

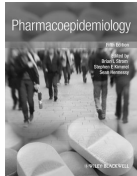
2012 ISPE Mid-Year Meeting
Introduction to Pharmacoepidemiology
April 22, 2012

A Brief Introduction to Pharmacoepidemiology

Tobias Gerhard, PhD
Assistant Professor, Ernest Mario School of Pharmacy
Institute for Health, Health Care Policy, and Aging Research
Rutgers University



Pharmacoepidemiology

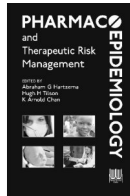


The study of the use of and the effects of drugs in large numbers of people. It applies the methods of epidemiology to the content area of clinical pharmacology.

In: Strom BL, Kimmel SE, Hennessy S, editors.
Pharmacoepidemiology

The study of the frequency, distribution, and determinants of disease in humans, with "determinants" being drugs, vaccines, or devices.

In: Hartzema AG, Tilson HH, Chan KA, editors.
Pharmacoepidemiology and Therapeutic Risk Management



Epidemiology in 2X2 Tables

		Disease	
		+	-
Exposure	+	A	B
	-	C	D

In the beginning, the epidemiologist created the cohort study and the 2X2 table, and exposure was dichotomized and disease was dichotomized, and thus the 2x2 table had four cells, the cell of A, the cell of B, the cell of C, and the cell of D. And the epidemiologist saw that it was straightforward and deemed that it was good.

- K. Rothman, 2001

US Regulatory Development

"History Matters"

- 1906: The Jungle –
Pure Food and Drug Act
 - Illegal to manufacture adulterated or misbranded foods or drugs
- 1938: Elixir of Sulfanilamide
Food, Drug, & Cosmetics Act
 - Safety, before marketing a drug
- 1962: Thalidomide
Kefauver-Harris Amendments
 - Efficacy, before marketing a drug (on-label/off-label)



US Regulatory Development (cont)

"History Matters"

- 1992: Lengthy approvals
PDUFA
 - Timeliness, funding, approval standards
- 2007: Vioxx and Other Drug Crises
FDAAA
 - Post-marketing drug safety, Sentinel, REMS



Clinical Development

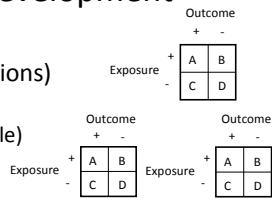
- Observation
 - Anecdote → Collection of anecdotes → Data?
 - Spontaneous case reports → Pharmacovigilance
 - Hospital-based surveillance
- Inference
 - Resolving the counterfactual
 - Patient took drug – patient had adverse outcome
 - What would have happened if, counter to fact, patient had not taken drug?
 - How?
- Mechanistic understanding
 - Physiology/pharmacology
 - Genetics

Methods Development

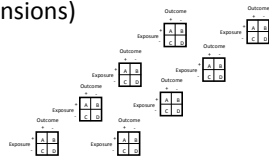
- Case reports/series
- Cross sectional studies
- Ecologic studies
- Cohort studies (+/- randomized allocation)
- Case control studies
- Case-based studies
- Grand unified theories

Analytic Development

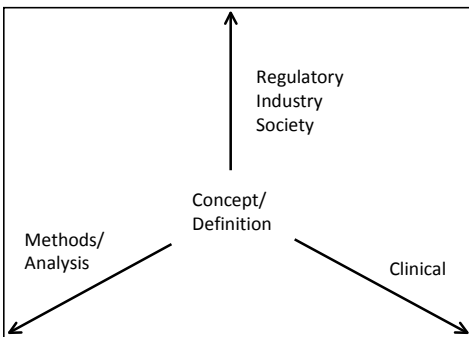
- World is flat (2 dimensions)
 - Case report(s)
 - The wheel (the 2x2 table)



- World is round (3+ dimensions)
 - Multivariable analyses
 - Survival analyses
 - Propensity scores
 - Etc...



Pharmacoepidemiologic Evolution/Drift



Presentations This Afternoon

- **Introduction**, Tobias Gerhard 8:30 - 8:40
- **Cohort Studies**, Almut Winterstein 8:40 - 9:30
- **Case-Control Studies**, Tobias Gerhard 9:30 - 10:20
- **Break** 10:20 - 10:50
- **Confounding and Bias**,
Soko Setoguchi, FISPE 10:50 - 11:40
- **Introduction to Pharmacovigilance**,
Syed Rizwanuddin Ahmad, FISPE 11:40 - 12:30

Thank you!

Contact:
tgerhard@rci.rutgers.edu
