Variability in Obtaining Institutional Review Board Approval for Quality Improvement Activities in Residency Programs

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Abstract

Introduction Quality improvement (QI) activities are an important part of residency training. National studies are needed to inform best practices in QI training and experience for residents. The impact of the Institutional Review Board (IRB) process on such studies is not well described.

Methods This observational study looked at time, length, comfort level, and overall quality of experience for 42 residency training programs in obtaining approval or exemption for a nationally based educational QI study.

Results For the 42 programs in the study, the time period to IRB approval/exemption was highly variable, ranging from less than 1 week to 56.5 weeks; mean and median time was approximately 18 weeks (SD, 10.8). Greater reported comfort with the IRB process was associated with less time to obtain approval ($r = -.50$; $P < .01$; 95% CI, −0.70 to −0.23). A more positive overall quality of experience with the IRB process was also associated with less time to obtain IRB approval ($r = -.60$; $P < .01$; 95% CI, −0.74 to −0.36).

Discussion The IRB process for residency programs initiating QI studies shows considerable variance that is not explained by attributes of the projects. New strategies are needed to assist and expedite IRB processes for QI research in educational settings and reduce interinstitutional variability and increase comfort level among educators with the IRB process.

Introduction

Efficient Institutional Review Board (IRB) processes are important in facilitating multi-institutional studies needed to accelerate improvements in training.[1] Recent literature highlights the tension that educators and IRBs experience when making distinctions between quality improvement (QI) work, QI research, and medical education research.[2,3] In situations where research and QI activities overlap, IRBs might require unnecessary levels of review and oversight which are complex, costly, and can impede evidence-based approaches to patient care.[4] A deeper understanding of how the IRB process affects the implementation and outcome of QI research is needed.

This report pertains to a multicenter study investigating the effectiveness of the American Board of Internal Medicine (ABIM) Care of the Vulnerable Elderly (CoVE) Practice Improvement Module (PIM) in improving care for elderly patients.[5,6] Challenges with the IRB process emerged as one important theme, highlighting how obtaining IRB approval or exemption impacts QI research in graduate medical education (GME).

Methods

Forty-two residency programs in internal medicine and family medicine participated in studies of the ABIM CoVE PIM.[5,6] Study protocol related to the IRB process was consistent across programs. We provided programs with a modifiable template and draft consent forms to use with local IRBs. We encouraged programs to begin the IRB process immediately and inquire about eligibility for exempt status.[7]

After study completion, we conducted an online survey of study leaders from all programs about their overall

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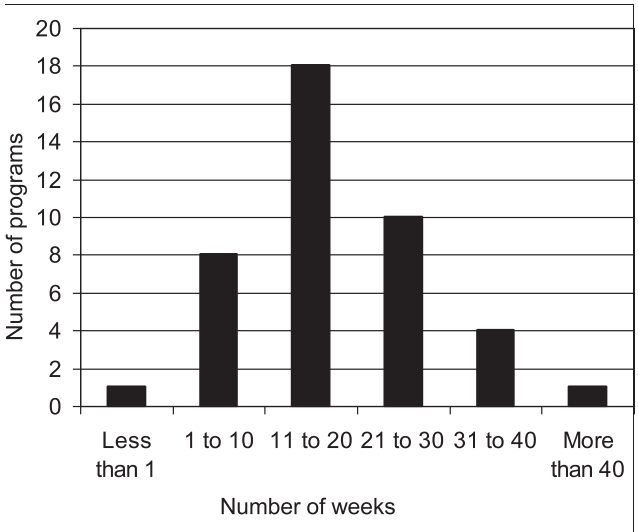

FIGURE **Length of Time in Weeks from Initiation (June 15, start date) to IRB Approval or Exemption for 42 Residency Programs Participating in a QI Study**

experience with the IRB process and their comfort with navigating the local IRB, which included space for free-text comments. We emailed the survey to study leaders, sending completion reminders when necessary.

Data Analysis

We calculated the time elapsed from process initiation to IRB approval/exemption among the residency programs, beginning June 15, 2006 (when sites were instructed to begin the IRB process). Comments from the online survey were coded by 4 independent reviewers and were classified as positive (complementary), negative (critical), or neutral. Discrepancies were resolved through discussion. We then related the time to IRB approval/exemption with survey responses. Spearman rank-ordered correlation was used to relate length of time to approval and comfort level and overall experience.

Results

Programs received different levels of IRB review at their institution. Four programs (9.5%) received exempt status, 8 (19%) programs expedited approval, and the remaining 30 (71%) programs underwent a full review process.

Calculated time to approval/exemption ranged from less than 1 week to 56.5 weeks; mean time was approximately 18 weeks (SD, 10.8) (FIGURE). (Not all programs began the IRB process on the June 15 date stipulated in the protocol. When we calculated actual (self-reported) start dates, mean time to approval was 7.5 weeks longer.) The study timeline allotted 4 months to obtain IRB approval; 22 programs (52%) did not receive IRB approval/exemption within that time. There was no association between time to approval and program size or type, location, or intervention or control arm.

Forty of 42 study leaders completed the online survey. Twenty-four (60%) leaders reported they were at least "somewhat comfortable" (on a 4-point scale: not at all comfortable, a little comfortable, somewhat comfortable, very comfortable) navigating the IRB process. Twenty-four (60%) leaders said their overall experience with their local IRB was "good" or "excellent" (on a 5-point scale where 1 = poor to 5 = excellent). Seventeen (42.5%) leaders provided positive comments about their experience; 15 (37.5%) leaders provided negative comments such as, "The IRB made the entire process onerous in all respects, from the outset to closure. It was needlessly complicated, repetitive and unfriendly. I am loathe to pursue further IRB-required activities as a result."

Participants' comfort level navigating the IRB process was inversely associated with the length of time to complete the IRB the process; less time was associated with greater comfort ($r = -.50$; $P < .01$; 95% confidence interval [CI], -0.70 to -0.23) and a more positive overall IRB experience ($r = -.60$; $P < .01$; 95% CI, -0.74 to -0.36).

Discussion

The variability in the IRB process for QI activities and research highlighted in this study has several implications. First, time to IRB approval was highly variable across institutions; more than half of the programs in this multisite study could not meet the timeline for initiating data collection because of the IRB process. IRB barriers markedly changed the "time zero" for study implementation, making meaningful comparisons more difficult in a study funded over a fixed time interval and investigating time-sensitive QI initiatives.

More than one-third of study leaders commented on negative experiences with their IRB, citing frustration with forms and processes that did not fit the goals of QI projects. This is troubling, considering increasing pressure in GME to demonstrate effective quality improvement activities.[8,9] The effort spent on difficult IRB processes can reduce motivation and "buy in" for study interventions, key factors in conducting QI projects.[10] Research in QI in residency training needs oversight but may require a type of consideration that is different from the typical framework for clinical trials.[2,3]

Comfort level navigating the IRB process and the overall quality of experience with the IRB correlated with time to IRB approval/exemption; participants who felt more comfortable completed the process more quickly. Experience is a facilitator, and many clinician-educators do not have substantial experience with IRBs. While we lack details for specific aspects of the IRB process that were

problematic for different study leaders, we note that ABIM provided substantial support throughout.

Finally, many local IRBs could benefit from a better understanding of QI research. Researchers and their IRBs should work to understand mutual needs.[11] Department chairs could provide IRB training to clinician educators who lead QI research. Groups with a stake in GME and QI research could educate IRBs, working with the Office of Human Research Protection to adjust IRB regulations for QI, raising awareness of QI research, and helping to support a national standard. Local IRBs not versed in QI could allow QI research to be approved by national IRBs. In 2011, the federal government began considering changes to how human subject research is governed, including focusing resources on higher risk studies and scrutinizing the number of IRBs of record needed for multisite studies.[12] These and other proposed changes have the potential to standardize IRB review for QI studies, helping inexperienced clinician-educators and those doing multisite studies.[12–16]

Limitations

Due to study design, we conducted the IRB experience survey 2 years after initiation of the IRB process, introducing possible recall bias. During that period, study leaders may have done other research, possibly contaminating responses to the IRB experience. We did not investigate in depth factors that could have contributed to the time needed at some institutions for IRB approval/exemption: some local investigators began the IRB review process after the suggested date; the larger study was complex; the IRB template may have been confusing to local investigators or IRBs; or IRBs could have had a backlog of studies awaiting review. Our results may not be generalizable beyond the 40 survey completers, although the training programs were diverse.

Conclusion

Publishing results of QI research is crucial to building and disseminating a robust body of knowledge about effective interventions across residency programs.[17] In order to accelerate this work, the IRB approval process needs to be efficient and timely. The federal government may be moving in this direction[12]; at the local level, researchers and clinician-educators can work together to increase the comfort level with the process.

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