



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Key considerations to inform policy for the collection, use and sharing of health and social care 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.

It has been well documented that further clarity is required on the collection, use and sharing of information in Ireland through a robust legislative framework that ensures data protection while also promotes better re-use of existing data.^(2,3,4) To address these issues, in January 2022, the Department of Health announced plans to develop new health information-specific legislation and in April 2022, the Minister for Health received Cabinet approval to develop the General Scheme of a Health Information Bill. This discussion paper will outline the findings from extensive consultation with the public, and key national and international stakeholders on this topic to identify key considerations to inform policy for the collection, use and sharing of health information in Ireland.

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

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Executive summary

Currently in Ireland, health information systems, policies and strategies are considered to be immature in terms of development compared to other European and OECD* countries.^(3,5,6,7) Electronic and digital advances are viewed as one of the cornerstones of providing safe and efficient care.^(2,3) The use and re-use of health and social care data is essential for care provision and other important uses of health information, such as the planning and management of services, public health, policy-making and research.⁽²⁾ The ultimate goal for health information is to collect once, and re-use many times for different purposes. To date, there has been an inadequate approach to re-using health and social care data in Ireland. This is primarily due to poor integration of systems, lack of standardisation of data, and underdeveloped infrastructure to support safe data sharing.^(2,3)

Although it has been recognised in many reports over the past 18 years that improved health information systems are needed, recent unprecedented events have heightened awareness in this area. The need for co-operation and a rapid response for improvements to how data is collected, used and shared has never been more obvious.^(3,8,9,10) Firstly, the COVID-19 pandemic has focused attention on the importance of data sharing for public health and the need to make data accessible for collaborative and timely research.⁽⁶⁾ Secondly, the cyber security breach within the HSE in 2021 emphasised that trust in data and information security, and especially in the protection of personal data, is essential for individuals in their decision to support and allow data sharing for further use.⁽¹¹⁾ This paper outlines the key elements required to build trust in this area, which will only be achieved by ensuring that the appropriate structures, systems and safeguards are in place.

This is an opportune time for change as there is strong evidence to suggest that Irish citizens understand the need for good health information and welcome a move towards the use of electronic records.^(12,13) The vast majority of people who took part in a national public engagement on health information, published in 2021, said they believe that electronic records are required: to allow for easier sharing of health information between healthcare professionals; to give a complete and up-to-date account of a person's health which could contribute to timely and appropriate care; and to make it easier for people to access their own information.⁽¹²⁾

Significant progress in the area of health information in Ireland is also required given the imminent policy changes occurring at a European level. This includes advances in the development of the European Health Data Space (EHDS), forthcoming European legislation focusing on re-use of data and encouraging better data sharing across sectors, and the European Union (EU) Path to the Digital Decade policy programme

* OECD: Organisation for Economic Co-operation and Development

setting a target that all citizens should have access to their electronic records by 2030.^(14,15,16,17) National policy-makers in Ireland have recognised the urgent need to revise and deliver on new health information strategy, policy and legislation.^(4,18,19,20)

This paper sets out the key policy considerations needed to drive transformational change in relation to the collection, use and sharing of health information in Ireland. It outlines four areas that advances are required in: undertaking effective engagement; developing a solid legislative framework; enhancing governance structures; and delivering technical and operational requirements. Each of these four areas as discussed in this paper are interdependent, meaning failure to address one area could impede or stall progress in the other areas. A solid legislative framework is the foundation for change as certain legal provisions will be the enablers for progression and developments in the other areas. Similarly, failure to undertake effective engagement will undermine public trust, impacting on the successful implementation of health information initiatives and shaping whether legislation is fit-for-purpose. Progress in all four areas is ultimately needed to promote a modern and future-focused data-rich environment for health and social care in Ireland. The key considerations for each of the four areas will be summarised in turn below.

Key considerations to inform policy

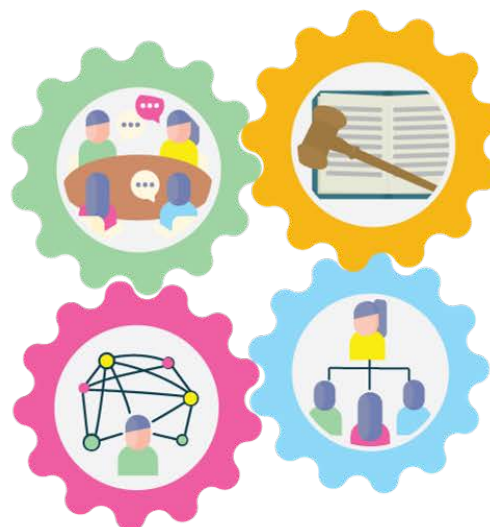
COLLECTION, USE and SHARING of health and social care information

Effective engagement

Coordinated and ongoing public and professional engagement is essential to build trust and ensure success of new initiatives. This requires strategic leadership and a clear strategy and implementation plan.

Technical & operational requirements

Infrastructure to support data use is needed, including a citizen health portal and data sharing service. These must be underpinned by technical, security and data quality standards. Appropriate resources must be allocated for implementation.



Legislative framework

New legislation should address the health information landscape in a holistic way and act as a catalyst for a more integrated health and social care sector. Regulations, guidelines, codes of practice and policy should be developed to support implementation.

Governance structures

Governance structures for the collection, use and sharing of health information, including a national strategic entity and relevant oversight committees, are critical. They must be underpinned by expertise at a local level, and supported by a standards-based data governance framework.

1. Engagement – building trust and transparency

Findings from the extensive evidence used to inform this paper highlighted very strongly that effective engagement, with both the public and health and social care professionals, in relation to health information is an essential element to build trust and to ensure successful progress of new developments in this area. The importance of public engagement has also been acknowledged in the Sláintecare Implementation Strategy and Action Plan 2021-2023 and the Digital Ireland Framework.^(18,19) The recent national public engagement on health information and citizen's juries has developed an initial understanding of the opinions and needs of the public in this area, noting a desire for better engagement, including enhanced transparency and control regarding how information is used.^(12,13)

Involving people in important decisions about their health information and ensuring that their rights in relation to their information are upheld is crucial, and will ensure that new technologies and initiatives are implemented in a way that is acceptable to the public as well as meeting professionals' requirements to support safe and effective care.^(2,21) Establishing a co-created model for health information, where engagement is the first step in the process and findings are used to inform developments, is key to building and maintaining trust, and responding to people's needs. Engagement must be undertaken in an independent, transparent, meaningful and authentic way. Furthermore, as systems evolve and practices change, ongoing engagement is necessary to monitor and evaluate the public's and professionals' views and opinions in this area.

This is an opportune time to engage meaningfully with the public and professionals in advance of the new health information legislation and to inform the significant developments on how health information is collected, used and shared in Ireland. A national health information engagement strategy and implementation plan is required to prioritise and coordinate efforts in this area. This strategy and plan should be organised with time-bound milestones and actionable deliverables to ensure progress can be assessed. The responsibility for the development of a national health information engagement strategy needs to be led by the Department of Health or, once established, by the national strategic entity for health information. In essence, a cross-government strategic approach is required to ensure consistency and stability of engagement over time. Co-design and co-monitoring with citizens and professionals should be the basis of the strategy to support successful implementation of changes or initiatives, and realise the benefits from the use and sharing of health information.

2. Legislative framework for health information

The forthcoming European-level policy changes will have significant impact on the

use and sharing of health information in Ireland. The consequence of these EU policy developments is that Ireland needs to expedite the development of new national legislation in relation to health information, and rapidly update national health information strategy and policy to keep pace with the changes occurring in this area. The decision by the Department of Health to develop health information-specific legislation is an opportunity to rethink the health information landscape in a holistic way, being the catalyst for a more integrated health and social care sector. To date, legislation has primarily focused on data protection. Policy-makers now need to consider how to safely and effectively promote better data sharing to achieve optimal safeguards and a balance between data protection and data sharing. This can be achieved by establishing a legal framework for appropriate governance structures and infrastructure. The new legislation needs to be comprehensive, and consider the variety of data sources and different uses of health information. This should include the use of information for both direct care and for secondary purposes, including data collected through key national data collections and the re-use of all existing and future data sources.

The new legislation needs to further regulate the sharing of data across public, private and voluntary organisations through the development of a national data governance framework. This will become critical as eHealth initiatives are implemented, and there may be an obligation on healthcare professionals to submit data to national eHealth systems. Therefore, the establishment of clear 'rules' for authorisation, access and control of such data will be an essential element to successful implementation. This framework needs to consider the processing of both paper and electronic records. The need to comply with a national information governance framework for health and social care should be mandated through the new health information legislation. However, the specific details of the framework should be outlined in supporting documents, such as regulations, codes of practice and guidance, allowing for flexibility in a rapidly-changing landscape. The data governance framework should also consider specific rules for the implementation of an individual health identifier in line with the relevant legislation.

In addition, the new legislation needs to include provisions to establish advanced governance structures and appropriate infrastructure to ensure that existing and future data sources can be used to their full potential. The establishment of a national strategic entity for health information, and the associated governance structures, should be outlined in the new legislation (this will be discussed further in the next section - governance structures). The development of new legislation also provides an opportunity to prioritise key national data collections where comprehensive data is required to inform planning and management of services and to identify what provisions need to be included in the legislation to establish a legal obligation for the collection, use and sharing of key national data. Furthermore, a

more structured and coordinated approach to the management of national data collections, in line with international best practice, should also be considered along with the appropriate governance structures required to support this; this should to be outlined in the new legislation. The new legislation should also provide a legal basis for the processing of data to perform a de-identification and linkage service by the national strategic entity for health information, as well as the specific organisational governance and information governance arrangements for the management of this service.

A rights-based approach should underpin the new legislation and the development process should sufficiently incorporate the citizen's perspective. As technologies continue to develop and the potential to use and share health information increases, the rights of individuals in relation to their personal information should be openly discussed, as well as the choices they have about this. Policy-makers need to determine their approach to rights, through effective engagement, and the findings need to be reflected in a new legislative framework and policy, and any conflicts in existing legislation need to be addressed.

As it has been acknowledged that the complexity of GDPR has presented challenges in terms of implementation, supporting instruments such as codes of practice and guidance should be developed to provide clarity on the application of GDPR for health and social care professionals. These supporting documents should outline what good practice is for those working in health and social care services; defining a data governance framework for the collection, use and sharing of information across the public, private and voluntary settings; and developing a common understanding around individuals' rights in relation to health information. Ultimately, a legislative framework should provide clarity and guidance on the rules for processing health information, which will in turn provide professionals with the knowledge and confidence to share confidential information in the best interest of patients and members of the public.

3. Governance structures

The effective use and sharing of information also depends on accountability which is essential to build trust and confidence. A national strategic entity for health information should be established with oversight for all aspects of health information. This entity should have strong legislative powers and have a strategic role to advance necessary developments in the area of health information in Ireland. The remit of the national strategic entity should cover three specific areas: eHealth development and implementation; the centralised coordination and governance of national data collections; and the management of a national data sharing service which builds on the DASSL (Data Access, Storage, Sharing and Linkage) proof of concept model, and has responsibility for managing activities such as de-identifying

and linking data, and creating a safe haven for data sharing.

Consideration must be given to the roles and responsibilities of the entity, links with existing entities in the health and social care sector, the proposed reporting structure and funding sources. It is also important that the development of these structures have adequate input and representation from a wide range of stakeholders, including citizens and representatives from the public, voluntary and private health and social care sectors.

As health and social care systems mature, the governance and coordination of key national data collections should be a key objective of this national health information entity. If forthcoming legislation mandates the submission of data from public, private and voluntary health and social care services, consideration needs to be given to the appropriate governance structures and future arrangements to support key national data collections. For example, restructuring of key national data collections may be required for the collection of data across all sectors in the processing of national-level data. A coordinated approach, as adopted by other countries, will have significant benefits, particularly in promoting the standardisation of policies and procedures to support the mandated submission of data across key national data collections.⁽²²⁾

As part of the establishment of the national strategic entity for health information, specific governance structures for the secondary use of information should be put in place. These governance structures are important not only to promote the safe and effective secondary use of information, but also to ensure expertise and capabilities are developed in line with international best practice. Extending the DASSL model beyond research will be critical to Ireland's ability to re-use existing data and align with developments at a European level. Learnings from the current DASSL proof of concept project will be central to guide the development of this service. Policy-makers must first consider the different governance options to identify the most appropriate operational model for the Irish context. The experience of the Central Statistics Office (CSO) and the Health Research Board (HRB) from implementing the COVID-19 Research Data Hub will also be valuable to guide progress.

The national strategic entity for health information should also have responsibility for implementing a national data governance framework. As such, a specific committee for the national data governance framework, which reports into an oversight committee, will be required to guide the development and implementation of the framework. A significant body of work is required to ensure the framework is underpinned by robust data standards that clearly set out the conditions for the collection, use and sharing of health information across public, private and voluntary services. A data governance framework will be essential to support an integrated care system and to ensure a consistent approach to the collection, use and sharing

of data across services and national data collections. Finally, coordination and oversight is also required to plan and manage investment in human resourcing, education and training to build capacity and expertise within the national strategic entity for health information and at a local level.

4. Infrastructure and operational requirements

Ireland is at an early stage of developing a policy for eHealth. The current health information environment lags significantly behind European counterparts.⁽⁵⁾ In order to provide citizens with access to their health information and to comply with forthcoming legislation on re-use of data, two initiatives need to be prioritised and rapidly progressed:

1. a citizen health portal, and
2. appropriate infrastructure for better secondary use of data (an extended DASSL model).

The development of a citizen health portal will be critical to support people's rights in relation to their health information. However, in-depth engagement needs to be undertaken with members of the public and health and social care professionals to inform the citizen health portal at all stages of development and implementation.[†] In addition, to support the effective and secure use of data for secondary purposes, appropriate infrastructure must be put in place to enable a national data sharing and linkage service, as managed by the national strategic entity for health information.

Development of a citizen health portal and infrastructure for a national data sharing and linkage service will only be successful if the operational capacity is also enhanced. Specifically, a national approach to developing health information standards is essential to achieve successful implementation. National-level improvements to data interoperability, data security and data quality are critical features to support the technical infrastructure. Given the cyber security attack in 2021, trust in security and the protection of personal data is an essential priority.^(6,23) Therefore, work on developing and implementing standards needs to occur in tandem with the technical developments. The standards should be incorporated into the national data governance framework to ensure consistent practices are adopted across all organisations collecting, using and sharing health information.

In addition, it is also essential that appropriate operational resources are put in place to support successful implementation of technical solutions and to outline

[†] As part of HIQA's 2022 Business Plan, recommendations are being developed on the implementation of a national portal for health and social care. A key stage of developing these recommendations is to undertake a national engagement with members of the public and care professionals to capture their opinions on the important considerations for the development and implementation of a health and social care portal in Ireland.

responsibilities and obligations in relation to the collection, use and sharing of health information. Furthermore, a process of 'benefits realisation' and rationalisation will help to identify the resources required and potential opportunities for consolidating, transferring or expanding resources to support implementation. Adequate investment and effective strategic leadership will be crucial to guide change and ensure technical and legislative advances are implementable at an operational level.

1. Introduction

The aim of this paper is to discuss key considerations to inform policy for the collection, use and sharing of health and social care information in Ireland (see **Appendix 1** for the methodology and stages of development of this discussion paper). Safe, effective, efficient and sustainable health and social care systems are highly dependent on good quality data and information.[‡]

For the remainder of this document:

Health information will be used to describe health and social care information. Please see glossary of terms for definition of health information.

A major challenge in Ireland is striving to achieve an appropriate balance between the protection of privacy and confidentiality in relation to personal health information, and the use and sharing of such information to improve care. The processing of health information is critical for managing direct care (primary use) and also for reasons beyond direct care (secondary use), such as for the management and planning of services, improvement of health and social care systems, medical device monitoring, public health, disease registries and research. Advances in eHealth have the potential to improve the quality of care and also promote better use of resources by providing information when and where needed. However, the consequence is that vast amounts of information will be available to use and share electronically. A recent national public engagement in Ireland on this topic identified that individuals welcome a move towards the use of electronic records; however, they want to be more informed about when and how their information is shared.⁽¹²⁾ There is also a need to provide assurances that adequate security measures are in place to protect against risks associated with the collection, use and sharing of both paper-based and electronic records.

1.1 Why change is needed?

The data environment and information needs have changed significantly in recent years and will keep changing to suit technological advances and associated needs and requirements of individuals and society.[§] The current legislation, governance systems and infrastructure do not have the flexibility needed to respond to current or future changes, hindering the value Irish citizens can gain from better use of their

[‡] Examples of sources of health data and information include health records, medical images, prescriptions, laboratory reports, claims and reimbursement data, patient reported outcomes, and data from wellness devices.

[§] For example, telemedicine has enabled clinicians to monitor readings from digital devices worn by patients in remote locations which can be transferred and uploaded to electronic records to inform clinical decision making.

health and social care information.

Ireland is at the formulation stage of developing a policy for electronic health records and is one of just two countries in the EU currently without a system that provides citizens with access to their electronic records^{**}.^(7,19) The health information system in Ireland is considered to be quite immature in terms of its stage of development, and lags significantly behind European counterparts.⁽⁵⁾ Significant progress is therefore required given the imminent policy changes occurring at a European level with regard to the European Health Data Space (EHDS) and forthcoming European legislation which will focus on the re-use of data and encourage better data sharing across sectors.^(15,16)

In addition, and of significant relevance for Ireland, is the recent proposal by the European Commission 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 that 100% of citizens will have access to their electronic records by 2030.⁽¹⁷⁾ This will place a renewed emphasis on the need to develop and enhance eHealth initiatives, which were proposed through the Sláintecare Programme implementation strategies.⁽¹⁸⁾ These EU policy developments make it clear that Ireland needs to expedite the development of new national legislation in relation to health information, as well as update national health information strategy and policy.⁽²⁰⁾ In addition, the ‘Harnessing Digital - Digital Ireland Framework’ identifies eHealth as a priority to provide consistent and integrated digital solutions.⁽¹⁹⁾ The strategy recognises the huge potential for digital technologies in the health and social care sector as they ‘can empower citizens to monitor their health status, adapt their lifestyles, support independent living, prevent non-communicable diseases, and bring efficiency to health and care providers and health systems’. In order to achieve this, the Government identifies the need to revise and deliver a renewed eHealth Strategy by 2030.⁽¹⁹⁾

The governance structure of care is unique within the Irish context as there are three categories of organisations that provide health and social care services: public, voluntary and private. These are all funded and governed in different ways which impacts the manner in which health information is collected, used and shared. Health information is routinely shared between private organisations, such as general practitioner (GP) practices, pharmacies, hospitals, and nursing homes, to public health and social care services, as well as voluntary-run health services. There are also many arrangements in place to use existing data for secondary purposes.

^{**} Of the countries surveyed, national systems are in place in 22 member states, regional systems are in place in five member states, an individual-level service is in place in one member state, and other types of systems are in place in five member states.

For example, there are over 85 national data collections in Ireland, with a large number of different ‘managing organisations’ responsible for collecting and storing these datasets including the HSE, Tusla, Government departments, independent organisations outside of the HSE, charities, hospitals and universities. This makes the governance of health information for secondary use in Ireland very complex, as much of this work is occurring in silos with little national coordination of these existing data sources. The lack of a national strategic entity for health information in Ireland has been identified as a reason for an inadequate health information system.⁽³⁾

It is well accepted that improved access and better use of data can lead to better health outcomes by improving the quality and efficiency of services, and ensuring action and resources are focused in the right places to achieve the best outcomes for individuals and society.⁽²⁾ However, transparency, trust, confidence, and integrity must be at the centre of any decisions around the use and sharing of health and social care data. This will only be achieved if data is kept safe, in a way that protects privacy and confidentiality. There also needs to be transparency in the way data is collected, used and shared, and citizens need assurance that the appropriate safeguards and protections are in place through the establishment of a strong legal framework, robust governance structures and enhanced infrastructure and resources. Given the cyber security breach which occurred within the HSE in 2021, trust in data and information security — and especially in the protection of personal data — is essential for individuals in their decision to share data for further use. In addition, there must be assurance that data use is appropriate and meets peoples’ expectations. This can only be achieved by listening to the needs and requirements of the public and professionals. To achieve this, national conversations and debates need to be facilitated to explore core issues such as data sharing, a rights-based approach to health information, data altruism, and data governance across public, private and voluntary organisations, to mention but a few.

To date, there has been a cautious and conservative approach to data re-use in Ireland which is limited by the poor integration of systems, lack of standardisation of data and underdeveloped infrastructure to support safe data sharing. This impacts on our ability to identify new insights and in turn the chance to improve health and social care outcomes. However, for innovation to occur, the legal framework, governance structure and infrastructure need to be adequate to align with expectations and needs of the public and professionals. If these strong foundations and safeguards are not in place, then data will not be used safely, and public trust and confidence will erode further. Change is ultimately needed to reflect a modern and future-focused data-rich environment.

1.2 Alignment with the paper on reform of health information system in Ireland

Over the last two decades, numerous national reports and policies have highlighted the critical need to improve health information in Ireland.^(3,9,24) A recent paper published by HIQA⁽³⁾ identified that there are basic requirements that underpin a health information system and outlined a number of core enablers required to develop a robust national health information system:

- 1. Strategy:** clear strategy for national health information underpinned by strong political commitment and aligned with the Sláintecare objectives.
- 2. Strategic Leadership and Governance:** need for a national strategic entity with a legislative remit to provide leadership and governance to support the collection, use and sharing of health information in Ireland across sectors.
- 3. Legislation:** a legislative framework is required to clearly set out how information should be collected, used and shared for primary and secondary use and should cover all data flows from primary care, community services, public and private hospitals.
- 4. Workforce:** a more strategic approach is required to the allocation of resources in health information to continue the delivery and operation of national health information systems, while also ensuring long-term strategic objectives for health information are met.
- 5. Standards and Interoperability:** a clear policy decision is required for a health information standards function which needs to be supported through legislation and resourcing, and should include both the public and private health and social care sector, including public sector services outside of the HSE.
- 6. Health Information Infrastructure and Security:** a need for continuous investment and strengthening of a secure health information infrastructure to support the integration of people's health information across public and private healthcare systems.

These core enablers outlined in HIQA's paper on health information system reform align closely with the findings from the extensive engagement that was undertaken to inform this paper on key considerations to inform policy.

1.3 Key considerations to inform policy

This paper on key considerations to inform policy for the collection, use and sharing of health and social care information will delve deeper into understanding the requirements for the safe and effective collection, use and sharing of health

information. It builds on some of the topics discussed in the paper on the reform of the health information systems in Ireland⁽³⁾ and focuses on the following four themes: effective engagement; legislative framework for health information; governance structures to support health information; and technical infrastructure and operational capacity.

The key considerations have been informed by international evidence, a review of the current situation in Ireland, and engagement with a broad range of national and international stakeholders (see **Appendix 1**). See also the associated [evidence synthesis paper](#) and a detailed description of the [international evidence](#) that has informed this paper.^(2,21)

The following sections outline key policy considerations for the collection, use and sharing of health information in Ireland:

- **Section 2:** Effective engagement – building trust and transparency
- **Section 3:** Legislative framework for health information
- **Section 4:** Governance structures to support health information
- **Section 5:** Technical infrastructure and operational capacity
- **Section 6:** Conclusion.

2. Effective engagement: building trust and ensuring transparency

1 Coordinated and ongoing public and professional engagement is a critical element of building trust, as well as essential to the success of new developments such as legislation and eHealth initiatives. Effective and meaningful engagement requires a clear strategy and implementation plan for which strategic leadership is essential.

2.1 Strategy and leadership for effective engagement

Findings from the international evidence, public consultation and key stakeholder interviews undertaken to inform this paper strongly indicate that effective engagement, with both the public and health and social care professionals, is an essential element of building trust in health information, as well as important to the success of new developments in this area.⁽²⁾ The need for political leadership to drive such engagement also emerged as a strong finding.

Engagement was viewed as an essential first step by respondents of the public consultation, and some feared that it is not being prioritised by policy-makers in the area of health information. Many also emphasised that engagement must be genuine and that the focus must be realistic relating to where change is possible, as alternatively the process would have the unintended consequence of undermining trust. Respondents emphasised that engagement should not be undertaken at the end of a project after key decisions have already been decided, but that it should be prioritised from the outset to ensure that any new legislation developed will be fit-for-purpose, that changes to how information is collected, used and shared will be supported, and that eHealth initiatives will be successfully adopted and implemented. This is critically important now as the Government has committed to developing new health information legislation in 2022 and progressing the Digital Ireland Framework.^(4,19) This provides an opportune time to engage meaningfully in advance of the legislation development and the forthcoming changes required in the area of health information in Ireland.

Respondents to the public consultation for this paper also believed that coordinated and ongoing public engagement in this area is essential. This is further supported by international evidence which shows that countries with mature health information systems have high levels of public trust that has been built-up and maintained over time through a process of ongoing engagement, using approaches like co-design and collaborative methods to design and develop initiatives.⁽³⁾ In Estonia, for example, public engagement and trust building are viewed as core components of health and social care initiatives. In the development of the national electronic health record

(EHR), engagement was conducted prior to implementation which led to a greater understanding of needs and building of trust from the outset. There is also a continued focus on engagement with the delivery of digital literacy sessions targeting citizens of most need.⁽²⁾ Therefore, effective and meaningful engagement requires a clear strategy and implementation plan, and this needs to be adequately resourced and funded. In addition, political buy-in and leadership is essential.

Internationally, there are a number of high-profile examples where major eHealth initiatives and digital technologies failed in some countries due to a lack of effective public engagement and an understanding of the needs and requirements of the public. In Australia, a lack of effective engagement with both the public and professionals resulted in poor uptake of electronic records when they were initially introduced.⁽²¹⁾ Subsequent engagement in Australia identified key areas to address, such as offering people the ability to opt out of an electronic record, the need for increased awareness of benefits for both patients and professionals, and additional resources to support implementation in practice.⁽²⁵⁾ In England, a lack of adequate public engagement contributed to the failure of '*care.data*', a national database of patient interactions with the healthcare system.⁽²⁾ In response to the issues faced in the implementation of '*care.data*', the National Data Guardian was established in England to act as an independent champion for patients and the public on matters relating to confidential health information. In 2018, it gained statutory powers to issue official guidance about the processing of health and adult social care data.⁽²⁶⁾ In addition, Understanding Patient Data was established with the unique purpose of helping the public understand how their health information is or can be used.⁽²⁷⁾ This organisation has assisted in promoting public engagement in the area of health information and influencing decisions in relation to policy and practice.

Respondents to the public consultation for this paper also proposed the appointment of a national data guardian for health information in Ireland who would be hosted in a national office and connected to the Data Protection Commission. Other suggestions from respondents included the appointment of a data sharing commissioner and or an Ombudsman for health information. This suggests that people see the need for an independent champion for members of the public in relation to how their health information is collected, used and shared. A positive development in this space is that the Department of Health has recently announced the establishment of a National Health Information Guardian who will be an independent champion for individuals and the public in how the health and social care system intends to use their information.⁽⁴⁾ It will be important for the Department of Health to consider what the precise remit of this role will entail and its alignment with the Data Protection Commission. For example, whether it will be purely an advocacy role, an advisory role for national policy, and or would have a remit in developing guidance and resources to support local information governance

roles through an established network (this will be discussed further in section 4). In order to build and maintain public trust, the role of the National Health Information Guardian should be co-created with citizens and a citizen panel should be established to guide the direction of this role and ensure it meets the needs of the public.

2.2 Strategy informed by evidence-based methods

In Ireland, there has been some, albeit limited, engagement undertaken in relation to health information thus far. The first national public engagement on health information in Ireland was undertaken in 2020 — a collaboration between HIQA, the Department of Health and the HSE. This found that there is now a readiness among Irish people to embrace technology in healthcare as advances in digital health technologies enable people to have a much more participative, person-centric and person-empowered role.⁽¹²⁾ However, results also highlight that people want to be more involved in key decisions about their health information and would like more control over how their information is collected, used and shared. Furthermore, the Irish Platform for Patient Organisations, Science & Industry (IPPOSI) facilitated a Citizens' Jury on Access to Health Information in 2021.⁽²⁸⁾ Jurors concluded that people must be involved in the development of relevant policies and emphasised that individuals should be able to actively manage and consent to the use of their information on an ongoing basis.⁽¹³⁾

As Ireland enters a new chapter with the drafting of health information legislation and the advancement of digital technologies, it will be highly beneficial to have a clear national strategy and plan in place that sets out how members of the public and professionals will be engaged on health information legislation and policy, and eHealth strategy and implementation. A national public engagement strategy needs to be founded upon evidence-based methods through a coordinated approach, whereby key stakeholders from across the health and social care sectors work in partnership to achieve common objectives. This aligns with the Digital Ireland Framework which highlights that involving all stakeholders, including the public, in the creation of digital services is key to ensure services meet the needs of society in a secure and privacy-centric way, while maximising the re-use of data wherever possible.⁽¹⁹⁾

International evidence shows that such engagement is typically undertaken or commissioned by Ministries of Government or health services agencies. For example, in New Zealand, the 'Data Futures Partnership' was commissioned by the New Zealand government to undertake an engagement process in relation to the use and sharing of data, and the New Zealand Ministry of Health completed a specific public engagement on the national health information platform. International evidence also highlights that the most successful programmes of engagement move beyond simply informing the public and incorporate active methods of engagement to ensure a

comprehensive approach is undertaken.⁽²⁾ A range of public engagement methods and tools are employed in different jurisdictions including: national communication campaigns, such as leaflets or posters, to inform people of upcoming changes; consultation workshops that involve the public and professionals in the design of any new initiatives; and more formalised deliberative processes, such as citizen's juries and citizen's assemblies, to achieve a deep understanding of needs and requirements.⁽²⁾ Continued public engagement is also considered essential to understand expectations and address concerns, and to support the continued success of health information and eHealth initiatives.

An international review, undertaken as part of Work Package 8 within the European Joint Action - TEHDAS (Towards the European Health Data Space) in 2022, found that citizens' perceptions of health data were mainly influenced by four factors: (i) the nature and objectives pursued by actors being granted access to health data (ii) the type of governance that regulates access to health data (iii) the measures taken to ensure the confidentiality and security of the data (iv) and the level of knowledge that citizens have of the topic.⁽²⁹⁾ It also identified that knowledge of health data is particularly low among the public, which impedes the establishment of trust between citizens and the other stakeholders of the health data system. Such elements are critical to consider in the process of developing a national strategy for effective engagement.

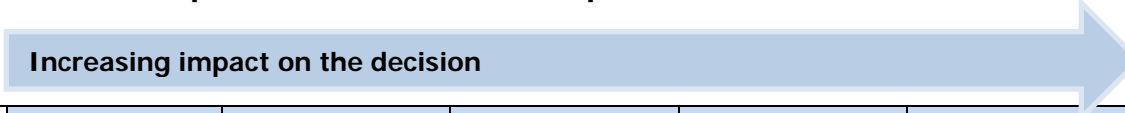
Respondents to the public consultation undertaken by HIOA for this paper also emphasised that it was important to engage with experts in the area of public and professional engagement to develop the strategy, and to ensure that it is informed by evidence-based approaches and frameworks. For example, the International Association for Public Participation (IAP2) developed a framework which details the different approaches to engagement and participation (see **Figure 1**). Respondents also noted that public engagement should be based on the 'Gunning principles' which consist of four rules which, if followed, are designed to make consultation fair and a worthwhile exercise. These are:

- (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.

Further, in line with the national digital framework, it is important that individual cohorts of society are not left behind and that focus is placed on improving basic digital skills and assisted digital services, where relevant, to ensure all citizens are in a position to avail of these advances in eHealth.⁽¹⁹⁾ A Universal Design approach is

essential to ensure that all elements of engagement are accessible to different groups, and tailored to their needs. For example, where relevant, resources are available in plain English, in different languages and accessible to those with digital and literacy issues.

Figure 1. IAP2 Spectrum of Public Participation⁽³⁰⁾



	Inform	Consult	Involve	Collaborate	Empower
Public Participation Goal	To provide the public with balanced and objective information to assist them in understanding the problem, alternatives, opportunities and/or solutions.	To obtain public feedback on analysis, alternatives and or decisions.	To work directly with the public throughout the process to ensure that public concerns and aspirations are consistently understood and considered.	To partner with the public in each aspect of the decision including the development of alternatives and the identification of the preferred solution.	To place final decision-making in the hands of the public.
Promise to the Public	We will keep you informed.	We will keep you informed, listen to and acknowledge concerns and aspirations, and provide feedback on how public input influenced the decision.	We will work with you to ensure that your concerns and aspirations are directly reflected in the alternatives developed and provide feedback on how public input influenced the decision.	We will look to you for advice and innovation in formulating solutions and incorporate your advice and recommendation into the decisions to the maximum extent possible.	We will implement what you decide.

During the public consultation for this paper, many suggestions were made on the topics which public and professional engagement need to address. From the analysis, two distinct approaches emerged — the need to increase general

awareness and the need for targeted engagement with both the public and professionals (see **Table 1**). The first approach, on the need to increase general awareness, focuses on having ongoing awareness campaigns and debates as Ireland progresses through a transformative stage. This aims to improve knowledge of key issues for both professionals and the public. For example, respondents to the public consultation identified a need to promote a national conversation to increase awareness of how information is collected, used and shared, what the benefits are to sharing, and what people's rights are in this area. Similarly, respondents identified a need for increased awareness among health and social care professionals around the application of GDPR in practice and to provide clarity on obligations and responsibilities for those working in health and social care services. The second approach focuses more on targeted engagement to gain a deeper understanding of the requirements of the public and professionals. Both approaches need to happen concurrently and on an ongoing basis as part of a strategy.

Table 1: Examples of focus of public engagement strategy for health information

General awareness	Targeted engagement
<ul style="list-style-type: none"> - what constitutes health and social care data and information - how health and social care information is shared - how information is used for direct care and beyond direct care - individual rights around health and social care information - risks and benefits of information sharing in paper and electronic systems - application of GDPR in practice and obligations and responsibilities for those working in health and social care service (professionals) 	<ul style="list-style-type: none"> - inform the drafting of new health information legislation - developing and designing eHealth initiatives - any significant changes to the way health information is collected, used and shared - to assess the public's and professionals' perceptions and specific needs

As plans for new legislation and eHealth initiatives are developed, the public should be able to trust that their personal health and social care information is used

appropriately in ways that are acceptable to them. People must feel that the digitalisation of society is of benefit to them and is underpinned by a rights-based approach. There is also a need to manage expectations and ensure that citizens acknowledge that change will take time as systems evolve and mature. Therefore, engagement must be undertaken in an independent, transparent, meaningful and authentic way to build trust and confidence. This will ensure that new technologies and initiatives, such as shared care records and a citizen health portal, are implemented in a way that is socially acceptable. It is important to learn from the challenges encountered by other countries, such as England and Australia, and to engage early and on an ongoing basis to ensure expectations are met and to support successful implementation of initiatives.

2.3 Key considerations – engagement on health information

1

Coordinated and ongoing public and professional engagement is a critical element of building trust, as well as essential to the success of new developments such as legislation and eHealth initiatives. Effective and meaningful engagement requires a clear strategy and implementation plan for which strategic leadership is essential.

Key considerations:

- In order to build and maintain trust, transparency and engagement is a fundamental requirement to ensure individuals can appropriately participate in decision-making about how their personal information is being collected, used and shared. This is an opportune time to engage meaningfully with the public and professionals in advance of the development of new health information legislation and the forthcoming changes to how health information is collected, used and shared. However, engagement must be undertaken in an independent, transparent, meaningful and authentic way to build trust and confidence. It is also important that engagement is the first step in the process in order to build and maintain trust and respond to people's needs.
- The responsibility for the development of a national health information engagement strategy needs to be led by the Department of Health or, once established, by the national strategic entity for health information and must align with emerging policy and legislation. In addition, policy-makers need to consider what organisations should be responsible for delivering on the different elements of the implementation plan. Consideration needs to be given to the importance of independence for certain elements of the health information engagement strategy. It might be appropriate to assign different national agencies with responsibility for leading on specific aspects of the strategy, such as the general awareness campaigns and debates, and targeted engagements with professionals through professional bodies or with the public and patients through relevant networks.
- Furthermore, as systems evolve and practices change, ongoing engagement is necessary to monitor and evaluate the public's and professionals' views and opinions in this area. It will be important that engagement is continued over time to build and maintain a trusted relationship with the public and professionals to support successful implementation of changes or initiatives, and to realise the benefits from the use and sharing of health information. A cross-government strategic approach is required to ensure consistency and stability of engagement over time.

- A national health information engagement strategy and implementation plan is required to prioritise and coordinate efforts in this area. This strategy and plan should be planned with time-bound milestones and actionable deliverables to ensure progress can be assessed. Co-design and co-monitoring with citizens and professionals will be important to build and maintain public trust. The following should be considered as part of the strategy and plan:
 - The strategy and plan should be based on two distinct areas: a **widespread national awareness campaign** at a broad level to communicate how health information is collected, used and shared, to improve health literacy, to provide clarity around individual's rights to health information, and to raise awareness of the risks and benefits of information sharing; and **targeted and specific engagement with the public and professionals** to establish preferences and opinions on a rights-based approach, the new health information legislation, new eHealth initiatives or any significant changes to how health information is collected, used and shared.
 - Effective engagement is required with both members of the public and health and social care professionals. The strategy and plan should be based on a partnership model and should be inclusive, incorporating a wide-range of stakeholders including patients, public, professionals, academics, and should include members of the public, private and voluntary health and social care sectors. Unless comprehensive engagement is undertaken, there is a risk that the conversation will be dominated by particular groups and not reflective of the totality of perspectives.
 - Engagement should be built on evidence-based methods guided by experts in the methodology of engagement. The aim of engagement should be to inform, consult, involve, collaborate with and empower citizens, and health and social care professionals, and to make decisions on proposed changes and ongoing initiatives which impact on how health information is collected, used and shared.
 - Engagement should also be based on the Gunning Principles and using a Universal Design approach to ensure that all elements are accessible to different groups, and tailored to their needs. For example, use of plain English, different languages and accessible to those with digital and literacy issues.

3. Legislative framework

2 The development of new health information-specific legislation should be used as an opportunity to rethink the health information landscape in a holistic way, considering the complexity of data sources and acting as a catalyst for a more integrated health and social care sector. A legislative framework should be developed to guide recommended practice in this area to include regulations, guidelines, codes of practice and policy.

The ultimate goal for our health system is to collect health information once and reuse it many times for different purposes. As part of the extensive engagement for this paper, a number of key challenges with the current health information landscape were identified which are impacting on the safe and effective collection, use and sharing of health information in Ireland. These include:

- Lack of clarity on the application of GDPR for a health and social care setting and alignment to existing and forthcoming legislation promoting better re-use of data.
- Lack of a national data governance framework across public, private and voluntary organisations to promote safe and effective care, and better re-use of data for both primary and secondary use of information.
- Lack of clarity on rights that individuals can apply depending on the different uses of data and the relevant legal basis for processing.
- Lack of a national strategic entity for health information with oversight for all aspects of health information including eHealth, the coordination of national data collections and secondary uses of information.
- Lack of appropriate infrastructure for primary use and secondary use of data such as electronic records and the infrastructure to enable the linking and de-identifying of data – an enhanced Data Access, Storage, Sharing and Linkage (DASSL) model.
- Lack of a legal basis for a national linkage and de-identification service and the processing of health information by a prescribed entity for this purpose.
- Lack of implementation of the Individual Health Identifier (IHI) which has significant implications for data linkage and use, both for primary and secondary use of data.

- Lack of general data protection and data sharing expertise at a service provision level, as well as guidance.

These challenges have led to a situation where existing data is not being shared and re-used to benefit individual care and the collective benefit of society. To date, legislation has primarily focused on data protection, but policy-makers now need to consider how to safely and effectively promote better data sharing. For example, by establishing the appropriate legal framework, governance structures and infrastructure to achieve optimal safeguards and a better balance between data protection and data sharing.

The decision by the Department of Health to develop health information-specific legislation is seen as an opportunity to rethink the health information landscape in a holistic way, being the catalyst for a more integrated health and social care sector. Respondents from the public consultation also articulated that failure to consider the system as a whole, or to only focus on specific aspects of health information, will impede progress in this area. Therefore, new health information legislation needs to be comprehensive, and consider the many data sources and different uses of health information. To improve the collection, use and sharing of health information in Ireland, progress is required across each of the four areas: undertaking effective engagement, developing health information legislation, enhancing governance structures, and improving infrastructure and operational capacity. Each of these elements are interdependent but a solid legislative framework is the foundation, as certain legal provisions will be the enablers for progression and developments in the other areas.

In addition, a comprehensive legislative framework is needed to guide practice in this area to include legislation, regulations, codes of practice and guidance. These elements of a framework are used in other jurisdictions to provide clarity on obligations and responsibilities for those working in health and social care services, and to build confidence that they are processing information appropriately. They promote better data management, as well develop a common understanding around individuals' rights in relation to health information.⁽²⁾ The considerations for a legislative framework will be discussed in more detail throughout this section. A discussion on current and forthcoming legislation will set the scene before considering key areas of focus for the new legislation.

3.1 Current and forthcoming legislation

3.1.1 EU legislation and policy direction

There are two main policy areas that impact on the collection, use and sharing of health information which have been categorised as:

- European vision for a data enabled future – policies and legal instruments seek to create the appropriate regulations, policy supports, investment and strategic direction that enable data to be shared to improve health outcomes for all people living in Europe.
- Digital transformation of healthcare – policies, initiatives and institutions look to modernise aspects of the health and social care sector and increase interoperability within member states and across borders, and to encourage collaborative networks that create new solutions for healthcare challenges.⁽⁶⁾

The forthcoming European-level policy changes will have significant impact on the use and sharing of health information in Ireland. The digital and data transformation initiative put forward by the European Commission in 2020 suggests setting up European Health Data Space (EHDS) as a part of the European data policy. 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. The objective of the EHDS is to strengthen and extend the use and re-use of health data for the purposes of research and innovation in the healthcare sector; to help healthcare authorities to take evidence-based decisions; to improve the accessibility, effectiveness and sustainability of healthcare systems; to support the work of regulatory bodies in the assessment ^(7,29) of medical products and demonstration of their safety, efficacy and quality; and to contribute to the competitiveness of the EU's industry. This work stems from the General Data Protection Regulation (GDPR)⁽³¹⁾ (see next section for further details on GDPR). The EU Commission also intends to enact other complementary pieces of legislation which will have implications on the re-use and sharing of health and social care data, including:

- EU Data Governance Act:⁽¹⁵⁾ which focuses on the re-use of data protected by the public sector, including health data.
- The Data Act:⁽¹⁶⁾ is dedicated to the European Health Data Space and 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.
- The Commission's proposal on the legislation on Artificial Intelligence⁽³²⁾ 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.⁽³³⁾

The consequence of these EU policy developments is that Ireland will need to

expedite the development of new national legislation in relation to health information, and rapidly update national health information strategy and policy to keep pace with the significant change occurring in this area at a European level and internationally.

General Data Protection Regulation (GDPR):

GDPR came into effect in 2016 and became applicable across all EU Member States on 25 May 2018.⁽³¹⁾ The GDPR has two objectives: 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. Member States can adjust the application of certain aspects of the regulation to their national situation, including specific processing of 'special categories' of data in the public interest. This means that countries can maintain or introduce further conditions, including limitations with regard to the processing of data concerning health.

Although GDPR is a comprehensive and detailed regulation, it is quite complex in the area of health and social care data. Processing requires both a legal basis under Article 6 GDPR, as well as meeting one of the conditions of Article 9 which allow such special category data to be processed. Processing must also comply with the principles of data protection set out in Article 5 (see **Table 2** and **Appendix 2**).

Table 2: Processing of health and social care data (GDPR)⁽³¹⁾

Article 5 - principles of data protection	Article 6 (1) - legal bases	Article 9 (2) - 'special category'
<ol style="list-style-type: none"> 1. lawfulness, fairness and transparency; 2. purpose limitation; 3. data minimisation; 4. accuracy; 5. storage limitation; 6. integrity and confidentiality (security); 7. accountability. 	<p>Sets out what these are, namely:</p> <ol style="list-style-type: none"> a) consent; b) contract; c) legal obligation; d) vital interests; e) public task; f) legitimate interests. 	<ol style="list-style-type: none"> a) Explicit consent b) Employment, social security and social protection c) Vital interests d) Non-profit bodies (legitimate activities) e) Data manifestly made public by the data subject f) Legal claims or judicial acts g) Substantial public interest

		<ul style="list-style-type: none"> h) Health or social care with a basis in law i) Public health with a basis in law j) Archiving, research and statistics with a basis in law
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A review of the implementation of GDPR in health and social care across EU countries found that countries have different approaches to the choice of legal basis for processing for different purposes.⁽⁷⁾ This is relevant as the EHDS has called for a ‘sound level of legal and operational governance’ across countries. There is concern that the varied approaches to the application of GDPR in the health and social care sector will have implications for the EHDS vision. Given the broad acknowledgement of the complexity of GDPR for health and social care data, countries have identified a need for a Code of Conduct to explain concepts from the GDPR and to ensure a consistent approach to health data exchange at a more practical level.⁽⁷⁾

3.1.2 National legislation

As previously documented, the current legislative landscape in Ireland for health and social care data is complex (see **Appendix 3** for a summary of relevant pieces of national legislation).⁽²⁾ It is also now well documented that further clarity on the collection, use and sharing of information is required through a legislative framework that is fit-for-purpose.^(2,3,4) To address these issues, in January 2022 the Department of Health announced plans to develop the General Scheme of a Health Information Bill. This is welcome news as plans for health-information specific legislation have been in existence in Ireland since 2007, the need for which was initially identified in the first national health information strategy in 2004.^(8,34) In April 2022, the Minister for Health received Cabinet approval to develop the General Scheme of a Health Information Bill.⁽⁴⁾ In a press release from the Department of Health, it stated that the proposed Bill will help ensure that Ireland has a “fit-for-purpose national health information system that enhances patient care and treatment and supports better planning and delivery of health services” and that:

“This is a necessary piece of legislation that demonstrates the Government’s commitment to building patient-centred, integrated health services. All those who use our health services and those who work in them already know that information must follow the patient. This Bill will provide the required legislation to ensure that happens in a way that builds public confidence in how health service providers handle health information, not only for care and

treatment, but for the achievement of other health service goals – ultimately delivering a better health service for those who need it.”⁽⁴⁾

The Department of Health also mentioned that the proposed appointment of a National Health Information Guardian and the proposed introduction of a National Health Information Centre — with clearly specified functions and governance rules in relation to the collection and processing of health information for population health purposes, and research and innovation — would lead to better outcomes for patients. At the time of writing, no further details have been provided on the remit and role of these new structures. This paper will further discuss key considerations for these policy decisions.

Respondents from the public consultation suggested that a comprehensive gap analysis is required to fully understand the current situation, and to ensure that the new health information legislation provides greater clarity to the system. Furthermore, the Data Protection Commissioner highlighted that consultation is required regarding any changes that may impact on data protection laws in accordance with Article 36 GDPR.

3.2 Key considerations for the new national health information legislation

The key considerations for the development of national health information legislation have been categorised into the following areas, each of which will be addressed in turn below:

- Further clarity on implementation of GDPR within a health and social care context
- National data governance framework
- National strategic entity for health information
- Legal basis for de-identifying and linking data
- Clarity on a rights-based approach.

3.2.1 Further clarity on implementation of GDPR

As outlined in 3.1.1, there are differing interpretations of GDPR across Member States so it is acknowledged that the complexity of GDPR has presented challenges in terms of implementation.⁽⁷⁾ For example, the legal bases used in Ireland for primary uses of data for direct care purposes and the secondary uses for planning and management of health and social care include a combination of Article 6 (1)(c), (e), (f) and Article 9 (2)(h), (i), (j) as detailed in **Table 2**. In a recent EU wide review, the legal bases used in Ireland for the different purposes were not always

the same as the most commonly applied legal bases in other countries for similar uses.⁽⁷⁾

The inconsistency of application highlights a possible opportunity to gain further insights into the implementation of GDPR in Ireland by reviewing approaches to the implementation of GDPR in other Member States. In addition, in Ireland, many respondents of the public consultation used to inform this paper echoed similar views in terms of the complexity of GDPR. Many reported that a lack of understanding has led to a genuine fear of sharing data among professionals, requesting further clarity on the legal bases for processing of health and social care data as a matter of urgency, as well as clear guidance for health and social care professionals in the short term. Furthermore, they highlighted the need for additional investment in training and education as the new health information legislation is enacted and the health information system evolves.

As mature health information systems develop, data processing may be based on specific legislation or it may be based on the 'public task' of health and public health institutions. Ideally, a country would provide a legal basis when national data is required and considered of essential need when incomplete data would put data consistency and quality at risk.⁽⁵⁾ This is relevant for both the primary and secondary uses of data. Currently, in Ireland there is a legal basis under the Data Protection Act 2018 that allows for personal health information to be collected, used and shared for the provision of direct care when it is undertaken by a healthcare professional or an individual who has a duty of confidentiality equivalent to a healthcare professional. However, many respondents to the public consultation believe that the new legislation should further regulate the sharing of information across public, private and voluntary organisations (see section on a data governance framework). This will become more critical as eHealth initiatives are implemented and a mandatory requirement for professionals to submit data to a national system may be necessary, as well as the need for clear 'rules' for authorisation, access and patient control.

The legal basis for the secondary use of information is less well defined. Although there are over 85 national data collections, only a few are nationally mandated for collection through specific legislation. For example, the Health (Provision of Information) Act 1997 allows the National Cancer Registry Board, the Minister for Health, a health board, hospital or other body or agency participating in any cancer screening programme authorised by the Minister for Health to request information in order to fulfil their functions in relation to cancer screening.⁽³⁵⁾ Under the Infectious Diseases (Amendment) Regulations 2020 (S.I. No. 53 of 2020), all medical practitioners are required to notify the Medical Officer of Health/Director of Public Health of certain diseases outlined in the legislation. They do this by notifying their regional Department of Public Health. These notifications are entered on the national

Computerised Infectious Disease Reporting (CIDR) surveillance system.

There are many national data collections which are used for planning and management of health and social care services which do not have national coverage due to the current legislative basis or do not have a mandatory requirement for submission of data that may be considered of national importance. For example, the Hospital In-Patient Enquiry (HIPE) database is the principal source of data on all inpatients and day cases discharged from publicly-funded acute hospitals. It is also one of the main health information systems used in Ireland to review healthcare management, performance and planning; to enable activity-based funding; to assist in policy-making; and to facilitate research, innovation and improvements in care. However, the COVID-19 pandemic highlighted major shortcomings of this system in that it currently does not operate in any private hospital site, which prevents its ability to capture national-level data.

This is one example of where a cohesive and comprehensive approach should be considered in determining key national data collections, and the need for access to national-level data for policy-making, planning and management of services, public health and epidemiology and research.⁽³⁶⁾ In England, the Hospital Episode Statistics (HES) is a data warehouse containing details of all admissions, outpatient appointments and accident and emergency attendances at National Health Service (NHS) hospitals in England and is used for monitoring and improving the management of health and care services. A legal obligation is the legal basis for processing HES data where a direction has been published under the Health and Social Care Act to instruct NHS Digital to put in place systems to collect and analyse information.⁽³⁷⁾

Another example of where supporting legislation would promote a strategic approach and better national coordination for key national data collections is in the area of disease registries. For some registries, data is processed based on a legal obligation (for example, National Cancer Registry Ireland) and others operate under the legal basis of consent. The issue in Ireland is that there is no coordinated approach to establishing registries. In many other countries, the processing of data for disease registries occurs in a centralised and mandated fashion. In Australia, for example, there is a framework for prioritising clinical quality registries outlining the national arrangements for the registries where jurisdictions can authorise and secure record-level data, to measure, monitor and report on the appropriateness and effectiveness of healthcare.⁽³⁸⁾ Other countries, such as New Zealand, are moving towards the use of virtual registers which means that data is identified through the use of health and social care services and extracted from hospital inpatient and outpatient, laboratory data, and pharmaceutical dispensing data collections.⁽³⁹⁾ The establishment of registries on a more regulated basis has been identified as an area for focus for the

new health information legislation in Ireland.

In Ireland, this is an opportune time to identify key national data collections for which comprehensive national datasets are required, and where new legislation may include provisions for a legal obligation for collection and submission. Furthermore, a more structured and coordinated approach to the management of national data collections, in line with international best practice should also be considered.⁽³⁾ In the development of new health information legislation, policy-makers should also consider international best practice and how to best utilise advances in technology in this area, such as in virtual registries and use of data from personal digital devices, or capturing patient reported outcome measures for further insights.

Legal basis of consent

In Ireland, the legal bases will generally depend on the existence of specific national legislation as provided for in Article 9 (2)(h), (i) or (j); where such legislation does not exist, consent will be the default option for data processing.^(7,40) This section will discuss the legal basis of consent as there are additional requirements for processing in this scenario. When consent is used as the legal basis for processing data, there is a need to obtain explicit consent under the conditions set out in GDPR.^{††} There are a number of important considerations when employing consent as a legal basis for processing: consent should be specific and informed; there is a need to demonstrate that consent is valid as an ongoing and dynamic obligation; and individuals can withdraw consent at any time using the same or a similar method as when they granted it. Therefore, there is a practical implication of using consent as a legal basis, as individuals and organisations need the systems to manage consent appropriately in compliance with law. This may limit the use of consent as a legal basis for processing in Ireland as the infrastructure is not always available to manage preferences.

This may become more relevant when the concept of data altruism is used more routinely in keeping with international developments⁽⁴¹⁾ and the proposals in the forthcoming Data Governance Act.⁽¹⁵⁾ Data altruism means “the consent by data subjects to process personal data pertaining to them, or permissions of other data holders to allow the use of their non-personal data without seeking a reward, for purposes of general interest, such as scientific research purposes or improving public services.”⁽¹⁵⁾ The Data Governance Act aims to facilitate data altruism by creating a framework for voluntary registration of entities that collect and process data made available for altruistic purposes⁽¹⁵⁾ As there is a move towards health and social care

^{††} Consent for processing of data as defined in GDPR is: ‘any freely given specific informed and unambiguous indication of the data subject’s wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her’.

data being collected and controlled by the patient, such as data from apps and devices, there is also a need to further regulate the collection, use and sharing of this type of data processing.^(7,29) It will also be important to consider how consent may be further used as the legal basis for processing which will open the possibility of using such data-rich sources in innovative ways. In the EU review of the implementation of GDPR, 18 member states used consent as the legal basis under Article 6 and 9 for processing mobile app or device-derived data. However, this was not the case for Ireland where there is reliance on a legal obligation, public or legitimate interest to process this data.⁽⁷⁾ This may suggest that a lack of infrastructure to manage consent preferences means that this data is not being used to its full potential for direct care and secondary purposes.

In Ireland, consent as a legal basis is most commonly used in the area of research, except when a consent declaration is granted by the Health Research Consent Declaration Committee (HRCDC) which provides an alternative basis for processing data under the Health Research Regulations, 2018.^{††} This enables individuals completing research projects of significant public interest to apply for a consent declaration, which can permit the use of personal data without individual consent in exceptional circumstances. A consent declaration will only apply to a subset of research projects which meet the specific criteria. Although this is a very positive development, Ireland still relies heavily on explicit consent under GDPR as a requirement for research. There is a major concern that existing health and social care data is not re-used effectively as consent is not always a viable option due to the practical implication mentioned in the previous paragraph. Interestingly, there is an ongoing debate at an EU-level that consent will not always be the appropriate legal basis for processing personal data in health research, particularly in the context of clinical trials, large-scale epidemiological studies or genetic studies. Others suggest the over-reliance on consent could, in some situations, devalue scientific methods and research, and create biases.⁽⁷⁾ Other countries have addressed this issue by developing the appropriate infrastructure to link and de-identify data which promotes greater innovation and re-use of data, and also eliminates the need for using personal data in many cases and hence the need for a legal basis for processing under GDPR (this will be discussed further in section 5).⁽²⁾

The public consultation and targeted engagement for this paper also identified a number of other areas where consent should be considered in the development of new legislation including: data of children, data of individuals that lack capacity to

^{††} The Health Research Regulation recognises that in Ireland, similar to other jurisdictions, that in limited situations, obtaining consent will not be possible and that the public interest of doing some research projects significantly outweighs the need for explicit consent.

make a decision and genetic data. These will be briefly discussed in turn. These areas may become more relevant as citizen health portals are developed, and the potential to control the use of data by individuals may become an option.

- *Children's data* - GDPR contains a number of specific provisions for children's data protection rights, including the specific provisions in Article 8 which set out the conditions applicable to obtaining a child's consent in relation to information society services. Where such services are offered directly to a child, and the controller seeks to rely on consent as a legal basis, the child must be at least 16 years old to consent independently or, if the child is younger, the holder of parental responsibility must have given or authorised the consent. Article 8(1) does allow for Member States to set the age at a lower level (between 13 and 16), but in Ireland, for data protection purposes, a child is somebody under the age 18. In December 2020, the Data Protection Commission published draft guidance entitled *Children Front and Centre: Fundamentals for a Child-Oriented Approach to Data Processing*, the outcome of which will need to be considered as part of the new health information legislation.⁽⁴²⁾ The new legislation should also consider children-parental consent, as well as situations when, and where, re-consent may be required for any such processing, and circumstances regarding a rights-based approach to health information. This is likely to become much more relevant when parents and children have access to records in citizen's portals and differences arise regarding control of data.
- *Decision-making capacity* - GDPR does not contain specific provisions on the capacity to consent for processing of personal data, but issues of capacity are aligned to the concept of 'informed' consent. It is the role of the controller to assess who provides personal data to their organisation and determine what information should be provided and how it should be presented to ensure consent is sufficiently informed.⁽⁴³⁾ An adult is presumed to have decision-making capacity to provide consent unless the contrary is shown, such as by an assessment of decision-making capacity or by a Court declaration making a person a Ward of Court. The HSE National Consent Policy outlines important principles in relation to a person's decision-making capacity to consent.⁽⁴⁴⁾ The Assisted Decision-Making (Capacity) Act 2015 is planned for full commencement in 2022 and puts the person at the centre of their healthcare treatment even where they lack capacity. This Act introduces new guiding principles about interacting with a person who has difficulties with their decision-making capacity and provides a human rights compliant legal framework for decision-making where a person lacks capacity. While this Act focuses on the decision-making capacity to consent to medical treatment and care, feedback from the national public engagement and public consultation

shows an appetite to consider the decision-making capacity to consent to the processing of personal data in future healthcare directives and the ability to assign a proxy to assist in decision-making in this regard.

- *Genetic and genomic data* - Genetic data is considered a special category of personal data under GDPR and, as such, requires both a legal basis under Article 6 GDPR, as well as meeting one of the conditions of Article 9 GDPR. Genetic data is becoming of increasing importance in the care and treatment of patients, and analysis of such data at a population level offers valuable insight into potential new therapeutics.⁽⁴⁵⁾ Feedback from the public consultation and the broader literature demonstrates that there are concerns about sharing genetic data for secondary purposes without consent due to the difficulties of anonymising genetic data. The other issue is that genetic and genomic data convey information not solely on the individual, but also on their relatives which raises debate on the appropriateness of obtaining consent from a single individual and the sharing of genetic data with different organisations, such as insurance companies.⁽⁴⁶⁾ Anonymised or aggregated partial genetic sequences or genetic test results are not considered personal data if they can no longer be linked back to a specific genetic identity, sample or profile; a patient record; or to any other identifier.⁽⁴⁷⁾ However, the risk of re-identification from even small samples of genetic data is evident which questions the ability to truly anonymise genetic data.⁽⁴⁶⁾ Therefore, this type of data requires further consideration in the development of new health information legislation as to the particular safeguards in place as technology advances and changes occur to the way data is re-used.

3.2.2 National data governance framework

As outlined in the introduction, the structure of the healthcare system in Ireland is unique as there are three categories of organisations that provide health and social care services, all of which are funded and governed in different ways. The varied governance structures impacts the way in which health information is collected, used and shared. Health information is routinely shared between private, public and voluntary organisations, such as GP practices, pharmacies, hospitals, nursing homes and social care services.

The lack of a national data governance framework impacts on the safe and secure use and sharing of information for primary and secondary purposes. For example, Tusla has significant challenges regarding the collection, use and sharing of information for care provision. This is due to the lack of integrated systems across the wide variety of organisations that people using services deal with and also due to differences in data governance policies across these varied organisations. This challenge is compounded when trying to use and share information for secondary

use — such as planning and management, policy-making and research — as relevant information is often collected across sectors and outside of health and social care, such as through educational setting like schools or through An Garda Síochána. In addition, the lack of implementation of the IHI has significant implications for data use and sharing, both for primary and secondary use, in such an example. The inability to identify patients across the entire system has significant implications for direct care, planning and management of services, public health and quality improvement which was recently highlighted in the Irish Heart Attack Audit.⁽⁴⁸⁾

General rules for health information

Currently, there are no clear rules for the collection, use and sharing of health information. There is therefore a need for data to be collected in a consistent way, using data standards, to promote interoperability and improve data quality. National policies and procedures are required to ensure data is managed in a standardised manner. In addition, health and social care professionals should be aware of their responsibilities and obligations when using and sharing information as defined through appropriate legal bases, regulations and codes of practice. The feedback from the public consultation that informed this paper identified that clear rules as set out through a national data governance framework is vital in this regard to promote appropriate management and the safe and secure sharing of data across these different services with distinct governance models.

A national data governance framework for health and social care should outline specific rules for the processing of health information. This would provide clarity on the obligations and responsibilities for those working in health and social care services, and build confidence that they are processing information appropriately. The development of a national data governance framework may be able to build on initial work progressed by the HSE to develop a Data and Information Management (DAIM) policy. A national framework would need an extended scope and include all data processing activities and to cover all organisations processing health and social care data, beyond the HSE. The need to comply with a national data governance framework would need to be mandated, as well as responsibilities assigned to its development and implementation, through the new health information legislation for it to be successfully adopted and implemented across all services in Ireland. The specific details of the framework should be outlined in supporting documents, such as regulations, codes of practice and guidance, allowing for flexibility in an ever changing landscape (this will be discussed further in section 4). The data governance framework should also consider specific rules for the implementation of an IHI in line with the relevant legislation.

Rules for new eHealth initiatives

In addition, as Ireland is in its infancy in the development of eHealth initiatives such as electronic records, ePrescribing, shared care records and a citizen health portal, there is no specific legislation to regulate the collection, use and sharing of health information through electronic methods. A data governance framework needs to also provide clear rules for data collected, used and shared electronically considering submission of data, access and control, storage, and retention of data for eHealth initiatives. Given the sensitive nature of health and social care data and the vast amount of data collected, used and shared, clarity around the implications for non-compliance by providers would need to be explicitly outlined in the legislation and the framework. Furthermore, specific rules would be key to outlining safe and secure authentication, the use of health information standards, obligations to submit data by providers and patient's rights. For example, in Estonia, Finland, and Denmark, there is legislation to enable the exchange of health data through electronic records, making it mandatory for healthcare organisations to submit to national repositories, and outlining the rules for such processing. There is also a need to consider data interoperability to ensure data is collected in a way that allows it to be shared safely and used across systems without compromising integrity and ensuring its availability where needed. While the GDPR itself does not address interoperability of data, there are provisions in GDPR that allow Member States to introduce legislation that ensures suitable safeguards are in place.⁽⁷⁾

Specific rules for private and commercial agencies

Due to the sensitivity of health and social care data, respondents of the public consultation noted some concerns about sharing information with 'for-profit' services, even hospitals and with private agencies providing care in the community. They acknowledged, however, that there were circumstances where sharing with private organisations is necessary. Other respondents identified that partnerships with private and commercial organisations for research and innovation may be beneficial for particular groups. All, however, acknowledged that strict controls and rules should be put in place for sharing information between public and private organisations. A national data governance framework should consider specific rules and safeguards for data shared with different types of private or 'for-profit' agencies, such as health insurance agencies or private providers of health and social care services.

In addition, the area of data governance will become more relevant as the EU Data Governance Act and Data Acts are approved.^(15,16) The aim for the Data Governance Act is to create a harmonised framework for data exchanges. The Data Governance Act will also establish robust procedures to facilitate the reuse of certain protected public sector data, and foster data altruism across the EU. A licensing regime will be

set up for “data intermediaries.” These are organisations which set up commercial arrangements between data holders and data users, but which do not themselves add extra value to the data. In addition, the Data Act aims to foster business-to-government data sharing for public interest purposes, and to support business-to-business data sharing.⁽¹⁶⁾ This means that, for example, public sector bodies can access and use data held by the private sector that is necessary for specific public interest purposes such as to develop insights to respond to a public emergency. In addition, the EHDS is calling for specific data governance legislation to be developed for the health and social care sector given the sensitive nature of data. Any developments at a European-level should be captured within a national data governance framework and underpinned within the new legislation.^(29,49)

3.2.3 National strategic entity for health information

Included in the press release by the Department of Health for the new health information legislation, is the proposed development of a National Health Information Centre with clearly specified functions and governance rules in relation to the collection and processing of health information. However, it is not clear what the remit of this organisation will be.

Recent international studies have highlighted that in comparison to other EU and OECD countries, Ireland has poor health information infrastructure and governance, fragmented practices, and limited capabilities for using health information beyond direct care.^(5,6) One reason for such lack of development and coordination of health information is that there is no one organisation in Ireland with responsibility for strategy and implementation of improvements to national health information. The eHealth Strategy, published in 2013, originally called for a single entity (eHealth Ireland) to be established, outside of the HSE, with a legislative remit to provide strategic and governance responsibility to support the collection, use and sharing of health information in Ireland.⁽⁹⁾ To date, eHealth Ireland has not been formally established as a separate entity to the HSE. HIQA’s recent paper on reform of health information systems recommended that a national entity should be established with responsibility for overall governance that is broader than eHealth and includes the centralised coordination and governance of national data collections and secondary uses of information at a national level across public, private and voluntary sectors.⁽³⁾ Respondents to the public consultation for this paper on key considerations to inform policy identified an urgent need for the establishment of such a national strategic entity for health information, identifying this as a critical success factor to the effective collection, use and sharing of health information in Ireland.

There is also a need for a more coordinated approach to ensure high-quality care provision and the effective use of data for secondary purposes. For example, in an OECD report, Ireland performed worst in terms of key national health datasets

availability, maturity and use.⁽⁵⁾ It identified that Ireland has considerable challenges 'integrating and linking data across the pathway of care than in other countries, as laws and policies governing health data accessibility and sharing would need to be considered and applied across multiple organisations'.⁽⁵⁾ As previously highlighted, HIQA's catalogue of national data collections identifies that there are over 85 national data collections in Ireland, with a large number of different 'managing organisations' responsible for collecting and storing these datasets. This makes the governance of health information for secondary use in Ireland very complex as many of this work is occurring in silos with little national coordination of these existing data sources. In line with international best practice, the coordination of key national data collections should be centralised within this national strategic entity for health information. Provisions in the new health information legislation would also be required to establish the remit and assign the responsibility for the coordination of key national data collections.⁽³⁾

The new legislation should outline clear provisions as to the remit of the national strategic entity for health information, reporting structures, and how it would interact with other relevant entities within the health and social care system, and with other sectors, as well as links with international health information agencies, both within the EU and beyond. Further discussion of this entity and its role in governance is presented in section 4 and 3.2.4 below.

3.2.4 Legal basis for de-identifying and linking data

The need for an entity in Ireland to perform de-identification and linking health and social care data has been widely acknowledged in Ireland.⁽²³⁾ The de-identification and linking of data for re-use for secondary purposes is in itself seen as a 'processing' activity and therefore, requires a specific legal basis. The Central Statistics Office (CSO) provides a 'trusted third party' and linkage service for researchers but its capacity to respond for health and social care data is limited. Other than the CSO, there is no national entity with responsibility for performing this function in Ireland at a national level. Given the proposal to develop such infrastructure, the new health information legislation should consider assigning this responsibility to the national strategic entity for health information, and provide the legal basis for such processing, as well as the specific governance arrangements and information governance rules for processing (this will be discussed further in section 4). Therefore, it is important that this entity is independent, but would develop and maintain links with the CSO to support its role in the production of national statistics, and as well as considering the broader need to link data outside the health and social care sector.

3.2.5 Clarity on a rights-based approach

The feedback from the public consultation and engagement with stakeholders identified that, in line with international evidence, the processing of health information should be underpinned by a rights-based approach, meaning that an emphasis is placed on protecting and promoting people's rights. This involves respecting their privacy but also their autonomy, dignity, values, preferences and diversity.⁽⁵⁰⁾ Data protection is a fundamental right set out in Article 8 of the EU Charter of Fundamental Rights.⁽⁵¹⁾ Under 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. Therefore, GDPR details specific rights of individuals in respect of their personal data. These include the right to: access, be informed, ratification, object, restriction and portability.⁽⁵²⁾

It should be noted, however, that data protection is not an absolute right.⁽⁵³⁾ It must always be balanced against other values, fundamental rights, human rights, or public and private interests. As this is the case, it can be confusing for individuals to understand the circumstances under which there may be grounds for them to exercise their data protection rights. Therefore, as technologies develop and the potential to use and share health information increases, the rights of individuals in relation to their personal information should be openly discussed, as well as the choices they have about this.

Internationally, a recurrent and sensitive debate relates to finding a proper balance between individual interests and societal benefits in terms of the use of health information. A review by TEHDAS on citizen's perception of health data highlights that the respect of individual's autonomy and the protection of privacy are strong ethical considerations in the governance of health data but despite the strong legal framework supporting data protection, these ethical principles are not well defined. Furthermore, as privacy rights are not absolute, this introduces additional complexities involving a need to evaluate the ratio between risks and benefits of particular situations.⁽²⁹⁾

On the other side of the debate, two connected yet more simplistic arguments justify the need to consider the societal benefits of sharing health data. The first is to preserve the public good and the second is that not sharing data could be harmful for society 'if progress in research is not made'. The concept of data ownership brings the conversation of rights-based approach to life. For example, who has the ultimate say in how personal data is collected, used and shared? This depends on the legal basis for processing (see **Table 2**). However, data ownership in the context of health and social care is not as straightforward as a care record is not only a record of data concerning a patient. It may also include details pertaining to professional interventions, a reflection of the opinions of the healthcare professionals

who interact with the patient, as well as information about others in the patient's circle, such as family and carers.⁽²⁹⁾

Table 3 – Applicable rights associated with the legal bases for processing (GDPR)⁽⁴⁰⁾

	Right of Access	Right to Rectification	Right to Erasure	Right to Restriction	Right to Portability	Right to Object
Consent	✓	✓	✓	✓	✓	~ Can withdraw consent
Contract	✓	✓	✓	✓	✓	✗
Legal Obligation	✓	✓	✗	✓	✗	✗
Vital Interests	✓	✓	✓	✓	✗	✗
Public Task	✓	✓	✗	✓	✗	✓
Legitimate Interests	✓	✓	✓	✓	✗	✓

Although **Table 3** seems to provide clarity, the findings of the review of the implementation of GDPR across countries shows that countries interpretation of the application of rights are varied and approaches differ significantly despite GDPR being common across all Member States.⁽⁷⁾ This is relevant when considering the control an individual should have over their own data, for example, given the implementation of electronic records and a citizen's portal. Interestingly, the review found that for care provision purposes (primary use), only 5 out of 22 countries indicated that it is not possible for a patient to prevent data sharing. In Ireland, clarity is also required in relation to a rights-based approach to health information. There is a legal basis for health and social care professionals to share data with other relevant professionals within a person's 'circle of care'.⁽¹⁾ It was highlighted by one respondent in the public consultation that even though there are a number of rights currently in place, not all are being sufficiently implemented. An example was provided 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 an individual should be provided with access to their health information. It was noted that it is important to identify all existing legislation and address any conflicts in the new health information legislation in line with the policy direction regarding a rights-based approach.

In particular, as there is no formal regulation or legislation for electronic records or the access of such data on a citizen's portal, it is unclear what approach policy-makers in Ireland will take regarding the right to object or to provide individuals with a level of control over their own data. This will become more pertinent as plans are progressed to implement national eHealth initiatives and clarity regarding access to highly sensitive health information will be critical to success. Currently, the HSE has an Information Classification and Handling Policy which classifies data into public, internal, confidential (information that is protected by Irish and or EU legislation or regulations, HSE policies or legal contracts) and restricted data (highly sensitive confidential information such as HIV status, sexually transmitted infection [STI] or mental health status). The level of control provided to individuals may depend on the categorisation of data. In some countries, such as Sweden, certain data may be blocked by individuals but health and social care professionals are notified that some data has been blocked.⁽⁷⁾

In terms of the right to data portability, as Ireland does not have a national EHR, it is worth noting that the current barriers to the application of this right result from the lack of infrastructure and lack of awareness among patients of their rights. The EU target that citizens should have access to an EHR by 2030 and development of the EHDS to standardise data collection across Member States will promote better rights of data access and also to portability.^(7,17) The rights-based approach debate is also linked to the importance of transparency and communicating the legal basis for processing as applicable rights differ depending on each legal basis under GDPR (see **Table 3**). In general, the exercise of the rights in the health and social care setting remain limited due to a lack of infrastructure to practically implement such rights. Policy-makers also need to address this issue and determine the approach, through public debate and conversation, to build sufficient trust within the public to progress eHealth plans. This needs to be planned and managed within the public engagement strategy. The approach will also need to be reflected in new legislative framework and policy.

3.3 Key considerations – legislative framework

2

The development of new health information-specific legislation should be used as an opportunity to rethink the health information landscape in a holistic way, considering the complexity of data sources and acting as a catalyst for a more integrated health and social care sector. A legislative framework should be developed to guide recommended practice in this area to include regulations, guidelines, codes of practice and policy.

Key considerations:

- The forthcoming European-level changes at a policy level will have significant impact on the use and sharing of health information in Ireland. The consequence of these EU policy developments is that Ireland will need to expedite the development of new national health information, and rapidly update national health information strategy and policy to keep pace with the significant change occurring in this area.
- To improve the collection, use and sharing of health information in Ireland, progress is required across each of the four areas: developing health information legislation, enhancing governance structures, improving infrastructure and operational capacity, and undertaking effective engagement. Each of these elements are interdependent. However, a strategic approach underpinned by a solid legislative framework is critical as certain legal provisions will be the enablers for progression and developments in the other areas.
- It is critical that the citizen's perspective is sufficiently incorporated and a rights-based approach should underpin the development of the new legislation. As technologies continue to develop and the potential to use and share health information increases, the rights of individuals in relation to their personal information should be openly discussed, as well as the choices they have about this. Policy-makers need to determine their approach to rights, through effective engagement, and the findings need to be reflected in new legislative framework and policy, and any conflicts in existing legislation need to be addressed.
- To address any conflicts and further opportunities for development, a comprehensive gap analysis of existing and forthcoming legislation is necessary to fully understand the future legislative requirements for health and social care data in Ireland as we move towards a data-rich environment.

- This should include a review of the approaches to the implementation of GDPR in other EU Member States that may identify further opportunities for the application of GDPR in Ireland, for example by reviewing the application of all six legal basis for processing health and social care information under GDPR in other countries.
- Identify areas where the legal basis of consent could be further used to promote additional re-use and sharing of data, with the appropriate infrastructure and governance models, such as exploring the concept of data altruism and methods being employed internationally to enable citizens to manage consent preferences on an ongoing basis.
- In addition, other areas where the legal basis of consent needs to be further explored in the development of new legislation have been identified as: data relating to children, data relating to individuals that lack capacity to make a decision, and genetic data.
- The development of new legislation provides the opportunity to further regulate the collection, use and sharing of health information across public, private and voluntary sectors, and to prioritise a more structured and coordinated approach to the management of key national data collections. In particular, the following should be addressed:
 - The need to comply with a national information governance framework for health and social care should be mandated through the new health information legislation; however, the specific details of the framework could be outlined in regulations and codes of practice, allowing for flexibility in the changing landscape. A national data governance framework is important for individual care to promote safe and effective care, but it is also needed for better re-use of data for primary and secondary use of information across sectors. The framework needs to consider processing of both paper and electronic records. Clearly outlining rules for health information will become more critical as eHealth initiatives are implemented and a mandatory requirement to submit data by professionals and organisations may be necessary, as well as clarity regarding authorisation, access and patient control. The data governance framework should also consider specific rules for the implementation of an IHI in line with the relevant legislation.
 - As it is also an opportune time to identify and prioritise key national data collections, the new health information legislation should provide a legal obligation for the use and sharing of data in such key datasets.

Furthermore, a more structured and coordinated approach to the management of national data collections, in line with international best practice, should also be considered in the development of new legislation.

- The establishment of a national strategic entity for health information and associated governance structures should be outlined in the new legislation, including a remit for eHealth, national data collections and a linkage and de-identification service.
- The new legislation should also establish a legal basis to perform de-identification and linking data by the national strategic entity for health information, as well as the specific governance arrangements and information governance rules for processing for these purposes.
- As implementation of new health information legislation may be challenging, a legislative framework with supporting regulations, codes of practice, guidance and policies should be developed. These supporting documents should help to define what good practice is for those working in health and social care services, to outline a data governance framework for the collection, use and sharing of information across the public, private and voluntary health and social care settings, and to develop a common understanding around individuals' rights in relation to health information. Policy-makers need to identify which organisations are responsible for developing each element of the legislative framework and assign clear responsibilities and timelines to ensure a coordinated approach to the development of the legislative framework.
- In particular, as it is firmly acknowledged that the complexity of GDPR has presented challenges in terms of implementation, supporting instruments such as codes of practice and guidance should be developed to provide clarity on the application of GDPR for health and social care professionals. Undertaking additional work to understand the challenges associated with implementation of GDPR from the professional's perspective would be useful to guide such developments.
- The new health information legislation should outline how compliance will be monitored and regulated, addressing current arrangements and future requirements, identifying which organisation would be responsible for monitoring compliance.
- The regulation and management of data in the health and social care sector will impact on the wider landscape in Ireland. Policy-makers also need to

consider the wider landscape and the governance of data as it moves between sectors and jurisdictions.

4. Governance structures

3 Governance structures, including a national strategic entity for health information with legislative remit and relevant committees for oversight of vision and implementation, are critical for the effective and efficient collection, use and sharing of health information. These national structures must be underpinned by adequate capacity and expertise at a local level, and supported by a standards-based data governance framework.

As discussed in section 3, the governance structures for health and social care health information in Ireland are lacking in comparison to other EU and OECD countries.^(5,6) The absence of a single organisation with strategic responsibility is a key factor. Inadequate development and coordination of governance at a national level results in inconsistent structures at a local level and hampers the effective collection, use and sharing of health information by health and social care professionals.

4.1 National governance structures for health information

4.1.1 Remit of national strategic entity for health information

As previously discussed, there is a need to establish a national strategic entity for health information 'with responsibility for overall governance around eHealth implementation — including funding, legal enabling, public awareness and stakeholder engagement through building the eHealth ecosystem in Ireland', as outlined in HIQA's paper on the need for reform of the health information system.⁽³⁾ The paper further recommends that 'the remit of this entity should be broader than eHealth and include the centralised coordination and governance of national data collections and the uses of information beyond direct care at a national level'.⁽³⁾ The public consultation responses for this paper on key considerations to inform policy demonstrate that there is significant support for the establishment of a national entity with responsibility for health information, with some viewing it as critical to achieving progress in this area.

In an absence of a national strategic entity, there will continue to be an overall lack of accountability and coordination for information across the health and social care system, with negative effects on direct care, research and innovation. Respondents to the public consultation emphasised that this entity must have strong legislative powers that go beyond an advisory or steering role to ensure sufficient progress in this area is achieved. Some respondents also commented that consideration must be given to the roles and responsibilities of the entity, links with existing entities in the health and social care sector, the proposed reporting structure and funding sources. Human resourcing at this entity is crucial and staff must have the expertise required

in relation to data protection, data sharing and other relevant areas to ensure it can stay in line with international developments in this area. A national Board, alongside relevant sub-committees, should be established for oversight of vision and implementation of governance arrangements for the national strategic entity for health information.

As health and social care systems mature, as well as overseeing and implementing eHealth initiatives, a strategy in relation to national data collections should be another key objective of this national strategic entity. Restructuring may be required as data is shared to a greater extent, especially from non-public services, and further consideration is required in relation to data ownership and organisational responsibilities. For example, some national data collections are currently managed within the HSE and primarily include data from public health services. If forthcoming legislation mandates the submission of data from private and voluntary health services, consideration needs to be given on the appropriate governance structures for future arrangements of such national data collections.

Furthermore, the national strategic entity for health information should have responsibility for a national data linkage and de-identification service. In some jurisdictions, such as in Finland and France, specific services are in place at a national level that have responsibility for managing data requests and applying linkage and de-identification techniques.⁽⁵⁴⁾ In Ireland, there is currently no such national service with the technical infrastructure or responsibility for governance and management of secondary use of health and social care data. Feedback from the public consultation for this paper noted that there are a number of specialised registries that have such capacity, which offers a learning opportunity for development and implementation at a national level. The lack of a national service in Ireland to process and make data available in an efficient manner was also highlighted in a recent OECD report.⁽⁵⁾ Respondents to the public consultation also noted that the lack of a trusted environment in Ireland meant that data sharing agreements were needed for data sharing; these were considered potential barriers as they added additional time and resources which was not available to all. Many believed that the proposal to develop a centralised service with responsibility to coordinate de-identification, linkage and secure sharing of data for secondary use was critical to Ireland's ability to re-use existing data and align with developments at a European level. Further discussion on the technical considerations for this data sharing service is presented in section 5.

Currently, the Central Statistics Office (CSO) provides a limited 'trusted third party' and linkage service for researchers, primarily in respect of official statistics and in accordance with strict protocols. However, its capacity to respond to such requests is limited which means that existing health and social care data is not used to its full

potential. This function was built upon with the establishment of the COVID-19 Research Data Hub, in collaboration with the Health Research Board, the HSE and the Department of Health. This development provided huge learning on areas such as the importance of a unique identifier for linking with non-COVID-19 data to address important policy issues, and the need for clarity on data ownership and the roles and responsibilities for sharing data between public bodies. This partnership approach also provided valuable learning on the implementation of a data de-identification and linkage service and such expertise will be critical for informing future policy decisions. Furthermore, from a governance perspective, a number of structures were put in place to manage and coordinate the data access and sharing process. A Research Data Governance Board provides appropriate oversight of the process and reviews applications for data access. Applications must also be made to institutional research ethics committees and the HRCDC, where relevant. Once approval has been given to the researcher, they must undergo appropriate training and sign a declaration of secrecy. Data is then appropriately de-identified by the CSO and shared with the researcher remotely via a secure online portal. This learning will be important when considering requirements for governance structures necessary to support the effective secondary use of information.

4.1.2 National governance structures for secondary use of information

A recent report from the TEHDAS project provides a useful insight into the governance structures that are in place in relation to accessing individual-level data for secondary use in EU Member States.⁽⁵⁴⁾ Typically, the national ministry has an overall supervision role, or this may be at a regional ministry level depending on the political structure in place. Advisory bodies are also in place to provide guidance on decision-making. There are usually three types of committees that make up the internal structures: an advisory board, a steering committee and a strategic or management committee. Other specific departments are also in place and are responsible for the day-to-day running of the service, such as communication, research and innovation, IT and methodology, or interaction with the health data ecosystem.

A report issued by the European Commission (DG SANTE) in 2021 on the assessment of the EU Member States' rules on health data in light of GDPR reports three non-mutually exclusive access mechanisms for the secondary use of health data among European Member States:

- Access is granted after authorisation by a research ethics committee (REC) or a data protection agency (DPA). (Adopted by 22 Member States).
- Data holder directly provides access without consulting a REC or a DPA. (Adopted in 7 Member States).

- Centralised governance body in place which reviews data requests. (Adopted in 13 Member States).⁽⁷⁾

In Ireland, at present, the various national structures discussed in this section are not in place for health and social care data. The establishment of these national governance structures for the secondary use of health and social care data were viewed as essential by respondents to the public consultation, namely that a national strategic entity for health information would have a remit for de-identification and linking health and social care data, alongside relevant committees for oversight of vision and implementation of governance arrangements for the secondary use of information. Their establishment was viewed as important not only to promote the safe and effective use of information, but also to ensure expertise and capabilities are developed in line with international best practice. Respondents also commented that it was important that these national structures must have adequate input and representation from a wide range of stakeholders and encompass all health and social care sectors.

The DASSL model was initially proposed as a solution to promote the effective and safe use of health information for research purposes in Ireland. However, there is a need to extend this model beyond research to inform further secondary uses such as planning, management, monitoring of services, quality improvement and policy making. The learnings from the DASSL proof of concept project will be important to assess the requirements for a scaled-up model and the necessary governance structures to support such a model.⁽⁵⁵⁾ Further discussion of an extended DASSL model is presented in section 5 and the particular technical considerations for its implementation.

4.1.3 Organisational governance for a national data governance framework

As set out in section 3, there is a need for a national data governance framework that clearly sets out the conditions for the collection, use and sharing of health and social care data across public, private and voluntary health and social care services. Currently, there are different governance structures in place across services which identifies a need for a more coordinated approach for data governance to ensure high-quality care provision and the effective use of data for secondary purposes. A national data governance framework requires a standards-based approach to health data and interoperability, which ensures that health information can be more easily shared regardless of the information system being used. This is discussed further in section 5.

A national data governance framework also requires appropriate organisational governance structures to develop and implement the framework which should be

managed by a specific entity, namely the national strategic entity for health information. Specific committees reporting into an oversight committee or Board for the national strategic entity for health information will be required to guide the development and implementation of the framework.

A data governance framework developed by the Australian Institute for Health and Welfare (AIHW) for the management of key national data outlines relevant organisational structures and their role in relation to data governance and ensuring accountability, and clearly details the responsibilities of key staff roles, such as the Chief Executive Officer and data custodians.⁽⁵⁶⁾ The framework also outlines the systems and tools in place to support data governance, such as those in the areas of ICT, data security and data quality. It is complemented by a range of policies, guidelines and procedures that provide clear sources of information to enable staff to perform their roles effectively and appropriately.

Following on from the detail in 3.2.2, a national data governance framework should also outline rules and standardisation of practice, as well as provide clarity on the legal obligation to share in particular circumstances. It is also important that the framework is developed to be sufficiently flexible to apply to new and emerging areas of data management, such as more sophisticated analytics associated with electronic records and the potential use of machine learning. Any developments at an EU level must also be incorporated, especially those that may arise from the enactment of the EU Data Governance Act which comes into force in 2023.

4.2 Local level structures for information governance

In Ireland, within the HSE, the overall accountability for the collection, use and sharing of health information lies with senior and local accountable officers in compliance with the delegation and performance and accountability frameworks. Accountable officers are fully responsible and accountable for the services they lead and deliver.^(57,58) Health and social care services must adhere to the principles of data protection which are set out in GDPR and the Data Protection Act 2018. GDPR requires the designation of a Data Protection Officer (DPO) for any organisation that processes personal data. A DPO informs and advises the controller or processor of their obligations under data protection law, monitors compliance with legislation, including staff training, and acts as a contact point for requests from individuals regarding the processing of their personal data and the exercise of their rights.

Public consultation feedback to inform this paper outlines the need for enhanced supports beyond the valuable role of the DPO, as there is a lack of consistency across services in terms of support and expertise which presents a knowledge gap at a service level. Respondents called for greater investment in human resourcing, infrastructure, and network development to address this gap. There are some

established networks for DPOs, such as the Health Research Data Protection Network and additional networks in place in Dublin acute teaching hospitals. A national network for DPOs had also been established but was stopped due to the pandemic and at the time of writing has not been re-instated. However, these supports vary across local services and some respondents suggested developing a national support network which would be broader than data protection, incorporating information governance more broadly.

The United Kingdom (UK) provides a good example of information governance practice. A National Data Guardian acts as an independent champion for patients and the public, and offers advice, guidance and encouragement to the health and social care system. The National Data Guardian is responsible for maintaining the Caldicott Principles.⁽⁵⁹⁾ The UK Caldicott Guardian Council (UKCGC) is a sub-group of the National Data Guardian Panel and is the national body for Caldicott Guardians, who are responsible for protecting the confidentiality of people's health and care information and making sure it is used properly. All NHS organisations and local authorities that provide social services must have a Caldicott Guardian. At a local level, there is an established network of Caldicott Guardians.⁽⁶⁰⁾ The aim of the national network is to assist and guide in developing consistent standards and guidance for information governance and the use of data at a service provision level.

As part of proposed health information legislation, the Department of Health recently announced the appointment of a National Health Information Guardian who will be an independent champion for the public on how health information is used. There is currently limited information on the proposed remit of the National Health Information Guardian, but it may be relevant for this role to coordinate a national network to support local information governance roles, similar to the approach taken in the UK, and support improved capacity at a local level. As stated previously, the role and remit of the National Health Information Guardian should be co-created with citizens to maintain public trust and ensure the needs of citizens are met.

4.3 Key considerations – governance structures for health information

3 Governance structures, including a national strategic entity with a legislative remit and relevant committees for oversight of vision and implementation, are critical for the effective and efficient collection, use and sharing of health information. These national structures must be underpinned by adequate capacity and expertise at a local level, and supported by a standards-based data governance framework.

Key considerations:

- As set out in HIQA's paper on the need for reform of the health information system, a national strategic entity for health information should be established with oversight for all aspects of health information, including eHealth, the centralised coordination and governance of national data collections and secondary uses of information, and for ensuring compliance with legislation.
- This national strategic entity for health information should have strong legislative powers and have a strategic role to advance health information in Ireland.
- A national board, with relevant subcommittees, should be established for overall direction and implementation of governance arrangements, including oversight for the national strategic entity for health information, secondary use and data governance framework. The board and subcommittees should have appropriate representation from a wide range of stakeholders and encompass health and social care services across private, public and voluntary sectors.
- A key responsibility for this national strategic entity for health information should be the provision of a national data sharing service which manages activities such as de-identifying and linking health and social care data, and offers a safe haven for data sharing. This will be critical to Ireland's ability to re-use existing data and align with developments at a European level. Learnings from the current DASSL proof of concept project will be crucial, as will the experience of the CSO and the Health Research Board from their implementation of the COVID-19 Research Data Hub.
- The national strategic entity for health information should also have responsibility for developing governance structures to enable it to establish and implement a national data governance framework that is underpinned by robust data standards. This framework should clearly set out the conditions for the collection, use and sharing of health information across public, private and voluntary services to support an integrated care system and to ensure

comprehensive national level data for secondary use. Specific committees reporting into an oversight committee or board for the national strategic entity for health information will be required to guide the development and implementation of the data governance framework.

- Investment in human resourcing and infrastructure and the creation of a national network is required to build capacity and expertise at a local level in the areas of health information. This should go beyond data protection and incorporate information governance.
- Consideration needs to be given to the role of the National Health Information Guardian in the establishment and oversight of this local network to improve information governance at a service level. Citizens should be consulted to inform the role and remit of the National Health Information Guardian to build and maintain public trust.

5. Technical infrastructure and operational considerations

4

As a priority, and in compliance with forthcoming EU legislation and targets, the infrastructure to support the primary and secondary use of data must be developed to include a citizen's portal and an extended DASSL model, as well as building knowledge and expertise within the system to ensure technical, security and data quality standards are the foundation of these technical requirements. It is also essential that appropriate operational resources are put in place to support successful implementation of technical solutions.

In order to support the effective and safe collection, use and sharing of health information, key technical and operational elements need to be developed. Electronic records are viewed as one of the cornerstones of the use and reuse of health data for both primary and secondary use. Ireland is lagging behind in terms of developing key national health information infrastructure, being one of just two countries in the EU without a system that provides citizens with access to their electronic records, such as a citizen's portal.⁽⁷⁾^{§§} The digital transformation in health and social care in response to the pandemic, such as the greater use of telemedicine and temporary provisions for ePrescribing, provides an opportunity to advance the current infrastructure to meet the needs and ensure the rights of current and future populations.

The Irish public also perceive 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.⁽¹²⁾ In the public consultation for this paper, a number of respondents commented that there is a huge gap between the current and desired infrastructure, and that a realistic strategy and implementation plan is required to move this agenda forward. There is also growing pressure from key national stakeholders and EU policy-makers to make better use of existing data through safe re-use of data. Forthcoming EU Data Governance legislation will place the sharing and re-use of certain data in a safe manner on a mandatory footing.⁽¹⁵⁾ This will also place a level of urgency on expediting key developments to infrastructure in Ireland to support the secondary use of data, specifically infrastructure to de-identify and link data, and create a safe environment for sharing and analysing data.⁽¹⁸⁾

The Sláintecare Implementation Strategy and Action Plan 2021-2023 lists a number

^{§§} Of the countries surveyed, national systems are in place in 22 member states, regional systems are in place in five member states, an individual-level service is in place in one member state, and other types of systems are in place in five member states.

of eHealth and technology actions that will be progressed to support integration and provide safe and timely access to care.⁽¹⁸⁾ Such initiatives include summary and shared care records, a citizen health portal, an electronic discharge system, and home support and residential care management systems. Immediate priority is focused on the continued rollout of Individual Health Identifiers (IHIs) to enable the creation of shared care records. In the public consultation for this paper, respondents identified the lack of a unique health identifier as a key barrier to the effective collection, use and sharing of data. For example, the recent Irish Heart Attack Audit also called for prompt implementation of a unique health identifier to enable identification of patients across the entire system.⁽⁴⁸⁾ Its absence limits the quality of the data used to inform the direct care of the patient and subsequent planning and management of services and related quality improvement of care pathways.

Advances in Ireland's technical infrastructure for health information will only be successful if appropriate resources are put in place to ensure operational feasibility. This will require careful consideration of the resources required, and related costs, for implementing these technical solutions at a national and local level. Failure to consider these operational requirements at the outset may impede on the ability of services to implement change and deliver the improvements in care that these technical solutions offer. For example, implementation of a summary care record, citizen health portal or a national data sharing service will all require operational teams to manage development and implementation. This will require a detailed assessment of the resources for each and an implementation plan that has appropriate resources and funding allocated to ensure success.

5.1 Technical considerations

5.1.1 Citizen health portal

An online citizen health portal for the Irish health system could provide individuals with access to medical records, appointment scheduling, secure messaging and resources for self-care. It also provides an opportunity to enhance people's rights in relation to health information by improving transparency, offering access to and control of information, and, if established in line with technical standards, portability of information for re-use by the individual. Findings from the national public engagement demonstrate that people want to be able to access their own information via a citizen health portal.⁽¹²⁾ The 'Path to the Digital Decade' Policy Programme outlines a target that 100% of EU citizens will have access to their electronic records by 2030.⁽¹⁷⁾ Ireland is one of just two countries in the EU without a system that provides citizens with access to their electronic records, such as via a digital portal.⁽⁷⁾ There is an urgency to progress portal development, as set out in the Sláintecare implementation strategies, to better align with international

counterparts.⁽¹⁸⁾

Findings from the national public engagement and public consultation which informed this paper also show that people want to know who has accessed their records and for what purpose, and they want to be able to control who can see certain types of information. The level of control provided to an individual differs across jurisdictions, both for the initiation of a portal account and the control of information thereafter. However, recent evidence shows that some jurisdictions are moving away from allowing control over the initiation of electronic records, on safety grounds, and moving towards a model that gives individuals greater control of information within their records.⁽²⁾ Some jurisdictions use online health portals as a means of managing individual preferences regarding data sharing, as well as consent preferences, when this is the legal basis for processing.⁽²⁾ In addition, some jurisdictions allow citizens to control who has access to their record, as well as removing access to certain information or documents. For example, in Finland, individuals can issue a 'refusal' to access information through the healthcare services or online through the portal in My Kanta Pages.⁽²⁾

There has also been a trend towards making it easier for individuals to review and decide how they want their information to be used for secondary purposes.⁽²⁾ Australia and England have implemented a data altruism model where individuals can decide if they want their information used for different secondary purposes, such as planning and research. In many jurisdictions, the infrastructure to enable people to manage their preferences is delivered through online portals, although England has a specific online platform in the absence of a national portal. In Ireland, the specific detail regarding the technology and capability to enable individuals to manage consent preferences should be explored through significant engagement with the public. The national public engagement on health information⁽¹²⁾ provides some insight into this topic, but there is a need for more in-depth engagement with both members of the public and health and social care professionals to ensure it is designed appropriately to meet the needs of all users. A greater discussion on the important considerations in relation to effective engagement is presented in section 2.

In the development of new infrastructure, it is necessary to carry out Data Protection Impact Assessments (DPIAs) to identify any potential risks to the rights and freedoms of individuals and to provide an opportunity to build in mitigating factors. GDPR requires the carrying out of DPIAs where processing is based on new technologies and taking into account the nature, scope, context and purposes of the processing. Therefore, the development of national infrastructures for the sharing of health and social care data will clearly require DPIAs to be conducted in relation to the various data processing operations.^(31,61)

In a complex and dynamic environment, the ability to capture and manage choice depends on the technical capacity to enable this. Investment and strategic leadership is required to develop a citizen health portal that meets such technical requirements and offers appropriate individual choice and control. This will build transparency and support people's rights in relation to their health information. HIQA is also currently developing recommendations in relation to a national health and social care portal in Ireland which will further address some relevant considerations identified in this section.

5.1.2 Effective use of data beyond direct care – extended DASSL model

As discussed in section 4, there is potential to extend the DASSL model beyond the research context and apply this infrastructure and services to inform further secondary purposes such as planning, management, monitoring of services, quality improvement and policy-making. The DASSL proof of concept project focuses on the technical implementation of infrastructure to support the DASSL model for research purposes. Learning will be crucial to assess the requirements for a scaled-up model that applies to secondary purposes beyond research, such as for ongoing data analysis requirements for planning and management of health and social care services.

In jurisdictions with advanced frameworks for the secondary use of information, specific services are in place that have responsibility for managing data requests and applying linkage and de-identification techniques, for example Findata in Finland.⁽³⁾ Findata facilitates the effective secondary use of information while safeguarding privacy by operating in a regulated environment that meets data security standards. When such data governance structures and technical infrastructure are in place, existing data and information can be anonymised and then shared securely ensuring the optimal use of data to inform policy and practice, and to support innovation. To manage this process in a safe and controlled environment, the appropriate infrastructure and expert skillset are required. As outlined in section 4, this service should be a key responsibility for the national strategic entity for health information.

Internationally, there are different operational models in place and these vary depending on the health and social care landscape and the legal and political structures present in a country.⁽⁵⁴⁾ Policy-makers need to consider the different options available and, drawing on the learning from DASSL, decide on which model is most appropriate for the Irish health and social care context. In federated models, data typically rests with the custodian and data requests are dealt with on an individual basis as required.⁽²³⁾ On the other hand, centralised models typically involve banking or warehousing of data.⁽²³⁾ Either model will require infrastructure that provides 'trusted third party' and 'safe haven' services. A trusted third party service de-identifies and links data to ensure data is available in a protected format

and appropriate for the required secondary use. This trusted third party service may be undertaken by a unit external or internal to the overall data sharing service. In either situation, the separation principle must apply whereby no one working with the data must have access to both identifiable data and clinical or event-based descriptive data. In Wales, for example, the de-identification and linkage service is undertaken within the health service, but by a separate unit who only gain access to files with identifying data.

Another essential component of the technical infrastructure is the provision of a safe haven, which is an environment in which data is held securely and can be accessed and manipulated safely under controlled conditions. The availability of secure environments would be welcomed by those involved in research and analysis in Ireland, as evidenced by responses to the public consultation, and they also help to build and maintain the confidence and trust of members of the public. There are three main types of safe havens: (i) an on-site safe haven in an entity, such as the national strategic entity for health information; (ii) an external, secure unit in a university or similar environment; or (iii) the provision of other remote access solutions.⁽²³⁾

External and remote access solutions need to provide the same protections to data privacy and security as on-site options. It may be that particularly sensitive data is only available via on-site options, but potential capacity and resourcing issues will need to be considered to ensure it can meet future demands as health and social care data becomes more available with the advancement of electronic records.⁽²³⁾

As previously outlined, consideration needs to be given to the different operational model options for an extended DASSL model, and the potential implications for local-level services. This will require discussions around data ownership and the infrastructure that must be in place to ensure interoperability and data integrity. The establishment of a national data sharing service will only be successful if supported by significant improvement at service provision level in relation to data quality and interoperability. Some respondents to the public consultation noted that poor data quality was a key issue for Findata in the early stages of its inception. It will be important to learn from such an experience, and to accept that the development of the required infrastructure will be an incremental process with sustained investment and leadership required across a number of areas. In addition, the most appropriate technical solutions will change as knowledge advances and it is important that the required expertise is in place to enable change as required. Expertise will be required in relation to data quality assurance, management and administration; statistical knowledge, including privacy protection, security and disclosure control; and database and IT systems.⁽²³⁾ The specific skillset required may vary depending on the specific choices made in relation to the model for implementation.

5.2 Operational considerations

5.2.1 Standards for data interoperability, data security and data quality

Development of a citizen health portal and national infrastructure to de-identify, link data and create a safe sharing environment relies on a number of key building blocks for successful implementation which include: data interoperability, data security and data quality.

In order to address the demands of interoperability, security and quality, many EU countries have adopted policies, guidelines or legal requirements that ensure standards are used by healthcare provider organisations. Approximately half of the EU Member States have national or regional interoperability policies regarding the technical standards that must be used to ensure that the structure and format of data are interoperable, so that data may be shared between health and social care professionals or incorporated into more than one database for secondary use.⁽⁷⁾ The development of standards needs attention to ensure that data is collected in a way that enables service providers and people using services to share health information regardless of the system they are using. It ensures confidentiality and integrity. This becomes of greater importance as advances are made in the sharing of data across borders; appropriate interoperability standards, which align with EU standards, will allow Ireland to engage more fully in cross-EU initiatives and research projects.

National data quality policies exist in a minority of countries. A considerable number, however, have regional or sectoral policies in place. The majority of EU Member States have a national health data security policy regarding technical standards to be used to ensure health data for primary use are processed and stored securely.⁽⁷⁾ Within the EHDS, proposals for EU-level guidance on security or a legislative act may be an option to mandate compliance with security standards. A key finding of the review of the cyber security attack within the HSE that transformational change involving people, process and technology is required and that developing relevant standards for the health and social care sector, alongside appropriate guidance, would support change and a move towards enhanced cyber resilience.

Ireland lags behind countries internationally in developing and implementing standards-based information systems for health and social care with a fragmented and uncoordinated approach. It is important that there is a national approach to developing health information standards in Ireland to realise an integrated health and social care system as set out in Sláintecare.⁽³⁾*** Respondents to the public

***HIQA is currently developing recommendations for a health information standards model to support the delivery of health and social care services in Ireland which will set out requirements in relation to progressing the process of standards development and advancing policy direction and stakeholder engagement in this space.

consultation for this paper commented that substantial investment was crucial, in relation to infrastructure, expertise, and capacity at a service level, in the area of health information. A national strategic entity for health information should be responsible for developing, implementing and maintaining consistent national health information standards and harmonisation of data privacy and security policies and practices.⁽³⁾

It is widely acknowledged that a huge body of work is required in Ireland to get in place the infrastructure for eHealth and an extended DASSL model for re-use of data. However, this should not deter progress and plans should be initiated with the recognition that improvements will occur as systems evolve. It is also necessary to concurrently develop the policy and guidance, and associated engagement and training to build knowledge and expertise within the system to ensure the building blocks of technical standards, security standards and data quality standards are the foundation of technical developments. These elements should be incorporated into the national data governance framework, as outlined in sections 3 and 4, to ensure adoption of consistent practices across all organisations collecting, using and sharing health information.

5.2.2 Resourcing considerations

A fundamental element of implementing technical solutions in health and social care services is consideration of the operational resources required at both national and local level and allocation of appropriate funding to achieve strategic goals. When new legislation or policy changes are being introduced, it is essential that services are appropriately resourced to deliver against these changes and ensure the best experience for people using health and social care services. A process of 'benefits realisation' will be important to identify the operational resources required. The 2015 Knowledge and Information Strategy clearly lays out the core elements of a benefits realisation framework, which includes business case rigour to justify investment and robust quality assurance of costs, including estimates and risks.⁽¹⁰⁾ It is also important to acknowledge the substantial resources that are already in place across services but that may not be currently employed optimally or may become less relevant as technology advances. A rationalisation process could identify opportunities for centralising or co-locating similar operational services while controlling costs, optimising resource utilisation and ensuring high-quality care continues to be provided.

An important element of this change management will involve consideration of the potential need for culture and behaviour change with funding required for relevant training and communication resources. It is important to acknowledge the extent of change that is required and a prioritisation exercise will be necessary to develop a staged implementation plan and allocate resources accordingly. Effective strategic

leadership will be required to guide change and ensure technical and legislative advances are implementable at an operational level.

5.2.3 Guidance to support the collection, use and sharing of health information

It is imperative that everybody working in the health and social care system understands their responsibilities in relation to the collection, use and sharing of health information. However, in the absence of a strong legal framework and related guidance, it can be difficult for health and social care professionals to use information to its full potential while ensuring that they respect individuals' rights to privacy and confidentiality. It is important to provide clarity on obligations and responsibilities for those working in health and social care services. Therefore, in parallel to developing the technical and operational requirements, detailed guidance would help to outline best practice and to build professional capacity to ensure an appropriate balance is achieved between data sharing and data protection. However, it will be important that guidance and codes of practice allow sufficient flexibility to support the range of roles and services in the health and social sector. Such flexibility will also be necessary to ensure continued alignment as health technologies advance. It was further emphasised in the public consultation feedback that the range of health and social care staff that will require guidance must be considered and resources should be tailored to ensure it meets the needs of all staff.

As this is a complex and evolving area, guidance and codes of practice would help to develop a common understanding around individuals' rights in relation to health information. Many respondents to the public consultation saw a significant need for the development of appropriate guidance and codes of practice, as there was perceived to be confusion at an individual level. They believed that if there was a better understanding of all of the legal bases for data processing, there would be less apprehension in health and social care professionals about data sharing. Respondents suggested that guidance for professionals should include clear, practical examples of relevance to their area of work. In New Zealand and Northern Ireland, for example, legally-mandated codes of practice that govern health information have been introduced. In Northern Ireland, the 'Code of Practice on Protecting the Confidentiality of Service User Information', published in 2019, supports and guides all those involved in health and social care regarding decisions relating to the protection, use and sharing of service user information.⁽⁶²⁾ Similarly, in 2020, New Zealand published the 'Health Information Privacy Code' which outlines rules for health agencies regarding the collection, use, storage and sharing of health information.⁽⁶³⁾ Furthermore, some respondents to the public consultation identified that in parallel to developing an extended DASSL model and to support the effective secondary use of information, detailed guidance would help to outline best practice

in relation to de-identification and linking of health and social care data.

5.3 Key considerations – technical requirements and operational arrangements

4

As a priority, and in compliance with forthcoming EU legislation and targets, the infrastructure to support the primary and secondary use of data must be developed to include a citizen's portal and an extended DASSL model, as well as building knowledge and expertise within the system to ensure technical, security and data quality standards are the foundation of these technical requirements. It is also essential that appropriate operational resources are put in place to support successful implementation of technical solutions.

Key considerations:

- Development of a citizen health portal will be critical to support people's rights in relation to their health information and to align with international counterparts. It is also critical in assisting in greater empowerment to better manage one's own care as an online citizen health portal could provide individuals with access to medical records, appointment scheduling, secure messaging and resources for self-care. This can further encourage citizens to monitor their health status, adapt their lifestyles, and bring greater efficiency to health and care providers and health systems.
- A citizen health portal should offer people control over what personal information is shared and who can access this information, while also providing an opportunity to manage consent preferences, where this legal basis is relevant.
- In-depth engagement should be undertaken with members of the public and health and social care professionals to inform the development of the citizen health portal at all stages of development and implementation, in line with considerations presented in section 2.
- In order to support the effective and secure use of data for secondary purposes, appropriate infrastructure must be put in place to enable a national data sharing and linkage service, as managed by the national strategic entity for health information. This service should include 'trusted third party' and 'safe haven' services. Policy-makers must consider the different options and draw on learning from the DASSL proof of concept model to identify the most appropriate operational model for the Irish context.
- It is essential that an expert skillset is in place within this data sharing and linkage service to ensure change can be managed effectively as knowledge

and technologies advance, and that appropriate measures are in place to support both data protection and data sharing.

- Development of a citizen health portal and infrastructure for a national data sharing and linkage service will only be successful if supported by improvements in relation to data quality, data interoperability and data security. A national approach to developing health information standards is essential to achieve such improvements. Work on developing and implementing standards needs to occur in tandem with the technical developments.
- These standards should be incorporated into the national data governance framework to ensure adoption of consistent practices across all organisations collecting, using and sharing health information.
- It is essential that appropriate operational resources are put in place to support successful implementation of technical solutions. A process of benefits realisation and rationalisation will help to identify the resources required and potential opportunities for consolidating, transferring or expanding resources to support implementation. Adequate investment and effective strategic leadership will be crucial to guide change and ensure technical and legislative advances are implementable at an operational level.
- Appropriate guidance and codes of practice should be developed for health and social care professionals that clearly outline responsibilities and obligations in relation to the collection, use and sharing of health information. Building on the feedback from the public consultation, a review should be undertaken to identify existing knowledge gaps and the resources required to build individual expertise.

6. Conclusion

Sharing personal information in a secure and controlled manner is an integral part of care provision. Health information is invaluable both for managing direct care and also for secondary purposes, such as health service planning and management, policy-making and research. The COVID-19 pandemic has heightened awareness and the need for co-operation, as well as rapid and responsive action, in the area of data sharing. It highlighted the importance of data sharing for public health in the reporting of disease incidence, contact tracing and in the need for accessible data for collaborative research. As time moves on, such data is now needed to evaluate the impact of treatment and vaccine effectiveness; therefore, the need for good quality, comprehensive and timely data is still ever present.⁽⁶⁾

Currently in Ireland, the legal and regulatory frameworks do not adequately cover provisions for the required eHealth innovations, coordination of key national data collections and effective re-use of health and social care data. There is also a lack of a comprehensive infrastructure for secure data access, storage, sharing and linkage of routinely collected health and social care data. While there are some governance structures in place, these need to be enhanced to keep pace with change. This is particularly important as plans for eHealth initiatives advance and health and social care becomes more integrated, which will vastly increase the potential for the collection, use and sharing of health information. However, this process demands the support of citizens and professionals to build the trust which is essential to progress in the development of health information systems. Active engagement and debate in this area will encourage individuals to act as agents in their own health and social care, with the capacity to exercise their data-related rights. This is, therefore, an opportune time to engage meaningfully with the public and professionals in advance of the development of new health information legislation and the forthcoming changes required to how health information is collected, used and shared.

This paper sets out the key policy considerations to drive transformational change in relation to the collection, use and sharing of health information in Ireland. Progress is needed across four areas: effective engagement; legislative framework; governance structures; and technical and operational requirements. Each of these elements are interdependent, similar to cogs on a wheel, meaning failure to address one area will impede or stall progress in the other areas. Progress in all four areas is ultimately needed to promote a modern and future-focused data-rich environment for health and social care in Ireland.

Glossary of terms

Aggregate data: Data that have been summed and or categorised to a level that ensures the identities of individuals or organisations cannot be determined by a reasonably foreseeable method.

Anonymisation: Processing of data or information with the aim of irreversibly preventing the identification of the individual to whom it relates. Data or information can be considered effectively and sufficiently anonymised if it does not relate to an identified or identifiable natural person or where it has been rendered anonymous in such a manner that the data subject is not or no longer identifiable.

Consent: Means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.

Citizen health portal: A citizen health portal, or patient portal as described in some jurisdictions, is specially created to allow online access for individuals to their own healthcare information through apps on their smartphone or other devices, or using a website. In many countries, patients use a portal to access their EHR, where they can see their latest test results, clinical correspondence, request repeat medications and to request appointments. Some portals also enable patients to add their own health information, to maintain their own record of home monitoring for conditions such as diabetes. In another example, the portal may provide a parent with the ability to add supplementary entries to an incomplete vaccination record for their child. The clinician reviewing the record can then review these and the original entries to gain a better understanding of the child's vaccination history.

Clinical audit: A clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria, and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements.

Data: Facts and statistics and individual detail are considered data. Data can be described as numbers, symbols, words, images and graphics that have been validated but are yet to be organised or analysed.

Data linkage: A method of bringing information from different sources together about the same person or entity to create a new, richer dataset.

De-identification: Processing of data or information so that there is a reduced likelihood of an individual being reasonably identified, although re-identification may be possible through deliberate techniques, such as linkage with other sources.

eHealth: eHealth enables health information to be managed in a coordinated way. The World Health Organization (WHO) defines eHealth as ‘the cost-effective and secure use of information and communications technologies in support of health and health-related field, including health care services, health surveillance, health literature, and health education, knowledge and research’.

ePrescribing: ePrescribing can be described as a three-step approach. First, at the time of prescribing medications for a patient, the prescriber’s clinical information system generates the prescription in electronic format. Second, the electronic format of the prescription is transmitted to a message exchange or mailbox and, when the patient presents in a pharmacy requesting their medication, the pharmacist retrieves the electronic prescription from the message exchange. Third, the pharmacist dispenses the medication and reports on the medicines given to the patient.

Genetic data: Personal data relating to the inherited or acquired genetic characteristics of a natural person which result from the analysis of a biological sample from the natural person in question, in particular chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or from the analysis of another element enabling equivalent information to be obtained.

Health and social care: Activities that focus on the preservation or improvement of the health or wellbeing of others; the diagnosis, treatment or care of those who are injured, sick, disabled or infirm; the resolution, through guidance, counselling or otherwise, of personal, social or psychological problems; the care of those in need of protection, guidance or support.

Health and Social Care Professional: A health or social care professional is any person that exercises skill or judgment relating to any activity included in the definition of health and social care.

Health and social care research: Research designed and conducted to generate new generalisable or transferrable knowledge that could lead to changes to treatments, policies or care in relation to health and social care. As defined in the Health Research Regulations 2018, health research is:

- research with the goal of understanding normal and abnormal functioning, at the molecular, cellular, organ system and whole body levels;
- research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury;

- research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals;
- research with the goal of improving the efficiency and effectiveness of health professionals and the health care system;
- research with the goal of improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status.

Health information: Information, recorded in any form, which is created or communicated by an organisation or individual relating to the past, present or future, physical or mental health or social care of an individual or group of individuals (also referred to as a cohort). Health information also includes information relating to the management of the health and social care system.

Health information system: Throughout the literature, the term ‘health information system’ varies, often with no clear or precise definition and has become an umbrella term encompassing a number of systems — both electronic and paper-based — for capturing and transferring health information. For the purpose of this paper, a health information system encompasses all health information sources required by a country to plan and implement its national health strategy. Examples of these data sources are electronic health records (EHRs), surveillance data, census data, population surveys, and national health and social care data collections.

Identifiable data: Data that identifies an individual or for which it is reasonably foreseeable in the circumstances that it could be utilised, either alone or with other information or data, to identify an individual.

Information: When data are processed, interpreted, organised, analysed, structured or presented so as to make them meaningful or useful, they are then information.

National data collections: are national repositories of routinely collected health and social care data.

National electronic health record (EHR): is a complete digital record of a patient’s journey, throughout their life, across all health and social care settings, for every citizen. An EHR contains the information documented by healthcare professionals when they interact with that patient — for example, the patient’s symptom history, past history of illnesses and operations, clinical observations made by the professional such as a blood pressure reading, blood and other test results, X-rays and scan results, prescriptions and other treatments, care advice, the course of the illness, preventive and public health activities such as immunisations, and

activities undertaken by patients to stay healthy. An EHR system can support healthcare professionals by facilitating, for example, the use of checklists, alerts, and predictive tools, and embedding clinical guidelines, electronic prescribing and the ordering of tests.

Personal data or information: Any data or information relating to an identified or identifiable individual. An identifiable individual is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that individual.

Pseudonymisation: Processing of personal data or information in such a way that the data can no longer be attributed to a specific data subject without the use of additional information, provided that— (a) such additional information is kept separately from the data, and (b) is subject to technical and organisational measures to ensure that the data are not attributed to an identified or identifiable individual.

Safe haven: An environment in which data is held securely and where access to data is highly controlled and restricted. Under agreed processes, health data may be processed and linked with other health data (and or non-health related data) and made available in a de-identified form for reasons beyond direct care. Safe havens may be developed as on-site facilities or provided through remote access solutions, as long as privacy standards can be equally maintained.

Glossary of abbreviations

Abbreviation	Explanation
CIDR	Computerised Infectious Disease Reporting
CPSYCHI	College of Psychiatrists Ireland
CSO	Central Statistics Office
DAIM	Data and Information Management
DASSL	Data Access, Storage, Sharing and Linkage
DNA	Deoxyribonucleic acid
DPA	Data Protection Agency
DPIA	Data Protection Impact Assessments
DPO	Data Protection Officer
EHDS	European Health Data Space
EHR	Electronic Health Records
EU	European Union
GDPR	General Data Protection Regulation
GP	General Practitioner
HES	Hospital Episode Statistics
HID	Health Identifiers Service
HIV	Human Immunodeficiency Virus
HIPE	Hospital In-Patient Enquiry
HIQA	Health Information and Quality Authority
HISI	Health Informatics Society of Ireland
HRCDC	Health Research Consent Declaration Committee
HSE	Health Service Executive
ICT	Information and communications technology

IHI	Individual health identifiers
IPPOSI	The Irish Platform for Patient Organisations, Science and Industry
NCRI	National Cancer Registry Ireland
NHIS	National Health Information Systems
NHS	National Health Service
NMBI	Nursing and Midwifery Board of Ireland
NOCA	National Office for Clinical Audit
NUIG	National University of Ireland, Galway
OECD	Organisation for Economic Co-operation and Development
REC	Research Ethics Committee
RNA	Ribonucleic acid
SIRT	Standards Information Research and Technology
TEHDAS	Towards the European Health Data Space
UK	United Kingdom
UKCGC	United Kingdom Caldicott Guardian Council
WHO	World Health Organisation

References

1. Health Act 2007 (Ireland). Available from: <https://www.irishstatutebook.ie/eli/2007/act/23/enacted/en/html>. Accessed on: 28 October 2021.
2. Health Information and Quality Authority. *Evidence Synthesis: Recommendations for a consent model on the collection, use and sharing of health information*. Dublin: 2021. Available from: <https://www.hiqa.ie/reports-and-publications/health-information/evidence-synthesis-recommendations-consent-model>. Accessed on: 22 November 2021.
3. Health Information and Quality Authority. *The need to reform Ireland's national health information system to support the delivery of health and social care services*. Dublin: 2021. Available from: <https://www.hiqa.ie/sites/default/files/2021-10/The-need-for-reform-of-the-health-information-system.pdf>. Accessed on: 28 October 2021.
4. Minister Donnelly receives Cabinet approval to develop new health information legislation [press release]. Available from: <https://www.gov.ie/en/press-release/3d605-minister-donnelly-receives-cabinet-approval-to-develop-new-health-information-legislation/>. Accessed on: 9 June 2022.
5. J. Oderkink. *OECD Health Working Papers No. 127 - Survey Results: National health data infrastructure and governance*. 2021. Available from: <https://www.oecd-ilibrary.org/docserver/55d24b5d-en.pdf?expires=1635850631&id=id&accname=guest&checksum=CE5C7CA6A1CFCCA3DF577F521A7810D4>. Accessed on: 2 November 2021.
6. Open Data Institute. *Secondary use of health data in Europe*. 2021. Available from: <http://theodi.org/wp-content/uploads/2021/09/Secondary-use-of-Health-Data-In-Europe-ODI-Roche-Report-2021-5.pdf>. Accessed on: 2 November 2021.
7. European Commission. *Assessment of the EU Member States' rules on health data in the light of GDPR*. Luxembourg: 2021. Available from: https://ec.europa.eu/health/system/files/2021-02/ms_rules_health-data_en_0.pdf. Accessed on: 31 March 2022.
8. Irish Government Department of Health and Children. *Health information: a national strategy*. 2004. Available from: <https://www.lenus.ie/bitstream/handle/10147/46386/1242.pdf;jsessionid=AD4C31F87AF2CDFD133E611F3D78EC5B?sequence=1>. Accessed on: 9 June 2022.

9. Irish Government Department of Health. *eHealth Strategy for Ireland*. Dublin: 2013. Available from: <https://assets.gov.ie/16174/092e7c62f97b472b83cdb6dfdcdfd5c7.pdf>. Accessed on: 28 October 2021.
10. Health Service Executive. *Knowledge & Information Strategy. Delivering the Benefits of eHealth in Ireland*. . Dublin: Health Service Executive. 2015. Available from: <https://www.ehealthireland.ie/knowledge-information-plan/knowledge-and-information-plan.pdf>. Accessed on: 18 May 2022.
11. PwC (Commissioned by the HSE Board in conjunction with the CEO and Executive Management Team). *Conti cyber attack on the HSE. Independent Post-Incident Review*. Dublin: PwC. 2021. Available from: <https://www.hse.ie/eng/services/publications/conti-cyber-attack-on-the-hse-full-report.pdf>. Accessed on: 9 June 2022.
12. Health Information and Quality Authority, Department of Health, Health Service Executive. *Findings from the National Public Engagement on Health Information 2020 - 2021*. Dublin: 2021. Available from: <https://www.hiqa.ie/sites/default/files/2021-09/Findings-from-the-National-Public-Engagement-on-Health-Information.pdf>. Accessed on: 28 October 2021.
13. Science and Industry (IPPOSI) Irish Platform for Patient Organisations. *Verdict from a Citizens' Jury on Access to Health Information*. 2021. Available from: https://www.ipposi.ie/wp-content/uploads/2021/09/IPPOSI_CJury_Full_Report_06092021.pdf. Accessed on: 3 November 2021.
14. European Union (Open Data and Re-use of Public Sector Information) Regulations, 2021. Available from: <https://www.irishstatutebook.ie/eli/2021/si/376/made/en/html>. Accessed on: 17 August 2022.
15. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act), 2020. Available from: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0767>. Accessed on: 17 August 2022.
16. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on harmonised rules on fair access to and use of data (Data Act), 2022. Available from: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2022%3A68%3AFIN>. Accessed on: 17 August 2022.

17. *Proposal for a DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing the 2030 Policy Programme "Path to the Digital Decade"*. 2021. Available from: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0574>. Accessed on: 31 March 2022.
18. Irish Government Department of Health. *Sláintecare Implementation Strategy and Action Plan 2021-2023*. Dublin: 2021. Available from: <https://www.gov.ie/en/publication/6996b-slaintecare-implementation-strategy-and-action-plan-2021-2023/>. Accessed on: 28 October 2021.
19. Irish Government Department of the Taoiseach. *Harnessing Digital - The Digital Ireland Framework*. Dublin: Irish Government Department of the Taoiseach. 2022. Available from: <https://www.gov.ie/en/publication/adf42-harnessing-digital-the-digital-ireland-framework/#>. Accessed on: 3 May 2022.
20. Irish Government Department of Health. *Slaintecare Action Plan 2022*. Dublin: Department of Health. 2022. Available from: <https://www.gov.ie/en/publication/0d2d60-slaintecare-publications/>. Accessed on: 9 June 2022.
21. Health Information and Quality Authority. *International review of consent models for the collection, use and sharing of health information*. Dublin: 2020. Available from: <https://www.hiqa.ie/sites/default/files/2020-02/International-Review%E2%80%93consent-models-for-health-information.pdf>. Accessed on: 28 October 2021.
22. Health Information and Quality Authority. *International review of national health and social care data collections*. Dublin: Health Information and Quality Authority. 2016. Available from: <https://www.hiqa.ie/sites/default/files/2017-01/International-review-National-Health-Social-Care-Data-Collections-2016.pdf>. Accessed on: 26 May 2022.
23. R Moran. *Proposals for an Enabling Data Environment for Health and Related Research in Ireland - A discussion document*. Dublin: 2016. Available from: https://www.hrb.ie/fileadmin/publications_files/Proposals_for_an_Enabling_Data_Environment_for_Health_and_Related_Research_in_Ireland.pdf. Accessed on: 28 October 2021.
24. Irish Government Department of Health. *Sláintecare Implementation Strategy*. Dublin: 2019. Available from: <https://assets.gov.ie/9914/3b6c2faf7ba34bb1a0e854cfa3f9b5ea.pdf>. Accessed on: 29 October 2021.
25. Siggins Miller. *Evaluation of the Participation Trials for the My Health Record*.

- Canberra: 2016. Available from: [https://www1.health.gov.au/internet/main/publishing.nsf/Content/A892B3781E14E1B3CA25810C00BF7C6/\\$File/Evaluation-of-the-My-Health-Record-Participation-Trials-Report.pdf](https://www1.health.gov.au/internet/main/publishing.nsf/Content/A892B3781E14E1B3CA25810C00BF7C6/$File/Evaluation-of-the-My-Health-Record-Participation-Trials-Report.pdf). Accessed on: 28 October 2021.
26. Health and Social Care (National Data Guardian) Act 2018 (United Kingdom). Available from: <https://www.legislation.gov.uk/ukpga/2018/31/contents/enacted>. Accessed on: 18 August 2022.
27. Understanding Patient Data *Understanding Patient Data* [Online]. Available from <https://understandingpatientdata.org.uk/>. Accessed on: 28 October 2021.
28. Science and Industry (IPPOSI) Irish Platform for Patient Organisations *Citizens' Jury on Health Information* [Online]. Available from <https://www.ipposi.ie/our-work/policy/health-information/citizens-jury/>. Accessed on: 3 November 2021.
29. Towards European Health Data Space. *Citizens' perception of and engagement with health data secondary use and sharing in Europe –a literature review*. 2021. Available from: <https://tehdas.eu/results/individuals-favour-data-sharing-and-use-if-benefits-are-clear/>. Accessed on: 31 March 2022.
30. International Association for Public Participation. *IAP2 Spectrum of Public Participation*. 2018. Available from: https://cdn.ymaws.com/www.iap2.org/resource/resmgr/pillars/Spectrum_8.5x11_Print.pdf. Accessed on: 29 October 2021.
31. General Data Protection Legislation 2016 (European Union). Available from: <https://gdpr-info.eu/>. Accessed on: 17 August 2022.
32. COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Artificial Intelligence for Europe, 2018. Available from: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A237%3AFIN>. Accessed on: 17 August 2022.
33. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the respect for private life and the protection of personal data in electronic communications and repealing Directive 2002/58/EC (Regulation on Privacy and Electronic Communications), 2017. Available from: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52017PC0010>. Accessed on: 17 August 2022.

34. Health Information and Patient Safety Bill (Ireland). Available from: <https://assets.gov.ie/11440/de4022eba9ea495c8a2d89efbca0bd77.pdf>. Accessed on: 17 August 2022.
35. The Health (Provision of Information) Act 1997 (Ireland). Available from: <https://www.irishstatutebook.ie/eli/1997/act/9/enacted/en/html>. Accessed on: 17 August 2022.
36. Health Information and Quality Authority. *Review of information management practices in the HIPE scheme*. Dublin: Health Information and Quality Authority. 2018. Available from: <https://www.hiqa.ie/reports-and-publications/health-information/review-information-management-practices-hospital>. Accessed on: 3 May 2022.
37. NHS Digital *Hospital Episode Statistics: GDPR information* [Online]. Available from <https://digital.nhs.uk/about-nhs-digital/our-work/keeping-patient-data-safe/gdpr/gdpr-register/hospital-episode-statistics-gdpr/hospital-episode-statistics-hes-gdpr-information>. Accessed on: 3 May 2022.
38. Australian Commission on Safety and Quality in Health Care (ACSQHC). *Framework for Australian clinical quality registries*. 2014. Available from: <https://www.safetyandquality.gov.au/sites/default/files/migrated/Framework-for-Australian-Clinical-Quality-Registries.pdf>. Accessed on: 9 June 2022.
39. New Zealand Ministry of Health *Virtual Diabetes Register (VDR)* [Online]. Available from <https://www.health.govt.nz/our-work/diseases-and-conditions/diabetes/about-diabetes/virtual-diabetes-register-vdr>. Accessed on: 3 May 2022.
40. Data Protection Commission. *Guidance on Legal Bases for Processing Personal Data*. Dublin: Data Protection Commission. 2019. Available from: <https://www.dataprotection.ie/en/dpc-guidance/guidance-legal-bases-processing-personal-data>. Accessed on: 3 May 2022.
41. NHS Digital *Choose if data from your health records is shared for research and planning* [Online]. Available from <https://www.nhs.uk/your-nhs-data-matters/where-your-choice-does-not-apply/>. Accessed on: 29 October 2021.
42. Data Protection Commission. *Children Front and Centre: Fundamentals for a Child-Oriented Approach to Data Processing. Report on Public Consultation*. Dublin: Data Protection Commission. 2021. Available from: https://www.dataprotection.ie/sites/default/files/uploads/2021-11/DPC_ChildrensRights_SummaryResponses_ENGLISH_2021.pdf. Accessed on: 3 May 2022.

43. European Data Protection Board. *Guidelines 05 / 2020 on consent under Regulation 2016/679*. Brussels: European Data Protection Board. 2020. Available from: https://edpb.europa.eu/sites/default/files/files/file1/edpb_guidelines_202005_consent_en.pdf. Accessed on: 3 May 2022.
44. Health Service Executive. *National Consent Policy*. Dublin HSE. 2022. Available from: <https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/hse-national-consent-policy.pdf>. Accessed on: 3 May 2022.
45. Health Research Charities Ireland (HRCI). *Using data for better health research*. Dublin: HRCI. 2022. Available from: https://hrci.ie/hrcis-2022-position-paper-using-data-for-better-health-research/?utm_source=rss&utm_medium=rss&utm_campaign=hrcis-2022-position-paper-using-data-for-better-health-research. Accessed on: 3 May 2022.
46. Mahsa Shabani, Luca Marelli. Re-identifiability of genomic data and the GDPR. *EMBO reports*. 2019; 20(6):[e48316 p.]. Available from: <https://www.embopress.org/doi/abs/10.15252/embr.201948316>. Accessed on: 3 May 2022.
47. Information Commissioner's Office *What is special category data?* [Online]. Available from <https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/special-category-data/what-is-special-category-data/>. Accessed on: 3 May 2022.
48. National Office of Clinical Audit. *Irish Heart Attack Audit National Report 2017–2020*. Dublin: National Office of Clinical Audit. 2022. Available from: <https://www.noca.ie/documents/irish-heart-attack-national-report-2017-2020>. Accessed on: 3 May 2022.
49. Towards European Health Data Space Consortium Partners. *Why health is a special case for data governance*. 2021. Available from: <https://tehdas.eu/app/uploads/2021/06/tehdas-why-health-is-a-special-case-for-data-governance-2021-06-23.pdf>. Accessed on: 5 May 2022.
50. Health Information and Quality Authority, Safeguarding Ireland. *Guidance on a Human Rights-based Approach in Health and Social Care Services* Dublin: 2019. Available from: <https://www.hiqa.ie/sites/default/files/2019-11/Human-Rights-Based-Approach-Guide.PDF>. Accessed on: 1 November 2021.
51. European Commission *EU Charter of Fundamental Rights* [Online]. Available

- from https://ec.europa.eu/info/aid-development-cooperation-fundamental-rights/your-rights-eu/eu-charter-fundamental-rights_en. Accessed on: 28 October 2021.
52. Data Protection Commission. *Guidance Note: Guidance on Anonymisation and Pseudonymisation*. 2019. Available from: <https://www.dataprotection.ie/sites/default/files/uploads/2020-09/190614%20Anonymisation%20and%20Pseudonymisation.pdf>. Accessed on: 28 October 2021.
53. Data Protection Commission *Data protection – not an absolute right* [Online]. Available from <https://www.dataprotection.ie/en/dpc-guidance/blogs/data-protection-not-absolute-right#:~:text=Data%20protection%20%E2%80%93%20not%20an%20absolute%20right%2008th,protection%20of%20personal%20data%20concerning%20him%20or%20her>. Accessed on: 28 October 2021.
54. Towards European Health Data Space Consortium Partners. *Description of steps in accessing individual-level data for national and EU researchers in a selection of centralised systems and decentralised systems*. 2022. Available from: <https://tehdas.eu/results/tehdas-scrutinises-data-access-processes-in-four-countries/>. Accessed on: 3 May 2022.
55. Health Research Board *Proof of Concept technical model for 'DASSL' (Data Access, Storage, Sharing and Linkage) award 2019 (Closed)* [Online]. Available from <https://www.hrb.ie/funding/funding-schemes/all-funding-schemes/grant/proof-of-concept-technical-model-for-dassl-data-access-storage-sharing-and-linkage-award-2019/>. Accessed on: 2 November 2021.
56. Australian Institute of Health and Welfare. *Data Governance Framework 2021 (Public edition)*. 2021. Available from: <https://www.aihw.gov.au/getmedia/c3e00f60-c40d-4989-ad22-de1be3ab5380/Data-Governance-Framework-2021.pdf.aspx>. Accessed on: 8 November 2021.
57. Health Service Executive. *Performance and Accountability Framework*. Dublin: 2020. Available from: <https://www.hse.ie/eng/services/publications/serviceplans/service-plan-2020/performance-and-accountability-framework-2020.pdf#:~:text=The%20objective%20of%20the%20Performance%20and%20Accountability%20Framework,context%20%E2%80%98Accountability%20is%20about%20delivering%20on%20a%20commitment>. Accessed on: 29 October 2021.
58. Health Service Executive National Delegations Office. *Delegation Policy*

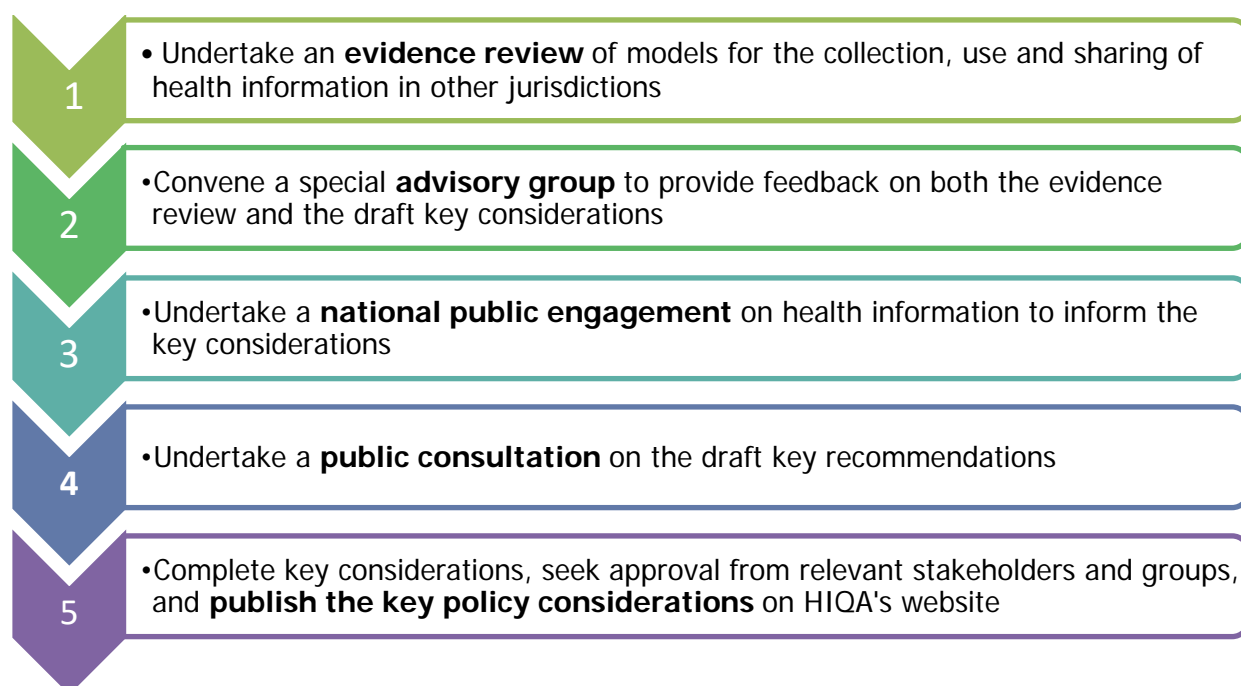
- Framework and Governance Arrangements version 5*. Limerick: 2015. Available from: <https://www.hse.ie/eng/about/who/delegations-office/delegation-framework-and-government-arrangements.pdf>. Accessed on: 29 October 2021.
59. The National Data Guardian. *The Eight Caldicott Principles*. London: 2020. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/942217/Eight_Caldicott_Principles_08.12.20.pdf. Accessed on: 28 October 2021.
60. United Kingdom Government *UK Caldicott Guardian Council* [Online]. Available from <https://www.gov.uk/government/groups/uk-caldicott-guardian-council>. Accessed on: 28 October 2021.
61. Health Information and Quality Authority. *Guidance on Privacy Impact Assessment*. Dublin Health Information and Quality Authority, 2017. Available from: <https://www.higa.ie/reports-and-publications/health-information/guidance-privacy-impact-assessment-pia-health-and>. Accessed on: 26 May 2022.
62. Northern Ireland Department of Health. *Code of Practice on Protecting the Confidentiality of Service User Information*. 2019. Available from: <https://www.health-ni.gov.uk/sites/default/files/publications/health/user-info-code2019.pdf>. Accessed on: 29 October 2021.
63. New Zealand Office of the Privacy Commissioner. *Health Information Privacy Code*. Wellington: 2020. Available from: <https://www.privacy.org.nz/assets/Codes-of-Practice-2020/Health-Information-Privacy-Code-2020-website-version.pdf>. Accessed on: 29 October 2021.

Appendix 1 – Methodology - stages of development

These key considerations were developed as per HIQA's legislative remit under the Health Act 2007 and subsequent amendments to the Act.⁽¹⁾ HIQA has a statutory remit to develop standards, evaluate information and make recommendations about deficiencies in health information. 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).

These key policy 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 each of the eight jurisdictions were contacted for an interview to ensure the most relevant and up-to-date information was gathered. The eight jurisdictions included in the reviews were:

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

Stage 2: Advisory group - An advisory group was convened five times to provide assistance in developing the key considerations (see **Appendix 4** 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 Health Service Executive (HSE), undertook a national public engagement to guide the development of the key considerations 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 survey was conducted with 1,200 members of the public to give their feedback on how their personal health information is collected, used and shared by health and social care services, and their opinions on the use of digital technologies in this area. In order to further understand the findings of the survey, 14 focus groups were held with the public, patients and representatives of different service user groups. The full report, [*Findings from the National Public Engagement on Health Information*](#), can be found on HIQA's website. The findings of the national public engagement on health information were used to inform these key considerations.

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. Further details on the public consultation process and the key findings from the public consultation are available in the '*Summary of stakeholder involvement: Key considerations to inform policy for health information in Ireland*'.

Stage 5: Publication of key considerations - After the public consultation, the key considerations were reviewed and amended to reflect the feedback. 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 also published on the HIQA website.

Appendix 2 – Legal bases for processing health data and special categories of personal data (GDPR)⁽³¹⁾

Article 6 - Lawfulness of processing;

Processing shall be lawful only if and to the extent that at least one of the following applies:

- a) the data subject has given **consent** to the processing of his or her personal data for one or more specific purposes;
- b) processing is necessary for the performance of a **contract** to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;
- c) processing is necessary for compliance with a **legal obligation** to which the controller is subject;
- d) processing is necessary in order to protect the **vital interests** of the data subject or of another natural person;
- e) processing is necessary for the performance of a task carried out in the **public interest** or in the exercise of official authority vested in the controller;
- f) processing is necessary for the purposes of the **legitimate interests** pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.

Article 9 - Processing of special categories of personal data

- a) the data subject has given **explicit consent** to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject;
- b) processing is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller or of the data subject in the **field of employment and social security and social protection law** in so far as it is authorised by Union or Member State law or a collective agreement pursuant to Member State law providing for appropriate safeguards for the fundamental rights and the interests of the data subject;
- c) processing is necessary to protect the **vital interests** of the data subject or of another natural person where the data subject is physically or legally incapable of giving consent;
- d) processing is carried out in the course of its **legitimate activities** with appropriate safeguards by a foundation, association or any other not-for-profit body with a political, philosophical, religious or trade union aim and on condition that the

processing relates solely to the members or to former members of the body or to persons who have regular contact with it in connection with its purposes and that the personal data are not disclosed outside that body without the consent of the data subjects;

- e) processing relates to personal data which are manifestly **made public by the data subject**;
- f) processing is necessary for the **establishment, exercise or defence of legal claims** or whenever courts are acting in their judicial capacity;
- g) processing is necessary for reasons of substantial **public interest**, on the basis of Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject;
- h) processing is necessary for the **purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract** with a health professional and subject to the conditions and safeguards referred to in paragraph 3;
- i) processing is necessary for reasons of **public interest** in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy;
- j) processing is necessary for archiving purposes in the **public interest, scientific or historical research purposes or statistical purposes** in accordance with [Article 89\(1\)](#) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

Appendix 3 – Summary of relevant legislation in relation to health and social care information in Ireland

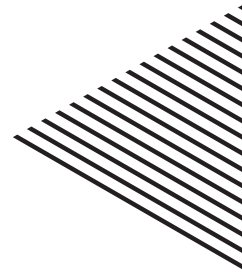
General information legislation	Health and social care legislation (including aspects relating to health and social care information)	Health and social care information legislation
<ul style="list-style-type: none"> ▪ Notification of Births Act 1907 ▪ Notification of Births (Extension) Act 1915 ▪ Data Protection Acts, 1988 - 2018 ▪ Statistics Act 1993 ▪ Civil Registration Act 2004 ▪ Freedom of Information Act 2014 ▪ General Data Protection Regulation (GDPR) 2018 ▪ European Union (Measures for a High Common Level of Security of Network and Information Systems) Regulations 2018 ▪ Data Sharing and Governance Act 2019 ▪ European Union (Open Data and Re-use of Public Sector Information) Regulations 2021 	<ul style="list-style-type: none"> ▪ Health Acts 1947, 1953, 2007 ▪ Health (Duties of Officers) Order 1949 ▪ Infectious Disease Regulations 1981 ▪ Childcare Act 1991 ▪ Child Care (Placement of Children in Residential Care) Regulations 1995 ▪ Education (Welfare) Act 2000 ▪ Children Act 2001 ▪ Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) ▪ Disability Act 2005 ▪ Child Care (Amendment) Act 2007 ▪ Child and Family Act 2013 ▪ European Union (Application of Patients' Rights in Cross-Border Healthcare) Regulations 2014 	<ul style="list-style-type: none"> ▪ Health (Provision of Information) Act 1997 ▪ Health Identifiers Act, 2014 ▪ Health Research Regulations, 2018 ▪ Data Protection (Access Modification) (Health) Regulations, 1989)

General information legislation	Health and social care legislation (including aspects relating to health and social care information)	Health and social care information legislation
	<ul style="list-style-type: none"> ▪ Assisted Decision Making (Capacity) Act 2015 ▪ Children and Family Relationships Act 2015 ▪ Children First Act 2015 ▪ Misuse of Drugs Regulations 2017 (as amended) ▪ Children Health Act 2018 ▪ Patient Safety (Notifiable Safety Incidents) Bill 2019 ▪ National Research Ethics Committee Bill 2019 ▪ Birth Information and Tracing Bill 2022 	

Appendix 4 – Membership of the Advisory Group

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

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



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