


REVIEW

Differentiating research and quality improvement activities: A scoping review and implications for clinical scholarship

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ABSTRACT

Background: Differentiating activities that are research or quality improvement (QI) is challenging.

Purpose: Compare tools that distinguish research from QI and evaluate the utility of tools to determine whether institutional review board (IRB) approval is required for a test-project.

Methods: Scoping review of the literature to identify tools that distinguish QI from research. Two reviewers independently screened records in PubMed, Embase, Cumulative Index to Nursing and Allied Health Literature, Web of Science and Google Scholar and extracted information from tools. Inclusion criteria were English language peer-reviewed publications or publicly available tools with scoring systems to differentiate between research and QI. The reporting of this review follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses. We then applied a test-project to evaluate the utility of the tools.

Findings: One-hundred forty sources were reviewed; 13 met inclusion criteria. Tools consistently used project intent/purpose, design and intervention as differentiating criteria; additional criteria varied. Five studies described tool development, and one reported that the tool had been tested. Our application of a test-project proved challenging as tools commonly presented research and QI as discrete activities.

Discussion: Based on the core criteria common across tools to distinguish research from QI, we propose a simple four-criteria decision tool for assessing the need for IRB submission.

1 | INTRODUCTION

One component of the nursing role is to engage in clinical scholarship over the course of their education and practice. Clinical scholarship includes evidence-based practice, quality improvement (QI) and research, and has been formally defined as, 'an approach that enables evidence-based nursing and development of best practices... and...the use of systematic observation and scientifically-based methods to identify and solve clinical problems...' (SIGMA THETA

TAU INTERNATIONAL, 1999). The National Academy of Medicine specifies that all healthcare professionals engage in evidence-based practice and apply QI approaches (Institute of Medicine, 2003). Similarly, the American Association of Colleges of Nursing includes evidence-based practice, QI, as well as the research process as part of the core curriculum for baccalaureate and masters nursing education (American Association of Colleges of Nursing, 2008). Indeed, nurses at varied educational levels are engaged in research activities. The American Nurses Credentialing Center requires that nurses

conduct research (regardless of educational training) for Magnet designation and the conduct of research is a requirement of many nursing doctoral degree programs (American Association of Colleges of Nursing, 2006, 2010).

Although academic nursing programs are designed to equip nurses with the knowledge and skills to engage in clinical scholarship, it is often difficult to determine where projects fall along the clinical scholarship continuum (Carter et al., 2017). Federal regulations require that research activities are overseen by an institutional review board (IRB), an independent ethics committee that helps to ensure that ethical research principles are followed (US Department of Health and Human Services). Yet, the identification of activities that are research remains a source of confusion, even among federal governing bodies such as the Office of Human Research Protection (OHRP) (Carter et al., 2017). This places nurse scholars in a quandary regarding how they may proceed with their activity, especially when procedures to differentiate QI activities from research are unspecified or unclear, and they are faced with the question, 'Is IRB review needed'? Should the nurse: (i) make the self-determination regarding whether a clinical project includes research procedures; (ii) submit the protocol to the IRB for their decision regarding whether the project meets criteria as research; or (iii) only perform projects that clearly circumvent this dilemma?

Formal algorithms and checklists have been developed to aid end users in distinguishing QI from research, but to our knowledge, there is no current compilation and examination of such tools. Hence, we conducted a scoping literature review to compare existing tools used to distinguish QI from research and to describe the elements of the published tools. We then developed and applied a clinical scholarship test-project to each tool to evaluate the utility of tools in determining whether IRB approval is required. Lastly, we propose a tool to graphically depict the overlap in clinical scholarship and activities that require IRB approval.

2 | METHODS

This review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline extension for Scoping Reviews (Supporting information).

2.1 | Search strategy

Comprehensive searches were run in the MEDLINE (PubMed), Embase, Cumulative Index to Nursing and Allied Health Literature (EBSCO) and Web of Science databases in December 2019. Searches were conducted for original studies and decision-making tools on the distinction between research and QI projects that were published through the date of the search. Search terms for three domains were combined with the AND operator: one relating to QI, one related to screening/tools, and one related to IRB/research. A Google search was also conducted over the same time frame.

HIGHLIGHTS

- 13 published tools were identified to distinguish quality improvement (QI) and research activities.
- Tools commonly placed QI and research into mutually exclusive categories.
- We propose a simple tool to depict overlap in clinical scholarship activities and resulting procedures.

Given the large potential number of results from initial testing of the Google Search strategy, it was pre-determined to only consider the first 200 pages of results (top 200 results for the review). This was a subjective decision that was made due to time constraints, as search results were sorted by relevance, which decreased substantially near the point of 200. The search terms were modified from those used in the database searches, though the three domains were the same. Full search strategies can be found in the Appendix. Study inclusion criteria were as follows: peer-reviewed publications or publicly available decision-making tools; scoring system to differentiate between research and QI; and English language. Publications and tools that were not publicly available or did not have scoring systems were excluded. No date restrictions were imposed.

2.2 | Selection of publications

A web-based systematic review platform (Covidence, <http://covidence.org>) was used for the process of screening the literature and extracting data from included studies and tools. Two reviewers independently screened titles and abstracts to determine which met the inclusion criteria. Then, these two reviewers met, along with the library informationist, to discuss disagreements and come to consensus before proceeding to full-text review. Two reviewers independently screened each full text of article for the same inclusion criteria used in the title/abstract review, and any disagreements were addressed by consensus from all three reviewers.

2.3 | Data extraction

Data extraction fields from identified tools were initially developed and iteratively refined to identify commonalities among them and to ensure that the distinguishing criteria specified in tools were captured. Distinguishing criteria consisted of 10 components: (i) intent/purpose, (ii) design, (iii) intervention, (iv) population, (iv) benefits, (vi) risks, (vii) dissemination of results, (viii) data, (ix) funding and (x) position of clinician/researcher in the project setting, Table 1.

Two reviewers independently extracted the following data from each article included in the review: author (if peer-reviewed), institution (if publicly available tool), year of publication, criteria the tool considered, whether the tool was original or adapted from another

TABLE 1 Components of tools assessed

Component	Description: To determine whether the activity is quality improvement or research, does the tool specify as a consideration....
C1. Intent/Purpose	The intent of the project?
C2. Design	The design of the study, for example randomised, prospective vs. retrospective design, inflexible vs. flexible procedures, etc.?
C3. Intervention	The testing of interventions/practices that are beyond usual or standard of care?
C4. Population	The selection/type of the study population?
C5. Benefits	Whether there are direct benefits of the activity to participants?
C6. Risks	Whether there are risks of the activity to participants?
C7. Dissemination of Results	The intent to disseminate findings?
C8. Data	The collection or sharing of types of data outside the institution?
C9. Funding	The funding agency or source?
C10. Position of researcher	The role of the researcher or clinician in the practice setting, for example works on unit, access to data, etc.?

Clinical Scholarship "Test-Project"

Marietta King works as a pediatric inpatient medical/surgical nurse. She is interested in implementing recommendations proposed by the American Nurses Association (ANA) and Centers for Disease Control and Prevention (CDC) to advance nurses' contributions to antibiotic stewardship (<https://www.cdc.gov/antibiotic-use/healthcare/pdfs/ANA-CDC-whitepaper.pdf>). Specifically, Marietta intends to implement an 'antibiotic timeout' on her unit, in which nurses' prompt prescribers to reassess a patient's antibiotic management plan 48 hours after the initiation of antibiotic therapy. Marietta proposes to use a pre-test, post-test study design and compare broad-spectrum antibiotic therapy pre and post-intervention through the manual chart review of patients.

Marietta recognizes that while nurses' initiation of an antibiotic time-out is recommended by the CDC and ANA, little has been published to evaluate the impact of this practice on antibiotic use and she is unaware of studies conducted in the pediatric setting to address this issue. Marietta believes her findings may be generalizable to other pediatric settings and is eager to contribute to the literature by disseminating her project findings through a peer-reviewed manuscript.

FIGURE 1 Clinical Scholarship Test-Project [Colour figure can be viewed at wileyonlinelibrary.com]

source, whether the tool provided information regarding administrative or ethical oversight of QI projects, the style of the tool (checklist or flowchart/algorithm), whether the development and testing of

the tool were described, the tool's intended audience, whether the completed tool was submitted to the IRB or equivalent body, and whether the IRB or equivalent body validated the tool's decision.

All three reviewers met to discuss the independent extractions and come to consensus on the final data elements to extract for each article.

2.3.1 | Clinical scholarship test-project

We developed a typical clinical scholarship test-project to highlight any overlap of clinical scholarship activities, in which a pediatric nurse proposes to implement and evaluate a professional practice recommendation, Figure 1.

2.3.2 | Application of clinical scholarship test-project

We applied the criteria identified in each tool (Table 1) to the clinical scholarship test-project to determine whether the tool concluded that the test-project required IRB approval, Figure 2.

3 | RESULTS

A total of 140 peer-reviewed publications and publicly available tools were identified; 13 met inclusion criteria and were included in this review (CHOP - Rachel Nosowsky, 2006; Cioletti et al., 2017; Duke University Health System - Human Research Protection, 2016; Foster, 2013; Hebrew Senior Life, 2017; Johnson et al., 2006; Kring, 2008; M. G. H. Partners Health, 2012; McNett & Lawry, 2009; Ottawa Health Science Network Research Ethics Board, 2016; Ryan

& Rosario, 2012; St. Joseph's Health Centre Toronto, 2014; TriHealth - Bethesda, 2015), Figure 3. Of these, 9 (69%) were obtained from the Google search and were developed and published by healthcare organisations such as a hospital or long term care facility; the remaining 4 (31%) were developed by researchers and published in the peer-reviewed literature. The intended audience of tools was specified as clinicians/investigators embarking on projects ($N = 10$, 77%), IRBs and oversight committees ($N = 1$, 8%) or unspecified ($N = 2$, 15%).

All but one tool were checklists ($N = 12$, 92%), one was an algorithm ($N = 1$, 8%). All tools specified the intent/purpose, project design and project intervention as criteria to identify projects necessitating IRB approval, Table 2. Additional distinguishing criteria pertained to participant risks ($N = 10$, 77%), the types of data being collected and/or being shared outside the institution ($N = 8$, 62%), funding mechanisms ($N = 7$, 54%), dissemination plans ($N = 7$, 54%), the position of the investigator in the clinical/research setting ($N = 6$, 46%) and the population under study ($N = 5$, 38%).

3.1 | Tool development, testing and use

Over half of the tools ($N = 7$, 54%) were adapted from another source and five (38%) included a description of how they were developed, based on either a review of the literature, regulatory requirements and/or partnership with IRB personnel. Most tools were designed for end users to complete without formal interaction or involvement with the IRB ($N = 9$, 69%). Four tools (31%) documented procedures in which end users submit the completed tool to an IRB or equivalent oversight committee and in two of these cases, the IRB validates

Clinical Scholarship “Test -Project” Components
<u>Intent</u> - The primary intent of the project is to improve care locally; a secondary intent is to demonstrate the impact of the nurse-initiated antibiotic timeout on antibiotic use in the pediatric setting (i.e., contribute to generalizable knowledge).
<u>Design</u> - The project uses a pre-test, post-test study design and medical chart review.
<u>Intervention</u> - The intervention is a nurse-initiated antibiotic timeout, which is not standard practice. While the intervention is proposed by leading professional organizations, limited evidence exists to support nurses' initiation of an antibiotic timeout.
<u>Population</u> - The project will be conducted in the pediatric setting. Project participants include patients, whose antibiotic treatment may be impacted as a result of the intervention, and whose charts will be reviewed.
<u>Benefits</u> – Participants may or not receive direct benefits.
<u>Risks</u> - The review of patient medical records may result in a loss of protected health information.
<u>Dissemination of Results</u> - Findings will be disseminated through a manuscript.
<u>Data</u> - Patient-level data will be obtained through manual chart review. Only aggregate-level data will be shared outside the organization.
<u>Funding</u> - No funding for this project.
<u>Position of researcher</u> - The clinician works in the project setting as a nurse.

FIGURE 2 Clinical Scholarship Test-Project Components

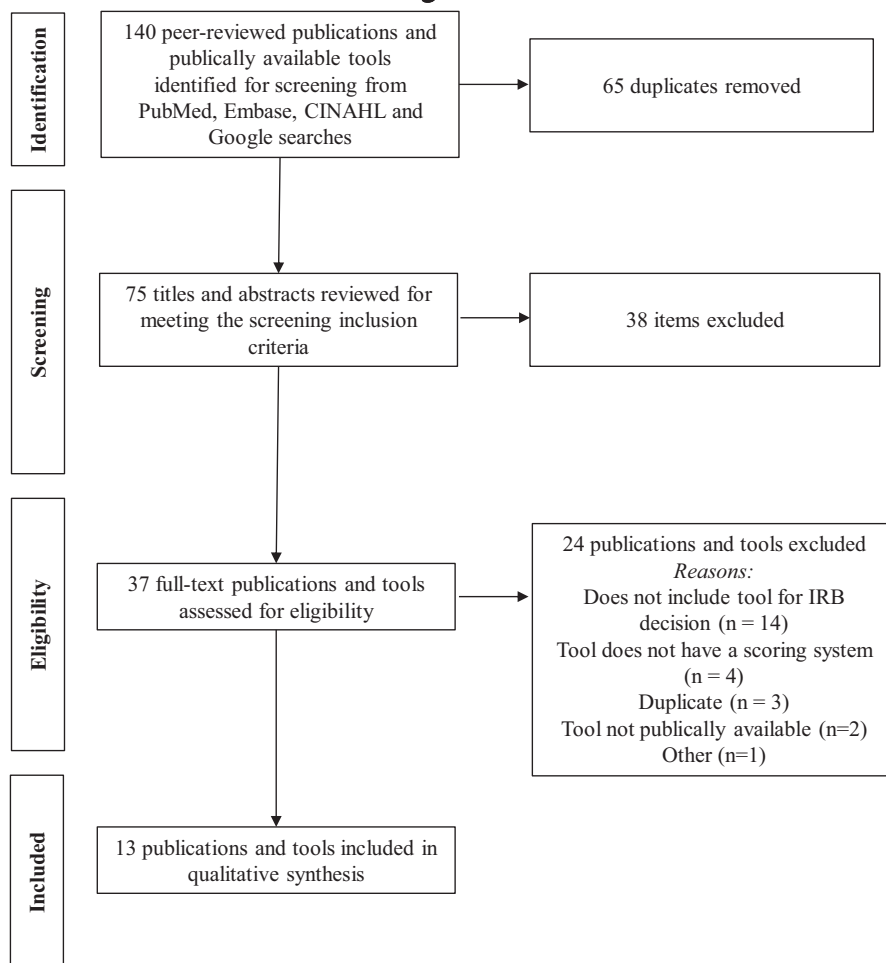


FIGURE 3 Flowchart of Study Selection. Tool Format and Research Distinguishing Criteria

TABLE 2 Components included in each tool to differentiate quality improvement and research

Tool author/institution (year)	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10
Cioletti (2017)	X	X	X			X	X	X		X
Duke University Health System (2016)	X	X	X	X	X	X				X
Foster (2013)	X	X	X	X	X	X		X		
Hebrew Senior Life (2017)	X	X	X						X	X
Johnson (2006)	X	X	X			X	X	X		
Kring (2008)	X	X		X	X	X	X		X	
McNett (2009)	X	X	X	X		X	X	X		
Nosowsky (2006)	X	X	X						X	X
Ottawa Health Science Network Research Ethics Board (2016)	X	X	X			X	X	X	X	
Partners Health (MGH) (2012)	X	X	X						X	X
Ryan (2012)	X	X	X			X	X	X		
St. Joseph's Health Center Toronto (2014)	X	X	X			X	X	X	X	
Tri Health Bethesda Foundation (2015)	X	X	X	X	X	X		X	X	X
Total N (%)	13 (100)	13 (100)	13 (100)	5 (38)	4 (31)	10 (77)	7 (54)	8 (62)	7 (54)	6 (46)

Note: C1, intent/purpose; C2, design; C3, intervention; C4, population; C5, benefits; C6, risks; C7, study dissemination; C8 data; C9, funding; C10, position of researcher.

tool determination. Eight tools (62%) referenced oversight committees and/or procedures that govern projects deemed as QI. One tool included a description of its testing, in which investigators compared investigators' classification of projects pre- and post-tool use.

3.2 | Application of clinical scholarship test-project

We applied the clinical scholarship test-project to tools to determine their utility in determining whether IRB approval is required. All 13 tools when applied to the clinical scholarship test-project specified that the project required IRB approval. Aspects of the project that categorised the study as research included the intent of the project to contribute to generalisable knowledge (e.g., scalable to other healthcare settings or potentially other populations), the testing of an intervention that is not standard of care and/or lack supporting evidence, and access to patient medical records, Table 3.

4 | DISCUSSION

We searched the literature to identify tools that aid end users to differentiate QI from research and identify activities that require IRB approval. Distinguishing criteria varied across tools and extended beyond the OHRP definition of research, '*systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge*' (US Department of Health and Human Services). Consistent with this definition, all tools specified the intent/purpose of activities and aspects of study design as criteria to identify research activities that require IRB approval. In contrast, several criteria included in some tools were not specified in, and in one case contradicted, guidance provided by the OHRP (<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>).

Distinguishing criteria that extend beyond OHRP guidance pertained to the study intervention, population, risk to participants, the types of data being accessed and/or shared outside the institution, and the position of the investigator conducting the project in the project setting. It is likely that these additional criteria were included in tools to operationalise the overarching principles of research, that is systematic investigation and knowledge generation, which are subject to interpretation as well as the dynamic nature of clinical scholarship since scholarly projects may have dual purposes of rapidly improving site-specific care and contributing to generalisable knowledge.

A common area of discordance between OHRP guidance and extant tools pertained to the dissemination of project findings. While the OHRP specifies that the intent to publish does not necessarily mean that the project is research, over half of tools, all of which were in the grey literature, included the intent to publish as a distinguishing feature of research. Some of the tools were published before this OHRP guidance was released, but this discordance may also reflect the perception that projects conducted in clinical practice settings

TABLE 3 Application of clinical scholarship test-project to tools

Component	Tool author/institution												
	Ciolletti (2017)	Duke University (2016)	Foster (2013)	Hebrew Senior Life (2017)	Johnson (2006)	Kring (2008)	McNett (2009)	Nosowsky (2006)	Ottawa (2016)	Partners (2012)	Ryan (2012)	St. Joseph's Health (2014)	Tri Health (2015)
Intent	R	QI	R	R	R	R	R	R	R	R	R	R	R
Design	QI	QI	R	R	QI	R	QI	QI	QI	QI	QI	QI	QI
Intervention	QI	R	R	QI	R		QI	R	R	R	QI	QI	R
Population		QI	QI			QI	QI						R
Benefits		QI	QI			QI							QI
Risks	R	QI	QI		R	R	R		R		R	R	R
Study Dissemination	R				R	R	R		R		R	R	
Data	QI		R		QI	R	R		QI		QI	QI	QI
Funding				QI		QI		QI	QI	QI		QI	QI
Position of researcher	QI	QI		QI				QI		QI			QI

Note: Grey-shaded areas denote criteria unspecified in tools. Abbreviations: QI, quality improvement; R, research.

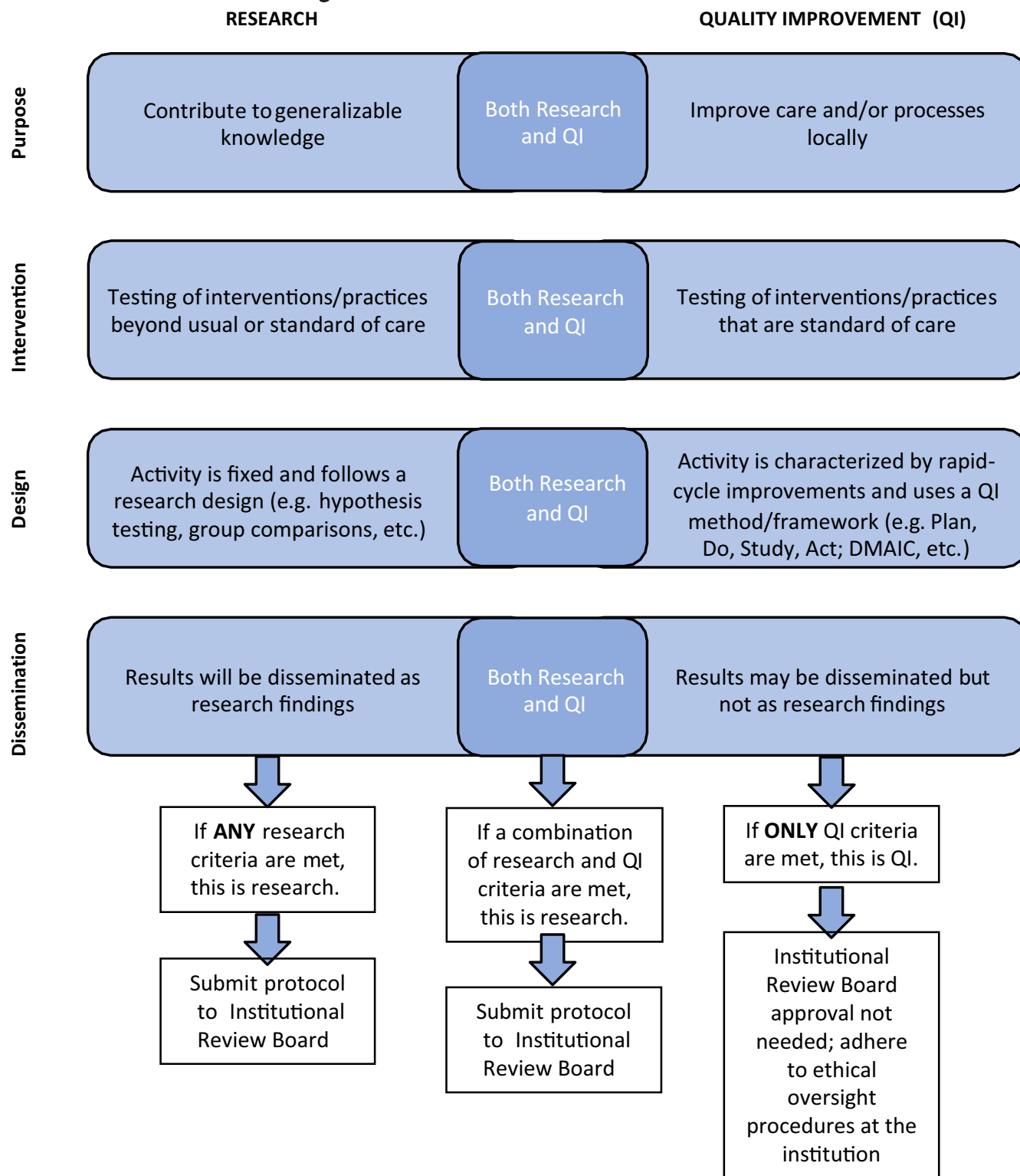


FIGURE 4 Tool to Distinguish Research and QI Activities [Colour figure can be viewed at wileyonlinelibrary.com]

are proprietary in nature and may therefore be inappropriate for widespread dissemination. The tools identified in the Google search were intended for use in healthcare delivery organisations, which suggests that the need is particularly great in practice settings for a decision-support tool to aid clinical users to identify activities necessitating IRB approval.

Another area of discordance was regarding the types of data being accessed. Several tools specified the acquisition of protected health information as a requisite for IRB approval (Foster, 2013; Kring, 2008; McNett & Lawry, 2009) which likely reflects the belief that access to patient data carries the risk of loss of confidentiality. However, this specification contradicts the privacy exclusion under

Health Insurance Portability and Accountability Act (HIPAA), which permits the use of protected health information data for QI activities (U.S. Department of Health and Human Services, 2016). Regardless of whether medical records are accessed for research and/or QI activities, there remains a need for secure data management procedures to maintain patient confidentiality and privacy.

We presented a clinical scholarship test-project example that could be conducted by nurses with varied educational backgrounds and that included a mix of clinical scholarship activities. Namely, the nurse was interested in adopting recommendations proposed by leading professional organisations (evidence-based practice) to improve care locally (QI) and believed that the project findings could be generalised elsewhere (research). While all tools indicated that the project necessitated regulatory review, it was challenging to make this determination as tools commonly placed QI and research activities into mutually exclusive categories, which can give the false impression that activities can be either research or QI, but not a combination of the two. Educational programs similarly separate scholarly activities into discrete buckets. This approach fails to appreciate the complexity and interdependence of scholarly activities and may result in activities requiring IRB approval to go unrecognised. We present a tool to graphically highlight the combination of scholarly activities, Figure 4, which may be used by educators and clinical scholars to inform discussions of scholarly activities requiring regulatory review. Future studies should assess the validity and usefulness of the tool in distinguishing QI and research activities.

To our knowledge, this is the first formal compilation of tools to distinguish QI and research activities. Major study strengths include our comprehensive search strategy and inclusion criteria that included peer-reviewed and grey literature. Further, two investigators independently screened publications and websites and extracted data from tools included in the review to enhance reliability and validity of the findings. Despite our comprehensive search strategy, it is possible that relevant articles were excluded. We excluded tools that did not include an explicit scoring system or algorithm to determine whether activities required IRB approval as we were interested in identifying decision-support tools rather than narrative discussions of similarities and differences in QI and research. We also excluded tools that were not publicly accessible including two tools (Medical University of South Carolina, 2019; Virginia Commonwealth University, 2019) that were only accessible via an organisational login. The contents of these tools would have likely added to the findings of this review.

5 | CONCLUSION

Several tools are publicly available to distinguish QI from research activities. These consistently specify the intent/purpose, project design and project intervention as criteria in determining IRB approval requirements. We applied a clinical scholarship test-project and found it challenging to use tools as many placed scholarly activities into discrete categories. To facilitate nurses' ability to contribute to

clinical scholarship, we present a tool that graphically depicts overlap in clinical scholarship activities and instances in which regulatory review is needed.

DISCLOSURES

None.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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