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| **GATE**: a **G**raphic **A**pproach **T**o **E**vidence based practiceWhite logo only FMHS_logo_blackH**GATE CAT – Case Control Studies**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 aboutBe 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 / P**articipants / 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 |
| **E**xposure(Interventions) | As above | OR | As above | OR | As above | AND |
| **C**omparison (Control) | As above | OR | As above | OR | As above | AND |
| **O**utcomes | As above | OR | As above | OR | As above | AND |
| **T**ime | 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. |

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| **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) |
| Cases: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? |
| Controls: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** | **Exposure Group Comparison Group** **(EG) (CG)****EG****CG** | 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** | **Cases****Controls** | 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 |  |
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| **Complete the Numbers on the separate GATE Calculator for Case-Control Studies** |

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| **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 meaningful in usual practice? |  | Are the E & C factors measurable, relevant & affordable 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 stratificationWere 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 correctly? |  | 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 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  |

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| **Case Control Studies about aetiology/risk/interventions****Step 4: Apply. Consider/weigh up all factors & make (shared) decision to act** |
| **The X-factor**   |
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| 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? |
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| 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?  |
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| **Decision**: Taking into account all the factors above what is the best decision in this case?  |
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| **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? |
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