The history of the active anti-screening campaign

The Cochrane Report:

Gøtzsche PC, Olsen O. Is screening for breast cancer with mammography justifiable?

Researchers asserting that the majority of previous findings on an issue are wrong have a responsibility to check their facts and methodology very carefully. The scientific community is unlikely to be dissuaded from its consensus by a paper containing errors of fact.
The history of the active anti-screening campaign

• Gøtzsche published his views on screening mammography twice: January 2000 and October 2001 in *The Lancet*, *first without informing the Cochrane Breast Cancer Review Group* and

• The second time he published a version that the review group refused to approve.

The history of the active anti-screening campaign

The publication emerging from the Nordic Cochrane Center (Director: Peter C. Gøtzsche)

- Lacks access to individual patient data and
- Fails to adhere to well established evaluation methods.

- These elementary limitations were immediately apparent to competent investigators, some of whom published rather harsh criticism.
The Cochrane Report:


“The Lancet paper by Gøtzsche and Olsen … is not simply controversial, it contains a number of serious statistical mistakes. It is a worthless piece of work which if it had been produced by one of our masters students, would have been sent back with demands for a complete rewrite“.

N Day, Professor of Public Health, University of Cambridge, UK
“Gøtzsche and Olsen’s paper lacks scientific merit.”
“The Lancet should not have published this paper”.
Nicholas Wald, Professor of Epidemiology and Institute Director, Wolfson Institute of Preventive Medicine, Barts and The London School of Medicine

"The most recent breast cancer screening controversy about whether mammographic screening benefits women at any age: nonsense and nonscience".
KEY MESSAGES

• There is good evidence from clinical trials that mammographic screening reduces the death rate from breast cancer.

• The critique by Gøtzsche and Olsen has little merit and has generated much confusion.
Gøtzsche’s Quixotic Antiscreening Campaign: Nonscientific and Contrary to Cochrane Principles

- Evaluations of evidence-based medicine should be performed by individuals who have personal competence in the subjects they choose to evaluate.
Gøtzsche’s Quixotic Antiscreening Campaign: Nonscientific and Contrary to Cochrane Principles


Gøtzsche has built his own antiscreening bias into a nonscientific, personal campaign to discredit breast cancer screening, breast cancer surgery, and breast cancer oncology.

In the process he has done harm to the Cochrane Collaboration, which has been powerless to censure his actions.
The history of the active anti-screening campaign

• Denmark has been a source of much of the criticism of breast cancer screening over the past decade, beginning with a published bias against all form of screening by Dr. Peter Goetzsche, the Director of the Cochrane Institute in Copenhagen.

• The Lancet, Vol 349
February 1, 1997.
Why does vehement opposition to screening come from Denmark, which has one of Europe’s highest breast cancer mortality rates?

The online publication by Jorgensen and Gotzsche in BMJ 2010; 340:c1241 doi:10.1136/bmj.c1241 failed to demonstrate a mortality reduction from breast cancer because the authors did not use reliable, individualized data: “Our data did not allow identification of individual women”.
Why does vehement opposition to screening come from Denmark, which has one of Europe’s highest breast cancer mortality rates?

The lack of precision of their analysis is reflected in their text “is unlikely”, “it may be reasonable”, “suggest”, “may have”, “would be expected”, “could be”, etc.
Why does vehement opposition to screening come from Denmark, which has one of Europe’s highest breast cancer mortality rates?

Denmark has been a source of much of the criticism of breast cancer screening over the past decade.

Denmark has one of the highest breast cancer death rates in Europe, similar to that of Serbia.
Finland and Sweden have among the lowest breast cancer mortality rates in Europe, although all the Nordic countries use identical breast cancer treatment guidelines.
Comment

The health care systems among these countries are similar in most other aspects as well, except that Finland and Sweden introduced nationwide screening more than two decades ago.
BBC Radio interview with the Director of the Cochrane Inst. in Copenhagen, Denmark, Dr. P. Goetzsche
"What women should do is, as they have always done, if they find something unusual, go and see a doctor, but don't examine yourself regularly. It has no effect and it doubles the number of biopsies and it also induces a lot of anxiety of course...so, so, there is general agreement now that women should not be advised to examine themselves every month. That's against recommendation".
“The most effective way to decrease women’s risk of becoming a breast cancer patient is to avoid attending screening”
A group of 41 screening experts, exasperated by the steady flow of non-scientific criticism, published a letter in The Lancet.


“Although the wider scientific community has long embraced the benefits of population-based breast screening, there seems to be an active anti-screening campaign orchestrated in part by members of the Nordic Cochrane Centre.”
These contrary views are based on erroneous interpretation of data from cancer registries and peer reviewed articles. Their specific aim seems to be to support a pre-existing opposition to all forms of screening.

41 signatures

The key players in the active anti-screening campaign

Dr. Peter Goetzsche and KJ Jørgensen
Denmark

Zahl P-H and Dr. Kalager
Norway

Dr. Philippe Autier
Belgium
The key players in the active anti-screening campaign

Dr. Cornelia Baines
Canada

Dr. Gilbert H. Welch
USA
The key players in the active anti-screening campaign

The Canadian Task Force

U.S. Preventive Services Task Force (USPSTF)
The medical journals giving a forum for the active anti-screening campaign

- The Lancet
- British Medical Journal
- New England Journal of Medicine (NEJM)
- Journal of the National Cancer Institute (JNCI)
- Archives of Internal Medicine
The term "controversy" hardly seems to apply to mammography screening.

What ought to be regarded as controversial is the regular opportunity provided by scientific journals and mass media for a group of pseudo-skeptics to repeat over and over again the same flawed science and logic to question the value of screening.

None of the publications questioning the benefit of early detection on mortality from breast cancer had access to individualized patient data, making their claims that modern mammography screening plays little or no role in reducing breast cancer death simply a biased guess.
Demonstration of the error introduced by one of their approximations

Incidence-based mortality within two ten-year periods in Dalarna County, Sweden.

Proportion of breast carcinoma deaths between 1978-1987, Dalarna, Sweden according to date of diagnosis occurring before (yellow columns) or during (red columns) this period.
A majority of breast cancer deaths occurring within the screening decade – were from breast cancers detected prior to that decade.

One cannot expect mammography screening to have an impact on patients whose cancer was treated before screening started.
Incidence-based mortality twenty years after introduction screening in W County, Sweden.

Proportion of breast carcinoma deaths between 1998-2007, Dalarna, Sweden according to date of diagnosis occurring before (yellow columns) or during (red columns) this period.

Jørgensen et al. “were unable to find an effect of the Danish screening programme on breast cancer mortality” (BMJ 2010; 340:c1241 doi:10.1136/bmj.c1241). We would have been surprised if they had been able to demonstrate an effect with respect to the method used.

"...for the period 1993-2002 at least 50% of the breast cancer deaths were diagnosed before the start of the screening program. Lennarth Nyström & Sven Tömberg, Cochrane centre produces flawed research BMJ 6 April 2010"
Mammography Screening and Breast Cancer Mortality in Sweden

P. Autier, A. Koechlin, M. Smans, L. Vatten, M. Bonio

Conclusion: “County-specific mortality statistics in Sweden are consistent with studies that have reported limited or no impact of screening on mortality from breast cancer”.

*J Natl Cancer Inst* DOI:10.1093/jnci/djs272 2012

Autier et al's methodological shortcomings caused them to inflate the number of breast cancer deaths in the screening period by including cases diagnosed before screening began.
It is unfortunate that a manuscript with such flawed methodology was published, an outcome that naturally leads to speculation about the robustness of the peer-review process in this instance.
“Screening is having, at best, only a small effect on the rate of death from breast cancer”.


H. G. Welch’s misleading conclusions were made without his knowing

- Which woman was or was not screened, or how often,
- or, even if a breast cancer was diagnosed in a woman who did or did not get a mammogram.
Welch admits: "Unfortunately, because the [Surveillance, Epidemiology, and End Results (SEER)] program does not collect data on the method of detection, we were unable to distinguish screening-detected from clinically detected cancers."

H. Gilbert Welch is a Professor of Medicine at the Dartmouth Medical School.
Welch et al state that "We were forced to make an assumption to capture the downstream benefit of screening"


The "new studies" published by Welch, which he calls "the view from space," can be considered several steps backward for scientific analysis.

They all lack key data required for accurate results, a deficiency which forces them to make multiple assumptions and even resort to guesswork.
Welch does admit to these deficiencies in his *New England Journal of Medicine* publication, as follows:

- "Tables 1 and 2, however, are based on assumptions ..."
- "We were forced to make some assumptions ..."
- "The simplest approach was to assume ..."
- "In our best-guess estimate ..."
- "Our assumption ... was admittedly arbitrary ..."
- "Fourth, our best-guess estimate ..."
- "Our method did not allow us to disentangle the two. We did, however, estimate ..."
- "This analysis suggested ..."
These terms of imprecision were used more than **71 times** in that *NEJM* article.

Women deserve information based on reliable evidence, but Welch offers women *statistical manipulations weakened by missing facts*; as Welch puts it, his research is "a view from space."
CLICK THE PICTURE BELOW TO VIEW THE VIDEO
Number of lives saved according to Dr. Welch

2,500 women needed to go through annual mammography screening examination to avoid one breast cancer death!
There were 1,334 mammographic screening examinations per death avoided. Had the screening continued for ten years the absolute benefit would have been higher, with approximately 300 women needed to screen to save one life.
The Two-County Swedish Trial

**Interpretation**

Between 8 and 11 breast cancer deaths would be prevented if we screened 1,000 women every two years from ages 40 to 69.
“For every **235** women invited for screening, one breast cancer death will be prevented, representing **43** breast cancer deaths prevented per 10,000 women aged 50 years invited to screening **for the next 20 years**.
Screening has benefits and harms

Among 2500 women age 50 undergoing annual mammography for 10 years...

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Harms</th>
</tr>
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<tbody>
<tr>
<td>1 - 2 will avoid a breast cancer death</td>
<td>=1000 will have at least one false positive result</td>
</tr>
<tr>
<td></td>
<td>(= half will have a biopsy)</td>
</tr>
<tr>
<td></td>
<td>5 - 15 will be overdiagnosed and receive unnecessary treatment for breast cancer</td>
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</table>
Cancer Survivor or Victim of Overdiagnosis?
By H. GILBERT WELCH
Hanover, N.H.

AuntMinnie Dec 13, 2012

Mammography’s alleged harms: Separating fact from fiction
By Dr. László Tabár, Dr. Peter B. Dean
In spite of his shaky statistical ground, Welch tries to convince his readers that improvements in therapy are steadily replacing the benefits of early breast cancer diagnosis with mammography.

Researchers from the U.S. National Cancer Institute and from Europe admit that "Without individual data it is impossible to completely separate the effects of improved treatment and health service organization from that of screening."
We can all agree that women need to be reliably informed about breast cancer screening, but evidence-based information requires access to individual patient data, which Welch and other foes of screening do not have. Instead, they base their arguments on inadequate data and multiple assumptions.

- They consider their own estimates on breast cancer mortality superior to the actual facts,
- They allow themselves to speculate on the relative impact of treatment versus screening on breast cancer mortality.
Such flawed statistics and misleading conclusions should not be used to misinform women and their doctors.

Letter to the Editor of NEJM Tabar L, PB Dean

Title: The alleged harm of having regular mammograms versus the actual harm of not having them: use data, not assumptions.

It is disconcerting that the NEJM has chosen to publish an article on the purported effect of mammography screening using a database lacking information on the detection and treatment modes of the individual cancer cases.
Dear Prof. Tabár,

I am sorry that we will not be able to print your recent letter to the editor regarding the Bleyer article of 22-Nov-2012. Thank you for your interest in the Journal.

Sincerely,

Dan L. Longo, M.D.
Deputy Editor. NEJM
Professor of Medicine
Harvard Medical School
Dear Dr. Longo,

Thank you for your mail, which was in line with our expectation: our letter would not be published by the NEJM since it uncovered the terrible flaw in the peer review process of the journal.

A more detailed description (see the attachment) might make the editorial board realize the problem when the authors use "assessment" and "estimation" instead of actual data to draw conclusions.

Sincerely

László Tabár, M.D.
Dr. Welch presents a mammogram (at YouTube timeline 0:40:52) which he falsely claims to be from the HIP trial from New York in the 1960s.
This 89 year old Swedish patient of mine had a 5 cm palpable cancer in 1980.
The truth is that Dr. Welch has copied a copyrighted mammogram from the “Teaching Atlas of Mammography” by László Tabár and P.B. Dean – it is case #60 in our book and it is not a screening mammogram. This 89 year old Swedish patient had a 5 cm palpable cancer in 1980. These deliberate misrepresentations in his lecture bring Dr. Welch’s integrity into question.
It is case #60 in our book and it is not a screening mammogram and it is not from the HIP study in New York!

An 89-year-old woman with a 1-year history of a slowly growing tumor in the right breast.

Physical Examination
A large, obviously malignant tumor in the right breast.

Mammography
Fig. 60a, b: Right breast, MLO and CC projections. Centrally located, large (5 cm diameter) stellate tumor. The nipple and areola are retracted. The skin is thickened and retracted over the lower and outer portions of the breast.

Comment
This is an illustrative example of an advanced stellate malignant breast tumor with a large central tumor mass and radiating spicules that retract the areola and skin.

Histology
Infiltrating ductal carcinoma. The tumor infiltrates the lymph vessels.

Fig. 60a
In addition to his misrepresentations below, Dr. Welch’s demeaning comments (at YouTube timeline 0:40:52) about the image quality of the mammogram uncover his incompetence at evaluating mammographic image quality.

Our book was awarded the First Prize in Radiology at the British Medical Association Medical Book Awards in 2012.