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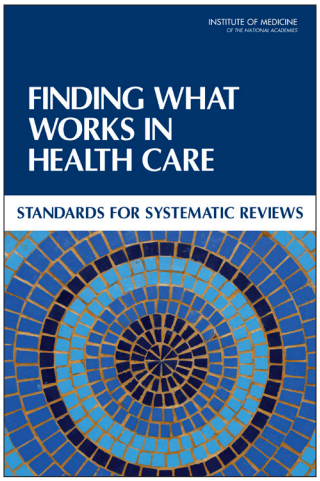
Finding What Works in Health Care

Standards for Systematic Reviews

These standards are for systematic reviews of comparative effectiveness research of therapeutic medical or surgical interventions



Standards for Initiating a Systematic Review

STANDARD 2.1
Establish a team with appropriate expertise and experience to conduct the systematic review

- **2.1.1** Include expertise in the pertinent clinical content areas
- **2.1.2** Include expertise in systematic review methods
- **2.1.3** Include expertise in searching for relevant evidence
- **2.1.4** Include expertise in quantitative methods
- **2.1.5** Include other expertise as appropriate

STANDARD 2.2
Manage bias and conflict of interest (COI) of the team conducting the systematic review

- **2.2.1** Require each team member to disclose potential COI and professional or intellectual bias
- **2.2.2** Exclude individuals with a clear financial conflict
- **2.2.3** Exclude individuals whose professional or intellectual bias would diminish the credibility of the review in the eyes of the intended users

STANDARD 2.3
Ensure user and stakeholder input as the review is designed and conducted

- **2.3.1** Protect the independence of the review team to make the final decisions about the design, analysis, and reporting of the review

STANDARD 2.4
Manage bias and COI for individuals providing input into the systematic review

- **2.4.1** Require individuals to disclose potential COI and professional or intellectual bias
- **2.4.2** Exclude input from individuals whose COI or bias would diminish the credibility of the review in the eyes of the intended users

STANDARD 2.5
Formulate the topic for the systematic review

- **2.5.1** Confirm the need for a new review
- **2.5.2** Develop an analytic framework that clearly lays out the chain of logic that links the health intervention to the outcomes of interest and defines the key clinical questions to be addressed by the systematic review
- **2.5.3** Use a standard format to articulate each clinical question of interest
- **2.5.4** State the rationale for each clinical question
- **2.5.5** Refine each question based on user and stakeholder input

STANDARD 2.6
Develop a systematic review protocol

- **2.6.1** Describe the context and rationale for the review from both a decision-making and research perspective
- **2.6.2** Describe the study screening and selection criteria (inclusion/exclusion criteria)
- **2.6.3** Describe precisely which outcome measures, time points, interventions, and comparison groups will be addressed
- **2.6.4** Describe the search strategy for identifying relevant evidence
- **2.6.5** Describe the procedures for study selection
- **2.6.6** Describe the data extraction strategy
- **2.6.7** Describe the process for identifying and resolving disagreement between researchers in study selection and data extraction decisions
- **2.6.8** Describe the approach to critically appraising individual studies
- **2.6.9** Describe the method for evaluating the body of evidence, including the quantitative and qualitative synthesis strategies
- **2.6.10** Describe and justify any planned analyses of differential treatment effects according to patient subgroups, how an intervention is delivered, or how an outcome is measured
- **2.6.11** Describe the proposed timetable for conducting the review

STANDARD 2.7
Submit the protocol for peer review

- **2.7.1** Provide a public comment period for the protocol and publicly report on disposition of comments

STANDARD 2.8
Make the final protocol publicly available, and add any amendments to the protocol in a timely fashion

Standards for Finding and Assessing Individual Studies

STANDARD 3.1
Conduct a comprehensive systematic search for evidence

- **3.1.1** Work with a librarian or other information specialist trained in performing systematic reviews to plan the search strategy
- **3.1.2** Design the search strategy to address each key research question
- **3.1.3** Use an independent librarian or other information specialist to peer review the search strategy
- **3.1.4** Search bibliographic databases
- **3.1.5** Search citation indexes
- **3.1.6** Search literature cited by eligible studies
- **3.1.7** Update the search at intervals appropriate to the pace of generation of new information for the research question being addressed
- **3.1.8** Search subject-specific databases if other databases are unlikely to provide all relevant evidence
- **3.1.9** Search regional bibliographic databases if other databases are unlikely to provide all relevant evidence

STANDARD 3.2
Take action to address potentially biased reporting of research results

- **3.2.1** Search grey literature databases, clinical trial registries, and other sources of unpublished information about studies
- **3.2.2** Invite researchers to clarify information about study eligibility, study characteristics, and risk of bias
- **3.2.3** Invite all study sponsors and researchers to submit unpublished data, including unreported outcomes, for possible inclusion in the systematic review
- **3.2.4** Handsearch selected journals and conference abstracts
- **3.2.5** Conduct a web search
- **3.2.6** Search for studies reported in languages other than English if appropriate

STANDARD 3.3
Screen and select studies

- **3.3.1** Include or exclude studies based on the protocol's prespecified criteria
- **3.3.2** Use observational studies in addition to randomized clinical trials to evaluate harms of interventions
- **3.3.3** Use two or more members of the review team, working independently, to screen and select studies
- **3.3.4** Train screeners using written documentation; test and retest screeners to improve accuracy and consistency
- **3.3.5** Use one of two strategies to select studies: (1) read all full-text articles identified in the search or (2) screen titles and abstracts of all articles and then read the full text of articles identified in initial screening
- **3.3.6** Taking account of the risk of bias, consider using observational studies to address gaps in the evidence from randomized clinical trials on the benefits of interventions

STANDARD 3.4
Document the search

3.4.1 Provide a line-by-line description of the search strategy, including the date of every search for each database, web browser, etc.

3.4.2 Document the disposition of each report identified including reasons for their exclusion if appropriate

STANDARD 3.5
Manage data collection

3.5.1 At a minimum, use two or more researchers, working independently, to extract quantitative and other critical data from each study. For other types of data, one individual could extract the data while the second individual independently checks for accuracy and completeness. Establish a fair procedure for resolving discrepancies—do not simply give final decision-making power to the senior reviewer

3.5.2 Link publications from the same study to avoid including data from the same study more than once

3.5.3 Use standard data extraction forms developed for the specific systematic review

3.5.4 Pilot-test the data extraction forms and process

STANDARD 3.6
Critically appraise each study

3.6.1 Systematically assess the risk of bias, using predefined criteria

3.6.2 Assess the relevance of the study's populations, interventions, and outcome measures

3.6.3 Assess the fidelity of the implementation of interventions

Standards for Synthesizing the Body of Evidence

NOTE: The order of the standards does not indicate the sequence in which they are carried out.

STANDARD 4.1
Use a prespecified method to evaluate the body of evidence

4.1.1 For each outcome, systematically assess the following characteristics of the body of evidence:
- Risk of bias
- Consistency
- Precision
- Directness
- Reporting bias

4.1.2 For bodies of evidence that include observational research, also systematically assess the following characteristics for each outcome:
- Dose-response association
- Plausible confounding that would change the observed effect
- Strength of association

4.1.3 For each outcome specified in the protocol, use consistent language to characterize the level of confidence in the estimates of the effect of an intervention

STANDARD 4.2
Conduct a qualitative synthesis

4.2.1 Describe the clinical and methodological characteristics of the included studies, including their size, inclusion or exclusion of important subgroups, timeliness, and other relevant factors

4.2.2 Describe the strengths and limitations of individual studies and patterns across studies

4.2.3 Describe, in plain terms, how flaws in the design or execution of the study (or groups of studies) could bias the results, explaining the reasoning behind these judgments

4.2.4 Describe the relationships between the characteristics of the individual studies and their reported findings and patterns across studies

4.2.5 Discuss the relevance of individual studies to the populations, comparisons, cointerventions, settings, and outcomes or measures of interest

STANDARD 4.3
Decide if, in addition to a qualitative analysis, the systematic review will include a quantitative analysis (meta-analysis)

4.3.1 Explain why a pooled estimate might be useful to decision makers

STANDARD 4.4
If conducting a meta-analysis, then do the following:

4.4.1 Use expert methodologists to develop, execute, and peer review the meta-analyses

4.4.2 Address the heterogeneity among study effects

4.4.3 Accompany all estimates with measures of statistical uncertainty

4.4.4 Assess the sensitivity of conclusions to changes in the protocol, assumptions, and study selection (sensitivity analysis)

Standards for Reporting Systematic Reviews

STANDARD 5.1
Prepare final report using a structured format

5.1.1 Include a report title

5.1.2 Include an abstract

5.1.3 Include an executive summary

5.1.4 Include a summary written for the lay public

5.1.5 Include an introduction (rationale and objectives)

5.1.6 Include a methods section. Describe the following:

- Research protocol
- Eligibility criteria (criteria for including and excluding studies in the systematic review)
- Analytic framework and key questions
- Databases and other information sources used to identify relevant studies
- Search strategy
- Study selection process
- Data extraction process
- Methods for handling missing information
- Information to be extracted from included studies
- Methods to appraise the quality of individual studies
- Summary measures of effect size (e.g., risk ratio, difference in means)
- Rationale for pooling (or not pooling) results of included studies
- Methods of synthesizing the evidence (qualitative and meta-analysis)
- Additional analyses, if done, indicating which were prespecified

5.1.7 Include a results section. Organize the presentation of results around key questions. Describe the following (repeat for each key question):

- Study selection process
- List of excluded studies and reasons for their exclusion
- Appraisal of individual studies' quality
- Qualitative synthesis
- Meta-analysis of results, if performed (explain rationale for doing one)
- Additional analyses, if done, indicating which were prespecified
- Tables and figures

5.1.8 Include a discussion section. Include the following:

- Summary of the evidence
- Strengths and limitations of the systematic review
- Conclusions for each key questions
- Gaps in evidence
- Future research needs

5.1.9 Include a section describing funding sources and COI

STANDARD 5.2
Peer review the draft report

5.2.1 Use a third party to manage the peer review process

5.2.2 Provide a public comment period for the report and publicly report on disposition of comments

STANDARD 5.3
Publish the final report in a manner that ensures free public access

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