Rubric for grading Clinical Research Studies

	Section or Item Description	
Title and Abstract		**Does the manuscript have this component? (Yes/No)**
1. Title	Does the title identify the type of clinical research (retrospective study, randomized trial, case study)?	
2. Abstract	a. Does the abstract provide adequate information to aid in searching and indexing? b. Does the abstract 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 ?	
Introduction	*Why did you start?*	
3. Available knowledge	Is there a summary of what is currently known about the problem, including relevant previous studies?	
4. Rationale	Does the manuscript have 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?	
5. Objectives/Hypothesis	Does the manuscript describe the questions the study was designed to answer? Does the manuscript have a pre-specified question (hypothesis) that is being tested?	
Methods	*What did you do?*	
9. Study Design (Prospective studies)	a. Are the methods described for recruitment of patient and criteria for inclusion /exclusion?	

	b. Are the settings and location where the data were collected described? c. How was the sample size determined? d. For randomized trials: If done, who was blinded after assignment to interventions?	
10. Study Design (Retrospective Studies)	a. Are the methods described for criteria for inclusion /exclusion of patients? b. Are the settings and location where the data were collected described? c. How was the sample size determined?	
11. Intervention(s)	a. Is there a description of the intervention(s) in sufficient detail that others could reproduce it b. Are the specifics of the team involved in the work described?	
12. Outcomes	Are the outcomes being tested clearly defined?	
13. Analysis	a. Were the standard methods of analysis performed? b. Are methods for understanding variation within the data, including the effects of time as a variable considered?	
14. Ethical Considerations (For prospective studies)	Are the 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. Were the findings of the study clearly described? b. Are the limitations addressing sources of potential bias,	

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	imprecision and limits of the study described? c. Is the interpretation of the results consistent with published data in the field? d. If applicable are the details about missing data described?	
Discussion	*What does it mean?*	
17. Conclusions	Are the following included in the discussion/conclusion section? 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	
Reviewers Comments:		

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For your information:

Table 2. Glossary of key terms used in 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 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)

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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 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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