One fundamental guarantee that we cannot give our patients is that faults and errors in the healthcare system won’t harm them. Of course, health care is by its nature risky. Not everyone undergoing surgery for an aortic aneurysm survives. Many interventions carry risks. But these risks are mostly small and usually quantifiable. Ideally, patients understand the possible risks and benefits before choosing to undergo a procedure. For some patients these are difficult decisions. Although healthcare professionals may discuss risks of treatment, they do not speak about risks of harm from the system—or even about such harm when it occurs.

Recent studies in the United States, Australia, and the United Kingdom and reports from the US Institute of Medicine and the UK Department of Health have drawn attention to the chronic “unsafeness” of health systems worldwide. This attention is not new. What is new is that preventable, iatrogenic injuries are being quantified and openly discussed. For example, adverse drug reactions have become a national issue in the United States—studies show that adverse drug events occurred in 6.5% of hospitalisations. These reports have highlighted the tensions between accountability and improvement, the needs of individual patients and benefit to society, and production goals and safety.

Most causes—and solutions—lie in the systems of care and how we work. Healthcare professionals, however, focus energy on individual patients, tackling difficulties in the system as they appear—often as separate problems and not in parallel. Individual care is, of course, crucial but, unless attention is given to the system, our patients are at risk from a faulty service. For example, inadequate handovers can mean that vital information is lost between different care givers and services. Is it that the word “system” is anathema to many healthcare professionals? Just getting health professionals to work harder or exhorting them to be safer will not help; the system of care must be redesigned. We must instil a chronic sense of unease—a constant awareness of risk in every action. Such attention to risk enables crews of aircraft carriers to launch and land several planes every day on decks the size of two football fields with virtually no adverse events. All hands know that one oversight can lead to disaster.

Theories of quality improvement in complex systems have helped the understanding of safety in health care. Safety is the aim, and improving skills and techniques is the method to get there. Much is known about how to build safer systems and reduce risk, but little of this knowledge is embedded in health care and, until it is, the sustained changes in behaviour of individuals and organisations that are needed for safer care are unlikely. Punishment will not help. The knowledge, skills, and attitudes needed for safe practice are not normally acquired, nor are they required, as part of pre-qualification experience. The disciplines in which risk management and quality improvement are important are wide ranging and cut across professional, clinical, and organisational boundaries. Some of these disciplines—cognitive psychology, ethics, bioengineering, mathematics, statistics, information science, ethics, and law—will be familiar. Others—such as change management, team work, organisational behaviour, systems theory, disaster analysis, and human factors—may not be. Not all these disciplines need be given their own space in the curriculum. The ethical imperative dictates that we should support the development of an understanding about safety from the first day of healthcare training. How long, though, should we wait before all medical schools and training programmes include a patient-centred safety curriculum?

Doctors in particular have mostly avoided the question of how safety can become central to their work. Employing an expert will not reduce harm. A general call to embrace safety may influence a few people but will not change systems. Care will be safer when we learn to work as teams and understand the team as a microsystem—a small, focused, organised unit with a set of patients, technologies, and practitioners. Some important changes that health professionals can make may be very “low tech” and seem trivial. How would methicillin resistant *Staphylococcus aureus* survive if all doctors always washed their hands after examining a patient? Removing concentrated potassium chloride from wards would prevent fatal concentrated injections, while designing unique connectors might prevent fatal intrathecal neurotoxic vincristine injection mix-ups. We know these changes will make a difference.

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*This is a version of an editorial which appeared in the BMJ 2001; 323:585–6.*
The difficulty lies in implementing what we know. How can we splice safety culture and practice into the genome of health care?

Improving safety of patients should be one of the highest priorities of healthcare leaders. Perhaps things are changing. In the UK, the National Patient Safety Agency has just been set up, and in the USA President Bush has increased the budget of the Agency for Healthcare Research and Quality by $150m to promote research on safety of patients.12

Easy access to research on improving safety may help health professionals and managers to make care safer. This journal has included papers on the safety of health care and on clinical risk management in the past. But, to reflect the increasing concern about the endemic “unsafe-ness” of healthcare systems worldwide and the need to find ways to reduce risk and, with that, the incidence of adverse events and harm suffered by patients, the journal will expand and, from March 2002, become *Quality and Safety in Health Care*. The new journal will also look different. The logo will change; the cover will be grey and green with the contents listed on the inside on the first page; and the layout will be different. We hope that these changes to the format of the journal will make it easier for readers. We will continue to publish as many papers on quality improvement, but the new issue will include many papers on safe care and safe practice. We invite readers to send us these. Changing attitudes and practices will be hard work. Patients are being placed at unnecessary risk and many are harmed; they expect that we will offer safer care. We believe that safety and quality will be the Holy Grail of medicine in the 21st century.

**Challenges to quality monitoring systems in care homes**

In the UK access to continuing care services is often a gamble and, as consumers of health care, older people have had little choice in where and how these services are provided as the continuing care of many older persons has shifted from the health service to the independent sector. This shift has raised concerns about the quality of care in private nursing homes and has placed the need to determine such quality high on the government’s policy agenda. The traditional quality assurance mechanism has relied on a registration and inspection system whereby local government authorities monitor and review service delivery. However, the processes are often bureaucratic and ineffective. More recently, the Care Standards Act (2000) and the Regulation of Care (Scotland) Act 2001 have set out the new regulatory framework for all care homes in the UK. This will provide national standards of registration and inspection, with increased authority for health and social care agencies to take action when poor quality is suspected or detected.

A registration and inspection system can only ever provide one component of a quality system for the continuing care of older people. Research by Wagner et al1 reported in this issue of *Quality in Health Care* highlights the difficulties in determining the most appropriate mechanism for monitoring quality in care homes, particularly when the emphasis is on “care outcomes”. The authors point out that it is difficult to determine the impact of quality systems on the quality of care of residents and conclude that there needs to be a greater emphasis on the qualitative aspects of care and, in particular, improvement in the measurement of quality of life.

Outcome can be defined as the end result of care, but outcomes do not directly assess quality of performance; they only permit inferences to be made about the quality of the processes of care. The focus on outcomes is not always appropriate in the context of continuing care. In much of healthcare provision a focus on “health gain”—that is, that the intervention results in a gain in health status for the patient—is seen as the most important outcome measure. In this issue of *Quality in Health Care* Meiland et al4 discuss the complexity of measuring outcome in residents of care homes. By assessing the burden on caregivers, the problems of delayed admission to care homes were identified as well as the continuing effect of these problems on the caregiver following admission of the patient. This suggests that measuring outcome with the patient alone only provides one part of the total picture. Outcomes in continuing care for older people should focus on increasing quality of life rather than longevity. Because quality of life is difficult to define and even more difficult to measure, particularly with physically and mentally frail people, outcomes from care inputs cannot always be clearly articulated as highlighted by Meiland et al. Furthermore, the care of older people in continuing care settings is predominantly based on the maintenance of a normal pattern of lifestyle. However, as pointed out by Wagner et al, such individualised patterns of lifestyle are difficult to measure using standardised instruments. This is not to argue that quality measurement in care homes should not focus on hard outcome data, but that it also needs to include subjective interpretation of quality of life and individual desire and...
ability. The emphasis should be on the individual’s potential to achieve his or her desired realistic health choices.

However, the most interesting finding of the research by Wagner et al is that, despite the dominant rhetoric of user involvement, “the opinion of residents was seldom used to evaluate the effectiveness of quality systems”. Who better to decide on the effectiveness of the end result of care inputs than the patients and others significant to them? In an era where individuals are encouraged to be experts in their own health and care needs, surely we should focus our energies on finding ways to enable older people and their supporters to identify changes in their health status and to establish self-report mechanisms for them to report satisfaction with the care and its outcomes. Reed et al reported on one such system (“Qual A Sess”) whereby care home residents engaged in a self-assessment of quality and included care home residents as self-assessors. If approaches such as this are to become the norm, then substantial investment is needed to enable older people to have such a voice. If we are going to be committed to enabling older people to plan their own destiny, we need to see investment in local models of peer review and quality improvement in addition to central government models of quality control.

However, there remains a paucity of high quality research with older people in care homes and, as such, there is little understanding of the most effective ways to deliver such services and measure their impact. If the new national framework of regulation is to be effective, a concerted effort must be made to understand the dynamics of care homes and the desired care outcomes of residents, as well as high levels of investment in staff development and continuing professional development. National standards can only ever be a blunt instrument to measure quality and, if the services for older people in care homes are to be consistently of a high standard, then the empowerment of care home staff and residents to determine their own quality destiny has to be part of the process.

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Improving teaching about improving practice

There is increasing evidence that the structured use of the principles and methods of continuous quality improvement (CQI) in healthcare settings will have a positive effect on improving care. Recognition of this in the UK can be seen from frequent references to CQI in Government publications driving the “modernisation agenda”. Government support of centrally funded initiatives such as the National Health Service Modernisation Fund, in addition to central government models of quality control.

However, there remains a paucity of high quality research with older people in care homes and, as such, there is little understanding of the most effective ways to deliver such services and measure their impact. If the new national framework of regulation is to be effective, a concerted effort must be made to understand the dynamics of care homes and the desired care outcomes of residents, as well as high levels of investment in staff development and continuing professional development. National standards can only ever be a blunt instrument to measure quality and, if the services for older people in care homes are to be consistently of a high standard, then the empowerment of care home staff and residents to determine their own quality destiny has to be part of the process.

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and self-confidence as a lifelong learner if they are to contribute effectively to continuously improving practice. If their learning about improvement does not achieve this, it will soon become a distant although interesting memory as they cope with the stresses and turbulence of everyday work. The use of “active learning” by Kyrkjebø et al is an important attempt to address this need and gives us clues about creating opportunities for practice based learning in mainstream education.

Their work raises many challenges of implementation for both education and service providers. With regard to the former, there is a particular need to develop the interest and skills of the academic staff who must themselves gain experience of facilitating improvement projects in practice. Unless they do so they will never be able to underpin their teaching with the personal feeling that is critical for helping students to learn. With regard to service providers, Kyrkjebø et al express the hope that their students’ experience “will enable them to take part actively in quality improvement when they are qualified”. This is unlikely to happen by chance and raises significant questions about the environments in which students must learn and will have to practise. In particular, practice based learning requires the creation of opportunities for students to participate in work settings where clinical teams are using systematic approaches to improve their care as part of their everyday work. After qualifying, they require opportunities to develop themselves and their improvement skills within routine organisational staff development programmes. Continuous improvement needs to be integral to both educational and healthcare institutions.

The final message that can be taken from the paper by Kyrkjebø et al is perhaps the most profound. Integrating our basic human enjoyment of learning with deep feelings about providing the best possible care for our patients provides an enormously powerful driver for improvement. It creates the demand for health profession educators and service providers to understand that they are part of the same system of care delivery with a shared underlying purpose. Put another way, how can we provide services that continuously improve care and education at the same time? This requires a sophisticated dialogue between employers and academics who will establish partnerships between healthcare providers and higher education and will provide benefits for learners, providers, and the wider community.

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Guidelines, judgement, opinion, and clinical experience

Over the past decade it has become a commonplace—almost a definitional truism—to subscribe to the Institute of Medicine’s view that clinical guidelines are (or should be) “systematically developed statements which assist practitioner and patient decisions about appropriate health care”. Guidelines now subserve other functions too: they systematically develop statements which assist practitioner and patient decisions about appropriate health care. They are used to modify the clinical behaviours of practitioners and reduce inappropriate variations in care.

It is conventional wisdom that the development and application of guidelines are especially appropriate in situations where clinicians are uncertain what—if anything—is the most effective way of treating a particular clinical problem and where there exists reliable scientific evidence which, properly interpreted, can offer a sound basis for developing guidance. Reliable interpretation of scientific evidence is dependent on the adoption of formal methods to inform guideline development and encompasses:

- an explicit approach to identifying areas of practice where guidelines could prove helpful;
- convening competent guideline development groups;
- retrieval, assessment, and synthesis of all relevant evidence to the clinical area addressed;
- translation of evidence into clinical recommendations;
- external review of guideline recommendations.

Since guidelines offer explicit recommendations with the definite intent of influencing what clinicians do, their clinical recommendations make claims which range beyond those which can be derived logically from the results of meta-analyses or randomised trials. The clinical scope of level I evidence is generally too narrow to allow clinically useful guidelines to be created from these sources alone, so recommendations require moorings to other evidential findings and information, including expert and consensus

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opinion. Guideline formulation thereby steps beyond the results of particular studies and beyond re-presentations of published systematic evidence to incorporate processes of judicious extrapolation, interpretation, and value judgement.7

The paper by Rycroft-Malone8 in this issue of Quality in Health Care illustrates how guideline developers can bring rigorous techniques to bear in tackling such tasks. In the context of an evidence-linked guideline development process, she describes the formal means adopted by the Royal College of Nursing Institute’s Quality Improvement Programme to develop a national guideline on assessment of risk and prevention of pressure ulcers. Ulcer risk assessment is a complex clinical area in which explicit evidence relating to a wide range of problems and techniques has been summarised.9–11 From these summaries, 200 statements relating to a wide range of problems and techniques has been summarised. From these summaries, 200 statements were derived and rated on a “disagree/agree” scale of 1–9 by 10 members of a panel composed of participants who reflected the range of people to whom the guideline would apply. The panel was sent summaries of the research evidence and was asked to rate each recommendation statement, taking account of the evidence, their own expertise, and the opinions and realities of healthcare provision in the UK. The results of this exercise were fed back to panel members by the guideline developers, and the panel considered again each statement with particular focus on those that had caused most disagreement. The threshold score for incorporation of each recommendation into the guideline was set at a median score of 7 or above, and an indication of the degree of agreement dispersion across the median score was included. A total of 160 recommendations were thereby adopted in the final guideline, which comprises a mixture of research based and consensus based recommendations. One wonders how many more would have been removed from the guideline had the median score been set at 7.5 or 8.5, or if a qualifying narrow interquartile range had been set to guarantee a minimum level of agreement.

The transparent approach of the Royal College of Nursing Institute to the development of a national guideline on assessment of risk and prevention of pressure ulcers goes some way towards reassuring those who for some time have warned of the dangers of treating guidelines as pronouncements which carry oracular authority. Ten years ago, for example, Tong wrote: “Medical practitioners should regard the recommendations of consensus development conferences as useful reference tools: not the rulings of philosopher kings, but the attempt of thoughtful people to share their knowledge—albeit imperfect—with other people.”12

Formal techniques for appraising the results and relevance of scientific studies and of systematic reviews are now relatively well established in the context of guideline development.13 The report by Rycroft-Malone offers an approach which also brings rigour and stringency to the equally important task of assaying diverse sources of judgement, expert opinion, and clinical experience in their construction.

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