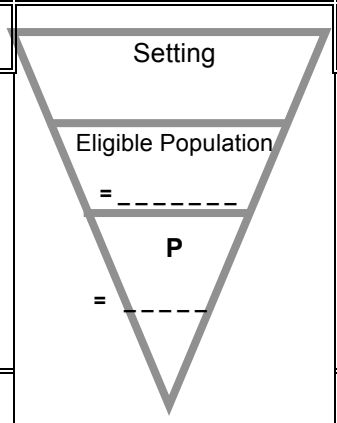
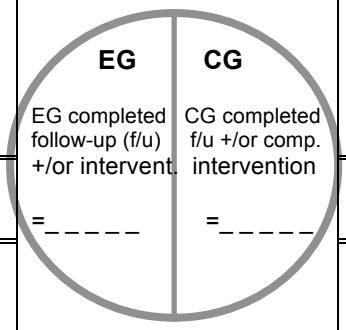
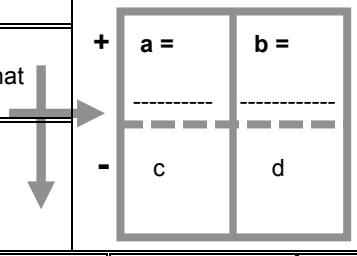
GATE-lite for RCTs & Observational (risk, prognosis, x-sectional) Studies 2013

Study details :

STUDY QUESTION & DESIGN - describe with **PECOT**	**STUDY NUMBERS -** hang on **GATE frame**	**STUDY ERROR -** assess using **RAMBOMAN**
P = Participants		**Recruitment** appropriate to study goals / able to define who findings applicable to?
Briefly describe - Setting: jlgmkdf;gH, rfjmlkkmdf;lbm:GB,":GB,"Gb fgl/mfglrm; erflejkfe'fgkl erfjeorfjnoeg;r Eligibility criteria: Recruitment process: % of invited eligibles who participated:		Setting & eligible population appropriate to goals & well described? Participants likely to be similar to all Eligibles? Participant risk/prognostic profiles well described?
EG = **Exposed** Group [Intervention / Risk factor]	**How allocated: randomly or by measurement?** **EG Allocated** =_ _ _ _ _ **CG Allocated** =_ _ _ _ _	**Allocation** to EG & CG done appropriately?
Describe Exposure (how measured if not RCT):		If allocated randomly: Was process concealed? Were EG&CG similar at baseline? If allocated by measurement: Was it done accurately? Done before outcomes? Were differences between EG&CG documented?
CG = **Comparison** Group [Control / comparison intervention / factor]		**Maintenance** in allocated grps & on allocated interventions/exposures during study sufficient?
Describe Comparison (how measured if not RCT):	EG incomplete f/u = _ _ _ _ _ CG incomplete f/u =_ _ _ _	Completeness of follow-up high? Compliance high, Contamination low? Co-interventions similar in EG&CG?
O =Outcomes Primary (& 2° / adverse) **T = Time** when outcomes counted (at what point in time or over what time period)		Participants/Investigators blind to EG/CG status?
Describe O & T - how / when measured:		**Blind** and **Objective Measurements?** Outcomes measured accurately?

STUDY ANALYSES

Outcomes (categorical or numerical) & Time	EGO=a/EG or mean= Σa/EG	CGO=b/CG or mean= Σb/EG	RR = EGO/CGO ± 95% CI	RD = EGO-CGO ± 95% CI	NNT = 1/RD ± 95% CI

ANalyses: Intention to treat (if RCT)?_____Adjusted if EG & CG different?_____**95% CIs** or p-values given?_____

Summary:

1. Non-random error sufficiently low? (AMBOM: amount & direction of bias)

2. Analytical error sufficiently low? (AN: ITT /adjusted analyses)

3. Random error sufficiently low? (95% CIs: and if no statistically significant effects demonstrated was study power/sample size sufficiently high)

4. Size of effects sufficient to be meaningful? (RR &/or RD)

5. If 1-4 ok, are findings applicable in practice? (R)

GLOSSARY

Use this form for questions about: interventions (RCTs & cohort studies), risk factors/causes (cohort & cross-sectional studies) or prognosis (cohort studies)

Hang the study on the GATE Frame

STUDY QUESTIONS/DESIGN: use PECOT to define study question & describe study design

Setting of study: Timing & locations in which Eligibles identified (e.g. country/urban/hospital).
Eligible population: those from study Setting who meet eligibility (i.e. inclusion / exclusion) criteria.
How were Eligibles identified from study setting: what kind of list (sampling frame) was used to identify potential participants: (e.g. hospital admission list, electoral rolls, advertisements).
P: Participants: recruited from Eligibles & allocated to EG/CG. How recruited from Eligibles (eg. randomly, consecutive)?
EG: Exposure Group: participants allocated to the main exposure (or intervention or prognostic group) being studied. If there are multiple exposures, use a new GATE frame for each exposure.
CG: Comparison Group: participants allocated to alternative (or no) exposure (i.e. control).
Outcome: specified study outcome(s) for analyses. If multiple outcomes, use additional GATE frames.
Time: when outcomes measured; at one point in time → (prevalence) or over a period of time ↓(incidence).

STUDY VALIDITY (non random error or bias): use RAMBOM to identify possible non random errors

Recruitment (mainly about external validity): were setting/Eligibles appropriate given the study goals &/or the reviewer's interests? If relevant, were participants similar to all Eligibles? Are the results applicable to relevant populations? This should be able to be determined from risk factor/prognostic profile of participants. In prognostic studies – were participants at similar stage in progression of their disease or condition?
Allocation: were participants allocated appropriately to E&C? If a trial were they **randomised** to E&C?
• If randomised, was allocation concealed (i.e. knowledge of group (EG or CG) participants allocated to concealed from staff & participants until after allocation documented)? Was randomization successful (i.e. EG & CG similar after randomisation – were baseline characteristics similar in each group)?
• If not randomised (observational study) were measurements of E&C accurate & done similarly for EG & CG? Were differences between EG & CG documented.
Maintenance: did participants remain in the groups and interventions /exposures (EG or CG) they were initially allocated to? Completeness of follow-up: was it high & similar in EG & CG? Compliance: % participants allocated to EG (or CG) who remained exposed to E (or C) during study? Contamination: % participants allocated to CG who crossover to EG (& visa versa if CG an exposure)? Co-intervention: other significant interventions received unequally by EG&CG during follow-up? Blinding: were participants / investigators blind to whether participants exposed to E or C?
Blind Measurement of outcomes: were outcome assessors unaware if participants in EG or CG? **and/or**
Objective Measurement of outcomes. eg. based on biopsies; automated tests, x-rays, validated questionnaires?

STUDY ANALYSES (estimates of occurrence [EGO & CGO], effect sizes [RR & RD]) and random error [95% CI]

Intention to treat (or expose) analyses: did analyses (i.e. calculation of EGO & CGO) include all participants allocated to EG & CG, including anyone who dropped out during study or did not complete follow-up)?
Adjusted analyses (for confounders): Were EG & CG similar at baseline? If not, were analytical methods used to adjust for any differences, e.g. stratified analyses, multiple regression?
EGO: Exposure Group Occurrence (either incidence or prevalence measures; also known as Experimental Event Rate (EER) in RCTs). **CGO:** Comparison Group Occurrence (or Control Event Rate (CER) in RCTs). **For categorical (yes/no) variables,** most studies report **cumulative incidence** or **prevalence** measures of occurrence and EGO = a/EG & CGO = b/CG, and you should document over what time period (cumulative incidence) or at what point in time (prevalence) EGO & CGO are measured. **For numerical variables** (e.g. blood pressure), EGO and CGO are usually reported as mean values fopr EG and CG. For example, EGO = the sum of all BP levels in EG (= Σa/EG) & CGO = Σb/CG,
Effect estimates (measures for comparing EGO & CGO): **Risk Ratio (RR) = EGO/CGO;** more commonly known as Relative Risk. Odds Ratios & Hazards ratios are similar to RR. **Risk Difference (RD) = EGO-CGO**; also known as absolute risk difference. **NNT (or NNE) = 1/RD**; the number Needed to Treat (or expose) to change the number of outcomes by one (in a specified time). NNT(B): if exposure/intervention BENEFICIAL. NNT(H): if exposure/intervention HARMFUL. Note: NNT(H) often called NNH.
Random error in estimates of EGO, CGO, RR, RD & NNT/E is assessed by width of confidence interval (CI). A wide CI (i.e. big gap between upper & lower confidence limits (CL) = more random error = less precision.

STUDY SUMMARY

Non-random error (bias): what was the likely amount & direction of bias: is bias likely to substantially increase or decrease the observed difference between EGO & CGO (and therefore the effect sizes)?
Analytical error: were analyses done appropriately? ITT analyses, adjusted analyses if differences between EG & CG.
Random error: would you make a different decision if the real effect was close to upper CL rather than the lower CL? Power: if the effect sizes were not statistically significant, was study just too small to show meaningful effects?
Effect sizes: was the magnitude of the RR or RD (or NNT) sufficient to be meaningful/useful in practice?
Applicability: if effect sizes meaningful & errors small, are the findings likely to be applicable in practice?

REFERENCE: Jackson et al. The GATE frame: critical appraisal with pictures. In: Evidence-Based Medicine. 2006;11;35-38. Also in: Evidence-Based Nursing 2006; 9: 68-71, and in ACP Journal Club 2006; 144: A8-A11.