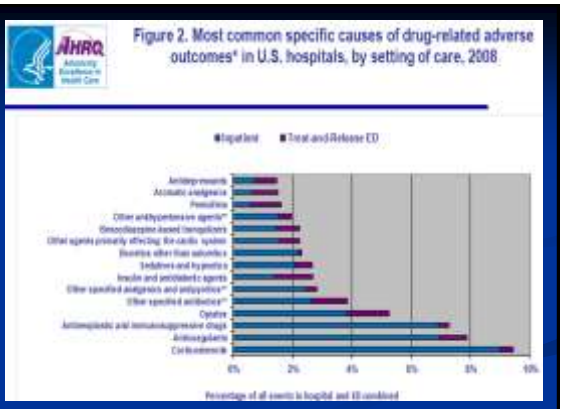
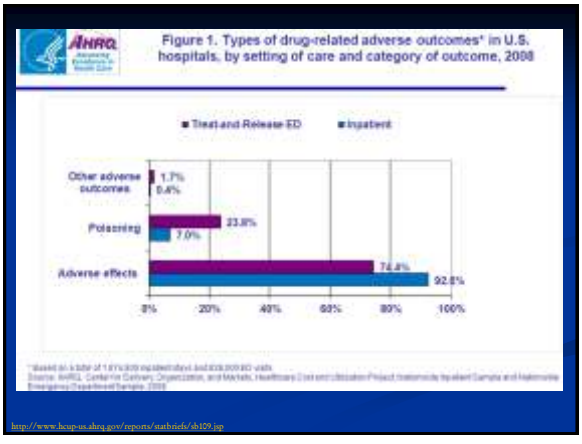
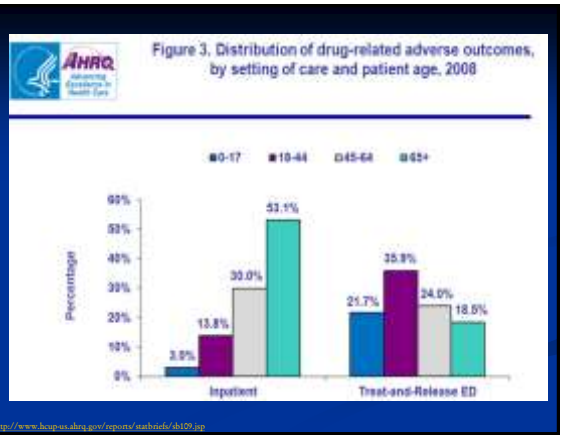
โรคหมอทำ ในอเมริกา

จำนวนคนตายปีละ	ชนิด
106,000	ให้ยาผิดหรือพิษจากยา
80,000	โรคติดเชื้อในรพ.
45,000	ความผิดพลาดอื่นๆ
12,000	ผ่าตัดเกินจำเป็น
7,000	หมอ พยาบาล บุคลากร ทำพลาด
250,000	รวม

JAMA, Dr. Starfield







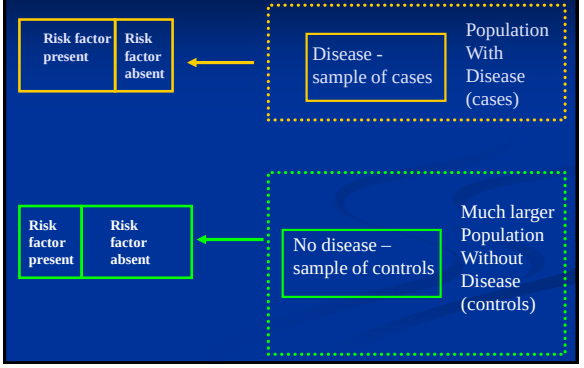
Concepts to take home

- Recognize types of studies
- Advantages and disadvantages of study designs
- Risk calculations/confidence intervals
- Number needed to harm

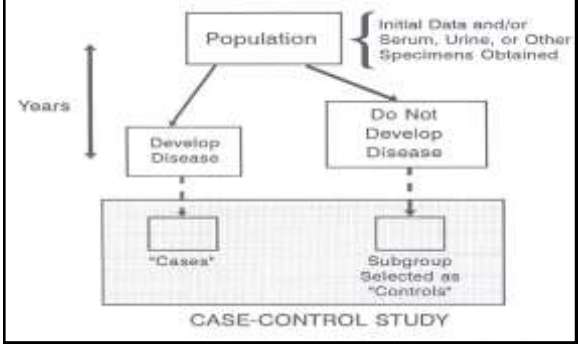
Types of studies

- **Observational studies**
  - Descriptive
    - Case report
    - Case series
    - Cross sectional
    - Longitudinal
  - Analytic
    - Ecological
    - Cross sectional
    - Case-control
    - Cohort - Prospective
      - Retrospective
- **Experimental studies**
  - Clinical trial (Randomized controlled trial)
  - Field trial / Community trial

Design of case-control study



Nested case-control study



Type of case-control studies

- Population based case-control
- Hospital based case-control

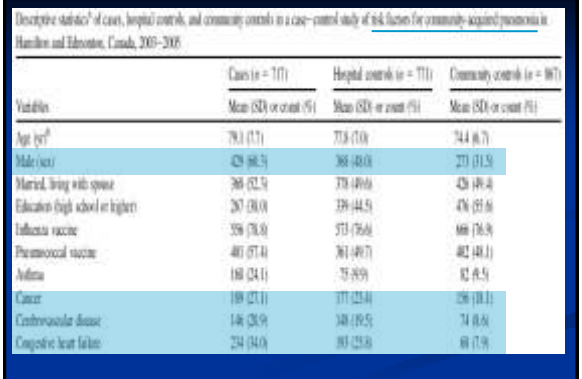
- Unmatched case-control
- Matched case-control

Sources of case

- Case diagnosed, identified
  - in a hospital , clinic
  - a disease registry
  - mass screening
  - through a prior cohort study
- Incidence or prevalent cases

Sources of control

- Population controls
- Neighborhood or friend controls
- Hospital control



Descriptive statistics[a] of cases, hospital controls, and community controls in a case–control study of risk factors for community-acquired pneumonia in Hamilton and Edmonton, Canada, 2005–2008

Variables	Cases (n = 707) Mean (SD) or count (%)	Hospital controls (n = 771) Mean (SD) or count (%)	Community controls (n = 867) Mean (SD) or count (%)
Age (yr)[b]	79.1 (7.7)	77.8 (7.0)	74.4 (6.7)
Male (sex)	429 (60.7)	368 (48.0)	273 (31.5)
Married, living with spouse	366 (52.7)	378 (49.6)	426 (49.4)
Education (high school or higher)	267 (38.0)	339 (44.5)	476 (55.6)
Influenza vaccine	556 (78.8)	573 (75.6)	666 (76.9)
Pneumococcal vaccine	401 (57.4)	361 (49.7)	402 (48.1)
Asthma	168 (24.1)	75 (9.9)	82 (9.5)
Cancer	189 (27.1)	177 (23.4)	236 (28.1)
Cerebrovascular disease	146 (20.9)	148 (19.5)	74 (8.6)
Congestive heart failure	234 (34.0)	193 (25.8)	68 (7.9)

http://www.uc.pt/en/fmuc/phdhs/Courses/Epidemiology/Community_controls_were_preferred_to_hospital_controls_in_a_casee control_study.pdf

ประเด็น	Hospital control	Community/ Population control
ความใกล้เคียงกับประชากรอันเป็นที่มาของ case	+	+ + + +
โอกาสเข้าถึงตัว	++++	++
โอกาสได้รับความร่วมมือ	++++	+
ปัจจัยเสี่ยงใกล้เคียงกับ case	+ + + +	+
Lab data available	+ + + +	+
Treatment data available	+ + + +	+

Example of unmatched case-control

	Cases (Reye's)	*Controls*
# who use ASA	26	53
# who didn't	1	87
TOTAL	27	140

X^2 value = 28.7 , p-value < 0.05
Odds ratio = 42.7 (95%CI = 5.9 - 869.5)

OR in matched case-control

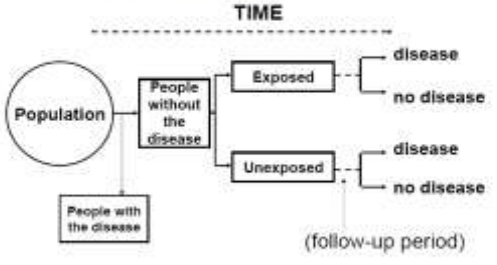
Case: E E E E E E E N N N N
Control: E E N N N N N E N N N

Control

Case	Exposed	Not exposed
Exposed	2	4
Not exposed	1	3

Odds ratio = ?
Ratio of unmatched pair
= 4/1 = 4

Design of Cohort Study



Example of cohort study

	GI bleeding (Side effect) Yes	No
Drug A	12	124
Drug B	6	178
TOTAL	18	302

X^2 value = 4.56 , p-value = 0.03
Relative risk = 2.7 (95% CI = 1.04-7.03)

CV Adverse Events: VIGOR

Patients: RA
Aspirin treatment: not allowed

Event Category	Patients With Events (Rates per 100 Patient-Years) Rofecoxib (n=4047)	Naproxen (n=4029)	Relative Risk (95% CI)
Cardiac	28 (1.0)	10 (0.4)	0.36
Cerebrovascular*	11 (0.4)	8 (0.3)	0.73
Peripheral vascular	6 (0.2)	1 (0.04)	0.17
Confirmed CV	45 (1.7)	19 (0.7)	0.42

0 1 2

* Not including hemorrhagic stroke.
FDA Advisory Committee Meeting, 2001.

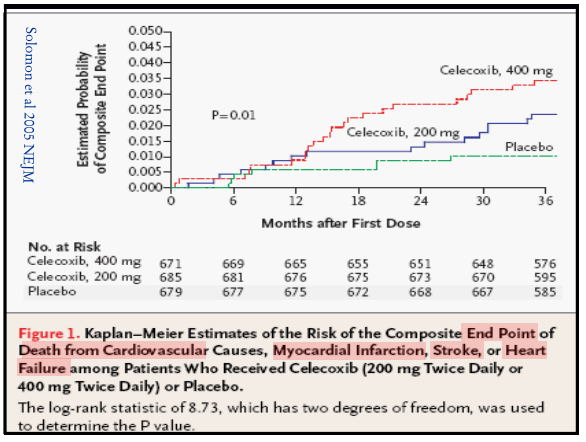


Figure 1. Kaplan–Meier Estimates of the Risk of the Composite End Point of Death from Cardiovascular Causes, Myocardial Infarction, Stroke, or Heart Failure among Patients Who Received Celecoxib (200 mg Twice Daily or 400 mg Twice Daily) or Placebo.
The log-rank statistic of 8.73, which has two degrees of freedom, was used to determine the P value.

Advantages & Disadvantages

Study design	Advantage	Disadvantage
Case-control	▪ Cheaper ▪ Valuable for rare condition ▪ Short duration	▪ Baseline risk- not measured ▪ No temporal relationship ▪ Recall bias
Nested case-control		
Cohort		

Number needed to harm

- Number of patients needed to be treated for one additional patient to be harmed.
- Deriving the NNH from odds ratio

$$NNH = \frac{CER(OR-1)+1}{CER(OR-1)(1-CER)}$$

Note *CER = control event rate (rate of outcome among the unexposed), OR = odds ratio*

- Deriving the NNH from risk ratio

$$NNH = \frac{1}{\text{Absolute risk increase}}$$