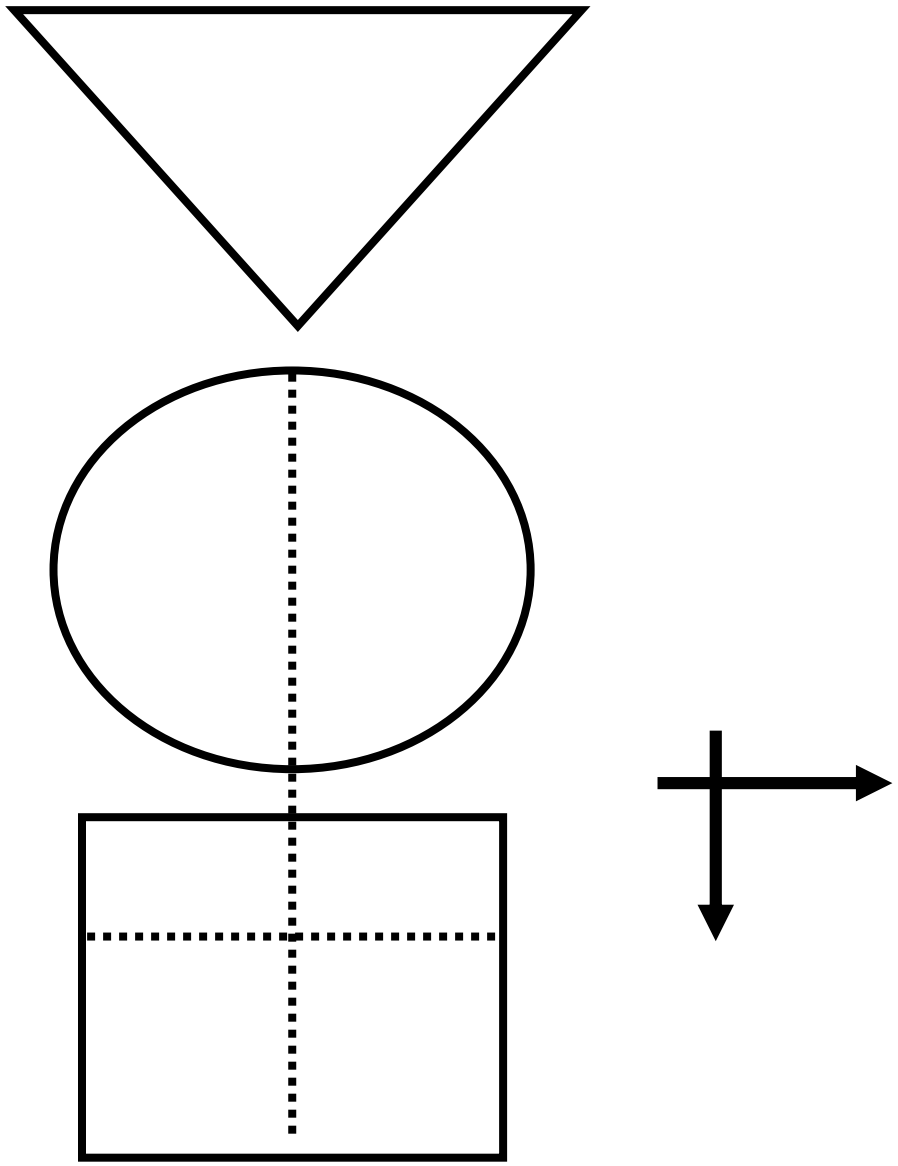


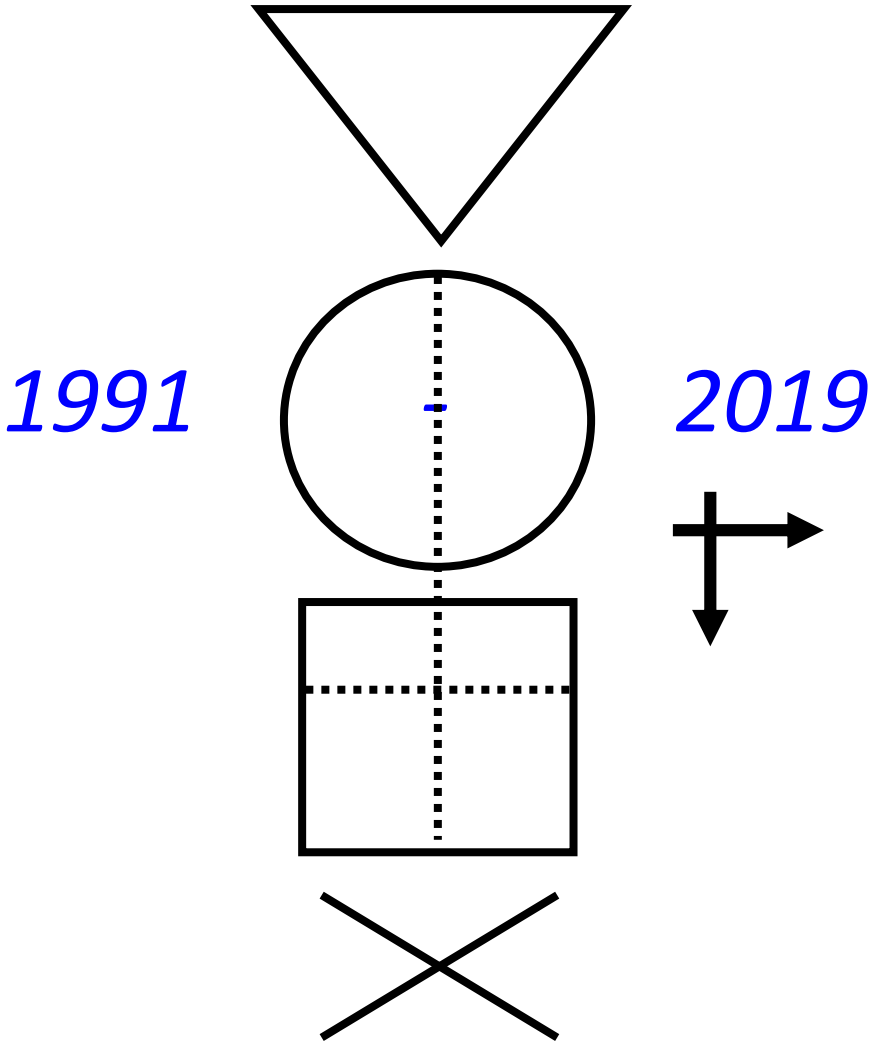
by the end of this session you will know how to use this picture to help you rapidly critique clinical studies (& to teach others how to use it)

Evidence-based medicine is the (explicit) application of clinical epidemiological evidence in clinical decision making

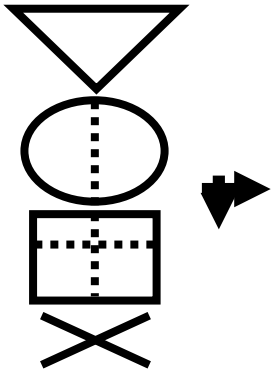
what makes a good teacher?

1. enthusiastic, energetic, excited, passionate & accessible, prepared
2. **highly knowledgeable in their area?**
3. maintains that knowledge base
4. life long reflective learner
5. changes and influences practice
6. **makes their area of expertise accessible**

GATE:
Graphic Appraisal Tool for Epidemiology



1 picture, 2 formulas & 3 acronyms



GATE:

Graphic Appraisal Tool for Epidemiology

Graphic Architectural Tool for Epidemiology

Graphic Approach To Epidemiology

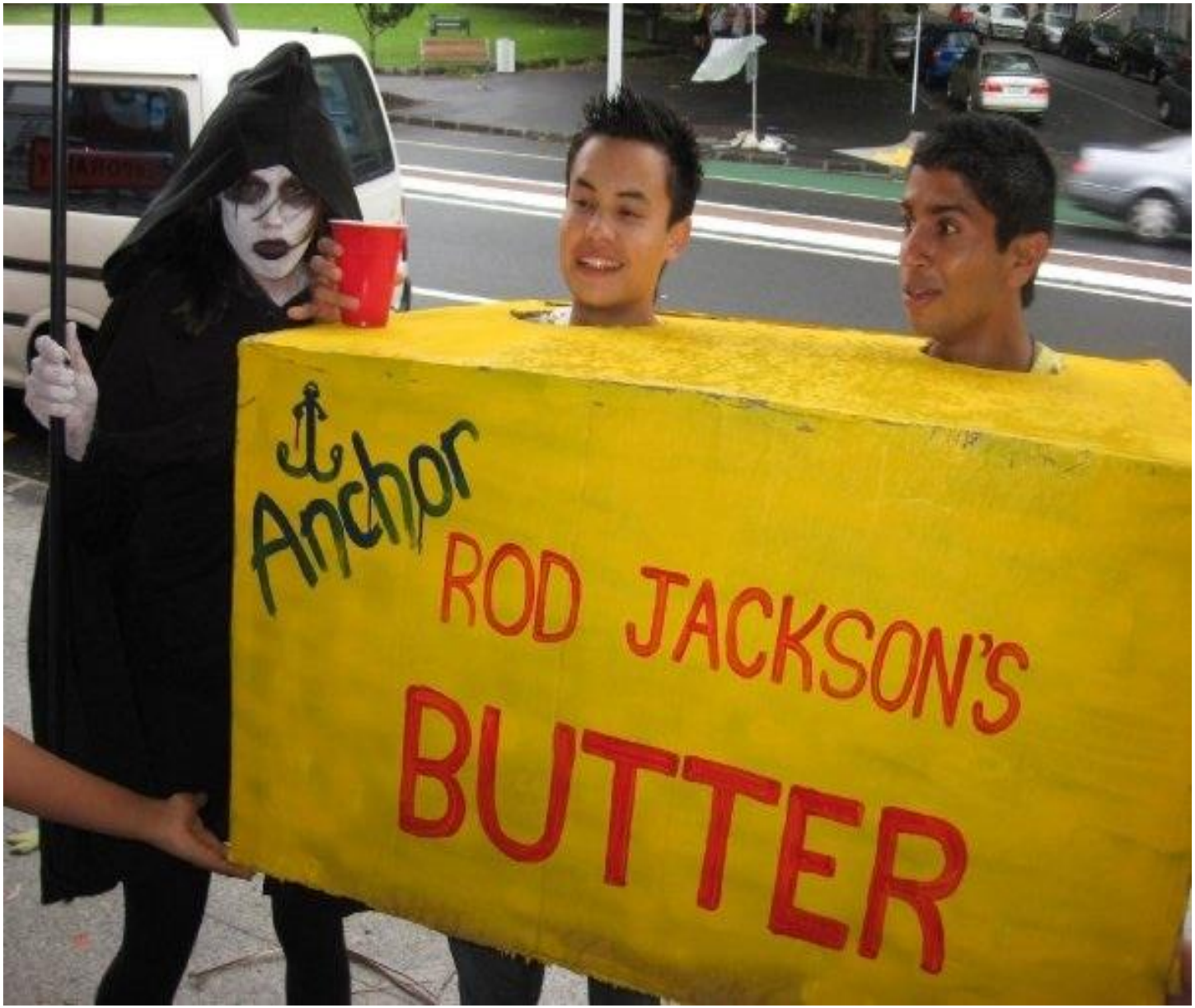
making epidemiology accessible

4th year medical students 1991

Jerry Morris

$$\text{epidemiology} = \frac{\text{numerator}}{\text{denominator}}$$

In: Uses of Epidemiology 1977



Medical Student Pub crawl

Contributions SF to NZ diet

Dear sir

I have just read what you said in the sunday paper
From this I can only conclude that you are some sort of fuckwit
How dare you describe good food like butter as poisonous
How long have you been in this country?
I bet you are one of the auckland wankers that drive around with thier lights on

presentation outline

GATE is a framework for:

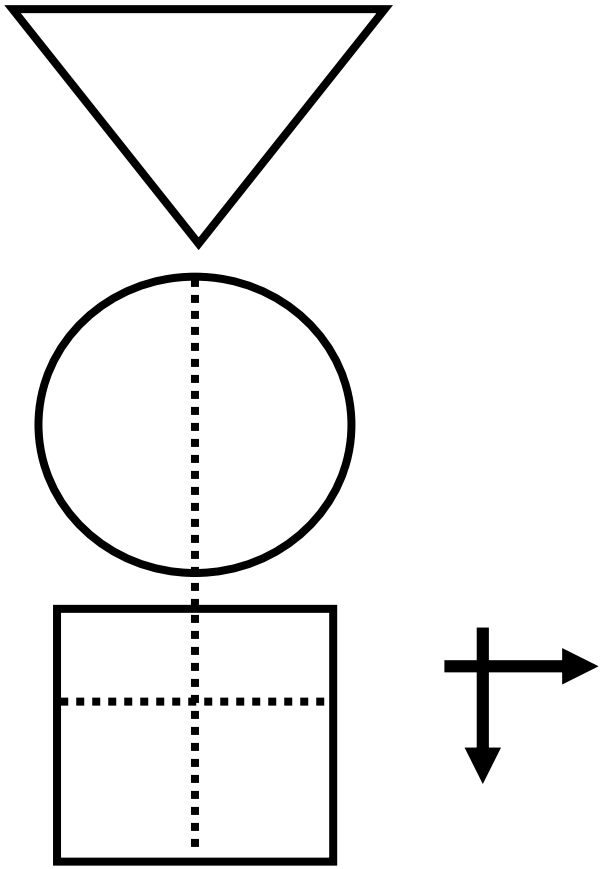
1. study design
2. study analysis
3. study error
4. practicing EBM

1 picture, 2 formulas & 3 acronyms

1

GATE: a framework for study design

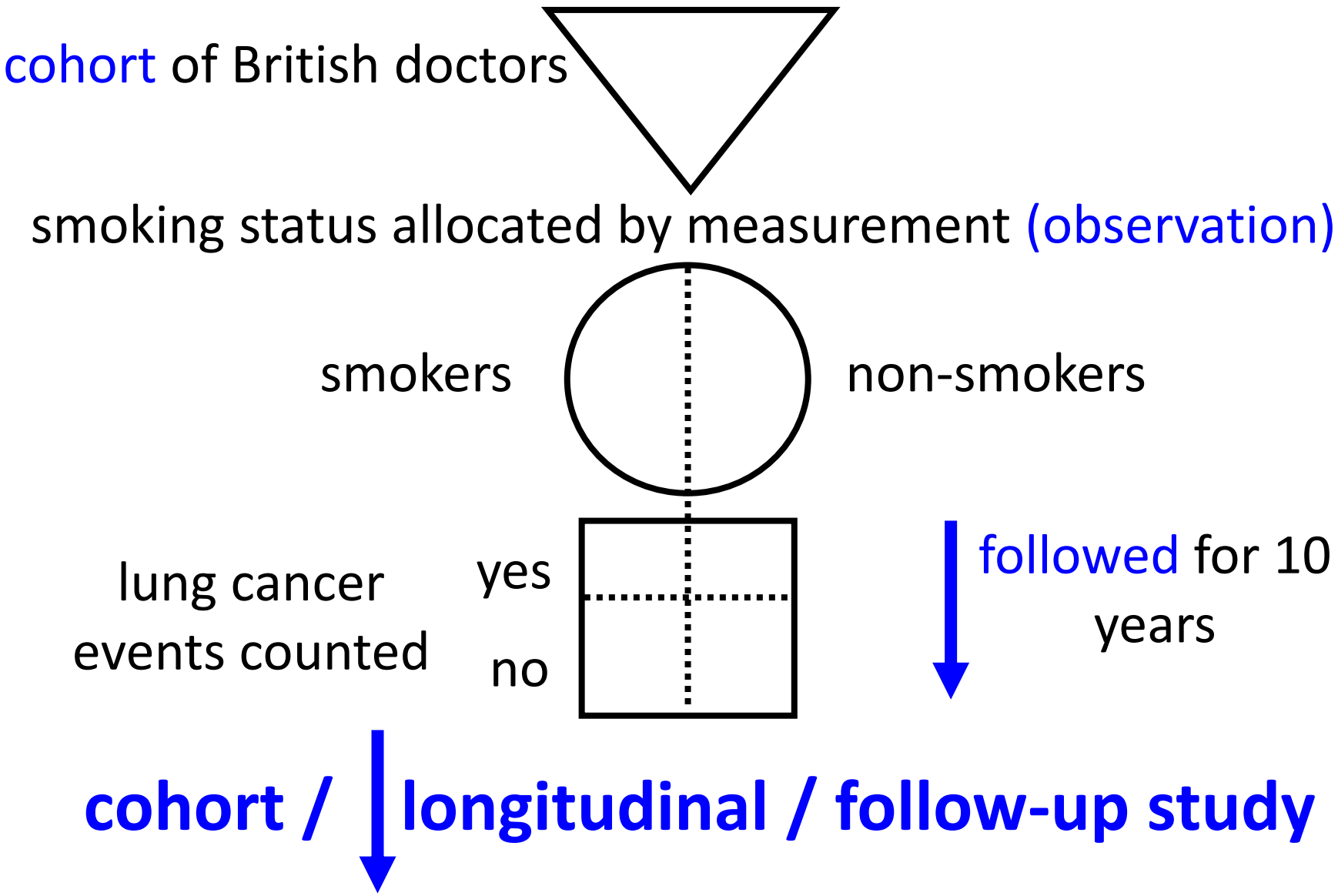
1 picture



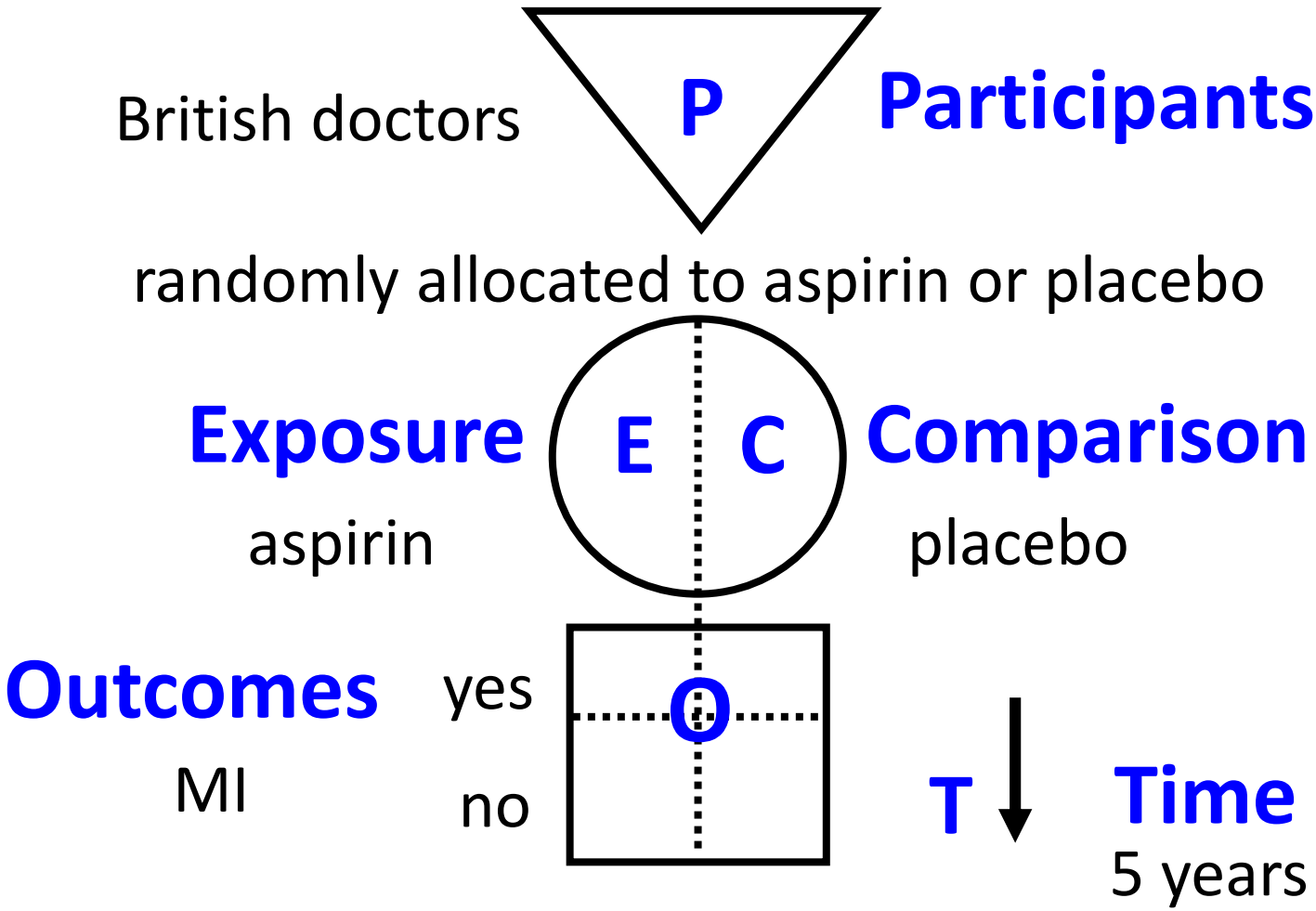
every epidemiological study can be hung on the GATE frame

*1 **picture**, 2 formulas & 3 acronyms*

1 picture: GATE frame

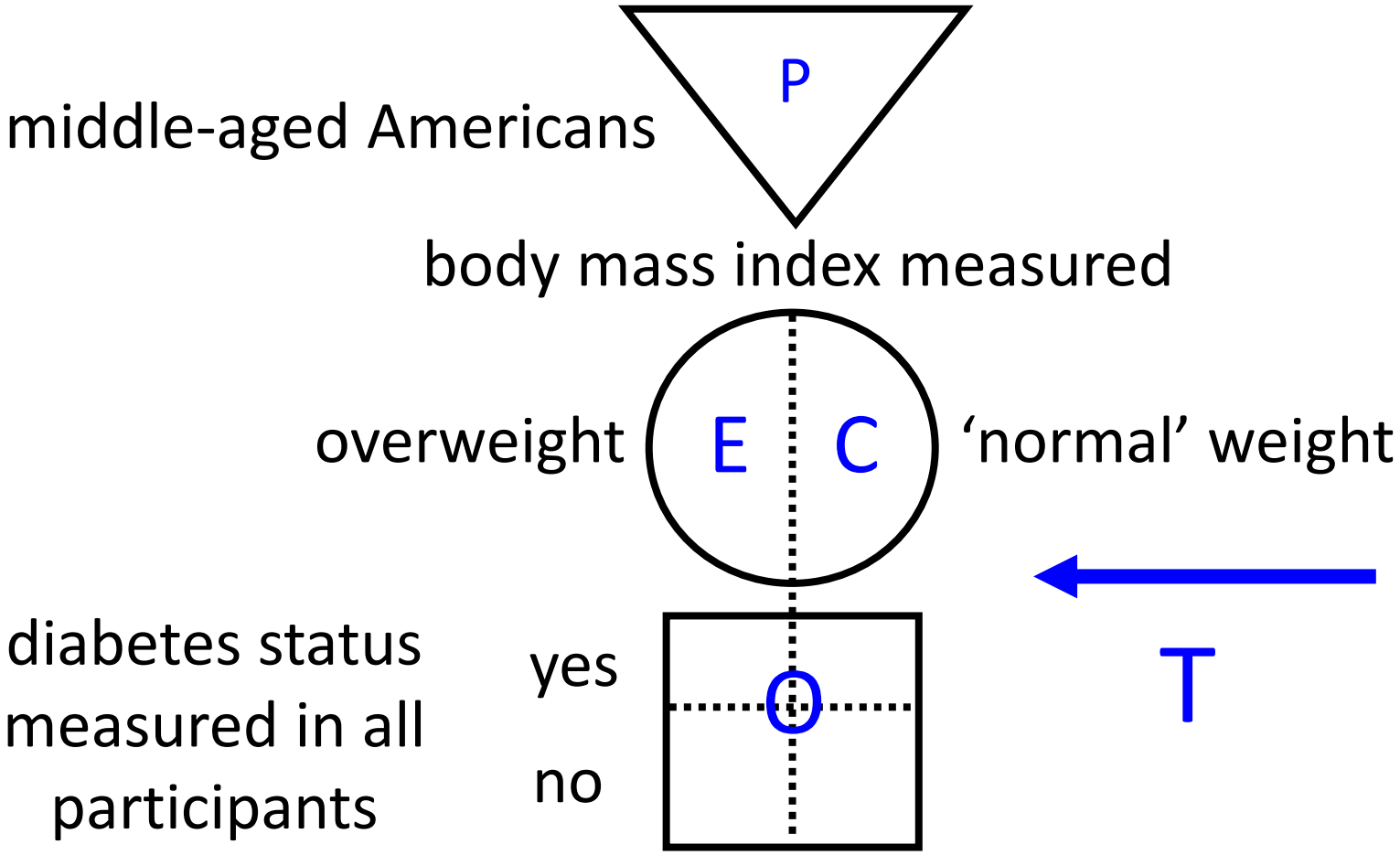


1st acronym: PECOT

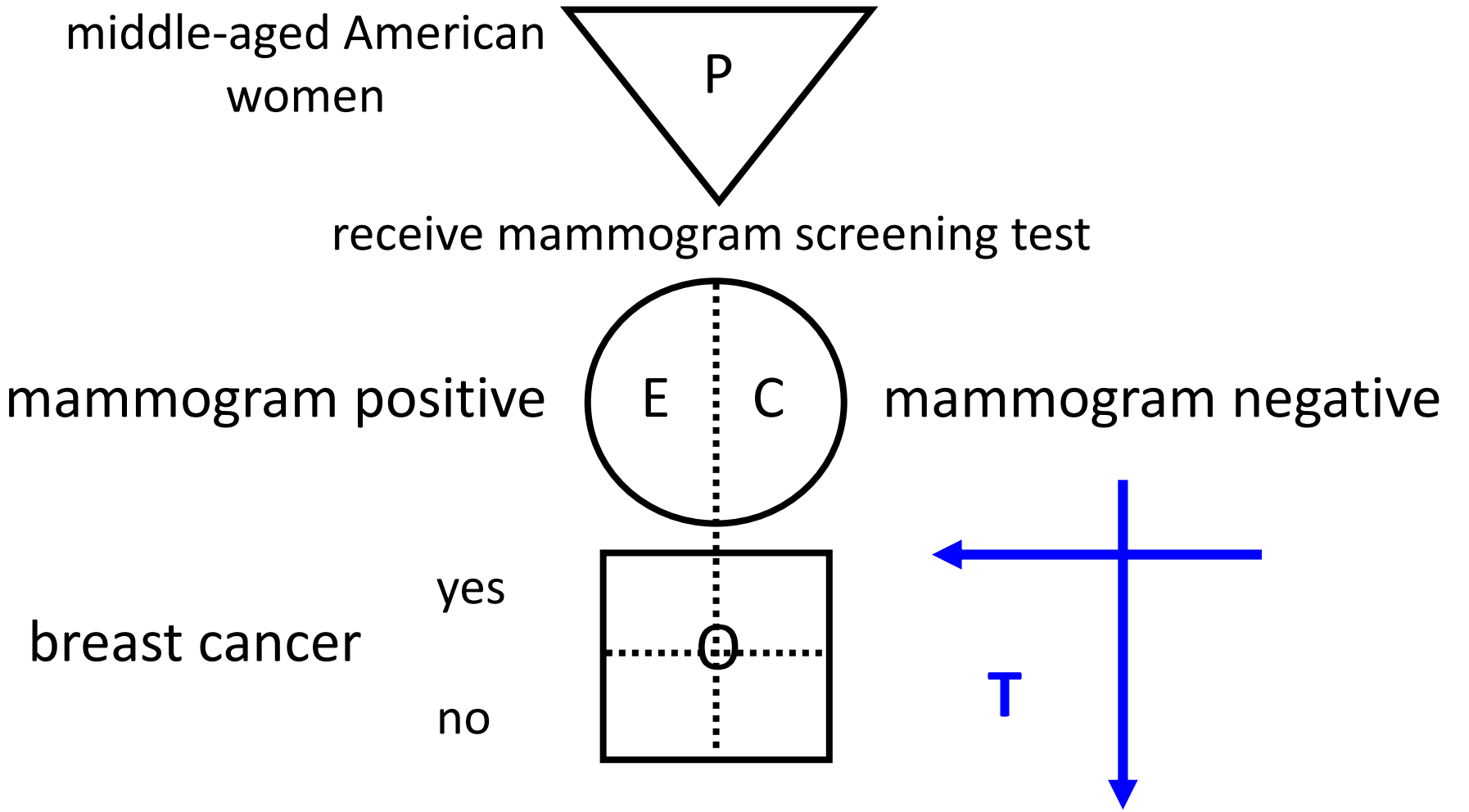


randomised controlled trial

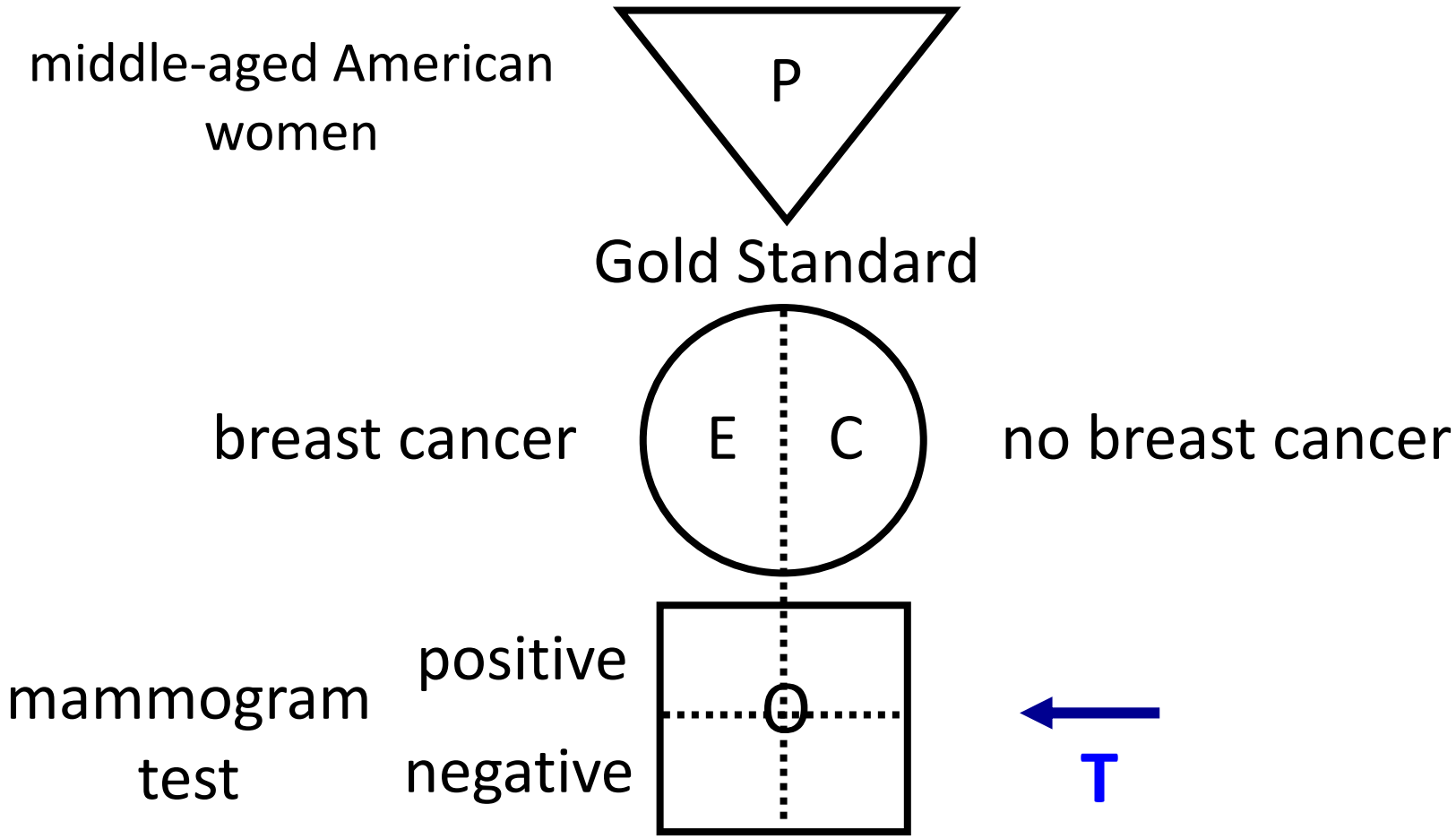
1 picture, 2 formulas & 3 ***acronyms***



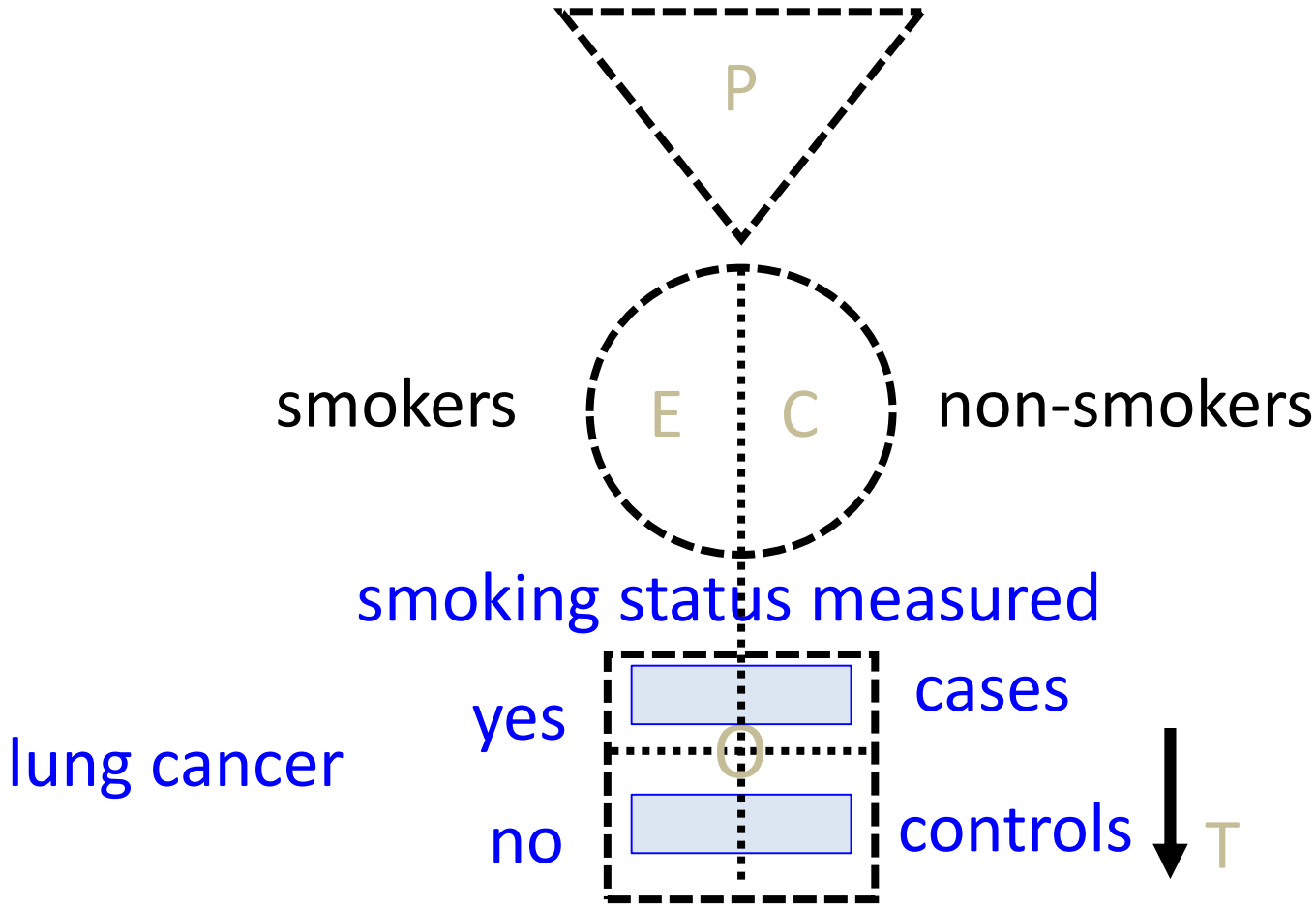
cross-sectional (prevalence) study



diagnostic test (prediction) study



diagnostic (test accuracy) study



case-control study

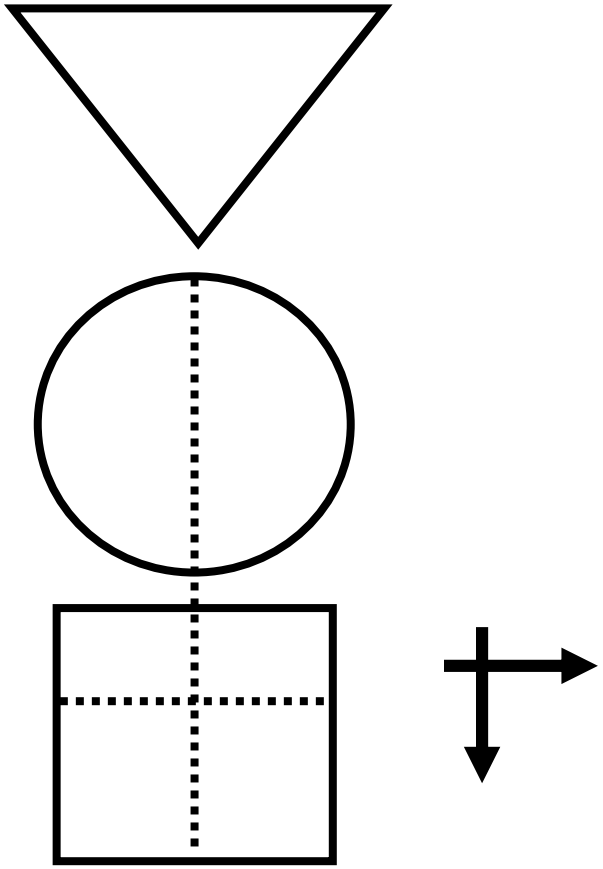
(all nested in virtual cohort studies)

$10,000

2

GATE: a framework for study analysis:

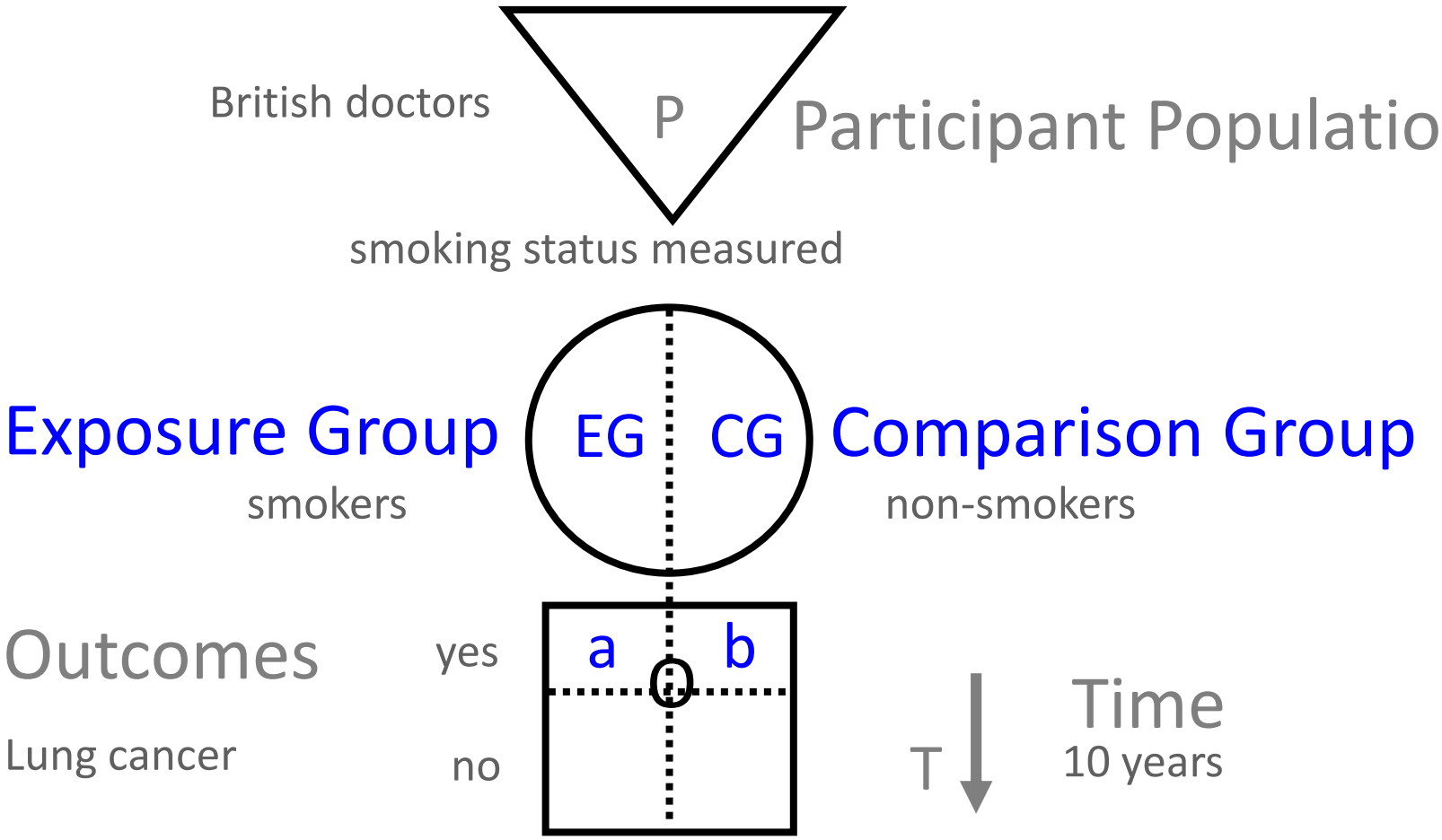
1st formula: occurrence = outcomes ÷ population

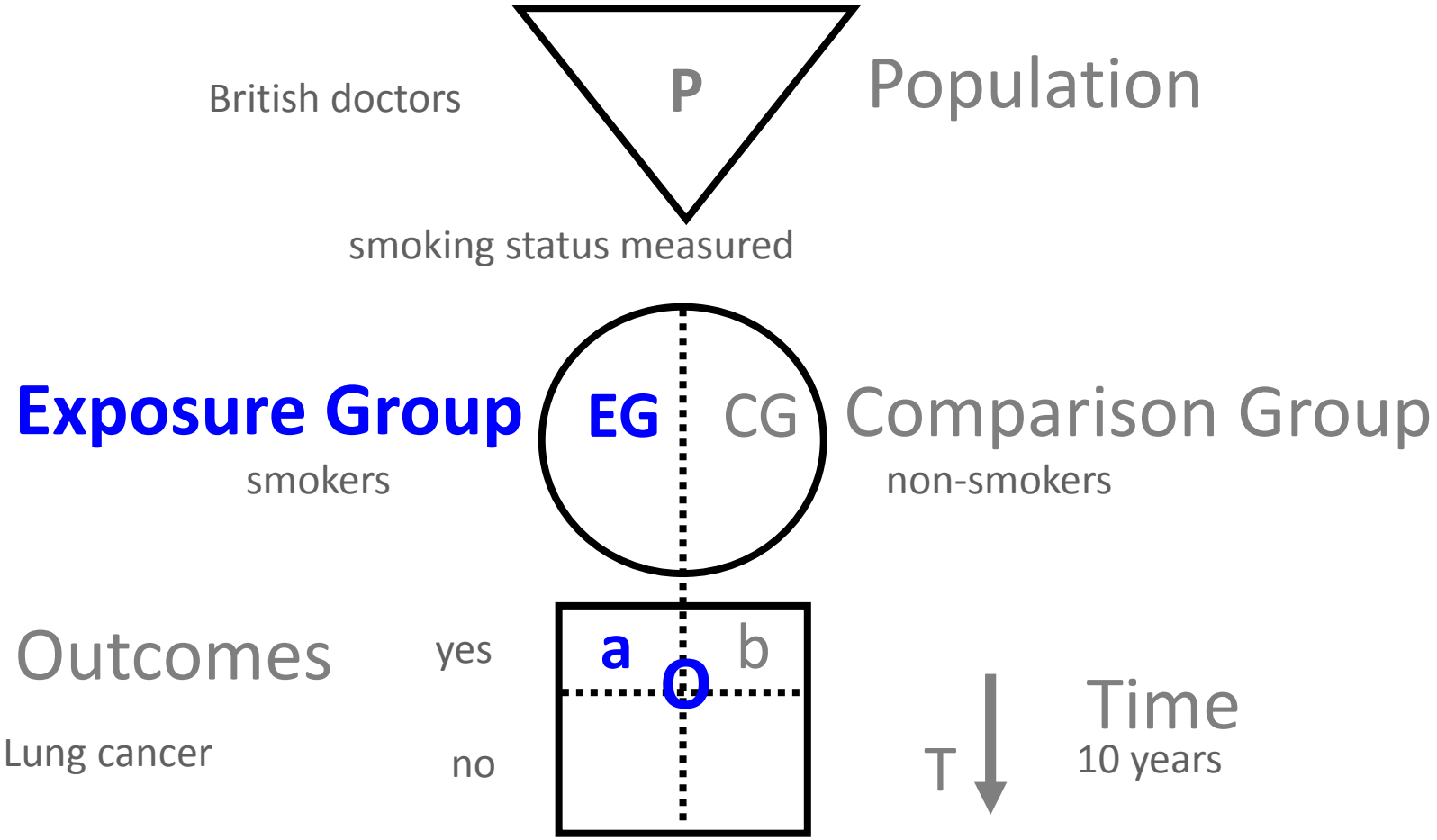


the numbers in epidemiological studies can be hung on the GATE frame

1 picture, 2 ***formulas*** *& 3 acronyms*

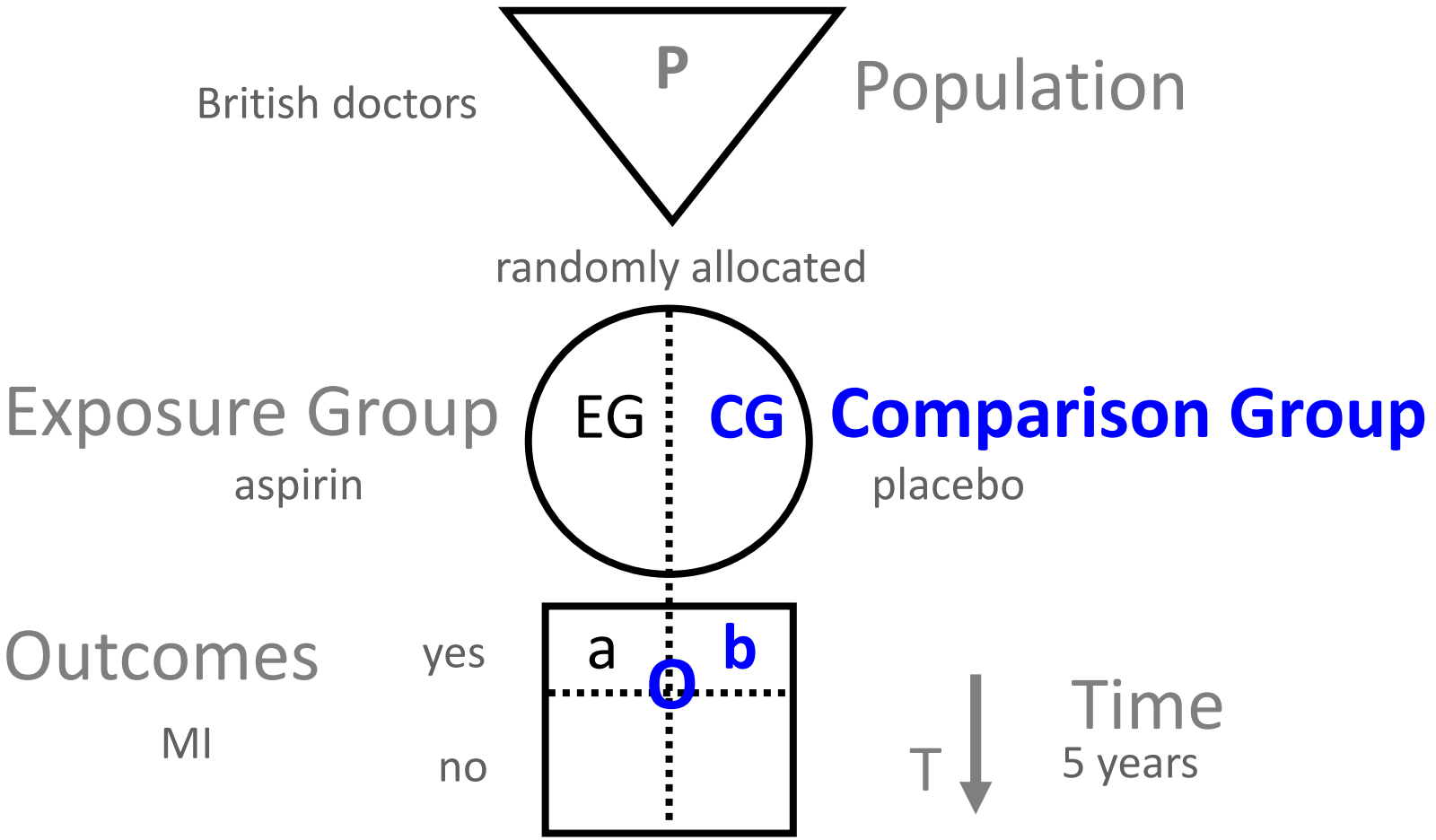
1st formula: occurrence of outcomes = number of outcomes ÷ number in population/group





Exposure Group Occurrence (EGO) = a÷EG

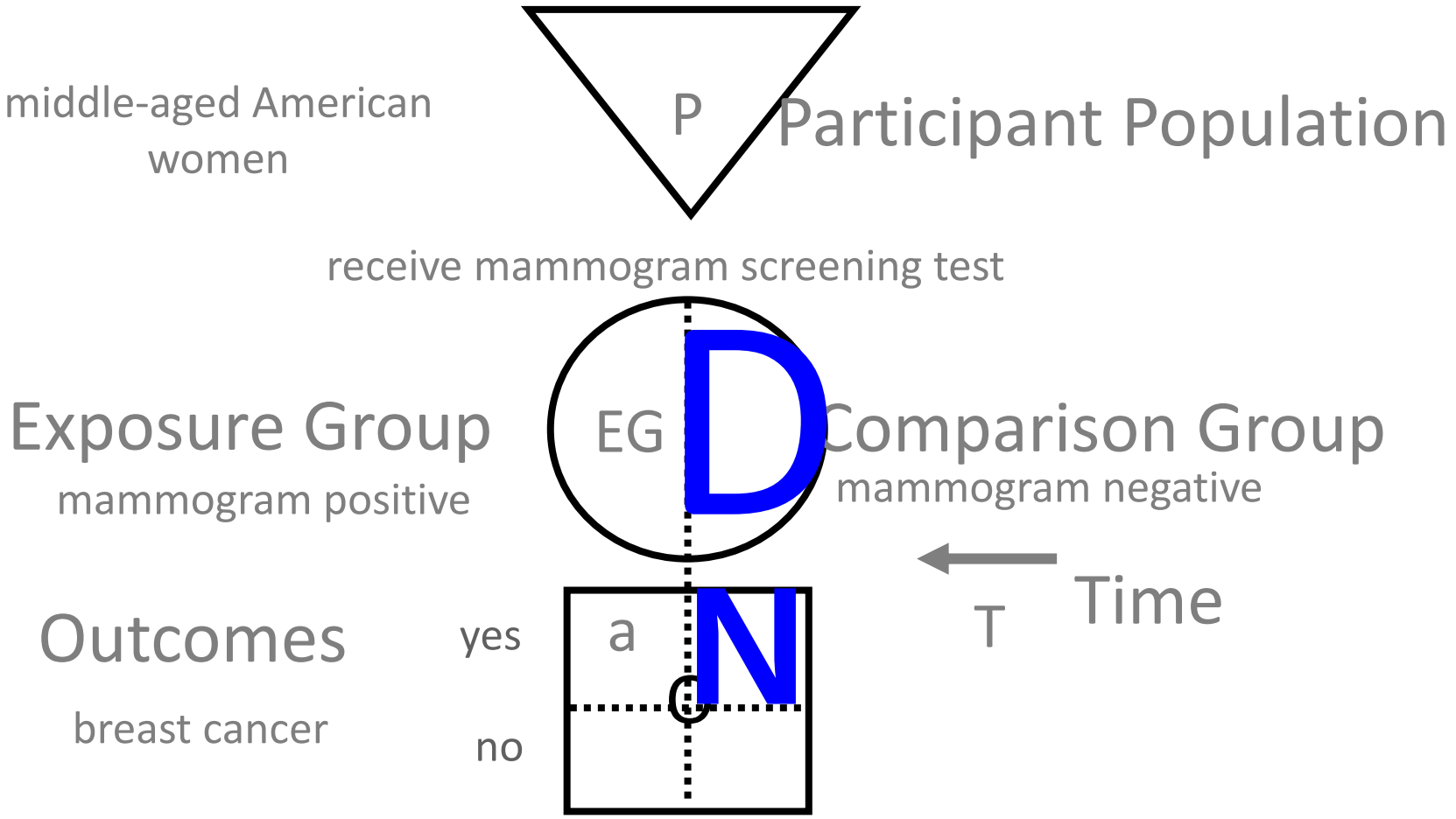
= number of outcomes (a) ÷ number in exposed population (EG)



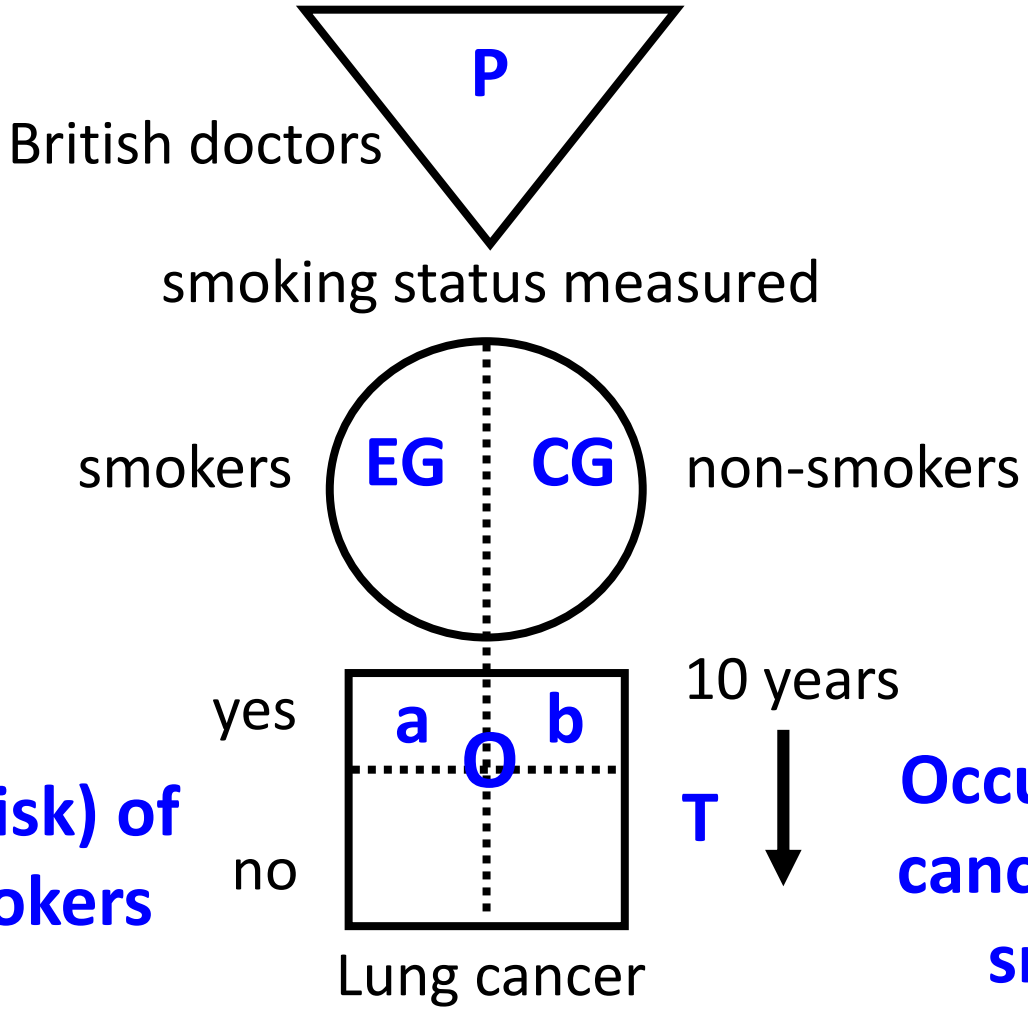
Comparison Group Occurrence (CGO) = b÷CG

= number of outcomes (b) ÷ number in comparison population (CG)

Epidemiology = Numerator ÷ Denominator

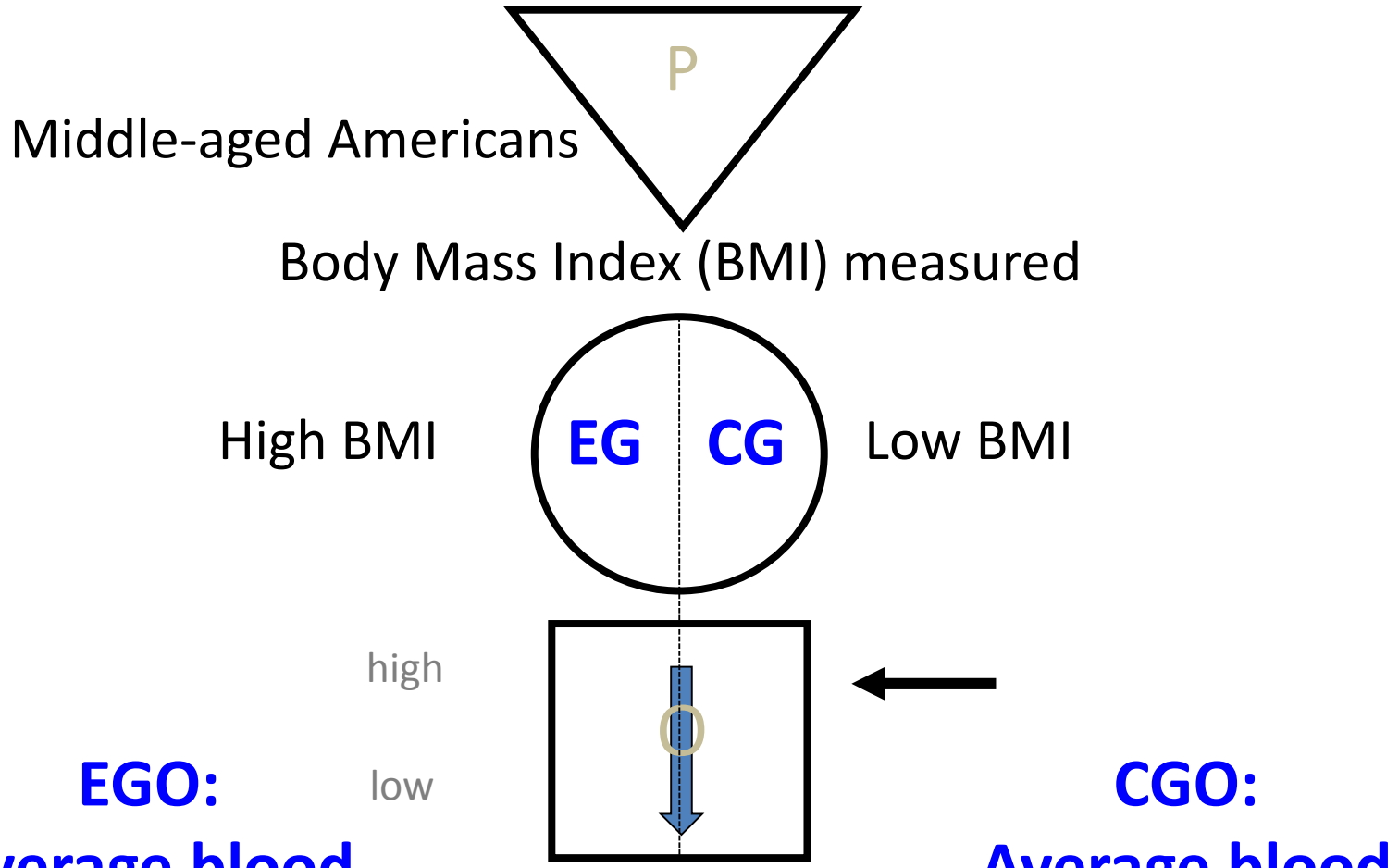


*the goal of all epidemiological studies is to calculate **EGO and CGO***



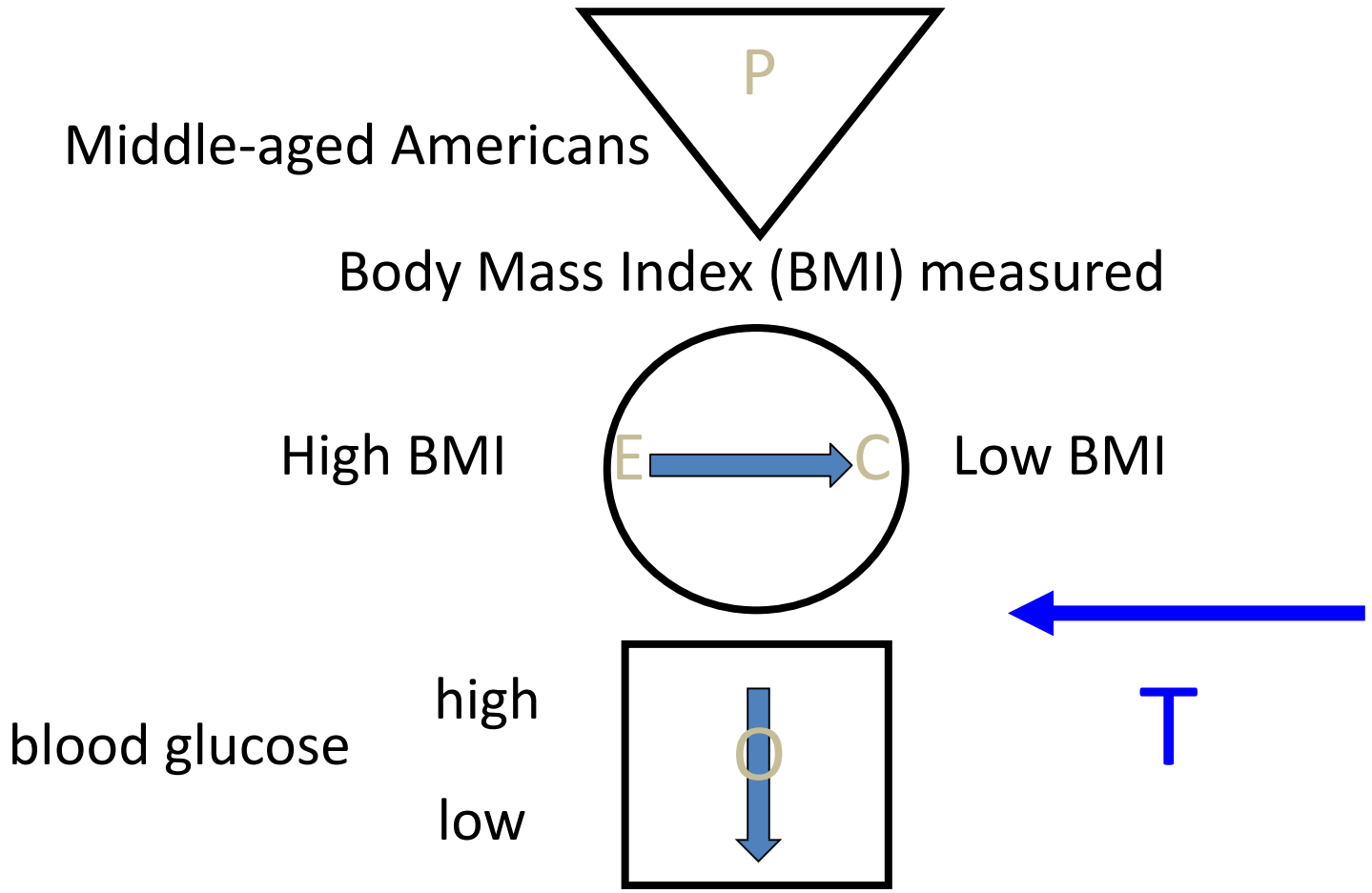
EGO: Occurrence (risk) of cancer in smokers

CGO: Occurrence of cancer in non-smokers

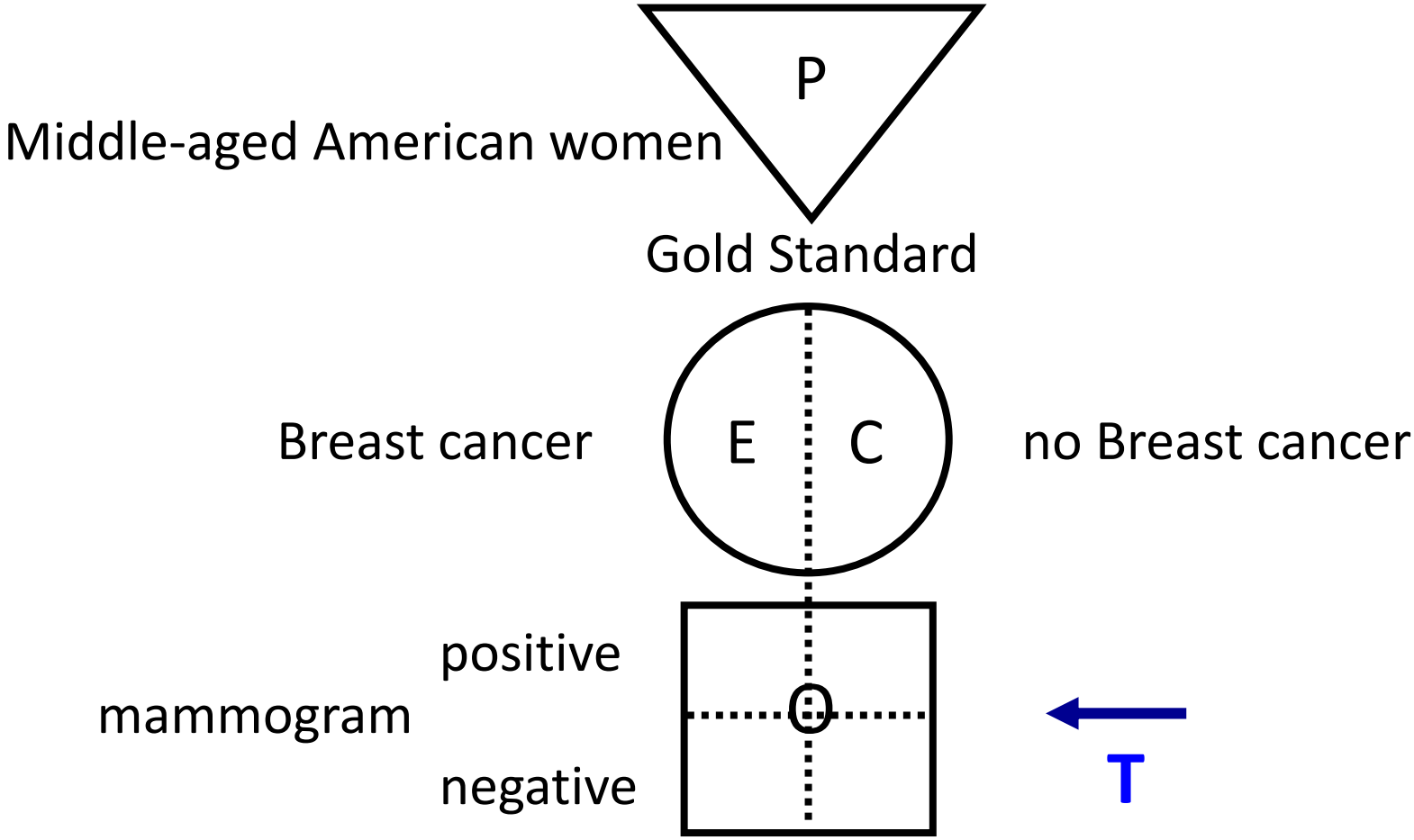


EGO: Average blood glucose in EG

CGO: Average blood glucose in CG



cross-sectional study with numerical measures



EGO:
likelihood of a positive mammogram if breast cancer

CGO:
likelihood of a positive mammogram if no breast cancer

1st formula:
occurrence = outcomes ÷ population

its all about EGO and CGO

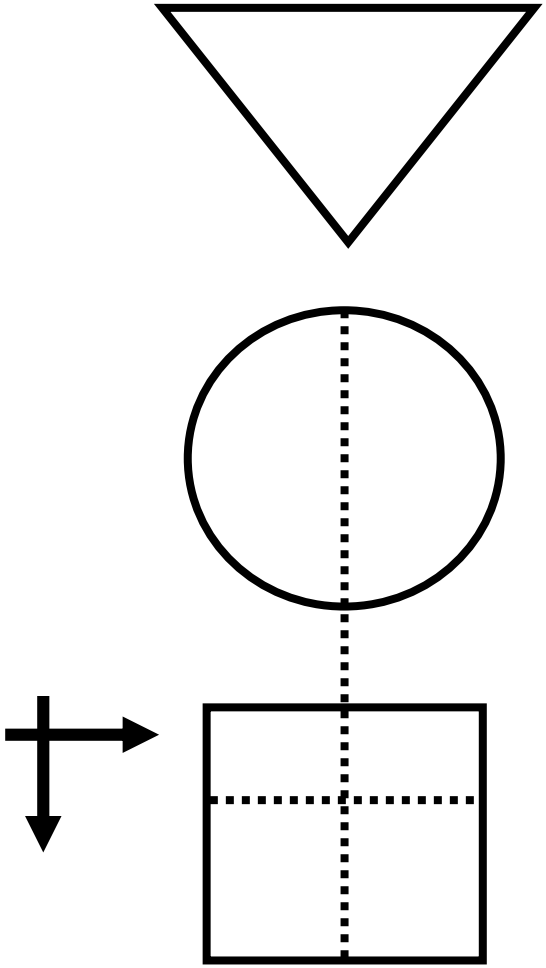
- EGO ÷ CGO = Relative Risk (RR)
- EGO – CGO = Risk Difference (RD)

measures of occurrence: risk; rate; likelihood; probability; average; incidence; prevalence

3

GATE: framework for nonrandom error

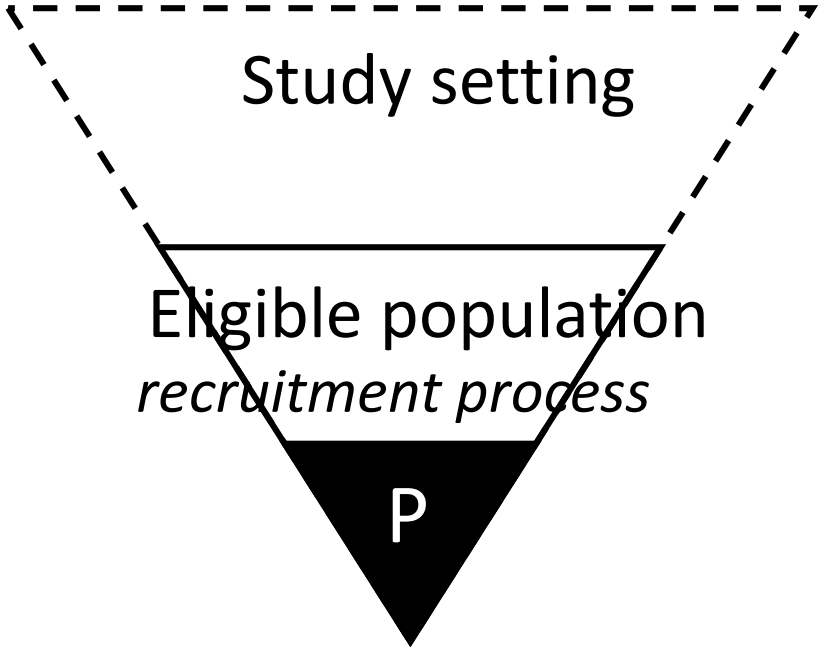
2nd acronym: RAMBOMAN



Measurements

ANalyses

1 picture, 2 formulas & 3 ***acronyms***

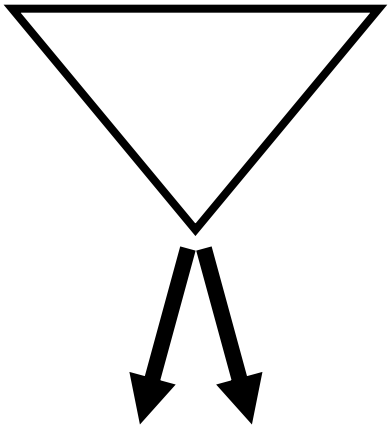


RAMBOMAN

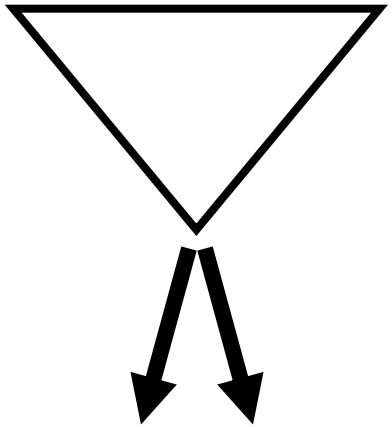
Recruitment of participants

'who** are the findings **applicable to?'

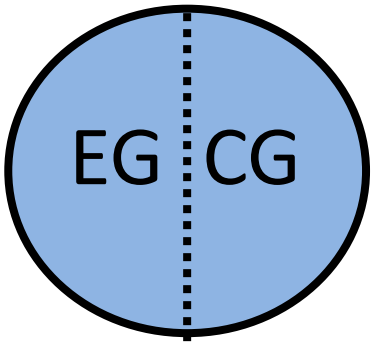
R**A**MBOMAN: '*how were participants **Allocated** to exposure & comparison groups?*'



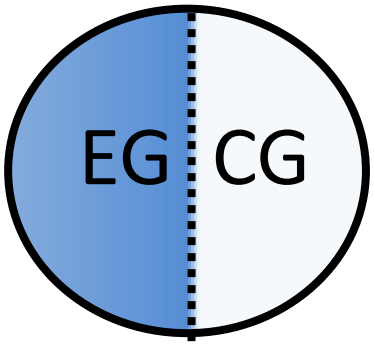
RCT: allocated by **randomisation** (e.g to drugs)

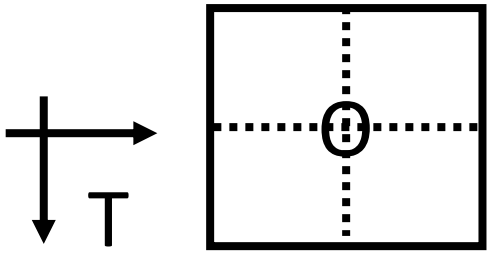


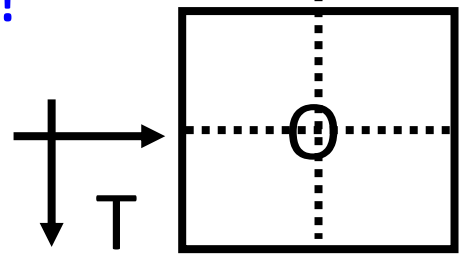
Cohort: allocated **by measurement** (e.g. smoking)



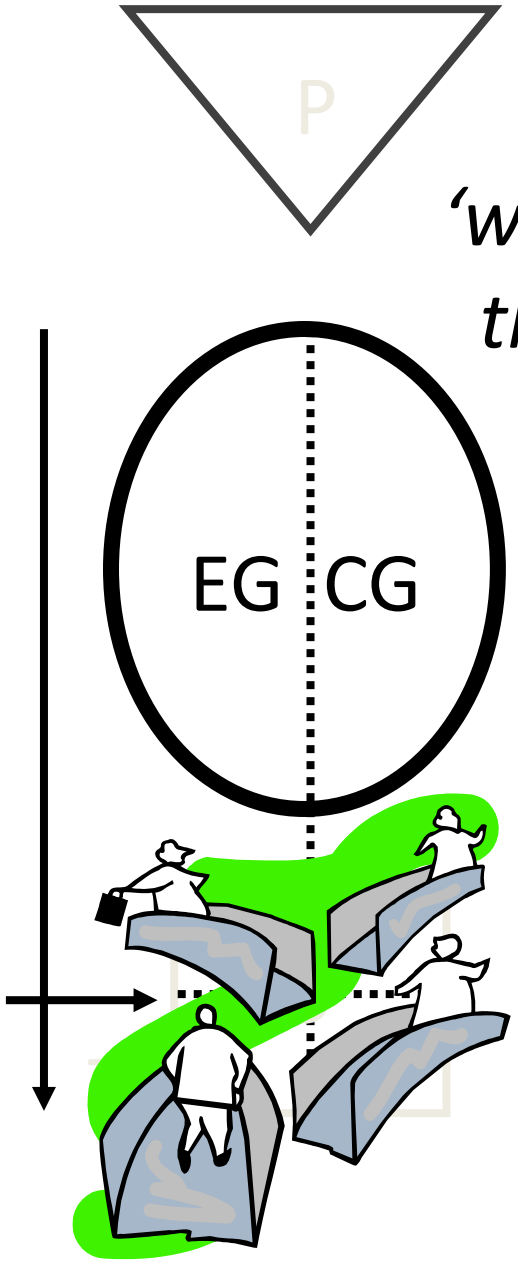
If randomised, were EG & CG similar at baseline?







RA**M**BOMAN



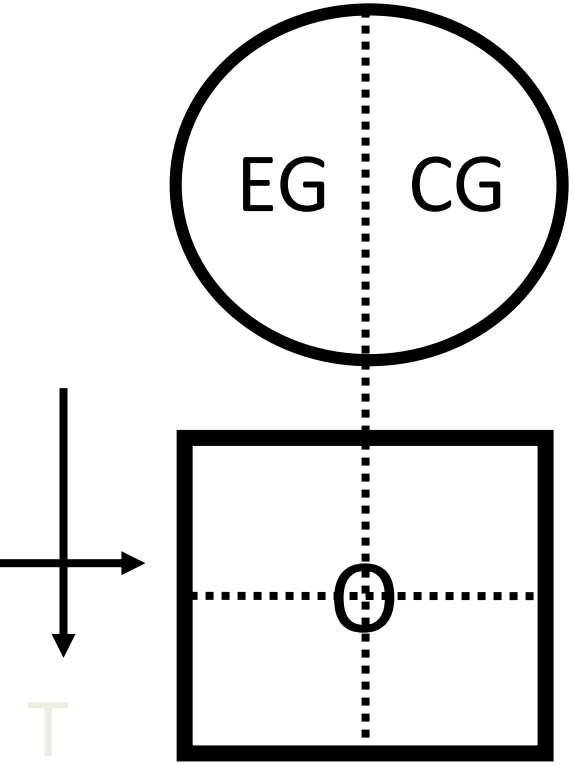
*'were Participants well **Maintained** in the groups they were allocated to?'*

completeness of follow-up
compliance
contamination
co-interventions

RAM**B**O**M**AN

*'were **exposures & outcomes well Measured**?'*

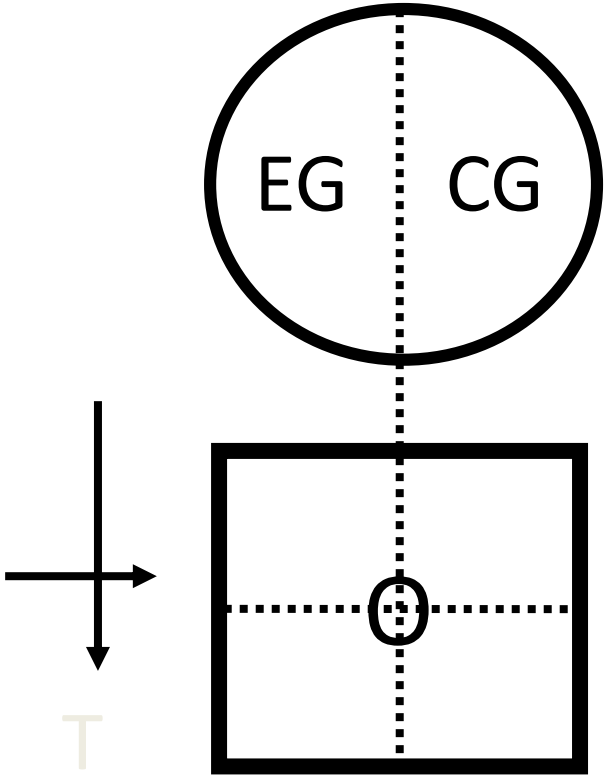
were outcomes measured **Blind** to whether participant was in EG or CG **(or vice versa)**?

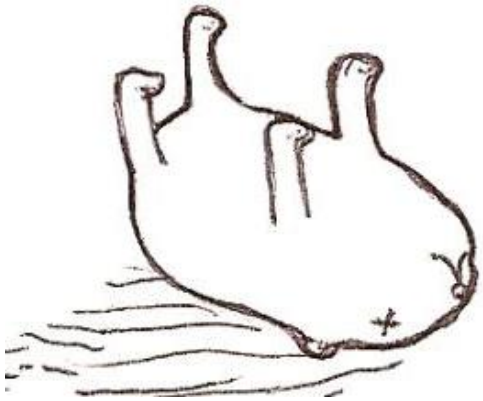


RAMB**OM**AN

*'were **exposures & outcomes well Measured**?'*

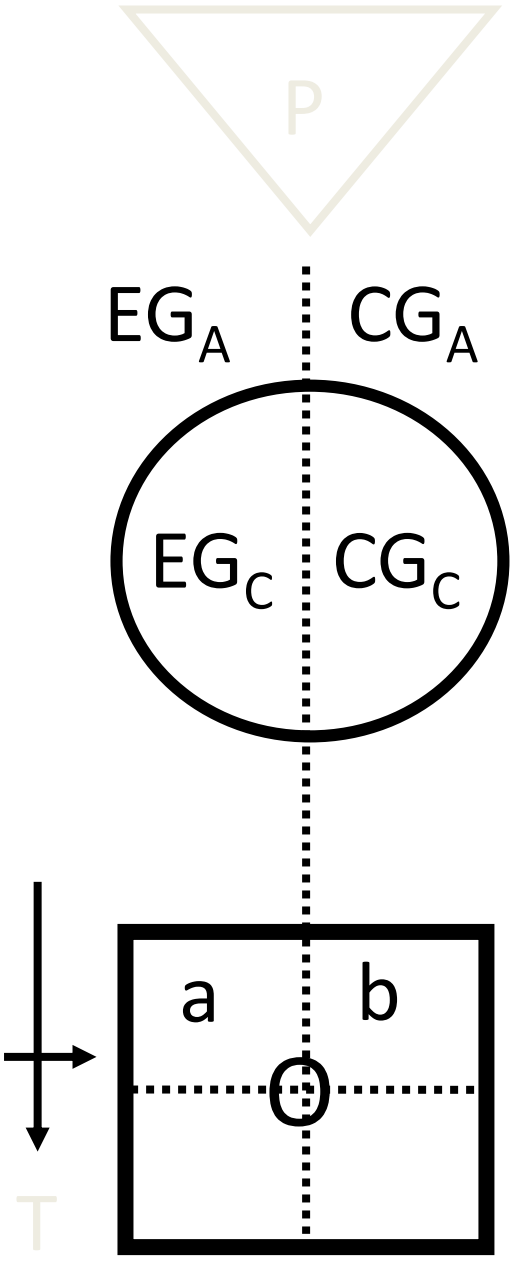
were they measured **Objectively**?





RAMBOM**AN**

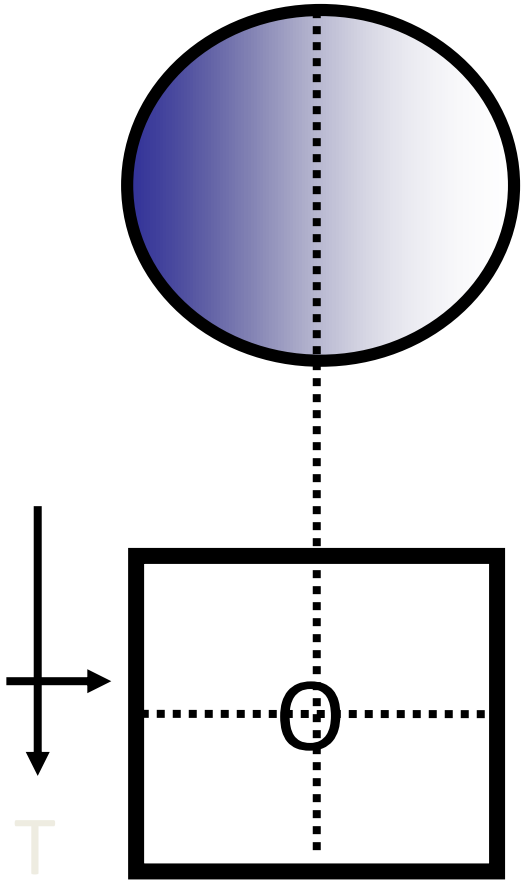
*'were the **ANalyses** done well?'*



If RCT were **Intention To Treat (ITT)** analyses done?

RAMBOM**AN**

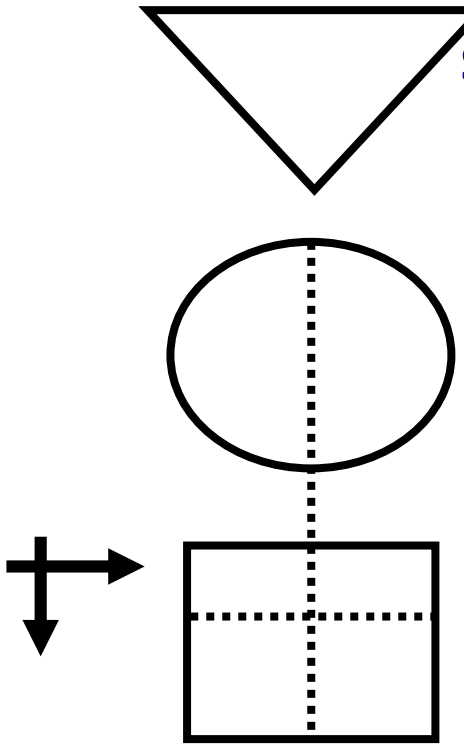
*'were the **ANalyses** done well?'*



adjustment for baseline differences / confounding?

GATE: random error: ***2nd formula:***

random error = 95% confidence interval



sample from a population

EGO ± 95% CI

CGO ± 95% CI

There is about a 95% chance that the true value in the underlying population lies within the 95% CI (assuming no non-random error)

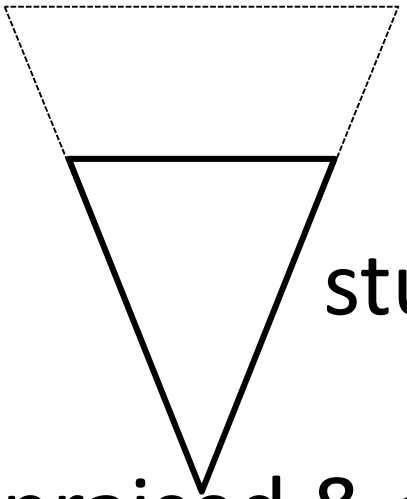
1 picture, 2 ***formulas*** *& 3 acronyms*

GATE: a framework for error in systematic reviews & meta-analyses:

3rd acronym: FAITH

1 picture, 2 formulas & 3 ***acronyms***

systematic review: a study of studies

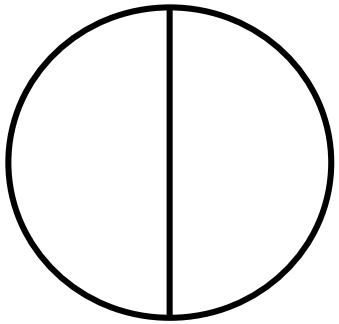


study sources

studies screened

studies appraised & allocated:

included



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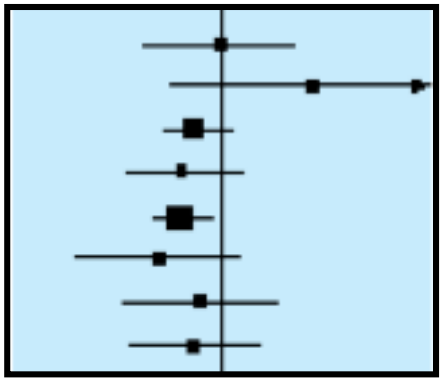
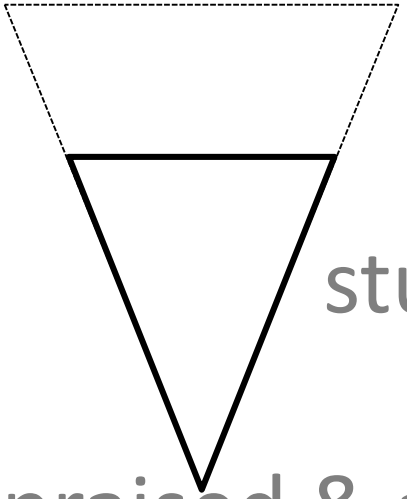


studies summarised & pooled if homogeneous

critical appraisal of SR: FAITH

Find



study sources

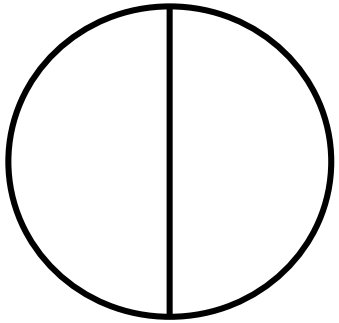
studies screened

Appraise

studies appraised & allocated:

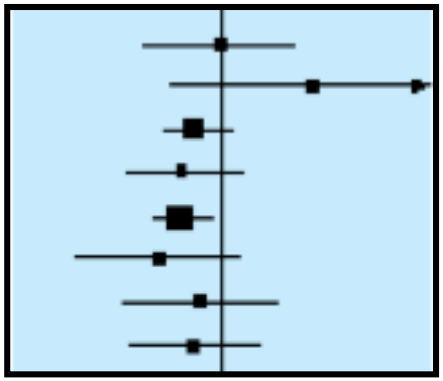
Include

included



excluded

Total

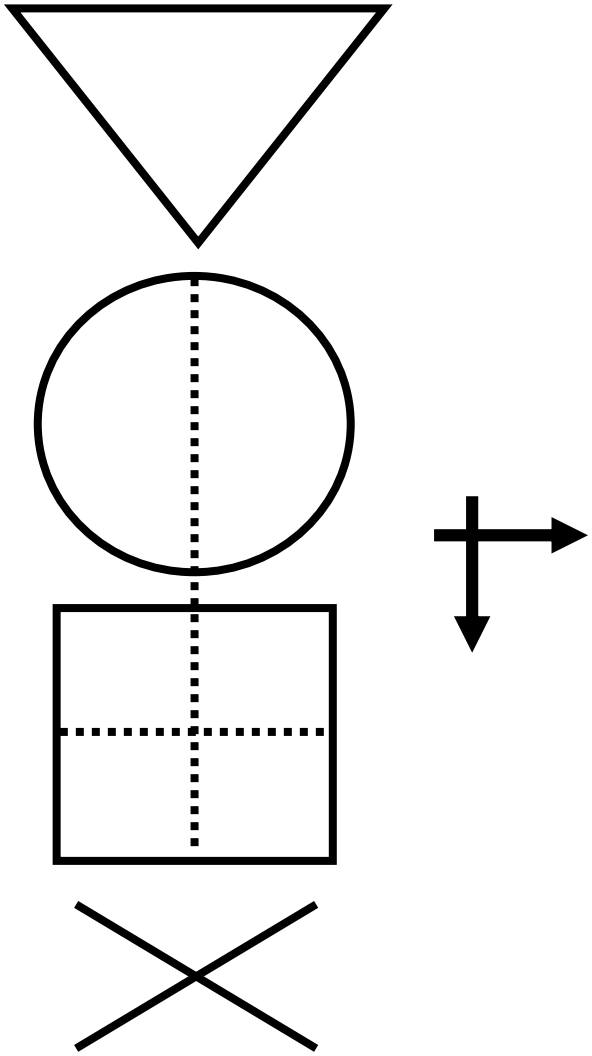


studies summarised & pooled if homogeneous

Heterogeneity?

4

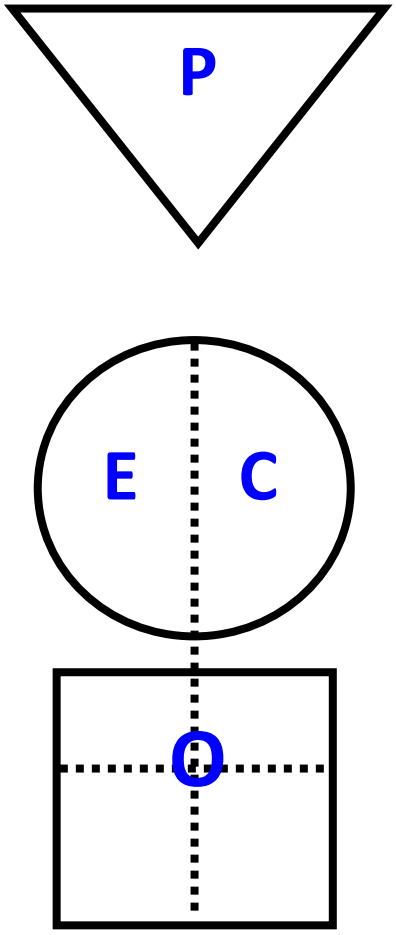
GATE: framework for the 4 steps of EBP



the steps of Evidence Based Practice (EBP):

1. Ask
2. Acquire
3. Appraise
4. Apply & Act
5. Audit

EBP Step 1: **ASK** - turn your question into a focused 5-part PECOT question



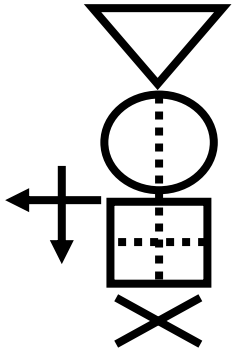
1. Participants

2. Exposure

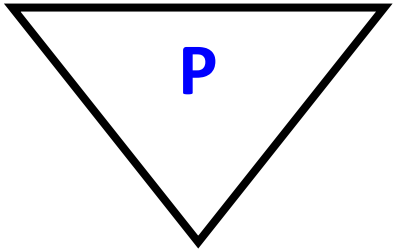
3. Comparison

4. Outcomes

5. Time

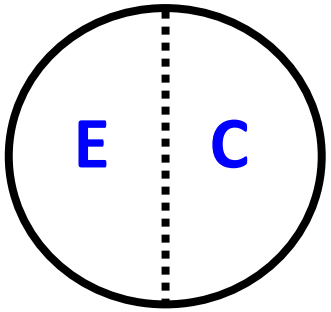


2: **ACQUIRE** the evidence – use **PECOT** to help choose search terms



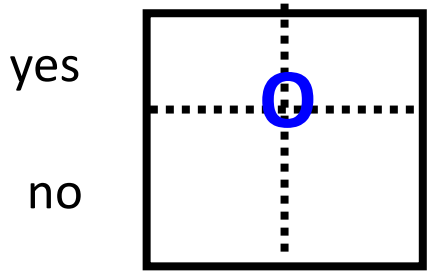
Participants

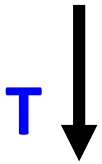
Exposure



Comparison

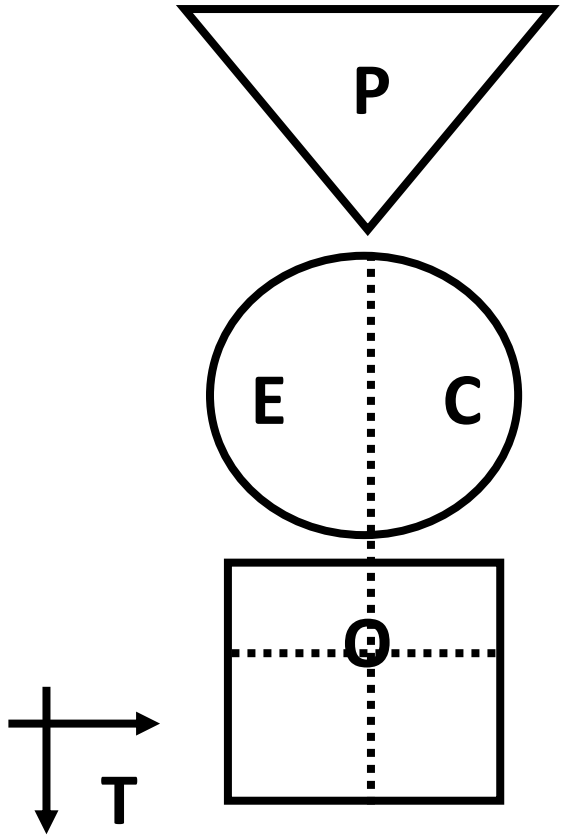
Outcomes





Time

3: **APPRAISE** the evidence – with the picture, acronyms & formulas



Recruitment

Allocation

Maintenance

blind

objective

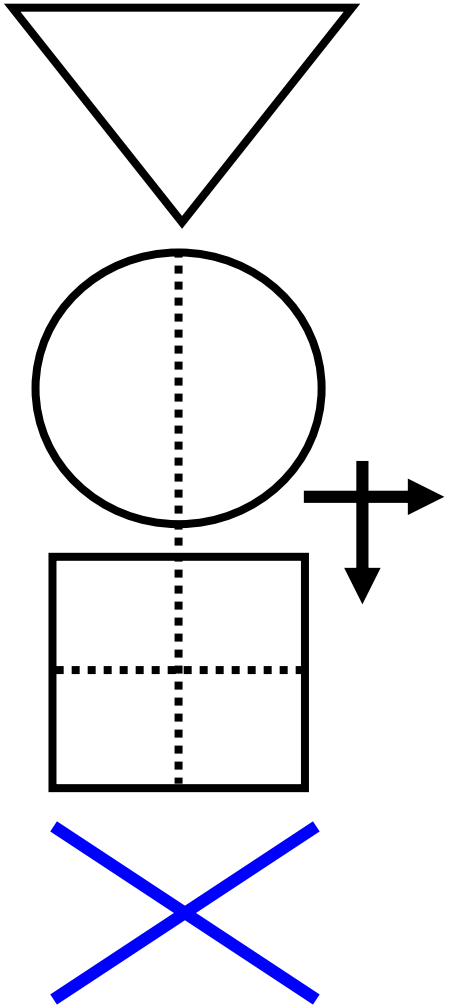
Measurements

ANalyses

Occurrence = outcomes ÷ population

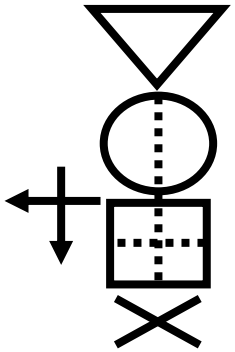
Random error = 95% Confidence Interval

4. **APPLY** the evidence by AMALGAMATING the relevant information & making an evidence-based decision:' **the X-factor**



SONY
PlayStation
START
ANALOG

X-factor: making evidence-based decisions

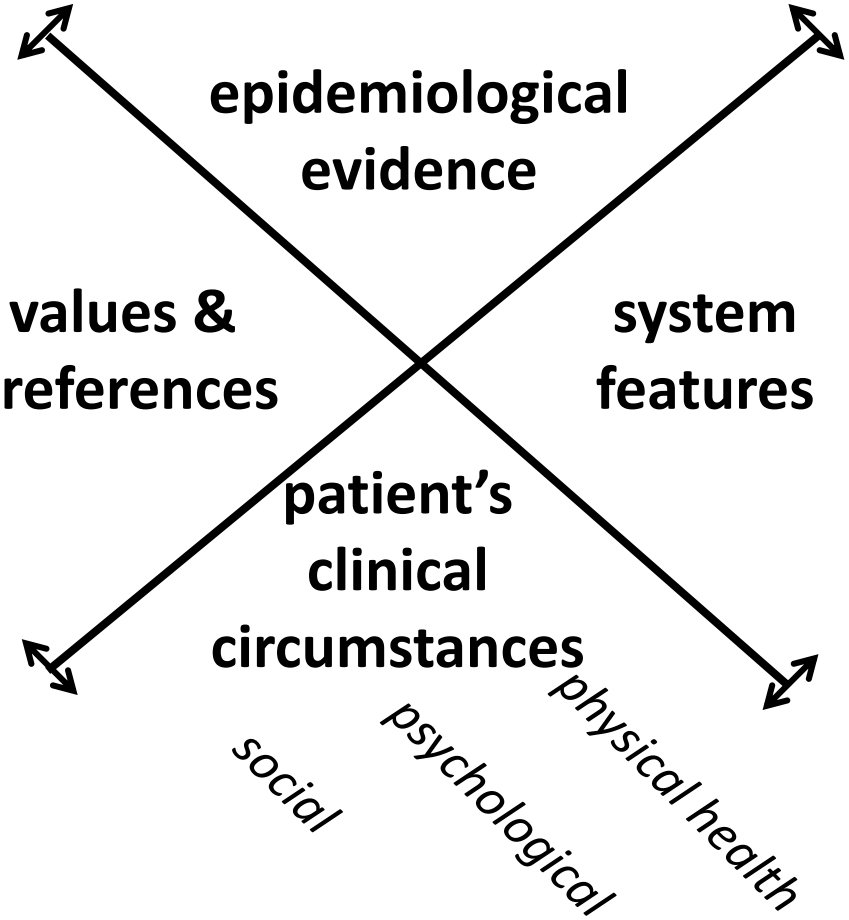


person

family

community

practitioner



economic

legal

political

Practitioner eXpertise: 'putting it all together' - the art of practice

Clinical expertise in the era of evidence-based medicine and patient choice. EBM 2002;736-8 (March/April)

EBP Step 5: Audit

audit practice against evidence-based standards and improve quality of practice

GATE critically appraised topic (CATs) excel workbooks:

1. Intervention & risk studies
2. Diagnostic test accuracy studies
3. Prognostic studies
4. Case-control studies
5. Systematic Reviews

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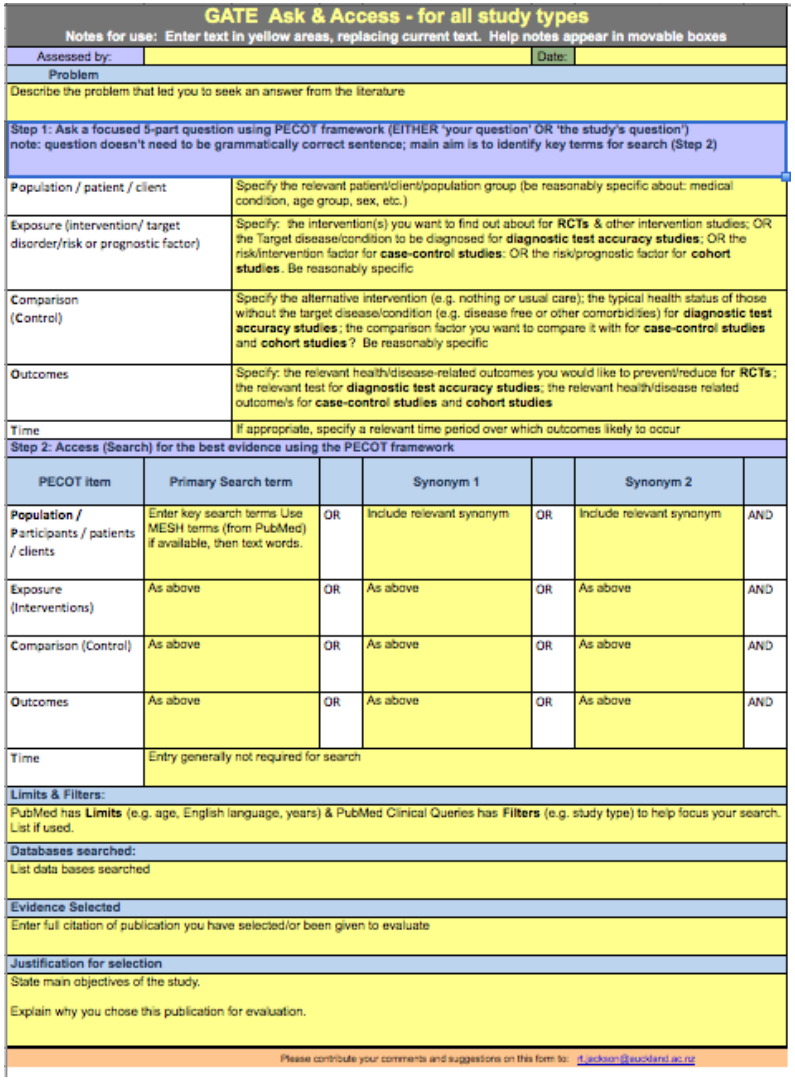
GATE CAT – 4-sheet workbook (in Excel) sheet 1: GATE-Ask & Acquire



GATE Ask & Access - for all study types

Notes for use: Enter text in yellow areas, replacing current text. Help notes appear in movable boxes

Assessed by:		Date:	

Problem

Describe the problem that led you to seek an answer from the literature

Step 1: Ask a focused 5-part question using PECOT framework (EITHER 'your question' OR 'the study's question')
note: question doesn't need to be grammatically correct sentence; main aim is to identify key terms for search (Step 2)

Population / patient / client	Specify the relevant patient/client/population group (be reasonably specific about: medical condition, age group, sex, etc.)
Exposure (intervention/ target disorder/risk or prognostic factor)	Specify: the intervention(s) you want to find out about for **RCTs** & other intervention studies; OR the Target disease/condition to be diagnosed for **diagnostic test accuracy studies**; OR the risk/intervention factor for **case-control studies**: OR the risk/prognostic factor for **cohort studies**. Be reasonably specific
Comparison (Control)	Specify the alternative intervention (e.g. nothing or usual care); the typical health status of those without the target disease/condition (e.g. disease free or other comorbidities) for **diagnostic test accuracy studies**; the comparison factor you want to compare it with for **case-control studies** and **cohort studies**? Be reasonably specific
Outcomes	Specify: the relevant health/disease-related outcomes you would like to prevent/reduce for **RCTs**; the relevant test for **diagnostic test accuracy studies**; the relevant health/disease related outcome/s for **case-control studies** and **cohort studies**
Time	If appropriate, specify a relevant time period over which outcomes likely to occur

Step 2: Access (Search) for the best evidence using the PECOT framework

PECOT item	Primary Search term		Synonym 1		Synonym 2	
Population / Participants / patients / clients	Enter key search terms Use MESH terms (from PubMed) if available, then text words.	OR	Include relevant synonym	OR	Include relevant synonym	AND
Exposure (Interventions)	As above	OR	As above	OR	As above	AND
Comparison (Control)	As above	OR	As above	OR	As above	AND
Outcomes	As above	OR	As above	OR	As above	AND
Time	Entry generally not required for search					

Limits & Filters:

PubMed has **Limits** (e.g. age, English language, years) & PubMed Clinical Queries has **Filters** (e.g. study type) to help focus your search. List if used.

Databases searched:

List data bases searched

Evidence Selected

Enter full citation of publication you have selected/or been given to evaluate

Justification for selection

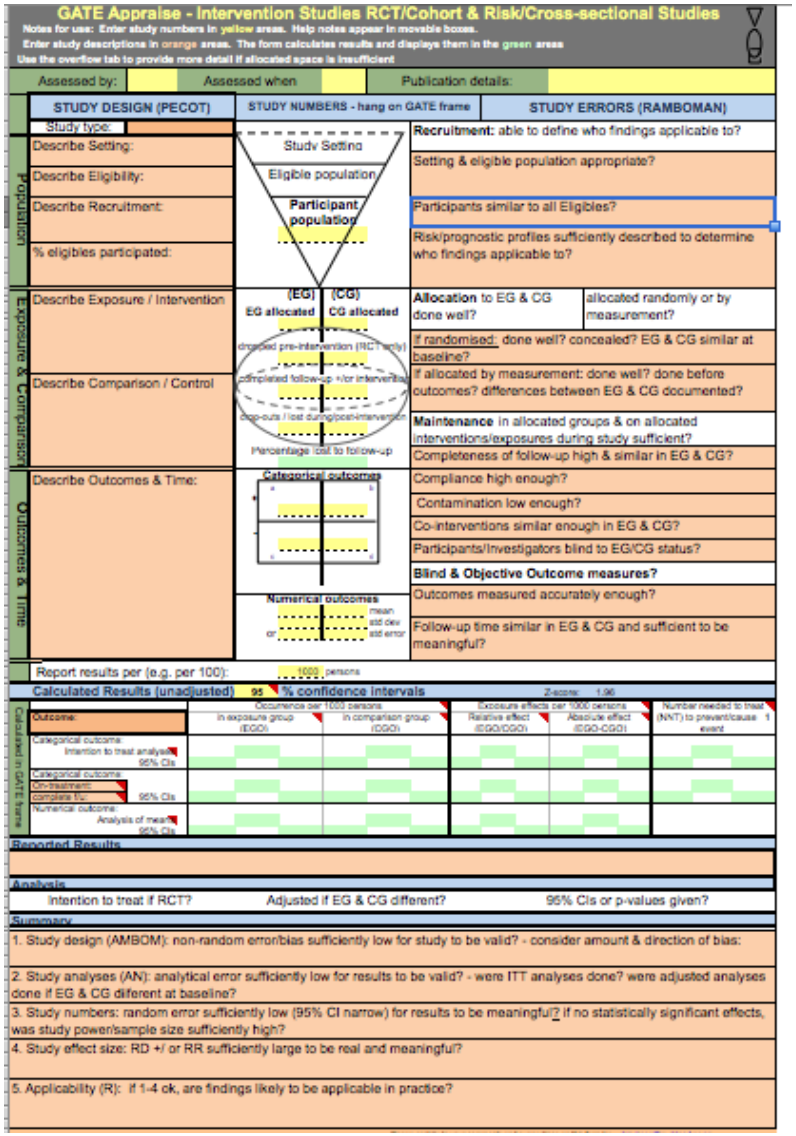
State main objectives of the study.

Explain why you chose this publication for evaluation.

Please contribute your comments and suggestions on this form to: r.jackson@auckland.ac.nz

GATE CAT – 3-sheet workbook (in Excel)

sheet 2: GATE-Appraise (with calculator)



GATE Appraise - Intervention Studies RCT/Cohort & Risk/Cross-sectional Studies

Notes for use: Enter study numbers in yellow areas. Help notes appear in movable boxes.
Enter study descriptions in orange areas. The form calculates results and displays them in the green areas
Use the overflow tab to provide more detail if allocated space is insufficient

Assessed by: | Assessed when | Publication details:

STUDY DESIGN (PECOT) | STUDY NUMBERS - hang on GATE frame | STUDY ERRORS (RAMBOMAN)

Study type:

Population
- Describe Setting:
- Describe Eligibility:
- Describe Recruitment:
- % eligibles participated:

Study Setting
Eligible population
Participant population

Recruitment: able to define who findings applicable to?
Setting & eligible population appropriate?
Participants similar to all Eligibles?
Risk/prognostic profiles sufficiently described to determine who findings applicable to?

Exposure & Comparison
- Describe Exposure / Intervention
- Describe Comparison / Control

(EG) EG allocated | (CG) CG allocated
dropped pre-intervention (RCT only)
completed follow-up +/or intervention
drop-outs / lost during/post-intervention
Percentage lost to follow-up

Allocation to EG & CG done well? | allocated randomly or by measurement?
If randomised: done well? concealed? EG & CG similar at baseline?
If allocated by measurement: done well? done before outcomes? differences between EG & CG documented?
Maintenance in allocated groups & on allocated interventions/exposures during study sufficient?
Completeness of follow-up high & similar in EG & CG?

Outcomes & Time
- Describe Outcomes & Time:

Categorical outcomes
Numerical outcomes
mean
std dev
or
std error

Compliance high enough?
Contamination low enough?
Co-interventions similar enough in EG & CG?
Participants/investigators blind to EG/CG status?
Blind & Objective Outcome measures?
Outcomes measured accurately enough?
Follow-up time similar in EG & CG and sufficient to be meaningful?

Report results per (e.g. per 100): 1000 persons

Calculated Results (unadjusted) 95 % confidence intervals Z-score: 1.96

Calculated in GATE frame

Outcome:	Occurrence per 1000 persons: in exposure group (EGO)	in comparison group (CGO)	Exposure effects per 1000 persons: Relative effect (EGO/CGO)	Absolute effect (EGO-CGO)	Number needed to treat (NNT) to prevent/cause 1 event
Categorical outcome: Intention to treat analysis 95% CIs					
Categorical outcome: On-treatment; complete f/u: 95% CIs					
Numerical outcome: Analysis of mean 95% CIs					

Reported Results

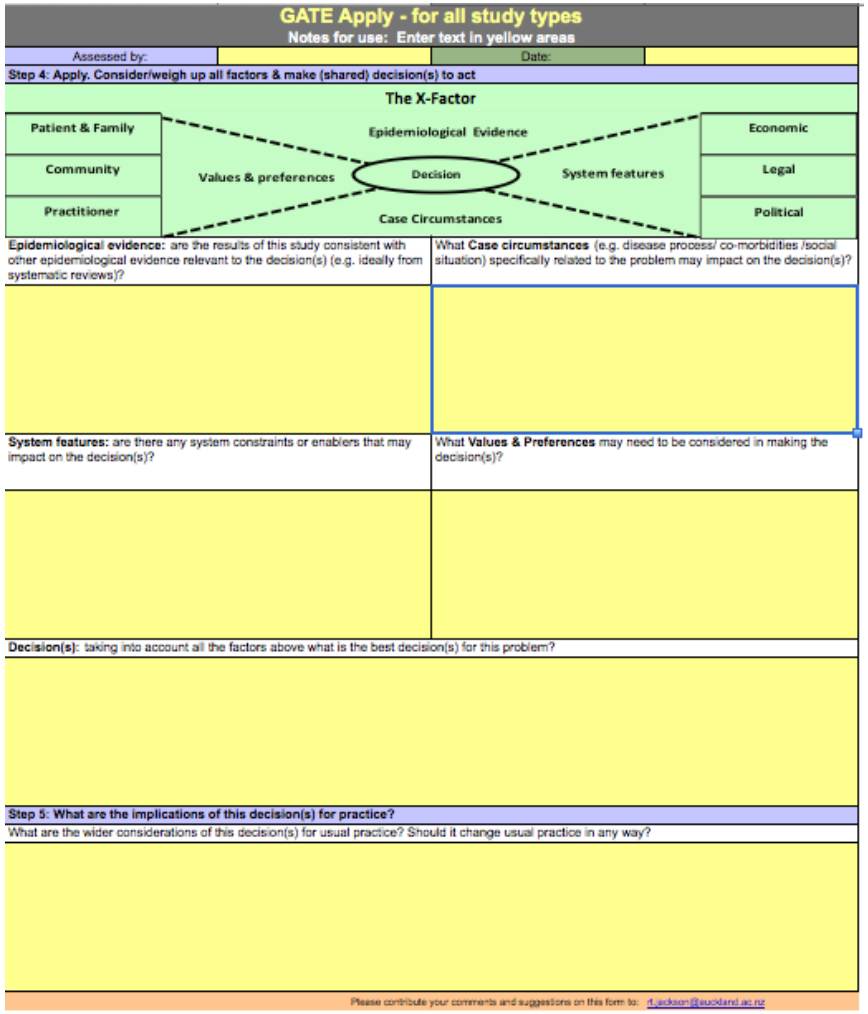
Analysis

Intention to treat if RCT? | Adjusted if EG & CG different? | 95% CIs or p-values given?

Summary

1. Study design (AMBOM): non-random error/bias sufficiently low for study to be valid? - consider amount & direction of bias:
2. Study analyses (AN): analytical error sufficiently low for results to be valid? - were ITT analyses done? were adjusted analyses done if EG & CG different at baseline?
3. Study numbers: random error sufficiently low (95% CI narrow) for results to be meaningful? if no statistically significant effects, was study power/sample size sufficiently high?
4. Study effect size: RD +/ or RR sufficiently large to be real and meaningful?
5. Applicability (R): if 1-4 ok, are findings likely to be applicable in practice?

GATE CAT – 3-sheet workbook (in Excel)
sheet 3: GATE-Apply



GATE Apply - for all study types

Notes for use: Enter text in yellow areas

Assessed by:	Date:

Step 4: Apply. Consider/weigh up all factors & make (shared) decision(s) to act

The X-Factor

Patient & Family	Epidemiological Evidence	Economic
Community	Values & preferences / Decision / System features	Legal
Practitioner	Case Circumstances	Political

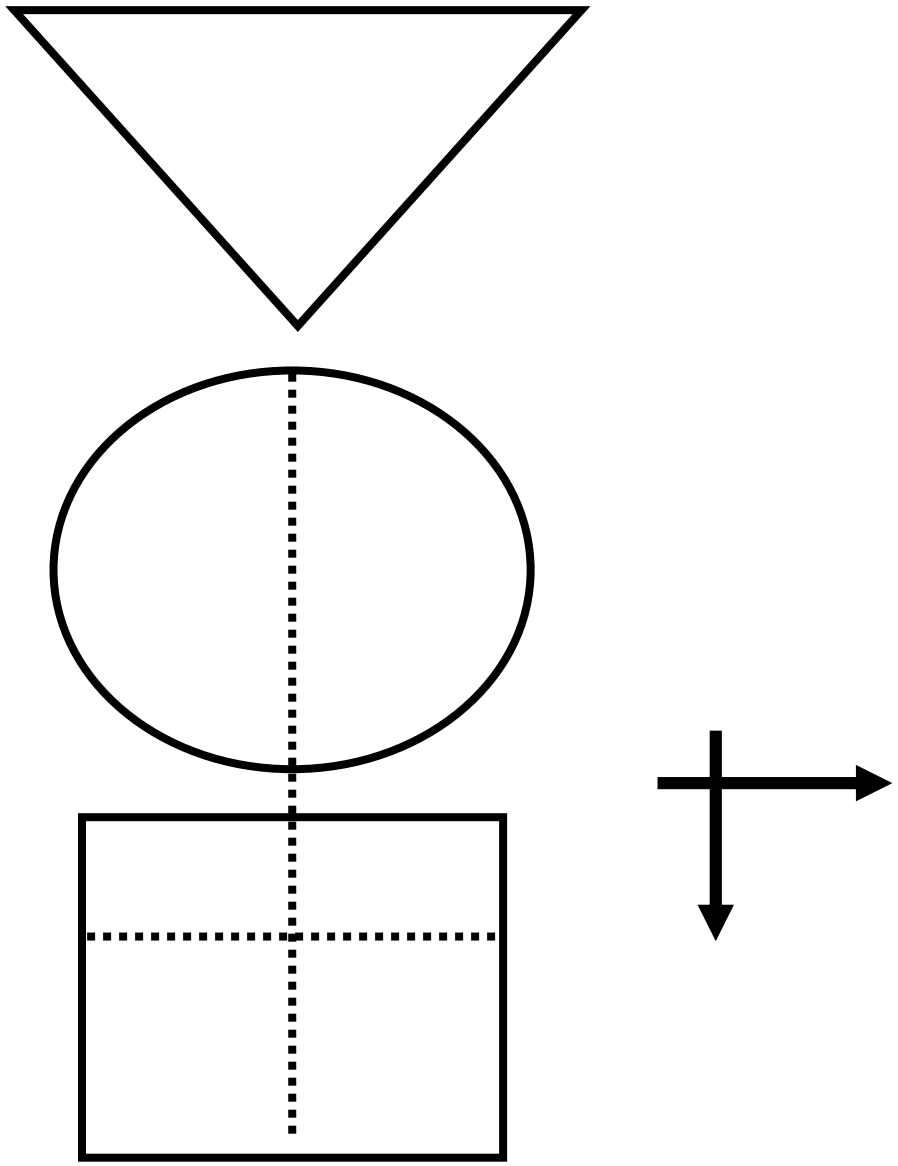
Epidemiological evidence: are the results of this study consistent with other epidemiological evidence relevant to the decision(s) (e.g. ideally from systematic reviews)?	What **Case circumstances** (e.g. disease process/ co-morbidities /social situation) specifically related to the problem may impact on the decision(s)?
System features: are there any system constraints or enablers that may impact on the decision(s)?	What **Values & Preferences** may need to be considered in making the decision(s)?

Decision(s): taking into account all the factors above what is the best decision(s) for this problem?

Step 5: What are the implications of this decision(s) for practice?

What are the wider considerations of this decision(s) for usual practice? Should it change usual practice in any way?

Please contribute your comments and suggestions on this form to: r.jackson@auckland.ac.nz



by the end of this lecture you will know how to use this picture to help you rapidly critique clinical studies (& to teach others how to use it)

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