EBM AND CRITICAL APPRAISAL

- EVIDENCE BASED MEDICINE
- CRITICAL APPRAISAL

EBM

- The Practice of Medicine is an Art Backed by Science
- As Trainers We Must Pass on the Art as has Occurred over the Centuries
- The Science:
  Basic Principles
  Evidence Based Medicine

EBM

- EBM Is Not Intended To Replace Clinical Judgement But Rather To Enhance It
- As Trainers We Must:
  - Teach our trainees the principles of EBM
  - Teach them how to critically appraise the evidence
    - Validity
    - Applicability

THE HIERARCHY OF EVIDENCE

Ia Systematic review of randomised clinical trials

Ib Single randomised clinical trials

II Cohort study

III Case-control study

IV Physiological studies, narrative overviews, consensus reports, opinion of 'experts'

DANGERS IN NON-RANDOMISED STUDIES

- **Biological Mechanisms**
  - Limited time of diseases
  - Cyclical progression of diseases
  - When do we see patients?
- **Psychological Mechanism**
  - The Rosenthal effect, we see what we want to see (BIAS)!
  - The Barnum effect, we believe what we want to believe (astrology)!
- **Confounding by indication**

IMPORTANT ASPECTS OF RANDOMISED CLINICAL TRIALS

- Random errors
- Systematic errors (bias)

RANDOM ERRORS IN SMALL TRIALS

- False positive results (type I error)
- False negative results (type II error)

SYSTEMATIC ERRORS (BIAS) IN RANDOMISED TRAILS

Methodological quality

Confidence that the design, conduct, and report of a trial restrict bias in the intervention comparison

HOW TO ASSESS METHODOLOGICAL QUALITY

- Generation of the allocation sequence
- Allocation concealment
- Double blinding
- Sample size
- Intention-to-treat analysis

CONCLUSIONS

Methodological quality of 'small' RCTs affects the estimated intervention effect

- On average, **high quality RCTs provide reliable estimates**
- On average, **low quality RCTs exaggerate the intervention effect with 50%**

CONCLUSIONS

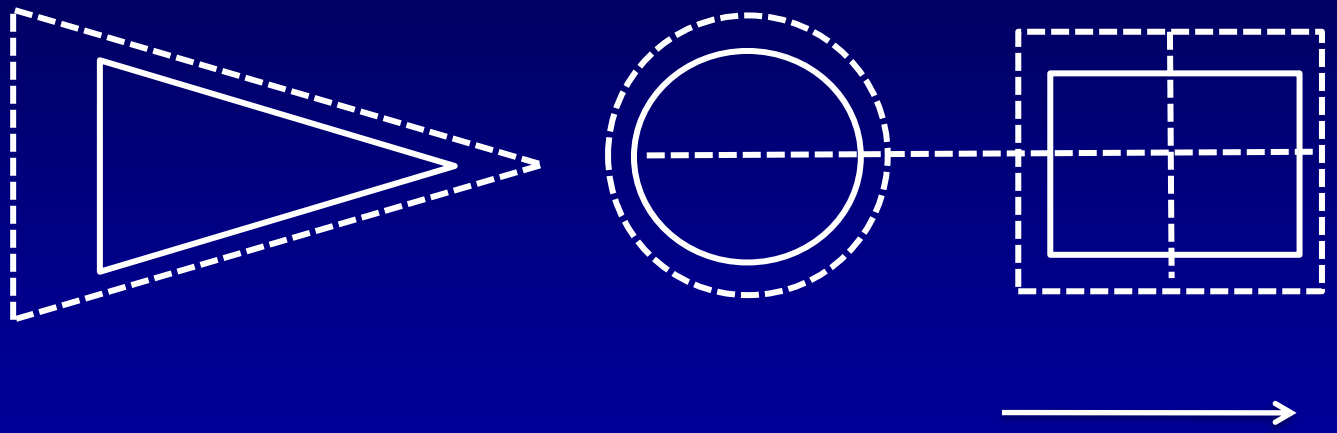
- The majority of trials in Gastroenterology have inadequate methodological quality regarding
  - Generation of the allocation sequence
  - Allocation concealment
  - Double blinding
- The methodological quality varies significantly within different disease areas

CRITICAL APPRAISAL

The 4 components of study appraisal

1) Is the study valid (i.e. good design / little bias)?
2) What's the magnitude of the effect?
3) Is the effect precise?
4) Are the findings applicable?

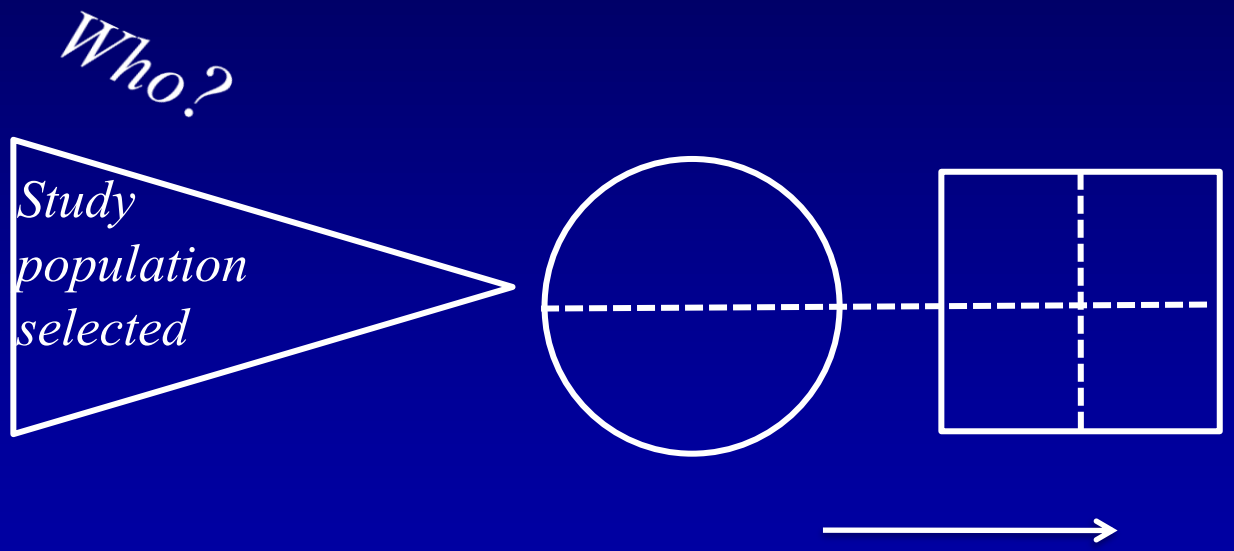
GATE: a Generic Appraisal Tool for Epidemiology



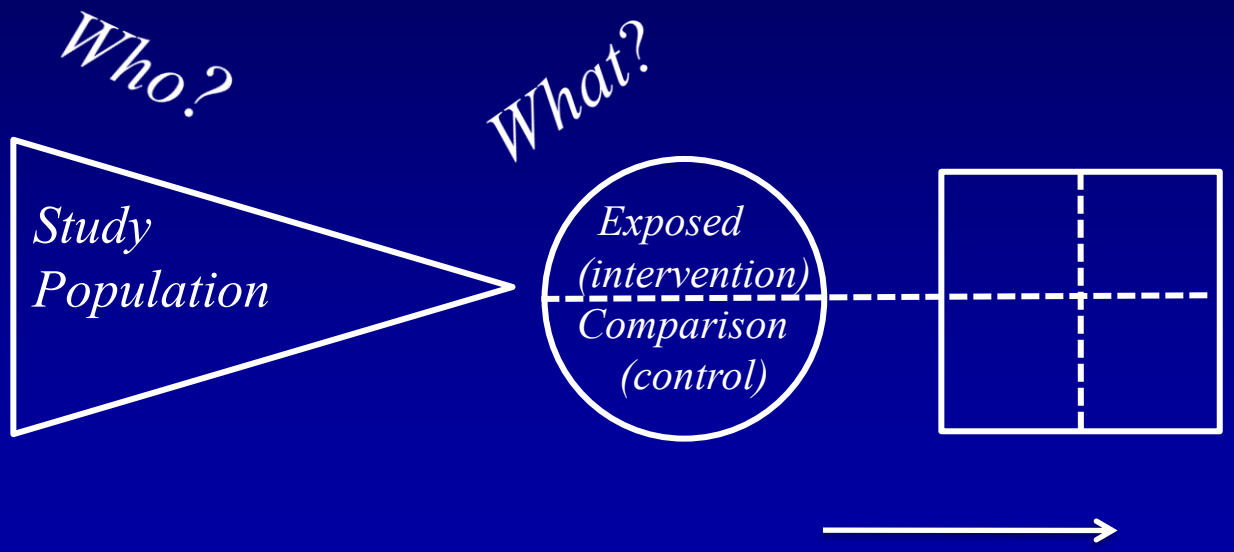
1) Is the study valid? (i.e. is it well designed?)

Study design

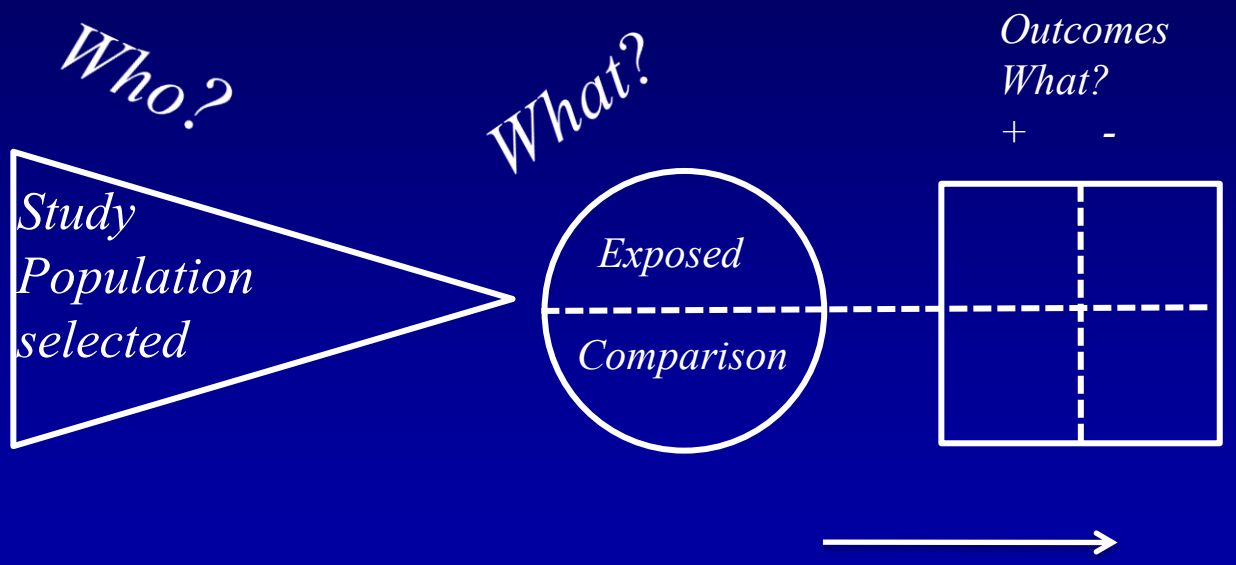
: design



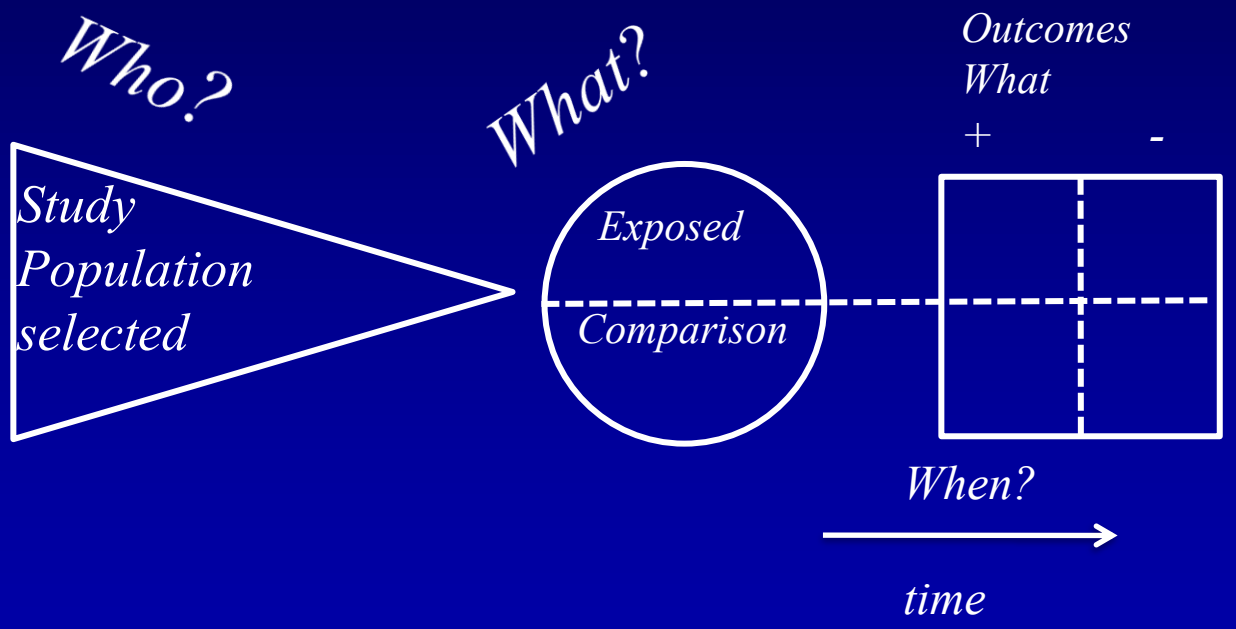
: design


Who?
What?
Study Population
Exposed (intervention)
Comparison (control)

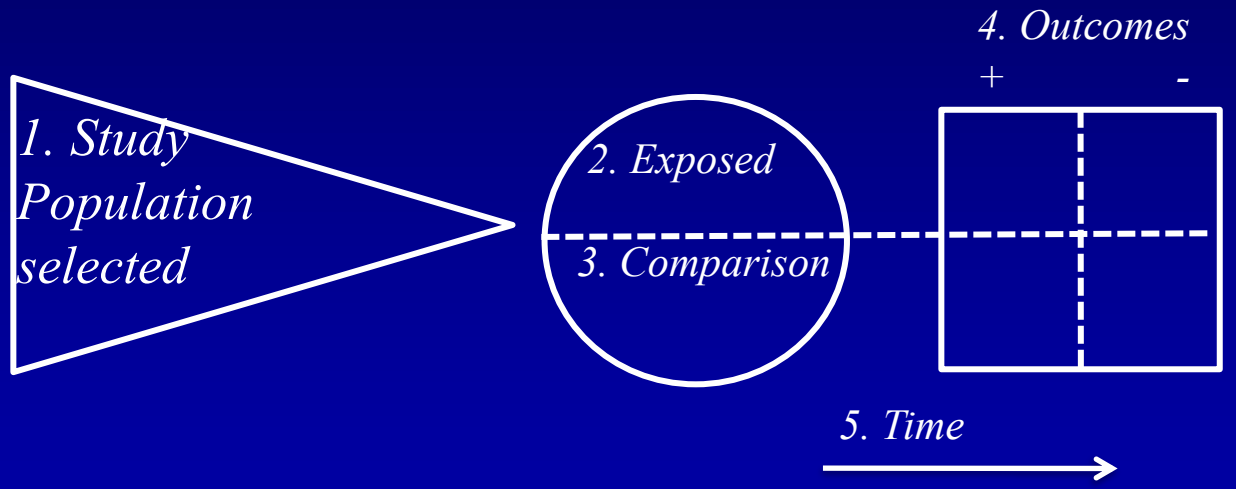
: design


Who?
What?
Outcomes
What?
+
-
Study
Population
selected
Exposed
Comparison

: design


Who?
What?
Outcomes
What
+
-
Study
Population
selected
Exposed
Comparison
When?
time

PECOT diagram: design components

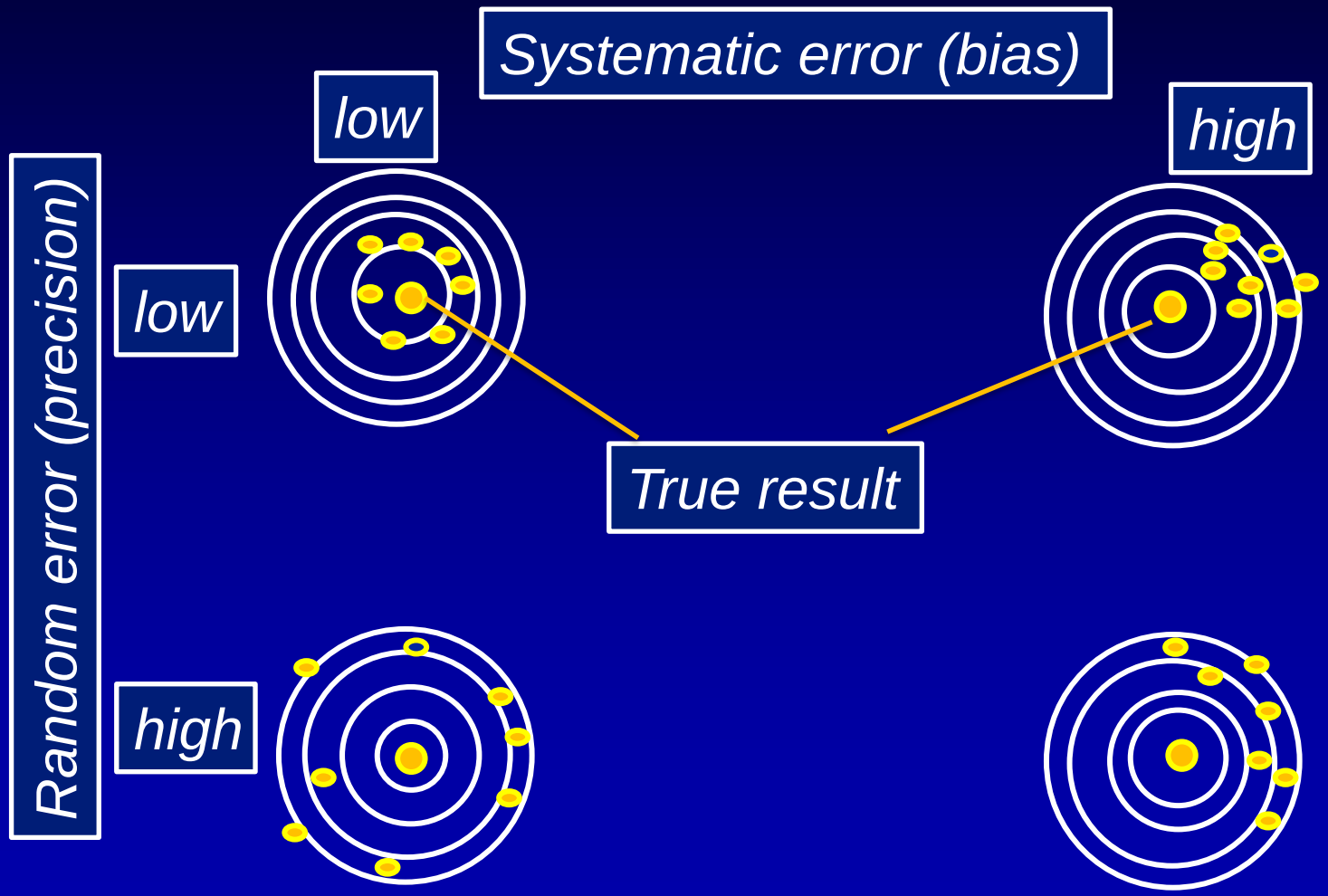


1) Is the study valid? (i.e is it well designed?)

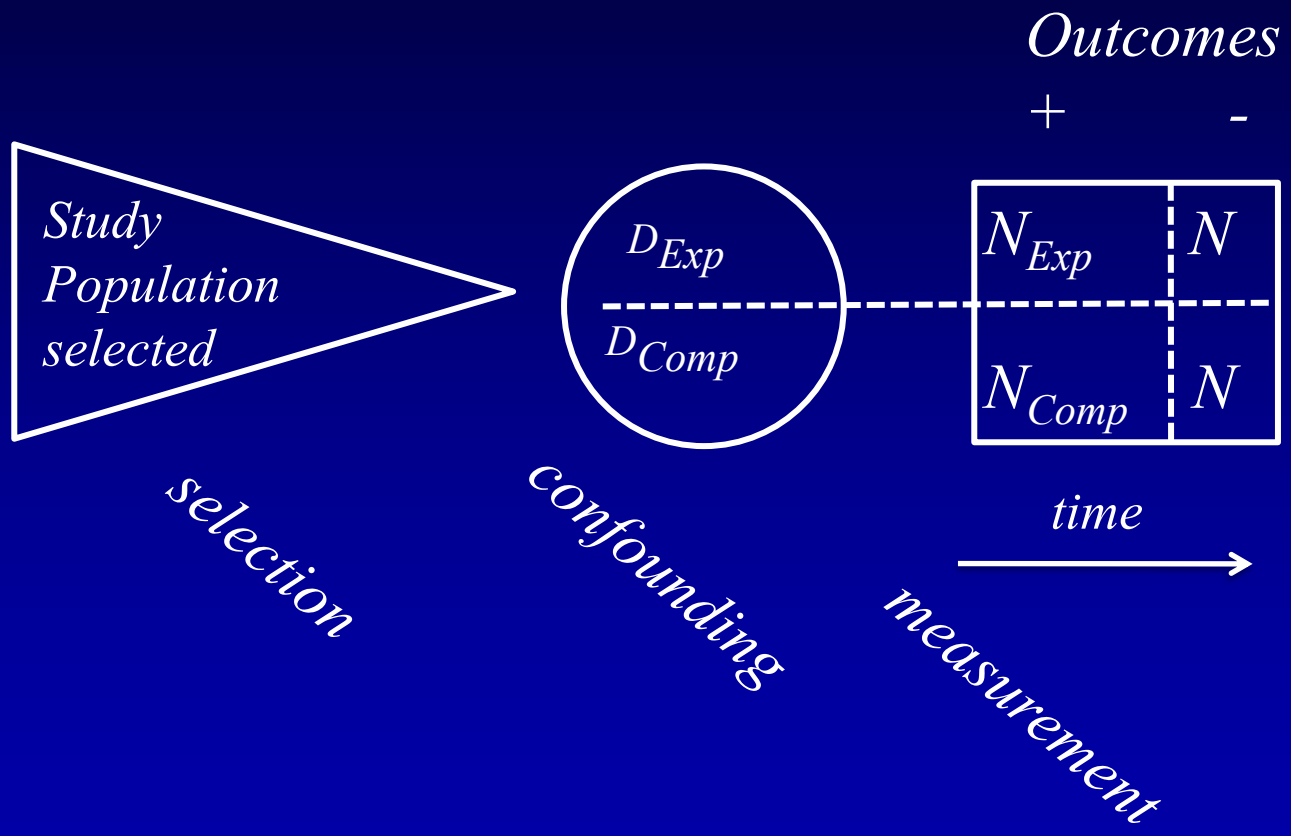
Absence of bias

(random or systematic error)

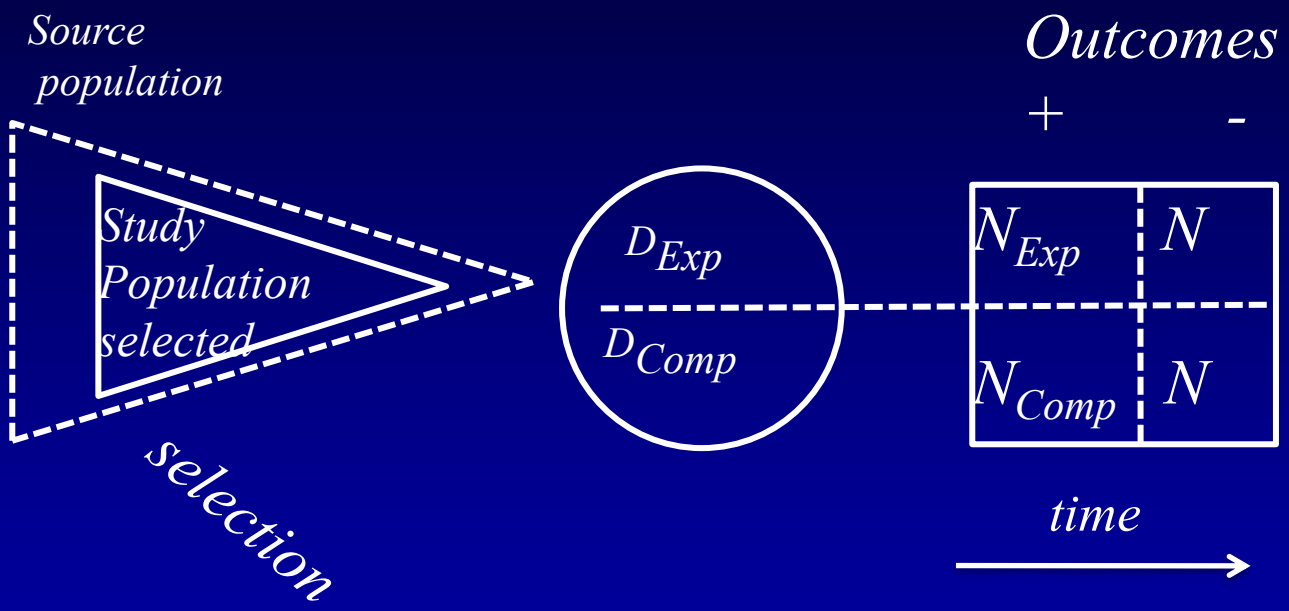
Systematic and random error



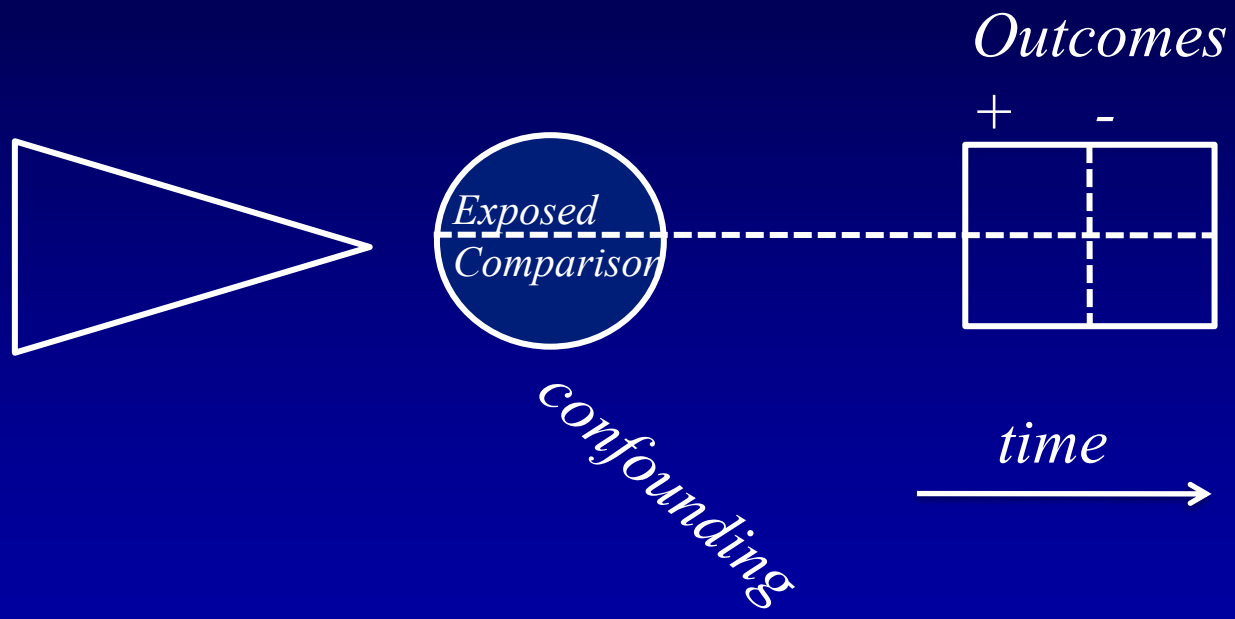
PECOT diagram:bias



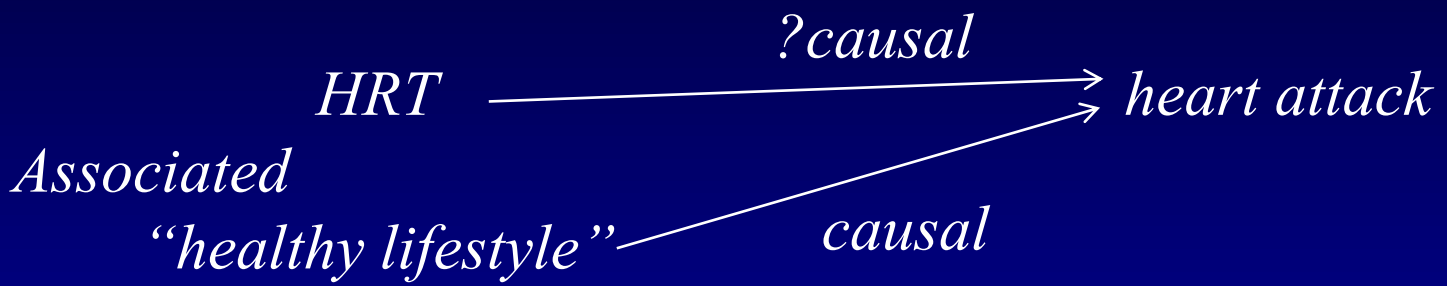
Selection


Source
population
Study
Population
selected
selection
D_{Exp}
D_{Comp}
Outcomes
+
-
N_{Exp}
N
N_{Comp}
N
time

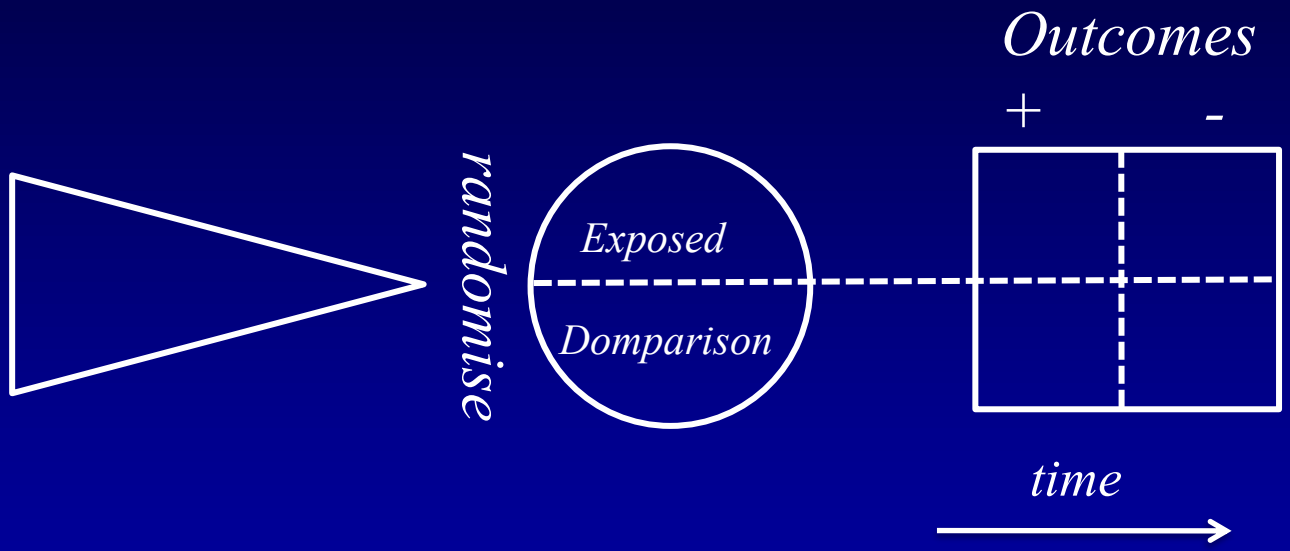
Confounding



Confounding

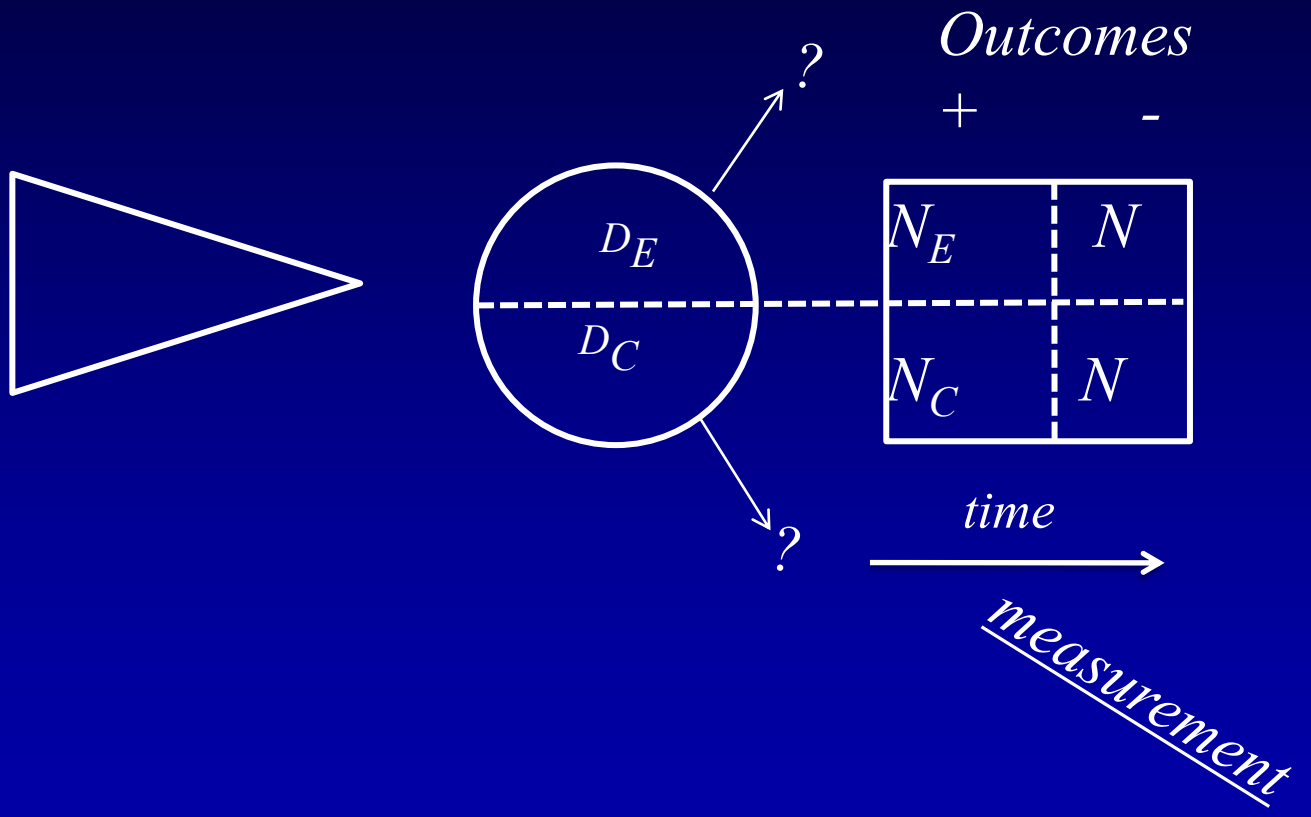


Minimising confounding



confounding

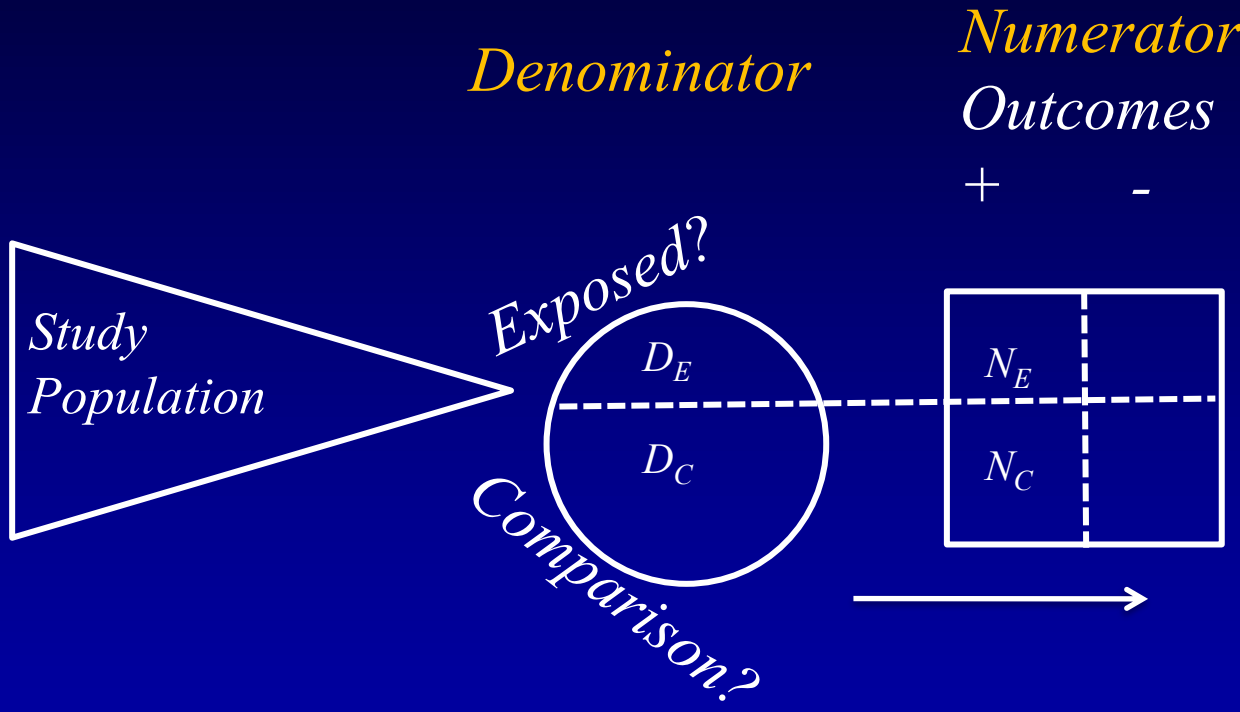
Measurement bias
loss f-p/compliance/contamination



2) What is the magnitude of the effects measured in the study?

The numbers

GATE approach: numbers



Relative Risk

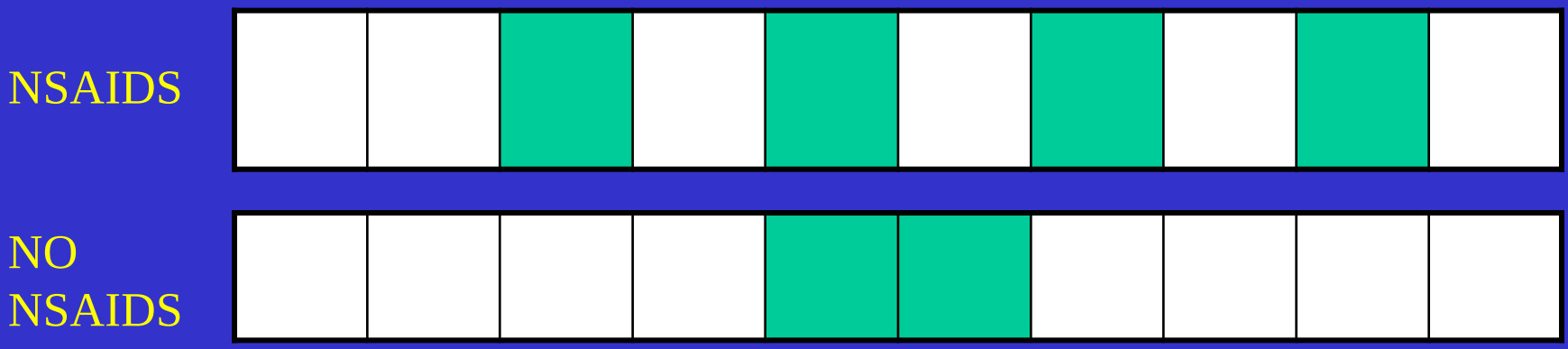
- Exposed
- Unexposed

$$\frac{A/(A+B)}{C/(C+D)}$$

Odds Ratio

Event	nonevent
A	B
C	D

$$\frac{A/B}{C/D}$$


NSAIDS
NO NSAIDS

treatment	Total	Develop an Ulcer	Did not
NSAID	10	4	6
Placebo	10	2	8
	Calculations made form these results		
Event Rate (ER)	4/10 = .4		
Control event rate (CER)	2/10 = .2		
Event Odds	4/6 = .66		
Control Odds	2/8 = .25		
Odds ratio	.66/.25 = 2.6		
Relative Risks (ER/CER)	.4/.2 = 2		
Absolute Risks (ER/CER)	.4 - .2 = .2		
NNT (1/)ER/CER)	1/.2 = 5		

3) Is the EFFECT Precise

THE NUMBERS TABLE
occurrence, effects & precision

Outcomes & time	Comparison occurrence (CO)	Exposure occurrence (EO)	Rel. Risk (EO/CO) ±95% CI	Risk Diff (CE-EO) ±95% CI	NRT (1/RD) ±95% CI

4) Are the findings Applicable

Relevant, feasible, affordable, generalisable

Train the Trainers 2003 - Education and Training Committee

CATs

Critically Appraised Topics

The 5 Steps of Practising EBHC

1. Translate info needs into answerable questions
2. Track down best evidence to answer them
3. Appraise evidence for validity, impact and applicability
4. Integrate evidence with practice expertise and apply in practice
5. Evaluate performance

Steps 1-3 =CAT

The 5 Steps of Generating A CAT

1. Scenario
2. 5-part question
3. Search strategy & article found
4. Critical appraisal summary with evidence table
5. Comments

Clinical Questions

1. Participants (patient group / problem)
2. Exposure (intervention if about therapy)
3. Comparison (if relevant)
4. Outcome
5. Time

Critical Appraisal Exercise

Pederzoli et al

Ward Round

. 80 yr man with acute severe biliary pancreatitis

. Glasgow criteria – score of 4

. What is the role of Antibiotic therapy to minimise necrosis

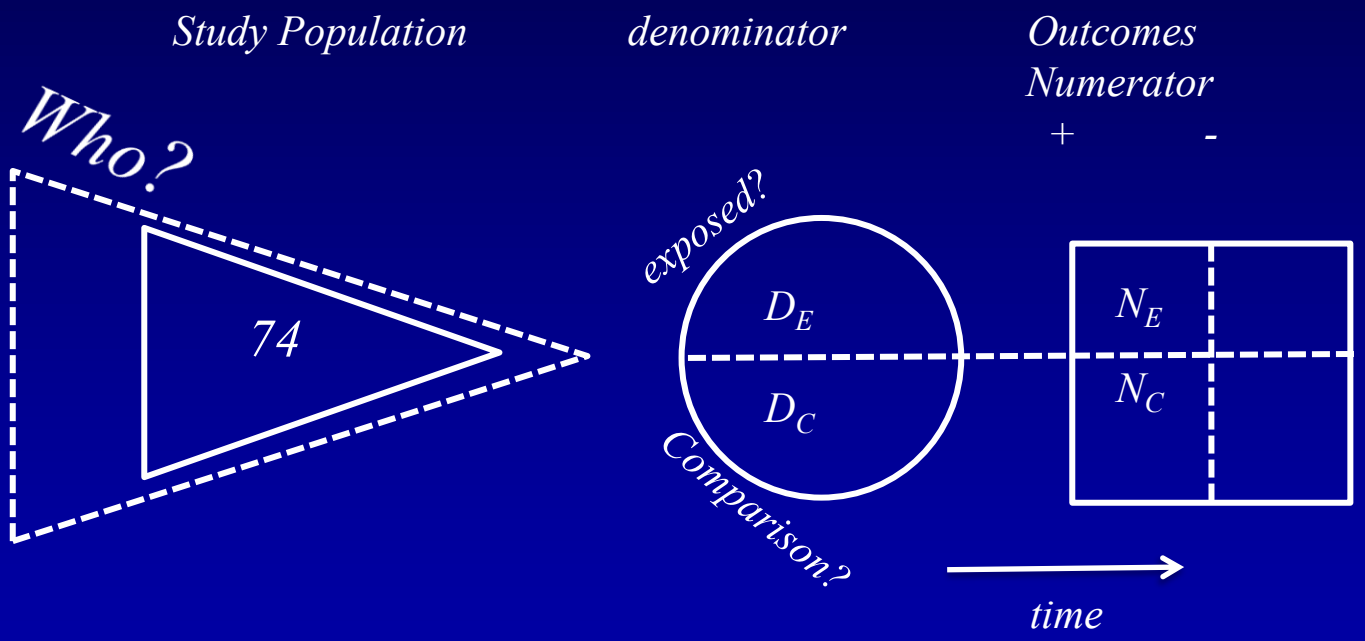
The 5 Steps of Generating A CAT

1. Scenario
2. 5-part question
3. Search strategy & article found
4. Critical appraisal summary with evidence table
5. Comments

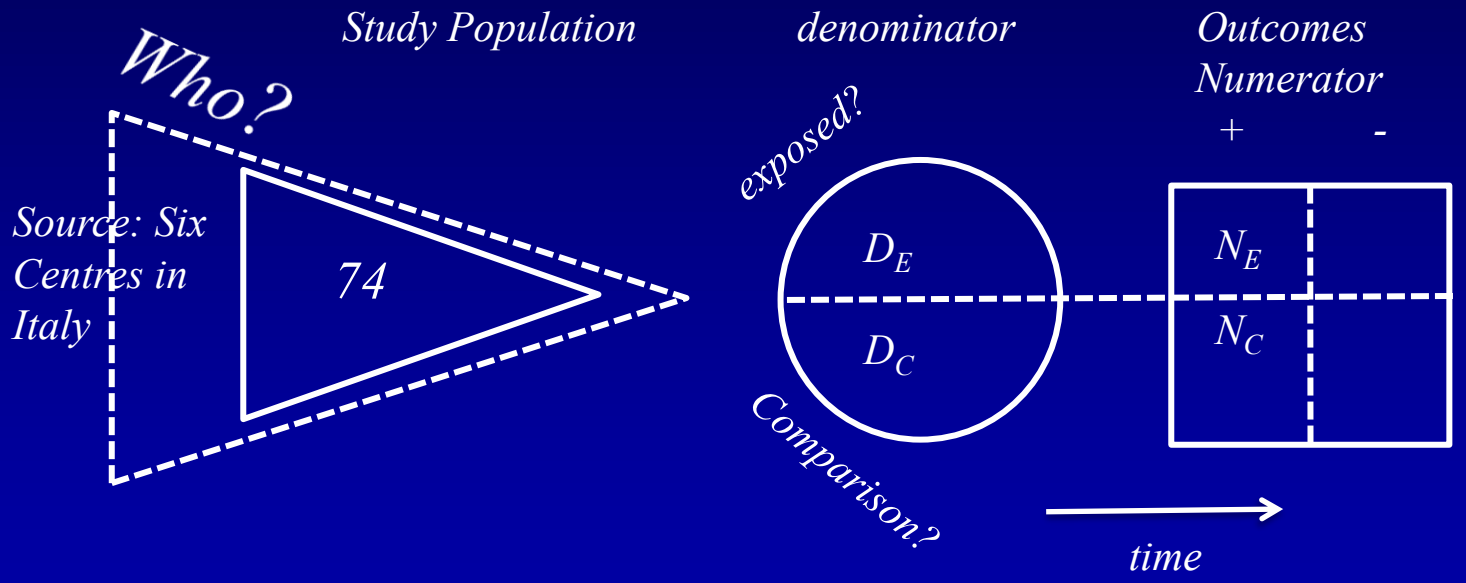
5 Part Question

- 1) In patients with severe pancreatitis
- 2) does the use of antibiotics
- 3) compared to no antibiotics
- 4) reduce the rate of abdominal sepsis
- 5) over the course of the acute illness(3 m)

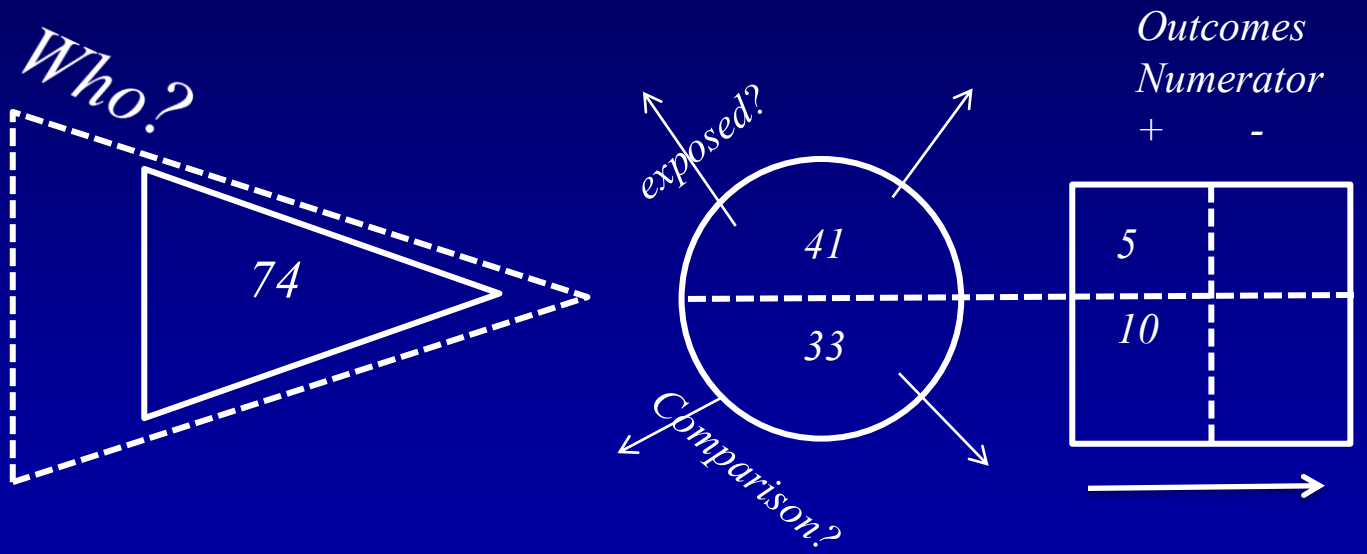
GATE approach: Pederzoli et al



GATE approach



GATE approach:



Magnituce Effect

Relative risk

$$= \text{Event Rate}_{\text{imep}} \div \text{Control}_{\text{placebo}}$$

Magnitude Effect/Benefit/Harm

Relative risk

= 0.122 ÷ 0. 303 = 0.403

Estimating risk

Risk difference

= 0.303 – 0.122 = 0.181

Estimating risk/benefit

NNT = 1 ÷ risk difference

= 1 ÷ 0.181 = 5.5

COMMENTS

- **Randomisation** – not good (more patients with greater necrosis entered into the exposure arm)

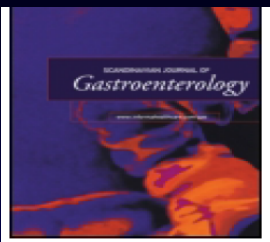
- **No Blinding** by the assessors

- **Difference in production of pancreatic sepsis** did not translate to differences in mortality nor the requirement for operative intervention

Bottom Line

- **Antibiotic therapy reduces the risk of pancreatic sepsis in patients with acute SNP diagnosed on CT , but no effect on Mortality , need for Surgery**

- **Imipenem is an appropriate antibiotic for use in acute SNP**



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Systematic review and meta-analysis of antibiotic prophylaxis in severe acute pancreatitis

Mathias Wittau, Benjamin Mayer, Jan Scheele, Doris Henne-Bruns, E. Patchen Dellinger & Rainer Isenmann

In summary, to date there is no statistically significant evidence that supports the routine use of antibiotic prophylaxis in SAP. However, in case of newly

SUNDAY
4 groups - leader

- Surgical
- Liver
- Reflux
- Varsity - Biologics
- Appraisal Tool Checklist 1/2

Summary: 4 components of study appraisal

1) Is the study valid (i.e. good design / little bias)?
2) What's the magnitude of the effect?
3) Is the effect precise?
4) Are the findings applicable?

THANK YOU