



A Public Consultation on a draft Policy Framework for Open Disclosure in the Irish Health Sector

Fields marked with * are mandatory.



A Public Consultation on a draft Policy Framework for Open Disclosure in the Irish Health Sector

Background Information

What is open disclosure?

“Open disclosure is an open, consistent, compassionate, and timely approach to communicating with patients and, where appropriate, their relevant person following patient safety incidents. Open disclosure 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”

The Department of Health is developing a national open disclosure framework (the Framework). This framework will provide a consistent approach to open disclosure. The framework will apply across the public and private healthcare sectors in Ireland. This includes health and social care service providers, regulators, educators, and other relevant organisations.

The development of the Framework was informed by the policy recommendations of the Independent Patient Safety Council 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.

Purpose of this survey

The Department of Health seeks the views and opinions of healthcare staff, interested members of the public and relevant organisations 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. It is recommended that participants read the draft framework prior to completing the survey. At a minimum, participants should read the executive summary. There is a link to both of these documents on the right hand side of this page under the 'Background Documents' section. These links will appear there throughout each page of the survey to assist participants.

Privacy Notice / Data Protection

This survey is aimed at healthcare professionals and members of the public who are interested in open disclosure. The survey is being conducted by the Department of Health in Ireland.

All responses to the questionnaire are anonymous. A report will be prepared based on the responses to this questionnaire, however, individual responses will not be reported.

Any personal information submitted to the Department will be treated strictly in accordance with the General Data Protection Regulation 2016/67 and the Data Protection Act 2018.

Please note people can request to see the submissions we receive under the Freedom of Information (FOI) Act 2014 so we may have to release submissions in response to an FOI request. This is more likely to happen for submissions from organisations. This means that the requestor might get your answers to the questionnaire, however, any personal information included in submissions would be redacted prior to release. If you have any queries, please e-mail opendisclosurepolicy@health.gov.ie

Survey Outline:

This survey will take 30 to 40 minutes to complete. Throughout the survey, you will be presented with short extracts from the relevant sections of the Framework. These are included to assist participants by giving some context to the questions. The questions that follow each extract will be centred around the topic in each extract. The survey will consist 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

Section 1: Your Details

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

at most 1 choice(s)

Organisation Personal Capacity

*** If completing on behalf of an organisation, what type of organisation?**

Health and Social Care Provider

Health and Social Care Service Regulator

Professional Regulator

Advocacy Organisation

Academic Institution/ Higher Education Institute Other

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)

“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”

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

Strongly Agree

Agree

Disagree

Strongly Disagree

Don't know

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

“It is the responsibility of each relevant organisation to adopt the Framework and to embed positive open disclosure cultures and behaviours into practice. Individual organisations will need to identify mechanisms and initiatives that support the consistent, coherent, and sustainable implementation of open disclosure in line with the principles of this Framework.”

*** 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?

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Don't know

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)

The Principles underpinning this Framework are:

Principle 1: Open, Honest, Compassionate, and Timely Communication

Principle 2: Patient/Service User and Support Person's Entitlement in Open Disclosure

Principle 3: Supporting Health and Social Care Staff

Principle 4: Promoting a Culture of Open Disclosure

Principle 5: Open Disclosure for Improving Policy and Practise in Health and Social Care *Principle 6: Clinical and Corporate Governance for Open Disclosure*

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

at most 1 choice(s)

- Very Important
- Important
- Somewhat Important
- Not Important
- Don't know

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

	1	2	3	4	5	6
Principle 1: Open, Honest, Compassionate, and Timely Communication	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Principle 2: Patient/Service User and Support Person's Entitlement in Open Disclosure	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Principle 3: Supporting Health and Social Care Staff	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Principle 4: Promoting a Culture of Open Disclosure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Principle 5: Open Disclosure for Improving Policy and Practise in Health and Social Care	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Principle 6: Clinical and Corporate Governance for Open Disclosure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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

“A supportive culture is critical to effective open disclosure...The health and social care system must avoid a “blame culture”, which seeks to place responsibility for patient safety incidents and adverse events on individual health and social care staff, in favour of a “just culture”, which promotes psychological safety.”

“A just culture is one based on fairness, which recognises the capacity for human error and the role of system and environmental factors in adverse events and patient safety incidents, and in which everyone seeks to learn and improve. It includes ensuring people are accountable for their actions and responsible for learning”

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

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Don't know

Question 2: In your experience, what are the factors that help promote a just culture? (Max 100 words)

- Good governance.
- Clear lines of responsibility and accountability.
- Trust between staff and management.
- Good communication between staff and management. Staff can raise issues.
- Strong collaboration and teamwork.
- Strong emphasis on learning. Staff engagement with a clear feedback loop and analysis of data to disseminate learnings.
- Behavioural and cultural change.
- Effective leadership and support from all management including both middle and senior managers.
- Management and clinicians hearing directly from patients lived experiences.
- Proactive risk management processes and awareness.
- Practitioners feeling supported.
- Reporting of incidents encouraged and facilitated through an accessible system.
- Openness and responsiveness from the outset following an incident.
- Accountability enforced where acts of negligence/misconduct contribute to incidents.

Question 3: In your experience, does the health sector in Ireland operate within a “just culture” or a “blame culture”? (Max 100 words)

We know from many reports into major healthcare failures in Ireland, e.g. the Scally scoping inquiry, that a lot of work needs to be done in this area and that healthcare failures typically feature a culture of non-disclosure and non-action by individuals, colleagues and healthcare providers.

Medical Council [surveys](#) of trainee doctors consistently report high levels of bullying and harassment a reluctance to report bullying (67.3%) and an inadequate response when bullying is reported. The 2019-2020 survey found that less than half of trainee specialists involved in an adverse event believed confidential support services were available at their training site.

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)

* 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

Question 1: Do you agree with this statement?

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Don't know

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

	1	2	3	4
An acknowledgment of what happened	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
An explanation of what happened and why	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
An apology and reassurance as to their ongoing treatment and care	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The steps being taken to prevent a recurrence of the incident	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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? (Max 100 words)

While the framework (4.6.6) includes ‘*The apology must be genuine, respectful, sincere and timely...*’ this could be emphasised more, especially in light of the Scally inquiry where many patients did not experience a positive disclosure meeting. The Scally report highlights how patients wanted “...*someone who was involved to say they are sorry, and mean it*”. Patient experiences of both negative and positive disclosure meetings could be shared during training to foster greater understanding of patient needs and expectations.

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)

The Patient Advocacy Service 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 the Patient Advocacy Service 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 the Patient Advocacy Service 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.

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

- Very Important
- Important
- Somewhat Important
- Not Important
- Don't know

Question 2: During the open disclosure process, do you think being offered independent advocacy support is beneficial for patients and families? (Max 100 words)

Independent advocacy support is very important in empowering and supporting patients and families who often know less about how the health system/service operates. The current scope of the PAS could be expanded to provide more tailored support and guidance, to meet the needs of each patient.

In addition, it's not clear how the requirement to arrange for similar independent support services for providers falling outside the scope of the PAS in 4.4.6 of the framework, would work in practice. We would envisage this to be particularly challenging for community pharmacies which are privately owned healthcare facilities.

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? (Max 100 words)

We do not hold sufficient information to be able to be able to provide a response to this question.

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

*"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."

Question 1: Do you agree with this statement?

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Don't know

Question 2: In your opinion, are there any other supports for health and social care staff that should be included?
(Max 100 words)

The literature shows that following adverse health events, a healthcare professional can experience symptoms of anger, guilt, flashbacks, difficulty concentrating and increased risk of further errors (Seys et al, 2013). It is estimated that up to half of healthcare professionals experience a second victim impact at least once in their lifetime (Wu, 2000). Second victim recovery is supported by active incident learning and debriefing processes as part of a just safety culture (Seys et al, 2013).

Sally (2018) emphasises the shared responsibility of the statutory duty of candour for both individual staff and the organisations for which they work.

Section 5 Open Disclosure for Non-Health Service Providers (This section relates to Chapter 5 of the draft Framework)

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

* “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.”

Question 1: Do you agree with this statement?

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Don't know

Question 2: In your opinion, are there any other existing regulatory mechanisms that could help to strengthen compliance with this framework? (Max 100 words)

Not that we are aware of. We consider that the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 when enacted will be fundamental in providing clarity for professional and service regulators, in how the open disclosure framework will affect how they conduct their existing regulatory functions in relation to undergraduate education and training, CPD, practice placements, standards, guidance and inspections, and the management of statutory complaints against service entities and professionals through fitness to practise.

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)

“In the approval, accreditation, and monitoring of undergraduate education and training programmes with clinical components and postgraduate training programmes with clinical components, the professional regulators must ensure that educational bodies have embedded communication skills, patient safety incident and adverse event management, and open disclosure into all programmes.”

*

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

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Don't know

Question 2: What do you think are the benefits of such an approach would be? (Max 100 words)

- Promoting a strong just culture within theoretical and practical training and experiential learning placements would provide a strong foundation as they enter their chosen profession.
- Would underpin delivery of ethics and professionalism modules.
- A strong just culture embedded in healthcare practitioner education and training programmes could lead to lower drop-out rates from students and trainees.
- Behaviours learned during undergraduate training will be applied and shared among the profession during experiential learning placements and upon entry to the profession.
- The Professional Standards Authority highlights the importance of teaching on errors and candour to equip students and trainees to manage errors in practice.

Question 3: What do you think are the potential challenges with such an approach? (Max 100 words)

It may take time for open disclosure culture to be truly embedded in all aspects of education and training but this should not delay its implementation. Legislation on open disclosure in Ireland has been in place for some time now. There has been a formal HSE open disclosure policy since 2013, which was reviewed in 2019, so it should not be a new concept for educators in this jurisdiction.

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)

“Health and social care service regulators must embed the principles of open disclosure, as outlined in the Framework, into their standards and guidelines for health and social care service providers and assess compliance as part of the inspection of services.”

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

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Don't know

Question 2: What do you think are the benefits of such an approach? (Max 100 words)

Inclusion in the regulator’s service and professional standards and in quality assessment and inspections, would increase likelihood of engagement by the health and social care sector. From our perspective, it would help those in governance roles in pharmacies (i.e. supervising pharmacists and superintendent pharmacists) to prioritise self-audit and reflection to identify lessons learned from safety incidents, taking corrective steps, and training and development needs of the pharmacy team. As a national system for reporting of errors/incidents in pharmacies is not yet in place, inclusion in standards and guidelines would assist pharmacies to further develop systems for error reporting and learning.

Question 3: What do you think are the potential challenges with such an approach? (Max 100 words)

This would be a significant departure from our previous inspection approaches which were focused on compliance with legislation, however, we are moving towards introducing a standards-based approach as part of our regulatory framework. Standards-based inspections would facilitate the process of triangulation, which would include talking and engaging with staff as well as reviewing documentation and observing workflows. This would be more amendable to assessing culture around open disclosure, just culture and the embedding of learning from incidents.

Section 6: Drivers for Change (This section relates to Chapter 6 of the draft Framework)

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)

The draft Framework identifies 5 drivers which will contribute to embedding a “just culture” of open disclosure in the Irish health services:

- a) Learning and Continuous Improvement
- b) Communication, Engagement, and Feedback
- c) Leadership
- d) Training and Development
- e) Open Disclosure Champions

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

- Very Important
- Important
- Somewhat Important
- Not Important
- Don't know

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.

	1	2	3	4	5
Learning and Continuous Improvement	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Communication, Engagement and Feedback	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Leadership	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Training and Development	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Open Disclosure Champions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Question 3: Are there any other factors that you consider to be drivers of change in promoting open disclosure?
(Max 100 words)

While it is important to have strong positive drivers for change, in particular for individual healthcare professionals, it should also be clear what the consequences of not engaging with the framework will be for the provider. How will providers (and other organisations) be held to account if they don't engage in embedding an open disclosure culture or fail to support staff to do so?

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)

"The mechanisms and indicators for monitoring and evaluation of open disclosure will depend on the type of organisation and its functions. Health and social care service providers, health and social care service regulators, professional regulators, and education bodies all have a role to play by collecting and analysing data on open disclosure."

* "Health and social care service providers, health and social care service regulators, and professional regulators will be required to submit an annual report each year to the Minister for Health outlining how they are complying with each of the sections of the Framework with the option to offer an explanation for any circumstances in which they are not complying."

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

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Don't know

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? (Max 100 words)

The challenges of changing the culture of organisations are widely acknowledged. Annual reporting alone is unlikely to be sufficient for open disclosure to be embedded. Structural, procedural and cultural reforms will be necessary across the health and social care system to embed open disclosure.

The Scally report highlights how the ability of staff to develop, implement and disclose the audit was compromised by inadequate levels and skill-mix of staff and inadequate management arrangements. The realities on the ground are that in an overstretched healthcare service, there are competing demands and pressures on staff and management.

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? (Max 100 words)

650 character(s) maximum

Yes there will be good compliance levels with the reporting requirements. However, the value of the reporting will be dependent on a culture of openness and transparency across the health and social care system, with some organisations being more mature in their safety culture than others.

The positive benefits of reporting should be emphasised in terms of opportunities for system improvements, safer systems for patients and safer systems to work in.

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)

Health and social care service providers’ annual reports should include the following information:

- a) Development and implementation of open disclosure policy.
- b) Development and implementation of open disclosure training for all clinical and non-clinical staff including agency staff.
- c) Evidence of the availability of support structure for all staff clinical and non-clinical including agency staff.
- d) The number of trained clinical and non-clinical staff including agency staff.
- e) The number of appointed and trained clinical and managerial open disclosure champions.
- f) The number of open disclosure events initiated and closed.
- g) Examples of learning from open disclosure events.

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

	1	2	3	4	5	6	7
Development and implementation of open disclosure policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Development and implementation of open disclosure training for all clinical and non-clinical including agency staff	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Evidence of the availability of support structures for all staff including clinical, non-clinical and agency staff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The number of trained clinical and non-clinical and agency staff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The number of appointed and trained clinical and managerial open disclosure champions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The number of open disclosure events initiated and closed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Examples of learning from open disclosure events	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Question 2: What else, if anything, should be captured in the reporting of Health and Social Care Service Providers?
(Max 100 words)

- Any feedback initiatives such as surveys to measure patient and staff feedback on open disclosure
- Information given to patients/service users and their support persons on open disclosure.
- Information on systems used to gather information on best practice initiatives and encourage organisations to think about these steps.

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

The health and social care service regulators’ annual report will focus on the implementation of the requirements of the Framework in the designated centres and other relevant services and registered mental health services and will include the following information:

- a) Development and implementation of open disclosure policy.
- b) Development and implementation of open disclosure training for all clinical and non-clinical staff including agency staff.
- c) Availability of support structure for all clinical and non-clinical staff including agency staff.
- d) Appointment and training of open disclosure champions
- e) Examples of learning from open disclosure events in the services regulated

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

	1	2	3	4	5
Development and implementation of open disclosure policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Development and implementation of open disclosure training for all clinical and non-clinical including agency staff	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Availability of support structures for all clinical, non-clinical and agency staff	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Appointment and training of open disclosure champions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Examples of learning from open disclosure events in the services regulated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Question 2: What else, if anything, should be captured in the reporting of Health and Social Care Service Regulators? (Max 100 words)

- Data on how effectively open disclosure policy and just culture is embedded across services.
- The standard line of enquiry used to monitor service providers’ compliance.
- Examples of good practice
- How the regulator is engaging, explaining, educating and enforcing open disclosure in the services they regulate.
- The lived experiences of patients who have been through the open disclosure process in a health and social care organisation.

A valuable example of quality assurance in this area are the two reports by Action against Medical Accidents (AVMA) on the Care Quality Commission’s inspection reports and regulation of the duty of candour in the UK - the AVMA reports ([2016](#) and [2018](#)) analysed inspection reports by the CQC to produce conclusions and recommendations.

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)

The professional regulators’ annual report will include the following information:

- a) Details of Open disclosure embedded in the code of conduct/ethics.
- b) Number of approved academic health and social care programmes with clinical components incorporating open disclosure training.
- c) Number of approved CPD courses on open disclosure.

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

	1	2	3
Details of Open Disclosure embedded in the code of conduct/ethics	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Number of approved academic health and social care programmes with clinical components incorporating open disclosure training	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Number of approved CPD courses on open disclosure	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Question 2: What else, if anything, should be captured in the reporting of professional regulators? (Max 100 words)

The Professional Standards Authority’s analysis of how professional regulators in the UK were performing in relation to the duty of candour, for example recent [2019 report methodology](#) could point to some useful ideas/tools on how to monitor implementation of open disclosure for both service regulators and Health and Social Care professionals.

Section 8: Additional Information

Question: Do you have an additional comments or feedback on any aspect of the Framework? (Max 300 words)

Firstly to add that, currently, there is no mandatory national system to report errors or incidents which occur in pharmacies and that under current legislation there are also limited statutory obligations on pharmacies to provide solicited information to the PSI. The PSI believes that this significant deficit presents patient safety risks and such a system should be developed as a matter of urgency.

In the interim, PSI has developed an [inspectors' advice article](#) on medication error management for pharmacies including frequently asked questions and templates for a medication error report form and medication near miss log.

PSI quality assessors also review medication error management records at routine pharmacy inspections. This review includes checking that the pharmacy has policies and procedures to assist all members of staff in dealing with and learning from medication errors and checking that records of medication errors and near misses are maintained at the pharmacy.

Secondly, in relation to the monitoring of the framework, we consider it essential that the framework is a living document, regularly promoted, nurtured and monitored.

The requirement to provide datasets as part of annual reporting is welcome and will encourage organisations to prioritise framework implementation, however, it is crucial that annual reporting does not become a 'tick-box exercise' and is perceived as a useful tool in improving the quality and safety of service delivery. The Scally report recommends the need for a strong governance framework which includes evaluation and audit.

We also consider that this reporting mechanism could be challenging for smaller health and social care providers such as pharmacies.

Finally, we wish to add, more generally, that PSI strongly welcomes the development and implementation of the National Open Disclosure Framework and looks forward to continuing to engage with the DoH and other stakeholders to support any future developments in this important area and, once it is finalised, to fully support its implementation as it relates to our role.

