

# COVERING MEDICAL RESEARCH

A Guide for Reporting on Studies



By Gary Schwitzer

for the Association of Health Care Journalists  
and Center for Excellence in Health Care Journalism

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“The press, on its own, if it chooses, can make the transition from cheerleaders of science to independent observers... The journalistic trumpeting of medical cures on the basis of wisps of evidence, even though accompanied by sober cautions against optimism, deserves to be severely throttled back, in recognition of an unfortunate reality: though news is sold around the clock, major advances in medicine come along infrequently.”

**Daniel Greenberg, author**  
**Science, Money and Politics**

## Introduction

This guide is intended to help you analyze and write about health and medical research studies. Its publication, however, should not be construed as an invitation to favor this kind of reporting over more enterprising stories that weave in policy and other issues.

Some people who follow research news closely believe that too much media attention is given to reporting on studies – that such a diet of news provides a distorted picture of the health care reality. We'll investigate some of the factors behind this argument in greater detail.

Clearly, reporting on major studies such as the ALLHAT trial – the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial – which tested blood pressure- and cholesterol-lowering drugs in more than 42,000 people, or the Women's Health Initiative – which, among other findings, put into question the hormone replacement therapy millions of women were prescribed – is important for any news organization to pursue to best serve its public.

Sometimes, what's important is reporting the problems, limitations and backstory of a study. Take the Jupiter trial, reported so widely in late 2008 (Ridker et al, NEJM, 2008). Jupiter was designed to determine whether cholesterol-lowering statin drugs could prevent heart attacks and strokes among people with normal cholesterol levels. They did, but with important caveats. Chief among them: The absolute numbers of heart attacks and strokes prevented were small. The better stories on Jupiter focused on those absolute (not just relative) risk reductions, the high costs of the drugs, and potential conflicts of interest.

But journalists covering health or medical news need to know about publication biases that exist in medical journals. Positive findings are reported far more often than negative. So if you live by the journals, you and your readers, viewers or listeners may have a distorted and overly enthusiastic picture of health/medical research.

Those who report on studies need to know that when they listen to a research presentation at a scientific meeting, the substance of that talk might have had very little or no peer review. So it, indeed, may be news. It might also be hogwash that even other scientists are hearing for the first time. When you go to them for reaction, they likely haven't been able to review the data in full.

So, yes, covering studies is one way to let the public know of important advances in health care. But, no, it is not for those who don't appreciate the complexity of the landscape.

If you don't have much experience in journalism, at your news organization, or in covering health, medical and science news, you probably don't feel you can simply put your foot down and tell an editor, "We really shouldn't cover this." We understand that. And it's difficult to say "no" when all of your competition is covering the story. This guide includes 10 questions you should answer to produce a meaningful and appropriately skeptical report. Then you can keep your editor happy, serve your audience well and have personal satisfaction in a job well done.

We hope this guide will be a road map to help you do a better job of explaining research results for your audience.

# PART I

# UNDERSTANDING STUDIES

## THE HIERARCHY OF EVIDENCE

Not all studies are equal. And they shouldn't be reported as if they were.

A study that finds an effect of an agent in the test tube is a far cry from a randomized clinical trial of the agent in 500 people over two years. The latter may deserve headlines. Few in the former category deserve such a spotlight.

What follows is a very brief overview of some of the key differences among different types of studies. There are textbooks written on this, so we emphasize that this is just an overview.

### Descriptive versus analytical studies

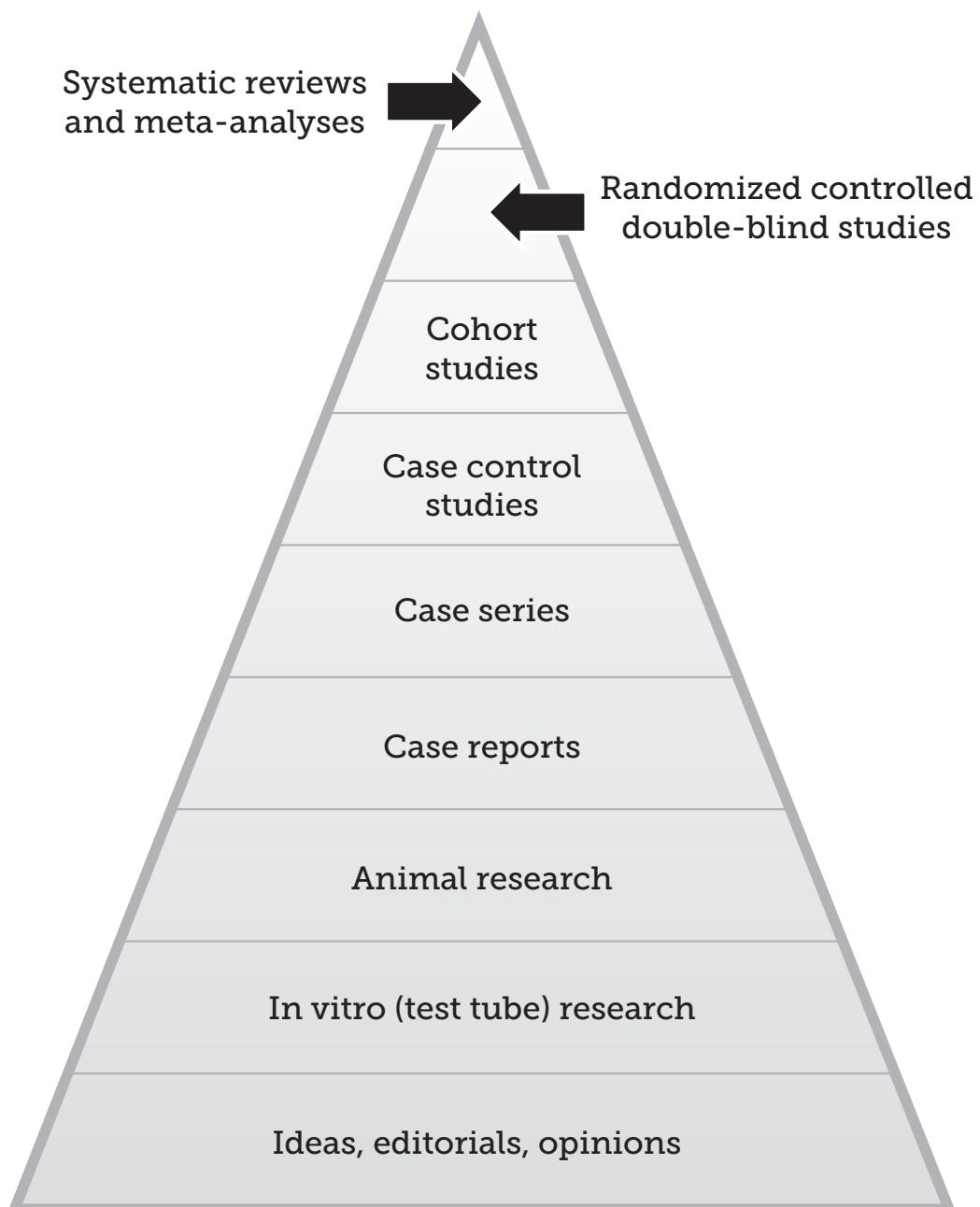
As the name implies, *descriptive studies* describe patterns or trends of disease in people or places. These are used to form theories – or hypotheses – about the causes of diseases. Case reports (or case series) and cross-sectional studies fit in this category.

*Analytical studies* test specific causal theories using a treatment group (people who receive the treatment under investigation) and a control group (people demographically similar to the experimental group who do not receive the investigated treatment). Randomized clinical trials, cohort studies and case-control studies are analytical studies.

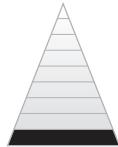
### The hierarchy or pyramid

Some find it helpful to think about a hierarchy of evidence, which ranks different types of studies in a pyramid, with those at the top having greater potential to answer questions with more certainty. Fans of the hierarchy model believe it's an easy way to remember that it takes a lot of studies at the bottom of the pyramid to overturn the findings of one well-done study at the top of the pyramid.

## THE HIERARCHY OF EVIDENCE PYRAMID



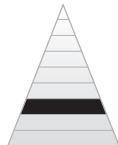
Starting at the bottom of the pyramid, some of the distinctive characteristics of the study types are obvious:



**Ideas, editorials and opinions**, while commonly published in medical journals, are just that – ideas, editorials and opinions – not necessarily backed up by evidence.



**In vitro** research means research in a test tube, culture dish, but not *in vivo* (Latin for “living thing”). Even a good news release will point out the distinction, as with one we saw that stated: **“This is an *in vitro* study ... It’s not clear that these levels could be achieved in animals or in humans.”**



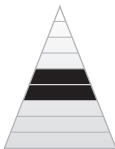
**Animal research** is the next rung up the ladder. Reporters covering animal research should always note the leap that may occur between animal research and any possible implications for humans.

Some of the limitations of this research were analyzed in an article in the journal *PLoS*, **Publication Bias in Reports of Animal Stroke Studies Leads to Major Overstatement of Efficacy**, and summarized by [Nature.com](#):

“Published animal trials overestimate by about 30% the likelihood that a treatment works because negative results often go unpublished, a study suggests.

A little more than a third of highly cited animal research is reproduced later in human trials, and although about 500 treatments have been reported as effective in animal models of stroke, only aspirin and early thrombolysis with tissue plasminogen activator work in humans. The lack of negative results in the literature may explain why so few drugs tested in animals are effective in humans.”

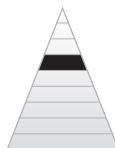
Then we get into some study types whose characteristics you may be less familiar with.



**Case reports** or **case series** are descriptions of cases – or patients – reported by physicians. The cases describe individuals (reports) or groups of patients (series) which may be the first alert that something is going on.

**A good example:** The very first evidence reported on HIV/AIDS was a case report in 1981. [www.aegis.com/pubs/MMWR/1981/MM3021.html](http://www.aegis.com/pubs/MMWR/1981/MM3021.html).

Be wary of the kind of case report we so often hear, such as “In a first of its kind, a Saskatchewan surgeon has transplanted five organs ...” And uncontrolled case series, wherein several people get the same treatment but there’s no comparison group. This leads to news story leads like, “A Saskatchewan surgeon reported his dramatic results from a new surgical procedure he performed on 12 patients with...”



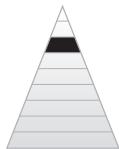
**Case control studies** look at groups of people – some of whom have a condition and some who don’t. The condition already exists; the exposure has already happened. Case control studies work well for rare diseases; in a cohort study you’d need a large sample to get even a few cases of a disease, but with case-control studies you simply select already-diseased individuals.

**A good example:** The early report on **Legionnaires’ Disease**. Researchers found men who had fallen ill and then compared them to men who did not get sick.

**Be careful:** The cases and controls might not be matched well, so the results could be flawed. For example, a study in the *British Medical Journal* addressed what the authors thought were flaws in 20 years of case control studies suggesting that appendectomy protects against the development of ulcerative colitis.<sup>1</sup> Previous studies had not taken appendicitis itself – as opposed to removal of the appendix, or appendectomy – as well as a condition called mesenteric lymphadenitis into account. It turned out to be those two factors, and not appendectomy, that were linked to a lower rate of ulcerative colitis.

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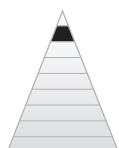
<sup>1</sup> Frisch M, Pedersen BV, Andersson RE. Appendicitis, mesenteric lymphadenitis, and subsequent risk of ulcerative colitis: cohort studies in Sweden and Denmark. *BMJ*. 2009 Mar 9;338:b716. Available at: [http://www.bmjjournals.org/cgi/content/full/338/mar09\\_2/b716](http://www.bmjjournals.org/cgi/content/full/338/mar09_2/b716)



**Cohort studies** select people based on their exposure to something of interest – estrogen pills, asbestos, etc. – and then follow those people to determine if a selected outcome, such as cancer, occurs. In a retrospective cohort, the exposure and outcome have already happened. In a prospective cohort, only the exposure has occurred, and the participants have to be followed for a specified period of time to observe outcomes. Cohorts are great if you're looking at a rare exposure – asbestos in a factory, radiation from a nuclear plant, etc. – and you want to know how many exposed versus unexposed people develop a particular disease.

**Good examples:** The [Framingham Heart Study](#) and the [British Doctors Study](#).

**Be careful:** There might be a problem with selection bias – that is, the people who are selected to be followed might be significantly different from others in ways that could be important to the study. Confounding variables are characteristics such as age or gender that could affect how a person responds to a treatment. If you're studying a possible link between a drug and hip fracture, age is a potential confounding factor because age is related to hip fracture. One group with an average age of 70 might only include people aged 70 while another with the same average age could consist of equal proportions of individuals aged 50 and 90. These are the kinds of confounders to look for in cohort studies.



**Randomized clinical trials** are the stars of the scientific world. The key feature that separates this study type from the others is that investigators randomly assign trial participants to a treatment or control group, which minimizes bias and factors that might skew the results.

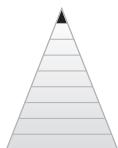
It is important that the two groups be as alike as possible in order to ensure effects are due to the treatment alone and not confounding variables.

When looking at clinical trials, check the number of participants and the length of the study. More people followed over more time will give a more accurate measure of treatment effects. Why not use clinical trials every time? They're expensive, take a lot of time, and could have ethical ramifications. (For example, is it ethical to put some sick people on a placebo?)

**A good example:** The [Prostate, Lung, Colorectal and Ovarian \(PLCO\) Cancer Screening Trial](#), which sought to determine whether certain cancer screening tests reduce deaths from prostate, lung, colorectal and ovarian cancer. The *Washington Post* reported on a randomized clinical trial that shot down an acupuncture claim at [www.washingtonpost.com/wp-dyn/content/article/2006/06/19/AR2006061900833\\_pf.html](http://www.washingtonpost.com/wp-dyn/content/article/2006/06/19/AR2006061900833_pf.html).

**Be careful:** Even “gold standards” aren’t perfect. First, you should think about who volunteers for randomized trials. These days, industry pays a lot to recruit volunteers. Might this skew the tested population to those who are poorer or have time because they don’t have a job? Be aware of subtle differences that could impact how the findings could be extrapolated to a wider population. Try to find out who got excluded for a trial and why? Who dropped out and why?

The GRADE Working Group – researchers trying to improve the grading of the quality of evidence – posted an example of a study that was flawed because researchers were not blinded from seeing who got what treatment in a study “with subjective outcomes highly susceptible to bias.”<sup>2</sup>



**Systematic reviews** are studies of studies. Their “subjects” are earlier studies that meet the criteria of the particular research question of interest. Those who employ systematic reviews try to use strategies that eliminate bias and random error.

**Meta-analysis** is a technique to help researchers combine studies. It is really a study of studies or a pooling of data from several studies with a goal of trying to establish the weight of the evidence. But, as often noted with the saying “garbage-in, garbage out,” the quality of the meta-analysis depends on the quality of the studies being analyzed.

Ray Moynihan, a veteran health journalist and author from Australia, writes an explanation of why systematic reviews are at the top of the pyramid.

“The systematic review is now widely regarded as the least biased and most rational way to summarize the research evidence that evaluates health care interventions meant to prevent and treat illness. A systematic review can help distinguish therapies or interventions that work from those that are useless, harmful, or wasteful. It can reliably estimate how well different options work, and it can identify gaps in knowledge requiring further research. ...

The basic steps of a systematic review include formulating a question; finding relevant studies; selecting and assessing the studies; summarizing and synthesizing study results; interpreting the review results; and maintaining and updating the review.

... But systematic reviews have significant limitations as well as benefits. The studies being reviewed are often incomplete, deficient or skewed toward the most profitable treatments. Sometimes systematic reviews themselves are poorly conducted, as for

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<sup>2</sup> Available at: [http://www.gradeworkinggroup.org/FAQ/E\\_HIT.htm](http://www.gradeworkinggroup.org/FAQ/E_HIT.htm)

example when the search for relevant studies has not been as comprehensive as possible. Often systematic reviews will conclude that there is not enough strong evidence to support or refute a technology that some clinicians and patients consider promising – yet decisions about its use must still be made and defended. Notwithstanding their pitfalls, systematic reviews promise to improve the quality of many health care decisions.”<sup>3</sup>

## WEB GEM



The Cochrane Collaboration is an international network of several thousand research specialists who have conducted several thousand systematic reviews. The Web site is [www.cochrane.org](http://www.cochrane.org).

**Good example:** A Cochrane review of studies on Vitamin C to prevent or treat the common cold. The review looked at 30 trials involving more than 11,000 study participants and found that huge doses of the vitamin did not cut down the number of colds, though there was some evidence that people who did severe exercise or were exposed to cold weather for long periods of time might benefit.

AHCJ members are given free access to the reviews as a member benefit. Learn about it at [www.healthjournalism.org/membership-benefits.php](http://www.healthjournalism.org/membership-benefits.php).

Here's one way of looking at such a hierarchy, by Mark Zweig, M.D., and Emily DeVoto Ph.D., two people who have thought a lot about how reporters cover medical research:

Each has worked with journalists at National Institutes of Health workshops and Zweig led a 2004 AHCJ conference session on understanding evidence-based medicine.

“A health writer’s first attempt at expressing results from a new observational study read ‘Frequent fish consumption was associated with a 50% reduction in the relative risk of dying from a heart attack.’ Her editor’s reaction? Slash. Too wordy, too passive. The editor’s rewrite? ‘Women who ate fish five times a week cut their risk of dying later from a heart attack by half.’ This edit seems fair enough – or is it? The change did streamline the message, but with a not-so-obvious, unintended cost to the meaning. Was the subjects’ fish consumption really responsible for their dying less frequently from heart attacks? The new wording suggests that’s the case, but the original study does not support a conclusion of cause and effect.

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<sup>3</sup> Moynihan, Evaluating Health Services: A Reporter Covers the Science of Research Synthesis (New York: Milbank Memorial Fund, 2004), 2. Available online at: [www.milbank.org/reports/2004Moynihan/Moynihan.pdf](http://www.milbank.org/reports/2004Moynihan/Moynihan.pdf).

This is what we call an observational, or epidemiologic, study. It examines the association between an exposure (e.g. a food or something in the environment, or a behavior) and an outcome (often a disease or death.) Can you see how this might lead to some pretty outrageous conclusions? Because of all the exposures that happen at the same time in the complex lives of humans, many things can never be completely accounted for. Such studies cannot provide evidence of cause and effect (did fish eating lower the risk of dying from a heart attack or was it just a coincidence?). A stronger design could explore that further.

There's only one study design involving humans that does rise to the level of demonstrating cause and effect. That's called a randomized trial. In this design, study subjects are assigned an exposure (or a control condition) at random, irrespective of anything else in their lives. We expect that other exposures even out between the treated group and the control group of subjects (and this can be demonstrated). As a result, the only difference between the groups is whether they receive the exposure under study or the control condition. This approach is a true experiment. Any difference in outcome seen between the control and the experimental group should be due to the one factor or variable that differs.

Do you see how the fish and heart attack conclusion isn't a random controlled study? First, it wasn't random. Second, there wasn't a control group. Thus, any 'link' between cause and effect in observational studies is speculative at best.

In reporting on observational research, language is crucial, because the audience may not appreciate the nuances. To a general audience, language such as, 'fish consumption is linked [or tied] to the risk of heart attacks' may sound causal even when a causal relationship is not warranted.”<sup>4</sup>

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<sup>4</sup> Originally published on HealthNewsReview.org on December 20, 2007. Revised for this guide. Original article: [www.healthnewsreview.org/DoesTheLanguageFit\\_Paper.php](http://www.healthnewsreview.org/DoesTheLanguageFit_Paper.php).

# WATCH YOUR LANGUAGE

On the following pages are examples of findings reported in the news in which the media mistakenly used causal language to describe the results of observational studies, along with suggested alternatives by Zweig and DeVoto.

## EXAMPLE 1

### **Study Design**

Prospective cohort study of dietary fat and age-related maculopathy (observational)

### **Researcher's version of results**

A 40 percent reduction of incident early age-related maculopathy *was associated with* fish consumption at least once a week.

### **Journalist's version of results**

Eating fish *may help preserve* eyesight in older people.

### **Problem**

*Preserve* and *help* are both active and causal; *may help* sounds like a caveat designed to convey uncertainty, but causality is still implied.

### **Suggested language**

“People who ate fish at least once a week were observed to have fewer cases of a certain type of eye problem. However, a true experimental randomized trial would be required in order to attribute this to their fish consumption, rather than to some other factor in their lives. This was an observational study – not a trial.”

## Example 2

### Study Design

Prospective cohort study of the relationship between free-living activity energy expenditure and mortality in older adults (observational)

### Researcher's version of results

Activity energy expenditure was *strongly associated with lower risk* of mortality in healthy older adults. For every 287 kcal/day in free-living activity energy expenditure, there is approximately a 30 percent lower risk of mortality.

### Journalist's version of results

The authors calculated that participants who did 75 minutes a day of activities... *lowered their risk of dying* by 30 percent.

### Problem

*Lowered their risk* is causal; *strongly associated with lower risk* is not.

### Suggested language

“The researchers observed that people who used more energy in daily living had a lower risk of dying (within a certain time period). However, an observational study like this one can't prove that using more energy in daily activity actually caused the lower risk of dying, because other factors may have played a role.”

## Example 3

### Study Design

Prospective cohort study of the relationship between coffee consumption and diabetes among postmenopausal women (observational)

### Researcher's version of results

Compared with women who reported 0 cups of coffee per day, women who consumed 6 or more... had a 22 percent lower risk of diabetes.

### Journalist's version of results

Overall, those who drank the most [coffee] were *22 percent less likely* to have diabetes, with decaf drinkers *reaping somewhat greater benefit*...

### Problem

*22 percent less likely* is correct; *reaping greater benefit* is causal.

### Suggested language

"Overall, those who drank the most coffee were 22 percent less likely to have diabetes. But, this type of study cannot prove that coffee drinking actually caused the lower chance of getting diabetes. A randomized trial is needed to show cause and effect."

## Example 4

### Study Design

Prospective cohort study of fish intake and coronary heart disease in women (Nurses' Health Study; observational)

### Researcher's version of results

Among women, higher consumption of fish... is associated with a lower risk of coronary heart disease (CHD), particularly CHD deaths.

### Journalist's version of results

Women who ate fish five times a week *cut their risk of dying* later from a heart attack by half.

### Problem

*Cut their risk of dying* is causal.

### Suggested language

"Compared to women who rarely ate fish, those who ate fish regularly had less heart disease and related death. But, this type of study, which just observes people, rather than randomly assigning them to eat fish or not, cannot prove that fish consumption had a protective effect."

## Example 5

### Study Design

Prospective cohort study of aspirin use and cancer incidence among U.S. men and women (observational)

### Researcher's version of results

Long-term daily use of adult-strength aspirin may be associated with modestly reduced overall cancer incidence.

### Journalist's version of results

Higher aspirin dose *seems to stave off* some cancers... The *strongest effect* was for colon cancer.

### Problem

*Stave off* is causal and active; *effect* is causal. *Seems to*, used as a caveat, does not undo the implication of causality.

### Suggested language

"Because the study was based on observation rather than a true experiment, we still don't know whether aspirin truly had a 'protective effect' against cancer. A randomized trial would be needed to prove that causal link."

## Example 6

### **Study Design**

Case-control study of alcohol use and risk of breast cancer (observational)

### **Researcher's version of results**

Ever-use of alcohol over the past 20 years was associated with a 1.3-fold increased risk of breast cancer.

### **Journalist's version of results**

...drinking alcohol at any time in the previous 20 years increased breast cancer risk 30 percent.

### **Problem**

*Increased* was converted into an active, causal verb, though researchers had used it as an adjective in a noncausal statement.

### **Suggested language**

"But readers shouldn't jump to the conclusion that alcohol use increases breast cancer risk. That's a conclusion that such an observational study can't reach. Other factors in the women's lives may have accounted for the risk. Only a randomized clinical trial can establish a cause."

## Example 7

### Study Design

Nested case-control study of the relationship between acid suppression and hip fractures in patients (observational)

### Researcher's version of results

Long-term [acid suppression] therapy, particularly at high doses, is associated with an increased risk of hip fracture.

### Journalist's version of results

Drugs that suppress acids *may make fractures more likely*...Taking proton pump inhibitors for more than a year *increased the likelihood of a hip fracture* by 44 percent.

### Problem

*Make fractures more likely* is causal, as is *increased the likelihood*; the caveat *may* does not undo the suggestion of causality.

### Suggested language

“The study showed that people who took proton pump inhibitors for more than a year were 44 percent more likely to have a hip fracture. Such a conclusion would require a randomized trial that includes a control group who didn’t take the drugs. In this observational study some other factor might have increased fractures. That doesn’t mean that the statistical link (association) isn’t real; it just means a study like this can’t prove that the drugs were the culprits.”

## PUTTING TYPES OF RESEARCH INTO CONTEXT

Dartmouth Medical School and VA researchers Steve Woloshin and Lisa Schwartz, whose work appears in more depth later in this guide, offer helpful tips on suggested language to use to inject caution into your reporting on studies. This is their chart:

Type of research	Suggested language
Preliminary research (e.g., unpublished scientific meeting presentations)	"The findings presented are a work in progress. Because the findings have not undergone final peer review, they have yet to be independently vetted, and may change."
Animal or lab study	"Because the study was based on animals, researchers cannot be certain whether the findings will apply to people."
Models (e.g., decision analysis)	"The findings are based on hypothetical relationships which may not exist."
No control group	"Because there was no control group (i.e., a group not taking the drug), it is impossible to know if the drug accounts for the findings."
Small study (e.g., less than 30 people)	"These findings are based on a small study; larger studies are needed to really understand how much the intervention works."
Surrogate outcomes	"It is not known whether (surrogate outcome) will translate into a clinically meaningful outcome such as [patient outcomes]." (e.g., PSA score vs. death)
Randomized trial	The benefit of [intervention] should be weighed against [side effects or other downsides like inconvenience, cost, etc.]"
New interventions	"The findings are based on short-term data. Since short-term benefits are always established before long-term benefits or harms, longer-term studies are needed."
New drugs	"[Drug] is a new drug (approved in --). Studies have shown that most serious side effects or recalls of new drugs happen during their first 5 years of approval."
Observational studies (with control group - but trial not possible, e.g. due to harmful exposure)	"Because the study was not a true experiment, it is not known whether it was really [exposure] or something else about the people who happened to be exposed to [exposure] that caused the difference."
Observational studies (with control group - trial possible, e.g., beneficial exposure)	"Because the study was not a true experiment, it is not known if [changing the exposure] will alter the outcome. A randomized trial is needed before widespread of adoption of [intervention]."

# PROS AND CONS THROUGH PRACTICAL EXAMPLE

AHCJ members Ivan Oransky (lead contributor of this guide) and Andrew Holtz took a clever approach to explain the hierarchy of evidence. It's a hypothetical example of a single case report of using orange juice to treat toenail fungus, which progressed all the way to a meta-analysis and systematic review. It includes pros and cons for each type of study outlined.

## VALUE OF EVIDENCE

### Case Report

Upon noticing that one of her patients with toenail fungus has had a complete recovery after drinking large amounts of orange juice, a physician sends a case report to the North American Journal of Fungal Disease .

WHAT IT IS  
A heads-up to colleagues by a physician who has seen something unusual in her practice

NUMBER OF SUBJECTS  
No more than a few

PROS  
Quick communication of worrisome or beneficial findings and a way to find out if anyone else has noticed the same thing

CONS  
Not controlled (so it's impossible to confirm causality); impossible to perform any statistical analysis



### CHRONOLOGY

Legend			
WHAT IT IS	NUMBER OF SUBJECTS	PROS	CONS

### Case Series

A doctor who has read the NAJFD letter gathers 10 such cases into a series, then publishes it in the Journal of Fungal Infections .

WHAT IT IS  
A report on the clinical experiences of multiple patients

NUMBER OF SUBJECTS  
Often just a handful, though dozens or hundreds may be reported

PROS  
Can quickly alert clinicians to a potential health threat or treatment and may help generate hypotheses for future studies

CONS  
Merely demonstrates that something has been observed more than once, without conclusive evidence about the cause of a condition or the effect of an intervention



### Case-Control Study

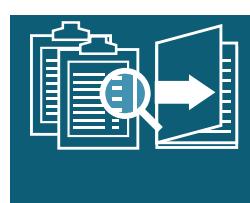
Intrigued by the case series, a dermatologist compares the orange juice consumption of toenail fungus patients with that of patients reporting other complaints. Sure enough, those who drink more orange juice show fewer cases of fungus. She publishes the findings in the Journal of Epidemiologic Nutrition.

WHAT IT IS  
A snapshot comparison of a group of patients with a selected group of similar people who lack that specific condition or exposure

NUMBER OF SUBJECTS  
Hundreds or even thousands (for example, when governments release information about residents in a particular zip code)

PROS  
Can determine whether an intervention is associated with a risk

CONS  
Cannot indicate the baseline risk of the general population; cases and controls may differ in ways the researchers haven't measured, which could skew results.



## Longitudinal Study

The Orange Growers' Association sponsors a study that tracks 300 patients who have toenail fungus. Half of the subjects drink orange juice; the other half do not. There's some evidence of benefit, so the research team publishes the results in the *Journal of Clinical Dermatology*.

?

Observations of individuals or groups over a period of time (thus, longitudinal)

?

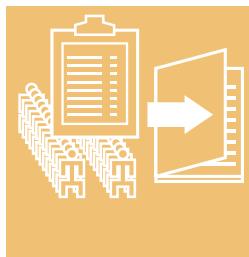
From dozens to hundreds of thousands, for studies using existing databases such as those compiled by Medicare

?

Can help distinguish cause and effect from mere correlations; researchers often observe subjects going about their lives, in contrast to the artificial conditions of many clinical trials

?

Because these studies are not controlled, unrecognized confounding factors may skew the results; studies that use existing data may lack crucial information about subject characteristics or exposures.



## Early Clinical Trials

In the lab, mice with toenail fungus respond to a compound in orange juice called ONA-34. Enthusiastic, the Orange Growers' Association sponsors a Phase I trial. A dozen college students are given large amounts of ONA-34 and watched for a week; side effects are minor. Researchers move on to a Phase II trial, in which patients with toenail fungus are given ONA-34. For more than half, symptoms improve within a week. Researchers present their findings at the annual Skin and Food Conference.

?

Small trials, following animal studies, to test safety and dosages in humans

?

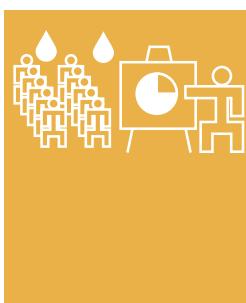
In Phase I, a dozen or so patients are given a treatment to test for side effects. In Phase II, as many as several hundred patients are treated to establish an effective dose.

?

Relatively inexpensive and quick

?

Though their data is often hyped, Phase II trials are not large enough to confirm whether a compound works. Also, these trials lack control groups.



## Randomized Controlled Clinical Trial

The Orange Growers' Association agrees to foot the bill for a Phase III trial, also known as a randomized controlled clinical trial. Two thousand people with toenail fungus receive an existing treatment; 2,000 more get ONA-34. It doesn't seem that ONA-34 is any better than the existing treatment.

Results are published in the Journal of the National Association of Doctors. Meanwhile, the Orange Juice Association has sponsored its own trial using a different existing treatment.

**?** A trial in which some patients get the treatment or intervention being tested while others receive an existing treatment or a placebo (if it's ethical to withhold possible treatment or if no treatment yet exists). To minimize bias, neither the subject nor the researcher knows which treatment the subject is getting.

**+** Hundreds or even thousands

**+** Considered the gold standard of clinical evidence from a single trial; rigorous, well controlled and subject to close oversight

**-** High cost prevents researchers from testing every hypothesis; some experiments are ruled out by ethics (for example, the link between smoking and lung cancer could not be confirmed by randomly assigning some people to start smoking).



## Editorial

A skeptical dermatologist writes an editorial accompanying the JNAD study, pointing out that the existing treatment given to the control group is not the best available, but that, if all it takes to cure toenail fungus is to drink orange juice, he's willing to recommend it to patients.

**?** Expert interpretation of the results of one or more studies

**+** None

**+** An independent expert analysis can highlight key strengths and limitations and suggest ways the results can be incorporated into clinical practice or further research.

**-** An editorial does not provide new data or other evidence. Also, the author may be biased.



## Review Article

A nutritionist summarizes the data on ONA-34 in the American Journal of Nutrition. However, she fails to disclose that she has received hundreds of thousands of dollars in grant funding from the Orange Growers' Association.

**?** A review of the medical literature with conclusions by an expert author or authors

**+** None

**+** A review neatly summarizes the trials and other data and saves time that would be spent reading all those papers.

**-** Merely expresses an opinion, even if it is based on previous papers. In a number of recent instances, review articles have been ghostwritten by writers paid by drug companies, although it is unclear how often this happens.



## Evidence-Based Review

The Archibald Foundation draws up an evidence-based review in which it questions whether ONA-34 should be brought to market. The problem, the foundation says, is that each trial used a different method of comparing the treatment and control groups, as well as a different existing treatment. It suggests two new randomized controlled clinical trials using the most effective standard treatment on the control group.

### Meta-Analysis

After publication of a third and fourth randomized controlled trial, a researcher analyzes all four studies and reports that there is, in fact, some benefit to ONA-34, but it's unclear whether there is enough in orange juice to make a difference. He suggests taking ONA-34 in pill form. This analysis is published in the British Journal of Medicine.

?

A statistical analysis of data pooled from multiple randomized controlled clinical trials

?

As many as tens of thousands, depending on the sizes of the original studies

?

By merging data from multiple trials, a meta-analysis is less likely to be affected by random variations or unrecognized flaws that may skew the results of an individual trial.

?

Researchers must depend on the quality of the original trials; sometimes, subjects enrolled in one trial center's protocol may end up in more than one published study, skewing results.



?

Systematic collection, evaluation and synthesis of existing studies to determine the sum of the evidence on a particular question. Frequently, reviews conclude that the evidence is insufficient.

?

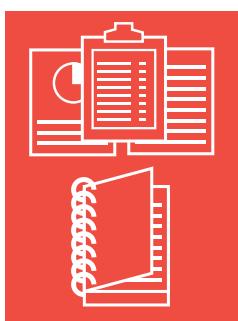
Often many thousands, depending on the size of the studies included

?

When the underlying data are similar, the review can estimate the effect of an intervention to a greater degree of confidence than the original trials and may resolve contradictions between the conclusions of individual reports.

?

The power of these reviews depends on the quality of the trials and the willingness of investigators to share unreported data. Also, not every expert may agree on the criteria for including trials in a review.



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## SCRUTINIZING THE QUALITY OF EVIDENCE

Jack Fowler, Ph.D., a social scientist who wrote the book *Survey Research Methods*, urges journalists not to make sweeping conclusions about the value of a study just because of its place on the pyramid. When asked how he would advise journalists in evaluating the quality of evidence, he emphasized certain issues that affect the validity of any study:

- a) **Internal validity.** Are the conclusions about the effects (or lack thereof) caused by some intervention (drug, treatment, test, operation) accurate? The most crucial issue with respect to these conclusions is usually the comparison group. Is there one? In the ideal, the comparison group is just like the treatment group except that it did not receive the treatment. The great strength of randomized trials is that, when carried out properly, they create two or more groups that are essentially the same. However, case control studies and cohort studies also try to create comparison groups, and a critical question about their quality is how well they succeeded in finding a group that was plausibly similar and, if there were limitations to the comparability, is it reasonable that statistical adjustments could be made to compensate for the differences. Finally, one needs information that the intervention was delivered as expected (the people took the pills, those assigned to surgery or acupuncture actually showed up and got the treatment they were assigned to get – and it was delivered as scripted).
- b) **External validity.** To what extent can we generalize the observed results to other populations and situations? This is obviously the big question about animal studies. Also, many trials limit subjects to those in certain age groups, or those without other conditions. It is important to note those criteria, because either the efficacy or the complication rates might be different for those with different ages, or those with other health problems, on whom physicians might want to use the treatments/tests/meds.
- c) **Implications for a pyramid.** There are two problems with the pyramid notion. First, the excellence of different kinds of studies is not necessarily the same for both validity issues. Randomized trials usually are strongest with respect to internal validity, but it is common for them to be weak on external validity. First, the subject eligibility rules are limiting. For many trials, many people are not willing to be randomized. Those who are willing might be different from others in important ways. In contrast, studies that follow cohorts often are particularly strong because they include more representative samples of patients. Their problem is likely to be getting a good comparison group. And meta-analyses – at the top of the pyramid – are no better than the trials available to examine. Second, it follows that how a particular study is designed and executed in ways that affect the validity issues is

as important as the particular kind of design that is used. Some cohort studies are better than some randomized trials when looked at as a whole. Ordering by type of design alone may send a message that is too strong.

One news organization has offered a regular column scrutinizing the quality of evidence in published research. Jeremy Singer-Vine's *Wall Street Journal* column, "Research Report/New Medical Findings," looks at a half-dozen published studies every two weeks. It gives a brief summary of the findings and then provides a short caveat. Examples of these caveats on various studies he has written about:

- "The researchers didn't report any attempts to test their technique on humans yet."
- "Mouse and human cancers can differ significantly."
- "The study was small, and the researchers cautioned that unrecognized environmental factors could have influenced the findings."
- "The researchers were unable to measure underlying factors, such as pre-existing diseases, that could have confounded the findings."
- "The study relied on parental reporting to determine when the infants reached major milestones. If enough parents deliberately or unintentionally avoided reporting delayed development, these findings could be skewed."
- "Subjects were predominantly Caucasian; the findings may not apply to other populations."
- "The study was small – just 275 subjects – and 40 percent of the patients dropped out before the end of the three month study (most of them because their symptoms became worse during the trial.)"

The fact that Singer-Vine wrote about the drop-out rate is very important. If you don't take drop-outs into account, you may inflate the significance of a study's findings.

Although we've only given you the punch lines to his caveats – and we encourage you to read Singer-Vine's entire columns – even the punch lines give you helpful reminders of things to look for in studies and how there may be flaws in any study design. Singer-Vine's column reminds us that there are often alternative explanations for many research results that are published or publicized.

We've spent a lot of time on this notion of a pyramid and a hierarchy of evidence because it is so important for journalists to understand that:

- Not all studies are the same.
- No study is perfect.
- You owe it to your readers, viewers and listeners to explain the caveats and uncertainties. Their health – and your reputation – may be at stake.

## Phases of clinical trials

Clinical trials are conducted in a series of steps, called phases - each phase is designed to answer a separate research question.

- **Phase I:** Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- **Phase II:** The drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
- **Phase III:** The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
- **Phase IV:** Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.
- Additional Resource Information on clinical trials can be found at  
<http://clinicaltrials.gov/info/resources>

## EXPLAINING RISK

### Absolute vs. relative risk

Famed radio commentator Paul Harvey had a feature called “The Rest of the Story.” Researchers, clinicians or journalists who report only on relative differences in making claims about a new idea should tell the rest of the story. It is absolute difference that probably matter most to people trying to make sense out of such claims.

Consider the risk for blindness in a patient with diabetes over a five-year period. If the risk for blindness is 2 in 100 (2 percent) in a group of patients treated conventionally and 1 in 100 (1 percent) in patients treated with a new drug, the absolute difference is derived by simply subtracting the two risks:  $2\% - 1\% = 1\%$ .

Expressed as an absolute difference, the new drug reduces the five-year risk for blindness by 1 percent.

The relative difference is the ratio of the two risks. Given the data above, the relative difference is:

$$\mathbf{1\% \div 2\% = 50\%}$$

Expressed as a relative difference, the new drug reduces the risk for blindness by half.

Each is accurate. But if your job is marketing manager for the new drug, you are likely to only use the relative risk reduction. If your job is journalist, you would serve your readers and viewers better by citing the raw data and pointing out the absolute risk reduction. That's the "rest of the story" often missing in news releases and direct-to-consumer prescription drug ads.

### **Number needed to treat**

The number needed to treat, or NNT, is the number of patients who need to be treated to prevent one additional bad outcome, calculated as  $1 \div$  Absolute Risk Reduction.

So, let's look at our hypothetical diabetes blindness drug example.

Let's say the risk for blindness in a patient with diabetes over a five-year period is 2 in 100 (2 percent) in a group of patients treated conventionally and 1 in 100 (1 percent) in patients treated with a new drug. So the absolute difference is derived by simply subtracting the two risks:  $2\% - 1\% = 1\%$ .

The number needed to treat would be  $1 \div 1\%$  (or .01) = 100.

So you would need to treat 100 people with diabetes for five years to prevent one case of blindness. You can see that this is an important way to look at new claims about new drugs.

Here's the advice Oransky of Reuters Health gives his staff on finding – and reporting – absolute risk:

- In the best-case scenario, a study spells out what the absolute risks of a given condition were in the treatment and control group (just for example). That just requires noting it in the story.
- In a close second-best scenario, the text doesn't note the absolute rates, but a table or figure – usually Table 2 – notes the percentages of each group, or the absolute numbers, that had the condition in question. Pick a few representative numbers and include them.
- Sometimes it is more difficult to tell. For example, when a cohort is stratified into quartiles based on a risk factor, and each group has a higher percentage of a given condition than the next, it may be necessary to give the overall number of subjects with a given condition. That's not ideal, of course, but it at least gives some context for "25% greater," etc.
- Finally, sometimes, the report does a particularly bad job of highlighting absolute

risk, and does none of the above things. That probably suggests some weaknesses, but in this case, we can note that the study did not include an absolute risk, but go to a source like Medline Plus to be able to find a general population figure for the condition. Again, that at least gives some context.

John Carey of *Business Week* reported an AHCJ award-winning cover story on the statin drug Lipitor and did an excellent job of explaining the significance of the “number needed to treat” to his readers.

It was an example of how a reporter made this statistical concept come to life for readers – driving home the point that number needed to treat is far more than just an academic exercise for biostatisticians.

...The second crucial point is hiding in plain sight in Pfizer's own Lipitor newspaper ad. The dramatic 36% figure has an asterisk. Read the smaller type. It says: “That means in a large clinical study, 3% of patients taking a sugar pill or placebo had a heart attack compared to 2% of patients taking Lipitor.”

Now do some simple math. The numbers in that sentence mean that for every 100 people in the trial, which lasted  $3\frac{1}{3}$  years, three people on placebos and two people on Lipitor had heart attacks. The difference credited to the drug? One fewer heart attack per 100 people. So to spare one person a heart attack, 100 people had to take Lipitor for more than three years. The other 99 got no measurable benefit. Or to put it in terms of a little-known but useful statistic, the number needed to treat (or NNT) for one person to benefit is 100.

Compare that with, say, today's standard antibiotic therapy to eradicate ulcer-causing H. pylori stomach bacteria. The NNT is 1.1. Give the drugs to 11 people, and 10 will be cured.

“Do Cholesterol Drugs Do Any Good?: Research suggests that, except among high-risk heart patients, the benefits of statins such as Lipitor are overstated.” *Business Week*. Jan. 17, 2008. Available at: [www.businessweek.com/magazine/content/08\\_04/b4068052092994.htm](http://www.businessweek.com/magazine/content/08_04/b4068052092994.htm)

## GET IMMersed – DON’T JUST GET YOUR TOES WET

I've often compared science to a winding stream. Journalists reporting on today's journal articles can be compared with someone who approaches the winding stream and dips his toes in for a second, then runs back to the newsroom to file the story, perhaps never to return to the stream to see that it has taken many turns and different directions downstream. If covering journals is a hit-or-miss practice, in which someone from general assignment might be assigned to cover a news release about a local medical center's study, that toe-dipping probably won't reflect the science that came before and that which will come after.

You might have been inclined to jump all over a story like this one, largely because it was in the prestigious *New England Journal of Medicine*.

The screenshot shows the homepage of The New England Journal of Medicine. At the top is the journal's logo, a circular seal with the text "THE NEW ENGLAND JOURNAL OF MEDICINE". Below the logo, the text "The NEW ENGLAND JOURNAL of MEDICINE" is displayed. A navigation bar below the logo includes links for "FREE NEJM E-TOC", "HOME", "SUBSCRIBE", "CURRENT ISSUE", "PAST ISSUES", "COLLECTIONS", a search bar with placeholder "Keyword, citation, or author", and buttons for "SEARCH" and "Advanced Search". The main content area features a red banner at the top with the text "ORIGINAL ARTICLE". Below the banner, the article title "Survival of Patients with Stage I Lung Cancer Detected on CT Screening" is shown in bold black text, followed by the subtitle "The International Early Lung Cancer Action Program Investigators".

But if you don't realize what came before this study – promoting the benefits of CT screening for lung cancer – and if you don't follow the journals all the time (if you're just tip-toeing in the stream), you might have missed the fact that a quite contradictory study was published in another journal just four months later.

The screenshot shows the homepage of JAMA (The Journal of the American Medical Association). The top features the large red "JAMA" logo with a registered trademark symbol. Below the logo, the text "The Journal of the American Medical Association" is visible. A horizontal menu bar includes links for "HOME", "CURRENT ISSUE", "PAST ISSUES", "TOPIC COLLECTIONS", "CME", "PHYSICIAN JOBS", "SUBMIT", "SUBSCRIBE", and "HELP". A blue banner at the top indicates the issue is "Vol. 297 No. 9, March 7, 2007". Below the banner, the section "Original Contribution" is highlighted. The main article title "Computed Tomography Screening and Lung Cancer Outcomes" is displayed in bold blue text. Below the title, the authors' names are listed: Peter B. Bach, MD, MAPP; James R. Jett, MD; Ugo Pastorino, MD; Melvyn S. Tockman, MD, PhD; Stephen J. Swensen, MD, MMM; Colin B. Begg, PhD. The copyright notice "JAMA. 2007;297:953-961." is at the bottom.

According to Dartmouth researchers Drs. Gilbert Welch, Steve Woloshin, and Lisa Schwartz, there were two problems with the original study: lead-time bias and overdiagnosis.

**Lead-time bias** refers to the fact that if you diagnose a disease at an earlier stage, more people will still be alive five years or 10 years after diagnosis. That is how the NEJM researchers measured survival: The percentage of people with a disease who are still alive a fixed period of time after diagnosis. But that does not mean people are living longer; they might still die at the same age they would have without the lung cancer diagnosis.

**Overdiagnosis** refers to finding cases of a disease that would not have caused serious harm, let alone death. “Perhaps the easiest way to understand this is to imagine if we told all the people in the country that they had lung cancer today: lung cancer mortality would be unchanged, but lung cancer survival would skyrocket,” wrote Welch, Woloshin, and Schwartz. Obviously, this is an exaggeration, but you can see how if you increase the number of people diagnosed with extremely mild cases of a given condition, you will improve your survival statistics.

## DIGGING DEEPER



For more on this important lesson, see an essay in *The New York Times*:

How Two Studies on Cancer Screening Led to Two Results

By H. GILBERT WELCH, STEVEN WOLOSHIN and LISA M. SCHWARTZ

Published: March 13, 2007

<http://www.nytimes.com/2007/03/13/health/13lung.html>

# PART II

# THE WINDING ROAD TO PUBLICATION

## A GLIMPSE INSIDE THE SAUSAGE FACTORY

You may be new to the beat and feel like a tsunami is about to wipe you out – a huge and endless wave of journal articles, abstracts from scientific meetings and news releases from industry or academic medical centers or journals. We want to paint just a bit of the landscape that shows how all this stuff gets disseminated.

Researchers submit their study results to peer-reviewed journals as the time-honored way of sharing – and seeking validation of – their results. If you’re curious, you can visit any journal’s website and explore the sections that are called something like “Submission Guidelines For Authors.” That will tell you about the criteria submitting authors must provide. For example, here’s a link to the *New England Journal of Medicine* “help for authors” page:

<https://cdf.nejm.org/misc/authors>.

There is tremendous pressure on academic researchers to publish. Publication in prestigious journals is the coin of the realm, especially for younger or tenure-track medical school faculty members. Their career survival might depend as much on how many journal articles they get published or in which journals they publish – as on the content of what they publish. Researchers who publish – and certainly the journals themselves – are very conscious of a journal’s “impact factor,” a measure of impact or importance based on how often articles in a journal are cited by other authors. We tell you this only to give you an indication of some of the behind-the-scenes pressure to publish.

Next, consider the competitive pressure to generate publicity about what gets published. Think of all the players who want to send news releases based on any positive finding in a journal article. Among them might be:

- A drug company or medical device manufacturer whose product was studied
- An academic medical center serving as the faculty home of the author
- A nonprofit organization such as a heart, cancer or diabetes organization wanting to alert members of news in its area of interest

- A patient advocacy group wanting to alert members of news in its area of interest
- The journal itself

Researchers Joel Lexchin and Donald Light are among those who remind us of the journal's interest in promoting articles that appear in its pages. They wrote:

Most high-profile, peer-reviewed journals produce press releases for newsworthy articles to generate media attention. Greater media attention leads to more subscriptions, more advertising and the sale of article reprints, all of which result in greater revenue. Journals aggressively advertise reprint sales, as shown by an advertisement on the Web page of the *BMJ* [British Medical Journal]: "Reprints are invaluable for direct marketing, exhibitions/seminars and sales support campaigns and for mailing new product information to doctors (and for distribution) to conference delegates and visitors at exhibitions." Companies may spend up to \$1 million (£0.53m; €0.77m) on purchasing reprints, and the former editor of the *BMJ*, Richard Smith, thinks that this situation can create a conflict for journal editors: "Publish a trial that will bring US\$100,000 of profit or meet the end-of-year budget by firing an editor."<sup>5</sup>

## DIGGING DEEPER



You can learn a lot about health, medicine and science by reading what former journal editors have to say about their experiences. For example:

Former *New England Journal of Medicine* editors Jerome Kassirer, Marcia Angell and Arnold Relman write about the move by many journal editors in 2001 to toughen standards for authors submitting papers about new drugs – "a reaction," they write, "to the growing control over clinical trials by corporate sponsors."

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<sup>5</sup> Commercial influence and the content of medical journals. *BMJ*. 2006 June 17; 332(7555): 1444–1447.

Patents, Profits & American Medicine: Conflicts of Interest in the Testing & Marketing of New Drugs.

By Marcia Angell and Arnold Relman. Daedalus, 2002.

Available at: [www.jstor.org/pss/20027764](http://www.jstor.org/pss/20027764)

The truth about drug companies: How they deceive us and what to do about it.

By Marcia Angell. 2005. New York: Random House.

On the take: How medicine's complicity with big business can endanger your health.

By Jerome Kassirer. 2004. New York: Oxford University Press.

Former *British Medical Journal* editor Richard Smith

Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies.

PLoS Med 2(5): e138 doi:10.1371/journal.pmed.0020138.

Available at [www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0020138](http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0020138)

**Excerpt:**

"A large trial published in a major journal has the journal's stamp of approval, will be distributed around the world, and may well receive global media coverage, particularly if promoted simultaneously by press releases from both the journal and the expensive public-relations firm hired by the pharmaceutical company that sponsored the trial. For a drug company, a favourable trial is worth thousands of pages of advertising, which is why a company will sometimes spend upwards of a million dollars on reprints of the trial for worldwide distribution. ... but unfortunately for the credibility of the journals who publish them — these trials rarely produce results that are unfavourable to the companies' products."

Medical journals and pharmaceutical companies: uneasy bedfellows.

BMJ 2003;326:1202-1205 (31 May), doi:10.1136/bmj.326.7400.1202.

Available at <http://www.bmjjournals.org/cgi/content/extract/326/7400/1202>

continued on following page

Former editor Smith summarizes, succinctly: “In one sense, all journals are bought – or at least cleverly used – by the pharmaceutical industry.”

*Lancet* editor Richard Horton

Editor claims drug companies have a “parasitic” relationship with journals

*BMJ* 2005;330:9 (1 January), doi:10.1136/bmj.330.7481.9.

Available at: <http://www.bmjjournals.org/cgi/content/extract/330/7481/9>

The reporter summarizes Horton’s testimony to Parliament:

“The relationship between medical journals and the drug industry is somewhere between symbiotic and parasitic,” according to the editor of the *Lancet*, Richard Horton. ...

He outlined some of the financial incentives that could, potentially, influence a commercially run medical journal to publish a paper. Many of the formal research papers in the *Lancet* are reprinted and bought in bulk by drug companies, which use them for marketing purposes, he explained. The drug companies regularly try to exert pressure on the journal to run a paper by arguing that, if the journal does so, they will buy reprints, which will earn the journal more money, he said.”

## EMBARGOES

Many journals release material to journalists in advance of the actual publication date – and before doctors or scientists receive their subscription copies – under an embargo agreement whereby the journalists promise not to report on the material until a set date and time. The stated intent is to give journalists a chance to digest the information and do a better job reporting on it by having some advance notice and time to prepare their stories.

But not everyone sees it that way. Some critics see it as a way to create demand and enthusiasm for news that otherwise wouldn't get covered.

Author Vincent Kiernan voices his objections in his book, “Embargoed Science.” In an interview on NPR, Kiernan said, “There are lots of problems with embargoed science, but the biggest issue is that it misdirects journalists. It sets up a system by which journalists are given powerful incentives to cover a certain kind of story about science – the latest “eureka moment” – and those eureka moments come several times each week. And so the journalists are directed toward those stories and away from critical, skeptical coverage of science as an enterprise, with all its fraud, with all its successes, with all the ethical issues. The journalists are directed away from those stories – stories that many in the scientific establishment are perfectly happy to have them not do.”

Kiernan quotes veteran journalists:

“To survive, reporters become dependent on the daily cascade of embargoed research papers, e-mailed press releases, university tip sheets, and conference abstracts,” says Robert Lee Hotz, then a science reporter at the *Los Angeles Times*.

“The goal of all of us ought to be to try to get around embargoes and packaged science journalism by finding new ways to get our collective noses under the tent,” says Cristine Russell, former science and medical reporter for *The Washington Star* and *The Washington Post*. “I think that we should not have such herd journalism. People should get out and cover science.”

Ivan Oransky, lead contributor of this guide, provided some additional insight into the embargo process in a guest post on the “Covering Health” blog. He challenged “all the talk of embargoes serving the public by allowing reporters to write more-informed stories,” claiming “there are serious questions about whether journals are the group that gains most from embargoes.”

Read the full posting at [www.healthjournalism.org/blog/2010/01/oransky-medical-study-embargoes-serve-whom/](http://www.healthjournalism.org/blog/2010/01/oransky-medical-study-embargoes-serve-whom/). Oransky now has a blog devoted entirely to embargoes, Embargo Watch: <http://embargowatch.wordpress.com>.

Some advice:

- Don’t ever rely solely on a news release.
- Read the journal article itself, not just the abstract.
- Was there really a study? Or is the news release about an editorial? Is it a university news release about a media-savvy researcher’s work that hasn’t been published?

## HOT TIP



### Where to find full-text studies:

AHCJ membership provides you free access to:

- the ***Journal of the American Medical Association*** and its nine specialty journals.
- the **Cochrane Library**, a clinical research database
- **Annual Reviews**, which publishes reviews in the biomedical, physical and social sciences.
- **Health Affairs**, the respected health policy journal
- the ***American Journal of Public Health***.

Increasingly, journals, such as *PLoS Medicine*, are open-access journals which you can access for free without a subscription.

### Where to find abstracts:

PubMed, with more than 19 million citations for biomedical articles from MEDLINE and life science journals. (When you find what you want, ask for full text from the journals, authors or press officers.)

## AN UNHEALTHY STEADY DIET OF NEWS FROM JOURNALS

It's easy to see how embargoed studies can make it possible to file a health or medical research story every day of the week and never leave your desk. But those who haven't covered health and medical news need to realize the primary reason why journals exist: to give researchers a peer-reviewed forum for sharing their work. "Show us what you've done and we'll tell you what we think about it."

So, while journalists are obliged to keep up on scientific developments reported in the journals, they must realize that can't be done with a casual commitment. Here are some of the key things to remember about reporting on studies published in journals:

1. Today's journal article is part of a continuing stream of scientific knowledge. It is not the end of the story and is not ready to be etched into stone tablets. Appearance in a prestigious journal does not make the study bulletproof.
2. There is a well-documented publication bias that favors positive over negative findings. In other words, journals tend to report good news about developments in health, medicine and science more often than bad.
3. The various journals have different policies about disclosure of authors' conflicts of interest. The AHCJ Statement of Principles advises: "Health care journalists should be vigilant in selecting sources, asking about, weighing and disclosing relevant financial, advocacy, personal or other interests of those we interview as a routine part of story research and interviews." So journalists must understand that with differing journal disclosure policies, you can't assume there aren't conflicts just because they're not listed.<sup>6</sup>

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<sup>6</sup> See "Tobacco Company Liggett Gave \$3.6 Million To Henschke For CT Screening Research," The Cancer Letter. Available at: <http://www.cancerletter.com/henschketobacco.pdf>

## PUBLICATION BIAS

Do you ever wonder why everything looks so promising in medical journals? We don't see too many stories that say "The new cholesterol drug ClotzAway was shown to be no better than a placebo in a study published in a leading journal today."

One research team gained access to FDA reviews of 74 company-sponsored studies of 12 antidepressant drugs. FDA reviewers judged there were positive results on 38 studies and all but one was published. But the researchers reported: "Studies viewed by the FDA as having negative or questionable results were, with 3 exceptions, either not published (22 studies) or published in a way that, in our opinion, conveyed a positive outcome (11 studies). According to the published literature, it appeared that 94% of the trials conducted were positive. By contrast, the FDA analysis showed that 51% were positive."

They concluded: "Selective reporting of clinical trial results may have adverse consequences for researchers, study participants, health care professionals, and patients."

Journal editorial policies favor positive findings. But let's move further backstream: Without a clinical trial registry in place, the results of many trials that came up with only negative findings have never been tracked. It was too easy to just bury that data, as if it never existed. So the deck has clearly been stacked in favor of positive findings.

That landscape is changing somewhat. The International Committee of Medical Journal editors now requires "as a condition of consideration for publication in their journals, registration in a public trials registry." (For example, see the International Clinical Trials Registry Platform on the World Health Organization website – [www.who.int/ictrp/en](http://www.who.int/ictrp/en) – or [ClinicalTrials.Gov](http://ClinicalTrials.Gov).) That means that at the very least, reporters and others can find out how many studies of a given drug were started. If most of them began a while ago and have never been published, the single positive study a company is trumpeting with a press release may not reflect the whole story.

You, as a reporter covering research, must appreciate the history of publication bias and take it into consideration as you make editorial decisions.

Journalist Alison Bass, in her book "Side Effects: A Prosecutor, A Whistleblower, and a Bestselling Antidepressant on Trial," wrote about publication bias:

"...most medical journals were (and still are) not particularly interested in publishing negative findings. Although many journals derive a lucrative income from the drug ads they publish, their desire for clear-cut results that will attract readership and publicity probably plays a bigger role in their bias against negative findings."

Dr. Mark Helfand, a professor of medicine at Oregon Health and Science University, has studied this issue as head of the Evidence-Based Practice Center there. Journals

“want to publish results that get them the top headlines,” he told me. “They are not interested in publishing the subtle clues that might reflect a mixed message, a more balanced view.”

Many prominent physicians agree. Dr. Joseph M. Heyman, a trustee of the American Medical Association, was quoted in a press release as saying, “Studies with positive findings are more likely to be published than studies with negative or null results.”<sup>7</sup>

## DIGGING DEEPER



“Bias, spin & misreporting” was the headline of an editorial accompanying the journal article “Reporting Bias in Drug Trials Submitted to the Food and Drug Administration” by Lisa Bero’s team.

### **Excerpt:**

“Many trials (of newly approved drugs) were still not published 5 years after FDA approval. Discrepancies between the trial information reviewed by the FDA and information found in published trials tended to lead to more favorable presentations of the (new drug application) drugs in the publications. Thus, the information that is readily available in the scientific literature to health care professionals is incomplete and potentially biased.”

Rising K, Bacchetti P, Bero L (2008) Reporting Bias in Drug Trials Submitted to the Food and Drug Administration: Review of Publication and Presentation. *PLoS Med* 5(11): e217 Available at:  
[www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0050217](http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0050217) or  
<http://tinyurl.com/bcmxwv>

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<sup>7</sup> Turner EH, Matthews AM, Linardatos E, et al. Selective publication of antidepressant trials and its influence on apparent efficacy. *N Engl J Med* 358:252-260, 2008. Available at: <http://content.nejm.org/cgi/content/short/358/3/252>

Any health journalist who hasn't read some of Dr. John Ioannidis' writings about flaws in research should get to know his work soon. *The Boston Globe* called one of his articles "an instant cult classic." And *The Wall Street Journal Health Blog* called him the "Pink Floyd of science," because it said, "Like the moody rockers' album 'Dark Side of the Moon,' Ioannidis's paper has proved an unexpected and surprisingly durable hit, setting records for downloads." He has become a leading author questioning the strength of the claims made in many published studies.

For reporters, that begs the question: Would you rather take the time to figure out whether something is right, or just accept that, because it's in a journal, it's correct?

Here is an overview of his findings:

- Ioannidis JPA (2005) Why most published research findings are false. *PLoS Med* 2(8): e124. Available at: [www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0020124](http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0020124) or <http://tinyurl.com/mnzxs>

**Excerpt:** "Most research questions are addressed by many teams, and it is misleading to emphasize the statistically significant findings of any single team. What matters is the totality of the evidence."

- Ioannidis JPA (2005) Contradicted and initially stronger effects in highly cited clinical research. *JAMA* 294: 218–228. Available at: <http://jama.ama-assn.org/cgi/content/full/294/2/218>

**Excerpts:** "Contradicted and potentially exaggerated findings are not uncommon in the most visible and most influential original clinical research... Evidence from recent trials, no matter how impressive, should be interpreted with caution, when only one trial is available. It is important to know whether other similar or larger trials are still ongoing or being planned. Therefore, transparent and thorough trial registration is of paramount importance in order to limit premature claims for efficacy."

- Young NS, Ioannidis JPA, Al-Ubaydli O (2008) Why current publication practices may distort science. *PLoS Med* 5(10): e201. Available at: [www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0050201](http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0050201) or <http://tinyurl.com/3l383f>

**Excerpts:** "The small proportion of results chosen for publication are unrepresentative of scientists' repeated samplings of the real world. ... Uncertainty is powerful and yet quite insufficiently acknowledged when we pretend prescience to guess at the ultimate value of today's endeavors."

## PITFALLS OF NEWS FROM SCIENTIFIC MEETINGS

Reporters covering medicine and science issues on a regular basis are often drawn to major scientific meetings – gatherings where researchers share their latest work in the form of abstracts. Sometimes it's the guarantee of a headline, sometimes it's the expectation of their editors, sometimes it's purely a matter of keeping up with the competition, who is sure to be there. The news peg of a meeting is irresistible to reporters, says Reuters Health's Oransky in a guest post on [HealthNewsReview.org](#).

"Medical societies, medical schools, and drug companies all whip deadline-driven journalists into a frenzy, burying them with press releases, often embargoed, they will feel pressure to cover. Results announced at conferences can change practice or wreak havoc on a stock price.

But how good are those conference presentations, really? Will most of them stand the test of time – and, perhaps more importantly, peer review – so they can make it into prestigious journals?

That's what a group of urologists from the University of Florida and Indiana University wanted to find out. So they looked at 126 randomized controlled clinical trials – those are the "gold standard" of medical evidence – presented at two American Urological Association meetings in 2002 and 2003.

The quality of that evidence wasn't pretty. None of the abstracts said how trial subjects were randomly assigned to different treatments or placebos, and none said how the study ensured that neither the researchers nor their doctors knew which they got. (I was particularly struck by the part of the study's abstract in which the authors reported those two data points. It's typical for studies to present percentages next to raw numbers, to put data in context. You'd think it would be clear to readers that "0%" meant zero studies, but they felt the need to spell them both out. Maybe journal style, maybe trying to make a point.) Only about a quarter of the studies said how long researchers followed the subjects in a trial.

Those are important things to know about a trial. Their absence makes it nearly impossible to judge whether a study is well-designed, free of bias, and strong enough to change clinical practice."

In a 2002 journal article, Woloshin and Schwartz ask whether the news media is jumping the gun by covering studies unveiled at scientific meetings.<sup>8</sup>

Here are excerpts:

Abstracts at scientific meetings receive substantial attention in the high-profile media. A substantial number of the studies remain unpublished, precluding evaluation in the scientific community.

Two examples from our study illustrate problems that might have been avoided had releases undergone a higher level of scrutiny. First, the headline of the press release for an abstract presented at the 1998 American Society of Clinical Oncology meeting (and reported on page 1 on the New York Times) read, “Canadian study is first to show screening reduces prostate cancer death”; however, the study is now widely criticized for serious methodological flaws apparent at the time of presentation and the data are not considered evidence that screening is beneficial. Second, a press release reporting the early results of a raloxifene trial stated in the headline that “[raloxifene] may reduce risk of endometrial cancer in postmenopausal women”; by the time the final report was published, no such risk reduction was evident.

In addition, news organizations might also consider raising their threshold for reporting on scientific meeting abstracts at all. If they do choose to report on such presentations, they might make a concerted effort to emphasize the preliminary nature of data presented, and apply the same level of skepticism in covering these stories that they do in reporting on political matters.

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<sup>8</sup> Media coverage of scientific meetings: too much too soon? JAMA. 2002; 287:2859-2863. Available at: <http://jama.ama-assn.org/cgi/content/full/287/21/2859>

# SPINNING STUDY RESULTS

Efforts by the Dartmouth Medical School/Veterans Administration research team of Schwartz, Woloshin and Welch to improve public understanding of research issues include a chart on how studies can be designed to stack the deck in favor of a company's product.

Phase of Research or Dissemination	Tactics to Generate Exaggerated Results
<b>Study Design</b>	<p>Conducting studies that stack the deck in favor of the product</p> <ul style="list-style-type: none"> <li>• by comparing it to a placebo rather than to another drug that treats the same problem, because it is much easier to look better than nothing (the placebo) than to look better than a proven drug</li> <li>• by comparing it to the “weakest” drug that treats the same problem (for example, choosing the least effective drug for comparison, or using the other drug at a low dose)</li> <li>• by measuring less important surrogate outcomes, where it is easier and faster to show a difference.<sup>9</sup></li> </ul>
<b>Publication of scientific results</b>	<p>Selectively publishing only the studies with the most favorable results (rather than all the studies)</p> <p>Selectively reporting only favorable outcomes in medical journal articles or in prescription drug labels (or purposely omitting worrisome outcomes)</p>

<sup>9</sup> Surrogate outcomes, or surrogate markers or endpoints, refer to measurements of intermediate events but not necessarily something that will tell you how a patient feels, functions or survives. For example, reporting cholesterol scores instead of telling you how many people had heart attacks or died.

<b>Phase of Research or Dissemination</b>	<b>Tactics to Generate Exaggerated Results</b>
<p><b>“Spinning” results to the public</b></p>	<p>Using unrepresentative patient anecdotes, citing a “miracle cure” rather than the typical effect among patients</p> <p>Making strong statements about how impressive the results are (but failing to provide any numbers)</p> <p>Using the biggest numbers possible to describe how many people have the problem or how big the benefit is (typically by providing only the relative<sup>10</sup> change in outcomes)</p> <p>Exaggerating what is good and minimizing what is bad about the product</p>
<p><b>Public campaigns to promote use of the intervention</b></p>	<p>Scaring people into adopting the intervention, by highlighting the great danger of the problem or the great danger of failing to take action</p> <p>Shaming people into adopting the intervention, by equating its use with being a socially responsible person<sup>11</sup></p>

The Dartmouth/VA team offers several other concise primers on such topics as probabilities, odds, absolute versus relative differences, confidence intervals, statistical significance and P values, and evaluating study designs. You can find a compendium of the primers at [www.vaoutcomes.org/downloads/Compendium\\_of\\_Primers.pdf](http://www.vaoutcomes.org/downloads/Compendium_of_Primers.pdf).

<sup>10</sup> Relative change is one number relative to another – such as 20 percent fewer. But you want to know 20 percent of what? That’s the absolute change. A 50 percent off sale for a Lexus is a lot more significant than a 50 percent off sale for a book. The 50 percent is relative. Taking \$5 off of a \$10 book is absolute.

<sup>11</sup> These are elements of what we call disease-mongering – which also includes exaggerating the natural history of a condition, or “medicalizing” a normal state of health or a normal variation of normal health (such as baldness, wrinkles, dandruff).

# CRITERIA FOR JUDGING YOUR STORY

For several years, the [HealthNewsReview.org](#) project – directed by this guide’s author – has evaluated and graded health news coverage of claims about treatments, tests, products and procedures.

Each story is evaluated by three reviewers, drawing from a team of several dozen people with a mix of backgrounds in journalism, medicine, public health and health services research. Reviewers apply 10 standard criteria. These criteria provide some handy guidelines on how you should cover studies.

## **Criterion No. 1: The availability of the treatment/test/product/procedure**

This criterion may apply most often in regard to news coverage about drugs in clinical trials. Journalists writing about an investigational drug (or an investigation into new uses for an existing drug) should provide their readers with information about what phase of research the drug is in.

Reporters:

- Should be clear that the drug is not currently available.
- Should not treat FDA approval of an investigational drug as a *fait accompli*.
- Should not make predictions about how the drug “could be” or “should be” approved and on the market within a given time frame.
- Should not make predictions about a time frame for future availability using only a company spokesman as a source.
- Should give a sense of how widespread is the adoption of the approach.
- Should address issues like the availability of trained personnel to deliver the approach.

## **Criterion No. 2: Whether/how costs are mentioned in the story**

Journalists should provide appropriate coverage of the likely cost to the individual or community of new treatments, tests, products or procedures. The proposed selling price is likely to be known at the time of launching of a new drug, although new procedures may be more difficult to cost. Journalists should be able to get an estimate from their sources.

Reporters:

- Should discuss the costs of an approach.
- Should not downplay cost as an issue without satisfactorily explaining why.
- Should compare the costs of a new approach with the costs of existing alternatives.
- Should address whether a new approach is likely to be covered by insurance.

If it’s not too early to talk about how well something might work, then it’s not too early to start discussing what it may cost.

**Criterion No. 3: If there is evidence of disease mongering in the story**

This item tries to analyze news stories that exaggerate or oversell a condition. There are different forms of “mongering” – turning risk factors into diseases (e.g., low bone-mineral density becomes osteoporosis); misrepresentation of the natural history and/or severity of a disease (e.g., early-stage, low-grade prostate cancer); medicalization of minor or transient variations in function (e.g. temporary erectile dysfunction or female “sexual dysfunction”); medicalization of normal states (baldness, wrinkles, shyness, menopause); or exaggeration of the prevalence of a disorder (e.g., using rating scales to “diagnose” erectile dysfunction).

Reporters:

- Should not present spurious statistics.
- Should not exaggerate the human consequences.
- Should not create undue fear.
- Should not treat surrogate markers endpoints as if they were disease.
- Should not include interviews with “worst-case” patients – holding such patients up as examples as if their experiences were representative of all with this condition.

**Criterion No. 4: Does the story seem to grasp the quality of the evidence?**

We are dealing with stories about new treatments, tests, products or procedures; the relevant standard is that the journalist is expected to present information about the quality of the clinical evidence on which claims are based. In the case of a major claim about the efficacy of a new treatment this should be based on the results of a randomized trial with relevant clinical endpoints. Sometimes, the first story about a new treatment is in the form of promising results from a case series. There is nothing intrinsically wrong with writing about this, but the story should make clear the limitations of the evidence, and contain a caution about interpretation of uncontrolled data. For example, a story about a non-randomized cohort or observational study should explain that researchers were not able to adjust for all factors that might account for an observed difference. The hierarchy of evidence is an important factor for journalists to consider, and to explain to readers and viewers, and we should look for it in these stories.

Reporters:

- Should point out the limitations of the evidence.
- Should include a caution about interpretation of uncontrolled data.
- Should make clear the limitations of a small study.
- Should point out if a primary outcome is a surrogate marker and caution readers/ viewers about extrapolating this to health outcomes.
- Should point out the limited peer review that may have taken place with findings presented at a scientific meeting.
- Should not present findings from an animal or lab experiment without cautioning

readers/viewers about the limited applicability to human health.

- Should not present anecdotes as evidence of a treatment's harms or benefits – rather as a single illustration of its use.

### **Criterion No. 5: How harms of the treatment/test/product/procedure are covered in the story**

The expectation is that the journalist will always mention potential adverse effects of any new treatment, test, product or procedure that is being covered in a story. Ideally the story should mention both the frequency and severity of adverse effects of treatments. Some so-called “minor” side effects may have dramatic impact on individuals’ lives. Balanced coverage should take even “minor” side effects into consideration.

Reporters:

- Should mention potential harms.
- Should quantify potential harms.
- Should describe the severity of potential harms.
- Should account for “minor” side effects that could have a significant impact on a patient’s life.
- Should not rely too heavily on a patient anecdote about safety.
- Should not rely too heavily on an investigator’s comment that an approach appears to be safe – without supporting data.

### **Criterion No. 6: Does the story establish the true novelty of the approach?**

Many “new” treatments, tests, products or procedures are not really novel. The agent may be another member of a well-established therapeutic class of drug; even if it represents a new class, it may offer no more than the drugs that are widely available. In the press release for a new drug this essential information may be lost in the hype and the drug is portrayed as “novel” in order to increase initial sales. Journalists should be able to make these distinctions by doing their research or by putting appropriate questions to independent sources; they should put an informative statement in their story about the novelty of a new product.

Reporters:

- Should avoid making inaccurate, misleading or incomplete statements about the novelty of a treatment, test, product or procedure.
- Should establish what’s new about the new approach compared with existing alternatives.
- Should not describe what is clearly an off-label use of an approved drug without making clear that this is the case.

### **Criterion No. 7: How the benefits of the treatment/test/product/procedure are framed**

The expectation is that the journalist will report a quantitative estimate of the benefits of a new treatment, test, product or procedure; generally this information is reported in the trials that are the basis of the therapeutic claims in the news story. However, it is important that the information is communicated accurately and in a way that helps readers understand the true value of the treatment. [[“Explaining risk” on page 31](#)]

Reporters:

- Should quantify benefits.
- Should not use only relative risk or benefit data.
- Should not rely too heavily on what may be unrepresentative patient anecdotes about benefits.
- Should cite statistics appropriately, but not allow even a single unchallenged exaggerated quote to throw the story out of balance.

### **Criterion No. 8: Whether the story appeared to rely solely or largely on a news release**

It is simply not sound journalistic practice to lift material directly from a news release without stating that this is the case.

Reporters:

- Should not repeat the exact same wording from a news release.
- Should include several independent sources.

### **Criterion No. 9: Is there an independent source and were any possible conflicts of interests of sources disclosed in the article?**

There must be an independent expert source quoted (someone not directly connected with the research) and there must be some attempt to let the public know about potential conflicts of interest.

Reporters:

- Should identify the source of the story (news release, journal article, editorial, scientific meeting presentation, etc.) and make obvious the extent to which that source is likely to be conflicted (e.g., “a PR consultant working for the company said,” or “Dr. Smith, who received a company grant to perform the study said.”)
- Should include the input of a trusted independent source with expertise on the subject to comment on the claims made. Ideally, more than one.

**Criterion No. 10: Whether alternative treatment/test/product/procedure options are mentioned**

The story should put the idea being discussed into the context of existing alternatives, mentioning availability of alternative treatments or tests or procedures with some assessment of their relative performance. If the treatment is genuinely novel, then the article should mention that there is no alternative treatment, or that only general supportive/symptomatic care has been provided up until now.

Reporters:

- Should not discuss a surgical approach without mentioning non-surgical alternatives.
- Should not discuss a new test without mentioning other tests that are available.
- Should discuss the advantages and disadvantages of the new idea compared with existing approaches.
- Should discuss how the new treatment, test, product or procedure fits into the realm of existing alternatives.



After four years and more than 1,000 stories reviewed, the three categories in which journalists performed most poorly were in discussing costs, and in quantifying benefits and harms.<sup>12</sup> Because we all learn from positive examples, you may wish to search for all the top-rated five-star stories at: <http://www.healthnewsreview.org/search.html>

The site also hosts a list of independent experts – highly regarded physicians and researchers who have stated that they do not have financial ties to industry and who are available to help journalists with their stories. The list is available at:

[www.healthnewsreview.org/list-of-independent-experts.php](http://www.healthnewsreview.org/list-of-independent-experts.php).

<sup>12</sup> The two-year, 500-story results were published in PLoS Medicine at <http://tinyurl.com/5bvg5w>

# CONCLUSION

The journalist who lives by a steady diet of stories about studies may find his/her reputation severely tarnished by that practice. Such stories may not give an accurate or helpful reflection of health care in this country. Nonetheless, they can't be ignored because they offer a chance to eavesdrop on the conversations among scientists. The principles espoused in this guide should make any individual or collective news production effort smarter as they attempt to explain medical research progress to consumers of news and of health care.

1. Not all studies are the same. You and your audience should appreciate the limitations inherent in any study design.
2. If you rely on medical journals as a main source of your news, you are getting and giving an imbalanced view of new treatments, tests, products and procedures.
3. Both industry interests and journal policies tend to promote positive findings.
4. If you rely on presentations at scientific meetings as a main source of your news, you may be promoting claims that have not been validated by any independent expert sources.
5. There are a growing number of resources that can help you evaluate claims and evaluate the underlying science in journal articles, presentations at scientific meetings, news releases and interviews with experts.

# PART III RESOURCES

## COVERING MEDICAL STUDIES & EVALUATING RESEARCH CLAIMS

**Coverage by the News Media of the Benefits and Risks of Medications.** Ray Moynihan et al. *NEJM*. 2000 June 1; 342:1645-1650.

<http://content.nejm.org/cgi/content/abstract/342/22/1645>

A team of researchers conducted a content analysis of 80 newspaper articles and 27 TV reports that covered drugs used to treat high cholesterol, osteoporosis and cardiovascular disease. The study found that the vast majority of the stories were misreported and included inadequate or incomplete data regarding the costs, risks and benefits of medications and the financial relationships between study participants and drug manufacturers.

**How Do US Journalists Cover Treatments, Tests, Products, and Procedures? An Evaluation of 500 Stories.** Schwitzer G. *PLoS Med*. 2008 May 27; 5(5): e95. doi:10.1371/journal.pmed.0050095

<http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0050095>

This peer-reviewed article on the experience of HealthNewsReview.org shows that after almost two years and 500 stories, the project found that journalists usually fail to discuss costs, the quality of the evidence, the existence of alternative options, and the absolute magnitude of potential benefits and harms.

**False Hopes, Unwarranted Fears: The Trouble with Medical News Stories.** The *PLoS Medicine* editors. *PLoS Medicine*. 2008 May. 5(5): e118. doi:10.1371/journal.pmed.0050118.

<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0050118>

**Excerpt:** “Schwitzer’s alarming report card of the trouble with medical news stories is thus a wake-up call for all of us involved in disseminating health research – researchers, academic institutions, journal editors, reporters, and media organizations – to work collaboratively to improve the standards of health reporting.”

**How the media left the evidence out in the cold. Gary Schwitzer. *British Medical Journal*. 2003 June 21; 326(7403): 1403–1404.**

<http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1126289>

Schwitzer examines journalistic coverage of “wonder drug” pleconaril, for which its manufacturer sought FDA approval in 2002 for reducing the duration of the common cold. Despite positive press and journalists’ predictions of its success, the FDA advisory committee unanimously rejected the drug’s application due to adverse effects measured during clinical trials. Schwitzer warns against an over-zealous press that helps market a medication before the full picture of its benefits and harms is understood.

**American College of Physicians’ primers**

[http://www.acponline.org/clinical\\_information/journals\\_publications/ecp/primers.htm](http://www.acponline.org/clinical_information/journals_publications/ecp/primers.htm)

The American College of Physician provides this collection of medical primers to encourage better practice on the parts of its members: internist physicians who specialize in the treatment and prevention of adult illnesses. But journalists also benefit from these primers’ clear and concise guidance on interpreting medical studies.

Included:

- Lead-Time, Length, and Overdiagnosis Biases
- 95% CIs for the Number Needed To Treat
- Before-After Studies: Evaluating a Report of a “Successful” Intervention
- Absolute vs. Relative Differences
- Probability and Odds and Interpreting their Ratios
- Statistical Significance and P Values

**Searching for Clarity: A Primer on Medical Studies. Gina Kolata. *The New York Times*. Sept. 30, 2008.**

<http://www.nytimes.com/2008/09/30/health/30stud.html>

Practical tips to help you sift through the statistics to determine what is (and is not) reliable research.

**Therapeutics Initiative (TI) and Therapeutics Letter**

<http://ti.ubc.ca>

This University of British Columbia panel has a mission to provide medical professionals with up-to-date, evidence-based, practical information on prescription drug therapy. But the site proves equally serviceable for journalists: The Therapeutics Letter provides quality reviews of recent pharmacological studies – a real bonus when reporting on drug effectiveness.

**Press releases: translating research into news. Woloshin & Schwartz. *JAMA*. 2002;287(21):2856-2858**

<http://jama.ama-assn.org/cgi/content/full/287/21/2856>

**Excerpt:** Press releases do not routinely highlight study limitations or the role of industry funding. Data are often presented using formats that may exaggerate the perceived importance of findings.

**Where the Naproxen Story Went Wrong: When NIH Halted a Major Study, Citing Risks From a Common Painkiller, the Media Played the News Big. That Was Just Part of the Problem. Woloshin, Schwartz & Welch. *The Washington Post*, Feb. 1, 2005.**

<http://www.washingtonpost.com/ac2/wp-dyn/A52625-2005Jan31>

**Excerpt:** Medical research often becomes news. But sometimes the news is made to appear more definitive and dramatic than the research warrants. This article dissects a recent health news story to highlight some common study interpretation problems we see as physician researchers and show how the research community, medical journals and the media can do better.

**The Media Matter: A Call For Straightforward Medical Reporting. Woloshin & Schwartz. *Annals of Internal Medicine*. Feb. 3, 2004. Volume 140. Number 3. 226-8.**

<http://www.annals.org/cgi/reprint/140/3/226.pdf>

**Excerpts:** “In general, don’t report preliminary findings. ... Communicate the absolute magnitude of differences. ... Include caveats.

**Ben Goldacre’s Bad Science column from *The Guardian***

<http://www.guardian.co.uk/science/series/badscience>

In his *Guardian* blog, physician-author Ben Goldacre plays the role of research cop: He scours the net for unsubstantiated claims and bogus science. But journalist readers beware. “If you’re a journalist who misrepresents science for the sake of a headline... your days are numbered,” the site warns.

**Alicia White. How to read articles about health and health care. NHS Choices website. January 6, 2009.**

[www.nhs.uk/news/pages/howtoreadarticlesabouthealthandhealthcare.aspx](http://www.nhs.uk/news/pages/howtoreadarticlesabouthealthandhealthcare.aspx)

Dr. Alicia White of the British “Behind The Headlines” website highlights eight questions that every reporter should ask before reporting on any “too-good-to-be-true” research claim.

**Journalist Ray Moynihan’s Tipsheet: For Reporting on Drugs, Devices and Medical Technologies. On the Commonwealth Fund website at:**

[www.commonwealthfund.org/Content/Publications/Other/2004/Sep/Tipsheet--For-Reporting-on-Drugs--Devices-and-Medical-Technologies.aspx](http://www.commonwealthfund.org/Content/Publications/Other/2004/Sep/Tipsheet--For-Reporting-on-Drugs--Devices-and-Medical-Technologies.aspx)

This tipsheet (available for free download as a PDF) provides a simple list of questions to consider before reporting health care interventions.

**Medical Journalism: Exposing Fact, Fiction, Fraud (Paperback)**

by Ragnar Levi. Publisher: Wiley-Blackwell; (November 1, 2001) ISBN: 978-0813803036

**News and Numbers: A Guide to Reporting Statistical Claims and Controversies in Health and Other Fields (Paperback)** by Victor Cohn & Lewis Cope. Publisher: Wiley-Blackwell; 2 edition (April 18, 2001) ISBN: 978-0813814247

## RESOURCES FOR REPORTING ON RESEARCH ETHICS

**Dr. Peter Mansfield’s Healthy Skepticism website**

[www.healthyskepticism.org](http://www.healthyskepticism.org)

The Healthy Skepticism team, which consists of 211 contributors from 25 countries, aims to improve health by reducing harm from inappropriate, misleading or unethical marketing of health products or services, especially misleading pharmaceutical promotion. To access premium content, you must register with the site and provide limited personal information.

**Guest Authorship and Ghostwriting in Publications Related to Rofecoxib.**

**JAMA. 2008; 299(15):1800-1812.**

<http://jama.ama-assn.org/cgi/content/abstract/299/15/1800>

To document the prevalence of ghostwriting in biomedical publications, the researchers reviewed approximately 250 documents published about the Rofecoxib trials between 1996 and 2004. The study concluded that ghostwriting was indeed common in biomedical literature and is diminishing the dependability of published articles.

**The Corporate Coauthor. Adriane Fugh-Berman. J GEN INTERN MED 2005; 20:546-548.**

[www.ncbi.nlm.nih.gov/articlerender.fcgi?artid=1490131](http://www.ncbi.nlm.nih.gov/articlerender.fcgi?artid=1490131)

This Journal of General Internal Medicine article highlights the ethical pitfalls associated with ghostwritten medical articles.

Dr. Fugh-Berman's [PharmedOut.org](http://PharmedOut.org) website is funded through the Attorney General Consumer and Prescriber Education grant program, created as part of a 2004 settlement between Warner-Lambert, a division of Pfizer, Inc., and the attorneys general of 50 states and the District of Columbia, to settle allegations that Warner-Lambert conducted an unlawful marketing campaign for the drug Neurontin ( gabapentin) that violated state consumer protection laws.

**The World Association of Medical Editors. Ghost Writing Initiated by Commercial Companies. J GEN INTERN MED 2005; 20:549.**

[www.wame.org/resources/policies#ghost](http://www.wame.org/resources/policies#ghost)

The World Association of Medical Editors issues its policy statement on the practice of ghostwriting.

**Wyeth's Use of Medical Ghostwriters Questioned. By Duff Wilson, The New York Times. December 12, 2008.**

[www.nytimes.com/2008/12/13/business/13wyeth.html](http://www.nytimes.com/2008/12/13/business/13wyeth.html)

This *New York Times* piece reports on Congressional investigations into the practice of ghostwriting.

**Profits and plagiarism: The case of medical ghostwriting.** Tobenna D. Anekwe. *Bioethics*. Volume 24, Issue 6, Pages 267-272. Published Online: 16 Feb 2009.

[www3.interscience.wiley.com/cgi-bin/fulltext/122204938/HTMLSTART](http://www3.interscience.wiley.com/cgi-bin/fulltext/122204938/HTMLSTART)

**Publication ethics and the ghost management of medical publication.** Sergio Sismondo and Mathieu Doucet. *Bioethics*. Volume 24, Issue 6, Pages 273-283. Published Online: 16 Feb 2009

<http://www3.interscience.wiley.com/cgi-bin/fulltext/122204937/HTMLSTART>

**Commentary: What's wrong with ghostwriting?** Carl Elliott and Amy Snow Landa. *Bioethics*. Volume 24, Issue 6, Pages 284-286. Published Online: 17 May 2010

<http://www3.interscience.wiley.com/cgi-bin/fulltext/123442700/HTMLSTART>

## HEALTH JOURNALISM REVIEWS

### HealthNewsReview.org

Independent expert reviews of medical stories.

[www.healthnewsreview.org](http://www.healthnewsreview.org)

The author of this guide, Gary Schwitzer, publishes this website with funding from the Foundation for Informed Medical Decision Making. The site is designed to help health journalists improve their scrutiny of claims about health care interventions, and to improve the quality of information that consumers receive.

### Media Doctor Canada

[www.mediadoctor.ca](http://www.mediadoctor.ca)

Much like HealthNewsReview.org, Media Doctor Canada applies 10 standardized criteria to the review of health news stories circulating in the Canadian market. The aim is to improve Canadian media coverage of drugs and treatments.

### Media Doctor Australia

[www.mediadoctor.org.au](http://www.mediadoctor.org.au)

The granddaddy of this genre, Media Doctor Australia became the model for both Media Doctor Canada and HealthNewsReview.org.

## Behind the Headlines: Your guide to the science that makes the news

A website of the UK National Health Service.

[www.nhs.uk/News/Pages/NewsIndex.aspx](http://www.nhs.uk/News/Pages/NewsIndex.aspx)

Britain's National Health Service provides this handy resource – which aggregates health articles, analyses them, and provides significant background on the studies they report on.

## REPORTING ON PREVENTIVE MEDICINE

### U.S. Preventive Services Task Force (USPSTF)

[www.ahrq.gov/clinic/uspstfix.htm](http://www.ahrq.gov/clinic/uspstfix.htm)

An independent panel of experts in primary care and prevention publishes its systematic review of evidence of preventive medicine's effectiveness and develops recommendations for clinical preventive services. It's a great source to turn to especially for evidence-based recommendations on screening tests.

## RESEARCH DATABASES

### PubMed.gov

Produced by the National Library of Medicine and the National Institutes of Health.

[www.ncbi.nlm.nih.gov/pubmed](http://www.ncbi.nlm.nih.gov/pubmed)

PubMed's search engine returns abstracts from studies published in MEDLINE, life sciences journals and online books.

### ClinicalTrials.gov

Produced by the National Institutes of Health.

<http://clinicaltrials.gov>

A registry of federally and privately supported clinical trials conducted in the United States and around the world. In an effort to promote transparency of the clinical trials process, the International Committee of Medical Journal Editors (ICMJE) now requires researchers to enter their clinical trials in a public registry such as this before enrolling patients – if they want to have their findings published by member journals. This is one way to overcome the past problems with negative findings being squelched or suppressed.

## The Cochrane Collaboration and Cochrane Library

[www.cochrane.org](http://www.cochrane.org)

More than 28,000 contributors produce up-to-date systematic reviews of research in the health and medical sciences. The reviews, which assess studies' validity and accuracy, are published and archived on the Cochrane Library, where upwards of 4,000 complete reviews are available for access.

AHCJ members are given free access to the reviews as a member benefit. Learn about it at [www.healthjournalism.org/membership-benefits.php](http://www.healthjournalism.org/membership-benefits.php).

## ABOUT THE AUTHORS

**Gary Schwitzer** has specialized in health care journalism in his more than 30-year career in radio, television, interactive multimedia and the Internet.

He is publisher of the website [HealthNewsReview.org](#), leading a team of more than two dozen people who grade daily health news reporting by major U.S. news organizations.

From 2001 to 2010, he was a tenured journalism professor at the University of Minnesota. He left that position to devote his time to his online publishing work.

Previously, he was founding editor-in-chief of the [MayoClinic.com](#) consumer health website, and produced groundbreaking decision-making videos for the Foundation for Informed Medical Decision Making, based at Dartmouth College in Hanover, N.H.

Earlier, he worked for four years at the national office of the American Heart Association in Dallas, was a television medical news reporter for 14 years, with positions at CNN in Atlanta, WFAA-Dallas, and WTMJ-Milwaukee, and was head of the medical news unit at CNN. Schwitzer has written about the state of health journalism in *JAMA*, *BMJ*, the *American Journal of Bioethics*, the *Journal of Medical Internet Research*, *PLoS Medicine*, *Nieman Reports*, *Quill*, *Columbia Journalism Review*, *Poynter.org*, *The Daily Beast*, *The American Editor*, and *MayoClinic.com*. In 2009, the Kaiser Family Foundation published and distributed his white paper on “The State of U.S. Health Journalism.”

He served two terms as a member of the AHCJ board of directors, and wrote the organization’s Statement of Principles.

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**Ivan Oransky** is executive editor of Reuters Health and currently serves as treasurer on the AHCJ board of directors.

Before joining Reuters in 2009, Oransky was the managing editor for online at *Scientific American*. He previously was the deputy editor of *The Scientist*.

He has served as editor in chief of *Pulse*, the medical student section of the *Journal of American Medical Association* (JAMA) and of *Praxis Post*, an online magazine of medicine and culture. Co-author of *The Insider’s Guide to Medical Schools*, (Peterson’s, 1999), he has written for publications including *The (Baltimore) Sun*, *The Boston Globe*, *the Forward*, *The Lancet*, *The New Republic*, *The New York Sun*, *Salon*, *Slate*, *USA Today* and *U.S. News & World Report*.

He received his bachelor’s degree from Harvard University, where he was executive editor of *The Harvard Crimson*, his medical degree from New York University, and completed an internship at Yale before leaving medicine to be a full-time journalist.

He also holds appointments as an adjunct professor of journalism and clinical assistant professor of medicine at New York University. He lives in New York City with his wife (and fellow AHCJ member) Cate Vojdik, whom he met at an AHCJ conference.

# **COVERING** MEDICAL **RESEARCH**

A Guide for Reporting on Studies



Association of Health Care Journalists  
Center for Excellence in Health Care Journalism  
[www.healthjournalism.org](http://www.healthjournalism.org)