Science cannot exist without writing

Only writing allows science to be:
- recorded
- evaluated
- reproduced
- systematic
- cumulative
- public

Publication is the final stage of research

If the results are not published, the research never happened.

“The Journal was invented for the relief of those either too indolent or too occupied to read whole books . . . It is a means of satisfying curiosity and becoming learned with little trouble.”

Denis De Sallo, 1626–1669
Evidence-based medicine is literature-based medicine
The quality of medical care is affected by the quality of published articles.

Evidence-Based Medicine
Most common findings
• Not a lot of evidence
• Even less good evidence

Keeping the Litter Out of the Literature
Lessons from the Environmental Movement
• Educate
• Reduce
• Reuse
• Repair

The writing taught in school is not the writing needed in science

Writing as Students
In school, students learn to write for:
• A single reader (the instructor)
• Who knows more than the student does about the topic
• Who does not need to use the information the student provides
Writing as Professionals
In science, authors must write for:
• A few to a few thousand readers
• Who don't know what the authors know about the topic
• Who may have to use the information authors provide

New and Needed Writing Skills
In school,
Students learn how to communicate with words
In science,
Authors also need to communicate with statistics, illustrations, tables, photographs, graphs, and diagrams

New and Needed Writing Skills
In other words, when writing in school,
• The flow of information is backwards
• Important scientific communication skills are not taught

Levels of Manuscript Review
1. Editing for Basic English: language-based review
2. Copyediting: rule-based review
3. Substantive Editing: logic-based review
4. Analytical Editing: documentation-based review
5. Peer Review: validity-based review

Analytical Editing
• Make sure that research designs and activities, statistics, and results are accurately and completely reported
• Must know reporting guidelines (e.g., CONSORT, statistics) and of specific types of figures and tables
• Must know research methods and sources of error, confounding, and bias

Goal: Move Toward Higher Levels of Review
1. Basic English Editing Focus on Presentation
2. Copyediting
3. Substantive Editing
4. Analytical Editing Focus on Content
5. Peer Review
Reducing Waste in Research

Physicians earlier in their careers

- Often under intense pressure to publish [clinical] research
- Often told that the article must be in a Western (English-language) journal with an impact factor above a given level

Reducing Waste in Research

- Often lack needed interest, training, supervision, and resources
- Often study something that can be studied, not what needs to be studied

The result is unremarkable research that consumes undue amounts of time and effort by the publication system

Stages of waste in the production of reporting of clinical research


Reusing Research

Physicians earlier in their careers could profit by

- Duplicating the work of others to verify published findings
- Conducting systematic reviews and meta-analyses
The Need for Peer Review

“There seems to be no study too fragmented, no hypothesis too trivial, no literature citation too biased or too egotistical, no design too warped, no methodology too bungled, no presentation of results too inaccurate, no argument too circular, no conclusions too trifling or too unjustified, and no grammar and syntax too offensive for a paper to end up in print.”

Drummond Rennie, MD

The Need for Critical Appraisal

In 2000 studies of schizophrenia

- Studied the wrong patients: 86% studied institutionalized patients, not those in the community
- Did not study enough patients: mean sample size was 65; adequate power required samples of up to 600

The Need for Critical Appraisal

In 2000 studies of schizophrenia

- Were not long enough: more than half were less than 6 weeks long, 6 months is more appropriate
- Studied different endpoints: studies used 640 different endpoints; 369 were used only once

What is Critical Appraisal?

- Ideally, what peer reviewers do (but often can’t or don’t)
- Requires studying and “dissecting” an article, not merely reading it
- Requires much time, training, and perspective to do well

The Need for Peer Review

“...when a well-done trial or experiment or observational study is fairly, honestly, and thoroughly reported, it will have so many warts and footnotes and exceptions that it may be hard for the uninitiated to believe that the work was of high quality.”

Frederick Mosteller, PhD
Problem #1

Authors are using only basic statistics if they use any at all.

Case Study

Statistical and Methodological Reporting Errors in the Literature

Statistics Used in Biomedical Articles

- Of 1828 articles published in 6 IM journals:
  - 48% used Chi-square tests
  - 31% used t tests
  - 23% used ANOVA
  - 17% used linear regression
  - 17% used logistic regression
  - 8% used nonparametric tests


Statistics in Biomedical Articles

- Of 144 articles from 6 pharmacy journals:
  - 28% used only descriptive statistics
  - Of the 99 articles using inferential statistics:
    - 33% used Chi-square tests
    - 26% used t tests
    - 18% used correlation analysis
    - 14% used ANOVA
    - 11% used logistic regression

CM Lee et al., Ann Pharmacother, 2004

Statistics Used in Biomedical Articles

- Of 51 articles in the journal, Burns:
  - 53% used t tests
  - 33% used ANOVA
  - 27% used Chi-square tests
  - 22% used nonparametric tests


Summary

- Many articles (up to 80% in some journals) use no or only descriptive statistics
- 60% to 90% contain only the statistics taught in 1st-semester statistics classes
- Maybe 20% use more advanced methods (e.g., multivariate analysis, ROC analyses)
Problem #2
Authors using statistics make lots of mistakes

Statistical and Methodological Problems in the Literature

"These reviews [of statistical errors] reveal a remarkable and depressing consistency, with typically around 50% of reviewed papers being found to contain clear statistical errors."

G.D. Murray, 1991

Statistical Problems in the Literature
Of 364 articles in the Archives of Dermatology
43% included statistical analyses
38% had errors or omissions in methods
26% had errors in the presentation of results
14% had errors in statistical methods


Statistical Problems in the Literature
Of 92 articles in the Journal of Urology
83% had errors in reporting odds ratios
78% did not report confidence intervals
53% had errors in reporting P values
24% had errors in descriptive statistics


Statistical Problems in the Literature
Of 125 articles in animal research journals
70% had at least one statistical error
56% used inappropriate post-hoc tests
52% did not use repeated-measures analysis but should have

Burke DA, J Neurotrauma, 2013

Statistical and Methodological Problems in the Literature
Of 133 RCTs in plastic surgery, only . . .
13% gave sample size calculations
30% gave details of random assignment
20% described allocation concealment
52% described details of blinding

Statistical and Methodological Problems in the Literature

Of 53 Cochrane reviews published in 1998:
- 29% had major errors
- 17% had unsupported conclusions
- 23% had problems with conduct or reporting
  All errors favored the target intervention.

Ole Olsen, BMJ, 2001

Summary

- Up to 70% of articles reporting statistics have statistical flaws
- Up to 10% have fatal statistical or design flaws
- Even Cochrane reviews often have serious methodological flaws; still better than non-Cochrane reviews

In other words, the overall quality of the biomedical literature is not great.

Statistical and Methodological Problems in the Literature

- Widespread
- Long-standing
- Potentially serious
- Largely unknown
- Concerns mostly basic statistics
- Found even in the top journals

Problem #3

Nobody is doing much about Problems 1 and 2.

Have we elevated peer review to a status that it doesn't deserve? (Another form of littering . . .)
Characteristics of Peer Review

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wide variability among reviewers</td>
<td>Comments rarely addressed in resubmittal of rejected articles</td>
</tr>
<tr>
<td>Time- and labor-intensive with little compensation</td>
<td>Not easy to identify good reviewers</td>
</tr>
<tr>
<td>Tends to promote conventionalism</td>
<td>Misses most cases of fraud</td>
</tr>
<tr>
<td>Does not assure quality (but does improve presentation)</td>
<td>Bias against women, foreign authors, and competitors</td>
</tr>
<tr>
<td>Peer review tends to determine where, not whether, an article is published</td>
<td></td>
</tr>
</tbody>
</table>

Other Notes on Peer Review

- Peer review is not going away (nor should it)
- Unpopular variations:
  - Pre-print servers
  - Open review (by anyone)
  - Publishing reviews (articles may not resemble original manuscripts)
  - Signed reviews (publishing reviewers’ names with articles; happening anyway)
  - Post-publication reviews

Organizational Resources

The “EPA” of the Scientific Literature
(Every Paper Analyzed)

- International Committee of Medical Journal Editors (ICMJE)
- World Association of Medical Editors (WAME)
- The EQUATOR Network (Enhancing the QUAlity and Transparency Of health Research)
- Committee on Publication Ethics (COPE)
- Council of Science Editors (CSE)
- European Association of Science Editors (EASE)
- The quadrennial Peer Review Congress
- Evidence-based medicine researchers

Organizations Working to Improve the Literature

The EQUATOR Network

- ~ 125 Guidelines for reporting research designs and activities (RCTs, cohort studies, nonpharmacologic interventions etc)
- ~ 65 Guidelines for reporting specific procedures (studies on intravascular ultrasound studies; exercise therapy for low back pain, etc)
Committee on Publication Ethics (COPE)
Established in 1997 by medical journal editors in the UK; now > 7000 members worldwide from all academic fields
Advises editors and publishers on all aspects of publication ethics, especially cases of research and publication misconduct

The Need for Different Perspectives

Causes of poor statistical reporting
No comprehensive reporting guidelines for authors (until publication of How to Report Statistics in Medicine, 1997)
No comprehensive guidance from journals’ instructions for authors (until publication of the SAMPL Guidelines, 2013)

How to Report Statistics in Medicine was written by an obscure medical writer/editor
Why wasn’t it written by:
• A statistician?
• A journal editor?
• A peer reviewer?
• A researcher?
• A clinician?
• An educator?

The SAMPL Guidelines (Statistical Analyses and Methods in the Published Literature) were developed for journals by an obscure medical writer-editor
Why weren’t they developed by:
• A journal editor?
• A peer reviewer?
• A publisher?
Tom Lang, MA
Tom Lang Communications and Training International
10003 NE 15th Lane
Kirkland, WA 98033
425-636-8500
tomlangcom@aol.com
www.TomLangCommunications.com

How To Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers
Thomas A. Lang, MA
Michelle Secic, MS
Foreword by Ed Huth, MD, MACP

How to Write, Publish, and Present in the Health Sciences: A Guide for Physicians and Laboratory Researchers
Thomas A. Lang, MA
Foreword by Stan Lemeshow, PhD, MSPH
(American College of Physicians, 2010)