Draft recommendations on a consent model for the collection, use and sharing of health information in Ireland

Public Consultation Feedback Form

November 2021

The Health Information and Quality Authority (HIQA) is holding a public consultation to give people an opportunity to provide feedback on the draft recommendations on a consent model for the collection, use and sharing of health information in Ireland. Your views are very important to us, and we will carefully assess all feedback received and use it to help develop the final recommendations which will be submitted to the Minister for Health for approval. **Please note:** the focus for this consultation is the content and structure of the draft recommendations. The final wording, design and layout of the recommendations will be developed after the public consultation. We welcome responses to all questions, and there will be an opportunity at the end of the survey to provide any additional general comments.

The closing date for the public consultation is Monday, 10 January 2022.

1. About you

1.1 In what capacity are you providing this feedback:

- ○ As a member of the public
- ◉ In a professional capacity

1.2 If you are providing feedback in a professional capacity, please specify your current role:

Chief Executive Officer

Research and Advocacy Manager

1.3 Are you providing this feedback as an individual, or have you compiled it on behalf of an organisation?

- ○ As an individual
- ◉ On behalf of an organisation

1.4 If you are providing this feedback on behalf of an organisation, please provide the organisation's name and contact details below.

Irish Platform for Patient Organisations, Science and Industry (IPPOSI)

1.5 If you would like to be contacted to participate in future stakeholder engagement in relation to this work, please provide your name and details below.

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2. Your feedback on the draft recommendations

In this section, we would like to find out what you think of the content of the draft recommendations on a model for the collection, use and sharing of health information in Ireland.

The questions are not intended in any way to limit your feedback, and other comments relating to the draft recommendations are welcome.

2.1 Please provide your feedback on Recommendation 1: to define key concepts in legislation.

Please provide specific feedback on the proposed definitions for health information; health information for direct care; and health information beyond direct care.

Defining health information: We find the phrase "other personal information required for the provision of health or social care" somewhat confusing, as it appears to raise the question of what is 'required' – and consequently – what is 'not required'. We propose that the phrase be amended to "other personal information collected during the provision of health or social care", as it avoids a judgement around what is 'required' and it makes 'all' personal information collected the subject of these recommendations.

We would like to raise a question about genetic/genomic information, and how it is considered in 'defining health information'. As our health system evolves, this category of information is likely to increase in importance, and the recommendations should include/make provision for how this information is covered under any future health information framework.

Defining health information for direct care: We agree that defining 'health information for direct care' as including case reviews, local clinical audits and emergency care is both appropriate and practical.

Defining health information beyond direct care: We believe that defining 'health information beyond direct care' or 'for secondary purposes' needs careful consideration. The current definition appears to limit the focus to the use and sharing of health information from within the current health system. We know that there are many more potential uses for health information, and we feel that the definition should reflect this (the decision to mandate for or against these additional uses is a separate issue and a later cause for consideration).

We propose deleting 'by health services and health service providers', as it places the emphasis on who can use and share health information, rather than on why the health information is being used or shared i.e. the purpose. We also suggest replacing 'activities that contribute to the provision of health and social care' with 'activities that contribute to the health and social care of', as it appears to limit the potential purposes to activities around health service provision.

2.2 Please provide your feedback on Recommendation 2: to follow a rights-based approach when implementing a consent model for health information.

We support a rights-based approach, and we urge the recommendations to recognise (and to call for the realisation of) a full spectrum of rights based on normative legal, social and ethical principles around health information.

Citizens have the right to have their information kept private and confidential, but the state also has a responsibility to provide a duty of care in line with standards befitting a modern health system. The collection, use and sharing of health information is central to ongoing efforts to move toward a modern health system. Indeed, the Caldicott Principles upheld in the UK emphasize the duty to protect information alongside the duty to share information.

Citizen rights are not limited to privacy and confidentiality, and privacy and confidentiality are not absolute rights. Citizens also hold rights to:

- be informed about what information is collected about them, how it is used, and to be provided with this detail in an accessible and understandable format

- be able to request access their own information, and to receive this access in a timely and unrestricted manner (ideally in real-time with the benefit of digital portals)
- be able to query, and potentially correct, inaccuracies found in their own information
- be facilitated to manage the access granted to others to their information, and to be able to indicate and revise their consent preferences
- be invited to participate in health information decision-making, and to be actively involved in developing and evaluating health information policy and practice

A rights-based approach must therefore detail how these rights have been balanced. To support the implementation of a rights-based approach, we propose that the rights enjoyed by citizens around the topic of health information, and the accompanying responsibilities placed on the State, are elaborated upon for the purposes of raising public awareness and promoting public transparency, accountability and participation. Without this step, there is no guarantee that the rights and responsibilities of different stakeholders is adequately or accurately understood.

It is worth noting, that several jurors participating in the IPPOSI Citizens' Jury on Access to Health Information in April 2021 expressed repeated frustration around not being informed about, or able to access, their own health information; "We are being told that we have the right to access our health data but why then is the process of accessing it so difficult?"

2.3 Please provide your feedback on Recommendation 3: the proposed consent model.

Please comment specifically on the four categories in the proposed consent model, as well as the proposed exemptions.

We believe that a consent model for health information must be as clear as possible in order to maximise public trust and confidence, and especially in instances where explicit consent is not required.

General Concern:

We wish to raise a concern about the scope of the model. The model proposes that health information be shared and used for the purposes of direct care without explicit consent, and for purposes beyond direct care when exemptions apply and when information is de-identified. The model requires consent for all other purposes, but instead of detailing what this model for consent might look like, it defers to a distinct consent model as established by the Health Research Regulations. In our opinion this position is short-sighted. The proposed consent model fails to offer a whole-system approach which the public can understand, and which citizens wishing to have their health information shared and used for health research and innovation can have their preferences indicated and acted upon (something which is not provided for in the Health Research Regulations). It also assumes that the regulations are fit-for-purpose from the perspective of meeting the information needs of the health research and innovation community, and it fails to adequately explore the potential for public-private-patient partnerships around the ethical sharing and use of health information, as part of a modern health information ecosystem.

We therefore believe that the scope of the proposed consent model requires greater consideration, and we suggest that a more holistic approach be adopted which seeks to work with the public and private health research and innovation community to review all the potential secondary uses of health information. Given the speed of progress at the European level - for example the European Health Data Space and the associated EU legislation to support the coordination of data sharing - Ireland will be required to facilitate secondary use of health information for public benefit. The coming years will usher in unprecedented levels of change in how we use information to meet our health challenges, and we need to future-proof our legislative and policy framework to ensure that the proposed consent model is not outdated by the time it is implemented. We should not shy away from the difficult conversations that need to be had about whether, and if so how, we share and use health information for purposes beyond direct care. We should allow the conversation to be led by the citizen, and ensure that inclusive and diverse voices are heard.

Feedback common to all categories:

While the requirement for explicit consent may be removed, the requirement for transparency is not. As a minimum standard, the proposed consent model must commit to establish a mechanism (digital or other) to inform the citizen of how and why their health information is being (or may be used) under each and every category. This applies whether health information is being used for direct care (category 1) or for beyond direct care (categories 2-4). Jurors participating in the IPPOSI Citizens' Jury on Access to Health Information in April 2021 indicated that they have very little knowledge about how or why or who is accessing their information, and that this concerns them – a position shared by a number of IPPOSI patient organisation members and individual patient advocates .

In addition to the requirement for transparency, we add a requirement for involvement. Citizens must not only be provided with a mechanism which informs them about how and what is happening to the health information, they must also be provided with a mechanism which allows them to manage their health information – including an ability to query, authorise, amend, withhold, and forbid the use of their identifiable health information. In particular, provisions must be made for the management of particularly sensitive health information, for example, mental or sexual health information.

Specific feedback on proposed categories:

- Category 1: We agree that explicit consent may not be required for health information shared and used for direct care. Jurors participating in the IPPOSI Citizens' Jury on Access to Health Information in April 2021 indicated that they believed that this was already happening and that they were comfortable with it.
- Category 2: As previously highlighted, we believe that a whole-system approach to consent is needed, and we believe that the Health Research Regulations do not cover all instances where health information may be shared and used for purposes beyond direct care.
- Category 3: We received some feedback from IPPOSI members that the exemptions listed were somewhat unclear. Some believed that the first three exemptions might be more succinctly incorporated into one exemption. Many believed that the exemption for professional education and training required more

detail before being acceptable to the public as there was likely to be less appetite (or understanding) around this proposed use.

- Category 4: We suggest that more detail is required here as the challenges of anonymisation or de-identification are well known. We received queries about how and what information might be realistically processed under this category.

2.4 Please provide your feedback on Recommendations 4 and 5: to develop specific legislation for uses of health information.

We agree that legislation is needed to provide for the collection, use and sharing of health information, and that this legislation should include use for direct care and for beyond direct care ('secondary purposes').

In line with our feedback around the scope of the consent model, we believe that this legislation should regulate (for or against) the use and sharing of health information for a wide range of purposes beyond direct care.

Given the sensitivity of the topic, and to ensure that the legislation meets citizen expectations around how their health information is managed going forward, we believe that an innovative approach to the legislative development process is required. A national conversation with citizens is needed around health information, and the legislation should be co-created between the Department and the citizenry. For example Finland, in drafting its own legislation on the secondary uses of health information, offers a model for how this might be done.

2.5 Please provide your feedback on Recommendation 6: governance structures.

Given the sensitivity of the topic, we call for the governance structures around health information to be co-created with the citizen. We do not believe a simple reinvigoration or reconfiguration of ehealth Ireland will meet public expectations. Trust and confidence is essential, and it is not likely that the entity responsible for collecting most of the health information (the HSE) is able to also ensure effective compliance around the management of this same information. Citizens must have full confidence in the entities charged with managing their health information and this can only be achieved through a complete reimagining of governance, arriving at a solution achieved through a process of co-creation.

As a starting point, we can share that jurors participating in the IPPOSI Citizens' Jury on Access to Health Information in April 2021 called for an independent public authority which acts in the best interests of the citizen. Several individuals went one step further and called for the introduction of citizen-led governance structures such as 'health information collectives'. While these ideas mark a clear departure from the normal way of doing business, it does indicate a public desire to move to a democratic, person-centered way of managing health information. The UK has had a Data Guardian in place for several years now, and Digital Health Europe has explored a number of citizen-led initiatives for scalability and success.

It is clear that any governance structures established must have meaningful citizen (and patient) involvement. We ask that representatives within these structures follow a public appointments process, and that the criteria for reviewing applications be fully transparent and

mindful of the need to include diverse voices among those selected. We underline that the voice of chronic and rare disease patients must be among those heard.

Governance structures must be co-created with the citizen to provide for sufficient numbers of citizen representatives, to ensure that the role of citizen representatives is sufficiently defined, to provide mechanisms for citizen representatives to raise issues and concerns directly with health information decision-makers in government and across the health system.

2.6 Please provide your feedback on Recommendations 7 and 8: the technical and operational considerations.

Again, given the sensitivity of the topic, we believe that the technical infrastructure and operational capabilities needed to implement the consent model must be co-created with stakeholders, including citizen (and patient) representatives. Jurors participating in the IPPOSI Citizens' Jury on Access to Health Information in April 2021 were very clear that individuals must have digital solutions (for instance, a citizen portal) which allow them to control their own health information. To ensure that the digital solutions developed are fit-for-purpose and citizen-accessible, a process of co-creation must be put in motion which focuses on meeting citizen needs and expectations.

We must move away from seeking to monitor public views and opinions, towards seeking to partner with the public in early design phases and throughout the lifecycle of major health information infrastructure projects. Opportunities like the implementation of the Electronic Health Record at the new Children's Hospital must embrace citizen involvement and seek to assess the added value of partnership working in arriving at the final, agreed digital solution.

The consent model describes instances where explicit consent is not required for the sharing and use of health information, however it may be possible to add conditions in line with the individual preferences. For instance, the possibility of creating 'locked boxes' for certain types of health information may need to be explored. In other jurisdictions, citizens have an access code which they can decide to give out to those seeking access to their information. Others offer citizens the possibility of preparing consent directives which detail how information can or cannot be accessed, and under what circumstances. Finally, audit trails to allow citizens to track who has accessed their information and when, are increasingly in place. These options and more will need to be explored with citizens.

The consent model details a fourth category of information which is anonymised and does not require explicit consent for use. The infrastructure needed to make much of this a reality is not yet in place, but more importantly the institutional leadership needed to plan for this infrastructure is also lacking. An independent entity (outside the HSE) must undertake a review of the infrastructure and capabilities within the health and social care system to generate quality health information, including securely de-identified health information.

2.7 Please provide your feedback on Recommendations 9 and 10: public engagement.

While we welcome the emphasis on public engagement, we are concerned that the call for a national public engagement strategy will be too little, too late. These recommendations show that decisions about our health information future are being made now, yet levels of true public engagement remain relatively low with discussion confined to those with an existing interest in the topic.

Based on our experience of the IPPOSI Citizens' Jury on Access to Health Information in April 2021 and on feedback from our patient organisation members, we believe that the scale and importance of this topic is such that traditional public participation mechanisms (surveys, consultations) will not suffice. We need a whole government, inter-agency approach to kick start a national conversation about our health information future as a society, and as individuals. This conversation needs to be an informed one and so we need a multi-channel public information campaign about health information to raise awareness around individual rights, around collective/public interests, and around the benefits and risks of sharing and using health information. We also need public education and training to improve digital health literacy so that people are equipped with the skills needed to manage their own health information.

The outputs from this national action must inform (rather than follow) our legislative, regulatory, policy, infrastructure and governance arrangements for health information going forward. Adopting a strategy with the goal of getting the public 'on board' a top-down vision, rather than with the goal of co-creating a future from the bottom-up is a missed opportunity to shift the culture.

3.1 In your opinion, are there any aspects not covered in these draft recommendations? If so, please describe them here.

No response

3.2 What are the greatest challenges that you currently face in collecting, using and sharing health information?

(If this question is not relevant to you, please move on to the next question.)

No response

3.3 Having read the draft recommendations and associated evidence synthesis, do you have any thoughts on a proposed 'opt-out' consent approach for using health information and how this might work in Ireland?

We believe that the argument is not so much about whether we adopt an 'opt-in' or an 'opt-out' approach, but rather about how we create digital solutions which facilitate the empowered citizen to opt to make these choices for themselves. A consent model co-created with the citizen will hopefully provide greater data autonomy for individuals, who will be able to decide who to share their identifiable health information with, what information to share, and for which purposes.

However, as not all citizens will be interested in actively managing their own health information, especially for purposes beyond their own care, de-identified information should be automatically available for sharing once any risks around the re-identification have been adequately managed.

A public registrar of examples of information which has been successfully shared should be maintained and the details regularly communicated to the public so as to grow awareness around the benefits of greater health information sharing.

A national advisory group of citizens, reporting directly to the authority identified as responsible for the health information, might be established to provide guidance on this and many more questions relating to the proposed consent model.

3.4 Are there any other comments that you would like to make about these draft recommendations?

Within IPPOSI, we have followed developments in the health information space for many years. Progress has been fragmented, and a stop-start approach has produced much frustration. While there is clearly a new momentum and appetite to make advances in this area, we believe the steps being taken could benefit from greater coordination across the health sector and from a more active person-centered focus.

We believe there is a need to turn the current process on its head. We would like to see a wide-ranging, in-depth, and inclusive national conversation with the public on the topic of health information. We propose that this conversation precede changes to legislative, policy, infrastructure or governance. Indeed, the experience & sequence of developments, in the UK (e.g. care.data, GP data sharing opt-out, ending of funding for 'Understanding Patient Data'), indicates that when and how to involve the public requires careful (and early!) consideration.

Rather than suggesting that all activity in this space should stop, we are proposing that a conversation be ignited with urgency, and that it be as open and as democratic as possible. Difficult political, ethical & legislative decisions will need to be made, but the process of arriving at these decisions should be a public one where all perspectives are provided with the opportunity and the space to weigh in.

By avoiding this important national conversation, not only do we risk receiving input only from those who are already engaged around the topic or from those who have a vested interested in having their voices heard, but we ultimately risk putting in place an approach to health information management which the public has neither understood nor endorsed, or at worst, which they reject. Citizen engagement impacts both opt-in or opt-out models, and so regardless of the direction of travel, waiting to involve citizens only when all the details have been ironed out is an error. As with any involvement, it must be early, it must be equal, and it must be inclusive.

The national conversation should be complemented by a public information campaign to introduce citizens to the potential benefits and risks of sharing and using health information, including with our European and global health partners.

We believe that consent ultimately boils down to transparency, access, and choice. Citizens need to know more about the information that is collected about them and how it is used and shared. Citizens need to be able to access and manage their own health information directly. And citizens need to be able to consent to a range of options around the management of their own health information which reflect a full spectrum of individual preferences.