Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Information and Standards

Draft National Standards for Information Management in Health and Social Care

Public Consultation Feedback Form

October 2022

Safer Better Care

The Health Information and Quality Authority (HIQA) is holding a public consultation to give people an opportunity to provide feedback on the Draft National Standards for Information Management in Health and Social Care (referred to in this document as the draft standards).

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

Please note: the focus for this consultation is the content and structure of the draft standards. The final design and layout of the standards will be developed after the public consultation.

We welcome responses to all questions, and there will be an opportunity at the end of the survey to provide any additional general comments.

Instructions for submitting feedback

- The draft standards document is available at www.hiqa.ie.

- If you are commenting in a personal capacity, there is no need to provide your name or any other personal information. However, if you would like to be contacted to take part in future stakeholder engagement, there is an option to provide your name and contact number.

- If you are commenting on behalf of an organisation, please combine all feedback from your organisation into one submission. In this case, we will request a name and contact number for a designated representative from your organisation in case we need to verify the authenticity of your contribution.

- When referring to a specific section of the standards document, please include the section and page number that you are commenting on.

- Do not paste other tables into the boxes already provided — type directly into the box as the box expands.

- Please spell out any abbreviations that you use.

   You can email or post a completed form to us. You can also complete and submit your feedback on www.hiqa.ie.

Data Protection and Freedom of Information

- HIQA will only collect personal information during this consultation for the purposes of verifying your feedback or where you have indicated that you would like to be contacted to partake in future stakeholder engagement. If you have any concerns regarding your data, please contact HIQA's Information Governance and Assurance Manager on infogovernance@hiqa.ie.

- Please note that HIQA are subject to the Freedom of Information (FOI) Act and the statutory Code of Practice in relation to FOI. Following the consultation, we will publish a stakeholder involvement report summarising the responses received, which will include the names and types of organisations that submitted feedback to us. For that reason, it would be helpful if you could explain to us if you regard the information you have provided to us as being confidential or commercially sensitive.

- If we receive a request for disclosure of the information under FOI, we will take full account of your explanation, but we cannot give you an assurance that confidentiality can be maintained in all circumstances.

1. About you

1.1　Are you providing feedback as:

☐　**an individual**

(If you would like to be contacted to participate in future stakeholder engagement, please provide your name and contact number below. Otherwise, please move on to the next question.)

Click here to enter text.

☒　**on behalf of an organisation**

(If you are responding on behalf of an organisation, please provide your organisation's name and contact details below for verification purposes.)

IPPOSI - the Irish Platform for Patient Organisations, Science and Industry

1.2　Are you commenting:

☒　**In a professional capacity**

(Please use the box below to specify your role in the organisation you currently work for.)

Derick Mitchell, Chief Executive Officer, and Laura Kavanagh, Research and Advocacy Manager

☐　**As a member of the public / user of health and social care services**

(If you would like to provide any additional details, please share in the box below.)

Click here to enter text.

2. Your feedback on the draft standards

In this section, we would like to find out what you think of the content of the Draft National Standards for Information Management in Health and Social Care. This section focuses on the three principles, standard statements and features presented in the draft standards. Taken together, the principles, standard statements, and the features provide a common language to describe what good information management practices in health and social care should look like.

The draft national standards are underpinned by three principles:

- A rights-based approach
- Accountability
- Responsiveness.

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

Please consider the following questions as part of your review of the draft standards:

1. Do you think all important areas have been covered in each standard statement or are there any areas that should be included or excluded?
2. Are the features listed sufficient to assist staff working in organisations that process health and social care information?

2.1 Please provide your feedback on the standard statements and features set out under Principle 1: A rights-based approach

NOTE: Suggested additions to the existing text are presented below in CAPITALS.

We welcome HIQA's recognition of the need for a rights-based approach to health information management. We believe that this approach should include both negative rights (e.g. the right of individuals to not have their privacy interferred with) and positive rights (e.g. the right of individuals to claim assistance in obtaining access to their information). Respecting positive rights impose a duty to act (e.g. action is needed to ensure that we facilitate an individual's access to their own information). We suggest that the text is reviewed to ensure that these positive rights are given the same consideration as the negative rights which are more traditionally discussed when exploring the topic of health information.

For instance in standard 1.1 we propose that the word 'fulfil' be added to imply the positive duty that organisations have to provide individuals with access. In the individual statement, "I understand how the organisation collects, uses and shares my information, I am confident that it has arrangements in place to protect AND FULFIL my rights relating to information, I feel empowered to make decisions about my information". In the organisation statement "The organisation is transparent about how it collects, uses and shares information, it has effective arrangements in place to ensure individuals' rights under relevant legislation are upheld AND FULFILLED, balancing these rights against other values, fundamental rights, human rights, or legitimate, public or vital interests".

For instance, on page 25/26 - In the paragraph which starts "at a service provider level" there could be a greater reference to (and explanation of) the positive rights individuals enjoy around accessing their own health information, and the responsibilities organisations have to ensure that these positive rights can be fulfilled (e.g. as detailed in article 15 of the GDPR). Page 25 talks first about staff access to an individual's information, with only the last line of page 26 including a reference to facilitating people's access to their own information. This gives the impression that this latter aspect is more of an afterthought rather than the focus of the principle.

Standards 1.1. and 1.3. are of interest to IPPOSI members. However, the exact distinction between the two is difficult to ascertain, and perhaps both could clearly spell out that an individual has a right to access their own health

information (although it can be inferred from the text, especially in standard 1.3).

For instance should one of the standards include in the individual statement "I KNOW HOW TO REQUEST ACCESS TO INFORMATION HELD ABOUT ME, AND I KNOW HOW AND WHEN IT WILL BE PROVIDED TO ME" and in the organisation statement, "AND IT HAS CLEAR PROCESSES IN PLACE TO PROVIDE INDIVIDUALS WITH ACCESS TO THEIR HEALTH INFORMATION."

The footnotes on page 27 are likely to cause further confusion within organisations, and potentially, an overly cautious interpretation of individual rights. As there are very limited circumstances in which the right to personal information is restricted in irish and european legislation, perhaps it is prudent to simply list these limited circumstances (e.g. when it impacts another individual's rights etc).

Standard 1.2 should include a commitment to communicate to the public the details of the "effective arrangements" put in place by an organisation to protect privacy and confidentiality.

Standard 1.3 should emphasise the agency which individuals have to make decisions about the management of their own health information. "THE ORGANISATION FACILITATES INDIVIDUALS TO MANAGE THEIR OWN HEALTH INFORMATION, AND WHERE APPROPRIATE TO MAKE (ADDITIONAL) DECISIONS ABOUT THE (FURTHER) USE AND SHARING OF THEIR OWN PERSONAL HEALTH INFORMATION IN LINE WITH THEIR OWN PREFERENCES".

Feature 1.3.4 should detail a commitment to include "the public and staff members, AND REGULAR SERVICE USERS" as those who need to access and use their health information regularly may have different suggestions and expectations for health information initiatives than the average 'health-interested' individual.

2.2   Please provide your feedback on the standard statements and features set out under Principle 2: Accountability

Standard 2.1, feature 2.1.3 & 2.1.4 should commit to publicly publish any arrangements or agreements reached to promote transparency for individuals whose data is being shared and used.

Standard 2.1, feature 2.1.5 should consider mentioning that any statement of purpose is developed with the input of public and patient representatives to ensure that the vision is person-centred and rights-based. The same might be said of Standard 2.2., feature 2.2.1 in the development of an organisation's strategic plan.

Standard 2.3, feature 2.3.5 should include a recommendation to produce an annual report detailing the complaints received from individuals and the resolution achieved, and the improvement actions identified at an organisational level to ensure that similar complaints are not received in the future.

Standard 2.4, feature, 2.4.2 should require PUBLICLY documented processes. Individuals need to be informed when an organisation has failed to comply, released information, reviewed risks, or breached legislation.

2.3   Please provide your feedback on the standard statements and features set out under Principle 3: Responsiveness

We welcome Principle 3 and the references made to meaningful stakeholder engagement which encourage organisations to ensure people have the opportunity to express their needs, preferences, and expectations. We underline that engagement should go further than listening to needs, preferences, and expectations. Organisations need to establish ways to weigh up and evaluate the 'evidence' they have 'heard'. In this weighing up and evaluation, stakeholder representatives need to be involved e.g. public and patient representatives need to be invited into discussions leading up to decision-making and into the decision-making process itself (where needs, preferences and expectations are weighed up against other considerations). Simply 'listening' and leaving the other stakeholder representative voices out of this part of the process does not achieve meaningful engagement. Equally, the stakeholder representatives brought into the decision-making part of the process should be facilitated to share the outcomes of the decision-making process with the wider stakeholder community. To ensure that a diverse representation of stakeholders is achieved at both the 'listening' and the 'decision-making' parts of the process, organisations should proactively reach out to stakeholders to invite and support them to become engaged. Many under-represented groups are often unaware of the opportunities which exist to express their needs, preferences and expectations.

Page 37 - at the service level, it may be important to mention that people

should have access to the information collected by a service (not to just focus on staff access). In principle, everytime the importance of health information for staff is referenced, the importance of information for patients/service users/the public should also be mentioned if there is to be a commitment to self-management and lifestyle wellness.

Standard 3.1, Feature 3.1.2 references organisational adherence to standards and arrangements to demonstrate compliance (nationally and internationally). This raises the question of how these standards are governed (at least nationally) - which is not clear from the document and which should potentially be spelt out in a specific section at the end of the three principles.

Standard 3.2 should specifically spell out a commitment for organisations to co-design the engagement strategy and plan with the very communities the organisation seeks to engage with (not just create it from the top-down). The last bullet point under feature 3.2.1. makes a suggestion in this regard, but it might benefit from a clear mention of public, regular service users and staff.

Standard 3.5, feature 3.5.2 should include a provision to inform the public about any data misuse or breach in the interests of transparency.

Standard 3.5, feature 3.5.4 should include an audit trail which is visible to the individual whose information has been accessed.

2.4 Are there any other comments or suggestions on the draft standards that you would like to make?

We wish for individuals to have trust and confidence in our national health information management strategy, and in the management within specific organisations. It is our experience in IPPOSI that patients and the public tend to grow in confidence if they are 1) informed and 2) involved (in as little or as much as they wish to be) in discussions and decisions about their own health information. Therefore, where possible, standards should be framed through this lens - i.e. providing information and facilitating involvement.

The numbers of individual members of the public engaging with issues relating to health information is very likely to increase as people begin to access and view their own health information. By having sight of their full health information they will be able to see the wealth of information collected about them and to better understand its value for both individual care and secondary purposes.

The standards - if implemented in full across all relevant organisations - would go a long way towards improving public trust and confidence. However, how organisations are required (or not) to implement the standards is unclear and the standards should detail the governance in place around the standards.

There are a few references to governance in the document (page 19, page 39) but these do not provide a clear, comprehensive governance framework. Are all organisations mandated to meet these standards, are they required to report progress, are they audited? If only HSE organisations are mandated, how do they report on progress and how are they monitored? Will all non-HSE organisations be encouraged to comply? Whatever the reality, this should be detailed in the final section of the document for transparency and accountability purposes.

From our experience, it is our assumption (this may not be the case) that each organisation (under the HIQA remit) should be mandated to produce a document outlining how it will implement the standards, and it should be required to report against the vision annually to HIQA. HIQA should carry out its own review of an organisation's progress to assess the accuracy of this self-reporting mechanism. Where an organisation is found to be lacking in progress, improvement actions and an improvement plan should be developed (and similarly, reported against). Greater consideration should be given to how standards can be progressed within organisations which are not currently under the remit of HIQA (and legislation may be needed here).

To faciliate implementation, the standards might benefit from providing some

checklists and tools to guide organisations.

The standards do not list the attributes that each organisation should include to ensure the data they collect adheres to e.g. accuracy, accessibility, comprehensiveness, consistency, definition, precision, currency, timeliness, relevancy etc.

The standards do not list any data security or privacy rules that the organisation's health information management systems must satisfy.

The standards do not provide the terminology and codes needed to standardise the quality of data elements collected by organisations.

3. General Feedback

3.1 Do you think the language used in the draft standards is clear, easy to follow and easy to understand?

☒ **Yes**

☐ **No**

3.2 Do you think the content and structure of the draft standards is clear, easy to follow and easy to understand?

☒ **Yes**

☐ **No**

3.3 Please provide any additional comments on the language, content and structure of the draft standards.

Click here to enter text.

3.4 Having read the draft standards, do you have a better understanding of what good information management looks like for organisations that process health and social care information?

☒ **Yes**

☐ **No**

Comments:

Click here to enter text.

3.5 If you work in an organisation that processes health and social care information, having read the draft standards, do you intend to make changes to your work practices?

☐ **Yes**

☐ **No**

Can you describe what these changes may be?

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

N/A

3.6 What is needed to support the implementation of these standards in the organisation that you work in?
(If this question is not relevant to you, please move on to the next question.)

Below are some perspectives from our patient members on the supports needed for organisations which are processing their health information:

- Education and training is needed at all stages of the health data/information process - from the people who collect the information, to the people who input the information, to the people who process information, to the people who share information, to the people who monitor the use of information.

- Standardised reporting is needed to evaluate progress made by an organisation against these standards.

- Public and patient involvement in health information management mechanisms and processes is needed to ensure a person-centred approach is designed and adopted.

- Clear guidance, good communication and appropriate information resources will all be important to ensure that these standards do not discourage smaller, patient-led organisations, from initiating their own data collections (for example rare disease registries).

3.7 Are there any other comments that you would like to make about these draft standards?

Page 12 & 13 & 16 - The standards could consider also recognising 'the development of new innovative therapies' as one of the benefits of sharing information (with third parties). The belief that health information can only support improvements within the public health service/system is a limited one - and it postpones conversations which need to be had around the appropriate sharing of data/information outside the public system, and how appropriate use is authorised and then facilitated. The lanugage of the European Health Data Space regulation may be helpful to consult https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197

Page 15 - The good management and governance of information could arguably include 'ensuring procedures and processes are in place to provide data subjects with timely access to their own health information'. Similarly,

the five overarching objectives could be expanded to include 'Information should be readily available to the person to whom it relates, where appropriate and where legal'.

Page 16 - There is no acknowledgement of the need for information to inform research and innovation during pandemics. Many countries were able to mobilise their R&D industry and create public-private-partnerships due to their existing health information management systems.

Thank you for taking the time to give us your views on the Draft National Standards for Information Management in Health and Social Care.

Please return your form to us by email or post.

You can **download** a consultation feedback form at www.hiqa.ie and then **email** the completed form to: healthinformation@hiqa.ie

or

Print the consultation feedback from and **post** the completed form to:

Health Information Quality Team,
Health Information and Quality Authority,
Unit 1301,
City Gate,
Mahon,
Cork
T12 Y2XT

You can also complete an **online consultation form** at www.hiqa.ie

If you have any questions on this document, you can contact the HIQA Health Information Quality Team by:

Phone: 021 240 9300 or **Email:** healthinformation@hiqa.ie

Please ensure that you return your form to us by **5pm on 19 December 2022**.