REVIEW

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The numeric threshold for the disclosure of risk: outdated and inapplicable to surgical consent

R Wheeler

Southampton General Hospital, UK

ABSTRACT

When describing the risks of surgery to a patient, there is a common and mistaken supposition by surgeons that there exists a numeric threshold of improbability beyond which there is no need to disclose. Where should the line be drawn?

KEYWORDS

Numeric threshold – Disclosure – Consent – Risk – Complications

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CORRESPONDENCE TO

Robert Wheeler, Consultant Paediatric and Neonatal Surgeon, Southampton University Hospitals NHS Trust, Tremona Road, Southampton SO16 6YD, UK

T: +44 (0)23 8079 4144; E: robert.wheeler@suht.swest.nhs.uk

Patients facing surgery may be at risk of devastating complications, the existence of which they have no knowledge. Why should an operation on your spine render you incontinent? Or unilateral ocular surgery result in bilateral blindness? Or a hernia repair reduce a man's chance of fathering children?

Such risks may seem readily foreseeable to doctors but are invisible to patients unschooled in medical science. Nevertheless, it would seem likely that most patients would wish to consider these risks while coming to a decision concerning consent.

Despite this, doctors are comfortable with ubiquitous numeric thresholds to guide their interventions and depend on plasma levels, physiological or radiological measurements to carry a patient across a threshold from non-treatment to treatment. However, the numerical risk of most complications of therapy is usually low and may not be caught by a realistic threshold. Is it right that such a threshold should (inadvertently) conceal relevant matters from the putative patient's consideration?

Courts have briefly explored the notion of a numeric threshold. In 1980 a Canadian court held that a 10% risk should automatically be disclosed when obtaining consent (in this case, to disclose the possibility of a stroke following surgery).[1] This built on the American concept of a material risk, where a reasonable person in the patient's position is likely to attach significance to the risk.

Since then, courts have steadily distanced themselves from a numeric threshold. Three years later, an American case determined that a 200:1 complication rate would not equate to a material risk.[2]

In a 'landmark' English consent case, one of the five judges, Lord Bridge, asserted that a 10% chance of grave adverse consequences of surgery should be disclosed.[3] Eventually, the court held that Mrs Sidaway, who had suffered spinal cord damage after surgery, failed to prove that a prudent patient would regard a <1% complication rate as constituting a significant risk.

In 1997 it was held that there was no certainty that an unqualified duty to disclose a risk of around 1% existed, in the context of a family who were not told that permanent neurological damage could flow from cardiac transplantation surgery.[4] An Australian case had held that the failure to warn of the 14,000:1 risk of blindness following ophthalmic surgery fell below the reasonable standard of care.[5] From the legal perspective, this was the death knell of the numeric threshold. To disclose all risks of this frequency would be impractical. The court was demanding that significant risks should be disclosed, irrespective of the likelihood of occurrence. The UK courts followed this lead in 1995, holding that failure to disclose the risk of spontaneous vasectomy reversal (2,300:1) equated to substandard care.[6]

The explicit switch from a quantitative to a qualitative approach came in a maternity case, when a patient lost her baby.[7] She had reluctantly agreed to the deferral of her delivery, in the absence of full disclosure of the possible consequences of so doing. Lord Woolf, giving the leading judgement, held that it was not necessarily inappropriate to fail to disclose a risk in the order of 0.1–0.2% but that the correct standard was to disclose '… A[ny] significant risk which would affect the judgement of the reasonable patient.'

In a subsequent case where it was held that there was a failure to warn parents of the risk of fetal abnormality of a pregnancy that coincided with maternal chickenpox,[8] the threshold that the disclosure had to satisfy was that of the *patient's* determination of a risk, albeit insubstantial; the

court accepted Lord Woolf's dictum proscribing the use of a numeric threshold. Legal scholars support this trend, warning against reducing the meaning of 'substantial' or 'grave' (or 'significant') to quantifiable (numeric) risks,[9] since such reduction misses the central point, that only the patient can judge what risk is material to him or her, irrespective of its frequency of occurrence.

Although primarily of interest due to its impact on the law of causation, the case of Chester v Afshar[10] saw the House of Lords approve Lord Woolf's judgement in Pearce.[7] This affirmed that 'any significant risk which would affect the judgement of the reasonable patient' was the correct test for disclosure. Since, at that time, the House of Lords was the superior court in the jurisdiction of England and Wales, this effectively closed the discussion on the threshold for consent and this remains settled law. It also has the effect of excluding the numeric threshold, which becomes irrelevant.

What is not irrelevant is the role of statistical risk when comparing two alternative treatments. In a case where a patient consented to a cerebral angiogram, with its attendant risk of stroke, in the ignorance that a magnetic resonance image would be associated with a lower risk, the court found that the clinician breached his duty in failing to provide comparative risk data.[11] Nevertheless, the data are being used only to *compare* risk. A numeric threshold is not being employed to make disclosure, at some arbitrary point, unnecessary.

The concept of a numeric threshold for disclosing risk is therefore outdated from the legal point of view. There is no reference whatsoever to a numeric threshold either from the General Medical Council[12] or the Department of Health[13] other than an admonishment to give information about all significant adverse outcomes.

The most common question asked by surgeons when discussing the law of consent is where to draw the line between matters that must be disclosed and those that require no mention. Invariably, they demand a numeric threshold and are disappointed when this is not forthcoming. Although it is understandable that doctors continue to use this artificial threshold, it is submitted that they should follow the lead of the courts because a better formula that identifies what needs to be disclosed has been provided for our use. It is better because it gives an assurance that patients will not be 'ambushed' by a serious complication that the surgeon could foresee but of which the patient remained oblivious until it was too late for him or her to avoid it.

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