Getting it Write in Outcomes Research

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Discussion Overview

- What it isn't:
  - A lesson in statistics
- What it is:
  - Discuss common problems with presentation of study methods and results

Science is nothing but developed perception, interpreted intent, common sense rounded out and minutely articulated.

George Santayana **(1863 - 1952)**

Research Communication

- Many submitted manuscripts are rejected
- Common rejection reasons are related to study design or methods selection
- Many are rejected due to poor research communication
  - Inadequately described purpose
  - Confusing/vague methodologies
  - Inappropriate or ambiguous results presentation

Deficiencies in Study Presentation

Deficiency	Number of Responses
Inadequate or inappropriate presentation of the data	9 (32%)
Rationale confused, contradictory	7 (25%)
Failure to give a detailed explanation of the experimental design	7 (25%)
Essential data omitted or ignored	2 (7%)
Poorly written; excessive jargon	2 (7%)
Boring	1 (4%)

Byrne DW. Common Reasons for Rejecting Manuscripts at Medical Journals: A Survey of Editors and Peer Reviewers. Science Editor. 2000; 23(2): 39-44.

Research Communication

- Deficiencies related to statistical methods are also common in submitted manuscripts.
  - Include issues with description of tests used, correct use of statistical tests, and presentation of statistical results

Number (%) of Deficiencies Identified in Sample of Submitted Manuscripts

Deficiency	All (n=57)	Accepted (n=28)	Rejected (n=19)
Inadequate statistical analysis of data	20 (35.1%)	12 (42.9%)	5 (26.3%)
Incorrect statistical tests used	15 (26.3%)	9 (32.1%)	6 (31.6%)
Statistical tests inadequately described	10 (17.5%)	5 (17.9%)	4 (21.1%)
No power calculation done, as appropriate	9 (15.8%)	4 (14.3%)	3 (15.8%)
Inadequate sample size to detect a significant result	12 (21.1%)	4 (14.3%)	7 (36.8%)

Taylor DM, Brown AFT. Analysis of the study design and manuscript deficiencies in research articles submitted to *Emergency Medicine*. 2001; 13:444-450.

Writing well means never having to say, 'I guess you had to be there.'

Jef Mallett

Pitfalls in Reporting Statistics

- Common statistical errors … in biomedical research articles
  - Taken from a ‘writers’ perspective
  - Series of articles by Tom Lang

Pitfalls in Reporting Statistics: Precision

- Which example would communicate the population data most effectively?
  a) The population rose from 29,942 to 94,347
  b) The population rose from 29,900 to 94,300
  c) The population rose from 30,000 to 94,000

Pitfalls in Reporting Statistics: Precision

- Which example would communicate the population data most effectively?
  - b) The population rose from 29,900 to 94,300
  - c) **The population rose from 30,000 to 94,000**

- Most people comprehend numbers to two or three significant figures.
  - In this example the population tripled, but it is not quickly apparent until rounded.
  - Significant figures determined by precision of measure

The skill of writing is to create a context in which other people can think.

Edwin Schlossberg

Pitfalls in Reporting Statistics: Precision

- Which of the following is a recommended way of reporting a p-value of 0.0032?
  a) p=<.05
  b) p=.01
  c) p=.003
  d) p=.0032

Pitfalls in Reporting Statistics: Precision

- Which of the following is a recommended way of reporting a p-value of 0.0032?
  c) **p=.003**

- What about p=.032?

- The smallest p-value that should be reported is .001
  - P-values ≥ 0.01 should be reported to 2 decimals

Pitfalls in Reporting Statistics: Significance

- Which example would communicate the significance of these results most accurately?
  a) A1C was reduced significantly ($p>.05$)
  b) A1C was reduced significantly by 0.7% points ($p=.02$)
  c) Mean change in A1C was a reduction of 0.7%, dropping from 9.5% to 8.7% (95% CI 1.6 – 0.1; $p=.02$)

Pitfalls in Reporting Statistics: Significance

- Which example would communicate the significance of these results most accurately?
  c) Mean change in A1C was a reduction of 0.7%, dropping from 9.5% to 8.7% (95% CI 1.6 – 0.1; p=.02)

- The change in A1C (0.7%) is an estimate of the change across the population;
  - Report 95% confidence intervals with estimates
  - Mean change may be significant, but the expected change may not always be clinically significant

"Do not put your faith in what statistics say until you have carefully considered what they do not say."

William W. Watt

Pitfalls in Reporting Statistics: Reporting Differences

- Which of the following, if reported alone is the most likely to be misleading?
  a) After 5 years of treatment 4.1% of patients on placebo died vs. 2.7% of patients in the active comparator arm.
  b) After 5 years of treatment 4.1% of patients on placebo died (84 of 2030) vs. 2.7% (56 of 2051) of patients in the active comparator arm.
  c) The relative risk reduction in death was 34% in the active comparator arm (RR=0.34).

Pitfalls in Reporting Statistics: Reporting Differences

- Which of the following, if reported alone is the most likely to be misleading?
  - c) The relative risk reduction in death was 34% in the active comparator arm (RR=0.34).

- Reporting only relative values can be misleading.
  - Relative risk reduction: 34% (1.4%/4.1%)
  - Absolute risk reduction: 1.4% (4.1% - 2.7%)

Pitfalls in Reporting Statistics: Reporting Differences

- What would be the next "most misleading"?
  a) After 5 years of treatment 4.1% of patients on placebo died versus 2.7% of patients in the active comparator arm.

- Reminder: numerator and denominator should always be reported

"Facts are stubborn, but statistics are more pliable."

Mark Twain

Pitfalls in Reporting Statistics: Descriptive Statistics

- After 6 months of therapy, the mean A1C dropped from 8.6% to 7.6%.
  - What descriptive statistics should be provided?

a) Mean change
b) Standard error of the mean
c) Standard deviation
d) 95% Confidence interval

Pitfalls in Reporting Statistics: Descriptive Statistics

- After 6 months of therapy, A1C was reduced to 7.6 from 8.6, a mean decrease of 1.0% (sd = 2.5; 95% CI 1.93 – 0.07).
  - What descriptive statistics should be provided.
  a) Mean change
  c) Standard deviation
  d) 95% Confidence interval

- SEM is a measure of precision vs. the distribution of data around the mean
  - SEM in makes measurements look more precise

Pitfalls in Reporting Statistics: Descriptive Statistics

- A better description would include data on with-in pair differences.
  - After 6 months of therapy, A1C was reduced to 7.6 from 8.6, a mean decrease of 1.0% (sd = 2.5; 95% CI 1.93 – 0.07). Of this population (n=50) 50% had a decrease in A1C (n=25), 30% had no change (n=15), and 20% had an increase in A1C (n=10).
  - Illustrates that not all patients experience A1C reductions with this treatment.

Pitfalls in Reporting Statistics: Descriptive Statistics

- Please critique this statement
  - Of those treated with an ACE (n=2132), the systolic blood pressure was significantly reduced by 1.1 mmHg ($p<.05$).

Pitfalls in Reporting Statistics: Descriptive Statistics

- Significance versus confidence
  - Of those treated with an ACE (n=2132), the systolic blood pressure was reduced by 1.1 mmHg (sd 1.2; 95% CI 0.82-0.99) p=0.04.

- Important to distinguish between statistical significance and clinical importance
  - While this reduction reached statistical significance due to the large sample size, it is not likely to have a meaningful clinical impact.

Pitfalls in Reporting Statistics: Methods Description

- What is missing from the following description?
  - After 18 weeks of treatment with an ACE, ARB or beta-blocker, follow-up blood pressures (BP) were measured and categorized as controlled or uncontrolled. The portion of patients with controlled BP were evaluated in a pair-wise comparison by treatment group using chi-square tests to determine if there were differences in BP goal achievement between treatment groups.

Pitfalls in Reporting Statistics: Methods Description

- What is missing from the description?
  - What is the operational definition of blood pressure control. What BP level defined controlled versus uncontrolled?
  - Details on adjustments for multiple comparisons

Pitfalls in Reporting Statistics: Methods Description

- What is missing from the following description of a cost analysis?
  - ".. we developed a multivariate linear regression model and included baseline patient characteristics and presenting signs and symptoms as covariates. We also included in hospital procedures … and length of stay in the model ... The criterion for retention of covariates in the model was a P value <.10."

Pitfalls in Reporting Statistics: Methods Description

- Indicator that the assumptions of the linear regression analysis were met
  - Linear relationship between covariates and outcome
  - Normally distributed data
  - Cost data seldom follows a normal distribution

“The scientist is not a person who gives the right answers, he's one who asks the right questions.”

Claude Lévi-Strauss

Other Common Pitfalls

- Methods
  - Not describing how continuous data was divided into ordinal variables
  - Not confirming that the data met the assumptions of the statistical test used to evaluate them (i.e., normally distributed for parametric tests)
  - Not reporting whether and how the model was validated
- Results
  - Unnecessarily reporting baseline statistical comparison in randomized trials
  - Interpreting studies with non-significant results and low statistical power as negative when in fact they are inconclusive
  - Confusing post-hoc analysis with planned analysis

Other Pet Peeves or Pearls of Wisdom?

Additional Resources

- Lang T. How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers. Philadelphia. American College of Physicians, 1997.
- Iverson C, Flanagin A, Fontanarosa PB, et al. American Medical Association Manual of Style: A guide for authors and editors, 9th Edition.. Baltimore, MD. Williams and Wilkens, 1998.
- Lang T. Twenty statistical errors even you can find in biomedical research articles. Croat Med J. 2004; 45(4):361-370.
- For more Detail: Common statistical errors even you can find.
  - Series of ten articles published by Lang in the American Medical Writers Association Journal
  - By topic such as descriptive statistics, multivariate analysis, correlation and regression analysis
  - http://www.tomlangcommunications.com/Publications.htm