MASON HAYES & CURRAN

HEALTH

Managing risk in a healthcare setting

Key takeaways

Dublin London New York San Francisco

MHC.ie

MASON HAYES & CURRAN

Managing risk in a healthcare setting

Key takeaways

Healthcare organisations work within an increasingly complex risk landscape.

The landscape is shaped by clinical decision-making, governance duties, transparency obligations and regulatory expectations. All of which is against a backdrop of heightened public scrutiny. We share some of the key takeaways from our recent webinar on managing risk in a healthcare setting. The discussion focused on the role and responsibilities of board members and what this means in practice for healthcare organisations. It also looked at how to approach investigations in a way that is fair and aligned with legal requirements. The session concluded with an overview of coroners' inquests, including when they arise and what they involve for providers.

Across all three sessions, one message came through clearly. Risk management is not only about responding when something goes wrong. It is about having the correct structures in place so incidents are handled properly. This, in turn, supports a consistent and lawful approach, while helping to maintain public trust and protect patient safety.

CONTENTS

MASON HAYES & CURRAN

KEY THEMES FROM THE WEBINAR

01

Governance

Directors can delegate their duties and authority, but they cannot delegate their responsibilities.

For many healthcare organisations, risk management starts with the board. Clarity around the board's roles, duties and responsibilities is essential.

Directors' duties have developed through common law, and over time have been codified in various statutes, particularly the Companies Act 2014. The Charities Act 2009 and the Charities (Amendment) Act 2024 also prescribe specific duties and responsibilities on directors of a charity, i.e. the charity trustees.

An organisation's governing documents and internal policies may also impose additional duties and responsibilities on directors which are specific to your organisation.

As many healthcare organisations in Ireland are regulated entities, directors also need to be aware of regulatory governance codes, standards and guidance as issued and updated by regulators from time to time.

Boards should treat delegations of authority as living documents. There should be clarity around what authority has been delegated, and the board should review and update delegations of authority regularly. There should be routine reporting to the board by those who have been delegated authority, and directors should question and challenge what is being presented to them.

"Make sure your charity's policies, terms of reference, codes of conduct, and records of meetings are all up to date, accurate and complete - you can use these as evidence of compliance."

Good governance is evidenced through up-to-date policies and clear terms of reference. It is also reflected in accurate minutes of meetings and proper recording keeping. These records should clearly show how risks are identified and dealt with by an organisation. This is particularly important where directors, or charity trustees, are required to certify compliance in accordance with regulatory or other legal requirements.

The webinar also highlighted the real-world consequences where a director is in breach of his / her duties and responsibilities. Personal liability and criminal liability can arise in certain circumstances.

The takeaway for directors and charity trustees is to:

- Stay current on legal developments and changes to existing legislation, and
- Ensure good governance is evidenced through proper record keeping of meetings and decisions, and through your organisation policies and other documentation, and
- Seek advice early where issues arise

KEY THEMES FROM THE WEBINAR

02

Patient safety incidents

A key risk area is incident classification and the reporting path it triggers. For adverse events affecting clinical care, the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 introduced mandatory open disclosure for a defined set of notifiable incidents. There are 12 events listed in Schedule 1 of that Act.

For other patient safety incidents, open disclosure under the Civil Liability (Amendment) Act 2017 is voluntary. However, many HSE and HSE-funded providers will still be required to follow the HSE Open Disclosure Policy.

Time limits matter. Under the 2023 Act, a written statement in a prescribed form must be provided at the open disclosure meeting or within five days.

Notifiable incidents must also be reported to the appropriate regulator within seven days. Failure to do so without reasonable excuse can constitute an offence.

Organisations must keep sight of other reporting regimes, such as:

- A 72-hour deadline for notifying the DPC of certain personal data breaches, and
- A short reporting window for prescribed incidents in registered centres

> *Open disclosure is, in summary, just that: a meeting with the patient (and where appropriate a relevant person) where certain information must be provided.*

Even where open disclosure is voluntary, the session underscored why it is often followed in practice. Both the 2017 and 2023 Acts include safeguards that allow appropriate communication, including apologies. These safeguards are designed to ensure that this communication is not treated as an admission of liability. They also protect against any negative impact on insurance cover.

In regulated settings, policy requirements and patient expectations frequently mean it is prudent to plan for open disclosure as a standard component of incident response.

MASON HAYES & CURRAN

KEY THEMES FROM THE WEBINAR

03

Investigations

When incidents occur, investigations are the bridge between learning and accountability. The webinar emphasised four fundamentals that apply regardless of whether you are operating under the HSE Incident Management Framework, an internal policy or a regulator-driven process.

"It is absolutely crucial that the investigator is independent... with no bias or conflict or perception of either of these things."

01

Start by selecting an investigator or team who is not involved in the incident. They also should not have any connection to the area where the incident arose or its management, both past and present. Where an external investigator is appropriate, ensure you have a lawful basis to share sensitive information outside the organisation. Put confidentiality and data sharing arrangements in place from the outset.

02

Next, get the terms of reference or action plan right. They should be clear about what is being investigated and why. However, the terms of reference should be flexible enough to capture issues that emerge during evidence gathering. Terms of reference should also set out:

- The methodology - how evidence will be gathered
- Whether staff will be interviewed and in what format the interview will take place
- The evidential standard to be applied
- Reporting lines
- The intended output - findings of fact, recommendations and/or conclusions, and
- Who has decision-making authority at the end of the process

"Individuals must know the details of any adverse findings or criticisms... and must be permitted the opportunity to present their case and defend themselves."

03

Fair procedure is not a box-ticking exercise. It shapes the credibility of the outcome and reduces downstream risk. This can include challenge, reputational harm and staff distress. Build time into your plan for representations at the end of the process and consider supports for witnesses and staff involved.

04

Finally, be realistic about timelines. Frameworks may suggest indicative durations. For example, up to 125 days in some guidance. Complexity, stakeholder engagement and fairness requirements will dictate what is achievable in terms of timelines.

MASON HAYES & CURRAN

KEY THEMES FROM THE WEBINAR

04

Coroners' inquests

Inquests are a process that healthcare organisations should plan for. An inquest is an inquisitorial, fact-finding exercise conducted within the Coroners Act 1962 (as amended). It is not a trial and there are no "sides". It is not designed to attribute blame or exonerate individuals. That said, it can be stressful for families and staff. Hearings are held in public with media attendance as a possibility.

The coroners' core questions are:

- Who died
- When and where they died, and
- The circumstances and medical cause of death

The process typically starts with requests for records, followed by witness identification and depositions. Sometimes additional information requests and preliminary hearings can occur before the inquest date is set. Depending on the district, and whether any related criminal proceedings must conclude first, it may take a significant period for an inquest to take place.

For witnesses, the practical guidance was clear. A deposition is not a memory test. It is acceptable to rely on the records and to say when you cannot recall. You should:

- Aim for clear, factual narrative
- Avoid speculation about others
- Explain clinical terminology for a lay audience, and
- Remember that families will be listening so tone matters, including an expression of sympathy

> *It is a fact finding exercise, not a means to either blame or exonerate anyone.*

"Doing a deposition is not a memory test."

"An inquest is an inquiry into a person's death. It's not an inquiry into their life."

Verdicts may include:

- Natural causes
- Accident
- Suicide, where intention is evidenced
- Medical misadventure
- Narrative verdicts, and
- Open verdicts, though these are rare

Coroners may also make recommendations aimed at preventing future fatalities or addressing public health and safety concerns. However, there is no direct enforcement mechanism. Recommendations and evidence are often reported publicly. Organisations should be ready to demonstrate lessons learned, improvements already implemented and, where appropriate, consider an apology or family engagement as part of a wider, sensitive response.

MASON HAYES & CURRAN

KEY THEMES FROM THE WEBINAR

05

What this means for you, depending on your role

Board members, directors and charity trustees: Treat governance processes as risk controls. Company delegations of authority, governance documentation and policies should be regularly reviewed and updated. Minutes of meetings should be detailed and maintained to evidence compliance. Challenge and verify what information you receive.

Risk, quality, patient safety and legal teams: Build or refresh a single, well-understood playbook for incident triage. It should include:

- How incidents are classified
- What triggers mandatory open disclosure
- Who must be notified and by when, and
- Who owns each step in the process

Maintain investigation templates. Ensure data sharing and confidentiality controls are ready if external investigators are engaged.

Clinicians and operational managers: If an incident occurs, focus early on clear documentation, escalation and getting the right supports around patients and staff. In open disclosure and later forums including inquests, accuracy and fairness matter more than speed in the moment. Stick to facts, rely on records where appropriate and avoid filling gaps with assumptions.

MASON HAYES & CURRAN

Dublin London New York San Francisco

We have the largest healthcare team in Ireland whose expertise and experience ensure that we deliver targeted, high-quality, sector-specific advice.

Our team is drawn from specialists across the firm and is comprised of lawyers having backgrounds in industry, science, and medicine.

We advise a variety of organisations involved in the provision and development of healthcare services and other businesses which support the healthcare sector. We also act for established public and private hospitals and voluntary organisations and governmental and non-governmental organisations.

ABOUT US

124 PARTNERS FIRMWIDE

33 HEALTHCARE PARTNERS

94 HEALTHCARE LAWYERS

Chambers AND PARTNERS — **BAND 1** HEALTHCARE LITIGATION

The LEGAL 500 — **BAND 1** HEALTHCARE AND LIFE SCIENCES

THE LAWYER European Awards 2025 — **LAW FIRM OF THE YEAR,** IRELAND 2025

MARKET RECOGNITION

"The Healthcare team in Mason Hayes & Curran are one of the most experienced healthcare teams in the country. The solicitors are exceptional through all levels. They are incredibly well trained and knowledgeable."

LEGAL 500 | 2026

"This is a firm with an excellent reputation for service, efficiency and legal skills. The partners and associates are very committed and solution oriented."

LEGAL 500 | 2025

KEY CONTACTS

AOIFFE MORAN
Consulting Partner, Public, Regulatory & Investigations
amoran@mhc.ie
+353 86 108 2738

DAVID HICKEY
Of Counsel, Medical Law
dhickey@mhc.ie
+353 87 677 1846

EIMEAR LYONS
Partner, Corporate
elyons@mhc.ie
+353 86 804 7749

ROBERT DICKSON
Partner, Healthcare Sector Lead
rdickson@mhc.ie
+353 86 460 3460

For more information and expert advice, visit:

MHC.ie/Health

MHC.ie