Navigating the Publication Process

Advocate Research & Innovation Forum 2012

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Disclosures

I am a paid staff member of the ACGME
Session Objectives

- What are editors and reviewers looking for?
- “Hot topics” and what is missing from the graduate medical education literature
- Aspects of research vs. quality improvement (QI)
- Common barriers to getting your research published
- Challenges in education research and overcoming them
- IRB 101
- Writing, submitting, editing and revising
Getting Published: What are editors, reviewers and readers looking for?

Importance
• Does the research address a major education, clinical or policy issue (relevant to the scope of the journal)?

Novelty/Innovation
• Is the knowledge new? Is the intervention innovative?
• Does it have practical applicability?

Impact
• Does it make a difference in an area that is important to the pertinent field?
• Does it have practical applicability, or provide actionable or translatable benefit?

Significance
• Does the new knowledge improve our understanding?
“Really Hot Topics” in Education Research

Characteristics of effective teachers and teacher retention, promotion and development (Including residents as teachers)
Effective educational transitions (UGME to GME, GME to practice)
Curriculum/goals mismatches between education and practice
Identification and remediation of “low-achieving” learners
Adequacy of the required educational experience
  • Justification of time, procedure and patient volume requirements
Instruction beyond traditional lecture, seminar or bedside
Simulation and rehearsal (High-, low-tech and no tech, SPs, OSCEs)
Does competency-based education and assessment (or any other educational intervention) produce an effect in practice
Looking for a GME Topic with Larger Relevance:

The Short List…

Institute of Medicine – *To Err is Human, 1999, Crossing the Quality Chasm, 2001, Resident Duty Hours, 2008*

Congress, House of Representatives Codification of Physician Competencies in Law (*Health Care Reform, Section 1505*) 2009

MedPAC Report, June 2010

Council on Graduate Medical Education (numerous reports, *Twentieth Report, Advancing Primary Care, 2010*)

National Patient Safety Forum, 2010


National Coordinator for Health Information Technology – February 2011
The Holy Grail of Impact: Kirkpatrick’s hierarchy of training outcomes

- **Reaction**: (awareness, attitude, satisfaction)
- **Learning**: (knowledge and skills)
- **Behavior**: (transfer to workplace)
- **Results**: (impact)

Outcomes in manuscripts submitted to medical education journal

- Almost Never
- Rarely
- Less often
- Often

Clinical Outcomes

Educational Outcomes
Larger intervention studies (multi-site, multi-center, large sample)

“Utility studies” to assess which approaches are the most efficacious, the most cost-effective

The effect of dysfunctionality in the learning environment on learning and in practice

- Many editorials and commentaries, very few studies

QI studies that are written up in an appropriate style (SQUIRE)

Systematic reviews and meta-analyses

- As a way to aggregate data from underpowered primary studies prevalent in medical education
Continuum of Quality Improvement and Research: Rigor vs. Relevance

**Operations**

“Relevant”
Context-Dependent
Problem Solving
Quantitative $>$, $<$, or $=$
Qualitative
Pre-test post-test or
Quasi-experimental designs
Tends to be NON-LINEAR

**Research**

“Rigorous”
Identify generalizable knowledge, i.e.,
negate the role of Context
Publishable
Quantitative preferred
over Qualitative
Tends to be LINEAR

Potential Synergy
Classic Research Designs

Comparing two interventions

Randomization to intervention vs. control
Helping with the write up of QI studies: What are the SQUIRE guidelines?

A Checklist: 19 items, information to consider in QI reports

Models: Other guidelines (e.g., CONSORT, STROBE, etc.)

Focus: Content, rather than study design

Development: Several years, iterative process, multiple endorsers

Immediate purpose: To increase completeness, precision, transparency

Ultimate purpose: To encourage more and better reports

Target audience(s): Mainly authors, but also reviewers, editors, users of QI reports; funders

Dissemination: website (www.squire-statement.org), 6 articles
Common Barriers to Getting Published

Getting the data (and getting the data together and presentable)
Knowing how to write and finding time to write
Editing and finishing
Submitting
The editorial process: Dealing with “Rejection”, “Major Revisions” (and understanding reviewers’ comments)
Finding time to revise (and, sometimes, revise again) and to resubmit
Focus on: Strategies to overcome the particular barrier that affects the stage of the process you are in
Particular challenges for medical education research

Difficulty controlling aspects of learning experience (too many “moving parts” (learners, patients, faculty, etc.)

Difficult to conduct longitudinal studies

Experimental design/randomization often not possible

Lack of good assessment tools and outcome measures

Threats to internal and external validity

Limits on generalizability from single site studies

Mismatch between the narrow scope of “good” research and the need for broad evidence to change teaching approaches or other elements of the learning environment
Things you should do (have done): Getting the Data

Planning
Is the problem important and relatively unexplored?
Can you generate a testable hypothesis or develop an intervention?

What are the envisioned
• Findings that could be generalized to other settings
• Practical benefits
• Starting points for other research (deeper exploration of the problem)

Design your experiment or intervention
• Does it test the hypothesis or address the problem?
Things you should do (have done): Getting the data together and presentable

**Execution**

Are your methods and approaches valid?

Decide which statistical methods you will use

Do you have the skills and resources you need?

If not, can you solicit the help of collaborators?

Consider consulting a statistician or other experts

How can you broaden your research or intervention (multiple sites, populations to increase generalizability)

Read the literature! (There is NO substitute for this!)

Connect with experts and potential mentors
Threats to Validity in GME Studies:
Internal Validity

History: Events unrelated to the intervention occurs during the study period (e.g., implementation of 2003 duty hour limits)

Testing effects: Participants learn from the test or interview (subjects guess desired answers, become “test savvy”)

Regression to the mean: A sample selected because of certain qualities may “regress” toward the mean (residents with low performance get better without an intervention)

Attrition: Some people in the group are more likely to drop out (students without learning problems from enhanced teaching)

Selection bias: Study group is nonrandom basis (students volunteer for a team-based approach because they like learning in teams)

Not easily avoided. Consider and address in limitations section
Threats to Validity in GME Studies: External Validity

Reactive effects: Factors that affect outcome may be associated with the study itself (e.g., subjects are aware they are in an experiment and work harder [“Hawthorne Effect”])

Testing-treatment interaction: Repeatedly given measures or tests affect whether the intervention works (e.g., participants “learn” from the questionnaire or interviewer and not from the intervention)

Selection-treatment interaction: The outcomes are relevant only to populations from which study groups were selected (e.g., the intervention works only in Boston, not nationally)
Think Intervention Study

Prospective and Controls – benefit of a “fair” comparison group

• Not necessarily randomized, but… use of historical controls may introduce bias
• Paired data (change measured in same resident at different points) - can be powerful, reduces measurement error
• More valuable if sustained change, not just immediate
• Perhaps randomize rotations rather than residents

Look for downstream outcomes for your intervention

• Move away from Kirkpatrick’s “reactions”
• Remember the holy grail is a “clinical” effect

Biggest Challenge in medical education research: Adequate power to detect differences

• Possible solution: aggregate data from multiple sites
Things you should do (have done): IRB and Informed Consent

### The Belmont Report – April 18, 1979

#### Ethical Principles and Guidelines for the Protection of Human Subjects of Research

<table>
<thead>
<tr>
<th>Principle</th>
<th>Guidelines</th>
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| Respect for Persons | - Informed Consent  
                      | - Capacity to Consent                                                        |
| Beneficence       | - Do no harm  
                      | - Maximize Benefit                                                           |
| Justice           | - Equitable Selection of Subjects  
                      | - Equitable Burdens and Benefits                                             |
Things you should do (have done): IRB and Informed Consent (2)

- Initial Review
- Prospective Review of All Changes
- Reporting/Review of Unanticipated Problems, Adverse Events
- Continuing Review at Least Annually

**Informed Consent** (DHHS 45 CFR Part 46 and FDA 21 CFR Part 50)
- Eight Required Elements
- Written Documentation
- Language Understandable to Subjects
- No Coercion or Undue Influence
- No Waiver of Subjects Rights
IRB and Informed Consent
Practical Points

• May need IRB for studies that do not require informed consent or volunteer participation (eg, as a researcher you are studying the entire cohort)
  • Informed consent always a good idea
• Studies may be exempt but most publications want the IRB (not the researcher) to make this determination
• Field studies and qualitative research present certain challenges:
  • Anonymity not possible (confidentiality is),
  • QI studies not automatically exempt (DHHS rule on multi-institution quality improvement studies)
• Grey area: DHHS considers IRB necessary for (clinical) research development, pilot studies (not always done that way in education research)
IRB Expedited Review: Criteria for Minimal Risk Research

- Research on individual or group behavior or characteristics -- cognition, motivation, identity, language, communication, cultural beliefs/practices, social behavior; survey, interview, oral history, focus group, program evaluation, human factor, quality assurance methodologies
Things you should do (have done): The Writing

Brainstorm ideas, develop an outline to organize your ideas

Read the instructions for authors of the Journal where you are most likely to submit (to avoid wasted time and effort)

Overcome “perfect first sentence syndrome” (start where you feel the most comfortable, the remainder will come)

Write a concise, clear research/methods statements

Structure paragraphs into topic sentences, main points and supporting details

Use active voice, vary sentence structure and length

Use signaling words sparingly (furthermore, consequently)

Use a style that balances data and interpretation
Things you should do (have done): Deciding where to Submit

Journal Scope:
- Look at the homepage, instructions to authors and recent articles

Audience access:
- Will the article be visible/accessible to the audience most interested

Journal impact and prestige:
- Aim high but be realistic

Editorial systems:
- Timely and efficient peer review

Production:
- After acceptance, will the article be published quickly

Longevity:
- Will the article still be available in 10 or 50 years time
The Editorial Process: Responding to Editors’ and Reviewers’ Comments

Read carefully - Rejection does not always mean “rejection”
Understand what you need to do to satisfy reviewers and editors
Prepare a point-by-point response that includes the reviewer comments: Editors and reviewers will love you
Make changes to the manuscript, don’t rebut the comments
   When you disagree with reviewers and editors, give a clear argument why you have not changed the manuscript
Do not give up if your paper gets rejected
   Use the reviews to improve the paper (look for editor’s cues)
   Rethink the journal and/or rethink the journal and format
10 things to do if you do NOT want to get published

Adopt a ponderous, wordy and ambiguous style with lots of passive tense, or better yet, tautology
• “Rats were killed until they were dead.”
Insert references to all your previous work, even work not remotely relevant to the current manuscript
Pick a journal at random or for its “impact factor”
Make sure you exceed the manuscript length by at least 1,000 words and two to three tables
Use inappropriate statistics (you saw them in an article and thought they looked cool)
10 things to do if you do NOT want to get published

Make wild leaps to conclusions not supported by your data, or jump to a completely different topic in your discussion section

Choose a different reference style from that required by the journal, or better, yet, use a mix of different reference styles

Do not check your references and include several incomplete or incorrect ones

Submit without a cover letter, or better yet, submit with the cover letter you used for the submission the last journal, without changing a word

ON NO ACCOUNT, EVER read the instructions to authors

Know and Pay Attention to Publication Ethics

Representing the contributions of co-authors and ensuring that co-authors made contributions
- “Authorship/intellectual ownership” results from work that contributed to the publication (conceptualization and design, data collection, data manipulation/analysis, writing and editing)

Full disclosure of
- Contributions of all co-authors
- Prior publications from the same study or the same topic
- Potential conflicts or competing interest (see guidance to authors)
- Ghost writers/editorial assistance

Avoid at all costs
- Plagiarism (even self plagiarism), “Salami” (Partial) Publications and “Goulash” Publications
- Deliberate misrepresentation of data
- Misquoting other authors (be sure they did or wrote what you report)
Closing Thoughts

• Be your own most avid critic
• Put yourself in the place of the reader
• Every part of the paper should support the take-home message
• Cite recent work in the field
  - Only cite review articles when important to support general statements
• Draft, re-draft and re-draft again
  - If English is not your first language, get help from an expert
  - Use an engaging style: capture the reader’s interest, help the story unfold
• Become a reviewer: offer your services (a service to the academic community and a tremendous learning opportunity)
• Get a mentor: we all need advice