Using research to make health care safer

Christine M Jorm and Sarah J White

Abstract

There is a fine balance that needs to be maintained between research and improvement in safety and quality in health care — when do we need more research and when can we just get on with it? The moral imperative to improve care may have been a distractor, preventing adequate attention to research. Three research areas are proposed as current priorities for patient safety: getting evidence into practice, measurement of safety, and the evaluation of complex interventions. A focus on these areas should ensure that research becomes more central to the process of making health care safer.

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What is known about the topic?

It is unsure how much safety and quality has improved over the last two decades. There is a deficiency of high quality research to support the design of safety improvement.

What does this paper add?

The lack of formal study means that neither clinicians nor policy makers understand the system in which they work sufficiently to reliably get evidence into practice. Inadequate measurement in safety prevents appropriate priority setting. Meaningful evaluations must include the study of failure. The use of a theoretical basis for both intervention and evaluation increases the likelihood of transferable learning.

What are the implications for practitioners?

Safety and quality advocates are requested to accompany their exhortations for change with funding for research. Researchers need to develop interdisciplinary capacities and collaborations that are required to evaluate interventions in our complex health system.

WHAT PLACE DOES RESEARCH play in safety and quality and when should we just "get on with it"? The discourse of modern government is crisp, if not blunt: the National Health and Hospitals Reform Commission had among its terms of reference the requirement to "reduce inefficiencies generated by cost-shifting, blame-shifting and buck passing".[1] (p. 357) The development of performance indicators continues apace, and the research community is not always seen as essential to the process of making health care safer.

The research–policy divide is well documented and has led to the modern development of new specialties such as knowledge transfer or translation,[2] and brokering and exchange.[3] However, policy imperatives mean policy makers are impatient with research timeframes and wary of recommendations that may make compromise difficult.[4] Human interaction has been described as "the engine that drives research into practice",[5] yet the inclusion of clinicians, managers and policy makers (or research users) into research funding programs is rare in Australia and only partial in Canada.[5]

In the case of quality and safety, however, there are further problems. Traditional quantitative research methods may be inadequate tools (particularly for areas such as clinical handover and other health care communication), and in addition, the need to improve safety and quality has been associated with a moral imperative which has been held to obviate the need for research and has been associated with denigration of its value. Berwick, in a recent piece *advocating* safety and quality research, used rhetoric displaying the customary antagonism of safety and quality exponents towards research: "Health care researchers

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who believe that their main role is to ride the brakes on change — to weigh evidence with impoverished tools, ill-fit for use — are not being as helpful as they need to be".[6]

The moral imperative to deliver safer care

The need to improve quality and safety in health care acquired urgency (the creation of what has been described as the "patient safety juggernaut"[7]) after the publication of a report from the United States Institute of Medicine (IOM) entitled *To err is human*.[7] This report used data from the 1991 Harvard Medical Practice Study to estimate that 44 000 to 98 000 deaths occur annually in US hospitals due to medical error. The number of deaths attributed to error in both this and subsequent studies were estimates that cannot be definitively substantiated.[8-10] Still, a substantial increase in patient safety publications followed the *To err is human* report.[11]

The release of the Quality in Australian Health Care Study in 1995 resulted in political uproar in Australia and led to the formation and funding of the Australian Council on Safety and Quality in Health Care. Several major public inquiries into disturbing health care scandals have also been a feature of the last two decades.[12] The trust of the public and of politicians in the health care system has been disturbed by revelations of poor quality and unsafe care.[13] Some harm is preventable. Thus it is not surprising that many discussions of safety and quality in health are dominated by ethically based exhortation: "Australians deserve better"[14] or "While research is usually seen as optional, quality improvement might well be more often morally required, both for the patient as a citizen and for the care provider as a professional responsibility".[15]

The place of research

If we *should* "get on with it" to improve safety and quality, can we? There is a general lack of scholarly accounts of methods, experiences, and results in the area of safety and quality.[16-20] Quality improvement interventions supported by too little evidence will be suboptimal at best, sometimes futile or may even cause harm.[21] For most safety and quality initiatives no cost–benefit analysis has been performed. Therefore we do not know the proportion of resources that should be devoted to activities such as incident reporting and root cause analysis versus, for instance, electronic decision support.[22,23] There needs to be a balance between resources dedicated to quality improvement and those dedicated to research. The wrong balance means either delayed delivery of a solution to a quality or safety problem or the implementation of an inadequately evaluated intervention.

Research approaches have been used for quality and safety health service outcomes that are not well suited to describing or solving the problems they have chosen to investigate. There is little evidence to date supporting linkages between organisational factors in health care, medical errors and patient safety.[24] Yet the absence of research or the existence of only research of limited scope or poor design has been used to reject proposals with high face validity such as the medical emergency team.[6,25] In light of these issues, we have identified three research areas that are priorities if patient safety is to be improved: getting evidence into practice; measurement of safety; and the evaluation of interventions. Argument is made for each area, and the conclusion develops some specific tasks for researchers and policy makers to ensure that research better underpins safety and quality work.

1. Getting evidence into practice

A high percentage of medical care that is delivered is not supported by evidence[26,27] but the absence of evidence does not mean that a treatment is not safe and effective. Of greater concern is that patients may only get 40%–50% of the care that is recommended for them by evidence[28] and that it takes lengthy periods for evidence to be taken into practice.[29] Where evidence is incompatible with existing values or the prevailing medical paradigm, for example treatment for scurvy, or germ theory, it may take 30–50 years

for evidence to be adopted into practice.[30] It could be argued that the teenaged field of safety and quality has struggled both in specific clinical cases and in general against prevailing medical paradigms; we have to be able to first conceptualise the complex system responsible for the outcomes of care before we can improve it. Australian doctors have been shown to be distanced and alienated by their very conceptualisations of the health care system in which they work.[31]

Let us take two specific clinical areas that have been safety and quality targets: the use of beta blockers after myocardial infarction and deep venous thrombosis (DVT) prophylaxis. In 2007, Lee wrote *Eulogy for a quality measure*.[32] The measure was the percentage of patients with acute myocardial infarction who receive a prescription for beta blockers within 7 days of discharge. Twenty-five years after the convincing demonstration of the significant reduction in mortality beta blockers provide for this patient group, nearly all now receive these drugs (in the US). The increase in prescription from one third of patients in the mid 1990s to nearly all in 2007 was driven by guidelines and policy. Compliance was required for accreditation; incentives and public reporting experimented with; and systems developed "that made it easier to do the right thing"[32] (p. 1177). Multiple interventions drove successful system improvement.

In contrast, the uptake of evidence-based risk assessment for DVT has been disappointing.[33,34] Yet, in the United Kingdom, it is suggested that DVT causes more than 25 000 potentially preventable deaths per year.[35] Mortality due to DVT after hospital admission is 10 times greater than after infection with methicillin-resistant *Staphylococcus aureus* (MRSA) (10% of hospital deaths being due to pulmonary embolism). An agreed measure for DVT is extremely difficult to obtain and many patients present after discharge (and some remain undiagnosed and untreated). Responsibility for assessment and prescription of prophylaxis are often confused, and the consequences of failure are rarely faced by those responsible for the former (indeed chronic venous insufficiency and leg ulceration may be problems that that patient faces 10–15 years later). Because policy designed to improve clinical safety and quality is rarely formally studied, it could be speculated that it will be some time before compliance with a hard problem like DVT prophylaxis becomes a measurable success.

We also need to develop methods of presenting data in ways that are able to educate and persuade patients, clinicians, managers, government and other policy stakeholders to implement evidence-based change that will improve the safety and quality of health care. Statistical process control charting is an important method for routinely presenting and tracking safety and quality data,[36] and while use is increasing,[37] it is still unfamiliar to many clinicians. The traditional randomised double blind controlled trial, familiar to, and therefore expected by clinicians, does not work well for safety and quality issues (as noted by the anonymous reviewer). In fact the failure to produce the kind of evidence that clinicians look for and that will convince clinicians amounts to a communication problem.

It has been suggested that the traditional methods of producing good science and disseminating it through conventional means, such as reports, journals and conferences, are "simply inadequate to the humbling need for vast improvements in the [US] health system".[38] (p. I-88) Social marketing aims to influence human behaviour on a large scale, using commercial marketing principles for the purpose of social benefit.[39] The use of social marketing techniques to get the attention of both the public and clinicians for specific safety and quality issues is overdue.

Doctors' knowledge about the evidence for safety and quality has been shown to be weak in both the US and Australia.[40,41] US doctors rated 34% of the six safety and quality interventions with published evidence and 29% of the seven interventions without published evidence as "very effective".[41] Clinicians have been shown to be relatively poor users of explicit evidence in a number of domains, yet collectively reinforced internalised tacit guidelines are important.[42] Hence, improving quality and safety knowledge

may require engaging with the local knowledge that is developed during the collaborative processes of care. A composite tool has recently been developed to measure the organisational context for evidence-based practice.[43] Assessment of organisational absorptive and receptive capacity should then enable support for the elements of organisational structure and culture that produce the capacity to implement evidence-based innovations. Similarly, it has been argued that using mixed methods to study organisations that are positive deviants, that is, those that deliver consistently excellent performance, can describe the details of their structure and practices so that others can learn how to improve.[44]

2. Measurement of safety

How do we work out what is important? Measurement may bias attention and efforts toward easily measured targets (eg, infection rates).[45] Indeed "a dark side of measurement",[45] has been described where less well developed measures mean problems may be ignored. It has been suggested that difficult areas to measure and research include diagnostic errors, errors in communication or errors due to discontinuous care. Diagnostic error has clearly been neglected, but what we do know is sobering. Studies comparing patient notes with autopsy show diagnostic error rates of 40%–60%.[46] Major error occurs in 2%–20% of radiological investigations;[47] 1%–43% of all anatomic pathology specimens;[48] and 27% of biochemistry and microbiology investigations.[49] Inter-observer diagnostic variability exists among experts,[48,50] and no test may exist that provides perfect separation between normal and abnormal results.[47]

Yet the IOM advocates "Six Sigma" reliability for health care.[7] This is a rate of fewer than 3.4 errors per 1 million events (beyond 6 standard deviations from the mean of a normal distribution) which apparently has been achieved by the airline and the nuclear power industries. It is clear both that diagnostic error is a neglected patient safety problem and that the rhetoric of Six Sigma may be less appropriate for health care than once thought. There are few identically repeated processes in health where deviation from procedures is an appropriate measure.[51] Most health care situations involve considerable variation and uncertainty.

Measurement also needs to include the patient perspective. A very low percentage of patients who experience adverse events actually complain.[52,53] However, of the complaints received by the New Zealand Health and Disability Commissioner, a preventable adverse event was identified in 51% of cases.[53] Patients, when given the opportunity, report quite different events compared with staff, for example, the medical record or x-ray not being available when needed, or insufficient painkillers being given.[54] As there are differences in perceptions regarding adverse events, involvement of health care consumers in understanding patient safety is essential.

Commonwealth Fund surveys in 2005 and 2007 revealed that about one in four Australian patients experienced a problem with coordination of their care (tests or records not available when needed, or duplicate tests or conflicting information being given).[55,56] The US and Australian rates were singled out for comment due to their particularly high rates of fragmented care.[56] In addition, only 43% of Australian patients said that their doctors always told them about treatment choices and asked for patient opinion.[55]

In a recent call for clinically relevant reform, Scott et al challenge health care providers and institutions to reconsider their safety and quality focus, to "tackle the core of first-order clinically relevant issues central to making hospital care visibly safer".[57] To actually decide on the clinically relevant issues and to measure "visibly" safer care, research is needed on ways to routinely and effectively include the patient view in decisions and measures. In an Australian institution with a routine comprehensive patient survey process, implementation of a new approach to clinical handover communications resulted in a measurable improvement in patient satisfaction about how staff work together.[58] A clear place for patient involvement has been recommended in the safety performance framework proposed by Wakefield and Jorm.[59] Patient outcomes and

experience may provide a new lens to define that which is important to measure.

3. Evaluation of complex interventions

Wensing, Wollersheim and Grol, while able to draw some conclusions, such as supporting multidisciplinary teams, integrated care systems for chronic conditions, and the use of computers, suggest that "for no strategies can the effects be predicted with high certainty".[60] Developing methods of understanding complex interventions is a research priority whether the intervention is a medical emergency team, root cause analysis or the "bundles" of practices that have been shown as able to reduce central line infections. This means a detailed examination of the nature of the intervention[61] and a broad examination of its effects, which may lay in other places than the predetermined area of interest; for example the effect of medical emergency teams on "not for resuscitation orders"[62,63] and palliative care, or the effect of participation in the root cause analysis process on improving organisational communication.[64] When the interventions themselves have a clearly described theoretical framework, meaningful evaluation is more likely.[65]

The spread of best practice has proven an elusive goal.[66] A failed attempt at reform, though, is a waste of money and of human capital — our energy and enthusiasm. Successes and failures of collaborative initiatives have been documented.[17] Many quality improvement approaches are predicated on standardising work processes that are generally much simpler than those found in the highly complex "industry" of health care.[51] Often, instead of confronting failures, advocates have invented language to justify them. They use terms like "barriers to change" and "culture" — terms that conceal more than they reveal. Checkland and colleagues suggest it is failures that harbour real learnings.[67] They ask what can be learned from something *not* being achieved. The problem that quality and safety work shares with more conventional medical research, they suggest, is that its outcomes are only regarded as adding to our knowledge if they are successful. This runs parallel with the well-documented academic publication bias: an appreciably greater proportion of "successful" than "unsuccessful" trials are published.[68] Similarly, failed improvement initiatives are rarely written up for publication or showcased by journals, as if these are without interest. It is hardly surprising then that public policy for the development and implementation of safety and quality initiatives[69,70] may be underinformed by research.

Conclusion

Should we just get on with it? This approach does not appear to have been as successful as hoped as the lack of measurement while "getting on with it" means we are not at all sure about the state of the safety in the health care system. It is easy to state that in 18 years since the Harvard Medical Practice Study little has changed[57] and the inadequacy of measurement cannot be disputed. Yet today multidisciplinary team work is normal, multidisciplinary stroke units are in widespread use and medical emergency teams are present in more than 75% of Australian hospitals. We have specialist emergency physicians in large numbers working extended hours in our major emergency departments and we all wear gloves to put in cannulas! We have pulse oximetry not just in operating theatres but high dependency areas and increasingly in all wards. Safer working hours are a reality. Certainly it is believed that all of these process improvements increase patient safety and improve patient outcomes.

This is a good time to be considering the contribution of research to safety and quality; at 18 (years since the publication of the Harvard Medical Practice Study), the infant that was the safety and quality movement has grown through a rather passionate adolescence to have the maturity to appreciate the need for research. Grol, Berwick and Wensing argued recently that initiatives to improve patient care have had only limited success and that to make bigger improvements we need rigorous studies using a variety of methods.[71] However, old research paradigms alone will not meet the needs of the energetic adult discipline of safety and quality. The safety and quality movement is about drive; inspiring

and committing people to work together to make patient care much better and safer — change with passion. It rightly remains impatient with tiny improvements and research that is endlessly inconclusive when faced with substantial numbers of preventable errors and substandard care. It has been suggested that commissioning more research sometimes may help to conceal our collective failure to have the societal will to use the evidence we have.[72]

Safety and quality advocates now must step back from their exhortations for change and instead fund research while they "get on with it", which must include experimenting with a range of policy levers via funding and reporting. Policy makers need to secure time for pilots that are well designed, with rigorous and honest evaluation,[73] and employ new methods such as realist review to synthesise research findings.[74] We need new and creative approaches to ensure safety and excellence become widespread and systemic, not just the province of exceptional units, or some elusive aspect of organisational culture.

For their part, the research community needs to find ways to better measure patient safety and find the factors that increase the likelihood of transferability (and sustainability) of change and improvement initiatives. The obvious start point is via developing increased capability in interdisciplinary research. This kind of research is more time consuming as substantial communication is required,[75] requiring funding for administration, meetings and travel. Current reward practices in academia do not support this work.[72] Also, there is as yet little written about the benefits of researcher involvement in policy-making processes,[3] and work is rarely designed in ways that facilitate this.

We have very few research groups able to integrate quantitative and qualitative research; able to mix built design, microbiology and anthropology; regression analysis and conversation analysis; and, most importantly, able to engage not just clinicians, but managers and patients in the research process. Groups that are able to do this are able to truly analyse structure, process, outcome, and the social dimensions of change, and by these means the research community will indeed be seen as central to the process of making health care safer and better.

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Competing interests

The authors declare that they have no competing interests.

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