Case Reports
Getting Published

José G. Merino, MD, MPhil
US Clinical Research Editor, The BMJ

Howard University, September 2015
Case Reports: An Editor’s Perspective

José G. Merino, MD, MPhil
US Clinical Research Research Editor, The BMJ

Howard University, September 2015
Disclosures

• I contribute to the overall strategy, lead policies and practices on research articles in the BMJ

• I influence and make decisions on which research to accept

• BMJ is founding member of ICMJE and COPE

• Outreach activities such as this one might increase submissions

• I am a full-time employee of Johns Hopkins Community Physicians. The BMJ pays JHCP for my services as an editor
Why Case Reports?

- Widely read
- Early evidence of harm
- Introduction to academic writing
- Experience and career development
Elements of a Good Case report

- Zebras vs. Horses?
- Focused message
- Clinical lessons
- Worthy of discussion
Types of Case Report

- Pathogenesis or adverse effects
- Global health
- Learning from errors
- Myth explored
- Important clinical lesson
- Rare disease
- New disease/syndrome
- New dx procedure
- New treatment
- Images in...
- Unexpected outcome
- Unusual association
- Unusual presentation
Elements of a Good Case Report

- Clear writing
- Courage
- Judicious use of tables and images
- Understand the audience
- Describe thought process
- Certainty about diagnosis
- Cautious interpretation
- Patient perspective
Finding and Writing Case Reports

- Look all around
- Do not procrastinate!
- Literature
- Images
- Consent
Getting Published in a High Impact Journal: An Editor’s Perspective

José G. Merino, MD, MPhil
US Clinical Research Editor, The BMJ

Howard University, September 2015
Research Question

SOUNDING BOARD

PICKING A RESEARCH PROBLEM

The Critical Decision

There is probably no question that plagues investors, especially young investors, more than how to pick a research project. This decision is not one that must be faced only once in a lifetime; rather, it must be continually revisited. Although it is easy to assume that success in research is just the difference between good and bad luck (and indeed there is a certain amount of luck in research), most highly regarded investigators will have many successful research experiences during their careers.

For the new investigator and junior faculty member just starting his or her career, the decision about a research project is further complicated by many other questions. How should one weigh high-risk, high-interest projects against lower-risk projects of lower interest? How similar or different should the project be from work done during one’s postdoctoral fellowship? Can one remain in the same institution as one’s postdoctoral mentor and still make an impact, and if so, how is this best achieved? How many different projects should an investigator attempt to be involved in or undertake? How important is complete independence? When is collaboration good, and with whom? Should the M.D. investigator do anything differently from the Ph.D. investigator in picking a research project? What do you do when you are faced with some aspect of a project for which you are not technically prepared? How should one balance projects funded by the National Institutes of Health (NIH) against projects without such funding? In contrast to the rich scientific base that underlies the research itself, little has been written to help the investigator facing these challenges.16 Clearly the answers to these questions depend on the exact circumstances, background, expertise, and desires of the individual investigator, but every investigator should have a strategy for picking a research problem that optimizes the chances of success.

The first step in picking a research project is to understand what makes research “good.” Indeed, considering the extremely competitive nature of research funding and the rigorous review process used by top academic institutions for promotion, this question should be more accurately phrased, “What makes a research project outstanding?” Certainly, there are fundamental characteristics that everyone would agree are important. The study should be well performed and use appropriate and up-to-date forms of technology. The data should be carefully analyzed and accurately reported. For studies involving animals and humans, ethical considerations must be dealt with appropriately. But is this enough? Are these the variables that make us feel that the work of one investigator is superior to the work of another? Usually not.

In my opinion, there are several features that make a research project “outstanding.” First, it must ask important questions. If the question is not important, then it is likely that no matter how carefully the study is performed, how accurately the results are tabulated, or how well the work is reported, this will not be viewed as an outstanding piece of work. Second, if possible, the project should have the potential to yield a “seminal” observation — one that creates truly new knowledge, leads to new ways of thinking, and lays the foundation for further research in the field. We often recognize a seminal observation as the first major publication in an area, which sets the stage for subsequent work and will be followed by many reports from the same and other laboratories extending and developing the point and expanding it to related areas. If these first two criteria are met, the remaining criteria for good research are usually easily fulfilled. Thus, the results of the project will be publishable in respected journals, recognized and cited by peers, presentable at high-quality meetings in the field, and of course, fundable on competitive grant review.
Research Design

What's going on?

- Descriptive (PO)
  - Survey (Cross sectional)
  - Qualitative
- Analytic (PICO or PECO)
  - Experimental
  - Observational
- Can it/does it work?

- (Randomised)
  - Parallel Group
- (Randomised)
  - Crossover
- Observational
  - Cohort Study
  - Cross Sectional
  - (Analytic)
  - Case-Control Study

How/why/when is it happening?

Population (P) Outcomes (O), Interventions (I) or Exposures (E)

Ethics
Registration
Authorship
Data Sharing

Centre for Evidence Based Medicine, Oxford, UK www.cebm.net
Disseminating Research

"[The scientist writes because] he (1965!) found something that was not known before."

Why did you start?
What did you do?
What answer did you get?
And what does it mean anyway?

Bradford Hill A. BMJ 1965 (ii); 870-1
36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports...

October 2013 modification

## Getting Published...

<table>
<thead>
<tr>
<th>Journal</th>
<th>Research papers</th>
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</tr>
<tr>
<td>JAMA</td>
<td>4700</td>
<td>4%</td>
</tr>
<tr>
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<td>3000</td>
<td>4%</td>
</tr>
<tr>
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<td></td>
<td>3%</td>
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<td></td>
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<td>Stroke</td>
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<tr>
<td>JACC</td>
<td></td>
<td>17%</td>
</tr>
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<td>PLoS One</td>
<td></td>
<td>69%</td>
</tr>
</tbody>
</table>

Data from websites accessed June 2, 2014
What Are Editors Looking For?

- Importance
- Originality
- Relevance to the audience
- Real potential to improve decision making
- Truth and transparency
- Clear writing that people want to read
- Excitement/ “wow” factor
Plan Ahead

Before you start your project
Reporting Guidelines

- CONSORT: RCT
- PRISMA: SR or MA
- MOOSE: MA (obs)
- STARDS: Dx accuracy
- STROBE: Observational
- GRADE: Guidelines
- CHEERS: Economics

Advice on information required to help readers assess the methodology

http://www.bmj.com/about-bmj/resources-authors/article-submission/article-requirements
The ICMJE member journals will require, as a condition of consideration for publication in their journals, registration in a public trials registry...
35. Every research study involving human subjects **must be registered in a publicly accessible database before recruitment of the first subject.**

October 2013 modification

Let others see what was done: who did what, to whom, how, and what happened (harms and benefits)

Zarin DA, Tse T. Science 2008;319:1340-42
# Trial Registration

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Beneficiaries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfill ethical obligations to participants and community</td>
<td>Patients, public, research community</td>
</tr>
<tr>
<td>Provide information to potential participants and referring clinicians</td>
<td>Patients, clinicians</td>
</tr>
<tr>
<td>Reduce publication bias</td>
<td>Users of the medical literature</td>
</tr>
<tr>
<td>Help editors and others understand the context of the study results</td>
<td>Journal editors, users of the medical literature</td>
</tr>
<tr>
<td>Promote more efficient allocation of research funds</td>
<td>Granting agencies, research community</td>
</tr>
<tr>
<td>Help IRBs determine appropriateness of a research study</td>
<td>IRBs, ethicists</td>
</tr>
</tbody>
</table>

Zarin DA, Kesselman A. Chest 2007;131:909-12
Common Deficiencies Addressed by Reporting Guideline and Registration

• Non-reporting of studies
• Incomplete reporting
  – Omission of crucial aspects (participants, interventions, randomization)
  – Incomplete results (cannot be included in MA)
  – Inadequate harm reporting
• Selective reporting
  – Outcomes
  – Analyses

Modified from Simera I.2013 in Science editor’s handbook. www.ease.org.uk
Common Deficiencies Addressed by Reporting Guideline and Registration

• Misleading reporting
  – Misinterpretation of study findings, “spin”
  – Misrepresentation of study design
  – Unacknowledged discrepancies between sources of information (protocol, registration, manuscript)

Modified from Simera I.2013 in Science editor’s handbook. www.ease.org.uk
Authorship

The ICMJE recommends that authorship be based on the following 4 criteria:

• Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
• Drafting the work or revising it critically for important intellectual content; AND
• Final approval of the version to be published; AND
• Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

http://www.icmje.org/roles_a.html
Contributors who meet **fewer than all 4 of the above criteria** for authorship should not be listed as authors, but they should be acknowledged.

- Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are
  - acquisition of funding
  - general supervision of a research group or general administrative support
  - writing assistance, technical editing, language editing, and proofreading.

http://www.icmje.org/roles_a.html
• Concerns
  – Ghost-writing
  – Guest authorship
  – Fraud and misconduct
Preparing The Submission

Writing the paper
Choosing a journal
Why did you start?
What did you do?
What answer did you get?
And what does it mean anyway?

Bradford Hill A. BMJ 1965 (ii); 870-1
Number of Titles Currently Indexed for *Index Medicus*® and MEDLINE® on PubMed®

As of November 2014, 5,642 journals are currently indexed for MEDLINE. MEDLINE includes journals that are cited as *Index Medicus* as well as other non-*Index Medicus* journals. A breakdown is provided:

<table>
<thead>
<tr>
<th>Number of Journals</th>
<th>Subset of Journals Currently Indexed*</th>
</tr>
</thead>
<tbody>
<tr>
<td>5,117</td>
<td>journals indexed as <em>Index Medicus</em></td>
</tr>
<tr>
<td>525</td>
<td>additional, non-<em>Index Medicus</em> journals in the following areas:</td>
</tr>
<tr>
<td></td>
<td>86 Dentistry (contribute to Citation Subset=D)</td>
</tr>
<tr>
<td></td>
<td>13 AIDS/HIV (contribute to Citation Subset=X)</td>
</tr>
<tr>
<td></td>
<td>12 Consumer Health (contribute to Citation Subset=K)</td>
</tr>
<tr>
<td></td>
<td>178 Nursing (contribute to Citation Subset=N)</td>
</tr>
<tr>
<td></td>
<td>97 Health care administration and delivery (contribute to Citation Subset=H)</td>
</tr>
<tr>
<td></td>
<td>61 Health care technology indexed by NICHSR/NLM (contribute to Citation Subset=T)</td>
</tr>
<tr>
<td></td>
<td>78 History of medicine core journals indexed fully by HMD/NLM (contribute to Citation Subset=Q or Q5S)</td>
</tr>
</tbody>
</table>

*NLM started a long-term project in July 2013 to identify indexed journals that may have ceased or for which NLM is no longer receiving data. This explains why the number of journals may decrease over time.*
Selecting a Journal

- Purview of the journal and topic match
- Audience
- Acceptance rate
- Access
- Measures of influence
“We publish research that translates scientific discoveries into practical applications and helps doctors make better decisions in the clinic and in research, public health, and health policy settings. If your research is novel, ethical, and methodologically robust, and it deals with questions that are directly related to clinical care, public health, or healthcare policy, we invite you to submit it to the BMJ.”

Research that the BMJ prioritizes (not in order of importance):
- Systematic reviews and meta-analyses of risk factors, outcomes, and treatments
- Studies of the risks, advantages, and properties of diagnostic tests
- Clinical and population based observational studies that look at the causes, prognosis, risks, and safety of common diseases or therapies
- Clinical observational studies that provide support for inferences applicable to clinical practice or healthcare policy
- Clinical trials that compare the effectiveness and safety of drugs, devices, or other interventions that are tested against the optimal current treatment at clinically valid doses

Merino JG. BMJ 2013; 346:f2433
A guide to research partnerships for pragmatic clinical trials

Karin E Johnson research associate, Chris Tachibana scientific editor and writer, Gloria D Coronado senior investigator, Laura M Dember professor of medicine, Russell E Glasgow associate director, Susan S Huang associate professor and medical director of epidemiology and infection prevention, Paul J Martin medical director, Julie Richards project manager, Gary Rosenthal professor, Ed Septimus medical director infection prevention and epidemiology, Gregory E Simon senior investigator, Leif Solberg associate medical director for care improvement research, Jerry Suls senior scientist, Ella Thompson project manager, Eric B Larson vice president for research

1Group Health Research Institute, Seattle, WA 98101, USA; 2Kaiser Permanente Center for Health Research, Portland, OR 97227, USA; 3University of Pennsylvania Perelman School of Medicine, Philadelphia, PA 19104, USA; 4Colorado Health Outcomes Program, University of Colorado School of Medicine, Aurora, CO 80045, USA; 5University of California Irvine School of Medicine, Irvine, CA 92697, USA; 6Clinical Research Support, Fred Hutchinson Cancer Research Center, Seattle WA 98109, USA; 7Internal Medicine, University of Iowa, Iowa City, IA 52242, USA; 8Clinical Service Group, Hospital Corporation of America, Nashville, TN 374022, USA; 9HealthPartners Institute for Education and Research, Bloomington, MN 55425, USA; 10National Cancer Institute, Bethesda, MD 20892, USA
Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith, Jill P Pell

Abstract

Objectives To determine whether parachutes are effective in preventing major trauma related to gravitational challenge.

Design Systematic review of randomised controlled trials.

Data sources: Medline, Web of Science, Embase, and the Cochrane Library databases; appropriate internet sites and citation lists.

Study selection: Studies showing the effects of using a parachute during free fall.

Main outcome measure: Death or major trauma, defined as an injury severity score > 15.

Results: We were unable to identify any randomised controlled trials of parachute intervention.

Conclusions: As with many interventions intended to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised controlled trials. Advocates of evidence-based medicine have criticised the adoption of interventions evaluated by using only observational data. We think that everyone might benefit if the most radical protagonists of evidence-based medicine accepted intervention was a fabric device, secured by strings to a harness worn by the participant and released (either automatically or manually) during free fall with the purpose of limiting the rate of descent. We excluded studies that had no control group.

Definition of outcomes

The major outcomes studied were death or major trauma, defined as an injury severity score greater than 15.

Meta-analysis

Our statistical approach was to assess outcomes in parachute and control groups by odds ratios and quantified the precision of estimates by 95% confidence intervals. We chose the Mantel-Haenszel test to assess heterogeneity, and sensitivity and subgroup analyses and fixed effects weighted regression techniques to explore causes of heterogeneity. We selected a funnel plot to assess publication bias visually and Egger’s and Begg’s tests to test it quantitatively. Stata software, version 7.0, was the tool for all statistical analyses.

Results
Choosing Your Audience

Specialist, Researcher, Clinician, Generalist...
Access

• Open access
  – the world-wide electronic distribution of the peer reviewed journal literature and completely free and unrestricted access to it by all scientists, scholars, teachers, students, and other curious minds

  Budapest Statement (Bethesda, Berlin)

  – Gratis open access- free online
  – Libre open access –gratis + usage rights (CC
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Open Access

• **Gold**
  – Document made available by publisher
  – Direct, delayed, hybrid
  – Gratis and libre

• **Green**
  – Self archiving in open access repository
  – Gratis access
    • Institution, central (PubMed Central)
## Acceptance Rate

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Data from websites accessed June 2, 2014
Measures of Influence

• Impact Factor
  – Developed to help librarians

  \[ \text{IF2013} = \frac{\# \text{ times that papers published in 2011-12 were cited in 2013}}{\# \text{ citable papers published in 2013}} \]

• Other measures to analyze scholarship
  – Based on social web
  – Altmetrics, ImpactStory, readerMetric, Sciencecard...
Role of quality measurement in inappropriate use of screening for colorectal cancer: retrospective cohort study

Sameer D Saini research scientist, Sandeep Vijn research scientist, Philip Schoenfeld research scientist, Adam A Powell research scientist, Stephanie Moser data analyst, Eve A Kerr director and research scientist

Abstract

Objective To examine whether the age based quality measure for screening for colorectal cancer is associated with overuse of screening in patients aged 70-79 in poor health and underuse in those aged over age 75 in good health.

Introduction

Individual risk/benefit to ensure that patients who are likely to benefit from a service receive it (regardless of age), and that those who are likely to incur harm are spared unnecessary and costly care.
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Submitting the Paper

Cover letters
Peer review
BMJ Peer Review Process

- Research submitted: 4-5000 annually
- Screen: 3-4000 rejected
- External review: Approx 1000 for open review, 500 then rejected
- Editorial meeting: 500 with Editor and adviser, statistician, BMJ team
- Accept: 4-7% with Open access, No word limits, BMJ pico Editorials
Peer Review

• “the evaluation of research findings for competence, significance and originality by qualified experts...”
  – Allchin D, 1993

• 1731 Medical Essays and Observations (RS of Edinburgh)

• 1893 BMJ

• 20th C other journals
Peer Review

- Slow
- Expensive
- Profligate of academic time
- Highly subjective
- Prone to bias
- Easily abused
- Poor at detecting errors
- Almost useless at detecting fraud

“Better for improving what is eventually published than for sorting out the wheat from the chaff”

• Fair hearing among scientists
• Advise editors, help authors
• What makes a good review
  – Critical, courteous and constructive
  – Address novelty, relevance, timeliness, clinical significance
• How do we identify reviewers?
• COI, confidentiality
Peer Review

• Limitations
  – Time
  – Expertise
  – “apt to be swayed by the current vogue in their discipline.” (Ian Douglas-Wilson, 1977)
Peer Review

• Different models
  – Blinded
  – Open
  – Very open
  – Post-publication

• Incremental increases in openness
Peer Review

- Arguments for open review
  - Secret judges
  - Accountability: Link privilege and duty, ... power and responsibility
  - Link accountability with credit
  - Eliminate secrecy (avoid procrastination, plagiarism, fraud)
Peer Review

• Arguments against open review
  – Less critical and less useful reviews
    • Trials
      – Open (tell reviewers authors will know identity)
      – Very open (tell reviewers comments posted online)
  – Negative effect on relationships among individuals in same field
    • Yellow card (1 episode in 5 years)
    • Large vs. small fields?
  – Extra time required
Addressing Reviews

• Most editors and reviewers want to be helpful
• Follow journal instructions
• Address all comments, OK to disagree
• Avoid shortcuts
• If rejected, tell next journal how you addressed these points
Post-Publication Review

• Rapid responses
• Letters to the editor
• Other models (F1000)
  – Pre-publication reviewers have little time, limited expertise, limited data access
Thank you!

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@JG_Merino