Statement of Outcomes

Report on the outcome of the public consultation on the Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

August 2015

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

About the Health Information and Quality Authority

The Health Information and Quality Authority (the Authority or HIQA) is the independent Authority established to drive high quality and safe care for people using our health and social care services. The Authority's role is to promote sustainable improvements, safeguard people using health and social care services, support informed decisions on how services are delivered, and promote person-centred care for the benefit of the public.

The Authority's mandate to date extends across the quality and safety of the public, private (within its social care function) and voluntary sectors. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, the Authority has statutory responsibility for:

- **Setting Standards for Health and Social Services** – Developing person-centred standards, based on evidence and best international practice, for those health and social care services in Ireland that by law are required to be regulated by the Authority.

- **Supporting Improvement** – Supporting health and social care services to implement standards by providing education in quality improvement tools and methodologies.

- **Social Services Inspectorate** – Registering and inspecting residential centres for dependent people and inspecting children detention schools, foster care services and child protection services.

- **Monitoring Healthcare Quality and Safety** – Monitoring the quality and safety of health and personal social care services and investigating as necessary serious concerns about the health and welfare of people who use these services.

- **Health Technology Assessment** – Ensuring the best outcome for people who use our health services and best use of resources by evaluating the clinical and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion activities.

- **Health Information** – Advising on the efficient and secure collection and sharing of health information, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

Overview of Health Information function

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 imperative 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 a key 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, the Health Information and Quality Authority (the Authority or 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), the Authority is charged with evaluating the quality of the information available on health and social care and making recommendations in relation to improving the 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 drive 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. Further to this, 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 Ireland's health and social care sector is highly fragmented with major gaps and silos of information which prevent the safe and effective transfer of

information. This results in service users being asked to provide the same information on multiple occasions.

Information can be lost, documentation is poor, and there is an over-reliance on memory. Equally, those responsible for planning our services experience great difficulty in bringing together information in order to make informed decisions.

Inconsistency in practice leads to inconsistency 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, clear 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.

The Authority has a broad statutory remit, including both regulatory functions, and functions aimed at planning and supporting sustainable improvements. In accordance with the Health Act 2007, [sections 8(1)(j) and 8(2)(d)], one of the key functions of the Authority is to provide advice to the Minister for Health and the HSE about deficiencies identified regarding health information. It is on this basis that the Authority is undertaking this project.

This document presents the statement of outcomes for the Authority's public consultation on the *Draft Information Governance and Management Standards for the Health Identifiers Operator*. These standards are aimed at the health identifiers operator[±] in Ireland. These standards aim to underpin the introduction of health identifiers in Ireland with a robust governance framework for the health identifiers operator. A robust governance framework will inspire trust and acceptance of health identifiers in Ireland.

[±] For clarity, the singular 'health identifiers operator' will be used throughout this standards document to refer to each business unit within the Health Service Executive (HSE) that is responsible for setting up and maintaining the National Register of Individual Health Identifiers and the National Register of Health Services Provider Identifiers.

Table of Contents

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

1.   Introduction and background

Being able to identify a service user uniquely is essential for patient safety in the provision and management of high quality healthcare. Being able to identify healthcare practitioners and healthcare services uniquely is essential for improving sharing healthcare information between healthcare practitioners.

An individual health identifier is a number that uniquely and safely identifies each person that has used, is using or may use a health or social care service in Ireland. The main benefit of using individual health identifiers are improvements to patient safety.

A health services provider identifier is a unique number that is assigned to a health services provider, such as a hospital or a healthcare professional. Using health services provider identifiers supports the secure and safe exchange of health information.

Previously the Health Information and Quality Authority (the Authority or HIQA) has made *Recommendations for a Unique Health Identifier for Individuals in Ireland* (March 2009)[1] and published an *International Review of Unique Health Identifiers for Individuals* (February 2010)[2]. The Authority also made *Recommendations for Unique Health Identifiers for Healthcare Practitioners and Organisations* (July 2011)[3].

The Health Identifiers Act 2014 is the law that underpins the introduction of health identifiers in Ireland. It provides the legal basis for setting up two new national data stores or registers:

▪ the National Register of Individual Health Identifiers

▪ the National Register of Health Services Provider Identifiers

The National Register of Individual Health Identifiers will contain an individual health identifier and associated demographic information for each person who is being, has been or may be provided with a health or social care service in Ireland. This identifier will be known as an individual health identifier. Its purpose is to uniquely identify each person so that patient safety can be improved within the Irish health and social care service. Benefits associated with introducing individual health identifiers include reducing the number of adverse events that may happen, such as giving the patient incorrect medication or vaccinations, or admitting the wrong person for surgery. Allocating an individual health identifier to new born babies helps link their healthcare records for life.

The National Register of Health Services Provider Identifiers will contain a health services provider identifier for each provider that offers health services in Ireland. This identifier will be known as a health services provider identifier. It is a unique, non-transferable number assigned to all health services providers. Health services providers include practitioners who provide health and social care services, for example, a general practitioner (GP) or a dentist, and the organisations where the health or social care service is provided, such as a laboratory or a hospital. Benefits associated with introducing health services provider identifiers include reducing administrative overhead and cost, while also providing clearer accountability by distinctly identifying the person and organisation responsible at each stage of a service user's care pathway. The National Register of Health Services Provider Identifiers provides a single trusted source of data which will allow for more comprehensive, accurate, health service human resource planning and research to take place.[4]

While the Minister for Health is responsible for overseeing its implementation, the Health Identifiers Act 2014 allows the Minister to delegate certain tasks, such as setting up and maintaining the National Register of Individual Health Identifiers and the National Register of Health Services Provider Identifiers to the Health Service Executive (HSE). Different business units within the HSE may be responsible for these tasks. Each business unit is known as a health identifiers operator.

The Authority have developed *Information Governance and Management Standards for the Health Identifiers Operator in Ireland* to support the health identifiers operator as it sets up and maintains these two new national registers. Implementing these standards will promote trust among the public that the registers are established in line with the law. In turn, this creates confidence that both health services providers and service users can be uniquely identified, which ultimately leads to improvements in patient safety.

The international experience of introducing health identifiers in other jurisdictions has been carefully considered when developing these draft standards. For example, a standard requiring that a privacy impact assessment is conducted has been included following lessons learnt in Australia which indicated that is it vital to identify and plan for privacy risks.[5] Communication and engagement with stakeholders that builds trust in the proposed system of health identifiers has also been identified as a key requirement.[5] Finally, it is important that any proposed system protects the privacy and accuracy of health identifiers and associated details.

This document presents the results of the Authority's public consultation on the *Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland*. This statement of outcomes:

- describes the methodology used in developing the draft standards and in conducting the public consultation

- provides a quantitative analysis of the results received during the consultation

- includes some of the comments the Authority received during the consultation.

2.   Overview of consultation submissions

The consultation consisted of 14 questions, which aimed to ascertain the public's opinion on the *proposed Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland*. This statement provides an overview of the submissions received for each question.

There were 70 responses, of which 76% responded on behalf of their organisation, and 24% of responses were from individuals. Appendix 1 lists the organisations that made a submission to the public consultation.

There was a number of ways of submitting feedback in order to facilitate the widest participation from all possible stakeholders. The choices were to respond using an online consultation form hosted by 'Polldaddy', via email or by post. Of the 70 responses, 36 responded via Polldaddy, 26 completed the consultation form and returned by email and eight sent a free text email that contained their feedback. No responses were received by post. This is illustrated below.

Response method	Number
Polldaddy	36
Consultation form by email	26
Free text email	8
Total	**70**

3.   Methodology

These Standards have been developed in accordance with the Authority's standards development policy. Figure 1 highlights the four main stages within the Authority's standards development process.

Figure 1: Stages of standards development process

Stage	Description
Initial preparation	The project's scope is agreed internally. In this case, the scope includes developing information governance and management standards for the health identifiers operator in Ireland. A literature review of relevant published research, standards in other jurisdictions, government policy and reports by national and international governmental and non-governmental organisations is undertaken. The draft standards take account of the findings from this literature review. An advisory group is established with relevant experts.
Standards development	The standards development team prepare a set of draft standards, which are then reviewed by key personnel internally. Amendments are made to these draft standards based on internal feedback.
Consultation	Two forms of consultation are conducted as part of the development of these standards: • An advisory group is established to seek guidance and feedback on the draft standards. The list of members on this advisory group is listed Appendix 2. • A public consultation is held, where the draft standards are published on the Authority's website so that comments and feedback can be received from the public in relation to them. A statement of outcomes document will be published following analysis of the feedback received from the public consultation. All feedback received from the advisory group and the public consultation is analysed and considered. Feedback is used to

Statement of outcomes – Report on the outcome of the public consultation on Draft Information
Governance and Management Standards for the Health Identifiers Operator in Ireland
Health Information and Quality Authority

	inform the final version of these draft standards.
Standards approval and publication	A standards approval process is followed once the final version of the standards is complete. In this case, approval to publish these standards is sought from the Executive Management Team and from the Board of the Authority. Once approval is obtained, the standards are sent to the Minister for approval and published.

4.   Feedback from public consultation

The consultation form was divided into two sections, as follows:

- Nine general feedback questions which asked for comments and feedback on the consultation document in general under different headings such as 'layout and design', 'content', 'comprehensiveness' and 'applicability'.

- Specific evaluation questions which asked for comments and feedback on the consultation document with respect to the specific Standards and features that are presented under each of the five themes.

Together, the 14 questions sought feedback on the *Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland*. The full list of questions can be found in Appendix 3.

Overall, the feedback was extremely positive. The feedback indicated that the document was written in language suitable for the target audience and highlighted the requirement for information governance and management standards for the health identifiers operator in Ireland. These Standards actively support the introduction of health identifiers in Ireland. The key findings that emerged from the public consultation included requests for:

- a mechanism that provides for two-way communication between the health identifiers operator and its stakeholders

- more information on how privacy impact assessments are conducted

- more information on how the National Register of Health Services Provider Identifiers would be set up and managed, and more details on how the health services provider identifier would be used by health services providers in their day-to-day work

- more guidance on how the Standards would be monitored and audited.

The following sections provide more detailed information on the feedback.

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

4.1   General feedback questions

4.1.1 Layout and design

Three questions were asked under this heading:

- Is the language used clear?

- Is the layout of the Standards clear, easy to follow and understand?

- Do you feel that the order and structure of the Standards is logical?

Overall, respondents felt that the language and layout used was clear and appropriate to the target audience. However, it was thought that there was repetition in Part 1: Introduction of the *Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland*. More clarity on how the National Register for Health Services Providers would be set up and operate was needed.

Question 1: Is the language used clear?

Question 1 asked if the language used in the Standards was clear. As shown in Figure 2, the majority respondents [73%] felt that the language used was clear.

Figure 2: Responses to consultation question 1
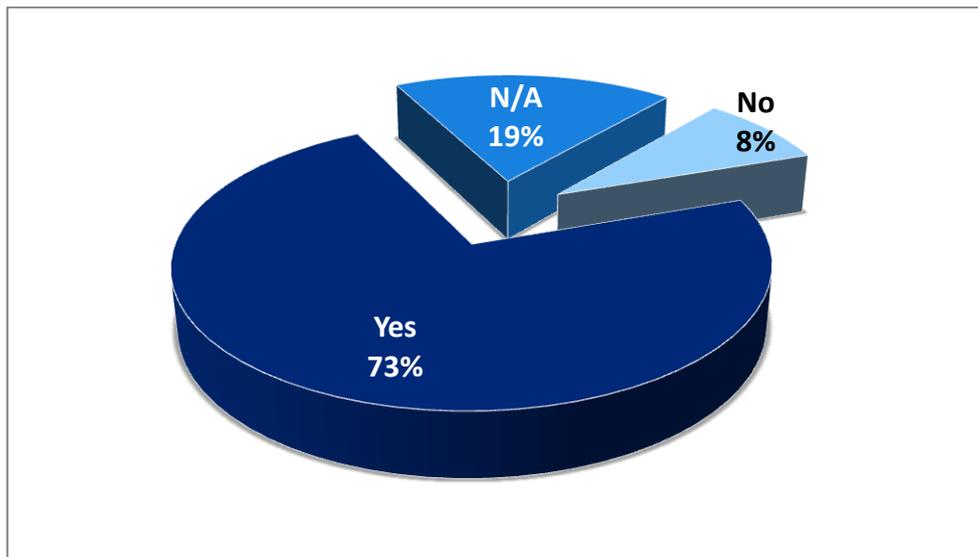
What the respondents said:

"Language is very clear with concise definitions for all terms given - very useful to ensure public understanding and reduce ambiguity."

"The language used throughout the standards is reasonable given the target audience."

"This is a well written document that is generally clear and reasonably easy to follow."

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

Question 2: Is the layout of the Standards clear, easy to follow and understand?

Question 2 asked about the layout of the draft Standards. The majority of respondents [67%] agreed that the layout of the Standards was clear, easy to follow and understand, as illustrated in Figure 3.

Figure 3: Responses to consultation question 2
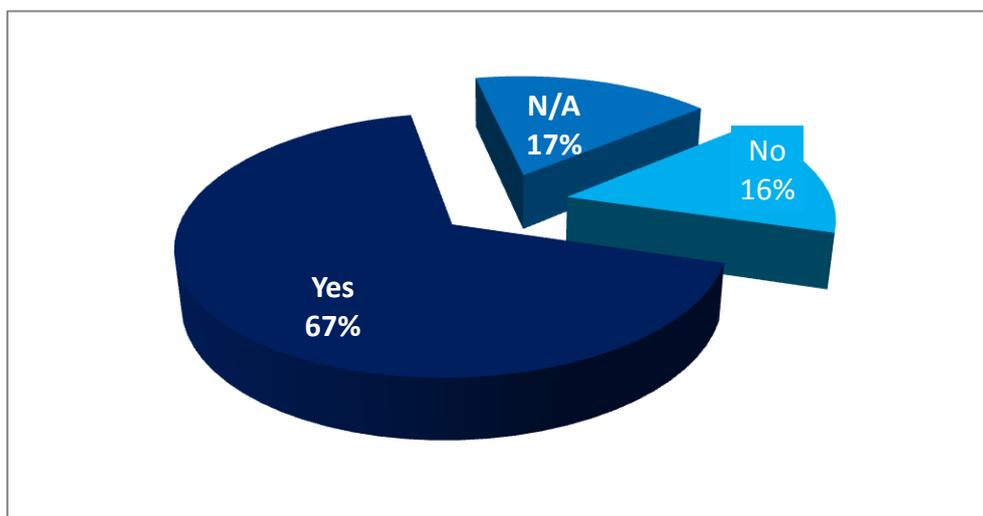
What the respondents said:

"Yes - there is obviously a degree of overlap between the different themes but this has been appropriately handled."

"Yes, the layout is clear, easy to follow and understand."

"Section one is very repetitive which takes from the clarity of the document."

Statement of outcomes – Report on the outcome of the public consultation on Draft Information
Governance and Management Standards for the Health Identifiers Operator in Ireland
Health Information and Quality Authority

> **Question 3: Do you feel that the order and structure of the Standards is logical?**

Question 3 asked whether the order and structure of the Standards is logical. 70% of respondents responded that the order and structure of the Standards was appropriate. Figure 4 shows the breakdown.

Figure 4: responses to consultation question 3
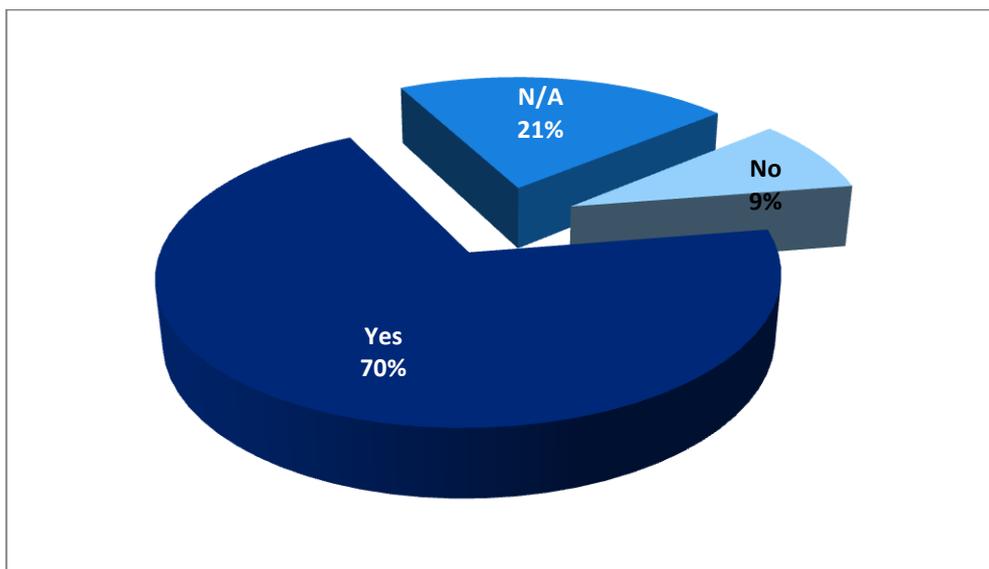
What the respondents said:

"Yes the order and structure is clear and easy to follow."

"Yes, the document is clearly structured and the order of the standards is logical. In addition, the categorisation of the Information Governance Standards for Health Identifier Providers around the seven themes of Person-Centred Support, Leadership, Governance and Management, Use of Information, Use of Information, Use of Resources, Workforce is useful in understanding the purpose."

"Yes, the flow from introduction and general background of the standards sets the scene for the following detailed description of each theme."

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

4.1.2 Content

> **Question 4: Do you feel the draft Standards protect the confidentiality and privacy of your health identifier record?**

One of the benefits of using health identifiers for both service users and health services providers is an improvement in patient safety. It is vital that the National Register of Individual Health Identifiers and the National Register of Health Services Providers Identifiers are set up and maintained so that appropriate accountability exists within the health identifiers operator, personal information is kept secure, accurate and confidential, resources are managed in line with the objectives of the two registers, and the workforce have appropriate skills, attributes and competencies.

The question asked under this topic queried whether the Standards protected the confidentiality and privacy of health identifier records.

The key findings from this question are that:

- Standards would protect privacy and confidentiality of health identifier records **provided** that they are fully implemented and applied consistently

- it is necessary to specify how these Standards would be monitored

- clarity is required around how access to the National Register of Individual Health Identifiers is controlled.

To address the concern about whether these Standards would protect the privacy and confidentiality of health identifier records, the Authority has strengthened the Monitoring section in the final version of the Standards. This section includes information about how the Standards would be monitored to assess compliance using the Authority's methodology for monitoring compliance against Standards.

What the respondents said:

"The standards, if supported by appropriate control frameworks that implement the status features of the standards, would protect the confidentiality and privacy of health identifier records. However, it should be noted that the standards, by their nature, do not contain sufficient detail to provide comfort that such control frameworks will be in place."

"I believe the draft standards provide the framework to protect confidentiality and privacy of the health identifier record."

"The standard provides a high level framework outlining the basic elements and actions needed to provide the required level of protection. However, many of the statements associated with the themes are quite abstract and need a further level of qualification and greater granularity to ensure an appropriate level of assurance."

"Need to be more explicit about data sharing, who the trusted sources are and who has access to the information within the Health Identifier Unit and whether the level of access for all staff is the same."

4.1.3 Comprehensiveness

The respondents were also asked how comprehensive the draft Standards are. The three questions under this topic were:

- Do you feel that all important topics have been covered or are there any topics that should be included or excluded?

- Having read the background information, do you feel that you understand the background to these draft Standards? Is enough background information provided?

- Do you feel that additional guidance on any of the concepts contained in the draft Standards should be provided? If so, what additional guidance do you feel is necessary?

There was a very positive response to this topic; in particular, it was felt that the Frequently Asked Questions document that accompanied the draft Standards was very clear and provided useful information to support the Standards.

The two main areas where more information was requested were how the health services provider identifiers would operate, and how privacy impact assessments are conducted. Many respondents also suggested that more patient involvement in developing and commenting on these draft Standards was needed. The Authority uses the public consultation as one method to elicit feedback from the public with respect to the draft Standards under development. All the feedback received from the public consultation was analysed and used to inform the final version of the Standards.

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

Question 5: Do you feel that all important topics have been covered or are there any topics that should be included or excluded?

Respondents provided a number of suggestions with respect to what other topics should be included in these Standards. Some of these suggestions were included in the final version of the Standards, while others have been addressed through the updated *Frequently Asked Questions about Health Identifiers* document. The remaining topics were considered out of scope for these Standards but may be addressed in the future.

Examples of what respondents felt should be included are:

- how the National Register of Health Services Provider Identifiers will be set up, and how health services provider identifiers will be used operationally

- how access to the National Register of Individual Health Identifiers will be controlled and managed

- how comments and complaints from service users and health services providers will be handled

- how privacy impact assessments will be conducted

- additional definitions for privacy, privacy risk and privacy impact.

What the respondents said:

"The document is very useful and gives a clear framework."

"I understand that the standards are at a high organization level. However, I would like to see standards that demonstrate front line activity at input level and how access to data will be controlled at the front end. While at present the standards state requirement of procedure, I would like to more detail around which procedures and what these entail. I am looking at this from the front end service provider perspective and feel to get buy in from staff and public this detail is essential."

> **Question 6: Having read the background information, do you feel that you understand the background to these draft Standards? Is enough background information provided?**

This question examined whether the background information provided was understandable. It also asked whether there was enough information provided. There were 49 responses to this question. As shown in Figure 5, the majority [84%] felt that enough background information was supplied and that the information was understandable, while 16% disagreed.

Figure 5: Responses to consultation question 6
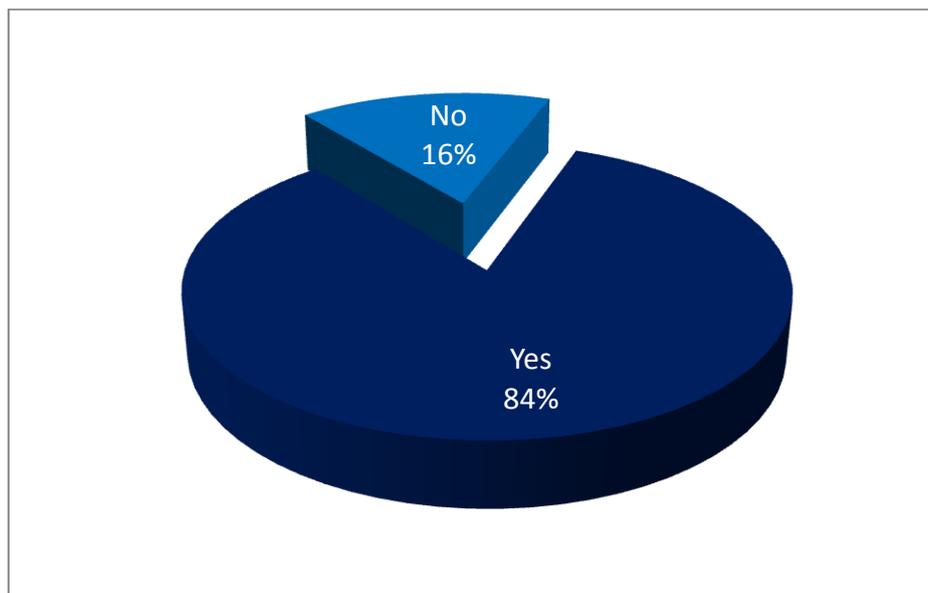
What the respondents said:

"Yes, the executive summary sets out clearly the background and need for the introduction of the health identifier operator and associated governance and management structures. It would helpful to reference in this summary however, that the structure of the Irish Health Service includes a mix of health providers across independent, voluntary and private health service providers. This will in turn emphasise the need for the introduction of a National Register of Individual Health Identifiers and National Register of Health Service Provider Identifiers."

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

"Considerable background information is provided about the rationale for and the process adopted in developing the Unique Health Identifier concept in Ireland. There is, however, insufficient attention given to the service provider aspect of the system and the interface between a very disparate range of health and social care providers (which will be included on the National Register of Health Service Provider Identifiers) and the National Register of Individual Health Identifiers."

"Background information is ok, would benefit from more background on the effect of a provider register, who will be on it and what does it mean to be on the register."

"There is too much background information."

> **Question 7: Do you feel that additional guidance on any of the concepts contained in the draft Standards should be provided? If so, what additional guidance do you feel is necessary?**

Question 7 asked whether additional guidance on any of the concepts contained in the draft Standards should be provided. It asked for suggestions as to what this additional guidance should be. Suggestions from respondents included the following:

- how compliance with the Standards will be conducted

- how information is shared between health and social care services

- what security measures should be in place to keep the National Register of Individual Health Identifiers and the National Register of Health Services Provider Identifiers secure.

What the respondents said:

"That the client is made fully aware of the process to allow them question if they feel the process is not being kept"

"The implications of a provider identifier register needs to be fleshed out more."

"Guidance detailing methods of compliance with the standards would greatly help ensure the identifiers service is implemented and operated correctly. This could include such detailed instructions as a framework for a quality management system for the health identifiers operator."

4.1.4 Applicability

These Standards are intended to be used by the health identifiers operator. Each business unit within the HSE responsible for setting up and operating the National Register of Individual Health Identifiers and the National Register of Health Services Providers Identifiers is known as a health identifiers operator. The two questions listed under this topic probed whether the draft Standards were 'fit for purpose' for use by the health identifiers operator, and asked what other Standards are needed to support the introduction of health identifiers in Ireland.

Overall, it was found that these draft Standards are appropriate for use by the health identifiers operator. However, guidance is required on auditing and compliance to ensure adherence with these Standards. Additionally, it was felt that using existing interoperability standards would support the introduction of health identifiers.

> **Question 8: Are these draft Standards 'fit for purpose' and appropriate for use by the health identifiers operator?**

There were 38 responses to this question. Most respondents felt that the Standards were appropriate and 'fit for purpose' for the health identifiers operator, although with some caveats.

What the respondents said:

"Yes, they cover all major management and governance requirements to aid the operator in meeting the legislative requirements while facilitating implementation and operation of the identifiers service. I do feel that without more tangible guidance on specific procedures to ensure compliance and also proof of compliance, there is a risk of non conformance and subsequent risk to operation of the identifiers with the main stated objective of patient safety at the core."

"The standards are fit for purpose. They specify a broad set of basic requirements which cover the key areas of concern."

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

> **Question 9: What other areas of standards are needed to support the introduction of individual health identifiers and health services provider identifiers?**

Question 9 asked what other standards are needed to support the introduction of health identifiers for individuals, healthcare professionals and organisations. The responses included suggestions for more standards and guidance in the following areas:

- interoperability standards, such as HL7, to allow for standardised exchange of information

- guidance that supports smaller health services providers to comply with the Health Identifiers Act 2014

- guidance for professional regulators that provides information which supports consistent population and update of the National Register of Health Services Provider Identifiers

- guidance on the secondary use of health identifiers for research and service planning.

What the respondents said:

"Standard 1.2 details the features of a communications plan which is extremely important in ensuring a high level of participation and compliance.

In addition to the above, perhaps a pilot exercise should be undertaken between the acute and primary health care providers in order to test and improve the proposed systems and to reduce unnecessary risk and threats in advance of a national rollout."

"Robust interoperability and messaging standards. In addition clear processes for the collection of the data from the third party trusted sources."

"The draft standards are at a very high level. Careful translation into operational plans will be required to ensure the spirit of the draft standards is attained."

4.2   Specific feedback questions

Section two of the consultation feedback form contained specific questions which asked for comments and feedback on the consultation document with respect to the specific Standards that are presented under the following five themes:

- Person-centred

- Leadership, governance and management

- Use of information

- Use of resources

- Workforce

The five themes are illustrated in Figure 6.

Figure 6: The Themes

Theme 3:
Use of information

Theme 2:
Leadership, governance and management

Theme 4:
Use of resources

Information governance and management standards

Theme 1:
Person-centred
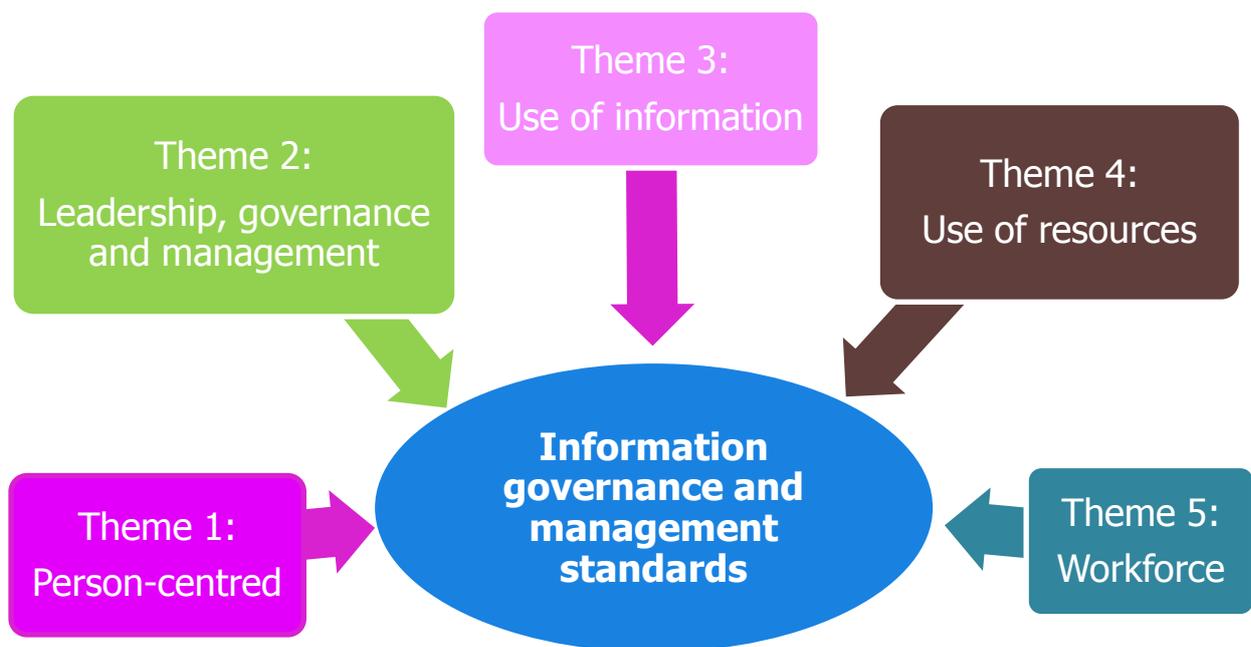
Theme 5:
Workforce

Respondents were asked to consider the following two questions with respect to each theme when providing comments or feedback in this section:

- Can these draft Standards and features be applied to the health identifiers operator in a manner that supports good information governance and management?

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

- In your opinion are the Standard statements and the features that follow each Standard statement clear and easy to understand?

Again, feedback was largely positive with useful and specific suggestions on changes that could be made to Standard statements and associated features.

4.2.1 Theme 1: Person-centred support

Respondents were asked to provide specific feedback on Theme 1 and the Standards and features it contained.

Theme 1: Person-centred support

- Standard 1.1: The health identifiers operator conducts privacy impact assessments at critical points during the establishment and operation of the national registers.
- Standard 1.2: The health identifiers operator develops, implements and reviews a communications plan that effectively informs service users in relation to the use of the national registers.

What the respondents said:

"It is difficult to understand the concept "Person-centred support" in the context of the standard. The identifier is not primarily to aid patient support but rather safety and quality of care."

"Standard 1.1 states that the health identifier operator conducts privacy impact assessments at critical points during the establishment and operation of the national register. It is not clear from the standard how a privacy impact assessment is defined and how this assessment would be carried out. A description of what this assessment involves is important for the purposes of public transparency which in turn will ensure public confidence that the health identifier's operation of the standards protect their privacy and confidentiality."

4.2.2 Theme 2: Leadership, management and governance

Respondents were asked to provide specific feedback on Theme 2 and the Standards and features it contained.

> ## Theme 2: Leadership, management and governance
>
> - Standard 2.1: The health identifiers operator has effective leadership, governance and management arrangements in place with clear lines of accountability.
> - Standard 2.2: The health identifiers operator maintains a publicly available statement of purpose.
> - Standard 2.3: The health identifiers operator complies with relevant Irish and European legislation and standards when establishing and managing the national registers.
> - Standard 2.4: The health identifiers operator has formalised arrangements with health service providers for the effective use of the national registers in line with relevant legislation and standards.
> - Standard 2.5: The health identifiers operator has data exchange agreements with trusted sources that protect personal information and define which data can be shared for the purpose of establishing and maintaining the national registers.
> - Standard 2.6: The health identifier operator monitors, reviews, evaluates and improves the service it provides on an ongoing basis.

What the respondents said:

"The focus on governance and monitoring (2.1 & 2.2) compliance with relevant legislative elements (2.3) and ensuring appropriate procedures are in place to manage the information (2.4 to 2.6) clearly supports good information governance and management. The focus on audit and risk management (2.3.1, 2.3.2, 2.3.3, 2.6.1) is particularly relevant. Standards and features are clear and easy to understand."

"We agree with the need for clear governance and leadership, transparency and compliance with legislation. In relation to Standard 2.4, SLAs between the HSE and GPs are critical to the successful implementation of IHIs and need to take account of

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

the initial high administrative workload in general practice of seeding, matching and authenticating IHIs for individual patients. The need for GP practice software system changes to manage the IHI is a crucial component of the work. Education and training for health care providers is important."

4.2.3 Theme 3: Use of information

Respondents were asked to provide specific feedback on Theme 3 and the Standards and features it contained.

<div style="border:1px solid #000">

Theme 3: Use of information

- Standard 3.1: The health identifiers operator maintains and reviews the privacy of health identifier records contained in the national registers.
- Standard 3.2: The health identifiers operator maintains and reviews the quality of data contained in the national registers.

</div>

What the respondents said:

"It is suggested that as part of their review procedure there is an Advisory Council attached to the Health Identifier Operator who would oversee and monitor

- That the governance and management standards are implemented and adhered to;

- That privacy impact assessments are carried out regularly and any potential risks and breaches addressed;

- That confidentiality and quality is being maintained.

This group could include external people from HIQA, the data commissioner, a patient advocacy group, as well as senior HSE staff for example. This group would also take on a review role in relation to Standard 3.2 "maintains and reviews the quality of data" and in relation to staff training in the operator under Standard 5.1."

"While the health identifier operator is only responsible for the setup and maintenance of the health identifier keys, they should have a role in the wider discussion of usage of key to link data components from a very wide variety of sources, some of which may be outside the creation control of health service providers. This discussion and approval for the use of data for operational management, clinical audits, evidence-based research and longitudinal studies is

Statement of outcomes – Report on the outcome of the public consultation on Draft Information
Governance and Management Standards for the Health Identifiers Operator in Ireland
Health Information and Quality Authority

*critical to unlocking the value of data in system. Other key discussion will be
required around opt-in and opt-out privacy discussion for patients and employees;
the right to be forgotten; and what is a reasonable amount of time to retain data
for."*

*"The operator should drive consistency where appropriate between the Data
Protection and FOI Regimes whilst maintaining compliance with the relevant acts. In
implementing the solution, due regard should be given to future interests for
secondary use of data, and also as to how such requests might be accommodated in
a non-identifiable manner."*

4.2.4   Theme 4: Use of resources

Respondents were asked to provide specific feedback on Theme 4 and the Standards
and features it contained.

> **Theme 4: Use of resources**
>
> - Standard 4.1: The health identifiers operator plans and
>   manages the allocation and uses of resources assigned
>   to it to meet the objectives of the national registers.

It was decided to remove this theme following a review of the feedback. A feature
that covers resource use and management has been included in Theme 2.

What the respondents said:

*"Some Guidance should be available on how available resources should be prioritised
to support the phased implementation of the system. For example, under the theme,
Leadership, governance and management, there could be a requirement for the
Health Identifiers Operator to put in place a phased implementation plan."*

*"The use of resources should also include information and communications
technology (ICT) as an important resource dimension in the creation and
development of the registers.*

*Implicit in many of the standards is the need to deploy considerable resources to
deliver on the implementation of the registers and on the implementation of the
standards themselves!*

*4.1.1 refers to clear plans that take account of funding and resources required but
the plan needs to guarantee that resources and funding will be made available to*

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

deliver on the workforce requirements associated with the registers and how the HSE will deliver this in the current climate."

4.2.5 Theme 5: Workforce

Respondents were asked to provide specific feedback on Theme 5 and the Standards and features it contained.

> **Theme 5: Workforce**
>
> - Standard 5.1: The health identifiers operator delivers regular evidence-based training programmes to its own workforce in relation to establishing, maintaining and using the national registers.

What the respondents said:

"Suggest there should be consideration not only of the provision of training, but importantly also some assessment of learning or of competence. Suggest also the goal should be more lofty that the workforce being "trained" - it should strive for broader professional development."

"The focus on provision of adequate induction and training throughout Standard 5.1 is welcome, particularly considering the requirement to ensure delivery of an effective and secure health identifiers operator. Standards and features are clear and easy to understand."

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

5.   Conclusion

The project team revised the *Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland* taking comments and feedback received from our consultation processes into account.

The resulting final *Information Governance and Management Standards for the Health Identifiers Operator in Ireland* was presented to the advisory group, which had been set up to provide advice on these Standards. Subsequently, the Standards underwent an internal review before being submitted to the Authority's Executive Management Team and to the Authority's Board for approval. Once Board approval was obtained, the Standards were sent to the Minister for Health for approval and published on the Authority's website http://www.hiqa.ie.

The level of engagement and interest of all stakeholders, including representatives from the HSE, Department of Health, patient groups, interest groups, professional bodies and academia in the *Information Governance and Management Standards for the Health Identifiers Operator in Ireland* was very encouraging.

The Authority welcomed all contributions and would like to thank all those who contributed to the public consultation on the *Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland.*

The Authority would also like to thank the members of the Advisory Group who provided valuable advice and feedback during the preparation of these Standards. Appendix 2 contains a full list of members of the Advisory Group.

Appendix 1   Organisations that made submissions

Organisations that made submissions
Association of Optometrists Ireland
Blackrock Clinic
Bon Secours Hospital Dublin
Cavan & Monaghan Hospital
Citizen's Information Board
Department of Health, Office of the Chief Medical Officer
Department of Health, Corporate Legislation Unit
Department of Health, External Systems Unit
Dental Health Foundation
Department of Nursing and Midwifery, University of Limerick
Economic and Social Research Institute
Federation of Ophthalmic and Dispensing Opticians FODO Ireland)
Health Products Regulatory Authority (HPRA)
Health Protection Surveillance Centre
Health Research Board
Hospital Pharmacists Association Ireland
Health Service Executive, Department of Public Health
Health Service Executive, Health and Wellbeing Division
Health Service Executive, Internal Audit
Health Service Executive, National Cancer Control Programme
Health Service Executive, National Clinical Programme in Surgery
Health Service Executive, National Office for Suicide Prevention
Health Service Executive, Office of Nursing and Midwifery Services, Clinical Strategy and Programmes
Health Service Executive, Office of the Chief Information Officer
Health Service Executive, Quality and Safety, Primary Care Division
Irish Heart Foundation
Irish Hospital Consultants Association
Irish Medical Organisation (IMO)
Irish Society of Chartered Physiotherapists
Kerry General Hospital

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

Manitex Limited
Mater Private Healthcare Group
Mental Health Commission
National Cancer Registry
National General Practice Information Technology Group
National Healthlink Project
National Office of Clinical Audit
National Rehabilitation Hospital
NHI National Nurses Committee
Noreen Roche Consultants
Nursing and Midwifery Board of Ireland
Pavee Point National Traveller Roma Centre
Pharmaceutical Society of Ireland
Pre-Hospital Emergency Care Council
Quality & Safety, Primary Care Division
St Patrick's Mental Health Services
St Vincent's Hospital Group
State Claims Agency
Temple Street Children's University Hospital
The National Maternity Hospital
Vasculitis Ireland Awareness

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

Appendix 2   Members of the Advisory Group

Name	Organisation
Rachel Flynn (Chairperson)	Health Information and Quality Authority (HIQA)
Damon Berry	National Standards Authority of Ireland
Patrick Burke	Health Service Executive (HSE)
Aidan Clancy	Department of Health
Kevin Conlon	Department of Health
Gerard Crotty	Irish Hospital Consultants Association
Ann Curran	Medical Council of Ireland
Peter Dennehy	Nursing and Midwifery Board of Ireland
Roisin Doherty	HSE
Jamie-Lee Ferguson	Dental Council of Ireland
Gemma Garvan	Healthlink
Damhnait Gaughan	Pharmaceutical Society of Ireland
Tessa Greally	HSE
Mairin Haran	Department of Social Protection
Sarah Jordan	HIQA
Sharon Hayden	Our Lady's Children's Hospital, Crumlin, Dublin
Chrissie Keane	National Standards Authority of Ireland
Ivan McConkey	HSE
Stephen McMahon	Irish Patients Association
Micheal O'Briain	Health Insurance Authority
Kevin O'Carroll	HIQA
Tracy O'Carroll	HIQA
Brian O'Mahony	Irish College of General Practitioners
Oliver Plunkett	HSE
Joe Ryan	HSE
Fran Thompson	HSE

Statement of outcomes – Report on the outcome of the public consultation on Draft Information
Governance and Management Standards for the Health Identifiers Operator in Ireland
Health Information and Quality Authority

Appendix 3   Consultation questions

The consultation questions were presented under two headings, as follows:

General feedback questions	
Question 1	Is the language clear?
Question 2	Is the layout of the standards clear, easy to follow and understand?
Question 3	Do you feel that the order and structure of the standards is logical?
Question 4	Do you feel that the draft standards protect the confidentiality and privacy of your health identifier record?
Question 5	Do you feel that all the important topics have been covered or are there any topics that should have been included or excluded?
Question 6	Having read the background information, do you feel that you understand the background to these draft standards? Is enough background information provided?
Question 7	Do you feel that additional guidance on any of the concepts contained in the draft standards should be provided? If so, what additional guidance do you feel is necessary?
Question 8	Are these draft standards 'fit for purpose' and appropriate for use by the health identifiers operator?
Question 9	What other areas of standards are needed to support the introduction of individual health identifiers and health services provider identifiers?

Specific feedback questions
The following questions were asked:
Can these draft standards and features be applied to the health identifiers operator in a manner that supports good information governance and management?
In your opinion are the standard statements and the features that follow each standard statement clear and easy to understand?
in relation to each of the five themes: • Theme 1: Person-centred support • Theme 2: Leadership, governance and management • Theme 3: Use of information • Theme 4: Use of resources • Theme 5: Workforce

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

Appendix 4   Main changes to standards document

The main changes made to the standard statements and features based on the feedback received were:

- Moving the Glossary to the start of the document.

- Shortening Part 1: Introduction, with the target audience being the health identifiers operator and moving extra information (concepts, definitions and so on) to Appendices.

- Updating Benefits and Monitoring sections.

- Changing Theme 1: Person-centred support to Theme 1: Person-centred to reflect its contents more accurately.

- Removing Theme 4: Use of Resources and including a feature relating to resource use into Theme 2.

- Changing specific Standard statements and associated feedback.

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

Glossary of terms

Health identifier record: a service user's individual health identifier and their identifying particulars.

Health services provider: any person, organisation, part of an organisation, and employees of persons or organisations that deliver health or social care services.

Health services provider identifier: a unique number that is assigned to a health services provider.

Individual health identifier: a unique number that is assigned to a service user, such as a patient, when a health service is being, has been or may be provided for that service user.

National Register of Individual Health Identifiers: a register that contains a service users' individual health identifier and their identifying particulars, as mandated in the Health Identifiers Act 2014. The Health Identifiers Act 2014 prescribes what data can be collected and used in the National Register of Individual Health Identifiers and is documented in Appendix 1.

National Register of Health Services Provider Identifiers: a register that contains a health services provider's health identifier and their identifying particulars, as mandated in the Health Identifiers Act 2014. Part 3, Section 14, Subsection 1 of the Health Identifiers Act 2014 prescribes what data can be collected and used in the National Register of Health Services Provider Identifiers and is documented in Appendix 2.

National registers: a term used to refer to two national registers that contain health identifiers. It is mandated in the Health Identifiers Act 2014 that two registers are set up to store individual health identifiers, health services provider identifiers and associated identifying information. These two data collections are known as the National Register of Individual Health Identifiers and the National Register of Health Services Provider Identifiers.

Privacy: the right of individuals to keep information about themselves from being disclosed; that is, people are in control of others access to themselves or information about themselves. Individuals decide when, where and with whom to share their personal health information[6]

Privacy risk: the likelihood of a breach to an individual's privacy.

Privacy impact: the effect that a breach of privacy has on an individual

Privacy impact assessment: a common tool that assists in the detection of potential privacy risks around the collection and use of personal health information.

Statement of outcomes – Report on the outcome of the public consultation on Draft Information Governance and Management Standards for the Health Identifiers Operator in Ireland

Health Information and Quality Authority

Its main purpose is to protect the privacy rights of service users. More information can be found in the Authority's *Guidance on Privacy Impact Assessment Health and Social Care*.[7]

Service user: people who use health and social care services, their parents, guardians, carers and family, their nominated advocates and potential users of health and social care services. Any reference to the term service user does not include service providers who use services on behalf of their patients, for example, family doctors using diagnostic laboratory services.

Trusted source: a term used to describe the data sources that are used to populate and update as required the national registers, since they are recognised as being highly reliable or accurate by the health identifiers operator.

Statement of outcomes – Report on the outcome of the public consultation on Draft Information
Governance and Management Standards for the Health Identifiers Operator in Ireland
Health Information and Quality Authority

References

(1) Health Information and Quality Authority (HIQA). *Recommendations for a Unique Health Identifier for Individuals in Ireland*. 2009. Available online from: http://www.hiqa.ie/system/files/Unique_Health_Identifier_Report.pdf. Accessed on: 12 September 2012.

(2) Health Information and Quality Authority (HIQA). *International Review of Unique Health Identifiers for Individuals*. 2010. Available online from: http://www.hiqa.ie/healthcare/health-information/health-identifiers.

(3) Health Information and Quality Authority (HIQA). *Recommendations for Unique Health Identifiers for Healthcare Practitioners and Organisations*. 2011. Available online from: http://www.hiqa.ie/publications/recommendations-unique-health-identifiers-healthcare-practitioners-and-organisations. Accessed on: 22 October 2012.

(4) Health Information and Quality Authority. *Recommendations for Unique Health Identifiers for Healthcare Practitioners and Organisations.* 2011. Accessed on: 9 June 2015.

(5) Health Information and Quality Authority. *Recommendations for a Unique Health Identifier for Individuals in Ireland*. 2009. Available online from: http://www.hiqa.ie/system/files/Unique_Health_Identifier_Report.pdf. Accessed on: 3 November 2014.

(6) Erickson JaMS. Caring for Patients while Respecting their Privacy: Challenges of Maintaining Privacy and Confidentiality. *Online Journal of Issues in Nursing 2005.* 2005; 10(2): Available online from: http://www.medscape.com/viewarticle/506840_4. Accessed on: 19 May 2015.

(7) Health Information and Quality Authority. *Guidance on Privacy Impact Assessment Health and Social Care*. 2010. Available online from: http://www.hiqa.ie/resource-centre/professionals/privacy-impact-assessments.