Open Disclosure in Healthcare Law

Current Position and Future Direction

Simon Mills BL

Dublin Castle, 12th September 2018

Overview

- Schemes for Open Disclosure
  - Professional Regulation
  - Civil Liability (Amendment) Act
  - Patient Safety Bill
- Pausing for thought?
  - Is there already a duty of candour?
  - Does Open Dislocure work reliably

Professional Regulation - I

- Medical Council *Guide to Professional Conduct and Ethics (2016)*

67.1 Open disclosure is supported within a culture of candour. You have a duty to promote and support this culture and to support colleagues whose actions are investigated following an adverse event. If you are responsible for conducting such investigations, you should make sure they are carried out quickly, recognising that this is a stressful time for all concerned.

67.2 Patients and their families, where appropriate, are entitled to honest, open and prompt communication about adverse events that may have caused them harm.

Professional Regulation – II

- Not currently in **Nursing and Midwifery Board** Professional Guidance: instead, appears in "Supporting Guidance" to Principle 3

  "Safe, quality practice is promoted by nurses and midwives actively participating in incident reporting, adverse event reviews and open disclosure."

- **Pharmaceutical Society of Ireland**:

  "Ensure that he/she practices, and encourages others to operate, in as open and transparent manner as possible" (Principle Six)

- CORU

  Appears in *Framework Code of Ethics* (reworded in some Codes)

Professional Regulation - III

- Implications of the presence of Open Disclosure in Codes of Conduct:
  1. Instructive
  2. Normative
  3. Capacity of Regulators to deal with breaches

- A breach of code of conduct can be grounds for complaint:
  - Fitness to Practice Hearings
  - Can be dealt with in a number of ways including significant punishments for serious breaches.

Civil Liability (Amendment) Act 2017 - I

- Part IV of the Act:
  - the legal framework to support voluntary open disclosure
  - applies to all patient safety incidents including near misses and no-harm events.
  - provides for an open and consistent approach to communicating with patients and their families
  - providing an apology, as appropriate,

Civil Liability (Amendment) Act 2017 – II

- Designed to give legal protection for the information and apology made to a patient during open disclosure once it is made in line with the legislation.
- Apology cannot be used in litigation against the provider. The approach
- Intended to create a positive voluntary climate for open disclosure.

Civil Liability (Amendment) Act 2017 – III

- Legislation commenced on 3 July 2018 and Regulations to accompany the Act signed on 4 July 2018.
- Regulations come into play on 23 September 2018
  - *Schedule 1*: parameters of Open Disclosure Meetings
  - *Schedule 2*: non-attendance by persons at Open Disclosure Meetings
- Scope for seeing how these regulations change the landscape?

Is there an existing legal Duty of Candour?

- Much talk about a **statutory** duty of candour.
  - There is – we have seen - a regulatory duty of candour
  - It seems probable that there is an ever greater recognition for the obligation of candour and increasing means to allow that duty to play out in an organized fashion.

- Would courts recognize that a duty of candour is one of the duties healthcare professionals owe to their patients as a matter of law?
  - English cases: *Naylor* (1987), *Powell* (1998)
  - Constitutional law?

Patient Safety Bill 2018 - I

- “mandatory open disclosure”: the required disclosures of any **serious** patient safety incident…any **unintended** or **unanticipated** injury or harm to a service user that occurred **during the provision of a health service.**

- Modelled on the approach taken by
  - UK Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20 (Duty of Candour)
  - Scottish Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016.

Patient Safety Bill 2018 - II

- Not intended to include ‘near misses’
- Safeguards for professionals who make the open disclosure
- Creates a Criminal Offence:
  - A registered **health service provider*** shall be guilty of an offence if the health service provider fails to make a mandatory open disclosure in accordance with Section 5 of the Act…
  - A fine (up to €7000) or imprisonment (up to 6 months) or both,

* 'health service provider' is **very** widely defined

Challenges for Open Disclosure? - I

- Imperative that the implementation phase of open disclosure does not produce cumulative problems:
  - a poorly developed understanding of open disclosure principles
  - poorly developed execution of the open disclosure process
- Extra training, research and support may be needed to ensure that openly disclosing clinical error will not produce a backlash as a result of
  - errors of process,
  - inconsistencies in disclosure, or
  - inadvertent errors in communication (too much or little).

Challenges for Open Disclosure? - II

- Slightly different approaches in 2017 Act and 2018 Bill
  - patient safety incident in the Act and a serious patient safety incident in the Bill: confusion may be obviated by clear guidance.
- Will criminalisation of organisations or practitioners “encourage” disclosure any more effectively than current regime?
  - What is the position of the person who does not disclose information in the present climate?

Thank you

smills@lawlibrary.ie