Report Writing

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Objectives

- Understand how to report statistical methods and results for academic articles
- Understand basics of when to consult a professional statistician

References

Annals of Internal Medicine; 108: 258-265

Annals of Internal Medicine; 108: 266-273

ACADEMIA & CLINIC

Uniform Requirements for Manuscripts Submitted to Biomedical Journals

INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS*

In January 1978 a group of editors from some major biomedical journals published in English met in Vancouver, British Columbia, and decided on uniform technical requirements for manuscripts to be submitted to their journals. These requirements, including formats for bibliographic references developed for the Vancouver group by the National Library of Medicine, were published in three of the journals early in 1979. The Vancouver group evolved into the International Committee of Medical Journal Editors (ICMJE). At the October 1981 meeting the requirements were revised slightly and published in a second edition in 1982. Since then the group has issued several separate statements, and these have been incorporated into the main part of this, the third, edition.

Over 300 journals have agreed to receive manuscripts prepared in accordance with the initial, previously published, requirements. It is important to emphasize what these requirements imply and what they do not.

Firstly, the requirements are instructions to authors on how to prepare manuscripts, not to editors on publication style. (But many journals have drawn on these requirements for elements of their publication styles.)

Secondly, if authors prepare their manuscripts in the style specified in these requirements, editors of the participating journals will not return manuscripts for changes in these details of style. Even so, manuscripts may be altered by journals to conform with details of their own publication styles.

Thirdly, authors sending manuscripts to a participating journal should not try to prepare them in accordance with the publication style of that journal but should follow the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals."

Nevertheless, authors *must also* follow the instructions to authors in the journal as to what topics are suitable for that journal and the types of papers that may be submitted (for example, original articles, reviews, case reports). In addition, the journal's instructions are likely to contain other requirements unique to that journal, such as number of copies of manuscripts, acceptable languages, length of articles, and approved abbreviations.

Participating journals are expected to state in their instructions to authors that their requirements are in accordance with "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" and to cite a published version.

This document will be revised at intervals. Inquiries and comments from Central and North America about these requirements should be sent to Edward J. Huth, M.D., *Annals of Internal Medicine*, 4200 Pine Street, Philadelphia, PA 19104, USA; those from other regions should be sent to Stephen P. Lock, M.D., *British Medical Journal*, British Medical Association, Tavistock Square,

Guidelines for Statistical Reporting in Articles for Medical Journals

Amplifications and Explanations

JOHN C. BAILAR III, M.D., Ph.D.; and FREDERICK MOSTELLER, Ph.D.; Boston, Massachusetts

The 1988 edition of the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals* includes guidelines for presenting statistical aspects of scientific research. The guidelines are intended to aid authors in reporting the statistical aspects of their work in ways that are clear and helpful to readers. We examine these guidelines for statistics using 15 numbered statements. Although the information presented relates to manuscript preparation, it will also help investigators in earlier stages make critical decisions about research approaches and protocols.

[MeSH terms: clinical protocols; clinical trials; eligibility determination; manuscripts, medical; probability; random allocation; statistics. Other indexing terms: blinding; blocking; confidence intervals; International Committee of Medical Journal Editors; matching; *P* values; software; statistical methods; stratification; study design; treatment complications; Uniform Requirements for Manuscripts]

In 1979, the group now known as the International Committee of Medical Journal Editors first published a set of uniform requirements for preparing manuscripts to be submitted to their own journals. These uniform requirements have been revised several times (1), and have been widely adopted by other biomedical journals. In the 1988 revision (2), the Committee added guidelines for presentDescribe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid sole reliance on statistical hypothesis testing, such as the use of *P* values, which fails to convey important quantitative information. Discuss eligibility of experimental subjects. Give details about randomization. Describe the methods for, and success of, any blinding of observations. Report treatment complications. Give numbers of observations. Report losses to observation (such as dropouts from a clinical trial). References for study design and statistical methods should be to standard works (with pages stated) when possible, rather than to papers where designs or methods were originally reported. Specify any general-use computer programs used.

Put general descriptions of methods in the Methods section. When data are summarized in the Results section specify the statistical methods used to analyze them. Restrict tables and figures to those needed to explain the argument of the paper and to assess its support. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Avoid non-technical uses of technical terms in statistics, such as "random" (which implies a randomizing device), "normal," "significant," "correlation," and "sample." Define statistical terms, abbreviations, and most symbols.

Our general approach is that scientific and technical

Title Page

1. Title (concise but informative)
2. Names of all authors
3. Name of department / Institution
4. Disclaimers
5. Corresponding author
6. "Reprints not available"
7. Source of grants
8. Short running header

Authorship

Authorship credit should be based only on substantial contributions to (a) conception and design, or analysis and interpretation of data; (b) drafting the article or revising it critically for important intellectual content; and on (c) final approval of the version to be published. Conditions (a), (b), and (c) must all be met. Participation

Abstract

150 words. Four paragraphs

- BACKGROUND: Purpose of article
- METHODS: Basic procedures
- RESULTS: Main findings
- CONCLUSIONS: Principle Conclusions

Key Words

- 3 to ten key words
- Chosen from MeSH List

Introduction

- State purpose of article
- Rationale for study
- Give only strictly pertinent references
- Do not review subject extensively
- No data or conclusions from the current study

Methods(1): Subjects

- Describe selection of subjects
- Reasons for selection
  - Scope
  - Eligibility
- Solid link between subjects and the population of inference

Methods: Ethics

- Ethics "Stuff"

Methods: Statistical Methods

- Put general methods in the methods section.
- Specific methods when summarizing data in the results when they are first used**

** Controversial. Check with the specific journal

Tips for Writing Statistical Methods (1)

Describe statistical methods with enough detail that reader with access to the original data could replicate the analysis

- Why this method was chosen
- Why other methods were not
- Weaknesses in study design
- Specify computer software and hardware

Tips for Writing Statistical Methods (1)

Trying several reasonable statistical methods is often appropriate, but this strategy must be disclosed so that readers can make their own adjustments for the authors' industriousness or skill in fishing through the data for a favorable result. Whatever statistical task is defined, it is inappropriate, and indeed unethical, to try several methods and report only those results that suit the investigator. Results of overlapping methods need not be present-

Tips for Writing Statistical Methods (2)

When possible quantify findings and give measurement error

- Mean / Standard Deviation
- Confidence intervals **
- P-values alone are not sufficient

Tips for Writing Statistical Methods (2)

which allows for a range of values for the difference). It is critical that both the null hypothesis and the alternatives be clearly stated, although many authors fail to do so. Clear reporting will not only help readers, it is also

Tips for Writing Statistical Methods (2)

It is critical also that authors specify how and when they developed each null hypothesis in relation to their consideration of the data. Statistical theory requires that null hypotheses be fully developed before the data are examined—indeed, before even the briefest view of preliminary results. Otherwise, *P* values cannot be interpreted as meaningful probabilities.

Tips for Writing Statistical Methods (3)

Give details of how randomization was performed

- Exact mechanism
- Blocking (factors and reasons)

Tips for Writing Statistical Methods (3)

dom" as a synonym for "haphazard." To prevent misunderstanding, simply tell readers how the randomization was done (coin toss, table of random numbers, cards in sealed envelopes, or some other method). Readers will

Tips for Writing Statistical Methods (4)

Other issues:

- Report methods and success of blinding
- Report any treatment complications
- Report any losses to observations

Results

- Results in logical sequence
  - Summary Statistics
    - Number of observations***
    - Graph data in simple way
  - Hypothesis testing for results
  - Post-hoc / Diagnostics
- Do not repeat in the text data from tables/figures except to explain significant points.

Results

The NEW ENGLAND JOURNAL of MEDICINE

- Except when one-sided tests are required by study design, such as in noninferiority trials, all reported P values should be two-sided. In general, P values larger than 0.01 should be reported to two decimal places, those between 0.01 and 0.001 to three decimal places; P values smaller than 0.001 should be reported as P<0.001.

Results

The NEW ENGLAND JOURNAL of MEDICINE

- For tables comparing treatment or exposure groups in a randomized trial (usually the first table in the trial report), significant differences between or among groups should be indicated by * for $P < 0.05$, ** for $P < 0.01$, and *** for $P < 0.001$with an explanation in the footnote if required. The body of the table should not include a column of P values.

Discussion

- Emphasize new and important aspects of study
- Link conclusion to goals of study
- Do not repeat in detail the results
- Implications of findings
- Limitations
- Relate to other studies
- Future implications / plans

Acknowledgements

- Persons who contributed but do not meet requirements for authorship

References

- Use standard format
- Avoid…
  - Abstracts
  - Unpublished data
  - Personal communications
- Reference statistical methods from text books or review articles not from the original articles

Tables

Tables:

Table 1 – Severe Weather Information Reception scoring

Mode of Alert	Points for Access	Points for Use
Radio	0.5	1
Television	0.5	1
Internet	0.5	1
Telephone	0.5	1
NOAA weather radio	0.5	1
Tornado siren	0.5	N/A
Total possible points	**3**	**5**

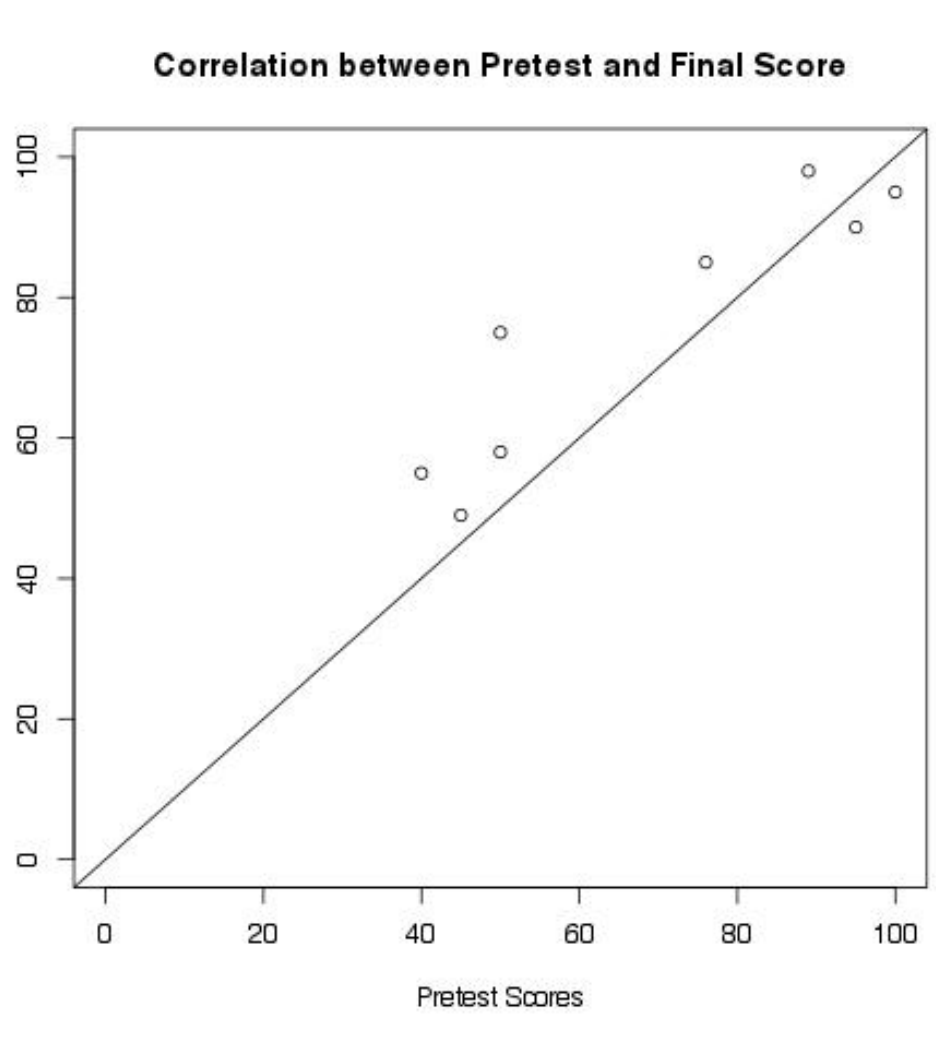
Key

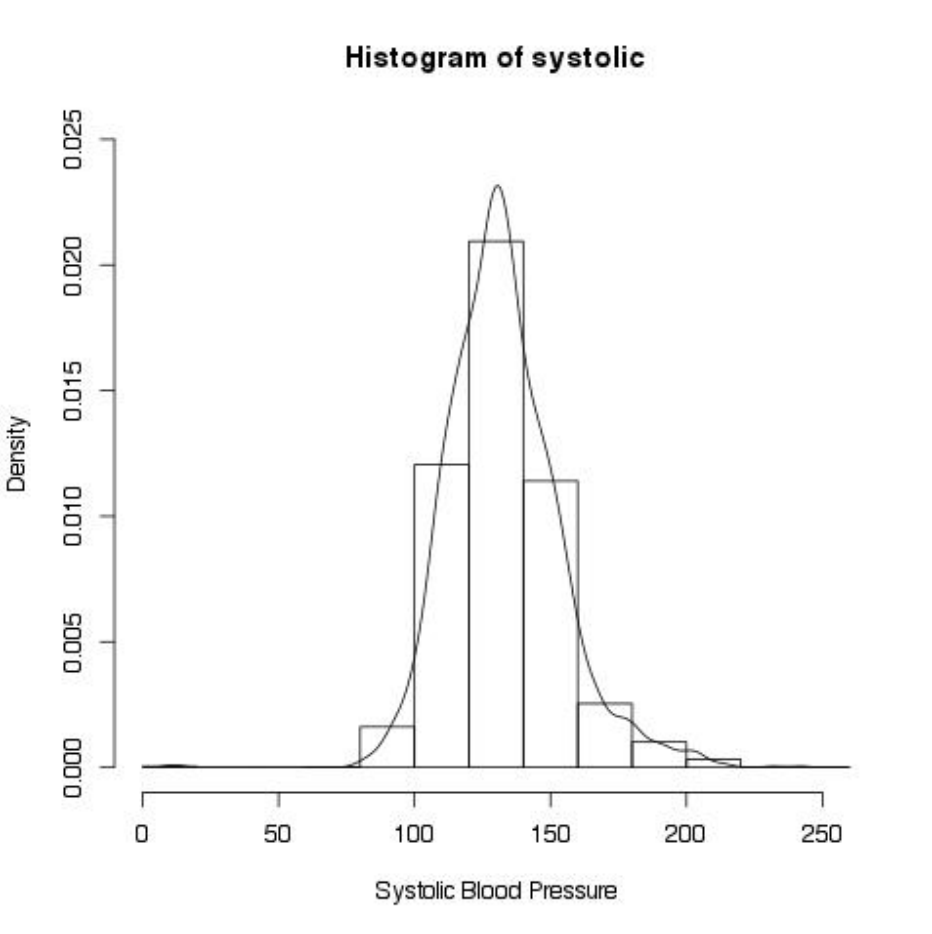
1-3 Poor access

4-5 Adequate access

6-8 Excellent

Figures


Correlation between Pretest and Final Score
0
20
40
60
80
100
Pretest Scores


Histogram of systolic
Density
0.000
0.005
0.010
0.015
0.020
0.025
0
50
100
150
200
250
Systolic Blood Pressure

General Style

Avoid casual use of technical statistical terms:

- Random
- Normal (Gaussian)
- Significance (Statistical vs Clinical)
- Correlation

General Style

Short clear sentences

Past Passive tense

Non-Academic Reports

General differences….

1. Usually include “executive summary” instead of abstract
2. Tables and figures embedded in the text not as separate items afterwards

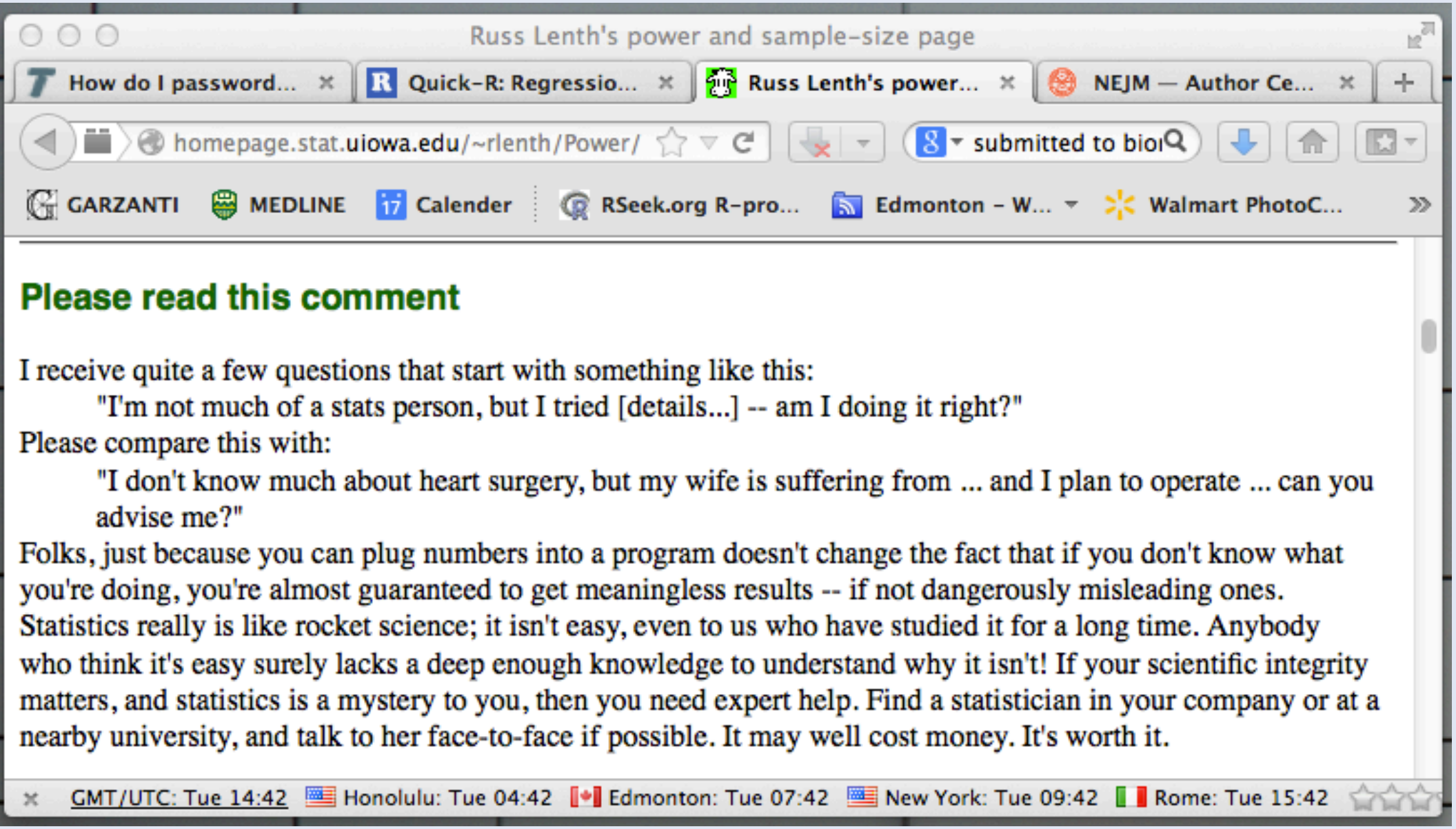
General Style

as editors. A basic point is that economy in writing and exposition gives an article its best chance of being read. Although many tables may help support the same basic point, and might be appropriate in a monograph, an article generally requires only enough information to make its point—the mathematician's concept of "necessary and sufficient."

Questions?

Report Writing

Working With a Statistician



Working With a Statistician

Finding the right person:

- Find someone you trust
- Find out about qualifications
- Understand professional statisticians will be holding to a professional code
  - ASQ
  - Professional Engineers

Working With a Statistician

Generally want to be involved early:

- Help format hypotheses correctly
- Help with methodology
- Ensure randomization is appropriate
- Ensure data collection includes all necessary information
- Ensure data is collected in a compatible format
- Authorship (?)

Working With a Statistician

Statistician will want to do his/her own analysis:

- Compatible data collection format
- Generally researcher doing summary statistics and simple analysis before submitting to statistician is not helpful
- "Can you look over what I have done": Usually *much more work* for the statistician

Working With a Statistician

Will usually want to see the final documentation

- Ensure that statistical results are not misinterpreted
- Authorship

Working With a Statistician

Objectives

- Understand how to report statistical methods and results for academic articles
- Understand basics of when to consult a professional statistician

Questions?

Math Lesson

Chi squares and Fisher's Exact test