

Critical Appraisal Training to Expand Health Literacy

American Public Health Association 2010

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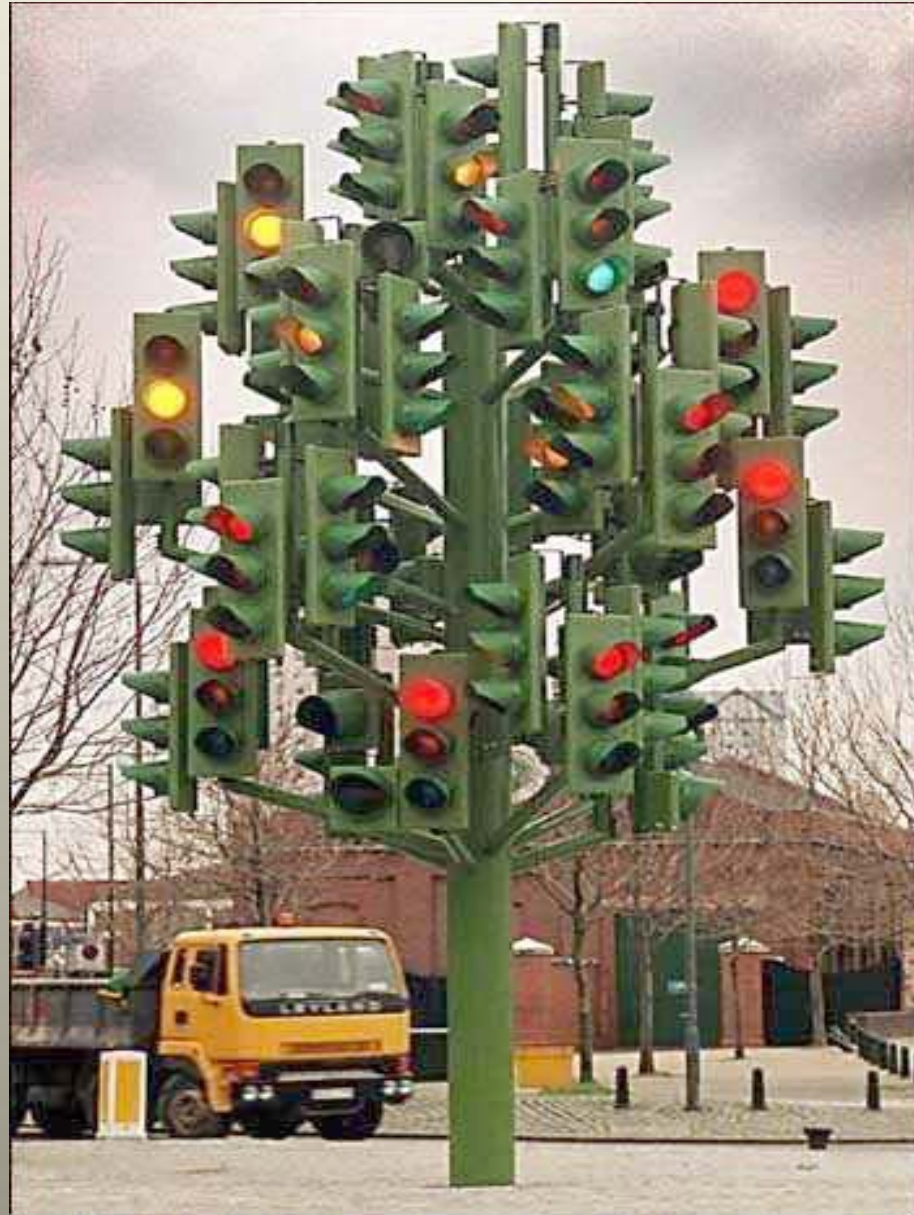
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Presenter Disclosures

Donna H. Odierna

The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months:

No relationships to disclose



Smokers' Advocate

JUNE 1991

A SERVICE OF PHILIP MORRIS U.S.A.

VOLUME 2 ISSUE 6

New Studies Find No Risk From "Passive Smoke"

A recent decision by an advisory board of the Environmental Protection Agency (EPA) to label environmental tobacco smoke (ETS) as a "known carcinogen" flies in the face of three new scientific studies — including the largest study ever conducted on ETS — which found no increased risk for lung cancer among non-smokers married to smokers.

Harbin, two Chinese industrial cities. Reporting on their findings in the British Journal of Cancer, Dr. Blot and his fellow authors wrote: "We observed no overall association between lung cancer risk and passive smoking."

At a preliminary SAB assessment of the EPA draft report last December, Dr. Blot chose not to



New Doubts About Celebrex

Yesterday Pfizer announced the results of a government-sponsored clinical trial, which showed that its own best-selling arthritis drug, Celebrex, more than doubled or tripled the risk of heart attacks, strokes and cardiovascular deaths, depending on the dosage.



Heart Attack Risk Seen in Drug for Diabetes

The Food and Drug Administration is trying to estimate the number of heart attacks that may be linked to GlaxoSmithKline's Avandia.



Health Literacy

The degree to which individuals have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions

– Healthy People 2010, HHS, HRSA

Groups with high rates of chronic disease and the most need for healthcare also experience low health literacy

- Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, American Medical Association

How can we enhance health literacy?

Through increasing critical appraisal skills:

- Identify useful health information
- Evaluate information for validity and applicability
- Analyze presentation of results

- Critical Appraisal Skills Programme, Oxford University

Objectives

- To increase the ability of **healthcare consumers** and **consumer advocates** to more effectively evaluate and use health evidence
- To optimize **clinicians'** ability to use research in decision making and communication
- To promote balanced and accurate reporting of research studies by **journalists**

Intervention

Critical appraisal workshops for:

- Healthcare consumers and consumer advocates (4 conducted in 2010)
- Clinicians (3 conducted in 2010)
- Journalists (1 conducted not analyzed)
- Additional workshops pending

Planning and Tailoring the Workshops

Community Engagement Strategy:



- Key informant interviews
- Workshop planning meetings with participant groups

Sample Consumer Workshop



- Introduction to evidence-based healthcare
- Critical appraisal of research

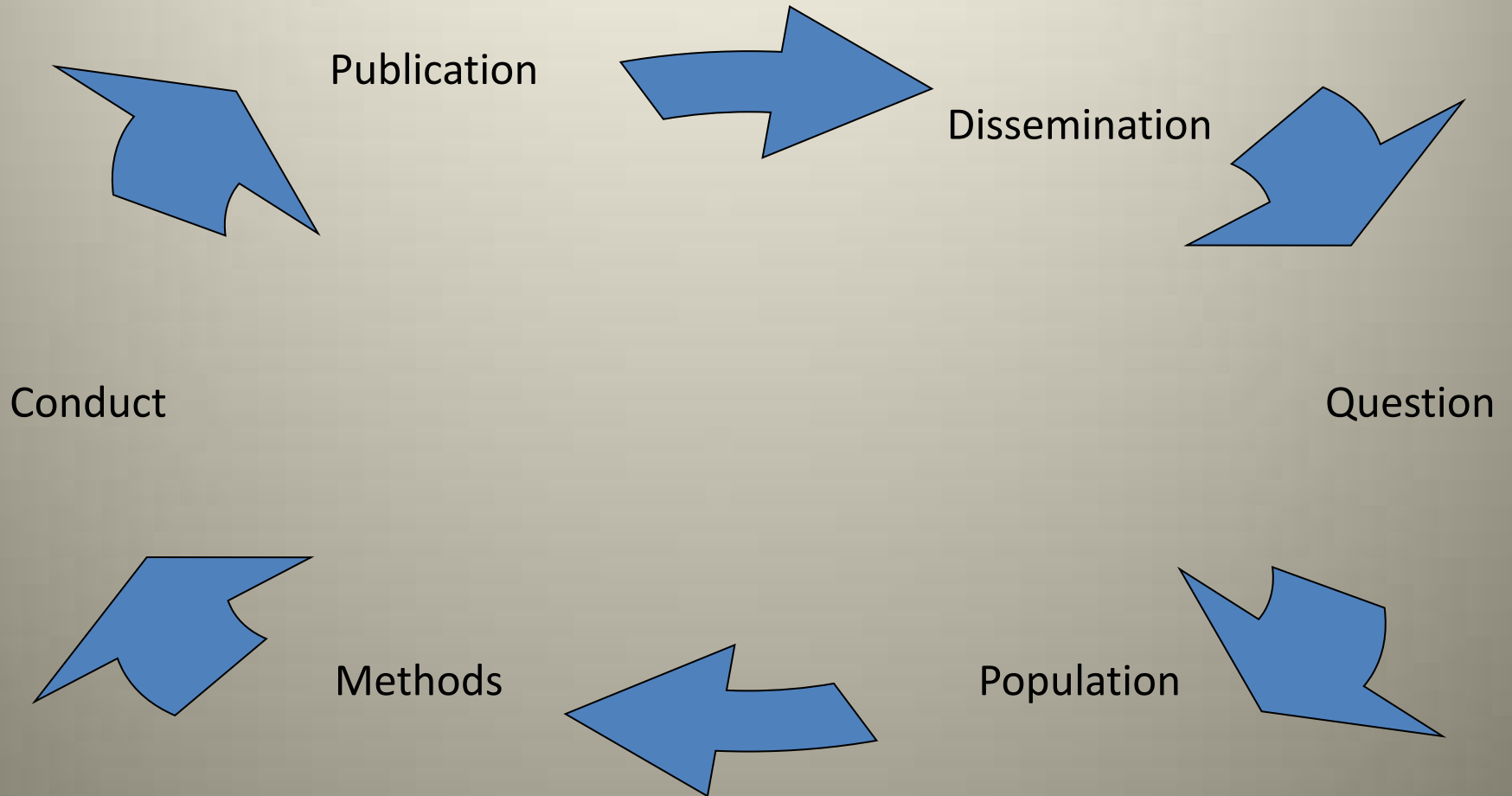
Study designs: Randomized clinical trials, cohort studies, systematic reviews



Methods, **presentations of results**
(absolute/relative risk)

- Hands-on **small group sessions** (1-2)
 - Problem-based learning
- Financial conflicts of interest, **bias in research**
- Recap, discussion, evaluation

Cycle of Bias in Research



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

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Rosuvastatin to Prevent Vascular Events in Men and Women with Elevated C-Reactive Protein

Paul M Ridker, M.D., Eleanor Danielson, M.I.A., Francisco A.H. Fonseca, M.D., Jacques Genest, M.D., Antonio M. Gotto, Jr., M.D., John J.P. Kastelein, M.D., Wolfgang Koenig, M.D., Peter Libby, M.D., Alberto J. Lorenzatti, M.D., Jean G. MacFadyen, B.A., Børge G. Nordestgaard, M.D., James Shepherd, M.D., James T. Willerson, M.D., and Robert J. Glynn, Sc.D., for the JUPITER

**High CRP: A risk factor for
cardiovascular disease**

RESULTS

The trial was stopped after a median follow-up of 1.9 years (maximum, 5.0). Rosuvastatin reduced LDL cholesterol levels by 50% and high-sensitivity C-reactive protein levels by 37%. The rates of the primary end point were 0.77 and 1.36 per 100 person-years of follow-up in the rosuvastatin and placebo groups, respectively (hazard

CONCLUSIONS

In this trial of apparently healthy persons without hyperlipidemia but with elevated high-sensitivity C-reactive protein levels, rosuvastatin significantly reduced the incidence of major cardiovascular events. (ClinicalTrials.gov number, NCT00239681.)

increase in this population during longer courses of therapy. However, no such increase was detected in an analysis of participants who continued to receive treatment for 4 or more years.

We did detect a small but significant increase in the rate of physician-reported diabetes with rosuvastatin, as well as a small, though significant, increase in the median value of glycated hemoglobin. Increases in glucose and glycated hemoglobin levels, the incidence of newly diagnosed diabetes, and worsening glycemic control have been reported in previous trials of pravastatin, simvastatin, and atorvastatin.^{26,27} However, systematic protocol-specified measurements showed no significant difference between our

in fasting blood glucose levels during the follow-up period. There was no increase in the rate of physician-reported diabetes in the rosuvastatin group could be established. In addition, further study is needed to determine if a protective effect can be established. Physicians' reports of diabetes were not the end-point committee, and review of participants' records will be needed to understand this possible effect.

Potential limitations of our study include the use of low levels of high-sensitivity C-reactive protein in our trial, since our hypothesis-generating analysis of high-sensitivity C-reactive protein in the Force/Texas Coronary Atherosclerosis Prevention Study (AFCAPS/TexCAPS)¹² showed event rates and no evidence that treatment lowered vascular risk among patients with neither hyperlipidemia nor elevated C-reactive protein levels. Thus, a trial involving people with both high and low high-sensitivity C-reactive protein would have been not only inefficient but also statistically powered and sample size would be unlikely to show a benefit.

Second, since the trial was stratified by independent data and safety results were reported after a median follow-up of less than 2 years, the effect of longer-term therapy should be verified. We verified that the assumption of no treatment hazards was not violated during the trial, and we found a robust benefit of rosuvastatin in analyses restricted to patients for more than 2 years after randomization. Our findings, as well as the demonstration of hospitalization and arterial

were reduced by 47% within a 2-year period, suggest that the strategy tested could be cost-effective. The strategy also could reduce the demand for imaging tests in asymptomatic populations. On the other hand, our trial evaluated the use of rosuvastatin for the prevention of first cardiovascular events; therefore, the absolute event rates are lower than would be expected among patients with a history of vascular disease, a fact that should be taken into account in considering whether the use of statin therapy among those with low LDL cholesterol levels but elevated high-sensitivity C-reactive protein levels would be cost-effective if applied widely.

Supported by AstraZeneca.

Dr. Ridker reports receiving grant support from AstraZeneca, Novartis, Merck, Abbott, Roche, and Sanofi-Aventis; consulting fees or lecture fees or both from AstraZeneca, Novartis, Merck, Merck-Schering-Plough, Sanofi-Aventis, Isis, Dade Behring, and Vascular Biogenics; and is listed as a coinventor on patents held by Brigham and Women's Hospital that relate to the use of inflammatory biomarkers in cardiovascular disease, including the use of high-sensitivity C-reactive protein in the evaluation of patients' risk of cardiovascular disease. These patents have been licensed to Dade Behring and AstraZeneca. Dr. Fonseca reports receiving research grants, lecture fees, and consulting fees from AstraZeneca, Pfizer, Schering-Plough, Sanofi-Aventis, and Merck; and Dr. Genest, lecture fees from AstraZeneca, Schering-Plough, Merck-Schering-Plough, Pfizer, Novartis, and Sanofi-Aventis and consulting fees from AstraZeneca, Merck, Merck Frosst, Schering-Plough, Pfizer, Novartis, Resverlogix, and Sanofi-Aventis. Dr. Gotto reports receiving consulting fees from Dupont, Novartis,

The New York Times

Cholesterol-Fighting Drugs Show Wider Benefit

By [PAM BELLUCK](#)

Published: November 9, 2008

“A large new study suggests that millions more people could benefit from taking the [cholesterol](#)-lowering drugs known as statins, even if they have low cholesterol, because the drugs can significantly lower their risk of heart attacks, strokes and death...

“The study, presented Sunday at an American Heart Association convention in New Orleans and published online in The New England Journal of Medicine, found that the risk of heart attack was more than cut in half for people who took statins...

Relative risk reduction!

“‘These are findings that are really going to impact the practice of cardiology in the country,’ said Dr. Elizabeth G. Nabel, director of the National Heart, Lung and Blood Institute, which was not involved in the research.”

The New York Times

November 18, 2008

WELL

A Call for Caution in the Rush to Statins

By [TARA PARKER-POPE](#)

Is it time to put [cholesterol](#)-lowering statin drugs in every medicine cabinet?

Judging by recent headlines, you might think so. Last week [heart researchers reported](#) that millions of healthy people could benefit from taking statins even if they don't have high cholesterol.

Although many doctors hailed the study as a major breakthrough, a closer look at the research suggests that statins (like [Crestor](#), from AstraZeneca, and [Lipitor](#), from Pfizer) are far from magic pills. While they clearly save lives in people with a previous [heart attack](#) or other serious heart problems, for an otherwise healthy person the potential benefit remains small.

Many doctors who believe in using statins for heart disease say they needn't be given to healthy patients. Instead, they say, the focus should remain on encouraging healthful behavior and screening for traditional risk factors like [high blood pressure](#) and cholesterol.

Evaluation

Pre-workshop

- Demographic questionnaire
 - Participant characteristics , behavior (consented)

During workshop

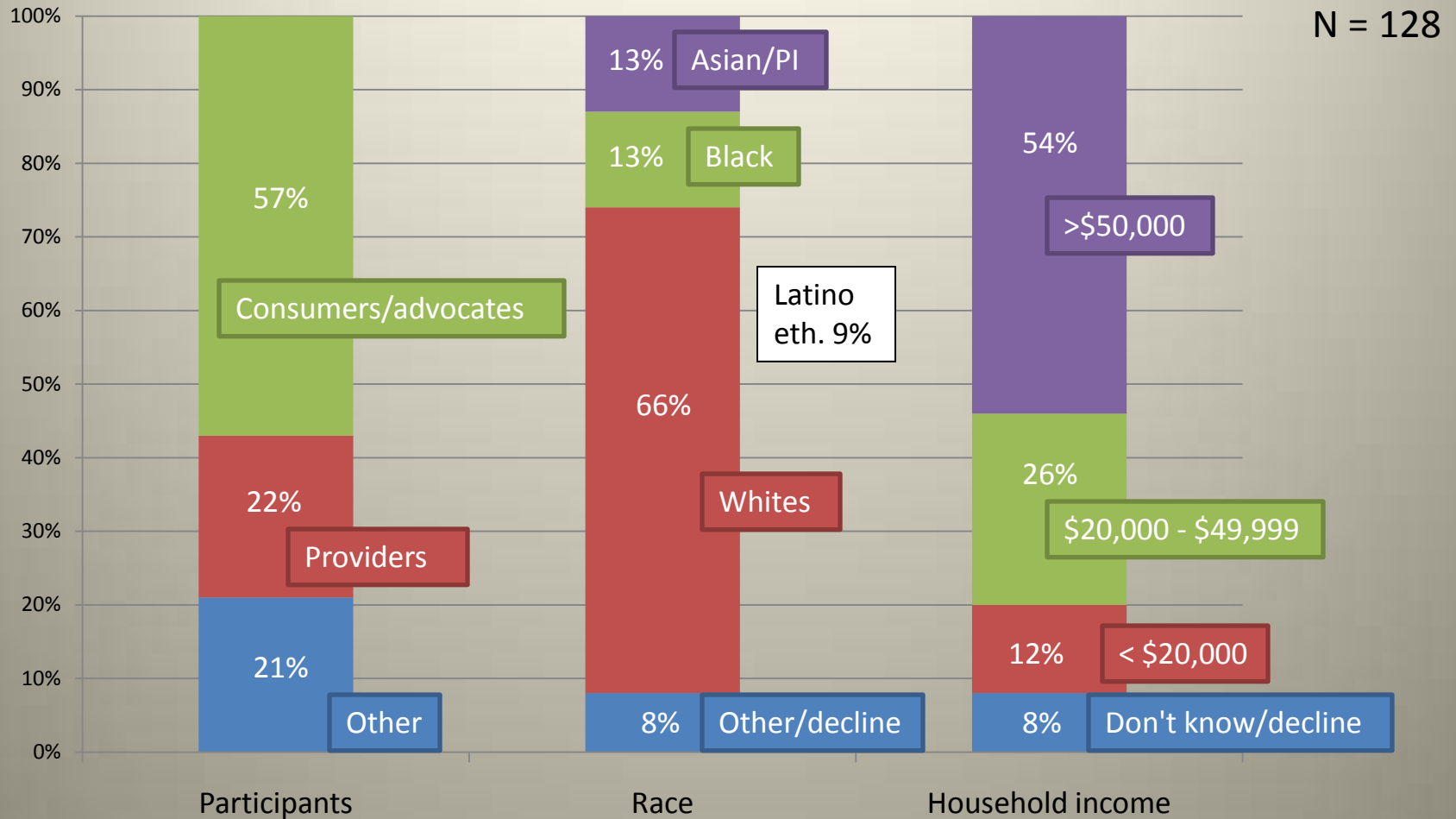
- On-screen pre/post questions
 - Confidence, knowledge (exempt)
- Record discussions
 - Attitudes (exempt)

Post-workshop

- 6-12 month online follow-up
 - Confidence, knowledge, behavior (consented)

Previous studies mostly conducted with healthcare professionals (results inconsistent)

Results: Characteristics of Participants



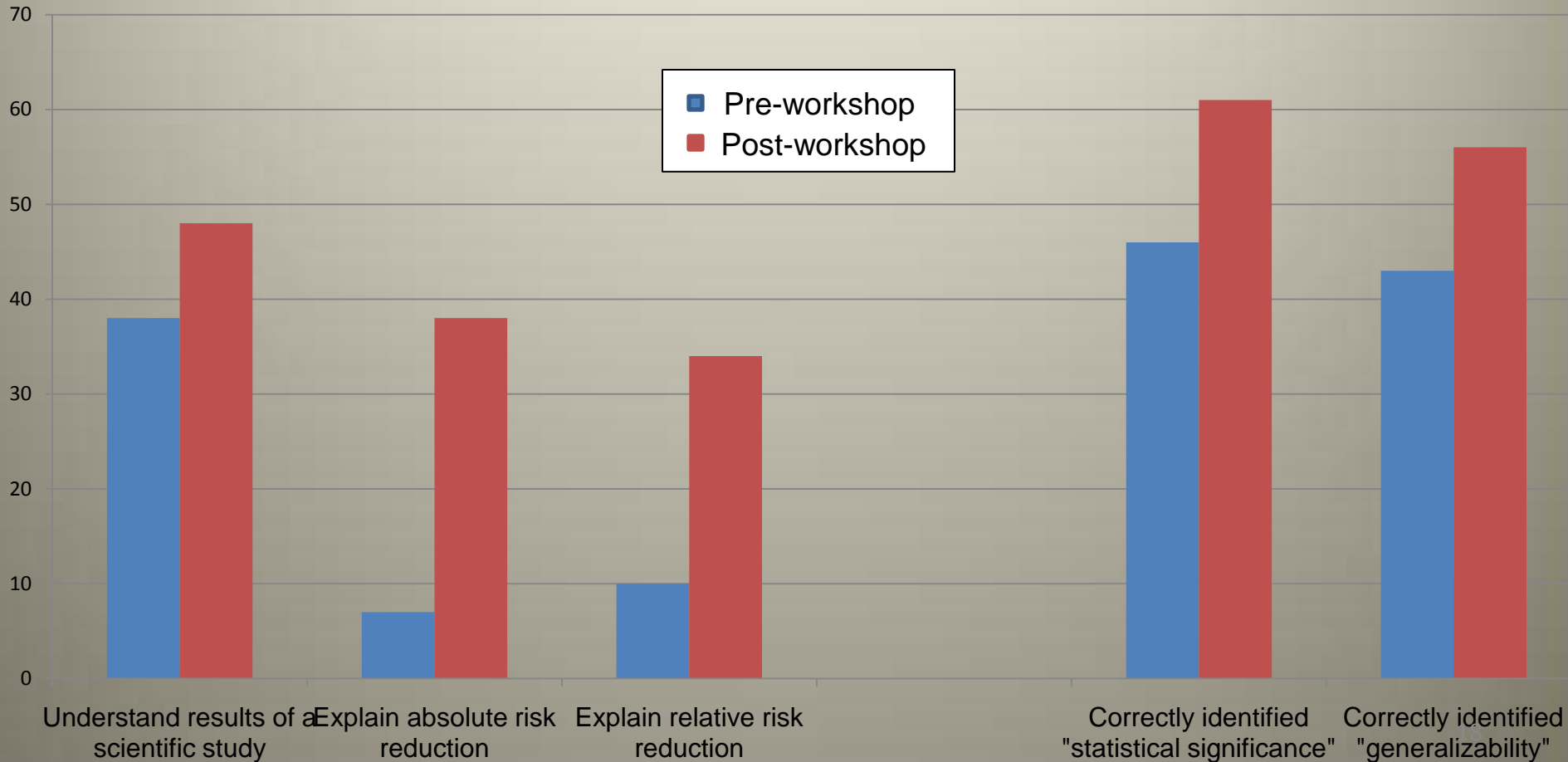
83% female. Education: 99% HS graduates, 73% college/graduate degree

Results

N = 128

Confidence change:
Percent of respondents reporting high confidence to:

Knowledge change:
Percent of respondents who:



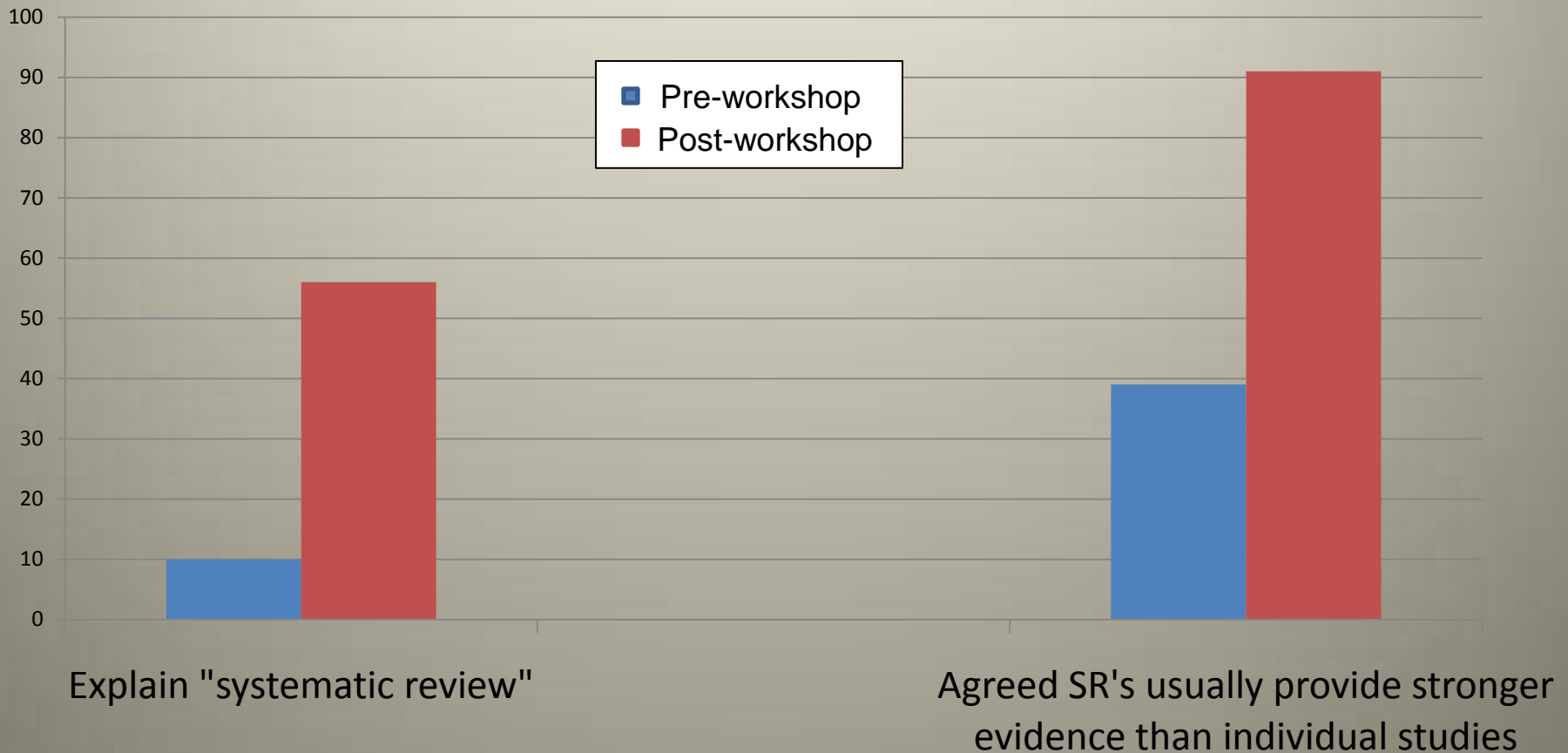
On systematic reviews:

Confidence change:

Percent of respondents reporting high confidence to:

Knowledge change:

Percent of respondents who:



End-of-Workshop Intentions:



- Use scientific articles to evaluate treatment options, educate clients, and plan programs



- “Ignore the headlines:” look critically at scientific articles, media stories, and drug ads
 - √ Watch out for relative vs. absolute risk reduction
 - √ Pay attention to which population is being studied



- **Watch for the funding source!**
- Use new resources, e.g. Cochrane reviews



...and 6 months later:

(n=40)

Changed Behavior:

- Found good sources of information
- Critically appraised papers for validity, reporting of risk/benefit, financial conflicts of interest
- Looked critically at ads and media reports

Used workshop skills in communication with:

- Family, friends, healthcare providers/patients
- In health advocacy work

Used workshop skills in healthcare decision-making:

- Evaluate options for self, others, patients

Limitations/Challenges

- Preliminary analysis
- No control group
 - Pre/post and follow-up questions
- Sampling by affiliation
 - Inclusion of interested participants
 - Recruiting low-income and minority participants proves challenging
 - Ongoing efforts with stakeholders from diverse groups
 - Difficult to recruit journalists and physicians

Discussion

- Critical appraisal training appears to be effective across diverse populations
 - Results similar across participant groups
 - The diverse participants generally enjoyed and found the workshops “useful” or “very useful.”
- Skills obtained in a one-day workshop are not at a sophisticated level.
- However, we saw a general increase in confidence, knowledge, and comfort-level in critically appraising health information.

Future plans: creating an online course



“Don't forget to look for ‘the little man behind the curtain.’ Follow the money.”

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Thank You!

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