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The Difference between Quality Improvement and Human Subject Research

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Keypoints

- Sample size is irrelevant in QI because these studies do not generalize results.
- Human subjects research leads to generalizable knowledge.
- QI results are limited to the institution where the scholarly activity took place.
- Whether doing QI or human subjects research, always submit a proposal to the IRB.
- The SQUIRE Statement should be used whenever doing a QI project.

Health care professionals make a difference in patient care in many sustentative ways within the health care paradigm.[1–4] Statisticians, peer reviewers, and health professions faculty contribute to anecdotal evidence which suggests that there is confusion related to misinformation concerning the methodology of quality improvement (QI) projects. Some clinicians perceive methodology as the discriminating factor that distinguishes QI projects from human subjects research (HSR). However, this distinction should be determined by the scope of the scholarly activity. The misunderstanding comes from how QI fits within the broader context of scholarly activity and the HSR model. In this article, the distinction between QI and HSR is made with the goal of explaining the differences between the two and eliminating misconceptions regarding QI.

Scholarship is defined as, "… the generation, synthesis, translation, application, and dissemination of knowledge that aims to improve health and transform health care" (p. 2).[5] The *Oxford Learner's Dictionary* defines research as, "a careful study of a subject, especially in order to discover new facts or information about it".[6] Melnyk and Fineout-Overholt differentiate QI from HSR as, "[QI is] identify[ing] and fix[ing] processes leading to an internal problem within the clinical setting, whereas the … human subjects research … generates new knowledge/external evidence" (p. 42).[7] Thus, scholarly

health care practice is characterized by both discovery and application of new discoveries in increasingly complex practice situations.

QI projects improve health care function and processes. Contextually finding a better way to do something is discovery and provides novel information in the same vein as discovering new facts does. QI is research within the context of health care research even if it does not involve human subjects. When scholars use evidence-based programs or national guidelines, they should disseminate outcomes of guideline implementation for the benefit of other clinicians and ultimately patient care.

Untangling QI Projects From HSR

QI falls under implementation science, improvement science, or translational science. "Implementation science is the study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice, and hence to improve the quality (effectiveness, reliability, safety, appropriateness, equity, efficiency) of health care".[8] Implementation science underscores rapid-cycle testing in order to learn about change and begin improvement.[9] Improvement science diverts from the HSR after defining the research question. Instead of hypothesis testing, health care professionals define what is considered improvement and continue with rapid-cycle testing guided by subject matter experts.[9,10] QI has a lot in common with HSR because it is dependent on the same qualitative and quantitative methods used in HSR.[11]

Because HSR and QI share methodologies, clinicians cannot determine based solely on methodology whether an investigation is QI or HSR. Baily et al. emphasized the difference between QI and HSR is determined by the generalizable intention and defined HSR by the Code of Federal Register Title 45 CFR §46.102(l) as "…a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to *generalizable knowledge*" (p. 136; emphasis added).[11,12]

A nuance many health care professionals miss is QI projects can and do produce generalizable knowledge. The challenge of distinction occurs when adequate training is not instilled in educational settings and carries over into practice settings. Some clinicians have a misconception that QI projects are not categorized as "human subjects research" solely based on methodology. Lynn et al. suggest the confusion regarding whether QI projects fall under Title 45 CFR §46 arises from interpretation differences of the phrase "…designed to develop or contribute to generalizable knowledge."[13] Here lies the nuance many miss. QI projects, strictly speaking, are not generalizable. They are specific to the institution where the investigation is conducted. However, if QI results are interpreted to be generalizable and applicable to others and involve human subjects, then a QI project would qualify as HSR.[13] Additionally, if in the course of implementing a QI project, generalizable knowledge is produced, then the investigation comes to represent both QI and research. As such, Lynn et al. argue if QI in the context of patient care is designed to improve local care and produce generalizable knowledge, the activity would qualify for both.[13] Most certainly QI projects are not HSR as formulated by those authoring Title 45 CFR §46. However, this does not pertain to methodology used in QI, only the conceptualization of how QI is to be conducted.[11]

The purpose of QI is to improve process, and it may use various frameworks such as the Plan-Do-Check-Act framework by Deming and later the Plan-Do-Study-Act, the Knowledge to Action Framework, Titler et al's. Iowa Model of Evidence-Based Practice to Promote Quality Care, or the ACE Star Model.[14–17]

Humans subjects research may use theoretical frameworks such as the Kolb's theory of Experiential Learning,[18] Bauman's Layered Learning Model,[19–22] or Bloom's Theory of Mastery Learning.[23] In QI, the project may change based on the evaluation or reevaluation of obtained outcomes with the sustainability of outcomes being examined over time. Direction may be changed, during the project, based on how the project is progressing; whereas in HSR, the study is not changed part way through the research project or based on the outcome.

Hence, the determination and designation of a QI project is not based on methodology, but the purpose of the study and how generalizable the results are. If the results can only be applied locally, the project is QI. The misconception of QI not qualifying as HSR does not lie in methodology, but in the conceptualization. Almost all designs, including randomization (experimental designs), can be QI. If the results are generalizable to other hospitals or clinics, the study must be viewed as HSR and falls under the regulations stated in Title 45 CFR §46. Key differences between HSR and QI projects are seen in Table 1.

Rigor is not necessarily a desirable characteristic in a QI project. QI prioritizes practicality and flexibility. Like Phase IV clinical trials, QI studies examine real-world health care settings where it is not possible to control for all extraneous variables. Examining the real world allows clinicians to avoid getting *bogged down* in excessive data collection.[24,25]

Determining What is a QI Project and What is a HSR Study

Guidance for determining what constitutes a QI project and what is HSR is available through several tools. One such tool is available online from the Virginia Commonwealth University and can be found here: https://perma.cc/WW42-VWWH.

Another tool is included as Table 2; the Quality Improvement Project Ascertainment Checklist (QuIPAC) assists in determining whether a proposed initiative is an HSR or a QI project.

However, the determination of whether a project is QI project versus HSR may be irrelevant in context of determining whether a proposal should be submitted to the Institutional Review Board (IRB), because the United States Office of Human Research Protection will decide if a project is research or QI. Incorrect classification of QI projects can have dire implications such as an institution losing all federal funding and further penalties being levied as a result of investigation by the Office of Human Research Protection.[26] We suggest an open discussion with the IRB as you are completing the IRB application to promote efficiency in the application process.

Table 1. **Differences Distinguishing Human Subjects Research from Quality Improvement[a]**

Element	Human subject research	Quality improvement practice
Intent	Develop or contribute to new knowledge	Improve the delivery of clinical care within a given system
Output	Results are generalizable	Results are only relevant to a specific site under study
Investigation	Addresses a specific question	Addresses a process or system
Design	Includes assessment measures pre and post	Includes ongoing assessment measures
Timing	Limited to discrete time period	Ongoing process
Focus	Addresses gap in knowledge	Addresses gap in implementation of a process
Goal	Proof of effectiveness of an intervention	Sustained improvement in care in a specific environment
Dissemination	Publication of results to scientific community may take months or years	Focused on implementing immediate improvement in care; should be shared within the system and with other similar systems
Risk to participants	Considered to be worthwhile for the benefit to society	Little or no risk; may be at a greater risk if not participating
Setting	May be independent of site where care is routinely provided	Takes place in a localized healthcare setting; incorporates specific features of the setting
Funding	Often comes from outside the agency in which the research is taking place	Often internal and managed by people who work in that setting
Management	Often conceived, funded, and managed as discrete projects	Ongoing process of continual, self-conscious change
Method	Strictly constructed protocol is maintained throughout data collection	Protocol may require repeated modifications over time and as the desired changes engage the local structures, processes, patterns, habits, and traditions
Context	Methods seek to eliminate the context	Methods are developed based on knowledge of the context

[a]Table reprinted from Mormer E, Stevans J. Clinical quality improvement and quality improvement research. *Perspect ASHA Spec Interest Groups.* 2019;4:27–37. doi:10.1044/2018_PERS-ST-2018-0003. This work is licensed under a Creative Commons Attribution-NonCommercial-NoDerivs 2.0 Generic License.

Toward More Rigor in QI Projects

In the early 21st century in response to the dearth of standards or guidelines related to QI projects, an interdisciplinary group was formed and created the Standards for Quality Improvement Reporting Excellence (SQUIRE Statement).[27] The SQUIRE statement provides a framework for reporting novel findings regarding health care improvements. The guidelines are intended for reports describing organizational or system-level projects improving health care quality, safety, and value. The SQUIRE Statement consists of a checklist of 19 items clinicians need to consider when writing articles describing formal projects of QI.[27] Between 2012 and 2015, the SQUIRE Statement was reexamined and revised.[28] The revised statements emphasize 3 key components of methodology for QI projects: (1) the use of theoretical frameworks in planning, implementing, evaluating, and interpreting QI projects; (2) the context in which the work is completed; and (3) the intervention being used.[28] The revised statement is intended to be more broadly applicable to methods specific to QI projects, recognizing their complexity and multidimensionality.

Summary

QI projects and HSR studies can be very similar in nature and often indistinguishable in terms of methodology. How the knowledge discovered in the project investigation will be used determines this classification. If results of a project are only applicable locally, an investigation is likely a QI project. If results of a study are generalizable beyond the confines of the institution or human subjects are involved, the study represents HSR. This discussion should help clinicians engaging

Table 2. **Quality Improvement Project Ascertainment Checklist (QuIPAC)**

This checklist will help you determine whether a proposed project is in fact QI or potentially human subjects research.

Consideration	Question				
Purpose	Is the primary aim or motive of this activity either to: • Improve care *right now* for the next patient seen? or • Improve efficiency or operations?	○	Yes	○	No
Rationale	Is there sufficient evidence for, or acceptance of, this approach to support implementing this activity or to create practice change, based on: • Consensus among clinician or clinical team, • Consensus statements, or • Literature?	○	Yes	○	No
Methods	Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback, and incremental change?	○	Yes	○	No
Risk	Is the risk related to the project minimal (see below) and no more than usual care and to privacy or confidentiality?	○	Yes	○	No
Benefits	Chiefly participants at local institution, not society.	○	Yes	○	No
Participants	Will the activity only involve participants (patients, parents, or institution faculty/staff) who are ordinarily seen, care for, or work in the setting where the activity will take place?	○	Yes	○	No
Results	Generalizability of results is possible, but not the main intent of the activity.	○	Yes	○	No
Funding	Is the project funded by any of the following? • A manufacturer with an interest in the outcome relevant to its products • A nonprofit foundation that typically funds research (see below) or by internal research accounts • An outside organization with an interest in the results	○	Yes	○	No
Dissemination	Are you planning to disseminate the *results*, not process, of the activity?	○	Yes	○	No

If all of the check marks are inside the shaded grey boxes, then the project is likely quality improvement and not human subjects research. Regardless of the categorization of the activity, institutional review board approval should be sought. For applicable definitions, please see the following sections of §45 Part 46 of the Code of Federal Register:[12]

- §46.102(e) Human Subject
- §46.102(j) Minimal Risk
- §46.102(l) Research

in investigative activities determine the difference between QI projects and an HSR studies. This paper assists health care professionals in determining whether the scholarly activity they are engaged in is a QI project or HSR. Regardless of the type of investigation, clinicians are encouraged to seek IRB approval to assure human rights protection and consider publishing your results in *JAVA*.

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SigmaStatsConsulting@gmail.com. Please put the title of the article in the Subject line.

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Author's Contributions

GEG conceived of the paper and drafted the original version. AEF contributed substantially to the manuscript content. EBB, LAP, and AEF provided critical revisions. All authors approved the final manuscript.

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