



The Society of Cardiothoracic Surgeons of
Great Britain and Ireland



Parliamentary
and Health Service
Ombudsman

Consent in cardiac surgery

A good practice guide to agreeing and recording consent





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As Health Service Ombudsman I am committed to sharing as widely as possible the learning from the complaints I receive. The issue of consent and communication of risk to patients is a key theme in a significant number of complaints about the National Health Service that my Office has investigated over a number of years. I therefore welcomed the opportunity to work with the Society of Cardiothoracic Surgeons, and others to develop good practice guidance for the use of cardiac specialists when dealing with this essential aspect of patient care and choice.

Ann Abraham, Health Service Ombudsman for England

The increasing focus on patient centred healthcare has led to greater interest in the issue of consent.

The growing complexity of modern intervention demands even more clarity in the whole consent process.

The Society of Cardiothoracic Surgeons is committed to improving patient care, and is therefore delighted to have the opportunity of working alongside the Ombudsman's Office on this initiative.

Patrick Magee, President of the Society of Cardiothoracic Surgeons of Great Britain and Ireland

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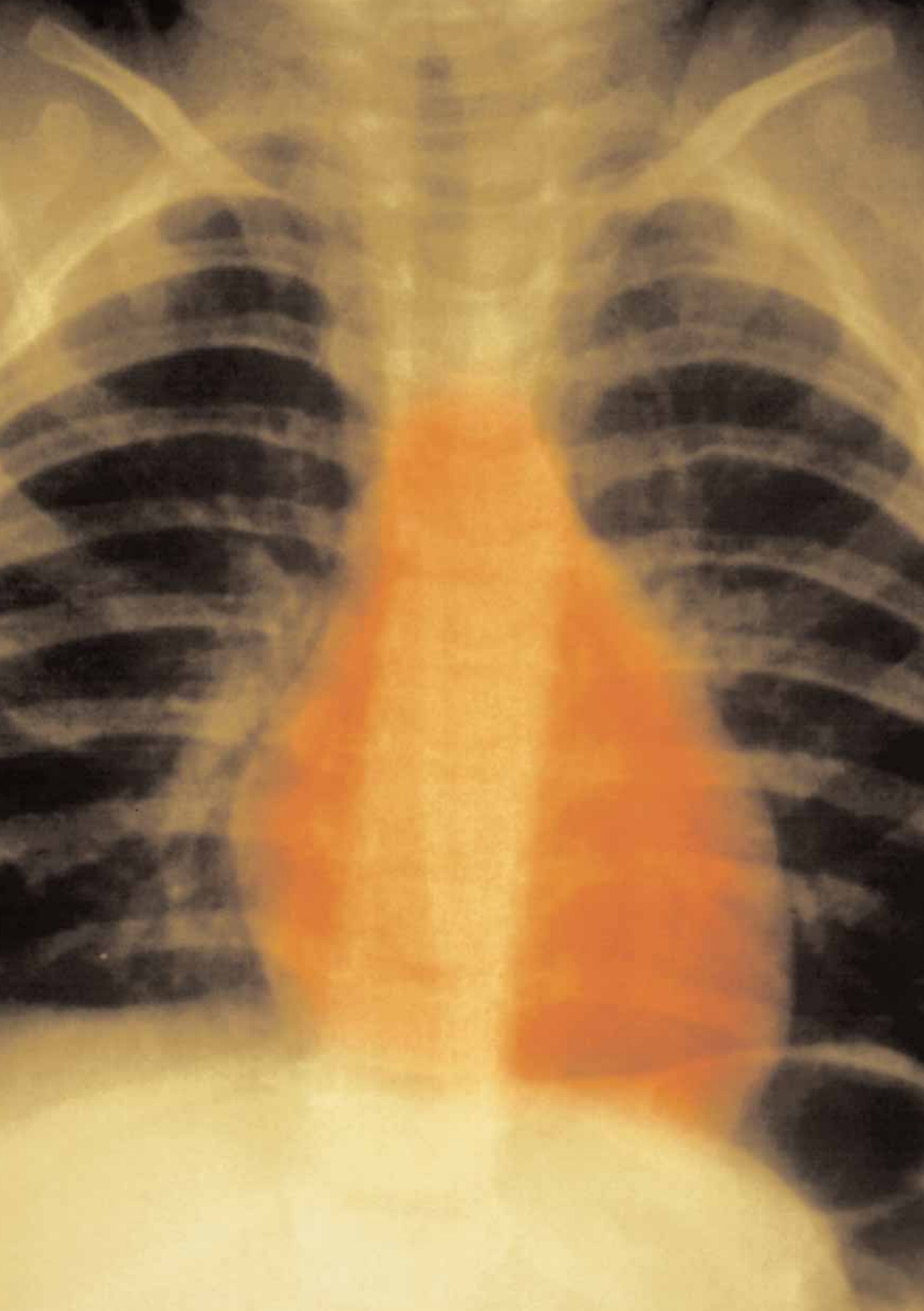
The aim of this guide is to improve the quality of informed consent in cardiac surgery.

There will be times when the outcome of surgery will not be the desired one. This guide aims to ensure that members of the cardiac surgical team have taken appropriate steps to recognise and discuss that possibility beforehand with the patient - so that unintended or unwanted consequences do not come as a surprise.

This guide has been prepared by the Health Service Ombudsman and the Society of Cardiothoracic Surgeons (SCTS) with the support of the General Medical Council (GMC), the Healthcare Commission and the Department of Health (DoH) and with input from patients and patient representative bodies. A full list of the organisations which have contributed appears on the back cover.

The guide concentrates on consent for adult elective cardiac surgery and does not address the areas of capacity, paediatric practice, advance refusals of treatment, withdrawal of life-prolonging treatment or research trials, although we recognise that these are important issues which may be the subject of future work.

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Background

The understanding of informed consent in UK surgical practice has shifted over recent years from a doctor-centred to a patient-centred approach. Previously the amount of information given to patients before surgery was judged against the Bolam principle.

Since 1998 this principle has evolved: especially in the light of events at the Bristol Royal Infirmary and developing case law. Current guidance on consent from the GMC and the DoH sets out the concept of a reasonable patient. Recent case law (*Chester vs Asfar* 2004) extends this further and brings the UK much closer into line with the US and Australian 'Prudent Patient Test'. More detail of the context in which consent has developed is set out on page 19.

This guide is informed by the report from the Bristol Royal Infirmary enquiry - *Learning from Bristol*. It takes full account of, and stands alongside, guidance produced by the DoH, and the GMC.

We aim to assist cardiac surgical teams in helping patients to make well-informed decisions about their treatment. In the team approach to care, patients may discuss consent with someone other than the surgeon. Against this background, this guidance aims to help ensure consistency in the way in which informed consent is achieved and in the terminology and data used in the process.

Communication

Our advice assumes the patient has the capacity to consent. However, cardiac teams need to recognise that patients vary: they include people with learning difficulties and the highly educated, and discussions should be tailored to meet the needs of each patient.

The consent process

Obtaining consent should be an ongoing process

The patient's journey through the consent process is incremental. Patients need to be given time to consider, understand and clarify the information provided and to come back to ask questions. The methods chosen to deliver the information, and the timescale needed, will vary depending on the needs of the individual patient.

Cardiac surgical teams need to see consent as the conclusion of a process of discussion and decision-making rather than something that is done to a patient.

The GMC guidance booklet *Seeking patient's consent: the ethical considerations* contains the following additional advice:

'If you are the doctor providing treatment or undertaking an investigation, you must give the patient a clear explanation of the scope of consent being sought. This will apply particularly where;

- a. treatment will be provided in stages with the possibility of later adjustments;
- b. different doctors (or other health care workers) provide particular elements of an investigation or treatment (for example anaesthesia in surgery);
- c. a number of different investigations or treatments are involved;
- d. Uncertainty about the diagnosis, or about the appropriate range of options for treatment, may be resolved only in the light of findings once investigation or treatment is underway, and when the patient may be unable to participate in decision making.

'In such cases, you should explain how decisions would be made about whether or when to move from one stage or one form of treatment to

another. There should be a clear agreement about whether the patient consents to all or only parts of the proposed plan of investigation or treatment, and whether further consent will have to be sought at a later stage.

'You should raise with patients the possibility of additional problems coming to light during a procedure when the patient is unconscious or otherwise unable to make a decision. You should seek consent to treat any problems which you think may arise and ascertain whether there are any procedures to which the patient would object, or prefer to give further thought to before you proceed. You must abide by patients' decisions on these issues. If in exceptional circumstances you decide, while the patient is unconscious, to treat a condition which falls outside the scope of the patient's consent, your decision may be challenged in the courts, or be the subject of a complaint to your employing authority or the GMC. You should therefore seek the views of an experienced colleague, wherever possible, before providing the treatment. And you must be prepared to explain and justify your decision. You must tell the patient what you have done and why, as soon as the patient is sufficiently recovered to understand.'

THE INFORMATION

By the time they give consent, the patient, and (with his/her agreement) the patient's carers, should have received a wide range of information about:

- The nature of the illness.
 - The nature of proposed surgery.
 - Any alternatives to surgical treatment such as:
 - > medical intervention
 - > medical drug therapy
 - > alternative surgical strategies (e.g. on-pump vs. off-pump, choice of conduits, valve repair vs. replacement).
 - The risks of surgery (see pages 12-13).
- Who will be doing the operation and the surgeon's experience with this procedure - patients often want to know if their surgeon is in training.
 - The mechanisms by which the unit's and surgeon's outcomes are monitored by external agencies, such as the SCTS, the DoH and the Healthcare Commission.
 - Any new or unusual procedures that have been proposed (these must be discussed in detail with the professional who will perform the operation).
 - The implications of no further intervention.

The consent process

(continued)

SHARING INFORMATION AND DISCUSSING TREATMENT OPTIONS

The patient must have some face-to-face contact with their surgeon and the cardiac team - backed up with other information sources in whatever media suits the patient's needs. Generally information should be given in parallel with the clinical assessment process. Information should be given by:

- Direct consultation with the surgeon.
- Providing generic information available in printed form and/or other formats, such as tapes, videos and web material (avoiding sending the patient on unstructured Internet searches).
- Providing informal contact with the multidisciplinary team / enablers to allow the patient to ask further questions, The 'enabler' may be a nurse, a patient care advisor or members of the rehabilitation team ('prehab').

There is evidence that people who do not speak English as their first language can achieve a far greater understanding of what they are consenting to than native speakers when a link worker is involved.

In addition, units could consider the use of regular open days to provide more in-depth information.

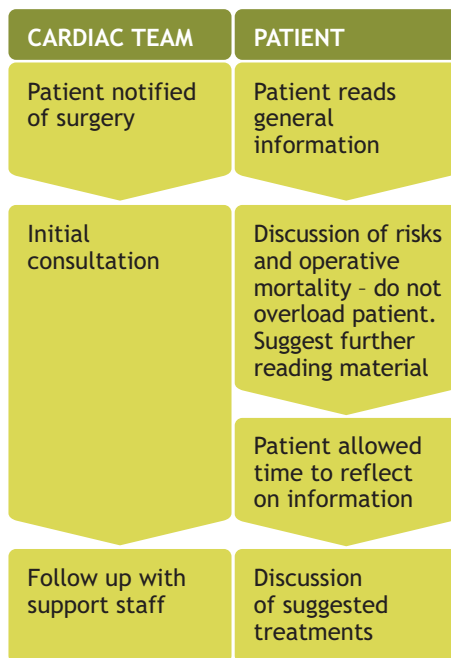
Surgical teams need to also recognise the possibility of 'functional illiteracy' in their patients and consider the use of specialists to aid the consent process in such cases. ('Functional illiteracy' describes the condition when patients appear able to make their way in life, yet are actually so deficient in reading and writing that they are essentially illiterate.)

STAGES IN THE PROCESS

A generic booklet/written information should be supplied before the patient's initial direct consultation with their surgeon to provide a framework for discussion. Some units send this routinely with the booking confirmation for the outpatient appointment.

During the initial consultation the surgeon should specifically discuss the most frequent and high impact risks to the patient including the risk of operative mortality. In giving information surgeons should aim to be consistent and clear whilst not overloading the patient. The aim is not to protect the surgeon but to inform the patient, avoiding defensive medicine.

Following this initial consultation the patient needs to be given access to further information in a format that they can take home. The patient can then consider this in detail (as part of their responsibility) and come back after time for reflection.



At the return visit the patient should see support staff such as nurses, care advisors and rehabilitation team workers who can check their understanding and get more information in an informal and possibly less threatening environment.

Patients undergoing repeat procedures need to have information repeated. As the risks of repeating a procedure are generally higher than the first intervention, it is important to take care in the consent process: it should not be assumed that the patient 'already knows all about it'.

The consent process

(continued)

Where an anaesthetist is involved in a patient's care, that person has the responsibility (not the surgeon) to seek consent for anaesthesia, having discussed the benefits and risks. In elective treatment it is not acceptable for the patient to receive no information about anaesthesia until their immediate pre-operative visit from the anaesthetist: at such a late stage the patient will not be in a position to make a decision about whether or not to undergo anaesthesia. Patients should therefore either receive a general leaflet about anaesthesia in outpatients, or have the opportunity to discuss anaesthesia in the pre-assessment clinic. The anaesthetist should ensure that the discussion with the patient and their consent is recorded in the anaesthetic record, in the patient's notes or on the consent form.

RELAYING RISK

Remember, it is the patient who is being asked to take the risk

Very few of us understand the concept of risk. To help patients make decisions based on risk clinicians need to tailor explanations to each individual whilst allowing them to apply their own value judgments.

When relaying degrees of risk members of the cardiac team will need to find out what 'high', 'medium' and 'low' mean to the patient by describing these in easily understandable terms.

When determining how to inform the patient the expected *frequency* of any adverse outcome and its potential *impact* on the patient's lifestyle needs to be considered.

The impact of an adverse outcome will vary between patients. For example, disfigurement may be more serious for a young person than for an elderly one, a speedy return to fitness may be significant for a worker and less so for someone who is retired. But only the individual can make those judgments, cardiac team members cannot know and should not make assumptions.

Care needs to be taken when presenting statistics (they are essential but must be supplied in a relevant context for the patient), and when using metaphors. All statistical information should be validated although a combination of statistics and stories can be used if necessary. When quoting percentages - pictorial examples (e.g. 1 in 100 dots on a page) can be useful.

Patients have told us that they feel metaphors are dangerous and are not a good way of explaining risk as they may not apply in context. Metaphors are subjective and culturally specific and generally should not be used.

When describing best and worst-case scenarios actual stories and cases can be useful for some patients.

In any discussion of risk patients should be told about:

- Potential benefits.
- Potential side effects.
- Potential complications (differentiating between side effects and complications).

- The outcomes for high volume operations, e.g. how many people have had complications in the unit during the year. (This needs to be made available on an institutional basis and where appropriate on a surgeon specific basis. In high risk cases patients need to be made aware that comparison to national and local results may be inappropriate.)
- Chances of success i.e. will the operation deliver what it is designed to achieve.
- Unit infection rates.

To help communicate risk we have included (as an insert to this leaflet) a simple ready reckoner guide for use in discussions with patients.

Risk chart

The chart overleaf is a standard risk assessment tool (we think it reasonable to use statistical risk models to arrive at objective estimates of patient-specific operative mortality).

The chart is a useful aid in discussing risk with patients. The accompanying leaflet for patients includes blank charts to be filled in for the patient - providing a record of the discussion about risk for the patient to take away and consider.

Patients need to be informed that the impact of a particular adverse event will vary according to the individual. The predicted frequency of an event will vary according to unit, surgeon and patient-specific factors and individual surgeons should know their own rates of mortality and morbidity and when they vary from national or international data.

The *Frequency* of an event can be described as:

- **Improbable** - unlikely to happen, exceptional circumstances only.
- **Highly unlikely** - occurs annually in UK.
- **Unlikely** - has occurred in last 3-5 years in this unit / surgeon's practice.
- **Potential** - occurs annually in this unit or in this surgeon's practice.
- **Possible** - occurs weekly / monthly in this unit or in this surgeon's practice.

The *Impact* on lifestyle can be divided into:

- **Catastrophic** - permanent disability or death.
- **Severe** - marked reduction in quality of life which is permanent or which has a recovery period of more than 12 months, and / or more than 10 days extra hospital stay.
- **Moderate** - temporary pain, disability and / or reduction in quality of life with recovery within 1 - 12 months and / or up to 10 days extra hospital stay, extra operative intervention required.
- **Slight** - temporary discomfort or loss of function, less than 3 days extra hospital stay, recovery within 1 month.
- **Low** - transient discomfort, no extra hospital stay.

Risks should be shown as generalised areas on the chart rather than as discrete points as their frequency and impact will fall within a range.

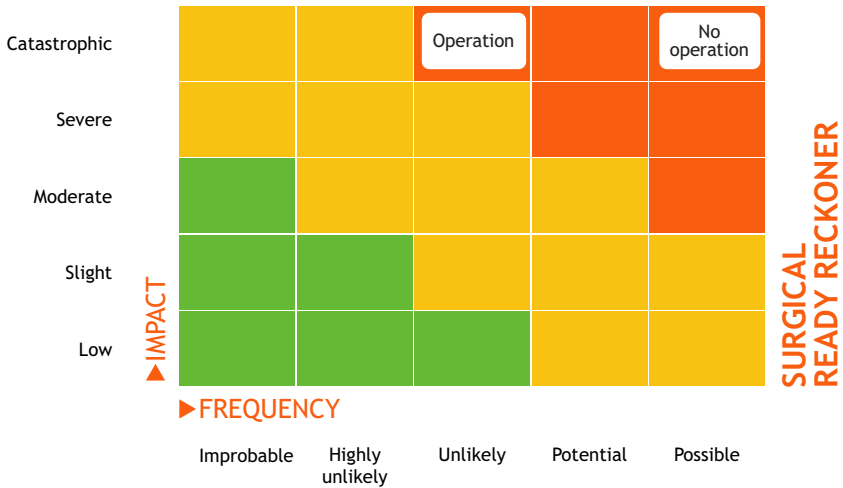
Patients need to decide on their own interpretation of the impact of a particular outcome but, having discussed this, relative risks can then be demonstrated by the surgeon using the chart.

Examples of how this chart could be used are given overleaf.

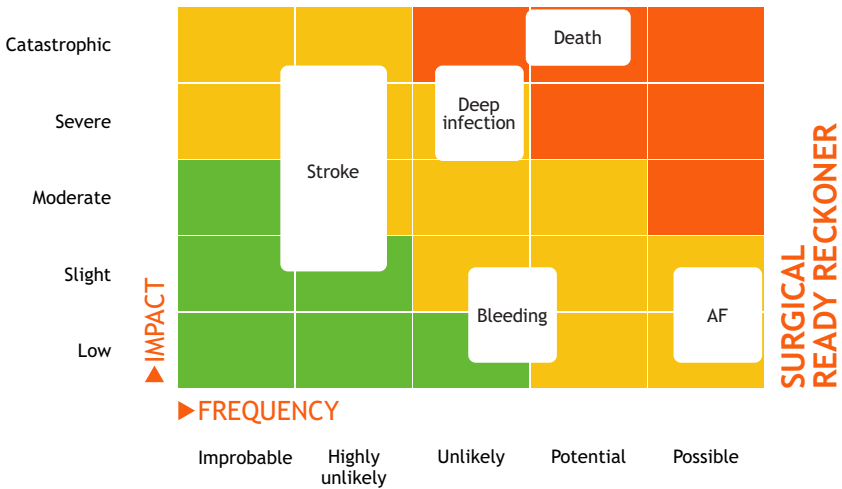
Risk chart

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Example 1, using the chart to explain risk to a patient visually, comparing the mortality risk of not proceeding with an operation to that of proceeding.



Example 2, using the chart to explain various risks to a patient, showing the relative risk of various complications after a proposed procedure. Red risks should be explained in the direct consultation between the surgeon and the patient, amber risks should be covered in the patient information at subsequent appointments with members of the cardiac team, as described above on pages 8-9. Green risks need only be discussed if the patient specifically asks.



When things go wrong

As this guidance acknowledges, there will be times when the outcome of surgery will not be the desired one. Following the advice in this guide should help ensure that unintended or unwanted consequences of surgery do not come as a surprise to the patient or their family.

Following surgery which has not been successful the surgeon should talk to patients and/or their families as soon as possible after the event. However, enough time needs to be allowed for thorough discussion and, if necessary, patients and/or relatives should be given a further opportunity to talk again at a later stage: perhaps, then, to members of the wider cardiac team.

It is especially important that, wherever possible, the surgeon who carried out the procedure should be directly involved. It is not acceptable to send a junior doctor to take on this role. The surgeon will need to demonstrate appropriate sympathy and, where appropriate, give an apology. It is important that the approach of the doctor concerned is honest and open and that a full explanation of events is given.

Discussions will need to take place in private and in a location that allows issues to be discussed in detail, with dignity.

Keeping a record

The process is more important than a signature on a form but it must be recorded.

Currently the language of consent can be a negative and defensive element in the relationship between the surgeon and the patient. There is a need to move instead to centre on the patient's choice about their treatment (including 'doing nothing').

A key issue is how to document consent in a way that provides an evidence trail for everyone involved in the different stages of the process. A standardised form is a way of doing this but a written record in the notes is more patient-centred.

Record who was present during each consultation, what was discussed, the patient's responses and your perception of their understanding of the information given. Record whether the patient wanted any carers present.

Record what additional information sources were given and highlight where specific mention has been made to certain topics within them. Show the patient any written record of consent in the notes and where possible obtain their signature in the case file.

An effective method of documenting the consultation is to dictate clinic letters describing the consultation in the presence of the patient and then send a copy to the patient.

References

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Appendix: The development of consent procedures

The GMC's guidance *Seeking patients' consent: the ethical considerations* (1998) is based on the following principles:

- Patients have a right to choose what treatment if any to accept, based on their own assessment of the likely benefits and burdens to themselves.
- Doctors have a duty to offer patients the treatments which are appropriate in meeting their clinical and non clinical needs.

The Department of Health has also issued a number of guidance documents on consent including; *12 key points on consent: the law in England* a one-page document which summarises those aspects of the law on consent which arise on a daily basis and in 2001; *Reference guide to consent for examination or treatment* a comprehensive summary of the current law on consent.

These documents introduced the concept of the reasonable patient in order to determine how much information should be supplied.

The 2001 Learning from Bristol report advanced this concept further with the following:

- 'Achieving patient partnership will require that patients are given the information that they want about themselves and their care and ensuring they are treated with respect as partners in their care.'
- 'The process of informing the patient, and obtaining consent

to a course of treatment, should be regarded as a process and not a one-off event consisting of obtaining a patient's signature on a form.'

- 'As part of the process of obtaining consent, except when they have indicated otherwise, patients should be given sufficient information about what is to take place, the risks, uncertainties, and possible negative consequences of the proposed treatment, about any alternatives and about the likely outcome, to enable them to make a choice about how to proceed.'

In November 2004 the Lords of Appeal passed judgment on the case of *Chester vs Asfar*. The 'headline' point in this case is the way the 'causation' test was interpreted, allowing the Claimant to recover damages for a complication that the surgeon should have - but didn't - warn the patient about, even though she would probably have had the operation had she been so warned.

The important issue raised by this judgment is the emphasis it places on the need to ensure a patient's autonomy in decision-making, bringing the UK much closer into line with the US and Australian 'prudent patient' test. This lays a considerably greater burden on clinicians to explain risks prior to treatment.

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Please note

The telephone numbers of the
Parliamentary and Health Service
Ombudsman changed on 15 March 2009.

The new contact details are:

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