

CHAPTER 4

A new instrument for the assessment of pharmacoeconomic studies

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Scorecard for the assessment of pharmacoeconomic studies

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Article title :
Article author :
Article reference (full) :
Article PMID (optional) :
Assessor's name :
Assessor's background (optional) :
Assessment date :

Nr.	Question	Explanation	Answers and scores	Weight	Score	Adjusted score	Adjusted maximum
1	RESEARCH QUESTION AND COMPETING ALTERNATIVES WELL DEFINED?						
1.1	Is the research question clearly stated?		Yes(1), No(0)	5		0	5
1.2	Is the studied patient group well defined?		Yes(1), No(0)	5		0	5
1.3	Does the study compare at least two alternative health technologies?	A pharmacoeconomic evaluation always compares two alternative health technologies, one of them can be an intervention in the control group, a placebo, or a 'do-nothing' option.	Yes(1), No(0)	5		0	5
1.4	Does the study examine both costs and outcomes of the health technologies?		Yes(1), No(0)	5		0	5
1.5	Is the alternative described comprehensively?		Yes(1), No(0)	4		0	4
1.6	Is the alternative relevant to the treatment of the patient group?		Yes(1), No(0)	4		0	4
1.7	Are any relevant alternative health technologies omitted?	Even a 'do-nothing' scenario can be a comparator.	Yes(0), No(1)	4		0	4
	TOTAL SCORE		Average	5	#DIV/0!	0	FAIL
2	EFFICACY/EFFECTIVENESS ESTABLISHED?						
2.1	Is the study demonstrating effectiveness rather than efficacy?	Efficacy is defined as the maximum effect under ideal circumstances, e.g. laboratory data, while effectiveness measures the effect in real life daily practice, e.g. dealing with patients' lack of compliance.	Yes(1), No(0), N/A	5		0	5
	If efficacy, proceed to 2.2, 2.3 and/or 2.4 (more than one of these sections may apply) If effectiveness, proceed to 2.5						
2.2	Does the evidence concern a single study?						
2.2.1	Is the evidence gathered prospectively (versus retrospectively)?	Data collection from historical medical files is retrospective.	Yes(1), No(0)	3		0	0
2.2.2	Is there selection bias?	Selection bias is defined as the systematic differences between patient groups in terms of characteristics of patients, groups, caregivers,...	Yes(0), No(1)	4		0	0
2.2.3	Is there performance bias?	Performance bias is defined as the systematic differences in care provided to patient groups apart from the intervention being evaluated.	Yes(0), No(1)	4		0	0
2.2.4	Is there attrition (exclusion) bias?	Attrition bias is defined as the systematic differences between patient groups in terms of dropouts and withdrawal over time.	Yes(0), No(1)	4		0	0
2.2.5	Is there detection bias?	Detection bias is defined as the systematic differences in the method as to how efficacy or outcome is evaluated.	Yes(0), No(1)	4		0	0
2.2.6	Is possible bias in the efficacy results or in the methodology mentioned or discussed?		Yes(1), No(0)	4		0	0
	PROCEED TO SECTION 3		Average	3.8			
2.3	Does the evidence concern a systematic review of trials?						
2.3.1	Are the search strategy and rules for inclusion and exclusion outlined?		Yes(1), No(0)	4		0	0
2.3.2	Are differences in design between studies discussed?		Yes(1), No(0)	4		0	0
2.3.3	Are different outcome parameters between studies comparable?		Yes(1), No(0)	4		0	0
2.3.4	Are different outcome parameters extrapolated to a comparable time frame or number of patients?	In order to compare outcome parameters it is necessary to extrapolate the values to a comparable time frame or number of patients.	Yes(1), No(0)	4		0	0
2.3.5	Are outcomes discounted to a reference year?	In order to compare monetary values it is necessary to discount them to a reference year when the time horizon is longer than one year.	Yes(1), No(0)	3		0	0
2.3.6	Did the author explain and justify the methodology used to generate the efficacy data?		Yes(1), No(0)	4		0	0
	PROCEED TO SECTION 3		Average	3.8			
2.4	Does the evidence concern an expert opinion?						
2.4.1	Is there bias in the efficacy results or the methodology?		Yes(0), No(1)	4		0	0
2.4.2	Is possible bias in the efficacy results or in the methodology mentioned or discussed?		Yes(1), No(0)	4		0	0
2.4.3	Is the conclusion based on a single expert opinion rather than a consensus of a panel of experts?		Yes(0), No(1)	3		0	0
2.4.4	Is the composition of the expert panel relevant for all aspects of the research domain?		Yes(1), No(0)	3		0	0
2.4.5	Is there a justification for the assumptions made by the author or the expert panel?		Yes(1), No(0)	4		0	0
	PROCEED TO SECTION 3		Average	3.6			
2.5	Does the evidence study effectiveness (rather than efficacy)?						
2.5.1	Is the evidence gathered prospectively (versus retrospectively)?		Yes(1), No(0)	3		0	0
2.5.2	Are individual patient data used (instead of assumptions or an expert opinion)?		Yes(1), No(0)	4		0	0
2.5.3	Is the selection of the method, used to compare the effectiveness data of the individual studies, discussed?		Yes(1), No(0)	4		0	0
2.5.4	Is there selection bias?	Selection bias is defined as the systematic differences between patient groups in terms of characteristics of patients, groups, caregivers, ...	Yes(0), No(1)	4		0	0
2.5.5	Is there performance bias?	Performance bias is defined as the systematic differences in care provided to patient groups apart from the intervention being evaluated.	Yes(0), No(1)	4		0	0
2.5.6	Is there attrition (exclusion) bias?	Attrition bias is defined as the systematic differences between patient groups in terms of dropouts and withdrawal over time.	Yes(0), No(1)	4		0	0
2.5.7	Is there detection bias?	Detection bias is defined as the systematic differences in the method as to how efficacy or outcome is evaluated.	Yes(0), No(1)	4		0	0
	PROCEED TO SECTION 3		Average	3.9			
	TOTAL SCORE				#DIV/0!	#DIV/0!	#DIV/0!

Nr.	Question	Explanation	Answers and scores	Weight	Score	Adjusted score	Adjusted maximum
3.	COSTS AND OUTCOMES?						
	COSTS (identification, measurement, valuation)						
3.1	Are the studied costs clearly defined?		Yes(1), No(0)	5		0	5
3.2	Are the studied costs relevant to the research question?		Yes(1), No(0)	4		0	4
3.3	Does the study consider all the significant costs that are relevant to the research question?		Yes(1), No(0)	4		0	4
3.4	Are costs clear and relevant for each alternative health technology?		Yes(1), No(0)	4		0	4
3.5	If relevant, are capital costs, e.g. costs of infrastructure, included?		Yes(1), No(0), N/A	3		0	3
3.6	Are relevant operating costs and labour costs included?	Conducting a study or running a service programme costs money and requires the necessary personnel. These costs should be included in the PE evaluation.	Yes(1), No(0), N/A	3		0	3
3.7	Are only drug costs considered?	Diagnostic procedures can also generate costs.	Yes(0), No(1), N/A	4		0	4
3.8	Are relevant indirect cost, e.g. productivity loss, assessed (besides direct healthcare costs)?	Indirect costs describes costs which are not directly or obviously associated with the healthcare intervention, such as loss of productivity due to illness or disability.	Yes(1), No(0), N/A	3		0	3
3.9	Are the data sources of costs described and justified?	Where does the data come from and are these data relevant to the question?	Yes(1), No(0)	4		0	4
3.10	Is the valuation, e.g. market/patient values, of costs described and justified?	The valuation of costs is relative to the perspective of the study, e.g. a company is interested in an acquisition price while the government will be interested in a reimbursement price.	Yes(1), No(0)	4		0	4
3.11	Is the valuation of costs relevant to the perspective of the study?		Yes(1), No(0)	4		0	4
3.12	Are costs adjusted to values on a reference date, e.g. the start of the observation period or intervention?	Adjustment of costs is necessary when the time horizon exceeds one year.	Yes(1), No(0),N/A	4		0	4
3.13	Are basic costs derived from expert opinion rather than based on objective data?		Yes(0), No(1)	3		0	3
3.14	Are tools and evaluating procedures validated?	Evaluation procedures and tools are developed for specific settings. In order to use them in another setting they should be validated. This can be done by using it on reference data and applying a sensitivity analysis for uncertain parameters.	Yes(1), No(0)	3		0	3
			Average	3.7	#DIV/0!	0	
	OUTCOMES (identification, measurement, valuation)						
3.15	Are the studied outcomes clearly defined?		Yes(1), No(0)	5		0	5
3.16	Are the studied outcomes relevant to the research question?		Yes(1), No(0)	5		0	5
3.17	Does the study consider all the significant costs/outcomes that are relevant to the research question?		Yes(1), No(0)	4		0	4
3.18	Are outcomes clear and relevant for each alternative health technology?		Yes(1), No(0)	4		0	4
3.19	Are the data sources of outcomes described and justified?		Yes(1), No(0)	4		0	4
3.20	Is the valuation of outcomes described and justified?	The method of valuing an outcome can be different, e.g. valuing the quality of life associated with a health state by means of utilities in a cost-utility analysis; valuing the benefits of a technology by means of willingness-to-pay in a cost-benefit analysis. This method should be mentioned and justified to have the correct interpretation of the data.	Yes(1), No(0)	4		0	4
3.21	Is the valuation of outcomes relevant to the perspective of the study?	The method of valuation should be relevant to the perspective.	Yes(1), No(0)	3		0	3
3.22	Are costs adjusted to values on a reference date, e.g. the start of the observation period or intervention?	Adjustment of values is necessary when the time horizon exceeds one year.	Yes(1), No(0), N/A	3		0	3
3.23	Are outcomes derived from expert opinion rather than based on objective data?		Yes(0), No(1)	4		0	4
3.24	Are multiple outcome measures combined into a single index to get an idea of the overall effectiveness?		Yes(1), No(0)	4		0	4
3.25	Are outcome measures related to final outcomes, e.g. mortality, versus intermediate outcomes, e.g. need to restart IV		Yes(1), No(0)	3		0	3
3.26	Are tools and evaluating procedures validated?	Evaluation procedures and tools are developed for specific settings. In order to use them in another setting they should be validated. This can be done by using it on reference data and applying a sensitivity analysis for uncertain parameters.	Yes(1), No(0)	3		0	3
			Average	3.8	#DIV/0!	0	
	TOTAL SCORE		Average	3.8	#DIV/0!	0	FAIL
4	METHODOLOGICAL QUALITY AND CONCLUSIONS?						
4.1	Is a sensitivity analysis conducted?	A sensitivity analysis determines the direction and the extent to which the results of the economic evaluation vary when estimates of input variables change.	Yes(1), No(0)	5		0	5
4.2	Did the author justify the choice of method used to perform the sensitivity analysis?		Yes(1), No(0)	4		0	4
4.3	Is there a justification for the range of the sensitivity analysis?		Yes(1), No(0)	3		0	3
4.4	Do the conclusions reflect the uncertainty in the data?	When data and findings are uncertain this should be reflected in the conclusions.	Yes(0), No(1)	4		0	4
4.5	Is potential bias in the used methodology discussed?	Every methodology has its own bias for each setting, the author should discuss this potential bias and its impact on conclusions.	Yes(1), No(0)	3		0	3
4.6	Does the study cover a representative period of time?		Yes(1), No(0)	4		0	4
4.7	Is the studied population representative of the whole population?		Yes(1), No(0)	3		0	3
4.8	Are the conclusions clearly defined and understandable?		Yes(1), No(0)	5		0	5
4.9	Are the differences in costs compared to differences in outcome?	Does the author mention how much it costs to achieve the better outcome?	Yes(1), No(0)	4		0	4
4.10	Is this ratio interpreted intelligently (versus in a mechanistic fashion)?	When expressing the ratio of differences in costs to differences in outcomes, this number should be interpreted intelligently rather than just comparing it with another ratio, e.g. in case of dominance the ratio will be very small.	Yes(1), No(0)	3		0	3
4.11	Are the results compared with those of other studies investigating the same question?	Other authors have possibly studied the same question. Obviously the author should compare the outcome to that of other investigators.	Yes(1), No(0)	3		0	3
4.12	Does the study discuss the generalisability of the results to other settings?		Yes(1), No(0)	4		0	4
4.13	Does the study take account of other important factors in the choice or decision under consideration, e.g. ethical issues?		Yes(1), No(0)	2		0	2
	TOTAL SCORE		Average	3.6	#DIV/0!	0	FAIL
	GENERAL SCORE				#DIV/0!	#DIV/0!	

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Nr.	Question	Explanation	Answers and scores	Weight	Score	Adjusted score	Adjusted maximum
5	TRANSFERABILITY TO YOUR SETTING						
5.1	Does the evidence discuss transferability to your settings or patient groups?		Yes(1), No(0)	4		0	4
5.2	Are the characteristics of the setting transferable to your own setting?		Yes(1), No(0)	3		0	3
5.3	Is the patient population transferable to your setting?		Yes(1), No(0)	3		0	3
5.4	Is the studied health technology compliant with local laws in your setting?		Yes(1), No(0)	3		0	3
5.5	Are all relevant alternative health technologies, used in your setting, included?		Yes(1), No(0)	3		0	3
5.6	Are the relevant cost data transferable to your setting?		Yes(1), No(0)	3		0	3
5.7	Are the relevant outcome data transferable to your setting?		Yes(1), No(0)	4		0	4
5.8	Is the study done from a perspective relevant to your interest?		Yes(1), No(0)	3		0	3
5.9	Is the perspective relevant to the research question?		Yes(1), No(0)	4		0	4
5.10	Is the research question relevant to your decision-making context?		Yes(1), No(0)	2		0	2
5.11	Are all calculations on key values transparent (so you can use them in your setting)?		Yes(1), No(0)	3		0	3
5.12	Is the effect of the relevant characteristics of the setting on the result considered, e.g. type of hospital, ward, expertise, ...?		Yes(1), No(0)	2		0	2
5.13	Are numbers and prices mentioned separately?	If not, it's not possible to compare the monetary values because your setting is probably dealing with other prices.	Yes(1), No(0)	4		0	4
TOTAL SCORE			Average	3.2	#DIV/0!	0	FAIL
OVERALL SCORE (multiplication 1-4 x 5)					#DIV/0!	#DIV/0!	

Methodological quality	#DIV/0!	#DIV/0!
Nr. sections passed (1-4)	0	FAIL
Transferability	0.00	FAIL
Combined score	#DIV/0!	#DIV/0!

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