Keeping the Litter out of the Literature

Improving the Quality of Scientific Publications

Tom Lang, MA • Tom Lang Communications and Training International

Thoth, the Egyptian god of medicine. . . and of writing

Science cannot exist without writing

Only writing allows science to be:

recorded
reproduced
cumulative
evaluated
systematic
public

Periodic Table of the Elements

1A	2B	NOT 2B	3D	4F	R2-D2	
Li LINT 1					Sc SCUM 2	A
De DENIM 3	To TOFU 4			Hy HYDROX 5	Cl CLOROX 6	B-C
Ny NYLON 7	Je JELL-O 8	Al ALIMONY 9	Ph PHLEGM 10	Ch CHOCOLATE 11	Wd WD-40 12	D-H
Te TEFLON 13	Ve VELVEETA 14	Feh IRONY 15	Me MENTHOLATUM 16	Bi BISMARCK 17	Dr DRANO 18	I-M
Ve VELCRO 19	Mz MARZIPAN 20	Ar ARGOT 21	Ln LANOLIN 22	Ga GARLIC 23	Lm LINOLEUM 24	N-W
Xe XEROX 25*	Pa PASTA 30	Po POLONIUS 31	Pr PRELL 32	Zi ZINFANDEL 33	Ma MASONITE 34	X-Y-
Ko KODACHROME 35†	Gr GRANOLA 40	Pd PANDEMONIUM 41	Lb LIBRIUM 42			Othe

*Insecticides	Fl FLIT 26	Ra RAID 27	Bu BUGGETA 28	St STEPONUM 29
†Fantasides	Kr KRYPTONITE 36	Di DILITHIUM 37	Ca CAVORITE 38	La LAETRILE 39

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**

- **Educate**
- **Reduce**
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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

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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

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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

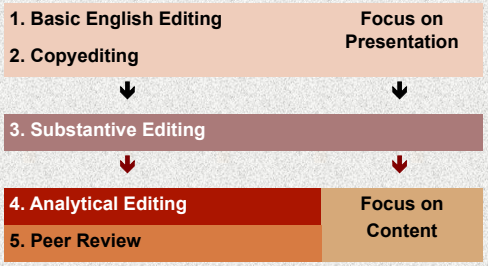
Levels of Manuscript Review

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



- Educate
- **Reduce**
- Reuse
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Reducing Waste in Research

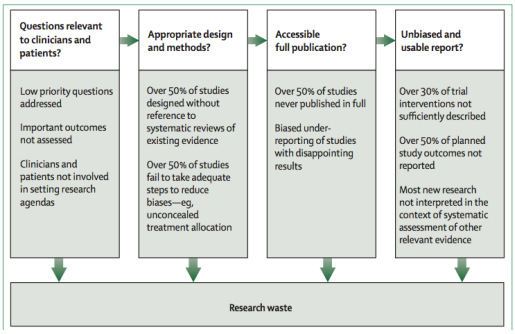
Physicians earlier in their careers

- **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
(Chalmers I, et al. Lancet 2009)

- Educate
- Reduce
- **Reuse**
- Repair

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**

- Educate
- Reduce
- Reuse
- Repair

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

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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

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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

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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

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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

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Case Study

Statistical and Methodological Reporting Errors in the Literature

Problem #1

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

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

Reed JF, et al. J Med Syst, 2003

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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

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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

Al-Benna S, et al. Burns, 2010

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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)

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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

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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

Neville JA, et al. Arch Dermatol, 2006

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

Afshar K, et al. J Urol, 2009

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

V Karri, J Plast Reconstr Aesthet Surg, 2006

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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

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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

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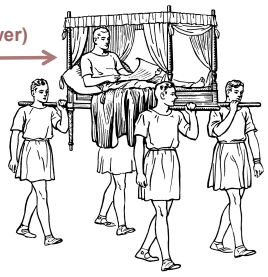
Problem #3

Nobody is doing much about Problems 1 and 2.

(Peer reviewer)



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

Characteristics of Peer Review

Wide variability among reviewers	Comments rarely addressed in resubmittal of rejected articles
Time- and labor-intensive with little compensation	Not easy to identify good reviewers
Tends to promote conventionalism	Misses most cases of fraud
Does not assure quality (but does improve presentation)	Bias against women, foreign authors, and competitors

Peer review tends to determine where, not whether, an article is published

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)

Organizations Working to Improve the Literature

- International Committee of Medical Journal Editors (ICMJE)
- World Association of Medical Editors (WAME)
- The EQUATOR Network (Enhancing the QUAlity and Transparency Of health Research)

Organizations Working to Improve the Literature

- 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

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)

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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

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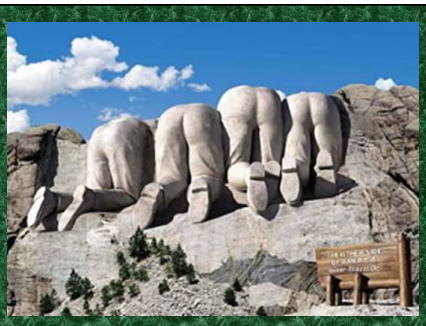

The importance of perspective:
Mt Rushmore from the Canadian side

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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?

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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?

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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

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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

(American College of Physicians, first edition, 1997; second edition, 2006)

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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)

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