An Roinn Sláinte
Department of Health

Report of the Public Consultation Process on the Draft Health Information Policy Framework

November 2018

Contents

Executive Summary

The healthcare landscape in Ireland is changing as a result of various demographic and organisational resourcing factors and the evolution of technology. These factors mean that future healthcare systems will need to be radically different in order to respond efficiently and equitably to forecasted demand.

Health information and eHealth have been identified in the Slaintecare Report as critical enablers for future healthcare reform. The roll out of the Individual Health Identifier and the opportunity to implement the eHealth strategy means it is now the right time to develop a new health information policy for Ireland that can connect the legislative requirements, governance and operational arrangements needed to exploit knowledge and information in a modern health service.

In 2017, the Department of Health consulted stakeholders on a draft Health Information Policy Framework via a workshop with attendees at the National Health Information Seminar on 4th October 2017 and a six week online public consultation in October/November 2017.

The aim of these consultations were to obtain the views of patients, healthcare professionals, health researchers, health service providers and other key stakeholders on policy proposals for health information in the areas of legislation, governance, operational arrangements and patient and professional awareness. Over 270 individuals attended the National Health Information Seminar and the online public consultation received 167 responses.

Feedback from the public consulation (both the online consultation and the consultative workshop) indicated broad support for the the core principles and the draft policy proposals under the four policy pillars. It also highlighted some areas for further clarification and suggested actions in the areas of patient engagement, transparency, governance and legislation:

Patient Engagement and Transparency

- Engage with and empower patients on policy proposals that affect them, this includes communicating with patients in a clear and accessible way and ensuring patients are represented on any advisory committee.
- Health service providers need to be transparent with patients about how personal health information is collected, used and shared for primary, secondary and research purposes.
- Individual privacy rights must be balanced with the public interest benefits of sharing personal health data for healthcare, health services management and research purposes.

Governance and Legislation

- Ensure governance and accountability for all policy measures and where appropriate, such measures should be on a statutory or independent footing.
- Consider how any proposed governance measures will interact with existing entities such as the Data Protection Commission and other statutory health bodies.
- Clear definitions need to be established in legislation on how personal data is processed for primary, secondary and research purposes.
- Future-proof any legislation, standards and infrastructure to support policy proposals and the eHealth agenda.

The findings and insights provided through this public consultation exercise will now inform and guide the ongoing health information work programme. As part of this programme of work, the Department of Health introduced the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 and are actively considering other regulations under the Data Protection Act to underpin and clarify the legal basis for the information flows necessary to support integrated care in a secure and confidential manner.

This work programme is now set to become a key part of the Sláintecare Reforms in which health information and eHealth are recognised as key enablers of the person-centred integrated model of care that is envisaged for Irish health and social care services. This has been recognised in the *Sláintecare Implementation Strategy* and will necessitate the finalisation of a health information policy framework in 2019 and the development of a *Data Strategy for the Irish Health Service* in 2020. The Department again wishes to express its appreciation for the high-quality engagement that this exercise has generated and we commit to continuing engagement as the policy development and implementation of eHealth initiatives and the Data Strategy progresses.

Introduction

The Department of Health held a public consultation from 4th October to 15th November 2017 to seek the views of the public and key stakeholders to inform the drafting of a national health information policy. As part of this process, the Department also held a consultative workshop at the National Health Information Seminar on 4th October 2017. This report outlines the views, opinions and recommendations of those who completed the consultation questionnaire, made submissions directly to the Department of Health or participated in the Department of Health's workshop at the National Health Information Seminar.

The consultation focused on the processing of personal health information in healthcare and health-related settings and it sought to receive views about how personal health information is collected, used and shared in our health services and what future health information policy should look like. A wide range of citizens responded including patients, healthcare professionals, health service providers, health researchers and others with an interest in health information.

Why do we need a National Health Information Policy?

The last statement of health information policy was in 2004 with the National Health Information Strategy [1]Since its publication, the healthcare delivery model, health information and eHealth have advanced in Ireland and we have seen changes including the:

- publication of an eHealth Strategy for Ireland
- reform of health structures including the establishment of the HSE, HIQA and the Office of the Chief Information Officer in the HSE
- advancement in digital technology and the digital economy including the 'Internet of Things' (IoT), Big Data and analytics
- legislative measures such as the Health Identifiers Act 2014, the General Data Protection Regulation, the Data Protection Act 2018 and the publication of the General Scheme of the Health Information and Patient Safety Bill.

The healthcare landscape in Ireland is also changing as a result of various demographic, organisational and resourcing factors and the evolution of technology. These factors mean that future healthcare systems will need to be radically different in order to respond efficiently and equitably to forecasted demand. Health information and eHealth have been identified in the Slaintecare Report as critical enablers for future healthcare reform.

[1] Department of Health. *Health Information: A National Strategy*. 2004.

Since the publication of the National Health Information Strategy in 2004, a number of areas requiring legislative and policy development have also been identified including establishing:

- robust governance arrangements for health information to drive transparency and accountability
- a clear legal basis for processing personal health information
- enhanced transparency and patient and professional awareness around how health information is collected, used and shared
- centralised operational arrangements for health information resources to reduce fragmentation and silos
- standards and guidance to reduce variability in practice and make data more accessible.

The implementation of the General Data Protection Regulation and Data Protection Act in May 2018 also places a higher level of scrutiny, transparency and accountability for how personal health information is processed and empowers citizens with rights around how their personal information is processed. It is therefore timely to revisit and reasssert health information policy to give legislative clarity on how personal health information should be processed and facilitate the implementation of robust policy proposals in the areas of governance, operational arrangements and patient and professional awareness to underpin future developments in health service reform and investment in eHealth as outlined in the eHealth Strategy[2], the Slaintecare Report [3]and the National Development Plan 2018-2027[4]**.**

[2] Department of Health. *eHealth strategy for Ireland*. 2013.
[3] Oireachtas Committee on Future Health. *Sláintecare Report*. 2017.
[4] Department of Public Expenditure and Reform. *Project Ireland 2040. National Development Plan 2018—2027*. 2018

Overview of the Consultation Process

The Department of Health consulted stakeholders on the draft Health Information Policy Framework via a workshop with attendees at the National Health Information Seminar on 4th October 2017 and a six week online public consultation in October/November 2017.

The aim of these consultations were to obtain the views of patients, healthcare professionals, health researchers, health service providers and other key stakeholders on policy proposals for health information in the areas of legislation, governance, operational arrangements and patient and professional awareness.

Over 270 individuals attended the National Health Information Seminar and the online public consultation received 167 responses. The following sections outline the views, opinions and recommendations of those who participated in the Department of Health's workshop at the National Health Information Seminar on 4th October and respondents who participated in the online consultation.

Consultation Workshop at the National Health Information Seminar 4th October 2017

The Department hosted a National Health Information Seminar with over 270 attendees in Dublin Castle with HIQA and the HSE on 4th October 2017. At the event, the Department held a consultative workshop with attendees on the draft health information policy framework. Each table had a moderator and a scribe and four questions were presented to participants around prioritisation, the public value of health information, security and privacy of personal information and how to involve the public in deciding how health information should be collected, used and shared. The notes from each table were collated and analysed and feedback is summarised below.

Question 1: What are the key priorities for national health information policy?

Participants in the workshop indicated that the key priorities for health information policy should include:

- Clear lines of governance and accountability for health information
- Reducing the silos of information and duplication of information
- Having the person at the centre of any policy outputs and using user-friendly language
- Consistent application of standards and guidelines and codes of conduct for processing personal health information
- Clear definitions and demarcation of primary and secondary uses of health information including requirements around processing health information for different purposes
- Protection and expansion of information infrastructure to support all policy proposals
- Legislation to cover public and private providers which aligns with the General Data Protection Regulation
- Building trust in how data is used by including all stakeholders, understanding stakeholders needs and enabling a platform for professionals and patients to discuss health information
- Having an ‘honest broker’, independent from the health service to govern health information.

Question 2: How can the importance and public value of using and sharing health information be best promoted?

Participants in the workshop highlighted that the importance and public value of using and sharing health information could be promoted by:

- Normalising the knowledge on the use of health data through clear messages with plain English
- Developing structures to hear people's priorities and concerns
- Showing the social and economic value of using and sharing health data
- Linking outcomes to information by providing concrete examples of how better information leads to better care
- Education and training for healthcare professionals
- Promoting transparency and honesty around the use of health information- if the public can see the benefits, the fear will be removed
- Having local 'champions' who promote public value of using and sharing health information
- Having clear communication with relatable examples to counteract misinformation
- Making data accessible
- Targeting GP and patient groups as advocates, information in GP surgeries.

Question 3: How can the security and privacy of personal health data be best protected?

Participants in the workshop indicated that the security and privacy of personal health data could be enhanced through:

- Further roll-out of the Individual Health Identifier
- Making the move to electronic information only
- Clearly defined responsibilities and local level committees to monitor security and privacy
- Protocols and procedures around access and sharing including audit and sanctions for data controllers who breach privacy
- Developing a 'safe haven' for data matching and warehousing
- Mandatory information governance training, refreshed on a regular basis
- GDPR compliance and good communication between the data controller and DPO
- Joined up thinking, especially in relation to legislation.
- User-friendly language to describe security and privacy by making it less technical and more accessible
- Education for patients on how IT works to support security and privacy.

Question 4: How can we successfully involve patients/citizens in deciding how we appropriately collect, use and share their information?

Participants in the workshop noted that citizen and patient involvement could be enhanced through:

- Placing the patient voice and patient experience on an equal footing and including the patient in policy development
- Early, widespread and effective communication using diverse media approaches and simple language e.g. national awareness campaigns and local engagement
- Supporting people to understand how to access their data and show them how their data is being used
- Fostering public/patient ownership of data and the empowerment that comes from sharing data
- Harnessing people's stories to show the good outcomes for patients from effective data use
- Having a citizens' jury to decide on issues relating to use of personal health information, patients need to be supported
- Minimising the opt-out opportunity- need to publicise that this will improve outcomes for all parties down the line, including the patient.
- Focus groups with patients and patient representatives.

Public Consultation on a Draft Health Information Policy Framework 4th October - 15th November 2017

The public consultation on the Draft Health Information Policy Framework was launched by the Minister for Health at the National Health Information Seminar in Dublin Castle on 4th October 2017 and advertised on the Department of Health's website. The consultation was also advertised with a press release and via the Department of Health Twitter account.

Nineteen questions were presented to respondents as part of the public consultation and respondents were asked to provide comments, opinions or recommendations on each of the proposals:

- Questions 1-5 related to demographic information
- Question 6 related to the proposed core principles for processing health information
- Questions 7-10 related to draft proposals in the area of legislation
- Questions 11-14 related to draft proposals in the area of governance,
- Questions 15-16 related to draft proposals in the area of operational arrangements
- Questions 17-18 related to draft proposals in the area of patient and professional awareness
- Question 19 provided respondents with the opportunity for any additional comments.

One hundred and sixty seven responses were submitted to the public consultation, with 158 responses submitted via the online questionnaire. A further nineteen responses were received via email and entered into the survey tool for analysis.

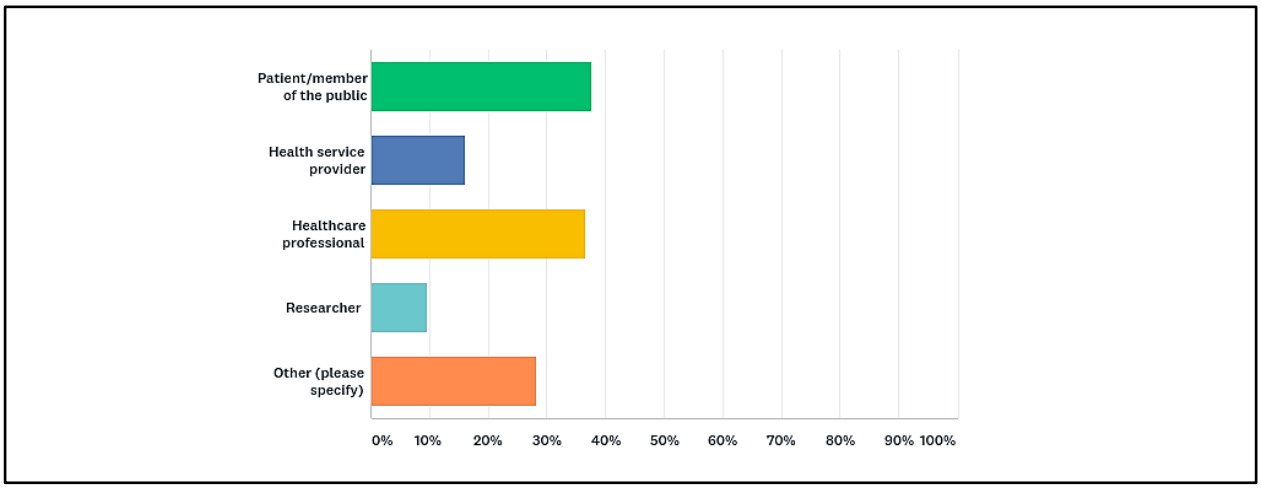
Demographic Information (Q1-5)

Of the 149 (89%) questionnaire respondents who entered a gender, 94 were female, 49 were male and 6 identified as 'other'. A total of 140 (84%) respondents answered the question on age, 17 were aged 18-35 years, 91 were aged 36-55 years, 29 were aged 56-75 years and 3 respondents were 75 years plus.

There was a good geographical spread among respondents, with the largest representation coming from Dublin (85 respondents).

Repondents were also asked if they were responding as a patient/member of the public, health service provider, healthcare professional, researcher or other. Some respondents selected multiple categories leading to a total of greater than 100%.

Chart 1: Breakdown of Respondents



Respondents to the online survey identified as follows:

- 63 (38%) respondents identified as a patient/member of the public
- 61 (36%) respondents identified as healthcare professionals
- 47 (28%) respondents identified as 'other' (for example, data protection officer, representative bodies, statutory bodies, charities, patient organisations, IT professional and regulatory body)
- 27 (16%) respondents identified as a health service provider
- 16 (10%) respondents identified as a researcher.

Core Principles for Processing Personal Health Information (Q6)

Respondents were asked to comment on a number of draft core principles to support a consistent approach to the processing of personal health information for primary, secondary and research purposes. The principles were derived from principles for processing personal health information highlighted by the Data Protection Acts, the National Data Guardian in the UK and the GDPR and included:

- Lawfulness
- Transparency
- Accountability
- Duty to Share
- Consent for research
- Access
- Data Security
- Data Minimisation
- Data Quality
- Privacy by Design.

A total of 109 respondents (65%) commented on the proposed core principles. There was broad support for the core principles with many welcoming the introduction of core principles for processing health information as sensible, comprehensive, appropriate and critical to ensuring information is processed in a manner that respects the rights of patients.

> ***The Core Principles are outlined in a clear and concise manner, they are evidence based, relevant,and have the dignity and rights of the patient at the centre***
> *(Office of Nursing & Midwifery Services, HSE)*

> ***The 10 core principles outlined in the consultation paper would certainly encompass all the elements of best practice in terms of creating an appropriate governance structure for the handling of personal health information*** *(Microsoft Ireland)*

Some feedback suggested refining the core principles to avoid overlap and providing more information/examples on what the principles will look like in practice and how they will be interpreted in different settings.

There is possibly some overlap within the concepts covered under 'duty to share' and 'consent for research'; and also 'transparency', 'accountability' and 'privacy by design'. Consideration could be given to further refinement of these principles and a clear explanation of these concepts *(HIQA)*

It was also highlighted that the core principles in the health information policy need to be cognisant of other policy principles.

The core principles for processing personal health data outlined in the consultation document should be cognisant of the principles underpinning key disability policy and legislation
(National Disability Authority)

There were suggestions for additional principles that could be included in the core principles such as 'duty to inform', data optimisation, social value and ethics.

Consideration must 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
(Irish Platform for Patients, Science & Industry)

Could the concept of 'data optimisation' be included in the principles i.e. not just that data is shared, but that shared data is used to improve patient outcomes and facilitate informed/shared decision making *(Mental Health Commission)*

Policy Pillars (Q7-18)

In addition to the core principles for processing personal health information, the draft policy framework is underpinned by draft proposals under four key policy pillars:

- Legislation
- Governance
- Operational Arrangements
- Patient and Professional Awareness.

An overview of the feedback from the online consultation on the key proposals under consideration are described in the sections that follow.

Legislation

Establishing a clear legal basis for the processing of personal health information

With the advent of the General Data Protection Regulation (GDPR) there was a requirement for Ireland to establish a clear legal basis for the processing of personal health information for primary, secondary and research purposes. The legal framework, when established, will enable patients, health service providers, healthcare professionals and researchers to have legal clarity on the processing of personal health information and information sharing. It will also support the implementation of improved governance and operational arrangements for health information.

Ninety- one respondents (55%) commented on the proposal to establish a clear legal basis for the processing of personal health information. There was strong support for legal clarity on the processing of personal health information in healthcare and health-related settings, including research.

We welcome the clarity that a legislative basis will bring to the processing of health information for care and research. Informed consent should be at the heart of all relevant legislation and the policy. The sharing of non-identifiable data for research purposes needs to be facilitated and encouraged and those sharing the data need clear guidance on how to do this legally and appropriately. This will help to ensure that valuable data with the potential to improve lives is not lost, without careful consideration *(Medical Research Charities Group)*

Establishing a clear legal basis is a good idea. That way hopefully there will be clarity for data subjects and as to how and why their personal health information is processed *(Medical Council)*

Feedback also suggested that any legislative proposals developed should:

- be clear and unambiguous on processing for primary, secondary and research purposes
- comply with GDPR and have the relevant accountability and sanctions
- harmonise the private/public divide
- be future-proofed and aligned to the eHealth agenda.

Any legal basis for the sharing and processing of personal health information including genomic data should include traceability, accountability and sanctions *(Patient/Member of the Public)*

Having a legal basis means being transparent, being clear and open with individuals about how their health information will be used. This is important as it allows individuals to make informed choices regarding if they want to share information *(COPE Galway)*

Health information legislation should be future-proofed to address the advancement of the eHealth agenda in Ireland, specifically in terms of summary care records, electronic health records (EHRs) and ePrescribing *(HIQA)*

Legal Basis for a Duty to Share

Ninety respondents (54%) commented on the proposal to establish 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. There was broad support for establishing a duty to share information among healthcare providers in legislation.

> ***We strongly agree with the principle of duty to share. Clients have an expectation of data sharing particularly in relation to health data and want clinicians involved in their care to be aware of all relevant information*** *(HSE National Immunisation Office)*

> ***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*** *(Irish Platform for Patients, Science & Industry)*

Some feedback received suggested that a duty to share is essential for seamless, integrated patient care and should be for both public and private providers.

> ***Sharing of information should be for the primary purpose of being in the patient's best interest. Further use of any specific data should be very carefully controlled. Sharing of data can avoid repetition of tests, reduce delays and improve efficiencies in the health service*** *(Healthcare Professional)*

It was also highlighted by respondents that there should be an opt-out to the duty to share where a patient does not wish his/her personal information to be shared.

> ***I would expect that a patient would have the right to find out who their information was shared with and they should also have the right to have the option to request that the information is not shared*** *(Patient/Member of the Public)*

A small number of respondents suggested a duty to share should be opt-in only.

> ***This should be opt-in, as with all other services that empower patients for what is patient data. I don't know anyone who would want their personal data shared without consent to share***
> *(Patient/Member of the Public)*

> ***Patients have the right to have their medical records confined to those in their care. The special relationship between GP and patient should be protected. Any sharing of information should be on an opt-in basis***
> *(Patient/Member of the Public)*

Legal Basis for processing of Personal Health Information for health research purposes

Eighty-one respondents (49%) commented on the proposal to establish a legal basis for the processing of personal health information for health research purposes.

Respondents suggested broad support for establishing a legal basis for the processing of personal health information for research.

> ***The conduct of scientific research is essential to improving patient outcomes. IPHA agrees with the principle of establishing a clear legal basis for the processing of personal health information for scientific research provided that the legislation does not restrict research (****(Irish Pharmaceutical Healthcare Association)*
>
> ***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*** *(Irish Platform for Patients, Science & Industry)*

It was suggested by some respondents that any legislation needs to define what is meant by explicit consent, health research and secondary use.

> ***Explicit consent needs to be defined – what is required for explicit consent, do you need to state what research or all research or some? Needs to be clear, concise and easy for patients to understand*** *(Office of the Chief Information Officer, HSE)*
>
> ***"Secondary use" needs definition & agreement. Surveillance is information for action so it a "Primary Use" of data*** *(Health Protection Surveillance Centre)*

Some respondents stressed the importance of any legal basis for processing health information for research purposes not creating any barriers to research.

> ***Policymakers must be aware of barriers when looking towards implementing any new regulatory regime for the processing of personal health information for health research purposes, and ascertaining whether new regulatory instruments would help to address these issues or prove to be a further complicating factor for researchers*** *(Microsoft Ireland)*
>
> ***This is a good proposal however it should not be made so complicated that it creates barriers to enabling research studies to be undertaken*** *(Clinical Strategy and Programmes Division, HSE)*

Some respondents suggested that the legal basis for research must be balanced between individual rights and the public interest.

> ***The patient's right to privacy should be paramount. Should be stated i.e. in consent how personal data are used if utilised for research*** *(Patient/Member of the Public)*
>
> ***It is important that the legal basis achieves a balance between individual rights and public good, is proportionate to the risks involved and enables research which can promote health and wellbeing and provide an evidence base for effective and efficient health service delivery*** *(Health Research Board)*

Feedback also stressed the need to balance consent opt-in/opt-out, offering alternative models of consent and promoting public trust in health research.

> ***The issue of consent is the key issue (to opt in or opt out). Consent works where patients/citizens trust the provider and there is legal certainty over the protection and use of health data. Opt-out is the ideal model, but only works where legal certainty exists and is understood by patients/citizens in all situations in the fragmented health system in Ireland*** *(Researcher)*

> ***Processing of personal health information for research purposes requires a comprehensive and refined consent model, allowing patients, or those acting on their behalf to make considered judgements about the specifics of what is being requested or acceded to. To make it more digestible and with a view to allowing a patient to make an informed decision knowing the impact of their decision on consent and the different options available to them*** *(Office of the Chief Information Officer, HSE)*

Legal Basis for Consent Exemption

Eighty-six respondents (52%) commented on the proposal to establish a legal basis for a 'consent exemption' for the use of identifiable health information for health research, in strict and limited circumstances.

There was broad support for the proposal to establish a consent exemption, but some respondents suggested that it required definition and scope and clarification on what constitutes 'strict and limited circumstances and how the exemption would work in practice.

> ***The strict and limited circumstances need to be set out clearly in the legislation so that no short cuts can be taken by individuals where they can hide behind legislation that is not clear*** *(Healthcare Professional)*

The legal basis around consent and the consent exemption must be robust enough to ensure that all those who wish to withhold consent are aware of their ability to do this and know how to register their objection. To ensure public confidence, the policy must clearly establish how the system will work in practice *(Irish Heart Foundation)*

Feedback also suggested that patients and families should be informed when a consent exemption is granted and be involved in developing protocols and criteria for granting a consent exemption.

There will be times when "consent exemption" is necessary however, we feel patients and families should be informed regardless if their information is being shared or used for research *(Clinical Strategy and Programmes Division, HSE)*

Identifiable patient data should only be used in research in very exceptional circumstances. Patients and their representative bodies and groups should be involved in a consultation process to draw up strict protocols around this, and develop a set of criteria for circumstances in which this might be permitted *(MS Ireland)*

Some respondents noted that details of consent exemptions and the process by which decisions were made should be transparent and publicly available.

A requirement to publish details of "consent exemption" cases should be included *(Patient/Member of the Public)*

Decisions on consent exemptions and the reasons for such decisions should be transparent and easily accessible by the public *(Medical Research Charities Group)*

A number of respondents expressed the view that that there should be a broader application of the consent exemption and that it could be considered for use for future research.

> ***The Consent Exemption mechanism is welcome along with its proposed safeguarding measures. However, it is extremely worrying that use of this mechanism is envisioned to operate only in 'strict and limited circumstances'. A rigid interpretation of the latter will without doubt be seriously harmful for health research*** *(Health Research Board)*
>
> ***Consideration should be given under this 'consent exemption' to alternatives for the requirement for consent for future studies that will be carried out on bio-banked samples*** *(Genomics Ireland)*

A small number of respondents (8 out of 86), mostly patients/members of the public, were not in favour of a consent exemption and would prefer consent as the only legal basis for processing personal information for health research.

> ***For research, there should not be a consent exemption*** *(Patient/Member of the Public)*
>
> ***I do not believe in exemption from consent under any circumstances. Implied consent, assisted decision making, and advance directives are the ethical alternatives in my opinion*** *(Patient/Member of the Public)*

Governance

Role of a National Data Advisor

Ninety respondents (54%) commented on the proposal to establish a national data advisor to ensure patient data is safeguarded and used appropriately. There was broad support for the role of a National Data Advisor for the Health Sector in the feedback received and many respondents noted it was a positive move and would enhance transparency, accountability and public trust.

> ***I think this role is required and important to maintain trust with Irish citizens*** *(Patient/Member of the Public)*

> ***The OOCIO regards the appointment of what will essentially be a 'Health Information Czar' as being an essential element of the future governance of health-related data. Having a 'one-stopshop' will allow for increased transparency and joining-up of the different data repositories that currently exist. This oversight is necessary in terms of separation of powers, as well as ensuring a rigorous culture of compliance and accountability*** *(Office of the Chief Information Officer, HSE)*

Some respondents emphasised the need to have clear terms of reference for the National Data Advisor and felt the role should be on a statutory footing as an independent and authoritative voice to safeguard patients' health data.

> ***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 Ireland. It 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***
> *(Irish Platform for Patients, Science & Industry)*

HIQA welcomes the consideration of the role of a national data advisor and an advisory committee on personal health data. However, it will be very important that these functions and associated governance structures are very clearly defined. These roles should be developed independently in order to allow for the provision of independent advice to the Minister for Health, particularly in sensitive areas such as the balance between the duty to protect patient privacy and confidentiality on the one hand, and the duty to share information on the other *(HIQA)*

Respondents also noted the need to distinguish how the role of the National Data Advisor will interact with the Data Protection Commissioner and other health entities and the importance of the role being independent to the Department of Health.

Need clear terms of reference, governance and resourcing structure for national data advisor to understand remit & potential overlap with Data Protection Commissioner. National data advisor should be independent of Department of Health
(Health Protection Surveillance Centre)

The ability to communicate clearly with the public on the issue is critical. Consideration should also be given to how a national data advisor would work with the Data Protection Commissioner
(Irish Medical Organisation)

Advisory Committee on Personal Health Data

Eighty-eight respondents (53%) commented on the proposal to establish an advisory committee to advise the Minister for Health on issues relating to the collection, use and disclosure of personal health data. There was broad support for the committee, but feedback emphasised the importance of clarification on its role and governance.

> ***The advisory committee is important in this area and will facilitate the evolution of personal health data to ensure it remains relevant to modern society. The central aim of the advisory committee should be for the greater public good and the good of patients"*** *(Healthcare Pricing Office, HSE)*

> ***HIQA welcomes the consideration of the role of an advisory committee on personal health data. However, it will be very important that these functions and associated governance structures are very clearly defined*** *(HIQA)*

Respondents indicated support for the committee having representation from patients and patient representatives/advocates and there were also suggestions that the committee consider membership from healthcare professionals, researchers, non-profit sector, regulatory bodies and data protection, with the required expertise.

> ***Patient representation is crucial*** *(Patient/Member of the Public)*

> ***If an advisory committee on personal health data is established, it is crucial that there is strong representation on it from patients/families and their representative bodies, and that their involvement is not 'tokenistic'. Expert representation on such a group should include members of the scientific research community as well as healthcare professionals*** *(MS Ireland)*

> ***A lay majority would be critical on this committee, with a mixture of experts on data management, clinical, patient advocacy, professional providers of services, regulator of services and representative of regulators of health and social care professionals*** *(CORU)*

Some respondents suggested that the committee should be independent or on a statutory footing and queried how the committee would interact with the National Data Advisor and other statutory bodies.

> ***Although sponsored by the Department of Health in England, the National Data Guardian operates independently, representing the interests of patients and the public. The National Data Guardian also appoints an independent group of experts – the NDG Panel – to advise and support this work. This could be replicated in Ireland*** *(Irish Hospital Consultants Association)*

> ***The proposed national data advisor and the advisory committee should be established on a statutory footing. Clarity should be provided as to how these established entities will interact with the HSE, eHealth Ireland, private hospitals, GPs, the Office of the Data Protection Commissioner (DPC) and HIQA*** *(HIQA)*

A small number of respondents (6 out of 88) queried the need for such a committee and suggested that the committee's role would be more appropriate as a substructure under the Data Protection Commissioner or the National Data Advisor.

> ***Not required. Use Data Commission structure***
>
> *(Patient/Member of the Public)*
>
> ***If there is a national advisor, then why a separate committee? Why not simply create a patient user committee with the data advisor?***
>
> *(National Rare Diseases Office)*

Establishing a Confidentiality Advisory Group to consider Consent Exemptions

Eighty-one respondents (49%) commented on the proposal to establish a confidentiality advisory committee of experts to consider consent exemptions for health research, in strict and limited circumstances. There was broad support from respondents for the Confidentiality Advisory Group, but some respondents highlighted the need for clear terms of reference, expertise and requiring the assessment process for an exemption be robust and transparent.

> ***Membership and governance of this group should also be clearly defined, document and available to the public. The decisions taken should be made public, with due regard to confidential nature of issues discussed*** *(Patient/Member of the Public)*

> ***The terms of reference would need to be clear about the objectives of promoting safe healthcare. Furthermore, what disciplines/areas will be represented on the expert committee which will be granting exemptions? Will this process be transparent? Shall explanations of decisions be provided for refusal of an exemption? Will there be a cost, and will it be prohibitive? This process requires further clarification*** *(Irish Medical Organisation)*

Some respondents also highlighted the need for balanced membership and representation for patients, digital rights and civil liberty groups on the advisory group in addition to healthcare professionals, researchers to enhance public trust.

> ***The makeup of such a confidentiality advisory committee is important. It should include representation from patient advocates, civil liberties and digital rights groups. If this advisory group is only made up of researchers, health care professionals and statisticians, then it will not be in a position to make balanced decisions that gain widespread public support*** *(National GP IT Group)*

> ***It is important that members of such committees represent relevant stakeholders including the general public, but it will be essential that they include experts in population data science, safeguarding technologies and processes*** *(Health Research Board)*

Some respondents suggested that the group should adhere to strict, transparent timelines and criteria.

> ***This group should work to strict, transparent timelines and criteria. The confidentiality advisory committee should have scheduled meeting dates and clear criteria for cut-off dates for submissions to this group. There should be a defined period for a final outcome (Irish Pharmaceutical Healthcare Association)***

> ***Good idea as long as there is access to the committee or representative for pre-submissions advice and discussion and that turnaround times for decisions are not lengthy (Information Officers Public Health Medicine, HSE North West)***

Respondents also queried how the confidentiality advisory group would interact with existing structures such as research ethics committees.

> ***This is essential, but consideration needs to be given as to how this committee would interact with existing Ethics Committees. There is potential for both overlap and conflict (Health Service Provider)***

> ***Clarity of how the committee coexists with existing research ethics committees, where considerable expertise already exists, is really important (Faculty of Public Health Medicine, Royal College of Physicians of Ireland)***

Operational Arrangements

Standardised Approach

Eighty-eight respondents (53%) commented on the proposal to progress a standardised approach to promote consistency across the health system to support information flows and eHealth. Most respondents supported a standardised approach and highlighted that it should be underpinned by robust governance and monitoring to promote consistency across the system.

Progress and consistency across the health system should be an ongoing process. Clear and robust governance structures for health information in Ireland, built on transparency and accountability and with patient safety at the core is a must (Patient/Member of the Public)

Having standardised and specified rules for collecting, processing, managing and sharing information in secure and confidential ways within the health service is key to our future eHealth strategy (Irish Hospital Consultants Association)

Standards may address matters relating to the privacy of data subject, confidentiality, quality assurance, security, storage, and destruction of such data. It is essential that the legislation underpinning the Health Information policy has appropriate checks and balances for proper regulation and control, thus ensuring public confidence in the process (HIQA)

Some respondents suggested the need to enhance digitalisation and interoperability of systems and investment in ICT infrastructure to support a standardised approach.

> ***It is crucially important to improve the current systems for information flow across healthcare services. As well as developing a standardised approach to this, there will also need to be a considerable investment in IT infrastructure to develop adequate eHealth systems (MS Ireland)***

> ***Old systems have no path to developing modern patient level interoperability methods without either costly upgrades or costly technology refresh. In lieu of this investment, standard interfaces should be defined to be ready for the next wave of technology (HSE Immunisation Office)***

It was also suggested that there were currently a large number of standards and it would be helpful to have a core set of standards while another respondent suggested a one-size fits all approach may require some prudence.

> ***The OoCIO has published a catalogue which provides an accessible overview of ehealth data standards, but as an overview it does contain a rather large number of ehealth data standards. It would be very useful if a shorter list of the core standards could be published (Office of the Chief Information Officer, HSE)***

> ***I would be very cautious of a "one size fits all approach" but standardised parameters would allow appropriate flexibility and promote consistency (Healthcare Professional)***

The implementation of the Individual Health Identifier (IHI) was also highlighted as a mechanism to support consistency in data flows with some respondents suggesting that it would be challenging to implement a standardised approach without an IHI.

> ***We need to have a unique patient identifier in order to have workable information platforms and data sharing and one standardised consistent national approach underpinned by a legal framework with national governance (National Cancer Control Programme, HSE)***
>
> ***Without solid foundations such as a robust Unique Health Identifier and interoperable platforms, we will be unlikely to achieve the above. (Healthcare Professional)***

Centralised Operational Arrangements for Health Information

Eighty respondents (48%) commented on the proposal to determine more centralised operational arrangements for health information. Respondents indicated broad support for a centralised approach to operational arrangements for health information to support an integrated approach to national information resources and to provide oversight, accountability, cost saving and reduce silos.

> ***Centralised operational arrangements are needed as the health service in Ireland is very fragmented. Need one body in charge of this and it needs the legal backing behind it (Healthcare Professional)***
>
> ***This would be a welcome move, again to ensure standardisation and consistency across the board. The proposed national organisation must ultimately promote integration; create ease of use for all, save time and money (Clinical Strategy and Programmes Division, HSE)***

Some respondents highlighted that a centralised approach could assist with data analytics, specialisation and a reduction in duplication of information. Other respondents highlighted their concern that centralisation could potentially bring delays or barriers to accessing information and could prove challenging for smaller organisations.

Developing more centralised operational arrangements for health information would undoubtedly be beneficial and reduce the number of data 'silos' in operation, which not only cause difficulties for research and monitoring but also cause problems for patients in the need to provide the same information multiple times (MS Ireland)

More centralised operational arrangements can assist with data analytics, specialisation and reduce duplication of effort. However, concerns regarding potential delays in and barriers to access would need to be addressed (Health Service Provider)

This is required, but there does need to be some level of localised flexibility. For example, acknowledging the burden on small organisation to progress within a centralise system – some support would need to be put in place (CORU)

Respondents also suggested that the 120 national data collections should be brought together on a single platform with accessible data and include the National Data Advisor and the Advisory Committee on Personal Data.

I think that those data collections should be brought onto a single platform with standardised and freely available metadata and application planning interfaces (where appropriate) (Patient/Member of the Public)

> ***There should be one centralised operational arrangement like the CSO but for Health (Health Service Provider)***

> ***I agree with a centralised operation and I think advisors and committees should be part of one centralised operation (Healthcare Pricing Office, HSE)***

Consolidated Approach for Data Warehousing for Health Research

Seventy-eight respondents (47%) commented on the proposal to the proposal to determine a consolidated approach for data warehousing of health information for health research and other health-related purposes. Most respondents were supportive of a consolidated approach but required further clarification on how it would work in practical terms.

> ***This would appear to be a positive step, but the practicalities would need to be ironed out. How this would work in practice would need to be made clear, retention times, security measures etc would need to be clearly outlined from the outset (Medical Council)***

> ***I think this would be a great idea. I would like there to be transparency on where the data is stored, who the vendor will be, where the back-up will be, what security measures are in place etc. (Genomics Ireland)***

Respondents also suggested that the Department consider adopting a model similar to those currently operating in Canada and the UK or the Data Access, Sharing, Storage and Linkage (DASSL) model proposed by the Health Research Board.

Strongly agree with the proposal to consolidate data in an anonymised data warehouse, the Canadian model (CIHI) is extremely robust and public confidence has grown over time in how it is governed (HSE National Immunisation Office)

I think this has merit in bringing the various data sources together for overall usage. The UK have moved towards this approach with the Farr Institute. Canada also have developed this methodology. I think that a similar mechanism could be developed in Ireland (Researcher)

Data warehousing of health information is done very well in the UK, including Northern Ireland. The Administrative Data Research Centre Northern Ireland works together with the centres in Scotland, England, Wales and the Administrative Data Service, to help researchers get access to de-identified, linked administrative data, while making sure the data remains safe and everyone's privacy is protected (Irish Medical Organisation)

Feedback from respondents also stressed the importance of transparency, data security, accessibility, consent and privacy considerations in any consolidated approach.

> ***Consent is a huge issue here. Security and access are also major issues. Issues like cost, management, data mining, etc. need to be fully considered and costed before this is even considered***
> ***(Office of the Chief Information Officer, HSE)***

> ***I would carefully look at how such a system was designed and delivered. I would have grave concerns on the security of such a system and would also be concerned about the ability of a data subject to access their personal information***
> ***(Patient/Member of the Public)***

> ***A consolidated approach for data warehousing should not supersede the rights of service users have full transparency in how their personal health information is processed***
> ***(St. Patrick's Mental Health Services)***

Patient and Professional Awareness

Awareness of the public health value of health information

Eighty-three respondents (50%) commented on the proposal to raise awareness of the public health value of health information. Respondents indicated support for proposals to promote transparency on the use of health information and enhance public trust and patient engagement.

The public are aware of the power of data and information and should be encouraged to use their own health data to take more direct control of their own health (Patient/Member of the Public)

It is important to recognise the existence of the 'language barriers' that exist in relation to health information and to take steps to minimise those barriers. Phrases such as 'health information architecture', 'data modelling', 'secondary uses' etc. make it difficult for most of the population to truly engage in conversations around health information (Medical Research Charities Group)

It is essential that there is transparency around why personal health data may be shared, and the potential benefits of sharing such information, without putting pressure on data subjects to share their personal health data unless they so wish (Medical Council)

Measures to Raise Awareness of the Benefits for the Public of Using and Sharing Health Information

Seventy-nine respondents (47%) commented on the proposal to raise awareness of the public health value of health information. Respondents suggested awareness could be enhanced by targeted media and educational campaigns and at GP/hospital level through direct patient engagement and patient advocacy groups.

Schools – special SPHE module (could be developed and rolled out quickly with the cooperation of the Department of Education). Internet, face book, YouTube, etc. will hit the teens to thirties. TV and Radio advertising for older people *(Office of the Chief Information Officer, HSE)*

Publicly available leaflets and other materials provided in digital and paper formats and are made available through numerous sources such as libraries, GP practices and also in all HSE sites and public offices, ensuring that all staff and the public are aware of the benefits, who their data is shared with and why, and how it is stored *(National Immunisation Office, HSE)*

More information on this being made available to patients each time they are engaging with service providers about their services and care. Patient advocacy organisations might come on board as well as patient groups and panels
(Clinical Strategy & Programmes Division, HSE)

Other suggestions included awareness raising using citizen juries or existing patient forums, having accessible information for patients and highlighting good practice in the health service where health information has been shared to benefit diagnosis and care.

> ***Think about accessibility for people with disabilities or illiterate groups. Use existing forums such as IPPOSI and make sure adequately resourced*** *(Patient/Member of the Public)*
>
> ***Worked through examples of where data use and sharing provides better health services including the safety and quality of the treatment and care that they receive. Transparency will inform discussion about sharing*** *(Irish EUROCAT Congenital Anomaly Registry)*
>
> ***The benefits should be provided in a way that directly relates to patients not in a way that shows benefits for the system*** *(Educator)*

Other Comments

Seventy-three respondents (44%) made additional comments to the 18 core consultation questions. The comments ranged from highlighting the positive steps taken by the Department of Health in holding the consulation process on health information policy to suggestions for training and guidance and the need to communicate the impact of the final policy.

> ***Plan stragically and flexibly. Build systems that can evolve into the future. Invest in internal expertise. And good luck!***
> *(Patient/Member of the Public)*

> ***A National Health Information Policy is necessary and the Department of Health is to be congratulated for undertaking this consultation process. When the policy has been developed it will be essential that it is communicated (via many different methods and media)*** *(Office of the Chief Information Officer, HSE)*

> ***Very exciting times ahead. I am delighted to have this public consultation opportunity and look forward to being in the workforce during the implementation of the Health Information Policy Framework and the digitalisation of healthcare in Ireland***
> *(Healthcare Professional)*

> ***Staff and health service providers will require comprehensive training and ongoing support to ensure there is a clear understanding of the policy and where it fits with all relevant legislative requirements*** *(Health Protection Surveillance Centre)*

Summary

Feedback from the public consulation indicated broad support for the the core principles and the draft policy proposals under the four policy pillars. There were a number of key recommendations highlighted by respondents which include:

- Placing the patient on an equal footing when considering any policy proposals
- Transparency in the health service on how how personal health information is collected, used and shared for primary, secondary and research purposes is key
- Engaging directly with patients and staff in the health service on how personal health information is collected, used and shared at the local level and through national media and education campaigns
- Including patients and individuals with the relevant expertise on any committees.
- Building trust in how personal health information is processed through transparency, direct engagement with patients, staff and researchers and through the use of Plain English to normalise discussions around personal health information
- Balancing individual privacy rights with the need to share personal health data for healthcare, health services management and research purposes.
- Clarity of legislation is welcome but requires clear definitions of how personal data is processed for primary, secondary and research purposes
- Ensuring there is transparency, governance and accountability for all policy measures and where appropriate, such measures should be on a statutory or independent footing
- Clarity on how draft policy proposals in the area of Governance and Operational Arrangements will interact with the Data Protection Commission and other statutory health bodies such as the HSE and HIQA.
- Future-proofing any legislation, standards and infrastructure to support policy proposals and the eHealth agenda.

Appendix 1: List of organisations that made submissions

Below is a list of the 42 organisations that made submissions to the public consultation. There were 125 submissions made in an individual capacity by patients/members of the public, healthcare professionals, health service providers, researchers and others.

Cancer Trials Ireland

COPE Galway

Coroners Society of Ireland

CORU

Cystic Fibrosis Ireland

Faculty of Public Health Medicine, Royal College of Physicians in Ireland

Genomics Ireland

GS1

Health Information and Quality Authority (HIQA)

Health Products Regulatory Authority (HPRA)

Health Research Board (HRB)

HSE- Office of the CIO (IHI Project and Enterprise Architecture / Design Authority)

HSE -National Screening Services; Health Intelligence; National Clinical Advisor for Health and Wellbeing

HSE- Public Health

HSE- Health Protection Surveillance Centre

HSE- National Immunisation Office

HSE - National Cancer Control Programme

HSE- National HR

HSE- Healthcare Pricing Office

HSE- Office of Nursing & Midwifery

HSE- North West Information Officers Public Health Medicine

HSE-South Department of Public Health

HSE-Mid West Department of Public Health

Huntington's Disease Association of Ireland

Irish Cancer Society

Irish Centre for High End Computing (ICHEC)

Irish EUROCAT Congenital Anomaly Registry

Irish Heart Foundation

Irish Hospital Consultants Association

Irish Medical Organisation

Irish Pharmaceutical Healthcare Association (IPHA)

Irish Platform for Patients, Science and Industry (IPPOSI)

Microsoft Ireland

Medical Council

Medical Research Charities Group

Mental Health Commission

MS Ireland

National Disability Authority

National General Practice Information Technology (GPIT) Group

National Rare Diseases Office

Neurological Alliance of Ireland

St Patrick's Mental Health Service

Appendix 2- Copy of the Consultation Document

Consultation on the Draft Health Information Policy Framework - Your Opinion Matters

This public consultation is being carried out to help the Department of Health to develop a national health information policy. The purpose of this consultation is to seek your views on the proposals to inform the drafting of a national health information policy in 2018.

We would like to find out what people think about how personal health information is collected, used and shared in our health services – what is working well and what needs to be improved. We would also like to hear the public's views on what future health information policy should look like and are particularly keen to hear from patients, healthcare professionals, health service providers and health researchers. However, everyone with an interest, including regulators, advocacy groups and representative organisations is welcome to participate.

This consultation is focused on the processing of personal health information in healthcare and health-related settings.

Closing date

The consultation process will run for a period of 6 weeks and the closing date for submitting your views is close of business on **Wednesday 15th November 2017**.

Data Protection and Privacy Provisions

The information shared by you in this consultation will be used solely for the purposes of policy development and handled in accordance with data protection legislation. An analysis of submissions received as part of the public consultation will be published online which will include a list of organisations and representative bodies that responded. Comments submitted by individuals may be used in the final consultation report, but these will be anonymised. All personal data is securely stored and subject to data protection laws and policies. For more information, see http://health.gov.ie/data-protection/. Please note that submissions received by the Department are subject to the Freedom of Information (FOI) Act 2014 and may be released in response to an FOI request. All submissions received will be subject to the Freedom of Information Act (2014). By responding to the consultation, you acknowledge that you are aware that your responses may be released in response to a Freedom of Information request.

Structure of this Consultation Questionnaire

There are four sections in this paper:

Section 1 gives some background to health information in Ireland and internationally

Section 2 asks for some details about you

Section 3 outlines the core principles for processing personal health information in healthcare and health-related settings and seeks your views on the proposed principles.

Section 4 outlines the policy pillars underpinning the draft framework and seeks your views on the proposed pillars.

If you would like a paper copy of the consultation form sent to you or you have any questions about the document, please contact the Department of Health at:

Health Information Policy Framework Consultation

Room 7.24

Department of Health

Hawkins House

Hawkins Street

Dublin 2, D02 VW90

Phone: (01) 6354706

1.0 Introduction

Millions of patients engage with the health service each year. The availability and analysis of health information can add significant value to patient care, health service planning and performance, health service delivery based on need and health research to discover innovations in healthcare delivery and care.

Patients share their personal health information with health services on a continuous basis at each step of their care pathway, beginning on the day of diagnosis and continuing through treatment and self-management. Ensuring access to the right information, at the right place, at the right time can lead to more effective decision-making on the part of healthcare professionals, which in turn supports patient safety and better outcomes for patients. Patients can also be empowered to be more informed and involved in their care by having access to their own health information which will support self-management of aspects of their care such as access to appointment booking systems, test results, immunization records or medication summaries.

Secondary uses of health data for the management of health services and health research are essential for high quality, safe, effective and equitable health services. Sharing information between health professionals or for health research can also help to build knowledge on health conditions, symptoms, prognosis and treatment for patients or for reviewing and improving the quality of care provided and planning efficient health services.

However, there is a need to strike an appropriate balance between using and sharing personal health information appropriately while continuing to protect a person's right to privacy and confidentiality. Patients must be assured that their personal health information is handled legally, securely, efficiently and effectively to deliver the best possible care.

The purpose of this draft consultation questionnaire is to set out the core principles and policy pillars required to provide overall direction to how health information is processed in healthcare and health-related settings (including research).

The draft framework, when finalised, will also support patients, health service providers, healthcare professionals and researchers to have absolute clarity on how personal health information should be protected, collected, used, and shared to benefit patient safety, quality of care and public health.

1.1 What is personal health information?

The EU General Data Protection Regulation (GDPR) defines *personal data concerning health* as all data concerning the health status of a living individual which reveal information relating to their past, current or future physical or mental health status.[5] This includes information about a person collected in the course of diagnosis/treatment or care by a health service or any number, symbol or particular assigned to a person to uniquely identify that person for health purposes. Health data can be identifiable[6] and non-identifiable (pseudonymised[7], anonymised[8] or aggregated[9]).

Identifiable health information is primarily used for the purposes of providing care or treatment and only the necessary amount of data should be collected for the required purpose. Where possible, non-identifiable health information should be used for all secondary purposes such as health service planning and performance, clinical audit, health research, health statistics. Where identifiable information is required for a secondary purpose other than direct patient care or the management of health services, explicit consent must be sought, unless a legal exemption applies.

1.2 Health information policies internationally

Evidence from other countries suggests that having a clear policy underpinning how health information is protected, used, managed and shared leads to a better health information environment.[10]

[5] REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation).
[6] Identifiable health information is any data that can be used to identify the individual person, either directly or indirectly, such as an identification number or factors specific to his/her physical, physiological, mental, economic, cultural or social identity.
[7] Pseudonymised data is where identifiable data is processed in such a manner that the identifiable data can no longer be attributed to a specific individual without the use of additional information.

[8] Anonymised data is where identifiable data is processed to remove all identifying elements to ensure that identification is not likely to take place. The GDPR applies to the process of anonymisation but not the anonymised data.
[9] Aggregated health information refers to the processing of combined identifiable information to high-level data where no individual is identifiable.
[10] Craig, S. *Health Information in Ireland: A Socio-technical Analysis*. Paper delivered at the Annual Garret Fitzgerald Lecture and Autumn School: The significance of Social Sciences for 21st Century Ireland, 19/10/2015.

The OECD, the European Union and the World Health Organisation have emphasised the importance of leveraging national policy in the area of health information.[11] [12] [13] [14]

They identified how health information can benefit countries and their populations through:

- maximising the potential value for patients and public health of routinely collected health information
- increased knowledge, empowerment and inclusiveness through more collaborative and informed decision making between patients and clinicians
- more transparency around how health information is used and shared
- a clear legislative framework for processing health information
- robust information governance and oversight arrangements
- having a central authority to house databases to support data access and research
- a standardised approach to health information management and infrastructure design to support interoperability and information sharing
- more integrated care through connected health mechanisms
- enhanced training and skills development in health informatics
- seeking consent or providing a safe alternative through de-identification.

In comparison to other countries, progress in relation to health information in Ireland is advancing but has been slow due to delays with legislation and the development of the necessary infrastructure. Recent developments in eHealth and increased investment in health ICT represent a renewed focus on health information policy and the development of this framework will support better information for more efficient planning and delivery of health services.

1.3 Why do we need a health information policy?

Recent changes in healthcare reform, the advent of eHealth and the requirement to underpin these developments with a clear legislative framework and policy proposals requires a robust health information policy to be able to respond to advancing future healthcare demand and modern health service delivery.

[11] OECD*. Recommendation of the OECD Council on Data Governance-The Next Generation of Health Reforms*. OECD Health Ministerial Meeting, Paris, 17 January 2017.
[12] [12] OECD. Strengthening Health Information Infrastructure for Health Care Quality Governance: Good Practices, New Opportunities and Data Privacy Protection Challenges. 2013.
[13] EU Task Force on eHealth. *Redesigning health in Europe for 2020.* 2012.
[14] World Health Organisation. *Health 2020. A European policy framework and strategy for the 21st century*. 2013

The publication of the National Health Information Strategy (NHIS) in 2004 emphasised the potential of health information to drive improvements in healthcare delivery for patients and population health.[15] Some of the potential benefits to the health system of the efficient and effective use of health information include:

- enhanced integration of care for patients and improvements in patient safety
- improved information flows between private and public health services
- improved service planning and design to meet population need
- more efficient and effective working, thus saving time and cost
- more effective responses to major public health issues.

Since the publication of the NHIS in 2004, the care delivery model, health information and eHealth have advanced in Ireland and we have seen changes including the:

- reform of health structures including the establishment of the HSE
- establishment of HIQA
- advancement in digital technology and the digital economy including the 'Internet of Things' (IoT), big data and analytics
- publication of an *eHealth Strategy for Ireland*[16]
- establishment of the Office of the Chief Information Officer in the HSE
- commencement of parts of the Health Identifiers Act 2014[17]
- publication of the *General Scheme of the Health Information and Patient Safety Bill*[18]
- publication of the *eHealth Ireland Knowledge and Information Plan*[19]
- publication of the *European Union General Data Protection Regulation*[20] .

The healthcare landscape in Ireland is also changing radically as a result of various demographic, organisational and resourcing factors and the evolution of technology. These factors mean that future healthcare systems will need to be radically different in order to respond efficiently and equitably to forecasted demand. Demographic changes resulting mainly from an ageing population have been projected to add significantly to our health care

[15] Department of Health. *Health Information: A National Strategy*. 2004.
[16] Department of Health. eHealth strategy for Ireland. Department of Health; Dublin: 2013.
[17] Health Identifiers Act, 2014. Stationery Office.
[18] Department of Health. *General Scheme of the Health Information and Patient Safety Bill*. 2015.
[19] Health Service Executive. *eHealth Ireland Knowledge and Information Plan.* 2015
[20] REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

costs while other costs will arise from expected rises in chronic disease rates as well as increasing demand and complexity of healthcare services.[21]

Health information and eHealth have been identified as critical enablers for future healthcare reform, as outlined in the Oireachtas Committee on Future Health's *SlainteCare Report*.[22] The Committee recommends future healthcare delivery is focused on integrated care, using integrated patient information (via information sharing and eHealth mechanisms) to deliver the universal, high quality health service envisaged in the report.

Since the publication of the NHIS in 2004, a number of areas requiring legislative and policy development have been identified including establishing:

- robust governance arrangements for health information[23] [24] [25]
- a clear legal basis for processing personal health information[26] [27]
- enhanced transparency and patient and professional awareness around how health information is collected, used and shared [28] [29] [30] [31]
- centralised operational arrangements for health information resources [32] [33] [34]
- standards and guidance to reduce variability in practice and make data more accessible. [35] [36]

[21]Department of Health. Health in Ireland: Key Trends in 2016.
[22] Oireachtas Committee on Future Health. *Sláintecare Report*. 2017.

[23] Health Information and Quality Authority. *International Review of Information Governance Structures*. 2009.
[24] Health Information and Quality Authority. *As-is Analysis of Information Governance in Health and Social Care Setting in Ireland*. 2010
[25] OECD*. Recommendation of the OECD Council on Data Governance-The Next Generation of Health Reforms*. OECD Health Ministerial Meeting, Paris, 17 January 2017.
[26] REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).
[27] Oireachtas Joint Committee on Health. Report on the Pre-Legislative Scrutiny of the Health Information and Patient Safety Bill. 2017.
[28] OECD*. Recommendation of the OECD Council on Data Governance-The Next Generation of Health Reforms*. OECD Health Ministerial Meeting, Paris, 17 January 2017.
[29] Whiddet R, Hunter I, Engelbrecht J, Handy J. (2016) Patients' attitudes towards sharing their health information. *International Journal of Medical Informatics*. 75(7):530-541.
[30] Aitken M., de St. Jorre J., Pagliari C., Jepsom R. & Cunningham-Burley S. Public responses to the sharing and linkage of health data for research purposes: a systematic review and thematic synthesis of qualitative studies. *BMC Medical Ethics*. 17: 73.2016.
[31] National Data Guardian for Health and Care. *Review of Data Security, Consent and Opt-Out.* 2016.
[32] Health Information and Quality Authority. *Catalogue of National Health and Social Care Data Collections in Ireland*. 2014.
[33] OECD. Strengthening Health Information Infrastructure for Health Care Quality Governance: Good Practices, New Opportunities and Data Privacy Protection Challenges. 2013.
[34] Health Information and Quality Authority. *Recommendations for a more integrated approach to national health and social care data collections*. 2014
[35] Health Information and Quality Authority. *Information management standards for national health and social care data collections*. 2017.
[36] EU Task Force on eHealth. *Redesigning health in Europe for 2020.* 2012.

The forthcoming implementation of the European Union General Data Protection Regulation on 25 May 2018 will also place a higher level of scrutiny, transparency and accountability for how personal health information is processed and will empower citizens to monitor how their personal health information is being used.

Having a clear statement of health information policy provides the opportunity to deliver legislative clarity on how personal health information should be legally, securely, efficiently and effectively processed to improve patient safety, quality of care and public health and will also facilitate the implementation of robust policy proposals to underpin future developments in eHealth and health service reform.

1.4 Scope of the Draft Policy Framework

This draft policy framework has been developed to support a consultative process and stakeholder engagement in 2017, which will be followed by finalisation of the national health information policy in 2018.

The scope of the framework is to ensure that health information used for the safe and effective treatment of patients, the planning and monitoring of health services and the potential for supporting health research is processed on sound information principles, has legal clarity and patients, health service providers, healthcare professionals and researchers clearly understand how health information should be collected, used and shared.

The policy framework is supportive of and complementary to other health policy goals, service improvements and the enablement of eHealth and integrated care through the appropriate collection, use and sharing of health information.

1.5 Vision for the Policy Framework

Our vision for this policy framework is a person-centred approach to the processing of health information in all healthcare settings according to core principles and where information is appropriately collected, used and shared to support the right *information* being available for the right *patient* in the right *place* at the right *time*.

2.0 Details about you

Questions

1. Name

2. Gender

- Male
- Female
- Other (Specify if desired)

3. Age (Optional)

- 18-35
- 36-55
- 56-75
- 75+

4. County of Residence (Optional) – drop down menu

5. Are you responding as a... (Click all that apply)

- Patient/member of the public
- Health service provider
- Healthcare professional
- Researcher
- Other (please specify)

3.0 Core Principles for Processing Personal Health Data

The following core principles should be applied by health service providers, healthcare professionals and researchers to enable a consistent approach to the processing of personal health information for primary, secondary and research purposes. These principles have been derived from principles for processing personal health information highlighted by the current Data Protection Acts[37], the National Data Guardian in the UK[38] and the GDPR[39] and include:

1. Lawfulness

Personal health information must be lawfully and fairly processed in all settings. Key legislative areas currently governing the processing of personal health information include European and national data protection and human rights law, the Constitution of Ireland, common law principles, freedom of information legislation and professional or regulatory codes. From 25 May 2018, the processing of data concerning health, as outlined in the GDPR, will apply in all Member States.

2. Transparency

Individuals and organisations are open and transparent as to their policies and procedures for processing personal health information, communicating such information publicly in an accessible format. Applying the transparency principle means that individuals and organisations processing personal health information clearly demonstrate how they collect, use and share information, supporting public trust in how personal health data is being collected, used and shared in the interests of patient safety, quality of care and public health.

3. Accountability

Individuals or organisations who process personal health information are accountable for the information they hold, and this requires that they have comprehensive procedures in place to ensure the processing is legal and adheres to technical and organisation measures to protect individual privacy and confidentiality, such as privacy impact assessments and privacy by design.

[37] Data Protection Acts, 1988 & 2003. Stationery Office.

[38] National Data Guardian. *Information: To share or not to share? The Information Governance Review*. Department of Health UK. 2013.

[39] REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data,and repealing Directive 95/46/EC (General Data Protection Regulation).

4. Duty to Share

The concept of a 'duty to share' personal health information is a statutory affirmation of existing best practice. For a health services provider to act in a patient's best interest, they need to be able to share health information to enable patient safety, high quality care and treatment and the effective management of health services. The National Data Guardian in the UK as part of its review on information governance recommended that that the duty to share personal health information is as important as the duty to protect patient confidentiality. Where patients expressly indicate that they do not wish their personal information to be shared, their wishes are respected. Non-identifiable health information should also be shared for important secondary purposes such as health service management or performance or health statistics.

5. Consent for research

Explicit consent must be sought from patients to use or share identifiable health information for research purposes, unless a legal exemption applies. Seeking explicit consent is central to the conduct of ethical research and potential research participants should be provided with all the information they need to help them to decide whether they wish to take part in a research study or not.

6. Access

Individuals and organisations processing personal health information should provide access to health information for those who require it, having regard to legal requirements, privacy, confidentiality and the public interest.

Patients should be empowered to access their own health information to understand their health conditions, make informed choices and to participate in decision making regarding their care. Access to health information should also be provided legally and securely to health service providers and regulators to support decision making and statutory obligations.

7. Data Security

Implementing data security measures is a critical component of processing personal health information and can prevent the misuse or inappropriate sharing of personal information. Without effective security measures, health information may become unreliable or may not be accessible in the right place at the time it is needed. Patients must be assured that individuals and organisations processing their personal health information have robust measures and procedures in place to assure data security and data quality.

8. Data Minimisation

When processing personal health information, individuals and organisations should only seek and retain the minimum amount of personal data needed to achieve the relevant purpose. Health service providers should not require patients to provide any additional personal information that is not necessary for the provision of care/treatment while health researchers should use de-identifiable health information, where possible, unless it is critical that identifiable health information is required for a research study, in which case explicit consent must be sought.

9. Data Quality

Quality health information is essential for monitoring health and for evaluating and improving the delivery of health services. Poor information quality can lead to errors in diagnosis, care and treatment, puts patient safety at risk as well as contributing to skewed analysis and reporting of health data. Individuals or organisations that collect and process personal health information should have a data quality statement which outlines in detail how data quality is being addressed.

10. Privacy by Design

Privacy by design requires individuals and organisations that process personal health information to consider the impact of processing on patient privacy and confidentiality. Individuals and organisations processing personal health information should consistently take steps to enhance and protect patient privacy and confidentiality, in advance of collecting personal health information, for example, by conducting privacy impact assessments. Non-identifiable information should be used for purposes other than direct care unless a legal exemption applies.

Questions

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

Section 3: Policy Pillars

In addition to the core principles for processing personal health information, the draft policy framework is underpinned by four policy pillars:

- Legislation
- Governance
- Operational Arrangements
- Patient and Professional Awareness.

A programme of work will be developed under each of the four pillars, following feedback from this consultation. Some of the key proposals under consideration are described in the sections that follow.

Legislation

The EU GDPR will become effective in Member States on 25 May 2018 and there is a requirement for Ireland to establish a clear legal basis for the processing of personal health information for primary, secondary and research purposes. The legal framework, when established, will enable patients, health service providers, healthcare professionals and researchers to have legal clarity on the processing of personal health information and information sharing. It will also support the implementation of improved governance and operational arrangements for health information.

Key proposals under consideration under the pillar of legislation are:

- To establish a clear legal basis for the processing of personal health information, in line with the requirements of the GDPR, for the purposes of:
    i. preventive or occupational medicine,
    ii. medical diagnosis,
    iii. provision of health or social care or treatment,
    iv. management of health and social care systems and services,
    v. public interest reasons in the area of public health.
- To establish a clear legal basis for a ‘duty to share’ personal health information among healthcare providers, in the interests of patient safety, high quality care and treatment and the effective management of health services, for the following purposes:
    i. preventive or occupational medicine,
    ii. medical diagnosis,
    iii. provision of health or social care or treatment,

iv. management of health and social care systems and services, including the regulation of such systems and services and the regulated professionals providing such services,
v. public interest reasons in the area of public health, and
vi. where the patient requests his or her information to be shared for his or her care and treatment.

- To establish a clear legal basis for the processing of personal health information for scientific research (to include health research), statistics and archival purposes.
- 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.

Questions

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

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?

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?

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?

Governance

Countries such as Canada, Australia, the UK and New Zealand have established governance structures in place for health information which provide oversight and monitoring arrangements for how services collect, use and share personal health information. Ireland is currently characterised by information silos and fragmented governance arrangements which highlights the need to establish clear and robust governance structures for health information in Ireland, built on transparency and accountability and with patient safety at the core.

Governance of health information also requires the use of standards and guidance to support interoperability of health information systems. The health service holds huge amounts of information in multiple locations and where there is a requirement for information to be searched, shared, or linked for patient safety or public health reasons, there needs to be a

common platform in place ensure information flows efficiently and effectively for the ultimate benefit of patients.

Key proposals under consideration under the pillar of governance are to:

- Evaluate the role of a national data advisor to advise and challenge the health system to ensure patient data is safeguarded and used appropriately
- Evaluate the role of an advisory committee on personal health data, with expert and patient representation, to advise the Minister for Health on matters relating to the processing of personal health information for the provision of health services.
- Evaluate the role of a confidentiality advisory committee (a sub-group of the advisory committee on personal health data) to consider consent exemptions for the use of identifiable patient data for health research, in strict and limited circumstances.
- Progress a standardised approach to health information exchange, data modelling, coding, health information architecture, data security, data matching, interoperability to promote consistency across the health system to support information flows and eHealth.

Questions

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

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

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?

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?

Operational arrangements

Centralising responsibility for health information resources has been shown to enhance data access and data quality, according to the OECD.[40] A more centralised approach to the operational arrangements for health information in Ireland was recommended by HIQA to support an integrated approach to national health and social care information resources.[41]

[40] OECD. *Strengthening Health Information Infrastructure for Health Care Quality Governance: Good Practices, New Opportunities and Data Privacy Protection Challenges*. OECD Health Policy Studies; OECD Publishing: 2013

[41] Health Information and Quality Authority. *Recommendations for a more integrated approach to national health and social care data collections*. Health Information and Quality Authority; Dublin: 2014.

This includes assigning accountability and oversight for all national health and social care data collections to a specific organisation at a national level.

The Health Research Board also identified the need for a secure environment for data access and linkage for health research, to harness the public value of our health information resources.[42] The establishment of more streamlined operational arrangements can facilitate health information to be used more effectively and efficiently within and between health services and for health research. It could also reduce operational costs and minimize the information silos that currently exist. These arrangements would be underpinned by a clear legal framework and robust governance structures.

Key proposals for consideration under the pillar of operational arrangements are to:

- Determine the optimal oversight arrangements for the 120 national health and social care data collections, following a review of current resources.
- Determine a consolidated approach for data warehousing of health information for health research and other health-related purposes via a secure environment with access and linkage capacity.

Questions

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

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?

Patient and Professional Awareness

Individuals and organisations processing personal health information should have a clear understanding of the public health value of health information, what purposes it can be used for and what the benefits are for sharing information. There is an onus on healthcare providers to communicate this knowledge with patients, healthcare professionals and researchers, in a clear and transparent manner, through awareness raising activities. Thus, supporting a dialogue between patients, healthcare providers, healthcare professionals, researchers, and policy makers on what constitutes the appropriate use and secure sharing of health information so that health information may be used and shared to benefit patient safety, quality of care and public health.

[42] Health Research Board. Proposals for an Enabling Data Environment for Health and Related Research in Ireland. 2016.

Key proposals under consideration under the pillar of education and awareness are to:

- Engage with patients, health service providers, healthcare professionals, researchers and other relevant stakeholders on their views in relation to the development of health information policy, as part of a public consultation process
- Promote patient empowerment by ensuring that health service providers develop transparency mechanisms in all aspects of information processing
- Work with other Departments and Statutory bodies to promote health information policy and the impact of GDPR on health data
- Work with healthcare providers, healthcare professionals and researchers to promote awareness/training on additional responsibilities for health data under GDPR and the core principles to be applied when processing health information.

Questions

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?

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

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