



## REVIEW ARTICLE

# Agency for Healthcare Research and Quality Evidence-based Practice Center methods provide guidance on prioritization and selection of harms in systematic reviews

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**Abstract**

**Objectives:** Systematic reviews should provide balanced assessments of benefits and harms, while focusing on the most important outcomes. Selection of harms to be reviewed can be a challenge due to the potential for large numbers of diverse harms.

**Study Design and Setting:** A workgroup of methodologists from Evidence-based Practice Centers (EPCs) developed consensus-based guidance on selection and prioritization of harms in systematic reviews. Recommendations were informed by a literature scan, review of Evidence-based Practice Center reports, and interviews with experts in conducting reviews or assessing harms and persons representing organizations that commission or use systematic reviews.

**Results:** Ten recommendations were developed on selection and prioritization of harms, including routinely focusing on serious as well as less serious but frequent or bothersome harms; routinely engaging stakeholders and using literature searches and other data sources to identify important harms; using a prioritization process (formal or less formal) to inform selection decisions; and describing the methods used to select and prioritize harms.

**Conclusion:** We provide preliminary guidance for a more structured approach to selection and prioritization of harms in systematic reviews. © 2018 Elsevier Inc. All rights reserved.

**Keywords:** Harms; Systematic reviews; Comparative effectiveness review; Study methodology; Recommendations; Adverse effects

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**1. Introduction**

Systematic reviews of interventions impacting health should provide balanced assessments of harms and benefits.

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In 2005, a White Paper funded by the Agency for Healthcare Research and Quality (AHRQ) highlighted challenges in synthesizing evidence on harms in systematic reviews [1].

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**What is new?****Key findings**

- Guidance on selection and prioritization of harms for inclusion in systematic reviews is lacking.

**What this adds to what was known?**

- Recommendations on methods for prioritizing and selection of harms were developed using a consensus process and informed by a literature scan and expert interviews.

**What is the implication and what should change now?**

- Clearer methods may help support reviewer decisions regarding selection of harms and help focus systematic reviews on the harms of greatest importance.

Subsequently, recommendations for synthesizing evidence on harms were developed and published in 2010 as a chapter in the AHRQ Evidence-based Practice Center (EPC) Program Methods Guide (Table 1) [2]. In 2015, AHRQ convened an EPC Methods Workgroup to update or expand on prior guidance for assessing harms. The workgroup elected to focus on prioritization and selection of harms in systematic reviews. Although the 2010 harms chapter recommended that EPC systematic reviews “always assess harms that are important to clinicians and patients,” the workgroup concluded that it lacked more specific recommendations and noted important challenges in this area. Unlike benefits, which are often similar across interventions for a given condition (e.g., medications, nonpharmacological therapies, and surgery for low back pain all aim to improve pain and function), different interventions for the same condition are frequently associated with diverse harms. For example, medications for low back pain are typically associated with harms distinct from surgical harms, and each medication class has unique harms. Other issues include whether to assess composite harms (e.g., “serious harms” or “withdrawal due to adverse events”) and how to address harms not specified in the original protocol but encountered during the review. Clearer methods would help support decisions regarding selection of harms and help focus systematic reviews on the outcomes of greatest importance.

The purpose of this report is to provide guidance on prioritizing and selecting harms for inclusion in systematic reviews. The immediate intended audience is the EPC program, though this guidance may be useful to all systematic reviewers and those who commission or use systematic reviews.

**2. Methods***2.1. Approach*

We assembled a workgroup of 12 methodologists from AHRQ, the EPC program, and the Scientific Resource Center (SRC) to develop recommendations on selection and prioritization of harms. To inform the development of recommendations, members sought information on selection and prioritization of harms through a literature search, a review of EPC reports, and interviews with experts. Detailed methods and data are available in the full report available on the AHRQ website: <https://effectivehealthcare.ahrq.gov/search/repor-types/MethodsGuideChapter/>.

*2.2. Literature search and review*

The SRC curates a bibliographic database on the methodology of systematic reviews and comparative effectiveness research [3]. The SRC librarian performed a search for articles published since 2007 (the year that the AHRQ EPC Program Methods Guide harms chapter was published) on “harms” or “adverse events” in the SRC Methods Library database ( $n = 357$ ) in November 2015 [2]. Two workgroup members (R.C. and N.S.) reviewed citations to identify articles providing guidance or empiric research on methods for selecting and prioritizing harms in systematic reviews. Because we anticipated sparse empiric research and sought literature to inform discussions and provide context, we did not apply strict eligibility criteria.

*2.3. Review of EPC reports*

From a nonrandom sample of 18 reports published in or after 2014 from various EPCs on a diversity of interventions, a workgroup member (L.S.) abstracted the year of publication, key questions related to harms and assessed harms, methods for prioritizing or selecting harms, data sources on harms, and main harms findings. We categorized harms as “individual” or “composite” harms; composite harms included measures such as any harm, serious harms, or withdrawal due to adverse events.

*2.4. Key informant interviews*

The SRC invited 14 key informants (KI) with expertise in conduct of reviews, assessment of harms in reviews, and/or representing organizations that commission and use systematic reviews for interviews guided by 12 questions on the following topics (Appendix A):

- Use of published guidance for prioritization and selection of harms
- Criteria for prioritizing harms
- Use of input from stakeholders to guide prioritization and selection of harms

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