

Cooperations between journals and institutions - *The Lancet's* experience

Keeping the Pool Clean

*Prevention and Management
of Misconduct Related Retractions
July 2016, Fort Collins, Colorado*

Sabine Kleinert

Senior Executive Editor, The Lancet
Steering Committee, The World Conferences on
Research Integrity

Interferon alfa-2b, colchicine, and benzathine penicillin versus colchicine and benzathine penicillin in Behçet's disease: a randomised trial

Behçet's disease is recurrent systemic vasculitis of unknown definite cause, characterised by recurrent genital ulceration, uveitis, skin lesions, deep vein thrombosis, arterial occlusion and oral, articular and central nervous system involvement. Several studies have suggested a role for microorganisms in Behçet's disease. A simple virus type 1 is thought to be a causative agent. Its genome has been identified in peripheral blood mononuclear cells of patients with Behçet's disease. *Streptococcus* spp. (*Streptococcus pyogenes*, *S. salivarius*, *S. pneumoniae*) have been isolated from oral and skin tissues of patients with Behçet's disease and symptoms can be relieved by skin tests with these antigens.¹ Because of various microorganisms that might be involved, a common antigen such as stress or heat shock protein may be responsible for the disease.² *Chlamydia* spp., *Mycoplasma* spp., *Coccidia* spp., *Gram-negative* cocci, mycoplasma, and other species of gram-positive and gram-negative bacteria may have a high degree

Lesaut 2007, 379-380

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Endometriosis is the growth of endometrial tissue outside the uterine cavity. Around 15% of women of reproductive age, and 50% of infertile women, have endometriosis. The disorder is thought to be caused in many cases by retrograde menstruation, in which menstrual blood flows down the fallopian tubes, depositing endometrial tissue in the fluid lands on tissues in the pelvic cavity and starts to grow. Menstrual cycle is 28 days.

logous myoblasts and fibroblasts ve
ment of stress urinary incontinence

The took history including details of immunisations and exposure to infectious diseases, and assessed the children. In 11 cases the history was obtained by the senior clinician (JW-S).

Lancet 1991; 356: 1359-66
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 October 1, 2005
 DOI: 10.1016/S0140-6736(05)25350-0

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According to the 2000 annual data, 40% of the Society for Dialysis Therapy (SDT) members are individuals on renal replacement treatment (RRT). In the Japanese population, 10% of the 100 patients newly treated for end-stage renal disease (ESRD), whereas 18.9% of the dialysis patients die due to cardiovascular events. In the last decade, the incidence of death with renal disease has increased at a rate of 7% per year. The annual cost of dialysis at treatments of ESRD is US\$10 billion, or 2% of the health-care budget. Although diabetic renal disease has been a leading cause of end-stage renal disease (ESRD) in dialysis patients, the incidence of this is upsurging, causing 40% of the disorder—32.5% of men and 46.5% of women. Other causes include glomerulonephritis, 7.6% of nephrosclerosis, and cystic kidney disease. Thus, halting or progressing renal disease is a high priority for the Society. For future, no treatment guidelines for non-

Findings After a median follow-up of 3.1 years (range 0.3–9.7), the primary endpoint was recorded in fewer in-given valsartan than in controls (92 vs 149; absolute risk difference 0.11 [95% CI 0.07 to 0.15], *p* = 0.0002). This difference was only partly attributable to fewer incidences of stroke and transient is-attack (29 vs 48; 0.10, 0.38–0.95, *p* = 0.0001), angina pectoris (19 vs 35; 0.35, 0.20–0.58, *p* < 0.0001), and heart-failure (16 vs 53; 0.37, 0.14–0.60, *p* = 0.0019) in the control group. Mortality or toler-

Methods

Articles

Reasons for retractions at Lancet journals

- Misconduct = 9
 - Fabrication = 4
 - Falsification = 4
 - Duplicate Publication = 1
- Error = 2 (both republished with errors corrected)

Correcting the scientific literature: retraction and republication



See [Comment](#) pages 400
and 402

See [Articles](#) page 441

This week we publish a comment with the unusual heading “Retraction and republication.....” linked to the China PEACE study. For the first time, we retract a version of a paper that was published online in June last year and republish a corrected version in print together with a supplementary appendix that clearly highlights the discrepancies. We made this decision because the paper needed substantive corrections of its findings. The authors had pointed out this error to us shortly after publication.

Retractions are never easy and journals and editors are still all too often reluctant to take this step. However, it is important to reiterate that the purpose of retractions is the correction of the scientific literature, if the findings as presented are invalid or unreliable. Retraction is not a punishment or tainting of the reputation of one or more authors. When a retraction is due to serious misconduct rather than honest error further appropriate actions against the researchers responsible must be taken by their employers, such as academic institutions or pharmaceutical companies. By contrast, a retraction due to an honest error in the form of a miscalculation or

misclassification can be followed by republication of a corrected paper, as in this case.

So where do we draw the line between a correction and a retraction followed by republication? The Committee on Publication Ethics states in its retraction guidelines that “journal editors should consider issuing a correction if a small portion of an otherwise reliable publication proves to be misleading (especially because of an honest error)”. So what should happen if a large portion is misleading? We believe that if many of the numerical findings in the results section change or the interpretation of the work is altered following a miscalculation or misclassification due to an honest error, republication should be considered. The corrected paper should pass peer review and editorial scrutiny once again and when republished the changes should be made transparent. Retraction and republication is a further example of correcting the scientific literature. In our opinion, it should be considered by journal editors in the interests of readers, research users, and the scientific community. ■ [The Lancet](#)

Retractions: a new era of transparency and accountability?

Retraction Watch

Tracking retractions as

Botanist pair's paper retracted, others questioned on PubPeer

with one comment

A plant sciences journal has pulled a 2016 paper for manipulated images after the study came under question at PubPeer.

According to the notice, the authors claim that the images were supplied by a “service provider;” the editor-in-chief of the journal told us he doesn’t have any details on this third party’s identity.

The first author of the retracted paper in *Plant Science Today* — [Dibyendu Talukdar](#), from the University of Calcutta in West Bengal, India — has several other papers being questioned on PubPeer. His co-author, [Tulika Talukdar](#), who is based at Acharya Prafulla Chandra Roy Government College in West Bengal, India, according to [her ResearchGate page](#), is a co-author on three of these papers. According to the present paper, however, Tulika Talukdar is affiliated with Raja Peary Mohan College, which is part of the University of Calcutta.



Here's the [retraction notice](#): [Read the rest of this entry »](#)

Share this:

... and a new reason for retractions

The Washington Post

Morning Mix

Major publisher retracts 64 scientific papers in fake peer review outbreak

An example of “informing the journal”

“The retraction of the Kyoto Heart Study⁵ in February, 2013 led to an investigation into the conduct of the Jikei Heart Study. An investigating committee headed by Professor Hashimoto from Jikei University was established. We became aware of this development on April 29, 2013, and on May 2 we wrote to Jikei University asking for details of the investigation and requesting that we be kept informed. We wrote again on June 4 and June 19 asking when the investigation might be completed. We wrote again on July 31 after we were made aware that a press conference had been held.”

Retraction—Valsartan in a Japanese population with hypertension and other cardiovascular disease (Jikei Heart Study): a randomised, open-label, blinded endpoint morbidity-mortality study.

www.thelancet.com Vol 382 September 7, 2013

Case example: The case of Jon Sudbø

Articles

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

J Sudbø, J J Lee, S M Lippman, J Mørk, S Sagen, N Flåtten, A Ristimäki, A Sudbø, I Maa, X Zhou, W Kibdel, J F Eversen, A Keith, A J Dannerberg

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 (279 men, 175 women, mean [SD] age at diagnosis 63.3 [13.2] years) and 454 matched controls (n=908); 263 (29%) 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 (0.41, 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.^{5,6} Complete surgical excision does not reduce the high risk of aggressive, lethal oral cancer associated with aneuploid oral leucoplakia.⁷ Smoking cessation could offer some protection in this setting,^{8,9} but is often difficult to achieve or sustain.^{10–12} 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.^{13–15}

NSAIDs inhibit cyclo-oxygenase (COX) activity and thereby suppress the synthesis of prostaglandin E₂. Raised concentrations of prostaglandin E₂ have been detected in both premalignant and malignant lesions, including squamous cell carcinoma of the oral cavity.^{16,17} This increase results from the overexpression of COX-2, the inducible form of COX.^{18,19} Several lines of evidence, beyond the finding of raised amounts of prostaglandin E₂ 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.^{20,21} Prostaglandin E₂ can stimulate cell proliferation and angiogenesis and inhibit apoptosis and immune surveillance.^{22,23} NSAIDs protect against the development of oral cancer in animals.^{24,25} Observational data have indicated that NSAIDs are associated with the reduced risk of several types of cancers,^{26–28} but we know of only two previously published reports of epidemiological studies of NSAIDs with respect to head and neck cancer.^{29,30} 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

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See <http://www.thelancet.com>

- Nested case-control study
- 454 cases (oral cancer): 454 controls
- NSAID use: Hazard ratio oral cancer = 0.47 (95% CI 0.37–0.60)
- NSAID use: Hazard ratio CV death = 2.06 (95% CI 1.34–3.18)

What happened?

Submitted
Sept 6, 2005

Peer review
Editorial debate

Revisions

Acceptance

Publication online
October 7, 2005

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6 September 2005 24–August 2005

The Editor, *THE LANCET*
32, Janes Row
London, NW1 7BY UK

Dear Editor:

We are pleased to send you our original primary report entitled "Nonsteroidal Antiinflammatory Drugs and the Risk of Oral Cancer" for your consideration for publication as an Article in *The Lancet*.

There are three main findings of our study. First, we show that long-term use of non-steroidal anti-inflammatory drugs (NSAIDs) halves the risk of oral cancer. Second, smoking cessation and continued NSAID use (in active smokers) have quantitatively equivalent protective effects against oral cancer. Third, long-term daily use of NSAIDs doubles the risk of cardiovascular death, thus offsetting the mortality benefit of halving the risk of oral cancer, as reflected by the equivalent overall mortality between people who do and do not have long-term NSAIDs usage.

Echoing cancer therapy, our study demonstrates the double-edged sword of many cancer preventive agents—reduced cancer risk but raised potential serious side effects—thus highlighting the importance of targeting cancer preventive treatment toward patients at highest risk of cancer and cancer mortality. Tailoring cancer prevention for highest risk patients will avoid treating a larger population at moderate-to-low risk and exposing them to the adverse effects frequently associated with effective cancer preventive agents, such as NSAIDs, which potentially can prevent oral cancer but appear to increase cardiovascular disease mortality. Aneuploid oral leukoplakia has an extremely high oral cancer risk and a 50-to-70-percent mortality rate within 5 years despite treatment with the best currently available therapy. The potential life-saving effects of NSAIDs may outweigh the risk of cardiovascular toxicity and even deaths, when considering NSAIDs for patients with aneuploid oral leukoplakia. The Discussion in our manuscript highlights both the need to carefully assess the risk-benefit ratios of promising agents and the importance of targeting high risk cohorts to maximize clinical utility.

Thank you for your consideration of our manuscript for publication as an Article in *The Lancet*. We look forward to hearing from you as soon as you have had the chance to review our work.

Sincerely,

Jon Sudbe

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

J Sudbe, J Lin, S M Lippman, M S Sagan, N Flattner, A Ristovski, A Sudbe, J Zhou, W Kild, J J Eremov, A Ristovski, A Ristovski

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 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 ($n=15$ pack-years), and matched controls were selected from the remaining heavy smokers (who did not have cancer).

Findings We identified and analysed 454 (9%) people with oral cancer (279 men, 175 women, mean [SD] age at diagnosis 63.5 [13.2] years) and 454 matched controls ($n=908$); 263 (28%) 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 0.37–0.61, $p<0.0001$). Smoking cessation also lowered the risk of oral cancer (0.41, 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 leukoplakia with the genetic instability marker aneuploidy have an 80% risk of developing oral cancer with a high relapse rate and a 70% risk of death in 5 years.^{4,5} Complete surgical excision does not reduce the high risk of aggressive, lethal oral cancer associated with aneuploid oral leukoplakia.⁶ Smoking cessation could offer some protection in this setting,^{7,8} but is often difficult to achieve or sustain.^{9–11} Therefore, there is an unmet medical need for new treatment strategies, such as chemoprevention with non-steroidal anti-inflammatory drugs (NSAIDs), to reduce the risk of cancer in patients with aneuploid oral leukoplakia.¹²

NSAIDs inhibit cyclo-oxygenase (COX) activity and thereby suppress the synthesis of prostaglandin E₂. Raised concentrations of prostaglandin E₂ have been detected in both premalignant and malignant lesions, including squamous cell carcinoma of the oral cavity.^{13,14} This increase results from the overexpression of COX-2, the inducible form of COX.^{15–17} Several lines of evidence, beyond the finding of raised amounts of prostaglandin E₂ 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.^{18,19} Prostaglandin E₂ can stimulate cell proliferation and angiogenesis and inhibit apoptosis and immune surveillance.^{20–22} NSAIDs protect against the development of oral cancer in animals.²³ Observational data have indicated that NSAIDs are associated with the reduced risk of several types of cancers,^{24–27} but we know of only two previously published reports of epidemiological studies of NSAIDs with respect to head and neck cancer.^{28,29} 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 oral leukoplakia, 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.

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Articles



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AVSLØ

av statsministeren

Hale OOOOO græsene er dybt opgrøet.

- January 13, 2006:
the story broke
- We were alerted to it by
journalists

Aftenposten

JOBB & UTDANNING

* Morgen, Tirsdag 17. januar 2006, Uke 5, Nr. 27.142, 8. og 15.

Pris/ekspres: Nord-Norge kr. 20.

○○○



- Gi en million pr. gullmedalje

(Aft 1 + Side 2)

36 sider med råd, tips og inspirasjon for studenter og jobbsøkere.

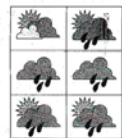


VIL ANMELDE LAKSEMINNERE

Forbrukerrådet ber Mattilynet om å politianmelde dem som har brukt maten i reklame. ØKONOMI • side 6

SV KNEBLER SEG SELV OM OLJE

Den store oljeboringssatsingen har senket seg over sosialistiske Venstrepartiet. Hva er egentlig SVs lågrense i Barentshavet? En spørsmål der partiet har vært tinnende klart i årevis, er svarene nå uoverensstemmende, vage eller ikke-eksisterende. Partilederet avviser imidlertid at hun har pålagt de tillitsvalgte minnkurs i saken. DEL 1 • side 8



MILD JANUAR- UKE HVERT ÅR

Klimaforskere skal undersøke hvorfor det alltid er mildere en drøy uke i januar. DEL 1 • side 4 og 7

RUBRIKKANNONSER - SE SIDE 2

The Lancets sjefredaktør etter forskersvindelen

Krever svar fra alle forskerne



«Vi kan aldri sikre oss helt mot svindel, sier redaktør Richard Horton i «The Lancet».

KREFTBLØFFEN. – Dette er den største svindelen fra en forsker verden noen gang har sett, sier Lancet-redaktør Richard Horton. Han mener det er ubegripelig at medforfatterne av den fabrikkerte kreftstudien ikke har visst noe.

DEL 1 • side 2, 3, 4 og 5

Første kvinne på topp i Afrika



Ellen Johnson-Sirleaf ble i går tatt i ed som president i Liberia, til stor jubel fra flere tusen fremmøtte i hovedstaden Monrovia. Landet ligger i ruiner etter 14 år med borgerkrig, og statsapparatet må gjenoppbygges. Det stilles store forventninger til kvinnen, som også vil bekjempe korrupsjon. DEL 1 • side 14 og 15

Stort greskaland da Liberia i går innvarte Ellen Johnson-Sirleaf som president (midten) var USA utenriksminister Condoleezza Rice, (h.v.) og presidenthuset Laura Bush, (v.h.) fra høyre. FOTO: JAMES BEHRENS

Det lønner seg å starte NÅ.

Verdi opp til **800,-**

Mange har allerede benyttet tilbudet. DU har fremdeles muligheten.

Meldt du deg inn 1.0-31. januar til du?

- 3 måneders medlemskap
- 12 måneders medlemskap til "gamle pris"
- Høve administrasjonsgebyret inn på din SATSkonto

SATS

Training du har glede av

Tough questions

- Is *The Lancet* more interested in great headlines than correct science?
- How often are you being warned about flawed research?
- Why didn't you listen to your peer reviewers?



**Karolinska
Institutet**

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Anders Ekblom
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Date
2006-01-26

Page
1 / 1

The Editor, THE LANCET
Dr Richard Horton
London Office
32 Jamestown Road
London, NW1 7BY United Kingdom

The Ekblom Commission

Dear Dr Horton,

On the behalf of the commission appointed by the University of Oslo and Rikshospitalet to investigate possible scientific misconduct by dr Jon Sudbo. I have the sad duty to inform you that the commission has concluded that the paper "Sudbo J, Lee JJ, Lippman SM, Mork J, Sagen S, Flatner N, Ristimaki A, Sudbo A. Non-steroidal anti-inflammatory drugs and the risk of oral cancer: a nested case-control study. Lancet. 2005 Oct 15-21;366(9494):1359-66" contains fabricated data and should in our opinion be retracted.

Yours sincerely

Anders Ekblom

Professor of Clinical Epidemiology

Expression of concern: January 21, 2006

Retraction:

February 4, 2006

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16/38 papers to be retracted in 11 journals

<i>Oral Oncol</i>	3
<i>N Engl J Med</i>	2
<i>Int J Cancer</i>	2
<i>Clin Oncol</i>	2

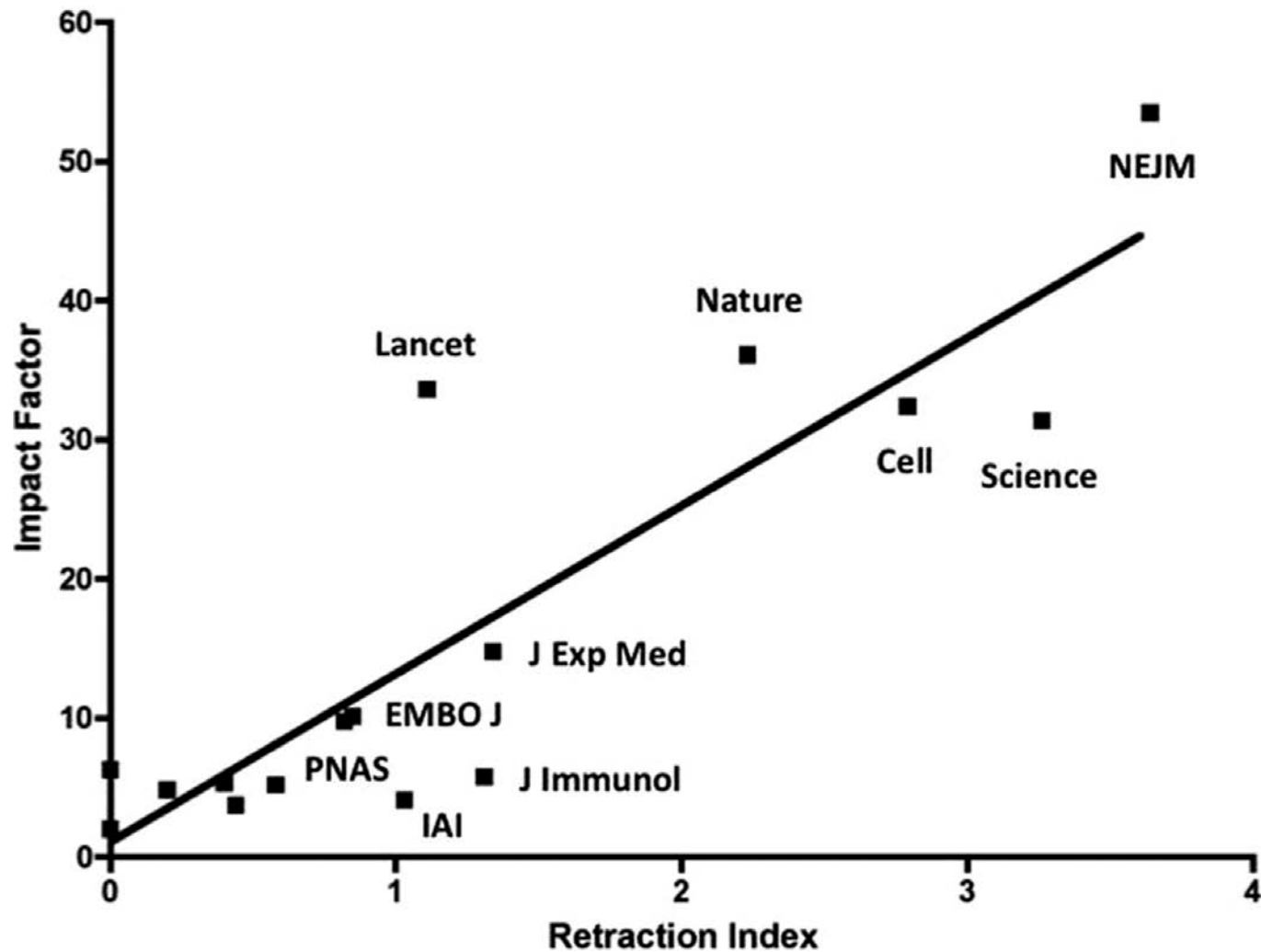
1 each in
*Clin Med Res, J Oral Pathol
 Med, J Pathol,
 Lakartindningen,
 Lancet, Oncology, Tidsskr
 Nor Laegeforen*

.... and another

“xxx Hospital are reviewing concerns about the integrity of certain data.... and included in the following published paper.....While the institutional review of the veracity of the data in this paper is ongoing..... we have determined.... that a retraction is warranted.”

“Because review of this paper is ongoing, we cannot provide additional details at this time”

Correlation between impact factor and retraction index.



Fang F C , Casadevall A Infect. Immun. 2011;79:3855-3859

Infection and Immunity

Fabrication/falsification – the journal's perspective

- Maybe difficult to detect before publication
- 'red flags' at peer review stage
- In basic science journals often found by detection of image manipulation
- Journals rely on institutions to investigate

What are red flags?

- Reviewers very critical, say 'data too good to be true'
- ?single author research papers
- Reluctance to engage at revision
- Undeclared conflicts of interests
- Effect size implausibly large
- Data too homogenous (CIs, SDs, group sizes...)
- Certain fields (stem cells) with exaggerated claims?

Fabrication/falsification

Important things for editors to remember

- Confidentiality of material
- Confidentiality of reviewer/whistleblower (ie reader if published paper) identity
- Paraphrase issues or ask whether identity can be disclosed (rarely necessary)
- We can't (and it's not our role) to assess 'raw' research data (research records, spread sheets...etc)
- We have a duty even if not interested in paper (we can reject paper and still instigate investigation)
- We must act as a matter of urgency if paper published



RETRACTION GUIDELINES

Summary

Journal editors should consider retracting a publication if:

- they have clear evidence that the findings are unreliable, either as a result of misconduct (e.g. data fabrication) or honest error (e.g. miscalculation or experimental error)
- the findings have previously been published elsewhere without proper crossreferencing, permission or justification (i.e. cases of redundant publication)
- it constitutes plagiarism
- it reports unethical research

Journal editors should consider issuing an expression of concern if:

- they receive inconclusive evidence of research or publication misconduct by the authors

Retractions: when (The COPE guidelines)

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Journal editors should consider **retractions**

- Evidence that findings unreliable (misconduct or honest error)
- Findings have been previously published (duplicate/redundant) without permission and/or cross-referencing
- Plagiarism
- Unethical research

Journal editors should consider expression of concern

- Inconclusive evidence of misconduct
- Findings unreliable but no investigation by institution
- Investigation has not been or would not be fair and impartial or conclusive
- Investigation underway but will take long time (and it is important to alert readers)

Retractions: how?

Retraction notes should

- Be linked to the retracted article
- Clearly identify retracted article
- Be clearly identified as retraction
- Be published as soon as possible
- Freely available and accessible
- State who is retracting
- State reasons
- Avoid statements that are potentially defamatory or libellous (cite investigation's findings, show legal counsel if unsure)

THE LANCET Oncology

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The Lancet Oncology, [Volume 8, Issue 12](#), Pages 1071 - 1078, December 2007 [Cite or Link Using DOI](#)
 doi:10.1016/S1470-2045(07)70345-5
 This article can be found in the following collections: [Genetics & Genomics](#), [Oncology](#) (Breast cancer, Translational oncology)
 Published Online: 14 November 2007

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This article was retracted

RETRACTED: Validation of gene signatures that predict the response of breast cancer to neoadjuvant chemotherapy: a substudy of the EORTC 10994/BIG 00-01 clinical trial

Prof [Hervé Bonnefoi](#) MD [✉](#), Prof [Anil Potti](#) MD [✉](#), Prof [Mauro Delorenzi](#) PhD [✉](#), Prof [Louis Mauriac](#) MD [✉](#), Prof [Mario Campone](#) MD [✉](#), Prof [Michèle Tubiana-Hulin](#) MD [✉](#), Prof [Thierry Petit](#) MD [✉](#), Prof [Philippe Rouanet](#) MD [✉](#), Prof [Jacek Jassem](#) MD [✉](#), Prof [Emmanuel Blot](#) MD [✉](#), Prof [Veronique Becette](#) MD [✉](#), Prof [Pierre Farmer](#) PhD [✉](#), Prof [Sylvie André](#) [✉](#), Prof [Chaitanya R Acharya](#) MS [✉](#), Prof [Sayan Mukherjee](#) PhD [✉](#), Prof [David Cameron](#) MD [✉](#), Prof [Jonas Bergh](#) MD [✉](#), Prof [Joseph R Nevins](#) PhD [✉](#), Prof [Richard D Gelber](#) PhD [✉](#)

Summary

RETRACTED

Background
 We have previously described gene-expression signatures that predict growth inhibitory and cytotoxic effects of common chemotherapeutic drugs in vitro. The aim of this study was to confirm the validity of these gene-expression signatures in a large series of patients with oestrogen-receptor-negative breast tumours who were treated in a phase III neoadjuvant clinical trial.

Methods
 This trial compares a non-taxane regimen (fluorouracil, epirubicin, and cyclophosphamide [FEC] for six cycles) with a taxane regimen (docetaxel for three cycles followed by epirubicin plus docetaxel [TET] for three cycles) in women with oestrogen-receptor-negative breast cancer. The primary endpoint of the study is the difference in progression-free survival based on TDC2

Retractions: common misunderstandings

- always indicates misconduct
- = punishment of authors
- has to be agreed by all authors
- retractions = 'taking down' articles
- ? expose the journal/editors to legal actions/libel
- thorough peer review can prevent misconduct

Retractions: safeguarding the scientific record

Who should retract ?

- Ideally all authors should agree
- If not all, state who does and who doesn't and why
- If authors don't agree, editors should retract (responsibility for journal's content!)

Difficulties and how to overcome these

Authors who dissociate themselves from publication

Authorship = joint responsibility!

Legal threats

Instructions for authors detail processes that might lead to retraction

Due and diligent processes

Legal advice for wording

If authors consent to wording = defence against libel

Outstanding (research) questions

Are increased retractions due to:

- ?increased awareness
- ?editors following guidelines
- ?more pressure to publish
- ?or a combination of all

Are 'predatory' open access journals increasing misconduct?

Is a more competitive research environment leading to misconduct?

Are certain areas more prone to misconduct? (stem cell research, anaesthesia, psychology....)



Cooperation between research institutions and journals on research integrity cases: guidance from the Committee on Publication Ethics (COPE)

Summary

Institutions and journals both have important duties relating to research and publication misconduct. Institutions are responsible for the conduct of their researchers and for encouraging a healthy research environment. Journals are responsible for the conduct of their editors, for safeguarding the research record, and for ensuring the reliability of everything they publish. It is therefore important for institutions and journals to communicate and collaborate effectively on cases relating to research integrity. To achieve this, we make the following recommendations.

Institutions should:

- have a research integrity officer (or office) and publish their contact details prominently;
- inform journals about cases of proven misconduct that affect the reliability or attribution of work that they have published;
- respond to journals if they request information about issues, such as disputed authorship, misleading reporting, competing interests, or other factors, including honest errors, that could affect

Reference
Cite this as: Wager E, Kleinert S on behalf of COPE Council.

3rd World Conference on Research Integrity

Montreal, May 5-8, 2013

>360 participants from 46 countries

>200 presentations

4 Focus Tracks

- International collaborations ('Montreal statement')
- **Collaboration between Journals and institutions in suspected misconduct cases**
- Responsible Conduct of Research instruction
- Societal implications

Copyrighted Material



Nicholas Steneck • Melissa Anderson
Sabine Kleinert • Tony Mayer

Editors

 World Scientific

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Chapter 22

Cooperation between Journals, Research Institutions and Funders over Research and Publication Integrity Cases: Defining the Challenges

Elizabeth Wager

Sideview, Princes Risborough, UK and

Sabine Kleinert

The Lancet

CLUE workshop:

Heidelberg, July 11-13, 2016

CLUE = Collaboration
and Liaison between
Universities and Editors



CLUE workshop participants

- From: UK, USA, South Africa, Germany, Croatia, Australia, Netherlands

Dean, Vice-Chancellor, Research Integrity Officers, Editors, Publishers, Funder, Lawyer, Director at ORI, Director of Research Integrity.

CLUE: next steps

- Discussion paper with 'Best Practice' recommendations – both high level and practical
- Answers to questions in Chapter 22
- Acknowledgement of current barriers
- Wider consultation
- Presentation and discussion at 5th WCRI Conference in Amsterdam



5th World Conference on Research Integrity



May 28 - 31, 2017
Amsterdam
The Netherlands

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