Medico-Legal Journal of Ireland 2021, 27(2), 71-74

Open Disclosure in Ireland: Legal Framework, Policy Considerations, and the Argument for a Unified Approach

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This is a pre-edited version of ME Tumelty, 'Open Disclosure in Ireland: Legal Framework, Policy Considerations, and the Argument for a Unified Approach' (2021) 27(2) Medico-Legal Journal of Ireland 71.

Subject: Health
Keywords: Health policy; Ireland; Medical ethics; Patients' rights; Provision of information; Safety

Introduction

Whilst definitions vary, the principles underlying open disclosure remain the same: patients must be provided with prompt, honest, accurate information about their care, including where something has gone wrong.[1] Open disclosure is a vital aspect of patient safety. As Quick explains, '[c]reating a culture of safety depends on a number of elements, but openness and honesty are critical.'[2] Patients have a right to learn about their care and be informed when a patient safety incident occurs. Open disclosure also aims to contribute to the important goal of patient safety through organisational learning. Various open disclosure policies and laws have been introduced over the past number of decades in countries throughout the world,[3] including Ireland.

The importance of open disclosure is well covered in the literature, and it is not proposed to detail the arguments here. Rather, the focus of this short article is on the open disclosure framework in Ireland, and the need for a unified approach. The article first provides background to open disclosure in Ireland, and the relevant legal framework. It then discusses some recent developments, namely the recommendations of the Independent Patient Safety Council on a national policy framework. Ultimately, the article argues that regulation and patient safety measures work best where the legal and ethical frameworks work in tandem, and concludes with some key learning points.

Open Disclosure in Ireland: Background and Legal Framework

In Ireland, open disclosure has been a focus of ensuring patient safety and creating a just culture since the recommendation for its introduction by the Patient Safety Commission in 2008,[4] and the subsequent Health Service Executive (HSE) pilot programme in 2010.[5] Following review of this pilot, the HSE launched its open disclosure policy in 2013. More recently in Ireland, open disclosure has been scrutinised in light of the failure of some healthcare practitioners to disclose, and the CervicalCheck controversy and subsequent recommendations of the Scoping Inquiry, were largely the impetus for the revised HSE policy on open disclosure in 2019.[6] Legislative safeguards for disclosure were also introduced in Ireland by virtue of the Civil Liability (Amendment) Act 2017, which was commenced in September 2018. The CervicalCheck controversy highlighted that despite the professional and ethical obligation to disclose patient safety incidents,[7] open disclosure does not always happen. As a result, there has been a marked increase in support for mandatory open disclosure, and the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 will introduce the mandatory disclosure of certain

'notifiable incidents.'[8]

A comprehensive discussion of the legislative framework is outside the scope of this article, however, it is necessary to provide some context before proceeding to analyse recent recommendations in relation to a policy framework. As such, this section of the article will give a brief overview of the Civil Liability (Amendment) Act 2017 and the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019.

The Civil Liability (Amendment) Act 2017

International studies have identified fear of litigation and/or sanction as a barrier to the implementation of open disclosure policies.[9] Similarly in the Irish context, the Pillinger report which reviewed the HSE open disclosure pilot highlighted this as a challenge to disclosure.[10] One such measure to overcome this barrier is so-called protective legislation, which provides that disclosure(s) and/or apologies are inadmissible in subsequent litigation, regulatory complaints processes, and from invalidating insurance. A variety of laws which provide protection for open disclosure exist around the world. In ***72** September 2018, the Civil Liability (Amendment) Act 2017 ("the 2017 Act") was commenced, which introduced legislative protection for the disclosure of patient safety incidents and apologies in Ireland.[11] However, such protections are only available when the process, as outlined by the Civil Liability (Open Disclosure) (Prescribed Statements) Regulations 2018, is adhered to.[12] The process has been criticised,[13] and described as 'unwieldly, bureaucratic, legalistic, and possibly detrimental to the desired ethos and principles of open disclosure.'[14] This is somewhat unsurprising given that international evidence tells us that patients value an open disclosure process which is respectful, conducted with openness and honesty, and is timely.[15] Holmes et al. have argued that '[t] he benefits from open disclosure will most often be seen when open disclosure is performed in an 'ideal' manner.'[16] In contrast, where the process is perceived to be formulaic and legalistic, the disclosure may be viewed by patients and/or their families as an exercise to minimise responsibility.[17]

Although the HSE policy highlights that the provisions of the 2017 Act are separate from its open disclosure policy,[18] and healthcare practitioners have professional and ethical obligations to disclose,[19] given that a widely reported barrier to open disclosure is fear of litigation,[20] it is disappointing that the 2017 Act and accompanying regulations mandate a formulaic and legalistic approach to disclosure.

The Patient Safety (Notifiable Patient Safety Incidents) Bill 2019

Despite the strong ethical guidance in relation to open disclosure, and the protective measures of the 2017 Act, there has been increasing support for mandatory open disclosure. The Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 ("the 2019 Bill") will mandate the disclosure of 'notifiable incidents.' This obligation will fall on health service providers,[21] and such incidents include more serious patient safety incidents, typically resulting in death.[22] The legislation will also bestow the power on the Minister for Health to add incidents to the list.[23] Similar to the 2017 Act, the 2019 Bill details the approach that should be taken in relation to open disclosure.[24] The 2019 Bill will also provide protection to open disclosure (from admissibility in civil litigation, regulatory complaints processes, and from invalidating indemnity insurance) which takes place in accordance with the procedure outlined in the legislation.[25] Failure to comply with the legislation without 'reasonable excuse' shall be an offence, and will attract a fine.[26]

In the context of increasing attempts to cultivate a 'just culture' rather than a 'blame culture',[27] the question as to whether or not a move towards punitive sanction is helpful must be asked.[28] The utility of the imposition of a financial penalty has been questioned elsewhere,[29] however, some authors note that

the imposition of a fine is also symbolic and can lead to reputational damage, and hence organisational change.[30]

Recent Developments and Looking Forward

Notwithstanding the strong political pressure to legislate for mandatory disclosure in Ireland, like many other areas of healthcare policy and practice, the COVID-19 pandemic has shifted priorities to the management of illness and death associated with the disease.[31] Progress on the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 has stalled, and at the time of writing (November 2021), the 2019 Bill remains at Committee Stage.

There have been some other notable developments in this space, namely, the publication of recommendations on a national policy framework for open disclosure in Ireland by the Independent Patient Safety Council ("the Council") in January 2021,[32] and the Report of the Expert Group to Review the Law of Torts and the Current Systems for the Management of Clinical Negligence Claims ("the Expert Group") in 2020, which included some recommendations on open disclosure.[33]

The recommendations of the Independent Patient Safety Council, in many instances, support the existing HSE open disclosure policy. In developing its recommendations, the Council relied on evidence provided in the *Crowe Report*,[34] which as part of its research conducted a patient survey with 265 responses. Key high-level recommendations made by the Council include: open, honest, compassionate, and timely communication;[35] the implementation of patient rights and/or entitlements in the open disclosure process, including the right to receive an explanation and apology;[36] the availability of appropriate education and supports for health and social care staff;[37] developing and maintaining a supportive culture;[38] the implementation of mechanisms for reporting and learning from patient safety incidents;[39] and governance frameworks which facilitate accountability.[40]

It is interesting to note, however, that some of the Council's observations and recommendations starkly contrast with the open disclosure process as mandated by the Civil Liability (Open Disclosure) (Prescribed Statements) Regulations 2018 (should healthcare practitioners wish to avail of the legislative protection). Reflecting the extensive literature in this area, the Council recommended that '[t]he instigation of formal open disclosure should be in addition to timely communication to patients / service users and/or their support persons to advise them of what has happened.'[41] They further advise that '[o]pen disclosure processes should be as simple and as accessible as possible for patients and staff.'[42] This indeed contrasts with the provisions of the 2017 Act ***73** and the 2018 Regulations due to the fact that, and as has been noted elsewhere, '[t]his process is highly specified and involves completing documentation in advance of any open disclosure meeting taking place.'[43] One succinct stakeholder observation noted that '[c]urrent legislation and open disclosure policies do not enable open, honest conversation and creates a "gap" between patients / service users and clinicians.' The gaps between the HSE open disclosure policy and the 2017 Act are problematic as it is argued that legal and ethical frameworks should overlap in order to maximise the potential for implementation and compliance.

Other recommendations include that a process to facilitate annual reporting on open disclosure should be put in place,[44] and open disclosure should be included as part of the Health Information Quality Authority (HIQA) and Mental Health Commission guidance and monitoring.[45]

Whether or not a mandatory legal duty, it is an ethical duty of medical practitioners to disclose patient safety incidents.[46] As previously noted, in Ireland in recent years, the debate has moved onto the appropriateness of mandating disclosure. A number of views exist in this regard. For example, some

authors argue that 'the strong signal sent by a statutory duty can help encourage greater openness and learning about safety and be a trigger for cultural change.'[47] Others caution that such a duty may result in defensive documentation and bureaucracy.[48] The Expert Group on Tort Reform expressed support for mandatory disclosure, noting that the provisions of the 2017 Act were unsatisfactory due to the fact that '[t]he working of the relevant sections are not phrased in a mandatory way.'[49] The Expert Group were also of the view 'that where there is a failure to make open disclosure that such failure should be the subject of sanctions' and in certain circumstances, failure to disclose should amount to 'either professional misconduct or poor professional performance by the healthcare provider involved, and should be the subject of an inquiry by the relevant professional body.'[50] They further note that 'a deliberate failure to make disclosure, when required by law to do so, should be liable to a criminal sanction.'[51] The Expert Group did not however, elaborate on the rationale for its recommendations.

In its report, the Council do not specifically address the issue of mandatory disclosure. However, the *Crowe Report* provides some guidance. Echoing international concern on the mandating of specific incidents,[52] the *Crowe Report* noted the challenge of creating a separate list of patient safety incidents whereby there is a risk that those incidents not listed may be perceived as not being subject to open disclosure.[53] It also highlighted the difficulties in monitoring compliance,[54] referencing the experience in England and Wales wherein the Care Quality Commission (CQC) has responsibility for regulating the statutory duty of candour in that jurisdiction. Space prohibits a detailed consideration of the experience of mandatory disclosure in England and Wales, but the regulations in that jurisdiction and their implementation provide a useful case study.[55] Finally, the *Crowe Report* also highlighted stakeholder concerns in relation to the 2019 Bill, namely doubt that the legislation would be effective in assisting with culture change and could potentially be counterproductive.[56]

As is the case with many other areas of healthcare law and practice, these arguments highlight the importance of achieving a balance between appropriate regulation and ensuring patient safety.

Conclusion

It is well established that open disclosure is the ethical and morally appropriate thing to do following a patient safety incident. Open disclosure is an integral part of patient safety and patient rights. It is also an important aspect of creating a just culture. Despite the strides made toward cultivating a culture of openness and honesty, the implementation of open disclosure in Ireland has not been without its challenges. Most notably, the restrictive nature of the 2017 Act contradicts best practice open disclosure principles. Similarly, the 2019 Bill which will introduce mandatory disclosure prescribes a procedure for disclosure. Ms Justice Irvine, writing extrajudicially, has previously noted 'the effectiveness of these laws very much depends on the way they are drafted.'[57] Whilst there is a need for frameworks for formal processes, measures which restrict informal conversations and discussions are not desirable. Additionally, as has been argued previously, open disclosure works best where the legal and ethical frameworks operate in tandem. As such, it is argued that broader legislative protection for conversations which may take place outside of the prescribed processes should be provided.

The argument for a clear and consistent approach to open disclosure is straightforward – where multiple sources (legislation, professional guidance, policies) repeat the same message and provide a supportive framework, the goal of implementing open disclosure is more likely to be achieved.[58] Thus, it is argued that it is time for a unified approach.

In this regard, the international experience can assist with some 'learning points', which include:

- Broader protections should apply to open disclosure, which would be likely to have the effect of increasing compliance and contributing to the overarching goal of patient safety.
- Legislation should support the open disclosure process, rather than being administratively burdensome. Where patients perceive the open disclosure process to be an exercise in minimising liability, the benefits of open disclosure are unlikely to be achieved.
- In combination with legislation, an approach which targets a change in culture (for example, policies; training; and support services), would encourage physicians to embrace an ethos of open disclosure.
- Hospitals supporting healthcare professionals through the disclosure process are likely to have a far greater impact. Thus, healthcare practitioners should be able to avail of appropriate supports throughout the disclosure process.[59]

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1 R Lamb, 'Open disclosure: The only approach to medical error' (2004) 13 Quality and Safety in Healthcare 3. Open disclosure is defined by the HSE as: '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 ongoing care and treatment, learning and the steps being taken by the health services provider to try and prevent a recurrence of the incident.' See, Health Service Executive, *Open Disclosure Policy: Communicating with Patients Following Patient Safety Incidents* (2019) p.7.

2 Oliver Quick, *Regulating Patient Safety: The End of Professional Dominance* (Cambridge University Press 2018) p.144.

3 See for example, Australian Commission on Safety and Quality in Healthcare, *Australian Open Disclosure Framework* (2013) 1; Canadian Patient Safety Institute, *Canadian Disclosure Guidelines: Being Open with Patients and Families* (2011); Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, Reg.20.

4 Department of Health and Children, *Report of the Commission on Patient Safety and Quality Assurance* (2008) p.82.

5 Open disclosure was piloted by the HSE in Cork University Hospital and the Mater Misericordiae University Hospital, Dublin, from 2010 to 2012. See, Jane Pillinger, *Evaluation of the National Open Disclosure Pilot* (2016).

6 Health Service Executive, *Open Disclosure Policy: Communicating with Patients Following Patient Safety Incidents* (2019) available at https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/opendisclosure/hse-open-disclosure-full-policy-2019.pdf (last accessed 24 November 2021); Additionally, the National Open Disclosure Office and the National Open Disclosure Steering Committee were established in 2019. In his scoping inquiry into CervicalCheck, Professor Gabriel Scally

was critical of the 2013 HSE open disclosure policy and made several recommendations in respect of same. See, G. Scally, *Scoping Inquiry into CervicalCheck Screening Programme* (2018) available at https://www.gov.ie/en/collection/030b53-scoping-inquiry-into-the-cervicalcheck-screening-programme/.

7 Medical Council, 'Guide to Professional Conduct and Ethics for Registered Medical Practitioners' (8th edn, 2016) para.6.72, p.43.

8 Sch.1 of the 2019 Bill contains a list of notifiable incidents.

9 See for example, Martin Smith and Heidi Forster, 'Morally Managing Medical Mistakes' (2000) 9(1) Cambridge Quarterly of Healthcare Ethics p.38; Marlynn Wei, 'Doctors, apologies, and the law: an analysis and critique of apology laws (2007) 39(4) Journal of Health Law p.107; Anna Mastroianni and others, 'The flaws in state "apology" and "disclosure" laws dilute their intended impact on malpractice suits' (2010) 29(9) Health Affairs p.1611.

10 Jane Pillinger, *Evaluation of the National Open Disclosure Pilot* (2016) p.48. Other barriers identified included: fear of loss of reputation or career opportunities; absence of training in how to disclose; lack of institutional support; and personal issues faced by physicians such as guilt and embarrassment.

11 Civil Liability (Amendment) Act 2017, s.10.

12 S.I. No. 237 of 2018.

13 For a full discussion see, Deirdre Madden and Mary-Elizabeth Tumelty, 'Open disclosure of patient safety incidents: legislative developments in Ireland' (2019) 25(2) Medico-Legal Journal of Ireland p.76.

14 Independent Patient Safety Council, *Recommendations on a National Policy Framework for Open Disclosure in Healthcare in Ireland* (2021), p.27.

15 See for example, Rick Iedema and others, 'The National Open Disclosure Pilot: Evaluation of a Policy Implementation Initiative' (2008) 188(7) Health Care 397; R. Harrison and others, 'Enacting open disclosure in the UK National Health Service: A qualitative exploration' (2017) 23(4) Journal of Evaluation in Clinical Practice p.713.

16 Alice Holmes and others, 'The potential for inadvertent adverse consequences of open disclosure in Australia: when good intentions cause further harm' (2019) 59(4) Medicine, Science and the Law 265, pp.267-268. According to Holmes et al. an 'ideal' disclosure process includes: early recognition of the incident, making the disclosure once sufficient information has been gathered whilst avoiding delay, recognising that the disclosure process is ongoing rather than a single meeting, reflecting on the incidents, identifying steps to prevent recurrence, and communicating this with the wider healthcare community, providing

an honest account and an apology to the patient.

17 Doug Wojcieszak and others, 'The Sorry Works! Coalition: Making the case for full disclosure' (2006) 32(6) The Joint Commission Journal on Quality and Patient Safety p.344.

18 Health Service Executive, 'Open Disclosure Policy: Communicating with Patients Following Patient Safety Incidents' (2019) p.10.

19 Medical Council, 'Guide to Professional Conduct and Ethics for Registered Medical Practitioners' (8th edn, 2016) para. 6.72, p.43.

20 See for example, Thomas H Gallagher and others, 'Patients' and physicians' attitudes regarding the disclosure of medical errors' (2003) 289(8) JAMA 1001; David M Studdert and others, 'Legal aspects of open disclosure II: attitudes of health professionals – findings from a national survey' (2010) 193(6) Medical Journal of Australia p.351.

21 The Patient Safety (Notifiable Patient Safety Incidents) Bill 2019, s.3.

22 Schedule 1 of the 2019 Bill lists the 'notifiable incidents' which are subject to mandatory disclosure.

23 The Patient Safety (Notifiable Patient Safety Incidents) Bill 2019, s.8.

24 The Patient Safety (Notifiable Patient Safety Incidents) Bill 2019, s.18(3).

25 The Patient Safety (Notifiable Patient Safety Incidents) Bill 2019, s.10.

26 The Patient Safety (Notifiable Patient Safety Incidents) Bill 2019, s.49(4).

27 Khatri et al. define a 'just culture' as '[a]n environment supportive of open dialogue to facilitate safer practices', Naresh Khatri and others, 'From a blame culture to a just culture in health care' (2009) 34(4) Health Care Management Review 312 at 315.

28 Bianca Perez and others, 'Understanding the barriers to physician error reporting and disclosure: a systemic approach to a systemic problem' (2014) 10(1) Journal of Patient Safety p.45.

29 Deirdre Madden and Mary-Elizabeth Tumelty, 'Open disclosure of patient safety incidents: legislative developments in Ireland' (2019) 25(2) Medico-Legal Journal of Ireland p.76.

30 See for example, Harvey Marcovitch, 'Governance and professionalism in medicine: a UK perspective' (2015) 313(18) JAMA 1823; Oliver Quick, *Regulating Patient Safety: The End of Professional Dominance* (Cambridge University Press 2018).

31 The World Health Organisation (WHO) declared COVID-19 a pandemic in March 2020. At the time of writing (24 November 2021), in Ireland, there have been 542,000 cases of

COVID-19 recorded, and sadly 5,652 deaths.

32 The Independent Patient Safety Council was appointed by the Minister for Health and convened for the first time on 27 January 2020. The terms of reference of the group include: providing policy advice and guidance on patient safety issues to the Department of Health; undertaking work on the basis of a work programme in support of national policy priorities; supporting the promotion of a culture of patient safety throughout the health services; examining the governance and implementation of policies; identifying best practices in relation to patient safety matters under consideration; and submitting reports to the Minister in relation to its activities https://www.gov.ie/en/publication/6d9878-the-independent-patient-safety-council/

33 Department of Health, *Expert Group Report to Review the Law of Torts and the Current Systems for the Management of Clinical Negligence Claims* (2020) available at https://www.gov.ie/en/publication/ffb23-expert-group-report-to-review-the-law-of-torts-and-the-current-systems-for-the-management-of-clinical-negligence-claims/ (last accessed 29 November 2021).

34 Crowe, *Final Report to the Department of Health: Evidence to Support the Independent Patient Safety Council for the Development of Recommendations on a National Policy Framework for Open Disclosure in Healthcare in Ireland* (2021) available at https://www.gov.ie/en/publication/6d9878-the-independent-patient-safety-council/#terms-of-reference (last accessed 29 November 2021).

35 Independent Patient Safety Council, *Recommendations on a National Policy Framework for Open Disclosure in Healthcare in Ireland* (2021), p.4.

36 *Ibid* p.6.

37 *Ibid* p.9.

38 *Ibid* p.11.

39 *Ibid* p.13.

40 *Ibid* p.15.

41 *Ibid* p.2.

42 *Ibid* p.14.

43 Crowe, *Final Report to the Department of Health: Evidence to Support the Independent Patient Safety Council for the Development of Recommendations on a National Policy Framework for Open Disclosure in Healthcare in Ireland* (2021) p.5 available at https://www.gov.ie/en/publication/6d9878-the-independent-patient-safety-council/#terms-of-reference (last accessed 29 November 2021).

44 Independent Patient Safety Council, *Recommendations on a National Policy Framework for Open Disclosure in Healthcare in Ireland* (2021), p.15. See also, Gabriel Scally, *Review of the Implementation of Recommendations of the Scoping Inquiry into the CervicalCheck Screening Programme* (2020) p.11 available at https://www.gov.ie/en/collection/030b53-scoping-inquiry-into-the-cervicalcheck-screening-programme/ (last accessed 29 November 2021); National Open Disclosure Programme, *Annual Report* (2019) available at https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/opendisclosure/national-open-disclosure-programme-publications.html (last accessed 29 November 2021).

45 *Ibid.*

46 Medical Council, 'Guide to Professional Conduct and Ethics for Registered Medical Practitioners' (8th edn, 2016) para. 6.72, p.43.

47 Oliver Quick, *Regulating Patient Safety: The End of Professional Dominance* (Cambridge University Press 2018) 145.

48 National Advisory Group on the Safety of Patients in England, *A promise to learn – a commitment to act: Improving the safety of patients in England* (2013) available at https://www.gov.uk/government/publications/berwick-review-into-patient-safety (last accessed 29 November 2021).

49 Expert Group Report to Review the Law of Torts and the Current Systems for the Management of Clinical Negligence Claims available at https://www.gov.ie/en/publication/ffb23-expert-group-report-to-review-the-law-of-torts-and-the-current-systems-for-the-management-of-clinical-negligence-claims/ (last accessed 25 November 2021).

50 *Ibid* p.10.

51 *Ibid* pp.10-11.

52 See for example, J.D. Wijesuriya and D. Walker, 'Duty of candour: a statutory obligation or just the right thing to do?' (2017) 119(2) British Journal of Anaesthesia p.175.

53 Expert Group Report to Review the Law of Torts and the Current Systems for the Management of Clinical Negligence Claims at p.28.

54 Crowe, *Final Report to the Department of Health: Evidence to Support the Independent Patient Safety Council for the Development of Recommendations on a National Policy Framework for Open Disclosure in Healthcare in Ireland* (2021) pp.23-24.

55 For a discussion on the shortcomings of the regulations in England and Wales see, Ruth Stirton, 'The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: A

Litany of Fundamental Flaws?' (2017) 80(2) Modern Law Review p.299.

56 Crowe, *Final Report to the Department of Health: Evidence to Support the Independent Patient Safety Council for the Development of Recommendations on a National Policy Framework for Open Disclosure in Healthcare in Ireland* (2021) p.31.

57 Ms Justice Mary Irvine and Laurenz Boss, 'Apologies, Disclosure and the Duty of Candour: A Discussion' (2019) 25(2) Medico-Legal Journal of Ireland pp.69, 72.

58 Oliver Quick, *Regulating Patient Safety: The End of Professional Dominance* (Cambridge University Press 2018) p.85.

59 Tanja Manser and Sven Staender, 'Aftermath of an adverse event: supporting healthcare professionals to meet patient expectations through open disclosure' (2005) 49(6) Acta Anaesthesiologica Scandinavica p.728. Manser and Staender argue, '[t]he better the support for the care-givers, the better they can meet the needs of the patient and family members.'