MHC
Coimisiún Meabhair-Shláinte | Mental Health Commission

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Statement of outcomes

Report on the outcomes of the public consultation on the Draft National Standards for the Conduct of Reviews of Patient Safety Incidents

October 2017

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high-quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered.

HIQA aims to safeguard people and improve the safety and quality of health and social care services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services.

Reporting to the Minister for Health and the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

- **Setting Standards for Health and Social Services —** Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.
- **Regulation —** Registering and inspecting designated centres.
- **Monitoring Children's Services —** Monitoring and inspecting children's social services.
- **Monitoring Healthcare Safety and Quality —** Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment —** Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.
- **Health Information —** Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

About the Mental Health Commission

The Mental Health Commission (MHC) was established under the Mental Health Act 2001 to promote, encourage, and foster the establishment and maintenance of high standards and good practices in the delivery of mental health services in Ireland.

The MHC's remit includes the broad spectrum of mental health services including general adult mental health services, as well as mental health services for children and adolescents, older people, people with intellectual disabilities and forensic mental health services.

The MHC's role is to regulate and inspect mental health services, support continuous quality improvement and to protect the interests of those who are involuntarily admitted and detained under the Mental Health Act 2001. Legislation focuses the MHC's core activities into regulation and independent reviews.

Regulation:

- Registration and enforcement — registering approved centres and enforcing associated statutory powers e.g. attaching registration conditions.
- Inspection — inspecting approved centres and community mental health services and reporting on regulatory compliance and the quality of care.
- Quality improvement — developing and reviewing rules under the Mental Health Act 2001. Developing standards, codes of practice and good practice guidelines. Monitoring the quality of service provision in approved centres and community services through inspection and reporting. Using our enforcement powers to maintain high quality mental health services.

Independent reviews:

- Mental Health Tribunal Reviews — administering the independent review system of involuntary admissions. Safeguarding the rights of those detained under the Mental Health Act 2001.
- Legal Aid Scheme — administering of the mental health legal aid scheme.

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1. Introduction and background

The Health Information and Quality Authority (HIQA) and the Mental Health Commission (MHC) developed these joint *National Standards for the Conduct of Reviews of Patient Safety Incidents*. These standards were commissioned by the Department of Health and are underpinned by findings from the Chief Medical Officer's 2014 *Report on Perinatal Deaths in HSE Midland Regional Hospital Portlaoise,* [(1)] which recommended the development of national standards on the conduct of reviews of patient safety incidents, following the identification of shortfalls with the current system in Ireland. These Standards provide a framework for best practice in the conduct of reviews of patient safety incidents. They cover the conduct of reviews of patient safety incidents including: review of the incident, implementation of recommendations of the review and sharing the learning from the review. The *National Standards for the Conduct of Reviews of Patient Safety Incidents* are designed to apply to acute hospitals under the remit of HIQA and mental health services under the remit of the MHC.

A focused desktop review of Irish and international literature was undertaken in November 2015 and used to inform the development of the Standards. The review took account of published research, investigations and reviews of patient safety incidents in Ireland and the structures in place in other countries for the conduct of reviews of patient safety incidents. HIQA and the MHC convened a Standards Advisory Group, which included representatives from patient advocacy groups, the Department of Health, the Health Service Executive (HSE), the Office of the Ombudsman, the State Claims Agency and Private Hospitals Association of Ireland. Three meetings of the Standards Advisory Group were held, two of which took place before the public consultation. The last meeting of the group took place on 9 January 2017 to discuss and agree final changes to the Standards resulting from the public consultation feedback.

In advance of the public consultation, HIQA and the MHC participated in and undertook a series of focus groups with service users, staff and management involved in patient safety incidents. These groups discussed the experience of reviews of patient safety incidents and obtained opinions as to what issues the draft standards should address. HIQA and the MHC would like to acknowledge with gratitude those who participated for taking the time to attend the sessions and contributing to the standards development process in such a meaningful way.

To facilitate stakeholder engagement and participation in the development of the Standards, HIQA and the MHC published the *Draft National Standards for the Conduct of Reviews of Patient Safety Incidents* in September 2016 for public consultation. The public consultation ran for six weeks. During this time, interested parties were invited to submit their views and feedback on the draft standards. In total, 47 responses were received over the six-week public consultation phase. All submissions to the consultation informed the final *National Standards for the Conduct of Reviews of Patient Safety Incidents*. HIQA and the MHC welcomed all of these submissions and would like to thank all those who took the time to contribute to the public consultation. A full list of the organisations that made submissions is documented in Appendix 1.

This document presents a Statement of Outcomes from the public consultation process and gives an overview of the submissions, suggestions and comments received as well as HIQA and the MHC's response to the submissions.

2. The consultation process

The draft standards were launched for public consultation on 26 September 2016 for a six-week period until 4 November 2016. The purpose of the public consultation was to gather feedback on the content and structure of the draft standards. The full text of the *Draft Standards for the Conduct of Reviews of Patient Safety Incidents*

was made publicly available in a downloadable format on the HIQA website www.hiqa.ie and the MHC website www.mhcirl.ie. A consultation form (see Appendix 2) was developed in order to assist people to make a submission. The form was available to download on www.hiqa.ie and www.mhcirl.ie and responses could be emailed to dedicated email addresses in each organisation or posted to the MHC or HIQA. It was also possible to make an online submission using the online survey tool Polldaddy. Of the 47 submissions, 15 (32%) responded via Polldaddy, 31 (66%) emailed their responses and one response (2%) was received by post.

At the start of the consultation, HIQA and the MHC notified the members of the Standards Advisory Group and other key stakeholders of the publication of the draft standards for the consultation process. HIQA and the MHC also requested that they disseminate information about the public consultation and encourage their colleagues to participate in the process.

Each submission received was read in its entirety and each individual comment was assessed to determine whether or not it would be incorporated. As these were a collaborative set of standards, all submissions were shared securely between HIQA and the MHC, and were then reviewed by the project team with all subsequent changes were agreed. In a number of cases, feedback was also discussed with the Director of the Standards and Quality Improvement Team in HIQA and the Director of Standards and Quality in the MHC. While it is not an exhaustive list of all comments received, this document highlights some of the key items raised during the consultation.

3. Overview of consultation submissions

The consultation comprised of three general feedback questions and two specific feedback questions on each of the five themes of the *Draft National Standards for the Conduct of Reviews of Patient Safety Incidents*. The aim of these general and

specific feedback questions was to ascertain public opinion on the draft standards. This document provides an overview of the submissions received for each question.

In total, there were 47 responses received over the six-week public consultation phase. In the 'About you' section, people were asked if they were commenting on behalf of an organisation or in a personal capacity. If they were making the submission on behalf of an organisation they were asked to include the name of the organisation. They were also requested to specify their role if they worked in an acute hospital or mental health service.

Of these 47 submissions, 40% (19 respondents) responded in a personal capacity and 60% (28 respondents) responded on behalf of an organisation.

The majority, 68% (n=32) of respondents, gave details on their role. However, three of these respondents cannot be measured within this category as they provided inadequate responses for this question. Fifteen respondents (32%) did not provide an answer for this question, indicating that they either do not work in an acute hospital or mental health service role or they may have simply skipped the question.

Examples of Acute Hospital or Mental Health Service roles provided:

- area director of mental health nursing
- assistant inspector of mental health services
- clinical nurse manager, mental health services
- clinical risk manager
- consultant psychiatrist/child & adolescent psychiatrist
- general manager, hospital
- head of occupational therapy
- Health Service Executive (HSE) staff member
- member of primary care, social care and mental health services
- member of the community mental health team, hse
- member of the national incident management and learning team/hse quality assurance and verification division
- Mental Health Act administrator
- QRPS for mental health
- quality and patient safety lead/manager
- quality and risk manager
- risk and incident monitoring, support and learning officer
- risk and patient safety advisor
- senior pharmacist.

A full list of the organisations that made submissions is documented in Appendix 1.

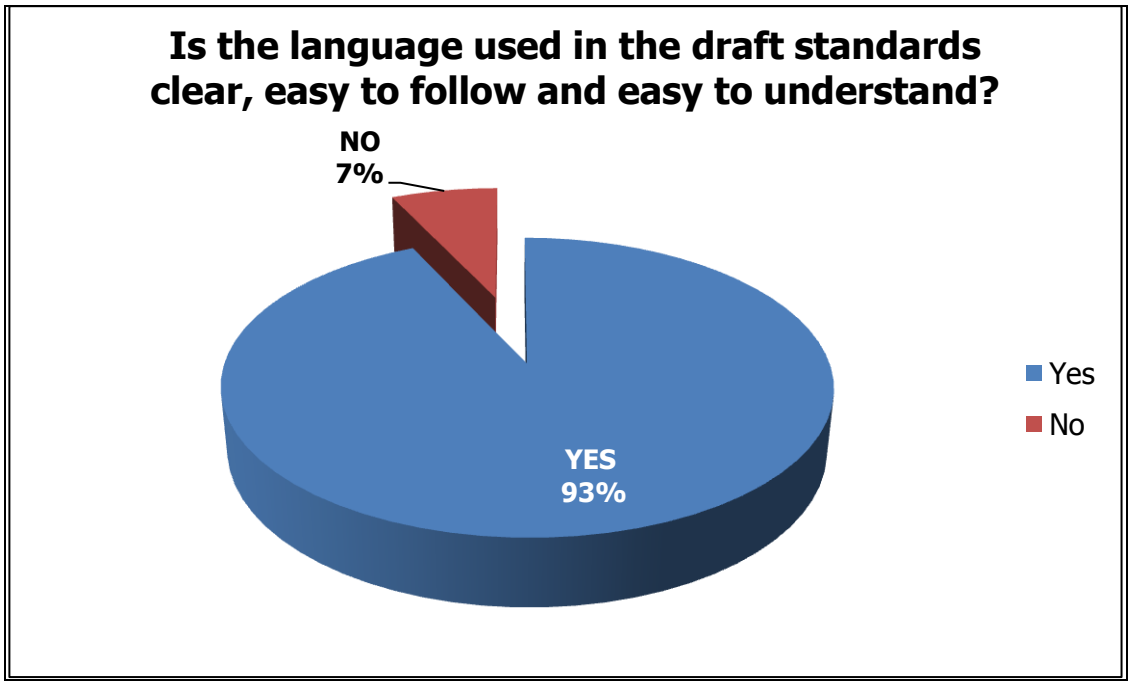
Feedback on the language, layout, accessibility and impact

Question 1 and 2 sought feedback on the language, layout and accessibility of the draft standards. Question 3 focused on the impact these standards will have on acute hospitals and mental health services, once they are in place. This section provides an overview of the responses received in relation to these questions.

Question 1: Content of the draft standards - Language

This question required respondents to state whether the language used in the draft standards was clear, easy to follow and easy to understand. Almost all (91%) respondents (n=43) provided feedback on this question and four respondents (9%) did not answer this question. Of the respondents who answered this question, 93% (n=40) stated that the language used in the draft standards was clear, easy to follow and easy to understand. Figure 1 presents the number of Yes/No responses for whether the language used in the draft standards is clear, easy to follow and easy to understand.

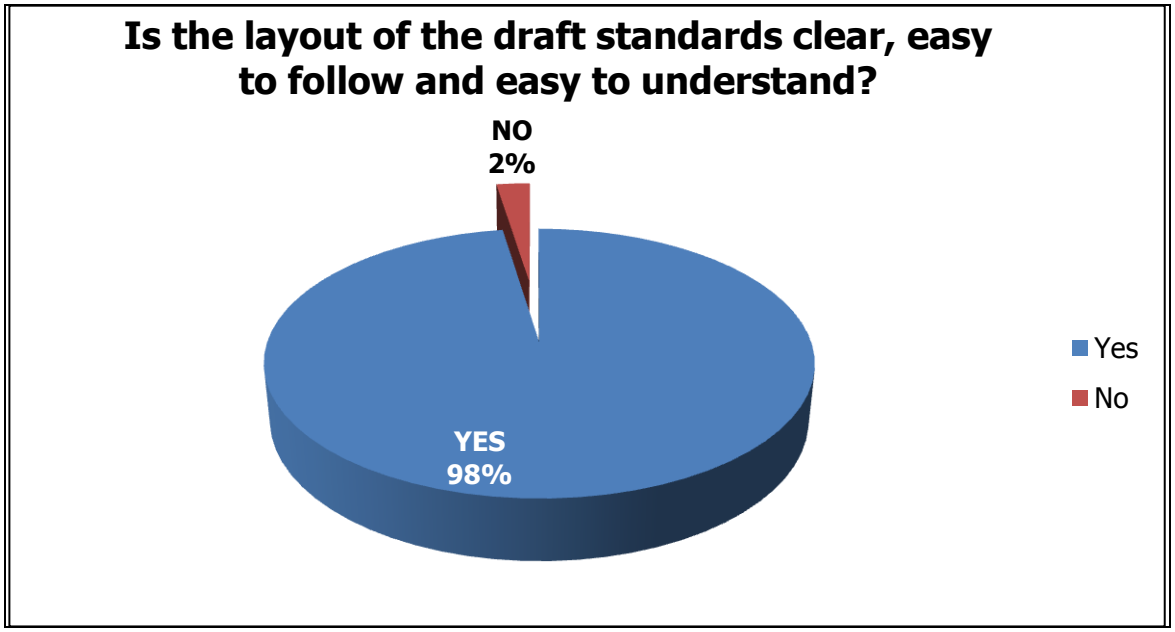
Figure 1: Responses to consultation Question 1 (a) n=43



Layout

This question required respondents to state whether the layout and design of the draft standards is clear, easy to follow and easy to understand. Forty-one respondents (87%) provided feedback on this question and six respondents (13%) did not answer the question. Of the respondents who answered this question, 98% (n=40) stated that the layout and design of the draft standards was clear, easy to follow and easy to understand. Figure 2 presents the number of Yes/No responses for whether the layout and design within the draft standards is clear, easy to follow and easy to understand.

Figure 2: Responses to consultation Question 1 (b), n=41



What the respondents said:

Fourteen respondents (30%) provided additional comments on the language and layout, which included:

"I think the language and the layout of the draft standards are very clear, easy to follow, and easy to understand."

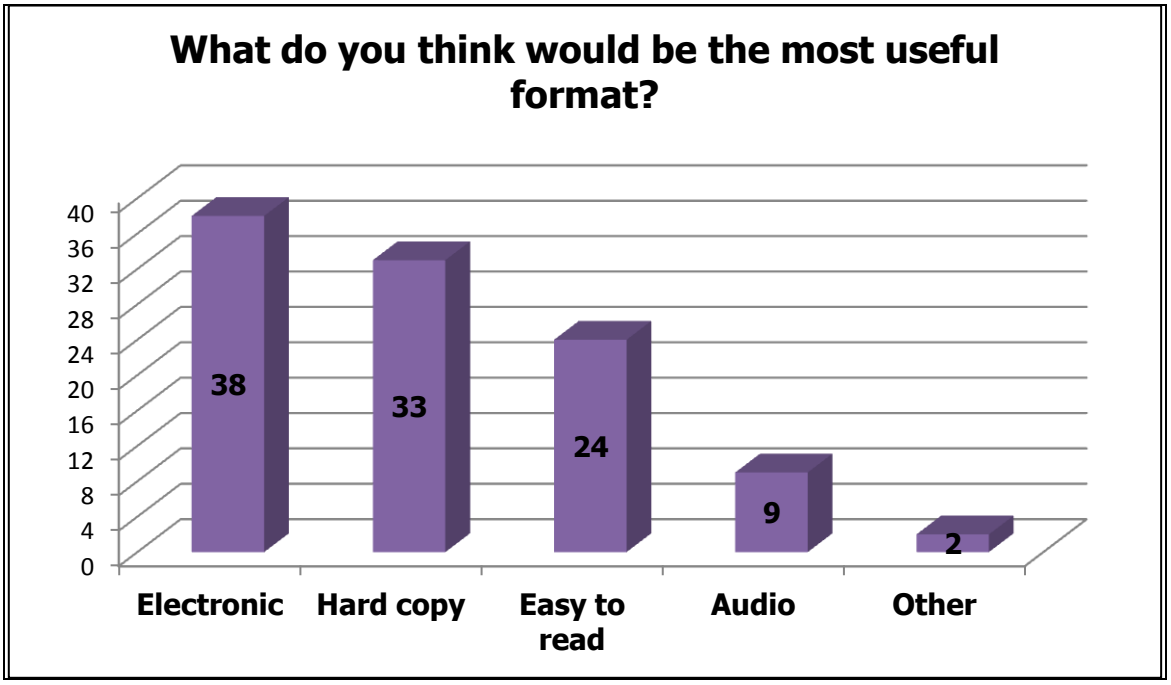
"It is very similar to NSSBH (The National Standards for Safer Better Healthcare) and I am very familiar with them"

"Standards are ambiguous and repetitious requiring you to read over them several times to get clarity."

Question 2: Content of the draft standards – Accessibility

This question required respondents to choose from six options selecting the most useful formats for the draft standards. Feedback was received from 87% of respondents (n=41). Figure 3 shows the breakdown of responses received.

Figure 3: Responses to consultation Question 2, n=41



Almost one in four (24%) respondents (n=10) provided additional comments on the most useful formats for the draft standards, which included the following:

- use of a summary document
- use of information sessions
- consider other languages
- compatibility with eBooks
- all of the options given in Figure 3.

Question 3: Impact on acute hospitals and mental health services

Question 3: What impact will the draft standards have on acute hospitals and mental health services in Ireland when they are in place?

This question sought the views of participants on the impact the draft standards would have on acute hospitals and mental health services in Ireland, when they are in place. Thirty-nine respondents (83%) provided feedback to this question. Figure 4 represents the most frequently used words in responses to this question.

Figure 4: Most frequently used words by respondents on the impact of the draft standards.

Respondents' views on the impact the draft standards will have on acute hospitals and mental health services in Ireland:

The majority of respondents that answered this question agreed that the draft standards will have a positive impact on acute hospitals and mental health services, when implemented across services in Ireland. Respondents also provided examples of areas in the conduct of reviews of patient safety incidents where improvements may occur when the standards are implemented. These improvements included standardising the relevant policies and procedures on reviews of patient safety incidents, which will in turn lead to more standardised practice with the relevant processes such as shared learning, monitoring implementation and the evaluation of effectiveness.

Respondents said:

"They will provide a succinct reference for services .... useful in ensuring a consistent approach in managing patient safety incidents ."

"The standards will positively affect the quality and standardisation in regard to the review and management of serious incidents."

Respondents stated that the draft standards will improve the overall quality of care and patient safety when in place in Ireland. They highlighted a number of areas of improvement such as; increased knowledge of patient safety incidents, enhanced quality of reviews, learning from error, as well as helping to prevent future incidents.

Respondents said:

"Put quality and safety to the forefront of service. Give guidance to service providers on review process from initiation, management and implementation of recommendations."

"These will increase knowledge of patient safety incident governance within the structures of the acute hospitals. They will also standardise practice across services."

"I would expect the quality of investigations may improve as well as compliance."

A number of respondents stated that these standards will improve practice and result in fewer delays during reviews of patient safety incidents, as well as ensuring better outcomes for those involved in patient safety incidents. Respondents said:

"Improve the quality and timeliness of services' response to incidents leading to better outcomes for patients and their families."

"There will be structures in place for issues to be addressed in a timely manner; responsibilities will be assigned; people will be treated with respect and courtesy."

Respondents also welcomed the inclusion of multiple methods of reviews for patient safety incidents in the draft standards. Respondents said:

"The pragmatic, practical approach to the level of review required, based on the complexity and other features of individual incidents is welcome and will assist with deploying resources where greatest learning is likely to occur."

" ... will provide pathways other than full system analysis reviews for incidents."

Feedback highlighted that the draft standards would be of great benefit to both service users and staff when in place; providing them with confidence as well as helping to ensuring that everyone can expect the same response to safety incidents. Respondents said:

"It will provide a greater voice for the service user and their families and a greater sense of empowerment for them."

"It has the potential to improve the relationship between service providers and service users."

"The Standards should have a positive impact in terms of setting expectations at service user, family, frontline and management level with regard to action to be taken to review and learn from Patient Safety Incidents."

Respondents also made reference to a number of implementation considerations for services. These included various resource requirements such as the allocation of protected time for staff, training requirements and delivery, peer mentoring and support as well as additional staffing requirements. Respondents also placed

emphasis on the need for additional investment in other areas such as Information Technology (IT) systems and in the publication process for review reports.

In addition to this, some comments provided under this question (the impact of the draft standards on acute hospitals and mental health services), overlapped with feedback provided in the last question (other general comments on the draft Standards). In this feedback, concerns were raised regarding the implementation of the draft standards in services with varying levels of capacity.

Respondents said:

"The resource implications for meeting and adhering to these standards will be significant but welcome, particularly in the smaller hospitals.... with limited staff."

"The smaller approved centres may struggle with governance structure, personnel, training and implementation. "

This feedback also suggested that there would be some duplication between these draft standards and other HSE documents already in place. However, feedback contrary to this was also received. Respondents said:

"The standards will now create 3 different sets of guidance on how to conduct investigations i.e. these standards, HSE policy and HSE guidelines."

"I think these standards will create confusion as to how they "fit in" with the HSE Safety Incident Policy (2014), and the Guidelines for Systems analysis investigations."

" While there have been policies and guidelines in place in the Irish healthcare system related to the conduct of such reviews for a considerable period of time, the development of national standards is very good as they will demonstrate where existing policies, procedures and guidelines are aligned to the standards and will also highlight any 'gaps' that need to be addressed."

Finally, a small number of respondents specifically stated that the draft standards will have little or no impact on the conduct of reviews of patient safety incidents across services when in place. Specific feedback in relation to this included an

increased burden on resources, additional workload on staff and difficulty in meeting the proposed timelines.

Respondents said:

"The timelines will make it impossible for them to deliver on. It will take staff away from service delivery (doing reviews, being service user liaison persons etc.)"

"I believe the standards will require more resources from an already depleted service and will add little to the improved care of patients and their families."

Feedback questions on specific themes

Within this section, respondents were required to provide comments on each of the draft standards and/or features. Respondents were asked to consider the following questions as part of their review:

- *Have all important areas been covered within each standard or are there any areas that should be included or excluded?*
- *Do the features listed provide sufficient guidance to service providers to meet the standard?*

When providing their feedback, respondents were asked to reference which standard and feature that they were commenting on. Table 1 provides a breakdown of the percentage of respondents that provided feedback in relation to each theme.

Table 1: Percentage of respondents that provided feedback on each theme

	Theme	Percent	Number
1	Governance and Accountability	77%	n=36
2	Person-centred Approach to the Review of Patient Safety Incidents	72%	n=34
3	Workforce	85%	n=40
4	Reviews of Patient Safety Incidents	81%	n=38
5	Sharing the Learning for Improvement	66%	n=31

Theme 1: Governance and Accountability

Over three out of four respondents (77%) (n=36) provided comments on Theme 1: Governance and Accountability.

What the respondents said

The inclusion of this theme was welcomed and the majority of comments received were positive. A number of respondents indicated that the standards were clear and comprehensive, that they would promote a more standardised approach to conducting reviews and lead to increased awareness of the need to identify if a review is required. In addition, the importance of a patient safety culture was also acknowledged.

Common areas raised by respondents for clarification included; lines of accountability, the requirement for a standardised process at national level, information governance requirements and solutions to issues relating to capacity and consent. Furthermore, a number of concerns were raised by respondents which included the increased burden of paper compliance and the requirement for investment in staff and IT systems to support implementation.

Finally, feedback was also received on Theme 1 which overlapped with feedback received in relation to Theme 3 (Workforce) and Theme 4 (Reviews of Patient Safety Incident). This was specifically in relation to the key roles and responsibilities for conducting reviews of patient safety incidents.

HIQA's and MHC's response

Text was revised to provide clarity in relation to lines of accountability. Other feedback on key roles was addressed by revisions throughout the standards. The requirement for a service-wide standardised approach was strengthened and examples of information governance legislation were included. Changes were also made to ensure that the expressed wishes of the service user regarding communication were included in the standards, however, specific issues in relation to capacity and consent were deemed to be beyond the scope of the standards.

The intention of the standards is to provide a framework, aligned to best practice, for what should be in place. Service providers will need to examine how to implement the standards within their individual service.

Theme 2: Person-centred Approach to the Review of Patient Safety Incidents

Seventy-two percent (n=34) of respondents provided comments on Theme 2 Person-centred Approach to the Review of Patient Safety Incidents.

What the respondents said

A number of language and wording revisions were proposed throughout Theme 2. This included amending the draft standards to ensure that a service user's right not to engage in the review process was included, as well as providing the service user with the opportunity to be interviewed during the review process and to give their account of events. Respondents also identified a number of areas that needed to be strengthened throughout Theme 2. This included ensuring that a service user's wishes are taken into account when involving their family in the review process, facilitating service users to access advocacy and support services where appropriate and ensuring that the use of personal health information is in line with the relevant legal requirements. It was also suggested that the service provider should give information to the service user in a format that is suitable to their needs.

Some feedback provided on Theme 2 overlapped with content covered in Theme 3 (Workforce). This was specifically in relation to the roles and responsibilities of staff involved in the review process, namely the service user liaison and the incident management team. Feedback was also received on content pertaining to Theme 1 (Governance and Accountability), highlighting the lack of reference to an open disclosure process or national policy in the draft standards.

HIQA's and MHC's response

Based on the feedback received, a number of amendments were made throughout Theme 2 to strengthen the content across a variety of areas. This specifically related to the service users' right to not engage in the review process, consent regarding the involvement of a service user's family during a review and the use of their personal health information. In relation to concerns raised regarding consent, revisions were made to ensure that service user permission is obtained where appropriate, when involving the family in the review process. A number of amendments were also made throughout the draft standards to ensure that any access to personal health information is in line with the relevant legislation.

A number of other areas were also revised across Theme 2, which included facilitating service users to access advocacy and support services and ensuring service users receive information in a format and language that is suitable to their needs.

As stated, some feedback was received that overlapped with content covered in other sections of the draft standards. Consequently a number of revisions were made throughout the draft standards to provide clarification on the role of the service user liaison and the incident management team in the review process and their level of engagement with the service user involved. Additional text was also incorporated throughout the relevant sections of Theme 1 (Governance and Accountability) and Theme 2, to reflect the feedback received regarding the lack of reference to open disclosure in the draft standards.

Theme 3: Workforce

Eighty-five percent (n=40) of respondents provided comments on Theme 3: Workforce.

What the respondents said

The inclusion of protected time for staff and the appointment of a staff liaison as support for those involved in a patient safety incident review were broadly welcomed.

A number of concerns were raised in the feedback received on Theme 3 such as the availability of trained reviewers, the appropriateness of staff involved in a patient safety incident commenting on the terms of reference for the review, how feasible the workforce requirements are for smaller services and the broad remit of the staff liaison which includes communication and support responsibilities.

Common areas raised by respondents for clarification included: the training requirements and necessary competencies for staff, the role and membership of the incident management team as well as access to peer support, mentoring and specialist supports for the incident management team and review team.

Finally, a small number of respondents suggested that in order to meet the required timeframes during reviews, it would be more beneficial to have dedicated review

teams rather than using staff that carry out reviews in addition to their substantive roles.

HIQA's and MHC's response

The scope of the staff liaison role was amended to reflect the purpose of this role as a point of contact that may facilitate access to support for staff. Features were amended to identify the requirement for adequate numbers of reviewers and to remove reference to staff involved in the incident commenting on the terms of reference. There is flexibility in the standards to allow each service to determine the resources required to implement the standards.

The scope of training was broadened to include all staff, and features were amended to highlight the requirement for services to identify the skills, experience and training requirements within their service to ensure capacity for conducting reviews. The role of the incident management team was revised and strengthened to reflect their broader role in the incident management process. Features were amended to include access to supports as highlighted by respondents.

Feedback in relation to dedicated review teams was considered. It was concluded that flexibility was required to allow services to determine how best to implement the standards and to ensure review teams were appropriate for the type of incident and review being undertaken.

Theme 4: Reviews of Patient Safety Incidents

Eighty-one percent (n=38) of respondents provided comments on Theme 4: Reviews of Patient Safety Incidents.

What the respondents said

Positive feedback was received on this theme. Respondents reported that it will provide clarity to the system and create a shared understanding of the review process. This will help maintain and build trust and respect between service users and service providers. process

Common areas raised by respondents for clarification included: the incident review report contents and report sign off process, the reference for levels of reviews, examples of review types, and the timing of the assessment of risk.

There were some concerns regarding the timeframes for completing a review and the impact that service user and staff engagement may have on the timeliness of the process.

Feedback was received on Theme 4 which overlapped with feedback received on the last question on the consultation form (general comments on the draft standards). In this feedback, respondents specifically welcomed the flexibility in relation to levels of review and review methods, but there were also some concerns raised in relation to how this aligns with current practice and the impact on comparing review findings if a single review method approach is not used.

HIQA's and MHC's response

The requirement for service-wide standardised tools to assist in determining the appropriate level of review and review method was strengthened, to address the concerns raised on having more than one level and type of review that may be used.

One of the key findings from the Chief Medical Officer's 2014 *Report on Perinatal Deaths in HSE Midland Regional Hospital Portlaoise*[1] was inconsistency in the time taken to conduct and complete reviews. The standards intend to provide a framework, aligned to best practice, which addresses timeframes for completion of reviews. The standards acknowledge that delays may occur and that service users and staff should be kept informed and updated on any delays.

Amendments were made to provide clarification on the contents of the incident review report and sign-off process. The reference source for the levels of reviews and a timeframe for completing the initial assessment were included, and less relevant examples of review types were removed.

Theme 5: Sharing the Learning for Improvement

Two out of three (66%) respondents (n=31) provided comments on Theme 5: Sharing the Learning for Improvement.

What the respondents said

It was apparent from respondent feedback that this theme was broadly welcomed and that the importance of sharing the learning from reviews of patient safety incidents to drive improvements was widely recognised.

A number of areas that needed to be strengthened in this theme were highlighted by respondents. It was suggested that any learning from the reviews should be shared nationally as well as locally and that learning should also be used to inform improved work practices. While minor rewording was requested throughout features concerning partnership work with external bodies, it also was proposed that more detail should be provided in relation to the approaches used to share the learning. In addition to evaluating the plan to share learning from reviews, respondents also suggested that the effectiveness of the learning process should be evaluated.

Some of the feedback provided on Theme 5 overlapped with content covered in Theme 1 (Governance and Accountability), specifically in relation to obtaining consent when publishing and or sharing learning from reviews. Feedback was also provided on content that related to Theme 4 (Reviews of Patient Safety Incidents) which included the importance of the thematic analysis of investigation reports to identify themes in causal factors for shared learning.

HIQA's and MHC's response

Following feedback, the plan to share learning from reviews was strengthened in Theme 5 and a list of specific mechanisms used to share the learning from reviews was included. A number of revisions were made to the language used in Theme 5 to reflect that learning from reviews should be shared nationally, as well as being used to inform work practices. Feedback to evaluate the learning process and implement improvements, where possible, were also incorporated in revisions made to the draft standards.

The term 'service-wide' was included in Theme 5 and throughout the relevant sections of the draft standards. This was based on the feedback received that all levels within the overall organisational structure, including national, hospital group or community health organisation and service delivery levels should be taken into account.

Where feedback provided under Theme 5 was more relevant to another theme, these comments were reviewed and revisions were made under the appropriate theme. For instance, concerns were raised regarding consent and the use of personal information in published review reports. As this feedback was more relevant to Theme 1, revisions were made to certain features under this theme to emphasise the importance of obtaining consent to access and publish such information.

General comments

Question 4: Are there any other general comments on the draft standards that you would like to make?

This question gave respondents the opportunity to provide further general comments on the draft standards. Over two out of three (68%) respondents (n=32) answered this question.

What the respondents said

The feedback was, in general, positive and the publication of the draft standards was seen as a welcome development. Many submissions expressed the view that the draft standards would drive improvements across acute hospitals and mental health services with regards to the conduct of reviews of patient safety incidents. Eighteen respondents (38%) provided positive feedback on the draft standards, while eight respondents (17%) specifically stated that they welcome them.

Respondents said:

"These standards set the features of a good clinical governance structure to support reviews of Patient Safety Incidents."

"I am delighted that HIQA standards have been drafted. They will help with compliance to HSE procedure. "

"Standards will be very useful in ensuring a consistent approach in managing patient safety incidents. "

"I welcome these standards... and the increased reference to the inclusion of the service user/ family. "

"(We) recognise the importance and value of a systematic approach to incident reviews and enhanced service user / family involvement. "

"Overall the standards are very well written and reflect the key components of the review process."

Feedback on certain terminology used in the standards was received. Two submissions sought clarification on the use of the term 'review' instead of the term 'investigation'. Clarification was also sought on the use of the terms 'patient' and service user' in two submissions received.

Feedback was received in the general comments on the draft standards, which overlapped with feedback provided on Theme 2 (Person-centred Approach to the Review of Patient Safety Incidents) and Theme 3 (Workforce). Clarification was sought around the specific roles, responsibilities and required skills of staff involved in the conduct of reviews of patient safety incidents. In addition to this, feedback was also received that overlapped with comments made on Theme 4 (Reviews of Patient Safety Incidents), concerning the methods for reviews of patient safety incidents and whether this should consist of a single method approach (systems analysis) or a suite of methods.

One respondent expressed the view that these standards may not contribute to improvements in the conduct of reviews of patient safety incidents within acute hospitals and mental health services. This feedback related to potential difficulties that services may face when trying to fully implement these standards, such understaffing and resource inequities across services. Further comments were also received in relation to specific challenges faced when implementing the standards such as an extra burden of paper compliance or that the timelines and protected time for staff may cause problems for those given the task of carrying out reviews.

HIQA's and MHC's response

Terminology used in the standards was informed by information gathered during the standards development process and agreed by the Standards Advisory Group.

In relation to comments provided in this question that overlapped with feedback received on other themes, these responses were considered under the relevant sections of the draft standards. A large amount of the feedback received in the general comments overlapped with comments provided under the impact question. This specifically related to the resource implications and the impact these standards will have on services when implemented. Some of the comments received were outside the scope of what the standards can address, specifically in relation to resources necessary to implement the standards. Where it was possible to address issues raised, the relevant themes were amended to include this feedback.

Conclusions and next steps

At the end of the consultation period the national standards were revised to take account of the feedback from the consultation. A summary of the feedback and subsequent changes was presented to the Standards Advisory Group at the final meeting and the revised National Standards were approved by the HIQA Board and subsequently by the MHC Board. The final National Standards were then submitted to the Minsiter for Health for approval.

The National Standards for the Conduct of Reviews of Patient Safety Incidents were mandated by the Minister and published by HIQA and the MHC on 25 October 2017.

References

1. Dr Tony Holohan CMO. *HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006-date).* Department of Health, 2014.

Appendix 1 – List of organisations that made submissions

This list includes the names of organisations that made submissions to the public consultation in an organisational capacity. Submissions were also made by 19 individuals in a personal capacity.

- Centre of Nursing and Midwifery Education, Mayo
- Clinical Governance Department, Cork University Hospital
- College of Psychiatrists of Ireland
- Community Healthcare Organisation Mental Health Services[1]
- Department of Public Health, East
- Dr. Steevens Hospital, Dublin
- Health Service Executive
- HSE, Mental Health Division
- Irish Hospital Consultants Association
- Irish Medical Organisation (IMO)
- Inspectorate of Mental Health Services, Mental Health Commission
- National Forensic Mental Health Service
- National Incident Management and Learning Team (NIMLT)
- Office of the Nursing and Midwifery Services, HSE
- Royal College of Surgeons Ireland (RCSI) Hospitals
- South Infirmary Victoria University Hospital Cork
- South Tipperary General Hospital, Clonmel
- St Patricks Mental Health Services
- St. Michael's Hospital, Dublin
- The Pharmaceutical Society of Ireland (PSI)
- Trinity College Dublin
- University Hospital Kerry

[1] Eight submissions were received from various Community Healthcare Organisation Mental Health Services

Appendix 2 – Consultation Feedback Form

Draft National Standards for the Conduct of Reviews of Patient Safety Incidents

Consultation feedback form

26 September 2016

Your views are very important to us. We would like to hear what you think about the *Draft National Standards for the Conduct of Reviews of Patient Safety Incidents.* Your comments will be considered and will inform the development of the final National Standards.

The draft National Standards contains twenty standard statements under five themes. Each standard statement describes an area of good practice for the conduct of reviews of patient safety incidents. Each standard statement also has a number of examples of good practice, called features, listed underneath them. You can comment on any or all of them, or you may wish to make general comments. When commenting on a specific standard or feature, it would help us if you tell us the reference number of the standard (such as Standard 12) or feature (for instance, feature 12.3) that you are commenting on.

The draft National Standards cover the conduct of reviews of patient safety incidents including: review of the incident, implementation of recommendations of the review and sharing the learning from the review. The draft National Standards are designed to apply to acute hospitals under the remit of HIQA and mental health services under the remit of the MHC.

Please note the focus for this consultation is the content and structure of the draft standards.

The closing date for consultation is Friday 4th November at 5pm.

Instructions for submitting feedback

- **If completing this form online, please scroll down and complete the full form.**
- **Include the reference number of the standard (such as Standard 2.3) or feature (such as Feature 2.3.1) that you are commenting on.**
- **If commenting on behalf of an organisation, please combine all feedback from your organisation into 1 submission.**
- **Do not paste other tables into the boxes already provided – type directly into the box as the box expands.**
- **Do not include medical information about yourself or another person from which you or the person could be identified.**
- **Spell out any abbreviations you use.**

Please note that HIQA and MHC are subject to the Freedom of Information (FOI) Acts and the statutory Code of Practice regarding FOI.

Following the consultation, we will publish a paper summarising the responses received. For that reason, it would be helpful if you could explain to us if you regard the information you have provided as confidential. If we receive a request for disclosure of the information, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances.

1. Sharing of information

These standards were jointly developed by HIQA and the MHC. Please note that any information you provide in this submission will be shared securely between HIQA and the MHC as these are a collaborative set of standards.

Question 1: Do you consent to your submission being shared between HIQA and the MHC?

Yes	☐
No	☐ if no, do not complete or submit this consultation feedback form

2. About you

(Any personal data collected as part of this consultation will be held securely and used only for the purpose of developing the draft standards and will be retained until the standards development process is complete. All personal data will be erased once the standards development process is complete.)

2.1 Name	
2.2 Contact details (We are requesting your contact details as we may need to contact you to seek clarification on specific aspects of your feedback. It is not mandatory to provide this information)	
2.3 Date	
2.4 Are you commenting on behalf of your organisation or in a personal capacity?	**Organisation** ☐ **Personal** ☐
2.5 Please include the name of the organisation if making this submission on its behalf	
2.6 If you work in an acute hospital or mental health service, please specify your role	

3. General feedback questions

In this section, please provide your comments on the content of the draft standards.

The *Draft National Standards for the Conduct of Reviews of Patient Safety Incidents* are intended to provide a framework for best practice in the conduct of reviews of patient safety incidents. They are being published to allow the public to offer feedback on them.

Therefore, we would like to hear your views on the use of these draft standards as part of an overall strategy to improve the quality of the conduct of reviews of patient safety incidents in Ireland. We would like to find out what you think of the draft standards, for example:

- Do you think that all of the areas you consider important are covered?
- Are the standards and features clear and easy to understand?

3.1 Layout

Please note that these are draft standards for consultation. The final document will contain different colours and images where suitable.

Question 1: a) Is the language used in the draft standards clear, easy to follow and easy to understand? **Yes** ☐ **No** ☐

b) Is the layout of the draft standards clear, easy to follow and easy to understand? **Yes** ☐ **No** ☐

Additional comments if necessary

3.2 Accessibility

It is intended that these draft standards will be frequently referenced by service providers and by members of the public.

Question 2: What do you think would be the most useful format for the draft standards? (please tick all that are applicable)

Hard copy	☐
Electronic	☐
Audio	☐
Easy to read	☐
Other	☐

If other, please specify

3.3 Services

Services are acute hospitals under the remit of HIQA and mental health services under the remit of the MHC. Service providers are any person, organization or part of an organization delivering these services.

Question 3: What impact will the draft standards have on acute hospitals and mental health services in Ireland when they are in place?

Comment

4. Specific feedback questions

In this section, please provide your comments on specific draft standards and or features. Please consider the following questions as part of your review:

- Have all important areas been covered within each standard or are there any areas that should be included or excluded?
- Do the features listed provide sufficient guidance to service providers to meet the standard?

In the case of each of your comments, please provide the reference number of the Standard (such as Standard 12) or feature (for instance, Feature 12.3) that you are commenting on.

4 (a) Theme 1: Governance and Accountability

Please include standard and or feature number

4 (b) Theme 2: Person-Centred Approach to the Review of Patient Safety Incidents

Please include standard and or feature number

4 (c) Theme 3: Workforce

Please include standard and or feature number

4 (d) Theme 4: Reviews of Patient Safety Incidents

Please include standard and or feature number

4 (e) Theme 5: Sharing the Learning for Improvement

Please include standard and or feature number

4 (f) Other: Are there any other general comments on the draft standards that you would like to make? Please feel free to use additional space or continue on a separate page.

Thank you for taking the time to give us your views on the *Draft National Standards for the Conduct of Reviews of Patient Safety Incidents*.

Please return your form to us either by email or post.

<table>
<tr><td>  </td><td>You can download a feedback form at:
www.hiqa.ie or www.mhcirl.ie

and email the completed form to either:
standards@hiqa.iee or standards@mhcirl.ie</td></tr>
<tr><td rowspan="2">  </td><td>You can print off a feedback form and post the completed form to either:</td></tr>
<tr><td>Health Information and Quality Authority
Draft National Standards for the Conduct of Reviews of Patient Safety Incidents Consultation
George’s Court
George’s Lane
Smithfield
Dublin 7
D07 E98Y

or

Mental Health Commission
Draft National Standards for the Conduct of Reviews of Patient Safety Incidents Consultation
St Martin’s House
Waterloo Road Dublin 4
D04 E5W7</td></tr>
<tr><td>  </td><td>If you have any questions on this document, you can contact the team by phoning 01 814 7400</td></tr>
</table>

Published by the Mental Health Commission and the Health Information and Quality Authority.

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