries. The ethical principles of respect and justice for the individual would indicate a need for consent. However this must be balanced with the principal of beneficence which indicates that to operate a registry which fails to produce any meaningful output due to inadequate coverage is to put the patient at risk of harm with no tangible benefit. In addition a balance must be achieved between the rights of individuals and the common good.

Therefore all of the identified guidelines allow a waiver or exemption from consent for registries. Generally this is allowed under the following circumstances:

- Where the consent process places a disproportionate burden on the registry. Where a requirement for consent would invalidate the registry findings through the introduction bias.
- Where the use of the information involves no more than minimal risk to the patient.
- Where the registry cannot operate without the information and
- Where the output of the registry cannot be achieved through any other means.

In England, registries were required to have ethical approval if they were engaged in research but in the other guideline documents ethical approval was required for all registries. In Australia, it was possible to get an exemption from this requirement under legislation.

Data standards
The quality of the data collected and analysed by registries is identified as a pivotal step in determining their success. The guidelines all specify the use of agreed standardised datasets and refer to the use of a written record of the data elements usually in the form of a data dictionary and/or a data map. The use of a case definition or defined target population is specifically recommended in three of the four sets of guidelines. The training and supervision of data collection and data entry staff is important to ensure data quality and is specified in two of the guidelines. All of the guideline documents recommend regular data validation and several indicate the importance of feeding the results back to the staff.

**Evaluation**
All guidelines recommended regular evaluation of registries. Both the UK and Swedish guidelines recommend that where an evaluation shows that the purpose of the registry is no longer valid or being met, then the registry would have to be changed to meet a valid purpose or dissolved. Some of the guidelines provide specific recommendations on how the evaluation can be carried out or list criteria that can be used in the evaluation process.

**Governance structures and processes**
Good governance is an essential requirement for registries. It includes processes and systems to ensure data quality, patient privacy, resource sustainability, dissemination of findings and continued evaluation. Accountability of staff and management were emphasised in the guidelines.

The Swedish guidelines (EyeNet, 2005) do not make recommendations on particular structures that registries should utilise but rather stress the principles of transparency, accountability, security and accessibility.

The other guidelines from United States (Gliklich and Dreyer, 2007), England (Newton and Garner, 2002) and Australia, (McNeil et al, 2008) 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.

**Resources and funding**
Security of funding is essential for registries from both an ethical and practical viewpoint. The Swedish guidelines provide a good outline of their funding system which is centrally operated with clear criteria against which new and established registries are judged. The system avoids the need for staff to be diverted from essential roles into fundraising.

**Central co-ordination**
A National role for overall oversight of registries is recommended in the UK guidelines. A system already exists in Sweden and is described in their guidelines.

Table 8 overleaf, presents a summary of the registry guideline documents in tabular form under six headings: ethics and privacy; data standards; evaluation; governance; resources and funding; and central co-ordination.
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<th>Table 8 Summary of International guideline documents</th>
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<td><strong>Ethics &amp; privacy</strong></td>
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<td>Freely given fully informed consent, can be waived if disproportionate effort/methodological problems involved. Separate storage for identifiable &amp; clinical data, or anonymised data. Research Ethics approval if registry involved in research.</td>
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<td><strong>Data Standards</strong></td>
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Chapter 4 Research results

Introduction

This section describes the results that emerged from the four strands of the research. All results are presented using either anonymised or aggregate data to protect the confidentiality of research participants.

Identification of patient registries

In order to identify registries, 250 letters were sent out to statutory and non-statutory agencies within the health service, a search was undertaken of the medical literature and the web, the office of the Data Protection Commissioner was contacted and an information board was erected at the annual meeting of the Healthcare Informatics Society of Ireland.

Contact with statutory and non-statutory agencies within the health service produced a 70% response with 175 replies from a total of 250 letters sent out. A total of 102 positive replies provided information on possible patient registries. A smaller number of registries were identified through the search of the internet and of PubMed.

Registries were identified for inclusion in the survey if they met the following criteria:

- They were based in Ireland.
- Records in the registry were person based rather than event based.
- Data collection was systematic and ongoing.
- Clinical data was recorded.

A total of 47 registries that were currently operating were identified following a data cleaning and validation exercise.
Registry questionnaire key findings

Survey response rate
A questionnaire was devised from a review of literature on patient registries and informed by previous surveys with registries in other countries (Newton and Garner, 2002 and NMHRC, 2007), and sent to the 47 registries identified. Thirty three responses were received giving a response rate of 70.2%.

General
Most registries operate on a national or regional basis and just over half register more than 100 new patients each year. Register development has increased in the last few years consistent with the experience elsewhere. Just under half of all registries follow patients from registration through to death and the majority (90%) record at least one outcome measure.

Data collection
In most cases (67%) register data was first captured locally and then transferred to the main register. Paper transfer was the main method or an additional method of data transfer for 72% of registries and only 21% had web enabled access to the registry data. Most registries (73%) used at least two sources of data for their register with the predominant sources being hospital/clinical notes, diagnostic information or GP notes.

Data quality and standards
Coverage rates were generally over 60% with 42% of registries having 100% coverage. However 29% reported coverage rates of less than 50%. The majority of registries did not use a data dictionary (60%) or a clinical coding system (73%). Compared to all registries, more registries that had ethical approval (47% V 40%) or a steering committee (44% V 40%) used a data dictionary.
In contrast the majority reported that they did use a case definition (59%) and a disease classification system (71%). Compared to all registries more registries
that had ethical approval (69% V 59%) or a steering group (65% V 59%) used a case definition.

Most registries carried out data cleaning and validation with 71% reporting de-duplication procedures, 78% following up on missing data and just over half (55%) carrying out data validation. Data de-duplication was mainly done using software (70.8%) while the follow up of missing data was achieved by the register or fieldworkers going back to the original source (72%).

Meetings with data providers were carried out by most registries (69%) with again most (61%) had regular scheduled meetings ranging from weekly to bi-annual meetings. Two thirds of registries had been involved in audit or evaluation with the majority (71%) audited or evaluated in the previous 12 months.

**Use of registry data**

The primary function most commonly identified by patient registries was improving patient safety or quality of care (44%). Overall the most frequently listed function (between primary, secondary and tertiary) was research (79%).

The majority (82%) of registries produced reports either annually or more frequently. Most registries (61%) did not have their reports on line. In most cases the main register (77%) or the local data providers (62%) could also run ad hoc reports as required. Most registries (63%) had utilised the register data to publish in journals.

The majority of registries (81%) were involved in some form of collaboration with either national, European, international or a combination of umbrella groups. Just under half (47%) had been involved in linking their data with data on another register or data base.

**Governance**

Most registries had some form of oversight committee either in the form of a management committee (57%), a steering group (68%) or a scientific/clinical committee (65%). The majority (79%) were registered with the data protection committee and almost two thirds (64%) had ethical committee approval. Patient representation was present in a minority (35.5%) of registries.
Data security and confidentiality
Most registries were password protected (91%) and the majority used data encryption techniques (58%) with just over half (52%) using anonymised data. Half of registries (50%) had written data access protocols and most had provided staff training in data protection (61%) and written confidentiality contracts for staff (79%). The majority (88%) had a disaster recovery mechanism to ensure recovery of data.

Resources
Just over one in five (21%) registries did not have any staff employed directly. Of those who had staff employed, the majority (69%) had two or less staff. Most registries (87.5%) had a named administrator even where the register had no staff employed. Registries had access to IT and clinical support in most cases, but access to statistical support was less readily available. Where funding was provided to registries, the main source was state funding with other sources less frequently cited.

Experiences, challenges and future direction for registries
Key lessons learnt
Registries were asked to indicate the key lessons learnt from running the registry. This section allowed for free text entry and was completed by 28 of the 33 registries. Recurring themes that emerged were issues related to data quality (18/28, 64.3%), stakeholder involvement (11/28, 39.3%) and resources (7/28, 25.0%).

In addition five registries (5/28, 17.9%) emphasised the importance of allocating sufficient time and resources to the planning and implementation phase.

Best way forward
Registries were asked for their recommendations on the best way forward and information was provided by 27 registries. There was more variety in the
responses to this question with the predominant issues being continuity of resources (7/27, 25.9%), development of a web based data entry system (6/27, 22.2%), introduction of national standards (6/27, 22.2%) and legislation to facilitate data provision to registries (5/27, 18.5%).

In addition four of the 11 registries that currently operate on a regional or hospital catchment basis wanted to develop into national registries.

**Comparative analysis**

A comparative analysis was carried out examining registries of different size and staffing levels.

Only two of the results were statistically significant. These results showed that registries without staff were less likely to use data validation processes (RR 0.29, 95% confidence interval 0.09-0.96, Fisher exact value 0.001) and registries with less than two staff were less likely to encrypt data (RR 0.51, 95% confidence interval 0.31-0.85, fisher exact value 0.03)

A pattern is suggested that registries without staff are less able to employ good practice across all of the parameters examined. This would not be unexpected as adherence to good practice requires staff and underlines the need for registries to be adequately resourced in order to comply with best practice.

**Semi-structured interviews key findings**

**Description of participants**

A total of 13 semi-structured interviews were conducted with a variety of key informants from the environment of patient registries. Participants came from a number of different backgrounds including legislative, regulatory, ethical, clinical and public health and a number of geographical locations including Offaly, Donegal and Cork.
Support for registries
Informants were supportive of registries when they were appropriately designed, where they operated to high standards and they met an information need within the health services that could not be met through alternate means.

Consent
All recognised that freely given fully informed consent was best practice. However circumstances were identified where this would not be feasible or where to impose a requirement for consent would introduce bias or reduce coverage to such levels as to negate any benefit from the registry. In such circumstances it was felt that legislative cover should be provided to allow specific registries to operate without obtaining consent but that this should be balanced by better monitoring of registries.

Research and data linkage
Research on registry data and the linkage of data from registries with other datasets for the purpose of supporting the function of the registry or maximising the potential benefit derived from the registry was deemed by most informants to be desirable. However there was consensus that such activity should not proceed if it had the potential to harm an individual or an identifiable group.

National framework
There was strong support for regulations to ensure that appropriate standards and governance structures were used by registries. It was recognised that registries function on public trust and that the operation of a registry without proper standards or governance structures could damage that public trust. Funding sustainability was considered essential from both a practical and ethical view point. The development of a national function for registries within a pre-existing organisation that could provide support and a streamlined funding mechanism was seen as a way forward.
Patient focus groups key findings

Focus groups were held with participants who either had a current or previous diagnosis of a long-term illness or were the parent of a child with a long-term illness. All participants were identified through patient support organisations.

Support for registries and data linkage

Patients are supportive of registries and the linkage of datasets within the health care system if the data is utilised for improvements in quality of care, service provision, available information on diseases/conditions or research and due measures are implemented to protect security.

Patients recognised that the creation of multiple registries increased the workload and perpetuated a system of fragmented care. In that context they supported a unique identifier to facilitate linkage between registries while acknowledging that others might not agree with unique identifiers.

Consent

In limited circumstances the majority of patients could accept a registry operating without consent but for some, consent based registries were preferable.

Regulations and data security

Patients supported regulation of patient registries, both as a guarantee of confidentiality and to ensure appropriate standards were utilised. They expected that access to registries would be tightly controlled through a gatekeeping function that could vet all applications from outside agencies for access.

It was felt that the greatest threat to confidentiality came not from external “hackers” but from staff employed in the health system who abused their
access rights or from system failures. There was agreement that staff who inappropriately accessed registry data should face sanctions.

Patients expressed concern about the data on registries being used by commercial concerns to prevent them purchasing financial services including income protection and mortgages.
Chapter 6 Discussion

This chapter brings together the findings from the four strands of the research (the literature review, the registry survey, the semi-structured interviews and the patient focus groups). The triangulation of the results obtained using this mixed methods approach identified a number of common issues which are discussed under the following seven headings:

1. Uses
2. Ethics and privacy
3. Data standards
4. Evaluation
5. Governance
6. Resources and funding
7. Central co-ordination

The discussion will also refer to current and proposed Irish legislation where relevant.

The identification of convergent validity between the different strands of the research strengthens the findings.

Uses

All the guideline documents refer to similar uses for patient registries namely: patient care (including quality and safety); service planning and evaluation; research; surveillance; and health technology assessment. Informants including patients identified the same uses.

The registry survey results in this research demonstrated that improving patient care was listed by 45.5% (15/33) of registries as their main primary function. When examining primary, secondary and tertiary functions together research was the most common function with 78.8% (26/33) registries listing this as either a primary, secondary or tertiary function.
A concern expressed by informants, particularly patients, in this study was that information would be collected for registries and would not be used or would be under-utilised. The under-utilisation of registry data was linked to a lack of resources or lack of access to specialist expertise especially by those directly involved with registries. All of the guideline documents advise that a multidisciplinary team should be involved in a registry and stress the importance of disseminating registry findings as a report at least annually.

Registry data, like other clinical information systems, can be under-utilised due to a lack of awareness of the registries that are available and the quality of data that they contain (Black et al, 2004). Research involving the linkage of registry data with data on other registries or databases has added to scientific knowledge (Birkeland and Storm, 2002, Hamalainen et al., 2004, Moloney et al., 2006 and Polesel et al., 2010). However in order for this and other research to occur there must be a method of identifying registries.

A solution that has been recommended is the establishment of a registry of registries (Newton and Garner, 2002). This has already occurred in Australia where the Centre of Research Excellence in Patient Safety has developed a web-portal which lists known “clinical quality registries” with their contact details, attributes and a link to their website (if available) (http://www.registries.org.au/cqr.html).

In United Kingdom, there is the UK Directory of Registers and Clinical Databases (http://www.hqip.org.uk/assets/NCAPOP-Library/Directory-of-Registers-as-of-September2011.pdf) hosted by the Healthcare and Quality Improvement Partnership which lists clinical registers, databases and surveillance registers in a free online database for everyone to access.

In the United States, the government is planning to establish a registry of registries building on the success of ClinicalTrials.gov (Heger, 2011). Initially it is envisaged that this database will act as a search tool to enable people to
identify what registries are operating and it will also provide details for the key contact person.

There are also initiatives in specific disease areas to establish global or European registries of registers with examples including the European Framework for the Evaluation of Organ Transplant (EFRETOS) project to establish a European register of registries that evaluate organ transplantation results [http://www.efretos.org/](http://www.efretos.org/) and the call for a global web-based registry of registries for craniofacial congenital anomalies supported by the World Health Organization. (Mossey and Castilla (eds) 2003).

In Ireland, the All Ireland Electronic Health Library, a network of interoperable websites, brings together knowledge resources from across the Island of Ireland. ([http://www.hse.ie/eng/About/Who/Population_Health/Health_Intelligence/Health_Intelligence_Work/Evidence_Based_Health_Care/Searching_for_Evidence/All_Ireland_electronic_Health_Library.html](http://www.hse.ie/eng/About/Who/Population_Health/Health_Intelligence/Health_Intelligence_Work/Evidence_Based_Health_Care/Searching_for_Evidence/All_Ireland_electronic_Health_Library.html)). It contains grey literature, data (quantitative and qualitative), policies and strategies which have been classified using metadata elements agreed by all the member sites. A registry of registries could be developed within this electronic health library.

**Ethics and privacy**

Issues relating to ethics and privacy are crucial to the operation of registries and to public trust in registries.

**Consent**

Consent is a central issue for patient registries. Requiring consent from all patients enrolled on registries can result in decreased coverage and selection bias (Busby et al., 2005, Ford, 2006 and Tu et al., 2004). All elements of the research agree that under ideal circumstances fully informed freely given consent should be obtained but that this is not always possible. All of the
guideline documents allow for circumstances where the requirement for consent can be waived.

This research found there is support from both patients and other informants for a system whereby consent can be waived in certain situations. However informants felt that the introduction of a system to allow consent to be waived should be limited to registries that could not operate on a consent basis and should be accompanied by greater monitoring of registries.

Currently in Ireland, only the National Cancer Registry in Ireland (NCRI) has a specific legal protection from the requirement to obtain consent. All other registries that collect information on living individuals are required to obtain consent under data protection legislation. However the registry survey showed that excluding the NCRI, 25% (8/32) of registries operate without consent. Of the eight registries that operated without consent, five (62.5%) did not provide a method to opt out of the registry.

The proposed Health Information Bill (DoHC, 2008) as it is currently outlined aims to address this issue by allowing the Minister of Health to specify under regulations those registries that can operate without consent and making it clear that all other registries require consent. At present it is envisaged that certain state supported registries will be able to apply for a derogation, but private registries will have to operate on a consent basis. This proposal is to be welcomed as it will reinforce the requirement for consent but will also provide a formal method for those registries that are struggling to work within the current legislation to seek a derogation from the requirement for consent.

The registries that currently experience the greatest difficulties in operating within the requirement for consent are large population based registries where the registry data collection process is not linked to the direct provision of care. For some registries this could be addressed by establishing registry data collection within primary care for chronic disease registries where treatment occurred within the primary care setting. Where this is not feasible, large
population registries would require a derogation form the consent requirement.

Another registry which is experiencing difficulties in the current regulatory environment regarding consent is the Eastern region EUROCAT registry. This registry enrolls participants at a very sensitive time in a families life and in the Eastern region, these difficulties are compounded by the fact that the maternity hospitals which are the chief data providers, are voluntary hospitals which are outside of the Health Service Executive. Congenital anomaly registries are extremely important for many reasons not least of which is to act as an early indicator of possible teratogenic events.

**Consent for those less than 18 years of age**

While participants recognised that there is no automatic lower age limit at which all young people would possess the capacity to consent to the use of their health information by registries, it was felt that the current limit of 18 years could be reduced. Participants felt that the development of capacity to consent was a gradual process that varied from one individual to the next.

This is consistent with the recommendations of the Law Reform Commission (2011) on consent and those under 18 years of age. The Commission recommends that young people aged 16 and 17 years should be given the right to consent to or refuse all aspects of medical treatment.

The proposed Health Information Bill (DoHC, 2008) as it is currently outlined will allow for individuals aged 16 and 17 years to consent to the use of their own personal health information.

**Consent and vulnerable adults**

Participants expressed the view that the capacity required to consent to enrolment in a patient registry was not that high. Many of those currently considered to lack capacity to consent could be demonstrated to have capacity if there was a formal assessment procedure available. Where it was determined that an individual lacked the capacity to consent, then there
should be a formal system available to assign this decision making ability to a nominated support person.

This is again consistent with the recommendations of the Law Reform Commission (Law Reform Commission, 2006). The commission recommends a functional assessment of capacity on an issue specific basis and allows for the appointment of a personal guardian to make healthcare decisions on behalf of someone who lacks the capacity to consent for themselves.

**Protection from disclosure**

Patients in this study were concerned about compelled authorisation, whereby individuals must agree to provide access to their medical records in order to be considered for employment or financial services/products. They were worried that their information would be used to disallow them access to employment or certain financial products or services. Some patients cited their own personal experience of this.

The issue of compelled authorisation can lead to patients concealing relevant health information from care providers (Bishop et al., 2005). Currently there is some protection of a patient’s confidentiality due to the fragmented nature of paper records but this will be eroded by the increasing use of electronic health care records for all or part of a patient’s care (Rothstein and Talbott, 2006).

Opinion among informants varied as to whether court ordered disclosure could happen under current Irish legislation. There was agreement that this should be clarified and legislation put in place if necessary.

Currently in Australia, registries can apply for “qualified privilege” which protects them from forced disclosure (McNeil et al. 2008). In the United States, registries can apply to the National Institutes of Health for a certificate of confidentiality which provides similar protection (Gliklich and Dreyer, 2007).

The benefits of clarification of the legal position regarding forced disclosure and compelled authorisation will apply beyond the area of registries. It would
be more advantageous to introduce measures to limit the scope of disclosure under compelled authorisation and to protect against forced disclosure at this juncture before any further advances towards the use of electronic healthcare records.

**Ethical approval**

The guidelines in Sweden (Eyenet, 2005) and the United States (Gliklich and Dreyer, 2007) specify that registries must have ethical approval. In Australia ethical approval is required unless the registry has a legal exemption (McNeil et al. 2008) and Newton and Garner (2002) recommend that in England, registries should have ethical approval if engaged in research.

In this research, informants who were directly involved with registries fully endorsed a system of approval for registries. However they had issues with the current system whereby a registry had to obtain ethical approval from each institution prior to collecting data. This was a timely and resource intensive process for registries as most ethical review committees had their own standards, forms and interpretation of the ethical issues for registries. This issue has also been raised in Australia (Cameron et al., 2004) with calls there for the development of a centralised ethical approval system (Williamson et al., 2004).

The survey demonstrated that 64% (18/28) of registries had obtained ethical approval. However a number of registries that had ethical approval did not use data standards such as a case definition (31.3%, 5/16) or a data dictionary (53.7%, 8/15). This suggests that some ethics committees are not familiar with the basic standards required by patient registries possibly because they have infrequent contact with them.

For those registries that listed research as their primary or secondary function, 91% (10/11) had ethical approval and the information was missing for the remaining registry.
For those who listed research as a tertiary function, 40% (6/15) had ethical approval with information not provided for three registries all of which contained anonymised data. The remaining six registries without ethical approval, that carried out research contained non-anonymised data.

Research using anonymised data where the registry did not carry out the anonymisation and has no ability to reverse the anonymisation or identify the information is not regarded as research on personal health data and as such is not subject to the requirements of data protection legislation though there may still be ethical implications. Data that is not anonymised is personal health data and is subject to data protection legislation and research involving such data should seek ethical approval.

Currently the Health Information Bill (DoHC, 2008) proposes to provide a centralised process for ethical approval. A centralised ethical approval system accessed by all registries would be beneficial due to:

- A streamlined and shorter ethical approval process.
- Greater expertise on the specific ethical issues related to registries including data standards and governance.

**Data anonymisation**

Both the English (Newton and Garner, 2002) and American (Gliklich and Dreyer, 2007) guidelines recommend that data be anonymised and that ideally this should be carried out by the source organisation that then retains the key. Where identifiable data must be kept by registries, it was recommended that this be stored separately from clinical data with restricted access.

Informants consulted for this research supported the use of anonymised data where this was possible. The use of anonymised data would address patients’ concerns about inadvertent disclosure of their information due to systems failings or staff deficiencies.
The survey results demonstrated that just over half of registries (51.6%) used data anonymisation. In 25% of cases the anonymisation was reversible and in 50% it was not. In the remaining cases, the question was not answered. Registries were not asked where the anonymisation occurred or in the case of reversible anonymisation who held the key.

In the absence of a unique health identifier, registries in Ireland need to record and retain patients’ personal details such as name, date of birth and address in order to link with other data sources, to carry out de-duplication, data validation and to follow patients over time. The introduction of a unique health identifier into the Irish healthcare system would reduce the need for registries to maintain this volume of identifiable data. There was support amongst informants for a unique identifier, although some patients while not opposed to it themselves felt there might be others who would be.

The introduction of a unique health identifier into the Irish healthcare system has been recommended in the National Health Information Strategy (DoHC, 2004) and by the Health Information and Quality Authority (HIQA, 2009). HIQA’s report, “Recommendations for a Unique Health Identifier for Individuals in Ireland” (HIQA, 2009) evaluated the suitability of a number of proposed systems for a unique health identifier. Their findings supported the development of a new built for purpose healthcare specific unique health identifier (UHI).

The Health Information Bill (DoHC, 2008) as outlined at present will provide the framework for the introduction of a unique health identifier. This development will greatly enhance the work of registries by facilitating processes such as case ascertainment, data validation and patient follow-up. It will also improve the quality and reliability of data contained on registries thereby enhancing their role within the health services.
Data standards

The standardisation of data contained in registries is important as it ensures both internal and external consistency and validity. These are key factors in the production of reliable data by the registry for use in the health services and in comparative studies.

The guideline documents all identify the need for a standardised approach to data collection and recording, including the use of case definitions, data dictionaries and regular data validation. In this piece of research, informants including patients recognised the importance of having data standards and supported the idea of a centralised approach to defining these standards and ensuring their utilisation.

The results of the survey with registries in Ireland demonstrate that 58% of registries use a case definition, 41% use a data dictionary and 54% carry out regular data validation.

The absence of a case definition and/or a data dictionary substantially affects the ability of a registry to produce meaningful outcomes, collaborate with other registries and participate in comparative studies. Regular data validation is a key factor in the production of reliable data. Like any health information system, registries are only useful if they contain high quality data (Stone, 2010). Therefore if registry data are to be used to drive change and monitor the impact of changes in policy or service delivery within the health system, they must contain data that is timely, accurate, valid, complete and relevant.

There is a gap between the data standardisation practices recommended in the guidelines and supported by the opinions of key informants and current practice amongst some registries in Ireland. This needs to be addressed to increase the number of registries that adopt a consistent approach to data collection and entry. In this regard the work by the Health Information and Quality Authority (HIQA) in developing Standards for National Health
Information Sources in Ireland and on Health Information Technical Standards will be particularly relevant. To date HIQA (2010b) have established a standard for general practice messaging which is a local customisation of HL7 and are working on terminologies for coding laboratory and radiological data.

The development by HIQA of data standards for use across the health services will help registries by:

- Providing them with approved data standards for data recording.
- Facilitating linkage to other registries and databases through the usage of common data standards.

The proposed Health Information Bill (DoHC, 2008) will support data linking (matching) in certain circumstances. The Bill requires that prior approval must be obtained from the Data Protection Commissioner and a privacy impact assessment must be carried out before data matching can proceed.

**Evaluation**

For a health system to rely on information produced by registries it must ensure that the registries are of adequate quality (Goldberg et al., 1980). However as Gliklich and Dreyer (2007) highlight, difficulties arise when evaluating registries due to the variation in their purpose, design and scope and the difficulty in differentiating between the quality of the design, methodology and the information available.

The guideline documents all support the regular evaluation of registries with consensus that the following elements need to be included

- Relevance- Registries continue to meet their key functions and that these functions remain valid.
- Data quality- High levels of completeness and accuracy are required.
- Timeliness- Timely data collection and reporting.

The Swedish (Eyenet, 2005) and Australian (McNeil et al., 2008) guidelines recommend that the outcome of the evaluation is linked to continual funding.
Informant opinion in this research supported the development of a formal external method of monitoring registries as the current environment where registries were unregulated was considered unacceptable. It was felt that registries should be able to demonstrate that they were utilising appropriate standards and meeting an information need within the health services.

In the survey of registries, less than two thirds of registries answered the question about evaluation and audit with 65% of those who answered, indicating they had undergone an audit or evaluation. Therefore for 61% of registries either they had not been evaluated or it is unknown if they had been evaluated.

Registries contain considerable volumes of personal health information on a large number of individuals and it is essential that there is a formal system in Ireland for assessing registries and ensuring adherence to best practice. The use of registry data in health service planning, quality improvement, research and surveillance in the absence of a formal system to demonstrate that the information is reliable is open to question.

**Governance**

The guidelines recognise a number of governance structures and processes that are important to ensure registries function legally, securely, ethically, efficiently and effectively. Accountability and transparency are identified as important principles underpinning good governance.

There is recognition of a requirement to have a high level oversight committee as well as a committee that is involved in the day to day management issues of the registry. Gliklich and Dreyer (2007) allow for these functions to be undertaken by one committee in smaller registries. These committees should have broad representation with clinical experts, epidemiologists, patient representatives, biostatisticians and database administrators.
The guidelines refer to a number of processes that are important for good governance. All mention procedures to protect data security and confidentiality and the importance of disseminating findings.

Informants in this research were supportive of the structures and processes inherent in good governance. They were concerned that except for the obligations under the Data Protection Acts, there was no other method of holding registries to account. Informants were worried that this could lead to a breach in patient confidentiality and a loss of public confidence in registries. Patients’ concerns were focused on system and staff failings that could result in a breach of security rather than an external agency hacking into a registry.

The survey of registries showed that this was an area where there was great scope for improvement. A number of variables that probed governance structures and processes demonstrated that they were absent in between 20-60% of registries.

Good governance is essential for registries given the large amounts of personal information that they hold. It is important that registries have internal oversight to ensure that they continue to meet their objectives, that their objectives remain relevant and that the registry is sustainable. In addition there is a need to ensure that the structures and process around data security, confidentiality and privacy are solid.

These governance structures and processes should be allocated sufficient resources in the planning stage to ensure their sustainability. For smaller registries several governance functions may be incorporated into a single structure.

The Health Information and Quality Authority (HIQA) is developing National Standards for Health Information Governance. HIQA have already reviewed information governance procedures currently in operation in the health and social care settings and looked at international information governance
structures. The national standards for information governance that HIQA is developing will cover the following areas:

- Privacy and confidentiality.
- Information governance management.
- Data quality.
- Secondary use assurance.
- Security.

The first in a series of guidance notes related to health information governance has been published dealing with privacy impact assessments (HIQA, 2010c). This is particularly relevant as privacy impact assessments (PIAs) will be required under the proposed Health Information Bill (DoHC, 2008). Under the current proposals in the Bill, a PIA will be required before the establishment and operation of a population registry to assess its impact on the privacy of those enrolled on the registry. A PIA will also be required before any data matching occurs to assess the impact of the data matching process.

**Resources and funding**

All of the guideline documents recommend that a mix of disciplines should be involved in a registry. Funding is a crucial issue for registries and is recognised as such in the guideline documents. In England (Newton and Garner, 2002) the recommendation is for funding to be provided on a three to five yearly basis to allow registries to plan and develop. In Australia (McNeil et al., 2008) security of funding is also endorsed provided a registry can demonstrate its continued relevance and maintenance of quality standards. The Swedish document (Eyenet, 2005) provides the greatest clarity on funding and describes the Swedish system which has set deadlines for applications and for decisions on funding. Funding in Sweden is linked to registry evaluation outcomes.

For those involved in operating registries in Ireland, the lack of security of funding was a crucial issue and for other informants, there were ethical issues regarding the lack of a sustainable funding mechanism.
The survey showed that where registries disclosed information on funding, the major source of income was from the government. However several registries (12%) reported no funding. Only a third of registries supplied details of the amount of funding received. Given the lack of funding for registries, it is not surprising that over a fifth of registries had no staff employed and that of those registries with staff; most (69%) had less than three staff members.

Funding and resources are vital for registries to continue to function and to maintain good standards. The lack of a sustainable funding mechanism diverts resources from the main function of the registry towards fundraising. The implementation of a transparent funding system would allow staff to concentrate their time on the core functions of the registry. In addition considerable ethical issues arise if a register runs out of funding before it has achieved its purpose. As most registries need several years before their potential is realised sustainable funding is crucial. There is also the issue of data storage or data destruction if a register ceases to function.

**Central co-ordination**

Currently in Sweden there is a central co-ordinating structure for registries (Eyenet, 2005). The English guideline document (Newton and Garner, 2002) recommended that registries should be co-ordinated through Public Health Observatories. The guidelines from the United States (Gliklich and Dreyer, 2007) and Australia (McNeil et al., 2008) do not cover this aspect as they are written as a user's guide for those operating registries.

Informants were supportive of a system to co-ordinate registries to decrease the duplication of resources, to ensure comparability between registries and to facilitate the sharing of expertise.

The survey showed that a minority (19%) of registries engaged in resource sharing with staff, information technology and data collection being listed as the areas where collaboration occurred. Registries also reported a difficulty in accessing statistical support with 39% having no access to this type of
expertise. In the free text field on the best way forward for registries, 41% indicated a national role in the form of either development of national standards (22%) or legislation (19%).

In the United Kingdom the Healthcare Quality Improvement Partnership (HQIP) provides support to clinical databases and registries on behalf of the Department of Health. This support includes the following:

- Commissioning of some databases and advice to others on commissioning databases.
- Advice to existing and new registers or databases.
- Limited funding.
- Support for networks of registers/databases that cover the same disease/condition.
- A platform to facilitate the wider dissemination of findings from registers/databases.

The current environment where there is no central co-ordination of registries is inefficient. The development of a central function in the area of registries would provide efficiencies by:

- Ensuring regional or local registries covering the same disease area utilised the same data standards and therefore produced comparable data.
- Preventing the development of overlap between registries with the possibility of patients providing data to different registries for the same condition.
- Facilitating the sharing of expertise between registries which is particularly important for new registries.
- Providing a pool of expertise so that all registries regardless of size would be able to access the various disciplines (e.g. information technology, biostatistics, and epidemiology) that are important to their successful operation.
Summary

This report identifies for the first time in Ireland the gaps and challenges for registries in light of international evidence. The demonstration of convergent validity through the use of a mixed methods approach adds strength to the findings of the research. Given the number of registries currently operating in Ireland and the possibility of more registries in development, it is timely that the issues identified in this report are addressed.

Other countries have taken steps to facilitate improvements for registries and Ireland should also adopt a more structured approach to registries in order to support the future role of registries and safeguard the patients enrolled on them. Recommendations to support this approach will be further discussed in Chapter 7.
Chapter 7 Conclusions and recommendations

There was a consensus of opinion between the information obtained through searching the literature and exploring the opinions of patients and key informants through qualitative research in the following areas:

- Registries that are fit for purpose and produce tangible outcomes which have a positive impact on healthcare systems have a beneficial role to play in the health services.
- While consent based registries are best practice, there are some situations where it is acceptable to waive consent in order to ensure that a registry can fulfil its function.
- Linkage of registry data with data on other registries or databases can avoid duplication in data collection and maximises the potential utility of the information collected while supporting the provision of integrated care.
- A national policy and guidelines for patient registries are important in ensuring standardisation and best practice.
- Good governance, both within registries and through a formal external oversight function, is essential to the successful operation of registries and to public trust.
- Confidentiality, privacy and security must be guaranteed with systems and procedures including, privacy impact assessments, written access protocols, access audits and regular security audits.
- Wider use of personal health information and linkage of datasets increases the potential for misuse of data. The introduction of sanctions would both act as a deterrent and provide public reassurance.
- A sustainable and transparent funding mechanism for registries linked to an ongoing process of evaluation is essential from both a practical and ethical viewpoint.

These areas will be outlined in more detail in the following sections.
Role of patient registries

Conclusion
Registries can have a positive impact on the health services in many areas including: improving quality of care; health service planning and monitoring; disease surveillance; and research. In order to reach this potential they should produce high quality reliable data and fully exploit the potential of this data in light of their purpose. However registries should not be considered to be the solution to all the information deficits in the healthcare system.

Recommendations

- A planned approach should be taken to the establishment of any new registries. Both the Institute of Public Health (2007) and the Health Information and Quality Authority (2010a) have carried out very useful work identifying and cataloguing information sources in the health system. This work should be used to establish areas where a registry is the only appropriate solution to an information deficit.
- Existing registries should be examined to identify possible opportunities for merger, rationalisation or economies of scale. Registries that are found not to be fit for purpose should be re-vamped or closed.

Consent

Conclusion
Consent based registries are best practice, but it is recognised that in certain circumstances there should be a mechanism whereby a waiver can be obtained.

Recommendations

- Legislation should be introduced to clearly outline the circumstances in which registries can operate without consent.
- Registries that are permitted to operate without consent must undergo an approval and on-going evaluation process.
• Areas where there is ambiguity regarding an individual’s ability to consent to the use of their health information in registries should be addressed by legislation. That is those aged 16 and 17 years of age and those over 18 years who, under current provisions, are deemed to lack the capacity to consent. The proposals from the Law Reform Commission reports (Appendix 3, Law Reform Commission 2006, 2011) in both these areas and the Health Information Bill (DoHC, 2008) in relation to those aged 16 and 17 years of age should be implemented.

• In the current legal situation, where a person under the age of 18 years is enrolled in a registry their assent to the use of their health information should be sought and documented along with their parent’s consent. Registries should have procedures in place to ensure consent is obtained as soon as practicable after an individual reaches the age of 18 years.

**Data linkage/data matching**

**Conclusion**
The linking of patient registry data with other databases or registries within the healthcare system is regarded as beneficial. The electronic transfer of data from other health information systems or databases, e.g. laboratory information systems, patient administration systems, to patient registries has the potential to improve the validity, accuracy, completeness and timeliness of registry data. The linkage of registry data with other health registries or databases would also enhance the research potential of registries.

**Recommendations**
• Introduction of legislation as proposed in the Health Information Bill (DoHC, 2008) to govern the circumstances and the rules under which data linkage/data matching can be done.
• Enactment of the Health Information Bill (part five) (DoHC, 2008) to allow for the introduction of a unique health identifier in accordance with the recommendations of the HIQA report (2009).

• Continued introduction of standards for the recording of information across the healthcare system to allow meaningful sharing of data and comparability of data between registries.

**National policy for patient registries**

**Conclusion**
There is currently no overall policy document in the area of patient registries though they are alluded to in the National Health Information Strategy (DoHC, 2004). In the absence of an overarching framework for patient registries, registries have developed on an ad hoc basis with little co-ordination between registries. This current scenario is regarded by most as unsatisfactory.

**Recommendations**
A national policy for patient registries should be developed to cover areas including:

• Priority areas for registry development having regard to:
  – National Health Information Strategy.
  – Current available information systems.
  – Impact of the health issue concerned on the population.
  – Potential for registry to drive change in the health system.

• Description and designation of a central oversight function for patient registries.

• Outline description of areas to be covered in national guidelines for patient registries and designation of the role of guideline development within the health services.
• Determination of a sustainable and transparent funding mechanism for patient registries that is linked to a central approval and evaluation process.

National guidelines for patient registries

Conclusion
Guidelines for registries are available in other countries such as England (Newton and Garner, 2002), Sweden (EyeNet, 2005), the United States (Gliklich and Dreyer, 2007) and Australia (McNeil et al., 2008). The development of a guideline document for registries in Ireland would be beneficial in ensuring registries are aware of best practice and have the ability to benchmark their own performance against an approved standard. The development of guidelines is a key factor in quality improvement for registries and would provide transparency for the public on the operating standards of registries.

Recommendation
• National guidelines for patient registries in Ireland should be informed by the international guidelines identified in this report and be cognisant of legal and ethical obligations in Ireland.

• The guidelines should be compatible with Department of Health (DOH) and Health Service Executive (HSE) policy and be cognisant of developing legislation and policy particularly the impending Health Information Bill (DoHC, 2008) and the work by the Health Information and Quality Authority (HIQA) in the area of health information technical standards and health information governance.

• The guidelines should cover areas including:
  – Consent.
  – Ethics.
  – Security.
  – Data standards.
  – Governance (structures and processes).
- Evaluation.
- Dissemination of registry outputs.

Central oversight function for patient registries

Conclusion
While it is important that individual registries have good governance structures and processes in place, it is equally important that there is governance for registries at a national level. In addition co-ordination of registries at a national level is important to ensure optimal use of scarce resources and to ensure that the development of registries occurs in line with national policy.

Recommendations
- A national function for the oversight of patient registries should be established.
- The roles encompassed in this function should include:
  - Development of national guidelines for patient registries.
  - Approval of new registries and evaluation of pre-existing registries.
  - Approval of funding of registries based on the outcome of the evaluation process.
  - Identification of appropriate data standards for use by registries in conjunction with the Health Information and Quality Authority (HIQA) to ensure meaningful sharing of data and comparability between registries.
  - Dissemination of best practice guidelines to registries.
  - Promoting and supporting adherence to best practice.
  - Maintenance of a directory of approved registries, a “registry of registries”.
  - Facilitation of access to specialised expertise (e.g. biostatistics, epidemiology) for all registries.
Confidentiality, privacy and security

Conclusion
Registries contain considerable volumes of personal health information on patients and therefore the issues of confidentiality, privacy and security are paramount. Concerns exist around inadvertent disclosure, forced disclosure and compelled authorisation.

Recommendations
- Registries should undergo regular security audits to identify and address potential threats to data security.
- All registries should carry out regular access audits to ensure that inappropriate access to data does not occur.
- The legal position around court ordered disclosure should be clarified and if necessary legislation enacted to protect against this.
- Consideration should be given to the feasibility of limiting the scope of compelled authorisation of access to personal health information.
- The proposed Health Information Bill (DoHC, 2008) contains a statutory prohibition on the advertisement for sale or the sale of personal health information and on the disclosure of personal health information for direct or indirect financial benefit. This proposal should be supported.

Funding for patient registries

Conclusion
Funding mechanisms for registries have to date been ad hoc, temporary, and lacking in accountability. Registries utilise a substantial amount of their limited resources in identifying and accessing funding on an annual basis. This is a poor use of resources and raises ethical concerns as to the sustainability of registries. There is a commitment in the Programme for Government (Department of the Taoiseach, 2011) to introduce a new funding system for the health services which provides an opportunity to introduce a more sustainable funding system for registries.
Recommendations

- Development of a centralised funding mechanism linked to the outcome of registry approval and evaluation processes.
- Uniform and transparent application procedures with set deadlines for submission of applications.
- Security of funding to registries that meet priority target areas identified in the national policy for patient registries subject to successful evaluation outcomes.

Evaluation and approval for registries

Conclusion

Registries contain sizable amounts of personal health information and there are ethical obligations on registries to ensure that they safeguard the information and that it is used for the purpose it was intended. Where governments allow registries to operate on a non-consent basis, they have an obligation to ensure that these registries are meeting their ethical and legal obligations. Public trust in patient registries is vital to their continued operation. Registries that are failing to meet appropriate standards need to be identified.

Recommendation

- The establishment of an approval process for new registries and an evaluation process for pre-existing registries.
- The approval process for new registries should include the following:
  - Evaluation of the relevance of the stated purpose of the registry.
  - Consideration of existing data sources.
  - Review of the function, duration and scope of the registry.
  - Assessment of the practical feasibility of the registry.
  - Probability of the availability of sufficient start up and maintenance funding.
  - Evaluation of the cost effectiveness of the registry.
The evaluation of existing registries should include the following:
- Continued relevance of the stated purpose of the registry.
- Data quality.
- Governance.
- Dissemination of findings.

Outcome of evaluation linked to funding and available to the public.
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Appendix 1 International directives, conventions and codes relevant to patient registries
**Nuremberg Code (1947)**
The Nuremberg code was developed following the revelations of the inhuman treatment inflicted on prisoners without their consent under the guise of medical experimentation. The code stresses the necessity of obtaining consent from all individuals who are participating in research. The individual must be provided with sufficient knowledge so that they can make an informed decision. Consent must be freely given.

**Universal Declaration of Human Rights (1948)**
Article 12 of the Universal Declaration of Human Rights addresses the issue of privacy and states that everyone is entitled to protection under law from attacks on their privacy, honour or reputation.

**World Medical Association Declaration of Helsinki (1964/2004)**
The World Medical Association drew up the Declaration of Helsinki in 1964 and a number of amendments have been made to it since. The declaration recognises the importance of research to medical progress. However paragraph 5 states that the wellbeing of the human involved in the research takes precedence over the interests of both society and science. Paragraph 21 addresses the issues of privacy and confidentiality of patient information stating that every effort must be made to protect these. Paragraphs 22 and 24 relate to consent and require that patients give consent preferably in writing. Patients should be provided with appropriate information in a manner that is understandable and must be aware of their rights to withhold consent or to withdraw consent after it has been given. Where a subject lacks the capacity to consent, then consent should be obtained from a legally recognised representative in accordance with local law.

**International Covenant on Civil and Political Rights (1966)**
The International Covenant on Civil and Political Rights was developed by the United Nations in 1966 to give legal force to the Universal Declaration of Human Rights.

**UN Convention on the Rights of the Child (1989)**
The Convention on the Rights of the Child was developed by the UN following on from the Declaration of the Rights of the Child (1959). This convention provided legal weight to the Declaration and specifically gave children the same rights to privacy as had been previously given to all in the Universal Declaration of Human Rights.

In 2002 CIOMS an international non-governmental organization issued a revised version of the biomedical research ethical guidelines. These guidelines were intended to provide a framework for national governments to develop their own policies in relation to biomedical research. In the document research is defined to include both medical and behavioural studies relating to human health. It differentiates between research and practice in that healthcare practice is designed to directly contribute to the health of individuals or communities.

The guidelines state that prospective informed freely given consent should be obtained and that the waiver of consent should occur only in exceptional circumstances. Consent should anticipate where possible future secondary uses of the data. Again there is provision to obtain consent from a legally recognised representative in accordance with local law where necessary.

The guidelines do provide for circumstances where the requirement for consent can be waived with permission from an ethical review committee. These are where the research involves minimal risk and obtaining individual consent would make the research impracticable or for epidemiological research where obtaining consent would not be feasible and where there were sufficient safeguards for patient confidentiality.

The guidelines recommend that under these circumstances, the institutions involved should inform patients about the research through a general patient information leaflet.

CIOMS International Guidelines for Epidemiological Studies (2009)

The Council for International Organisations of Medical Sciences (CIOMS) in collaboration with the World Health Organisation (WHO) updated its guidelines for the ethical governance of epidemiological studies. This guidance was first published in 1991 when it was recognised that ethical guidance was needed for public health research as well as biomedical research.
Guideline four in the document deals with individual informed consent and states that consent must be obtained for all epidemiological research. Waiver of individual consent is regarded as exceptional and must in all cases be approved by an ethical review committee unless sanctioned under national legislation that conforms with the ethical principles laid down in the guidelines.

The guidelines list several circumstances where informed consent might be waived including:

- The use of personally non-identifiable materials.
- The use of personally identifiable materials with special justification.
- Studies performed within the scope of a regulatory authority.
- Studies using health related registries that are authorised under national regulations.
- Cluster randomised trials.

The guidelines give some additional details on health registries that supports the practice of requiring all practitioners to submit all relevant data to such registries: the importance of having complete information on all members of the population on the register, the importance of avoiding the introduction of selection bias and the general ethical principle that the benefits and burdens should be distributed equally across a given population.

For these reasons the guidelines regard it as common practice that registries that are established or sanctioned by government authorities require mandatory rather than voluntary collection of data.

Studies that use data from registries or that link data from one registry with another registry or publicly available dataset can therefore involve the use of data that has been collected without the individual’s consent. Any such study should have both ethical approval and approval from the competent authority that is legally responsible for running the registry.

Where an investigator wishes to contact the registry subjects to obtain additional data, ideally the register should approach the individuals beforehand and explain the purpose
of the research and the conditions under which the investigator has access to the registry data.

Guidelines five and six contain further detail on the information to be provided to an individual to ensure that a person can give informed consent and on the obligations on investigators and sponsors in the informed consent process.

Guideline eight deals with the importance of balancing the risks, benefits and harms of participation in epidemiological research. Some forms of research provide the prospect of some form of therapeutic benefit for the participant (beneficial interventions) while some exist only to answer a research question (non-beneficial interventions). Many registries would be included in the category of non-beneficial interventions which are assessed differently than beneficial interventions. Here the outcome is likely to be generalizable knowledge or findings that are of use to a particular subset e.g. public health officials.

In order to achieve the social benefits from research, the findings must be published. The guidelines advise that publication should be carefully managed to ensure that there is no discrimination or stigmatisation of individuals or recognisable groups. Therefore when seeking ethical approval consideration should be given to the harms of forgoing the research versus the harms of publishing the findings.

The guidelines refer to research with subjects who are unable to give informed consent. Research with such subjects which will not provide them with a direct benefit may only proceed if the harm that might arise is no more than minimal and where an ethics review group finds that:

• The research involves a disease/condition affecting the prospective subjects or to which they have a greater susceptibility.
• The objective of the research is of sufficient importance to justify the risk.
• The interventions involved are sufficiently similar to the interventions that the group would ordinarily undergo for treatment of that condition.
• When the subject becomes capable of giving informed consent that consent to their continued participation is sought.
Guidelines 13, 14 and 15 deal with research with vulnerable people, children and those who are not capable of giving adequate informed consent. The basic principles involve ensuring that the research could not be carried out on a group that could consent, that the participants will benefit from the findings and will have reasonable access to any new intervention. That they will be asked for their agreement and consent will be obtained from a parent/guardian/legal representative. That their refusal to participate will be respected at all times and that when they have the capacity to consent they will be asked to consent to continued participation.

Guideline 18 deals with safeguarding confidentiality and the responsibilities of the custodian of the database and the investigator in maintaining confidentiality. Research subjects have a right to know what steps have been taken to safeguard the data, the limits of these provisions and the likely consequences of a breach of confidentiality.

Patients have an expectation of confidentiality from their treating physician and that details of their medical records will only be disclosed to those who are directly involved in their care. Where an institution has permission to further process patient records without consent then patients should be notified of this practice, usually by means of a patient information leaflet. This should provide details of the research/secondary use and of the opt out methods available to patients who decline to participate. It should be made clear to patients that non-participation will not compromise their current or future care.

**UN Declaration on Bioethics and Human Rights (2005)**
This declaration required member states for the first time to commit to respect and apply fundamental principles of human rights to the area of bioethics. The declaration affirmed the importance of respect for an individual’s privacy and confidentiality of their personal information. Disclosure of such information should be in keeping with the purpose for which it was collected or consented and be consistent with international law especially international law regarding human rights.
European

European Convention on Human Rights (1950 as amended) EHCR
The Council of Europe introduced this convention following the United Nations Universal Declaration of Human Rights (1948) in order to harmonise the enforcement of human rights amongst its members.
Article eight underscores the individual’s right to privacy and states that a public authority may not interfere with this right except in exceptional circumstances which includes the protection of health.

European Data Protection Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (1995)
This directive was established to allow the free movement of information for the purpose of the internal market by coordinating the laws in the different member states.
Article six, paragraph one refers to the collection and processing of personal data. It requires that data is collected for a specified explicit and legitimate purpose and any further processing must be compatible with that purpose. It allows member states to provide for further processing for historical, statistical or scientific purposes as long as appropriate safeguards are observed.
Article eight, paragraph one prohibits the processing of data relating to an individual’s health or sex life except under the following conditions:
• The data subject has given explicit consent.
• It is necessary in the field of employment law.
• It is necessary to protect the vital interests of the data subject or another person.
• It is necessary for the purposes of preventative medicine, medical diagnosis, the provision of care or treatment or the management of health services. In such circumstances, the data must be processed by a health professional and with due regard for the national, legal and ethical obligations of confidentiality.
Member states are permitted to set out additional exemptions for reasons of substantial public interest provided appropriate safeguards exist.
This document expands on the rights contained in the ECHR and has been signed and/or ratified by many EU states. Ireland has not signed it to date. However the European Court of Human Rights has drawn on this convention when making judgments including cases involving countries who have not ratified the convention.

Articles five and six cover the area of consent and require freely given informed consent by the subject or in the case of a minor or person lacking the capacity to consent, a legally authorized representative. In the case of minors and those lacking capacity, they should be consulted and their opinions taken into account in accordance with their capacity. An individual should be able to withdraw their consent at any time.

Article ten affirms the individual's right to privacy in respect of health information and of the right to know any information that is collected about their health.

Article 16 covers the area of research and refers to the consent principle in article five and to a number of other conditions that must be met before research can proceed as follows:
• There is no equally effective available other than the proposed research.
• The potential risks to the person are not disproportionate to the potential benefits.
• The research has the approval of a competent authority.
• The research subjects have been informed of their rights and the safeguards prescribed under law for their protection.

There is an allowance in the convention for the restriction of rights under limited circumstances; however this restriction cannot be applied to article 16 which governs research.

European Standards on Confidentiality and Privacy in Healthcare (2006)
These ethical standards developed for healthcare professionals cover the protection use and disclosure of confidential information for patient care and for healthcare purposes that are not directly related to patient care.

The standards specify that express consent should be obtained from the patient or their authorized representative before any proposed secondary uses of their personal
information. Identifiable information should only be kept if this is essential for the purpose that the information was collected. Where patient data is to be anonymised, patients should be informed and the consequences of that process should be explained, specifically the inability for a patient to know what their data is being used for once it is anonymised and subsequently to object to that use.
Appendix 2 Irish Law, directives and codes relevant to patient registries
Bunreacht na hEireann (Irish Constitution)

The constitution contains a number of explicit enumerated rights and there are a number of unenumerated rights that have arisen due to judicial interpretations. There is no express right to privacy in the Irish Constitution but the Supreme Court has ruled that an individual may invoke the personal rights enshrined in Article 40.3.1 to establish an implied right to privacy. Article 40.3.1 states,

"the State guarantees in its laws to respect, and as far as practicable, by its laws to defend and vindicate the personal rights of the citizens"

Data Protection Acts 1988 and 2003

These acts provide the legislative basis for the protection of personal data across all sectors of Irish society. The 2003 Data protection Amendment Act transposed the 1995 EU Directive 95/46/EU into Irish law. This directive has specific minimum requirements for the processing of personal health information which is regarded as a "special category of data".

Under the Data Protection Acts it is the data controller who is legally responsible for ensuring the fair processing of data and for ensuring that confidentiality of personal data is maintained.

In general, where personal health information is used for purposes other than the provision of direct patient care, it is expected that patient consent will be obtained. There are some exceptions to this rule including processing of certain information by not for profit organisations, where information is processed in accordance with the Statistics Act 1993 or where it is necessary to protect an individual's vital interests, health or property.

In addition where the data controller carries out research on personal data and does not disclose this information to a third party and there is no damage or distress to the data subject, then the data will not be considered to be unfairly obtained despite the fact that the use of data for research was not disclosed.
In order for consent to be valid, it must be freely given, specific and informed. In order for an individual to give informed consent, the data controller must have predetermined explicit, specific and legitimate purposes for data collection which can be clearly communicated to the patient. Data must not be further processed in a way that does not meet the original purpose for which it was obtained unless the data subject is contacted and re-consents to this additional use. This would include the linking of data held on different registries.

The data controller must ensure that the minimal amount of data is kept to achieve the specified purpose(s) and that the data kept is up to date, accurate and complete.

Appropriate security measures relevant to the sensitivity of the data must be taken to protect against unauthorized access, alteration, disclosure, loss or destruction of data.

The transfer of data outside the state can only occur where the receiving country has comparable data protection laws and all other aspects of Irish Data Protection legislation are observed.

**Health (Provision of Information) Act 1997**
This legislation was enacted to allow for the operation of the National Cancer Registry of Ireland and national cancer screening programmes. It allowed for the release of information to these bodies without the normal data protection requirements relating to disclosure of information. All other aspects of data protection legislation still apply.

**Disability Act 2005**
This act introduced a definition for genetic data as data relating to a living person derived from the genetic testing of that person. The act provides safeguards for individuals who may be affected by genetic disorders as follows:
- Genetic testing can only take place with an individual's consent.
- The results of genetic tests cannot be used in relation to insurance, mortgages, pensions or employment.
• The individual being tested must be informed of the intended use of the test results and of the possible outcomes of the test.

Guide to Professional Conduct and Ethics for Registered Medical Practitioners (2009) Irish Medical Council
This guide underlines the fundamental importance of confidentiality to the doctor patient relationship. It states that confidential patient information should not be disclosed except in limited circumstances. These are outlined in paragraphs 26 to 30 and cover the areas of disclosure to relatives, disclosure under law, disclosure in the patient's interest to other people and disclosure in the public interest. Generally the guide advises seeking patient consent for disclosure or using anonymised data. Where for the purpose of audit, quality assurance or education, it is not possible to anonymise patient information, then patients should be informed and any objection raised should be respected. In the area of public interest the issue of consent may be set aside after careful consideration of the relative harms and benefits to the patient and the public. Paragraph 31 refers specifically to “registers of illness” and states that the principles of confidentiality must be adhered to where registries are being kept.

This guide which governs the professional conduct for all nurses and midwives again stresses the importance of patient confidentiality and for patients to have the appropriate information to allow them to make informed judgments including in the area of research.
Appendix 3 Reports of the Law Reform Commission
The report contains two central elements:

1. Defining capacity

Current Irish law begins with a presumption of capacity. This may be displaced by evidence that establishes that a person lacks capacity. There is currently no generally applicable definition of capacity at common law or in statute. The report looked at a three models used for defining capacity. These were:

   i. An outcome approach which looked at the decision an individual made and if it conformed to societal norms the individual was deemed to have capacity. This model was rejected as it did not allow for individual variation.
   
   ii. A status approach which looks at the overall status of an individual and determines their capacity on an all or nothing basis. It is the approach adopted by the Wardship and Enduring Power of Attorney processes. It does not allow for fluctuating levels of capacity or capacity to make decisions in some areas but not others.
   
   iii. A functional or understanding approach which looks at capacity on an issue specific basis. This is now regarded as the most widely accepted approach and it enhances an individual’s decision making autonomy.

The Commission recommended a predominantly functional approach should be taken. This would allow maximum respect for an individual’s right to make their own decisions while recognising that in some limited circumstances (e.g. persistent vegetative state) an individual may not have the capacity to make any decisions and repeated assessment of capacity in such circumstances would be unwarranted.
The commission also recommended that the law should contain a statutory definition of capacity which should be a broad definition in the form of guiding principles.

2. Proposed Structures/Framework
The commission recommends the establishment of a new comprehensive statutory framework for the unified protection of vulnerable individual’s property and person. This structure within this framework should exist only when required and should not affect arrangements which currently do not require any formal intervention or encroach on areas where legal intervention is not required.

Within the framework there should be clarification of circumstances where day to day decisions can be taken on behalf of a person who lacks capacity without the need to undergo a formal procedure. In keeping with the aim to maximize an individual’s personal autonomy, the commission proposes a system of incremental orders which would be cognizant of an individual’s current capacity.

The first of these would be an Intervention Order to be used in circumstances where an individual continues to have capacity, but that capacity may not be sufficient to make a decision in a particular area. In such circumstances only limited intervention is required and a once off order can be made.

The second order proposed is a Guardianship Order, which would result in the appointment of a personal guardian to make decisions on behalf of an individual. This order would be subject to two conditions:

i. That the individual did not have legal capacity.

ii. They were in need of protection in the substitute decision making sense in relation to decisions on either their property and affairs or their personal and healthcare concerns.

The commission recommends that decisions on general legal capacity be made by a new structure, the Guardianship Board rather than a court. However the High Court would remain as the ultimate appeals body. The commission also recommends the establishment of an independent office, the Office of Public Guardian. This would take over many but not all of the functions of the Registrar of Wards of Court but in addition
would have new functions and more extensive supervisory powers. The Public Guardian would have a supervisory and supportive role in relation to personal guardians.

In the area of healthcare, the commission recommended that the legislation should make provision for the establishment of a Working group on Capacity to make Healthcare Decisions and for the formulation of a code of practice in relation to capacity and decision making in the healthcare arena. This code should include the following areas:

i. The assessment of capacity to make healthcare decisions

ii. The circumstances in which urgent treatment may be carried out without the consent of the adult concerned and the type of treatment that can be provided where it is likely that the adult will imminently recover capacity

iii. The categories of decision likely to require adjudication by a court or specialist board (e.g. Non-therapeutic sterilization, Electro-convulsive therapy, Withdrawal of life sustaining treatment)

The assessment of capacity to make healthcare decisions should be based on the proposed statutory functional test of capacity. It should encompass the individual’s ability, after a discussion pitched to the level of the individual’s cognitive function, to:

- Understand in broad terms the reasons for and the nature of the healthcare decision to be made.
- Have sufficient understanding of the principle benefits and risks involved in the treatment option being presented and relevant alternative options.
- Understands the personal relevance of the decision.
- Appreciates the advantages and disadvantages in relation to the choices open to them.
- Makes a voluntary choice.

The commission felt that healthcare capacity and decision making should be incorporated within the capacity and substitute decision making framework to bring clarity to an area where currently many medical practitioners are working without clear legal guidance.
The new role of personal guardian proposed in the report would have the power to make decisions on minor or emergency healthcare matters unless specifically excluded. This would include the ability to give consent on behalf of the individual to any necessary routine or minor medical treatment. The commission recommends that this power also be extended to attorneys operating under enduring power of attorney who can currently make personal care decisions on behalf of someone, but not healthcare decisions on medical and surgical treatments.
(LRC 103-2011)

Background
In 2009, the Law Reform Commission published a Consultation Paper on Children and the Law: Medical Treatment (LRC CP 59-2009). Following publication, a number of submissions were received by the Commission and a number of consultative meetings were held. The outcome from these informed the Commission’s report “Children and the Law: Medical Treatment” which contains the Commission’s final recommendations in this area.

The Report contains an examination and discussion of the law concerning medical treatment and a wide range of health-related issues that apply to young people who are under 18 years of age. Although the report recommends that persons under the age of 18 may be regarded as being capable of consenting to, or refusing, medical treatment, there is no recommendation on a general reduction in the age of majority.

The report notes that individuals mature in a gradual manner from infancy to adulthood and that this is influenced by the environment they grow up in. Therefore both parents and healthcare practitioners have a responsibility to adjust the amount of direction and support offered to a child, gradually allowing children to participate more in the exercise of their rights. The authority and responsibility of parents for their children can be viewed on a sliding scale, with greater authority and responsibility when children are very young which lessens as a child reaches their teenage years and approaches 18.

Current Situation
Under the Age of Majority Act 1985, the key threshold between childhood and adulthood is, the date of a person’s 18th birthday when a person becomes an adult for many purposes of civil law. Many protections granted to children and young people by virtue of their young age and their position as children or minors end at the age of majority. The date of a person’s 16th birthday also marks a major progression in law from childhood to adulthood.
In terms of health care and medical law, the age of 16 has been largely accepted as the age of consent to medical treatment in a number of countries worldwide, including Ireland. Under the *Health Acts 1947 to 1970*, a person aged 16 years may choose his or her own doctor, obtain a medical card, consent to an operation and apply for a disability allowance.

Pending legislation under the Department of Health’s *Draft Human Tissue Bill 2009* and the proposed *Health Information Bill* (now due in 2012) propose to define a child as a person less than 16 years of age.

While there is some variation in practice the Commission notes that in general, young people are not treated in a paediatric setting once they reach 16 years of age.

Section 23 of the *Non-Fatal Offences Against the Person Act 1997* provides, in the context of criminal law, that consent to medical treatment by a 16 and 17 year old has the same status as an 18 year old. It does not make any reference to young people under the age of 16 years. The right to refuse treatment is generally viewed as the natural corollary of the right to consent to treatment and therefore it can be argued that, as a 16 or 17 year old can consent to medical treatment under the 1997 Act, he or she can also refuse. There remains a fundamental difference between, the limited nature of a defence to the criminal offence of assault provided for in section 23 and the wider acknowledgement of a minor’s entitlement to autonomy in terms of healthcare decisions.

Decisions in the Supreme Court and the High Court in Ireland have indicated a similar approach here to the capacity of 16 and 17 year olds to consent to treatment in the context of civil liability to that in England where case law has determined that in certain circumstances those under 18 years can consent to medical treatment.

The various pieces of legislation outlined above indicate the confusing nature of the present legal situation. This is epitomized by the legal position of a person under 16 years of age who is a parent. It is largely accepted that a young mother can consent to medical treatment on behalf of her child yet her legal capacity to make decisions in relation to her own medical treatment is unclear.
Assessment of capacity

A functional, decision-specific, test of mental capacity has been used by the courts when assessing an adult’s ability to refuse life-saving treatment. This functional, decision-specific, test of mental capacity is consistent with the Commission’s key recommendation in its 2006 Report on Vulnerable Adults and the Law that a functional test of mental capacity should be enacted into law.

The Commission’s approach is that consent to and refusal of medical treatment for those under 18 should be as consistent as possible with the proposed reform of the law on mental capacity for those over 18, and the Commission therefore favours a functional test of capacity for those under 18.

The functional approach to capacity is preferred because this is consistent with an approach based on the individual’s personal rights and it determines whether the person understands the specific decision being considered at the time it is being made. This is also consistent with the right-based approach in the 2006 UN Convention on the Rights of Persons with Disabilities.

Legal situation in other countries

In the report, the Commission reviewed the legal situation in this area in other countries including Australia, Canada, New Zealand, Scotland, Northern Ireland, England and Wales. The report concluded that as far as health care treatment is concerned, virtually all countries have taken the view, both in terms of health care practice and the relevant legislative framework, that a 16 year old and 17 year old should, in general, be regarded as competent to consent to, and refuse, medical treatment.

Recommendations of the Commission

The Commission makes a number of recommendations in the report, including:

- A minor aged 16 and 17 years of age is presumed to have the capacity to consent to, and to refuse, any health care treatment and this capacity is, in the context of any potential civil liability, as effective as it would be if he or she were 18 years of
age. In addition where a minor has given consent to, or refused, any treatment it will not be necessary to obtain consent for it, or refusal of consent for it, from his or her parent or guardian.

- A minor aged 16 and 17 years of age – like an 18 year old under the present law – will be presumed to have capacity and therefore it must be proven that they lack capacity to make a healthcare decision. In such circumstances, the parents or guardians will, be able to make the healthcare decision on their child’s behalf in accordance with the provisions of the Constitution and relevant international instruments concerning the role of parents and guardians.

- Where life sustaining treatment is refused by a person under the age of 18, an application may be made to the High Court to determine the validity of the refusal. The High Court may order treatment that is necessary to save life where this is in the person’s best interests. In any such application the person under 18 will have separate legal representation.

- A 16 or 17 year old is presumed to have capacity to make an advance care directive. It is recommended that where an advance care directive is being considered by or for a 16 and 17 year old a specific assessment be made by a trained and experienced health care professional of that person’s capacity to understand the nature and consequences of the directive.

- Capacity will not be presumed for those under 16, but that a person under 16 may consent to, and refuse, health care treatment where it is established that he or she has the maturity and understanding to appreciate the nature and consequences of the specific health care treatment decision. In the case of health care treatment for those under 16, the usual situation should be that parents or guardians, are involved in the decision-making process and the person under 16 should be encouraged to communicate with his or her parents or guardians. It should only be in exceptional circumstances, where the rights and the best interests of the person under 16 have been taken into account, that health care treatment would be provided the knowledge or consent of parents or guardians.
A defence of good faith for health care practitioners who treat children and young people under 18 years of age should be provided. The Commission also recommends that acting in good faith and exercising due diligence would be defined as where the health care professional acts consistently with the general principles in the proposed statutory framework.

When assessing whether a minor under 16 has the maturity and capacity to consent to, and to refuse, health care treatment, the following factors should be taken into account:
(a) whether he or she has sufficient maturity to understand the information relevant to making the decision and to appreciate its potential consequences;
(b) whether his or her views are stable and a true reflection of his or her core values and beliefs, taking into account his or her physical and mental health and any other factors that affect his or her ability to exercise independent judgement;
(c) the nature, purpose and utility of the treatment;
(d) the risks and benefits involved in the treatment, and
(e) any other specific welfare, protection or public health considerations, in respect of which relevant guidance and protocols must be applied.

The Minister for Children and Youth Affairs, in consultation with the Minister for Health, should establish a broad-based Working Group which would assist the Minister in preparing a Code of Practice which would provide detailed guidance as to the application of the proposed statutory framework.

Summary
Young people aged 16 and 17 years should be presumed to have the capacity to consent unless proven otherwise. For those aged under 16 healthcare decisions should be made in consultation with parents if at all possible and only in exceptional circumstances should decisions be made without informing parents.
Appendix 4 Proposed Health Information Bill
The proposed Health Information Bill deals directly with issues related to registries and other issues like the unique health identifier that considerably impact on the functions of registries. Definitions used in the Bill that are relevant to registries are included at the end of this appendix.

Part six of the Bill deals specifically with what are called population health registries (see definition at the end of this section). This part of the Bill states that population health registries must operate on a consent basis unless they are specified in regulations made under the Bill as being exempt from the consent requirement. Any registry that is established under regulations and “operated, maintained or otherwise financially supported by the Minister, Executive or Authority” will be obliged to provide information to any of these bodies when requested.

The disclosure of information to these registries may be made mandatory or not depending on the regulations used to establish the registry. The areas covered by the regulations made for each registry will also include; development and maintenance of the registry, measures to protect the data from unauthorised access or use and steps that would be taken to deal with such breaches, measures to protect the confidentiality of the personal health information, terms of reference and timeframe for review of the registry.

For registries where there is no legal obligation to disclose information, the person/entity disclosing the information must obtain the individual’s consent to disclosure. Where disclosure is required under law, then the person/entity that discloses the information must insure that the individual is informed of the disclosure.

Before any regulations are made under the Act to allow for registries to operate without consent, a “privacy impact assessment” will be made jointly by the Data Protection Commissioner and the Health Information and Quality Authority. This will examine the likely impact of the establishment of the registry on the privacy of the individual and shall make recommendations on how an individual’s privacy and the security and confidentiality of an individual’s information can be protected.
Part five of the legislation authorises the Minister to introduce regulations that will allow for a health identifier for individuals and for health care providers. These regulations will outline the introduction, issuing and uses of the health identifier and also set limits on the use that can be made of the identifier even with an individual’s permission. There will also be an offence established where the use of the identifier does not meet its primary purpose or where the use is not covered by legislation.

While the Bill does not specify what the unique health identifier will be as this is to be determined by regulations, it does provide, in the explanatory notes, some additional detail. Here it states that the unique identifier will not be used outside the health sector for reasons of data protection. This then requires that the health care system will have to be defined and the permitted uses of the identifier within the health care system will also have to be defined.

The explanatory note also provides detail on what the identifier must not do:

- Contain substantive information on an individual.
- Be used to establish a single national database of all health records.
- Be used as a basis for a national identity card.
- Have no facility for individuals to object to having a health identifier.

Only those providing health services or those authorised by law may request a health identifier and an individual may refuse to provide their identifier to health service providers. It will be an offence to attempt to use the health identifier to match other identifiable data unless mandated by law.

Part three refers to the processing of personal health information and part 19 deals with the rules governing data matching. Data matching may occur only with the consent of the individual or where it is allowed under the Act. Before data matching occurs, a privacy impact assessment must be carried out. If data matching is carried out for the purposes of research, those involved in the data matching process must also meet their obligations under part four of the Health Information Act which covers research and the establishment of research ethics boards.

The Bill also contains provisions prohibiting the sale of personal health information or profiting directly or indirectly from an individual’s personal health information.
Definitions

Population health registries are defined as “a scheme for the processing of personal health information relating to individual cases of a particular disease, illness, disability or other health condition in and of a defined population”

Personal health information means personal information that relates to

a) The physical or mental health of an individual as well as any genetic data or human tissue that could be predictive of the health of the individual or his or her relatives or descendants;

b) The actual, required or intended provisions of health care services to the individuals and the individual’s express wishes about the future provision of health services to him or her;

c) The donation by an individual of a body part or a bodily substance, including information derived from the testing or examination of a body part or bodily substance;

d) A drug as defined by the Pharmacy Act prescribed for or provided to an individual;

e) A health care aid, device, product, equipment or other item provided to an individual pursuant to a prescription or other authorisation by a healthcare professional;

f) The amount of any benefit paid or payable under an insurance or assurance or like scheme in relation to a health related condition;

g) Payment for a health service provided to an individual;

h) An identification number, symbol or other reference assigned to an individual and intended to assist the provision of health services to the individual;

i) Other identifying information about an individual that is collected in the course of, or is incidental to, the provision of his or her health care;

j) Any other information relating to an individual which is collected for or in connection with the provision of a health service but does not include information that is not written, photographed or otherwise recorded.