

IPPOSI Submission to the Oireachtas Health Committee on the Health Information & Patient Safety Bill (pre-legislative phase)

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Introduction

This submission reflects IPPOSI's (the Irish Platform for Patient Organisations, Science and Industry) well-established patient-centred perspective on ensuring patient access to health innovation.

IPPOSI is a unique, patient-led partnership in Ireland and internationally. The platform brings together patient groups, scientists, clinicians, industry (and where possible, State Agencies) to discuss and build consensus on policy, legislation and regulations relevant to all involved in delivering treatments and innovations to people with unmet medical needs.

The IPPOSI vision is one where patients in Ireland have early, equitable access to innovations in health for improved patient outcomes. To this end, IPPOSI focuses on a variety of issues relating to the development of and access to health innovations and engagement of patients in health policy development. Since its establishment in 2005, the office of IPPOSI has become the go-to for members and policymakers to connect with disparate stakeholders in a complex health environment.

Notwithstanding the reservations outlined below, IPPOSI remains generally supportive of the Health Information and Patient Safety Bill with a view to improving quality and patient safety in Ireland. The Bill contains many positive initiatives and its urgent passing is required to provide assurances for members of the public in the areas of research oversight, ethics and data protection.

Indeed, it is paramount that this legislation focuses on the person, rather than on the health institutions involved. The use of health information in Ireland must be person-focused and should form part of a change in the national approach on how health data is seen as a public asset and how health and social care services are delivered through improved infrastructure and better relationships.

IPPOSI remains willing to continue to work closely with the Department of Health and HIQA in the the enactment and implementation of the Bill and for the subsequent legislation in this area to enable the sharing of electronic health records, to uphold the privacy rights of individuals and to achieve semantic, technical, organisational and legal interoperability.

IPPOSI Feedback and Recommendations on the Draft Bill

Part 2: Personal Data, Personal Health Data and Personal Health Information

The provisions in this part of the Bill aim to promote public trust in health service providers and public confidence in health authorities, in particular in the case of breaches of data protection, and thus, in general, are supported by IPPOSI.

1. IPPOSI's experience is that the Irish public are willing to share their personal health data¹ provided they receive in advance a clear explanation of: a) what the data will be used for; b) under what circumstances; and c) by whom it will be accessed. Protecting and safeguarding Irish people's health information is fundamental to building public confidence. IPPOSI therefore proposes that Ireland establish the statutory position of a 'public health data champion' – similar to that of the National Data Guardian for Health and Care in the UK - to scrutinise and challenge those that hold health data, and ensure that they protect it and use it appropriately and safely.
2. IPPOSI encourages the DoH to continue to advance the eHealth agenda in Ireland, as set out in the eHealth Strategy. However, the Bill in its current format does not provide for, or even promote the sharing of, electronic patient data. More explicit, specific text and terminology should be included which reflects the on-going work to implement an electronic health record for all the citizens of Ireland where information will be available electronically across the whole healthcare system.
3. It is imperative that provision is made in the Bill for the electronic storage and transfer of health information, and that this should be nominated as the preferred mode of communication. This will impact the national approach for the electronic health record and the benefit it will have for the citizen.
4. IPPOSI supports the incremental, standards-based approach to increasing the interoperability of IT systems used in the health service (Head 11). It is vital that the HSE will be required to follow the standards once approved, but also to report to the Minister on the extent to which they have been implemented and observed.

¹ "Report into the General Public's Attitudes towards Clinical Research", Drury Research, on behalf of IPPOSI, 2009: <http://www.ipposi.ie/public-attitudes>

Part 3: Research Ethics Approval

The aim to provide a national approach to research ethics, which legislates for HIQA to become the supervisory body for recognising and monitoring RECs is welcomed by IPPOSI. The current organisation of ethics committees is a major roadblock to the effective conduct of clinical research in Ireland. Delays in the ethics committee application and approval process can significantly hamper all categories of research thereby having an adverse influence on patients access to cutting edge therapies and diagnostics, on the ability of academia to undertake patient and disease focused research, and on the reputation of Ireland as a country in which industry-led research can be undertaken in a predictable fashion.

1. The first sentence in Part 3 includes medical device research under types of research already covered by existing legislation. However, Clinical Trial legislation covers drug trials only, and there is no provision in medical device legislation (including the 2016 EU regulation) for a single national opinion for device research. If medical device research is excluded in this Bill then there will be an anomaly whereby all research – except medical devices – can have a single opinion.
2. It is IPPOSI's understanding that further national legislation will confer a similar function on HIQA with regard to research ethics approval for clinical trials (in line with the upcoming Clinical Trial Regulation 536/2014² in 2018). IPPOSI therefore encourages the DoH and HIQA to work together to ensure that the requirements of both systems of research ethics approval and governance are harmonised as much as possible.
3. Implementation in this area of the Bill will only be successful if there is a positive response to it in the research community coupled with a desire to make it work. IPPOSI therefore encourages HIQA, as part of its training role to improve the quality of operations of RECs (Head 42), to promote increased interaction between researchers and RECs and specific ethics training for undergraduate and postgraduate researchers.
4. In order to deliver the important societal oversight for RECs, the stipulation that over a quarter of committee members should be lay members (Head 24) is supported in principle by IPPOSI. However, this may prove challenging as attraction of lay members is an issue for many committees. Alternatively, IPPOSI believes that the legislation could state what the minimum numbers (quorum) for holding a meeting of an AREC should be, and also *who* they should be. As a suggestion, a committee could be required to need 2 lay members as a quorum.
5. IPPOSI believes that as part of the development of national standards for RECs which includes their remit, composition, function, management and accountability³, that membership of RECs needs to be recruited from a wider mix of society and that all members of RECs need to be supported by appropriate training.
6. The role of patients, patient representatives and patient experts as members of RECs needs to be defined, supported and promoted⁴. Where a patient or patient representative progresses through a training period followed by a period of appointment on an REC, the boundaries between lay and expert may become blurred. IPPOSI recommends that under

² <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AAOJ.L..2014.158.01.0001.01.ENG>

³ <https://www.hiqa.ie/system/files/IntI-Review-Research-Ethics-Structures.pdf>

⁴ [https://www.eupati.eu/clinical-development-and-trials/guidance-for-patient-involvement-in-ethical-review-of-clinical-trials/#Introduction to patient involvement in ethical review](https://www.eupati.eu/clinical-development-and-trials/guidance-for-patient-involvement-in-ethical-review-of-clinical-trials/#Introduction%20to%20patient%20involvement%20in%20ethical%20review)

these circumstances the patient / patient representatives be permitted to maintain their status as a lay member. The 'Interpretation' section of Part 3 therefore may need adjustment regarding the definition of expert member, particularly part (c) which may be interpreted as classifying someone with experience of ethics as an expert whereas in part (b), this issue has been dealt with through the inclusion of a caveat.

7. Head 24: Clarification is required on the definition of a "fit and proper person"?
8. The Bill does not offer any guidance for scenarios of international research involving health data where content comes from Ireland and some from other jurisdictions. We suggest that provisions be included to permit an AREC to be able to support but also oversee Irish contributions to international research initiatives and registries.

Part 4: Data Matching Programmes

1. Existing health data is one of our most valuable national assets. However, the enormous potential value for research from data matching is not reflected in the current version of the Bill. IPPOSI recommends that the DoH engage with the work of the European Institute for Innovation through Health Data (I²HD)⁵ in order to drive greater levels of interoperability with health data and to enable better research through the use of such data.
2. IPPOSI proposes to create an enabling data environment for health and related research in Ireland where patient and health data is used in a safe and responsible way. The proposed "DASSL" model – Data, Access, Sharing, Storage, and Linkage – from the Health Research Board 'Data Report'⁶ would enable a robust data-sharing environment, facilitating and enabling health research and other data analysis for the betterment of Irish society. Key elements of this model include a health research data "hub", trusted third-party data linkage services, a "safe haven" for storage, and a research support unit for outputs. DASSL-like infrastructure has been used successfully in other jurisdictions. IPPOSI proposes that the necessary legislative supports to facilitate such a structure be investigated and implemented as soon as possible.
3. The Bill does not address the consent model approach that may be taken for the exchange and sharing of patient information; and the resulting consequences of either decision. The latest Caldicott report in the UK⁷ outlines a simple model which retains the requirement to get informed consent from individual patients to use their data in research, but also allows a large amount of data to be flowed for health service and are provision purposes. IPPOSI proposes that the DoH investigate the tractability of such a model in the Irish healthcare environment. The first step would be to engage with the different perspectives that exist in relation to greater information sharing in our health system.
4. While this Bill makes advances in providing an information governance framework for the management of health data, IPPOSI questions why it does not address the sharing and collection of data to/from or within the private sector? For example, how can patient data be collected and shared where a health insurer is also a healthcare provider (VHI Swiftcare

⁵ <http://www.i-hd.eu/>

⁶ <http://www.hrb.ie/publications/hrb-publication/publications//709>

⁷ <https://www.gov.uk/government/publications/review-of-data-security-consent-and-opt-outs>

Clinic)? The guidance from the Data Protection Commissioner's office⁸ in this area should be built upon from a legislative perspective.

5. The issue of compelling data controllers to provide data (Head 45) does not suggest any penalties for those who do not provide the data when requested. Penalties could be useful to enforce software vendors to keep their data/information open. Also in Head 45, there seems to be a typo in subhead 9, regarding penalties: (9) A person who knowingly or recklessly contravenes subhead (9) is guilty of an offence and is liable—
 - (a) on summary conviction, to a Class A fine, or
 - (b) on conviction on indictment, to a fine not exceeding €200,000.
6. Head 52: The *format* of data during communication could be included in the list provided in point 2. This would have significance for developers of apps, particularly apps to be used by patients to collect health information.
7. The potential of future matching with the Individual Health Identifier (IHI) is of great public interest. However, the only reference to the IHI in the Part is in Head 50;4(e). IPPOSI recommends that more provisions for the relationship between the IHI and existing public datasets and registries be inserted into the Bill.
8. The Bill seems to be focused on individual identity and matching data regarding individual patients. IPPOSI recommends that the concept of a national standard demographic dataset⁹ with standardisation of core demographic data (delivering benefits to primary, secondary care and the research community) should be further explored in the context of this Bill. There may also be a case for considering identity and matching in a broader sense (for example, genetic data relating to families or groups, or identification of DNA samples or samples in general¹⁰).

Part 5: Health Information Resources

From IPPOSI's perspective, the effective use of data, and its access, interoperability and compatibility are critical factors for realising the full potential of health information resources, including patient registries. However, this Bill, while of importance, largely focuses on issues related to data protection issues for registries and does not provide substantive direction to encourage and support the development of patient registries in Ireland.

1. Under this Bill the Minister will be able to insist that people mandatorily return to a limited number of gold standard registries. However, the challenges of creating and maintaining patient registries are stark and include challenges with patient consent, data management, governance, the cost of capturing data, etc. In addition, a European strategy¹¹ for patient registries (including a registry of registries) is forming. Therefore, what standard we wish for patient registries in Ireland, should be informed by the HIQA recommendations in 2014¹²

⁸ <https://www.dataprotection.ie/docs/Commissioner-launches-new-guidance-on-data-sharing-in-the-private-sector/530.htm>

⁹ <https://www.hiqa.ie/publications/national-standard-demographic-dataset-and-guidance-use-health-and-social-care-setting-1>

¹⁰ Chen, X., Berry, D. and Grimson, W., 2009. Identity management to support access control in e-health systems. In 4th European Conference of the International Federation for Medical and Biological Engineering (pp. 880-886). Springer Berlin Heidelberg

¹¹ <http://patientregistries.eu>

¹² <https://www.hiqa.ie/healthcare/health-information/data-collections>

should align with the European perspective, and should be supported by a national strategy¹³.

2. IPPOSI recommends the establishment of an independent “trusted third party” / Irish registry foundation which could meet the challenge of maintaining quality repositories of clinical patient data in Ireland, initially for multiple chronic and rare diseases, but ultimately to include any disease. There is an increasing international trend to use patient registries to support part of pharmaco-vigilance and the audit of longitudinal patient outcomes. Patient registries are seen as an ideal trusted source of analysed de-identified data that can be outsourced by the healthcare industry as a paid for service.
3. Therefore, Ireland urgently needs networked patient registries in place to offer value-based healthcare and to improve significantly the ability to share anonymized patient data both within Ireland and across borders. The capability of monitoring the “right patient, right treatment, right time” can be achieved through setting up a centre of excellence that would support the development of networks of high quality, standards-based, disease-specific registries¹⁴.
4. The Bill seems to suggest that the sharing of data will be in one direction only (i.e. if patient registry data is supplied to a national individual health identifier (IHI) type programme, the registry will not be able to use the output to validate their own patient data. This seems like an inefficient and ineffectual use of data which can potentially lead to errors. In addition, as mentioned above, research is conducted on a global scale. There is therefore a need for regulations and legislation to accommodate a bi-direction movement of health data in furtherance of high research goals (for example comparisons of health lifestyle and disease-specific data or outcomes across international borders).

¹³http://www.ipposi.ie/images/Towards_a_National_Strategy_for_Patients_Registries_Report_-_Considerations_for_Government.pdf

¹⁴<http://www.ipposi.ie/images/Towards%20a%20National%20Strategy%20for%20Patients%20Registries%20Report.pdf>