

# GATE-lite for RCTs & Observational (risk, prognosis, x-sectional) Studies 2012

STUDY QUESTION & DESIGN: describe with <b>PECOT</b>	STUDY NUMBERS: hang on <b>GATE</b> frame	STUDY ERROR: assess using <b>RAMBOMAN</b>						
<p><b>P = Participants:</b></p> <p>Describe:</p> <ul style="list-style-type: none"> <li>- Setting</li> <li>- Eligibility criteria</li> <li>- Recruitment process</li> <li>- % of eligibles who participated</li> </ul>		<p><b>Recruitment</b> appropriate to study goals?</p> <p>Setting/eligible population appropriate, given study goals?</p> <p>Participants representative of Eligibles?</p> <p>Participant risk/prognostic profile reported?</p>						
<p><b>EG = Exposed Group</b> [Intervention/Risk factor]</p> <p>Method of allocation</p> <p>Describe E (how measured if not RCT)</p>	<p><b>Allocated: randomly or by measurement</b></p> <p><b>EG Allocated</b>    <b>CG Allocated</b></p> <p>= _____    = _____</p>	<p><b>Allocation</b> (<math>\pm</math> adjustment) to EG &amp; CG successful/done accurately?</p> <p>If allocated randomly: Was process concealed? Were EG&amp;CG similar?</p> <p>If allocated by measurement: Was it done accurately? Done before outcomes? Were differences between EG&amp;CG documented?</p>						
<p><b>CG = Comparison Group</b> [Control/comparison]</p> <p>Describe C (how measured if not RCT)</p>		<p><b>Maintenance</b> of EG &amp; CG as allocated sufficient?</p> <p>Compliance high, Contamination low?</p> <p>Co-interventions similar in EG&amp;CG?</p> <p>Completeness of follow-up high?</p> <p>Participants/Investigators blind to Exp. status?</p>						
<p><b>O = Outcomes:</b> Primary (&amp; 2° include adverse)</p> <p><b>T = Time</b> when outcomes counted (at what point in time or over what time period)</p> <p>Describe O &amp; T: how / when measured</p>	<table border="1" style="margin: auto;"> <tr> <td style="text-align: center;">+</td> <td style="text-align: center;">a =</td> <td style="text-align: center;">b =</td> </tr> <tr> <td style="text-align: center;">-</td> <td style="text-align: center;">c</td> <td style="text-align: center;">d</td> </tr> </table>	+	a =	b =	-	c	d	<p><b>Blind and Objective Measurements?</b></p> <p>Outcomes measured accurately?</p>
+	a =	b =						
-	c	d						
<b>STUDY ANALYSES</b>	Outcome & Time	EGO = a/EG	CGO = b/CG	RR = EGO/CGO $\pm$ 95% CI	RD = EGO-CGO $\pm$ 95% CI	NNT = 1/RD $\pm$ 95% CI		
<p><b>ANalyses:</b> Intention to treat (if RCT)? _____ Adjusted if EG &amp; CG different? _____ 95% CI or p-values given? _____</p>								
<p><b>Summary:</b></p> <p><b>Non-random error:</b> amount &amp; direction of bias (<b>RAMBOM</b>)?</p> <p>ANalyses done well?</p> <p><b>Random error:</b> sufficiently low Power/sample size sufficiently high (if no statistically significant effects demonstrated)?</p> <p><b>Applicability of findings?</b> Any important adverse effects?</p> <p>Size of effects sufficient to be meaningful (RR &amp;/or RD)?</p> <p>Can findings be applied in practice?</p>								

## 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).

Eligibles: 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 RANBOM 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 representative of Eligibles? Could the results be generalised 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:** how well were participants allocated 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 (EG or CG) they were initially allocated to? **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? **Completeness of follow-up:** was it high & similar in EG & CG? **Blinding:** were participants / investigators blind to whether participants were exposed to E or C?

**Blind Measurement** of outcomes: were outcome assessors unaware if participants in EG or CG? **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). 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. However if EGO & CGO are calculated as **incidence rates** per unit time (T) (e.g. per year), then  $EGO = a/(EG \times T)$  &  $CGO = b/(CG \times T)$ . EG x T and CG x T describe 'person-time.'

**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)?

**Random error:** would you make a different decision if the real effect was closer to upper CL than 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.