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SQUIRE 2.0 (*Standards for QUality Improvement Reporting Excellence*): revised publication guidelines from a detailed consensus process

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ABSTRACT

Since the publication of Standards for QUality Improvement Reporting Excellence (SQUIRE 1.0) guidelines in 2008, the science of the field has advanced considerably. In this manuscript, we describe the development of SQUIRE 2.0 and its key components. We undertook the revision between 2012 and 2015 using (1) semistructured interviews and focus groups to evaluate SQUIRE 1.0 plus feedback from an international steering group, (2) two face-to-face consensus meetings to develop interim drafts and (3) pilot testing with authors and a public comment period. SQUIRE 2.0 emphasises the reporting of three key components of systematic efforts to improve the quality, value and safety of healthcare: the use of formal and informal theory in planning, implementing and evaluating improvement work; the context in which the work is done and the study of the intervention(s). SQUIRE 2.0 is intended for reporting the range of methods used to improve healthcare, recognising that they can be complex and multidimensional. It provides common ground to share these discoveries in the scholarly literature (http://www.squire-statement.org).

In 2005, draft publication guidelines for quality improvement reporting debuted in *Quality and Safety in Health Care*.[1] At that time, publications of scholarly work about healthcare improvement were often confusing and of limited value. Leaders in the field were working to consolidate the evidence for a science of improvement[2 3] and without guidance on how to write their findings, authors struggled to report their improvement work in a reliable and consistent way.[4 5] These factors influenced the initial publication in 2008 of the Standards for QUality Improvement Reporting Excellence (SQUIRE),[6] which we will refer to as SQUIRE 1.0. The guidelines were developed in an effort to reduce uncertainty about the information deemed to be important in scholarly reports of healthcare improvement and to increase the completeness, precision and transparency of those reports.

In the intervening years, the reach of systematic efforts to improve the quality, safety and value of healthcare has grown. Health professionals' education worldwide now includes improvement as a standard competency.[7–11] The science of the field also continues to advance through guidance on applying formal and informal theory in the development and interpretation of improvement programmes;[12] stronger ways to identify, assess and describe context;[13–16] recommendations for clearer, more complete descriptions of interventions[17] and development of initial guidance on how to study an intervention.[18]

In this setting, we have undertaken a revision of SQUIRE 1.0. When we began, it rapidly became apparent that a wide variety of approaches had developed for improving healthcare, ranging from formative to experimental to evaluative. Rather than limiting the revised guidelines to only a few of these, we fashioned them to be applicable across the many methods that are used. We aimed to reflect the dynamic nature of the field and support its further development. This article describes the development and content of SQUIRE 2.0 (table 1).

SQUIRE 2.0 DEVELOPMENTAL PATH

We developed SQUIRE 2.0 between 2012 and 2015 in three overlapping phases: (1) evaluation of the initial

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Table 1 Revised Standards for QUality Improvement Reporting Excellence (SQUIRE 2.0) publication guidelines

Text section and item name	Section or item description
Notes to authors	▶ The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare. ▶ The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). ▶ A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. ▶ Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. ▶ The SQUIRE glossary contains definitions of many of the key words in SQUIRE. ▶ The explanation and elaboration document provides specific examples of well-written SQUIRE items and an in-depth explanation of each item. ▶ Please cite SQUIRE when it is used to write a manuscript.
Title and abstract	
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centredness, timeliness, cost, efficiency and equity of healthcare).
2. Abstract	a. Provide adequate information to aid in searching and indexing. b. Summarise all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions.
Introduction	*Why did you start?*
3. Problem description	Nature and significance of the local problem.
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies.
5. Rationale	Informal or formal frameworks, models, concepts and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s) and reasons why the intervention(s) was expected to work
6. Specific aims	Purpose of the project and of this report.
Methods	*What did you do?*
7. Context	Contextual elements considered important at the outset of introducing the intervention(s).
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it. b. Specifics of the team involved in the work.
9. Study of the intervention(s)	a. Approach chosen for assessing the impact of the intervention(s). b. Approach used to establish whether the observed outcomes were due to the intervention(s).
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions and their validity and reliability. b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency and cost. c. Methods employed for assessing completeness and accuracy of data.
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data. b. Methods for understanding variation within the data, including the effects of time as a variable.
12. Ethical considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest.
Results	*What did you find?*
13. Results	a. Initial steps of the intervention(s) and their evolution over time (eg, time-line diagram, flow chart or table), including modifications made to the intervention during the project. b. Details of the process measures and outcomes. c. Contextual elements that interacted with the intervention(s). d. Observed associations between outcomes, interventions and relevant contextual elements. e. Unintended consequences such as unexpected benefits, problems, failures or costs associated with the intervention(s). f. Details about missing data.

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Table 1 Continued

Text section and item name	Section or item description
Discussion	*What does it mean?*
14. Summary	a. Key findings, including relevance to the rationale and specific aims. b. Particular strengths of the project.
15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes. b. Comparison of results with findings from other publications. c. Impact of the project on people and systems. d. Reasons for any differences between observed and anticipated outcomes, including the influence of context. e. Costs and strategic trade-offs, including opportunity costs.
16. Limitations	a. Limits to the generalisability of the work. b. Factors that might have limited internal validity such as confounding, bias or imprecision in the design, methods, measurement or analysis. c. Efforts made to minimise and adjust for limitations.
17. Conclusions	a. Usefulness of the work. b. Sustainability. c. Potential for spread to other contexts. d. Implications for practice and for further study in the field. e. Suggested next steps.
Other information	
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organisation in the design, implementation, interpretation and reporting.

SQUIRE guidelines, (2) early revisions and (3) pilot testing with late revisions.

We began the evaluation of SQUIRE 1.0 by collecting data to assess its clarity and usability.[19] Semistructured interviews and focus groups with 29 end users of SQUIRE 1.0 revealed that many found SQUIRE 1.0 helpful in planning and doing improvement work, but less so in the writing process. This issue was especially apparent in the efforts to write about the cyclic, iterative process that often occurs with improvement interventions. SQUIRE 1.0 was seen by many as unnecessarily complex with too much redundancy and lacking a clear distinction between 'doing improvement' and 'studying the improvement'. A recent independent study and editorial also documented and addressed some of these challenges.[20 21]

In the second phase, we convened an international advisory group of 18 experts that included editors, authors, researchers and improvement professionals. This group met through three conference calls, reviewed SQUIRE 1.0 and the results of the end-user evaluation, and provided detailed feedback on successive revisions. This advisory group and additional participants attended two consensus conferences in 2013 and 2014 where they engaged in intensive analysis and made recommendations that further guided the revision process.

In the third phase, 44 authors used an interim draft version of the updated SQUIRE guidelines to write sections of a manuscript. Each author then provided comments on the utility and understandability of the draft guidelines, and in their submitted section, identified the portions of their writing samples that fulfilled the items of that section.[22] We also obtained detailed feedback about this draft version through semistructured interviews with 11 biomedical journal editors. The data from this phase revealed areas needing further clarification, and which specific items were prone to misinterpretation. Finally, a penultimate draft was emailed to over 450 individuals around the world, including the advisory group, consensus meeting participants, authors, reviewers, editors, faculty in fellowship programmes and trainees. This version was also posted on the SQUIRE website with an invitation for public feedback. We used the information from this process to write SQUIRE 2.0 (table 1).

SQUIRE 2.0

Many publication guidelines, including CONSORT (randomised trials), STROBE (observational studies) and PRISMA (systematic reviews) focus on a particular study methodology (http://www.equator-network.org). In contrast, SQUIRE 2.0 is designed to apply across the many approaches used for systematically improving the quality, safety and value of healthcare. Methods range from iterative changes using plan–do–study–act cycles in single settings to retrospective analyses of large-scale programmes to multisite randomised trials. We encourage authors to apply other

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publication guidelines—particularly those that focus on specific study methods—along with SQUIRE, as appropriate. Authors should carefully consider the relevance of each SQUIRE item, but recognise that it is sometimes not necessary, nor even possible, to include each item in a particular manuscript.

SQUIRE 2.0 retains the IMRaD (introduction, methods, results and discussion) structure.[23] Although used primarily for reporting research within a spectrum of study designs, this structure expresses the underlying logic of most systematic investigations, and is familiar to authors, editors, reviewers and readers. We continue to use A. Bradford Hill's four fundamental questions for writing: Why did you start? What did you do? What did you find? What does it mean?[24] In our evaluation of SQUIRE 1.0, novice authors found these questions to be straightforward, clear and useful.

SQUIRE 2.0 contains 18 items, but omits the multiple subitems that were a source of confusion for SQUIRE 1.0 users.[19] A range of approaches exists for improving healthcare, and SQUIRE may be adapted for reporting any of these. As stated above, authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE item in a particular manuscript. In addition, authors need not use items in the order in which they appear. Major changes between SQUIRE 1.0 and 2.0 are concentrated in four areas: (1) terminology, (2) theory, (3) context and (4) studying the intervention(s).

Terminology

The elaborate detail in SQUIRE 1.0 was seen by users as both a blessing and a curse[19]: helpful in designing and executing quality improvement work, but less useful in the writing process. The level of detail sometimes led to confusion about what to include or not include in a manuscript. Consequently, we made the items in SQUIRE 2.0 shorter and more direct.

A major challenge in the reporting of systematic efforts to improve healthcare is the multiplicity of terms used to describe the work, which is challenging for novices and experts alike. Improvement work draws on the epistemology of a variety of fields, and depending on one's field of study, the same words can carry different connotations, a particularly undesirable state of affairs. Terms such as 'quality improvement', 'implementation science' and 'improvement science' refer to approaches that have many similarities, but can also connote important (and often-debated) differences. Other terms such as 'healthcare delivery science', 'patient safety' and even simply 'improvement' are also subject to surprising variation in interpretation. To address this problem in semantics, we created a glossary of terms used in SQUIRE 2.0 (box 1). The glossary provides the intended meaning of certain key terms as we have used them in SQUIRE 2.0 (table 1). These definitions may be helpful in other endeavours, but are not necessarily intended to be adopted for use in other contexts. Overall, we sought terms and definitions that would be useful to the largest possible audience. For example, we chose 'intervention(s)' to refer to the changes that are made. We decided not to use the word 'improvement' in the individual items (although it remains in the SQUIRE acronym) to encourage authors to report efforts that did not lead to changes for the better. Reporting well done, negative studies is vital for the learning in this discipline.

Theory

SQUIRE 2.0 includes a new item titled 'rationale'. Biomedical and clinical research is driven by iterative cycles of theory building and hypothesis testing. Healthcare improvement work has not consistently based the planning, design and execution of its programmes solidly in theory, to the detriment of the work. For this reason, SQUIRE 2.0 explicitly includes an item devoted to theory, although we chose to use the broader and less technical label 'rationale' to encourage authors to be explicit in reporting formal and informal theories, models, concepts or even hunches as to why they expected a particular intervention to work in a particular context. A plain language interpretation of 'rationale' might be, 'why did you think this would work?' A recent narrative review of the nature of theory and its use in improvement describes the many types and applications of theory, and considers pitfalls in using and not using theory.[12]

The addition of the 'rationale' item is intended to encourage clarity around assumptions about the nature of the intervention, the context and the expected outcomes. The presence of a well thought out rationale will align with appropriate measures and with the study of the intervention; it may also be the starting point for the next round of work. The 'summary' item in the discussion section encourages authors to revisit the original rationale in the light of its findings and in the larger context of similar projects.

Context

SQUIRE 2.0 accepts 'context' as the key features of the environment in which the work is immersed and which are interpreted as meaningful to the success, failure and unexpected consequences of the intervention(s), as well as the relationship of these to the stakeholders (eg, improvement team, clinicians, patients, families, etc).[13–16] Systematic efforts to improve healthcare should contain clear descriptions and acknowledgement of context, rather than efforts to control it or explain it away. SQUIRE 1.0 included context with items in all sections of the manuscript, but context did not rise to the level of a distinct item itself. SQUIRE 2.0 recognises context as a fundamental item in the methods section, but its relevance is not limited to this section. In addition to affecting the

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Box 1 Glossary of key terms used in Standards for QUality Improvement Reporting Excellence (SQUIRE) 2.0. This glossary provides the intended meaning of selected words and phrases as they are used in the SQUIRE 2.0 guidelines. They may, and often do, have different meanings in other disciplines, situations and settings

Assumptions
Reasons for choosing the activities and tools used to bring about changes in healthcare services at the system level.
Context
Physical and sociocultural make-up of the local environment (eg, external environmental factors, organisational dynamics, collaboration, resources, leadership and the like), and the interpretation of these factors ('sense-making') by the healthcare delivery professionals, patients and caregivers that can affect the effectiveness and generalisability of intervention(s).
Ethical aspects
The value of system-level initiatives relative to their potential for harm, burden and cost to the stakeholders. Potential harms particularly associated with efforts to improve the quality, safety and value of healthcare services include opportunity costs, invasion of privacy and staff distress resulting from disclosure of poor performance.[25]
Generalisability
The likelihood that the intervention(s) in a particular report would produce similar results in other settings, situations or environments (also referred to as external validity).
Healthcare improvement
Any systematic effort intended to raise the quality, safety and value of healthcare services, usually done at the system level. We encourage the use of this phrase rather than 'quality improvement', which often refers to more narrowly defined approaches.
Inferences
The meaning of findings or data, as interpreted by the stakeholders in healthcare services—improvers, healthcare delivery professionals and/or patients and families.
Initiative
A broad term that can refer to organisation-wide programmes, narrowly focused projects or the details of specific interventions (eg, planning, execution and assessment).
Internal validity
Demonstrable, credible evidence for efficacy (meaningful impact or change) resulting from introduction of a specific intervention into a particular healthcare system.
Intervention(s)
The specific activities and tools introduced into a healthcare system with the aim of changing its performance for the better. Complete description of an intervention includes its inputs, internal activities and outputs (eg, in the form of a logic model) and the mechanism(s) by which these components are expected to produce changes in a system's performance.[17]
Opportunity costs
Loss of the ability to perform other tasks or meet other responsibilities resulting from the diversion of resources needed to introduce, test or sustain a particular improvement initiative.
Problem
Meaningful disruption, failure, inadequacy, distress, confusion or other dysfunction in a healthcare service delivery system that adversely affects patients, staff or the system as a whole, or that prevents care from reaching its full potential.
Process
The routines and other activities through which healthcare services are delivered.
Rationale
Explanation of why particular intervention(s) were chosen, and why it was expected to work, be sustainable and be replicable elsewhere.
Systems
The interrelated structures, people, processes and activities that together create healthcare services for and with individual patients and populations. For example, systems exist from the personal self-care system of a patient to the individual provider–patient dyad system, to the microsystem, to the macrosystem and all the way to the market/social/insurance system. These levels are nested within each other.
Theory or theories
Any 'reason-giving' account that asserts causal relationships between variables (causal theory) or that makes sense of an otherwise obscure process or situation (explanatory theory). Theories come in many forms, and serve different purposes in the phases of improvement work. It is important to be explicit and well founded about any informal and formal theory (or theories) that are used.

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development of the rationale and subsequent design of the intervention(s), context plays a key role in the iterations of intervention(s) and the outcomes. While it is often not simple to capture or describe context, understanding its impact on the design, implementation, measurement and results make it a vital contributor in identifying and reporting the factors and mechanisms responsible for the success or failure of the intervention(s).

Studying the intervention(s)

The study of the intervention is, perhaps, the most challenging item in SQUIRE. In the evaluation of SQUIRE 1.0[19] and in the pilot testing,[22] many were perplexed by this item and its subelements. This item was intended to encourage a more formal assessment of the intervention and its associated outcomes. In SQUIRE 2.0, this section is called 'study of the intervention(s)' (table 1).

'Doing' an improvement project is fundamentally different from 'studying' it. The primary purpose of 'doing' improvement is to produce better local processes and outcomes rather than contribute to new generalisable knowledge. In contrast, the reason for 'studying' the intervention is mainly to contribute to the body of knowledge about the efficacy and generalisability of efforts for improving healthcare. Both 'doing' and 'studying' are required for a deep understanding of the nature and impact of the intervention(s) as well as the possible underlying mechanisms. 'Study of the intervention(s)' focuses mainly on whether and why an intervention 'works'. It should align with the rationale and may include, but is not limited to, preplanned formal testing of the proposed theory that the intervention(s) actually produced the observed changes, as well as the impact of the intervention(s) on the context in which the work was done.

SQUIRE 2.0 asks authors to be as transparent, complete and as accurate as possible about reporting 'doing' and 'studying' improvement work as both aspects of the work are key to scholarly reporting. The 'summary' and 'interpretation' items in the discussion encourage authors to explain potential mechanisms by which the intervention(s) resulted (or failed to result) in change, thereby developing explanatory theories that can be subsequently tested.

CONCLUSIONS

The development of SQUIRE 2.0 consisted of a detailed analysis of SQUIRE 1.0, input from experts in the field and thorough pilot testing. Many methods and philosophical approaches to improve the quality, safety and value of healthcare are available. The systematic efforts to improve healthcare are often complex and multidimensional, and their effectiveness is inherently context dependent. SQUIRE 2.0 provides common ground on which the discoveries contributed by the various approaches can advance the field by sharing them in the published literature.

At the same time, we recognise that simply publishing SQUIRE 2.0 will not effect this change; additional efforts and resources are required. For example, we have created an explanation and elaboration (E&E) document (Goodman D, Ogrinc G, Davies L; personal communication, 2015) to accompany this article. For each item in SQUIRE 2.0, the E&E provides one or more examples from the published literature and a commentary on how the example(s) meets or does not meet the item's standards; this information brings the content of each item to life. The SQUIRE website (http://www.squire-statement.org) contains a number of resources in addition to the guidelines themselves, including interactive E&E pages and video commentaries. The website supports an emerging online community for the continuous use, conversation about and evaluation of the guidelines.

Writing about improvement can be challenging. Sharing successes, failures and developments through scholarly literature is an essential component of the complex work required in order to improve healthcare services for patients, professionals and the public.

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