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Welcome to the Medico-Legal Magazine

Welcome to Issue 17 of the Medico-Legal Magazine, produced by SpecialistInfo and publishing partner Iconic Media Solutions Ltd.

This issue of the magazine includes a summary of the Medico-Legal Conference held in June.

Vinod Nargund, Consultant Urological Surgeon, highlights the best ways to avoid and handle patient complaints or litigation.

Beth Poland, indemnity expert from Servca, discusses the indemnity insurance options in healthcare.

Also in this issue, regular contributor and healthcare law expert, Laurence Vick, completes his 2-part article on safety issues arising with clinical guidelines and protocols.

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 is published on the Medico-Legal Section of the Specialistinfo.com website, 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

Contents:

04

SpecialistInfo Medico-Legal Courses 2020
By Lisa Cheyne

07

Avoiding Patient Complaints and Litigation
By Vinod Nargund PhD FRCSEd FRCSUrol FEBU

13

Clinical Guidelines 2 - the Potential Flaws in Clinical Guidelines: the Stenting v Surgery Controversy
By Laurence Vick

19

What are the Legal Requirements and Options Surrounding Medical Malpractice Insurance?
By Bethan Poland

21

Medico-Legal News
By Lisa Cheyne

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By Lisa Cheyne,
Medico-Legal Manager,
SpecialistInfo

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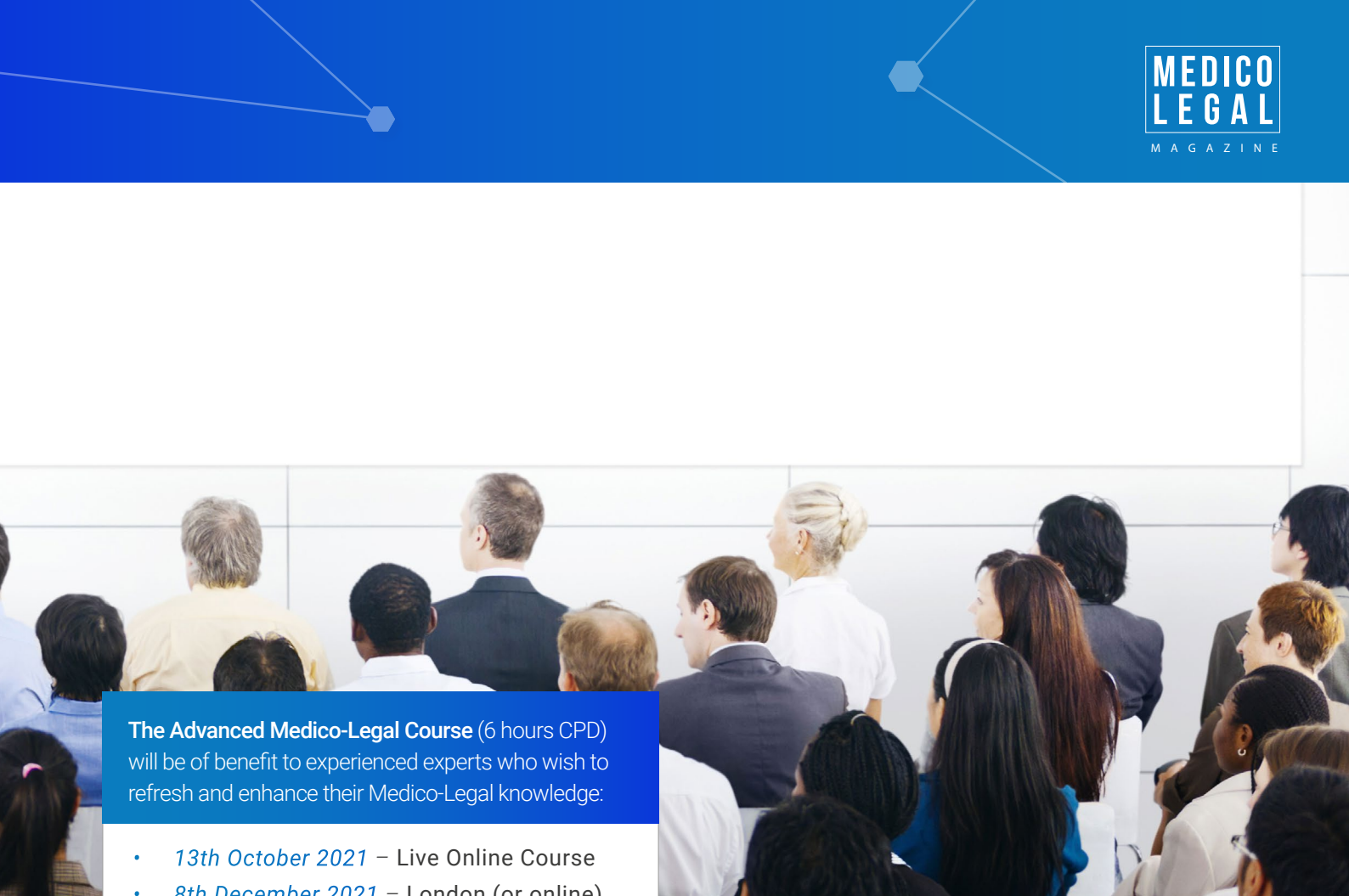
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Kind regards

Lisa Cheyne
Medico-Legal Manager



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AVOIDING PATIENT COMPLAINTS AND LITIGATION

By Vinod Nargund PhD FRCSEd FRCSUrol FEBU, Consultant Urological Surgeon, The Princess Grace and Wellington Hospitals, previously at Homerton and Barts Hospitals, London
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There are a variety of reasons why patients or their carers resort to complaints or litigation. Complaints are a way of showing their frustration or anger and even indicating a breakdown of communication between the doctor and the patient. Doctors and nurses care a lot about

patient complaints. Even a minor complaint from a patient can be quite upsetting and distressing for the doctor, leading to sleepless nights; particularly when they get a complaint from someone they thought had received unblemished care. On a positive note, complaints are an important source

of feedback from patients and can be invaluable in improving the quality of care, service and patient safety. They also help in raising the standard of care, improving patient experience and thereby helping in governance and delivering a higher quality care.

Any complaint has a potential to progress into a legal claim. In modern clinical practice any clinical mishap could escalate into a litigation. A complaint and a claim are two different categories. Although a complaint could often help the claimant (patient) in bringing a claim against a hospital or medical professional, it is not necessarily essential for claims of clinical negligence. Complaints, verbal or written, are managed according to the hospital protocol, whereas claims go through a tortuous course with the involvement of legal teams. It is possible to lessen the impact of litigation, even in indefensible cases, by following some ground rules. A good medical practice not only protects the doctor and their patient, also helps to prevent complaints and potential litigation.

The course of clinical negligence is complex, as a claimant takes their medical practitioner to a civil court for compensation. In some cases, there could be a criminal prosecution by the state. The claimant's solicitors investigate the claim by getting the clinical documents and then send a letter of claim which outlines the facts and sets out the details of breach of duty and causation. In successful civil actions there will be a monetary compensation to the claimant by the doctor's defence organisation or by their employing Trust. When there is a successful criminal prosecution by the state, the Defendant will get a custodial sentence and referred to the GMC. In any medical litigation, the clinical evidence is important, which means clinical notes are invaluable resources for doctors and the claimants alike and could ultimately determine the outcome. The onus, therefore, is on medical practitioners to follow good medical practice and adhere to the basic principles, thereby helping their own cause in the event of litigation.

Reasons for Complaints

1. Lack of Information. Patients say they did not get enough information or it was not clear. They may claim lesser involvement in decision making.
2. Poor communication, dismissiveness by the doctor, poor comprehension of the treatment options.
3. Slipshod consultations not allowing patients to address their worries, anxieties, insecurities; brushing off patients queries
4. Unprofessional behaviour
5. Inappropriate conduct or communication by the clinician
6. Treatment and its complications; adverse events (AE)
7. Quality of care and patient dignity and respect.
8. Administrative shortcomings - waiting times, delayed treatment, breach of confidentiality, cancellations, not giving enough notice.

Reasons for Litigation

1. Delay in diagnosis resulting in poor prognosis
2. Incorrect procedures/treatment/techniques/medications
3. Medical errors - during surgery, anaesthesia or a medical treatment with wrong dosage.
4. Adverse event

Progress of a Complaint

Once the complaint has been lodged and investigated through the NHS procedure, it could lead to:

1. A written response to the patient, who then has to lead the way further depending on whether they are satisfied. Most of the complaints are settled with an apology and proper analysis and explanation.
2. A disciplinary investigation of the doctor
3. The doctor being referred to the GMC
4. An inquest if the patient has died or institute a procurator fiscal enquiry in Scotland
5. The hospital instituting an audit on doctor's work
6. Criminal investigation by the hospital.



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Prevention

There is no single action that can prevent a complaint or litigation but for prevention. The cardinal rule is to be adhere to good medical practice at all times.

1. Rapport with the patient.

With the advent of the internet, patients do some research on your background and reputation. Be professional, stay out of religion, political beliefs, avoid any compliments on patient's appearance etc. Eye contact, listening, allowing the patient to express their concerns, showing empathy, appropriate body language. Being nice to them and their relatives are essential precursors for a good rapport. I prefer to give a free hand to my patient at the beginning and just listen to what they are saying. Surprisingly it is quite short and to the point, then I start my questions. Do not show your frustration or anger, which is really unfair and rude. Ideally consultation should go in an order - history taking, examination, investigations, discussion, questions and answers. If the patient forwards the test results to you even before taking any history, refrain from looking at them before taking the history and examination unless they are relevant to what information you are seeking.

When ordering investigations always explain why a specific test is needed and give a brief description how it is done. It is important to discuss the results and explain their significance. It is a dilemma when patient refuses to attend or fails to attend, particularly when they are in need of a further treatment for a life-threatening condition. It is vital to contact the patient or their family doctor in such cases. It is also necessary to do it in writing to the patient and their family doctor.

2. Helping hand, positive interaction and communication

Listening to patients sends a positive signal to the patient, it helps to build trust. Explaining medical jargon in simple language with diagrams is useful in furthering trust. Patients appreciate when you go that extra mile to guide and help them.

Contact details, in particular after surgery or hospital treatment, should be readily available to patients.

3. Documentation

Unambiguous record keeping, whether computer or hand-written is extremely important. Start with your name, date, time, place of consultation and type of consultation - new or follow up. Important medical history and allergy should be highlighted at the beginning. Good case records will not only help in the clinical management but also immensely aid in dealing with complaints or litigations. Medical records are crucial elements when a doctor is defending their case. In fact, documentation can make or break legal claims.

4. Discussing the treatment

Explaining the limitations of the treatment with honesty and transparency is our duty. Nobody expects doctors to know everything about every disease or treatment. If you are not aware of a condition, tell the patient you would like to get more information and would come back to them. If you are not sure about the dosage or side effects of a drug, refer to the sources such as BNF but explain to the patient why it is necessary to get the correct information. You could also say new data are added every year and it is obligatory to check all the details. However, it is unprofessional to google and read the contents to the patient. There are several disease/treatment-specific guides published by professional societies/associations and charities which could be given to the patient.

5. Asking for help

It is important for a doctor to know their limitations and when to ask for help, particularly when they are not familiar with a specific condition.

When a patient makes a bizarre decision, which is not in their best interest, and does not listen to your advice, it is important to advise the patient to get a second opinion and also help to facilitate it.

6. Surgical procedures

Make sure that you have the right diagnosis and be clear about the procedure you are performing. For

bilateral organs (like kidneys, limbs) the correct side is identified in the notes and marked on the body preoperatively. Pre-operative assessments are necessary to prevent cancellations on medical grounds. Consenting should be preferably done in the outpatient clinic when the patient is booked in for surgery; in the consent all material risks are explained to the patient and also alternative treatments. A copy of the completed consent form should be given to the patient to read and understand the contents so that the patient has opportunity to go through all the aspects of the consent and has enough time to clarify any doubts.

Preoperative and Postoperative Ward Rounds: Before starting your list do the preoperative ward rounds, preferably accompanied by a junior and a nursing staff, introduce yourself to the patients, check the consent and make sure all the imagery is available. Mark the side where indicated. Answer the queries patients/relatives may have. When the patient is on the table, look at the notes again after the theatre checks have been made and make sure that the correct procedure is being planned. Record the procedure step by step in a legible handwriting or on the computer sheet; also, difficulties encountered during the procedure and how they were addressed. If another surgeon is involved, they should write their part of the procedure. Add a diagram if required. Postoperative care instructions and contact number and name at the end of the record must be included in the operation notes. If you have relegated the care to another colleague, their name and number or contact details should be provided.

7. Multi-disciplinary team (MDT) meetings

The main purpose of an MDT meeting is to bring together a group of different specialists to plan the patient's clinical management. They are a great source of learning and help to improve standard of patients care and outcomes, and successful patient recruitment to the clinical trials. As far as the legal standing is concerned individual's duty of care still counts, as medical law does not include

groups, but MDT documentation is useful in the investigation of complaints and claims.

8. Handling the situation when things go wrong

Any operative intervention, major or minor, should be carefully monitored throughout until the patient is discharged from the hospital. Side effects and complications need to be identified and managed actively, which is only possible by a continuity of care with the help of a competent team and diligent recording of the events. While discharging from the hospital, patients should be advised about signs and symptoms that might warrant medical attention or admission.

Adverse Event (AE) is defined as an injury resulting in prolonged hospitalisation, disability or death caused by healthcare management (Rafter et al, 2015). Generally, a good number of AEs are preventable. It is important to know the protocol.

9. What do I do if I make a mistake?

This can happen to anyone and to those who have a totally unblemished career. Firstly, it is important to identify the problem and take a swift remedial action, and if necessary, take help of a senior colleague. Next contact your medical defence organisation and also the Clinical Director.

Then it is time to explain the events to the patient and/or relatives in an honest, truthful and transparent manner (duty of candour) and a plan of management. Listen to their concerns and explain how they would be addressed. It is important to apologise to the patient or family about the mistake. Please remember not all errors automatically count as clinical negligence and apologising does not necessarily put blame on you.

10. Patients' expectations

It is natural that patients and their relatives would like to hear positive aspects of their treatment. It is the responsibility of the doctor to give a correct explanation that should include pros and cons, ▶

side effects and complications of a treatment; also, other treatment modalities that are available for the condition, not forgetting to explain the likely results of those treatments or procedures. As mentioned above, consenting should be done at least 1-2 weeks in advance.

11. Do not make promises that you cannot keep

For example, you may say that you will definitely see the patient yourself on their next visit; let us assume that on patient's next visit you are on annual leave. It may erode the trust because patients do not understand how doctors work out their holidays!

12. Continuing Medical Education and Professional Development

Stay up to date with advances in your specialty. Reading relevant papers from specialty journals. Your specialty medical headlines in the lay press. Learn from your colleagues' mistakes. Maintain a high level of learning by reading specific articles in your specialty journals. Maintaining a logbook would be useful. Get involved in audit projects, writing guidelines and take up projects that are useful to the institution, community and your patients.

13. Appraisals and audits

They are supposed to reflect the clinical performance of a doctor and their competence. Keep them up-to-date. It is useful to document meetings, conferences, MDTs etc as you attend.

14. Administration

Referrals, new and follow-up appointments, results of investigations, MDT clinics, letters and maintenance of clinical records are all managed by non-clinical staff and it is crucial that these staff are well supervised, looked after and helped by the managers and medical staff. Mistakes in administration could be catastrophic in patients' care.

15. Interdepartmental communication

If the patient is seen in more than one department it makes sense that they communicate with each other about the patient's management.

References:

[1] Rafter N, Hickey A, Condell S, et al. Adverse events in healthcare: learning from mistakes. QJM 2015; 108: 273-77

Further Reading:

[1] A Review of the NHS Hospitals Complaints System- Putting Patients Back in the Picture. Final Report. Rt Hon Ann Clwyd and Prof Tricia Hart. October 2013.

[2] Panting G. How to avoid being sued in clinical practice. Postgrad Med 2004; 80: 165-167

[3] Good Medical Practice-GMC www.gmc-uk.org

CLINICAL GUIDELINES 2

THE POTENTIAL FLAWS IN CLINICAL GUIDELINES: THE STENTING V SURGERY CONTROVERSY

By **Laurence Vick**, Consultant Solicitor, Medical Negligence

 @LaurenceVick

Laurence is a regular contributor to Medico-legal Magazine and is an active patient safety advocate, following his retirement from practice in 2020. He has over 30 years' experience of clinical negligence litigation, representing claimants and their families in many high-profile cases, including the families affected by the Bristol children's heart surgery scandal of the 1990s.

This follows my first article commenting on the HSIB final report of 17 December 2020¹, following their investigation into safety concerns over placement of nasogastric (NG) feeding tubes (see Medico-Legal Magazine, Issue 16).

Despite patient safety alerts and warnings, and the fact that misplacement had continued to result in severe complications and avoidable harm to patients, some practitioners had admitted to HSIB investigators that they were aware of the existence of guidelines issued by the Society of Radiographers in 2012 intended to avoid this preventable error – an NHS “Never Event” - but had not read them as they were “too long to read.”

The failure of individual Hospital Trusts to ensure awareness and implementation of the established guidelines by their staff through rigorous clinical governance came as a major surprise.

In recent years there has been a significant increase in clinical guidelines and protocols issued at local, national and international level by professional bodies, regulators, Royal Colleges, NHS Trusts and other organisations. They provide

the courts with a benchmark by which to judge clinical conduct. Although they do not set legal standards for clinical care, inevitably guidelines and protocols are likely to play an increasingly important part in a clinical negligence claim. As more cases are reported in which the relevance and effect of a guideline is a material issue, we will gain a better idea of the weight a court may give to a guideline and the implications for a negligence claim of a medical practitioner complying or, on the other hand, failing to comply with a particular guideline.

Where a guideline relevant to a particular form of treatment is endorsed as authoritative by an expert, the Court will usually give significant weight to that evidence, but only as part of the overall expert evidence.

The Sepsis 6 guidelines (reflected in NICE guideline 51²) are perhaps the closest we get to Commandments: protocols that are clear and unambiguous, known and respected universally, which must be obeyed without good reason. Negligence claims on behalf of injured patients in which the guidelines for the diagnosis and early management of this life-threatening illness have not been followed would be difficult to defend.

There must be a presumption that doctors should be aware of current guidelines relevant to their practice areas as part of their duty to exercise reasonable skill and care, even in those specialties in which keeping up to date with journals and guidelines amounts to a significant burden. Many

clinicians are likely to feel that they now face a deluge of guidelines from multiple sources. GPs, for example, will often see patients with multimorbidities, so compliance with a number of single disease guidelines is not without its difficulties.

It is doubtful that a Court would be sympathetic to any suggestion that guidelines should not apply because they were prolix, and practitioners, although aware of their existence, don't have time to read them. Similarly, ignorance of an authoritative, relevant guideline would be unlikely to afford a defence.

In this article I have considered the potential arguments that might be raised to challenge the validity of an apparently trustworthy, authoritative guideline.

It isn't clear to what extent a Court will be prepared to consider detailed argument between the parties over the validity of a particular guideline, how it was developed and the process by which it has been adopted by professional organisations and other bodies. To be accepted as authoritative in a particular area of clinical practice a guideline should result from an unquestioned process, reflecting evidence-based research.

NICE recommendations, for example, are stated to be based on 'systematic reviews of best available evidence and explicit consideration of cost effectiveness. When minimal evidence is available, recommendations are based on the guideline development group's experience and opinion of what constitutes good practice'.

The European Society of Cardiology (ESC) states on its website³:

"A great number of guidelines have been issued in recent years by different national and international organisations. However, this profusion of documents can endanger the authority and validity of guidelines, which can only be guaranteed if they have been developed by an unquestionable decision-making process. This is one of the reasons why the ESC and others have issued recommendations for formulating and issuing guidelines".

Guidelines - usually based on the results of extensive research and randomised controlled trials - may provide more up-to-date evidence of a current standard of care than a textbook, which may have taken several years to be published. As such they provide evidence to which a Court can refer in assessing the appropriate standard of care.

The problem of conflicts of interest

The validity of a guideline may be in dispute where research or the guideline development process has been tainted by an actual or potential conflict of interest or bias reflecting a perceived lack of impartiality. The process by which the authors of a research study cherry-pick the positive results that support the conclusions they are seeking to achieve and ignore or downplay any adverse results that are nevertheless relevant is known as 'selective outcome reporting'.

As it was put in the Lancet 31 August 2019 study *Managing Conflicts of interest in Clinical Guidelines*⁴ "Conflicts of interests are pervasive in medicine, and their influence on guidelines impacting on patient care has been a major concern."

Ideally there should be clear separation between those running clinical trials and those responsible for formulating guidelines arising from those trials, however, the difficulty is that in the absence of industry support, expensive trials - in some cases taking place over many years - would not take place.

There have also been instances of conflict between guidelines issued by different organisations representing practitioners in the same field.

Published guidelines provide guidance to facilitate and promote good medical practice. It is unlikely they will be accepted as a substitute for conventional expert evidence in a clinical negligence trial. Claimant and Defendant lawyers need to be alive, however, to the potential for challenging an expert's assertion as to an appropriate standard of care by pointing to differing opinions evident from the body of

contemporaneous information that has informed and led to the adoption of a particular guideline. A relevant research study resulting in the adoption of an evidence-based guideline may well be preferred over an individual expert's assertion, for example, to support a Bolam 'reputable minority' defence. Since the 1997 Bolitho case⁵ the court will in any event examine the expert evidence and may subject a form of treatment and any relevant guideline to logical scrutiny and conclude that negligence has been established even if a body of medical opinion suggests otherwise.

Guidelines are introduced into the court process by expert witnesses as evidence of accepted and customary standards of care. The mere fact that a guideline exists can neither establish its authority nor support the view that in the circumstances before the court, compliance with the guideline would be reasonable and non-compliance negligent.

Guidelines and protocols did not play a significant part in the paediatric cardiology and cardiac surgery cases in which I specialised following my involvement for the families in the Bristol Royal Infirmary Public Inquiry⁶ into the shortcomings at the children's heart unit and related litigation (see Medico-Legal Magazine, Issues 15 and 16). In this high-risk specialty the experience and skills of the medical and surgical team are crucial. The liability issues are likely to be multifactorial and may depend on the age of the child, the type of congenital heart defect, the form of surgery involved, the complexity of the child's medical condition and any co-existing cardiac defects and co-morbidities, the accuracy of diagnosis and timing of surgery, the post-operative care and the way in which the unit or surgeon was able to cope with the complications inherent in these procedures.

Achieving the appropriate level of scientific significance in paediatric cardiac surgical and cardiological procedures, in order to formulate evidence-based guidelines, has been a problem as a result of the lack of sufficiently large cohorts

of comparable cases. Single centres may not deal with adequate operation numbers to enable proper classification and comparison, making it difficult to establish standards of care and form robust conclusions. With low patient numbers there may otherwise be a tendency to lump similar but technically different conditions together because the necessary granularity of data isn't available.

Those practicing in adult cardiology, on the other hand, have to be familiar with multiple guidelines. A substantial number of guidelines and methodologies in the adult cardiovascular field have been published by the European Society of Cardiology (ESC) and it's US counterpart the American Heart Association (AHA). These cover a wide range of cardiology procedures and treatments including coronary artery bypass grafting (CABG) and stenting, management of thrombolysis, diabetes and pre-diabetes, heart failure, myocardial infarction, as well as the use of aspirin and statins.

The majority have been accepted as authoritative and reliable but there have been instances of conflict between the guidelines issued by the European and American bodies. Differences of opinion between professional bodies can occur across other areas of clinical practice, but the issues of contention that have arisen in cardiology demonstrate the importance of examining the guidelines development process itself.

A number of cardiovascular and adult cardiology trials and guidelines have generated controversy. The large-scale EXCEL study⁷ (Evaluation of XIENCE versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization) into the merits of coronary artery bypass grafting (CABG) over stenting is a case in point. CABG involves open-heart surgery, with longer hospital stays and a longer period of recovery and rehabilitation than occurs with stenting. Stenting (percutaneous coronary intervention - PCI) is a minimally invasive procedure involving coronary angioplasty using a balloon catheter to widen blocked or narrowed arteries, combined with a

drug-eluting stent coated with medication to help prevent blood clots inserted into the artery to allow blood to flow more freely.

As a minimally invasive procedure enabling a speedier recovery and a shorter period of hospitalisation, stenting has a number of advantages over CABG. A question has nevertheless remained over the comparative effectiveness of the two procedures over the longer term.

The EXCEL trial sponsored by the US medical technology company Abbott Laboratories followed 1900 volunteers with left main stem (coronary) disease (LMS) over a five-year period.

The coronary stent market in the US, dominated by major companies including Medtronic, Boston Scientific as well as Abbott Laboratories is currently worth approximately US \$10.31 billion annually, an annual compound growth rate of 7.6% over the last 5 years.

The study's authors concluded that bypass surgery and stents were equally effective in the prevention of deaths in patients with less severe forms of LMS and that clinical outcomes after 5 years were similar. This led in 2018 to the European Association for Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC) revising and updating their guidelines.

The study was dogged by controversy over the reported rates of mortality following heart attacks and the actual definition of heart attack (myocardial infarction) which was felt to be crucial to the analysis of outcomes. This was the subject of a BBC Newsnight programme on 18 February 2020⁸, which reported the view of some experts that if the "Universal Definition" was adopted for the definition of a heart attack, rather than the "popular standard definition" developed by the Society for Cardiovascular Angiography (SCAI) and Interventions used by the EXCEL authors, patients receiving a stent were at higher risk of heart attacks than those who underwent CABG. The dispute over how to define a heart attack

and the implications for the study's conclusions was reported to have prompted some European clinicians to question these findings. The EACTS, the body representing European cardiac surgeons, was reported to have withdrawn support for the updated European guidelines that reflected the recommendation of stenting or open heart surgery as equally effective, saying that it was "a matter of serious concern" that some patients may have received incorrect advice and that "patients with left main coronary artery disease treated with stents were 35% more likely to die than those treated with conventional open heart surgery."

Patients, particularly in the post-Montgomery⁹ era, are of course entitled to be advised as to the options and the comparative advantages and risks of each procedure as part of the consent process.

The ESC stood by its revised guidelines, stressing that they were based on wider evidence in addition to the results of the EXCEL study. The EXCEL authors responded that the Universal Definition "was not suitable" for comparing the two procedures. The Universal Definition requires a highly sensitive blood test to identify damage to the heart muscle, a test so sensitive it may detect minor damage caused by the procedure itself. Many doctors, they said, don't perform this test on patients undergoing stenting or CABG. The EXCEL authors argued the higher mortality rate in the stent group was largely due to causes that were not heart-related, particularly cancer and infections that appeared several years after stenting or surgery. They said there had been no attempt to hide meaningful data - the EACTS had withdrawn from the guidelines "without so much as even asking the EXCEL study group for clarification."

In order to restore public and patient trust in these findings, and good relations between the stenting and cardiothoracic communities the EXCEL trial is undergoing independent review.

Guidelines and their impact on women's health

Numerous studies in recent years have demonstrated that heart disease and the ways

in which it can uniquely and specifically affect women has been under-researched and women continue to face a greater risk than men of having their heart conditions misdiagnosed, diagnosed late or not treated as intensively or as effectively when a diagnosis has been made. This potential for disparity in treatment options and outcomes for women reflects what is seen as a gender bias, whether conscious or implicit, and represents a health disadvantage for women who are losing out on treatments that may result in better management of their symptoms and improvements in their quality of life. The concern is that guideline-recommended tests and therapies have been based on studies and randomised controlled trials in which women have been under-represented as participants and therefore do not reflect the difference in presentation of women's symptoms. Higher representation of women as authors has also been associated with a higher recruitment of women to join studies. There has been an increase in research into sex differences in heart disease and there is likely to be a corresponding increase in the release of guidelines specific to women and gender-based revision of existing guidelines.

Conclusion

Inevitably guidelines will have implications for a Court's determination of the relevant standard of care in a particular case, but we are a long way from a Court finding that a failure to adhere to a relevant guideline automatically amounts to breach, or that compliance enables a Defendant to escape liability. Clinical negligence remains a field in which lawyers are heavily reliant on expert evidence in its traditional forms: written reports and oral evidence based on an expert's clinical experience of standards at the time when the treatment took place, supported by published sources including textbooks and journals.

As stated, guidelines are not a substitute for experience and informed clinical judgement, and it remains to be seen if guidelines will usurp the role of expert evidence. In the meantime, we are likely

to see an increase in legal scrutiny of guideline development procedures and challenges to their validity in negligence claims coming before the courts.

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WHAT ARE THE LEGAL REQUIREMENTS AND OPTIONS SURROUNDING MEDICAL MALPRACTICE INSURANCE?

By Bethan Poland, Group Marketing Manager, Servca

Here at Servca, we understand that the Medical Indemnity market can be a very overwhelming place. It's hard to know where to go and whom to trust. Sometimes it can be very hard to tell what it is you actually need in the first place. Indemnity comes in different shapes and sizes, dependent on various factors, including medical speciality, treatments provided, and number of patients seen.

Another way of looking at it is how much exposure (of a claim) there is to the indemnifier.

In the UK, it is a legal requirement to hold appropriate Medical Indemnity. Within the NHS, the Crown extends Indemnity for negligence, but there needs to be additional cover for regulatory or disciplinary hearings. In private practice, Indemnity needs to be arranged ground up (to include claim compensations).

There are various Indemnity providers, but not all coverages are equal, and importantly not all coverages extend guaranteed cover. If Indemnity is not adequately arranged, it could leave you personally liable to pay for defence costs and even claims compensations.

Therefore, it is essential to understand the different options available to you and the main differences between 'Discretionary Indemnity (through a Medical Defence Organisation) and 'Contractual Indemnity' (an insurer).

Discretionary & Contractual: What do they mean?

Discretionary Indemnity is coverage provided by a Medical Defence Organisation. As suggested, this type of Indemnity is at the discretion of the

Medical Defence Organisation and therefore it is not guaranteed to be provided if a claim is made. If the Defence Organisation does not accept a claim, the medical practitioner will be personally liable for any claim-related costs.

On the flip side, Contractual Indemnity is coverage bound by a contract. This is provided by a commercial insurer through a specialist broker, like Servca. The majority of these contractual policies work on a claims-made basis, covering you for any claim made during the active time of coverage.

So, in short, Discretionary Indemnity means there is no guarantee your insurer will pay-out, meaning you have to pay out of your own pocket; whereas, Contract-certain Indemnity means you have guaranteed cover from your insurer within the terms of a policy.

Claims Made Vs. Claims Occurred

You will often see various insurance clauses and terminology on your quote documents and insurance contracts. It is essential that you understand exactly what your insurance policy covers you for and for what periods, as this can often be the deciding factor in a claim being paid out or rejected by insurers.

A claims-made policy is an insurance policy that covers an insured for claims on active policies, regardless of when the claim event occurred. Medical Malpractice and Professional Indemnity are 'claims-made' insurance contracts. Therefore, if the policy stops, gets cancelled, or lapses, so does the cover. For this reason, 'run off' cover

should be purchased when you/your business ceases to trade/work, either due to the closure of a limited company, partnership dissolution, or retirement.

However, claims occurring policies will respond to the claim regardless of when the claim is reported, even if you have changed insurers, cancelled or lapsed the insurance policy. This is a rare type of insurance coverage, as the insurers have a long-tail exposure, meaning that they are covering you for many years in advance in the event a claim is reported. It is also important to note that if you have an occurrence policy, it is still up to the Medical Defence Organisation whether they do or do not provide any representation, legal costs, or claim pay-outs.

How does this affect Medical Indemnity Cover?

Contractual Indemnity will always cover you for claims agreed within the contract, whereas Discretionary Indemnity policies can be selective, leaving you responsible for paying for whatever they refuse to cover.

One of the reasons you may want Indemnity in the first place is to protect you from devastating financial losses in the event of a very serious claim. Policies are agreements where an insurer agrees to pay off a claim regardless of the overall cost or how much you initially paid.

So, which should you choose?

As specialist Medical Malpractice providers, we strongly recommend Contractual Indemnity coverage, as you get what you have actually paid for - coverage that protects you from claims made against you. This is why Servca only offers contractual Indemnity and never discretionary. Via contractual cover, your insurers will have to pay off any claim made within the agreed guidelines of your insurance policy, and you would only be required to pay for the policy itself.

Sure, there is always the chance you might never receive a claim, but is it worth the risk? Claims can

be managed but they can't be fully prevented from happening. The risk you take as a practitioner and the kind of policy you pick either reduces or increases how vulnerable you are to that risk.

No matter how good you are at your job, you should prepare for a worst-case scenario.

If you are unsure what kind of policy you have and are worried you may have accepted Discretionary cover over Contractual, our consultants can answer any questions you have about your policy. In addition, we offer a free silent review service where we will happily talk you through your policy and inform you of any risk exposures you may be partial too.

If you are interested in knowing more about our Silent Review service or how you can go about getting Contractual Indemnity, we are available via 0207-846-9010 and info@servca.com.

MEDICO -LEGAL NEWS:

By Lisa Cheyne,
Medico-Legal Manager,
SpecialistInfo

A round-up of news in the
industry for the second quarter
of 2021

New whiplash rules and tariffs came into force from 1st June 2021

NEWS

All RTA claims worth less than £5,000 will now go through the new claims portal designed to be used by unrepresented litigants and, in theory, result in quicker settlements with insurers.

<https://www.officialinjuryclaim.org.uk/>

This follows recent updates to the Civil Procedure Rules as summarised below on gov.uk:

These Rules amend the Civil Procedure Rules 1998 (S.I. 1998/3132). The amendments give effect to, or are consequential upon—

(a) changes to Part 26 of the Civil Procedure Rules regarding the allocation of personal injury claims arising from road traffic accidents which occur on or after 31st May 2021 to the small claims track and fast track;

(b) new Practice Direction 27B: Claims Under the Pre-Action Protocol for Personal Injury Claims Below the Small Claims Limit in Road Traffic Accidents – Court Procedure; and

(c) the Pre-Action Protocol for Personal Injury Claims Below the Small Claims Limit in Road Traffic Accidents ("the RTA Small Claims Protocol").

Updated civil procedure rules and full explanatory note can be accessed below.

Read more:

<https://www.legislation.gov.uk/ukxi/2021/196/contents/made>

Personal Injury and insurance companies announce partnership

Personal Injury firm Minster Law has announced five-year deals under which it will act for customers of insurers esure Group and LV= in motor personal injury and other legal claims. The aim is to 'simplify the claims journey' with digital technology, including the portal introduced under the PI reforms.

Commenting for esure Group, Graham Hughes, Chief Claims Officer, said: "We were impressed by Minster Law's appetite to look at motor claims differently and capability

to provide a digital offering for our customers. We have a shared desire to support our customers at a stressful time. The recent reform in motor personal injury is an opportunity to 'iron out' poor practices and simplify the claims journey."

The new claims portal is seeing a shift in the way lower value claims are being handled across both the PI and insurance industry.

Read more:

<https://www.minsterlaw.co.uk/news/>

Mandatory (alternative) dispute resolution (ADR) is lawful and mediation should be encouraged

The Civil Justice Council's report on compulsory alternative dispute resolution (ADR) was published in July.

In January 2021, the Master of the Rolls asked the Civil Justice Council to report on the legality and desirability of compulsory ADR.

The report concludes that mandatory (alternative) dispute resolution is compatible with Article 6 of the European Human Rights Convention (the right of access to a public trial) and is, therefore, lawful.

Chair of the Judicial/ADR Liaison Committee, Lady Justice Asplin DBE, concluded:

"We think that introducing further compulsory elements of ADR will be both legal and potentially an extremely positive development".

"We would make three specific observations:

1) Where participation in ADR occasions no expense of time or money by the parties (as with answering questions in an online process as to a party's willingness to compromise) it is very unlikely that the compulsory nature of the system will be controversial – as long as the ADR is otherwise useful and potentially productive.

2) Judicial involvement in ENE, FDR and DRH hearings is proving highly effective and these are of course available free to the parties. Again as long as they seem appropriate for the particular type of case being

considered and can be resourced within the court system, we cannot see that compulsion in an even wider range of cases will be unacceptable.

3) We think that as mediation becomes better regulated, more familiar and continues to be made available in shorter, cheaper formats we see no reason for compulsion not to be considered in this context also. The free or low-cost introductory stage seems the least likely to be controversial. Above all, as long as all of these techniques leave the parties free to return to the court if they wish to seek adjudicative justice (as at present they do) then we think that the greater use of compulsion is justified and should be considered".

In response to the report, the Master of the Rolls, Sir Geoffrey Vos, chair of the Civil Justice Council and Head of Civil Justice, said: "I am grateful to Lady Justice Asplin and the working group for this excellent report. They conclude that it is possible, where a court process remains available, lawfully to mandate (alternative) dispute resolution".

Read more: <https://www.judiciary.uk/wp-content/uploads/2021/07/Civil-Justice-Council-Compulsory-ADR-report.pdf>

If you are interested in training to become a Civil Mediation Council Accredited Mediator, then have a look at the Mediation courses available on the SpecialistInfo training page:

https://www.specialistinfo.com/a_ml_mediation.php



The Medico-Legal Conference – 24th June 2021, held virtually this year, was a resounding success.

Speakers included the Keynote Address from Mr Justice Pepperall, High Court Judge and barrister member of the Civil Procedure Rule Committee and the chief architect of the 2015 reforms to Part 36, "A Judicial Perspective on Expert Evidence" and Master of Ceremonies, Professor Dominic Regan, Civil Litigation expert who spoke about "Vicarious liability for wrongdoing".

In his second year speaking at the conference, Warren Collins, Partner at Penningtons Manches Cooper – international commercial/shipping practice that handles Claimant and Defendant PI work, and also Chief Assessor of Law Society PI Accreditation and Assessor for APIL Brain Injury and Spinal Cord Injury Specialist Accreditation, was very well received with his "Top Tips for Medical Experts".

Covering a lot of information in his allotted time, including: Do I have the expertise and what am I letting myself in for; Roles and obligations – contents of report; Seeking Directions from Court; Depositions, Joint Discussions, Settlement Meetings and Going to Trial; Reputation, repeat business and getting paid.

Also highly rated by delegate feedback, Alexander Hutton QC, Hailsham Chambers, summarised "The Latest on the law of Consent to Medical Treatment". Running through some recent important cases, including Montgomery, and covering application in new/novel/innovative treatments, duty to warn of departure from NICE Guidelines, and is a warning on the day of elective surgery sufficient?

Jeff Zindani LLB, MA Solicitor and Management Consultant, brought conference up to date on the "End of Whiplash?: The New Landscape for Low Value RTA Claims."

Covering: Civil Liability Act 2018 ("CLA")-Key Provisions; Definition of Whiplash and the Regulations; The Tariff Figures and a Reality Check; Exceptions; MEDCO; Market response and What Next?

Simon Hammond, Director of Claims Management NHS Resolution, spoke about the use of alternative dispute resolution in negligence claims in his talk entitled "The Opportunity for Change", as well as touching on the pandemic response in healthcare with the Coronavirus Act 2020 and the Clinical Negligence Scheme for Coronavirus (CNSC).

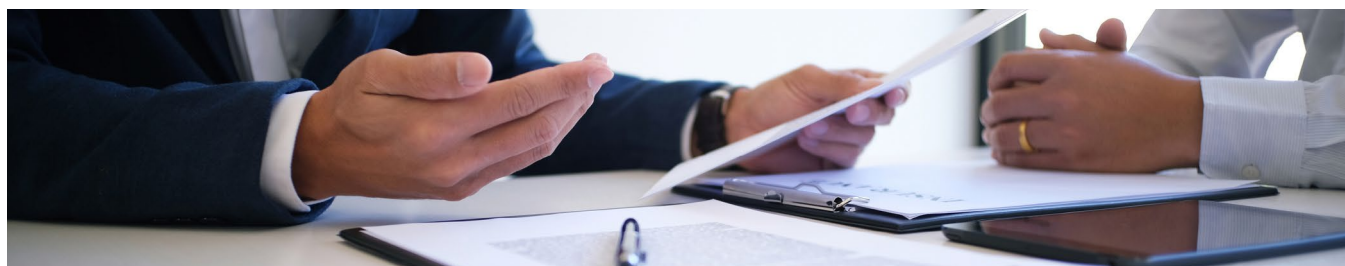
Lionel Stride, Barrister, Temple Garden Chambers, discussed in more detail "Covid-19 in a medical negligence context". His Key Topics included: Litigation risks faced by healthcare provers (hospitals and care homes); Non-delegable duty to provide 'safe systems of work'; and Legal Defences.

Look out for articles in upcoming issues of Medico-Legal Magazine from Alex Hutton, Lionel Stride and Simon Hammond on these topics.

If you missed the event this year, then please visit the website where the 2021 recording and materials from all the speakers can still be downloaded, and early-bird tickets are already available 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 next year in London on 28th June 2022.



Learning from Litigation Claims

The Getting It Right First Time (GIRFT) and NHS Resolution best practice guide for clinicians and managers was released in May.

The guide reports that, "As GIRFT clinical leads have visited trusts across England it has been clear that many clinicians and managers are unaware of the claims against their department.

"It is important that trusts recognise the direct link between clinical incidents, claims for compensation and their financial contribution to the Clinical Negligence Scheme for Trusts (CNST)."

The guide gives a recommended structure for learning from clinical negligence claims that should be led by trust legal departments, supported by clinicians and managers.

The application of GIRFT methodology in obstetrics and orthopaedics, for example the Maternity Incentive Scheme and the Early Notification scheme, has already helped to ensure that learning is shared across departments to improve safety and drive better patient outcomes.

The guide recommends, "Claims learning should have the same parity as learning from clinical incidents. It is a rich resource to help improve patient safety in addition to learning from complaints, incidents and inquests."

Read more:

<https://www.gettingitrightfirsttime.co.uk/wp-content/uploads/2021/05/Best-practice-in-claims-learning-FINAL.pdf>

Bux v The General Medical Council [2021] EWHC 762 – GP struck off for holiday sickness racket.

GP Dr Zuber Bux appealed against the findings of the Medical Practitioners Tribunal and against the decision directing his erasure from the Medical Register in 2019. Mr Justice Mostyn dismissed his appeal agreeing that he dishonestly and deliberately wrote formulaic reports diagnosing food poisoning.

Dr Bux acted as an expert witness preparing medico-legal reports in respect of holiday sickness claims from a firm of solicitors in which his wife was a salaried partner. He gave deliberately false answers to questions posed to him as an expert witness and he made diagnoses without proper evidence and without identifying the existence of a range of opinions.

The High Court judge said: "...he produced expert medical reports on an industrial scale." Dr Bux wrote nearly 700 reports between 2016 and 2017 generating over £100,000 for Bux Incorporated Ltd, of which he held 55% of the shares and his wife 45%.

This case highlights the need for experts to always remember their duty is to the court, to be honest and not to put self-interest first.

Read more:

<https://www.bailii.org/ew/cases/EWHC/Admin/2021/762.html>



Breakingbury v Croad, Cardiff County Court April 2021 - an example of non-delegable duty in dental negligence

There are certain duties of care that cannot be outsourced onto anyone else. These are non-delegable duties of care, which can be found in statute or at common law.

In a clinical setting, following the NHS Act 2006, it is now well-established that claimants can sue a Trust or GP Surgery directly for the negligent acts of its practitioners. However, this is not necessarily the case in claims involving dental practices, where the alleged negligent acts were performed by associate dentists, who were liable to face civil proceedings rather than the dental practice itself.

In this case, however, Judge Harrison, sitting at Cardiff County Court, held that Mr Croad, a former dentist who had been retired for 20 years and who had sold his practice many years before the litigation commenced, owed a non-delegable duty of care to the Claimant at the material time.

The Claimant had been a registered patient at Mr Croad's former practice, where she had been treated many times over several years. She was always given an appointment and seen by whichever associate dentist was available at the time.

After some bridgework treatment in 2011-2012 resulted in swelling and pain 4 years later, she sought a second opinion at another practice, and was informed that the bridge that she had received was of very low

quality and that the Claimant should sue the dentist who performed it. The Claimant then sued Mr Croad.

Mr Croad accepted that he was the 'Provider' of the dental services for the purposes of his contract with the local health board, and that he had an obligation to ensure that the dental services provided were safe and met the requisite standard. The Defendant met his contractual obligations by using self-employed associate dentists. The Court accepted that this was a common arrangement within dental practices.

The Defendant provided the associates with a non-exclusive licence and authority to practice dentistry and surgery at the practice, while also imposing restrictions, including forbidding them from taking a patient to another practice should they move.

The Judge found that it was the practice itself that had a contractual obligation with the local health board and that the Claimant could not choose which dentist treated her.

Although this judgement may be worrying for dental practice owners, they will likely be entitled to an indemnity from individual negligent associate dentists and should ensure that all dentists working at their practice have suitable individual professional indemnity cover.

Read more:

<https://www.civillitigationbrief.com/wp-content/uploads/2021/05/Breakingbury-v-Croad-Judgment-1.pdf>

A report by the Health and Social Care Committee on The safety of maternity services in England has also just been published

The report, published in early July, found a 'Blame culture' in maternity safety failures.

The CQC's Chief Inspector of Hospitals reporting evidence of a 'defensive culture', 'dysfunctional teams' and 'safety lessons not learned'. Professor Ted Baker told the inquiry that more than a third of CQC ratings for maternity services identified requirements to improve safety, larger than in any other specialty. MPs recommend urgent action to address staffing shortfalls in maternity services, with staffing numbers identified as the first and foremost essential building block in providing safe care.

Health and Social Care Committee Chair Rt Hon Jeremy Hunt said:

"Although the majority of NHS births are totally safe, failings in maternity services can have a devastating outcome for the families involved. Despite a number of high-profile incidents, improvements in maternity safety are still not happening quickly enough. Although the NHS deserves credit for reducing baby deaths and stillbirths significantly, around 1,000 more babies would live every year if our maternity services were as safe as Sweden.

"Our biggest concerns were around staffing and culture: staffing levels have now started to improve but we found a persisting 'culture of blame' when things go wrong which not only prevents people admitting that mistakes were made, but crucially, prevents anyone learning from them.

"Our independent expert panel gave an overall verdict of requires improvement"

The National Maternity Review, Better Births, described the process for compensating birth injuries as failing on its three objectives to provide rapid and compassionate support

to parents; effective learning for staff and improved outcomes; and reduced incidences of harm.

Maternity incidents remain the highest cost of claims against the NHS in England. NHS Resolution paid out £2.3 billion in compensation in total for clinical negligence claims in 2019/20 of which 40% related to maternity.

A review of compensation schemes around the world found that "a quiet but notable shift has occurred away from adversarial court-based dispute resolution to administrative compensation schemes". The result of that shift has been significantly lower costs.

Sweden uses a no-blame compensation scheme for medical injuries administered by healthcare insurers. Compensation is awarded based on whether an incident was considered avoidable rather needing to prove negligence. Compensation is paid if it had been established that care had not been given "according to best practice" which negates the need to prove negligence.

Read more:

<https://publications.parliament.uk/pa/cm5802/cmselect/cmhealth/19/1906.htm#idTextAnchor032>



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