What is *QA/QI*?

There is no regulatory definition but often QA/QI is described as "systematic, data-guided activities designed to bring about immediate (or nearly immediate) improvements in health care delivery"[1], and the combined efforts of everyone to make changes that will potentially lead to better patient outcomes, better system performance, and better professional development.[2] In medical institutions, QA/QI is a necessary, integral part of hospital operations and is not subject to review as research, as defined under federal regulation. Rather, it is governed by Joint Commission and hospital standards. Human Subject Research (HSR) is governed by federal regulation, under IRB oversight.

What are some differences between QA/QI and Research?

Points to consider	Research	QA/QI
Purpose	To test a hypothesis OR establish clinical practice standards where none are accepted	To assess or promptly improve a process, program, or system; OR improve performance as judged by accepted/established standards
Starting Point	To answer a question or test a hypothesis	To improve performance
Benefits	Designed to contribute to generalizable knowledge and may or may not benefit subjects	Designed to promptly benefit a process, program, or system and may or may not benefit patients
Risks/ Burdens	May place subjects at risk and stated as such	By design, does not increase patient's risk, with exception of possible privacy/confidentiality concerns
Data Collection	Systematic data collection	Systematic data collection
End Point	Answer a research question	Promptly improve a program/process/system
Testing/ Analysis	Statistically prove or disprove a hypothesis	Compare a program/process/system to an established set of standards.

[3]

Activities conducted by one or more institutions whose primary purposes are limited to:

(a) implementing a practice to improve the quality of patient care, and

(b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes

are considered to be quality improvement rather than research. However, if the project involves introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results, that quality improvement project may also constitute human subjects research (HSR) under HHS regulations.

QA/QI generally refers to a range of activities conducted to assess, analyze, critique, and improve current processes of health care delivery in an institutional setting. QA/QI activities are typically observational and unobtrusive and can involve the collection and analysis of data to which investigators have legitimate access through their institutional roles. These activities do not prevent or hinder the delivery of clinically-indicated care to patients, nor do they impose more than minimal additional risks or burdens on patients.[4]

What are some examples of QA/QI?

- ensuring new evidence-based interventions are incorporated into practice
- improvement of over-all quality of life
- reduction of morbidity and mortality
- ensuring that patients receive evidence-based interventions for their particular illness
- improvement in patient and family comprehension
- reduction in in-patient admissions and length of stay
- reduction of ER visits
- reduction in costs of service
- evaluating procedures no greater than minimal risk to patients,
- usual care practices, and
- interventions offered to all patients.[5]

Quality Assessment and Improvement consist of systematic, data-guided activities to bring about prompt positive changes in the delivery of health care and involve deliberate actions to improve care. Depending on the activity, QA/QI can look like practical problem solving, an evidence-based management style or the application of a theory-driven science of how to bring about system change. Introducing QA/QI methods often means encouraging people in the clinical care setting to use their daily experience to identify ways to improve care, implement changes on a small scale, collect data on the effects of those changes, and assess the results.[6]

What is a Learning Health Care System?

Traditional definitions are becoming more and more blurred as a new model of health care is emerging in which practice and learning are integrated, and where a central goal of the health care system is to collect, aggregate, analyze and learn from patient-level data (learning health care systems).[7] This paradigm suggests that a learning health care system is a natural outgrowth and product of health care delivery, and need not be subject to oversight by the IRB in many instances.

In contrast, what is HSR?

The Office of Human Research Protections (OHRP) defines ***research*** as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)). For example, if a project is designed to test a novel hypothesis, replicate another researcher's original study, or withhold any aspect of conventional care shown to be beneficial in prior studies, OHRP's definition of human subject research would apply.

The FDA does not use the term research, but considers it to be synonymous with ***clinical investigations***, meaning any experiment that involves a test article and one or more persons (21 CFR 56.102(23)(c)). For example, if you are comparing the safety and/or effectiveness of a drug, or comparing a regulated device to another, you are engaged in a clinical investigation and must follow FDA regulations.

Can a project be both QA/QI and HSR?

Yes. The following characteristics **make it more likely** that a project involves both QA/QI and research and would fall under the jurisdiction of both the Hospital and IRB. Consult with the IRB if you are uncertain.

- Randomization of patients into different intervention groups in order to enhance confidence in differences that might be obscured by nonrandom selection (but not to achieve equitable allocation of a scarce resource).
- Testing issues that are beyond current science and experience, such as new treatments.

- The involvement in key project roles of researchers who have no ongoing commitment to improvement of the local care situation.
- Delayed or ineffective feedback of data, especially if feedback is delayed or altered in order to avoid biasing the interpretation of results.
- Funding from an outside research organization with an interest in the use of the results.[8]

If a study includes randomization, is it always considered HSR?

No. An example of a QA/QI study that involved medication compliance included the randomization of patients to one of three arms:

- in one arm patients were given a cell phone and a reminder call when it was time to take their medication.
- patients in a second arm were given a reminder call but no cell phone.
- patients in a third arm took their medication while being directly observed by staff (direct observation therapy--DOT).

Is it research if I intend to publish?

The intent to publish is an 'insufficient criterion' for determining whether a quality improvement activity involves research, according to OHRP.

When QA/QI is published or presented, the intent is usually to discuss potentially effective models, strategies, assessment tools or to provide benchmarks, rather than to develop or contribute to 'generalizable' knowledge.[9]

What if I am getting funding for my project?

Outside external funding may make a difference in distinguishing between QA/QI and research. An NIH research grant to support a project would often be considered research. Internal funding to improve a program may not.

What if I need to access PHI?

HIPAA makes an exception for QA/QI activities, including outcomes evaluation and development of clinical guidelines or protocols. These activities fall under the category of 'health care operations' for which no HIPAA Authorization or Waiver of Authorization needs to be sought. The hospital's Privacy Office can authorize the use of PHI for QA/QI projects.

What if I still don't know if I need IRB review?

Submit an application for Determination of Human Subject Research and/or contact irbeducation@lists.stanford.edu if you are still uncertain how to proceed.

Click for Resources and References.

Resources and References

[1] Lynn J, et al. *The ethics of using quality improvement methods in health care.* Ann Intern Med 2007:146:666-674

[2] Lo B, Field MJ, eds. *Conflict of Interest in Medical Research, Education*, and Practice, National Academies Press, 2009. http://www.nap.edu/catalog.php?record_id=12598, p. 29.

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[4] Carillion Clinic Institutional Review Board, *Application to Determine if Project is Quality Assurance/Quality Improvement*, August 2012, Roanoke VA

[5] Dubler N, *A Process of Quality Improvement: Informed Participation and Institutional Process*, from a lecture given at Yale University 10/23/2008, Montefiore-Einstein Center for Bioethics, The Albert Einstein College of Medicine

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[7] Kass N, Faden R, et al. "The Research-Treatment Distinction: A Problematic Approach for Determining Which Activities Should Have Ethical Oversight," *Ethical Oversight of Learning Health Care Systems, Hastings Center Report Special Report 43*, no 1 (2013): S4-S15. DOI: 10.1002/hast.133, http://onlinelibrary.wiley.com/doi/10.1002/hast.132/pdf

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[9] *Quality Improvement FAQs* from OHRP Guidance: http://answers.hhs.gov/ohrp/categories/1569