

Revealed: High level fears over patient consent abuse

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The Care Quality Commission and NHS England have raised concerns that the current system for securing patient consent for treatment is open to abuse. It comes amid allegations that some doctors have retrospectively altered consent forms, HSJ can reveal.

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In a letter seen by HSJ, the two bodies wrote to General Medical Council chief executive Niall Dickson to warn that patients were not always being given copies of their completed consent forms.

The concern is that this leaves scope for rogue clinicians to amend forms after the treatment to hide mistakes or procedures undertaken without informed consent.

Investigations by HSJ have identified two cases where there are allegations that consent forms have been amended; another where forms were retained by a hospital trust; and a case of a patient being treated without consent. Clinical negligence lawyers have also expressed concerns over the current consent process.

Invasive procedures without consent, such as surgery, can be considered criminal assault under common law.

The intervention by the CQC and NHS England came after executives at the inspectorate met with the son of a patient who believes his mother's consent form was altered after surgery at Nottingham University Hospitals Trust. The trust denies the claims.

Sir_Mike_Richards5

CQC inspectors always look at medical records including consent forms, Sir Mike Richards said Nottinghamshire Police told HSJ it was currently "working with" John Clarke, whose mother now has terminal cancer, to ascertain the facts of his allegations.

In a separate incident, a 2013 CQC investigation of the privately run BMI Mount Alvernia Hospital in Surrey revealed a consent form filled out in two different coloured pens, with some details scribbled out. Inspectors were told the form had been changed after it was discovered a patient had been scheduled for two procedures but had only consented to one.

Mr Clarke told CQC chief executive David Behan that consent forms were often completed with procedures written in the centre of the page, leaving space for additions to be made retrospectively.

Mr Behan later said in a letter to Mr Clarke that while the CQC did not have “any solid proof that the consent system is being abused as a consequence”, it was “aware of allegations that this has happened”. He was persuaded “that there is a potential for retrospective additions to be added”.

Writing to Mr Dickson in October, CQC national adviser on safety James Titcombe and NHS England director of patient experience Neil Churchill called on the GMC to review its 2008 guidance on patient consent. They noted that the Department of Health no longer issued standard consent forms, as responsibility for their design was handed to trusts in 2009. They said this increased the importance of the GMC’s guidance to doctors.

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They suggested that patients’ interests would best be protected if they were always given a copy of the consent form or asked to initial the form to confirm they did not want it. They added that there may be “better ways of registering consent” such as a “template that requires each procedure to be written in a separate box”.

Mr Dickson replied in November that the GMC shares “your concern about the alleged amending of forms” and said the 2008 consent guidance was due to be reviewed in the near future.

However, while he wrote that there “may be more we can say” about recording consent and sharing those records, the doctors’ regulator considered it beyond its remit to give “detailed operational advice” on how good practice principles should be applied. It did not, therefore, provide model consent forms or give advice on “the structure or content of forms”.

The GMC told HSJ it would begin the 18 month process of revising its guidance, including public consultation, around the end of this year.

David Lock QC, a healthcare barrister and former Labour government minister, authored two chapters on consent in the textbook Principles of Medical Law.

He told HSJ a robust system for consent was “protection for good doctors because it ensures doctors do not commit criminal offences and only undertake medical procedures where proper consent has been given... Having lax procedures around consent is a recipe for disaster.”

He said there was an “overwhelming” case for the Department of Health, Monitor or NHS England to mandate a single consent system.

CQC chief inspector of hospitals Sir Mike Richards said consent was one of the fundamental standards it uses to assess providers, and that inspectors “always” look at medical records including consent forms. He added: “Should any further evidence of consent form alteration be given to us we would, of course, investigate further.”

A DH spokeswoman said: “It is essential that patients’ rights are respected and we expect robust action to be taken against any individual or organisation that does not follow fundamental guidance on consent.”