action against medical accidents

LAWYERS SERVICE NEWSLETTER

OCTOBER 2014

EDITORIAL

INSIDE THIS ISSUE

The Court of Appeal decisions in the cases of Denton, Decadent Vapours Limited and Utilised TDS **[2014] EWCA Civ 906**, will no doubt have come as huge relief for practitioners. The judgments given by The Master of the Rolls, Lord Dyson, Jackson LJ and Vos LJ on Friday 4th July suggest that the courts are now prepared to take a more relaxed approach to applications for relief from sanctions for non-compliance with any rule, practice direction or court order. It is hoped that this will mark a distinctly different approach to that taken following the much criticised decision in Mitchell last November. We will have to wait and see how the three stage test is actually applied in day to day practice and whether we will see consistency of approach from the judiciary in (i) identifying and assessing the seriousness and significance of the breach – where it is not serious or significant then relief should now be granted. In serious cases the court should (ii) examine why the breach occurred and (iii) evaluate all the circumstances of the case.

Separately, July also saw Lord Dyson rejecting the recommendations of the Civil Justice Council Costs Committee on guideline hourly rates (GHR) as he was unhappy with the evidence which had been gathered in support. GHR's have not gone away however, and further discussions are taking place with the Law Society and others to identify what additional evidence can be obtained to inform the process generally.

On the subject of the Civil Justice Council, this may prove to be an opportune time to draw attention to the "Guidance for the Instruction of Experts in Civil Claims" which was updated on 15 & 21st August 2014. A link to the guidance is at: http://www.judiciary.gov.uk/wp-content/uploads/2014/08/experts-guidance-cjc-aug-14-amended1.pdf

We have also seen the NHSLA lamenting the unprecedented level of new claims as personal injury lawyers move into the clinical negligence market, an 18% rise on previous years. This may lend further fuel to the already, widely held suspicion that claimant clinical negligence practitioners may see a lot more professional negligence claims in the future.

The case of Coventry v Lawrence is one to watch. Although Coventry & Lawrence is not a clinical negligence case, rather a nuisance case it is potentially an important one, for two reasons. First, Lord Neuberger's acknowledgment of the difficulties in achieving proportionality in low value claims which are nonetheless complex cases in terms of law, fact and expertise. Factors, which will no doubt

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resonate with clinical negligence practitioners. In the Coventry case the respondent's home is worth £300,000, the nuisance claim £74,000, however the respondents liability to costs is estimated to be in excess of £640,000.

Secondly, and perhaps more importantly, the respondent in the Coventry case has contended that the requirement that they pay 60% of the additional cost liabilities (the full value of the success fee at 100% is estimated at £319,000 and the ATE premium at £350,000) amounts to an infringement of their article 6 European Convention Human Rights (right to a fair trial). The Supreme Court has taken the view that it would be wrong for it to decide the point without the government first having the opportunity to address the Court on the issue. The matter has been adjourned pending a response from the Attorney-General and the Secretary of State for Justice.

If the article 6 ECHR argument is successful it may affect the recoverability of ATE premiums in clinical negligence cases pre April 2013 and result in the Court making a Declaration of Incompatibility. If this happens, anyone who was required to pay the additional liabilities as part of a costs order may be able to recover them from the government. It also means there will be ramifications for cases which are still being run under CFA's and ATE insurance products taken out before April 2013, but have yet to settle.

We will be looking at the Coventry case, the likely effects of the Denton case and others at the AvMA Panel Meeting on 4th December – flyers are coming out in the very near future.

The beginning of the summer also saw AvMA enter into a pilot scheme with Care Quality Commission (CQC). The aim of the pilot is to help raise public awareness of the standards people are entitled to expect whenever they receive care. More details about the pilot and a general recap on the functions of the CQC are included in this month's newsletter.

We are pleased to draw your attention to Edward Ramsay's (12 KBW) article on the difficulties in arguing the line between individual and systemic error at the coroner's court. Edward was counsel in the case of Chandler which received considerable media attention following the conclusion handed down on 23rd July 2014 where the Coroner found a number of failings in the care provided by the trust, both individual and system had contributed to the death.

Counsel, Saara Idelbi (7 Bedford Row) has provided an article on the prescription and use of tramadol in morbidly obese patients. AvMA has had two cases where the use of tramadol has been

[1] *Mitchell v News Group Newspapers Ltd [2013] EWCA Civ 1537, [2014] 1 WLR 795*

[2] *Coventry and others (Respondents) v Lawrence and another (Appellants) (No 2) [2014] UKSC 46*

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raised as an issue as a drug of choice to manage pain in patients suffering with chronic obstructive pulmonary disease (COPD) and chronic respiratory failure. Saara represented both families at the respective inquests. We would be interested in hearing from you if you have any cases where you have had similar concerns, please forward the information to Norika Patel at norika@avma.org.uk .

We welcome Alicia Hayes who joined the medico-legal team on 1st September, Alicia has 7 years' experience of practising at the Bar in the Republic of Ireland. As many of you will be aware, Irish firms are increasingly challenging care provided by the health system and a body of litigation expertise is fast gathering pace. Demand is such that we now hold an annual conference in Dublin.

We are also pleased to confirm that Julia Cotterill has been appointed Medico-Legal Coordinator. Demand for our Pro Bono Inquest Service outstrips what we can supply, among other things Julia will help to streamline procedures in the service which will hopefully maximise our capacity and enable us to take on more inquest cases.

We continue to strive to improve the services to the public and recent improvements to the helpline mean that we are now capturing an additional 50 calls a week. If you are interested in volunteering and can commit to providing assistance on a regular basis, whether that is weekly, fortnightly or monthly, then please let us know. Training will be provided and I draw your attention to Gill Savage's call for more volunteers in the Newsletter.

Finally, to all AvMA panel members we ask you to hold the date of **Monday 4th December** to attend the panel meeting, full details will be sent out in the near future. We look forward to seeing you then.

Lisa O'Dwyer

Director Medico-Legal Services

AVMA POLICY & NEWS

PETER WALSH, CHIEF EXECUTIVE

Duty of Candour

The statutory duty of candour on healthcare organisations is due to come into force in England in November and will also apply to social care organisations from April 2015. The duty is one of the new 'fundamental standards' contained in the statutory regulations relating to the Care Quality Commission (CQC). The CQC recently consulted on the guidance underpinning the duty of candour which will be crucial to its success. AvMA succeeded in ensuring that the duty applies to any incident which has or which 'may' cause significant harm. The final guidance is due to be published shortly.

Meanwhile AvMA have also been working with the health professional regulators to try to ensure they strengthen the wording of the professional duty of candour and how they regulate health professionals who may be in breach of the duty. A join t statement by all the regulators is expected in October and the GMC and NMC are launching new guidance on complying with the duty of candour on 3rd November.

Please let AvMA know if you come across any cases where there appears to have been a breach of the duty of candour. We will want to monitor that it is being implemented properly and that the regulators are enforcing it appropriately.

AvMA are in discussion with ministers / health departments in Scotland, Wales and Northern Ireland, all of whom are now actively considering introducing a statutory duty of candour and what form it should take.

NHS Complaints & legal action / Parliamentary & Health Service Ombudsman

We advised previously of AvMA' success (following threat of judicial review) in getting the Department of Health to issue clear guidance to NHS bodies in England that involvement in or potential clinical negligence litigation should not get in the way of NHS patients' right to an investigation and response under the NHS complaints procedure. **Please let AvMA know if you are still encountering any instances of NHS bodies refusing to investigate NHS complaints, or delaying doing so against clients' interests, because they are considering or have started legal action.**

AvMA has also recently intervened with the Ombudsman following several callers to our helpline saying that they had been told by the Ombudsman's helpline advisers that the Ombudsman would not investigate whilst there was a possibility of a clinical negligence action. Whilst the Ombudsman's regulations are separate from the NHS complaints procedure, there is no good reason why they can not or should not investigate a complaint on the basis that there is a clinical negligence action. This is because the 'remedy' they are seeking through a complaint is quite different and distinct from the objective of obtaining compensation through a clinical negligence claim. We are awaiting confirmation that the Ombudsman has issued fresh guidance and training for its staff to this effect. **Please let AvMA know if you come across instances of the Ombudsman refusing to investigate on these grounds.**

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PETER WALSH, CHIEF EXECUTIVE

Whistleblowing / 'Freedom to speak up' Review

AvMA is contributing to the 'Freedom to Speak up Review' https://freedomtospeakup.org.uk/ being conducted by Robert Francis QC. The review report and recommendations are expected by the end of this year.

Current Consultations

Members of AvMA may wish to be made aware of the forthcoming consultations and the closing date for responses. AvMA **would also welcome your suggestions to help us inform our own response.**

DoH Transparency in care: visible ratings for health and care providers	13.10.14 (published 15.9.14)	https://www.gov.uk/government/consultations/transparency-in-care-visible-ratings-for-health-and-care-providers
CQC Guidance for all providers on meeting the fundamental standards and on CQCs enforcement powers	17.10.14	http://www.cqc.org.uk/sites/default/files/20140725_fundamental_standards_and_enforcement_consultation_final.pdf
GMC Reviewing how we deal with concerns about doctors - A public consultation on changes to our sanctions guidance and on the role of apologies and warnings.	14.11.4	https://gmc.e-consultation.net/econsult/consultation_Dtl.aspx?consult_Id=483&status=2&criteria=I

AVMA POLICY & NEWS

PETER WALSH, CHIEF EXECUTIVE

Medical Innovation Bill (The 'Saatchi Bill')

AvMA is doing all it can to prevent this misguided and dangerous Bill from becoming law and would encourage all of our members to do likewise. Please lobby any politicians who you have good links with. If you have contacts with any politicians who are prepared to speak up against the Bill please let us know. The next reading of the Bill in the House of Lords is on 24th October. Details of the Bill can be found here: http://services.parliament.uk/bills/2014-15/medicalinnovation.html

AvMA's briefing on the Bill (with thanks to Nigel Poole QC for his help) can be found here: http://www.avma.org.uk/data/files/Medical_Innovation_Bill_Briefing_16_06_14.pdf

Peter Walsh's blog on the Bill can be found here:

http://www.clinicalnegligencelaw.co.uk/2014/07/03/threat-medical-innovation-bill/

AvMA/CQC PILOT SCHEME

In July this year, AvMA and the Care Quality Commission (CQC) entered into a pilot to help raise awareness of the standards the public are entitled to when receiving care and increase the regulator's access to people's experiences of care to inform its work. The pilot is due to run for 6 months.

AvMA and CQC are developing leaflets and posters to help draw attention to the pilot. It is hoped that these will be displayed in PALS offices, Hospital Complaints departments and a range of other help and advice agencies. The aim is to encourage the public to share their experience of the care they received, whether good or bad by contacting either the AvMA Helpline or by going directly to CQC's website to complete and submit a CQC webform.

AvMA will facilitate the pilot primarily through calls received to its Helpline but also through its written work including the pro bono inquest service. The pilot is open to any member of the public who consents to being part of the scheme; our Helpline Form has been amended to ensure the requisite consents are obtained from callers. AvMA does recognise that sometimes people need a "cooling off" period so to ensure consent to the pilot is properly obtained, no webform is submitted by us until the caller has been called back by the AvMA office some 24 hours or so after their initial contact with us. The call back system enables us to ensure that individuals going through the process have had the opportunity to further consider being part of the pilot and the concerns they wish to raise.

AvMA is encouraging its clients to enter the pilot as a way of ensuring that CQC is made aware of the standard of care and treatment currently being offered to the public by health services across England.

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AvMA/CQC PILOT SCHEME cont.

AvMA hopes that by working with CQC to bring areas of poor care to their attention this will enable them to examine areas of concern in more detail. In turn, this should help to improve standards across the country and avoid poor care being perpetuated and putting lives and outcomes at risk.

If you have any cases which you think should be brought to CQC's attention then please encourage your clients to share the information with the CQC. **We would be happy to submit a CQC feedback form on your behalf. If you have any questions regarding the AvMA pilot with CQC, please contact Harriet Jones at harriet@avma.org.uk who will be happy to help you.**

Information can be submitted through one of two ways:

1. **By contacting AvMA Helpline service at 0845 123 23 52 (open 10am to 5pm Monday to Friday) or by sending a written request [link to written request page]**
2. **Alternatively, you can submit concerns to CQC directly on their website: http://www.cqc.org.uk/share-your-experience-finder Please make sure you complete the drop down box to say that you have been referred by us following the question "Did you hear about this form through one of the charities below?"**

Recap on Functions CQC

CQC is England's health and social care services regulator. CQC's principles are to:

- put people who use services at the heart of its work have an open and accessible culture
- be independent, rigorous, fair and consistent
- work in partnership across the health and social care system
- commit to being a high-performing organisation
- promote equality, diversity and human rights

What does the CQC do?

CQC carries out its role in the following ways:

- Setting national standards of quality and safety that people can expect whenever they receive care.
- Registering care services that meet national standards.
- Monitoring, inspecting and regulating care services to make sure they continue to meet the standards.
- Protecting the rights of vulnerable people, including those whose rights are restricted under the Mental Health Act.
- Listening to and acting on patient concerns and experiences.

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AvMA/CQC PILOT SCHEME cont.

- Working in partnership with other organisations and local groups.
- Challenging all providers, with the worst performers getting the most attention.
- Making fair and authoritative judgements supported by the best information and evidence.
- Taking appropriate action if care services are failing to meet the standards.
- Carrying out in-depth investigations to look at care across the system.
- Reporting on the quality of care services, publishing clear and comprehensive information, including performance ratings to help people choose care.

Who do CQC regulate?

CQC regulate:

- Treatment, care and support provided by hospitals, GPs dentists, ambulances and mental health services.
- Treatment, care and support services for adults in care homes and in people's own homes (both personal and nursing care).
- Services for people whose rights are restricted under the Mental Health Act.

How are bodies regulated?

In accordance with 'The Scope of Regulation – August 2013' CQC Guidance Leaflet, the CQC say that all health and social care services in England need to register with them. In practice however, this is confined to those who carry out any of the CQC's fifteen regulated activities.

These regulated activities are listed in Schedule 1 of the **Health and Social Care Act 2008 (Regulated Activities) Regulations 2012**. These include:

1. **Personal care** (which is provided to them in the place where those people are living at the time when the care is provided)
2. **Accommodation for person who require nursing or personal care**
3. **Accommodation for persons who require treatment for substance misuse**
4. **Accommodation and nursing or personal care in the further education sector**
5. **Treatment of disease, disorder or injury** (if provided by a listed health care professional, social worker or multi-disciplinary team)
6. **Assessment or medical treatment for persons detained under the Mental Health Act 1983** (only in hospitals)
7. **Surgical procedures** (carried out by a healthcare professional, some exceptions for minor procedures, eg foot and nail treatment, tattooing, piercing, removal of hair and blemishes etc)
8. **Diagnostic and screening procedures** (radiation, ultrasound and MRI etc)
9. **Management of supply of blood and blood-derived products** (includes NHS Blood and

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AvMA/CQC PILOT SCHEME cont.

Transplant)

10. **Services in slimming clinics** (that include giving medicines AND are led by a registered medical practitioner)
11. **Transport services** (where the vehicles primary purpose is for transporting people who require treatment)**, triage and medical advice provided remotely** (where the advice is medical AND responsive i.e. for immediate attention or action OR it constitutes triage AND is provided by a body responsible for that service)
12. **Maternity and midwifery services**
13. **Termination of pregnancies** (does not include the 'morning after pill' when used as an emergency contraceptive)
14. **Nursing care** (where not under another regulated activity)
15. **Family planning services** (services for the insertion or removal of an intrauterine contraceptive device by, or under the supervision of, a health care professional)

Any organisation that carries out these regulated activities in England must register with CQC. Separate provisions are available in the rest of the UK.

For any bodies that carry out these services in England from neighbouring countries for short periods of time (eg. Ambulance services) the CQC have said that they will take a 'proportionate' and 'reasonable' approach to registration.

Registration takes many forms and varies slightly for different practice groups (eg. Corporate groups, franchises, partnerships). This includes the fact that a GP surgery is normally registered under their partner's (lead doctor's) name, rather than the surgery itself.

Failure to register

Any service that provides one or any of the fifteen regulated activities who fails to register will be liable for a criminal offence and may face prosecution.

Section 10 of the Health and Social Care Act 2008 states:

(1) Any person who carries on a regulated activity without being registered under this Chapter in respect of the carrying on of that activity is guilty of an offence.

.....

(4) A person guilty of an offence under this section is liable—

(a) on summary conviction, to a fine not exceeding £50,000, or to imprisonment for a term not exceeding 12 months, or to both;

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(b) on conviction on indictment, to a fine, or to imprisonment for a term not exceeding 12 months, or to both.

Exemptions to regulation

From time to time AvMA receives calls on the helpline which involve bodies that are not subject to regulation by CQC.

The following bodies aren't covered currently, even though they provide regulated activities:

- **Scottish, Irish, Welsh and non-Mainland UK services**
- **Non-NHS primary pharmaceutical services** – eg. Boots, Superdrug, Lloyds
- **Non-NHS primary ophthalmic services** – eg. Specsavers, Vision Express
- **Some mobile treatment units** – eg. Blood donation, breast scanning. Often broader registration is kept with the CQC.
- **Some fertility clinics after 01 October 2013**
- **Independent practitioners** – acting as a 'designated body' providing services in a surgery or consulting room, treatment does not include anaesthesia or intravenous sedation, childbirth services and termination of pregnancy, certain cosmetic surgery, haemodialysis etc.
- **Independent midwives** - exemption if midwife is self-employed AND providing non-NHS care AND providing services to their patient ONLY in their home.
- **Third party exemptions -** Occupational health schemes; defence medical/dental teams for the armed services; forensic medical service (eg in police custody); medical assessment or treatment linked to insurance schemes (does not exclude services through private medical insurance schemes); medical services organised by a government department that do not involve treatment requiring admission to hospital (eg. medical assessments to determine eligibility for social security benefits).
- **Individual budgets, individual user trusts and self-funded personal care or nursing care -** Where a person, or a related third party on their behalf, makes their own arrangement for nursing care or personal care, and the nurse or carer works directly for them and under their control

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without an agency or employer involved in managing or directing the care provided, the nurse or carer does not need to register for that regulated activity.

- **Any health or social care activity carried out by a carer for a member of their family or someone in a personal relationship** – where there is no commercial consideration.

- **School nurses** - who are employed and managed by the school and who provide services to the school's pupils. In general, this will exempt school nurses in independent schools, but not in public sector schools where the school nursing service will be included in the registration of the relevant provider.

- **Aircraft operators** – that only carry out the activity of transport services and do not carry out other regulated activities (such as treatment of disease, disorder or injury)

- **Aircraft operators or air ambulance providers within the confines of event** grounds - may fall out of regulation if their transport is confined to the event ground.

Archived services

Beyond these exempted services, the CQC have also removed a number of healthcare providers from their website.

These services include those where:

- The provider has voluntarily closed it – for example, a service closed because it is no longer profitable.
- The CQC has taken enforcement action to close it – for example, a service whose registration is cancelled after CQC inspectors found evidence of poor care or abuse.
- The legal entity providing the service has changed – for example, a service where a sole trader has been replaced by a partnership as the provider.
- The service has changed address - for example, a service that has moved to a new building to take advantage of better facilities.
- The provider is no longer required to be registered with the CQC - for example, some fertility clinics that have no longer been regulated by the CQC since 01 October 2013.

This means that it is very important to record the correct name of the healthcare provider when taking feedback from a helpline caller. Common mistakes may include recording a trust under a generic name (eg ‘Manchester Hospital’) or failing to specify which trust is being discussed.

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AvMA/CQC PILOT SCHEME cont.

What are the potential risks for service users?

When services are exempted by CQC, service users cannot feedback their experiences. This means that if poor care is experienced, or members of the public know that poor care is being provided, the information cannot be collected and acted upon by the CQC, these cases are not included in the AvMA/CQC pilot. However, AvMA is still keen to know of any difficulties members of the public have had with these services as part of our continuing commitment to patient safety and justice.

CQC continues to expand in the services it regulates and covers. Changes to the CQC regulations were made following a consultation by the Department of Health in 2011. These amendments were then approved by Parliament in 2012. These changes mostly address technical points in the regulations that make them clearer in order to provide greater clarity.

Further changes in October 2013 meant that some further healthcare providers were no longer required to be registered with the CQC. The CQC have responded by saying that many of these services were already exempted by the regulations by another means.

Any issues arising from CQC's regulation and coverage will be monitored throughout AvMA's pilot scheme with CQC in the following months. Any important issues arising from the pilot scheme will be raised in meetings between AvMA and CQC, which will take place at regular intervals throughout the scheme.

Volunteer work placements wanted for our Helpline Service

We currently are looking for more people to help man the AvMA Helpline. We already have over 80 regular volunteers with legal or medical backgrounds who have found volunteering on the Helpline to be rewarding work. Many of our existing volunteers have said that hey have found the experience to be extremely helpful when dealing with clients back at their place of work.

All volunteers are trained by specialist AvMA staff. Following training you will be given an allocated Helpline Session which you can carry out either by attending the AvMA offices in Croydon or remotely from your own office. Those volunteers who do come into our offices find us friendly and helpful. By being based at our Croydon office volunteers have also enjoyed getting to know the AvMA staff and more about the organisation as a whole, with many volunteering far longer than anticipated.

Due to an increase in the number of calls to the helpline we are looking to recruit more volunteers to staff the line and double the number of advisors taking calls during busy periods. however cover for other days are also needed.

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The helpline is open Monday-Friday 10am-5pm. Volunteer sessions are on a Rota system and each volunteer has an allocated 1 ½ or 2 hour session either once a week, fortnightly or once every 4 weeks. Opportunities to volunteer for a full or half day rather than short sessions will also be considered. We ask that volunteers commit to a minimum of 6 months and give 6 weeks' notice if possible if they are no longer able to volunteer.

Volunteering for the helpline can provide greater awareness of the Complaints System and help to gain a clearer understanding of the clients' perspective. A training program will be tailored to meet the volunteers' needs which would include a one day intensive training day and follow up training if needed. Opportunities may also be available to get involved with research projects and written casework.

If you are a qualified Solicitor, trainee solicitor, paralegal, Barrister or medically qualified we would like to hear from you.

Please contact Gillian Savage, Helpline Development Officer.

Email: **support@avma.org.uk** or Tel: 020 8688 9555 for further information. Or download an application form our website www.avma.org.uk

LEGAL NEWS

HOSPITAL 'NEVER EVENTS' AND INQUESTS - THE DIFFICULT LINE BETWEEN INDIVIDUAL AND SYSTEMIC ERROR

Introduction

Hospital "never events" are defined by NHS England as "*serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers".*

The never events list 2013/14 update identifies 25 types of never event, including:

- ***wrong site surgery***
- ***retained instrument post operation***
- ***wrong route administration of chemotherapy.***

Incidents are considered to be never events if:

- ***there is evidence that the never event has occurred in the past and is a known source of risk (for example, through reports to the National Reporting and Learning System or other serious incident reporting system)***
- ***there is existing national guidance or safety recommendations, which if followed, would have prevented this type of never event from occurring (for example, for 'Retained foreign object post procedure' the referenced national guidance is related to the peri-operative counting and checking processes that would be expected to occur at the time of the procedure, including suturing after a vaginal birth)***
- ***occurrence of the never event can be easily identified, defined and measured on an ongoing basis.***

Data concerning the nature and number of never events happening at each hospital trust in England are now published on a monthly basis (as of 2014/15) and can be found at http://www.england.nhs.uk/ourwork/patientsafety/never-events/ne-data/.

Where a never event leads to the death of a patient it is very likely that the Coroner will investigate.

The duty to investigate is now contained in Part 1 of the CJA 2009 ("the Act").

The investigation may need to be widened pursuant to section 5(2) of the Act, which provides as follows:

> *(2) Where necessary in order to avoid a breach of any Convention rights (within the meaning of the Human Rights Act 1998), the purpose mentioned in subsection (1)(b) is to be read as including the purpose of ascertaining in what circumstances the deceased came by his or her death.*

Herbert Chandler

The case of Mr Chandler is one example.

Mr Chandler was admitted as an in-patient to the William Harvey Hospital on 17 January 2013 with a history of chronic obstructive pulmonary disease. Investigations on admission showed that he had a pneumothorax of the left lung. He was investigated and treated conservatively with antibiotics, nebulizers, and steroids even though his respiratory rate was above 30 from 19 January 2013 and above 32 from 20 January 2013. On 22 January 2013, out of hours, an attempt was made to aspirate the pneumothorax by a junior doctor but an error was made and the right lung was aspirated instead of the left. The left was then aspirated once the error had been detected but Mr Chandler died shortly afterwards, the cause of death being an acute right tension pneumothorax resulting from the erroneous aspiration.

During the course of the evidence heard over two days at the inquest it transpired that the junior doctor who carried out the aspiration on the right lung had failed to check the radiology prior to beginning the procedure; instead she had relied on a consultant's plan entered in the medical notes on 18 January 2013, which incorrectly identified the right lung as requiring a chest drain.

It further transpired that not only was the consultant's entry incorrect, but it had been written on a standalone page in an incorrect section of the medical pathway documentation, some distance away from the clinical notes. It was asked why the error had not been spotted by medical staff on any of the days leading up to Mr Chandler's death. It was said on behalf of the family at the inquest that the error

had been 'hiding' and the failure to detect it had contributed to the risk of harm.

A new system of clinical notes had been introduced only a matter of weeks before Mr Chandler's death and it was said by the consultant who wrote the incorrect entry that the system had been 'confusing'.

HM Coroner concluded that '*systemic errors*' and a '*series of failings*' caused or contributed to the death, including "*a confusing format of medical records which prevented sequential recording of entries by health care professionals*".

HM Coroner also ruled that a Prevention of Future Death Report (previously Rule 43) was to be made pursuant to paragraph 7(1) of Schedule 5 to the Coroners and Justice Act 2009 and Regulation 28 of The Coroners (Investigations) Regulations 2013.

The conclusions and findings of the inquest were reported in the local and national press and by the BBC.

Systemic error and Article 2 of the European Convention on Human Rights

It is now well established that simple clinical or human error, what Smith LJ in ***Humberstone*** termed 'ordinary medical negligence' is not sufficient to engage Article 2 so as to require an enhanced investigation of the type envisaged in ***Middleton***.

The difficulty is that 'never events' may include individual or human error as they clearly did in *Chandler* – most obviously the incorrect (and no doubt inadvertent) entry made in the medical notes by the respiratory consultant. However these were individual errors which should never have been allowed to happen and to that extent they were systemic.

In ***Middleton*** itself Lord Bingham made an interesting observation:

"There is force in the criticism made by all parties of the distinction drawn

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> *between individual and systemic neglect, since the borderline between the two is indistinct and there will often be some overlap between the two:* ***there are some kinds of individual failing which a sound system may be expected to detect and remedy before harm is done.*** *There will, moreover, be individual failings which need to be identified even though an individual is not to be named."* [emphasis added].

In ***Humberstone***, it was pointed out that *"it is not possible to say that an allegation of individual negligence will never engage article 2".*

But it has also been suggested that there is a distinction to be made between systems which are fundamentally lacking and those which are improperly implemented or operated. The former is potentially more serious (but not, it is submitted, necessarily so); and therefore establishing at an early stage whether a never event resulted from a fundamental as opposed to an operational failing will be important when making submissions to the Coroner, sometimes at a pre-inquest review hearing (PIRH), as to the proper scope of the inquiry. Sometimes, as was the case in *Chandler*, the failings will be part fundamental and part operational but the fact that the death resulted from a never event will mean, it is submitted, that, at least to a degree, any error(s) will have been systemic.

However the fact that a hospital trust may have internally investigated the incident by way of SUI (as was the case in *Chandler*) and declared a never event will not mean that the point will be conceded. It will have to be argued, usually at a PIRH, about which the Chief Coroner has given recent guidance in the case of ***Brown v HM Coroner for Norfolk*** **[2014] EWHC 187 (Admin**):

> *39 A pre-inquest review hearing, where held, is an important stage towards the final hearing. In each case the coroner should ensure that all interested persons, particularly bereaved families, have sufficient notice of the matters to be discussed at the pre-inquest review hearing. The claimant asserted in this case that he had no notice of what was going to be discussed at the hearing and was therefore unprepared when asked which witnesses should attend to give evidence and whether he accepted that the cause of death could not be established. Coroners should therefore provide a written agenda in advance and, if appropriate, express provisional views so that agreement or opposition can be*

expressed.

40 The agenda which should be tailored to the individual case should include, amongst other things, and particularly in the more complex or difficult cases, a list of interested persons, a proposed list of witnesses identifying those who may be called and those whose statements may be read, the issues to be considered at the inquest, the scope of the evidence, whether a jury will be required, whether Article 2 of the European Convention on Human Rights is engaged, any issues of disclosure, the date of the final hearing, and any other relevant matters. In a complex or difficult investigation interested persons should be invited to respond to the coroner's agenda in advance of the pre-inquest review hearing in writing, stating what they agree with and what they do not agree with.

41 The coroner should also ensure that interested persons, particularly those unrepresented, have sufficient disclosure of relevant statements and documents before the pre-inquest review hearing so as to be able to address the agenda on an informed basis. The claimant asserted in this case, as the coroner's note of the hearing states, that 'he had not received copies of the post mortem and toxicology reports'. If correct, that would have placed him at a considerable disadvantage for the pre-inquest review hearing.

42 The claimant's view of the pre-inquest review hearing was that the coroner had made up his mind what the outcome of the inquest would be. ***Coroners should avoid giving the impression at a pre-inquest review hearing (and in any documentation supplied before it) that the findings and conclusions of the inquest are in any way pre-determined, even when the evidence points substantially in one direction****. It may be necessary to explain in clear language to unrepresented families that there is a difference between seeking to identify the key issues and coming to a final con-*

clusion.

The PIRH is the first, but, by no means, the last opportunity to make representations that section 5(2) of the Act should be engaged. It is submitted that in each case where there are credible concerns that a 'never event' has caused or contributed to a death the starting point should be that an enhanced investigation is required.

In ***R (on the application of Takoushis) v HM Coroner for Inner North London & Ors*** **[2005] EWCA Civ 1440** the Court of Appeal held that the Respondent Coroner had erred in principle by determining the issue of systemic failure before the evidence had been heard and the system properly investigated.

> *For the reasons we have given we would allow the appeal. We should add that, in reaching the above conclusions, we are conscious of the fact that in Middleton,, the House of Lords observed in paragraph 47 that there is force in the criticism made by all parties in that case of the distinction drawn between individual and systemic neglect, since the borderline between them is indistinct and there will often be some overlap between the two: there are some kinds of individual failing which a sound system may be expected to detect and remedy before harm is done. There will, moreover, be individual failings which need to be identified even though an individual is not to be named. On the other hand, the distinction has a clear meaning as applied to the facts of this case.* ***The problem here was that the system was not sufficiently investigated****.* [emphasis added].

In *Chandler,* although there was no PIRH, HM Coroner made a ruling at the outset that she would investigate the system before deciding whether this was a case of *"a catastrophic error on the part of one person or whether the systems themselves were at fault".*

Thus in cases involving hospital never events submissions should be directed first and foremost to ensuring that the system is thoroughly investigated <u>before</u> a proper decision on Article 2 can be made. That means, perhaps confusingly - it may be said - that the investigation is widened to establish

whether it needs widening. Beware opposing submissions alluding to carts and horses; but as has already been said the distinction between *Jamieson* and *Middleton* inquests is perhaps less important that it was once thought to be.

In the recent case of ***R (on the application of Sreedharan) v HM Coroner for the County of Greater Manchester & Others*** **[2013] EWCA 181** it was noted that:

> *"There is now in practice little difference between the Jamieson and Middleton type inquest as far as inquisitorial scope is concerned. The difference is likely to come only in the verdict and the findings. (R (Smith v Oxford Assistant Deputy Coroner 2011 1 AC)".*

For that reason those representing bereaved families should be prepared to make submissions at the conclusion of the evidence that Article 2 should be applied 'retrospectively'; that the investigation has been a *Middleton* one in all but name; and that the Article 2 'label' will allow the Coroner to identify specific failings that caused or contributed to the death.

Conclusion

It hardly needs saying that in modern healthcare the line between individual and systemic error is fraught with conceptual difficulty. Where the circumstances of a patient's death give rise to concerns that a never event may have been involved, the Coroner should be invited to hold a PIRH at the earliest opportunity and submissions made from the outset that, without more, the issues are likely to be systemic in nature. Errors which should never happen are synonymous with those that a sound system should detect and remedy before harm is done. The system will need investigating in any event whether or not Article 2 is engaged.

Edward Ramsay

15 September 2014

Edward Ramsay of 12 King's Bench Walk (instructed by Morrisons Solicitors LLP) acted on behalf of the family of Herbert Chandler at the Inquest into his death.

LEGAL NEWS

[1]http://www.england.nhs.uk/ourwork/patientsafety/never-events/

NHS Commissioning Board, Serious Incident Framework March 2013: An update to the 2010 National Framework for Reporting and Learning from Serious Incidents Requiring Investigation;

[2]http://www.england.nhs.uk/wp-content/uploads/2013/03/sif-guide.pdf

http://www.england.nhs.uk/wp-content/uploads/2013/12/nev-ev-list-1314-clar.pdf

[3]ibid

[4]ibid

[5]http://www.bbc.co.uk/news/uk-england-kent-28479366

http://www.kentonline.co.uk/weald/news/ashford-hospital-lung-death-20740/

[6]*R (On the application of Humberstone) v Legal Services Commission* [2010] EWCA Civ 1479 per Smith LJ at [58].

[7]*R (Middleton) v HM Coroner for West Somerset* [2004] UKHL 10 at [47]:

[8]per Smith LJ at [71].

[9]*R (on the application of Takoushis) v HM Coroner for Inner North London* [2005] EWCA Civ 1440 at [51].

[10]*R (on the application of Takoushis) v HM Coroner for Inner North London & Ors* [2005] EWCA Civ 1440 at [68].

[11]per Hallett LJ at [18].

LEGAL NEWS

Inquests – Concerns about use of Tramadol

Saara Idelbi

7 Bedford Row

Patients with obesity often present complex medical challenges for healthcare professionals to appropriately manage pain and the various other conditions that afflict them. This is particularly the case where patients suffer from COPD and chronic respiratory failure. The choice of analgesics is limited, and opioids are the first port of call. But one drug has emerged in the work of AvMA to present a particular concern; tramadol.

In the BNF, the use of tramadol in patients with COPD and chronic respiratory failure is restricted because of the risk of respiratory depression and subsequent death, but it appears that it is still being administered to patients with these complexities.

In two cases handled by AvMA recently, the risks of tramadol have entered the arena of the coroner's court. Whilst both coroner's declined to consider whether the ready prescription of tramadol in the face of the contra-indication of the BNF gave cause for concern in medical practice, the behaviour of tramadol in both patients was particularly curious. In both cases, the deceased were obese with Chronic Obstructive Pulmonary Disease (COPD) and chronic respiratory failure, both of whom were living in constant pain.

In the first case of Ms U, the deceased was sadly found dead at home in bed. Her GP had attended to her the day previous and whilst she was a state of delirium, no change to her medication was made. Her blood toxicity levels indicated extremely high doses of tramadol but there was no surrounding evidence, multiple empty drug sheets etc, to suggest that she had deliberately taken an overdose. The coroner considered that she may have accidently and unintentionally overmedicated because of the level of pain.

In the second case of Ms W, the deceased was found over a plate of food at her dining table. Ms W was meticulous at ensuring that she took her medication, keeping the majority of it in a dosset box. On the day of her death, she spent the day with her daughter and whilst shopping momentarily lost focus and crashed her scooter into a display. Although Ms W's daughter contacted the GP practice raising the concern, it was not considered that Ms W's confusion might have been medication related. Again, Ms W's blood toxicity levels were extremely high, and the toxicologist for the coroner suggested overdose as the only explanation for the high toxicity levels.

However, owing to Ms W's practice and approach to her medications, along with the fact that she took it upon herself to privately pay carers to assist her at two points in the day, an unintentional overmedication was not as readily available as a verdict. A further report from a pharmacologist considered that the surrounding information taken together with the toxicology results lead to the conclusion that the sample was contaminated.

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The coroner did not consider there was enough evidence to substantiate that the two deaths were caused by the normal use of tramadol. The expert evidence did not deal with the dual-action pharmacology of tramadol that lent itself to the risk of adverse effects such as overdose. This was something that the Advisory Council of the Misuse of Drugs (ACMD) noted in their own consideration of tramadol. It also found that there were an increasing number of tramadol related deaths in the UK, a fact that was recognised by the ACMD's consideration of the use of tramadol in February 2013. The ACMD notes that whilst a percentage of the increase was concerned with the increased access to tramadol by non-prescribing routes, some concern was expressed about the exponential increase of prescription of opioid analgesics over the same period. In its recommendations to government, it recommended better training for prescribers of tramadol, as yet this does not appear to have been adopted. However, the Medicines & Healthcare Products Regulatory Agency (MHRA) confirmed that as of 10th June 2014, Tramadol was to be considered a Class C drug.

The risks presented by tramadol whilst explored appear in the UK to have been dismissed owing to there being no better alternative to pain management (R. B. Raffa PhD, Pharmacology of oral combination analgesics: rational therapy for pain - http://onlinelibrary.wiley.com/doi/10.1046/j.1365-2710.2001.00355.x/full).

Nevertheless, the fact that there is no better alternative to pain management is unlikely to blunt the bereavement of a family who has just lost their loved one in a situation where tramadol may or may not be implicated. I am not a medical expert, and cannot definitively suggest that tramadol is the operating cause of these deaths. However, plentiful case examples may be the only way to encourage courts to consider that further investigation needs to be done in a case context to identify whether it is. That in itself appears to be a complex medical challenge.

If you have any similar case examples of deaths caused or contributed to by the use of Tramadol then do let AvMA know. By attempting to collate information on this, it may be that we can assist with properly identifying the risks of administering tramadol to patients in similar circumstances. Please forward any information you may have to Norika Patel, Norika@avma.org.uk

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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.

Medico-Legal Issues in Obstetric & Neonatal Care
9 October 2014, Radisson Blu Royal Hotel, Dublin
This popular AvMA conference is coming to Dublin for the first time. Leading experts will cover screening for fetal abnormality and examine how best to manage medical problems in pregnancy and labour, and issues in neonatal care and neurological birth injuries. Causation issues in obstetric and neonatal care will also be discussed, in what will be a key event to assist your caseload.

Best Practice in Quantum
5 November 2014, De Vere Holborn Bars, London;
19 November 2014, Manchester Conference Centre
Quantifying damages and costs in clinical negligence cases requires maintaining balance between the clients' needs and financial compensation. Following the popularity of the 'Legal Update in Quantum Cases' session at this year's Annual Clinical Negligence Conference in Brighton, AvMA brings you an in-depth conference on 'Best Practice in Quantum', which will be held in both London and Manchester.

The event will assess quantum in general and special damages; future loss of earnings and life expectancy; negotiating and settlement; client best practice; quantifying in professional negligence both in client conflict and loss of chance, and life after settlement from the clients' perspective.

Medico-Legal Issues in Oncology
26 NOVEMBER 2014, DE VERE HOLBORN BARS, LONDON
5 FEBRUARY 2015, MANCHESTER CONFERENCE CENTRE
This vital course will provide in-depth knowledge and understanding of Oncology in a medico-legal context relevant to your case load. The day combines a mix of presentations from leading experts to cover types of tumour; staging and classification; diagnostic tools and treatments; medico-legal issues in the delay of diagnosis; advances of surgery and causation issues arising in cancer claims.

AvMA Specialist Clinical Negligence Panel Meeting & Christmas Drinks Reception
4 December 2014, De Vere Holborn Bars, 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 negligence law. This year's meeting will take place on the afternoon of Thursday 4th December - registration and a networking lunch will commence at 12.30, with the meeting starting at 13.30 and closing at 17.30.

AvMA's Christmas Drinks Reception, which is also open to non-panel members, will take place immediately after the meeting, also at De Vere Holborn Bars. The event provides an excellent op-

CONFERENCE NEWS

portunity to catch up with friends, contacts and colleagues for some festive cheer!

Clinical Negligence Issues in Neurosurgery & Neurological Disease
11 December 2014, De Vere Holborn Bars, London
Neurological injuries are amongst some of the most devastating clinical negligence cases. This new AvMA event will give you an in-depth insight into the conditions relevant to your caseload. Stroke medicine, spinal and cranial surgery and medico-legal issues in neuro-intensive care and neurological rehabilitation will all be covered by leading medical experts. Quantum in neurosurgery and neurological disease will also be examined.

Clinical Negligence: Law Practice & Procedure
29 – 30 January 2015, De Vere Colmore Gate, 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.

Complications in Pregnancy
11 March 2015, Marriott Royal Hotel, Bristol
Infection, genetic disorders, maternal health, cardiomyopathy, miscarriage, rhesus disease, obesity, multiple births, maternal age, fertility treatments and liver disease are among the topics to feature in this essential AvMA conference. The programme will be available and booking will open in December.

AvMA Annual Charity Golf Day
25 JUNE 2015, RUDDING PARK, HARROGATE, YORKSHIRE
The eleventh AvMA Charity Golf Day will take place on Thursday 25 June 2015 at the stunning Rudding Park in Harrogate. The Welcome Event for the Annual Clinical Negligence Conference will take place later that evening in Leeds (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 (total £117.60) per golfer, which includes bacon 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. Booking will open in the New Year.

Annual Clinical Negligence Conference 2015
26-27 JUNE 2015, ROYAL ARMOURIES MUSEUM, LEEDS
AvMA's Annual Clinical Negligence Conference (ACNC) is **the event that brings the clinical negligence community together** to learn and discuss the latest developments, policies and strategies in clinical negligence and medical law.

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The ACNC 2015 full conference programme will be available early in the New Year. As ever, it will be an event not to be missed, with the usual high standard of plenary presentations and focused breakout sessions that you would expect from this event, ensuring that you stay up to date with all the key issues and providing 10 hours CPD (SRA, Bar Council and APIL).

There will again be discounts available for junior solicitors and barristers, paralegals and trainee legal executives to attend the conference, as well as greater savings for group bookings. 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.

Sponsorship and Exhibition Opportunities at ACNC 2015

The unique environment of the ACNC offers companies the ideal opportunity to focus their marketing activity by gaining exposure and access to a highly targeted group of delegates and experts. Further details will be available soon on the exciting opportunities available to promote your organisation at ACNC 2015.

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Blood Pressure - Implications and Outcomes

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When: available now until June 2015

Blood pressure is an important clinical measurement. In the community, high blood pressure is the main cause of concern; however, in hospitalised patients low blood pressure can indicate serious complications. This session will give solicitors involved in medico-legal cases an understanding of what is blood pressure and why it is important to control it.

Presented by: Dr Duncan Dymond, Consultant Cardiologist, St Bartholomew's Hospital, London

Location: Your desk

CPD points: 1 hour Bar Council & APIL

Medico-legal Issues in Laser Eye Surgery

On demand webinar

When: available now until February 2015

Understand the issues surrounding Laser Eye surgery. This session will cover the types of laser surgery, contra-indications to treatment, consent issues, vision threatening complications and negligent and non-negligent treatment.

Presented by: Mr Damian Lake, Consultant Ophthalmic Surgeon, Queen Victoria Hospital, East Grinstead

Location: Your desk

CPD points: 1 hour SRA, Bar Council & APIL

Medico-legal Issues in Maxillofacial Injuries

On demand webinar

When: available now until February 2015

This webinar will give solicitors involved in medico legal cases an understanding of the concerns in relation to maxillofacial surgery. This session will discuss nasal, check bone and orbital fractures and the failure to diagnose and treat appropriately as well as missed or delayed diagnosis of maxillofacial cancers.

Presented by: Mr Laurence Newman, Consultant Maxillofacial Surgeon, Queen Victoria Hospital, East Grinstead

Location: Your desk

CPD points: 1 hour Bar Council & APIL

Medico-legal Issues in Anaesthesia

On demand webinar

When: available now until February 2015

This webinar will discuss the issues surrounding the care of patients under anaesthesia and will cover pre-op checks, consent issues, anaesthetic awareness**,** patient monitoring and post-operative care.

Presented by: Dr David Levy, Consultant Anaesthetist, Nottingham University Hospitals NHS Trust

Location: Your desk

CPD points: 1 hour Bar Council & APIL

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Understanding Biochemistry Test Results
On demand webinar
When: available now until February 2015
This webinar will give solicitors involved in medico-legal cases an understanding of how biochemical test results are used to monitor patients' vital functions and how failure to request/monitor may impact on the patient.
Presented by: Dr Ken Power, Consultant in Anaesthesia and Intensive Care and Lead Consultant for Critical Care Services, Poole Hospital NHS Trust
Location: Your desk
CPD points: 1 hour Bar Council & APIL

Inquest-Post Mortem
On demand webinar
When: available now until March 2015
In July 2013 New Coroners Rules and Regulations came into force. Some of the issues affecting Inquests into death following medical treatment arise from changes related to post-mortem examinations, what is considered "natural death" and how this will affect further investigation. Watch this webinar to get some practical guidance on how to deal with the issue of post mortem examination, when to request post-mortem imaging and how to fund it and what is considered "natural death".
Presented by: Professor Peter Vanezis, Professor of Forensic Medical Sciences; &
Dr Peter Ellis, Barrister, 7 Bedford Row & Assistant Coroner, West London Coroners Court
Location: Your desk
CPD points: 1 hour Bar Council & APIL

Hospital Acquired Infections - the current state of play
On demand webinar
When: available now until May 2015
This webinar will update solicitors on medico-legal challenges around hospital acquired infections. During the session you will hear about the common hospital acquired infections, pre-hospital admission monitoring, hospital infection policies/infection control meeting, new generation of antibiotics and issues surrounding delay in treatment.
Presented by: Dr Peter Wilson, Consultant Microbiologist, University College Hospital
Location: Your desk
CPD points: 1 hour Bar Council & APIL

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Medical Legal Issues Arising from Bariatric Surgery

Live webinar

When: 24 April 2013, 12.00-13.00

This webinar will discuss the best practice in Bariatric Surgery. At the end of this session you will be able to identify negligent and non-negligent surgery and complications arising from the treatment.
Presented by: Marcus Reddy, Consultant Gastrointestinal Surgeon, St George's Healthcare NHS Trust, London

Orthopaedic Radiology

Live webinar

When: 5 June 2013, 12.00-13.00

This webinar will discuss the role of radiology in diagnosing fractures using X-ray, CT and MRI modalities. At the end of this session the viewer will be able to understand the role of different imaging techniques and how an orthopaedic injury maybe missed.
Presented by: Dr David Wilson, Consultant Radiologist, Nuffield Orthopaedic Centre, Oxford

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Professor Dominic Regan, Visiting Professor at City University, London

Working Productively with your Medical Expert

Recorded webinar
When: on demand – available now
This one hour pre-recorded webinar will discuss the best practice in instructing medical experts. This session will identify the current difficulties that may be encountered when dealing with medical experts and how best to approach them.
Presented by: Paul McNeil, Partner, Field Fisher Waterhouse LLP

Costs Budgeting

Recorded webinar
When: on demand – available from now until 24 September 2013
This webinar provides an overview of the requirements relating to costs budgeting, and practical tips to make sure the process is dealt with as efficiently as possible.

Presented by: Teresa Aitken, Managing Director, Pi Costing Ltd; &
Deborah Burke, Director, Deb- 

orah Burke Costing Limited

Oncology & GP Referral

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This webinar will discuss the duties of a GP in the treatment of cancer patients. At the end of this webinar you will be able to identify when cancer should be suspected and when a referral should be made.
Presented by: Dr Nigel Ineson, General Practitioner

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Presented by: Catherine Hopkins, Legal Director, AvMA; &
Richard Money-Kyrle, Partner, Darbys LLP

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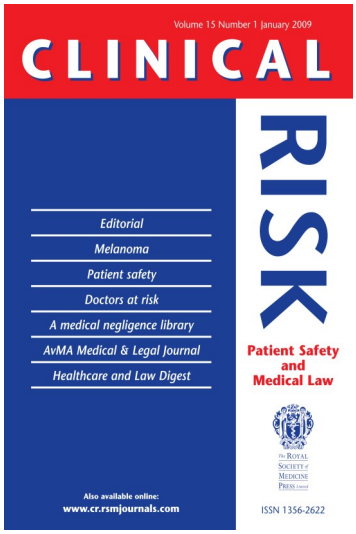

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