action against medical accidents

LAWYERS SERVICE NEWSLETTER

JUNE 2016

EDITORIAL

INSIDE THIS ISSUE

I do hope that the next time I write the editorial for the Lawyers Service Newsletter we will be commenting on the proposals in the government's consultation on Fixed Recoverable Costs (FRC)! However, the impact from the recent Brexit vote may mean that this consultation will be delayed further. Certainly before the referendum was held the Department of Health had said that they would like to roll out the consultation as soon as possible after 23rd June; either late June or early July – it remains to be seen.

We understand the consultation will be for FRC for claims up to £250k, and will include draft amendments to the Civil Procedure Rules (the scheme will only require secondary legislation) and a draft scheme for consultation. The consultation is expected to be 12 weeks. Following representations from AvMA and others, the Department of Health have also confirmed to us that they accept that their proposals will not be implemented in October 2016 as originally forecasted; they have not given any indication as to the revised implementation date or the triggers for implementation.

We also understand that the consultation on non -recoverability of ATE premiums is to be published around the same time.

Peter Walsh, our chief executive, has taken part in an equalities advisory group set up as part of the consultation on FRC. The group has been considering the implications of the proposals and Peter has concentrated on ensuring serious concerns about the impact on older people and other vulnerable groups are noted.

As well as gearing up for our own response to the FRC proposals and seeking to influence them, AvMA continues to work with the Law Society, APIL and SCIL to share intelligence as well as ideas for raising awareness of our shared concerns about the proposals and to explore what an alternative to FRC scheme might look like. These discussions remain confidential and are being used as an opportunity to discuss and explore possible options. Nothing definite has been agreed and much depends on what the FRC consultation actually says.

AvMA met with Ben Gummer on 8th June to discuss FRC and patient safety and in particular how better learning could come out of litigation. We were encouraged that at least the DH sees AvMA as a leading organisation representing the patient/public perspective on matters of access to justice and patient safety. In particular, we have suggested that the current situation would be improved if there were a uniform system for reporting both litigation outcomes and clinical failings which have been identified. Our suggestion is that that all breaches of duty identified (not just those that result in settled litigation) and

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clinical failings should be set out in a "patient safety letter". Clinical Failings would include issues such as notifiable safety incidents and issues that trigger a Serious Incident Report (SIR). The care provider would then have to respond setting out what they have done to address the breaches and/or clinical failings. We suggest that the patient safety letter and the care provider's response are sent to the claimant and are published so that the public has access to it.

More generally, we are keeping the momentum going about our concerns over access to justice by continuing to lobby politicians and liaise with fellow patients' charities, many of these charities have formed part of a coalition sharing concerns about the proposals. We have also met with the NHS LA to look more closely at areas where we might agree and those areas of difference; we are pushing for greater recognition of the importance of accreditation in clinical negligence litigation and there appears to be some support for this.

On a slightly separate note, the NHS LA has recently established an in house litigation team. This move will enable some of the NHS LA's staff to go on the court record in cases where court proceedings are served. We understand the NHS LA has made this move in an attempt to avoid outsourcing certain types of work to the NHS LA legal panel.

The NHS LA litigation team's authority will kick in, where the value of a claim is no more £50,000 and where the claimant is represented. This move has been rolled out as a pilot for 12 months commencing 1st May 2016. The costs savings and effectiveness of the team will be reviewed next year.

Whilst the FRC issue has certainly dominated activities in recent months there have been several other important developments in other healthcare related areas. Many of you will recall that AvMA has been involved with looking at the Independent Patient Safety Investigations Service (IPSIS), now known as the Healthcare Safety Investigation Branch (HSIB). For further information on HSIB, I refer you to Peter's update which is in this Newsletter.

Another issue of concern is the Rapid Resolution and Redress Scheme for maternity claims which is currently being considered. This scheme was first alluded to in the National Maternity Review, published in February 2016 and led by Baroness Cumberlege: https://www.england.nhs.uk/wp-content/uploads/2016/02/national-maternity-review-report.pdf

The report recommends that claims for compensation arising out of birth injuries and still births should be modelled on a no-fault system similar to that which exists in Sweden. This scheme looks to provide a separate, voluntary administrative compensation scheme specifically for babies born with avoidable birth injuries resulting in brain damage. AvMA welcomes the opportunity for families to access an alternative to litigation that provides for high quality and consistent investigations into birth injuries and deaths. However, any such scheme should not deny families their right to litigation.

In support of introducing this scheme the government has sought to make comparisons with the Swedish model of no-fault compensation. However AvMA has been clear that damages in the UK should not be capped to replace compensation payments; we have been at pains to point out that unlike Sweden our social security provisions are not adequate. AvMA understands that whilst Sweden has allegedly seen a 50% reduction in serious birth injury over the last 7 years, the fact that Sweden is ahead of us on both per capita midwives and doctors cannot be ignored either – staffing is a key issue.

At the same time as a no-fault scheme is being considered for maternity claims in England, it is probably no coincidence that the Scottish government is consulting on proposals for a No-Blame Redress

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Scheme of Compensation for harm resulting from NHS clinical treatment in Scotland. The consultation closes on 24th June, details can be found at the link: https://consult.scotland.gov.uk/independent-living-fund-scotland/no-blame-scheme. Again, I refer you to Peter's update which outlines the key proposals.

This edition of the Newsletter includes some very important articles which may help clinical negligence practitioners. I am grateful to Katie Gollop QC at Serjeants' Inn, for her excellent article on "Aspirin/Stroke Claims: Is Rothwell a Game Changer?" Katie carefully examines Professor Rothwell's recent paper on the benefits of aspirin following transient ischaemic attack (TIA), published in the Lancet May 2016 and considers how his findings might be used to bolster causation arguments.

We live in a time when cosmetic procedures are increasingly popular and common place among the public; Elise Bevan's (Senior Associate Solicitor at Penningtons) article on anaplastic large cell lymphoma (ALCL) looks at the need to warn patients of this rare cancer risk before breast implant surgery and is a salutary reminder that these procedures are not without risks.

Part 36 offers have always been a potentially powerful weapon in litigation, if FRC are introduced such offers are likely to play an increasingly important part in litigation tactics. The judgment in ABC v Barts Health NHS Trust confirmed the costs consequences of late acceptance of a part 36 offer, judgment having been given in March 2016. Although this case has already been widely reported we are pleased to include an article from the Claimant solicitor in this case, Janine Collier, Executive Partner at Tees Law. Janine looks at the key points arising from this judgment and provides an insight into the complications of this case which gave rise to the defendant's Pt 36 offer initially being rejected to the reassessment of that same offer some eight months later.

Mental health services in the UK remain underfunded, patients are often poorly served. Lamb Chambers barrister, Ross Beaton's article "When psychiatric care goes wrong – the benefits of representation at a Coroner's inquest" is likely to resonate with many practitioners. Ross provided representation to C's family through AvMA's Pro Bono Inquests Service; he worked with Julia Cotterill, Medico-Legal Coordinator at AvMA to explore the quality of mental health care provided by the Trust in the community. Without the benefit of representation it is quite likely that the coroner would not have been aware that before C's death a CQC inspection had identified no less than eighty-five ligature risks on the ward. A further inspection shortly after the death found a lack of effective systems in place.

We look forward to seeing you at the AvMA annual conference on 30th June to 2nd July, when we return to our old haunt, Brighton. There are a few nonresidential bookings available, please contact the conference department for further information. The traditional annual AvMA golf day on Thursday continues so do sign up if you are interested. This year, we are again offering an alternative to the golf day with a wine tour and tasting at the Bolney Wine Estate in Sussex, full details of which are included in the Newsletter.

Best wishes

Lisa O'Dwyer
Director Medico-Legal Services

POLICY UPDATE

Healthcare Safety Investigation Branch (HSIB)

There is to be a new investigation arm within NHS Improvement in England, using a model based on the Air Accidents Investigation Branch. However it has been confirmed that Healthcare Safety Investigation Branch (HSIB) may deny patients access to information about what happened in their treatment in order to create a "safe space" for health professionals who give evidence.

The expert advisory group report on the establishment of the Healthcare Safety Investigation Branch (HSIB) published in May contains an unequivocal recommendation that any information relevant to a patient's care should be shared with them, and they should be free to use it as they wish.

This is a sensible recommendation about which consensus was reached by a broad church of patient safety experts on the advisory group set up by the Department of Health.

However, statutory directions on how the HSIB must work were published by the Department of Health last month. These fly in the face of the expert group's recommendation and restrict the circumstances in which patients might be told about what is found out about their own care, and on how they could use it.

AvMA Chief Executive Peter Walsh said:

"We desperately want HSIB to succeed, which is why we are so disappointed that the Department of Health has flatly rejected the expert group's recommendation about sharing information with patients and families.

"We think it will damage public confidence in the HSIB if patients know there is a possibility that information about their own care may not be shared with them and even if it is, there will be restrictions on what they could do with it.

"We are calling on Jeremy Hunt to change the directions so that they are consistent with the duty of candour, which he himself has championed."

Scottish Government consults on "No-blame Redress" proposals

The Scottish Government is consulting on proposals to establish a 'no-blame redress' scheme for claims of upto £100,000. The proposals also contain a proposal to repeal Section 2(4) of the Law Reform (Personal Injuries) Act 1948, which stipulates that personal injury defendants must disregard NHS care when paying compensation. The initiative will no doubt be watched very carefully in England and Wales also, where there have been calls for changing the system so that care packages are provided by the NHS and local authorities rather than allowing for the purchase of packages from private providers in clinical negligence cases.

The Maternity Review in England also proposed a form of 'no-fault compensation' for birth related injuries. The consultation closes on 24th June. The consultation information can be found here http://www.gov.scot/Publications/2016/03/7618

AvMA is currently working with the Scottish Government over implementation plans for the new statutory Duty of Candour in Scotland which has been legislated for in the HEALTH (TOBACCO, NICOTINE ETC. AND CARE) (SCOTLAND) ACT 2016

SERJEANTS' INN CHAMBERS

Aspirin/Stroke Claims: Is Rothwell a Game Changer?

What is the Litigation Issue?

Reporting on Rothwell's research, The Telegraph stated that more than 46,000 suffer a TIA in the UK every year and more than 150,000 have a stroke so the numbers are huge.

Major stroke is very common and it can be devastating. But sometimes there is an opportunity to intervene. That is because major stroke is often preceded by either a Transient Ischaemic Attack (a TIA or "mini-stroke") where symptoms are mild and resolve within 24 hours or a minor stroke where again, symptoms are mild but take slightly longer to resolve. And for a few days after a TIA/minor stroke, the risk of a major stroke is about 1,000 times higher than the background rate.

In the last 8 years or so there has been public education about stroke recognition including publicity of the acronym FAST: Face, Arms, Speech, Time. And the NHS response has been overhauled with NICE Guidelines in 2008 and the development of stroke units. Despite all this, the opportunity to intervene continues to be missed: many patients presenting to their GP or a junior doctor in the Emergency Department after a TIA or minor stroke are misdiagnosed and sent home without any treatment or advice. And because they are at such a heightened risk, a substantial number of these patients go on to have a disabling major stroke in the hours, days or weeks that follow.

Unsurprisingly, these patients often seek legal advice.

AVMA members will be well aware that whilst establishing breach of duty in these circumstances is often relatively straightforward, establishing causation is not.

Why is Causation Difficult?

Generally, the treatment options are thrombolysis (clot busting drugs) or aspirin (an anti-coagulant). Thrombolysis will not be prescribed unless treatment can be started within about 4 hours (6 in some units) of stroke symptom onset. Few people who have a stroke in the community make it in time not least because even if they get to hospital rapidly, there is an inevitable delay while the diagnosis is made and a brain scan done to exclude a haemorrhagic cause of the stroke. And not all units offer thrombolysis.

So for most claimants, the case comes down to the causative effect of a negligent failure to administer aspirin.

Since there is no other immediate treatment, claimants are in straight balance of probabilities territory. In each case, the burden is on the claimant to prove that aspirin alone would probably have prevented the later, disabling, major stroke event. To date, medical evidence that reaches that standard of proof has been lacking particularly when the time interval between the TIA/minor stroke and the major, disabling stroke is short ie hours or days. In a recent case, decided in April 2015 when Rothwell was lecturing about his research but had not yet published, the experts agreed that the percentage contribution made by aspirin in preventing recurrent ischaemic stroke was about 23% (see

Choudhury v South Central Ambulance Service NHS Trust and Another [2015] EWHC 1311 (QB) at paragraph 113).

Now that Rothwell has published, causation in many TIA/Aspirin/Major Stroke claims has changed to the benefit of claimants.

So How Does Rothwell Help?

Professor Peter Rothwell is an internationally renowned stroke expert working at the University of Oxford who has dedicated his life to working on stroke prevention. It was his research – the EXPRESS study – that prompted the 2008 NICE Guidelines.

On 18 May 2016, he and his team published in The Lancet "*Effects of aspirin on risk and severity of early recurrent stroke after transient ischaemic attack and ischaemic stroke: time-course analysis of randomised trials"*.

The headline is that aspirin alone (not aspirin when combined with other agents) reduces the risk of early recurrent stroke after TIA/minor stroke.

The key word here is "early" since the research shows that those given aspirin within 0-2 weeks of a TIA obtain the greatest benefit though benefit accrues for the first 12 weeks.

There are two upsides. Aspirin not only prevents stroke but also, if a major stroke is experienced aspirin reduces the severity of the final outcome. And those beneficial effects were experienced regardless of the dose, the patient's characteristics or the aetiology of the TIA/minor stroke.

Rothwell considers the research findings so important and (importantly) aspirin so safe, that he suggests doctors suspecting a TIA or minor stroke should treat with aspirin immediately without waiting for further assessment. The Stroke Association goes further and recommends that in addition to seeking emergency medical help, anyone who has stroke symptoms which are improving while medical treatment is awaited should take 300mg of aspirin while they wait.

What Is the Ideal Set of Facts?

The ideal foundation for a successful stroke/aspirin claim will contain the following ingredients: a TIA or a minor stroke leaving no more than moderate deficit, consultation with a doctor, a negligently missed opportunity to make the diagnosis and prescribe aspirin and a major stroke occurring no fewer than 48 hours and no more than 14 days after the time when aspirin should have been started.

In these circumstances, the probability of aspirin preventing major stroke could be as much as 80%. In the litigation context, barring some confounding factor, the new research should get such a Claimant home on a clear balance of probabilities.

There is a grey area where the major stroke occurs very quickly – within 24-48 hours – of the TIA/minor stroke. That is because in the original trials, it took time to randomise patients to an aspirin or control group. Such claimants will experience greater difficulty but given what we now know about the efficacy of aspirin after 48 hours has elapsed, there may well be enhanced scope for a *Bailey v MOD*, material contribution or increase in material risk argument.

Can Rothwell be Applied to Major Stroke followed by Further Major Stroke Cases?

The short answer is not in any straightforward way. Cases such as *Choudhury* where the claimant had a major stroke and then a severely disabling stroke event (which left him with locked-in-

syndrome) will continue to be a causation challenge. That said, the fact that early aspirin ameliorates the outcome may assist and again, the new research may be a more promising platform for a material contribution/*Bailey v MOD* argument than EXPRESS. It would certainly be worth obtaining an informal opinion from a neurologist or stroke physician.

How are defendants likely to respond?

The research is so new that at the moment, we just don't know.

An attack on Rothwell's methodology is possible. Because aspirin is known to be effective it is no longer ethical to undertake randomised control trials. So the research published in May 2016 is meta-analysis of existing data (the Rothwell team pooled analysis of individual patient data from all available trials of aspirin versus control after TIA or ischaemic stroke). The EXPRESS trial has been criticised by some and there may be further criticism.

The way in which the graphs have been plotted is also likely to be scrutinised. In depth consideration of these issues requires input from a neurologist/stroke physician (and, possibly, a statistician) but it is likely that Claimants will want to focus on the Hazard Ratios (the basis for which is not easy to discern at the moment) and Defendants on the Confidence Intervals, which are wide.

There may be more focus on neuroradiology with an attempt to show that the first stroke type event was more seriously disabling than claimed.

More prosaically, the graphs are small and the data is not published day by day. That may mean enlarging the curves, getting a ruler out and arguing which side of the 50% mark the dot falls.

A defendant struggling on causation (which is likely in a classic case where the major stroke occurs 2-14 days after the TIA + negligent failure to give aspirin) can be expected to defend breach of duty more vigorously. Early attention to the detail and duration of the symptoms suffered and the history given to the doctor with as much corroborating evidence as possible will continue to be very important.

Final Thoughts

In cases with the ideal set of facts described above, Rothwell is likely to be a real gamechanger since it enables claimants to clear the 50% threshold.

And the pool of defendants may widen. Once the implications of the new research have bedded in, it may be possible to argue that ambulance personnel and paramedics, the 111 service and perhaps 999 operators have a duty to recommend, and where appropriate dispense, immediate aspirin.

The 2008 NICE Guidelines are due to be updated in July 2016 and we can expect to see Rothwell's latest research underpinning new recommendations.

For stroke sufferers who have sought medical help and been denied a treatment as cheap, accessible and, as we now know, safe and effective as aspirin, the new research will make for difficult reading. As ever, damages are scant compensation for a life-changing injury but at least now, a larger number of cases should succeed.

A word of caution: Professor Rothwell has not reviewed this article and all errors are the author's own.

KATIE GOLLOP QC
SERJEANTS' INN CHAMBERS

PENNINGTONS MANCHES

Breast implant patients should be warned of rare cancer risk before surgery

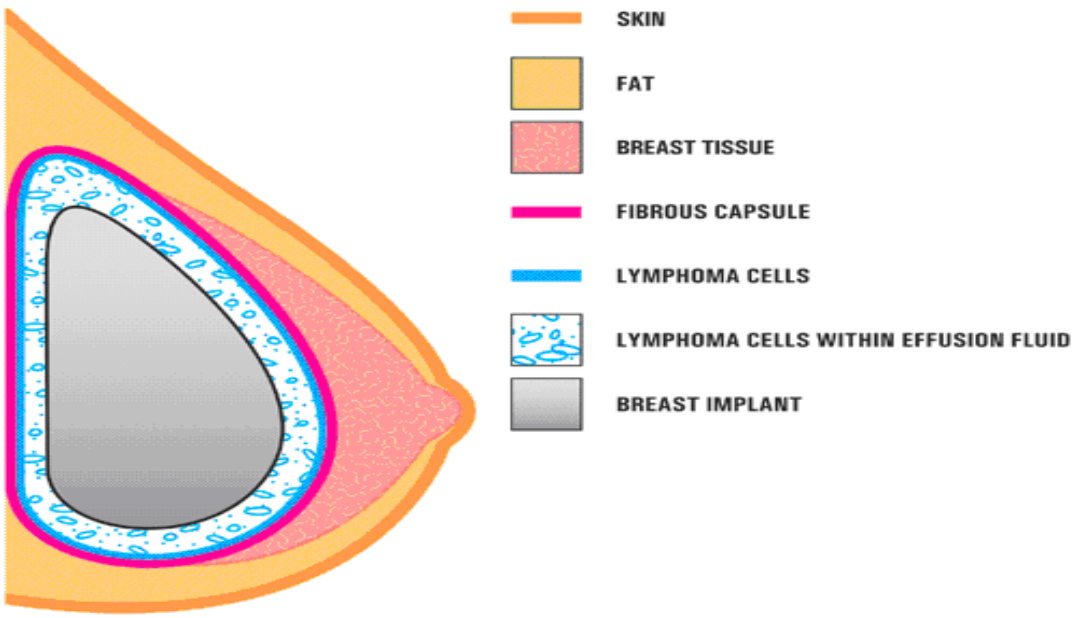
It is important that all women considering any type of breast implant surgery are informed of the risk of a rare but serious type of cancer called anaplastic large cell lymphoma (ALCL). They should also be counselled on the signs and symptoms of this breast implant associated cancer and should be made aware of when to take action.

What is breast implant associated ALCL?

ALCL is a rare type of non-Hodgkin Lymphoma. Like all lymphomas, it is a cancer of the lymphatic system - part of the body's immune system. ALCL develops when abnormal T-cell lymphocytes, a type of white blood cell, divide in an uncontrolled way. These build up in parts of the body like the lymph nodes, lungs or skin.

When breast implants are placed in the body, they are inserted behind the breast tissue or under the chest muscle. Over time a fibrous scar called a capsule develops around the implant, separating it from the rest of the breast. In women with breast implants, the ALCL was generally found adjacent to the implant itself and contained within the fibrous capsule.

The illustration below demonstrates that the normal containment of the ALCL is in the fibrous capsule in close proximity to a breast implant. In most cases, the ALCL cells were found in the effusion fluid (seroma) surrounding the implant or contained within the fibrous capsule.



Although ALCL has been found in the breasts of some women with breast implants, it is important to be clear that it is not cancer of the breast tissue. ALCL may appear in several parts of the body including the lymph nodes, skin, bones, soft tissue, lungs or liver.

Diagnosing implant associated ALCL

ALCL is often difficult to diagnose as the symptoms are non-specific and can vary from person to person. This can often lead to cases of late diagnosis.

The more common symptoms include a spontaneous fluid collection in the breast, developing many months or years after receiving a breast implant, and redness and swelling of the breast around an implant that is not from an infection.

Other less common symptoms are tenderness and contraction of the scar tissue capsule surrounding the breast implant. If left untreated, patients can develop a firm distinct mass in their breast.

Surgeons are being encouraged to ensure that patients are aware of the most common signs and symptoms. The US Food and Drug Administration (FDA) advises patients that there is no need to change their routine medical care and follow-up. Currently, there is no recommendation to remove the implants in patients who are not showing any signs or symptoms.

The FDA does advise patients to follow standard medical recommendations including:

- Monitor your breast implants.
- If you notice any changes, contact your health care provider promptly.
- Be aware that symptoms of ALCL, such as pain, lumps, swelling or differences between breasts can occur as late as eight to nine years after surgery.
- Get routine mammography screening.
- If you have silicone gel-filled breast implants, get periodic magnetic resonance imaging (MRI) to detect ruptures.

FDA guidance for plastic/cosmetic surgeons

The FDA has also issued guidance to health care providers, specifically plastic/cosmetic surgeons, on what to do if a patient presents to them with pain, lumps, swelling or asymmetry of the breasts, particularly if these occur a long time after insertion of the implants.

The recommendations are as follows:

- Consider the possibility of ALCL when you have a patient with late onset, persistent peri-implant seroma. In some cases, patients present with capsular contracture or masses adjacent to the breast implant.

- If you have a patient with suspected ALCL, refer her to an appropriate specialist for evaluation.

- When testing for ALCL, collect fresh seroma fluid and representative portions of the capsule and send for pathology tests to rule out ALCL.

- Diagnostic evaluation should include cytological evaluation of seroma fluid.

- Report all confirmed cases of ALCL in women with breast implants to the FDA.

- The FDA also recommends reporting cases to the PROFILE Registry where more comprehensive case data can be provided.

- Develop an individualised treatment plan in coordination with the patient's multi-disciplinary care team.

Additional tests may be conducted to give doctors more information about the disease and whether or not it has spread (and if so, how far) in the body. The assessments can include blood tests, a computed axial tomography (CAT) scan, a positron emission tomography (PET) scan, a magnetic resonance imaging (MRI) scan, and a bone marrow biopsy.

Treatment of implant associated ALCL and prognosis

A study published in the J Clin Oncol. 2014 Jan concluded that, for patients where the ALCL is confined by the fibrous capsule, treatment may be limited to implant removal and capsulectomy - removal of the surrounding scar tissue.

If ALCL is diagnosed late or in a more aggressive form or recurs after a capsulectomy, additional treatment is likely to be required. In these cases, a distinct mass often develops. When this occurs, treatment with chemotherapy and or radiotherapy is usually required.

The study referred to above found that 39 of 42 patients (93%) with ALCL confined by the fibrous capsule achieved complete remission, compared with complete remission in 13 of 18 patients (72%) who had a distinct mass.

This evidence suggests that ALCL is more likely to be fatal for women who have developed a solid mass than for those where the cancer cells were limited to the surrounding fluid (ALCL effusions). In the above study, patients with effusion-type ALCL were still alive five years after their diagnosis compared to only 75% of the patients with solid masses. The recurrence rate was higher when a solid mass was present. The implication from this data is that the earlier the diagnosis, the better the outcome.

The link between ALCL and breast implants

In January 2011, the US Food and Drug Administration (FDA) issued a warning about a possible link between breast implants and ALCL.

This link came to light when a study found that 34 women diagnosed with ALCL in a breast had implants. FDA scientists looked at results from other studies, consulted implant experts and manufacturers and contacted international health agencies. The scientists found six more US women and about 24 international women who were diagnosed with breast ALCL in a breast with an implant.

According to the National Cancer Institute, approximately one in 500,000 women is diagnosed with ALCL in the United States each year. ALCL in the breast is even more rare – only around three in 100 million women per year in the US are diagnosed with ALCL in the breast.

Although ALCL is extremely rare, the FDA has concluded that women with breast implants may have a very small but increased risk of developing this cancer. Currently this cannot be confirmed with statistical certainty nor is it possible to identify whether a type of implant (i.e. silicone versus saline) has a smaller or greater risk.

The FDA has been gathering data to learn more about the actual incidence of ALCL in women with breast implants, the characteristics of breast implants that might increase the risk of ALCL, and the pathological characteristics and clinical features of ALCL in women with breast implants.

Based on information gathered by the FDA between August 2010 and September 2015, their current estimate is that there have been 100-250 known cases of ALCL in women with breast implants worldwide. All the information to date still suggests that women with breast implants may have a very low but increased risk of developing ALCL. They continue to reconcile the data between the various sources and will provide updated findings as new information and analyses become available.

Ensuring that patients understand the risk

Women considering any type of breast implant surgery should understand their risk of ALCL according to a special topic paper in the April issue of *Plastic and Reconstructive Surgery*, the official medical journal of the American Society of Plastic Surgeons (ASPS).

Dr Mark Clemens of the University of Texas M.D. Anderson Cancer Centre said: *"Breast implant associated ALCL should be included during preoperative counselling on the risks of breast implantation when obtaining informed consent".*

While the true rate of breast implant associated ALCL is unknown, the risk of developing the cancer is at least 18 times higher than in women without implants. Informal surveys suggest that up to three quarters of surgeons do not discuss ALCL when obtaining informed consent for breast implant procedures. This is likely to be in part due to the difficulty in determining an accurate assessment of the risk.

The law on informed consent has changed following a recent Supreme Court judgment. Doctors must now ensure that patients are aware of any "material risks" involved in a proposed treatment, and of reasonable alternatives, following the judgment in the case *Montgomery v Lanarkshire Health Board*.

The Supreme Court's ruling defined the new test: *"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."*

The review conducted by Dr Clemens and his team concluded that the legal threshold for inclusion of a specific risk in informed consent is vague. Although the decision to make inclusion of breast implant associated ALCL in the informed consent process is not mandatory, it is strongly encouraged and patients should be made aware of the existence of the risk, the common presenting symptoms and what to do should these occur.

Elise Bevan, a solicitor in the clinical negligence team at Penningtons Manches LLP, said: "While there are still significant knowledge gaps in the association between ALCL and breast implants, we believe that patients should be made aware of the existence of this rare cancer and be able to use the available information to make an informed decision when considering breast implants.

"Implant manufacturers and surgeons have been quick to dismiss the FDA's findings. Allergan, a manufacturer of both silicone and saline breast implants, said "a woman is more likely to be struck by lightning than to get this condition". Although the chance of developing implant related ALCL is very low, there is still an increased risk and we believe that advising patients of this risk should form part of the informed consent process.

"More importantly, the topic of implant associated ALCL should be discussed with the patient to ensure that they are aware of the signs and symptoms. It is clear from the evidence that early diagnosis and treatment leads to a better prognosis. Surgeons should be encouraged to make patients aware of the existence of this rare cancer and the most important things to look out for. Surgeons may feel more inclined to do this if they are educated and trained on the signs and symptoms.

"If you have a breast implant, be reassured by the FDA's advice for women and their doctors about implants but do not hesitate to call your doctor if you are concerned. Definitely call your doctor if you have symptoms or problems with your implant such as pain, lumps, swelling or asymmetry."

Case note

Penningtons Manches is currently acting for a young woman who was diagnosed with implant associated ALCL four years after first presenting with swelling. After multiple procedures to drain the fluid causing the recurring swelling, the surgeon decided to refer her for further investigation and at this point a diagnosis of ALCL was made.

In this case better training for the surgeon and the patient being alert to the signs and symptoms, may have prevented the late diagnosis.

ELISE BEVAN
SENIOR ASSOCIATE
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Late acceptance of Part 36: An insight into the litigation of *ABC v Barts Health NHS Trust [2016] EWHC 500 (QB)*

The costs judgement handed down in *ABC v Barts Health NHS Trust* has been widely reported across the legal industry. This article serves to set out the facts of the case; the issues in the litigation; the key points arising from the costs judgement; and also to provide an insight into the journey from rejecting the defendant's Part 36 offer of £50,000, to accepting it eight months later, some twelve days before trial.

Facts of the Case

The facts were highly complex and arose out of a negligent 20 day delay in diagnosing and managing an aortic dissection in the 34 year old claimant with a history of hypertension and end stage renal failure.

The claimant presented to the Accident and Emergency department at Whipps Cross Hospital on 30 January 2003, complaining of the sudden onset of crushing central chest pain radiating to his neck. Examination identified classic signs of aortic dissection. Whilst records noted a need to rule this out, the claimant was treated for fluid overload attributable to poor dialysis and discharged.

The claimant was re-admitted to hospital on 19 February 2003 following a low-speed road accident. Imaging demonstrated extensive dissection of the aorta extending as far as the leg arteries. Emergency surgery was carried out, including a fasciotomy and femoro-femoral cross-over bypass graft.

The claimant thereafter attended follow-up appointments which noted the following:

(a) He was variously reported to have moderate aortic regurgitation albeit with good left ventricular function

(b) He was shown to have a persistent patent false lumen at the origin of the dissection around the aortic arch down the descending aorta and to the bifurcation of both common iliac arteries extending further in the right leg into the external iliac whilst the external iliac on the left side. The blood vessels leading from the aortic arch to the brain, including the carotid arteries were implicated in the false lumen / dissection process. By February 2006, serial imaging had shown that the false lumen was enlarging – an increase from 4cm to 4.6cm.

(c) The claimant had had a transient ischaemic attack (TIA) which was thought at the time to be potentially associated with the residual false lumen.

(d) The left iliac grafts became over 60% occluded and in July 2004, the claimant was advised that that he was no longer a suitable renal transplant candidate - there would have been inadequate blood supply to the transplanted kidney if placed to the left, and placing it to the right would have proved too much of a challenge, as the right iliac system would have had to supply blood not only to the kidney, but also both legs.

On 5 April 2006 the claimant suffered a significant Cerebral Vascular Accident (CVA), an extensive left-sided middle cerebral artery infarction causing right sided hemiplegia and global aphasia. This has resulted in a very severe injury to his brain which has resulted in severe cognitive difficulties, and mobility problems, requiring around the clock care.

As a consequence of his numerous co-morbidities, the severe aortic regurgitation was inoperable. He was in end stage renal failure secondary to hypertension and was on long term peritoneal dialysis. He has suffered with Encapsulating Peritoneal Sclerosis and is PEG fed. His life expectancy is limited to just one to two years.

The issues in the case

The claimant, ABC who was a protected party, brought his claim by his wife and litigation friend DEF.

It was alleged that on initial presentation in January 2003, the claimant presented with risk factors and signs and symptoms entirely consistent with an aortic dissection; that it was inappropriate to treat the claimant with Clexane & Aspirin (contraindicated in patients with an aortic dissection); that appropriate investigations should have been ordered; and that the aortic dissection should have been diagnosed. Thus, there was a delay of some 20 days in making the diagnosis. Breach of duty was admitted by the Defendant in its Letter of Response (served nearly a year after the Letter of Claim) and subsequently in its Defence.

As to causation, it was the claimant's case that:

- the aortic dissection on 30-31 January 2003 would have been more limited than the dissection demonstrated on the CT scan on the 19 February 2003. Specifically, the dissection would not have extended beyond the left subclavian artery and into the iliac arteries.
- the dissection would have been treated surgically with an operation to replace the ascending aorta and to repair (re-suspend) the aortic valve (as occurred).
- he would not, however, have required the fasciotomy and femoro-femoral cross over bypass graft.
- on the balance of probabilities, the claimant would have survived this operation and made a complete recovery.
- whilst the claimant would likely have suffered some aortic incompetence, this would have been amenable to surgery.
- he would not have suffered a residual false lumen.
- neither the TIA nor the stroke would have occurred.
- he would have remained suitable for renal transplant and would not have developed Encapsulating Peritoneal Sclerosis (EPS).

Initially, notwithstanding the admission of breach of duty, the Defendant denied causation of any injury, loss and damage in its entirety. However some way through the litigation and over two years after the Letter of Claim was served, the Defendant amended its defence to admit that the admitted breach of duty caused the claimant to suffer some injury necessitating a fasciotomy and a femoro-femoral crossover bypass graft repair (which had been carried out on 20th February 2003 at the same time as the repair to the dissection in the aorta). The Defendant denied that its negligence resulted in the claimant being unable to undergo renal transplantation or his suffering the extensive

left-sided middle cerebral artery infarction, averring that this was caused by intrinsic atherosclerotic disease.

There were, therefore, a number of distinct issues in the litigation:

- Breach of duty and delay in surgery (which was admitted in February 2014).
- The extent of the surgery in 2003 where in its amended defence (in April 2015), the defendant admitted that the fasciotomy and femoro-femoral crossover bypass graft would have been avoided but for the delay in surgery.
- Causation and consequences of the stroke in 2006 and the claimant's inability to undergo renal transplantation. This issue gave rise to the overwhelming majority of the quantum claimed in respect of which all the quantum expert evidence and therefore costs were incurred.

The trial was due to commence on 7 March 2016. However, on 24 February 2016 the claimant accepted the defendant's Part 36 offer of £50,000 (inclusive of an interim payment of £25,000) which offer had in fact expired on 25 June 2015 (it having been made on 4 June 2015). The terms of the offer were "*to pay compensation as set out in this letter in settlement of the whole of this claim*." In addition, to "*pay the Claimant's reasonable costs up until 25.06.15 or the date of acceptance of the Defendant's offer, whichever is the earlier, such costs to be agreed or assessed on the standard basis in accordance with CPR Part 36.13*." In other words, the offer had been expressed to be a settlement of the whole of the claimant's claim.

The claimant being a protected party, the court's approval for the terms of settlement was necessary. The Parties were unable to agree the costs order and it, therefore, fell to the court to approve the terms of settlement and decide the appropriate costs order. The hearing took place on 7 March 2016.

Submissions on Costs

The claimant contended that there was no good reason to depart from '*the usual order*' provided for in CPR Part 36.13(5), namely the claimant is awarded its costs up until 25 June 2015 with the claimant paying the defendant's costs between 25 June 2015 and 25 February 2016.

The defendant's core submissions were that having regard to all the circumstances of the case, such an order would be unjust because it fails to reflect that the claimant had failed in relation to the vast majority of his pleaded claim. The defendant contended for an order that the claimant's costs up to 25 June 2015 be limited to the issue of the femoro-femoral bypass graft (thus excluding all other causation, condition and prognosis and quantum costs) and that the claimant should pay the defendant's costs relating to the causation of the stroke and the losses consequent thereon up until and including 25 June 2015 and all the Defendant's costs of the action thereafter. The defendant argued that to allow a Claimant to reject a 'generous' Part 36 offer (which was pitched to facilitate early settlement); to effectively 'bank' the costs, pursue the case up to trial and then accept shortly before trial would be entirely unjust. In the alternative, the defendant submitted that a proportionate costs order should be made.

The Judgement

At the hearing, HH Judge McKenna largely accepted the thrust of the claimant's submissions and found that "*there was nothing unjust about making the usual order in the circumstances of this case*". HH Judge McKenna found that:

1. The material provisions of the defendant's offer of 4 June 2015 were expressed to be in settlement of the whole of the claim.

2. Part 36 is a separate, self-contained code and must be applied as such as Lord Justice Ward put it in *Shovelar v Lane* [2012] 1 WLR 637.

3. Moreover, the court's discretion to depart from the usual order is constrained by the precondition that its full enforcement would be unjust.

4. It follows that the discretion is more circumscribed than the broad discretion under CPR 44.2. Additionally, the specific considerations identified in CPR 36.17(5) have a common feature in that they focus analysis on the circumstances of the making of the offer, the provision or otherwise of the relevant information in relation to it rather than more general issues as to conduct although the requirement to take into account all the circumstances does enable the court to take a broader view and to consider the various matters relied upon by the defendant.

5. The defendant had the means and opportunity to protect itself in relation to the costs that it was going to have to incur in respect of the causation issue but chose for whatever reason when making its Part 36 offer to frame the offer as a settlement of the whole claim and then subsequently when that offer was not accepted did not make any revised offer excluding causation.

6. Whilst it may be said that in rejecting the offer and pursuing the action up to or close to trial the claimant acted unreasonably, Part 36 expressly provides an effective remedy to cater for that very situation in that the claimant will have to pay all the defendant's costs incurred post expiry of the Part 36 offer. In the circumstances of this case, the assessment of those costs was on the indemnity basis.

Comment

Whilst there are a number of cases which deal with costs consequences following late acceptance of a Part 36 offer, there were a number of interesting individual features in this case:

- The specific issues had not been decided at a trial. How, therefore, could the Court consider whether the claimant had 'won' or 'lost' a particular issue?

- The claimant was a protected party and the costs issue was heard at the approval hearing. It was, therefore, not possible for the Claimant to provide oral representations or replies to the defendant's attack on the reasonableness (or rather unreasonableness) of the claimant's conduct in, shortly before trial, accepting an offer made some eight months earlier. Had the court not approved the settlement and the case proceeded to trial, the weaknesses in the claimant's case would have been laid bare for all to see.

Claimant's conduct: reasonable or unreasonable?

HH Judge McKenna found that the claimant had acted unreasonably in rejecting the offer and pursuing the action up to or close to trial. Could the finding have been different had the claimant been able to make oral representations in open court?

There were many reasons why it was felt reasonable to reject the offer in June 2015, but necessary to accept the same offer in February 2016, some twelve days before trial. As is always the case in litigation, evidence changes and new evidence emerges as a case progresses.

<u>Rejection</u>

The offer was rejected in June 2015 as it was felt that, on the available evidence, the chances of proving the stroke case were greater than 50% and thus, the claimant was likely to achieve a settlement at trial in excess of £50,000. As a protected party, any settlement would have had to be ap-

proved in court and it was considered that such a settlement could not be recommended in light of his severe disabilities and extensive care requirements.

Was it reasonable to form this view at the time? What evidence was available?

Exchange of expert liability evidence had taken place and the Cardiothoracic Surgeons had met.

The claimant had served the Schedule and supporting documentation, including expert condition, prognosis and quantum evidence.

The claimant's case on causation of the stroke was that: the stroke was caused by a clot; the clot was caused by turbulent and/or slow blood flow within the aorta in the vicinity of the left common carotid artery; the altered blood flow, itself being caused by the presence of the false lumen. It therefore followed that in order for the claimant to succeed in causation, he had to establish, on the balance of probabilities, that the persistent patent false lumen would not have occurred, thus avoiding the stroke.

The defendant's cardiothoracic expert considered that even with timely diagnosis and surgery, the claimant would have had a residual patent false lumen, citing various literature which suggested that most patients who undergo surgical repair for an AD suffer a persistent patent false lumen. The claimant's cardiothoracic expert acknowledged this, but considered that:

- much of the literature was outdated
- it was clear from the imaging that the AD extended during the admitted negligent delay
- the most relevant study, which reported that 69% of patients with a repaired aortic dissection do have a persistent false lumen, had to be treated with caution because the claimant had more favourable prognostic factors which were considered to reduce the probability of him having a persistent false lumen. In particular, he did not require long term anticoagulation (this increased the risk of a residual false lumen fourfold) and had valve sparing surgery. Further, some of the surgical techniques included within the study data were significantly outdated and are were known to significantly increase the risk of an adverse outcome.
- the more favourable prognostic factors, combined with the possible additional damage caused to the aorta and the lining thereof during the 20 day delay, were sufficient to suggest that with timely diagnosis and repair, on the balance of probabilities, the claimant would not have had a persistent patent false lumen.

It is, therefore, fair to say that causation of the stroke was always very tricky. It was clear that the dissection had extended, but the aortic arch (where even on the claimant's case, the clot likely arose) was always implicated in the original dissection. It was not possible to say whether the diameter of the original dissection would have extended during the delay and/or whether the lining of the aorta involved in the original dissection would have sustained additional damage. Both parties agreed that the claimant received the same surgery to repair the dissection as he would have received with timely diagnosis and repair. Perhaps the alarm bells should have been ringing and claimant should have taken the view that the defendant's evidence was likely to have been preferred at that time? However, the claimant's cardiothoracic expert (a well respected medico-legal expert) remained supportive of the case and the focus was on achieving the best possible outcome for a catastrophically injured patient.

<u>Re-assessing the offer</u>

As the litigation proceeded, the Defendant's offer was regularly re-assessed and considered to be insufficient. The defendant's own conduct suggested that they too considered there to be vulnerabilities in their case.

The defendant maintained the pleaded Defence that the most likely cause of the stroke was intrinsic atherosclerotic disease, a defence which was disavowed by the defendant's own stroke physi-

cian in the experts' meeting in July 2015. This re-inforced the claimant's decision to reject the offer which had been just a fraction of the overall value of the case.

Additionally, on 4 September 2015 the defendant served fresh liability expert evidence, including, inter alia, comment from a Cardiologist, this referencing an undisclosed liability report commissioned over 2 years previously and raising additional and alternative mechanisms for causation of the stroke (which the defendant had chosen not to plead in their Defence, instead preferring atherosclerosis). The Court had not given permission to rely on expert liability evidence from a Cardiologist. Thereafter, they delayed some two months in disclosing the report itself and a further month making an application for permission to rely on this.

A hearing date was set with fewer than four weeks until trial. The Master refused the defendant's application, noting the issue had been raised very late in the day and it was unreasonable to open a new speciality in relation to new causation issues when there were qualified experts who could already deal with the issue. It was however ordered that the cardiothoracic surgeons, already instructed, hold a further joint meeting to discuss outstanding causation issues. The resulting joint statement was submitted on 22 February 2016, just fourteen days before trial was due to commence.

Acceptance: what changed?

Whilst the Defence had pleaded no real plausible positive case on the likely mechanism of the stroke, the burden of proof was on the claimant.

With the trial around the corner, there had been a last minute additional expert meeting and the defendant had introduced a number of additional possible non-negligent alternative mechanisms of stroke into the equation including:

- the claimant had End Stage Renal Disease; was on dialysis and was at risk of systemic embolization from hypertensive heart disease which causes enlargement of the left atrium which per se is a risk for cerebral embolization.
- in any event, the 'turbulent' blood flow was not related to a residual false lumen but the unavoidable aortic incompetence

Inevitably, this increased the litigation risks. Further, and additionally, notwithstanding approaches to the author of the study relied on by the claimant's Cardiothoracic expert, detailed data relating to the sub-groups was not available to support the expert's logical argument as to why the claimant would not, with timely diagnosis have suffered the persistent, residual patent false lumen.

The claim was funded by CFA with ATE Insurance and whilst the claimant's case was arguable, even if the claimant were to win on the renal transplant point, losing on the causation of the stroke would have placed the claimant at risk of failing to recover more than the £50,000 offered. Thus, the ATE Insurer would not indemnify the claimant to proceed to trial. In such circumstances, the claimant had little choice but to accept the offer.

Other points of note

One other observation is that throughout the claim, the defendant persistently refused to engage in ADR.

As should always be the aim in litigation, both parties were directed by the court "*to consider settling this litigation by any means of Alternative Dispute Resolution.*" Whilst early resolution may not be achieved, such an approach to litigation can serve to narrow the outstanding issues between the parties and duly reduce costs and disbursements incurred thereafter.

On 4 November 2015 the claimant proposed a round table meeting (RTM). The defendant declined to engage.

On 2 February 2016 the claimant again proposed a RTM noting that even if a settlement were not to be achieved, it would still serve to narrow or agree some issues. For example the possibility of narrowing quantum issues subject to liability at trial, with the effect that many, if not all, of the quantum experts could be released from trial. A significant saving of costs to both parties. Again, this was rejected, the defendant concluding that the RTM would not serve any purpose as there was no intention to make an increased offer.

HH Judge McKenna made no comment on this failure in the judgement.

Conclusion

Whether the claimant's conduct was or was not unreasonable is, perhaps a moot point, given HH Judge McKenna's finding that even if a claimant acts unreasonably by rejecting the offer and pursuing the action up to or close to trial, Part 36 expressly provides an effective remedy to cater for that very situation in that the claimant will have to pay all the defendant's costs incurred post expiry of the Part 36 offer.

This costs order is a promising decision for claimant firms following litigation in complex clinical negligence cases.

With the introduction of fixed fees in clinical negligence seemingly on the horizon, this judgement surely bolsters the view that it is not always reasonable to measure costs against any final settlement figure, particularly where investigation of complex medical issues is required to fairly investigate the claimant's case. Said comparison will only encourage early resolution against the best interests of the claimant.

This judgement, together with the option of ADR, demonstrate that appropriate conduct and efficient use of Part 36 may be an effective means of reducing costs. Fixed fees are not, and should not, become the manner in which litigation costs are reduced.

Joe Rose, Costs Lawyer at PiC comments:

"*This is a refreshing judgment as it reinforces the fundamental principle that hindsight will not be a consideration when determining the issue of costs.*

This case, like with so many other clinical negligence claims, had extremely difficult causation issues and is indicative of the technical difficulties frequently encountered in clinical negligence cases.

This decision may result in Defendants putting forward Part 36 offers in a specific way so as to protect their position, so Claimant firms should be aware of this."

JANINE COLLIER, EXECUTIVE PARTNER
CLINICAL NEGLIGENCE AND PERSONAL INJURY
& KATHERYN RIGGS, PARALEGAL OF TEES LAW

When psychiatric care goes wrong – the benefits of representation at a Coroner's inquest

C was a young man with a stable job in an electronics factory, a wife who worked at the same factory, and parents and a brother living nearby who he was close to, saw regularly, and supported in whatever practical ways he could. In 2010, he had an episode of poor mental health, including paranoia, which he saw his GP about, but this seems to have passed away almost as unexpectedly as it came on and he did not receive any treatment for it. He remained well, physically and mentally, until the summer of 2013. Again he saw his GP, who was concerned and sought treatment for him from his local community mental health team. By the autumn his family, concerned by the risk of suicide, persuaded him that he needed to be admitted to a specialist mental health centre.

Unbeknownst to them, the centre had been the subject of a highly critical recent report by the CQC, had been taken over by another NHS Trust in an attempt to improve the standard of care, and remained in a state of crisis. In autumn 2013, not long after two previous incidents of self-harm at the centre, C was left alone in a shower room, probably for over an hour, and hanged himself from a tissue dispenser which had been bolted securely to the wall in the usual way by maintenance workers, contrary to the centre's policy of using anti-suicide dispensers. C's parents instructed AvMA to represent them at the Coroner's inquest into C's death, with the hope that the failings in his care would be highlighted and lessons learned from them.

The Coroner found that Article 2 was engaged, and said in his short conclusion that:
C was admitted to the X Centre… as a voluntary patient suffering from severe depression and paranoia. He was subject to standard observations and was noted and seen 10.00am on [day D] when he was allowed to use the shower room. He killed himself whilst suffering from a psychiatric illness. The assessment carried out when C was admitted on [day D-3] was inadequate. There was also a failure in assessing the level of observations necessary and a failure to carry out the observation appropriately.

While the conclusion was limited to a few lines which specifically related to those matters considered directly causative of the death, in line with current guidance for Coroners, the scope of questioning during the inquest was not so limited. We were able to explore the quality of mental health care provided by the Trust in the community and in the centre, and to ask questions about what improvements had been made since the death. The failures in the care of this young man provide lessons to learn for the care of mental health patients across the country.

Care in the community, prior to admission

C had become mentally unwell in summer 2013, telling his wife that he was hearing things. He continued to work until September, then took time off as he was too unwell. A few days later, he saw his GP, complaining of paranoia. The GP referred him to the Trust's community treatment team, but that team made no appointment for him. A few days later, C's wife called the GP's out of hours service, passing the phone to C. The GP on the telephone called the community treatment team and said he needed to be seen urgently, but was told that no appointments were available and the deceased

should go to A&E if he needed to be seen urgently. He attended A&E, where he was kept waiting for several hours in a noisy environment before being prescribed Diazepam and sent home. The A&E liaison team contacted the community treatment team themselves and were told that an appointment was being facilitated for early the next week.

C's mental state continued to deteriorate, but no appointment was made. Family members called the community treatment team on several occasions, and the deceased called them himself, in a distressed state, saying that he had memories which related to hurting people. He and his father were told that he could only be seen if he came to A&E again. Just over two weeks after his initial GP's appointment, C had still not been seen by the community treatment team. A few days later again, he was observed by his father threatening to cut his wrists with a piece of plastic. His father called an ambulance, and when the paramedic arrived he called the community treatment team, who said they had an appointment for that evening. When the paramedic asked for that appointment to be brought forward, he was told that if C could not keep himself safe, he should be brought to A&E. He was taken there by ambulance, where he was assessed on arrival as "*having thoughts of wanting to hurt people and to harm himself, he believes that things he sees on the TV and hears on the radio are influencing these thoughts… He is at risk of harming himself and potentially if untreated of acting on his thoughts and harming others*". He was admitted to hospital, as an informal patient (mental health patients who come to hospital voluntarily are ordinarily admitted informally, rather than under a section), within minutes of being brought to A&E, just over two weeks after first seeing his GP.

First admission

C was assessed on admission as having "*thoughts of harming himself and also… thoughts of ending his life. For this reason he has been placed on intermittent observations*". The ward, like many mental health facilities, had three basic levels of observation – standard, meaning patients should be seen by a nurse once an hour; intermittent, meaning they should be seen every 15 minutes; and one-to-one, which essentially meant a nurse sitting in front of them watching them continuously. The observation levels were supposed to be adjusted according to the patient's level of risk.

The day following admission, C was recorded as having cut his wrist with a squashed coke can (which should not have been allowed on the ward in the first place) and he was taken to A&E. On his return to the ward about five hours later, his wounds having been stitched, the matron apologised to his family for the coke can having been found on the ward, but said that "*we also have to rely on service users also coming to staff with concerns if they feel like self harming*". His risk level was not reassessed despite his having just self-harmed, and he was left on intermittent observations. A few hours later, he was found to have broken a toothbrush and used it to unpick his stitches, so he was returned to A&E for further treatment. On return to the ward, his risk level was raised and he was placed on 1-to-1 observations for the next three days. At the inquest it was conceded by the consultant, who was not on duty during the night, that if he had been on the ward when the first incident of self-harm occurred, he would have adjusted C's risk level immediately and thereby probably avoided the second incident.

Around two weeks later, C was thought to have stabilised on clonazepam (a tranquilliser, which would have tended to keep him inactive but would not have treated his underlying mental condition) and was discharged from the ward to the care of the community treatment team. He went to live at his parents' house, where his father was able to keep him under continuous observation.

Second period of care in the community

C's mental state fluctuated while he was at home. Ten days after he came home, his father called the community care team, saying that he was concerned that the deceased would self harm, but was told that he could only be reviewed if he attended A&E, where there would be a long wait. He

did not attend, and the next day he was rushed to A&E having overdosed on his clonazepam. A couple of days later, he was visited at home by a community care team nurse. He told her that he was "*getting some messages from the television and people in the form of gestures to harm himself by cutting*", but denied any current intention to act on these, to harm others, or to end his life. The next day, he was reviewed by a doctor, who diagnosed him (probably correctly) as suffering from a severe depressive episode with psychotic features and prescribed sertraline (an antidepressant) and quetiapine (an antipsychotic). These would have begun to treat his mental illness, but it is necessary to observe and review patients whose medication has just been changed in this way as their mood may fluctuate.

One day later, C was watching a film on television with his father. There was a man with a black eye in the film. Around 16:40, C's wife arrived from work and he immediately punched her in the face. His father contacted the community care team, who updated his risk summary to say "[*C] is at risk of harming others in response to gestures from the television, also at risk to himself*". His father brought him back to the hospital, where he was again admitted as an informal patient.

Second admission and death

In spite of this reassessment of C's risk level by the community care team, the recent change in his medication following the diagnosis of a depressive episode with psychotic features, his previous instances of self-harm, and the recent escalation of his behaviour to harm his wife following what he described as a signal from the television, C was placed on standard observations on readmission. It is not clear how that risk assessment was made, but it is clear that it was not done by the Duty Doctor, who was too busy and left him to be assessed the next morning, and that it was made in spite of concerns raised by some of the nurses who were familiar with C from his previous admission. The next morning, he was assessed by the Duty Doctor, who assessed his risk of self-harm and harm to others as moderate and put him on standard observations. Again, it is not clear how the doctor reached the conclusion that his risk level was lower than it had been on his previous admission.

Thereafter, C mostly remained in his room for the next two days, not interacting with staff and not eating. One morning, he asked to have a shower room unlocked for him. This was done, and he was left unobserved in the shower room for well over an hour, contrary even to the low level of observations prescribed, giving him the opportunity to make a ligature from his towel and hang himself.

Concerns about the safety of the ward

Prior to C's death, a CQC inspection had identified 85 points on the ward as ligature risks. Following the death, they inspected the ward again, and found that there was "*a lack of effective systems in place to ensure that staff identified and responded appropriately to a patient's deteriorating condition", "in patient observation charts… observations were not being completed contemporaneously… so we could not be assured that the details recorded were accurate*" and that on risks arising from the physical environment, "*[a need for] action was identified in March 2013 and when we raised this with staff to determine when work would be completed we were told that these remained outstanding due to the current feasibility study… toilet doors… were unlocked. The taps and spouts inside were ligature risks. When raised with staff they said the corridor was always observed by staff however we observed this was not always the case… [in relation to dangerous items] for example on the day of the inspection glass jars were found in the female kitchenette. There were no systems or processes in place to identify when this occurred and for the items to then be removed. Therefore the risk had not been mitigated by the actions put in place*".

On being referred to this CQC report, the Coroner had some concerns that patients at the hospital may remain at risk and that not enough was being done actively to treat mental health patients in

the Trust area, as opposed to simply observing them. He allowed questioning of the Trust's witnesses in relation to steps which had been taken since the CQC report, and adjourned his conclusion until after the Trust's Internal Investigation Report and the individual interviews with medical staff conducted in the preparation of that report were provided to him. By the point at which the inquest formally concluded, just over two years after the death, it had become adequately clear that no Report to Prevent Future Deaths was required, as improvements had been made.

The role of legal representation

Access to legal representation for families at inquests of this sort is increasingly difficult to fund. The family, in this case, were clear that they could not have afforded legal representation of any kind and would therefore have been unrepresented if AvMA's pro bono inquest service had not been available to them. This was a complex inquest which was initially listed for two days, and was ultimately adjourned for further evidence and submissions on conclusion at a later stage. Seven medical witnesses gave live evidence, referring to medical notes running to hundreds of pages. The Trust had not provided its Internal Investigation Report to the Coroner at the time of the hearing, and the Coroner appeared to be unaware of the two critical CQC reports until these were provided to him by the family's representatives. He was not minded to view the inquest as engaging Article 2 until he was persuaded to do so by the family's representatives, relying on *Rabone v Pennine Care NHS Trust* [2012] UKSC 2. It would simply not have been feasible for the family to represent themselves.

Instead, the availability of professional legal representation through AvMA, combined with a Senior Coroner who was genuinely committed to understanding the particular needs of mental health patients and to investigating the adequacy of provision for them in his community, succeeded in achieving a thorough investigation into C's death which appears already to have had a positive impact on the care for mental health patients now provided by the Trust. Following the inquest, C's parents were introduced by AvMA to David Kerry, of Attwaters Jameson Hill, on the basis that they might have a claim for damages under the Human Rights Act 1998, this being an Article 2 case. Once David Kerry became involved, he was able to advise them, and C's widow, that they may also have substantial claims under the Fatal Accidents Act 1976 and the Law Reform (Miscellaneous Provisions) Act 1934. Prior to the inquest, C's widow in particular had been unaware of any such potential claims, and would have been unlikely to become aware of them had it not been for AvMA's involvement in the case. Attwaters Jameson Hill are now pursuing a civil action for damages against the Trust on behalf of C's family.

ROSS BEATON
LAMB CHAMBERS

AVMA FUND RAISING EVENTS

Wine Tour & Tasting in Sussex
30th June 2.30pm

An alternative to the Thursday Golf Day

A chance for non-golfers to kick off their AvMA conference 2016 with a bit of Fizz!

A two hour tour and tasting
The Bolney Wine Estate in Sussex has agreed to AvMA holding a charity wine tour and tasting. They will share with our delegates their enthusiasm and knowledge that produces great English wine.

First a tour of the vineyards followed by a tour of the winery guide on how the wine is produced. Guests can walk amongst the vines, experience our state of the art winery and sample the finished product in a tutored tasting!

All important tasting!
Guests will sample three different wines and be given instruction on wine tasting.

Contact Phil Walker at AvMA for more details
020 8688 9555 philipwalker@avma.org.uk

Travel and getting there:
Delegates can stop off on their way to Brighton.

Bolney is 10 minutes cab ride from Haywards Heath mainline station.
This is on the main London to Brighton line and fast trains from Haywards only take 20 minutes to Brighton.

If driving the Bolney Estate is close to the main London Brighton route A23.

AVMA FUND RAISING EVENTS

Fourth AvMA Legal Choir Challenge 2016

Share in the Fun and enjoy an evening of great music

NOVEMBER 15TH 2016 6.30pm

St Clement Danes Church - The Strand – London

Joint winners in 2015 The Shoosmiths Singers

Choirs from legal and medical backgrounds will be performing in a friendly & fun challenge to see who can generate the loudest and most sustained applause from the audience.

The challenge - Each choir performs, you show your support then the judges decide it is that simple!

FREE French WINE included!

Tickets £15 Group tickets 10 for £120

Contact Phil Walker at AvMA 020 3096 1121 or philipwalker@avma.org.uk

Visit the AvMA website: www.avma.org.uk

CONFERENCE NEWS

FORTHCOMING EVENTS FROM AvMA

For programme and registration details on all of our forthcoming events, plus sponsorship and exhibition opportunities, go to **www.avma.org.uk/events**, call the AvMA Events team on 0203 096 1140 or e-mail conferences@avma.org.uk.

If you have not already booked your place at the Golf Day, Wine Tasting or Annual Clinical Negligence Conference, you still have time to do so!

AvMA Annual Charity Golf Day

30 JUNE 2016, MANNINGS HEATH GOLF CLUB, WEST SUSSEX

The 2016 AvMA Charity Golf Day will take place on Thursday 30 June at Mannings Heath Golf Club, near Horsham. The Welcome Event for the Annual Clinical Negligence Conference will take place later that evening in Brighton (30 minutes' drive away) so the Golf Day offers the perfect start to the essential event for clinical negligence specialists.

We will be playing Stableford Rules in teams of four and you are invited to either enter your own team or we will be happy to form a team for you with other individuals. The cost is only £98 + VAT per golfer, which includes breakfast rolls on arrival, 18 holes of golf and a buffet and prize-giving at the end of the day. All profits go directly to AvMA's charitable work.

AVMA WINE TOUR & TASTING IN SUSSEX

30 JUNE 2016 (2.30PM), BOLNEY WINE ESTATE, SUSSEX

Kick off your 2016 AvMA Annual Conference with a bit of fizz! The Bolney Wine Estate in Sussex has agreed to AvMA holding a charity wine tour and tasting. They will share their enthusiasm and knowledge that produces great English wine as you enjoy a tour of the vineyards and experience the state of the art winery and sample the finished product in a tutored tasting. The fee is just £25, of which £10 is a donation to AvMA. Bolney is 10 minutes taxi ride from Haywards Heath mainline station, which is on the main London to Brighton line, and fast trains from Haywards Heath only take 20 minutes to Brighton. If driving, the Bolney Estate is close to the main London - Brighton route.

Annual Clinical Negligence Conference 2016

1-2 JULY 2016, HILTON BRIGHTON METROPOLE

As the Department of Health's consultation on fixed recoverable costs for clinical negligence claims is expected to be published at the end of June, just before the Annual Clinical Negligence Conference, we are going to run an additional 'Essential Costs Update' plenary session at 08.45 on the Saturday morning, 2nd July.

It is anticipated that this session will be the first opportunity to discuss the government's proposals and the likely implications for clinical negligence practitioners. In any event, there are some important costs updates which you should be aware of such as new budgeting rules, CFA assignments and recent case law including the decision in *Broadhurst v Tan* concerning the recovery of indemnity costs on a successful part 36 offer made within a fixed costs regime. The session will be led by Reuben Glynn, Managing Director of PIC, and Professor Dominic Regan, of City Law School & NLJ columnist.

CONFERENCE NEWS

#ACNC2016 also offers you:

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As well as providing you with a top quality, thought provoking, learning and networking experience, the success of the conference helps AvMA to maintain its position as an essential force in promoting justice. If you haven't yet booked your place, make sure you don't miss out! We look forward to welcoming you to Brighton.

The Future of Clinical Negligence – Commercial Realities
21 September 2016, America Square Conference Centre, London
In a particularly challenging and crucial time for clinical negligence specialists, this highly practical conference will examine the major issues, challenges and opportunities facing clinical negligence practitioners today. The programme will be available and booking will open in July.

Representing Families at Inquests
6 October 2016, Doubletree by Hilton Piccadilly, Manchester
The important work conducted by AvMA's Inquest service is the basis for this conference, which is designed to be a comprehensive guide to the practice and procedures when representing a family at an inquest. The day will take you through the preparation process, helping you to understand the complex issue of disclosure, management of expert evidence and Article 2. An update on case law, funding issues and post-inquest remedies will also be discussed. The event is aimed at intermediate to advanced level solicitors, junior barristers and healthcare professionals. The programme will be available and booking will open in July.

Medico-Legal Issues in Accident & Emergency Care
13 October 2016, College of Anaesthetists of Ireland, Dublin
This popular AvMA conference is coming to Dublin for the first time. Emergency care services are facing intense pressures to sustain a high-quality urgent and emergency care system. There is a vital need to continually monitor these services to ensure that high quality care remains consistent. With this in mind, this conference will examine the current standards, issues, roles and responsibilities, investigations and management of key areas in accident and emergency care. The programme will be available and booking will open in July.

AvMA Specialist Clinical Negligence Panel Meeting & Christmas Drinks Reception
2 December 2016, America Square Conference Centre, London
The annual meeting for AvMA Specialist Clinical Negligence Panel members provides the opportunity to meet, network and discuss the latest key developments and issues facing clinical negli-

CONFERENCE NEWS

gence law. This year's meeting will take place on the afternoon of **Friday 2nd December** - registration and a networking lunch will commence at 12.30, with the meeting starting at 13.30 and closing at 17.30. The programme will be available and booking will open in September.

AvMA's Christmas Drinks Reception, which is also open to non-panel members, will take place immediately after the meeting, also at **America Square Conference Centre**. The event provides an excellent opportunity to catch up with friends, contacts and colleagues for some festive cheer!

Medico-Legal Issues in Diabetes
8 December 2016, Doubletree by Hilton Hotel, Leeds
Many people with diabetes have multiple and complex health problems and, with this significant risk in mind, the potential delay or missed diagnosis of the patient can have serious consequences. This conference looks at the condition in detail, types of diabetes, risk factors and complications of treatment, co-morbidity, including gestational diabetes, cardiac complications, peripheral vascular disease and diabetic neuropathy and retinopathy. The impact of diabetes on causation arguments will also be discussed highlighting how the condition affects the way the clinical negligence practitioner looks at injuries. The programme will be available and booking will open in September.

Clinical Negligence: Law Practice & Procedure
2-3 February 2017, Jury's Inn Hotel, Birmingham
This is ***the*** course for those who are new to the specialist field of clinical negligence. The event is especially suitable for trainee and newly qualified solicitors, paralegals, legal executives and medico-legal advisors, and will provide the fundamental knowledge necessary to develop a career in clinical negligence. Expert speakers with a wealth of experience will cover all stages of the investigative and litigation process relating to clinical negligence claims from the claimants' perspective. Places are limited to ensure a focused working group. The programme will be available and booking will open in October.

Details of further events for Autumn and Winter 2016 and early 2017 available soon.

Tel **0203 096 1140** e-mail **conferences@avma.org.uk** web **www.avma.org.uk/events**

WEBINARS

AvMA Medico-Legal Webinars

Working on a client file and looking for more information to assist with your case? AvMA medico-legal webinars give you immediate access to medico-legal talks on subjects ranging from interpreting blood test results to medico-legal issues in surgery.

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To book you webinar go to www.avma.org.uk/learning

WEBINARS

New webinar titles available:

Medico-Legal Issues in Ambulance and Paramedic Care
James Petter - Head of Eductation and Professional Development, South Western Ambulance Service NHS Foundation Trust
The role of ambulance services has changed over the last few decades. This webinar will consider what is the role and scope of practice of paramedics and the range of discretion they have to make decisions. Case studies relating to paramedic and ambulance service negligence will also be discussed.

CPD points - 1 hour accredited by APIL and Bar

Medico-Legal Issues Arising from Facial Cosmetic Surgery
Mr Nicholas Parkhouse, Consultant Plastic & Reconstructive Surgeon, Queen Victoria Hospital, East Grinstead
This webinar will consider medico-legal issues arising from facial cosmetic surgery, consent issues and risk factors will also be discussed. Case studies will be used to identify negligent and non-negligent care.

CPD points - 1 hours accredited by APIL and Bar

Medico-Legal Issues in Acute Medicine
Dr Ken Power, Consultant in Anaesthesia and Intensive Care and Lead Consultant for Critical Care Services, Poole Hospital NHS Trust

AvMA's inquest work has provided representation to families where the deceased patient's NEWS score had not been correctly calculated or acted upon appropriately and consequently care was not escalated.

The objective of this webinar is to help the clinical negligence solicitor to understand how patients are monitored, when and how their care should be escalated and transfer to intensive care unit should be considered. At the end of the session, the clinical negligence solicitor should be able to understand how a patient should be monitored and understand the difference from an acute patient versus negligence management of an acute patient.

CPD points - 1 hours accredited by APIL and Bar

For more titles visit www.avma.org.uk/learning

Annual Clinical Negligence Conference 2016

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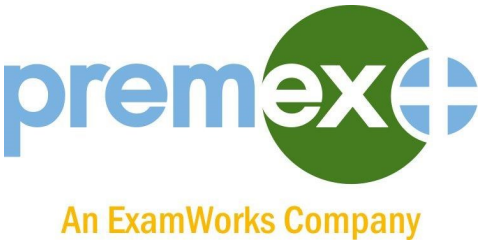

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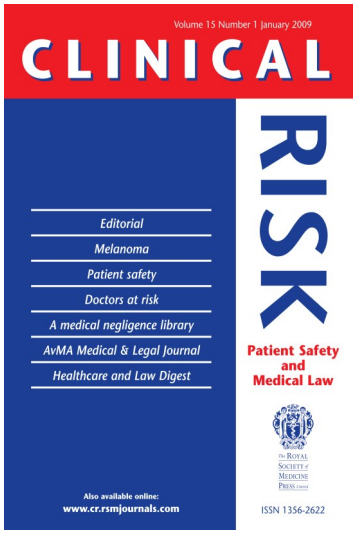

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