Chapter 1

Risk and risk assessment

A. Howie and A. Adams

What is risk?

- Risk is a concept that denotes a potential negative impact to an asset or some characteristic of value that may arise from some present process or future event.
- Implicitly negative, risk is suggestive of potential danger or hazard and therefore is associated with discomfort and loss and not gain or well-being.
- *Risk* is often used synonymously with the *probability* of a known loss.
- Paradoxically, a probable or possible loss may be uncertain and relative in an individual event, but may be much more certain over an aggregate of multiple events.
- Risk is the probability of an event occurring that will have an impact on the achievement of objectives. Risk is measured in terms of impact and likelihood.
- In 1983, the Royal Society in the U.K. defined *risk* as "the probability that a particular event occurs during a stated period of time or results from a particular challenge." They defined a *hazard* as a situation that could lead to harm. The chance or likelihood of this occurring is its associated *risk* [1].
- Risk is part of life whether we like it or not [2]. All medical interventions carry risks but anesthesia is often perceived to be especially risky, although in general, the risks of anesthesia are small. Risk communication, understanding, and perception are fundamental to all decision making, including consent for surgical operation.
- Risk evaluation by individuals is not a purely statistical phenomenon. It is widely accepted that individuals tend to evaluate risk not solely on statistical data but on many other subjective qualitative aspects of risk. This means that the assessment and perception of risk may incorporate subconscious, subjective, personality-dependent factors and may not follow any rational or methodical pattern [3].

Identifying risk

There are numerous potential hazards and we have many ways of predicting and quantifying the risks associated with these hazards. Experience of each procedure undertaken gives us an idea of the hazards associated with it. Pooled experience within a department gives us the experience of our colleagues as well, but this requires openness and a platform from which this information can be shared. Peer-reviewed journals and specialist literature, freely available now on the internet, allows us to evaluate not only our own practice, but that of others throughout the world.

Anesthesia and Perioperative Care of the High-Risk Patient, Third edition, ed. Ian McConachie.
Published by Cambridge University Press.

Frequently occurring adverse events are fairly straightforward to identify simply because they are common. The rarer an event, the less likely it is that an individual practitioner will encounter such an event during his/her practice. Without accurate reporting, these events may go undocumented and lead to inaccuracies in the pooled data. For a very rare event, this will cause large discrepancies in the estimated risk level for that event.

For very rare adverse events or for procedures that are not performed regularly, it may be difficult to recruit enough patients for a study to be adequately powered to show anything meaningful. For this reason one must be cautious in interpreting the results of many smaller studies. Multi-center co-operation is increasingly being organized to produce data from large numbers of patients that could not possibly be recruited from a single center.

An alternative method of producing some relevant conclusion from a number of smaller studies, which themselves do not show anything statistically significant, is to conduct a meta-analysis. This pools the patient numbers from smaller studies so as to give a number large enough to reach significance. One must be wary in interpreting these results as often it is difficult to find studies that are similar enough to be comparable.

The timing of an adverse outcome will affect both our ability to identify and report it, and the way in which patients will perceive it. Immediate events are identifiable by staff caring for patients in the postoperative period, either in the operating room (ORm), the post-anesthesia care unit (PACU), or on the wards. Immediate adverse outcomes will also be reported by the patients themselves. Later complications may be reported less frequently by the patient especially if deemed not to be too serious. If there is a long lead-time between treatment and complication, the association may go unnoticed.

Perceiving risk [4]

The timing of the event can have an effect on the way risk is perceived. Early complications, for example, often have a greater impact than those that are delayed. These tend to have a diminished perceived risk value.

The duration of an adverse event can also affect risk perception. Similarly, the ease with which something can be treated will reduce the severity of risk perceived. The possibility of postoperative pain or nausea is usually transient and easily treated, and therefore is perceived as having lower risk severity than a possible longer term or irreversible disability.

Many studies have been done to evaluate the particular aspects thought relevant to the way risk is perceived and many mental biases exist to prejudice our view [5]. These characteristics include both conscious and subconscious elements:

- magnitude
- severity
- vulnerability
- controllability
- familiarity
- acceptability
- framing effect

Risk probability or magnitude

This is usually expressed as a mathematical probability. As already mentioned, these numbers come from our personal experiences and from published data from previous studies.

The populations investigated by previous studies may not be comparable to your population. There may be medical, age, gender, or ethnic differences that need to be considered before the data presented is accepted as applicable to your population.

The magnitude of the risk can be biased. There are two types of error known as availability and compression bias.

- Availability bias is also known as exposure bias or publication bias. This results in an overestimation of risk due to over exposure and increased publicity associated with a rare but catastrophic event. When rare events are sensationalized in the media, the perception of risk associated with them increases. The perceived frequency is also increased.
- The general public are increasingly worried about terrorism, but the chance of being involved in a terrorist attack is very low. As these events command high profile media coverage, the perceived risk is greatly exaggerated. Similarly, airline accidents command dramatic and sensational media coverage, which increases public anxiety. However, car travel is vastly more dangerous in terms of fatalities per kilometer traveled.
- Common events are, by definition, less dramatic, and therefore are perceived to occur less frequently.
- Compression bias occurs because in many cases we do not know exactly how frequently something occurs. Usually there will be a range of probabilities and this range may be vast for rarer events. Patients tend to overestimate small risks and underestimate large ones. To use the earlier example here, compression bias causes the risk of dying in a car crash to be underestimated, but the risk of dying in a plane crash to be overestimated.

Risk severity

This may be thought of as a combination of the actual probability and the weight or perceived impact that the event may have on the patient. Therefore, this entity is subjective. The worst outcomes, death or permanent disability, will have great impact on the way the risk is perceived, even if the probability is low.

A mathematical concept used in the past in an attempt to analyze the process of risk perception was to compare different risks using an expectation value [6]. This is only of use, though, if a numerical value can be assigned to severity:

$$\text{expectation value} = \text{probability} \times \text{severity}$$

This is an over-simplification of the processes involved in risk perception and evaluation. For example, risks with a very low probability but high severity, such as death or disability, are perceived worse than risks with a higher probability and less severe outcome even though they have the same expectation value.

- An example of events with the same expectation value: if people are offered the choice of being given £5000 or of winning £10 000 on the toss of a coin, the majority will choose the £5000 certainty rather than the uncertain alternative. This has been interpreted as evidence that, if possible, people will try to avoid risk and uncertainty.

Vulnerability

Vulnerability is the extent to which people believe an event could happen to them, or alternatively it is the degree of immunity one possesses to a risk. Generally, we tend to

exhibit unrealistic optimism and a feeling of immunity or invincibility; thus, people tend to not behave cautiously. Feeling invulnerable, we underestimate or downgrade our own risk but overestimate the risk to others.

- For example, one might fear more the catastrophic but rare risk of nuclear accident than the common but minor risk of passive smoking.

Controllability

As we like to be in control of things that affect us, the possibility of something happening that cannot be controlled tends to magnify the perceived severity of the risk. The perception of being in control or having choice downgrades the perceived severity of the risk [4].

- Risky pastimes, e.g., skiing, diving, parachuting, etc. all have major risks associated with the undertaking of that activity, including death. The individuals involved are aware of the risk, but because they are in some control of their outcome, they perceive the risk to be lower. The likelihood of accepting higher risk is greater when people have the choice whether to participate.
- Involuntary or imposed risks are significantly less acceptable and incite resentment.

Familiarity

Repeated exposure to a risk induces overconfidence and familiarity. This in turn desensitizes us to the risks present. On the contrary, unfamiliar risks incite a much greater degree of fear and dread. This is known as miscalibration bias.

Acceptability

This is another very subjective issue. Individual attitudes resulting from upbringing, class, ethnic, religious, and cultural background can significantly affect the concept of acceptability or non-acceptability of the risk.

Characteristics of the hazard affect the acceptability including how severe, transient, controllable, familiar, and vulnerable or immune the patient perceives themselves to be.

Risk comparison may help the patient reach a conclusion as to the acceptability of a risk. This is achieved by comparing the risk in question with an alternative event more familiar to the patient that has a similar numerical level of risk. This shows them that they have accepted similar risks in the past.

There are many other variables including the trust the patient has in the team responsible for his/her care and any support network, including family, that are close to the patient.

Framing effect or framing bias

This is how the presentation of the risk information can affect the perception.

- It is well recognized that differences in the presentation of risk information can strongly affect the perception of risk in both lay people and doctors, and thereby influence decision making [7].
- The order in which clinicians discuss advantages and disadvantages of treatment may have an impact on a patient's perception and final decision.
- Emphasizing positive aspects before discussing risks may be more likely to persuade an individual to accept a particular treatment.

- A therapy reported to be 60% effective would be evaluated more favorable than one with a 40% likelihood of failure, although the two statements mean the same thing.
- Similarly, a treatment with a 10% mortality will be more positively perceived if phrased as having a 90% chance of survival.

This is called positive framing.

- One study[8] compared the way in which a treatment option for cholesterol lowering and hypertension was presented to patients. Relative risk reduction, absolute risk reduction, number needed to treat (NNT), average gain in disease-free years, and stratified gain in disease-free years were the methods compared. Relative risk reduction was the most likely to persuade patients to agree to treatment whereas the NNT was the least persuasive.

Communicating risk levels

As the assessment of risk and therefore the prediction of risk is not an exact science, it is almost impossible to convey an accurate picture of what an individual's clinical risk actually is. There is no way of translating population risk data into specific data for an individual [9].

The range of probabilities when expressing risk can be large, due to the lack of accurate data and to patient individuality and variability. This leaves us with the difficult issue of trying to be as accurate as we can but also communicating this to the patient in a way that is best understood. When several orders of magnitude are covered by the range, integer logarithmic scales are often used as a way of presenting information in a manageable format for the patient.

- Examples of logarithmic scales in everyday use are the Richter scale for earthquake magnitude, the pH scale for hydrogen ion concentration, and the decibel scale for sound intensity.
- Logarithmic scales may be helpful to some people, but they simply replace very large numbers with smaller ones, sometimes with the effect of overestimating very small risk.
- By substituting a word or a descriptive phrase instead of a number, Calman's verbal scale [3] and the community cluster classification [4] goes some way to being more meaningful to the layperson (Table 1.1). It is quite easy to visualize one person in a street where you live, or one person in a small town compared with one person in a large city.

Table 1.1. Risk scales

Risk level 1 in:	Calman's verbal scale	Calman's descriptive cluster	Community scale
1–9	Very high		
10–99	High	Frequent, significant	Family
100–999	Moderate		Street
1000–9999	Low	Tolerable, reasonable	Village
10 000–99 999	Very low		Small town
100 000–999 999	Minimal	Acceptable	Large town
1 000 000–9 999 999	Negligible	Insignificant, safe	City

Other analogies more meaningful to the layperson have been sought. The U.K. Lotto, formerly U.K. National Lottery, and the probability of winning has been used [10]:

3 balls	1 in 57
4 balls	1 in 1032
5 balls	1 in 55 491
5 balls + bonus	1 in 2 330 636
6 balls	1 in 13 983 816

Number needed to treat

This is a concept introduced by Laupacis et al. in 1988 [11]. It is a method used to compare the efficacy of treatments and is calculated from the reciprocal of the absolute risk reduction. In other words, it is the number of patients needed to be treated for one patient to benefit.

- It has been used to compare analgesics and a league table has been drawn up. This has been helpful to clinicians as NNT is said to convey both statistical and clinical significance [12]. Paracetamol (acetaminophen) and ibuprofen have NNTs of 3.6 and 2, respectively, and are therefore effective, whereas codeine has a rather poor NNT of 18 in comparison.

This concept has evolved when looking at risk to number needed to harm (NNH) and if you do not treat (IYDT). The same principle calculates the number of patients needed to treat before one patient suffered the adverse effect in question.

- The higher the NNH, the safer the treatment.
- IYDT gives a number of patients from whom treatment is withheld before an adverse incident occurs.

An extension into anesthetic practice would be the number needed to monitor (NNM) to prevent one anesthetic-related death.

- This number may be very high, but is worthwhile to preserve the safety of anesthesia [13].

While trying to communicate risk to a patient, it must be remembered that what is actually perceived may not be the same as was intended. Differing knowledge base and past personal experience may result in the two people essentially "coming from opposite directions" and misunderstandings should be expected and predicted. As there are clearly many methods of trying to convey actual levels of risk to our patients, it is likely that their ability to understand is very variable and more than one approach may well be required for many patients.

If booklets are used as a way of conveying information, it must be remembered that factual information is not the only thing that is communicated. The patient will respond on an emotional level as well and this is all too often neglected by doctors. It could be that this is because we fail to appreciate the importance or are not comfortable with the way the patient might be feeling.

What is high-risk ?

When evaluating risk, we have already said it is difficult to convey a probability in terms that mean something to the layperson. Using an actual number may be misleading as well.

- When asked, 85% of the population thought they had a better than average sense of humor.
- Many patients, however, are disturbed to learn that 49% of doctors show below average performance.

We need to find a way to give a meaning to a number. When a likely risk, or a numerical probability, is displayed directly alongside a series of day-to-day events corresponding to the same probability of occurring, then the impact is greater and has some relevant meaning [14]. Figure 1.1 shows this as a risk ladder.

- A risk level of 1 in 100 000 has been deemed *acceptable* [4] and a risk level of 1 in 1 000 000 is deemed *safe*.
- The risk of death by road traffic accident in the U.K. in one year is 8000 – a risk that a large proportion of us take every day on our way to and from work. This corresponds to a risk level less than 1 in 1000, which is deemed *tolerable* or *reasonable* [3].
- There are those who do not believe that any degree of risk is universally acceptable [2].
- When evaluating risk perception, we have already seen that there are numerous subjective criteria to be considered alongside the numerical magnitude of risk.

When considering overall risk, one must consider the baseline risk and then add on, or superimpose, the relevant additional risk to reach the real risk.

- For example, we all have a risk of dying every day. This baseline risk increases as we get older. Any other risk of premature death such as smoking or murder need to be added to the baseline to see the actual risk of death for that day.
- In anesthesia, the number given as baseline for death under anesthesia is 1 in 185 000. We all know that this is an artificial figure as people are generally not given anesthetics without some operation or procedure also happening to them.
- The risk of death after surgery is much greater than this figure because the surgery, the patient, the surgeon, and the anesthetist all have a little extra risk to add on.
- The extra risk may not always be quantifiable, but will be additive.
- The more closely we can form a personalized estimate of risk for an individual, the more the gap between population-based data and the subjective experience of the patient will narrow and the more informed that patient's decision will be [15].

Relative and absolute risk

These two terms can be used solely or together to convey risk. When used solely, the relative risk of an event can be very misleading.

- If the absolute risk of an event occurring is very small, say 1 in 1 000 000, this is often perceived quite correctly as a very unlikely occurrence. If the absolute risk were 2 in 1 000 000, most observers would still perceive the risk as very unlikely.
- When described in terms of relative risk, we can say that the risk has doubled or is twice as likely, or has increased by 100%. All of these terms tend to be more alarming and likely to result in the perception of a greatly increased risk.

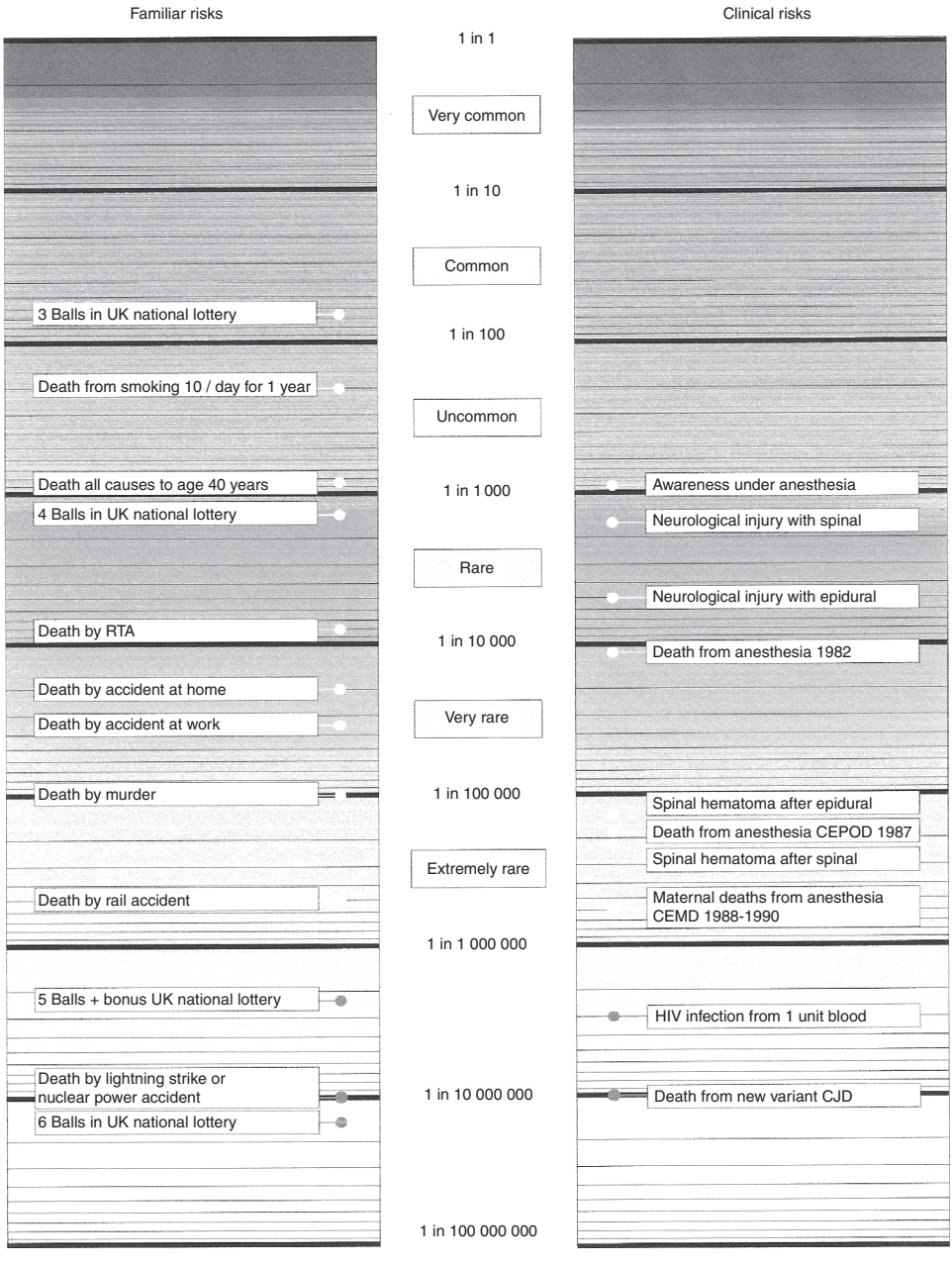

Figure 1.1. Risk ladder.

This is a method the media use frequently to over-dramatize a story.

- A very good example of this is the risk of venous thromboembolism (VTE) while taking a "low-dose" third-generation oral contraceptive pill (OCP) [15]. The press revealed accurate but misleading relative risk figures without adequately stressing the absolute risk.

- This was further compounded by the general public, and many medical professionals, not having extra information to put these figures into context.
- The actual risk of VTE when pregnant is higher again and the risk to someone not on either pill does not equal zero.

	Incidence of VTE per million women per year	Mortality; deaths per million women per year
No oral contraceptive	50	0.5
2nd-generation OCP	150	1.5
3rd-generation OCP	300	3.0
Pregnancy	600	6.0

Risk–benefit analysis

In the U.K., the General Medical Council has issued guidance on consent, which entitles patients and doctors to make decisions together [16]. It makes the points that:

- All efforts should be made to involve the patient in the decision making process and that assumptions should not be made about what they would and would not want.
- Patients should be given sufficient information before deciding to give their consent and must be warned of serious risks before proceeding even if they do not want to know detailed information regarding the treatment.
- It states that information should be personalized to each patient as much as possible and presented in a way that s/he can understand and be given time to reflect on the information presented before coming to a decision.
- If a patient states that s/he does not want information, this must be documented clearly in the medical notes and it be made clear that s/he can change her/his mind and have more information at any time.

We have moved from a concept of "the reasonable doctor," where the doctor knew what was best for the patient and decided what the patient needed to be told, to the concept of "the reasonable patient."

- Doctors now are expected to give much more information as a matter of course so the patient is empowered fully to decide what happens to her/him. But is this always in the patients' best interests?
- Although patients have the power to make decisions about their healthcare, it brings with it a significant amount of responsibility that many patients simply do not want or cannot deal with.
- Furthermore, the giving of information, some of which will have negative implications, may well frighten a patient just at the time when s/he is looking for reassurance and comfort.
- Is it justifiable that we scare our patients so that we can satisfy ourselves that we have disclosed all the risks?

The subject of consent throws into conflict two important ethical principles:

- autonomy (the individual having the right to determine what happens to her/him)
- beneficence (the obligation for doctors to do only good for the patient)

Doctors may exercise "therapeutic privilege," which allows us to withhold certain information if it is deemed that it would be contrary to the patient's best interests, cause harm to the patient, or deter the patient from proceeding with a therapeutic procedure considered essential. All risks discussed and those not discussed, with the reasons for not doing so, should be documented in the patient's notes [17].

The "reasonable" patient who is fully informed may sometimes turn out to be an "unreasonable" patient.

- Patients sometimes choose the option that the doctor would not choose for the patient [18]. If a patient states a preference for a procedure that increases the risks for the patient (e.g., a patient requesting general anesthesia [GA] for an elective cesarean section instead of a spinal technique), does this mean the patient has made a wrong choice?
- Should the anesthetist accept the decision and proceed while managing the extra risk, or should the anesthetist have the right to refuse to treat the patient on the grounds that she is putting herself at unnecessary extra risk?

When making an assessment of risk acceptability, there needs to be a complete assessment of all the risks and benefits.

- Perception of the advantages of an event versus the disadvantages of the hazards associated with the event are personal to each individual.
- This is an unpredictable process and it is often surprising what patients are prepared to accept in terms of high-risk for what might appear to be little gain.
- Conversely, some individuals will refuse treatment that is likely to have a positive outcome because of fears about something we perceive to be quite trivial.
- Our duty is to be as honest and as accurate as we can with the information we have and allow the patient time to perform her/his own individual risk–benefit analysis.
- Depending on the urgency, this process can take months and sometimes even years.

The mnemonic BRAN (Benefits, Risks, Alternatives, Nothing) offers a useful way of approaching this analysis. This covers the benefits and risks associated with a course of action. It also prompts us to think of alternative treatments and what would happen if nothing were done.

What are the benefits?

- Identify the benefits.
- Assess the likelihood of benefit.
- Assess the perceived value of the benefit.
- How soon could benefit occur?
- Is the benefit permanent or temporary?

What are the risks?

- Identify the risks.
- Assess the likelihood or probability of risk.
- Assess the perceived magnitude of the risk.
- How soon could the risk occur?
- Is the risk permanent or temporary?