Health Legal Update

Introduction .........................................................................................................................................2

NHS Management: Monitor .........................................................................................................2
  DH seeks view on NHS pricing system .................................................................................... 2

NHS management: contract matters .....................................................................................3
  The inextricable link between insurance clauses and caps on liability: Can the former
undermine the latter? ....................................................................................................... 3
  Lifting the automatic suspension of a contract................................................................... 4

NHS management: real estate ...................................................................................................5
  Community Infrastructure Levy and section 73, double counting problem solved?........... 5

NHS management: list management .....................................................................................6
  National list proposed to track GPs, dentists and ophthalmologists ................................. 6

NHS management: regulatory matters..................................................................................6
  Roll out of Medical Revalidation: December 2012............................................................... 6

Employment.........................................................................................................................................7
  Employment Tribunal procedure: identifying and calling witnesses .................................... 7

Patient matters: children..............................................................................................................8
  GMC Child Protection Guidance now in effect ................................................................. 8

Patient matters: patient care......................................................................................................9
  Waiting for the Francis report ........................................................................................... 9

Patient matters: DOLs ..................................................................................................................10
  Court sets out approach to addressing questions of capacity in Deprivation of Liberty cases

Patient matters: provision of treatment and care ...............................................................11
  Use of NICE appraised medicines in the NHS in England: 2010 and 2011 ........................ 11
  Proposals for a new Clinical Trials Directive ........................................................................ 12

Patient matters: best interests................................................................................................12
  Permission granted for Trust to operate against cancer patient’s wishes........................... 12

Patient matters: health and safety........................................................................................14
  Health and Safety Executive consults on sharp instruments regulations ............................ 14

Patient matters: Mental Health Act....................................................................................... 14
  Further clarity on section 117 of Mental Health Act 1983 .................................................. 14
  EC v Birmingham and Solihull Mental Health NHS Trust .................................................... 15

Patient matters: safeguarding...................................................................................................15
  Changes to the Vetting and Barring Scheme ....................................................................... 15

Patient matters: inquests...........................................................................................................16
Introduction

Welcome to the latest edition of our Health Legal Update, which delivers you key developments within the health sector at a time where transition is advancing at a fast pace with much to do before new structures are established. The ‘People Transition’ process is now in its most intensive phase. It is also a time where effective joint commissioning across health and social care is highlighted as a key priority together with the development of a robust and diverse provider sector.

Next month heralds the introduction of the long-awaited medical revalidation system with all doctors licensed with the GMC having to demonstrate their fitness to practice. Clearly for revalidation to be a success it must work in tandem with robust and transparent clinical governance systems.

The articles we have for you this month highlight a wide range of duties from procurement through to safeguarding and regulatory as well as focusing on consultations arising from the Health and Social Care Act.

We shall be attending the NHS Alliance Conference and Exhibition in Bournemouth on 21-22 November 2012, which will focus on ‘The Road to Integration, Trusting local leadership, Innovation and Expertise’. If you are able to attend, please do look out for us at our stand.

As usual we invite you to look at the healthcare resource centre, health commissioning portal, procurement portal, health broadcast centre and our seminar programme. These are just some of the resources we provide to support you, another is our new online tailored inquest service, which helps health sector clients to control legal spend, reduce outlay on low risk inquests and offers fixed fees. If you are interested in learning more about this service, then please contact either Dawn Brathwaite on 0121 456 8224 or Stuart Knowles on 0121 456 8461.

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NHS Management: Monitor

DH seeks view on NHS pricing system

From April 2014, sector regulator Monitor and the NHS Commissioning Board (NHSCB) will take over responsibility for pricing NHS services from the DH through the national tariff. The DH has now launched a consultation on proposals for objecting to a proposed pricing methodology used by Monitor in setting the new national tariff. Under the Health and Social Care Act 2012, if a certain number of commissioners and/or service providers object then Monitor must either reconsider its pricing methodology or refer the matter to the Competition Commission for determination.
The DH is now consulting on setting the thresholds for triggering this objections process. It is proposing that the objection percentage thresholds be set at 51 per cent of the total number of commissioners and 51 per cent of the total number of providers (both unweighted and by share of supply).

According to the Government, an effective pricing system is critical to achieving value for money, and the national tariff will include prices for specified services or bundles of services, delivered to prescribed standards.

However, "it is not about the cheapest price. It is about paying a fair price for the services patients want, delivered to high standards," the DH stressed.

The consultation is open until 21 December 2012.

Monitor’s duties will include developing the methodology for setting prices, setting out the prices, and setting the rules for local price setting, where services are not included in the national tariff.

Commissioners will describe "what currencies [the unit of reimbursement for services] they will need in contracting for health services, while ensuring these are aligned with their priorities for service improvement."

The NHSCB will be responsible for defining the scope of the tariff, determining currencies, and setting rules to variations to the tariff.

For further information or advice please contact Tania Richards on 01223 222476.

NHS management: contract matters

The inextricable link between insurance clauses and caps on liability: Can the former undermine the latter?

The recent case of The Trustees of Ampleforth Abbey Trust v Turner & Townsend Project Management Ltd highlights how contractually committing to hold more insurance than the amount of the liability cap can render a limitation of liability clause unenforceable.

In this case, the judge decided that the limit on liability was unreasonable, and was consequently unenforceable, because Turner & Townsend had contracted to hold £10 million of professional indemnity insurance, which exceeded the contractual liability cap.

For NHS providers holding unlimited cover with the NHSLA, this may mean that inserting a liability cap has no legal effect.

However, one shouldn’t give too much emphasis to this point as only 11 paragraphs out of the 200 paragraph judgment dealt with it and so it was hardly a central issue in the case. In addition, insurance is often subject to an aggregate cap on the total value of all claims. This means that there is good reason to have a liability cap which is less than the insurance cover, to ensure that the insurance is not exhausted for future claims, or in order to avoid an increase in the premiums payable.

Providers should take note of this case and be wary of disclosing the full extent of cover within a contract, especially when dealing with third parties.

When commissioning, it is advisable to confirm what insurance cover a provider has in place, when dealing with the independent sector, and to record in the contract the minimum level of insurance the supplier commits to hold.
Obviously, in the NHS Standard Contract, liability is unlimited and so this issue does not arise.

For further information or advice, please contact Emily Brown on 01223 222496.

**Lifting the automatic suspension of a contract**

A recent case which involved two NHS bodies, *Newcastle Upon Tyne Hospital NHS Foundation Trust v Newcastle Primary Care Trust & Others*, demonstrates that when bidding for contracts NHS providers will seek a legal remedy (in this case, suspension of the procurement process) if a provider is of the view that the procurement is flawed. This is an important case on suspension of contract conclusion. Once proceedings are issued during the standstill period a contracting authority cannot enter into the contract. In this case, the court set out the issues to take into account an application to lift the automatic suspension.

Stockton on Tees Teaching Primary Care Trust (the PCT) had invited tenders on behalf of itself and three other Primary Care Trusts for a contract to provide diabetic retinopathy screening services (DRS services). Newcastle Upon Tyne Hospital NHS Foundation Trust (the Trust) had been partly providing the existing DRS services. Northumbria Healthcare NHS Foundation Trust (NHCFT) was the other provider. The Trust’s bid was unsuccessful and the PCT awarded the contract to another bidder. The Trust challenged the decision in March 2012, claiming that the PCT had breached its duties under regulation 4(3) of the *Public Contracts Regulations 2006* (the regulations) which requires contracting authorities to treat all economic operators equally, in a non-discriminatory way and to act transparently. The procurement process was therefore automatically suspended under regulation 47G of the regulations.

The invitation to tender and the template which bidders were required to complete specified that the minimum required screening activity was to be 80 per cent of the total North of Tyne diabetic population. The Trust submitted that the PCT had confused the “total diabetic population”, and the diabetic population which was “eligible” for screening and adduced expert evidence to show that it was impossible to screen 80 per cent of the total population.

Whilst the automatic suspension was in place, the PCT was informed that the other existing provider, NHCFT, which, along with the Trust provided the current DRS services, could not extend the contract after 1 October 2012. This would mean that whilst the automatic suspension was in place and with the possibility that the dispute could last a year or more, the PCT would be forced to enter into a short term contract with the Trust. The Trust offered to provide the entirety of the services after October but the PCT did not think adequate systems were in place for this. The PCT therefore applied for the automatic suspension to be lifted to allow them to award the contract to the successful bidder.

The court had to look at three issues in order to decide whether or not to lift the suspension using its powers under regulation 47H (note that these three issues reflect those considered when issuing interim injunctions).

- Firstly, does the claimant’s claim (ie, the Trust’s claim) raise a serious question to be tried?
- Secondly, if there is a serious question to be tried, when it came to trial, would damages be an adequate remedy for either party in relation to the lifting or non-lifting of the current suspension?
- Lastly, if damages were not adequate where does the balance of convenience lie? In looking at this last point, the court must have regard to the public interest and how it may be affected.
In relation to the first issue, whilst the court favoured the PCT’s arguments, it stated that the threshold for deciding whether there was a serious question to try was low and therefore it would reach its decision based on the other two issues.

As to the adequacy of damages, the court found that the Trust had not shown that damages would be an inadequate remedy for any losses it was likely to suffer. On the other hand, the court took the view that damages would not be an adequate remedy for the PCT as it would be left with a short term interim solution possibly involving the transfer of staff between numerous contracts. The court also made clear that damages are not a substitute for the procurement process being implemented according to the regulations and that this was in the public interest.

On the balance of convenience issue, the court found that it would not be just to either the PCT or the successful bidder to put the PCT in the position where they had no choice but to enter into a short-term contract with the Trust which had bid unsuccessfully. The court held that the balance of convenience favoured lifting the suspension because it would not be just to put the defendant PCT in a position where it had no choice but to award an interim contract to an unsuccessful bidder, who was the existing service provider, when the PCT did not consider that to be the correct course of action.

For further information or advice please contact Gill Thomas on 01223 222237 or Rona McPherson on 01223 222299.

NHS management: real estate

Community Infrastructure Levy and section 73, double counting problem solved?
The Community Infrastructure Levy (CIL) is a levy that local authorities can charge on new developments, in place, to a large extent, of imposing obligations under planning agreements (section 106s).

The “section 73 issue”
Under the Community Infrastructure Levy Regulations 2010, (CIL regulations), liability for CIL does not arise in respect of a development if, on the day planning permission is granted for that development, it is situated in an area in which no CIL charging schedule is yet in effect.

Under section 73 of the Town and Country Planning Act 1990, you can apply to vary a condition subject to which a planning permission has been granted and the result of such a successful application is that a new consent is granted.

If this is granted after a CIL charging schedule comes into force, the varied development could, under the terms of the original CIL Regulations, attract a CIL charge. This therefore risks a development being subject to both a negotiated section 106 package (pursuant to the original consent) and a CIL liability (pursuant to the section 73 consent).

Problem solved?
When in force, The Draft Community Infrastructure Levy (Amendment) Regulations 2012 will provide that there will be an offset of the CIL payable pursuant to a section 73 consent to the value of any CIL which would have been payable if the development was permitted by the original consent on the same date that the section 73 consent first permitted it.

The result of this will be that if the section 73 consent does not result in an increased floor space compared to the original consent, no CIL will be payable.
The regulations are not retrospective and will only apply to section 73 consents issued after the regulations come into force.

For further information or advice, please contact Caroline Bywater on 01223 222365.

NHS management: list management

National list proposed to track GPs, dentists and ophthalmologists

A Department of Health consultation proposing that in future there is one national list of general practice doctors, dentists and ophthalmic practitioners approved to provide NHS primary care services was launched on 19 October 2012.

Currently medical, dental and ophthalmic practitioners may not perform NHS primary care services in England unless they are included on a performers list held by a PCT. The performers list system provides PCTs with powers to manage these performers and protect the public from any that fall below the required standards. Currently, poorly performing doctors who are removed from one list can continue practising in other areas.

The consultation will consider recommendations made by two reviews that looked at the performers' list system. It discusses the three different options that could be pursued and the option that has been chosen.

It seeks responses to proposed changes, including:

- The introduction of national lists
- Changes to the “minimum service” that performers on the list will need to perform
- Changes to suspension powers, including immediate suspension and additional powers at suspension hearings
- Changes to the requirement to submit criminal records checks

The closing date for responses to the consultation is 14 December 2012. The 2012 Act requires changes to be made to the National Health Service (Performers Lists) Regulations 2004. From April 2013, the performers lists will become the responsibility of the NHS Commissioning Board.

For further information or advice, please contact Dawn Brathwaite on 0121 456 8224.

NHS management: regulatory matters

Roll out of Medical Revalidation: December 2012

The Health Secretary, Jeremy Hunt, has announced that medical revalidation, the process by which all doctors licensed to practise by the General Medical Council (GMC) will demonstrate that they are up to date and fit to practise, will commence in December 2012.

Doctors will continue to undergo annual appraisals but will, additionally, be revalidated every five years. Responsible Officers, appointed by designated bodies, will review the evidence from those appraisals (including any significant events, examples of quality improvement activity and feedback from patients and colleagues) in order to make a recommendation to the GMC about the doctor’s continuing fitness to practise. The GMC will then make a decision on the renewal of the doctor’s licence to practise.
The scheme has not been without its opponents and the road to revalidation has been anything but smooth. Concerns over who will bear the financial brunt of getting poor performers back on track were only put to bed to the British Medical Council’s satisfaction when the NHS Commissioning Board committed to supporting GPs who needed to take time out of work to complete retraining and said that commissioners would fund remedial placements and assessments for GPs. Many in management tiers, however, remain sceptical that remediation will root out and deal with that small but worrying percentage of deficient doctors who refuse to co-operate with existing systems.

For further information or advice, please contact Jane Williams on 0121 456 8421.

**Employment**

**Employment Tribunal procedure: identifying and calling witnesses**  
*North Bristol NHS Trust v Harrold* concerned a nurse who brought unsuccessful employment claims against North Bristol NHS Trust (the Trust) in 2004 and 2006. In 2006 the Trust referred the nurse to the Nursing and Midwifery Council (NMC) for alleged professional misconduct, citing two letters written by her in 2006 in which she made accusations about the Trust and its employees.

The nurse later brought a claim alleging victimisation. The tribunal decided during the hearing that the nurse was complaining of race discrimination in the letters she wrote in 2006 and could therefore rely on these for her victimisation claim. The Trust applied to adjourn the case so they could obtain evidence from those who referred her to the NMC. The tribunal refused on the basis the Trust should have called them as witnesses anyway as the reason for the referral was the critical issue. The tribunal upheld the nurse's claim, concluding that her claim against the Trust in 2006 was the reason they referred her to the NMC.

The Trust appealed the decision and argued that they should have been granted an adjournment due to the introduction of the race element in the claim. It also argued that the tribunal should allow the witness evidence from the employees who had referred the nurse to the NMC.

The court held that the tribunal did not make an error in its judgment. The Trust should have known to call those witnesses even before the tribunal's finding about race. The fact that they failed to do so did not entitle them to an adjournment to obtain this evidence.

The point to note from this case is that employers must be prudent in gathering all relevant evidence prior to a hearing, otherwise the tribunal may just proceed without giving a further opportunity to obtain that evidence.

For further information or advice, please contact Stuart Craig on 01223 222280, Martin Brewer on 0121 456 8357 or Jog Hundle on 0121 456 8206.

**Number of Employment Tribunals falls**  
The Employment Tribunal and EAT statistics for 2011/12 recently published by the Ministry of Justice reveal a 15 per cent fall in the number of employment tribunal claims. The number of claims is expected to fall further in view of the increase to the qualifying period for bringing unfair dismissal claims, which has been increased to two years for claims brought post 6 April this year. Of the total 186,300 claims accepted by the employment tribunal during the year, there was an average of 1.73 jurisdictional complaints per claim which resulted in the Tribunal accepting 321,800 complaints.

Of the 230,000 jurisdictional complaints disposed of, 33 per cent were conciliated by ACAS, 27 per cent were withdrawn, 13 per cent were struck out and 27 per cent were disposed of at hearing. ACAS look set to take on a
greater workload if pre claim ACAS conciliation becomes mandatory as proposed in the Enterprise and Regulatory Reform Bill, which recently received its first reading in the House of Commons.

The current forecast by the Government is a 20 per cent decrease in the number of claims as a result of the introduction of fees which is anticipated to be brought in by July 2013.

The statistics also demonstrate an uplift in the number of costs awards made by the Tribunal from 487 to 1,411. An overwhelming 92 per cent of those costs orders were made in favour of respondents. While these figures are skewed given that 800 of the 1,411 costs awards arose from a multiple case, the revised increase in costs awards from 487 to 612 perhaps still represents a slight shift in the attitude of the tribunal in favour of making costs awards.

The largest sum awarded by the tribunal in 2011/12 was £445,023 and was awarded in a race discrimination claim. Significant awards were also made in claims for age and disability discrimination. The highest unfair dismissal award of £173,408 was in excess of the statutory cap of £72,300, as the cap does not apply where the unfair dismissal is for whistleblowing or for raising certain health and safety concerns.

For further information or advice, please contact Simon Parkes on 0121 456 8398.

Patient matters: children

GMC Child Protection Guidance now in effect

We reported on the GMC Guidance on protecting children and young people in our August Health Legal Update which came into effect on 3 September 2012. The guidance followed a two year working group consultation about guidance for doctors when suspicions of child abuse arise. Mills & Reeve participated in the development of this important guidance by responding to the consultation.

The guidance advises doctors on:

- Their duty to identify the risk of abuse to children and young people, even when they are not their patient
- Balancing parental freedoms with child protection concerns
- The importance of communication with children, parents and families when there are child protection concerns
- How to balance respecting confidentiality with sharing information
- Good record keeping practice
- Seeking consent before conducting child protection examinations
- Developing an understanding of the work of other professionals involved in child protection
- The need for continuous training and skills development in this area
- Duties when acting as a witness of fact and as an expert witness in court

In relation to confidentiality versus information sharing, the guidance emphasises the importance of asking for consent to share information unless there is a compelling reason not to do so. For example, this could be the case...
if it is justified in the public interest or required by law. Additionally, the guidance emphasises the need to make sure that notes relevant to keeping a child safe are available to other clinicians providing care to them.

The issue of child protection examinations is explored in some detail in the guidance. This will be of particular help to clinicians who can find this to be a deeply sensitive issue which must be addressed with caution.

The guidance aims to reassure clinicians who may otherwise be nervous about raising concerns of abuse of children or young people for fear of making a mistake. The guidance states that even if the concerns are not founded, doctors will be justified if they can show the concerns were held honestly and reasonably. It will be interesting to see how the use of this guidance develops in practice.

For more information and advice, please contact Jill Mason on 0121 456 8367 or Helen Burnell on 020 7648 9237.

Patient matters: patient care

Waiting for the Francis report

The health and social care charity coalition, National Voices, claims another scandal on the scale of Mid Staffordshire Foundation Trust could occur while the health service is forced to wait for the delayed Francis report.

As readers will know a full public inquiry headed by Sir Robert Francis QC was launched in summer 2010. Its findings are now expected in January 2013. Publication has been delayed twice.

In response to the latest delay, National Voices has produced Not the Francis Report in which it says there is “growing evidence of systematic deficiencies in the way our services are designed and run, and growing concern among patient and professional groups about the quality and sustainability of our health and care systems.”

It says the NHS is under financial stress, subject to increased demand and that reforms are “distracting time and attention from front-line care.” Waiting for the Francis report, it says, is paralysing improvements to safety and care quality.

The report recommends:

- A change in the law to create a “statutory duty of candour” to overcome a “long-standing and persistent culture of secrecy, cover-up and authoritarian management in the NHS”
- Implementation of the Dilnot reforms as a necessary first step for ensuring sufficient funding for social care
- Urgent work to ensure that the safety and quality of hospital care does not vary according to how old the patient is or when they are admitted
- A concerted drive by NHS organisations to involve and listen to patients and carers

The NHS Commissioning Board, local health and social care commissioners, and the professionals need to lead on the creation of an integrated health service based around primary care

Sir Robert is due to present his final report to the Secretary of State in January 2013. It is expected that the report will propose far reaching changes at all levels of the system, including to the external organisations that regulate quality, so as to ensure that gross failings of the nature seen in Mid Staffs do not occur again.

For further information or advice, please contact Tania Richards on 01223 222476.
Patient matters: DOLs
Court sets out approach to addressing questions of capacity in Deprivation of Liberty cases

The recent Court of Protection judgment in the case of *CC v KK and STCC* is a very useful and detailed analysis of the approach to be taken when addressing capacity issues. This is also one of few cases where the Court has disagreed with the consensus of expert and professional opinion in relation to capacity.

KK was an 82-year-old lady, suffering from vascular dementia, Parkinson's Disease and paralysis of her left side. The Local Authority had taken the view that she lacked capacity and it was in her best interests to be placed in a nursing home. Initially her deprivation of liberty (DOL) was authorised, however, once trial visits to her own home commenced subsequent requests for authorisation were refused on the basis that there was no DOL. By the time of the final hearing, KK was spending part of every day visiting her own home.

She had challenged the standard authorisation and had always expressed a strong wish to return home.

Contrary to the unanimous views of the independent expert psychiatrist and all professionals involved, the Court agreed with KK that she had the capacity, at present, to make decisions regarding her residence and care.

The decision helpfully sets out the approach that courts should follow when addressing questions of capacity:

- The court must make the final decision in relation to the person’s functional ability after considering all of the evidence, not merely the views of the independent expert
- Professionals and the court should not be unduly influenced by the perceived need to protect the vulnerable adult (the “protection imperative”), but instead any assessment of capacity must be detached and objective
- The person need only be able to comprehend and weigh up the salient points relevant to their decision and not necessarily all of the peripheral details
- Different individuals may give different weight to different factors. This does not necessarily mean that an individual lacks capacity
- Capacity assessors must not start with a blank canvas. Instead the person must be presented with detailed options so that their capacity to weigh up the options can be fairly assessed

In this case, whilst KK underestimated some of her needs, she did not do so to an extent that would suggest that she lacked capacity to weigh up information.

In relation to the DOL the court decided that she was not being deprived of her liberty before the introduction of home visits and, once she was able to go home on a daily basis, the circumstances fell well short of a DOL.

It was KK’s disability itself which imposed a degree of restriction on her life and it was not considered that the circumstances of her placement in the nursing home significantly added to that restriction.

Pending the determination by the Supreme Court of the appeals in the cases of P and Q and Cheshire West, the judge noted that there is currently some uncertainty on the future interpretation of the DOL provisions. However, he...
said that “the right course is to have regard to the purpose for a decision as part of the overall circumstances and context, but to focus on the concrete situation in determining whether the objective element is satisfied.”

Whilst KK was completely dependent on others for her care and treatment, when considering the “relevant comparator”, anybody with the same disability would experience a significant physical restriction on the life that they are able to lead. There was no suggestion that the manner in which KK was cared for in the nursing home was significantly more restrictive than if she were to live at home in her bungalow.

Overall it was concluded that the arrangements for her care could not be described as continuous control and KK had not lost a significant level of personal autonomy as a result of her residence at the nursing home.

Since the joint appeals of Cheshire West and P and Q are unlikely to be heard by the Supreme Court until well into 2013, it is anticipated that the approach of Mr Justice Baker in this case is likely to be followed in similar cases in the interim.

For further information or advice, please contact Charlotte Mawdesley on 0121 456 8402, Jill Mason on 0121 456 8367 or Helen Burnell on 020 7648 9237.

Patient matters: provision of treatment and care
Use of NICE appraised medicines in the NHS in England: 2010 and 2011

As part of the Pharmaceutical Price Regulation Scheme, which came into operation on 1 January 2009, it was agreed between the DH and the Association of the British Pharmaceutical Industry that the DH would review the variation in the uptake of selected medicines in the NHS in England.

The NHS Health and Social Care Information Centre (HSCIC) was accordingly asked to produce a bulletin examining variation in the use of certain medicines in relation to the number of eligible patients as estimated by NICE. In the absence of data on the number of patients being treated, predicted use (utilising the average dose and length of treatment) was compared with observed use taken from prescribing data from NHS Prescribing Services and IMS Health. Some pharmaceutical companies also provided their own data.

The report covers 52 medicines and 35 Technology Appraisals, grouped into 25 therapy groups. Of these, it was possible to compare observed or actual use with expected use for 13 treatment groups. Of these, use appeared higher than expected for six and lower than expected for another six. For the drug ranibizumab (Lucentis), the results varied according to the method of calculation.

Although HSCIC’s Chief Executive cautions against reading too much into the experimental data, when there may be gaps in it, differences in demography and disease prevalence, small cohorts and local prescribing preferences, it is interesting to note that the drugs whose use was higher than expected included statins and drugs for osteoporosis, smoking cessation and type 1 diabetes, whereas drugs whose use was lower than expected included trastuzumab (Herceptin).

The data in the report is classed as “experimental” and HSCIC welcomes feedback on its future development.

For further information or advice, please contact Jane Williams on 0121 456 8421.
Proposals for a new Clinical Trials Directive

The European Commission has published proposals to amend the existing European Union (EU) Clinical Trials Directive. These are relevant for all NHS bodies carrying out clinical research on medicinal products. The 2001 Directive aimed to address the diverse approaches taken by European countries to regulating clinical trials. This was only achieved to a limited extent, as member states interpreted the directive differently and took varied approaches to implementation.

The proposed legislation will be in the form of a regulation, meaning the EU law will apply directly in each member state without the need for national regulation alterations. This will ensure that the rules for conducting clinical trials will be more consistent throughout the EU.

The key changes proposed are:

- Simpler authorisation procedure. This is particularly relevant to trials involving more than one EU country
- Protection of subjects and informed consent. The regulation does not change the substance of the rules, with the exception of new rules for urgent circumstances, however it does provide clarity
- Simpler safety reporting. The rules have been streamlined and follow the recommended guidance documents
- Conduct of the trial. The proposed regulation brings together rules contained in the 2005 commission directive and commission guidelines
- Investigational medicinal products, manufacturing and labelling. The proposed regulation brings together rules that are currently in different directives
- Co-sponsorship will be possible. Thus facilitating more partnership working between organisations
- Compensation for damages. This will remove the insurance requirements for clinical trials posing negligible risk and requiring member states to establish national indemnification schemes for non commercial trials
- Inspections. The proposed provides a legal basis for commission staff to perform inspections in member states
- Lighter regime for clinical trials defined as “low risk”

The proposed regulation will now pass through the EU legislative procedure and once agreed will repeal Directive 2001/20/EC. However, it is suggested that both sets of rules will apply in parallel for three years to ensure a smooth transition to the new regulatory regime.

For further information or advice, please contact Gill Thomas on 01223 222237.

Patient matters: best interests

Permission granted for Trust to operate against cancer patient’s wishes

In the case of An NHS Trust v K and another, the court had to consider whether it was in the best interests of K to have surgery against her wishes.
**Background**

K was suffering from cancer of the uterus. She also suffered from a psychotic disorder and a form of chronic schizophrenia. Potentially life saving treatment was proposed by her clinicians that would involve a hysterectomy, the removal of her uterus, fallopian tubes, ovaries and potentially her lymph nodes. Co-morbidities, including obesity, meant there was a risk that K could die during or after the operation.

K denied that she had cancer and resisted the operation. She lacked capacity to make informed decisions about major medical treatment. An earlier attempt to perform the surgery failed as K became agitated and resistant prior to anaesthesia. The treating clinicians and K’s sons favoured the operation despite the risk to her life. Expert evidence assessed the overall risk of mortality as 40-50 per cent. Another expert assessed the risk of perioperative mortality at around 5 per cent.

The court had to determine:

- If it was in K’s bests interests to have the operation
- If K could be lightly sedated before being told about operation, in the hope that this would make her compliant
- Whether there should be a ‘power of veto’ regarding surgery

The court concluded that:

- The benefits of the operation outweighed the risk of death. The risk was worth taking as she might be cured of cancer and spared a painful, undignified and premature death
- If no attempt was made to remove the lymph nodes the risk of morbidity was lowered. Therefore the operation should be limited to the hysterectomy, the removal of her uterus, fallopian tubes and ovaries
- It could be lawful and in K’s best interests to be sedated to enable the operation to take place. It would therefore be lawful for sedation to take place before she was told what was proposed
- The consultant in intensive care and psychiatrist should have the temporary power of veto

Doctors were not being ordered to take a particular step and it remained a matter for the professional judgement of the anaesthetist and surgeon about whether the circumstances merited sedation, anaesthesia and surgery. Although their consent was not needed for the operation, the operation would be put on hold if one of K’s sons notified doctors that he no longer supported the operation.

This case highlights the significance of presenting the court with evidence of, for example, the risks and benefits of proposed treatment, as this plays such an important part in the balance sheet exercise of determining what is in a patient’s best interests. It also shows the importance of involving families in discussions about the care and treatment being given to patients.

For more information or advice, please contact Sarah Garrood on 01603 693291.
Patient matters: health and safety

Health and Safety Executive consults on sharp instruments regulations

The yearly reporting of 40,000 sharp injuries in the healthcare sector is a cause of worry in the NHS. A new European Directive aims to reduce that number.

EU countries must implement the directive’s provisions into national law by 11 May 2013. The Health and Safety Executive (HSE) is therefore seeking the views of NHS managers on UK proposals to introduce new regulations to protect health sector workers against the risk of injury and infection from sharp medical instruments.

In summary, HSE’s proposal, is to require healthcare employers and their contractors to:

- Have effective arrangements in place for the safe use and disposal of medical sharps
- Provide necessary training and information to workers
- Investigate and follow up work-related sharps injuries

This is a good opportunity for NHS managers to have a hand in shaping the implementation of the Directive. To participate responses should be sent to Michael.wood@nhsconfed.org by 8 November 2012.

For more advice and information, please contact Duncan Astill on 01223 222477.

Patient matters: Mental Health Act

Further clarity on section 117 of Mental Health Act 1983

The Court of Appeal handed down judgment on 9 October 2012 in a dispute between Sunderland City Council (S) v South Tyneside Council (T).

The issue was which of the two councils was the local social services authority with responsibility under section 117 of the Mental Health Act (MHA) for the aftercare of a young woman after discharge from the hospital where she was receiving treatment and was detained under the MHA.

The patient had been a student at a college in S’s area from 14 September 2009 to 3 October 2009. Following an attempt to commit suicide she was moved to a hospital in T’s area. She consented to this move. She was then detained under section 2 MHA on 10 October and section 3 MHA on 24 December. On 23 October (so after her detention under section 2) her placement at the college was terminated. This meant that she lost her licence to live in the halls of residence.

It was agreed that she was resident in S’s area up to 3 October 2009. The key issue in the case related to what happened after she ceased to be resident there.

At first instance the court decided that she had been resident at the hall of residence in S’s area and that she was not present at the hospital in T’s area for a settled purpose. This was because her presence in the hospital was not for a “settled purpose”.

The Court of Appeal disagreed.

They thought that the guidance in the case of R v Barnet LBC ex p Shah on the meaning of “is resident” was not helpful.
They noted the decision in *R (Hertfordshire County Council) v Hammersmith and Fulham LBC* that any period of compulsory detention is to be excluded and that the word residence, in section 117, does not mean the same as ordinary residence in s48 National Assistance Act 1948.

They then referred to another case involving the same *Mohamed v The London Borough of Hammersmith & Fulham*. They observed that in this case, the court was of the view that the meaning of normal residence was a place where at the relevant time the person in fact resided and that so long as the place where that person ate and slept was voluntarily accepted by them the reason why they were there and not somewhere else did not prevent that place from being their normal residence.

This meant that when the college terminated the placement on 23 October the only place that the patient could have been regarded as resident was the hospital in T’s area.

For further information or advice, please contact Jill Mason on 0121 456 8367.

**EC v Birmingham and Solihull Mental Health NHS Trust**

A recent Upper Tribunal decision in *EC v Birmingham and Solihull Mental Health NHS Trust* dealt with two appeals which raised the question whether a patient detained under the *Mental Health Act 1983* can challenge a decision by a First Tier Tribunal to refuse to make an extra statutory recommendation as to future care or treatment.

The Upper Tribunal here would not express any view as to the circumstances in which the First Tier Tribunal should or should not make extra statutory recommendations in mental health cases save that, if some panels are routinely spending a great deal of time considering issues not necessary for the exercise of their statutory functions for no better reason than that a party has asked them to do so then they would deprecate that practice.

The Upper Tribunal observed that courts and tribunals of all types and at all levels make comments or suggestions that are not necessary for their decisions but that it is a matter of judgment when to do so. Among the matters taken into consideration are likely to be whether the court or tribunal considers itself sufficiently well informed to make a useful comment or suggestion, and whether doing so is likely to be seen as inappropriate interference with another body's decision making.

They commented that if extra statutory recommendations are regarded as a useful contribution to decision making in a significant number of cases it may be that consideration should be given to either formalising such recommendations (through a Practice Direction) or legislating.

Finally, they also highlighted that the responsible clinician had not needed to attend. They suggested that the Upper Tribunal needed to publish guidance for hospital managers as to what is expected of them when they are respondents to appeals but do not wish to take an active role.

For further information or advice, please contact Jill Mason on 0121 456 8367 or Ruth Creed on 0121 456 8323.

**Patient matters: safeguarding**

**Changes to the Vetting and Barring Scheme**

Draft regulations titled *Protection of Freedoms Act (Disclosure and barring Service Transfer of Functions) order 2012* have been published, which transfer the functions of the Independent Safeguarding Authority (ISA) and the functions of the Secretary of State in England and Wales under various Acts to the Disclosure and Barring Service (DBS).
Currently the ISA is responsible for maintaining the barred lists which work to bar inappropriate people from engaging in regulated activities relating to either children or vulnerable adults. It also has functions relating to the exchange of information with providers of regulated activities. However, the 2011 review of the Vetting and Barring Scheme recommended a scaling back of the criminal records checking and barring system and suggested streamlining these processes by creating a new, single organisation.

This new organisation is the DBS which takes over the functions of both the Criminal Records Bureau and ISA. It will be a non-departmental public body of the Home Office. A number of reforms will be implemented by the DBS which will result in a reduction in the number of posts requiring checks from 9.3 million to 5 million. These changes will come into force on 1 December 2012.

For further information or advice, please contact Tania Richards on 01223 222476.

Patient matters: inquests

Court rules that even though article 2 doesn’t apply coroner can still call a jury

In the case of R (on the application of Kent County Council) v HM Coroner for the County of Kent and Mr and Mrs Barry, Kent County Council applied for judicial review of the decisions of the Coroner that:

- Article 2 of the European Convention of Human Rights applied to the inquest into the death of a 14 year old boy, Edward Barry
- That the inquest should be held with a jury

The deceased was a 14-year-old who was known to social services (but not looked after by them). The boy was struggling with a methadone addiction and the parents had sought help from the council. The council had tried to find a foster placement for a short period but were unable to and the boy then died from a methadone overdose (which did not appear to be deliberate).

The Coroner had ruled that it should be an article 2 inquest with a jury to examine in detail the council's response to the parent's concerns. The council sought to have the Coroner's decisions judicially reviewed. The court ruled that there was no operational duty on the part of the council because it could not be shown that there was a real and immediate risk of harm, therefore there could be no breach of the operational duty as required for article 2 to apply. If there was no breach of the operation duty then the procedural duty to carry out an article 2 inquest did not arise.

Despite this the court also said that the coroner was within his rights to call a jury in any event.

For further information or advice, please contact Jacqueline Haines on 0121 456 8453.

Prisons and Probation Ombudsman and the Coroners’ Society publish updated Memorandum of Understanding

The Prisons and Probation Ombudsman (PPO) and the Coroners’ Society (CS) have published a revised version of their Joint Memorandum of Understanding (MoU).

The purpose of the MoU is to promote effective working relationships between the two organisations in relation to investigations into the death of prisoners in custody.
It recognises that the remit of the two organisations is different and helpfully summarises the PPO’s terms of reference for its investigations as follows:

- To establish the circumstances surrounding the death
- To consider whether any changes in operational matters would help prevent a recurrence
- To examine the relevant health matters
- To provide explanations for relatives
- To assist the coroner’s inquest to fulfil article 2 of the European Convention of Human Rights by ensuring the full facts are brought to light

The PPO investigation must include:

- An examination of the records
- A visit to the establishment where the death occurred
- Meetings with relevant staff and other prisoners (which will usually be recorded)
- A clinical review

Investigators are expected to maintain contact with the police and the coroner, although it is stressed that the investigation is not carried out on the coroner’s behalf who must conduct his own investigation. The MoU also requires the coroner to provide the PPO investigator with the post mortem report and in turn the PPO will disclose redacted documentation to the coroner unless there are any specific reasons it should not be disclosed, for example, if it is felt that disclosure could jeopardise the security of the establishment where the death occurred. The coroner must not disclose the information to other interested parties without consent from the PPO.

The MoU also recognises that the PPO investigator may be called to give evidence at the inquest by the coroner and that he may be asked questions about issues that might not be central to the inquest but are nonetheless of concern. For example where, recommendations have been made in earlier cases but not acted upon and which could have made a difference to the case in question. It also recognises that the PPO investigator might also be asked to give evidence about national legislation and guidelines concerning the prison service.

For further information or advice, please contact Jacqueline Haines on 0121 456 8453.
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