



Setting standards to improve women's health

PRESENTING INFORMATION ON RISK

This is the first edition of this clinical governance advice.

General principles on how best to communicate risk

- RISK PERCEPTION**
People's perception of risk is as important as the actual risk presented to them and it varies according to a number of 'risk attributes'. D
- DECISION MAKING**
Risks associated with a clinical decision are a critical element of an informed decision. ✓
Research has not yet identified best practices for communicating uncertainty about harms and benefits of treatment to patients. ✓
- PERSONALISED RISK COMMUNICATION**
Personalised risk communication may lead to a small increase in the uptake of screening tests. There is a trend that personalised risk communication enhances decision making, although this is not significant. A
- DECISION AIDS**
Decision aids improve people's knowledge of the options, create realistic expectations of their benefits and harms, reduce difficulty with decision making and increase participation in the process. More detailed decision aids are better than simpler ones. Decision aids significantly reduce decisional conflict. A
- COMMUNICATION TOOLS**
Using a range of presentation styles is the most effective form giving information about risks. Communication tools that are structured, tailored and/or interactive are more effective. A
- FRAMING RISK**
People receiving information framed as a gain are more confident of a treatment than those receiving information presented as a loss. When presenting information to patients, it should be framed in a variety of ways. D
- DESCRIBING RISKS**
Information on probability is best presented as numbers rather than words and as event rates (natural frequencies) rather than probabilities or relative risk reduction. Use visual aids for probabilities to help people to put things into perspective. A

Descriptive terms such as ‘very low risk’ or ‘high risk’ need to be quantified by giving a figure, such as a frequency. Use frequencies rather than percentages to portray risk. Use a consistent denominator to describe risk. Absolute risks should be used rather than relative risks to compare different options. Put benefits or risks into perspective; for example, number needed to treat. Put the information into context.

D

The duration of risk should be presented when the amount of risk is discussed.



8. Describing risk in guidelines

The appropriate terms to use in a guideline to define risk are those that are most easily understood by clinicians and their patient.



1. Terminology

Throughout this advice, we have used the term ‘patients’ rather than ‘women’. Very often, women are not ill and they may be healthy women having babies. However, we have used the term ‘patient’ to reflect the fact that the advice discusses how best to present information on risk about healthcare issues and it therefore applies to patients and to women in general, as well as their families and supporters.

2. Purpose and scope

Healthcare workers frequently need to discuss risks with patients. When defined as the chances that an activity or hazard will give rise to harm, risk is generally given in terms of numerical odds or probabilities and the risk is used as a mathematical term. There are two aspects to risk that must be considered when describing risk: the first is the frequency of the risk and the second is the amount of associated harm.¹ For instance, the risk of scar rupture during vaginal birth after caesarean section has a frequency of 1:100, which is moderate, but this must be qualified by the amount of associated harm, such as stillbirth or major haemorrhage. Research has shown that most people, whether they be healthcare workers or patients, find it hard to understand risk in terms of numerical odds and probabilities.² In addition, patients and their carers may not understand certain terms that are used by healthcare workers to explain risk.³

The RCOG, through the Guidelines and Audit Committee, produces guidelines and parallel patient information is produced under the aegis of the Patient Information Subgroup. The patient information aims to educate and improve delivery of health care and women’s understanding of their care. The aim of this advice is to provide a standardised approach that is methodologically robust to ensure that developers of guidelines:

- use epidemiological definitions optimally and appropriately in the guideline using standardised linguistic and numerical descriptions of risk
- define levels of risk for clinicians and patients
- describe how to present information on risk to patients in the best possible way.

It is envisaged that this advice will be used as an aid by those who develop and write guidelines and patient information.

3. Background

Risk communication was first recognised as a specific scientific issue in the 1970s and much of the work on successful risk communication has developed in response to industrial development, especially of the chemical industry. However, it is increasingly recognised that risk communication is important to patients and to their satisfaction with health care.

Professionals and patients may think about risk in different ways.¹ Healthcare professionals may consider risk as the mathematical probability of something happening within a whole population group (for example, the

chance of breast cancer in women over 50 years of age) which is supported by statistical information. This way of assessing risk is important but it is objective, impersonal and deals with populations rather than individuals. Patients, on the other hand, use an everyday concept of risk that is bound up in the individual's concerns, anxieties and fears about the present and the future. This way of thinking about risk is very personal and subjective and is therefore influenced more by individual issues and priorities than by statistical probabilities.

There is evidence that good communication helps to build trusting relationships between patients and professionals, leads to greater satisfaction on both sides,² helps people to take more responsibility for their own health and reduces medical errors and mishaps.³ The closer the doctor-patient partnership, the more likely the patient is to be satisfied.³ Malpractice claims are also less likely. Primary care physicians with no malpractice claims against them were more likely to state to patients what to expect, enabling discussion to take place and taking time to explore the human dimensions, when compared with those primary care physicians who had been the subject of such claims.⁴ Communicating risk to patients in an effective way is important in achieving a good outcome in patient care.⁵

4. Identification and assessment of evidence

The Cochrane Library (including the Cochrane Database of Systematic Reviews), the Database of Abstracts of Reviews and Effects (DARE), EMBASE, TRIP, National Electronic Library of Health (NeLH), Medline and PubMed (electronic databases) were searched for relevant studies and restricted to articles published between 1966 and September 2007. The databases were searched using the relevant MeSH terms, including all subheadings, and this was combined with a keyword search. Search words included 'presentation of risk', 'public perception of risk', 'communication of risk', 'consent' and the search was limited to English language. The search engines Google, Yahoo! and Ask.com were searched using the above phrases. In addition, the following websites were searched using the above phrases: Bandolier, Medicines and Healthcare products Regulatory Authority, Royal College of Physicians, Royal College of Anaesthetists, Royal College of Surgeons, Royal College of Obstetricians and Gynaecologists, Department of Health, Medical Defence Union, National Institute for Health and Clinical Excellence, Scottish Intercollegiate Guidelines Network, National Screening Committee, World Health Organization, the Risk Information Institute (www.trci.info), King's Fund, the Royal Society, Research Findings Register, the National Health and Medical Research Council of Australia, the International Patient Decision Aid Standards Collaboration, the Institute of Risk Management. Where possible, recommendations are based on available evidence and the areas where evidence is lacking are annotated as 'good practice points' ().

5. What is risk?

There are multiple conceptions of risk. The term risk is commonly used in the following ways:

- a hazard; for example, the risks of blood transfusion
- a probability; for example, 1:100 risk of miscarriage after an amniocentesis
- a consequence; for example, what is the risk of having a caesarean section?
- a potential adversity or threat; for example, how great is the risk of pulmonary embolus when taking the combined oral contraceptive pill?

A risk is often defined by healthcare professionals as the likelihood (or probability) that harm will occur from a particular hazard or the product of the probability of an outcome and the severity of that outcome.² People, on the other hand, are concerned with broader, qualitative attributes, such as the origin of the risk (natural or technological), whether a risk is imposed or there is a choice, whether the risk is short-term (temporary) or long-term, the distribution of risk over a population, and the power of individuals to influence or control the risk.^{6,7}

Living is a risky business, since every activity has an associated risk. People will generally take risks if they perceive that there is an advantage or benefit. Normally, the benefits should outweigh the risks by a significant margin but there is no such thing as a zero risk.^{8,9}

People's perception of risk is as important as actual risk presented to them.

D

Individuals do not act on the basis of 'actual' risk presented to them but act on the basis of their perception of the risk; risk perception is subjective.⁴ For example, women attending a familial breast cancer clinic for hereditary breast cancer screening were interested in genetic testing according to their perceived likelihood of being a mutation carrier rather than the objective risk of being a mutation carrier based on expert opinion of clinical geneticists.¹⁰

Evidence level 4

Perception of risk varies according to a number of 'risk attributes'.

D

People's assessment of the importance of risk for themselves can vary even if the actual risk does not.¹¹

Research has identified a number of known factors or 'risk attributes' that influence the perception of risk.¹² People place different weights on different risks according to these risk attributes even where the numerical magnitude of the frequency of a bad outcome from those risks is the same. Risk attributes include:

- the relative voluntariness of risk
- the potential for catastrophic or chronic harm
- the degree of familiarity with the situation
- the degree of uncontrollability of the risks
- the benefits accrued from accepting risk
- trust.

Evidence level 4

Risks that are involuntary or controlled by others have little or no benefit for the person concerned and are typically interpreted as far less tolerable than voluntary and familiar risks, such as the consumption of alcohol. Because of the effect of perception of risk, patients' estimates of risk may differ from those of the healthcare worker who counselled them and this must be taken into consideration.^{13,14}

6. What is the best way to describe or illustrate risk to patients?

6.1 Is it important to communicate risk to patients?

Risks associated with a clinical decision are a critical element of an informed decision.



Research has not yet identified best practices for communicating uncertainty about harms and benefits of treatment to patients.



Very often the terms 'risk' and 'benefit' are discussed with patients when considering a treatment. However, there is often considerable uncertainty with regard to which patients may benefit from a certain treatment, let alone whether the treatment may be beneficial to any patient. It is important that this uncertainty be communicated effectively to patients, since discussing the many risks associated with a clinical decision is thought to be a critical element of an informed decision.^{15,16}

Analysis of 1057 clinical encounters by primary care physicians and surgeons found that only 16-18% of discussions met the minimum criteria for an informed decision by discussing the risks and benefits of treatment.¹⁷

A review of the literature on various issues related to uncertainty in decision making found that there are no clear best practices for presenting uncertainty and recommended further research into this area.¹⁵

6.2 Is there a best way to communicate risk?

Risk should be individually tailored following the general principles set out on the following pages.



Risk needs to be communicated clearly: 'How well we communicate is determined not by how well we say things, but how well we are understood.' Andrew Grove, Co-founder of Intel.

Risk-perception research has found that the more uncertain we are, the more afraid we are.⁵ In addition, we are more afraid of a risk if it puts us in personal peril than if it threatens somebody else.¹ Risks in reproductive health care are personal and rich in uncertainty.

Some general principles on how best to communicate risk to individual patients can be summarised as follows:⁶

- Accept and involve patients as a partner by informing them of the risk.
- Plan what you will say and be appropriately informed about the patient's medical, social and educational circumstances.
- Ensure that your advice is up to date and in line with your departmental practice.
- Evaluate the patient's understanding of what you have discussed.
- Listen to their concerns.
- Maintain trust and credibility by being honest, frank and open.

Evidence level 4

6.3 *Does personalised risk communication aid patients' understanding, affect screening or improve decision making?*

What is personalised risk information? People considering participation in screening may receive information about the general risk of having the disease or condition or information that is tailored to their personal risk status.

Personalised risk communication may lead to a small increase in the uptake of screening tests.

A

A systematic review of 22 studies assessed the effects of different types of personalised risk communication for consumers making decisions about taking screening tests.¹⁸ Risk estimates or calculations which were categorised into high, medium or low strata of risk increased the uptake of the test (odds ratio 1.42; 95% CI 1.07-1.89). There was insufficient evidence to report on other key outcomes of risk perception such as intention to take tests, anxiety, satisfaction with decisions, decisional conflict, knowledge and resource use.

Evidence level 1++

There is a trend that personalised risk communication enhances decision making although this is not significant.

A

In three studies, personalised risk communication interventions showed a trend towards more accurate risk perception (OR 1.65; 95% CI 0.96-2.81) and three other trials with heterogeneous outcome measures showed improvements in knowledge with personalised risk interventions. However, there was insufficient evidence to demonstrate whether people given personalised risk information are making more informed decisions.¹⁸

Evidence level 1++

6.4 *Are decision aids useful for patients?*

Decision aids such as pamphlets or videos prepare patients to participate in decisions by providing information about treatment or screening options and their associated outcomes.

Decision aids improve people's knowledge of the options, create realistic expectations of their benefits and harms, reduce difficulty with decision making and increase participation in the process.

A

A systematic review¹⁹ of decision aids compared decision aids with usual care. Decision aids performed better in terms of:

- greater knowledge
- more realistic expectations
- lower decisional conflict related to feeling informed
- increased proportion of people participating in decision making and
- reduced proportion of people who remained undecided post intervention.

Evidence
level 1++

More detailed decision aids are better than simpler ones.

A

The use of more detailed decision aids when compared with simpler decision aids lead to a significant improvement in:

- knowledge
- more realistic expectations and
- greater agreement between values and choice.¹⁹

Evidence
level 1++

Decision aids significantly improve knowledge and reduce decisional conflict.

A

A randomised controlled trial (RCT) investigated the effect of a decision aid booklet for women with one previous caesarean section, describing the risks and benefits of elective repeat caesarean section and trial of labour. Knowledge was significantly improved and decisional conflict was significantly reduced in the decision aid group.²⁰ More recently, a randomised controlled trial investigated two computer-based decision aids in women with one previous caesarean section. Both interventions reduced decisional conflict and there was a [non significant] trend towards a higher rate of vaginal birth for women in the decisional analysis group.²¹

Evidence
level 1++

Use of a decision aid in women with breech presentation at term resulted in significantly lower decisional conflict and increased knowledge. Women were more likely to feel that they had enough information to make a decision, had no increase in anxiety and reported greater satisfaction with decision making and overall experience of pregnancy and childbirth.²² There was a similar finding in an RCT of a decision aid to help women choose between surgical and medical methods of pregnancy termination.²³

6.5 Which is the most effective format for communicating risk?

Using a range of presentation styles is the most effective form giving information about risks.

A

A number of studies have shown that using a range of presentation styles improves risk communication with patients. An RCT of women's understanding of the effectiveness of contraceptive methods found that tables with categories communicated relative effectiveness better than numeric tables. However, women grossly overestimated the risk of pregnancy unless they were shown tables with numbers, so a combination of both methods is best.²⁴ A study of women's understanding of hormone replacement therapy risks also indicated that a combination of words and numbers is most helpful.²⁵

Evidence
level 1++

A study in general practice, using either verbal descriptions of risk numerically or by using a graph,²⁶ showed that graphs were the quickest and easiest way to present information. Looking at a graph with the consumer helped the general practitioner to build a relationship with the person and allowed them to convey absolute and relative risks without having to explain these concepts. There were some benefits in all the communication techniques used, suggesting that using a range of presentation styles would probably be most effective for giving information about risk that is

unbiased, easily understood and comprehensive. General practitioner registrars found that having a range of risk communication tools from which to choose when discussing treatment options was more appropriate and flexible for clinical practice than single strategies.²⁷

Evidence level 1++

Communication tools that are structured, tailored and/or interactive are more effective.

A

An RCT comparing methods of presenting risk of Down syndrome to women at low risk at booking showed that an interactive method of communicating risk (opaque box containing 100 numbered ping-pong balls to represent 1:100 risk) was more effective than either a written or graphic presentation method. The interactive method most significantly altered patients' perception and anxiety about the risk of Down syndrome.²⁸ A systematic review addressed the effectiveness of evidence-based communication tools, including how best to increase patient understanding of evidence.²⁹ Communication tools in a variety of formats, such as verbal, written, video, provider-delivered or computer-based, increase patients' understanding but are more likely to do so if they are structured, tailored and/or interactive. Illustrations such as cartoons, or graphs (vertical bar charts) appear to aid understanding.

Evidence level 1++

6.6 Does the way in which information is presented affect patient's perception of risk?

There are social and psychological biases that affect the way people make decisions but these will not be discussed in this guideline.^{7,8,30,31}

The way that information is 'framed' or presented can affect patient understanding of risk³⁰ and affects consumer confidence in treatments.³¹ Emphasising one aspect of a health decision while leaving out another may change how people understand and perceive risks and benefits. This effect is called 'framing' of information. For example, health information can be framed as:

- negative or positive: that is, giving the chances of an operation failing (negative framing) versus the chances of it succeeding (positive framing); for example, a patient can be counselled about the oral contraception pill by giving the risk of failure in a good user of less than 1:100 versus the chance of successful contraception of over 99:100.
- loss or gain: for example, emphasising the risks or disadvantages of not having a particular screening procedure (loss) versus emphasising the benefits or advantages of having the procedure (gain).

People receiving information framed as a gain are more confident of a treatment than those receiving information presented as a loss.

D

A UK study investigated how consumer confidence in the safety of blood transfusion is affected by the way in which information is presented.³² The investigators counselled 250 adult students about blood transfusion and additional information was given to the students in different formats:

- a) a gain: information on risk of viral infections was given in terms of number of people who would not contract these infections
- b) a loss: information on risk of viral infections was presented in terms of number of people who might contract infections
- c) a combination of these factors.

People receiving the information framed as a gain were more confident of the safety of blood transfusion than either of the other two groups.

Evidence level 4

When presenting information to patients, it should be framed in a variety of ways.

D

Since framing of information can have such a profound effect on patient perception of risk, it is useful to present information framed in a variety of ways; for example, a patient may be told that

Evidence level 4

the risk of their baby having Down syndrome after the quadruple screening test is 1:100 or alternatively that they have a 99 out of 100 chance that their baby is chromosomally normal.³³

Evidence level 4

Information on probability is best presented as numbers rather than words and as event rates (natural frequencies) rather than probabilities or relative risk reduction.

A

A systematic review addressed the effectiveness of evidence-based communication tools, including which were the most effective formats for representing probabilistic information.²⁹ For both written and verbal information, patients have a more accurate perception of risk if probabilistic information is presented as numbers rather than words. Natural frequencies or event rates are better understood by most people than probability formats with varying denominators and changes in risk are better understood if absolute risk reduction or relative risk reduction with baseline risk formats are used.

Evidence level 1++

6.7 Does quantifying risk aid patient understanding?

Describing risks quantitatively can help patients to understand the risk better. Quantitative information, when it is available, should be expressed clearly. There are various ways of expressing quantitative information, such as frequencies, percentages, relative risk and absolute risk.

Descriptive terms such as ‘very low risk’ or ‘high risk’ need to be qualified by giving a figure, such as a frequency.

D

Descriptive terms reflect the speaker’s perspective, with the patient often understanding the risks to be of a totally different order of magnitude.^{34,35} From a regulatory perspective (for example, in patient information leaflets) the main emphasis in expressing risk is in terms of statistical probability and a corresponding verbal descriptor such as ‘very rare’ corresponds to ‘up to 0.01% (less than 1/10 000)’. European Union (EU) guidelines recommend verbal descriptors of risk.⁹ However, research into what individuals understand by terms such as ‘very rare’ or ‘common’ suggests that the current EU guidelines on verbal descriptors are not correctly matched with statistical probabilities.^{38,39}

Evidence level 4

Use of the term ‘risk’ has substantially increased in the last decade (personal communication, Professor B Toft, Professor of Patient Safety, Department of Health and Life Sciences, Coventry University, UK). The public equate the verbal descriptors (very rare, common, and so on) to risks that are substantially higher than those defined in regulatory documents. Perceiving very small risks is particularly problematic and a number of models have been proposed in the literature to help with this. One scale is based on a different set of verbal descriptors (high, moderate, low, very low and minimal) but this also may not be in accord with people’s actual interpretations.³⁶ Other scales attempt to relate potentially hazardous events to familiar concepts, such as the size of various communities or events as risk comparators. Using a pictorial format, the Royal College of Anaesthetists has published a risk ladder to compare everyday risks with clinical risks of anaesthesia: for example, the risk of neurological injury with a spinal anaesthetic is approximately the same as the chance of guessing four balls correctly out of six in the UK National Lottery (less than 1:1000).³⁷ Table 1 shows the current EU guidelines, which are provided in the context of other strategies that should be used to describe risk in RCOG guideline documents and in terms of reference with which patients may be familiar.³⁶

Use frequencies rather than percentages to portray risk.

D

Percentages are an abstract way of portraying risk, whereas the actual number of people who could be affected is more vivid. Using frequencies (for example, five of every 100 people) should be used rather than percentages (for example, 5%).³⁸

Evidence level 4

Table 1. Risk table (modified from Calman *et al.*)³⁶

Verbal description ^a	Risk	Risk description ^b
Very common	1/1 to 1/10	A person in family
Common	1/10 to 1/100	A person in street
Uncommon	1/100 to 1/1000	A person in village
Rare	1/1000 to 1/10 000	A person in small town
Very rare	Less than 1/10 000	A person in large town

^a EU-assigned frequency
^b Unit in which one adverse event would be expected

Use a consistent denominator to describe risk.

D

When expressing risks as frequencies, using a consistent denominator helps to compare risks.³⁹ For example, when counselling a woman about vaginal birth after caesarean section, describe the risk of uterine rupture as 36/10 000 women in spontaneous labour with a risk of 102/10 000 women if labour is induced (rather than 1/3529 women).

Evidence level 4

Absolute risks should be used in addition to relative risks to compare different options.

D

Presenting risks and benefits as absolute or relative affects how people perceive them.³⁸ Using relative risks alone to compare different options can be misleading. For example, a drug is marketed as halving the risk of preterm labour (that is, it reduces the risk by 50%) gives the relative risk and makes the drug sound highly effective. However, it is impossible to fully understand the meaning of this without knowing to what the 50% relative reduction actually refers. If the initial chance of a person having a preterm delivery were only 1/2000 (0.05%), then reducing the risk by 50% would only mean bringing the chance down to 1/4000 (0.025%). Describing the effect of the drug in terms of the reduction in absolute risk does not sound nearly as dramatic or persuasive as using the relative risk. Using absolute data allows the consumer to put into perspective the relative risk or comparison between different risks.³⁸ To avoid bias, provide both absolute and relative data.

Evidence level 4

Put benefits or risks into perspective example number needed to treat.

D

Benefits or risks can be more easily understood if they are expressed as a 'number needed to treat' (NNT); that is, how many people would need to have a treatment or test for one person to experience a particular benefit or harm.³⁸

Evidence level 4

These can be calculated from the absolute risk difference as in the examples below:

Example 1: Counselling a woman about membrane sweep at term

By using membrane sweeping we can reduce the number of women requiring formal induction of labour. From systematic review data,⁴⁰ the following number needed to treat can be derived:

The number of women requiring induction of labour **if membrane sweeping is not used** is 36.3% and the number needing induction of labour **if membrane sweeping is used** is 21.2% (RR 0.59; (95% CI 0.50–0.70).

Absolute risk difference: From 36.3% to 21.2%, which represents a 15% reduction in induction of labour

Number needed to treat: $100/15 = 6.66 = 7$

Hence, seven women need to have a membrane sweep to avoid one formal induction of labour. In a unit with 3000 deliveries a year where, on average, 20% of women are induced, there are 600 inductions annually. If every woman had a membrane sweep, this could avoid over 80 inductions a year.

Example 2: The number of people likely to have preterm labour without the use of tocolysis

The number of women who deliver **if the drug is NOT used** is 1/2000 (0.05%) and the number of people likely to have deliver preterm **if the drug is used** is 1/4000 (0.025%).

Absolute risk difference: From 0.05 to 0.025, which represents a 0.025% reduction in the number of women delivering preterm

Number needed to treat: $100/0.025 = 4000$

Hence, 4000 women need to be treated with the drug to avoid one episode of preterm delivery.

The magnitude of the NNT needs to be put in context with the consequences of the treatment. Hence, a large NNT of 500 for post-term induction to avoid one perinatal death may be considered worthwhile because of the poor outcome, whereas such an NNT might not be considered worthwhile in other circumstances.

Put the information into context.

D

Giving the likelihood of a risk or a benefit as a number or percentage can be confusing for patients, because numbers are difficult to put into context. It is often helpful to compare a particular risk with a familiar risk, such as the probability of winning the lottery or dying in a car crash.³⁸ See Table 1.³⁶

Evidence level 4

Use visual aids for probabilities to help people put things into perspective.

A

When simple visual communication tools are shared between doctor and patient, they offer an opportunity to deepen the bond between them.²⁷ Use appropriate visual aids to help patients from all backgrounds to understand your explanations.²⁶ These can include:

- pie charts
- graphs
- the Paling palette; such as for displaying most medical risks with a probability of higher than 1/1000.

The Paling palette® (Risk Communication Institute; www.riskcomm.com/paling_palettes.htm) is a chart showing 1000 people, with some coloured in to show the number experiencing a particular effect.⁴¹ For example, illustrated in yellow are the odds of a 39-year-old woman producing a child with Down syndrome or other chromosomal abnormality (12/1000) and, in red, the odds of a woman having a miscarriage as a result of amniocentesis (4/1000) (see Table 1).

The revised Paling Perspective Scale® can be used for displaying risks covering widely different orders of magnitude, allowing some comparison to be made between the risk being presented (for example, death from vaginal birth after caesarean) with a risk they are 'at home' with (such as the risk of being struck by lightning). (Risk Communication Institute; www.riskcomm.com/scales.htm). See appendix.

Evidence level 1

The duration of risk should be presented when the amount of risk is discussed.

✓

The Medicines and Healthcare products Regulatory Agency's Committee on Safety of Medicines recommends that, if possible, the duration of the risk should be discussed with the patient at the same time as discussing the amount of risk.⁴²

7. Are there any legal aspects of risk pertaining to consent documents?

It is the responsibility of the doctor to inform a patient of a significant risk which might affect their judgement of the risk.

✓

In deciding whether to warn of a particular risk, a doctor must consider the severity and likelihood of the risk compared with the need for the procedure, the ability of the patient to understand, the patient's physical and emotional state and the patient's rights.



All medical interventions carry risk attached to them. However, many are insignificant and it is not possible or useful to discuss all the risks with patients. But at what level of risk and for what seriousness of conditions should the doctor inform the patient? A doctor has a duty of care to the patient; a duty that includes providing them with sufficient information, in terms that they can understand, to make an informed choice. The main reason for obtaining informed consent is to ensure that a patient has sufficient information to make an informed judgement about the proposed course of treatment.

The legal position on whether or not a doctor or other healthcare professional is negligent in failing to mention a risk to a surgical patient was decided in the UK in the case of Sidaway.⁴³ The House of Lords confirmed that the test to be applied is the same as that used in deciding whether a doctor has been negligent in any other aspect of their work, known as the Bolam test. A doctor is not ordinarily negligent for failing to mention a risk if a reasonably competent doctor in a similar position would not have mentioned it, and if a responsible body of relevant professional opinion would support that decision. Since Sidaway, judgements in a number of negligence cases (relating both to the provision of information and to the standard of treatment given) have shown that courts are willing to be critical of a 'responsible body' of medical opinion. It is now clear that the courts will be the final arbiter of what constitutes responsible practice, although the standards set by the health professions for their members will still be influential.⁴⁴ It is therefore advisable to inform the patient of any 'material' or 'significant' proposed treatment, any alternatives to it and the risks incurred by doing nothing. Additionally, patient's questions should be answered as truthfully and as fully as possible.⁴⁵ A recent Court of Appeal judgement stated that it will normally be the responsibility of the doctor to inform a patient of 'a significant risk which would affect the judgement of a reasonable patient'.⁴⁶

An obligation to impart medical information is included in Article 8 of the European Convention on Human Rights. This may be advanced as an argument that more information should be given to a patient. The right to medical information does not mean that every risk, however small, must be explained to a patient. In deciding whether to warn of a particular risk, a doctor must consider all relevant factors, including the severity and likelihood of the risk compared with the need for the procedure, and take into account the ability of the patient to understand and the patient's physical and emotional state. Doctors should be able to demonstrate that they have properly considered the patient's rights and be able to justify withholding information.⁴⁷ It may be appropriate to warn of a relatively rare risk for an elective procedure, such as sterilisation or a screening test.

8. Which terms should be used in a guideline to define risk?

The best terms to use in a guideline to define risk are those that are most easily understood by clinicians and their patient.



If possible, the following should apply:

- Use a common denominator to compare risks, such as 102/10 000 compared with 36/10 000.
- Provide absolute risks in addition to relative risks or odds ratios.*
- Describe the number needed to treat when comparing treatments.

* Relative risk should be used when discussing data from randomised trials, systematic reviews of randomised trials or cohort studies. Where data from case controlled studies is presented then odds ratios should be presented.

An example of how reporting results as relative risks causes confusion can be found in the 1995 'pill scare'. Epidemiologists reported that third-generation oral contraceptives doubled the risk of thromboembolism compared with second generation oral contraceptives.⁴⁸ The initial reports did not mention that the absolute risks were low: 1/3000 compared with 1/6000, that the background risk in non-users was 1/20 000 or that the

increased risk of death was around 1/1 000 000. The risk was not put into context and media and public panic ensued.⁴⁹ Medical editors learned the lesson and major journals now require reports to include absolute as well as relative risks.⁵⁰

9 Glossary of terms used to describe risk

This glossary defines terms that are used frequently to describe risk and explains why some terms are better used than others when communicating with patients.

9.1 *Number needed to treat (NNT)*

The number of patients that, on average, must be treated to prevent a single occurrence of the outcome of interest. It specifies the treatment, its duration and the adverse outcome being prevented. The concept of numbers needed to treat (NNT) is one way to define effectiveness and is easier to interpret than absolute risk or relative risk.⁵¹

9.2 *Odds and odds ratio*

These are measures of treatment effectiveness.

Odds

Odds are the probability of an event occurring divided by the probability of the event not occurring.

Odds ratio

A measure of treatment effectiveness. The odds of an event happening in the treatment group, expressed as a proportion of the odds of it happening in the control group. The 'odds' is the ratio of non-events to events.

When the probability of the disease is low (for example, less than 10%), the odds ratio approximates the true relative risk. As the event becomes more common, however, the exaggeration grows and the odds ratio can no longer be used as proxy for the relative risk. Its use should probably be limited to case-control studies and logistic regression, for which odds ratios are the proper measures of association, because of the difficulty in understanding odds ratios.¹¹

9.3 *Absolute risk and relative risk*

Absolute risk reduction (risk difference)

The difference in event rates between two groups (one subtracted from the other) in a comparative study.

Relative risk (RR)

Relative risk is the ratio of the risk of a given event or outcome (for example, an allergic reaction to the drug being tested in one group of subjects compared with another group). When the risk of the event is the same in both groups, the relative risk is 1. In a study comparing two treatments, a relative risk of 2 would indicate that patients receiving one of the treatments had twice the risk of undesirable outcome than those receiving the other treatment. Relative risk is sometimes a synonym for risk ratio.

In trials and cohort studies (where the prevalence is above 5%), the relative risk is used. Relative risk cannot be used in case-control studies because the true incidence of the risk in the whole population is unknown. Odds ratios should be used in case control studies instead.

The use of relative risk estimates has been shown repeatedly to give a more favourable impression of the effectiveness of a drug than absolute risk estimates.^{31,52-54} In practice, pharmaceutical companies manipulate the presentation of risk information (by using relative risk reduction) to enhance the apparent effectiveness of cholesterol lowering drugs.⁵⁵ It is thus better to use absolute risk rather than relative risk where possible.

9.4 Hazard rates and ratios

These are used in survival analysis to describe the effect of a variable on the hazard or risk of an event, such as pulmonary embolus, deep vein thrombosis or death.

For example, consider two groups (for example, in the Women's Health Initiative, group 1, women who took hormones and group 2, those who did not). The hazard rate for pulmonary embolus in group 1 is the ratio of pulmonary embolus within group 1 to total number of pulmonary emboli within group 1 over a given time period, such as 5 years. The hazard ratio is the ratio of hazard rates for group 1 to group 2 over the same time period and with the same risks except for hormone.

9.5 Forest plot

Forest plots show the information from the individual studies that went into a meta-analysis at a glance.⁵⁶ The results of component studies are shown as squares centred on the point estimate of the result of each study. A horizontal line runs through the square to show its confidence interval, which is usually, but not always, a 95% confidence interval. The overall estimate from the meta-analysis and its confidence interval are put at the bottom, represented as a diamond. The centre of the diamond represents the pooled point estimate and its horizontal tips represent the confidence interval. Significance is achieved at the set level if the diamond is clear of the line of no effect. Forest plots show the amount of variation between the studies that make up a meta-analysis, at a glance, and give an estimate of the overall result.

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APPENDIX

Clinical guidelines are: 'systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions'. Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in Clinical Governance Advice No. 1: *Development of RCOG Green-top Guidelines* (available on the RCOG website at www.rcog.org.uk/index.asp?PageID=75). These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.

The evidence used in this guideline was graded using the scheme below and the recommendations formulated in a similar fashion with a standardised grading scheme.

Classification of evidence levels	Grades of recommendations
1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias	A At least one meta-analysis, systematic reviews or randomised controlled trial rated as 1++ and directly applicable to the target population; or A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results
1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias	B A body of evidence including studies rated as 2++ directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+
1- Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias	C A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++
2++ High-quality systematic reviews of case-control or cohort studies or high-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal	D Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+
2+ Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal	Good practice point
2- Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal	<input checked="" type="checkbox"/> Recommended best practice based on the clinical experience of the guideline development group
3 Non-analytical studies; e.g. case reports, case series	
4 Expert opinion	

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The final version is the responsibility of the Guidelines Committee of the RCOG

The Clinical Governance Advice review process will commence in 2012
unless otherwise stated

DISCLAIMER

The Royal College of Obstetricians and Gynaecologists produces guidelines as an educational aid to good clinical practice. They present recognised methods and techniques of clinical practice, based on published evidence, for consideration by obstetricians and gynaecologists and other relevant health professionals. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor or other attendant in the light of clinical data presented by the patient and the diagnostic and treatment options available.

This means that RCOG Guidelines are unlike protocols or guidelines issued by employers, as they are not intended to be prescriptive directions defining a single course of management. Departure from the local prescriptive protocols or guidelines should be fully documented in the patient's case notes at the time the relevant decision is taken.