MEDICO LEGAL

MAGAZINE

ISSUE 16

Presented by:

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Welcome to the Medico-Legal Magazine

Welcome to Issue 16 of the Medico-Legal Magazine, produced by SpecialistInfo and publishing partner Iconic Media Solutions Ltd.

This first packed issue of 2021 includes articles from healthcare employment lawyer, Martin Cheyne, discussing whistleblowing and Covid-19 in the NHS.

Laura Scott, from Hempsons Healthcare Litigation Team, reports on her recent successful case resulting in a claimant receiving a custodial sentence for an exaggerated claim against the NHS.

Orthopaedic Surgeon, Professor Mahmoud Hafez, highlights the pros and cons involved in the increasing use of patient-specific instruments and computer-assisted orthopaedic surgery.

Jonathan Godfrey, clinical negligence barrister, discusses recent cases that have affected informed consent since the landmark Montgomery judgement.

Edwin Rajadurai, indemnity expert from Servca, discusses the growing importance of cyber insurance in healthcare.

Also in this issue, regular contributor and healthcare law expert, Laurence Vick, completes his 2-part article on lessons learned from the Bristol heart scandal and, in a separate article, he discusses the recent findings of The Healthcare Safety Investigation Branch inquiry report on nasogastric feeding tube misplacements.

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:

Presented by: specialist info

Published by: ICONIC MEDIA SOLUTIONS

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MEDICO -LEGAL COURSES:

By Lisa Cheyne,
Medico-Legal Manager,
SpecialistInfo

Training Courses for Expert Witnesses

The dates and locations for the confirmed ML courses that we are holding during 2021 are listed below with links to our booking page.

The **Medico-Legal Essentials Course** (Personal Injury, 5 CPD points) concentrates on the key skills and knowledge for correctly preparing medico-legal reports in personal injury cases:

- *28th April 2021* – Live Online Course powered by Zoom
- *14th September 2021* – London
- *17th November 2021* – Manchester

£245 (plus VAT)

to book the Essentials course, please visit: www.specialistinfo.com/a_ml_standard.php

The **Clinical Negligence Course** (5 CPD points) is invaluable for doctors who write reports in (alleged) CN cases against medical staff. Knowledge of this area can also help in avoiding allegations of clinical negligence:

- *29th April 2021* – Live Online Course powered by Zoom
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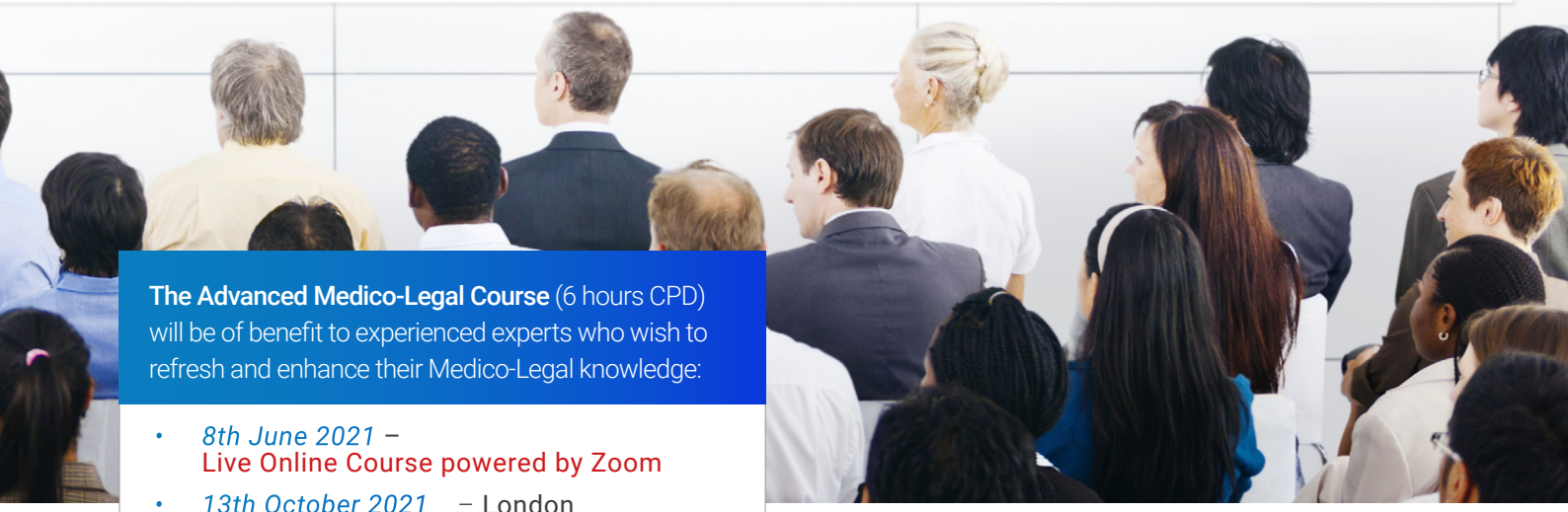
- *18th November 2021* – Manchester

£245 (plus VAT)

to book the Clinical Negligence course, please visit: www.specialistinfo.com/a_ml_clinicalneg.php



The Advanced Medico-Legal Course (6 hours CPD) will be of benefit to experienced experts who wish to refresh and enhance their Medico-Legal knowledge:

- *8th June 2021* – Live Online Course powered by Zoom
- *13th October 2021* – London
- *8th December 2021* – London

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SpecialistInfo is committed to expanding our growing range of **Online Medico-Legal and Mediation Training Courses**, to keep expert witnesses compliant with CPR.

Please be aware: Rules for expert evidence changed in 2020 and it is recommended that all experts book an updating session to ensure they are compliant.

Details of our upcoming Medico-Legal and Mediation courses are below and all confirmed dates are available on our course **website**.

To book your place(s) and for more information about all our 2021 courses, please click **here**, email **lisa@specialistinfo.com** or call me on **01423 787984**.

Kind regards

Lisa Cheyne
Medico-Legal Manager

specialist info

WHISTLEBLOWING AND COVID-19: IMPLICATIONS AND KEY CONSIDERATIONS

COVID-19 HAS BROUGHT SAFETY CONCERNS AND WHISTLEBLOWING PROTECTIONS INTO SHARP RELIEF. MARTIN CHEYNE, PARTNER, HEMPSONS EMPLOYMENT TEAM, EXPLORES SOME IMPLICATIONS

by Martin Chenyne - m.cheyne@hempsons.co.uk

What is whistleblowing?

This is the raising, by a worker, of some concern about a danger, a risk or wrongdoing or the potential for any of these. If a worker raises this, then if they are to be protected by the whistleblowing regime, their concern must:

1. contain sufficient information;
2. be made to the appropriate person or organisation;
3. be made in the public interest; and
4. be a concern about which the worker reasonably believes is wrong

These can be very technical requirements, but the starting point for all employers should be to treat the whistleblowing protections as very broad and relatively easy to apply. It is generally in the public interest for whistleblowing protections to be afforded to workers and so the technical requirements are often not substantial hurdles to overcome.

What are the protections afforded to workers who blow the whistle?

If a worker suffers a detriment of any type or is dismissed because of their having raised protected concern, then they can:

- apply to an Employment Tribunal to have their employment immediately reinstated whilst they bring their claim;
- seek reinstatement or re-engagement of their employment (and all related back pay) at conclusion;

- compensation for any dismissal;
- compensation for any other detriment to their employment

In all cases, the compensation that could be payable is uncapped. This can be substantial, particularly if the worker is unlikely or unable to find similarly remunerated alternative employment. Some of the largest awards made have involved employees who have had to retire after they raised their concern, having failed to rapidly find new similar work.

As part of ensuring that workers are protected, there is no minimum period of service before workers are protected. Even a new employee, still in their probation period, would be afforded the protection of the whistleblowing legislation. In the NHS, following the Francis review of Mid Staffs, 2013, this protection is extended further to the recruitment process and this applies to most NHS public bodies.

How do we know if it is a whistleblowing concern?

A whistleblowing concern does not need to expressly say "this is a protected concern and I am blowing the whistle". It could be raised with the employer openly as a whistleblowing concern, but it may wrongly state or suggest that it is merely a grievance. If the concern being raised relates to a wider public interest, has potentially wider implications or has the possibility of impacting other workers, then it may well be a whistleblowing concern.

Often the nature of the concern can be clarified with the individual raising it, though if there is doubt whether to treat it as a whistleblowing concern, professional advice should be sought.

To whom should the concern be raised?

The majority of whistleblowing concerns are raised with the employer. This would usually be the recommended, best and first place for a worker to raise their concern. However, raising something with the employer is not a mandatory requirement of the whistleblowing regime and concerns can be raised with legal advisers, regulators or another relevant body.

It is not uncommon, for instance, for the HSE, NHS England or CQC to be the initial recipient of a concern and these regulators will likely expect a full investigation to be undertaken and outcome report provided to them.

What types of concern are covered?

The whistleblowing regime covers a wide range and overlapping variety of subjects. They are (this includes their concealment):

- Criminal offences;
- Breach of any legal obligation;
- Miscarriages of justice;
- Danger to health and safety of any individual;
- Damage to the environment

What Covid examples are there?

Covid and issues relating to Covid are very likely to cover at least two or three of the whistleblowing subjects. We are already seeing media coverage of concerns where the whistleblowing regulations could apply. Some examples:

- Failures to follow government guidance;
- Inadequacy of government guidance;
- Rapid developments or contradictions in government guidance;
- Workplaces failing to be properly risk assessed as Covid secure;
- Concerns about travelling to work in shared or on public transport;
- Inadequate workplace ventilation;
- Inadequate washing facilities;
- Inadequate distancing between workers;
- Co-workers failing to undertake mandatory self-isolation;
- Exposure to patients who are or are likely to be Covid positive;
- Inadequate measures to protect clinically vulnerable staff;
- Inadequate, insufficient or failing Personal Protective Equipment;

- Patient failure to comply with good Covid secure practice;
- Patient behaviour and complaints

One of the most widely reported Covid interventions was by the Health and Safety Executive in September 2020, where the HSE found multiple failings by management at the Department for Work and Pensions. They found:

- A line manager giving instruction to a group of staff, without maintaining social distancing;
- Designated two-way walkways, despite being only one metre wide;
- Designated walkways passing too close to desks designated as useable;
- Stairwells inappropriately designated as two-way, when even passing places failed to provide 2 metre distances;
- Small tables, breakout pods and benches without "do not use" signage.

The HSE undertook their inspection having received a report of a "workplace concern". It is likely that a worker reported their concerns to the HSE – that worker would almost certainly be protected by the whistleblowing legislation.

So what should the organisation do?

Most healthcare organisations will have in place an existing whistleblowing policy. That should always be the start point for consultation and be a reference material. Other policies (such as the grievance policy) may also be relevant. An investigator will usually be appointed and they should then carefully consider what has been raised and whether they have sufficient information. Investigating during the Covid pandemic though may mean that inquiries are made using remote systems rather than face to face.

It is vital to ensure that the worker is not, at that early stage, punished in some way. This can easily be inadvertent: taking action to protect an employee can easily be construed by the worker as "punishment". Take care to avoid simply sending an employee home, thinking that would be in the

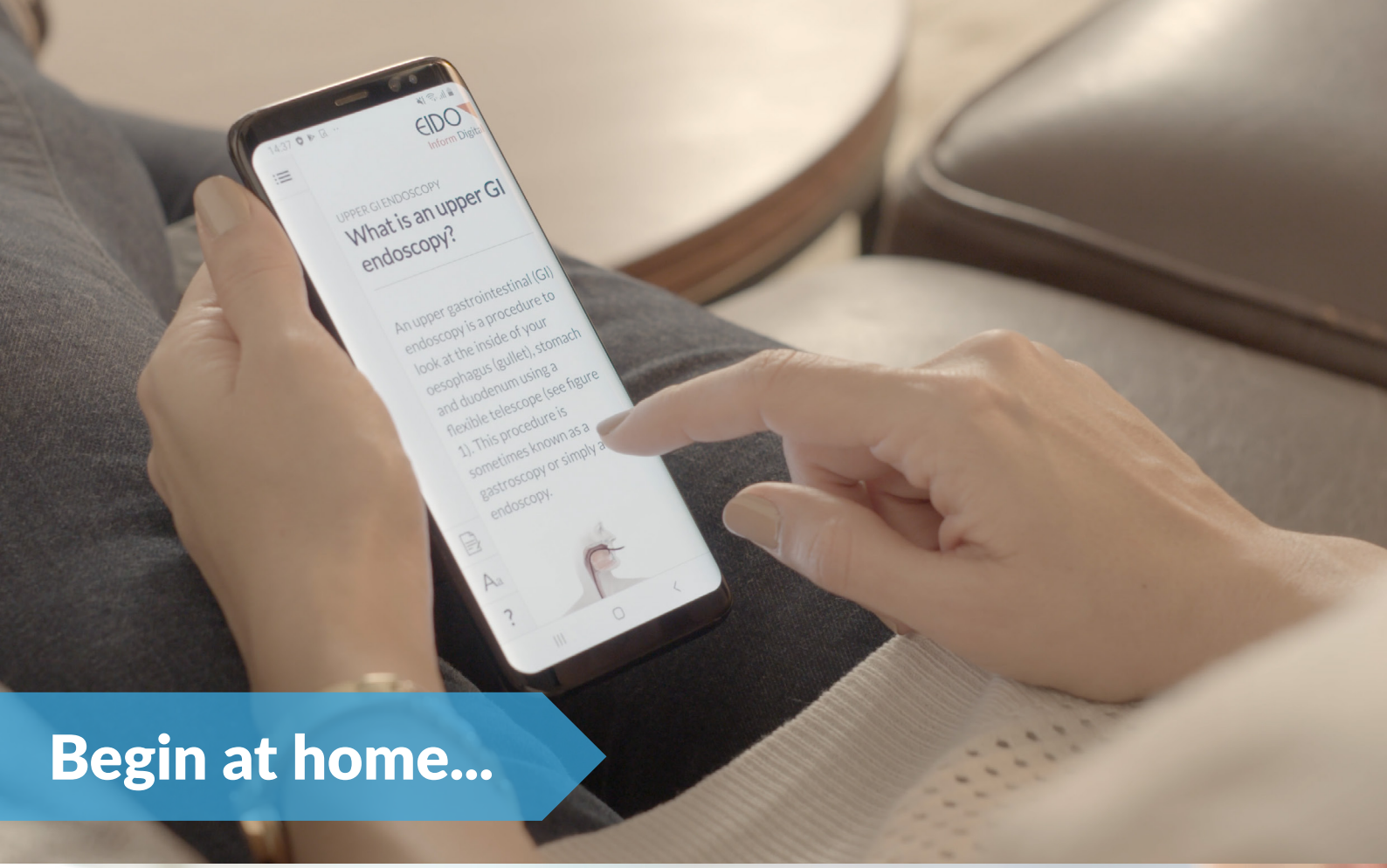
employee's interests. Explore with the employee what they may want and need: if a whistleblower is to be open about their concerns, they may want or need their identity kept confidential.

Communication is always key and where an employee or worker is already raising a concern, it is vital to engage with them rapidly and, where possible, look to immediately ameliorate things or provide the worker with assistance.

A particular issue that healthcare organisations face in winter 2020/21, is their simple capacity to deal with an investigation. Covid, staff absence, winter pressures and even vaccination programmes will all impact on the ability to progress. If this is going to mean that an investigation cannot swiftly be undertaken, then consider seeking external support but be open about the likely delays and seek the forbearance and agreement of those involved.

After the issue is investigated, there needs to be a form of reporting back to the individual (and possibly a regulator or other body). At the very least, this ensures that it is appreciated that the concern is taken seriously, but it also allows any remediation to be transparent and clearly understood.

Finally, organisations will need to have regard to data protection principles in what feedback can be provided, particularly if the concerns raised involve the actions of individuals or other staff. For instance, it is unlikely to be appropriate to describe the extent of disciplinary action that is to be applied to co-workers.



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THE ODYSSEY OF INFORMED CONSENT POST MONTGOMERY – HAVE WE REACHED ITHACA?

By Jonathan Godfrey, Barrister at Parklane Plowden Chambers (Leeds and Newcastle)

Jonathan specialises almost exclusively in clinical negligence work and his expertise covers the whole area, including orthopaedic injury, cancer misdiagnosis, cerebral palsy birth injury, surgical mishap and wrongful treatment and consent. He has worked with SpecialistInfo for over three years training expert witnesses in this area of law.

It is now 6 years since the Supreme Court seemingly changed the legal landscape in respect of informed consent in its judgment in Montgomery v Lanarkshire Health Board [2015] UKSC 11. The test of materiality was born. A doctor was now *"under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative treatments". The test of materiality was described as "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 be aware that the particular patient would be likely to attach significance to it".* Patient choice had found its way to the fore in informed consent, replacing the previous incarnation of medical paternalism.

Has there been any change in the legal (and also medical) landscape following the Montgomery decision? In particular:

1. How have the courts implemented the materiality test from a practical perspective?
2. Has Montgomery had any noticeable impact on the number of cases brought before the courts? and;
3. Has there been any change in focus from the medical profession in terms of informed consent following the decision?

A Gentle Reminder

In assessing materiality, the Supreme Court gave the following guidance:

1. The assessment of whether a risk is material cannot be reduced to percentages. The significance of a given risk is likely to reflect a variety of factors in addition to its magnitude: the nature of the risk, its effect on the patient's life, the importance to the patient of the benefits sought by the treatment, the alternatives available, and the risks involved in the alternatives; and
2. The doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands all the matters involved. The information provided is to be comprehensible and is not fulfilled by bombarding with technical information.

Practically Speaking

In Duce v Worcestershire Acute Hospitals NHS Trust [2018] EWCA Civ 1307, the Court of Appeal, in the judgment of Hamblem LJ, gave practical guidance regarding the nature of the duty that was involved in informed consent. It is a twofold test and is described by Hamblem LJ, at paragraph 33 of the judgment as:

1. *"what risks associated with an operation were or should have been known to the medical professional in question. This is a matter falling within the expertise of the medical professionals; and*
2. *Whether the patient should have been told about such risks by reference to whether they were material. This is a matter for the Court to determine. The issue is not therefore the subject of the Bolam test and not something that can be determined by reference to expert evidence alone".*

Accordingly, on a case-by-case basis, the medical experts instructed are to deal with the risks that that should have been known or ought to have been known by the medical professional in question (and in so doing this limb retains homage to Bolam). In relation to the Duce case, Hamblem LJ, specified at Paragraph 42 of the judgment that whether gynaecologists were or should have been aware of the relevant risks at issue *"is a matter for expert evidence"*. Thereafter, whether those risks should have been communicated to the patient by reference to whether they were material is a question for the court to determine.

The test is replicated at Paragraph 12 of the judgment of Yip J, in the subsequent case of Hazel Kennedy v Dr Jonathan Frankel [2019] EWHC 106 (QB). This is an unfortunate case in that the Defendant doctor had provided his diagnosis and treatment gratuitously, but it did not absolve him from his duties in respect of informed consent.

Hamblem LJ, repeated at Paragraph 35 of the Duce judgment, those factors relevant to determining materiality that were previously elucidated by the Supreme Court in Montgomery.

Alternative treatment

Determination of materiality brings with it a need to inform not only of the risk involved in the treatment but also *"any reasonable or variant treatments"*.

In Bailey v George Elliott Hospital [2017] EWHC 3398, HHJ Worster, sitting as a Deputy High Court Judge, considered what test should be applied as to whether an alternative treatment was "reasonable". HHJ Worster determined that the matter was to be judged by what was known, or ought to have been known, about the alternative treatment at the relevant time. The question of reasonableness had to be approached by reference to all the circumstances, including the particular patient concerned, their condition and their prognosis.

The case of Mills v Oxford University Hospitals NHS Trust [2019] EWHC 936 (QB) highlights the need to advise as to alternative treatments in addition to the risk involved in the treatment proposed.

Causation

A failure to provide informed consent still brings with it the need to establish that the failure was

causative. It is not a presumptive sequitur. This is best exemplified in the case of Diamond v Royal Devon and Exeter NHS Foundation Trust [2019] EWCA Civ 585. The Claimant had had an abdominal hernia repaired using surgical mesh, but was not advised of the alternative of a suture repair. At first instance, HHJ Freedman held that the Claimant had not been given the appropriate information required for informed consent, but that had she been so informed she would have proceeded with the mesh repair, which in fact took place. The Court of Appeal approved the trial judge's approach adopted to the question of factual causation. The court re-iterated that the but for test applies to causation in informed consent cases.

A recent exposition of the consideration given by a trial judge as to the facts to establish causation (which was established) is usefully illustrated in the judgment of Stacey J in Betty Plant (by her son and Litigation Friend, Rodney Winchester) v Mr Ahmed El-Amir and London Eye Hospital Limited [2020] EWHC 2902 (QB).

Montgomery Consequences

A study conducted at Queen Mary University of London: *"the effect of the Montgomery judgment on settled claims against the NHS due to failure to inform before giving consent to treatment"* published in March, 2020 (by DS Wald, JP Bestwick, P Kelly in the *Quarterly Journal of Medicine*, DOI: HCAA082), gives a fascinating insight into the practical effect of the Montgomery decision in so far as claims initiated as against the NHS concerning a failure to provide informed consent.

The research established that while the rate of increase of other clinical negligence claims has remained steady, cases relating to consent have risen four times as fast since the Montgomery decision in March, 2015, and where failure to inform was added as a contributory claim, the rise was nearly ten-fold.

Data established that as between 2005 and 2019 the NHS settled 70,000 cases, of which 2,300 were linked to a failure to inform (either primary or secondary) with a total value of nearly £400 million. Between 2011 and 2015, costs for settling informed consent cases rose from £25 million to £28 million per annum. Thereafter, from 2015 (post Montgomery) to 2019, costs rose to £62 million per annum. The rise was purely due to the increase in the numbers of claims, as the cost per claim remained steady. The study found that lawyers' fees accounted for about 40% (£155 million) of costs paid by the NHS in settled claims due to a failure to inform.

Professor Wald remarked that *"claims involving failure to inform are normally invisible in the overall numbers of negligence claims, but the rise we have identified is striking and shows no signs of stopping. The data support concerns that lawyers are adding consent-related claims to other allegations, which on their own may not be successful in court. The Montgomery ruling now makes these cases much easier to win, and the NHS is paying the bill"*. Professor Wald's study is symbolic evidence of the growth in informed cases being brought post Montgomery.

From the medical perspective, some 5 ½ years post the Montgomery decision, the GMC issued new guidance to doctors entitled **"Decision Making and Consent"** on 30th September, 2020, and which came into practical effect on **9th November, 2020**. It replaces its guidance on consent last issued in 2008. It focuses on *"the importance of meaningful dialogue, personalised communication and potential benefits and harms, and how doctors can support patients to make decisions with them about treatment and care"*. At its core are *"the seven principles of decision making and consent"*. The seven principles find their genesis and meaning in the Montgomery judgment. At the heart of the new guidance is the concept of meaningful dialogue. The new guidance translates the Montgomery decision into practical guidance for medical professionals.

Where has the journey brought us so far?

It is clear as per the research by Professor Wald and his co-authors, that the Montgomery decision has seen a rise in informed consent cases per se,

or in unison with substantive allegations. It will be interesting to see whether the upward trend continues.

From a personal perspective, in presenting the medico-legal clinical negligence course for SpecialistInfo, it is apparent in discussions with medical professionals that in the main they have taken on board the ratio of the Montgomery decision. Meaningful discussion now forms the mainstay of their informed consent discussions moving forward. Another very apparent insight is that there appears to be the commended adoption of ensuring that the contemporaneous medical notes and correspondence properly detail the informed consent process undertaken.

In the light of the new guidance on consent from the GMC, together with the informed consent process that I have had outlined reported to me by medical professionals, it will be interesting to see whether there is a levelling off or decline in informed consent cases being brought. Whether we have reached the ultimate destination in so far as informed consent cases are concerned, or whether the journey continues with vigour remains to be seen.

If you are interested in attending Jonathan's Clinical Negligence training for expert witnesses, please follow the link below to SpecialistInfo's booking page:

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

AI | ROBOTICS IN MEDICINE CONFERENCE 2021

Draft Programme

6th May 2021

Virtual Conference

9.30 - Registration

Welcome and introduction from the Master of Ceremonies

Dr Rizwan Malik, Consultant Radiologist and Divisional Medical Director, Bolton NHS Trust

Keynote Address: Artificial Intelligence in healthcare

Christopher Kelly, Clinician Scientist, Google Health

But does it do what it says on the tin? Building an evidence base for AI in healthcare.

Dr Danny Ruta, Clinical AI Lead, Guy's Cancer Centre, Guy's and St Thomas' NHS Foundation Trust

Pinpointing cancerous lymph nodes in real time with radio-guided surgery

Dr Maarten Grootendorst, Clinical Research Lead, Lightpoint Medical & **Mr Jim Adshead**, Consultant Urological Robotic Surgeon, Lister Hospital, East & North Herts NHS Trust

Refreshment Break

Robot vs Surgeon

Mr Chris Coulson, CEO / Consultant ENT Surgeon, University Hospitals Birmingham and endoscope-i Ltd

Robotic thoracic surgery – why should patients and hospitals choose this?

Mr Tom Routledge, Consultant in Thoracic Surgery, London Bridge Hospital

MagnifEye and SENSE (TBC)

Alan Payne, Chief Information Officer, Sensyne Health

Lunch Break

Considerations about Data Governance when deploying AI:

Lived experiences from the NHS

Dr Rizwan Malik, Consultant Radiologist and Divisional Medical Director, Bolton NHS Trust

Computer-assisted orthopaedic surgery (CAOS): An overview

Professor Mahmoud Hafez, Consultant Orthopaedic Surgeon, Faculty of Medicine, October 6 University, Cairo, Egypt, Executive committee member of Computer Assisted Orthopaedic Surgery (CAOS) International Society and International Federation of Inventors Association (IFIA)

Clinical Deployment of Medical Imaging AI Tools: The Challenges Ahead

Yvonne W Lui MD, Associate Professor, Associate Chair, Artificial Intelligence Department of Radiology, NYU Grossman School of Medicine / NYU Langone Health

Electrophysiology Robotics Platform of the Future

Dr Peter Weiss, Director of Ventricular Arrhythmia Management and Robotics, Banner University of Arizona Medical Center and **Professor Sabine Ernst**, Consultant in Cardiology, Royal Brompton & Harefield NHS Foundation Trust and Professor of Practice in Cardiology at Imperial College London

Refreshment Break

The Present and Future of Head and Neck Robotics

Dr Michael Persky, Head and Neck Surgeon, NYU Langone Health

Robotic Surgery: Who's to blame when things go wrong

Edwin Rajadurai, Managing Director, Servca

AI in healthcare and patient harm: a need to reframe the law?

Paul Sankey, Partner, Enable Law

Live Question & Answers

17.00 Closing Comments and Close

Programme may be subject to change

BOOK NOW

LEGAL UPDATE: CALDERDALE AND HUDDERSFIELD NHS FOUNDATION TRUST V LINDA METCALF

By Laura Scott, Associate, Healthcare Litigation Team, Hempsons

37-year-old Linda Metcalf received an immediate 6-month custodial sentence at the Leeds High Court on 11 February 2021 for her deliberate attempt to defraud the NHS and deceive the Court.

Ms Metcalf had pursued a clinical negligence claim against the Trust for an alleged delay in diagnosing cauda equina syndrome in June/July 2012. The Trust admitted liability for a 24-hour delay in diagnosing her spinal condition at the pre-action stage; a formal apology was made by the Trust and an early voluntary interim payment of £75,000 was agreed and paid.

Quantum investigations were undertaken. The Claimant alleged injury to her bladder and bowels, and severe limitations to her mobility, amongst other symptoms. Ms Metcalf reported that her standing and walking tolerance were severely limited even with walking aids (as little as 1-minute standing and 5 yards walking); she said that she was unable to drive, required assistance with transfers in/out of a vehicle, was unable to leave her home alone and her ability to take part in leisure and social events was severely restricted due to mobility difficulties and pain levels. A Schedule of Loss was served in January 2019 totalling £5,712,773.40.

Due to inconsistencies in the evidence, covert surveillance was obtained. Ms Metcalf was observed:

- Driving;
- Walking without apparent difficulty and without walking aids;
- Climbing stairs without holding a handrail; and
- Shopping independently (including supermarket shopping trips in which she pushed a trolley and carried what appeared to be a heavy shopping basket).

Ms Metcalf was observed transferring into a wheelchair to attend appointments with the Trust's medical experts and using two walking sticks when attending physiotherapy appointments; she was not observed using walking aids when doing any activity unconnected to her claim.

It also became apparent from online sources that Ms Metcalf was travelling frequently within the UK and abroad (including South Africa, Thailand, Singapore, Fiji, New Zealand and Hong Kong) throughout the claim. The surveillance footage and internet search material was disclosed to Ms Metcalf's Solicitors in February 2019 and the Trust's Defence was amended to plead fundamental dishonesty.

Ms Metcalf initially denied fundamental dishonesty in her Reply to the Amended Defence and quantum investigations continued ahead of the Trial listed to take place from September 2019. Further witness statements and updated expert reports were obtained, putting both parties to additional cost. A round table meeting in June 2019 was unsuccessful but Ms Metcalf agreed to an Order that her claim be dismissed for fundamental dishonesty later that month. She also agreed to repay the £75,000 and, to her credit, has done so.

Hempsons applied for permission to bring committal proceedings on behalf of the Trust in March 2020. In an open letter from her solicitors, Ms Metcalf admitted contempt in April 2020 and confirmed that she would not contest the

Application. Ms Metcalf subsequently formally accepted that she had interfered with the due administration of justice, misled the independent experts instructed in the claim and had made false statements in legal documents, verified by a statement of truth.

Permission was granted by consent in June and the committal Application was made in July. The matter came to a final hearing before Mr Justice Griffiths on 11 February 2021.

Ms Metcalf sought to avoid a custodial sentence and put forward the following points (amongst others) in mitigation:

- Ongoing health problems related to the index claim – including management of a catheter in prison;
- The impact on her 2-year-old daughter;
- Remorse and engagement with the process;
- The interim had been repaid in full;
- She had lost the ability to recover compensation for the genuine aspect of her claim (estimated to be around £350,000);
- Good character;
- The pandemic making conditions in prison worse; and
- She had been aware that she could go to prison since the surveillance evidence was disclosed in February 2019 and had had the matter "hanging over her".

Mr Justice Griffiths considered that the length of deception (approximately 4 years) and the amount claimed from a public body, justified a custodial sentence of 18 months. However, taking into account points in mitigation, the sentence was reduced to 9 months. A further one third deduction was then applied as contempt had been admitted at the permission stage, prior to the Application for committal being made. As such, Ms Metcalf received an immediate custodial sentence of 6 months and an Order to pay the Trust's costs of the proceedings (summarily assessed at £23,000).

This case highlights the very serious consequences of submitting a dishonest and

exaggerated claim against the NHS. This is the third case that has come to a final hearing in which NHS Resolution and an NHS Trust has pursued and obtained a custodial sentence, but this is the longest sentence to date which is reflective of the length of deception and amount claimed, despite the mitigating factors and early admission.

Nevertheless, a sentence of 6 months in respect of an attempt to use the courts as a weapon to pull off a fraud valued at >£5 million still does not seem very high. It may be that in future cases the courts will impose heavier sentences, particularly in cases where the Defendant does not a have a young child who may be punished by the incarceration.

The Trust was represented by Laura Scott of Hempsons and Claire Toogood of Crown Office Chambers.

THE GROWING IMPORTANCE OF CYBER INSURANCE IN HEALTHCARE

By Dr Edwin Rajadurai (MBBS), Managing Director, Servca

Over the years, the healthcare sector has become more invested and reliant on technologies to provide care.

With Covid-19 hitting, these requirements have escalated even further.

An acceleration in telemedicine and other varying forms of online, digital, or software-based treatments and services also demonstrate a growing cybersecurity threat within the healthcare sector.

These threats can affect large and small organisations alike, and education and resources should be invested within the healthcare sector to minimise cyber-related incidents.

Today, Servca looks at the varying examples, exposures, and steps that can be taken to try and minimise cyber threats.

Please note that this article is intended to serve as value-adding information, and you should consult with a professional when taking steps in arranging cyber liability protections.

What is Cyber Security?

The National Cyber Security Centre dictates that Cyber security's core function is "to protect the devices we all use (smartphones, laptops, tablets, and computers), and the services we access - both online and at work – from theft or damage".

What are some examples of Cyber Security threats?

1. Ransomware - is a type of malware that infects systems and files, making them inaccessible until a ransom is paid. When this occurs in the healthcare industry, critical processes are decelerated or become impossible.
2. Data Breaches - can be caused by many different types of incidents, including credential-stealing malware, an insider who either purposefully or inadvertently divulges patient data, or loses a laptop or other devices with confidential information on it.
3. Insider Threats - the insider presents a threat because they have indisputable access to the systems and knowledge of the network capabilities and weaknesses.
4. Fraud - scammers use a compromised account or fake email to trick employees into initiating a money transfer to an alternative (fraudulent) account. The scammers almost always pretend to be a person of power within the organisation.

Why is the Healthcare sector at higher risk?

1. Private patient information is worth much money - it can be sold on the dark web for close to £1,000 – 200 times the black-market value of a financial record.
2. Medical technologies are an easy access point for attackers – the use of devices, computers, servers, and software provides an increased number of entry points for attackers to focus on.
3. Data is often accessed remotely, allowing more opportunities for attacks.
4. Healthcare staff are not educated and trained enough in online risks.
5. Extensive network of connected medical devices – particularly within larger organisations, it is not easy to manage and stay on top of all these devices.
6. Outdated technology means the healthcare sector is ill-equipped for attacks.

Steps that can be taken to improve Cyber Security in Healthcare

1. Cybersecurity training for staff and employees - mandatory training ensures that all employees know their role in keeping the organization's systems and data safe. It keeps them mindful of the most common cyber threats.
2. Apply regular system checks and software updates – developers often regularly release updates for their applications and software that ensure the most up-to-date patches limit opportunistic threats.
3. Controlled System Access - granting a specific employee is the system privileges they need to execute their job effectively will ensure a monitored and considered approach to accessing and using the systems.
4. Regular Risk Assessments - conducting a technology risk assessment at least once a year allows organisations to detect new threats before third parties exploit them.
5. Data Recovery - data loss is far worse than unauthorized data access. It not only damages the organisation's reputation but can also cause a crippling effect on the way services and treatments are rendered.

Therefore, a data recovery mechanism will ensure data is intact if the information on systems is rendered unusable due to a breach.

Case Study – WannaCry

In May 2017, the National Audit Office (NAO) issued that more than a third of NHS trusts in the UK were affected by the WannaCry ransomware attack.

WannaCry, which circulated to more than 150 countries globally, was a form of malware-encoded data on infected computers that demanded a ransom (to be paid) roughly equivalent to £230.

Approximately 7,000 NHS appointments were cancelled as a direct consequence of the incident, of which around 140 were for people potentially with cancer, who had urgent referrals rescinded.

An evaluation of 88 out of 236 trusts discovered that none passed the necessary cyber-security specifications.

Our Summary

As you can see from the case study we have highlighted, any type and size of organisation can be affected by cyber-attacks, with devastating effects.

Furthermore, within the healthcare sector specifically, a cyber attack or incident can consequentially result in a claim of medical malpractice. In the WannaCry case study, we highlighted that nearly 7,000 NHS appointments were cancelled. If any of these patients fell ill, they could try and file a negligence claim (or misdiagnosis).

Since most cyber policies have a bodily injury exclusion, it is vital to understand that relevant and essential coverages are in place to protect against a host of scenarios of claims.

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LESSONS LEARNED FROM THE BRISTOL HEART SCANDAL AND THE 2001 KENNEDY INQUIRY – PART 2

By Laurence Vick, Retired Solicitor, Medical Negligence @LaurenceVick

This second instalment follows part 1 published in the December 2020 issue of Medico-Legal Magazine.

The Inquiry and the Duty of Candour

The Kennedy report[1] found serious, systemic failures at a unit that had clothed itself in a 'club culture' of wilful blindness to safety concerns and poor practice, with staff closing ranks to protect their colleagues. On the eve of publication of the Kennedy report, which documented the lethal consequences of a toxic culture of denial within the collusive community operating at Bristol, the Chief Medical Officer at the time demanded that doctors should admit to patients when an error in their surgery had occurred.

The need for a duty of candour became obvious after Bristol: a duty on doctors and hospitals to report untoward incidents and to raise concerns. They should also, the report recommended, feel able, if necessary, to blow the whistle on failings and incompetence of colleagues or systemic issues within their hospitals, with proper legal safeguards to protect them from dismissal or victimisation if they have cause to take action.

My experience of acting for parents of these very sick children has shown that they have a heightened awareness and a desperate desire to place their children in the safest possible hands to give them the best chance of achieving a successful outcome. They want to know the truth before and after surgery. They want to know that the surgeon and medical team have the necessary resources and expertise in the procedure they are to carry out. As occurred at Bristol in the 90s, and as repeated across the country since, parents have little option but to place their trust in the surgeons and in the cardiologists who diagnose their children's conditions and refer them for their life-saving surgery.

Patients and families seek information and explanations if treatment has failed. This isn't 'hospital complaint' territory. It shouldn't be left for us as lawyers, after obtaining expensive expert reports, to have to explain to grieving parents what really happened to their child. In many cases, sadly, this was how they learned the truth.

I have misgivings as to whether patients and families in the context of high-risk surgery, where much depends on the experience of a unit or surgical team, will benefit significantly from the duty of candour introduced for NHS healthcare providers in 2014. Children's heart surgery has unique features, in that it is carried out at a number of specialist units across the country. One unit may have a specific expertise or superior safety record in a particular procedure, less so in another. A classic example from Bristol in the 90s was the truncus arteriosus operation. Although on any level this is a highly complicated procedure, parents were not informed that the unit had a significantly higher mortality rate than comparable units in this same operation. It was revealed in a BBC Newsnight programme in October 1998 that, prior to a truncus arteriosus procedure Wisheart performed on a child in 1993, he had performed 11 of these operations in which nine children had suffered 'early' deaths. The patient in the 1993 operation sustained catastrophic brain damage. Clearly his chances

of surviving without injury would have been significantly increased, and the NHS would not have had to pay substantial damages for those injuries and his future care needs, if he had been referred to another unit with a superior safety record. Would this explanation - to me, a full and meaningful explanation that I would want - be given to parents today with the duty of candour in place? I doubt it.

Those who sought explanations after their children died received limited explanations from the surgeons. In most cases, parents only came forward in response to the news reports around the time of the GMC hearings in 1998 and the Public Inquiry that began in 1999. Many of the operations had been carried out three or four years previously. Letters to parents from the Trust's new Chief Executive were written in sympathetic, compassionate tones but, as he was relying on medical and surgical staff still at the hospital for his information, they were of little benefit. The hospital sought to explain that the surgeons had encountered unexpected presentations of the children's particular defects or abnormal anatomies that could not have been foreseen. I do not recall any letter accepting that the surgeons or cardiologists or other members of the team had been in any way to blame.

Parents were given no insight into the experience of the surgeons and their medical support team. Before surgery, the surgeons had given highly optimistic assessments of the likelihood of survival, often quoting 80 or 90% survival but with no warning of the risk of surviving with brain damage – a risk inherent in the best hands in these open-heart operations requiring cardio pulmonary bypass (CPB). Parents had been given optimistic success rates in the various procedures, which reflected national but not local experience. They were not given the choice of a second opinion or a referral to another centre with a superior safety record. None of the 25-30 sets of parents of children who had suffered permanent neurological injury over the 10-year time span covered by the Inquiry were, to my knowledge, offered any explanation, even though they had to return to Bristol for their children's continuing cardiology care. We referred to these unfortunate parents and children as the 'forgotten families'. I pursued an unsuccessful judicial review of the GMC's decision to limit the charges to mortality rates, excluding consideration of the unit's non-fatal morbidity record, in a narrow category of operations.

All of the brain damage cases from Bristol in the 1990s were litigated and contested to the fullest extent in spite of the findings of the GMC and Public Inquiry. The financial cost to the NHS of these claims was enormous. The cost in damaged human lives was incalculable.

A generation later, how have developments in the law of consent and the introduction of the duty of candour affected the position?

In many ways, little has changed in children's heart surgery since the 1990s. Parents of a child with the extremely complex Hypoplastic Left Heart Syndrome, for example, may not know, but should be told, that a particular unit is pre-eminent as the leading centre for corrective surgery on this defect. Inevitably, units with a greater degree of expertise in these immensely difficult procedures achieve better outcomes in terms of lower mortality rates and a lower incidence of, and ability to cope with, post-operative complications. Units with this leading national expertise should of course be appropriately resourced by the NHS so that they can admit these children.

So, what can parents expect from the Duty of Candour if their child has undergone surgery at a unit that lacked expertise in this procedure? They may be given a frank explanation of why their child died, or why he or she suffered complications, but in the same way that they should have been informed of the facts before surgery, surely they should be informed that there may have been a quite different outcome if their child had been operated on at another centre with a superior safety record?

Data
"Comparative data" - performance of comparable units

Kennedy[1] called for greater transparency in data recording so that no hospital could allow poor outcomes to go unscrutinised.

These features of the children's cardiac specialty raise a number of points. How can the outcomes and competence of a surgeon or unit be measured and how can a patient be advised of the risks if the surgeon doesn't know what other surgeons and units are achieving and how his outcomes compare with those of other units? How can a surgeon fulfill the requirement of a genuine consent process before surgery, or of a meaningful duty of candour when explaining why surgery has failed, without knowing how his or the unit's outcomes compare with similar units?

A recent article in the World Journal for Pediatric and Congenital Heart Surgery[2] discusses how parents of children with a life-threatening congenital heart defect interpret and perceive risk. Eight in every 1000 babies are born with a cardiac anomaly. Pre-surgery discussions as to risk are difficult for clinician and parent. Many parents are too anxious (if not terrified) to take in Montgomery options. A number of the sets of 106 parents who participated in this UK study felt that the decision to operate or not should rest with the clinician, not the parents. Parents simply want to know that they are placing their child in the hands of a competent, experienced surgeon in a well-performing unit, giving their child the best chance of surviving with a successful repair. The availability of readily understandable data to enable these comparisons to be made and units to monitor their performance becomes a crucial element in both consent and candour.

Although the Public Inquiry concluded that, between 1990 and 1995, up to 35 children and babies had died as a result of poor care at Bristol, we calculated by extrapolation from the data that in fact as many as 170 might have survived if they had been treated elsewhere. We never knew the numbers of how many children had survived surgery but suffered brain damage and other serious injury. The Trust denied that it held data to establish this. Even now, accurate, informative data can be difficult to locate and there is still no centralised collection of data on cardiac morbidity. So, a generation later, we have no measure of success or failure of a surgeon or unit other than 30-day mortality rates – if a child survives for a month he is regarded as a statistical success, even if he has suffered injury in the process. In reality, rates of mortality should provide an alert system only.

Families choosing a cardiac centre often struggle to interpret the data to make properly informed decisions about units and surgeons. The availability of readily understandable data is surely a facet of a meaningful duty of candour across the wider NHS. Reflecting this, Great Ormond Street hospital announced in 2016 that they were leading an ambitious National Institute for Health Research (NIHR) funded joint project to achieve a better understanding and categorisation of the non-fatal complications that can occur in children after heart surgery.

Despite cardiac surgery leading the way in the publication of data after Bristol, serious problems relating to reporting in this field have persisted. Operations at the children's cardiac unit at Leeds were controversially suspended in 2013 after NHS Medical Director, Sir Bruce Keogh, announced he wasn't satisfied with incomplete data disclosed by the unit, in response to concerns that were reported to have been brought to his attention. The unit was soon re-opened, but it became difficult to establish whether, and if so to what extent, there really were problems at Leeds, because the available data were hard to interpret or allow comparisons to be made with the performance of other units.

In March 2016, following reports of long-standing problems at the adult cardiac unit at Queen Elizabeth Hospital, Birmingham, an editorial in the Guardian referred to the unit's 'disdain for the data' and the fact that, two decades on from the Bristol Scandal, the NHS 'continues to harbour some dangerously defensive instincts'.

More transparency is needed, but the recommendation in the recently published Paterson report[3] that every surgeon's expertise and experience should be published on a website may be too simplistic. Paediatric cardiac surgery in particular is a 'team sport' involving a wide range of specialisms and this would not reveal the full picture.

Many of the Kennedy recommendations remain unresolved.

Whistleblowing

Sadly, whistleblowing in the NHS continues to be career suicide for medical staff. It is inexplicable that this is still the case given the cost to the NHS of ignoring warnings over dangerous practices that could have been addressed if the concerns of a whistleblowing doctor or nurse had been investigated. Every scandal that has emerged over the years since Bristol seems to have involved whistleblowers who have been ignored or worse, suppressed and intimidated.

Professor Sir Ian Kennedy carried out a detailed, robust review of disgraced breast surgeon Ian Paterson's NHS activities in 2013 and found that whistleblowers had repeatedly been ignored. He said this was "a blight on the NHS and is one of the principal areas where lessons must be learned."

Twenty years after Kennedy's Bristol report, NHS Trusts still go to astonishing lengths to suppress whistleblowers, spending significant sums defending cases brought by employees who have blown the whistle. Whistleblowers are still gagged as part of pay-off deals. Investigative journalist Tommy Greene made a number of FOI requests and revealed in a Telegraph report in January 2020 that NHS Trusts had spent £20m over a 4-year period battling whistleblowers and contesting discrimination claims. So much for a learning culture we wanted to see in the NHS after Bristol.

Reorganisation of children's heart units: Reconfiguration

Reconfiguration of our children's heart units, intended to concentrate expertise in a smaller network of national centres, was never completed as originally envisaged in the 2001 Kennedy report[1]. The Government tried unsuccessfully to force through what became a long-delayed programme of national reorganisation and closure of units first proposed by Kennedy. The Safe and Sustainable Review[4], established in the wake of the Inquiry, brought about the suspension of operations at the John Radcliffe unit, Oxford in 2010, over which there had been worrying issues ever since the time of the Kennedy report. Even then, it was several years before action was taken.

Although there was a will to progress this in the early years, reconfiguration became a highly controversial issue. Local populations and their MPs became involved in campaigns to resist closure; Leeds enlisted the support of the Archbishop of York. NHS medical director, Professor Sir Bruce Keogh, later described the delay in implementing this Kennedy recommendation as a 'stain on the soul of the specialty.'

"Forgotten Inquiries"

When the report into the long-running scandal at Mid Staffs hospital[5] was published in 2013, Dr Phil Hammond suggested in Private Eye that many of Sir Robert Francis QC's 290 recommendations could have been cut and pasted from Kennedy's 198 recommendations in the 2001 Bristol report. Dr Hammond made a similar 'cut and paste' observation in February this year regarding the recommendations in Bishop Graham James' Paterson report[3]. The Paterson scandal which had its roots as far back as 2003 when colleagues first raised concerns involved the rogue surgeon carrying out unnecessary and inappropriate operations and inflicting life-changing harm on patients over a 14-year period before he was eventually stopped. The "culture of avoidance and denial" in a "dysfunctional" healthcare system where there was "wilful blindness" to his actions identified in the report sounded all too familiar. The Inquiry recommended that 11,000 former Paterson patients should be recalled for their surgery to be assessed.

Incredibly there were problems again in Bristol in the years 2012 to 2014. Following a series of deaths at the children's heart unit Professor Sir Ian Kennedy was called in again after families tweeted their concerns to NHS Medical Director, Sir Bruce Keogh, who appointed Eleanor Grey QC to carry out the New Bristol Review for NHS England with Kennedy as Consultant Adviser. The CQC had issued a Warning Notice in 2012 after Inspectors noted a lack of sufficiently experienced staff to meet the needs of children requiring high dependency care. We represented 10 families at inquests into deaths over the period covered by the Review. The report, published in June 2016[6] (which parents described as 'inexcusably weak'), found that much of the care was good but the treatment of 27 children raised particular concerns. Bristol's 30-day mortality was found to be the 6th lowest in the UK out of 13 units. The report included 32 recommendations including the need for a national review of paediatric intensive care units.

The call for a public inquiry so that scandals can be scrutinized and for lessons to be learned has become the inevitable and wholly understandable reaction of governments since Bristol and, before that, the 1969 inquiry into the abuse of patients at Ely Hospital, Cardiff. Many similar recommendations had been made even earlier than that in the Platt Report into the Welfare of Children in Hospital published in 1959. The problem is the failure of governments to follow up Inquiries and introduce a statutory mechanism making it mandatory to review and ensure implementation of recommendations of these hugely expensive investigations.

So, have the lessons of the Bristol Scandal of the 1990s been learned? Sadly, many of the issues investigated by the Kennedy Report still arise today. Some of the systemic, cultural failures at Bristol in the 90s have been repeated more than a generation later.

Much is rightly made of the need for a learning rather than a blame culture but with scandals including those that have emerged in Shrewsbury & Telford – described as the biggest in maternity services in the history of the NHS – and East Kent which involves reports of over 300 babies suffering brain damage as a result of oxygen deprivation during birth over a 4-year period - steps have to be taken to make doctors and managers accountable. This seems to be unavoidable. Sadly, it is a case of the bad apples spoiling it for the overwhelming majority of doctors who are dedicated and conscientious, but the medical profession seems collectively to have turned a blind eye and allowed these problems to grow from manageable failings into major scandals. The NHS simply can't afford these scandals. A dangerous state of affairs which exposes patients to a real risk of avoidable harm of which senior staff and management are aware but have failed to address exposes the NHS to negligence claims which it will find difficult to defend.

What is the solution? Listening to concerns raised by medical staff on the ground is crucial. Whistleblowing, like litigation, a blunt instrument to correct errant behaviour, helps to drive up safety standards and achieve a measure of accountability, but why not impose a duty on managers to ensure that whistleblowers in their organisations are encouraged and protected and their concerns properly investigated. What's the harm? I can't think of any whistleblowers whose concerns over patient safety have not eventually been vindicated.

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MEDICO LEGAL CONFERENCE 2021

Draft Programme

24th June 2021

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Mr Justice Pepperall, High Court Judge, Ministry of Justice

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Warren Collins, Partner and Solicitor-Advocate, Penningtons Manches Cooper

Expectations of an Expert

Flora McCabe, Head of Healthcare Claims, Solicitor, Lockton LLP

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Andrew McAulay, Costs Lawyer and Partner, Clarion

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Alexander Hutton QC, Hailsham Chambers

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Simon Hammond, Director of Claims Management, NHS Resolution

Assessing the Risk of Osteoarthritis after Trauma

Mr Nicholas Savva, Consultant Orthopaedic Surgeon, Dorset County Hospital NHS Foundation Trust

Treatment Options for Post-Traumatic Osteoarthritis

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BOOK NOW

PATIENT-SPECIFIC INSTRUMENTS: AN ADEQUATE MIDDLE-GROUND ALTERNATIVE IN KNEE SURGERIES

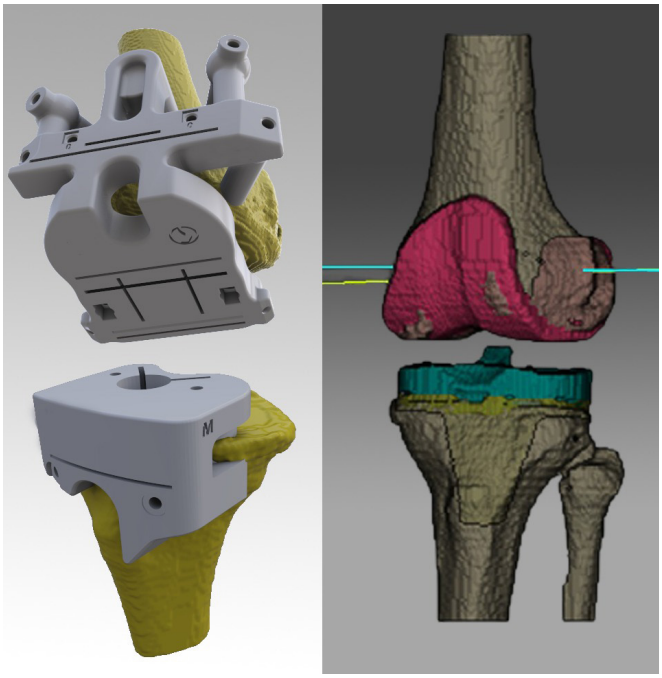
By Mohamed S El-Assawy, B.Sc, Research Fellow, and **Mahmoud A Hafez**, FRCS Ed, MD, Professor & Head of the Orthopaedic Dept, Faculty of Medicine, October 6 University, Cairo, Egypt
Email: mhafez@msn.com

Introduction

Total Knee arthroplasty (TKA) is a common and successful surgical procedure. However, surgeons, engineers and scientists are trying to employ the new technologies of robotics, navigation and 3D printing to improve the outcome and patient's satisfaction of TKA. As with any new healthcare technology, there are issues related to safety, cost effectiveness, and medicolegal aspects that could affect the ability to obtain FDA or CE certification. Patient-specific instruments (PSI) involve five different steps: imaging, planning, 3D production, packing/sterilization and finally the surgery. PSI are currently produced by the implant companies, but some of these steps are outsourced. This raises the medicolegal question: who is responsible for its failure?

De facto necessity of new technologies use

Since the emergence of 3D printers in the 80s, their use has been incorporated into many fields, including medical applications where conventional complicated tools and kits were replaced by PSI. They have been important and necessary for use in many complicated cases where conventional instruments were impossible to use, such as cases of dwarfism (achondroplasia), excessive femoral and tibial bowing, or even in cases of bleeding tendency such as haemophilia. They have been essential for use with cases of severe bone loss, such as revision total hip arthroplasty surgeries with custom-made implants, to the extent that they have become the de facto go-to-treatment for complicated cases such as cervical pedicle screw placement, revision total shoulder arthroplasty and complicated cases of bone osteotomy. With more technological advancements, other more sophisticated techniques, such as computer aided navigation (CAN) have been incorporated and this offers more accuracy and versatility with complicated cases. It should be noted that the term is used interchangeably with Computer-assisted orthopedic surgery (CAOS). It is expected that as cost of machinery decreases, CAN will become an essential part of day-to-day use[1]. For example, the use of CAN in comparison to traditional 2D fluoroscopy has shown that lesser operative and insertion time is needed with CAN. Also, blood loss and incidence of complications were lower with CAN[2].



PSI prologue and scanning perplexities between MRI and CT scans

PSI is a technique that is used in bone surgeries and dental implant placements. The input generally consists of a scan of the region of interest, in addition to a model of the implant to be used, whether it is a pedicle screw, a dental prosthesis or a femoral and tibial implant in TKA surgeries. Once the input data are obtained, preoperative planning is performed to specify the location of the implant and accordingly match it with the PSI, which may have cutting slots to guide saw blades in bone resection, or drill holes to guide the drilling of dental implant, or a pedicle screw. The PSI is aligned to the patient anatomy using CAN software, so that in surgery, theoretically, the implant is placed in the exact position of its preoperative planning. The use of these techniques calls for the availability of a 3D model of the region of interest, which is obtained by the means of computed tomography (CT) or magnetic resonance imaging (MRI). Choosing a CT scan will give certain benefits for planning the case and increasing the accuracy, because the rate of changing bone in arthritis is much slower than the degradation of cartilage. Designing PSI for such a case is much easier than with MRI, which requires the presence of an experienced technician who will be able to make out the details of the already degrading cartilage from the rest of the soft tissue, especially in patients with obesity. Although a CT scan is cheaper than MRI, it also entails the risk of radiation exposure from X-rays. On the other hand, MRI may not be feasible for patients that have implants such as a pacemaker. Similar Computer aided techniques are employed during the use of robotics and computer navigation in TKA surgeries, which offer superior accuracy. Ironically, one of the methods for obtaining data in computer navigation is based on a CT scan, which is then coupled with the use of reflection pins that are used for referencing the position of the bone with respect to the robot.

Accuracy appraisal: TKA case study

The accuracy of PSI in TKA in comparison to conventional methods is generally comparable. According to a retrospective study that evaluated primary TKA in 150 cases, PSI offered better outcomes in the restoration of the kinematic axis, where the conventional instruments group had more valgus outliers than the PSI group[3]. On the other hand, Victor et al. stated that PSI doesn't offer much improvement in TKA[4]. Regarding tibial and femoral component rotation, it was noticed that surgeons may not be able to recognize a 10-degree flexion secondary to flexed femoral and tibia components[5]. Thus the femoral component may be rotated internally. In PSI, the stem, keel in tibial implant and the pegs in the femoral implant are incorporated into the design of the guide and are thus predetermined and can be performed correctly. The final alignment of the PSI is of paramount importance. It is then preferred that a hospital-based system where the surgeon is more engaged in the positioning of the implant in preoperative planning (and thus the PSI) is used[5], which is preferred than a having a technician perform the planning of the case to reduce legal liability.

Surgical challenges with navigation techniques, PSI and conventional instruments

In TKA surgery (and many other similar arthroplasty surgeries), the operating time is very important for many considerations, such as hospital capacity and possibility of infections in prolonged surgeries. The operating time consists of two parts, a fixed part and a variable part. The fixed part generally consists of time that is the same across all surgeries such as anaesthesia time, sterilizing operating site, tourniquet application and wound closure. The variable part is where the main operations of surgery occur and that is where PSI, CAN and conventional technique competes in time reduction. It was concluded that the use of PSI have yielded similar outcomes as with conventional surgeries. However, there some caveats to this, for example in TKA, the tibial PSI is said to have the highest percentage of inaccuracies, it is thus recommended that tibial PSIs are used very carefully along with verifying planned cut by means of CAN for a specific number

of cases to help the learning curve[5]. However, it has been reported that in many cases, PSI had errors in them that rendered them unusable and, in such cases, switching to a conventional tool will prolong the time of surgery. In some cases, duplicate PSI for one part were delivered, which may affect surgery schedule[6]. Furthermore, CAN offers more options with regard to soft tissue release in case of a wrong planned cut, where trial implant can be used and the amount of soft tissue release is planned.

Outcome of each technique

In terms of each technique being compared, CAN offers the most accurate surgical performance, however, its cost is relatively a lot higher in comparison to PSI or conventional tools. Additionally, CAN-employed robots required very special calibration measures and may cause serious legal liability for both the manufacturing companies and the using surgeon.

Conclusion

The PSI technique is a promising toolkit and considered to be a middle ground alternative in knee surgery. It is user friendly and more cost-effective than robotics and navigation. From the medicolegal aspect, the responsibility toward its failure is divided between all parties involved in PSI production, and the source of errors should be identified and attributed to whoever was performing each step. Implant companies should not produce PSI without obtaining an approval of the planning from the surgeon. Recently, the author (MAH) has implemented a hospital-based PSI technique, where all five steps of PSI (imaging, planning, 3D production, packing/sterilization and finally the surgery) are done in one location[7]. This could eliminate the divided responsibility and the difficulty in identifying the source of errors.

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PLACEMENT OF NASOGASTRIC FEEDING TUBES AND THE "TOO LONG TO READ" CLINICAL GUIDELINES: PART 1

By Laurence Vick, Retired 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 January 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.

The Healthcare Safety Investigation Branch (HSIB) published their final report on 17 December 2020 following their investigation into safety issues surrounding the placement of nasogastric feeding tubes raised. The report raised concerns on a number of levels, not least the reference to practitioners telling investigators that the relevant guidelines intended to address the avoidable problem of misplaced tubes – a Never Event - were "too long to read".

https://www.hsib.org.uk/news/hsib-highlights-patient-safety-risks-nasogastric-tube-never-events/

The HSIB launched its national investigation into the problem of misplaced nasogastric (NG) tubes after reports of a 26-year-old man having 1,450ml of liquid, enteral feed mistakenly fed into his lungs in December 2018 following a motorcycle accident. He suffered a significant deterioration before the error was discovered, even after staff had performed an X-ray, but did recover and was discharged two weeks later.

Misplacement of an NG tube into a patient's lungs rather than his or her stomach and the failure to identify this before the tube is used for feed, fluid or medications constitutes a Never Event: defined by NHS Improvement as a patient safety incident considered to be preventable because there is national guidance or safety recommendations that provide strong systemic protective barriers which should have been implemented by health care providers.

In spite of patient safety alerts and warnings and reports of clinical negligence claims and inquests over the last 15 years, the incidence of NG related Never Events has continued to rise. Between September 2011 and March 2016, there were 95 incidents of a misplaced tube reported by NHS staff. The latest data shows there were 14 incidents between April and September 2020: alarming statistics given that incorrect placement has the potential to cause severe complications and avoidable harm.

In 2017 a Regulation 28 Prevention of Future Deaths report was issued by the Coroner for Cumbria to the North Cumbria University Hospitals NHS Trust following the deaths of Amanda Coulthard, 57, at Carlisle Cumberland Infirmary the previous year and Michael Parke, 40, at West Cumberland Hospital Whitehaven in 2012. Both had NG tubes inserted into their lungs – a "failing of the highest magnitude" according to the Coroner who concluded that both had died from neglect.

A number of NHS staff admitted to the HSIB investigators that they knew of the existence of the guidelines issued by the Society of Radiographers in 2012 intended to avoid this preventable error but had not read them as they were "too long to read."

The HSIB said staff had suffered from "inattentional blindness", missing what should have been visible

because, the HSIB suggested, their attention had been diverted elsewhere out of concern to avoid a worsening in the condition of an often critically ill patient.

The HSIB investigation revealed systemic problems which left patients at increased risk of harm. As well as the failure of staff to read and heed the guidelines, there was no consistency in training staff in how to carry out testing or interpret results, and no adequate system to check their competence. Performing an X-ray or pH testing of acidity of fluids from the stomach as methods of checking correct NG tube placement were potentially unreliable. There was no standardised method of interpreting X-rays. It would be beneficial if chest X-rays for acutely ill patients were interpreted and reported by a radiologist, or a radiographer who has undertaken training. The report should include the position of an NG tube if one is present on a chest X-ray. Manufacturers of pH testing strips used different colour coding with no universal process for reading them.

The HSIB recommended a national programme of training and a formal NHS-wide system of accreditation for those qualified to clinically evaluate and record their findings.

The HSIB called for improvements in the design of devices as well as in the reporting of safety incidents.

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.

As a misplaced NG tube constitutes an avoidable Never Event, a negligence claim on behalf of an injured patient would be difficult to defend. Ignorance of a relevant, authoritative, well-known guideline would be unlikely to afford a defence. There are a number of arguments that could be raised to challenge the legitimacy and relevance of a guideline, but I doubt that a Court would be sympathetic to any suggestion that a guideline should not apply because it was too long for practitioners to read. There must be a presumption that doctors should be aware of current guidelines as part of the duty to reasonable skill and care, even in those specialties in which keeping up to date with journals and guidelines constitutes a significant burden.

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. Their aim is to promote best practice in a standardised way, ensuring a consistent level of care, ultimately leading to improvements in patient safety, reducing avoidable harm and in turn driving down the cost of negligence claims against the NHS.

Medical practitioners have not always been receptive to guidelines. In general practice doctors complained of a "flood" of guidelines twenty years ago and the impression is that clinicians do indeed feel that they face a deluge of guidelines from multiple sources. GPs, after all, will often see patients with multi-morbidities, so compliance with a number of single disease guidelines is not without its difficulties.

In 2003 Professor of Cardiology, John Hampton, wrote "Guidelines—for the obedience of fools and the guidance of wise men"

https://pdfs.semanticscholar.org/88be/52abb7babfbecc4c72af540db838f15b1762.pdf Clin Med. 2003; 3: 279–284

Guidelines are just that: *guidance*. "Guidelines, not tramlines," said Professor David Haslam, then Chair of NICE in a lecture to the Royal College of Physicians in June 2016. They provide doctors with a guide to options and recommendations as to best practice, to be consulted as a support to clinical decision-making. Guidelines have the potential to improve the quality of clinical decision-making and ultimately change beliefs. Provided they are seen to be authoritative, reflecting evidence-based research, guidelines may play an important role in persuading doctors

to abandon outdated practices. Life will hopefully become increasingly difficult for the maverick doctor or surgeon.

We don't know yet if the existence of relevant guidelines has resulted in improved safety standards. The Sepsis 6 guidelines are perhaps the closest we get to Commandments: protocols that are clear and unambiguous, known and respected universally and which must be obeyed. Greater awareness of sepsis and the sepsis guidelines among medical professionals and the public will inevitably have resulted in earlier diagnosis and treatment, but it isn't yet clear if this has resulted in a decrease in negligence cases coming forward. Sadly, we still see reports in the press of hospitals failing to comply with the guidelines.

Guidelines and protocols are likely to play an increasingly important part in clinical negligence litigation. The impact on the litigation process, though, is difficult to assess due to the lack of reported cases in which their relevance and validity and the weight to be afforded to a guideline and the implications of compliance or non-compliance have been fully argued and tested in Court. I will give my take on the medico-legal implications of clinical guidelines and the potential arguments that might be raised to challenge the validity of an apparently authoritative guideline in Part 2 of this article in the next issue of Medico-Legal Magazine.

UK MEDIATION JOURNAL

Advocating mediation in the workplace

MEDICO -LEGAL NEWS:

By Lisa Cheyne, Medico-Legal Manager, SpecialistInfo

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

NEWS

Government announces plan to scrap EU Vnuk motor insurance law

The EU Vnuk motor insurance law, covering vehicles used on private land like tractors, lawn mowers, mobility scooters, quad bikes, and off-road motorcycles, may be removed from British law.

The Government claims this will ensure British drivers will avoid £50 a year insurance hike, but accident prevention groups have condemned the decision.

"The Government's decision not to adopt an EU rule that would ensure much-needed compensation for people injured by off-road vehicles is illogical and inexcusable," said Sam Elsby, president of the Association of Personal Injury Lawyer (APIL). "Brexit and the promise of insurance premium savings have been used as an excuse once again for dismissing the needs of injured people."

"Paying insurance premiums is both an incentive to drive safely, and a way to ensure injured people can receive proper compensation to help put their lives back on track."

Transport Secretary, Grant Shapps, said in the announcement that "bypassing Vnuk will also protect the existence of the UK's world-leading motorsports industry. The EU rules would have meant any motorsports collision involving vehicles from go-karting to F1 would have been treated as regular road traffic incidents requiring insurance. This could have decimated the industry due to the additional insurance costs of roughly £458 million every single year."

Read more:
https://www.gov.uk/government/news/government-announces-plan-to-scrap-eu-law-ensuring-british-drivers-avoid-50-a-year-insurance-hike

Coronavirus (COVID-19) vaccines added to the Vaccine Damage Payments Act 1979

The VDPA 1979 provides for a single, tax-free payment of £120,000 to anyone who has suffered severe mental and/or physical disablement as a result of a vaccination against one or more specified diseases. From 31 December 2020, it will include coronavirus vaccinations, pursuant to the Vaccine Damage Payments (Specified Disease) Order 2020, SI 2020/1411. The vaccine damage payment scheme under the VDPA 1979 (VDPA scheme), is a state-financed, no-fault scheme, whose barriers to access are meeting the high threshold test of 'severe disablement'. This means at least 60% disablement, and it has to be demonstrated through medical evidence from the sufferer's treating clinicians. The applicant must also show that this disablement has been caused by the vaccination(s). Both the level of disablement and causation are decided on the balance of probabilities.

The vaccination which is the subject of the claim must have taken place in the UK or Isle of Man (unless it was part of armed forces medical treatment), and must have (i) occurred at a time of outbreak of a disease, in response to that disease, or (ii) prior to the individual's 18th birthday, or (iii) in response to one of a handful of specified diseases. VDPA 1979, s 1(3) also enables claims to be made in respect of vaccines given to a claimant's mother before they were born, as well as potentially in respect of individuals who acquired the disease from a person who was vaccinated against it. A claim on behalf of a child can only be made once the child reaches the age of two. Claims can also be made by the personal representatives of a deceased person, provided that, as per VDPA 1979, s1(1)(a), the deceased was severely disabled as a result of a relevant vaccination 'immediately before his death'.

Read more:
https://www.gov.uk/vaccine-damage-payment

UK maternity hospitals still failing to follow guidelines on Group B Strep (GBS)

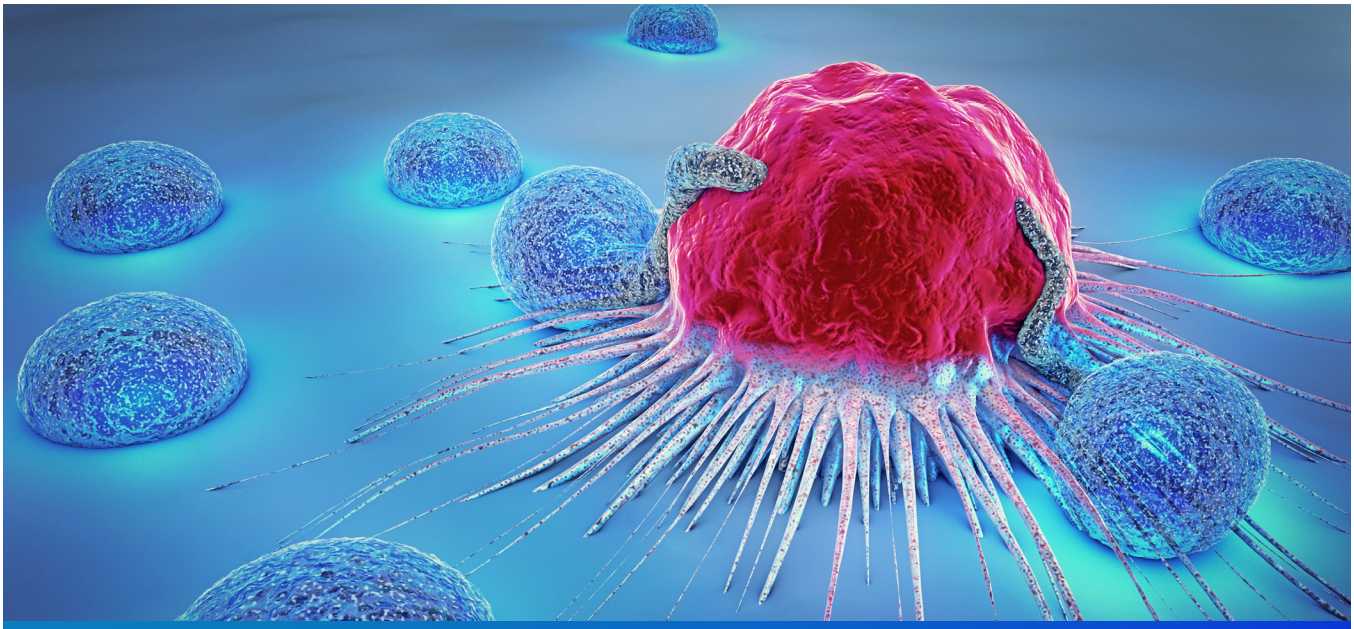
The Group B Strep Support Group recently published their report highlighting that failure to follow national guidelines to prevent group B Strep infections in newborn babies is leading to opportunities to stop deadly infections being missed. They found a shocking nine out of ten hospitals in the UK are not using the recommended test for GBS carriage (costing about £11) despite clear guidance issued by the Royal College of Obstetricians and Gynaecologists (RCOG) and Public Health England (PHE) that the test can significantly decrease false-negative results.

GBS is the UK's most common cause of severe infection in newborn babies, causing sepsis, pneumonia, and meningitis. Approximately 800 babies a year in the UK develop preventable GBS infection in their first 3 months of life, more than 100 of these babies will either die or be left with life-changing disabilities.

The report found that only a few NHS Trusts are following the key new recommendations around giving pregnant women information on group B Strep, offering testing to some pregnant women, and following PHE guidelines on testing for group B Strep.

The majority of Trusts could be leaving themselves open to expensive clinical negligence claim were a baby to develop GBS infection as a result.

Read more:
https://gbss.org.uk/wp-content/uploads/2020/12/Preventing-Group-B-Strep-infections-in-babies-failure-to-turn-national-recommendations-into-local-guidelines.pdf



Cancer Research UK estimates 40,000 fewer people starting cancer treatment services during COVID-19

As well as the sustained disruption on cancer treatment that the pandemic caused throughout 2020, it has left a shortfall in cancer patients coming forward for diagnosis, with 40,000 fewer people starting cancer treatment across the UK last year, according to Cancer Research UK.

Numbers have recovered since the beginning of the pandemic, with urgent suspected cancer referrals rising through 2020, hitting pre-COVID-19 levels in England and Wales by Autumn. Numbers of urgent referrals for suspected lung cancer are still the most impacted, followed by suspected urological cancers – such as prostate and kidney cancer.

CRUK also monitored diagnostic tests for cancer and found a mixed picture. Endoscopies, CT scans, non-obstetric ultrasounds and MRI – can all give a picture of how cancer services are running and how many people are being referred into secondary care.

Endoscopy services have been particularly impacted by the pandemic, with around 600,000 fewer endoscopies performed in England between March and November and the number of endoscopies performed in November still not back to pre-pandemic levels.

Cancer surgery has been heavily impacted for a number of reasons, including intensive care capacity being used for Covid patients.

Other cancer treatments – radiotherapy or chemotherapy for example – have kept running throughout the second wave.

The Lancet Oncology journal recently predicted that delays in treatment and diagnosis of cancer since the start of the UK lockdown in March 2020 could lead to around 3,500 avoidable cancer deaths in England within the next five years. This is likely to lead to a surge in clinical negligence cases relating to delayed diagnosis and treatment of cancer in the years to come.

What is yet to be seen is whether the courts will allow such claims or whether the NHS will be able to successfully defend them by arguing that in order to deal with the COVID pandemic, many NHS resources had to be redirected which meant that it was reasonable for other services to suffer.

Read more:
https://scienceblog.cancerresearchuk.org/2021/02/02/cancer-services-during-covid-19-40000-fewer-people-starting-treatment/

The Medico-Legal Conference – 24th June 2021, is on track to be a live event at The Congress Centre, 28 Great Russell St, Bloomsbury, London WC1B 3LS

Tickets are now available for both live and virtual attendees (both can be converted to either format as necessary nearer the time) get yourself an early bird deal!

Confirmed speakers include the Keynote Mr Justice Pepperall, High Court Judge, and Master of Ceremonies, Professor Dominic Regan, Civil Litigation expert.

Please visit the website for more details and to book: 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.

Nadine Dorries, patient safety minister, makes statement on the Paterson Inquiry report

The independent inquiry report states that between 1997 and 2011 Paterson saw 6,617 patients of whom 4,077 underwent a surgical procedure in the independent sector, and between 1998 and 2011 he saw 4,424 patients at HEFT of whom 1,207 underwent mastectomy.

In the statement to Parliament in February, Nadine Dorries apologised to the harmed patients saying, "The report contains a shocking and sobering analysis of the circumstances surrounding Ian Paterson's malpractice. It sets out the failure in the NHS, the independent sector and the regulatory and indemnity systems. As a result of these failures, patients suffered unnecessary harm."

A full response to the inquiry's 15 recommendations will come later in 2021, but the minister responded to the following, which have or are currently being addressed:

Information to patients: clear and simple written information to patients will be improved;

Consent: the GMC published its revised good practice guidance on consent on 30 September 2020;

Multidisciplinary Team (MDT): specific questions relating to MDT are already included in appropriate CQC service frameworks; and

Patient Recall and Ongoing Care: University Hospitals Birmingham NHS Foundation Trust board and Spire have contacted several thousand potentially affected patients and have ensured they are getting the support and care that they needed.

Read more: https://www.gov.uk/government/speeches/nadine-dorries-statement-on-the-paterson-inquiry-report

New whiplash rules and tariffs to come into force from 31 May 2021

New draft statutory instruments published by the MoJ in February have indicated the tariff levels at which damages will be set for soft tissue injuries suffered in road traffic accidents (RTAs).

The total damages for pain, suffering and loss of amenity payable is limited to £240 for injuries lasting less than three months. There are then incremental increases for every extra three months that injuries continue, to a maximum of £4,215 for cases where injuries linger up to 24 months.

A limited fixed amount is added to the tariff to cover 'minor' psychological injuries suffered on the same occasion as the whiplash injury.

If a claimant suffers more than one whiplash injury through the same incident, the injury with the longest duration will apply.

The legislation allows for an uplift of up to 20% in 'exceptional circumstances', where a court may determine that damages should be greater than the tariff allows. In these cases, the court must be satisfied that the whiplash injury is 'exceptionally severe' or where the person's circumstances increase the pain, suffering or loss of amenity.

The amendments to the Civil Procedure (Amendment No.2) Rules 2021, establishing how the new whiplash portal will work, confirm they come into force on 31 May 2021.

The portal will be designed to handle claims from unrepresented claimants, because the small claims limit is rising to £5,000, meaning that costs are no longer recoverable for claims below that figure.

Claimants must state in the claim form whether they expect to recover more or less than £5,000.

Claims involving children and protected parties are not to be allocated to the small claims track.

The new rules, which can be found in the link below, include provisions on obtaining a second medical expert report and claims which do not continue under the RTA small claims protocol.

Read more:
https://www.legislation.gov.uk/uksi/2021/196/contents/made

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