Risk statistics and the Media.

Phil Hahn
Queen's University

Take home messages

- Risk statistics are easy to calculate and understand.
- Relative values can be misleading.

Resources

Evidence-based summaries of recent news stories.

- Hitting the headlines (UK)
- Media doctor (Canada)

Women Health Initiative (WHI)

- Largest single research study by the NIH
- $625 million
- Primary prevention trial started in 1993
- 40 US Centers
- Planned duration of 8.5 years
- Generally healthy postmenopausal women
- 50 to 79 years old

WHI Trial (JAMA, July 17, 2002)

373,092 women screened
↓
18,845 provide consent
↓
16,608 Randomized
↙ ↘
8,506 HRT **8,102 Placebo**

The most commonly used combined hormone preparation in the US.

Prempro (Wyeth Ayerst)
Conjugated equine estrogen (0.625)
Medroxyprogesterone acetate (2.5 mg)

Randomized Controlled Trial

July 2002

WHI Trial → **HRT** / **Placebo**

… showed a 29% increase in coronary heart disease.

Observational cohort study

June 1995

Nurses Health Study (cohort design)

… women on HRT have half the incidence of heart disease.

Question

- What type of bias might partially explain these opposite effects?

Question

- What type of bias might partially explain these opposite effects?
- *Hint:* Observation cohort study versus experimental randomized controlled trial (RCT).

Answer

- Selection bias!
- Women who choose to take HRT differ from other women.
- These differences (rather than HRT) may have accounted for the better outcomes.

Healthy User Effect

- Simply put: women who choose to use HRT are healthier, more affluent, and better educated… [they are] younger, leaner, more active physically, and less likely to have a worrisome family history, to smoke cigarettes, and to have diabetes.
- Attempts to control for these potentially confounding effects have apparently been inadequate to date.

David Grimes and Rogerio Lobo
Perspectives on the Women's Health Initiative Trial of Hormone Replacement Therapy.
Obstet Gynecol 2002;100(6):1344-53.

The New York Times

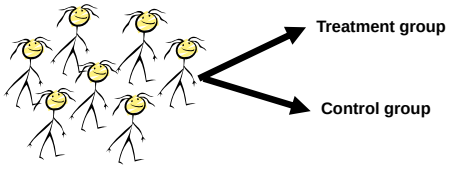
GARY TAUBES September 16, 2007

Do We Really Know What Makes Us Healthy?

- One thing epidemiologists have established with certainty, is that **women who take H.R.T. differ from those who don't** in many ways, virtually all of which associate with lower heart-disease risk.

Random Allocation

- The most important part of any RCT.



Random Allocation

- Produces comparable groups.
- Balances potential confounders: age, BMI…
- The addition of "blinding" helps eliminate other biases related to preconceived patient and investigator attitudes and expectations.

THE KINGSTON WHIG-STANDARD

October 12, 2002

HRT a confusing option for women

THE DOCTOR IS IN By Dr. David Hepburn

Never has confusion in the medical world been more evident...

In the wake of the WHI, we have learned that in women who take combined HRT, there is a:

- 41% increase in strokes
- 29% increase in heart attacks
- 26% increase in breast cancer

- 37% reduction of colorectal cancer
- 33% reduction in hip fractures

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PROBLEM:

RELATIVE RISK ESTIMATES ARE MISLEADING

Survey of Family Physicians (n=42)

The greater Kingston Area (Oct 2, 2002)

Reporting by the media has resulted in:

- General confusion and uncertainty about the appropriate use of HRT (64%).
- Increased anxiety among their patients (83%).
- Some or many of their patients discontinued HRT (45%).

Risk Measures

- Relative Risk
- Absolute Risk Difference (Attributable Risk)
- Number Needed To Treat (NNT)

WHI Trial (JAMA, July 17, 2002)

Table 2: Clinical Outcomes by Randomization Assignment

Outcomes	No. of Patients (Annualized %)			
	Estrogen + Progestin (n=8506)	Placebo (n=8102)	Hazard Ratio	95% CI
Breast Cancer	166 (0.38)	124 (0.30)	1.26	1.00 – 1.59

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How did they come up with the annualized %?

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How did they come up with the annualized %?

Average follow in study was 5.2 years.
Incidence of breast ca over study period = 166 / 8506 = 0.01928 = 1.928%
Incidence per year = 1.928% / 5.2 years = 0.38%

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What's this?

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Hazard Ratio is a measure of Relative Risk (RR).

Does it mean that 26% of women on HRT will get breast cancer?

No… although this is what many women may have thought.

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RR = Incidence of disease in treated (exposed) group
Incidence of disease in control (unexposed) group

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RR = Incidence of disease in treated (exposed) group
Incidence of disease in control (unexposed) group

= 0.38 / 0.30 = 1.26

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What does a Relative Risk of 1.26 mean?

WHI Trial (JAMA, July 17, 2002)

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Breast Cancer	166 (0.38)	124 (0.30)	1.26	1.00 – 1.59

A Relative Risk of 1.26 corresponds to a 26% increase in the incidence breast cancer for those on HRT compared to those on placebo (baseline).

Important: A Relative Risk estimate is meaningless without knowing the baseline risk.

WHI Trial (JAMA, July 17, 2002)

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What's does this mean?

WHI Trial (JAMA, July 17, 2002)

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95% Confidence Interval (CI) is the range of values that is likely to include to "true" value, at a given level of confidence.

If we were to repeat the same trial 100 times, the true result would fall outside this range 5 times.

WHI Trial (JAMA, July 17, 2002)

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Because the 95% Confidence Interval (CI) includes the *"null value",* the estimate is *not* statistically significant.

Relative Risk = 1 = *No risk.*

WHI Trial (JAMA, July 17, 2002)

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WARNING: When the baseline risk is low (0.30%) a relative risk measure tends to magnify the effect… *"makes it appear bigger than it really is."*

Absolute versus Relative Risk (Benefit)

Absolute Risk Reduction

- If disease A occurs in 2 out of 100 people, the absolute risk of disease = 2%
- If taking drug X reduces the frequency to 1 in 100, the absolute risk reduction = 1%

Relative Risk Reduction

- Drug X could also be said to reduce the risk by 50% because 1% is half of 2%.

Relative Risk can mislead particularly when baseline is low.

Absolute Risk Reduction

- If disease A occurs in 2 out of 100 people, the absolute risk of disease = 2%
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- Drug X could also be said to reduce the risk by 50% because 1% is half of 2%.

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Important: to calculate the Absolute Risk Difference (ARD) *(or Attributable Risk)* which is simply the difference in rates**.**

ARD = (0.38 – 0.30) = 0.08% … *"less than 0.1%"*

Risk of breast cancer increases by less than 0.1% per year of HRT use.

WHI Trial (JAMA, July 17, 2002)

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Important: to calculate the Absolute Risk Difference (ARD) *(or Attributable Risk)* which is simply the difference in rates**.**

ARD = (0.38 – 0.30) = 0.08% = 0.08 per 100
= 0.8 per 1,000
= 8 per 10,000

WHI Trial (JAMA, July 17, 2002)

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Question: How can you calculate Number Needed to Harm (NNH)?

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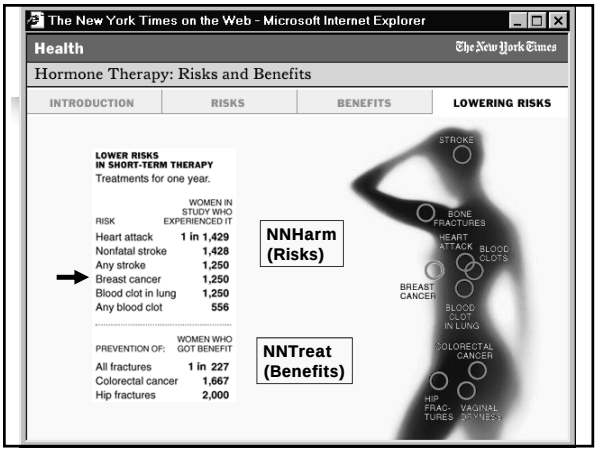
Answer: NNHarm (Risk) or NNTreat (Benefit) = 1 / ARD in decimal format.

1 / (0.0038 – 0.0030) = 1 / 0.0008 = 1250.

One extra case of breast ca for every 1250 women on HRT per year.



THE KINGSTON WHIG-STANDARD

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October 12, 2002

HRT an option for some women

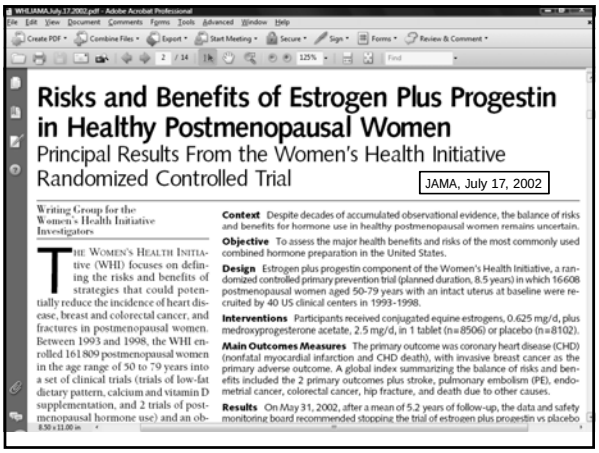
By Dr. Phil

Let's put these risks and benefits into perspective... the absolute risks (and benefits) were very low.

Over 1 year, 10,000 women taking HRT compared to placebo might experience:

- 8 more strokes
- 7 more heart attacks
- 8 more invasive breast cancer

- 6 fewer colorectal cancers
- 5 fewer hip fractures



Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women

Principal Results From the Women's Health Initiative Randomized Controlled Trial

JAMA, July 17, 2002

Writing Group for the Women's Health Initiative Investigators

Context Despite decades of accumulated observational evidence, the balance of risks and benefits for hormone use in healthy postmenopausal women remains uncertain.

Objective To assess the major health benefits and risks of the most commonly used combined hormone preparation in the United States.

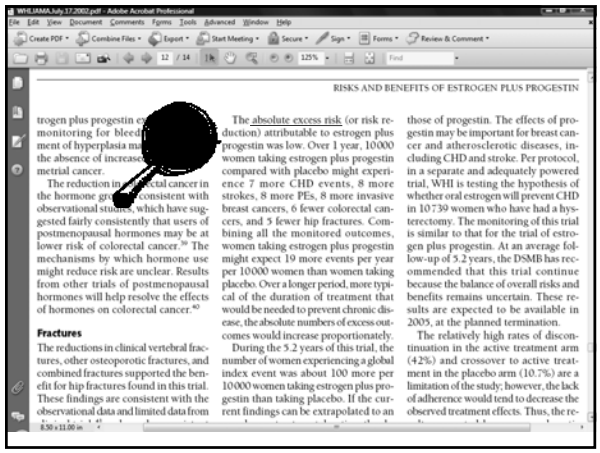
Design Estrogen plus progestin component of the Women's Health Initiative, a randomized controlled primary prevention trial (planned duration, 8.5 years) in which 16608 postmenopausal women aged 50-79 years with an intact uterus at baseline were recruited by 40 US clinical centers in 1993-1998.

Interventions Participants received conjugated equine estrogens, 0.625 mg/d, plus medroxyprogesterone acetate, 2.5 mg/d, in 1 tablet (n=8506) or placebo (n=8102).

Main Outcomes Measures The primary outcome was coronary heart disease (CHD) (nonfatal myocardial infarction and CHD death), with invasive breast cancer as the primary adverse outcome. A global index summarizing the balance of risks and benefits included the 2 primary outcomes plus stroke, pulmonary embolism (PE), endometrial cancer, colorectal cancer, hip fracture, and death due to other causes.

Results On May 31, 2002, after a mean of 5.2 years of follow-up, the data and safety monitoring board recommended stopping the trial of estrogen plus progestin vs placebo

THE WOMEN'S HEALTH INITIATIVE (WHI) focuses on defining the risks and benefits of strategies that could potentially reduce the incidence of heart disease, breast and colorectal cancer, and fractures in postmenopausal women. Between 1993 and 1998, the WHI enrolled 161809 postmenopausal women in the age range of 50 to 79 years into a set of clinical trials (trials of low-fat dietary pattern, calcium and vitamin D supplementation, and 2 trials of postmenopausal hormone use) and an ob-



trogen plus progestin ex
monitoring for bleed
ment of hyperplasia
the absence of increase
metrial cancer.

The reduction in
the hormone gr
observational studies, which have suggested fairly consistently that users of postmenopausal hormones may be at lower risk of colorectal cancer.[39] The mechanisms by which hormone use might reduce risk are unclear. Results from other trials of postmenopausal hormones will help resolve the effects of hormones on colorectal cancer.[40]

Fractures

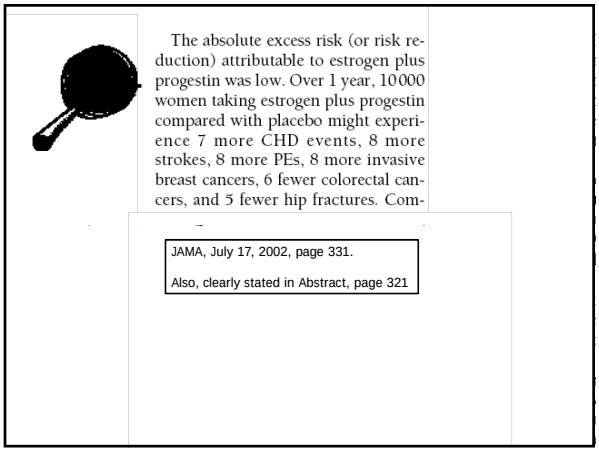
The reductions in clinical vertebral fractures, other osteoporotic fractures, and combined fractures supported the benefit for hip fractures found in this trial. These findings are consistent with the observational data and limited data from

The absolute excess risk (or risk reduction) attributable to estrogen plus progestin was low. Over 1 year, 10000 women taking estrogen plus progestin compared with placebo might experience 7 more CHD events, 8 more strokes, 8 more PEs, 8 more invasive breast cancers, 6 fewer colorectal cancers, and 5 fewer hip fractures. Combining all the monitored outcomes, women taking estrogen plus progestin might expect 19 more events per year per 10000 women than women taking placebo. Over a longer period, more typical of the duration of treatment that would be needed to prevent chronic disease, the absolute numbers of excess outcomes would increase proportionately.

During the 5.2 years of this trial, the number of women experiencing a global index event was about 100 more per 10000 women taking estrogen plus progestin than taking placebo. If the current findings can be extrapolated to an

those of progestin. The effects of progestin may be important for breast cancer and atherosclerotic diseases, including CHD and stroke. Per protocol, in a separate and adequately powered trial, WHI is testing the hypothesis of whether oral estrogen will prevent CHD in 10739 women who have had a hysterectomy. The monitoring of this trial is similar to that for the trial of estrogen plus progestin. At an average follow-up of 5.2 years, the DSMB has recommended that this trial continue because the balance of overall risks and benefits remains uncertain. These results are expected to be available in 2005, at the planned termination.

The relatively high rates of discontinuation in the active treatment arm (42%) and crossover to active treatment in the placebo arm (10.7%) are a limitation of the study; however, the lack of adherence would tend to decrease the observed treatment effects. Thus, the re-



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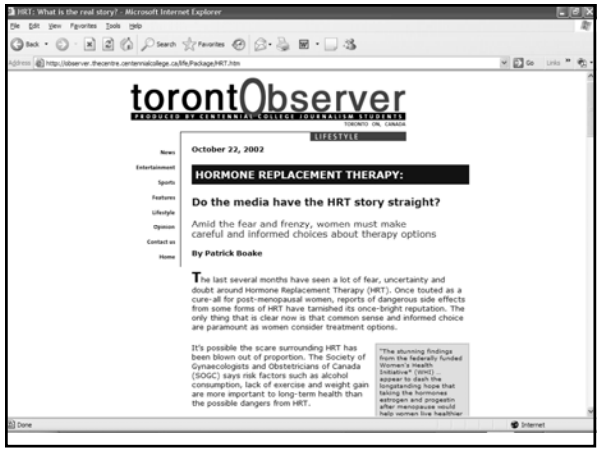
JAMA, July 17, 2002, page 331.

Also, clearly stated in Abstract, page 321



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TORONTO ON, CANADA

LIFESTYLE

October 22, 2002

HORMONE REPLACEMENT THERAPY:

Do the media have the HRT story straight?

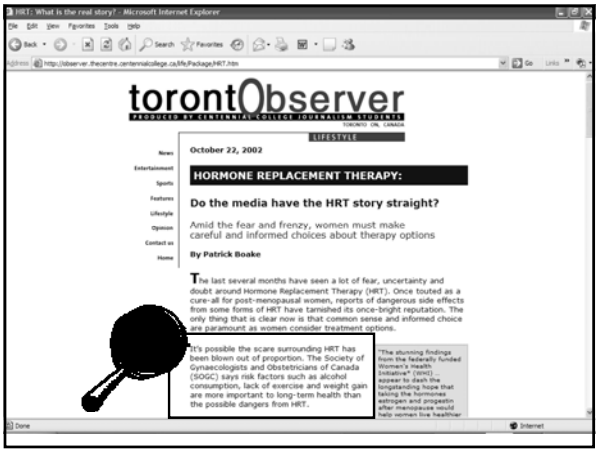
Amid the fear and frenzy, women must make careful and informed choices about therapy options

By Patrick Boake

The last several months have seen a lot of fear, uncertainty and doubt around Hormone Replacement Therapy (HRT). Once touted as a cure-all for post-menopausal women, reports of dangerous side effects from some forms of HRT have tarnished its once-bright reputation. The only thing that is clear now is that common sense and informed choice are paramount as women consider treatment options.

It's possible the scare surrounding HRT has been blown out of proportion. The Society of Gynaecologists and Obstetricians of Canada (SOGC) says risk factors such as alcohol consumption, lack of exercise and weight gain are more important to long-term health than the possible dangers from HRT.

"The stunning findings from the federally funded Women's Health Initiative* (WHI) ... appear to dash the longstanding hope that taking the hormones estrogen and progestin after menopause would help women live healthier



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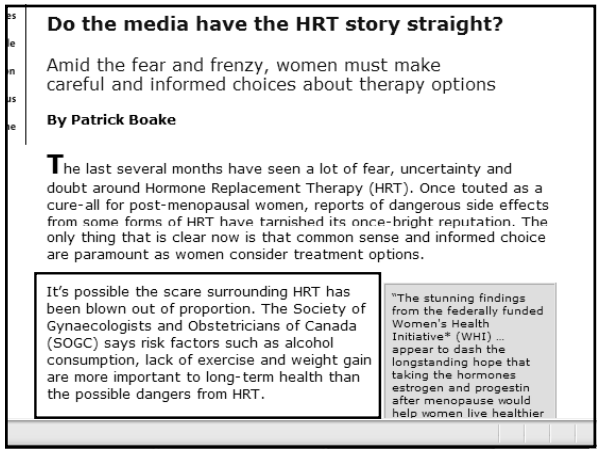

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GLOBEANDMAIL.COM

July 11, 2002

Hot Flashes, Who's a woman to trust?
Margaret Wente, COUNTERPOINT

I think it is important to put the increased risks in context, says Dr. Messner. The risk of breast cancer from being sedentary or having a couple glasses of wine a day are higher than from using HRT for 10 or more years.

We all take risks every day and, for some women, the increased quality of life that they may experience may well be worth the small risk.

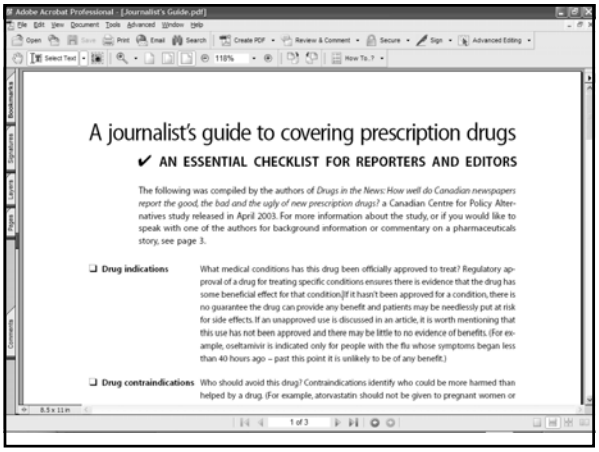
Dr. Sandra Messner is Medical Director, Health Watch Centre for Sunnybrook and Women's College Health Sciences Centre in Toronto

Drugs in the news: an analysis of Canadian newspaper coverage.

Alan Cassels et al., CMAJ, Apr. 29, 2003

- Looked at newspaper coverage (2000) of 5 prescription drugs launched in Canada.
- 62% of the articles did not quantify benefits or harms.
- 26% of the effect sizes (magnitudes) were presented in relative terms, which can be misleading.
- Only 16% mentioned non-drug treatment options such as exercise or diet.

Alan Cassels, Independent drug policy researcher, Victoria, B.C.
Research Associate, Canadian Centre for Policy Alternatives

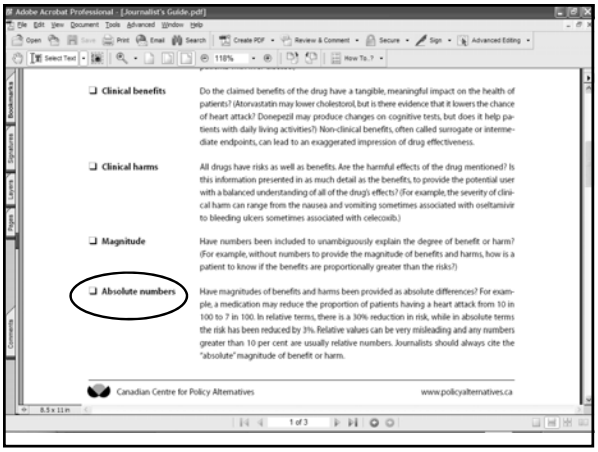

A journalist's guide to covering prescription drugs

✔ AN ESSENTIAL CHECKLIST FOR REPORTERS AND EDITORS

The following was compiled by the authors of *Drugs in the News: How well do Canadian newspapers report the good, the bad and the ugly of new prescription drugs?* a Canadian Centre for Policy Alternatives study released in April 2003. For more information about the study, or if you would like to speak with one of the authors for background information or commentary on a pharmaceuticals story, see page 3.

❑ **Drug indications** What medical conditions has this drug been officially approved to treat? Regulatory approval of a drug for treating specific conditions ensures there is evidence that the drug has some beneficial effect for that condition.If it hasn't been approved for a condition, there is no guarantee the drug can provide any benefit and patients may be needlessly put at risk for side effects. If an unapproved use is discussed in an article, it is worth mentioning that this use has not been approved and there may be little to no evidence of benefits. (For example, oseltamivir is indicated only for people with the flu whose symptoms began less than 40 hours ago – past this point it is unlikely to be of any benefit.)

❑ **Drug contraindications** Who should avoid this drug? Contraindications identify who could be more harmed than helped by a drug. (For example, atorvastatin should not be given to pregnant women or


❑ **Clinical benefits** Do the claimed benefits of the drug have a tangible, meaningful impact on the health of patients? (Atorvastatin may lower cholesterol, but is there evidence that it lowers the chance of heart attack? Donepezil may produce changes on cognitive tests, but does it help patients with daily living activities?) Non-clinical benefits, often called surrogate or intermediate endpoints, can lead to an exaggerated impression of drug effectiveness.

❑ **Clinical harms** All drugs have risks as well as benefits. Are the harmful effects of the drug mentioned? Is this information presented in as much detail as the benefits, to provide the potential user with a balanced understanding of all of the drug's effects? (For example, the severity of clinical harm can range from the nausea and vomiting sometimes associated with oseltamivir to bleeding ulcers sometimes associated with celecoxib.)

❑ **Magnitude** Have numbers been included to unambiguously explain the degree of benefit or harm? (For example, without numbers to provide the magnitude of benefits and harms, how is a patient to know if the benefits are proportionally greater than the risks?)

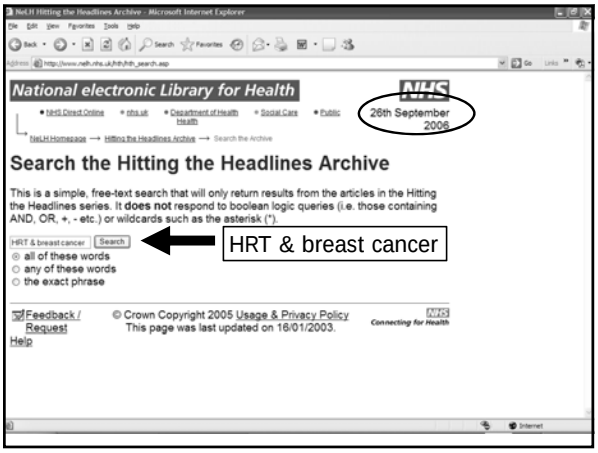
❑ **Absolute numbers** Have magnitudes of benefits and harms been provided as absolute differences? For example, a medication may reduce the proportion of patients having a heart attack from 10 in 100 to 7 in 100. In relative terms, there is a 30% reduction in risk, while in absolute terms the risk has been reduced by 3%. Relative values can be very misleading and any numbers greater than 10 per cent are usually relative numbers. Journalists should always cite the "absolute" magnitude of benefit or harm.

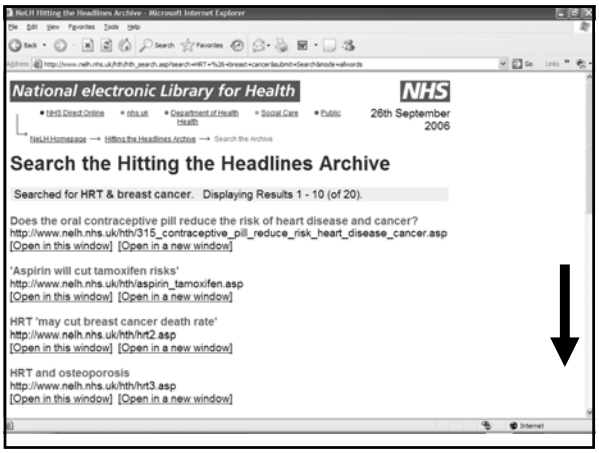
Canadian Centre for Policy Alternatives www.policyalternatives.ca

Resources

Evidence-based summaries of recent news stories

- Hitting the headlines (UK)
  Discontinued: March 31, 2008
  Replaced with: Behind the headlines (UK)
- Media doctor (Canada)
  http://www.mediadoctor.ca/




National electronic Library for Health
NHS
26th September 2006
Search the Hitting the Headlines Archive
Searched for HRT & breast cancer. Displaying Results 1 - 10 (of 20).
Does the oral contraceptive pill reduce the risk of heart disease and cancer?
http://www.nelh.nhs.uk/hth/315_contraceptive_pill_reduce_risk_heart_disease_cancer.asp
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'Aspirin will cut tamoxifen risks'
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HRT 'may cut breast cancer death rate'
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HRT and osteoporosis
http://www.nelh.nhs.uk/hth/hrt3.asp
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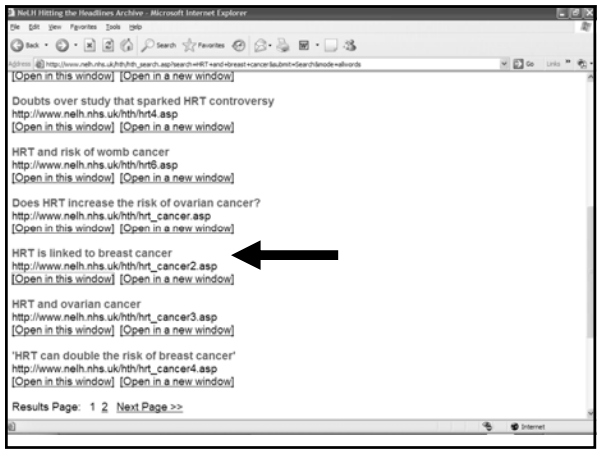
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Doubts over study that sparked HRT controversy
http://www.nelh.nhs.uk/hth/hrt4.asp
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HRT and risk of womb cancer
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Does HRT increase the risk of ovarian cancer?
http://www.nelh.nhs.uk/hth/hrt_cancer.asp
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HRT is linked to breast cancer
http://www.nelh.nhs.uk/hth/hrt_cancer2.asp
[Open in this window] [Open in a new window]
HRT and ovarian cancer
http://www.nelh.nhs.uk/hth/hrt_cancer3.asp
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'HRT can double the risk of breast cancer'
http://www.nelh.nhs.uk/hth/hrt_cancer4.asp
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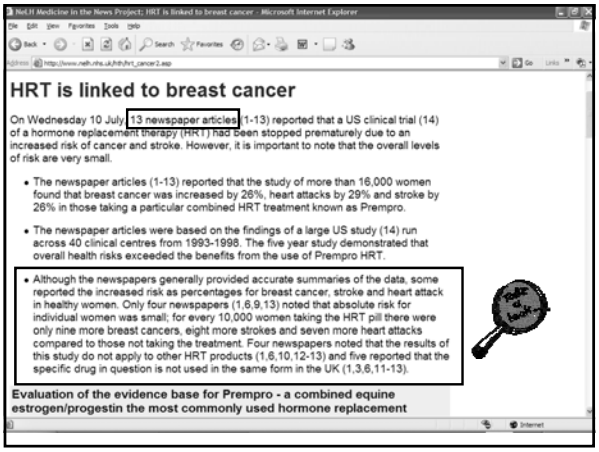
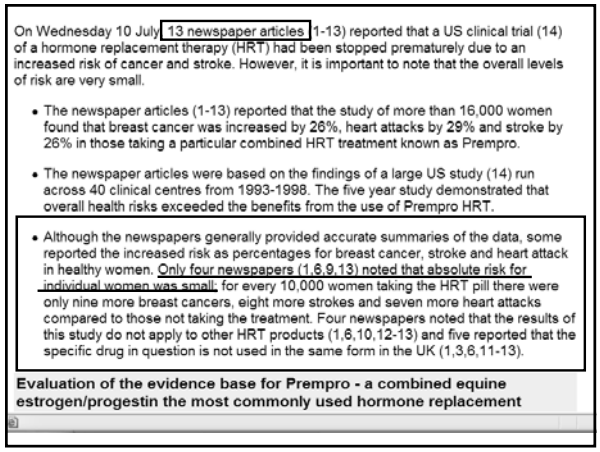
Results Page: 1 2 Next Page >>


HRT is linked to breast cancer
On Wednesday 10 July 13 newspaper articles (1-13) reported that a US clinical trial (14) of a hormone replacement therapy (HRT) had been stopped prematurely due to an increased risk of cancer and stroke. However, it is important to note that the overall levels of risk are very small.
• The newspaper articles (1-13) reported that the study of more than 16,000 women found that breast cancer was increased by 26%, heart attacks by 29% and stroke by 26% in those taking a particular combined HRT treatment known as Prempro.
• The newspaper articles were based on the findings of a large US study (14) run across 40 clinical centres from 1993-1998. The five year study demonstrated that overall health risks exceeded the benefits from the use of Prempro HRT.
• Although the newspapers generally provided accurate summaries of the data, some reported the increased risk as percentages for breast cancer, stroke and heart attack in healthy women. Only four newspapers (1,6,9,13) noted that absolute risk for individual women was small; for every 10,000 women taking the HRT pill there were only nine more breast cancers, eight more strokes and seven more heart attacks compared to those not taking the treatment. Four newspapers noted that the results of this study do not apply to other HRT products (1,6,10,12-13) and five reported that the specific drug in question is not used in the same form in the UK (1,3,6,11-13).
Evaluation of the evidence base for Prempro - a combined equine estrogen/progestin the most commonly used hormone replacement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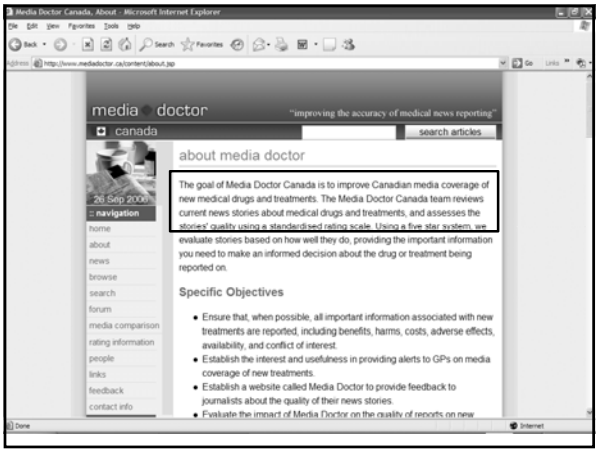
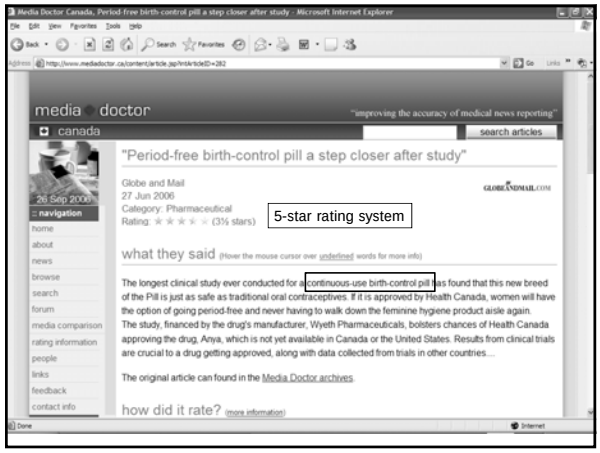
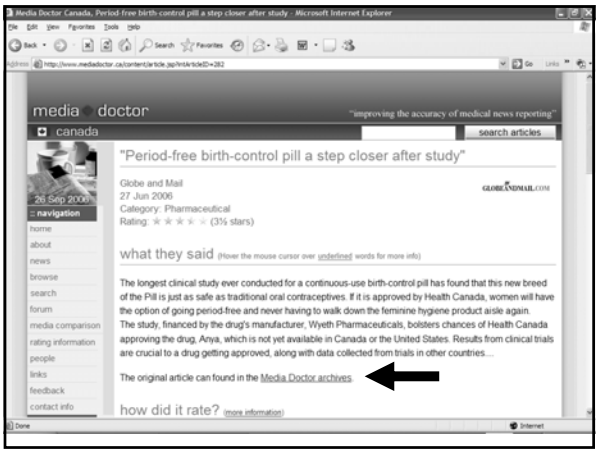

media doctor
"improving the accuracy of medical news reporting"
canada
search articles
about media doctor
The goal of Media Doctor Canada is to improve Canadian media coverage of new medical drugs and treatments. The Media Doctor Canada team reviews current news stories about medical drugs and treatments, and assesses the stories' quality using a standardised rating scale. Using a five star system, we evaluate stories based on how well they do, providing the important information you need to make an informed decision about the drug or treatment being reported on.
Specific Objectives
• Ensure that, when possible, all important information associated with new treatments are reported, including benefits, harms, costs, adverse effects, availability, and conflict of interest.
• Establish the interest and usefulness in providing alerts to GPs on media coverage of new treatments.
• Establish a website called Media Doctor to provide feedback to journalists about the quality of their news stories.
• Evaluate the impact of Media Doctor on the quality of reports on new


media doctor
"improving the accuracy of medical news reporting"
canada
search articles
"Period-free birth-control pill a step closer after study"
Globe and Mail
27 Jun 2006
Category: Pharmaceutical
Rating: (3½ stars)
5-star rating system
what they said
The longest clinical study ever conducted for a continuous-use birth-control pill has found that this new breed of the Pill is just as safe as traditional oral contraceptives. If it is approved by Health Canada, women will have the option of going period-free and never having to walk down the feminine hygiene product aisle again. The study, financed by the drug's manufacturer, Wyeth Pharmaceuticals, bolsters chances of Health Canada approving the drug, Anya, which is not yet available in Canada or the United States. Results from clinical trials are crucial to a drug getting approved, along with data collected from trials in other countries....
The original article can found in the Media Doctor archives.
how did it rate?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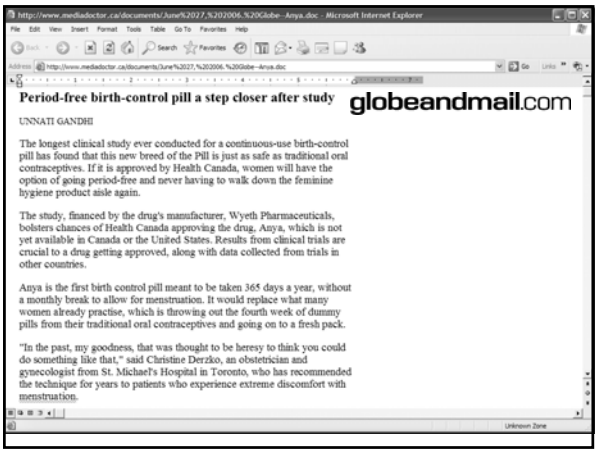
Period-free birth-control pill a step closer after study
globeandmail.com
UNNATI GANDHI
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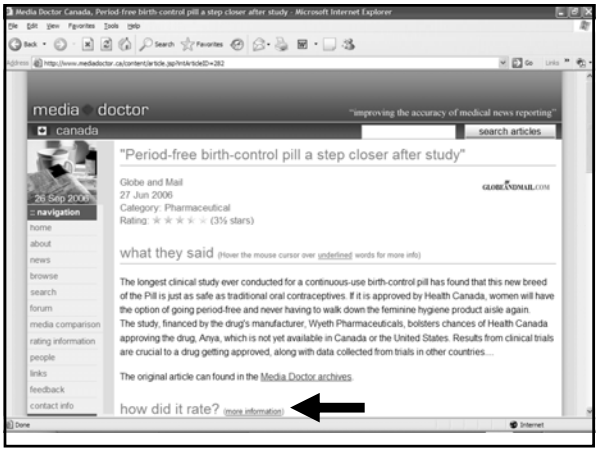
Anya is the first birth control pill meant to be taken 365 days a year, without a monthly break to allow for menstruation. It would replace what many women already practise, which is throwing out the fourth week of dummy pills from their traditional oral contraceptives and going on to a fresh pack.
"In the past, my goodness, that was thought to be heresy to think you could do something like that," said Christine Derzko, an obstetrician and gynecologist from St. Michael's Hospital in Toronto, who has recommended the technique for years to patients who experience extreme discomfort with menstruation.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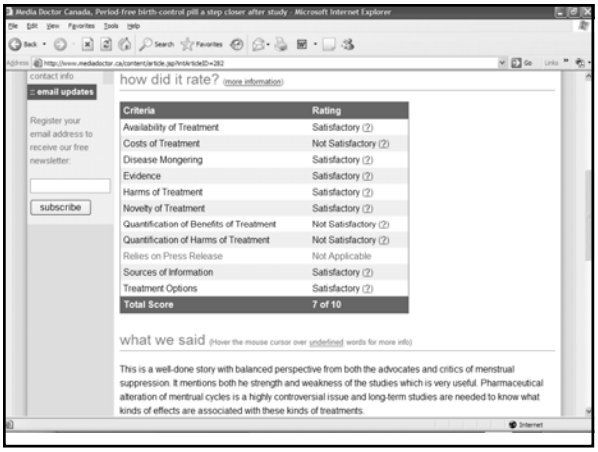
how did it rate?
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subscribe
Criteria | Rating
Availability of Treatment | Satisfactory
Costs of Treatment | Not Satisfactory
Disease Mongering | Satisfactory
Evidence | Satisfactory
Harms of Treatment | Satisfactory
Novelty of Treatment | Satisfactory
Quantification of Benefits of Treatment | Not Satisfactory
Quantification of Harms of Treatment | Not Satisfactory
Relies on Press Release | Not Applicable
Sources of Information | Satisfactory
Treatment Options | Satisfactory
Total Score | 7 of 10
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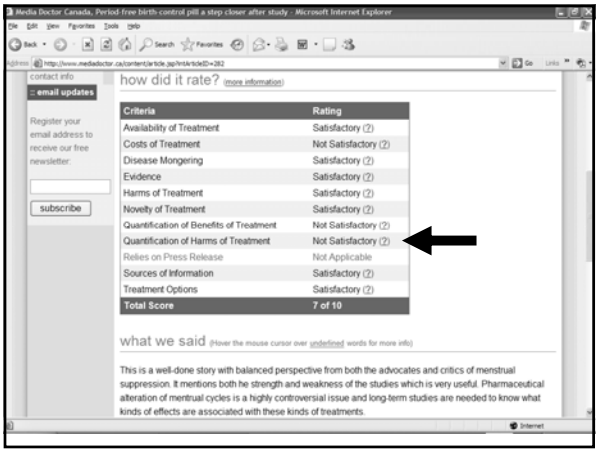
This is a well-done story with balanced perspective from both the advocates and critics of menstrual suppression. It mentions both he strength and weakness of the studies which is very useful. Pharmaceutical alteration of mentrual cycles is a highly controversial issue and long-term studies are needed to know what kinds of effects are associated with these kinds of treatments.


how did it rate?
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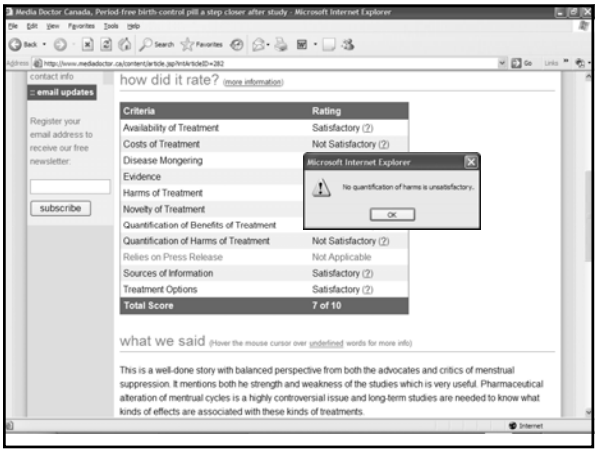
how did it rate?
email updates
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Microsoft Internet Explorer
No quantification of harms is unsatisfactory.
OK
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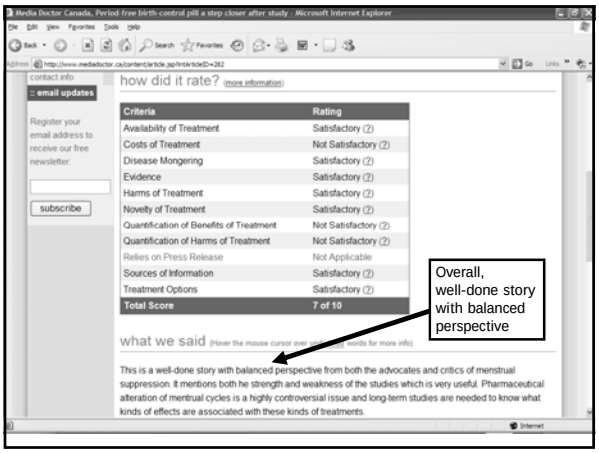

Take home messages

- Relative values can be misleading.
- Quote the magnitudes of benefits and harms as absolute differences.
- Check out Media Doctor Canada!

http://www.mediadoctor.ca/