



An Roinn Sláinte
Department of Health

Regulatory Impact Analysis

Health Information Bill 2024

Health Information Policy Unit
June 2024

POLICY OPTIONS			
	COSTS	BENEFITS	IMPACTS
Policy Option A	<ul style="list-style-type: none"> - poor value-for-money in maintaining the existing, fragmented health information landscape - risk of EU fines for non-compliance 	<ul style="list-style-type: none"> - NA 	<ul style="list-style-type: none"> - patients and providers are left behind in digital transformation - undermines ability to deliver on policy goals - reputational damage
Policy Option B	<ul style="list-style-type: none"> - time lost for national preparation - risks a 'big-bang' approach to implementation - risk of missed deadlines 	<ul style="list-style-type: none"> - time for lesson-learning from other MS experience in EHDS implementation 	<ul style="list-style-type: none"> - delay of the positive impact of planned measures for patients and providers
Policy Option C	<ul style="list-style-type: none"> - costs will arise in the context of Ireland's new Digital Health Framework using Exchequer funding through the Estimates process as well as HSE investment in digitally enabled integrated care - phased implementation: first patient summaries then 	<ul style="list-style-type: none"> - national challenges addressed without delay: provision of basis for digital health records; strengthening of unique identification; and enhanced information-sharing - transformation initiatives in the Digital Health Framework are enabled and strategic communications can commence 	<ul style="list-style-type: none"> - care and treatment of patients is improved, along with the experience of those working in the health services - improved provision of health information for public-interest purposes in health, policymaking & regulatory activities, and statistics - does not delay implementation of EHDS requirements regarding broader secondary-use purposes

	shared care records	- need for primary legislation minimised	
Policy Option D	<ul style="list-style-type: none"> - reliance on detail in EU implementing acts and guidelines risks confusion and conflicting provisions, with increased need for amendments to Act - excessive primary legislation which contravenes best practice and uses resources poorly - ambitious planning increases risk of missed deadlines 	<ul style="list-style-type: none"> - national challenges addressed without delay: provision of basis for digital health records, strengthening of unique identification, and enhanced information-sharing - transformation initiatives in the Digital Health Framework are enabled and strategic communications can commence 	<ul style="list-style-type: none"> - care and treatment of patients is improved, along with the experience of those working in the health services - cost of digital transformation is unnecessarily increased - improved provision of health information for public-interest purposes in health, policymaking & regulatory activities, and statistics - health data access for broader secondary use provided for but not sufficiently aligned to developing EU framework

Introduction

The initial regulatory impact analysis (RIA) for the Health Information Bill was published with the approved General Scheme of the Bill in April 2023. The RIA is a living document and has remained under review and subject to update in light of pending EU regulatory developments relating to the EU Digital Strategy and the proposed 'European Health Data Space' (EHDS) in particular. The EHDS Regulation was adopted by the European Parliament in April 2024 and will come into force from autumn 2024.

Ireland's aim in health information policy is to develop an integrated health information system to support the development and delivery of integrated care and to ensure efficient, secure sharing of health information for care and treatment, as well as for relevant secondary purposes such as health policymaking, service planning, research and innovation. Primary legislation is required to enable this and there is much alignment between the General Scheme of the Health Information Bill and the EHDS Regulation.

Policy measures in common include:

- **Enhanced sharing of health information** for care and treatment supported by digital technologies, including electronic patient records that can be accessed for care and treatment
- Development of standards that underpin the **quality of health information**
- Enhanced electronic **collection and use of health information** for a range of important secondary purposes such as policymaking, research, innovation, education & training, enhanced service planning and management
- Development of **organisational and infrastructural frameworks** to move and manage health information effectively and securely, and
- **Provision of strong governance rules**, especially on privacy, security and transparency, to build public confidence in the processes.

Following the adoption of the EHDS Regulation, it is now necessary to update the RIA to:

- Ensure the appropriate sequencing of regulatory measures for health information and the best mode to deliver on the policy intent and EU obligations (i.e. through primary legislation, secondary legislation or guidelines)
- Ensure full alignment with and enablement of the EHDS
- Mitigate the risk of any duplication or conflict between national and EU measures.

Purpose of this RIA

The purpose of this RIA is to set out the various options / legislative approaches for preparing for entry into force of the EHDS Regulation in autumn 2024 and for meeting the associated national requirements to support the following inter-related policy objectives:

- Enhancing the collection, use and sharing of health information for care and treatment as well as for relevant secondary-use purposes as set out in the approved General Scheme
- Strengthening our national health data collections and infrastructure and readying the health data landscape for primary and secondary use
- Developing a robust identity management system of health information and data linkage through unique identification as part of the digitalisation of public services
- Building trust in our national health information system and in the governance and use of health data through engagement with the public
- Empowering patients and health services providers with greater access to health information
- Participating fully in the EHDS, including providing cross-border access to health information for care and treatment and for relevant purposes such as research, health registry development, innovation, and personalised medicine.

Background and Policy Context

Background

All health service providers must keep patient records and, while most now have electronic systems, optimum flow of health information between health service providers remains an issue. This can mean that patients have to provide the same information repeatedly – an issue raised by patients in earlier consultations on the Health Information Bill. It also means that health professionals may not have the full picture of their patients' health which can impede continuity of care. Integrated care and treatment requires an integrated health information system. This means the right information is available in the right place at the right time – a goal of the Sláintecare programme and a core principle of Digital for Care – A Digital Health Framework for Ireland 2024-2030 (Department of Health, 2024). This vision is aligned with the current Programme for Government, the Public Service Data Strategy, and the national digital strategy 'Harnessing Digital' (Department of the Taoiseach, 2022).

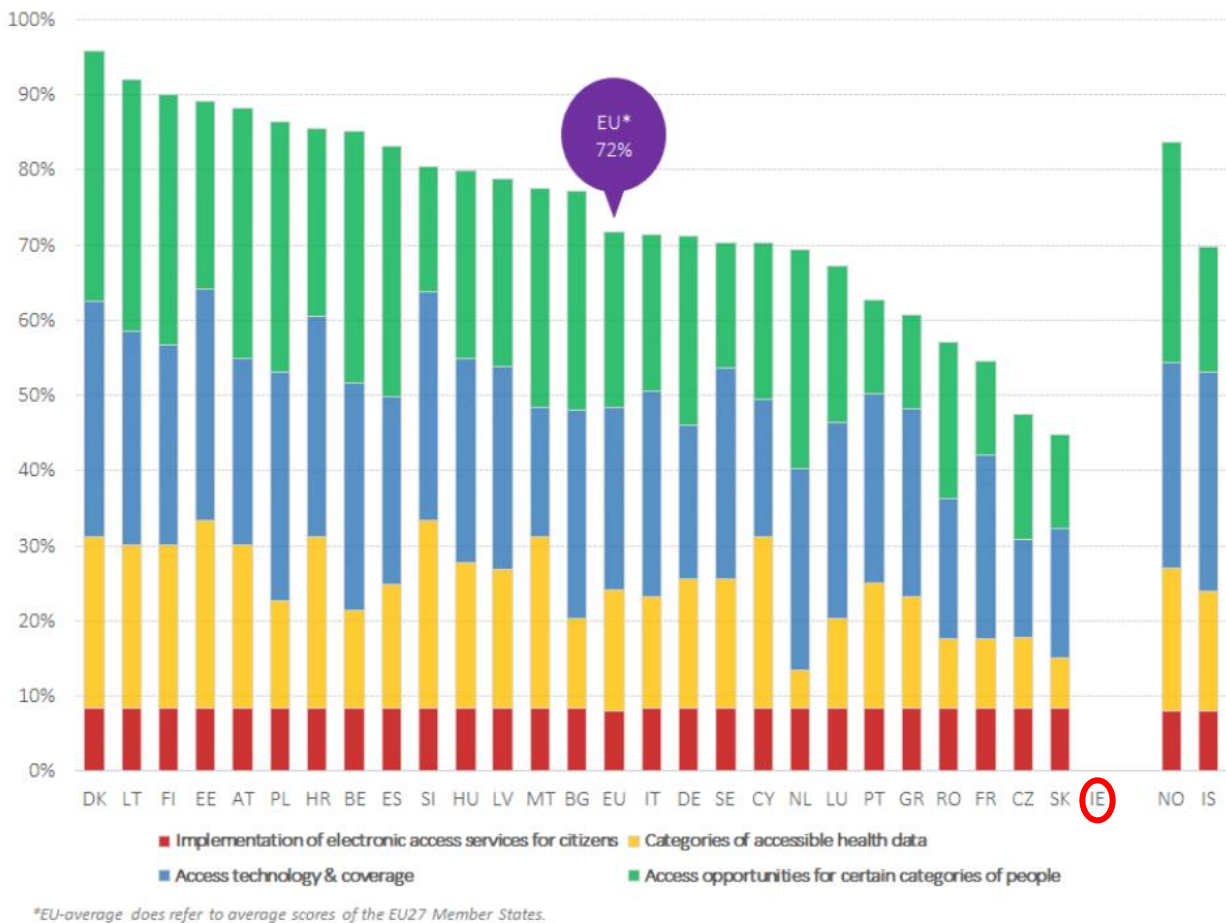
Health information also has an important role outside of care and treatment which centres on the secondary use of health information in delivering improved healthcare services, e.g. better policymaking and management of health services (national, regional and local), supporting clinical & patient safety and promoting research and innovation. Health information can be used for these secondary purposes to help deliver a high performing health service that benefits everyone and helps ensure value for money.

The experience of the COVID-19 pandemic provided both those involved in health services and the Irish public with a new understanding on the importance of data collection and sharing for public health protection and research. The benefits of using health information to support innovation and public health interventions were seen first-hand. It also demonstrated that the public were comfortable sharing health information and using unique identifiers (PPSN) to ensure accurate public records on vaccination and for personal Digital COVID Certificates. That was also the view that emerged from the consultations with the public on this Bill.

European Health Data Space

The concept of the EHDS comes from the European Data Strategy (February 2020) which seeks to make the EU the global leader in the digital world to the benefit of its citizens. The European Digital Decade Policy Programme 2030 sets the ambitious target that 100% of EU citizens will have access to their electronic health records by 2030. A 2022 assessment of EU countries' progress towards delivering this target identified Ireland as a clear outlier, with a 0% composite score for citizen access to electronic health records (European Commission, 2023).

Figure 1: Citizens' access to their electronic health records in the EU (combined layer scores), 2022.



The EHDS has three main objectives:

- 1) empower individuals to take control of their health data and facilitate the exchange of data for the delivery of healthcare across the EU (primary use of health data)ⁱ
- 2) foster a genuine single market for electronic health record systems
- 3) provide a consistent, trustworthy, and efficient system for reusing health data for research, innovation, policy-making, and regulatory activities (secondary use of health data).ⁱⁱ

The European Commission conducted an impact assessment of the EHDS Proposal which sets out the need for action, policy aims, and the options considered (European Commission, 2022). Following detailed and intensive negotiations with Member States (MS), the text of the Regulation was agreed at EU level and is due to enter into force from autumn 2024.

The EHDS Regulation provides for a common governance framework and harmonised infrastructure for the use of electronic health data for primary purposes. It provides for the use of EU standardised and interoperable electronic health records (EHRs) for the cross-border exchange of health data through the MyHealth@EU platform. The Regulation also establishes a series of patient rights to ensure transparency of health data access and use.

The Regulation provides for the secondary use of health data for the purposes of:

- public interest in health including public health activities, patient safety, and safety of medicinal products and medical devices
- policymaking and regulatory activities
- national, multi-national and EU statistics
- education and training
- scientific research in the health area including innovation and the training, testing and evaluating of algorithms for medical devices, AI systems & health apps
- healthcare improvement activities.

A key aspect of national infrastructure will be the establishment of Health Data Access Bodies (HDABs) to support access to anonymised and pseudonymised datasets for secondary use. A HDAB is a service allowing data users such as researchers and policymakers to apply for access to health datasets to support research and innovation, education and training, policymaking, health service management and statistics. Access to datasets will be on a permit basis and facilitated in approved secure processing environments. Data users will be able to apply for access to datasets from different controllers which will be gathered and linked by the HDAB services. Data discovery will be facilitated through the creation of national health metadata catalogues maintained by the HDABs, while cross-border exchange of health data for secondary use will be facilitated through the HealthData@EU platform.

Categories of health data for secondary use include:

- health data from EHRs
- pathogen data
- healthcare-related administrative data, including insurance status, claims and reimbursement data
- human genetic and genomic data
- person-generated health data through medical devices, wellness applications or other digital health applications
- data on professional status, specialisation and institution of health professionals
- population-based health data registries (public health registries)
- data from medical registries and mortality registries

- data from clinical trials and clinical investigations (after completion)
- survey data
- data from biobanks and associated databases.

The EHDS Regulation will apply two years after entry into force (i.e. by end 2026), with a longer lead-in time for certain categories of data to support a phased implementation (4-6 years). This means MS will have two years in which to prepare any necessary national legislation to support the EHDS and implement any administrative changes required to support implementation. EU legislation that has direct effect, meaning MS are obligated to implement the measures at national level, can be given effect nationally through secondary legislation under the 1972 European Communities Act. However, within many EU Regulations, including the EHDS, there are a number of areas that are left to MS discretion. These areas, which permit or require MS to develop a position at national level, require primary legislation.

While the Health Information Bill was not intended to be the vehicle for EHDS implementation, its drafting has required careful regard to European requirements which will shortly come into force. It is imperative that the interaction of the two frameworks does not give rise to confusion for end-users and those to whom obligations will apply. It is also desirable to now use the Health Information Bill where possible to give effect to those provisions in the EHDS Regulation that require primary legislation.

Policy Context

Ireland ranks lowest in the OECD (and the EU) in terms of ability to access and link datasets in healthcare. This is measured by: timely data access that covers the national population across care settings and clinical registries; use of interoperable clinical data standards and identifiers that enable linking across datasets; and use of linked data for primary and secondary health purposes. The 2019-20 OECD survey of health data development, use, and governance found that Ireland ranked lowest for availability, maturity, and use of health datasetsⁱⁱⁱ and dataset governance (Oderkirk, 2021) (Figures 2-4).

Figure 2: Key national health datasets availability, maturity and use (OECD, 2019)

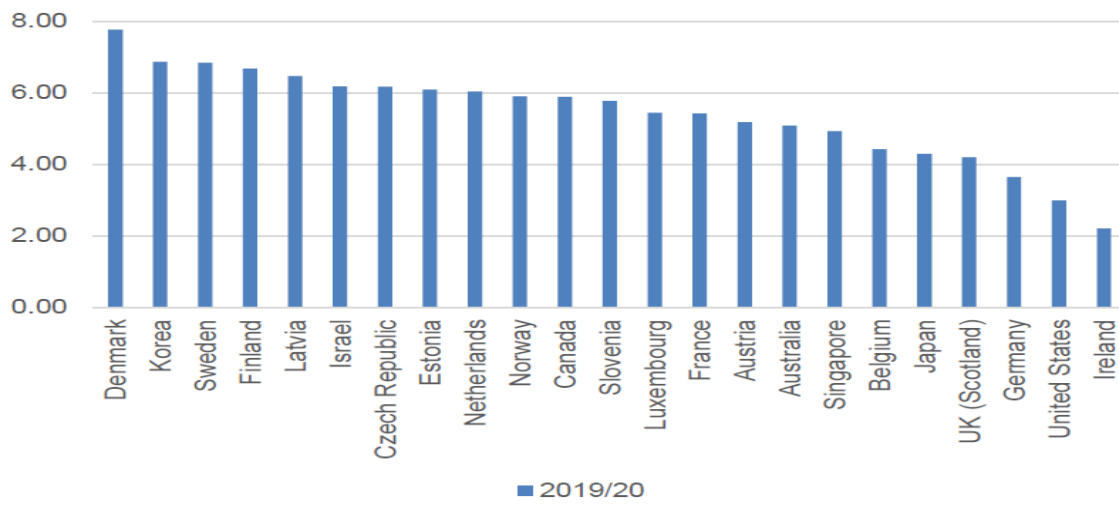


Figure 3: Key national health care datasets governance elements (OECD, 2019)

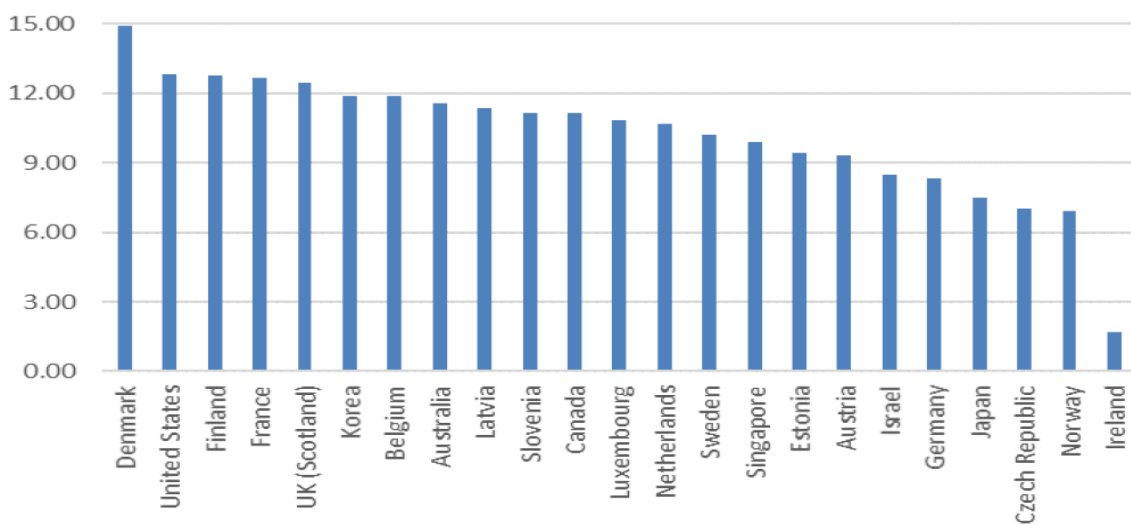
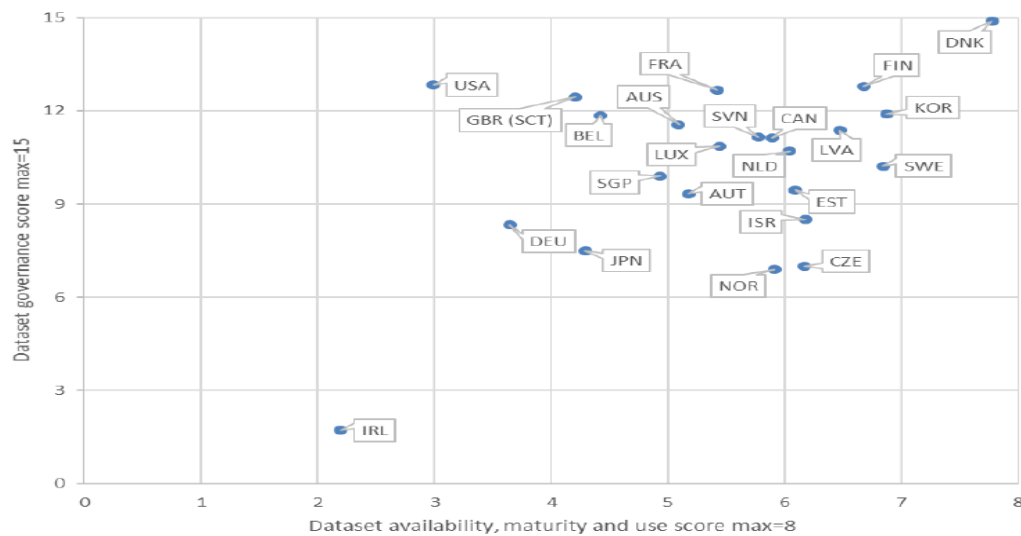


Figure 4: Dataset availability, maturity and use and dataset governance (OECD, 2019)



In Ireland at present, the health information system does not exist at a coherent and co-ordinated national level or with a sufficient level of digital maturity. Instead, it operates at organisational level with considerable reluctance to share information for both primary and secondary purposes and across the public, private and voluntary settings that make up the healthcare system. This directly adversely affects patients, healthcare providers and policymakers who need data to improve healthcare provision.

While Ireland has benefited from the 2022 EU Data Governance Act, there is no specific health data governance framework in Ireland. Data users encounter a lack of legal clarity on sharing health information without a clear legal basis for approving access to data and data linkage. Reporting by private healthcare providers is not complete or interoperable, creating data gaps. Consent is generally needed before data can be used for research though, under the Health Research Regulations, the Health Research Consent Declaration Committee can waive the need for consent for research in the public interest.

Ireland currently does not have a legal framework in respect of the collection, use, sharing and governance of health information across the public and private sector. This lack of legislation is hindering overall coordination between the key health information entities and organisations involved in health information and there is a need for continued political ownership in this regard (Health Information and Quality Authority, 2021).

Historically, Ireland has significantly underinvested in health information in comparison with other European countries and the current health IT infrastructure is fragmented with major deficits. However, significant resources have been made available in recent years to develop systems to help manage the response to the COVID-19 pandemic, with significant investment in health information systems and eHealth capital (HIQA 2021).

Fully leveraging investments in eHealth to date is a clear policy priority as evidenced in Sláintecare, Harnessing Digital: The Digital Ireland Framework, and the new Digital Health Framework.

Findings from HIQA, the HSE, and the Department of Health's National Public Engagement on Health Information show a readiness among the Irish public to embrace technology in healthcare. This engagement found that people see the importance of health information, for both direct patient care and for uses beyond direct care, such as service planning, quality improvement and research. The public also clearly recognises the value in moving towards a more electronic health system and the need to safeguard that data as they believe it will contribute to timely and appropriate care. This provides further impetus to drive forward a strategy to build public trust and confidence in a health information system that can provide assurances that a safe and reliable IT infrastructure is in place (HIQA, 2021).

A Health Information System Assessment carried out by the World Health Organisation (WHO) Regional Office for Europe in 2019, identified several gaps in the Irish system:

- Lack of a central coordinating body for access to and collection of health data (e.g. a HDAB service)
- Under-resourcing in registries and in the DoH
- Limited interaction between health information system and policymakers
- No national e-Health infrastructure or governance body yet
- Lack of central coordination of health information in Ireland
- Lack of data linkage opportunities due to the Individual Health Identifier not being rolled out
- No legal mandate to collect data from the private sector and GP sector
- Lack of workforce information.

A report from the Economic and Social Research Institute (ESRI, 2021) identified significant gaps across the health system specifically in the health information system, health data infrastructure, and the use of health technologies. Basic information, such as a systematic minimum dataset for public healthcare services provided in the community, was found to be lacking. The report also noted a fragmentation between public and private healthcare providers. Similarly, poor public health data infrastructure was highlighted during the COVID-19 pandemic. It is widely acknowledged by policymakers that integration of an Individual Health Identifier (IHI) and national electronic health record (EHR) into the Irish healthcare system could help transform the health data landscape (HSE, 2016).

More generally, the ESRI report also highlighted gaps in the recording, collection, and collation of important patient care data across the public and private sectors, particularly with regard to healthcare utilisation and expenditures. This prevents adequate tracking or

follow-up of discharges across multiple episodes of care. There are also severe deficiencies in data made available from the primary, social and community care sectors, which would improve healthcare planning. Furthermore, many private providers currently furnish little information on the amount and type of care they perform. This gap in knowledge around private healthcare poses a large challenge to the development of a robust and broad health information system in Ireland for the sharing of accurate information to coordinate the health sector response and effectively communicate public health advice and guidelines. A remarkable feature of the pandemic has been the general public's interest in, and engagement with, health statistics and data. The experience of COVID-19 highlighted the importance of communicating accurate, regular health information to the public so that they could use this information to make better-informed decisions. This strengthens the case for continued improvements, investment and public buy-in for a modern Health Information System (HIS) and health data collection (ESRI, 2021).

Recommendations from the report (ESRI, 2021) include:

- Development of a nationwide health information system, with a robust data health infrastructure inputting into this system i.e. widespread adoption of the IHI and, in time, a national EHR across public and private health systems. Standards must be set so that information recorded is as complete as possible, accessible to the relevant parties and standardised for comparative purposes.
- The health data infrastructure should be robust, structured and rigorous, capturing data from public and private providers to allow for resource, capacity, and workforce planning.
- Privacy protections for data subjects and cybersecurity provisions must continue to be developed in accordance with relevant legislation and the General Data Protection Regulation (GDPR). This process should be transparent and well communicated to the public.
- Continued investment in current and capital Information and Communications Technology (ICT) and eHealth funding. Antiquated healthcare technologies should be replaced with technologies and systems that ensure modern capabilities and functions.
- Health literacy should be promoted so that the general public understand the benefits of eHealth and how to use eHealth services. Specific supports will be needed for vulnerable populations such as older people and those with lower digital literacy. Consideration must be given to the connectivity of those in rural areas and in lower socioeconomic groups.
- The healthcare workforce is a key factor in the successful integration of a HIS. Supporting and training the healthcare workforce is necessitated to allow for the adoption of new health technologies and eHealth.

Health Information Bill - Policy Aims and Objective

A high performing health service must be patient-centred and support healthcare staff in the critical role they play. The Health Information Bill aims to improve the use and management of health information to deliver multiple benefits for patients and healthcare staff and to drive greater efficiency in healthcare delivery through improved service management, research and innovation. Those benefits include:

- Access to comprehensive, consistent, and timely information about patients for more effective, safer, and better coordinated care
- Empowering patients and families through access to their own health information
- Improving interactions between patients and providers and patient experience
- Promoting access for patients to emerging treatments, medicines and technologies
- Better targeting of personalised interventions and avoiding unnecessary treatment
- Evaluating current as well as new and innovative treatments and practices
- Enabling population-based research and harnessing the benefits for patients
- Improving public health monitoring and responses to public health emergencies
- Supporting the move towards more home- and community-based care
- Supporting integrated patient care between home, community and acute care
- Identifying waste, inappropriate practice, and inefficiency to improve policy making, governance, and stewardship, including better funding and remuneration
- Increasing productivity in the delivery of patient care.

It is vital that the Bill aligns with the forthcoming EHDS Regulation and addresses national challenges in information policy to prepare for full effect to be given to the Regulation in Ireland in the most appropriate manner with regard to timelines and legislative modalities.

Policy Options

- A. Do nothing
- B. Do not legislate until the EHDS Regulation comes into force in autumn 2024
- C. Legislate now to address national challenges in preparation for EHDS
- D. Legislate now to give fullest effect to all EHDS requirements

Option A: Do nothing

Under this policy scenario, no new legislation would be prepared or enacted. It is a requirement of the Regulatory Impact Analysis (RIA) process that this Option is always analysed to fully examine where regulation is necessary or whether the desired policy goals can be realised through other policy levers.

A robust health information system coupled with more effective information management is essential for the development of cohesive and integrated healthcare system as envisaged in Sláintecare. Given the scale and impact of the challenges in our health information system, and the evidence to inform legislative action as outlined above, it is considered that a policy decision to take no action would significantly undermine the ability to deliver on Sláintecare goals and wider public sector policy strategy e.g. Harnessing Digital and the new Digital Health Framework.

Continuation of the status quo is not cost neutral; this option demonstrates poor value-for-money in maintaining the existing, fragmented health information landscape where health records are not accessible for care and treatment or for relevant purposes. This means for instance the continued inability to effectively evaluate aspects of health services performance including from a value-for-money perspective. Importantly, health services providers and patients would continue to be left behind in the digital transformation of society and Ireland would lose credibility in taking health information challenges seriously.

Moreover, a do-nothing option neglects to prepare for the new European regulatory framework for health information (EHDS Regulation) and raises the risk of non-compliance and the associated fiscal cost, where hefty daily fines can accrue. Under Article 260 of the Treaty of the Functioning European Union (TFEU), a decision against Ireland by the Court of Justice citing a violation of Ireland's obligations to the EU could result in a lump sum fine of up to €1,181,000. Additionally, daily fines could then also be applied; in the past, these fines have been as high as €12,000 per day (Case C-372/11). The added risk of reputational damage among European peers is considerable and would impact Ireland's ability to influence future EU policy. Additionally, in 2026 Ireland will host the EU presidency and failure to implement EU regulation would impact our ability to effectively guide the Council through our term holding this position.

Option B: Do not legislate until the EHDS Regulation comes into force in autumn 2024

This option of waiting and introducing legislation once the EHDS Regulation comes into force has some benefits. Once the EHDS Regulation becomes law at EU level, it will be possible to give full effect to its mandatory provisions through a Statutory Instrument (SI) under Section 3 of the European Communities Act 1972. However, primary legislation would still be required to address national challenges – including the absence of a digital health record system and measures to ensure the use of trusted public service identifiers in the health sector. Primary legislation is also required to give effect to the approximately 80 measures in the EHDS Regulations where MS have flexibility to introduce discretionary measures in national law. Ireland may have the possibility of benefiting from lessons learned in other EU countries taking similar legislative measures.

However, the benefits of awaiting the EU Regulation are significantly outweighed by the costs of waiting to take action. The already tight two-year timeline for application would become significantly compressed and drive towards a ‘big-bang’ approach to implementation of the Digital Health Framework and accompanying HSE Implementation Roadmap. Both are cognisant of EHDS obligations and EU Digital Decade targets for 2030. In the interim, Ireland would continue to have a below-average score on its Digital Decade targets. The ability to implement the EHDS Regulation will require readying the entire Irish healthcare sector to improve data quality, ensure interoperability of data, and understand their legal obligations as data holders. Continued uncertainty in national arrangements would delay actions in support of a phased implementation and could undermine planning for the optimal use of resources; it risks non-delivery on EHDS commitments that could still result in EU fines being applied, adding a further associated cost to this delay. Waiting for the EU Regulation at a time when national challenges have been identified and implementation plans have been developed represents an unnecessary risk and will delay the positive impact of these measures for patients and health service providers.

Option C: Legislate now to address national challenges in preparation for EHDS

This option would see primary legislation, focusing on the development of digital health records, brought forward without delay to both prepare for the EHDS Regulation and to address national challenges in health information. In essence, this action focuses the Health Information Bill on the foundational requirements of what is necessary to improve our national digital health landscape and to prepare for the EHDS. Once the EHDS has been transposed in secondary legislation, we could then expand the Health Information Act to focus on enhancing our national landscape for the exchange of health information for secondary purposes, based on the new health data landscape provided by our national digital health record system.

The EHDS Regulation is drafted on the assumption that MS have a digital health record system in place, albeit at different levels of digital maturity. Ireland is an outlier in this regard and requires foundational legislation to provide the legal underpinning for the development and deployment of digital health records. The Health Information Bill would provide such a basis, while enhancing unique identification through mandating collection of PPSNs and Eircodes for patient records as well as necessitating the introduction of health service provider identifiers. Recognising the immediate necessity to improve health information for secondary use by the HSE, the Bill would provide for national measures to enhance information sharing for primary and secondary purposes and improved information provision to the HSE (i.e. measures outside the scope of the EHDS Regulation).

This approach would see HDAB arrangements delivered in line with the EHDS Regulation and legislated for through 1) an SI under the European Communities Act to

give effect to the very detailed mandatory provisions in the EU Regulation; and 2) an expansion of the future Health Information Act to allow for national application of discretionary EHDS ‘may’ clauses. An SI would mean significantly less primary legislation – a best-practice approach to transformation processes reliant on regulation.

It is important to note that this re-sequencing would not delay provisions for the re-use of health information for secondary purposes such as research and innovation purposes. These provisions would be made in keeping with EHDS requirements and within the established EHDS timelines. EHDS legal provisions on the use of health information for research and innovation are more detailed than those set out in the General Scheme and, notably, include provisions to facilitate EU-wide and multi-country research activities.

Work is already underway to establish HDAB services in Ireland through projects and initiatives put in place by the EU. The Department of Health was awarded a direct grant under the EU4Health Programme to fund a €6 million project to establish a HDAB. The project runs from 2024-2027 and will build the core capabilities of a HDAB service including the development of a national metadata catalogue, preparation for receipt of data access applications and issuance of data use permits, and establishment of a secure processing environment. Ireland is participating in a complementary EU ‘HDAB Community of Practice’ which brings together MS data access teams for knowledge-sharing and peer support, while a Capacity-Building Team has been established to develop training materials for HDAB staff.

The TEHDAS-2 Joint Action convenes experts from thirty countries to prepare guidelines on the operation of HDAB services under EHDS. Ireland is participating through the Department of Health and an academic partner. Some TEHDAS outputs will be adopted by the European Commission as implementing acts, in keeping with the provisions of the EHDS Regulation. This option means that national legislation on the use of health information for broader secondary use including research and innovation can be informed by TEHDAS outputs and the full suite of EU legislation on the EHDS.

Overall, acting without delay to introduce primary legislation for digital health records would improve the care and treatment of patients, as well as the experience of those working in our health services. It would provide for basis for concrete communications with the public regarding digital transformation in health including digital health literacy initiatives. It also lays solid foundations for valuable, standards-based population datasets from digital health records, to be made available in an anonymised and pseudonymised form for relevant secondary purposes.

Option D: Legislate now to give fullest effect to all EHDS requirements

This option would mean proceeding with the Health Information Bill at this point in accordance with the General Scheme and expanding it to try to fully meet requirements of the EHDS as much as possible.

Updated regulatory analysis indicates that the best way of giving effect nationally to EHDS requirements on secondary use is through an SI under Section 3 of the of the European Communities Act 1972. However, this will not be an option until the Regulation is officially enacted in EU law in autumn 2024. To proceed with the relevant provisions at this stage would require extensive primary legislation, building out of the General Scheme.

It is recognised that Parts 3 & 5 of the Bill, dealing with health data access and secondary use, have been superseded by the provisions in the EHDS Regulation. The provisions drafted for the General Scheme are no longer fit-for-purpose and, if progressed at this point, would need to be largely amended in 2025-26 to ensure alignment with the EU legislation. Furthermore, the drafting of these provisions relies on detail to be worked through in the Commission implementing acts which are due to be developed during 2024-26, risking the need for further amendment of any provisions drafted at this point. Amending large volumes of primary legislation in this manner would be time-consuming and represent a poor use of resources. While this option represents an attempt to meet EHDS requirements ahead of time, the process is very likely to be frustrated to the extent of actually missing EHDS deadlines and further delaying the deployment of our own national HDAB service.

Summary of policy analysis – costs/benefits/impacts of preferred option ‘C’

This option delivers fully on foundational, transformative aspects that were key provisions of the General Scheme and necessary for the success of the Bill and EHDS in Ireland: a duty to share health information; clarity on when information can and should be shared; the use of PPSN as a unique identifier for health; and maximising the completeness of information available to the HSE for secondary use in line with its mandate. The option delivers fully on the creation of digital health records and strengthens patient access to and control over their own health data. The streamlining of the Health Information Bill will establish now the legislative foundations for the digitisation of healthcare. Secondary purposes including health research and innovation will be progressed in parallel in full alignment with the emerging European Health Data Space. The streamlined approach involves no slippage on delivery timelines.

The decision to legislate now for digital health records, and to await the EHDS Regulation to make provision for secondary use, has a number of impacts on the Bill being brought forward. First is the removal of provisions for a National Health Information Authority

whose role was to focus on secondary use. Instead, the provisions of the EHDS Regulation will be used to establish a HDAB service in Ireland. As this designation will require additional resources and an expansion of current services, these arrangements remain subject to business planning processes.

In the absence of an Authority, the policy intent is for the Minister to convene or cause to be convened a Consultative Forum on Health Information (previously provided for in Part 6 General Scheme) in the interim. This can be delivered without legislation so the corresponding provisions have been removed from the Bill.

In the broader regulatory analysis, we have also determined that the functions of the National Health Information Guardian (Part 7) are sufficiently fulfilled by common rules and safeguards across the final EHDS Regulation text and, if progressed, would render Ireland an outlier, risk duplication of investment, and present a challenge to national policy coherence in this area. The corresponding functions have therefore been removed from the Bill to follow the EHDS model. We have consulted with key stakeholders, including the Data Protection Commission which has given its view of this change and which will be working collaboratively with the HDAB and Digital Health Authority to be established under the EHDS to support the implementation of these functions.

Similarly, it is determined that the provisions for suitable and specific safeguards (Part 4) are sufficiently captured across other provisions: we note that that the governance regime for primary use of health data is set out quite uniformly in the EHDS Regulation text and with considerable safeguards in place, a number of which are integrated into the draft Bill. The EHDS text allows for additional MS safeguards in relation to secondary use (e.g. for use genetic and genomic data) and there is scope to return to make such provisions through expansion of and regulations under the (forthcoming) Health Information Act. At this stage, a number of additional specific safeguards have been introduced into the Bill's provisions on information to be provided to the HSE for relevant secondary use, in anticipation of the future framework under the EHDS Regulation.

Benefits of the preferred option

- The Bill will provide the enabling legal framework for the new Digital Health Framework, supporting the development and deployment of digital health records which will mean:
 - Patients will be able to access and digitally transmit their health information as well as enable access to it, irrespective of healthcare provider and data source.
 - Health information will be brought together from across the health system – public, private, and voluntary – to provide a more complete view of the patient and facilitate integrated care. This includes information from primary

care, community care and diagnostics, scheduled care, unscheduled care (Emergency Departments/ Out of Hours), etc.

- Health services providers will be able to access priority categories of health information in relation to their patients for the purposes of care and treatment.
 - Improved use of data will reduce wait times across the system and help delivery of more prompt diagnoses and treatment plans.
 - The data contained in digital health records will be in scope for secondary purposes under EHDS, subject to strict conditions and safeguards. The development of digital health records will support secondary use including research and innovation activities by ensuring that valuable, standards-based population datasets are established before HDAB services 'go live' in 2028.
 - Enhanced unique identification of patients through use of identifiers (PPSN, Eircode) will improve data linkage and help to support more efficient and safer care.
- Patient information will be made available to the HSE for public-interest purposes in the area of public health, for policymaking and regulatory activities, and for statistics.
 - Digitalisation can reduce unnecessary tests and ensure transparency in spending, allowing savings to the health budget. EU funds will also provide support for digitalisation.
 - The regulation of HDAB services chiefly through secondary legislation means much less primary legislation is needed.
 - EU policymaking on HDAB services is ongoing. This option ensures our national approach can be fully informed by EU legislation and guidelines on EHDS.

Costs

- The Health Information Bill provides the foundational legislation for the development and deployment of the digital health records in preparation for the EHDS Regulation, whilst supporting the Sláintecare reform programme.
- Costs will arise in the context of Ireland's new Digital Health Framework using Exchequer funding through the Estimates process as well as HSE investment in integrated care. This will be a phased implementation, with focus initially on patient summaries and then the more complex shared care record.
- According to the European Commission's RIA for the proposed EHDS Regulation, the overall costs of implementing the Regulation are expected to be between €0.7-2.5 billion above the baseline over ten years. This includes completing the coverage of MyHealth@EU and the full rollout of the necessary digital infrastructure connecting HDABs, research infrastructures and EU bodies. Actions

on promoting interoperability through mandatory certification and voluntary labels are also expected to trigger costs.

- Denmark's Ministry of the Interior commissioned a costs analysis for implementation of EHDS in their national context. It identified the following main cost drivers on the primary-use side:
 - Extensive integration into existing medical record systems vs access via portal solution (similar to the existing Danish "Sundhedsjournalen")
 - Identification solution and solution for authorising other natural persons
 - Implementing citizen rights regarding health data
 - Exchange of image data
 - Scope of the implementation task for European exchange formats
 - Establishing the gateway to MyHealth@EU.
- Overall, Denmark estimated the development costs of implementation of EHDS (primary use) at €475.6m as well as operational costs of €137.3 (based on the maximum cost scenario).

Impacts

Jobs

Policy implementation will have specialist staffing and workforce implications in the areas of data science, analytics, data architecture, clinical and biostatistics, data privacy and legal. These considerations will form part of business planning. All efforts are being made to utilise existing resources and expertise. The Minister also notes that any role with a salary above Principal Officer standard pay scales requires DPENDR sanction and that the creation of any new CEO-level post (i.e. Director) requires a business case and appropriate sanction.

North-South, East-West Relations

The Bill provides for reciprocal arrangements for sharing information contained in digital health records with health services providers in third countries, including UK, for the purposes of care and treatment. This will help to support and enhance cross-border healthcare on the island of Ireland.

Gender Equality

Gender information is often collected inconsistently, and provisions in this Bill will support the forthcoming Equality Data Strategy being prepared by the Department of Children, Equality, Disability, Integration and Youth. Implementation of the provisions contained in the Bill will provide greater access to health information for service planning and delivery, in line with the principles of equality, diversity, inclusion and person-centred care.

Governance structures which will implement the policies of this legislation will reflect equality, diversity, and inclusion policy.

Poverty Proofing

The development of digital patient records will enhance a person's access to their health records. Improved data linkage and analysis will support more targeted health service planning and delivery. All governance structures to implement the policies of this legislation will reflect equality, diversity, and inclusion policy.

Competitiveness & Industry Costs

No impacts in relation to this Bill. The Department notes that the EHDS Regulation will implement a single market for electronic health record (EHR) systems and SMEs will have to comply with mandatory requirements on interoperability and security for EHRs. This will also apply to any medical devices or wellness applications that claim interoperability with EHR systems. While these measures may increase the burden on SMEs, common requirements across the EU will increase the chances to be selected in procurements or reimbursement schema and will reduce the entry barriers to the markets of other MS, partially or totally offsetting such costs.

Rural Communities

The use of digital health records will improve the portability of and access to health information for care and treatment irrespective of geographic location and thus it is a positive development for rural communities. The consistent use of Eircodes in health records and datasets will support geospatial analysis to inform public health, population needs assessment, and service planning and improvement.

Quality Regulation

The Department has critically analysed and aligned the Health Information Bill with the EHDS Regulation to identify and remove any areas of duplication and conflict and to limit the use of primary legislation where secondary legislation and guidelines are best suited. As the Bill is digital-first legislation, measures in the Bill include regulation-making powers and guidelines to future-proof the legislation. This will support ongoing digital transformation and developments in health information systems. The RIA has been updated to reflect this analysis.

People with Disabilities

The development and deployment of digital health records will support the provision of integrated care and continuity of care. This will enhance the quality and experience of care for persons frequently engaging with health and social care in the acute and

community setting. HSE-led digital literacy initiatives, as required under the EHDS, will also ensure that patients with diverse literacy needs are supported in the deployment and adoption of these records.

Climate Impact and Mitigation Potential

The new Digital Health Framework, underpinned by the Bill, advances the Government Framework 'Harnessing Digital' which re-enforces work towards achieving Ireland's climate targets.

Enforcement

Updated regulatory analysis indicates that the policy intent behind the offences provisions in the General Scheme is sufficiently met elsewhere, including through analogous provisions in the Data Protection Act 2018, and will be further enhanced by provisions in the EHDS Regulation. Therefore, these offences have been removed.

Review

The operation of the legislation, particularly its implementation, will be kept under review in the context of the Minister's responsibilities for policy and political accountability. The Bill further specifies that the Minister shall review or cause to be reviewed the operation of this Act no later than five years after its enactment.

Publication

This Regulatory Impact Analysis will be published on the Department's website in tandem with the publication of the Health Information Bill 2024.

References

Department of Public Expenditure, NDP Delivery and Reform (2018). Public Service Data Strategy 2019-2023.

<https://assets.gov.ie/7107/7ac4ae109cd944dc99c9e178962fa095.pdf>

Department of the Taoiseach (2022). Harnessing Digital – The Digital Ireland Framework.

<https://www.gov.ie/en/publication/adf42-harnessing-digital-the-digital-ireland-framework>

Department of Health (2024). Digital for Care —A Digital Health Framework for Ireland 2024-2030. <https://www.gov.ie/en/publication/0d21e-digital-for-care-a-digital-health-framework-for-ireland-2024-2030/>

ESRI 2021 - Developments In Healthcare Information Systems In Ireland And Internationally - ESRI Survey And Statistical Report Series Number 105.

<https://www.esri.ie/publications/developments-in-healthcare-information-systems-in-ireland-and-internationally>

European Commission (2023). Digital decade e-Health indicators development – Final report, Luxembourg: Publications Office of the European Union.

<https://data.europa.eu/doi/10.2759/530348>

European Commission (2022). IMPACT ASSESSMENT REPORT Accompanying the document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space.

https://health.ec.europa.eu/publications/impact-assessment-european-health-data-space_en

European Commission (2020). COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS: A European strategy for data. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0066>

Health Information and Quality Authority (2021). The need to reform Ireland's national health information system to support the delivery of health and social care services.

<https://www.hiqa.ie/reports-and-publications/health-information/need-reform-irelands-national-health-information-system>

HSE (2016). National Electronic Health Record: Strategic Business Case Health Service Executive. <https://www.ehealthireland.ie/strategic-programmes/electronichealth-record-ehr-/progress/national-business-case.pdf>.

Oderkirk, J. (2021), "Survey results: National health data infrastructure and governance", *OECD Health Working Papers*, No. 127, OECD Publishing, Paris. <https://doi.org/10.1787/55d24b5d-en>

Journal of the European Union (2022). European Digital Decade Programme 2030 (2022). <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022D2481>

ⁱ https://health.ec.europa.eu/ehealth-digital-health-and-care/electronic-cross-border-health-services_en

ⁱⁱ <https://tehdas.eu/>

ⁱⁱⁱ Dataset availability, maturity and use includes eight elements: dataset availability, coverage, automation, timeliness, unique identification, coding, data linkage and regular reporting of indicators of health care quality and system performance.