MEDICO LEGAL

MAGAZINE

ISSUE 8

Presented by:

specialist info

Welcome to Issue 8

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

In this second issue of 2018, Enable Law Legal Director Laurence Vick comments on the safety concerns over outsourcing by the NHS to private sector hospitals.

We present an overview of the methods of determining cognitive impairment in a claimant using cognitive functioning tests, by Clinical Neuropsychologists Professor Gus Baker and Dr Perry Moore.

Mr Michael Gaunt, Consultant Vascular Surgeon, discusses causes of arterial conditions affecting the legs, a common area for negligence claims.

Greg McEwen, Healthcare Expert and Partner, BLM discusses the rising use of artificial intelligence for diagnostic purposes.

We are also pleased to include an article on finger-tip injuries in personal injury by hand surgeon Mr Maxim D Horwitz.

Mr Nikhil Shah, Consultant Trauma and Orthopaedic Surgeon, discusses reasons for litigation after total hip replacement surgery.

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 training 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, or share your news and experiences with us.

Lisa Cheyne
SpecialistInfo
Medico-Legal Magazine

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MEDICO -LEGAL COURSES:

By Lisa Cheyne, Medico-Legal Manager, SpecialistInfo

Training Courses for Expert Witnesses

The dates and locations for the confirmed ML courses that we are holding during 2018 are listed below with links to our booking page.

Medico-Legal Essentials Course (a general overview for anyone starting a medico-legal practice, focussing on personal injury):

- *18th September 2018* – London
- *21st November 2018* – Birmingham

£330 (plus VAT)

For further information about the Essentials course, please visit: www.specialistinfo.com/a_ml_standard.php

Clinical Negligence Medico-Legal Course (specific training for experts undertaking higher value medical negligence cases):

- *19th September 2018* – London
- *22nd November 2018* – Birmingham

£355 (plus VAT)

For further information about the Clinical Negligence course, please visit: www.specialistinfo.com/a_ml_clinicalneg.php

Advanced Medico-Legal Course (now including court-room skills and an update to the law and procedures for experienced experts):

- *20th June 2018* – London
- *20th September 2018* – London
- *6th December 2018* – London

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Mediation Training Course (5 days):

- *4th-8th June* – London
- *13th-14th & 26th-28th September* - Aberdeen
- *24th September* - London

£1,250 (plus VAT)

For further information about the Mediation course please visit: www.specialistinfo.com/a_ml_mediation.php

To book your place on one of the above courses please complete the booking form on our website by clicking on one of the above links (discounts are available for multiple bookings – please call Lisa to discuss or to book over the phone).

Please contact me, Lisa Cheyne, on 01423 727 721 or email me at lisa@specialistInfo.com

Numbers are strictly limited so early booking is advised to make sure you do not miss out on these enjoyable and highly informative courses.

I look forward to hearing from you soon.

Kind regards

Lisa Cheyne
Medico-Legal Course Manager

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FINGERTIP INJURIES IN PERSONAL INJURY

By Mr Maxim D Horwitz MBChB FRCS (Orth) DipHandSurg, Consultant Orthopaedic Hand and Wrist Surgeon, Chelsea and Westminster Hospital, London SW10 9NH

Maxim Horwitz is a Consultant Orthopaedic Hand and Wrist Surgeon in the Hand Unit at Chelsea and Westminster Hospital where he leads the paediatric hand surgery service. He is also an Honorary Consultant for the Major Trauma Unit at St Mary's Hospital.

Mr Horwitz receives instructions from solicitors and insurance companies and acts for both Claimant and Defendant. Drawing on his broad clinical knowledge and in-depth expertise in traumatic injury he is well placed to provide expert witness reports. He can be contacted on E-mail: info@thehanddoctor.co.uk; Website: www.thehanddoctor.co.uk

Fingertip and nail injuries are common in the general population, and more common in children, mechanics, carpenters and people who work in manual trades. The tip of the finger is extremely sensitive and when crushed or lacerated can be associated with an injury to the bone, nail bed or nail plate.

If appropriately treated, these injuries will often make a good recovery with the following caveats. Despite anatomical repair of the nailbed, the nail may grow with a bump, split or ridge. This will usually result in a cosmetic problem and very rarely a functional one. If there is any loss of bone at the tip of the finger, then the nail may hook over the edge of the finger. The shape or contour of the pulp may change permanently but usually without any functional deficit unless the finger is significantly shorter. The fingertip will often have abnormal sensation for up to a year with persistent redness or swelling for a similar period. Cold intolerance and hypersensitivity can last for between two and ten years after an injury, particularly worse in cold weather and may abate but may never completely disappear.

The nail takes nine months to take on a normal appearance, colour and shine. Various strategies can be used to take away the sensitivity at the tip of the finger and these include simple massage and desensitising by touching different surfaces. Very occasionally, a neuroma (nerve scar) can occur on the tip of the finger after an open injury. These can be challenging to treat and often respond very well to a course of hand therapy. Trying to excise or remove the neuroma can often move the problem to a different location more proximally up the limb and is not recommended unless it is a last resort.

Several problems can occur after a simple fingertip injury. If the patient has extended periods of immobilisation this can result in stiffness of the digit or the adjacent fingers and in the worst-case scenario this could be permanent in nature with Complex Regional Pain Syndrome. Wounds with excess granulation may take a prolonged period to heal that occasionally needs surgical debridement. Finally, if there is a very small fracture in the tip of the finger, it may not heal and this may need excision once the soft tissues have settled. This is again a very rare occurrence as the majority of the fractures go on to a solid union.

With regards to occupation, the initial period after a fingertip injury can be challenging, as there is usually a dressing on the finger tip for a period between two and four weeks and the initial pain and occasionally sensitivity makes it difficult to grab and hold items. If the patient works in an area that involves adherence to strict health and safety rules, it is not appropriate to work. The other problem is that food preparation such as chopping and cutting, is often difficult due to sensitivity in the more commonly injured longer digits; i.e. the index and middle finger. Manual labourers usually need between 2 and 6 weeks off due to the need to prevent further injury. This means that patients often need assistance with these simple tasks, even though it is a minor injury, in the initial four to six weeks after the injury. It is usually possible to maintain personal hygiene with an isolated fingertip injury.

In summary, the majority of minor fingertip injuries make a very good recovery. However, the appearance of the skin and the nail can often be permanently changed because of the loss of a small amount of bone or soft tissue at the time of the injury. This is usually cosmetic in nature and has no functional implication.

Treatment options do exist to improve the cosmesis; however, this often involves a significant procedure, which could result in further sensitivity and stiffness in other fingers, and again is not routinely recommended.

Mr Horwitz sees between 10 and 15 such injuries for medico-legal purposes per year, both for the claimant and the defence. He sees approximately 55-75 of these injuries per year in the NHS.

ARE WE SAFE IN A PUBLIC-PRIVATE HEALTH SERVICE?

Laurence Vick Legal Director at Enable Law

Outsourcing medical treatment to private providers is common practice in many areas of the NHS, with private companies increasingly operating alongside NHS trusts. The result, in some places, is an NHS that is neither fully public nor fully private, leading to concerns over gaps in safety where the two sectors overlap.

In this article Enable Law Legal Director Laurence Vick comments on the safety concerns over outsourcing by the NHS to often inadequately vetted private sector hospitals and shortcomings in the supervision and monitoring of those contracts when in progress.

The Paterson scandal inevitably looms large over the private healthcare sector and serves as a reminder of the sometimes uneasy relationship between the NHS and private providers. Paterson had been employed by the Heart of England NHS Foundation Trust (HEFT) and had practising privileges at Spire's Solihull Parkway and Little Aston hospitals. Spire, BMI and other private companies carry out a significant amount of work for the NHS. The NHS is now contracting out a fifth of its total healthcare budget, equivalent to more than £20 billion a year.

Spire's NHS referrals nationally are reported to account for almost a third of its £926m annual revenues. Although nearly a quarter of their activity at the Solihull and Little Aston hospitals is funded by the NHS, none of Paterson's surgery appears to have been outsourced by the NHS.

Nearly half of the patients treated by BMI in their hospitals are NHS referrals. In her 29 January 2017 report for the Bureau of Investigative Journalism on the concerns over consultant orthopaedic surgeon Mohammed Suhaib Sait's treatment of patients at the private Fawkham Manor BMI hospital, Melanie Newman noted the current lack of a national system for monitoring the care provided to NHS patients treated in the private sector. Regional NHS Clinical Commissioning Groups (CCGs) are responsible for handing out and overseeing contracts, but senior NHS sources quoted in the TBIJ article said that these bodies are overstretched, unable to carry out adequate checks and rarely carry out audits: 'NHS commissioners are funding these treatments but don't know which patients have had what done…they get a bill for a list of services and they pay it'

We may not be sliding into full-scale privatisation of our healthcare as many fear. After Circle's unhappy experience running the Hinchingbrooke NHS hospital there must be a doubt over the private sector's appetite for taking over and accepting the operating risk and indemnity cost of running a full-service hospital, or a maternity unit or A & E department. Circle pulled out less than a third of the way through their 10 year contract after Hinchingbrooke had been placed into special measures following a CQC report revealing a catalogue of serious failings. An increase in outsourcing of specific elective treatment and services by the NHS to private providers seems inevitable though.

My experience of these cases going back over 10 years echoes these findings and has revealed failures in outsourcing on a number of levels: the private companies and the staff they employ are not always assessed as fully as they should be; contracts do not appear to receive an appropriate level of supervision and monitoring by commissioning NHS organisations, and there is a concern that local NHS management may not be in a position to intervene swiftly if problems occur. I have also found a gap when seeking to establish who has overall responsibility at the highest level for the safety of outsourced care.

As patients we need to know that any outsourced treatment we undergo is carried out to the same if not better standard than if performed in the NHS. The vast majority of treatment carried out in the private sector goes ahead without mishap but how can we be sure and how can this be put to the test? The sector will point to the high quality of private health care but, given the lower transparency requirements, how do we know that the treatment provided - whether to outsourced NHS or wholly private patients - is safe?

Whereas NHS hospitals treat all-comers, adults and children, with the full range of medical conditions, illnesses and diseases, private hospitals carrying out outsourced work for the NHS can effectively 'cherry pick' the most profitable, usually low-risk, forms of treatment that can be delivered at a predictable cost. This should present no difficulty for surgeons and their teams but problems do occur. There should be few if any complications, so the 50% complication rate – attributed to not one but to a 'constellation' of failures – only four days in to the outsourcing contract for cataract procedures carried out by Vanguard Health in 2014 for the Musgrove NHS Trust in Taunton was alarming.

A lack of transparency and a culture of secrecy often seems to prevail when the private sector is involved in NHS contracting. A fundamental problem is that private operators are not subject to the Freedom of Information Act. As taxpayers and users of our NHS shouldn't we have the right to investigate the terms and details of contracts made with private operators and how they are to be monitored and supervised? Private hospitals can also be reticent when it comes to publishing information which would allow their outcomes to be analysed and compared with NHS hospitals.

As appeared to be the case with the Musgrove-Vanguard cataract contract, the impression is that the private sector can be reluctant to participate in open joint investigations with the NHS when problems have occurred. This should surely be an automatic requirement so that information can be shared, standards and outcomes in the NHS and private sector compared and lessons learned. We won't see the culture we have moved towards in the NHS if private providers, with obligations to shareholders as well as patients, are able to hide behind 'commercial confidentiality.' If private providers are to do business with the NHS, it seems only reasonable that they should be required to face the probe of FOI requests and adhere to the standards of openness and transparency we are increasingly seeing in the NHS. Otherwise we risk losing the key advances that have been made in the law relating to consent before treatment and the duty of candour after treatment has been carried out. The concern where NHS care has been outsourced is that the private provider may thwart the commissioning NHS body in complying fully with the duty imposed on them. I don't see how we are going to get an accurate explanation of the risks inherent in a procedure or the reasons why treatment has failed if a private provider is reluctant to disclose its outcomes. The 'insurance factor' may also play a part. Will a private provider's insurers be happy for their insured hospital or clinic to explain the full reasons why an operation may have failed? Paterson's NHS and private operations pre-dated the introduction of the duty of candour but it would be interesting to know what patients could expect from the duty of candour if they had taken place today.

The ISTC programme and Netcare

My own involvement in handling failed outsourcing cases goes back to the Netcare ISTC (Independent Sector Treatment Centre) contracts of 2006. An ISTC contract to provide orthopaedic and cataract operations was negotiated by Hampshire and Isle of Wight Strategic Health Authority with the South African healthcare provider Netcare, which flew in surgeons and nursing staff from South Africa to carry out operations at the Haslar Hospital, Portsmouth.

One of our clients, a patient of Plymouth's Derriford NHS Hospital, underwent a hip replacement at the Haslar under this ISTC initiative. The hip surgery failed and during the procedure she suffered a severe burn on the leg from the diathermy wand used to cauterise blood vessels. She was left in the invidious position of having to wait while her local NHS hospital argued with Netcare over responsibility for her care. Derriford argued that clinical as well as legal responsibility for her care had effectively been transferred to Netcare. This impasse was resolved by Derriford accepting responsibility for the treatment of the burn injury. They also arranged for the hip surgery to be re-done by a leading orthopaedic surgeon at a local private hospital. On the morning of the revision procedure, however, our client faced the private clinic's receptionist demanding to know who would be paying for the operation. This was resolved with the NHS Trust picking up the bill; the revision surgery went ahead at no cost to our client, but not without a great deal of distress. We never discovered if the NHS recovered these costs or the damages paid to our client from Netcare but the suspicion was that they did not.

The report commissioned by the Strategic Health Authority into these failures in 2006 identified a range of shortcomings: inadequate vetting of the medical and surgical staff employed by Netcare; inadequate liaison, and often tension, between Netcare and local NHS personnel when addressing surgical complications and inadequate monitoring of the contract when in progress. We submitted evidence of the Netcare failures and the safety concerns to the Commons Health Select Committee as part of their investigation into ISTCs in 2006. Their review revealed concerns over regulation and monitoring of quality of care demonstrated by ISTCs and included the recommendation that all organisations providing services to patients, public or private, must be regulated with the CQC.

The Musgrove/Vanguard contract

Taunton and Somerset NHS Foundation Trust set up an outsourcing arrangement in May 2014 by which Vanguard Healthcare Limited was to carry out cataract operations in their mobile units at Musgrove Park hospital. The contract was reported to be worth £320,000, covering over 400 operations at a rate of 20 a day – at least six more than NHS consultants at Musgrove would routinely carry out each day. After only 4 days the contract had to be terminated by Musgrove after an alarming 31 of the 62 patients treated suffered complications. The already over-burdened (but highly regarded) NHS ophthalmic staff had raised concerns over the large number of patients they were having to treat after they had come to emergency eye services with post-operative complications. One of our clients, elderly like most of those affected, also suffering from dementia, was left blind in one eye.

The failure of the Musgrove/Vanguard contract is a classic example of all that can go wrong when the NHS outsources treatment to private contractors. I have chosen this contract not to single out Musgrove but because it illustrates the problems that can arise when the NHS outsources to the private sector.

To their credit, the Musgrove NHS Trust promptly announced that that they would commission a full internal report investigating the failings that had occurred and 'Any financial responsibility would rest with us. If any patients wish to pursue compensation, we would work with them.' The impression was that Musgrove wanted to get a report out as swiftly as possible. After a significant delay publication only took place after the report was leaked to the BBC.

The report established that there had been no single clear cause for the 'constellation' of failures that had occurred over the very short life of the contract.

The report also exposed a complex chain of sub-contracting whereby three companies provided various elements of the outsourced service: Vanguard as main contractor, The Practice PLC supplying the surgeons, and Kestrel Ltd the equipment.

Complication rates in cataract procedures are generally less than 5%, so a 50% rate after only four days raised questions over the monitoring of the contract and when the first alarm bells began to ring. It emerged that the ophthalmic NHS staff at Musgrove had raised concerns from the outset. We gained the impression of an argument behind the scenes over responsibility for these failures and a reluctance on the part of Vanguard, or possibly the sub-contractors, to participate in or agree to the publication of the NHS investigation. There was even a suggestion that the report would expose the Trust to an action for defamation. Kestrel later claimed never to have had access to the report at all.
Vanguard acknowledged in media statements that there were lessons to be learned "by all parties".

Further details only emerged when the Trust responded to our FOI request. We asked the Trust if their report had been officially published and why there had apparently been a threat of legal action if the report was circulated to the press. The Trust said they had been advised that the report could only be shared with 'patients, a core group of staff directly involved in the matter and key stakeholders'. They said this decision had been made to protect the hospital against a number of potential legal claims: 'In sharing a report with these groups we informed them that the report is strictly confidential and not to be disclosed to anyone else.' They added that the report had been shared with Vanguard for them to comment on matters of 'factual inaccuracy or concern'. We asked the Trust to disclose documentation evidencing the vetting of Vanguard and The Practice, including data and outcomes from previous outsourcing contracts between the Trust and those companies. We were told that this information was 'commercially sensitive' and therefore would not be disclosed. In response to the enquiry as to the type of implant and the supplier used by Vanguard and/or The Practice under the contract we were told that this question should be directed to Vanguard as the 'contracted organisation'.

The RNIB expressed concern in press reports on the Musgrove-Vanguard contract over the wider issue of whether NHS ophthalmic safety guidelines, to which they contributed with the Royal College of Ophthalmologists in 2011, were being adhered to when cataract treatment is outsourced. This remains a concern as ophthalmic procedures are increasingly subject to rationing by the NHS and outsourcing to the private sector.

The Health Select Committee

Our clients were far from happy with the responses we had received on their behalf and I submitted their concerns to the Health Select Committee chaired by Dr Sarah Wollaston MP in March 2016. Dr Wollaston raised our concerns over patient safety and indemnity at the highest level. She wrote to and received detailed replies from Jeremy Hunt Secretary of State at the Department of Health, Simon Stevens Chief Executive of NHS England and David Behan Chief Executive of the Care Quality Commission.

The correspondence was published on the Commons Health website on 13 August 2016 'Responsibility for subcontracted services & detection of system-wide safety/quality issues' (https://www.parliament.uk/documents/commons-committees/Health/Correspondence/2016-17/NHS-subcontracting-2016.pdf)

The responses received by the Health Committee reveal a confusing picture with potentially dangerous gaps in the vetting of providers and monitoring of contracts when in progress. The position as to the overall high-level responsibility for outsourcing by the NHS remained far from clear. Despite the assurances she received Dr Wollaston remained concerned as to the lack of defined responsibility for vetting of contractors and monitoring and identifying systemic issues which may arise when the NHS outsources or sub-contracts services: she referred to this as the need to 'join the dots.' Jeremy Hunt and NHS England Chief Executive Simon Stevens suggested that

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responsibility for identifying any 'systemic problems' under outsourcing and subcontracting arrangements lay with the CQC. In his response to Dr Wollaston, CQC Chief Executive David Behan, however, was emphatic that this did not fall within the responsibility of his organisation.

The correspondence also suggests there is uncertainty over indemnity and the suspicion remains that the NHS continues to pick up the bill for failures of outsourced contracts

Paterson

The case of breast surgeon Ian Paterson, now serving 20 years in prison on counts of causing grievous bodily harm and wounding with intent after performing unnecessary radical mastectomies and 'cleavage-sparing' mastectomies - which increased the risk of cancer returning - has highlighted multiple failures of governance and patient care at all levels in the NHS and private sector. The Independent Review announced in December and expected to announce its findings by the summer of 2019, is to consider a range of issues including the responsibility for the quality of care and the appraisal and validation of staff working in the private sector, information sharing between the private sector and the NHS, the role of insurers of private providers and the extent of the medical indemnity cover doctors working in the independent sector are expected to hold.

Paterson had been allowed to continue his dangerous practices in the NHS and in the private sector where he worked at BUPA hospitals from 1993 and at the two Spire hospitals from 2007 onwards. Spire maintained in the court proceedings that they had allowed Paterson to operate on their private patients but relied on the NHS to vet his competence and warn them of concerns over his treatment. Prior to the eventual settlement of the court action Spire were reported to be suing the NHS Trust which employed Paterson for not warning them of his dangerous practices: surely a damaging position for a private health care provider to adopt?

Whereas NHS Resolution, formerly the NHSLA, which covers the liabilities of NHS hospitals, has paid out £17 million to compensate Paterson's NHS victims, his private patients faced many obstacles in their battle for justice. The contract for undertaking an entirely private operation in the private sector with no element of outsourcing is between the patient and the surgeon, with a separate contract between the patient and the hospital for the use of the hospital's facilities and services. Until the recent settlement, his private patients were unable to recover compensation from Paterson personally and his professional indemnity insurers refused to meet claims on his behalf. Spire refused to accept responsibility for compensating his private patients, relying on the more limited role of the private hospital in line with this traditional formulation of the private hospital/surgeon/patient relationship.

The liability position of private hospitals would have faced a severe testing at the trial listed for hearing later in 2017 but Spire, many believe, bowed to the inevitable and agreed to pay £27.2m into a fund to compensate 750 of Paterson's private patients, equivalent to £49,600 per patient. A further £10m is to be provided by Paterson's insurers and his former NHS Trust. Neither the NHS nor Spire have actually admitted liability.

After it emerged that Paterson had been allowed to continue operating as a surgeon for such a lengthy period, President of the Royal College of Surgeons Derek Alderson commented in a BBC Panorama interview on 16 October 2017 that private hospitals are not reporting enough data on patient outcomes: 'We don't know exactly what's going on in the private sector… It cannot be as robust or as safe as the NHS at the moment for the simple reason that you do not have complete reporting of all patients who are treated… It's not good enough. Things have to change' The RCS recommended that private hospitals must be required to participate in clinical audits as a condition of registration by the CQC and should be forced to report similar patient safety data including 'never events,' unexpected deaths and serious injuries as required of NHS hospitals.

Even now there is concern that numbers of both NHS and private patients operated on by Paterson have not been contacted and followed up by HEFT or Spire, suggesting an apparent lack of liaison between the NHS and private sector. Former Paterson patient Deborah Douglas who helps run the Breast Friends support group told the Guardian in December: "For me the big thing now is how many other people were affected. We want those facts – we want those figures."

Whistleblowing

The NHS does not have a good track record when it comes to their treatment of whistleblowers but it is likely they are made to feel even less welcome in the private sector. Little seems to be known of how whistleblowers who raise concerns over outsourced contracts would be treated. It is hard to imagine there won't have been employees at Spire as well as the NHS who attempted to raise concerns over Paterson's practices but may have been suppressed. The Daily Mail reported in June 2017 that up to ten doctors who worked with Paterson are being investigated by the GMC and the Nursing and Midwifery Council said it was investigating 'a small number of nurses' linked to Paterson. These may be the former colleagues who turned a blind eye to his activities.

Facilities in the private sector

In their 2016 report 'Privatisation an independent sector provision of NHS healthcare' the BMA found that some private hospitals still lack intensive care facilities. Private hospitals were often ill-equipped to deal with surgical complications; an estimated 6,000 patients each year required NHS care after failed treatment at private hospitals and clinics, with around half of that number classed as emergency cases requiring admission to NHS A&E departments.

The CHPI thinktank reported in 2011 that five of the 17 private hospitals providing in-patient care in central London had no 'critical care' beds. More recently in their 20 October 2017 report 'No Safety Without Liability: Reforming Private Hospitals in England after

the Ian Paterson Scandal' the CHPI found that little had changed since their earlier reports. There were a number of systemic patient safety risks specific to the private hospital sector; some junior doctors in private hospitals were left in charge of up to 96 beds and working weekly shifts of 168 hours; surgeons were often absent after carrying out surgery and not on site to deal with any complications. The absence of intensive care facilities in many private hospitals remains a concern.

Establishing the facilities at private hospitals where outsourced treatment is to be performed is not easy but clearly this should be part of the NHS's vetting process. Quite apart from the safety issues and the question of whether the NHS should be outsourcing to hospitals lacking what would seem to be essential facilities, surely in the interests of transparency patients should be warned about these shortcomings so they can make an informed choice and give a valid consent?

FOI in the private sector

Information Commissioner, Elizabeth Denham, who oversees FOI and data protection in the UK confirmed in an interview in July 2016 that she is seeking to improve the transparency of public services delivered by private companies. "Private contractors above a certain threshold for a contract or doing some specific types of work could be included under the FOI Act. The government could do more to include private bodies that are basically doing work on behalf of the public." This would be a welcome reform.

CONCLUSION

As our public-private health service becomes increasingly fragmented it is difficult not to harbour anxieties over the safety issues of outsourcing arrangements. The concern is that if private hospitals continue to escape legal liability for the actions of doctors working in their premises and who are using their equipment and working alongside their staff, then they have come to regard themselves as untouchable and lack the incentive to monitor the activities going on in their hospitals. As private companies often employ NHS doctors, surely they

should not be able to argue – as appears to have been Spire's reported intention – that it is the responsibility of the NHS and not the private hospital to vet those doctors. The private sector should be accountable for the treatment carried out in their hospitals and the NHS should not be out of pocket as a result of their failures.

Regardless of the political considerations and fears over what is seen as the increasing privatisation of the NHS, it is imperative that patient safety remains paramount. Outsourcing to the private sector may be inevitable as the NHS confronts its many challenges, but the standard of care must be equal to, if not better than, that which patients can expect to receive in the NHS. Outsourcing can only be sustainable if contracts are monitored, and private providers to the NHS properly vetted and held to account for their errors. If the private sector wishes to work with the NHS it should face the same level of scrutiny and meet the same standards of transparency and disclosure as the NHS and should accept the probe of Freedom of Information requests.

For a list of references and suggested further reading, please visit (https://www.enablelaw.com/nhs-outsourcing-suggested-reading/)

Footnote 1

CHPI thinktank report 'The Contracting NHS: can the NHS handle the outsourcing of clinical services?' March 2015

https://chpi.org.uk/wp-content/uploads/2015/04/CHPI-ContractingNHS-Mar-final.pdf

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VASCULAR SURGERY – THE PROBLEM WITH LEGS

Mr Michael Gaunt MA, MD, FRCS. Consultant Vascular Surgeon, Cambridge.

In previous articles I have described how the speciality of Vascular Surgery is concerned with the diagnosis, assessment and treatment of conditions of the arteries, veins and lymphatics of every part of the body apart from the heart (cardiology/cardiac surgery) and the brain (neurology/neurosurgery).

Vascular surgery is a high-risk speciality for medicolegal claims because when problems occur they do so quickly and with severe limb and life-threatening complications.

My previous papers have provided a brief overview of vascular surgery, but in this article, I am going to concentrate on a common problem area for arterial disease – the legs. Medical negligence in this area frequently results in amputation of the limb and long-term disability requiring significant modifications to all areas of a claimant's life including employment, social life, home life, relationships and life expectancy.

Arterial Conditions Affecting the Legs

In general, arteries carry blood rich in oxygen and nutrients to supply the muscles and tissues of the legs. In humans the muscles of the legs are much bigger and require much more arterial blood supply than the arms, therefore, arterial conditions such as atherosclerosis, which causes arterial narrowing/blockages, have much greater effect. Two situations significantly increase the blood requirement of the leg – exercise and injury/wound healing. Problems occur when the arterial blood requirement of a limb exceeds the ability of diseased arteries to meet that requirement. In exercise this means the muscles go into oxygen debt, produce lactic acid and seize-up – intermittent claudication. In injury/wound healing it means that healing does not occur and in fact wounds deteriorate and extend - the classic example is gangrene of a little toe which extends until the whole leg turns gangrenous. Therefore, all conditions which affect the arteries require timely and accurate assessment and treatment to avoid unnecessary pain and disability.

For the purpose of this article I am going to describe conditions according to the common areas of claims:

1. Delays in diagnosis and treatment of acute and chronic arterial conditions
2. Complications of treatment
3. Amputation

Acute conditions represent a sudden deterioration in blood supply. These can occur from intrinsic reasons such as an embolus from the heart or aorta, or extrinsic reasons such as a sharp transection of the artery or blunt injury such as overstretching of the

arteries by unstable bone fractures and dislocations. In acute conditions there is no time for the body to adapt and, if the interruption to blood flow is complete, then there are six hours to restore arterial blood flow before significant muscle death occurs. Depending on anatomy, after 12-24 hours of ischaemia the limb frequently becomes non-viable. Therefore, delays in diagnosis and treatment are a common cause of disability and source of claims. Closed arterial injury associated with fractures can be easily missed, especially in cases of multiple trauma, and a high index of suspicion is essential to ensure prompt referral to vascular surgery.

Chronic conditions represent a gradual worsening in blood supply, which may go unrecognised by patient and doctors until a final deterioration such as a patch of dry gangrene or non-healing ulcer. The common cause of arterial problems is atherosclerosis (hardening of the arteries) caused by smoking, diabetes (particularly type 2 diabetes) and old age. While smoking is in decline the prevalence of obesity-related type 2 diabetes and old age is increasing. Chronic arterial disease develops over years. Classically, symptoms in the legs progress, as more arteries block off, deteriorating from pain in the muscles on walking (claudication), to pain in the feet at night as the nerves are deprived of oxygen, to pain in the feet all the time to, finally, non-healing ulcers and gangrene.

Diagnostic difficulties arise because some patients can progress straight to non-healing ulcers or gangrene without passing through the other stages. For example, non-mobile patients may never walk sufficiently to experience claudication, while diabetic patients with peripheral neuropathy may never experience pain in the feet due to decreased sensation.

The majority of type 2 diabetics will not die as a result of blood sugar abnormalities but due to heart attacks, strokes and peripheral arterial disease – in this regard type 2 diabetes can be considered more of a cardiovascular, atherosclerotic disease rather than an endocrine disorder.

Patients with chronic arterial disease may undergo acute deterioration when diseased arteries suddenly thrombose, resulting in critical ischaemia requiring urgent intervention to save the leg. The time scale for intervention is generally longer but may be more difficult to diagnose and treat. Sometimes, doctors who are used to seeing a patient with long-term, but stable, arterial disease, may not recognise that a small amount of further deterioration has resulted in the leg becoming critically ischaemic and fail to treat the situation with sufficient urgency.

Non-healing leg ulcers are a particular problem in both diabetics and the elderly. Whatever the cause, once the ulcer occurs the blood requirement of the limb to achieve healing increases significantly. If diseased arteries cannot supply the extra blood then healing never occurs unless the arterial supply can be improved. In the NHS, the majority of leg ulcers are managed in the community with treatment provided by nurses supervised by GPs who may have limited training of knowledge of peripheral vascular matters. There is NICE guidance regarding the management of leg ulcers and those that fail to heal in the community should be referred for specialist assessment within a given time-frame, but this advice is not always followed and this can be an important factor in leg ulcer related claims.

Complications of Treatment

The two main elements of the treatment of peripheral arterial disease are the specific lesions causing a reduction in blood flow and the management of the patient's overall risk of cardiovascular events. In arterial patients, risk management substantially reduces the risk of death, heart attacks, strokes etc. and includes: lifestyle advice, blood pressure management, cholesterol/lipid lowering, antiplatelet agents etc. Failure to implement this management in patients with known arterial disease who go on to suffer an adverse cardiovascular event can be a source of claims.

Treatment of specific arterial lesions disease to improve blood flow includes: interventional procedures such as thrombolysis, balloon angioplasty/stenting and arterial operations including bypass surgery. These interventions are potentially high risk with potentially serious complications and side-effects, therefore, the consent process is particularly important especially with regard to the Montgomery judgement.

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Thrombolysis is the administration of 'clot busting' medication directly into an artery to dissolve the occluding thrombus. The main complications include haemorrhage, damage to the arteries and failure to remove the thrombus. Thrombolysis may be considered appropriate if the limb is not immediately threatened and the clinicians feel there is sufficient time for the lysis to work. Even then, frequent assessment of the leg during lysis is required to ensure that the limb is not becoming non-viable. One of the worst outcomes is to eventually clear the arteries of thrombus but the leg muscles are dead, requiring amputation.

Balloon angioplasty is an interventional radiology procedure involving the direct puncture of an artery to introduce an angioplasty balloon catheter to stretch open a stenosed or blocked artery. Depending on the anatomical site, a metal stent can then be inserted to keep the artery open. Complications include bleeding, damage to the artery, failure to get across the lesion, embolization (where thrombus is dislodged and blocks more distal arteries), early re-occlusion and allergic reaction to radiological contrast solutions. Angioplasty is often performed under local anaesthetic and is less invasive than surgery but, once again, valuable time may be wasted at multiple attempts at angioplasty and the opportunity for limb-saving surgery is missed.

All arterial surgery may be considered major surgery. Examples of arterial surgery include endarterectomy and bypass surgery. Surgery is generally employed when there are extensive occlusions of the leg arteries, the anatomical site means that the lesions are not suitable for angioplasty or the urgency of the situation means that other forms of treatment cannot by tried. Success depends on a high level of technical skill and close monitoring in the post-operative period to detect early complications such as bypass occlusion causing further ischaemia. Poor clinical decision making, technical errors and failure of post-operative care are common sources of claims.

Amputation

Leg amputation is frequently considered by patients to be an unpopular, disabling and disfiguring operation, but can be both life-saving and transformative when arterial disease and ischaemia are too extensive.

However, patients are right to believe that amputation is a major life-changing event, which affects all aspects of life including mobility, occupation, home life, personal care, transport, leisure activities, relationships, holidays and reduced life-expectancy. Despite the inspiring feats of para-Olympian athletes the sad truth is that many elderly amputees will never manage to mobilise fully with a prosthetic limb and many rely predominantly on a wheelchair and have extensive care needs for all aspects of daily living. Therefore, when amputation occurs as the result of negligence the resulting claims can be substantial.

RISE OF THE ROBO-DIAGNOSIS

Greg McEwen, Healthcare Expert and Partner, BLM

With the rapid progression in medical technology and a greater global reliance on big data, the role of the doctor as sole diagnostician is changing dramatically. Greg McEwen, BLM, considers what this might mean for our trust in human decisions and the accuracy of diagnoses.

The word “diagnosis” can be defined as “the act of identifying a disease from its signs and symptoms”. As a society, we have traditionally looked to our healthcare professionals to diagnose and treat our ailments, from minor aches and pains to major, life-threatening conditions.

The existence of lawyers who specialise in clinical negligence, from both a claimant and defendant perspective, is a reminder of the industry that has grown up around litigation in this area. In the year 2015-16, the NHS Litigation Authority received nearly 11,000 new claims for clinical negligence and nearly 1,000 referrals about the performance of doctors, dentists and pharmacists. Of course, not all claims relate to diagnostic error. Likewise, not every error in diagnosis results in a claim. Nor should it, since the mere fact of an incorrect diagnosis does not equate to negligence. But could advances in technology lead to earlier or more accurate diagnoses?

Technology has long played a part in the diagnostic process. From cancer screening to MRI scanning, to optometry, computers have been employed with a view to informing and improving key decision making. The caveat to this is that the technology is operated and, most importantly, interpreted and acted upon by people exercising judgment. Diagnosis remains an art as much as a science but that has not stopped the onward march of technology, with AI and big data seeking to chip away at the role of diagnostician and decision maker. Whether it's through a wearable consumer device such as a Fitbit, or AI trained to identify potentially cancerous tumours, the average patient today is exposed to technology that can monitor heart rate, nutritional intake and sleep patterns, all the way up to identifying serious, life-threatening conditions.

Some of this technology has the potential to reduce or replace human input, but will it lead to better outcomes? There certainly seems to be a belief that it will amongst some major stakeholders, both healthcare providers and technology companies alike. IBM's Watson supercomputer is currently being used in the US to help produce tailored treatment plans for cancer patients. Here in the UK, Babylon Health is reported to have secured £50m to further develop its AI diagnostic tool, itself a development on its existing clinical triage app, trialled in the NHS.

Are we hurtling head first into futuristic healthcare, then? Does this threaten the role of doctor as sole diagnostician? And what happens if AI gets it wrong?

The obvious concern over AI diagnoses centres around the issue of liability for errors. Where would medical and legal responsibility fall if a patient incorrectly receives the all-clear on the basis of an AI algorithm? It seems unlikely that this technology will be used to diagnose patients in isolation for various reasons, not least that the lines of clinical responsibility and legal liability need to remain clear. Patients need to know who is ultimately responsible for their medical treatment and who they can look to for redress in the event that something goes wrong. Primary responsibility is likely to remain with the healthcare provider therefore.

Yet whether healthcare professionals will be able to measure the accuracy and reliability of AI-output remains uncertain, given the complexity of the software and the protection of proprietary information. For insurers and healthcare organisations, this step into the unknown opens up the important issue around digital malpractice, lengthening the chain of responsibility to manufacturers and software developers. Increasingly, we have to consider whether mishaps and mistakes fall into the category of negligence, product liability or both, particularly as we move through a period in which doctors increasingly work in tandem with AI and big data.

There's cause for optimism as well. AI also brings great opportunity. People are not machines and human error is as much a possibility in healthcare as any walk of life. The number of known diseases in humans has been put at anywhere between 10,000 and 30,000 depending on the criteria employed. Some estimates have suggested that as any as 1 in 6 diagnoses within the NHS turn out to be incorrect. Using AI as an assistive tool has the potential to improve accuracy and reduce diagnostic errors, within an increasingly stretched Health Service. The use of AI to detect heart disease, for example, has been estimated to save the NHS over £300 million a year.

There is however a flip side when comparing machines with their human counterparts. Diagnoses and treatment plans are not simply a matter of logic and deduction. They affect real people. The fact that a computer aided cancer diagnosis is accurate doesn't make it any less devastating for the recipient. Machines cannot empathise. There will always be a need for healthcare professionals in the diagnostic process, however advanced the technology becomes.

What we can say is that the risks are broadening along with the benefits, for all involved in the delivery of healthcare in the digital age. As technology increasingly plays a part in the diagnostic process, we're likely to see a host of new issues arising around the attribution of liability, arguably the price of progress.

For more infortmation go to:
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LACK OF INFORMED CONSENT TO SPINAL SURGERY: TRACY HASSELL V HILLINGDON HOSPITALS NHS FOUNDATION TRUST

By Paul Sankey, Partner, Enable Law

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Hassell v Hillingdon Hospitals NHS Foundation Trust is a successful claim for damages by a patient who was inadequately advised of the risks of spinal surgery. During the operation she suffered an injury to her spinal cord. She was left with permanent disability in the form of tetraparesis (weakness of all 4 limbs). She recovered damages of £4.4 million.

Tracy Hassell v Hillingdon Hospitals NHS Foundation Trust [2018] EHWC 164 (QB)

The Facts

Mrs Hassell was 41 at the time of surgery to her neck in 2011. She worked full-time as head of year for years 7,8 and 9 at a secondary school and had 3 children.

Prior to her surgery she had undergone 2 previous operations. In June 2009 she had undergone spinal surgery for pain in her back, left leg and foot. The operation involved decompression and transforaminal interbody fusion in her lower spine. Her surgeon, Mr Ridgeway, explained the risks of surgery but not including injury to the spinal cord. On the day of surgery, she signed a consent form which included a number of risks including 'nerve damage (numbness)'. In evidence Mr Ridgeway said that 'nerve injury' could include numbness, weakness or paralysis.

The operation improved her back pain but not her left foot and leg pain. She underwent physiotherapy.

By July 2010 she had developed pain in her left groin and hip. She saw an orthopaedic surgeon who arranged a steroid injection and then carried out a left hip arthroscopy in May 2011. She signed a consent form which included risks of no improvement, infection, DVT/PE, haematoma, nerve injury and the need for further treatment.

In the meantime, she saw Mr Ridgeway again on 25 January 2011. Although her main problem was groin pain, she also reported pain in her left arm. She struggled to hold a steering wheel whilst driving because of reduced strength and pain. Mr Ridgeway arranged an MRI scan which showed a left paracentral disc lesion at C5/6, some deformity of the dural sac and flattening of the spinal cord on the left. A CT guided injection failed to relieve her symptoms.

Mrs Hassell saw Mr Ridgeway again on 28 June 2011. What happened at this consultation was an important issue in the subsequent claim. She complained of neck pain radiating down the C6 nerve distribution. Her surgeon advised an anterior cervical discectomy with either fusion of C5 and C6 or disc replacement depending on the surgical findings. There was a conflict of evidence as to what was said about the risks of surgery and about alternative conservative treatments.

On 27 July 2011 she had a pre-operative assessment. The record shows a tick by the heading 'no limitation of physical activity' and a handwritten comment 'limited by back/neck problems only'. There was a statement next to the airway assessment, 'very limited neck movement – hence planned op!'.

On the day of surgery, 3 October 2011, she signed a consent form. The form listed among the risks 'cord injury'. She had been expecting to be second or third on the list but Mr Ridgeway arrived with a porter to take her to theatre earlier than expected. Her husband was elsewhere and she had not been able to say goodbye to him. She felt nervous and that everything was done in a rush.

Unfortunately, she woke from the operation with tetraparesis. She was told that the spinal cord had been damaged although Mr Ridgeway did not know why. She was left with a severe disability.

The Claim for Damages

Mrs Hassell brought a claim for damages against the hospital trust responsible for her care. She alleged breach of duty in the performance of the operation. She also alleged that she had not given informed consent to the procedure, having not been advised of alternative treatments or warned of the risk of spinal cord injury. With adequate advice she would not have agreed to surgery.

Damages were agreed at £4.4 million subject to liability. The issue of liability was tried between 15th and 23rd January 2018 before Mr Justice Dingemans. Judgment was given on 6th February 2018.

Mr Justice Dingemans found that there the operation had been performed to a reasonable standard and Mr Ridgeway was not to blame for the spinal cord injury. The cause of that injury was unknown. However, he found that Mrs Hassell had not given informed consent to surgery and, given proper advice, would not have gone ahead. He found that she had neither been warned of the risk of spinal cord injury nor advised of alternative treatments.

The Surgeon's Advice: The Conflict of Evidence

According to Mrs Hassell, Mr Ridgeway did not discuss alternative treatments in the form of analgesia or physiotherapy during the appointment of 28 June 2011. He warned her of the anaesthetic risk and the risk of infection. He mentioned the risk of a hoarse voice for a couple of weeks which he put at 1 in 1,000. This was a matter of concern to her because of her work and the need to shout across the playground at times. He did not mention DVT, PE, nerve damage, risks to the spinal cord or paralysis. She said that had she been advised of the risk of paralysis at 1 in 1,000 she would have asked more and opted for alternative treatment.

Mr Ridgeway said that he discussed alternatives but Mrs Hassell felt she had exhausted those options. He wrongly thought she had had physiotherapy on her neck. He had explained the risks including hoarseness at 2 in 100 (and not 1 in 1,000 as she said) and paralysis at between 1 in 500 and 10,000. He said that he encouraged patients to carry out their own research and directed them to his website which contained 'all the relevant information to enable them to fully understand the risks and benefits of the planned procedure'. In fact, the website did not mention the risk of paralysis.

He then dictated a letter of 1st July 2011 in front of Mrs Hassell. The letter gave the risk of a hoarse voice at 1 in 1,000 and did not mention the risk of paralysis. At trial he said in effect that there was a transcription error because 1 in 1,000 was the risk of paralysis not

hoarseness. Unlike other letters, it was not marked 'cc patient' and Mrs Hassell did not know whether she had seen it prior to the operation.

Informed Consent

The judge found that Mrs Hassell had not been told of the risk of paralysis from spinal cord injury or advised on conservative treatment options. Montgomery v Lanarkshire Health Board [2015] UKSC 11 required Mr Ridgeway to take reasonable care to ensure she was aware of the material risks of surgery and alternative treatment options. He had failed to do so.
There were several reasons for his findings.

1. Mr Ridgeway was mistaken in thinking Mrs Hassell had previously undergone physiotherapy to her neck. Montgomery requires a dialogue between patient and doctor. Had there been a dialogue Mrs Hassell would have corrected his misunderstanding.

2. The judge formed the view that, whatever his surgical skills, Mr Ridgeway was not a good communicator about the risks of operations. There were inconsistencies between his evidence at trial and his witness statement as to what his normal advice would be.

3. Mrs Hassell's gave clear evidence that she had not been warned. Although there is evidence that patients do not always have an accurate memory of what they are told about risks, she had a clear recollection. She was concerned at the risk of a hoarse voice and asked questions about it. As the mother of 3 children and a full-time head of year this would have concerned her.

4. Mr Ridgeway said in a subsequent letter that surgery could result in paralysis and that this was 'similar to risks explained with previous spinal surgery'. In fact, his letter explaining the risks of lower back surgery did not mention paralysis.

5. His website, to which he said he referred patients for 'all the relevant information', did not mention the risk of paralysis.

6. The letter of 1 July 2011, which he dictated in front of Mrs Hassell, did not mention the risk. The judge did not accept that this was because of a transcription error. Further, the absence of 'cc patient' suggests that it was not sent to her.

Although she was told about the risk of 'cord damage' on the day of surgery 3 October 2011, a warning then was not sufficient. Her mind was not engaged on the consent form on the day.

Causation

The judge also found that, with proper advice, she would have elected for conservative treatment rather than surgery. Having had surgery to her lower back in 2009 and to her hip in 2011, she was prepared to undergo operations. She was prepared to run risks. She had considered the risk of a hoarse voice and was prepared to run it but this was very different from permanent disability. She had also benefitted from conservative management in the form of osteopathy before. She was 41 at the time of surgery and surgery with a risk of paralysis would have been a frightening prospect to her. Her evidence on that point accorded with the judge's findings that she was able to assess risks that were significant to her.

Comment

This is one of a number of cases exploring the implications of Montgomery v Lanarkshire Health Board [2015] UKSC 11. Montgomery requires a doctor 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 or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it'.

Various points of interest arise:

1. It seems that spinal surgery – with its risk of cord damage – is an area where the adequacy of consent has generated litigation. The other main area is obstetrics. Other spinal surgery cases include Jones v Royal Devon & Exeter NHS Foundation Trust [2015] (a County Court decision) and Thefaut v Johnston [2017] EWHC 497. The claimants succeeded on all 3.

2. The Montgomery duty requires patients to be given choice. It is not enough to advise of the risks and benefits of a recommended treatment. Patients must

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be told of the risks of 'the recommended treatment, and of any reasonable alternative or variant treatments'. The failure to advise about conservative treatment gave rise to a successful claim in Thefaut v Johnston as well as Hassell.

3. Warnings on the day of surgery are risky. As in Jones v Royal Devon and Exeter NHS Foundation Trust, the court was not persuaded that a consent form signed on the day of surgery indicated informed consent. Mrs Jones felt committed to go through with surgery by the time she found out that her operation would be performed not by the consultant she was expecting (and had chosen) but by his registrar. Mrs Hassell was feeling nervous, being unable to say goodbye to her husband and her mind was not engaged on the form.

4. Consent forms are only part of a process of advising and providing consent. As in Jones v Royal Devon and Thefaut v Johnston, the claimant was found not to have given informed consent despite having signed a consent form.

5. Unusually this is an area of clinical negligence litigation where witness evidence is crucial. The judge considered very carefully and gave detailed reasons for rejecting the surgeon's evidence in favour of that of the claimant.

6. The court considered expert evidence in relation to consent. The role of experts is to give evidence as to the reasonable range of treatments and the medical risks and benefits of those options. However, whether a risk is material or advice is adequate is not a matter to be judged by the standards of the medical profession. It is for the court. Experts should not be commenting on these issues. It is surprising therefore that the judgment records an agreement between the experts that 'if the risk of cord damage had first been mentioned to Mrs Hassell on the day of the operation that would not be sufficient in order to obtain informed consent…'

LITIGATION AFTER TOTAL HIP REPLACEMENT SURGERY

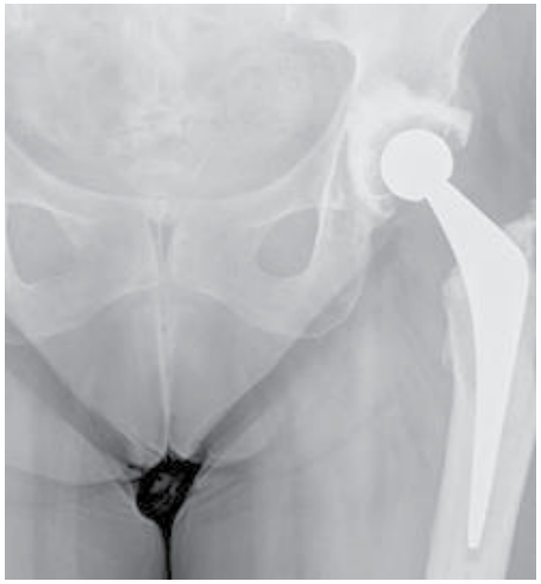
By Mr Nikhil Shah, Consultant Trauma and Orthopaedic Surgeon, Wrightington Hospital Lancashire

Total hip replacement (total hip arthroplasty) has been described as the "Operation of the Century" (The Lancet 2007). It is one of the most successful procedures to improve the quality of life and relieve the pain of patients afflicted with crippling painful hip arthritis. It was pioneered by Sir John Charnley in the 1960s at Wrightington hospital in Lancashire. The cemented Charnley hip replacement (commonly referred as Low Frictional Torque arthroplasty) performed for the first time in 1962, still remains the Gold Standard when one talks about long term results, now entering the fifth decade of prosthetic survivorship.

Unfortunately, like all other surgical procedures, it has well-recognised although often uncommon complications. Sometimes these complications can give rise to litigation.

One of the common reasons for litigation is nerve injury during surgery. This is a recognised complication in approximately 1% after primary hip replacement. There are important nerves that lie in close proximity to the hip joint and surgeons are trained to protect these nerves. It is important to assess patients thoroughly before surgery to check if there are pre-existing nerve problems or weakness arising from spine conditions. Despite the surgeon's best efforts however, rarely nerves can get injured. Injury can occur due to pressure, stretch or direct trauma from sharp instruments. However, in as many as 50% of the cases, the cause might remain unknown. If the injury is incomplete the nerve may recover but complete injury may result in permanent long term problems such as pain, reduced sensation or weakness of muscles. Nerve injury is not synonymous with negligent surgery.

Leg length inequality is also a common problem leading to complaints and litigation. It can be



associated with dissatisfaction, pain, poor function or even nerve injury. The primary goal of a hip replacement is to relieve pain and achieve a stable hip. It is nearly impossible in every case to assure equal leg lengths. Many patients (up to a third of the normal population) may have unequal leg lengths even before surgery. This may be due various causes such as the arthritis itself, hip deformity, spinal curvature, old fractures of the long bones, pelvic obliquity, or childhood developmental problems.

It is important to perform a meticulous clinical examination of the patient including spinal examination and document leg lengths before surgery. Some asymmetry of leg lengths is almost inevitable after hip replacement even after using techniques to measure leg lengths during surgery. It is important that patients are appropriately counselled and their expectations managed in a realistic manner before surgery. Documentation of intra-operative difficulties in achieving equal leg lengths is also important.

Dislocation (separation of the ball of the hip joint from the socket) is recognised to occur in 1-3% of cases despite appropriate positioning of the components at the correct angles. This may be related to patient factors (such as high BMI, neurological problems) or technical factors (soft tissue tension, offset, impingement of components against bone). Positioning the components of a hip replacement can be difficult even in experienced hands due to variability in the shape of the patients' bony socket and pelvis, movement during surgery, or the alignment between the spine and pelvis. There is no single perfect angle for positioning components which is correct for all patients and a range of component positions is compatible with a successful outcome. There is no substitute to educating the patient before surgery and looking for factors that might increase this risk.

Persistent pain after hip replacement is sometimes a reason for litigation. Regrettably, a small minority of patients may not get adequate pain relief even with well-performed surgery. Correct patient selection and thorough assessment before surgery goes a long way in avoiding these problems. It is important to avoid pitfalls by ensuring before surgery that the pain is definitely coming from the hip joint arthritis and not from the soft tissues around the hip or from the spine.

Persistent pain is not synonymous with a failed operation. Alternative causes such as infection, loosening, fractures or referred pain from the back also need to be excluded. Infection can have variable presentations and a thorough diagnostic evaluation needs to be performed when evaluating a painful arthroplasty. Infection is not always easy to diagnose and it is not uncommon to find delayed diagnosis of infection in the list of reasons for litigation.

Many of these problems associated with litigation can be avoided or minimised by spending time with the patient before surgery and explaining the benefits and risks of the procedure in detail. Inadequate consenting is also a common allegation in negligence cases. Obtaining informed consent is a methodical process and starts with the first consultation.

It is often difficult to find adequate time in busy clinics to spend with patients and these are real difficulties. The surgeon and the team should ensure that a robust process is followed and the patient is well-informed. There is no substitute for a frank and forthright discussion with the patient before surgery.

Every effort should be made to ensure that the patient has properly understood the risks before proceeding. Use of information booklets, the internet, websites with good quality information, pictures, diagrams, x-rays, models, or audio-visual aids often help in enhancing the patient's understanding. Giving information at multiple points in time of a patient journey is helpful to enhance their understanding and retention. Most units also have patient education classes to provide information to the patient.

Despite a good process, it is not uncommon to hear a patient state that a particular risk was not explained properly. It is a good idea to check the patient's understanding of the risks where possible.

The surgeon should also meticulously document the consenting process. Many surgeons routinely copy their clinic letters to the patient to help with their understanding. Recent changes to consent law after the Montgomery judgement have thrown these issues into stark prominence.

In the event of an unfortunate complication, an honest explanation, maintaining open communication (following the duty of candour), acknowledging a problem, and making a genuine attempt to diagnose and treat it can go a long way in avoiding litigation, which any form of health service can ill-afford.

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WHY EFFORT TESTS SHOULD BE EMPLOYED AS STANDARD IN NEUROPSYCHOLOGICAL ASSESSMENTS

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Introduction

Neuropsychologists are frequently invited to report to the court on the extent of an individual's level of cognitive impairment. The opinion of the neuropsychology expert on the type and extent of cognitive impairment will typically be informed by a range of evidence, including the available medical records, an interview with the claimant, and the results of objective tests of cognitive functioning. A low score on an objective test might indicate a cognitive impairment directly related to the impact of the index event on brain functioning. However, performance on tests of cognitive functioning may be affected by a number of factors, including pre-existing ability level, other aspects of functioning such as sensory or motor ability, medications and so on. The resulting score on a cognitive test may also be a product of how well the individual engaged with the tests. This concept is sometimes referred to as effort but more contemporary terminology favours the concept of performance validity.

Importance of Performance Validity

It is widely recognised, that external incentives in terms of financial rewards, compensation or the avoidance of unwanted scenarios increases the likelihood that cognitive dysfunction will be exaggerated or even fabricated. Behaviour aimed at exaggerating or fabricating cognitive impairments could directly threaten the validity of tests designed to provide objective information about cognitive functioning relevant to a determination of an individual's underlying level of ability and the impact of an injury that might have affected those abilities, such as from brain damage incurred in the course of an accident.

It is well established that "good practice" in neuropsychological assessment requires the issue of data quality to be addressed and, in particular, includes the testee's motivation to adhere to the test requirements. According to MacMillan et al 2009 "Motivation that is at variance with test requirements can distort test findings, limit the relevance of the assessment and even invalidate it."

Malingering or Performance Validity

The latest edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) defines malingering as the intentional production of false or grossly exaggerated physical or psychological symptoms, these being motivated by external incentives including avoiding military duty or work, obtaining financial compensation, evading criminal prosecution, or obtaining drugs. The International Classification of Diseases (ICD-10) also highlights an intentional component, associating malingering with conscious simulation.

However, it is important to recognise that threats to the provision of invalid test data are not limited to deliberate attempts to subvert the assessment process. There may for example be strong psychological factors that can undermine performance validity, including an individual's desire to express distress through their behaviour. In reality, a multitude of factors might affect engagement with cognitive tests, the 'effort' put forth, and therefore performance on them. The neuropsychologist will typically consider a number of possible factors including but not limited to pain, fatigue, mood and distress among the possible threats to the extent to which measured performance on a cognitive test can be reliably inferred to represent the true level of underlying cognitive functioning in an individual.

The Assessment Process

The value of any neuropsychological assessment is dependent on the quality of the contributing test data. There are a number of factors that have been known to influence data quality in testing. These include the following:

- The psychometric properties of the test
- The competence of the tester
- Influences affecting the test performance of the testee including identification of sub-optimal effort.

In a medicolegal neuropsychological assessment setting, it is common practice for the individual being assessed to be advised by the examiner that they should try their hardest on the tests being administered. Neuropsychologists will frequently comment on their observations of how the examinee appeared to approach the assessment tasks and note specific behavioural observations that could be relevant in understanding and explaining their presentation. However, we advise caution in the reliance on conclusions that an examinee engaged appropriately with the assessment process and that their performances are a valid reflection of their underlying abilities based solely on the observations of the examiner. It has long been established that clinicians struggle to identify invalid presentations in all cases. Neuropsychologists are not exempt above such difficulties, for example a recent study reported that neuropsychologists would have incorrectly classified 24% of cases without consideration of validity measures. This highlights the need for approaches sensitive to distortions of motivation and underpins the development and use of performance validity tests.

The Development and Use of Performance Validity Measures

Over the last two decades there has been growing interest in the development of methods in which to identify individuals performing below their level of capability such that there are now an array of measures aimed at detecting suboptimal performance. Such tests aim to be highly sensitive and specific, and to be administered relatively easily in a routine clinical situation.

Performance validity tests are typically stand-alone procedures or are embedded in other tests. Such tests aim to detect signs (patterns of test performance) inconsistent with those expected in neurological and psychiatric conditions. The determination of invalid presentations, based on reported symptoms, indicative of deliberate distortion is frequently described as tests of symptom validity. Our focus here is performance validity, though symptom validity may be important in the overall consideration of the claimant's presentation.

Choice of Performance Validity Test

The requirement that standardised approaches to the consideration of performance validity should be considered by the neuropsychology expert when formulating their opinion is lent support by British Psychology Society (BPS) guidance which specifies that "Effort tests should be given routinely as part of clinical assessment of cognitive function". A position paper by the National Academy of Neuropsychology (NAN) in the United States goes further, indicating a need for a neuropsychologist "to justify a decision not to assess symptom validity as part of a neuropsychological evaluation."

Considering such guidance in the context of medicolegal neuropsychology assessments, where the presence of external incentives is well-established and a substantial body of evidence regarding exaggeration of symptoms exists, supports our view that the use of performance validity measures in forensic neuropsychology practice should be considered standard practice. However, exceptions might be argued to exist and careful interpretation of performance on effort tests is required.

There are now in existence a number of independent tests of effort of which some are more commonly applied than others. Recommendations for a particular test is usually dependent on how well established they are in terms of their psychometric properties which include reliability, validity, sensitivity and specificity.

Importance of Sensitivity and Validity

The neuropsychologist should be familiar with published research examining the sensitivity and specificity of the PVTs that they use. Sensitivity in this context refers to the proportion of individuals correctly identified as performing sub-optimally (true positive rate) as opposed to those incorrectly identified as performing sub-optimally (false positives). Whereas test specificity refers to the proportion of individuals correctly identified as not performing sub-optimally (true negatives) as opposed to incorrectly classifying individuals as not performing optimally (false negatives). An important further consideration is how common suboptimal performance is expected to be in a given group, this is referred to as the base rate. It is perhaps unsurprising to find that the base rate of suboptimal performance on cognitive testing in, for example, a group of patients with multiple sclerosis in a clinical assessment setting is much lower than the reported base rate of suboptimal performance in litigating individuals with a mild head injury.

Additionally, different performance characteristics may occur on PVTs depending on individual factors on the person being assessed, including any neurological condition. A familiarity with relevant research conducted on groups of specific individuals can be advantageous in informing the degree of confidence with which the neuropsychologist might place on the PVT results. For example, validation studies of some PVTs have provided different cut-offs in different patient groups, and a number of studies have reported that identification of suboptimal performance can be improved by adjusting conventional PVT cut-offs in individuals presenting following Mild Traumatic Brain Injury.

A consideration of the psychometrics of effort test performances quickly identifies the important considerations that below cut-off performance on a PVT (which may end up reported as failing the effort test) could be a false positive result, and conversely that an above cut-off performance (which may be reported as passing the effort test) may be undetected suboptimal performance i.e. a false negative.

Maximising the Accuracy of Performance Validity Testing

There are a number of approaches available to the neuropsychologist that might enhance the accuracy of their PVT approach and their ability to make a reasoned and robust conclusion about the validity of the obtained test results. These include the following:

- The use of multiple effort tests
- The importance of the overall neuropsychological formulation of the case
- The need to consider a range of possible explanations for failure
- The importance of providing context to the results obtained when reporting the results
- The recognition of the importance of preventing misinterpretation

Conclusions

In conclusion, effort is recognised as a complex and multifactorial construct. We consider the term performance validity more helpful when forming an opinion on the extent to which the cognitive test data commonly collected as part of a neuropsychological evaluation can be relied upon as representing the true level of underlying functioning for an individual. The assessment of performance validity, and crucially the interpretation of effort tests demands appropriate expertise on the part of the neuropsychologist in order to reliably formulate an individual case and communicate to the Court the basis for and implications of that formulation.

Performance validity testing has evolved rapidly as a field over recent years. A knowledge of relevant current evidence and the ability to synthesize this into assessment procedures and case formulation is in our view a crucial component of contemporary clinical practice when providing expert neuropsychology opinion for the Court. While exceptions may occur, it is our opinion that the availability of performance validity measures, the evidence base regarding their use, and their potential role in providing the Court with evidence regarding the validity or otherwise of obtained cognitive test data, indicates that effort tests should be employed as standard in neuropsychology assessments and that the considerable demands in using them appropriately requires highly developed and appropriate neuropsychological expertise.

Key Points on the Use of Performance Validity Testing:

[1] Cognitive test results are not valid if the testee does not try hard on the tests.
[2] Effort tests should be given routinely as part of clinical assessment of cognitive function.
[3] There are some exceptions where routine assessment of effort is not appropriate.
[4] Failure on effort tests requires careful interpretation. Although a number of causes are possible, deceit should always be considered.
[5] Clinicians should be aware of the sensitivity and specificity of the effort tests that they use and the base rates of sub-optimal performance in the population from which their testee comes and take these factors into account when interpreting findings.
[6] Interpretation of failure on effort tests needs to be reported as clearly as possible.

MEDICO -LEGAL NEWS:

By Lisa Cheyne, Medico-Legal Manager, SpecialistInfo

A round-up of news in the industry for the first quarter of 2018.

GMC Response to the Case of Dr Bawa-Garba

The GMC has asked Dame Clare Marx, Chair of the Faculty of Medical Leadership and Management, to lead the independent review to explore how gross negligence manslaughter cases, such as the recent investigation involving Dr Hadiza Bawa-Garba, are initiated and investigated in the UK.

Dame Clare said: *'Each step of the process will be explored from local investigations post incidents, to diversity matters surrounding the doctors subject to investigation and whether regulatory processes at the GMC could be improved in such cases.*

'Doctors are often working in an immensely pressurised system where mistakes can happen. This work will be valuable for the medical profession and I am pleased the GMC has decided to take this work forward.'

Charlie Massey, Chief Executive of the GMC, said: *'As well as addressing the issues with criminal prosecutions a further aim of this review is to encourage a renewed focus on enabling a learning, no-blame culture, reflective practice and provision of support for doctors in raising concerns.'*

The GMC aims to complete the review by the end of the year.

On the 28th of March, leave was granted by the Right Honourable Lord Justice Simon to take Dr Bawa-Garba's case to the Court of Appeal stating: *"The grounds meet the second appeal test in all respects".*

See: https://www.gmc-uk.org/news/31576.asp

NEWS
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Drug errors in England cause unacceptable levels of harm and deaths

A government commissioned study by researchers at Manchester, Sheffield and York universities has concluded that GPs, pharmacists, hospitals and care homes may be making 237 million errors a year.

The study said most errors caused no problems, but in more than a quarter of cases the mistakes had the potential to cause harm. Drug errors are likely to be a factor in more than 22,000 deaths a year.

The mistakes include:

- wrong medications being given
- incorrect doses dispensed
- delays in medication being administered

Health Secretary, Jeremy Hunt, said last month: "We are seeing four to five deaths every single day because of errors in prescription, or dispensing, or the monitoring of medications."

He added that the study was not about blaming NHS staff, but about creating a culture where checks were in place to stop errors happening.

A fifth of the mistakes related to hospital care, including errors made by doctors administering anaesthetic before surgery, with the rest being split between GPs and care homes.

The initial plan is to allow hospitals to access prescribing data collected by an admitted patient's GP for patients being treated for gastro-intestinal bleeding. To check, for example, if a patient has been taking a non-steroidal anti-inflammatory drug without gastroprotection. The system will be extended to other conditions in the future.

The Department of Health and Social Care believe the roll out of electronic prescribing systems across more hospitals could reduce errors by 50%.

A change in the law is being introduced that will mean pharmacists will not be prosecuted for owning up to genuine mistakes, so that the NHS can learn from these errors.

Full report can be accessed here: http://www.eepru.org.uk/article/prevalence-and-economic-burden-of-medication-errors-in-the-nhs-in-england/

MoJ unveils sweeping PI reform in expanded Civil Liability Bill

Lord chancellor, David Gauke, announced reforms to the Civil Liability Bill on 20 March, which will contain not only reforms to whiplash claims but also changes to the way the discount rate applied to personal injury settlements is calculated.

'The number of whiplash claims has been too high for too long, and is symptomatic of a wider compensation culture,' said Gauke. 'We are putting this right through this important legislation, ensuring whiplash claims are no longer an easy payday and that money can be put back in the pockets of millions of law-abiding motorists.'

Fixed amounts will be set for compensating whiplash claims, and seeking or offering to settle whiplash claims without medical evidence will be banned.

Online private GP safety still not acceptable

The Care Quality Commission has been investigating the private online GP market since November 2016, inspecting 55 companies running services in England. After its inspections this February 40% were not providing 'safe' care in accordance to the relevant regulations. However, the inspectors said this was an improvement on their findings a year ago when 86% were not meeting the required standards.
After its recent inspections, five online GPs stopped trading and 13 were found to be in breach of safety standards.

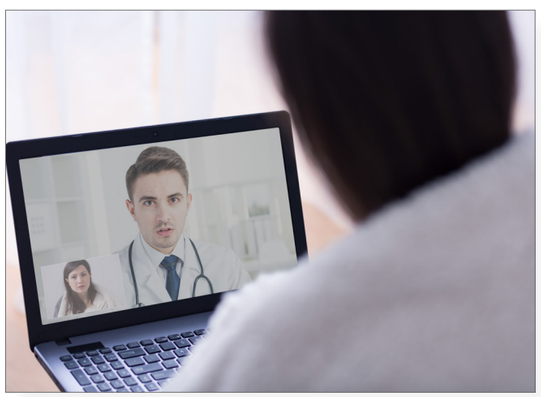
The CQC highlighted problems with prescribing drugs and carrying out checks on patients including cases where:

- antibiotics had been prescribed inappropriately
- opioid-based painkillers prescribed without contacting the patients' registered GP
- unsatisfactory approaches to safeguarding children and adults without the mental capacity to consent to a consultation
- lack of checks when prescribing drugs to women who may be pregnant or breastfeeding
- not collecting or sharing patient information with a patient's NHS GP
- inappropriate prescribing of medicines for long-term conditions

The CQC also warned there is a gap in its inspection system, as it can only look at firms that are based in England and are offering services to English patients. It has restated its commitment to work with the Department of Health and Social Care and with its partners outside of England to close the gaps in the regulation of online services that fall outside of CQC's remit.

Prof Steve Field, CQC chief inspector of general practice, said online services have a "huge potential". But he added: "While innovation should be encouraged, it must never come at the expense of quality."

Full report can be accessed here: http://www.cqc.org.uk/news/releases/signs-improvement-some-concerns-remain-regarding-providers-online-gp-services



Trust liable for hypoxic birth injury and psychiatric injury caused to mother and grandmother in landmark case: RE (a minor) v Calderdale & Huddersfield NHS Foundation Trust [2017] EWHC 824 (QB) (High Court, 12 April 2017 – Goss J)

In a landmark hypoxic birth injury case, involving Calderdale & Huddersfield NHS Foundation Trust, the High Court awarded damages for Post Traumatic Stress Disorder to two "secondary victims" (the mother and grandmother) caused by the index event.

Judge Goss found that the infant had suffered from a shoulder dystocia following crowning of the head and had become stuck. As a result of the failure of the midwife to recognise this, she suffered a hypoxic insult caused by a negligent delay in delivery.

In relation to the psychiatric injury claims, Goss J accepted that the mother was a primary victim and was entitled to damages for her injury. This was on the basis that at the point at which the negligence occurred, and the onset of the condition (PTSD), the infant was not a legally separate entity from her mother, still being in the birth canal.

She was also a secondary victim (as was the grandmother) and satisfied not only the Alcock criteria but also the new criterion set out in Ronayne v Liverpool Women's Hospital NHS Foundation Trust [2015] PIQR P20, that there must be a sudden appreciation of an objectively horrifying event. Goss J found that the sight of the baby satisfied that criterion. Judgment was accordingly entered for all three claimants.

The case has potentially powerful implications for secondary victim claims in a clinical negligence setting, as this is one of only very few reported cases where such claims have succeeded.

https://high-court-justice.vlex.co.uk/vid/hq14x01554-677397069

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The Future Direction of Alternative Dispute Resolution (ADR)

A workshop was held on 6 March this year to obtain practitioner and service provider views on a new approach to ADR. About 70 delegates attended, representing not only the judiciary, practitioners and mediators, but also service providers, NHS Resolution (the re-named NHS Litigation Authority) and HMCTS. Unmet needs were identified including clinical negligence – building on the existing NHSR Mediation Pilot but including arbitration. And, following a significant intervention by Andrew Ritchie QC, separating liability from quantum to facilitate earlier resolutions.

The place of online solutions to enable ADR was discussed for the predicted increase in litigants in person (LiPs) using the system after the increase in the personal injury small claims limits in April 2019. This could be bad news for experts working in the personal injury sector, who may find their instructions dry up in 2019.

Read more at: https://www.lawgazette.co.uk/comment-and-opinion/adr-at-a-turning-point/5065313.article

NHS failing patients with mental health problems

Vulnerable patients with mental health conditions are being badly let down by the NHS, causing them and their families needless suffering and distress, according to a Parliamentary and Health Service Ombudsman report published in March.

The Ombudsman has also found that NHS mental healthcare staff can lack the capacity, skills and training they need to do their job effectively, and do not always have the support they need to learn from mistakes.

Following an analysis of over 200 mental health complaints upheld by the Ombudsman, the report highlights five common failings that are compromising patients' safety and dignity:

- Failure to diagnose and/or treat the patient
- Inappropriate hospital discharge and aftercare of the patient
- Poor risk assessment and safety practices
- Not treating patients with dignity and/or infringing human rights
- Poor communication with the patient and/or their family or carers

Full report available at: https://www.ombudsman.org.uk/news-and-blog/news/nhs-failing-patients-mental-health-problems

SpecialistInfo Expands the Faculty of Expert Witnesses (the FEW)

The Faculty of Expert Witnesses (the 'FEW') promotes high quality expert witnesses to law firms and insurance companies. All grades are expected to adhere to specified standards of good practice covering compliance, availability and service by conforming to a Code of Good Practice.

Associates (AFEW) are Consultants and GPs who:

- Have their Medico-Legal CV listed on SpecialistInfo

Members (MFEW) are Consultants and GPs who in addition:

- Have undertaken appropriate Medico-Legal training and agreed to undertake CPD training every 3 years so that they are consistently up to date with all the latest rules and procedures.

Fellows (FFEW) are Consultants and GPs who in addition:

- Have satisfied SpecialistInfo's lawyers as to the quality of their reports, including presentation and compliance with Civil Procedure Rules, by submitting an anonymised sample report for review

Subscribers to the Specialistinfo.com Medico-Legal Section can search for the contact details of over 10,000 expert witness doctors and see whether they are FEW Associates, Members or Fellows.

Please contact emma@specialistinfo.com for subscription information.

http://www.specialistinfo.com/a_medico_legal_services.php

CIVIL MEDIATION COUNCIL PRESENTS:

Bullying and Sexual Harassment: **Can Mediation Help?**

Acas recently revealed that bullying and harassment in the workplace is costing employers up to £18bn per year. An impact on workplace morale and productivity has been felt by nearly 75% of workers. Harassment in the workplace has never had a higher priority than it does now, with many employers introducing measures expressly designed to encourage the reporting of potentially inappropriate behaviours. How will you handle such a complaint?

Join us for an in-depth and interactive look at the resolution of these most potentially confrontational and high-profile allegations and hear about alternative options for addressing them swiftly and discreetly in the way least damaging to both the business and the people concerned.

Keynote and speakers include:

- **Peter Cheese**, Chief Executive at the Chartered Institute of Personnel and Development (CIPD)
- **Gareth Jones**, HR Director, M&G Investments
- **Jane Farrell**, Chief Executive, EW Group
- **Sam Smethers**, Chief Executive, The Fawcett Society
- **David Whincup**, Partner, Squire Patton Boggs LLP
- **Hannah Coulson**, Chief Human Resources Officer, Callastone
- **Henicka Uddin**, Area Director, London, Acas

A panel of mediation providers will join the debate.

Who should attend?

This session is aimed at anyone with an interest in dealing with bullying and harassment in the workplace, including HR professionals, team leaders/managers, senior executives/directors, wellbeing officers, consultants, trade union and employee representatives and in-house legal departments.

28th June 2018
LONDON

M&G Investments,
Laurence Poutney Hill,
London EC4R 0HH

Registration from 2.45pm
Conference: 3.15pm - 6.30pm
Followed by drinks reception

Cost: £40 + vat per person

Student discount also available
CMC Members £35 + vat

3 Hours CPD

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