American Board of Internal Medicine

Length of Time Needed for Institutional Review Board Approval or Exemption of Quality Improvement Projects Among Subset of US Training Programs

Lisa Conforti, Kathryn Ross,
Brian Hess, Lorna Lynn,
and Eric Holmboe

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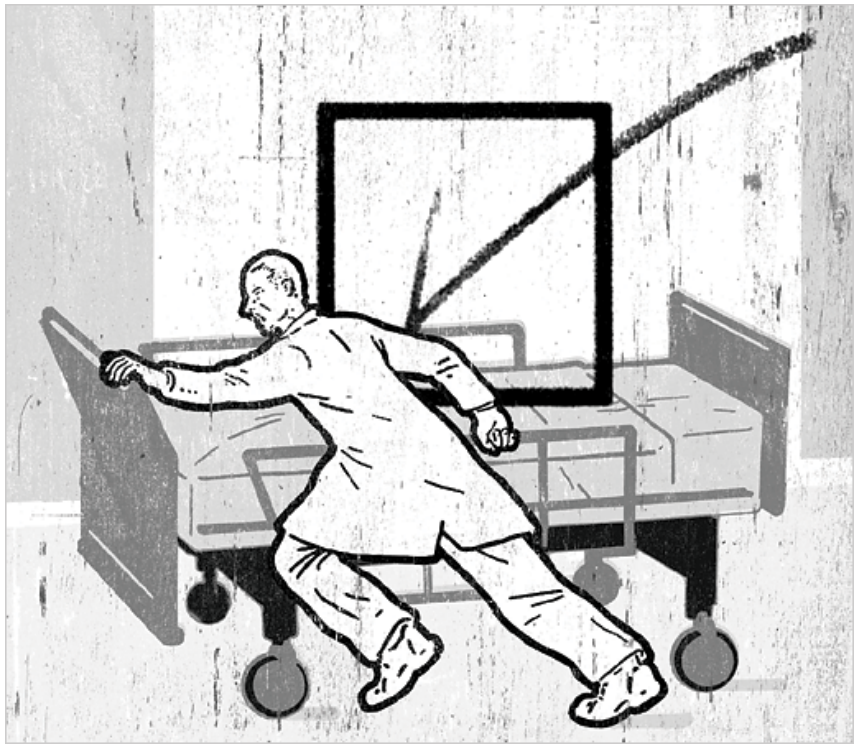


Dan Page

"They [the IRB members] are lackluster in their responses and often seem to create roadblocks rather than a straight course to completion."

- Study participant

Background: *Improving Quality of Care for Elderly Patients in the Educational Setting Study*

- Purpose

  Investigate the effectiveness of ABIM's CoVE PIM to improve teaching and quality of care for elderly patients

- Participants

  Forty-six IM and FM residency programs

- Methods and activities
  - Pre and post tests of geriatric and quality improvement knowledge and attitudes (trainees and faculty)
  - Data collection at baseline and follow-up
    - Patient satisfaction surveys, patient chart abstractions, and a practice system assessment
  - CoVE PIM for intervention groups

Results

Of the 46 programs...

- 4 withdrew
  (IRB approval pursuit unknown)
- 4 exempt
- 8 expedited
- 30 full approval process

- 48% (22) programs were unable to begin the study within the pre-specified time zero period

Methods

- Calculated the length of time to completion
  - With same start point (June 15, 2006)
  - With program reported start point
- Brief online survey
  - Program actual start point (self-reported)
  - Comfort level with IRB
  - Overall IRB experience for this study
  - Free text about overall IRB experience coded and categorized by 4 independent reviewers
- Related time to completion to survey responses

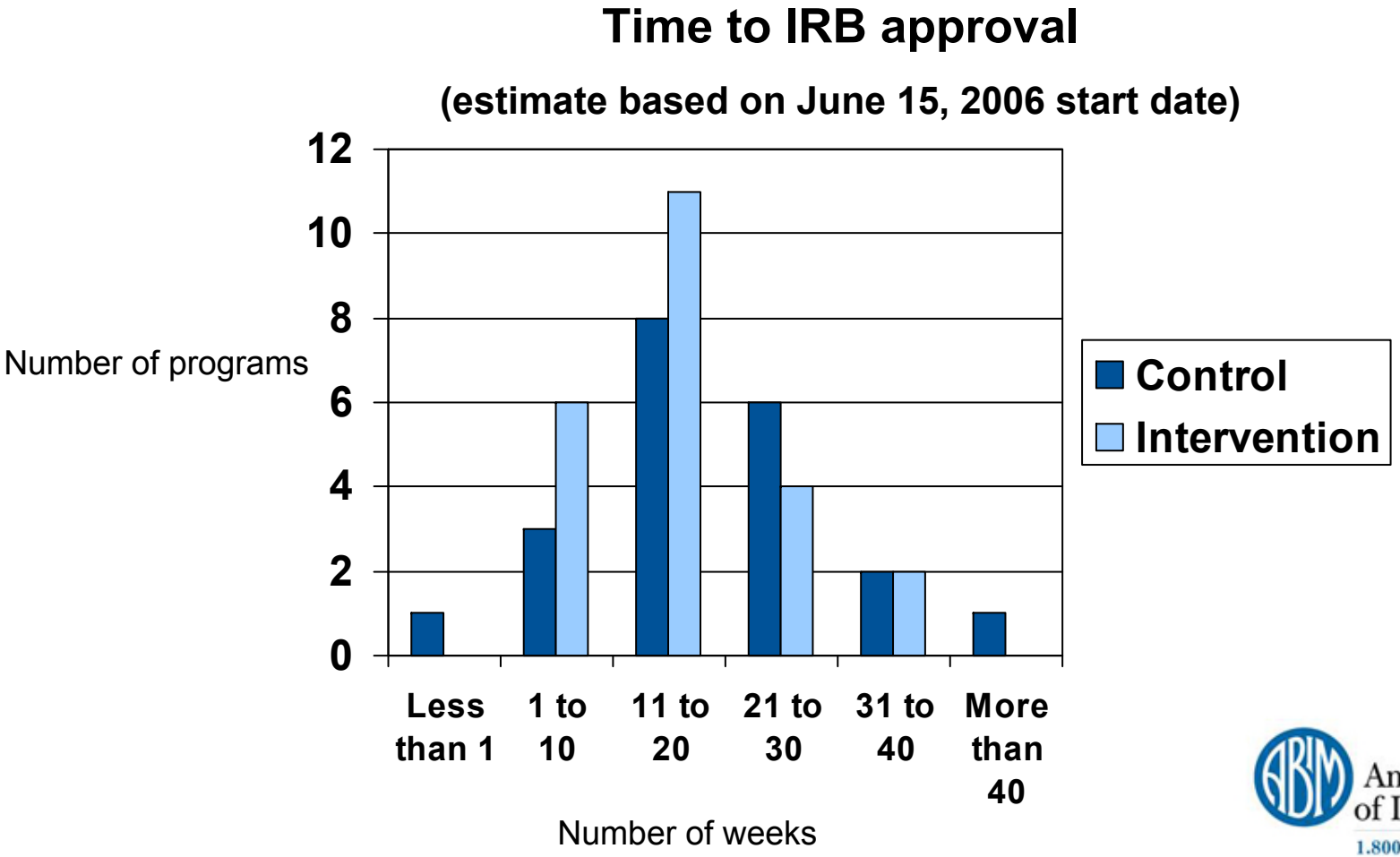
Strengths and weaknesses

- Strengths
  - Multi-institutional study of IRB experience in training programs
  - IRB process with regards to a QI study

- Weakness
  - Data collected about the IRB experiences was collected 2 years later
  - Some data is still being collected

Results

- Time period to approval or exemption (n=42)
  - Range = < 1 - 56.5 weeks
  - Mean = 18.3 weeks
  - Median time = ~18 weeks



Results: Actual time to approval longer than expected

- Time period to approval or exemption (n=29)
  - Range = 3 - 58 weeks
  - Mean = 25.9 weeks
  - Median time = 25 weeks

- An average of 7.5 weeks LONGER then we had estimated

- Many people did not respond (26%)

Majority were at least "somewhat" comfortable navigating the IRB process

n=40

- *At the start of the study, what was your level of comfort with your ability to navigate the IRB process at your institution?"*

Scale	N (%)
Very comfortable	10 (25)
Somewhat comfortable	14 (35)
A little comfortable	8 (20)
Not at all comfortable	8 (20)

} 24 (60%)

Majority report IRB experience "excellent" or "good"

n=40

- *How would you characterize your experience with your local IRB?*

Scale		N (%)
Excellent	5	8 (19%)
	4	16 (38%)
	3	7 (17%)
	2	3 (7%)
Poor	1	6 (14%)

24 (57%)

Majority report IRB experience "good" or "excellent", though comments don't support this n=40

- *How would you characterize your experience with your local IRB?*

Scale	N (%)
Excellent 5	8 (19%)
4	16 (38%)
3	7 (17%)
2	3 (7%)
1	6 (14%)

- *Please provide a rationale for your response*

Comment type	N (%)
Positive	17 (42.5%)
Negative	15 (37.5%)
Neutral	5 (12.5%)
No comment	3 (7.5%)

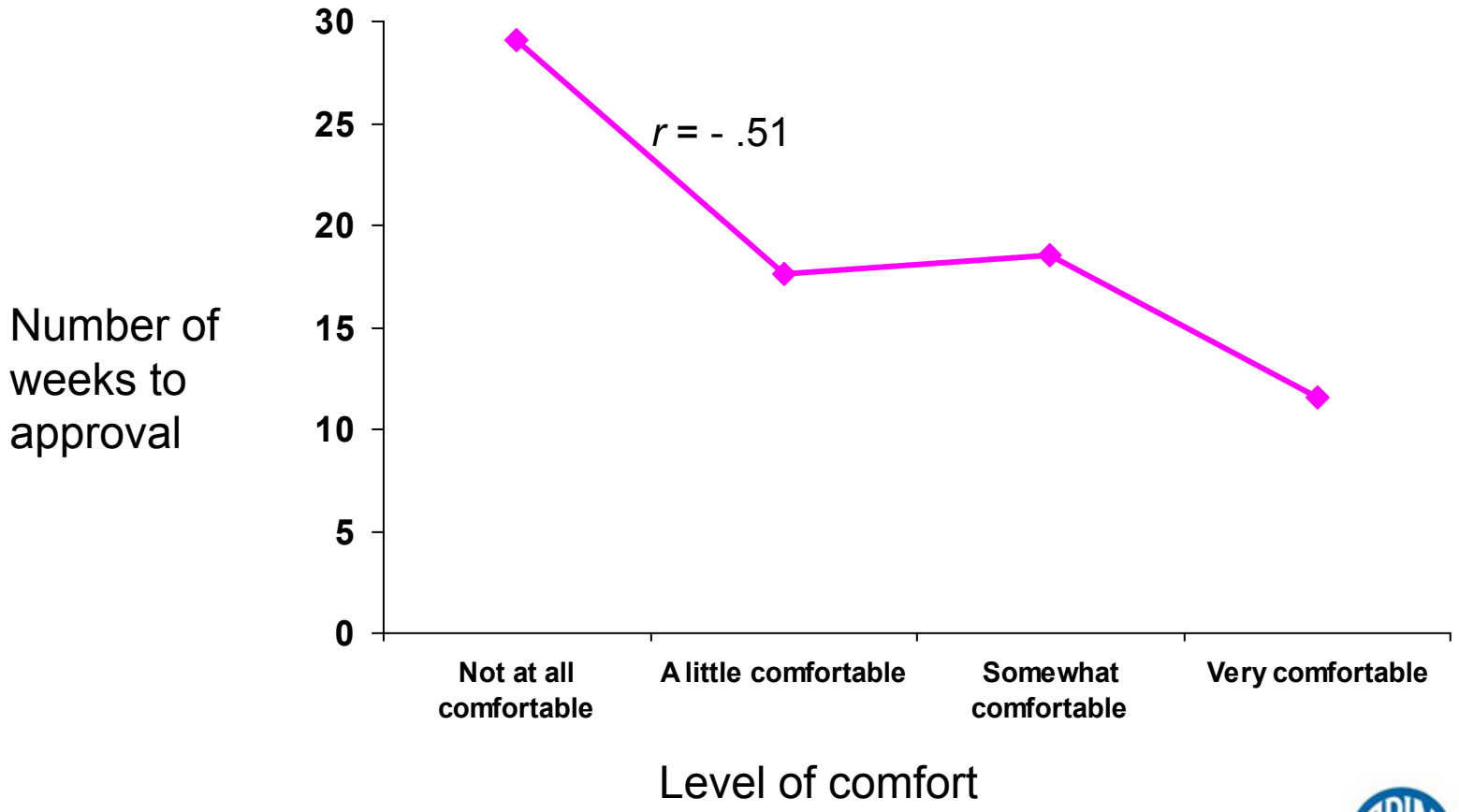
Emphasis and tone matter

"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. ..."

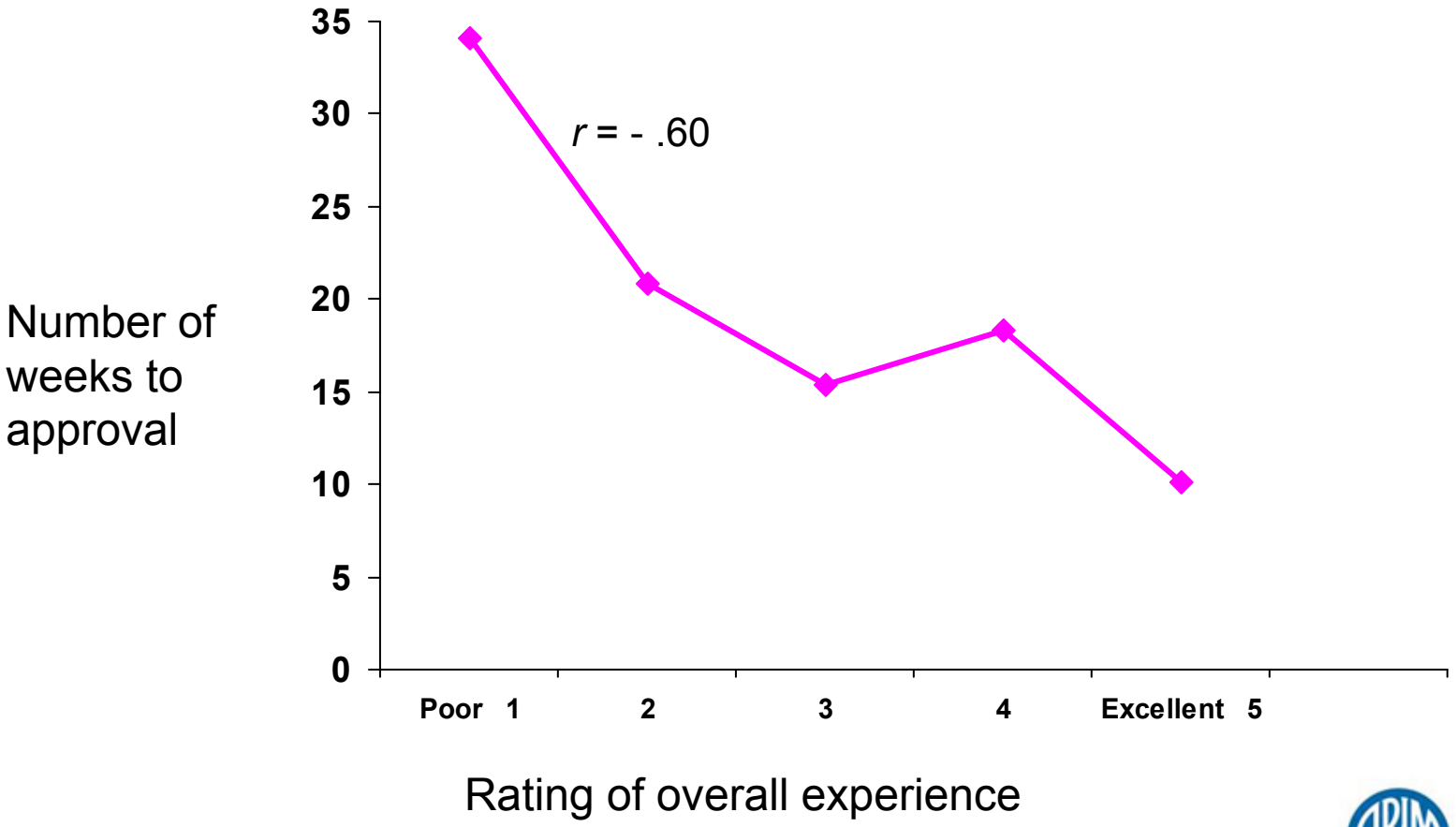
- Study participant

(took 27 weeks for IRB approval)

Comfort level related to weeks to approval



Overall IRB experience related to weeks to approval



Methods for IRB pursuit

- All programs received...
  - A completed IRB template
  - Draft consent forms
    - Trainees and faculty
    - Patients (English and Spanish)
  - Participants instructed to contact their local IRB four months before study commencement
    - to learn about requirements
    - inquire about exemption eligibility (no identified data would be leaving the practice site)

Still the nagging question – why so long to approval?

- Why did 48% of the programs start late? (after 4 months)
- Clearly there are other factors
- Further investigation is in process
  - Specific IRB processes and certifications necessary
  - Number of submissions
  - Specific reasons for need to re-submit
  - Learn from “best practice”

Conclusions and Recommendations

- Length of approval process time is highly variable across institutions
- Comfort level with IRB process is related to the length of time that process takes
- Standardization of IRB review specific to QI projects/studies
  - Could help inexperienced clinician-educators with the process and to implement QI research projects
  - Could also help those doing multi-institutional research better instruct study subjects
- Encourage relationships with the IRB

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