Performance Improvement/Research Advisory Panel: A Model for Determining Whether a Project Is a Performance or Quality Improvement Activity or Research

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ABSTRACT The determination of whether an activity is performance improvement governed by The Joint Commission standards and local hospital policy or research governed by federal regulation and requiring institutional review board (IRB) review and approval can be complex, especially in academic clinical organizations. Both processes can address scientific validity, fair participant selection, favorable risk–benefit ratio, respect for participants, and independent review. In an attempt to guide staff as to whether their project needs IRB review or not, a performance improvement/research advisory panel (PIRAP) was formed to serve two military organizations. In this article, performance improvement and quality improvement is differentiated from research as much as possible, the composition and function of PIRAP is described, and guidelines for publishing findings that support the nature of the project are provided.

INTRODUCTION

The regulatory oversight of research in a clinical environment is growing increasingly complex. Part of this complexity is related to an increasing number of activities or projects that fall into uncertain or overlapping territory between being a performance improvement (PI) or quality improvement (QI) and clinical research. Identifying the difference and categorizing an activity as PI/QI or clinical research is critical in establishing what, if any, federal regulations for conducting human subjects research apply. Incorrectly identifying an activity as research puts unnecessary additional burdens on both the project staff and the institutional review boards (IRBs). Misclassifying a clinical research study as a PI/QI activity may inadvertently expose participants to risk and violate federal regulations protecting human research subjects.

To provide guidance in these areas, the U.S. Army Institute of Surgical Research (USAISR) and Brooke Army Medical Center (BAMC) Department of Clinical Investigation have developed a performance improvement/research advisory panel (PIRAP) for reviewing proposed activities and providing consultation as to whether an activity is a PI/QI initiative or clinical research. In this article, we differentiate, as much as possible, PI/QI from research, describe the composition and function of PIRAP, and provide guidelines for publishing findings of PI/QI activities.

The PI/QI Versus Research Debate

PI/QI and research are easily confused because they share similar characteristics. Both ask clinically relevant and important questions of social or scientific value. Both aim for scientific validity, fair participant selection, favorable risk–benefit ratio, respect for participants, and independent review.[1] Definitions for PI/QI and research are numerous, broad, and not mutually exclusive. The purpose of PI/QI is to determine quality, improve patient services, and/or improve the provision of medical care usually within a specific unit, service, or institution. PI/QI can be defined as "the systematic, data-guided activities designed to bring about immediate improvements in the health care delivery" within the standard of care at the institution.[1] PI is a Joint Commission standard.[2] Standard PI1.10 states "the hospital collects data to monitor performance," specifically "to monitor the stability of existing processes, identify opportunities for improvement, identify changes that lead to improvement, or sustained improvement.[2] There is no formal review or concurrence for a PI project before the collection of data; initiatives are expected to be conducted and actions taken based upon the PI project findings. In contrast, research is defined by the Common Rule [46 CFR 102(d)] to be "a systematic investigation, including research development, testing

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The views of these authors are their own and do not purport to reflect the position of the Army Medical Department, Department of the Army, or the Department of Defense.

Report Documentation Page

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
01 APR 2010	**N/A**	**-**

4. TITLE AND SUBTITLE	5a. CONTRACT NUMBER
Performance Improvement/Research Advisory Panel: a model for determining whether a project is a performance or quality improvement activity or research	5b. GRANT NUMBER
	5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S) **Platteborze L. S., Young-McCaughan S., King-Letzkus I., McClinton A., Halliday A., Jefferson T. C.,**	5d. PROJECT NUMBER
	5e. TASK NUMBER
	5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) **United States Army Institute of Surgical Research, JBSA Fort Sam Houston, TX 78234**	8. PERFORMING ORGANIZATION REPORT NUMBER
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)	10. SPONSOR/MONITOR'S ACRONYM(S)
	11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release, distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			
unclassified	**unclassified**	**unclassified**	**UU**	**4**	

and evaluation, designed to develop or contribute to generalizable knowledge." Review and approval of a research project by an institutional review board operating under the auspices of an assurance is a highly structured process mandated by federal regulations.

Although PI/QI projects do not require IRB review,[3] most IRBs will not make a determination about a specific project unless a protocol is submitted. Even if a protocol is submitted, PI/QI is not a category "exempt from research" in 45 CFR 46 or 32 CFR 219, leaving both the person desiring to conduct a PI/QI project and the IRB in a quandary.

Although often used as a discriminator, intent to publish does not determine whether an activity is research or not. This misconception leads to a desire by staff conducting PI/QI projects for IRB review and approval. Further complicating the determination of projects as PI/QI or research is the understandable fear that journals will not publish manuscripts describing PI/QI projects involving human subjects without IRB approval. In an effort to assist staff, IRBs may agree to conduct a review, unnecessarily increasing the burden of the board for oversight of projects for which they actually have no regulatory authority.

The PI/QI research debate was heightened recently with the publication of the findings from a project designed to reduce infection in central lines.[4] Finding that the use of a 5-item checklist when inserting central lines decreased the infection rate at Johns Hopkins Hospital from 10% to 0%, the same checklist was introduced into 103 intensive care units in 51 Michigan hospitals. The 5-item checklist called for checking to be sure that providers (1) washed their hands; (2) cleaned the skin; (3) used sterile drapes; (4) wore a sterile mask, hat, gown, and gloves; and (5) used a sterile dressing over the catheter site. After the findings of the Michigan experience were published in the prestigious *New England Journal of Medicine*, the Department of Health and Human Service (HSS) Office of Human Research Protection (OHRP) determined that federal regulations for informed consent in the conduct of the project had been violated,[5] adding even more confusion to the differentiation of PI/QI from research.

Formation of the PIRAP

In response to the increasingly confusing differentiation of QI/PI projects from research, the USAISR and BAMC Department of Clinical Investigation formed the Performance Improvement/Research Advisory Panel (PIRAP) to review proposed activities and provide consultation as to whether an activity is a PI/QI initiative or clinical research. The purpose of PIRAP is to provide a determination, upon request, of whether a proposal is PI/QI or research. Currently, consultation from the PIRAP is voluntary within our institutes.

PIRAP Composition

PIRAP membership is interdisciplinary so that the panel will have sufficient understanding of standard of care practices, quality assurance, and/or clinical research regulations to adequately evaluate all pertinent information and make an informed decision. Membership includes a chair, three Research Compliance and Quality Management/Assurance personnel, and a clinical researcher knowledgeable in the area of the activity. Both institutions that submit requests for determination to the PIRAP (i.e., BAMC and USAISR) are represented on the PIRAP, and at least one member of the panel is also a member of the IRB. The BAMC IRB serves as the IRB for both BAMC and USAISR.

Determination Process

Staff desiring a determination from PIRAP completes a one-page form briefly addressing the following:

- — description of project including purpose of the activity and procedures,
- — description of how information will be obtained/collected,
- — explanation of long term goal of project, and
- — indication of risk to patients.

The form is submitted electronically to the PIRAP chair. The chair electronically disseminates the request to the panel members within 1 week of receiving the request. Panel members may discuss and vote on the proposal via e-mail or, when a more in-depth discussion is warranted, by in-person meeting. A minimum of three panel members review and vote on requests. The goal is to provide a written determination to the requestor within 3 weeks of submission.

On the basis of a review of the literature and the panel's written standard operating procedure, the PIRAP considers factors when determining a project or activity to be PI or research (see Table I).

There are three types of determinations made by the panel:

- — The activity as described is a PI/QI project. Submission of an IRB application is not required.

TABLE I. Indicators That Help Determine Whether a Project is PI/QI or Research

Indicators That a Project Is PI/QI Include the Following:
Evaluates procedures that are no greater than minimal risk to patients.
Includes only usual care practices.
Allows for ongoing modification of the project.
Generally involves personnel working at the local institution.
Indicators That a Project Is Research and Should Be Reviewed by the IRB Include the Following:
Testing of issues that go beyond current knowledge based on science and experience, such as new treatment.
Random allocation of patients into different intervention groups to enhance confidence in differences that might be obscured by nonrandom selection.
Deliberate delay of feedback of data from monitoring the implementation of changes to avoid biasing the interpretation of data.
Funding external to the clinical setting or organization.

— The activity as described is not exclusively a PI project. Submission of an IRB application is recommended before conducting the activity.
— A determination cannot be made on the basis of the information provided. Specific additional information is requested.

The requestor may appeal a determination in writing to the PIRAP chair and the appeal will be reviewed and discussed by the panel. A final determination is then made and provided to the requestor in writing.

Experience over the First Year

Although some staff feared that the PIRAP would be overwhelmed with workload, this has not been the case. In the first year of operation, the PIRAP reviewed 11 requests. Of these, 2 required additional information for a determination to be made. Six were determined to be a PI/QI project and 5 were determined to require IRB submission. One example of a project that was determined to be a PI/QI project was submitted by the Physical Therapy Service. The staff proposed to record the amount of time it takes staff working in the burn rehabilitation clinic to perform various types of treatments. The information was going to be used to determine the staff needed to conduct a comprehensive rehabilitation program for severely burned patients at the USAISR.

Publication of PI/QI Activities

Regardless of whether a project is a PI/QI activity or research, dissemination of findings to the larger medical community is important. In the environment where journals may require documentation of IRB review and approval before publishing research findings, we now have a process to provide staff documentation from an impartial panel to provide to a journal that an activity was determined to be PI/QI.

It is important that PI and QI projects be described appropriately in publications. For projects determined to be PI or QI by the PIRAP, requestors are provided additional guidance on how to report and describe these projects in the literature. See Table II.

TABLE II. Headings Suggested for Use in Manuscripts Describing Research Findings as Compared with Headings Suggested for Use in Manuscripts Describing PI/QI Projects or Activities

Research	QI/PI Activities
Research Questions	Issue
Review of Literature	Imperative for Project
Methods	Procedures for Collecting and Evaluating Data
Results	Information Found
Study Limitations	Lessons Learned

CONCLUSIONS

Increasingly, the boundaries between research and PI/QI projects are not clear due to numerous shared characteristics. The PIRAP was established at our clinical facilities as a resource to help define the boundaries for activities and projects falling into uncertain territory. PIRAP provides a mechanism for determining a project's status as PI/QI or research proactively working to consider and document the rights and privacy of our patients as well as of our providers and administrators caring for our beneficiaries.

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