

**Forum**

# SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): Revised Publication Guidelines from a Detailed Consensus Process

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**D**raft publication guidelines for quality improvement reporting debuted in 2005,<sup>1</sup> when publications of scholarly work about health care improvement were often confusing and of limited value. Leaders in the field were working to consolidate the evidence for a science of improvement,<sup>2,3</sup> and without guidance on how to write their findings, authors struggled to report their improvement work in a reliable and consistent way.<sup>4,5</sup> These factors influenced the initial publication in 2008 of the Standards for Quality Improvement Reporting Excellence (SQUIRE),<sup>6</sup> which we will refer to as SQUIRE 1.0. The guidelines were developed to reduce uncertainty about the information deemed important in scholarly reports of health care 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 health care has grown. Health professions education worldwide now includes improvement as a standard competency.<sup>7-11</sup> The science of the field also continues to advance through guidance on applying formal and informal theory in the development and interpretation of improvement programs<sup>12</sup>; stronger ways to identify, assess, and describe context<sup>13-16</sup>; recommendations for clearer, more complete descriptions of interventions<sup>17</sup>; and development of initial guidance on how to study an intervention.<sup>18</sup>

Soon after beginning to undertake a revision of SQUIRE 1.0, it became apparent that a wide variety of approaches had developed for improving health care, ranging from formative to experimental to evaluative. Rather than limit 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, page 475).\*

\* A slightly different version of this article is being published in other journals. This article is therefore not copyrighted and may be freely reproduced and distributed.

## **Developmental Path**

We developed SQUIRE 2.0 between 2012 and 2015 in three overlapping phases: (1) evaluation of the initial SQUIRE guidelines, (2) early revisions, and (3) pilot testing with late revisions.

In the first phase, we collected data to assess the clarity and usability of SQUIRE 1.0.<sup>19</sup> 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 particularly apparent in 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.<sup>20,21</sup>

In the second phase, we convened an international advisory group of 18 experts that consisted of editors, authors, researchers, and improvement professionals. This group, which 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 his or her submitted section, identified the portions of their writing sample that fulfilled the items of that section.<sup>22</sup> 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, we

**Table 1. Revised Standards for QUality Improvement Reporting Excellence (SQUIRE 2.0) Publication Guidelines**

Text Section and Item Name	Section or Item Description
<b>Notes to Authors</b>	<ul style="list-style-type: none"> <li>• The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare.</li> <li>• 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).</li> <li>• A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these.</li> <li>• Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript.</li> <li>• The SQUIRE Glossary contains definitions of many of the key words in SQUIRE.</li> <li>• The Explanation and Elaboration document provides specific examples of well-written SQUIRE items and an in-depth explanation of each item.</li> <li>• Please cite SQUIRE when it is used to write a manuscript.</li> </ul>
<b>Title and Abstract</b>	
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare).
2. Abstract	<ol style="list-style-type: none"> <li>a. Provide adequate information to aid in searching and indexing.</li> <li>b. Summarize 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.</li> </ol>
<b>Introduction</b>	<b>Why did you start?</b>
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
<b>Methods</b>	<b>What did you do?</b>
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)
8. Intervention(s)	<ol style="list-style-type: none"> <li>a. Description of the intervention(s) in sufficient detail that others could reproduce it</li> <li>b. Specifics of the team involved in the work</li> </ol>
9. Study of the Intervention(s)	<ol style="list-style-type: none"> <li>a. Approach chosen for assessing the impact of the intervention(s)</li> <li>b. Approach used to establish whether the observed outcomes were due to the intervention(s)</li> </ol>
10. Measures	<ol style="list-style-type: none"> <li>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</li> <li>b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost</li> <li>c. Methods employed for assessing completeness and accuracy of data</li> </ol>
11. Analysis	<ol style="list-style-type: none"> <li>a. Qualitative and quantitative methods used to draw inferences from the data</li> <li>b. Methods for understanding variation within the data, including the effects of time as a variable</li> </ol>
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
<b>Results</b>	<b>What did you find?</b>
13. Results	<ol style="list-style-type: none"> <li>a. Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project</li> <li>b. Details of the process measures and outcome</li> <li>c. Contextual elements that interacted with the intervention(s)</li> <li>d. Observed associations between outcomes, interventions, and relevant contextual elements</li> <li>e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s)</li> <li>f. Details about missing data</li> </ol>

(continued on page 476)

**Table 1. Revised Standards for Quality Improvement Reporting Excellence (SQIRE 2.0) Publication Guidelines (continued)**

Text Section and Item Name	Section or Item Description
<b>Discussion</b>	<i>What does it mean?</i>
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 generalizability 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 minimize 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
<b>Other information</b>	
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting.

e-mailed a penultimate draft to more than 450 persons around the world, including the advisory group, consensus meeting participants, authors, reviewers, editors, faculty in fellowship programs, and trainees. We also posted this version on the SQIRE website with an invitation for public feedback. We used the information from this process to write SQIRE 2.0 (Table 1).

### The Revised Publication Guidelines

Many publication guidelines, including CONSORT (randomized trials), STROBE (observational studies), and PRISMA (systematic reviews), focus on a particular study methodology.<sup>23</sup> In contrast, SQIRE 2.0 is designed to apply across the many approaches used for systematically improving the quality, safety, and value of health care. Methods range from iterative changes using Plan-Do-Study-Act (PDSA) cycles in single settings to retrospective analyses of large-scale programs to multisite randomized trials. We encourage authors to apply other publication guidelines—particularly those that focus on specific study methods—along with SQIRE, as appropriate. Authors should carefully consider the relevance of each SQIRE item but recognize that it is sometimes not necessary, nor even possible, to include each item in a particular manuscript.

SQIRE 2.0 retains the IMRaD (Introduction, Methods, Results, and Discussion) structure.<sup>24</sup> 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?<sup>25</sup> In our evaluation of SQIRE 1.0, novice authors found these questions to be straightforward, clear, and useful.

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

### 1. TERMINOLOGY

The elaborate detail in SQIRE 1.0 was seen by users as a both a blessing and a curse<sup>19</sup>: 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 SQIRE 2.0 shorter and more direct.

A major challenge in the reporting of systematic efforts to improve health care 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 *health care 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 (Sidebar 1, page 478). 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 endeavors 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.

## 2. 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. Health care improvement work has not consistently based the planning, design, and execution of its programs 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.<sup>12</sup>

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.

## 3. CONTEXT

SQUIRE 2.0 accepts "context" as the key features of the environment in which the work is immersed and that 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 (for example, improvement team, clinicians, patients, families).<sup>13-16</sup> Systematic efforts to improve health care should contain clear descriptions and acknowledgment 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 recognizes context as a fundamental item in the Methods section, but its relevance is not limited to this section. In addition to affecting the 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. Although 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).

## 4. STUDYING THE INTERVENTION(S)

The study of the intervention is, perhaps, the most challenging item in SQUIRE. In the evaluation of SQUIRE 1.0<sup>19</sup> and in the pilot testing,<sup>22</sup> many participants 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 generalizable knowledge. In contrast, the reason for "studying" the intervention is mainly to contribute to the body of knowledge about the efficacy and generalizability of efforts for improving health care. 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)

Sidebar 1. Glossary of Key Terms Used in Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) Publication Guidelines\*

**Assumptions**

Reasons for choosing the activities and tools used to bring about changes in healthcare services at the system level

**Context**

Physical and sociocultural makeup of the local environment (for example, external environmental factors, organizational 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 generalizability 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.†

**Generalizability**

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 organization-wide programs, narrowly focused projects, or the details of specific interventions (for example, 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 (in the form of a logic model, for example), and the mechanism(s) by which these components are expected to produce changes in a system’s performance.‡

**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 a particular intervention(s) was 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.

\* 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.

† Baily M., et al. The ethics of using QI methods to improve health care quality and safety. *Hastings Cent Rep.* 2006;34(4):S1–40.

‡ Hoffmann TC, et al. Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. *BMJ.* 2014 Mar7;348:61687 (reference 17 on page 479).

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 health care are available. The systematic efforts to improve health care 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 recognize that simply publishing SQUIRE 2.0 will not effect this change; additional efforts and resources are required. For example, an explanation and elaboration (E&E) document is in preparation for publication.<sup>26</sup> For each item in SQUIRE 2.0, the E&E will provide 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 contains a number of resources in addition to the guidelines themselves, including interactive E&E pages and video commentaries.<sup>27</sup> 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 health care services. **J**

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