NATIONAL OPEN DISCLOSURE FRAMEWORK

(2022 PUBLIC CONSULTATION REPORT)

National Patient Safety Office Department of Health

Introduction

The Department of Health (DOH) has developed a draft national open disclosure framework (Framework) to provide a unified and consistent approach to open disclosure across public and private health and social care service providers, service regulators, and health and social care professional regulators, health and social care educators, and other relevant bodies and organisations. The development of the Framework was informed by the policy recommendations of the Independent Patient Safety Council (IPSC) to the Minister for Health in 2021 on open disclosure in Health and Social Care in Ireland.

The Framework aims to further embed a culture of open disclosure across the entirety of health and social care services and in the practice of all health and social care professionals. In the event of a patient safety incident or adverse event, it is important that patients/service users and their support persons are provided by the service provider and their staff with acknowledgment, an explanation of what happened and why, and a genuine and sincere apology or expression of regret, and reassurance as to their ongoing treatment and care as well as information on steps undertaken to prevent a recurrence of the incident.

All stakeholders should adopt the Framework and identify mechanisms and initiatives that will support the embedding of a culture of openness, and the consistent, coherent, and sustainable implementation of open disclosure in their organisations.

The DOH has conducted an online public consultation from August 29 to September 30, 2022, seeking the views and opinions of health and social care professionals, organisations, and interested members of the public, on some of the key elements of the draft framework. The views and opinions collected will be considered and will be used to inform the final draft of the framework prior to publication.

A. The Draft National Open Disclosure Framework

The Framework is composed of 7 chapters and below is a short introduction to each of the chapters.

Chapter 1 – Introduction

This chapter presents the importance of open disclosure when something has gone wrong with patient/service user care. It provides an understanding of the application of the Framework to patient safety incidents and adverse events and defines the following:

1. Open Disclosure- is an open, consistent, compassionate, and timely approach to communicating with patients and, where appropriate, their relevant person following patient safety incidents. It includes expressing regret for what has happened, keeping

the patient informed, and providing reassurance in relation to on-going care and treatment, learning, and the steps being taken by the health services provider to try to prevent a recurrence of the incident.

- 2. Patient Safety Incident is an incident which occurs during the course of the provision of a health service" which:
 - a) has caused an unintended or unanticipated injury, or harm, to the patient
 - b) did not result in actual injury or harm to the patient but was one which the health services provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm or
 - c) unanticipated or unintended injury or harm to the patient was prevented, either by "timely intervention or by chance", but the incident was one which the health services provider has reasonable grounds for believing could have resulted in injury or harm, if not prevented.

(Civil Liability Amendment Act 2017)

3. Adverse Event - An adverse event is an incident which resulted in harm that may or may not be the result of an error (*HSE 2019*).

It also introduces the Principles of Open Disclosure, and a detailed summary of each principle is provided in Chapter 3.

Chapter 2 – Context

This chapter explains the role of the IPSC in the development of the Framework, the role of the DOH, and the role of the individual organisations that are going to implement the Framework. The chapter provides a bird's eye view of the practice of "duty of candour/open disclosure" in countries outside of Ireland. It also outlines what current Irish legislation, policy, and regulatory standards are in place supporting the practice of open disclosure.

Chapter 3 – Principles of Open Disclosure

This chapter provides a summary of each of the principles of open disclosure:

- Open, Honest, Compassionate, and Timely Communication
- Patient/Service User and Support Persons' Entitlements in Open Disclosure
- Supporting Health and Social Care Staff
- Promoting a Culture of Open Disclosure
- Open Disclosure for Improving Health and Social Care Policy and Practice
- The Importance of Good Clinical and Corporate Governance for Open Disclosure.

The chapter also offers an explanation of the need for open disclosure to be practiced in all health and social care services in Ireland. It describes the positive effect of having open disclosure in place for patients/service users, health, and social care staff, and health and social service care providers. It also talks about the importance of open communication, creating a culture of open disclosure, and the development of local policies to support these.

Chapter 4 - Open Disclosure in Practice (Health Service Providers)

This chapter explains the whole process of open disclosure as applied by a health and social care service provider when a patient safety incident or an adverse event occurs. It also includes the patient/service user considerations and entitlements and the role of the Patient Advocacy Service in the open disclosure process.

The Patient Advocacy Service (PAS) is available to support patients/service users and their families who have been affected by patient safety incidents and adverse events in acute public hospital settings and public nursing homes. The services of PAS will be expanded in time to support patients/service users of other publicly funded health and social care services.

Health and social care service providers falling outside the scope of PAS must arrange for similar independent support services to support patients/service users and their families who have been affected by patient safety incidents and adverse events. Such independent support services must be appropriately qualified and have sufficient experience to support patients/service users and their families. The support service must be independent of the health and social care service provider.

Chapter 5 - Open Disclosure in Practice (Non-Health Service Providers)

This chapter describes the role of the professional regulators, education bodies and training providers, clinical placement sites, and health and social care service regulators in promoting and ensuring the principles of open disclosure is embedded in the following: undergraduate and postgraduate education including continuing professional development training, professional practice, workplace policies and procedures, and regulatory standards and guidance.

Chapter 6 – Drivers for Change

This chapter presents 5 drivers that will support culture change in different health and social care organisations. These drivers are:

- a. learning and continuous improvement
- b. communication, engagement, and feedback
- c. leadership
- d. training and development
- e. and open disclosure champions.

The successful embedding of open disclosure into practice in a consistent way across the health and social care sector in Ireland is heavily dependent on cultural change. The culture change also requires a multi-faceted approach and strong leadership and governance.

Chapter 7 – Monitoring and Evaluation

This chapter illustrates the importance of ongoing monitoring and evaluation of open disclosure to ensure the successful implementation of the Framework and embedding a culture of open disclosure across the Irish Health and Social Care Sector. Monitoring involves activities such as reporting, recording, and measurement of open disclosure in practise, training, education, and policy implementation. Evaluation involves the collection and analysis of open disclosure data to inform future policy. The chapter also includes the Framework annual report requirements for each stakeholder (health and social care service providers, professional regulators, and health and social care service regulators) that will be submitted to the Minister for Health to demonstrate their compliance.

B. Public Consultation

The public consultation was conducted online using a survey questionnaire from August 29 to September 30, 2022. The survey was hosted through the EU Survey platform for the duration of the public consultation.

The DOH invited health and social care professionals, organisations, and interested members of the public to participate in the online public consultation and give their views on some of the key elements of the draft framework. The views and opinions collected will be considered and used to inform the final draft of the Framework prior to its publication.

The online survey required 30 - 40 minutes to be completed. The structure of the online survey was a mixture of the Likert scale, ranking, and open text with a limit of 100 words. Throughout the survey, the participants were presented with short extracts from the relevant sections of the Framework. These were included to assist the participants by giving some context to the questions.

The questions that follow each extract were centred around the topic in each extract. The survey also consists of the following 8 sections:

- Section 1: Your Details
- Section 2: Importance of Open Disclosure
- Section 3: Principles of Open Disclosure
- Section 4: Open Disclosure for Health Service Providers
- Section 5: Open Disclosure for Non-Health Service Providers
- Section 6: Drivers for Change
- Section 7: Monitoring and Evaluation
- Section 8: Additional Information

C. Survey Results

The responses received for the online survey were processed and analysed and the findings are presented in this section using tables, graphs, and pie charts. This report follows the format of the online survey.

Section 1. Details of Participants

Question 1: Are you completing this survey on behalf of an organisation or in a personal capacity?

	Number of Respondents	Percentage (%)
Organisation	37	42.52
Personal Capacity	49	56.32
No Answer	1	1.14
Total	87	99.98

Question 2: If completing on behalf of an organisation, what type of organisation?

	Number of Respondents	Percentage (%)
Health and Social Care Provider	13	14.94
Health and Social Care Service Regulator	2	2.29
Professional Regulator	3	3.44
Advocacy Organisation	7	8.04
Academic Institution/		
Higher Education Institute	3	3.44
Other	10	11.49
No Answer	49	56.32
Total	87	99.96

Section 2. Importance of Open Disclosure (This section relates to Chapters 1 & 2 of the draft Framework)

2.1. Open Disclosure (This is described in Chapter 1 of the draft Framework under subsection 1.2).

Question 1: Should an open disclosure policy be in place in all health and social care services?

	Number of Respondents	Percentage (%)
Strongly Agree	60	68.96
Agree	24	27.58
Disagree	0	0
Strongly Disagree	1	1.14

Don't Know	1	1.14
No Answer	1	1.14
Total	87	99.96

2.2 Relevant organisation should adopt the Framework (This is covered in Chapter 2 of the draft Framework under subsection 2.1, item 2.1.3)

Question 1: Should all professional regulators, health and social care service regulators, and education bodies should promote and support the embedding of the Open Disclosure Framework?

	Number of Respondents	Percentage (%)
Strongly Agree	54	62.06
Agree	29	33.33
Disagree	1	1.14
Strongly Disagree	1	1.14
Don't Know	1	1.14
No Answer	1	1.14
Total	87	99.95

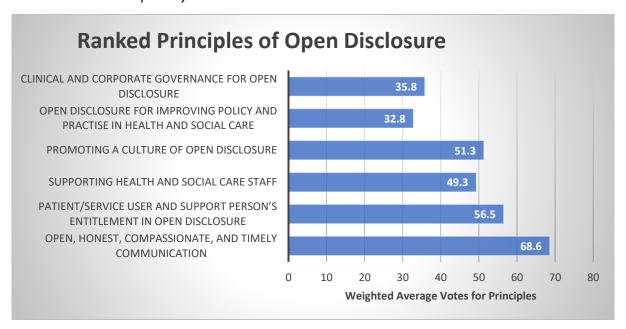
Section 3. Principles of Open Disclosure (This section relates to Chapter 3 of the draft Framework)

3.1. The principles (This is presented in Chapter 3 of the draft Framework under subsection 3.1).

Question 1: How important are the principles of Open Disclosure as outlined in the Framework?

	Number of Respondents	Percentage (%)
Very Important	65	74.71
Important	19	21.83
Somewhat Important	2	2.29
Not Important	0	0
Don't Know	0	0
No Answer	1	1.14
Total	87	99.97

Question 2: Please rank the principles in order of priority with 1 being the highest priority and 6 as the lowest priority.



3.2 Promoting a supportive culture (This is covered in Chapter 3 of the draft Framework under subsection 3.4., item 3.4.1).

Question 1: Should organisations promote a 'just culture' and avoid a 'blame culture' to follow the principles of open disclosure?

	Number of Respondents	Percentage (%)
Strongly Agree	71	81.6
Agree	13	14.94
Disagree	0	0
Strongly Disagree	1	1.14
Don't Know	1	1.14
No Answer	1	1.14
Total	87	99.96

Question 2: In your experience, what are the factors that help promote a just culture? (Open Text)

Findings: The respondents of the survey cited the following factors in promoting a just culture; open and clear communication, the avoidance of blame, and good leadership. This was followed by accountability, provision of staff training and support, and lastly, ensuring psychological safety, and consideration of human factors.

Question 3: In your experience, does the health sector in Ireland operate within a "just culture" or a "blame culture"? (Open Text)

Findings: The majority of the respondents felt that blame culture is still widespread in the health sector. A small percentage of the respondents believed that both just culture and blame culture exist in the health sector and there are some who think that neither exists.

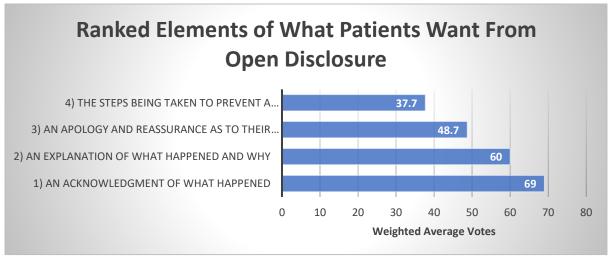
Section 4. Open Disclosure for Health Service Providers (This section relates to Chapter 4 of the draft Framework).

4.1 What do patients/service users and their support persons want when a patient safety incident or adverse event occurs? (This is described in Chapter 4 of the draft Framework under subsection 4.6, item 4.6.5).

Question 1: When a patient safety incident or adverse event occurs, patients/service users and their support persons want the following: 1) An acknowledgment of what happened 2) An explanation of what happened and why 3) An apology and reassurance as to their ongoing treatment and care 4) The steps being taken to prevent a recurrence of the incident. Do you agree with this statement?

	Number of Respondents	Percentage (%)
Strongly Agree	67	77.01
Agree	16	18.39
Disagree	0	0
Strongly Disagree	2	2.29
Don't Know	1	1.14
No Answer	1	1.14
Total	87	99.97

Question 2: Please rank these elements of open disclosure in order of priority with 1 being the highest priority and 4 as the lowest priority.



Question 3: In your opinion, are there other elements/components of open disclosure not listed here that are of particular importance to patients/service users? (Open Text)

Findings: The respondents believed that the timeliness of communication, apology, and review should be included as one of the elements/components of open disclosure. A few also cited the importance of highlighting the limited information available at the start of open disclosure.

4.2 Independent Support Services (The Independent Support Services are described in Chapter 4 of the draft Framework under subsection 4.4, item 4.4.6).

Question 1: Do you think the role of the Patient Advocacy Service is important in the open disclosure process?

	Number of Respondents	Percentage (%)
Very Important	36	41.37
Important	30	34.48
Somewhat Important	12	13.79
Not Important	8	9.19
Don't Know	0	0
No Answer	1	1.14
Total	87	99.97

Question 2: During the open disclosure process, do you think being offered independent advocacy support is beneficial for patients and families? (Open Text)

Findings: The majority of the respondents deemed that providing independent advocacy support is beneficial because it empowers the patients and their families. They also pointed out that while it is beneficial it is important to provide information to the patients and their families about the advocacy service to promote a better understanding of its function. Few of the respondents did not see any benefit in having independent advocacy support.

Question 3: In your experience are there any benefits for health and social care service providers when they offer independent support to patients during the open disclosure process? (Open Text)

Findings: Many of the respondents believed that when a health and social care service provider offers independent support during open disclosure to patients that they are showing good faith, patients feel that they are supported, and it promotes a successful outcome of the open disclosure process. In addition, providing independent support also helps rebuild relationships and regain trust. There are a few respondents who believed that it is not

beneficial for health and social care service providers to offer independent support to patients.

4.3 Support for Health and Social Care Staff (The Support for Health and Social Care Staff are described in Chapter 4 of the Framework under Section 4.5).

Question 1: It is important to identify the staff involved in and/or affected by the patient safety incident or adverse event and to ensure that they are being supported in the immediate aftermath of the incident and on an ongoing basis for as long as is required, in recognition of the impact of such incidents on staff. All staff delivering health and social care must be: a) encouraged, facilitated, empowered, and obliged to recognise and report patient safety incidents and adverse events. b) provided with training and education in open disclosure and communication skills. c) prepared to participate in open disclosure. d) supported through the open disclosure process by the health and social care provider." Do you agree with this statement?

	Number of Respondents	Percentage (%)
Strongly Agree	58	66.66
Agree	27	31.03
Disagree	0	0
Strongly Disagree	0	0
Don't Know	1	1.14
No Answer	1	1.14
Total	87	99.97

Question 2: In your opinion, are there any other supports for health and social care staff that should be included? (Open Text)

Findings: Although the responses may be considered part of "d) supported through the open disclosure process by the health and social care provider" as described in chapter 4 of the Framework, the respondents indicated the importance of staff having access to counseling services, peer and management support, and overall organisational support. The availability of dedicated staff advocacy was also mentioned.

Section 5. Open Disclosure for Non-Health Service Providers

5.1 Professional Code of Conduct, Ethics, and Guidance (This is explained in Chapter 5 of the draft Framework under subsection 5.2).

Question 1: "Professional regulatory bodies must include clear and unequivocal obligations for open disclosure in codes of conduct, ethics, and guidance for regulated practitioners aligned to the definitions and terminology as outlined in the Framework." Do you agree with this statement?

	Number of Respondents	Percentage (%)
Strongly Agree	55	63.21
Agree	26	29.88
Disagree	4	4.59
Strongly Disagree	1	1.14
Don't Know	0	0
No Answer	1	1.14
Total	87	99.96

Question 2: In your opinion, are there any other existing regulatory mechanisms that could help to strengthen compliance with this framework? (Open Text)

Findings: Considerations that were raised by respondents included; the embedding of Open Disclosure principles in HIQA's processes; a greater role for the office of the Ombudsman, and; the inclusion of Open Disclosure in professional training and the tracking of compliance with such training requirements. Of lesser frequency in the responses, but worth noting was a concern with the increased regulatory burden that such measures would bring.

5.2 Approval, accreditation, and monitoring of undergraduate and postgraduate education and training programmes with clinical components. (This is explained in Chapter 5 of the draft Framework under subsection 5.2)

Question 1: Do you agree that it is important to embed open disclosure in all undergraduate and postgraduate training programmes?

	Number of Respondents	Percentage (%)
Strongly Agree	62	71.26
Agree	21	24.13
Disagree	0	0
Strongly Disagree	2	2.29
Don't Know	1	1.14
No Answer	1	1.14
Total	87	99.96

Findings: Two main benefits were identified by a majority of respondents; higher compliance with Open Disclosure principles as a result of the approval, accreditation, and monitoring of undergraduate and postgraduate education, and; better preparation of new entrants to the health sector workforce as a result of such training. Other points noted were that it could serve to address the power imbalance between different medical and clinical grades and that it could prepare the way for any subsequent legislative measures.

Question3: What do you think are the potential challenges with such an approach? (Open Text)

Findings: The key challenge identified in these responses was the need for a supportive culture in any organisation that is implementing these Open Disclosure measures. Another challenge identified by a smaller cohort was the difficulty in ensuring that appropriate trainers were available and in place to deliver the required programmes. Related to this were some concerns about finding space in the curricula, and that academic teaching was not relevant to the real world.

5.3 Embedding of the principles of open disclosure in Health and social care service regulators' standards and guidelines (This is explained in Chapter 5 of the draft Framework under subsection 5.4)

Question 1: Do you agree that all health and social care service regulators should embed open disclosure in their regulatory standards and guidelines?

	Number of Respondents	Percentage (%)
Strongly Agree	49	56.32
Agree	27	31.03
Disagree	3	3.44
Strongly Disagree	0	0
Don't Know	5	5.74
No Answer	3	3.44
Total	87	99.97

Question 2: What do you think are the benefits of such an approach? (Open Text)

Findings: The key benefit identified in these responses was that health and social care service regulators embedding the principles of open disclosure into their standards and guidelines would lead to a much higher level of compliance with Open Disclosure. Other points noted were that it would enable a standardised approach to Open Disclosure across

the sector, and it would give greater clarity to health service providers as to what was expected of them.

Question 3: What do you think are the potential challenges with such an approach? (Open Text)

Findings: Potential challenges of this approach identified by respondents were; a concern that there would be considerable resistance from service providers; related to this, a worry that this approach would be seen as too heavy-handed, a concern that the culture of the HSE would not support such an approach, and; a concern that existing legal frameworks do not take account of Open Disclosure. A number of respondents also spoke about the need for open disclosure policies to be evidence-based and patient centred.

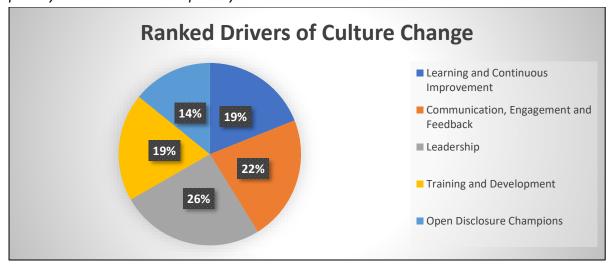
Section 6. Drivers for Change

6.1 Drivers that contribute to the embedding of a "just culture" (This is explained in Chapter 6 of the draft Framework under subsection 6.1)

Question 1: How important do you think are these primary drivers to embedding a 'just culture' of open disclosure?

	Number of Respondents	Percentage (%)
Very Important	54	62.06
Important	19	21.83
Somewhat Important	7	8.04
Not Important	6	6.89
Don't Know	0	0
No Answer	1	1.14
Total	87	99.96

Question 2: Please rank the drivers for change in the order of priority with 1 being the highest priority and 5 as the lowest priority.



Question 3: Are there any other factors that you consider to be drivers of change in promoting open disclosure? (Open Text)

Findings: When asked what other factors could be considered drivers of change for open disclosure, the most common response to this question was an open and positive culture. The importance of leadership was also stressed by a number of respondents. Other factors which received a number of mentions were the importance of patient input into the Open Disclosure process, the importance of peer support, adequate resourcing of organisation to conduct Open Disclosure, and the clarity of policies and procedures.

Section 7. Monitoring and Evaluation (This section relates to Chapter 7 of the draft Framework).

7.1 Aggregated report to be compiled by DOH and presented to Minister for Health (This is explained in Chapter 7 of the draft Framework under subsection 7.2).

Question 1: Do you agree with this approach to monitoring the effectiveness of the Framework?

	Number of Respondents	Percentage (%)
Strongly Agree	19	21.83
Agree	37	42.52
Disagree	17	19.54
Strongly Disagree	6	6.89
Don't Know	5	5.74
No Answer	3	3.44
Total	87	99.96

Question 2: Will such an approach be sufficient to embed Open Disclosure in the health and social care sector? If yes, why, or if no, why not? (Open Text)

Findings: A number of respondents to this question highlighted the limitations of self-reporting and the risk of non-compliance with the framework. Key themes arising throughout the responses to this question were the need for accountability for embedding a culture of open disclosure, the methods of evaluating success, including patient and staff feedback and audit, and finally the need for support from senior leaders within organisations to ensure the transition from a defensive culture to a just culture.

Other notable issues raised in response to this question were the need to avoid monitoring becoming a "tick-box" administrative process and to avoid placing an onerous regulatory burden on overworked healthcare staff. There is also a need to ensure appropriate governance of Open Disclosure and clear reporting structures within each organisation.

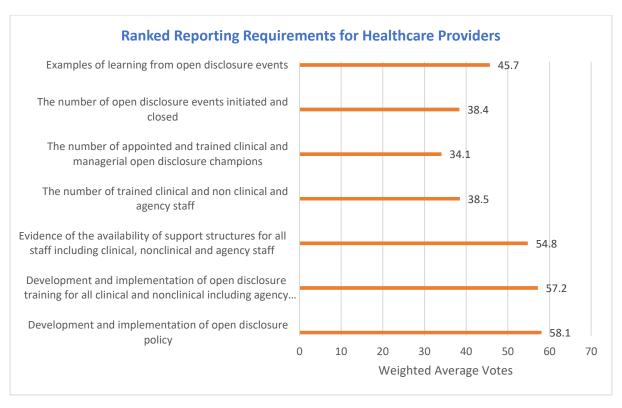
Question 3: In your opinion, is it likely that there will be widespread compliance in the health sector with such an approach? If yes, why, or if no, why not? (Open Text)

Findings: It was highlighted that a defensive culture exists within the system and a number of supportive factors were identified including leadership, audit, and staff support. Staff supports included the establishment of clear structures for communication and reporting in which staff are trusted to report, staff education and training and in some instances, additional resources such as protected time are required. Audit of open disclosure was considered important to ensure compliance.

Leadership was also identified as a key factor in enhancing compliance. Leaders need to engage with and support staff and use data to drive culture change from the top.

7.2 Reporting requirements for Health and Social Care Service Providers e.g., Health Service Executive, Private Hospitals, etc. (This is explained in Chapter 7 of the draft Framework under subsection 7.3).

Question 1: When thinking about the importance of embedding a culture of open disclosure, please rank these reporting requirements in order of priority: (1-7) with 1 being the highest priority and 7 being the lowest priority.



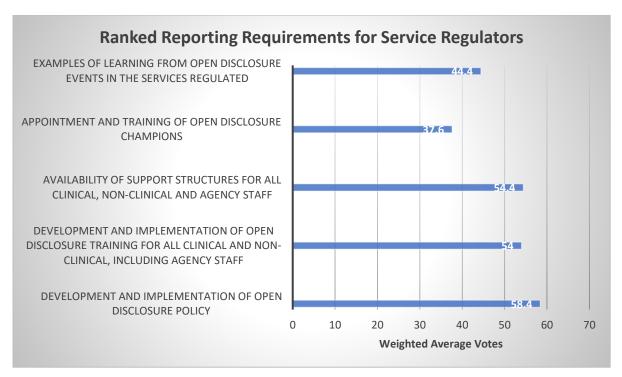
Question 2: What else, if anything, should be captured in the reporting of Health and Social Care Service Providers? (Open Text)

Findings: Replies to this question considered reporting on the patient's experience via feedback from patients on their experience of open disclosure to be of significant importance for health and social care providers.

Respondents also considered reporting on audits, governance structures including accountable persons, training including the number of trained trainers in Open Disclosure per organisation, face-face communication skills training and mandated safety culture surveys to be important for health and social care providers.

7.3 Reporting requirements for Health and Social Care Service Regulators e.g., Health Information and Quality Authority, Mental Health Commission, etc. (This is explained in Chapter 7 of the draft Framework under subsection 7.4).

Question 1: When thinking about the importance of embedding a culture of open disclosure, please rank these reporting requirements in order of priority with 1 being the highest priority and 5 as the lowest priority.



Q2 Question 2: What else, if anything, should be captured in the reporting of Health and Social Care Service Regulators? (Open Text)

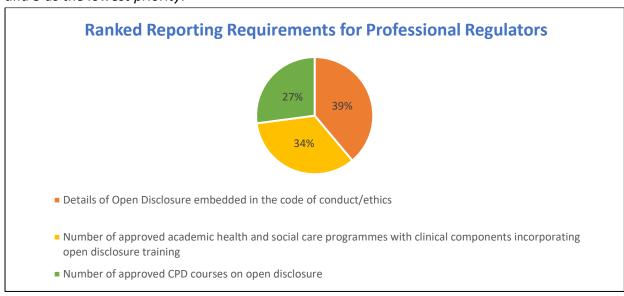
Findings: Patient experience of open disclosure as well as patient support including access to independent advocacy services, were also considered to be an important requirement for inclusion in the reports of health and social care service regulators.

Other measures considered important for reporting were improvements in policy and practice that have been implemented based on learnings from incidents and open disclosure as well as barriers and facilitators of embedding Open Disclosure in practice.

Replies to this question also considered publication of the numbers of open disclosures, role modelling by senior leaders, and the number of complaints received and appealed in relation to open disclosure as possible reporting requirements for health and social care regulators.

7.4 Reporting requirements for Professional Regulators e.g., Irish Medical Council, Nursing and Midwifery Board of Ireland, etc. (This is explained in Chapter 7 of the draft Framework under subsection 7.5).

Question 1: When thinking about the importance of embedding a culture of open disclosure, please rank these reporting requirements in order of priority with 1 being the highest priority and 3 as the lowest priority.



Question 2: What else, if anything, should be captured in the reporting of professional regulators? (Open Text)

Findings: Replies to this question indicated that it would be useful for professional regulators to report on the number of complaints they receive related to Open Disclosure with some degree of analysis applied to these numbers.

Replies to this question also indicated that professional regulators should report on the number of staff who have completed open disclosure training, including de-briefing, and learning, and the number of staff who have completed CPD training. Replies also suggested that examples in which open disclosure had a positive outcome and where it led to changes in policy and practice should be reported.

Section 8- Additional Information

Question: Do you have any additional comments or feedback on any aspect of the Framework? (Open Text)

Findings: Replies to this final section indicated that people want to see a just culture where psychological safety is practiced. A just culture should be about accountability, not liability. Replies also indicated that the reporting requirements should be simple, avoid unnecessary duplication, and avoid placing an unnecessary burden on staff. Finally, replies indicated broad support for the framework provided it is implemented effectively and patient involvement, patient feedback, and staff support were considered to be drivers of successful implementation.

Conclusion

There were 87 people who participated in the public consultation in a personal capacity or representing an organisation and provided their views on the key elements of the draft framework. Their responses were processed and analysed, and the findings show positive support for the open disclosure policy framework.

The findings of the public consultation will be considered and used to inform the final draft of the Framework prior to its publication.