Quality vs Research

Modified: October 2019

Background:

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.

1. What is QIPR and what approval is needed in order to conduct a QA/QI project?

All Quality projects conducted at UFHealth at both the Gainesville and Jacksonville campuses should be registered within the software program called QIPR at https://qipr.ese.ufhealth.org/ The purpose of QIPR is to inform the UFHealth Quality Department of all “Quality” project being conducted within UFHealth and to help match faculty, staff and students with others who may be involved in similar projects. When you project is properly registered, you will receive a “Registration Certificate” which provides certain requirements you must follow when conducting your quality project.

2. Does QIPR help determine if a project is Quality Only or also involves Human Subjects Research (HSR)?

Yes. Near the end of the QIPR submission, there are 6 questions that will help determine if your project might need IRB approval. Once answered accurately, if you do not receive you “Quality” registration certificate, the system will have determined that your project might require IRB approval.

3. What should be done if QIPR indicates a project might require IRB approval?

At this point you have 3 options:
   a. Submit the protocol to the IRB in the normal process
   b. If you still believe it is a “Quality Only” project, complete the QA vs Research form found on the IRB website and email it to Dr. Iafrate iafrate@ufl.edu for a decision.
   c. Change your project so that it will become a Quality Only project

4. What are some differences between QA/QI and Research?

<table>
<thead>
<tr>
<th>Points to consider</th>
<th>Research</th>
<th>QA/QI</th>
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</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>To test a hypothesis OR establish clinical practice standards where none are accepted</td>
<td>To assess or promptly improve a process, program, or system; OR improve performance as judged by accepted/established standards</td>
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<tr>
<td><strong>Starting Point</strong></td>
<td>To answer a question or test a hypothesis</td>
<td>To improve performance</td>
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<tr>
<td><strong>Design</strong></td>
<td>Typically a fixed protocol with fixed interventions that are not revised as data is collected.</td>
<td>Typically interventions are adjusted based on data collected if quality goal is not being attained.</td>
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<tr>
<td><strong>Benefits</strong></td>
<td>Designed to contribute to generalizable knowledge and may or may not benefit subjects</td>
<td>Designed to promptly benefit a process, program, or system and may or may not benefit patients</td>
</tr>
<tr>
<td><strong>Risks/Burdens</strong></td>
<td>May place subjects at risk and stated as such</td>
<td>By design, does not increase patient’s risk, with exception of possible privacy/confidentiality concerns</td>
</tr>
<tr>
<td><strong>Data Collection</strong></td>
<td>Systematic data collection</td>
<td>Systematic data collection</td>
</tr>
<tr>
<td><strong>End Point</strong></td>
<td>Answer a research question</td>
<td>Promptly improve a program/process/system, typically has a quality goal to measure improvement.</td>
</tr>
<tr>
<td><strong>Testing/Analysis</strong></td>
<td>Statistically prove or disprove a hypothesis</td>
<td>Compare a program/process/system to an established set of standards.</td>
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Activities conducted by one or more institutions whose primary purposes are limited to:

- implementing a practice to improve the quality of patient care, and
- 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.

**5. What are some examples of QA/QI?**

- a) ensuring new evidence-based interventions are incorporated into practice
- b) improvement of over-all quality of life
- c) reduction of morbidity and mortality
- d) ensuring that patients receive evidence-based interventions for their particular illness
- e) improvement in patient and family comprehension
- f) reduction in in-patient admissions and length of stay
- g) reduction of ER visits
- h) reduction in costs of service
- i) evaluating procedures, no greater than minimal risk to patients
- j) usual care practices, and interventions offered to all patients.
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

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.

7. In contrast, what is Human Research Protection (HRP)?

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.

8. 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\University 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.
9. If a project includes randomization, is it always considered HSR?

Not always, but it usually is. An example of a QA/QI project that involved medication compliance included the randomization of patients to one of three arms provided all arms are currently in use, and the risk to patients is minimal:
- 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).

Information obtained is feedback to the process to improve compliance.

10. Is it research if there is an intent to publish?

No. 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.

11. Q: What should you do if the journal requires IRB approval before accepting the publication?

Some journals now require a letter, or other acknowledgement, from an IRB prior to publication of a quality project. Specifically, they wish to know whether IRB approval was obtained or was not required for the described project.

If this should occur, please contact the IRB chairperson; send a copy of the proposed publication to the IRB chairperson. Provided the publication meets the guidelines presented here, the IRB chairperson will provide you with a letter acknowledging that the IRB is aware of the publication, and that it meets the IRBs guidelines as a quality project. You can then provide this letter to the requesting journal.

12. What if the project is funded?

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.

13. What if there is a 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.

14. What if I still don’t know if I need IRB review?

Contact the IRB at 352-273-9600.
Resources and References

4 Carillion Clinic Institutional Review Board, *Application to Determine if Project is Quality Assurance/Quality Improvement*, August 2012, Roanoke VA
9 *Quality Improvement FAQs* from OHRP Guidance: http://answers.hhs.gov/ohrp/categories/1569