Quality-Assurance Research: Studying Processes of Care

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To conduct a successful research study, several criteria must be satisfied: the research question must be important (not only to the investigators but to clinicians and managers in other institutions); the research question must be answerable with the available resources; the investigators must be motivated and capable; and the research setting must be appropriate for the study (the institution must have a supportive culture and analytical resources, and the local institutional review board must approve the proposed study). Quality-assurance (QA) research poses some special challenges and requirements. First, although QA studies should be hypothesis-driven, they are usually before-and-after studies, rather than randomized controlled trials. Second, in before-and-after studies the investigators must address and minimize several possible sources of bias that could confound the results. For example, the compared groups must be similar in important features that could affect development of the outcome(s) of interest, and clinical practices other than the practice change that is being tested during the study must be shown not to independently affect the outcome(s) of interest. We discuss several examples of QA studies, and we offer a checklist for the process of considering, designing, executing, presenting, and publishing a QA study. *Key words: research, quality assurance, research methodology, publishing, study design, institutional review board.* [Respir Care 2004;49(10):1175–1180.

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Introduction

Because delivering respiratory care services frequently requires adjusting processes and changing implementation strategies to achieve optimal care, research is needed on how care is delivered. Implicit in any measurement activity or effort to optimize care is the idea that a change can effect benefit and that the new process can be compared with the current process. A quality assurance (QA) program requires research to understand and improve practice.

In this article, I review the elements of a successful QA research study, emphasizing the differences between QA studies and other types of research. I then discuss examples of QA research from experience in The Cleveland Clinic Foundation's Section of Respiratory Therapy, discuss the types of questions that can be addressed with QA research,[1–4] and close with a checklist for QA research.

Criteria for a Quality-Assurance Study

Successful conduct of a research study, including one undertaken for QA, requires the satisfaction of several criteria regarding the type of question being addressed, the characteristics of the setting in which the research is being done, and the qualities of the investigators. I will first review these criteria and then discuss several special considerations that distinguish QA research from other types of research.

I propose 6 criteria for beginning a research project, of which the first 3 relate to the study question:

1. The clinical issue is important; that is, current clinical processes have shortcomings with regard to outcomes that matter to patients and/or providers, and/or proposed new clinical processes promise substantial and important improvements.

2. Assuming the research is conducted with the intent to publish the findings, the study question should have generalizable interest and value; that is, the study question also affects practice in other institutions and matters to others.

3. There is reasonable likelihood that the study question can be answered; that is, the study's design and methods, and the resources available for the study will permit a firm answer to the research question.

The remaining 3 criteria relate to the research setting, the investigators, and the ideal conditions for undertaking research.

4. There is interest in and support for research; that is, the "culture" of the institution supports the value of asking and answering questions and has respect for the power of data.

5. There is the necessary infrastructure for conducting the research. The investigators must have the appropriate resources to collect accurate, reproducible data that will answer the research question. Research proposals must win the approval of the institution's institutional review board, and in almost all cases the institutional review board will require written, informed consent from the research subjects. Fortunately, in this era of freestanding institutional review boards and widespread availability of computers, personal digital assistants, and statistical software, these conditions are satisfied in most situations.

6. Finally, the investigators must be committed and capable. Specifically, they must be motivated to answer the research question and they must regard the question as worthwhile to pursue. The investigators must possess the necessary time, energy, knowledge, and skills to conduct the study and analyze the results. The successful investigator will also have the resourcefulness to identify colleagues who can help with research activities in which the investigator is less skilled or knowledgeable. An investigator who has less research experience should have a highly-experienced advisor or mentor who can help guide the research and the presentation of the results.

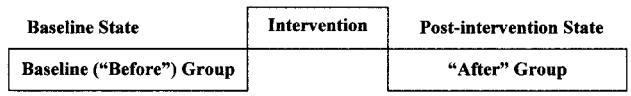

Fig. 1. Design of an observational, before-and-after study. A group of patients is evaluated at baseline, after which a new clinical process (intervention) is implemented. In the "after" arm of the study, a group (possibly the same patients as the baseline group) is evaluated with regard to the outcome of interest. Assuming no bias (see text), the differences between the "before" and "after" groups can be ascribed to the intervention; hence, this is considered a cause-and-effect study.

In considering factors that make QA research possible, note that there are special conditions that distinguish QA research from other types of cause-and-effect studies (ie, studies that ascribe an outcome to the practice change being tested). First, although QA research may be hypothesis-driven and may involve studying a new clinical process or intervention, the QA studies are often *observational*, with a before-and-after format. That is, as shown in Figure 1, the assignment of a patient to one clinical process or another is by usual clinical practice rather than by randomization, and QA studies often involve assessing a baseline period during which one process or practice is in place (the "pre-intervention" or "before" period), followed by implementing a process change and then assessing the impact of the new process (the "post-intervention" or "after" period). In a randomized controlled trial, patients are randomly assigned to either receive or not receive the study intervention (ie, the clinical process being tested); this lessens the chance that a baseline difference between the compared groups will affect the likelihood that the patient will develop the outcome of interest. Also, in a

randomized controlled trial the compared groups (treatment group and control group) are studied concurrently. In contrast, studies that have a before-and-after design are prone to 2 sources of bias that can threaten the validity of the study:[5]

1. If the "before" and "after" groups are dissimilar in a way that affects the likelihood of a patient developing the outcome of interest, then the differences in the outcome of interest between the groups cannot be reliably ascribed to the intervention. This is called "susceptibility bias."[5]

2. Over the course of a before-and-after study, if the patients or clinical processes change in ways that affect the likelihood of a patient developing the outcome of interest, then it may be impossible to reliably ascribe differences between the groups to the intervention (rather than to those evolving conditions). Feinstein called this "performance bias."[5]

Investigators planning QA research should assure that the aforementioned criteria are satisfied and that the possible effects of susceptibility bias and performance bias are minimized.[5]

Types of Questions That Can Be Addressed With Quality-Assurance Research

In theory, any clinical practice is amenable to QA study, but depending on the degree to which the aforementioned study criteria are satisfied, some questions are more amenable than others to QA research. The QA questions that best merit study are those that have the biggest impact on improving or optimizing care and those that address the biggest challenges to offering optimal care in a specific setting.

My objective in this article is to provide insight into the climate and context in which QA research can best be done and to identify some subtle aspects that encourage or constrain QA research. I shall limit this discussion to examples of QA research we have conducted in the Section of Respiratory Care at The Cleveland Clinic Foundation. The QA studies I will discuss asked the following questions:

1. What is the frequency of misallocation of respiratory care services?[1]
2. What is the rate of employee turnover among respiratory therapists, and what are the correlates of better employee-retention?[2]
3. How has the scope of respiratory care practice changed?[3]
4. Do respiratory care protocols improve allocation of respiratory care services?[4]
5. How frequently do respiratory therapists use "unpaid time off," and would revising the priority system for vacation affect the use of unpaid time off?

I will briefly describe the conditions and context that prompted the study question and then summarize our findings and the impact of the results on respiratory care practice at The Cleveland Clinic Foundation (Table 1). I will discuss how the aforementioned study criteria were met and hope these examples will prompt similar QA research at other institutions.

Examples of Quality-Assurance Research From The Cleveland Clinic Foundation

Allocation of Respiratory Care Services

The first example study[1] was a retrospective study undertaken to assess the amount of misallocation of respiratory care services (ie, providing treatments to patients who did not need or were unlikely to benefit from those treatments, or failing to provide treatments to patients who did need them) at The Cleveland Clinic Foundation. We found that 25% of the respiratory care orders we assessed (using lenient criteria) were not justified, and that 11% of patients did not receive respiratory care services they should have received. That misallocation of respiratory care services was important in the context that the demand for respiratory care services was increasing, so we designed a Respiratory Therapy Consult Service that involved respiratory-therapist-driven, algorithm-based respiratory care plans. The study satisfied the criteria for undertaking research: the issue was important to our institution, it had generalizable importance to other institutions, the question was answerable, and the question had the interest of investigators who were engaged in a setting conducive to research.

Employee Turnover Among Respiratory Therapists

The second example study[2] concerned the rate of employee turnover among respiratory therapists. This study was prompted by discussions with respiratory therapy colleagues at the various hospitals within The Cleveland Clinic Health System as we collectively evaluated the employee-turnover rates at our respective hospitals and considered what factors contribute to employee turnover. Our main findings were that there were substantial differences in employee-turnover rate among our hospitals and that the employee-turnover rate correlated with ratio of the number of hospital beds to the number of staff therapists. In the context that "inquiry is intervention," this study prompted greater focus on therapist retention throughout system hospitals. The criteria allowing a research study were satisfied: namely, the issue was important, had generalizable interest, and was conducted by investigators who were interested in the results (because they were stakeholders), in a setting conducive to research.

Table 1. Summary of Findings and Impact of Selected Quality-Assurance Studies at The Cleveland Clinic Foundation

Study	Quality-Assurance Research Question(s)	Main Findings	Impact on Practice
Kester L, Stoller JK. Ordering respiratory care services for hospitalized patients: Practices of over- and under-use. Cleve Clin J Med 1992;59:581–585[1]	What is the frequency of misallocation of respiratory care services at The Cleveland Clinic Foundation?	Misallocation occurred moderately frequently, including both over- and under-ordering.	Prompted development and study of our Respiratory Therapy Consult Service
Stoller JK, Orens DK, Kester L. The impact of turnover among respiratory care practitioners in a healthcare system: Frequency and associated costs. Respir Care 2001;46:238–242[2]	What is the frequency of employee turnover among respiratory therapists in the 9 Cleveland Clinic Health System hospitals, and does the ratio of therapists to hospital beds relate to turnover?	1. The turnover rate differed greatly among the 9 CCHS hospitals. 2. The turnover rate correlated with the ratio of hospital beds to therapists on staff: the higher the ratio of beds to therapists, the greater the turnover rate.	1. Helped to highlight the importance of turnover among therapists 2. Provided benchmark values for turnover rates in the Cleveland Clinic Health System hospitals
Stoller JK, Orens D, Ahmad M. Changing patterns of respiratory care service use in the era of respiratory care protocols: An observational study. Respir Care 1998;43: 637–642[3]	How has the pattern of respiratory care services delivery changed over time?	The severity of disease and the volume of respiratory therapies delivered has increased, but the number of respiratory care treatments per patient has decreased, possibly because our Respiratory Therapy Consult Service improved allocation of respiratory care services.	Allowed better planning regarding equipment and staffing needs, to meet the changing requirements for respiratory care services
Stoller JK, Mascha EJ, Kester L, Haney D. Randomized trial of physician- vs respiratory therapy consult-directed respiratory care. Am J Respir Crit Care Med 1998;158:1068–1075[4] (a randomized controlled, clinical trial)	Is The Cleveland Clinic Foundation's Respiratory Therapy Consult Service effective in improving the allocation of respiratory care services?	Our Respiratory Therapy Consult Service improved the allocation of respiratory care services, with no adverse clinical effects and with a trend toward lower costs.	Evidenced the efficacy of respiratory care protocols, which supported adopting the Respiratory Therapy Consult Service as the usual strategy for delivering respiratory care to most patients
Stoller JK et al. (research underway)	How frequently do respiratory therapists claim "unpaid time off," and does a new policy that ties the amount of unpaid time off to vacation preference favorably affect the use of unpaid time off?	Preliminary findings show that the current use of unpaid time off amounts to approximately 1.5 full-time equivalents.	1. The preliminary data shows that unpaid time off poses a substantial challenge to maintaining consistent staffing, especially when demand for respiratory services is high. 2. If the vacation priority system favorably affects use of unpaid time off, it will be adopted and offer a valuable example for other departments.

Changes in the Pattern of Respiratory Care Services

The third example study[3] concerned the changing pattern of respiratory care services delivered at The Cleveland Clinic Foundation.[3] This issue is important because staffing needs are closely related to the demand for services, and the issue is important in every respiratory care department.

Respiratory Therapy Consult Service

The fourth example study[4] addressed whether our Respiratory Therapy Consult Service enhanced the allocation of respiratory care services. This study differed from the abovementioned studies in that it was a randomized controlled clinical trial rather than an observational study, and

thus it "stretches the definition" of QA research. However, in this study the control group received the usual care (ie, physician-directed care, as opposed to the protocol-guided care that was the subject of the study), so the study was a QA activity. Also, the study question arose from the study on misallocation of respiratory care services,[1] so the fourth example study was actually completion of a line of inquiry that began with a QA question about practice shortcomings. As part of our commitment to quality improvement, analysis of those shortcomings led to a proposed solution that we rigorously tested with a randomized controlled trial of the intervention (ie, the Respiratory Therapy Consult Service).

Use of "Unpaid Time Off" by Respiratory Therapists

The final example is a study currently underway. We are conducting an observational, cause-and-effect study with a before-and-after design regarding the use of "unpaid time off" by respiratory therapists. We have found that frequent use of unpaid time off is an important problem because it poses a substantial challenge to maintaining consistent staffing, especially when the demand for respiratory care services is high. We have implemented an intervention aimed at decreasing the use of unpaid time off by tying the employee's vacation priority to the amount of unpaid time off the employee uses. Like the randomized controlled design of the fourth example study,[4] this cause-and-effect study examines the impact of an intervention that is designed to improve an outcome, but this is a before-and-after study: a problem is identified, an intervention is designed and implemented, and the impact of the intervention is assessed. Like the other example studies, this study satisfies the criteria of importance, generalizability, motivated investigators, and conducive setting.

A Proposed Checklist for Undertaking Research Regarding Quality Assurance

Based on the above discussion of 1 randomized controlled QA study and 4 observational QA studies, I propose the following checklist of 16 items to address in considering, designing, executing, presenting, and publishing a QA study.

Considering Whether to Undertake the Study

In considering whether to undertake the study, ask:

1. Is the issue important?
2. Do other hospitals or services also experience this issue, will the findings help others, and will others be interested in the study?
3. Is your setting conducive to the research?
4. Are you and your co-investigators committed to the study and capable of conducting it?

Planning the Study

In planning the study, the investigators must assure that the study design and methods make it likely that the question will be answered. Specifically,

5. Has the primary outcome to be measured been determined and can it be measured well?
6. Are those conducting the research well trained in the study methods?
7. Can enough participants be assembled to permit a suitable analysis of the results?
8. Has the study been reviewed and approved by an appropriate review body (usually the hospital's institutional review board)?
9. Has attention been given to potential sources of bias that may threaten the validity of the study, especially if it is a before-and-after observational study?

Conducting the Study

During the study the investigators must assure that it is being performed as designed, by asking:

10. Is recruitment of patients going as planned? For example, if the design calls for recruiting consecutive patients (which lessens the chances of bias from selection of study participants), are consecutive patients being recruited?
11. If the study involves an intervention, is the intervention being implemented exactly per the study design?
12. Is the measurement of outcomes unbiased? Specifically, if the investigators are not blinded to which intervention study participants receive, there is the possibility that the investigators (who may have a bias for or against the intervention) will be biased in measuring outcomes, usually in favor of the intervention. That risk is inherent in a before-and-after study because it is not possible to blind the investigators; this is called "detection bias."[5] Investigators must guard against detection bias as much as possible.
13. Are patients being lost to follow-up differently in the control group than in the treatment group, and is the reason for patient drop-out tied to the development of the outcome of interest? When patients in compared groups are lost to follow-up, there is the possibility of "transfer bias,"[5] meaning that the drop-out will bias the results because the reason for drop-out relates to whether the participant experiences benefit from the intervention. For example, in a placebo-controlled trial of corticosteroids for stable chronic obstructive pulmonary disease, the patients who benefit from the corticosteroids might drop out because they now feel better and thus have less motivation to

come back for follow-up. That differential loss of responders could cause the investigators to underestimate the benefit of steroids for chronic obstructive pulmonary disease. Thus, when patients drop out from follow-up, it is important to determine whether those lost to follow-up resemble those who remain in the study and that there was no evident bias favoring drop-out.

Presenting and Publishing the Study

After the study is completed, the investigators will consider presenting the results to hospital or institutional decision-makers and to the respiratory care community, especially if the results are potentially important to other institutions. The investigators may prepare an abstract, a poster, a lecture, and/or submit a report to a medical journal. In preparing reports for publication the investigator should:

14. Decide which publication is most suitable for this report; the objective is to bring the results to the most appropriate and widest audience. For QA research in respiratory care, the investigators should consider submitting the report to RESPIRATORY CARE, which has a large and diverse readership of clinicians, and is indexed in PubMed. Other journals that address the respiratory/critical care community include *The American Journal of Respiratory and Critical Care Medicine*, *Chest*, *The European Respiratory Journal*, and *Thorax*. Reports primarily concerned with health care management may be appropriate for *The Journal of Healthcare Quality*, or *Medical Care*, or *Health Affairs*. If you believe your results are very important and would be of interest to a wide medical audience, you could submit to *JAMA*, *The New England Journal of Medicine*, *Annals of Internal Medicine*, or *The American Journal of Medicine*, but those journals' rejection rates are very high.

15. Prepare the report in the format designated by the target journal. Carefully read and strictly follow the journal's rules for preparing the manuscript and its references, figures, tables, appendixes, and submission form.

16. Persist in pursuing publication. If your report is rejected without receiving peer-review by the first journal to which you submit it (a very common occurrence), carefully review your report in light of any comments the journal's editor gave. Did you submit the report to the wrong journal? If so, reconsider where to submit the report. Identify and address the shortcomings that caused the rejection. Carefully reconsider your data and conclusions, and aggressively edit your report before submitting it to another journal. If your report is accepted for peer review, diligently, thoroughly, promptly , and respectfully respond to comments from peer reviewers and the editor.

Summary

QA research is the assessment of current practice with the objective of improving the health care we provide. I hope this brief review will enhance would-be investigators' interest in and ability to conduct and report QA research.

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