Abstract

The umbrella review is a synthesis of systematic reviews which allows the results of relevant assessments in a review question can be compared and contrasted. The umbrella review this type of synthesis evidence only considers the inclusion of the higher level of evidence, i.e., systematic reviews and meta-analysis. The purpose of this article is to describe the methodology and methods developed for driving an umbrella review in cardiovascular research.

Introduction

Systematic reviews (SR) are pivotal to the practice of healthcare based on evidence, and they also provide the highest level of evidence to guide the decision-making process.1-4

SRs offer rigorous information so that decision-makers use the best evidence available to make decisions. Due to the growing number of available SRs, the next logical step would be to evaluate them, which allows the results of separated analyses to be compared and contrasted and also provides better evidence to decision-makers.5-6

The reason for an umbrella review (UR) is the necessity to summarize the evidence of numerous research synthesis and also offer a quick evaluation of the evidence elements to treat a comprehensive high-quality evidence based on one topic.7

Moreover, a UR allows an evaluation on review topics of similar questions, and with that we can obtain similar results independently and arrive at generally similar conclusions. The objective of a UR is to provide a global vision of results for particular questions or phenomena. It can provide a more comprehensive view of several treatments, and thus more usefully give the guidelines and clinical practices when all management options need to be considered.8

UR evaluation methodology – summary of evidence and research syntheses

A UR must be preceded by a peer review protocol and include a clear question, detailed inclusion criteria, a structured research process to locate and select relevant existing studies, a critical evaluation method of the included studies and a formal process for data extraction, followed by a summary and presentation of that data. The main objective of a UR is to provide a summary of existing review syntheses related to a certain topic or question and not to re-synthesize the results of existing reviews or syntheses as it happens in a meta-analyses or meta-syntheses.1-3

Inclusion objectives and criteria

The objective of a UR must be clearly indicated. The objectives must be comprehensive and inform the specificities of the UR. Inclusion criteria should indicate the fundamentals for which the available studies will be considered for inclusion, serve as a guideline for the reader to clearly understand what is being proposed by the authors, and be the base of selection for studies to be included during the screening phase of the UR.3

One of the unique characteristics of a UR is that all the analysis units, or studies to be included, are extracted exclusively from systematic reviews and meta-analyses, and not from primary or original research. The presentation of a UR’s inclusion

Keywords

Evidence-Based Medicine; Evidence-Based Practice; Epidemiology; Review.

Understanding Umbrella Review of the Cardiovascular Research

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criteria must review the efficacy assessment of an intervention (population, intervention, comparator, result). All the presented inclusion criteria must be coherent with the review objective and with the question to be answered.1-3

Types of participants
Participants characteristics must be detailed, including age, gender, ethnicity, body mass index, among other qualification criteria that must clearly define each group.1-3

Interventions and interest phenomena
Interventions may be focused – i.e. consider only drug treatments, diets, exercise, or behavioral therapy of a group of patients – or broad – including pharmacological and other types of intervention (i.e. therapy, devices, diets, exercise, surgery). URs that include multiple interventions and treatments should clearly define each interest potential intervention.1-3

Context and setting
The context should be clearly defined and may include, without being limited to, a counterpart of geographical location or cultural factors, as well as gender and ethnicity. In some cases, it may also comprehend details on the specific health context, such as intensive and primary care, and community health.1-3

Outcome
Interest outcomes must be pre-defined in a UR. Also, results must be relevant to the determined question, and adopted measures must be included in the description and in the use of the health questionnaires. Substitute outcomes must be explained and presented when there is a clear association with the patient and the results, and beneficial and adverse results must be reported.1-3

Types of study
The UR should only include systematic reviews and meta-analyses. In this section, the investigation methodology and synthesis must be considered for the studies to be included in the UR.1-3

Search strategy
The search strategy for a UR must aim to identify all the research synthesis relevant to the evaluation of the question. Moreover, the search must be comprehensive, and employed research filters must be detailed and presented in a sequential way, together with research dates and databanks of biomedical citations,1-3 in only one appendix for all the researched databanks.

UR results presentation
An introductory section for UR results must start with a narrative description of the review process, accompanied by a flow-chart, as stipulated in the items of the preferred report for systematic reviews and meta-analyses. This section must provide a sufficient context for the results. For the results to support the inclusion of the synthesis of investigation in the UR, the relevance of the research synthesis must include the critical question of the UR.1-3

Qualities of the methodology
Systematic reviews and meta-analyses that are eligible for inclusion in a UR must be assessed by the available tools to evaluate the research synthesis, which includes AMSTAR and ROBIS.9-10

A list for the critical evaluation of UR has been recently developed, and is depicted in Table 1.2

The quality evaluation results presentation must include a global methodological descriptive summary of the quality of included studies.

UR findings
To minimize the risk of biases in the UR process, it is recommended to use a standard data extraction tool that must be employed by two independent reviewers to extract the data of each study. This information should include the following:2
a) Citation details;
b) Review inclusion objectives and criteria;
c) Type of evaluation;
d) Participants’ details;
e) Definition and context;
f) Number of databanks researched;
g) Date of databank search;
h) Publication date of the studies included in the evaluation, and the information of each interest outcome;

i) Several studies, types of study and country of origin included in each evaluation;

j) The used instrument to assess the primary studies and classification of their quality;

l) The reported results that are relevant to the UR question;

m) The synthesis method of the synthesis/analysis employed to synthesize the evidence;

n) UR authors’ comments or notes that may concern any study inclusion.

The interest details for the UR, such as the range of interventions, interest phenomena, population details or result differences must be extracted in detail. The presentation of the findings and results must be in line with the UR question and be presented according to Table 2.11-12

When the evidence is qualitative, results must be presented according to Table 3.

Evidence summary

The evidence summary for quantitative and qualitative results are presented in Table 4.

In conclusion, UR is a summary of the synthesis of systematic reviews about a certain topic, which should be used in healthcare, is based on evidence, and should be used in the decision-making process.

Author contributions

Conception and design of the research, Acquisition of data, Analysis and interpretation of the data, Writing of the manuscript and Critical revision of the manuscript for intellectual content: Borges LSR e Biondi-Zoccai G.

Potential Conflict of Interest

Dr. Giuseppe Biondi-Zoccai received assistance from lectures and consultancies by Novartis and Bayer.

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Study Association

This study is not associated with any thesis or dissertation work.

<table>
<thead>
<tr>
<th>Table 1 – Critical evaluation of a UR</th>
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<tbody>
<tr>
<td>Is the question clear and explicit?</td>
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<td>Were the inclusion criteria appropriate for the review question?</td>
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<tr>
<td>Was the search strategy appropriate?</td>
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<tr>
<td>Were the sources and resources used to find the adequate studies?</td>
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<tr>
<td>Were the criteria to evaluate the studies appropriate?</td>
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<td>Was the critical review done independently by two or more reviewers?</td>
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<td>Were the methods used to combine the studies appropriate?</td>
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<td>Was the probability of publication bias assessed?</td>
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<tr>
<td>Were the recommendations for the policies and/or practices supported by the reported data?</td>
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<tr>
<td>Were the guidelines specific and adequate for the new investigation?</td>
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<th>Table 2 – Tabulation of quantitative results for a UR</th>
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<tr>
<td>Review topic</td>
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<tr>
<td>Intervention</td>
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Table 3 – Tabulation of qualitative results for a UR

<table>
<thead>
<tr>
<th>Review topics</th>
<th>Synthesized findings</th>
<th>Strategy details</th>
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<tbody>
<tr>
<td>Interest phenomena/context</td>
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Table 4 – Evidence summary of the research synthesis

<table>
<thead>
<tr>
<th>Quantitative</th>
<th>Intervention</th>
<th>Author/year</th>
<th>Topic (example: heart failure)</th>
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References