# Tell me about the context, and more

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The scholarly publication of patient safety initiatives must contribute more to accelerating reliable, safe patient care. Reports of safety initiatives generally describe specific safety practices and the resulting clinical outcomes. So why is progress so slow to make patients safer?[1–3] Do the reported safety practices in such reports in fact lack convincing and plausible supporting evidence?[4] Or, do the patient safety practices work, but require more explicit attention to implementation strategies?

We suggest "Yes"—to both questions. Moreover, context lies at the heart of the answers to both. The lack of useful focus on context has led to heterogeneity in both evaluation of effective patient safety practices and successful implementation strategies.[5–7]

In this issue of *BMJ Quality & Safety*, three papers report a project led by researchers from RAND with a national team of US researchers and international group of technical advisors that investigated the role of context in scholarly patient safety reports.[8–10] Together with an earlier paper from the same group,[7] they found that few reports actually define context in sufficient detail to offer strategies for replication. They report that most publications omit any empirical assessment of the impact of context on implementation of safety practices.[10] They also provide an extensive list of specific contextual elements relevant to patient safety interventions and a typology for organising them.[8 9]

## TOWARDS A USEFUL DEFINITION OF CONTEXT

The shortest definition of context is everything that is not the intervention itself.[10 11] In conventional clinical research, this distinction is simple. For example, a medication under study constitutes the intervention. Clinic staff that educate patients about the medication and other infrastructure that enables patients to adhere to their treatment represent elements of context. Quality improvement scholars would agree these elements of context have the makings of a worthwhile intervention. In fact, case management interventions focus precisely on such elements—educating patients and maintaining contact with them to determine their medication adherence.

Similarly, in a study of inpatient mortality, the timely availability of critical care personnel might represent a relevant contextual element. In quality improvement, this contextual element can become the intervention in itself, as has happened with rapid response teams, where timely involvement of critical care personnel in the management of patients with signs of clinical deterioration becomes the foreground, not a background element of context.

Two useful examples of difficulty distinguishing context from the intervention itself are, in fact, rapid response teams, as well as checklists. For rapid response teams, distinguishing between the elements of institutional context that facilitated the team and the intervention itself can pose difficulties. In fact, proponents of rapid response teams have argued that a better term is rapid response systems, because of the important ways in which aspects of the organisation determine not just the initial implementation but also its ongoing effectiveness.[12] With regard to checklists, the apparent intervention—the items on the checklist—can be difficult to distinguish from elements of context, such as the teamwork and institutional support required to achieve the intended effects each time the checklist is used.[13]

Given this blurring between intervention and context, defining context as 'everything that is not the intervention itself' is probably insufficient. A more useful definition calls for an enquiry into the complex nature of 'local care settings—their processes, habits, and traditions'.[14] The original Institute of Medicine report *To Err is Human*[15] also emphasised the external environment, in particular the explicit actions that 'the external environment can take to increase attention by the delivery system to issues of patient safety.' While the external environment certainly represents an important category of contextual factors, patient safety investigators who have worked in the years since the Institute of Medicine report recognise many other important categories.

The expert panel that provided consensus advice to the RAND study framed 4 overarching domains to group 42 distinct contextual elements: external environmental factors; structural organisational dynamics; cultural organisational factors; and collaboration, resources and leadership.[8 9] The investigators took two approaches to identifying

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these elements. Following the lead of many in the field of program evaluation,[16 17] they considered the different theoretic models that might explain the effects of patient safety interventions and the categories of contextual factors relevant to these models.[7] In addition, taking a bottom-up approach, they also reviewed the evidence supporting five specific patient safety interventions: prevention of catheter-related bloodstream infections, the U.S. Joint Commission's 'universal protocol' (including pre-procedure verification process, checklist to ensure that required elements are available, a time-out before starting procedure to verify these elements), computerised order entry, interventions to prevent inpatient falls, and medication reconciliation. The investigators used input from the expert panel members to select these specific interventions based on the expected variation in which different aspects of context would affect the evidence of effectiveness and implementation efforts for these interventions.[8]

## MAKING SENSE OF A LONG LIST

The work reported in these four papers[7–10] provides a useful starting place for the field: a comprehensive list of contextual elements relevant to the design, reporting, and interpretation of patient safety research. More is needed, however. Confronted with a long list of contextual elements, producers and consumers of patient safety research need an approach to determine effectively which items on the list pertain in a given situation.

It is reasonable to anticipate that in selected approaches to patient safety research, for example, checklist development or implementation, reporting some elements of context will likely become routine, for example, hospital size, teaching status, support for the initiative from senior leaders, the motivation for undertaking the initiative. The useful consideration of additional elements of context, however, will require reflection on the hypothesised mechanism of effect for the checklist. If effectiveness depends on the checklist fostering teamwork and multidisciplinary collaboration, then investigators must report contextual factors relevant to institutional culture, relationships between different professional groups, etc. Additionally relevant elements of context might include the degree to which the institution has a data-driven culture, with a history of acting on performance data, such as compliance rates for the checklist, or the presence of clinical leaders willing to champion use of the checklist.

Importantly, reflecting in this manner does not depend on a clear distinction between context and intervention. Whether one regards improved teamwork and inter-professional communication as part of the checklist intervention,[13] or one categorises them as important elements of context, the point remains that institutional features relevant to fostering teamwork and inter-professional collaboration represent important considerations in carrying out the improvement initiative and reporting its results for others to interpret.

## IDENTIFYING CONTEXT IS JUST THE FIRST STEP

Thus far, reports of improvement initiatives in patient safety have usually lacked explicit exploration of the aspects of the context that contribute both to successful implementation of safety practices and potentially to assessments of the effectiveness of the practices themselves—again, recognising the frequent difficulty in distinguishing between context and intervention. Noteworthy exceptions to this omission are two analyses[5 18] that systematically explored the contextual factors that likely contributed to the successful reduction of central line infections in the Michigan ICU study.[19]

We welcome further such analyses. However, while identification of relevant elements of context represents a crucial first step, little progress will occur without methods for characterising specific elements in a useful and reproducible manner. For instance, how can researchers measure and report 'collaboration across healthcare professionals' or 'leadership support' in ways that permit meaningful distinctions between organisations that have these elements in place to a greater or lesser degree? Using variations in elements of context to make sense of the differing effects seen across reports of the same patient safety interventions will bear little fruit without reliable methods for measuring these elements.

## A CALL FOR MORE COMPLETE AND TRANSPARENT STUDY OF CONTEXT IN SCHOLARLY SAFETY REPORTS

The SQUIRE scholarly publication guidelines[20] focus on complete, accurate, transparent and useful reports of implementation of healthcare improvement. They recommend attention to context for many of the sections of a given publication. For instance, the statement of the local problem that motivated the research or improvement effort should include a detailed description of 'relevant elements of the…settings (eg, geography, physical resources, organisational culture, history of change efforts) and structures and patterns of care (eg, staffing, leadership) that provided context for the intervention.' The guidelines also recommend that the Methods section address 'the contributions of intervention components and context factors to effectiveness of the intervention.' Authors are similarly advised that the Discussion

**Box 1** A call for authors to provide more accurate description of relevant context and its contribution to success or failure of implementing a patient safety practice

1. Address explicitly the author's local problem and setting, and particularly their impact on the observed outcomes.
2. Define the predominant theory(s) for how this patient safety practice achieves its intended effects and use such theory to identify relevant elements of context for purposes of reporting.
3. Describe any empiric evidence that supports the relevance of the crucial context elements for an intervention of this type.
4. Enumerate those factors, which the authors believe were absolutely essential to its effectiveness and implementation, based on experience with the implementation, implications of the theory of the intervention, and consideration of other routinely encountered elements of context in the patient safety literature.
5. Discuss how the intervention itself or its implementation might (or might not) play out in different settings.

should pay 'particular attention to components of the intervention and context factors that helped determine the intervention's effectiveness (or lack thereof), and types of settings in which this intervention is most likely to be effective.'

We certainly support these and the other recommendations in the SQUIRE guidelines, but suggest that they contain little specific guidance for authors to identify elements of context relevant to their research. The four papers[7–10] from the RAND group provide the beginnings of precisely this type of guidance for authors. They argue for explicit consideration of the theoretical underpinnings of a given intervention and attention to a list of potentially relevant contextual elements encountered in the literature.[7–10] We agree and suggest that scholarly reports of patient safety initiatives should go further.

In this regard, we propose five additional steps when preparing evaluations of patient safety practices for publication (see box 1). Although we have articulated these activities as guidelines for reporting, ultimately these recommendations, like those in the SQUIRE guidelines,[20] generally will apply to conduct of the research, as well as the process of research reporting.

We share the impatience of others[1–3] with the slow progress in dissemination of patient safety practices. In that spirit, we suggest that this and other scholarly journals can facilitate progress by building on the work reported by the RAND group.[7–10] Towards this end, we invite contributing *authors* of *BMJ Quality and Safety* to address context issues more explicitly in their reports. We will invite *reviewers* to contribute to this effort as they review submissions to the journal. And, of course, we invite our *readers* to comment on our proposal.

**Competing interests** Dr Shojania is editor-in-chief and Dr Stevens is editor emeritus of BMJ-*Quality and Safety*. Both Drs Shojania and Stevens were members of the technical expert panel for the AHRQ-funded RAND Patient Safety Practices initiative described in this editorial. Dr Stevens is a member of the SQUIRE development group.

**Provenance and peer review** Commissioned; not externally peer reviewed.

*BMJ Qual Saf* 2011;**20**:557–559.
doi:10.1136/bmjqs-2011-000206

## REFERENCES

1. Leape L, Berwick D, Clancy C, *et al*. Transforming health care: a safety imperative. *Qual Saf Health Care* 2009;18:424–8.
2. Landrigan CP, Parry GL, Bones CB, *et al*. Temporal trends in rates of patient harm resulting from medical care. *N Engl J Med* 2010;362:2124–34.
3. Wachter RM. Patient safety at ten: unmistakable progress, troubling gaps. *Health Aff (Millwood)* 2010;29:165–73.
4. Auerbach AD, Landefeld CS, Shojania KG. The tension between needing to improve care and knowing how to do it. *N Engl J Med* 2007;357:608–13.
5. Dixon-Woods M, Bosk CL, Aveling EL, *et al*. Explaining Michigan: developing an *ex post* theory of a quality improvement program. *Milbank Q* 2011;89:167–205.
6. Davidoff F. Heterogeneity is not always noise: lessons from improvement. *JAMA* 2009;302:2580–6.
7. Foy R, Ovretveit J, Shekelle PG, *et al*. The role of theory in research to develop and evaluate the implementation of patient safety practices. *BMJ Qual Saf* 2011;20:453–9.
8. Dy SM, Taylor SL, Carr LH, *et al*. A framework for classifying patient safety practices: results from an expert consensus process. *BMJ Qual Saf*. Published Online First: 24 May 2011. doi:10.1136/bmjqs.2010.049296.
9. Taylor SL, Dy S, Foy R, *et al*. What context features might be important determinants of the effectiveness of patient safety interventions? *BMJ Qual Saf*. Published Online First: 26 May 2011. doi:10.1136/bmjqs.2010.049379.
10. Ovretveit J, Shekelle PG, Dy SM, *et al*. How does context affect interventions to improve patient safety? An assessment of evidence from studies of five patient safety practices and proposals for research. *BMJ Qual Saf* 2011. Published Online First: 13 April 2011. doi:10.1136/bmjqs.2010.047035.
11. Kaplan HC, Brady PW, Dritz MC, *et al*. The influence of context on quality improvement success in health care: a systematic review of the literature. *Milbank Q* 2011;88:500–59.
12. Ranji SR, Auerbach AD, Hurd CJ, *et al*. Effects of rapid response systems on clinical outcomes: systematic review and meta-analysis. *J Hosp Med* 2007;2:422–32.
13. Bosk CL, Dixon-Woods M, Goeschel CA, *et al*. Reality check for checklists. *Lancet* 2009;374:444–5.
14. Batalden PB, Davidoff F. What is "quality improvement" and how can it transform health care. *Qual Saf Health Care* 2007;16:2–3.
15. Institute of Medicine. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academies Press, 1999.
16. Mackenzie M, O'Donnell C, Halliday E, *et al*. Do health improvement programmes fit with MRC guidance on evaluating complex interventions? *BMJ* 2010;340:c185.
17. Pawson R, Tilley N. *Realistic Evaluation*. London: Sage, 1997.
18. Pronovost PJ, Berenholtz SM, Needham DM. Translating evidence into practice: a model for large scale knowledge translation. *BMJ* 2008;337:963–5.
19. Pronovost PJ, Needham D, Berenholz S, *et al*. An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med* 2006;355:2725–32.
20. Davidoff F, Batalden P, Stevens D, *et al*; SQUIRE development group. Publication guidelines for quality improvement in health care: evolution of the SQUIRE project. *Qual Saf Health Care* 2008;17 (Suppl 1):i3–9.