RESEARCH METHODS & REPORTING

Publication guidelines for quality improvement studies in health care: evolution of the SQUIRE project

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Studies of quality improvement are often poorly reported. The Standards for Quality Improvement Reporting Excellence (SQUIRE) Group describes how its guidelines could improve standards

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SUMMARY POINTS

Quality improvement is an applied science not an academic discipline
Studies of improvement work need to balance experimental and pragmatic methods
Good reporting of improvement studies is essential to further development of the discipline
SQUIRE guidelines provide a model for informative reporting

A great deal of meaningful and effective work is now done in clinical settings to improve the quality and safety of care. Unfortunately, relatively little of that work is reported in the biomedical literature, and much of what is published could be described more effectively. Failure to publish is potentially a serious barrier to the development of improvement science, because public sharing of concepts, methods, and findings is essential to the progress of all scientific work, both theoretical and applied. To help strengthen the evidence base for improvement in health care, we proposed draft guidelines for reporting planned original studies of improvement interventions in 2005.[1] Our aims were to stimulate the publication of high calibre improvement studies and to increase the completeness, accuracy, and transparency of published reports of that work.

Our initial draft guidelines were based largely on personal experience with improvement work and were intended only as an initial step towards the creation of recognised publication standards. We have now refined and extended that draft and present here the resulting revised version, which we refer to as the standards for quality improvement reporting excellence or SQUIRE (table). In this narrative progress report, we describe the special features of quality improvement that are reflected in SQUIRE and briefly outline the consensus process used to develop the guidelines. We also consider the limitations of and questions about the SQUIRE guidelines, describe ancillary supporting documents and various versions currently under development, and explain plans for their dissemination, testing, and further development.

Special features of quality improvement

Unlike conceptually neat and procedurally unambiguous interventions such as drugs, tests, and procedures that directly affect the biology of disease, and are the objects of study in most clinical research, improvement is essentially a social process. Improvement is an applied science rather than an academic discipline[2]; its immediate purpose is to change human performance rather than generate new, generalisable knowledge,[3] and it is driven primarily by experiential learning.[4 5] Like other social processes, improvement is inherently context dependent; it is reflexive, which means that improvement interventions are repeatedly modified in response to feedback on outcome, with the result that both its interventions and outcomes are relatively unstable; and it generally involves complex, multicomponent interventions. Although traditional experimental and quasi-experimental methods are important for learning whether improvement interventions change behaviour, they do not provide appropriate and effective methods for addressing the crucial pragmatic (or "realist") questions about improvement that are derived from its complex social nature: what is it about the mechanism of a particular intervention that works, for whom, and under what circumstances?[2 3 6]

Using combinations of methods that answer both the experimental and pragmatic questions is not easy because the two contrasting methodologies can sometimes work at cross purposes. For example, true experimental studies are designed to minimise the confounding effects of context (such as the heterogeneity of local settings, staff, and other study participants, resources, and culture) on measured outcomes. But trying to control context out of improvement interventions is both inappropriate and counterproductive because improvement interventions are inherently and strongly context dependent.[2 3]

Similarly, true experimental studies require strict adherence to study protocols because this reduces the effect of many potential confounders. But rigid adherence to initial improvement plans is incompatible with an essential element of improvement, which is continued modification of those plans in response to outcome feedback (reflexiveness). We have attempted to maintain a balance between experimental and pragmatic (or realist) methods in the SQUIRE guidelines; both are important and necessary, and they are mutually complementary.

Differences between SQUIRE and draft guidelines

The SQUIRE guidelines differ in several important ways from the initial draft guidelines. Firstly, as noted, SQUIRE highlights more explicitly the essential and unique properties of improvement interventions, particularly their social nature, focus on changing performance,

Short version of SQUIRE guidelines (standards for quality improvement reporting excellence)*	
Title and abstract	Did you provide clear and accurate information for finding, indexing, and scanning your paper?
1. Title	Indicates the article concerns improvement of healthcare quality, and the specific aim of the intervention
2. Abstract	Summarises all key information using chosen journal's abstract format
Introduction	Why did you start?
3. Background knowledge	Summarises knowledge about the care problem and characteristics of organisations in which it occurs
4. Local problem	Describes the nature and severity of the local problem that was addressed
5. Intended improvement	Describes the specific aim of the proposed intervention; also who and what triggered the decision to make changes and why now
6. Study question	States the primary and secondary study questions
Methods	What did you do?
7. Ethical issues	Describes the ethical aspects of implementing and studying the improvement and how ethical concerns were addressed
8. Setting	Specifies how relevant context factors were identified and characterised
9. Planning the intervention	Describes the intervention itself, why it was chosen, and what was to be done initially and by whom
10. Planning the study of the intervention	Describes plans for assessing how effectively the intervention was implemented, mechanisms by which intervention components were expected to cause changes, study design chosen, and efforts to maximise internal and external validity
11. Methods of evaluation	Describes instruments used to assess effectiveness of implementation; contributions of intervention components and context factors to intervention effectiveness; primary and secondary outcomes; validation of instruments; methods for assuring data quality and adequacy
12. Analysis	Describes qualitative and quantitative analytical methods, variability expected in implementing the intervention, expected change in outcomes, power of study to detect such effects, methods used to demonstrate effects of time as a variable
Results	What did you find?
13. Outcomes	*(a)* Nature of setting and improvement intervention—Characterises elements of setting and structures and patterns of care that provided the context; actual course of the intervention; degree of success in implementing the intervention; evolution of the initial plan, and lessons learnt from that evolution
	(b) Changes in processes of care and patient outcomes associated with the intervention—Presents data on changes in care delivery process and patient outcomes; benefits, harms, unexpected results, problems, failures; evidence on strength of the association between outcomes and intervention/context factors; summary of missing data for intervention and outcomes
Discussion	What do the findings mean?
14. Summary	Summarises key successes and difficulties in implementing the intervention, observed changes in care delivery and clinical outcomes, and study's particular strengths
15. Relation to other evidence	Compares and contrasts study results with relevant findings of others
16. Limitations	Considers possible confounding, bias, or imprecision that might have affected accuracy (internal validity) and factors affecting generalisability (external validity); likelihood that observed gains may weaken over time, and plans for monitoring and maintaining improvement; efforts to minimise and adjust for study limitations; effects of study limitations on interpretation and application of results
17. Interpretation	Explores reasons for differences between observed and expected outcomes; inferences about strength of evidence, causal mechanisms, and size of changes; modifications to improve future performance; opportunity costs and actual financial costs
18. Conclusions	Considers overall usefulness of the intervention locally; settings in which this intervention is likely to be effective; implications for further studies of improvement
Other information	Were there other factors relevant to the conduct and interpretation of the study?
19. Funding	Describes funding sources, if any, and role of funding organisation in design, implementation, interpretation, and publication of study

*These guidelines provide a framework for reporting formal, planned studies designed to assess the nature and effectiveness of interventions to improve the quality and safety of care. It may not always be appropriate, or even possible, to include information about every numbered guideline item in reports of original studies, but authors should at least consider every item in writing their reports. The full version of the SQUIRE guidelines, and this short version of the guidelines plus a glossary of technical and unfamiliar terms in the guideline items, are available on the SQUIRE website (www.squire-statement.org).

context dependence, complexity, non-linearity, adaptation, and iterative modification based on outcome feedback. Secondly, SQUIRE distinguishes more clearly between improvement practice (planning and implementing improvement interventions) and the evaluation of improvement projects (designing and carrying out studies to assess whether those interventions work and why they do or do not work). Thirdly, SQUIRE explicitly specifies elements of study design that make it possible to assess both whether improvement interventions work (by minimising bias and confounding) and why interventions are or are not effective (by identifying the effects of context and identifying mechanisms of change). And, finally, SQUIRE explicitly addresses the often confusing ethical dimensions of improvement projects and improvement studies.[7 8] Other differences between SQUIRE and the draft guidelines are available on the SQUIRE website (www.squire-statement.org).

Development process

The SQUIRE development process was designed to produce consensus among a broad constituency of experts and users on both the content and format of guideline items. We first obtained informal feedback on the utility, strengths, and limitations of the draft guidelines from potential authors in a series of seminars at national and international meetings, as well as from experienced publication guideline developers at the organisational meeting of the EQUATOR network (Enhancing the Quality and Transparency of Health Research, www.equator-network.org). Authors, peer reviewers, and journal editors then "road tested" the draft guidelines as a working tool for editing and revising submitted manuscripts.[9 10] Next, we solicited and published commentaries on the initial version of the guidelines.[11-15] We also did a literature review on epistemology, methodology, and the evaluation of complex interventions, particularly in social sciences. In April 2007, we held a two day meeting of 30 stakeholders, who subjected the draft guidelines to intensive analysis, comment, and recommendations for change. After the meeting we obtained further critical appraisal of the guidelines through three cycles of a Delphi process with an international group of more than 50 consultants.

Limitations and questions

During the development process, the SQUIRE guidelines were characterised as providing both too little and too much information: too little, because they fail to represent

adequately the many unique and nuanced issues in the practice and evaluation of improvement[2-4 11-18]; too much, because the detail and density of the item descriptions might seem intimidating to authors. We recognise that the SQUIRE item descriptions are much more detailed than those of some other publication guidelines. In our view, however, the complexity of the improvement process, plus the relative unfamiliarity of improvement interventions and of the methods for evaluating them, justify that level of detail, particularly in light of the diverse backgrounds of people working to improve health care. Moreover, the level of detail in the SQUIRE guidelines is quite similar to that of recently published guidelines for reporting observational studies, which also involve considerable complexities of study design.[19] To increase the usability of SQUIRE, we are making available a shortened electronic version on the SQUIRE website, accompanied by a glossary of terms used in the item descriptions that may be unfamiliar to users.

Applying SQUIRE

Authors' interest in using publication guidelines increases when journals make them part of the peer review and editorial process. We therefore encourage the widest possible use of the SQUIRE guidelines by editors. Unfortunately, little is known about the most effective ways to apply publication guidelines in practice. Therefore, editors have been forced to learn from experience how to use other publication guidelines and the specifics of their use vary widely from journal to journal.

We also lack systematic knowledge of how authors can use publication guidelines most productively. Our experience suggests, however, that SQUIRE is most helpful if authors simply keep the general content of the guideline items in mind as they write their initial drafts, then refer to the details of individual items as they critically appraise what they have written during the revision process. Since rigid or mechanical application of guidelines can constrain the flow of complex information and distort its meaning, the SQUIRE guidelines must always be used as signposts, rather than shackles. The most effective way to use publication guidelines in practice seems to us to be an empirical question. We therefore strongly encourage editors and authors to collect, analyse, and report their experiences in using SQUIRE and other publication guidelines.

Current and future directions

A SQUIRE explanation and elaboration document is being published elsewhere.[20] This provides much of the necessary depth and detail that cannot be included in a set of concise guideline items. It presents the rationale for including each guideline item in SQUIRE, with published examples of reporting for each item, and commentary on the strengths and weaknesses of those examples.

The SQUIRE website (www.squire-statement.org) provides an authentic electronic home for the guidelines and a medium for their progressive refinement. We also intend the site to serve as an interactive electronic community for authors, students, teachers, reviewers, and editors who are interested in the emerging body of scholarly and practical knowledge on improvement.

Although the primary purpose of SQUIRE is to enhance the reporting of improvement studies, we believe the guidelines can also be useful for educational purposes, particularly for understanding and exploring further the epistemology of improvement, and the methodologies for evaluating improvement work. We believe, similarly, that SQUIRE can help in planning and executing improvement interventions, carrying out studies of those interventions, and developing skill in writing about improvement. We encourage these uses, as well as efforts to assess SQUIRE's effect on the completeness and transparency of published improvement studies[21 22] and to obtain empirical evidence that individual guideline items contribute materially to the value of published information in improvement science.

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