GATE: a **G**raphic **A**pproach **T**o **E**vidence based practice

GATE CAT – Intervention RCT/Cohort Studies

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

updates from previous version in red

Critically Appraised Topic (CAT): Applying the 5 steps of Evidence Based Practice
Using evidence about interventions from randomised controlled trials (RCTs) & non-randomised cohort studies

Assessed by:	**Date:**

Problem

Describe the problem that led you to seek an answer from the literature about the effectiveness of interventions.

Step 1: Ask a focused 5-part question using PECOT framework (EITHER 'your question' OR 'the study's question')

Population / patient / client	Describe relevant patient/client/population group (be specific about: medical condition, age group, sex, etc.)
Exposure (intervention)	Describe intervention(s) you want to find out about Be reasonably specific: e.g. how much? when? how administered? for how long?
Comparison (Control)	Describe alternative intervention (e.g. nothing or usual care?) you want to compare it with? Be reasonably specific
Outcomes	List the relevant health/disease-related outcomes you would like to prevent/reduce/etc
Time	Enter a realistic time period within which you would expect to observe a change in these outcomes?

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 for at least P, E & O. C & T may not be so useful for searching. 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	As above	AND	As above	AND	As above	
Limits & Filters	PubMed has **Limits** (eg age, English language, years) & PubMed Clinical Queries has **Filters** (e.g. study type) to help focus your search. List those used.					

Databases searched:

Database	Cochrane SRs	Other Secondary Sources	PubMed / Ovid Medline	Other
Number of publications (Hits)	Enter number of hits from Cochrane database search for Systematic Reviews (SR).	Enter number of hits from other secondary sources (specify source)	Enter number of hits from PubMed /Ovid/etc (specify database)	Enter number of hits from other sources (e.g. Google scholar, Google)

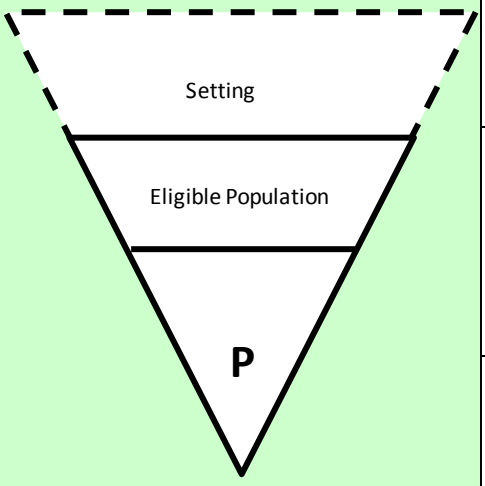
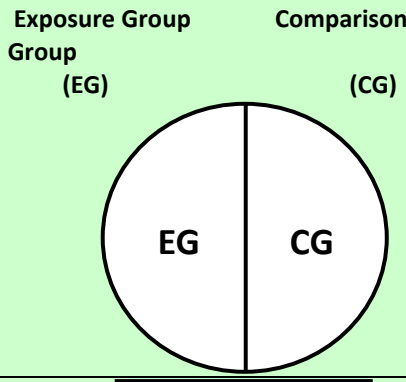
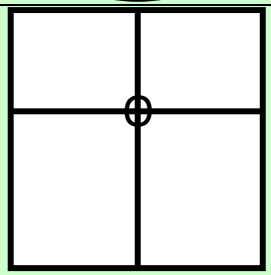
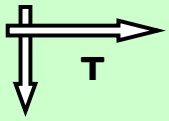
Evidence Selected

Enter the full citation of the publication you have selected to evaluate.

Justification for selection

State the main objectives of the study.
Explain why you chose this publication for evaluation.

Intervention Studies
Step 3: Appraise Study
3a. Describe study by hanging it on the GATE frame (also enter study numbers into the separate excel GATE calculator)

Population		Study Setting	Describe when & from where participants recruited (e.g. what year(s), which country, urban / rural / hospital / community)
		Eligible population Recruitment process	Define eligible population / main eligibility (inclusion and exclusion) criteria. Describe recruitment process (e.g. were eligibles recruited from electoral / birth / hospital admission register, or media advert, etc). How they were recruited (e.g. random sample, consecutive eligibles)
		Participants	What percentage of the invited eligibles participated? What reasons were given for non-participation among those otherwise eligible?
Exposure & Comparison		Allocation methods	<u>For RCTs:</u> describe method used to generate random allocation sequence and method used to ensure that the allocation outcome could not be changed by the participants or those assigning interventions <u>For non-randomised studies:</u> describe method/measures used to allocate participants to EG & CG
		Exposure	Describe main intervention: what, how much, how, when, for how long & by whom administered.
		Comparison	Describe comparison intervention (given to CG): as above
Outcomes		Primary Outcomes	Describe the primary outcome. How was it defined? How & by whom was it measured? Is it categorical (the variable is grouped into categories; e.g. dead/alive) or numerical (the variable has a numerical value; e.g. weight, days in hospital)
		Secondary Outcomes	Describe any secondary outcomes How & by whom were they measured?
		Adverse Outcomes	Describe any adverse outcomes measured How & by whom were they measured?
Time		Time	If outcomes measured cross-sectionally (e.g. diabetes, BP), state when it was measured in relation to when the intervention(s) began. If outcomes measured over a period of time (e.g. deaths), state the length of follow-up time after initiation of intervention(s)

Reported Results	**Enter the main reported results ➔**	Outcome	Effect estimate	Confidence Interval
			Include type of measure; eg. RR, HR	

Complete the Numbers on the separate GATE Calculator for Intervention Studies				

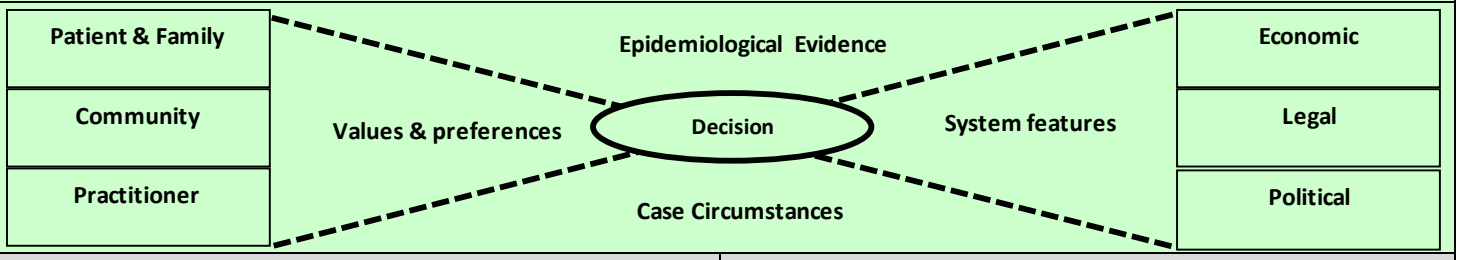
Intervention Studies **Step 3: Appraise Study** **3b. Assess risk of errors using RAMboMAN**			
Appraisal questions (RAMboMAN)		**Risk of errors +, x, ?, na**	Notes
Recruitment/Applicability '**errors'**: questions on risks to application of results in practice are in blue boxes			
Internal study design **errors**: questions on risk of errors within study (design & conduct) are in pink boxes			
Analyses **errors**: questions on errors in analyses are in orange boxes			
Random **error**: questions on risk of errors due to chance are in the green box			
Key for scoring risk of errors: + = low; x = of concern; ? = unclear; na = not applicable			
Participant Population	**Recruitment** - are the findings based on these recruited participants applicable in practice?		
	Study Setting relevant to practice?	Score risk of error: +, x, ? or na (see key above)	Is the study setting (e.g. what year(s), which country, urban / rural, hospital / community) likely to influence the applicability of the study results?
	Eligible population relevant to practice?		Was the eligible population from which participants were identified relevant to the study objective and to practice? Were inclusion & exclusion criteria well defined & applied similarly to all potential eligibles?
	Participants similar to all eligibles?		Did the recruitment process identify participants likely to be similar to all eligibles? Was sufficient information given about eligibles who did not participate?
	Key personal (risk/prognostic) characteristics of participants – that would influence applicability in practice - reported?		Was there sufficient information about baseline characteristics of participants to determine the applicability of the study results? Was any important information missing?
Exposures & Comparisons	**Allocation** to EG & CG done well?		
	Were E & C randomised?		Were the exposure/comparison interventions reported to be allocated randomly?
	If RCT: method of Random sequence generation adequate?		Was the method of random sequence generation likely to produce similar groups (EG & CG)?
	Allocation process concealed?		Could person(s) determining allocation &/or implementing interventions have changed the allocation outcome before or during enrolment? If yes, was it sufficient to cause important bias?
	Allocation process successful?		Were EG & CG similar at baseline? If not, was this sufficient to cause important bias without adjustments in the analyses (see Analysis section below)?
	E & C interventions sufficiently well described?		Were E & C interventions described in sufficient detail for the study to be replicated or the interventions to be replicated in practice?
	E & C interventions applicable in practice?		Is the E intervention available, implementable & affordable? Was the C intervention a relevant alternative?
	Maintenance in allocated groups and on allocated interventions sufficient throughout study?		

	Completeness of follow-up sufficiently high?		Was the proportion of participants lost-to-follow-up /dropped / lost pre-/ during/ post- intervention acceptably low? Did the proportion followed up differ in EG & CG? Was this sufficient to cause important bias?
	Compliance with EG & CG interventions sufficiently high?		Did most participants in the EG & CG remain on their allocated interventions throughout the study? Was it sufficient to demonstrate the effect of the interventions?
	Contamination sufficiently low?		Did any of the CG receive the EG intervention or vice versa? If so, was it sufficient to cause important bias?
	Co-interventions: were all other interventions similar in both groups?		Were the groups treated / behave similarly other than the EG & CG interventions? Did either group receive additional interventions / have services provided in a different manner / change their behaviour? Was this sufficient to cause important bias?
	Participants / study staff blind to interventions?		If participants/staff aware of the interventions received, were the EG & CG treated differently / did they behave differently in ways that influenced follow-up/compliance/contamination/co-interventions differentially in EG & CG? Was this sufficient to cause important bias?
Outcomes	**blind or objective Measurement** of Outcomes: were they done accurately?		
	Outcomes measured blind to EG & CG status?		Were outcome assessors (or participants) aware of whether participants were in EG or CG? If yes, was this likely to lead to biased outcome measurement?
	Outcomes measured objectively?		How objective were outcome measures (e.g. death, automatic test, strict diagnostic criteria)? Where significant judgment was required, were independent adjudicators used? Was reliability of measures relevant (inter-rater & intra-rater), & if so, reported?
	All important outcomes assessed?		Both benefits and harms assessed? Was it possible to determine the overall balance of benefits and harms of the exposure/comparison?
Time	Follow-up time similar in EG & CG?		If not, was it sufficient to cause important bias?
	Follow-up time sufficient to be meaningful?		Or was it either: too short to have time for the risk/prognostic factors to have influenced the outcome(s); or too long, e.g. the effect may have worn off?
Results	**ANalyses:** were they done appropriately?		
	Intention-to treat-analyses done?		Were all participants analysed in the groups (EG & CG) to which they were originally allocated?
	If EG & CG not similar at baseline was this adjusted for in the analyses?		e.g. using multivariate analyses or stratification
	Estimates of Intervention effects given or calculable? Were they calculated correctly?		Were measures of occurrence (EGO & CGO) & effect estimates (e.g RRs, RDs, NNTs) given or possible to calculate? If entered into GATE calculator, were GATE results similar to reported results?
	Measures of the amount of random error in estimates of intervention effects		Were confidence intervals &/or p-values for effect estimates given or possible to calculate? If they could be

	given or calculable? Were they calculated correctly?		entered into GATE calculator, were GATE results similar to reported results? If effect estimates not 'statistically significant' were power calculations given or possible to calculate?
	Summary of Study Appraisal		
	Study design & conduct: was risk of error low (i.e. results reasonably unbiased)?		Use responses to questions in pink boxes above
	Study analyses: was risk of error low (i.e. results reasonably unbiased)?		Use responses from the orange boxes above
	Random error in estimates of intervention effects: were CIs sufficiently narrow for results to be meaningful?		Use responses to questions in green box above. Would you make a different decision if the true effect was close to the upper confidence limit rather than close to the lower confidence limit?
	Applicability: are these findings applicable in practice?		Use responses to questions in blue boxes above

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

The X-factor



Epidemiological evidence: summarise the quality of the study appraised, the magnitude and precision of the measure(s) estimated and the applicability of the evidence. Also summarise its consistency with other studies (ideally systematic reviews) relevant to the decision.	Case circumstances: what circumstances (e.g. disease process/ co-morbidities [mechanistic evidence], social situation) specifically related to the problem you are investigating may impact on the decision?
System features: were there any system constraint or enablers that may impact on the decision?	What values & preferences may need to be considered in making the decision?

Taking into account all the factors above what is the best decision in this case?

Step 5: Audit usual practice (For Quality Improvement)

Is there likely to be a gap between your usual practice and best practice for the problem?