PEDE Quality Appraisal Questionnaire

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'Consequences' refers to impact on health, health status, well-being, disease incidence, etc. It does not include monetary benefits, such as savings. *The research question should appear in the body of the text (not merely title or abstract).*	**Economic Evaluation** 1. Is the research question posed in terms of costs and consequences? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
CMA, CEA, CBA, CUA or Cost-consequence analysis (CCA). *An analytic technique should be specified, beyond the use of 'cost-effective' or 'cost-benefit' as a generality or adjective.*	2. Is a specific type of economic analysis technique performed? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
(Check all that apply) *Indicate what the authors state is performed, even though they may be incorrect, such as labeling as a CBA what is actually a CEA. (Errors in identifying the technique or valuing the outcomes are addressed in Q38).*	3. What type of analytic technique is performed, according to the authors? ☐ 1. CMA ☐ 2. CEA ☐ 3. CBA ☐ 4. CUA ☐ 5. Cost-consequence analysis ☐ 6. Unknown/can't tell ☐ 7. Other (Specify: _____)
	Comparators 4. Is there a rationale for choosing the intervention(s) being investigated? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
The rationale for comparators that are 'do nothing' or 'usual care' or pre-intervention practice may not be explicitly stated but may sometimes be inferred.	5. Is there a rationale for choosing the alternative program(s) or intervention(s) used for comparison? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No

What are the setting, mode of delivery and timing of the investigational intervention(s) and comparator(s)? What is the dosing or administration regimen or intensity of exposure?	6. Does the report describe the alternatives in adequate detail? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
Are details describing disease and treatment-related events following the intervention(s) provided? For comparisons of screening interventions for detection of cases, the treatment pathway may not be described (not applicable). If screening is followed by treatment, or for prevention studies, an event pathway should be described.	7. Is a description of the event pathway provided? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Not applicable
Were costs and consequences modeled in a decision tree with chance node probabilities derived from a variety of sources or established directly from a specific patient population? Includes Markov models. A decision analysis may have been performed even if the tree is not depicted.	8. Is a formal decision analysis performed? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Unknown/Not stated
For whom will the intervention be of value? What is the population for which an allocation decision is required?	**Target Population** 9. Is the target population for the intervention identified? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Not applicable
Is the study sample similar to the target population with respect to age, sex, severity of disease, co-morbidities, health care system jurisdiction and other characteristics relevant to the intervention and research question? If the subjects are purely hypothetical, then indicate 'Not applicable'.	10. Are the subjects representative of the population to which the intervention is targeted? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Unknown/Not stated/Can't tell ☐ 5. Not applicable
If only one is explicit and the other is not explicit but can be inferred, then indicate: Yes (inferred from text, tables, or figures). Sometimes the time horizon can be inferred from the result, e.g. costs per episode of care, annual number of cases prevented, etc. It is possible to have costs incurred over a short period (< 1year) with outcomes assessed over a longer period. In this case, the time horizon is long, with costs incurred up front.	**Time Horizon** 11. Is there a time horizon for both costs and outcomes? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No

The time frame should be long enough to capture all significant benefits, harms, and costs and relevant periods of child development. If no time horizon is stated, the response is 'no'.	12. Do the authors justify the time horizon selected? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
	Perspective 13. Is a perspective for the analysis given? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
	14. Is a societal perspective taken, either alone or in addition to other perspectives? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Unknown/Not stated
If only one perspective was studied, then check 'Not applicable'.	15. When there was more than one perspective, are the results of each perspective presented separately? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Not applicable
Does the range of costs accurately reflect the perspective? When necessary, were fixed, capital costs and overhead costs included? Were costs incurred or averted related to subsequent follow-up and treatment of disease or complications considered?	**Costs and Resource Use** 16. Are all relevant costs for each alternative included? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
In a societal perspective, these may be included as cost items (in the numerator) or as part of utility assessment (in the denominator). A patient or family perspective may also require these costs, if the lost time results in an income loss to the individual. For other perspectives, indicate 'Not applicable'. These costs may appear in the base case or in a sensitivity analysis.	17. Are opportunity costs of lost time (productivity costs) for parents and informal caregivers measured when required? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Unknown/Not stated ☐ 5. Not applicable

This would be expected for interventions such as screening or vaccination programs, that are directed at school age children. Interventions related to learning or behaviour would also involve school and/or community resources.	18. Do cost item identification and valuation extend beyond the health care system to include school and community resources when necessary? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Unknown/Not stated ☐ 5. Not applicable
Either within the stated time horizon of the study or a time horizon that is clearly appropriate for the research question. *This is relevant for papers that state that the prevention or treatment of the condition may impact on lifetime productivity as part of the rationale for doing the study.*	19. Are future salary and productivity changes of the child taken into consideration when appropriate? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Unknown/Not stated ☐ 5. Not applicable
Examples: questionnaires, interviews, chart abstraction, administrative databases, literature. *If some sources were missing or not mentioned, indicate 'No'.*	20. Were all of the sources for estimating the volume of resource use described? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
Possible sources include fee schedules, formularies, patient self-report, standard cost lists, wholesaler catalogues, case-costing databases, references to other costing papers. If some sources were missing or not mentioned, indicate 'No'.	21. Were all the sources for estimating all of the unit costs described? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
For example, cases detected, for a screening intervention.	**Outcomes** 22. Is a primary health outcome given? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
	23. Do the authors justify the health outcome(s) selected? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
Effectiveness = routine use in a diverse population; Efficacy = experimentally controlled use in a uniform population *For screening interventions, effectiveness may be expressed as sensitivity and specificity.* *"Efficacy" is sometimes the term used when "effectiveness" is really what is measured.*	24. Is effectiveness, rather than efficacy assessed? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Unknown/Not stated/Can't tell

(Check all that apply) *Prospective may include clinical trials or observational studies using surveys or questionnaires. Retrospective may include chart reviews, or databases (insurance claims, prior surveys, completed studies). Prospective or retrospective data collection may involve examining data from the study institution.*	25. What approach was used to assess the effectiveness/efficacy? ☐ 1. Prospective data collection ☐ 2. Retrospective data collection ☐ 3. Literature sources ☐ 4. Expert opinion ☐ 5. Other (Specify:_____)
Citation of a reference is inadequate (indicate 'No') as this does not permit evaluation of the quality of the evidence.	26. Are the details of the design of the effectiveness/efficacy study(s) provided? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Not applicable
This is also relevant for a CMA.	27. Are the results of the efficacy/effectiveness of alternatives reported? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Not applicable
Measurement of absences may not be applicable to studies of very young children or studies where the outcome is 'cases detected/prevented'. Measurement of absences may be a cost item to represent parental work absences or a health status/function measure.	28. Are school/day care absences taken into consideration? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Not applicable
Almost all outcomes are intermediate and include: cases detected, lab or physical function measures, symptom reduction, complication rate. End benefit would be survival or life years gained. There must be evidence to link or extrapolate the intermediate measure to the final value for survival or life years gained. For CMA, check 'not applicable'.	29. If intermediate outcome variables are used, are they linked by evidence or reference to the end benefit? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Not applicable
(Check all that apply) *If not measured, check 'Not applicable'.* *Standard generic instruments include the SF-36 and Child Health Questionnaire. If quality of life was part of a utility assessment, this is considered generic, preference-based. Direct preference includes standard gamble, time trade-off and visual analog. Indirect preference includes HUI, QWB. EQ-5D, EuroQol.*	**Quality of Life** 30. If quality of life was measured, what type of instrument was used? ☐ 1. Disease-specific ☐ 2. Generic, standard instrument ☐ 3. Generic, direct preference ☐ 4. Generic, indirect preference ☐ 5. Other (Specify:_____) ☐ 6. Not applicable

(Check all that apply) *For studies that include both children and adults, indicate the response relevant to the pediatric evaluation.*	31. Whose quality of life was assessed? ☐ 1. Child ☐ 2. Parent ☐ 3. Caregiver (if OTHER than parent) ☐ 4. Other (Specify: _____) ☐ 5. Not applicable
(Check all that apply)	32. Who performed the quality of life assessment? ☐ 1. Self assessment (child, parent or caregiver) ☐ 2. Parent on behalf of child ☐ 3. Caregiver on behalf or child ☐ 4. Health provider on behalf of child ☐ 5. Other (Specify: _____) ☐ 6. Not applicable
For example, costs should be measured in a currency unit and outcomes should be expressed as a natural unit for CEA, QALY (or equivalent) for CUA and currency unit for CBA. *If only costs or only outcomes are measured in appropriate units, then indicate 'No'.*	**Analysis** 33. Were costs AND outcomes measured in units appropriate for the indicated analytic technique? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Unknown/Not stated
(Check all that apply) *If data collection was retrospective (e.g. charts, database, literature), then check 'Not applicable'.* *The age limit for direct elicitation of responses may vary from study to study. For infants, indicate 'Not applicable'. For studies of interventions administered to pregnant or breastfeeding women, indicate 'Not applicable'.*	34. For prospective studies that used interviews, questionnaires or surveys, how were data obtained in studies involving young children? ☐ 1. Directly ☐ 2. Parent proxy ☐ 3. Other proxy (specify:_____) ☐ 4. Joint measure (specify:_____) ☐ 5. Not applicable
(Check all that apply)	35. How were direct costs valued? ☐ 1. Opportunity cost ☐ 2. Fixed, overhead, capital or administrative costs ☐ 3. Charges or fees ☐ 4. Deflated charges (using cost to charge ratios) ☐ 5. Market or wholesale prices, replacement costs ☐ 6. Average cost (per patient day, etc.) ☐ 7. Assumption, opinion, expert panel ☐ 8. Unknown/Not stated ☐ 9. Other method (specify:_____)

(Check all that apply) *Two types of Human Capital Approach:* *1. Market value = cost to hire a person, e.g. homemaker, to perform labour* *2. Opportunity cost = earned income if caregiver was in workforce* *Valuation may pertain to parent or caregiver or child's future earnings.*	36. How were productivity costs valued? ☐ 1. Market value approach ☐ 2. Opportunity cost approach ☐ 3. Average statistical wage from population database ☐ 4. Friction cost method ☐ 5. Other method (specify: _____) ☐ 6. Not applicable
When necessary, were adjustments for inflation or currency conversion made? Were costs allocated properly? Where market values were absent (e.g. volunteers), or market values did not reflect actual values, were adjustments made to approximate market values?	37. Were costs valued appropriately? ☐ 1. Yes (explicitly stated) ☐ 2 Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Unknown/Not stated/Can't tell
For example, in CBA, was the outcome monetarized using willingness-to-pay or other method? Health care savings resulting from disease prevention is insufficient as a monetarized outcome in CBA. For CUA, was utility assessed using a valid instrument or method? If assumptions or expert opinion was used to assign values for utilities or other outcome measures, indicate 'No'.	38. Was the valuation of outcomes appropriate for the type of analysis? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Unknown/Not stated/Can't tell
Check all that apply. *If the unit costs or an intermediate step express the result per patient but the final result is per population, indicate only 'per population'. If the result is expressed per study sample, then extrapolated to the population, check both. "Per family" refers to costs incurred by multiple members. "Per joint parent-child" refers to a single measure developed to link the parent and child.*	39. What was the unit of analysis used for expressing the **final** results? ☐ 1. Per child or patient or case ☐ 2. Per parent ☐ 3 Per family ☐ 4. Per joint parent-child ☐ 5. Per patient sample or study sample ☐ 6. Per population (e.g. per 10,000 or whole population)
In the case of decision analysis, if probabilities of events are stated explicitly with a description of the consumption of resources associated with each event, indicate 'Yes (explicit)'.	40. Were quantities of resources used reported separately from their unit costs? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Not applicable
Were cost items summed correctly for each perspective? Was the "math right"? *If the aggregation is not explicit but the results can be reproduced from the data provided, then indicate 'Yes (inferred from text, tables, or figures)'.*	41. Were the costs aggregated correctly? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Unknown/Not stated/Can't tell ☐ 5. Not applicable

	42. Were details of statistical tests and confidence intervals given for stochastic data? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Not applicable
Discounting is not required if the time horizon is less than or equal to 1 year (indicate 'Not applicable'). *If only costs but not benefits were discounted, check 'No'.*	**Discounting** 43. When required, were costs and consequences that occur over more than one year discounted to their present values? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Unknown/Not stated ☐ 5. Not applicable
If the time horizon was less than or equal to 1 year, check 'Not applicable'. If time horizon was greater than 1 year and costs and benefits were discounted, check 'Not applicable'. *If an explanation was not provided for benefits when costs alone were discounted, check 'No'.*	44. If costs or benefits were not discounted when the time horizon exceeded 1 year, was an explanation provided? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Not applicable
	Incremental Analysis 45. Are incremental estimates of costs and outcomes presented? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Not applicable
Were the additional cost generated by one alternative over another compared to the additional effects generated? *An incremental ratio is 'not applicable' when one alternative is dominant over the other or when a CMA is conducted. A CBA can be expressed either as a ratio or a linear equation.*	46. Are the incremental estimates summarized as incremental ratios? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Not applicable
If incremental estimates for costs and outcomes (separate or in a ratio) were not reported, then check 'No'.	47. Were confidence intervals/limits calculated for incremental ratios or incremental estimates of costs and outcomes?

	☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
(e.g. discount rates, missing or imprecise resource use, missing prices)	**Sensitivity Analysis** 48. Were all important assumptions given? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
	49. Was a sensitivity analysis performed? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
If a sensitivity analysis was not performed, then check 'No'.	50. Do the authors justify the alternative values or ranges for sensitivity analysis? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
Check all that apply.	51. What methods were used to assess uncertainty? ☐ 1. One-way sensitivity analysis ☐ 2. Two-way sensitivity analysis ☐ 3. Multi-way sensitivity analysis ☐ 4. Bootstrapping or Monte Carlo simulations ☐ 5. Other (Specify: _____) ☐ 6. None performed
For a statement of funding support in the Acknowledgements, Title page or footnote, indicate 'Yes (explicitly stated)'.	**Conflict of Interest** 52. Does the paper present the relationship with the sponsor of the study? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
If the sponsor is a government granting agency or the research was performed independently (self-supported) then response is 'not applicable'. If nothing is indicated, check 'No'.	53. Does the paper indicate that the authors had independent control over the methods and right to publish? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No ☐ 4. Not applicable
	Conclusions 54. Is the answer to the study question provided?

	☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
	55. Are the most important limitations of the study discussed? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
This relates to how the information derived from the study can be used for allocation decisions.	56. Do the authors generalize the conclusions to other settings or patient/client groups? ☐ 1. Yes (explicitly stated) ☐ 2. Yes (inferred from text, tables, or figures) ☐ 3. No
	57. Global impression of the quality of the paper. ☐ 1. Excellent ☐ 2. Very Good ☐ 3. Good ☐ 4. Fair ☐ 5. Poor ☐ 6. Worthless