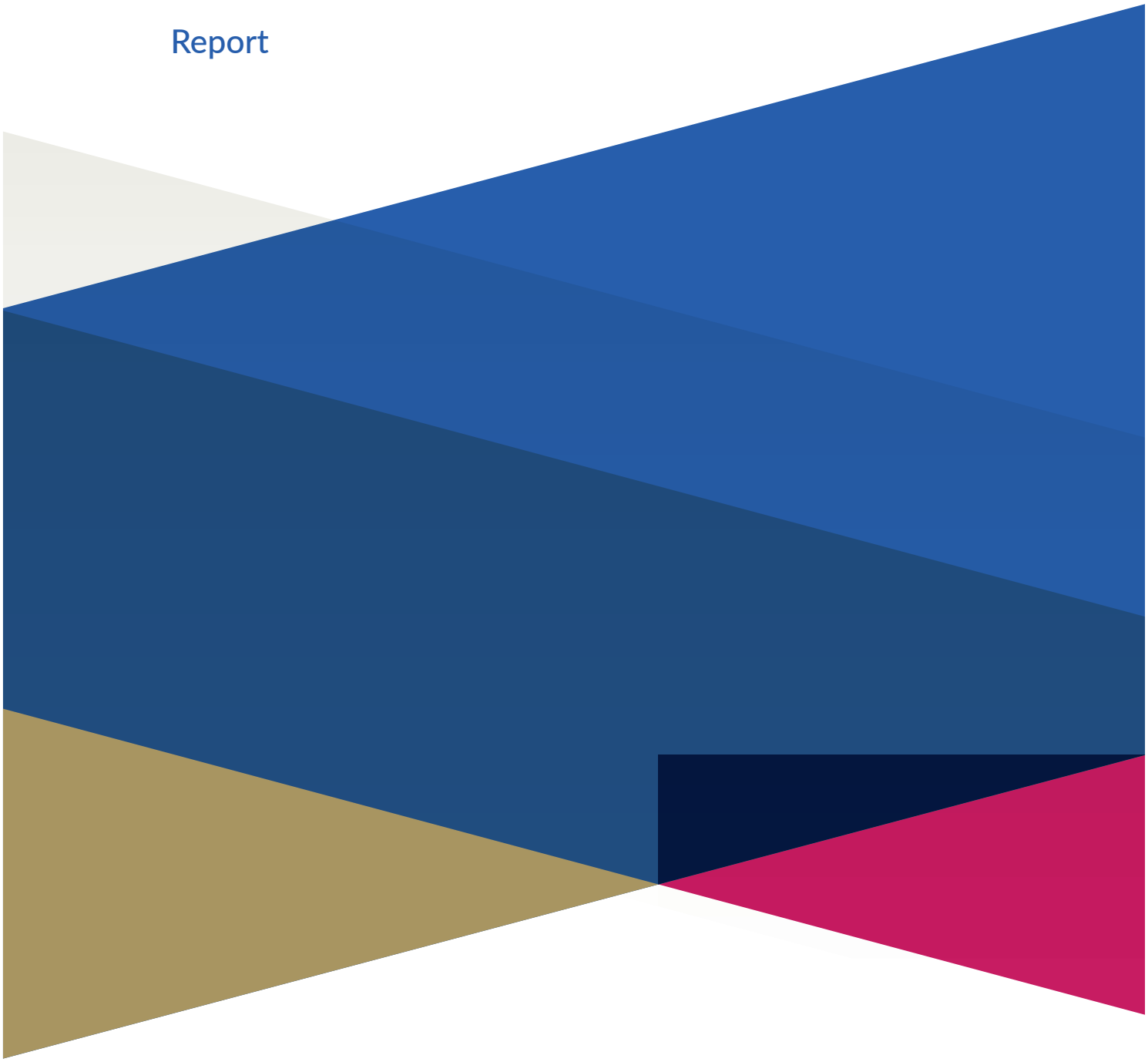
An Roinn Sláinte
Department of Health

Interdepartmental Working Group on the Rising Cost of Health-Related Claims 2024

Report



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Section One:
Introductory Remarks, Executive Summary and Recommendations

Foreword / Introduction

No patient wishes to find themselves seeking compensation for harm that has occurred because of a failure or error in care that may have had a devastating impact on their life and that of their loved ones. No clinician or healthcare practitioner wants to cause harm. Sadly, unanticipated harm occurs across every health system in the world despite best human endeavour to provide safe care and best possible outcomes. In the midst of the many lives saved and assisted, errors are made and unanticipated consequences harm patients. The human cost at the centre of this reality is inestimable but society is charged with addressing harm by providing care and compensation to those affected and by devising strategies to prevent harm in clinical settings.

When unanticipated harm occurs, the first priority must be appropriate empathetic care underpinned by clear, accurate and comprehensive information and explanation. Patients deserve that the impact of harm caused is acknowledged and validated and that a sincere apology is advanced. When things go wrong clinically, accountability and leadership are hugely important and individuals and institutions must learn from adverse events so that this learning informs clinical practice. We must audit and have knowledge of our clinical outcomes so that we are best placed to research and direct strategies to prevent harm where possible. In turn, it is important that personal and systemic learning is balanced so that we also learn from good practice and positive outcomes.

Nonetheless, litigation remains a necessary and important redress for patients who are harmed as a result of clinical errors or poor care. The present litigation system in Ireland is adversarial, while claims can take several years to resolve adding to distress for claimants and healthcare workers alike.

The State functions within limited resource and just as the delivery of healthcare occurs within available financial, personnel and material resources, the medical negligence system also functions within an environment of limited resource. Ultimately, the cost of litigation is drawn from the health budget and as the costs increase, financial resource is drawn away from healthcare provision.

The Constitution rightly demands that an individual receives fair compensation for harm occurring as a result of clinical negligence as determined by the Courts. However, the systems and processes that deliver compensation must endeavour to ensure that costs entailed are kept to a minimum and that appropriate compensation is provided. The cost of claims in Irish healthcare has been rising at a significant rate over the last decade, similar to that in other jurisdictions such as the UK. We have sought as a group to determine the reasons for this rise and to propose any actions or interventions that might assist in preventing the requirement to litigate but, when litigation occurs, to propose strategies to resolve claims in a more efficient and less costly way. We have attempted to provide a snapshot of current costs and their associated trajectory with some background context of contributing issues. We have placed a strong emphasis on the human cost of litigation in our considerations. The dearth of research in Ireland relating to personal experience of litigation is striking and we are deeply grateful to those patients, families and clinicians who shared their personal experiences with us in order to assist our deliberations. We are also very grateful to the wide variety of experts who gave so generously of their time and expertise.

Finally, I would like to add my sincere personal thanks to Madeline Meade, Brenda Lynch and Greg Dempsey along with all members of the Interdepartmental Working Group (IDWG) who have contributed so generously to this Report. It has been such a pleasure to work alongside you. I hope that this report will have real impact in driving forward reforms that will create a less adversarial civil litigation environment and galvanise our efforts to use our expertise and data to prevent harm in healthcare settings, while fostering open honest communication and enhanced care when harm occurs.

Professor Rhona Mahony
UCD Perinatal Research Centre, School of Medicine, University College Dublin, National Maternity Hospital, Dublin, Ireland.
April 2024

Overview of the Work of the Group

Government, at its meeting on 31st January 2023, approved the establishment of an Interdepartmental Working Group to examine the rising cost of health-related claims and consider mechanisms to reduce costs. The Group, chaired independently by Professor Rhona Mahony and comprised of membership from across relevant Government Departments and Agencies, held its first meeting in March 2023. The full terms of reference and membership of the Group are set out at Appendix 1.

The Group's considerations focussed on the following key themes:

- Examining best international practice to establish how we compare and what lessons can be learned from elsewhere in terms of indemnity models that are in place in other jurisdictions, the cost of claims, the clinical incident rate and the incidence of cerebral palsy;
- Examining whether there are ways to further improve the quality of services/improve patient safety and thereby reduce the number of adverse incidents;
- When an incident occurs, exploring ways to enhance the process to resolve matters faster and more efficiently;
- Seeking to identify ways to reduce costs through a number of civil justice reforms, including the resumption of Periodic Payment Orders (PPOs), the development and implementation of a pre-action protocol (PAP), case management rules and stabilising issues regarding the Real Rate of Return and;
- Considering the health system's approach to mass action claims.

The Group met on 14 occasions. The meetings were a combination of regular working meetings of the Group, alternated with consultation meetings with relevant parties.

Given the importance of appropriate consultation with patients with due regard to the inherent sensitivities, careful consideration was given to the best approach. Following this, it was agreed that a qualitative study to be carried out by a third party with relevant expertise was the most appropriate approach to take and the HSE agreed, on behalf of the Group, to commission University College Cork (UCC) to undertake this work. The findings of this research, 'Plaintiff experiences of the medico-legal environment in Ireland', are outlined and discussed primarily in Chapters 1 and 7. A copy of the final report is published separately and can be found at https://www.gov.ie/en/publication/9bcc5-interdepartmental-working-group-on-the-rising-cost-of-health-related-claims-report/.

As it would not be possible for the Group to consult with every individual or representative group who might have an interest in the matter, a notice was placed in the Irish Times and the Irish Independent on 6th June 2023, inviting submissions from interested parties. The invitation to make a submission was also published on the consultation section of the Government website and 9 submissions were received.

A number of other relevant stakeholders also made submissions, either through invitation or as part of their consultation with the Group.

Details of consultation meetings held and submissions received are set out in Appendix 2.

As part of the Group's work, it received updates/ presentations from members of the Group regarding the state of play on key policy initiatives and programmes that are underway, which are relevant to the terms of reference of the Group, as follows:

- State Claims Agency (SCA) – an overview of claims liability and numbers, service user incidents reported on the National Incident Management System (NIMS), a context for the data, an outline of the SCA's clinical risk management function, and an overview of the SCA's approach to managing mass action claims.
- Health Services Executive, National Quality and Patient Safety Directorate – an overview of the Patient Safety Strategy, the Incident Management

Framework, tackling the leading causes of harm and quality assurance.

- HSE – National Women's and Infants Health Programme (NWIHP) – an overview of its work.
- National Patient Safety Office (NPSO) – an overview of work ongoing relating to Patient Safety Legislation, Patient Advocacy and the Open Disclosure Framework, Complaints Policy and Patient Safety Incidents.
- Department of Health – an overview of the final Scally Report.
- Department of Justice – progress update on the Justice-related Meenan Report recommendations, along with the Civil Justice Reform Measures.
- Department of Health – an update on the Health-related Meenan Report recommendations.

In addition, the Chair held bilateral meetings with the Department of Justice and the National Patient Safety Office to receive progress reports and plans on policy issues that are key to the work of the Group and its Terms of Reference.

In relation to the work on international comparisons, the Health Research Board (HRB) was engaged to carry out an evidence brief entitled 'A Comparative analysis of clinical negligence claims in a range of jurisdictions'. The full report is published separately and can be found at https://www.gov.ie/en/publication/9bcc5-interdepartmental-working-group-on-the-rising-cost-of-health-related-claims-report/.

Executive Summary

On 31st January 2023, Government approved the formation of an Interdepartmental Working Group to examine the rising cost of health-related claims, with a particular focus on high value claims and to identify measures that could be put in place to reduce future costs. The Terms of Reference included examining international best practice and the exploration of strategies to reduce adverse incidents and to enhance measures to address patient concerns and improve care following adverse events. The Group was also asked to provide updates on the implementation of the recommendations set out in the report of the "Expert Group to Review the Law of Torts and the Management of Clinical Negligence Claims" (Meenan Report), and to consider the health system's approach to mass action claims.

In Section One, we set out an overview of the work undertaken by the Group.

In Section Two, we aim to provide context to the question of the rising costs of clinical negligence claims. We have placed a strong emphasis on the human cost of litigation and open the report with this exploration to acknowledge the harm that is central to the decision to litigate and to ensure that the experience of affected patients and their families is central to all our considerations. In this section, we also address the rising financial costs of health-related claims and include a stand-alone chapter on maternity care and perinatal brain injury.

In Section Three, we set out strategies to minimise the human and financial cost of healthcare claims. Our central philosophy must be to reduce the incidence of adverse events and clinical harm. We identify strategies to enhance patient safety through learning from adverse events and enhancing the care available to patients following an adverse event. Again, we place a strong focus on catastrophic perinatal brain injury. We provide an update on the range of civil justice reforms that are currently in progress or have been proposed and finally, we address the question of mass action claims.

Several strong themes emerged from our considerations. While the majority of patients in Irish healthcare experience excellent outcomes, unanticipated adverse events arise and cause harm leading some affected individuals to seek resolution through civil litigation. Litigants and healthcare practitioners (HCPs) alike find the current adversarial civil litigation process in Ireland protracted and traumatic, while failing to address the deeper emotional and psychological needs of resolution.

The financial costs are rising at a significant rate and the current estimated outstanding liability (EOL) of almost five billion euro could rise by multiples over the next two decades if unchecked. Over half the total annual costs of healthcare litigation in Ireland are associated with claims for catastrophic injuries that account for only 2% of claims annually. It is the rising cost of damages paid in these cases to provide for care for affected individuals that is the standout driver of rising costs.

There are a number of measures that can be instituted quickly to improve the civil litigation process and reduce costs, but the fundamental solution is rooted in the prevention of clinical harm arising from unanticipated adverse events and enhanced care for those affected by such harm. This is particularly the case for infants who sustain perinatal brain injury and go on to develop cerebral palsy or other catastrophic injuries where early intervention is key.

The Human Cost

The human cost of harm associated with litigation is well described in the academic press. For the purpose of this report, a qualitative research study of fifteen patients/families who have litigated in Ireland was undertaken. Participants reported a very negative experience of seeking justice through the civil litigation system in Ireland. They variously described it as triggering, re-traumatising, jarring, insulting, shocking, horrible, not fit for purpose, and a battle. Several participants identified the system as particularly unsuited to those who have already experienced a significant trauma.

The decision to pursue litigation following an adverse event is influenced by a variety of factors including the requirement for information and explanation, the need for an apology, and the desire to prevent recurrence and make the health system safer. Financial compensation was a critical consideration for some who required financial means to support care for infants or loved ones with catastrophic injuries, but it is limited by its failure to address the deeper emotional and psychological needs of resolution. In some cases, such as bereavement, financial compensation exacerbated claimant distress.

Several participants indicated that their wellbeing continued to be adversely affected long after the legal process had concluded.

A strong theme that emerged from participant testimonies was the need to move away from the current adversarial environment to one which fosters open honest communication where errors are admitted and acknowledged, questions are answered, and genuine dialogue is maintained.

Adverse events can also affect healthcare practitioners (HCPs) with feelings of fear, guilt, shame, depression and post-traumatic stress disorder (PTSD) recognised. HCPs described the current medicolegal environment as adversarial and can be exacerbated by media reporting that can feel unbalanced while there is no ability to reply. They felt that the current system does not always defend HCPs but rather cases settle early to avoid cost. They also felt that it was difficult to defend cases because of an effective approach of strict liability by the Courts whereby any deficiency in care identified, whether a contributing factor to the outcome or not, led to decisions not to defend cases. HCPs described being fearful of the multiple protracted processes that arise after an adverse event including internal reviews, external reviews, HSE and HIQA reviews, Coroners' Court inquests, civil proceedings and Medical Council proceedings. In a survey of 200 Medical Protection Society (MPS) members who have experienced a claim, it was reported that over half of the HCPs surveyed reported lower self-esteem and a negative impact on family life. Evidence from the stakeholder consultation suggested that in some cases, litigation can lead HCPs to seek alternative work practice and to practice defensively, which is of particular concern in high risk, highly specialised areas of medicine. In these environments it can be extremely difficult to replace staff with others of similar experience. Some expressed a wish that patients would be appropriately compensated particularly in cases of catastrophic infant brain injury, where they felt it was unfair that there is such a gap between provision of care awarded by the Courts and care available to those reliant on HSE care packages.

The Financial Cost

It typically takes a number of years for a claim to be finalised, during which time transactional costs, such as expert witnesses' fees and legal fees, will be incurred. The amount paid by the HSE in any one year represents the cash payments associated with claims finalised in the year, in addition to the cash payments associated with active claims not yet settled or finalised. To understand the full costs to the State of healthcare-related claims, it is necessary to look at both cash payments made in any year, and the estimated liability amount which is still required to be paid in the future.

Claims are analysed over four categories: clinical catastrophic claims which include perinatal brain injury and cerebral palsy, clinical non-catastrophic claims encompassing the majority of claims arising from alleged clinical negligence, general claims including those arising from slips, trips and falls, biological hazards including infection and personal injury claims such as psychological injury, and finally mass action claims where a single issue, product or device generates a high incidence of claims.

The rising cost of clinical claims costs is predominantly driven by the rising costs of individual claims rather than by increasing numbers of new claims. The primary driver of rising claims costs is the rising cost of care in a relatively small number of clinical catastrophic injury claims. Clinical catastrophic claims represented 59% of total estimated outstanding liability (EOL) at year end 2022, and the EOL for clinical catastrophic claims has increased by 59% over the five years 2018 to 2022. The total annual cost of clinical catastrophic claims (as measured by the sum of the year-on-year difference in the estimated liability plus the transactional costs) has been rising each year, from €364m in 2018 to €585m in 2022, an increase of 61%. This is despite a reduction in the number of new claims received annually in this category over the period. While clinical catastrophic claims accounted for 53% of total costs for the period 2018 to 2022, they accounted for 2% of the number of new claims annually.

The primary driver of the increased cost of clinical catastrophic claims is an increase in the settlement cost of new claims with the average estimated liability for new claims increasing by 83% (from €4.6m to €8.4m) over the period, and the average estimated outstanding liability of claims increasing by 29% (€6.0m to €7.7m) in the same period. The majority of clinical catastrophic claims relate to perinatal brain injury and cerebral palsy. It is the special damages sum including the cost of care into the future, accommodation costs and loss of earnings that account for the large and increasing settlements made in catastrophic injury cases with settlements of up to €35m reported. In these cases, the Courts seek to provide an allowance for all care possibly required into the future for a child. Increases in life expectancy, advances in costly assistive technologies, complex multidisciplinary care and accommodation requirements, rising inflation and loss of earnings are just some of the elements that contribute to these large claim resolution costs. The calculation of costs is strongly influenced by the personal injury discount rate, known as the real rate of return (RRoR), general claims inflation, and legal costs.

Clinical non-catastrophic claims (excluding mass action claims) accounted for 31% of all new claims over the period 2018 to 2022, and 23% of the total costs. The principal driver of the total annual cost for this category is the number of new claims in any year, rather than the settlement cost of claims. The total annual cost has reduced from €240m to €162m between 2018 and 2022. The reduction in large part reflects a lower number of new claims, partly offset by an increase in the average estimated costs of individual claims. The reduced number of new claims in 2021 and 2022 may reflect reduced levels of activity in health services immediately following the COVID-19 pandemic. This trend may reverse over the coming years, further increasing costs.

General claims (excluding mass action claims) account for 59% of new claims, but only 14% of total costs. The total annual cost of claims is primarily driven by the number of new claims in the year, with the reduction in the cost of claims from €132m to €84m reflective of the lower number of new claims in the latter year.

Mass action claims accounted for 8% of all new claims over the period, and 10% of the total costs. By their nature, the claims which comprise this category do not support consideration of trends over time as they relate to diverse issues which generate variable numbers of claims, as can be seen in the variation in both the costs and number of new claims annually. A further factor is that the claims, when first notified, are novel, and there can be a large final adjustment to the costs in the year of settlement, particularly where all claims within a mass action are resolved simultaneously.

It is important to note that, with the exception of mass action claims, the number of new clinical claims received has been decreasing over the past few years, although the number of new claims received each year still exceeds the number of claims finalised in any year, leading to an increase in the open active claims being managed.

Legal costs are also a contributor to the rising cost of claims and accounted for 23% of total costs in the period 2018 to 2022. Whereas SCA legal costs for healthcare claims have risen by 32% between 2018 and 2022, plaintiff legal costs have risen by 73% in the same period. In addition, costs increase as the time taken to resolve claims increases.

International Comparison

While Ireland is not alone in facing a significant rise in the cost of clinical negligence claims, caution is required in interpreting direct international comparisons as different countries have different health systems, state provision of services, legal systems and insurance systems. Differences in terminology and accounting standards also hamper direct financial comparisons.

While the ability to compare data is limited, common trends are found across a range of jurisdictions employing tort models, no-fault systems, and a combination. These trends include an increase in both the actual costs being paid for claims, and in the outstanding liability where that information is available.

The key drivers of rising costs include increasing compensation awards, increasing claimant legal costs and an increase in the volume of claims.

Brain injury sustained at birth is a major driver of the increased cost of resolving clinical negligence claims internationally. In England obstetric claims account for 13% of clinical claims reported in 2022/23 but for 64% of those claims by value. While the number of cases of brain injury is small, the cost of care into the future for affected children is high and is increasing.

The cost of care in catastrophic injury cases is heavily influenced by the personal injury discount rate applied to determine future costs in present-day terms and the variation in discount rates applied across different jurisdictions is a major contributor to the variation in the cost of resolving claims in the catastrophic injury category.

The most comparable data comes from England with a population of some 57 million people and operates within a similar tort-based system to Ireland. As in Ireland, England has experienced significant increases in the cost of clinical claims. The cost of claims rose from £1.3bn in 2012/13 to £2.4bn in 2021/22, an increase of 85%, while the provision for liabilities increased from £22.7bn to £128.2bn over the same time period. Of note, the NHS Resolution Annual Report and Accounts 2022/23 records a sharp decrease in provision for liabilities arising from claims from £128.6bn to £69.6bn. This is mainly a consequence of changes to His Majesty's Treasury (HMT) Discount Rate, which is a discount rate (or rates) that UK Government bodies are required to use to discount future liabilities for the time value of money when presenting their reports and accounts. (It should not be confused with the Personal Injury Discount Rate, also known as the "Ogden Rate", which is analogous to the Real Rate of Return in Ireland, and which is set by Government rather than Court precedent).

New Zealand operates a no-fault compensation system for medical injuries. Injured patients receive government funded compensation, giving up the right to sue an at-fault party, except in cases of reckless conduct. The overall costs paid have risen from NZD$111.4m in 2014/15 to NZD$209m in 2019/20, an increase of 87%, while the projected outstanding liability for all accepted treatment injury claims has risen from NZD$5.1bn in 2015/16 to NZD$9.18bn in 2019/20, an increase of 80%. The volume of accepted claims has risen from 8,881 in 2015/16 to 11,285 in 2019/20.

Florida also operates a no-fault system for birth-related neurological injury claims. Information drawn from the Neurological Injury Compensation Association (NICA) reports show that there were 226 active participants in 2022 and that total compensation paid rose from US$49.1m in 2021 to US$76.5m in 2023.

The system in France combines elements of tort and no-fault schemes. In 2002, the French Parliament passed the Patient's Rights Law of March 4, 2002, which established a compensation scheme that allows patients to seek compensation without proving fault by healthcare professionals or institutions. This scheme aims to provide compensation for victims of serious medical accidents resulting in significant disability or temporary incapacity of greater than six months. Total standard compensation paid for these claims has risen by 60% from 2015 to 2021.

In their Global Health Care Brief: A Quantum Comparison – assessment of damages around the world, (Feb 2023), Kennedys used a recently settled English claim as a case study to compare what the settlement value may have been, based on the legislation and principles applied in ten other jurisdictions. While there are significant differences in how the legal systems operate across the comparison countries and what might be included in the cost of such a claim, there is also a significant variation in potential damages awards across the different countries – ranging from just under £22m (based on a capitalised sum) in England and Wales through to in the region of US$500,000 (approximately £417,000) in Latin America. The Kennedys Report argues that reductions in the cost of claims are unlikely to occur without some form of tort reform, such as caps placed on damages and higher discount rates.

A report by the Medical Protection Society (MPS), based on their own claims data from 2011 to 2022, found that the average legal cost for claims in Ireland was 191% more expensive than the UK, 26% more expensive than Singapore, 56% more expensive than Malaysia and 250% more expensive than South Africa. They attribute the increased cost of claims in Ireland to increased legal fees and increased time taken to resolve claims. Legal costs make up almost a quarter (23%) of the costs paid by the SCA in 2022 to resolve and manage ongoing clinical negligence claims. The MPS contend that claims in Ireland take longer to resolve than in any other country where MPS has members. Average length of proceedings in MPS cases in Ireland was 1,462 days compared with 1,401 in Malaysia, 1,279 in South Africa, 940 in Hong Kong, 939 in the United Kingdom and 938 in Singapore. They recommend the introduction of a pre-action protocol, case management of litigated claims and the introduction of specialist courts and judges.

Perinatal Brain Injury and Cerebral Palsy

We include particular focus on perinatal brain injury and cerebral palsy because litigation associated with these outcomes and other catastrophic outcomes accounts for over 50% of total annual litigation costs.

In Ireland, the incidence of brain injury sustained at birth called hypoxic ischaemic encephalopathy (HIE) is 1.1/1,000 and appears to be stable suggesting consistent factors in causation (NNEAG Report 2021). HIE is a significant risk factor for the subsequent diagnosis of cerebral palsy (CP), and these are cases which constitute the majority of claims for clinical catastrophic injury. At present, Ireland does not keep a national CP register. Where data is available in higher income countries, prevalence rates are generally reported between 1.2 and 2/1,000 live

births. A recent large-scale study, using the data from 26 population registers across Europe, suggests an overall reduction in prevalence of CP in Europe from 1.90 to 1.77 per 1,000 live births in the 1980 to 2003 period.

HIE may occur as a result of an acute hypoxic event in labour called a sentinel event, but more commonly occurs in the absence of an acute event. HIE may be considered a subtype of Neonatal Encephalopathy (NE). We do not yet fully understand the aetiology of HIE and CP. Genetic, epigenetic, metabolic, prenatal, perinatal, and postnatal factors may impact to protect, cause or exaggerate neonatal brain injury. Major antenatal risk factors for HIE include structural abnormalities such as brain and heart anomalies, growth restriction, placental abnormalities, infection, and genetic causes. Placental abnormalities are very common in cases of HIE, but the placenta can only be examined after delivery. Despite the use of fetal heart rate monitoring (CTG) in labour to predict HIE, the rate of HIE appears to be stable in Ireland but there is a steep rise in caesarean section rates over the last decade. Almost 40% of women in Ireland are now delivered by caesarean section. A significant proportion of caesareans performed in first time mothers are performed because of concerns regarding fetal hypoxia during labour. At present, the use of CTG does not prevent HIE in Ireland or in any other jurisdiction.

Strategic Priorities Identified

Arising from the analysis above, we identified six strategic priorities that aim to reduce the requirement for litigation in healthcare and improve the litigation process for those compelled to take this path.

- → Capturing data, learning from adverse events and promoting key research
- → Strategies to prevent adverse events within available resources
- → Enhanced response when harm occurs
- → Enhanced care for babies born with neonatal encephalopathy and other maternity initiatives
- → Faster and more efficient resolution of claims
- → A standardised approach to mass action claims.

1

Strategic Priority 1: Capturing Data, Learning from Adverse Events and Promoting Key Research

It is important that we have accurate data on adverse events and patient experience so that we learn and inform strategies to improve patient care and safety within the Irish health system.

It is inevitable that adverse events (AEs) will occur in healthcare organisations, with profound impact on affected patients, on individual practitioners, on healthcare teams and institutions. When an AE is identified and a concern expressed, immediate and comprehensive action should be taken. This requires trying to understand the whole phenomenon in its complexity and understanding the needs of all those affected including the patient and their families, the healthcare professionals and the institutions.

Learning from analysis of clinical claims is a very valuable resource in promoting better awareness and understanding of adverse events. This in turn facilitates strategic programmes to prevent harm. The dissemination of this learning to the frontline is critical.

The dissemination of learning is also a key requirement in individual and systemic learning from clinical outcomes and the experience of patients and healthcare workers. It is important that strategies to disseminate learning are strongly supported on the frontline. This includes empowering clinical directors and clinical leaders with the tools and resources to develop and deliver learning programmes deriving from their own institutional or national experience. Consideration should be given to centrally monitoring the dissemination of learning from adverse events and claims data. This could be a role undertaken within the HSE.

2

Strategic Priority 2: Preventing Adverse Events: Strategy, People and Resources

The most effective strategy to reduce the cost of claims is to minimise incidents of avoidable harm. The HSE works continuously to monitor and improve patient safety and to reduce incidents of harm and minimise risk. Implementation of the HSE Patient Safety Strategy 2019 to 2024 is key in achieving this goal and deserves national investment and support. Nonetheless, it is impossible to address strategies to minimise harm if shortages of staff and resources combine to create potential risk for the very harm the system is trying to reduce. The Group acknowledges the progress made in the increased recruitment of clinical staff in recent years allied with an increase in the number of medical students.

Nonetheless, serious problems still exist in relation to recruitment and retention of frontline clinical staff. Addressing the number of doctors on the general register and recruitment of clinical staff in high-risk specialties should be prioritised. The role of allied health staff in creating multidisciplinary care teams is of huge importance and the ongoing workforce planning being undertaken by the Department of Health is also required in key fields including physiotherapy, occupational therapy, speech and language therapy, counselling and support services.

3

Strategic Priority 3: Enhanced Response When Harm Occurs

There is a crucial period following an adverse event, when the response by the health system and health professionals can have a significant impact on a patient's outcome and experience. When things go wrong in healthcare and unanticipated harm occurs the principles of open disclosure must be adhered to in serious reportable events and should be employed in the wider context of all adverse events.

Patients should have clear and empathetic information on what has happened and what will happen, with an apology, and acknowledgment of the impact the harm has had on an individual.

Patients require a clear management plan and an opportunity to express their needs and have their needs responded to by staff trained in the delivery of compassionate care when things go wrong.

Particular attention should be paid to care plans on discharge from acute care and liaison with available community supports.

The inherent principles and concepts of care elements contained in the HSE National Bereavement Standards including high-quality care when things go wrong, development of systems within care units to address adverse events, a focus on patient needs and appropriate training and care of affected staff have broader application across the wider healthcare system and should be adopted in the development of care services for individuals harmed by adverse events.

Strategic Priority 4: Care for Babies Born with Neonatal Encephalopathy and other Maternity Initiatives

Hypoxic ischaemic encephalopathy (HIE) is the most important cause of long-term disability in normally formed term infants. It happens when there is reduced oxygen and reduced blood flow to the infant's brain before birth. New treatments, including therapeutic hypothermia (TH), have proved to be effective in reducing death and severity of HIE. Despite the proven efficacy of TH, up to 40% of affected infants will die or suffer from long-term neuro-development impairment.

The creation of a national cerebral palsy register would permit standardised collection of data which would assist in international and national comparative analysis, the identification of preventative and care strategies to optimise outcomes for children and would drive thematic research to inform national public health strategy.

The first objective is to focus on strategies to prevent HIE by learning from audit of previous cases and using this information to identify the at-risk fetus by analysing antenatal risk factors and incorporating them into the rationale for care during labour and delivery.

When a baby is born with HIE, appropriate neonatal resuscitation and assessment is essential to optimise outcome.

Early diagnosis and early intervention make a significant difference in the outcomes for children with cerebral palsy. Various care initiatives have commenced in recent years, some within a research setting, but it is evident that the provision of standardised experienced multidisciplinary care must be a priority for children and families affected by HIE who are at high risk of cerebral palsy. Current initiatives to develop early intervention clinical pathways should be supported. There are experts in Ireland delivering excellent care for children with cerebral palsy, but care expertise needs to be developed and expanded so that evidence-based care can be standardised and delivered nationally. At present, there is a strong reliance on private care, while a number of voluntary and charitable organisations fill in important gaps. Standardised multidisciplinary care should continue through the lifetime of the affected child.

Current research initiatives should also be supported – we have much to learn about the antecedents of neonatal brain injury and cerebral palsy. In turn, as we learn more, we will increase the opportunity to develop therapies that may be transformational.

Strategic Priority 5: Faster and More Efficient Resolution of Claims

Philosophically our aim should be to avoid litigation in the first place but, when necessary, it should be concluded at the earliest possible stage and preferably long before going to Court. Previous reports and recommendations made by relevant parties have identified a number of key reforms which will significantly improve the current process of civil litigation. There is particularly strong support for the introduction of a pre-action protocol, case management in the Courts and the resumption of periodic payment orders (PPOs). The required legislation is now in place for these key reforms, and they should be implemented without any further delay.

In Ireland, it is difficult to envisage the successful implementation of a number of alternative dispute resolution approaches. No-fault compensation and capping of certain damages have been employed in other jurisdictions with some success, although the perfect solution remains elusive. In Ireland, common law and the provisions of our Constitution include the right of all to access the Courts, the right to compensation for loss and damage occasioned by others to be assessed in accordance with well-established legal principles which must largely be determined by the Courts. The very premise of Tort Law demands that there must be a breach of duty or negligence to proceed with compensation. These provisions make legal alternatives complex.

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Strategic Priority 6: Standardised Approach to Mass Action Claims

There is no one solution to dealing with healthcare-related mass actions. They are usually complex, sensitive, diverse claims, frequently complicated by the involvement of multiple parties e.g., pharmaceutical company manufacturers, insurers, distributor companies etc.

However, experience in recent years has shown that various forms of Alternative Dispute Resolution (e.g., mediations, binding mediations, ex-gratia schemes, compensation schemes, evaluations, assessments and tribunals) can be used to achieve successful, efficient, and cost-effective resolution of mass action claims. For all involved, most particularly the injured parties, it is optimal that resolution can take place in a less stressful and adversarial manner than the alternative, adversarial court process.

Conclusion

The human cost of healthcare litigation in Ireland deserves recognition. Protracted and adversarial civil litigation proceedings propagate a cycle of harm: the process exacerbates harm already suffered by patients and families, it harms healthcare practitioners, and it harms the public interest through a continuing upward trajectory of financial cost. It fails to address the deeper psychological and emotional needs of those seeking resolution after unanticipated clinical harm. Those who have directly experienced the litigation process in Ireland advocate a move away from the current adversarial environment to one which fosters open honest communication where errors are admitted and acknowledged, questions are answered, and genuine dialogue is maintained.

The estimated outstanding liability for healthcare claims in Ireland has risen by 64% between 2018 and 2022 from €2.8bn to €4.6bn representing an average rise of approximately 13% per year. The transactional cost of claims has risen from €326m in 2018 to €501m in 2022, an increase of 54%. This is despite an overall fall in the number of new claims annually and is primarily driven by a steep rise in the cost of damages in clinical catastrophic claims, which account for over 50% of costs and just 2% of new claims annually.
If such a trajectory were to continue a five billion euro cost today could increase substantially over the next decades.

It is clear that there is much work to be done and that there is no single intervention that will prevent the need for litigation or solve the problem of rising costs of litigation in the immediate term. Nonetheless, there are a number of initiatives that can happen quickly with significant impact. These include the proposed civil litigation reforms recommended by the Meenan Group and other legal experts in earlier reports. In our engagement with a variety of stakeholders, we found strong consistent support for the introduction of a pre-action protocol (PAP), case management rules and the resumption of PPOs. Mediation options need to be developed and used increasingly to shorten the time frame of claims resolution and to avoid costly court proceedings. Sanctions should apply for the failure to adhere to a PAP and case management rules. The introduction of a pre-action protocol in England and Wales resulted in reduced legal costs and it is anticipated that its introduction in Ireland would have a similar effect leading to swifter resolution of claims.

The fundamental solution is to avoid harm arising from adverse events in a clinical setting in the first place. While successful strategies may reduce the incidence of unanticipated harm and should be pursued vigorously, it is unlikely that any healthcare system in the world will succeed in completely eradicating adverse events.

It also takes time to see healthcare safety initiatives translate into measurable outcomes. Support should be given to the HSE Patient Safety Strategy and learning from claims should be optimised, with particular attention paid to the dissemination of learning to the clinical frontline. While recognising and acknowledging the increased recruitment of clinical staff in recent years, deficits in staffing and resources in some areas still need to be addressed. It is important that HSE workforce planning initiatives are supported in key areas.

Enhanced care is required when an adverse event occurs and there is a crucial period following an adverse event when the response by the health system and healthcare professionals can have a positive impact. When things go wrong, our aim must be to assist patients and families with clear and accurate information and timely care and compassionate support. This entails an apology for any failures or shortcomings in care and an acknowledgement of the harm sustained and its impact. The principles of open disclosure and bereavement care should be broadened to encompass the care of all those affected by adverse events.

Most importantly, we must further develop and support strategies to reduce the occurrence of HIE at birth. We strongly recommend the creation of a cerebral palsy register to inform care strategy. Early intervention is critical in infants born with brain injury to optimise outcomes and potentially reduce future care requirements. The State provision of such care within existing core allocations could facilitate immediate and more effective evidence-based care and lead to growing national expertise, reducing the reliance on ad hoc private care arrangements. In addition, the provision of early claims resolution in the context of perinatal brain injury has the potential to meet family needs in real time, facilitate early clinical intervention and reduce the risk of claims increasing in value due to inflation or unmet needs translating into higher costs. We must aim to reduce the gap between the large court settlements and the care provided by the HSE.

If we did these things, we would significantly reduce the human suffering and the financial cost associated with healthcare litigation in Ireland.

Recommendations by Strategic Priority

	Strategic Priority	List of Recommendations
1	Capturing Data, Learning from Adverse Events and Promoting Key Research	1. For consistency and standardisation in the recording, reporting, analysis and learning from adverse events, the Group recommends that all publicly-funded healthcare providers/settings providing clinical care should use the National Incident Management System (NIMS). 2. The Group recommends that, in line with the Incident Management Framework, each healthcare provider/setting should ensure that robust mechanisms are in place to disseminate learnings to all relevant staff and in particular to frontline workers derived from: a. the services own data relating to adverse events, b. the analysis by the HSE and the State Claims Agency of incident and claims data. 3. The Group recommends that each healthcare provider/setting should provide reassurance to the SCA, when requested, that learnings and outputs from the SCA's analysis of claims and incidents have been shared with frontline staff, that risk mitigation strategies are in place and demonstrate efforts made to implement any recommendations made. 4. Clinical Directors or equivalent should be supported with tools to enhance feedback to frontline clinical staff on: common causes of harm, clinical care incident analysis and common themes associated with litigation. This could be achieved through a combination of clinical meetings, local alerts and through the delivery of standardised on-line courses which should be prioritised for continuing professional development (CPD) accreditation. The dissemination of learning from adverse incidents and claims data should be monitored centrally. This could be a role undertaken within the HSE. 5. The Group recommends that every healthcare setting providing clinical care should have the capability to undertake swift and comprehensive analysis of and response to serious adverse events that occur within its own setting. External support in accordance with HSE guidelines should be provided when requested and in major adverse outcomes. 6. The Group recommends that healthcare providers should endeavour to capture positive outcomes and promote a balanced culture of learning. 7. The Group recommends that each clinical care unit should audit their primary clinical outcomes annually and publish their results in an annual clinical report.

	Strategic Priority	List of Recommendations
2	Prevention of Adverse Events: Strategy, People and Resources	1. Recognising that having appropriately qualified and adequate numbers of staff is a key driver of patient safety, the Group recommends that workforce planning initiatives across the system be further supported, with priority given to high-risk critical areas such as delivery and neonatal units. 2. The Group recommends that all units delivering clinical care should be supported to develop and maintain responsive clinical governance functions, in accordance with HSE guidelines. 3. The Group advocates continued support for HSE patient safety initiatives and in doing so, recommends that available funding be prioritised and ring-fenced within the existing core allocations, to support ongoing patient safety initiatives in healthcare settings. This includes: → Funding to support evidence-based interventions aligned to the patient safety strategy, including data collection, analytical tools, training (including multi-disciplinary training in maternity services and simulation) and other tools for the sharing of learning. → Consideration should be given to making some elements of core training mandatory. → Continued focus on initiatives to address the common causes of harm.
3	Enhanced Response When Harm Occurs	When an event occurs a patient should be made aware of what happened and provided with appropriate care and supports. These recommendations are made in service of this. 1. The Group recommends the adoption of the National Open Disclosure Framework by all relevant stakeholders and the incorporation of the Framework into their organisational policies and procedures at the earliest opportunity. 2. The Group recommends that a team of trained personnel should be available to each hospital dedicated to responding to serious adverse events, when they occur. Where appropriate, this team may comprise external regional support. An example of this is the Obstetric Event Support Team (OEST) in maternity care. 3. The Group recommends that rapid access to appropriate clinical investigations and care when complications occur be prioritised in each hospital. 4. The Group recommends that guidelines and training for meaningful debriefing with the patient/family following an adverse event should be put in place in each hospital.

	Strategic Priority	List of Recommendations
		5. The Group recommends that all hospitals should ensure that bereavement or adverse event nurse/counsellors are available to liaise with families, along with a family liaison person or social worker, to signpost families to services and entitlements (it is acknowledged that elements of this care already exist in many hospitals). 6. The Group recommends that necessary supports should be available immediately, within existing resource allocation, to assist parents with the additional care needs of children with catastrophic birth injuries while the longer-term support needs are being determined and arranged. Early intervention has been shown consistently to optimise outcomes and has the potential to reduce the risk of claims increasing due to inflation or unmet needs or suboptimal outcomes translating into larger costs. This may ultimately reduce the cost of damage settlements determined by the Courts. 7. The Group recommends that the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 be commenced by the Minister for Health at the earliest possible opportunity. All relevant stakeholders should be required to familiarise themselves with the provisions of the Act through mandatory training. All healthcare providers should take steps to ensure that patients are made aware of their entitlements under the Act. 8. The Group recommends that a robust complaints and patient experience feedback mechanism should be developed within all clinical care units. This data should be collated and analysed by individual units as part of a broader assessment of patient experience within our healthcare institutions. These should be shared with frontline staff to assist learning and understanding of positive and negative experiences of healthcare.

	Strategic Priority	List of Recommendations
4	Care for babies born with Neonatal Encephalopathy and other Maternity Initiatives	1. The Group recommends that data on Neonatal Encephalopathy (NE) be collected on a statutory basis, and that a register of cerebral palsy cases in Ireland should be developed. 2. The Group recommends that the work of the National Neonatal Encephalopathy Action Group (NNEAG), and its efforts to reduce to the greatest extent possible the incidence of birth-related CP/ catastrophic birth injury, should receive ongoing support and endorsement. 3. The Group recommends that the investigation and follow-up of infants with HIE needs further development and standardisation. All babies presenting with HIE should have a standardised assessment including placental examination, MRI brain scan and follow-up neurodevelopmental assessment. 4. The Group recommends that research initiatives that advocate earlier diagnosis and intervention in cerebral palsy should be supported and that a taskforce should be put in place to devise a model of care for babies with HIE so that standardised follow-up will lead to the early detection and intervention in those babies with CP. 5. The Group recommends that care pathways, once developed, which start at birth and continue through life, for children who have suffered a catastrophic birth injury, should be considered for implementation on a national basis. The Group recognises that the initial development of new care pathways will be managed within existing resources. The State provision of such care could facilitate immediate and more effective evidence-based care and lead to growing national expertise, reducing the reliance on ad hoc private care arrangements. In addition, the provision of early claims resolution in the context of perinatal brain injury has the potential to meet family needs in real time, facilitate early clinical intervention and reduce the risk of claims increasing in value due to inflation or unmet needs translating into higher costs. While initially these care pathways would be limited to the cohort of children who have suffered a catastrophic birth injury, consideration should also be given in the future to rolling out these services to all children with cerebral palsy over a longer period of time, as national expertise and capacity develops and a review has been undertaken with regard to their effectiveness and efficiency for the initial targeted cohort. This would also need to be informed by an assessment of the feasibility of potentially increasing eligibility including resourcing constraints.

	Strategic Priority	List of Recommendations
5	Faster and More Efficient Resolution of Claims	1. The Group recommends the implementation without delay of recommendations made in a number of previous reports, along with some additional recommendations, advocating changes and improvements to the management of clinical negligence claims to include: a. The introduction of a pre-action protocol with sanctions for a party who fails to adhere to the protocol, as recommended in the Meenan Report. b. The facilitation of earlier mediation, where possible and agreeable to both parties. c. Amendments to case management Rules of Court should be made, to include a stipulation that equivalent rules apply to both sides, and that joint expert meetings (hot-tubbing) should be required to take place. d. A dedicated Court list should be established with judges in place with specialist knowledge of medical negligence litigation, or other appropriate measures to facilitate the earlier hearing of medical negligence cases. 2. The facility for Courts to award Periodic Payment Orders should be resumed. 3. The Group recommends that a panel of medical expert witnesses should be developed initially on a voluntary basis. This could be overseen by an existing regulatory body with appropriate expertise. Members of the panel would meet a series of criteria including that they are in active practice or recently retired, with relevant expertise and are trained as expert witnesses. They should be available to appear as expert witnesses for plaintiffs and defendants. Membership should function as a quality assurance and members of the panel should receive continuing development accreditation (CPD) accreditation. 4. The Group recommends that the personal injury discount rate, also known as the real rate of return, should be reviewed at regular intervals by the Minister for Justice. 5. The Group recommends that a medical records system, with unique identifiers, be put in place to facilitate better and more timely provision of records and that a system be put in place so that a patient or their solicitor can view their electronic medical records. In addition, a training programme for hospital staff should be put in place regarding best practice around medical records.

	Strategic Priority	List of Recommendations
6	Standardised Approach to Mass Action Claims	1. As set out in the Report, a range of alternative dispute resolution processes have been implemented. The Group recommends that the State should continue to use various forms of alternative dispute resolutions (e.g., mediations, binding mediations, ex-gratia schemes, compensation schemes, evaluations, assessments and tribunals) as appropriate, in order to offer an alternative to the adversarial court process. 2. The Group also recommends the development of a Vaccine Damage Scheme to ensure a controlled approach to management of potential claims, which should be undertaken urgently in line with previous commitments.

Table 1: Recommendations by Strategic Priority

The Group suggests that any potential implementation plan arising from this report, should include performance indicators to assess the impact of individual measures over time on the overall sustainability of State Claims expenditure (e.g. impacts on human and financial costs as well as savings).

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Section Two:
Setting The Scene - Where We Are Now

Chapter 1: The Human Cost of Adverse Clinical Events

Introduction

Our aim was to examine the rising cost of health-related claims in Ireland, and we felt that this assessment must include the human cost of litigation. We wanted to learn about the personal experience of patients and healthcare staff who have experienced litigation in order to assist our consideration of how the current medical litigation environment could be improved to better serve claimants, healthcare staff and the wider public interest. Most importantly, we wanted to acknowledge the harm that is central to the decision to litigate so that patient experience would be central to all our considerations.

In this Chapter, we set out to examine why patients and their families sought recourse to litigation following unanticipated harm in a clinical setting, the emotional toll associated with this course and in turn, the emotional toll on healthcare practitioners who are the subject of litigation.

Plaintiff Experience of the Medicolegal System

The Group recognised the importance of listening to patients and families speak of their personal experiences in a sensitive manner and carefully considered how that engagement might take place. We concluded that patients and their families might be more comfortable engaging with an independent third party. The HSE agreed, on behalf of the Group, to commission University College Cork (UCC), to carry out a qualitative patient experience study by a team of professionals with appropriate experience engaging with patients on sensitive issues.

The study consisted of a literature review and a small qualitative study of individuals who have direct experience of litigation.

This research presents the views and experiences of fifteen participants, consisting of twelve females and three males. Eleven participants shared their experiences relating to an adverse event which impacted a family member (one participant spoke about two family members), nine of whom were children (including both minors and adult children), and three were a spouse. Of the twelve individuals discussed, eight were deceased.

Four participants spoke about their personal experience of an adverse event.

The experiences discussed by participants related to a diverse range of adverse events including misdiagnoses and missed diagnoses, cases related to CervicalCheck, neonatal injuries, and surgical complications. The participants also had varying experiences following the adverse event; some pursued legal proceedings and settled prior to trial, one participant described proceeding to trial and some initiated but did not pursue a case. The adverse events and the experiences discussed span from approximately twenty years ago until 2023.

The full findings of the qualitative patient study, along with a literature review, are published separately and can be found at https://www.gov.ie/en/publication/9bcc5-interdepartmental-working-group-on-the-rising-cost-of-health-related-claims-report/.

Why do Patients Sue?

Literature Review

Every year approximately 2,000 people in Ireland undertake litigation proceedings on the foot of serious harm sustained because of perceived medical negligence in publicly-funded services. This is not an easy decision, and it is commonly found that the process of litigation compounds the distress and trauma of harm arising from adverse events and fails to meet individual hopes for resolution. In a study examining the relationship between medical malpractice claims and adverse events attributed to negligence, it was found that litigation infrequently compensates patients injured by medical negligence (Localio et al). The decision to pursue litigation following an adverse event is influenced by a variety of factors with common themes identified. Tumelty [2023] categorises these factors into those "with realistic legal aims", such as seeking financial compensation and a "day in court" and those with "extra-legal aims", including the requirement for information and explanation, the need for an apology, and the desire to prevent recurrence. Many seek acknowledgement that they were wronged. A key expectation for taking cases regardless of the verdict was a desire to be heard and make positive improvements to the healthcare system.

In a UK study, conducted by Opinium, it was found that compensation is "not life changing", but a step in the process of patients rehabilitating their lives and reassuring them for the future for both medical bills and any potential loss of earnings. The study spoke of the two facets of medical negligence cases, firstly the physical disability, and secondly the mental health component. A Norwegian study noted patients accepted that in all hospital practices there is an element of risk, however they felt that when negligence did become clearly evident, the hospital staff engaged in defensive and "cover-up" practices and were not forthcoming towards the patient in providing explanations, support or in some instances refusing follow-up care. This left many patients with an impression that their wellbeing and health was being severely undervalued by the hospital, e.g., reasons for delays and mistakes in diagnosis not being properly explained and sometimes in fact being trivialised as part and parcel of the recovery process.

A Scottish study reported that the desire to litigate related to a lack of proper communication or explanation during the complaint process, and a desire to safeguard future patients from similar incidents. Again, as in similar studies, patients stated that financial reward was not the main rationale for pursuing litigation.

Results of the Patient Qualitative Study

Regardless of motivation, several participants expressed reluctance to litigate emphasising that it was not a decision they took lightly, with some expressing a strong aversion to such a course.

The necessity for financial compensation was a critical consideration for some participants, particularly in cases involving infants and children. In these cases, ongoing clinical care and assistive supports were essential for the well-being of infants and children and to optimise future outcomes. Equally, adults may require expensive therapies and care well beyond their financial capability. An additional driver was the need to obtain compensation for loss of earnings.

Nonetheless, financial compensation is an imperfect mode of compensation (*Kearney v McQuillan* [2012] IEHC 127, [2012], IESC 43) and often falls short of addressing the deeper emotional and psychological needs of affected individuals. This was a recurring theme among participants, highlighting the limitations of financial remedies in addressing the emotional and psychological toll of patient harm. In some cases, the prospect of financial compensation increased distress. For one participant, the receipt of money as compensation for the loss of their children was hugely distressing, highlighting the profound grief and sense of loss that cannot be assuaged by financial means. Another participant expressed the view that they had no need for money but that they needed answers.

These accounts collectively underscore the complex and multifaceted nature of seeking justice and resolution in the aftermath of patient harm.

In contrast to the day in court concept, described in the literature, our participants expressed a clear aversion to the courtroom setting. One participant emphasised the reluctance of parents, whose children have experienced catastrophic birth injuries, to engage in litigation, highlighting the emotional burden and desire to avoid reliving traumatic experiences. On the other hand, another participant expressed regret over not having the opportunity for a day in court, seeing it as a means to seek justice and hold responsible parties accountable in a public forum. This sentiment reflects a nuanced perspective within the participant cohort.

Extra-legal Aims

Participants also identified a range of 'extra-legal aims', aims which the legal system is either less able or entirely unable to deliver.

Explanation and Seeking Truth

Seeking an explanation and uncovering the truth emerged as a primary driver for many participants considering litigation following harm. One participant was clear that had she received answers and satisfactory follow-up for her child, litigation would not have been necessary. A number of participants articulated a desire for accountability and acknowledgment of system failures, underscoring the significance of seeking explanations through the legal process. Participants spoke of receiving information in dribs and drabs over years and the need to honour those harmed by establishing the truth particularly in the context of bereavement.

Apology

This study found that the absence of an apology for the occurrence of the event and the treatment of patients and families thereafter was another strong driver pushing people towards litigation. For some, this was the primary goal from the outset and participants conveyed a clear desire for an apology as a crucial step towards resolution and healing in the aftermath of adverse events.

Preventing Recurrence

Participants demonstrated a strong sense of responsibility towards others and a desire to prevent the recurrence of similar incidents, viewing litigation as a potential avenue to achieve this goal. One participant articulated a strong sense of personal duty to ensure that such tragedies were avoided in the future, echoed by others who hoped their litigation would lead to preventative measures to safeguard against similar occurrences and for awareness, accountability and change within the healthcare system.

Accountability

Participants emphasised the importance of accountability and ownership in relation to their patient safety cases, expressing a desire for acknowledgment and acceptance of responsibility from the healthcare professionals and institutions involved. Participants sought validation of their experience and a commitment to improvement from the healthcare providers involved, reflecting a broader aspiration for accountability and learning within the healthcare system.

Advocacy for Women's Health Equity

Several participants in the study voiced strong concerns about the treatment of women within the Irish healthcare system, highlighting systemic issues and advocating for significant change to prioritise women's health needs. They expressed frustration with what they perceived as a patriarchal system that often dismisses or diminishes women's concerns, particularly in the context of childbirth and women's reproductive health. Participants emphasised the need for medical professionals and healthcare institutions to provide empathy, compassion, and dignified care to women, regardless of their background or circumstances.

Particular Challenges Posed by Litigation

Several participants recognised the limitations of the litigation route in addressing their extra-legal aims such as obtaining an apology, the admission of liability and the acknowledgement of negligence that caused harm. Some struggled with the significant financial risks associated with pursuing litigation and worried that financial loss would further compound the already devastating emotional toll of grief and loss. A strong theme that emerged from participant testimonies was the need to move away from the current adversarial environment of blame to one which fosters open honest communication where errors are admitted and acknowledged, questions are answered, and genuine dialogue is maintained.

"It's just, no matter what side of the fence you are on this, there's no winners like. It's all losers."

Patient Experience of Litigation

Participants were unified in their view that their experience of seeking justice through the civil litigation system was negative. They variously described it as triggering, re-traumatising, jarring, insulting, shocking, horrible, not fit for purpose and a battle. Several participants identified the system as particularly unsuited to those who have already experienced a significant trauma. One participant considered the experience of taking legal proceedings to be more traumatic than the original adverse event. Participants described a sense of loss of control, of being pawns on a chessboard, ancillary to the process. Participants also describe the lengthy nature of the process and the failure of an adversarial system centred on financial settlement and a culture of victory and defeat to meet their needs. There was a lack of clarity as to how cases are settled especially in relation to the distinction between settlement talks and mediation and a sense that the full potential of mediation was not embraced. One participant described a sense that people were playing games and using dirty tactics to reduce liability.

Experience of Engaging with their own Legal Team

In contrast, participants broadly described very positive experiences with their own legal team. A number of participants reported finding the empathy and understanding they encountered in this sphere to be in contrast with their experience in the healthcare system in the aftermath of the adverse event. Some described negative experiences, particularly in one case where a mother describes a sense that her legal team wanted to settle out of court rather than let her take the stand as she disagreed with her legal team on elements of diagnosis. She felt bound by her contract with the legal team to continue.

Loss of Control During the Legal Process

Several participants, despite maintaining relatively positive connections with their legal teams, expressed a sense of losing control once the legal proceedings commenced and felt part of an inevitable process. One participant described a sense of being sidelined in "a joust between the experts".

Power Dynamics

The challenges created by perceived structural imbalances inherent in litigation by an individual against a hospital and/or medical professionals were highlighted with the system described as a "David and Goliath experience until the 11th hour" and a system which favours the defendant "both in areas of finance and resources". The financial risk entailed in commencing litigation taken by participants was an additional issue identified. Participants also described feeling intimidated by highly educated professionals.

Failure of Civil Litigation System to Meet Plaintiff Aims/Alteration of Participant's Aims During the Process

Several participants pointed to the fact that the civil litigation process, focused as it is on financial compensation, did not meet their aims. Participants described feeling pressure from a legal system where it seemed success was measured in monetary terms with the focus on the value of the settlement above other aims. Some litigants also felt they were viewed negatively because they had received financial compensation.

Prolonged Nature of the Process

Some participants resolved their cases in a time ranging from 2 to 8 years and the prolonged nature of the process to reach a settlement exacerbated an already stressful process and some felt that delays were deliberately created to cause distress.

There was also a sense amongst some participants that professionals involved in litigation may have been incentivised to prolong proceedings.

Litigation Strategy when Liability is Admitted

The narratives presented highlight a dissatisfaction with the litigation strategy adopted by the State, particularly in cases where liability has been admitted. Participants felt this was a waste of State resources and added significantly to the burden experienced by those impacted by an adverse event.

Perception of Litigants

Several participants reported how they felt that the attitude of medical professionals towards them had changed, becoming colder and more distant, because they had taken a legal action. One participant described this feeling as like an 'Iron Curtain' coming down, while another felt that medical professionals were less trusting of her.

Mediation not Operating as Intended

While some participants did engage in a mediation process as part of the resolution process, they felt their actual involvement was limited with little involvement of the litigants, little exploration of alternative outcomes and often taking place many months into a litigation process.

This research has also highlighted the need for clearer communication with plaintiffs about how the case is proceeding. Some participants were unclear about how their cases were resolved. It would seem a clearer outline of the litigation process might be of benefit to plaintiffs.

Emotional and Mental Health Impact of Litigation on Plaintiffs

This qualitative patient review explored the emotional and mental health impact of the personal experience of litigation, identifying the impact of delays and also of repeated medical assessments, including invasions of privacy and feelings of violation. Participants identified how these additional burdens are experienced on top of bereavement or dealing with complex medical needs, either of the participant or of their child. Some participants also identified the long-lasting negative impact of these harms on their well-being and mental health.

All participants interviewed had experienced harm as a result of the original adverse event. Some were bereaved, some were experiencing ongoing physical and/or psychological harms, and some were engaged in supporting children with complex needs. For some, the experience of the legal process was more traumatic than the underlying adverse event and one participant describes a period of depression and a wish to commit suicide.

One of the strongest findings to emerge from participant interviews across all contexts was the additional harms imposed by the medical and psychological assessments which were part of the legal process. The repeated and invasive nature of assessments were very challenging. This was particularly felt in relation to assessments of children. Both the experience of being assessed and the way in which participants or their children were described in the reports were traumatic for many participants, particularly in cases where trust in the medical system was lost.

Several participants indicated that they continued to have mental health/well-being difficulties which in some cases continued long after the legal process had concluded. One participant describes leaving the Court and almost walking under a bus and explained that "It took me months, months for my body to regulate again."

Impact of Litigation on Healthcare Practitioners (HCPs)

The process of litigation also has a profoundly demoralising impact on health practitioners. The emotional and psychological impact can progress from shock and worry to profound numbness, guilt and isolation. Like litigants, HCPs who are the subject of litigation find the process deeply adversarial and the negative experience is compounded by the long duration of civil litigation and by the multiple processes that might arise following an adverse event. In addition, stress can be exacerbated by the requirement to keep practising during the resolution of a claim. Like litigants, HCPs describe longstanding emotional impacts, including anxiety and depression for years after a case and the emotional impact can lead people to choose alternative areas of clinical practice or leave practice altogether.

Literature Review

We conducted a limited review of current literature in relation to the impact of adverse events and litigation on healthcare practitioners. The international literature cites numerous original research articles addressing the concept of second victim. The term "second victim" is a commonly used term in the current academic literature describing the distress experienced by healthcare professionals involved in severe adverse events. In a recent literature review [European Journal of Obstetrics and Gynaecology and Reproductive Biology 213 (201) 11-16] of the second victim, it was noted that this phenomenon was common with a prevalence of anything from 10% to 73% of all healthcare practitioners. Reactions are influenced by the outcome of the error and the degree of personal responsibility the clinician may feel. Stress may be higher if the incidents involve young healthy people and multiple lives. The experiences of second victims are largely negative – fear, guilt, shame, physical symptoms, depression, PTSD and occasionally self-harm and suicide.

A number of studies suggest that second victims are highly prevalent in maternity care. A study of Australian midwives reported the majority had witnessed a traumatic birth event. Feelings of horror and guilt were prevalent and significantly more likely if care-related issues arose. 17% of midwives surveyed met the criteria for PTSD. Similarly, a Swedish study reported that 15% of obstetricians and midwives reported PTSD after their worst obstetric event. A Danish study revealed that 85% of obstetricians and midwives had been involved in a traumatic delivery and that internal feelings of guilt and shame were worse than the experience of external review. On a positive note, 65% of respondents felt that they became a better midwife or doctor following the traumatic incident. The prevalence of trauma among healthcare staff has prompted calls internationally for further research on how "present risk investigation, compensation or negligence schemes for avoidably damaged individuals may impact on birth culture, staff turnover and morale."

In January 2024, the Medical Protection Society (MPS), (which is a not-for-profit mutual organisation, that provides indemnity and support to medical professionals on a worldwide basis and to approximately 19,000 health professionals in Ireland), published "The human and financial cost of clinical negligence claims: The case for pre-action protocols". They report on their survey of 200 Medical Protection Society members who experienced a claim in the past five years. 78% of respondents rated their wellbeing as "worse" while the claim was ongoing compared to before, and 91% said they were worried about their wellbeing. 70% said they were worried about the wellbeing of their loved ones. Some healthcare professionals described the need for psychotherapy and professional assistance while others described suicidal thoughts while undergoing a claim against them. 44% of respondents said the claims process was more stressful than they imagined it would be. Concerns included the claim proceeding to trial and giving evidence, while 92% of respondents cited fear of reputational damage. Over half of the doctors surveyed reported lower self-esteem and a negative impact on family life. 20% of doctors had experienced negative media or social media coverage and 16% reported abuse from the claimant or their relatives.

Engagement with Healthcare Practitioners

We met with a group of midwives, nurses, NCHDs and consultant doctors and although this was not a formal qualitative assessment, a number of themes emerged, including shame, guilt and abandonment; difficulty meeting patient expectations; adversarial nature of proceedings; lack of control; protracted and complex nature of proceedings; the practice of defensive medicine; altering practice or leaving practice; and the wish to see patients compensated.

Shame, Guilt and Abandonment

HCPs we engaged with expressed guilt that patients had suffered adverse events and a deep sense of shame that they had failed in delivering good care. Some described feeling very stressed when adverse events arose, with high levels of anxiety and inability to sleep and eat. This impacted their normal daily activities. Some described feeling unsupported, particularly NCHDs who move frequently between hospitals who felt that they could be judged before they had a chance to prove themselves or that people in a new environment did not understand. They were reluctant to exhibit distress as this may be interpreted as an inability to cope.

In one submission, a senior midwife describes how she struggled to cope with a case that spanned 8 years from the event to the High Court proceedings. The case consumed her life for that period and for many years later. She felt profound isolation and abandonment and ceased practice with an overwhelming sense of despair and loss. She felt she was unprepared for several aspects of the litigation process. She recalls being intimidated by the Court environment and found cross examination extremely stressful. She found the media coverage devastating.

These feelings of shame and despair permeated every aspect of her life. After the case settled, she felt the system "cut me loose to sink or swim". She did not feel supported practically or emotionally as she endeavoured to resume her work. She had questions about the process but there was an unwillingness for the hospital to talk about it and it took six years for her to get a meeting to discuss her concerns. She went on to say "you don't get over something like this. The person after the event is not the same as before. The wounds never fully heal." She was told to get on with her life, but she felt unable to continue practising as a midwife. "I felt incredibly low and had never realised I could be in such a dark place…. Something inside of me had died… I was standing on the edge of a black hole".

A submission from a senior Director of Midwifery notes that a catastrophic outcome is devastating for all involved - for the parents and their families and for the staff involved. During care, a bond of trust and care builds up and poor outcomes can lead to profound feelings of failure and self-blame. Staff can be traumatised by feelings of guilt and devastation and this trauma persists during long protracted adversarial legal processes. Meeting journalists on entry and exit from the Coroner's Court or High Court can be very distressing. "I felt incredibly low and had never realised I could be in such a dark place. Something inside of me had died. I was standing on the edge of a black hole".

Difficulty Meeting Patient Expectations

HCPs felt that at times patients had an unrealistic expectation of what was possible and perceived clinical scenarios to be of low risk when in fact significant risks were present. This was particularly the case in maternity care which has witnessed a significant demographic change with women presenting at older ages with complex co-morbidities and following reproductive therapies. There was a sense that when complications arise, people look for someone to blame and that this can make difficult clinical scenarios more challenging.

Adversarial Nature of Proceedings

Senior clinicians who have practiced over several decades described the medicolegal environment as becoming increasingly adversarial resulting in the clinical environment becoming more uncomfortable and adverse.

They described the receipt of notification of legal proceedings as among the most stressful occurrences in their career - a stress which persisted long after official proceedings had completed. They found the language of letters of claim aggressive and noted that accusations are made about numerous elements of care, not all of which were accurate or fair. Doctors felt that inevitably the therapeutic relationship was damaged after a serious adverse event and that it was difficult for patients to retain trust particularly if civil proceedings commenced. Doctors also described not being permitted to engage with patients after an adverse event on the direction of legal teams representing the claimant.

Lack of Control

HCPs reported a fear of unbalanced and distorted media reporting which was not always accurate, compounded by their inability to reply and lack of protection in relation to the widespread exposure and reputational damage that can occur. This had a huge impact on their families and exacerbated feelings of fear, guilt and shame. They did not always understand the process of litigation or felt uninformed in relation to the progress of cases.

Some felt that they had little influence over decisions to defend cases and felt that the current system does not defend doctors but settles early regardless of the circumstances to save money. They felt that the reasonable doctor test was not applied but that effectively a policy of strict liability by the Courts pertained, in which any deficiency in care identified whether a contributing factor to outcome or not, led to a decision not to defend cases. They felt that even when patients were counselled about recognised risks, the consent process was meaningless when recognised complications occurred. Some felt that having taken part in reviews of adverse events, the information given was used against them. Other concerns expressed by doctors was a sense of inevitability about being sued and that a whole career of good practice, long hours and study could be obliterated by one case of adverse event.

Protracted and Complex Nature of Proceedings

As with litigants, HCPs described being fearful of the multiple processes that arise after an adverse event including internal reviews, external reviews, HSE and HIQA reviews, the Coroner's Court, civil proceedings and Medical Council proceedings.

A number of clinicians highlighted the time and resource involved in compiling in-depth reviews and that numerous review processes can ensue after an adverse event. These proceedings may take several years to conclude and have a deeply demoralising impact. Those interviewed were fearful about the prospect of going to Court and felt that the publicity arising in a court case meant that they were perceived as guilty regardless of the outcome. Some felt that for several years, there had been a reliance on particular expert witnesses.

The Practice of Defensive Medicine

Invariably clinicians felt they practiced defensively and at times ordered tests, sought extra opinions or retained patients in hospital because of a fear of being sued if there was an adverse event. The tendency to practice defensive medicine is echoed in a survey of surgeons in Ireland and in a survey of Irish obstetrics and gynaecology consultants. One non-consultant hospital doctor noted that some reference to litigation in conversation was a daily occurrence.

Altering Practice or Leaving Practice

A Director of Midwifery and Nursing noted that over a period from 2006 to 2018, cases heard in the High Court or Coroner's Court have resulted in at least one senior midwife in each case ceasing practice in the delivery ward in their hospital.

We could not find national comprehensive Irish data on the link between litigation and ceasing or changing practice, but this phenomenon is described in the literature. In a survey of surgical practice in Ireland more than 50% of respondents had experienced a medical negligence claim against them. Over one third were considering early retirement and one in five would consider emigrating due to a fear of being sued. In a survey of obstetric trainees, almost three quarters of doctors in training would consider leaving the specialty because of the risk of litigation and negative media coverage. Similar fears were expressed in a survey of medical students.

The Wish to see Patients Compensated

Those interviewed expressed a wish that patients would be appropriately compensated in the case of harm, particularly in cases of catastrophic brain injury where it seemed unfair that vastly different packages of care were available to those who obtained

compensation through the Courts and those reliant on HSE care packages.

Conclusion

A qualitative research study of patients/families who have litigated in Ireland found that participants were unified in their view that their experience of seeking justice through the civil litigation system was negative. They variously described it as triggering, re-traumatising, jarring, insulting, shocking, horrible, not fit for purpose and a battle. Several participants identified the system as particularly unsuited to those who have already experienced a significant trauma.

The decision to pursue litigation following an adverse event is influenced by a variety of factors, including the requirement for information and explanation, the need for an apology, and the desire to prevent recurrence and make the health system safer. Financial compensation was a critical consideration for some who required financial means to support care for infants or loved ones with catastrophic injuries, but it is limited by its failure to address the deeper emotional and psychological needs of resolution. In some cases, such as bereavement, financial compensation exacerbated claimant distress.

A strong theme that emerged from participant testimonies was the need to move away from the current adversarial environment to one which fosters open honest communication where errors are admitted and acknowledged, questions are answered, and genuine dialogue is maintained.

The protracted nature of legal proceedings left long lasting emotional scars and an adversarial system centred on financial settlement and a culture of victory and defeat, failed to meet the true resolution needs of participants. Several participants indicated that they continued to have mental health/well-being difficulties, which in some cases continued long after the legal process had concluded.

Patients who find themselves forced to litigate can experience profound distress and frustration at a very vulnerable time, when they are already navigating the challenge and impact of unanticipated harm. Delays in obtaining appropriate compensation can lead to delays in accessing important early care.

Adverse events can also affect healthcare workers with feelings of fear, guilt, shame, depression and PTSD recognised. Experience of litigation can lead healthcare workers to seek alternative work practice, which is of particular concern in high risk, highly specialised areas of medicine. In these environments, it can be extremely difficult to replace staff of similar experience. We need to ensure that clinicians are supported to provide care according to clinical requirements and to minimise defensive practice which can lead to increased healthcare costs and workload.

The human cost of healthcare litigation in Ireland must be addressed. Protracted and adversarial litigation proceedings propagate a cycle of harm: the process harms patients and families already harmed, it harms HCPs, and it harms the public interest. We need to focus on understanding and addressing the true needs of those harmed because of clinical errors, medical negligence and unanticipated harm. When things go wrong, our aim must be to assist patients and families to achieve meaningful resolution that addresses the fundamental need and right to access clear and accurate information, timely care and compassionate support, along with an apology and acknowledgement of the harm sustained and its impact. It is critical that HCPs and healthcare institutions learn from adverse events and that every effort is made to prevent further harm. Financial compensation is also required to assist patients and families to optimise potential health and psychological outcomes and the earlier this is achieved, the better.

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Chapter 2: Financial Cost of Claims

Introduction

In this chapter, we consider the trend in both the volume of claims and the associated financial costs. We then examine the factors which are driving this trend. Given the complexity of the subject, the initial section of the chapter provides the reader with explanations of terms used.

Role of the SCA and State Indemnity Schemes

The State Claims Agency (SCA) manages personal injury claims against the State and state authorities, as delegated to it by Government, and provides related risk management services. It also manages claims for legal costs against the State and state authorities, as delegated to it, however so incurred.

The SCA is obliged by statute to manage claims in such a manner as to ensure that the liability of state authorities is contained at the lowest achievable level. In performing this function, the SCA seeks to act fairly, ethically and sensitively in dealing with people who have suffered injuries, and their families. The SCA interprets this as meaning no injured patient or family should go undercompensated or overcompensated.

The State indemnity schemes are schemes which operate on a 'pay as you go' basis, whereby the financial costs associated with claims are paid as they arise in the individual cases. The figures presented in this report are costs and estimates as calculated by the SCA and are in keeping with figures published by the SCA in its annual reports. Although reported by the SCA, the liability, including future liability, for claims costs rests with the HSE.

Clinical negligence claims, which arise out of alleged negligence in relation to the provision of professional medical services, are managed through the Clinical Indemnity Scheme (CIS). For the purposes of the CIS, state authorities are primarily the HSE and organisations in the voluntary health and social care sector to which the Minister for Health has provided an indemnity in respect of clinical claims.

General claims are managed under the General Indemnity Scheme (GIS). This category of claims includes claims related to patients, e.g., claims related to hazards such as physical hazards (slips, trips and falls) or biological hazards (e.g., healthcare acquired infections, vaccines), as well as personal injury claims taken by family members of patients alleging psychological injury as a consequence of injuries to a patient.

General claims also include non-patient-related claims in a health or social care setting, including alleged personal injury to healthcare workers, to members of the public or third-party property damage.

For the purposes of this report, healthcare claims are considered to be those claims that occur in a health or social care setting, which may be managed under the CIS or GIS, as outlined above. The GIS also covers claims against other state authorities, e.g., An Garda Siochana, the Minister for Defence, and these claims are not considered in this report.

Understanding the Costs of Claims

There is usually a time lag between the occurrence of an adverse event and its later notification as a claim. In addition, it typically takes a number of years for the claim to be finalised, during which time transactional costs, such as expert witnesses' fees and legal fees, will be incurred. The amount paid by the SCA in any one year represents the cash payments associated with claims finalised in the year, in addition to the cash payments associated with active claims not yet settled or finalised. To understand the full costs to the State of healthcare-related claims, it is necessary to look at both cash payments made in any year, and the estimated liability amount, which is still required to be paid in future years.

The total cost of a claim (described by the SCA as the incurred total cost of a claim) is the total cost of resolving a claim, including all damages paid, legal costs and expert witness costs. The total amount is only determined when a claim is fully resolved, which is typically a period of time after the claim has been settled or a court award made. When a claim is first notified, the SCA calculates the total estimated liability of the claim, which is the Agency's estimate of what the likely overall cost of the claim will be; this estimate is revised over the course of the claim as new information is received.

The estimated outstanding liability (EOL) refers to the State Claims Agency's best estimate, at a particular point in time, of the total cost of resolving claims that have been received but are not yet finalised, less any payments already made. Estimated outstanding liability figures are published in the NTMA Annual Report.

Transactional costs (TC) are the costs paid in a given period (e.g., a particular year). They include the final payments made in relation to any claims finalised in the period and payments relating to the ongoing management of claims not yet finalised, such as legal costs and expert witness costs. They may include interim payments made on claims which were settled in prior years on an interim payment basis.

The annual transactional costs, reported by the SCA in the NTMA Annual Report, represent the actual expenditure on claims in any year. It does not take account of the estimated outstanding liability for new claims received (but not finalised in the year), or changes to the State's estimated outstanding liability for existing claims. **For the purposes of this report,** a figure is presented which captures both the annual transactional costs (TC) and annualised changes in estimated outstanding liability (EOL). This figure assists with understanding the factors driving claims costs. It is calculated as the sum of the year-on-year difference in the estimated outstanding liability plus the transactional costs in the period (TC+EOL).

It is important to note, as indicated above, that the State, unlike an Insurance Company, does not set aside a reserve of money, calculated by reference to the cumulative reserves on individual cases. The State indemnity schemes are *'pay as you go'* schemes, whereby the financial costs associated with claims are paid out as they arise in the individual cases.

The transactional cost figures used in this section are equivalent to the annual cash spend (as voted by the Oireachtas).

The table below shows the key figures for the entire healthcare claims portfolios. We have limited the analysis to the period 2018 to 2022. Please note that figures in tables may not add precisely due to rounding.

Total portfolio	**2018**	**2019**	**2020**	**2021**	**2022**
Estimated outstanding liability at year end	€2,821m	€3,304m	€3,688m	€4,185m	€4,627m
Movement in year	€458m	€483m	€384m	€496m	€442m
Transactional costs in year	€326m	€394m	€384m	€464m	€501m
Total annual cost of claims	**€784m**	**€878m**	**€768m**	**€960m**	**€944m**
Estimated total cost of new claims	€573m	€718m	€623m	€675m	€622m
Revision of liability for existing claims	€212m	€159m	€145m	€284m	€322m
Total annual cost of claims	**€784m**	**€878m**	**€768m**	**€960m**	**€944m**
Number of new claims	2,163	2,396	2,101	1,927	1,934
Total number of active claims	**6,553**	**7,325**	**7,657**	**7,827**	**8,163**

Table 2: Key Figures for Entire Health Claims Portfolios 2018 to 2022

The upward trend in costs is not matched with an equivalent rise in new claims at portfolio level. However, to understand the relationship between numbers of claims and overall costs, we need to consider the composition of the overall healthcare claims portfolio, which is made up of different categories of claims, with different characteristics.

The table below gives a description of each of the four categories of claim type:

Category	Description of each category of claim
Clinical Catastrophic	Claims which arise out of alleged negligence in relation to the provision of professional medical services, where the estimated total cost is greater than €4m and/or where a catastrophic injury* is sustained. Clinical catastrophic claims account for the minority of clinical claims but may result in total damages in excess of €10m, with a number of cases resulting in total damages of €30m or more.
Clinical Non-Catastrophic	Claims which arise out of alleged negligence in relation to the provision of professional medical services, and which do not fall within the definition of catastrophic clinical claims.
General	This category of claims includes claims related to patients, e.g., claims related to hazards such as physical hazards (slips, trips and falls) or biological hazards (e.g., healthcare acquired infections, vaccine), as well as personal injury claims taken by family members of patients alleging psychological injury as a consequence of injuries to a patient. General claims also include non-patient related claims in a health or social care setting, including alleged personal injury to healthcare workers, to members of the public or third-party property damage. This category tends to have a higher number of claims, but a lower (relatively) level of settlement.
Mass Action, Clinical and General	This category is made up of claims where a single incident or issue generates a high number of claims. Examples include claims relating to National Screening Services (cervical cancer litigation), Kerry Children & Adolescent Mental Health Services (CAMHS), H1N1 flu vaccination and transvaginal implants. Because of the diverse nature of the different issues, the numbers of claims and costs of settlement vary.

Table 3: Description of each category of claim

*For the purpose of this report, a catastrophic injury claim, as defined by the State Claims Agency, is one where an injury arises that results in serious disability/permanent incapacity (for example, cerebral palsy), or where the estimated liability is over €4m. This definition is applied to the categories of claims described, recognising however, that there are other claims, not included in the definition, which involve catastrophic injury, ordinarily understood.

The tables below show the total annual cost of claims analysed over the four categories of claim type, and the numbers of new claims for those categories:

Total annual cost of claims	2018	2019	2020	2021	2022	Total over period	%
Clinical Catastrophic	€364m	€474m	€359m	€494m	€585m	€2,277m	53%
Clinical Non-Catastrophic	€240m	€188m	€231m	€193m	€162m	€1,015m	23%
General	€132m	€141m	€121m	€119m	€84m	€597m	14%
Mass Action - Clinical and General	€48m	€75m	€57m	€153m	€112m	€445m	10%
Total all categories	**€784m**	**€878m**	**€768m**	**€959m**	**€943m**	**€4,333m**	

Table 4: Claims costs over categories 2018 to 2022

Total numbers of new claims notified	2018	2019	2020	2021	2022	Total over period	%
Clinical Catastrophic	52	54	39	44	35	224	2%
Clinical Non-Catastrophic	688	703	758	583	517	3,249	31%
General	1,269	1,419	1,175	1,139	1,163	6,165	59%
Mass Action - Clinical and General	154	220	129	161	219	883	8%
Number of new claims notified in year	**2,163**	**2,396**	**2,101**	**1,927**	**1,934**	**10,521**	
Cumulative claims outstanding	**6,553**	**7,325**	**7,657**	**7,827**	**8,163**		

Table 5: Numbers of new claims notified by category 2018 to 2022

While there is not a direct relationship between total annual cost of claims and the number of new claims, because the annual costs include costs relating to existing claims, it is nevertheless the case that clinical catastrophic claims account for 53% of total costs for the period, despite accounting for 2% of the number of new claims annually. By contrast, general claims account for 59% of new claims, but only 14% of total costs.

In the sections below, we have considered each category in more detail:

Category: Clinical Catastrophic Claims

Clinical Catastropic Claims	**2018**	**2019**	**2020**	**2021**	**2022**
Estimated outstanding liability at year end	€1,724m	€1,993m	€2,151m	€2,398m	€2,740m
Movement in year	€217m	€269m	€158m	€247m	€342m
Transactional costs in year	€147m	€205m	€201m	€247m	€243m
Total annual cost of claims	**€364m**	**€474m**	**€359m**	**€494m**	**€585m**
Estimated total cost of new claims	€241m	€359m	€267m	€292m	€294m
Revision of liability for existing claims	€124m	€115m	€92m	€202m	€291m
Total annual cost of claims	**€364m**	**€474m**	**€359m**	**€494m**	**€585m**
Number of new claims	52	54	39	44	35
Total number of active claims	289	323	325	335	355
Average estimated outstanding liability per claim for new claims	€4.6m	€6.7m	€6.8m	€6.6m	€8.4m
Average estimated outstanding liability per claim for active claims	€6.0m	€6.2m	€6.6m	€7.2m	€7.7m

Table 6: Clinical Catastrophic Claims 2018 to 2022

As can be seen from the table, the total annual cost of this category of claims has been rising steadily, with 2022 costs 61% higher than 2018. This is despite a reduction in the number of new claims received annually in this category over the period.

The primary driver of the increased cost is an increase in the settlement cost of new claims with the average estimated liability for new claims increasing by 83% (from €4.6m to €8.4m) over the period, and the average estimated outstanding liability of all active claims increasing by 29% (from €6.0m to €7.7m) in the same period.

The increase in the total liability for this category of claim can be attributed to a number of factors, which in turn are associated with how the settlement amount is arrived at. This is discussed in more detail in the section on “Reserving Claims”.

Category: Clinical Non-Catastrophic Claims

Clinical Non-Catastrophic	**2018**	**2019**	**2020**	**2021**	**2022**
Estimated outstanding liability at year end	€606m	€677m	€791m	€875m	€912m
Movement in year	€121m	€71m	€114m	€85m	€37m
Transactional costs in year	€119m	€117m	€117m	€109m	€125m
Total annual cost of claims	**€240m**	**€188m**	**€231m**	**€193m**	**€162m**
Estimated total cost of new claims	€168m	€168m	€203m	€170m	€154m
Revision of liability for existing claims	€72m	€20m	€28m	€24m	€8m
Total annual cost of claims	**€240m**	**€188m**	**€231m**	**€193m**	**€162m**
Number of new claims	688	703	758	583	517
Total number of active claims	2,760	2,831	2,887	2,916	2,983
Average estimated outstanding liability per claim for new claims	€0.24m	€0.24m	€0.27m	€0.29m	€0.30m
Average estimated outstanding liability per claim for active claims	€0.22m	€0.24m	€0.27m	€0.30m	€0.31m

Table 7: Clinical Non-Catastrophic Claims 2018 to 2022

This category of claims accounted for 31% of all new claims over the period, and 23% of the total costs. The total annual cost has reduced from €240m to €162m between 2018 and 2022.

The principal factor influencing the total annual cost for this category is the number of new claims in any year, rather than the settlement cost of claims. The reduction in the total annual costs in large part reflects a lower number of new claims, partly offset by an increase in the average estimated costs of individual claims. The reduced number of new claims in 2021 and 2022 may reflect reduced levels of activity in health services immediately following the COVID-19 pandemic. This trend may reverse over the coming years, further increasing costs.

Category: General Claims

General	2018	2019	2020	2021	2022
Estimated Outstanding liability at year end	€373m	€452m	€519m	€569m	€583m
Movement in year	€82m	€79m	€67m	€50m	€14m
Transactional costs in year	€50m	€61m	€54m	€69m	€71m
Total annual cost of claims	**€132m**	**€141m**	**€121m**	**€119m**	**€84m**
Estimated total cost of new claims	€116m	€128m	€108m	€126m	€97m
Revision of liability for existing claims	€16m	€13m	€13m	€-6m	€-13m
Total annual cost of claims	**€132m**	**€141m**	**€121m**	**€119m**	**€84m**
Number of new claims	1,269	1,419	1,175	1,139	1,163
Total number of active claims	3,231	3,695	3,860	3,930	4,003
Average Estimated Outstanding liability per claim for new claims	€0.09m	€0.09m	€0.09m	€0.11m	€0.08m
Average Estimated Outstanding liability per claim for active claims	€0.12m	€0.12m	€0.13m	€0.14m	€0.15m

Table 8: General Non-Clinical Claims 2018 to 2022

This category of claims accounted for 59% of all new claims over the period, and 14% of the total costs.

Category: Mass Action Claims – Clinical and General

Mass Action - Clinical and General	2018	2019	2020	2021	2022
Estimated Outstanding liability at year end	€118m	€183m	€228m	€342m	€392m
Movement in year	€38m	€65m	€46m	€114m	€50m
Transactional costs in year	€10m	€10m	€11m	€39m	€62m
Total annual cost of claims	**€48m**	**€75m**	**€57m**	**€153m**	**€112m**
Estimated total cost of new claims	€48m	€63m	€44m	€88m	€76m
Revision of liability for existing claims	€0m	€12m	€13m	€65m	€36m
Total annual cost of claims	**€48m**	**€75m**	**€57m**	**€153m**	**€112m**
Number of new claims	154	220	129	161	219
Total number of active claims	273	476	585	646	822
Average estimated outstanding liability per claim for new claims	€0.31m	€0.29m	€0.34m	€0.55m	€0.35m
Average estimated outstanding liability per claim for active claims	€0.43m	€0.38m	€0.39m	€0.53m	€0.48m

Table 9: Mass Action Claims - Clinical & General 2018 to 2022

This category of claims has accounted for 8% of all new claims over the period, and 10% of the total costs.

By their nature, the claims which comprise this category do not support consideration of trends over time as they relate to diverse issues which generate variable numbers of claims, as can be seen in the variation in both the costs and number of new claims annually. A further factor is that the claims, when first notified, are novel, and there can be a large final adjustment to the costs in the year of settlement, particularly where all or most claims within a mass action are settled simultaneously. For example, in 2021, the estimated outstanding liability was revised upwards reflecting the revision of estimates associated with the H1N1 narcolepsy and cataplexy cohort of claims following the settlement of an initial pathfinder case.

Consideration of Settlement Amount

Settlement damages in claims comprise two distinct elements:

1. General damages are paid for pain and suffering

2. Special damages compensate for expenses that arise because of a claimant's injuries.

The general damages tariff for injury types was addressed by the introduction of Personal Injury Guidelines in 2021 in accordance with the Judicial Council Act 2019. The most severe cases of catastrophic injury will incur compensation payments in the region of €550,000 for general damages.

The special damages paid on any claim will vary depending on a range of factors, including the severity of the injury sustained, the age of the claimant, the life expectancy of the claimant and their personal circumstances. Court awards for special damages have increased along with the inclusion of additional heads of damages in claims. It is often the special damages, including the cost of care and loss of earnings, that account for the large and increasing settlements made in catastrophic injury cases. Claims may result in total damages in excess of €10m, with a number of cases resulting in total damages of €30m or more. Such high value settlements are particularly seen in cases of catastrophic birth injury / cerebral palsy where the Courts seek to provide all care possibly required into the future for a child. Increases in life expectancy, advances in costly assistive technologies, complex multidisciplinary care and accommodation requirements, rising inflation and loss of earnings are just some of the elements that contribute to these large claim settlement costs.

While life expectancy has been increasing over time for everyone, this is also the case for those people with catastrophic injuries. This can be attributed to improvements and advances in healthcare and advances in medical technology. The ongoing development of new and improved medicines and treatments contributes to increased life expectancy for all.

In summary, the rising court awards for special damages, particularly in clinical catastrophic claims, including CP, are being driven by additional heads of damage in relation to care requirements, assistive technologies and accommodation, increased life expectancy due to advances in medical care, and inflation. The impact of these factors is compounded by the reduction in the real rate of return following the Court of Appeal Judgment in *Russell (a minor) v HSE* [2016] 3 IR 427. This is considered further in the section below on "Reserving Claims".

Reserving Claims

The SCA's claims managers, as part of the claims management discipline, allocate an estimated liability to every case following a claim or where it is adjudged to be a potential claim. The estimated liability is the best guesstimate of the most likely financial outcome of an individual case, based on the relevant information, medical and otherwise, to hand when allocating the estimated liability. The estimated liability, a dynamic figure until it eventually hardens at an ultimate point in the life cycle of a claim, is based on a multitude of factors, namely, the severity and nature of the Plaintiff's injury or injuries (General Damages) and the potential impact of the pecuniary and non-pecuniary losses which flow from the injury or injuries. The estimated liability includes an estimate in respect of potential loss of earnings, likely future care, aids & appliances and future therapies, and if applicable, the likelihood of future accommodation/ housing needs (Special Damages). The estimated liability also factors in experts' cost and the claimant's and the defendant's potential legal costs in any individual case.

In a case involving a fatality, consideration of the likely dependency loss to the family is factored into the estimated liability.

The process of allocating an estimated liability to an individual case takes into account the prevailing real rate of return/personal injury discount rate.

Real Rate of Return (RRoR)

The real rate of return is the investment return that a Plaintiff is assumed to obtain on a present-day basis should he/she invest his/her lump sum settlement award. A higher real rate of return will result in a lower lump sum award, whereas a lower real rate of return will require a higher lump sum award. The current rate is 1% for future wage-related care, and 1.5% for all items other than care such as loss of earnings, aids and appliances and ancillary needs *(Russell (a minor) v HSE* [2016] 3 IR 427).

The real rate of return was reduced following the Court of Appeal Judgement in *Russell (a minor) v HSE* [2016] 3 IR 427 and led to a substantial increase in damages awarded but accorded with the principle of full compensation (the purpose of an award of damages for personal injuries is, so far as money can do, to restore the injured person to the same position as if the injury involved had not happened. This is sometimes referred to as the principle of restitutio in integrum. Essentially, this means that the injured person is entitled to full compensation for the wrong committed. It is a long-standing principle in tort law.)

The real rate of return for all future costs was reduced from 3% to 1% for future care costs and 1.5% for other future financial losses. This had the immediate effect of increasing the level of special damages by a factor of 38%. The SCA estimated that the application of this level of real rate of return increased the transactional cost of meeting clinical negligence claims by approximately €100m per annum.

Section 24 (1) of the Civil Liability and Courts Act 2004 gives the Minister for Justice the power to prescribe by regulation the real rate of return that shall apply for the purposes of the assessment of damages in respect of future financial loss.

Following a recent review, it has been determined that the Minister for Justice should exercise her existing powers under section 24 of the 2004 Act. The Minister established an expert group chaired by Judge Brian McGovern to advise her in respect of an appropriate real rate of return and the assumed risk profile of claimants. The Group comprises expertise in legal matters, actuarial matters, economics and risk assessment. This report is currently being finalised and is expected to be submitted to the Minister for Justice in the second quarter of 2024. Once approved, work will begin on the drafting of the necessary Statutory Instrument.

Legal Costs

Legal costs have risen for the period 2018 to 2022 and represented 23% of total transactional costs of healthcare-related claims for that period.

SCA Transaction costs by category

Category	2018	2019	2020	2021	2022	Grand Total
Agency Legal Costs	€26.40m	€31.73m	€33.96m	€35.34m	€34.91m	€162.35m
Damages	€237.65m	€292.46m	€277.70m	€355.94m	€367.41m	€1,531.15m
Expert Costs	€12.21m	€9.41m	€10.72m	€10.65m	€13.84m	€56.83m
Plaintiff Legal Costs	€49.38m	€60.61m	€61.41m	€61.69m	€85.24m	€318.33m
Grand Total	**€325.64m**	**€394.21m**	**€383.78m**	**€463.63m**	**€501.4m**	**€2,068.66m**

Table 10: Breakdown of Costs by category 2018 to 2022

Whereas SCA legal costs for healthcare claims have risen by 32% between 2018 and 2022, plaintiff legal costs have risen by 73% in the same period; when expressed as a percentage of total costs, agency legal fees have fallen from 8% to 7%, and plaintiff legal costs have increased from 15% to 17%. The increased expenditure on plaintiff legal costs was due to several factors, including increased activity and an increase in expenditure on H1N1 plaintiff legal fees in 2022 compared with 2021.

The SCA's statutory legal costs management mandate is to manage claims for legal costs in such a manner as to ensure that the liability of the state authorities is contained at the lowest achievable level. The SCA's Legal Costs Unit deals with third-party legal costs of the State and state authorities as delegated to it, however such costs are incurred.

In 2022, the Legal Costs Unit achieved legal cost savings of 38.8% in relation to clinical claims and 38.5% in relation to general claims (healthcare and non-healthcare).

The introduction of a Pre-action Protocol (PAP) in England/Wales resulted in reduced legal costs and it is anticipated that their introduction in Ireland would have a like effect in terms of bringing about swifter resolution of claims with associated reductions in legal costs.

Lump Sum Payments v Periodic Payment Orders

Catastrophic injuries, particularly in babies or younger persons, which result in high value claims, necessitate the provision of compensation for complex care and loss of earnings long into the future. Lump sum awards are compensation payments calculated at a certain point in time based on estimates, which attempt to provide for all the compensation envisaged during the injured person's life. This is a complex process and given its speculative nature, can only estimate likely future costs based on a number of assumptions that may or may not come to pass. This can lead to over or undercompensation, particularly if the plaintiff dies earlier or lives longer than anticipated.

Periodic Payment Orders (PPOs) are an alternative to lump sum awards as provided for by the Civil Liability (Amendment) Act 2017. Traditionally, Courts awarded lump sum payments for all past and future losses in personal injury cases. The Civil Liability (Amendment) Act, 2017, empowers Courts to make consensual and non-consensual Periodic Payment Orders (PPOs) in cases where long-term permanent care is required due to catastrophic injuries. The Court may order that all or part of the damages for future medical treatment, care and assistive technology be paid through periodic payments. PPOs provide financial security for ongoing care needs and allow injured parties to receive regular payments tailored to their specific requirements. The overall benefit of a PPO is that the continuity of payment is secured for the lifetime of the injured party. Once a Court awards the original PPO payment, subsequent payments follow on an annual basis, for the lifetime of the injured party, without the necessity to revisit the settlement or involve Court hearings.

PPOs allow for a more real time compensation mechanism for as long as a plaintiff requires care. In England, most claims above an annually specified threshold (£3.5m in 2021/22) will settle as PPO, although some will settle as a lump sum. The costs of PPO settlements (considered as a proxy for high-value claims) in England have increased substantially over the past 20 years as a result of reductions in the personal injury discount rate allied with a volatile claims inflation environment.

Soon after the introduction of PPOs in Ireland, they were temporarily halted following the case of *H (a minor) v HSE* [2019] IE HC 788. In this case, the Court found that linking the indexation of periodic payments to the Harmonised Index of Consumer Prices (HICP – a harmonised index in the euro area used to measure consumer price inflation), as provided by the Civil Liability (Amendment) Act 2017, would lead to significant undercompensation of a plaintiff, estimated to be in the order of 26% after 20 years and 48% by the time the 5-year-old plaintiff reached 55 years. This would fail to meet the full compensation test as regards pecuniary loss. It was argued that PPOs should be linked to a wage-based index given that the bulk of the award comprises future care and medical costs. The Government set out to address these difficulties in two main ways including an amendment to the current legislation, which would allow the Minister for Justice, with the consent of the Minister of Finance, to set the indexation rate by way of regulations. Secondly an interdepartmental working group was established to advise the Minister for Justice as to the most appropriate indexation rate for use in Periodic Payment Orders.

The legislative amendments were enacted as part of the Courts and Civil Law (Miscellaneous Provisions) Act 2023 and were commenced on 31 July 2023. The interdepartmental working group to review indexation rates applicable to Periodic Payment Orders (PPO Group) is currently examining options for progress in this area and the Minister expects to receive its report and recommendations in the coming weeks. Following receipt of the PPO Group's report, it is expected that the Minister for Justice will move, as quickly as possible, to introduce the necessary regulations to establish the new indexation rate. It is hoped that PPOs can be resumed as soon as possible as an appropriate approach to compensation in high value claims.

Given the current cessation of PPOs set out above, the SCA seeks, where appropriate, and usually in relation to catastrophic injury claims, to put in place interim payment orders, agreed by both parties.

Conclusion

It is clear that the overall cost of claims has risen, whether measured by transactional costs or outstanding liabilities.

The data suggests that the rising cost of clinical claims is driven more by the rising costs of individual claims rather than by rising numbers of new claims occurring. In fact, the number of new catastrophic and non-catastrophic clinical claims has fallen in recent years.

The data presented in this chapter also shows that a key driver of rising healthcare claims costs is the high and rising costs of care in a relatively small number of high value catastrophic injury claims.

It is therefore important that this Group identify ways in which the needs met by the costs of claims can be addressed in better ways to improve the experience of claimants and to provide better and more consistent care to those who need it while always acknowledging the right of people to litigate.

This chapter also demonstrates that the cost of claims may be contained by other measures including an adjustment of the real rate of return, the introduction of a pre-action protocol (PAP) as discussed in more detail in chapter 9, measures to reduce the incidence of adverse events and measures to contain legal costs.

Chapter 3: International Comparison – Costs, Claims Models and Incident Rates

Introduction

In accordance with the Group's Terms of Reference, we set out to examine international practice in the area of health-related claims to facilitate comparative analysis, where possible and to explore potential learning from other jurisdictions. Caution is required when attempting to interpret comparisons between countries as there is a huge variation globally in populations, health systems, legal systems and insurance systems. There is also marked variation in terminology and definitions employed internationally, while reporting requirements also differ significantly.

Countries including Ireland, UK, Australia and Canada have tort law systems, while countries including Sweden, Denmark and New Zealand have adopted compensation schemes.

Tort law systems can be seen as more adversarial, with claims negotiated between claimant and defendant solicitors. If there is no agreement on liability and/or the amount of compensation to be awarded, they will ultimately go to trial in the Courts. In comparison, compensation schemes are more inquisitorial with claims generally taken to an administrative body which decides on eligibility and compensation.

The UK is among the most comparable jurisdictions to Ireland, employing Tort law. In addition, there are close medical links between the two jurisdictions with many Irish doctors and nurses working for a period in the UK. Many Irish doctors are members of the UK medical and surgical colleges such as the Royal College of Obstetricians and Gynaecologists and practice according to similar medical guidelines. Similar links operate across a range of medical specialties.

In the time permitted, it was not possible to consider a large number of jurisdictions, but we chose to consider five different countries based on existing work providing international comparison and evidence from insurers who work across a range of jurisdictions. The five jurisdictions chosen included Ireland, England, France, New Zealand and Florida, based on the variety of legal frameworks, previous knowledge of these jurisdictions and the fact that all operate in high income countries with advanced medical care.

Methodology

Our aim was to examine the following key questions:

1. How is clinical indemnity dealt with in each jurisdiction?
2. What is the cost of clinical negligence claims in each jurisdiction?
3. What is the clinical incident rate in each jurisdiction?

In order to address these questions, we obtained information from the following sources:

1. Engagement with NHS Resolution, the English equivalent of the State Claims Agency, including meeting with the Chief Executive and gathering of relevant reports.
2. Commissioning of the Health Research Board (HRB)* to carry out an evidence brief.
3. Contribution from consultation with Insurers – some of whom operate across other jurisdictions and provided statistical and other information comparing their experience of dealing with claims in Ireland and other countries, in terms of the approach, legal costs and the length of time it takes to deal with cases.
4. Other international comparative data.

*The HRB is the lead funding agency for health research in Ireland. It oversees a €45m investment in health research activity each year. In relation to the work on international comparisons, the Health Research Board (HRB) was engaged to carry out an evidence brief entitled *'A Comparative analysis of clinical negligence claims in a range of jurisdictions'*. The full report is published separately and can be found at https://www.gov.ie/en/publication/9bcc5-interdepartmental-working-group-on-the-rising-cost-of-health-related-claims-report/.

What is the Clinical Indemnity Model in Place in each Jurisdiction?

Ireland

The clinical indemnity model in Ireland operates within a tort-based system. All clinical negligence claims against state authorities are managed by the State Claims Agency under the Clinical Indemnity Scheme (CIS). General claims are managed under the General Indemnity Scheme (GIS). This category of claims includes claims related to patients, e.g., claims related to physical hazards (e.g., slips, trips and falls) or biological hazards (e.g., healthcare acquired infections, vaccine), as well as personal injury claims taken by family members of patients alleging psychological injury as a consequence of injuries to a patient. General claims also include non-patient related claims in a health or social care setting, including alleged personal injury to healthcare workers, to members of the public or third-party property damage. In addition, a number of group compensation schemes have been established by the Irish Government to manage mass actions.

The clinical negligence claims process involves several entities responsible for managing claims. To start a claim, the potential claimant needs to consult a lawyer. The process then proceeds by involving medical and other experts to evaluate the claim's validity and collecting vital evidence from medical records and other relevant sources. The State Claims Agency plays a significant role in this process through its management of claims against state authorities involved in clinical negligence claims.

In cases of evident clinical negligence, parties may opt for settlements. However, where liability is disputed and a settlement cannot be reached, cases proceed to court. The damages awarded compensate claimants for pain and suffering and financial losses resulting from medical negligence. Clinical negligence compensation against state authorities is funded through the Central Fund (Exchequer). The HSE reimburses the State Claims Agency for payments made under the Clinical Indemnity Scheme from its budget secured through the Health Vote, and the costs are not passed on to hospitals or units where the incidents occurred.

England

England operates a tort-based system similar to Ireland. NHS Resolution (NHSR) is a Special Health Authority with an operational focus and is legally known as the NHS Litigation Authority. It was established in 1995 for the purposes of establishing and administering indemnity schemes for meeting the liabilities of health service bodies. Costs of compensation are funded by a levy on NHS trusts.

Florida

Florida operates a tort-based model, except for birth-related neurological injuries, where a no-fault scheme is applied through the Florida Birth-Related Neurological Injury Compensation Association (NICA). NICA provides lifetime benefits and care for eligible infants and claimants do not need to establish fault. Funding for NICA comes from assessments paid by healthcare providers and medical malpractice insurers.

The tort system applies to other claims in Florida and is governed by legislation. Funding for the tort system comes from healthcare provider insurance, self-insurance or participation in a risk retention group.

New Zealand

New Zealand operates a no-fault compensation system for medical injuries. Injured patients receive government funded compensation, giving up the right to sue an at-fault party, except in cases of reckless conduct. The Accident Compensation Corporation (ACC) is responsible for administering the no-fault compensation scheme, for all types of injuries. To be eligible for compensation, there is no need to prove a breach of duty of care, just that the injury is caused by the treatment received and is not an ordinary consequence or necessary part of the treatment. The funding of the ACC is through a combination of levies and government contributions.

France
The system in France combines elements of tort and no-fault schemes. In 2002, the French Parliament passed the Patient's Rights Law of March 4, 2002, which established a compensation scheme that allows patients to seek compensation without proving fault by healthcare professionals or institutions. This scheme aims to provide compensation for victims of serious medical accidents resulting in significant disability or temporary incapacity of greater than six months. The scheme is underpinned by the principle of social solidarity in a civil liability tradition.

The compensation process is overseen by three bodies:

- ONIAM – Office National d'Indemnisation des Accidents Médicaux, des Affections Iatrogenes et des Infections Nosocomiales - this group organises compensation for patients who experienced medical accidents.
- CCIs – Commissions de Conciliation et d'Indemnisation des Accidents Médicaux, des Affections Iatrogenes et des Infections Nosocomiales - this group facilitates amicable settlement of disputes related to medical accidents.
- CNAMed – Commission Nationale des Accidents Médicaux - oversees medical accident experts and ensures uniform application of the system.

The compensation process for serious medical accidents varies depending on whether fault is established. If fault is established, the liability insurer of the healthcare provider is responsible for compensation. If no-fault is identified, the individual is compensated through a state fund managed by ONIAM. There are specific compensation schemes for certain medical injuries such as those caused by mandatory vaccinations, certain conditions arising from contaminated blood transfusions and sodium valproate.

Funding for the scheme comes from different sources - if fault is established, the health professional's insurer covers the damages. If no-fault is determined, ONIAM assumes responsibility for compensation. ONIAM is funded though the health insurance branch of the social security system and an annual state allowance.

How do we Compare Internationally on Costs?

Ireland is not alone in experiencing a significant increase in recent years in the costs of health-related claims, and in particular in the cost of claims relating to catastrophic birth injuries. The most comparable data comes from England which has a population of some 57 million people. As in Ireland, England has experienced significant increases in the cost of clinical claims. In England, which operates a similar tort-based system to Ireland, the cost of claims had risen from £1.3bn in 2012/13 to £2.4bn in 2021/22, an increase of 85%, while the provision for liabilities increased from £22.7bn to £128.2bn over the same time period (NHS Resolution Annual Report and Accounts 2021/22).

Of note, the NHS Resolution Annual Report and Accounts 2022/23 records a sharp decrease in provision for liabilities arising from claims from £128.6bn to £69.6bn. This is mainly as a consequence of changes to His Majesty's Treasury (HMT) Discount Rate, which is a discount rate (or rates) that UK Government bodies are required to use to discount future liabilities for the time value of money when presenting their reports and accounts. (It should not be confused with the Personal Injury Discount Rate, also known as the "Ogden Rate", which is analogous to the Real Rate of Return in Ireland, and which is set by Government rather than Court precedent). Due to prevailing economic conditions, a lower value in today's prices is placed on the future cost of settling all potential claims arising from incidents that occurred before March 31st, 2023. Similarly, the total estimated cost for clinical claims reduced from £13,285m to £6,278m with this reduction again attributed to an increase in the HMT Discount Rate. The change in the discount rate does not reflect changes in the main drivers of claims experience, such as the number of claims that result in damages being paid or the cost of paying these claims. Indeed, payments for settling claims increased by £232.4m (almost 10%) to £2,690.9m in the period 2022/23, with administrative costs increasing by 18%.

In England, the overall cost of clinical negligence claims continues to rise and remains of concern. Three key drivers of rising costs are identified, including increasing compensation awards, increasing claimant legal costs and an increase in the volume of claims. The increase in costs is driven primarily by damages for those who are severely harmed and who need provision for specialist care. Obstetric claims account for 13% of clinical claims reported in 2022/23 but for 64% of those claims by value. As a consequence, there is significant focus in the NHS Resolution Annual Report 2022/23 on addressing the causes and management of brain injury sustained at birth, which have a life-long and devastating impact.

PPO settlement costs, considered as a proxy for high value claims, have increased substantially over the past decade in England. Most claims above a £3.5m threshold will settle as PPO although some may settle as a lump sum. In a 2022 provisioning exercise, the value of a PPO claim in England was assumed to be £22m per claim. PPO claims (high value claims) have grown at a much higher rate than the CPI and show much more volatility. In a 2022 snapshot, the cost of claims in England was significantly higher than in other jurisdictions. The number of settled claims in England rose from 8,922 in 2012/13 to 13,070 in 2021/22.

Costs of Clinical Negligence Claims in New Zealand, France and Florida

New Zealand
In New Zealand, the Accident Compensation Corporation has published annual reports which provide data in relation to volume and value of claims from 2014/15 to 2019/20. The overall costs paid have risen from NZD$111.4m in 2014/15 to NZD$209m in 2019/20, an increase of 87%, while the projected outstanding liability for all accepted treatment injury claims has risen from NZD$5.1bn in 2015/16 to NZD$9.18bn in 2019/20 which is an increase of 80%. The volume of accepted claims has risen from 8,881 in 2015/16 to 11,285 in 2019/20.

France
In France, the data available on the volume and value of medical accident claims only covers claims processed under the general compensation scheme for serious medical accidents deemed no-fault and some other specific compensation schemes handled by ONIAM. As such the comparability of the information is limited. The total standard compensation paid for these claims has risen from €80.94m in 2015 to €129m in 2021, an increase of 60%. The total number of claims accepted by ONIAM in the same period rose from 747 to 861, an increase of 15%.

Florida
In Florida, data relating to volume and value of claims from the National Practitioner Data Bank (NPDB) shows an increase in the cost of medical malpractice reports from US$259m in 2015 to US$381.66m in 2022, an increase of 49%. The increase in the number of medical malpractice payment reports for the same time period rose from 1,012 in 2015 to 1,249 in 2022, a 23% increase. All entities, including insurance companies, engaged in making payments for medical malpractice claims against healthcare practitioners are required to report information to the NPDB. The figures include payments made under insurance policies, self-insurance arrangements or other means linked to the settlement or judgement of such claims in Florida.

Florida also operates a no-fault system for birth-related neurological injury claims. Information drawn from the Neurological Injury Compensation Association (NICA) reports shows that there were 226 active participants in 2022 and that total compensation paid rose from US$49.1m in 2021 to US$76.5m in 2023. This significant increase may be due to the impact of a court ruling in 2020, as a result of which NICA is no longer the "payer of last resort".

While the ability to compare data is limited, the overall trend that emerges from the international comparisons undertaken is that there is an increase in both the actual costs being paid for claims, and in the outstanding liability where that information is available. This increase in costs exceeds the increase in the number of claims.

Other Information from Reports/Consultations

In their Global Health Care Brief: A Quantum Comparison – assessment of damages around the world, (Feb 2023), Kennedys used a recently settled English claim as a case study to consider and compare what the settlement value may have been, based on the legislation and principles applied in ten other jurisdictions – Australia, Canada, France, Hong Kong, Ireland, Israel, Latin America, Portugal, Spain and the UK.

In the case study selected, the claimant suffered a serious hypoxic brain injury at birth (in 2002) following a delay in delivery. The brain injury resulted in left sided spastic hemiplegic cerebral palsy and associated developmental delay, behavioural problems, epilepsy and cognitive function half that of her chronological age. The case was settled in 2021 following a settlement meeting for just under £22m (based on a capitalised sum).

While there are significant differences in how the legal systems operate across the comparison countries and what might be included in the cost of such a claim, there is also a significant variation in potential damages awards across the different countries – ranging from just under £22m (based on a capitalised sum) in England through to in the region of US$500,000 (approximately £417,000) in Latin America.

One of the key contributory factors identified, is whether a discount rate is applicable to future losses and if so, the level of that discount rate and the multiplier that is applied. England and Wales appear to be the only jurisdiction with a significant negative discount rate for the duration of the claimant's life and is why multipliers of 90 are applied.

Periodic Payment Orders (PPOs) were also another interesting point of difference in the approach to compensation awards. A PPO is a form of compensation paid at regular intervals rather than in one lump sum. They effectively transfer the risk of mortality and investment from the claimant to the provider. PPOs are generally used in catastrophic injury cases where complex support will be required long into the future. It is very difficult to accurately predict future medical treatment, future care costs, the provision of evolving assistive technologies and the provision for future loss of earnings in cases where requirements and life expectancy is uncertain. Lump sum payments risk undercompensation or overcompensation as the Courts face the very difficult tasks of providing fair and just compensation where life expectancy is uncertain or disputed. PPOs give more certainty to plaintiffs, defendants, insurers and the Courts alike in relation to fair compensation. They facilitate realistic payments in line with economic changes through indexation and stepped payments. Whilst common in England and Wales, in Ireland their use is on hold, although their resumption is strongly advocated by a range of legal experts. In France they are at the discretion of the judge. This is dealt with in more detail in Chapter 9.

The Kennedys Report argues that reductions in the cost of claims are unlikely to occur without some form of tort reform, such as caps placed on damages, similar to those implemented in Australia as part of tort law reforms which occurred in the early 2000s. The objective was to reduce premiums and improve insurance availability, through regulating the recovery of damages. This resulted in removing smaller claims from the system while setting caps and thresholds on particular heads of damage for very large claims. A discount rate of 5% in Victoria and New South Wales and 6% in Western Australia (calculated weekly) is applied and acts to temper compensation payments. The Australian discount rates are prescribed by state governments and have remained unchanged since the tort law reforms.

MPS Data

Based on their own data, the MPS report that the average legal costs for claims in Ireland are €34,646 and are 191% more expensive than the UK, 26% more expensive than Singapore, 56% more expensive than Malaysia and 250% more expensive than South Africa. They attribute the increased cost of claims in Ireland to increased legal fees and increased time taken to resolve claims. The MPS contend that claims in Ireland take longer to resolve than in any other country where MPS has members. Average length of proceedings in Ireland was 1,462 days compared with 1,401 in Malaysia, 1,279 in South Africa, 940 in Hong Kong, 939 in the United Kingdom and 938 in Singapore.

MPS note that legal and expert costs made up almost a quarter (22.7%) of the costs paid by the SCA in 2022 to resolve and manage ongoing clinical negligence claims. In their report, MPS strongly advocate the introduction of a pre-action protocol, case management of litigated claims and specialist courts and judges.

International Comparison of Clinical Incident Rates

The rise in the cost of settling clinical claims begs the question as to whether this represents a deterioration in the quality of clinical care.

We drew from available Irish and international data in published reports and from the international comparative work of the HRB to determine current trends in incident reporting. Unfortunately, meaningful international clinical incident comparison is almost impossible because of differences in definitions, reporting mechanisms and KPIs.

The WHO recognised patient safety as a global health priority in 2019. The WHO defined an adverse incident as "any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. The definition includes errors, preventable adverse events, and hazards".

In Ireland, an adverse incident refers to "an event or circumstance which could have or did lead to unintended and/or unnecessary harm. Incidents include adverse events which result in harm; near misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention". Under the National Treasury Management Agency (Amendment) Act 2000, state authorities are required to report incidents to the State Claims Agency.

NIMS serves as the platform for reporting incidents in HSE and HSE-funded health and social care services and its outcomes align with the HSE's risk assessment tool categories.

The trend in clinical incident reporting has remained relatively stable from 2018 to 2022, with an increase in minor and moderate incidents, while major and extreme incidents have decreased. Negligible incidents have shown relative stability during this period.

In addition, as shown in Chapter 2, the rising cost of claims in Ireland seems to be driven more by a rise in the cost of individual claims, rather than by increasing number of claims occurring.

Trends in clinical incident reporting, 2018 to 2022

Category	2018	2019	2020	2021	2022
Negligible	111,946	109,705	107,523	110,421	109,627
Minor	16,521	18,166	19,784	21,995	22,072
Moderate	12,533	12,631	14,623	15,010	13,448
Major	427	426	287	149	146
Extreme	997	993	1,147	1,040	731
Total	**142,425**	**141,921**	**143,364**	**148,615**	**146,169***

Table 11: Clinical service user incidents in Ireland by severity; trends in clinical incident reporting, 2018 to 2022

*Total figure in 2022 extracted directly from source material. 145 (0.1%) clinical incidents in 2022 were not assigned a severity rating and have not been included in this table.

Source: State Claims Agency

Comparison of clinical incident rate in New Zealand, France, Ireland and Florida.

Clinical incident rate reported per million population

	2015	2016	2017	2018	2019	2020	2021	2022
New Zealand	N/A	148.1	153.1	176.3	160.3	166.0	N/A	N/A
France	N/A	N/A	4.3	7.9	17.6	16.0	27.7	N/A
Florida	251.9	282.0	342.4	388.2	441.1	364.0	368.7	391.0
Ireland	N/A	N/A	N/A	292.6	287.6	287.6	236.2	172.4

Table 12: Comparison of clinical incident rates in New Zealand, France, Ireland and Florida 2015 to 2022

Source: Health Research Board (HRB) 'A Comparative analysis of clinical negligence claims in a range of jurisdictions, An evidence brief' Chapter 3 'Findings' Section 3.1.5 Jurisdiction comparisons

In all four jurisdictions studied, there has been an increase in the reporting of adverse incidents, but the HRB suggest that this rise is likely due to improved transparency in health systems, rather than an actual increase in adverse events.

Notably, Ireland has a significantly higher rate of reporting adverse incidents, possibly influenced by the longer establishment of the NIMS platform. In addition, varying definitions across the jurisdictions impact what types of adverse incidents are reported, with France only reporting serious adverse events, while New Zealand, Florida and Ireland record more comprehensive data on minor event categories. We would like to emphasise that differences in reporting methods, varying definitions of clinical incidents, maturity of reporting platforms and whether reporting is mandatory or not, severely limit the comparability of the synthesised data across jurisdictions. For example, the reporting system in France is relatively new, reporting of clinical incidents in New Zealand is not mandatory, and different categories are reported in Florida. Whatever the reason, we would caution against direct comparison of clinical incident reporting between the chosen jurisdictions.

Conclusion

While Ireland is not alone in facing a significant rise in the cost of clinical negligence claims, caution is required in interpreting direct international comparisons as different countries have different health systems, State provision of services, legal systems and insurance systems. Differences in terminology and accounting standards also hamper direct financial comparisons.

While the ability to compare data is limited, common trends are found across a range of jurisdictions employing tort models, no-fault systems, and a combination. These trends include an increase in both the actual costs being paid for claims, and in the outstanding liability where that information is available.

The key drivers of rising costs include increasing compensation payments, increasing claimant legal costs and an increase in the volume of claims.

Brain injury sustained at birth is a major driver of the increased cost of resolving clinical negligence claims internationally. In England obstetric claims account for 13% of clinical claims reported in 2022/23 but for 64% of those claims by value. While the number of cases of brain injury is small, the cost of care into the future for affected children is high and is increasing.

The cost of care in catastrophic injury cases is heavily influenced by the personal injury discount rate applied to determine future costs in present-day terms and the variation in discount rates applied across different jurisdictions is a major contributor to the variation in the cost of resolving claims in the catastrophic injury category.

PPO settlement costs, considered by NHS Resolution in the presentation of their data as a proxy for high value claims, have increased substantially over the past decade in England. Most claims in England above a £3.5m threshold will settle as PPOs although some may settle as a lump sum. PPO payments are currently on hold in Ireland and are discussed in more detail in Chapter 9. The resumption of PPOs is strongly recommended by a range of legal experts.

Drawing on their own data, the MPS argue that legal costs are higher in Ireland than in any other jurisdiction where they have members. They note that legal costs paid by the SCA in Ireland account for 22.7% of total costs of clinical negligence claims in 2022, and that the high level of costs can be attributed to increased legal fees and increased duration of cases. They strongly advocate the introduction of a pre-action protocol, case management of litigated claims and the introduction of specialist courts and judges.

Some countries have introduced caps on claims and set relatively high discount rates but under the current constitutional provisions which provide for fair compensation, to include full compensation as regards pecuniary loss, as determined by the Courts and the right of all to access the Courts, it is questionable whether caps are implementable in Ireland.

It is almost impossible to draw meaningful conclusions for comparison of clinical incident data as differences in reporting methods, varying definitions of clinical incidents, the maturity of reporting platforms, and different requirements for reporting, severely limit the comparability of data across jurisdictions.

Chapter 4: Maternity Care, Cerebral Palsy and Neonatal Encephalopathy

Introduction

We have chosen to present a dedicated chapter on maternity care because of the particular contribution the maternity sector makes to the rising cost of clinical claims in Ireland. While the vast majority of maternity outcomes in Ireland are excellent, rare devastating outcomes occur including maternal death, perinatal death and severe maternal and perinatal morbidity.

Clinical negligence claims in maternity care are characterised by a small number of very high value claims and a higher volume of lower cost claims. A small number of "catastrophic claims", the majority of which relate to the development of CP associated with perinatal brain injury, accounted for 59% of the total estimated outstanding liability of all claims managed by the SCA at year end 2022. The estimated outstanding liability for clinical catastrophic claims has risen by 59% over the five-year period of 2018 to 2022 from €1.7bn to €2.7bn.

The cost of resolving claims in cases of catastrophic brain injury attributed to birth has been increasing at a sharp trajectory over the past decade and this trajectory looks set to continue. Proportionately the cost of resolving claims in relation to perinatal brain injury is the standout driver of the increasing cost of resolving clinical negligence claims, not just in maternity care but across the entire health sector.

For this reason, in this chapter, we set out major outcomes in Irish maternity care to give comparative context to our outcomes. We further discuss the aetiology of perinatal brain injury given its major contribution to resolution costs and we then briefly discuss other causes of litigation in maternity care which account for a much lower proportion of costs.

Major Outcomes in Irish Maternity Care

Maternity care is unique in medicine due to the complexity of pregnancy physiology, the balance of risk between fetus and mother and the specific inherent risks of pregnancy and childbirth. In countries with poor or scanty maternity care, the associated morbidity and mortality associated with unassisted childbirth is enormous. Over 90% of maternal deaths globally occur in developing countries and perinatal mortality rates can reach 50-60/1,000 live births (WHO, Unicef, UNFPA).

It is impossible to present all available maternity outcomes for the purpose of this report, but we present some major outcomes to provide some sense of where Ireland lies in relation to international comparison. We recommend the National Perinatal Epidemiology Centre (NPEC) and Irish Maternity Indicator System (IMIS) annual reports for further information.

Demographic Changes in Women giving Birth in Ireland

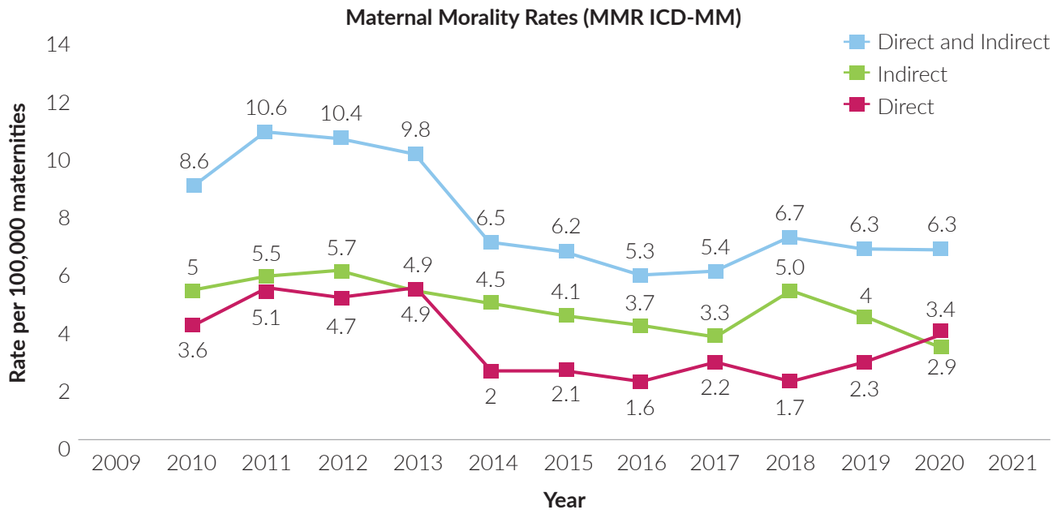
The demographic changes of women giving birth in Ireland are striking. At National Maternity Hospital (NMH) in Dublin in 2022, 11% of obstetric patients were over 40 years of age with a significant proportion of these women giving birth to their first baby, 17% of mothers were living with obesity, and an increasing proportion have become pregnant following assisted reproduction. This demographic is associated with increasing co–morbidities requiring multidisciplinary management. Nationally, the caesarean section rate is 36% and the operative delivery rate in first time mothers is 33%. Despite the challenging demographic, Ireland compares well internationally in terms of obstetric outcome.

Maternal Mortality Rate (MMR) in the Republic of Ireland

Maternal mortality is now thankfully a rare outcome and is no longer regarded as a marker of quality of service. Numbers are small, so triennial reporting is used to smooth out fluctuations in data. Maternal mortality rates (MMR) are based on maternal deaths due to direct or indirect causes and do not include deaths due to coincidental causes or late maternal deaths.

It is international practice to use the number of live births as the denominator for MMR, whereas the number of maternities is used by the UK and Ireland CEMD to calculate rates, as this represents a figure closer to the true number of women at risk.

Direct and Indirect Maternal Mortality rates per 100,000 maternities in Ireland using ICD-MM classification on cause of death: rolling three year data 2009 to 2021

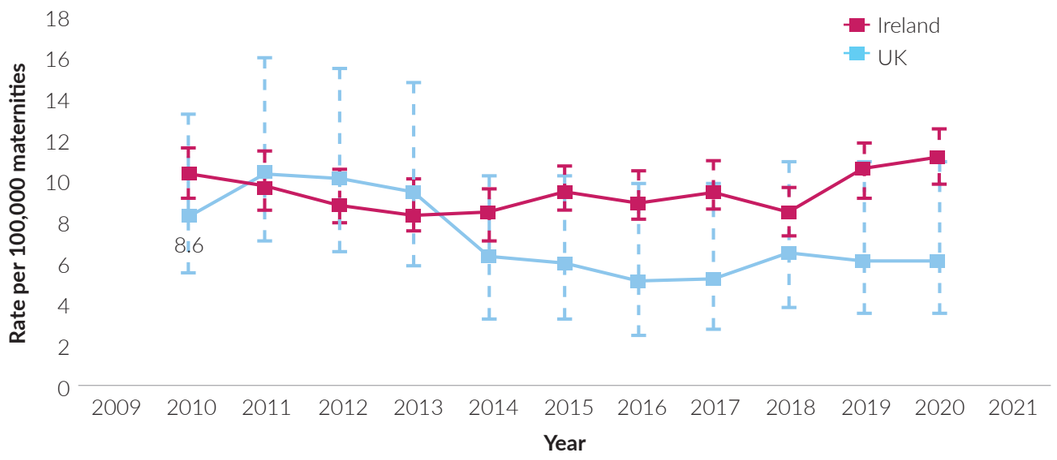


Note: Three-year moving average rates are plotted in middle year of triennium

Figure 1: Direct and Indirect Maternal Mortality rates per 100,000 maternities in Ireland using ICD-MM classification on cause of death: rolling three year data 2009 to 2021

The maternal mortality rate (MMR) was 6.3 per 100,000 maternities (95% CI 3.2-11.3) for the triennium 2019 to 2021.

Comparison of Maternal Mortality Rates: Ireland and the UK 2009 to 2021



Note: Three-year moving average rates are plotted in middle year of triennium

Figure 2: Comparison of Maternal Mortality Rates: Ireland and the UK 2009 to 2021

For the triennium 2019 to 2021, the Irish MMR was 6.3 per 100,000 maternities (95% CI 3.2-11.3) and the UK MMR was 11.6 per 100,000 maternities (95% CI 10.14-13.3). The MMR in the UK 2019 to 2021 adjusted to exclude deaths attributed to COVID-19 was 9.97 per 100,000 maternities (95% CI 8.65-11.42). In the same triennium there were no deaths attributed to COVID-19 in Ireland.

In a review of European maternal mortallity, rates varied from 2.7/100,000 live births in Norway to 9.6/100,000 in the UK and 10.9/100,000 in Slovakia.

Perinatal Mortality in Ireland

For the purpose of calculating perinatal mortality rates (PNMR), the denominator used is the number of births (live birth and stillbirths) from 24 weeks gestation or birth weight >500g. The corrected PNMR refers to births and stillbirths in normally formed infants, excluding congenital anomalies.

Trend in Perinatal Mortality Rates in Ireland, 2012 to 2021

Decreasing rates of perinatal mortality were observed in the decade prior to 2012. Since then, rates have remained relatively stable at approximately 3.2-3.7/1,000 total births. Similarly, the stillbirth rate is consistent at 3.5-3.7/1,000 total births, while the neonatal death rate (death within 7 days of birth) is 1.77-1.96/1,000 live births. These are very similar to UK figures which demonstrate a corrected PNMR of 3.1/1,000 births in 2021 and a stillbirth rate of 3.5/1,000 total births.

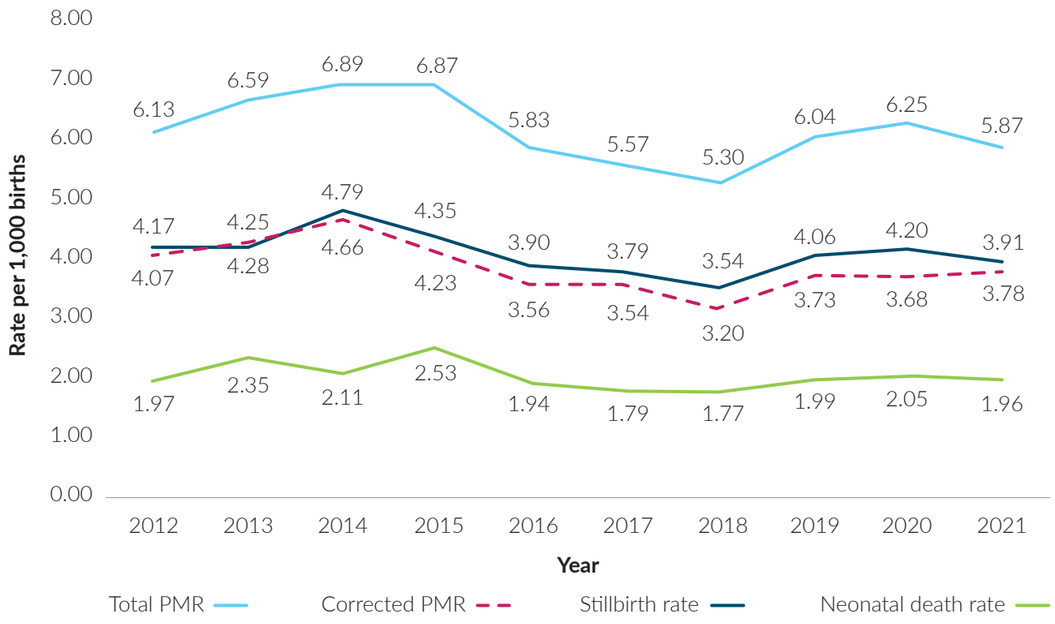


Figure 3: Trend in perinatal mortality rates in Ireland, 2012 to 2021

Severe Maternal Morbidity (SMM)

The SMM rate is a composite rate of a group of 16 clearly defined severe maternal morbidities.

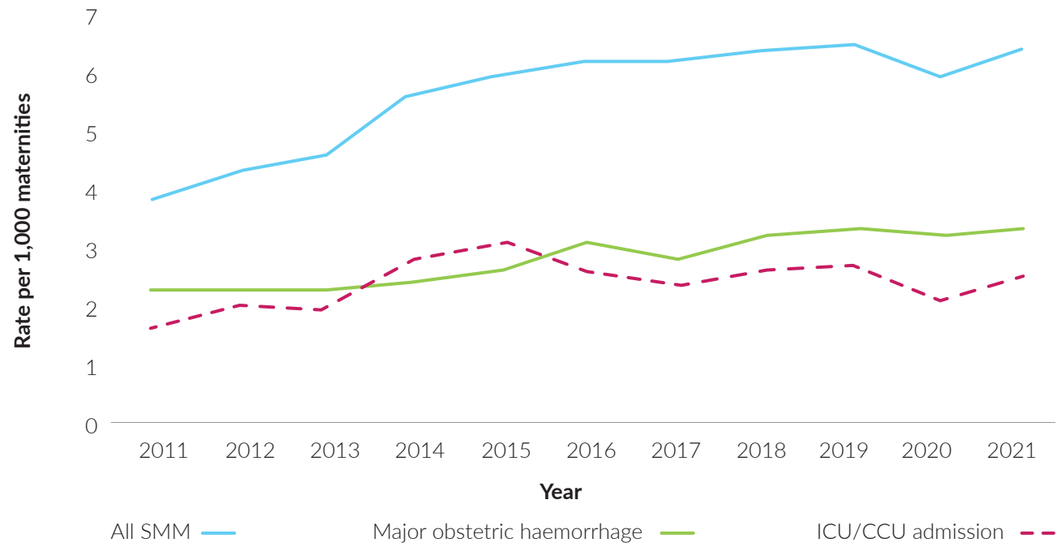
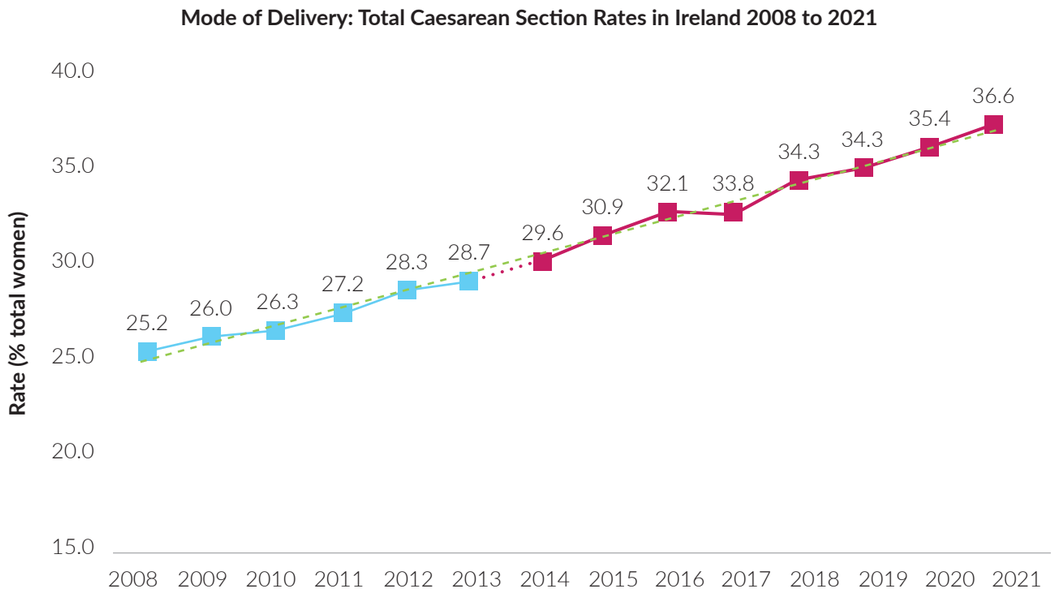


Figure 4: Trend in the rate of severe maternal morbidity (SMM), major obstetric haemorrhage and intensive care unit/coronary care unit (ICU/CCU) admission, 2011 to 2021

The Severe Maternal Morbidity (SMM) rate of 6.34 per 1,000 maternities in 2021 was 65% higher than the rate of 3.85 per 1,000 maternities in 2011. Thus, the incidence has changed from one case of SMM for every 260 maternities in 2011, to one case in 158 maternities in 2021.

Similar to previous years, major obstetric haemorrhage (MOH) was the most reported morbidity in 2021, accounting for over half of all SMM cases (53%). Obstetric haemorrhage is also a leading outcome resulting in litigation among maternity outcomes in Ireland. The second most common reportable SMM was ICU/CCU admission, which was experienced by 151 women (40.4%).

Direct international comparison of the composite SMM rate is difficult due to different definitions. The absolute numbers are small but do show a small upward trend which may reflect a changing demographic. It is positive to note that an increase in SMM has not translated into an increase in mortality.



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Rate*	25.2	26.0	26.3	27.2	28.3	28.7	29.6	30.9	32.1	32.1	33.8	34.3	35.4	36.6

*Per 100 women delivered (%)

Figure 5: Mode of Delivery: Total Caesarean Section Rates in Ireland 2008 to 2021

Sources: HIPE (closed national files for 2008 to 2013); NPRS 2008 to 2013; IMIS 2014 to 2021

One of the most striking demographic changes has been the increasing rate of caesarean section (CS) in Ireland. This is associated with rising rates of induction of labour which have reached 35% and a decline in the overall vaginal operative from 16% to 13%. The primary driver for increased CS rates is an increase in elective CS, the majority of which are performed in women who have had a previous CS. In first time mothers, induction of labour is associated with higher CS rates than spontaneous labour. The majority of caesarean sections performed in labour in first time mothers are performed because of dystocia and fetal heart rate abnormalities on cardiotocograph that may suggest poor fetal tolerance of labour.

Severe Perinatal Morbidity and CP

For the purpose of this report, it is not possible to consider all major perinatal outcomes, but we include the incidence of brain injury thought to arise from birth and rates of cerebral palsy which are the leading drivers of increased costs in resolving clinical negligence claims. In Ireland the incidence of perinatally acquired brain injury called hypoxic ischaemic encephalopathy (HIE) is 1.1/1,000 and appears to be stable, suggesting consistent factors in causation (NNEAG Report 2021). At present, Ireland does not keep a national cerebral palsy register. Currently only the Eastern Region Register remains active, and therefore information on epidemiological trends in recorded CP cases are now confined to that geographical area only. Extrapolating from this data in 2019, Ireland had a CP rate of approximately 1.77 per 1,000 births with an estimation that nationally there should be approximately 110 new cases per year (Craig M. Ir Mred J The National Cerebral Palsy register; Vol 113;no.8;p149).

Studies in Australia, Europe, Canada, Sweden, and Japan have suggested a declining prevalence of CP – particularly among low birth weight and preterm infants. Where data is available in higher income countries prevalence rates are generally reported between 1.2 and 2/1,000 live births. China reports a decline from 1.6/1,000 to 1.25/1,000. (Korzeniewski et al. Nature: September 2018 Vol 14).

New Zealand estimates suggest a prevalence of two cases per 1,000 live births.

In France, two regional cerebral palsy surveillance systems operate in Grenoble and Toulouse areas. These provide a prevalence estimate of 1.6 - 1.7 cases per 1,000 children.

In Europe, the Surveillance of Cerebral Palsy Network (SCPE) comprises a central database of CP registers using agreed standards, definitions and classifications. Data is available on more than 21,000 children with CP. The central database allows meaningful analysis and eliminates the challenges associated with interpretation of data when registers do not share the same harmonised methods and are dealing with small numbers. A 2016 large-scale study, using the data from 26 population registers across Europe, confirmed previous reports, in that there was an overall reduction in prevalence of CP in Europe from 1.90 to 1.77 per 1,000 live births in the 1980 to 2003 period (Sellier E et al. 2016. Dev Medical Child Neurology).

It was not possible to identify any cerebral palsy surveillance system in Florida. However, information on prevalence in the USA is collected through three surveys. The National Health Interview Survey and National Survey of Children's Health provided national estimates of cerebral palsy prevalence in children aged 3 to 17 years of approximately 3.2 cases per 1,000 children. The higher figure of 3.2/1,000 is from Florida and includes children aged 3-17 years, which may include cases acquired following birth (HRB data 2023).

Clinical Negligence Claims in Maternity Care

Clinical negligence claims in obstetrics are characterised by a small number of very high value claims. Damages costs in catastrophic brain injury cases are the major driver of the increasing cost of clinical negligence claims in Ireland, but other obstetric injuries including anal sphincter injury, make their contribution. In a review of claims between 2018 and 2022, 430 claims had paid damages of between €1 and €500,000, 105 had paid damages of more than €500,000 and 13 cases had paid damages of more than €10m. Almost 60% of claims related to labour and delivery. We consider the two types of claims, catastrophic and non-catastrophic.

Claims for Catastrophic Brain Injury

Clinical catastrophic claims represented 59% of total estimated outstanding liability (EOL) at year end 2022, and the EOL for clinical catastrophic claims has increased by 59% over the five years 2018 to 2022. The total annual cost of clinical catastrophic claims (as measured by the sum of the year-on-year difference in the estimated liability plus the transactional costs) has been rising each year, with 2022 annual costs 61% higher than those of 2018. This is despite a reduction in the number of new claims received annually in this category over the period. While clinical catastrophic claims accounted for 53% of total costs for the period 2018 to 2022, they accounted for 2% of the number of new claims annually.

Similarly in England, maternity-related claims account for 41% of annual clinical negligence payments, 64% of notified claim value and 65% of total clinical negligence provision. The majority of claims for catastrophic injury are made on behalf of infants who are believed to have sustained lack of oxygen during birth which has led to brain injury and the subsequent development of cerebral palsy. As advances are made in determining the causes of cerebral palsy, we are developing a better understanding of the contribution of events during pregnancy, labour and delivery to perinatal brain injury and CP. This facilitates the development of strategies to reduce or prevent the incidence of perinatal brain injury. We are now seeing some modest reductions in reported CP prevalence in high income countries. Importantly, as our understanding of the aetiology of cerebral palsy advances, so will our ability to provide treatment modalities and early intervention which could make a real impact on the outcome for affected children. While a detailed consideration of these issues is beyond the scope of this report, we felt it was important to address current clinical theories relating to the causes and risk factors for the development of CP and particularly the role played by perinatal brain injury associated with lack of oxygen during labour. We have also considered current key initiatives to improve the outcome in perinatal brain injury – initiatives which may significantly impact on the future course of litigation for this devastating condition.

What is Cerebral Palsy and what are the Causes of Cerebral Palsy?

Cerebral Palsy does not designate a specific disease but describes a collection of non-progressive neuromotor disorders of the brain. Rosenbaum et al defined it as: "A group of permanent disorders of the development of movement and posture, causing activity limitation, that are attributed to non-progressive disturbances that occurred in the developing foetal or infant brain".

It is a devastating condition characterised by

a) Motor problems both gross motor and fine motor with secondary musculoskeletal problems
b) Feeding problems – inability to suck and swallow
c) Sensory problems with irritability, difficulty in settling, problems with noise and texture
d) Sleeping problems – sleep problems in children with cerebral palsy are common due to drooling leading to respiratory difficulties, gastro-oesophageal reflux, bruxism (teeth grinding) and impairment of melatonin secretion
e) Pain – this is common due to muscle spasm and involuntary muscle movements
f) Epilepsy

Causes of Cerebral Palsy

Preterm birth accounts for up to 50% of cases of CP and the prevalence of CP among infants born before 28 weeks gestation is 10-50-fold higher than the prevalence in children born at term. The prevalence of CP among twins is fourfold higher than among singletons and this increased risk is higher again for higher order multiples, largely because of preterm birth and lower birth weight. Additional risk is conferred when twins share a placenta (monochorionicity) and are connected by blood vessels in the placenta particularly if one twin dies and the other survives.

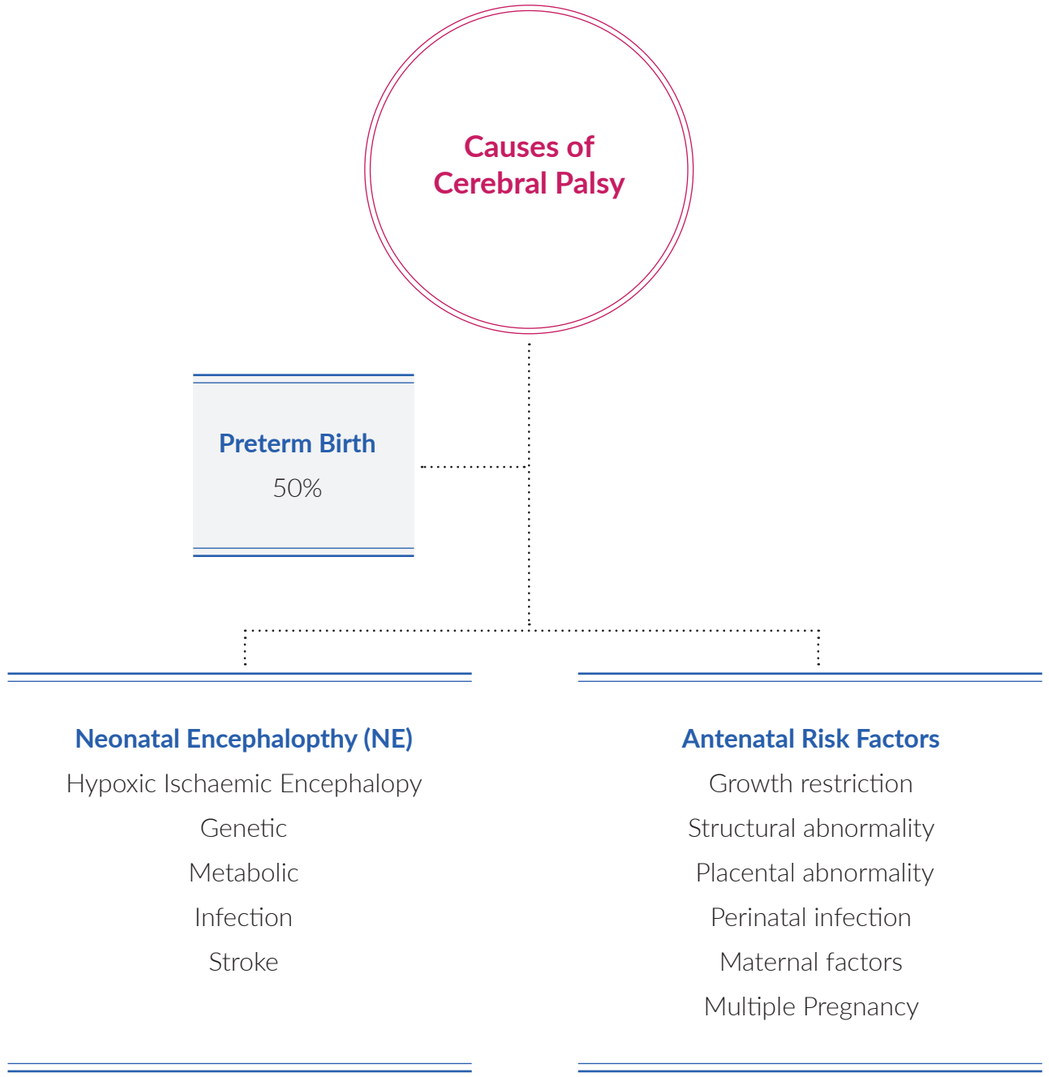


Figure 6: Major Causes of Cerebral Palsy

CP at Term or Near-Term Birth (>35 weeks gestation)

The cause of CP in infants born at or near term is more difficult to define. Several risk factors have been identified but they overlap and interact with each other making a clear singular cause difficult to identify. When catastrophic brain injury is presented as a cause of CP, it generally indicates babies who have presented with a condition called neonatal encephalopathy (NE) at birth and who have gone on to develop CP.

NE is an umbrella term for a heterogenous group of disorders that affects 1-4/1,000 babies in well-resourced countries. There are a variety of presentations at birth including poor tone, depressed consciousness, poor feeding, abnormal neurological examination, and neonatal seizures. The broad clinical definition does not specify subgroups, cause, or guide management. NE is etiologically heterogenous and linked to a wide range of risk factors. Over one third of affected babies develop long term neurodevelopmental sequelae and one quarter die within 2 years.

Antenatal Risk Factors

The pooling of data from a number of large national CP registers including Australian data and the Surveillance of CP in Europe, suggests a significant excess risk of CP among infants with fetal growth restriction and babies with structural abnormalities, particularly abnormalities of the heart and brain. In a significant number of cases, these findings are associated with genetic abnormalities. In the only prospective population-based study, NE was associated with an abnormal placenta, family history of seizures, infertility treatment, maternal thyroid disease, low socio-economic group and congenital malformation. Antenatal stroke is well described, and other genetic, metabolic, and infective causes can lead to the development of NE which is a strong risk factor for the subsequent development of CP. CMV infection has been implicated on the pathway to CP in a significant number of cases. As genetic testing advances, an underlying genetic explanation for CP is increasing. This is particularly the case in presentations of CP with spastic paraplegia and ataxia where monogenic testing increasingly identifies a genetic cause. It is important to establish exact causation where possible because this helps direct appropriate care to infants and gives families the most accurate prognostic information.

Hypoxic Ischaemic Encephalopathy

Legal cases generally focus on evidence that lack of oxygen to the fetus during labour and delivery caused injury to the fetal brain which resulted in cerebral palsy. It is estimated that up to about 15% of cases of CP are related to acute hypoxia-ischaemia in term or near-term infants. This evidence usually derives from the history of an acute event called a sentinel event which causes reduced oxygen flow to a fetus. Acute hypoxic events or sentinel events include placental abruption when the placenta separates prematurely from the lining of the womb, uterine rupture, cord prolapse, severe antenatal haemorrhage or shoulder dystocia when the shoulders of the fetus impact against the mother's pelvis preventing or delaying delivery of the body after the fetal head has delivered. This can result in impaired blood flow to the trapped fetus and is a very challenging fetal emergency requiring skilled manoeuvres to achieve delivery.

Sentinel events are rare. Much more commonly, a baby demonstrates signs of lack of oxygen (hypoxia) at birth in the absence of a sentinel event. Babies who have been deprived of oxygen during birth develop a condition called hypoxic ischaemic encephalopathy (HIE) which is characterised by depressed consciousness, difficulty breathing, abnormal tone, abnormal reflexes, and neonatal seizures in varying combinations. HIE is essentially a subgroup of neonatal encephalopathy. While there is significant overlap, the American College of Obstetrics, Gynaecology and Paediatric task force suggested that HIE should be a retrospective diagnosis when all other causes have been out-ruled. They suggest that the likelihood of HIE is increased when associated factors include Apgar score less than 5 at 5 and 10 minutes, pH <7.0 and base deficit >12mmol/L., a sentinel hypoxic event, fetal heart rate HR patterns consistent with an acute peripartum or intrapartum event, timing and type of injury observed, brain imaging consistent with an acute peripartum event and developmental outcome of spastic quadriplegia or dyskinetic cerebral palsy.

More recently Sudden Unexplained Postnatal Collapse has been described occurring rarely in approximately 1 in 20,000 births in babies at term or near term >35 weeks gestation. In these cases, infants are well at birth but collapse within 2 hours of birth. In half of these cases the cause is unknown but postulated causes include infant airway obstruction. Infants with congenital anomalies are overrepresented in this group.

In Ireland the incidence of HIE is 1.1/1,000 and appears to be stable suggesting consistent factors in causation.

When the blood supply to a fetus is acutely interrupted, it is easy to imagine that lack of oxygen has caused perinatal brain injury. However, in the absence of a sentinel event it is more difficult to identify a point in time when lack of oxygen might have occurred. In these instances, there is frequently a reliance on the interpretation of the recording of fetal heart rate pattern and uterine contractility (CTG) employed during labour to monitor fetal wellbeing. Fetal heart rate monitoring is predicated on the assumption that abnormal fetal heart rate patterns in labour predict hypoxia and that interventions based on suspected hypoxia can prevent HIE. Internationally, the use of CTG has been disappointing in the prevention of HIE and CP. It has also been strongly associated with the steep rise in caesarean section rates over the past three decades, with at least one in three women in Ireland now delivered by caesarean section. Countries with available prevalence rates of CP have seen scant or modest reduction in prevalence rates of CP despite spiralling caesarean section rates. It is likely that small reductions in CP rates are partly related to improved management of preterm birth and the introduction of TH.

Various theories have been advanced to explain the disappointing performance of electronic FHR monitoring to reliably identify the at-risk fetuses and allow preventative intervention. Many discussions focus on errors in pattern interpretation, variations in pattern interpretation among practitioners, and inadequate standardisation of pattern management. Efforts continue to improve pattern recognition and intervention from visual observation of FHR patterns. In practice, abnormal FHR patterns are seen frequently on the labour ward every day, but most babies are well.

It is argued that the use of electronic FHR monitoring is based on the existence of a correlation between certain FHR patterns and a low fetal pH level reflecting hypoxia, and on a second assumption that pH is a reliable reflection of fetal tolerance of the hypoxic stress of labour. In one evaluation of 30,000 deliveries, there was a weak or non-existent association with neonatal status at birth and a wide variation in cord pHs that did not correlate with HIE or poor fetal condition. The authors interpret this finding to mean that CTG reflects pH values with some accuracy but that babies have a huge biological variation and ability to withstand changes in pH during labour. They believe this variability, rather than poor pattern interpretation, to be the "weak link" in the chain responsible for the observed increased rate of caesarean delivery with no measurable reduction in long-term adverse events (Johnson GJ et al. Obstet & Gynecol 2021).

This difference in biological ability to withstand the stresses of labour fits with the concept that there are other factors at play. As discussed, it is clear from large epidemiological studies that there are a number of contributing factors prompting some authors to suggest that events surrounding labour and delivery play a relatively small but important role in the development of CP and that antenatal maldevelopment contributes to the development of CP. Genetic, epigenetic, metabolic, prenatal, perinatal, and postnatal factors may impact to protect, cause or exaggerate neonatal brain injury. In 2019, the National Neonatal Encephalopathy Action Group (NNEAG) in Ireland examined events surrounding the delivery of 281 babies treated for HIE with therapeutic hypothermia (TH) over a period from 2016 to 2019, including 72 babies treated in 2019. Only 4 infants of the combined total of 281 infants who required TH were delivered by elective section, suggesting that labour and delivery contribute to the causation of HIE (Neonatal Therapeutic Hypothermia in Ireland Aggregate Report 2016 to 2019).

In line with international evidence, the NNEAG report shows that infants born to first-time mothers are at increased risk of needing TH. Based on data for 2016 to 2019, the observed risk for these infants was 1.76 per 1,000 births, more than twice the risk of 0.75 per 1,000 observed for infants born to multiparous mothers. In mothers with a BMI >30, the TH rate was 1.5 per 1,000 maternities, compared with 0.9 per 1,000 maternities in those with a BMI <30. Mothers from Asian and Black ethnic groups accounted for 10% of the mothers whose infants' received TH in 2016 to 2019. Prelabour events of significance included abruption and presentation with reduced fetal movements. Labour events associated with HIE included first labour, induction of labour in first pregnancy – particularly when the cervix is unfavourable and presentation with pains deemed not in labour. Shoulder dystocia was identified as a particular risk factor.

Placental Factors

Placental examination provides additional insight. Abnormalities of the placenta are present in many infants with NE. A variety of placenta lesions are recognised to occur in the absence of an obvious intrapartum sentinel event. Chronic placenta malfunction may directly damage the developing fetal brain or may increase the risk of fetal intolerance to labour due to diminished utero-placenta reserve. Multiple placenta lesions can act synergistically to increase the risk of brain injury while the combination of acute injury superimposed on a chronic underlying placental abnormality is highly prevalent in cases of brain injury. In one study 85% of 321 cases of HIE with available placentae showed acute, chronic, or combined changes in the placenta. Chronic abnormalities were associated with a significantly greater base deficit supporting a role for chronic placental changes in HIE. Placental examination in all cases of NE should be a standard of care.

Clinical Advances in the Management of HIE

One of the biggest advances in obstetric care in the last 15 years has been the introduction of therapeutic hypothermia (TH) in the treatment of HIE. Cooling a baby to low body temperature over 72 hours reduces the level of inflammation and damage in ischaemic brain injury resulting from lack of oxygen. TH has been consistently shown to reduce the incidence of death and risk of CP in neonates with HIE. It is now a standard of care internationally and has been one of the most exciting developments in the management of HIE. It also facilitates the collection of data on babies who develop HIE and are cooled according to standardised criteria.

Despite the use of TH, 30-50% of infants born with moderate to severe HIE will either die or develop significant neurological sequelae. Current research is focused on additional treatments that might improve outcomes.

When a brain injury occurs as a result of lack of oxygen, there is an initial transient recovery of oxidative metabolism followed by progressive activation of inflammatory pathways associated with cell death and a secondary deterioration after approximately 4 to 8 hours. This provides a window of opportunity for intervention and provides the basis for therapeutic hypothermia which is instituted within hours of birth.

It is now understood that an inflammatory and abnormal immune response can persist for weeks and even months after initial injury opening the door to the concept of additional adjunctive therapies which can be commenced following TH. There are numerous therapies which have been postulated to be potentially effective including allopurinol, xenon gas, and magnesium sulphate but current research is particularly focused on three potential adjunct strategies including better control of seizures, stem cell therapies and melatonin. New antiepileptic drugs such as Levetiracetam may achieve better control of seizures which can further damage the developing brain. Stem cell therapies are postulated to inhibit cell death, and inflammation and to promote regenerative responses in brain cells. Melatonin is a hormone produced by the pineal gland in response to light. It has anti-inflammatory and anti-oxidative properties and prevents the activation of inflammatory pathways in the brain. These therapies are the subject of current international research and hopefully will provide additional improvement in outcomes associated with neonatal brain injury.

The Newborn Brain Society has recently been established as an international body and it will likely play an important role in setting clinical practice guidelines, facilitating international registries and co-ordinating multiple research activities to advance care of affected infants. Current Irish collaborative research deserves support.

Litigation in Maternity Services due to Non-Catastrophic Claims

In 2022, 86 non-catastrophic maternity claims were concluded by the SCA with paid damages of €14.4m. In comparative terms, this approximately equates with the cost of resolving two cases of CP. The table below represents the top five categories of litigation arising in maternity care when claims for catastrophic injury are excluded. The anxiety and trauma category in most cases represents psychological injury claims taken by families for a variety of serious adverse events including stillbirth, neonatal death, and other adverse events. Deterioration represents failure to appreciate that the maternal, fetal or infant condition was objectively deteriorating, and that this deterioration was not appreciated in a timely way.

Non-catastrophic claims in maternity services:
The top five injury types in descending order by claims number in 2022

Row Labels	Count of Record Number	Sum of Paid Damages
Anxiety/Trauma	26	€3,522,329
Deterioration	9	€1,355,000
Perineal tear	8	€2,290,023
Post-Partum Haemorrhage	6	€629,869
Damage to organ/body part	6	€702,020

Table 13: Non-catastrophic claims in maternity services: the top five injury types in descending order by claims number in 2022

Perineal Tears

85% of women following first vaginal delivery will sustain a perineal tear. Perineal tears can result in chronic perineal pain, and when a tear extends to the anal sphincter, this can rarely result in faecal incontinence, which is a devastating outcome. IMIS data (2021) reports an incidence of anal sphincter injury nationally of 1.8%, with a range of 0.7-2.9%. It has been shown that up to 30% of women following vaginal delivery will have some evidence of scarring of the anal sphincter. The majority of patients will have a good outcome. Over 75% of patients will have no or minimal symptoms related to anal sphincter injury but approximately 4% of affected women will have a poor outcome. Increasing age, parity, instrumental delivery, and internal sphincter injury are associated with poorer outcome. The use of episiotomy has not been consistently shown to reduce the incidence of obstetric anal sphincter injury, although right mediolateral episiotomy as practiced in Ireland is associated with more favourable outcome compared with midline episiotomy.

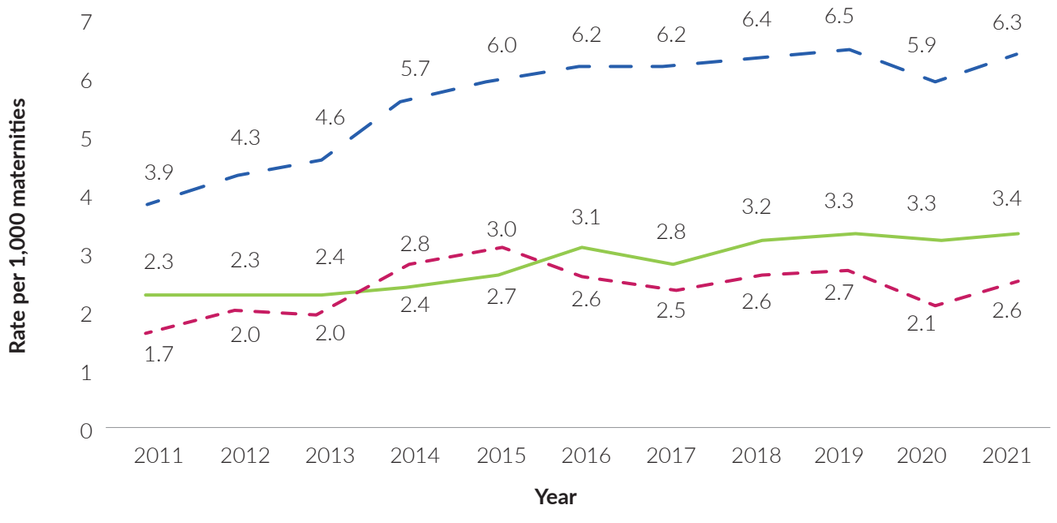


Figure 7: Major Obstetric Haemorrhage 2011 to 2021

Major Obstetric Haemorrhage is defined as more than a 2.5L blood loss and/or more than 5 units of blood transfused. In addition to bleeding at the time of delivery, it includes ectopic pregnancy, miscarriage, and termination of pregnancy. The rate nationally has increased from 2.3 /1,000 in 2011 to 3.4/1,000 in 2021. It is the most commonly reported serious maternal morbidity. Associations include increased maternal age, increased BMI, multiple pregnancy, operative delivery, induction of labour and retained placenta.

Damage to organ/body part includes unexpected organ injury at the time of a surgical procedure including bowel and bladder injury. The risks of organ injury at the time of surgery are generally included in the consent procedure.

Conclusion

Maternity claims account for a significant proportion of the total cost of clinical negligence claims in Ireland and this cost is rising.

This high proportion of total cost results predominantly from the high value claims seen in catastrophic brain injury but the cost of other claims which are of lower value, but higher volume, is also rising.

In Ireland, the incidence of brain injury sustained at birth called hypoxic ischaemic encephalopathy (HIE) is 1.1/1,000 and appears to be stable and in line with international comparison. HIE may occur as a result of an acute hypoxic event in labour but more commonly occurs in the absence of an acute event. HIE may be considered a subtype of
Neonatal Encephalopathy.

Genetic, epigenetic, metabolic, prenatal, perinatal, and postnatal factors may impact to protect, cause or exaggerate neonatal brain injury.

Major antenatal risk factors for HIE include structural abnormalities such as brain and heart anomalies, growth restriction, placental abnormalities, infection, and genetic causes.

Despite the use of fetal heart rate monitoring (CTG) in labour to predict HIE, the rate of HIE appears to be stable in Ireland but there is a steep rise in caesarean section rates over the last decade. Almost 40% of women in Ireland are now delivered by caesarean section. At present, the use of CTG does not prevent HIE in Ireland or in any other jurisdiction.

Abnormalities of the placenta are present in many infants with HIE. A variety of acute and chronic placenta lesions are recognised to occur in association with HIE and stillbirth.

There is an urgent need for more research globally into the causes of HIE and CP.

Other significant causes of litigation in the maternity sector include perineal tears, shoulder dystocia, stillbirth, and unexplained neonatal death.

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Section Three: Key Strategic Priorities Identified

Introduction

Key Strategic Priorities to Address the Rising Cost of Clinical Health-Related Claims

In this chapter, we set out to identify key strategic priorities that would aim to reduce the requirement for litigation in healthcare and improve the litigation process for those compelled to take this path. We are very mindful of the litigation experience of families presented in Chapter One. Patients harmed and their loved ones consistently articulate the need to obtain clear accurate information, to be heard, for their suffering to be acknowledged, for an apology to be given and to know that the system has learned from their experience so that the risk of similar harm happening to others is minimised.

It is important that healthcare professionals involved in clinical care incidents are also supported to review and learn from the events in a supportive environment and that the institution plays its role in addressing the systemic actions that can respond appropriately, learn and adopt preventative strategies.

The need to learn from patient experience is also paramount and this learning will provide an invaluable tool in informing strategies to address the human distress that is central to unanticipated harm. In turn, the wider health system needs to provide support at all levels to develop a national system that is competent, caring and responsive to the needs of patients and their loved ones.

Despite best endeavours, adverse events occur, and patients harmed rightly have recourse to litigation to be appropriately compensated. Currently this is an arduous and complex legal process in Ireland. There are a number of key steps in this process where there are opportunities to implement changes that could lead to speedier and more efficient resolution of claims. This would be hugely positive for patients and their families and would likely reduce the cost of litigation in healthcare.

In this section, we have laid out the progression of a clinical claim to assist in identifying the various points within the claims process amenable to interventions which could make the resolution of a claim more efficient and less costly.

When a healthcare professional undertakes the care of an individual, they owe them a duty of care. Civil liability for medical negligence requires a duty, a breach of duty and damage or loss caused by that breach of duty. The claimant must prove the injury and prove that the injury occurred because of an intervention or failure to make an intervention that caused the injury.

The traditional test for the healthcare practitioner (HCP) is whether the HCP has acted in accordance with the practice accepted as proper by a responsible practitioner skilled in that area of medical care. This principle derives from *Dunne v National Maternity Hospital* [1989] IR 91 which led to the Supreme Court laying out a series of six principles which set out that a HCP cannot be considered negligent unless they take a course of action that no reasonable practitioner of equal status would have taken in those circumstances. The principles recognise that in highly complex and emergency situations, there may be multiple solutions and it is not for the court to determine in hindsight which was better, but rather that the course taken was one which no medical practitioner of like specialisation and skill would have followed according to the ordinary care required of their specialisation and skills.

In *Ruth Morrissey and Paul Morrissey v HSE, Quest Disgnostics Incorporated and Medlab Pathology Ltd.* [2020] IESC 6, the Supreme Court stated that the starting point in any professional negligence case requires the identification of the standard of approach which would have been applied by a professional of the appropriate standing or skill as the person against whom the allegation of negligence is made. This ruling qualified Dunne by mentioning “standard of approach”.

A claim of trespass is based on the principle that the patient did not give consent or informed consent to a procedure and a claim may also be based on breach of contract where the applicable duties and liability will be similar to the tort of negligence.

When someone feels they have been harmed as a result of clinical negligence, the first step is to consult a solicitor who will then obtain the medical records so that they can be reviewed by an independent expert in the field.

If it is felt a claim is appropriate, a Letter of Claim is sent to the alleged negligent HCP(s), outlining the nature of the claim and inviting them to make a settlement in respect of the injury.

The defendant will also seek independent expert opinion based on which they may decide to admit liability and settle the claim. Alternatively, they may conclude that there is no negligence and make a formal response indicating that they are not admitting liability and will defend the claim. At this point the plaintiff will decide whether or not to proceed.

If a plaintiff decides to continue with the case, High Court proceedings are issued and all parties are notified and a summons served within four months. After this, witness statements and expert reports will be exchanged and attempts made to mediate and reach a settlement. If this is not possible the case proceeds to court.

It is interesting to view the claims process as a cycle and to determine opportunities for intervention. We identified key junctures that might provide opportunity for intervention to reduce the cost of claims.

The first and most obvious is to prevent the error or negligent care in the first place and that requires focus to determine common sources of litigation and common causes of harm and to then develop strategies of prevention.

The second is to focus on the period between an episode of harm occurring and the decision by a patient to litigate. Patients cite a range of reasons for pursuing litigation - these include lack of information and transparency, lack of care and the sense that they have been abandoned. Patients also wish to be heard and to receive an acknowledgement and a meaningful apology for the harm that has occurred. Enhanced care in this period may not reduce the need to litigate but will certainly alleviate the suffering experienced when unanticipated harm has occurred.

The third element is to care for the healthcare professionals, including learning from review of the incident, and support strategies to address their emotional needs.

In turn, the institution must learn from an episode of unintended harm and focus on organisational strategy to understand the event and prevent a recurrence of similar harm.

Despite all these endeavours, some patients will require recourse to litigation and when this happens, it is important that the process is humane, efficient and cost effective. These concepts are dealt with in a pre-action protocol, the purpose of which is to encourage early resolution of allegations of negligence, promote timely communications between parties and ultimately reduce the number of clinical negligence claims being brought. The longer cases run, the higher the administrative costs and when cases are ready for hearing, the costs increase considerably. It is important that this process is as cost effective as possible. It is also important that we learn from the experience of those forced to litigate and further research is required in this regard.

Mass action claims are considered separately.

Strategic Priorities Identified

Arising from the analysis above, we identified six strategic priorities to reduce the burden and cost of litigation. These include capturing data, learning from adverse events and promoting research, the prevention of adverse events with particular focus on perinatal brain injury and maternity care, the provision of enhanced clinical care when there is an adverse event, and improved management and resolution of claims when they occur. Finally, we advocate a standardised approach to mass action claims.

Chapter 5: Capturing Data, Learning from Adverse Events and Promoting Key Research

Introduction

An adverse event (AE) is defined by the HSE's Incident Management Framework 2020, as an incident which results in harm, which may or may not be the result of an error. Adverse events are estimated to occur in one in ten patients in a hospital setting (deVries et al. 2008). A quarter of these events in Europe are healthcare-associated infections; other events include medication errors, surgical errors, diagnostic errors, medical device failures or failure to act on test results. Adverse events can have catastrophic consequences including death and disability.

Three kinds of victims of AEs are identified in the academic literature. The "first victims" are conceptualised as patients and their families. Patients can suffer from an AE in two ways: firstly, from direct harm caused and then from superimposed harm relating to the manner in which an AE is handled. The "second victims", a concept originally introduced by Wu are healthcare providers, including physicians, nurses, allied clinicians, support personnel, students and volunteers, who have been involved in a patient-related AE and subsequently experience emotional or physical distress.

The "third victims" are the healthcare organisations in which the AE occurs. The impact on third victims can also be considerable, as AEs may create an organisational crisis leading to long-term operational difficulties.

It is imperative that we understand and monitor clinical outcomes and patient experience if we are to deliver the best possible care within the resources available. It is impossible to determine service quality without knowledge of clinical outcomes. We must learn from adverse events and the experience of patients and healthcare professionals in order to prevent further adverse events and improve patient safety. History has shown us that failure to monitor clinical outcomes can lead to abnormal clinical practices continuing inappropriately because the data that might demonstrate outlying practice is not there. Lack of data also thwarts our understanding of the natural history of an adverse event and the risk factors that might contribute to a particular outcome. This hampers the development of preventative strategies that could have meaningful impact.

It is equally important to learn from what we do well so that we foster a balanced culture that is focused on creating best possible outcomes. The capture and analysis of outcome and experience data facilitates knowledge of outcomes and comparative analysis within and between institutions of the positive and negative trends in patient care that identify opportunities for improvement and enhanced patient safety.

National Incident Management System

The National Incident Management System (NIMS) is a confidential national end-to-end incident and claims management system, which was developed by the SCA, endorsed by the Department of Health (DOH) in 2015 and which is jointly governed and managed by the HSE and SCA. It helps organisations manage incidents and facilitates comparative analysis from year to year and between institutions.

There is a statutory obligation on health and social care services indemnified by the State to report incidents to the SCA. Likewise, there is a requirement on health and social care services to report incidents to the HSE in line with the HSE Incident Management Framework. Recording incidents on NIMS fulfils the dual requirements to report incidents to the SCA and the HSE.

However not all incidents are reported on NIMS. In its report on the management of the Clinical Indemnity Scheme in 2021, the C&AG reported on SCA data which showed that only 25% of claims received for the period 2017 to 2021 had previously been reported on NIMS as incidents prior to claim notification. Of the 75% of claims not previously reported, the SCA concluded that it was reasonable for the incident giving rise to the claim to have been reported in 21% of cases. In 22% of cases, there was insufficient information to determine whether the incident should have been reported and, in the remaining 32% of cases, the delegated state authority would not have been aware of the incident and so could not reasonably have been expected to report it.

Role of the State Claims Agency in Learning from Claims and Adverse Incidents

The SCA has a statutory risk management role as set out in Section 8(4) of the NTMA (Amendment) Act 2000. This requires the SCA to advise and assist a state authority whenever it considers it appropriate to do so or is requested by such an authority to do so, in relation to matters of clinical risk. Its priorities lie in advising and assisting authorities in highlighting and addressing those risks that create the greatest liability for the State.

SCA Clinical Risk Unit

The SCA implements its statutory clinical risk management role through the Clinical Risk Unit. The unit's activities include reviewing, analysing and extracting learning from incident and claims data; advising health and social care services at local and national level on risk mitigation strategies; sharing learning from claims and incident analysis with health and social care services through a range of channels; and providing advice at national level to inform the development of legislation, policies, standards and guidelines.

The SCA's Clinical Risk Unit undertakes thematic analysis of claims. For example, it has recently published a review of catastrophic claims relating to babies in maternity services. Such analysis informs recommendations to the HSE, hospitals and other health and social care services, where appropriate. Learning is also shared widely through a variety of channels including published reports, articles in the SCA's Clinical Risk Insights newsletter and educational events such as webinars and conferences. It also forms the basis of education provided directly to health and social care services, undergraduate and post-graduate training institutions.

The SCA also undertakes analysis of individual claims and shares lessons learned directly with individual hospitals and services. Where appropriate, the SCA seeks reassurance that risks identified are being mitigated and may make specific recommendations, the implementation of which is monitored.

Since the origin of any claim is an adverse incident, the SCA also conducts surveillance of incidents reported on NIMS on an ongoing basis in order to identify issues of concern. This allows for emerging risks to be identified early. Identification of risk may prompt engagement with hospitals or services to ensure that appropriate risk mitigation is in place. The identification of a trend may prompt the issuing and publication of a Patient Safety Notification, engagement with a relevant national programme or stakeholders or other action to address the issue.

The learning from claims and incident analysis also informs engagement with the HSE in relation to significant risk issues. For example, the SCA works closely with the National Women and Infants Health Programme (NWIHP) in relation to claims and incidents occurring in maternity services and, in partnership with NWIHP and the Department of Health, has formed the National Neonatal Encephalopathy Action Group (NNEAG) to address issues resulting in avoidable brain injury in babies.

In addition, the SCA engages with the HSE in relation to clinical risk and learning from claims in a variety of ways, including a joint SCA/HSE Governance group, a Clinical Risk Forum, which considers significant clinical risk issues, and a number of forums for senior healthcare managers.

The HSE's Role in Disseminating Learning from Adverse Events

On a national level, the HSE launched *"Patient Safety Together: learning sharing and improving (PST)"*, which is a website-based platform that was launched by the HSE in January 2023. This platform allows the HSE to identify and share learning, including from patient safety incidents. Key to the success of Patient Safety Together is ensuring the most appropriate information is accessible to all, in a format and of a quality that is trusted and supports improvement and change. A small, dedicated PST team and a multidisciplinary supporting committee continually analyse quality and patient safety (QPS) data, identifying and understanding trends and the learning to be extrapolated from healthcare safety incidents. There are structured processes and governance arrangements, including clinical governance, to identify, classify, review, approve and manage relevant sources of information that can contribute to learning from patient safety incidents.

The Value of Clinical Audit within Hospitals

Healthcare systems face challenges in tackling variations in patient care and outcomes. Audit and feedback aim to improve patient care by reviewing clinical performance against explicit standards and directing action towards areas not meeting those standards. It is a widely used foundational component of quality improvement. Audit and feedback generally work. A Cochrane review of 140 randomised trials found that they produced a median 4.3% absolute improvement (interquartile range 0.5% to 16%) in healthcare professionals' compliance with desired practice, such as recommended investigations or prescribing (Ivers N. Audit and feedback effects on professional practice and healthcare outcomes. Cochrane database systemic Review 2012). This is a modest effect, but cumulative incremental gains through repeated audit cycles can deliver transformative change. Audit and feedback also influence wider populations through scaled up national programmes. Conversely, lack of audit can allow adverse events to continue as a result of systemic or personal poor performance. Clinical audit is a vital tool in directing quality improvement.

The HSE conducted a national review of clinical audit and on the foot of this, established the National Centre for Clinical Audit in 2022 within the National Quality and Patient Safety Directorate (NQPSD) and have produced a clinical guide which provides updated guidance to healthcare professionals in relation to clinical audit design, governance, data protection and ethical issues.

Individual Clinical Reviews

Despite best efforts, clinical care can lead to unanticipated harm and when things go wrong it is important that the events surrounding an adverse event are reviewed systematically. When adverse events are analysed, a combination of contributing factors are generally found including errors in the delivery of care, the particular set of circumstances in which care is delivered and the ever-increasing complex nature of the healthcare environment.

The HSE's Incident Management Framework (IMF) developed in 2018 and replaced in 2020, seeks to put in place a person-centred response to the management of these occasions, termed 'safety incidents'. The approach in the Framework was to align the response with the HSE's values of Care, Compassion, Trust and Learning.

The process used to develop the IMF was one of collaboration with both service users and patients which ensured it was both relevant and practical. Implementation was supported throughout 2018 with many briefing sessions and a tailored training programme for Quality and Safety Advisors. The Incident Management Framework lays out guidelines for the conduct and governance of clinical reviews.

Following individual reviews, a series of recommendations will be developed, designed to respond to contributory factors identified in the Review. The implementation of these recommendations is key. An Irish study examining the findings of maternity enquiries found that 9 reports contained 258 recommendations. There was lack of clarity as to who was responsible for ensuring that all recommendations were implemented. It is important that recommendations made are clinically important and are capable of being implemented and that the number of recommendations is reasonable. The implementation of recommendations should be monitored to ensure that, as far as possible, the implementation is completed.

Strong mechanisms are required to promote dissemination of learning throughout the healthcare system. There are many good examples of how healthcare learning is shared, both locally and nationally such as collaboratives, quality and risk learning days, morbidity and mortality meetings, incident reviews, conferences, publications etc. However, these initiatives can be fragmented and overly dependent on individual service approach. It is important that all units delivering clinical care develop the capacity to audit and analyse their outcomes to promote local learning. Effective feedback of key risks and learning from adverse events to frontline clinicians is critical. Long detailed systematic reviews are really helpful in individual cases in identifying contributing factors but nationally, learning from the system needs to be condensed into meaningful applicable guides to practice. The dissemination of such learning needs to be monitored so that assurances are provided that important learnings are reaching frontline clinical staff.

There are good international examples of the dissemination and use of national incident data to foster quality improvements on the frontline.

A key strategic priority of NHS Resolution is the sharing of data and insights gleaned from their unique datasets as a catalyst for improvement benefitting patients and the healthcare and justice systems. They describe two core approaches to sharing data and insights: using information to identify emerging patient safety risks; and supporting a greater understanding of the causes of incidents, sharing these insights with stakeholders across the system.

To ensure appropriate identification and response to patient safety concerns, they use a framework to manage concerns, which is overseen by a Significant Concerns Group. The key aim of the framework is to ensure that the handling of each concern is appropriate, timely and robust. The framework considers notifications from individual functions and ensures a co-ordinated and consistent response at a corporate level, where this is required. They have developed a series of workstreams aimed at using data to enhance patient safety.

An Insights Programme shares learned insights from claims dataset analysis to a wide range of stakeholders across the healthcare system. They use a wide range of dissemination tools including events webinars, e-learning tools, animations, thematic reviews and practitioner performance insights. They launched the "Learning from Litigation Claims: GIRFT (Getting It Right First Time) and NHS Resolution best practice guide for clinicians and managers", which advocates and facilitates practical, clinical changes based on learnings and recommendations from NHS claims.

In its Annual Report, it monitors a number of Key Performance Indicators including audit of the response to serious concerns raised by claims data to ensure that appropriate steps have been taken. They examine feedback received from e-learning modules and actively seek feedback from all national service stakeholders tasked with delivering actions arising

from national thematic review recommendations. They also report on projects designed to explore the relationship between their claims data and national incident data (NHS Resolution Annual Report and Accounts 2022/23).

In Ireland, lessons learnt from litigation are used to inform national standards, policies, procedures and guidelines (PPGs). The SCA has made specific recommendations in relation to standards and PPG development and is represented on groups and/or provides data to groups developing PPGs. The SCA is also represented on the National Clinical Effectiveness Committee (NCEC), which develops national clinical guidelines.

In addition, the Obstetric Event Support Team (OEST) was established to explore the circumstances of the birth of babies that required cooling, intrapartum deaths and early neonatal deaths. Members of OEST are external to the institution in which the event occurred and an oversight group oversees the work of the team with direct reporting to NWIHP. The responsibility for carrying out the review of the event and the accountability remain with the maternity unit in which the event occurred (Submission OEST).

Mandatory Open Disclosure and Notification of Serious Patient Safety Incidents

The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (PSA 2023) provides for mandatory open disclosure to patients, and/or their families/caregivers, of specified serious patient safety incidents and also provides for the mandatory external notification of those same events to the appropriate body.

The PSA 2023 includes a Schedule listing a number of the most serious notifiable patient safety incidents, including maternity-related incidents, which are subject to mandatory open disclosure. The incidents listed are of a very serious nature, resulting in the main in unintended or unanticipated death.

Notification of these specified serious events is to be conducted through NIMS, as noted above. A new module to NIMS to facilitate the notification of these specified, or "notifiable incidents", in line with the requirements of the PSA 2023, is currently being designed and tested.

The PSA 2023 also sets out a process by which the Minister for Health may make regulations expanding the list of notifiable patient safety incidents over time, in line with the advancement in clinical practice and international developments.

Conclusion / What Needs to be Addressed

It is inevitable that AEs will occur in healthcare organisations with profound impact on affected patients and their families and caregivers, on individual practitioners, on healthcare teams and institutions. When an AE is identified and a concern expressed, immediate and comprehensive action should be taken. This requires trying to understand the whole phenomenon in its complexity and understanding the needs of all those affected including the patient and their families, the healthcare professionals and the institutions. More research is required regarding the needs of all those involved in adverse events.

Learning from analysis of clinical claims is a very valuable resource in promoting better awareness and understanding of adverse events. This in turn facilitates strategic programmes to prevent harm. The dissemination of this learning to the frontline is critical.

Local clinical audit and review is also imperative if we are to understand what went wrong and why. Only then can we develop coherent preventative strategies. Collaboration is needed between policymakers, nursing and healthcare managers and educators in order to develop such systems and the necessary culture to support them.

In addition to robust review of individual outcomes, it is important that key clinical outcomes in every institution are monitored and audited against national and international standards.

Future education, research, policy and practice developments should incorporate a move to a more balanced approach incorporating both learning from adverse events and from positive outcomes.

The dissemination of learning is also a key requirement in individual and systemic learning from clinical outcomes and the experience of patients and healthcare workers. It is important that strategies to disseminate learning are strongly supported on the frontline. This includes empowering clinical directors and clinical leaders with the tools and resources to develop and deliver learning programmes deriving from their own institutional or national experience. Consideration should be given to centrally monitoring the dissemination of learning from adverse events and claims data. This could be a role undertaken within the HSE.

Recommendations

1. For consistency and standardisation in the recording, reporting, analysis and learning from adverse events, the Group recommends that all publicly-funded healthcare providers/settings providing clinical care should use the National Incident Management System (NIMS).

2. The Group recommends that, in line with the Incident Management Framework, each healthcare provider/setting should ensure that robust mechanisms are in place to disseminate learnings to all relevant staff and in particular to frontline workers derived from:

   a. the services own data relating to adverse events,

   b. the analysis by the HSE and the State Claims Agency of incident and claims data.

3. The Group recommends that each healthcare provider/setting should provide reassurance to the SCA, when requested, that learnings and outputs from the SCA's analysis of claims and incidents have been shared with frontline staff, that risk mitigation strategies are in place and demonstrate efforts made to implement any recommendations made.

4. Clinical Directors or equivalent should be supported with tools to enhance feedback to frontline clinical staff on: common causes of harm, clinical care incident analysis and common themes associated with litigation. This could be achieved through a combination of clinical meetings, local alerts and through the delivery of standardised online courses which should be prioritised for continuing professional development (CPD) accreditation. The dissemination of learning from adverse incidents and claims data should be monitored centrally. This could be a role undertaken within the HSE.

5. The Group recommends that every healthcare setting providing clinical care should have the capability to undertake swift and comprehensive analysis of and response to serious adverse events that occur within its own setting. External support in accordance with HSE guidelines should be provided when requested and in major adverse outcomes.

6. The Group recommends that healthcare providers should endeavour to capture positive outcomes and promote a balanced culture of learning.

7. The Group recommends that each clinical care unit should audit their primary clinical outcomes annually and publish their results in an annual clinical report.

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Chapter 6: Prevention of Adverse Events: Strategy, People and Resources

Introduction

It is estimated that 10 to 15% of healthcare expenditure is consumed by the direct sequelae of healthcare-related patient harm (Panagioti et al., BMJ 2019). In 2019, it was estimated that strategies to reduce the rate of AEs in the European Union alone could prevent more than 750,000 harm-inflicting medical errors per year. This translates into a potential 3.2 million fewer days of hospitalisation, 260,000 fewer incidents of permanent disability and 95,000 fewer deaths per year (WHO Regional Office for Europe patient Safety, data and statistics). The economic consequences of AEs leading to serious harm are not limited to healthcare. Increased absence from work and experienced staff opting to leave or change clinical practice are just some of the additional consequences.

AEs also result in the rising cost of clinical negligence claims in Ireland, which now costs over €400m annually in transactional costs, with an outstanding liability of €4.6bn at the end of 2022. The prevention of even one case of CP would alleviate so much human suffering but would also significantly reduce the cost of litigation – financial resource that could be deployed elsewhere.

Examination of the rising costs of claims identifies three specialties – maternity, surgery and medicine as the specialties that account for the majority of claims. The SCA has identified particular themes in relation to claims which provide a focus for risk mitigation initiatives. In its analysis of clinical claims finalised in 2017, it identified a series of themes relating to substandard communication or inadequate consent, failure to adequately monitor a patient, delays in performing or following up on diagnostic tests, delays in initiating treatment, inadequate treatment and inappropriate deviation from clinical practice guidelines.

Environmental factors identified included inadequate staffing and resources to meet demand, lack of availability of diagnostic equipment and equipment failure due to inadequate maintenance.

Patient Safety Strategy

The HSE has identified common causes of harm within the Irish health system and has devised strategies to mitigate this harm in their Patient Safety Strategy (2019) which sets out a vision for patient safety where "all patients using our health and social care services will consistently receive the safest care possible." Nurturing a culture of patient safety which places emphasis on a culture of transparency and organisational learning is key to this. This must be supported by meaningful involvement of patients and staff, effective governance and leadership and a commitment to enhancing our safety capability, including embracing safety science, in order to design safe systems of care.

The strategy makes six commitments:

1. *Empower and Engage Patients to Improve Patient Safety*
2. *Empower Staff to Improve Patient Safety*
3. *Anticipate and Respond to risks to Patient Safety*
4. *Reduce Common Causes of Harm*
5. *Measure and Learn to Improve Patient Safety*
6. *Provide effective Leadership and Governance to Improve Patient Safety*

It follows many years of systemic quality and patient safety activity and builds on frameworks such as the HSE's *People Strategy*, the *Framework for Improving Quality (2016)*, *Incident Management Framework (2018)*, the framework for change *People's Needs Defining Change (HSE 2018)* and the *National Standards for Safer Better Healthcare (HIQA 2012)*.

Common Causes of Harm

Commitment 4 of the Strategy outlines 13 Common Causes of Harm, as shown in the image below. International evidence indicates these are high-impact patient safety risks, which, if tackled effectively, can improve safety and quality across all health settings. The National Quality and Patient Safety Directorate (NQPSD) works with services to build capacity and capability to use Quality Improvement approaches to address these common causes of harm. The NQPSD also engages with national clinical programmes and teams to address common causes of harm and support a programmatic approach.

Patient Safety Improvement Priorities

Figure 8: 13 Common Causes of Harm – Patient Safety Improvement Priorities

The NQPSD has operational governance for a number of national programmes which address multiple common causes of harm, including the National Clinical Programme for Sepsis, the National Medication Safety Programme, the Recognition and Response to Clinically Deteriorating Patients, and the National Improvement Programme for wound management.

NQPSD has also developed a range of resources to enable services to use information to monitor service quality and continuously improve it, including the recently published Improvement Collaborative Handbook. This provides a step-by-step approach to organising and leading short-term Improvement Collaboratives, bringing together teams from various healthcare settings to address focused topics. Through continuous monitoring and evaluation, teams identify areas for further improvement and make data-driven decisions to drive sustainable change. Virtual and in-person workshops provided by NQPSD also provide coaching and capacity-building for service teams in practical methods and approaches to using data and measurement to drive and document improvement efforts and measurable change.

The Quality and Patient Safety Improvement (QPSI) Team, within NQPSD, works with teams and services to design and deliver programmes and resources to build skills, knowledge and confidence to address patient safety priorities. As of November 2023, these teams include:

- National Clinical Programme for Stroke in Ireland
- National Clinical Programme (NCP) for Early Intervention in Psychosis
- National Critical Care Programme
- National Heart Programme
- Irish National Intensive Care Unit Audit Team

This enables our health service to deliver better care and outcomes for staff and patients. By working at numerous levels in the system, the QPSI team is well placed to understand the context and challenges facing services and can effectively provide support and coaching to drive improvement forward. This improvement effort aims to address the 13 common causes of harm as outlined above.

A programmatic approach is used to enable services to focus on the whole quality cycle, from planning to improvement to control, with the enhanced use of data intelligence, clinical audit, incident management, and performance management as part of an overall quality management system to support improvement. This is also an effective method of closing the "improvement loop" on clinical audits, and supporting services to develop and implement meaningful quality improvement plans to improve their services.

Quality, Risk and Safety Governance

Healthcare Governance

The delivery of healthcare carries unique challenges. Patient expectations are high and errors can have catastrophic outcomes. It is emotionally charged and carries high risk. In recent times the field of healthcare risk – which includes clinical risk, quality and patient safety has developed significantly but remains a very complex area.

For all healthcare organisations irrespective of size, discipline, service or location, evidence indicates that reliable management of quality, risk and patient safety is significantly dependent on effective organisational governance and leadership which assures accountability and responsibility (Doyle & Feeney, 2015).

Whilst the word "governance" has many definitions, organisational governance refers to the degree to which an organisation is in control and takes overall accountability and responsibility for the work done and services provided. Critically including leadership, governance seeks to provide assurance to all interested parties that an organisation is being managed and run correctly (Doyle & Feeney, 2015). In simple terms, organisational governance is concerned with how an organisation is run, how it structures itself, how it is led and how it is held to account.

Effective and transparent healthcare governance (*which critically includes clinical governance as a sub-component*) is the backbone of reliable, effective and efficient quality risk and patient safety.

Assurance and the "Three Lines of Defence"

Assurance is a statement or indication that inspires confidence. In the context of governance, (Dixon et al. 2012) suggests three (3) lines of defence to underpin healthcare assurance:

1. "Sharp end" healthcare professionals (*clinical and managerial*).
2. Healthcare boards and senior leaders.
3. External structures and systems.

The three lines of defence to support healthcare organisational assurance

	Line of defence	Description
1.	**"Sharp end" healthcare professionals**	The "first line of defence" is frontline professionals (*clinical and managerial*) dealing directly with patients and carers who are responsible for their own professional conduct and competence as well as for the reliability, quality and safety of the care they provide. Frontline professionals are "first-hand witnesses" when things go wrong and often have valuable ideas about how the quality and safety of care can be improved. **It is *crucial* that they speak up and are empowered to act to prevent failings in care – and thus are provided with a culture and platform to do so.**
2.	**Healthcare boards and senior leaders**	The "second line of defence" is the Board and Senior Leaders (*management*) who are responsible for ensuring the quality and safety of care delivered by their organisations. They are ultimately accountable when things go wrong and must be able to address issues/problems that arise (*potentially due to a lack of systems and processes*). **It is crucial that Boards and Senior Leaders are able to monitor the quality and safety of care, take action to resolve issues/problems as well as create a culture of openness and learning to support staff to identify and solve issues/problems.**
3.	**External structures and systems**	The "third line of defence" is the external structures and systems (*usually at a national level – regulators and legislators*) that are responsible for assuring the public about the quality and safety of care. Such external structures and systems can mandate that healthcare organisations shall be transparent and give an account of their performance and actions. **It is crucial that they are aware of the need to take action when local organisations fail to resolve issues – and they take it in a timely, suitable and adequate manner.**

Table 14: The three lines of defence to support healthcare organisational assurance (Adapted from Dixon et al., 2012)

Healthcare governance is an all-inclusive concept combining corporate governance (*management*), clinical governance (*clinical practice*) and non-clinical services to promote an integrated approach to the management of healthcare service inputs, structures and processes and thereby improve outcomes in an environment where healthcare staff have greater accountability for clinical quality and safety (McSherry & Pearce, 2010; Som, 2004).

The Role of HIQA

Over recent years, the health service has placed an important emphasis on quality and service user safety by developing an infrastructure for integrated quality, safety and risk management with the aim of achieving excellence in governance for quality and safety. *The HIQA National Standards for Safer Better Health Care* (2012) Theme 5 *Leadership Governance and Management* states that service providers should have clear accountability arrangements to achieve the delivery of high-quality, safe and reliable healthcare.

The Health Information and Quality Authority (HIQA) is the independent Authority established to drive continuous improvement in Ireland's health and personal social care services, monitor the safety and quality of these services and promote person-centred care for the benefit of the public. Its role includes setting standards for health and social services based on evidence and best international practice, for those health and social care services in Ireland that by law are required to be regulated by the Authority.

It also carries responsibility for monitoring the quality and safety of health and personal social care services and investigating as necessary serious concerns about the health and welfare of people who use these services.

Key Strategies to Prevent Adverse Events in Maternity Services

National Maternity Strategy

The first National Maternity Strategy was published in 2016 on the foot of the investigation into the death of Savita Halappanavar. The Report ("The investigation into the safety, quality and standards of services provided by the Health Service Executive to patients including pregnant women at risk of deterioration, including those provided in Galway University Hospital and as reflected in the care provided to Savita Halappanavar") recommended the formulation of a national maternity strategy to implement standard, consistent high-quality care. The strategy was informed by a review of the international literature and by public consultation. It articulates a vision where all women and babies have access to care in a setting most suited to their needs. Women and families are placed at the centre of their care and are treated with dignity, respect and compassion. Four strategic priorities are identified which include:

1. A health and wellbeing approach so that all babies get the best start and life. Mothers and families are supported and empowered to improve their own health and well-being.
2. Women have access to high-quality, nationally consistent, women centred maternity care.
3. Pregnancy and childbirth are a physiological process, and in so far as it is safe to do so, a woman's choice is facilitated.
4. Maternity services are appropriately resourced, underpinned by strong effective leadership, management and governance arrangements, and delivered by a skilled and competent workforce, in partnership with women.

National Women and Infants Health Programme (NWIHP)

The NWIHP was established to drive the implementation of the National Maternity Strategy. Its role in the Health Service Executive (HSE) is to lead the management, organisation and delivery of maternity, gynaecology and neonatal services, strengthening these services by bringing together work that is currently undertaken across primary, community and acute care.

In 2022, €8.7m invested into the implementation of the National Maternity Strategy is having a positive impact on women's healthcare, with the targeted investment translating into improvements for patients. For example, over 100 full-time staff were funded for maternity services in 2022, allowing an increase in choice of care even further by ensuring that all 19 maternity units now have an advanced midwifery practitioner to implement the supported care pathway. Clinical midwifery specialists have also been added in areas such as diabetes, parent craft and high-risk pregnancy, and the development of postnatal care hubs have been funded and advanced. The Ambulatory Gynaecology Model of Care has continued to be rolled out, with a total of 12 clinics operational by the end of 2022. There has also been significant development in the areas of menopause, endometriosis, and fertility, with new services delivered and progressed.

National Neonatal Encephalopathy Action Group (NNEAG)

In 2015, the National Neonatal Encephalopathy Action Group (NNEAG) was established under the remit of NWIHP. This group is a tripartite partnership between the HSE, NWIHP and the Department of Health, with representation from a variety of relevant stakeholders. The aim of the NNEAG is to reduce avoidable cases of Neonatal Encephalopathy (NE) through the identification of risk factors and the development and implementation of initiatives in the maternity services that will reduce these risks. The group's work includes the setting up of a National Obstetric Clinical Advisory Group, the development of a maternity specific adverse event tool and the development of national standards for mandatory training in obstetric emergencies, fetal monitoring and neonatal resuscitation.

In addition, the Obstetric Event Support Team (OEST) was established to explore the circumstances of the birth of babies that required cooling, intrapartum deaths and early neonatal deaths. Members of OEST are external to the institution in which the event occurred and an oversight group oversees the work of the team with direct reporting to NWIHP. The responsibility for carrying out the review of the event and the accountability remain with the maternity unit in which the event occurred (Submission OEST).

NHS Resolution Strategies

The NHS Resolution Annual Report contains 4 strategic priorities. The third priority is a standalone priority to "Collaborate and improve maternity outcomes" to support the Government's maternity safety ambition to halve rates of stillbirths, neonatal deaths, maternal deaths and brain injuries that occur during or shortly after birth, by 2025.

In England, financial incentive is used to address the implementation of designated safety actions. The Maternity Incentive Scheme (MIS) works by creating an incentive fund by charging trusts an additional 10% of trusts' maternity contribution to the Clinical Negligence Scheme for Trusts (CNST) indemnity scheme. Trusts that demonstrate they have achieved all ten safety actions recover their 10% contribution and will also receive a share of any unallocated funds. Trusts that do not meet all ten safety actions do not recover their contribution but may be eligible for a smaller discretionary payment to help them make progress against any actions they have not achieved. Trust submissions are checked against Care Quality Commission (CQC) findings in addition to a range of other external verification points.

The MIS provides opportunity to identify and share early intelligence regarding potential maternity safety concerns with maternity stakeholders via their Collaborative Advisory Group (CAG).

NHS Resolution have also commenced the development of a maternity team review service, with support from NHS England's (NHSE) Maternity Safety Support Programme.

People and Resources

According to the HSE's February 2024 Personnel Census report, the workforce has increased by over 28,000 since December 2019. However, it is impossible to address the prevention of adverse events without addressing the requirement for appropriate staff and resources to deliver care.

Overcrowded clinical environments create risk and place healthcare staff under enormous pressure as they juggle and prioritise multiple clinical presentations within environments that may not have the acute capacity to deal with patient needs. Delays in accessing diagnostics, delays in admission to hospital, delays in admission from the emergency room (ER), lack of acute care beds and delays in commencing treatment are just some of the problems experienced on the frontline.

International research has confirmed, for example, that emergency department (ED) overcrowding leads to significant patient harm. A recent French study demonstrated that for every 21 older patients kept overnight in an ED awaiting a ward bed, there is one extra death at 30 days. This follows previous UK research which pointed to one excess death for every 82 patients delayed in the ED greater than six hours. Public hospital inpatient units, outpatient facilities and EDs all remain under increased pressure and require urgent capacity expansion.

Significant effort has been made to increase staffing in the Irish health system in recent years, with substantial increases in health expenditure. The total acute workforce has grown by 29%, with two thirds of this growth accounted for by medical, nursing and health and social care professionals. This is all welcome investment. Nevertheless, challenges remain within the system. In their submission, the IMO reported "IMO members have repeatedly expressed concerns about inadequate staffing levels, insufficient hospital capacity, overcrowding and growing waiting lists for outpatient and elective care".

Ironically, as we set out to elevate care, we can impose guidelines and standards that can be difficult to achieve within the constraints of available resources. This is particularly true of highly skilled high-risk specialties such as maternity and neonatal care, genetic medicine, neurosurgery and vascular surgery, which are characterised by a small pool of qualified staff and where it takes many years to achieve appropriate training and experience to practice independently.

In addition, demand for health services continues to increase driven by a wide range of factors including increasing population, an ageing population, increased prevalence of complex co-morbidity, increased patient expectation and rapidly advancing technologies. A 2022 ESRI report suggests that up to an additional 15,000 healthcare staff may be required by 2035, in the public acute hospital workforce.

Workforce Intelligence

The Irish Medical Council 2021 Workforce Intelligence Report makes sober reading. The Report describes the continued trend of a growing register, predominantly in the General Division, which was created as a transition for doctors progressing from internship to the Specialist Division and which does not offer specialist training and supervision. According to the 2021 report, 35% of doctors who were clinically active in Ireland were on the General Division, with non-consultant hospital doctors (NCHD's) making up over half the doctors on the General Register with the attendant implications for lack of specialist training, and the clinical risk of a high proportion of NCHDs not in formal supervised training. At a specialist level, there are consistently around 100 doctors employed as consultants by the HSE who are not on the specialist register. The Government and HSE should ensure that all consultants appointed to public hospitals are on the specialist register, in order to reduce this inherent patient safety risk.

The Report also cites an over-reliance on NCHDs to deliver care. This has long been recognised and national policy advocates the development of a consultant provided service. The Report also describes attrition among doctors practicing in Ireland, resulting from lack of access to training, poor working conditions, excessive work hours, work-life balance challenges and natural retirement.

The final report from the Department of Health's National Taskforce on the Non-Consultant Hospital Doctor (NCHD) Workforce in February 2024, recommended an increase in the number of consultant posts in line with workforce planning projections to 6,000 with a target ratio of 110 consultants per 100,000 of population, an increase in the number of NCHD postgraduate training posts to between 5,800 to 6,000, and a consultant to NCHD ratio of 1:1.3 NCHDs.

Medical Migration

There are large outflows of doctors after internship from the Irish health system. Many of these junior doctors, in common with other young Irish people, are likely to go to Australia. In 2005, 22 doctors in Ireland were issued with a visa to work in Australia. In 2022, 442 Irish doctors were issued with temporary work visas for Australia. Medical migration is not a new phenomenon in Irish Healthcare. UK research estimated that 71% of Ireland's medical graduates of 1950 to 1966 had emigrated by 1969. Ireland has a culture of medical migration and in many specialties, a period of training or fellowship abroad is almost an essential element of preparation for a consultant role in Ireland. It is widely acknowledged that the majority of young doctors return to Ireland to pursue further training or take up consultant posts.

However, dissatisfaction with working conditions in Ireland is emerging as a strong driver of current medical migration. In 2014, Humphries surveyed 307 emigrant doctors and found that many had emigrated due to difficult working conditions in the Irish health system. Emigrant doctors were enjoying the opportunity to work in better-resourced health systems with superior working conditions. Among those doctors surveyed, only one in four intended to return to Ireland. And the decision to return was for personal rather than professional reasons – for instance, to be closer to family and friends. In 2018, she surveyed 40 emigrant doctors in Australia. Once again, only a minority of those interviewed, (one in three), planned to return to Ireland, indicating the risk of non-return inherent in all emigration decisions.

The HSE's NDTP Annual Medical Retention Report 2023 shows that for the 2015 to 2022 intern cohorts, an average of 50% left the Irish health system in the year after their internship. Of the 2015 to 2018 intern cohort, 82% had started Basic Specialist Training or GP training prior to 2023. An average of 87% of this cohort had returned to the Irish public health system by 2023.

In its 2021 report, the Medical Council identified a risk of reliance on international medical graduates and said that the majority of NCHDs are doctors who have trained overseas and who have not been able to access specialist training in Ireland. These doctors report being overworked, undervalued and experience significant discrimination and difficulty in accessing specialist training. Acute shortages of doctors across the Irish health system, particularly at specialist and consultant level poses a real challenge to patient safety. A number of improvements have been made to the arrangements for work permits for Non-EEA doctors to assist them in having greater access to postgraduate training places.

Consultant Shortage

Recruitment and retention issues have been clearly documented by the Irish Medical Organisation (IMO), Irish Hospital Consultants Association (IHCA) and HSE National Doctors Training and Planning (NDTP). An increase of 36% in the number of approved consultant posts will be required to meet the target of 6,000 consultants by 2030 recommended by the Department of Health's Taskforce on the NCHD workforce. The HSE NDTP estimates a 38% increase in trainees by 2030 is required to support the projected growth in consultant posts. A significant programme of international recruitment will also be required to support this target. The available graduates to take up consultant posts up to 2030 are predominantly already in higher specialist training. The HSE NDTP has estimated the number of consultants trained outside of the Irish system i.e., that did not complete Higher Specialist Training (HST) in Ireland, that would need to be recruited is approximately 1,000. A forecasted potential 42% increase in the number of general practitioners (GPs) may be required to respond to the universal free GP care policy.

In 2018, there were 3,089 consultants employed in HSE-funded services regardless of tenure (permanent, locum, temp). The HSE NDTP Medical Workforce Report 23/24 reports in December 2023 that there were 4,254 consultants employed regardless of tenure, an increase of 1,165 (38%) in the number of consultants working for the HSE when compared to 2018. The number of permanent consultants employed has risen from 2,595 to 3,611 in the same period, an increase of 1,016 (39%).

In the HSE Medical Workforce Report 2022 to 2023, it is noted that Ireland has among the lowest ratios of consultants per 100,000 population in the OECD at 52-66/100,000 across the hospital groups. This is despite a significant increase in the number of medical consultants in Ireland - medical and dental consultant numbers (WTE) have increased by 34% over the period 2016 to 2022, rising from 7,331 to 9,882 (IGEES 2024). It is of concern that Ireland has the highest ratio of non-training scheme doctors. In fact, Ireland has the lowest number of specialists (consultants and NCHDs) per 1,000 population in the EU at 1.70, 34% below the EU average. As such, Ireland would need an additional 4,500 medical specialists to achieve the EU average number of specialists on a population basis.

Some disciplines such as Emergency medicine have particularly high proportions of NCHDs to consultants. The Model 3 Hospitals are particularly problematic with 18% of consultant staff in non-permanent posts and a high reliance on non-training scheme doctors. In Model 3 Hospitals, 7% of consultant staff are also not on the specialist division of the Medical Council register (HSE Medical Workforce Report 2022 to 2023).

The HSE NDTP Medical Workforce Report 23/24 reports 445 Consultant vacancies as of December 2023, and 161 of those posts were vacant for more than 12 months. There were 393 consultant posts approved in 2023 which may explain some of the vacancies as consultant posts can take significant time from approval to recruitment. More recent HSE data confirms that the number of approved permanent consultant posts that are either vacant or filled by temporary or agency staff was 921 in December 2023. This figure of 921 relates to the number of approved consultant posts not filled on a permanent basis, and comprises 445 permanent consultant posts that were vacant, a further 476 posts filled by temporary and locum consultants or agency staff. There are a variety of reasons why a consultant post would be filled on a temporary basis including cover for maternity and sick leave.

The IHCA believes it is important to count the number of totally vacant consultant posts together with the number of approved permanent consultant posts filled on a temporary, locum or agency basis to give a total figure for the number of posts not filled as needed. Hospital departments generally have a relatively small number of consultants in any one specialty. In this context, operating with high levels of temporary, agency or locum consultant appointments and vacancies negatively impacts on patient care due to the lack of cohesion that accompanies the regular changes and flux in locum consultant staff. This undermines the continuity and quality of care to patients. A reliance on agency and locum consultants is not recommended for these and other reasons, such as the need for a sustainable integrated health service.

Maternity Services

The maternity services stand out in terms of claims liability and the 2016 Maternity Strategy includes a section on workforce planning. Based on existing consultants in 2015, it was estimated that an additional 100 Obstetricians and Gynaecologists (O&G) were required, with a plan to increase numbers over a phased period rather than recruiting a large number of consultants from developing countries. Ireland currently has approximately 192 (175 WTE) consultant Obstetricians, which is among the lowest per capita in OECD comparison and between 2021 and 2022 O&G showed the lowest consultant growth rate among medical disciplines in Ireland at 4%, with 9% of posts held by locum or agency staff or those on the General Register. There is hope that the favourable terms of the new Sláintecare contract will increase consultant appointments, although the effective cessation of private practice in in-patient obstetric care may have a detrimental effect on consultant recruitment in Obstetrics and will significantly reduce hospital income.

Similar recruitment and retention problems are seen in nursing and midwifery, despite an overall increase in nursing and midwifery staff of 26% from 20,902 to 26,496 in the period 2016 to 2022. In the Nursing and Midwifery Board Ireland (NMBI) "State of the Register" Report 2023, it is noted that almost 50% of those registered as midwives actually practice as midwives. Of the 3,905 who are practicing in patient-facing roles, many are working outside the acute setting in community posts. Approximately 2,600 midwives are working in the 19 maternity units and approximately 10% of these posts are vacant.

In recent exit interviews at a tertiary Dublin hospital, the reasons given for leaving included:

- Cost of living and rent in Dublin.
- Childcare costs prohibitive.
- Travel opportunities, especially Australia - offering very attractive packages including 6 months free accommodation.
- Shift work and night duty unattractive - more quality of life working in a 9-5 role with no weekend or shift work.
- Level of responsibility in the role not worth the salary.

1. It is important to note that since 2022, UK registrants are no longer included in the EU figures

NMBI State of the Register 2023

When all nursing and midwifery posts are considered, there is a similar gap between those registered and those in patient-facing roles. As with doctors, there is a high reliance on non–national nurses. As of 1 June 2023, there were 6,257 new registrants. Of these 73% were from non-EU countries[1], 2% from the EU, and 25% were from Ireland. By far the majority of non-EU new registrants were from India.

Division	Registered	Practising	Patient-Facing
Advanced Midwife Practitioners	30	19	17
Advanced Nurse Practitioners	809	605	573
Children's Nurses	4,975	3,458	3,044
General Nurses	71,239	57,295	50,951
Intellectual Disability Nurses	5,169	4,026	3,315
Midwife Prescribers	83	34	31
Midwife Tutors	27	15	3
Midwives	9,316	4,574	3,905
Nurse Prescribers	2,221	1,425	1,326
Nurse Tutors	787	552	126
Psychiatric Nurses	9,211	7,472	6,537
Public Health Nurses	2,721	2,286	1,903
Grand Total*	**106,629**	**81,771**	**71,738**

*Please note that one nurse or midwife could be registered/practising/patient-facing in multiple divisions of the Register. Information on practising and patient-facing is self-declared during the annual renewal of registration process.

Table 15: Breakdown of registered/practising/patient-facing nurses and midwives by division of the Register. NMBI State of the Register Report 2023.

Workforce planning in all allied healthcare areas is beyond the scope of this report but recruitment and retention problems also pervade allied specialties including physiotherapy, laboratory scientists, speech and language therapy and occupational therapy.

Resources

The population has grown by 10.5% since 2013. The largest change was seen in the over 65 age group which increased by 35% between 2013 and 2022.

Population increases, especially at older ages, will continue to increase demand for hospital care. The Irish population is projected to increase by 1 per cent on average per annum out to 2035, with the population aged 65+ projected to increase by 3.5 per cent on average per annum. The number of people aged over 65 years is projected to double to 1.6 million in Ireland in 2051. In 2019 there were 73,000 people aged over 85 years – this is projected to rise to 301,000 in 2051. This means that additional public acute hospital capacity will be required.

Patients over 65 years are more likely to suffer from chronic disease and account for over 50% of total in-hospital patient bed days and up to a quarter of all emergency department (ED) attendance. While 15% of the population are over 65 years, they use 58% of available beds. In one study, patients aged 70 or over accounted for 20% of all attendances to ED. In addition, older people have longer length of stay with emergency admissions in 85 year olds leading to an average length of stay of 11.9 days (IGEES 2024). If admitted to hospitals, elderly patients have

complex medical needs and account for a significant proportion of prolonged hospital admissions. It has been estimated that up to 600 patients cannot leave hospital after acute care has completed because of lack of transitional care arrangements. Further, 10% of total hospital activity is lost annually in Ireland due to delayed discharges. The associated opportunity cost increases risk in a system that is struggling to restore sufficient bed capacity to serve population needs.

OECD and European Union statistics consistently find the public acute hospital system in Ireland to have amongst the lowest inpatient bed per capita rate compared to comparator countries (Walsh et al., 2020a; OECD and European Union, 2022). This is despite 989 additional acute beds being added to the system between 2016 to 2022. Over the past four years ICU beds have increased by 30% to 330 beds, with plans to continue the expansion to 458 by 2031. Bed occupancy has decreased from 94.6% in 2016 to 92.3% in 2022, which remains the highest in the OECD and is much higher than the frequently referenced 85% occupancy rate above which patient safety risk can arise (Bagust et al., 1999). In fact, bed occupancy rates in Irish hospitals often exceed 100%, which result in regular bed shortages, increased numbers of admitted patients being treated on trolleys, higher levels of healthcare acquired infections and cancellation of appointments in addition to growing waiting lists, with the potential for poor outcomes. The HSE has accepted that occupancy rates at this level are “unsafe”. Without a sufficient number of hospital beds, public hospitals will not have the required flexibility to respond to unexpected increases in demand, unsafe practices will persist, and waiting lists will continue to increase.

An ESRI Research note on inpatient bed capacity requirements in Ireland in 2023 finds that while absolute, and per capita, public acute hospital inpatient bed capacity has increased in recent years, large bed capacity deficits remain. Focusing on scenarios that assume an 85% occupancy rate, we estimate that in 2023 there may be an immediate bed capacity deficit of approximately 1,000 inpatient beds in public acute hospitals and a requirement for an additional 330 beds a year on top of this, just to keep up with demand from population pressures.

The Group acknowledges however, that since 2020, this Government has opened 1,182 new acute inpatient beds. In addition, a further 91 acute beds are planned to open in 2024, with another circa 250 acute beds either under construction or have funding commitments to progress to construction over the next number of years.

The revised National Development Plan (NDP) capital allocations agreed by Government in March 2024 included an additional capital allocation of €245m towards healthcare infrastructure. This increased NDP allocation now allows the launch of Phase 1 of the next 1,500 Acute Bed programme. The Department of Health and the HSE are now progressing with plans for approximately 300 of these beds in Phase 1 of this new programme.

The new national elective hospitals under development will enable the separation of scheduled, elective care from emergency and critical care. This will lead to fewer cancellations and delays for elective care caused by seasonal surges, localised outbreaks, and surges in emergency attendances. The Group is hopeful that this increase in capacity will be key to tackling future waiting lists and times.

Latest National Treatment Purchase Fund (NTPF) figures show that 877,700 people were on some form of hospital waiting list at the end of January 2024. This indicates that more patients are being added to waiting lists than are being taken off, because demand for care is significantly increasing and hospital capacity is insufficient. When separate diagnostic waiting lists are added, over 1 million people are awaiting appointments, diagnostics or treatment. This will inevitably lead to some cases of delayed treatment or diagnosis, and potential poor outcomes for patients, which may in turn lead to claims.

The Group acknowledges the work underway in relation to the Waiting List Action Plan (WLAP) multi-annual approach, initiated in September 2021, which encompasses a two-pronged approach of short-term actions to increase capacity and activity in the immediate term, and longer-term reform measures to sustainably reduce and reform hospital waiting lists and waiting times. This WLAP approach is having a positive impact on hospital waiting lists, with each of the WLAPs to-date having achieved a reduction in the overall waiting list numbers (*5.4% reduction from September to December 2021, and 4.1% and 2.7% annual reductions for WLAP 2022 and 2023 respectively*). A further 6% reduction is targeted for 2024.

It is acknowledged that significant progress was made last year with an 11% reduction in the number of patients breaching the Sláintecare waiting times. There was also an 85% reduction in the number of people waiting over 4 years, and the number of people waiting over 12 months fell by 32%. Also importantly, the average outpatient department (OPD) waiting time reduced from 9.7 months to 7.5 months last year, a 23% improvement.

This focus on long waiting times is maintained in the 2024 WLAP, with 3 of the 4 over-arching targets specifically focused on waiting times.

Conclusion / What Needs to be Addressed

The most effective strategy to reduce the cost of claims is to minimise incidents of avoidable harm. The HSE works continuously to monitor and improve patient safety, reduce incidents of harm and to minimise risk. Implementation of the HSE Patient Safety Strategy 2019 to 2024 is key in achieving this goal and deserves national investment and support. It is important that teams and services across the country are supported to engage with the resources and initiatives of the NQPSD, and that these are available as appropriate to all healthcare providers, so that as many incidents as possible are prevented and in turn the cost of claims both at a human level and financial level are avoided.

The Group acknowledges the progress made in the increased recruitment of clinical staff in recent years, allied with an increase in the number of medical students. Nonetheless, serious problems still exist in relation to recruitment and retention of frontline clinical staff. Addressing the number of doctors on the general register and recruitment of clinical staff in high-risk specialties should be prioritised. The role of allied health staff in creating multidisciplinary care teams is of huge importance and workforce planning is also required in key fields including physiotherapy, occupational therapy, speech and language therapy, counselling and support services.

Recommendations

1. Recognising that having appropriately qualified and adequate numbers of staff is a key driver of patient safety, the Group recommends that workforce planning initiatives across the system be further supported, with priority given to high-risk critical areas such as delivery and neonatal units.

2. The Group recommends that all units delivering clinical care should be supported to develop and maintain responsive clinical governance functions, in accordance with HSE guidelines.

3. The Group advocates continued support for HSE patient safety initiatives and in doing so, recommends that available funding be prioritised and ring-fenced within the existing core allocations, to support ongoing patient safety initiatives in healthcare settings. This includes:

    - Funding to support evidence-based interventions aligned to the patient safety strategy, including data collection, analytical tools, training (including multi-disciplinary in maternity services and simulation) and other tools for the sharing of learning.

    - Consideration should be given to making some elements of core training mandatory.

    - Continued focus on initiatives to address the common causes of harm.

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Chapter 7: Enhanced Response When Harm Occurs

Introduction

The majority of services provided by healthcare organisations are safe and result in good outcomes. However, healthcare provision is complex, and sometimes things can go wrong despite best efforts, resulting in adverse events which harm patients. There is a crucial period following an adverse event when the response by the health system and health professionals can have a significant impact on a patient's outcome and experience. If this response is positive and a patient feels cared for and supported, with access to timely information and appropriate care, the trauma associated with unanticipated harm may be lessened with huge short and long term benefit. In addition, the need to litigate may potentially be ameliorated. Constructive management of the aftermath of AEs can also assist healthcare professionals and can have a positive impact on the safety culture and effectiveness of healthcare organisations.

Nonetheless, there is a view that when things go wrong, the health system "closes ranks", that information about what happened is difficult to obtain, with patients left attempting to access care in very difficult circumstances. There is also a concern that lessons are not learnt, either in the treating unit or across the general healthcare system.

In our study of plaintiff experience of litigation in Ireland referenced in Chapter 1, we examined participants' experience of support received following an AE that led them to litigate. The following themes emerged and are presented below.

Navigating the Aftermath of a Patient Safety Event - The Patient Experience

Communication

Effective, compassionate communication following patient safety incidents is paramount, yet many participants in the Plaintiff's experience study, detailed in Chapter 1, highlighted deficiencies in the communication they received. Some participants faced challenges from the outset, with issues arising during the disclosure of the incident, while others described a lack of compassion and unsatisfactory disclosure.

Some participants described initial positive interactions with healthcare professionals marked by "initial, honest and humane reactions", after which they noted a shift in dynamics during subsequent meetings, where a discernible "process of damage limitation kicked in" and they felt "it became about protecting the brand".

Furthermore, participants experienced a lack of transparency and described the withholding of crucial information in the aftermath of the patient safety incident. Participants also referred to the manner in which information was conveyed to them, both in terms of the verbal and the non-verbal cues, and the impact this had on them. One participant highlighted how the use of medical jargon led to confusion and lack of understanding of the severity of their child's condition. Another highlighted how upset they were by the language used to describe them and that this factor drove them to pursue litigation.

Participants also spoke of non-verbal elements of communication which gave a negative impression.

Power Dynamics

The complex interplay of personal circumstances and perceived power dynamics in the participants' experiences with healthcare professionals in the aftermath of patient safety events was highlighted by several participants. The feeling of being taken advantage of during a vulnerable time was expressed by one participant describing a sense of pushback and "wrong footing" such that the participant felt that the consultant was attempting "to take power".

Support

Participants in the study conveyed the absence of emotional, practical and financial support, from healthcare professionals and/or the healthcare system and revealed a notable failure to address the needs of individuals and their families following a serious patient safety event. The absence of emotional

support following an adverse event was a consistent theme in this research. The promise of follow-up that did not occur was particularly problematic. The accounts collectively illustrate a systematic failure in providing the necessary emotional support to patients and their families facing the repercussions of serious patient safety events.

Participants also discussed the absence of financial and practical support in the aftermath of the patient safety incident and their need for more medical support following the incident and the harm suffered. It was clear that practical support was particularly important in cases involving neonatal injuries, where timely intervention is key.

Some participants also spoke of the impact of the adverse event on their ability to work and a recognition of the financial implications of this was important.

Abandonment

Participants' frustration with communication received and the lack of engagement and support culminated in a pervasive sense of abandonment. One participant felt strongly that lack of communication from the hospital amounted to disrespect which was exacerbated by a failure of the treating doctor to follow-up and enquire as to how she and her son were. Lack of engagement and a sense of indifference added to the sense of abandonment among participants.

Some participants acknowledged the impact of the patient safety event on the healthcare professional(s), recognising that healthcare professionals were also often abandoned in the aftermath of patient safety cases. One participant characterised the situation as "shared abandonment", expressing concern not only for themselves but also for a younger doctor.

The Need for Timely Empathetic and Clear Information

Throughout all the testimonies of participants, the requirement for honest, clear and empathetic information is a strong consistent finding. Communication and care emerge as key issues following an Adverse Event.

While the circumstances are different, the ultimate response to the Cervical Check controversy of 2018 is instructive.

The National Cervical Screening Programme (NCSP) was established in Ireland in 2008. In 2016, an internal quality assurance audit was performed to assess previous cytology findings in women who had developed interval cervical cancers between 2008 and 2016. In Ireland there was no policy overseeing the disclosure of the results of the QA audit to women and in many cases, women were not informed and in others the disclosure was ad hoc and suboptimal.

The NCSP set out to devise a strategy of disclosure that would prevent women in the future being subjected to a similar experience. They consulted with the women from the 221+ advocacy group to ask them what would have worked better. Patient advocates advised that the key principles that must be adhered to included: (i) preparing the woman in advance for the potential review findings (ii) ensuring a support person is available for patients during the process (iii) using simple language to explain review findings and (iv) ensuring post disclosure support available. The infographic below captures a summary of their advice to improve the discussion of reviews after an adverse event.

Figure 9: Monitoring systems to evaluate patient experience on ongoing basis to ensure improvement and cultural change. https://221plus.ie/app/uploads/2023/03/QM_221-Report.pdf

A key provision of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 is to ensure that patients and their families have access to comprehensive and timely information in relation to serious patient incidents, including an apology where appropriate and an acknowledgement of the incident and the impact it has had. It includes a discussion about what has happened, why it happened, and what is being done to prevent it from happening again. This contributes to embedding a culture whereby clinicians, and the health service as a whole engage openly, transparently, and compassionately with patients and their families if things go wrong in the provision of care.

The National Open Disclosure Framework complements the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 and aims to promote a clear and consistent approach to open communication and guides the operational procedures and standards in communication when something goes wrong in the course of clinical care. Effective open disclosure can improve patient/ service user, staff, and community confidence in how the healthcare system responds to patient safety incidents and adverse events and can be fundamental for maintaining or re-building trust between healthcare staff and patients.

The Department of Health will monitor the implementation of this Framework in keeping with the principles set out in the policy document. All relevant stakeholders will be required to submit an annual report to the Minister for Health outlining their compliance with each relevant section of the Framework. This will also include their learning, experiences, and progress in implementing the Framework and insight into any aspects of the Framework which are proving challenging.

The Minister and Department of Health will publish an annual report on open disclosure to share the nationwide progress of the implementation of the open disclosure framework.

The Department of Health has indicated that all relevant stakeholders should start the adaption of the Framework into their organisational processes in 2024 and will be required to submit their first annual report to the Minister for Health in Q2 of 2025, and yearly thereafter.

Providing Support and Care When an Adverse Incident Occurs

Communication

Patients in the midst of an adverse event are unwell and may be frightened of their situation and the potential outcome. It can be equally distressing for family and loved ones. In addition to clear communication, patients need a clear plan as to what is going to happen and why. This should include a discussion on what the suspected problem is, what diagnostic tests are required and ultimately a clear treatment plan. While acutely unwell, it may be difficult for patients to fully grasp large swathes of unfamiliar information particularly if this information is couched in complex medical language. The clinical situation may also be evolving and changing at a rapid rate making clear comprehension more challenging. Information needs to be repeated and updated and communication needs to be particularly skilful when patients require transfer to an alternative institution to access specialised care.

Similarly, information on an adverse event needs to be communicated clearly among the different healthcare teams involved in a patient's care. A key element is comprehensive handover between shifts so that everyone involved in care has a clear understanding of the issues arising and the care plan.

Care and Support

A dedicated multidisciplinary approach is required in caring for people when serious harm occurs because care delivery has gone wrong. This multidisciplinary approach is particularly important to ensure timely delivery of care in the aftermath of an AE in hospital but also in preparation for discharge from acute care. Patients may need additional assistance with discharge arrangements and may require specific care packages or assistive aids.

It is important that community care teams are provided with timely and comprehensive information so that they are better equipped to assist. It is also important to note that patients may have care and support requirements long after discharge from hospital. In a recent study of patients undergoing complex high risk obstetric surgery, patients reported that the period six months after their surgery was very challenging when the intense care had ceased, and they were left to get on with normal life (Bartels HC 2020).

One of the recurring themes identified in our study, was failure of follow-up and the onus left to patients to contact hospitals to try to access follow-up care. This is unfair and leads to resentment. Effort needs to be made in organising follow-up care but also in ensuring that patients have a liaison person to contact in the event of issues arising before scheduled appointments.

It is patients themselves who are best placed to determine what they need in addition to appropriate medical care and they should be asked directly about their needs.

Bereavement Care as a Template for Care after an Adverse Event

While thankfully most adverse events do not end in loss of life, there is much to be learned and adapted from the HSE National Standards in Bereavement Care. The standards promote multidisciplinary staff involvement in preparing and delivering a comprehensive range of bereavement care services that assess immediate and long-term needs of patients bereaved while under the care of the maternity services. Between 2017 and 2021, an expert group set out to establish and develop standards in bereavement care. The expert group included representatives from obstetrics, midwifery, psychiatry, paediatrics, social work, chaplaincy and the Irish Hospice Foundation. Their extensive work was informed by a national audit of bereavement services in maternity units, an extensive public consultation process, consultation with practitioners and voluntary support organisations that support parents and families as well as the development of the new National Maternity Strategy and the draft HIQA Maternity Standards. The standards are built around principles of high-quality care, the development of appropriate systems of care central to the care missions of units, a focus on patient needs and on training and education of staff in the delivery of compassionate care.

All maternity hospitals/units will now establish or develop further Bereavement Specialist Teams to assist and support parents, families and professionals dealing with pregnancy loss. These teams will comprise staff members who have undertaken specialist and extensive education in bereavement care and will include a dedicated clinical midwife specialist in bereavement care for each maternity unit. They will be supported in their work by staff from other disciplines including obstetricians, paediatricians, neonatologists, chaplains, social workers and palliative care teams. The new standards also acknowledge the impact of pregnancy loss and perinatal death on staff and the importance of having formal structures in place to support staff.

Many of the principles inherent in the development of standards for bereavement care lend themselves to a broader application and adaptation to the wider healthcare system. Multidisciplinary specialist teams trained in the support of patients who have been harmed as a consequence of adverse incidents could make a huge contribution in assisting clinical teams to wrap around patients and ascertain and respond to their individual needs. They could be extremely impactful in optimising discharge arrangements, ensuring community care partners have appropriate information and can be an important liaison link for patients when they have left hospital.

Clinical Complaints System

Dr. Scally, in his final implementation review report published in November 2022, makes reference to a provision in the Health Act 2004, which prohibits a person from making a complaint to the HSE about the clinical judgement of a doctor or other health professional providing care on behalf of the HSE. He also states that *'An adequately constituted clinical complaints system is one thing that might help address the serious problem of patients being left with no choice but to take legal action if they are concerned that their clinical care may have been deficient'*. It is to be hoped that the requirement for a formal complaint will be lessened by the provision of supportive care and good communication from the outset, so that patient concerns are addressed at that early stage. Nonetheless, at times formal complaints are necessary and provide valuable institutional feedback on quality of care. It is important that themes and trends of complaints are evaluated by Executive Management teams in treating units so that care deficiencies are highlighted and addressed promptly. The Coombe Women & Infants University Hospital (CWIUH) recently performed an interesting study of patient complaints, and they examined the number and type of complaints that progressed to litigation with significant differences between the gynaecological and maternity sector. This would be worth tracking in every unit to give further institutional insight into the deficiencies in care that lead to litigation.

Further Learning

Further research is required in relation to patient experience in the aftermath of an AE so that support mechanisms can be optimised in direct response to patient needs. It is also important that the needs of healthcare practitioners and institutions are also considered.

Conclusion / What Needs to be Addressed

There is a crucial period following an adverse event, when the response by the health system and health professionals can have a significant impact on a patient's outcome and experience. When things go wrong in healthcare and unanticipated harm occurs, the principles of open disclosure must be adhered to in serious reportable events and should be employed in the wider context of all adverse events.

Patients should have clear and empathetic information on what has happened and what will happen with an apology and acknowledgment of the impact the harm has had on an individual.

Patients require a clear management plan and an opportunity to express their needs and have their needs responded to by staff trained in the delivery of compassionate care when things go wrong.

Particular attention should be paid to care plans on discharge from acute care and liaison with available community supports.

The inherent principles and concepts of care elements contained in the HSE National Bereavement Standards including, high-quality care when things go wrong, development of systems within care units to address adverse events, a focus on patient needs and appropriate training and care of affected staff, have broader application across the wider healthcare system and should be adopted in the development of care services for individuals harmed by adverse events.

Recommendations

When an event occurs a patient should be made aware of what happened and provided with appropriate care and supports. These recommendations are made in service of this.

1. The Group recommends the adoption of the National Open Disclosure Framework by all relevant stakeholders and the incorporation of the Framework into their organisational policies and procedures at the earliest opportunity.

2. The Group recommends that a team of trained personnel should be available to each hospital dedicated to responding to serious adverse events, when they occur. Where appropriate, this team may comprise external regional support. An example of this is the OEST in maternity care.

3. The Group recommends that rapid access to appropriate clinical investigations and care when complications occur be prioritised in each hospital.

4. The Group recommends that guidelines and training for meaningful debriefing with the patient/family following an adverse event should be put in place in each hospital.

5. The Group recommends that all hospitals should ensure that bereavement or adverse event nurse/counsellors are available to liaise with families, along with a family liaison person or social worker, to signpost families to services and entitlements (it is acknowledged that elements of this care already exist in many hospitals).

6. The Group recommends that necessary supports should be available immediately, within existing resource allocation, to assist parents with the additional care needs of children with catastrophic birth injuries while the longer-term support needs are being determined and arranged. Early intervention has been shown consistently to optimise outcomes and has the potential to reduce the risk of claims increasing due to inflation or unmet needs or suboptimal outcomes translating into larger costs. This may ultimately reduce the cost of damage settlements determined by the Courts.

7. The Group recommends that the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 be commenced by the Minister for Health at the earliest possible opportunity. All relevant stakeholders should be required to familiarise themselves with the provisions of the Act through mandatory training. All healthcare providers should take steps to ensure that patients are made aware of their entitlements under the Act.

8. The Group recommends that a robust complaints and patient experience feedback mechanism should be developed within all clinical care units. This data should be collated and analysed by individual units as part of a broader assessment of patient experience within our healthcare institutions. These should be shared with frontline staff to assist learning and understanding of positive and negative experiences of healthcare.

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Chapter 8: Care for Babies Born with Neonatal Encephalopathy and Other Maternity Initiatives

Introduction

Hypoxic ischaemic encephalopathy (HIE) is the most important cause of long-term disability in normally formed term infants. It happens when there is reduced oxygen and reduced blood flow to the infant's brain before birth. Despite the proven efficacy of therapeutic hypothermia (TH), up to 40% of affected infants will die or suffer from long-term neuro-development impairment.

The prevention of even one case of neonatal brain injury leading to CP has huge benefit in preventing the human suffering associated with such a devastating outcome, reducing the need for long-term complex care, and avoiding costly adversarial litigation.

The first objective is to focus on strategies to identify the at-risk fetus by analysing antenatal risk factors and incorporating them into the rationale for care during labour and delivery. Neonatal brain injury is a complex multifactorial process. Genetic, epigenetic, metabolic, prenatal, perinatal, and postnatal factors impact to protect, cause, or exaggerate neonatal brain injury. Babies may present with HIE in combination with other aetiologies and every effort should be made to identify the precise aetiology as far as possible. Precision in defining aetiology may facilitate targeted neuroprotective strategies and treatment.

Care for Infants with HIE

Current Care Provision

The HSE provides and funds a wide range of specialist disability services to those with physical, sensory, intellectual disability and autism, including supports to children with complex needs, some of which may have arisen from catastrophic birth injury.

Services are provided in a variety of community and residential settings in partnership with service users, their families and carers and a range of statutory, non-statutory, voluntary and community groups. Specialist disability services are delivered through a mix of HSE direct provision as well as through over 400 voluntary Section 38 and 39 funded service providers, and private providers.

The range of specialist disability services provided to people with disabilities includes Residential, Respite, Day Services & Rehabilitative Training, Assisted Living Services (Home Support & Personal Assistant Services), Early Intervention and School-aged Services - Progressing Disability Services for Children & Young People (0-18 years), Multidisciplinary supports, Aids and Appliances, Neuro-Rehabilitation Services, Financial Allowances and Miscellaneous Support Services.

Specialist Disability Services has been allocated €2.9bn in 2024.

The Review of Disability Social Care Demand and Capacity Requirements up to 2032 demonstrates significant unmet need at present, while projected demographic changes of the disability population indicate that this unmet need will grow over the coming decade.

The importance of early intervention and effective services for children and young people is particularly important to optimise outcomes so that the requirement for future complex care, including residential care, is reduced.

Work is underway by the Department of Children, Equality, Disability, Integration and Youth Affairs (DCEDIY) on implementing an Action Plan for Disability Services 2024-2026 published in December 2023, to progressively address the shortfall identified in care provision, subject to the required funding being made available. Significant investment is required to close the gap between what a court would award based on a 'total compensation' principle, and care provision under the support needs model operated by HSE Disability Services.

We spoke to one charitable organisation which provides in-home nursing care and respite to families caring for children up to the age of six with neurodevelopmental delay. Approximately one quarter of their annual budget is funded by the HSE, with the remainder accrued through fundraising. They report that the transition from hospitals to primary and social care in the community can be problematic, with lack of clarity as to whether care requirements belong to primary or social care.

In their opinion, respite care is the biggest gap and even comprehensive care packages may not provide sufficient respite, although they did acknowledge improved resources and care from the HSE in recent years. They found that families were deeply worried by the unpredictability of the future and desperately wanted to maximise their child's potential. In their experience, parents wanted acknowledgement and an apology and they wanted the system to learn from events around their child's birth. They also emphasised the bigger picture of care for siblings, which can be challenging, when so much resource is required for their affected sibling. Parents may have to give up careers which can have a whole range of detrimental, economic and psychological effects.

In relation to services for children, they advocated a central information repository of what services exist and how to access them. They advocated one system of care with financial support available from the beginning. Of note, they warned about therapies offered to patients in the private sector that are not of proven benefit. They felt that the key to care was early information, early intervention, clear patient pathways and psychological support services with enhanced respite care.

Prediction and Prevention Pathways for HIE

Identification of Risk Factors

As our understanding of the aetiology of CP and specifically HIE grows, we need to translate this understanding into strategies that will identify antenatal risk factors and use that knowledge to enhance peripartum care. Review of the literature and clinical experience in Ireland identifies clear risk factors for the development of HIE and CP. In 2016, the National Maternity Strategy placed significant emphasis on the value of risk stratification in the delivery of antenatal care and this is a valuable approach. However, the course of pregnancy can be complicated by a variety of events which may alter the risk profile or create a particular risk profile for induction of labour, labour, or delivery. For example, disorders of fetal growth, multiple pregnancy, maternal disorders including diabetes, hypertension, and thrombophilia. In view of the potentially devastating outcome of HIE and other adverse events, such as shoulder dystocia and postpartum haemorrhage, it would be beneficial to explore a targeted risk profile at the onset of labour or induction of labour.

Key associations identified by NNEAG include nulliparity, induction of labour and shoulder dystocia. Women who present with pains, and who are deemed not in labour and discharged home or to the antenatal ward, emerged as another key group in the 2019 review of infants presenting with moderate to severe HIE. The diagnosis of labour is a critical step and should be made by an experienced midwife or doctor. It may be that prolonged pains without cervical dilation consistent with dystocic labour may increase the hypoxic stresses for a fetus and this group requires attention. A similar phenomenon may be seen in some cases of induction of labour.

Senior Experienced Staff

Labour is a natural physiological process, but it carries significant risks, and it is critical that senior experienced staff attend women in labour. It is not enough to ensure adequate headcount on the delivery ward – it is the experience of staff that is crucial and staff in training should be well supervised and have the opportunity to learn in a supportive environment. Enhanced consultant presence on the labour ward should be a priority and in the large tertiary units, consideration should be given to 24–hour consultant presence on the labour ward.

Complications in labour can arise unpredictably and are time critical. For example, in shoulder dystocia, delivery must be effected within minutes to avoid hypoxic brain injury. This requires skilled manoeuvres which will be required for individual staff on rare occasions only. This is the reason why dedicated Drills and Skills training is of such value in maternity care and should be mandatory for all practicing clinicians delivering obstetric care. Training in CTG interpretation is now audited and all units are responsible for ensuring that relevant staff have

completed online CTG modular training. Many units also have weekly labour ward meetings for case review, journal review and teaching. These initiatives should be strongly supported and instigated if not already in place.

Neonatal Management

The acute neonatal care of HIE and subsequent follow-up requires an integrated operating system. There are 19 maternity units in Ireland. Each hospital has a consultant led neonatal unit on the same site. The four tertiary neonatal units – Rotunda, NMH, Coombe, CUMH – are designated centres for the provision of therapeutic hypothermia (TH). The incidence of HIE requiring TH in Ireland is 1.2 per 1,000 births. Sixty per cent of the affected infants are born in one of the four tertiary centres. The other 15 hospitals transfer infants to one of these four centres. The infants are retrieved by the National Neonatal Transport Programme (NNTP). The cooling process is commenced in the local hospital and is administered also by the NNTP during the transport to the tertiary centre where it continues for a total of 72 hours.

At birth, standardised assessment is required to identify neonatal encephalopathy and once identified there are four key strands to the clinical management.

1. The acute clinical care.

2. Accurate assessment - a full work-up should be instituted to determine the severity and specific subtype of neonatal encephalopathy, for example - NE sepsis, NE-genetic, NE-HIE, NE-metabolic etc. This ensures that families receive the most accurate information possible.

3. High-quality communication with the infant's parents.

4. Skilled multidisciplinary follow-up and early targeted intervention to address any adverse neurological sequelae during the early period of maximum neuroplasticity.

The 4 Strands of Neonatal Management

Acute Clinical Care: This consists of immediate, effective resuscitation at birth followed by timely commencement of TH before 6 hours of age. The decision to commence TH is based on standardised modified Sarnat criteria. The TH treatment consists of the reduction of the infant's temperature to 33.5°C for 72 hours. This therapy reduces the cascade of neural injury following asphyxia by lowering the cellular metabolism.

Assessment of the Infant with HIE: The accurate evaluation of the neurological status of the infant is important. It forms the basis of the communication with the parents.

If the encephalopathy is in the mild category, severe disability is unlikely but as the degree of encephalopathy increases, the likelihood of future disability increases.

It is also important that other causes of NE are sought as HIE can occur in association with other causes. Neuroimaging with MRI and detailed examination of placenta histology should be a standard of care in all babies undergoing TH for HIE.

Communication with the Parents: When an infant suffers HIE, it is a very distressing time for the parents. The factors that make HIE so upsetting are the unexpected nature of the event, and the uncertainty about the infant's outcome. Skilled communication is very important at this difficult time particularly when an infant requires transfer to one of the tertiary neonatal units for TH.

Follow-Up of the Infant and the Multi-Disciplinary Team (MDT): Infants who have suffered HIE are at high risk of a long-term disability. The risk is higher in those with an abnormal MRI brain scan in association with HIE, compared with those who have a normal MRI brain scan. A normal MRI means that the infant is unlikely to have cerebral palsy, but they could have communication and cognitive problems. A hospital multidisciplinary team plays a critical role in the assessment and provision of therapy for infants who have had HIE. This hospital-based team consists of the following members – physiotherapist, speech & language therapist, occupational therapist, clinical psychologist, dietician, pharmacist, and social worker.

Complications require early and skilled intervention in order to improve the well-being of the infant and to reduce the burden of care. In particular, poor sleeping with repeated wakening is exhausting for parents. The key to good care is the ability to diagnose problems early and administer the appropriate intervention. A Bailey Scales of Infant and Toddler Development should be undertaken on all infants with HIE at age 2 years. This test assesses the developmental domains including motor, cognitive, language, social emotional development, and adaptive behaviour. The Bailey Scales can be used to assess either global or domain specific delay. The examination takes between 1–1.5 hours to complete. Scores within the bottom 10th percentile signify developmental delay – children who score within this range require examination and intervention by the MDT.

Current research is focused on early diagnosis of CP and developmental delay with enhanced prediction at 9 months of age. This has the benefit of earlier intervention associated with enhanced outcome. Early detection strategies include MRI combined with General Movements assessment or The Hammersmith Infant Neurological Evaluation (HINE) for infants older than 5 months of age. Early intervention using motor specific task approaches enhances cognitive and motor outcomes, while early physiotherapy can prevent hip dislocation, scoliosis and muscle contractures. It also increases support for families and ultimately could play an important role in reducing cost of care into the future.

The Current Status of the Service Provision for Infants with HIE

Much has been done to achieve a better outcome for infants suffering from HIE, but there are existing challenges particularly in relation to follow-up.

1. The techniques of neonatal resuscitation are standardised across all neonatal units. Every midwife, neonatal nurse, and paediatrician holds a certificate of NRP (Neonatal Resuscitation Programme) training, which is revised every 2 years. The programme is co-ordinated by the national neonatal NRP co-ordinator (NWIHP).

2. When an infant is being reviewed for possible HIE the 'Candidacy Checklist for Neonatal Therapeutic Hypothermia (Cooling)' is used. This clinical tool has proven to be very reliable in the identification and selection of the infants who require therapeutic hypothermia.

3. The majority of infants, who receive TH reach 33.5°C by the target of 6 hours of age. In the case of outborn infants, the NNTP performs 80% of the transports with 20% being undertaken by the local hospital when the NNTP is busy on another call.

4. Ninety-eight per cent of infants presenting with HIE had a brain MRI undertaken by day 10 of age, which is in keeping with international best practice.

However, significant challenges remain in the follow-up of infants following discharge from hospital. A significant number of infants are not getting timely assessment.

In an attempt to address these follow-up deficiencies a QI programme called ACoRN (Allied Care of at-Risk Newborns) has been established at the NMH. This group of hospital-based HSCPs-SLT, physiotherapist, psychologist, OT, dietician, pharmacist, social worker – are working with infants and their families both while they are on the neonatal unit and after discharge home. Following a period of observation and assessment, the group are well placed to identify any special developmental needs that the infant may have. Their developmental plan is communicated with the therapists in the community. It is important to emphasise that these services can only be provided by the appropriately trained therapists.

The ACoRN programme could be rolled out to the other 3 NICUs that provide therapeutic hypothermia to HIE infants. It will require a modest increase in HSCP staff. In time it is hoped that this multidisciplinary expertise can be developed nationally and provided in a programmatic way to infants presenting with HIE.

The development of standardised multidisciplinary national services designed to care for children with CP must be a goal. It would improve both quality of care and national expertise, allowing for economy of scale and the potential to enhance services for other children with similar disability. As Judge Meenan commented in the Report of the Expert Group on Tort Reform and the Management of Clinical Negligence Claims - "the aim must be to close the gap between what the HSE can offer and what a court would award."

The Development of a National Cerebral Palsy Register

The Value of a National CP Register

Although CP is a relatively rare condition, it is the commonest cause of childhood disability with one in 345 children identified as having CP. In the past Irish regional registers provided accurate data on CP but it was impossible to ascertain national data and lack of standardisation prohibited comparative analysis nationally and internationally.

Experts in the area have long called for a national register and have laid out a compelling rationale for the introduction of a CP Register in Ireland (Craig et al). A national register could address a range of themes including aetiology, classification, severity, co-morbidity, treatment outcomes and cost of care across a range of collected variables. It would facilitate the planning of more equitable and appropriate services for all affected children. A register would permit meaningful comparisons with other countries through collaboration and strengthened links with the Surveillance of Cerebral Palsy in Europe (SCPE). Data from registers is increasingly used across Europe to develop specific CP public health indicators (PHI's) addressing critical themes such as peri-natal interventions, burden of disease, access to facilities and preventative health strategies. At a national level this includes a greater emphasis on prevention and population health initiatives. In a recent report, the Economic, Social and Research Institute (ESRI) recommend the need for accurate data on the specific characteristics of children with a disability for the development of effective public policy and service provision (ESRI, 2021).

The estimation of lifetime costs associated with supporting an individual with CP are high. Registry data can also be used to accurately predict costs associated with care, including the means to justify interventions using cost/benefit measures that demonstrate the impact/outcomes of such measures. Costs to society through loss of productivity also need to be considered in that more than 2/3 of people with CP, regardless of severity or type, never enter the labour market (Kruse, 2009). And of course, the legal costs of resolving claims for CP must be considered.

Finally, a register would play a key role in assisting a variety of research initiatives from preventative and care provision strategies to the identification of specific aetiological factors which might advance our understanding of the cause of CP in a transformative way. Epidemiological research must continue to document current and evolving aetiological factors of importance and ascertain that results from the ACPR and Europe are reflective of a true downward trend. In this sense, it is important that mechanisms to facilitate research continue to allow the identification of significant factors in the pre, peri and postnatal periods which might be aetiologically important and potentially avoidable.

The creation and sustainability of a national CP register in Ireland would require a sustainable funding plan, along with necessary supports.

Consideration of Statutory Registration

Based on the international experience, there is little doubt that registers operate more effectively and are likely to produce greater benefits for participants when there is a statutory entitlement to collect data. However, bypassing a system that fundamentally protects individual rights is ethically controversial. Only 50% of parents agreed to participate in the pilot study. Rates as low as 50% would significantly affect the overall quality and validity of a national register that aims to be complete.

The Evaluation of Treatments and Early Intervention

There is no known cure for CP but the improvements observed in the past two decades are largely driven by population registers which accurately capture the condition. This is underpinned by a falling birth prevalence and an increased focus on early detection and targeted intervention to improve outcomes for affected children (Badawi et al, 2020). A national CP register could assist the national ability to optimise specific programmes to help all Irish children affected reach their full potential.

Collaboration with Key National Organisations

It is essential that if established, the register would engage and collaborate with key national organisations responsible for the governance and management of national health information systems in Ireland if it is to be sustained. The most relevant of these include:

- The Department of Health (DoH)
- The Health Service Executive (HSE)
- The Health Information and Quality Authority (HIQA)
- Central Statistics Office (CSO)
- The State Claims Agency (SCA)

Collection of Biomarker and Genetic Data

The register could play a significant role in the systematic collection of biomarker data and genetic testing to increase the possibilities for the identification of factors of aetiological importance. This will overlap with existing and ongoing efforts by the *International CP Genomics Consortium* who are compiling a database to allow genetic and clinical data to be shared globally (See www.icpgc.org).

Early Notification Scheme

NHS Resolution (England) introduced an Early Notification Scheme in 2017 for reporting specific brain injuries at birth to determine if the harm occurred as a result of care that might be considered negligent. It is a requirement to notify NHS Resolution of incidents which meet a certain clinical definition. The scheme allows NHS Resolution to:

- Investigate potential eligibility for compensation and to take action to reduce legal costs while improving the experience for patients' families and affected staff.
- Share learning rapidly with the individual trust and the wider system in order to support safety improvement in an effort to prevent such an outcome happening again.
- Build on the open disclosure principles to acknowledge harm and to apologise to families and ensure that the process to obtain compensation is not a barrier to openness, candour and learning.
- Preserve evidence should a case be taken at a later date.
- Improve the process for obtaining compensation for families. Meeting needs in real time where possible and trying to reduce the risk of claims increasing in value due to inflation or unmet needs translating into larger losses.

The scheme has already achieved reductions in the time between an incident occurring, an investigation into eligibility for compensation initiated, and admissions of liability being made. Seeking early notification of maternity incidents means that NHS Resolution can proactively investigate liability sooner, while trusts are encouraged to be open about incidents, be candid with families and maximise opportunities to learn from them.

Conclusion

Catastrophic perinatal brain injury leading to significant neurodevelopmental compromise is a devastating outcome for the individual, for their families and for wider society. Care for those affected is complex and is required for the duration of that person's life. The cost of this care into the future is the single most important driver in the rising cost of healthcare litigation in Ireland.

As new technologies and innovations permit better outcomes and longer lives, the cost of care will continue to rise, but at present care for affected children is poorly standardised and difficult to access with a heavy and costly reliance on private sector care.

The first objective is to focus on strategies to prevent cases of HIE by learning from audit of previous cases and using this information to identify the at-risk fetus by analysing antenatal risk factors and incorporating them into the rationale for care during labour and delivery.

When a baby is born with HIE, appropriate neonatal resuscitation and assessment is essential to optimise outcomes. Early diagnosis and early intervention make a significant difference in the outcomes for children with cerebral palsy. Various care initiatives have commenced in recent years, some within a research setting, but it is evident that the provision of standardised experienced multidisciplinary care must be a priority for children and families affected by HIE who are at high risk of developing cerebral palsy. In infants who go on to develop CP, standardised multidisciplinary care should continue through the lifetime of the affected child.

Early intervention is increasingly recognised to optimise outcomes in patients at high risk of developing CP as a consequence of HIE and current initiatives to develop early intervention clinical pathways should be supported. There are experts in Ireland delivering excellent care for children with cerebral palsy, but care expertise needs to be developed and expanded so that it can be standardised and delivered nationally. At present, care is not standardised in Ireland, while a number of voluntary and charitable organisations fill in important gaps.

Current research initiatives should also be supported – we have much to learn about the antecedents of neonatal brain injury and cerebral palsy. In turn, as we learn more, we will increase the opportunity to develop therapies that may be transformational.

Standardised pathways of expert multidisciplinary care would potentially optimise outcomes for children potentially reducing the cost of care into the future. It would also reduce reliance on expensive ad hoc care arrangements and develop critical national expertise.

The creation of a national cerebral palsy register would permit standardised collection of data which would assist in international and national comparative analysis, the identification of preventative and care strategies to optimise outcomes for children and would drive thematic research to inform national public health strategy.

Early intervention is also important in relation to clinical negligence claims. Litigation is a huge additional burden for families dealing with the complex care requirements and emotional burden of catastrophic brain injury. The current claims process is tardy and arduous with individual cases taking several years to resolve. We need to improve the process for obtaining compensation for families and ensure that we meet their needs in real time where we can. In turn, the Courts could adjust the cost of care provisions in the knowledge that care is provided by the State and to an expert standard, ultimately closing the gap between the State provision of services and the care packages provided by the Courts. In addition, the provision of early claims resolution in the context of perinatal brain injury has the potential to meet the financial needs of families in real time and optimise clinical outcomes with the potential to reduce the risk of claims increasing in value due to inflation or unmet needs translating into larger losses.

Recommendations

1. The Group recommends that data on Neonatal Encephalopathy (NE) be collected on a statutory basis, and that a register of cerebral palsy cases in Ireland should be developed.

2. The Group recommends that the work of the National Neonatal Encephalopathy Action Group (NNEAG), and its efforts to reduce to the greatest extent possible the incidence of birth-related CP/ catastrophic birth injury, should receive ongoing support and endorsement.

3. The Group recommends that the investigation and follow-up of infants with HIE needs further development and standardisation. All babies presenting with HIE should have a standardised assessment including placental examination, MRI brain scan and follow-up neurodevelopmental assessment.

4. The Group recommends that research initiatives that advocate earlier diagnosis and intervention in cerebral palsy should be supported and that a taskforce should be put in place to devise a model of care for babies with HIE so that standardised follow-up will lead to the early detection and intervention in those babies with CP.

5. The Group recommends that care pathways, once developed, which start at birth and continue through life, for children who have suffered a catastrophic birth injury, should be considered for implementation on a national basis. The Group recognises that the initial development of new care pathways will be managed within existing resources.

   The State provision of such care could facilitate immediate and more effective evidence-based care and lead to growing national expertise, reducing the reliance on ad hoc private care arrangements. In addition, the provision of early claims resolution in the context of perinatal brain injury has the potential to meet family needs in real time, facilitate early clinical intervention and reduce the risk of claims increasing in value due to inflation or unmet needs translating into higher costs.

   While initially these care pathways would be limited to the cohort of children who have suffered a catastrophic birth injury, consideration should also be given in the future to rolling out these services to all children with cerebral palsy over a longer period of time, as national expertise and capacity develops and a review has been undertaken with regard to their effectiveness and efficiency for the initial targeted cohort. This would also need to be informed by an assessment of the feasibility of potentially increasing eligibility including resourcing constraints.

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Chapter 9: Faster and More Efficient Resolution of Claims

Introduction

A considerable body of work has already been undertaken in the past twenty years relating to the reform of the civil litigation system and a number of recommendations advanced. We draw on this previous work and acknowledge that in several cases we are repeating recommendations made previously. Work on progressing some of these recommendations is at an advanced stage of development and we hope that their implementation will occur close to the publication of this Report. Indeed, the Group's Terms of Reference acknowledge the Report of the "Expert Group to Review the Law of Torts and the Management of Clinical Negligence Claims" (the 'Meenan Report'), and the Civil Justice reform measures being undertaken in the Department of Justice, tasking the Group with identifying actions to accelerate these reforms and maximise their impact on management of health-related claims. The table below sets out some previous reports and interventions aimed at improving the management of clinical negligence claims.

Year	Reports and work advocating civil justice reforms
2005	Report of the Legal Costs Working Group
2010	The Working Group on Medical Negligence and Periodic Payments publishes its report on Periodic Payment Orders (Justice John Quirke)
2012	New Taxing Master Appointed
	The Working Group on Medical Negligence and Periodic Payments, established in 2010, publishes its report on Pre-action Protocols (Judge Irvine)
2013	Public Expenditure on Legal Services Report
	The Working Group on Medical Negligence and Periodic Payments publishes its report on Case Management (Judge Irvine)
2015	Legal Services Regulation Act
	Oireachtas: Joint Committee on Health and Children, Report on Cost of Medical Indemnity Insurance
2017	Review of the Administration of Civil Justice Group established, chaired by Mr. Justice Peter Kelly
2020	Report of the Expert Group on Tort Reform and the Management of Clinical Claims (Judge Meenan)

Table 16: Some previous reports and interventions aimed at improving the management of clinical negligence claims

The three reports of the Working Group on Medical Negligence and Periodic Payments on Periodic Payment Orders (2010), Pre-Action Protocols (2012) and Case Management (2013) set out important recommendations that remain to be implemented in full, but which have been consistently endorsed by relevant stakeholders over the past decade.

The Meenan Report identified measures which could be taken in both the health and justice areas. These are addressed throughout this report and a summary of the recommendations and their current status, as well as any relevant recommendations arising from this report, are set out in Appendix 3.

There are a number of fundamental principles that underpin any potential change in the legal processes involved in the resolution of clinical negligence claims and these derive from the provisions within our Constitution.

The right of any individual to access the Courts and the right to bodily integrity are principles enshrined in the Constitution and these must be upheld within the laws of the land.

The requirement to provide fair compensation, to include full compensation as regards pecuniary loss and to vindicate bodily integrity, is restated in *Russell (a minor) v HSE* [2016] 3 IR 427. The Court of Appeal noted "it is mandatory for the Court to approach its calculation for a future pecuniary loss on a 100% basis……. The damages awarded are, after all, destined to do no more than restore a plaintiff in financial terms to as close a position as they would have enjoyed in terms of wealth and independence had they not been the unwitting victim of the defendant's wrongdoing".

Under the Law of Tort, the requirement to determine negligence and breach of duty in clinical negligence cases has implications for a number of potential alternative legal processes. In addition, determination of compensation in clinical negligence cases generally falls under the remit of the Courts. As Judge Meenan notes: "The Expert Group has considered in detail, a number of alternative systems. Any alternative system has to operate in an area defined by the provisions, both express and implied, of the 1937 Constitution. A clinical negligence claim involves not only the laws of negligence but also, more fundamentally, the constitutional rights of the parties involved. The 1937 Constitution expressly limits the jurisdiction of bodies other than the Courts to determine the types of issues that arise in such claims. The scope for non-court bodies to resolve clinical negligence claims is very limited. Any reforms to our current legal system, which are undoubtedly required must have regard to the constitutional rights of both claimants and defendants".

When these principles are considered, it is clear that the introduction of alternative pathways for the resolution of clinical negligence claims is limited. The concept of no-fault compensation is one that receives much attention as it could potentially ameliorate the adversarial nature of claim management under Tort. Judge Meenan and his Group examined this system in detail, drawing on international experience in New Zealand and other countries. They determined that such a scheme could be potentially unconstitutional by restricting a person's right of access to Court and the right to general damages to vindicate bodily integrity. Although negligence and breach of duty would not have to be established, fault would have to be established and this can be as difficult as establishing liability, particularly in the case of high cost claims such as cerebral palsy where causation can be very complex. Another reason advanced was that lessons would not be learnt.

The Meenan Group also considered a Medical Injuries Assessment Board (MIAB) as currently clinical negligence claims are excluded from the Personal Injuries Assessment Board (PIAB). The Expert Group concluded that a MIAB would be complex to operate as injuries, loss and damage from clinical negligence claims are complex and have a psychological component which is excluded from PIAB assessment. Given the varied and complex nature of injuries, a Book of Quantum would be very difficult to draw up and the Group felt that establishing a MIAB would not necessarily lead to faster resolution of clinical claims.

Ex-Gratia schemes were also considered and were designed to deal with specific situations where events had occurred many years before. One example is the Surgical Symphysiotomy ex-gratia payment scheme. Overseen by Justice Maureen Harding Clarke, it cost just under €34m and made awards of €50,000, €100,000 or €150,000 to 399 women. However, a person cannot be compelled to take part in such a scheme as every person has a constitutional right to access the Courts and as observed in the Meenan Report, awards by way of compensation tend to be below those awarded in Court. The Group concluded that ex-gratia schemes had limited application.

The Meenan Group also made a series of recommendations in relation to patient safety, open disclosure and the extension of HIQA's ability to carry out investigations. Importantly the Meenan Report recommended that the wider availability of supports and care packages to those who suffer injury or disability as a result of alleged clinical negligence could have the effect of reducing claims. The Group acknowledges the difficulty of the HSE in matching the care packages that would be provided by the Court but contests that it must be "the aim to close the gap between what the HSE can offer and what a court would award." We have discussed this concept in more detail earlier in this report.

What Needs to be Addressed

Court proceedings are adversarial, distressing for patients and clinicians and by their nature may not be conducive to early resolution. It can take time to agree upon expert evidence or even to agree upon the extent of experts' disagreement. In presenting oral evidence, claimants and clinicians can find the experience, particularly of cross examination, intimidating and stressful. The conduct of litigation, particularly in its later stages, entails the incurring of significant legal costs.

The Meenan Group made a series of recommendations including the implementation of a pre-action protocol, enhanced case management, and the provision of medical records in a timely way, with sanctions to be applied if the PAP is not adhered to. These recommendations were almost universally echoed by many of the experts the Group met with in the course of its work (including the legal firms, the Bar of Ireland, the Law Society, the judiciary, the Insurers and the IMO). The introduction of a PAP, enhanced case management and the resumption of PPOs on a statutory footing were by far the most common recommendations advanced to us in terms of legal process. These recommendations echo those of Judge Irvine over a decade ago and in the Report on the Review of the Administration of Civil Justice by Mr Justice Kelly, when he recommended the early introduction of regulations in respect of a PAP in clinical negligence cases. He also recommended the introduction of case management rules where case progression would be overseen by Masters and Deputy Masters of the High Court.

The Introduction of a Pre-action Protocol

The 2012 Report of the Working Group on a pre-action protocol and referenced in the Meenan Report, identified the benefits of a pre-action protocol, as follows:

(a) A pre-action protocol should secure earlier disclosure of patient records than currently is the case, thus facilitating an informed consideration by the parties of any potential claim or defence;

(b) A pre-action protocol affords an opportunity for the parties to settle the dispute between themselves or to explore alternative dispute resolution options where appropriate – thus reducing the number of claims which ultimately proceed to litigation;

(c) Where a claim does proceed to litigation, a pre-action protocol identifies, at a much earlier stage, the issues which are actually in dispute; and

(d) A pre-action protocol provides an appropriate context for a patient to seek, and in appropriate circumstances, obtain, a suitable apology in respect of the adverse event experienced.

Case Management Rules

The Meenan Report also references the Report of the Working Group on Medical Negligence and Periodic Payments on Case Management, published in 2013, and expresses the view that the implementation of its recommendations would considerably improve the current system to the benefit of litigants. The Meenan Report documents the benefits that would arise from case management as follows:

(a) 'The identification of the issues involved in the case. This can lead to an early settlement;

(b) Establishing that mediation becomes part of the process;

(c) Encouragement of a spirit of cooperation between the parties and the avoidance of unnecessary combativeness which results in unnecessary additional stress to the parties, expense and delay;

(d) Identification and reduction of issues prior to the trial;

(e) Where settlement cannot be achieved by negotiation or mediation cases can progress to trial as speedily as possible; and

(f) The provision of witness statements, which should be agreed in advance of any hearing, would serve to reduce the upset and stress of persons who may be required to give evidence of their medical condition and its effects.'

The Meenan Report concludes that *'the introduction of pre-action protocols and case management will reduce the adversarial nature of the system'.*

Earlier Mediation/Resolution of Claims

Mediation is already used in Ireland and increasingly claims are settled at mediation stage before reaching the Courts. According to the SCA's annual report 2022, 58% of claims resolved by the SCA in 2022 were resolved without court proceedings being served. Just under 2% of cases resolved by the SCA in the same year were the subject of a court judgement. 34% of claims concluded by the clinical claims team in 2022 and where damages were paid involved a mediation process, compared to 25% in 2020. Mediation also forms an integral part of the Scheme of Settlement put in place by the SCA to resolve H1N1 vaccination claims.

Given the expected benefits that would result from the implementation of a PAP and case management rules, it is anticipated that the combination of these two measures would likely result in more claims being resolved through mediation and afford an earlier opportunity for mediation than is currently the case. This would allow time and space to explore the clinical issues arising and to admit liability before a Court process. This would also address patient concerns about transparency and allow patients to receive comprehensive expert opinion on the details of their care. Importantly, clinical negligence claims would only reach a Court hearing after early and full engagement between the parties and an understanding reached on elements that are agreed and those remaining at issue.

So called 'Hot-Tubbing' (the practice whereby both parties' experts give their evidence together in the form of a discussion chaired by a judge) could facilitate agreement if causation is at issue and in cases of resolution, a court appointed expert could determine cost of care, with a mechanism to fast track cases when liability is admitted. A PAP also allows for the provision of written witness statements in advance of a Court hearing so that a plaintiff could avoid giving direct evidence in Court if they wished. Clinical negligence PAPs were introduced in the UK in 1999 and have been successful in improving the civil litigation environment.

Following on from the recommendation by Judge Irvine's Working Group, a provision was introduced in the Legal Services Regulation Act 2015 for the making of regulations by the Minister for Justice for the introduction of a pre-action protocol relating to clinical negligence actions. Unfortunately, difficulties arose regarding the statutory basis for making pre-action protocols under the 2015 Act.

Consequently, a legislative amendment to the 2015 Act was enacted in 2023 as part of the Courts and Civil Law (Miscellaneous Provisions) Act 2023. The overall effect of the amendment is to allow the drafting of pre-action protocol regulations in relation to clinical negligence actions. The Group understands that the regulations are being drafted at present and that there will be a consultation process in due course, in line with the governing legislation. It is expected that the regulations will come into effect in 2024.

Timely Provision of Medical Records

In order to litigate, medical records must be available to expert witness for review. Delays in obtaining medical records can be problematic. Recent experience with electronic records has shown that it can be difficult to decipher core chronological information in large volume print outs that contain significant amounts of interspersed texts that are not relevant. The Meenan Group makes recommendations regarding the timely provision of medical records to ensure that they are provided at an early stage in the legal process that could be implemented as part of a PAP.

Expert Witness Reports

Another important issue that was cited by a variety of those interviewed was the difficulty in obtaining expert witness (EW) Reports. Clinicians have reported that they are too busy to accommodate this work, that the work is too onerous and that they are worried about securing leave for cases that might go to court for several days or more. In a small country like Ireland, clinicians may know each other personally and do not wish to get involved in the legal cases of colleagues. This potentially creates a reliance on a small pool of expert witnesses from within the jurisdiction and experts from overseas who may not have any experience of practicing medicine within Ireland. Clinicians who have ceased practice for long periods may also be less preferable to those in active expert practice.

The question of expert witnesses (EWs) has been considered in a number of reports in the UK. The Williams Review into Gross Negligence Manslaughter in Healthcare, 2018 promotes the development of standards and training for EWs and that EWs should have relevant clinical practice and be in current practice. The review advocates that professional bodies should encourage healthcare professionals to participate as EWs and that this work should be recognised by continuing professional development programmes. These views are echoed in the GMC Hamilton Review (2019) - Independent Review of Gross Negligence Manslaughter and Culpable Homicide, which recommends that EW reports should be calibrated according to specified standards and the EWs should only address matters which occurred while they were in active and relevant clinical practice. This might best be addressed by creating an independent panel of available expert witnesses within Ireland or abroad, where appropriate, who may be called on to provide either plaintiff or defendant opinion.

Dedicated List in the High Court

The Meenan Group's recommendation that there be a dedicated list in the High Court to deal with the management and hearing of clinical negligence was also considered. A Judicial Planning Working Group was established to address reforms in the judicial system including the current shortage of judges throughout the Court System. Following the publication in February 2023 of the final report of that Group, the Government committed to an historic increase of the number of judges. A first tranche of 24 additional judges were approved by Government on 21 February 2023 and the legislative provisions for judicial posts were made under the Assisted Decision Making (Capacity) (Amendment) Act 2022 and the Courts Act 2023 to allow for creation of the posts. The 24 additional judges included 8 extra judges for the District Court, 8 for the Circuit Court, 6 for the High Court and 2 for the Court of Appeal. All of these 24 additional positions were filled in 2023.

The establishment of a new court for clinical negligence claims was not felt to be feasible given the additional Judicial and administrative staff required to create such an entity but the provision of a dedicated Court list was explored. The Group engaged in extensive consultation with claimants, legal practitioners and the judiciary. Arising from that consultation, some of those engaged with postulated that the provision of additional judges with particular expertise in medical negligence (within the current Personal Injury List), would effectively create a dedicated High Court list with appropriate ability to fast track urgent cases and those in which liability has been admitted. However, others consulted, continued to advocate for a dedicated list, in line with Judge Meenan's recommendation.

Resumption of Statutory PPOs

Periodic Payment Orders can spread the cost of claims over the lifetime of the victim, rather than providing for the lifetime cost of care in the year in which the award is made. Statutory PPOs are provided for under Part 2 of the Civil Liability (Amendment) Act 2017, which commenced in October 2018. This empowers the Courts, as an alternative to lump sum awards of damages, to make consensual and non-consensual PPOs to compensate injured parties in cases of catastrophic injury where long-term permanent care is required. As outlined in chapter two of this report, in 2019, the High Court found that this indexation provision was inadequate to meet the cost of future care needs of catastrophically injured people.

Pending a change to the index, all claims are currently being settled on a lump sum or interim payment order basis. We welcome the steps being taken by the Minister for Justice to allow for the resumption of PPOs and are hopeful that the facility to make PPOs will be again extended to the Courts shortly.

Personal Injury Discount Rate also known as the Real Rate of Return (RRoR)

A personal injury discount rate/RRoR, provided for in legislation, to be reviewed at set periods, would remove uncertainty and introduce transparency and better predictability for all parties. We note that the report of the Expert Group established by the Minister for Justice and chaired by Judge Brian McGovern is currently being finalised and that it is expected to be submitted to the Minister for Justice in the second quarter of 2024. Once approved, work will begin on the drafting of the necessary Statutory Instrument.

Culture and Collaboration

In our study of Irish plaintiff's experience, reference was made to the culture of victory and defeat that pervades the civil litigation process and to the sense that there were no winners - just losers. It is clear from the available literature describing the personal experience of litigation and from the direct reported experiences in our plaintiff study, that civil litigation in Ireland is polarised with plaintiffs perceiving themselves as patients being pitted against health practitioners and their lawyers being pitted against doctors. In truth, medicine and the law are aligned in seeking the best interests of patients. Far more collaboration is required to serve that interest. We need to do further research to understand and appreciate the plaintiff experience and seek ways for the various stakeholders to work together and oversee the improvements that are so badly needed. When claims occur, early resolution should be the gold standard and delays in settling claims should be flagged and evaluated. Consideration might be given to the establishment of a working group comprised of relevant stakeholders to oversee the reforms that are so needed and to bring medicine and the law much closer in the aspiration to care for those harmed by clinical error, recognised complications and unanticipated outcomes.

Conclusion

Philosophically our aim should be to avoid the need for litigation in the first place but, when necessary, it should be concluded at the earliest possible stage and preferably long before going to Court. NHS Resolution places a huge emphasis on the shift from an adversarial environment to a greater use of alternative dispute resolution. Their initiatives include mediation, global settlement meetings and early neutral evaluation. They are also invested in creating a cultural shift aimed at enhanced collaboration between the NHS and claimant lawyers, aimed at early speedy resolution of claims in the patient's interest.

Previous reports and recommendations made by the relevant parties have identified a number of key reforms which will significantly improve the current process of civil litigation. There is particularly strong support for the implementation of a pre-action protocol and case management in the Courts and the resumption of periodic payment orders. The required legislation is now in place for these key reforms and they should be implemented without any further delay.

Recommendations

1. The Group recommends the implementation without delay of recommendations made in a number of previous reports, along with some additional recommendations, advocating changes and improvements to the management of clinical negligence claims to include:
    a. The introduction of a pre-action protocol with sanctions for a party who fails to adhere to the protocol, as recommended in the Meenan Report.
    b. The facilitation of earlier mediation, where possible and agreeable to both parties.
    c. Amendments to case management Rules of Court should be made, to include a stipulation that equivalent rules apply to both sides, and that joint expert meetings (hot-tubbing) should be required to take place.
    d. A dedicated Court list should be established with judges in place with specialist knowledge of medical negligence litigation, or other appropriate measures to facilitate the earlier hearing of medical negligence cases.
2. The facility for Courts to award Periodic Payment Orders should be resumed.
3. The Group recommends that a panel of medical expert witnesses should be developed initially on a voluntary basis. This could be overseen by an existing regulatory body with appropriate expertise. Members of the panel would meet a series of criteria including that they are in active practice or recently retired, with relevant expertise and are trained as expert witnesses. They should be available to appear as expert witnesses for plaintiffs and defendants. Membership should function as a quality assurance and members of the panel should receive continuing professional development (CPD) accreditation.
4. The Group recommends that the personal injury discount rate, also known as the real rate of return, should be reviewed at regular intervals by the Minister for Justice.
5. The Group recommends that a medical records system, with unique identifiers, be put in place to facilitate better and more timely provision of records and that a system be put in place so that a patient or their solicitor can view their electronic medical records. In addition, a training programme for hospital staff should be put in place regarding best practice around medical records.

Chapter 10: Standardised Approach to Mass Action Claims

Introduction

Mass actions are claims taken by multiple claimants against the same defendant or group of defendants, generally in relation to harm said to have been caused in the same or similar manner.

Current Approach

The SCA manages multiple mass actions on behalf of state authorities, including the HSE.

Current healthcare-related mass actions being managed by the SCA include CervicalCheck, Kerry CAMHS, H1N1 and Gardasil Vaccines and Transvaginal Implant claims. In the recent past, the SCA has managed mass actions involving claims arising out of Symphysiotomy procedures, DePuy Hip Implants and hospital acquired infections.

There is no collective or "class" action legal framework for clinical claims[2] in Ireland. The SCA therefore manages each mass action on an individual basis. Mass actions are managed internally by a specialist claims team which appoints an external, dedicated legal team together with a relevant panel of expert witnesses.

Historically, mass action claims went through the traditional litigation process which tends to be long drawn out, combative, posing risk for the claimant and defendant parties and involving extensive legal costs. The outcome for plaintiffs, if successful, is monetary damages and, in some cases, an apology.

Alternative Dispute Resolution

In recent years, alternatives to litigation have been trialled by the Government, SCA and others e.g., the Government set up the **Surgical Symphysiotomy Ex-Gratia Payment Scheme** in November 2014. Within 2 years, the Scheme had completed its work, 399 women had received awards and legal costs were a fraction of High Court litigation costs.

In April 2022, the **Kerry CAMHS Compensation Scheme**, designed and operated by the SCA, was established to deliver compensation to the families and young adults involved in the Maskey Review. The Scheme is non-adversarial, liability is not at issue and proceedings take the form of a binding mediation. As of 12th April 2024, the SCA had received 202 applications to the Kerry CAMHS Scheme. Payments on account are ongoing and have been made to 197 applicants, following an applications' verification process.

Mediations are also ongoing - 33 mediations have taken place to date. In 31 cases settlement has been agreed, with 5 of these settlements still to be ruled in the High Court (as they involve minors). Further mediations are planned.

A previous, similar binding mediation process was successfully used to resolve the **H1N1 Vaccine claims.**

In the **DePuy Hip** mass action, an independent evaluation process was used with success to resolve hundreds of claims.

The **CervicalCheck Tribunal**, set up as an alternative to the court process, had a less successful uptake and the majority of cases in that mass action are still dealt with by way of litigation.

Conclusion

There is no one solution to dealing with healthcare-related mass actions. They are usually complex, sensitive, diverse claims, frequently complicated by the involvement of multiple parties e.g., pharmaceutical company manufacturers, insurers, distributor companies etc.

However, experience in recent years has shown that various forms of ADR (e.g., mediations, binding mediations, ex-gratia schemes, compensation schemes, evaluations, assessments and tribunals) can be used to achieve successful, efficient, and cost-effective resolution of mass action claims. For all involved, most particularly the injured parties, it is optimal that resolution can take place in a less stressful and adversarial manner than the alternative, adversarial court process.

Recommendations

1. As set out in the Report, a range of alternative dispute resolution processes have been implemented. The Group recommends that the State should continue to use various forms of alternative dispute resolution (e.g., mediations, binding mediations, ex-gratia schemes, compensation schemes, evaluations, assessments and tribunals) as appropriate, in order to offer an alternative to the adversarial court process.

2. The Group also recommends the development of a Vaccine Damage Scheme to ensure a controlled approach to management of potential claims, which should be undertaken urgently in line with previous commitments.

References

General Medical Council. *Independent review of gross negligence manslaughter and culpable homicide*. Jun 2019.

2. The Protection of the Collective Interests of Consumers Act 2023 expands the use of collective (or class) actions in Ireland. Under the new Act, representative actions can be brought on behalf of groups of consumers by designated Qualified Entities ("QEs") in respect of a wide range of EU Consumer protection law. The Act does not apply to personal injuries/clinical claims although it does apply to breaches relating to Medical Devices and Medicinal Products and to Data Protection and Privacy, which will be relevant.

4

Section Four:
Appendices

Appendix 1: Terms of Reference and Membership of the Group

Terms of Reference:

The Interdepartmental Working Group will examine the rising cost of clinical negligence claims in the health system, with a particular focus on high value claims, and identify measures that could be put in place to reduce future costs. In particular, the Group will:

1. Assess the reasons why costs of claims are continuing to rise;

2. Examine best international practice in the area of health-related claims;

3. Develop a plan to implement risk management and other initiatives to reduce the occurrence of adverse incidents, particularly in the category of high value claims (>€4m), that could improve outcomes and reduce costs in the future (consider engagement with, inter alia, the National Neonatal Encephalopathy Action Group, which is a collaboration between SCA, NPSO and HSE and is examining strategies to mitigate risk relating to preventable birth injuries);

4. Recommend measures to address patient concerns following incidents, (e.g., disclosure procedures, trauma counselling, provision of supports) that will reduce the need for patients to initiate legal proceedings. In considering this, the Group should give consideration to those measures suggested by Dr. Scally in his final implementation review report published in November 2022;

5. Receive updates on the implementation of the recommendations set out in the Report of the "Expert Group to Review the Law of Torts and the Management of Clinical Negligence Claims" (the 'Meenan Report'), and Civil Justice reform measures being undertaken in the Department of Justice where relevant to the issue of reducing the cost of HSE-related claims and identify actions to accelerate these reforms and maximise their impact on health claims;

6. Examine the health system's involvement in the claims process, in particular its role in the provision of evidence/medical records in the course of discovery with a view to streamlining processes that could reduce the administrative cost of claims, including but not limited to legal costs;

7. Consider the policy and health system approach to Mass claims, including examining whether there is scope for the Department/HSE to improve or standardise its approach when dealing with calls for redress and inquiries.

The Group will examine these issues only within the parameters set out in the Terms of Reference, as approved by Government.

Membership of the Interdepartmental Working Group

Chairperson:
Professor Rhona Mahony

Department of Health:
Mr Greg Dempsey, Deputy Secretary

Clinical Indemnity Unit:
Ms Brenda Lynch
Ms Madeline Meade

National Patient Safety Office:
Ms Kate O'Flaherty, Director (with an alternate of Mr Maurice O'Donnell)

Chief Medical Officer Division:
Ms Claire Gordon

Department of Justice:
Mr Michael Holohan (with an alternate of Mr. Liam Coen) (Civil Justice Policy)

Department of Public Expenditure and Reform:
Mr Eoin Dormer (with an alternate of Mr Terry Jennings) (Public Service Delivery)

Department of Finance:
Mr Pat Leahy (Banking Division)

Department of An Taoiseach:
Ms Ellen Stewart (Social Policy and Public Service Reform Division)

Office of the Attorney General:
Mr Micheál Corry (Advisory Counsel)

HSE:
Dr Orla Healy, National Clinical Lead for QPS
Dr Cliona Murphy, Clinical Director NWIHP

State Claims Agency:
Dr Cathal O'Keeffe, Deputy Director and Head of Clinical Risk

Appendix 2: Submissions Received and Consultations undertaken by the Group

Submissions Received in Response to Notice Published on 6th June 2023

A1	Muireann O'Briain	Member of the Public
A2	Eoghan Mooney	Consultant Histopathologist, NMH
A3	John Murphy	Emeritus Professor of Neonatology, RCSI
	Alf Nicholson	Emeritus Head of Pediatrics
A4	John Brendan Healy	Retired Orthopaedic Surgeon
A5	Peter McKenna	NWIHP
A6	Anonymous	Member of the Public
A7	Andrew Macey	Consultant Orthopaedic Surgeon
A8	Philip Comyn	Coroner, Cork City
A9	Patricia Hughes	Member of the Public

Submissions Received Separate to the Notice

B1	Irish Medical Organisation (IMO)
B2	Legal Firms - Michael Boylan Litigation Law Firm, Cantillon Solicitors, Coleman Legal LLP, Cian O'Carroll Solicitors
B3	Medical Protection Society (MPS)
B4	Medisec
B5	Health Information and Quality Authority (HIQA)
B6	The Bar of Ireland
B7	National Screening Service (NSS)
B8	Director of Nursing and Midwifery, National Maternity Hospital
B9	NHS Resolution
B10	National Women & Infants Health Programme (NWIHP) including the National Neonatal Encephalopathy Action Group (NNEAG)
B11	The Law Society of Ireland

List of External Bodies/parties who attended Consultation Meetings with the Interdepartmental Working Group

- Medical professionals
- Representative bodies
- Professional Regulatory bodies
- Training houses of the Medical Profession
- Medical Indemnity Insurers
- Legal firms who represent plaintiffs in medical negligence litigation
- NHS Resolution - (the equivalent of the State Claims Agency for England)
- The Bar of Ireland
- Representatives of the Judiciary
- The National Neonatal Encephalopathy Action Group (NNEAG)
- Jack and Jill Foundation
- State Claims Agency (approach to mass claims)

Appendix 3: Meenan Report Recommendations Overview

	Recommendation	Department	Update/Progress
1.	The Expert Group does not recommend the introduction of a no-fault system to deal with certain negligence claims.	Health	The Minister accepts this recommendation and the reasons outlined in the Report relating to constitutional issues that arise when considering 'no-fault schemes'. The Minister remains open to considering specific no-fault schemes for specific categories of clinical negligence cases as they arise.
2.	That a compensation scheme is established to deal with certain vaccine damage claims.	Health	Some preliminary scoping work has been undertaken by the Department of Health, regarding the potential development of a vaccine damages scheme. Work on this matter, to include consideration of legal issues surrounding and envisaged scheme, is to be progressed as a priority in 2024.
3.	The Expert Group does not recommend the establishment of a Medical Injuries Assessment Board (MIAB).	Health	The Minister understands the views set out in the Report that a MIAB could not deal with circumstances where liability is not contested and also that the SCA currently resolve these cases in a speedy manner.
4.	That a system for the "restoration of trust" as is provided for in Chapter 5 of the CervicalCheck Tribunal Act, 2019, be made available for other clinical negligence claims.	Health	Preparations and arrangements to facilitate Restoration of Trust Meetings relating to CervicalCheck have been finalised. Those eligible can now apply. Lessons learned from this process will inform consideration as to whether such a process could be made available for other clinical negligence claims in the future.
5.	Ex-gratia payment schemes only have limited application.	Health	This recommendation has been accepted. Nevertheless, there may be circumstances in the future where such a scheme is necessary and appropriate, and the Department of Health will incorporate this recommendation, along with DPER's recently published guideline on Redress schemes when considering options relating to compensation/redress outside of the court process.

	Recommendation	Department	Update/Progress
6.	That care packages provided by the HSE be funded to reduce the difference between what the HSE can offer and what Courts award.	Health	The Review of Disability Social Care Demand and Capacity Requirements up to 2032 estimates the scale of current unmet need for these services, and of meeting requirements arising from demographic change. DCEDIY published an Action Plan in October 2023 to begin to progressively address the shortfall identified in the volume of services relative to need, subject to the required funding being made available. However, it should be acknowledged that there will always be some divergence between what a court would award, based on a 'total compensation' principle, and what would be provided under the support needs model operated by HSE Disability Services.
7.	That the disclosure of certain patient safety incidents be made mandatory.	Health	The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 provides for mandatory open disclosure to patients, and/or their families/caregivers, of specified serious patient safety incidents and also provides for the mandatory external notification of those same events to the appropriate body. The Act includes a Schedule listing a number of the most serious notifiable patient safety incidents, including maternity-related incidents, which are subject to mandatory open disclosure.
8.	That failure to make a disclosure when required by law to do so, should be considered professional misconduct or poor professional performance by the healthcare provider involved, and should be the subject of an inquiry by the relevant professional body.	Health	The issue of open disclosure and duty of candour to patients is generally provided for in practitioners' 'Ethical Guidelines or Codes of Conduct'. The health profession regulators including the Medical Council have considered the issue of failure to disclose and advise that their existing legislation already provides sufficient scope for the investigation of a complaint on the grounds of either professional misconduct or poor professional performance. Accordingly, it is not considered that further legislation is required in order for a complaint to be investigated. Nevertheless, the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 will bring additional clarity on the obligations on a practitioner and the regulators will be invited to further examine their legislation and guidelines now that the Act's provisions are finalised.

	Recommendation	Department	Update/Progress
9. (i)	It should be a criminal offence for a healthcare provider: • To deliberately fail to make a disclosure of a serious reportable patient safety incident when required by law to do so.	Health	The Patient Safety (Notifiable Patient Safety Incidents) Act 2003 provides a legislative framework for a number of important patient safety issues, including the mandatory open disclosure of a list of specified serious patient safety incidents that must be disclosed to the patient and/or their family. A health service provider which fails to comply with this obligation without reasonable excuse shall be liable on summary conviction to a class A fine. Informed by international experience, best practice and building of the policy foundation of Part 4 of the Civil Liability (Amendment) Act 2017, it is the policy not to place an offence on individual practitioners, in order to support a "no blame" culture and embed a culture of openness and transparency within the health service.
9. (ii)	It should be a criminal offence for a healthcare provider: • To alter medical records with the intent to mislead or deceive.	Health	This recommendation is being considered by the Department of Health.
10.	That the provisions of the Health Act, 2007 be amended to enable HIQA to carry out investigations other than those currently provided for.	Health	A number of initiatives are underway in the Department of Health relating to the expansion of HIQA's remit. These include provisions in the Patient Safety (Notifiable Patient Safety Incidents) Act 2003 for the expansion of HIQA's remit into private hospital services and an amendment to the Health Act, providing discretionary powers to HIQA to review certain serious patient safety incidents occurring in nursing homes.
11.	As clinical negligence claims involve issues that do not arise in other personal injury actions, practices and procedures must be introduced to reflect this.	Justice	This will be addressed by the introduction of the pre-action protocol as outlined under recommendation 12.

	Recommendation	Department	Update/Progress
12.	A pre-action protocol to be implemented together with the commencement of the provision extending the Statute of Limitations period from two years to three years.	Justice	Following on the recommendation by Judge Irvine's Working Group, a provision was introduced in the Legal Services Regulation Act 2015 which provided for the making of regulations by the Minister for Justice for the introduction of a pre-action protocol relating to clinical negligence actions. Unfortunately, difficulties arose regarding the statutory basis for making a pre-action protocol under the 2015 Act. Consequently, a legislative amendment to the 2015 Act was enacted in 2023 as part of the Courts and Civil Law (Miscellaneous) Provisions Act 2023. The overall effect of the amendment is to allow the drafting of pre-action protocol regulations in relation to clinical negligence actions. The regulations are being drafted at present and are expected come into effect in 2024. Once implemented, time will be required to assess the operation and use of a pre-action protocol to inform the need to amend the statute of limitations.
13.	Procedures allowing for the case management of clinical negligence claims to be implemented.	Justice	This action is a matter for the Judiciary and Rules Committees and is set out in CJERM plan 2022 (action 5.2). The introduction of case management rules is dependent on the introduction of a pre-action protocol.
14.	That there be a dedicated list in the High Court to deal with the management and hearing of clinical negligence claims.	Justice	This is listed as Action 5.32 – 2025 Courts Service judicial resources. Its introduction is dependant to some degree on the introduction of a pre-action protocol.
15.	That medical records when requested, are provided in a timely way and in a legible form.	Justice	It is envisaged that this will form part of the pre-action protocol regulations.
16.	That failure to comply with the requirements of a pre-action protocol should be penalised with costs or, where there is persistent non-compliance, an order to dismiss the claim or defence.	Justice	The draft Pre-Action Protocol Regulations contains provisions regarding non-compliance. Non-compliance by a party will relieve the other party of his or her obligations under the Protocol and may be taken into account by a court when determining liability for costs in the event that proceedings are issued. Further sanctions may require primary legislation.
17.	That Section 26 of the Civil Liability and Courts Act, 2004 be amended to provide for sanctions where a defendant files a defence containing matters in respect of which there is no supportive expert report.	Justice	This requires primary legislation and cannot be brought in until the pre-action protocol regulations are in place.

Appendix 4: Glossary of Terms and Definitions

ACC	Accident Compensation Corporation (based in New Zealand)
ACoRN	Allied Care of at-Risk Newborns
ADR	Alternative Dispute Resolution
AE	Adverse Event
CAMHS	Child and Adolescent Mental Health Services
CCIs	Commissions de Conciliation et d'Indemnisation des Accidents Médicaux, des Affections Iatrogenes et des Infections Nosocomiales (based in France)
CEMD	Confidential Maternal Death Enquiry
CIS	Clinical Indemnity Scheme
CJERM	Civil Justice Efficiencies and Reform Measures
CMV	Cytomegalovirus
CN	Clinical Negligence
CNAMed	Commission Nationale des Accidents Médicaux (based in France)
CNST	Clinical Negligence Scheme for Trusts (part of NHS Resolution)
CP	Cerebral Palsy
CSO	Central Statistics Office
CTG	Cardiotocography
DOH	Department of Health
EOL	Estimated Outstanding liability
EU	European Union
EW	Expert Witness
FHR	Foetal Heart Rate
GIS	General Indemnity Scheme
HICP	Harmonised Index of Consumer Prices
HIE	Hypoxic Ischaemic Encephalopathy
HIPE	Hospital In-Patient Enquiry
HIQA	Health Information and Quality Authority
Hot-tubbing	Also known as *'concurrent evidence'*. The practice whereby both parties' experts give their evidence together in the form of a discussion chaired by a judge.
HRB	Health Research Board
HSCP	Health and Social Care Professions
HSE	Health Service Executive
ICD-MM	International Classification of Diseases – Maternal Mortality
IDWG	Interdepartmental Working Group
IGEES	Irish Government Economic and Evaluation Service
IHCA	Irish Hospital Consultants Association
IMO	Irish Medical Organisation
IMIS	Irish Maternity Indicator System
KPI	Key Performance Indicator
MDT	Multi-Disciplinary Team
Meenan Report	Official Title: 'Expert Group Report to Review the Law of Torts and the Current Systems for the Management of Clinical Negligence Claims'
MIAB	Medical Insurance Advisory Bureau
MMR	Maternal Mortality Rate
MOH	Major Obstetric Haemorrhage
MPS	Medical Protection Society
NCEC	National Clinical Effectiveness Committee
NCHD	Non-consultant Hospital Doctor
NCP	National Clinical Programme
NDTP	National Doctors Training and Planning
NE	Neonatal Encephalopathy
NHS	National Health Service, England's publicly-funded healthcare system.
NHS Resolution	Operating name of 'NHS Litigation Authority'. 'NHS Resolution is an arm's length body of the Department of Health and Social Care. We provide expertise to the NHS on resolving concerns and disputes fairly, sharing learning for improvement and preserving resources for patient care.'
NICA	Neurological Injury Compensation Association (based in Florida, US)
NIMS	National Incident Management System
NMH	National Maternity Hospital
NNEAG	National Neonatal Encephalopathy Action Group
NNTP	National Neonatal Transport Programme
NPDB	National Practitioner Data Bank (based in the US)
NPEC	National Perinatal Epidemiology Centre
NPSO	National Patient Safety Office
NQPSD	National Quality and Patient Safety Directorate
NTMA	National Treasury Management Agency
NTPF	National Treatment Purchase Fund
NWIHP	National Women and Infants Health Programme
NTPF	National Treatment Purchase Fund

NRP	Neonatal Resuscitation Programme
NZD	New Zealand Dollar
OD	Open Disclosure
OECD	Organisation for Economic Co-operation and Development
ONIAM	Office National d'Indemnisation des Accidents Médicaux, des Affections Iatrogenes et des Infections Nosocomiales (based in France)
OPD	Outpatient Department
PAP(s)	Pre-Action Protocol(s)
pH	A scale used in chemistry to denote acidity or basicity - 'potential of Hydrogen'
PNMR	Perinatal Mortality Rate
PPO	Periodic Payment Order
PST	Patient Safety Together
PTSD	Post-Traumatic Stress Disorder
RRoR	Real Rate of Return
QE	Qualified Entity
QI	Quality Improvement
QPS	Quality and Patient Safety
QPSIM	Quality and Patient Safety Incident Management
SCA	State Claims Agency
Scally Report	Official Title: 'Review of the Implementation of Recommendations of the Scoping Inquiry into the CervicalCheck Screening Programme'
SLT	Speech and Language Therapist
SMM	Severe Maternal Morbidity
TH	Therapeutic Hypothermia
UCC	University College Cork
UNFPA	United Nations Population Fund
WLAP	Waiting List Action Plan
WTE	Whole-Time Equivalent

An Roinn Sláinte
Department of Health