Pitfalls in Research

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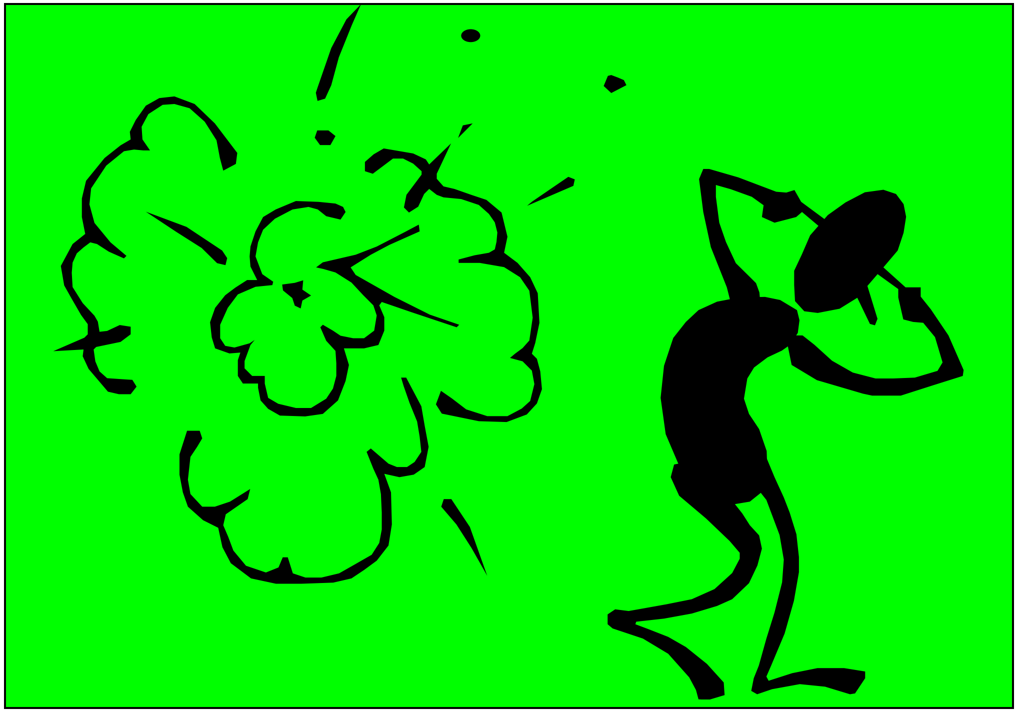
Objectives

Following this lecture, the participants will be able to

1. List common pitfalls in selecting the clinical ***research question***
2. Describe ***method*** pitfalls
3. List common ***ethics review*** problems
4. Outline ***budget*** research pitfalls
5. List areas where ***time*** is the constraint in research
6. Discuss the factors that lead to ***misleading or erroneous research conclusions*** and prevention steps



Problems with the Research Question…

1. The Question

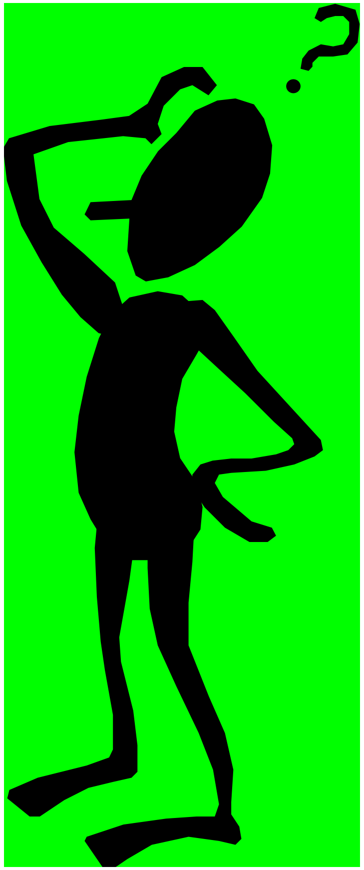
F easible

I nteresting / important

N ovel

E thical

R elevant



Farrugia P et al. Research questions, hypotheses and objectives. Can J Surg 2010; 53: 278-81.

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FINER - Feasibility

Can this question/ project be done?

Subjects

– How many?
– From where?
– How will you recruit them?

How will you collect and analyze the outcome data?****

– Has it been done before and can you use the same tools?
– Expertise?
– Money?
– Equipment?

*** MR problems

FINER – Feasibility cont'd

- Is your question tight enough or are there too many secondary questions?

The Question → **the QuestionSSSSS.....**

- How long will it take?

“PICOT”

If checking on an intervention or making a comparison:

P= PATIENTS or POPULATION

I =INTERVENTION

C=COMPARISON

O=OUTCOME

T=TIME

PICOT may help you think your question through

FINER - Interesting?

- Do you really care about this?
- Will you still care about it in a year?
- Does your team care about this? Your mentor/coach?
- Would your target audience care about the answer(s) to this question? (community, health leaders, journal readers, etc)

Nothing great is ever achieved without enthusiasm. Emerson

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FINER – Novel?

- Has this been addressed before?
- If yes, how would this differ?
- Would your project provide any new information?
- Would your project confirm/refute earlier findings?

FINER - Ethical Issues

- Is there a sound scientific research design?
- Is the risk/benefit balanced?
- Is there a plan for safety monitoring if this is an intervention?
- Do the researchers have a conflict of interest?

STAY TUNED FOR MORE ON ETHICS later in the workshop

FINER – Relevance

- Will it be of interest to anyone else?
- Will it be important to the community/population you are studying?
  - Beyond this community?
- Will the outcome potentially change health practices/training and/or policies?

2. Problems with the Methods….

"A researchable question is an uncertainty about a problem that can be challenged, examined, and analyzed to provide useful information"

Methods must fit the question

2. The Methods

Most common error

Methods not match question

	Quantitative	Qualitative
Research Aims	***Test hypotheses*** and establish cause and effect	***Understand social phenomena*** in their natural settings
Study Design	***Formal, objective, and systematic***	***Observational, holistic, and flexible***
Sampling	Unbiased cross-section **representative** of the study population	Strategically ***selected*** to collect the most meaningful data
Methods	Measurement yielding ***numeric data***	Interviews and observations yielding ***textual data***
Analysis	Emphasis on statistical techniques to determine ***significance***	Identify ***themes*** that emerge from the data

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Experimental Design

Investigators

same paradigm,

different design,

different results

marcocg.com/.../PAIN_Logo_final.png

e.g. pain assessment

patient survey vs healthcare worker observation

RCT vs cohort study vs case series

Carefully plan research design

2. The Methods- cont'd

No Patients/no patience

Barriers & obstacles: timing (season), hiring

Changes during study- protocol, personnel, pop, techniques

Data missing or not accurately recorded

Ordinality of Data

Ordinality: a number denoting relative position in a sequence, such as *first, second, third*.

Data: **first order**- directly from lab machine or weight scale print out

second order- HCW writes down these numbers in chart

third order- researcher extracts these numbers from chart

Errors increase as ordinality increases- try for first order data if possible. Minimize # times human records data

Problems with the Ethics Review….

3. Ethics Review

Research design issues

- question
- population
- randomization/controls
- methods- validation
- benefits vs risks/
    - safety and safety monitoring
- technical: qualitative, quantitative analysis
- COI

Consent issues

Data integrity, management, storage

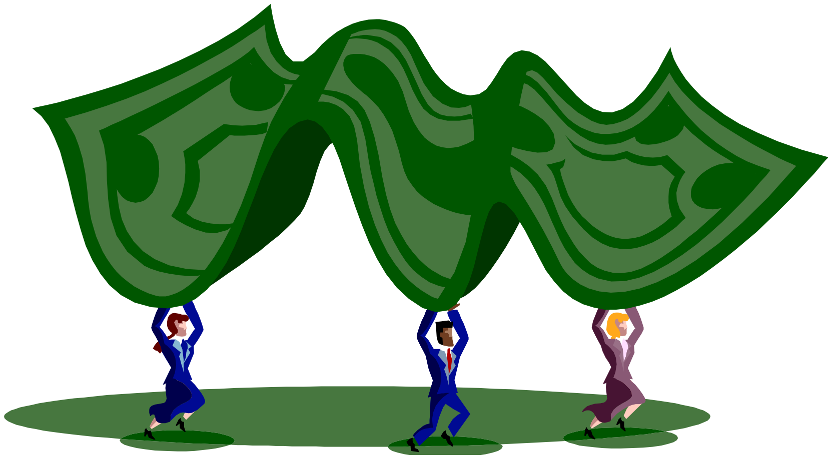
Outcomes/feedback to participants

Problems with the Budget…..

4a. Budget Preparation

- Budget not add up!
- Over budget allowed by granting agency
- Vague or little justification for costs
- Costs not allowed by granting agency
- Not realistic; not related to grant content

4b. Budget Application



“Leaking” money

Unanticipated costs & inflation

Timing of budget

Time/paperwork spent on budgeting

Audits- “paper” trail

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Problems with Time….

5. Time

Time to write grant

Time to get Ethics approval

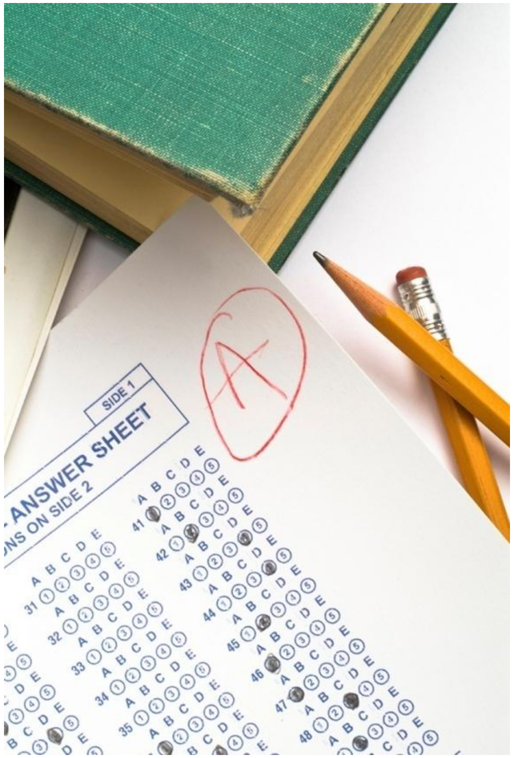
Time to recruit

Time to manage grant

Time to collect data

Time to analyze and write up

6. Problems with misleading or erroneous results or conclusions



Investigator / Experimenter

- maybe one and same
- very different tasks

Investigator:

design, analyze, interpret, report

Experimenter:

does the study

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6A. Misleading Results or Conclusions

Investigator Effects

1. Paradigm
2. Experimental Design
3. Loose Procedure
4. Data Analysis
5. Fudging

Theodore Barber. *pirate.shu.edu/~hovancjo/exp_read/barber.htm*

1.Paradigm Problem

Investigator:

Experienced problem solvers

Work well within paradigm

Fail to see "events' not fit assumptions in paradigm

H pylori and ulcers- Marshall and Warren *Lancet 1984;1: 1311-1315*.

Mortality after fluid bolus in African children with severe infection- Maitland et al *N Engl J Med 2011 364(26):2483-95*

Test multiple hypotheses not only one preferred

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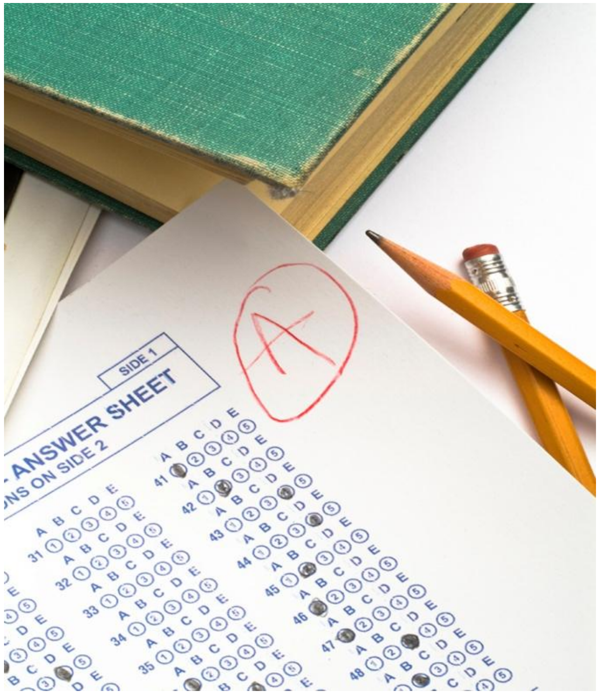
2. Design Problem

Study design	Common errors
Randomized trial	lack of blinding lack of concealed randomization exclusion of dropouts type II (beta) errors – insufficient sample size type I (alpha) error – overuse of statistical tests and multiple outcomes
Prospective cohort (with comparison group)	lack of adjustment for differences in characteristics between treatment and comparison groups type II (beta) errors – insufficient sample size type I (alpha) error – overuse of statistical tests and multiple outcomes
Prospective case series (without comparison group)	lack of independent or blinded assessment of outcomes lack of follow-up
Case-control study	recall bias problems in ascertainment of cases and controls type II (beta) errors – insufficient sample size type I (alpha) error – overuse of statistical tests and multiple outcomes
Retrospective case series (with comparison group)	recall bias type II (beta) errors – insufficent sample size type I (alpha) error – overuse of statistical tests and multiple outcomes incomplete reporting in patient charts
Retrospective case series (without comparison group)	incomplete reporting in patient charts lack of follow-up recall bias

Zlowodzki M et al. Med Princ Pract 2005; 1-8.

3.Loose Procedure



Experimental protocol -imprecise

Survey - no formal script
- no systematic prompts
- none or limited documentation

Intervention – not verified actually occurred

Take care all procedures developed in advance and clear - do test run

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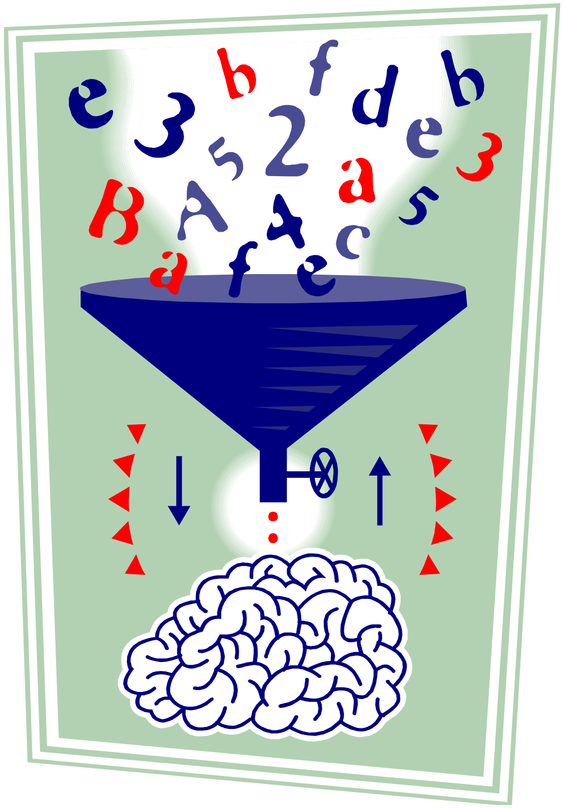
4. Data Analysis



Not pre planned

Incidental unrelated data
report this only

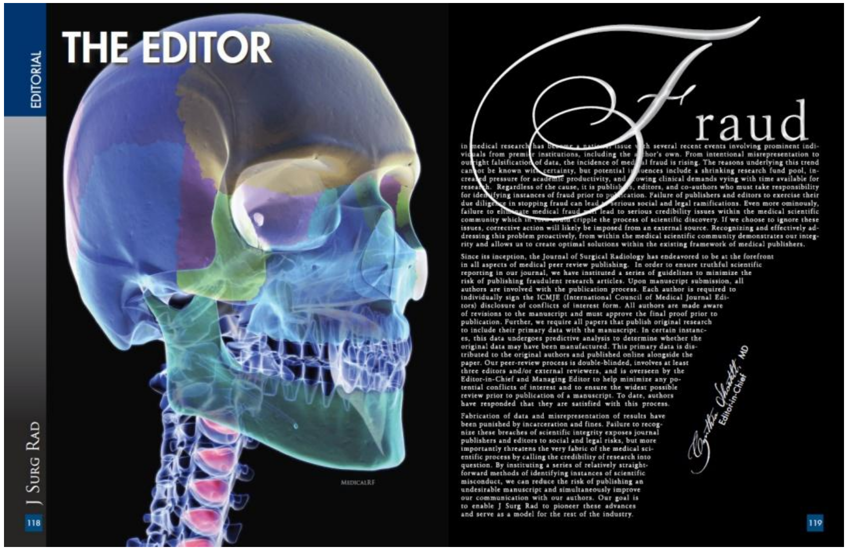
Re-analyze until find significance

Fail to report negative data –omit selection bias

Strength of association not given – only signif

Get professional help, plan in advance

5. “Fudging”



www.surgisphere.com/…/E01/Figure-1.jpg

Investigator intentionally reports results that are not actually obtained….

6B. Misleading Results or Conclusions cont’d

Experimenter Effects

6. Personal Attributes
7. Failure to Follow the Procedure
8. Experimenter Mis-recording
9. Fudging
10. Unintentional Expectancy
    -looking for the effect

Select, train and supervise experimenter well

Additional Problems: Authorship

For grant

papers

abstracts

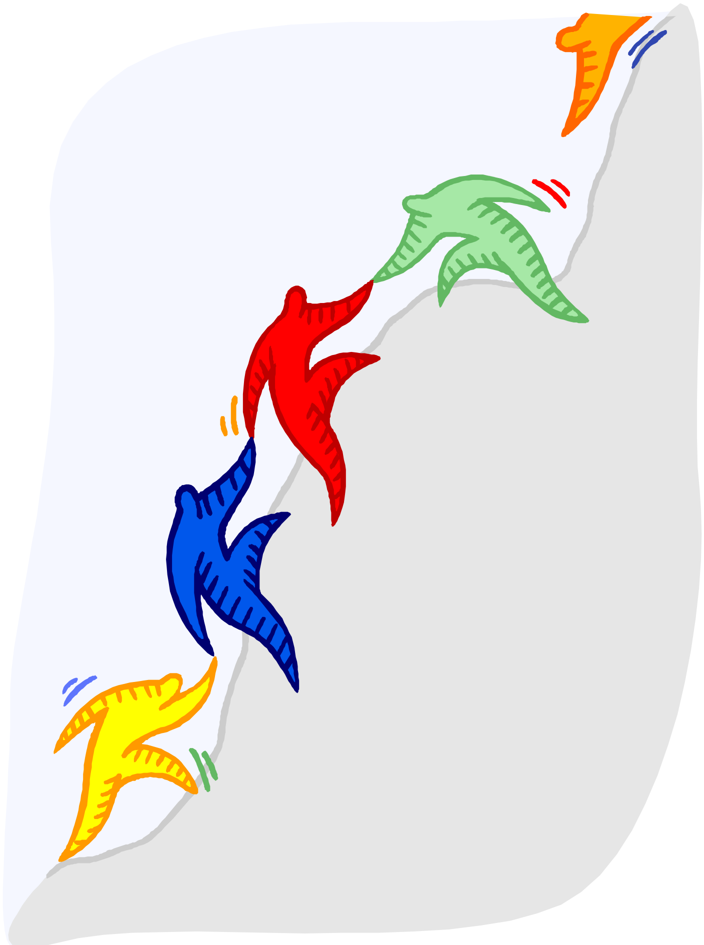
Discuss in What Editors are Looking for

Research Preparations: Be Wise

Time spent in preparation reaps big benefits in the quality and usefulness of the research results

Next Steps- MR Teams

What are the “ golden rules” for good MicroResearch team function?



10 Rules for Good MR Team Work

1. **MR Team proposal** has the **highest priority** Commit to the MR team selected project over personal agendas is essential.
2. **Be present, contribute and listen to the contributions of others – there is no inequality in a MR team.** All must be welcomed to participate; all need to be punctual and respectful
3. **Decisions are based on what's right – not who's right.** Position, status, seniority or authority are not reasons for a MR team to make a decision based on any individual's recommendations.

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Adapted form Suzanne Murphy, Work Systems Affiliates. http://www.wsa-intl.com/210-top-10-rules-for-teams

10 Rules cont'd

4. **Contribute with energy, homework and hard work and flexibility –** bring your time, skills and an open mind to the table.

5. **Share the MR proposal development work load-** and complete your MR team tasks in timely fashion

6. **Proposal decisions are based on MR teams finding of facts and analysis** – not on opinions

10 Rules cont'd

7. **Don't let perfection be the enemy of good - the 80-20 rule prevails-** An 80 percent solution is better than the continued search for the "perfect" proposal without any action.

8. **Consensus prevails –**do not get stuck; make decisions

9. **Choose a chair for the MR Team.** Does not mean will be Proposal Leader- but leads Team now

10. **Make an email list serve to help with communication**

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Team Work – Day 2

1. Choose a Chair for the MR Team; make an email list for communications
2. Each team member presents their burning research question
3. MR team reviews each question through the FINER lens
4. Discuss and choose the question MR Team will develop and the rational for why this question
5. Start to refine question –think about methods could use as refine question

Team Work – Day 2 cont'd

Prepare short PPT

1. List team #i.e. MR Team 1, members of team, their profession
2. List each burning question reviewed by the team (not name who suggested it)
3. List the selected question (and why met FINER criteria- this can be done verbally not on slide)
4. Select a MR Team member to present this PPT on Day 3 i.e. tomorrow.