Issues of risk: 'this unique opportunity'

Professor Sir Kenneth C Calman, KCB, FRSE

Introduction

IT was a privilege to be invited to deliver the William Pickles Lecture this year. He has always been a hero of mine, and his book, *Epidemiology in country practice*,[1] has been a source of inspiration. The introductory chapter of his book sets the scene for this lecture — he describes the population at risk, assesses their vulnerabilities, and then carries out meticulous and detailed epidemiological studies. The charts of the development of infectious disease as they progress through the practice are a model of acute observation, as well as great depth of knowledge of his patients. The compassion shows, and it is clear that his work is not directed at more publications or awards but driven by a wish to improve the health of the population he looked after. At the end of the introduction he describes the role of the general practitioner and finishes with the phrase, '… make use of this unique opportunity'. What a wonderful way of describing general practice: as a unique opportunity to improve health, well-being and quality of life. In the management of risk the general practitioner has a 'unique opportunity' to assist patients and the wider public in reducing and modifying risk; for example, in changing lifestyle (smoking, alcohol, drugs, nutrition, exercise), in the appropriate use of medicines, in identifying and counselling about genetic risks, and in modifying social factors. The general practitioner also has a wider role in improving the public health through observation and intervention and by advocacy for the population. There are therefore many ways in which the general practitioner can influence risk.

Background

Scarcely a day goes past without some scare, risk or alert on a matter of health or health care being raised in the media. Over the past few years numerous issues have caught the public attention, including: pesticides, organophosphates, cot mattresses and sudden infant death, passive smoking, climate change, toxic waste, genetically modified foods, nuclear accidents, *E. coli* 0157, bovine spongiform encephalopathy, and medical risks of all sorts.

What does the public make of all this? How can they begin to sort out what is a real risk from one that has been inflated by the media? Who is telling the truth, and has there been a cover up? How do professionals make sense of the issues and advise patients and members of the public? This paper sets out to examine some of the background to the issue of risk communication and makes some suggestions as to the way forward.

The objective, from the patient's and the public's perspective, is to ensure that any risks to health are minimised and that full information is openly and freely available. It is to improve the health, health care, and quality of life of the population. This applies equally to the patient–doctor (or other health care professional) relationship as it does to giving information to the public. This is supplemented by a further objective, that of involving the public and patients in making decisions.

The communication of risk is complicated by several factors:

1. The problems are often complex, with no simple 'yes' or 'no' answer.
2. There is often major uncertainty as to the outcome. This may be because of lack of evidence or because the nature of the issue is not fully understood.
3. When there is real uncertainty and decisions have to be made, someone has to make a judgement as to the likely consequences and hence the need for action, or no action, to be taken. In public health terms, in dealing with a large population it is a fair assumption that not all of the public will agree with the decision.
4. Public perceptions of the consequences of any intervention, or lack of it, are critical. This is at the heart of understanding the public's thinking and fears. It is not to be dealt with simply by re-stating the scientific case more loudly and trying to explain the underlying science. It is much more than this. It is trying to understand the public's viewpoint fully. The public has considerable commonsense and experience. Their views need to be taken into account, and taken seriously

Each of the factors listed above makes it difficult to identify methods of risk communication that will be effective in all instances. Indeed, it is a good question as to what would constitute a satisfactory outcome. Is it full public information, the avoidance of exposure to a risk, no public outcry, or more research being generated? No matter how careful the professional is in carrying out a procedure, some adverse events will, and do, occur. This is in the nature of dealing with a complex biological entity, such as a human being. Not all consequences can be foreseen. What is important is the development of openness and trust so that the relationship is such that adverse events can be identified early, and if possible dealt with.

K C Calman, KCB, FRSE, vice-chancellor and warden, University of Durham. The text is based on the 2000 William Pickles Lecture, which was delivered at the Spring Symposium of the Royal College of General Practitioners in Crieff, Scotland on 16 April 2000.

Address for correspondence

Professor Sir Kenneth C Calman, Vice-Chancellor and Warden, University of Durham, Old Shire Hall, Durham DH1 3HP.
Submitted: 15 June 2000; Editor's response: 31 July 2000; final acceptance: 31 October 2000.

This raises a further point that has already been alluded to briefly. In the presentation of a risk to a patient (side-effects of a treatment, dangers of an investigation, a lifestyle issue) it is possible to have a full discussion, review the evidence, give detailed answers, and raise specific questions. The patient's preferences and choices can be taken into account. This would be the normal process of the medical consultation. At the end of this the patient and the doctor would be agreed on a course of action. This is more difficult when dealing with a population of 56 million. Trust is essential in dealing with a large population, as the decision will generally be made without the in-depth discussion having taken place. With the great variations in the population's views on most subjects, it is not difficult to see how discontent may arise. Newer electronic methods of engaging the public may be helpful in reducing this and in developing a dialogue.

Risk perceptions

The subject of risk perception was discussed briefly in the introduction. Its understanding is central to ensuring effective risk communication. There are several components to perceptions of risk.[2,3] These include a list of 'fright factors' that raise particular concerns, such as lack of choice, the unfamiliar and inescapable, man-made problems, those that affect children or pregnant women, some specific illness associated with pain and fear, poorly understood science, and conflicting evidence.

Perceptions of risk also relate to comparisons between risks and how a particular risk matches up with another. An analysis of this may help but it is only one part of the story. In a similar way, risks can be put in particular frames of reference for comparative purposes and such framing effects may be quite different between doctors, scientists, and the public. Risk familiarity also affects the perception. If we regularly face risks, such as those associated with driving a car, it is less frightening some years on than when we began driving. Or, if we have to take a passenger who requires special care, such as a child, our driving pattern may be modified. Finally, there is the important factor of social amplification of risk. This is not uncommon when a risk is rapidly communicated across a population such that there is a major change in behaviour for a large section of the community. Examples of this might be the public's response to salmonella and eggs, genetically modified foods, and cot mattresses and sudden infant deaths. In each instance the public response was rapid and widespread and based on national dissemination of information.

The public have great sophistication and commonsense. They react appropriately even if it is not in the way some might wish. Evidence of this can be seen daily in the newspapers where cartoons and jokes on such risk issues are laughed at and appreciated, even though the science is quite complex. It was Immanuel Kant who said, 'We see things not as they are but as we are.' The perception is as important as the reality. It should also be recognised that knowledge, by itself, is neutral and inert. It is the perception of that knowledge that is subsequently translated into behaviour.

Risk communication

What do we mean by risk communication? It might be said to be a process by which an individual or a population is given access to information about a risk that explains what it means, what its consequences might be, and what might, or might not be done about it. Communication is a two-way process and this therefore assumes that the possibility for dialogue exists. The difficulties with implementing this have already been described. There is a considerable research background already on this subject and this is available in both books and journals.[4,5] Specific monographs on particular issues can be very helpful, and a good example of this would be the note by the Government's Chief Scientists on genetically modified organisms.[6]

Before developing this theme further, some definitions are required and, in particular, that of hazard and risk. A *hazard* is a 'set of circumstances that may have harmful consequences'. A *risk* is 'the probability of the hazard causing an adverse effect'. Thus, the probability of a hazard causing such effects is the risk of the adverse event occurring.

One way of describing the difference between the two is to consider a bottle of aspirin tablets and their potential adverse effects on children. The tablets are a hazard and if the bottle is left on a low-lying table with the top off, the risk that a small child might find them and swallow them is high. On the other hand, if the bottle is sealed, placed in a locked cupboard and stored in an elevated place, although the hazard remains the risk is greatly reduced. However, it should be clear that the risk is not zero.

The assessment of risk and its presentation is a complex subject and will not be dealt with in any detail here, save to identify the problems of expressing the risk assessment. The assessment can be communicated in many ways: as a ratio (e.g. 1:1000), or as a percentage (e.g. 2%) of the population or patient group at risk. These may not be easy to understand and might also be expressed in a different way, such as the numbers of people in your street or village who might be affected.[7] The alternative view of the consequences of expressing risk in these ways also needs some thought. For example, if the probability of response to a particular treatment is 1:20 then for every one patient who responds, 19 do not and may have side-effects. Alternatively, if the risk of food poisoning is 1:2000 then 1999 will not be affected. In addition, it is important to consider the difference between relative and absolute risk. This became apparent in the issue related to the contraceptive pill and thromboembolic episodes. The relative risk was doubled; however, the absolute risk was very small (mortality rising from 1.5 deaths per million to 3 deaths per million). In such instances, it is important that the distinction between the two is made as it may significantly affect choice.

Understanding the language of risk

Finding a language to describe risk is no easy task. Not only does it need to be understandable but the words have to be unambiguous; in particular they need to avoid having 'values' related to them. For example, words such as 'justifiable', 'tolerable', and 'not serious' probably should be avoided. They may be used in qualifying or describing but not as the primary words used. The reason for this is that some might question in whose judgement a risk is described as 'justifiable' or 'not serious'. Perhaps not theirs, or yours.

An attempt has been made to do this using, as far as possible, neutral language.[8] In addition, some numerical values were assigned to the terms. These are: 'high' (≥1:100), 'moderate' (1:1000), 'low' (1:10 000), 'very low' (1:100 000), 'minimal' (1:1 000 000), 'negligible' (≤1:1 000 000), and 'unknown'.

This latter category of 'unknown' is important to retain. For any such list there are a series of health warnings. Thus, where the terms fall is for debate. They may vary from time

to time and changes in knowledge will alter the assessment. A risk may be low when it first appears but as information and new knowledge becomes available this may become high, or vice versa. It is also impossible to predict in any individual how they will react to a risk. Some enjoy risk, and take up sports and other activities to demonstrate this. In other instances, people do not think of themselves first and display courage to save others.

Finally, if the word 'safe' is to be used then it must be seen to mean 'negligible' but should not imply no, or zero risk. The word, in common usage, is plainly used in the context that the risk is not zero. For example, a 'safe driver' or a 'safe pair of hands' certainly does not imply that there will be no problems. Other examples would include 'completely safe' or 'quite safe', each phrase using a qualifying word.

Preparing a framework for response

In communicating risk it is useful to have a framework within which to conceptualise the way in which the process can be managed. This framework must be able to apply to those working in different settings, such as a large hospital, a health centre, a primary trust, or in a single-handed practice. Three 'phases of response' can be identified: the preparatory or anticipatory period, dealing with the incident and, finally, the learning experience.

The preparatory period

It is during this period, which can be of variable length, that potential problems are identified. Anticipation of problems is of the essence. This can be done in a variety of ways, including consideration of different scenarios, planning for an incident, testing the internal communications system, assigning clear responsibility for the functions, and ensuring that risk management is firmly embedded in the culture. Thinking ahead is vital no matter where you work.

The intelligence function in any organisation is therefore essential. It is not a hit and miss affair. Intelligence, as evaluated information, is an essential part of the management process and assists in decision-making. Many of the problems of any organisation, no matter how large or small, are already known about. Memos may have been sent, complaints received, and warning signs identified. This is in no way unique to public health or health care, hospitals or general practice, but is a feature of all organisations. Most people near the top of a management tree know where the problems are, or they should. The question is why do they not do something about it? It is for this reason that the preparatory phase is the most important.

Dealing with the incident

This is the part of the process that is most in the public eye and indeed figures most prominently in concerns of the trust or practice: What will the public think of us? How will we minimise the damage? As discussed in the previous section, most crises are predictable and may already be known about in the system. Each part of the management system will need to think through the requirements but research over the years has suggested that some aspects are of particular importance.[5] These might include the use of checklists, built up over the years to reflect the particular issues faced. The importance of stakeholder involvement is clear, as is the need to engage those most concerned and with special expertise. The development of trust built up over a period of time allows uncertainties to be acknowledged. Finally, the media; they are essential allies in the process and need to be involved and assisted. They require information and copy and can be of enormous value.

Incident management requires great care and attention to detail. Teamwork doesn't just happen — it has to be grown, and it is best not tested in a crisis. The communication system also requires a great deal of work. There is a particular issue that is relevant in the communication with professionals. They need the information to manage the problem 'out there'. If they don't get it then they feel both frustrated and let down. The development of electronic communications should make this much easier in the future. The 'Friday night syndrome' is familiar to everyone working in this field: that's when the crises occur. Everyone has gone home, the phone book is in the wrong place, you are expected at a dinner, and there's no coffee left. Managing crises cannot be left to chance. It is a professional matter, whether in the health care sector or public health. In clinical work we know what to do in an emergency, we have trained and practiced. Our patients and public expect the same in how we manage the organisation and deal with difficult problems. The process of prevention, early diagnosis, management, follow-up and learning the lessons carry the same responsibilities in management as in clinical practice.

Learning from the experience

This should be the most obvious consequence following an incident. Yet experience suggests that some places do not take it seriously. 'It couldn't happen again', 'It was a special set of circumstances', 'The doctor concerned has left'. These and other excuses tend to put off the learning process. There is much to be gained from an effective audit of what happened and how it might be improved. The analogy, once again with clinical practice, is clear.

Many of the lessons that have been learned from similar incidents in other types of organisation are available for reflection. Some have already been mentioned. They include the need for credible sources of advice, openness, sharing uncertainty, involving the public as partners, careful planning, listening to concerns, co-ordinating with other sources of advice (such as specialist agencies), and meeting the needs of the media.

Clinical risk

Much of the discussion so far has been related to the management of risks to the public's health or to how health care organisations deal with problems. A similar process is relevant to clinical risks and hazards. It is often known that there is a problem in a hospital or a primary care team, yet no action has been taken. The anticipatory period is just as relevant with clinical risk, as is the need, when an incident arises, to be open about the problem. Clinical audit processes are exactly analogous to auditing the management of a public health problem.

In dealing with environmental risks, one of the most powerful methods used is that of the Hazard Analysis Critical Control Point process (HACCP). In this process key factors are identified which, if something goes wrong, are of particular concern. A similar methodology can be used in clinical work. For example, in surgical procedures certain steps in the operation may be especially critical, such as the completion of an anastomosis or the removal of swabs before closure. By identifying such critical points the operation can be performed with these points checked, with a reduction in adverse events.

Certainty in science

Much of the argument so far has been based on the fact that certainty in science is in some senses illusory. Indeed, one of the purposes of the scientific method is to test existing ideas and concepts and to see new possibilities and solutions. A fact is only a fact if the concept with which it is associated remains intact. Shifts in scientific thinking occur all the time and in philosophical terms the idea of what is true at one moment in time may not remain so for ever. Thus, the public requirement (and scientific and political) for a clear and unambiguous statement about a particular issue may not be possible in all instances. 'Is it safe?' and 'Will there be long term damage?' are questions that may not be answerable; hence the difficulty in knowing whom to believe when different figures, statistics, and views are expressed. It may be that there is no 'correct' view at present. It is in such instances when someone, somewhere, has to make a judgement about a particular issue and, as has been discussed previously, not everyone therefore will be satisfied with the outcome. Human beings are difficult to quantify accurately, as are all biological systems. We do not have a series of Newtonian Laws that predict outcome under all circumstances. We suffer from 'physics envy'. The problem of risk in populations and in individuals is therefore not certainty, but uncertainty.

The precautionary principle

This takes us directly into the issues of the use of the precautionary principle in which action is taken, either to do something or to stop doing something to prevent something happening. Two quotations set this in context:

> *'Epidemics resemble great warning signs on which the true statesman is able to read that the evolution of his nation has been disturbed to a point which even a careless policy is no longer allowed to overlook'.*
>
> Rudolph Virchow, 1848

> *'When trouble is sensed well in advance it can be easily remedied ... So it is in politics. Political discords can be healed quickly if they are seen well in advance.*
>
> Niccolo Machiavelli **[Author: from *The Prince*?]**

There are considerable differences in the way in which the principle is interpreted and used.[9] A consideration of a number of instances in which it has been invoked suggests that there are at present no simple rules that govern its introduction in any specific instance. Generally, as the science is uncertain, the judgement is based on non-scientific factors and the process is a political one. The person taking the decision in the organisation bases the action on values and beliefs, as well as the incomplete science. As always, the problem for decision-makers is not when the evidence is clear but when the facts are disputed and a scientific consensus has not been achieved.

The purpose of invoking the precautionary principle is to protect the health of the public or the patient. In general, it will require legislation that will (a) restrict choice and freedom, and is (b) punitive. Thus, the freedom of choice for one person restricts the freedom of choice of another. In most instances in which the principle is used, someone, or some group, will be disadvantaged, and may even be fined or imprisoned for not obeying the rules.

At the heart of the issues is the question of how to deal with uncertainty. Three choices are possible for the decision-maker:

1. go beyond the evidence and take action;
2. make no changes and await further research; and
3. find some third way and make the reasons explicit.

In trying to make a decision, three major questions or issues arise. What is the level of certainty of the risk and how strong is the evidence? Does the individual have any choice? What is the magnitude of the risk? Based on the answers to these questions a decision can then be made. As has been mentioned, the problem for decision-makers is not when the evidence is clear but when it is weak or incomplete, or even simply at the level of a hypothesis.

How can it be justified to take action to stop something when there is no evidence and which may cost billions of pounds? How can it *not* be justified to take action if even one human life is at stake? These are the two extremes of the issues and those taking the decisions need to consider both ends of the spectrum. Thus the process of decision-making requires first an examination of the three questions posed earlier. Secondly, a consideration of non-scientific factors is required to identify issues in the perception of the public that might have a bearing on the topic. The previously described fright factors are relevant to this. Finally, the decision is made taking all of these factors into account and is essentially a political one, and as such it does not matter whether the organisation is a government, a health care trust or a private company. At the end of the day someone has to make a judgement.

There are two parts to making the decision public. The first is to set out the scientific background to the issue, making clear any differences of view and any deficiencies in the data. This is the proper function of scientific advice to policy makers from experts in the particular area of research. The second — and equally important — is to set out the non-scientific reasons for making the decision so that the public can also come to a view on their validity. This second part is not within the remit of scientific or expert committees. The translation of scientific evidence into public policy is complex and difficult. Scientists, in general, find this more of a problem as it does not leave room for doubt, for more research, or for the ambiguities and questions that remain. We are very fortunate in having access to a remarkable range of scientific skills, knowledge, and expertise to call on when we need to. We should use them to their best advantage.

Even when a clear decision has been made some problems remain. In some instances there will be continuing discontent. The decision will not please everyone and there may be repeated attempts to change the decision. This is a legitimate exercise in a democratic society but can take a considerable amount of time. Managing the disagreement can be an important part of the follow-through once the decision has been made. The timing of the decision can also be a problem. Generally, it is easier to stop something before it starts than to take action against an existing procedure, unless the evidence is very clear.

The pleasures of risk

It is generally assumed that risk is always harmful and associated with fear and fright. However, for some risk, and for some people, it is linked to pleasure and excitement. Individuals actually seek circumstances of risk and enjoy it. This may be related to sport, outdoor pursuits, lifestyle issues or personal relationships that carry risk. These are seen to be enjoyable and are sought after. It is thus impor-

tant to recognise that aspect when making assumptions about how individuals will view an issue of risk. It is unlikely that we will ever be able to eliminate risk. Living with risk has always been part of life and it is always likely to be so.

Some conclusions

A number of conclusions can be drawn from this brief review. First, the problem of managing uncertainty is at the heart of communicating risk and making decisions about invoking the precautionary principle. The three phases of dealing with the communication of risk have been outlined and emphasis placed on the anticipatory period. The problem of language has been described and the need for clarity outlined. While the scientific evidence is important, in some cases it will be weak or inconclusive. In such cases the decision is likely to be based on non-scientific factors and they also need to be described and identified. The value base for these decisions is critical and sets the tone for all decision-making. The general practitioner has a significant role in the identification and management of risk. At the end of the day it is the importance of people, either as individuals or as communities and populations, which matters, and in doing everything possible to safeguard human health. The following quotation emphasises the importance of involving all of the people, all of the time:

'I know of no safe depository of the ultimate powers of society but the people themselves; and if we think them not enlightened enough to exercise their control with a wholesome discretion, then the remedy is not to take it from them, but to inform their discretion.'

Thomas Jefferson (Letter to W C Jarvis, 28 September 1820)

Endpiece

I have the privilege of treasuring my own first edition of *Epidemiology in country practice*. During my research for this lecture I found another first edition in the library of the Royal College of Physicians and Surgeons of Glasgow, signed by William Pickles on 31 August 1944 at his home in Aysgarth and given to a gifted friend, Professor Sir Charles Illingworth. Sir Charles was Professor of Surgery at Glasgow and President of the College, at that time a Faculty. In the flyleaf Pickles quotes from a letter by T H Huxley and as it fits well into the subject of this lecture it is a most suitable endpiece. It emphasises, as Pickles himself did, the 'great opportunity' there is in general practice to continue to improve health and wellbeing.

'Sit down before fact as a little child: be prepared to give up every preconceived notion: follow humbly and blindly wherever nature leads or you shall learn nothing'.

References

1. Pickles WN. *Epidemiology in country practice*. Bristol: John Wright and Sons, 1939.
2. Calman KC, Bennett P, Coles DG. Risks to health: some key issues in management, regulation and communication. *Health Risk and Society* 1999; **1:** 107-116.
3. Bennett P, Calman KC. *Risk communication and the public health*. Oxford: Oxford University Press, 1999.
4. The Royal Society. *Risk: analysis, perception and management*. 2nd Edition. London: The Royal Society, 1992.
5. British Medical Association. *Living with risk*. Harmondsworth, England: Penguin Books, 1990.
6. May R. *Genetically modified foods: Facts, worries, policies and public confidence*. London: Office of Science and Technology, 1999.
7. Calman KC, Royston G. Risk, language and dialects. *BMJ* 1997; **315:** 939-942.
8. Calman KC. Cancer: science and society and the communication of risk. *BMJ* 1996; **313:** 799-802.
9. Department of Health. *Communicating risks about public health: pointers to good practice*. 2nd Edition. London: The Stationery Office, 1998.
10. Calman KC, Smith D. The precautionary principle. 2001 (In Press) **[Author: any further details?]**