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

GATE CAT – Case Control 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 aetiology/risk/interventions from Case Control Studies

Assessed by:	**Date:**

Problem

Describe the problem that led you to seek an answer from the literature about aetiology/risk/interventions.

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

Population / patient / client	Describe the relevant patient/client/population group (be specific about: medical condition, age group, sex, etc.)
Exposure (intervention)	Describe the risk/intervention factor(s) you want to find out about Be reasonably specific: e.g. how defined? when? by whom?
Comparison (Control)	Describe an appropriate comparison group - be reasonably specific
Outcomes	List the relevant health/disease-related outcome you wish to investigate
Time	Enter a realistic time period within which you would expect to observe 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 your 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	Other Secondary Sources	PubMed / OvidMedline	Other
Number of publications (Hits)	Enter number of hits from Cochrane search.	Enter number of hits from other secondary sources.	Enter number of hits from PubMed /Ovid/etc (specify database)	Enter number of hits from other sources (e.g. Google scholar, Google)

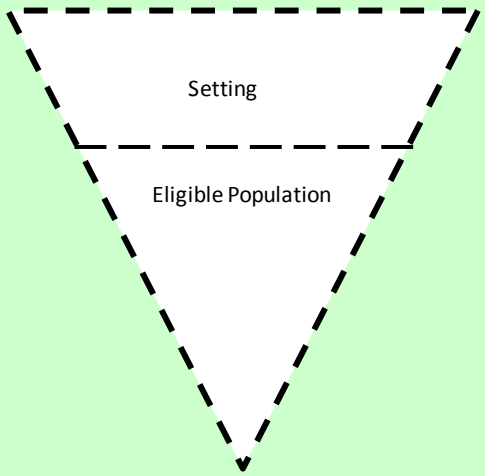
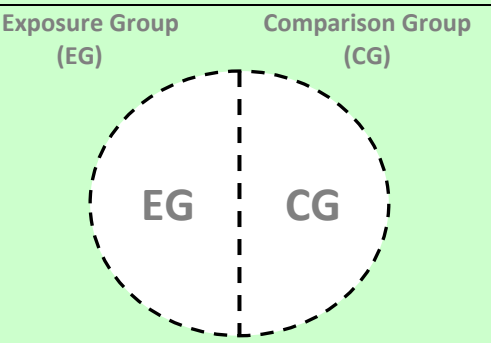
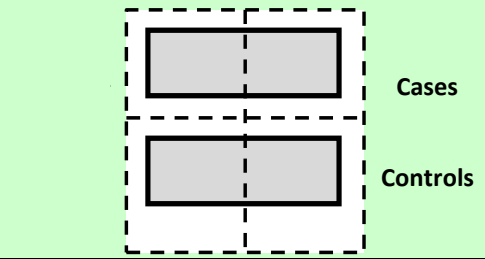
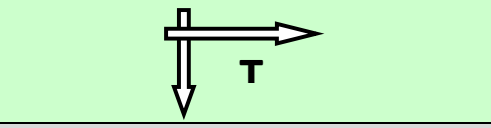
Evidence Selected

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.

Case Control Studies about aetiology/risk/interventions
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)
		<u>Cases:</u> Eligible population Recruitment process	Define eligible population (if possible) from which the cases were recruited (e.g. by age / gender / geographic / administrative region). Describe case recruitment process (e.g. were they recruited from electoral / birth / hospital admission register, media advert, etc). How recruited (e.g. consecutive eligible cases). What percentage of invited eligible cases participated? What reasons were given for non-participation?
		<u>Controls:</u> Eligible population. Recruitment process	Define eligible population (if possible) from which the controls were recruited (as above). Describe control recruitment process (as above for cases). What percentage of invited eligible controls participated? What reasons were given for non-participation?
Exposure & Comparison		Allocation method	Cases and controls allocated by measurement of risk/intervention factors
		Exposure	Describe risk/intervention factor(s): what, how defined, how measured, when, by whom – for cases and for controls
		Comparison	Describe comparison risk/intervention factor(s) as above
Outcomes		Outcome (case definition)	Describe the outcome that made a person a case. How was it defined? How, when & by whom were cases identified?
Time		Time	State the relevant time between when participants were exposed to risk factor/intervention and the outcome.

Reported Results	**Enter the main reported results ➔**	Outcome	Risk estimate	Confidence Interval
			Incl.measure eg. OR	

Complete the Numbers on the separate GATE Calculator for Case-Control Studies

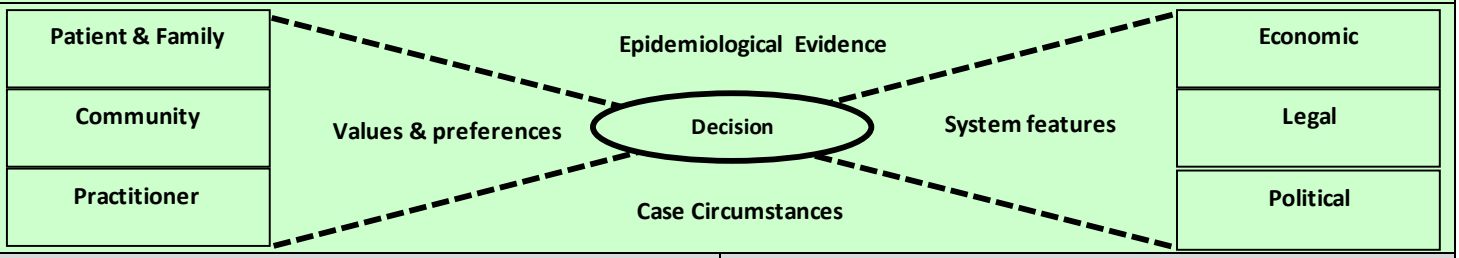
Case Control Studies about aetiology/risk/interventions Step 3: Appraise Study 3b. Assess risk of errors using RAMboMAN		
Appraisal questions (RAMboMAN)	**Risk of errors +, x, ?, na**	Notes
Recruitment/Applicability '**errors'**: questions on application of results in practice & risk of errors due to differences in recruitment of cases and controls 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 as: +, 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 for cases relevant to practice?		Was the eligible population from which cases were identified relevant to the study objective and to practice? Were inclusion & exclusion criteria explicit and applied similarly to all eligible cases?
Eligible population for controls relevant to practice?		Was the population from which controls were identified relevant to the study objective? Were inclusion & exclusion criteria explicit and applied similarly to all eligible controls?
Cases and controls recruited from same population?		e.g. all cases and controls on the same electoral roll/ geographic area?
Recruited cases and controls similar to all eligible cases and controls?		Was sufficient information given about eligibles who did not participate? Were response rates similar in cases & controls? The control group provides the background proportion of exposure within the eligible population (& therefore the expected proportion in the case group). Recruitment of controls **must** be independent of the main exposure(s) being investigated.
Key personal (risk/prognostic) characteristics of cases and controls – that would influence applicability in practice - reported?		Was there sufficient information about the characteristics of cases & controls to determine the applicability of the study results? Was any important information missing?
Exposures &Comparisons	**Allocation** to EG & CG done well?	
E & C (risk/intervention) factors sufficiently well defined and well measured so cases and controls allocated to correct exposure status?		Were E & C definitions described in sufficient detail for the measurements to be replicated? Were the measurements done accurately and similarly in cases & controls? Were criteria / cut-off levels of categories well justified
E & C (risk/intervention) factors measured prior to outcomes occurring in cases?		If E or C status assessed retrospectively in cases: i. were they likely to have been affected by the study outcomes (e.g. angina –the outcome - can influence level of physical activity - the E or C); ii. were cases and controls likely to have different recall of exposure information?
E & C (risk/intervention) factors		Are the E & C factors measurable, relevant & affordable in usual practice?

	meaningful in usual practice?		
	Maintenance in allocated groups and throughout study sufficient?		
	Response rates of eligible cases and controls sufficiently high and similar?		Were the proportions of eligible cases and controls identified but who did not participate acceptably low? Did this differ between cases & controls? Was it likely to differ depending on E or C status?
	E/C (risk/intervention) definitions accurately classified exposures throughout exposure period of interest (virtual follow-up period)?		Did the E/C definitions include length of time cases & controls had been exposed to E or C?
	E & C cases/controls treated similarly?		Had E/C cases & E/C controls been treated / behaved similarly other than in regard to the E & C factors?
	Cases & controls blind to their risk/intervention status?		If cases & controls aware of their risk/intervention status, were E & C cases or E & C controls treated differently or did they behave differently in ways that influenced response rates or exposure status differentially?
Outcomes	**blind or objective Measurement** of Outcomes: were they done accurately?		
	Outcomes (case status) measured blind to E or C status?		Were outcome assessors aware of the risk/intervention status of the cases prior to the case status being determined? If yes, could this have caused errors in outcome diagnosis/classification?
	Outcomes (case status) 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?
	Was the outcome meaningful/relevant in usual practice?		
Time	Exposure period of interest (virtual follow-up time) sufficient to be meaningful?		Was the time period of exposure to E or C prior to identifying cases & controls sufficient to demonstrate an association between the factor(s) and the outcome(s)? Or was it either: too short to have time for the risk/intervention factors to have influenced the outcome; or too long (e.g. the effect may have worn off)?
Results	**ANalyses:** were they done appropriately?		
	If E/C cases & controls not similar at baseline was this adjusted for in the analyses?		e.g. using multivariate analyses or stratification Were there likely to be residual differences causing confounding?
	Estimates of associations between E or C and outcome(s) given or calculable? Were they calculated correctly?		Were ORs or RRs given or possible to calculate? If entered into GATE calculator, were GATE results similar to reported results?
	Is the Odds Ratio (if calculated) likely to approximate a relative risk?		ORs & RRs are likely to be similar when the outcome (cases) is relatively uncommon. If less than 10-15% of the eligible population are cases, then the OR will approximate an equivalent RR.
	Measures of the amount of random error in estimates of associations given or calculable? Were they calculated		Were confidence intervals &/or p-values for estimates of association given or possible to calculate? If they could be entered into GATE calculator, were GATE results similar to

	correctly?		reported results? If 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

Case Control Studies about aetiology/risk/interventions
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 constraints or enablers that may impact on the decision?	What values & preferences may need to be considered in making the decision?

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?