Cassel Lecture

John Cassel
1921-1976

Epidemiology for Public Health: Are We Missing the Boat?

Moyses Szklo, MD, DrPH, MPH

Knowing is not enough; we must apply

Willing is not enough; we must do

Johann Wolfgang von Goethe

Morton Levin

Prevalence of smokers among male patients by type of smoking and diagnosis*, Roswell Park Memorial Institute, Buffalo, New York

Diagnosis	No. of cases	Cigarette smokers†	
		%	*p* value
Lung cancer	230	66.1	
Compared with			
Other cancers	66	48.1	0.01
Lung nontumors	121	53.1	0.02
Other noncancers	481	41.1	0.01

Levin ML, Goldstein H, Gerhardt PE. Cancer and tobacco smoking: a preliminary report. *J Am Med Assoc* 1950;143:336-8, modified from Table 2, Winkelstein Jr W. *Am J Epidemiol* 1997; 146:896-906

Morton Levin

"*When I got the Frost Award from the APHA for my contributions to epidemiology, I was surprised, as I always saw myself as a public health officer. I believe my main contribution was to have facilitated the polio trials when I was a Public Health Officer in New York.*" Morton Levin (personal communication)

*Unadjusted

EPIDEMIOLOGY FOR PUBLIC HEALTH: TRANSLATIONAL EPIDEMIOLOGY

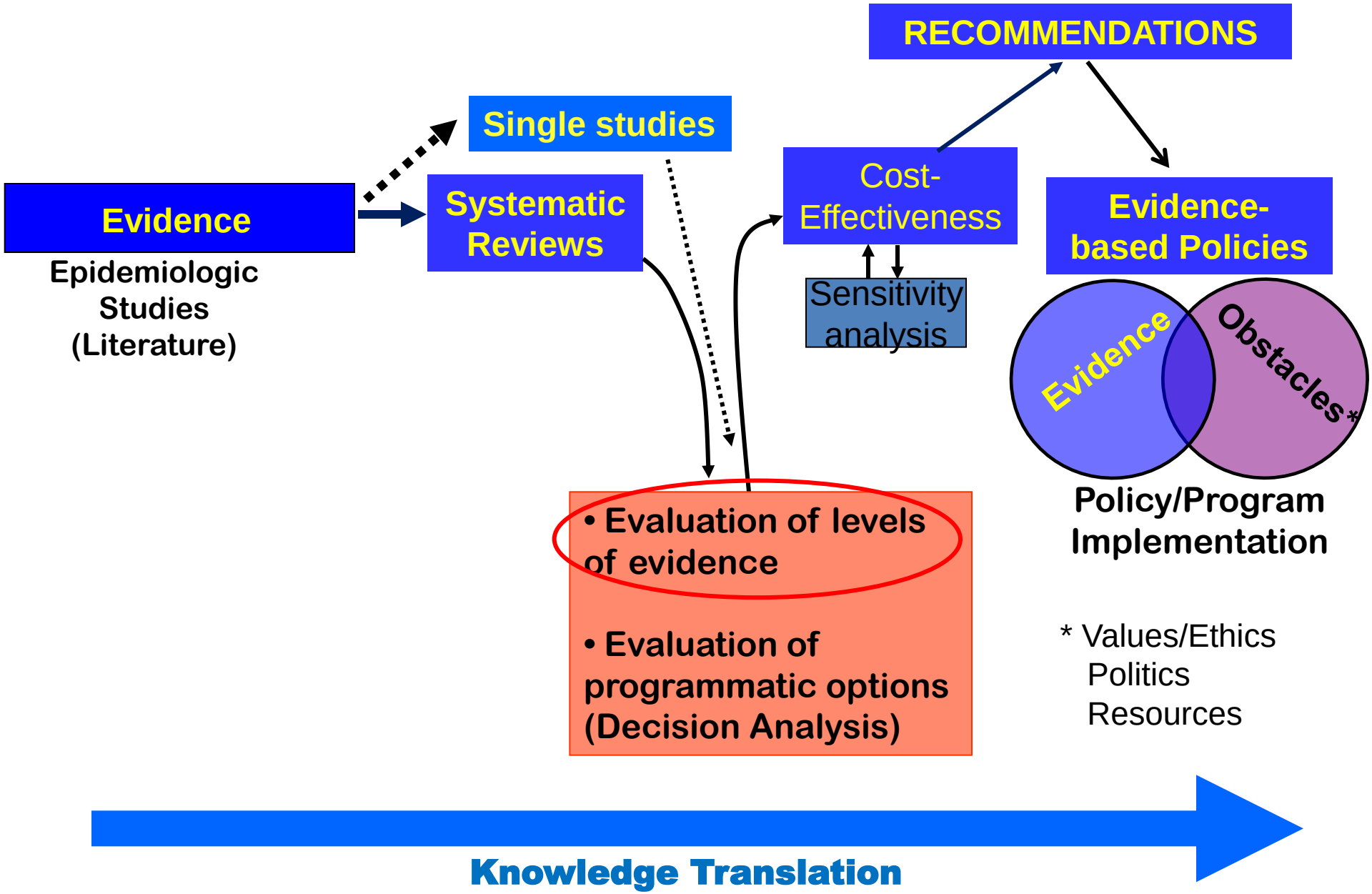
Translational Epidemiology: Effective transfer of new knowledge resulting from epidemiologic studies (including trials) into the planning of population-wide and individual-level disease control programs and policies.

Epidemiology: (1) The study of the distribution and determinants of health-related states or events in specified populations……and……(2) the application of this study to control health problems (Porta M. *Dictionary of Epidemiology*, 2008)

Epidemiology: (1) The study of the distribution and determinants of health-related states or events in specified populations **translation** → (2) the application of this study to control health problems (Porta M. *Dictionary of Epidemiology*, 2008)

(S. Harris cartoon removed)

TRANSLATIONAL EPIDEMIOLOGY



Levels of evidence, translation and implementation

Levels of evidence (simplified)		
Levels		**Definition**
I		Experimental (RCT)
II		Observational
III		"Natural experiments" with dramatic results
IV		Expert opinion, not evidence-based

Assumption: the health problem is 'important'
(re: disability, mortality, cost of health care, etc)

(Based on the United States Preventive Services Task Force and Canada's Periodic Health Examination Task Force)

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William Farr (1807–1883) once remarked, '*Death is a fact. All else is inference*'. (quoted by John Last, The Gale Group Inc., Macmillan Reference USA, New York, 2002).

(Mark Anderson cartoon removed.)

(Based on the United States Preventive Services Task Force and Canada's Periodic Health Examination Task Force)

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Translation		
Grade of evidence	**Level of certainty**	**Expected net benefit**
A	High	Substantial
B	High	Moderate-substantial
C	Moderate or high	Small
D	Moderate or high	None
I	Evidence is lacking or poor	Unknown

(Based on the United States Preventive Services Task Force and Canada's Periodic Health Examination Task Force)

Levels of evidence, translation and implementation

Levels of evidence (simplified)	
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Translation			Implementation
Grade of evidence	**Level of certainty**	**Expected net benefit**	
A	High	Substantial	Implement program/policy
B	High	Moderate-substantial	
C	Moderate or high	Small	Case by case basis*
D	Moderate or high	None	Discourage implementation or use of program/policy
I	Evidence is lacking or poor	Unknown	Case by case basis*

*The balance of benefits and harms should be explained

(Based on the United States Preventive Services Task Force and Canada's Periodic Health Examination Task Force)

Translating Epidemiologic Knowledge into Public Health – Relevant Concepts

- Is confounding always a bias?
- The primacy of the additive model
- Assessing homogeneity
- Decision Analysis

Translating Epidemiologic Knowledge into Public Health – Relevant Concepts

- Is confounding always a bias?

Cartoon removed: People I disagree with are biased

Translating Epidemiologic Knowledge into Public Health – Relevant Concepts

- Is confounding always a bias?

In some epidemiology and biostatistics textbooks:

- Bias due to confounding
- Bias not due to confounding

In observational studies, residual confounding is an important threat to causal inference, which is *sine qua non* for primary prevention

Examples of Primary Prevention Policies Influenced by Observational Epidemiologic Findings

- Indoor smoking ban
- Smoking advertisement ban
- Salt content in baby foods
- Saturated fat content of food items
- Radiation exposure standards
- Air pollution standards
- Smallpox eradication

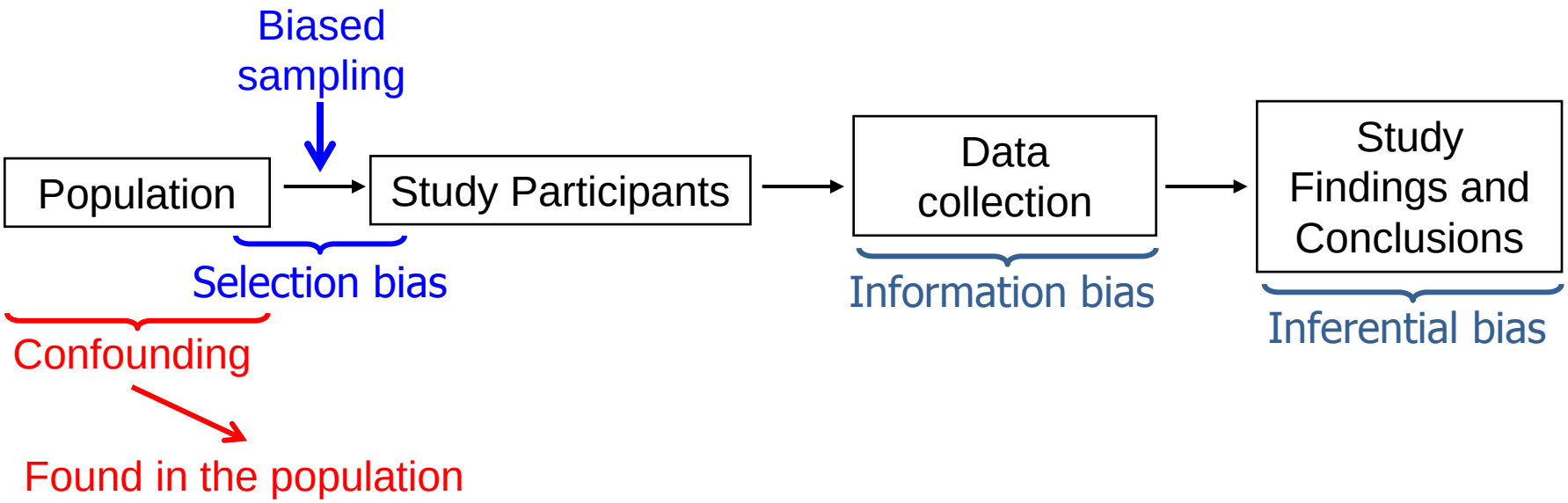
Observational Studies

- Good company: Geology, Astrophysics, Ecology, etc.

Observational Studies

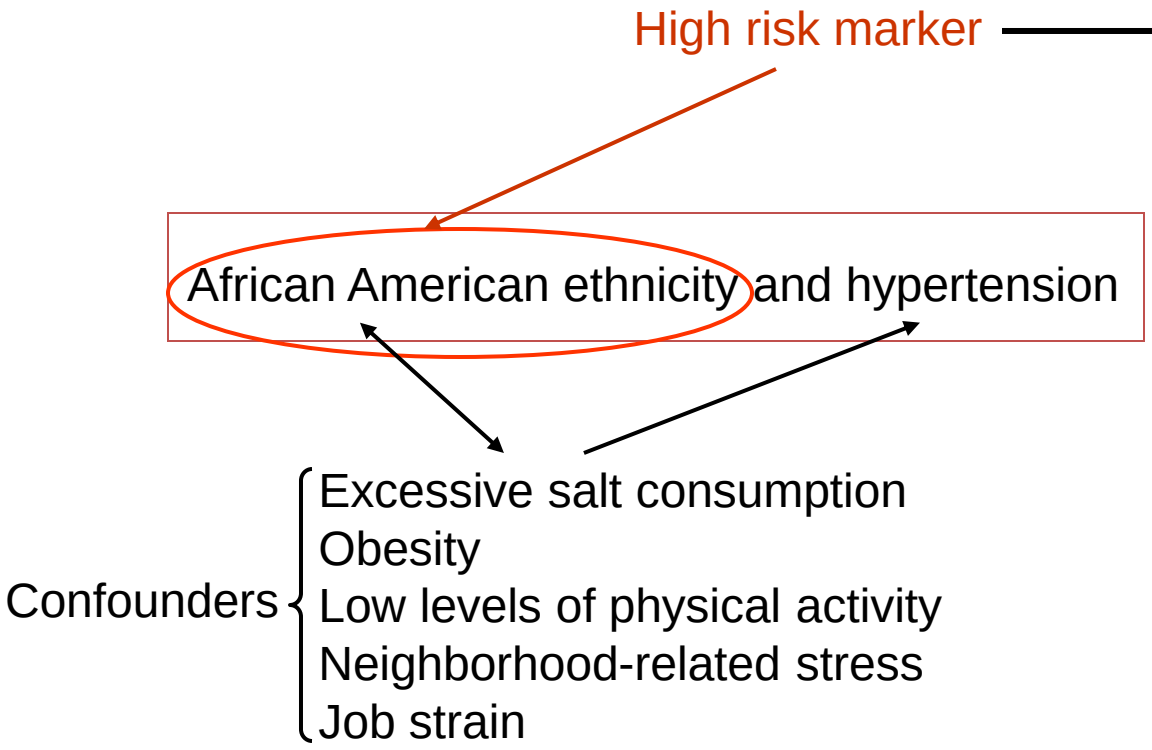
- Good company: Geology, Astrophysics, Ecology, etc.
- **Key question**: If there is confounding, is a (confounded) association useful for Public Health?

Confounding and Bias Occur in Different Phases of the "Natural History" of a Study



(Based on: Samet J)

An Example of a Useful Confounded Association



Useful for:

(a) Screening of this high risk group for control of established hypertension, and

(b) Focus on this high risk group to promote prevention or cessation of modifiable risk factors

IS CONFOUNDING A BIAS?

It depends...

- **Yes**, if the purpose is to infer a causal association: Etiologic confounding
- **No**, if the purpose is to identify risk markers: Public Health confounding*

*Donna Spiegelman, personal communication

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  Issue: adjustment model vs application model

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  Example: when modeling ratio-based measures of association, heterogeneity is usually assessed using a multiplicative scale

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- Is confounding always a bias?

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  Issue: adjustment model vs application model

  Example: when modeling ratio-based measures of association, heterogeneity is usually assessed using a multiplicative scale

  Question: Should the model dictate the application or should the application dictate the model?

Vadlo cartoon removed: Data don’t make sense

Data don’t make any sense, we will have to resort to statistics

ADDITIVE INTERACTION IS MORE RELEVANT TO PUBLIC HEALTH AND MEDICINE

Lung Cancer Death Rates/100 000 Person-Years According to Smoking and Asbestos Exposure, 1971-2005

Smoking	Asbestos exposure*	No. Person Years	Rate*	Rate Ratio
Never ?	Low	280 812	2.8	1.0
	High	23 686	33.8	12.1
Current	Low	581 497	81.3	1.0
	High	50 590	636.5	7.8

Negative multiplicative interaction

Counter-intuitive!

*per 100 000

*Low: <10 years of occupational exposure to asbestos

High: ≥30 years of occupational exposure to asbestos

(Frost G, et al. *Ann Occup Hyg* 2011;55:239-247)

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Negative multiplicative interaction

Strong positive additive interaction

*per 100 000

"Public Health Interaction" (Rothman)

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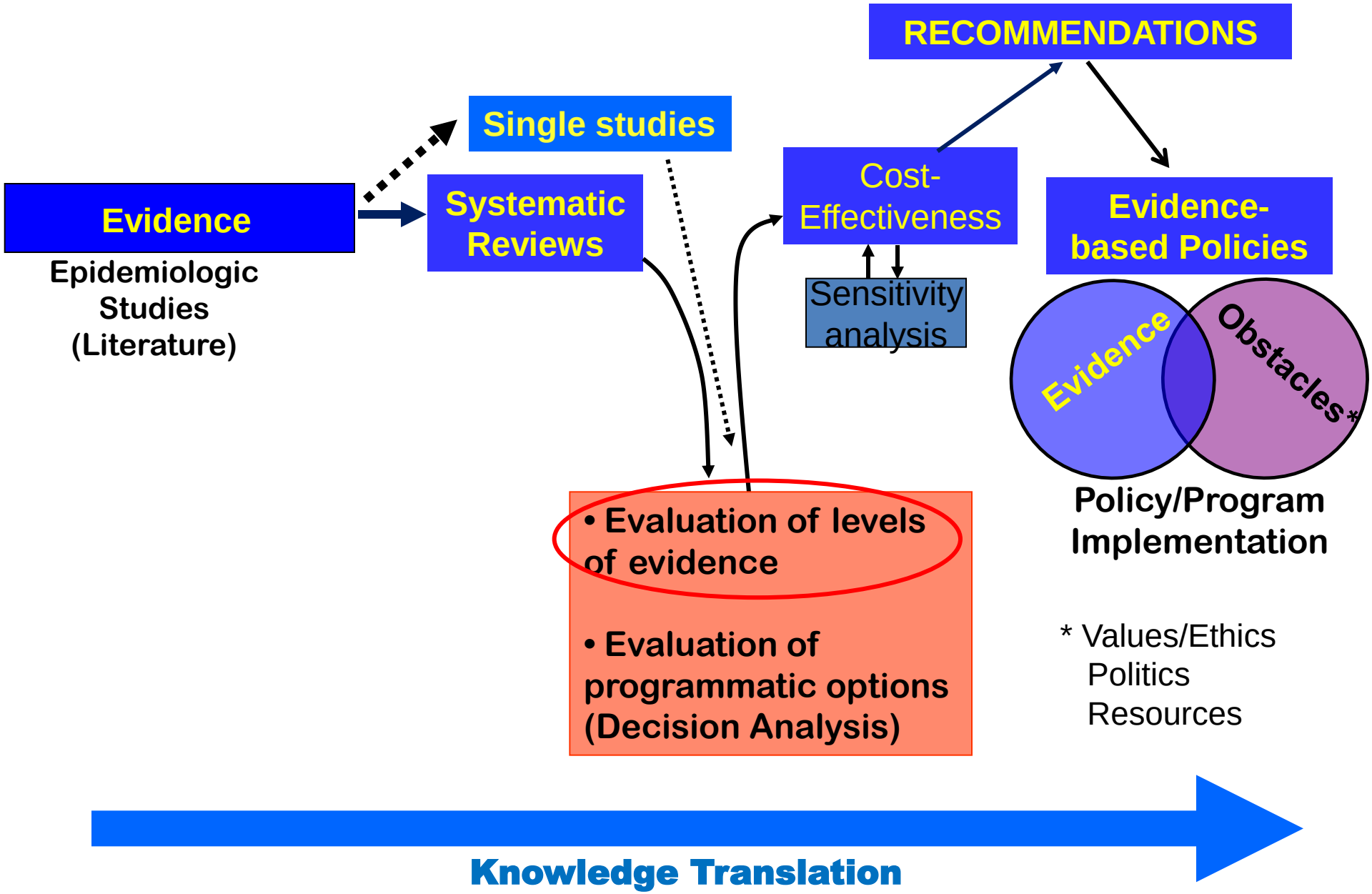
Translating Epidemiologic Knowledge into Public Health – Relevant Concepts

- Is confounding always a bias?
- The primacy of the additive model
- **Assessing homogeneity**

TRANSLATIONAL EPIDEMIOLOGY



Rules of Evidence: *Criteria for judging the **effectiveness** of an available intervention/program (preventive measure or treatment)*

Grade	Level of Evidence	Description of Level
A (Best)	1a	Systematic review of **randomized trials** with homogeneity – including meta-analysis
	1b	Individual RT of good quality with narrow confidence interval
	1c	All or none interventions with dramatic effects – e.g., streptomycin for Tb meningitis ("Natural experiment")
	2a	Systematic review of **cohort studies** of good quality with homogeneity – including meta-analysis
	2b	Individual cohort study of good quality (e.g., with >80% follow-up) with narrow CI
B	2c	"Outcomes" research (based on existing records)
	3a	Systematic review of **case-control studies** with homogeneity – including meta-analysis
	3b	Individual case-control study of good quality with narrow CI
C	4	Case-series (and cohort and case-control studies of lesser quality)
D (**Worst**)	5	Expert opinion without explicit critical appraisal, or based on logical deduction

(Modified from http://www.indigojazz.co.uk/cebm/levels_of_evidence.asp)

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Translating Epidemiologic Knowledge into Public Health – Relevant Concepts

- Is confounding always a bias?
- The primacy of the additive model
- **Assessing homogeneity**
  - Pseudo-homogeneity

THE MAIN THREAT TO TRUE HOMOGENEITY

PUBLICATION BIAS: RESULTS FROM ALLOWING FACTORS OTHER THAN THE QUALITY OF THE MANUSCRIPT TO INFLUENCE THE LIKELIHOOD OF ACCEPTANCE FOR PUBLICATION.

RELEVANT QUESTION

ARE AUTHORS AFRAID OF REJECTION OF “NEGATIVE” RESULTS?

Peanuts cartoon about manuscript submissions removed –
love to hear an editor beg (multiple slides)

Some Determinants of Publication Bias

- Increased odds of publication if findings are significant
- Decreased odds of publication for completed clinical trials' results vis-à-vis observational results
- Industry-sponsored studies more likely to report findings that are significant than publicly-funded studies
- English-written reports more likely to report findings that are statistically significant

Evaluation of publication bias in systematic reviews

- Begg's funnel plot
- Tests of symmetry

Translating Epidemiologic Knowledge into Public Health – Relevant Epidemiologic Concepts

- Population vs. high risk strategies in prevention
- Is confounding always a bias?
- The primacy of the additive model
- **Assessing homogeneity**
  - Pseudo homogeneity
  - **Pseudo heterogeneity**

Some Determinants of Heterogeneity of Study Results

- Differences in study design, procedures, analytic strategies and quality

Some Determinants of Heterogeneity of Study Results

- Differences in study design, procedures, analytic strategies and quality

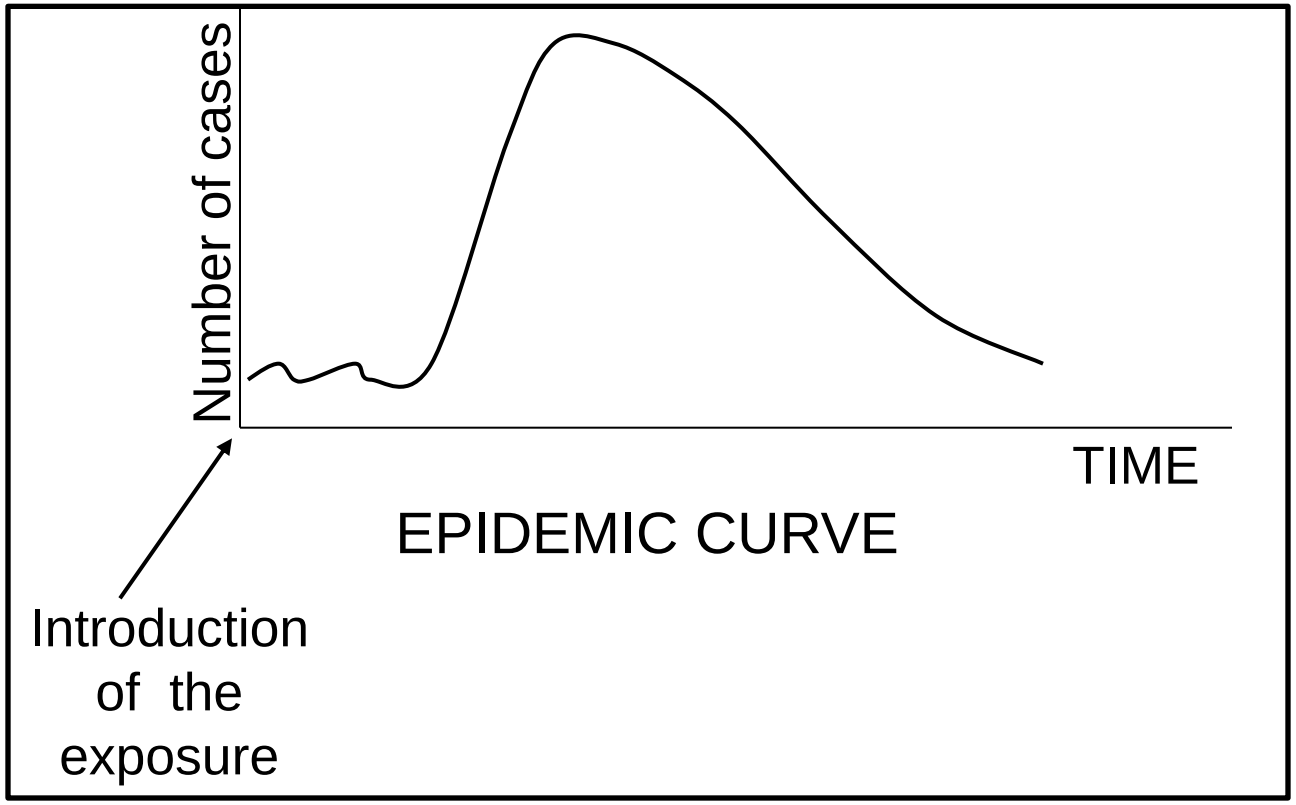
- Differences in the phase of the natural history when study is done

Armenian HK, Lilienfeld AM. *Am J Epidemiol* 1974;99:92-100

After the introduction of the exposure, point epidemic curves of non-transmissible diseases have the same log-normal shape as that observed in point epidemics of transmissible diseases

Point epidemic curves of non-transmissible diseases have the same log-normal shape as that observed in point epidemics of transmissible diseases

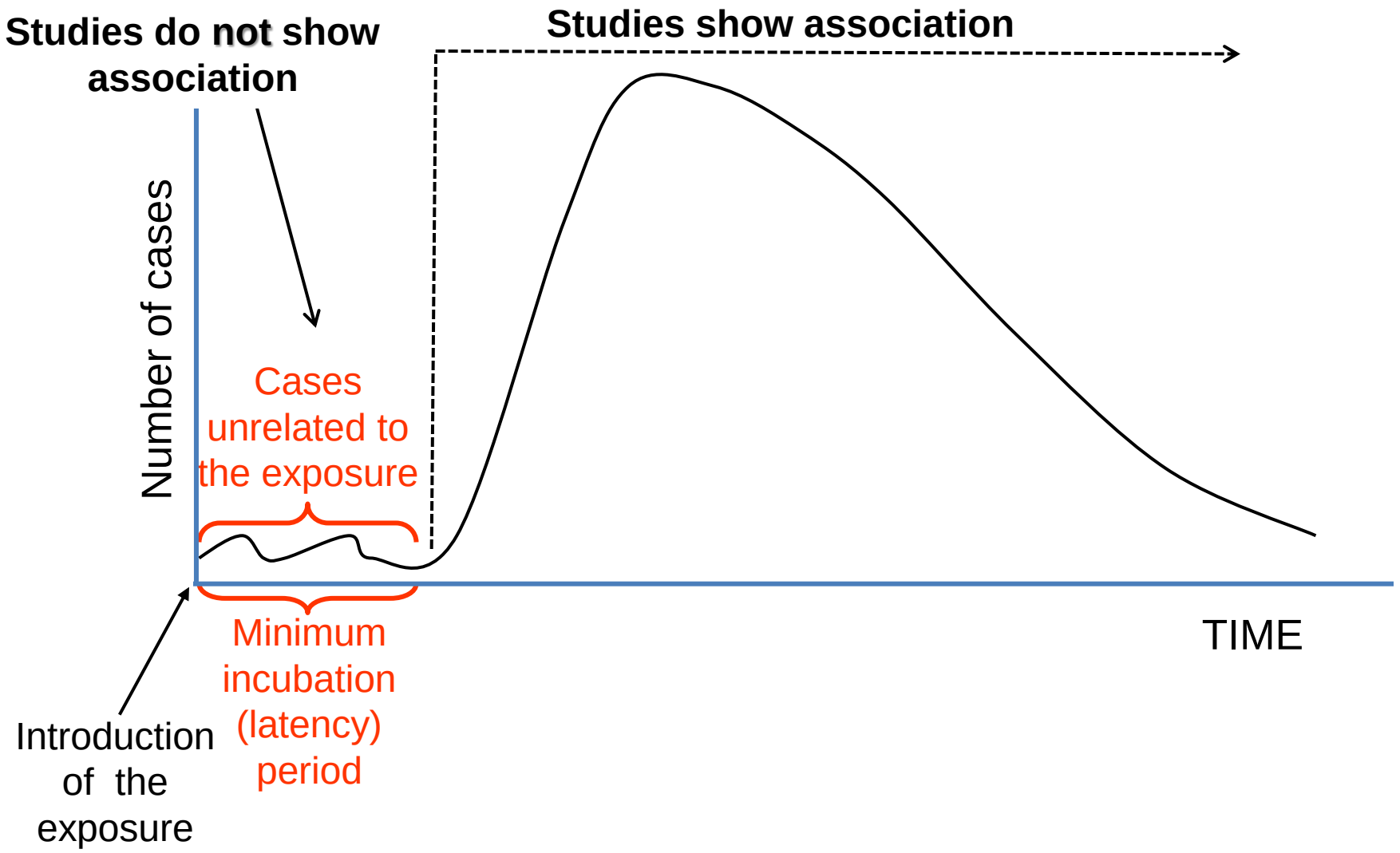
(Armenian HK, Lilienfeld AM. *Am J Epidemiol* 1974;99:92-100)



Examples

- Bladder tumors in dyestuff workers
- Leukemia after the atom bomb explosion

EPIDEMIC CURVE



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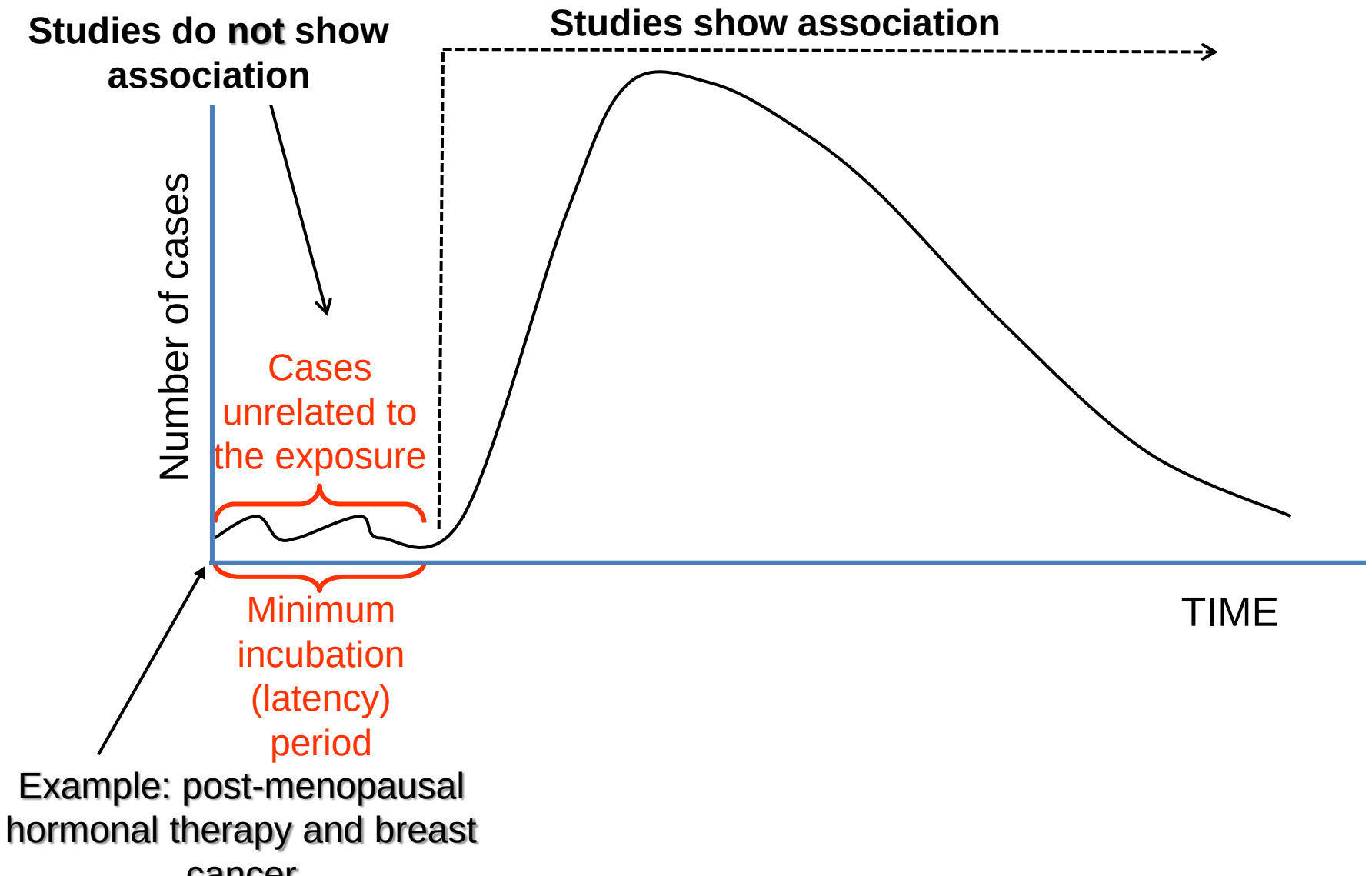

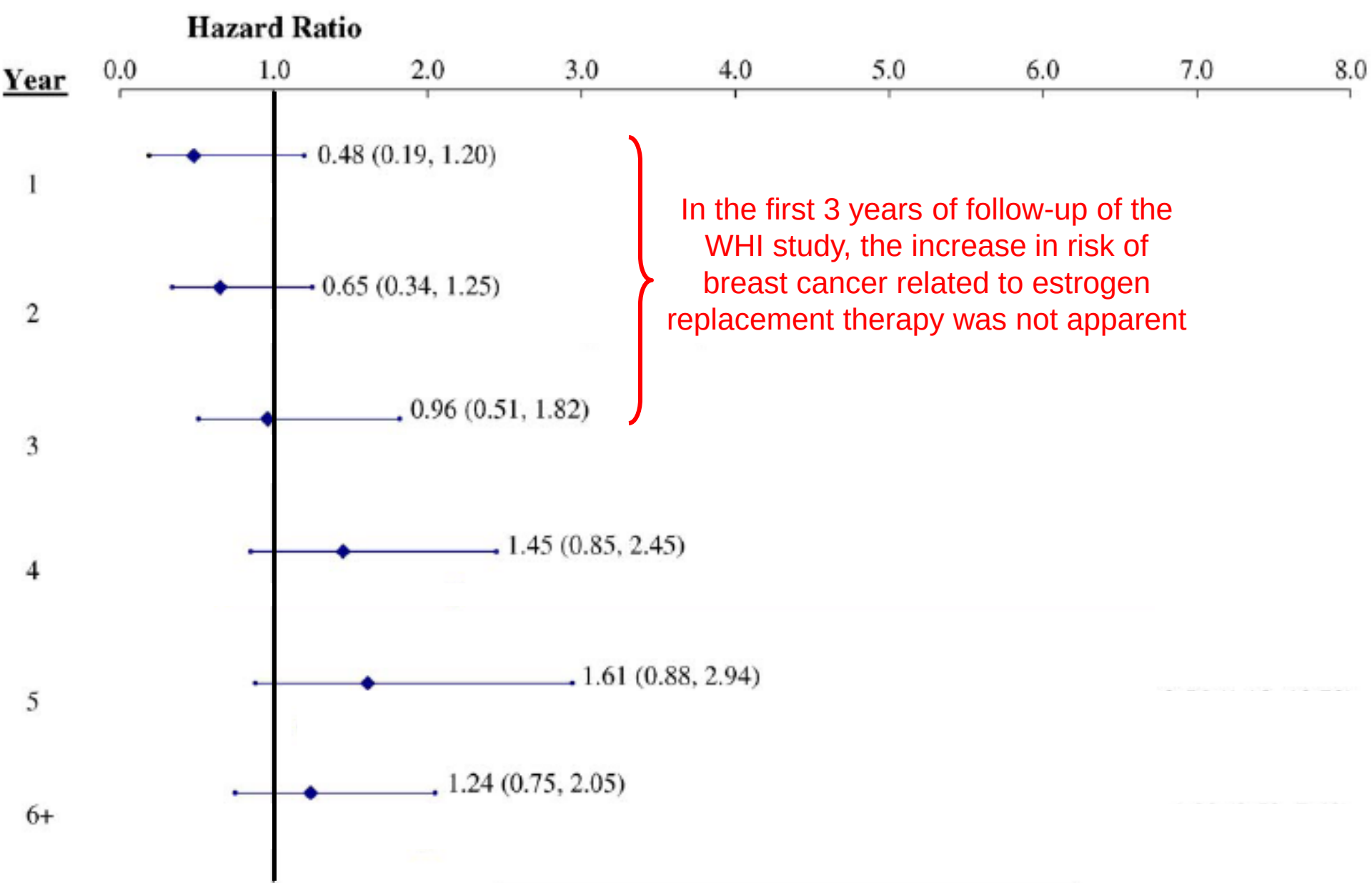

Estrogen plus progestin hazard ratios (95% CIs) for invasive cancer by year of study in women without prior hormone therapy at baseline. The Women's Health Initiative (Modified from: Anderson GL et al, *Maturitas* 2006;55:103-15)

Some Determinants of Heterogeneity of Study Results

- Differences in study design, procedures, analytic strategies and quality
- Differences in the phase of the natural history when study is done
- Differences in the prevalence of effect modifiers

EFFECT OF THE PREVALENCE OF AN EFFECT MODIFIER ON HETEROGENEITY BETWEEN STUDIES

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*per 100 000

*Low: <10 years of occupational exposure to asbestos

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Positive additive interaction

(Frost G, et al. *Ann Occup Hyg* 2011;55:239-247)

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*per 100 000

Study A: nonsmokers

*Low: <10 years of occupational exposure to asbestos

High: ≥30 years of occupational exposure to asbestos

(Frost G, et al. *Ann Occup Hyg* 2011;55:239-247)

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*per 100 000

Study B:smokers

*Low: <10 years of occupational exposure to asbestos

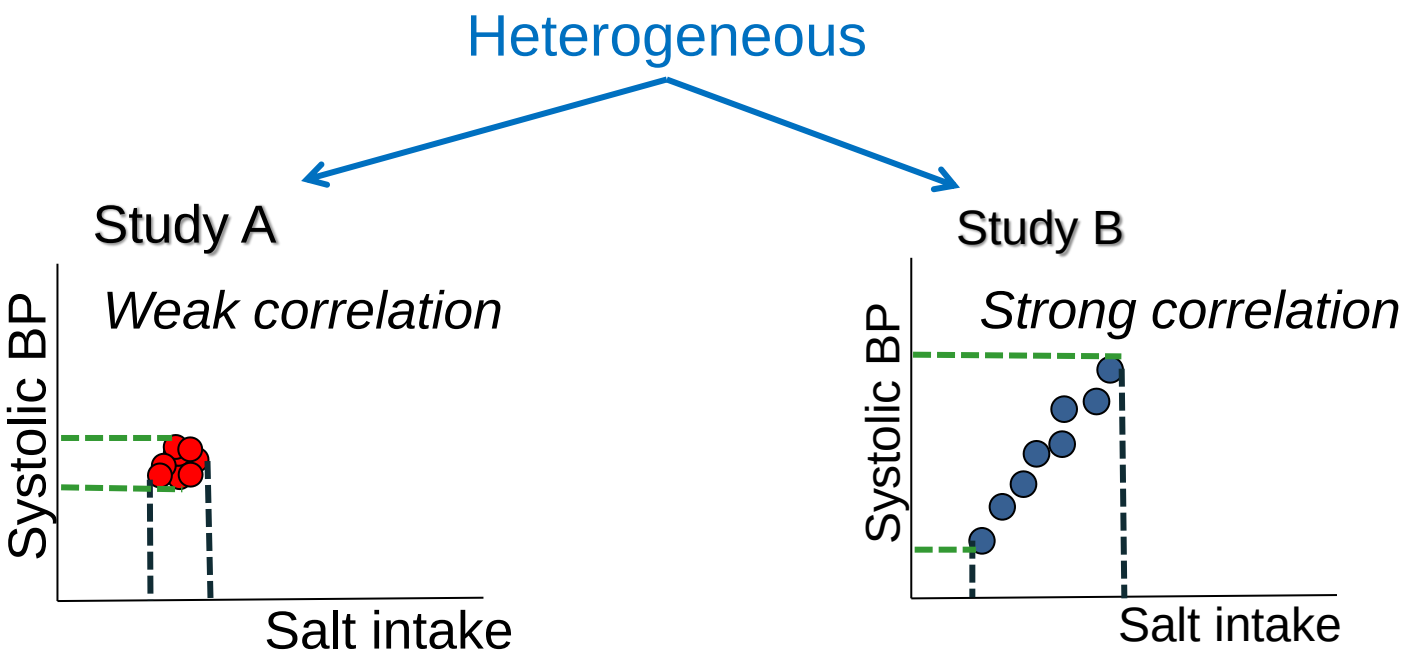
High: ≥30 years of occupational exposure to asbestos

(Frost G, et al. *Ann Occup Hyg* 2011;55:239-247)

Some Determinants of Heterogeneity of Study Results

- Differences in study design, procedures, analytic strategies and quality
- Differences in the phase of the natural history when study is done
- Differences in the prevalence of an effect modifier
- Differences in the variability of the exposure and/or the outcome

Difference in the Variability of Exposure

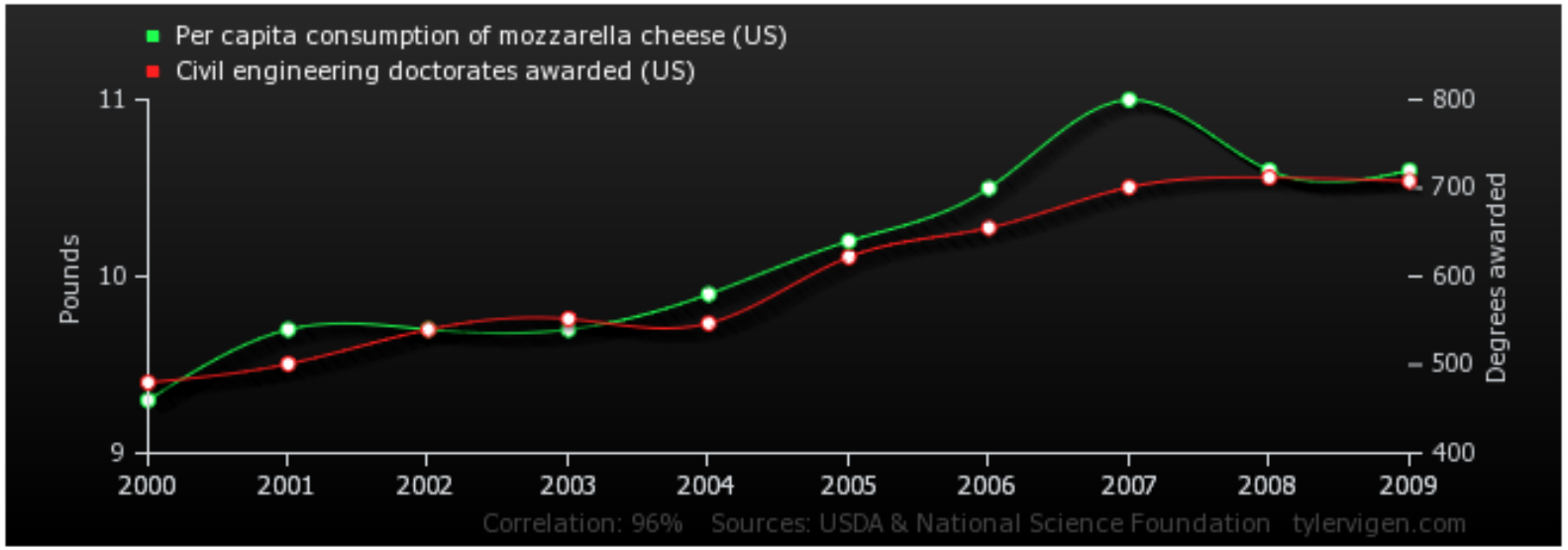


$$\text{Coefficient of Variability} = \frac{\text{Standard Deviation}}{\text{Mean}} \times 100$$

EPI INTRODUCTORY COURSES: BEWARE OF ECOLOGIC CORRELATIONS!!

Cartoon removed – correlation does not imply causation

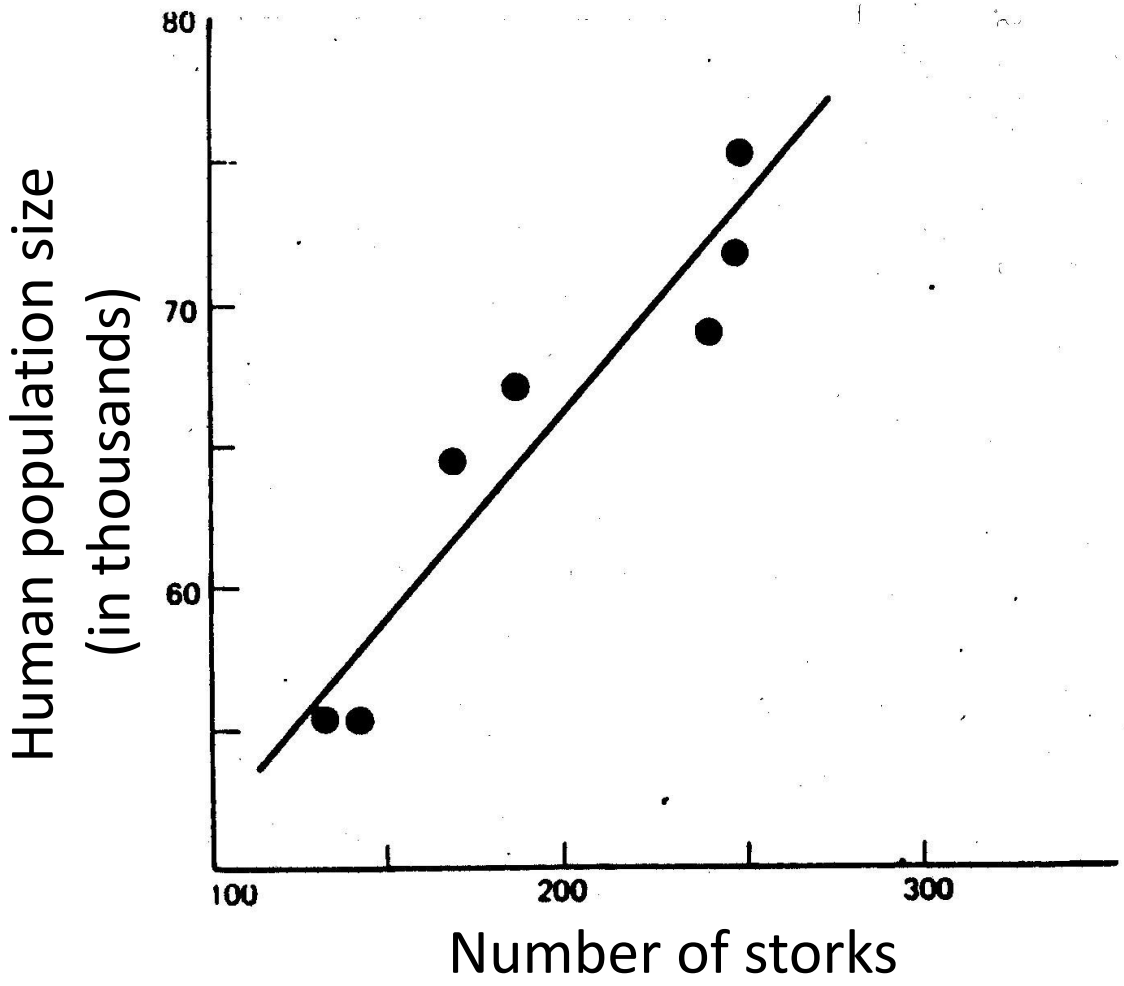
Per capita consumption of mozzarella cheese (US)
correlates with
Civil engineering doctorates awarded (US)



Upload this chart to imgur

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Per capita consumption of mozzarella cheese (US) *Pounds (USDA)*	9.3	9.7	9.7	9.7	9.9	10.2	10.5	11	10.6	10.6
Civil engineering doctorates awarded (US) *Degrees awarded (National Science Foundation)*	480	501	540	552	547	622	655	701	712	708

Correlation coefficient = 0.99



A plot of the population of Oldenburg at the end of each year against the number of storks observed in that year, 1930-1936.

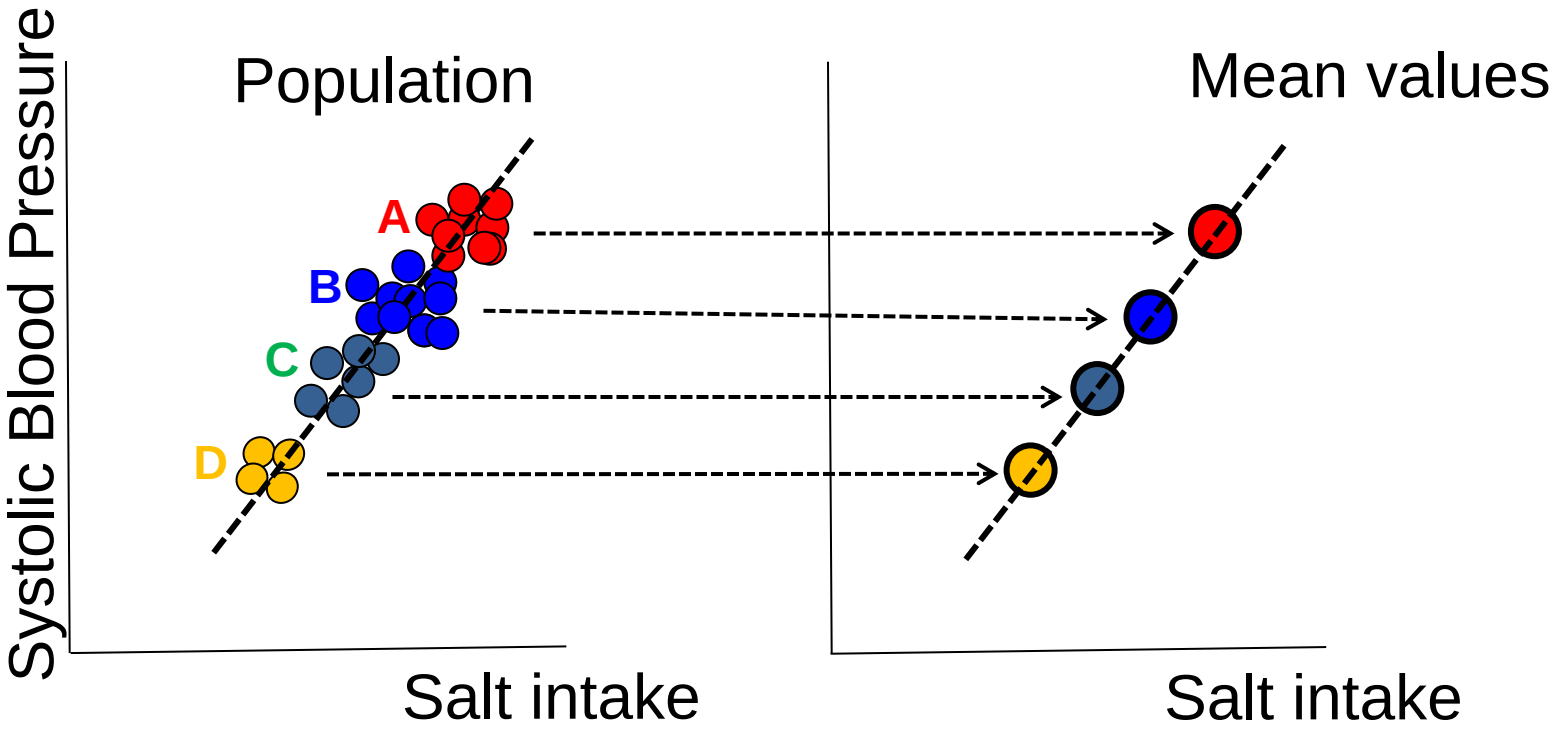
Ornitholigische Monatsberichte 1936;44(2)

Correlation coefficient ≈ 0.70

NOT ALL ECOLOGIC CORRELATIONS ARE ECOLOGIC FALLACIES!

…IN OBSERVATIONAL STUDIES, WHEN WITHIN-POPULATION VARIABILITY OF AN EXPOSURE (OR AN OUTCOME) IS SMALL…AN ECOLOGIC CORRELATION MAY GIVE US THE RIGHT ANSWER

Example: Relationship of salt intake to blood pressure



Relation between sodium (Na) excretion and age increase in systolic blood pressure (SBP) in centers in the INTERSALT cohort*

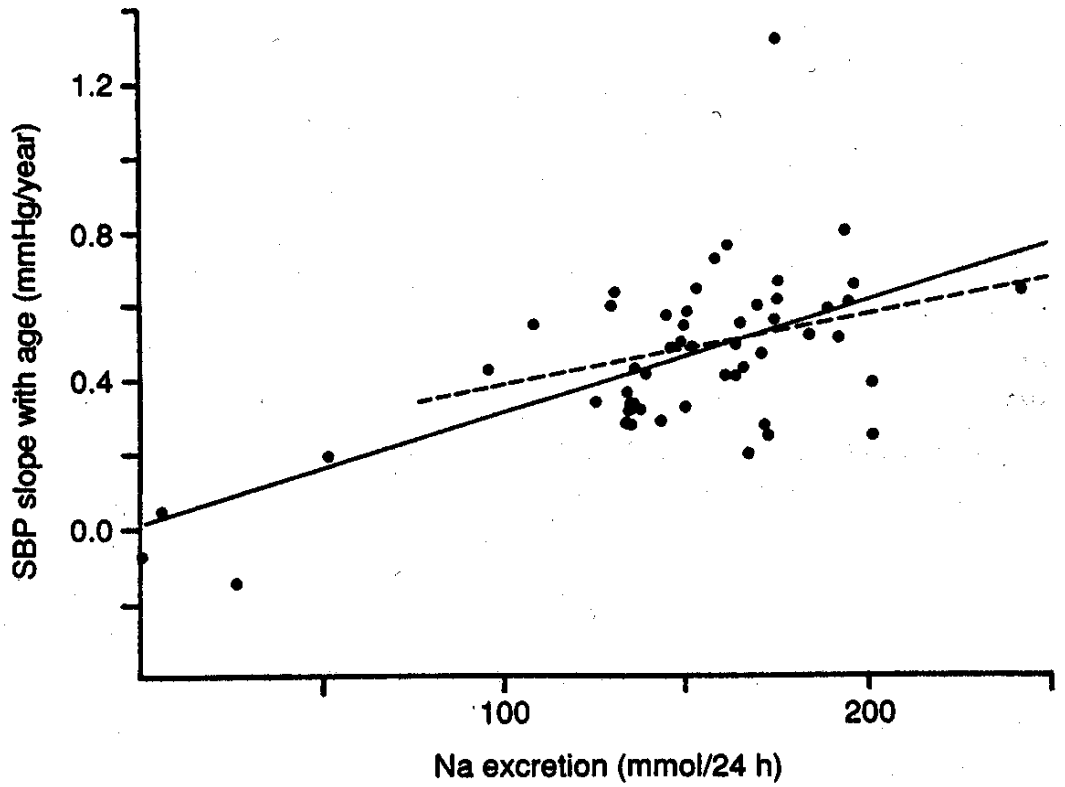


Fig. 12.3 Scatter plot of age–sex standardized median SBP slope with age (mmHg/year) against median 24 hour sodium excretion (mmol) and fitted regression lines: INTERSALT, 52 centres (full line) and 48 centres (broken line). Regression coefficients: 52 centres, $b = 0.030$ (SE 0.006) mmHg/year/10 mmol; 48 centres, $b = 0.019$ (SE 0.010) mmHg/year/10 mmol.

*Elliot, in Marmot and Elliot (eds.): *Coronary Heart Disease Epidemiology, Oxford,* 1992, pp.166-78.

- Homogeneity is not necessarily evidence in favor of causality/effectiveness (publication bias)

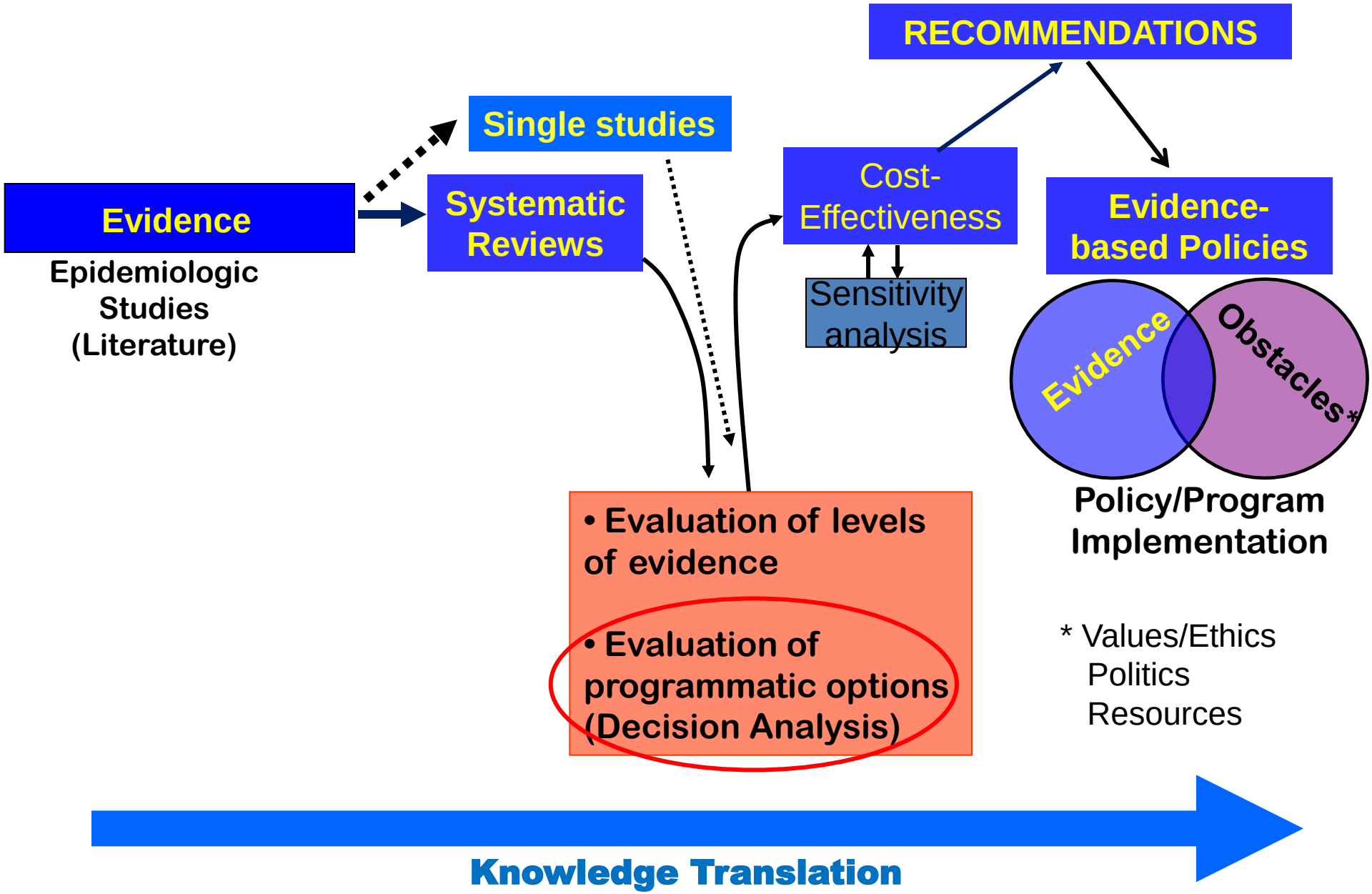
- Heterogeneity is not necessarily evidence against causality/effectiveness

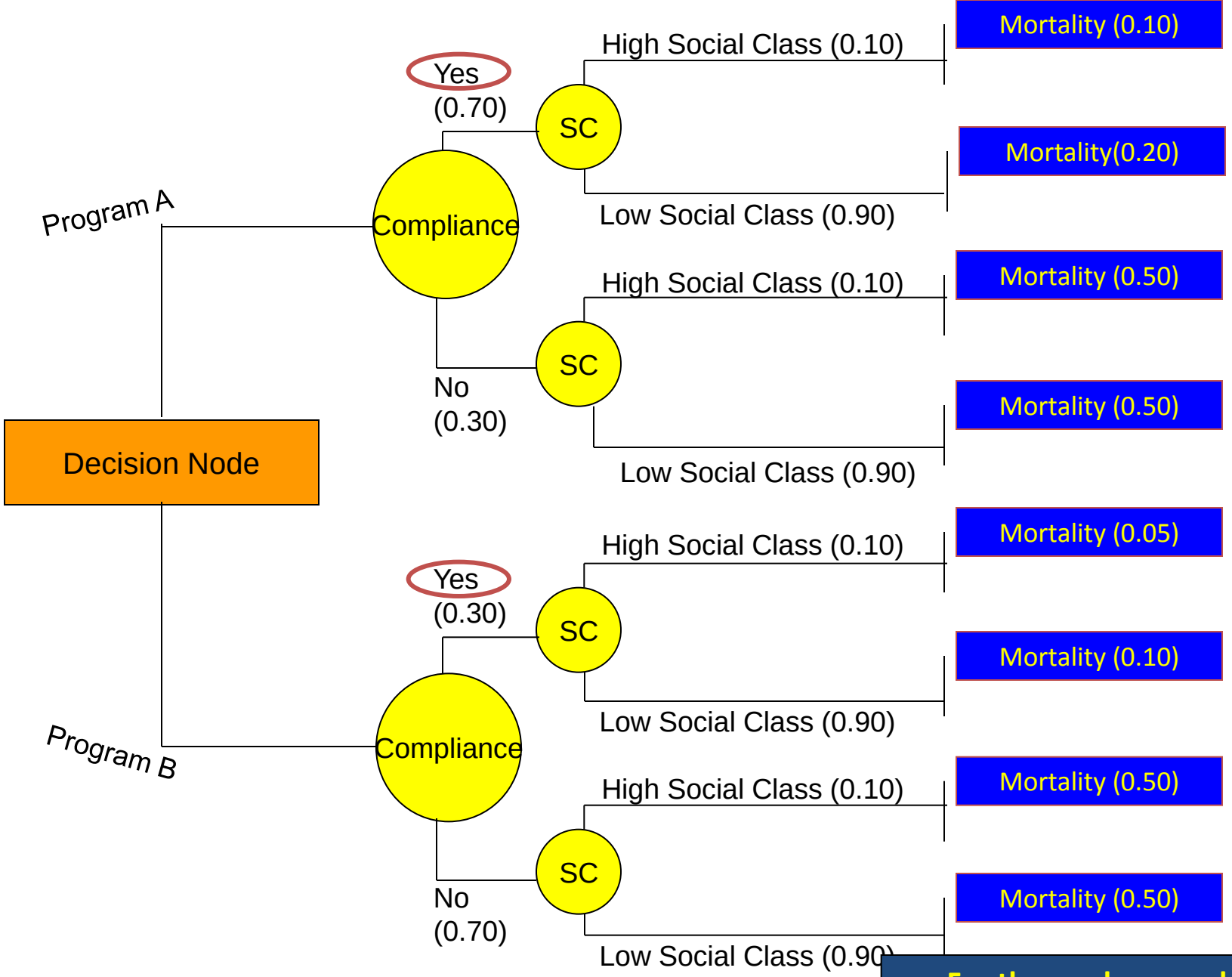
Thus, determinants of homogeneity and heterogeneity should be better understood before using these concepts in support of causality/effectiveness or lack thereoff, respectively

Translating Epidemiologic Knowledge into Public Health – Relevant Epidemiologic Concepts

- Is confounding always a bias?
- The primacy of the additive model
- Assessing homogeneity
- **Decision Analysis**

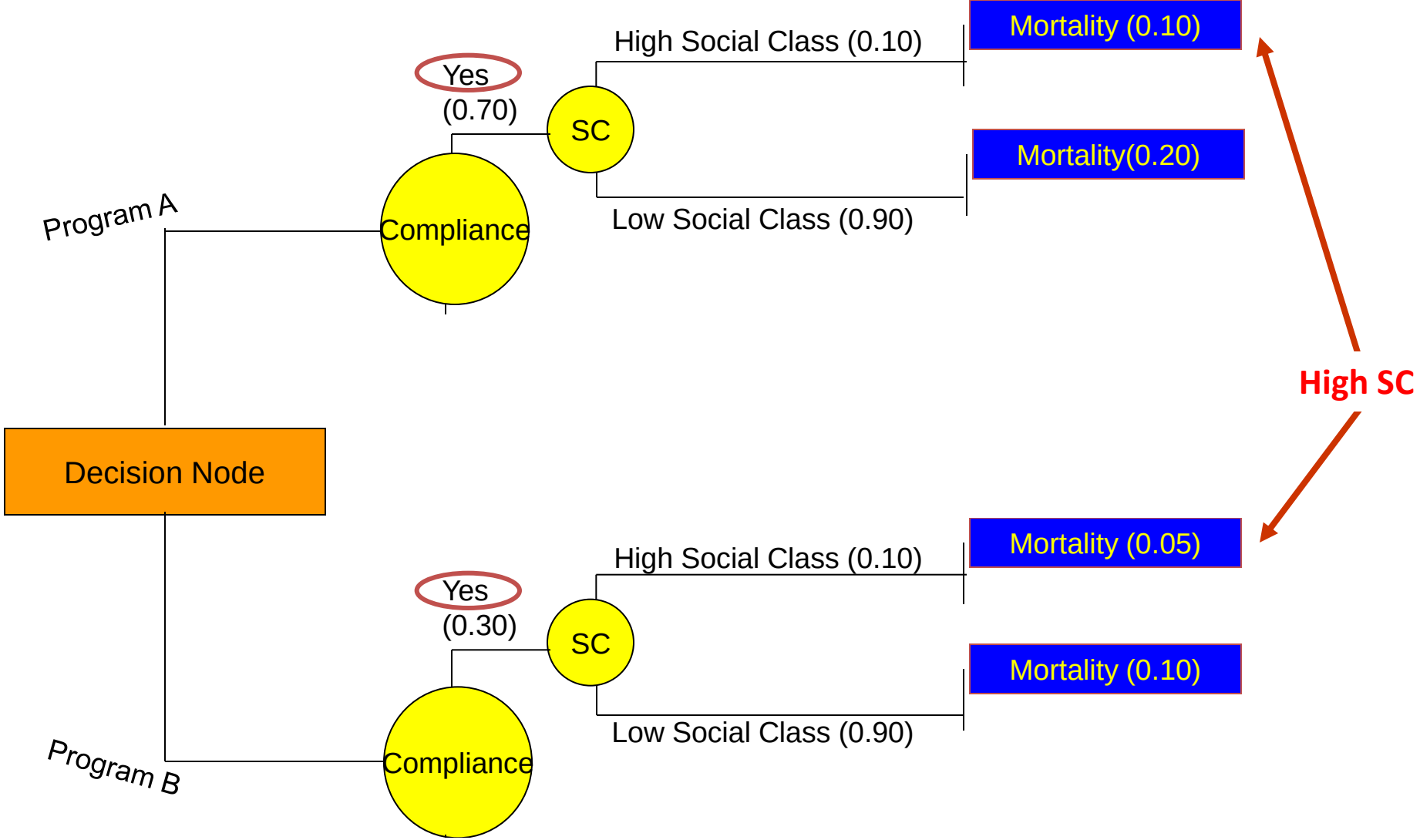
TRANSLATIONAL EPIDEMIOLOGY





Example of decision tree with two chance nodes

For those who comply with the intervention, Program B has a lower mortality than A



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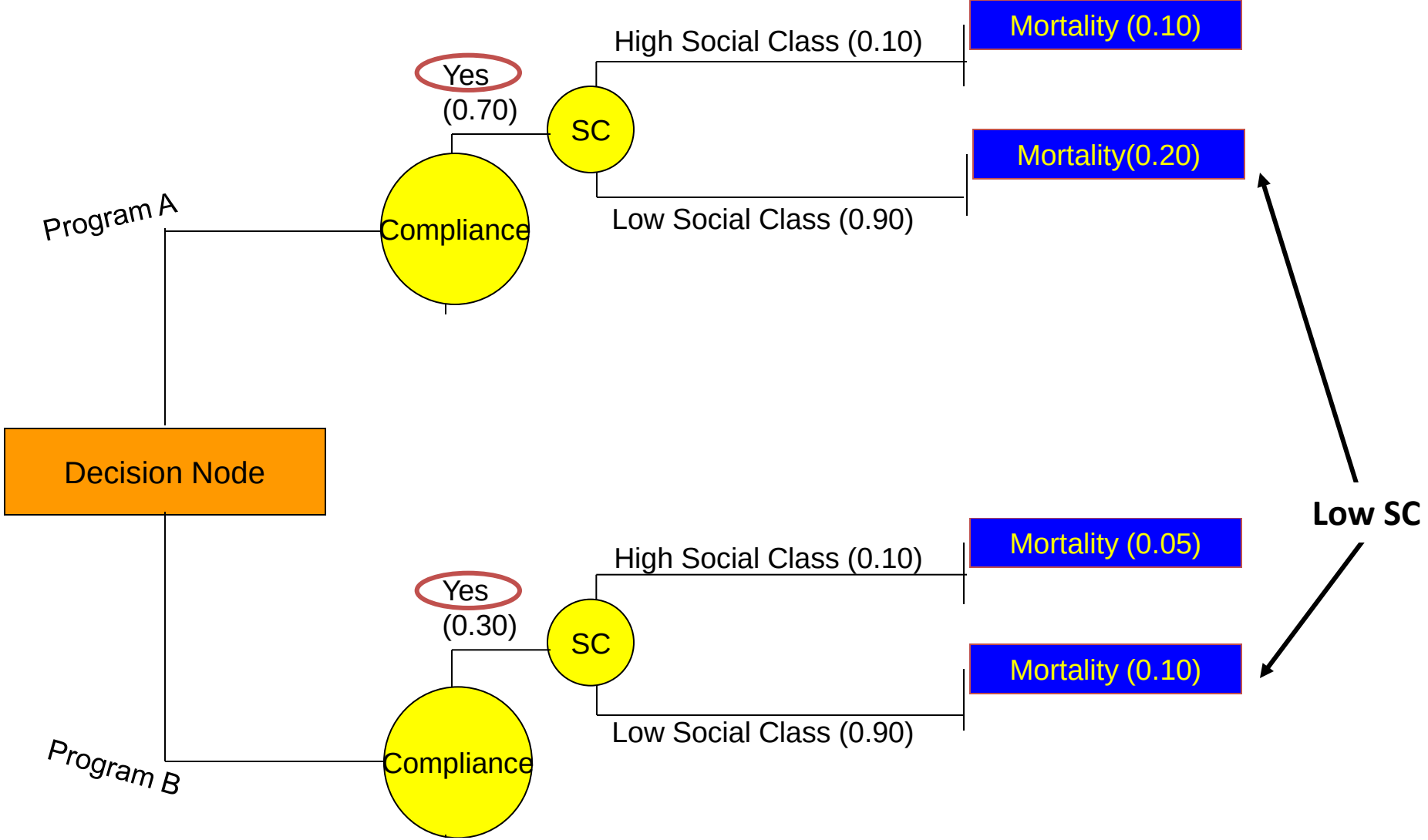

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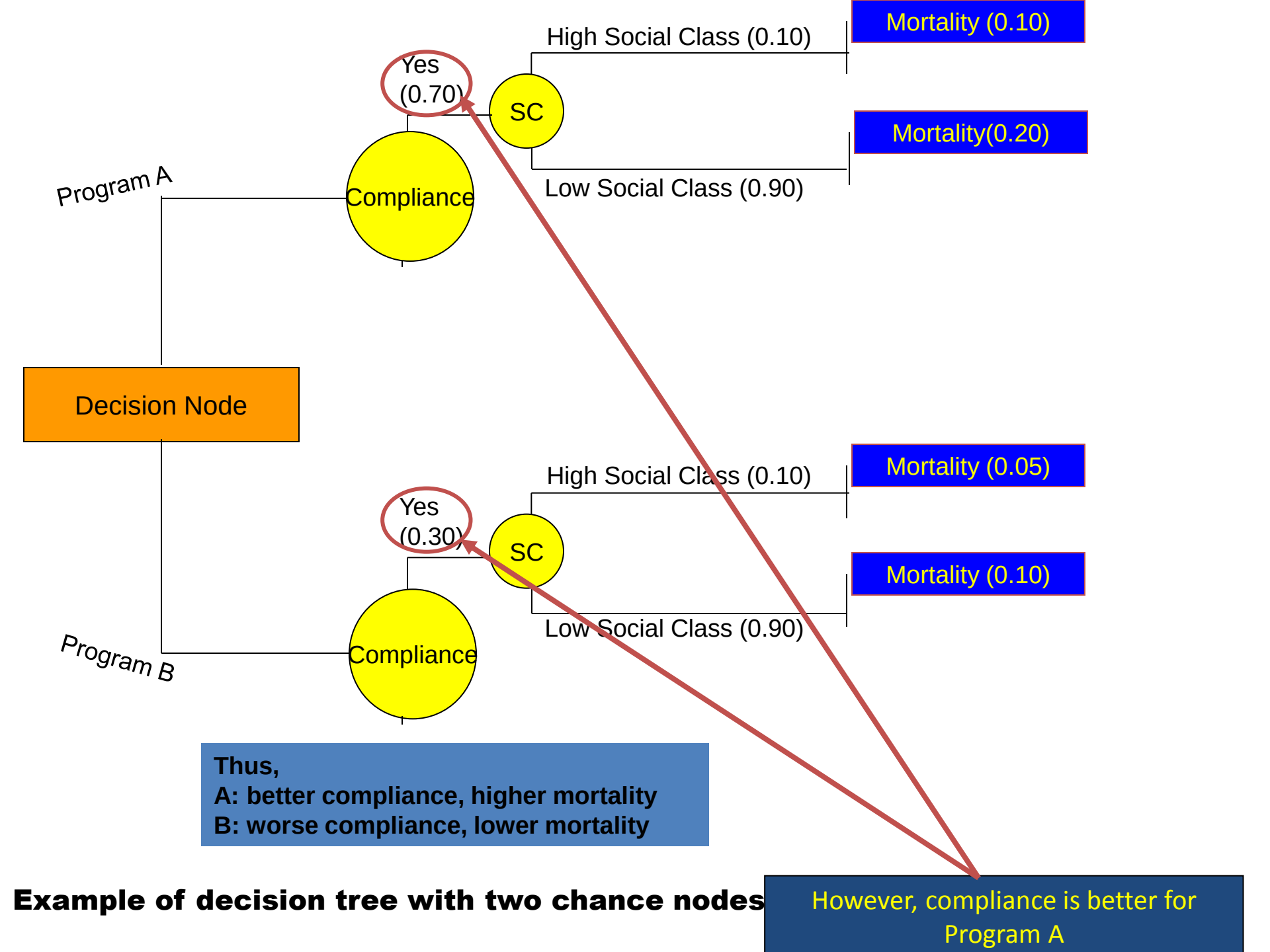

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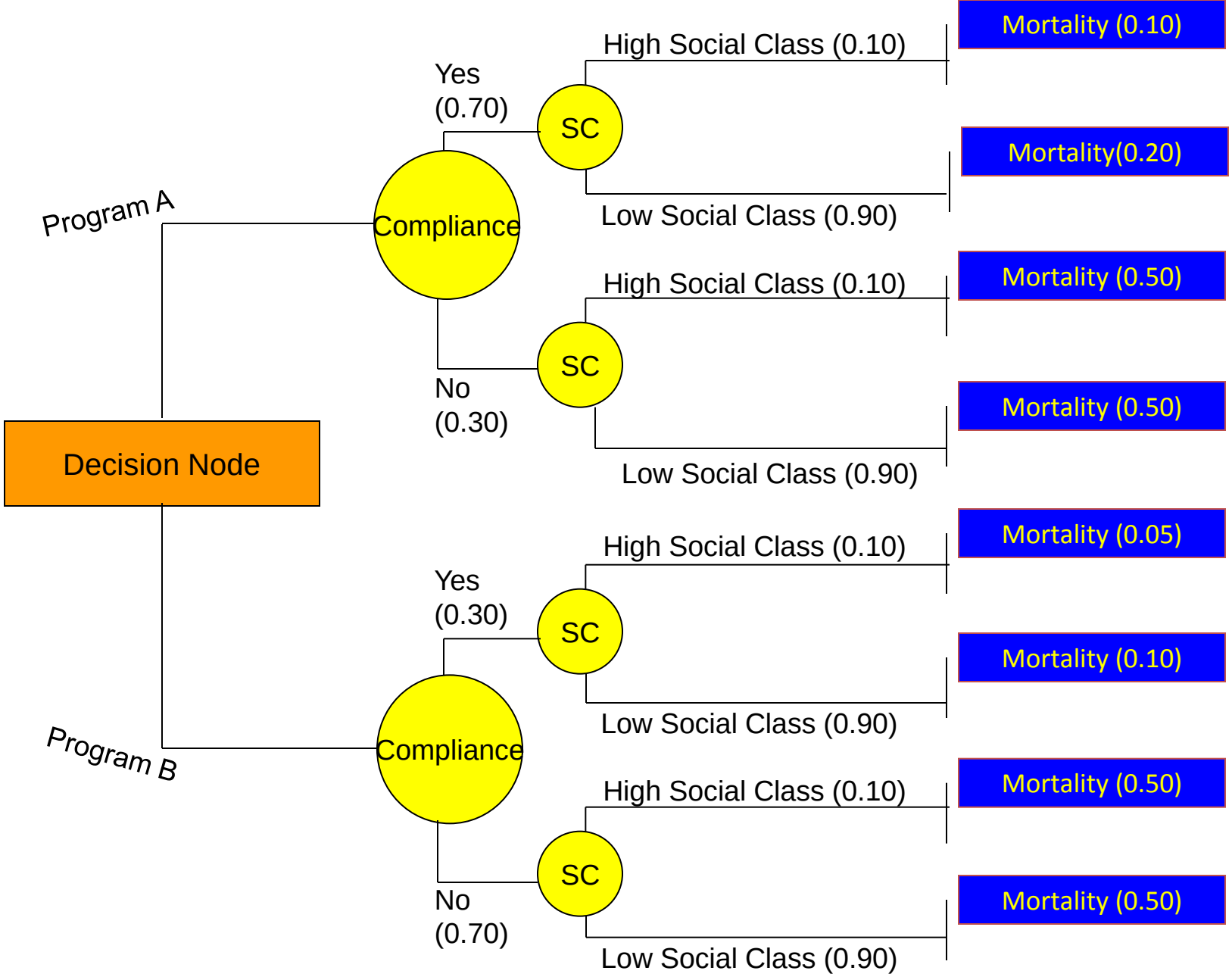

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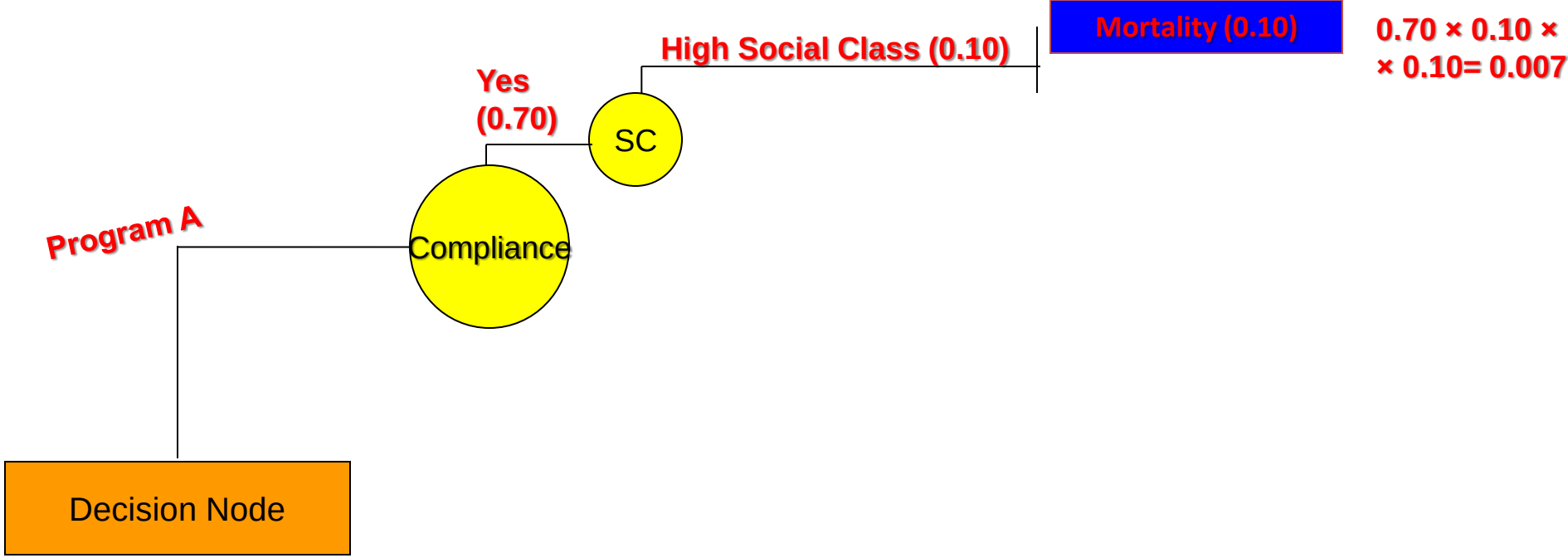

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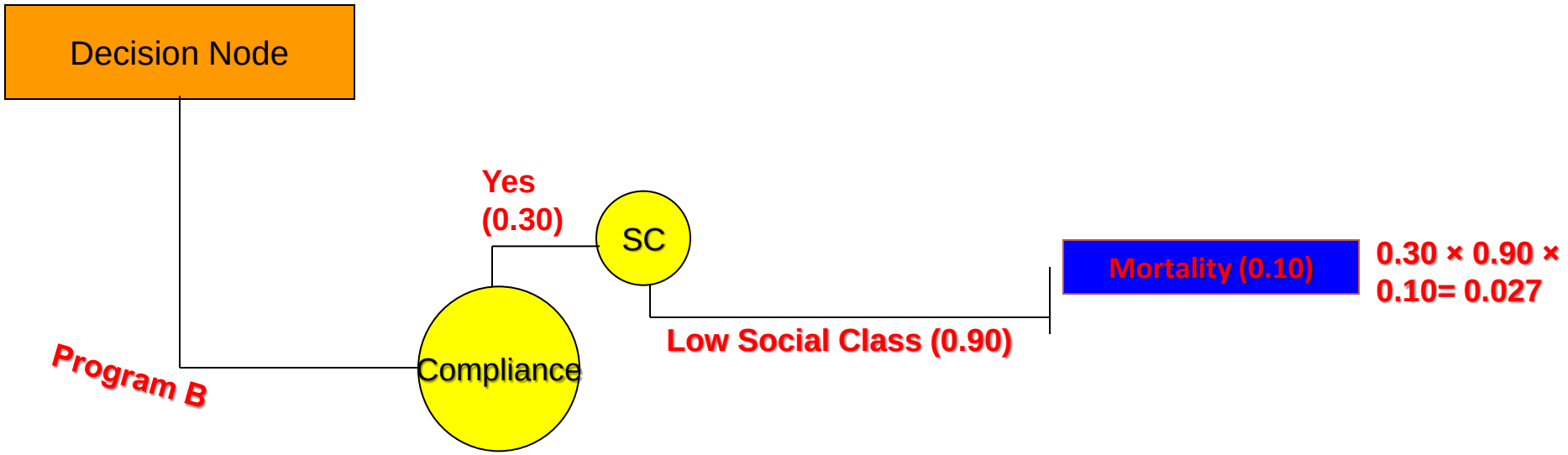


Example of decision tree with two chance nodes

What would happen to the total mortality associated with Program B if its compliance increased to 50%?

Calculation of Community Effectiveness of Programs A and B, Based on a Decision Tree

Program A: higher mortality in compliers, but better compliance (70%)

Compliance		Social Class		Mortality		Joint probability
0.70 (Y)	×	0.10	×	0.10	=	0.007
0.70 (Y)	×	0.90	×	0.20	=	0.126
0.30	×	0.10	×	0.50	=	0.015
0.30	×	0.90	×	0.50	=	0.135

Total mortality (0.007 + 0.126 + 0.015 + 0.135) × 100 = **28.30%**

Program B: lower mortality in compliers, but worse compliance (30%)

Compliance		Social Class		Mortality		Joint probability
0.30 (Y)	×	0.10	×	0.05	=	0.0015
0.30 (Y)	×	0.90	×	0.10	=	0.027
0.70	×	0.10	×	0.50	=	0.035
0.70	×	0.90	×	0.50	=	0.315

Total mortality (0.0015 + 0.027 + 0.035 + 0.315) × 100 = **37.85%**

Conclude: Program B has greater efficacy (i.e., lower mortality in compliers), but because compliance in Program A is higher, its effectiveness is higher than that of B.

Sensitivity Analysis: Compliance of B Increased to 50%

Program A: higher mortality in compliers, but better compliance (70%)											
Compliance		Social Class		Mortality		Joint probability					
0.70	×	0.10	×	0.10	=	0.007					
0.70	×	0.90	×	0.20	=	0.126					
0.30	×	0.10	×	0.50	=	0.015					
0.30	×	0.90	×	0.50	=	0.135					
Total mortality	(0.007 + 0.126 + 0.015 + 0.135) × 100 = **28.30%**										

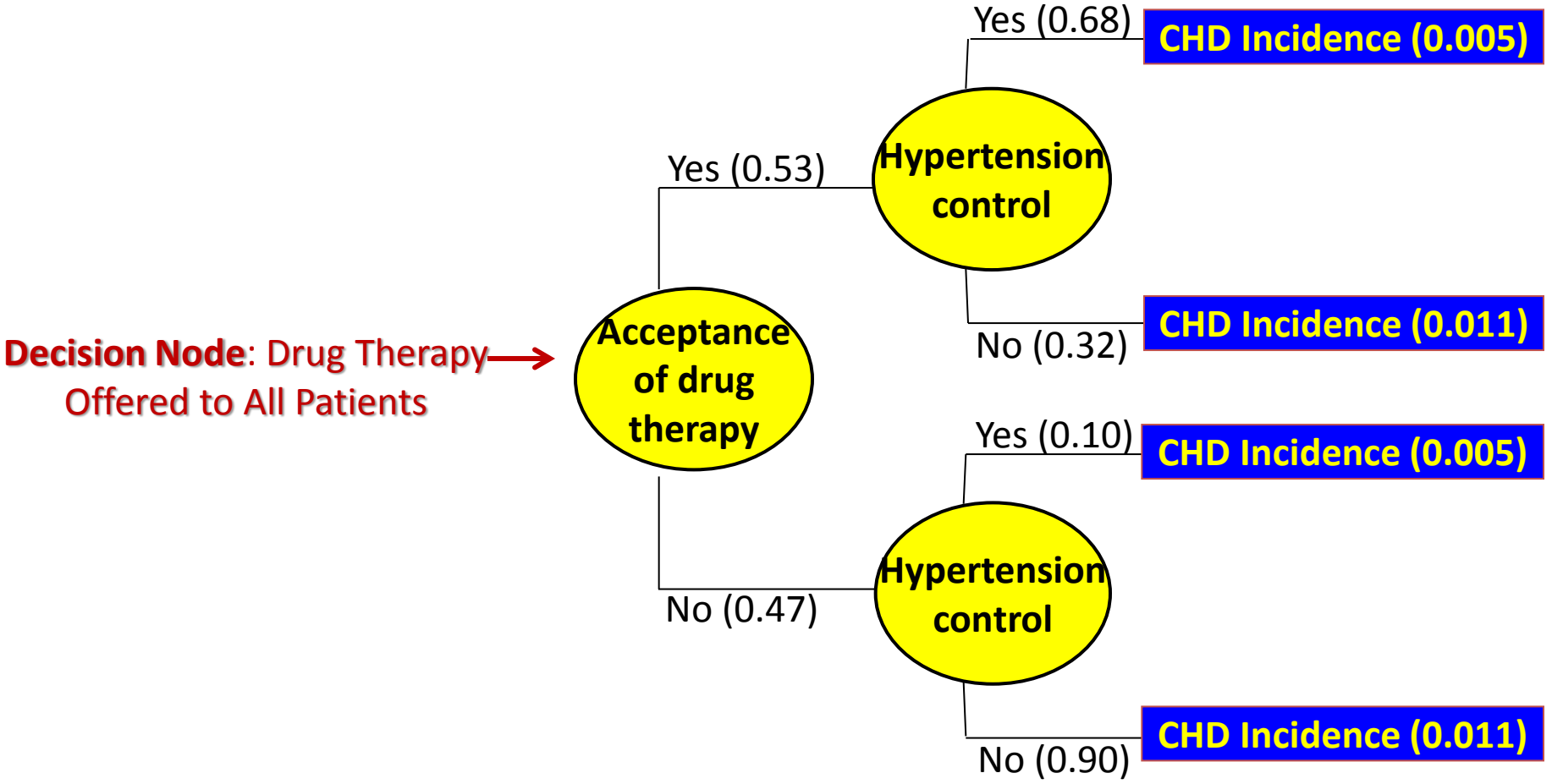
Program B: Program B: lower mortality in compliers: **Compliance increased to 50%**											
Compliance		Social Class		Mortality		Joint probability					
0.50 (Y)	×	0.10	×	0.05	=	0.0025					
0.50 (Y)	×	0.90	×	0.10	=	0.045					
0.50	×	0.10	×	0.50	=	0.025					
0.50	×	0.90	×	0.50	=	0.225					
Total mortality	(0.0025 + 0.045 + 0.025 + 0.225) × 100 = **29.75%**										

(Before: 37.85%)

Conclude: Total mortality is still a bit higher for Program B, but if B is less expensive, it may be cost-effective to implement B.

Decision Tree of Hypertension (HT) Medication Therapy with One Decision Node Using Average Annual Incidence of Coronary Heart Disease (CHD) as Outcome

Decision Tree of Hypertension (HT) Medication Therapy with One Decision Node Using Average Annual Incidence of Coronary Heart Disease (CHD) as Outcome



(Nieto FJ, et al. Population awareness and control of hypertension and hypercholesterolemia. *Arch Intern Med* 1995;155:677-684; Chambless LE, et al. Association of coronary heart disease incidence with carotid arterial wall thickness and major risk factors. *Am J Epidemiol* 1997;146:483-494; Moore J. Hypertension. Catching the Silent Killer. *The Nurse Practitioner* 2005;30:16-35)

Overall Incidence in Target Hypertensive Population= (0.53 × 0.68 × 0.005) + (0.53 × 0.32 × 0.011) + (0.47 × 0.10 × 0.005) + (0.47 × 0.90 × 0.011)= 0.00855 = 8.5/1,000

Incidence According to Acceptance of Drug Therapy

Yes: (0.53 × 0.68 × 0.005) + (0.53 × 0.32 × 0.011)= 0.0037= 3.7/1,000

No: (0.47 × 0.10 × 0.005) + (0.47 × 0.90 × 0.01)= 0.0049= 4.9/1,000

TRANSLATIONAL VS. ACADEMIC EPIDEMIOLOGY

Translational Epidemiology	“Academic” Epidemiology

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Translational Epidemiology	"Academic" Epidemiology
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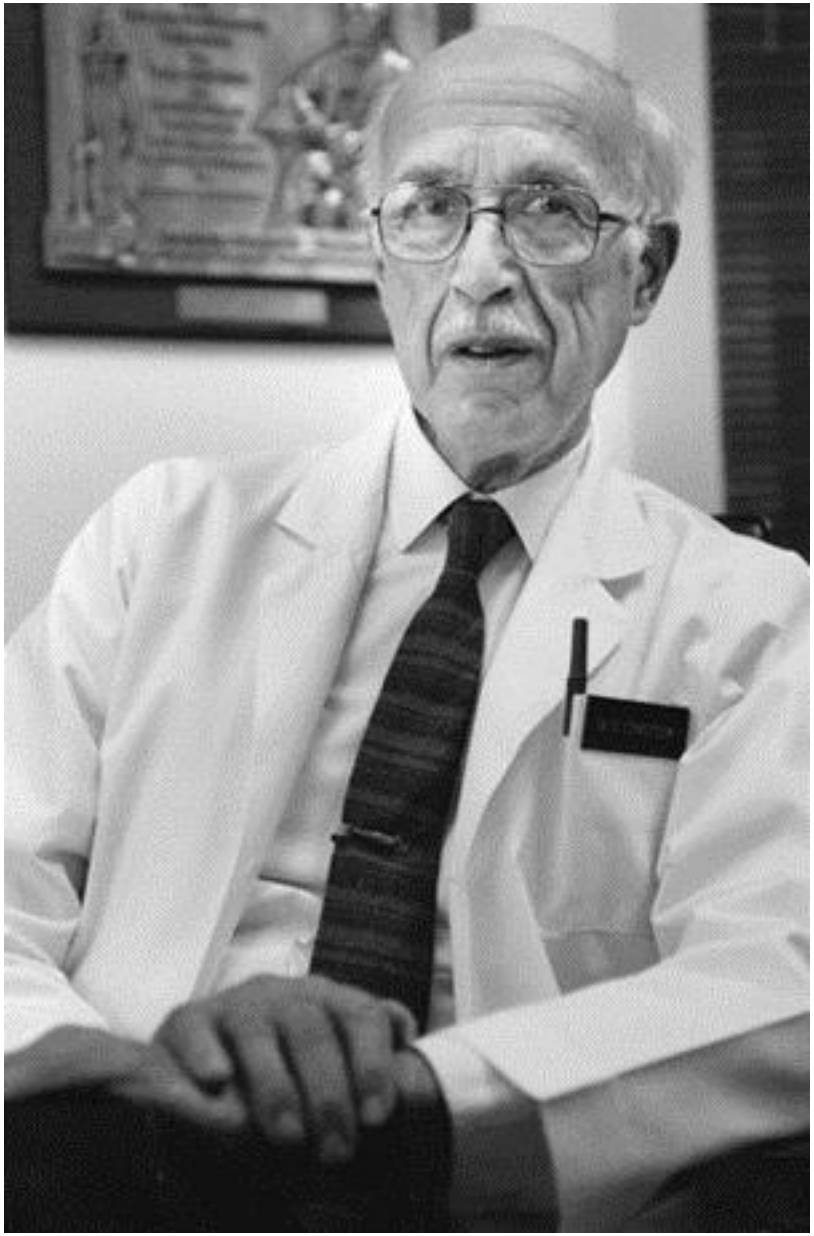
Favors effectiveness ("real life" setting, estimated by decision analysis)	Favors efficacy (estimated under ideal conditions in a RCT)



George W. Comstock

"If it isn't ultimately aimed at policy, it's not worth doing" *(*Morabia A interviews G. Comstock. *Am J Epidemiol 2013;177:595)*

THANK YOU

Wall Street Journal cartoon removed – “Next question please”