

CONSUMERS' VIEW**Patient safety: what about the patient?****C A Vincent, A Coulter***Qual Saf Health Care* 2002;**11**:76–80

Plans for improving safety in medical care often ignore the patient's perspective. The active role of patients in their care should be recognised and encouraged. Patients have a key role to play in helping to reach an accurate diagnosis, in deciding about appropriate treatment, in choosing an experienced and safe provider, in ensuring that treatment is appropriately administered, monitored and adhered to, and in identifying adverse events and taking appropriate action. They may experience considerable psychological trauma both as a result of an adverse outcome and through the way the incident is managed. If a medical injury occurs it is important to listen to the patient and/or the family, acknowledge the damage, give an honest and open explanation and an apology, ask about emotional trauma and anxieties about future treatment, and provide practical and financial help quickly.

The most remarkable feature of the many faceted patient safety movement is surely the lack of attention paid to the patient. Safety is addressed and discussed in many ways, and lessons are sought from all manner of other industries and experts including the disciplines of psychology, ergonomics, and engineering. Yet the one source of experience and expertise that remains largely ignored is that of the patient.

Patients have indirectly been a powerful driving force for patient safety when acting as litigants. In Britain risk management was driven by the growth in litigation and was initially seen as a means of dealing with and controlling litigation costs, gradually evolving to include the prevention of harm. With the realisation of the nature and extent of harm to patients, risk management broadened into an active concern with patient safety. The recognition that health care—previously thought of as benign, if far from perfect—often causes harm has been salutary.

Two key areas have not been addressed by any of the major reports on patient safety—the contribution patients themselves can make to patient safety, whether individually or collectively, and the impact of lapses in safety on patients and their families. There has been insufficient recognition that what happens after an incident may well be as important as what led up to it. In this paper we argue that the patient safety movement will be incomplete if the patient perspective is not brought fully into focus. We discuss some of the major issues and suggest some ways forward.

WHAT ROLE CAN PATIENTS PLAY?

The patient's perspective ought to be a key component of any quality improvement strategy. Quality from the patient's perspective includes access to care, responsiveness and empathy, good communication, clear information provision, appropriate treatment, relief of symptoms, improvement in health status and, above all, safety and freedom from medical injury.

There have been few studies of patients' views on the safety of health care or the risk of medical errors, but some evidence from the US indicates a significant level of awareness of safety issues among the general population. For example, in a national telephone survey carried out in 1997 by Louis Harris and Associates on behalf of the National Patient Safety Foundation, 42% of respondents disagreed with the proposition that the current healthcare system had adequate measures in place to prevent medical mistakes, and 42% indicated that they or their close friends and relatives had experienced a medical mistake.¹

Patients are usually thought of in a passive way as the victims of errors and safety failures, but there is considerable scope for them to play an active part in ensuring that their care is effective and appropriate in preventing mistakes and assuring their own safety. It is, of course, important not to place an additional burden of responsibility on people who are already anxious and vulnerable because of injury or serious illness. However, most clinical encounters are not times of crisis for patients and additional involvement in their treatment should not be a burden. When patients are seriously ill it may be even more important to take their views and wishes into account, either by involving them directly or by using family members as surrogate decision makers. Instead of treating patients as passive recipients of medical care, it is much more appropriate to view them as partners or co-producers with an active role in their care which needs to be recognised and enhanced (box 1).

Box 1 The patient's role in promoting safety

The patient is involved in:

- Helping to reach an accurate diagnosis.
- Deciding on appropriate treatment or management strategy.
- Choosing a suitably experienced and safe provider.
- Ensuring that treatment is appropriately administered, monitored and adhered to.
- Identifying side effects or adverse events quickly and taking appropriate action.

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Accepted for publication
17 January 2002

Diagnostic accuracy

Poor communication is at the heart of the vast majority of complaints about clinicians' performance. Misdiagnosis sometimes results from a failure to listen to what the patients say about their symptoms, or dismissing their concerns too hastily. In the UK the majority of GP consultations last less than 10 minutes,² so it is hardly surprising that some patients feel they do not have sufficient time to get across the information they feel is important. In a national survey of general practice patients only 60% of those surveyed reported that their GP always listened to them, only 51% said the GP always took their opinions seriously, and only 46% felt their GP always made the right diagnosis, while a further 38% felt their GP got it right most, but not all, of the time.²

Most patients prefer to consult a sympathetic doctor interested in their worries and expectations who discusses and agrees the problem and treatment.³ This type of consulting style is more likely to foster the type of full information exchange necessary to reach an accurate diagnosis, but it may require longer consultations than is currently the norm.⁴ Failure to institute appropriate management following receipt of test results could probably be reduced if patients were encouraged to ask for explanations of these, but many patients do not receive clear explanations at present.⁵ Accurate diagnosis depends on taking a full history from the patient together with careful assessment of clinical signs and symptoms. If the patient's role is diminished, the likelihood of error is increased.

Appropriate treatment

If clinicians are ignorant of patients' values and preferences, patients may receive treatment which is inappropriate to their needs. Doctors sometimes fail to understand patients' preferences resulting in inappropriate treatment decisions,^{6,7} and the quality of clinical communication has an effect on outcome.^{8,9} Patients who are well informed about the prognosis and treatment options—including benefits, harms, and side effects—are more likely to adhere to treatment, leading to better health outcomes.¹⁰ They are also less likely to accept ineffective or risky procedures. Patients who were given full information about the pros and cons of PSA screening for prostate cancer were less likely to undergo the test than those who were not fully informed,¹¹ and in another study patients were less likely to undergo prostatectomy for benign prostatic hyperplasia when they had an opportunity to review the evidence on risks and benefits.¹² It seems that patients are often more risk averse than the clinicians they consult.

This evidence supports the view that patients ought to be offered information about treatment options and likely outcomes and encouraged to participate in decisions about which option is most appropriate for them.¹³ Techniques for doing this, based on shared decision making principles, have been developed, evaluated, and found to work well.¹⁴ What is needed now is a concerted effort to implement these techniques, supported by training programmes for health professionals and the production of evidence-based decision aids for patients.¹⁵

Choice of provider

If the parents of babies who died or were damaged while undergoing heart surgery at the Bristol Royal Infirmary had been told that the unit which was proposing to operate on their children had an abnormally high mortality rate, they would probably have chosen to go elsewhere.¹⁶ This information was known to professional bodies but was not made available to the public. Following the events at Bristol the British government has promised to end this lack of openness. They have announced their intention to publish information about the quality of care in hospitals to enable patients and their GPs to make informed choices about hospital referrals.¹⁷

There are also plans to provide public information about the training and track record of individual surgeons and the Department of Health is working with a commercial information provider (Dr Foster) to make this type of information accessible to the public via websites.¹⁸

Such information has been available for some time in parts of the US.¹⁹ Evidence of an association between the number of procedures carried out and the quality of outcomes has led the federal government's Agency for Healthcare Research and Quality (AHRQ) to recommend that patients should check how many procedures have been carried out in particular hospitals or by individual surgeons before agreeing to undergo treatment there. Evidence that patients can make use of this type of information to reduce their risk is currently sparse.²⁰ Nevertheless, faced with growing public awareness of the potential for harm, the case for greater transparency seems overwhelming.

Effective treatment and disease management

Patients who know what to expect in relation to quality standards can check on appropriate performance of clinical tasks. The Foundation for Accountability in the USA promotes consumer information about evidence-based care so that patients know what should happen during the course of an illness. For example, patients with diabetes are encouraged to check that they receive regular HbA1c tests, regular retinal and foot examinations, and advice on how to quit smoking (www.facct.org). If patients had access to clinical guidelines (or patient versions of these) they could ensure that their care was compliant with recommended standards.

Prescribing errors are relatively common.²¹ These include administration of drugs or dosages which are inappropriate for the patient because of contraindications or unnoticed adverse reactions, failure to communicate essential information, and errors in transcribing medical records. Many of these errors could be avoided if communication with patients was improved and they were encouraged to speak up when they notice unexplained changes in their medication. Patients who are given full information about the purpose of medicines and their likely effects, including side effects, are more likely to take them as recommended, leading to better health outcomes.²² Unfortunately, there is evidence that this type of information provision is often neglected.⁵ Failure to inform patients is a major cause of non-compliance with treatment recommendations.¹⁰

Monitoring adverse events

Schemes which rely on doctors to report suspected adverse reactions to medicines suffer from widespread underreporting.^{23,24} These could be enhanced if patients were encouraged to report adverse events directly to a central scheme. Such a scheme has existed in Sweden for the past 25 years. Operated by KILEN, the Consumer Institute for Medicines and Health, the project provides reporting forms to patients who wish to report adverse reactions to medicines (www.kilen.org). The submitted forms are entered onto a database which is analysed and reports are submitted to relevant government agencies. In the USA patients can report adverse reactions directly to the Food and Drug Administration if they wish. The UK Consumers Association is now calling for the establishment of a similar scheme in Britain.²⁵

Patients should be encouraged to report postoperative complications promptly so that swift action can be taken if necessary. Unfortunately, lack of information about what to watch out for after discharge from hospital is a very common complaint. In a postal survey of patients discharged from hospital, 31% of respondents said they were not given clear explanations of the results of their surgical procedures, 60% were not given sufficient information about danger signals to watch out for at home after discharge from hospital, and 61% were

not told when they could resume their normal activities.⁵ If greater attention was paid to providing this type of information, it could lead to a reduction in the rate of complications and readmissions.

AFTER THE EVENT: THE IMPACT OF SERIOUS INCIDENTS ON PATIENTS AND THEIR FAMILIES

People who are seriously ill are obviously worried about their poor health and its impact on their work and family. In addition to the stresses associated with the illness itself, there are a number of additional stresses associated with treatment. These include difficulties in understanding diagnosis and treatment, coping with a hospital environment, adverse effects of diagnostic or therapeutic procedures, forced changes in lifestyle, and difficulties in relationships with staff.²⁶ Reports are also appearing which suggest that even routine procedures and normal childbirth may produce post-traumatic symptoms.^{27, 28} Patients are often in a vulnerable psychological state, even when diagnosis is clear and treatment goes according to plan. When they experience harm or misadventure, therefore, their reaction is likely to be particularly severe.

The impact of a medical injury differs from most other accidents in two important respects. Firstly, patients have been harmed, unintentionally, by people in whom they placed considerable trust, so their reaction may be especially powerful and hard to cope with. Secondly, and even more important, they are often cared for by the same professions, and perhaps the same people, as those involved in the original injury. As they may have been very frightened by what has happened to them and have a range of conflicting feelings about those involved, this can be very difficult even when staff are sympathetic and supportive.

In addition, patients and relatives may suffer in two distinct ways from injuries due to treatment: firstly, from the injury itself and, secondly, from the way in which the incident is handled afterwards. Many people harmed by their treatment suffer further trauma through the incident being insensitively and inadequately handled. Conversely, when staff come forward, acknowledge the damage, and take the necessary action, the overall impact can be greatly reduced. Injured patients need an explanation, an apology, to know that changes have been made to prevent future incidents, and often also need practical and financial help. The absence of any of these factors can be a powerful stimulus to complaint or litigation.²⁹

Psychological responses to medical injury

The speed and extent of recovery from an injury depends on many different factors including the nature and extent of the injury, the level of pain, and the degree of subsequent disability. The personality of the patient involved, the history of previous trauma and loss in their life, their financial security and employment prospects may also influence subsequent adjustment. While reactions vary greatly, certain constellations of symptoms recur.

Traumatic and life threatening events produce a variety of symptoms over and above any physical injury. Anxiety, intrusive memories, emotional numbing, and flashbacks are all common sequelae and are important components of post-traumatic stress disorder. Sudden, intense, dangerous, or uncontrollable events are particularly likely to lead to such problems, especially if accompanied by illness, fatigue, or mood disturbances.³⁰ Awareness under anaesthesia is an example of such an event. In other cases the initial incident may be less important than the long term consequences of the event in terms of pain, disability, and the effect on family relationships and ability to work. Depression is a more usual response to chronic pain, disability, and disruption of social and family relationships.³¹ Whether people actually become depressed and to what degree will depend on the severity of

their injury, the support they have from family, friends and health professionals, and a variety of other factors.³²

Studies of people involved in serious accidents such as road accidents suggest that 20–30% of patients suffer long term psychological impairment.^{33–35} Accidental injury during treatment, although little researched, also appears to produce serious psychological symptoms. Vincent *et al*³⁶ reported a study of patients injured during surgery and involved in or considering litigation. Damage to organs and nerves, perforations, and wound infections accounted for the majority of the injuries. The consequences of these injuries were both sustained and severe. The overall effect on the patients' lives, as judged by them, was considerable, including increased pain, disability, psychological trauma, effects on their work and social lives. They frequently suffered from disturbing memories, depression and anxiety. Three quarters of them considered that the incident had had a severely detrimental effect on their life.

When a patient dies the trauma is obviously even more severe and may be particularly severe after a potentially avoidable death.³⁷ Lehman *et al*³⁸ studied people 4–7 years after they had lost a spouse or child in an accident. Many continued to ruminate about the accident and what could have been done to prevent it, and they appeared unable to accept, resolve, or find any meaning in the loss. Relatives of patients whose death was sudden or unexpected may therefore find the loss particularly difficult to bear. If the loss was avoidable in the sense that poor treatment played a part in the death, their relatives may face an unusually traumatic and prolonged bereavement. They may ruminate endlessly on the death and find it hard to accept the loss.

Box 2 shows an illustrative case of a woman who suffered a perforation of the colon. Traumatic experiences, chronic pain, and physical weakness combined to produce a serious depression which lasted several years. The depression was marked by classical symptoms of low mood, tiredness, fatigue, low self-esteem, and sleep disturbance but was nevertheless unnoticed by any of the health professionals involved in her care. Although the term "post-traumatic stress disorder" is frequently used as a "catch all" for reactions to injury, this is in fact seriously inaccurate and misleading. Depression is a far more common response, particularly where chronic pain is involved, although other post-traumatic symptoms may be present to some degree in the early stages.

Caring for patients harmed by treatment

Caring for patients who have been harmed by treatment involves consideration of a number of issues, particularly when psychological trauma is involved. Some of the main considerations discussed in more detail elsewhere³⁹ are:

- Believing people who say their treatment has harmed them. Given the scale of harm from medical treatment, such a claim should always be considered seriously in the first instance.
- Continuing duty of care and maintenance of the therapeutic relationship. After an injury patients and families will need more support, although both patient and clinician may feel a natural wish to distance themselves.
- Honesty and openness about what has occurred. The lack of an explanation, and apology if appropriate, can be experienced as extremely punitive and distressing.
- Asking specific questions about emotional trauma and considering psychological treatment where severe reactions are apparent, particularly anxieties about future treatment.
- Informing patients of changes and efforts to prevent future similar incidents.
- Providing practical and financial help quickly. Relatively small sums of money can make a major difference to the impact of an injury when spent wisely on child care or disability aids to alleviate temporary financial hardship.

Box 2 Perforation of the colon leading to chronic pain and depression

A woman underwent a ventrosuspension—the fixation of a displaced uterus to the abdominal wall. After the operation she awoke with a terrible pain in her lower abdomen which became steadily worse over the next 4 days. She was very frightened and repeatedly told both doctors and nurses but they dismissed it as “wind”.

On the fifth day the pain reached a crescendo and she felt a “ripping sensation” inside her abdomen. That evening the wound opened and the contents of her bowel began to seep through the dressings. Even then, no one seemed concerned. Finally, the surgeon realised that the bowel had been perforated and a temporary colostomy was carried out.

The next operation, to reverse the colostomy, was “another fiasco”. After a few days there was a discharge of faecal matter from the scar, the wound became infected, and the pain was excruciating, especially after eating. She persistently asked if she could be fed with a drip but the nursing staff insisted she should keep eating. For 2 weeks she was “crying with the pain, really panicking—I just couldn’t take any more”. She was finally transferred to another hospital where she was immediately put on a liquid diet.

A final operation to repair the bowel was successful but left her exhausted and depressed. She only began to recover her strength after a year of convalescence. Three years later she was still constantly tired, irritable, low in spirits and “I don’t enjoy anything any more”. She no longer welcomes affection or comfort and feels that she is going downhill, becoming more gloomy and preoccupied.

Her scars are still uncomfortable and painful at the time of her periods. Her stomach is “deformed” and she feels much less confident and attractive as a result. As her depression has deepened, she has become less interested in sex and more self-conscious about the scar. Three years later the trauma of her time in hospital is still very much alive. She still has nightmares about her time in hospital and is unable to talk about it without breaking into tears. She feels very angry and bitter that no one has ever apologised to her or admitted that a mistake has been made.

The initiatives of individual clinicians and risk managers must be strongly supported by board level policy and directives. It is quite unreasonable to expect any clinician to be honest and open about problems that have occurred if they will later face sanctions or disapproval from senior management. All healthcare organisations need a strong proactive policy of active intervention and monitoring of those patients whose treatment has caused harm, whether or not anyone was at fault and irrespective of whether complaints have been made or litigation is likely to ensue. The care of an injured patient is, at bottom, little more than the continuing duty of care routinely assumed by all clinicians and healthcare organisations. A small number of organisations (such as the Minneapolis Children’s Hospital) have successful strongly proactive policies and there are now examples of innovative and successful interventions in a number of British hospitals.³⁹ This is an area where much could be done relatively quickly to reduce suffering and to regain the trust of patients and their families.

BRINGING PATIENTS INTO PATIENT SAFETY

At most stages of patient care there is the potential for patients to contribute to their own care through provision of diagnostic information, participation in treatment decisions, choice of provider, the management and treatment of disease, and the

Key messages

- Patients have a key role to play in ensuring the safety of medical care.
- The psychological consequences of medical injury must be recognised and dealt with effectively.
- Improving communication with patients, listening to their concerns, and facilitating active partnerships should be central to any patient safety strategy.

monitoring of adverse events. This requires that healthcare professionals encourage and support a more active stance from patients, but also that patients are prepared, where possible, to take more responsibility for their health and their care. The same principles apply, less obviously, in the care of injured patients. While we have emphasised the role of clinicians and risk managers in recognising and treating trauma, it is equally important to respect and support the active involvement of patients and their families in seeking explanations and deciding how best they can be helped. Indeed, at a time which is often characterised by a breakdown of trust between clinician and patient, the principle of actively involving patients and families becomes even more important.

While we stand by the argument that there is much to gain from actively involving patients in patient safety, it must be acknowledged that this is a relatively unexplored area, that many problems—both practical and ethical—will undoubtedly emerge, and that there is an urgent need for research in this area.⁴⁰ There is preliminary evidence that these approaches are likely to be productive, but the degree to which patients can be involved will vary considerably from specialty to specialty and will depend on the nature and complexity of the treatment and the degree of technical knowledge required to understand the treatment process. Most importantly, it will depend on the extent to which patients feel willing and able to play a more active part, which undoubtedly varies enormously from person to person. At the one extreme are those people who prefer, whether from temperament or custom, to leave all decisions to their doctor and to take a passive role, while at the other are those who wish to be involved in the minutest details of their treatment. Both these approaches can be appropriate in particular circumstances: for an acute medical emergency the sensible patient does, indeed, leave decisions to the treatment staff. In the case of a long term chronic illness the actively involved enquiring patient is likely to receive more appropriate treatment and to cope more effectively.

There is also a risk that encouraging patient participation will place additional burdens on staff in terms of longer consultations and more time spent answering questions. In some cases this may be justified, but we would emphasise that active patient involvement must not come at the expense of staff but should be to their benefit as well. Greater use of information resources, whether paper or from websites, reduced errors and adverse events, and more appropriate treatment can all reduce the burden on staff and healthcare resources.⁴¹

We need to learn more about the process and effects of giving patients a greater role, but the general principles are unlikely to be undermined by the results of these investigations. Honest information, clear supportive communication, and a participative approach should be the watchwords in promoting safety at all levels of health policy. These principles apply to the one to one encounter in the clinic, to published information about quality standards and outcomes among providers, to government advice on public health risks, and to dealing with the consequences of mistakes and harm when they occur. Patients and citizens have a legitimate interest in, and responsibility for, their own safety. It is incumbent on providers and policy makers to take active steps to involve them in efforts to improve the safety of medical care.

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Qual Saf Health Care 2002 11: 76-80
doi: 10.1136/qhc.11.1.76

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