emphasis on disease treatment than on illness prevention is slow to reward doctors and students when the "dynamic non-event" of patient safety happens.

Davidoff has suggested that one additional cultural barrier to improvement in the healthcare system is shame because " . . . improvement means that, however good your performance has been, it is not as good as it could be".[5] By extension, educators who have devoted their careers to educational systems that were historically successful, but now are insufficient, must embrace the need for valid improvement if knowledge for safety is to find its way to their students.

"Improving health and health care begins with the focus on improving medical education"

Finally, effective and safe clinical systems require leaders who are relentlessly committed to safety and reliability.[4 11] This requirement may necessitate new criteria for educational institutions in the recruitment and promotion of their organizational leadership.

Aron and Headrick serve patients well with their proposal that medical educators should radically rethink systems for preparing future doctors.[7] Improving health and health care begins with the focus on improving medical education. Strategic improvement—based on adoption of a systems approach, reflection on the realigned doctor-patient and teacher-learner relationships, transformed culture, and strong leadership—provides the appropriate start. The pace of change in medicine and health care insists on a measure of urgency. Patients rightfully trust the profession to educate doctors to incorporate such change into their care. Finding safety in medical education can provide reassuring confirmation of that trust.

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Quality improvement research

Quality improvement research: understanding the science of change in health care

R Grol, R Baker, F Moss

Essential for all who want to improve health care.

Expectations of healthcare services are ever increasing and those delivering care no longer hold the monopoly of opinion on what constitutes good or best care. To earn the label "good enough", care must meet standards expected by consumers as well those of expert providers. Headlines in newspapers, statements in policy documents, and many analyses, surveys and reports repeatedly highlight serious problems in healthcare delivery related to underuse, overuse, or misuse of care.[1] Health systems are sometimes unsafe and frequently we harm patients who have trusted us with their care. There is an endemic failure to engage patients with decisions about their care. We know there are problems; we just need to change so that care can be made safer and better.

Everyone—authorities, policy makers, and professionals—seems to accept the need for change. New initiatives aiming to cure our ailing systems come in droves. This is an international phenomenon. Many initiatives are linked to programmes that capture a particular approach—for example, evidence based medicine; accreditation and (external) accountability; total quality management; professional development and revalidation; risk management and error prevention; organisational development and leadership enhancement; disease management and managed care; complex adaptive systems; and patient empowerment. They may differ in perspective. Some focus on changing professionals, others on changing organisations or interactions between parts of the system; some emphasise self-regulation, others external control and incentives; some advocate "bottom up" and others "top down" methods. Despite their differences, however, each aims to contribute to better patient care—and they might, but the evidence for understanding their likely impact is not robust and many seem based more on belief than rigorous research of value, efficacy, or feasibility.[2] From what we know, no quality improvement programme is superior and real sustainable improvement might require implementation of some aspects of several approaches—perhaps together, perhaps consecutively. We just do not know which to use, when to use them, or what to expect.

More evidence and understanding is required. At least 40 good systematic reviews and numerous controlled trials are available,[3 4] but many of the trials can be criticised because, for example, randomisation or analysis was conducted at the patient level while the intervention focused on professionals or teams, and outcome parameters are often poorly chosen or are difficult to compare. Most studies were conducted in the USA, limiting generalisations to other systems. Some strategies are better studied than others. We know more

about CME, audit and feedback, reminders and computerised decision support than about organisational, economic, administrative and patient mediated interventions. New methods including the effects of problem based education or portfolio learning, TQM, breakthrough projects, risk management methods, business process redesign, leadership enhancement, or sharing decisions with patients are not well studied. Studying the effects of specific strategies in controlled trials will provide some answers to some questions about effective change, but will not address some of the basic questions about the critical success factors in change processes. They need to be complemented by observational and qualitative studies.

Health care is becoming increasingly complex and the problems are large. It is unrealistic to expect that one specific approach can solve everything. A qualitative study by Solberg *et al*[5] of critical factors supporting implementation of change showed that a mixture of professional and organisational factors is crucial. "Give attention to many different factors and use multiple strategies" is the message.[6] Although we may know that multifaceted strategies combining different actions and measures linked to specific obstacles to change are usually more successful than single interventions,[7] we know little about which components of such complex interventions are effective in different target groups. So, while there is some general knowledge, there is little detailed understanding of the "black box" of change.

We need to learn about change in the real world of health care and the crucial determinants of successful improvement. New thinking about healthcare settings as complex adaptive systems emphasises the importance of experimenting with multiple approaches and discovering what works best.[8] Small changes can sometimes have large effects—but we have little understanding about which small changes to use in which settings and their likely impact.

For real change and sustained improvement a tailored research methodology is essential. The full range of methodology has yet to be established, but will include contributions from epidemiology, behavioural sciences, educational research, organisational and management studies, economics, and statistics (box 1). Theoretical models of evaluations of complex interventions propose a phased approach (theoretical phase, definition of the components of the intervention, small scale explanatory trial, followed by larger trials and research into long term implementation). Clearly, different research methods are required for different phases,[9] but it is essential that, despite the eclectic base of the research, researchers from different faculties and disciplines come together to collaborate in this complex field and that the vogue for "quick fixes" is replaced with sustained research.

Box 1 Some research approaches for quality improvement research

- Observational studies of existing change processes
- In-depth qualitative studies on critical success factors and barriers to change improvement programmes
- Systematic reviews of both the impact of different strategies and the influence of specific factors on change
- Well designed cluster randomised trials
- Systematic sampling and interpretation of experiences of change
- Methods for developing valid and sensitive indicators for measuring change
- Meta-analyses of large samples of improvement projects
- Methods for evaluation of large scale implementation and change programmes
- Economic analyses of resources needed for effective change and improvement of care
- Statistical process control

To stimulate and support debate about research on quality improvement and change management in health care we have commissioned a series of papers to provide an overview of some relevant methodologies. The first two papers are published in this issue and more will follow. Pope *et al*[10] explore some of the qualitative methods that can be used to gather information about the delivery of good quality care, and Wensing and Elwyn[11] consider some of the key issues related to measurement of patients' views. Forthcoming issues of *QSHC* will include papers that describe research methods for indicator development in primary care; a methodology for evaluating small scale improvement projects; methods for evaluating quality improvement programmes; research designs for randomised controlled trials in quality improvement; and economic evaluations of change management.

There is a recognised process for the development of new drugs, their introduction into routine practice, and their establishment in the treatment of defined conditions. As knowledge about a drug is accrued, new and better patterns of treatment gradually become established. Similar measured approaches are needed to help develop and establish better, safer systems of care. "Change management" is a discipline central to health care. The academic base that supports change management and quality improvement in health care should underpin all clinical and managerial learning programmes. The science of change management is not new, but there is a long way to go before we will understand enough to be able to transform care so that it is "good enough" to meet everyone's expectations of quality and safety.

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