

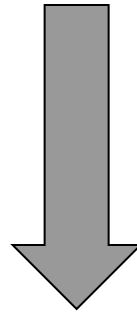
From Epidemiologic Evidence to Policy

**Jonathan M. Samet, MD, MS
Professor and Flora L. Thornton Chair
Department of Preventive Medicine
USC Keck School of Medicine**

**Johns Hopkins Summer Institute,
June 25, 2010**

Evidence to Policy—It's Easy!

Evidence



Policy

NOT

“Evidence”

“Scientific knowledge. Results of research used to support decision making.”

Porta M. (2008) *A Dictionary of Epidemiology*, 5th Ed.

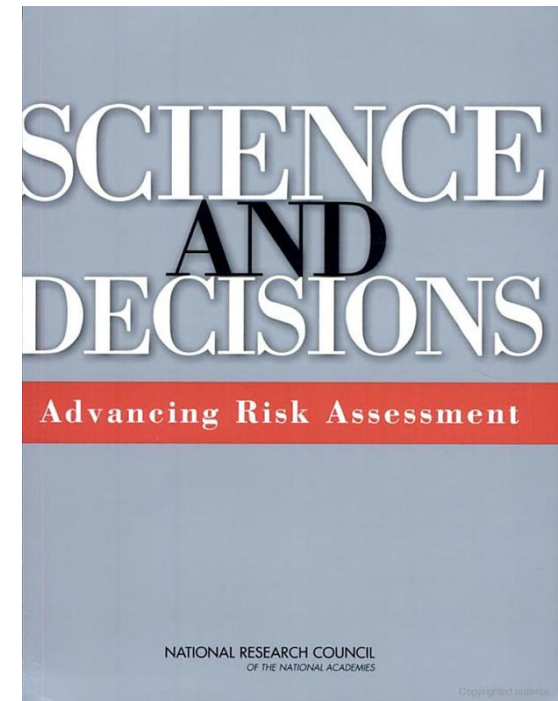
“Evidence is information, such as facts, coupled with principles of inference (the act or process of deriving a conclusion), that make information relevant to the support or disproof of a hypothesis.”

Wikipedia

“Uncertainty”

“Lack or incompleteness of information. Uncertainty depends on the quality, quantity, and relevance of data and on the reliability and relevance of models and assumptions”

National Research Council (2009)
*Science and Decisions:
Advancing Risk Assessment.*



Warming or not??

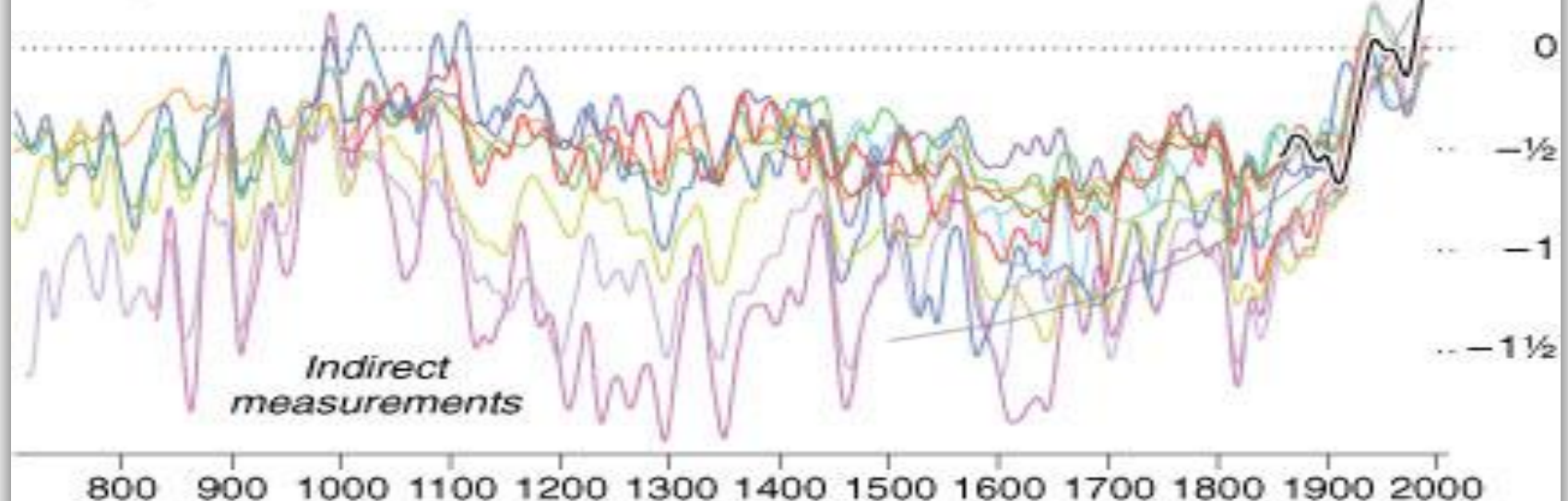
Evidence of a Warming Planet

A 2007 report by the Intergovernmental Panel on Climate Change reviewed multiple reconstructions of temperature over the past 1,300 years (below) based on ice cores, tree rings and other indirect measurements. The panel concluded that evidence for global warming was “unequivocal.”

Temperature anomaly

Degrees warmer or cooler than the 1961–90 average temperature in the Northern Hemisphere

Measured
temperatures
since 1856



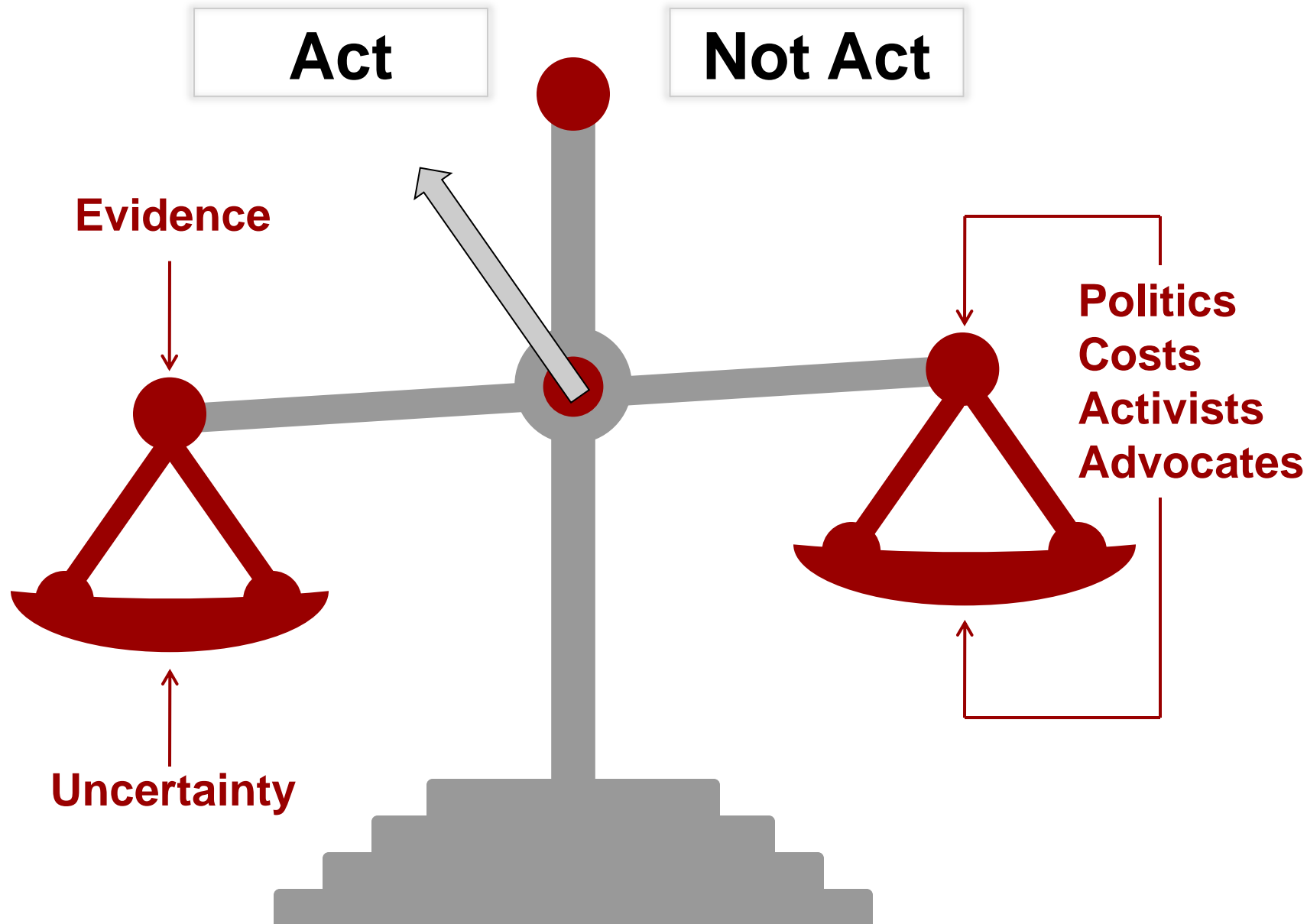
Source: Intergovernmental Panel on Climate Change

THE NEW YORK TIMES

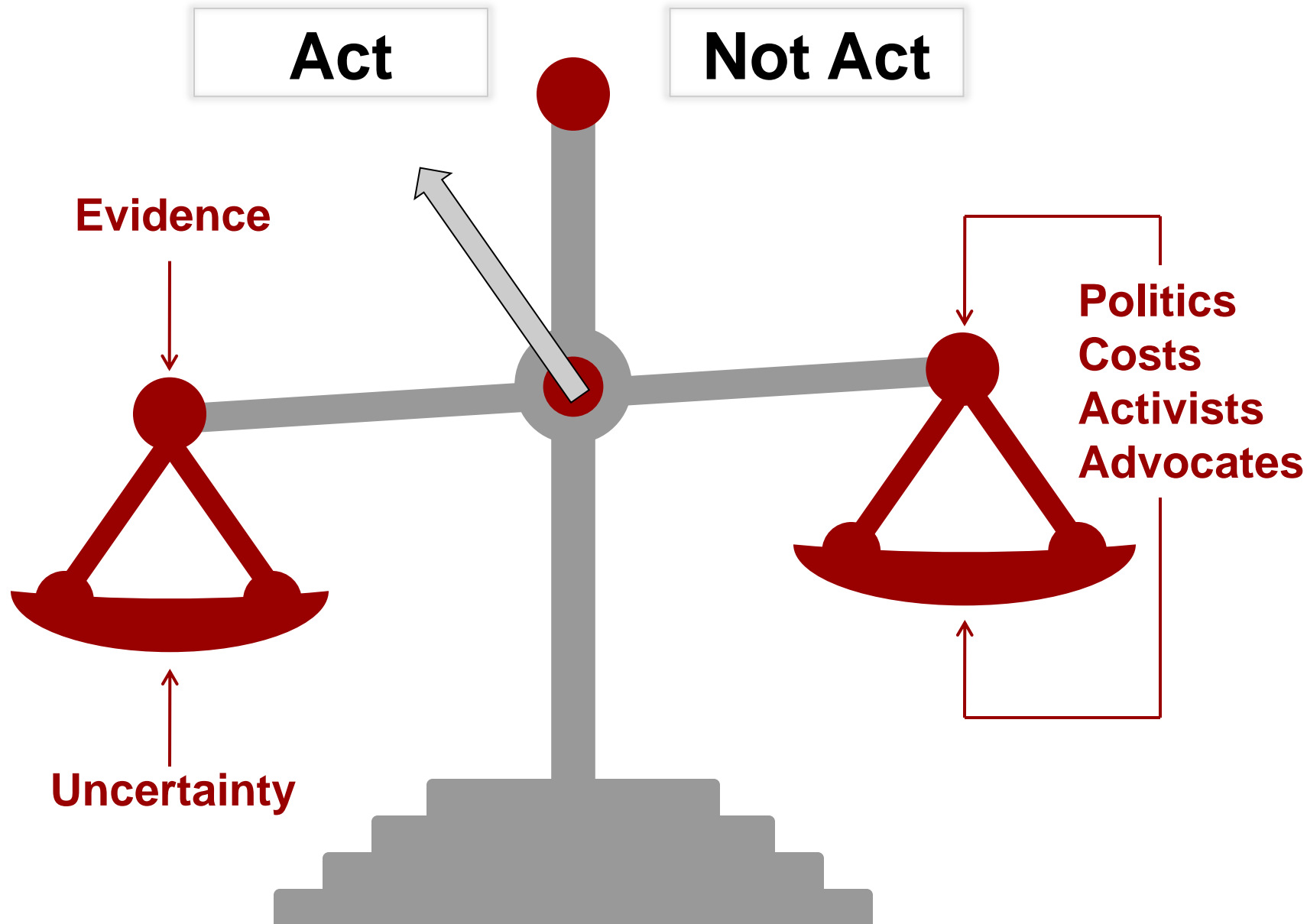
Characterizing Strength of Evidence and Uncertainty

- ***Strength of evidence***
 - Verbal descriptors
 - Hierarchical classification
 - Probability distributions
- ***Degree of uncertainty***
 - Verbal descriptors
 - Probability distributions
 - Beyond confidence intervals

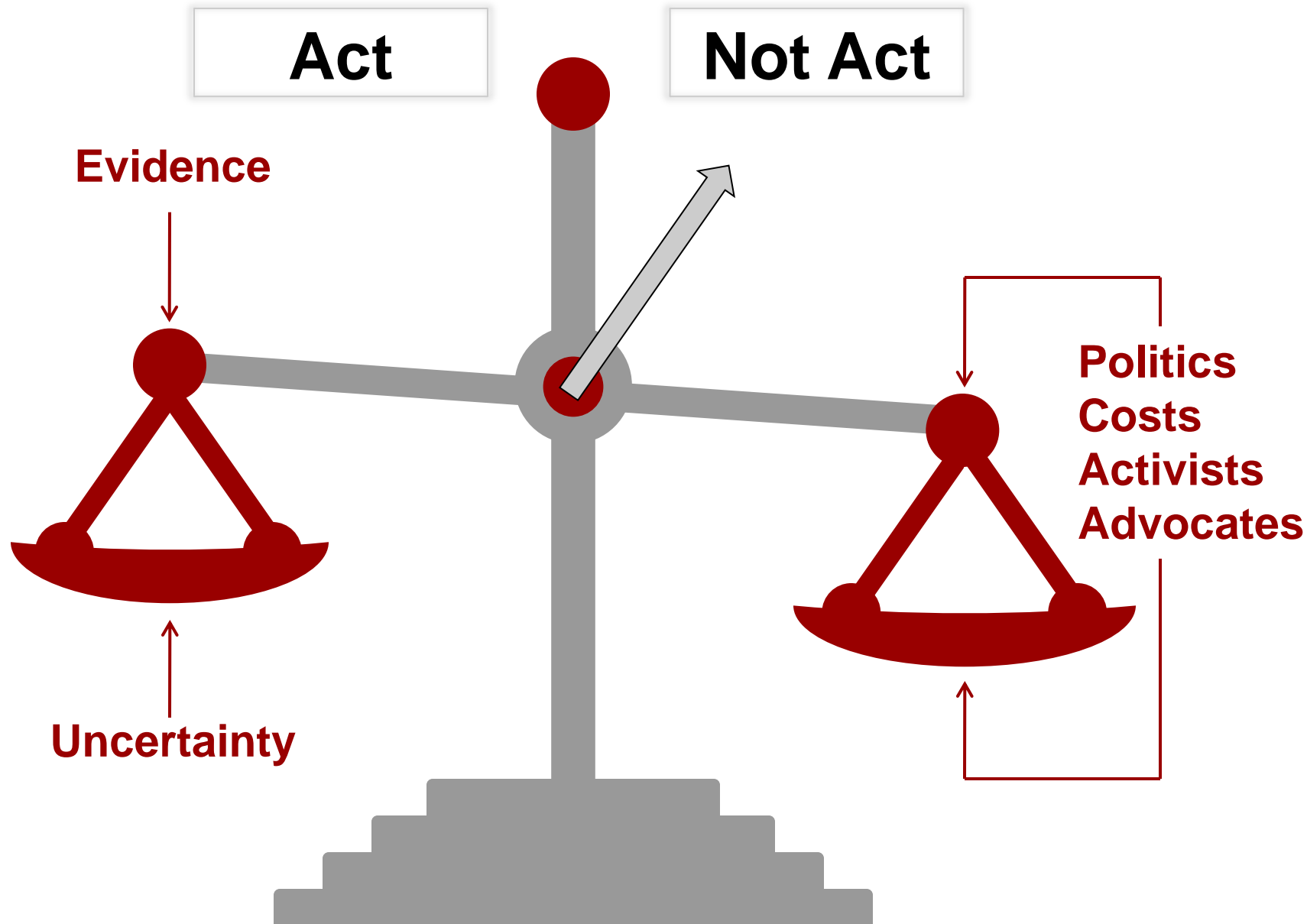
The Evidence Scale



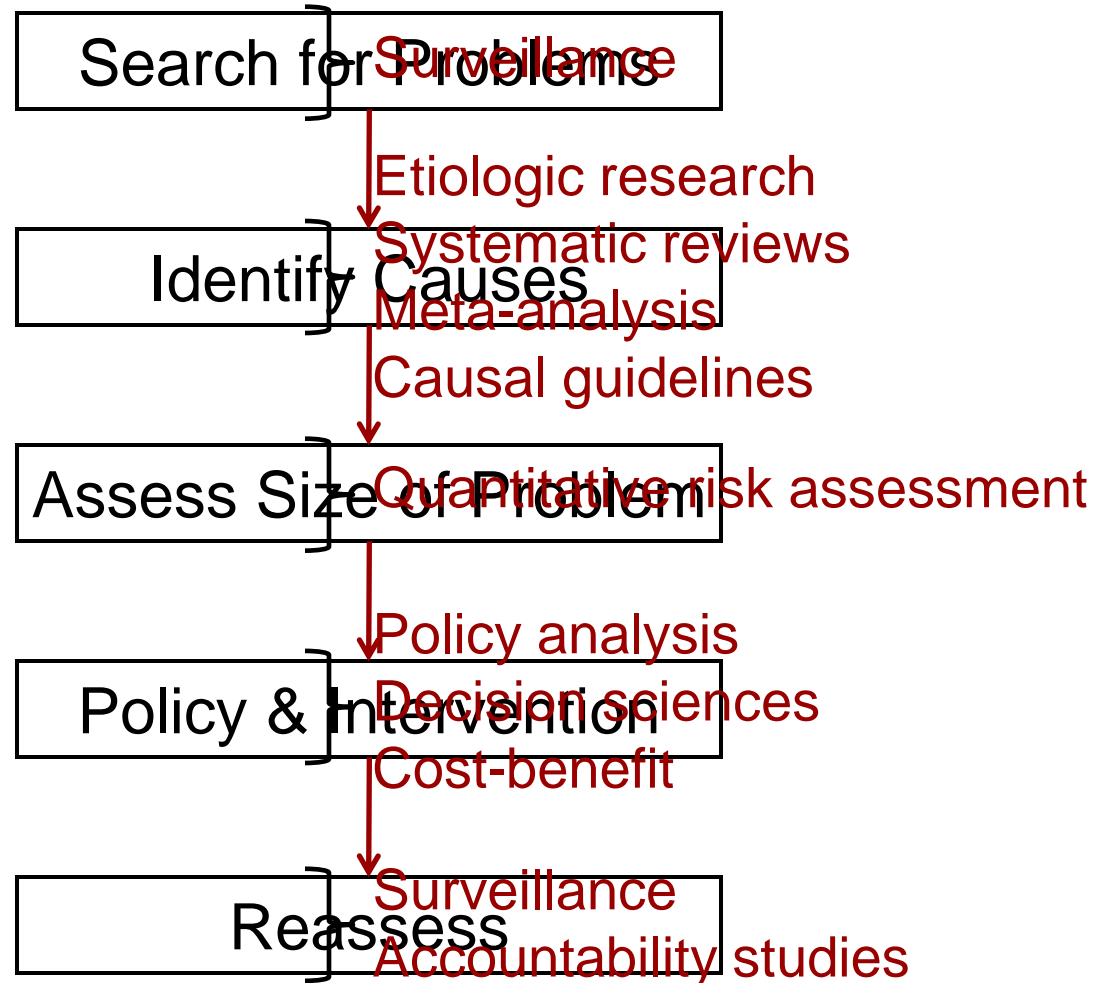
The Evidence Scale



The Evidence Scale



Steps in Evidence-Based Public Health



Some Paths from Epi to Policy

- Diverse
- Personal → Societal
- Specific → General
- Regulatory
- Non regulatory
- Litigation

What is the role of epidemiology in this schema?

- **Epidemiologic Evidence**

- Evidence for causal inference
- Hypothesis generation
- Program evaluation

- **Epidemiologists**

- Carry out and report research
- Participate in evidence synthesis and evaluation
- Become decision-makers

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FROM EPIDEMIOLOGY TO POLICY: PROCEEDINGS OF A SYMPOSIUM ON THE
TRANSLATION OF EPIDEMIOLOGIC EVIDENCE INTO PUBLIC HEALTH POLICY
July 27-29, 1998, Renaissance Hotel, Washington, DC

- S1 **Bridging the Gap: Perspectives on Translating Epidemiologic Evidence Into Policy.** *Jonathan M. Samet and Nora L. Lee*
- S4 **How Public Health Policy is Created: Scientific Process and Political Reality.** *Alfred Sommer*
- S7 **Some Attributes of Risk Influencing Decision-making by Public Health and Regulatory Officials.** *Joseph V. Rodricks*
- S13 **The Evaluation of Epidemiologic Evidence for Policy-making.** *Moyses Szklo*
- S18 **Epidemiology in the Regulatory Arena.** *Lynn R. Goldman*
- S27 **Epidemiology in the Legal Arena and the Search for Truth.** *Arthur H. Bryant and Alexander Reinert*
- S36 **Conflicts Between Two Cultures: Implications for Epidemiologic Researchers in Communicating with Policy-Makers.** *Genevieve M. Matanoski*
- S43 **Contrasting Roles of Epidemiology in Dioxin-related Policy: Lessons Learned.** *Joseph V. Rodricks, James J. Collins, William H. Farland, and David J. Tollerud*
- S50 **Electric and Magnetic Fields and Cancer: Case Study.** *Leeka I. Kheifets, Raymond S. Greenberg, Raymond R. Neutra, Gordon L. Hester, Charles L. Poole, David P. Rall, and Gail Lundell*
- S60 **Folate Fortification for the Prevention of Birth Defects: Case Study.** *Manning Feinleib, Shirley A.A. Beresford, Barbara A. Bowman, James L. Mills, Jeanne I. Rader, Jacob Selhub, and Elizabeth A. Yetley*
- S70 **Needle Exchange Programs for the Prevention of Human Immunodeficiency Virus Infection: Epidemiology and Policy.** *David Vlahov, Don C. Des Jarlais, Eric Goosby, Paula C. Hollinger, Peter G. Lurie, Michael D. Shriver, and Steffanie A. Strathdee*
- S78 **Particulate Air Pollution Standards and Morbidity and Mortality: Case Study.** *Daniel S. Greenbaum, John D. Bachmann, Daniel Krewski, Jonathan M. Samet, Ronald White, and Ronald E. Wyzga*
- S91 **Radiation Exposure and Cancer: Case Study.** *Genevieve M. Matanoski, John D. Boice, Jr., Stephen L. Brown, Ethel S. Gilbert, Jerome S. Puskin, and Tara O'Toole*



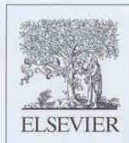
COMMENTARY

From Epidemiology to Policy

ROSS C. BROWN
AND ROBERTA L. MCKAY

How can the best evidence in populations be brought to bear? Can epidemiologists help? Can lessons from recent U.S. experience even reveal a more general picture of future opportunities?

Although these lines of policy have been written (1, 2), clear guidance is lacking. There has been a longstanding debate about how active epidemiology can advance advocacy. Epidemiology is a given health policy. The perceived loss of objectivity in research on the same topic is a problem in policy making. Epidemiology by improving methodological criteria to meta-analysis methods to parts of the policy. Policy makers will continue to set health policy with explicit



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ANNPE3

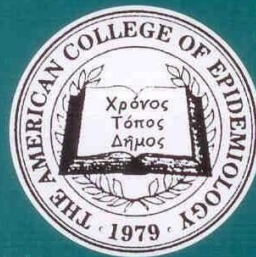
Annals of Epidemiology

www.annalsofepidemiology.org

In This Issue

- Early life effects:
 - Neighborhood deprivation and adverse birth outcomes
 - Early life socioeconomic influences on mortality
- Late life effects:
 - Hearing impairment and mortality risk
 - Physical activity and cognitive decline
 - Cognitive changes in elderly Japanese Americans

From the Editor: The American College of Epidemiology continues to have an active voice in health policy debates. Four policy analyses and a commentary compose a mini-symposium in this issue. The topics are diverse—the legal blood alcohol limit for drivers; compensation for veterans; smoke-free indoor spaces; and promotion of physical activity in schools—but the approaches are similar. These are considered critiques and reasoned arguments, a departure from the media combatants who arrive with “the answer” and a portable sound-proof booth.



The Official
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Translating Evidence into Policy:

Compensation for Veterans

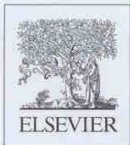


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AND ALLEN J. V

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Veterans

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TOM PHILPOTT | Webb: Delay Agent Orange Claims, Stop Bigger Pay Raises

Staff Reports

Saturday, June 5, 2010

Sen. Jim Webb (D-Va.), chief architect of the pricey Post-9/11 GI Bill education benefit for veterans of the Iraq and Afghanistan war era, could become a new champion, for taxpayers, against what he perceives as excess spending on military pay and on a new wave of Agent Orange claims.

Webb, a former Navy secretary and decorated Vietnam War veteran, risked the anger of thousands of veterans from that war when he won Senate approval last week of an amendment to block, at least temporarily, the Department of Veterans Affairs from paying new disability claims on three prominent diseases presumed linked to wartime herbicide exposure.

As many as 86,000 Vietnam veterans with ischemic heart disease, Parkinson's disease or B-cell leukemia are awaiting a final VA regulation to receive disability compensation based on a decision last fall by VA Secretary Eric Shinseki of evidence linking these diseases with exposure to deadly defoliant used during the war. Many more vets could file first-time claims.

VA officials not only have published interim regulations already but, for months, have been encouraging veterans stricken with these diseases, or their surviving spouses, to file new claims or re-file claims as soon as possible because benefits would be paid back to claim filing dates.

But Webb proposed, and senators accepted May 27, an amendment to the fiscal 2010 war supplemental funding bill (HR 4899) to limit spending on claims filed for these new presumptive Agent Orange diseases for 60 days. That will allow Congress time to study



June 16, 2010

Agent Orange issues set for Sept. hearing[TOM PHILPOTT](#)

2010-06-18 10:15:22

VA Secretary Eric Shinseki will get the Senate hearing he didn't want.

Sen. James Webb, D-Va., says he will use a Senate Veterans Affairs Committee hearing — rescheduled now for Sept. 23 — to have Shinseki explain his decision to compensate Vietnam veterans, and many

It was the Carter administration, he said, that adopted a presumption “that everyone who was in Vietnam was exposed” to Agent Orange. At the time, he said, the decision wasn’t “onerous” on VA budgets because the department only had linked Agent Orange to some rare illnesses.

More recently, VA has found links to ailments generally associated with aging, committing VA to pay billions in additional compensation. **Webb felt the scientific evidence linking Type II diabetes to Agent Orange in 2001 was soft.** He is reluctant to say the same about the three illnesses Shinseki has endorsed until he hears his testimony.

But Webb does intend to question the science behind presuming everyone who served in Vietnam was exposed to defoliants. He knows his own Marine Company was, he said, as were many other units who were engaged in combat in the countryside or handled Agent Orange directly.

“On any given day in Vietnam they say about 10 percent of the people were actually out in direct combat. Percentages are actually higher than that because of rotations...But the majority of the people weren’t in combat” where defoliants were used. “That’s just the reality of it.”

“This is an area where we have a responsibility to pump for more (information) to tell us specifically how they made the connection. The only appropriate way to do that is say, ‘Let’s fence the money for 60 days and get some clarification here.’”

Webb said he was unaware on finding the \$13.4 billion in the bill that Shinseki had asked Sen. Daniel Akaka, D-Hawaii, chairman of the VA committee, not to hold a hearing on this issue. Akaka had scheduled one for April, then rescheduled for early May when VA declined to send witnesses.

One theme he ran on in 2006, Webb said, was restoring a proper balance of power between the legislative and executive branches. Too much authority had been conceded to, or usurped by, recent administrations.

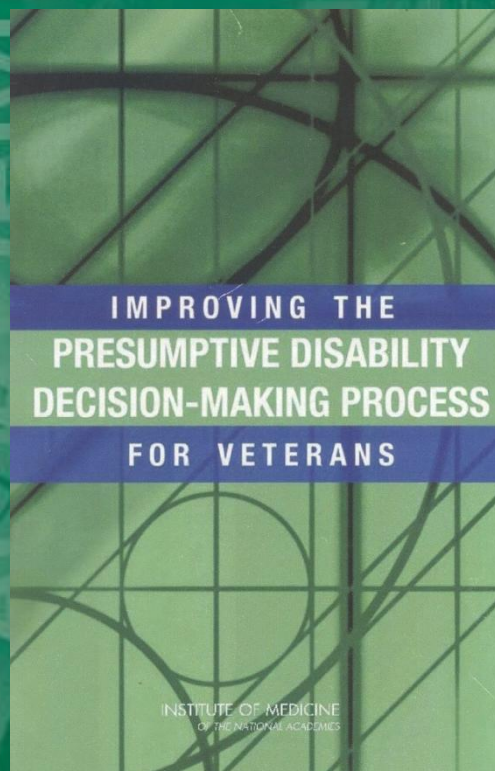
Harmful Exposures to Veterans

- Military personnel sustain a wide array of potentially harmful exposures, ranging from weapons and exposure to combat to the same exposures that are harmful to civilians (e.g., asbestos, combustion fumes, and solvents)
- These exposures may cause specific, signature problems, i.e., PTSD, or contribute to the burden of disease generally in military personnel and veterans

INSTITUTE OF MEDICINE



Improving the Presumptive Disability Decision-Making Process for Veterans



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National Academy of Sciences
National Academy of Engineering
Institute of Medicine
National Research Council

What is the problem?

- Veterans may be injured or sustain disease-causing exposures consequent to their service.
- Compensation is provided to Veterans for service-related conditions and diseases.
- Decisions related to compensation should be evidence-based, **but** the evidence on exposure, general causation and specific causation is often incomplete.

Compensation for Veterans

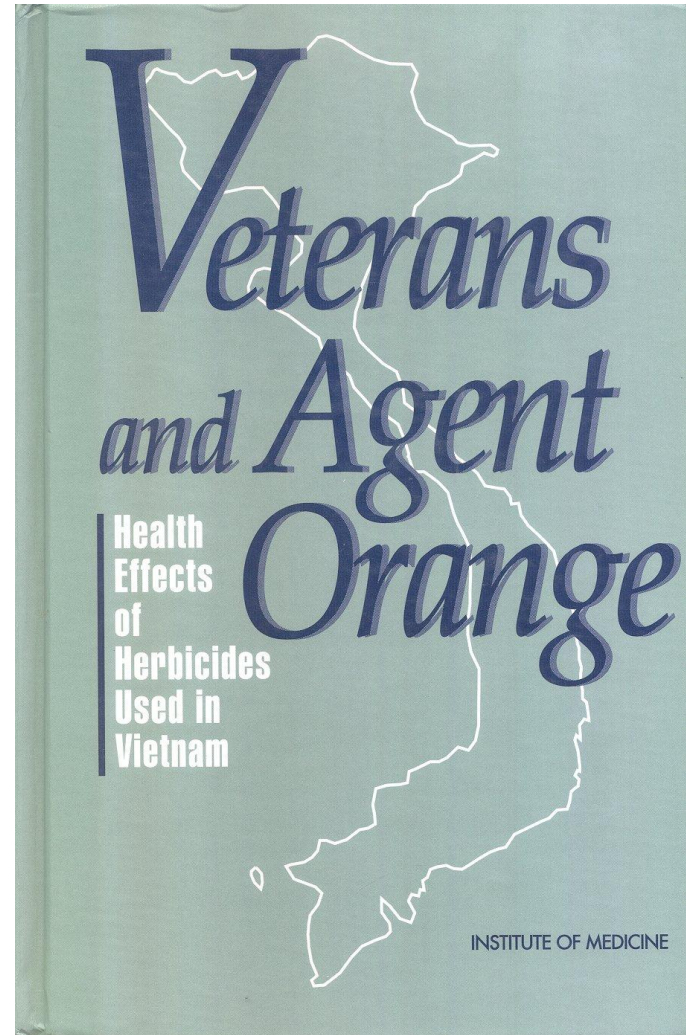
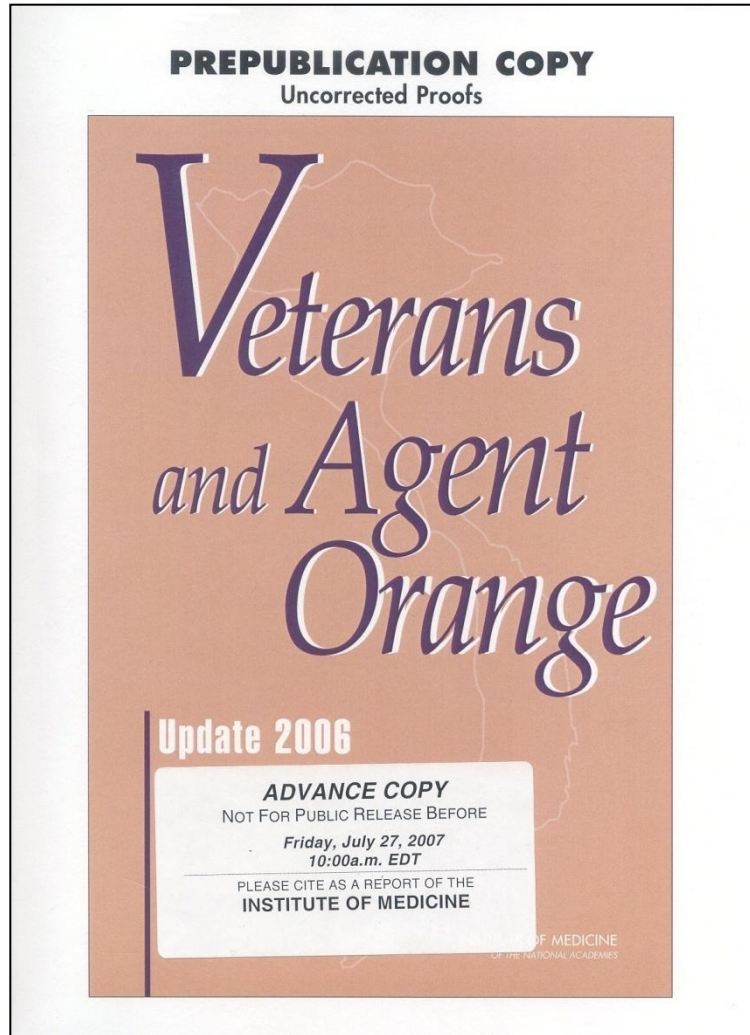
- Veterans are awarded compensation by VA, with benefits including health care and monetary compensation.
- Decisions need to be made, even as evidence is accumulating and uncertain.
- When information is incomplete, a “presumption” may be made, possibly in regard to either exposure or causation
- The costs for Veterans compensation are substantial

Definition of Presumption

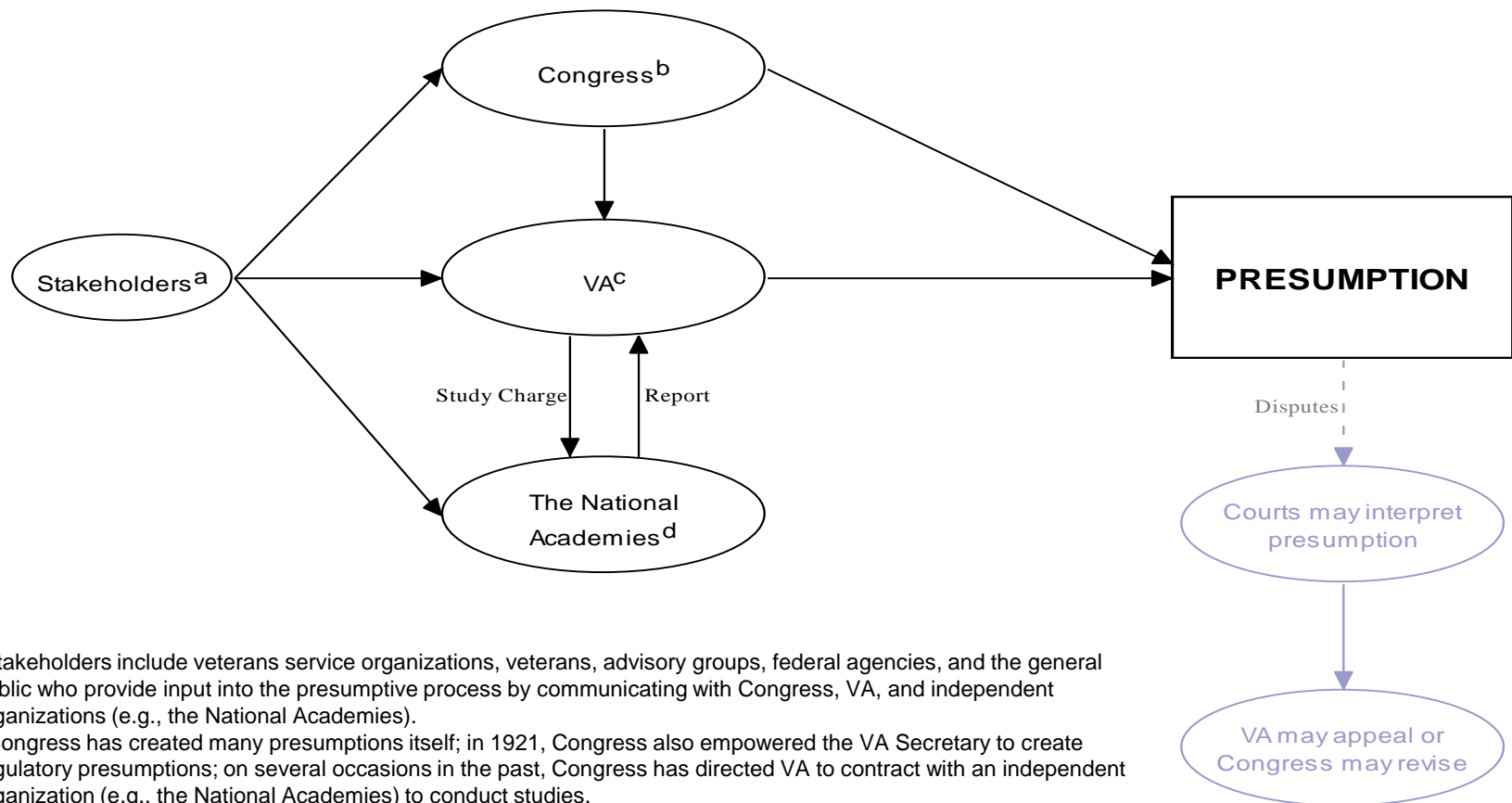
Presumption. A procedural device that dictates that once basic fact A is established, the existence of fact B must be assumed unless the presumed fact is rebutted. A presumption therefore operates to relieve a party of the burden of establishing facts that it would otherwise be required to prove in order to prevail on its claim.



Compensation for Vietnam veterans



The Current Presumptive Disability Decision-Making Process



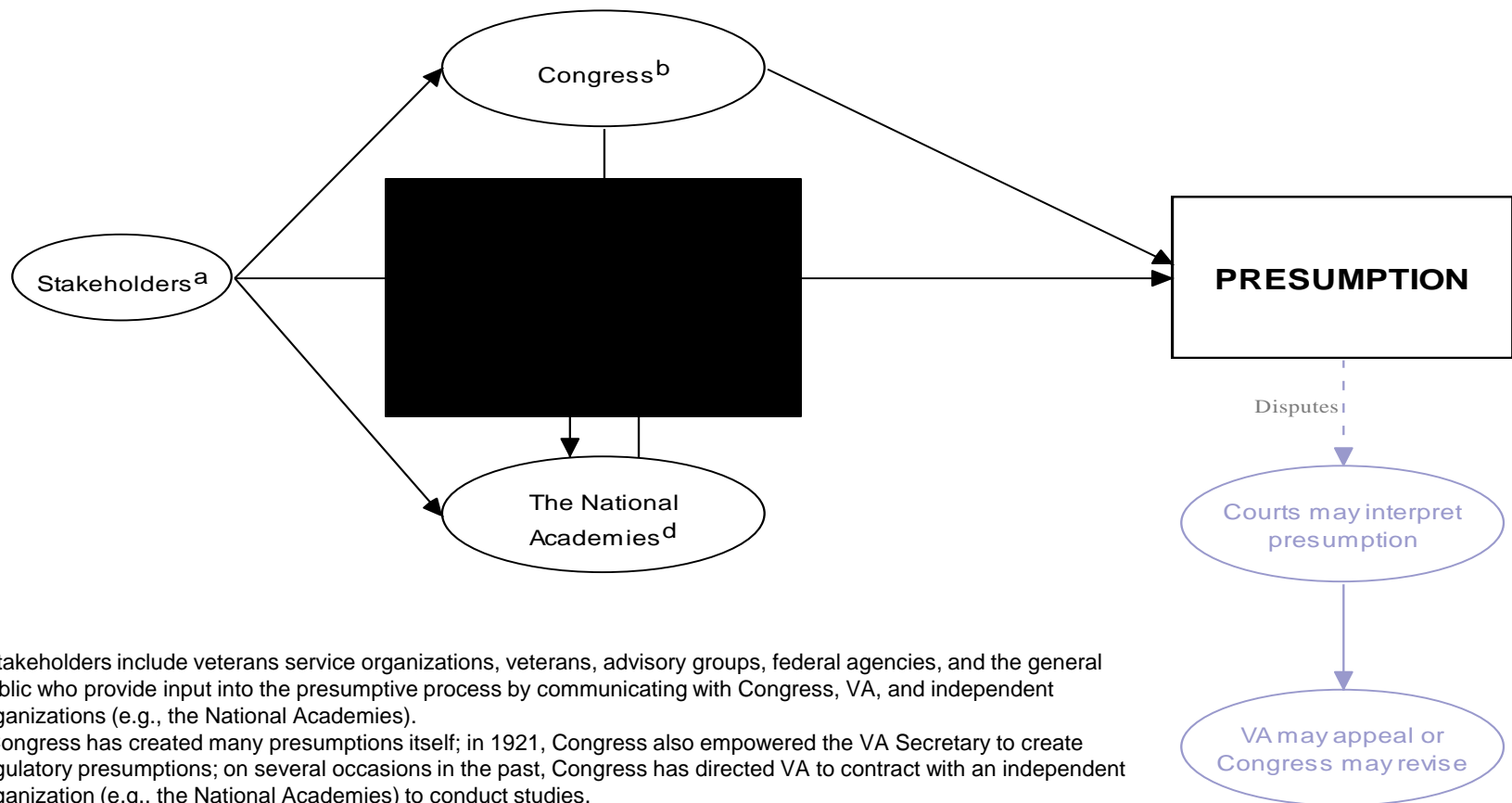
^aStakeholders include veterans service organizations, veterans, advisory groups, federal agencies, and the general public who provide input into the presumptive process by communicating with Congress, VA, and independent organizations (e.g., the National Academies).

^bCongress has created many presumptions itself; in 1921, Congress also empowered the VA Secretary to create regulatory presumptions; on several occasions in the past, Congress has directed VA to contract with an independent organization (e.g., the National Academies) to conduct studies.

^cVA can establish regulatory presumptions; VA sometimes contracts with the National Academies to conduct studies and uses the organization's report in its deliberations of granting or not granting regulatory presumptions.

^dThe National Academies (Institute of Medicine and National Research Council) submit reports to VA based on requests and study charges from VA.

The Current Presumptive Disability Decision-Making Process



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What's in a word?

PUBLIC LAW 102-4—FEB. 6, 1991

1

Public Law 102-4
102d Congress

An Act

To provide for the Secretary of Veterans Affairs to obtain independent scientific review of the available scientific evidence regarding associations between diseases and exposure to dioxin and other chemical compounds in herbicides, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Agent Orange Act of 1991”.

SEC. 2. PRESUMPTION OF SERVICE CONNECTION FOR DISEASES ASSOCIATED WITH EXPOSURE TO HERBICIDES.

(a) IN GENERAL.—(1) Chapter 316 of title 38, United States Code, is amended by adding at the end thereof the following new section:

“§ 316. Presumptions of service connection for diseases associated with exposure to herbicides.

“(a)(1) For the purposes of this section, the following definitions shall apply:—

“(A) a disease specific to the Republic of Vietnam during the Vietnam era; and

“(B) each additional disease which is determined in regulations to be associated with herbicide exposure. Such regulations shall be based on a positive association with herbicide exposure which becomes manifest within the regulations in a veteran’s service, served in the Republic of Vietnam during the Vietnam era and while so exposed to herbicides as an agent,

shall be considered to have been exposed to herbicides during service, notwithstanding that the disease during the period of service was not associated with herbicide exposure.

SEC. 3. AGREEMENT WITH NATIONAL ACADEMY OF SCIENCES.

38 USC 316 note.

(a) PURPOSE.—The purpose of this section is to provide for the National Academy of Sciences, an independent nonprofit scientific organization with appropriate expertise which is not part of the Federal Government, to review and evaluate the available scientific evidence regarding associations between diseases and exposure to dioxin and other chemical compounds in herbicides.

(b) AGREEMENT.—The Secretary shall seek to enter into an agreement with the National Academy of Sciences for the Academy to perform the services covered by this section. The Secretary shall seek to enter into such agreement not later than two months after the date of the enactment of this Act.

(c) REVIEW OF SCIENTIFIC EVIDENCE.—Under an agreement between the Secretary and the National Academy of Sciences under this section, the Academy shall review and summarize the scientific evidence, and assess the strength thereof, concerning the association between exposure to an herbicide used in support of the United States and allied military operations in the Republic of Vietnam during the Vietnam era and each disease suspected to be associated with such exposure.

(d) SCIENTIFIC DETERMINATIONS CONCERNING DISEASES.—(1) For each disease reviewed, the Academy shall determine (to the extent that available scientific data permit meaningful determinations)—

(A) whether a statistical association with herbicide exposure exists, taking into account the strength of the scientific evidence and the appropriateness of the statistical and epidemiological methods used to detect the association;

(B) the increased risk of the disease among those exposed to herbicides during service in the Republic of Vietnam during the Vietnam era; and

(C) whether there exists a plausible biological mechanism or other evidence of a causal relationship between herbicide exposure and the disease.

Diseases **Associated** With Exposure to Agent Orange

- Acute and Subacute Transient Peripheral Neuropathy
- AL Amyloidosis
- Chloracne (or Similar Acneform Disease)
- Chronic Lymphocytic Leukemia (Now Being Expanded to B Cell Leukemias)
- Diabetes Mellitus (Type 2)
- Hodgkin's Disease
- Ischemic Heart Disease
- Multiple Myeloma
- Non-Hodgkin's Lymphoma
- Parkinson's Disease
- Porphyria Cutanea Tarda
- Prostate Cancer
- Respiratory Cancers
- Soft Tissue Sarcoma (other than Osteosarcoma, Chondrosarcoma, Kaposi's sarcoma, or Mesothelioma)

Compensation for Vietnam veterans

Limited or Suggestive Evidence of Association

Evidence suggests an association between exposure to herbicides and the outcome, but a firm conclusion is limited because chance, bias, and confounding could not be ruled out with confidence. There is limited or suggestive evidence of an association between exposure to the chemicals of interest and the following health outcomes:

Laryngeal cancer

Cancer of the lung, bronchus, or trachea

Prostate cancer

Multiple myeloma

AL amyloidosis

Early-onset transient peripheral neuropathy

Parkinson's disease (category change from Update 2006)

Porphyria cutanea tarda

Hypertension

Ischemic heart disease (category change from Update 2006)

Type 2 diabetes (mellitus)

Spina bifida in offspring of exposed people

Policy Concerns

- What is the appropriate threshold of evidence for decision-making?
- Is association or causation the appropriate criterion?
- What are the risks of “false-positives” and “false-negatives”?
- Can transparency be assured?
- What about attributable and relative risks?

Outcomes at Present

- Presumptions by VA
- Process not transparent and appears inconsistent
- No organized evidence gathering by DoD and VA
- Substantial costs
- Lack of trust by Veterans groups



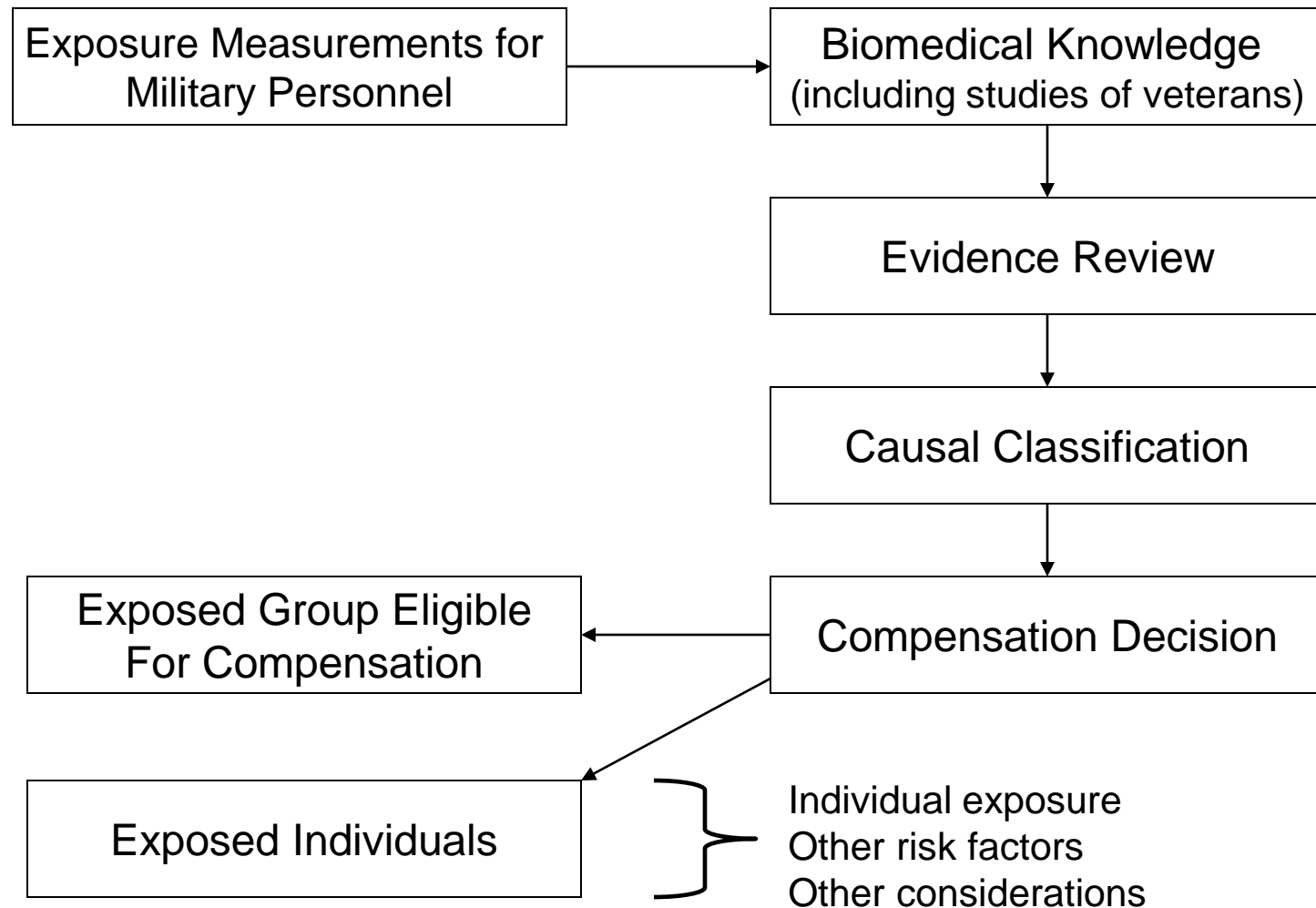
Improving the Presumptive Disability Decision-Making Process for Veterans

What was recommended?

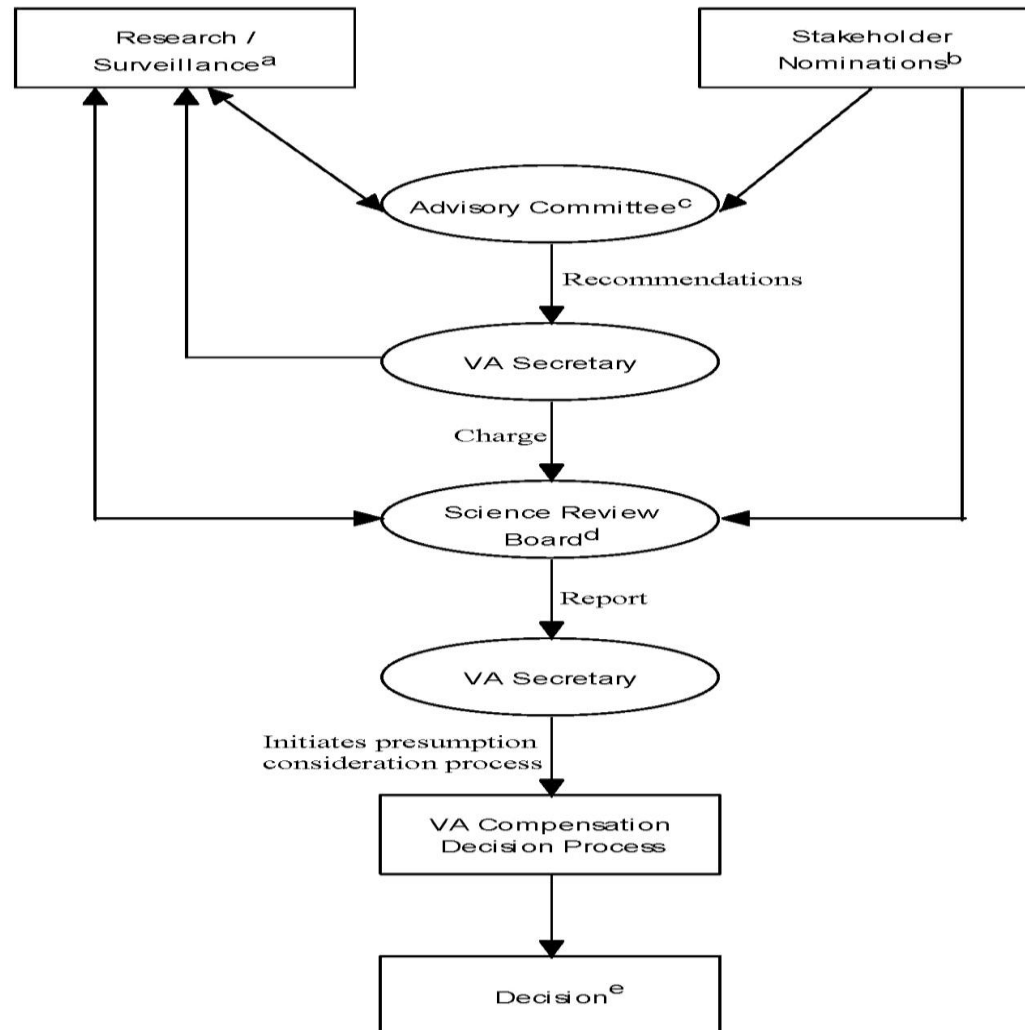
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National Academy of Sciences
National Academy of Engineering
Institute of Medicine
National Research Council

Information Gathering and its Use in Making General and Specific Compensation Decisions



Proposed Framework for the Future Presumptive Disability Decision-Making Process



Proposed Framework for Establishing Presumptions

- Evidence-based, principle driven
- Four-level evidence classification for causation
- Organizational framework
- Surveillance for exposure and health condition



Principles for the Presumptive Disability Decision-Making Process for Veterans

- Stakeholder inclusiveness
- Evidence-based decisions
- Transparency
- Flexibility
- Consistency
- Causation, not just association, as the target for decision making

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Causation, Not Just Association, as the Target for Decision-Making

- Presumptive disability decisions are based on two judgments: (1) that a group of veterans was *exposed* to a potentially harmful agent or condition during service, and (2) that the agent or condition *is able to cause* disease leading to disability.
- The second proposition states a causal association, not just an association for which causation has not been established. An association between an exposure and health condition can be good evidence for a causal claim, but it is not the same as a causal claim.

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Proposed 4-Level Classification Scheme for Causation

Sufficient: the evidence is sufficient to conclude that a causal relationship exists

Equipoise and Above: the evidence is sufficient to conclude that a causal relationship is at least as likely as not, but not sufficient to conclude that a causal relationship exists

Below Equipoise: the evidence is not sufficient to conclude that a causal relationship is at least as likely as not, or is not sufficient to make a scientifically informed judgment

Against: the evidence suggests the lack of a causal relationship

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Equipose and Evidence What is it?

FOR



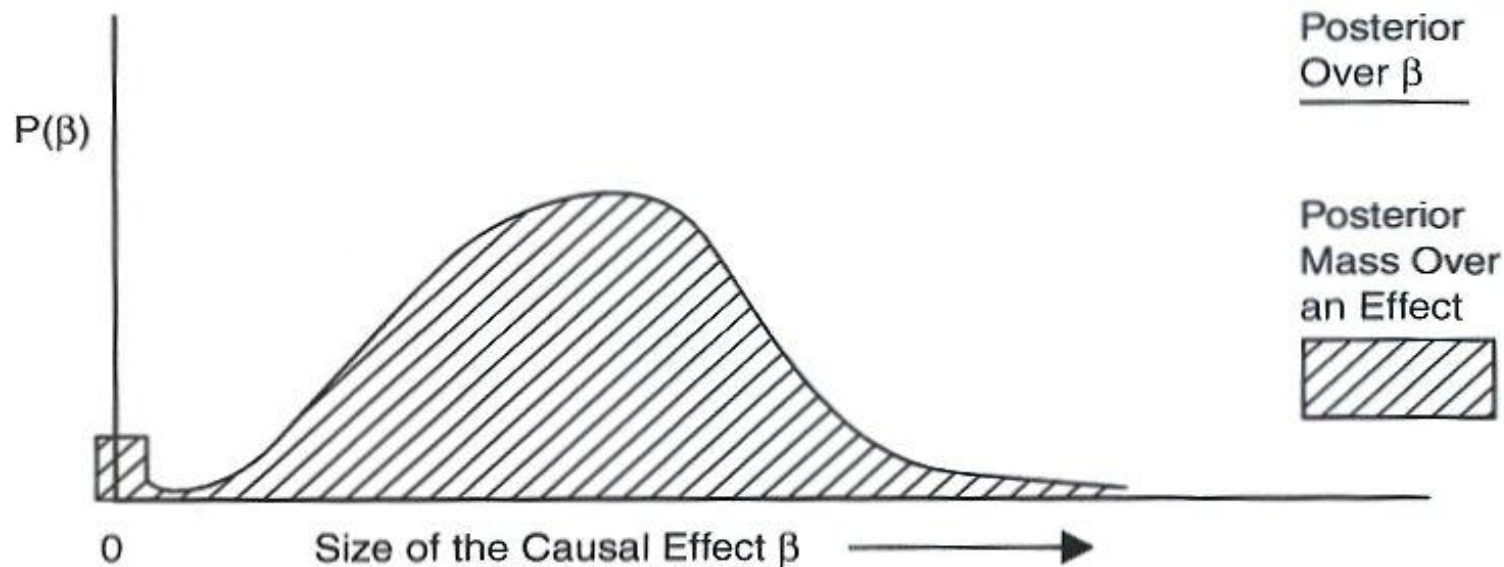
AGAINST

**The balance point for strength
of evidence on causation**

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Example posterior for *sufficient*

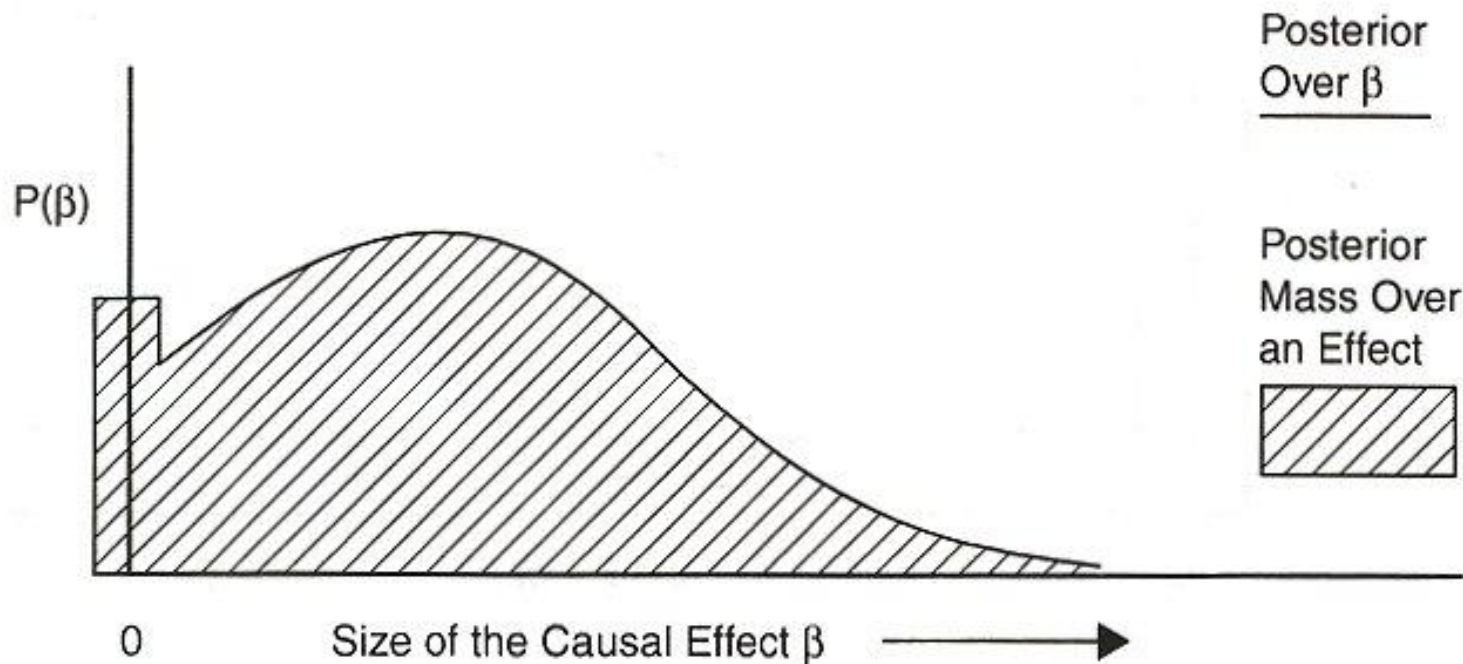
Synthesizing evidence for causation



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Example posterior for *equipoise and above*

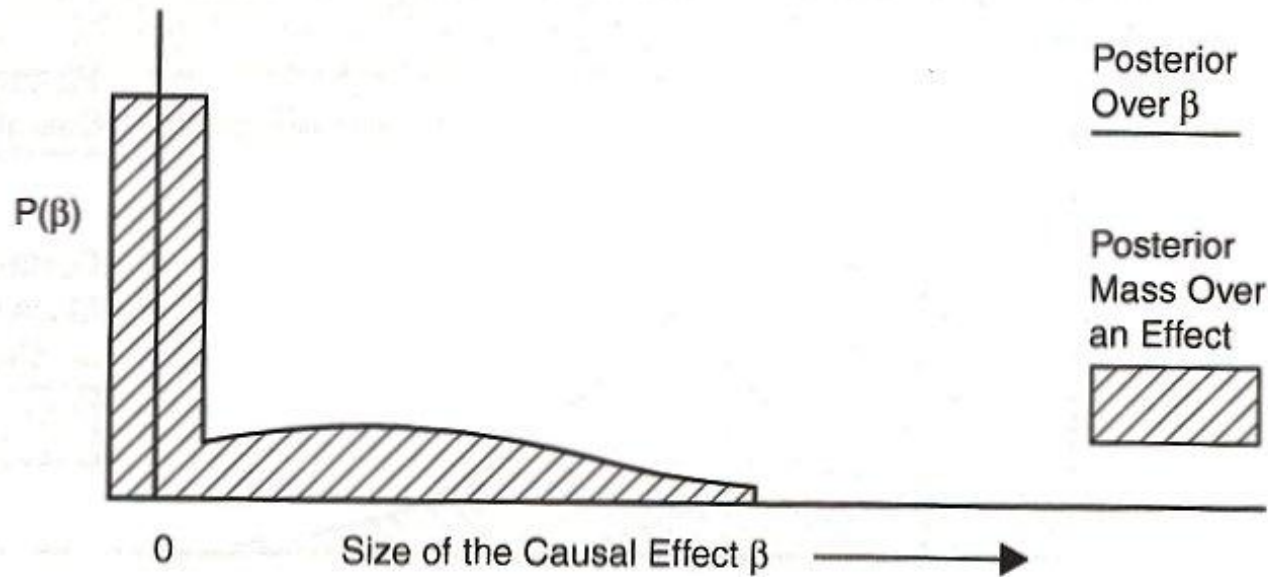
Synthesizing evidence for causation



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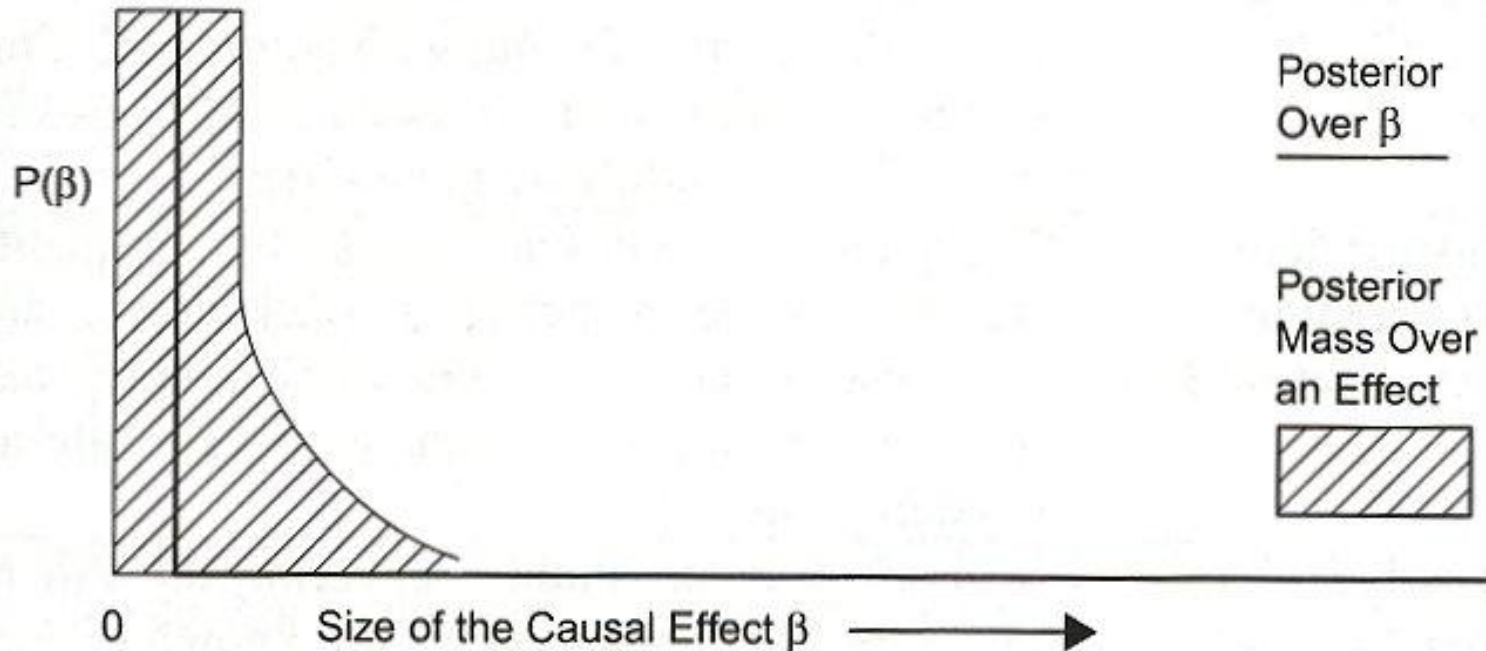
Example posterior for *below equipoise*

Synthesizing evidence for causation

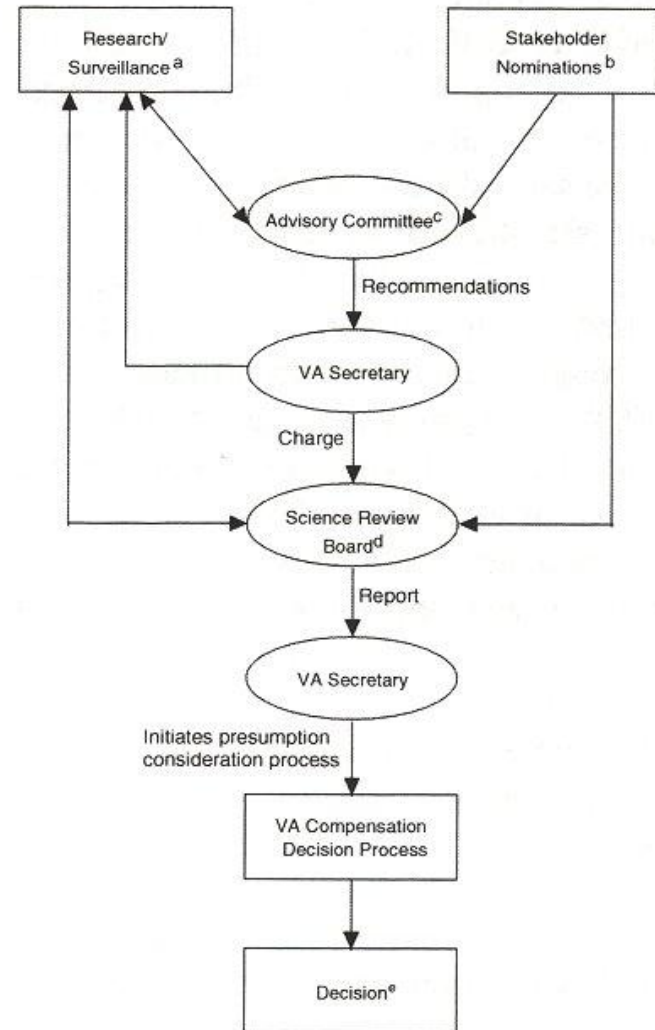
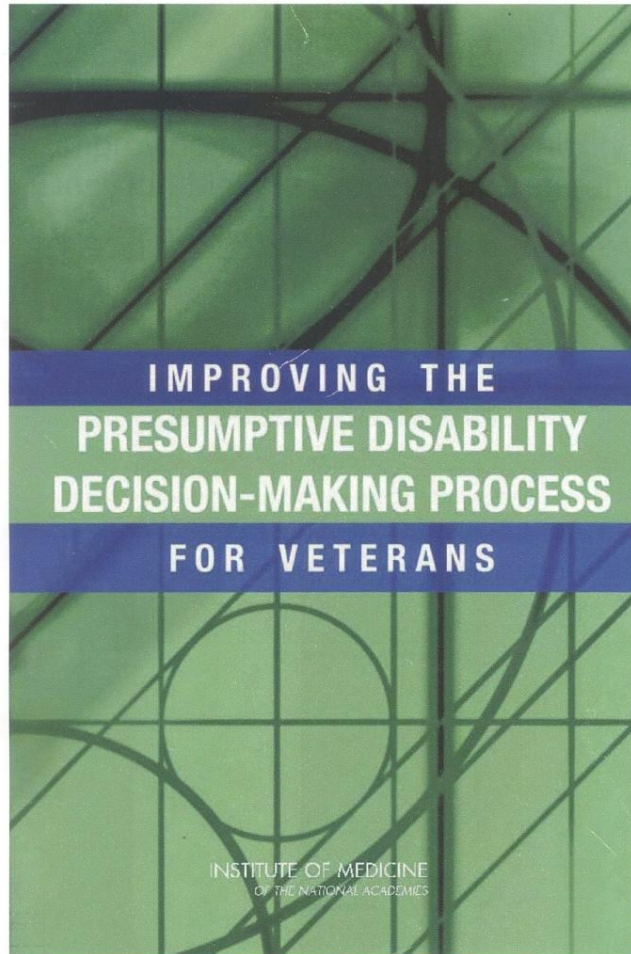


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Example posterior for *against* Synthesizing evidence for causation



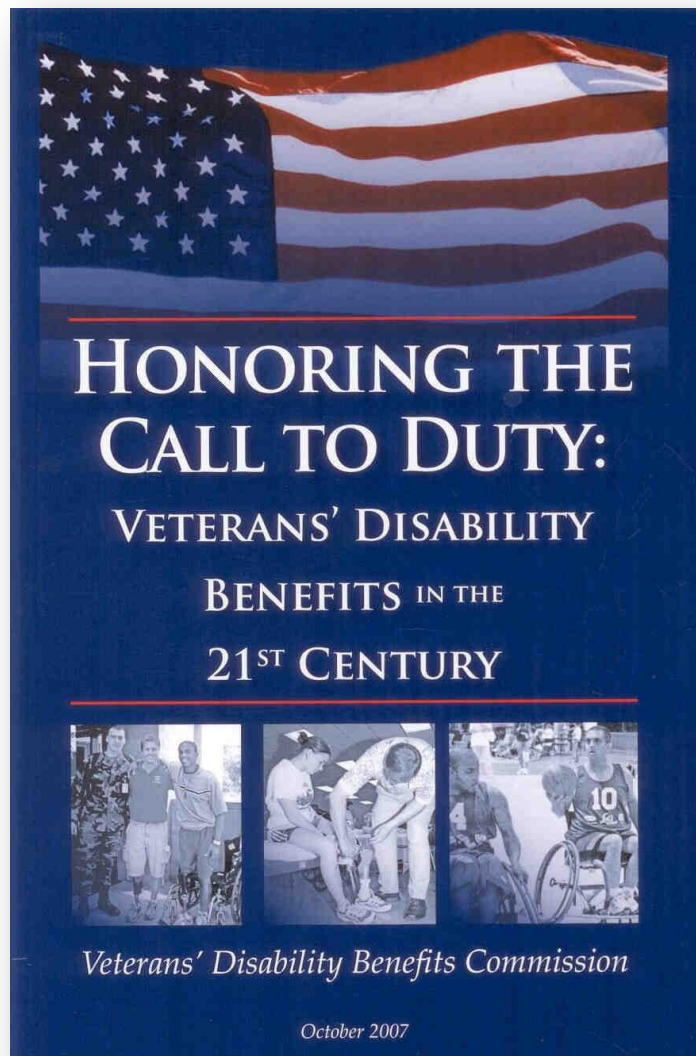
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IOM. 2007. *Improving the Presumptive Disability Decision-Making Process for Veterans*. Washington, DC: The National Academies Press.

Lessons Learned—Case Study

- Can identify elements of one existing process: Epi evidence to IOM to VA
- The identification of a framework provides an opportunity to assess it
- Prospective data collection needed
- New framework proposed to better use evidence
- Exploration of association vs causation and classification of strength of evidence



“Perhaps most importantly, the approach includes using a causal effect standard for decision making rather than a less-precise statistical association. The Commission endorses the recommendations of the IOM but expresses concern about the causal effect standard.”

Translating Evidence into Policy:

Lessons Learned from the Case of Lowering
the Legal Blood Alcohol Limit for Drivers

Slides attributed to American College of
Epidemiology Policy Committee

Overview

- Evidence of alcohol-impaired driving as a public health threat
- Examine the successful use of the processes of the Guide to Community Preventive Services to translate this evidence into policy
- Present valuable lessons learned that may be helpful to others seeking to translate evidence into policy

“In order to advocate effectively for lifesaving legislation, advocates must have clear and compelling scientific evidence to provide a basis for policy change. The combination of scientific research and advocacy efforts is key to success at the federal level, in state legislatures, and in communities across the nation... We weave research findings into every piece of our advocacy efforts.”

--Millie Webb, Mothers Against Drunk Driving

Alcohol-Impaired Driving: A Serious Public Health Problem

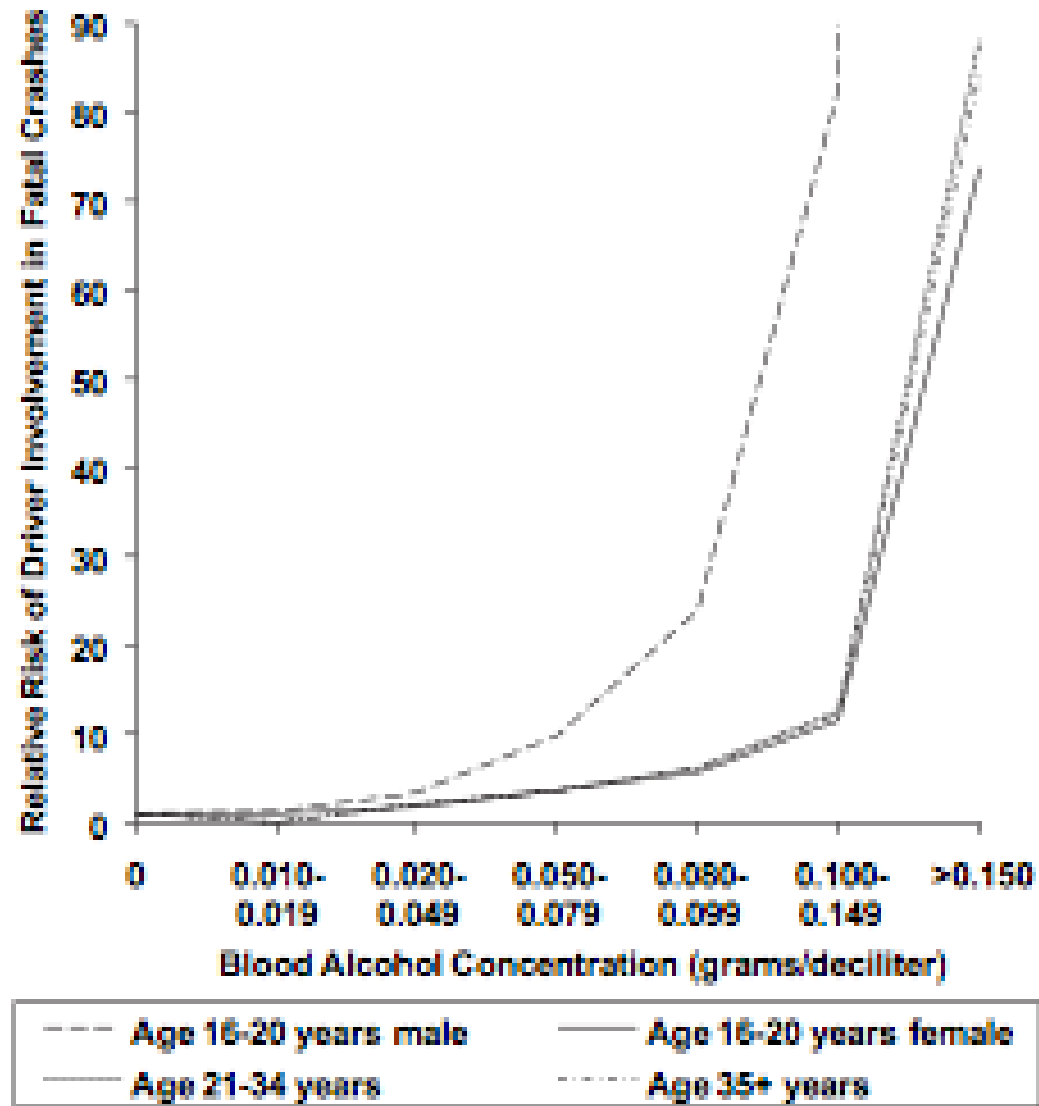
- 11,773 people were killed in alcohol-impaired driving crashes in 2008
- 1/3 of traffic related deaths involve alcohol-impaired drivers
- 224 children age 0-14 fatalities in 2008 involved alcohol-impaired driver
- 32 people in the US die daily in motor vehicle crash involving alcohol-impaired drivers
- More than \$51 billion spent on alcohol-related crashes in 2000

Blood Alcohol Concentration

- Alcohol-impaired driving fatality is a death resulting from a crash involving a driver with a BAC over the legal limit
- BAC measures the amount of alcohol in a person's bloodstream
- BAC measured in grams of alcohol per 100 milliliters of blood, abbreviated as g/dL
- Breath tests, blood or urine samples measure BAC levels

Evidentiary Rationale for BAC Laws

- 0.08 BAC law specifies illegal per se to operate a vehicle with a BAC of 0.08 g/dL or greater
- Older laws set limit at 0.10 g/dL
- lab and epi research demonstrates nearly all drivers are substantially impaired at 0.08 BAC
- impairments in braking, steering and lane changing begin at 0.02 g/dL
- As BAC increases, seat belt use drops, speed increases



Source: Zador P, Krawchuk S, Voas R. Alcohol-related relative risk of driving fatalities and driver impairment in fatal crashes in relation to driver age and gender: An update using 1996 data. J Stud Alcohol. 2000; 61: 387-395

0.08 BAC Policy Considerations and Decisions in the 1990s

- 1992 - NHTSA proposed all states adopt 0.08 BAC laws
- 1997 – only 15 states had 0.08 laws
- 2000 – 31 states had 0.10 BAC laws
- US with among the highest and most lenient legal limits for BAC in the world—2 or more times the level in Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Japan, the Netherlands, Norway, Portugal, Russia and Sweden

0.08 BAC Policy Considerations and Decisions in the 1990s

- 1998 legislation introduced which would have provided for sanctions for States that failed to adopt 0.08 BAC laws and that 0.08 BAC be included as a requirement for Basic Grants
 - Clinton Admin endorsed
 - but Conference Committee replaced with incentive grant program which provided \$500 million in grants over 6 years to states that had enacted and enforced 0.08 BAC laws

0.08 BAC Policy Considerations and Decisions in the 1990s

- As of 1999, seven published studies had examined the effectiveness of 0.08 BAC laws
 - NHTSA characterized the studies as establishing that 0.08 BAC was effective
 - General Accounting Office (GAO) raised methodological concerns, disputed 0.08 BAC effective in reducing severity and number of alcohol-related crashes

Building a Bridge Between Evidence and Policy

- Motor Vehicle Injury Prevention Team in the Division of Unintentional Injury Prevention worked to develop process that would be:
 - Impartial
 - Use rigorous methods to assess evidence on effectiveness of 0.08 BAC laws and other interventions in reducing morbidity and mortality from motor vehicle crashes
 - Produce and disseminate resulting policy-related recommendations
 - Selected Community Guide process
- Selected Community Guide process
 - Systematic reviews of the effectiveness of community-based public health interventions

Community Guide's Essential Group Processes

- Based on the principle that active participation by intended users in both the conduct and dissemination of systematic reviews increases the relevance and accessibility of the findings and recommendations to those user
- Coordination Team of 6-15 subject matter and methodologic experts who are involved in all decision making
- Consultation Team of subject matter experts provided consultation at key points in the review

Community Guide's Synthesis Methods

- Develop a clear intervention definition
- Research questions
- Logic model
- Search and screen for all available studies
- Evaluate quality of all candidate studies
- Detailed abstraction of qualifying articles, reports
- Generate evidence tables
- Summarize and synthesizing the results

Motor Vehicle Team Review

- Review of the effectiveness of state laws that lower BAC for motor vehicle drivers from 0.10 g/dL to 0.08 g/dL
- Assessed benefits, harms of intervention, barriers to implementation, economic efficiency, and applicability of the intervention to multiple settings and situations
- Considered the body of empirical evidence on 0.08 BAC laws as a whole rather than as a series of discrete studies

Motor Vehicle Team Review

cont'd

- Primary outcome: fatal injuries from alcohol-related crashes
- 12 studies, 10 included concurrent comparisons to control for threats to validity
- Pattern emerged when graphed, indicating lowering BAC limit to 0.08 was effective at reducing fatalities from alcohol-related motor vehicle crashes
- Potential to save 500 lives a year if implemented in all states
- Task Force issued recommendation that 0.08 BAC laws be implemented based on evidence

After the Task Force: from Evidence to Policy Action

- During congressional hearings on the Department of Transportation's 2001 Appropriations legislation, requests were raised about the effectiveness of 0.08 BAC laws in saving lives
- Non-Federal member of the Community Guide Motor Vehicle Consultation Team arranged systematic review findings be presented
- House and Senate approved Transportation Appropriations bill
- Clinton signed bill into law on October 23, 2000

Decision Making by Stakeholders of Policy Action

- New bill included provision that required states to enact 0.08 BAC laws by October 2003 or face losing funding for federal highway construction
- DUIP developed and implemented dissemination plan to:
 - Raise awareness of the systematic review results and Task Force recommendations among motor vehicle safety experts, law enforcement, public health professionals, and policy makers
 - Foster wider, third-party distribution of review findings through emails, listservs, newsletters, etc.
 - Facilitate evidence-informed decision making among stakeholders of legislative and policy action at state and local levels

Decision Making by Stakeholders of Policy Action

- DUIP identified stakeholders and partners and key audiences which which to share findings
 - Presentations national and international conferences
 - Leaders of NHTSA, Advocates for Highway Safety, Society for Public Health Education, Insurance Institute for Highway Safety, Mothers Against Drunk Driving
 - Distributed flyers and copies of the systematic review publications at key national and international public health and motor vehicle safety conferences and meetings
 - Governors Highway Safety Association mailed letters

Impact of Policy Actions

- By July 12, 2004, all 50 states had passed 0.08 BAC laws
- Community Guide findings and Task Force recommendation influenced federal Appropriations process, resulting in sanction for states
- Sanction influential in the state legislative processes
- Wide dissemination of findings and recommendations helped facilitate state legislative processes in the post-appropriation period

Impact of Policy Actions

- Other key government agencies, constituents, advocates, and voluntary and not-for-profit groups that helped diffuse and apply the results on a wider scale:
 - National Association of County and City Health Officials
 - New York State
 - US Department of Transportation
 - American Automobile Association Foundation
 - Insurance Institute for Highway Safety
 - International Council on Alcohol, Drugs, and Traffic Safety
 - United Kingdom's Health Development Agency
 - World Health Organization and World Bank
 - Global Road Safety Partnership
- NHTSA continues to highlight the Community Guide 0.08 BAC laws and related reviews on its website and in its educational training for enforcement officials

Lessons Learned

- Salience of the health problem and policy intervention, and the compelling relationships between the health problem, policy intervention, and health outcomes
- Use of systematic review methods to synthesize the full body of evidence
- Use of a recognized, credible, and impartial process for assessing the evidence
- Development of evidence-based policy recommendations by an independent, impartial body
- Ability to capitalize on readiness and teachable moments
- Active participation of key partners and intended users throughout all stages of the process
- Use of personalized channels, targeted formats, and compelling graphics to disseminate the evidence
- Capacity to involve multiple stakeholders in encouraging uptake and adherence
- Attention paid to addressing sustainability

Conclusions

- Study suggests value of preparing from the outset for and moving in a deliberate progression from:
 - Clearly outlining the relationships between health problems, interventions and outcomes
 - To systematically assessing and synthesizing the evidence
 - To using a credible group and rigorous process to assess the evidence
 - To having and impartial body make specific policy recommendations on the basis of the evidence
 - To being ready to capitalize on briefly opening policy windows
 - To undertaking personalized, targeted, and compelling dissemination of the evidence and recommendations

Conclusions cont'd

- Case study also highlights:
 - Importance of engaging key partners and stakeholders throughout production and dissemination of evidence and recommendations
 - Value of involving multiple stakeholders in encouraging uptake and adherence of policy recommendations and of addressing sustainability
- Lessons learned are actively being used by Community Guide to enhance dissemination and translation into action of evidence on the effectiveness of other policy interventions
- Lessons may help others working to translate epidemiologic and other forms of evidence into policy

Science, Prudence, & Politics:

The Case of Smoke-Free Indoor Space

Slides attributed to American College of
Epidemiology Policy Committee

Overview

- History of the development of evidence and policies related to secondhand smoke (SHS) exposure
- Tobacco industry opposition efforts
- Research agenda shaped by opposition
- Detail SHS policy in New York
- Discovery to delivery process illustrated
- Clear scientific evidence does not automatically lead to optimal policy

History of epidemiologic evidence on dangers of SHS

- Smoking permitted anywhere most of 20th century
- 1971 – first Surgeon General's Report proposed government ban on smoking in public places in response to the risk of smoking and pregnancy
- 1972 – Surgeon Generals Report identifies SHS exposure as health risk

History of epi evidence cont'd

- Studies link SHS exposure to increased risk for illness including respiratory illnesses in infants and children
- 1981 – Hirayama et al. study documents higher lung cancer rates in Japanese women married to smokers than those married to non-smokers
- 1986 – Surgeon General's Report states that SHS causes lung cancer in non-smokers

History of epi evidence cont'd

- 1992 – EPA concluded exposure to SHS is serious public health threat and classified SHS as Group A carcinogen
- 1994 – Fontham study, noted for size and rigor, confirmed SHS exposure threatens health
- 2006 – Surgeon General report made it clear that SHS causes lung cancer, heart disease, other illnesses in non-smokers

Policies to limit SHS exposure

- 1975 AZ, CT, MN implement first policies requiring smoke-free public spaces
- After 1986 Surgeon General's Report wave of smoke free policies began to gain momentum
- 1995 CA became first state to require smoke-free restaurants, policy expanded to bars in 1998

Policies to limit SHS exposure

- Today over 3,000 jurisdictions have smoke-free workplace, restaurant, or bar laws
- Half of U.S. lives in a municipality or state with indoor public space smoke-free law
- Policies rest on principle that workers should not be required to inhale toxic substance
- Smoke-free spaces progress would not be as successful if not for epidemiologic

Opposition Efforts

- 1950s tobacco industry began opposition efforts
- Tobacco industry repeatedly tried to dispel notion that SHS causes disease
 - Funded efforts that counter research, instill doubt
 - 1992 EPA decision and likely OSHA consequences prompted strong tobacco industry campaigns, organized to promote their findings as “sound” and other evidence as “junk”

Opposition Efforts

- Worked to strengthen the evidence and support smoke-free policies
- Arguments that the public did not support these policies, enforcement of policies would be difficult, that businesses would suffer were all were defeated
- Debate then turned to public health versus private rights

How much evidence is enough?

- Evaluation of potential for harm inevitably associated with some uncertainty
- Amount of evidence necessary to motivate action differs by purpose
- According to Gostin's multiple step model, the level of risk needed to justify an intervention depends upon the potential burdens that intervention places on society

How much evidence is enough?

- Evidence demonstrating the harm of SHS exposure increased the need for policies to reduce exposure and harm
- There was need for further research on unintended consequences of smoke-free policies
- Research demonstrating the economic impact of such policies helped facilitate their implementation
- Thus, epidemiological evidence, generated by careful assessment, helped usher in smoke-free policies

New York State

- Smoke-free indoor workplaces except restaurants and bars during the 1990s
- Introduction of bill to ban smoking in dining areas of restaurants with 50 + seats
- 3 public hearings and small modification (35 fewer seat restaurants exemption) helped pass the bill
- Bill effective April 1995

New York State

- Arguments which supported smoke-free law:
 - SHS is health hazard
 - Current law does not protect workers, patrons from SHS
 - Law would have no adverse economic impact on restaurants
- Opponents shifted argument to new issues:
 - Ban would be bad for business
 - Law was unnecessary, unfair, impossible to enforce

New York State

- Only one published study on economic outcomes of smoke-free laws and it concluded there were no adverse effects
- No published studies on compliance issues
- Testimonials demonstrated support for smoke-free law and that little additional resources would be necessary to enforce the law
- Other major areas of the state adopted similar laws, leaving the state with patchwork of legislation

- Studies showed people supported the law, little expense associated with adoption of new law, and that business actually benefited from law
- Demonstrating SHS poses risk, proposed policy solution has greater benefits than burdens was just first step
- Follow-up studies strengthened evidence showing SHS policy and health promotion
 - Hospitality workers had lower urinary cotinine levels after ban
 - Fewer hours of total SHS exposure and less sensory irritation

Discovery to Delivery Process

- Epi evidence alone did not fuel policy change
- Advocates and communication campaigns were key in the fight against opposition voices
- Smoke-free air advocacy from grassroots coalitions to national organizations also contributed to efforts
- Thus implementation and dissemination research is important area of training for future epidemiologists

Discovery to Delivery Process

- Strong scientific evidence can drive healthy public policy
- Slow translation from discovery into delivery
- Reconnect policy scientists to epidemiologists
- Committed leadership and advocacy are essential
- Media campaigns and well constructed messages

Lessons Learned

- Need for epidemiological evidence and inquiry remains even after a policy goal has been achieved
- Community-based dissemination and implementation research is necessary
- The best and most necessary research questions do not always come from epidemiologists
- There is a need for epidemiologists to work with other researchers across disciplines
- Anticipate and address the opposition
- Focused, well-organized advocacy is needed to translate even the strongest epidemiological evidence into policy change
- Train future epidemiologists to engage and interact with public health advocates, practitioners, and policy makers.

Conclusions

- Epidemiologists working on the forefront of translating other risk prevention areas can learn from barriers faced and successes achieved by SHS policy
- Working locally with those outside of the discipline of epidemiology is essential
- Science is not the only factor considered
- Opposition to public health policies can be very effective, so answering opposition must be dynamic, iterative endeavor
- Continuous, ongoing, and local policy evaluations are important to spread effective and protective policy initiatives

Translating Epidemiology into Action: Towards a Research to Policy Framework

The Case for Promoting Physical Activity in School Settings

Slides attributed to American College of
Epidemiology Policy Committee

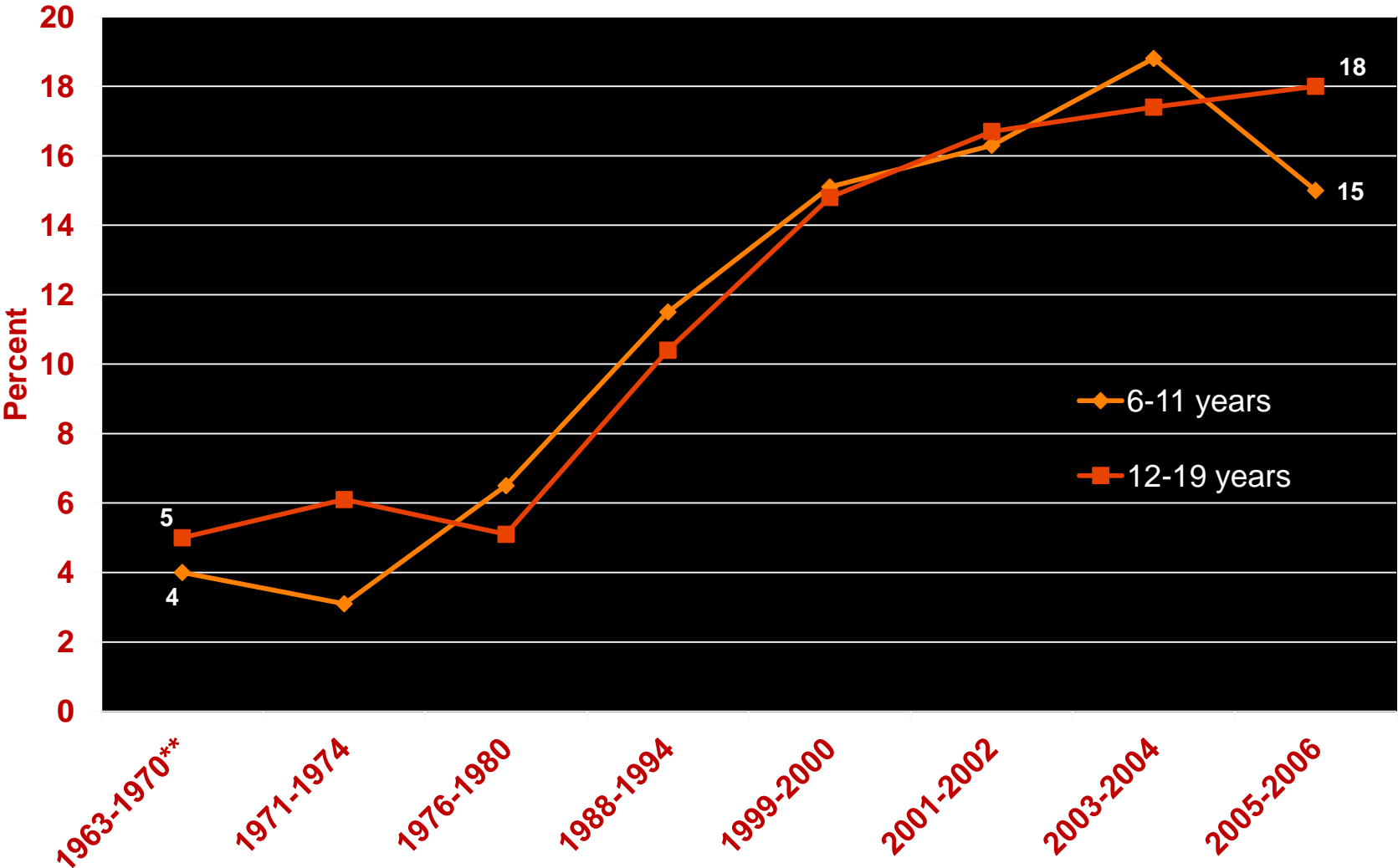
Presentation Overview

- Brief overview of childhood obesity and physical inactivity/activity trends
- Ecological framework for promoting physical activity
- Relevance of epidemiologic data throughout the policy making process using physical activity/education examples
- Opportunities for continued study

Childhood Obesity and Physical Inactivity

- During past 3 decades, obesity rates tripled among U.S. children and adolescents
- 16% of children and adolescents aged 2-19 are obese
- Obesity causes numerous chronic diseases
- Only 1/3 of high school students meet recommended levels of physical activity

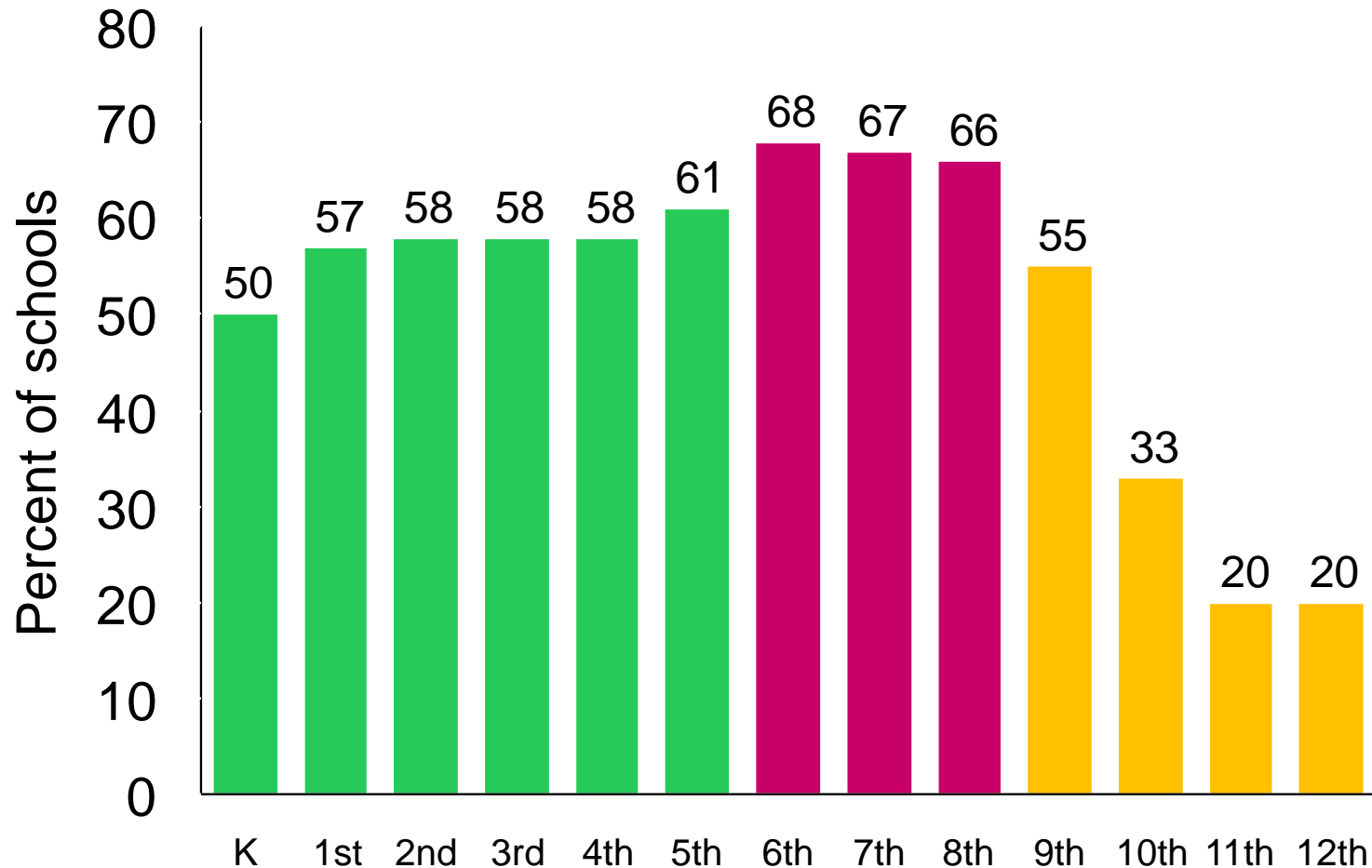
Overweight U.S. Children and Adolescents, 1963-2006*



***1963-1970 data are from 1963-1965 for children 6-11 years of age and from 1966-1970 for adolescents 12-17 years of age.*

Source: CDC, National Center for Health Statistics

Physical Education Requirements by Grade, 2006*

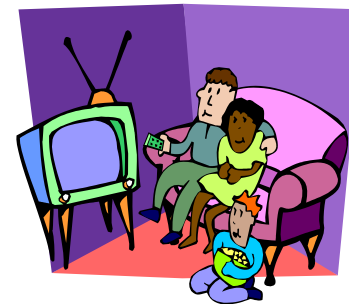


*Among schools that had students in that grade.

Source: CDC, School Health Policies and Programs Study 2006

Physical Inactivity

- Increase in TV, Internet, Computer Use
- Physical activity declines steadily during adolescence.
 - MMWR, CDC Guidelines, 1997
- Only 36% of kids in the US have daily PE class
- Only $\frac{1}{2}$ of all American youth regularly participate in vigorous physical activity
 - Youth Risk Behavior Survey



“No Child Left Inside”

Nature programs' goal: No child left inside

Updated 11/22/2006 8:16 PM ET

E-mail | Save | Print | Reprints & Permissions



By Wendy Koch, USA TODAY

A back-to-nature movement to reconnect children with the outdoors is burgeoning nationwide.

Programs, public and private, are starting or expanding as research shows kids suffer health problems, including obesity, from too much sedentary time indoors with TV and computers.

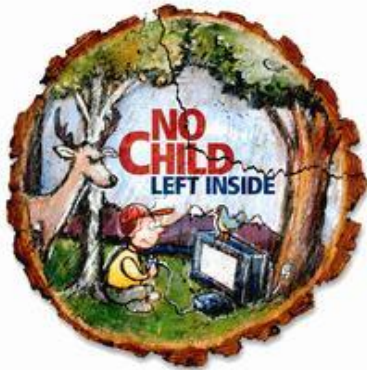
NATURE CALLS: Group aims to 'plant seeds' with youth




Enlarge

AFP 2002 file photo


President Bush autographs the shirt of London Smith, 7, as she sits in a canoe, with (from left) Toraine Clark, Jamar Crawford and Tareeq Turner during a fitness expo on the White House's South Lawn. The children belong to the Wonderful Outdoor World program, a program that takes urban





"There's a increasing Woods: Sa 2005 book studies sh depression



**CT DEPARTMENT OF ENVIRONMENTAL PROTECTION**

SEARCH

OUR STATE PARKS

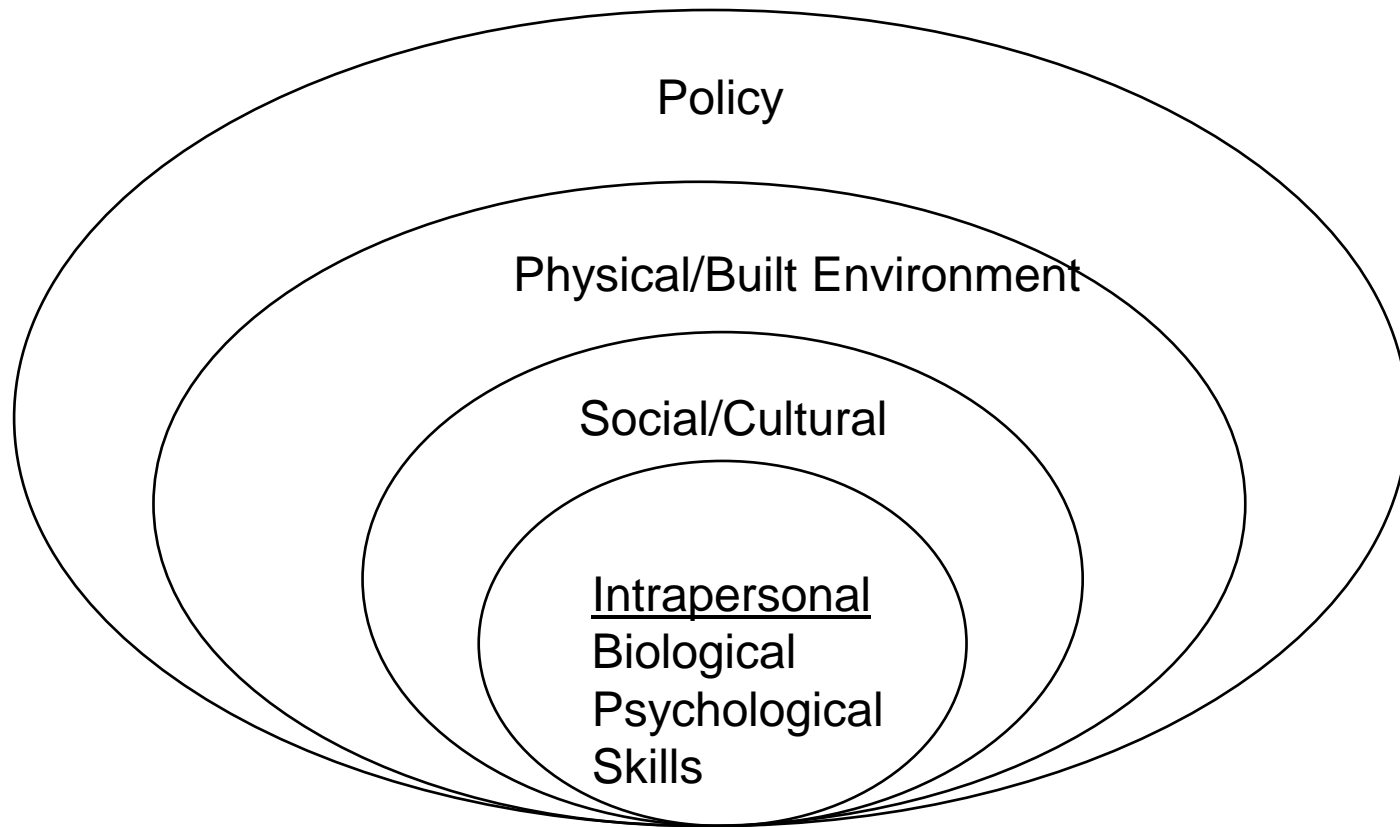
GREAT ACTIVITIES

LEARN MORE



Welcome to "No Child Left Inside," a special initiative of Connecticut Governor M. Jodi Rell, coordinated by the Connecticut Department of Environmental Protection to encourage Connecticut families and visitors alike to enjoy all the recreational resources and outdoor activities available in Connecticut's state parks, forests and waterways. From Kent Falls in Kent to Stratton Brook in Simsbury to Fort Trumbull in New London, it's time to discover the great outdoors!

An Ecologic Approach to Promoting Physical Activity



Relevance of Ecological Models for Physical Activity

- Changes to the school-related PA policies often emanate from state/school district policies:
 - Changes in state law requiring a specific amount of time for physical education
 - District/school policies requiring that elementary students be provided recess for 20 minutes daily

Physical activity-related policymaking cannot wait for “perfect” information

- Inverse evidence law/conducting RCTs not practical with policy interventions
- Models that weigh risks and benefits are first step
- Consider harm from inaction as well as action

Data needs vary based on the stage of the policy making process: Examples from school-based physical education policymaking

Policy Stage	PA-related example	Relevance of Epidemiologic Data
Agenda setting	Statewide data indicate high levels of sedentary behavior among youth which is related to increased obesity	HIGH
Policy formulation	Various school-based PE/PA policy options considered	HIGH
Policy adoption	State law adopted based on evidence reviewed in formulation stage requiring minimum time requirements for PE class time (150 mins/week ES; 225 mins/week MS/HS)	Limited
Policy implementation	School districts/schools implement minimum PE time	Limited
Policy evaluation	Impact of new PE time req. evaluated	High
Feedback loop	Evaluation informs ways to expand upon PE time law and other options for increasing PA time	Moderate-to-High

Analytic Tools to Inform Policy Interventions for PE in Youth

- Systematic reviews, economic evaluations, and health impact assessments
 - *Guide to Community Preventive Services* (the *Community Guide*)
www.thecommunityguide.org
- Provide efficient way to indentify, assess and present relevant research findings
- Follow an explicit set of decision rules
- Yet many existing reviews have lacked a focus on external validity

School-based PE Curricula and Policy



Effective School-Based PE

Recommendations from the *Community Guide*

- Increase in minutes of PE
- Inclusion of moderate or vigorous activity in PE class
- Specification of PE teacher certification or professional development
- Inclusion of environmental enhancements (facilities, equipment)
- Adaption of interventions to specific target population

Coordinated Approach To Child Health

CATCH



CATCHTexas.org
CATCHInfo.org

Lessons Learned

- Enhance the focus on external validity
- Understand that policymaking is political
- Better articulate the factors that influence policy dissemination
- Build transdisciplinary teams for policy progress

Possible Next Steps

- Develop new ways of capturing data on external validity (to ensure it's generalizable beyond just the study at hand)
- Develop a process/mechanism that better engages researchers and policy makers so they understand each other's language
- Engage policy makers more fully in the debate to understand how evidence could be better presented for their use
- Support pilot projects that bring together transdisciplinary teams

Conclusion

- Policy changes recommended to address childhood obesity and physical inactivity
 - Recommendations often not put into action
- Lessons learned illustrate key issues for practitioners, policy makers, and researchers

Epidemiology in Health:

Policy, Regulation and Law

Slides attributed to Patricia Hartge, Sc.D., M.A.

Question

What are the best ways for epidemiology to inform laws, regulations, and policies to improve health?

- Seen from the epidemiologist's perspective
- Using four case studies
- American College of Epidemiology project

John Snow Cholera Research



Epidemiology

- Epi (upon) dem(people)
- **Epidemiology** is the study of factors affecting the health and illness of populations
- Randomized trials, prospective cohorts, case-control studies, cross-sectional surveys, population trends, maps and patterns, clinical series, case-reports and anecdotal data

Lessons in Brief

- Use the right mix of research
 - Epidemiology: effect of an exposure on health
 - Policy research: effects of policy itself, “natural experiments”
- Recognize constraints and costs
 - Possible health gains will be balanced against them
- Recognize that policy is politics
 - It ought to be
 - Legal, financial, cultural context dominates
- Study the process by which epidemiology affects policy
 - Conduct it, weight it, summarize or synthesize it
 - Expect to use teams with many disciplines

Childhood Obesity



<http://www.topnews.in/files/Michelle-Obama-ring4.jpg/>

<http://www.sbs.com.au/documentary/resize/index/id/1086/w/627/h/352/>

http://www.france24.com/en/files/imagecache/aef_ct_article_image/article/image/20100210-michelle-obesity-m_0.jpg

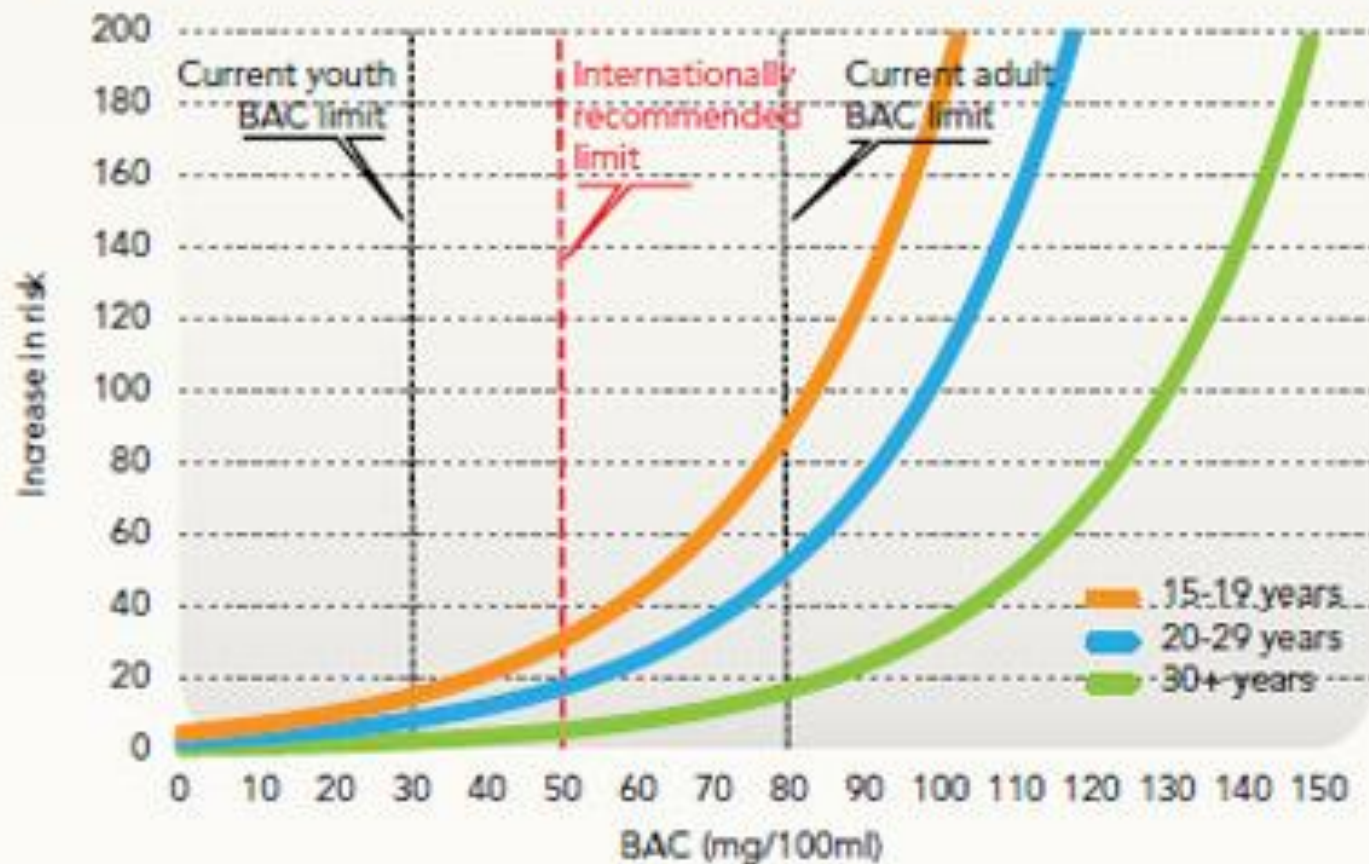
Physical Activity & Childhood Obesity

- Choosing the goal (“endpoints”)
 - Obesity
 - Energy intake
 - Physical activity
- The role of evidence
 - Acting with limited evidence, gathering more
 - Considering costs and benefits
 - Key analytic tools: systematic reviews
- The role of advocates

Drugs, Alcohol and Fatal Crashes



Figure 8: Relative risk of fatal crash by blood alcohol level



Lowering Blood Alcohol Limits

- Epidemiologic data shows the problem
 - Curves, continuous data always challenging
- Policy changes create natural experiments
 - Powerful evidence: lives saved
- Advocacy critical
 - Needs relevant evidence
 - Systematic reviews, expert opinions helped

Ban on Smoking in Bars



Secondhand Smoke Bans

- The importance of evidence on causation
 - The powerful role of critics
- When evidence does not motivate action
 - Understand the hurdles
 - Therefore: study the costs
- Persuasiveness of local data
- Policy evaluation, akin to epidemiology

Veterans Compensation



Compensation of Veterans for Injuries

- High-stakes decisions with multiple exposures
- Expert panel syntheses key
- Association or causation
- Populations or individuals
- Uncertainty and probability

Mammography Guidelines



Mammography Guidelines

- Long history or research and revision
- Intuitively, screening must help
 - Can epidemiologists explain it better?
 - Do we pull our punches on harms?
 - Could communications plan and timing have mattered?
- Strong constituencies, market forces

Over The Counter DNA Testing

NEWS | LOCAL BEAT

Over The Counter DNA Test Coming To a Walgreens Near You

By VICKY NGUYEN

Updated 6:34 AM PDT, Wed, May 12, 2010

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San Diego-based Pathway Genomics will start selling its "Insight" personal genetic testing kits in Walgreens nationwide this Friday.

Just spit and send. The kits cost \$20 to \$30. For another \$250, you can get a detailed report that shows whether you have the genetic markers for more than 70 different diseases, including Parkinson's

Over-the-Counter DNA Test

- Clarifying FDA role; diagnosis and risk prediction
- Scientific data on limited benefits accruing rapidly but...
- High public interest

President's Cancer Panel

- Basis of synthesis
- Body of evidence
- Evaluators

Cancer Panel: Chemicals 'Grossly Underestimated' as Carcinogens

POSTED: 05/12/10

FILED UNDER: ENVIRONMENT, WOMAN UP, LOBBYING, MEDICINE

21 Comments + [Join the discussion »](#)

TEXT SIZE: A A A PRINT  SHARE 



Pat Sullivan, AP

Just as we're once again treated to the sight of volunteers scrubbing oil off wildfowl (ah, memories), along comes the President's Cancer Panel report that says we're being polluted to death.

12 tweets

retweet

Get the new PD toolbar!

And I quote: The "true burden of

environmentally induced cancer has been grossly underestimated." According to the report, "more than 80,000 chemicals are in use, and 1,000-2,000 new chemicals are created and introduced into the environment each year." Only a few hundred have been tested for safety.

Says [The Washington Post](#), "The current system places the burden on the government to prove that a chemical is unsafe before it can be removed from the market. The standards are so high, the government has been unable to ban chemicals such as asbestos, a widely

Cell Phones and Brain Cancer



Cell Phones and Brain Cancer

- Body of evidence no effect
- Long-awaited additional data published
- Cultural context alters reactions
 - France: precautionary principle

Vogue magazine, July 2010

Wake-up CALL

WITH RECENT RESEARCH RAISING QUESTIONS ABOUT THE DANGERS OF CELL-PHONE RADIATION, ESPECIALLY TO CHILDREN, ROBERT SULLIVAN WONDERS WHY MORE PEOPLE AREN'T LISTENING. PHOTOGRAPHED BY NICK KNIGHT.

Faced with the daunting task of replacing my cell phone the other day, I marveled at the options: Am I the only person left on the planet who just wants a phone to call ahead for dinner reservations? Won over by the salesperson, I bought the Black Berry Tour. When I got home and paged through the directions, my eyes began to glaze over until I came to the part about exposure to radio-frequency signals. According to the instructions, I should hold the phone *away* from my ear and avoid letting it even touch my head—about an inch away, in fact. (It also says, almost comically, “reduce the amount of time spent on calls.”)

This seemed counterintuitive to me—don't you put a phone to your ear? The idea also surprised David O. Carpenter, M.D., director of the Institute for Health and Environment at the State University of New York at Albany. Carpenter first learned of the recommendation while at a hearing on cell-phone safety in the Maine state legislature this past March. A man who was testifying happened to mention that manuals suggest keeping some space between you and your phone. “I didn't know that, and I don't think anybody knows that,” Carpenter said.

That is about to change as politicians, researchers, and public-health officials are once again grappling with questions

about the effects of radio-frequency radiation, the kind emitted by wireless devices. For years the cell phone–safety debate has seemed stalemated: The Food and Drug Administration and the Federal Communications Commission have said that cell phones are safe or, more specifically, that they have not been proven to be harmful. “The weight of scientific evidence has not linked cell phones with any health problems,” reads the FDA's statement. The cell-phone industry has concurred. But mounting evidence of the possible adverse effects of cell-phone radiation in Europe and in Israel has spurred some state legislatures in the United States to take precautionary action. In California, a proposed bill would require cell-phone manufacturers to prominently display the amount of radiation a phone emits, along with the price and other features. (Currently, you have to wade through the manuals or surf the FCC's Web pages to find this information.) In Maine this past spring, a legislator went even further, introducing a bill to require cell-phone manufacturers to put a safety warning in the packaging, similar to the one on cigarette packs, stating that the radiation emitted by the phone has been linked to cancer.

In each case, the cell-phone industry has marshaled forces to resist the legislation, claiming that the warnings are unnecessary. In Maine, the bill was changed under pressure from the cell-phone

CHILD'S PLAY

Many children see cell phones as toys, but concerns about safety persist. *Sittings Editor: Phyllis Posnick.*



INTERPHONE STUDY

Commentary: Call me on my mobile phone...or better not?—a look at the INTERPHONE study results

Rodolfo Saracci^{1*} and Jonathan Samet²

¹Istituto di Fisiologia Clinica (IFC), National Research Council, Pisa, Italy and ²University of Southern California, Department of Preventive Medicine and USC Institute for Global Health, Los Angeles, CA, USA

*Corresponding author. IFC-National Research Council, Via Trieste 41, 56100, Pisa, Italy. E-mail: saracci@hotmail.com

Accepted 12 April 2010

Mobile phone (cell phone) use is increasing extraordinarily rapidly worldwide. There are now 4.6 billion mobile phone subscribers worldwide.¹ In many low- and middle-income countries use of cell phones has made communications possible in vast areas lacking cable connections. Increasingly, in high-income countries, cell phones have replaced 'land lines' for personal telecommunications. Users of mobile phones are exposed to electromagnetic radiation, which has long been hypothesized to have adverse health effects, including increased risk of cancer.^{2,3} Research on biological mechanisms of cellular and tissue injury by electromagnetic radiation has been inconclusive, and consequently epidemiological studies have been the principal source of evidence on potential health risks of mobile phone use. Brain tumours have been of particular concern because the electromagnetic radiation generated by mobile phones passes through the brain when the phones are used without a hands-free device. To date, findings of diverse studies on mobile phone use and brain tumour risk have been reported with mixed findings, but with no clear indication of increased risk for cancer.^{4,5} To provide needed evidence on the potential risk of brain cancer associated with mobile phone use, the International Agency for Research on Cancer (IARC) initiated a multi-centre case-control study, the INTERPHONE study, in 1998–99.

A much awaited report from this large international study on mobile phone use and brain tumours is published in this issue of the *IJE*.⁶ A number of previous papers cited in the article reported only partial findings from components of the multicentre study, heightening expectations on what the full data set would eventually show. The component studies were relatively underpowered, but they exhibited a rather consistent and baffling *reduced* risk among cell phone

users. We now have the complete results and the researchers' interpretation of them. The INTERPHONE investigators conclude that 'There were suggestions of an increased risk of glioma, and much less of meningioma, at the highest exposure levels, for ipsilateral exposures and, for glioma, for tumours in the temporal lobe. However, biases and errors limit the strength of the conclusion we can draw from these analyses and prevent a causal interpretation'.⁶ This statement, as with a similar one ('...these biases and errors prevent a causal interpretation of the results.') at the end of the Appendix 2 of the article⁶ added during the editorial process of revision, is both elegant and oracular. Similar to any oracle it tolerates diametrically opposite readings. If more weight is given to the first sentence, a conclusion is reached in favour of an increased risk, albeit not definitively manifest yet, from intensive use of mobile phones. Giving more weight to the second sentence leads to the conclusion that there are enough sources of errors in the study to dismiss the apparent elevated risks as not real. With equal weight to the two sentences, any conclusion hangs in the balance.

Is there any way out of this ambivalence? INTERPHONE is the largest study yet carried out and published on mobile phone use and cancer. It includes 2409 cases of meningioma, 2708 cases of glioma and two series of, respectively, 2662 and 2972 controls matched by age, sex and region of residence. With the coordination of IARC it has mobilized investigators in multiple centres within 13 countries '...to determine whether mobile phone use increases the risk of [brain] tumours and, specifically, whether radiofrequency energy emitted by mobile phones is tumorigenic'.⁶

Certainly this is the question that scientists, people and public health decision-makers have in mind, as

patterns of reduced risk, would have a by chance. Having a study of a protective biological evidence—of bias from a variety of most likely explanations—already noted,⁸ this a probable consequence of the study sources of bias are quantified. The bias as an example several routes. The rate appreciably for centres: 53%) % for meningioma sample of participants in 11 centres) who respond to a brief and controls, lifetime prevalence rates. Since the par- lower than among he request for par- quency of regular an among cases. his sample to the chers estimated^{6,9} bias may have led alar use of 5–15%, the bias observed glioma [21%, 95% glioma (19%, 95% rd and generalized ease in risk would f statistical signifi- e with the highest is been observed in e top decile of cu- ehensive metric of ly underestimated d 1.40 for glioma in the top decile of ≥ 1640 h, still /s pattern: spread f this category is ensitivity analyses x 1 of the article⁶) e fairly consistent further increased d 1.96 for glioma) g the phone on the stematically higher use, even at low ing bias and casts

awaiting the re- ll be disappointed ling a precaution- nanner of use of rt in the elevated hest exposures. ing for more re- quitious use of n and the indica- the INTERPHONE increase risk for minimize selection d previously by of mobile phone d via company through record ge cohorts would rain cancers that order of 10 per tage is that once ly followed up in nts in cases and a of investigation atrol studies con- as elapsed since the emergence of s. This approach ough litigation.¹⁴ dic replication of comparable with although the po- registries are in ie world and de- occurrence can be going analyses to eased risk from is needed' fully ore research the ability of cancer n unanswered. ablication charges qual parts by the in Epidemiology nia. aracci is Visiting raining section of arch on Cancer, ientific Advisory celona. Jonathan ientific Advisory ona.

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hone use and
cohort. *J Natl*

l. Prior hospi-
e and subse-
ker *Epidemiol*

n C. Risks of
mobile phone
t study. *PLoS*

er NA. Utility
epidemiologic
ology 1996;7:

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Brain tumour risk in relation to mobile telephone use: results of the INTERPHONE international case-control study

The INTERPHONE Study Group*

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*List of members of this study group is available in the Appendix.

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Background The rapid increase in mobile telephone use has generated concern about possible health risks related to radiofrequency electromagnet-

Conclusions Overall, no increase in risk of glioma or meningioma was observed with use of mobile phones. There were suggestions of an increased risk of glioma at the highest exposure levels, but biases and error prevent a causal interpretation. The possible effects of long-term heavy use of mobile phones require further investigation.

lifetime number of phone calls and nine deciles of cumulative call time. In the 10th decile of recalled cumulative call time, ≥ 1640 h, the OR was 1.40 (95% CI 1.03–1.89) for glioma, and 1.15 (95% CI 0.81–1.62) for meningioma; but there are implausible values of reported use in this group. ORs for glioma tended to be greater in the temporal lobe than in other lobes of the brain, but the CIs around the lobe-specific estimates were wide. ORs for glioma tended to be greater in subjects who reported usual phone use on the same side of the head as their tumour than on the opposite side.

Conclusions Overall, no increase in risk of glioma or meningioma was observed with use of mobile phones. There were suggestions of an increased risk of glioma at the highest exposure levels, but biases and error prevent a causal interpretation. The possible effects of long-term heavy use of mobile phones require further investigation.

Keywords Brain tumours, mobile phones, radiofrequency fields

Los Angeles Times

LA Times, May 17, 2010

No answer from cellphone study

Research on a link between use and brain cancer is inconclusive.

ASSOCIATED PRESS

GENEVA — A major international study into the link between cellphone use and two types of brain cancer has proved inconclusive, according to a report scheduled to be published in a medical journal Tuesday.

A 10-year survey of almost 13,000 participants found most cellphone use didn't increase the risk of developing meningioma — a common and frequently benign tumor — or glioma — a rarer but deadlier form of cancer.

There were "suggestions" that using cellphones for more than 30 minutes a day could increase the risk of glioma, according to the study by the World Health Organization's International Agency for Research on Cancer. But the authors added that "biases and error prevent a causal interpretation" that would directly blame radiation for the tumor.

Longer call times appeared to pose a greater risk than the number of calls made, the study found.

Among the factors that weren't examined were the effects of using hands-free devices during calls or the risk of having cellphones nearby while not making calls — such as in a pocket or next to the bed at night.

The authors acknowledged possible inaccuracies in the survey because participants were asked to remember how much and on which ear they used their mobiles over the last decade. Results for some groups showed cellphone use appeared to lessen the risk of developing cancers, something the researchers described as implausible.

The authors said further investigation was necessary before they could conclude with certainty that there was no link between cellphone radiation and brain cancer, partly because people's use of the devices has changed considerably since the start of the study in 2000.

Scientists are also planning to examine whether cellphone use increases the risk of tumors in the ear's acoustic nerve and the parotid gland, where saliva is produced. A separate study will look into the effects of cellphone use on children.

The paper, which will be published in the International Journal of Epidemiology, was compiled by researchers in 13 countries including Britain, Canada, France, Germany and Japan, but not the U.S. Scientists interviewed 12,848 participants, of which 5,150 had either meningioma or glioma tumors.

Almost a quarter of the \$24 million required to fund the study was provided by the cellphone industry, though the World Health Organization said measures were taken to protect the scientists' independence.

THE WALL STREET JOURNAL.

WSJ.com

MAY 28, 2010, 9:46 PM ET

Static In Search for Cellphone-Tumor Link

My [print column](#) this week examines a long-term [study of cellphone use](#) meant to examine whether it causes brain tumors. Reading press reports about the research was confusing; the study either concluded that there was no risk, or that the study was inconclusive, or that there was some risk.

"This perhaps speaks to the oracular nature of the findings," said Jonathan Samet, professor of preventive medicine at the University of Southern California, who commented on the study in [an accompanying editorial](#).

That's consistent with prior research that also hasn't firmly determined whether holding a cellphone to one's head while talking into it is risky behavior. "It's unfortunate that we're so far into the adoption of this technology and we know so little about the long-term effects — or about the short-term effects for that matter," said Joel Moskowitz, director of the Center for Family and Community Health at the University of California, Berkeley.

The new study was of a type called case-control, though the term control is a bit confusing. In a study of a pharmaceutical company's new drug, people who receive the drug are compared with those who don't — a control group, in which what varies is the input. But brain cancer is so rare — about six diagnoses for every 100,000 Americans each year — that the study would have to enlist an enormous number of volunteers to identify small differences in cancer rates. That, or using cellphones would have to have a big effect on cancer rates, akin to smoking's impact on lung cancer. "You can do a really lousy job [with a study] and still find out that smoking causes lung cancer," said Dan Wartenberg, professor of environmental and occupational medicine at Robert Wood Johnson Medical School.

TIME magazine,
May 31, 2010

Briefing
Spotlight
TIME

The results “tell us that the question as to whether mobile-phone use increases risks for brain cancers remains open,” wrote epidemiologists Rodolfo Saracci and Jonathan Samet in an accompanying editorial.

Still waiting The Interphone report fails to answer questions definitively

IT HAS BECOME ONE OF THE MORE CONTROVERSIAL questions in cancer medicine: Can cell-phone use cause brain tumors? The mobile-phone industry and the U.S. government have maintained that there is no scientific data to support a link between cell-phone radiation and cancer, but some scientists are skeptical, suggesting that what evidence *does* exist is enough to warrant a warning to consumers before serious harm is done. Enter Interphone, a \$24 million long-term study that matched rates of brain cancer with cell-phone use among more than 10,000 participants in 13 countries. The long-awaited report—published in the *International Journal of Epidemiology* on May 17 after four years of delay—is by far the most comprehensive look at the issue to date and was meant to provide a possible conclusion to the debate. Medical science would finally give us a clear answer, just as it had for tobacco, asbestos and a host of other toxins.

And the results are...inconclusive. The study found no obvious connection between cell-phone use and brain cancer. Yet despite the seeming clarity of that conclusion, the results are anything but

4.6 BILLION
Number of mobile-phone subscriptions worldwide

straightforward. Of the study's subjects, the 60% who used their phones most often and for the longest time had a 40% higher risk of developing some form of brain cancer than those who didn't use a mobile phone. Meanwhile, the study found that people who used their cell phones infrequently had a lower risk of developing brain tumors than those who used corded telephones exclusively—as if mobile phones in small doses might offer some protection from brain cancer, which even some researchers involved with the study said made no sense.

The mobile-phone industry was quick to trumpet the study's most basic findings, while consumer advocates concerned about cell-phone dangers countered that it did find cancer risks among the heaviest users (and “heavy” users were those on the phone about 30 minutes a day—not that much by today's standards). But the reality is that the Interphone study is flawed, plain and simple. The results “tell us that the question as to whether mobile-phone use increases risks for brain cancers remains open,” wrote epidemiologists Rodolfo Saracci and Jonathan Samet in an accompanying editorial.

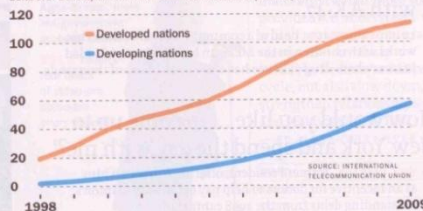
Both activists and the mobile-phone industry called for more research, but the truth is we're unlikely to find epidemiological evidence of a clear risk from cell phones (if it even exists) for some time. That's the uncomfortable place we find ourselves today: technology rushes ahead, but it can still take epidemiologists decades to zero in on potential cancer risks, leaving policymakers and consumers pretty much on their own in the meantime. Which is exactly the opposite of what we hope science will do for us. —BY BRYAN WALSH

‘Until stronger conclusions can be drawn one way or another, it may be reasonable to reduce one’s exposure [to cellular radiation]. It can’t hurt.’

—Dr. Elisabeth Cardis, leader of the Interphone study



YAKETY YAK Mobile-phone use in developing countries has more than doubled since 2005; China and India alone have a combined 1.2 billion subscribers. Below, the number of mobile subscriptions per 100 inhabitants



June 15, 2010

Critic details flaws of cell phone safety study

Posted: 12:01 AM ET



CNN, June 15, 2010

By Danielle Dellorto
CNN Medical Senior Producer

Critics are speaking out against the the controversial [Interphone cell-phone safety study](#) released last month.

U.S. researcher Lloyd Morgan presented a report in Seoul, South Korea this week, challenging Interphone's findings at the Bioelectromagnetics Society's annual meeting. Morgan's presentation is based on his re-evaluation of the Interphone study. He says it emphasizes several design flaws.

"The Interphone study is giving people false hope. Most people only hear the headline, Cell phones don't cause cancer yet the devil is in the details," Morgan, Senior Research Fellow at the Environment Health Trust, said. "When I read study papers, I look for what they are not saying – and this study isn't saying a lot."

According to Morgan, the bias of the participants in the study, the exclusion of data from children and young adults, the exclusion of people who died from brain tumors as well as a limit to the type of tumors studied are among the study's design flaws and are all reason to question the validity of the Interphone research.

Interphone's international study concluded cell phone usage doesn't increase the risk of brain tumors for the "average" person but also acknowledged that the study's findings were not definitive and called for more research.

Other scientists and researchers, like Lloyd Morgan, say the study's findings were not only misleading to the general public but also reference out-of-date data that doesn't correlate to the average cell-phone user today.

"The average study participant used his phone only 2-2.5 hours a month. In contrast, the typical person in the U.S. today uses his phone about 2.5 hours a week—about 4 times as much and will exceed the lifetime use of the typical Interphone study participant in less than a year," said University of California, Berkeley School of Public Health director, Dr. Joel Moskowitz.

For now, the potential health risks of cell phones usage remain unclear.

"I want to be clear that I don't believe all cell-phones need to be abandoned but consumers can't read headlines from studies like this and think they are completely safe," said Morgan. "I don't want people to wake up 10 years from now and say, 'Oh my god, why weren't we told.'"

Editor's Note: Medical news is a popular but sensitive subject rooted in science. We receive many comments on this blog each day; not all are posted. Our hope is that much will be learned from the sharing of useful information and personal experiences based on the medical and health topics of the blog. We encourage you to focus your comments on those medical and health topics and we appreciate your input. Thank you for your participation.

Posted by: Danielle Dellorto - CNN Medical Senior Producer
Filed under: Cancer • Cell Phones • Global Health

What to Expect Now

- More demand for impartial expert reviews
- Synthesis guidelines proliferating
- Epidemiologists revisiting policy impact

public health and epi departments do?

- With regard to education in policy?
- With regard to engagement in policy-related activities?
- With regard to fostering skillful engagement of faculty/researchers in policy?
- With regard to tracking and highlighting these activities?