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FEATURE ARTICLE

An Instrument to Differentiate between Clinical Research and Quality Improvement

by Greg Ogrinc, William A. Nelson, Susan M. Adams, and Ann E. O'Hara

There is increasing recognition of the importance of quality improvement (QI) initiatives to ensure the consistent, effective, and efficient delivery of safe, patient-centered care.[1] There also is support for the value of ensuring that QI activities be conducted within an ethical framework.[2] Yet unlike the federally required institutional review boards (IRBs) that review and monitor research projects involving human subjects,[3] there is no formally established review process governing QI activities. In recent years, health care institutions have considered reviewing and tracing QI activities, thus raising the question: What mechanism should be used to conduct the review of QI activities to ensure their ethical integrity? It is unclear whether IRBs should be the entity that reviews and monitors QI activities.

Related to this structural and procedural issue is the problem of the sometimes-subtle differences and frequent overlap between clinical research and QI activities. The human research regulations define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[4] QI has been variously defined, but perhaps the best definition is by Batalden and Davidoff: "the combined and unceasing efforts of everyone—health care professionals, patients and their families, researchers, payers, planners, educators—to make changes that will lead to better patient outcomes, better system performance, and better professional development."[5] QI focuses on providing the right care to the right patient by designing, assessing, and changing the health care delivery system. Yet many activities may fall in a middle ground and have a research component within a QI activity (Figure 1). Any component of a proposal that is clinical research will necessitate an IRB review to be consistent with the ethical framework for research with humans and to comply with human research regulations.

Health care professionals, researchers, quality improvement specialists, and IRB members have conflicting perspectives regarding the distinction between clinical research and quality improvement activities.[6] For example, fellows from six Veteran's Health Administration medical centers and

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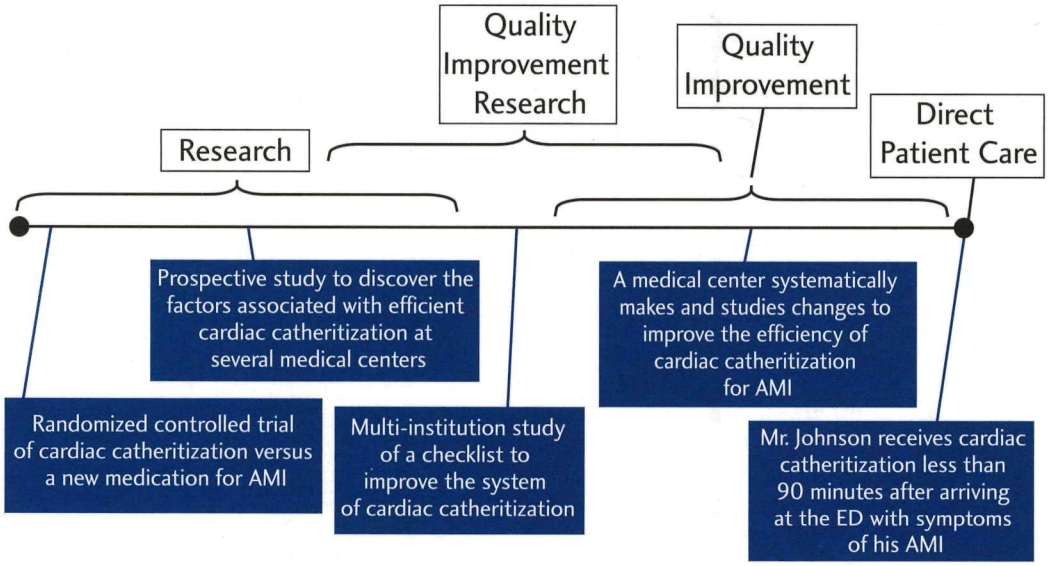
Figure 1.
Depiction of the continuum of clinical research, quality improvement, and patient care activities. Examples are provided relating to care, improvement, and research for acute myocardial infarction (AMI).



university affiliates who participated in the VA National Quality Scholars program were asked to review their center's criteria for determining whether a particular proposed project was QI and/or human subjects research. Their findings noted the lack of uniformity between the various sites in making such a determination.[7] Even if a QI review process existed, significant concern remains regarding how to achieve a uniform process to distinguish QI activities from clinical research. A characteristic used by some in the past to distinguish between the two—whether the results of an activity will be published or not—is no longer a reliable criterion because journals regularly publish reports about QI activities. Thus, the publication criterion cannot be the sole determinative factor going forward.[8]

Because of the recognized need for QI efforts in today's health care organizations, the inconsistent local decision–making regarding the determination of whether a project is QI and/or research, and the uncertainty surrounding who should review such proposals, we believe that a checklist instrument to distinguish QI activities from clinical research is an important first step toward an appropriate review process. We describe here the development and pilot testing of such an instrument.

The Development Process

In the autumn of 2009, a planning group was formed that consisted of the director of the Dartmouth College IRB (SMA), a quality improvement leader (GO), a health care ethicist (WAN), and an IRB staff member (AEO). The group began with an initial checklist that consisted of 15 general attributes such as "intent or purpose," "scientific methodology and analysis," "permissions," and "formal regulation." These attributes were used as domains to differentiate QI from clinical research. The regulatory definition of research was used to identify specific components of research within each attribute.[9] For example, when considering the item "scientific methodology and analysis," it is clear that clinical research uses a specific methodology to answer the questions that are posed. For QI activities, the methods used in the design, execution, and analysis are different.

The planning group used a set of guidelines, Standards for Quality Improvement Reporting Excellence (SQUIRE), to specify the criteria for QI activities. The SQUIRE guidelines were developed in an effort to increase the completeness, precision, and transparency of published QI reports. Over the past few decades there has been considerable uncertainty as to how QI activities should be reported in the health care literature compared to research findings. Early published QI findings were often presented as case studies similar to management reports that did not fit well into the scholarly literature. Reports of QI activities involving formal hypothesis testing were often published in the health care literature following the standard format for reporting research results. These

publications brought QI work to a wide audience, but left out details that might allow readers to apply the findings in their local setting. The QI field needed guidance merging the iterative, context–dependent, social change characteristics of QI into the hypothesis-testing publication framework required in traditional clinical research. Development of SQUIRE began with publication of draft guidelines in 2005,[10] which were then critiqued and revised by an expert panel. This process built a consensus among a broad community of stakeholders—including quality improvement professionals, clinicians, clinical researchers, statisticians, and journal editors—regarding the structure and content of the emerging guidelines. The resulting SQUIRE guidelines were published in *Quality & Safety in Health Care* (now *BMJ Quality and Safety*) and concurrently in five other medical, nursing, and medical specialty journals in late 2008 and were also made available on a Web site.[11] Since their publication, other uses of the SQUIRE guidelines have emerged including for guiding the preparation of posters at national and international conferences, preparing internal quality improvement reports at hospitals, and even informing quality improvement activities prospectively. We surmised that using the defined QI criteria of the SQUIRE guidelines in relationship to the ethical framework would provide a foundation for specifying QI activities and distinguishing between QI activities and clinical research.

Our planning group winnowed the initial list of 15 attributes to six to eliminate redundancies and highlight those that have the greatest contrast between QI activities and clinical research. Next, an expert panel was convened to further develop the checklist. The panel totaled 11 members, including the original four members of the planning group plus clinical researchers, QI leaders, and a QI fellow. This expert panel reviewed the work of the planning group, challenged underlying assumptions about the attributes, and added content such as the consideration of vulnerable populations. Through nine months of face-to-face meetings the expert panel developed an instrument that includes four overarching questions and six attributes (Figure 2).

Key Attributes of the Instrument

The purpose of the instrument is to assist IRB staff, quality improvement specialists, and researchers in determining whether a project is QI or has components of clinical research and thus requires review by an IRB. Figure 2 presents the screening construct we adopted that our affiliate VA medical center uses.[12] The screening construct starts with four key questions that address important considerations about the entire proposal, such as whether the activities occur within the current standard of care, whether there is a clear physical or psychosocial risk to the participants, and whether the project involves vulnerable populations. Responding "yes" to these is likely an indication that IRB review is required. For example, an activity, whether QI or clinical research, that occurs outside of the standard of care should be reviewed by the local IRB. Alternatively, an activity, whether QI or research, that involves risk may or may not require IRB oversight because the level and category of risk (physical, psychosocial, legal, confidentiality of medical information) is further delineated in the main table of the checklist.

The six attributes in the checklist (Figure 2, left hand column) are key points of distinction between QI and clinical research and are consistent with the proposed ethical framework for QI that Lynn et al. developed [13] and with current human research regulations.[14] If any item is determined to be in the clinical research column, then the proposal has significant components of research and must be reviewed by the IRB. If all items are in the QI column, then the project can proceed according to local requirements for QI activities, which vary between institutions. The six attributes are as follows:

- ***Intent and Background.*** Quality improvement is generally used to describe and close a specific, local performance gap. The focus is to improve a specific aspect of health or health care delivery that is not consistently being implemented. This goal differs from clinical research, which addresses a specific deficit in scientific knowledge so as to develop new generalizable knowledge or advance existing knowledge.
- ***Methods.*** The methods of quality improvement differ from research. In QI, the intervention is expected to evolve over time because QI is an iterative activity. The intervention and analysis include an assessment of the system, and the statistical methods account for changes over time in the outcomes. Analysis is aimed at gaining insight into the changes that occur within a system. Research methods use specific, clearly defined protocols that specify the intervention and the collection of data. Qualitative or quantitative methods are used to make observations and comparisons between groups or sometimes to generate further hypotheses.
- ***Intended Benefit.*** QI seeks a direct benefit to the participants or to the system in which the changes occur. This intended benefit should be clearly described in a QI proposal. It may be indirect, such as lowering the risk of infection through more frequent hand hygiene, or direct, such as ensuring that the proper medications are prescribed after a heart attack. The intended benefit of research moves beyond the standard provider–patient therapeutic relationship.[15] It is possible there will be a direct benefit to an individual participant in research or even to an

Figure 2.
Instrument to Assess the Differences between QI and Clinical Research with Human Subjects

This table is intended to compare and contrast the general characteristics of quality improvement (QI) and clinical research activities and is for use by Institutional Review Boards (IRBs), administrative reviewers, investigators, and improvers. This table is intended to guide discussion among these individuals and is not intended to supplant the judgment of IRBs or local QI ethics review committees. Please start by considering these overarching questions:

1. Will the activities of this project occur within the standard of care? If NO, then proceed to IRB review.
2. Is there risk? If YES, use chart below to determine whether this project requires QI review or IRB review.
3. Is this project primarily intended to generate generalizable knowledge? If YES, proceed to IRB review.
4. Does this project involve vulnerable populations? If YES, use chart below to determine whether this project requires QI review or IRB review.

For each item, choose the column to which the project most closely relates—QI or research. You may only choose one answer. Leave the item blank if neither choice applies.

Attribute	*Quality Improvement*	*Clinical Research with Human Subjects*
Intent and Background	☐ Describes the nature and severity of a specific local performance gap	☐ Identifies a specific deficit in scientific knowledge from the literature
	☐ Focus is to improve a specific aspect of health or health care delivery that is currently NOT consistently and appropriately being implemented at this site	☐ Proposes to address or identify specific hypotheses in order to develop new knowledge or advance existing knowledge
Methods	☐ Mechanisms of the intervention are expected to change over time (i.e., an iterative activity) in response to ongoing feedback	☐ Specific protocol defines the intervention, interaction, and use of collected data and tissues, plus project may rely on the randomization of individuals to enhance confidence in differences
	☐ Plan for intervention and analysis includes an assessment of the system (i.e., process flow diagram, fishbone, etc)	☐ May use qualitative or quantitative methods to make observations, make comparisons between groups, or generate hypotheses
	☐ Statistical methods evaluate system level processes and outcomes over time with statistical process control or other methods	☐ Statistical methods primarily compare differences between groups or correlate observed differences with a known health condition
Intended Benefit	☐ Intervention would be considered within the usual clinician-patient therapeutic relationship	☐ Intervention, interaction, or use of identifiable private information occurs outside of the usual clinician-patient therapeutic relationship
	☐ Direct benefit to participants is indicated (e.g., for the decrease in risk by receiving a vaccination or by creating a safer institutional system)	☐ Direct benefit to each individual participant or for the institution is not typically the intent or is not certain
	☐ Potential local institutional benefit is specified (e.g., increased efficiency or decreased cost)	☐ Potential societal benefit in developing new or advancing existing generalizable knowledge

institution, but this result is not typical of research activities. Clinical research is intended to have a more general, societal benefit through the development of new generalizable knowledge.

• ***Risk.*** The potential risks to patients from QI activities typically involve concerns about privacy or the confidentiality of health information. Because QI aims to bridge a gap in local practice, the risk may be considered higher if patients are *not* involved in QI activities. The risks in research may be minimal but can include physical, psychological, emotional, social, legal, or financial risks, as well as risks to patient privacy or the confidentiality of health information. The informed consent process clearly describes these risks to participants who individually and voluntarily decide whether to participate in research.

• ***Applicability of Results.*** QI is intended to produce immediate results that occur throughout the process. The results are used in a cyclical pattern to inform the next QI activity. The extrapolation of results to other settings is possible, but it is not the main intent of the activity. Research results and analysis are unlikely to be immediate; they are most often delayed or periodic. The results are primarily used to inform new investigations, although it is possible that research results can be directly implemented into clinical

Attribute	*Quality Improvement*	*Clinical Research with Human Subjects*
Risk	☐ Risk is to privacy or the confidentiality of health information	☐ Risks may be minimal, but may include physical, psychological, emotional, social, or financial risks, as well as risk to privacy or the confidentiality of health information from participation in the project
	☐ Risk may be described as higher for patients by not participating in this activity	☐ The informed consent process describes the risks to participants, who individually and voluntarily decide whether to participate or an IRB grants an alteration or waiver of the consent process
Applicability of Results	☐ Implementation is immediate so that review of results occurs throughout the process and may be used for next QI activity	☐ Results and analysis may be delayed or periodic throughout the duration of the project, except to protect patient safety. The results will primarily be used to inform further investigations, but may be implemented directly into clinical practice.
	☐ Extrapolation of results to other settings is possible, but not the main intent of the activity	☐ Results are intended to generalize beyond the study population
Sharing & Disseminating	☐ System level outcomes, processes, refinement of the intervention, and the applicability of the intervention in specific settings/contexts may be shared through peer-reviewed publication and presentation outside the institution.	☐ It is expected that results will be published or presented to others through a peer-reviewed process

Interpretation

Any checkmarks (even one) in the "Clinical Research" column indicates that there are components of clinical research in the proposed activity. The IRB or local QI ethics review committee should initiate a discussion with the improver/investigator to clarify the proposal. If an activity such as public health practice, program evaluation, or quality improvement includes a research component, then IRB review should occur under current federal guidance and the policies of many institutions.

Explanation and Elaboration of Terms

1. **Vulnerable population.** Any study population that includes students, employees, children, pregnant women, prisoners, active military personnel, individuals who have impaired decision making capacity, or those who are educationally or economically disadvantaged.
2. **Intent.** The state of the investigator's mind that directs the activity.
3. **Quality improvement.** The combined and unceasing efforts of everyone—health care professionals, patients and their families, researchers, administrators, payers, planners, educators—to make changes that will lead to better patient outcome, better system performance, and better professional development.
4. **Clinical research.** A systematic investigation in a clinical setting designed to develop or contribute to generalizable knowledge (The Common Rule definition of research)

practice. These results are explicitly intended to generalize beyond the study population.

• ***Sharing and Disseminating Results.*** Both QI and research seek to share results with a wide audience. QI work often reveals system–level outcomes or processes in the development of the intervention that can be useful to others both within and outside the organization. The QI intervention's specific characteristics and iterations may be shared through peer–reviewed publication or presentations outside the institution. The SQUIRE publication guidelines explicitly encourage the sharing of QI results.[16] In clinical research, it is expected that results be routinely shared through peer–reviewed literature or presentations at national and international meetings.

The expert panel concluded that this instrument provided a strong foundation to determine whether a proposal was QI or whether it contained elements of clinical research. As described in Figure 1, the proposals that fall in the middle ground are often ambiguous and the most challenging to evaluate. We tested the instrument first on proposals that had previously been submitted to the Dartmouth IRB, and then prospectively on two new proposals.

Testing the Instrument

■ ***Proposals Already Submitted to the Dartmouth IRB.*** A Dartmouth IRB staff member (AEO) and the IRB Director (SMA) identified six proposals that had been submitted and were challenging to classify as clinical research or QI. Three had been submitted as "research," and three had been submitted as "quality improvement." All had required considerable time and energy by IRB staff to classify properly. We reviewed these proposals with the

QI–Research instrument (Figure 2) to determine whether the items in the instrument identified the important components of each proposal needed to classify it as QI or clinical research. The instrument correctly identified (and confirmed) the intent, methods, and intended benefits of each proposal. Several of the proposals (3) were classified as QI, one was program evaluation, and others (2) were classified as clinical research that required IRB review. Importantly, using the instrument did not change any of the prior decisions of the IRB, but it provided clarity in the evaluation, classification, and discussion about each proposal.

■ ***Use with Prospective Proposals.*** The instrument was used prospectively for two proposals submitted to the White River Junction VA Research and Development Review Committee. One proposal was submitted with a stated intent to close a quality gap in the care of patients with rheumatologic disease and to decrease the costs of care. When reviewed with the QI-research instrument, the proposal intended to close a local quality gap by decreasing the number of laboratory tests required by each patient, was focused on making the care better at this one institution, and posed only a risk of privacy violation to patients. Each of these is clearly a component of the QI column in the instrument. The proposal's methods, however, were to compare outcomes associated with specific laboratory tests. While the goal was to decrease necessary testing, the methods included a comparison of groups and generation of new generalizable knowledge. These are components of research, so the proposal was reviewed as a research proposal.

Another proposal intended to use a collaborative breakthrough series (BTS) model to assess patient safety indicators and improve care for patients at multiple facilities. The BTS model employs QI and content experts who facilitate improvement work, often at many sites. The proposal was submitted as QI, but concern arose that it involved multiple sites and that it would collect and compare data from these sites. Upon review with the QI–Research Instrument, the project sought to close a quality gap at individual institutions by applying well–known evidence in each specific setting. The methods were clearly QI and included understanding the local system of care delivery and studying the effect of interventions over time. The intent was to make care safer for patients. The activity would pose no risk to patients. In fact, there was likely higher risk to patients who were *not* receiving the evidence-based intervention. Finally, the intent of the activity was that the results would be used locally, but the system level outcomes and insights that were gained about the processes would be shared within and outside the participating institutions. Combining information from many sites would increase the power of the analysis, but would not constitute research. While this was a large study across many sites, the work was deemed to be QI and was reviewed according to local QI review criteria.

Discussion

QI and research occur along a continuum but contain identifiable elements in the intent, methods, risks, and applicability of results. The instrument we described to distinguish between QI activities and clinical research was developed through expert panel deliberation and has a solid foundation because it is grounded in the criteria for QI activities established by the SQUIRE guidelines.[17] Our pilot work with this instrument demonstrated significant content validity and demonstrated it to be a valuable tool for us. It was capable of clearly differentiating between QI activities and clinical research for proposals previously submitted to the IRB, which showed how an instrument such as this can illuminate the discussion about QI versus research. Prospectively, it provided clarity when reviewing newly-submitted proposals. Additionally, the instrument has received positive feedback from presentations about it at educational workshops in the United States and at international conferences.[18] The instrument is not intended to be an absolute adjudicator about determining whether an activity is QI or research, but offers a step forward for IRBs that face this challenge. We invite others to use the instrument, refine it, and share their experiences.

The vexing issue of distinguishing QI activities from clinical research highlights the need for health care organizations to ensure the ethical integrity of both types of work. Perhaps a thornier issue is how to review and monitor the ethical conduct of QI activities. The ethics of QI work lies at the nexus of clinical, research, and organizational ethics. While there is considerable overlap in the ethical framework of these domains of health care ethics, there has been less focus on the ethical issues related to QI. Lynn and colleague's ethical framework for QI activities is a helpful starting place because it builds on the thinking about research ethics;[19] however, QI work is also linked to clinical and organizational ethics. Regardless of the underlying framework, QI activities must be conducted in an ethical manner. Taylor and colleague's survey of hospitals that participated in the 100,000 Lives Campaign by the Institute for Health Care Improvement showed that many considered their work to be ethical and to pose only minimal risk, but few sites were able to specify exactly how the safety of QI activities were reviewed or monitored.[20] Many would agree that unless they significantly improve their expertise and capacity, IRBs are not the appropriate body to review and monitor QI activities.

Others have recommended local administrative oversight, but this relies on those who might not have ethics or QI expertise and who are already consumed by multiple tasks. The model from Babalis and colleagues of an independent QI ethics committee is appealing and functional, but it requires administrative resources and appropriate expertise.[21] We anticipate that other models will emerge as organizations increase their focus on QI activities.

In the United States and elsewhere, there is tremendous urgency for guidance regarding the ethical conduct of QI activities. The U.S. Affordable Care Act of 2010 includes substantial funding for both QI activities and for comparative effectiveness and translational research. This new wave of QI initiatives and clinical research will likely put additional pressures on IRBs. Clearly understanding the continuum between QI and research and implementing appropriate ethical review of QI will ensure the sound stewardship of limited resources, help to reduce the demand on IRBs, and have the potential to improve the quality of the QI work.

We present this instrument as a starting point since it is based on published QI guidelines and has been pilot tested at our site. In truth, the development and use of checklists rarely results in a single, intractable intervention. We feel that this checklist instrument provides a starting point for IRBs, quality improvement specialists, administrators, and researchers to differentiate between QI and research and recognize when overlap occurs. We recognize that this work is limited because it was completed at one U.S. institution. Ethical review of research is guided by local regulations and policies. More formal testing of the instrument would help refine it. We are aware that many institutions have developed and used similar instruments, but believe that the strength of this one is its foundation in QI publication guidelines.[22]

The structures and procedures of IRBs help to protect human subjects engaged in clinical research. IRB review offers a stable set of criteria for reviewing and monitoring the ethical acceptability of proposed clinical research. As QI activities grow in number, scope, and complexity within organizations, the ethical review and monitoring of QI becomes even more important for the protection of patients, staff, and organizational resources. The instrument we developed to distinguish between QI activities and clinical research offers assistance in realizing one step of that process.

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■ **Greg Ogrinc, MD, MS,** is Senior Scholar, White River Junction VA Quality Scholars Program; Associate Professor of Community and Family Medicine and of Medicine and Director, Office of Health Systems and Clinical Improvement, Geisel School of Medicine at Dartmouth; **William A. Nelson, PhD,** is Associate Professor, Dartmouth Institute for Health Policy and Clinical Practice and Associate Professor, Community and Family Medicine, Geisel School of Medicine at Dartmouth; **Susan M. Adams, BA, JD,** is Director, Committee for the Protection of Human Subjects, Dartmouth College; **Ann E. O'Hara, BS, CIP,** is Human Research Analyst, Committee for the Protection of Human Subjects, Dartmouth College.

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