

Draft Health Information Policy Framework

IPPOSI consultation response

The text below has been submitted by IPPOSI in response to the public consultation on a Draft Health Information Policy Framework opened by the Department of Health¹.

Questions 1-5 asked for information about the organisation and the standard responses were provided.

Question 6. Do you have views/comments on the proposed core principles for processing personal health data?

IPPOSI agrees with the core principles outlined in the consultation document, in particular those pertaining to the duty to share, consent for research, and access.

In particular, we wish to underline that providing patients (or their families and/or carers) with access to their own health data should be an essential and important priority for any future national health information policy. We propose that the issue of access should also seek to address the challenges faced by seldom-heard and/or vulnerable patient communities (e.g. computer illiterate patients, second language patients etc). To build public trust, we believe patients need to be urgently engaged in a dialogue about what data is collected from them and how this data can be used and accessed in line with their wishes.

We wish to emphasize that, in addition to the flow and governance of information, the quality of the information also needs to be considered when processing personal health data. There are many aspects to information quality as outlined by HIQA². Adhering to standards-based terminology systems and data dictionaries can support the creation and sharing of quality data.

IPPOSI proposes that consideration also be given to including the following principles:

- 'Duty to inform': Patients should be kept up-to-date on what health data is being collected about them, how this data is being used, and who it is being shared with.
- Social value/ethics: Patients should be confident that – without their explicit consent – their health data is only being collected, used and shared for reasons of substantial public interest.³
- Equality: Health data should capture information which allows for health management of, and health research into, issues which affect all patients. Health inequalities can only be measured if the necessary data is captured – “what does not get counted does not count”.

Question 7. Do you have views/comments on the proposal to establish a clear legal basis for the processing of personal health information?

IPPOSI believes a National Health Information Policy which provides a clear legal basis for the management of health data is both timely and important.

Data protection is increasingly a topic of public debate, and many health stakeholders in Ireland are looking for guidance in advance of the entry into force of the EU General Data Protection Regulation (GDPR) in May 2018. In overseeing the proper implementation of the regulation in Ireland, IPPOSI maintains that government and regulatory bodies need to strike a balance between encouraging individuals, organisations and businesses to protect patient privacy while supporting health innovation and research environments. A strong national policy framework will ensure greater uniformity and compliance in the management of data and will help patients and society reap the benefits of the appropriate and safe processing of their health data.

¹ <http://health.gov.ie/consultations/>

² <https://www.hiqa.ie/reports-and-publications/health-information/information-management-standards-national-health-and>

³ <https://datasharing.chathamhouse.org/ethical-principles/>

GDPR gives member states the scope to impose further conditions on the handling of genetic, biometric and health data (Article 9 (4)). It is important that private and public individuals, organisations and businesses operating in Ireland are aware of their obligations in managing the health data of Irish patients, as these may differ from other European countries.

The health data management situation in Ireland is further complicated by the existence of a two-tier health system and the provision of services and care by both public and private providers. The presence of a proportionately large number of digital corporation headquarters – many of whom are interested in procuring health data – also presents additional challenges.

There are many varying regulations and codes of practice concerning information sharing which depend on for example

- the type of information
- the care setting (e.g. hospital, GP, community care and patient organisations)
- the person who collected the information and
- regulatory and professional bodies.

This policy should work together with these various regulations and codes of practice to support appropriate information sharing towards promotion of integrated care.

The *OECD Recommendation on Health Data Governance* published in January 2017 and the *WHO Guidelines on Ethical Issues in Public Health Surveillance* published in June 2017 may be useful tools to consult in finalising a national policy framework⁴.

Question 8. Do you have views/comments on the proposal to establish a clear legal basis for a 'duty to share' personal health information among health service providers, in the interests of patient safety, high quality care and treatment and the effective management of health services?

IPPOSI believes a National Health Information Policy which provides a clear legal basis for a 'duty to share' is urgently needed.

The Irish health system is made up of many different organisational parts and individuals. IPPOSI believes that we should move away from a culture where different health providers each 'hoard' their own data in 'silos' – which is not in the interests of the patient and allows us to only capture a fragmented impression of their health experience. In the short term, this practice results in patients being repeatedly asked for the same information. In the long term, it contributes towards a health system which lacks the evidence (or actionable data) it needs to provide the right services for its patient at the right time, or to improve and innovate for its patients. Introducing a legal 'duty to share' places an obligation on organisations to make changes to the way they do business and it opens the possibility of using available data for the benefit of patients.

Guidance for individuals and/or organisations on the applicability of 'duty to share' as well as checklists for consideration of data sharing requests should be developed.

To ensure that a 'duty to share' is effectively implemented, a national policy should require the data controllers in organisations to:

- develop organisational policies and procedures around information sharing
- complete information sharing assessments and establish information sharing agreements/protocols when sharing health data with other organisations⁵.
- report annually on progress against information sharing policies and standards

⁴ <http://www.oecd.org/health/health-systems/Recommendation-of-OECD-Council-on-Health-Data-Governance-Booklet.pdf> & <http://apps.who.int/iris/bitstream/10665/255721/1/9789241512657-eng.pdf?ua=1>

⁵ Both Scotland and Wales have undertaken work on the topic of Information Sharing Protocols: <http://www.isdscotland.org/Health-Topics/Health-and-Social-Community-Care/Health-and-Social-Care-Integration/docs/FINAL-ISP-TEMPLATE-Nov-2014.pdf> & <http://www.waspi.org/home.cfm?orgid=702>

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- consider privacy impact assessments so that patients and the public are fully informed about the sharing

To monitor compliance with a 'duty to share', a national competent body should be appointed to:

- assess the policy and practice of organisations against information sharing standards
- consider any appeals or complaints either from organisations who have been denied access to information or from individuals who feel their information has been wrongly shared
- provide training, advice and support to organisations around effectively implementing a 'duty to share'.

As mentioned previously in question 7, in Ireland, private health providers currently play a large role in treating patients. As such, IPPOSI believes the 'duty to share' should extend to both public and private health providers. However, an information sharing agreement should commit the private provider to appropriately safeguard data from third parties, including associated businesses or contractors. At every step we must remember that patient health data must be processed legally, fairly and transparently for a specified, explicit and legitimate purpose. Data controllers are accountable, and they must be able to demonstrate compliance with this principle.

IPPOSI recommends that patients who do not want to have their health data shared with certain providers should have the option to opt-out. IPPOSI believes that maintaining patient control over their data and public confidence in data management is paramount, and that lessons should be learnt from the UK experience in this regard.

In order to prevent an 'all or nothing' approach to data sharing, consideration should be given to the granularity / level of depth of the data. A policy on using standard information models would support this approach and would also help to mitigate against the risk of IT vendor lock-in.

Question 9. Do you have views/comments on the proposal to establish a clear legal basis for the processing of personal health information for scientific research (to include health research), statistics and archival purposes?

IPPOSI believes a National Health Information Policy which provides a clear legal basis for processing health data for scientific research is essential.

IPPOSI seeks to underline the potentially life-changing impact which research can have on patients today and in the future. Therefore, continuing to ensure that researchers have access to the health data they need to undertake their valuable work is of critical importance if patients are to benefit from scientific breakthroughs and innovation in Ireland in the future. A national policy provides the opportunity to standardise how data is collected, used and shared with (and within) the scientific research community⁶.

We believe that research, statistics and archiving should be specifically recognised in a national policy as areas which should be able to benefit from the (lawful) use of health data. Researchers need to be able to legally maintain the datasets and registries which they already have within their possession, as well as be able to use data collected by others for new research.

As stated previously in question 7, we call for a national policy that will help strike the balance between protecting patients' privacy and supporting health innovation and research environment. We believe that restrictions should not be imposed which unnecessarily hinder the completion of scientific research with a legitimate public health purpose. Nor should the definition of a legitimate public health purpose be sufficiently narrow as to preclude innovation in health research.

However, access to health data is not unconditional, and IPPOSI believes that promoting a culture where patients are involved in research decisions around the use of their data represents the best way forward. A national policy should seek to encourage the research community to nurture closer relationships with the patient community. IPPOSI has worked in this space, and a national policy

⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5243137/>

should seek to support future initiatives which help publicly showcase the benefits of greater patient-researcher co-operation.

In the interests of ensuring the continuity of cross-border and international research, Ireland should look to the measures implemented in other European countries and should seek to adopt a legal basis which facilitates international collaboration.

IPPOSI supports open science and open data initiatives. Governments, especially as public funders of research, have an important role to play in developing policies to foster greater access to and use of scientific research. We recommend that a National Health Information Policy consider issues around open access, including a lawful use of text and data mining. A statement made by the European University Association in October 2017 may be of interest here⁷. In the US, the National Institutes of Health requires all recipients of research grants in excess of \$500,000 to prepare a data sharing plan. The Institute also has many other policies which address aspects of data sharing.⁸

In consultation with our research community members IPPOSI has established that even when the issue of access is resolved, new issues arise. Most commonly, the issue of data quality comes to the fore. We believe that patient registries are uniquely positioned to be the independent trusted third party for patient data that can provide analysed data to any of the approved interested parties (researchers, patient bodies, health administrators, pharma) that is non biased. Action is needed to establish a national body which can tackle some of these data management issues and which can serve as a central repository for available data.

Question 10. Do you have views/comments on the proposal to establish a clear legal basis for a 'consent exemption' for the use of identifiable health information for health research, in strict and limited circumstances?

IPPOSI believes a National Health Information Policy which provides a clear legal basis for 'consent exemption' is needed.

IPPOSI believes that health data is patient data, and that issues of consent are important for patients. We believe that a national policy should address consent in general, as well as the specific question of 'consent exemption'. We believe that patients, researchers and regulators should engage in a national conversation around consent, the outcome of which should be an easier pathway to consent rather than a culture of consent exemption.

That said, there are instances where consent exemptions are needed. We believe that those applying for exemptions should carefully explain their position, and in response, they should receive careful consideration. Reviewing and authorising bodies should not adopt an overly strict interpretation of applicable legislation to pursue a line of least resistance (i.e. more denied exemptions and less legal challenges). Rather, where lawful, exemptions should be granted but procedures should be put in place to monitor the execution of the research project and to ensure that there are no breaches of data protection.

IPPOSI believes that patient representatives should be involved in the consent exemption process to ensure that a patient-led perspective is presented. And in the interest of broader transparency, at a minimum, a list of consent exemptions should be maintained and publicly accessible on the website of the relevant supervising authority.

IPPOSI has already undertaken some work around the topic of consent, and this experience has led us to conclude that:

- Consent should be active. Patients need to be clearly asked for their consent and they need to understand clearly what they are consenting to. Consent should not be ambiguous or assumed. Consent should not be bundled with other paperwork.

⁷ <http://eua.be/Libraries/publications-homepage-list/eua-statement-on-open-science-to-eu-institutions-and-national-governments-2017>

⁸ <https://grants.nih.gov/policy/sharing.htm>

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- Consent should be a dynamic and ongoing process. Patients need to be kept updated about what their data is being used for and they need to be asked to re-consent when necessary. Paper consent forms do not seem to provide the scope for dynamic consent, digital solutions are needed. Patients also need a dynamic consent model to be able to easily and immediately withdraw consent⁹.
- Consent should be accessible for a range of patients of varying ability. For example, consent for children should employ child-friendly language. IPPOSI's public information campaign around clinical trials represents a successful and practical example¹⁰.

The work on data security, opt-out and consent recently completed in the UK may be of interest in addressing the issue of consent in the policy framework¹¹.

Ensuring patients/patient organisations are fully informed to give consent on topics of data sharing is at the core of providing consent. Educational resources, awareness campaigns and information sheets are some practical initiatives that could be supported in this policy.

Question 11. Do you have views/comments on the proposal of a national data advisor to ensure patient data is safeguarded and used appropriately?

IPPOSI believes that it would be beneficial to institute a position – akin to the role of the National Data Guardian in the UK – here in Ireland¹².

IPPOSI proposes that a National Data Advisor should be a statutory role which serves as an independent and authoritative voice which can raise questions about the management and safeguarding of health data on behalf of the patient and the public. In order to do this effectively, the Advisor should be provided with a mechanism and the resources needed to consult regularly and widely with the public and patients.

The office of a National Data Advisor should be adequately resourced to complete its functions and an annual reporting process should be put in place to share priorities, progress and challenges. The Minister of Health should commission the Advisor to conduct reviews and to offer recommendations on specific data protection issues. There should be a clear distinction between the duties undertaken by a National Data Advisor and the Data Protection Commissioner¹³. The role and the functions of a National Data Advisor should be put out to public consultation.

In addition to focusing on the data itself, a National Data Advisor could also take a view on the information architecture which needs to be flexible enough to support the varied uses of the data and also independent from IT vendors.

Question 12. Do you have views/comments on the proposal of an advisory committee on personal health data?

In general, IPPOSI cautions against the establishment of additional mechanisms which draw on limited resources (both human and financial), especially when health budgets are coming under increasing pressure. New mechanisms must be able to demonstrate added value and they must be required to provide evidence of this added value against measurable indicators and objectives.

⁹ <http://www.ipposi.ie/wp-content/uploads/2017/07/Consent-Outcome-Report-July-2017.pdf>

¹⁰ <http://www.clinicaltrials.ie/>

¹¹ <https://www.gov.uk/government/publications/review-of-data-security-consent-and-opt-outs>

¹² <http://www.ipposi.ie/wp-content/uploads/2017/01/IPPOSI-submission-on-the-Health-Information-Patient-Safety-Bill-pre-legislative-phase.pdf>

¹³ Useful documents include the *UK government's Summary and Feedback to the Consultation on the Role of the National Data Guardian* <https://www.gov.uk/government/consultations/the-role-of-the-national-data-guardian-for-health-and-social-care> and the *Manual for Caldicott Guardians* https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/581213/cgmanual.pdf

IPPOSI believes that the success of an advisory committee on personal health data would be reliant on its membership/composition. Without the involvement of the public, and specifically of patients, an advisory committee would lack the critical friends capable of ensuring that proposals put forward address the needs and concerns of data owners/subjects. As previously mentioned, data protection is a balancing act. With this in mind, we believe that it would also be important to have members of the research community represented on an advisory committee to ensure that Ireland's data protection response is proportionate.

We believe that consideration should be given to the positioning of the committee. Ideally it should operate within an independent, apolitical space – allowing sector experts to provide a frank assessment of Ireland's progress.

Question 13. Do you have views/comments on the proposal of a confidentiality advisory committee to consider consent exemptions for health research, in strict and limited circumstances?

As previously mentioned, IPPOSI believes that establishing additional mechanisms must provide demonstrable added value.

We also reiterate the importance of including patient representatives in deciding upon the membership/composition of the sub-committee. In England and Wales, the Confidentiality Advisory Group (CAG) of the Health Research Authority (HRA) counts several lay members among its members¹⁴.

IPPOSI believes a centralised sub-committee tasked with considering consent exemptions for health research may contribute towards an increasingly standardised research approval process. Allowing the current diverse network of research ethics committees to individually consider consent exemptions could result in widely divergent interpretations of acceptable conditions for exemptions.

Question 14. Do you have views/comments on the proposal to progress a standardised approach to promote consistency across the health system to support information flows and eHealth?

IPPOSI believes that, having established the lawful and appropriate provisions for sharing data, we need to urgently and intensively respond to the technological challenges of sharing data. Poor data collection and management systems cannot be an excuse for failing to share and use data which can ultimately improve outcomes for patients.

IPPOSI supports the work undertaken by HIQA to develop standards for improved interoperability¹⁵. These standards now need to be implemented. IPPOSI believes that organisations should both receive support and training and that they should be required to report on progress and meet achievable timeframes for full compliance.

Question 15. Do you have views/comments on the proposal to determine more centralised operational arrangements for health information?

IPPOSI believes that lessons can be learnt from the information sharing aspects of the implementation of the National Integrated Medical Imaging System (NIMIS). The information sharing aspects of the NIMIS operational design include a mix of local and centralised operations which have largely worked well. The fact that the images adhere to the DICOM standard has facilitated this success. Other types of information do not have such a strong and widespread information standard but, where possible, standards and a broad standards-based approach (as advocated by HIQA) needs to be considered.

¹⁴ <https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/>

¹⁵ <https://www.hiqa.ie/system/files/Healthcare-Interoperability-Standards.pdf> & <https://www.hiqa.ie/hiqa-news-updates/hiqa-has-launched-new-public-consultation-ehealth-interoperability-standards>

In addition to both the technical possibility of sharing information and the meaningfulness of that information, lessons from NIMIS and the GP eHealth systems concerning ownership of the information within the eHealth system also need careful consideration. Otherwise there may be costs incurred by the state to access this data for research.

Question 16. Do you have views/comments on the proposal to determine a consolidated approach for data warehousing of health information for health research and other health-related purposes?

Regardless of the approach used to allow health information to support health research, the crucial aspect of information aggregation comes to the fore. Aggregation of information from disparate sources in a way that protects the data quality, context and clinical meaning depends on the information models, terminology and dictionaries used when storing the information. Using standardised information models, terminology systems and data dictionaries eases both the technical and financial burden of aggregation and most importantly supports the preservation of clinical meaning in a transparent way.

Appropriate resources should be allocated to ensure that data warehousing objectives can be achieved.

Question 17. Do you have views/comments on the proposal to raise awareness of the public health value of health information, what purposes it can be used for and what the benefits are for sharing information?

IPPOSI believes in the power of the educated patient and we continue to undertake a number of initiatives within this space. One of our most recent initiatives has been the launch of a pilot patient education programme for Ireland in cooperation with a number of universities and regulators. 21 patients are currently enrolled in a number of six-week modules to learn more about different aspects of health innovation including clinical trials, health technology assessment and medicines regulation¹⁶.

We would strongly agree with the proposal to raise public awareness around the importance of health data, and we would welcome the opportunity to contribute our patient education expertise to this process. We are working with the UK initiative 'Understanding Patient Data' and we believe that a similar approach might be explored and adopted in Ireland¹⁷. As always, any materials designed for the purposes of informing or educating patients should be developed and finalised with patients.

Engaging in a national conversation around health data will help both data subjects (patients and public) and data users (various) to address issues and identify solutions. Media reports often appear to suggest that patients and the public are naturally suspicious of how, and why their health data is being used. At least among our patient community, we do not find this to be the case. On the whole patients appear to support the lawful use of their data to improve health management and/or health research¹⁸. Robust data protection rules and processes would reassure those who may feel vulnerable and / or have a lack of control over where their data is stored and how it might be made available to others.

IPPOSI believes that the best way to raise public awareness of the benefits of sharing health information *for research* is to involve patient communities in the design and dissemination of research. Individuals engaging in data collection should be minded to examine research questions which have been identified in concert with patient communities. New research should show evidence of having consulted relevant patients before proceeding. This would include discussing the data/outcomes that should be measured to ensure that the findings are also relevant to (similar) patients. A feeling of 'owning' their own data and 'gifting' it to the research would increase trust among those participating in the research.

¹⁶ <http://www.ipposi.ie/our-resources/patientsinvolved/>

¹⁷ <https://understandingpatientdata.org.uk/>

¹⁸ http://www.ipposi.ie/images/Health_Info_2015_FINAL.pdf

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The inclusion of information management education on the curricula of health care providers is something that this policy could also influence.

Question 18. What other measures could be taken to raise awareness of the benefits for the public of appropriately using and sharing health information?

IPPOSI is willing to explore, in conjunction with the Dept. of Health, the possibility of hosting Citizen Juries to raise public awareness of the benefits of using and sharing health information.

This approach has been trialled in the UK by the Connected Health Cities programme¹⁹.

Question 19. Thank you for your participation in this public consultation. Do you have any final comments regarding the draft health information policy framework?

Moving forward, IPPOSI believes it is helpful to provide worked examples where possible. The UK Information Commissioner's Office adopts this approach in issuing guidance²⁰.

¹⁹ <https://www.connectedhealthcities.org/get-involved/citizens-juries/>

²⁰ <https://ico.org.uk/for-organisations/guide-to-data-protection/exemptions/>