

NPSA launches *Never Events* policy

The National Patient Safety Agency (NPSA) has launched a ***Never Events*** policy for the NHS in England.

The eight core *Never Events* identified by the NPSA are serious patient safety incidents that should not occur if preventative measures have been put in place.

From April 2009 primary care trusts (PCT's) will use the policy to ensure that they commission the safest services for patients, working with hospitals and other health care providers to monitor and publicly report *Never Events* annually. PCT's will use contractual obligations to require providers to report and conduct investigations into *Never Events*.

The *Never Events* identified are:

- Wrong site surgery
- Inpatient suicide using non-collapsible rails
- Wrong-route administration of chemotherapy
- Retained instruments post-operatively
- Undetected misplaced naso/orogastric tube
- Escape of prisoners from secure NHS mental health units
- Maternal deaths from haemorrhage following caesarean section
- I.V. administration of mis-selected Potassium Chloride

www.npsa.nhs.uk

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NEWSLETTER CLINICAL NEGLIGENCE

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Consent

Welcome to the Summer edition of the [JMW Clinical Negligence](#) newsletter.

In liberal democracies it is generally accepted that there exists a moral obligation to respect the autonomy (or self determination) of others and it is this that underlies the requirement for consent. It is an ethical principle reflected in legal rules and is particularly important in medicine where attempts to do good often involve risk of harm.

In order to be valid, consent must be given voluntarily by a person who is *appropriately* informed and who has the requisite capacity either to consent or to refuse treatment. Consent does not necessarily have to be written and may be expressed or implied.

Although there is little dispute nowadays about the moral and legal imperative to obtain consent from all patients there remains some disagreement regarding the extent of information required for this consent to be valid.

Some still hold the (somewhat paternalistic) view that some patients are not capable of making an informed decision when presented with a choice of complex procedures, all of which involve certain risks. Assessing the comparative risks of different treatments is notoriously difficult, and patients may be more or less keen to be involved in the decision making process.

However, providing insufficient information for a patient to make an informed decision about treatment may be a breach of duty, as illustrated in the first of our case studies in this newsletter.

In English courts the burden of proving lack of consent is upon the patient, although this is not so in all countries.

Consent case study 1

62 year old EG had a long history of lower back pain and sciatica. She underwent spinal surgery in 1999 followed by a number of facet joint injections, but her pain continued.

In May 2003 her consultant (Mr S) advised further spinal surgery involving bilateral decompression of some of the lumbar nerves. EG was keen to proceed as her pain was becoming intolerable and disabling.

In March 2004 EG was admitted to hospital and consented to “*instrumented fusion L4 – S1 + L4/L5 nerve root decompression*”. Consent was obtained by Mr N, a locum spinal surgeon, whom EG had not previously met. Mr N claims that he discussed the planned operation with EG in some detail and warned of possible risks and complications, but this is not documented. EG remembers nothing of the consenting procedure and it is unclear whether she signed the consent form before or after administration of the pre-medication (Temazepan).

The surgery actually performed by the locum, Mr N was more extensive in nature and more risky than the operation originally contemplated by the first consultant (Mr S) or expected by EG. During the very lengthy operation there was excessive blood loss suggesting possible inexperience on the part of the surgeon.

Post operatively EG had problems passing urine and then developed a degree of perineal numbness – in other words symptoms of incomplete cauda equina syndrome. Although at first the back pain seemed to have settled it soon returned. These symptoms were almost certainly due to compression of the sacral nerves during surgery.

EG now has no bladder control and has to self catheterise routinely to avoid incontinence. She also suffers from frequent urinary infections. The pain in her back is now worse than before the operation and her lumbar spine flexes to only 20 degrees. She is considerably disabled and no improvement is anticipated.

EG claimed that had she been aware of the seriousness of the operation and the fact that it was intended to insert metalwork into her spine she would not have consented, on the basis that the risks were too great.

Before the exchange of evidence could take place the defendant made an offer of £150,000, which was accepted.

Consent case study 2

JP was 40 years old when, in mid 2004, she noticed a lump in her vagina. Her GP referred her to a consultant gynaecologist who made the diagnosis of urethral cyst and referred her to a consultant urologist for a further opinion and treatment.

She saw the urologist in November 2004 and he advised surgical removal of what he considered to be a large para-urethral cyst. JP was told that this was a minor operation and possible complications were not discussed.

At operation 3 weeks later it became clear that the diagnosis was incorrect and that in fact JP had a urethral diverticulum (bulging of the urethra) rather than a cyst on the outside of the urethra. The removal of the diverticulum involved cutting into the urethra and the resulting defect was sutured.

Post-operatively the sutures in the urethra broke down resulting in a urethro-vaginal fistula (a known complication of this type of surgery) and an unsuccessful attempt was made to repair this in January 2005.

JP continued to leak urine per vagina which, understandably, she found distressing, embarrassing and socially isolating. She was referred to a specialist urologist who undertook further repair surgery in September 2005. This was successful as far as the urethral repair was concerned but left JP with stress incontinence. Further surgery to rectify the incontinence in May 2006 resulted in urinary retention.

Although no longer incontinent JP now has to self-catheterise regularly and because of this suffers from recurrent urinary tract infections. She has been advised not to undergo any further urological surgery which means that this situation is likely to be permanent.

It was alleged that the first urologist had breached his duty of care to JP by failing to make a correct diagnosis of urethral diverticulum. Had the correct diagnosis been made, some kind of imaging (either MRI or ultrasound) would have been undertaken and JP would have been informed of the possible complications of surgery, including urethro-vaginal fistula.

Had she been aware of these risk factors JP would not have consented to the surgery. She had no pain and little discomfort and was a single mother with a small child and solely responsible for a mortgage.

The case was eventually settled for £150,000 to include considerable loss of earnings.