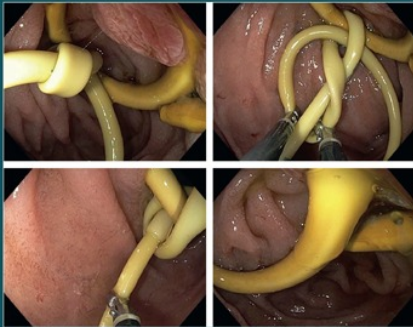


GIE Reviewers' Course

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GIE[®]

Gastrointestinal Endoscopy




Magnets for therapy
in the GI tract

Assessment of mucosal
healing in inflammatory
bowel disease

Self-expandable metal
stents vs plastic stents
for malignant biliary
obstruction

Success of single-balloon
enteroscopy in patients
with surgically altered
anatomy

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Updated August 2015

Aim

- To establish our processes and professional norms in peer-review

Outline

1. General Principles of Peer Review
2. Importance of the Research Question
3. Originality
4. Validity
5. Ethical Issues
6. Presentation of the Research
7. Issues You Need to Tell the Associate Editor Privately
8. Tips for Specific Types of Studies
9. Accept or Reject?
10. How You are Judged as a Reviewer

General Principles I

- Be courteous and constructive.
 - “*This is a pointless study...*”
 - “*...anything can be proven with statistics without regard for context.*”
- Be specific and give examples to prove your point.
 - “*This study does not give any significant contribution...*” Elaborate on what is already out there.
 - “*comparing apples to oranges...*” Suggest a better way to analyze and present the data.

NOTES

We reject the majority of papers sent to us. The number of articles submitted to GIE increases every year. Therefore, we have to reject more and more papers.

The success of our journal is dependent on attracting high-quality papers. Even if you don't think a paper is right for GIE, be as constructive as possible, so that the authors can revise and improve their work before submitting it to another journal. Through constructive criticism, you will help the authors write a better paper, and, more importantly, the experience will encourage them to submit to GIE in the future. In other words, we want our “customers” to keep coming back.



General Principles II

- Maintain strict confidentiality.
- Declare conflict of interest.
- Be punctual.
- Stay committed for the long-term.

NOTES

- GIE reviewers are expected to uphold the highest ideals of integrity and mutual respect. Thus, do not discuss the article with anyone else, including the authors (not even mentioning that you reviewed a particular paper on a specific topic).
- If you are member of the Editorial Review Board or the International Editorial Board, you are expected not only to provide excellent quality reviews, but also to perform in a timely manner and not habitually reject invitations to review. Those who are ineffective in their roles as reviewers will be excused from the roster.



Research Question

- The question is more important than the answer. If the question was important and the answer is valid, then it doesn't matter if the answer is negative.

NOTES

- Journals are often guilty of rejecting work because its results are negative or dull, thus biasing the evidence base toward positive results
- Because we receive so many papers, Associate Editors have to reject more than 50% without even sending them for review.

Originality I

- Always perform a literature search. Has this ever been done before?
- If the question has been addressed before, what value does this paper add (for example, a much bigger or better designed study)?
- If you think the research is unoriginal, please give us references to previous work. Don't just say "it's unoriginal."



Validity of the Research I

- Identify the strengths as well as the weaknesses of the study.
- Is the design right for answering the research question?
- The study endpoint should be clearly described.

NOTES

- It is common to forget to mention the strengths of the study, but this is equally as important as outlining the weaknesses of the study. This helps reinforce to both author and Associate Editor that you were not biased against the study.



Validity of the Research II

- Were the data collected adequately? Was the method of sampling right?
- Were the methods described adequately?
- Were the analyses appropriate?
- Was the method of follow-up adequate to ensure that there was no under-representation of complication rates?
- Studies with dropout rates $>15\%$ should be interpreted cautiously.

NOTES

- On the other hand, it is rare to achieve 100% follow-up rate in any study.
- Whether the study is retrospective or prospective, the circumstances as to why subjects were lost to follow-up should be explained.

Reference:

How to Report Statistics in Medicine. Lang TA and Secic M. ACP 1997. ISBN 0-943126-44-4.

Validity of the Research III

- If you are not strong on statistics say so; we have a statistician to whom you can ask us to clarify a specific issue.
- Ideally, confirm that the tables add up correctly, and that the numbers correspond to what is stated in the text.

NOTES

- You should check for appropriateness of the statistical method used for all papers (for example, using likelihood ratio instead of specificity and sensitivity).
- However, you are not required to check whether the calculations are accurate.



Validity of the Research IV

- Do you think that the conclusions are supported by the data?
- Did the authors go beyond the evidence in their conclusions?
(This is very common.)
- Did the conclusion answer the main objective of the study?



Ethical Issues I

- Think about the ethical aspects of the research, even if there is a mention of approval by an ethics committee.

NOTES

- Does the paper say enough about the information participants were given before consenting to take part in a study?



Ethical Issues II

- When a new, unproven endoscopic technique is being studied (for example, a novel hemostatic agent for acute GI bleeding), were the subjects given the option to undergo standard endoscopic treatment?



Presentation of the Research I

- You do not need to correct spelling mistakes and grammatical errors. This is the responsibility of the editorial staff.
- If you feel the style of writing can be more succinct, say so.

NOTES

- We welcome advice on whether all tables and figures are really useful or necessary. Remember, fewer tables and figures translates to lower printing costs and a less bulky journal.
- The quality of figures and video is important in a journal such as ours, so your comments are needed to direct the authors to improve the images if needed.



Presentation of the Research II

- Is the number of references appropriate?
- Draw attention to relevant papers that were not cited by the authors
- Are the references up to date? Take note if none of the references are within 10 years old.
- Does the study warrant an editorial?

Issues You Need to Tell the Associate Editor Privately

- Suspicion of unethical conduct during the study period
- Undeclared conflict of interest by the authors
- Suspicion for plagiarism or poor paraphrasing (provide citation)

NOTES

- Research misconduct covers a wide spectrum of activity, including:
 1. Duplicate publication in a different journal.
 2. “Salami” studies or unnecessarily slicing up the output from one piece of research into ever smaller slices (i.e., cut off from a larger study but is being presented as an original paper).
 3. Fraudulent studies or manipulated data.
 4. Misrepresenting retrospective data as prospective.
- All reviews should have specific comments to the Associate Editor. This is your chance to have a “no holds barred” conversation with the editor, and yet remain non-judgmental and courteous in your approach to the author.



Tips for Randomized Trials

- Sample size calculations should be clearly described.

NOTES

- The experience of the endoscopist for the procedure (for example, ERCP) should be stated.
- The assessor(s) of outcome should ideally be blinded. For example, in a study where a radiologist tries to determine if there is chronic pancreatitis based on MRCP, the radiologist should be blinded to the patient's history and results of other imaging studies.
- If the calculated sample size was not achieved, it should be explained in detail in the Discussion to ensure that this did not lead to major bias. Was this due to inadequate recruitment? Lost to follow-up? Was the trial stopped early due to statistically significant results?
- Refer to the CONSORT checklist at their website: <http://www.consort-statement.org/>

Reference:

- Handbook of Essential Concepts in Clinical Research. Schulz KF and Grimes DA. Elsevier 2006. ISBN 0 08 044866 6



Tips for Retrospective Trials

- Increasingly being rejected by GIE, unless:
 1. It concerns a rare condition (for example, annular pancreas).
 2. Performing a prospective study is unethical or prohibitively expensive.
 3. It encompasses a large database.



Tips for Pilot Studies

1. Not uncommonly, the source of funding to purchase or develop the medical device prototype is not specified. This could raise issues in terms of conflict of interest. Even if the prototypes were received *at no cost* from a commercial entity, this should be clearly stated.
2. The novel endoscopic method or device should be clearly described and illustrated for a practicing endoscopist to understand.

Tips for Assessing Adverse Events:

Common Poor Reporting Practices I

1. Using generic or vague statements, such as *“the drug or procedure was generally well tolerated”* or *“the comparator drug or procedure was relatively poorly tolerated.”*
2. Failing to provide separate data for each study arm
3. Providing summed numbers for all adverse events for each study arm, without separate data for each type of adverse event.

Reference:

- Better Reporting of Harms in Randomized Trials: An Extension of the CONSORT Statement. *Ann Intern Med* 2004;141:781-788.
- CONSORT statement. 2010. <http://www.consort-statement.org/consort-statement/> (accessed Aug 2015).

Common Poor Reporting Practices II

4. Providing summed numbers for a specific type of adverse event, regardless of severity or seriousness.
5. Reporting only the adverse events observed at a certain frequency or rate threshold (for example, >10% of participants).
6. Reporting only the adverse events that reach a *P* value threshold in the comparison of the randomized arms (for example, $P < .05$).

Reference:

- Better Reporting of Harms in Randomized Trials: An Extension of the CONSORT Statement. *Ann Intern Med* 2004;141:781-788.
- CONSORT statement. 2010. <http://www.consort-statement.org/consort-statement/> (accessed Aug 2015).



Common Poor Reporting Practices III

7. Reporting measures of central tendency (for example, means or medians) for continuous variables without any information on extreme values.
8. Improperly handling or disregarding the relative timing of the events, when timing is an important determinant of the adverse event in question.

Reference:

- Better Reporting of Harms in Randomized Trials: An Extension of the CONSORT Statement. *Ann Intern Med* 2004;141:781-788.
- CONSORT statement. 2010. <http://www.consort-statement.org/consort-statement/> (accessed Aug 2015).



Common Poor Reporting Practices IV

9. Not distinguishing between patients with one adverse event and participants with multiple adverse events.
10. Providing statements about whether data were statistically significant without giving the exact counts of events.
11. Not providing data on harms for all randomly assigned participants.

Reference:

- Better Reporting of Harms in Randomized Trials: An Extension of the CONSORT Statement. *Ann Intern Med* 2004;141:781-788.
- CONSORT statement. 2010. <http://www.consort-statement.org/consort-statement/> (accessed Dec 2011).



Accept or Reject?

Examples of Non-remediable Errors:

1. Methodological flaws that lead to bias:
 1. Patient recruitment.
 2. Measurement of outcome.
2. Ethical issues, including informed patient consent and suspicion of fraud.

NOTES

■ Before recommending to the Associate Editor whether to accept or reject a paper, the first question you need to ask yourself is whether the paper's deficiencies are fixable or not.

Partly adapted from:

■ Baxt WG, Waeckerle JF, Berlin JA, Callaham ML. Who reviews the reviewers? Feasibility of using a fictitious manuscript to evaluate peer reviewer performance. *Ann Emerg Med.* 1998 Sep; 32(3 Pt 1):310-7.



Accept or Reject?

Examples of Remediable Errors:

1. Non-compliance to GIE format guidelines.
2. Inappropriately stated conclusion (not supported by the data).
3. Minor statistical errors.
4. Inconsistent data between table and text.
5. Design flaws not highlighted in the Discussion section under “limitations of the study.”

Other Issues We Don't Want

- Too many objectives for the study to adequately address.
- Those that rely on subgroup analysis to answer the main question of the study.
- When the implications of the study are controversial and potentially harmful if applied in clinical practice.

How You are Judged as Reviewer

1. Ability to identify *both* strengths and weaknesses of the study.
2. Constructiveness of comments.
3. Level of detail of the review.
4. Substantiation of comments.
5. Were you biased?
6. Did you make distinct comments to the editor explaining the rationale of your decision?
7. Punctuality.
8. Motivation (how often you accepted invitations to review over a period of time).

NOTES

- These are weighted scores and assessed on a regular basis.
- Remember, you are being monitored not only on the quality of your work, but also your punctuality and level of motivation. An expert, renowned reviewer may produce high-quality reviews, but if he or she is consistently tardy or habitually turning down invitations to review, then this could definitely affect his or her score as a reviewer. Please note that we “clean house” periodically by removing the lowest-scoring reviewers from the list.



Key Points to Consider

- Was the research question important?
- Is this an original work?
- Is there a better method to answer the research question?
- Were the outcomes clearly specified and adequately assessed?
- Was the conclusion supported by the data?

References:

What do editors want from reviewers? Richard Smith, Editor.

BMJ http://www.bmj.com/advice/peer_review/want.ppt

How to Be an Outstanding Reviewer for the Journal of General Internal Medicine ... and Other Journals. Carlos Estrada MD, MS, Adina Kalet MD, MPH, Wally Smith MD, Marshall H. Chin MD, MPH *Journal of General Internal Medicine* 2006 21:3 281



More About Peer Review

NOTES

Partly adapted from:

<http://www.bmj.com/about-bmj/resources-reviewers/guidance-peer-reviewers/> (Accessed August 2015).



Aims of Peer Review

1. To decide whether an article should be published.
2. To improve the article before publication.



Some Problems

- Slow
- Expensive
- Subjective
- Open to abuse (if the reviewer is a competitor of the authors)
- Almost useless at detecting fraud

NOTES

Peer review may delay release of important data to patients and the general public. However the Editor of GIE has the option to place a study on a fast track system for the most important papers—typically randomized controlled trials.

Bias

Author or Institution-related

- Prestige

Paper-related

- Positive results
- English language
- Research grants and awards
- Oral presentation in DDW

NOTES

Author-related bias:

- Bias towards successful researchers - Merton RK. Science 1968;159:56-6
- Bias against women - Wenneras C, Wold A. Nature 1997;387:341-3
- Publication bias - if the research question is important and interesting, the answer should be less important.
- Of note, we have rejected papers despite the fact that they received society research funding, or even if it made it as an oral presentation in DDW. Not surprisingly, we have also turned down papers from prestigious institutions. However, we are also aware that peer review has its limitations, and we have rejected papers that were later accepted in higher impact journals.



What Makes a Good Reviewer?

- Age under 40
 - Good institution
 - Known to the editors
 - Methodological training (statistics & epidemiology)
-

NOTES

Surprisingly, some well-known established authors may serve poorly as reviewers. Conversely, obscure people from the community may actually function well as reviewers. There are, however, certain characteristics that are consistently found among top-reviewers for GIE and these are similar to those outlined in the above slide. To be a good reviewer you need to be idealistic (thus good reviewers tend to be younger), with a deep passion to search for the truth. You also need to be committed and to take your work seriously. Some would say that reviewing is akin to flying a commercial jet; to be good at it you need to hone your skills by doing it on a fairly regular basis (not just once or twice a year). If you want to review more papers but are not getting invited enough, you need to let the editorial team know, or make yourself known to the Associate Editors.

Slide contents from:

- Black N, van Rooyen S, Godlee F, Smith R, Evans S. What makes a good reviewer and a good review in a general medical journal. *JAMA* 1998;280:231-3.
- Evans et al. The characteristic of peer reviewers who produce good-quality reviews *J Gen Intern Med* 1993;8:422-8.
- 226 reviewers of 131 papers submitted to the journal. 43% of reviews were good (on a 5 pt editors' scale). The characteristics on this slide had 87% chance of predicting a good review.

How long does it take to do a good review of an average manuscript?

- 15 minutes
- 30 minutes
- 1 hour
- 3 hours
- 5 hours
- 10 hours
- 24 hours
- 48 hours

NOTES

Reading and understanding the paper thoroughly, doing a literature search, and writing a critique takes at **least 3 hours**. This is based on a our survey of experienced, top-performing reviewers for GIE who are experts in their field. New reviewers, or international reviewers whose primary language is not English, may take longer than 3 hours to thoroughly review a manuscript.



Do I always have to do a literature search, even if I am an expert in the field?

- The answer is definitely yes.
- Based on a recent survey, top-performing GIE reviewers always set aside some time to review the literature before putting into writing their critique.

NOTES

Budget your time wisely. You may want to request from your local library relevant articles soon after you accept an assignment in order to meet the 2-week deadline. Remember, you are being judged not only on the quality of your work, but also your punctuality.

Guide for a Successful Review

1. Always search for similar papers in Medline.
2. After providing a brief summary of the study, break down your critique into *Major* and *Minor Comments*.
3. Identify conflicts of interest and ethical issues.
4. Section by section identification of strengths & weaknesses (Abstract, Methods, Results, Discussion).
5. Does it need to be reviewed by a statistician?
6. All reviews should have specific comments to the Associate Editor.

NOTES

We also have reviewers who are radiologists and pathologists if you have concerns on the quality and accuracy of the images. If so, you need to alert the Associate Editor.

Give specific instructions to authors on improving the Discussion section. For example, provide a brief description of alternative therapies and results from similar studies in the literature, and discuss possible sources of bias (patient recruitment, lost to follow-up, etc).

What might improve the quality of reviews?

- Reward/acknowledgement?
- Careful selection?
- Training?
- Greater accountability (open review on the web)?
- Associate Editor feedback to the reviewer?
- CME credits

NOTES

The Editorial team of GIE is well aware that reviewing can be a thankless job. Rest assured your efforts do not go unnoticed. We are also open to innovative ideas to improve the review process. If you have any comments or questions, please contact us.

Other Helpful Resources

1. GIE Sample Peer Review of a Fictitious Manuscript.

<http://www.asge.org/assets/0/71542/71546/8FB08AFA-9230-422C-9BB5-AEFDEC2EA04A.pdf>. Accessed August 2015.

2. A guideline for reviewing a clinical research paper.

Gastrointest Endosc. 2015 Aug;82(2):233-6.

Congratulations! You have completed the *GIE*
Reviewers' Course.

Time to take the test!

Please click on the link below to complete a brief test.

<http://www.zoomerang.com/survey.zgi?p=WEB22683S6L2B3>

Thank you!