Response to the Department of Health consultation on a draft health information policy framework

November 2017

1. Introduction

HIQA welcomes the opportunity to contribute to this consultation which will inform the drafting of a new national health information policy for Ireland. There have been many changes in the health information landscape in Ireland since the publication of the last national health information strategy, *Health Information: A National Strategy*, in 2004. The developments in the area of eHealth have been the most notable, for example the 2013 publication of an *eHealth Strategy for Ireland*[1] by the Department of Health, and the HSE's *Knowledge and Information Strategy*,[2] published by the Office of the Chief Information Officer in 2015.

HIQA strongly endorses the development of new national health information policy and recognises the need for a strong health information environment, which will allow health information to be used to the greatest benefit of those involved in decision-making and, most importantly, to those using our health and social care services. It is essential that a new health information policy and associated legislation is progressed to ensure a safe, effective and person-centred approach to health and social care. This policy is a critical enabler of eHealth and integrated, patient-centred care. It is also particularly relevant in light of the EU's General Data Protection Regulation (GDPR), due to be enacted in May 2018.

HIQA's role

HIQA was established ten years ago to regulate Ireland's health and social care sector and to promote quality and safety in services. Our remit has grown substantially since then; however, our core activities remain the same, that is, to monitor and regulate health and social care services, develop standards, carry out health technology assessments (HTAs) and advise on the collection and sharing of information across our healthcare services. All of these functions are focused on making services safer and better, providing assurance to the public as to the quality

of these services and ensuring that the findings of our work are reflected in decision-making at local and national levels. Access to high-quality health and social care information is fundamental to the achievement of HIQA's objectives.

HIQA's Health Technology Assessment (HTA) Directorate uses health information to inform the HTAs that it undertakes and it is essential that this information is accurate, relevant, complete and timely. Within HIQA's *National Standards for Safer Better Healthcare*[3], a strong emphasis is placed on the importance of health information. Theme 8, 'Use of Information', addresses the need to use accurate and timely information to promote effectiveness and drive improvements in healthcare. The active use of information as a resource for planning, delivering, monitoring, managing and improving care is one of the four key capability and capacity factors required to have safe, effective, and person-centred services.

Information is also fundamental to our role in the regulation and monitoring of health and social care services. During the ten years of HIQA's existence, several health information deficiencies have been identified, particularly in the context of our statutory investigations. For example, the report of the patient safety investigation into the death of Savita Halappanavar (2013) noted that there were significant inconsistencies in the recording and reporting of maternal sepsis. The report also highlighted the fact that there was no nationally-agreed definition of maternal sepsis.[4] The investigation also identified that a number of data collection sources were involved in the collection of maternal morbidity and mortality data in Ireland, and that there was no centralised or consistent approach to reporting same.

HIQA's specific statutory remit in relation to health information is set out in the Health Act 2007. HIQA's Health Information and Standards Directorate is responsible for developing a coherent and integrated approach to health information. We set standards and develop guidance for all aspects of health information. We also provide leadership in defining the health information landscape in Ireland by influencing policy and legislation through collaborating with the health information community and developing recommendations.

An important set of recommendations were made by HIQA in relation to the fragmented health information landscape in our 2014 publication *Recommendations for a more integrated approach to National Health and Social Care Data Collections in Ireland*.[5] This report highlighted that a strategic framework for national health and social care data collections in Ireland should be prioritised, setting out a roadmap and informing policy development for these national data collections.

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A number of other key recommendations to the Minister for Health have also been made, including the 2009 recommendations for a unique health identifier for individuals in Ireland, [6] the 2014 recommendations on adopting SNOMED Clinical Terms as a national standard for Ireland, [7] and the 2016 recommendations on the coordination of patient safety intelligence in Ireland.[8]

In addition, during 2017, HIQA commenced a new review programme to assess compliance with information management standards with a view to promoting improvements in the governance, quality and use of data held by national health and social care data collections.

Health Information and patient safety

Undoubtedly, health information plays a fundamental role in improving patient safety. Better information means better decisions and better, safer care. It is thus of paramount importance that information is governed correctly and that personal health information is protected. This was particularly evident in a number of healthcare investigations undertaken by HIQA —one of the eight recommendations made in the 2015 report into the safety of services in Portlaoise hospital focused specifically on deficiencies in health information. This report stressed the need for the timely sharing of health information in order to identify and manage patient safety risks.[9]

There is a clear and pressing need to develop a coherent and integrated approach to health information and eHealth in Ireland, based on standards and international best practice. A strong health information environment will allow all stakeholders, including the general public health professionals and policy makers, patients and the people who use services, to make decisions based on the best information available. This is a fundamental requirement of a reliable and efficient healthcare system.

2. Core principles for the processing of personal health data

HIQA is in overall agreement with the core principles for processing personal health data as outlined in the draft framework document. There is possibly some overlap within the concepts covered under 'duty to share' and 'consent for research', and also 'transparency', 'accountability' and 'privacy by design'. Consideration could be given to further refinement of these principles and a clear explanation of these concepts.

While it was noted that the vision for the policy framework puts forward a 'person-centred approach' to the processing of health information, we feel that this concept should be further addressed within the principles themselves. A person-centred approach to health information focuses on the needs and privacy of the individuals about whom data is recorded.

Best practice in this area ensures that personal information, such as that contained in a health and social care record, is dealt with appropriately in order to deliver the best possible care. It also ensures that health information is fully integrated around the individual. Furthermore, a patient-centric model not only ensures that health information is readily available to healthcare practitioners to deliver care, but also provides patients with easy access to information on their own care.

3. Policy pillar — legislation

Unlike other European countries, no legal framework exists in Ireland to support electronic health records. A national information governance framework to allow for the sharing of information across the public and private sectors is also lacking. Personal health information is currently governed by Irish data protection legislation, but from 2018 will come under the General Data Protection Regulation (GDPR). Notably, healthcare data under the GDPR will be subject to a higher standard of protection than personal data in general. Many EU Member States will have national provisions that apply directly to the healthcare sector.

From an international perspective, legislation regulating information governance practices falls into the following categories:

(i) general privacy legislation (such as data protection legislation)

(ii) health legislation with provisions for the use of information (e.g. provisions within the health acts), and

(iii) health information-specific legislation, e.g. in countries such as Canada and Australia.

Having conducted a review of models in place in other jurisdictions, HIQA strongly supports the development of the latter option, i.e. legislation specific to health information.

In order to ensure a true person-centred approach to the processing of health information, the focus must be on the health and social information gathered at the point of delivery of care. Some confusion exists in Ireland under current data protection legislation with respect to the sharing of information, and it is likely that further confusion will arise under GDPR. There is therefore a need for clear policy, legislation and guidance to ensure that GDPR is implemented consistently across Ireland's health and social care sectors.

Legislation specific to health information should clearly outline the rules for the collection, use and sharing of personal health information. A key component of this legislation should be to outline a specific consent model to enable the processing of personal health information. This consent model should detail the legal basis for the processing of personal health information, precisely define the circumstances whereby explicit or implied consent is required and the circumstances where there is a legal basis for the use of personal health information without consent (consent exemptions).

Legislation must also specifically address how personal health information is collected, used and shared by named delegates, i.e. by legally-defined 'information custodians', and specify all those with a responsibility for handling personal health information.

Tailored health information legislation in other jurisdictions aims to balance an individual's right to privacy over their personal health information, with the legitimate requirement on behalf of healthcare professionals to access and share this information. With limited exceptions, such legislation would require health and social care professionals to obtain consent before they collect, use or disclose personal health information. In addition, individuals should have the right to access and request correction of their own personal health information.

The legislation must also outline whether consent needs to be explicit or implicit. When a health or social care professional discloses personal health information to another professional for the purpose of providing healthcare, the consent of the individual may be implied, unless the individual has specifically withheld or withdrawn the consent. If the purpose of the disclosure is not to provide healthcare, consent must be explicit. Also, consent for disclosures to third parties must, in general, be explicit.

The legal underpinning of such a consent model would take account of the circumstances for which a legal basis needs to established, as listed in the draft

policy framework, for example: for the provision of health and social care, for the sharing of personal health information among healthcare providers, for research purposes, and any consent exemptions. Another way to approach this is to consider how personal health information is used 'for direct patient care', and 'for purposes beyond direct patient care'.

As previously stated, health information legislation should be future-proofed to address the advancement of the eHealth agenda in Ireland, specifically in terms of summary care records, electronic health records (EHRs) and e-prescribing. The *eHealth Strategy for Ireland* identifies a set of key objectives that need to be achieved to enable integration of all information and knowledge sources involved in the delivery of healthcare via information technology-based systems. Furthermore, the *HSE Knowledge and Information Strategy* specifically lays out the transformation required to enable data and information integration to deliver patient-centred and seamless care. Health information legislation should be fully aligned to the plans laid out in both of these documents.

Furthermore, new legislation should allow for the establishment of the proposed national data advisor, the advisory committee on personal health data and the confidentiality advisory committee, as outlined in the policy framework document.

The General Scheme of the Health Information and Patient Safety (HIPS) Bill only addresses a subset of the issues outlined above in relation to health information. For example, it does not take a fully patient-centred approach, nor does it fully address the issue of consent or the use of information to deliver health and social care services. The definition of 'sensitive personal data' in the HIPS Bill is much narrower than that proposed in the context of GDPR.

Summary of key points in relation to a legislative framework:

- in line with international evidence, Ireland should develop patient-centred legislation specific to health information.
- legislation needs to be future proofed and aligned to the eHealth agenda. This should be prioritised in light of the business case for the EHR currently being developed by the HSE.
- legislation should focus on specific aspects of collection, use and sharing of personal health information.
- the issue of a consent model needs to be addressed in legislation, national policy and associated guidance.

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- The roles of a national data guardian/advisor and advisory committee on personal health data should also be laid out in legislation. The details of how such roles would interact with entities such as HIQA, HSE, the Department of Health and the Office of the Data Protection Commissioner also need to be clearly set out.

4. Policy pillar — governance

Health information plays a vital role in improving patient safety. Better information means better decisions and better, safer care. Information is crucial to improving patient safety and it is essential that information is governed correctly and that personal health information is protected.

The main aim of information governance in healthcare is to create a balance between providing high-quality care for every patient, while also respecting patients' privacy. In order to do this, we need to effectively use information and implement the necessary legislation and structures, while at the same time remaining cognisant of the evolving health information landscape. We are under increasing pressure to move away from our paper-based systems towards e-Health, but are still challenged with the many silos of information which force patients to provide the same information many times. Data quality is also a key issue. It is clear that we need the legislation and information governance structures to encourage the appropriate use, collection and sharing of information without compromising a patient's privacy.

In accordance with international evidence and best practice, the governance of personal health information needs to be addressed at a number of levels, as outlined here:

- organisations that provide oversight and develop strategy for information governance
- organisations that perform an advisory role on best practice and develop standards and guidance, including privacy and security management framework standards on information governance
- organisations that provide operational guidance, such as codes of practice, policies and procedures
- organisations that monitor implementation and compliance to legislation and standards.

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The draft health information policy should clearly define the roles and responsibilities of established entities and organisations already in place (e.g. the Department of Health, the Office of the Data Protection Commissioner, the HSE and HIQA) in respect of information governance and also set out where new structures are required.

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

HIQA believes that the proposed national data advisor and the advisory committee should be established on a statutory footing. Clarity must also be provided as to how these established entities will interact with the HSE, eHealth Ireland, private hospitals, GPs, the Office of the Data Protection Commissioner and HIQA.

While it is important to address the governance arrangements necessary to allow for the safe sharing of information at the point of delivery, the governance of the secondary use of information must also be addressed. As outlined in HIQA's *Recommendations for a more integrated approach to National Health and Social Care Data Collections in Ireland*, the health information landscape is highly fragmented and it is therefore essential that the governance of these valuable resources is addressed in policy and, where possible, legislation.

Summary of key points in relation to governance:

- in line with international evidence, governance structures need to be in place at the levels of oversight and strategy development; and in advisory, operational and regulation/monitoring capacities.
- the proposed national data advisor and the advisory committee should be established on a statutory footing.
- clarity needs to be provided in relation to the monitoring/regulation of information governance and the interaction of established organisations such as the HSE, eHealth Ireland, private hospitals, GPs, the Office of the Data Protection Commissioner and HIQA.

5. Policy pillar — operational arrangements

HIQA is in agreement with the operational arrangements described in the policy framework document in relation to the need for a more integrated approach to the oversight of national health and social care data collections. This was previously outlined in recommendations developed by HIQA in 2014. We also concur with the proposed establishment of more streamlined operational arrangements to health research, as recommended by the Health Research Board (HRB).

In addition, however, there is a need for cultural change in terms of the use and sharing of personal health information across the entire health service. It is important that operational arrangements for health information are centred on the individual. Most people who use health and social care services accept and expect that healthcare professionals will need to share personal confidential data in order to provide optimum care. However, when it comes to the sharing of information between healthcare professionals there is a lack of clarity in relation to data protection laws. This can lead to a culture of anxiety.

Clarity is essential in order to build trust and facilitate the sharing of information to achieve a seamless, integrated care service. For the purposes of direct care, relevant personal and confidential data should be shared among registered and regulated health and social care professionals who have a legitimate relationship with the individual. The operational arrangements detailed in the policy framework document currently do not address the use of information for direct patient care. Other countries have addressed some of the operational practicalities of this within a consent model, detailing the conditions for implied consent and the options available when implied consent cannot be assumed (e.g. concepts such as 'circle of care', provisions for 'lock box' and 'break glass').[10,11]

Consideration should be given to the role analogous to that of the 'Caldicott Guardian' in the NHS, whereby a senior person in a healthcare organisation is responsible for protecting the confidentiality of information relating to patients and people using services. This person is also responsible for information sharing.

A fundamental component of any operational model for the processing of personal health information is the development of guidance. Consideration also needs to be given to the drafting of a detailed training plan.

Summary of key points in relation to operational arrangements:

- as outlined in the draft framework, the focus on operational arrangements is quite narrow and must be broadened to include the operational arrangements needed to deliver care.
- a consent model should be explicitly defined in legislation and supported by specific guidance with respect to operational arrangements.
- a training plan needs to be developed.
- the roles and responsibilities of different players need to be taken into account and consideration given to the complexity of the health and social care sector (e.g. the public/private mix).

6. Policy pillar —patient and professional awareness

HIQA welcomes the inclusion of this policy pillar and acknowledges the importance of patient and professional awareness and engagement in promoting the benefits of health information. Individuals and organisations processing personal health information should have a clear understanding of the importance and public-health value of health information, its purposes and the benefits of sharing information. There is an onus on healthcare providers to effectively communicate this knowledge to patients, healthcare professionals and researchers in a clear and transparent manner.

Dialogue between patients, healthcare providers, healthcare professionals, researchers and policy makers on what constitutes the appropriate use and secure sharing of health information must be supported. We particularly welcome the focus on promoting patient empowerment in terms of how personal data is accessed. A model should be developed to empower patients to access their own healthcare records in a transparent easy and uncomplicated way. Future advances in relation to eHealth should be taken into consideration when developing such a model.

Patients should also be empowered not only to know how their information is being used, but also to exercise control over who can access their data. In this regard, HIQA advocates for the establishment of forums for patient engagement.

Summary of key points in relation to patient and professional awareness:

- professional bodies should be involved in developing guidance.
- training and development for healthcare professionals must be provided.
- patient forums should be established to actively engage patients on all aspects of the processing of health information.

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