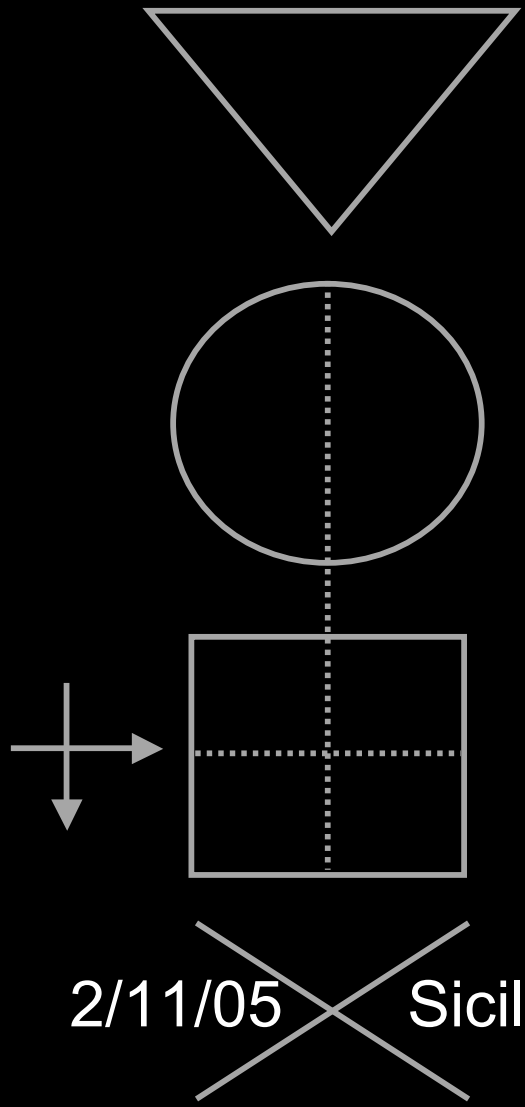
GATE: 'EBP with pictures'

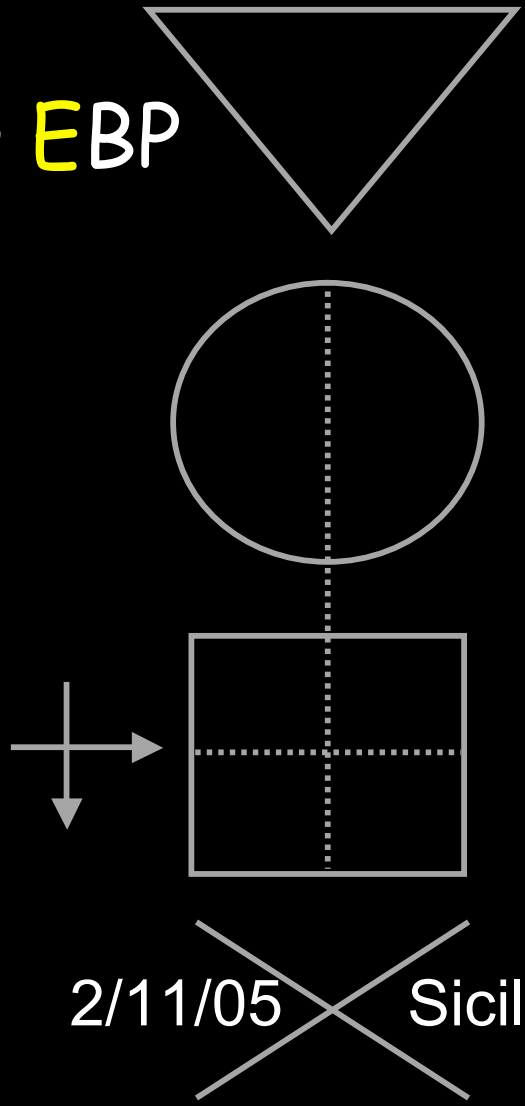


Rod Jackson
EPIQ group
University of Auckland, NZ
www.epiq.co.nz

2/11/05 Sicily

GATE: 'EBP with pictures'

Graphic Approach to Teaching EBP



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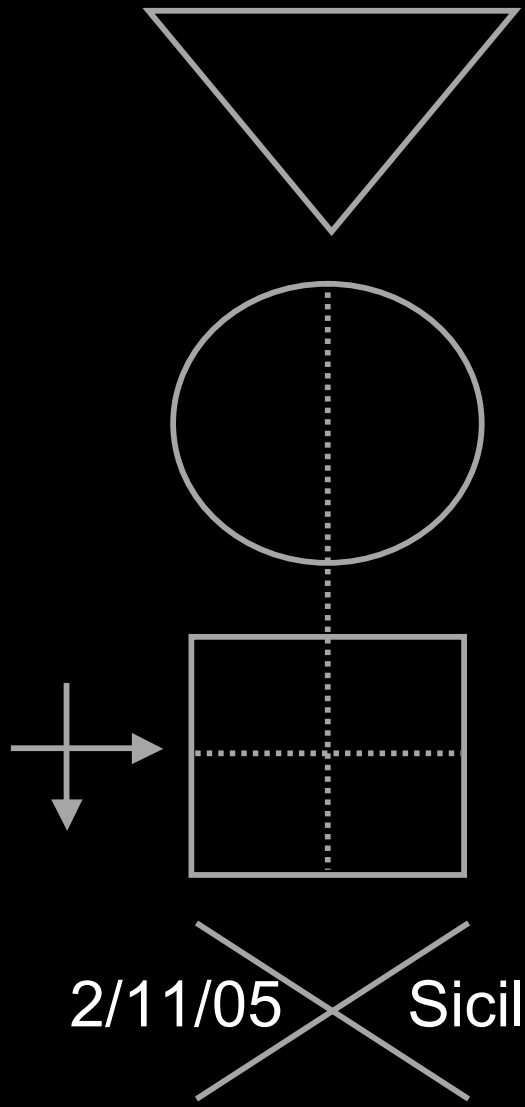
GATE: 'EBP with pictures'



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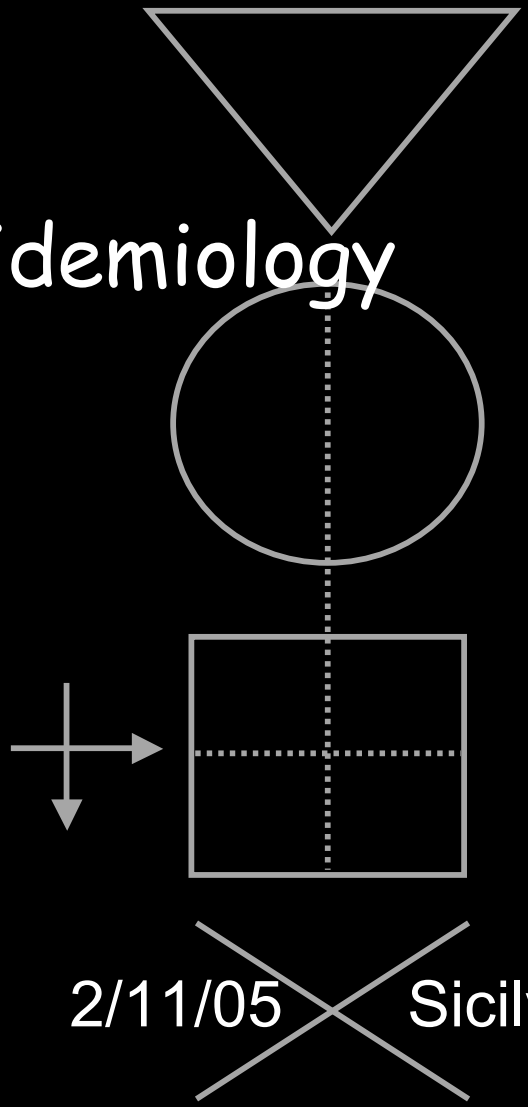
GATE: 'EBP with pictures'

Graphic Appraisal Tool for Epidemiology



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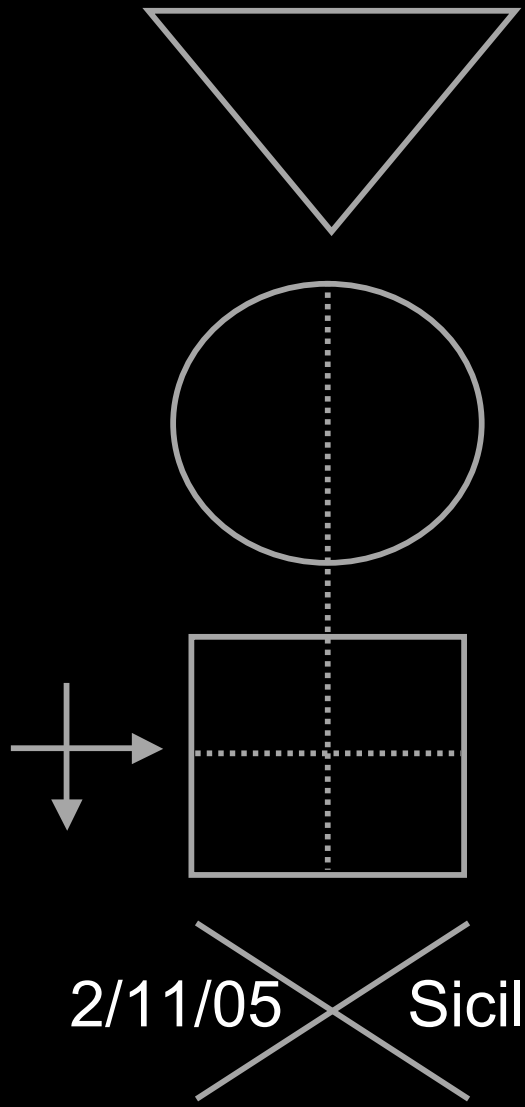
GATE: 'EBP with pictures'



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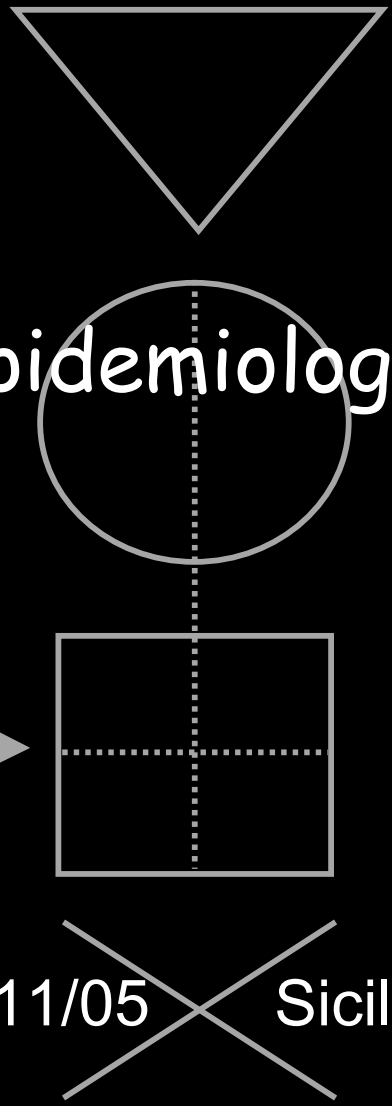
2/11/05 Sicily

GATE: 'EBP with pictures'

Graphic Architectural Tool for Epidemiology



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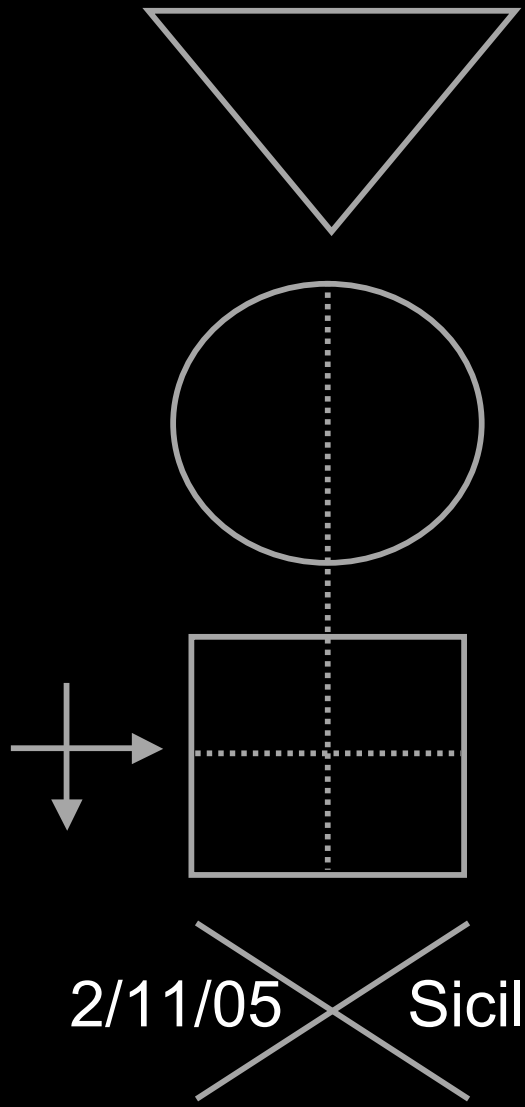
GATE: 'EBP with pictures'



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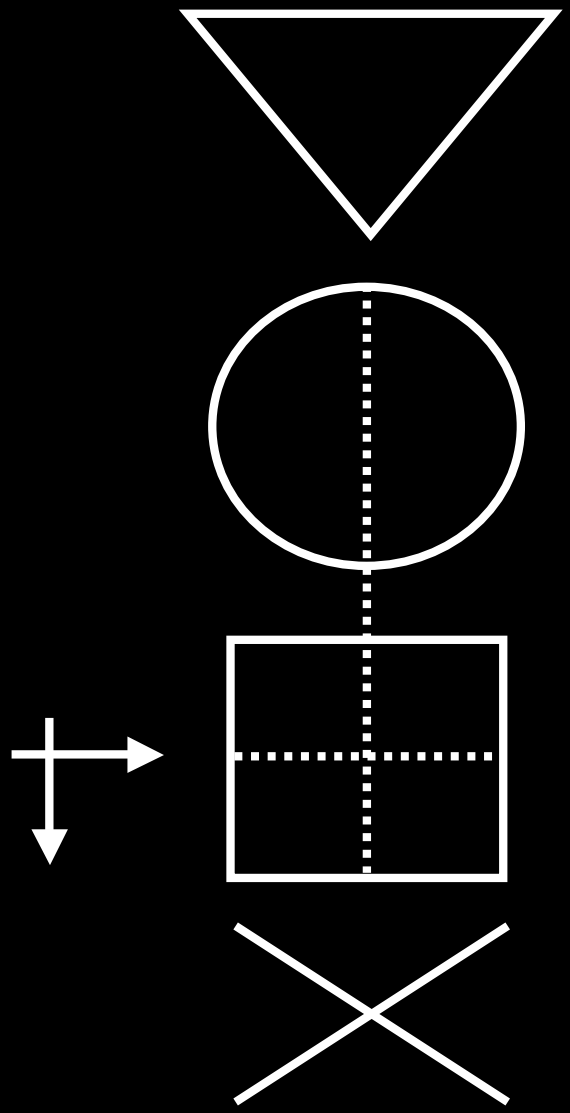
EPIQ group
University of Auckland, NZ
www.epiq.co.nz

2/11/05 Sicily

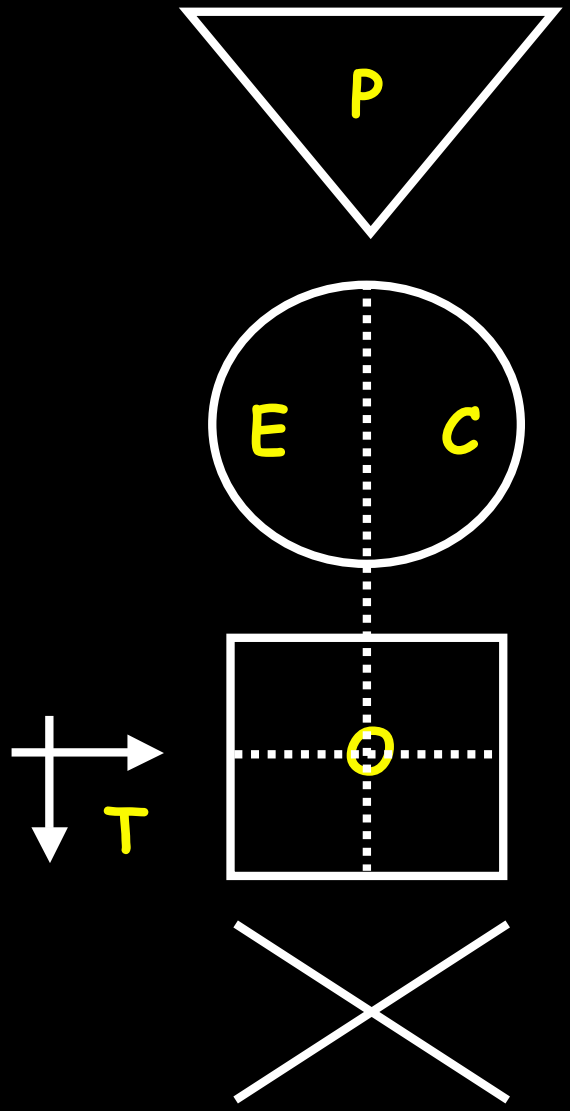
GATE Frame



©

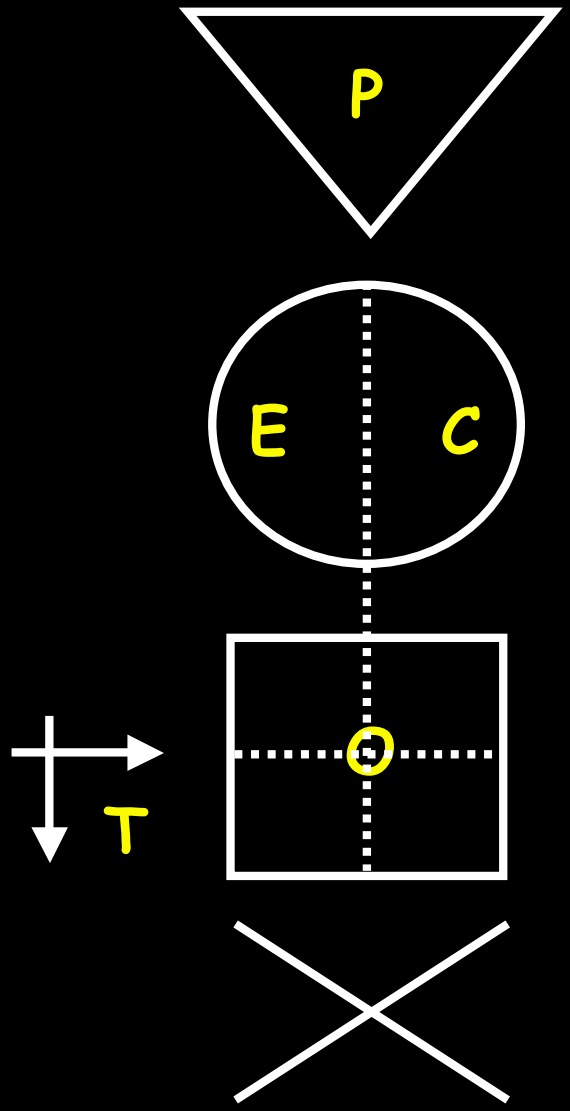
GATE: Graphic Appraisal Tool for Epidemiology

GATE Frame: PECOT (design)



GATE Frame: PECOT (design)

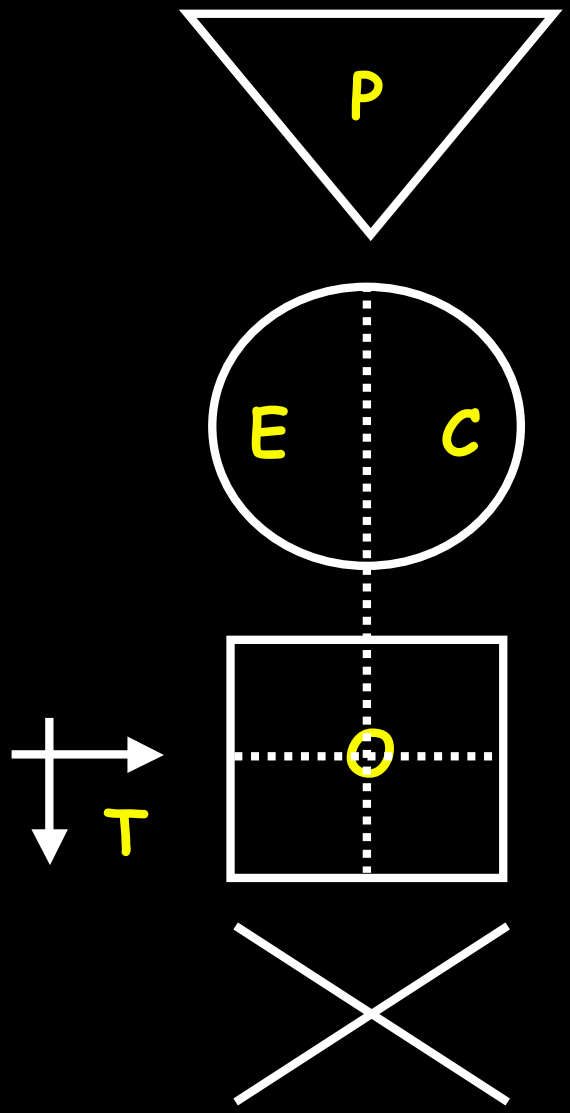
- Population



GATE Frame: PECOT (design)

- Population
- Exposure

(Intervention)

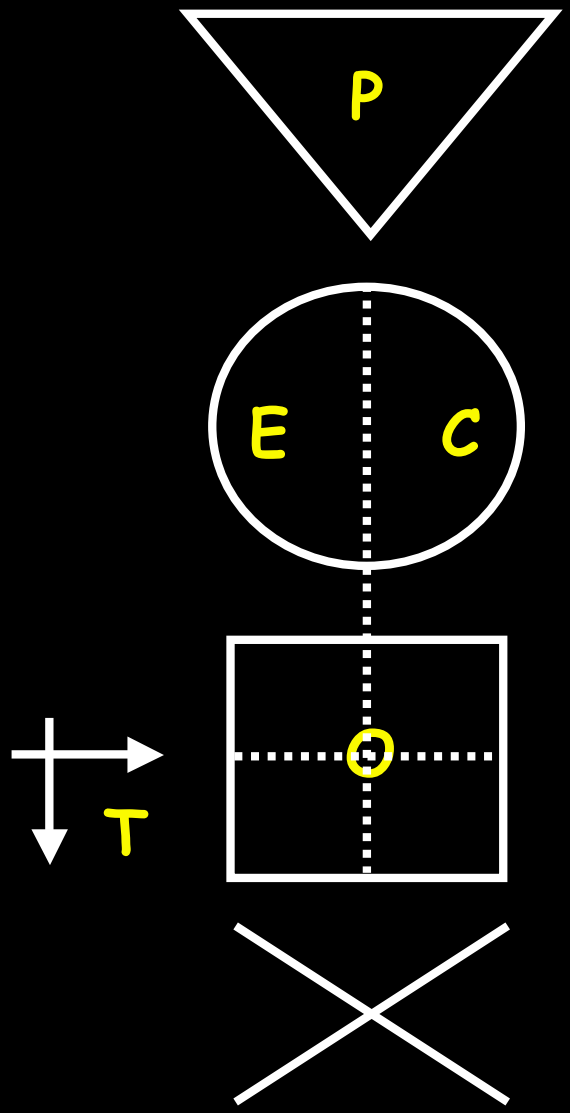


GATE Frame: PECOT (design)

- **P**opulation
- **E**xposure

(Intervention)

- **C**omparison

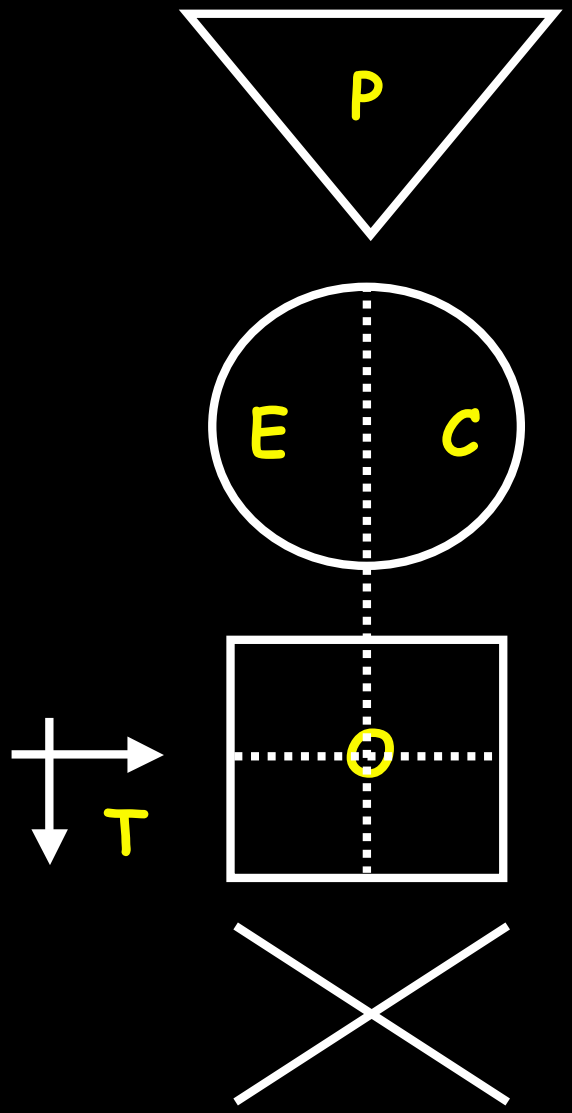


GATE Frame: PECOT (design)

- **P**opulation
- **E**xposure

(Intervention)

- **C**omparison
- **O**utcome

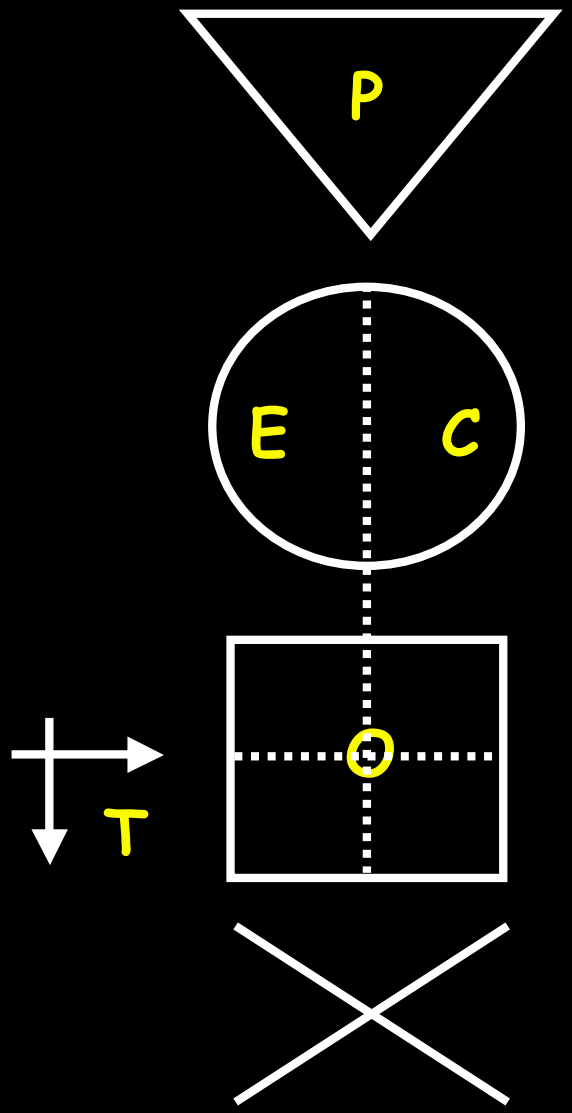


GATE Frame: PECOT (design)

- **P**opulation
- **E**xposure

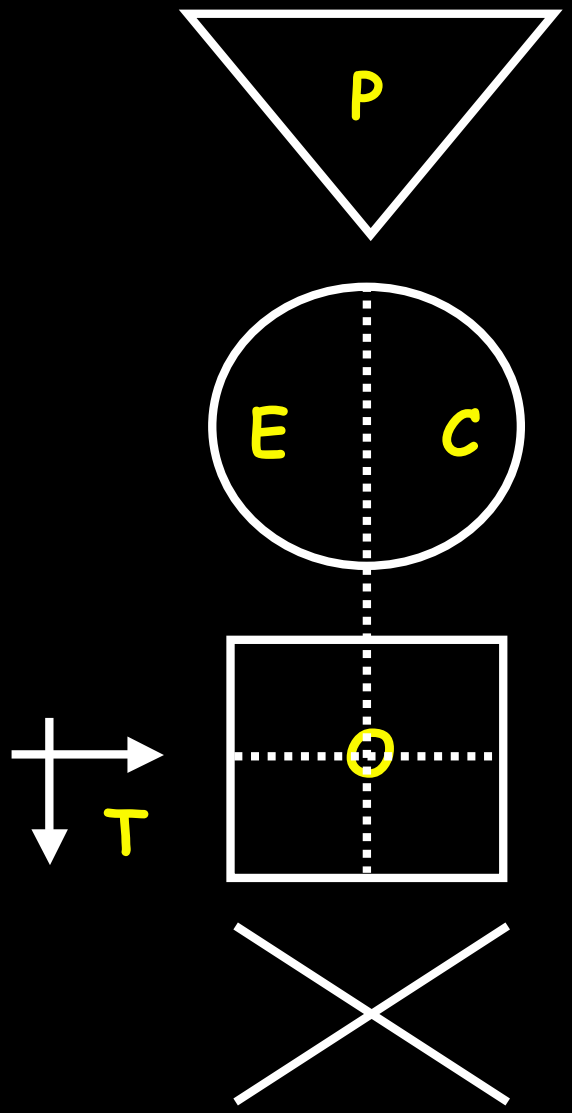
(Intervention)

- **C**omparison
- **O**utcome
- **T**ime



GATE Frame: PECOT (design)

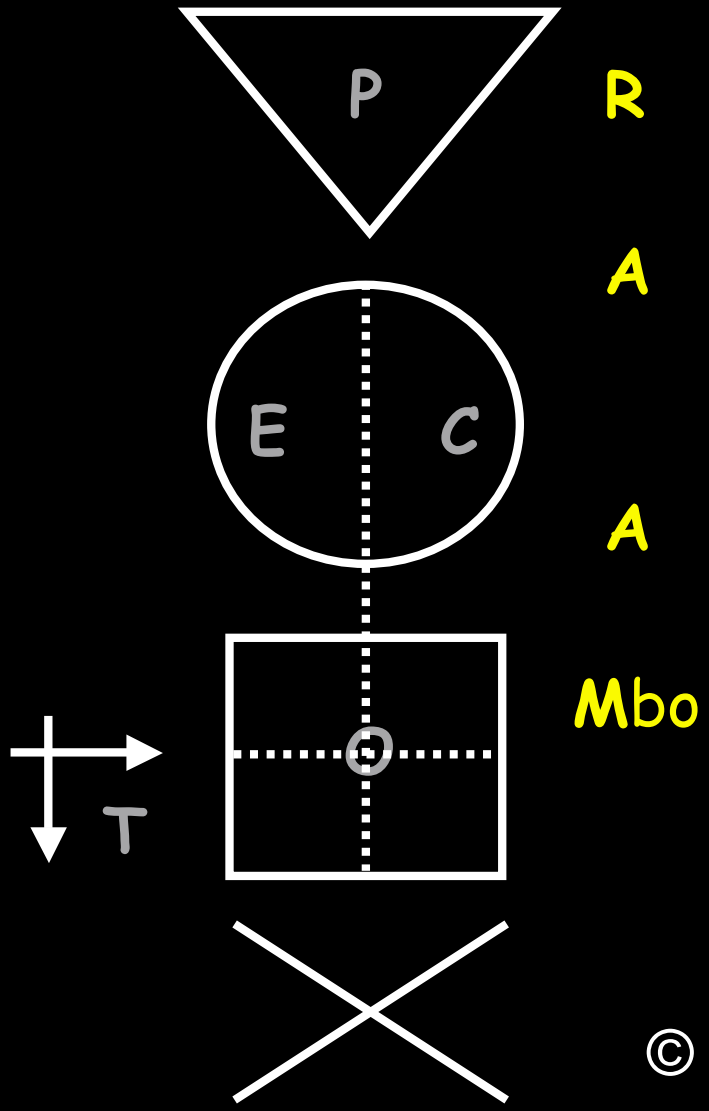
- **P**opulation
- **E**xposure
(Intervention)
- **C**omparison
- **O**utcome
- **T**ime



'hang the study on the GATE frame'

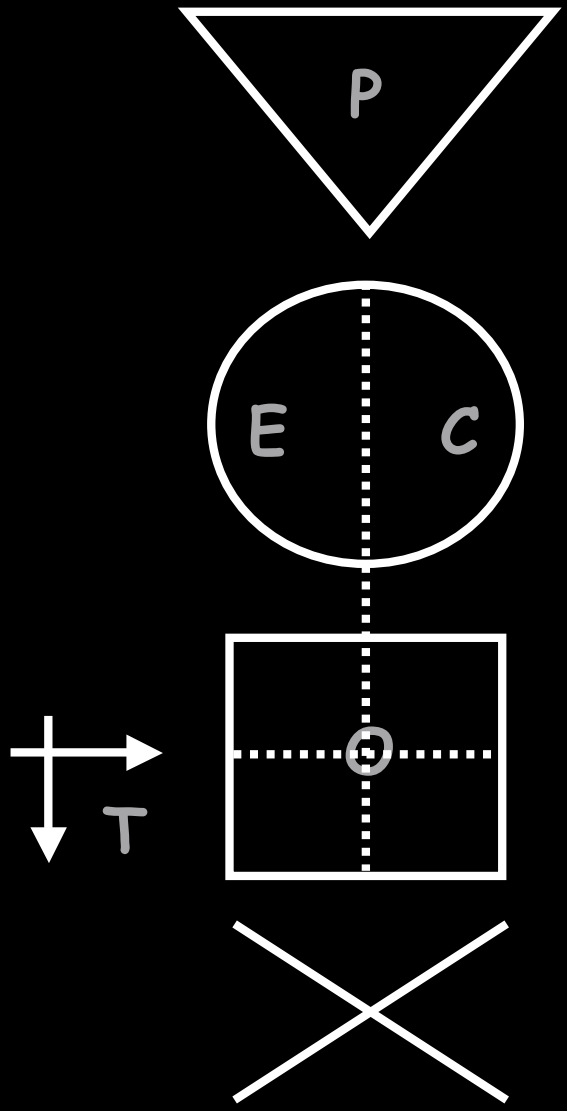
GATE Frame: RAAMbo (study appraisal)

- Population
- Exposure
- Comparison
- Outcome
- Time



GATE Frame: RAAMbo (study appraisal)

- Population
- Exposure
- Comparison
- Outcome
- Time



R

A

A

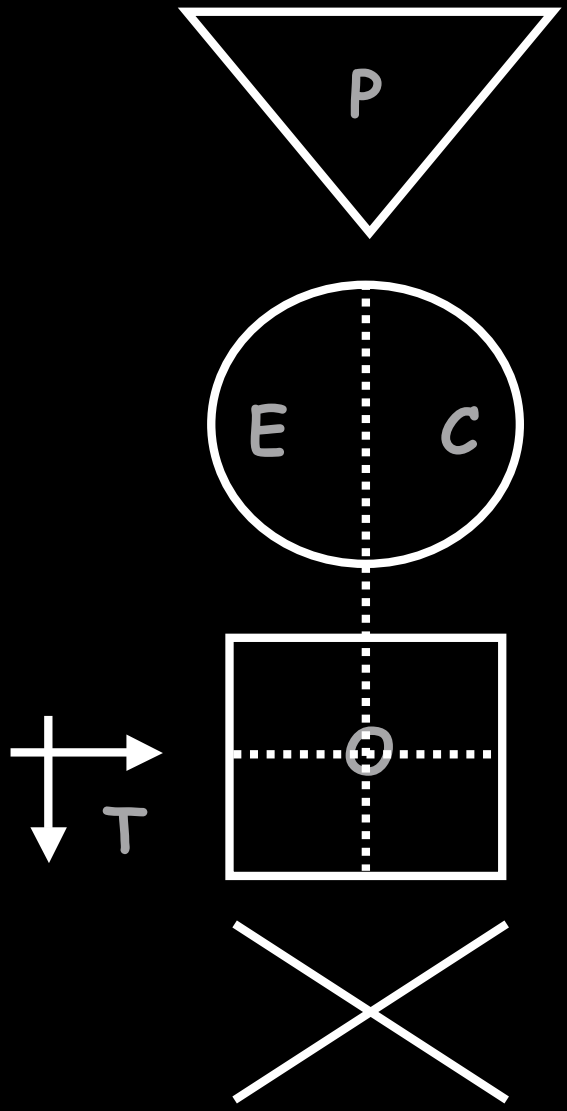
Mbo

©

- Representative?

GATE Frame: RAAMbo (study appraisal)

- Population
- Exposure
- Comparison
- Outcome
- Time

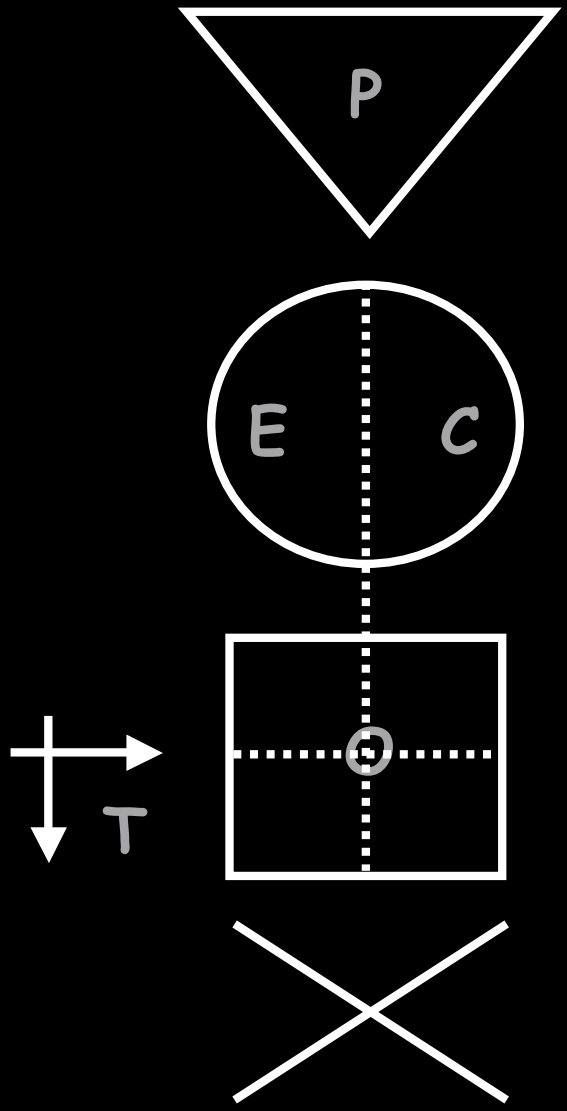


R
A
A
Mbo

- **R**epresentative?
- **A**llocated or **A**djusted?

GATE Frame: RAAMbo (study appraisal)

- Population
- Exposure
- Comparison
- Outcome
- Time



R · **R**epresentative?

A · **A**llocated or **A**djusted?

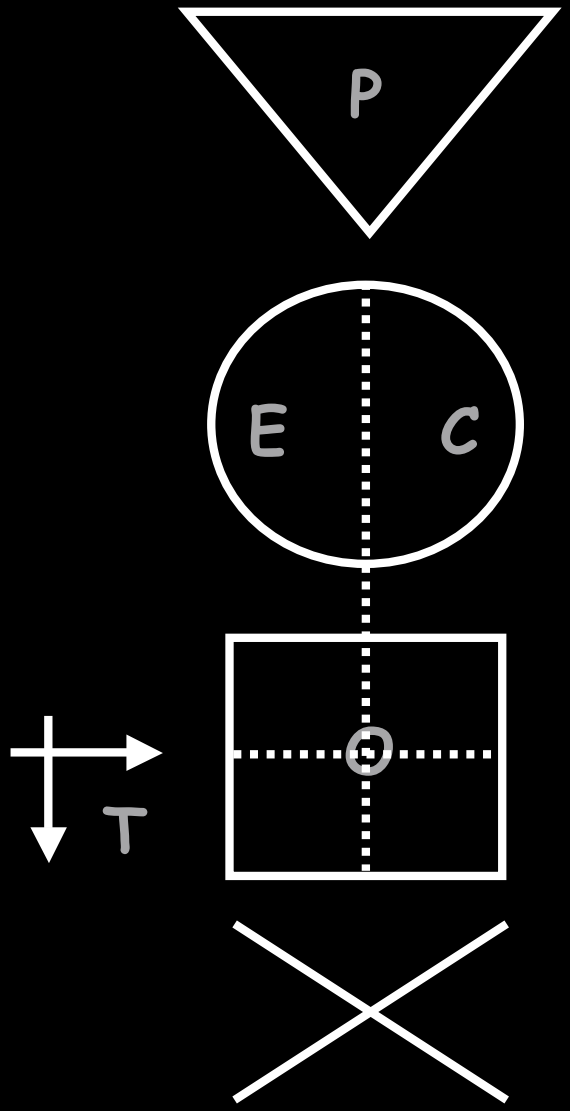
A · **A**ccounted for?

Mbo

©

GATE Frame: RAAMbo (study appraisal)

- Population
- Exposure
- Comparison
- Outcome
- Time



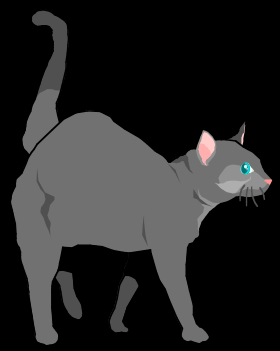
R · **R**epresentative?

A · **A**llocated or **A**djusted?

A · **A**ccounted for?

Mbo · **M**easured?
- blind or
- objective?

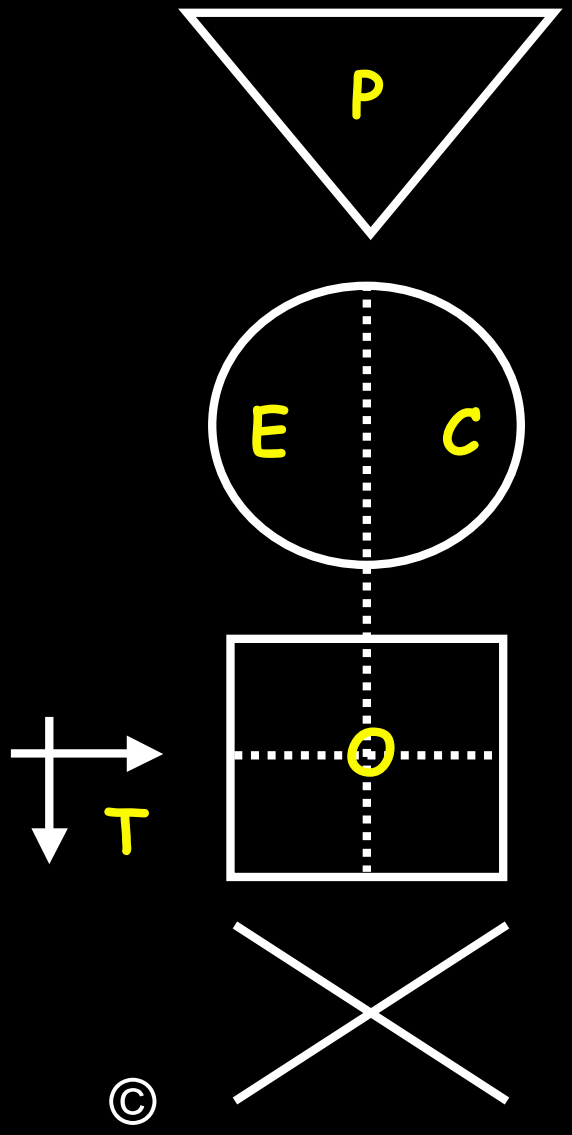
The 4 + 1 steps of EBP (AAAAA)



1. **Ask** a focussed question
2. **Access** (ie. search) appropriate evidence
3. **Appraise** evidence for validity, impact & precision
4. **Apply** evidence accounting for patient values, clinical & policy issues (i.e. answer question)
5. **Audit** personal skills in doing steps 1-4; **Audit** your practice (do you apply step 4 in usual practice).

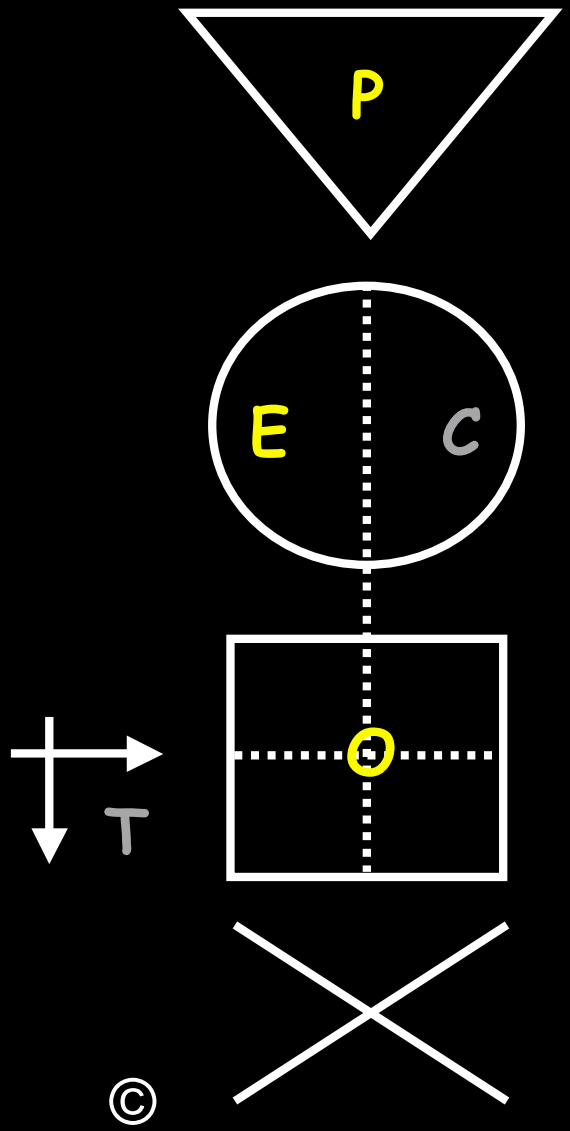
Modified from DS et al

Q1. Ask a focussed 5-part question



1. Population……
2. Exposure……..
3. Comparison……..
4. Outcome…….
5. Time…….

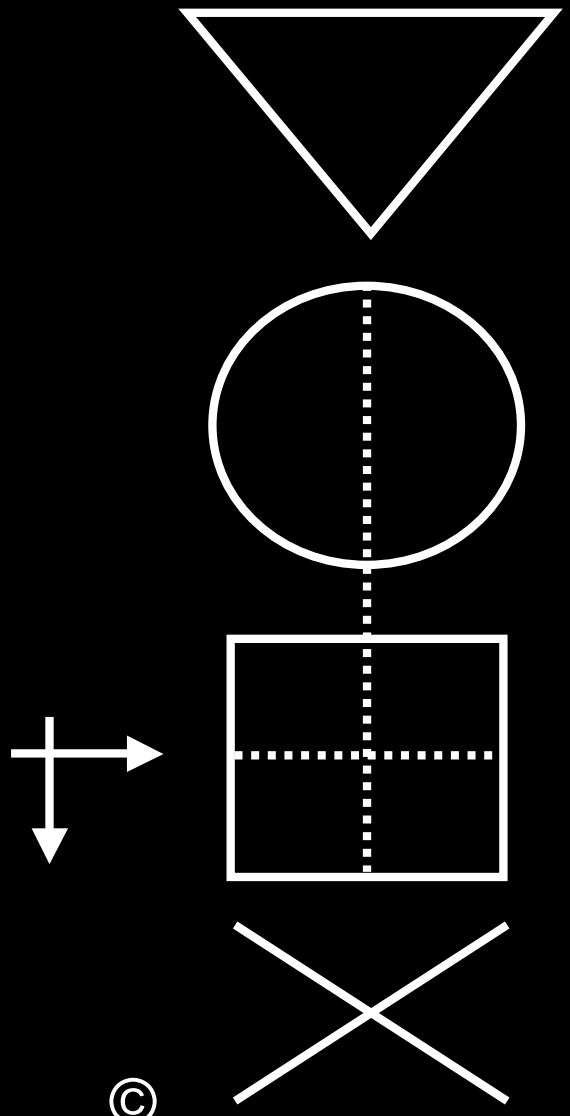
Q1. Access appropriate epidemiological evidence



1. Population……
2. Exposure……..
3. Comparison……..
4. Outcome…….
5. Time…….

Q3. **Appraise** evidence for validity, impact & precision

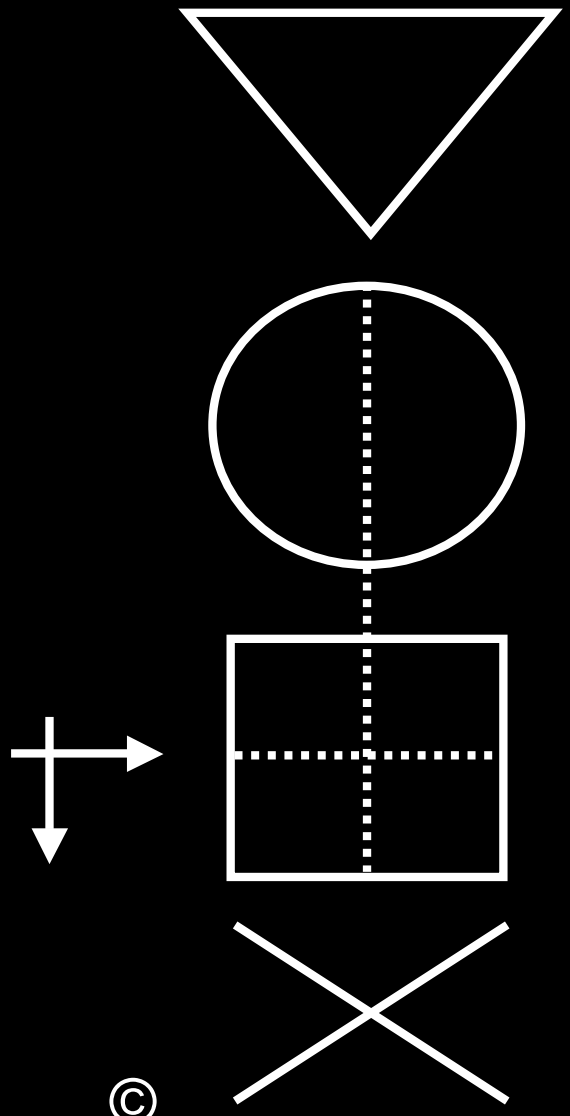
P
E
C
O
T



R
A
A
Mbo

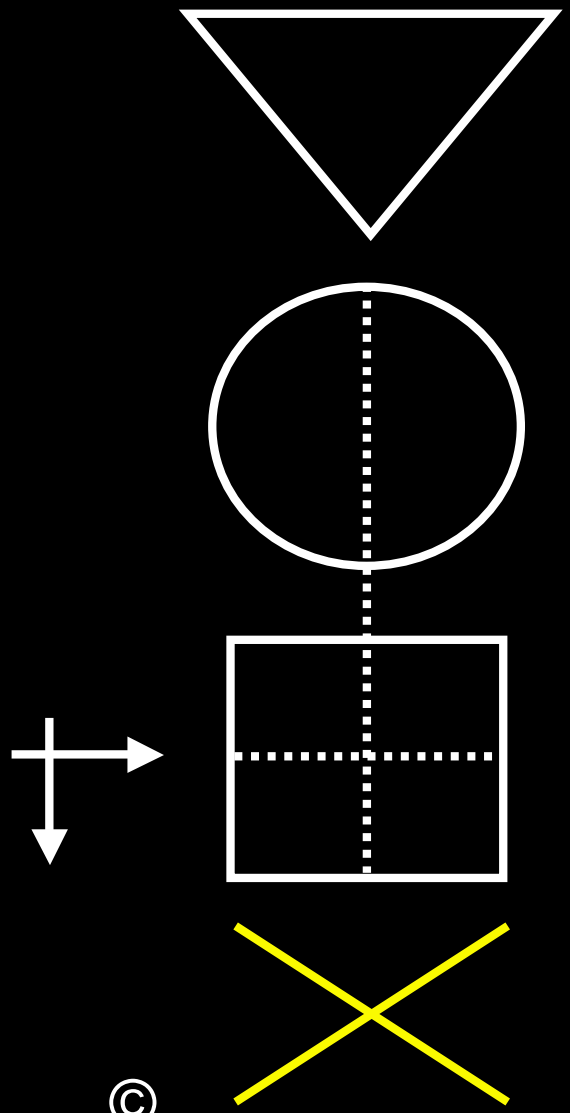
Q3. **Appraise** evidence for validity, impact & precision

P
E
C
O
T



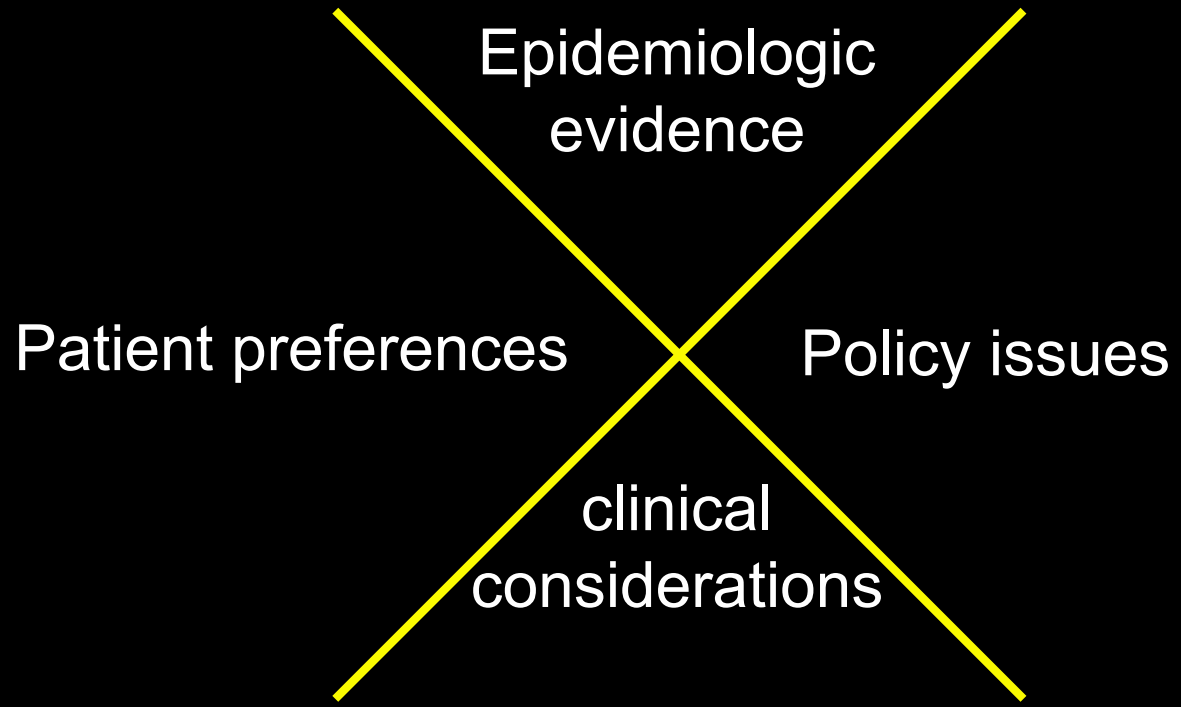
R
A
A
Mbo

Q4. Apply the evidence

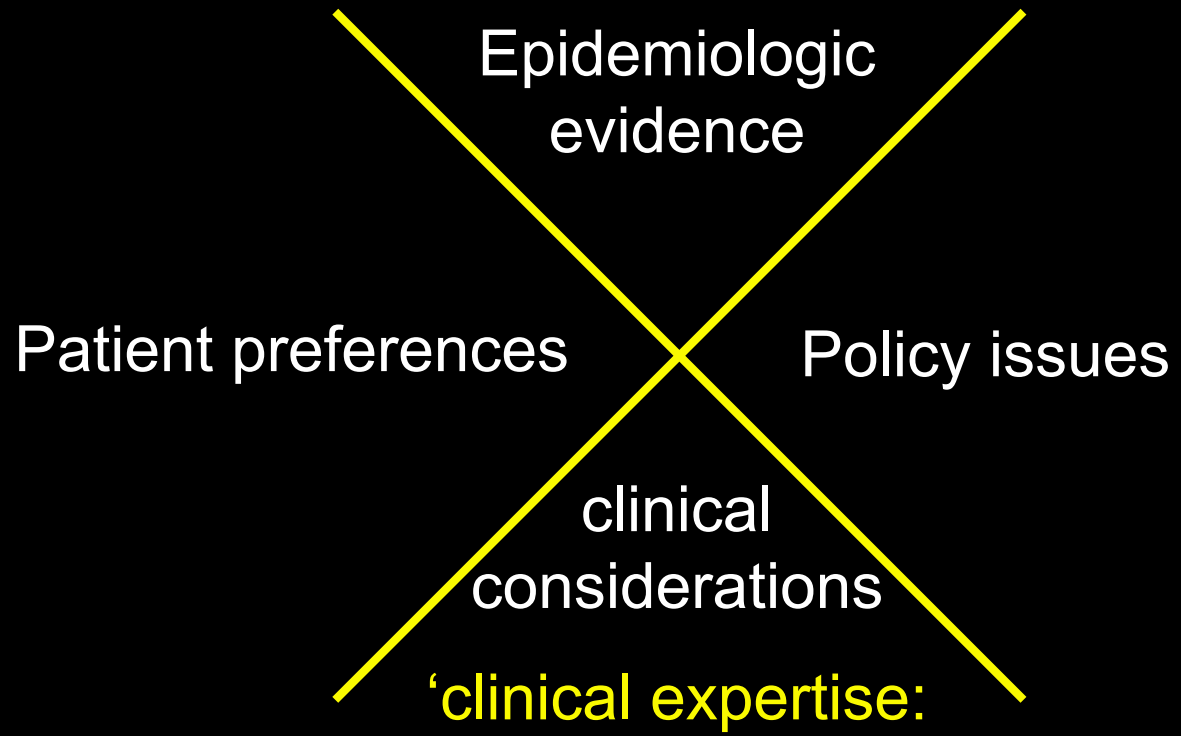


Apply

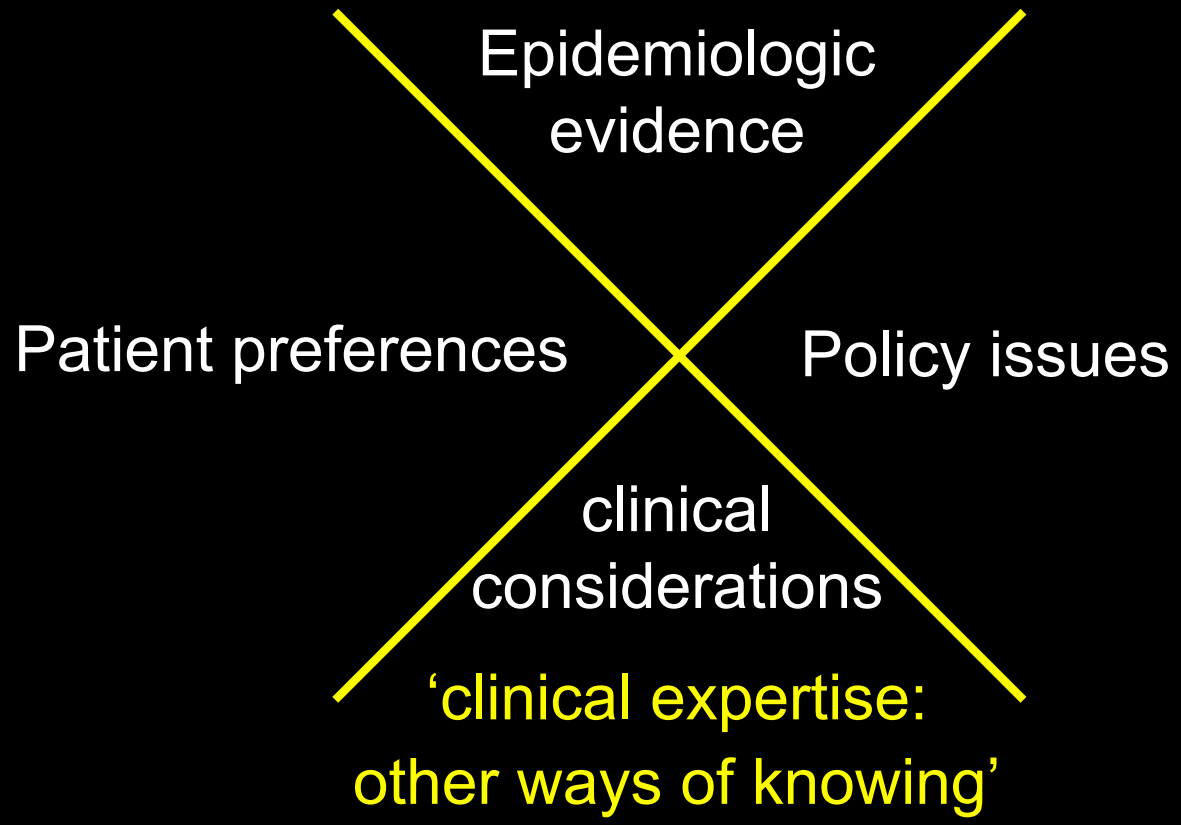
Q4. Apply evidence accounting for patient values, clinical & policy issues



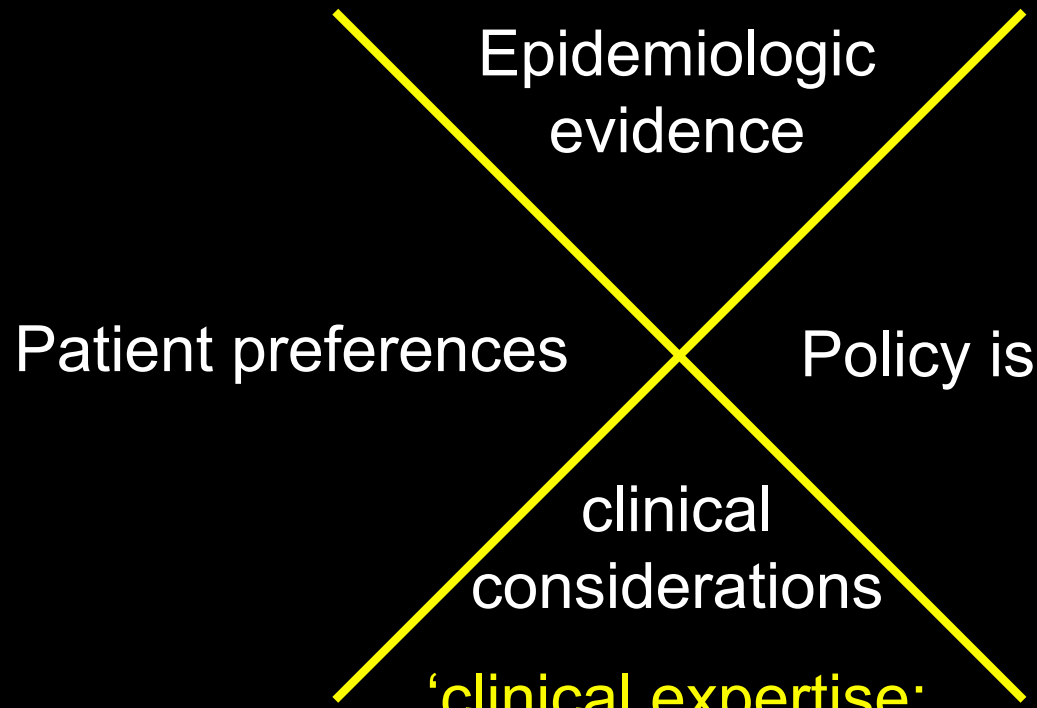
Q4. Apply evidence accounting for patient values, clinical & policy issues



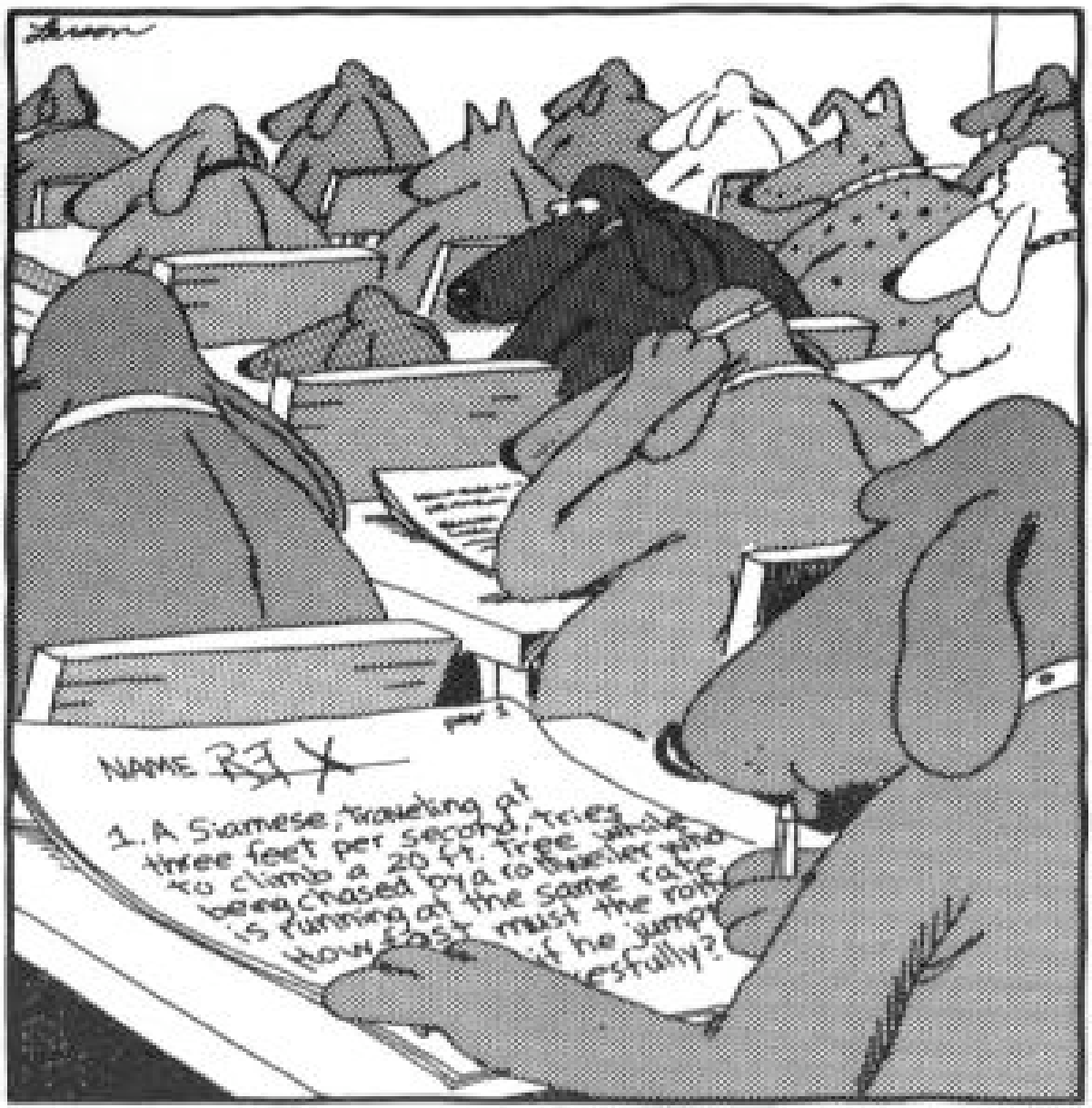
Q4. Apply evidence accounting for patient values, clinical & policy issues



Q4. Apply evidence accounting for patient values, clinical & policy issues



the X-factor: 'integrating & applying' = clinical expertise



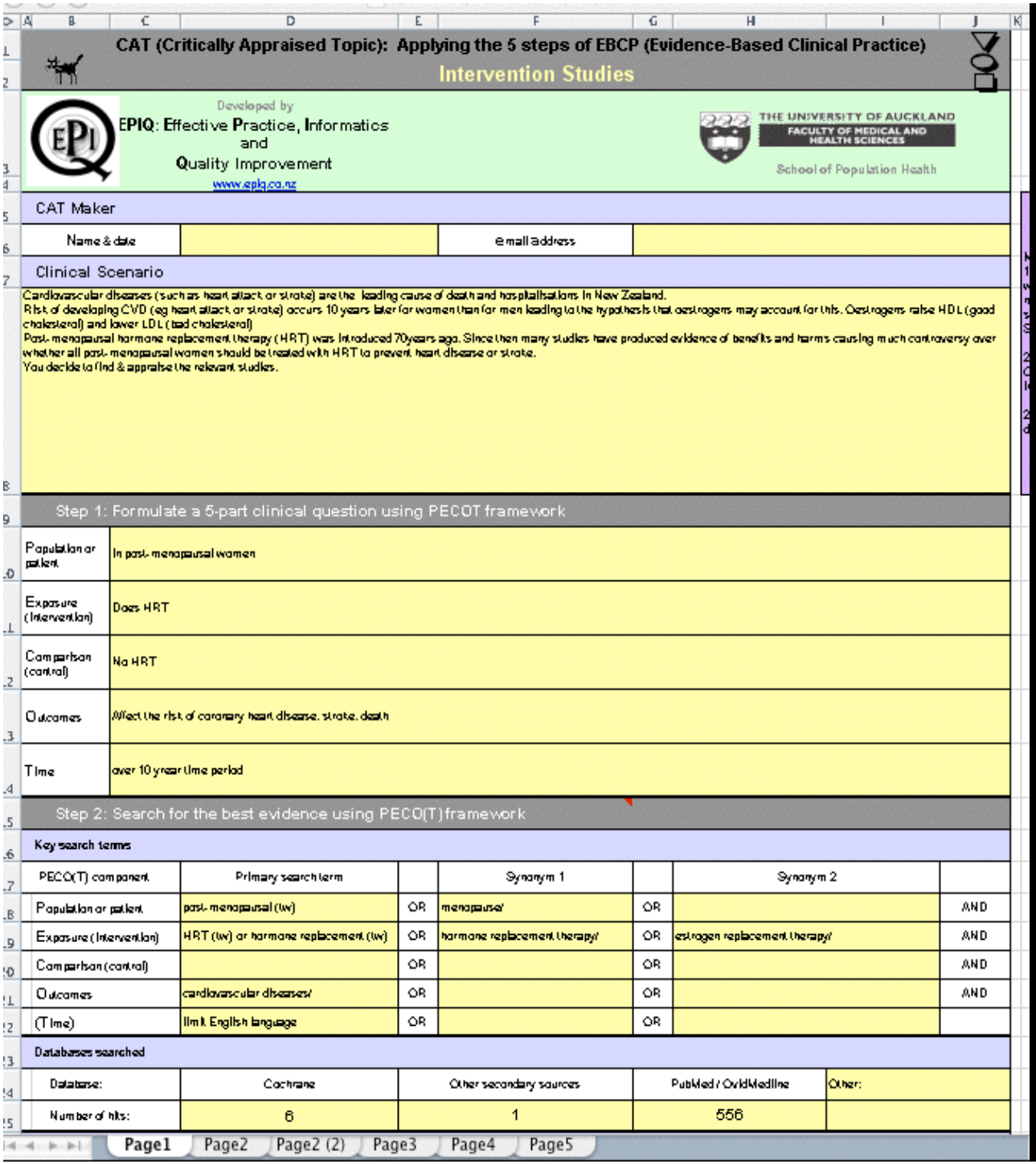
Before their admission to any canine university, dogs must first do well on the CATs.

CATs:

Critically Appraised Topics:

'a tool for modeling the 5 steps of EBP'

www.epiq.co.nz



CAT (Critically Appraised Topic): Applying the 5 steps of EBCP (Evidence-Based Clinical Practice)

Intervention Studies

Developed by

EPIQ: Effective Practice, Informatics and Quality Improvement

www.epiq.co.nz

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES
School of Population Health

CAT Maker

Name & date		e mail address	

Clinical Scenario

Cardiovascular diseases (such as heart attack or stroke) are the leading cause of death and hospitalisations in New Zealand.
Risk of developing CVD (eg heart attack or stroke) occurs 10 years later for women than for men leading to the hypothesis that oestrogens may account for this. Oestrogens raise HDL (good cholesterol) and lower LDL (bad cholesterol)
Post- menopausal hormone replacement therapy (HRT) was introduced 70years ago. Since then many studies have produced evidence of benefits and harms causing much controversy over whether all post- menopausal women should be treated with HRT to prevent heart disease or stroke.
You decide to find & appraise the relevant studies.

Step 1: Formulate a 5-part clinical question using PECOT framework

Population or patient	In post- menopausal women
Exposure (Intervention)	Does HRT
Comparison (control)	No HRT
Outcomes	Affect the risk of coronary heart disease, stroke, death
Time	over 10 year time period

Step 2: Search for the best evidence using PECO(T) framework

Key search terms

PECO(T) component	Primary search term		Synonym 1		Synonym 2	
Population or patient	post- menopausal (tw)	OR	menopause/	OR		AND
Exposure (Intervention)	HRT (tw) or hormone replacement (tw)	OR	hormone replacement therapy/	OR	estrogen replacement therapy/	AND
Comparison (control)		OR		OR		AND
Outcomes	cardiovascular diseases/	OR		OR		AND
(Time)	limit English language	OR		OR		

Databases searched

Database:	Cochrane	Other secondary sources	Pubmed / Ovid Medline	Other:
Number of hits:	6	1	556	

Page1 Page2 Page2 (2) Page3 Page4 Page5

CAT forms:

(in Excel)

Intervention

Diagnosis

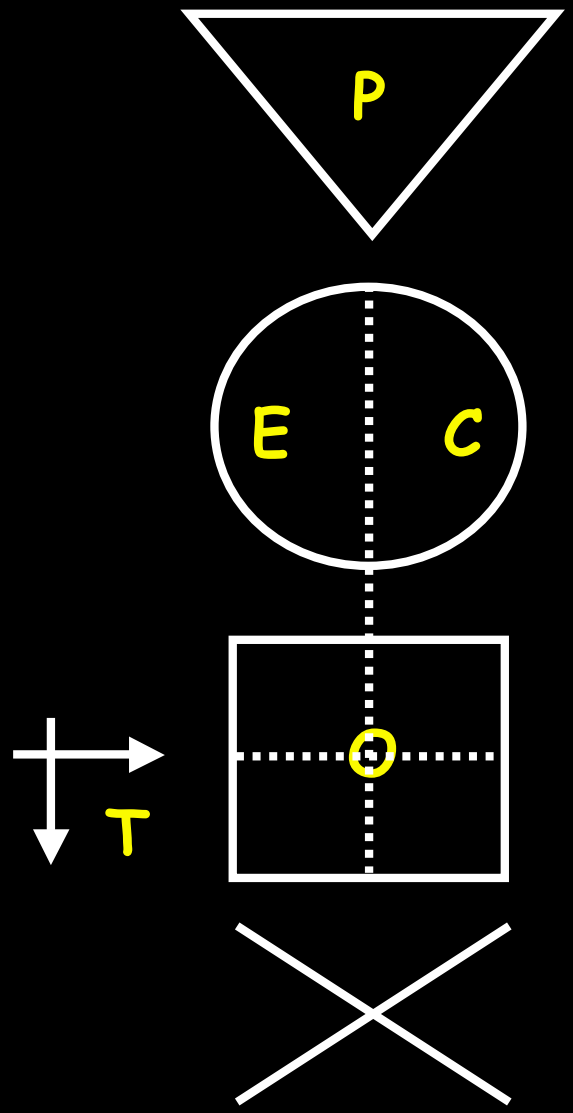
Prognosis/Risk

Systematic Reviews

download from:

www.epiq.co.nz

GATE Frame: PECOT (design)



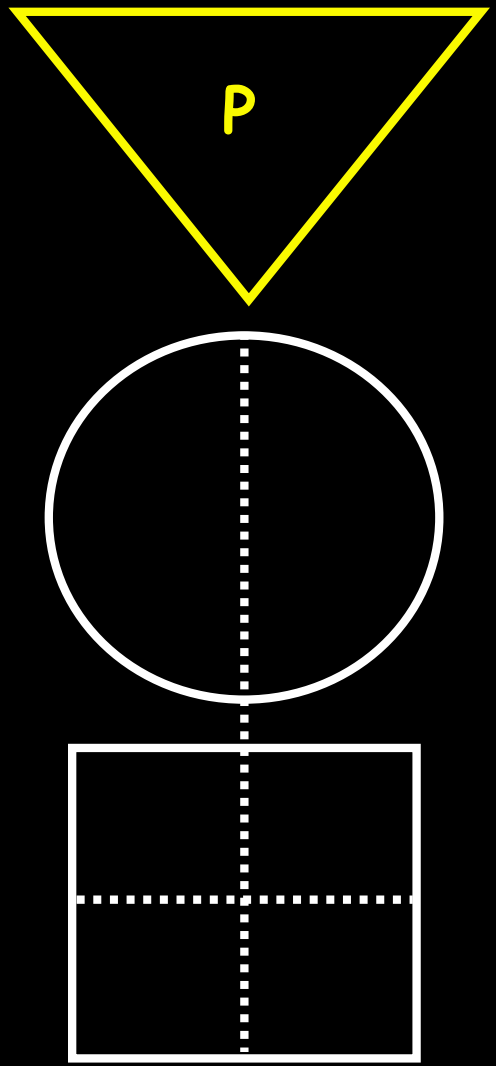
- **P**opulation .....
- **E**xposure .....
- **C**omparison .....
- **O**utcome .....
- **T**ime .....

©

'hang the HERS study on the GATE frame'

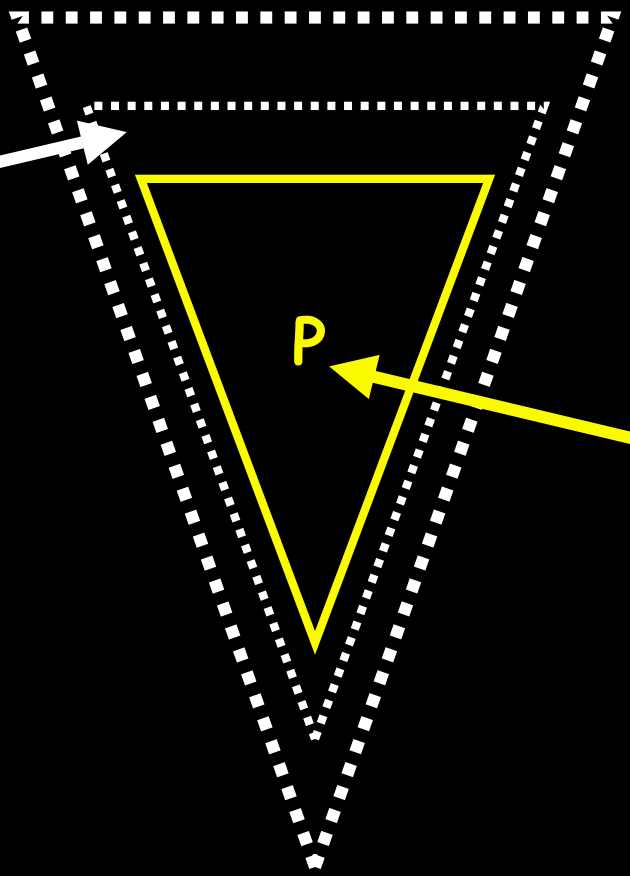
GATE: epi study design (P)

Population



Source Population:

68,561 women screened from 20 outpatients/community screening centres



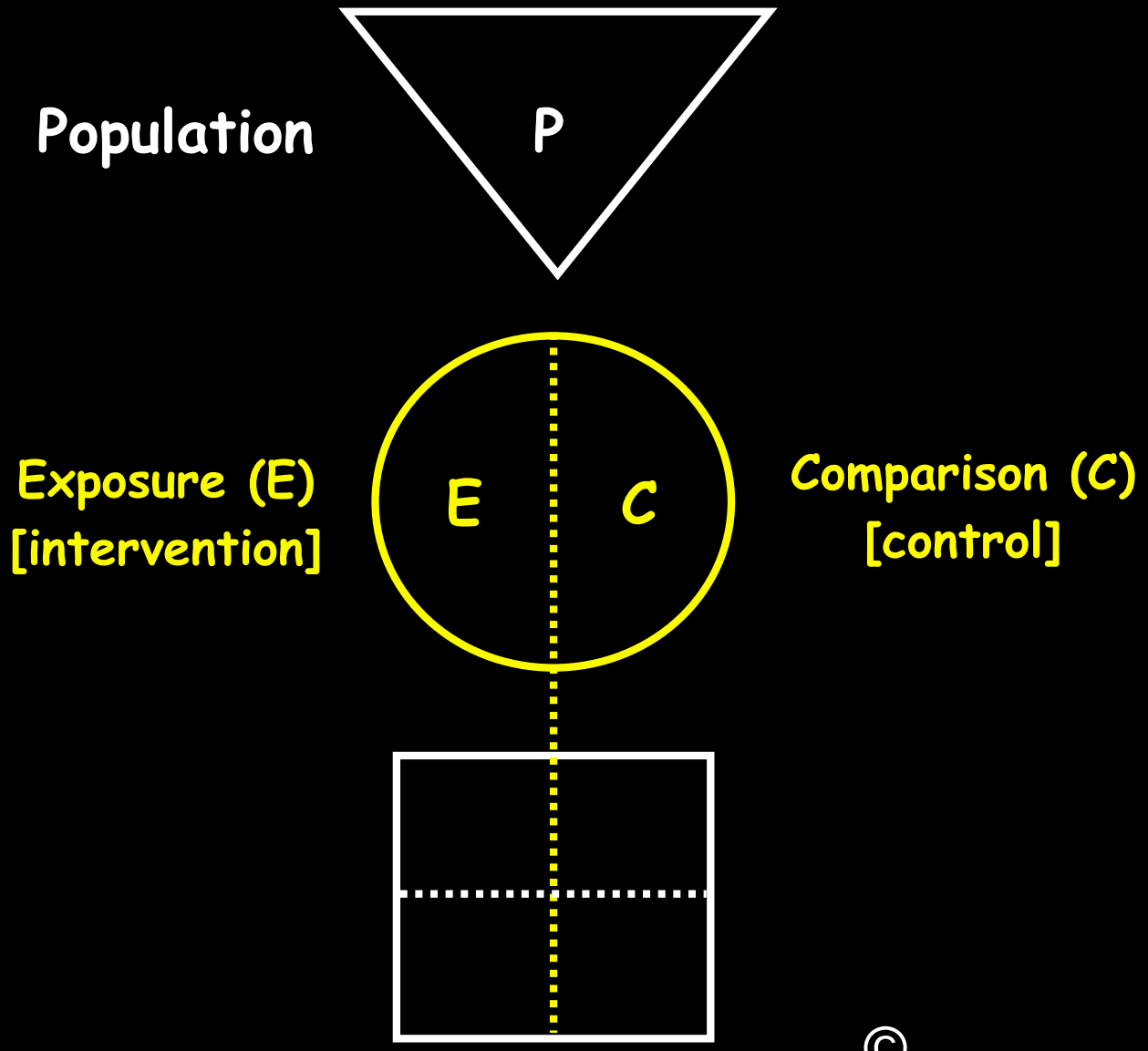
Eligible Population:

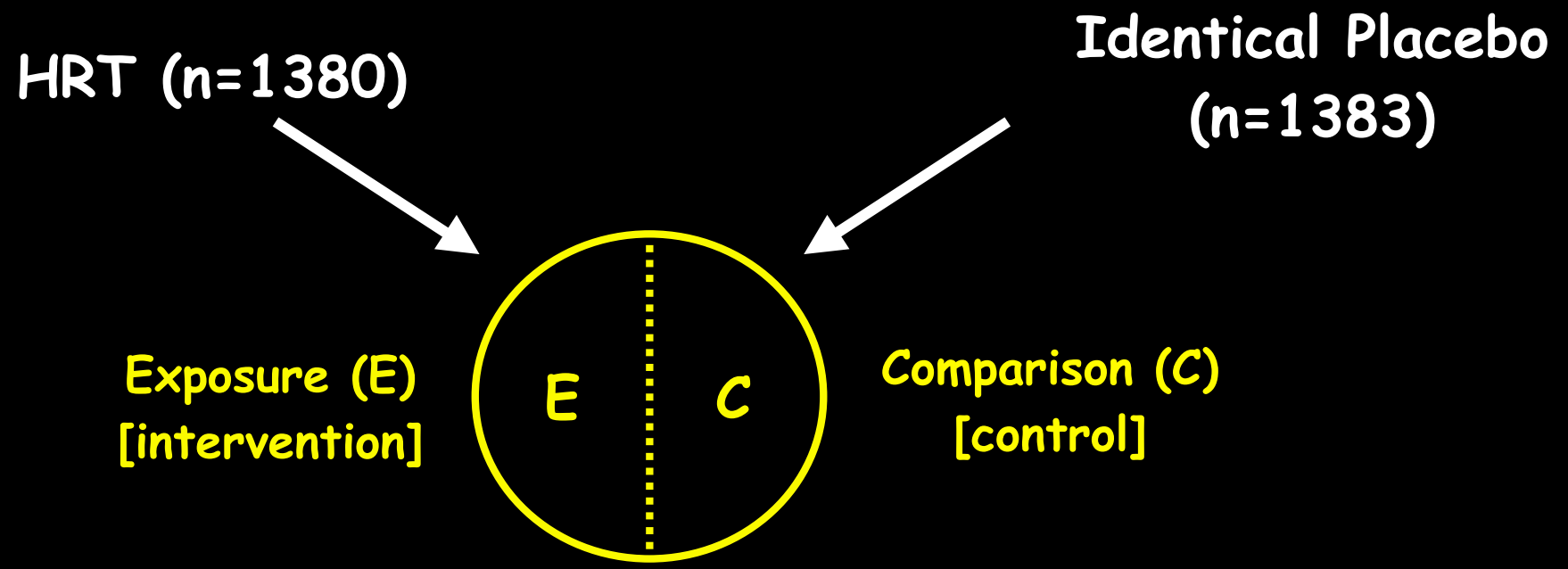
Post-menopausal, established CHD, < 80 yrs, no MI in last 6 mths, no HRT last 3 months

Participant Population:

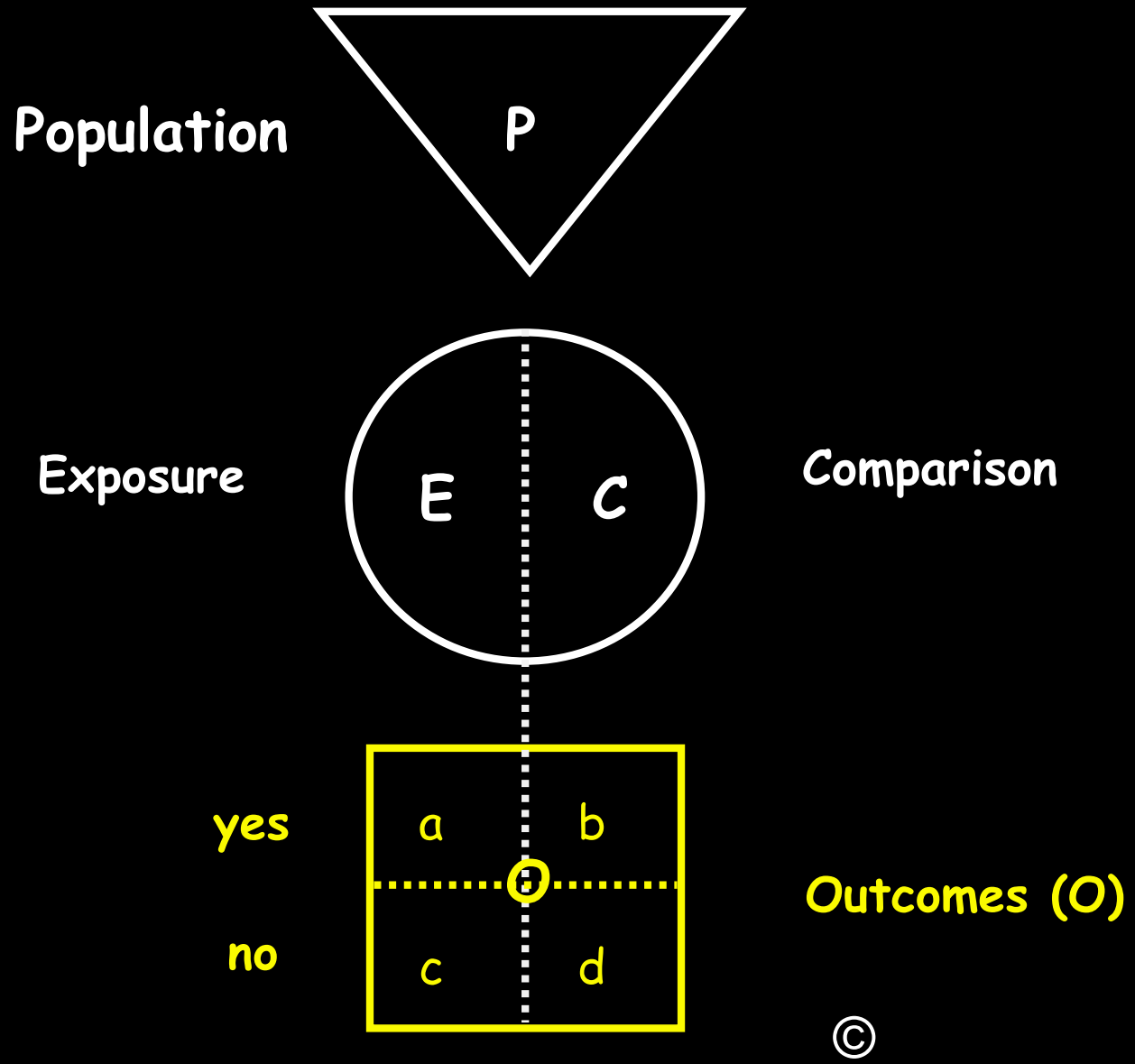
all eligibles invited (2763)

GATE: epi study design (E&C)

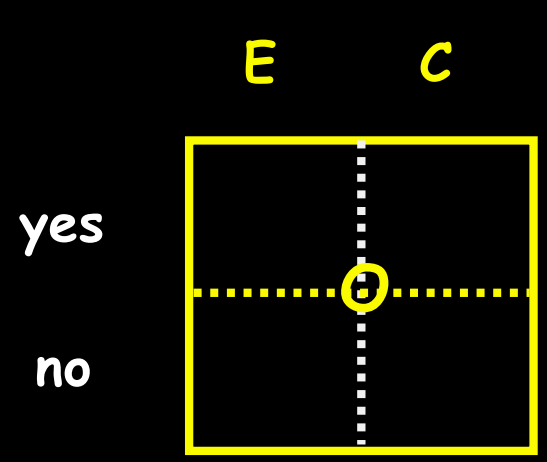



HRT (n=1380)
Identical Placebo
(n=1383)
Exposure (E)
[intervention]
E
C
Comparison (C)
[control]

GATE: epi study design (O)

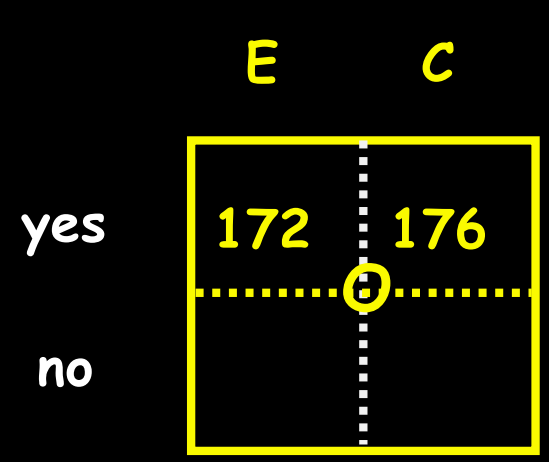


1° outcome: non fatal
MI or CHD death



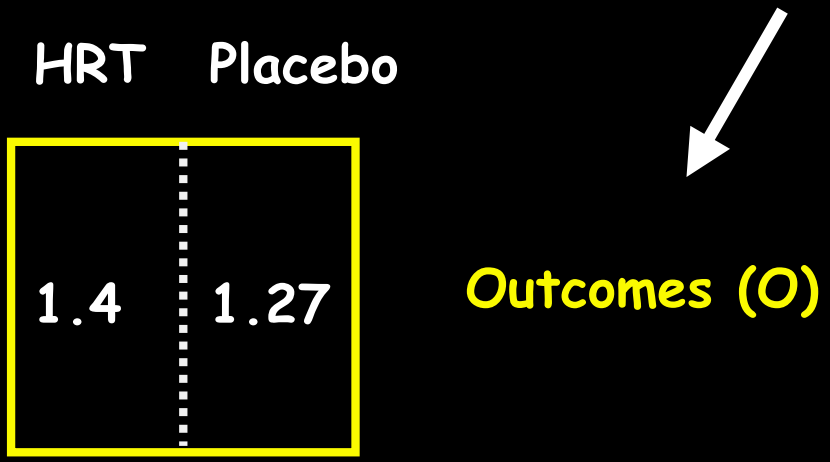
Outcomes (O)

1° outcome: non fatal
MI or CHD death



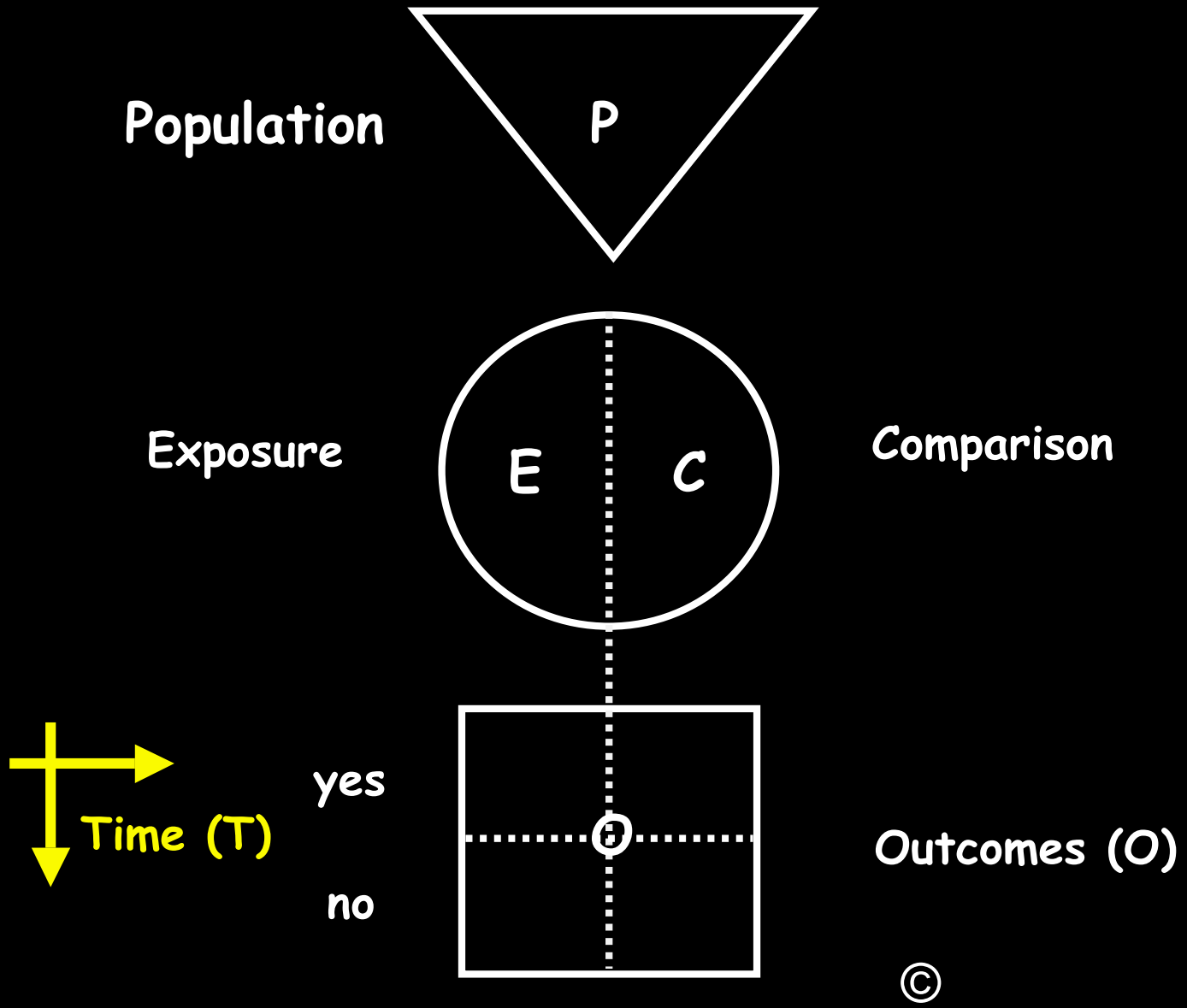
Outcomes (O)

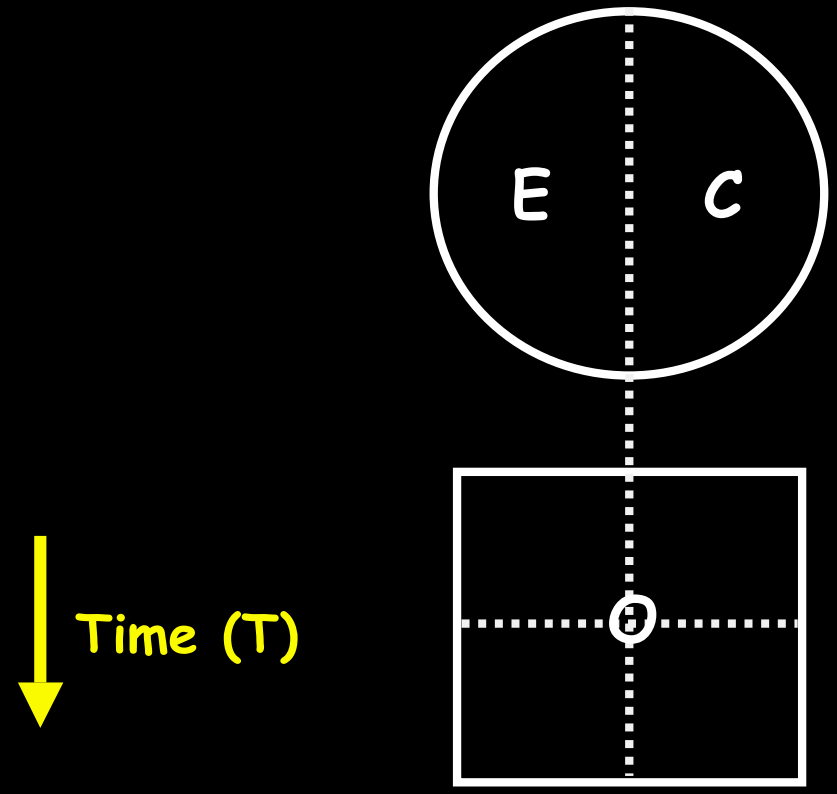
mean HDL cholesterol (mmol/L)



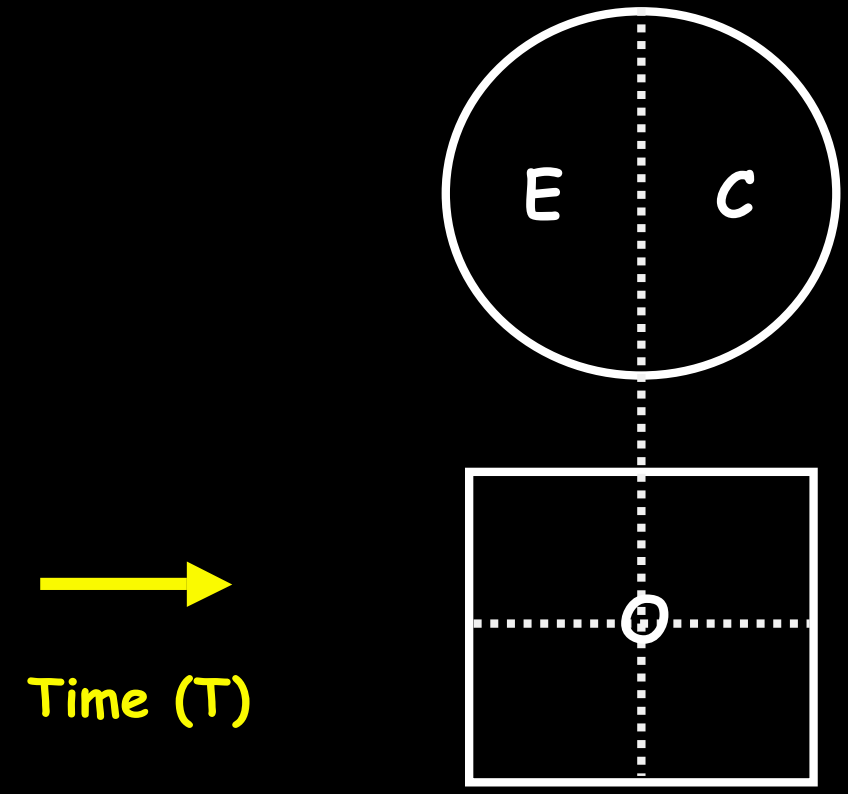
Outcomes (O)

GATE: epi study design (T)





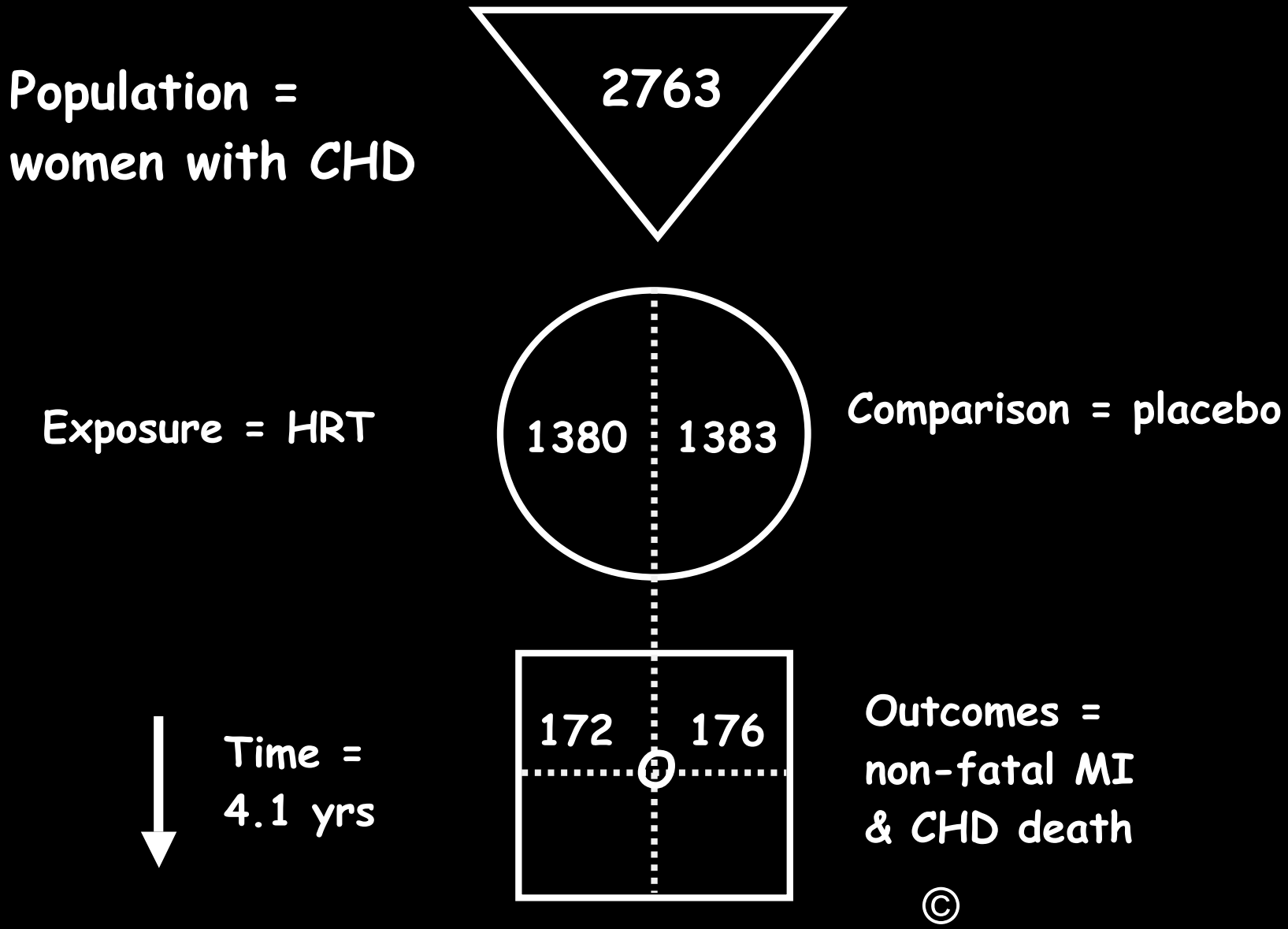
CHD outcomes measured
over 4.1 years
(longitudinal)



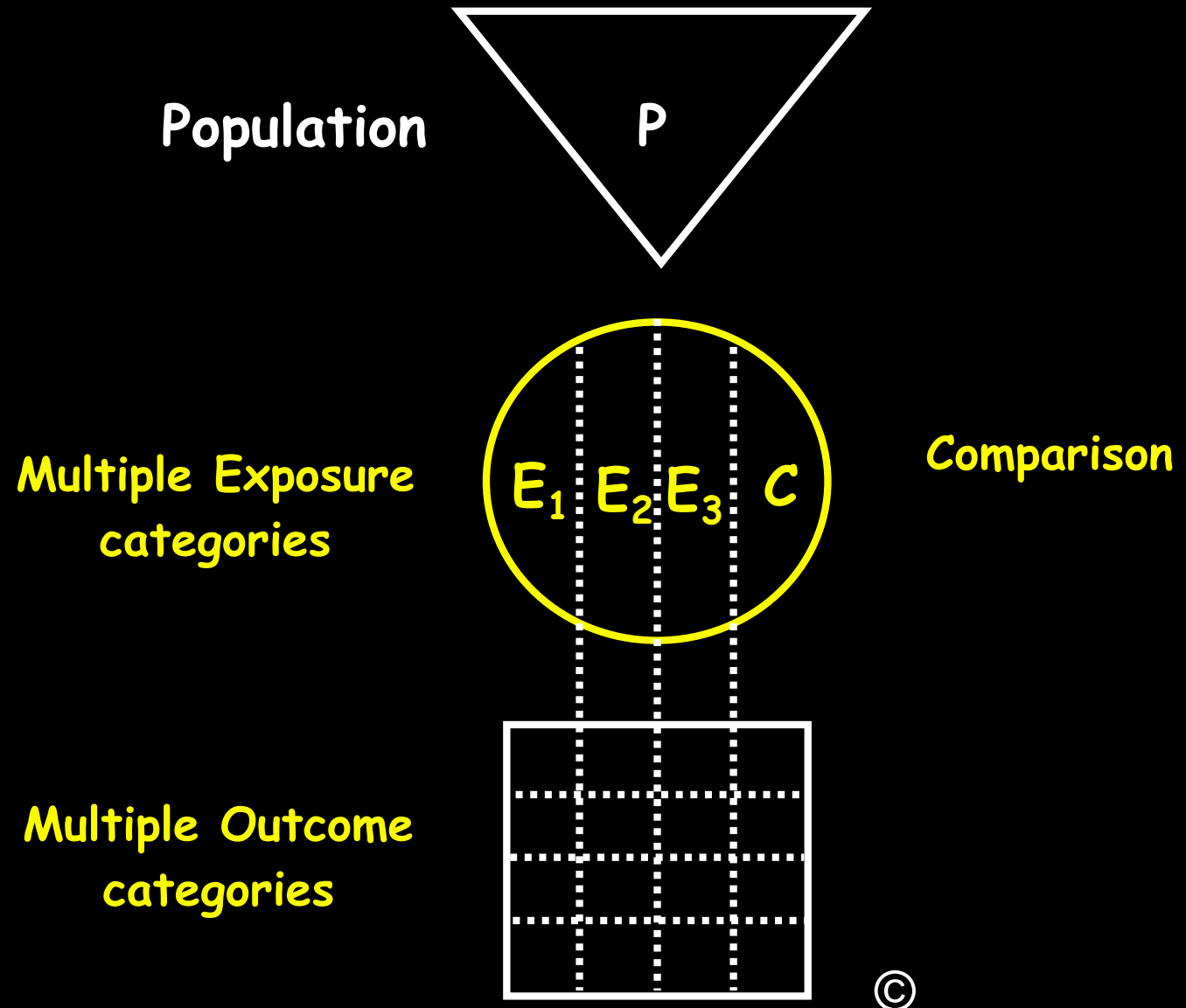
Time (T)

HDL cholesterol
measured at 1 year
(cross-sectional)

GATE: HERS

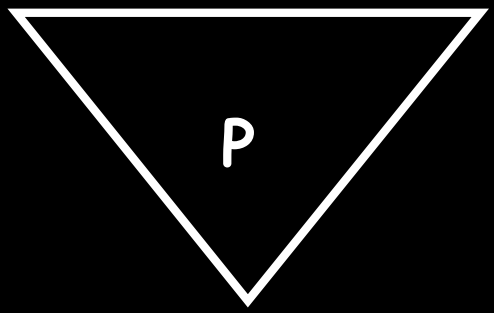

Population =
women with CHD
2763
Exposure = HRT
1380
1383
Comparison = placebo
Time =
4.1 yrs
172
176
Outcomes =
non-fatal MI
& CHD death

GATE: epi study design



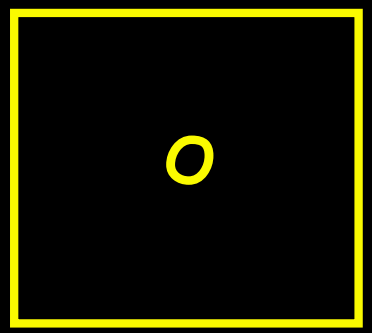
GATE: epi study design

Population



Continuous measure of Exposure: e.g. body mass index

Continuous measure of Outcomes e.g. lipids

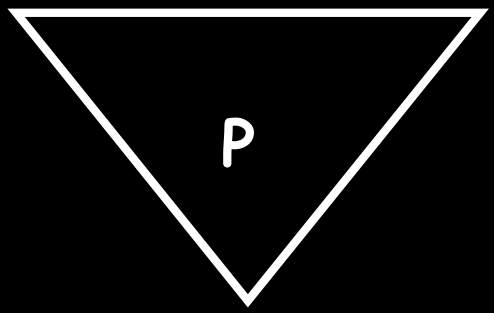


low

medium

high

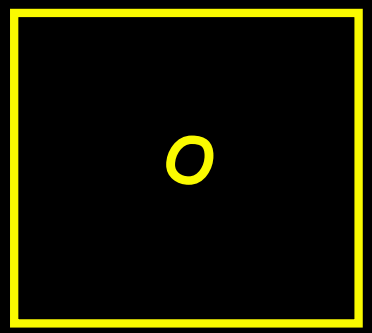
GATE: epi study design



Population

Continuous measure of Exposure: e.g. body mass index

Correlation coefficient



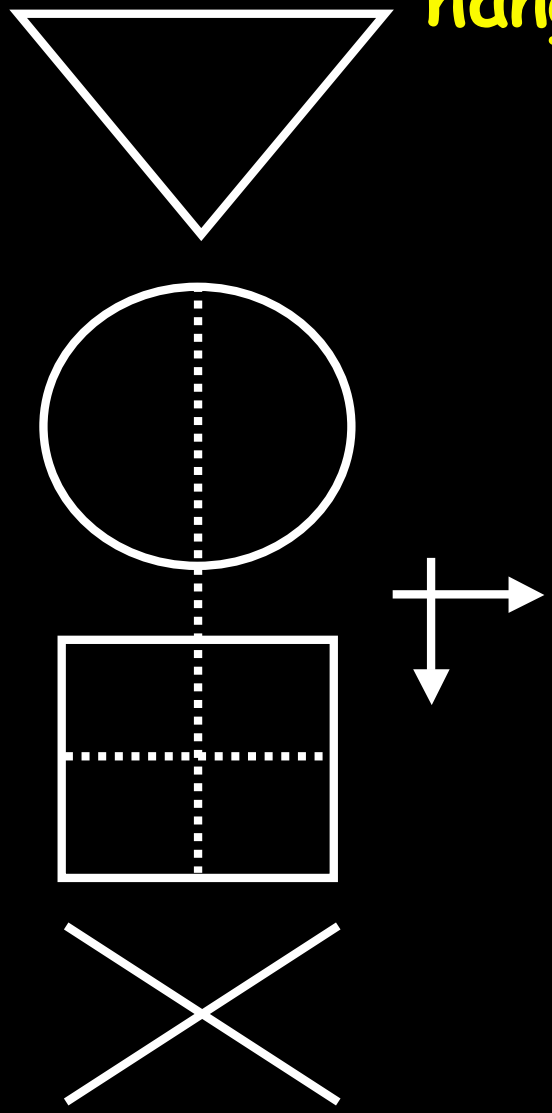
Continuous measure of Outcomes e.g. lipids

low

medium

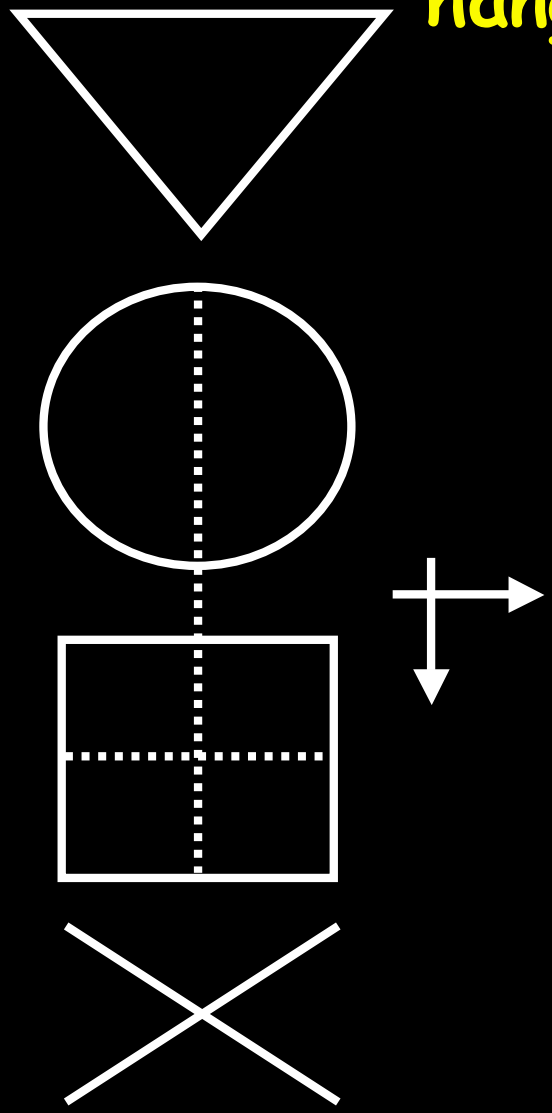
high

The GATE Approach: every epidemiological study hangs on the GATE frame



GATE: Graphic Appraisal Tool for Epidemiology

The GATE Approach: every epidemiological study hangs on the GATE frame



there is only one study design:

GATE: Graphic Appraisal Tool for Epidemiology

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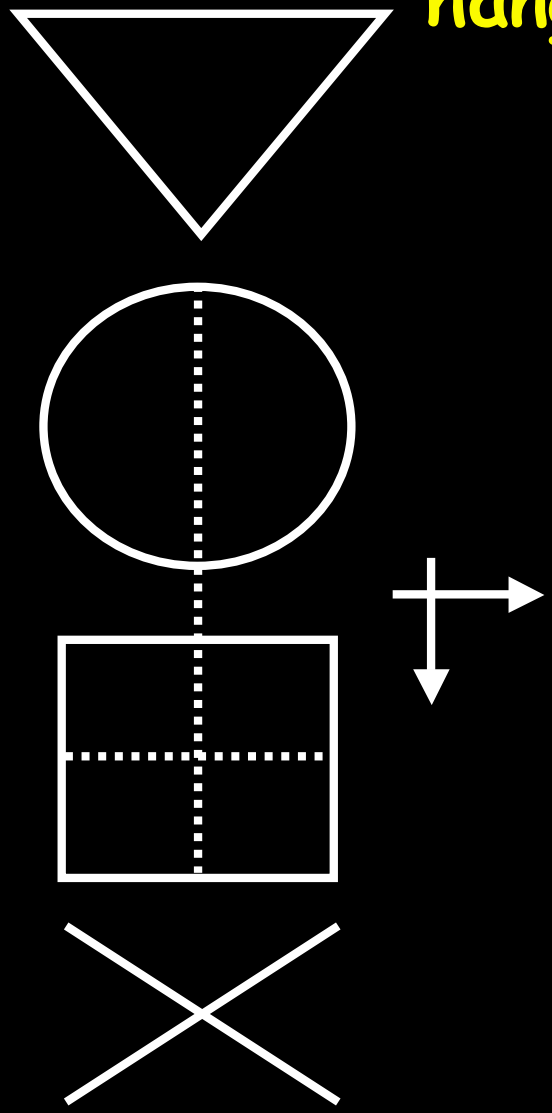

there is only one study design:

- RCT - interventions

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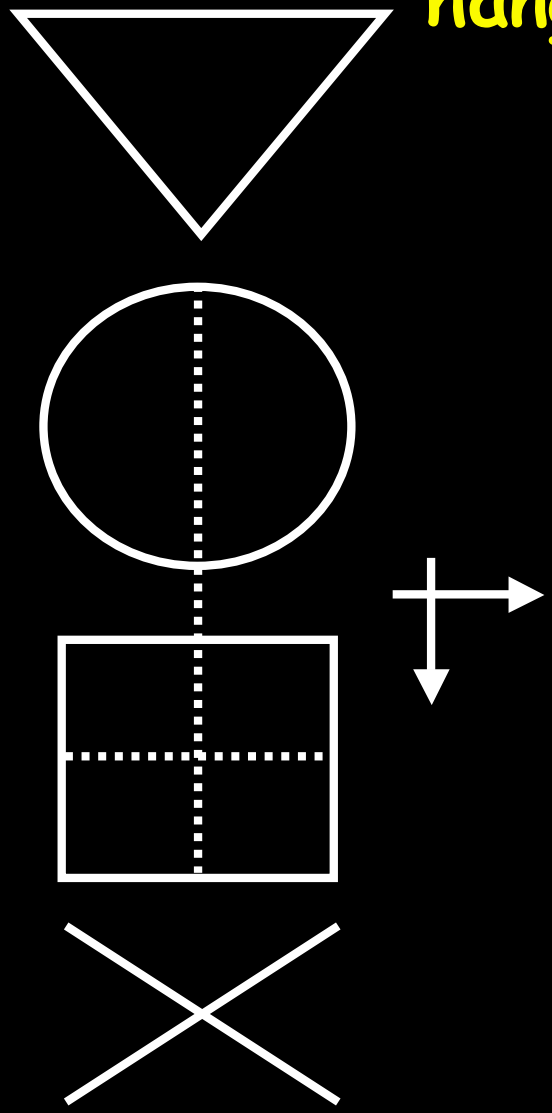
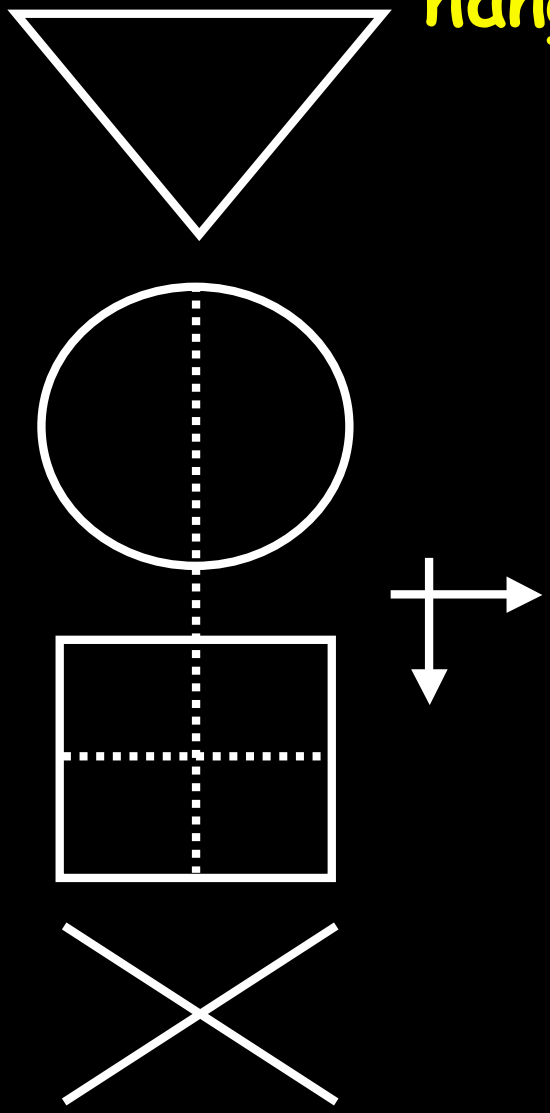


there is only one study design:

- RCT - interventions
- Cohort studies - prognosis / interv./ aetiology

GATE: Graphic Appraisal Tool for Epidemiology

The GATE Approach: every epidemiological study hangs on the GATE frame

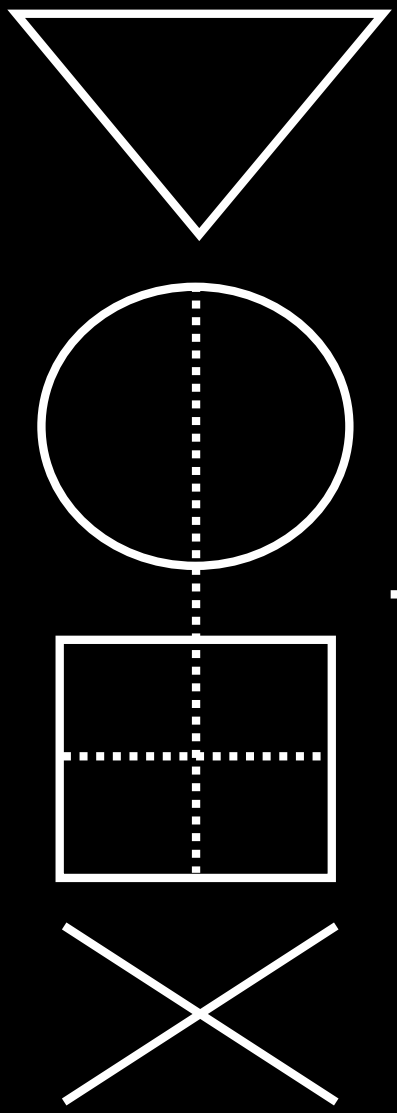


there is only one study design:

- RCT - interventions
- Cohort studies - prognosis / interv./ aetiology
- Cross-sectional studies - diagnosis

GATE: Graphic Appraisal Tool for Epidemiology

The GATE Approach: every epidemiological study hangs on the GATE frame

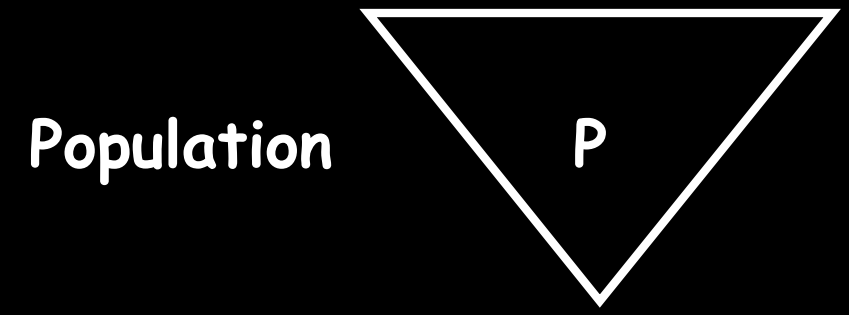


there is only one study design:

- RCT - interventions
- Cohort studies - prognosis / interv./ aetiology
- Cross-sectional studies - diagnosis
- Case-control studies - interv./aetiol.

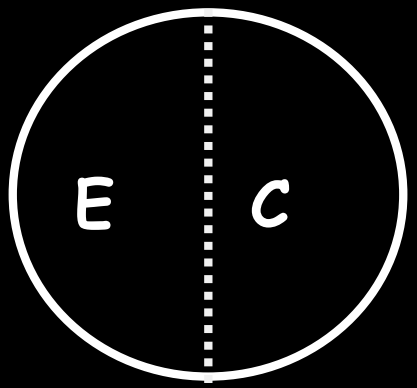
GATE: Graphic Appraisal Tool for Epidemiology

Cohort (Follow-up) study: archetypal epidemiological study



Population

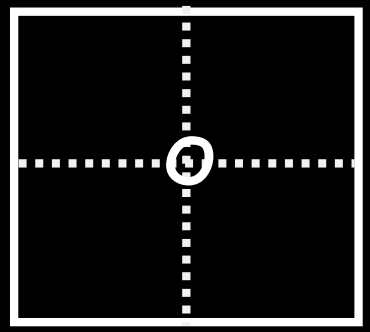
cohort



Exposure

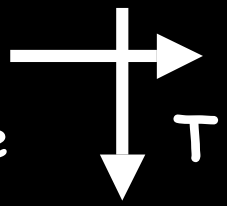
Comparison

non-randomised allocation

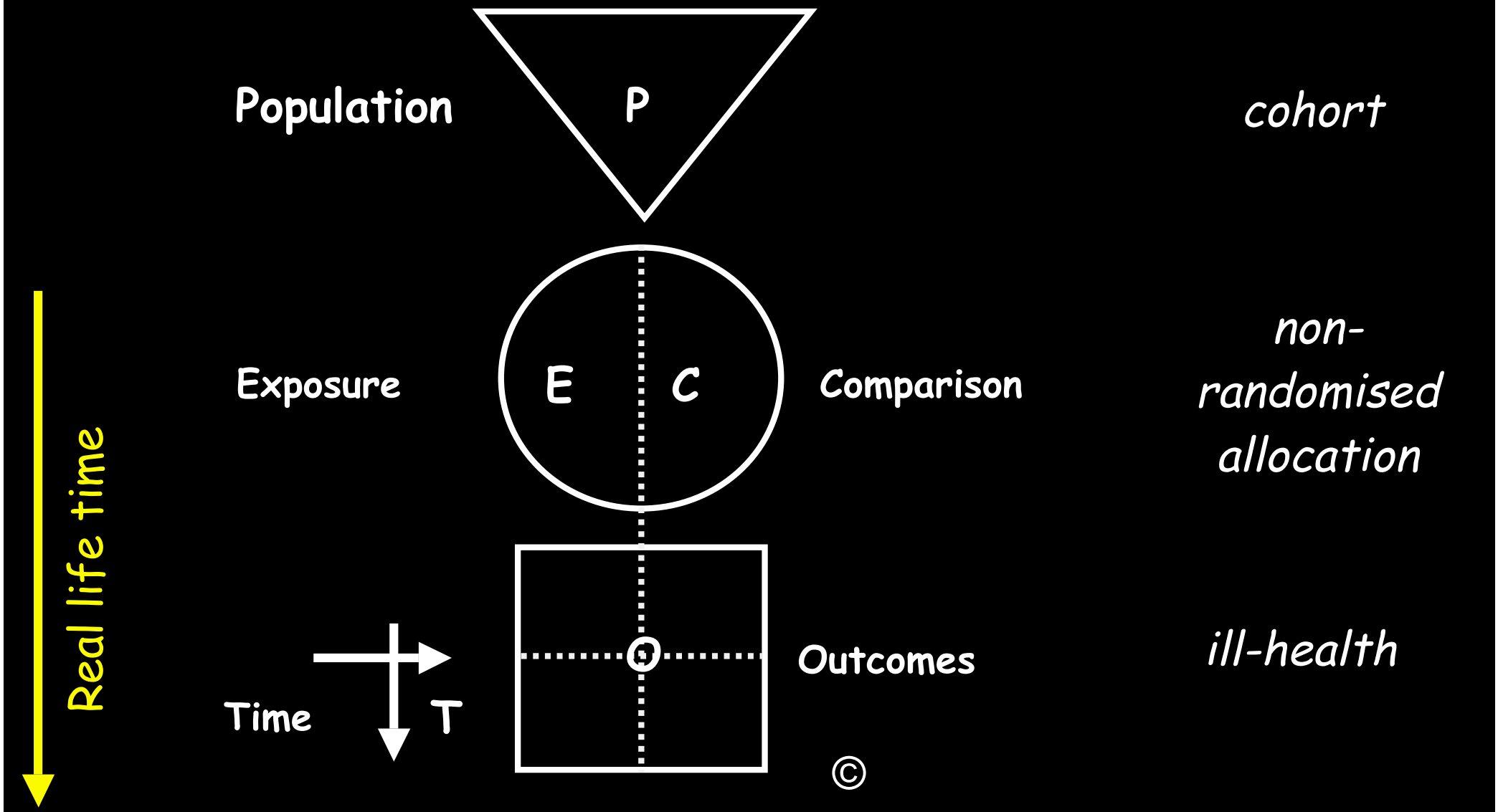


Outcomes

ill-health

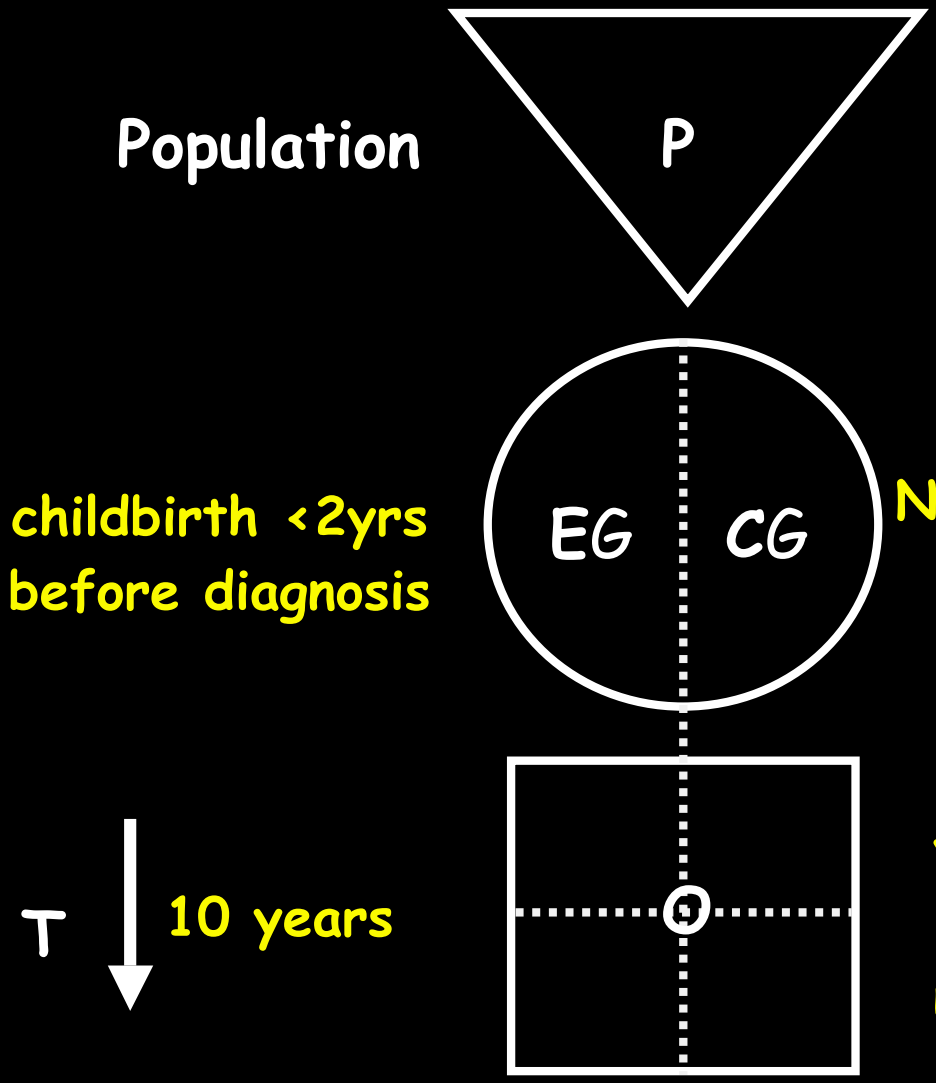


Cohort (Follow-up) study: archetypal epidemiological study



"Life" is a cohort study: a "natural experiment"

Cohort study (prognosis): Danish Breast Cancer Cooperative

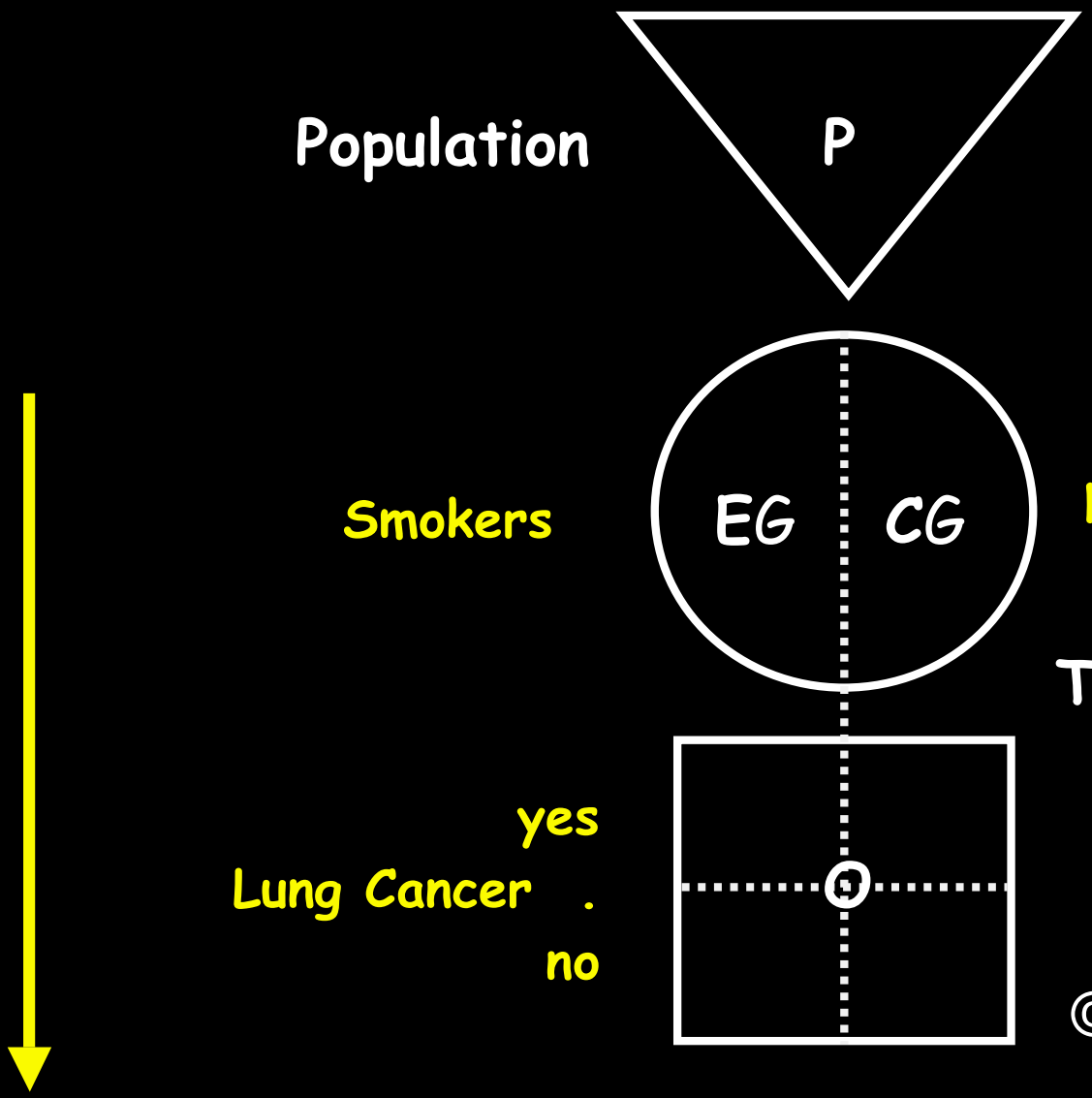


Cohort of women diagnosed with breast cancer

Non-randomised allocation to prognostic groups

Kroman et al. BMJ 1997;315:851-5

Cohort study (aetiology): British Doctors Study

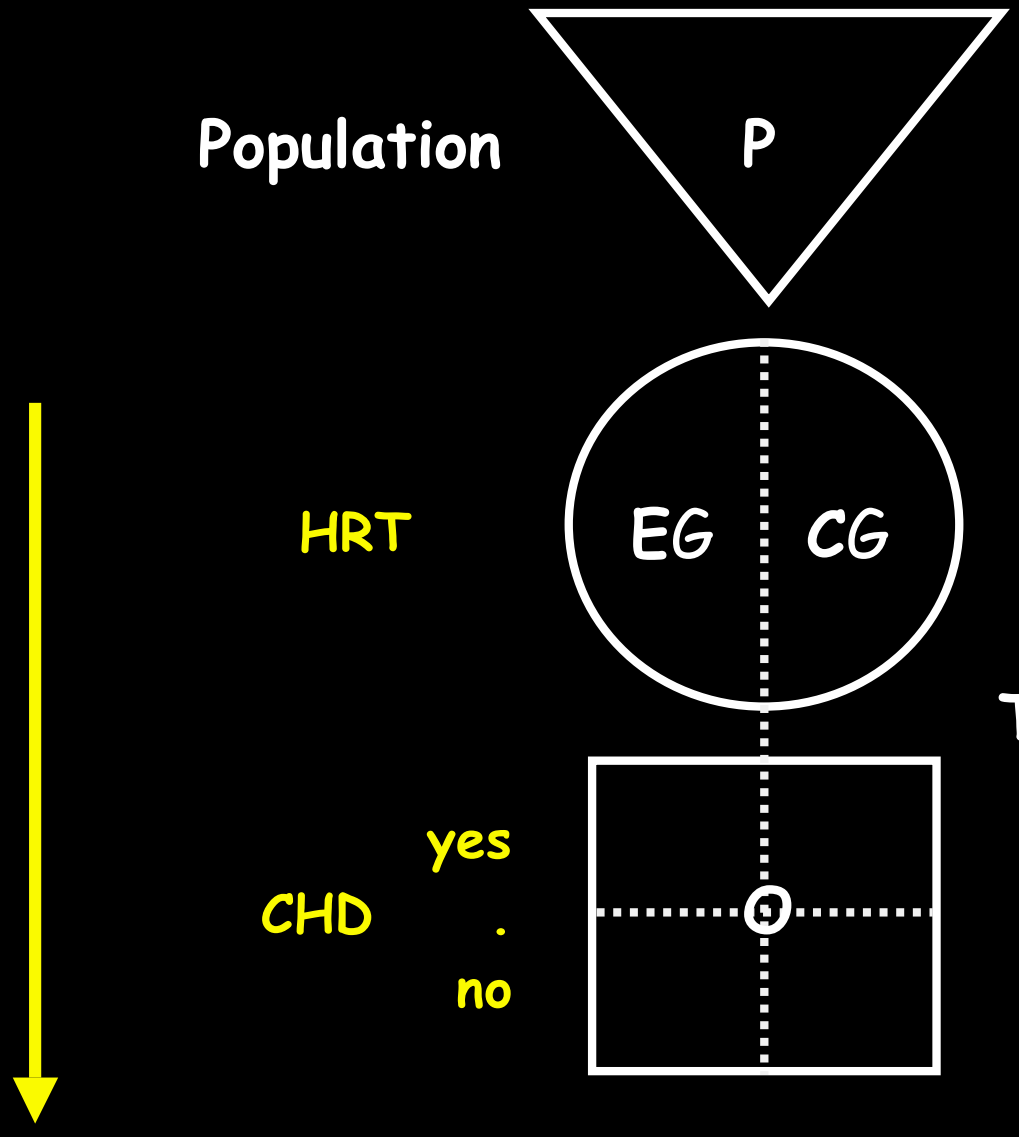


Cohort of British Doctors established in 1951

Non-randomised allocation (self-reported smoking)

Doll et al. BMJ 2004;328:1519

Cohort study (intervention): Nurses Health Study

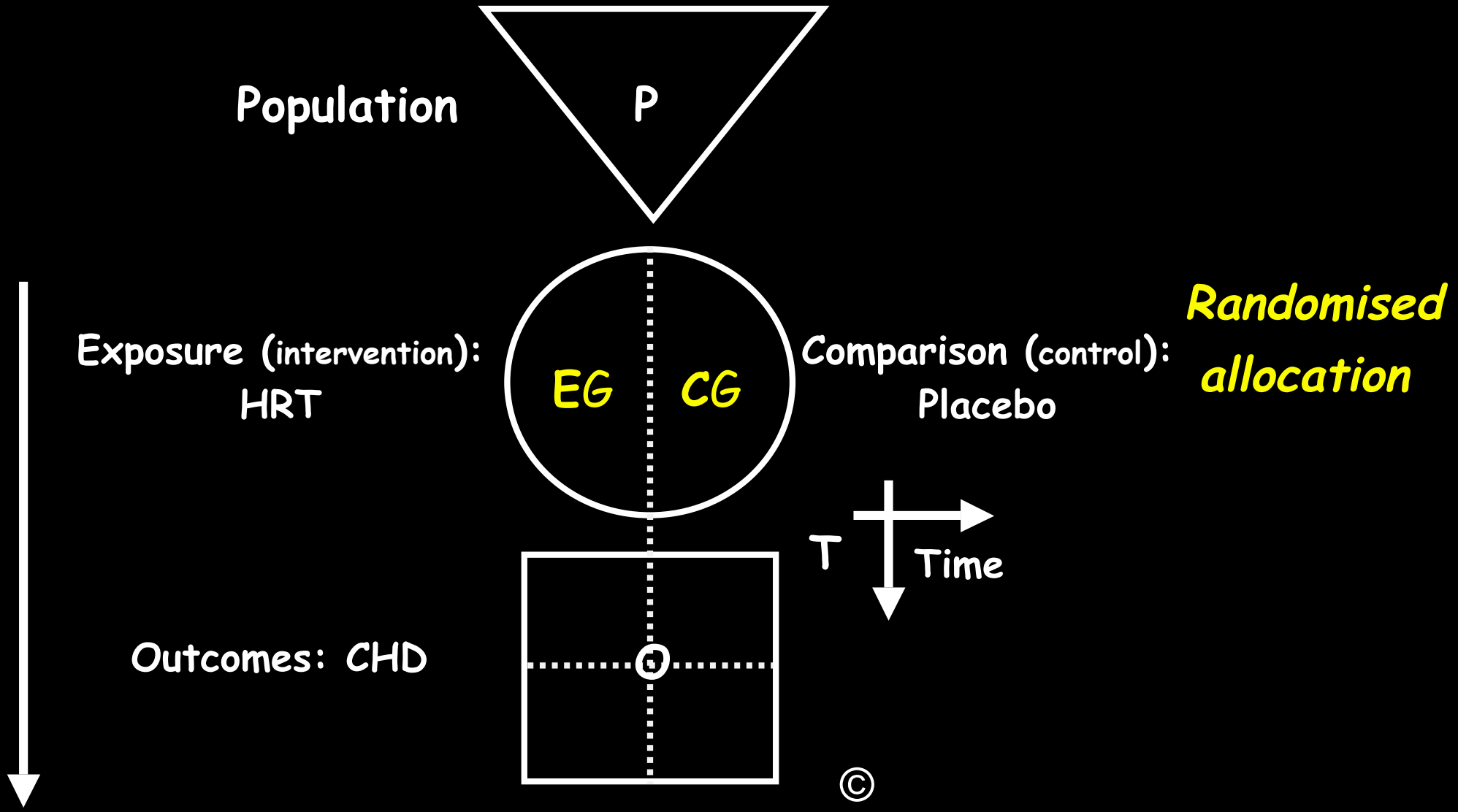


Cohort of US Nurses

Non-randomised allocation (self-reported use)

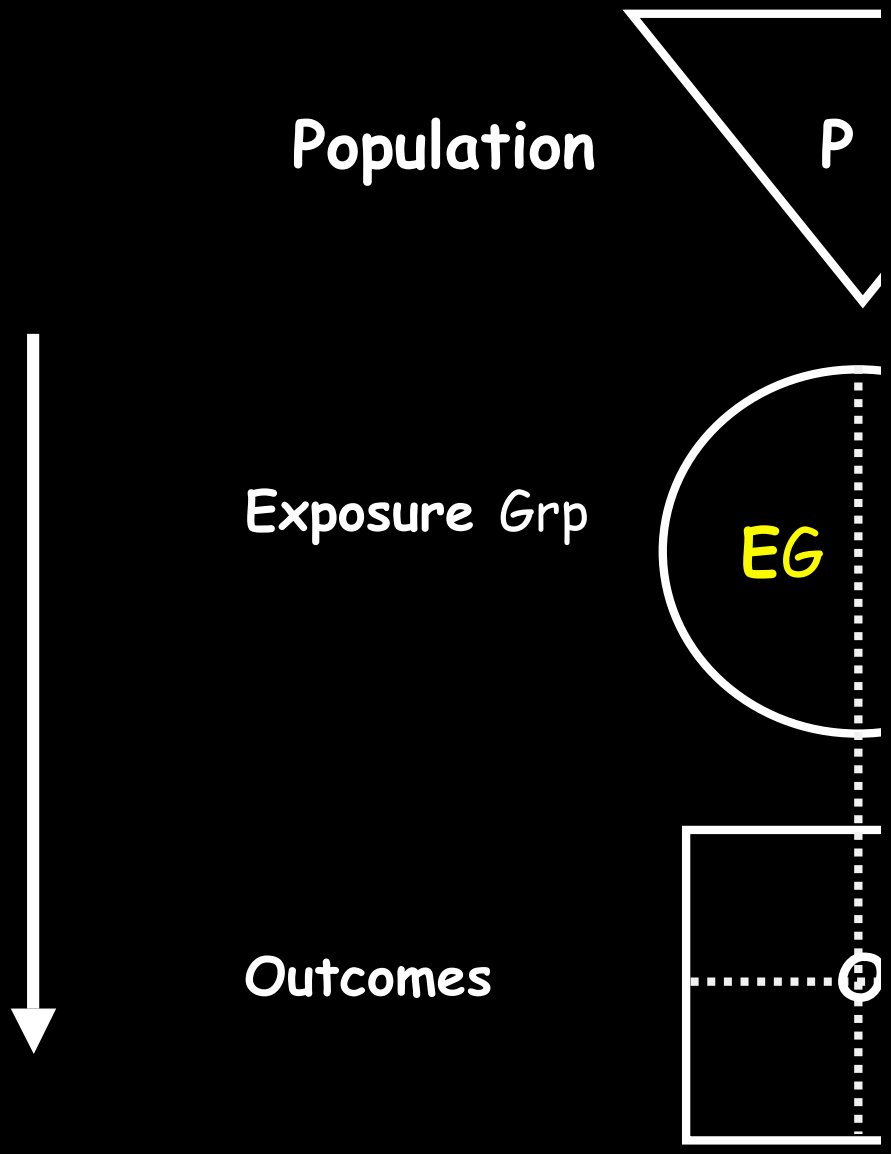
Stampfer et al. NEJM 1991;325:756-62

Randomised Controlled Trial (RCT): HERS

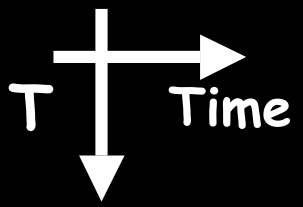


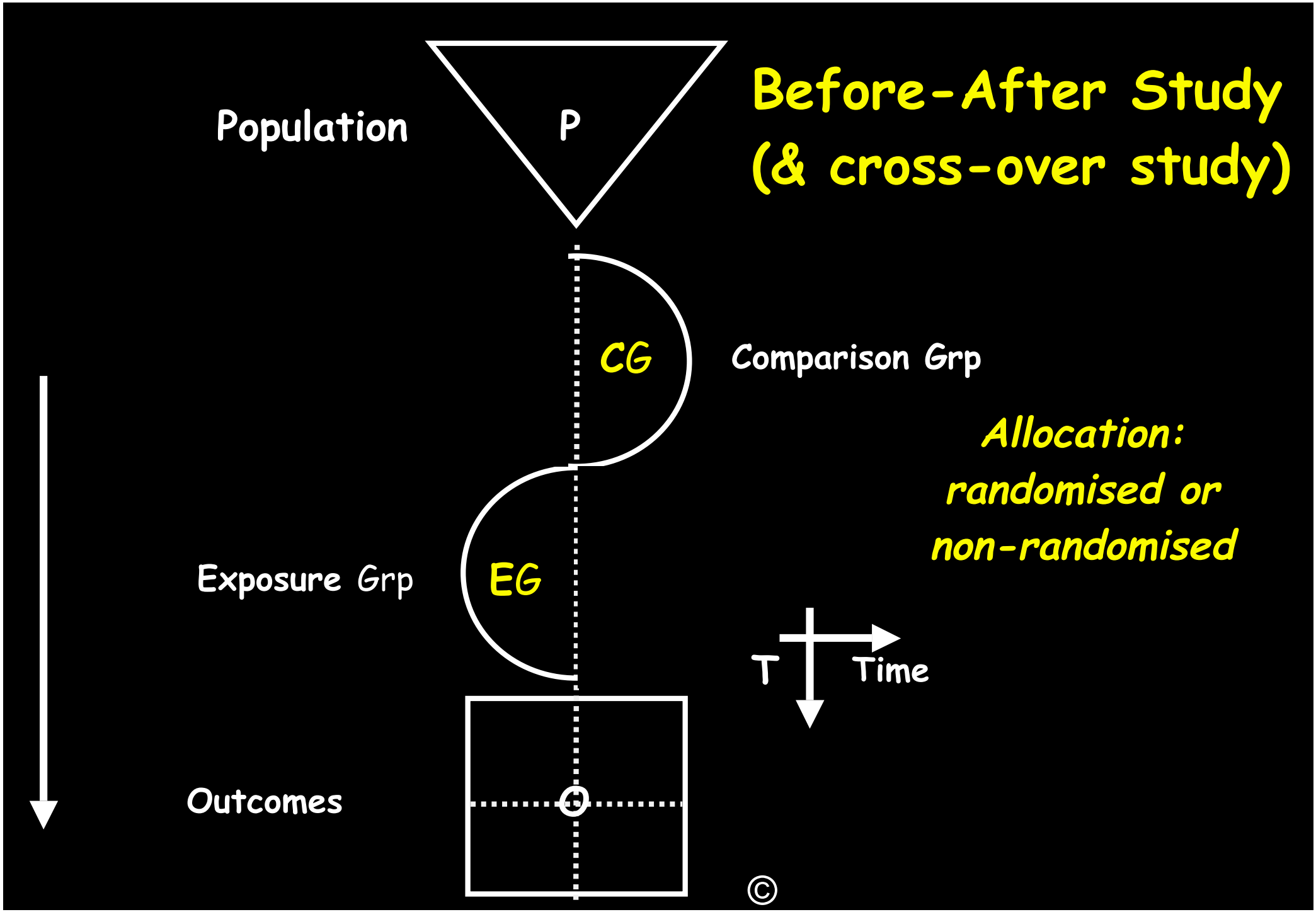
Hulley et al. JAMA1998;280:605-13

Case series

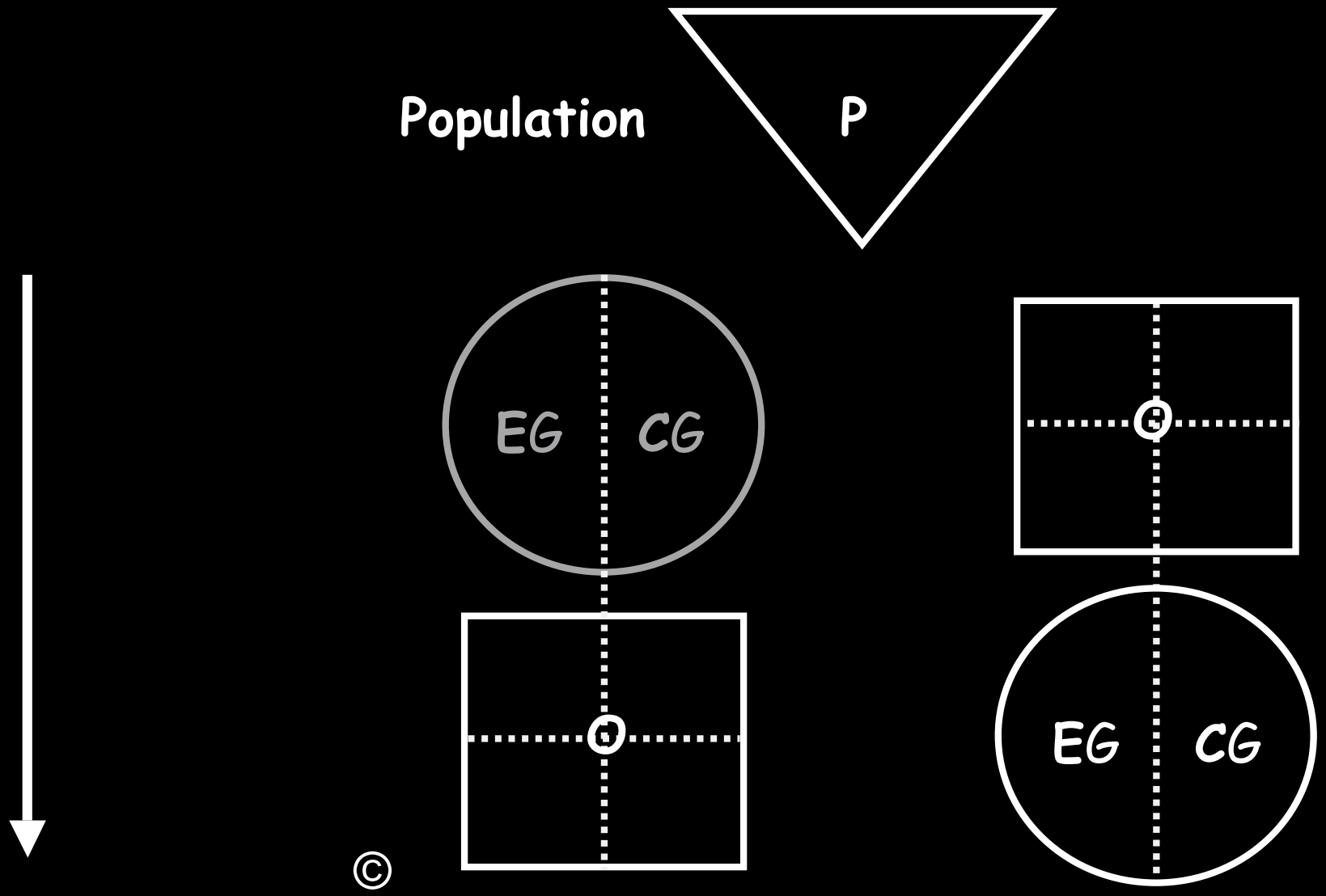


No one allocated to Comparison Group

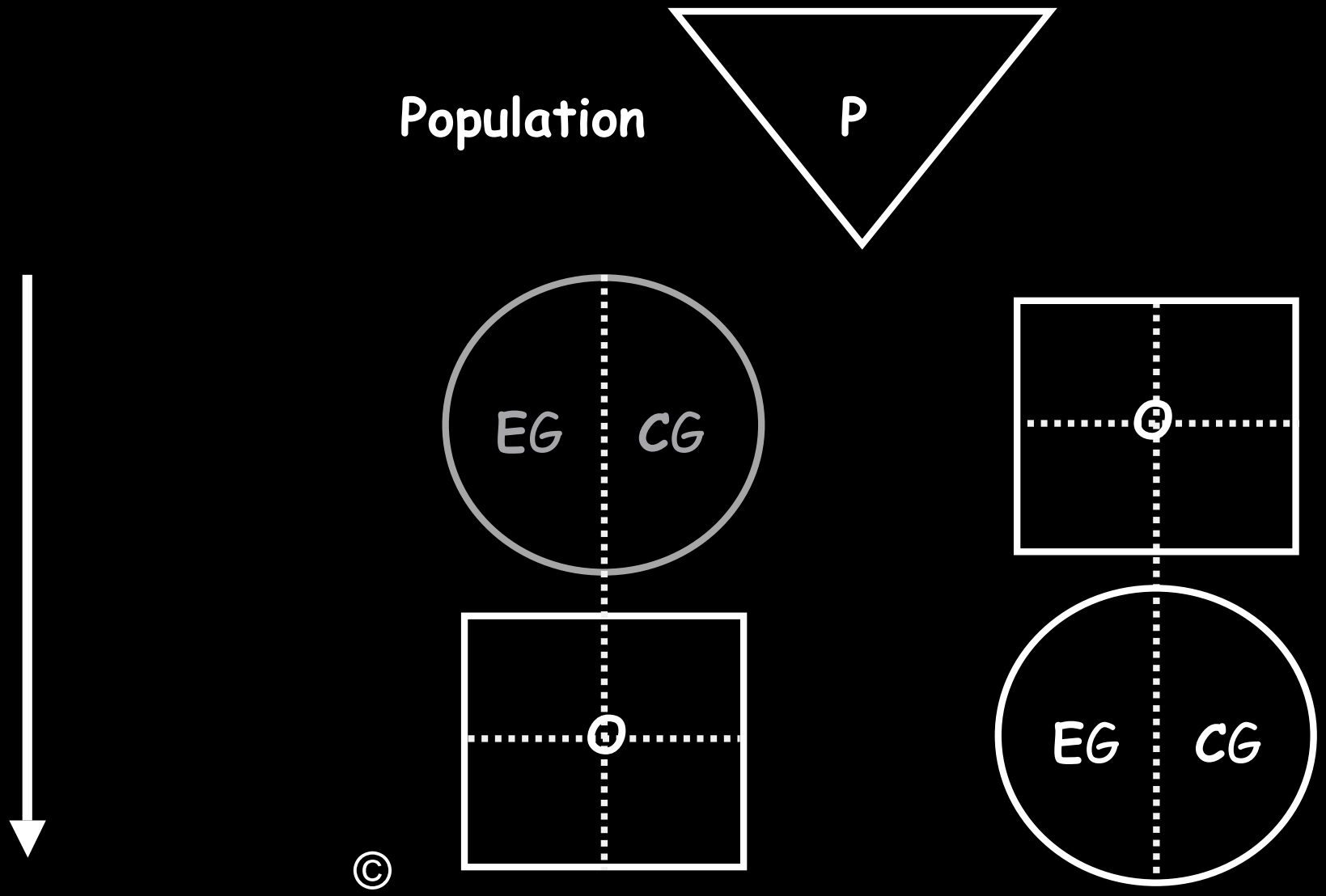



Population
P
Before-After Study
(& cross-over study)
CG
Comparison Grp
Allocation:
randomised or
non-randomised
Exposure Grp
EG
T
Time
Outcomes
O
©

Cross-sectional (prevalence) study/survey: PECO

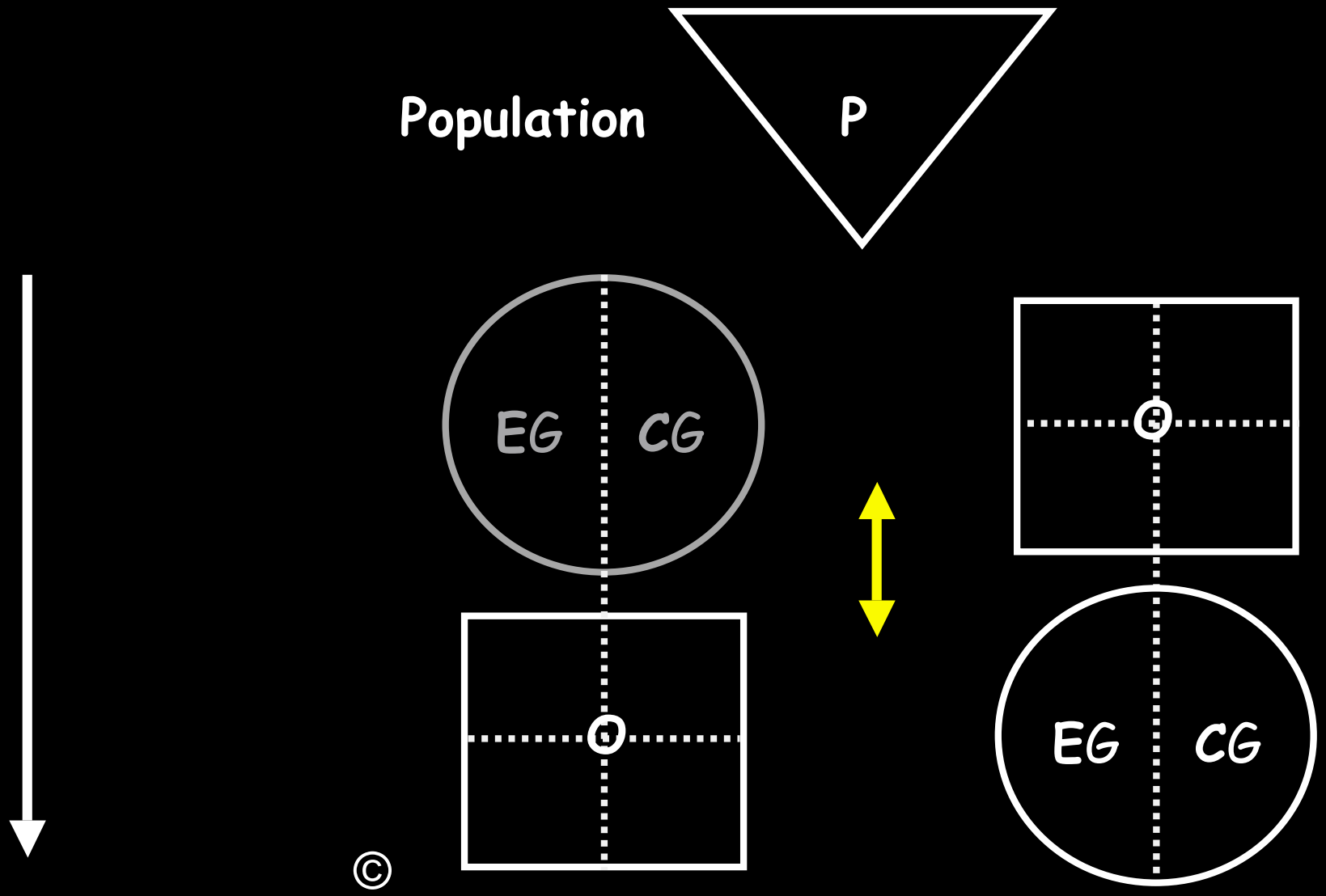


Cross-sectional (prevalence) study/survey: PECO



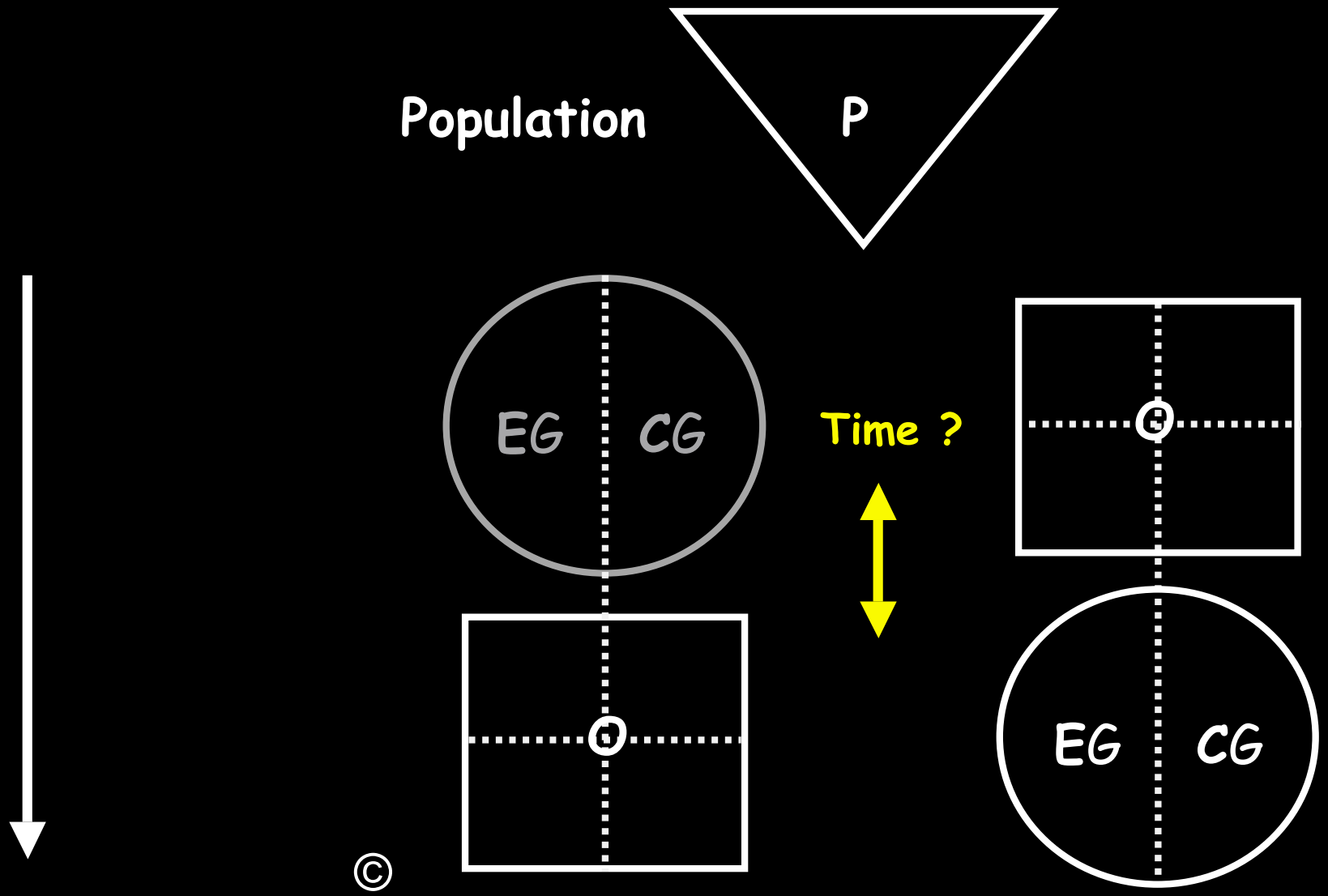
E/C assignment & Outcomes assessed in cohort at same Time

Cross-sectional (prevalence) study/survey: PECO



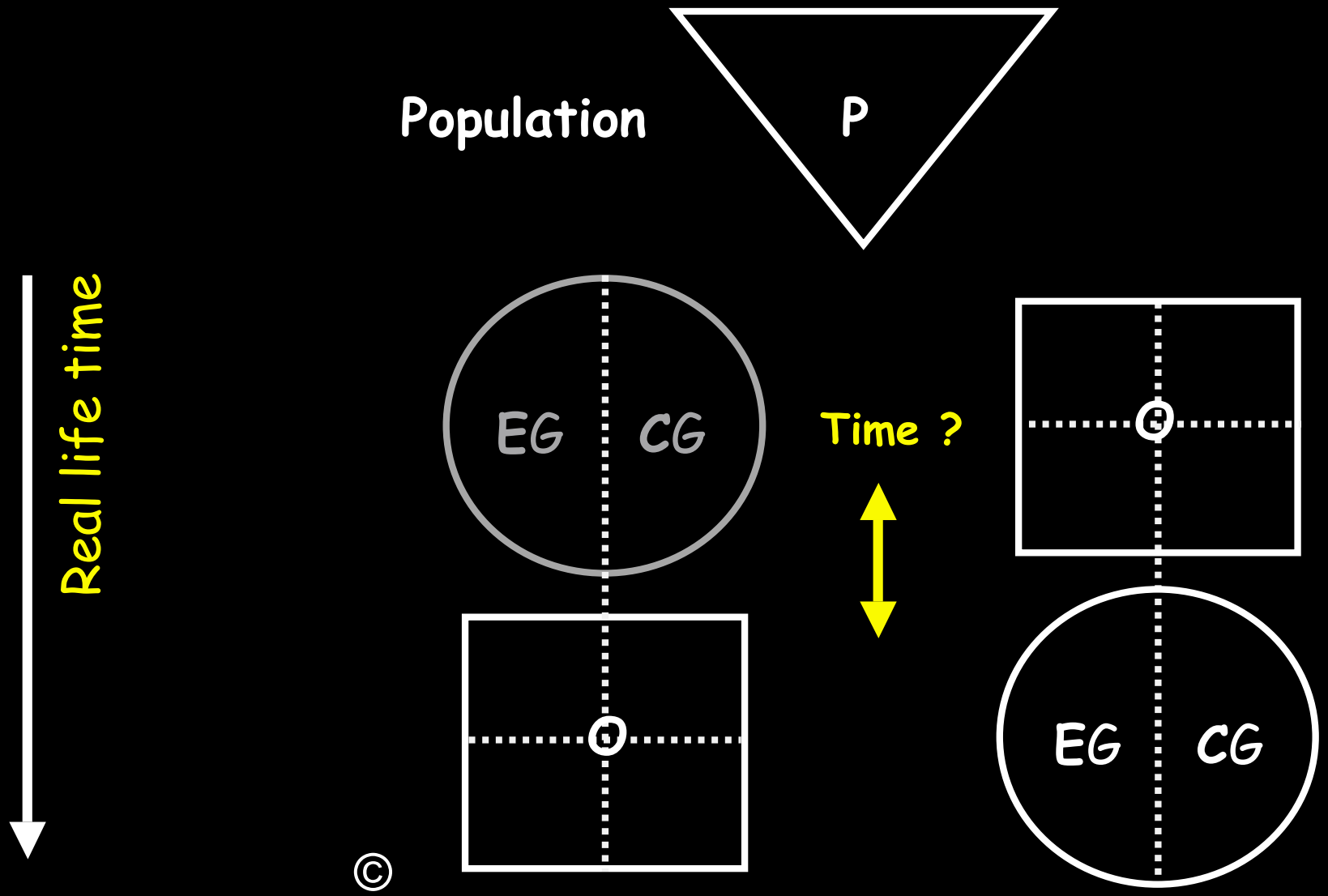
E/C assignment & Outcomes assessed in cohort at same Time

Cross-sectional (prevalence) study/survey: PECO



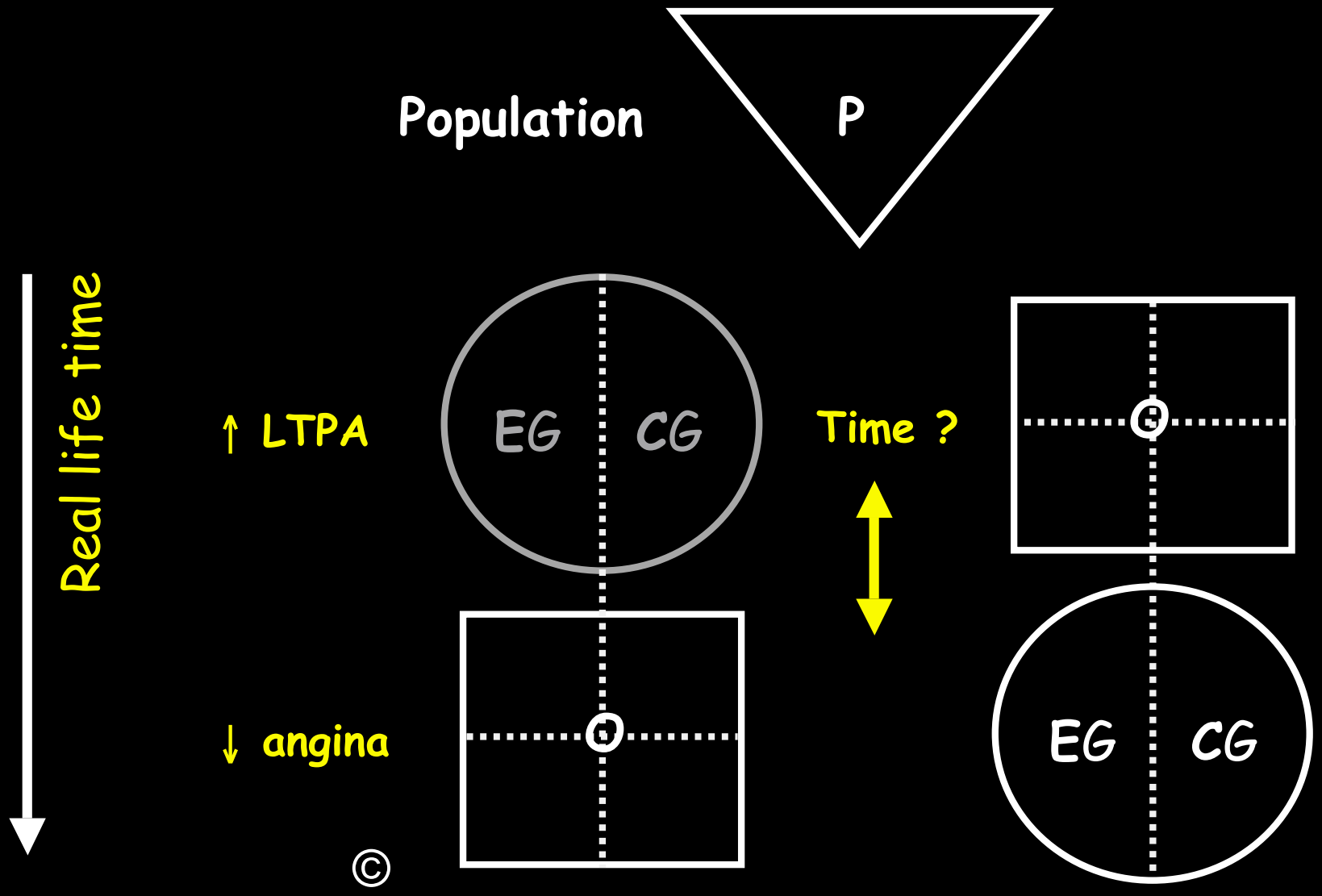
E/C assignment & Outcomes assessed in cohort at same Time

Cross-sectional (prevalence) study/survey: PECO



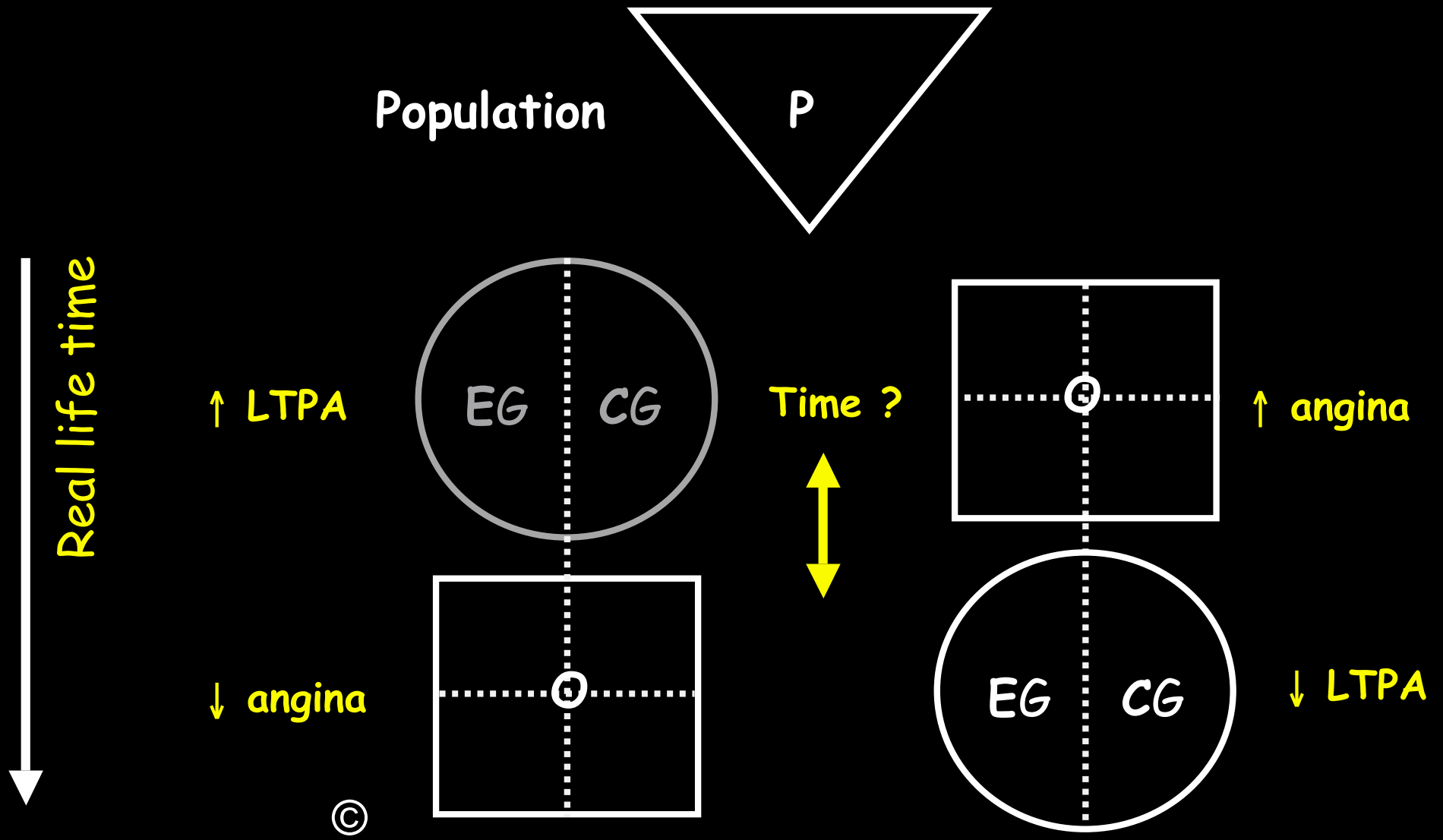
E/C assignment & Outcomes assessed in cohort at same Time

Cross-sectional (prevalence) study/survey: PECO



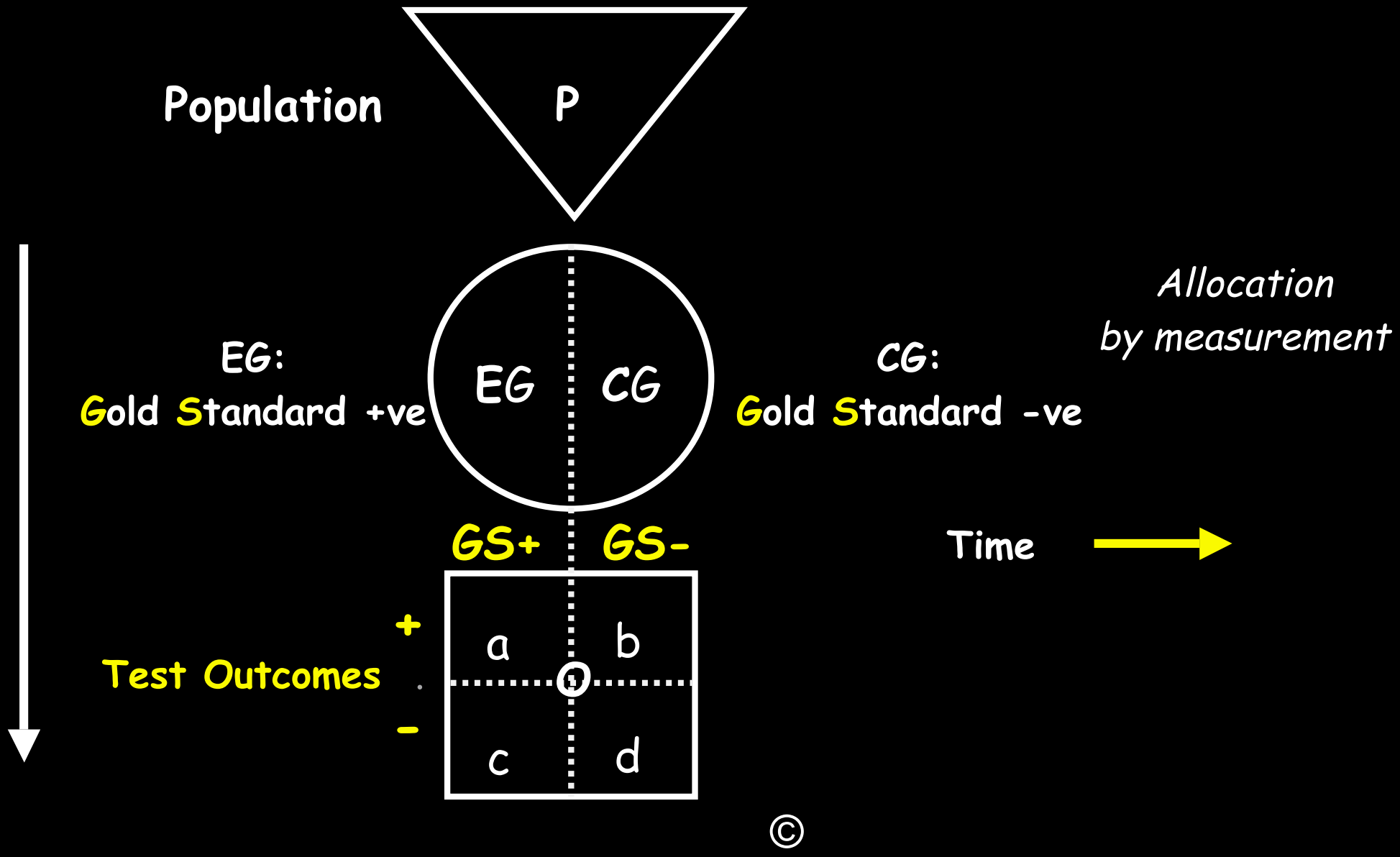
E/C assignment & Outcomes assessed in cohort at same Time

Cross-sectional (prevalence) study/survey: PECO

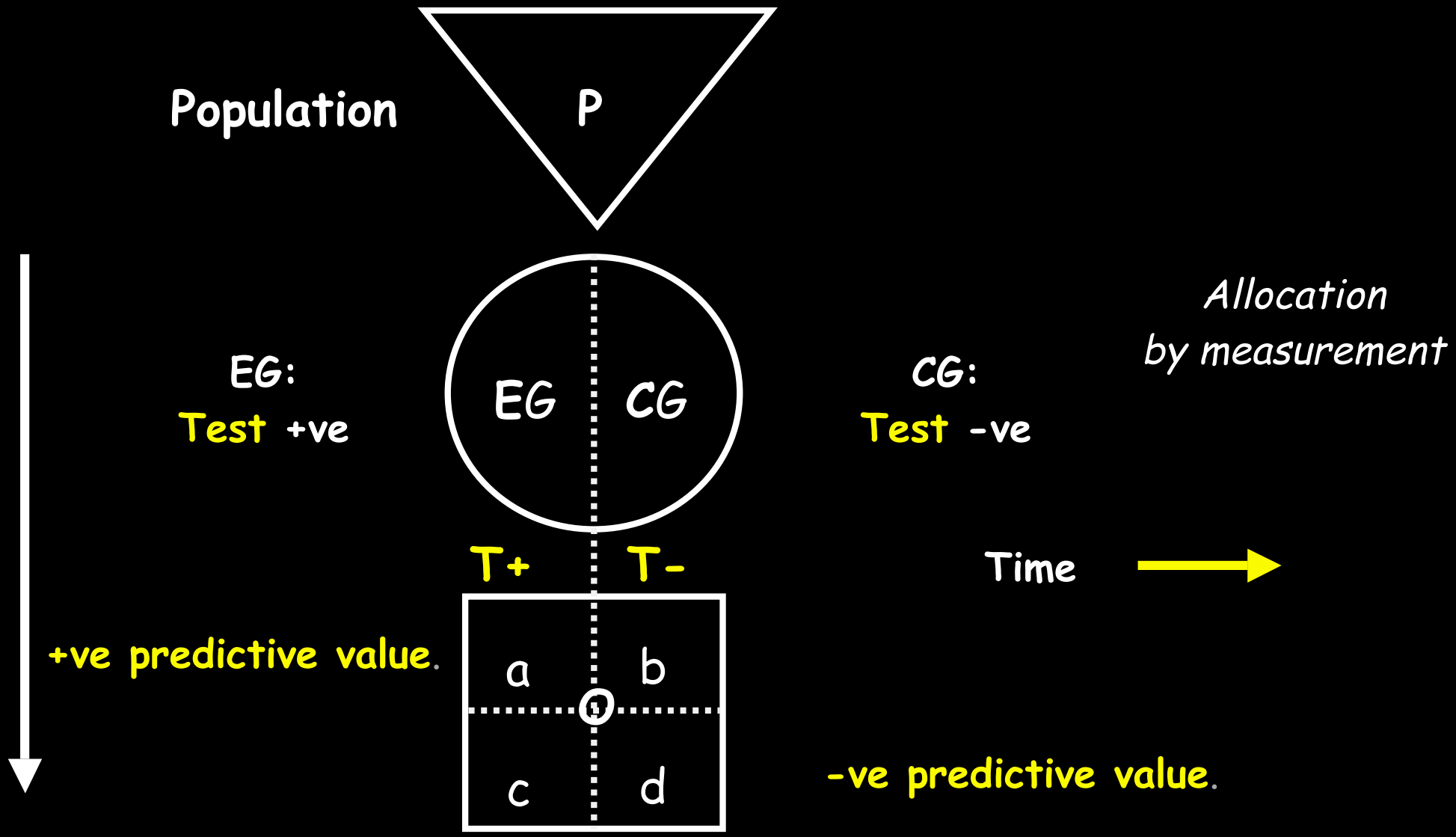


E/C assignment & Outcomes assessed in cohort at same Time

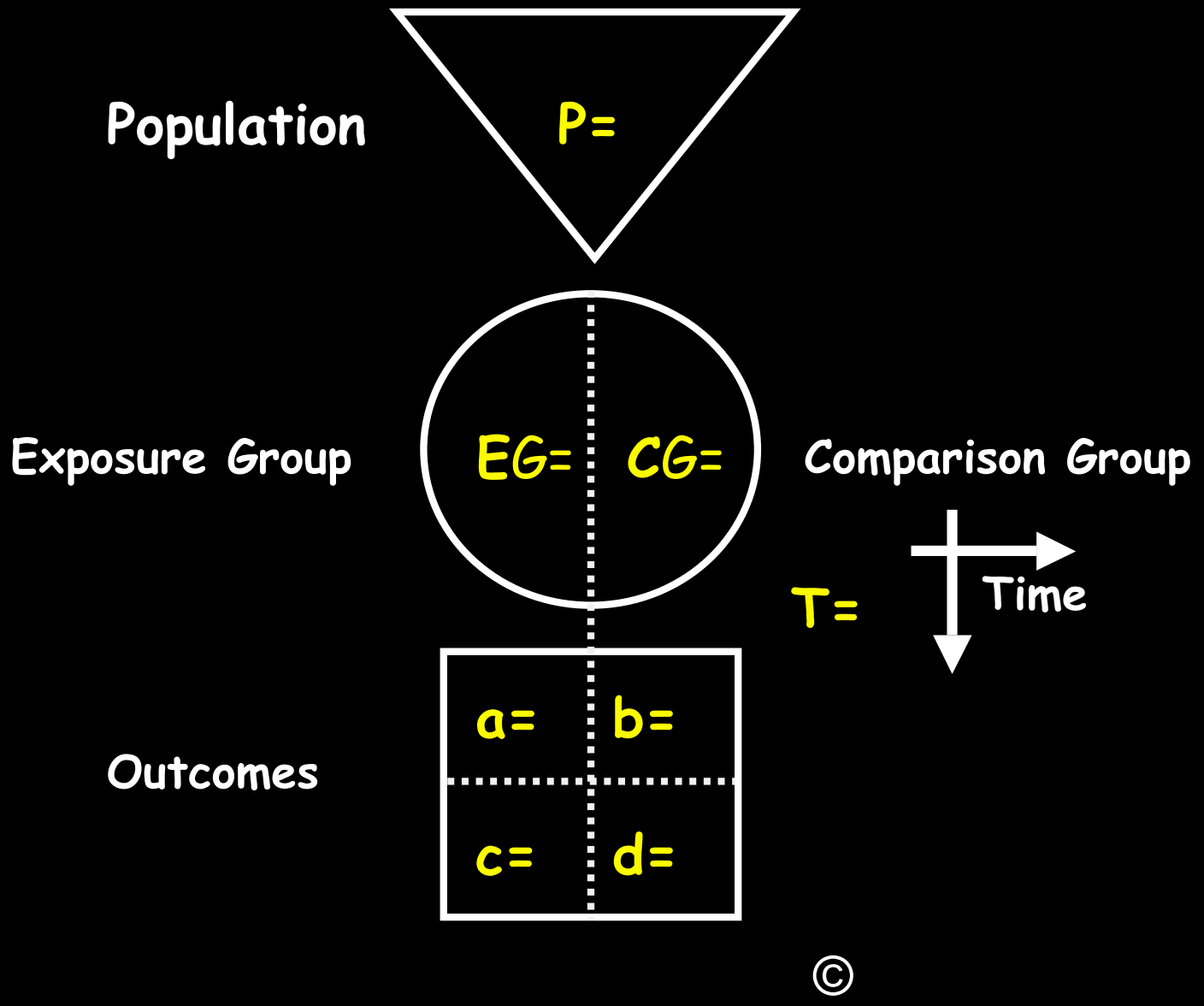
Diagnostic Test Accuracy Study (cross-sectional)



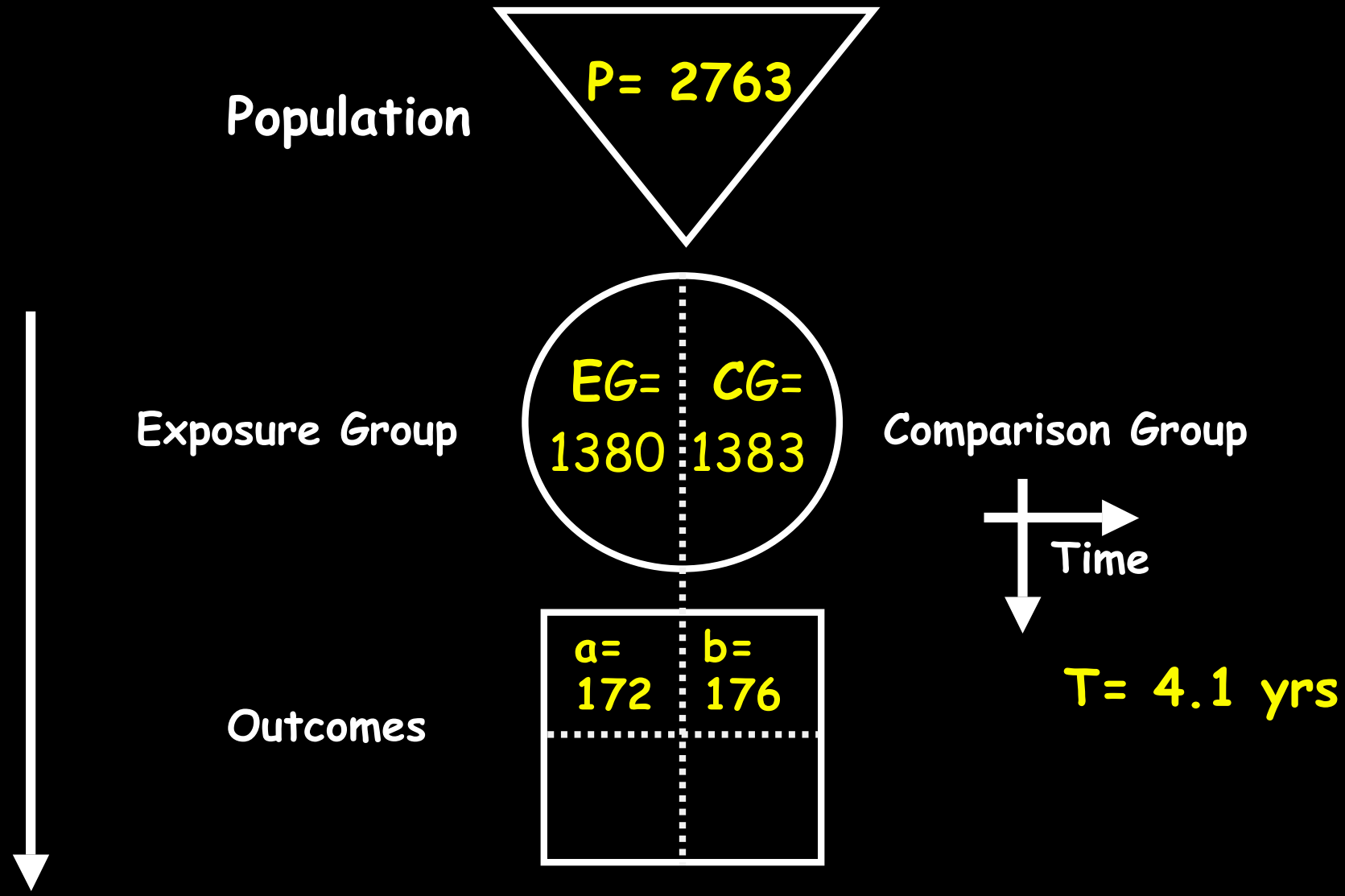
Diagnostic Test Study Application (cross-sectional)



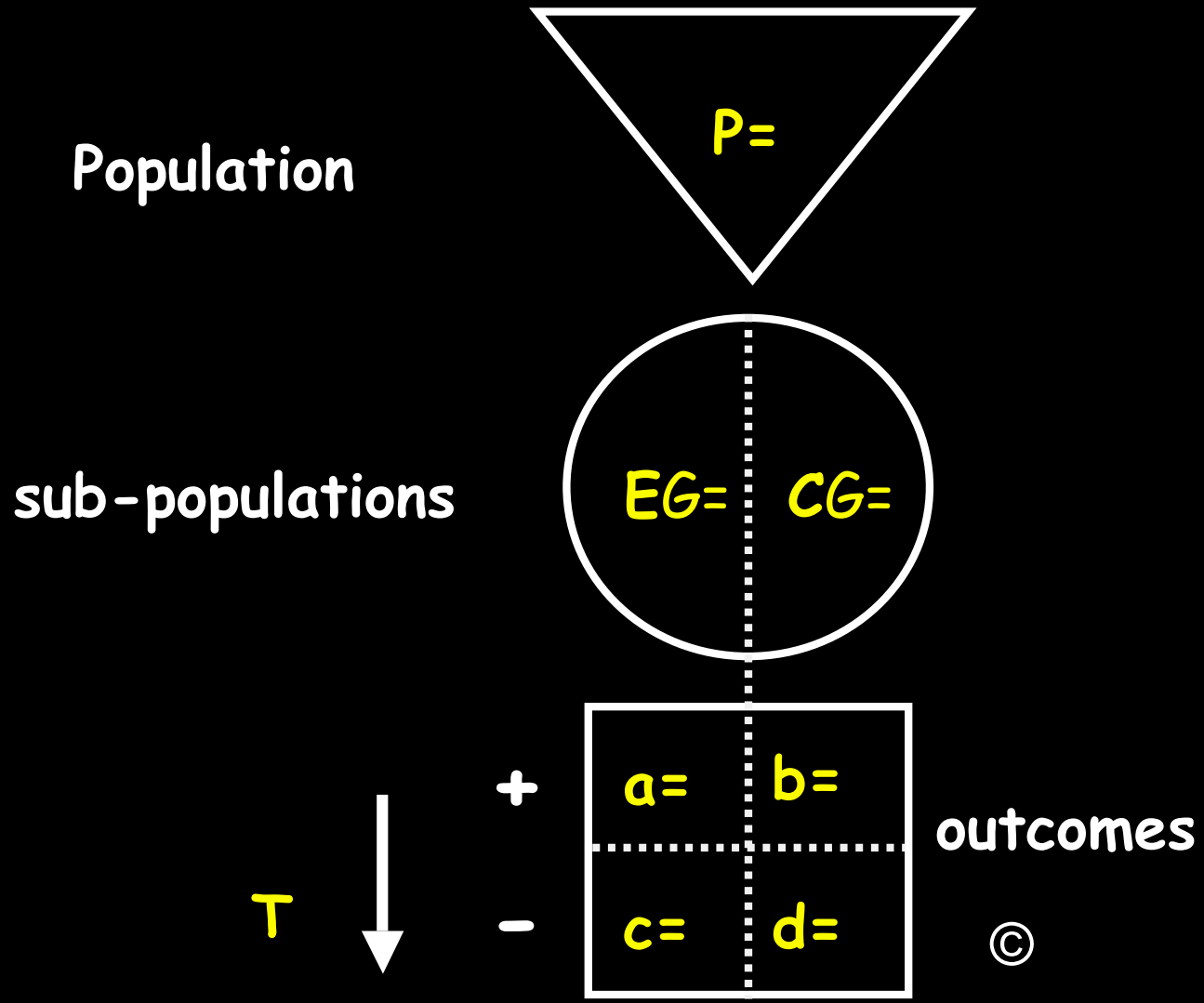
GATE: the NUMBERS



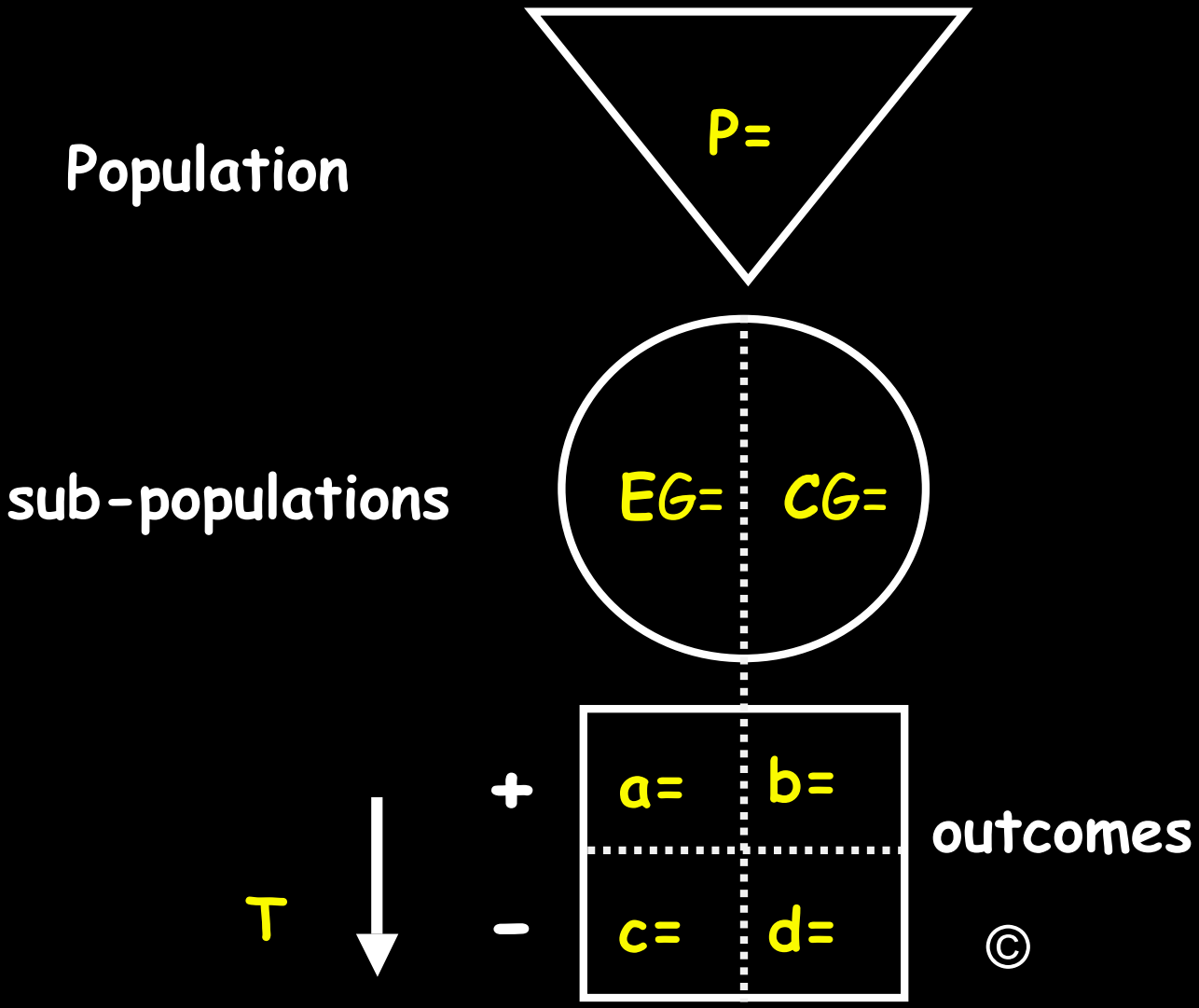
GATE: the numbers = HERS



Occurrence = outcome / population

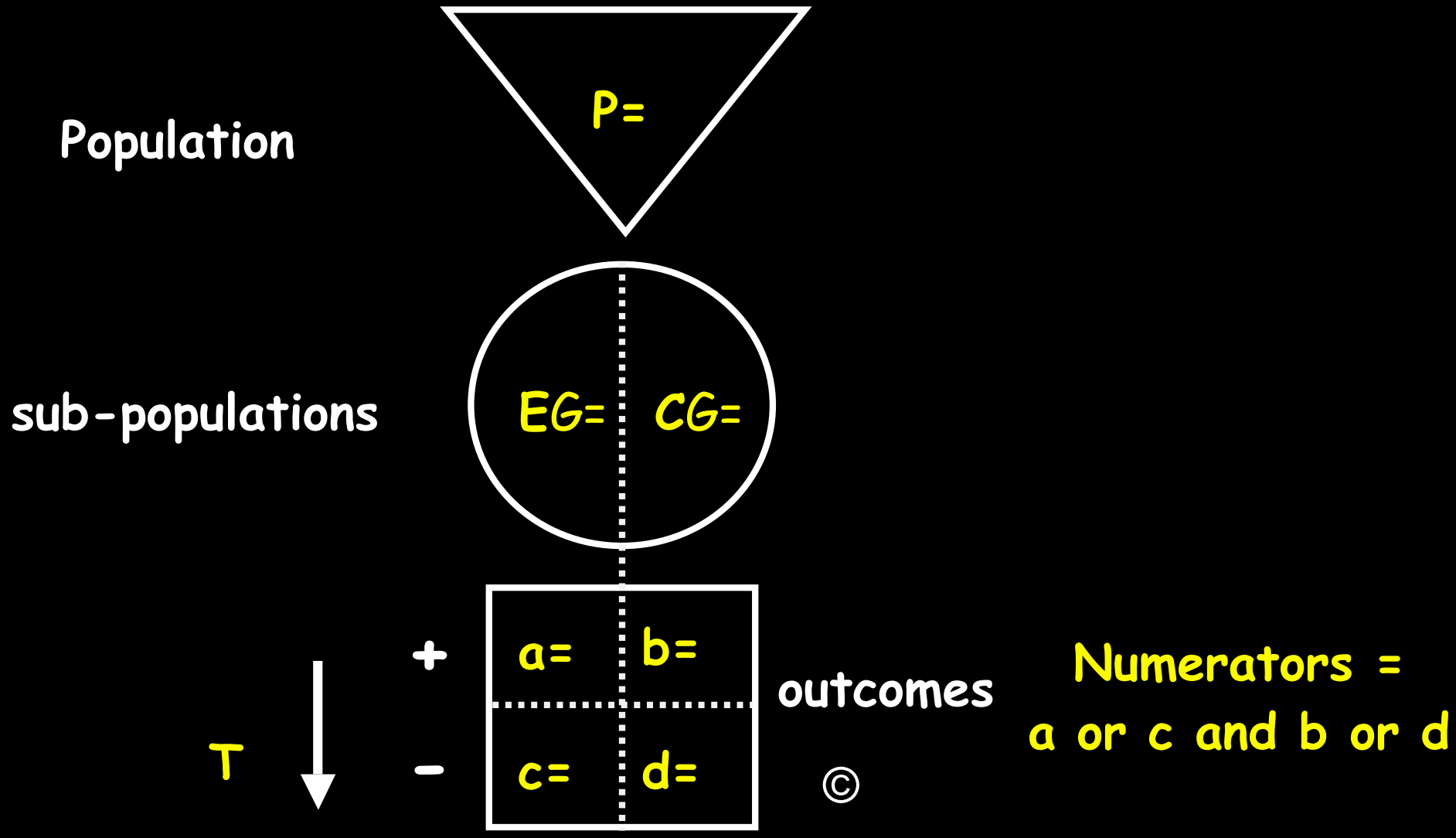


Occurrence = outcome / population



Epidemiology = numerator / denominator (E=N/D)

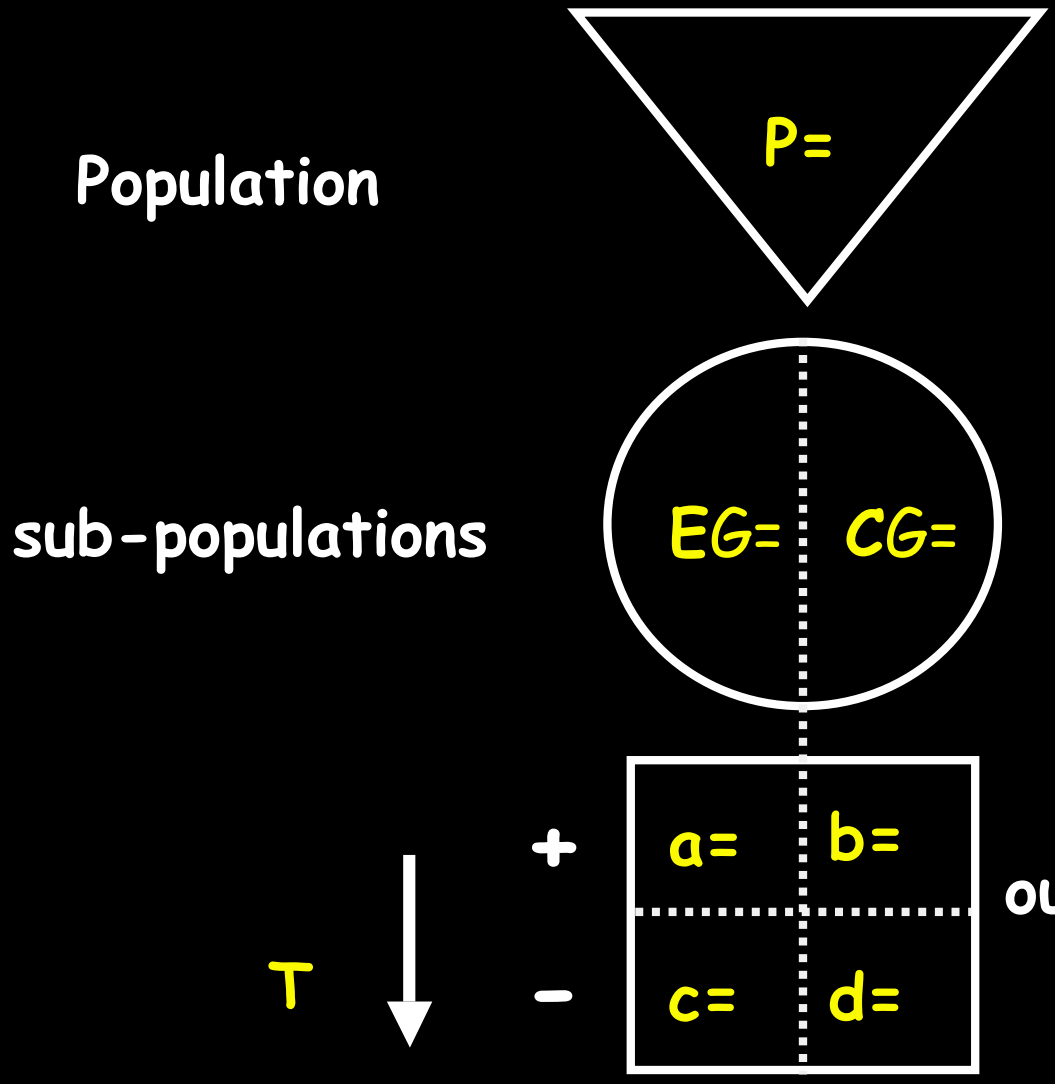
Occurrence = outcome / population



Numerators =
a or c and b or d

Epidemiology = numerator / denominator (E=N/D)

Occurrence = outcome / population

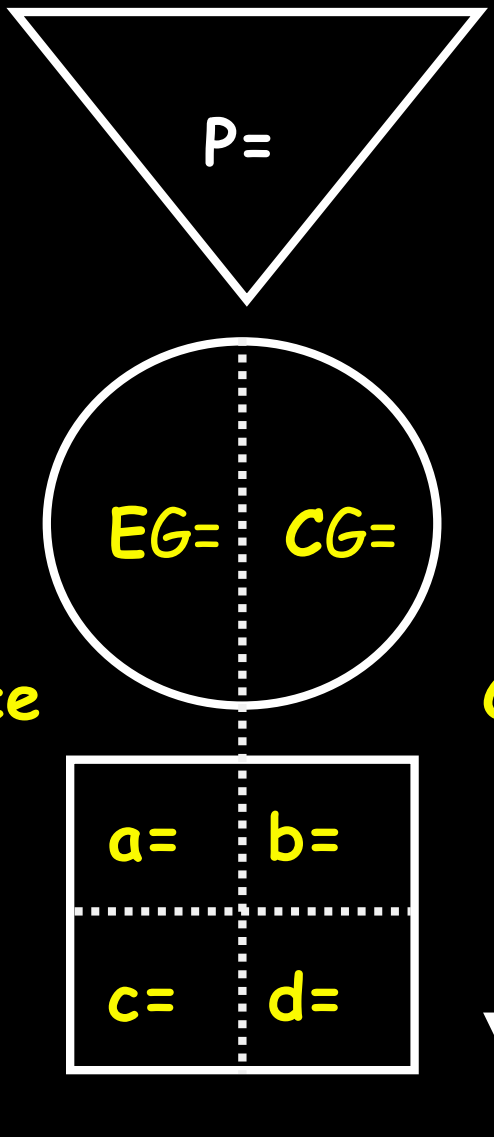


Denominators =
EG (x T) and CG (x T)

Numerators =
a or c and b or d

Epidemiology = numerator / denominator (E=N/D)

GATE: occurrence = numerator / denominator



Exp. Group Occurrence
EGO = a / EG x T

Comp. Group Occurrence
CGO = b / CG x T

GATE: occurrence HERS

Exp. Group Occurrence

EGO = A / EGxT

= 172/1380 x 4.1

= 30.40/1000/yr

Comp. Group Occurrence

CGO = B / CGxT

= 176/1383 x 4.1

= 31.04/1000/yr

Intervention Studies

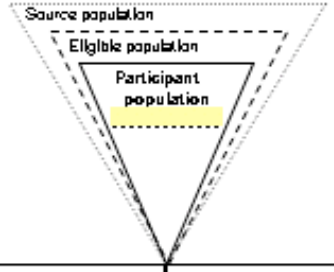
Step 3: Critically appraise the study using the PECOT framework

a. "hang" the study on the GATE (Graphic Appraisal Tool for Epidemiology) Frame

Assessed by:		Assessed when:		Publication details:	

Populations

Notes for use show to right of screen



Source Population	
Eligible Population	
Participant Population	

Exposure & Comparison

	Exposure Group (EG)	Comparison Group (CG)
Participants in each group:		
Follow-up: dropped pre-intervention:		
completed follow-up:		
lost during/post-intervention:		
Percentage lost to follow up:		

Method of assignment to groups	Randomised or non randomised
Exposure(s)	
Comparison	

Outcomes

If categorical.... what e.g. death?	a	b
participants with outcome:		
without outcome:	c	d
If continuous... what measure?		
mean:		
standard deviation:		
or . standard error:		

Outcomes: ...primary	
...secondary	
...adverse	

Time

Unit of time (e.g. year) If rate wanted:		
If rate wanted, enter average length of follow-up. If a proportion, enter 1.0:	1.00	1.00
Report results per (e.g. per 100):	persons	

Time	

Calculated in GATE frame

Results (unadjusted) with 95 % confidence intervals

	Occurrence per 1 persons		Intervention effects per 1 persons		Number needed to treat (NNT) In 1 person-
	In exposure group (EGO)	In comparison group (CGO)	Relative effect (EGO/CGO)	Absolute effect (EGO-CGO)	
Categorical outcome: Intention to treat analyses?	0.00	0.00	0.00	0.00	0
95% CIs			0.00 0.00	0.00 0.00	0 0
Categorical outcome: On-treatment analyses?	0.00	0.00	0.00	0.00	0
95% CIs			0.00 0.00	0.00 0.00	0 0
Continuous outcome: Analysis of means?	0.00	0.00	0.00	0.00	
95% CIs					

Key outcome & analysis method.

Occurrence

EGO = Exposure Group Occurrence (A/[EGxT])

CGO = Comparison Group Occurrence (B/[CGxT]

Occurrence

EGO = Exposure Group Occurrence (A/[EGxT])

= 30.40 / 1000 persons / year

CGO = Comparison Group Occurrence (B/[CGxT]

Occurrence

EGO = Exposure Group Occurrence (A/[EGxT])

= 30.40 / 1000 persons / year

CGO = Comparison Group Occurrence (B/[CGxT]

= 30.40 / 1000 persons / year

Effects: comparing occurrences

Relative Effect/Risk (RR) $= \frac{EGO}{CGO}$

e.g. relative risk, risk ratio, prevalence ratio, incidence ratio

Absolute Effect/Risk Difference (RD) = EGO - CGO

e.g. risk difference, absolute risk

Effects: comparing occurrences

Relative Effect/Risk (RR) $= \frac{EGO}{CGO}$

e.g. relative risk, risk ratio, prevalence ratio, incidence ratio

Absolute Effect/Risk Difference (RD) = EGO - CGO

e.g. risk difference, absolute risk

Number Needed to Treat (NNT) to prevent/cause 1 event = 1/RD

R

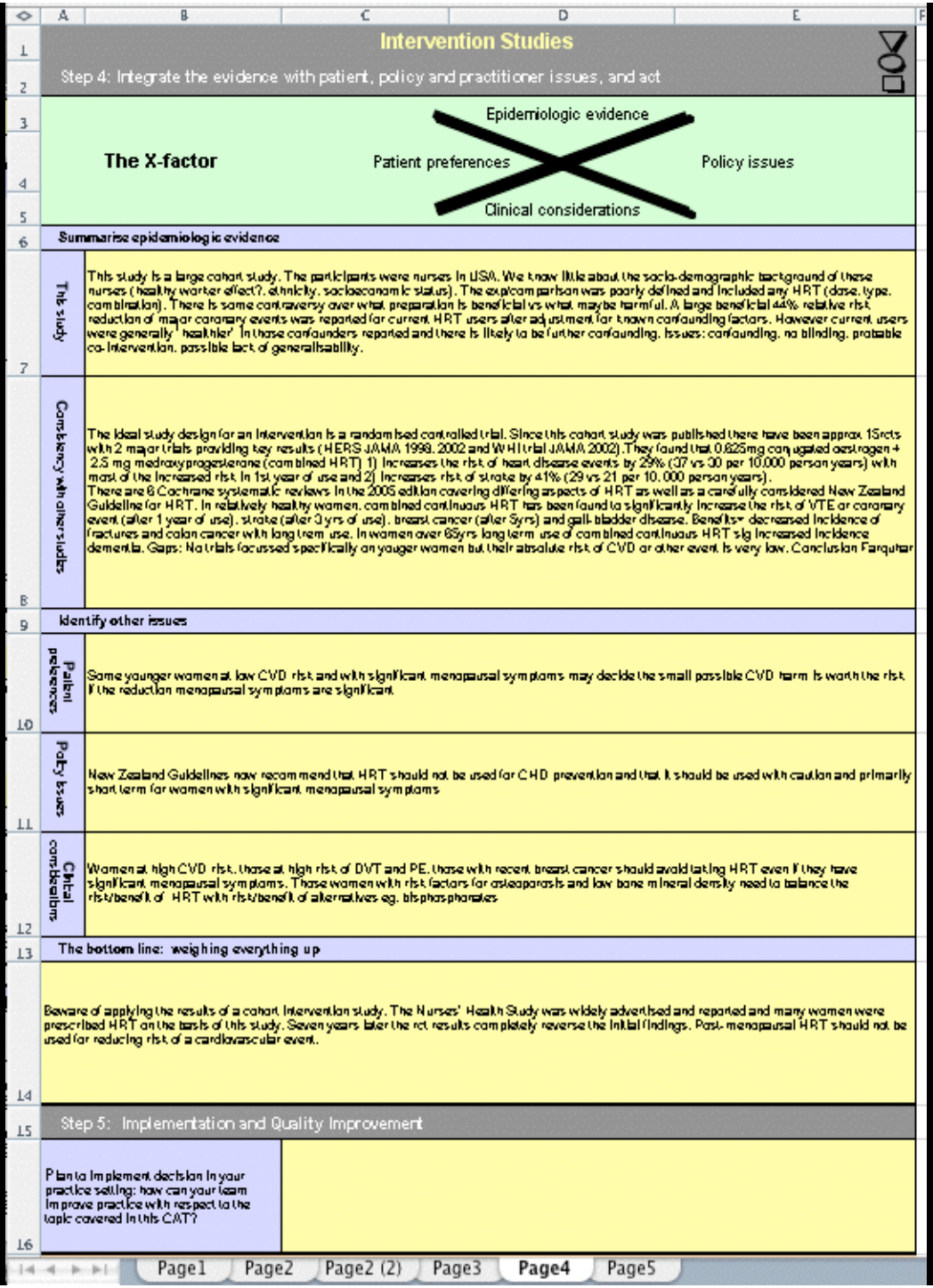
A

A

Mbo

	Evaluation criteria (RAMM)	Quality + ~ x nr na	
Populations	well Represented?		
	Source population well described?		
	Eligible population well described?		
	Participants representative of eligibles?		
	Were relevant prognostic indicators in participants reported?		
Exposure & Comparison	well Allocated & well Measured?		
	Exposure & comparison interventions well described & valid?		
	Allocation to exposure and comparison groups randomised?		
	Allocation concealed?		
	Exposure and comparison groups similar at baseline?		
	Participants and/or staff blind to exposure and comparison?		
	Compliance with exposure and comparison adequate?		
	Contamination acceptably low?		
	Other interventions similar in both groups?		
	All participants accounted for at study conclusion?		
	Could interventions be applied in real life?		
Outcomes	well Measured?		
	Outcome measures well described and valid?		
	Blinded outcome measurement?		
	Outcome measurement complete?		
	Were all important outcomes assessed?		
Time	Similar follow-up time in exposure & comparison groups?		
	Was follow-up time meaningful?		
Results	Intention to treat analysis?		
	Estimates of intervention effects given or calculable?		
	Precision of intervention effects given or calculable?		
	Analytical methods appropriate?		
Summary	Are the study results internally valid (i.e unbiased)?		
	Are results precise enough to be meaningful? If not, was power sufficient?		
	Can the applicability of the results (i.e external validity) be determined?		
	Overall study quality		

Step 4



Intervention Studies

Step 4: Integrate the evidence with patient, policy and practitioner issues, and act

The X-factor

Epidemiologic evidence

Patient preferences

Policy issues

Clinical considerations

Summarise epidemiologic evidence

This study

This study is a large cohort study. The participants were nurses in USA. We know little about the socio-demographic background of these nurses (healthy worker effect?, ethnicity, socioeconomic status). The exp/com parison was poorly defined and included any HRT (dose, type, combination). There is some controversy over what preparation is beneficial vs what maybe harmful. A large beneficial 44% relative risk reduction of major coronary events was reported for current HRT users after adjustment for known confounding factors. However current users were generally 'healthier' In those confounders reported and there is likely to be further confounding. Issues: confounding, no blinding, probable co-intervention, possible lack of generalisability.

Consistency with other studies

The ideal study design for an intervention is a randomised controlled trial. Since this cohort study was published there have been approx 15rcts with 2 major trials providing key results (HERS JAMA 1998, 2002 and WHI trial JAMA 2002).They found that 0.625mg conjugated oestrogen + 2.5 mg medroxyprogesterone (combined HRT) 1) Increases the risk of heart disease events by 29% (37 vs 30 per 10,000 person years) with most of the increased risk in 1st year of use and 2) Increases risk of stroke by 41% (29 vs 21 per 10, 000 person years).
There are 6 Cochrane systematic reviews in the 2005 edition covering differing aspects of HRT as well as a carefully considered New Zealand Guideline for HRT. In relatively healthy women, combined continuous HRT has been found to significantly increase the risk of VTE or coronary event (after 1 year of use), stroke (after 3 yrs of use), breast cancer (after 5yrs) and gall-bladder disease. Benefits= decreased incidence of fractures and colon cancer with long term use. In women over 65yrs long term use of combined continuous HRT sig increased incidence dementia. Gaps: No trials focussed specifically on younger women but their absolute risk of CVD or other event is very low. Conclusion Farquhar

Identify other issues

Patient preferences

Some younger women at low CVD risk and with significant menopausal symptoms may decide the small possible CVD harm is worth the risk if the reduction menopausal symptoms are significant

Policy issues

New Zealand Guidelines now recommend that HRT should not be used for CHD prevention and that it should be used with caution and primarily short term for women with significant menopausal symptoms

Clinical considerations

Women at high CVD risk, those at high risk of DVT and PE, those with recent breast cancer should avoid taking HRT even if they have significant menopausal symptoms. Those women with risk factors for osteoporosis and low bone mineral density need to balance the risk/benefit of HRT with risk/benefit of alternatives eg. bisphosphonates

The bottom line: weighing everything up

Beware of applying the results of a cohort Intervention study. The Nurses' Health Study was widely advertised and reported and many women were prescribed HRT on the basis of this study. Seven years later the rct results completely reverse the initial findings. Post-menopausal HRT should not be used for reducing risk of a cardiovascular event.

Step 5: Implementation and Quality Improvement

Plan to implement decision in your practice setting: how can your team improve practice with respect to the topic covered in this CAT?

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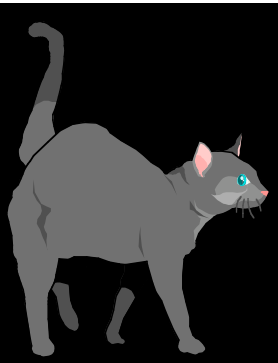
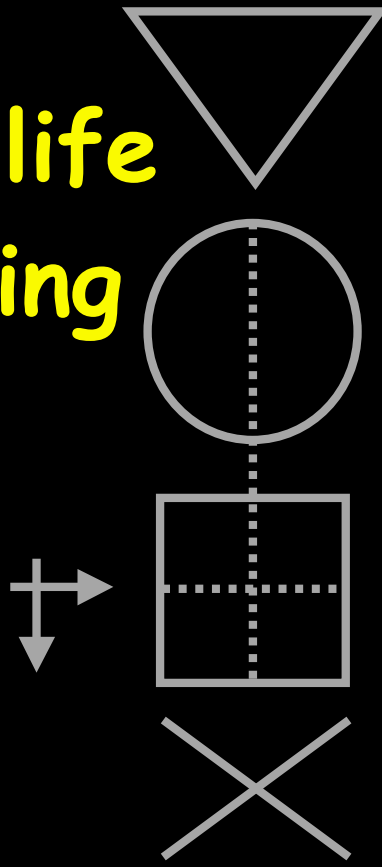


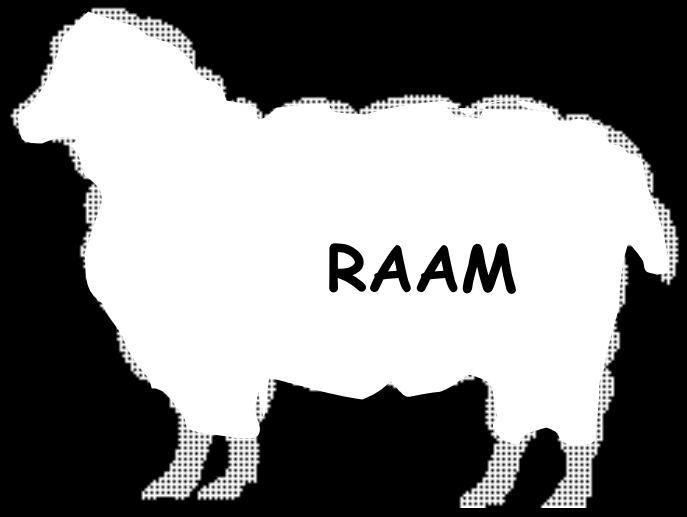
the CAT:

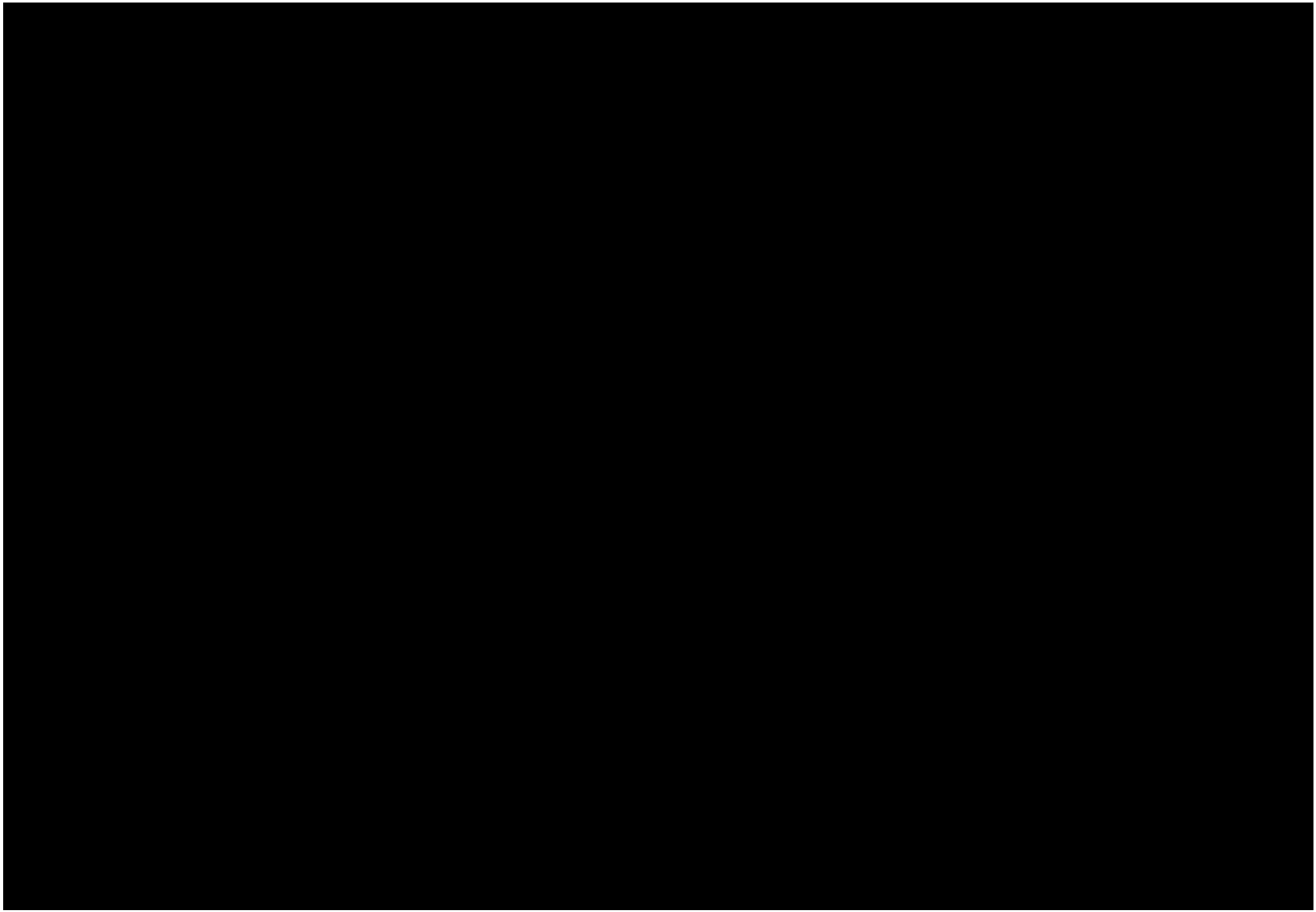
a tool for life long learning



"...and, as you go out into the world, I predict that you will, gradually and imperceptibly, forget all you ever learned at this university."

the evidence based practitioner





Using GATE to frame all the steps of EBP

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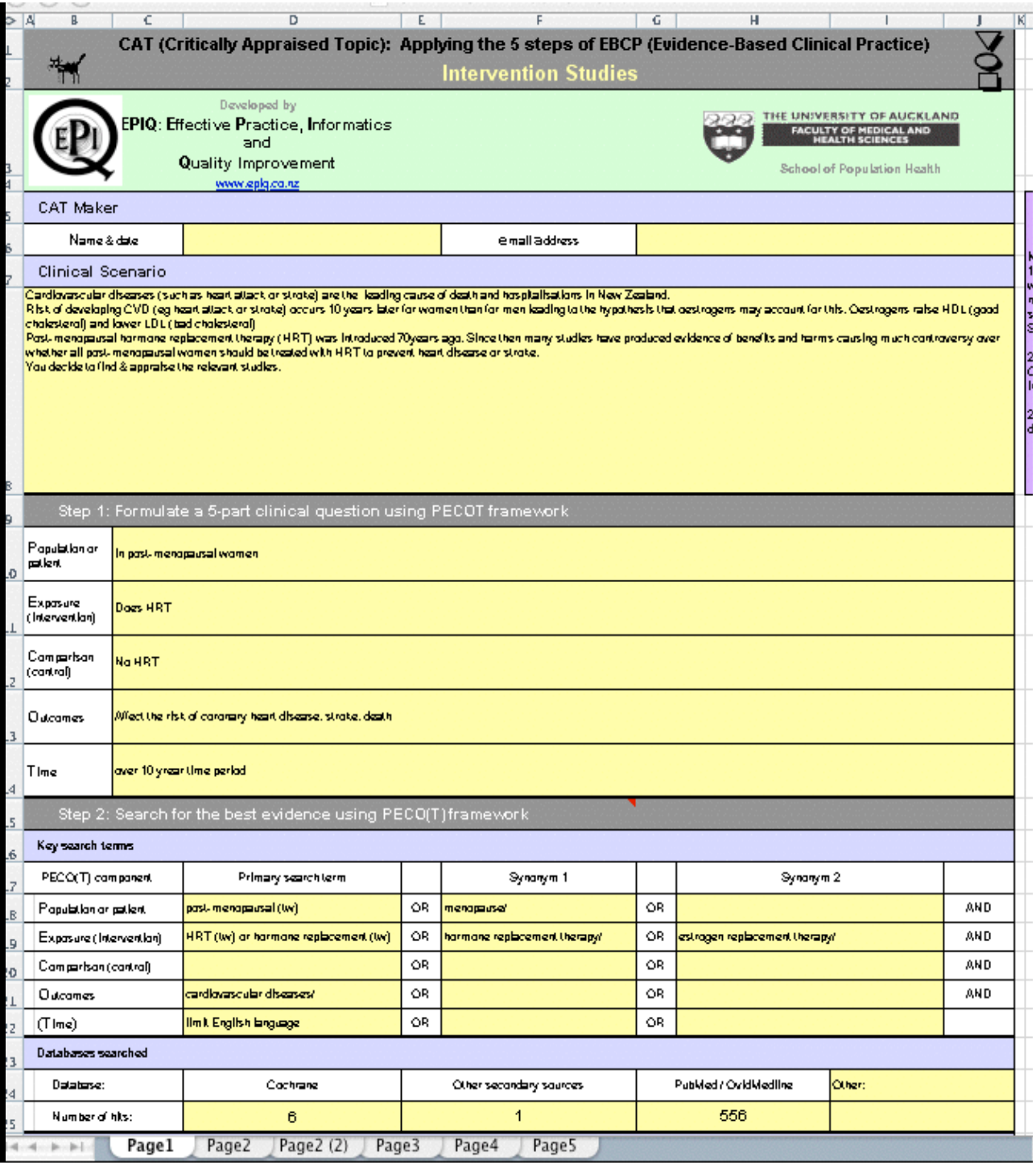

CAT (Critically Appraised Topic): Applying the 5 steps of EBCP (Evidence-Based Clinical Practice)

Intervention Studies

Developed by

EPIQ: Effective Practice, Informatics and Quality Improvement

www.epiq.co.nz

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES
School of Population Health

CAT Maker

Name & date		e mail address	

Clinical Scenario

Cardiovascular diseases (such as heart attack or stroke) are the leading cause of death and hospitalisations in New Zealand.
Risk of developing CVD (eg heart attack or stroke) occurs 10 years later for women than for men leading to the hypothesis that oestrogens may account for this. Oestrogens raise HDL (good cholesterol) and lower LDL (bad cholesterol)
Post- menopausal hormone replacement therapy (HRT) was introduced 70years ago. Since then many studies have produced evidence of benefits and harms causing much controversy over whether all post- menopausal women should be treated with HRT to prevent heart disease or stroke.
You decide to find & appraise the relevant studies.

Step 1: Formulate a 5-part clinical question using PECOT framework

Population or patient	In post- menopausal women
Exposure (Intervention)	Does HRT
Comparison (control)	No HRT
Outcomes	Affect the risk of coronary heart disease, stroke, death
Time	over 10 year time period

Step 2: Search for the best evidence using PECO(T) framework

Key search terms

PECO(T) component	Primary search term		Synonym 1		Synonym 2	
Population or patient	post- menopausal (tw)	OR	menopause/	OR		AND
Exposure (Intervention)	HRT (tw) or hormone replacement (tw)	OR	hormone replacement therapy/	OR	estrogen replacement therapy/	AND
Comparison (control)		OR		OR		AND
Outcomes	cardiovascular diseases/	OR		OR		AND
(Time)	limit English language	OR		OR		

Databases searched

Database:	Cochrane	Other secondary sources	PubMed / OvidMedline	Other:
Number of hits:	6	1	556	

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Ask an answerable question:on HRT

Participants	Exposure (eg. Cause, risk factor, Rx)	Comparison	Outcome	Time
In women with coronary heart disease (CHD)	Does oral hormone replacement therapy	No hormone replacement therapy	Reduce the risk of further CHD events	Over the next 5 yrs

Search for the appropriate epi. evidence

Participants	Exposure (eg. Cause, risk factor, Rx)	Comparison	Outcome	Time
postmenopause	hormone replacement therapy	(placebo)	Coronary disease	