Recent legislative developments in patient safety

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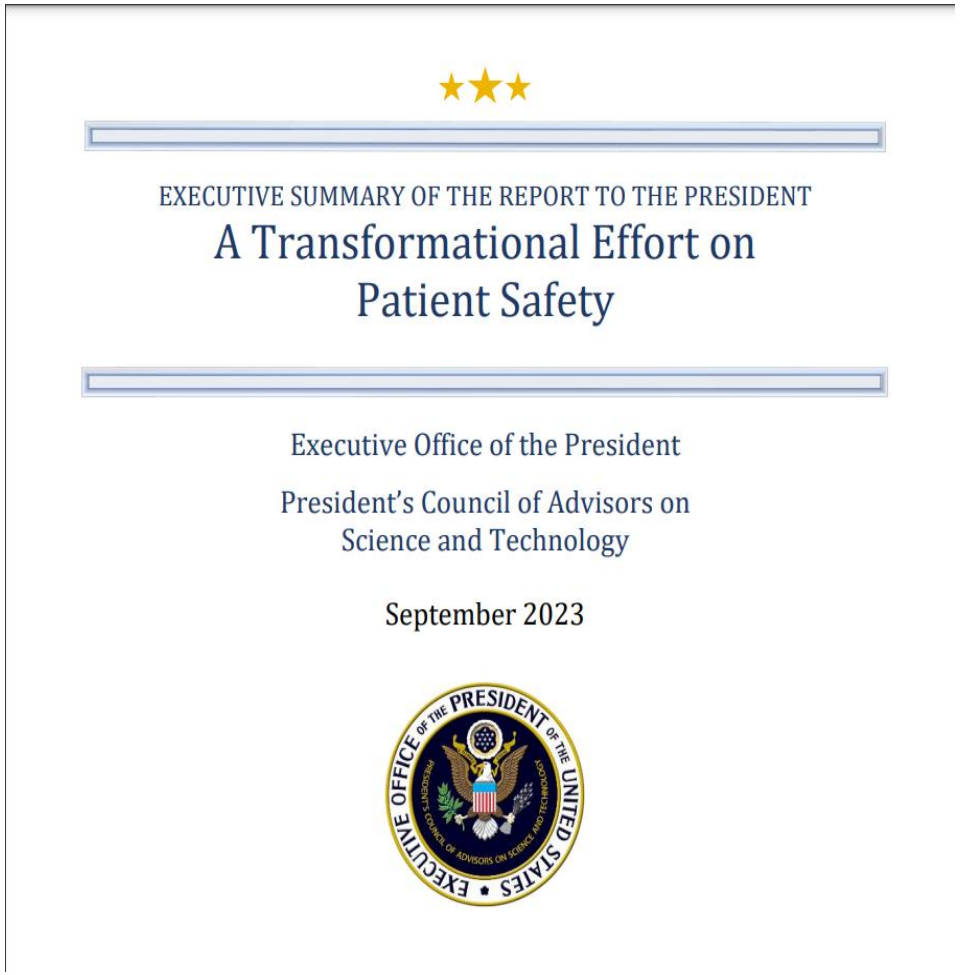
- Patient safety is a global health issue with multiple reports, research studies, policies, handbooks, recommendations, training modules etc.
- Doctors, nurses, and other healthcare staff are passionate, dedicated professionals who care deeply for the patients in their care. Nonetheless, dangerous and preventable events continue to occur.
- Significant progress has been made in understanding and developing evidence-based practices to address the root causes of many categories of avoidable adverse outcomes.
- **Is there a role for law in improving safety & quality?**



- Law can play a role in improving safety and quality of healthcare not only through liability and sanctioning mechanisms when things go wrong, but more proactively, in helping to create the conditions for patient-centred, safe, effective, efficient and equitable healthcare.

- Many patient safety and quality improvement initiatives that involve legal interventions are also designed to achieve greater transparency and accountability, leading to improved trust and better partnership with patients.

Learning from mistakes:

- Health care can be opaque to those outside it with very complex, hierarchical structures and perceived failure to learn from mistakes or take accountability.

- Service providers are expected to be transparent with patients and the public in terms of how treatment decisions are made, how much care costs, whether conflicts of interest exist, and when and why errors and unexpected outcomes of care occur.

- This is motivated in part by the expectation that openness will help improve quality.

"I just wanted them to say sorry…"

- Many jurisdictions have a legal duty of candour which obliges providers to be open with patients and families regarding errors and outcomes of care which have led to harm.
- This is designed to foster trust, bring about a culture of honesty, openness and safety, and lead to quality improvement as part of an early response and investigation of an adverse incident, which will hopefully help prevent its recurrence.
- Telling patients the truth is a professional and ethical duty, but it is difficult - it can cause self-doubt, self-recrimination, embarrassment, shame, fear and anxiety.
- It has often been translated into legal complexity by numerous detailed clauses in legislation. This can result in challenges with definitions, applicability and enforcement.
- In some jurisdictions where openness is expected, there is evidence to show that the levels of claims (in number and value) decreases but this is not universally true… there is also a counter argument that apology laws increase rather than limit medical malpractice liability risk.

Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023:

- Open Disclosure (OD) is currently voluntary under the Civil Liability (Amendment) Act 2017 Part 4 but is strongly encouraged by national HSE policies and ethical guidelines for medical practitioners from the IMC.
- The recently enacted Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 provides for mandatory OD by doctors of serious incidents such as a medication error, retention of a foreign object in a patient after surgery, transfusion of incompatible blood, wrong site surgery. All notifiable incidents listed in Schedule 1 Part 1 resulted in death. Schedule 1 Part 2 requires OD where a baby requires therapeutic hypothermia.
- The Minister may add to the list over time, subject to certain criteria being met. These incidents must also be notified to appropriate health regulators.
- The Act sets out a detailed framework for who, what, when and how the disclosure should be made. If disclosure is made within the legal framework provided in the Act, the information disclosed will not invalidate professional indemnity insurance, constitute an admission of liability or fault or be admissible in proceedings (clinical negligence or complaint to IMC).
- The Act has not yet been commenced but this is expected within the next 6-9 months.

Item	Notifiable Incident
1.1	Surgery performed on the wrong patient resulting in unintended and unanticipated death which did not arise from, or was a consequence of, an illness, or an underlying condition, of the patient, or having regard to any such illness or underlying condition, was not wholly attributable to that illness.
1.2	Surgery performed on the wrong site resulting in unintended and unanticipated death which did not arise from, or was a consequence of, an illness, or an underlying condition, of the patient, or having regard to any such illness or underlying condition, was not wholly attributable to that illness.
1.3	Wrong surgical procedure performed on a patient resulting in an unintended and unanticipated death which did not arise from, or was a consequence of, an illness, or an underlying condition, of the patient, or having regard to any such illness or underlying condition, was not wholly attributable to that illness.
1.4	Unintended retention of a foreign object in a patient after surgery resulting in an unanticipated death which did not arise from, or was a consequence of, an illness, or an underlying condition, of the patient, or having regard to any such illness or underlying condition, was not wholly attributable to that illness.
1.5	Any unintended and unanticipated death occurring in an otherwise healthy patient undergoing elective surgery in any place or premises in which a health services provider provides a health service where the death is directly related to a surgical operation or anaesthesia (including recovery from the effects of anaesthesia) and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.
1.6	Any unintended and unanticipated death occurring in any place or premises in which a health services provider provides a health service that is directly related to any medical treatment and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.
1.7	Patient death due to transfusion of ABO incompatible blood or blood components and the death was unintended and unanticipated and which did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.
1.8	Patient death associated with a medication error and the death was unintended and unanticipated as it did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.
1.9	An unanticipated death of a woman while pregnant or within 42 days of the end of the pregnancy from any cause related to, or aggravated by, the management of the pregnancy, and which did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.

Item	Notifiable Incident
1.10	An unanticipated and unintended stillborn child where the child was born without a fatal foetal abnormality and with a prescribed birthweight or has achieved a prescribed gestational age and who shows no sign of life at birth, from any cause related to or aggravated by the management of the pregnancy, and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the child.
1.11	An unanticipated and unintended perinatal death where a child born with, or having achieved, a prescribed gestational age and a prescribed birthweight who was alive at the onset of care in labour, from any cause related to, or aggravated by, the management of the pregnancy, and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the child or an underlying condition of the child.
1.12	An unintended death where the cause is believed to be the suicide of a patient while being cared for in or at a place or premises in which a health services provider provides a health service whether or not the death was anticipated or arose from, or was wholly or partially attributable to, the illness or underlying condition of the patient.

Part 2

Item	Notifiable Incident
2.1	A baby who— (a) in the clinical judgment of the treating health practitioner requires, or is referred for, therapeutic hypothermia, or (b) has been considered for, but did not undergo therapeutic hypothermia as, in the clinical judgment of the health practitioner, such therapy was contraindicated due to the severity of the presenting condition.

Transparency & public reporting of quality data:

- Legal obligation in some countries to report clinical outcomes - rationale is that it allows patients to "vote with their feet," which in turn may press providers to compete on quality. However, health insurance plans often limit patients' choices about where to obtain care and clinical circumstances also act as a constraint.

- Even for elective care, publicly reported quality data appear to have minimal effect on the choices of patients or referring providers. Patients tend to choose based on convenience more than quality.

- Publishing the data may motivate hospitals to pursue patient safety improvements so that they may reap the reputational benefits associated with being perceived as having a commitment to quality, continuous improvement, and transparency. However, publishing league tables of outcomes in a public healthcare environment is more problematic as hospitals may have less control over their budget and patients have less choice.

- Is there evidence that this has led to an improvement in quality? Hard evidence of its effects on quality and safety remains elusive.

Importance of clinical audit:

- *"Clinical audit arguably constitutes the single most important method which any healthcare organisation can use to understand and ensure the quality of the service that it provides. It is one of the principal methods used to monitor clinical quality and the results provided by clinical audit are a source of indispensable information to patients, the public, clinicians and healthcare managers. It also provides a powerful mechanism for ongoing quality improvement, highlighting incidences where standards are not met and identifying opportunities for improvement."* Commission on Patient Safety (2008)

- Concern that clinicians may be hesitant to carry out audits and other QI and QA activities in circumstances where the audit data could give rise to their subsequent involvement in clinical negligence cases. Look-back reviews or audits of practice may show areas requiring improvement but that is with the benefit of hindsight and should not be equated with negligence.

- Once commenced, the new Patient Safety Act will provide legal protection for clinical audit, but eligibility criteria are narrow, complicated and overly burdensome and may not include small local/departmental audits, other QI activities such as benchmarking exercises, peer reviews, unpublished audits, or other patient safety collaboratives.

- It would have been preferable to include all QI and QA activities and to provide for a definition that is less prescriptive and more flexible.

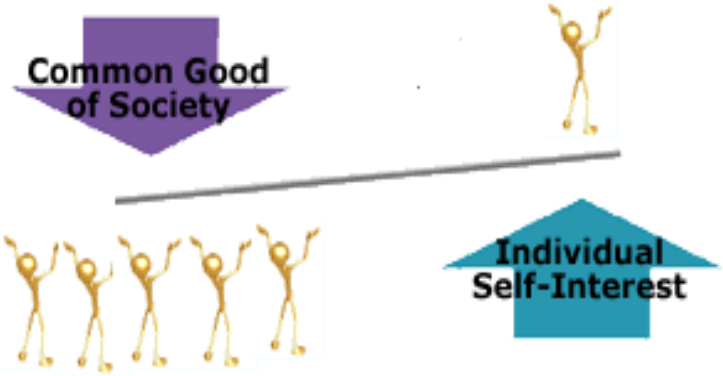
A bigger conversation is required:

- Where is the balance to be struck between societal aims of improving healthcare and the legal rights of patients to use information gleaned from such activities to assist their claims for compensation?

- In some states, the legislature has explicitly chosen to place the goal of improving the quality of health care ahead of any litigation advantage that may accrue to a party using reports generated for QI purposes and therefore such documents are precluded from disclosure.

- For example, in Nova Scotia, the Quality Improvement Protection Act 2015 provides for the formation of QI committees to carry out QI activities which are part of an approved program for the purpose of assessing, investigating, evaluating or making recommendations with a view to improving the quality of health services. Information which is communicated for the purpose of carrying out a QI activity is not admissible in legal proceedings.

- Such provisions are in the public interest in continuing to enable and support vital quality assurance and improvement activities. These legal protections will not disadvantage individual patients who remain free to pursue legal action or rely on the complaint process if they so wish and can of course still glean substantial information from medical records, policy documents etc.



Reform of liability system:

"The number of outstanding clinical claims that are yet to be resolved as well as their associated estimated costs are at a record high in Ireland. By the end of 2022, the Irish government face 3875 active clinical claims which are expected to cost €3.85 billion in total. This does not account for future claims yet to be brought. The financial burden will be borne by the Irish healthcare system which is already facing unprecedented pressures on its services and staff. If current trends continue, the opportunity costs of the current medicolegal landscape will impact the future provision of healthcare. Aside from the financial consequences, clinical claims have numerous negative impacts on all parties involved."

Forrest C, O'Donoghue K, Collins DC*, et al* 'Current Irish medicolegal landscape: an unsustainable trajectory' *BMJ Open Quality* 2023

- Most frequently cited plaintiff aims in medical negligence litigation are an explanation, an apology, and an assurance that it won't happen again – the adversarial nature of medical negligence actions is not conducive to learning or to healing relationships between patients and doctors.

- Do no-fault compensation (NFC) systems do better in improving safety and quality?

- Such systems provide more equitable access to compensation more efficiently than malpractice systems.

- However, all NFC schemes seem to require some level of causation to be proved for a patient to qualify for access to the scheme. When there is a question of causation, there is legal challenge and argument. NFC does not eliminate legal disputes; it merely re-defines them or moves the goal posts.

- In theory these schemes should improve patient safety by enabling doctors to disclose iatrogenic injury through the removal of personal liability and decoupling compensation from disciplinary procedures. They should also improve patient safety by enabling the pooling and sharing of information about medical errors and by reframing the compensation process as a patient safety strategy rather than a risk management strategy.

- In reality it is difficult to establish strong possible causal pathways between NFC and improvement in patient safety because assessing a unitary influence on practice is always going to be challenging given the myriad of factors at play.

- Despite widespread interest in malpractice reform as a means of slowing the rate of growth of healthcare costs, separating accountability from compensation does not *appear* to make all that much difference to doctors. Processes to hold doctors to account are important in any medical regulatory structure, but they can instil fear and drive behaviour regardless of the system of compensation. For example, it has been argued that New Zealand's no-fault system may drive over-utilisation as much as any malpractice system.

Ireland:

- Expert Group Report to Review the Law of Torts and the Current Systems for the Management of Clinical Negligence Claims 2020:

- "Though there are benefits in a no-fault system, in that negligence and breach of duty do not have to be established, we are of the view that a number of disadvantages outweigh such benefit. Firstly, it would have to be established that the "*fault*" caused the injury. In many cases, this is as fraught an issue as establishing liability. Secondly, as referred to, the introduction of a no-fault system could be in breach of a person's constitutional rights. Thirdly, concern was expressed that a no-fault system could lead to lessons not being learnt. Where fault is identified, this can lead to prevention of such events occurring again."

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/

Conclusion:

- ✓ Law has an important role to play in improving quality in healthcare if drafted with that objective.
- ✓ Not a 'one size fits all' approach in complex healthcare systems that are often resistant to change and that function at multiple interconnected levels – what works in one setting may not work elsewhere and this can be difficult for the law to countenance.
- ✓ Fears about litigation and complaints have real impact on clinical practice – the 'chilling effect'...
- ✓ Financial incentives don't necessarily work very well in publicly funded healthcare systems.
- ✓ No-fault litigation systems do not (yet) provide sufficient data on safety & quality improvement.