Key developments in 2023 and what is to come in 2024

There were a lot of interesting developments in the health and social care sector and decisions by civil courts, coroners and regulators of professionals and providers in 2023. In this article, **Anna Walsh**, Partner in CMS' Insurance and Reinsurance Group and CMS' global Life Sciences & Healthcare Sector Group, takes a look back at what we saw in 2023, how 2024 will be shaped by last year's developments and what is on the horizon generally in 2024 for those working in health and social care and those indemnifying professionals and providers.

Significant decisions on informed consent

There were two particularly significant decisions on informed consent in 2023:

1. The Court of Appeal decision in Bilal and Malik v St George's University Hospital NHS Trust [2023] EWCA Civ 605; and
2. The Supreme Court decision in *McCulloch v Forth Valley Health Board* [2023] UKSC 26.

The appeal in *Bilal and Malik* was against an adverse judgment at trial dismissing the claim that the Defendant's surgeon had been negligent in failing to obtain informed consent to spinal surgery, resulting in serious neurological injury. The Claimant's case was that Mr Malik (Deceased) should have been informed of alternative treatments and that, if he had, he would have chosen these instead of surgery. At trial, the primary issue was whether the Deceased had been suffering from severe intercostal pain, which the surgeon believed was caused by compression of a nerve root. The Judge at trial accepted that the Deceased was indeed experiencing such pain and that it was reasonable for the surgeon to recommend surgery without discussing alternative treatments. The Judge also ruled that even if alternative treatments had been discussed, the Claimant had not proven that the Deceased would have declined surgery.

In the Judgment handed down in June 2023, dismissing the appeal, the Court of Appeal explained that the *Bolam* principle pertains to the assessment of treatment options, while the *Montgomery* principle focuses on the duty to explain material risks to the patient. The Court of Appeal concluded that it is the doctor's role to assess reasonable alternatives, while the court determines the materiality of the risks from the patient's perspective.

A month later in July 2023, the Supreme Court handed down its decision in *McCulloch*, clarifying the meaning of the words "reasonable alternative or variant treatments" in *Montgomery*. That claim arose from the family of the Deceased alleging that he: (i) should have been advised of the option of treatment with NSAIDs (non-steroidal anti-inflammatories); (ii) had such advice been given, the Deceased would have taken the NSAIDs; and (iii) had he taken the NSAIDs, he would not have died.

The Supreme Court unanimously held that whether a treatment is a reasonable alternative is to be determined by the application of *Bolam* (the professional practice test). The Court confirmed that doctors could not restrict the options they give to a patient to those options they themselves consider to be the most appropriate. Instead, doctors have a duty to advise on alternative options that are clinically appropriate options in the circumstances, but do not have to explain all possible alternatives to a patient. What are reasonable alternative treatments will be determined by the *Bolam/Bolitho* tests.

Looking Ahead – It is enormously helpful to have this clarification from the Court of Appeal and the Supreme Court on the interplay between the *Bolam* and *Montgomery* principles and the duty to discuss alternative treatments. Going forwards, claims arising from allegedly deficient discussions around alternative treatment options are likely to have a focus on what was clinically appropriate and exactly what that means in all the circumstances.

Clarification from the Supreme Court on vicarious liability

In *Trustees of the Barry Congregation of Jehovah's Witnesses v BXB* [2023] UKSC15, the Supreme Court held that the rape by an "elder" of the Congregation in the home of Mrs B was outside the course of employment as it was carried out in a private setting when MS was not engaged in any kind of work connected with his role as an elder and MS was not exercising control over Mrs B. Mrs B successfully established vicarious liability against the employer, which was upheld by the Court of Appeal. However, the employer appealed to the Supreme Court which upheld the appeal and provided clarity as to the two-stage test for vicarious liability.

It was held as settled law that stage 1 of the test for vicarious liability is that there must be a relationship "akin to employment' and that this can also include "quasi-employment". The fact that MS' work was unpaid was not a decisive factor. The important features were that: (a) MS was carrying out work on behalf of and assigned to him by the organisation; (b) he was performing duties which were part of the aims and objectives of the organisation; (c) he was an elder who was appointed and removed by a process in the organisation; and (d) there was a hierarchal structure to the organisation.

Stage 2 was the main issue in the appeal, which looked at the connection between the relationship and the wrongdoing. In *WM Morrisons Supermarkets v Various Claimants* [2020] UKSC 12, the Supreme Court held that the correct formulation of the test was that "the wrongful conduct must be so closely connected with acts the employee was authorised to do that…. it may fairly and properly be regarded as done by the employee while acting in the ordinary course of his employment". This was upheld in *Trustees*, but the Court recognised that "employment" extends to "quasi employment" and removed the word "ordinary" before "course of employment" as it was potentially misleading.

Looking Ahead – This decision brings further clarity to the law on vicarious liability particularly in the context of sexual misconduct cases. It is an additional helpful judgment in the context of medical malpractice claims, as was the 2022 Court of Appeal decision in *Hughes v Rattan*, in which it was affirmed that a dental practice owner was not vicariously liable for the actions of associate dentists operating as independent contractors. Whilst all cases will turn on their specific facts, *Trustees* is likely to be helpful in defending allegations of vicarious liability going forwards.

Much awaited Supreme Court decision on secondary victim claims

In May 2023, the Supreme Court heard three conjoined appeals (*Paul, Purchase and Polmear*) in claims by an Appellant for psychiatric illness caused by viewing a traumatic event which was caused by a Respondent's negligence. In each case, the Appellant witnessed or attended shortly after a death caused by the Respondent's negligence.

This month, the Supreme Court handed down its much anticipated Judgment and dismissed the appeals. Reviewing the extensive previous case law on the criterion of those who could bring claims as secondary victims, the Court held that what was required to satisfy the legal requirements was twofold:

1. The happening of an accident, in terms of a traumatic, violent, unexpected, discrete, external event, which was external to the primary victim which immediately caused or had the potential to cause injury to him/her; and
2. The witnessing of the accident by a close relative of the person involved in the accident and the suffering of a psychiatric injury as a result of having witnessed it.

If someone witnesses the medical crisis of a primary victim, that does not satisfy the legal requirements for a claim for injury suffered by the close relative. A duty of care is owed to the patient, but the responsibility of a medical practitioner does not extend to protecting the patient's close family from witnessing a death or other traumatic experience relating to their relative.

Looking Ahead – After much secondary victim case law in the medical malpractice context over the last few years, the clarity now provided by the Supreme Court as to the legal requirements to satisfy in order to bring such a claim is welcome. Those who are currently handling such claims will need to carefully consider the pleadings and the prospects of success in the light of the judgment. It is possible we may see some claims discontinued or compromised sooner than they might have been in the light of this judgment. It will be critical for the legal requirements laid down in *Paul* to be applied to all cases going forwards.

Costs: changes to QOCS and recovery of defence costs and FRC

In April 2023, significant changes to CPR 44.14 were brought in, which had the effect of permitting defendants to enforce costs orders made in their favour against costs orders made in favour of claimants. The changes also made it possible for defendants to enforce costs orders in the overwhelming majority of cases in which the claim is concluded by way of acceptance of Part 36 offers or Tomlin Orders.

2023 also saw the much-awaited announcement by the government that there will be a new Fixed Recoverable Costs ("FRC") regime and streamlined process for clinical negligence claims with a damages value of £1,501 to £25,000 in England and Wales. It was expected that this would be implemented for claims notified from 1 April 2024, but we still await the outcome of the consultation relating to disbursements.

Looking Ahead – If the new FRC for low value clinical negligence claims is implemented for claims notified from 1 April 2024, those handling those types of claims will need to quickly get up to speed on the steps required by both claimants and defendants at the pre-action stage. Also expect the CPR 44.14 changes to continue to have an effect on claims strategy, particularly in relation to Part 36 offers and considering whether to make or resist interlocutory applications.

Personal Injury Discount Rate (PIDR)

The PIDR reflects the return that a personal injury claimant could reasonably be expected to receive from investing a lump sum award of damages for future financial loss in a diversified low risk portfolio. The current rate is -0.25% and the Lord Chancellor's next review of the PIDR will be taking place this year.

This month saw the government announce a Call for Evidence from stakeholders on a number of issues, some of which include: claimant investment experience; expenses and tax payable by claimants on their investments; the impact and practicalities of adopting a dual / multiple PIDR driven by duration of award or by heads of loss; and the usage of Periodical Payment Orders (PPOs).

Looking Ahead – Stakeholders will have until 9 April 2024 to assist the expert panel in providing evidence and medical malpractice insurers may wish to contribute. A change to the existing PIDR will have an impact on medical malpractice claims reserving where claimants have future financial losses.

Artificial Intelligence

You would be hard pushed not to have heard about the developments and regulatory questions around Artificial Intelligence ("AI") in 2023, which health and social care providers and developers were at the heart of. We heard about a number of innovative devices and/or research projects. To name a few:

— **New devices / projects:** A heart device which detects congestion before it is clinically symptomatic (developed by Cordio Medical); a foundation AI model to predict the likelihood of a person's future health problems based on their existing conditions (University of Oxford project); a project to develop AI that improves the mammogram analysis process (University of Surrey); and expansion of virtual wards to additional groups of patients where remote monitoring technology will be used which automatically transmits data on patients' conditions to teams of doctors and nurses several miles away.

— **Resources & Guidance available:** The AI and Digital Regulations Service was launched by a collaboration of healthcare organisations including NICE, CQC, MHRA, and the Health Research Authority, aiming to support the adoption and implementation of digital and AI technologies in the NHS and social care systems. The service provides a range of resources and assistance to both developers and adopters of these technologies. Its website serves as a centralised platform for accessing regulatory content, offering up-to-date guidance curated from all 4 participating organisations, ensuring that developers and adopters have comprehensive information at their disposal. There is also the MHRA's recently updated guidance around Software and AI as a Medical Device and its Roadmap towards the future regulatory framework for medical devices.

— **AI recommended by NICE for the first time:** In draft guidance NICE recommended that doctors use AI to map out cancer patients' radiotherapy treatment. It was said to be the first time that the NHS will use AI outside of trials and that it will speed up the outlining of tumours and avoid exposing healthy organs and cells to toxic radiation. The change to AI automated mark-up was not expected to affect patient outcomes. Contouring conducted by the technology will still need to be reviewed, and edited if needed, by trained professionals before any radiotherapy is carried out.

— **A cautionary tale:** It was reported that doctors in Australia had been writing medical notes using ChatGPT, which the Australian Medical Association warned against given there was no assurance of patient confidentiality using such systems.

Looking Ahead – AI is not going anywhere. In 2024 we expect to see even more entrants to the health and social care market, with the promise of greater efficiencies and outcomes in terms of prevention, diagnosis, monitoring and treatment. For now, AI working in conjunction with health and social care professionals is likely to be what we will see in practice. For those managing claims arising in circumstances where AI has played a role in a patient's care or treatment, there may be both product liability and medical malpractice allegations and the responsibility of all parties involved in the chain of services is likely to be scrutinised.

CQC New Assessment Framework

We saw a lot of guidance and preparation around the CQC's new single assessment framework in 2023, with the announcement in November that the CQC would start using it in various counties in the South and then expand their new assessment approach to all providers based on a risk-informed schedule.

Looking Ahead – Providers ought to now be familiar with and start to prepare for assessments based on the CQC's new approach. Many of those in risk and governance positions will be, but it will be important for the approach and any improvements identified during inspections to be disseminated widely across organisations.

Inquiries

The Covid-19 Inquiry continued into 2023 and in December 2023, Module 6 opened which will consider the impact of the pandemic on the adult social care sector across the UK. Additionally, in 2023 The Thirlwall Inquiry was set up to examine events at the Countess of Chester Hospital following the convictions for murder and attempted murder of babies at the hospital by former neonatal nurse, Lucy Letby. The Terms of Reference have already set out what the Inquiry will investigate and the Core Participant application ended in December.

Looking Ahead – The Covid-19 Inquiry is aiming to hold preliminary hearings for Module 6 (the care sector) in early 2024 and we are likely to hear opening statements from some Core Participants. It is possible that evidence heard may have an impact on claims books. With respect to the Thirlwall Inquiry, a preliminary hearing will likely take place in the spring and public hearings are likely to start in autumn 2024. We expect recommendations to be made by The Inquiry Chair in her final report to the Secretary of State, which could have an impact on all providers across the NHS and independent sectors.

Review of statutory duty of candour

At the end of 2023, the Department of Health and Social Care ("DHSC") announced that it will lead a review into the effectiveness of the statutory duty of candour for health and social care providers in England. Many will already be aware that the focus of this duty is to ensure that people have openness and transparency from their health or care provider and that when something goes wrong, patients and families have a right to receive explanations for what happened as soon as possible and a meaningful apology. All providers regulated by the CQC are required to comply with this duty.

The review will focus on three aspects relating to the duty:

1. to what extent the policy and its design are appropriate for the health and care system in England;
2. to what extent the policy is honoured, monitored and enforced; and
3. to what extent the policy has met its objectives.

Looking Ahead – The findings of the review will be published in spring 2024, which will include an appropriate level of recommendations for better meeting the policy objectives of the duty. It will be key for all health and social providers to keep up-to-date with the review findings and recommendations.

Licensing regime for non-surgical cosmetic procedures

Historically, non-surgical procedures have remained relatively unregulated, but the DHSC announced in 2023 that licensing regulations are to be introduced for cosmetic procedures such as fillers, laser hair removal and botox, which will be administered and enforced by local authorities. The regulations are to be introduced to ensure consistent standards across the industry and to make certain that those carrying out the procedures are adequately trained, hold indemnity cover and meet the required hygiene and safety standards. A public consultation was launched in 2023 to determine the additional details of the regulations.

Looking Ahead – We are expecting further consultations in 2024, including in relation to the standard of education and training and the potential economic impact of the proposed regime. We are, however, not expecting the regulations to become law for another 2-3 years.

What are your concerns for 2024?

Should you or your business have a particular interest in a particular topic addressed here or otherwise, do not hesitate to get in touch with Anna or Richard.

We would also be really interested to hear from you as to how the developments from last year impacted your business and what you are particularly interested to hear more about in 2024. Do reach out to Anna or Richard to discuss.

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Anna is a Partner in CMS' Insurance and Reinsurance Group and specialises in defending medical malpractice claims of the highest complexity and value and is also instructed by insurers and health and social care providers on inquests and other investigations by regulators (such as the CQC) and the police. Anna has a specialist interest in resolving disputes where multiple parties (often NHS and private) are involved in the delivery of healthcare services and advises clients on protecting their interests by ensuring appropriate indemnity arrangements are in place in those circumstances. Anna also advises health and social care providers on expansion into the UK market.

Anna's experience means she can support health and social care clients with safety, learning and risk management to help them minimise their clinical risks.

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Richard is Head of Healthcare for PIB Insurance Brokers, one of the largest and fastest growing insurance brokers in the world. He has 20 years' experience in the healthcare & life sciences sector, servicing a wide range of clients from SME to large Corporates, both in the UK & Internationally.

Richard and his team are heavily client focussed and take a keen interest in the ever-evolving healthcare landscape. They enjoy supporting, advising and providing effective insurance solutions for individuals and entities for their insurance & risk management requirements; these include Private hospitals, Private & NHS Doctors, Surgeons, Cosmetics, Pharmacists, Digital health, Fertility, Medicinal Cannabis, Care, Dentists, Medical repatriation, and Life sciences.

Richard enjoys working with CMS and other leading clinical negligence providers, so that his clients have the strongest possible service when unfortunate claims or circumstances that may give rise to a claim occur.