Best Practices for Partnering with a Biostatistician in your Research

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K-Club
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Accompanying Panelists

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Agenda

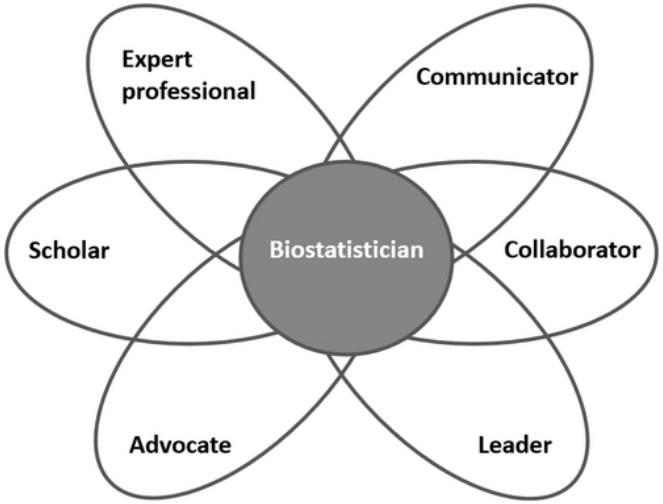
- What is a biostatistician? (Brief Introduction)

- Tips for effectively partnering with a biostatistician in your research
  - Panel discussions and audience participation (4-5 minutes per tip)

What is a biostatistician?

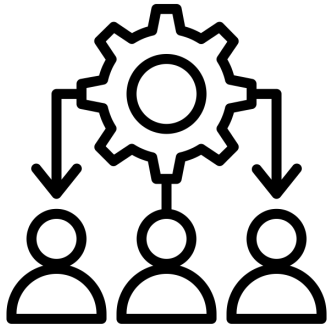
- Biostatisticians develop and apply statistical methods to biomedical and health data

- Partner with other health field professionals to advance scientific discovery:
  - Design studies
  - Make data collection decisions
  - Analyze and interpret data
  - Write articles for dissemination



Biostatistician Make-up

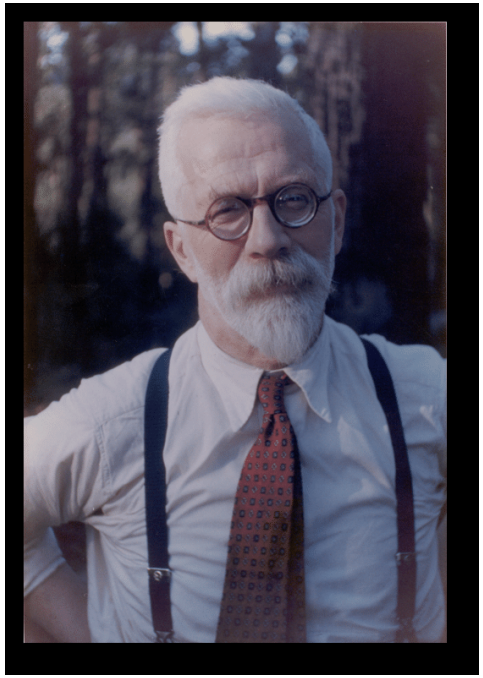
- An experienced biostatistician is competent in four areas:
  1. Technical and analytical
     - Familiar with modern statistical methods and software coding
  2. Broad subject knowledge
     - Working knowledge of the biomedical content
  3. Communication
     - Ability to understand and be understood
  4. Problem-solving
     - Synthesize critical study components to answer research questions



Tip #1: Involve a biostatistician early!

To call in the statistician after the experiment is done may be no more than asking them to perform a post-mortem examination: they may be able to say what the experiment died of.

-RA Fisher



When to contact your biostatistician

A. Study conceptualization 

B. Study is conceptualized, but needs polishing 

C. Data collection phase, before study starts 

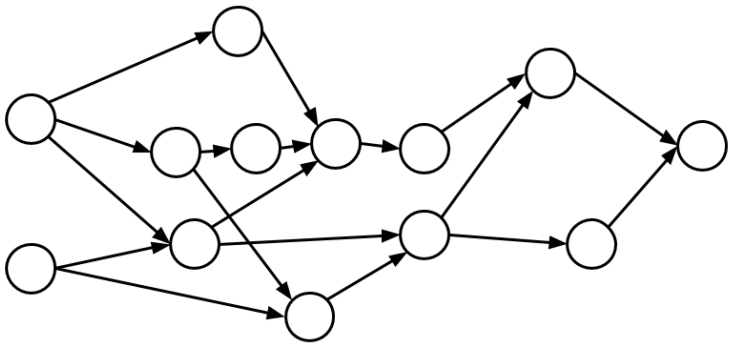
D. Data collected and needs analysis help 

E. Performed own analysis and needs checking 

F. Manuscript submitted, answering reviewer criticisms 

Advantages

- Help you think through technical objectives of research study
- Reconstruct research questions into research hypotheses, and ultimately, into statistical hypotheses to inform analysis
- Help identify variable types and roles
- Ensure available data and planned analysis are appropriate for answering the research question(s)



Tip #1: Involve a biostatistician early

Panel and Audience Discussions

Tip #2: Biostatisticians know more than you think

- Three broad areas where biostatisticians add value to the research enterprise:
  1. Data analysis
     - Interpretation; technical write-ups
  2. Study design
     - Hypothesis refinement; conceptualization of complex relationships between variables
  3. Education/communication
     - Presentations; journal clubs; one-on-one consultations

- Good data analysis should follow a SAP that compliments a strong study design and is understandable to PI(s)

But also…what information we may not know

- A statistician may lack specific subject knowledge for your study
  - You should not assume we are familiar with all acronyms, jargon, or instruments you propose to use (communication is key here)
- We are generally not database experts and may not be familiar with your data collection software
  - At Emory, we do see and can advise on, Redcap, Excel, some SQL databases
- We may not have experience with a niche method or analysis plan that is common for your field
  - Early contact, providing relevant papers, and table/figure mock-ups are helpful to educate your statistician on your data

Tip #2: Biostatisticians know more than you think

Panel and Audience Discussions

Tip #3: Biostatisticians are part of your expert team

- A complex study should bring together people of various expertise:
  - Scientists/clinicians
  - Biostatisticians
  - Data managers
  - Qualitative experts
  - Informaticians

- These individuals should be viewed as **co-collaborators** and <u>not just as a service</u>

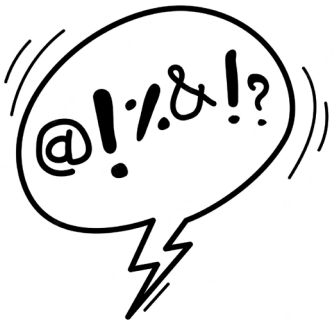
Inappropriate uses of a biostatistician

- Messages that make a biostatistician quiver:

"The grant is done. I just need a couple lines for the stats."

"Can you quickly look over my manuscript before I submit? I'm happy to make you a co-author."

"Can you help me with a quick power calculation?"



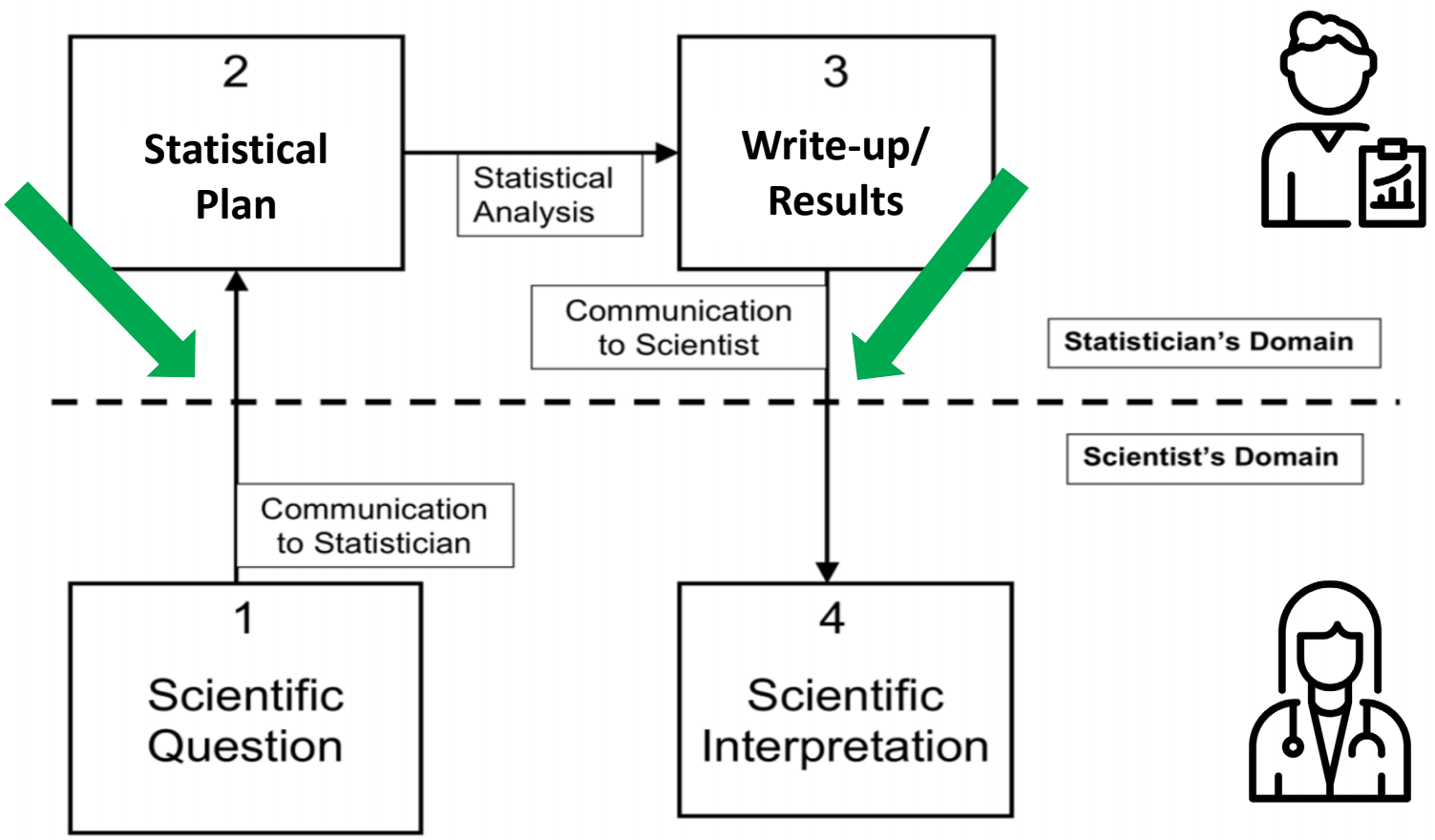
“Can you help me with a quick power calculation?”

- Statistical power calculations are often recommended when submitting a grant
  - Sample size needed to show a statistically significant effect (i.e., $p<0.05$, if one exists in the population of study)

- A power calculation should:
  - Ideally be based on data from the literature or pilot information
  - Flow naturally (and holistically) with the study aims and SAP

- Requesting a power calculation without knowledge of aims/SAP is akin to asking a doctor to diagnose without knowledge of symptoms or prior medical history

General collaboration flow for a biostatistician



Samsa, GP. "A day in the professional life of a collaborative biostatistician deconstructed: Implications for curriculum design. *Journal of Curriculum and Teaching*. 2018. Vol. 7(1): pp 20-31. doi:10.5430/jct.v7n1p20"

Tip #3: Biostatisticians are part of your expert team

Panel and Audience Discussions

Tip #4: Plan appropriately for collaboration

- General timing recommendations:
  - **20 business days** for **initial report**
  - **30 business days** for **intramural** grant preparation
  - **40 business days** for **single project extramural** grant preparation (e.g., R03, R21, R01, K grants, small foundation awards)
  - **60 business days** for **complex multi-project extramural** grant preparation (e.g., P30, P50, P01, U54, large foundation awards)

Collaboration Deliverables: Grants

- Not just about including a SAP and power analysis
- A biostatistician should provide critical review of your full proposal
- We look for clarity and consistency in language around:
  - Aims
  - Exposure-Outcome relationships
  - Study design
  - Data types, variables collected, and data management

Improving a Grant Aim

- Aim: Assess changes in redox potential following glucose ingestion
- Sub-Aim: Older age, female sex, and lower insulin production will be associated with weaker effect of glucose ingestion on redox potential

- Statistician Thoughts
  - No identification of cohort(s) or data sources
  - Needing clarity on temporality of “changes”
  - Are data paired? What are the data types?
  - Sub-aim: What does “weaker effect” mean?

Improving a Grant Aim

- Aim
  - Assess for paired change in redox potential from 0 to 120 minutes, following glucose ingestion, in a single cohort of CF patients aged 3-7 years at risk for developing CFRD

- Sub-Aim
  - Older age (6-7 yrs) will be associated with a reduced paired change in redox potential, following glucose ingestion, relative to younger age (3-5 yrs)

- Clearly defined sample, data types, exposure-outcome relationships, and anticipated relationships

Collaboration Deliverables: Grants

- Contingent on duration, size, and scope of your study, a biostatistician should provide you with feedback on FTE budget
  - Generic R01-type example

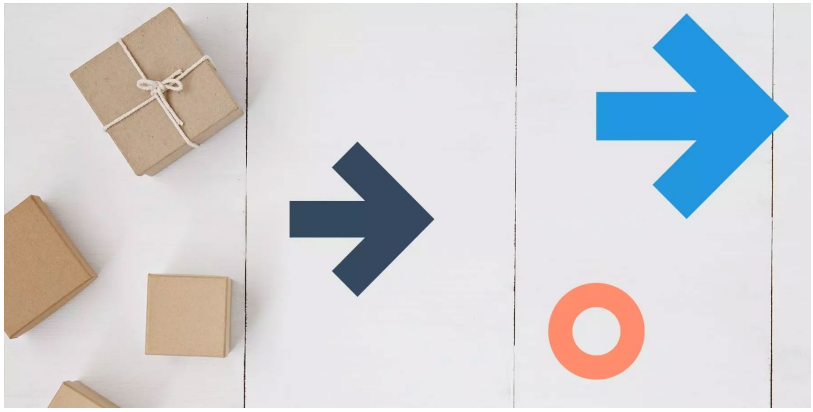
Grant Year 1	Grant Year 2	Grant Year 3	Grant Year 4	Grant Year 5
Biostatistician				
20%	10%	5%	5%	35%
Data Manager				
30%	15%	10%	10%	15%

- Speak with your expert team for specific FTE numbers appropriate for your study

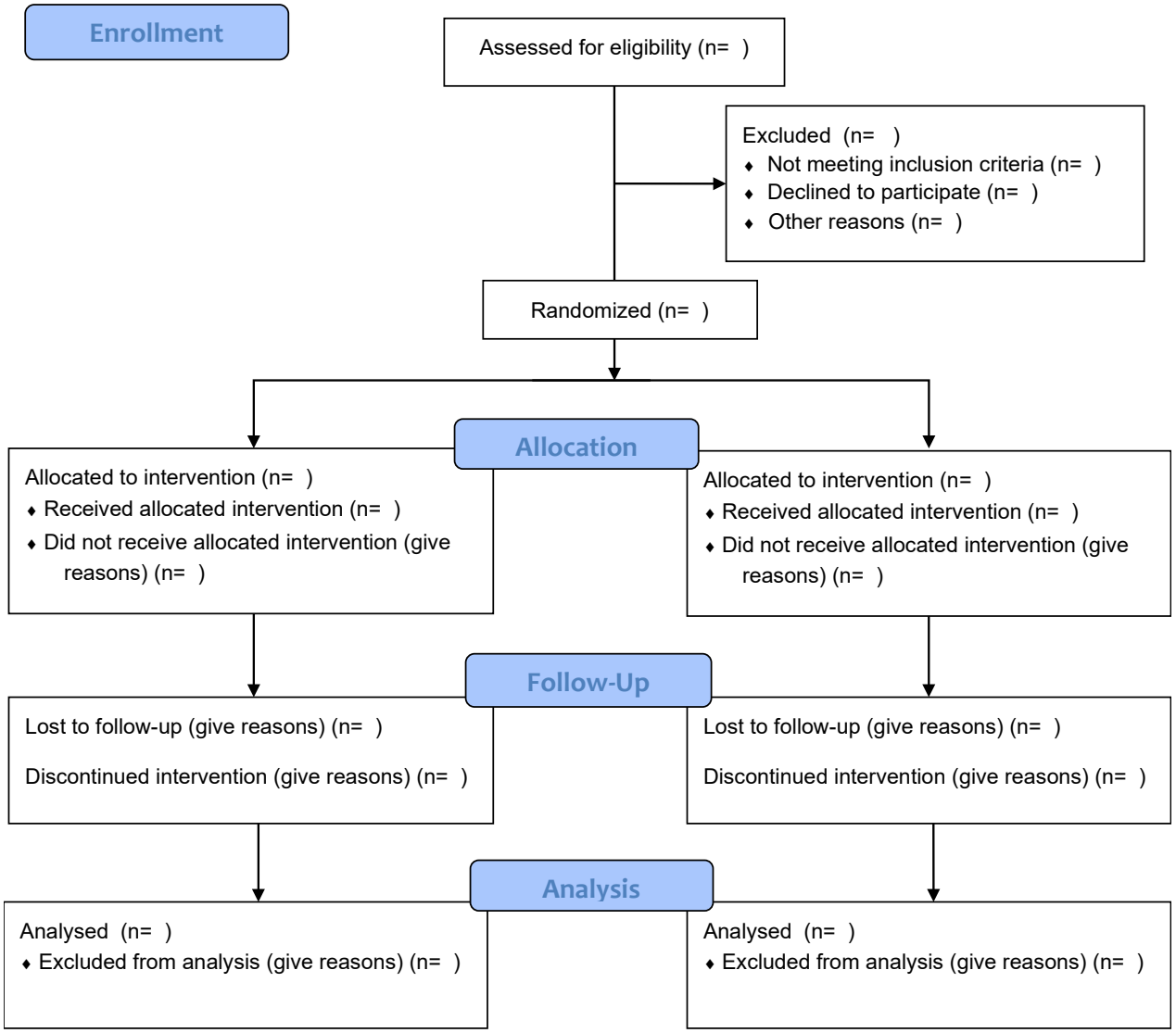
Collaboration Deliverables: Analysis

- The 80/20 rule for analysis:
  - 80% of analysis time is spent on data wrangling (cleaning, standardizing, general processing)
  - 20% on actual analysis

- Analysis deliverables are standardized based on study design:
  - CONSORT (randomized clinical trials)
  - STROBE (observational studies)



CONSORT (Randomized Clinical Trials)



STROBE (Observational Studies)

- Common designs:
  - Cohort study
  - Case-control
  - Cross-sectional

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why

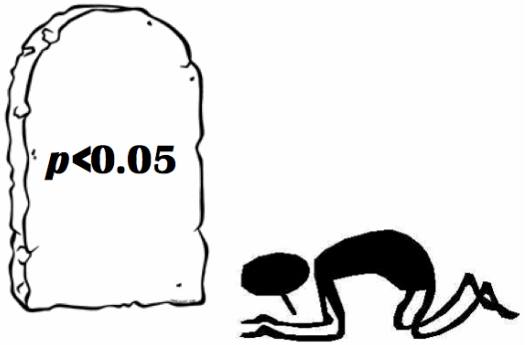
Tip #4: Plan appropriately for collaboration

Panel and Audience Discussions

Tip #5: Presentation of conclusions is a team effort

- Clinical significance versus statistical significance
  - Moving away from sole reliance on p-values (with sufficient sample size, any effect can be < 0.05)
  - Increasingly prefer measures of effect size (e.g., standardized differences, risk/odds ratios) and 95% CI
  - Ask researchers, “What difference would lead you to re-think your practice?”

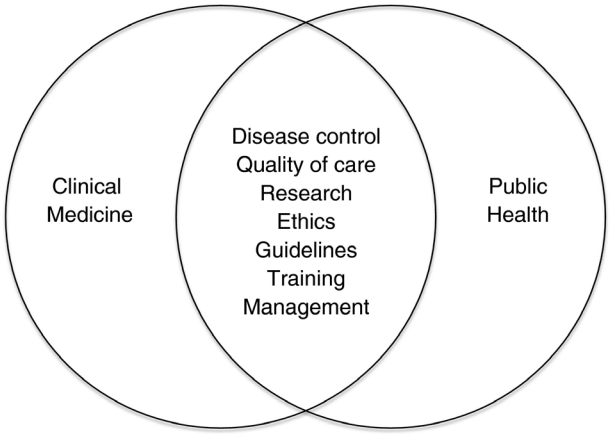
- Adds validity to the research and improves chances of other researchers replicating the findings



Tip #5: Presentation of conclusions is a team effort

- Biostatisticians should review a full product
  - Ensure conclusions do not go beyond the results
  - Check estimates are interpreted correctly (risk v. odds ratios)
  - Evaluate if bias/confounding were appropriately handled

- Researchers should know what and why certain statistics were used
  - Results should not be a black box
  - Researcher interprets in public or clinical health context



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