Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Summary of Stakeholder Involvement: Key considerations to inform policy for health information in Ireland

2022

About the Health Information and Quality Authority (HIQA)

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services —** Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the Health Service Executive (HSE).

Overview of the health information function of HIQA

Health is information-intensive, generating huge volumes of data every day. Health and social care workers spend a significant amount of their time handling information, collecting it, looking for it and storing it. It is, therefore, very important that information is managed in the most effective way possible in order to ensure a high-quality safe service.

Safe, reliable healthcare depends on access to, and the use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. For example, when giving a patient a drug, a nurse needs to be sure that they are administering the appropriate dose of the correct drug to the right patient and that the patient is not allergic to it. Similarly, lack of up-to-date information can lead to the unnecessary duplication of tests — if critical diagnostic results are missing or overlooked, tests have to be repeated unnecessarily and, at best, appropriate treatment is delayed or at worst not given.

In addition, health information has an important role to play in healthcare planning decisions — where to locate a new service, whether or not to introduce a new national screening programme and decisions on best value for money in health and social care provision.

Under Section (8)(1)(k) of the Health Act 2007,[(1)] the Health Information and Quality Authority (HIQA) has responsibility for setting standards for all aspects of health information and monitoring compliance with those standards. In addition, under Section 8(1)(j), HIQA is charged with evaluating the quality of the information available on health and social care and making recommendations in relation to improving its quality and filling in gaps where information is needed but is not currently available.

Information and communications technology (ICT) has a critical role to play in ensuring that information to promote quality and safety in health and social care settings is available when and where it is required. For example, it can generate alerts in the event that a patient is prescribed medication to which they are allergic. Furthermore, it can support a much faster, more reliable and safer referral system between the patient's general practitioner (GP) and hospitals.

Although there are a number of examples of good practice, the current ICT infrastructure in health and social care services in Ireland is highly fragmented with major gaps and silos of information. This results in individuals being asked to provide the same information on multiple occasions.

In Ireland, information can be lost, documentation is poor, and there is an overreliance on memory. Equally, those responsible for planning our services

experience great difficulty in bringing together information in order to make informed decisions. Variability in practice leads to variability in outcomes and cost of care. Furthermore, we are all being encouraged to take more responsibility for our own health and wellbeing, yet it can be very difficult to find consistent, understandable and trustworthy information on which to base our decisions.

As a result of these deficiencies, there is a clear and pressing need to develop a coherent and integrated approach to health information, based on standards and international best practice. A robust health information environment will allow all stakeholders — patients and people using services, health professionals, policy-makers and the general public — to make choices or decisions based on the best available information. This is a fundamental requirement for a highly reliable healthcare system.

Through its health information function, HIQA is addressing these issues and working to ensure that high-quality health information is available to support the delivery, planning and monitoring of services.

Table of contents

1. Introduction

This report sets out a summary of stakeholder involvement in the development of key considerations to inform policy for the collection, use and sharing of health information in Ireland. Between November 2021 and January 2022, the Health Information and Quality Authority (HIQA) conducted a public consultation to gather stakeholders' views on draft recommendations on the collection, use and sharing of health information.

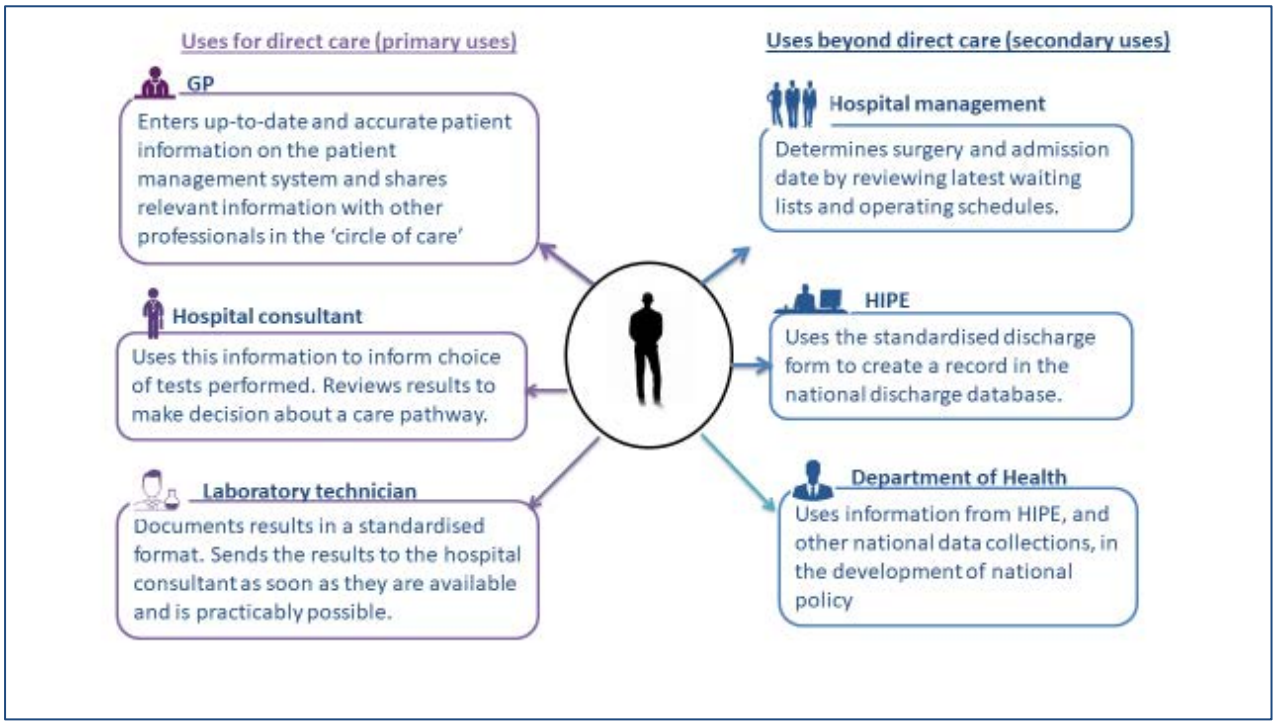
For the remainder of this document:

Health information will be used to describe health and social care information.

The basis for a safe, effective and efficient health and social care service is the appropriate collection, use and sharing of health information. The processing of health information is therefore an integral part of health and social care provision. It is essential for managing direct care where information is often shared between health and social care professionals to inform care provision. In this document, this is referred to as the 'use of information for direct care'. Health information can also be used for additional purposes, such as health and social care service planning and management, quality improvement, policy-making and research.[2] In this document, this is referred to as the 'use of information for beyond direct care'. Figure 1 provides some examples of the different uses of health information.

Note: different terms can be used for the uses of health information. Often, the use of information for direct care can be referred to as the '**primary use'** of information and the use of information for reasons beyond direct care can be referred to as the '**secondary use'** of information. Examples are shown in Figure 1 below.

Figure 1: Examples of uses of health information*



Improved sharing of health information can ensure a more efficient health service by providing information when, and where, needed.[3] Advances in digital health technologies have the potential to improve quality and safety of care as they increase the availability and use of health information[4,5] and subsequently can improve organisational efficiency. For example, the availability of electronic health records (EHRs) ensures that health and social care professionals have access to the most up-to-date health information, such as medicines prescribed and diagnostic test results across different care settings. Sharing health information for purposes beyond direct care, in a safe and controlled manner, is also critical to the services and activities that indirectly support care provision. For example, information is used by management within the Health Service Executive (HSE) to review waiting lists and plan and organise resources, such as hospital operating theatres, to ensure they are used to optimal capacity. Furthermore, information can be used to review care processes across large numbers of people to understand the circumstances which lead to the best care outcomes. This learning can be used to develop guidelines to promote the best level of care, such as the development and implementation of national clinical guidelines.[6]

As health information systems are further developed and become more integrated in Ireland, and advances are made in relation to digital health, it is important that there is an appropriate balance between the protection of an individual's personal health

* 'Circle of care' is a term used to describe the collection, use or sharing of personal information between health and social care professionals for the purpose of providing health and social care.

information and the use and sharing of that information to improve care. There is a need for strict rules and procedures to ensure these processes occur in a safe and controlled manner. Health and social care provision depends on trust. People should be assured that they can discuss sensitive aspects of their care with their health and social care professionals without fear of this information being inappropriately used and shared. They should also be able to trust that health information systems are secure and that their information will be stored and shared safely and appropriately.[7]

The processing of health information must be underpinned by a rights-based approach, meaning that an emphasis is placed on protecting and promoting people's rights and respecting their autonomy, privacy, dignity, and their values, preferences and diversity. Data protection is a fundamental right set out in Article 8 of the European Union (EU) Charter of Fundamental Rights.[8] Under the General Data Protection Regulation (GDPR), health data is recognised as a 'special category' of data, due to its sensitive nature, giving it more stringent protections than other types of personal data.[9] It must be noted, however, that data protection is not an absolute right. It must always be balanced against other values, fundamental rights, human rights, and or public and private interests.[10] The Caldicott Principles,[11] which underpin the use of confidential information within health and social care organisations in the United Kingdom (UK), emphasise that the duty to share information for individual care is as important as the duty to protect patient confidentiality.[11]

A key principle of data protection is that any processing of personal data should be clear and transparent to individuals. Furthermore, under Articles 13 and 14 of the GDPR, individuals have the right to be informed, and organisations are obliged to ensure individuals are appropriately informed on the risks, rules, safeguards and rights in relation to the processing of personal data and how to exercise relevant rights. Any information or communication relating to the processing of personal data must be accessible and easy to understand. There should be transparency, clarity and 'no surprises' for people in how their health and social care data is used and they should have clear expectations about how and why their personal information is used, and what choices they have about this.[9]

Involving people in important decisions about their health information and ensuring that their rights in relation to personal information are upheld is crucial, and will ensure that new technologies and initiatives, such as EHRs and citizen health portals, are implemented in a way that is acceptable to all citizens.[12] Results from a *National Public Engagement on Health Information* — run by HIQA, the Health Service Executive (HSE) and the Department of Health — found that Irish people are ready to embrace technology in healthcare, and understand that advances in

eHealth and digital health technologies will enable patients to have a much more participative, patient-centric and patient-empowered role. However, results also highlight that people want to be more involved in key decisions about their health information and would like control over how their information is collected, used and shared.[13] The need for extensive and meaningful engagement with the public on this highly sensitive and relevant topic was also clear from international evidence.[12,14] Public engagement must be undertaken in a meaningful and authentic way to build trust, confidence and awareness surrounding the benefits of using and sharing health information.[15]

2. Background to key considerations

HIQA is developing key considerations to inform policy for the collection, use and sharing of health and social care information in Ireland. The key considerations are being developed as per HIQA's legislative remit under the Health Act 2007 and subsequent amendments to the Act. Under the Health Act 2007, HIQA has a statutory remit to develop standards, evaluate information and make recommendations about deficiencies in health information.[1] The responsibilities of HIQA in this regard are outlined in the following sections of the Act:

- Section 8(1)(i): to evaluate available information respecting the service and the health and welfare of the population.
- Section 8(1)(j): to provide advice and make recommendations to the Minister for Health and the HSE about deficiencies identified by HIQA in respect of the information referred to in paragraph (i).

2.1 EU developments – European Health Data Space (EHDS) and forthcoming EU legislation

Policy-makers in Ireland need to consider the significant changes underway at a European-level in the area of health information. The digital and data transformation initiative put forward by the European Commission in 2020 aims to promote EU efforts to increase the use of data, including health-related data. This vision suggests setting up a European Health Data Space (EHDS) as a part of the European data policy.[16,17] Its aim is to develop the future policy, legal and technical framework for the sharing and secondary use of health data in the future EHDS. Member States have supported this proposal, which stems from GDPR. The objectives of GDPR are twofold: to facilitate the free movement of personal data, including cross-border exchange, and to protect the fundamental rights and freedoms of natural persons with regard to privacy and protection of personal data.[17] The EU Commission intends to enact other complementary pieces of legislation, including:

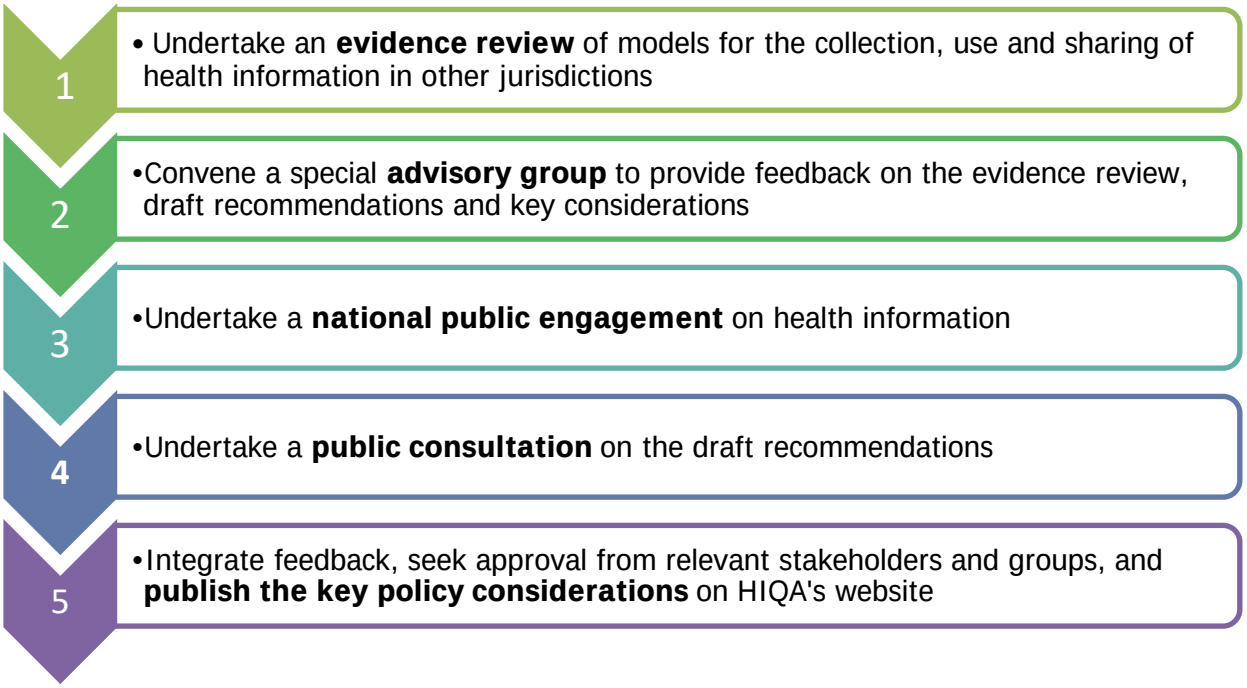
- **EU Data Governance Act**:[18] which focuses in particular on the re-use of data protected by the public sector, including health and social care data.
- **The Data Act:**[19] legislation dedicated to the EHDS which aims to foster business-to-government data sharing for public interest purposes, and to support business-to-business data sharing. It will also evaluate the intellectual property rights framework to further enhance the access and use of data, and to ensure fairness in the allocation of the value of data among actors from the data economy.

- The Commission's proposal on the legislation on **Artificial Intelligence**[20] will also have an impact on the protection of individual rights with regards to health data processing.
- The directive on privacy and electronic communications is currently being revised to become the **ePrivacy Regulation**, concerning the processing of personal data and the protection of privacy in the electronic communications sector.

The consequence of these developments is that Ireland needs to expedite the development of new national legislation in relation to health information, as well as updating national health information strategy and policy. Of significant interest in this regard is a recent proposal by the European parliament and the EU Council to establish a Policy Programme entitled 'Path to the Digital Decade'. One aspect of this programme is that countries can sign up to a target, which aims to get 100% of citizens with access to their electronic records by 2030.[21] This will place a renewed emphasis on the need to improve eHealth initiatives, which were proposed through the SláinteCare implementation strategies.[22]

2.2. Stages to development of the key considerations to inform policy

The key considerations were developed in line with the methodology outlined in HIQA's Health Information and Standards Quality Assurance Framework and include the following stages:



Stage 1: Evidence review - At the initial stage of the development process, HIQA undertook a review of consent models for the collection, use and sharing of health information to identify examples of best practice internationally. In addition, an

updated evidence synthesis was completed in 2021 which includes an 'as-is' analysis of the current health information landscape in Ireland and a summary of the latest international evidence. Experts in eight jurisdictions were contacted for interview to ensure the most relevant and up-to-date information was gathered. The eight jurisdictions included in the review were:

- Australia
- Denmark
- England
- Estonia
- Finland
- New Zealand
- Northern Ireland
- Ontario (Canada).

Stage 2: Advisory group - At the beginning of the process, an advisory group was established to provide expert advice (see **Appendix 1** for list of members). The Advisory Group is made up of a diverse range of interested and informed parties, including health and social care professionals, patient advocacy groups, professional representative organisations, health research groups, Tusla, the HSE, and the Department of Health. At each stage of the process, members of the Advisory Group had an opportunity to input into the development of the key considerations. This included informing the scope of the project, providing feedback on the draft recommendations prior to public consultation, submitting a response to the public consultation, and providing further feedback on the key considerations following the public consultation process.

Stage 3: National public engagement - HIQA, in partnership with the Department of Health and the HSE, undertook a national public engagement between 2020 and 2021. The national public engagement on health information aimed to understand the opinions and attitudes of the Irish public in relation to the collection, use and sharing of personal health information.

A national telephone survey was conducted with 1,228 members of the public from October to December 2020. The survey asked the public for their feedback on how their personal health information is collected, used and shared by health and social care services in Ireland and their opinions on the use of digital technologies in this area. Participants were nationally representative of the Irish population which allowed the findings to be generalised to the Irish population. In addition to the national survey, 14 focus groups were held between January and March 2021 with 85 people. As part of the focus groups, HIQA spoke with members of the public, patient representatives, people using addiction services, people using disability

services, people using homeless services, people using mental health services, representatives of migrant and asylum seeker communities, people using sexual health services, people from the Traveller community, and young people aged 16 to 18 years old. The focus groups provided a deeper understanding of the survey findings and of some of the key issues and challenges faced by people who have specific health and social care needs.

The full report, *Findings from the National Public Engagement on Health Information*, can be found on HIQA's website. A technical report, which presents the methodology, methods and procedures implemented during the National Public Engagement on Health Information, and a response document, which outlines how each partner organisation will use the findings in their future work, are also available on HIQA's website. Please see **Appendix 2** for a summary of findings from the national public engagement on health information.

Stage 4: Public consultation - An eight-week public consultation ran from 23 November 2021 to 10 January 2022 to gather feedback on the content and structure of the draft recommendations. The draft recommendations document was made publicly available to download on www.hiqa.ie and a consultation feedback form was developed to assist people to make submissions (**Appendix 3**). Submissions could be made using an online survey tool, emailed to a dedicated email address, or posted to HIQA. All details were provided on www.hiqa.ie.

At the start of the public consultation, the Project Team notified members of the Advisory Group and asked that they notify the organisations and groups they represent. The Project Team also contacted relevant health and social care professionals, policy-makers, advocacy groups and interested stakeholders by email to inform them of the process and request that they share information about the public consultation and encourage their colleagues and members of the public connected to their services to participate in the process. In order to reach as wide a range of stakeholders as possible, the public consultation was advertised in HIQA's newsletter and on its website. In addition, a press release about the public consultation was issued, and the consultation was advertised periodically via HIQA's social media channels, including Twitter, Facebook, LinkedIn and Instagram.

A total of 30 separate written submissions were received as part of the public consultation. Respondents were asked if they were commenting on behalf of an organisation or as an individual. Of the 30 responses to the public consultation, nine (30%) respondents responded in an individual capacity and 21 (70%) respondents responded on behalf of an organisation.

Twenty-four (80%) respondents gave details of their roles. Examples of the roles of respondents include:

- Director of Nursing
- Director of Digital Health
- Policy and Advocacy Specialist
- Head of National Health Information Systems
- Senior Data Protection Advisor
- Consultant in Public Health Medicine
- Research and Advocacy Manager
- Chief Clinical Officer
- Consultant Clinical Geneticist
- Quality and Operations Manager
- Strategic Policy Officer
- Information Rights Policy Officer
- Chief Nursing Information Officer
- Person in Charge
- Head of Enforcement, Legal and Governance
- Head of Policy Research and Public Affairs.

See **Appendix 4** for a list of the organisations that responded to the public consultation.

During the public consultation process, the Project Team held five focus groups to discuss the draft recommendations. HIQA collaborated with the Irish Platform for Patient Organisations, Science and Industry (IPPOSI) to facilitate four focus groups with members of the public and patient representatives, and 22 people took part in these focus groups. Participants were recruited by IPPOSI through their patient representative networks and through a call to individuals that had previously expressed an interest to participate in its Citizens' Jury on Access to Health Information. One additional focus group was held with health and social care professionals, and these individuals were recruited from professionals that previously contributed to the development of the National Public Engagement project. A total of seven professionals took part. For each focus group, a copy of the draft recommendations, the consultation feedback form, and a briefing document on the aims and process of the focus group were sent to participants. Due to public health restrictions as a result of COVID-19, all of these groups were held online.

Individual meetings were also held with targeted stakeholders to discuss specific details of the draft recommendations based on their particular expertise. Eleven individual meetings were held and a list of the organisations represented is available in **Appendix 5**.

Stage 5: Publication of key considerations – All responses from the public consultation, including written submissions, focus group responses and individual interview notes, were reviewed and used to inform the development of key considerations to inform policy for the collection, use and sharing of health information. The key considerations were presented to the Advisory Group for its consideration in May 2022. Following analysis and review of the additional feedback, the key considerations document was completed and sent for approval to the HIQA Executive Management Team, before approval by the HIQA Standards Information Research and Technology (SIRT) committee, a sub-committee of its Board, and then the HIQA Board. After the HIQA Board approved the key considerations, they were submitted to the Minister for Health and published on the HIQA website.

2.3 Aim of the stakeholder involvement report

The purpose of this paper is to present the key findings of the public consultation process (Stage 4). These findings, alongside relevant international literature and examples of good practice, informed the development of the key considerations to inform policy for the collection, use and sharing of health information in Ireland.

3. Analysis of Public Consultation Feedback

This section provides a high-level summary of the feedback received for each draft recommendation from respondents to the public consultation. Feedback from focus groups and individual interviews are also incorporated, where relevant, to provide further clarity to findings.

3.1 Recommendation 1 – to define key concepts in legislation

In this section of the feedback form, respondents were asked to provide feedback on the proposed definitions for health information, use of information for direct care, and use of information for beyond direct care. For this recommendation, 25 comments were received through the public consultation process. The proposed draft recommendation for the public consultation was:

Draft recommendation 1: Definitions
Based on a review of international best practice and stakeholder consultation, HIQA recommends that the following terms are defined in legislation:

Health information is "information[†] which relates to the physical or mental health or condition of an individual; the health or social care that is being, has been, or may be provided to an individual, or an individual's expressed wishes about the future provision of health or social care; and other personal information required for the provision of health or social care".

The **use of health information for direct care** is "information used to inform the provision of direct care to an individual; activities that focus on improving direct care and are undertaken by health and social care professionals with a legitimate care relationship,[‡] such as case reviews and local clinical audit; and emergency situations where information use is necessary to lessen or prevent a threat to an individual's life, health or safety".

The **use of health information beyond direct care** is "information used and shared by health services and health service providers for activities that contribute to the overall provision of health and social care to a population as a whole, or a group of individuals with a particular condition, but which fall outside the scope of direct care. Uses beyond direct care include: health services management and planning, health and social care research, public health, statistics, and training and education".

[†] Information sources include a wide variety of material, including but not limited to: handwritten notes; electronic records; correspondence, including oral correspondence, between health and social care professionals; visual and audio recordings; laboratory report; and communication with patients and services users (including oral communication, texts and emails).
[‡] A 'legitimate care relationship' is one where a health and social care professional is involved in informing and delivering the direct care of an individual.

3.1.1 Public consultation feedback

Generally, there were mixed views on the proposed definitions. Some respondents commented that the definitions were comprehensive and that it was worthwhile to include the proposed definitions in future legislation as they would bring clarity and consistency to this space; this was something that was highlighted by respondents as a current issue. The inclusion of social care in the scope of the proposed definitions was also welcomed. Other respondents felt that the proposed definitions were unnecessary and that the concepts were sufficiently defined in existing legislation, such as GDPR and the Data Protection Act, and that introducing new definitions might cause confusion.

> *"The definitions and measures proposed…overlap with [current] regulations in a way that is likely to result in unhelpful and complex legal lacunae".*

There was general agreement that current existing legislation and policy documents should be analysed to ensure there is consistency in the terminology used and to identify any gaps where clarity is needed; this should include both national and EU contexts. While some respondents were positive about using the terms 'use for direct care' and 'use for beyond direct care', others expressed some concerns. They commented that moving away from the terms 'primary use of information' and 'secondary use of information' would create confusion as these terms are most likely to be used in significant developments in this area across Europe.

There were some concerns about specifically defining the use of information for direct care and beyond direct care and potential unintended consequences. Some respondents outlined the need to consider data on a continuum, as they do not think it is practical nor possible to specifically define use of information for direct care and for beyond direct care. Examples were provided where public health professionals give care advice directly to individuals, as well as at a population level. In these instances, the use of information also relates to direct care but respondents did not think that the current definitions adequately covered this. Clinical trials were provided as another example where the use of information for direct care and beyond direct care was less distinct. This points to the fact that data can be collected once and used for many different purposes. Such feedback suggests that there may be some confusion between the legal basis for the collection of health information and the legal basis for the use and sharing of this information. It is important that if data is being used and shared for different purposes, each purpose must have a legal basis for processing.

A number of respondents identified the potential need for clarity of additional concepts, which were consent, anonymisation, pseudonymisation, social care, and 'professional with a legitimate care relationship'. These concepts do not necessarily have to be defined in legislation but there should be clear definitions provided in

guidance or policy documents. Respondents also identified a number of gaps in the proposed definitions and relevant concepts that should be considered in future legislation. The absence of genetics or genomic data from the definition of health information was a key issue for many respondents, who noted that there are additional considerations for the different uses of this data. The main issue is that genomic data cannot be fully anonymised and can only be at best pseudonymised. Therefore, it requires additional safeguards for use and sharing beyond direct care. This is particularly relevant due to the close links between genetic research and gene therapies for an individual's direct care.

> *"Maybe problematic in the context of genomic medicine where often research and clinical care are intimately related and intertwined"*

Some respondents commented that further consideration is needed in relation to information that related to family members that may be captured in an individual's health information. A number of respondents commented that it was important to explain what aspects were included and excluded in any of the definitions, so that there was a clear understanding of the scope of health information and its uses.

3.2 Recommendation 2 - a rights-based approach

In this section of the feedback form, respondents were asked to provide feedback on the need to follow a rights-based approach when implementing a consent model for health information. For this recommendation, 26 comments were received. The proposed draft recommendation for the public consultation was:

Draft recommendation 2: Rights-based approach
The collection, use, and sharing of personal information should follow a rights-based approach.

In all circumstances, individuals should be informed of:

- how, and why, their personal information is being, or may be, collected, used and shared.
- their rights to privacy and confidentiality in relation to their personal information, and what choices they have about this.

To support a rights-based approach, it is important that everybody working in the health and social care system understands their responsibilities and obligations in relation to the collection, use and sharing of personal information. In addition, a system-wide approach is needed to actively inform individuals about how their personal information is used and what individual's rights are in relation to privacy and maintaining confidentiality.

3.2.1 Feedback from public consultation

There was broad agreement amongst respondents that following a rights-based approach was important, and that this aligned with other relevant legislation and policy. A small number of respondents commented that it may be more accurate to say that the model should be 'underpinned' by a rights-based approach, as opposed to 'should follow a rights-based approach'. The latter would require specific information on applicable rights and the practical application of these rights.

It was highlighted by one respondent that even though there are a number of rights currently in place, not all are being sufficiently implemented. For example, they said that the right to access personal health information is not sufficiently implemented, and under the Data Protection (Access Modification) (Health) Regulations 1989 a doctor may still decide whether someone can have access to their health information. They commented that it was important to identify existing conflicting legislation and address such conflicts to support a rights-based approach. Furthermore, there was a general consensus that there was a lack of knowledge and clarity about rights in this area. One respondent specifically highlighted that clarity and guidance is needed for all stakeholders as currently there is *"legal uncertainty (no clear lawful basis) regarding the sharing of health information where a service user explicitly objects to this"*. Furthermore, some respondents commented on the

principle of 'real' transparency in terms of rights and lawfulness. In all circumstances, individuals should be informed about the legal basis for processing their information, how data is being used, and who is accessing data. Respondents emphasised that people should not be surprised at how their information is used and shared.

> *"The idea that a person should be fully informed about what is being done with their data cannot be an ideal or a goal of the state. The state is legally obliged to ensure that such a person is informed. Our institutions will only maintain trust if they uphold the law."*

Many highlighted the need to emphasise that there are competing rights in this area, and no individual has an absolute right to privacy. They commented that more detail is needed on the full spectrum of rights in this area and related issues.

> *"Notwithstanding the rights that individuals can exercise under data protection and privacy legislation and common law (confidentiality), it is equally important to ensure that individuals are fully informed of any limitations to those rights regarding their health information, as the right to privacy and data protection is not an absolute right."*

For some respondents, the concept of a rights-based approach opened up the debate between what is best for an individual, versus broader society, and how such a balance can be found. Some respondents highlighted that an example of a key area for consideration is in relation to child welfare and protection where the risk to a child is the priority and must guide decisions when assessing rights in relation to access to information and erasure of information. There was general agreement that there is a need to find balance between duty of care, data protection rights and duty of confidentiality. A number of respondents also emphasised the need to provide detail on the rights of those who lack capacity and those aged under 18, particularly when the legal basis for processing information is that of explicit consent.

There was general agreement among respondents that there needs to be widespread public awareness of the different rights that are in place and the balance that needs to be achieved between these different rights. Many respondents noted that clear communication and ensuring that people are adequately informed is central to the process. They noted that public campaigns to help citizens understand when they can exercise particular rights are of key importance. Many respondents emphasised the need for education for both members of the public and for health and social care professionals to ensure that there is clarity of understanding of different rights and appropriate application of rights.

> *"A rights based approach needs to be coupled with an education campaign for the public".*

3.3 Recommendation 3 - to define the consent model and exemptions in legislation

In this section of the feedback form, respondents were asked to provide feedback on the four categories outlined in the proposed consent model, and the proposed exemptions listed under category three of the model. For this recommendation, 27 comments were received through the public consultation process. The proposed draft recommendation for the public consultation was:

Draft recommendation 3: Consent model

Based on a review of international evidence, HIQA recommends the introduction of the following consent model for the collection, use and sharing of personal information, and that this model should be defined in legislation (see recommendation 4):

Note: As a general principle, anonymised or aggregate data should be used in all circumstances where the purpose of use can be achieved without personal information.

Use of information for direct care

- **Category 1:** Explicit consent is not required for direct care. The collection, use and sharing of personal information is lawful under the Data Protection Act 2018[23] and the General Data Protection Regulation[9] where it is necessary for the provision of health and social care. This means that professionals with a care relationship can collect, use and share personal information to ensure they have accurate and timely information to deliver safe and effective care. However, the principles of data protection and transparency still apply, so individuals should always be fully informed of how, and why, their personal information is being, or may be, used.

Use of information beyond direct care

- **Category 2:** Explicit consent is required for the collection, use and sharing of personal information for reasons beyond direct care (except where exemptions apply – see Category 3).[§]
- **Category 3:** Explicit consent is not required for the collection, use and sharing of personal information if the use is considered one of the following exemptions, as defined below:
  - **Identification, prevention, control, and surveillance of population health and disease**: the use of information to support the identification, prevention, control and surveillance of population health and disease, including both communicable and non-communicable diseases.

[§] In limited situations, when the public interest of doing research significantly outweighs the need for explicit consent, the Health Research Consent Declaration Committee (HRCDC) will review applications and make a final decision on the need for consent. Research consent declarations are covered within the health research regulations and therefore are outside of the scope of these recommendations.

- **Compilation or analysis of statistics relevant to health and social care**: the collection, compilation, analysis or interpretation of data, expressed in either numerical or non-numerical form, relevant to health and social care.
- **Management and planning of health and social care services:** the use of information to inform the planning, monitoring, delivery, improvement, auditing and evaluation of health services.
- **Health and social care professional education and training:** the use of information to develop resource materials or the sharing of information during structured professional development activities in order to support the education and training of health and social care professionals.
- **Alternative legislative basis for the collection, use and sharing of personal information:** the collection, use and sharing of personal information is required by law.

o Each exemption should be clearly defined in legislation and the permitted uses of data within each exemption should be described in supporting regulations and guidance.

Category 4: Explicit consent is not required for the sharing of health information if the information is considered anonymised in accordance with the Data Protection Commission's 'Guidance on Anonymisation and Pseudonymisation'.[24] As advances are made in this area, there is a need to ensure that this processing occurs in a regulated and controlled environment with the appropriate governance and infrastructure in place (see recommendations 6 and 7). To support best practice, it is recommended that a code of practice is developed (see recommendation 8).

3.3.1 Feedback from public consultation

There were mixed views on the proposed consent model. A number of respondents commented that consent was not an appropriate legal basis for the model. They commented that it would be more appropriate to include all six legal bases for the processing of personal information, as outlined in GDPR, and their relevance to the collection, use and sharing of health information in Ireland. Some respondents commented that it may be better to view health and social care data on a continuum where data is collected once but used numerous times; hence there may be a different legal basis for each use. Some respondents commented that the focus should be on the use and sharing of information to ensure good quality care, and in some instances, alternative legal bases may be more appropriate. As a result, some respondents queried whether the title of the draft recommendations should include 'consent model' and outlined that it may be more appropriate to say that the focus is on the processing of health and social care data or on the legislative and governance arrangements required for the collection, use and sharing of health information.

> *"Consent is not the only legal basis for processing personal data. It is just one of six legal bases for processing personal data in the GDPR, with the others*

being contract, legal obligations, vital interests of the data subject, public interest and legitimate interest, as stated in Article 6(1) GDPR. We do not believe consent is the best legal basis upon which to base the proposed model."

Similar to feedback for Recommendation 1, some respondents commented that it was sometimes difficult to differentiate between direct care and beyond direct care in practice. Public health was a key example provided here because, as outlined previously, it may involve care at an individual level or at a population level. A small number of respondents commented that the focus should be on the 'circle of care' and believed that this would bring clarity to the use and sharing of information for direct care. It was also noted that the proposed model appeared to be heavily focused on healthcare and that there was a need to ensure the model aligned with social care policy and practice. One respondent from the social care sector commented that there may be further complexity associated with social care data as it is often shared across different sectors and that this requires additional consideration.

Some respondents commented that there was a lack of clarity in some of the categories of the consent model. They felt that there should be more specific information, such as who would be responsible for obtaining consent, and the process to be followed in the case of assisted decision-making. There was general agreement that the model must be aligned with existing legislation and policy, and the following were specifically mentioned by respondents: the Health Research Regulations, Statistics Act, Assisted Decision Making (Capacity) Act, and the HSE National Consent Policy. Additional gaps identified by respondents included: sharing with private entities, data relating to people under 18 years, genetic and biological data, family history, and if the model related to living persons only.

In relation to **category one (use of information for direct care),** respondents commented that there is a need for clarity on sharing information outside of the public sector. This was important for both members of the public and health and social care professionals. One respondent commented that there was a conflict between the lack of requirement for explicit consent for direct care and the call for consent preferences to be recorded in Recommendation 7; they called for further clarity.

Respondents also called for greater clarity in relation to **categories two, three and four (use of information beyond direct care)**. They commented that there needs to be clearer discussion of what activities would fall into either of these categories and who would be responsible for obtaining consent or deciding if a certain activity was considered an exemption. One respondent highlighted that the use of the term 'exemption' was inaccurate in the context of GDPR as it is necessary

to outline the specific legal basis for processing for each use of health information. Many respondents stated that category four was problematic, as anonymisation is likely not possible nor useful in many circumstances. There were concerns that it is not possible to truly anonymise health information, and that this was especially true for genetic data. One respondent stated that there have been a number of developments in this area since the enactment of GDPR, and that it was more appropriate to use the term 'de-identification', as this acknowledges the risk of re-identification which is critical in this debate. Some respondents noted that technology is evolving rapidly, and developments in areas such as artificial intelligence and synthetic data are essential considerations as they may have an impact on the risk of re-identification and subsequent risks in relation to bias and profiling. It was highlighted by many respondents that anonymising data is still processing of data and would still require a legal basis for processing. The legal basis may be consent or another legal basis, such as legislative provisions for a specific entity to perform such processing activity, and that legal basis needs to be clearly outlined.

> *"Caution should be applied in operationalising the proposal that consent is not required for health information that is 'anonymised'. Several issues can arise including genetic data may never truly be anonymised and that data linkage with other sources may render health information identifiable."*

Some respondents commented that anonymised data may not be useful for research as it prohibits the ability to link health and social care data with alternative datasets. They were worried that the proposed consent model would introduce additional barriers to data sharing rather than promote the use and sharing of data to inform the health and social care system. They also noted that it was important that key statutory organisations still have access to data to fulfil their legislative functions, such as the Central Statistics Office (CSO). A number of respondents emphasised the need for well-developed infrastructure to enable data sharing in a secure environment as they believed that this is essential to protect data as well as promote effective data sharing in a modern system. They further highlighted the need for a robust governance framework and security measures to achieve this balance between data sharing and data protection.

> *"There is overlap in practice between Category 3 and Category 4 as it could be proposed that one of the key safeguards to enable the sharing of data for secondary purposes without explicit consent is the requirement to show that you are doing this via a controlled and regulated and secure environment, which utilises leading linkage and de-identification techniques and only provides access to the anonymised or pseudonymised data on a secure*

platform. A well-developed infrastructure and governance model can address all of these issues."

Many respondents commented on the need to consider research and how it would fit within a future model. Some respondents acknowledged that research was outside of the scope of the recommendations, but they indicated that it still needs to be discussed and included in the conversation as there are clear links. They commented that the alignment with the Health Research Regulations and the Health Research Consent Declaration Committee (HRCDC) needs to be much clearer, so that the public has a better understanding of how the recommendations fit in the broader landscape. Some respondents wanted clarification on what might be considered research and what might be considered other secondary uses of health information.

3.4 Recommendations 4 and 5 - Legislation

In this section of the feedback form, respondents were asked to provide feedback on the need to develop specific legislation for uses of health information. For this recommendation, 26 comments were received through the public consultation process. The proposed draft recommendations for the public consultation was:

Draft recommendations 4 & 5: Legislation

4. Building on the data protection principles outlined in GDPR** and in line with HIQA's recommendation in the position paper for a legislative framework in the area of health information,(3) the Department of Health should develop specific legislation in relation to the collection, use and sharing of personal information. The legislation should:

- incorporate the recommended definitions and proposed consent model, and promote a rights-based approach to the use and sharing of personal information (see recommendations 1-3);
- outline how the consent model should be monitored and regulated, addressing current arrangements and future requirements.

5. To complement new health information legislation, a legislative framework should be developed with supporting regulations, codes of practice and policies. These supporting documents should help to define what good practice is for those working in health and social care services and to develop a common understanding around individuals' rights in relation to health information (see recommendation 8).

3.4.1 Feedback from public consultation

Many respondents supported the call for legislation and commented that it would bring clarity to this area. Respondents identified a number of areas where clarity was needed and gaps in legislation were identified. Many believed it was important that new legislation considered the whole health and social care system, rather than focus on specific aspects, and that failure to do so would impede progress. Specific considerations for new health information legislation included:

- what constitutes the appropriate use and sharing of information for direct care (which was considered more complex in the context of social care);
- specific legal bases for different uses of information for beyond direct care;
- regulate the use and sharing of health information for a comprehensive range of purposes beyond direct care;
- use and sharing of information across public, private and voluntary entities for both direct care and purposes beyond direct care (requires a data governance framework);

** The seven data protection principles include: lawfulness, fairness and transparency; purpose limitation; data minimisation; accuracy; storage limitation; integrity and confidentiality; and accountability.

- legal basis for processing information for de-identification;
- legal basis for the establishment of a national health information entity and organisation to undertake de-identification and linking of data;
- transfer of data outside of EU and process of verification of legislative frameworks and security standards in non-EU countries;
- and record retention schedule for different uses.

Respondents believed that such clarity and regulation would support best practice in the collection, use and sharing of health information, as well as create the legal remit required for the creation of appropriate national governance structures. Some respondents called for greater discussion in the recommendations document on why current legislation is not fit-for-purpose.

If new legislation is to be developed, the legislative landscape at a broader level must be considered. Many respondents identified the need to ensure legislation aligns with other domestic and EU health and social care legislation and policy. Specific legislation and policies named by respondents were Health Research Regulations 2018, Statistics Act 1993, cross-border data sharing legislation, bio-banking related legislation, upcoming European legislation regarding secondary use of and interoperability of health information across jurisdictions, EU Data Governance framework, EU Privacy legislation (ePrivacy Directive), Assisted Decision-Making (Capacity) Act 2015, and the forthcoming HSE National Consent for Research policy. The EU Data Governance Act was seen as a *'game-changer'* by respondents, as it introduces different opportunities in relation to the re-use of public sector data, including health data. Some respondents noted that there is an opportunity to customise EU legislation in each member state and that Ireland must carefully consider the needs of the broader health information system to ensure that wide-ranging benefits are gained and that the particular needs of the Irish health and social care context are met. A number of respondents commented on the need to more clearly consider alignment with social care legislation, as social care information may have specific requirements that differ from health information. They also noted the potential need to engage with other government departments in relation to social care, such as the Department of Children, Equality, Disability, Integration and Youth. One person commented on the need to consider access to information in the context of adoption services.

> *"It is also important to consider that any new proposed legislation should be aligned with existing and future legislation, including upcoming European legislation."*

A small number of respondents, however, questioned the need for new health information-specific legislation as they believe that GDPR and the Data Protection Act provides sufficient legal basis for the collection, use and sharing of health

information. Some argued that insufficient resourcing to enact GDPR is the real issue and that increased resourcing, in terms of IT infrastructure and human resourcing, would allow legislation to be enacted adequately and support improved data sharing and data protection. Some respondents considered it more important to undertake a gap analysis of existing legislation. The purpose of the gap analysis may include to identify what must be addressed to meet the requirements of Article 9 GDPR, and to identify potential conflicting legislation, such as the Data Protection (Access Modification) (Health) Regulations 1989. It was noted that GDPR Article 9(g) allows for the development of member state legislation in relation to data processing necessary for reasons of substantial public interest, and it may be relevant to develop new legislation to address gaps. One respondent emphasised that new legislation does not automatically supersede old legislation and there is a need to clearly call this out.

> *"It is our position that Ireland already has legislation outlining how we collect, use and share health information. The state must comply with that law. There may be gaps in the health legislation which need to be filled to meet the requirements of Article 9 GDPR. These gaps need to be identified and analysed."*

It was noted by a number of respondents that the Department of Health is currently working on a proposed Health Information Bill and clarification is needed on its connection to the legislation being called for in the draft recommendations. Respondents commented that new legislation needs to be comprehensive and consider the many data sources and different uses of health and social care data. A small number of respondents noted that a Data Protection Impact Assessment (DPIA) must be undertaken before legislation is developed and that the Data Protection Commission (DPC) must be consulted if legislation relates to the area of data protection. The CSO emphasised that it is important that any future legislation recognises the difference between official statistics, as set out in the Statistics Act 1993, and statistical work for other purposes. It also noted that it needs access to health and social care data as part of its remit under the Statistics Act 1993 to allow linkage with other datasets for national planning. These are essential elements of the CSO's role and it is important that they are not restricted, even unintentionally, through the wording of new legislation.

All respondents, even those that supported the call for new legislation, acknowledged the role of GDPR as a legislative framework in this area. They commented that GDPR is complex and there is a lack of clarity at an individual level on how GDPR may be translated into practice in the health and social care sector. They identified a need for additional resources, such as guidance and codes of practice, to support members of the public and health and social care professionals

to correctly interpret relevant legislation and to inform every day, practical issues around the collection, use and sharing of health and social information. Such resources should be available for current and any future legislation in this area. Many respondents commented that members of the public and health and social care professionals should be appropriately engaged to inform the development of such resources, as well as in the development of the legislation.

> *"The implementation of a legislative framework with supporting Regulations, Code of Practices and policies is welcomed as it would enhance and complement the application of data protection law in the health and social care sector, where this is not done so already."*

3.5 Recommendation 6 - Governance structures

In this section of the feedback form, respondents were asked to provide feedback on the proposed governance structures to support proposed health information legislation and consent model. For this recommendation, 25 comments were received through the public consultation process. The proposed draft recommendation for the public consultation was:

Draft recommendation 6: Governance structures

As set out in the eHealth Strategy (2013)[25] and HIQA's recent position paper[3] on the reform of Ireland's national health information system, **eHealth Ireland** should be established as an independent entity with oversight for all aspects of health and social care information.

eHealth Ireland should have overall responsibility for governance and for ensuring compliance with the new health information legislation and consent model, including:

i. providing strategic leadership to enhance the effective use of information beyond direct care. Specifically, eHealth Ireland should establish new national level governance structures, to include:
   - implementing the Data Access, Storage, Sharing and Linkage (DASSL) model for the use of information beyond direct care. This should be expanded beyond research to include information for the management and planning of health and social care services. eHealth Ireland should have responsibility for managing activities such as anonymising and linking data, and creating a safe haven for data sharing at this level.
   - establishing a 'National Data Governance Board for the use of information beyond direct care'. The Board should be comprised of independent specialists in the area of health information, as well as public and patient representatives. Primarily, this Board would be responsible for overseeing and governing a framework for the use and sharing of data for purposes beyond direct care (see Recommendation 7).

ii. Enhancing current information governance structures in place at local and regional levels within health and social care services, by establishing a network to support Data Protection Officers, and others responsible for information governance at a service-provision level. The aim of this network should be to assist and guide in developing consistent standards and guidance for the use of data and information within health and social care services in compliance with the new health information legislation.

3.5.1 Feedback from public consultation

There was strong support from respondents for enhanced national governance structures for health information in Ireland. A number of respondents stated that

there was an urgent need for progress in this area as there was a real lack of clarity, at some levels, in relation to data ownership and management. Respondents felt that enhanced structures would support improved data sharing as it would provide confidence to data controllers, and believed that a lack of data sharing was considered a key challenge for the provision of quality care.

There was significant support for a national organisation with responsibility for health information, and some commented that its establishment was critical to progress in this area. Many respondents did not think that it should be called 'eHealth Ireland' due to the connection with the current unit and believed that it should be independent of the HSE. Respondents commented that this entity should be given a name so there is clarity in what is being spoken about, and that *"a broader name such as Health Information Ireland would be more appropriate*". It was emphasised by a number of respondents that this organisation must have sufficient powers and that its role must go beyond being an advisory or steering group. One respondent commented that it must be *"something that has the teeth to make public service bodies to have responsibility to share in a supportive way".* The Data Protection Commission was provided as an example of a national organisation that is independent but has strong legislative powers.

> *"[We] see the benefit of establishing an independent national office, which would engender public and patient trust and demonstrate a level of national coordination, strategy and governance for health information in Ireland."*

There was also general support for the establishment of a National Data Governance Board, but again further clarity on its role was required and its relationship to other governance committees. There were also some suggestions for potential new roles which were: a national data governance officer; a national data guardian for health information who would be hosted in a national office and connected to the Data Protection Commission; a data sharing commissioner; and an Ombudsman for health information. Many respondents emphasised that the establishment of a national organisation needs input from a wide range of stakeholders, and that a governance board must have adequate representation from all health and social care sectors. The following were specifically mentioned: private and public care providers, carers organisations, and patient and citizen representation.

Many respondents commented that there were insufficient details on the proposed national organisation and requested that more consideration is given to the roles and responsibilities of the organisation, links with existing organisations (such as the HSE, Department of Health, Data Protection Commission, Health Research Board (HRB), Health Research Consent Declaration Committee, CSO), the proposed reporting structure and funding sources. It was proposed by one respondent that this organisation could undertake a review of the infrastructure and capabilities

required to generate quality health information. It was noted by respondents that this organisation must have the breadth of expertise required to undertake these roles to ensure it can stay ahead of the requirements in relation to data protection, data sharing and other relevant areas.

> "*More information however is required on the proposed composition, structure and financing of these new entities and how they will interact with existing bodies."*

Some respondents queried the wide-ranging remit of this proposed organisation and whether it should be established as an independent entity. Some commented that the HSE could not abdicate such responsibility and that a greater focus should be placed on strengthening existing governance arrangements within the HSE. It was proposed that existing arrangements should take a broader focus on information governance, rather than just data protection, and that this approach would have benefits for both data protection and data sharing. It was highlighted by one respondent that there are already a small number of specialised registries that have the technical infrastructure or responsibility for governance and management of the use of information beyond direct care, and that there would be benefit from engaging and learning from such expertise. Another respondent noted that the model for the collection, use and sharing of health information should be agreed prior to developing governance structures to ensure the structures were comprehensive and appropriate.

> *"There is already governance in place, but these existing governance arrangements should be strengthened to support more consistent and nuanced interpretation to achieve the required goals."*

There was strong support for increasing the capacity of data officers at a local level to provide support and expertise in the area of data protection and data sharing, as this was an important knowledge gap for many in practice. It was noted by a number of respondents that there are some relevant officers in place at a local level but they may only do so in a part-time capacity which can lead to inadequate support. Some respondents commented that there is a lack of consistency across services. It was noted that information governance committees generally cover data protection at a hospital level, especially in larger hospitals. However, in smaller hospitals there may just be an individual contact with limited capacity for this role, or there may be no one in place. The Data Protection Commission emphasised that the role of a Data Protection Officer (DPO) *"has a specific definition and mandate under the GDPR"* and that any change to their remit to become involved in making decisions about the use of personal data would conflict with their legislative function and compromise their independence.

There was also general support for the development of a national network of data officers or the development of a broader role, such as information governance officers. It was noted by one respondent that the Data Protection Commission had initially set up a national network for DPOs but that this was stopped due to the pandemic and has not been re-instated. Respondents also commented that there are a number of relevant networks already in place across various sectors where partnerships could be made, such as the Health Research Data Protection Network and networks in place in Dublin in acute teaching hospitals.

> *"The current Health Research Data Protection Network could be enhanced and expanded to provide support to DPOs. This recommendation is welcomed and could bring consistency to data protection measures and standards nationally."*

3.6 Recommendations 7 and 8 - Technical and operational requirements

In this section of the feedback form, respondents were asked to provide feedback on the technical and operational requirements to support implementation of the proposed consent model. For this recommendation, 23 comments were received through the public consultation process. The proposed draft recommendations for the public consultation was:

Draft recommendations 7 & 8: Technical and operational requirements

7. eHealth Ireland, through consultation with stakeholders, including the new 'National Data Governance Board for the use of information beyond direct care', should develop an implementation plan outlining the requirements for the technical infrastructure and operational capabilities necessary to implement the consent model for the collection, use and sharing of health information, taking into account both current and future needs. This plan should include specific details on:

- how the health and social care system will manage individuals' consent and control preferences for how personal information is used and shared.
- an anonymisation, linkage and secure sharing service for the use of information beyond direct care – DASSL model.

8. The Department of Health should identify the appropriate organisations with responsibility to develop codes of practice and guidance materials to support the consent model for the collection, use and sharing of health information, as well as the new proposed legislation.

As a priority, this should include:

- guidance for individuals to explain: the reasons how, and why, personal information is being used; and rights to privacy and maintaining confidentiality of health information, and what choices people have about this.
- a Code of Practice on protecting individuals' confidentiality for health and social care professionals.
- a Code of Practice to outline best practice in relation to anonymisation[††] and linking of health data, and details as to who is authorised to undertake such activities in compliance with the consent model and new health information legislation.

3.6.1 Feedback from public consultation

There was strong agreement that there is a significant need for better infrastructure and operational capacity, and that this is critical for the collection, use and sharing of health information in Ireland. Some respondents noted that the lack of adequate infrastructure limits the efficiency of data sharing between public bodies which can have a negative impact on care as it impedes the responsiveness of an organisation.

[††] Effective anonymisation may not always be possible due to the nature or context of the data or the purpose(s) for which it is collected and used.

The lack of a unique health identifier was highlighted by a number of respondents as a key issue and that many important questions cannot be addressed due to the lack of a unique identifier. A number of respondents commented that there is a huge gap between current infrastructure and the proposed model. They noted that significant investment is needed to meet requirements and to bring Ireland in line with international counterparts which have invested significantly in developing patient portals and infrastructure to effectively use data for purposes beyond direct care. Some respondents fear that Ireland will lag behind international counterparts in terms of research and innovation without such investment. They state that Ireland will need to have infrastructure in place that allows the secure transfer, linkage and de-identification of health and social care data and relevant codes of conduct to be eligible to apply for larger EU-funded projects. Consultation with key stakeholders, including members of the public, before the implementation plan is developed will also be important. Some respondents noted the opportunity to learn from exemplars in this area, which included the CSO, HRB, the Business Information Unit (BIU) within the HSE, National Cancer Control Programme (NCCP), National Cancer Information System (NCIS), St. Patrick's Mental Health Services (SPMH), and Towards the European Health Data Space (TEHDAS).

Consent and control preferences

Many respondents believe there is a need for improved transparency on how health information is collected, used and shared and that there should be a clear understanding of each use and any changes to such uses. Some respondents discussed the need for control of personal information and wanted options such as virtual ‘lock boxes’ (where particular information is hidden from certain care professionals) to be available. Some respondents spoke about dynamic consent options as most preferable but that appropriate infrastructure needs to be in place to support this. It was noted by a number of respondents that the infrastructure in Ireland is not in place to support dynamic consent currently. One respondent argued that dynamic consent is not practical nor possible to implement in many circumstances, even with advanced health information systems. Some respondents commented that the management of individual preferences is quite complex and can be resource heavy, and that any future plan must be realistic and cognisant of the resources needed.

There was strong support for an online portal, or similar resource, where people could access their health information easily, and could also see who else has looked at their information. Some respondents identified a portal as a means to enable greater patient empowerment to manage care and also to support greater control and management of ‘sensitive’ information. It was noted that data records need to be standardised to ensure data portability and to ensure the portal is standardised

across users and services. In advance of this, it is important to clearly define what is considered health and social care data as this will inform the design of the portal. It was noted that the portal must be designed to enact patient consent preferences and that this may be a challenge. The European Commission was cited as undertaking some work in this area which was an opportunity for learning for the Irish context. Identity validation was identified by one respondent as another potential challenge.

> *"Give patients and the public as much information as possible in hard or soft copy or both. Have a website to log onto to see your personal information and other information."*

Other respondents cited concerns in relation to providing people with options on the use and sharing of their health information, as they fear it may limit information sharing. In relation to direct care, a lack of information sharing may be a risk for patient safety, as withholding relevant information from a care professional does not allow for informed treatment. It was acknowledged by respondents that consideration should be given to offering the right to not share particular information with certain care professionals, but that the patient must be sufficiently informed of the potential impact that this may have on their care. In relation to 'beyond direct care', some respondents commented that a lack of information sharing may compromise the integrity of the information system and threaten the value of the data; this also relates to the use of datasets for research. They cautioned that careful consideration is needed to find an appropriate balance.

> *"When we empower people to have absolute control over their data, this can compromise the integrity of the system and threaten the value of the data. Need to be careful in wording to ensure this is addressed."*

Linkage and secure sharing system (extension of the DASSL-type model)

The creation of a centralised agency with responsibility to coordinate an anonymisation, linkage and secure sharing service for the use of information beyond direct care was welcomed by many respondents. It was viewed by one respondent as *"critical to coordinate national health information access, sharing and linkage for secondary purposes".* Some respondents noted that currently there is a lack of trusted environments in Ireland which means that data sharing agreements have to be created in many instances, and the other consequence is that existing data is not used to full potential. This is considered a potential barrier to analysis and research as the need to create data sharing agreements requires additional time and resources, and the availability of trusted environments would reduce the need for such agreements.

"A centralised agency would help alleviate concerns regarding the use of data under GDPR. I see it as being helpful for patients and public."

For some respondents, there was a lack of clarity on what this agency would look like and greater detail was needed to provide a clearer understanding of its roles and responsibilities, process and overall vision. Such detail would also inform the resources required for this agency and would ensure that it was able to effectively complete its objectives. A number of respondents commented that it is important to consider if this model will be a single agency which collects all health and social care data; a network of agencies that can apply to be linkage agencies through accreditation; or a central model which has a mandate to request data from local bodies, only when required, and can complete subsequent linkage and anonymisation if needed. This will require discussions around data ownership and the infrastructure that must be in place to ensure interoperability and data integrity. It was noted that poor data quality was a key issue for 'Findata' in the early stages of its inception and it was important to learn from their experience, and to accept that the development of such infrastructure will be an incremental process. It was also noted that it is important that there is alignment with developments at a European level.

One respondent noted that it is important that the agency is independent from professionals who have access to clinical data and that there is some separation between the people doing the analysis and doing the linkage. A small number of respondents expressed concern regarding whether there would be appropriate security arrangements to protect such vast quantities of sensitive data. They believe that this goes beyond governance structures and that appropriate technical structures need to be in place; this was viewed as especially important since the cyberattack in the HSE in 2021. Drawing on the learnings from the DASSL proof-of-concept project was welcomed as respondents saw the need to move this model beyond a research context. Some respondents commented that there will likely be a need to put health and social care data into the broader context which will require access to additional datasets. Consequently, they see the need for an extension of the current DASSL model beyond the health and social care context.

While some respondents named the CSO as a potential option to undertake this role, others expressed caution and that such a move may be viewed negatively as it *"may be viewed a perceived infringement of people's rights if CSO or similar entity has data [across all sectors]".* The CSO noted that they currently do not have the legislative remit to undertake such a role nor do they have appropriate infrastructure to ensure appropriate de-identification of certain data, such as MRI scans, where there is a high risk of re-identification. The CSO were, however, cited as a key stakeholder from which learning could be garnered through their experience in

running their administrative data centre, the development and implementation of the COVID-19 research hub, and from their 'safe haven' service for some areas of health and social care. Also, there is likely to be a need for a robust relationship between the proposed new organisation and the CSO as it was highlighted that the CSO Director General is responsible for all official statistics under the Statistics Act 1993. It will be important to consider their statutory obligations in this space and their connection with any potential future agency.

Guidance and codes of practice

Many respondents saw a significant need for the development of appropriate guidance and codes of practice to support the collection, use and sharing of health information and future developments in this area. Many respondents emphasised the need for a code of practice, or guidance specific to health and social care professionals, in relation to data sharing and data protection as there is much confusion on the implementation of GDPR in practice. The HSE deputy DPOs developed an online programme on the implications of GDPR after it came into force. They spoke of the huge demand for this programme by health and social care professionals which demonstrates the need and desire for suitable resources. Other respondents commented that some resources currently exist and that a gap analysis should be undertaken to build on existing resources and to remove inaccurate or outdated guidance. This clarity would improve data sharing and subsequently support direct care, and the use of data for reasons beyond direct care such as quality improvement, research and planning. One respondent commented that there was too much focus on the legal basis of consent with little understanding of the other legal bases for processing, even though consent to processing is not used as often in health and social care. They believed that if there was a better understanding of all of the legal bases for data processing, there would be less apprehension amongst health and social care professionals about data sharing. **Table 1** outlines the specific topics that should be addressed in guidance and codes of practice, as identified by respondents.

Table 1. Examples of topics that should be addressed in guidance and codes of practice, as identified by respondents.

Public	Professionals
Rights in relation to health information	What is a rights-based approach and dealing with expectations of patients and the public
Different uses for health information (direct care and beyond direct care)	Informing individuals on how information is used (transparency)
Legal bases for processing health information	Legal bases for processing health information
Importance, benefits and risks of data sharing and data de-identification	Correct interpretation of GDPR, including professional responsibilities and obligations
	When consent should be obtained and by whom
	Implications of not capturing consent
	Processing children's data
	Consent in relation to sharing of health information versus 'medico-legal' consent for procedures and link with other relevant policies
	Data governance
	Anonymisation and pseudonymisation
	Data linkage
	Cybersecurity
	Post quantum cryptography

Respondents suggested that guidance for professionals should include clear, practical examples and simple 'soundbites' that would help professionals to explain the processes of consent and data sharing to patients. Useful resources that were identified by respondents were simple infographics, eLearning modules on HSeLanD, FAQ pages, and seminars on specific topics. A number of respondents emphasised that it will be important to consider the range of staff that will require such guidance and that resources should be tailored to ensure it meets the needs of all. The National Disability Authority advised that any resources, including a portal and guidance, must be designed using a Universal Design approach and emphasised the

need to comply with the EU Web Accessibility Directive and Part 3 of the Disability Act which relates to access to information.

> *"There needs to be clear guidance as opposed to solely policy. This guidance needs to be discrete and clear. Guidance should be simple. This level of implementation is often overlooked and can lead to legislation/policy not working in practice."*

3.7 Recommendations 9 and 10 – Public engagement

In this section of the feedback form, respondents were asked to provide feedback on the need for ongoing public engagement and the development of a national public engagement strategy. For this recommendation, 23 comments were received through the public consultation process. The proposed draft recommendation for the public consultation was:

Draft recommendations 9 & 10: Public Engagement
9. In order to build and maintain trust with the public, there must be transparency and ongoing engagement to ensure individuals can appropriately participate in decision-making about how their health information is being collected, used and shared.
10. Using a partnership model, the Department of Health, the HSE and HIQA should develop a national public engagement strategy for health information to inform, consult, involve, collaborate with and empower[‡‡] citizens, and health and social care professionals, to make decisions on proposed changes and ongoing initiatives which impact on how health information is collected, used and shared. The strategy should detail a system-wide approach to actively informing individuals about how their personal information is used, and what individuals' rights are in relation to privacy and maintaining confidentiality. Public engagement should be undertaken to establish preferences and opinions on: ▪ the new health information legislation ▪ the consent process, including considerations on an 'opt-out model' ▪ new eHealth initiatives ▪ any significant changes to how health information is collected, used and shared.

3.7.1 Feedback from public consultation

Respondents believed that coordinated and ongoing public engagement in this area was essential and a critical element of building trust, as well as an essential element to the success of new developments in this area such as new legislation and eHealth initiatives. Many respondents emphasised that engagement must be genuine and that the focus must be realistic and relate to where change is possible or people will lose trust. An example given by one respondent was that it would not be useful to engage members of the public on changing EU law as that is not within our remit to change. The need to build trust was a clear issue for many respondents, with some commenting that certain events have eroded trust in the health and social care sector, including the rising cost of the Children's Hospital, the cyberattack, and the SláinteCare resignations. Respondents believed that trust was necessary to build a

[‡‡] Based on the framework for public participation developed by the International Association for Public Participation.

successful health information system and that the other proposed recommendations were not likely to be implementable if there was little trust in the system. Consequently, many respondents saw public engagement as a critical first step.

> *"We need to inform, consult and collaborate with the public. We need to know how to go out and inform the public. We need public and patient involvement from the beginning and then it becomes a more inclusive exercise."*

In their responses about the importance of public engagement, some respondents highlighted that a key element related to the broader health and social care system and the opportunities to build trust. They commented that there needs to be sufficient expertise in the area of health information and data security for people to have sufficient trust in the system. Some respondents think that this expertise and motivation is currently lacking and do not have confidence in the system or organisations. Additionally, respondents believed that having appropriate infrastructure in place to ensure data security was also a key element for trust building. They stated that it should be very clear how data is being kept secure and there should be widespread awareness of this. Transparency on how information is collected, used and shared was also emphasised by respondents as a key element for building trust, including the organisations which data is shared with; which professionals have access to the data; and the outputs and outcomes of data sharing. The HSE website was specifically mentioned in that there is a distinct lack of information on the collection, use and sharing of health information which they felt did not lend itself to transparency. One respondent highlighted that transparency is a legal obligation and that the Government must ensure that people are sufficiently informed about data processing. It was acknowledged that building trust may take time as people want to see benefits in relation to data sharing.

Some respondents emphasised the need to consider the current capacity of the system in relation to informing the public. They noted that this will also take time and that it is important that the public are aware of this. In addition, respondents also noted that the infrastructure is not in place currently to support widespread data sharing and that the public need to be aware that there may be limits on data sharing until appropriate infrastructure is in place. Some respondents believed that putting appropriate structures and standards in place will build people's trust in the system over time.

There was general support for developing a national strategy for public engagement, although one respondent commented that the focus should be on developing a national public engagement action plan rather than a strategy. For some respondents, the proposed elements are considered do-able and the challenge will be to get them on the agenda of relevant national organisations. One respondent recommended that expertise in the area of effective engagement should be used to

help develop the strategy and plan for engagement. Many respondents commented that there was insufficient detail in the draft recommendations on how proposed actions would be implemented. One respondent commented that research should also be included in future plans or strategies due to its close connection to the topic. Many respondents commented that public engagement should be undertaken prior to making any decisions, such as developing legislation or introducing new eHealth initiatives. However, a number of respondents were concerned that *"the horse had already bolted"* as there had been a number of important developments recently, but insufficient engagement had been undertaken. They urged the prioritisation of public engagement before further advances were made in the area of health information legislation and policy to ensure a more inclusive approach, and to ensure the legislative framework is fit-for-purpose.

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

In examining the feedback from respondents, two distinct elements were identified that should be included in an effective public engagement strategy. The first relates to the need to increase awareness at a broad level on how health information is collected, used and shared. Respondents noted that people are becoming more aware of their data in all aspects and that there is an appetite for appropriate changes to be made. They believed that it is important to have a national conversation around this to address misinformation and ensure there is clarity at an individual level on what constitutes health and social care data and information; how health and social care data is shared; how it is used for direct care and for reasons beyond direct care; individual rights around health and social care data; and the risks and benefits of data sharing and paper versus electronic systems. Some respondents noted that these may be difficult conversations as it may open up different avenues of thought. However, they believe that a national debate is essential at this stage to build trust, and that "*we should not shy away from the difficult conversations that need to be had*" in terms of a rights-based approach and different uses of information. Respondents emphasised that building public awareness is an ongoing process and such approaches must be sustained and not considered one-off events. A number of respondents highlighted that many members of the public are not aware of the benefits of sharing data and that this should be a key part of the national conversation.

> *"There isn't a language of data sharing in Ireland and that's about communication. There is no emphasis on that and we are going to have to get that in there to build awareness and address these misconceptions."*

Respondents suggested a number of potential approaches to increase public awareness:

- short information clips for sharing on social media
- scenario-based animations of different data sharing processes which illustrate how sharing data can benefit direct care and its importance for beyond direct care
- appointing social media champions and getting relevant influencers involved that would appeal to different population groups
- developing an app called 'My Health Info'
- information adverts in local newspapers and libraries
- campaign across all media outlets
- information leaflets through the post
- national roadshows where engagement sessions are held in local venues across Ireland. An example was provided of roadshows undertaken by Science Foundation Ireland as part of their 'Creating Our Future' project which is a national conversation on research in Ireland and the role it can and should play in the future.

The second element of public engagement relates to effective consultation with key stakeholders in relation to key decisions in relation to the collection, use and sharing of health information. Respondents highlighted that public engagement should be a coordinated, collaborative exercise with all key stakeholders who are controllers and users of health information. They commented that it should not just involve the Department of Health, HIQA and HSE, as outlined in the draft recommendations, but needs to follow a multi-agency and multidisciplinary approach. People must be at the centre but buy-in from health and social care professionals will also be important. Potential stakeholders that were noted by respondents were: public and patient representatives, such as support and advocacy groups; professional medical bodies, such as the Royal College of Surgeons Ireland (RCSI) and Royal College of Physicians of Ireland (RCPI); World Health Organization's (WHO's) Age Friendly City and Counties Network; clinician representative bodies; community leaders; DPOs; HSE consent working group; Towards a European Health Data Space Joint Action Project (TEHDAS); HRB; NCCP; Data Protection Commission; Department of Children, Equality, Disability, Integration and Youth; Department of Justice; Department of Education; and Institute of Public Administration (IPA).

One respondent mentioned that the Department of Public Expenditure and Reform's Open Data Governance Board apply Gunning Principles regarding public

engagement, and that this might be an important practice to follow. The Gunning principles [26] are that: (i) consultation must take place when the proposal is still at a formative stage; (ii) sufficient reasons must be put forward for the proposal to allow for intelligent consideration and response; (iii) adequate time must be given for consideration and response; and (iv) the product of consultation must be conscientiously taken into account.

Some respondents emphasised the importance of employing good deliberative processes for effective engagement. Some respondents cited the citizen's jury approach employed by IPPOSI as valuable. Another respondent suggested a series of focus groups where facilitators listened first and explored any gaps in subsequent meetings. There was general agreement that there needs to be different approaches taken for different groups as some people are already engaged in this area but in others there is apathy and distrust. One respondent emphasised that *"there is not just one public, but many publics"* with many respondents commenting that intentional engagement is required with specific groups that may be disadvantaged or have specific needs. A number of respondents emphasised the need to ensure that all elements of engagement are accessible to different groups, and tailored to their needs, where relevant. They highlighted the importance of using plain English; ensuring resources are accessible to younger and older age groups; relevant to people that use health and social care services frequently; available in different languages; and accessible to those with digital and literacy issues. The National Disability Authority advised that a Universal Design approach must be taken in the design of public engagement, and were open to engaging in the future to provide advice in this area.

> *"We believe that the scale and importance of this topic is such that traditional public participation mechanisms (surveys, consultations) will not suffice. We need a whole government, inter-agency approach to kick start a national conversation about our health information future as a society, and as individuals."*

3.8 General feedback – aspects not covered

In this section of the feedback form, respondents were asked to provide feedback on any aspects that they did not think were covered in the draft recommendations. For this section, 17 comments were received through the public consultation process.

3.8.1 Feedback from public consultation

Respondents identified a number of areas which they believed were missing from the scope of the draft recommendations and required further consideration and discussion. A key gap for respondents was the collection, use and sharing of information in relation to children. Respondents wanted further details on how information relating to children fits within the model, especially in relation to children's rights, child protection information, and provision of consent.

> *"Please consider the engagement of the 1.25 million of our population under 16. Make reference to this population cohort."*

Another important gap for some respondents was the sharing of health with private and commercial organisations. Respondents were aware of instances where personal information might be shared with organisations such as health insurance agencies or private providers of health and social care services, and believed that it was important to be explicit about how this would be covered within the model.

Some respondents commented that partnerships with private and commercial organisations for research and innovation may be beneficial for particular groups. It was acknowledged, however, that there may be some sensitivities related to this with some respondents specifically mentioning genetic data. For example, one respondent commented that sharing genetic data with insurance companies may be an issue for people with disabilities.

> *"[The Recommendations] fail to adequately explore the potential for public-private-patient partnerships around the ethical sharing and use of health information, as part of a modern health information ecosystem."*

It was acknowledged by many respondents that research was not wholly in the scope of the proposed model. However, they still believed that greater discussion is needed on how research, including relevant legislation, governance structures, and practice fit within the proposed model, as research was seen as an important element of the broader landscape.

In addition, a number of respondents emphasised the need to address the issue of capacity to provide explicit consent. The Assisted Decision-Making Act 2015 was referenced by some respondents and mentioned that the HSE is in the final process

of developing two national consent policies, both for clinical care and for research. It was important that there was greater alignment with other relevant policies.

> *"Consent for data in healthcare cannot take place in a vacuum and it is often associated to other aspects of consent."*

An important gap that was identified by a number of respondents was the absence of discussion on the implementation of proposed recommendations. Many respondents commented on the need for a clear implementation plan that identified priorities and presented a staged approach for implementation — that is to say, short, medium and long-term priorities — as well as a presentation of key outputs and actions for each stage. It was acknowledged by respondents that some aspects will take a long time, such as legislation, but that there needs to be progress in the interim. For this reason, a staged implementation plan is important. Some respondents noted that there is potential to build on existing structures and learn from the experience of others, such as the CSO/HRB COVID-19 data research hub, Hospital In-Patient Enquiry Scheme (HIPE), National Cancer Registry, HRB's national health information systems, and the HRCDC. It was also acknowledged by a number of respondents that there are many examples of good practice across the country and that it is important to identify those examples, examine the barriers and facilitators to implementation, and adapt for a broader model.

> *"Need to look at the steps required to go from current situation to ideal situation and think about implementation – what needs to happen at each stage? Need to think of interim processes and not just the final outcome."*

Many respondents identified the need to ensure that any implementation plan is future-proofed. Respondents commented that the areas of health information and eHealth are rapidly changing and that it is important that any future model can adapt as needed. A number of respondents also emphasised that it is important that an implementation plan acknowledges the current capacity of the health and social care system. Currently, there is very little capacity or resources afforded to health information, data protection, or data sharing and any immediate plans must be aware of this as a key barrier to implementation.

In addition to these broad themes, a number of specific gaps were identified by respondents. Respondents wanted further details on where an opt-out consent model had been used in countries that must align with GDPR legislation; dynamic consent models in practice; and existing health information registries and databases, such as the CSO, COVID 19 data research hub, HIPE, National Cancer Registry, and the HRB's national health information systems. Respondents also wanted clarity on whether the model relates to deceased individuals, genetic and biological data, sharing information with family members, and the role of patient advocacy.

3.9 General feedback – challenges

In this section of the feedback form, respondents were asked to provide feedback on the challenges currently faced in collecting, using and sharing health information. For this section, 18 comments were received through the public consultation process.

3.9.1 Feedback from public consultation

Respondents identified a number of challenges in relation to the collection, use and sharing of health information in Ireland. For some respondents, the Irish health and social care system was considered a challenge due to the involvement of public, private and voluntary services in health and social care. Many of these respondents emphasised the need to allow information sharing across services, regardless whether they were public, private or voluntary, to ensure quality care, but they commented that this was often a challenge. A small number of respondents had some concerns about sharing information with 'for-profit' services, even hospitals, and with private agencies providing care in the community. They wanted strict controls to be in place for sharing information between public and private organisations, including restrictions on which private organisations may be able to receive information from public organisations.

The current information and communications technology (ICT) infrastructure in Ireland was viewed as inadequate for supporting effective data sharing while ensuring data privacy; this was a key challenge for many respondents and considered a critical barrier to progression in this area. There was an appetite for this inadequacy to be addressed as respondents saw the potential benefits for direct care. Particular issues that were mentioned by respondents were: inconsistent data protection standards, inconsistent technical and governance measures, lack of a unique identifier, and the lack of data standards which limits the ability to inform planning and policy in some instances.

The lack of investment in health information, both in terms of financial investment and professional expertise, was cited by many respondents as a key challenge. Respondents were keen for substantial investment in relation to infrastructure, expertise, and capacity at a service level. Respondents believed that this would increase overall capacity in the system and support data protection and improve data sharing and use. For some respondents, there was a lack of understanding as to who was responsible for data protection at a local level and they believed that such capacity needs to be addressed. There was a note of caution from some respondents, however, that there was a fear that such a project would be abandoned as substantial investment would be required.

"The combined lack of staff, space and ICT resources in Irish hospitals makes the collection of health information in Ireland very challenging."

Many respondents acknowledged that the current context in Ireland was challenging for the health and social care sectors, due to the COVID-19 pandemic and the 2021 cyberattack on the HSE. However, they acknowledged that these events have highlighted the critical importance of good health information and therefore should be seen as an optimal opportunity to build an effective and sustainable health information system. Some respondents noted that a number of new committees, such as the Data and Information Management committee in the HSE, and relevant structures, such as the CSO COVID-19 Data Research Hub, have recently been established. These provide an opportunity for learning and should be built upon to inform a new model for the collection, use and sharing of health information. Some respondents also commented that if new legislation is being introduced, it will be an opportunity to identify and address gaps in this area.

"The pandemic and the use of technology present an opportunity. They could help provide a service that improves people's experience. We could be leading post-COVID. Need to move forward now."

3.10 General feedback – 'opt-out' consent model

In this section of the feedback form, respondents were asked to provide feedback on a proposed 'opt-out' consent approach for using health information and how this might work in Ireland. For this section, 22 comments were received through the public consultation process.

3.10.1 Feedback from public consultation

There were mixed views on an 'opt-out' consent approach in relation to health information. Some respondents commented that opt-out consent does not exist. Under GDPR, consent has to be explicit and unambiguous which means that it *"must always be given through an opt-in, a declaration or an active motion".* While people may be able to opt-out of their information being processed under other legal bases cited in GDPR, this does not apply to the legal basis of consent. Consequently, these respondents believe that an 'opt-out' consent approach would not be valid in countries aligned with GDPR.

> *"There is no such thing as "opt-out consent" and we are concerned about this proposal."*

Some respondents were not in favour of an 'opt-out' approach due to its potential negative impact on direct care and patient safety, and its subsequent negative impact on the integrity of critical datasets for secondary use. Other respondents, however, were in favour of an 'opt-out' approach for certain secondary uses, for which complete datasets may not be required. If such an approach was in place, respondents commented that public engagement would be essential to ensure people were aware of how their data was being used and to ensure they understood their rights. Respondents also noted that the current system is not set up to offer different options and this needs to be considered.

> *"any 'opt-out' model should be accompanied with clear and transparent guidance and educational material for individuals explaining the implications of 'opting-out' and how their information will be managed, safeguarded and respected, if they opt-out."*

3.11 Other comments

In this section of the feedback form, respondents had the opportunity to outline any other comments about the draft recommendations. For this section, 17 comments were received through the public consultation process.

3.11.1 Feedback from public consultation

The majority of responses in this section related to topics that were addressed in other sections of the feedback form. In order to provide a comprehensive analysis of the feedback on each topic in this report, these responses were combined with the other sections to which they were relevant.

The remaining comments in this section welcomed the publication of the draft recommendations, as they felt this was an area where progress is urgently needed. One respondent commented that *"there is clearly a new momentum and appetite to make advances in this area"* and welcomed the draft recommendations as an impetus to drive developments. A number of respondents commented that they hoped there would be quick implementation of the draft recommendations to achieve the potential associated benefits.

> *"Well done, great to read the document and have learnt more about the possibilities that lie ahead. Really keen to see investment nationally to realise the potential."*

4. Conclusion and next steps

Overall, there was significant and substantial engagement from policy organisations, professional representative bodies, such as general practice and pharmacy, patient organisations, research bodies, public and private hospitals, service providers, members of the public and other key stakeholders on this topic. Feedback from the public consultation was largely supportive of the draft recommendations, but identified a number of areas where further clarity was required and greater consideration of the wider health information landscape was needed. The depth of the feedback indicates a very high level of interest in the need to put in place appropriate measures for the collection, use and sharing of health information to promote more effective data sharing while ensuring data protection.

HIQA has used this detailed feedback to inform the development of key considerations to inform policy for the collection, use and sharing of health information in Ireland. The draft key considerations were presented to the Advisory Group for review in May 2022 and members' feedback was subsequently incorporated. The key considerations were then sent for approval to the HIQA Executive Management Team, before approval by the HIQA Standards Information Research and Technology (SIRT) committee, a sub-committee of its Board, and then the HIQA Board. After the HIQA Board approved the key considerations document, it was submitted to the Minister for Health and published on the HIQA website.

HIQA would like to thank all of those who contributed to the development of these key considerations through the Advisory Group, public consultation, focus groups, as well as individual stakeholder meetings.

Glossary of Abbreviations

Abbreviation	Explanation
BIU	Business Information Unit
CSO	Central Statistics Office
DASSL	Data Access, Storage, Sharing and Linkage
DPC	Data Protection Commissioner
DPO	Data Protection Officer
DPIA	Data Protection Impact Assessment
EHDS	European Health Data Space
EHR	Electronic Health Record
EU	European Union
FOI	Freedom of Information
GDPR	General Data Protection Regulation
HIPE	Hospital In-Patient Enquiry Scheme
HIQA	Health Information and Quality Authority
HRB	Health Research Board
HRCDC	Health Research Consent Declaration Committee
HSE	Health Service Executive
ICT	Information Communication Technology
IPA	Institute of Public Administration
IPPOSI	The Irish Platform for Patient Organisations, Science and Industry
NCCP	National Cancer Control Programme
NCIS	National Cancer Information System
NUIG	National University of Ireland, Galway
RCPI	Royal College of Physicians of Ireland
RCSI	Royal College of Surgeons Ireland
SIRT	Standards Information Resource and Technology
SPMH	St. Patrick's Mental Health Services
TEHDAS	Towards the European Health Data Space
UK	United Kingdom
WHO	World Health Organization

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Appendix 1 – Membership of the Advisory Group

Name	Nominated representative
Alan Cahill	Department of Health *Senior Statistician, Statistics and Analytics Unit*
Alan Reilly	Irish Pharmacy Union *Head of Information and Technology*
Anne Lynott	Institute of Community Health Nursing *Director, Public Health Nursing*
Collette Tully	Royal College of Surgeons Ireland *Executive Director, National Office of Clinical Audit (NOCA)*
Colm Lawlor	Nursing and Midwifery Board of Ireland (NMBI) *Data Protection Officer*
David Hanlon	Health Service Executive *Clinical advisor to HSE/Summary Care Record team*
Derick Mitchell	Irish Platform for Patients' Organisations Science & Industry, IPPOSI *Chief Executive Officer*
Eileen O'Sullivan	Irish Platform for Patients' Organisations Science & Industry, IPPOSI *Patient Representative*
Fergus Ó'Cuanacháin	Child and Family Agency (Tusla) *Director of ICT*
Jacinta Hastings	National Patient Forum *Patient Representative*
Joe Ryan	Health Service Executive *National Director - Operational Performance and Integration*
John Sweeney	Irish College of General Practitioners *National ICT Project Manager*
Kieran Culhane	Central Statistics Office *Senior Statistician, Statistical System Coordination Unit*

Niall Sinnott	Department of Health *Head of eHealth and Information Policy*
Noreen Noonan	Health Service Executive *ICT Delivery Director for Public Health*
Peter Connolly	Health Service Executive *Head of Enterprise Architecture & the Design Authority, Office of the Chief Information Officer*
Roisin Doherty	Health Service Executive *ICT Director Access to Information (A2I) and HIDs (Health Identifier Programme)*
Sarah Craig	Health Research Board *Head of National Health Information Systems*
Sheila Fitzgerald	Irish Platform for Patients' Organisations Science & Industry, IPPOSI *Patient Representative*
Simon Woodworth	Health Information Systems Research Centre UCC *Director, Health Information Systems Research Centre*
Suzanne Browne	Health Informatics Society of Ireland (HISI) Nurses and Midwives *Chief Nursing Informatics Officer*
Yvonne Goff	Health Service Executive *National Director - Change and Innovation*
Zetti Azvee	The College of Psychiatrists of Ireland *College of Psychiatrists Ireland (CPSYCHI) representative*

Appendix 2 – Summary of findings from the National Public Engagement on Health Information

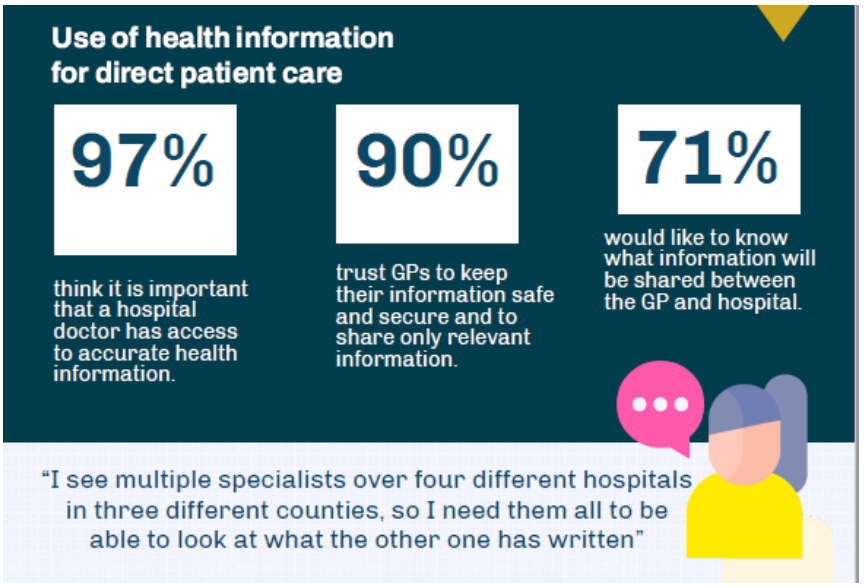
HIQA, in partnership with the Department of Health and the HSE, undertook a national public engagement in 2020 and 2021 to inform the development of the key considerations. The aim of the national public engagement on health information was to understand the opinions and attitudes of the Irish public in relation to the collection, use and sharing of personal health information. An overview of the number of people involved in the public engagement is presented in Figure 1.

Figure 1: National public engagement on health information

This public engagement identified that people see the importance of using personal health information for their direct care and purposes beyond their direct care, but that they want to be assured that safeguards are in place to keep their information secure and that their right to privacy will be protected. The focus groups found that people were mostly concerned about the security of their sensitive information, such as information related to mental or sexual health. The survey findings show that 88% of people want to be informed about how their information would be kept safe and secure; this would make them more comfortable with sharing their health information. The public engagement also shows that people think it is important for health information to be collected, used and shared by healthcare professionals who are providing them with care. However, they would like to be more informed about who will use it and for what purpose. For example, 71% would like to know more about what information is shared between healthcare professionals who are treating

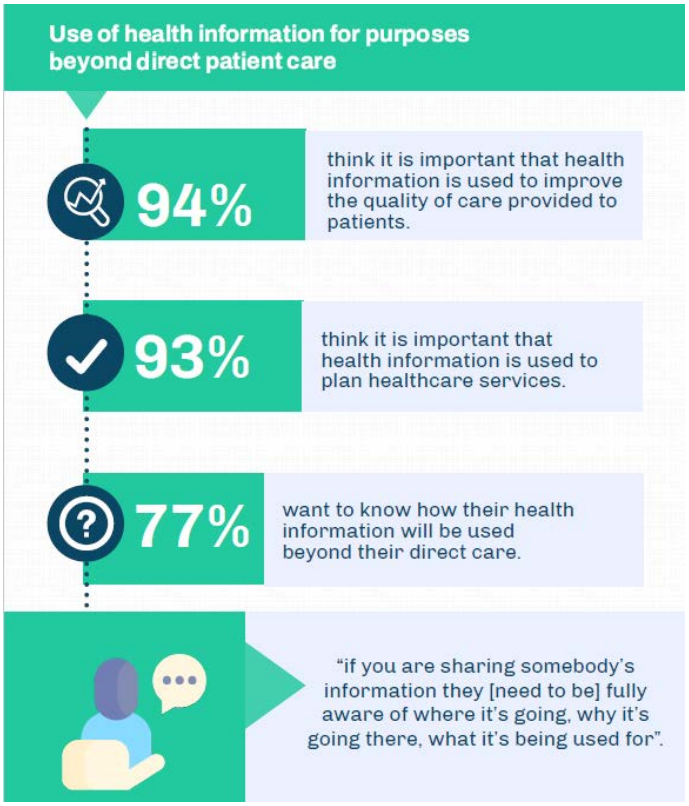
them, and 82% of people think that it is important to be able to see who has accessed their records. Additional findings are presented in Figure 2.

Figure 2: Findings on use of information for direct care



The findings show that people see the importance of using health information for purposes beyond their direct care, such as for quality improvement, health service planning and research. The focus groups found that people are generally happy for their information to be used for these purposes as long as it provides personal or public benefit. People are more comfortable with their information being used if identifiable information has been removed. The survey findings show that 77% of people would like to be more informed about how their information will be used for purposes beyond their direct care. Additional findings are presented in Figure 3.

Figure 3: Findings on use of information for purposes beyond direct care



The findings also show that people are comfortable with their health information being stored and shared electronically, and see the benefits of moving towards a more integrated digital healthcare system, but they need to be assured that safeguards are in place to protect their privacy. People consider certain types of information to be more sensitive than others, and would like to have some control over who can access it. People are mostly concerned about being judged and discriminated against as a result of this information being viewed. People want to be able to access their own health information to allow them to be more actively involved in their own care. The focus groups highlighted that health information must be accessible to everyone, and there is a need to consider different formats for people with specific needs. People also want to be actively involved in any decisions that are made about the collection, use and sharing of their health information. Additional findings are presented in Figure 4.

Figure 4: Findings in relation to digital records

Appendix 3 – Public consultation feedback form

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

The Health Information and Quality Authority (HIQA) is holding a public consultation to give people an opportunity to provide feedback on the draft recommendations for a consent model for the collection, use and sharing of health information in Ireland.

Your views are very important to us, and we will carefully assess all feedback received and use it to help develop the final recommendations which will be submitted to the Minister for Health for approval.

Please note: the focus for this consultation is the content and structure of the draft recommendations. The final wording, design and layout of the recommendations will be developed after the public consultation. We welcome responses to all questions, and there will be an opportunity at the end of the survey to provide any additional general comments.

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

Data Protection and Freedom of Information

- HIQA will only collect personal information during this consultation for the purposes of verifying your feedback or where you have indicated that you would like to be contacted to partake in future stakeholder engagement.
- If you have any concerns regarding your data, please contact HIQA's Information Governance and Assurance Manager on infogovernance@hiqa.ie.
- Please note that HIQA is subject to the Freedom of Information (FOI) Act and the statutory Code of Practice in relation to FOI. Following the consultation, we will publish a statement of outcomes document summarising the responses received, which will include the names and types of organisations that submitted feedback to us.
- For that reason, it would be helpful if you could explain to us if you regard the information you have provided us as being confidential or commercially sensitive. If we receive a request for disclosure of the information under FOI, we will take full account of your explanation, but we cannot give you an assurance that confidentiality can be maintained in all circumstances.

Instructions for submitting feedback

- This public consultation is in relation to the draft recommendations for a consent model for the collection, use and sharing of health information in Ireland. You can find the draft recommendations, alongside the evidence synthesis paper that has informed these recommendations, on www.hiqa.ie.
- There is also an option to complete a fully online survey, which you can find here.
- If you are commenting in a personal capacity, there is no need to provide your name or any other personal information. However, if you would like to be contacted to take part in future stakeholder engagement, there is an option to provide your name and contact number.
- If you are commenting on behalf of an organisation, please combine all feedback from your organisation into one submission. In this case, we will request a name and contact number for a designated representative from your organisation in case we need to verify the authenticity of your contribution.
- Do not paste other tables into the boxes already provided — type directly into the box as the box expands.
- Please spell out any abbreviations that you use.

1. About you

1.1 In what capacity are you providing this feedback?

☐ As a member of the public

☐ In a professional capacity

1.2 If you are completing this in a professional capacity, please specify your current role:

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

☐ As an individual

☐ On behalf of an organisation

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

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

2. Your feedback on the draft recommendations

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

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

Recommendation 1: to define key concepts in legislation.

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

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

Recommendation 2: a rights-based approach.

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

Recommendation 3: to define the consent model and exemptions in legislation

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

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

Recommendations 4 and 5: Legislation

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

Recommendation 6: Governance structures

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

Recommendations 7 and 8: Technical and operational requirements

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

Recommendations 9 and 10: Public engagement

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

3. General feedback

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

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

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

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

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

Appendix 4 – Organisations that responded to the public consultation

The following organisations submitted a response to HIQA's public consultation on draft recommendations on the collection, use and sharing of health information:

- Central Statistics Office
- Children's Health Ireland
- Data Protection Commission
- Digital Rights Ireland and Irish Council of Civil Liberties
- Donegal Community Hospital
- Health Research Board
- Health Research Consent Declaration Committee
- Hospital In-Patient Enquiry (HIPE) Office (HSE)
- Irish Platform for Patient Organisations, Science & Industry
- National Biobank Working Group and the Trinity St. James's Biobank Network
- National Cancer Control Programme
- National Cancer Registry of Ireland
- National Disability Authority
- National Office of Clinical Audit
- National Office for Human Rights and Equality Policy (HSE)
- National Perinatal Epidemiology Centre
- National Suicide Research Foundation
- Office of the Chief Clinical Officer (HSE)
- Pharmaceutical Society of Ireland
- Royal College of Physicians of Ireland
- St James's Hospital, Dublin
- St Patrick's Mental Health Services
- Trilateral Research.

Appendix 5 – Individual Stakeholder Meetings

As part of this project, HIQA stakeholder meetings with representatives from the following organisations:

- Central Statistics Office
- DASSL Working Group and Irish Centre for High-End Computing, National University of Ireland Galway (NUIG)
- Data Protection Commission
- Data Protection Office (HSE)
- Digital Rights Ireland
- Health Research Board
- Health Research Consent Declaration Committee
- Office of the Chief Information Officer (HSE)
- Office of the National Director, Operational Performance & Integration (HSE)
- Tusla.

Published by the Health Information and Quality Authority (HIQA).

For further information please contact:
Health Information and Quality Authority
George's Court, George's Lane
Smithfield, Dublin 7
D07 E98Y

+353 (0)1 8147400
info@hiqa.ie
www.hiqa.ie