IPPOSI Submission to the Department of Health and Children

"Discussion Paper on Proposed Health Information Bill"

Submitted to the Department of Health and Children: Friday, 17th October 2008
Introduction

The Irish Platform for Patients’ Organisations, Science and Industry (IPPOSI) is a unique Irish organisation established in 2001 and formally incorporated in 2005. Comprised of patients’ organisations, medical charities, scientists, clinicians, industry and, where possible, State Agencies, founded by the Medical Research Charities Group (MRCG), the Platform provides a structured way of facilitating interactions, information sharing, dialogue, consensus building, networking and influencing between its constituent members. The aim - to aid the progress of new medicines and therapies from basic science in laboratories, to patients in Ireland who need them.

Since its establishment, IPPOSI has held meetings on topics such as the Orphan Medicinal Products Regulation, the Commercialisation of Health Research; the EU Clinical Trials Directive, the Development of a National Clinical Research Infrastructure, Patient Registries and, in November 2008, it will hold a meeting “Access to Medicines and New Medical Technologies in the era of Health Technology Assessments in Ireland”.

IPPOSI was supported\(^1\) in the 2001 Irish Government Health Strategy document “Making Knowledge Work for Health” and was a contributor to the Advisory Council for Science, Technology and Innovation’s 2006 report “Towards Better Health: Achieving a Step Change in Health Research in Ireland”. In the past twelve months IPPOSI has contributed to a number of national and international consultations namely “Consultation on the Draft Expert Group Report on Recommendations for a National Cancer Biobank”, “EU Public Consultation on Legal Proposal on Information to Patients”, and “EU Public Consultation - Rare Diseases: Europe’s Challenges”. These consultation submissions represent the consensus view of our membership on these topics.

\(^1\) Making Knowledge Work for Health – Strategy for Health Research, Department of Health and Children, June 2001, p. 35

“... the Minister would welcome the establishment of a platform to facilitate dialogue and linkages between healthcare industry and research charities. He looks forward to discussing in due course how health services can support this important initiative".
Department of Health and Children – Discussion Paper “Proposed Health Information Bill”

IPPOSI is now delighted to be in a position to submit to this important Department of Health and Children Discussion Paper “Proposed Health Information Bill” (June 2008).

On September 22nd 2008, IPPOSI hosted a meeting “Patient Registries in Ireland - Where we go from here?”. This event brought together experts, science, industry and patient groups/medical charities and other key stakeholders including State Agencies to examine the issue of patient registries in Ireland, looking specifically at why patient registries are important, key elements of successful registries, the Health Information Bill Discussion Paper, legislative and ethical considerations etc., as well as examining a number of registries in Ireland as important case studies.

Working, as IPPOSI does, with stakeholders to enhance the development of therapies, devices and diagnostics for the benefit of patients, the organisation would encourage the growth of secure, accurate patient registries and lends its voice in support of the need for more of these valuable resources. Patient registries, containing as they do, information about clinical characteristics of a patient population with a specific disease are particularly useful for diseases that are rare or relatively rare. Understanding how valuable registries are for rare or orphan diseases\(^2\), IPPOSI sees the value in registries that can merge a geographically diverse patient population and encourage clinical and scientific investigation towards the enhancement of patient care. In addition to providing robust sources of data for outcomes research and disease management, well developed, secure and accurate patient registries also provide comprehensive, longitudinal information on diagnosis, treatment, course of illness/disease, outcomes, quality of life. Registries are extremely important for the effective planning and design of clinical trials and for recruitment to these. At the IPPOSI meeting, participants affirmed their support for patient registries; recognising that registries are hugely useful resources that can contribute, inter alia to:

- facilitating clinical trials
- enhanced research and understanding (informing research hypotheses and contributing to greater bodies of knowledge),

\(^2\) Rare/orphan diseases are very difficult to study given limited patient numbers
• the evaluation of drug treatment, safety and effectiveness,
• health service planning
• provision of better patient care,
• improving patient safety,
• accountability for health funding
• informing education programmes

A full and detailed report arising from this meeting will be available later in October 2008 but key observations, lessons learned, challenges and recommendations arising from this IPPOSI Patient Registries meeting have fed into this consensus IPPOSI response to the Discussion Paper on the Proposed Health Information Bill and have informed much of the content therein.

IPPOSI notes that the purpose of the Discussion Paper is to “facilitate the preparation of the Health Information Bill by ensuring an informed consideration of the relevant issues”\(^3\). In this regard IPPOSI would like to thank Mr Peter Lennon from the Department of Health and Children for participating in the IPPOSI “Patient Registries in Ireland – Where we go from here?” meeting, explaining the content of the proposed Bill, outlining the consultation process itself and, importantly, for actively contributing to the IPPOSI discussions with regard to the health reform process and the position of the Health Information Bill within that.

IPPOSI acknowledges and welcomes the confirmation that the Bill is “about the better use of personal health information – whether in manual or electronic form – for improved patient care and safety and the achievement of other health service objectives”\(^4\). As a patient-led organisation, IPPOSI sees patient wellbeing and care as central to healthcare discussion and to policy development in the healthcare arena including the development of policy proposals for health system change/reform. Improving care for patients, improving health standards and ensuring patient safety are paramount considerations.

IPPOSI is of the view that, among other key elements, this Information Bill must contribute to the development of an appropriate legislative framework for the use of information towards the enhancement of healthcare and patient safety while also ensuring that effective, responsive and accountable governance structures are in place to safeguard the use of patient information, the privacy and confidentiality of patient records. Given increasing technological advances, data

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\(^3\) “Discussion Paper on Proposed Health Information Bill”, DOHC, 2008, p2

\(^4\) Ibid, p2
security and data management are integral – rights to privacy and confidentiality must never be taken lightly. Maintaining patient confidence and trust is key to success and every effort must be made to foster and strengthen that trust relationship between health care providers and patients.

Reforming a health system is a challenging undertaking. IPPOSI acknowledges that Health Service Reform is a major Government priority and recognises that reforming a healthcare system is a major task that is both time consuming and costly. Building on the previous major reform in 1970\(^5\), the current reform process has been based on, and informed by, a number of studies and reports including the “Value for Money Study” (2001), “Quality and Fairness – The Health Strategy” (2001) “Primary Care Strategy” (2001), “Prospectus Report” (2003), “Brennan Report” (2003) and the “Health Information Strategy” (2004). Combined, these reports have pointed to the need for better health information management – making a call for health information to become more readily available and appropriately used throughout the health sector. This would help to ameliorate health standards and to facilitate research which in turn informs healthcare service planning, evaluation and service delivery and affords the opportunity to further enhance patient care.

The public health system takes up a large slice of public finance – 16 billion Euros has been spent on the public health system - representing 78% of the total amount of money spent on the health system\(^6\). In other words, put simply, three out of every ten Euros spent by the Government is spent on the health system. IPPOSI is of the belief that with such large sums from the public purse being spent on the healthcare system it is important that the resources are used to the maximum advantage to give Ireland a first class health care system and patients in Ireland, first class care.

We live in a society of inter-dependent individuals where advances in medical research can benefit us all and, where they do not benefit us directly, they are likely to benefit someone we know or some future generation. A careful balance needs to be struck between individual rights and the needs of society and this throws up issues around privacy, consent, use of personal data and health information which will be discussed later in this submission under “Challenges”.

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\(^5\) 1970 Health Act based on the 1966 White Paper

\(^6\) Peter Lennon, Department of Health and Children presenting at IPPOSI meeting 22 September 2008
The idea of having better patient registries, unique patient identifiers and enhanced information is not a new one and has been around for some time. Indeed the “Quality and Fairness – Health Strategy” (2001) outlines a number of proposed reforms in information and organisational areas among others. Some examples can be found in Table 1 below.

**Table 1**

**Some proposed reforms outlined in “Quality and Fairness” (2001)**

<table>
<thead>
<tr>
<th>Action 111</th>
<th>Independent Health Information and Quality Authority will be established (estimated date 2002)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action 115</td>
<td>National Health Information Strategy will be published and implemented – target date December 2001</td>
</tr>
<tr>
<td>Action 116</td>
<td>There will be a sustained programme of investment in the development of national health information systems as set out in the national health strategy.</td>
</tr>
<tr>
<td>Action 117</td>
<td>Information and communications technology will be fully exploited in service delivery</td>
</tr>
<tr>
<td>Action 118</td>
<td>Information sharing systems and the use of electronic patient records will be introduced on a phased basis.</td>
</tr>
<tr>
<td>Action 121</td>
<td>Health Information legislation will be introduced (Bill to be published in 2002)</td>
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</tbody>
</table>

Similarly, calls for legislative reform and health information actions were also made in the subsequent “Health Information Strategy” (2004) – see Table 2 below.

**Table 2**

**Some Actions called for under Health Information Strategy (2004)**

| Action 13 | Health information will be geo coded by a small area |
| Action 17 | A legislative framework to support the National Health Information Strategy will be developed |
| Action 18 | A framework for information governance will be developed |
| Action 19 | National Health information standards framework will be developed. |

IPPOSI acknowledges therefore that this proposed Health Information Bill is just one of the recommendations arising from a series of past developments on the path to Health Service
reform in Ireland. There has however been some delay\textsuperscript{7} in publishing this much awaited Bill but, since the Health Information and Quality Authority (HIQA) has similarly taken some time to be established\textsuperscript{8} and, since its functions are key - standards setting, development and definition of health information standards, monitoring, it is perhaps best that the proposed Health Information Bill should arrive when HIQA has been established and is firmly in a position to inform this important process.

Since its establishment in May last year, HIQA has set up a National Steering Group for Health Information Standards, Chaired by HIQA with representatives from the Department of Health, National Standards Authority of Ireland (NSAI), National Cancer Registry, ESRI and other stakeholder groups. This Steering Group is tasked with examining what standards exist in Ireland and internationally with respect to data definitions, clinical concepts, terminologies, coding and classification systems, messaging including Electronic Health Records. Once this research has been undertaken the Group will then prioritise areas for standards development in Ireland. This important work is to be welcomed and with a strong and relevant stakeholder presence it is to be hoped that the outputs from the group will very much help to improve healthcare information and data collection in this country.

IPPOSI is very pleased that the Department of Health and Children has recognised that while examining other health care systems abroad is both beneficial and informative, it would be unhelpful to assume that importing solutions from other jurisdictions is an appropriate way forward or, indeed, a solution to the health system reform endeavour in Ireland. IPPOSI is heartened that the Department understands that each health system is unique and that it should be a question of adaptation and NOT adoption should suitable/interesting initiatives/proposals be identified from abroad. IPPOSI particularly welcomes and fully supports the statement contained in the proposed Health Information Bill that “the establishment of the new institutional framework for the Irish Health System and the creation of robust information structure will work best where information is placed at the centre of decision making”\textsuperscript{9}.

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\textsuperscript{7} DOHC, Quality and Fairness – Health Strategy (2001) indicated under Action 121 that the Health Information Bill would be published in 2002. The proposed Health Information Bill – Discussion Paper was published in June 2008 – the Health Information Bill itself is yet to be drafted and discussed in the Oireachtas.

\textsuperscript{8} Ibid under Action 111 indicated that HIQA would be established in 2002 – HIQA was established on 15\textsuperscript{th} May 2007 as result of the Health Act.

\textsuperscript{9} DOHC, Discussion Paper on Proposed Health Information Bill, 2008, p. 10
Policy Objectives of the Health Information Bill.

IPPOSI observes that the proposed Health Information Bill outlines 16 different policy objectives. These are admirable and ambitious and, if fully achieved, would guarantee a first class, effective, system-wide, health information governance framework focused on patient care and safety. IPPOSI welcomes the thought that has gone into the development of these objectives and notes that all key elements are included eg; sound legislative base for use of information throughout the health system; health information flow; access to health information; development of modern information systems and technologies that benefit the patient including Electronic Health Records (EHR); facilitation of the establishment of national population registries; definition of personal health information; protection of privacy, confidentiality, security and integrity of personal health information; clarity for clinicians and others in relation to what information they have discretion to disclose and circumstances in which they are required to disclose; special rules, where appropriate for dealing with particular categories of personal health information; safeguarding the rights of children in relation to their personal health information; enhancing consistency, where necessary between Data Protection and Freedom of Information Acts; facilitation of the development of best practice codes. IPPOSI would also like to point to the Audit Document, accompanying the Health Information Bill Discussion Paper and observes that this has been helpful in providing additional information with regard to the existing regulatory framework. At the IPPOSI meeting “Patient Registries in Ireland – Where we go from here?”, Mr Gary Davis, Deputy Data Protection Commissioner also provided comprehensive, helpful insights in this area to assist the discussions.

What are the key challenges?

From the debate and discussion at the IPPOSI meeting “Patient Registries in Ireland – Where we go from here?” held in the Clarion Hotel, IFSC on Monday 22 September 2008 the general consensus was focused on a number of key areas namely:

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10 Ibid, pp 11-13 inclusive
Quality Health Information

It is acknowledged that health is information intensive. In Ireland health information is predominantly collected in paper form\(^{11}\) and this is problematic for a number of reasons. Paper records lack structure and are a fragmented and cumbersome way to manage patient information. Additional difficulties exist around the fragility and degradability of these records in addition to the challenges presented by attempting data retrieval from these. The sharing of information using paper records is also problematic. We have been slow in Ireland to record information using information systems for clinical concepts and, remain somewhat wary of making the move to electronic recording systems. Media stories highlighting the theft of electronically held data heightens public awareness of the potential dangers and, creates unease in the use of electronic records containing personal and health information.

In general, across the country, hospital medical records are currently collected in a suboptimal fashion. Computerising the entire collections of currently held patient records and health information is neither advisable nor workable\(^{12}\).

Legal Issues

Legal Impediments to linking data from a number of databases/registries

Securing resources for service development depends on an ability to demonstrate benefits and outcomes of service provision and the value of medical interventions. In instances it is technically possible to demonstrate results of service provision but it may not be legally permissible to do so given the current legislative environment. Some examples of the difficulties include legal impediments to examining a number of databases together (to link data contained in one, to data contained in the other) to establish whether overlaps exist and if they do, if they might hold the key to a difficult, yet important, unanswered question.

Methadone Database and the Hepatitis C database - a case in point.

Hepatitis C has been an important infection in Ireland for a number of reasons. Acquisition of HepC infection has been the subject of a number of different Tribunals and Public Inquiries. From the literature it is known that Hepatitis C worldwide is predominantly acquired through

\(^{11}\) Rachel Flynn (HIQA) IPPOSI meeting 22 September 2008
\(^{12}\) Professor Douglas Veale, St Vincent’s Hospital speaking at IPPOSI meeting 22 September 2008
blood. It was only in 2004-2005 that HepC became statutory notifiable in Ireland. In that period, in the Dublin, Wicklow, Kildare area, 2014\textsuperscript{13} Hepatitis C cases were reported. Two thirds (1247) of these infections were acquired through drug use. It is not known how the remaining one third (767) acquired their infection (possibly through drug use - infected needles, blood transfusions). If it were permissible to examine the methadone database and the HepC database and link data from both\textsuperscript{14} it would be possible to shed some light on the 767 cases by establishing if there was an overlap – if any of the 767 cases had a history of attending drug services. It would then be known if drug use was responsible for some, or any, of the 767 infections. If we are to acquire an enhanced understanding of risk factor of epidemiology, changes to some of the existing legislation would be required.

**Record keeping of vaccinations eg HPV vaccine**

There is no requirement by the State to collect information on females being vaccinated with the HPV vaccine. If, for example, women who have been vaccinated with HPV under private healthcare come back into the health service in years to come, presenting with some gynaecological cancer or ailment, there is no way of establishing whether or not they were vaccinated with HPV in the past. Again this highlights some of the challenges that are present under existing legislation.

**Variations in legal interpretations of concepts**

Variations in legal interpretations of concepts particularly with regard to the common law position of doctor-patient confidentiality continue to present problems. Eg. On one occasion the cancer registry was unable to collect information for a number of years from an institution in the country because of the institution’s legal team’s interpretation of the concept of “confidentiality”.\textsuperscript{15}

**Enabling and Mandatory Legislation**

The 1997 Health Provision of Information Act is an enabling piece of legislation rather than a mandatory piece of legislation. Enabling legislation allows persons to have no liability under data protection legislation if they release information but, this lack of liability does not in and of itself, ensure that the person does actually release information. Additionally the 1997 Act

\textsuperscript{13} Professor Joe Barry, Consultant in Public Health Medicine, HSE – Presentation – IPPOSI 22 September meeting

\textsuperscript{14} At present it would not be compliant with current Data Protection Legislation to do this

\textsuperscript{15} Common Law problems need to be carefully examined and addressed in the Health Information Bill
exempts people who release information from the data protection provisions but makes no reference to Common Law. This can therefore lead to a situation where information may be provided without sanction under the Data Protection Act but the provider of the information may face sanction under the Common Law for breach of confidentiality. The distinction between enabling piece of legislation and mandatory legislation is therefore an important one to highlight and one, IPPOSI would suggest, requires further examination.

**Data Security and Data Protection**

Public/patient trust and confidence in those involved in the collection and recording of patient data and patient information and, in the supporting systems managing and retaining this information, are crucial. Patient data is a valuable resource and can be useful for a number of purposes including, disease investigation, surveillance and intervention, epidemiological and longitudinal studies.

In the 2008 Data Protection Commissioner Survey\textsuperscript{16}, 1,000 participants were asked “Is privacy important?”. 84% of those polled responded saying they felt privacy of personal information was very important. In the same survey, respondents indicated that medical records were the item where privacy mattered most. This was followed by financial history (2), credit card details (3) and the PPS number (4).

It is absolutely critical to any clinical service or any research endeavour, that public and patient trust and confidence in the security of systems is fostered, maintained and built upon. This is a challenge that must be risen to.

**Ethical Considerations**

One of the key challenges faced by health researchers is protecting the privacy of individuals and the confidentiality of personal information at a time of great change in research. Research plays a critical role in improving health and supporting an evidence-based health care system. “Epidemiologic studies based on data from clinical registries have contributed to tremendous advances in modern medicine by, enhancing our understanding of the natural history of disease and the value of many medical and surgical interventions. Studies using

\textsuperscript{16} This survey is conducted by Lansdowne Marketing for the Data Protection Commissioner. The survey is carried out every three years. The results referred to relate to the 2008 survey.
these databases have increased the use of evidence-based medical therapies and have lowered the mortality rate associated with common conditions. It is important to note that health information is also a hugely valuable resource for informing service planning and for health funding accountability. Challenges exist in securing consent for the use of health information for these purposes also.

Decisions regarding what personal data and health information is stored, where it is stored, who has access to it and what it can, and can not, be used for are, in addition to practical considerations, also ethical and legal matters.

Consent - Patients have a right to decide what information is stored about them and where. There are however conflicts between individual rights and utilitarianism (the common good) - conflicts between personal privacy and societal needs.

To be valid – all consent must be informed. This means that an individual must be given sufficient information, in an environment where s/he can make an informed choice. Informed consent is the cornerstone of the EU Directive 95/46/EC “Protection of Individuals with regard to the Processing of Personal Data and on the Free Movement of such Data” and the Data Protection legislation.

Arguments in favour of informed consent for inclusion in patient registries for example, and for the use of patient data, focus on the safeguarding of patient autonomy. If, for any reason a person is unable to give consent due to intellectual disability, mental or health disorder etc. consent should be obtained from a person or organisation that can legally give consent. This is a challenge in Ireland because in this jurisdiction nobody can consent on behalf of another person over the age of 18 unless, they are made wards of court.

Additional challenges in relation to consent arise with regard to statutory protection for registries. “Unless a register is established under statutory protection, access to information held on the register can, potentially, be sought under subpoena and register staff could be compelled to give it either in court cases to Governmental Departments or to the Gardaí.”

18 Professor David Smith, (RCSI), presentation at IPPOSI 22 September 2008 meeting
Further challenges relate to the obtaining of written consent before participation in a broad registry. For example it can often be impracticable and a requirement to seek written consent can result in poor enrollment rates.

Consent and The Cystic Fibrosis Registry

The Cystic Fibrosis Registry is one example where patient consent and trust are key and central elements of a hugely successful, highly secure, accurate resource. The registry collects and analyses information relating to cystic fibrosis in order to improve the quality of care for all CF patients in the Republic of Ireland. The registry has a 96% subscription level – this is vital as critical mass is an issue – there needs to be enough data to be representative of the total population, so high rates of patient “buy-in” are crucial. There must be a minimum ascertainment level of 80% to be statistically relevant. Patient consent is required from all adult CF patients and, guardian approval, for all CF minors, until they reach adulthood and are in a position to give consent and approval to be included in the registry themselves.

Consent and the Cancer Registry

The Cancer Registry is another example of a successful, secure and accurate registry in Ireland. A registry which, like the CF Registry enjoys the support and confidence of the Irish public and patient communities. Unlike the CF registry however, the Cancer Registry does not need to seek patient consent for inclusion in the register. The 1997 Provision of Health Information Act exempts those providing the registry with information from the fair obtaining and processing of the Data Protection Act¹⁹ and consequently from the need to obtain patient consent. The reasons for this are manifold and largely operational; information is, in the main, collected retrospectively, there are cases where patients may not be informed that they have cancer so obtaining consent would be difficult, the huge numbers of cases involved²⁰ make obtaining consent an impossibility.

¹⁹ Although it does exempt from the fair obtaining and processing requirements of the Data Protection Act it does not exempt from any of the other provisions of the Data Protection Act in terms of security, confidentiality, passing information on but does exempt from the need for consent.

²⁰ 20,000-25,000 cases annually (Dr Harry Comer presentation, IPPOSI meeting 22 September 2008)
Personnel

Looking at the health system in Ireland, at who is involved in research and, who is involved in patient care, it is clear that personnel in these settings are pivotal to the success or otherwise of a health system. We know that staff need to be in a position where they can operate effectively and efficiently in their work and assistance must be provided in the area of data collection and data management to facilitate this.

Despite personnel (including data managers and research nurses) being one of the key resources, many are funded on 3 year recurring grant cycles from the HRB. As a result staff remain on temporary contracts and are easily attracted away to permanent jobs. This creates a high turnover of staff and is problematic.

Length of Time Data kept and Ethics Committees

Clinical registries and audit for research purposes need local ethics committee approval – local ethics committees tend not to favour data being kept for lengthy periods of time and are likely not to approve a project if the data is to be kept in excess of 5 years. There needs to be a long term approach to this issue because the stability of doing a series of overlapping clinical trials at different stages in a number of diseases in a hospital or network of hospitals is not a short term venture.

RECOMMENDATIONS FOR CONSIDERATION

Ensuring the collection of Quality Health Information

_Data must be collected in a prospective fashion_; from the very outset it must be clear what is being collected and why and, appropriate systems must be in place for the proper management and governance of this valuable resource. It is absolutely critical to any clinical service or any research operation that trust and confidence in the security and use of records is maintained. Too often large and complex datasets are collected with little thought for how they are to be analysed, the skill mix which is needed to do this and the supportive technologies that are required. Resources spent in collected, unused data are always wasted.
**First class IT platforms are required.** The complexity of the infrastructure for the IT platforms to support data capture, data retrieval and information sharing must not be underestimated.

**Introduction of Electronic Health Records.** An Electronic Health Record has a lot of advantages; it is available, transferrable, shareable, it can support multiple views, provide abstraction, reporting, embedded decision support etc. It is a rich source of clinical data for research and provides support to clinical audit. Electronic healthcare records, record the data as close to the point of care as possible and can then feed into registries, for example. This is not only the most cost effective way of collecting data but it also, importantly, enhances quality.

There is a need for personnel to be involved in quality assuring the data, reporting of the data etc, if the successful move to an electronic health record is to be made. Systems must be in place with proper health information standards in situ. The work of the National Steering Group for Health Information Standards outlined on page 7 will be important in this regard. In addition, HIQA ultimately plans to have a process to define data items, clinical concepts and terminologies using coding and classifications to describe clinical concepts as well and messaging so that data transfer from one hospital to another is possible. The plan is to have a process to define these and to store them in a data dictionary which HIQA would then oversee – with the eventual aim of having electronic health records. Ultimately if it were possible to collect quality information once, at point of care and use it multiple times that would be the ideal scenario. This however raises legal questions and brings the issue of consent into focus.

**Unique Patient Identifier.** IPPOSI sees the introduction of a unique patient identifier as a positive development and recognises the value that such an identifier would have. IPPOSI agrees that far from being a threat, a unique patient identifier would contribute to reducing the need to hold personal information.

IPPOSI notes the work HIQA and HSE are currently undertaking in reviewing requirements for a unique health identifier and this is to be welcomed. IPPOSI understands that a proposal outlining the benefits of a unique patient identifier is being developed and that criteria will be put forward to establish how the PPSN might work should it be decided that this unique identifier is the one to be adopted.
While IPPOSI welcomes a unique patient identifier, it feels the need to express concern with the regard to the use of a PPSN for this purpose. The use of the PPSN would allow for individuals’ information to be joined up across all sectors of the economy. This raises a number of important privacy concerns. In this regard IPPOSI notes that the PPSN was not specifically intended for use in the health sector and its use would have wide and important implications. IPPOSI is concerned at the possible choice of PPSN as a unique identifier and would not favour, or be supportive, of the use of a PPSN for this purpose.

IPPOSI suggests that in-depth discussion with the Data Protection Commissioner in this regard will be important as privacy is a key concern.

**Addressing Legal Issues**

Consideration needs to be given to what is being lost, what opportunities are being missed, as a result of the current restrictions imposed by legislation (some examples include failure to account for HepC acquisition of 767 persons in one geographic area of the country at a particular period of time, inability to know if a woman has been vaccinated for HPV, difficulties collecting cancer data) to name but a few. Consideration might also be given to legislating for the common good\(^\text{21}\).

IPPOSI would recommend that the Health Information Bill should build on the legislative framework that already exists and that legislation should be altered where necessary, to address the consensus issues raised through the consultation process.

**Provision of clarity re distinction between enabling and mandatory reporting concepts** IPPOSI believes that consideration must be given to provision of greater clarity with regard to the distinction between enabling and mandatory reporting concepts\(^\text{22}\). This is a key point particularly when one considers the importance of patient and public confidence in the system and in the sharing of information/data.

**Provision of clarity and resolution with regard to the common law position of doctor-patient confidentiality.** IPPOSI understands that the lack of clarity with regard to

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\(^{21}\) The recommended public information campaign could be used as a vehicle to provide clear demonstration of potential benefits – framed in the common good.

\(^{22}\) The reader is referred back to the Key Challenges section of this submission p. 10 where “Enabling and Mandatory Legislation” is outlined in greater detail
the common law position of doctor-patient confidentiality causes difficulties and would welcome resolution of this matter in the Health Information Bill.

**Length of time data is kept.** Acknowledging that the storage and management of personal data is a primary concern, IPPOSI suggests that thought might be given to providing guidelines/guidance to data controllers re:

(a) period of data storage post study completion
(b) areas where encryption is essential, or mandated, by the Data Protection Act.

**Data Security and Data Protection**

**Achieving a Balance**

IPPOSI recognises that this is a complex and challenging area. Testing boundaries of privacy and confidentiality by seeking to allow data flow for medical research especially in the area of public health. Achieving a balance between (a) growing calls from medical and scientific communities for greater access, (b) societal demand for better health which is informed by research and evaluation, (c) concerns for confidentiality and protection of patient data.

IPPOSI would suggest that it is important as much as possible, and, from the outset, to marry the interests of the individual with the so called common good or public interest. IPPOSI suggests that this will reduce the margin of error in terms of misuse of information. If information is absolutely collected in the patient’s or individual’s best interests as well as in the public good, then potential for misuse is minimised from the outset.

In the 2008 survey carried out by Lansdowne Marketing for the Data Protection Commissioner, participants²³ were asked “in relation to your health or medical records, given a choice would you consent to medical practitioners releasing elements of your medical record to health researchers for the purpose of advancements in research for particular medical conditions?”, 42% responded negatively, 43% responded positively.

In the same survey, participants were asked “would you allow health research organisations to access your medical records for the purpose of advancing health research?”. 43% responded

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²³ 1,000 participants.
negatively, 44% responded positively. Recognising that the sampling was a small one, and acknowledging that drawing conclusions from such a small sample would be inappropriate, the responses do, nonetheless, provide pause for thought – indicating that the issue is not a clear cut one. This would support IPPOSI’s view that attempting to achieve a balance is perhaps the most appropriate way to proceed.

Examining the Ethical Issues

**Consent.** Consent is a very difficult concept for which to fully legislate; with continuous technological advances it is not always possible to know what potential future uses patient data might be used for. IPPOSI recognises that this is one issue that it will be difficult to achieve consensus on.

Some observations in this regard include:

Use of a once off broad consent for all future uses of patient data can help to remove the need to continuously re-consent. Alternatively, thought might be given to the use of a waiver. Options to “Opt Out” might also be considered although these raise Data Protection issues. There is also a recognition that researchers generally wish to study aggregate trends and do not necessarily wish to, or necessarily need to know exact patient details and in this regard, the removal of as many identifiers as possible may be the way forward, as with anonymisation of data, there are no data protection concerns. If there is to be a move to the creation of more registries then legislation in this area will need to be carefully examined.

**Personnel**

*Periodic review of funding initiatives* so that the highest research is funded by the public purse and protection of staff is considered.

**Partnerships**

*Building on strong initiatives that are working well - Clinical Research Centres (CRCs), Molecular Medicine Ireland (MMI), Irish Platform for Patients’ Organisations, Science and Industry (IPPOSI), Medical Research Charities Group (MRCG), Health Information and Quality Authority (HIQA).* The Government has, as
IPPOSI alluded to earlier in this submission, invested heavily in the health system. There are now major Clinical Research Centres in development in most of the academic teaching hospitals in the country. These Clinical Research Centres now form a critical building block for the formation of a clinical research network that could really provide state of the art facilities to allow patient registry information to be collected in an efficient and effective manner. These networks together with Molecular Medicine Ireland (MMI) provide a real opportunity to build on what has been heavily invested in, in what is working so that quality, reliable data can be collected going forward.

At the IPPOSI meeting on 22 September\textsuperscript{24}, participants were given a real life example of a successful, secure, international working database (METEOR) funded by the Merit Foundation. The example highlights how across 11 different European countries, with an effective infrastructure and people willing to work together, an effective and efficient way of collecting data can be easily achieved.

IPPOSI believes that by harnessing the goodwill and support of those involved in CRCs across the country together with MMI a similar outcome could be reached.

IPPOSI is also ideally placed to play a key role in this endeavour to facilitate information exchange, networking and dialogue. As a platform, IPPOSI has shown itself to be an engaging partner and, a willing and capable entity bringing all key stakeholders together to examine challenges, identify potential solutions and assist with driving forward workable solutions.

The Medical Research Charities Group (MRCG) too has had a significant role and has played an important part in bringing together State Bodies and Patient Organisations to move the issue of Patient Registries along – creating a Steering Group involving MRCG, HSE, HRB and laterally HIQA to oversee research into the whole patient registries area in Ireland. The aim – to identify the existing patient registries in Ireland, to describe those registries in detail (functions, methodologies, standards, funding mechanisms) and also to identify best practice and guidelines for quality standards in this area. The MRCG working group on patient registries has afforded a positive sharing of perspectives between health service providers and health service users leading to greater understanding and strengthened collaboration.

\textsuperscript{24} Professor Douglas Veale – Presentation - IPPOSI meeting 22 September 2008
Health Information and Quality Authority. HIQA’s work needs to be supported and encouraged; in particular the work of the HIQA Steering Group for Health Information Standards so that the Group’s output can inform and assist in enhancing healthcare information and data collection in Ireland.

In the challenging economic climate in which we find ourselves it would be wise, and advisable, not to duplicate efforts but, to bring all stakeholders together and to build on the valuable resources that we currently have. The CRCs, MMI, MRCG, IPPOSI, HIQA have a key role to play we believe. Fostering partnerships is a way forward and IPPOSI would argue that a golden opportunity in this regard now presents itself and should be grasped.

Proactive, Strong Public Information Campaign

IPPOSI believes that in the absence of any clear debate or public discussion on the issues of patient privacy, common law traditions of confidentiality, ethical codes on using and safeguarding personal health information as well as enhanced use of eHealth initiatives and technology advances – a strong proactive public awareness campaign by the State is required. This would afford patients and the general public an opportunity to understand the issues, to appreciate the range of options regarding the processing of patient data, to understand concepts of consent etc. This would help to raise the profile of the issues and generate a healthy debate on this, most important of topics. It would also enhance understanding of the needs for research, the public health advantages of involvement in research etc. One of the biggest challenges facing the health service in relation to information is a cultural and attitudinal one about using and sharing information – a public information campaign could be very advantageous in this area. It will be important to convince and persuade the public that allowing their information to be used in a properly safeguarded environment is the way forward, not just to benefit each individual but to benefit society generally. There are strong examples out there that exist – the Cystic Fibrosis Registry and the Cancer Registry - both have the confidence, trust and support of the patients and general public.

25 The issue of consent is particularly important in the area of registries. Unless a register is established under statutory protection, access to information on the register could potentially be sought under subpoena and register staff could be compelled to give it either in court cases to Governmental Departments or to the Gardai. If this be the case, it must be clearly explained to the public and to patients before they sign up to a register that this is a potential danger that they could face. (Professor David Smith, RCSI, presentation, IPPOSI meeting, 22 September 2008)
Strategy for addressing legitimate concerns

IPPOSI feels that in addition to a proactive public information campaign by the State, that a strategy ought also be developed for addressing legitimate concerns raised in relation to patient data and information use, electronic health records, patient registries etc.

Similarly, there is a need to ensure that the fact that being on a patient register or participating in genetic research does not cause a patient difficulty with, for example, a bank or insurance company.

Married to this idea also is a need for mechanisms by which trust can be demonstrated – demonstrable, audited, accredited. Where highly sensitive information finds its way, unintentionally and inappropriately into unintended domains – there needs to be mechanisms to address these breaches.

Sanctions

IPPOSI believes that in the interests of maintaining patient and public confidence and the integrity of the healthcare record keeping system that sanctions must be in place to deal with breaches of security. Accountability is important.

CONCLUSION

In conclusion IPPOSI would like to respond briefly to the 9 Key Issues for Consideration\textsuperscript{26} posed in the Health Information Bill Discussion Paper\textsuperscript{27}.

What are the benefits to patient care and safety which should be the objectives of any legislation?

IPPOSI observes that the proposed Health Information Bill outlines 16 different policy objectives\textsuperscript{28}. These are admirable and ambitious and, if fully achieved, would guarantee a first class, effective, system-wide, health information governance framework focused on patient care.

\textsuperscript{26} IPPOSI would draw attention to the fact that the IPPOSI response to the Discussion Paper is both the main text of this submission and the responses to the 9 questions but not the 9 responses in isolation.

\textsuperscript{27} DOHC, Discussion Paper on Proposed Health Information Bill, 2008, p4

\textsuperscript{28} Ibid, pp 11-13 inclusive
and safety. IPPOSI welcomes the thought that has gone into the development of these objectives and notes that all key elements are included.

With regard to legislation - IPPOSI would like clarification with regard to

(a) what is permissible and what is not
(b) enabling and mandatory legislation
(c) doctor-patient confidentiality

Clarity and guidance in relation to these matters will enhance healthcare service provision, patient care and patient safety.

What is the balance to be struck between the right of individuals to control their healthcare information and the needs of those managing healthcare systems, providing healthcare services and undertaking medical research (including the role of Research Ethics Committees) to have limited and controlled access, without individual consent, to such information for legitimate purposes?

Researchers generally wish to study aggregate trends and do not necessarily need to, nor do they necessarily wish to, have details that would identify individuals. In this regard the removal of as many identifiers as possible may be the way forward, as with anonymisation of data there are no data protection concerns.

In circumstances where limited and controlled access, WITHOUT individual consent, for LEGITIMATE purposes is being considered a solution such as currently operates with the Cancer Registry might be considered. Eg. Exemption from “fair obtaining and processing” of the Data Protection Act (but NOT exempt from any of the other provisions of the Data Protection Act in terms of security, confidentiality, passing information). IPPOSI would suggest that the Cancer Registry, which operates under these terms, does ensure high standards with regard to security, confidentiality, passing information etc. and it should be expected, IPPOSI would argue, that others exempted in a similar fashion for legitimate and sound purposes would be required to do likewise.

IPPOSI does however recognise the difficulty that can arise in deciding what is “identifiable information and what is not”. Patients with a rare condition may be readily identifiable by gender and geographic location alone. IPPOSI also recognises that establishing what is “identifiable” might necessitate a case by case basis consideration especially where doubt exists. The Data Protection Commissioner’s Office has, IPPOSI understands, been very helpful to organisations and entities operating in Ireland when questions in this regard have arisen.
What rules should accompany the introduction of a Unique Health Identifier for both patients and healthcare providers? In particular, what factors should influence the regulation of the collection, use, disclosure and linkage of such an identifier: IPPOSI sees the introduction of a unique patient identifier as a positive development and recognises the value that such an identifier would have. IPPOSI agrees that far from being a threat, a unique patient identifier would contribute to reducing the need to hold personal information.

IPPOSI notes the work HIQA and HSE are currently undertaking in reviewing requirements for a unique health identifier and this is to be welcomed. IPPOSI understands that a proposal outlining the benefits of a unique patient identifier is being developed and that criteria will be put forward to establish how the PPSN might work should it be decided that this unique identifier is the one to be adopted.

While IPPOSI welcomes a unique patient identifier, it feels the need to express concern with the regard to the use of a PPSN for this purpose. The use of the PPSN would allow for individuals’ information to be joined up across all sectors of the economy. This raises a number of important privacy concerns. In this regard IPPOSI notes that the PPSN was not specifically intended for use in the health sector and its use would have wide and important implications. IPPOSI is concerned at the possible choice of PPSN as a unique identifier and would not favour, or be supportive of, the use of a PPSN for this purpose.

IPPOSI suggests that in-depth discussion with the Data Protection Commissioner in this regard will be important as privacy is a key concern.

What legal issues need to be considered in establishing a National Electronic Health Records system: especially as regards an individual’s choice to participate or not and his or her control over the extent of any participation?

Given the increasing use of technology and moves across Europe to enhance EU citizens mobility to seek healthcare outside their own country of residence but within the EU Member States, IPPOSI would suggest that issues such as

(1) informed consent,

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30 Proposed EU Directive – Cross Border Healthcare
(2) access to information/data (nationally and internationally) including degree of access and identification of those persons with access,

(3) security of IT systems and inter-operability of systems, and

(4) accountability

are concepts that need careful and comprehensive consideration if a National Electronic Health Record system is to be introduced.

What principles should guide the development and regulation of National Health Population Registers, such as the National Cancer Registry, and the instances in which reporting to such registers should be mandatory?

IPPOSI believes that consideration must be given to provision of greater clarity with regard to the distinction between enabling and mandatory reporting concepts. This is a key point particularly when one considers the importance of patient and public confidence in the system and in the sharing of information/data\(^\text{31}\).

What needs to be done to provide consistency and clarity in, and between legislation, other legal rules and professional ethical codes in the treatment of personal health information having regard to the considerations of privacy, confidentiality, consent and security?

IPPOSI would suggest that one of the key issues here would be to give consideration to the development of nationally acceptable standards for personal health information informed by agreed protocols/guidance from perhaps Data Protection Commissioner in conjunction with HIQA. IPPOSI would suggest that if a draft national standard could be developed and shared with all relevant stakeholders and, a comprehensive consultation on these undertaken to agree a final, acceptable, national standard - this would be beneficial. Consideration might also be given to examining how e-health systems in EU jurisdictions operate, as the efficient and safe provision of e-health services (which is increasingly becoming the norm) requires shared formats and standards that can be used between different systems and between different countries. Inter-operability is a key consideration.

\(^\text{31}\) See pp. 10-11 of this submission
Is there a need for a comprehensive definition of personal health information and, if so what should it encompass?

It would be valuable if such a comprehensive and universally acceptable definition could be developed but, IPPOSI would not underestimate the challenge developing such a definition would create.

To what extent do certain categories of personal health information – for example, mental health information and information on children and deceased individuals – require special rules on collecting, keeping, using, disclosing and accessing?

IPPOSI would suggest that the issue of “Consent” is of particular importance here. As outlined earlier\(^3\) with regard to the cystic fibrosis patient registry, patient consent is required from all Cystic Fibrosis patients and guardian approval, for all CF minors, until they reach adulthood and are in a position to give consent and approval to be included in the registry themselves.

IPPOSI has also drawn attention, earlier in this submission\(^3\), to the issue of consenting on behalf of another person over the age of 18. In Ireland this is not possible unless the person has been made a ward of court.

Should the Health Information Bill be a comprehensive piece of legislation dealing with all the relevant information or should it build on the legislative framework (data protection and freedom of information acts) that is already there and working well?

IPPOSI would be in favour of the current legislative framework being built on and adapted as necessary, enlightened by the feedback from the consultation process on the Discussion Document for the Proposed Health Information Bill, particularly in areas where there has been consensus or in areas where there has been large degrees of support for change.

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\(^3\) See p. 13 of this submission regarding the Cystic Fibrosis Registry

\(^3\) See p. 12 of this submission dealing with Consent