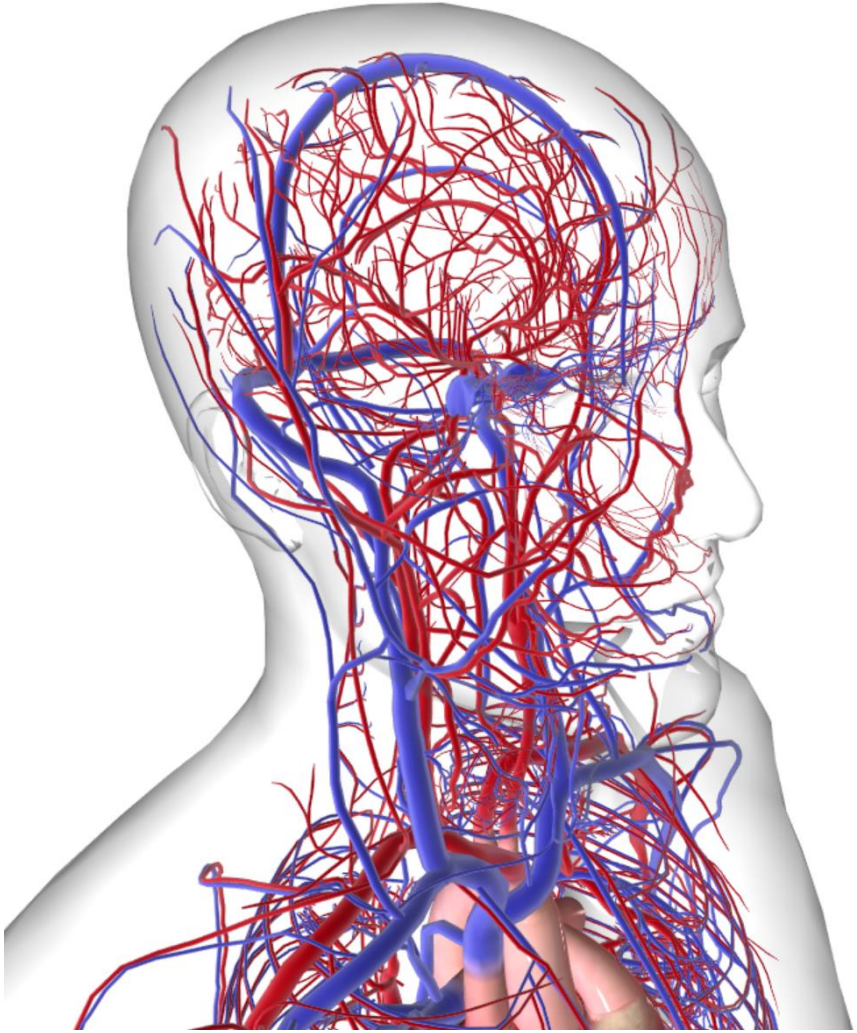
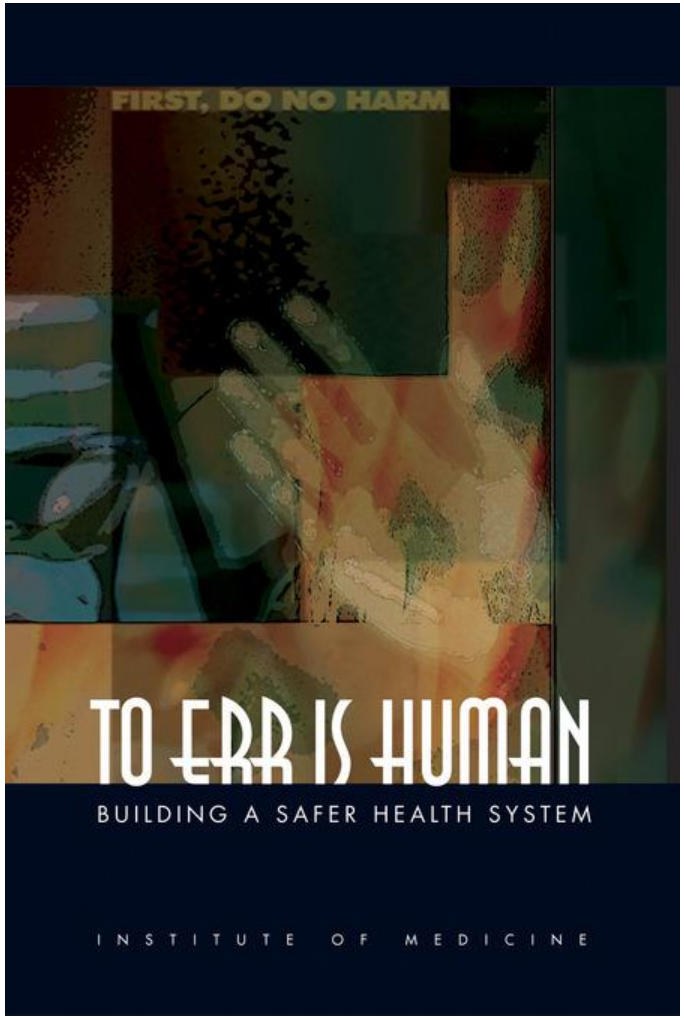
Open Disclosure in the Medical Negligence landscape

Sean Tierney

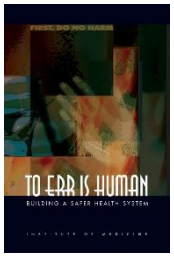
IMO November 2019

https://uglymugs.ie/wp-content/uploads/justice-626461_1920.jpg





Kohn, Corrigan, Donaldson . Institute of Medicine 2000. *To Err Is Human: Building a Safer Health System*.
Washington, DC: The National Academies Press.



Kohn, Corrigan, Donaldson . Institute of Medicine 2000. *To Err Is Human: Building a Safer Health System*.
Washington, DC: The National Academies Press.

"Punitive action is not an effective way to prevent recurrence because large system failures "represent latent failures coming together in an unexpected way." The same mix of factors is unlikely to occur again, and "efforts to prevent specific active errors are not likely to make the system any safer"… "discovering and fixing latent failures, and decreasing their duration, are likely to have a greater effect on building safer systems than efforts to minimize active errors at the point at which they occur"

Just Culture: A Foundation for Balanced Accountability and Patient Safety

Philip G. Boysen II, MD, MBA, FACP, FCCP, FCCM

ABSTRACT

Background: The framework of a just culture ensures balanced accountability for both individuals and the organization responsible for designing and improving systems in the workplace. Engineering principles and human factors analysis influence the design of these systems so they are safe and reliable.

Methods: Approaches for improving patient safety introduced here are (1) analysis of error, (2) specific tools to enhance safety, and (3) outcome engineering.

Conclusion: The just culture is a learning culture that is constantly improving and oriented toward patient safety.

The Ochsner Journal 13:400–406, 2013

Patient Safety Bill

An Roinn Sláinte
DEPARTMENT OF HEALTH

PATIENT SAFETY BILL 2018

A Bill to provide for mandatory open disclosure of serious reportable patient safety incidents, notification of reportable incidents, clinical audit to improve patient care and outcomes and extend the Health Information Quality Authority remit to private health services

5 July 2018

https://health.gov.ie/wp-content/uploads/2018/07/General-Scheme_Patient-Safety-Bill_5-July-2018.pdf

Patient Safety Bill

- Part 1: Preliminary Matters
- Part 2: Patient Safety Incidents
- Part 3: Clinical Audit
- Part 4: Amendment of Health Act 2007 (HIQA Remit Extension
- Part 5: Offences
- Part 6: Miscellaneous

https://health.gov.ie/wp-content/uploads/2018/07/General-Scheme_Patient-Safety-Bill_5-July-2018.pdf

Mandatory Open disclosure

Serious patient safety incidents

- require mandatory open disclosure
- **obligation on provider**
- provisions for open disclosure in Part 4 Civil Liabilities (Amendment) Act 2017

https://health.gov.ie/wp-content/uploads/2018/07/General-Scheme_Patient-Safety-Bill_5-July-2018.pdf

Patient Safety Bill - Part 2: Patient Safety Incidents

Forum Position

We suggest that **Mandatory Open Disclosure** be normally carried out in the manner described in the HSE Policy on Open Disclosure. This has the advantage of being more in keeping with what was envisaged in the Madden Commission Report and there are already a large number of staff trained in its application.

Serious patient safety incidents

- unintended or unexpected incident or harm that occurred in the provision of a health service including:

  (a) death

  (b) “severe harm”,

  (c) harm

  (d) or such serious patient safety incidents as may be prescribed by the Minister by regulation under this section.

https://health.gov.ie/wp-content/uploads/2018/07/General-Scheme_Patient-Safety-Bill_5-July-2018.pdf

Patient Safety Bill - Part 2: Patient Safety Incidents

Serious patient safety incidents

Severe Harm

a permanent lessening of bodily, sensory, motor, physical or intellectual functions (“severe harm”),

https://health.gov.ie/wp-content/uploads/2018/07/General-Scheme_Patient-Safety-Bill_5-July-2018.pdf

Patient Safety Bill - Part 2: Patient Safety Incidents

Serious patient safety incidents

Harm (which is not severe) but which results in

(i) increase in treatment

(ii) changes to the structure of the body

(iii) reduced life expectancy

(iv) impairment of sensory, motor or intellectual functions > 28 days,

(v) pain or psychological harm for a continuous period of at least 28 days,

https://health.gov.ie/wp-content/uploads/2018/07/General-Scheme_Patient-Safety-Bill_5-July-2018.pdf

Patient Safety Bill - Part 2: Patient Safety Incidents

Forum Position

List of Reportable Events which will be subject to Mandatory Open Disclosure

The creation of a separate list in addition to the existing HSE Serious Reportable Events (SRE) list would lead to confusion in the system. **There should be one list**

Clinical Audit

- aggregate data must be published
- content (including records created) are
  - FOI exempt
  - Discovery exempt

Include

- NOCA audits
  - INOR
  - Hip #
  - Trauma
  - Critical care
  - Perinatal

Exclude

- unit based
- Retrospective
- Observational
- Non-systematic
- = PCS in many cases

Forum Position

Reported Outcome Measures and that all clinical audit, completed in accordance with the Medical Council guidance on maintaining professional competence, is provided with FOI exemptions and legal protections.

Penalties

(2) A registered health service provider guilty of an offence under subsection 1 is liable to:

(a) on summary conviction to a fine not exceeding €5,000 or imprisonment not exceeding 3 months or both,

or

(b) on conviction on indictment to a fine not exceeding €7,000 or imprisonment for a term not exceeding 6 months or both.

https://health.gov.ie/wp-content/uploads/2018/07/General-Scheme_Patient-Safety-Bill_5-July-2018.pdf

Patient Safety Bill - Part 5: Offences

Candour

- **obligation & penalties on “registered provider”**
- “modelled on the approach taken in the UK (Duty of Candour)
- UK Duty of Candour applies to NHS Bodies & care providers registered with Care Quality Commission
- places the onus on health services providers not on individual health practitioners *

* Reddan & Clarke McDowell Purcell 2018

Next steps:

Incorporate the key changes proposed by the Forum of Postgraduate training bodies

Apply responsibility for Mandatory Disclosure on healthcare provider organisation

Avoid criminalising error

@theseant
stierney@rcsi.ie

Open Disclosure in the Medical Negligence landscape

Sean Tierney

IMO November 2019

@theseant
stierney@rcsi.ie

https://uglymugs.ie/wp-content/uploads/justice-626461_1920.jpg