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MAGAZINE

ISSUE 10

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The **Medico-Legal Conference** is set to be the UK's leading event bringing together medico-legal professionals & industry experts. Attend to experience our high-level programme of speakers, interactive exhibition zone and networking. The event takes place at London's prestigious Queen Elizabeth II Centre, Westminster on May 16th 2019.

Keynote Speaker: Sir Rupert Jackson, retired Justice of the Court of Appeal of England and Wales. During his time in the Court of Appeal he produced the comprehensive Review of Civil Litigation Costs (known as the 'Jackson Reforms').

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For more information and to book your place please visit:
www.medicolegalconference.com

Welcome to Issue 10

Welcome to the tenth issue of the Medico-Legal Magazine, produced by SpecialistInfo and publishing partner Iconic Media Solutions Ltd. In this final issue of 2018, we focus on the unthinkable experience for all doctors - facing litigation themselves.

Ophthalmologist and expert witness, Mr Amar Alwitry, describes how his specialty is working with NHS Resolution to develop a scheme which can learn from litigation to reduce common incidents of avoidable harm.

Barrister and Mediator, Jonathan Dingle, focusses on the growing use of mediation in medical negligence cases. He demystifies the process and explains why clinicians can make excellent mediators. We are also pleased to include an article by Dr Edwin Rajaduria of Servca, who summarises the different types of indemnity insurance available for doctors and medical expert witnesses.

Bernard Ross of Sky Medical Technology, explores how med-tech companies can work directly with the NHS as part of the "Five Year Forward View" to improve patient care by harnessing technology and innovation.

Enable Law Legal Director, Laurence Vick, comments on the recent landmark judicial review decision in the case between the pharmaceutical industry and various UK Trusts, which should allow the use of the affordable drug Avastin for wet age-related macular degeneration in the UK.

Finally, please don't forget to book your places on SpecialistInfo's Medico-Legal Conference, which will take place on the 16 May 2019 at the prestigious Queen Elizabeth II Centre, Westminster, London. We have secured several high-profile speakers, including Sir Rupert Jackson as keynote speaker. Our 2019 Medico-Legal courses are also now available to book.

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 MAGAZINE

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 2019 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):

- *22nd January 2019* – London
- *3rd April 2019* – York
- *17th September 2019* – London
- *More TBC*

£340 (plus VAT)

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

Clinical Negligence Medico-Legal Course
(for higher value medical negligence cases):

- *23rd January 2019* – London
- *4th April 2019* – York
- *18th September 2019* – London
- *More TBC*

£365 (plus VAT)

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

Advanced Medico-Legal Course
(refresher for experts now including court-room skills):

- *14th March 2019* – London
- *19th June 2019* – London
- *19th September 2019* – London
- *6th December 2019* – London

£365 (plus VAT)

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

Mediation Training Course

Workplace and Employment Mediation (2 days)

- *22nd-23rd January 2019* - London

Foundation Training (5 days)

- *14th - 18th January 2019* - Bristol
- *4th - 8th February 2019* - Manchester
- *11th-15th February 2019* - London
- *1st -5th April 2019* - London
- *More TBC*

2 day courses £550, 5 days £1,600 (No 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

specialist info

WHAT IS MEDICAL INDEMNITY & WHO NEEDS IT?

by Dr Edwin Rajadurai (MBBS), Managing Director Servca, London email: erajadurai@servca.com

The GMC states; "*A doctor must have adequate and appropriate insurance or indemnity in place when they start to practise medicine in the UK*" – which begs the question, what is Medical Indemnity?

Medical Indemnity policies protect individual practitioners and medical entities for acts of medical negligence, accidents and incidents that result in (proven) bodily injury and or mental anguish of any given patient as a result of professional medical services provided.w

Medical Malpractice compensatory costs can often be large, rising to millions of pounds in certain cases. Whilst compensatory values (paid to claimants) contribute to the claims value, an often overlooked element is the defence (legal) costs that are incurred in defending practitioners and medical entities. Even when a claim or allegation has been successfully defended (and no compensatory claim amount is paid), the legal costs can easily build up to a substantial amount.

What types of indemnity are available?

There are two types of Medical Indemnity available:

- Medical Defence Organisation (MDO) memberships.
- Private Insurance/Indemnity policies.

What are the differences?

MDO memberships.

- MDOs are discretionary membership services. Claims are settled from an accumulative "pot" of premiums that are collected from all their members on a yearly basis.
- MDOs are **discretionary** organisations – they are within their rights to decline to pay claims or offer legal representation at their own discretion. The relevant individual/entity may be left responsible for claims and legal representation costs.
- MDOs are not regulated organisations.
- MDOs offer **claims occurring policies** – a policy covering claims that arise during the policy period regardless of when the claims are made.
- No limit of indemnity – if a claim is accepted, the MDO will pay for the total claim value without a limit/cap to costs.
- MDOs typically use internal legal teams to represent members.

Private Insurance/Indemnity

- Private Medical Indemnity is offered by commercial insurers (**typically within Lloyd's of London**). The terms that are offered, are contract certain and follow a strict adherence to the policy wordings (the contract) that are provided with the policy schedule.
- Each policy has a set **limit of indemnity** – claims are paid up to the total value of the limit of indemnity offered. (Limits can be aggregated over a year or per individual claim).
- Private Insurers offer **claims-made policies** - a policy that is triggered when a claim is made during the policy period regardless of when the wrongful act that gave rise to the claim took place. (The one exception is when a retroactive date is applicable to a claims-made policy).
- Regulated by the Financial Conduct Authority (FCA).
- Lawyers instructed by **Lloyd's of London** insurers are typically the top 10 in the UK - examples include Brown Jacobson, Capsticks, DAC Beachcroft and Kennedys Law.

Summary

There are pros and cons for both options with many variables that need to be considered by the "policyholder" (individuals or group entities).

In certain situations, whereby an MDO declines membership, respective practitioners are forced to follow the route of private Medical Indemnity. Unfortunately, a declinature by an MDO labels the practitioner as being "distressed" and as such, premiums may be proportionally inflated (depending on the circumstances of declinature by the MDO). In these scenarios, it is the role of an insurance broker to negotiate and structure a policy for the practitioner in question.

If a Practitioner converts to Private Medical Indemnity through their own choice (and not as a result of a declinature/previous claims), the Practitioner's chosen broker may be able to negotiate a premium that is cost-effective in comparison to the MDOs premiums.

Whichever of the two routes a Practitioner chooses to follow, it is worth understanding the differences between the types of cover - one may be more beneficial than the other for certain individuals.

For more information and free consultations on Medical Indemnity, please get in contact with me.

CHANGING MINDS – MEDIATION IN HEALTHCARE

by Jonathan Dingle FRSA FSOM, Barrister and NHS Resolution-approved mediator[1]

It was a wet Tuesday morning in February a few years ago. You were up early and into the hospital before it was light. Patients were already waiting. Your list was long and the flu epidemic meant colleagues were away, nurses missing, and the general public's dripping noses making you very glad you had had the jab. In short - a typical working day in the austerity NHS of the then Health Secretary, Jeremy Hunt.

You don't really recall Mrs Goggins. One of thirty patients that morning. Nothing unusual as a patient though of course, you remind yourself, unique as a human being. Your only memoriam are the notes you wrote that morning. They seem fine. No mention of the *Montgomery* words – risks, benefits, alternatives, options – but you always give those. No reason to think you did not. And then you treated the patient.

And now she is suing you. Well not you – the Trust you work for – though it is you brought into a meeting with its risk manager, the clinical director, and the solicitors from a firm who (you later learn) are on a panel appointed by the NHS Litigation Authority – the Trust that operates as "NHS Resolution". It feels like you are on trial. No doubt about it. Words like "sub-standard care" and "Bolam" are thrown around. Piles of medical notes are on the table.

Then the barrister arrives. A splendidly-combed QC who, you vaguely recall, has a title. All of them here to discuss your alleged errors or omissions – not only with you but with the "other side" as they call them and someone else. Not a judge. Or an arbitrator. But instead with - "the mediator" – who would not decide anything at all. What on earth is going on? This article explores the process.

The quantum of solace

We all know that litigation places a substantial burden on the NHS. Inspiring outlets of accurate journalism such as the Daily Mail regularly belittle scroungers who fleece hospitals and line the pockets of ambulance-chasing lawyers. The truth is far more complex (and a long way distant from the lambasts in 65 points across the front pages of a tabloid). But it is expensive.

Helen Vernon, Chief Executive of NHS Resolution said in July 2018 -

"The growing interest both from our NHS members and those who act for injured patients in working together to resolve claims for compensation without going to court has been very encouraging and we hope to build on this so that mediation is no longer seen as novel in healthcare. However, the cost of clinical negligence is at all-time high. The total provisions for all of our indemnity schemes continue to rise from £65 billion last year to £77 billion as of 31 March 2018 which brings a renewed urgency to efforts across government to tackle the drivers of that cost."

According to the NHS Resolution annual report published in the summer[2], formal litigation reduced to the lowest recorded level as NHS Resolution mediated more claims in a single year than in its entire history. This was accompanied by an (expressly welcomed) reduction in claimant legal costs (by £31.8 million) for the first time in many years as NHS Resolution implemented the first year of its five-year strategy – delivering fair resolution and learning from harm under what many (including the author) consider to be inspiring leadership from CEO Helen Vernon.

However, despite a plateauing in the numbers of new clinical negligence claims, the cost of those claims continued to rise, largely due to a change to the way in which compensation was calculated. Figures for the past year show that the NHS paid out more than £1.63 billion in damages to claimants in 2017/18, an increase from £1.08 billion in 2016/17. £404 million of the increase (33%) was due to a change in personal injury discount rate (PIDR – the method by which future loss is calculated, and

completely controlled by the Secretary of State for Justice) from 2.5% to minus 0.75[3].

This shift towards mediation is a very new feature. Indeed, the author must declare an interest – as a barrister representing many claimants and some doctors – work has been consistent for three decades. As a mediator, approved by NHS Resolution to mediate clinical negligence, personal injury, and costs cases, the author has seen his mediation work rise from just a few healthcare mediations a year to (this year) on average almost one a week. That is a common experience and it is suspected that some 750 mediations of all kinds will take place in the NHS this calendar year. That may be an underestimate. It does not include the use of mediation in problems between staff members ("workplace mediation") which is increasingly in use.

A brief history of talking

It is a far cry from even two years ago. Helen Vernon then bemoaned a lack of uptake from claimant lawyers for the failure of the NHS mediation scheme to do more than about 70 mediations[4] in 2016. Formal mediation was still a relatively new feature in the NHS. More traditional forms of conciliation had consisted of informal meetings between patients and clinicians in the hospital setting, referred to as negotiation, with mixed results. There has been a push for more mediation specifically prior to litigation.

The NHS Litigation Authority (NHSLA) had in fact been offering to mediate on cases since 2002 – since the then newly established Civil Mediation Council and CEDR offered a pilot scheme. It was widely reported then that claimant solicitors generally did not take it up. Nor were the panel firms of defendant solicitors back then any more enthusiastic. Income streams were guarded and the lack of information about outcomes and options – as well as the refusal to pay costs meant that many solicitors simply did not want to risk their profits[5].

In his "Making Amends", published in 2003[6], Sir Liam Donaldson recommended the creation of a new NHS Redress Scheme to be used when NHS care and treatment goes wrong. It was proposed that a national organization will administer the redress scheme which would offer remedial treatment, rehabilitation and care where needed; explanations and apologies and financial compensation where appropriate.

Sir Liam said: "Patients deserve to receive high quality healthcare from their NHS. And, for the vast majority of the millions of people treated every year, the NHS provides excellent, effective healthcare. However, patients occasionally do not receive the treatment they should, and mistakes are sometimes made. Patients deserve to be told what happened when things go wrong and to be compensated if appropriate." A Scheme was intended by 2005. It took a nearly a decade.

Even in 2003, mediation when it was used, it usually produced good outcomes, with some 75% settling on the day and 5% in the following week. The reluctance stemmed from concerns over increased costs and not having complete evidence. Lawyers had only (in 2003) recently been forced (from 26th April 1999) to enter the modern era of litigation in England with the Civil Procedure Rules. As a result, cases were still handled slowly, and (by present standards) luxuriously. Doctors of a certain age will remember that "hired gun" experts were still all-pervasive and personal injury solicitors boasted about their gold bathroom taps. You could even still get Legal Aid for clinical negligence cases.

The NHS Redress Act 2006, which received the Royal Assent on 8th November 2006, was the official intended response to Making Amends. It contained (and still contains) enabling legislation for a new scheme for providing "quick and appropriate" responses to cases of clinical negligence which are of low monetary value. The NHS Litigation Authority was supposed to take charge of the scheme, which would only apply to cases being brought within a certain time limit below a certain value.

The 2006 Act was intended to offer patients a quicker and fairer alternative to expensive and lengthy legal battles, which have caused the cost of NHS negligence to spiral dramatically in recent years. Mediation was intended to be at the core of this glasnost. But the Department of Health failed to produce the necessary secondary legislation to make it operational, leaving the Act unworkable in England.

In 2010, the Government claimed it was considering implementing the new scheme after "recent reforms to the complaints system (had) been fully assessed [7]". An attempt to revive the Act with a private member's bill in October 2010 failed. A Welsh version of Scheme was introduced in 2011 and the Scottish scheme – based on their Patient's Rights Bill and the McLean Report also proceeded.

Fast forward to 2015: the use of the courts was steadily becoming less common: in July 2013 it was reported[8] that fewer than 1.7% of the cases handled by the NHSLA were finally disposed of by a liability trial in court, with the remainder being settled out of court (48.3%) or abandoned "without a penny paid" (40%) by the claimant. Mediation, though, played a tiny (0.07%) part of that process.

By 2015 in Europe, some Courts were requiring cases to go through some type of Alternative Dispute Resolution, and especially mediation, before permitting the parties to present to a judicial court. Indeed, the European Mediation Directive (Directive 2008/52/EC) expressly contemplated so-called "compulsory" mediation. The EU thought that there were many advantages for harmonisation and its citizens in compelling mediation: the most important and most obvious ones were the cost and time saving achievable.

Mediation had become much less costly than civil litigation. It is quicker: the mediation process, in fact, can take only a few hours. It is an informal process that is confidential and without prejudice. Preparation is easy and simple. No particular location is needed, and lawyers are not necessary (although they may participate at the request of a party). No less, mediation can protect parties from some of the extra problems associated with civil litigation, such as punitive awards, if applicable. Mediation also allowed a more transparent process. It is more suitable to answer the needs of the parties – especially after mid-Staffs[9] and the duty of candour under Regulation 20[10].

Mediation was then by 2015 at last widely recognised as allowing all parties to bring their needs, problems, concerns and expectations to the table. Indeed, in mediation the parties are full participants and can express their own opinions and concerns, whereas in civil litigation the parties' lawyers are the only ones who represent their party unless the party "takes the stand" and is subject to cross-examination by the opposing lawyer.

Mediation allows parties to have direct control, to work together and reach a settlement even in a friendly way, while in civil litigation most often there is a decision by a judge which the parties accept, but their relationship comes to an unfriendly end. Mediations were not constrained by judicial outcomes – apologies, letters, changes in practice, and party-designed solutions are all available in strict contrast to the financial remedy which is the only judicial option: damages.

So, change was needed. A solution present. The NHS Resolution mediation scheme came into being[11] to deliver the gains that Jeremy Hunt, the EU and professionals increasingly demanded. After a pilot scheme and some teething and learning, CEDR and Trust Mediation[12] were appointed following tenders to administer the full project. It has now become a success.

Or else what follows?[13]

Mediation is very often now (in 2018/19) the preferred means of resolution for cases of complexity, or high value, or a range of possible judicial outcomes. It is also sometimes used where the NHS wishes the better to understand a case that does not at first blush seem likely to end in damages but where (often unrepresented) people are advancing what may become a time-consuming case.

Mediation provides a full range of options in these cases, as well as the traditional. It leaves the right to go to court unimpeded but that "bloody constraint" is in around 80% of NHS Resolutions mediations permanently eschewed through an agreement to settle the matter.

The mediators are doctors and lawyers, (barristers and solicitors) and they work impartially, neutrally, and determinedly to help the conversation. Mediators do not provide solutions but, by intelligent (they hope) questioning and careful probing can elicit options which the parties adopt. The mediators must not suggest outcomes – but they use the process of mediation to make a resolution more likely. Mostly, they (or actually and more correctly, the parties) succeed.

So how does it affect me?

Those finding themselves in health care disputes can discuss with NHS Resolution - or indeed increasingly the MPS or MDU who both have recently moved to adopt this process, in England and across the Irish Sea. Hilary Steele, Claims Lead for Republic of Ireland at Medical Protection Society (MPS)[14] said in July 2018:

"(The) Medical Protection Society (MPS) fully supports the Government's decision to set up an expert group to look at alternative ways to resolve some clinical negligence claims. Our experience dealing with claims worldwide provides us with a unique insight into best practice when resolving clinical disputes. A culture of transparency and sharing of information will lead to earlier resolution of claims. MPS has been instrumental in advancing the introduction of a voluntary pre-action protocol with the State Claims Agency and four leading plaintiff clinical negligence firms. We now need the government to finalise a compulsory pre-action protocol to provide a statutory framework for claim resolution without the additional pressure and cost of having to attend and give evidence at Trial.

"There are significant delays in resolving claims through the current court system. MPS would encourage the introduction of specialist judges taking a proactive approach to case management where pre-action resolution has not been possible. Parties should also be actively encouraged to resolve disputes by alternative means such as mediation, which has been shown to be beneficial for both patient and doctor by facilitating discussion and an understanding of events and their impact."

It is thus increasingly likely that clinicians who have a claim against them may have an opportunity to speed resolution, without prejudice and confidentially, at a mediation. The reduction in hassle and strain is universally reported as a major benefit – so too is the chance for the doctor to have their say in a setting which is neither hostile nor public. The mediator ensures a quiet, business-like setting where everyone is listened to with dignity and respect. There is no cross-examination and no verdict.

In some mediations, there are tears and shared hugs. In others, a simple shake of hands. It is a remarkably cathartic experience. Changing minds has never been so good.

Footnote: can I mediate?

Yes! It is important to know, however, that all mediators in health care matters have been trained on a week-long training course, have shadowed experienced mediators and carry insurance. They demonstrate their background skills to a panel and a willingness to be neutral and thoughtful. The training involves practical assessments and workshop learning. It is specifically aimed at healthcare.

If you are interested in training as a mediator, please contact Lisa Cheyne at SpecialistInfo. Courses are available with the leading training organisation *The Society of Mediators* (a charitable body providing education and dispute resolution) direct from SpecialistInfo. These courses run in London and Manchester and fill quickly. The feedback is remarkable. Call 01423 727721 or see the website https://specialistinfo.com/a_ml_mediation.php

References

[1] Co-author of the textbook "Practical Mediation" (2017)https://www.amazon.co.uk/Practical-Mediation-Mediators-Commercial-Employment/dp/1911035355 and long-time Specialist Info course leader

[2] See: https://resolution.nhs.uk/wp-content/uploads/2018/08/NHS-Resolution-Annual-Report-2017-2018.pdf

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[7] DoH Response 30 August 2009

[8] https://www.gov.uk/government/uploads/system/uploads/.../0527.pdf

[9] https://www.gov.uk/government/publications/report-of-the-mid-staffordshire-nhs-foundation-trust-public-inquiry

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[13] See Henry V Act 2 Scene 4 – per The King of France and the Duke of Exeter's reply. Bloody constraint. http://shakespeare.mit.edu/henryv/henryv.2.4.html

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MEDICO LEGAL MAGAZINE

LEARNING FROM LITIGATION – A MISSED OPPORTUNITY

by Mr Amar Alwitry, Consultant Ophthalmologist

Back in 2000 the Chief Medical Officer, Sir Liam Donaldson, chaired a piece of work commissioned by the then Secretary of State for Health, Alan Milburn, entitled "An Organisation with a Memory -Report of an expert group on learning from adverse events in the NHS". We are now 18 years on and still some of the recommendations from then have not been implemented.

Key comments from that work:

"Once potential and actual risks have been identified, they must be properly analysed to identify lessons for policy and practice. Lessons can be extracted from the pool of available information through analysis, but then need to be distilled – to make sure that the essence of the learning points is properly captured – and their validity tested in theory or practice."

"The second part of the learning process, once sound solutions have been derived, is to make sure that they are put into practice. Learning points need to be translated into practical policies and actions that can be implemented at the appropriate level. These practical changes then

need to be prioritised, to provide a clear agenda for action, and disseminated to the relevant audience. Training is a vital tool in ensuring that information on change is both disseminated and acted on."

We are all encouraged to learn from our mistakes and also to learn from the mistakes of others. On top of this we have a duty of candour to patients to explain to them when we have made a clinical error. We hope that they would understand that we are human and we err, and yet still some cases go forward to formal complaints and then some to litigation. As medico-legal experts we see the chain of events in full technicolour from the index incident, through the immediate explanation to the patient, the internal investigation and then the final end point of a letter of claim.

We review a case in the cold light of day from the comfort of our study and whether we act for Defendant or the Claimant we see the sequence of errors which occurred and, in line with our overriding duty to the Court, we have to determine what errors happened and how. I often think to myself "there but for the Grace of God go I".

My experience is that patients want an apology and to know that it will never happen again, and we are good at instituting change locally to make sure the learning points are acted upon, but we are not good at disseminating that information across the whole NHS.

NHS Improvements does excellent work in detecting and implementing learning strategies that address system errors and serious incidents that result in death or serious harm, but fails to address lower level clinical errors, which are still happening throughout the NHS and causing repeated avoidable harm to patients. Front line clinicians are key stakeholders in patient safety and they need to be involved in the detection and reporting of clinical errors, but also in the assessment of these errors, identification of common themes and learning points and the subsequent dissemination to the clinicians who need to hear these safety messages.

In my medicolegal work I see a lot of cases where a clinical error is repeated time and again and this is not being picked up. The simple clinical learning point is missed and the opportunity to intervene to prevent harm to another patient lost. I consider to this to be a major system flaw within the NHS. Many hundreds of NHS manhours are spent investigating and undertaking root cause analysis; however, the learning points, which are often simple, are actioned locally but not disseminated throughout the NHS.

Don't get me wrong, from a selfish perspective I love seeing the same error happening, as I can cut and paste from previous reports, the background research is already done and I can still charge my usual fee to make up for the cases where I unexpectedly get four lever arch files of notes to review on what I thought would be a simple case. However, it breaks my heart seeing the same avoidable error happening time and time again. How can we learn from these errors? A case report in a journal? Who really reads them? Present the case at a conference? Who's awake and listening?

Around 2,000,000 incident reports are received by the National Reporting and Learning System (NRLS) each year, on over 130,000 disease and injury types, 6,000 medication types, 9,000 treatment modalities and an almost uncountable range of medical devices used within the NHS, according to data from direct communication with NHS Improvements (NHSI).

Of the 2M incident reports per year submitted to NHSI, 30,000 are serious incidents or patient safety incidents which cause death or serious harm. There are also 200 'dives' which look at approximately 20,000 lower harm incidents. Taking out these 50,000 scrutinised incidents, there are 1,950,000 incidents reported per year that receive no scrutiny whatsoever and are not read by anyone outside the local Trust. This means that 97.5% of all clinical incident reports via the NHSI are not scrutinised externally at all, and all those potential learning points are missed and not appropriately disseminated. Assuming that only 1% of those unscrutinised incidents refer to avoidable clinical errors, this means that there are 19,500 episodes of clinical harm due to avoidable errors per year that are going unrecognised. Not addressing that gap is letting patients down, increasing the risk of harm, hampering doctors' abilities to learn from others' mistakes and increasing our litigation bill.

Clearly the key is identification of these learning opportunities, and currently NHSI does not have the facilities or systems to assess every clinical error. We need a mechanism for identifying which incident reports have a clinical learning message, and targeting those for particular attention. Rather than scrutinise them after the fact, the logical route is to ask those clinicians/allied professionals submitting the report to identify if there is a clinical learning point, thereby flagging up their importance so they can be singled out for special scrutiny and any learning points picked up. The new data processing systems being developed by the NHSI gives us an ideal opportunity to facilitate data entry processes which can make it easy for those entering data on incidents to highlight any potential learning points.

Albeit potentially delayed for several years, due to the length of time litigation takes, we have a system already in place whereby the worst clinical errors which cause harm to patients and may be negligent are already picked up and assessed by highly skilled clinicians in the field, ie, you, my learned audience. Part of our work as an expert is to determine where things went wrong and work out whether there was a breach of duty. So, we, as experts in the field, have already done the hard work and identified the error and the learning point. We work on the front line and can determine what is truly an avoidable clinical error and determine what learning point should be disseminated to our colleagues.

I would have no hope of determining whether a clinical error in nephrology was important and not just some weird unfortunate and unpredictable happenstance. Currently NHS Improvement have a group of health professionals such as nurses, doctors, pharmacists, physios, midwives, and paramedics who look at the information submitted but do they have the expertise to pick up the nuances of what are actually important clinical learning

points for clinicians at the coal face? You, my fellow expert do.

A clinical error was made, a patient came to harm, there is a clinical learning point which, if appropriately disseminated to the front-line clinician, could prevent harm to another patient. A medical expert witness will determine this as part of their work and, I hope, be keen to help disseminate this message to their colleagues and trainees within their speciality.

How should this valuable and patient centred information be disseminated? The Colleges play a vital role but there is inconsistency in the delivery of these important messages. Not everyone is a College member and arguably those who are not may be the ones who we need to target the most with patient safety messages. For the Royal College of Ophthalmologists approximately 90% of Ophthalmology Consultants, 50% of Trust and SAS doctors and all trainees in recognised training posts are members. It is not known how many trainees in non-recognised posts are members. These clinicians do not receive communications from their College. Do we accept that, even if the College systems are robust in disseminating this information, these clinicians are left out?

Avoidable harm is repeatedly happening which can and should be avoided. Should we neglect this issue because it is not a core part of our role as an expert witness or should we work together to develop a robust and consistent process to

detect repeated clinical errors from the litigation we see, develop learning points for those errors, and then make sure they are securely, reliably and consistently disseminated to the people who need to hear them, the front line clinicians.

Work has already commenced with NHS Resolutions exploring piloting a mechanism to study the Ophthalmology litigation and distil out recurrent errors in the hope of feeding back learning points to the wider NHS.

The proposal which I hope to be working with NHS Resolutions on is that all expert witnesses are asked a simple question; "was there a clinical error that caused harm?". If the answer is yes, then the expert will be asked to describe the learning point in less than 250 words. This anonymised report will be sent to an expert in that clinical field who will determine whether there is a learning point or whether an error is being repeated. The aim of this work is not to develop definitive guidance or proscriptive learning points but rather to disseminate points for practice reflection.

The same clinical errors are happening again and again. They do not reach the serious harm criteria for patient safety alerts and some are not system errors (which the current NHSI/NRLS processes handle well). They do not warrant NICE guidance or National Patient Safety Alerts and so they get left behind and patients are coming to harm time and again from avoidable clinical errors. Some of the worst cases of harm result in litigation and only a few go to Court where a formal judgment is reached. All however go through the hands of the medical expert and the knowledge of those clinical errors and any learning points therein are being missed. As a medico-legal profession we have the opportunity to make a difference and protect patients from harm through cooperation and a teamwork approach with NHS Resolutions and the wider NHS.

CCG POLICY ON PRESCRIBING AVASTIN FOR WET AMD NOT UNLAWFUL (BAYER PLC V NHS DARLINGTON CCG; NOVARTIS PHARMACEUTICALS UK LTD V NHS DARLINGTON CCG)

Laurence Vick, legal director at Enable Law @LaurenceVick

Legal director at Enable Law, Laurence Vick, considers the landmark judicial review decision in the case of Bayer Plc v NHS Darlington CCG, in which pharmaceutical company Roche was permitted to offer 'off-label' drug Avastin to treat the serious eye condition wet age-related macular degeneration (wet AMD). Novartis is appealing against the High Court ruling — so the situation may yet change.

Bayer plc v NHS Darlington CCG and others; Novartis Pharmaceuticals UK Ltd v NHS Darlington CCG and others [2018] EWHC 2465 (Admin)

What are the practical implications of this case?

The decision is likely to have far-reaching implications for the NHS.

The Royal National Institute of Blind People's Helen Lee welcomed the ruling:

'It is critical each patient has the opportunity to have a full discussion with their clinician to give consent prior to switching or embarking on treatment. All savings generated by providing Avastin rather than licensed anti-VEGF drugs—ie vascular endothelial growth factor—must be invested in eye care services.'

Novartis said it was 'disappointed' because patients were being asked to accept an unlicensed treatment to save the NHS money:

'The policy undermines the well-established legal and regulatory framework that is there to protect both patients' safety and to ensure healthcare professionals can prescribe with confidence.'

Clinicians confused over what they can and can't prescribe now have clarification of their legal and professional responsibilities, and will be reassured that they will not face criticism or the possibility of a referral to the General Medical Council (GMC) if they prescribe 'off-label' Avastin instead of Lucentis or Eylea.

Does this judgment impact only the use of Avastin for wet AMD, or does it have a potentially broader implications for the supply of medicines?

The option for the NHS of permitting the use of 'off-label' drugs at lower cost has now been clarified. NHS Confederation chief executive Niall Dickson said:

'This is great news for patients, taxpayers and the NHS. Having to pay far too much for one medicine, when another much cheaper one is just as good, is a nonsense and the court has recognised that scarce NHS resources must be protected. Within evidence-based guidelines, clinicians need to be able to use their professional judgment to make the best decisions for their patients.'

What was the background to the case?

In a landmark ruling, a group of 12 clinical commissioning groups (CCGs) successfully defeated a judicial review brought by the pharmaceutical companies Novartis and Bayer seeking to prevent NHS doctors offering patients a choice between their two licensed medicines

MEDICO LEGAL MAGAZINE

Lucentis (ranibizumab) and Eylea (aflibercept), and Roche's significantly cheaper alternative Avastin (bevacizumab) for the serious eye condition wet AMD. The policy adopted by the CCGs stated that Avastin will be offered to certain patients with wet AMD 'as the preferred treatment option'.

Age-related macular degeneration affects over 600,000 people in the UK, with 40,000 of those suffering from wet AMD. Wet AMD develops when abnormal blood vessels form and damage the cells at the back of the eye. Timely diagnosis and treatment is crucial—drugs are injected into the eye to stop the growth of the abnormal blood vessels. Left untreated, the condition results in visual impairment or blindness within three years. Lucentis is licensed for the treatment of wet AMD, whereas Avastin—although recommended by the World Health Organisation for treating eye conditions and used widely by doctors in the UK private sector as well as across Europe and in the US, where most prescribing decisions are taken by health insurers—is only licensed in the UK for the treatment of certain cancers.

The CCGs had argued that prescribing Avastin 'off-label' for wet AMD saved the NHS 'hundreds of millions' a year—the cost to the NHS of Avastin is about £28 per injection compared with £551 per injection of Lucentis and £816 for Eylea. The NHS annual spend on Lucentis is £244m, the second highest amount for any drug. The NHS justified its policy on the basis that studies had shown Avastin to be as safe and to have the same level of clinical effectiveness as the two more expensive drugs.

NHS doctors concerned as to their legal position when prescribing a drug 'off-license', which would save the NHS money and was regarded as safe and effective, sought clarification from the GMC.

In January 2018 the National Institute for Health and Care Excellence (NICE) issued guidelines on the treatment of AMD, and the GMC also clarified its approach to clinicians who prescribed Avastin for ophthalmic use. Following submissions from the Royal College of Ophthalmologists, the GMC

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issued a statement reassuring doctors that where they are 'working in partnership with patients, following clinical guidance and making prescribing decisions in good faith on the basis of evidence and experience, the use of Avastin would not cause us any concerns'.

The claimants Bayer and Novartis challenged the lawfulness of the CCGs' policy on four grounds:

- that the supply of Avastin was unlawful because it was not licensed for ophthalmic use
- it undermined European drug regulation
- it undermined patients' right to access drugs recommended by NICE
- the patient information and Q&A sheets accompanying the policy were misleading and inaccurate

What did the court decide?

The High Court had to consider a wide range of issues and arguments.

Is there a mature and established market in compounded bevacizumab prepared for ophthalmic use?

The judge found that there is an established, mature market in Avastin in the UK and Europe for ophthalmic use.

The claimants argued that the European regulator had effectively ruled out blanket policies allowing off-label prescribing of medicines on grounds of cost, which was also reflected in the Medicines and Healthcare products Regulatory Agency guidelines stipulating that cost, convenience or operational needs cannot be factors driving prescribing decisions.

Can treating clinicians lawfully choose Avastin on grounds of cost?

The claimants challenged the competency of NICE and the NHS to make decisions over whether their drugs were safe, clinically effective or cost-effective and argued that clinicians are not permitted, when prescribing, to take account of the cost of a drug. Mrs Justice Whipple dismissed the judicial review application on all grounds and found in favour of the CCGs.

The ways in which the CCGs had implemented the NHS policy were entirely lawful. Clinicians have a professional duty to make the most appropriate use of NHS resources.

Is Avastin safe for ophthalmic use?

The judge rejected the claimants' contention that Avastin was not as safe for ophthalmic treatment as their own licensed alternatives. It was unnecessary for the court to consider the safety issues and the expert evidence produced by the claimants because CCGs and NICE were legally competent to make their own decisions as to whether drugs were safe and clinically effective. The judge placed significant weight on the fact that NICE had published a 500-page report after the CCGs had adopted the NHS policy, which concluded that 'Avastin is as safe as the licensed alternatives'.

The judge rejected the claimants' argument that the CCGs' policy undermined NICE's guidance which requires NHS patients to be given options.

This article was first published on Lexis®PSL Local Government on 10 October 2018. Click (http://www.lexisnexis.co.uk/en-uk/products/pslfreetrial.page) for a free trial of Lexis®PSL.

CLINICAL PARTNERSHIPS: A LIFELINE FOR THE NATIONAL HEALTH SERVICE?

by Bernard Ross, CEO, Sky Medical Technology

With the NHS currently facing some of its greatest challenges in a 70-year history, clinical trials for new treatments and technologies could provide the solutions to seemingly insurmountable problems: endless surgery waiting lists, bed-blocking, and clinicians and nurses stretched to their limit. Do public-private partnerships between the NHS and med-tech developers hold the key?

Successful outcomes in device development and the development of clinical and health economic benefits rely heavily on the strong partnerships between clinicians and med-tech developers, with both parties committed to improving outcomes for patients. It's the clinicians that embrace innovation and that are forward thinking that must be championed. Collaborating with those willing to invest in and introduce evidence-based therapies, to simplify treatments, will help build a much more robust health system that is moving forward rather than stuck in its tracks under strain.

Bernard Ross, CEO of Sky Medical Technology, discusses how the pharmaceutical and biotech industry must prioritise its clinical partnerships, taking a clinician-first approach when supporting the doctors, nurses and Trusts embarking on trials, whilst balancing the needs of key stakeholders and strategic partnerships.

2018 marked the NHS's 70th birthday, and as the British institution celebrated seventy years of service, the general public rushed to express their gratitude; from cradle to grave, the NHS was hailed for its care for every citizen, no matter their condition, circumstance or means.

Though a source of national pride, it is difficult to ignore that after seven decades, the NHS now faces some of its greatest challenges yet. As the British population grows and ages, the institution must contend with evolving crises in care and funding. For years, the NHS has rallied for a much-needed extended budget, to increase support for the clinicians and nurses stretched to their limit and combat ever-growing demand to services, which can have knock on effects of bed-blocking and lengthy surgery waiting lists.

Working Together

Whilst the case for further funding is clear, the NHS itself recognises that innovative solutions are vital to achieve its ambitions. Could external partnerships with some of the world's leading med-tech developers hold the key to battling certain problems and sources of frustration within UK healthcare? The common goal is clear: clinicians, funding bodies and med-tech developers are committed to improving outcomes for patients, whether it's through new treatments, tech to support patient treatments, or reducing GP waiting lists.

This means the institution must strike a careful balance between recognising the need for innovative solutions to ease cost-pressures, whilst still building a strong case calling for further government funding. For med-tech manufacturers, respecting this balance is crucial when partnering with NHS Trusts and hospitals to introduce potentially game-changing tech into clinical use.

Planning for the future

The Five Year Forward View, a plan to cover all aspects of improving the NHS, includes intentions to "harness technology and innovation". As well as improving patient access to care through apps and digitising its hospitals, the plan outlines the NHS' support of the UK's booming life-science industry, noting that many healthcare technologies we take for granted today – vaccines, MRI scanners – were originally nurtured in British universities.

The NHS commitment to harnessing technology and innovation includes such schemes as the National Clinical Entrepreneurs Programme and the Innovation Accelerator, both supporting the quick and safe adoption of innovations within NHS Trusts. These schemes have enjoyed significant success in allowing clinicians to pursue entrepreneurial aspirations during their training period, and in turn developed close relationships between young UK-based med-tech companies and the NHS.

These relationships will be key for our health service going forward, as the ability of clinicians, funding bodies and med-tech developers to collaborate are crucial to the innovation process.

In practice

The need for, openness to and support for new medical technology is apparent; introducing new technologies and devices into the NHS is not quite as straightforward as it seems.

The NHS prides itself on safe, effective patient care, and due diligence is rightfully taken when introducing new treatments and devices into the health service. Most device manufacturers will be familiar with NICE – the National Institute for Health and Care Excellence – guidelines, specifically its assessment of health technologies within the NHS.

Clinical trials are a vital part of bringing in new tech, and, done well, they should involve the collaboration of multiple parties; device developers, funding bodies, clinicians, nurses, to name a few. Whilst all share that same common goal – improving patient outcomes – each party faces separate pressures.

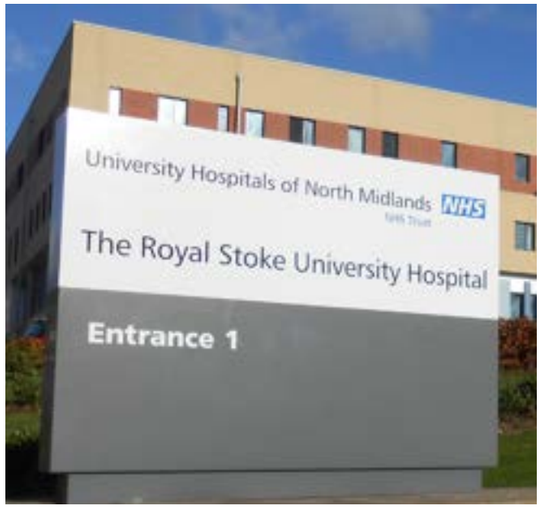
For the clinicians, it is ensuring the use of a device truly supports positive patient outcomes, for the funding body, the results must clearly demonstrate the economic benefit of the device for the clinical application being trialled. For the device development company, then, the focus must be on the clinicians and NHS Trust involved, ensuring the pressures they face are met and supported at every stage. Get this clinician-first approach right, and the potential to do good is huge.

The Rise of Med-tech

Med-tech is one of the spaces demonstrating a real appetite to improve patient care and efficiencies. According to the National Institute for Health Research's report on developing medical technologies for the NHS, the scale of Med-Tech activity in the UK is substantial; it is a £17bn industry that employs over 75,000 people with expectations it will grow even further. The UK is currently at the forefront of medical innovation, exporting its expertise on the global stage; this needs to be an opportunity seized by the NHS.

There are a number of clinicians making headway in achieving this already, actively developing productive partnerships with industry leaders to get new innovations into NHS hospitals. In our own experience, we are enjoying strong relationships with a rapidly growing number of clinical partners that are keen to collaborate to get to grips with products that improve the health service.

For example, we are currently working with clinicians at places such as the NHS Royal Stoke University Hospital, Welsh Wound Innovation Centre, and James Cook University Hospital, Middlesbrough, where we have the pleasure of working with clinical teams that are eager to embrace and evaluate innovation, and this



has generated clinical and health economic data we can share widely across the NHS and internationally. For example, the results from a study, at the James Cook Hospital, to determine the reduction of pre-operative oedema in ankle fracture patients showed a 2-day improvement in readiness for theatre, and average cost savings of £569 per patient. These results could not have been achieved without close-up partnership with the lead clinicians.

This all comes down to knowledge transfers between clinicians and industry players, clinicians on the ground know their patients and the most pressing problems at play, and the UK med-tech industry has the means to refine and tailor their product solutions. Through a more open dialogue and interaction between the two, the NHS can only benefit.

Overview

The UK med-tech industry may well hold the key to solving many of the critical issues the NHS is currently facing, and the realisation of these solutions depends on enhancing the relationship between clinicians and industry heads.

Schemes such as the NHS Innovation Accelerator, Clinical Entrepreneurs program and the Innovation and Technology Payment (ITP) are heading in the right direction, as they indicate what can be achieved through proactive partnership. At their centre, is a clinician-first approach – and there is clear evidence to indicate clinicians want to be at the forefront of implementing game-changing innovations. As the NHS looks towards the next 70 years – this approach will have a great part to play in determining how the much-loved health service will look in the future.

About Sky Medical Technology Ltd

Sky Medical Technology is a highly innovative UK based medical devices company that has developed a ground-breaking neuromuscular electrostimulation technology platform, OnPulse®. The company develops a range of products tailored to the needs of different medical application areas selling both direct and through strategic partnerships or distributors in each major clinical area. Clinical areas of interest include reduction of oedema, prevention of VTE, wound healing and elite sport recovery. The goal in each clinical area is to improve clinical outcomes and patient care whilst saving health system resources.

MEDICO -LEGAL NEWS:

By Lisa Cheyne, Medico-Legal Manager, SpecialistInfo

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

Hernia mesh complications

After a BBC investigation, the scale of patients living with hernia mesh complications has been revealed as shockingly high.

One in 10 people will develop a hernia and the most common treatment involves surgical mesh.

There have been between 90,000 and 100,000 hernia mesh operations in England each year since 2011-12, so if the complication rate is estimated to be 12-30%, up to 170,000 patients could have been adversely affected in the past six years.

Mesh has been increasingly used for hernia repairs since the 1990s, rather than traditional suture techniques, so the total number who have experienced complications since its introduction is thought to be much higher.

With the cost of treating those experiencing serious hernia mesh complications estimated to be upwards of £25,000 per patient, the cost to the NHS could be high.

Labour MP Owen Smith, who chairs the All Party Parliamentary Group on Surgical Mesh Implants, said he feared the UK could "potentially have another scandal on our hands".

"It reflects the flawed system we have in place," he said. "Neither the MHRA or the manufacturers have to follow up on problems".

A spokesperson for the Royal College of Surgeons said "A recent 2018 study found that both mesh and non-mesh hernia repairs were effective for patients and are not associated with different rates of chronic pain. A minority of hernia mesh operations are associated with complications. However, it is also important to stress that such complications range dramatically from minor and correctable irritations to more serious complications."

NHS trusts in England still have no consistent policy for guidelines on treatment or follow-up with patients.

Read more:
https://www.bbc.co.uk/news/health-45604199

The Medico-Legal Conference – 16th May 2019, at the Queen Elizabeth Hall, South Bank, London

Tickets are now selling fast for SpecialistInfo's ML Conference in London on 16th May 2019.
Please visit the website for details of the programme and to book:

http://www.medicolegalconference.com/programme.html

Please contact nicola@specialistinfo.com for further information if you are interested in presenting or sponsorship.

The independent public statutory inquiry into the use of infected blood

Following his appointment as Chair of the Infected Blood Inquiry earlier this year, Sir Brian Langstaff and the Inquiry Team conducted a consultation on the Inquiry's Terms of Reference and will investigate as follows:

What happened and why?
Impact on those infected and their families.
The response of Government and others.
Consent - whether and to what extent people were treated or tested, and their infection
status was recorded without knowledge or consent.

To examine the circumstances in which patients treated by the NHS were given infected blood and infected blood products, since 1970, and to what extent people given infected blood or infected blood products were warned beforehand of the risk that they might thereby be exposed to infection, and if so whether such warnings as were given were sufficient and appropriate.

The Inquiry will be holding meetings for people affected throughout the UK in the first months of 2019, ahead of the public hearings starting at the end of April.

Liz Carroll, chief executive of The Haemophilia Society, called on the inquiry to work diligently to "uncover the truth, bring justice and ultimately closure for victims and their families".

If the new inquiry finds culpability, it opens the door to victims seeking large compensation pay-outs through the courts.

Read more: https://www.infectedbloodinquiry.org.uk/

Darnley (Appellant) v Croydon Health Services NHS Trust (Respondent) [2018] UKSC 50 On appeal from [2017] EWCA Civ 151

The Supreme Court unanimously allowed the above appeal alleging a breach of duty by the reception staff on the basis that the duty of care is owed by the respondent and it is not appropriate to distinguish, in this regard, between medical and non-medical staff

BACKGROUND TO THE APPEAL

The appellant, Michael Mark Junior Darnley, was struck on the head on 17 May 2010. A friend drove him to the A&E Department at Mayday Hospital, Croydon which was managed by the respondent, NHS Trust.
The trial judge found that at the A&E reception, the appellant informed the receptionist that he thought he had a head injury and that he was feeling very unwell. The receptionist told him that he would have to wait up to four to five hours before he could be seen by a clinician and that if he did collapse then it would be treated as an emergency. The A&E receptionists' usual practice when a person with a head injury asked about waiting times would be to say that they could expect to be seen by a triage nurse within 30 minutes of arrival.

The appellant left after 19 minutes because he felt too unwell to remain and went to his mother's home. He later became distressed and an ambulance was called. He was taken back to Mayday Hospital and a CT scan identified a large extradural haematoma. He was transferred to St George's Hospital and underwent surgery the same night. Unfortunately, he suffered permanent brain damage in the form of a severe and very disabling left hemiplegia.

The appellant brought proceedings against the respondent alleging a breach of duty by the reception staff concerning the information he was given about the time he would have to wait and the failure to assess him for priority triage. The High Court dismissed the claim. The appellant appealed to the Court of Appeal. The appeal was dismissed by a majority on the grounds that neither the receptionist nor the health trust acting by the receptionist owed any duty to advise about waiting times, the damage was outside the scope of any duty owed, and there was no causal link between any breach of duty and the injury. The appellant appealed to the Supreme Court.

JUDGMENT

The Supreme Court unanimously allows the appeal and remits the case to the Queen's Bench Division for assessment of damages. Lord Lloyd-Jones gives the sole judgment with which the other Justices agree.

CAUSATION

The appellant's decision to leave was reasonably foreseeable and was made, at least in part, on the basis of the misleading information from reception staff. The trial judge made further findings of fact that, (1) had the appellant been told he would be seen within 30 minutes he would have waited, been seen by a doctor and admitted, and (2) had the appellant suffered the collapse at 21:30 whilst at the Mayday Hospital, he would have undergone surgery earlier and he would have made a nearly full recovery. Thus, the appellant's departure did not break the chain of causation.

Read more:
https://www.supremecourt.uk/cases/uksc-2017-0070.html

NHS Resolution launch permanent mediation scheme after successful trial

Following a successful mediation pilot scheme to resolve clinical claims, NHS Resolution's new claims mediation service has been designed to support patients, families and NHS staff in working together towards the resolution of incidents, complaints, legal claims and costs disputes – avoiding the unnecessary expense, time, stress and potential emotional distress of going to court. The service will provide access to an independent and accredited mediator, selected from a panel drawn from a wide range of backgrounds.

Partners for its mediation service are:

The Centre for Effective Dispute Resolution (CEDR) and Trust Mediation Limited, appointed to mediate disputes arising from personal injury and clinical negligence incidents and claims.

Costs Alternative Dispute Resolution (CADR), appointed to mediate disputes arising from the recoverability of legal costs.

Read more at: https://resolution.nhs.uk/

Low NHS staffing levels are risking patients' lives

Research commissioned by the *General Medical Council (GMC) for its 2018* The state of medical education and practice in the UK report, published on 5 December 2018, reveals continued pressure on health services.

"Doctors are telling us clearly that the strain that the system is under is having a direct effect on them, and on their plans to continue working in that system." Professor Sir Terence Stephenson, Chair of the GMC

Dr Kailash Chand OBE, Honorary Vice president of the BMA, also claimed recently that the NHS in England has dangerously low staffing levels and is currently estimated to have a shortfall of 100,000 employees out of its approximately 1.8 million staff.

The NHS is the world's fifth largest employer, but the chronic staff shortage is predicted to worsen over the next 5-10 years as the average age of GPs, nurses and midwives is high and many will retire, combined with the recent reduction in recruitment from EU countries.

Reasons given by staff who leave the NHS include: rising workloads, worsening moral, NHS pay cap combined with austerity, and the insecurity around Brexit.

Read more: http://flickread.com/edition/html/index.php?pdf=5b86bd48a793b#38

A coalition of British breast and plastic surgeons welcome the news that over 20,000 operations have been recorded on England's Breast and Cosmetic Implant Registry

In November, The British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS), The British Association of Aesthetic Plastic Surgeons (BAAPS) and The Association of Breast Surgery (ABS) welcomed the news that England's Breast and Cosmetic Implant Registry (BCIR) has published its first report, detailing over 20,000 breast implant operations across England.

The BCIR was launched in October 2016 in response to safety concerns following the high rupture rate of Poly Implant Prosthese (PIP) and the inability to trace women who might be affected.

BAAPS, ABS and BAPRAS have long-championed the need for a registry and are pleased to sit on the steering committee responsible for the development and running of the BCIR alongside NHS Digital.

With over 20,000 women receiving breast implants for reconstructive or cosmetic reasons in the last year, the registry is a vital patient safety initiative which enables the collection of long-term safety data and ensures the patient recipients of specific makes of implants can be traced, if needed.

Due to the recently identified link between breast implants and a rare form of cancer called Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) the importance of accurately recording this data is crucial.

Currently, submission to the registry is not mandatory, but BAAPS, ABS and BAPRAS encourage all women receiving implants to consent to the submission of data. The associations look forward to this invaluable patient safety asset becoming available across all devolved nations.

BAAPS is also supporting calls for a register of aesthetic medical providers using dermal fillers, and

for these treatments to only be performed by doctors, nurses and dentists.

Dr Marc Pacifico, a consultant plastic surgeon from the British Association of Aesthetic Plastic Surgeons (BAAPS), said dermal fillers are a "complete wild west in the UK".

"We are one of the few western countries who regard [fillers] as a device not a medicine," he said. "There have even been cases of blindness.

"It was really about time stronger regulation was brought in."

Read more: https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/breast-and-cosmetic-implant-registry

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