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Sparkebeat

Australia's Legal Environment – Health Law Update

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INTRODUCTION

Marie-Clare Elder
Health Team Leader

Welcome to the fifteenth issue of the Health Update - Sparkebeat, where Sparke Helmore's market leading national Health team brings you the latest in local news and knowledge from across Australia and abroad.

The past six months has delivered a wave of developments across Australia's health and regulatory landscape, from renewed scrutiny of Triple Zero performance following high-profile delays, to fresh trend data from the Office of the Queensland Health Ombudsman highlighting persistent pressure points in patient safety and complaint handling. Alongside this, the sector's push to drive healthcare-associated infections to zero continues to sharpen, while Ahpra advances its work on adding sexual-misconduct-related information to the register of practitioners.

Emerging risks are also in focus, with new commentary on AI's hidden pitfalls in healthcare claims and insurance, a striking case involving a claim bought nearly two decades after negligent surgery, and ongoing debate about the safe integration of AI into medical devices.

We hope you find this issue informative and useful. If there are any topics you would like us to cover in the future, please contact Marie-Clare Elder at marie-clare.elder@sparke.com.au.

Sparke Helmore's national Health team

Our health team advises medical defence organisations, insureds (including hospitals, clinics, practitioners and other medical and allied health service providers), insurers, underwriting agencies cover holders and brokers, both locally and internationally including in the Lloyd's market.

Our team specialises in clinical negligence litigation, investigations, professional conduct hearings, and coronial inquiries. We also advise on matters related to regulatory compliance, policy drafting, coverage and indemnity issues.

This unique experience allows us to meet the needs of our clients regardless of jurisdiction, volume or complexity.

TRIPLE ZERO – WHY IS IT IN THE NEWS?

Author: Hamish Fraser (Partner)

Every clinical emergency begins before the patient reaches care.

A stroke recognised at home, a child with anaphylaxis at school, a worker injured on a remote site. In each case, the first critical action is a call to Triple Zero. If that call does not connect, the entire medical response is delayed from the outset.

Triple Zero is a dependency so fundamental that the profession, indeed all Australians, after Australians have largely taken it for granted. Recent outages suggest this assumption needs revisiting.

See our deep dive on what has happened and why and importantly what has been the legal and regulatory response since these recent outages hit the headlines.

To keep a long story short, the underlying cause is the fundamental shift from old fashioned telephony with a dedicated connection to the local telephone exchange — characteristics that made the system exceptionally robust in a crisis — to mobile and voice-over-IP communications.

Tied into this shift is that call volumes to Triple Zero have increased 44% over the past decade, from 8.1 million in 2014 to 11.7 million in 2024, which suggests significant growth through a system where resilience has arguably worsened.

The November 2023 Optus outage exposed the consequences.

The subsequent Government review found that each participant in the Triple Zero ecosystem maintained a siloed view of the system, with poor cross-system coordination on the day of the failure. This is a pattern that will be recognisable to clinicians familiar with serious adverse event investigations in health services.

In response, the *Telecommunications Legislation Amendment (Triple Zero Custodian and Emergency Calling Powers)* Act 2025, commenced on 1 November 2025. The Act established a formal Triple Zero Custodian, expanded the information sharing powers for the Australian Communications and Media Authority, and raised maximum civil penalties from $1.25 million to $30 million.

For medical practitioners and health service administrators, there is an important consequence of this shift. Namely, network failure is a recognised patient safety risk that belongs in business continuity planning alongside power outages and IT system downtime.

QUEENSLAND OFFICE OF THE HEALTH OMBUDSMAN: TRENDS AND UPDATES

Authors: Mark Sainsbury (Partner) and Sara Wainwright (Associate)

The Office of the Health Ombudsman (**OHO**) 2024-2025 Annual Report has highlighted an ongoing rise in both the volume and complexity of health services complaints.

The number of complaints received by the OHO for 2024-2025 was 9,812 representing a 6% increase on 2023-2024. Of those complaints:

3201 (33%) were accepted with 'further relevant action taken' including:

- 39% referred to the Australian Health Practitioner Regulation Agency (**Ahpra**)
- 30% underwent assessment (where further information and analysis was required)
- 17% referred to another entity
- 14% underwent local resolution (a voluntary process for resolving complaints with the assistance of OHO)
- <1% underwent investigation (where OHO conducts a formal investigation for a serious matter), and
- <1% conciliation (a voluntary process for resolving complex and/or sensitive complaints).

3509 (36%) were accepted by the OHO and no further action was taken.

2958 (31%) were not accepted by the OHO.

The total number of matters dealt with by the OHO totalled 10,061 in 2024-2025 when own motion matters were included in the figures. The top issues identified in complaints were professional performance (40%) and professional conduct (29%). Fifty seven per cent of complaints were also assessed as a high risk or 'priority matter in 2024-2025 compared to 48% in 2023-2024. Priority matters involve complaints with a significant adverse treatment outcome including serious harm or death, serious conduct and/or performance concerns, sensitive consumer vulnerabilities, or the complaint involves an Aboriginal or Torres Strait Islander person and requires culturally safe management.

A record number of investigations were finalised by the OHO in 2024/2025 (238 vs 180 in 2023-2024). However, the number of open investigations has been increasing each year (331 as of 30 June 2024 to 353 as of 30 June 2025) with the overall proportion of investigations being finalised within 12 months, falling from 2023-2024 (52.5% in 2024-2025). The OHO attributes this to the overall increase in complex matters.

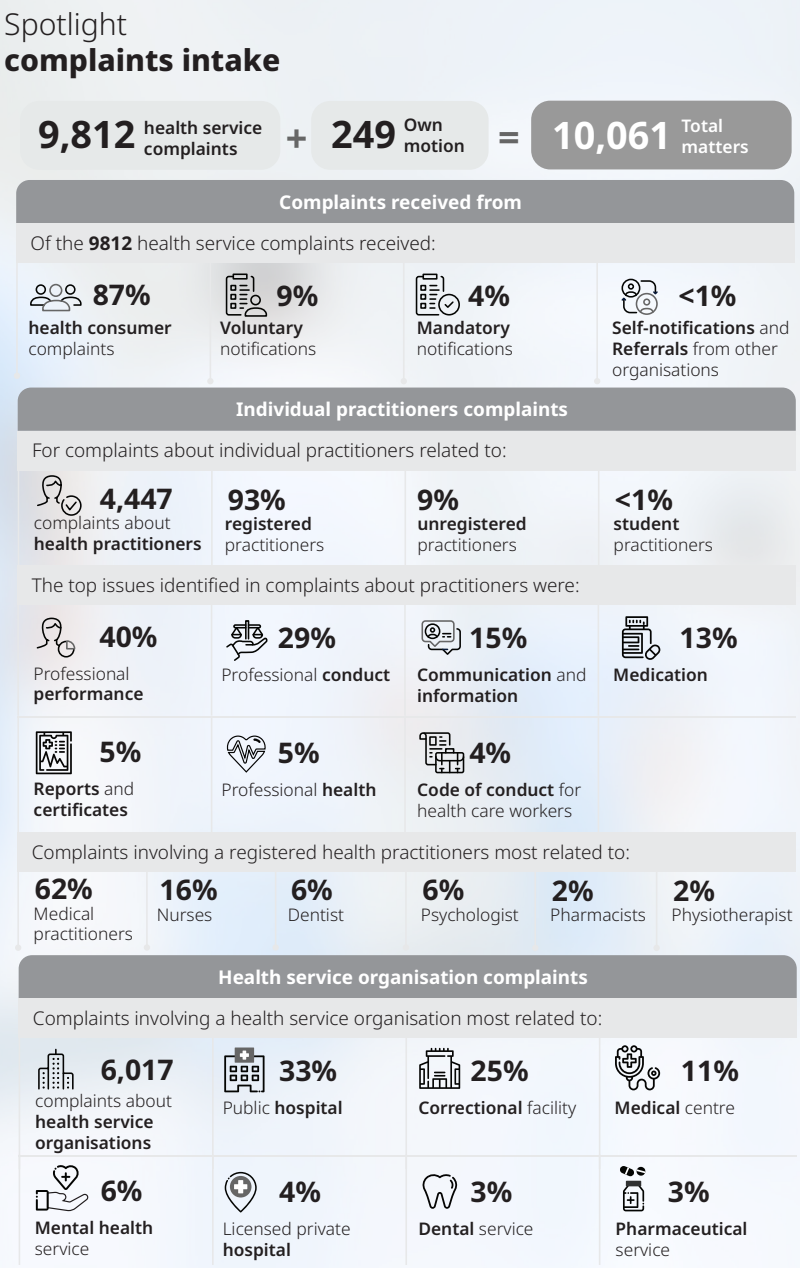
> There was a sharp rise in permanent prohibition orders made against unregistered health practitioners representing a two-fold increase (35 in 2024-2025 vs 14 in 2023-2024). There was also a 14% increase in disciplinary matters for registered health practitioners being filed in the Queensland Civil and Administrative Tribunal (**QCAT**) compared to 2023-2024.

Other key highlights from the OHO's 2024–2025 annual report include:

Health professions with the highest percentage of complaints received were medical practitioners (62%), nurses (16%) and dentists (6%).

Health service organisations with the highest percentage of complaints received were public hospitals (33%), correctional facilities (25%) and medical centres (11%).

A snap-shot of the 2024/2025 OHO report's figures is shown below:



Source file: https://www.parliament.qld.gov.au/Work-of-the-Assembly/Tabled-Papers/docs/5825T1376/5825t1376.pdf

1. A single complaint can be about an individual practitioner or multiple practitioners, and a health service organisation.

Joint consideration for complaints made by OHO and Ahpra

Since 6 December 2021, the OHO and the Australian Health Practitioner Regulation Authority (**Ahpra**) have undertaken joint consideration for complaints and notifications about registered health practitioners in Queensland. In the 2024/2025 period, Ahpra and the OHO responded together to 3,975 notifications, with 33% referred to Ahpra to manage.

Similar to the OHO, Ahpra have also reported a trend of increasing complaint numbers. In 2024/2025, Ahpra received 13,327 notifications, a 19% increased on 2023/2024 of which:

- around 50% were categorised as lower risk and managed by an early determination process (an increase from 34.5% last year)
- there was an increase in notifications relating to the practitioner's behaviour (6.9% from 4.8% the previous year), and
- notifications increased across all professions except midwifery and Aboriginal and Torres Strait Islander Health Practice.

The health practitioners with the highest percentage of notifications were medical practitioners (6.1% of all registered medical practitioners received a notification), dentists (4.0%), and psychologists (2.3%).

Like the OHO, most notifications made to Ahpra related to professional competence. Thirty-five per cent of notifications to Ahpra related to clinical care, 16.5% to communication, 10% to management of medication, 7.1% to behaviour, 6.0% to record keeping and documentation, with 25.4% of notifications pertaining to an 'other' concern. A nominal 1.4% of notifications received by Ahpra resulted in the practitioner losing their registration or being disqualified.

There was an increase across all professions in notifications pertaining to boundary violations with Ahpra receiving 1991 notifications of this nature in the 2024/2025 period.

Ahpra closed 8.3% more notifications (12,086) compared to the previous year, with 5,627 open notifications as of 30 June 2025. A large percentage of all notifications – 81.1% - were closed within six months of receipt, with the average time to complete a notification now at its lowest recorded since the start of the scheme. However, the number of notifications open for 12 months or more now sits at 20%, an increase from the previous year (which Ahpra attributed in part to the overall increase in notifications received). Additionally, 229 notifications were closed at the Tribunal stage, of which 94.3% resulted in disciplinary action.

Recent legislative changes affecting the Queensland Health Sector

Following the Queensland Parliament enacting the *Health Practitioner Regulation National Law and Other Legislation Amendment Act 2025* (**National Law**) in April 2025, the following changes are now in place:

From 1 December 2025:

- non-disclosure agreements preventing notifiers from making complaints to Ahpra and other health regulators are now illegal under s 263A of the National Law unless the agreement clearly states in writing that it does not limit a person from making a notification or providing assistance to regulators, and
- persons who make a complaint against a health practitioner now have greater protections from reprisals or retaliation under increases to consumer protections through amendments to s 261 of the National Law. It is now an offence to threaten, intimate, dismiss, refuse to employ, or subject a person to other detriment or reprisal because they intend to or have made a notification. This includes assisting others to do so.

From early 2026, practitioners who have a tribunal finding of professional misconduct involving sexual misconduct will have the information permanently published on the public register under ss 225A and 225B of the National Law.

Conclusion

The changes to consumer protections for people making a complaint against a health practitioner have extended protections already in place where a person making a complaint was protected from liability for information provided to Ahpra. Practitioners also need to be aware that non-disclosure agreements cannot be entered into unless it clearly states in writing that it does not limit a person from making a notification or assisting regulators.

It remains to be seen whether these protective measures will have an impact on complaint numbers or the types of complaints submitted to OHO or Ahpra.

In any event, both regulators are reporting increases in notifications, with a greater number of notifications also remaining open for longer than 12 months. The OHO, in particular, reports an increase in the complexity of the notifications received which is contributing to a fall in the proportion of investigations being finalised within 12 months.

This dual regulation system in Queensland and the increasing complexity and duration of complaints continues to cause pain for both the practitioners subject to a complaint and their insurers that offer 'inquiry' or 'investigation' costs cover that typically responds to complaints of this nature. Based on our own experiences in acting for insureds in this area, this is being compounded by complainants using artificial intelligence to draft complaints, which tends to broaden the allegations and conflate areas of law, and an increasing number of seemingly vexatious complaints made across both regulators and often into the courts.

SPOTLIGHT
DAYLIGHT FOUNDATION: DRIVING INFECTIONS TOWARD ZERO

Author: Angus Dixon, Founder & CEO, Daylight Foundation

Each year in Australia, an estimated 170,000 Healthcare-Associated Infections (**HAIs**) occur within the healthcare system. These infections contribute to more than 7,500 deaths annually — a mortality burden higher than breast and prostate cancer combined.

HAI's are costly and many are avoidable. Costly to the tune of multiple billions of dollars per annum in Australia alone. When Daylight Foundation Board member and colorectal surgeon, Glen Guerra suffered a life-threatening HAI in 2010 - it was so significant a prominent video was made. However, rates of infections remain the same. Dr Alex Padiglione, Infectious Disease Physician states in the video, 'We believe the majority of catheter related bloodstream infections are preventable'. Then goes on to say, 'preventing these infections is everyone's business - and most importantly the management, the CEO's and the Board of Directors of Hospitals need to take this on as well.'

Unlike many high-profile diseases, HAIs receive limited public attention and are often viewed as unavoidable complications of medical care. Daylight Foundation was established to challenge this view. Its mission is clear and ambitious: to help drive infections toward zero.

Founded in 2023, the Daylight Foundation is an Australian not for profit (**NFP**) organisation focused on advancing research, digital integration, and translational innovation to reduce infection risk across healthcare settings. The Foundation operates on a simple principle — preventable harm should never be accepted when stronger systems, better data integration, and improved coordination can enhance patient safety.

A focus on women's cancer care

A key research priority involves improving infection surveillance and management in women undergoing treatment for breast, ovarian, and endometrial cancers.

Women receiving treatment for these cancers experience complex clinical pathways involving surgery, chemotherapy, radiotherapy, invasive procedures, and periods of immunosuppression. These essential therapies increase vulnerability to infection.

When infections occur in this population, consequences extend well beyond temporary setbacks. HAIs can delay or interrupt cancer treatment, trigger unplanned escalation of care, prolong hospital stays, increase healthcare costs, and compromise recovery during critical stages of therapy.

Infection detection in oncology care remains largely reactive. Clinical, pathology, and operational data are routinely collected across hospitals. Integration across systems remains limited, reducing the ability to identify deterioration early in its course.

The Daylight Foundation's research aims to characterise the incidence, timing, and clinical impact of HAIs in women's cancer care. The program also seeks to design an integrated digital ecosystem aligning existing hospital data with real clinical workflows.

The objective remains straightforward — equip clinicians with practical, workflow-aligned tools supporting earlier recognition and improved patient safety.

170,000

Austustralian each year acquire a hospital infection.*

7,583

Die from infections each year.*

1. *Russo et al. Antimicrobial Resistance and Infection Control. 2018.

Wearables and proactive surveillance

Beyond oncology-focused research, the Foundation is leading a Wearables Surveillance Platform study evaluating whether continuous physiological monitoring enables earlier detection of postoperative infection deterioration.

Traditional monitoring relies on intermittent vital sign observations and episodic review. Medical grade wearable technologies enable continuous collection of physiological data across inpatient and post-discharge settings. Deviations from expected recovery trajectories — including subtle changes in temperature trends, heart rate patterns, or activity levels — may signal deterioration earlier in its progression.

Research operates within a strong clinical governance framework. Alerts undergo clinician review. No automated decision-making occurs. Focus remains on feasibility, acceptability, workflow integration, and measurable impact on timeliness of recognition and severity at diagnosis.

The aim centres on responsible innovation strengthening existing systems and supporting earlier intervention.

Strengthening education and clinical practice

Technology alone does not reduce infection risk. Clinical behaviour, communication, and escalation practices remain critical components of patient safety.

Daylight Foundation is assisting with the development of an infection prevention control platform using Virtual Reality (VR) to improve quality and consistency in the education process for our clinicians. The VR platform complements existing simulation laboratory programs and provides immersive rehearsal of high-risk scenarios. Clinicians can prepare prior to simulation sessions or refresh critical escalation skills before upcoming procedures.

By reinforcing situational awareness and communication in high-pressure environments, the platform supports more consistent application of infection prevention and escalation principles across healthcare teams.

A broader commitment to safer healthcare

Daylight Foundation operates at the intersection of clinical research, digital health, translational data / AI and patient safety. Across all initiatives, the unifying objective is to shift infection management from reactive response toward proactive, data-informed prevention.

Driving infections toward zero represents a long-term commitment to rigorous research, practical system redesign, and ethical implementation. For women undergoing breast, ovarian, and endometrial cancer treatment — and for surgical patients nationwide — reducing infection burden protects treatment continuity, strengthens recovery, and reduces avoidable harm.

If you would like to learn more about Daylight Foundation's work, or believe you could assist in advancing this mission, please reach out to Angus Dixon, CEO and Founder of Daylight Foundation, or speak with Marie-Clare Elder, one of the Foundation's board members.

Further information is available at www.daylightfoundation.org.au.

Angus Dixon can be contacted via angus@daylightfoundation.org.au.

SPOTLIGHT NATIONAL BOARDS' NEW GUIDANCE AHEAD OF REGISTER UPDATES

Authors: Marie-Clare Elder (Partner) and Marie Panuccio (Special Counsel)

The Australian Health Practitioner Regulation Agency (Ahpra) has published the National Boards' new Guidance on adding information about sexual misconduct to the register of practitioners.

Under changes to the National Law, practitioners who have a tribunal finding of professional misconduct with a basis of sexual misconduct will have this information permanently added to the public register.

The measure provides the public with the information they need and expect when choosing a health practitioner. It will be retrospective and come into effect in April 2026.

National Boards are responsible for deciding if a tribunal finding of professional misconduct included a basis of sexual misconduct. Any matters that meet the requirements will be referenced on the relevant practitioner's register entry with a link to the tribunal decision where publicly available.

In 2024, Health Ministers decided that sexual misconduct findings should be added to the register. After parliaments passed the necessary legislative amendments, Ahpra embarked on extensive legal and policy analysis in order to implement the changes. The new Guidance has been significantly improved as a result of consultation feedback on an earlier, initial draft in September-October.

The Guidance: Sexual Misconduct and the National Law published in December 2025, is a key resource for National Boards and also provides information for practitioners and the public. It outlines the process Boards will follow, the scope of their considerations, the factors affecting their decisions, how they will engage with affected practitioners, and when and how information will be published on the register.

THE TRUST DEFICIT: AI'S HIDDEN PERILS IN HEALTHCARE CLAIMS AND INSURANCE

Authors: Jehan Mata (Partner), Dinah Amrad (Associate) and Kaylee Nguyen (Paralegal)

Traditionally, claims assessment has always been one of the most labour-intensive, costly and time-consuming functions within the insurance industry. Claims assessors are required to review and interpret thousands of pages of complex documentation including medical reports, case histories and historical policy terms and conditions. However, Artificial Intelligence (**AI**) is increasingly transforming this process simply by automating routine tasks and enhancing analytical capabilities, streamlining claims handling and reducing administrative burdens. According to Insurance Business, 88% of Australian insurers now use generative AI (**Gen AI**) in claims resolution.

Interestingly, technologies such as optical character recognition allow insurers to automatically review and extract information from documents, including handwritten medical reports. The use of chatbots and messaging tools further reduces the need for human resources to perform repetitive administrative tasks. These tools facilitate the reporting of claims, gather initial information from insureds and provide real-time updates throughout the claims process.

With the above in mind, AI-driven tools therefore enable faster and more accurate claims assessments while reducing the risk of human error. Beyond claims management, AI is playing a significant role in transforming health data into actionable insights for health insurers. As customer expectations evolve, insurers are increasingly investing in digital health technologies to manage costs, deliver more proactive services and improve customer engagement. Through AI-enabled data analysis, insurers can identify patterns and predict health risks, allowing them to provide personalised advice, preventative care programs and early intervention strategies.

This capability can also enhance actuarial models, enabling insurers to develop more personalised insurance products and improve the efficiency of claims processing. Take the example from NIB, a major Australian-based health insurer, that has introduced an application for their consumers known as *GreenPass* program which essentially gathers data on customers' daily activities and health metrics through wearable devices such as smart watches and smartphones. This information allows insurers to provide personalised health insights and recommendations aimed at improving wellbeing. Similarly, AI-powered chatbots used by insurers allow customers to access health advice, lodge claims and receive responses to queries instantly.

While these innovations present significant opportunities for efficiency and improved customer experience, the increasing use of AI within insurance also introduces substantial risks.

Healthcare data as a prime target

As we know, healthcare data is one of the most valuable forms of information for cyber criminals due to its highly confidential nature and a great potential for high ransom demands and major risk of services interruption. An example is the recent Genea IVF Clinic case which resulted in sensitive patient data leaked to the dark web and was discussed in our previous edition of Sparkebeat.

Another example is the highly consequential Medibank breach in 2022 which was also previously discussed in Sparkebeat, and remains one of the most significant data breaches in Australian history. As such, it is important for insurers to mitigate these risks through adopting security frameworks such as:

- encryption of sensitive health data
- strong access control systems and multi-factor authentication
- implementing continuous monitoring and threat detection systems
- regular security audits and penetration testing, and
- strict data minimisation practices to limit the amount of personal data stored.

Regulatory and compliance challenges

The use of automated decision-making by insurers has no doubt raised significant regulatory concerns such that from 10 December 2026, the Office of the Australian Information Commissioner (**OAIC**) has highlighted that the newly introduced Australian Privacy Principles 1.7, 1.8 and 1.9 (the **Privacy Principles**) will come into force. In a nutshell, these Principles aim to address privacy risks associated with automated decision-making systems and focusing on enhancing transparency for those affected. Insurers must comply with the updated Privacy Principles when using automated systems if they are making decisions impacting an individual's rights or interests, based on their personal data. Ahead of the implementation of the Privacy Principles, it is a must for insurers to include information about automated decision making in their private policies if the following requirements are met:

- they have arranged for AI to make, or do a thing that is substantially and directly related to making a decision, and
- the decision could reasonably be expected to significantly affect the rights or interests of an individual, and
- personal information about the individual is used in the operation AI to make the decision or do the thing.

Following amendments to the *Privacy Act 1988* (Cth) that came into force on 11 December 2024, the OAIC now has discretion to issue infringement notices of up to $330,000, if corporations are found to have a non-compliant privacy policy.

Key takeaways

For insureds

While AI can significantly improve the speed and efficiency of claims processing while providing faster responses and interaction, the increasing use of automation in claims will likely reduce the important human interaction aspect of health insurance claims especially when dealing with vulnerable emotions in sensitive situations.

For insurers

While AI-driven tools can automate parts of claim processing which enables faster and more accurate assessments reducing human error which is essential to meet customer expectations, manage costs and deliver a proactive approach. Insurers should be wary that over-reliance on integrating AI into decision-making and the resultant lack of human oversight can lead to serious consequences. For example, AI algorithms can inadvertently perpetuate biases embedded in historical data leading to discriminatory outcomes in claims processing and potentially decisions in relation to claims coverage.

Further and as indicated above, ahead of the implementation of the Privacy Principles, it is a must for insurers to include the required information about automated decision-making in their privacy policies.

Finally, it is without saying that insurers must regularly review and update privacy policies to reflect information handling practices and to ensure compliance.

For underwriters

While AI can support underwriting through advanced analytics and predictive modelling, it also presents risks from an underwriter's standpoint. In its current form, AI lacks the capacity for contextual judgment and the ability to appreciate social and emotional nuances both of which are often critical in assessing health risks. As a result, reliance on automated outputs may lead to gaps or oversights in risk evaluation. By contrast, an experienced underwriter applies professional judgment to interpret complex, nuanced information, ensuring that risks are assessed more comprehensively, and that coverage is appropriately tailored to the insured's individual circumstances.

COURT OF APPEAL EXTENDS LIMITATION PERIOD FOR A CLAIM BROUGHT 19 YEARS AFTER NEGLIGENT SURGERY

Authors: Mark Sainsbury (Partner) and Emma Frylink (Associate)

Case note on *Ringelstein v Metro North Hospital and Health Service [2025] QCA 188*

Facts

On 15 June 2004, the claimant underwent a total abdominal hysterectomy and posterior repair at Caboolture Hospital. This surgery was negligently performed, and the claims suffered significant complications from that surgery, which included urinary incontinence and a stoma. She subsequently underwent numerous other surgeries which did not resolve her health issues.

The claimant apparently made a complaint to the Caboolture Hospital in 2004 about the standard of treatment she received, which she says was 'shutdown internally meaning she was unable to gain a resolution to her complaint.

In late 2008, the claimant approached Clewett Lawyers who required her to pay $2,200 for an expert report, which she could not afford. In late 2010, the claimant approached Slater & Gordon who advised that they could not provide her with a 'no win no fee' arrangement, and the claimant was unable to afford the fees to pursue a limitation period application.

The claimant then did not take any steps in her claim again for 12 years (2010 to 2022), which she says was because: *'I did not think there was any way I would be able to pursue a claim…I gave up and didn't pursue it any further and concentrated on my physical and mental health.'*

The claimant met with representatives of the respondent hospital on 27 June 2022 and received a concession from the hospital that she had received 'care below the expected standard' and was offered a goodwill payment of $10,000. The claimant did not retain a lawyer until March 2023, when she again approached Slater & Gordon, and retained them under different arrangements.

On 23 June 2023, the claimant started proceedings in the Queensland Supreme Court against the hospital, approximately 19 years after her surgery.

In October 2023, the claimant obtained two reports from Dr Reid, gynaecological surgeon, who opined that there was evidence of a lack of due care in the conduct of the surgery, and in post-operative care provided to the claimant. He considered that on the balance of probabilities, the claimant's complications following the surgery were caused by a failure to provide an appropriate standard of care.

Considerations for application

The claimant brought an application pursuant to s 31(2) of the *Limitation of Actions Act 1974* (Qld) which permits the Court to extend a claimant's limitation period if 'a material fact of a decisive character' was not within the means of knowledge of the plaintiff until after the limitation period expired. The key issue in this case was whether the claimant had taken 'reasonable steps' to find out the material fact.

The claimant had to show that a material fact was not within her means of knowledge until after 23 June 2022, being one year before she filed proceedings. She relied upon the meeting with the hospital on 27 June 2022, and the reports of Dr Reid obtained in October 2023. The hospital conceded that the October 2023 expert reports constituted a material fact of a decisive character, which were after the

claimant filed proceedings. The Court therefore focussed on whether the claimant had taken reasonable steps to ascertain that material fact earlier.

The claimant had been advised by the solicitors that she approached in 2008 and 2010 that her limitation period had expired. She was advised that she needed to act urgently to obtain a report from a doctor to pursue her claim. However, she states her personal circumstances precluded her from taking further steps to investigate whether the surgery was performed below the standard of care expected.

The claimant and her husband produced evidence to their precarious financial position following her surgery. She also provided evidence on the significant toll that the impacts of the multiple surgeries took on her physical and mental health.

Decision

At first instance, the claimant's application failed. The primary judge found that, even taking into account the claimant's personal circumstances, there was no satisfactory explanation for the lengthy delay in pursuing her claim. The judge held: *'Mrs Ringelstein failed to take all reasonable steps to obtain the relevant facts – whether that be the statements made to her in June 2022 or the reports of Dr Reid in 2023.'*

On appeal, the Court found that the claimant had taken all reasonable steps to find out the material facts.

A summary of the findings is at paragraph 91 of the judgment when Doyle JA states:

'In my view, a demoralised person in physical and mental distress, with no available evidence of negligence by the hospital, who has twice been unable to enlist the help of solicitors except on terms that she pay a sum she could never have paid, and whose health and mental condition continued to require her attention, cannot be said not to have acted reasonably by not trying yet another approach to another law firm which would itself be futile if (as was to then her only experience) she was to be called on to provide any funds.'

That is, the relevant considerations in determining whether the claimant had taken "reasonable steps" to find out the material facts were:

- the claimant's financial hardship
- limited education and legal experience
- recurring medical issues
- unsuccessful attempts to seek legal advice (precluded due to cost), and
- the claimant's explanation for her delay.

Comparison with prior Health Care Update article: reflections five years later

In a previous issue of Sparke Helmore's Health Update (Issue 9 from December 2021), we discussed the 2021 Queensland Supreme Court decision of *Margarey v Sunshine Coast Hospital and Health Service (Nambour Hospital)*. This case also turned on whether the material fact was within her means of knowledge' before the expiry of her limitation period. In *Margarey*, the Court denied the plaintiff's application for an extension of her limitation period because she did not take reasonable steps to follow up her lawyers to ensure that her claim was being progressed.

In *Ringelstein*, the judge at first instance explicitly compares the circumstances of the two cases, saying *'the position in which Mrs Ringelstein found herself had some similarities which existed in Margarey.'* Ms Margarey was also dealing with the complication of her other health issues including the trauma of her leg amputation, and she depended on her solicitors to pay for the expert report. There was a period of three years between Ms Margarey engaging solicitors and them obtaining the expert report (which was relied upon as a 'material fact'). The Court found that she should have followed up her solicitors.

The primary judge in *Ringelstein* reasoned that even taking into account all of the claimant's personal circumstances, there is no evidence to satisfactorily explain the lengthy delay in Mrs Ringelstein pursuing this matter. However, on appeal, the Court reversed this finding.

To reconcile the two decisions, it seems that a Court is sympathetic towards a claimant who, due to significant financial hardship and ongoing health complications, was unable to engage solicitors at all. On the other hand, Ms Margarey had successfully retained lawyers, but did not ensure that those lawyers were advancing her claim and protecting her interests.

As stated in our article of December 2021, the important message from these cases for insurers, MDOs and health facilities is the longtail nature of medical malpractice claims and cover. Even if a claimant's limitation period date has passed many years prior, they may still be granted leave by a Court to proceed with their civil action. This message continues to ring true with *Ringelstein*.

REVISITING THE REGULATION OF ARTIFICIAL INTELLIGENCE (AI) MEDICAL DEVICES

Authors: Jason Kwan (Partner)
and Ella Sourdin Brown (Lawyer)

The increasing use of medical software and AI in healthcare has led the Therapeutic Goods Administration (**TGA**) to conduct a review into whether existing legislation and guidance is fit for purpose. While software-based medical devices (including AI models and systems) have been regulated for many years, the TGA's report Clarifying and strengthening the regulation of Medical Device Software including Artificial Intelligence (**Report**) highlights a number of areas for clarification and further consultation.

Current regulation of software and AI

The TGA regulates '**Medical Devices**'. Software or AI products, including apps, websites, programs, and internet- based services will be regulated as medical devices if they are intended for:

- diagnosis, prevention, monitoring, treatment or alleviation of a disease, injury or disability
- investigation, replacement or modification of the anatomy or of a physiological process, or
- control or support of conception.

Examples of Medical Devices that use AI include:

- apps that help diagnose melanoma from photos taken on a mobile phone
- cloud-based analytics that predict patient deterioration
- chatbots that suggest, deliver or monitor treatment to consumers or health professionals
- clinical decision support tools that use generative AI to provide diagnostic or treatment recommendations
- eye disease screening apps for conditions such as diabetic retinopathy and glaucoma
- radiology image analysis to aid in diagnosing pneumothorax, pneumonia and tumours

Key takeaways

Takeaway 1: Improving the interpretation of the Medical Device definition

The *Therapeutic Goods Act* 1989 (**Act**) uses terminology that does not easily translate to the entities involved in the distribution of software products, models and systems. For example, terms like 'developer', 'deployer', 'distributor' and 'end user' are now more commonly used, but do not appear in the Act.

Further consultation is required on whether similar terms should be included in the TGA or additional guidance provided.

Takeaway 2: Assigning responsibility

Further review and consultation (including with health practitioner agencies and commissions) is required to determine whether the Act assigns responsibility to the appropriate entity across the AI lifecycle. In particular, responsibility needs to be appropriately assigned for the outputs of AI where:

- AI replaces services traditionally provided by a human, and
- the person who deployed the AI was not aware of the outputs that constituted an offence.

Takeaway 3: Regulation for specific subtypes of AI

AI comprises various subtypes including generative AI, neural networks, and narrow AI. As the capabilities and applications of different subtypes of AI are virtually limitless, it is not appropriate to regulate AI based on the subtype. As a result, specific definitions and requirements should not be introduced for specific subtypes of AI. Instead, regulatory requirements should remain technology-agnostic.

Takeaway 4: Amending corresponding legislation

The TGA recommends further review and potential reform of the following legislative instruments that also regulate TGA goods.

Legislation instrument	Recommendations for legislative reform and guidance
Therapeutic Goods (Excluded Goods) determination 2018 (‘**Excluded Goods Determination**’)	Under the Excluded Goods Determination, there are 15 software subtypes excluded from TGA regulation. Stakeholders recommended that the following be reviewed: • **revisiting exclusion list:** whether some exclusions were appropriate, for example digital mental health tools, and • **additional guidance:** greater guidance is needed to better support stakeholders understanding whether a tool meets the conditions of ‘exclusion’.
Therapeutic Goods (Therapeutic Goods Advertising Code) instrument 2021 (‘**Advertising Code**’)	Stakeholders recommended two changes be made to the Advertising Code: • **identification codes:** the ability to identify when a good has been assessed or approved by the TGA. For example, through the use of a Unique Device Identification (UDI) system to mark goods that are regulated, and • **more information about assessment and approval processes:** in particular, the TGA should provide the following information: – which devices have been assessed – what requirements have been met by an assessed device, and – what it means if a device has been approved. and Developers of AI should provide the following information: – what datasets are being used to train and test the AI – what is changing when an update is made to a device, and – informing users of risks through in-app or in-product notifications.

Takeaway 5: Guidance to ensure compliance?

The TGA recommended greater guidance and educational resources, in particular to address the following risks:

- deploying Medical Devices without proper registration under the TGA due to uncertainty about whether the AI product meets the definition of 'Medical Device', and
- inappropriately using AI-enabled products, often due to a lack of understanding about the tool's intended purpose.

Guidance material topic	Current approach	Recommended guidance material
Adaptive AI	Device manufacturers must notify the TGA if a 'Significant Change' has been made to their Medical Device which may lead to the device requiring registration.	Greater guidance regarding what constitutes a 'Significant Change' in the context of software as a Medical Device as well as monitoring and continuous review to address the adaptive nature of AI.
Use of datasets or software from unknown origins	There are several ISO/IEC standards governing the use of software and datasets of unknown provenance. However, the TGA has not provided guidance on how to manage risks emerging from data and software of unknown provenance.	Greater guidance on how to handle open datasets and software from unknown origins to align the TGA's regulatory regime with available standards.
Performance monitoring	Clinical data is a critical component for monitoring and evaluation AI's accuracy. However, there are privacy concerns around using health data from patients in commercially available AI products.	The TGA will provide feedback to the Office of Australian Information Commissioner's recent publication relating to privacy concerns.
Healthcare service delivery	Industry groups have developed resources about the safe use of AI, however the TGA is yet to develop a resource for stakeholders outside the medical device industry.	More resources for consumers and health care practitioners to assist them in understanding the limitations of AI-enabled products and the evaluation of product. Developers and deployers to assist stakeholders in developing appropriate labels, warnings and instructions to help users mitigate known and residual risks.

Looking forward

While the AI is currently regulated by the Act and needs to be assessed against the existing Medical Devices definition, developers and deployers of AI should keep a close eye on further consultation and reform in the space as the TGA looks to ensure regulation is fit for purpose.

FINDINGS INTO THE DEATHS OF DIMOSTHENIS GESIOS AND MAUREEN MCGREEVY

Authors: Marie-Clare Elder (Partner) and Lani Carter (Special Counsel)

On 27 February 2026, Deputy State Coroner Magistrate Derek Lee (**Coroner**) provided his findings regarding the deaths of Dimosthenis Gesios (**Mr Gesios**) and Maureen McGreevy (**Ms McGreevy**). Both Mr Gesios and Ms McGreevy were residents of the same aged care facility. They died nine months apart, both from choking incidents. The inquests were heard together for convenience and the common issues to both deaths.

The Coroner, under the *Coroners Act 2009*, has a responsibility to investigate all reportable deaths. The cause and manner of both deaths was not immediately clear. The facility, the Acacia Centre based in Marrickville New South Wales, has now closed for unrelated reasons.

This article concerns the findings made by the Coroner and key takeaways for aged care facilities and their insurers and brokers.

Circumstances of the death of Mr Gesios

As recently as 2018, Mr Gesios had been diagnosed with a variety of conditions, including dementia, non-convulsive status epilepticus, hemiplegia, mixed astrocytoma, paranoid psychosis and falls. He was non-verbal.

On 7 June 2019, at around 8.00am, Assistant in Nursing (**AIN**) Khanal entered the room with a tray of food, including scrambled eggs, porridge, a cup of Milo and two slices of bread. The AIN began to feed Mr Gesios, including bread that was dipped in the cup of Milo. After about 8-10 minutes of feeding, Mr Gesios' eyes started to flicker and his upper body began to shake. He coughed and some food flew out. The AIN called for assistance and AIN Prasad entered, who called for Registered Nurse (**RN**) Koirala. The RN reported he was in High Fowler position, blue in colour, and unresponsive to motor functions.

A suction machine obtained and was used to remove pieces of food from Mr Gesios' throat. The Facilities Services Manager for the Acacia Centre, Dr Stein, was notified and he contacted 000, reporting that Mr Gesios was choking. At around 8:47am paramedics arrived. Mr Gesios was not breathing and had no pulse. The paramedics did not attempt to resuscitate him due to a Do Not Resuscitate order.

Dr Calligeros then attended to provide a Medical Certificate of Cause of Death (**MCCD**). He recorded the cause of death as a complication of a seizure disorder whilst being fed. He further noted a right temporal astrocytoma, which was listed as an antecedent cause of death.

An incident report of 7 June 2019 (completed by RN Koirala and Dr Stein) stated that Mr Gesios had a seizure whilst being assisted with breakfast (**Incident Report**). On 19 June 2019, a postmortem examination by Dr Bailey (forensic pathologist) revealed a cause of death of choking due to foreign material obstructing his airway.

The Coroner had to determine the cause of death, noting the two different stated causes. After assessing the reports, including an expert report of Professor Cook, the Coroner made various findings. He stated that *'**Although it is not possible to demonstrate seizure activity in the post-mortem setting**, the expert evidence of Professor Cook establishes that whilst the possibility of Mr Gesios experiencing a seizure leading to death cannot be entirely excluded, **it is far more likely that Mr Gesios experienced a choking episode leading to airway obstruction and death. The cause of Mr Gesios' death was therefore choking**.'*

Circumstances of the death of Ms McGreevy

Ms McGreevy had been diagnosed with many conditions, including schizophrenia, rheumatoid arthritis, high blood pressure, indigestion, strokes, significant cortical blindness in both eyes and Bell's Palsy. She was largely non-verbal. On 13 March 2020, at around 5.00pm, Ms McGreevy was prepared a meal of mince, rice and capsicum on her request, which was placed on a meal tray.

At around 5.00pm, AIN Sun delivered to Ms McGreevy a different meal tray which contained pumpkin soup, coffee and half a slice of buttered bread and did not stay with her to feed. Sometime between 5.00pm and 5.45pm, RN Wenting gave Ms McGreevy her medication in her room.

Nursing staff then saw her walking around the facility and appeared to have difficulty breathing. Emergency services were contacted. She passed away, and paramedics retrieved a lump of bread from her throat. She was found to have eaten the bread from the tray provided to her, rather than another source in the facility. Paramedics, and a subsequent autopsy report, confirmed the cause of death to be choking.

Diet & relevant food standards

Both Mr Gesios and Ms McGreevy were on a 'minced and moist' diet at the time of their deaths. As defined by the Australian Standards, there is a scale of food texture grading, which includes regular, soft, minced and moist, and smooth pureed foods. For minced and moist foods, gelled bread is listed as a recommended food whilst 'gelled breads that are not soaked through the entire food portion is listed amongst foods to avoid.

The 2017 publication of the International Dysphagia Diet Standardisation Initiative (**DDSI**) Framework provides 8 levels for terminology relating to food and drink, where Level 5 sets out the characteristics of minced and moist foods. A 2019 framework was implemented one month before Mr Gesios' death. Both frameworks had a similar definition for pre-gelled breads as 'soaked' breads, which are very moist and gelled through the entire thickness.

The Coroner found that dry bread was not permitted on a minced and moist diet; Mr Gesios had been fed bread dipped in liquid prior to the date of his death, and Ms McGreevy was not provided with gelled bread. Some Acacia Centre staff considered that bread could be fed to residents on minced and moist diet it was 'wet', 'soaked', or dipped in liquid, although the Coroner found it is not entirely clear whether this constituted gelled bread for the purposes of the Australian Standard.

The feeding of Mr Gesios

The Coroner found that the AIN feeding Mr Gesios did not correctly check that he was chewing his food. He was either fed a mouthful too large for him or was not given an opportunity to swallow between mouthfuls. In any event, this created a bolus of food which caused his choking.

The Coroner further found that the AIN feeding Mr Gesios did not promptly seek assistance for Mr Gesios or convey the urgency of his need for assistance.

Reporting of Gesios' death

There was evidence consistent with the fact that RN Koirala had, at the time, realised Mr Gesios was choking on food and subsequently discussed that he had choked while being fed bread. Yet, despite this, RN Koirala did not mention in the Incident Report that Mr Gesios had been fed bread and choked. RN Koirala initially sought to explain that he wanted the Incident Report to be consistent with Mr Gesios' care plan, which indicates that he was aware that Mr Gesios was not meant to be fed bread. RN Koirala gave various unreliable explanations for as to why he neglected to include this information in the Incident Report.

Dr Stein was also found to have deliberately omitted relevant information in the Incident Report and to the Aged Care Quality and Safety Commission (the **Commission**). She acknowledged it was equally or more likely possible that Mr Gesios had suffered a choking incident yet failed to include that in the Incident Report.

The Coroner provided a transcript of evidence to the Nursing and Midwifery Council as there were reasonable grounds to believe that a complaint could be made about the conduct of RN Koirala and Dr Stein, as per s 151A(2) of the National Law.

Regarding the MCCD, the Coroner found Dr Calligeros completed it with information provided to him at the time. He was found to have appropriately examined Mr Gesios before completing the MCCD.

Recommendations

The Coroner provided a copy of the findings to the Commission for consideration, particularly around the development of minimum training expectations for kitchen and nursing staff in residential aged care facilities relating to the IDDSI and identification and management of choking risk among residents.

The Coroner further recommended that the Commission consider including a structured approach to assist aged care providers to:

a. assess and document the competency of nursing staff, particularly Assistants-in-Nursing, in recognising and managing choking risk, and

b. implement periodic review or quality assurance processes to promote consistency and ongoing effectiveness.

Further noting that gelled bread is not well described in the IDDSI Frameworks, a copy of the findings was provided to the Board of the International Dysphagia Diet Standardisation Initiative for consideration of whether:

a. gelled bread ought to be removed as a permissible food as part of a minced and moist diet, or

b. gelled bread, and its preparation, ought to be m ore well defined and described.

Key takeaways

The unfortunate deaths of Mr Gesios and Ms McGreevy resulted from them both choking on bread. They were both on minced and moist diets which do not allow the consumption of regular, dry bread. In light of the events, we provide the following key takeaways from this Coroner's Report:

- Ensure that aged care facilities, particularly their kitchen and nursing staff, have a clear understanding of foods that provide a choking hazard.
- Implement and maintain policies and frameworks that prevent the mix-up of food, particularly of food that certain residents are not allowed to consume.
- Explain and reinforce the importance of truthful and thorough reporting of Reportable Incidents, noting the potential for complaints to be made against those who obscure evidence.
- Implement and maintain guides and policies that teach and reinforce to staff the importance of reasonably paced feeding. These guides should teach the indicators for swallowing food. Particularly, it is important for residents that have difficulty communicating.

WHAT CONSTITUTES AN 'ACCIDENT' FOR THE PURPOSE OF A SECONDARY VICTIM CLAIM?

Authors: Marie-Clare Elder (Partner) and Justine Anderson (Senior Associate)

In our twelfth edition of Sparkebeat, we reported on the UK case of *Paul & Anor v Royal Wolverhampton NHS Trust* (**Paul**). Below we analyse a recent UK case decided following *Paul*.

Brief Overview: *Paul & Anor v Royal Wolverhampton NHS Trust; Polmear & Anor v Royal Cornwall Hospital NHS Trust; Purchase v Ahmed* [2024] UKSC 1

Each claimant sought compensation for psychiatric illness caused by the experience of witnessing the death of a close family member in distressing circumstances. In each case, the death was allegedly caused by the negligence of the defendant doctor or health authority in failing to diagnose and treat a life-threatening medical condition.[1]

By a majority of six to one, the Supreme Court dismissed the appeals. The Court concluded that, while doctors owed a duty of care to protect the health of their patients, they did **not** owe a duty of care to members of the patient's close family to protect them against the risk of illness from the experience of witnessing the death or medical crisis of their relative from a condition which the doctor had negligently failed to diagnose or treat. The Court of Appeal's order dismissing the claims was, therefore, upheld.[2]

The decision reaffirmed that UK common law claims for compensation for pure mental harm, or 'nervous shock' have no place in clinical negligence cases (subject to exceptions that may arise on the individual facts of each matter).[3] The Supreme Court held that a secondary victim must be present at the scene of an accident or its immediate aftermath to be entitled to damages for nervous shock.[4]

Australian proposition

In Australian, liability for nervous shock **can** extend to secondary victims in a medical negligence context and is determined by assessment of the foreseeability test. The analysis centres around foresight; whether it was reasonably foreseeable in the circumstances to predict or anticipate that the harm inflicted would result in a psychiatric injury – this analysis must not be tainted by hindsight bias.

1. https://supremecourt.uk/uploads/uksc_2022_0038_0044_0049_press_summary_15d039960d.pdf
2. https://supremecourt.uk/uploads/uksc_2022_0038_0044_0049_press_summary_15d039960d.pdf
3. *Paul v The Royal Wolverhampton NHS Trust* [2020] EWHC 1415 (QB) at [123]; Sparke Helmore Lawyers, Sparkebeat, June 2024, Issue 12, page 5.
4. Sparke Helmore Lawyers, Sparkebeat, June 2024, Issue 12, pg 5.

Since *Paul*

Brief overview: *MIM v Sheffield Teaching Hospitals NHS Foundation Trust* [2026] EWHC 562 (KB) – 17 March 2026 – High Court of Manchester

This case was an analysis of what constitutes an 'accident' for the purpose of a secondary victim claim. A claim of this nature is an exception of general rule of *Paul*.

This case concerned whether MIM had any prospect of succeeding in his claim for damages for psychiatric injury he suffered as a result of witnessing the labour of his wife and subsequent delivery of his son who, due to the admitted negligence of the Defendant in the management of the labour, was born requiring resuscitation having suffered an acute profound hypoxic brain injury, or whether his claim must fail following the decision of the Supreme Court in *Paul*.

An application was filed to strike out the claim on the basis the Particulars of Claim lacked reasonable grounds for bringing the claim, or in the alternative enter summary judgment. The pleadings were subject to several criticisms, however putting that aside, if MIM could establish he witnessed an 'accident' then he could then proceed to bring a claim as a secondary victim, and it followed then the application must fail.[5]

Facts

- MIM's wife was admitted to the Defendant's Royal Hallamshire Hospital (the **Hospital**) on the evening of 30 May 2020 for induction of labour.
- On the evening of 31 May 2020, she was provided with Syntocinon and labour progressed through the early hours of 1 June 2020.
- At 0650 hours on 1 June 2020, she wanted to start pushing. At approximately 0810 hours onward the CTG trace deteriorated.
- At 0947 hours, she birthed a son by spontaneous vaginal delivery. The baby was in poor condition and required resuscitation and therapeutic cooling in the NICU.
- MIM remained with his wife throughout the duration of her labour. As a result of witnessing the labour and birth, MIM developed an adjustment disorder.

MIM claimed *inter alia* that an abdominal monitor worn by his wife had alarmed every now and again and the Midwife silenced it. It was his observation that the Midwife appeared irritated at its regular alarming. MIM and his wife were reassured that their baby was alright however the couple remained concerned about the baby's wellbeing. On advice from the consultant at or about 0855 hours they were told to wait about 15 minutes to see how her labour was progressing and if there was no progress then intervention would be required. Intervention by way of episiotomy was provided and the baby was delivered. MIM's perception of the labour was that there was confusion as to who was doing what and the situation was at '*panic stations*'.

MIM claimed that there need not be an '*accident*' for a viable secondary victim claim. MIM argued that the 'accident' was witnessed as a continuum during which he feared the worst and eventually the worst happened. He submitted that the accident ran from the time when he observed that the midwives did not appear to know what was going on, the alarm kept sounding and culminated in the delivery of his son. Further he submitted that it was not easily possible to pinpoint the occurrence of the accident giving rise to the secondary victim.

5. MIM v Sheffield Teaching Hospitals NHS Foundation Trust [2026] EWHC 562 (KB), at [9]

The Hospital admitted the labour was managed negligently in that there was a deteriorating CTG trace; MIM's son should have been delivered at 0930 hours and was not delivered until 0947 hours. It admitted that delivery by 0941 to 0944 hours would have avoided all injury.[6]

The Defendant argued that MIM had not established that the events were capable of being construed as an "accident" as required by *Paul*. In particular, the requirement of the injury having been caused by violent external means and / or being external to the primary victim was not met. The Defendant's case was that it was a medical crisis or medical mishap rather than an accident.[7]

Analysis of *Paul*

The conclusion arrived at by the Court in *Paul* was that such cases, where the death or manifestation of the injury was caused not by an external traumatic event in the nature of an accident but as a result of pre-existing injury or disease, are not analogous to those involving witnessing an accident and cannot succeed.[8]

Her Honour Judge Claire Evans in this case considered *Paul* and the analysis of 'accident' versus 'medical crisis'.

The Court in *Paul* identified the occurrence and witnessing of an accident as **integral** in defining the limits of the category of claims by secondary victims in three ways. Of particular relevance in this case were the first and third:

> *First, an accident is, by definition, a **discrete event** in the ordinary sense of that word, meaning something which happens at a **particular time, at a particular place, in a particular way**. Whether someone was present at the scene and whether they directly perceived an accident are in most cases questions which admit of a clear and straightforward answer. These criteria for determining whether a person is eligible to claim compensation as a secondary victim therefore have the great merit of **providing legal certainty**. … A third significant feature of accident cases is that it is often difficult or arbitrary in such cases to distinguish between primary and secondary victims.*

6. MIM v Sheffield Teaching Hospitals NHS Foundation Trust [2026] EWHC 562 (KB), at [4]
7. MIM v Sheffield Teaching Hospitals NHS Foundation Trust [2026] EWHC 562 (KB), at [7]
8. MIM v Sheffield Teaching Hospitals NHS Foundation Trust [2026] EWHC 562 (KB), at [12]

Her Honour Judge Evans held:

The use of the word 'continuum' to characterise the 'accident' suggests the opposite of a discrete event.[9] Nor can they be said to amount to an unexpected and unintended event which caused injury to MIM's son by external means, whether violent or otherwise.[10]

MIM relied on the fact that everything that had happened in the management of the mother was external to the baby, that did not assist his claim either. There was no 'accident' upon which MIM could found his claim.[11]

The decision in *Paul* does not preclude a secondary victim from **ever** succeeding in a claim arising out of clinical negligence (although as Lord Burrows said in his dissenting judgment, it will only be in rare cases that such a claim will succeed). The Court left open in paragraph 123 the question of whether the hypothetical scenarios canvassed there might constitute an accident, but that does no more than make clear that whether what a claimant witnessed amounted to an accident or a medical crisis will be a question to be decided on the facts of each individual case.[12]

The facts as pleaded in this case did not disclose any legally recognisable claim against the Hospital, because they could not amount to the witnessing of an 'accident' as was required for MIM to be able to recover as a secondary victim.[13] It was also noted that a close temporal connection between the negligence and the injury was not necessary in order to recover as a secondary victim.[14]

The claim fell to be struck out.[15]

Key takeaways

It has largely been accepted in the UK that secondary victim claims in a clinical negligence context will fail for most claims. There are still claims that may succeed when the individual facts and circumstances are considered, particularly if family members have witnessed their family member's suffering and or death directly.

Secondary victim claims can continue in the context of workplace accidents, public disasters and road traffic accidents.

Whilst *Paul* seems, on its face, a damning end to secondary victims claims in the clinical negligence context; it should be anticipated that further attempts to challenge this will be fraught with difficulty as espoused by Lord Burrows in *Paul*.

Further matters will be required to test the limits of the carve out for secondary victim claims in the UK.

The impact of *Paul* and subsequent cases to be tested is not yet clear. Considering the differences in the operation of our approaches to mental harm cases in Australia, it is not yet clear if the UK case law would be compelling enough for a reconsideration of our legislation with regard to access to this head of damage.

9. MIM v Sheffield Teaching Hospitals NHS Foundation Trust [2026] EWHC 562 (KB), at [32]
10. MIM v Sheffield Teaching Hospitals NHS Foundation Trust [2026] EWHC 562 (KB), at [33]
11. MIM v Sheffield Teaching Hospitals NHS Foundation Trust [2026] EWHC 562 (KB), at [35]
12. MIM v Sheffield Teaching Hospitals NHS Foundation Trust [2026] EWHC 562 (KB), at [36]
13. MIM v Sheffield Teaching Hospitals NHS Foundation Trust [2026] EWHC 562 (KB), at [37]
14. MIM v Sheffield Teaching Hospitals NHS Foundation Trust [2026] EWHC 562 (KB), at [34]
15. MIM v Sheffield Teaching Hospitals NHS Foundation Trust [2026] EWHC 562 (KB), at [37]

INQUEST INTO THE DEATH OF MISS SERENA LEE

Authors: Marie-Clare Elder (Partner) and Zara Smith (Law Graduate)

On 17 March 2026, her Honour Deputy State Coroner Hosking delivered her findings of the inquest into the death of Miss Serena Lee (the **Inquest**). Miss Lee's death was referred to the Coroner for investigation as her death was considered preventable. The reasons for her death were due to premature discharge from Campbeltown Hospital where practitioners inappropriately identified her as low risk and did not treat her properly for hypoglycaemia arising from an intrauterine growth restriction (**IUGR**).

Important guidelines and programs

The Neonatal Hypoglycaemia Management Guidelines (**NHM Guidelines**) lists both IUGR and small for gestational age (**SGA**) as criteria for glucose monitoring. A neonate weighing less than 2300 grams is at risk of developing hypoglycaemia, thus requiring glucose monitoring.

The Midwife Support Program (**MSP**) is a program designed to assesses low-risk mothers and babies who are eligible for early discharge, however medical staff are permitted to decline women seeking early discharge if there is cause for concern. The discharge assessment may be conducted by either the midwife on the ward, the obstetrics team or the paediatrics team at the hospital. If a patient is found suitable for early discharge, the mother and baby may leave the hospital within four to six hours of birth, the postnatal ward within 48 hours for normal vaginal birth or within 96 hours for a caesarean section. Under the MSP, the mother and baby are to receive follow up care at home.

The facts

Grace, Miss Lee's mother, fell pregnant in February 2021 with an expected due date of 11 November 2021. Grace's first two trimesters of pregnancy were unremarkable however, in her third trimester, Grace exhibited faltering intrauterine growth, with serial ultrasound estimates and birthweight indicating a downward trajectory across centiles.

On 31 October 2021 at 1am, Grace's membranes spontaneously ruptured whereby her spouse was informed to monitor the frequency of contractions. Grace and her spouse, Zan, later arrived at the hospital at 2.15am, where a cardiotocography was undertaken noting deceleration of the fetal heartbeat. A fetal scalp electrode was place showing that the fetal heart rate was taking longer than anticipated to recover following the decelerations and the decision was made to expedite delivery.

Miss Lee was born vaginally at 3.23am weighing 2485 grams. Her birthweight was below the 10th centile, being considered small for gestational age. A newborn risk assessment conducted at 4:55am identified no risk factors or signs of clinical deterioration. At 5am an assessment of maternal risk factors was undertaken and the progress noted reflected there was no risks identified.

Prior to transferring Grace and Miss Lee to the Post Natal Ward, Grace and Zan expressed a desire to be discharged home directly from the Birthing Unit. When Miss Lee was transferred from the Birth Unit to the Post Natal Ward the following was noted: hearing test passed in both ears, she was breastfeeding, she was born 10 days early and had hyper-flexed feet bilaterally.

At 7.36am, Dr Denesh Hewa-Gamage conducted a newborn examination and did not identify any issues in respect to Miss Lee, nor was she suspected to be suffering from IUGR or require glucose monitoring. Seven hours post birth, Miss Lee and Grace were discharged home at 10:15am. It's important to note that Dr Hewa-Gamage was the only doctor who reviewed Miss Lee prior to discharge from hospital.

Retrospectively, as Miss Lee was SGA and likely had UGR which predisposed her to a risk of hypoglycaemia, she should have remained admitted to hospital until three consecutive normal blood glucose levels were achieved and was therefore not suitable for discharge to the MSP until this had occurred.

It is advised that babies weighing less than 2.8 kg require a feeding plan and should be feed at least every three hours. Aside from this information, there was no record that Grace and Zan were verbally informed of what to do if Miss Lee failed to feed over a prolonged period. Grace reported having difficulty feeding Miss Lee once at home and it was not until 9pm on the evening of 31 October 2021 that she latched on.

Grace provided two videos of Miss Lee's breathing patterns on 31 October 2021. The first video demonstrated Miss Lee swaddled and laying on her back facing upwards taking six breaths in 24 seconds, resulting in a respiratory rate of 15 breaths per minute. The other video demonstrated a similar breathing pattern.

In the early hours of the morning on 1 November 2021, Grace attempted to breastfeed Miss Lee however she had no success. Grace reported that whilst Miss Lee was sleeping she sounded like she had mucus in her nose and was making a slight wheezing noise. After Miss Lee woke up around 7:30am, Grace attempted to feed her, but she did not latch on, making it eight and a half hours since her last feed.

On 1 November 2021, Miss Lee and Grace who were scheduled to be seen by the MSP by registered midwives C Faulds and F Marshall. At around 10am, Faulds and Marshall observed Grace's unsuccessful attempt to feed Miss Lee. Faulds examined Miss Lee with an APGAR assessment. A transcutaneous bilirubinometer reading of 'about 99' was reported to be 'well under the treatment range'. Additionally, Faulds provided some guidance on breastfeeding to Grace. Further attempts to breastfeed were made, however were unsuccessful and Faulds advised Grace and Zan would need to return to hospital if Miss Lee did not feed. Additionally, Marshall told Zan to purchase formula from the shops as soon as the midwives departed.

Following their visit, Faulds and Marshall noted the following:

- Miss Lee fed twice in the first 24 hours and was reported to have licked a few drops of colostrum that Grace had expressed
- Miss Lee had been put to bed around 4am and awoke around 7am, and was noted to be alert
- Miss Lee had displayed some feeding cues, and was not crying excessively
- Miss Lee had passed urine and meconium overnight consistent with normal output from a newborn, and
- Miss Lee was mucousy providing a reasonable explanation for her failure to feed.

Faulds informed Grace and Zan that she would call later in the day for a check-in and intended to return to assess Miss Lee. Prior to departure, Faulds and Marshall provided guidelines for breastfeeding babies, sudden infant death syndrome, safe sleeping and information on newborn infection . It should be noted that Faulds and Marshall were relying on a 2012 Royal Hospital for Women document titled 'Breastfeeding in the First week' which was not intended as clinical guidance for midwives but as general guidance for new mothers.

At around 11am, the midwives departed and Miss Lee was asleep. Zan went to the store to collect some formula, and when he returned home about 11:30am heard Miss Lee make what was described as a little cry or yelp. About 10 minutes later, Zan prepared a bottle of formula and asked Grace to pick up Miss Lee. Grace noticed that Miss Lee's chest was not rising as normal and appeared to not be breathing. Grace attempted to play with Miss Lee but she was unresponsive and her skin felt slightly cold. Grace informed Zan that Miss Lee was not breathing, to which Zan put Miss Lee up to his face and could not feel her breathing. Grace called triple zero at 12:10pm and was advised to perform CPR on Miss Lee.

Paramedics arrived at Grace and Zan's house at 12:21pm and upon arrival confirmed Miss Lee was not breathing and had no pulse. On the way to the Campbelltown Hospital the paramedics placed an airway delivering oxygen via the Bag Valve mask and began 3:1 compression to ventilations, however noticed Miss Lee had blueish discolouration of the skin.

At 12:45pm, Miss Lee arrived at the emergency department (**ED**) where Dr Catriona Maclean noted that Miss Lee had low blood sugar on her gas, consistent with hypoglycaemia. Dr Maclean opined that survival was not possible for Miss Lee as she arrived at the hospital in full arrest.

Miss Lee's biochemistry results showed elevated levels of creatine and urea. She had very low bicarbonate levels and elevated potassium levels, consistent with severe acidosis. Her blood film showed normal white cell count, with borderline low haemoglobin and platelets. At 1:38pm, another blood gas was performed showing severe metabolic acidosis of pH less than 6.8 with lactate equalling 17.8 mmol/L and a repeat glucose level of 0.9mmol/L.

It was agreed by all doctors present, Grace and Zan that resuscitation should not continue and Miss Lee was confirmed dead around 2pm.

A coronial post-mortem examination was conducted by Dr Isabel Brouwer on 3 November 2021. Her report dated 22 March 2023 reported that Miss Lee was small for gestational age, however noted some findings raising suspicion of early sepsis. Dr Brouwer concluded that the cause of Miss Lee's death was 'unascertained'.

In the neonatologist reported dated 26 June 2025 by Dr Andrew McPhee, noted the significance of the videos taken by Miss Lee's parents in demonstrating that Miss Lee had severe airway obstruction during sleep. Dr McPhee opined that Miss Lee died as a complication of Obstructive Sleep Apneoa (**OSA**) with hyperglycaemia related to IUGR, and that it was unlikely that neonatal sepsis contributed to Miss Lee's death.

In Dr McPhee's oral evidence, he opined that due to Miss Lee's smaller, leaner body and noticeably larger head she should not have been discharged early and if her SGA status had been appropriate assessed, her death would have been avoidable. Despite this, as she was demonstrating signs of 'poor feeding' an ambulance should have been called by 10am, 1 November 2021, which would have increased her chances of survival.

Ultimately, Dr McPhee opined that Miss Lee should not have been discharged early onto the MSP.

Issues

Deputy State Coroner Hosking examined several key questions, including:

1. Whether the South Western Sydney Local Health District (**SWSLHD**) policies concerning early postnatal discharge as well as the monitoring and assessment of neonatal hypoglycaemia were adequate and adhered to.

2. Whether premature discharge of Miss Lee was appropriate, and whether during her period of hospitalisation she exhibited any symptoms of illness which should have been detected.

3. The reasonableness of the MSP review conducted by Faulds and Marshall in determining:
   a. whether Miss Lee should have been referred to hospital, and
   b. whether Miss Lee's blood glucose level should have been measured during the review.

4. Whether the registered midwives were shown video evidence of the deceased in respiratory distress and if so, whether they should have taken action in response to those videos.

The findings

Deputy State Coroner Hosking found that Miss Lee's cause of death was due to OSA arising from unrecognised hypoglycaemia affiliated with intrauterine growth restriction. Deputy State Coroner Hosking stated that Miss Lee's death would have been prevented had she remained in hospital and the appropriate treatment for hypoglycaemia was administered in accordance with the SWSLHD NHM Guidelines.

Her Honour stated that there was an oversight of Miss Lee's diagnosis and that there were many warning signs including faltering intrauterine growth, that she was small for gestational age, she had IUGR and head-sparing growth all of which should have alerted practitioners that she was not eligible for early discharge. Deputy State Coroner Hosking considered that whilst Dr Hewa-Gamage did not identify Miss Lee's SGA status and her subsequent IUGR, he should have been capable of making such a diagnosis as a paediatric resident, irrespective of being a junior doctor.

Deputy State Coroner Hosking opined that Miss Lee ought to have been identified as an infant at risk requiring further monitoring and observation whereby policy triggers were missed and resulted in her death. As such, Faulds and Marshall were entitled to assume that the hospital's decision for early discharge signified that Miss Lee was low risk, however they should have recognised that Miss Lee was poorly fed and as a potential consequence, was at risk of hypoglycaemia. Moreover, had Miss Lee been subject to a blood glucose test, she would have been found to be hypoglycaemic and appropriate action could have been taken. Deputy State Coroner Hosking does note that at the time of Miss Lee's death MSP midwives did not have access to glucometers however they are now accessible in the MSP.

Recommendations

Pursuant to s 82 of the Coroners Act 2009, Deputy State Coroner Hosking recommended that the SWSLHD should conduct an audit into all equipment utilised in the MSP Policy to ensure all equipment is working and properly calibrated. Additionally, she opined that all staff should be trained on the use of all accessible equipment.

Deputy State Coroner Hosking further recommended that the SWSLHD should immediately review all material provided by and relied upon by the MSP Midwives and ensure that all information is current and consistent with present best practice.

Due to the circumstances surrounding Miss Lee's death, Deputy State Coroner Hosking recommended that further amendments be made to the MSP policy to provide more stringent guidance about circumstances which require a neonate's blood glucose levels to be tested and monitored. Additionally, that the SWSLDH undertake a review of the MSP Policy seeking feedback from midwives and potentially amend the threshold for patients to be admitted into the program to be only low-risk.

Due to the public health and safety matters that arose on the available evidence, Deputy State Coroner Hosking recommended that a copy of the brief of evidence and the transcript of the coronial inquest be provided to the President of the Medical Council of NSW. Additionally, she recommended that Dr Hewa-Gamage be referred for further investigation regarding his decision to discharge Miss Lee.

Implications

Since Miss Lee's death, there have been a number of policy changes implemented by the SWSLHD including:

- Availability of discharge information packs in the Birthing Unit for women discharged early;
- MSP policy revision to ensure babies under 2,500 grams are to be recognised to be at increased risk of hypoglycaemia and are not eligible for discharge within 24 hours; and
- Further education to midwifery staff on newborn risk assessment.

Accordingly, NHM Guidelines have been revised to reflect these policy changes.

This inquest demonstrated the significance of conducting thorough risk assessment of newborns, and the potential implications of early discharge when appropriate protocols have not been adhered to. Additionally, this inquest reflected the importance of recognising and acting upon subtle clinical warning signs and administering appropriate treatment accordingly. The findings emphasised that the MSP requires ongoing review to ensure that midwives have access to necessary medical equipment as well as the most current up-to-date clinical guidance in order to provide the best possible care.

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