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AN COMHCHOISTE UM SHLÁINTE

Tuarascáil ar an nGrinnscrúdú Réamhreachtach ar fhorálacha 'Nochtadh Oscailte' a chuirfear san áireamh sa Bhille um Dhliteanas Sibhialta (Leasú)

Feabhra 2017

JOINT COMMITTEE ON HEALTH

Report on the Pre-Legislative Scrutiny on the 'Open Disclosure' provisions, to be included in the Civil Liability (Amendment) Bill

February 2017

32H004

Chair's Foreword

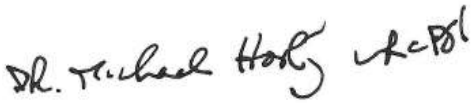
In a letter dated 28 July 2016 the Secretary General at the Department of Health submitted the General Scheme of the 'Open Disclosure' provisions for its consideration. The provisions are to be incorporated in the Department of Justice and Equality's Civil Liability (Amendment) Bill. Open Disclosure, as a clinical practice of transparently sharing information about adverse events with affected patients, is a concept which the Joint Committee on Health of the 32nd Dáil (the Committee) approves of and wishes to see enacted across our health services. It is to this end that the Committee undertook the Pre-Legislative Scrutiny which has led to the creation of this report.

The Committee first embarked on its consideration of Open Disclosure in October 2016, meeting with officials from the Department of Health to discuss the topic. Subsequently, the Committee heard evidence from a number of stakeholders on the topic, viz. the Irish hospital Consultants Association (IHCA), the Irish Medical Organisation (IMO), the Irish Nurses and Midwives Organisation (INMO), the Irish Patients Association (IPA) and the State Claims Agency (SCA).

The aims of the Committee in consulting these stakeholders were to gain practical insight into the reality of healthcare from clinicians and patients, ascertain how Open Disclosure could improve these stakeholder's experiences during the inevitable and unfortunate occurrence of adverse events and to seek counsel as to how a culture of Open Disclosure can be best implemented across Ireland's health services. With regard to the latter point, taking heed of practical experience is vital, and the Committee trusts that the Open Disclosure pilots in Cork University Hospital (CUH) and the Mater Misericordiae University

Hospital, Dublin (MMUH), which were evaluated in the HSE pilot review[1], will inform the welcome rollout of a culture of, and formal framework for, Open Disclosure in Ireland.

All of the witnesses from whom the Committee heard indicated their support for legislating for Open Disclosure in Ireland, and international experience (as cited in this report) indicates that it can be hugely beneficial for both patients and clinicians. While the Committee generally welcomes the Draft Heads of Open Disclosure to be included in the Civil Liability (Amendment) Bill, on which this Pre-Legislative Scrutiny report is based, there are certain details of the proposed legislative framework which stakeholders have questioned. Based on this, the Committee has made recommendations for aspects of the Draft Heads to be reviewed, which we hope will lead to the legislation being as robust, precise and practical as possible when it comes before the Houses of the Oireachtas.



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Michael Harty T.D.
Chair
Joint Committee on Health
8th February 2017

[1] See https://www.hse.ie/eng/about/Who/qualityandpatientsafety/nau/Open_Disclosure/opendiscFiles/Evaluation-of-the-Open-Disclosure-Pilot-2016-.pdf

Membership of the Joint Committee on Health

Deputies:

Bernard Durkan (Fine Gael)

Dr. Michael Harty (Rural Independent Technical Group)

Billy Kelleher (Fianna Fáil)

Alan Kelly (Labour)

Kate O'Connell (Fine Gael)

Margaret Murphy O'Mahony (Fianna Fáil)

Louise O'Reilly (Sinn Féin)

Senators:

Colm Burke (Fine Gael)

John Dolan (Civil Engagement Technical Group)

Rónán Mullen (Independent)

Dr. Keith Swanick (Fianna Fáil)

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Summary

Open Disclosure involves informing a patient as soon as possible when there has been an adverse incident in their care. Disclosure may or may not include an apology. Some potential benefits of Open Disclosure are that it is believed to be:

- more ethical;
- improves patient safety and;
- reduces litigation.

The Medical Council's Guide to Professional Conduct and Ethics 2016 stipulates a duty to inform patients and their families about adverse events. In 2013 the HSE launched a national policy and guidelines on Open Disclosure. However, there is no legislation in Ireland which protects Open Disclosure from being used in litigation proceedings. This is seen as a barrier to the implementation of Open Disclosure policy, as health service providers anticipate that disclosure may be used against them in such proceedings.

The intention of the proposed legislation is to allow health service providers to inform their patients when something goes wrong, without this being used as an admission of legal liability. Under the proposed legislation, disclosure would not be admissible as evidence against the person disclosing, so long as the disclosure is in accordance with regulations to be designed by the Minister for Health in consultation with the Health and Information Quality Authority (HIQA) and the Mental Health Commission (MHC).

However, the proposed legislation does not provide for a mandatory requirement of Open Disclosure to patients. Also, the proposals define an apology as “an expression of regret” and would not therefore appear to include an admission of fault. This could mean that a doctor would be legally protected to say “I’m sorry this happened” but not “I’m sorry we made this mistake.”

Internationally, many jurisdictions with well-developed Open Disclosure policies, as well as laws, continue to under-report medical errors. The reasons for this include: fear of reputational damage, litigation, as well as a lack of adequate training to support disclosure. Commentators argue that laws need to be supported by training, institutional buy-in and a culture which encourages openness, in order for Open Disclosure to take place.

Most stakeholders who made submissions to the Committee welcomed the introduction of legislation to support Open Disclosure. However, a number of concerns were raised in submissions. These concerns may be summarised as follows:

- That the definition of "patient safety incident" in the general scheme, which includes where harm is not caused, is broader than in the HSE National Guidelines. The Irish Hospital Consultants Association are concerned that this may lead to Open Disclosure in cases where patients are waiting on trolleys, or have surgeries cancelled ;
- That the legislation could lead to an increase in clinical negligence claims and the introduction of a mediation service might reduce this likelihood;
- That the definition of health care would not seem to cover a social outing in a social care setting.

In relation to use of records gathered through the Open Disclosure process:

- Concern was expressed by the INMO that the proposed legislation does not prevent regulatory bodies from admitting records relating to Open Disclosure in professional regulatory proceedings.
- The Medical Injuries Alliance believes that Open Disclosure records should be allowed to be admitted in civil cases, so that the court is able to consider all factual data.

A number of stakeholders consider that training is required to support health care staff and create a culture conducive to Open Disclosure.

As regards whether or not Open Disclosure should be mandatory or voluntary, most groups that made submissions to the Committee, representing healthcare providers, agreed that the voluntary approach contained in the general scheme is the correct approach. The State Claims Agency (SCA) call this the "optimal approach" and believe it strikes an appropriate balance between protecting patients and practitioners involved in Open Disclosure.

However, the Irish Patients' Association believe that Open Disclosure should be mandatory.

Key Issues

1) The General Scheme provides for legislative protection for, among other things, expressions of regret by health service providers. It does not however appear to protect disclosures which also admit fault. While this is consistent with many other jurisdictions, legislation in Canada protects expressions of regret as well as admissions of fault. This enables health service providers to fully disclose an error without fear of litigation and has potential benefits for the patient's relationship with their healthcare provider.

While the Committee agrees in principle with the HSE Guideline that apologies and expressions of regret "…should not include any admission of fault until the facts are known"[2], it is also important not to dilute disclosure and maintain its integrity as a frank exchange of information.

2) While the *Programme for a Partnership Government* (2016) set out to introduce mandatory Open Disclosure to patients, the General Scheme provides for a system based on voluntary disclosure in line with the Madden Report (2008) recommendations.

This issue may be considered in the context that international evidence suggests that legislation which protects Open Disclosure has not had the desired effect in terms of compliance. [3]

Although most of the stakeholders the Committee heard evidence from were in favour of voluntary disclosure, the Irish Patients Association was strongly in favour of mandatory disclosure.

The Committee is sympathetic to stakeholder claims that cultural buy-in to Open Disclosure is necessary to its success and that voluntary disclosure backed by "apology laws" is the best way to achieve this. The Committee is wary of introducing a mandatory burden on front-line workers which could hinder desired outcomes.

[2] See https://www.hse.ie/eng/about/Who/qualityandpatientsafety/nau/Open_Disclosure/opendiscFiles/opendiscinformationbooklet.pdf

[3] Wu et al. (2014). Disclosing Adverse Events to Patients: International Norms and Trends. Accessed on 25 August 2016 at http://openindezorg.nl/wp-content/uploads/2015/11/01209203-900000000-99752.pdf

3) Ireland's HSE pilot review[4] outlined a number of critical success factors which should be implemented in order for Open Disclosure to succeed. These include (p.viii) a supportive hospital environment and organisational culture, as well as resources such as a risk management department in each hospital. The full list is provided in text box 5 of this paper.

The Committee strongly recommends utilising the knowledge gained from the pilot review of Open Disclosure so that the health service as a whole has the best possible chance of implementing a successful national rollout of open disclosure.

4) In their evidence to the Committee, representatives from the IHCA highlighted their concern that the inclusion of incidents where no harm has occurred in the General Scheme's definition of "patient safety incidents" does not account for variation in care.

From the General Scheme's definition of Patient Safety Incident:

"(c) an incident that was prevented from occurring due to timely intervention or chance and which there are reasonable grounds for believing could have resulted, if it had not been so prevented, in unintended or unanticipated injury or harm to a service user during the provision of a health service to that service user;"

5) The IHCA's evidence to the Committee also stated that the proposed legislation would be enhanced if it included a mediation service. This is especially relevant in the context of reducing litigation, which has been cited as a potential benefit of Open Disclosure legislation.

As mentioned in Chapter 4 of this report, an upcoming Mediation Bill is expected to promote the use of mediation services.

6) The INMO pointed out in its evidence to the Committee that the definition of "health service" in the General Scheme does not seem to cover adverse events which may occur in a social care setting, for example during a social outing.

7) The INMO also told the Committee that, in their view, Open Disclosure legislation should protect disclosures from being used in professional regulatory proceedings in the same manner that it is proposed that disclosures would be inadmissible in court. The Committee notes that the prospect of disclosures being used in regulatory proceedings could act as a deterrent to honest and immediate disclosure.

[4] See https://www.hse.ie/eng/about/Who/qualityandpatientsafety/nau/Open_Disclosure/opendiscFiles/Evaluation-of-the-Open-Disclosure-Pilot-2016-.pdf

8) Lastly, the INMO told the Committee that the protective definition of what disclosure does not constitute in Head 6 (2) is not broad enough:

"(2) A disclosure by a health services provider, made in accordance with standards set under head 4, does not constitute an express or implied admission of unprofessional conduct, carelessness, incompetence or unsatisfactory professional performance, for the purposes of any enactment regulating the practice or conduct of an employee."

They stated that if the definition was amended to include "or any other ground of complaint", this would help to allay potential fears of healthcare professionals who might be in a position to disclose.

Glossary of terms[5]

Adverse event

An incident which results in harm to a person that may or may not be the result of an error.

Apology

An apology is a genuine expression of being sorry for what has happened. It is an expression of regret.

Error

The failure of a planned action to be completed, as intended, or use of a wrong inappropriate or incorrect plan to achieve an aim.

Harm

Any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury.

Near Miss event

An incident which could have resulted in harm but did not, either by chance or timely intervention.

No harm event

An incident occurs which reaches the service user but results in no injury to the service user. Harm is avoided by chance or because of mitigating circumstances.

Open Disclosure

An open, consistent approach to communicating with service users when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the service user informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event.

[5] As cited in the HSE. (2015). Open Disclosure: National Policy. Accessed on 5 September 2016 at http://www.hse.ie/eng/about/Who/qualityandpatientsafety/nau/Open_Disclosure/opendiscFiles/opendiscpolicyoct13.pdf

1. Introduction

1.1 Pre-legislative scrutiny (PLS) of the General Scheme

In November 2015 the General Scheme of Open Disclosure provisions were referred to the then Joint Committee on Health and Children. Pre-legislative scrutiny (PLS)[6] was not conducted on the General Scheme before the dissolution of the 31st Dáil.

On 28 July 2016 the Secretary General of the Department of Health referred the General Scheme, agreed in November 2015, to the Joint Committee on Health, "the Committee" for its consideration. The Committee met with officials from the Department of Health on 13 October 2016 to discuss the proposed legislation. The Committee also held meetings on 8 December 2016 with stakeholders to discuss the legislation.

1.2 Why legislate?

Open Disclosure, sometimes known as 'Duty of candour', is defined by the Australian Commission on Safety and Quality in Health Care as:[7]

> "…an open, consistent approach to communicating with service users when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the service user informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event."

There is evidence that Open Disclosure can lead to early resolution of disputes and reduce litigation and legal costs[8] as well as fostering cultures of openness and trust.[9]

Government policy supports Open Disclosure and the *Programme for a Partnership Government* states:[10]

[6] PLS is explained in detail in the L&RS Spotlight Pre-legislative scrutiny in Parliament.
[7] As cited in the HSE Managing Incidents Open Disclosure.
[8] McLennan, S. et al. (2015). Apologies in medicine: Legal protection is not enough. Accessed on 23 August 2016 at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4361125/
[9] Australian Commission on Safety and Quality in Health Care 2012. As cited in the HSE Evaluation of the National Open Disclosure Pilot 2016.
[10] A Programme for a Partnership Government. (2016). Accessed on 22 August 2016 at http://www.taoiseach.gov.ie/mwg-internal/de5fs23hu73ds/progress?id=D2JmcMyiaB2pjKwTHE-Yi1qx2jdbFgnUCgr5umMuSfw

> "We consider Open Disclosure as an essential component of patient safety and, in line with the recommendations of the Madden Commission on Patient Safety and Quality Assurance (2008), will progress a number of measures to support it."

As noted by Sheikh (2016), while there is currently no legal duty for Open Disclosure in Ireland, the Medical Council's Guide to Professional Conduct and Ethics 2016 stipulates a duty to inform patients and their families about adverse events.[11] These guidelines state that the practitioner must explain what occurred and apologise if appropriate. However, fear of litigation is a barrier to Open Disclosure.[12] As noted by the Irish Nurses and Midwives Organisation when they met with the Committee on 8 December 2016:[13]

> "…health care professionals, including our members, experience significant anxiety about how disclosures might be made, the consequences of these disclosures, the messages they might be seen to communicate to service users and the potential consequences of these messages in terms of civil litigation and regulatory processes."

Box 1: Medical Council Guidelines relating to Open Disclosure

Section 67.2 of the Medical Council's Guide to Professional Conduct and Ethics 2016 states:

Patients and their families, where appropriate, are entitled to honest, open and prompt communication about adverse events that may have caused them harm. When discussing events with patients and their families, you should:

• acknowledge that the event happened;

• explain how it happened;

• apologise, if appropriate; and

• assure patients and their families that the cause of the event will be investigated and efforts made to reduce the chance of it happening again.

[11] Sheikh, A. (2016). The Practice of Medicine and Open Disclosure - Asim Sheikh B.L. Accessed on 23 August 2016 at http://challenge.ie/challengeblog/the-practice-of-medicine-and-open-disclosure-asim-sheikh-b-l

[12] HSE. (2013). Open Disclosure: National Guidelines. Accessed on 23 August 2016 at https://www.hse.ie/eng/about/Who/qualityandpatientsafety/nau/Open_Disclosure/opendiscFiles/opdiscnationalguidelines2013.pdf

[13] A transcript from this meeting is available at this link http://oireachtasdebates.oireachtas.ie/Debates%20Authoring/WebAttachments.nsf/($vLookupByConstructedKey)/committees~20161208~HEJ/$File/Daily%20Book%20Unrevised.pdf?openelement

The main aim of the proposed provisions is to provide protective legislation which would facilitate Open Disclosure in the health service, without admission of liability. Such laws are sometimes known as 'apology laws,' i.e. laws which provide that an apology given after an adverse event cannot be used in legal proceedings. It should be noted however that Open Disclosure is not limited to and does not necessarily require an apology; it may simply consist of providing information on the incident which occurred.

On 16 June 2016 the Minister for Health, Mr. Simon Harris T.D. said:[14]

> "The intent of this legislation is to provide certain legal protections for healthcare staff for open disclosure. This will give further support to those staff in their communications with patients and family members if an adverse event occurs. The Ethical Code of Practice set out by the Medical Council also makes clear the responsibilities of doctors in relation to open disclosure."

Box 2: Benefits of Open Disclosure

The benefits of open disclosure include:[15]

For patients

• ameliorating feelings of anger, guilt, grief or helplessness

• restoring trust in health care

• encouraging patients to participate in health care quality improvement processes.

For healthcare providers

• enabling healthcare professionals to mitigate ongoing negative consequences of harmful incidents

• enabling healthcare professionals to manage the stress and affective consequences of a harmful incident or complaint

• ameliorating feelings of guilt and shame

• facilitating a full and frank incident investigation which can be used to improve safety and quality

• fulfilling professional, ethical and moral obligations to truthfully disclose information on harmful incidents.

For health systems

• improved system responsiveness to patient needs

• improved clinical communication skills resulting in better care, diagnostic skills and patient-centred outcomes

[14] PQ ref no. 16454/16

[15] Australian Commission on Safety and Quality in Health Care. (2012). Open Disclosure Standard. Accessed on 24 August 2016 at http://www.safetyandquality.gov.au/mwg-internal/de5fs23hu73ds/progress?id=0bA8dPgJ01aIxzCHSiBeLtuoul8nsohCsUDZLiBnt94,

• leverage for cultural reform through -- embedding transparency and openness into healthcare services -- flattening hierarchies, reducing barriers between disciplines and professions, and promoting a team-based ethic • increased and improved notification, reporting and investigation of incidents (including the patient's perspective on the trajectory of their care), resulting in more targeted quality improvement activity • improved staff morale and retention • strengthened public trust in healthcare institutions, including the patient–provider relationship.

Source: Australian Commission on Safety and Quality in Health Care (2012)

1.3 Background to the legislation

Prompted by a number of high profile incidents regarding patient safety, in particular the Lourdes Hospital Inquiry (2006);[16] the Commission on Patient Safety and Quality Assurance was established in January 2007 and published their report (the Madden report) in July 2008.[17] The report made a number of recommendations regarding Open Disclosure, including the development and implementation of national standards and legislation to provide legal protection for Open Disclosure.[18]

Table 1: Timeline of reports/inquiries around patient safety

Report/Inquiry	Year
Lourdes Hospital Inquiry	2006
Commission on Patient Safety and Quality Assurance (Madden report)	2008
HSE Open Disclosure National Policy	2013
General Scheme of Open Disclosure Provisions	2015

Source: L&RS 2016

[16] Report available at this link http://health.gov.ie/wp-content/uploads/2014/05/lourdes.pdf
[17] The full report can be accessed at this link http://health.gov.ie/blog/publications/building-a-culture-of-patient-safety-report-of-the-commission-on-patient-safety-and-quality-assurance/
[18] See recommendations R4.16 and R4.17

As set out in the Department of Health briefing note provided to the Committee (2016) Ireland has no express protective legislation to assist the Open Disclosure process where patient safety incidents (adverse events) occur. The Madden Report (2008) recommended that legislation be enacted to provide legal protection/privilege for Open Disclosure of adverse events to patients within a voluntary rather than mandatory framework

On 12 November, 2013, the then Minister for Health Dr. James Reilly, T.D. launched a National Policy on Open Disclosure with three supporting documents, as follows:

- a staff support booklet;
- patient information leaflet; and
- a staff briefing guide.[19]

Also in 2013 the National Policy on Open Disclosure was developed by the State Claims Agency and the HSE.[20]

The recommendations in the Madden Report form the basis of the legislative provisions on Open Disclosure approved by the last Government in November 2015 (as set out in the General Scheme). The Department of Health (2016) states that the provisions are also informed by national and international developments regarding Open Disclosure since the publication of the Madden Report.

[19] https://www.inmo.ie/MagazineArticle/PrintArticle/11229
[20] The National Policy, published in October 2013, can be accessed at this link https://www.hse.ie/eng/about/Who/qualityandpatientsafety/nau/Open_Disclosure/opendiscFiles/opendiscpolicyoct13.pdf

Box 3: Open disclosure as part of a wider patient safety environment

The Department of Health information note (2016) supplied to the Committee states that a strong patient safety culture is linked to external incident reporting **as well as** disclosure to the patient.

In that context, the National Incident Management System (NIMS) established by the State Claims Agency should be noted. The NIMS has the capacity to manage no harm incidents, near misses and dangerous occurrences. All incidents in the healthcare sector including Serious Reportable Events (SREs) (the most serious forms of error that cause harm to patients in the public health system) must be reported directly on to NIMS since June 2015.

The *Programme for a Partnership Government* makes clear that Open Disclosure is an essential component of patient safety. The Programme also states it will be made mandatory to report specified patient safety incidents or SREs to the authorities and to the patient. Provisions in the General Scheme of the Health Information and Patient Safety Bill, which was approved by the last Government (and now intended for further Pre-Legislative Scrutiny), contain requirements for mandatory external reporting of serious patient safety incidents to HIQA, the Mental Health Commission and the State Claims Agency. The **General Scheme of the Health Information and Patient Safety Bill also has provisions on voluntary external reporting of non-serious incidents to the State Claims Agency. That will meet the first element of the Government statement in terms of reporting to authorities.** It will also support and complement the reporting to NIMS already in place as described above.

Open Disclosure Pilot

A two year Open Disclosure pilot took place in two acute hospitals, Cork University Hospital (CUH) and the Mater Misericordiae University Hospital, Dublin (MMUH) from November 2010 to November 2012. The lessons learnt from the pilot informed the development of the national policy and guidelines on Open Disclosure and the subsequent national roll-out of Open Disclosure. Evaluation of the pilot was carried out in 2014 and a review of the pilot was published by the HSE in 2016.

The review found that overall, the two hospitals demonstrated:[21]

> "…overwhelming evidence of the benefits of open disclosure for both staff and patients."

The review also identified the main barriers to implementing Open Disclosure, which were:

- concerns over increased litigation costs;
- fear of damaging or losing the relationship with the patient;
- fear of a loss of reputation or career progression;
- lack of institutional support;
- lack of training on how to practice Open Disclosure; and
- the emotional impact on clinicians of adverse events.

Joint Committee for Health and Children (JCHC) Report on the Cost of Medical Indemnity Insurance 2015

In 2015 the JCHC held discussions around the increasing costs of medical indemnity insurance.[22] The Committee heard from several stakeholders, representing patients and doctors, who argued that full implementation of an open disclosure policy would reduce the number of negligence claims, as it would give patients answers without resorting to the Courts. These sentiments were echoed by the then Minister for Health, Dr. Leo Varadkar, T.D. in February 2015 when he told the Joint Committee on Health and Children that doctors failing to live up to their duty of candour was the equivalent of a motoring 'hit and run'. The Minister said that he intended to legislate to make Open Disclosure a legal requirement. The Minister also said that if more doctors were open about making mistakes there would be fewer lawsuits.[23]

During the Committee's deliberations, the introduction of a statutory Duty of Candour/Open Disclosure policy was supported by the Irish Medical Organisation, Bar Council of Ireland, Law Society of Ireland, Medical Injuries Alliance, Medical Protection Society and the State Claims Agency.

[21] The HSE 2016 report can be accessed at this link http://www.lenus.ie/hse/handle/10147/617915

[22] The Joint Committee on Health and Children (2015) Report on the Cost of Medical Indemnity Insurance is available at this link http://www.oireachtas.ie/parliament/media/JCHC-Report-on-The-Cost-of-Medical-Indemnity-Insurance.pdf

[23] Irish Times. (2015). Doctors must tell patients of errors, under new Varadkar law. Accessed on 18 August 2016 at http://www.irishtimes.com/news/politics/doctors-must-tell-patients-of-errors-under-new-varadkar-law-1.2092525

The Committee's final report placed a strong emphasis on Open Disclosure and recommended that:

> "Since 2013, the HSE has piloted an open disclosure policy in a small number of hospital sites. The Committee recommends that consideration be given to accelerating implementation of an open disclosure policy at all public hospitals."

2. Summary of the General Scheme

What patient safety incidents are to be reported?

There are three types of "patient safety incident" defined in the General Scheme:

1. an unintended or unanticipated injury to a person (actual adverse event);
2. an event which put the patient at risk but did not result in any harm or injury (no harm events); and
3. an incident which could have caused harm or injury to the patient had it not been prevented (near misses).

What is meant by disclosure?

Disclosure is defined in the General Scheme as any statement which may include an apology, made by or on behalf of a health service provider to a service user or a connected person. A connected person is defined as: a parent, guardian, son, daughter, spouse, or civil partner of the service user.

What is meant by an apology?

An apology is defined in the General Scheme as "an expression of regret in respect of a patient safety incident."

Who should make disclosures and who should they disclose to?

The proposals outlined in the General Scheme will apply to a range of healthcare providers including medical doctors, dentists, pharmacists, nurses and midwives. It is intended that the proposal will apply to the HSE, public voluntary hospitals, private hospitals, GP practices and other healthcare entities.[24]

The General Scheme specifies that a disclosure can be made to a "connected person" if it cannot be made to the service user.

Speaking to the Committee on 13 October 2016, Dr. Tony Holohan, Chief Medical Officer at the Department for Health said:[25]

[24] As stated in the Explanatory Note to Head 1.
[25] Transcript is available at this link http://oireachtasdebates.oireachtas.ie/Debates%20Authoring/WebAttachments.nsf/($vLookupByConstructedKey)/committees~20161013~HEJ/$File/Daily%20Book%20Unrevised.pdf?openelement

> "The current draft provisions state the disclosure should be made as soon as practicable and that the information given should cover a description of the patient safety incident, the date it happened, the date the provider became aware of the incident and how the provider became aware of it. Information must be given on any known physical, psychological or emotional effects arising from the incident and how these are to be managed. The patient is also told about any actions being taken to ensure learning from the incident to avoid a recurrence."

Who will create regulations?

The information note provided by the Department to the Committee states that the Parliamentary Counsel has advised that regulations would provide more legal certainty than standards. It has therefore been agreed that regulations would be laid before the Houses of the Oireachtas. The Minister will consult with HIQA and the MHC before making any regulations. This implies that Head 4 of the General Scheme no longer reflects the approach that will be taken in this area when the Bill is drafted.

The purpose of the regulations is to ensure that health service providers follow the same process in making a disclosure. Only disclosures which are in accordance with these regulations will be protected by the legislation.

Can a disclosure made in accordance with these regulations be used in litigation?

Head 6 of the General Scheme states that any disclosure made in accordance with the standards under Head 4 will not be relevant to a determination of liability, or constitute an admission of liability.

Table 2: Summary of the provisions of the General Scheme.

Head 1	This Head defines terms used throughout the General Scheme such as "disclosure", "health service provider", "health practitioner", "connected person", "apology" etc.
Head 2	This Head provides for commencement issues.
Head 3	This Head provides the Minister for Health with powers to make regulations.
Head 4	While this Head states that the HIQA and the MHC will create standards, the Department has, under advice from the Parliamentary Counsel, decided that Ministerial regulations would provide more legal certainty. Regulations will likely cover among other things: who may make disclosures and any arrangements to assist the service user to understand the nature of what is being disclosed. The regulations may also address the records to be kept by the provider in relation to the disclosure.
Head 5	This Head sets out the procedure for publication and consultation regarding draft standards and publication of standards once they have been approved by the Minister.
Head 6	This Head provides certain legal protections where a disclosure is made in accordance with the standards set out under Head 4. Under this Head a disclosure does not constitute an admission of liability, unprofessional conduct, or affect indemnity coverage for any person affected by the

	disclosure.
Head 7	This Head provides that a record made solely for the purpose of making a disclosure, under Head 4, is not admissible in any civil proceedings as evidence of liability in connection with any personal injury or death. They would be admissible in evidence in other civil proceedings and in criminal proceedings.
Head 8	This Head amends the *Health Act 2007* and the *Mental Health Act 2001* to provide for the HIQA and the MHC to set standards for open disclosure.

Source: L&RS 2016

3. Issues to consider

The purposes of this General Scheme are to:

- ✓ help promote a culture of Open Disclosure throughout the health system. It is intended that this will be achieved by providing certain limited and specific legal protections where healthcare providers make Open Disclosures in line with regulations; and

- ✓ support the National Policy on Open Disclosure. This was developed jointly by the HSE and the State Claims Agency (and launched in November 2013).

3.1 Protecting expressions of regret and/or admissions of fault

Open Disclosure laws may provide legal protection when expressions of regret, such as "I'm sorry this happened" are made rather than admissions of fault, e.g. "I'm sorry we made this mistake," or both.[26] The proposals contained in the General Scheme appear to only protect disclosure which expresses regret. The HSE Guidelines state that an apology: "…should not include any admission of fault until the facts are known."[27]

The Australian state of New South Wales' *Civil Liability Act 2002* protected both expressions of regret and admissions of fault. This Act was the model for British Columbia's legislation around Open Disclosure, which was subsequently the basis for other Canadian provinces.[28]

However McLennan et al. (2015) write that:

> "…most apology legislation that has been enacted internationally — 29 of 36 laws in the United States and 6 of 8 laws in Australia — protect only expressions of sympathy or regret."

[26] McLennan, S. et al. (2015). Apologies in medicine: Legal protection is not enough. Accessed on 23 August 2016 at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4361125/
[27] See https://www.hse.ie/eng/about/Who/qualityandpatientsafety/nau/Open_Disclosure/opendiscFiles/opendiscinformationbooklet.pdf
[28] Ibid.

Box 4: British Columbia Apology Act 2006

Definitions

1. In this Act:

"apology" means an expression of sympathy or regret, a statement that one is sorry or any other words or actions indicating contrition or commiseration, whether or not the words or actions admit or imply an admission of fault in connection with the matter to which the words or actions relate.

"court" includes a tribunal, an arbitrator and any other person who is acting in a judicial or quasi-judicial capacity.

Effect of apology on liability

2(1) An apology made by or on behalf of a person in connection with any matter

a. does not constitute an express or implied admission of fault or liability by the person in connection with that matter,

b. does not constitute an acknowledgement of liability in relation to that matter for the purposes of section 24 of the Limitation Act,

c. does not, despite any wording to the contrary in any contract of insurance and despite any other enactment, void, impair or otherwise affect any insurance coverage that is available, or that would, but for the apology, be available, to the person in connection with that matter, and

d. must not be taken into account in any determination of fault or liability in connection with that matter.

2(2) Despite any other enactment, evidence of an apology made by or on behalf of a person in connection with any matter is not admissible in any court as evidence of the fault or liability of the person in connection with that matter.

Source: McLennan et al. (2015).

In 2013 the Deputy Ombudsman of New South Wales made a presentation on this issue and urged that a full apology , i.e. one which also admits fault, has a range of benefits, including:[29]

- Moral/ethical benefit
- Better transparency
- Emotional/psychological benefits
- A reduced likelihood of litigation

3.2 Mandatory versus voluntary Open Disclosure

Where jurisdictions have introduced legislation around Open Disclosure it is usually to (a) introduce a statutory obligation to disclose patient safety incidents when they occur, or (b) to provide legislative protections for Open Disclosure, so that these disclosures are not used as an admission of liability. These are not mutually exclusive and some jurisdictions have introduced both.

In the *Programme for a Partnership Government*, it states:

> "It will be made mandatory to report specified patient safety incidents or serious reportable events to the authorities **and to the patient harmed**, and it will be an offence not to do so." (Emphasis added).

However the provisions outlined in the General Scheme will not make Open Disclosure to patients mandatory. The Department, in its submission to the Committee, states:

> " 'Apology' laws which protect disclosures – as distinct from requiring them in law – are more common internationally and international experience indicates that open disclosure will happen best by fostering the development of an open and honest culture."

The Commission on Patient Safety and Quality Assurance (2008) cites research (Cohen 2000) showing that where reporting is mandatory, service providers are less likely to report near misses, whereas voluntary systems encourage practitioners to report hazardous situations and mistakes which had the potential to cause harm.

[29] Ombudsman New South Wales. (2013). Open disclosure and apology – time for a unified approach. Accessed on 25 August 2016 at https://www.ombo.nsw.gov.au/__data/assets/pdf_file/0012/10470/Open-disclosure-and-apology-Nat-Admin-Law-Conference-19-July.pdf

Cohen (2000) writes:[30]

> "A major reason is that voluntary programmes provide frontline practitioners with the opportunity to tell the complete story without fear of retribution."

International experience

In Canada, laws which protect rather than mandate disclosure (i.e. apology laws) are more common and exist in British Columbia (2006), Saskatchewan (2007), Manitoba (2007), Alberta (2008), Nova Scotia (2008), Ontario (2009), Newfoundland and Labrador (2009), Nunavut (2010), Prince Edward Island (2009) and Northwest Territories (2013). However legislation mandating disclosure has been enacted in Quebec (in 2002) and Manitoba (in 2005).[31]

The UK legislated for Duty of Candour in November 2014 on foot of the Francis Inquiry into failings in care at Mid Staffordshire NHS Foundation Trust between 2005-2009.[32] According to the Department of Health (UK) the duty of candour will be a legal requirement and Care Quality Commission (CQC) will be able to take enforcement action when it finds breaches. In more serious cases this could involve the courts.[33]

In the USA at least 36 states have passed immunity for apology laws and five states have passed mandatory disclosure laws.[34]

[30] Cohen, M.R. (2000). Why error reporting systems should be voluntary. *British Medical Journal*.
[31] McLennan, S. et al. (2015). Apologies in medicine: Legal protection is not enough. Accessed on 23 August 2016 at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4361125/
[32] Joint Committee on Health and Children. (2015). Report on the Cost of Medical Indemnity Insurance accessed on 18 August 2016 at http://www.oireachtas.ie/parliament/media/JCHC-Report-on-The-Cost-of-Medical-Indemnity-Insurance.pdf
[33] Department of Health (UK). (2014). Statutory duty of candour for health and adult social care providers. Accessed on 23 August 2016 at https://www.gov.uk/government/consultations/statutory-duty-of-candour-for-health-and-adult-social-care-providers
[34] National Institute for Health Research. (2014). Health Service and Delivery Research. Accessed on 24 August 2016 at http://www.ncbi.nlm.nih.gov/books/NBK259828/

3.3 Putting policy into practice

While most commentators and experts agree that Open Disclosure has a range of benefits (as set out earlier in this paper), it has been challenging to implement the policy, even in jurisdictions that have introduced laws to protect or mandate disclosure.

Data from a number of countries with well-developed Open Disclosure policies show that only one-third of patients are told about harmful errors in their care.[35]

Likewise Guillod (2013) finds that 'apology laws' have a 'debatable' effect and:[36]

> "Indeed, there seems to be little evidence that such laws have significantly encouraged open disclosure of medical errors."

However, it should be borne in mind when making international comparisons that "Health care systems stem from specific political, historical, cultural and socio-economic traditions",[37] i.e. that the Irish health care system has, for example, different origins to other systems and that culture is an important element in how it has and is being developed.

The barriers to Open Disclosure identified in the HSE pilot review (2016), such as concerns over increased litigation and fear of reputational damage are echoed in other jurisdictions. A broader, cultural attitude towards disclosure may also be at play. McLennan et al. (2015)[38] find that:

> "Legal fears may surely be a factor in clinicians' reluctance to apologize, and to disclose adverse events in general. However, the underlying reasons are usually more complex, including a professional and organizational culture of secrecy and blame, professionals lacking confidence in their communication skills, and the shame and humiliation associated with acknowledging a mistake that caused harm — to oneself, one's patient and one's peers."

[35] Wu et al. (2014). Disclosing Adverse Events to Patients: International Norms and Trends. Accessed on 25 August 2016 at http://openindezorg.nl/wp-content/uploads/2015/11/01209203-900000000-99752.pdf

[36] Guillod, O. (2013). Medical Error Disclosure and Patient Safety: Legal Aspects. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4147746/

[37] European Parliament Directorate General for Research. (1998). Working Paper: Health Care Systems in the EU: A Comparative Study. Public Health and Consumer Protection Series SACO 101 EN (1998, p.5).

[38] McLennan, S. et al. (2015). Apologies in medicine: Legal protection is not enough. Accessed on 23 August 2016 at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4361125/

How to ensure that laws are implemented

McLennan (2015) argues that for legislation to make a difference, training must be provided to health care staff. Wu et al. (2014) recommend that the term "disclosure" be replaced with "being open", as has been done in the UK and Canada as this:

> "…implies an ongoing process of honest communication both before and after adverse events…"

Box 5 outlines the "Critical success factors" for open disclosure identified in the HSE (2016) pilot review.

Box 5: Critical success factors for open disclosure

• A supportive culture for disclosure that promotes staff confidence and capacity to implement open disclosure across the whole organisation.

• Having a pilot lead in each hospital responsible for implementation, policy development, awareness raising, training, and championing open disclosure.

• External resources and expertise from the HSE/SCA to progress organisational policy, guidance and procedures on open disclosure.

• Sufficient resources within the hospital, including a risk management department in each hospital with expertise to support and engage clinical and non-clinical staff.

• Good quality training by experienced clinicians with an in-depth knowledge of open disclosure, including targeted training in clinical specialties, induction training and ongoing training to keep staff up-dated and motivated.

• Multidisciplinary approaches to reporting and learning from incidents, fostering team and peer support and peer learning.

• Clear guidance about how and when to carry out open disclosure, including how to report on and how to utilise the learning from incidents to prevent future errors.

• Open disclosure embedded as an integral part of relevant hospital policies on quality and patient safety.

Source: HSE 2016,[39] adapted by the L&RS.

[39] HSE. (2016). Evaluation of the National Open Disclosure Pilot.

4. Stakeholder views

Most stakeholders who made submissions to the Committee welcomed the introduction of legislation to support Open Disclosure. However, a number of concerns were raised in submissions, as set out in Table 3. These concerns may be summarised as follows:

- That the definition of "patient safety incident" in the general scheme, which includes where harm is not caused, is broader than in the HSE National Guidelines (IHCA);
- That the legislation could lead to an increase in clinical negligence claims and the introduction of a mediation service might reduce this likelihood (IHCA);
- That the definition of health care would not seem to cover a social outing in a social care setting (INMO).

In relation to use of records gathered through the Open Disclosure process:

- Concern was expressed that the proposed legislation does not prevent regulatory bodies from admitting records relating to Open Disclosure in professional regulatory proceedings (INMO).
- The Medical Injuries Alliance believes that Open Disclosure records should be allowed to be admitted in civil cases, so that the court is able to consider all factual data.

A number of stakeholders consider that training is required to support health care staff and create a culture conducive to Open Disclosure.

As regards whether or not Open Disclosure should be mandatory or voluntary, most groups who made submissions representing healthcare providers, agreed that the voluntary approach contained in the General Scheme is the correct approach. Also, the State Claims Agency (SCA) believes it strikes an appropriate balance between protecting patients and practitioners involved in Open Disclosure.

However, the Irish Patients' Association argue that Open Disclosure should be mandatory, as does Ms. Margaret Murphy, the External Lead Advisor of the World Health Organization's patients for patient safety programme. Ms. Murphy told the Committee:

> "It is an inalienable right of any patient entrusting their own care and that of loved ones to the health care system to have the assurance that in the event of error, open disclosure will be practised, learning will occur and improvements to prevent recurrence will be put in place."

Table 3: Summary of stakeholders' concerns regarding Open Disclosure legislation as submitted to the Committee during PLS.

Irish Hospital Consultants Association	Irish Nurses and Midwives Organisation	Irish Medical Organisation	Irish Patients' Association
• Definition of patient safety incident is more expansive than national guidelines (general scheme includes where no harm has occurred). Standards contained in the National Guidelines should be applied instead. • Open Disclosure could increase the number of clinical negligence claims in the court. To mollify this risk the proposed legislation could provide for a mediation service.	• The INMO are concerned about the professional regulatory consequences of Open Disclosure. • The predominance of nurses and midwives in the provision of direct care may leave them more responsible for Open Disclosure, than other members of their multi-disciplinary team. As such, professionals must be adequately supported by their line managers, risk management departments and the broader system in which they work. • Head 6(2) should be amended by adding "any other ground of complaint" to ensure the maximum possible protection for health care professionals. • The definition of health service may need to be broadened to cover the provision of social services e.g. the legislation would not seem to cover a social	• The HSE and other healthcare organisations must ensure that supportive structures and resources are in place in hospitals, general practice and community settings, including: education and training programmes, support from colleagues and line managers, guidance material, counselling services and risk management teams. • There must be some recognition that Open Disclosure will reduce time spent on clinical duties.	• Open Disclosure should be mandatory

	outing in a social care setting. • Any records created for the purposes of Open Disclosure are protected from admission in professional regulatory proceedings.		

Source: L&RS (2017), based on submissions to the Committee.

The Mediation Bill[40] aims to promote mediation as an alternative to court proceedings. The Bill was included on the list of priority legislation on the Government legislation programme for the Spring/Summer session 2017.[41] The Bill has not yet been published but according to recent media reports, it is due to be brought to Cabinet early in the New Year.[42]

The Bill creates statutory obligations for legal practitioners to advise clients about mediation in respect of civil disputes. In relation to solicitors, this involves:

- advising clients, prior to commenting civil proceedings, to consider using mediation;
- to provide information on mediation services;
- to provide an estimate of legal costs in the event of court proceedings.

Barristers must, prior to commencing civil proceedings, advise clients on the use of mediation and must certify in writing such advice was provided. A court can also invite parties to consider mediation and may consider an unreasonable refusal to do so when deciding on costs.

The Bill does not make mediation compulsory, nor does it provide for the establishment of a mediation service. Instead, it seeks to promote mediation as an alternative to court proceedings. The use of mediation as an alternative to litigation, particularly in respect of medical negligence litigation, has been welcomed by the Courts, particularly due to the impact that such litigation may have on both plaintiffs and defendants.[43]

[40] For further information on the Bill, see the L&RS Bills Tracker page
[41] Government Legislation Programme, Spring/Summer Session 2017, available at http://www.taoiseach.ie/eng/Taoiseach_and_Government/Government_Legislation_Programme/
[42] See: 'Lawyers will be forced to suggest mediation under new Bill', Irish Times, 30 December 2016, available at http://www.irishtimes.com/news/crime-and-law/lawyers-will-be-forced-to-suggest-mediation-under-new-bill-1.2920418
[43] See: 'Boy with Cerebral Palsy awarded final lump sum of €8m', Irish Times, 12 May 2016, available at http://www.irishtimes.com/news/crime-and-law/courts/high-court/boy-with-cerebral-palsy-awarded-final-lump-sum-of-8m-1.2645484

The Courts service, in conjunction with other agencies, currently provides mediation options as an alternative to litigation in respect of certain types of disputes.[44]

[44] According to the Courts Service Annual Report 2015 : ''A mediation option continued to be made available in Dublin Circuit and District Court Civil Office for those seeking certain court remedies…Disputes where parties were asked to consider mediation included boundary disputes, private prosecutions for breach of the peace, complaints about noise or nuisance pets, and disputes between adult family members on questions of property.' The Courts Service supported a pilot scheme to help Chambers Ireland members and other business and commercial enterprises resolve business disputes through mediation as well as operating a mediation initiative, along with other agencies, in respect of family cases in certain District Courts.

5. Recommendations

The following numbered recommendations link directly to the Key Issues identified earlier in this report.

1) The Committee recommends that analysis be conducted of disclosures made during the Open Disclosure pilots to confirm that the lack of provision for admitting fault did not impact negatively on exchange of information or patient experience. If that cannot be shown in the Pilot projects, the Committee recommends that this issue be revisited in the legislation.

2) The Committee recommends that after a set amount of time, decided by the Department of Health, the success of voluntary Open Disclosure based on the legislation as proposed, which protects disclosures from being used in subsequent legal proceedings, be assessed. If it is determined that a voluntary system is not having a satisfactory impact in increasing rates and quality of disclosure, the Committee recommends that the possibility of mandatory disclosure be considered.

3) The Committee recommends that the proposed legislation be accompanied by supports (in hospitals and other clinical settings) which complement the critical success factors outlined in the HSE pilot review.

4) The Committee recommends that the definition of a no harm patient safety incident be expanded to explicitly state that it does not refer to general variation in care, but specifically to prevented adverse events.

5) The Committee recommends that the Department of Health (a) assess whether a specific mediation service for dealing with adverse events would be practicable and (b) consider implementing such a service in healthcare settings across Ireland.

6) The Committee recommends that the Department of Health examine whether or not the definition of health service should be broadened to include social care settings and if not, to explain why this would not be beneficial.

7) The Committee recommends that the Department of Health consult with relevant regulatory bodies in case there could be unforeseen drawbacks to making Open Disclosures inadmissible in professional regulatory proceedings and, after receiving this feedback, consider whether to expand the protective element of the legislation to include professional regulatory proceedings.

8) The Committee recommends that the INMO's request that Head 6 (2) be amended to include "or any other ground of complaint" be taken into account when the Bill is being drafted, and that such an amendment be considered.