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| **GATE**: a **G**raphic **A**pproach **T**o **E**vidence based practice  White logo only FMHS_logo_blackH  updates from previous version in red  **GATE CAT – Risk Factor Cohort Studies** | | | | | | | | | | |
| **Critically Appraised Topic (CAT): Applying the 5 steps of Evidence Based Practice**  **Using evidence about aetiology/risk/prognosis from Cohort Studies** | | | | | | | | | | |
| **Assessed by:** | | | | | **Date:** | | | | | |
| **Problem** | | | | | | | | | | |
| Describe the problem that led you to seek an answer from the literature about aetiology/risk/prognosis. | | | | | | | | | | |
| **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 the risk/prognostic 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 (if relevant)  Be reasonably specific | | | | | | | | | |
| Outcomes | List the relevant health/disease-related outcomes 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 / Ovid Medline | | | 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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| **Cohort Studies about aetiology/risk/prognosis**  **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** | **Exposure Group Comparison Group**  **(EG) (CG)** | Allocation method | Allocated by measurement of risk/prognostic factors | | |
| Exposure | Describe risk/prognostic factor(s): what, how defined, how measured, when, by whom | | |
| Comparison | Describe comparison risk/prognostic factor(s) (if there is one) 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? | | |
| **Time** |  | Time | If outcomes measured cross-sectionally (e.g. diabetes, BP), state when it was in relation to when the measurement of risk/prognostic factors(s). If outcomes measured over a period of time (e.g. deaths), state length of follow-up time after the measurement of risk/prognostic factors(s). | | |
| **Reported Results** | **Enter the main reported results ** | Outcome | | Risk estimate | Confidence Interval |
|  | | Include type of measure; eg. RR, HR |  |
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| **Complete the Numbers on the separate GATE Calculator for Risk Factor Cohort Studies** | | | | | |

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| **Cohort Studies about aetiology/risk/prognosis**  **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 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 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 similar to all eligibles? Was sufficient information given about eligibles who did not participate? | |
| Prognostic studies: participants at common point in course of condition |  | Were participants relatively homogeneous with regard to their prognosis or was it possible to stratify? (e.g. at similar stage in course of cancer) | |
| 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? | | | |
| E & C (risk/prognostic) factors sufficiently well defined and well measured so participants allocated to correct groups? |  | | Were E & C definitions described in sufficient detail for the measurements to be replicated? Were the measurements done accurately? Were criteria / cut-off levels of categories well justified) |
| E & C (risk/prognostic) factors measured prior to outcomes occurring? |  | | If E/C status assessed retrospectively were they likely to have been affected by the study outcomes (e.g. angina – the outcome - can influence level of physical activity - the exposure/comparison) |
| E & C (risk/prognostic) factors meaningful in practice? |  | | Are the E & C factors measurable, relevant & affordable in practice? |
| **Maintenance** in allocated groups and throughout study sufficient? | | | |
| Completeness of follow-up sufficiently high? |  | | Was the proportion of participants lost-to-follow-up acceptably low?  Did the proportion followed up differ in EG & CG?  Was this sufficient to cause important bias? |
| Change in risk/prognostic status of participants sufficiently low during follow-up? |  | | Was it possible to determine if most participants’ initial risk factor/prognostic factor status was maintained throughout the study? (i.e. were they re-measured?) Was it sufficient to demonstrate an association between the factor(s) and outcome(s)? |
| EG & CG treated similarly during follow-up? |  | | Were the groups treated / behave similarly other than in regard to the E & C factors?  Did either group receive new interventions / have services provided in a different manner / change their behaviour?  Was this sufficient to cause important bias? |
|  | Participants / study staff blind to participants risk/prognostic status? |  | | If participants/staff aware of the risk/prognostic status, were the groups treated differently / did they behave differently in ways that influenced follow-up/change in risk status 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? | | | |
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| If EG & CG not similar at baseline was this adjusted for in the analyses? |  | | e.g. using multivariate analyses or stratification |
| Estimates of associations between E/C and outcome(s) given or calculable? Were they calculated correctly? |  | | Were measures of occurrence (EGO & CGO) & estimates of association (e.g RRs, RDs, NNTs) given or possible to calculate? If entered into GATE calculator, were GATE results similar to reported results? |
| Intention-to follow-up-analyses done? |  | | Were all participants analysed in the groups (EG & CG) to which they were originally allocated? |
| 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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| **Cohort Studies about aetiology/risk/prognosis**  **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 constraint 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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