

WHITE PAPER

Communicating and Enforcing Hospital Policies: The Legal Backdrop

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Though commonplace in the U.S., the concept of hospital policy enforcement and 'credentialing' for commercial visitors is relatively new to the UK. Its primary aim is to safeguard patients, staff and the hospital itself by managing access to sensitive areas, improving infection control and ensuring that the right people have the right credentials to be in the right hospital zones.

Policy enforcement, where it has been implemented, has helped improve patient safety and driven down costs.

Most UK hospitals have not yet implemented a specific policy compliance and enforcement service. But that doesn't mean there aren't good legal, clinical, and budgetary reasons to do so. This White Paper gives a brief backdrop to the topic and goes on to look at some of the legal aspects that hospitals may want to review when considering whether a service is right for them.

What Is Policy Enforcement?

It is a service for communicating and managing compliance with hospital policies, managing check-in and enforcing credentialing: the process of obtaining, checking and assessing commercial visitors' qualifications to visit restricted or patient-sensitive areas. It helps ensure that commercial visitors:

- are properly immunised if visiting patient sensitive areas
- have had appropriate training and relevant background checks
- fully understand health and safety procedures of the location they are visiting
- have demonstrably agreed to be bound by relevant hospital policies and procedures.

Policy enforcement, by managing sales visits, also assists procurement departments by making it harder for representatives to circumnavigate central buying policies e.g. through unscheduled sales visits to individual clinicians.

Why should hospitals be considering policy enforcement?

Policy enforcement, where it has been implemented, has helped improve patient safety and driven down costs. The positive impacts have been such that these hospitals now consider it "due diligence" rather than simply an option for improved operational efficiency and patient safety. It is a mechanism for minimising exposure to a set of specific but manageable risks created by having commercial visitors on-site, something which is necessary in the modern healthcare environment.

As a result, the UK is now looking to see what policy compliance and enforcement has to offer. Some of the driving factors for this are:

1. Patient safety - an NHS priority

2014 saw Health Secretary Jeremy Hunt launch the 'Sign up to Safety' campaign to safeguard patients and reduce preventable harm, with the aim of saving 6,000 lives over the next three years. Tackling preventable healthcare associated infections such as MRSA is a key NHS priority. Therefore, ensuring commercial visitors have received relevant immunisations and training on infection control/decontamination policies and procedures is vital. Indeed, according to the National Audit Office, compliance with hospital policies is among the top three most important measures for combating hospital infections.

2. NHS budgets

The NHS is facing a deficit of some £2 billion and in 2014, for the first time in eight years, almost a quarter of NHS hospitals reported an annual loss. Now consider that the annual amount set aside by the NHS for negligence claims is £22.7 billion – alarmingly, an amount exceeding the entire non-pay budget of the NHS.

Another important cost area is NHS supplies, covering anything from catering items to forceps and knee implants. A report by consultants Ernst and Young at the end of

2012 revealed that pricing disparity in the supply of products is costing the NHS £500m a year – a massive drain on the NHS budget. The causes of this are many and varied, and include the sidestepping of central procurement by representatives and the purchase of unsanctioned products without sign off from procurement.

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The sums therefore make a compelling case for reducing risk and avoidable expenditure – two areas that policy compliance and enforcement help address. The situation is similar in the private healthcare sector, where managers face the same pressure to keep costs down and clinical standards high.

Legal and ethical obligations

The mention of negligence claims immediately thrusts legal considerations into the spotlight. What are the main issues that hospitals need to be aware of in this respect? A useful starting point is the following from the NHS Code of Practice 2003:

'Anyone who is invited into hospitals or any areas of clinical care in an advisory capacity is bound by the same legal and ethical obligations of those employed by the hospital.'

In other words, commercial visitors - for example medical device experts visiting clinicians or administrative teams on hospital premises - effectively become members of staff in the eyes of the law. As a result, the hospital is potentially liable for their behaviour and actions, and the impact of these, on the safety of staff and patients.

When you consider that, for example, one of the UK's largest NHS Trusts, Leeds Teaching Hospitals, has around 30 such visitors on hospital premises at any one time, the level of responsibility and need for risk management should be clear.

The legal view that commercial visitors are members of staff while on site also places a

responsibility on the hospital as an 'employer' to ensure their security and safety.

The Management of Health and Safety at Work regulations (1999) therefore apply. They state that every employer shall make a suitable and sufficient assessment of:

- *The risk to health and safety of persons not in his employment, arising out of or in connection with the conduct by him or his undertakings.*
- *The risks to the health and safety of his employees to which they are exposed while at work.*

Not only does the law require that employers carry out risk management assessments, but they must also provide clear written evidence that they have done so.

In the eyes of the law, therefore, hospitals have a duty of care for commercial visitors and are vicariously liable for their actions while these visitors are on site. Vicarious liability refers to a situation where someone is held responsible for the actions or omissions of another person. In this context the hospital as 'employer' is liable for the acts or omissions of commercial visitors as 'employees', provided it can be shown that these acts or omissions took place in the course of their employment (i.e. visit to the hospital). In view of this, it is vital that hospital managers ask themselves:

- Do I know, at all times, what commercial visitors we have on the premises?
- What is the extent of their activities?

Assessing and managing risk

Given that hospitals have a legal obligation to assess risk and prevent commercial visitors from harming others or themselves, are the risks really that great? Potentially, yes.

Commercial visitors often have very close contact with patients, and work in sensitive hospital areas where following decontamination protocols or having the right immunisations can significantly impact patient outcomes.

In the UK it is common practice for representatives from medical device companies to attend and verbally assist, in a technical capacity, procedures involving their products.

For example, representatives may be present in theatre to assist with a surgeon's use of a particular instrument, implant or other product. The level of expertise offered can be such that procedures may be cancelled if the appropriate product specialist is not present.

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Of course, 'medical involvement' (i.e. an attending representative making a medical judgment or participating in the procedure) is prohibited and should this occur then the hospital, the medical device representative and the company they represent could be held liable should there be an adverse incident as a result of those actions.

But risk is not restricted to the operating theatre. Any commercial visitor on site has the potential to directly influence patient health outcomes through their actions, omissions or health status. That is why training is so important.

This is highlighted by industry bodies such as BAREMA (the Association for Anaesthetic and Respiratory Device Suppliers) in their support and promotion of best practice training for industry representatives. Infection control, decontamination, consent, confidentiality, risk management and operating room procedures/protocols are just some of the areas that representatives should have training on before entering hospital premises in a consultative capacity.

But what if commercial visitors don't have the necessary training or if a particular visitor known to a hospital has changed companies or product specialism? Expecting them to have the necessary training and assuming that they do, is very different to demonstrating verifiable competence – particularly in terms of liability and negligence.

It is also important not to forget the training obligations of those medical professionals that healthcare industry representatives advise:

*"A healthcare organisation could be held responsible, under both health and safety law and civil liability in the event that a patient or member of personnel died or suffered personal injury or damage, as a result of inappropriate purchase or prescription of a device."*¹

(Managing Medical Devices Bulletin April 2014)

Risk assessment and management processes therefore need to include analysis and verification that hospital personnel have received the right level of training on a product or device. In this respect, it could be argued that an audit trail showing that a representative has visited a site and delivered training to a member of hospital staff is just as important as checking the representatives' credentials.

Vicarious liability and medical negligence

In admitting a patient, hospitals immediately take on a 'duty of care' for that individual. For medical negligence claims against a hospital to be valid both of these parameters need to be established:

- A breach in that duty of care is established
- AND
- The breach is proven to have caused harm to the patient

So, what has this to do with policy compliance and enforcement? Consider the following scenario.

A patient is admitted to surgery for a hip implant that is new to the market. Though he has received training, it is the first time that the surgeon has used this implant, and so a representative from the medical device company is present for consultation during the procedure. The surgery goes well but the patient develops an infection during the post-operative recovery phase.

On investigation it is found that the representative has not been appropriately trained in theatre protocols for decontamination and hand hygiene and is the likely source of infection. The infection occurred during surgery and would have been avoided had correct protocols been followed.

Applying the first of the above parameters, by not following protocols, a breach in duty of care can be established. The second parameter is established by the fact that the infection developed by the patient during the post-operative recovery phase has harmed the patient.

This is therefore a case of medical negligence. However a secondary question now arises – namely who is liable?

¹ Managing Medical Device Bulletin April 2014
Retrieved from:

As we have previously established, while on hospital property and working in a consultative capacity the representative is the responsibility of the hospital. Because the hospital failed to check that the representative - effectively an employee here - had the appropriate training in theatre protocols, a patient was harmed while in the hospital's care. It was a foreseeable risk that could have been avoided. Therefore the hospital is deemed liable.

This is just one scenario, but it demonstrates that the legal implications of the privileged access to patients and property that representatives have (and need) in doing their job are not always cut and dried.

The small print of the commercial visitor's liability insurance often stipulates that cover is only valid if the individual specifically signs-in for each visit to denote that they are on formal 'company business'.

Furthermore, often only material contribution has to be proven i.e. the contribution to blame has to be 'more than minimal'. It's possible, for example, that something as apparently harmless as a reduction in the hospital's cleaning budget could contribute to a patient contracting a harmful bug that might have serious health implications. As long as contribution to blame is more than minimal, there is a potential claim against the hospital. With that in mind, it is easy to see how the hospital's failure to suitably enforce patient safety policies and hospital procedures could come under fire.

The importance of commercial visitor sign-in

A common expectation that hospitals have is that commercial visitors are covered by general liability insurance, which protects them, and their employer against third-party claims arising from incidents for which they and the hospital may be held liable.

However, an important point which can often be missed is that the small print of the commercial visitor's liability insurance often stipulates that cover is only valid if the individual specifically signs-in for each visit to denote that they are on formal 'company

business'. If sign-in does not happen, then liability coverage may not be in place – something that needs to be borne in mind when a hospital is reviewing its sign-in procedures.

The policy compliance and enforcement protective umbrella

Managing risk to avoid the liability issues outlined in this paper cannot be accomplished in one single step and policy enforcement is not the sole answer. But it can significantly help by:

- assisting the hospital to demonstrably execute on its duty of care obligations
- ensuring that commercial visitors meet the hospital's requirements for access to patient sensitive or restricted areas
- ensuring that hospital management know who is on site at any time, and why
- providing an audit trail of activity

In effect, it is a vital safety umbrella that can not only reduce risk to patients but also reduce risk and cost for the hospital.

Negligence and liability are sometimes overused words in healthcare settings, and can lose their meaning - until a theoretical case becomes reality. Effective risk management is essential to protect patients and healthcare providers - and so policy compliance and enforcement is an important consideration that everyone should address.



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