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ISSUE 19

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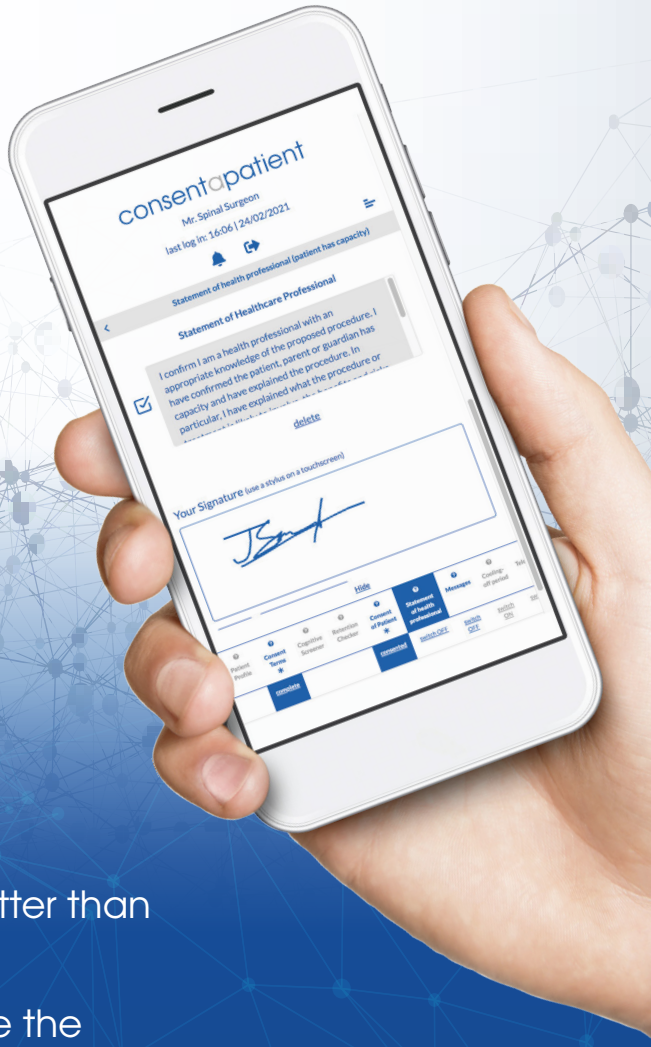

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Welcome to the Medico-Legal Magazine

Welcome to Issue 19 of the Medico-Legal Magazine, produced by SpecialistInfo and publishing partner Iconic Media Solutions Ltd.

This spring issue of 2022 includes articles from two of the confirmed speakers at the Medico-Legal Conference coming up this summer:

Alex Hutton, QC, Hailsham Chambers, and Keynote Speaker at the Conference this year, discusses the law on Consent; and Miss Lorin Lakasing, Consultant in Maternal and Fetal Medicine, shares her insight on Maternity Risk Management and missed learning opportunities.

Also in this issue, Abigail Telford, Specialist Clinical Negligence and Personal Injury Barrister at Parklane Plowden, Leeds, summarises a recent landmark case involving non-delegable duties and vicarious liability;

Finally, Martin Cheyne, Healthcare Employment Partner, Hempsons, Harrogate, summarises the current situation regarding vaccination as a condition of deployment.

Once again, the magazine will be circulated to up to 40,000 people in the industry, including doctors, insurance companies, law firms and medico-legal agencies. It now has a dedicated website www.medicolegalmagazine.co.uk and a page on the Medico-Legal Section of the Specialistinfo.com website, where all the back issues can be viewed, and printed copies can be ordered from Iconic.

Specialistinfo maintains a database of contact details for up to 90,000 UK consultants and GPs, including approximately 11,000 consultants and GPs who undertake medico-legal work. We also provide Medico-Legal courses for expert witnesses and promote the members of the Faculty of Expert Witnesses (the FEW).

We welcome feedback from our readers, so please contact us with any suggestions for areas you would like to see covered in future issues or share your news and experiences with us.

Lisa Cheyne

Specialistinfo
Medico-Legal Magazine

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MEDICO -LEGAL COURSES:

By Lisa Cheyne,
Medico-Legal Manager,
SpecialistInfo

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The dates and locations for the confirmed ML courses that we are holding during 2022 are listed below with links to our booking page.

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- *14th September 2022* – London

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Clinical Negligence Medico-Legal Course (for higher value medical negligence cases, with Barrister Jonathan Godfrey from Parklane Plowden Chambers):

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To book your place(s) and for more information about all our 2022 courses, please click **here**, email **lisa@specialistinfo.com** or call me on **01423 787984**.

Kind regards

Lisa Cheyne
Medico-Legal Manager

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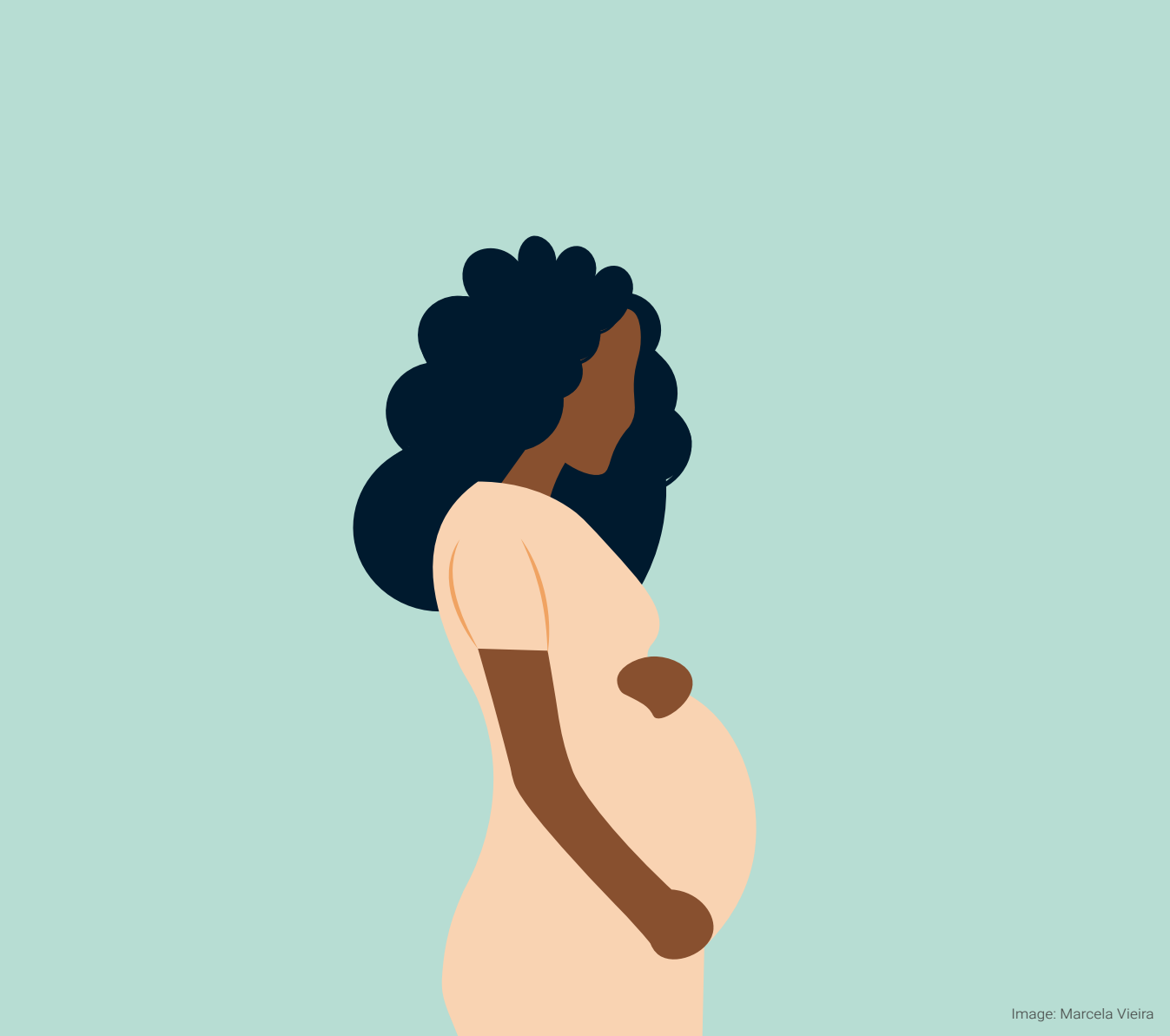

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MATERNITY RISK MANAGEMENT – MISSED LEARNING OPPORTUNITIES

By Miss Lorin Lakasing, Consultant in Obstetrics and Fetal Medicine,
St Mary's Hospital, Paddington, London

Introduction

On a worldwide scale, the UK is a safe place to have a baby and recent data suggest a welcomed reduction in the stillbirth rates[1]. But complacency can breed failure and we should not ignore the fact that despite the odd ray of sunshine, maternity services in the UK are in trouble. Scarcely a

month goes by without some bad news story and there have been multiple independent enquires - Barrow in Furness (2013), Morecambe Bay (2015), Llantrisant/Merthyr Tydfil (2019), Newham Hospital (2019), Shrewsbury and Telford (2020), East Kent (2021), Nottingham (2021), Worcester (2021), London North West (2021), Wye Valley Maternity Unit (2021). Every corner of the country is affected. Tragically, these enquiries are usually prompted by an excess of maternal/neonatal deaths but this mortality represents the tip of the iceberg. Beneath it lies the mass of morbidity which fuels the litigation process. Obstetric settlements are now reaching eye-watering sums of money, which will have a major impact on the public finances in the future[2].

It has long been recognised that the problems in delivering a safe maternity service are multifactorial[3]. Expectant mothers do not always have access to high quality, objective information and are instead subjected to anecdotes and social narratives around childbirth which influence their choices. There are significant problems around training in both midwifery and obstetrics, and recruitment and retention are more challenging than in many other specialities. There is hardly a unit in the country with adequate numbers of frontline staff on every shift. Flawed processes surround collection and interpretation of clinical data, workflows are inefficient and poor infrastructure exists in many units. Each of these are topics in their own right, but in this article I shall concentrate on the Maternity Risk Management (MRM) process because this is usually the first step in identification and analysis of adverse clinical outcomes. The reports generated are used for training purposes, shaping the service, managing complaints, providing information to commissioners and regulators, and disclosed to external reviewers, NHS Resolution or litigation lawyers.

Maternity Risk Management – its purpose and evolution

In 1995 the NHS Litigation Authority introduced clinical risk management and all UK maternity units have been required to have a formal MRM process in place ever since. Its aim then, as it is now, was to analyse adverse outcomes, so we learn from our mistakes and put in place safeguards that mitigate against similar events in the future. Back then the process was simple – cases were reported on an ad hoc basis and a self-appointed panel of no more than three, typically a senior consultant, a senior midwife and an administrator, met up once a month to discuss. They spoke to staff involved and wrote a one paragraph conclusion with bullet points to be read out at the next Perinatal Meeting. The mother met with her consultant, a two-line summary of the discussion was recorded in the case notes and a plan drawn up for any future pregnancy. Since then, MRM has exploded into an increasingly complex spiderweb of formal procedures and processes[4]. It now involves online datix reporting systems, healthcare staff from a range of disciplines, dozens of specially appointed administrators, and individuals with specialist job titles - safety experts, complaints managers, communications champions. Reports require laborious and repetitive transcribing of medical records, staff witness statements are formal signed documents, investigators write lengthy reports outlining recommendations and naming individuals who will be accountable for completion of each task. Cases are presented in front of an MRM panel of 10 or more who will further scrutinise the events and invariably make amendments. Reports are then shared with the mother and her relatives, and they too can challenge the contents prompting further redrafting. It is not unusual for each case to involve 12 versions and be circulated in over 40 e-mails taking several months to complete. Cases are graded according to the severity of harm caused and the likelihood of recurrence. Staff involved are required to reflect upon the findings of the investigation during their next appraisal. To avoid criticisms of bias or blame, serious or complex cases have traditionally been referred for external review, a process made formal by the establishment of the Healthcare Safety Investigation Branch (HSIB) in 2017[5].

This organisation proports to use a standardised approach to maternity investigations to identify common themes and influence systemic change without apportioning blame or liability. Currently just over 1000 maternity cases per year fulfil the criteria for HSIB investigation.

One might think that after almost three decades of increasingly elaborate MRM processes in place, few maternity service delivery problems would remain undetected and unaddressed. During this time, I have attended countless Perinatal Meetings, listened first-hand to mothers' accounts of their care, helped staff prepare witness statements, undertaken external review, written expert witness reports and attended trials and I have observed that the stories are all the same. I have also read the reports following local/regional/national enquiries and I note that the problems identified are also depressingly recurrent – "a lethal mix of failings"; a "culture of denial, collusion and incompetence"; "pursuit of normal childbirth at any cost"; dysfunctional relationships between staff; staff lacking in skills and knowledge; failure to escalate concerns; "drive to keep the Caesarean rates low"; "multiple missed opportunities"; poor skill mix; poor leadership. And of course, after each investigation come the recommendations and yes, that's right – these too are all the same. More CTG training, more simulation training, encouraging better communication between disciplines, restructuring teams - again, continuity of care – again, better supervision and mentoring – again, improving workplace culture - again. Often new names given to the same old concepts. These recommendations inevitably prompt an immediate call to arms from maternity service managers and obtain the automatic and unchallenged support from wider organisations such as the Royal College of Obstetricians & Gynaecologists (RCOG) and the National Institute for Clinical Excellence (NICE). To do otherwise would be unacceptable. So why, after several decades of being the focus of national scrutiny and much reform, are there still persistent and recurring problems?

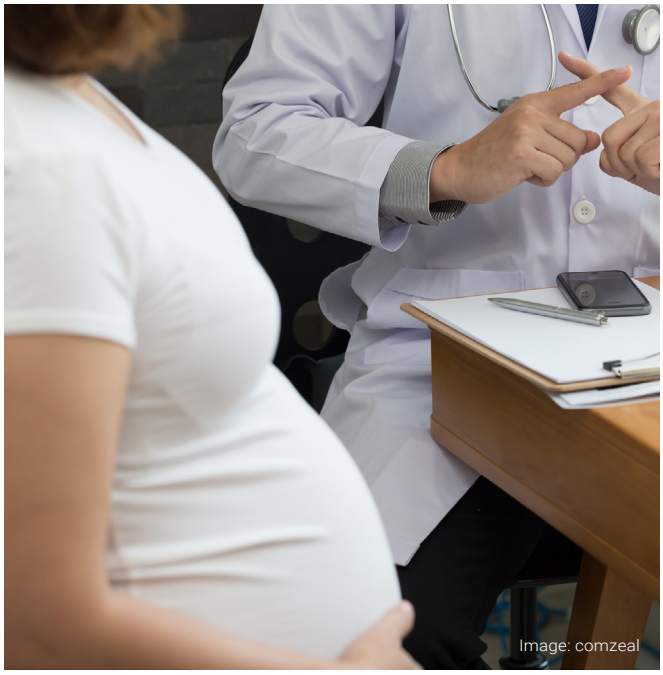
Maternity Risk Management – why it does not work

In short, the reason MRM does not work is because the people in charge of administering and overseeing the process are not the people directly tasked with delivering the service. MRM panels are largely made up of clinical managers and administrative staff whose main job is to achieve targets set out by healthcare commissioners such as those related to Caesarean section rates, or follow processes as set out by NHS regulatory bodies such as the Care Quality Commission. Thus, MRM has been reduced to a managerial tick box exercise where the emphasis is on demonstration of compliance with targets, systems and procedures rather than improvement in perinatal outcomes. Most maternity managers are from a midwifery background, but their clinical experience is meagre and historical and often obtained elsewhere. To maintain Royal College of Midwifery accreditation they do occasional daytime shifts, typically where they are supernumerary, certainly never out of hours or on Bank Holidays, and definitely not involving sole charge of a complex intrapartum case or acting as a Labour Ward Co-ordinator. Therefore, their operational knowledge of workflows is limited. This problem is not confined to midwifery. I have encountered cases where obstetricians on MRM panels are either retired or do not participate in an on-call rota or have jobs which are predominantly gynaecological in nature. These staff have no active experience of the everyday running of the service but are nonetheless in a position to comment on how well or otherwise frontline staff performed. But why should this disconnect matter?

Understanding this helps explain the oft highlighted problem of NHS workplace culture. Key members of MRM panels are typically Heads of Midwifery, Heads of Speciality or Clinical/ Divisional Directors, all of whom are also in charge of appraisal/revalidation, interview panels, facilitating promotions, writing references, signing off job plans, sanctioning sick/annual/

maternity leave, exit interviews and so on. Thus, all frontline staff are acutely aware that if any criticism is made of the care they provided, even if anonymised, their recourse to objection or appeal is limited and may have consequences. Many have seen close colleagues destroyed by this process and resign themselves to silence despite knowing that the investigations are poorly conducted and the conclusions ill-judged. They resolve that it is better to be overlooked than to be identified as a protester. In the event of litigation, the lawyers will take weeks if not months to scrutinise decisions they needed to make in a matter of a few split seconds and although this treatment at the hands of "one of your own" is more hurtful, the fear of future ill-treatment ensures their compliance, and the status quo remains. External reviews are slightly more palatable in that they are conducted by individuals not necessarily known to frontline staff, but the quality of the investigation and thus the conclusions reached are the same and, in any event, it will be the local MRM team that is left to implement the recommendations, so interaction between the shop-floor workers and their immediate line managers cannot be by-passed.

Actions that flow from investigations must, in managerial terms, involve change. Ironically, in the NHS most change takes months if not years to action, but there are examples where major changes can occur overnight. For example, drugs that have been successfully used for decades in countless women can be withdrawn from the hospital formulary at the click of a manager's e-mail simply because a relatively minor adverse drug interaction occurred in one individual. Managers must be seen to have acted on a poor outcome, the greater good is not considered. In another almost comical example of change for the sake of change following a retained swab event, the pre-counted swabs disappeared from delivery packs within a matter of days. It appears not to have dawned on those who issued this instruction that swabs would still be needed for a delivery only now staff would have to open a separate pack, and still have the problem of counting swabs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after the delivery, which is where the problem lay in the first place! But these knee-jerk, reactive changes are easy to effect and serve as evidence of actions taken in response to issues raised by MRM, actions which healthcare regulators reward with improved ratings. Other popular changes include introduction of new proformas or re-writing protocols/guidelines, changes that require evermore retraining and engagement from frontline staff. This process has become so complex in recent years that when I review cases now in addition to NICE/RCOG guidelines, I am often sent regional, local, Trust-specific and, in the case of Trusts which operate over several sites, site-specific guidelines! This makes a mockery of standardised practice and probably explains at least in part the observation reported in the recent Getting in Right the First Time review of maternity services of large variations in practice up and down the country[6].

Perhaps the greatest disappointment is not that MRM is ineffective or a waste of precious resources. These criticisms could be levelled at most managerially driven processes within the NHS. It is the fact that after hundreds of thousands of maternity investigations this process has failed

to put the vast amount of collective information obtained to any use. For example, we know that postdates, problems with fetal monitoring in labour, meconium, intrapartum sepsis, fetal malpresentation, unrecognised macrosomia, unrecognised fetal growth restriction, prolonged use of Syntocinon, difficult instrumental deliveries, Caesarean section performed too late or at full cervical dilation are all disproportionally represented in adverse maternity outcomes. Algorithms using these data could better define the dynamic nature of obstetric risk and promote pro-active rather than reactive care. These data could identify factors that influence emergency response times in real life scenarios or be used to help define avoidable versus unavoidable harm, a concept that both clinicians and litigation lawyers struggle with. Analysis of near miss outcomes is equally valuable in that it highlights interventions that steered the course of events away from disaster. Precursors to poor outcome often lie in the antenatal period, so intelligent application of the root cause analysis model could highlight areas of service deficiencies such as obstetric ultrasound or maternity triage where relatively small investments may yield big returns, not to mention help inform mothers better and assist staff in navigating the choppy waters of informed consent in advance of the fraught intrapartum period. These data could have been used to shape a safe service fit for the future by informing intelligent debate and scrutiny of all aspects of maternity care. Instead, it has failed to address the real problems, failed to include women in the maternity safety debate and left frontline staff fearful, demoralised, disengaged and resigned to the status quo. At a recent HSIB training update course a brave participant asked the panel of mainly ex-clinicians the killer question – "what evidence was there that HSIB had improved outcomes?" This was met with the usual fumbling excuses that this was not something that could be quantified, and that this sort of metric was meaningless, and how much Trusts appreciated their input. It seems evidence-based practice does not apply to managerial processes.

Summary

The Maternity Risk Management System has not helped us learn from our mistakes otherwise we would not keep making the same ones repeatedly. This process has failed to improve outcomes, failed to engage staff, failed to address patient concerns and serves only as a template by which maternity management teams are judged. It is no surprise that the recent report into the Safety of Maternity Services in England[7] concludes that key areas relating to risk require improvement. We shall only begin to learn from our mistakes and address them meaningfully when we learn to truly value our frontline staff, reward and remunerate them adequately, address the challenges they face, allow them to drive change that is relevant to outcome, limit the reach of managerial power and establish an open dialogue with women using risk data to inform them truthfully and accurately. Only then can we shape a maternity service with safety at the heart of clinical strategy.

Reference:

[1] www.ons.gov.uk – birth characteristics, 2019
[2] NHS Resolution Annual Report and accounts 2019/2020, published July 2020
[3] Health care professionals' views about safety in maternity services, King's Fund 2008
[4] RCOG- Improving Patient Safety: Risk Management for Maternity and Gynaecology, Sept 2009
[5] www.hsib.org.uk
[6] GIRFT National Report – Maternity and Gynaecology, September 2021
[7] House of Commons Health and Social Care Committee: The Safety of Maternity Services in England, June 2021

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HUGHES V RATTAN [2022] EWCA CIV 107: NON-DELEGABLE DUTIES AND VICARIOUS LIABILITY: A CASE SUMMARY TO SINK YOUR TEETH INTO

By Abigail Telford, Specialist Clinical Negligence and Personal Injury Barrister at Parklane Plowden, Leeds

Summary

The Defendant was a dental practice owner who owed the Claimant a non-delegable duty of care in respect of the treatment provided to her by self-employed Associate Dentists. He was not, however vicariously liable for their actions on the basis that the relationship between the Defendant and Associate Dentists was not one akin to employment.

Case Note

Between August 2009 and December 2015, the Claimant received dental treatment at the Manor Park Dental Practice ("the Practice"). The Practice was owned by Dr Rattan ("the Defendant"), who was the principal dentist and Practice Owner.

The Claimant brought a claim against the Defendant in relation to treatment provided to her by four Associate Dentists.

The Defendant denied that he was liable either by virtue of vicarious liability or a non-delegable duty of care.

As a preliminary issue, the case addressed matters of the duty owed by the Defendant to the Claimant.

At first instance, Heather Williams QC (now Heather Williams J) found for the Claimant in relation to both vicarious liability and the non-delegable duty of care.

Non-delegable duty

On appeal the Court of Appeal held that the Claimant satisfied the five criteria identified by Lord Sumption at paragraph 23 of *Woodland v Swimming Teachers Association and others* [2014] AC 537 such that the Defendant owed her a non-delegable duty of care:

The Claimant was a patient and was therefore vulnerable or dependent upon the protection of the Defendant against the risk of injury.

An antecedent relationship between the Defendant and the Claimant was established on each occasion that the Claimant signed a Personal Dental Treatment Plan, which she was required to do before NHS treatment was carried out. This placed the Claimant in the Defendant's care because he was the owner of the Practice. The duty was a positive one to protect the patient from injury, not simply to avoid acting in a way that foreseeably caused injury, and it involved an element of control over the patient.

The Claimant had no control over how the Defendant chose to perform his obligations. Any preference she expressed to a choice of dentist was only a preference.

Criteria 4 and 5 were not in issue. The Defendant had delegated to a third party a function that was integral to the positive duty owed (4) and that party had been negligent in how it performed that function (5).

Accordingly, the appeal was dismissed.

Vicarious liability

Although the Claimant had been successful in respect of the non-delegable duty of care, the Court nonetheless went on to express its views as to vicarious liability on an obiter basis.

In summary, the Defendant averred that the judge attached too much weight to factors suggesting his relationship with Associate Dentists was akin to employment and insufficient weight to factors pointing in the other direction.

The Court noted that in *Various Claimants v Barclays Bank Plc* [2020] UKSC 13, Baroness Hale stated that "the question therefore is, as it has always been, whether the tortfeasor is carrying on business on his own account or whether he is in a relationship akin to employment with the defendant". The Court of Appeal found that in this case, this criteria was not met for various reasons including:

Associate Dentists were free to work at the Practice for as many or as few hours as they liked and for other Practice Owners and business owners.

The Defendant had no right to control nor had he sought to exercise any control over the clinical decision made nor the manner treatment was carried out.

Associate Dentists were responsible for their own tax and national insurance payments and were treated as independent contractors by HMRC.

The Defendant took most financial risks, but Associate Dentists shared the risk of bad debts.

Associate Dentists were required to indemnify the Defendant against any claims made against him in respect of their treatment of patients.

Although there were some factors weighing in the other direction, those factors did not outweigh other factors against a finding of vicarious liability.

Opinion

This is a useful case in when considering non-delegable duties of care and vicarious liability in that it sets out some of the factors that can work in favour and against such findings, particularly where there is not a clear employer-employee relationship.

First published on the Parklane Plowden website, 9 February 2022

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THE LAW ON CONSENT TO MEDICAL TREATMENT: THE FATE OF TWO GROUND-BREAKING AUTHORITIES

By Alexander Hutton QC, Hailsham Chambers

In recent years, the entitlement of individuals to make their own informed decisions about what happens to their bodies has been recognised increasingly by the courts, reflecting wider changes in society. People are less willing simply to accept the conclusion of a professional that, for instance, particular medical treatment is in that person's interests, without being in a position to know more about it themselves, to question or challenge the professional and in some cases to reject that advice.

The principle of personal autonomy in this regard underlies what, at the time, were seen as ground-breaking decisions by the UK's highest court in *Chester v Afshar* [2005] 1 AC 134 in the House of Lords and *Montgomery v Lanarkshire Health Board* [2015] AC 1430 in the Supreme Court. Both cases relate to allegations of non-disclosure of risk in obtaining the patient's consent in advance to particular medical treatment where that patient then goes on to suffer the very complication they were not warned about. This article considers what the longer-term impact on the law has been of each such decision. Has each proved to have been as revolutionary and game changing as they seemed at the time?

The Traditional Approach to the Law of Disclosure of Risks in Medical Treatment

In *Sidaway v Bethlem Royal Hospital* [1984] AC 871 Mrs S underwent spinal surgery and suffered a non-negligent complication of surgery, namely partial paralysis through damage to her spinal cord. It was agreed expert evidence that there had been less than 1% risk of this occurring, but she had not been warned in advance of that risk. Expert spinal surgeons agreed that it was an accepted practice of a responsible body of spinal surgeons not to warn of this risk as part of the consent process. Thus, if the *Bolam* test, from *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 (a doctor is not negligent if he/she acts in accordance with a practice of a responsible body of doctors in that specialism) applied to the principle of disclosure of risks to the patient, then the Defendant had a good defence to the claim.

The main question thus was whether the Bolam test applied to the disclosure of risks or whether "the doctrine of informed consent" should be adopted instead, i.e.:

1. Is the adequacy of the disclosure of risk in undergoing the recommended medical treatment a matter for the medical profession to determine itself as to what are its own acceptable standards (on the *Bolam* principle of judicial deference to those who undertake such treatment) – sometimes known as the "doctor-centred" approach, or
2. Is it to be determined by the patient's entitlement to have all the information which might reasonably be material to them in order for them to make up their own mind? This approach had been adopted in some other common law jurisdictions. This is sometimes known as the "patient-centred" approach.

By a 4-1 majority, the House of Lords decided that Bolam applied to the disclosure of risks of medical treatment just as it applied to all other aspects of medical treatment. Lord Bridge accepted that

there may be an exception to this if there was an obvious risk (he gave the example of a 10% change) of a seriously adverse outcome even if a responsible body of practitioners would not have warned of that risk. But that was as far as it went.

Reading those speeches now, there seems to have been a strong hint of paternalism in their approach: Doctor knows best, it is all very complicated and patients cannot be expected to absorb and process all the information, and furthermore they may as a result make "wrong" decisions by being scared off by an endless list of seriously adverse outcomes, where in fact the chance of each would be very small.

Lord Scarman was the only dissenting voice. He would have held that (a) it was not for the medical profession to determine what should and should not be disclosed, and (b) Patients have the right to self-determination over their own bodies: so doctors are required to provide all material information as to risks of treatment and alternatives, and then it is for the patient to decide in the light of this.

The Traditional Approach on Causation

If Mrs Sidaway had prevailed on breach of duty in contending that there was a culpable failure to disclose the small risk of a seriously adverse outcome, namely paralysis, then there is no doubt that in 1985, the hurdle she would have faced on causation would have been that she would then have to prove that, on the balance of probabilities, if she had been warned, she would not have gone ahead with the operation and thus would have avoided the paralysis. This is sometimes known as "but for" causation.

Judicial Disquiet about the Traditional Approach

From the late 1990s judges in the lower courts started to undermine the *Sidaway* approach on disclosure of risks as they did not like it in changing times. Lord Bridge's exception that if there was an obvious risk of a seriously adverse outcome (where he had used an example of a 10%) started to be applied in much less extreme circumstances. The language of the judges was very much of Lord Scarman's minority approach: human rights, bodily integrity and autonomy, self-determination: i.e. the patient centred approach. But, of course, they could not overrule *Sidaway* itself, just find a way around it in some cases.

Chester v Afshar[2005] 1 AC 134

The traditional approach in the context of consent to medical treatment was apparently blown open by the House of Lords in this case, albeit on the question of causation rather than on breach of duty.

This was another spinal surgery case, this time the relevant risk was 1-2% chance of post-operative non-negligently caused cauda equina syndrome, a life-changing condition which impairs bowel and bladder function and can sometimes have an effect on mobility. Ms Chester had the surgery and suffered cauda equina syndrome. The trial judge found that the spinal surgeon Mr Afshar had failed to warn Ms Chester of this risk. It is to be noted that the consent was taken only three days before the surgery.

However, on causation, he could not find that, had she been so warned, Miss Chester would have refused surgery altogether. He found instead that, if she had been warned, she would have put off having surgery at the scheduled time in order to discuss with others. And if she had decided to go ahead with surgery later, it would have been at a different time and possibly with a different surgeon. But it was found that the risks of non-negligently contracting the cauda equina would have been exactly the same on such a notional later occasion.

On a traditional approach to causation, her claim would have failed on causation, as she did not satisfy the "but for" test: she would ultimately have had the same operation and the risks on that occasion would have been the same as on the occasion she did have the operation. This

was acknowledged by all five law lords. But nevertheless, she succeeded in the House of Lords by a 3-2 majority. Why?

The majority created an exception to "but for" causation in these circumstances. They did so on the grounds of the need for the law to give proper effect to the principle of "personal autonomy" embedded in the principle of informed consent (and notwithstanding that *Sidaway* apparently remained good law at that time on the duty of care). As Lord Steyn put it: *"[The patient's] right of autonomy and dignity ought to be vindicated by a narrow and modest departure from traditional causation principles."* The function of the law was to vindicate the right to self-determination. The damage was thus to be considered *"intimately linked"* to the duty to warn and so sounded in damages.

Lord Hope said: *"I would accept that a solution to this problem which is in Miss Chester's favour cannot be based on conventional causation principles"*. But in this instance the doctor's essential duty to warn patients of risks would be "*hollow*" if these principles were to be adopted here to allow her to succeed. Further, if the traditional approach was adopted, it would punish the honest claimant who wasn't able to say that they would not have gone ahead with the operation.

Thus, the majority's decision was explicitly an exception to traditional causation principles on the basis of policy and not, as is sometimes thought, on the same grounds as the trial judge found, namely that traditional causation was satisfied where a patient would have delayed if warned and the risk would then only have been 1-2% on that notional later occasion.

However, there were powerful dissenting voices of Lord Bingham and Lord Hoffman. Lord Bingham considered that the majority view was *"a substantial and unjustified departure from sound and established principle"* and that a claimant is not entitled to be compensated for damages which was not caused by the negligence complained of.

Lord Hoffman used a casino analogy to critique the trial judge's approach that it was about as logical as saying that if one went into a casino and the chances of winning were 1 in 37, you would then go away and come back another day: *"The question is whether one would have taken the opportunity to avoid or reduce the risk, not whether one would have changed the scenario in some irrelevant detail. The judge found the risk would have been precisely the same whether it was done then or later or by that competent surgeon or by another."* He considered that it undermined the law to create exceptions to established principles where such an exception is not justified.

At the time, there was a lot of discussion as to whether the majority decision meant that this was an end to the need to prove causation of injury in non-disclosure of risk cases: all you had to prove was the failure to warn of a risk which ought to have been warned about, and the claimant then succeeded automatically on causation as the damage was "intimately linked" with the breach. Or was it a case of (as suggested the minority) "hard cases make bad law."

Montgomery v Lanarkshire Health Board [2015] AC 1430

Mrs Montgomery was a pregnant lady, and she was of small stature, she had longstanding diabetes, which made it likely her baby would be large and thus, combination with small hips, increased the risks of her baby's shoulders getting stuck during a vaginal delivery, known as "shoulder dystocia". Shoulder dystocia is dangerous as the baby cannot receive oxygen in that position and yet if the baby is pulled out, it can cause a brachial plexus (shoulder) injury. It was agreed expert evidence that there was, in her case, a 9-10% risk of shoulder dystocia occurring; a 0.2% risk of a brachial plexus injury, a 0.1% risk of prolonged deprivation of oxygen, and a less than 0.1% risk of cerebral palsy or death.

Mrs Montgomery had a vaginal delivery and her child suffered shoulder dystocia delaying delivery

for 12 minutes and resulting brachial plexus injury and cerebral palsy. She alleged a negligent failure to warn her of the risks of vaginal delivery in her case, and that if she had been warned, she would have opted for a Caesarean Section.

The obstetrician in question had not warned her of the risk of shoulder dystocia, let alone the risk of a brachial plexus injury or cerebral palsy. She argued that if you to warn diabetic patients of such a risk, *"then everyone would ask for a Caesarean Section and it's not in the maternal interests for women to have Caesarean Sections."* The lower courts in Scotland applied *Sidaway/Bolam* and found that a responsible body of obstetricians would not have warned of any of these risks and, even if she had been warned, she would have opted for vaginal birth anyway.

The Supreme Court disagreed. They finally adopted the doctrine of informed consent on the basis that things had moved on in society since *Sidaway*:

1. Patients are now accepted as having rights (including human rights), rather than merely being *"passive recipients of care from the medical profession"*;
2. They are consumers who exercise **choice**;
3. Patients have more information from the internet: there can no longer be a default assumption of **ignorance**;
4. **GMC guidance** about the doctor-patient relationship has changed (since at least 1998): it is a partnership founded on the basis that the doctor provides options with risks and benefits, and the patient decides.

Thus, the test in a claim which relies on non-disclosure of risk was set out at paragraph 87 of the Montgomery judgement:

"The doctor is under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in the recommended treatment, and of any reasonable alternative or variant treatments.

The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it."

Thus, *Bolam* is not a test that applies to all aspects of a doctor's duty to a patient in relation to treatment: it no longer applies to disclosure of risk/consent. There are further points to note about the judgment:

1. The approach to whether a risk is material cannot be reduced to mere percentages: the "materiality" of it varies, including the seriousness if it occurs – e.g. eye surgery on one eye when the other eye is already blind suggests an even greater need to disclose even tiny risks of blindness in such circumstances as the consequences are so much more serious;
2. The information provided must be comprehensible so that the patient understands and is in a position to make an informed decision.
3. Therapeutic exception – that the disclosure of the risks would harm the patient – is limited and should not be abused. It is rarely relied on.

The ultimate conclusion in the case was that, while the risk of brachial plexus injury or cerebral palsy was too small to need to warn about, the 9-10% of shoulder dystocia in that case should have been disclosed: it is a medical emergency in itself.

It is important to recognise that the duty probably goes beyond traditional negligence: even if the doctor has not disclosed a particular risk because, for instance, they were extremely busy dealing with an unexpected surge in patients and they did not have time to run through all the risks, and such an approach would be supported by a responsible body of such doctors, the doctor would nevertheless still be liable under the test in Montgomery. And it imposes on the doctor an obligation to assess what a reasonable patient

would want to be warned about, which may be difficult for them to judge.

On causation, the Supreme Court found that, if Mrs *Montgomery* had been warned of the significant risk of shoulder dystocia in her case, she would probably have opted for a Caesarean Section and the shoulder dystocia (and consequential injuries) would never have occurred. Indeed, that is what her obstetrician had said would happen if you warn diabetic patients of the risks of shoulder dystocia. They applied traditional "but for" causation. They stated specifically that it was unnecessary for them to consider whether "she might establish causation on some other basis in the light of *Chester v Afshar*". Thus, they gave no endorsement of *Chester v Afshar*.

Various criticisms have been made of *Montgomery*, including:

1. It is unfair to apply it retrospectively to consent taken before the decision in March 2015. But is that really true? The Supreme Court was relying on GMC guidance in place since the 1990s;
2. It works fine for elective surgery but what about the dynamic situation of labour: does the doctor have to outline the option of a Caesarean Section every time he/she reviews the patient? Undoubtedly the onus is greater in such moving situations.
3. Is the doctor obliged to outline all alternative treatments, even those they positively do not recommend just because another doctor might? The courts have yet to fully grapple with this.

But it is to be recalled that (subject to the courts approach to *Chester* discussed below), the Claimant has to prove causation: they would not have gone ahead with the treatment if they had known. And that is often a very difficult hurdle to clear, particularly where emergency treatment is required.

What is clear is that the old days of sending the SHO down to see the patient 10 minutes before the anaesthetic to get a piece of paper signed should be long gone. Consent matters, it needs to be taken seriously.

How have *Chester* and *Montgomery* worked in practice?

In *Duce v Worcestershire Acute Hospitals NHS Trust* [2018] EWCA Civ 1307 the claimant underwent a hysterectomy but had not been warned of the risk of suffering chronic pain, which she then went on to suffer. The gynaecological experts said that the risk of chronic pain after hysterectomy was not widely known by gynaecologists. The Court of Appeal held there was a two-fold test in this situation:

1. What risks were or should have been known by the medical professional in question. If not, there is no liability. That is a matter for the *Bolam* test;
2. If the risks should have been known, then whether the patient should have been told such risks by reference to whether they are material: that is a matter for the *Montgomery* test.

The Court of Appeal also considered the application of *Chester v Afshar*. The claimant failed on the "but for" test but argued that *Chester* applied. It was held *Chester* was limited to facts very similar to *Chester*, namely if they had been warned of it, they would have delayed treatment to think about it. Here, it was found the claimant would have gone ahead anyway on the same occasion.

In *Correia v University Hospital of North Staffs NHS Trust* [2017] EWCA Civ 356, the claimant had a neuroma in his foot, the surgeon set out a 3-stage treatment, with the third stage involved surgery with relocation of proximal nerve. However, when the surgery went ahead, the surgeon then failed to do the third stage. The claimant argued that *Chester* applied because the defendant had not performed the operation that the claimant had consented to, so that the claimant recovered damages without the need to prove any causation.

The Court of Appeal (Simon LJ) found:

1. The facts of *Chester* were unusual as the claimant had been "consented" on the Friday and had had the operation on the following Monday, and the finding was that the operation would have been delayed if there had been proper consent;
2. The application of *Chester* was limited to its own facts, that if warned, the claimant would have deferred the operation. It did not apply more generally;
3. Here the consent was appropriate when it was given, so the fact that the surgeon negligently omitted to move the neuroma did not vitiate her consent to the operation.
4. The omission in the operation was a separate breach of duty which could sound in damages if it was proved that it caused her injury.
5. If the claimant had been correct, there would have been far-reaching consequences about vitiation of consent, assault etc in relation to many operations;
6. If *Chester* is to be relied upon, it must be pleaded and supported by evidence. The injury here was not "intimately linked" with the duty to warn, and so *Chester* did not help the claimant.

Similarly, in *Brint v Barking, Havering & Redbridge University Hospitals NHS Trust* [2021] EWHC 290 (QB) HHJ Platts held that without the claimant proving deferral of the procedure if properly warned, Chester does not apply: the "But for" test applied as normal.

In *Mills v Oxford University Hospitals NHS Trust* [2019] EWHC 936 (QB) a surgeon recommended removal of a brain tumour by minimally invasive keyhole surgery without mentioning the option of the standard open operation, let alone the relative risks of each. Karen Steyn QC (as she then was) held that there was a duty under *Montgomery* to tell the patient your recommended treatment was new and the limitations of the research into it: you can recommend it, but you must balance it by telling them of the alternative and the relative risks and benefits. There was a breach of the duty to warn, and it was held the patient would have opted for the standard operation so he succeeded.

In *Price v Cwm Taf University Health Board* [2019] EWHC 928 (QB) Birss J (as he then was held that there was no strict principle that a doctor must warn the patient that their technique was not recommended in the NICE Guidelines: the consent process had to be looked at in the round and as a whole to see if it was adequate.

It is clear that a warning of the risks, even if the content was sufficient, given for the first time immediately before undergoing an elective procedure was not sufficient under *Montgomery*: see *Thefaut v Johnson* [2017] EWHC 497 (QB). The pressures of time and the psychological commitment to undergo the operation by that stage made it not compatible with informed consent. The position of course may necessarily be different in emergency situations.

One issue that has not been fully clarified in the authorities is the extent on the doctor to discuss alternatives, which the doctor reasonably thinks would be totally inappropriate, but which some surgeons might recommend.

Conclusions

Two cases, both revolutionary, but it appears only one has stood the test of time. *Chester* seemed to open a motorway for claimants but has turned out to be a cul-de-sac: judges don't like it because it conflicts with underlying established principles, and it has been confined to its particular facts (deferral of surgery). It is difficult to understand why, if it still exists, it should apply where the patient decides to defer surgery only for a day but not if the patient would have thought about it further but opted to go ahead at the planned time. It is to be wondered whether, if the point ever reached the Supreme Court, *Chester* might be put out of its misery.

In contrast, *Montgomery* has transformed the landscape and is raised in almost every clinical negligence claim. It has turned out to be a better expression of the patient's rights of autonomy. But while it is raised in many cases, often the challenge of traditional but for causation is the hardest to surmount.

WHAT NOW: VACCINATION AS A CONDITION OF DEPLOYMENT

By Martin Cheyne, Partner, Hempsons, Harrogate m.cheyne@hempsons.co.uk

Martin is an employment lawyer with the specialist healthcare firm, Hempsons

On 31 January 2022, Sajid Javid announced a reversal of government policy to implement mandatory vaccinations throughout much of the health and social care sectors. He explicitly stated that he was:

"announcing that we will launch a consultation on ending Vaccination as a Condition of Deployment in health and all social care settings"

The 2021 (Care Home) Regulations imposed mandatory vaccination for those who work in care homes. The new 2022 Vaccine as a Condition of Deployment Regulations (VCoD) applied much more widely in the health and social care sectors and were scheduled to come into place on 1 April. To revoke them, a statutory consultation is required first.

The Secretary of State has relied on the powers under sections 20(1) to (3) and (5) of the Health and Social Care Act 2008 to make the regulations imposing the VCoD requirements, and is relying on the same powers to repeal these requirements. These regulations concern the requirements on those carrying out regulated activities.

Section 162(3)(b) of the HSCA 2008 requires that for regulations to be made or altered under section 20, there must be a positive resolution of each House of Parliament. The reason for


Image: master1305

this, under HSCA 2008, is that the contravention of regulations made under section 20 can be an offence punishable by a fine. As such Parliament has, as is quite common for such provisions, required its consent to create or abolish criminal offences.

Section 20(8) of the Act also requires the Secretary of State to consult "such persons as the Secretary of State considers appropriate" before making such regulations, unless the regulations do not effect substantial change. It would be a difficult argument to make that the introduction or removal of these requirements do not amount to a "substantial change."

The government consultation was launched on 9 February and closed on 16 February 2022. The outcome of the consultation came out on 1 March 2022, confirming that the mandatory Covid vaccination requirements in Health and Social Care are being repealed from 15 March 2022.

The new Regulations revoking the 2021 Care Home Regulations and the 2022 Vaccine as a Condition of Deployment (VCoD) Regulations went before Parliament and were also formally "made" on 1 March 2022. They confirmed that from 15 March 2022, the mandatory vaccination requirements both in Care Homes and more widely with VCoD are being revoked.

Guidance

At the end of January, NHS England/Improvement issued an update and requested:

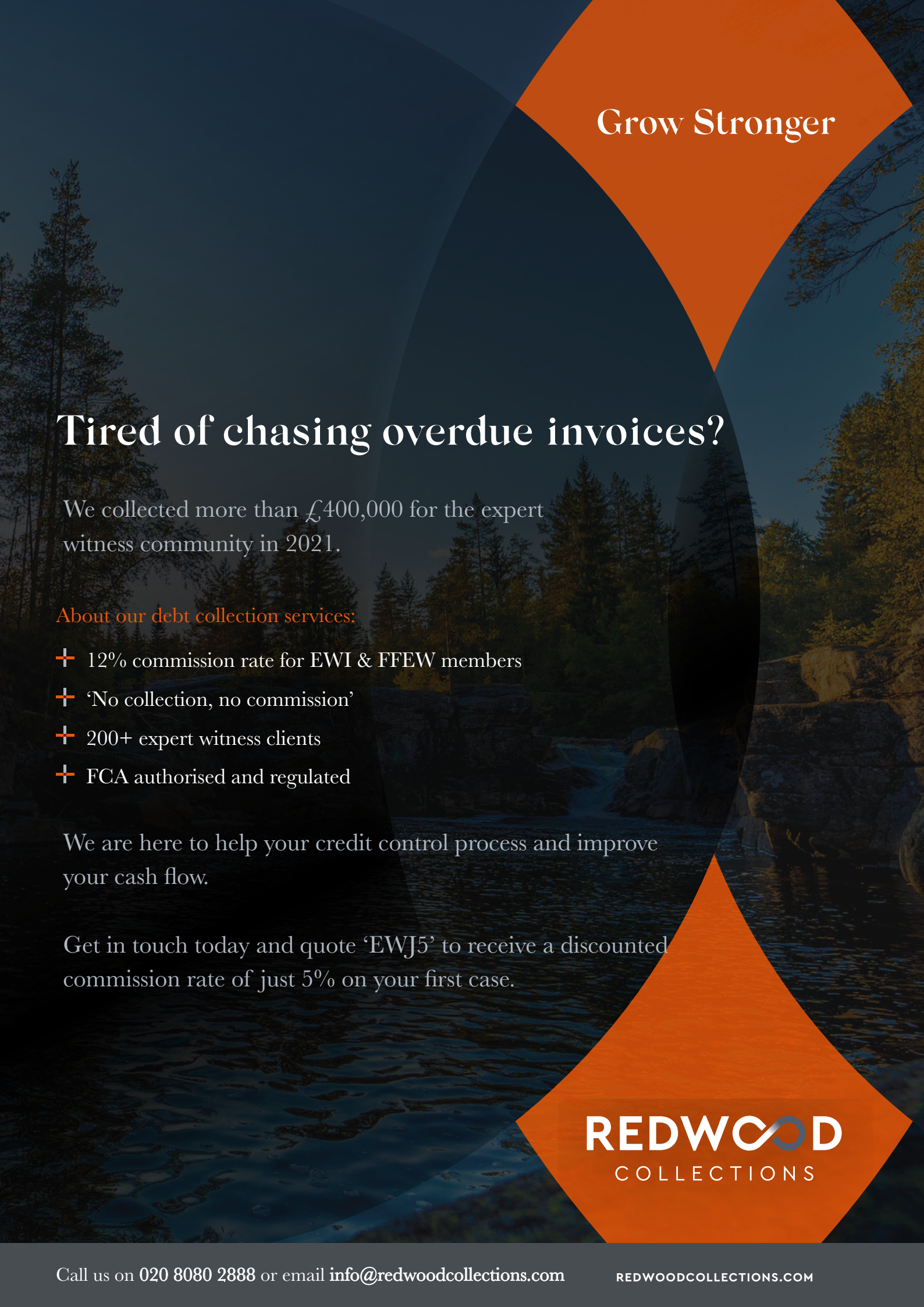
"This change in Government policy means we request that employers do not serve notice of termination to employees affected by the VCoD regulations"

What Now?

For staff recruited to commence employment on or after 15 March 2022, there is no longer a requirement that they be fully vaccinated. If staff who were not fully vaccinated left employment or were dismissed due to the Care Home vaccine Regulations, they can legally be re-engaged from 15 March 2022.

For those staff in the wider health and social care sectors who were subject to VCoD consultation about their vaccination status (potentially unvaccinated) and likely had their consultations paused, those consultations can now be ended. We finally have certainty and the 1 April 2022 deadline for mandatory vaccination will not now come into effect. For new recruits there is no longer a requirement that they be fully vaccinated.

For organisations liaising with their contractors to ensure VCoD compliance by staff not directly employed, those consultations can now also be concluded as contractor staff will also no longer need to be vaccinated. If mandatory vaccination obligations have already been imposed or agreed with contractors, then consideration should be given to reversing or implementing those obligations.



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MEDICO -LEGAL NEWS:

By Lisa Cheyne,
Medico-Legal Manager,
SpecialistInfo

A round-up of news in the industry for the last quarter of 2021 and early 2022.

NEWS

E-scooter reform needed as illegal rider makes injury claim

A private e-scooter rider, who was injured when he was overtaken by a London bus on a public road, could bring a test case for establishing liability rules in accidents involving e-scooters ridden illegally.

The claimant, a man in his fifties, suffered multiple injuries when he was in contact with the wing mirror of the bus in 2021. He was wearing a hi-visibility jacket and a helmet when the incident happened and took reasonable precautions to ride his e-scooter safely.

The current law states that a private e-scooter can be driven only on private land. The only legal e-scooters on public roads are those that can be hired through official schemes. That would appear to prevent anyone riding a privately owned e-scooter, who is injured on a public road, from bringing a claim against a motorist.

A cyclist with similar injuries would be able to claim for compensation.

The case should help to determine riders' rights to compensation if they are injured on public roads

Recently, the Department for Transport estimated that 750,000 private e-scooters were owned across England, based on survey results from its transport technology tracker.

Last year, the government wrote to retailers with concerns that they were not providing clear, visible and consistent information to ensure customers understood the law.

Read more: https://www.lawgazette.co.uk/news/lawyer-demands-e-scooter-reform-as-illegal-rider-makes-injury-claim/5111092.article

Clinical Negligence: Standard Directions Orders for use in County Court as well as High Court have been updated, January 2022.

The annotated version of the Updated Directions are probably most helpful (see link below).

In particular for expert witnesses:

Agendas and the input of experts into them:

If an agenda is used, "Claimants' solicitors and counsel should note the obligation to prepare the draft Agenda jointly with the relevant expert. Experts should note that it is part of their overriding duty to the court to ensure that the Agenda complies with the following direction which may be used:

The preamble should state: the standard of proof : the Bolam test : remind the experts not to attempt to determine factual issues : remind them not to stray outside their field of expertise and indicate the form of the joint statement. It will also be helpful to provide a comprehensive list of the materials which each expert has seen,

Alternative Dispute Resolution:

"At all stages the parties must consider settling this litigation by any means of Alternative Dispute Resolution (including round table conferences, early neutral evaluation, mediation and arbitration); any party not engaging in any such means proposed by another is to serve a witness statement giving reasons within 21 days of receipt of that proposal. That witness statement must not be shown to the trial judge until questions of costs arise".

Read more: https://www.gov.uk/government/publications/clinical-negligence-standard-direction-orders#full-publication-update-history

Government consultation on fixed recoverable costs launched 31st January 2022

A consultation on Fixed Recoverable Costs for Lower Value Clinical Negligence Claims was published recently by the Department of Health and Social Care (DHSC).

The main objective is to provide faster resolution, with legal costs that are proportionate to the value of compensation.

This consultation proposes a new scheme to enable claimants and defendants to achieve faster resolution of 'lower value' clinical negligence claims (claims valued up to and including £25,000) at a lower, more proportionate cost than under the current system.
This includes:

- a new streamlined process for claims
- limits to the amount of legal costs that can be recovered by claimant lawyers for lower value clinical negligence claims
- The proposals would only affect the amount of legal costs that claimant lawyers can recover following a successful claim, not the compensation that a claimant could receive.

The consultation runs from 31 January to 24 April 2022. It is available to view and comment on in the link below.

Read more: https://www.gov.uk/government/consultations/fixed-recoverable-costs-in-lower-value-clinical-negligence-claims

Four months until The Medico-Legal Conference 2022 in London on 28th June 2022.

Alexander Hutton QC, Hailsham Chambers, has agreed to be Keynote Speaker for the 2022 conference.
Several other speakers have now been confirmed including:

- **Lorin Lakasing,** Consultant in Obstetrics & Fetal Medicine, NHS
- **Pankaj Madan,** Barrister, Exchange Chambers & 12 King's Bench Walk
- **Flora McCabe,** Head of Healthcare Claims, Solicitor, Lockton LLP
- **Doireann O'Mahony,** Barrister, Bar of Ireland & Normanton Chambers
- **Angus Piper,** Barrister, 1 Chancery Lane
- **Prof Dominic Regan,** City Law School, London. Head of Know-How, Frenkel Topping. Legal Speaker, Writer and Broadcaster. Wine Critic, 'Counsel' Magazine.
- **Clare Stapleton,** Medicolegal Consultant, Medical Protection Society

Please visit the conference website below for more details and to secure an early-bird ticket for 2022:
www.medicolegalconference.com

Please contact craig.kelly@iconicmediasolutions.co.uk for further information if you are interested in sponsoring the programme or hosting a stand at the event in London on 28th June 2022.

The Healthcare Safety Investigation Branch (HSIB) Maternity Investigation Programme Report, and the New Special Health Authority (SHA)

Since April 2018 the HSIB maternity investigation programme has started over 1,000 independent safety investigations in NHS maternity services in England. Once completed, all maternity safety investigation reports are provided to the family and the NHS trust involved to ensure appropriate actions are taken.

Eight prominent themes have emerged through analysis of completed maternity investigations:

- Early recognition of risk
- Safety of intrapartum care
- Escalation
- Handovers
- Larger babies
- Neonatal collapse alongside skin-to-skin care
- Group B Streptococcus
- Cultural considerations

Future HSIB maternity investigations will now be conducted by a new Special Health Authority (SHA) after an announcement by Sajid Javid in late January 2022.

The SHA (as yet unnamed) will become operational over 2022-2023 for up to five years and will:

- Provide independent, standardised, and family-focused investigations to provide answers
- Provide learning to the health systems at reports to improve clinical and safety practices in Trusts
- Analyse data from investigations to identify trends and monitor improvements, or lack of improvements
- Be a system expert in standards for maternity investigations

Collaborate with system partners to escalate safety concerns and share intelligence

Read more: https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/hsib-national-learning-report-summary-themes-maternity-programme.pdf

https://www.hsib.org.uk/what-we-do/maternity-investigations/reports-and-publications/

Group Action Launched Alleging Treloar College Failed in Its Duty of Care for Children with Haemophilia in the Infected Blood Scandal

A group of survivors and relatives of people who died in the infected blood scandal are suing the school where they contracted hepatitis and HIV after being given experimental factor VIII treatment without informed consent.

A group action, lodged by Collins Solicitors in the High Court in January, alleges that Treloar College in Hampshire, failed in its duty of care to several pupils in the 1970s and 80s.

The claim, based on new testimony given by former staff at the school to the ongoing infected blood inquiry, could result in payouts totalling millions of pounds.

Read more: www.infectedbloodinquiry.org.uk

Image: Kiwis

Care home employee dismissed for refusing covid 19 vaccination in January 2021

An employment tribunal has found that a care home employee was fairly dismissed for refusing vaccination in January last year. The requirement was a reasonable management instruction and the employee had no medical authority or clinical basis for refusing.

It will be interesting to see what happens next if reversal of government policy on compulsory vaccination comes into force. See the article by healthcare employment lawyer Martin Cheyne in this issue.

Read more: https://t.co/9F79c1qvd0

GMC acknowledges the pandemic in fitness-to-practise cases

When assessing complaints, The GMC have updated their guidance about dealing with concerns arising during the pandemic. They have confirmed that they will take into account factors such as fatigue, availability of resources and workforce shortages experienced by doctors during the pandemic in their recent report: Supporting doctors during the pandemic - GMC (gmc-uk.org)

Read more: https://www.gmc-uk.org/about/what-we-do-and-why/data-and-research/the-state-of-medical-education-and-practice-in-the-uk

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