



McGill University

*Departments of Epidemiology &
Biostatistics and Oncology
Summer Session - June 2010*



**Course EPIB 645:
Publishing in Epidemiologic and Clinical
Research**

Course Instructor:

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Editorial Board Member: American Journal of Epidemiology (1993-98); Cancer Detection and Prevention (2001-08); Cancer Epidemiology, Biomarkers & Prevention (1995-); Epidemiology (1993-2009); International Journal of Cancer (2009-11); Medical and Pediatric Oncology (2000-04); Oral Diseases (2005-); PLoS-Medicine (2004-); Preventive Medicine (2008-11)

Course EPIB 645: Writing and Publishing in Epidemiologic and Clinical Research - 2010

Departments of Epidemiology & Biostatistics and Oncology, McGill University

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<http://www.mcgill.ca/cancerepi/courses/writing/>

Session	Date	Topics to be covered	Reading assignments
1	June 8 (Tue)	The process of scientific research; reasoning while reading; recognizing what to avoid	Slide set, course webpage materials
2	June 15 (Tue)	Structure of a scientific paper; selecting journals and the market of ideas; authorship; conflict of interest; research misconduct	Slide set, course webpage materials
3	June 22 (Tue)	Journal club discussions I	Andriole, Saad
4	June 29 (Tue)	Journal club discussions II	Frazier, Montazeri

Note: All sessions from 2-5 pm



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▪ **EPIB 645 (Summer session)**

▪ EPIB 671 (Summer Session)

▪ Environmental Carcinogenesis

▪ Biology of Cancer

▪ Conferences

▪ Job and research opportunities

▸ Cancer Research Society

▸ Useful links

EPIB 645 (Summer session)

Files to download for students registered in EPIB 645

1. **Course announcement**
[Course announcement](#) [.pdf]
2. **Slide set**
[Slides EPIB 645](#) [.pdf]
3. **Reading materials on authorship**
[ICMJE: Uniform Requirements for Manuscripts](#) [.pdf]
4. **Reading materials on research integrity**
[NEJM: Controlling Conflict of Interest \(Steinbrook\)](#) [.pdf]
[ORI: Responsible Conduct of Research](#) [.pdf]
[ORI: Managing Allegations of Scientific Misconduct](#) [.pdf]
[Science: Cleaning Up the Paper Trail \(Couzin\)](#) [.pdf]
[Annals of Internal Medicine: Research Misconduct \(Sox\)](#) [.pdf]
[Roig - Plagiarism](#) [.pdf]
5. **Articles for discussion in class**
[AJCO: Radiation Therapy With or Without Chemotherapy for Cervical Cancer With Periaortic Lymph Node Metastasis](#) [.pdf]
[BMC: Disclosure of cancer diagnosis and quality of life in cancer patients: should it be the same everywhere?](#) [.pdf]
[CCC: Adolescent diet and risk of breast cancer](#) [.pdf]
[NEJM: Mortality Results from a Randomized Prostate-Cancer Screening Trial](#) [.pdf]

Next: [EPIB 671 \(Summer Session\)](#)

Bibliography

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- Day RA. How to Write and Publish a Scientific Paper. 5th ed. Phoenix, Ariz: Oryx Press; 1998.
- Day RA. Scientific English: A guide for scientists and other professionals. Phoenix, Ariz: Oryx Press; 1992.
- Huth EJ. Writing and Publishing in Medicine. 3rd ed. Baltimore, Md: Lippincott, Williams & Wilkins; 1998.
- International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals. JAMA. 1997;277:927-934.
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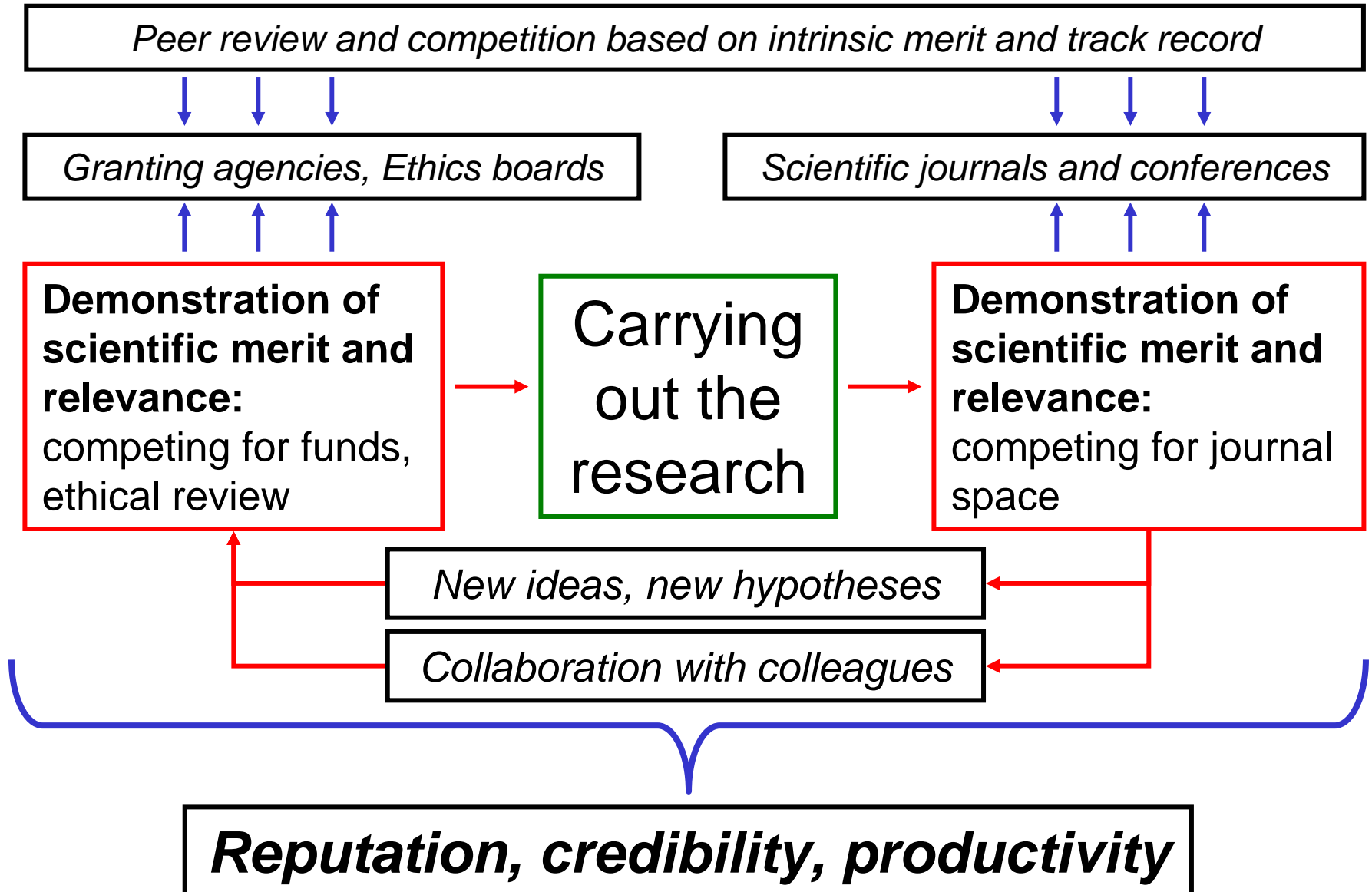
Journal Club Articles

- Andriole GL, Crawford ED, Grubb RL 3rd, Buys SS, Chia D, Church TR, Fouad MN, Gelmann EP, Kvale PA, Reding DJ, Weissfeld JL, Yokochi LA, O'Brien B, Clapp JD, Rathmell JM, Riley TL, Hayes RB, Kramer BS, Izmirlian G, Miller AB, Pinsky PF, Prorok PC, Gohagan JK, Berg CD; PLCO Project Team. Mortality results from a randomized prostate-cancer screening trial. *N Engl J Med*. 2009 Mar 26;360(13):1310-9. Epub 2009 Mar 18. Erratum in: *N Engl J Med*. 2009 Apr 23;360(17):1797. PubMed PMID: 19297565.
- Montazeri A, Tavoli A, Mohagheghi MA, Roshan R, Tavoli Z. Disclosure of cancer diagnosis and quality of life in cancer patients: should it be the same everywhere? *BMC Cancer*. 2009 Jan 29;9:39. PubMed PMID: 19178719; PubMed Central PMCID: PMC2639611.
- Saad A, Lo SS, Han I, Keole S, Lee CP, Tekyi-Mensah S, Munkarah A, Malone J, Morris R, Deppe G. Radiation therapy with or without chemotherapy for cervical cancer with periaortic lymph node metastasis. *Am J Clin Oncol*. 2004 Jun;27(3):256-63. PubMed PMID: 15170144.
- Frazier AL, Li L, Cho E, Willett WC, Colditz GA. Adolescent diet and risk of breast cancer. *Cancer Causes Control*. 2004 Feb;15(1):73-82. PubMed PMID: 14970737.

Points to Cover / Objectives

- 1) The process of scientific research and the proven value of peer review
- 2) Elements of scientific reasoning that are used in epidemiologic or clinical research and mentorship
- 3) Recognizing the ingredients of a good scientific paper
- 4) The paradigms for communicating research results
- 5) Overview of principles of good scientific practice as applied to research on human subjects

The process of scientific research



Peer review as the gatekeeper

- 1) To ensure that the best and most useful research ideas are favoured
- 2) To reward creativity, productivity
- 3) To point out flaws, excessive costs, lack of pertinence, in proposed studies so that researchers have an opportunity to improve their projects
- 4) To filter out irrelevant, bad science, thus improving the signal-to-noise ratio of the scientific information

"The chief aim of science is not to open a door to infinite wisdom but to set a limit to infinite error."

Bertolt Brecht, in "The Life of Galileo" (1940)

Reading a paper

- What are your impressions?
- What features of the paper you are more likely to notice?

Anatomy of a published study: Key questions

Where was the study published?

- 1) Do you have a pre-formed opinion about the journal?
About the authors? About the country of origin?
- 2) Does that give you pre-conceived ideas about the quality and merit of the research?
- 3) Do you feel less or more inclined to read the paper?
- 4) If so, do you fight your instinct and read the paper to enhance your knowledge about the disease and the means to control it (via diagnosis, treatment, improved survival)
- 5) Do you find yourself accepting or challenging the study depending on the above?

Anatomy of a published study: Key questions

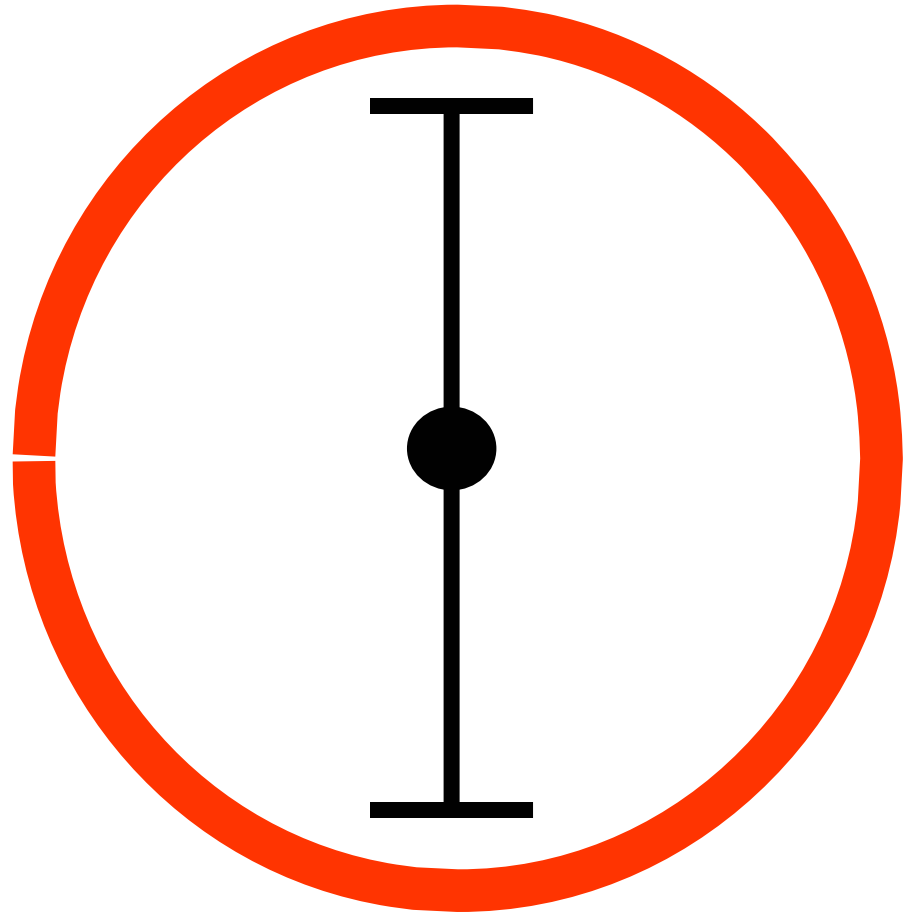
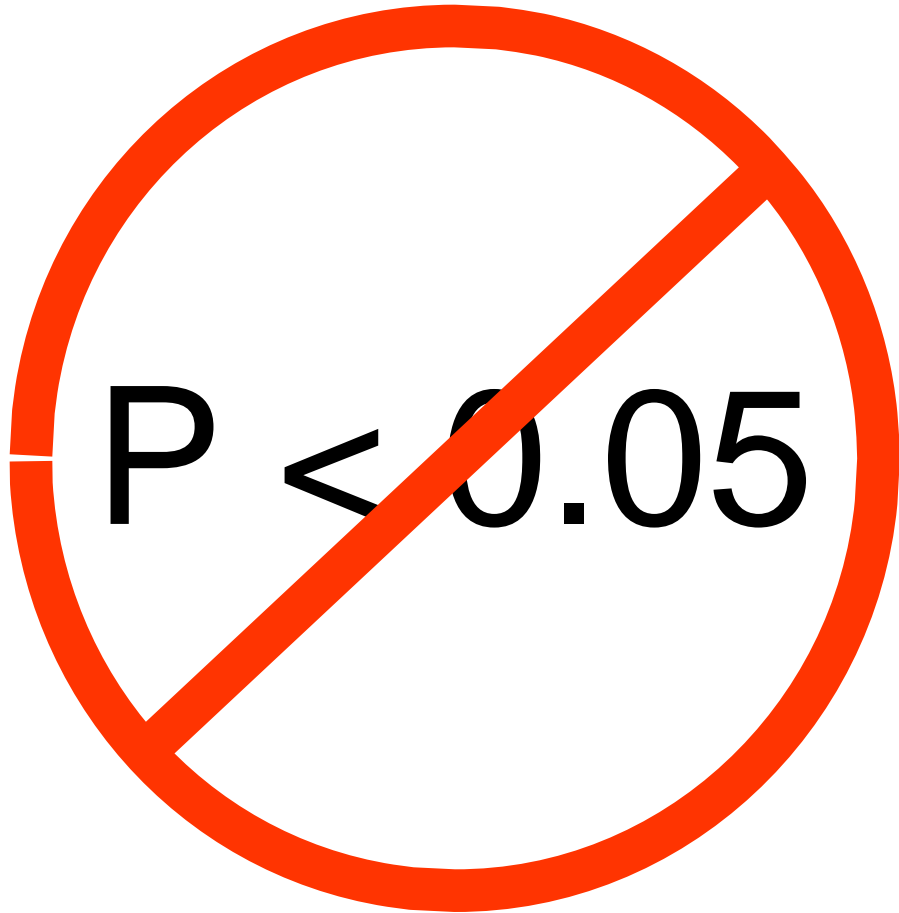
What type of study is this?

- 1) Can you find in the abstract the message or point of the study?
Does that make you more or less inclined to read the article?
- 2) Is there a clear hypothesis that was tested by the authors?
- 3) Is this an observational study that attempted to focus on mechanisms of disease, on diagnostic or prognostic markers, or that hinted at the superiority of treatment or diagnostic/screening approaches?
- 4) Is there an underlying model that the authors propose to test?
- 5) Is it a randomized controlled trial?
- 6) Is it a case report?
- 7) Is it a review or meta-analysis article? With or without original observations by the authors?

Anatomy of a published study: Key questions

Reading the paper:

- 1) Is the narrative pleasant to read? Are the arguments logical? Is it concisely written?
- 2) Is the reason for doing the study explicitly laid out by the authors? Is it convincing?
- 3) Are the methods sufficiently and concisely described so as to permit others with comparable resources and skills to reproduce the study?
- 4) Is the selection of patients/subjects clearly explained? Are possible selection biases or measurement errors discussed?
- 5) Are the statistical analysis methods appropriate for the design, goals, and structure of the investigation?
- 6) Modern epidemiology: emphasis on properly measuring the magnitude and precision of an effect, not on significance testing



Anatomy of a published study: Key questions

Interpreting the evidence:

- 1) Did the authors do what they said they would do? Did they over- or under-interpret the data?
- 2) Are complex explanations backed up by plausible and necessary assumptions?
- 3) Two equally effective styles :
 - First acknowledge the limitations of the study before considering its implications
 - Start the discussion with the answer to the research question and then recognize the limitations.
- 4) Are the findings interpreted in light of prior work by others, both in terms of favourable and unfavourable arguments?
- 5) Was credit given to the studies that formed the knowledge on which the present study rests?

Competitive Interactions Between Neotropical Pollinators and Africanized Honey Bees

David W. Roubik

Science, New Series, Vol. 201, No. 4360 (Sep. 15, 1978), 1030-1032.

Fig. 1. The relations of Africanized and stingless (meliponine) bee abundances on flowering *Melochia villosa*. The dashed line is a quadratic polynomial (given by $y = -0.516 + 1.08x - 0.023x^2$) which gave the best fit to the points (7).

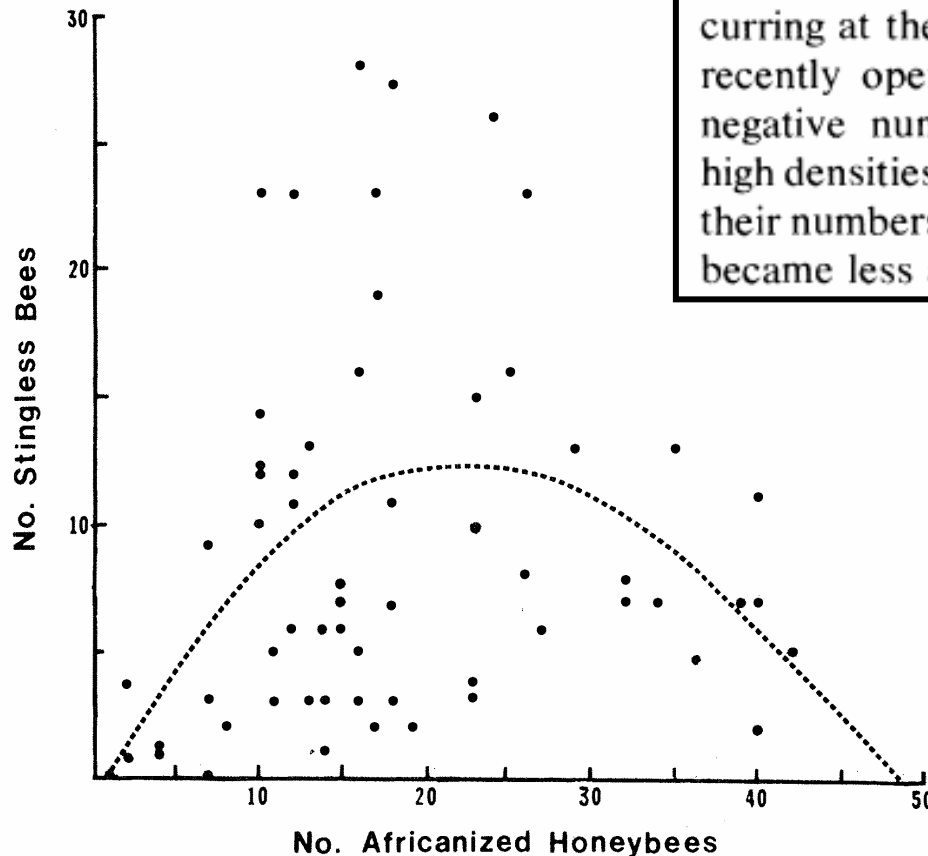


Figure 1 illustrates the relationship between Africanized and stingless bee abundance on *Melochia* (7). At low densities of each forager class, usually occurring at the first observations made at recently opened flowers, there was no negative numerical interaction. But at high densities of Africanized honey bees, their numbers increased as stingless bees became less abundant.

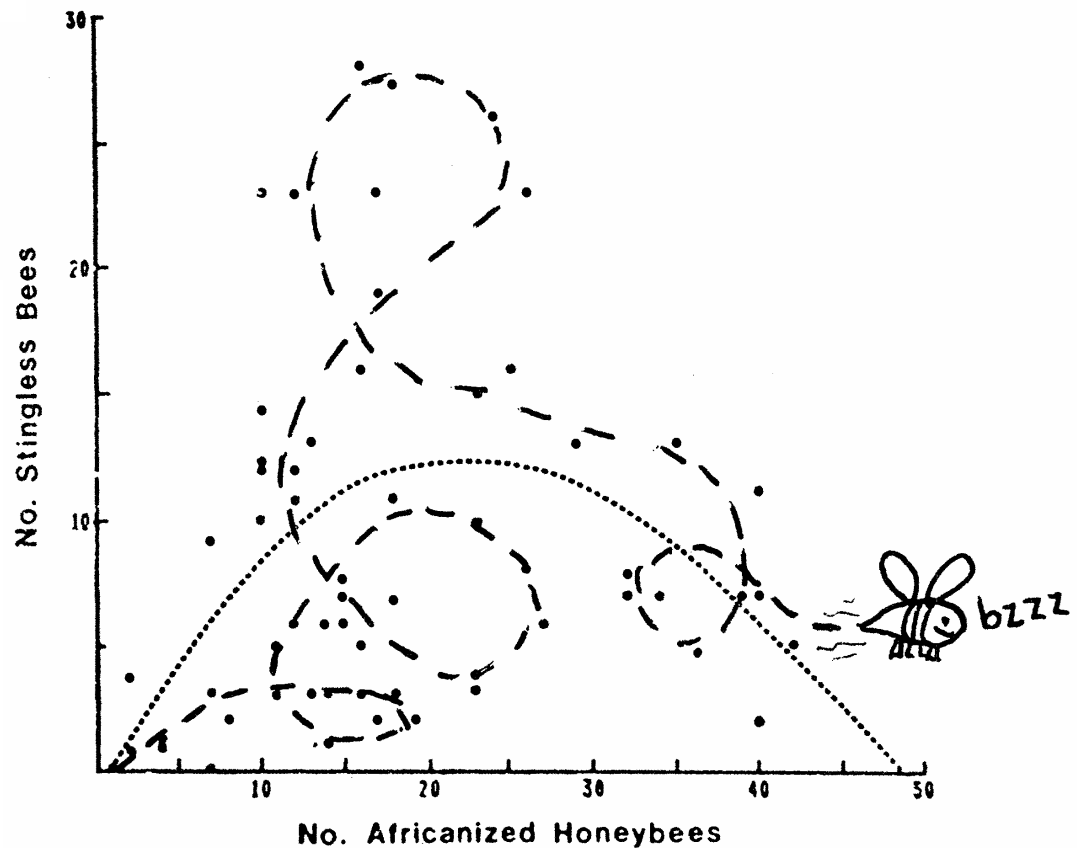
Author's interpretation

Curve-Fitting

The rather fanciful curve-fitting of Roubik (Reports, 15 Sept., p. 1030, Fig. 1) has prompted me to propose an alternative interpretation of his data

ROBERT M. HAZEN

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Carnegie Institution of Washington,
Washington, D.C. 20018*



When statistics can be hazardous to your health... (1)

“A large, prospectively derived database was analyzed to ascertain whether BSI independently predicted death by logistic regression analysis.”

Ann Surg 2001; 233: 549–555

“Although odds ratio for sudden death by logistic regression was 1.9 (95% confidence interval: 0.5 to 6.5) in patients with NSVT and 2.4 (95% confidence interval: 0.5 to 12.4) in patients with combined NSVT and 5 couplets and 200 PVCs, neither of these associations achieved statistical significance ($p > 0.05$).”

J Am Coll Cardiol 2005;45:697-704

“Significant risk factors for death by logistic regression modeling were inappropriate treatment due to antimicrobial resistance, HIV infection, other underlying infectious diseases, malnutrition and bloodstream infection caused by Enterobacteriaceae, other Gram-negatives and candida.”

BMC Infectious Diseases 2007;7:43

“Table 3A Univariate and multivariate predictors of death by logistic regression”

European Heart Journal 2001;22:849–856

When statistics can be hazardous to your health... (2)

“Although a variety of resuscitation endpoints correlated with surviving critical illness, only pHi at 24 h proved an independent predictor of death by logistic regression.”

J Trauma 2004;57:898-912

“In our study only preoperative shock and abscess involving both the mitral and aortic annuluses emerged as predictors of operative death by Cox regression analysis.”

Eur J Cardiothorac Surg 2007;31:43-48

“Univariate and bivariate analysis were performed with initial and sequential CD4+ cell counts and viral load values to estimate the risk of progression and death by Cox regression models.”

Med Clin (Barc) 1998;110:761-7

“The factors associated with death by Cox regression analysis are shown in Table 4.”

J Clin Oncol 2002;20:1527-1536

When statistics can be hazardous to your health... (3)

“The following factors were significantly associated with death by Cox regression analysis: metastatic disease at presentation (hazard ratio = 9.0, $P < .0001$) and poor response to chemotherapy (hazard ratio = 6.0, $P = .0004$).”

Ann Surg. 2001; 234: 215–223

“Prolonged door-to-balloon times (0 to 1.4 h vs. 1.5 to 1.9 h vs. 2.0 to 2.9 h vs. 3.0 h) were associated with higher in-hospital mortality (4.9% vs. 6.1% vs. 8.0% vs. 12.2%, $p < 0.0001$) and late mortality (12.6% vs. 16.4% vs. 20.4% vs. 27.1% at 7 years, $p < 0.0001$) and were an independent predictor of late mortality by Cox regression ($p = 0.0004$).”

“Table 4. Multivariable Predictors of Late Cardiac Mortality by Cox Regression”

J Am Coll Cardiol, 2006;47:289-295

“Statistical considerations: Survival analysis evaluated the proportional hazards for mortality by Cox regression.”

J Am Coll Cardiol, 2000; 36:1774-1780

When statistics can be hazardous to your health... (4)

“METHODS: Retrospective comparison of hospital mortality by Cox regression in three main areas of Italy adjusted for age, Glasgow Coma Scale and source of admission.”

Eur J Epidemiol 2008;23:289-94

“Increasing APACHE (acute physiology and chronic health evaluation) II scores (adjusted odds ratio, 1.13; 95% confidence interval, 1.09 to 1.18; $p < 0.001$), presence of malignancy (adjusted odds ratio, 3.20; 95% confidence interval, 1.79 to 5.71; $p = 0.044$), and the administration of IDAAT (adjusted odds ratio, 7.68; 95% confidence interval, 4.50 to 13.09; $p < 0.001$) were identified as risk factors independently associated with hospital mortality by logistic regression analysis.”

Chest 2002;122:262-268

“DMI also tended to reduce seizure severity, but the results did not quite reach significance ($P=0.07$ for both tonic extension and death by Fisher's Exact Test; Table 3).”

Neuropsychopharmacology 2006;31:730–738

Dangling modifiers and other awkward constructions: The classics

“It is all right to give raw milk to your baby, but first you must boil it.”

“Antibiotic-Combination Drugs Used to Treat Colds Banned by FDA”

“A large mass of literature has accumulated on the cell walls of staphylococci”

“Dr. [X] presented evidence that women who smoke are likely to have pulmonary abnormalities and impaired lung function at the annual meeting of the American Lung Association.”

“Free information about VD. To get it, call 555-7000.”

“Physicians today lost the right to intubate patients in Superior Court.”

Source: Day, 1998; Coffin, 2004

Writing a paper

- What led you to this point?
- What do you want to communicate?

Who is best qualified to conduct a research study on human subjects?

Conceiving research hypotheses requires multi- and interdisciplinary thinking:

- **Team:**

Epidemiologist, molecular biologist, geneticist, clinician, pathologist, microbiologist, statistician, psychologist, etc.

- **Attributes:**

Proven (not perceived) competence; affinity is a must; ability to commit to study protocol

- **Epidemiologist as the “study broker”:**

Make sure that intellectual ownership for the study is shared by all collaborators

*"far better an approximate
answer to the right question ...*

*than an exact answer to the
wrong question ..."*

Tukey, 1962

“We have to remember that what we observe (what we learn about) is not nature in itself, but nature exposed to our method of questioning..”

W Heisenberg

Key questions in planning to write a paper

- 1) What is the message of the paper?
- 2) Is the paper worth writing?
- 3) Have I already given the message with the same data?
- 4) What is the audience for the paper?
- 5) What is the format for the message?
- 6) What is the journal for the paper?

What is the message of the paper?

What is the point of the paper and its contents?

A research study:

- To report the findings of a randomized controlled trial of adjuvant therapy
- To report the diagnostic or prognostic utility of a new biomarker
- To identify relevant clinical variables in a retrospective chart review study

A review article or meta-analysis

- To identify gaps in knowledge, new research questions
- To examine the weight of evidence concerning a particular treatment, screening method, or prognostic factor to help clarify a controversy

A case report

- To enhance our understanding of a particular disease

Is the paper worth writing?

Is the message relevant? Is it publishable?

Is there an ethical obligation to report the study's findings?

The public has the right to know: grant funding originates from public taxes, charitable donations

Does it add new information? What is in the literature?

Is there a need for the information? Will it appeal to readers? Can editors and readers be convinced of the utility of the message?

The ethics of parsimony

If the message is not new or relevant will it prevent a beneficial gain in knowledge if left unpublished?

Can the findings be concisely reported in another paper?

Consideration to one's career and those of associates

Have I already given the message?

Have I already published a paper with the same or similar data or findings?

Carefully consider the merit of updating findings

Accrued follow-up in cohort studies may provide more stable estimates of treatment or prognostic effects

Did you incorporate a new technology since the previous report?

If decided to update findings

Make a clear case that the new paper improves upon the previous report

Try to shed light into new angles of the original question

Consider the risk of misperception by your peers

Reputation is the most important asset; yours and your collaborators'

*“Believe those who are seeking
the truth; doubt those who find it.”*

Andre Gide, 1869-1951

What is the audience for the paper?

Who will care about the message and findings?

How restricted or broad is the message?

Will it appeal to a sub-specialty only?

Who is likely to request reprints or PDF files?

The authors' perception may be wrong

Ask colleagues both from within your specialty and from the outside

What is the format for the message?

How much documentation is needed?

Will readers want detailed information on design and methods?

Reports of specific findings and associations require more details on methods and potential sources of biases (e.g., case selection, dropouts, etc.)

Descriptive reports without specific hypotheses require fewer details

Choice of journal: of general medical interest or specialty

Maximum size of manuscript depends on the journal; high-impact, general interest medical journals around 2500 words and specialty technical journals around 4000 words

What is the journal for the paper?

Does it reach the intended audience? Is the message of the paper within the scope of journal?

Has the journal published comparable papers recently?

Check the instruction for authors and recent issues to verify the goodness of fit of the submission

What is the overall impact of the journal?

Check scientific impact indices and consult experienced colleagues

Circulation is not necessarily related to impact

Does it publish fast enough?

Consult experienced colleagues and check journal statistics

Has it been rejected previously?

Were reviewers' critiques taken into account when revising?

Indices of Scientific Influence by ISI's Journal Citation Reports

Impact Factor

Identifies the frequency with which an average article from a journal is cited in a particular year. Used to compare a journal's relative importance to others in the same field. It represents the average number of citations received per year per article during the first two years after a journal volume is published.

Immediacy Index

Measures how quickly the average article from a journal is cited within the year of publication. Useful for evaluating journals that publish cutting-edge research.

Cited Half-life

The cited half-life benchmarks the age of cited articles by showing the number of years back from the current year that account for 50% of the total number of citations to a journal in the current year. Useful in making collection management and archiving decisions.

Journal h-index

Proposed in 2005 by Jorge Hirsch as a metric for evaluating individual scientists. The h-index can be applied to any group of articles, including those published in a particular journal in any given year. If a set of papers is arranged in descending order of the lifetime citations received, the h-index h is the highest number for which it is true to say that h articles have each received at least h citations.

SCImago Journal Rank

Developed by SCImago, University of Granada (Madrid). Based on citation data of the more than 15,000 peer-reviewed journals indexed by Scopus from 1996 onwards (www.scimagojr.com). The journal rank of journal J in year X is the number of weighted citations received by J in X to any item published in J in $(X-1)$, $(X-2)$ or $(X-3)$, divided by the total number of articles and reviews published in $(X-1)$, $(X-2)$ or $(X-3)$. It is a measure of the number of times an average paper in a particular journal is referred to, which makes it conceptually similar to the Impact Factor. A major difference is that instead of each citation being counted as one, as with the Impact Factor, the SCImago Journal Rank assigns each citation a value greater or less than one based on the rank of the citing journal. The weighting is calculated iteratively from an arbitrary constant using a three-year window of measurement. Detailed methodology can be found at www.scimagojr.com/SCImagoJournalRank.pdf.

Eigenfactor and Article Influence

The Eigenfactor and Article Influence are recently developed metrics based on data held in Thomson Reuters' Journal Citation Reports. They are freely available at www.eigenfactor.org.

The Eigenfactor of journal J in year X is defined as the percentage of weighted citations received by J in X to any item published in (X-1), (X-2), (X-3), (X-4), or (X-5), out of the total citations received by all journals in the dataset. Only citations received from a journal other than J are counted. The Eigenfactor is not corrected by article count, and so is a measure of the influence of a particular journal; bigger and highly cited journals will tend to be ranked highly.

As with the SCImago Journal Rank, each (non-self) citation is assigned a value greater or less than one based on the Eigenfactor of the citing journal. The weighting to be applied is calculated iteratively from an arbitrary constant. Detailed methodology can be found at www.eigenfactor.org/methods.htm.

Article Influence is calculated by dividing the Eigenfactor by the percentage of all articles recorded in the Journal Citation Reports that were published in J. Article Influence is therefore is conceptually similar to the Impact Factor and SCImago Journal Rank.

Rank	Abbreviated Journal Title	Impact Factor	5-Year IF	Immediacy Index	Cited Half-Life	Eigenfactor Score	Article Influence Score
1	EPIDEMIOL REV	12.13	10.039	0.2	>10.0	0.00455	4.023
2	ENVIRON HEALTH PERSP	6.123	7.069	0.897	5.6	0.06532	2
3	ANNU REV PUBL HEALTH	6.045	7.491	1.68	7.9	0.00781	3.091
4	WHO TECH REP SER	5.923		0	>10.0	0.00248	
5	INT J EPIDEMIOL	5.838	5.845	2.06	7.7	0.03692	2.53
6	AM J EPIDEMIOL	5.454	6.404	1.258	9.5	0.07706	2.588
7	EPIDEMIOLOGY	5.406	5.705	1.645	7.4	0.02221	2.141
8	CANCER EPIDEM BIOMAR	4.77	5.148	0.532	4.8	0.06422	1.692
9	TOB CONTROL	4.438	4.213	0.514	5.6	0.01502	1.621
10	AM J PUBLIC HEALTH	4.241	4.984	0.784	8.5	0.06395	1.981
11	B WORLD HEALTH ORGAN	3.803	4.746	1.223	8.2	0.02186	1.881
12	AM J PREV MED	3.766	4.863	2.883	5.3	0.03486	1.82
13	CANCER CAUSE CONTROL	3.69	4.01	0.445	6.5	0.01954	1.443
14	DRUG SAFETY	3.537	3.498	0.611	6.6	0.00804	0.903
15	J TOXICOL ENV HEAL B	3.316	4.341	1.167	5	0.00205	1.127
16	OCCUP ENVIRON MED	3.302	3.524	0.707	6.1	0.01714	1.054
17	MED CARE	3.194	4.165	0.785	9.5	0.03263	1.736
18	J EPIDEMIOL COMMUN H	3.186	4.098	0.408	6.5	0.02845	1.494
19	ENVIRON RES	3.038	3.377	0.787	6.7	0.01307	0.958
20	J ADOLESCENT HEALTH	2.91	3.679	0.471	5.9	0.02152	1.238
21	J CLIN EPIDEMIOL	2.896	3.581	0.658	>10.0	0.02503	1.367
22	INFECT CONT HOSP EP	2.834	3.156	0.424	6	0.02387	1.116
23	SCAND J WORK ENV HEA	2.802	2.807	0.17	>10.0	0.0062	0.818
24	PREV MED	2.757	3.661	0.607	6.8	0.0275	1.229
25	ANN EPIDEMIOL	2.621	3	0.496	6.7	0.01534	1.21
26	EUR J EPIDEMIOL	2.572	2.413	0.323	7.4	0.01183	0.855
27	NICOTINE TOB RES	2.539	3.764	0.332	4.7	0.01518	1.282
28	PSYCHIAT SERV	2.481	2.896	0.439	6.3	0.01647	0.868
29	AM J TROP MED HYG	2.45	2.715	0.456	9	0.0342	0.858
30	J URBAN HEALTH	2.409	2.791	0.239	4.4	0.00955	1.11
31	HEALTH EXPECT	2.397		0.611	5.1	0.00251	
32	EPIDEMIOL INFECT	2.36	2.337	0.482	7	0.01341	0.803
33	TROP MED INT HEALTH	2.312	2.511	0.652	5.1	0.01583	0.812
34	PATIENT EDUC COUNS	2.219	2.543	0.307	5.2	0.01346	0.698
35	GENET EPIDEMIOL	2.203	3.548	0.718	5.9	0.01375	1.718
36	J EXPO SCI ENV EPID	2.196	2.652	0.759	5.7	0.00602	0.86
37	VECTOR-BORNE ZOONOT	2.195	2.529	0.409	3.5	0.00443	0.839
38	EUR J PUBLIC HEALTH	2.176	2.412	0.26	4	0.00829	0.815
39	QUAL LIFE RES	2.169	2.985	0.328	6.3	0.01433	0.857
40	INT J HYG ENVIR HEAL	2.158	2.191	0.324	4.3	0.00454	0.603
41	PUBLIC HEALTH NUTR	2.123	2.688	0.86	5.3	0.01269	0.868
42	STAT MED	2.111	2.315	0.438	8.8	0.03358	1.128
43	J AEROSOL MED	2.108	2.314		6	0.00269	0.587
44	J OCCUP ENVIRON MED	2.085	2.512	0.372	7.6	0.01131	0.741
45	T ROY SOC TROP MED H	2.062	2.164	0.442	>10.0	0.01174	0.696
46	BMC PUBLIC HEALTH	2.029	2.256	0.217	2.6	0.0154	0.759
47	COMMUNITY DENT ORAL	1.963	2.757	0.238	9.6	0.00514	0.817
48	J WOMENS HEALTH	1.943	1.935	0.124	3.8	0.00654	0.597
49	INT ARCH OCC ENV HEA	1.938	2.031	0.439	8.6	0.00554	0.56
50	PALLIATIVE MED	1.874	2.813	0.265	5.9	0.00698	0.816

**Top 50
journals in
Public,
Environmental
&
Occupational
Health in 2008**

**(ranked by
impact factor)**

**Source: Journal
Citation Reports
(Thomson-Reuters,
2008)**

Rank	Abbreviated Journal Title	Impact Factor	5-Year IF	Immediacy Index	Cited Half-Life	Eigenfactor Score	Article Influence Score
1	NEW ENGL J MED	50.017	49.911	12.225	7.3	0.6806	18.764
2	JAMA-J AM MED ASSOC	31.718	27.957	7.556	7.2	0.38132	11.153
3	LANCET	28.409	27.264	8.505	8.1	0.41221	9.953
4	ANN INTERN MED	17.457	16.117	4.574	8.8	0.12606	6.268
5	BRIT MED J	12.827	10.665	6.032	8.7	0.15954	3.789
6	PLOS MED	12.185	13.18	3.684	2.4	0.05747	6.142
7	ANNU REV MED	10.985	10.278	4.088	6.6	0.01344	3.837
8	ARCH INTERN MED	9.11	9.665	2.279	7.4	0.11379	3.572
9	CAN MED ASSOC J	7.464	7.559	3.305	6.9	0.02836	2.455
10	ANN MED	5.435	4.59	0.75	6.6	0.01166	1.686
11	J INTERN MED	5.412	5.472	1.523	6	0.02672	1.91
12	COCHRANE DB SYST REV	5.182		1.131	3.9	0.10078	
13	AM J MED	5.105	5.23	1.045	>10.0	0.04895	1.725
14	MAYO CLIN PROC	4.811	4.466	1.228	7.9	0.02333	1.363
15	MEDICINE	4.329	6.778	0.25	>10.0	0.00783	2.006
16	AM J PREV MED	3.766	4.863	2.883	5.3	0.03486	1.82
17	ANN FAM MED	3.541		2.339	3.6	0.01155	
18	MED J AUSTRALIA	3.32	3.315	1.239	6.4	0.02037	0.769
19	BRIT MED BULL	3.277	4.182	0.256	8.8	0.00567	1.414
20	BMC MED	3.276		1.037	3.3	0.0048	
21	J HOSP MED	3.163		0.557	2.1	0.00112	
22	J LAB CLIN MED	2.795	2.274		>10.0	0.00417	0.669
23	EUR J CLIN INVEST	2.784	2.961	0.472	7.2	0.01267	0.887
24	PREV MED	2.757	3.661	0.607	6.8	0.0275	1.229
25	J GEN INTERN MED	2.72	3.601	0.611	5.9	0.03183	1.337
26	J PAIN SYMPTOM MANAG	2.681	3.328	0.411	6.8	0.01384	0.974
27	CURR MED RES OPIN	2.596	2.866	0.709	3.3	0.01745	0.676
28	QJM-INT J MED	2.483	3.306	0.368	>10.0	0.00812	0.974
29	J URBAN HEALTH	2.409	2.791	0.239	4.4	0.00955	1.11
30	BRIT J GEN PRACT	2.278	2.29	1.719	7	0.00838	0.69
31	AM J MANAG CARE	2.22	2.553	0.833	4.4	0.01137	0.955
32	MED CLIN N AM	2.214	2.226	0.27	8.8	0.00455	0.604
33	DM-DIS MON	2.161	1.695	0.269	5.3	0.00098	0.466
34	PAIN MED	2.125	2.981	0.4	3.7	0.00443	0.743
35	J AM BOARD FAM MED	2.097	2.195	1.329	5	0.00525	0.671
36	INTERN MED J	2.027	1.903	0.468	3.6	0.00639	0.53
37	INT J CLIN PRACT	2.007	1.567	0.595	3.4	0.01115	0.367
38	TRANSL RES	1.984	1.992	0.52	1.7	0.00167	0.601
39	CLEV CLIN J MED	1.969	1.512	0.65	5.2	0.00316	0.395
40	J WOMENS HEALTH	1.943	1.935	0.124	3.8	0.00654	0.597
41	AM FAM PHYSICIAN	1.94	2.107	0.345	6.2	0.00936	0.507
42	INDIAN J MED RES	1.883	1.772	0.504	6.7	0.00592	0.429
43	PALLIATIVE MED	1.874	2.813	0.265	5.9	0.00698	0.816
44	J EVAL CLIN PRACT	1.843	1.769	0.559	4	0.00357	0.46
45	SCAND J PRIM HEALTH	1.724	1.621	0.333	7.6	0.00164	0.36
46	J INVEST MED	1.723	1.736	0.364	7.4	0.00267	0.611
47	AMYLOID	1.714	1.909	0.103	6.2	0.00207	0.532
48	FAM PRACT	1.63	2.099	0.226	7.1	0.00691	0.619
49	FAM MED	1.626	1.594	0.463	6.7	0.00423	0.499
50	POSTGRAD MED J	1.587	1.599	0.177	7.9	0.00802	0.447

Top 50 journals in Medicine, General & Internal in 2008

(ranked by impact factor)

Source: Journal Citation Reports (Thomson-Reuters, 2008)

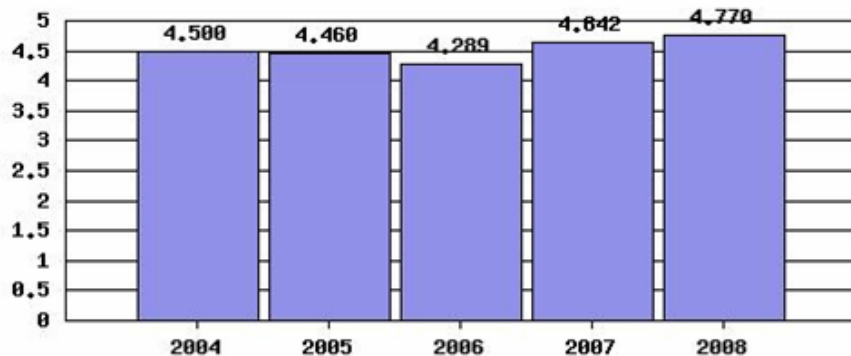
Rank	Abbreviated Journal Title	Impact Factor	5-Year IF	Immediacy Index	Cited Half-Life	Eigenfactor Score	Article Influence Score
1	CA-CANCER J CLIN	74.575	50.766	24.684	3.3	0.03648	17.506
2	NAT REV CANCER	30.762	35.007	4.612	4.5	0.13538	15.265
3	CANCER CELL	24.962	23.332	5.359	3.9	0.11911	11.73
4	J CLIN ONCOL	17.157	15.556	4.294	4.3	0.34752	4.164
5	J NATL CANCER I	14.933	16.03	3.338	8.2	0.09924	5.791
6	LANCET ONCOL	13.283	12.494	3.4	3.4	0.0351	3.947
7	BBA-REV CANCER	10.283	10.27	1.074	5	0.00985	3.864
8	NAT CLIN PRACT ONCOL	9.113		1.429	2.5	0.01116	
9	LEUKEMIA	8.634	6.896	2.067	4.8	0.05949	2.216
10	SEMIN CANCER BIOL	8.284	7.708	1.939	5.4	0.01677	3.113
11	STEM CELLS	7.741	8.212	1.526	2.9	0.06039	2.673
12	CANCER RES	7.514	7.98	1.153	6.7	0.43486	2.827
13	ONCOGENE	7.216	6.729	1.419	5.6	0.25962	2.676
14	CANCER METAST REV	6.766	7.47	0.691	5.6	0.01095	2.469
15	ONCOLOGIST	6.63	6.284	1.048	3.7	0.02021	1.704
16	CLIN CANCER RES	6.488	6.646	1.022	4.3	0.21531	2.023
17	BREAST CANCER RES TR	5.684	4.961	1.119	4.4	0.03459	1.425
18	MOL CANCER	5.362		0.551	2.7	0.01376	
19	CANCER	5.238	5.517	1.109	9.8	0.12256	1.671
20	ENDOCR-RELAT CANCER	5.236	5.827	0.483	3.8	0.01558	1.757
21	NEOPLASIA	5.191	5.124	1.682	3.6	0.01733	1.541
22	J PATHOL	5.121	5.583	1.63	6.6	0.03838	1.884
23	BREAST CANCER RES	5.052	4.97	1.143	3.7	0.02245	1.69
24	MOL CANCER THER	5.003	5.428	0.645	3.2	0.04619	1.676
25	NEURO-ONCOLOGY	5	5.268	0.934	3.8	0.00613	1.646
26	ANN ONCOL	4.935	5.303	1.377	4.6	0.05407	1.404
27	CARCINOGENESIS	4.93	5.21	0.812	7.5	0.04969	1.615
28	BRIT J CANCER	4.846	4.637	0.78	6.7	0.09494	1.419
29	CANCER EPIDEM BIOMAR	4.77	5.148	0.532	4.8	0.06422	1.692
30	INT J CANCER	4.734	4.656	1.023	6.3	0.11463	1.453
31	CANCER TREAT REV	4.729	4.569	1.07	4.6	0.00876	1.322
32	ADV CANCER RES	4.721	5.818	0.957	9	0.00427	2.191
33	INT J RADIAT ONCOL	4.639	5.015	0.894	6.5	0.06914	1.065
34	CRIT REV ONCOL HEMAT	4.589	4.215	0.864	4.8	0.01221	1.234
35	MOL CANCER RES	4.533	5.195	0.529	3.6	0.01888	1.91
36	EUR J CANCER	4.475	4.635	1.009	6.6	0.05028	1.367
37	CURR CANCER DRUG TAR	4.316		1.03	3.5	0.00887	
38	SEMIN RADIAT ONCOL	4.312	4.989	0.879	4.8	0.00594	1.497
39	J MAMMARY GLAND BIOL	4.167	4.539	0.524	6.5	0.0054	1.727
40	CURR OPIN ONCOL	4.116	3.663	1	4.8	0.00854	1.139
41	RADIOTHER ONCOL	3.99	3.918	1	6	0.02094	0.968
42	SEMIN ONCOL	3.956	2.919	0.176	7.2	0.01638	0.863
43	EXP CELL RES	3.948	3.91	0.804	8	0.06642	1.579
44	GENE CHROMOSOME CANC	3.925	3.557	0.935	6.4	0.01944	1.396
45	ANN SURG ONCOL	3.898	4.507	0.976	4.6	0.02695	1.13
46	CANCER IMMUNOL IMMUN	3.804	3.525	1.042	4.1	0.01572	1.058
47	CANCER CAUSE CONTROL	3.69	4.01	0.445	6.5	0.01954	1.443
48	J IMMUNOTHER	3.662	3.797	0.333	4.4	0.00837	1.195
49	MOL CARCINOGEN	3.571	3.12	0.699	6	0.00966	1.045
50	J THORAC ONCOL	3.508	3.514	0.55	1.7	0.00648	0.883

Top 50 journals in Oncology in 2008

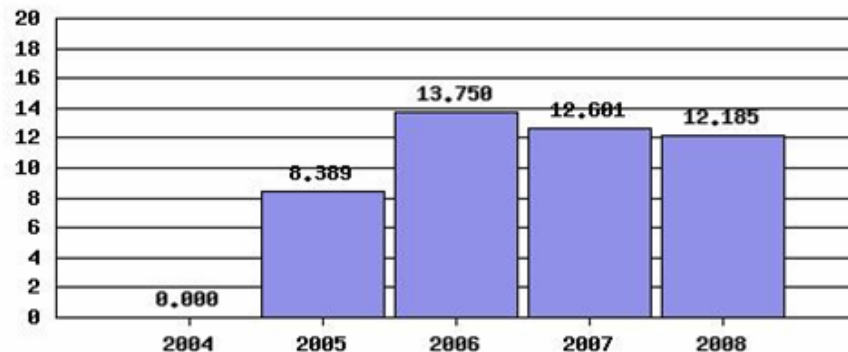
(ranked by impact factor)

Source: Journal Citation Reports (Thomson-Reuters, 2008)

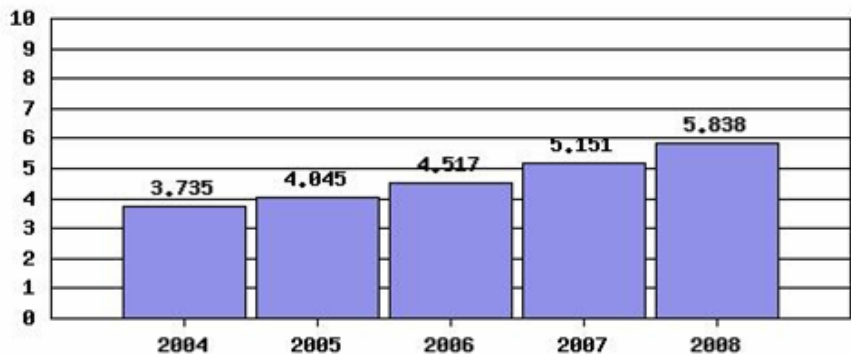
CANCER EPIDEMIOLOGY BIOMARKERS & PREVENTION



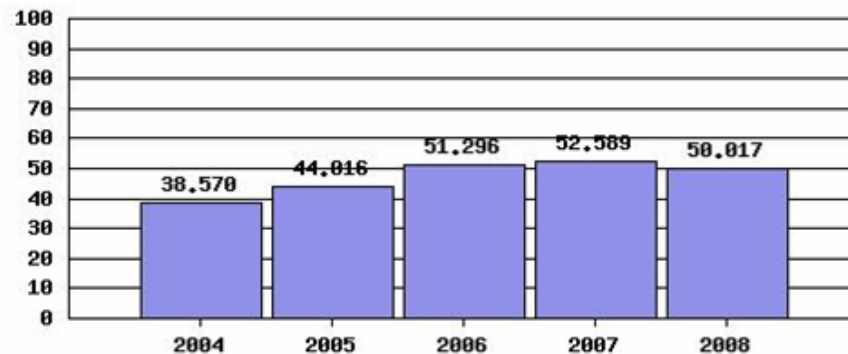
PLOS MEDICINE



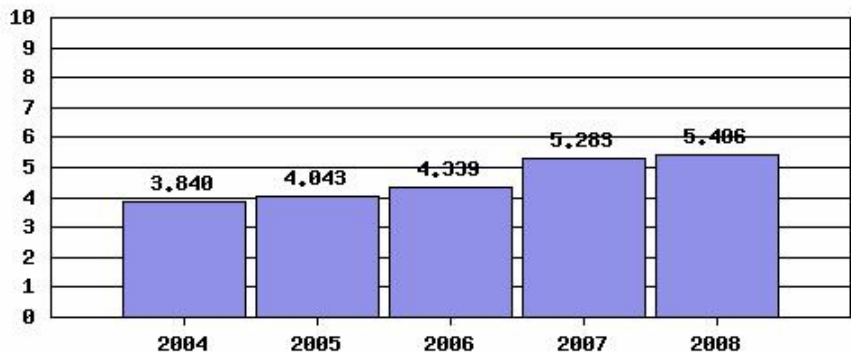
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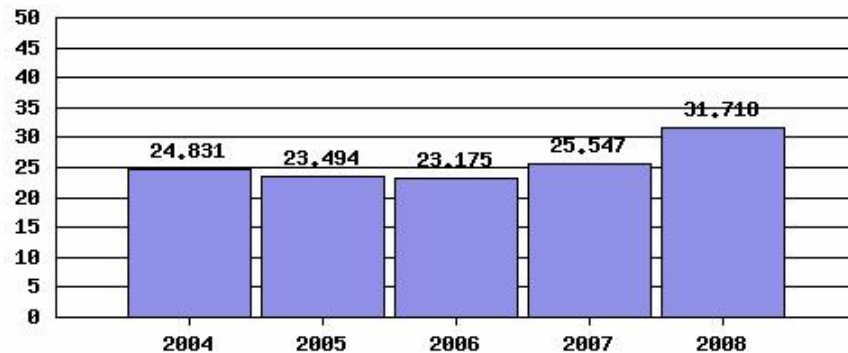
NEW ENGLAND JOURNAL OF MEDICINE



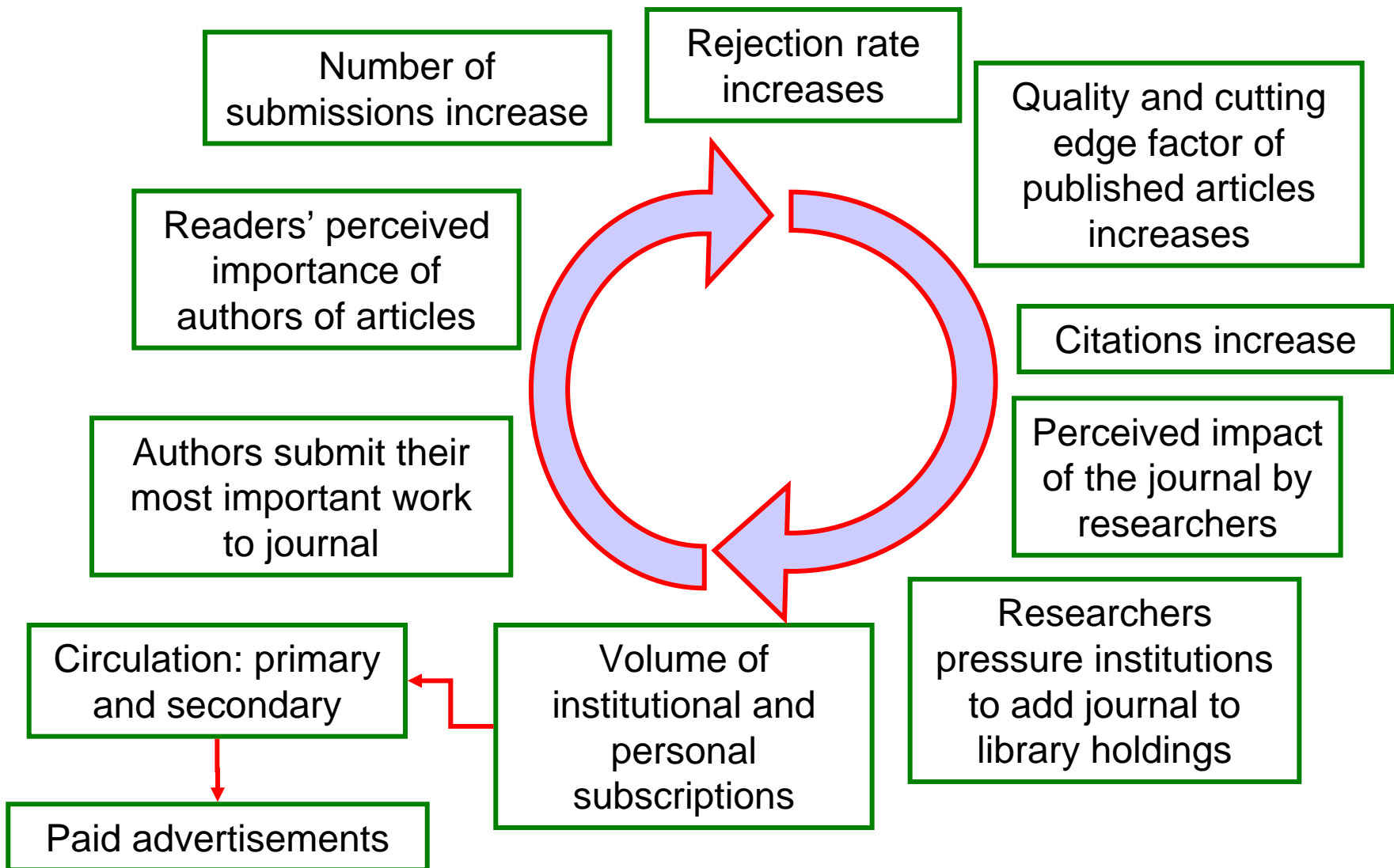
EPIDEMIOLOGY



JAMA—JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION



Emergence and life cycle of scientific journals



Paper and Internet Journals

Classic paper journals

- Peer review
- Publication serialized and grouped by issue and volume
- Restrictive manuscript length policy

Internet journals

- Peer review (the scholarly ones)
- Pace of publication less reliant on chronologic grouping by issue and volume
- Less restrictive manuscript length policy

Paradigms of revenue generation for journals

Classical (> 100 years)

- Supported by professional societies or scholarly communities
- Subscriptions sold to libraries and individuals
- Small page charges to authors
- Sale of reprints and offprints
- Advertisement
- Lately: packaged internet subscriptions to institutions and sale of individual article PDF files

Open access (from early 2000s)

- Equitable, free access to all individuals (must access journal via internet)
- Some are supported by scholarly communities
- Fixed manuscript publication fee (US\$1000-2500) charged to authors (who transfer the expense to granting agencies)
- Examples: Biomed Central series and Public Library of Science (PLoS-Biology and PLoS-Medicine)

Communicating research

Elements of the rational argument	Components of a scientific article
Summarize background, objectives, methods, results, and discussion	Abstract
Statement of the research problem	Introduction
Credibility of the means to collect evidence	Material & Methods
Obtaining the evidence: main and subsidiary points	Results, Tables, Figures
Assessment of opposing and supporting evidence by others, weighing the evidence in light of study's limitations, making recommendations	Discussion, Conclusions
Credit previous studies whose findings led to the present study and formed the knowledge base anchoring the new evidence	References

“Not everything that can be counted counts, and not everything that counts can be counted”

Albert Einstein (1879-1955)

“When you can measure what you are speaking about, and express it in numbers, you know something about it, but when you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind; it may be the beginning of knowledge, but you have scarcely, in your thoughts, advanced to the stage of science, whatever the matter be.”

Lord Kelvin, 1858

Examples of Language Editing Services (Elsevier: publisher of over 2000 Scientific Journals)

<http://www.elsevier.com/wps/find/authorsview.authors/languagepolishing>

- American Journal Experts
- Asia Science Editing
- Diacritech Language Editing Services
- Edanz Editing
- International Science Editing
- International Science Editing - China
- ScienceDocs Editing Services
- SPI Publisher Services

Rules of authorship



Source: ORI Manual on
Research Integrity; Illustrations:
Copyright by David Zinn

Rules of authorship

Come to an agreement about authorship early enough

Avoid unnecessary friction

Balance fairness, generosity, and responsibility

Diplomacy versus acquired right: Authors must take public responsibility for the article's content (CBE Manual, 1983)

Rule 1: Authors must have generated at least part of the intellectual content: e.g., conception, design, analyzing and interpreting data, justification for a case report, ideas in an editorial or position paper

Rule 2: Authors must have taken part in writing the paper, reviewing it, or revising its intellectual content

Rule 3: Authors must be able to defend the intellectual content of the paper to the scientific community and publicly

Rules of authorship

International Committee of Medical Journal Editors: Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication (*Updated February 2006*)

“**Authorship credit** should be based on

- 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
- 2) drafting the article or revising it critically for important intellectual content; and
- 3) final approval of the version to be published.

Authors should meet conditions 1, 2, and 3.”

Rules of authorship

International Committee of Medical Journal Editors: Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication (*Updated February 2006*)

- ✓ “Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
- ✓ All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- ✓ Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.
- ✓ The order of authorship on the byline should be a joint decision of the co-authors.
- ✓ Authors should be prepared to explain the order in which authors are listed.”

Disclosure of Roles and Conflicts



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“We ask that you make clear who designed the study, who gathered the data, who analyzed the data, who vouches for the data and the analysis, and who wrote the paper (see editorial in the September 13, 2001 issue). The Methods section should include a brief statement about this. We also ask that you prepare a financial disclosure statement for publication with the paper. The statement should describe the authors’ relationships with companies that make products relevant to the paper. The statement should specify the type of relationships (e.g., consulting, paid speaking, grant support, equity, patents) EACH author has with EACH company. The information should be consistent with the authors’ signed financial disclosure forms. The statement should be located before the Acknowledgement section of the text and labeled ‘Disclosure.’ “

Disclosure of Roles and Conflicts



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DISCLOSURE FOOTNOTE SAMPLE

Dr. Johnson reports having served as a consultant to Bayer. Dr. Williams reports having been paid lecture fees by AstraZeneca, Merck, and TAP. Drs. Allen, Jones, and Williams report having received grant support from Merck. Dr. Lewis reports having equity interests in Pfizer and Merck. A U.S. patent entitled “Methods of Assessing Transplant Rejection” (6125876) was issued on January 10, 2002; Dr. McCarthy is one of the inventors. The patent is owned jointly by Harvard and Massachusetts General Hospital. A patent on the use of canalept (CNA4XMP) for the treatment of this condition has been assigned to Pfizer and the University of Illinois; neither Dr. Ames nor Dr. Hamilton has a financial interest in the patent. Dr. Ames and Dr. Hamilton are consultants to Pfizer, as well as to other companies that manufacture treatments for this condition. Drs. Roberts and Jenkins have assigned to Biotech Pharmaceuticals their inventions made as employees of the company and have received no royalties from Biotech for these inventions. Dr. Roberts receives royalties for inventions he made before becoming an employee of Biotech. Dr. Simon reports having served as an expert witness in tobacco litigation during the past five years. Dr. Levy reports having received consulting fees from Unilever, Wyeth, and Monsanto and having received a grant and holding stock options and related patents with Panacea. Dr. Elton, who was an employee of GIBCO while the study was being carried out, is currently a consultant to GIBCO and has stock options in Genentech. Dr. Sullivan and Dr. Smith are employees of GIBCO. Dr. Fuller reports having served on the advisory boards of Wyeth–Ayerst, Pfizer, and Otsuka. Dr. Hastings reports having been a member of speakers’ bureaus sponsored by Bristol-Myers Squibb and Parke-Davis and is a stockholder or has other ownership interest in Pfizer and Eli Lilly.

The JUPITER trial
"Reductions in both
LDL cholesterol and
hsCRP are indicators of
the success of treatment
with statin therapy."

1	2	3	4	5

“Conflict of interest

A conflict of interest exists if authors or their institutions have financial or personal relationships with other people or organisations that could inappropriately influence (bias) their actions. Financial relationships are easily identifiable, but conflicts can also occur because of personal relationships, academic competition, or intellectual passion. A conflict can be actual or potential, and full disclosure to The Editor is the safest course. Failure to disclose conflicts might lead to publication of a statement in our Department of Error. All submissions to The Lancet must include disclosure of all relationships that could be viewed as presenting a potential conflict of interest [...]. The Editor may use such information as a basis for editorial decisions, and will publish such disclosures if they are believed to be important to readers in judging the manuscript.”

The JUPITER trial
"Reductions in both
LDL cholesterol and
hsCRP are indicators of
the success of treatment
with statin therapy."

- “The corresponding author should confirm that he or she had full access to all the data in the study and had final responsibility for the decision to submit for publication.”
- “At the end of the text, under a subheading “Conflict of interest statement”, all authors must disclose any financial and personal relationships with other people or organisations that could inappropriately influence (bias) their work. Examples of financial conflicts include employment, consultancies, stock ownership, honoraria, paid expert testimony, patents or patent applications, and travel grants, all within 3 years of beginning the work submitted. If there are no conflicts of interest, authors should state that.”

American Journal of Epidemiology
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Title:

Author(s): _____ Ms number: _____

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MANUSCRIPT AUTHORS: If you have been asked to do so by the Corresponding author, please complete **Part I** or **II**. At the point of submission, *American Journal of Epidemiology* policy requires that each author reveal any financial interests or connections, direct or indirect, or other situations *that might raise the question of bias* in the work reported or the conclusions, implications, or opinions stated - including pertinent commercial or other sources of funding for the individual author(s) or for the associated department(s) or organization(s), personal relationships, or direct academic competition.

When considering whether you should declare a conflicting interest or connection please consider the conflict of interest test: Is there any arrangement that would embarrass you or any of your co-authors if it was to emerge after publication and you had not declared it?

If the manuscript is published, this information will be communicated in a statement in the published paper.

I. There have been no involvements that might raise the question of bias in the work reported or in the conclusions, implications, or opinions stated.

Printed name

Signature Date

OR

II. Conflict of interest statement.

Sample statement: I hold stock* in [business name], the makers of [product], and am currently conducting research sponsored by this company. I am also a member of the speakers' bureau for [business name].

* Please provide details of stock where this reveals a pertinent conflict of interest.

My statement is as follows:

Printed name

Signature Date



“In March, 2008, *The New York Times* and *The Cancer Letter* reported a seminal lung-cancer screening study published in the *New England Journal of Medicine* on Oct 26, 2006, had been partly funded with money from a tobacco company. The International Early Lung Cancer Action Programme Investigators (I-ELCAP) study declared funding from the Foundation for Lung Cancer: Early Detection, Prevention and Treatment, but did not state that this charitable foundation was supported by US\$3.6 million from the Vector Group—parent company of the Liggett Group, which manufacture cigarettes. Of note, the foundation had been set up by the lead investigators of the I-ELCAP group who it now transpires also failed to disclose patents related to CT diagnostics in papers published in other journals. The I-ELCAP findings suggest lung cancer can be caught early and treated successfully, thereby potentially allowing tobacco companies to continue to peddle their products with impunity. So in light of these nondisclosures, can the I-ELCAP findings be trusted?”

“...The Liggett grant was fully disclosed in a press release at the time it was awarded in 2000 and formed only a small part of the overall funding of the I-ELCAP study. But although scrutiny of funding sources in 2000 was not as rigorous as today, surprisingly, this public announcement was not reiterated when the paper was submitted to the *New England Journal of Medicine*.”

“[...] [T]he latest disclosures shed additional light on the already controversial interpretation of the I-ELCAP findings [...] Many people have a fundamental problem with accepting that research funded by companies producing the causal instrument of a disease (eg, cigarettes), or advocating a test that the authors could financially benefit from, is truly impartial... [T]his ... episode reflects badly not only on the authors of the New England Journal of Medicine paper, but also damages the reputations of their institute and the other journals that have become embroiled in the controversy.”

Research Misconduct



Source: ORI Manual on
Research Integrity; Illustration:
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Definition of Research Misconduct

“Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.”

“Fabrication is making up data or results and recording or reporting them.”

“Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.”

“Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.”

“Research misconduct does not include honest error or differences of opinion.”

Plagiarism

- Theft or misappropriation of intellectual property.
- Substantial unattributed textual copying of another's work.
- Unattributed verbatim or nearly verbatim copying of sentences and paragraphs which materially mislead the ordinary reader regarding the contributions of the author.
- Does not include authorship or credit disputes.
- Unauthorized use of ideas or unique methods obtained by a privileged communication, such as a grant or manuscript review.

“Many allegations of plagiarism involve disputes among former collaborators who participated jointly in the development or conduct of a research project, but who subsequently went their separate ways and made independent use of the jointly developed concepts, methods, descriptive language, or other product of the joint effort. The ownership of the intellectual property in many such situations is seldom clear, and the collaborative history among the scientists often supports a presumption of implied consent to use the products of the collaboration by any of the former collaborators.”

Is this plagiarism?

Original (reference 104 cited below):

“Perhaps one of the most neglected aspects of the ongoing debate on the potential impact of prophylactic HPV vaccination is the need to examine existing screening practices to permit synergy between primary and secondary prevention efforts.”

Suspected text:

“One of the most neglected aspects of the potential effect of prophylactic HPV vaccines is the evaluation of existing screening practices to permit synergy between primary and secondary prevention efforts (104).”

Original (reference 15 cited below):

“These randomized controlled trials, embedded in on-going opportunistic or organized screening programs, will provide the level of evidence necessary for public health policymakers to make informed decisions about the future of their cervical cancer screening programs.”

Suspected text:

“Ongoing randomized control trials of primary HPV screening will yield the degree of evidence necessary for public health policymakers to make informed decisions about the future of cervical cancer screening programs (15).”

Is this plagiarism?

Original (not referenced below):

“Organized screening has contributed to a decline in cervical cancer incidence and mortality over the past 50 years. However, women in developing countries are yet to profit extensively from the benefits of screening programs, and recent trends show a resurgence of the disease in developed countries. The past 2 decades have witnessed substantial progress in our understanding of the natural history of cervical cancer and in major treatment advances. Human papillomavirus (HPV) infection is now recognized as the main cause of cervical cancer, the role of coexisting factors is better understood, a new cytology reporting terminology has improved diagnosis and management of precursor lesions, and specific treatment protocols have increased survival among patients with early or advanced disease. Current research has focused on the determinants of infection with oncogenic HPV types, the assessment of prophylactic and therapeutic vaccines and the development of screening strategies incorporating HPV testing and other methods as adjunct to cytology. These are fundamental stepping stones for the implementation of effective public health programs aimed at the control of cervical cancer.”

Suspected text:

“Organised screening services have contributed much to the decline of cervical cancer incidence and mortality over the past 50 years. However, women in developing countries are yet to profit extensively from the benefits of screening programs, and recent trends show a resurgence of the disease in developed countries. The past 2 decades have witnessed substantial progress in our understanding of the natural history of cervical cancer and in major treatment advances. Human papillomavirus (HPV) infection is now recognized as the main cause of cervical cancer, the role of co-existing factors is better understood, a new cytology reporting terminology has improved diagnosis and management of precursor lesions, and specific treatment protocols have increased survival among patients with early and advanced disease. Current research has focused on the determinants of infection with oncogenic HPV types, the assessment of prophylactic and therapeutic vaccines and the development of screening strategies incorporating HPV testing and other methods as adjunct to cytology. These are fundamental stepping stones for the implementation of effective public health programs aimed at the control of cervical cancer.”



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1	7587703 [Chai, B et al., 1995][Medline]	9275340 [Chai, B et al., 1996][Medline]	16	chi eng	0.91	Y	DUPLICATE	2007-02-14		By Classification All DISTINCT DUPLICATE ERRATUM NO ABSTRACT SANCTIONED UNVERIFIED UPDATE Filter by <input type="checkbox"/> Authors (SA/DA) <input type="checkbox"/> Journals (SJ/DJ) <input type="checkbox"/> Reviews(R) <input type="checkbox"/> Comment <input type="checkbox"/> Other <input type="checkbox"/> Languages <input type="checkbox"/> Medline Label (ML) <input type="checkbox"/> Medline Issue (MI) <input type="checkbox"/> PMC full text <input type="checkbox"/> Discovery methods <input type="checkbox"/> Curator 1 <input type="checkbox"/> Curator 2 <input type="checkbox"/> Full Text Examined
2	16475345 [He, Hong et al., 2005][Medline]	16494333 [Liu, Junfeng et al., 2006][Medline]	2	eng eng	0.59	Y	DUPLICATE	2007-02-14		
3	16734501 [Battershill, Anna J et al., 2006][Medline]	16526829 [Battershill, Anna J et al., 2006][Medline]		eng eng	0.96	Y	DUPLICATE	2007-02-14		
4	8199193 [Birchmeier, W et al., 1994][Medline]	7587628 [Birchmeier, W et al., 1995][Medline]		eng eng	0.79	Y	DUPLICATE	2007-02-14		
5	8980928 [Mahmood, I,1996][Medline]	8893036 [Mahmood, I et al., 1996][Medline]		eng eng	0.91	Y	DUPLICATE	2007-02-14		
6	15497674 [O'Hagan, Derek T et al., 2004][Medline]	16480788 [O'Hagan, Derek T et al., 2006][Medline]	19	eng eng	0.90	Y	DUPLICATE	2007-02-14		
7	16868161 [Kim, Hyun S et al., 2006][Medline]	16967220 [Kim, Hyun S et al., 2006][Medline]		eng eng	0.68	Y	DUPLICATE	2007-02-14		
10	8957676 [Schodel, F et al., 1996][Medline]	8717391 [Schodel, F et al., 1996][Medline]		eng eng	0.58	Y	DUPLICATE	2007-02-14		
11	8202635 [Plebani, M et al., 1994][Medline]	7587835 [Plebani, M et al., 1995][Medline]		eng eng	0.61	Y	DUPLICATE	2007-02-14		
12	7529528 [Jensen, K E et al., 1994][Medline]	7491720 [Hansen, B et al., 1995][Medline]	12	eng dan	0.68	Y	DUPLICATE	2007-02-14		
13	7718867 [Shen, J et al., 1994][Medline]	7781134 [Ye, Q et al., 1995][Medline]	2	eng chi	0.88	Y	DUPLICATE	2007-02-14		
14	8659291 [Lopez Pereira, P et al., 1995][Medline]	8962819 [Lopez Pereira, P et al., 1996][Medline]	11	spa spa	0.75	Y	DUPLICATE	2007-02-14		
15	17124098 [Bauer, Kenneth A,2006][Medline]	16475045 [Bauer, Kenneth A,2006][Medline]		eng eng	0.70	Y	DUPLICATE	2007-02-14		
16	11399544 [Gupta, S et al., 2001][Medline]	12223969 [Cotsarelis, G,2002][Medline]		eng fre	0.82	Y	DUPLICATE	2007-02-14		
17	12584723 [Ito, Hisanori et al., 2003][Medline]	15484817 [Ito, Hisanori et al., 2004][Medline]	17	eng jpn	0.89	Y	DUPLICATE	2007-02-14		
18	11343524 [Johnson, J G et al., 2001][Medline]	12407497 [Johnson, Jeffrey G et al., 2002][Medline]		eng ger	0.83	Y	DUPLICATE	2007-02-14		
19	3528300 [LaRochelle, W J et al., 1986][Medline]	10949830 [Santora, K E et al., 2000][Medline]	166	eng eng	0.87	Y	DUPLICATE	2007-02-14		
20	11584721 [Reuter, M et al., 2001][Medline]	12964072 [Reuter, M et al., 2003][Medline]	25	ger ger	0.94	Y	DUPLICATE	2007-02-14		
21	9719790 [Kann, L et al., 1998][Medline]	9854692 [Kann, L et al., 1998][Medline]	3	eng eng	0.98	Y	DUPLICATE	2007-02-14		
22	10947928 [Bemporad, J A et al., 2000][Medline]	11331230 [Bemporad, J A et al., 2001][Medline]	6	eng eng	0.75	Y	DUPLICATE	2007-02-14		
23	11194429 [Apodaca, C C et al., 2000][Medline]	11111214 [Apodaca, C C et al., 2000][Medline]		eng eng	0.75	Y	DUPLICATE	2007-02-14		
24	8936767 [Henderson, N J et al., 1996][Medline]	11923918 [Henderson, N J et al., 1997][Medline]	8	eng dut	0.86	Y	DUPLICATE	2007-02-14		
25	9237709 [Herbert, S et al., 1997][Medline]	9471626 [Herbert, S et al., 1997][Medline]	3	eng ger	0.79	Y	DUPLICATE	2007-02-14		



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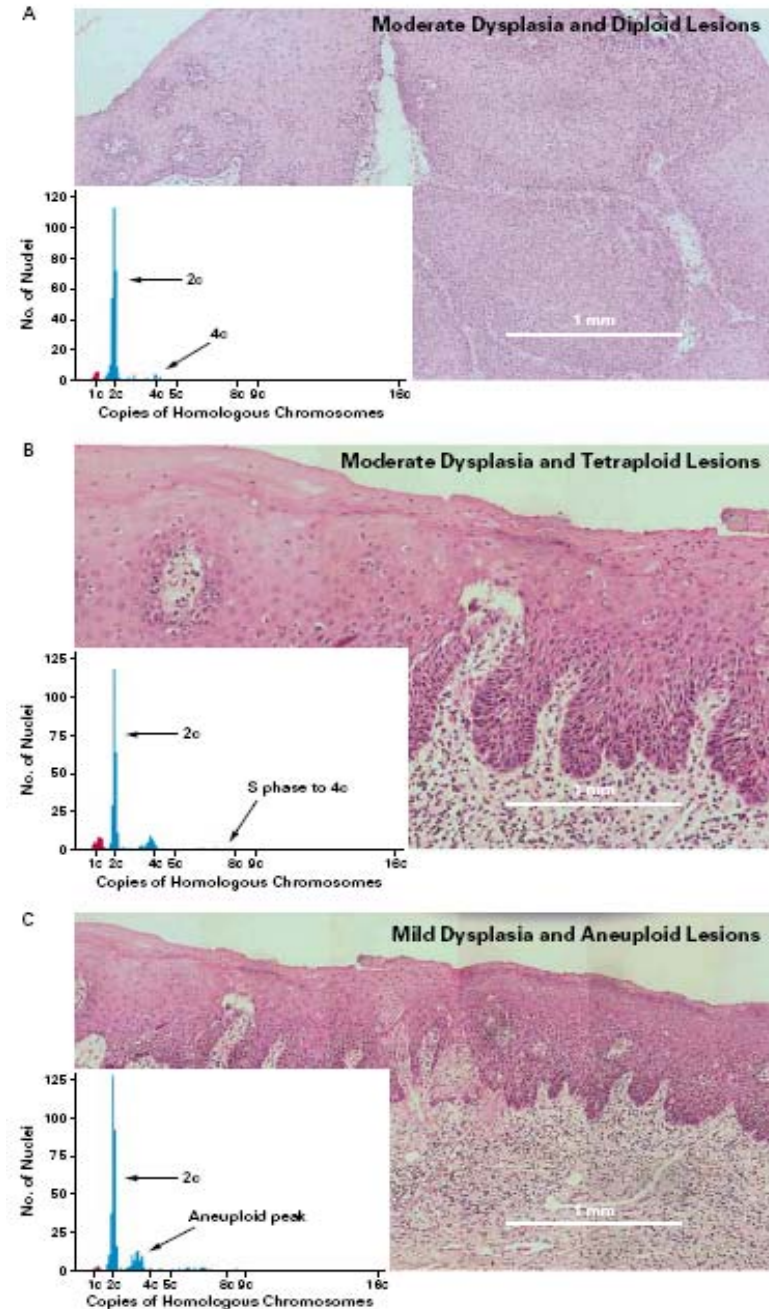
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DNA CONTENT AS A PROGNOSTIC MARKER IN PATIENTS WITH ORAL LEUKOPLAKIA

JON SUDBØ, M.D., D.D.S., WANJA KILDAL, M.SC., BJÖRN RISBERG, M.D., PH.D., HANNA S. KOPPANG, D.D.S., PH.D., HAVARD E. DANIELSEN, PH.D., AND ALBRECHT REITH, M.D., PH.D.

(N Engl J Med 2001;344:1270-8.)

Figure 3 (facing page). Ploidy (Insets) and Histologic Findings in Two Patients with Moderate Dysplasia (Panels A and B) and One Patient with Mild Dysplasia (Panel C) (Hematoxylin and Eosin). In each histogram, c denotes copy or copies, and the red columns to the left of the 2c (diploid) peak are internal controls. In the histogram shown in the inset in Panel B, "S phase to 4c" indicates cells in synthesis phase that are about to double their DNA content.



Retraction: Sudbø J et al. DNA Content as a Prognostic Marker in Patients with Oral Leukoplakia. *N Engl J Med* 2001;344:1270-8 and Sudbø J et al. The Influence of Resection and Aneuploidy on Mortality in Oral Leukoplakia. *N Engl J Med* 2004;350:1405-13

Gregory D. Curfman, M.D., Stephen Morrissey, Ph.D., and Jeffrey M. Drazen, M.D.

On February 9, 2006, we published an Expression of Concern¹ about two articles we had published by Jon Sudbø et al.^{2,3} In the Expression of Concern, we indicated that we were awaiting the results of an investigation by Dr. Sudbø's institution. That investigation was undertaken by a commission appointed by the Rikshospitalet–Radiumhospitalet Medical Center and the University of Oslo. The commission's report was filed on June 30, 2006, in Norwegian (http://www.rikshospitalet.no/content/res_bibl/6621.pdf), and we received an official English translation on September 1, 2006 (see the Supplementary Appendix, available with the full text of this article at www.nejm.org).

In early September, we sent copies of the translated report to all the authors of the two *Journal* articles by Jon Sudbø et al. We asked each author to respond before September 30, 2006. We have now received responses from all authors except Asle Sudbø. Each of the responding authors,

except Jon Sudbø, has indicated that the data that form the foundation for the articles have been called into question by the findings of the commission, and each of them has requested that the articles be retracted. Jon Sudbø alone does not agree with the commission's report. Given the weight of evidence offered in the commission's report and the requests of most of the authors of the articles, we retract both articles.

1. Curfman GD, Morrissey S, Drazen JM. Expression of concern: Sudbø J et al. DNA content as a prognostic marker in patients with oral leukoplakia. *N Engl J Med* 2001;344:1270-8 and Sudbø J et al. The influence of resection and aneuploidy on mortality in oral leukoplakia. *N Engl J Med* 2004;350:1405-13. *N Engl J Med* 2006;354:638.

2. Sudbø J, Kildal W, Risberg B, Koppang HS, Danielsen HE, Reith A. DNA content as a prognostic marker in patients with oral leukoplakia. *N Engl J Med* 2001;344:1270-8.

3. Sudbø J, Lippman SM, Lee JJ, et al. The influence of resection and aneuploidy on mortality in oral leukoplakia. *N Engl J Med* 2004;350:1405-13.

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Non-steroidal anti-inflammatory drugs and the risk of oral cancer: a nested case-control study

J Sudbo, J Lee, S M Lippman, J Mork, S Sagen, N Flatner, A Ristimäki, A Sudba, L Mao, X Zhou, W Kildal, J F Evensen, A Reith, A J Dannenberg

Summary

Background Non-steroidal anti-inflammatory drugs (NSAIDs) seem to prevent several types of cancer, but could increase the risk of cardiovascular complications. We investigated whether use of NSAIDs was associated with a change in the incidence of oral cancer or overall or cardiovascular mortality.

Methods We undertook a nested case-control study to analyse data from a population-based database (Cohort of Norway; CONOR), which consisted of prospectively obtained health data from all regions of Norway. People with oral cancer were identified from the 9241 individuals in CONOR who were at increased risk of oral cancer because of heavy smoking (≥ 15 pack-years), and matched controls were selected from the remaining heavy smokers (who did not have cancer).

Findings We identified and analysed 454 (5%) people with oral cancer (277 men, 175 women; mean [SD] age at diagnosis 63.3 [13.2] years) and 454 matched controls ($n=908$); 263 (26%) had used NSAIDs, 83 (9%) had used paracetamol (for a minimum of 6 months), and 562 (62%) had used neither drug. NSAID use (but not paracetamol use) was associated with a reduced risk of oral cancer (including in active smokers); hazard ratio 0.47, 95% CI 0.37–0.60, $p<0.0001$. Smoking cessation also lowered the risk of oral cancer (0.40, 0.32–0.52, $p<0.0001$). Additionally, long-term use of NSAIDs (but not paracetamol) was associated with an increased risk of cardiovascular-disease-related death (2.06, 1.34–3.18, $p=0.001$). NSAID use did not significantly reduce overall mortality ($p=0.17$).

Interpretation Long-term use of NSAIDs is associated with a reduced incidence of oral cancer (including in active smokers), but also with an increased risk of death due to cardiovascular disease. These findings highlight the need for a careful risk-benefit analysis when the long-term use of NSAIDs is considered.

Introduction

Squamous cell carcinoma of the oral cavity is associated with severe disease-related and treatment-related morbidity and a poor prognosis that has not improved greatly over the past three decades.^{1,2} Tobacco smoking is the major cause of this disease.³ Patients who have oral leucoplakia with the genetic instability marker aneuploidy have an 80% risk of developing oral cancer⁴ with a high relapse rate and a 70% risk of death in 5 years.^{1,4} Complete surgical excision does not reduce the high risk of aggressive, fatal oral cancer associated with aneuploid oral leucoplakia.⁴ Smoking cessation could offer some protection in this group, but this is often difficult to achieve or sustain.⁵ Therefore, there is an unmet medical need for new treatment strategies, such as chemoprevention with non-steroidal anti-inflammatory drugs (NSAIDs), to reduce the risks of cancer in patients with aneuploid oral leucoplakia.^{6–11}

NSAIDs inhibit cyclo-oxygenase (COX) activity and thereby suppress the synthesis of prostaglandin E_2 . Raised concentrations of prostaglandin E_2 have been detected in both premalignant and malignant lesions, including squamous cell carcinoma of the oral cavity.^{12,13} This increase results from the overexpression of COX-2, the inducible form of COX.^{14,15} Several lines of evidence, beyond the finding of raised amounts of prostaglandin E_2 in tumours, suggest that COX enzymes contribute to the development of oral cancer. COX can convert polycyclic

aromatic hydrocarbons in tobacco smoke to reactive metabolites, which form mutagenic DNA adducts.^{16,17} Prostaglandin E_2 can stimulate cell proliferation and angiogenesis and inhibit apoptosis and immune surveillance.^{18,19} NSAIDs protect against the development of oral cancer in animals.^{20,21} Observational data have indicated that NSAIDs are associated with the reduced risk of several types of cancers,^{22,23} but we know of only two previously published reports of epidemiological studies of NSAIDs with respect to head and neck cancer.^{24,27} These reports only included aspirin and showed conflicting results. Before undertaking a trial to investigate NSAIDs in reducing the risk of oral cancer in the very high-risk group of patients with aneuploid leucoplakia, we did a population-based study to examine the potential association between long-term NSAID use and the risk of oral cancer in current and previously heavy smokers. We also examined the potential associations of overall and cardiovascular mortality with NSAID use.

Methods

Risk identification in population-based health-survey database

We did a nested case-control study within the population-based Cohort of Norway (CONOR), which prospectively obtains data for the Norwegian Health Survey from three longitudinal health surveys covering all geographical regions of Norway (Health Surveys of

Lancet 2005; 366: 1359–66

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See <http://www.thl.no>

Case Summary - Scott E. Monte

[[Federal Register: January 23, 2008 (Volume 73, Number 15)]]

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[wais.access.gpo.gov] [DOCID:fr23ja08-52]

DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of the Secretary

Findings of Scientific Misconduct

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

Scott E. Monte, Huntington Memorial Hospital, Pasadena, CA: Based on the findings of an investigation conducted by Huntington Memorial Hospital (HMH) and information obtained by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Scott E. Monte, L.V.N., former Clinical Research Associate, HMH, engaged in scientific misconduct by knowingly and intentionally falsifying and fabricating clinical research records in HMH cancer prevention and treatment protocols supported by National Cancer Institute (NCI), National Institutes of Health (NIH), awards U10 CA69651, U10 CA12027, U10 CA32012, and U10 CA86004.

Specifically, Mr. Monte knowingly and intentionally:

- (1) Entered falsified and fabricated laboratory data or physical examination results on five (5) research protocol case report forms (CRFs);
- (2) Falsified a gynecological examination report in a physician's progress note and entered the falsified document in the patient's research chart; and
- (3) Fabricated progress notes for four patients and a case report form for one of these patients.

ORI has implemented the following administrative actions for a period of three (3) years, beginning on January 7, 2008:

- (1) Mr. Monte is debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government pursuant to HHS' implementation of the OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 CFR Part 376; and
- (2) Mr. Monte is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT:

Director, Division of Investigative Oversight

Office of Research Integrity

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Case Summary - James David Lieber

[Federal Register: July 23, 2007 (Volume 72, Number 140)]

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[wais.access.gpo.gov] [DOCID:fr23jy07-55]

DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of the Secretary

Findings of Research Misconduct

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

James David Lieber, University of California at Los Angeles: Based on the findings of an inquiry report by the University of California at Los Angeles (UCLA) and additional analysis and information obtained by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that James David Lieber, Staff Research Associate, Semel Institute for Neuroscience and Human Behavior, Integrated Substance Abuse Programs, UCLA, engaged in research misconduct in research funded by National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH), grant R01 DA15390.

Mr. Lieber knowingly and intentionally falsified and fabricated multiple follow-up interviews, urine samples, and urine sample records of human subject study participants and entered such false and fabricated data into the study's data base. A total of 914 follow-up interviews of opiate users were planned to be completed as part of a study of gender differences in a follow up of opiate users in California. Mr. Lieber was assigned to interview 53 of the 132 subjects located for the follow-up study. Over a six-month period, Mr. Lieber falsely claimed to have conducted face-to-face interviews for the study while subsequent contacts with the subjects revealed that they had not been interviewed for the study. A review by the institution determined that the respondent fabricated interviews for 20 of the 53 interviews assigned to him. In addition, he falsified the urine specimens for those 20 subjects and caused the entry of false information into the study tracking and locating data base for 11 subjects. Aggravating factors included the theft of \$5180 for incentive payments to subjects and travel expenses.

ORI has implemented the following administrative actions for a period of three (3) years, beginning on July 2, 2007:

- (1) Mr. Lieber is debarred from eligibility for any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" as defined in HHS' implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 CFR part 376, et seq.; and
- (2) Mr. Lieber is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT:

Director, Division of Investigative Oversight

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Case Summary - Jong Hyuk Park

Federal Register: January 9, 2007 (Volume 72, Number 5)]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of the Secretary

Findings of Research Misconduct

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

Jong Hyuk Park, Ph.D., University of Pittsburgh: Based on accumulated evidence including the University of Pittsburgh (UP) investigation committee report and additional analysis and information obtained by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Jong Hyuk Park, Ph.D., former postdoctoral fellow, Pittsburgh Development Center of the Magee-Womens Research Institute, UP, engaged in research misconduct in research funded by National Center for Research Resources (NCRR), National Institutes of Health (NIH), grant R24 RR13632 and National Institute of Child Health and Human Development (NICHD), NIH, grant P01 HD047675.

Specifically, Dr. Park:

- (1) Intentionally and knowingly falsified various versions of two figures in a manuscript entitled "Rhesus Embryonic Stem Cells Established by Nuclear Transfer: Tetraploid ESCs Differ from Fertilized Ones" that was being prepared for submission to Nature;
- (2) Repeatedly misrepresented to the UP investigative panel the accuracy of one of the figures;
- (3) Presented the false figures as true to members of the laboratory; and
- (4) Falsified the record of revisions of the figures by deleting all prior versions from the laboratory server.

ORI has implemented the following administrative actions for a period of three (3) years, beginning on November 29, 2006:

- (1) Dr. Park is debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government as defined in the debarment regulations at 45 CFR Part 76; and
- (2) Dr. Park is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT:

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Case Summary - Kui Zhu

Federal Register: August 24, 2006 (Volume 71, Number 164)]

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[DOCID:fr24au06-58]

DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of the Secretary

Findings of Misconduct in Science

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

Kui Zhu, Ph.D., Cleveland Clinic Research Foundation: Based on accumulated evidence including the Cleveland Clinic Research Foundation (CCF) investigation report (CCF Report) and additional analysis and information obtained by the Office of Research Integrity (ORI) during its oversight review of the CCF Report, the U.S. Public Health Service (PHS) found that Kui Zhu, Ph.D., former postdoctoral fellow, CCF, engaged in misconduct in science by intentionally and knowingly fabricating and falsifying data for figures in two publications and with research funded by National Cancer Institute (NCI), National Institutes of Health (NIH), grants R21 CA84038, R01 CA76204, and T32 CA09056.

ORI has implemented the following administrative actions for a period of three (3) years, beginning June 7, 2006:

(1) Dr. Zhu is debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government as defined in the debarment regulations at 45 CFR part 76; and

(2) Dr. Zhu is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT:

Director, Division of Investigative Oversight

Office of Research Integrity

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