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Using the Grey Literature to Identify Best Evidence

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This information brief shares important concepts about searching for and using studies from non-traditional, usually non-peer-reviewed studies—*the grey literature*—in order to identify best evidence on clinical questions. We first present an overview of evidence-based practice and the systematic review process, focusing on questions of intervention effectiveness, which involves extensive searching of the vast literature found in peer-reviewed scientific journals and study selection. If little is found, search of the grey literature can identify additional studies that further one's understanding of best evidence. We offer recommendations on search strategies and sources and on evaluating and synthesizing evidence from both traditional and grey literature to draw conclusions. Finally, we summarize guidance for using grey literature in intervention study reviews.

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Introduction

Evidence-based practice (EBP) involves a systematic process to identify best evidence and to translate it into recommendations for clinical practice (GRADE Working Group, 2023; Sackett et al., 1996; Seel et al., 2012). To identify best evidence, the literature search needs to be complete; it should not overlook relevant studies, issues, or data. Systematic reviews in health care and rehabilitation are based on evidence derived from searches of scientific databases that catalog published, peer-reviewed studies. This search strategy, coupled with expert panel knowledge of the literature, is usually sufficient to identify the full range of available quality data on a clinical question (Gronseth et al., 2017; Straus et al., 2018).

Current evidence review processes are based on searches of the peer-reviewed scientific journals indexed in major health-related databases (Johnston & Dijkers, 2012). Peer review is a valuable process to screen for higher quality studies but may be of variable quality and does not function as a substitute for a thorough evaluation of level and type of evidence and conclusions supported by the study methodology and data. There are circumstances in which systematic reviewers, researchers, and clinical leaders who want true expertise in a clinical topic will find it valuable to go beyond the usual peer-reviewed literature and searches of the most popular databases to obtain a complete understanding of existing evidence on a topic. The additional literature to be searched is typically referred to as the *grey literature*.

Frankly, search of major health-related databases (e.g., MEDLINE, Cochrane, and PsycINFO for behavioral interventions) with a detailed appraisal and summary of results is itself a substantial effort for clinicians. A formal evidence synthesis using extant, best-respected, and best-developed methods (e.g., American Academy of Neurology, Cochrane, GRADE, and others) is a much greater effort, though necessary to truly identify and synthesize best evidence on a defined topic. Grey literature searches are time intensive and add to the burden of conducting the literature search, and there is no guarantee that good quality, relevant additional evidence will result.

There are, however, circumstances that motivate additional literature search and synthesis to go beyond the usual literature to ensure that *all* relevant, potentially good evidence is found and reviewed (e.g., Adams et al., 2016; Balshem et al., 2014). One may have done a thorough search of the primary health-related databases and found that little has been done on the specific topic of concern, and you are very motivated to see if you have missed important information from other sources. Research is increasingly being published on the internet, where quality and thoroughness of peer review is unclear.

This information brief on using the grey literature presents an overview of EBP and the systematic evidence review process supporting it, focusing on questions of intervention effectiveness. Our fundamental viewpoint is that strength of evidence for a defined clinical question or recommendation is the *core* issue; peer review and expert opinion are very valuable, practical screens, but they are not substitutes for scientific appraisal of strength and nature of evidence on the clinical question. If such appraisal is not done in published reviews by trusted experts, you may have to do it yourself, and certainly you should know

the primary questions to ask. Grey literature can and should be included in evidence reviews, if an appraisal of the strength, level, and nature of empirical data provided and of the methodology employed indicate a relatively high quality of evidence.

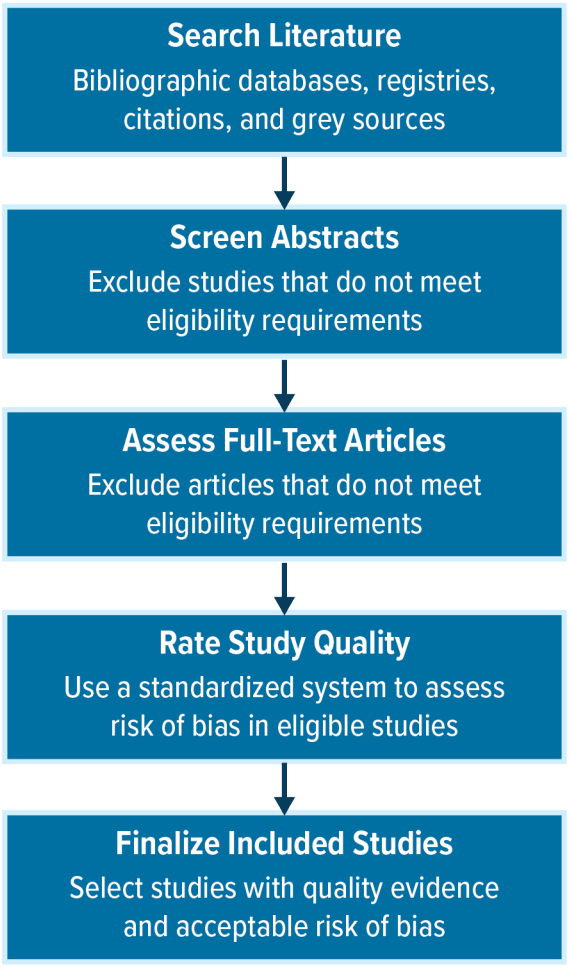
We will define the grey literature and describe situations in which systematic reviewers, clinician educators, and others interested in best evidence should consider searching the grey literature. We offer recommendations on search strategies and methods. Finally, we summarize guidance for using grey literature in intervention study reviews. Sources in our reference list offer more detailed explanations and procedures for conducting systematic reviews using both the main and the grey literature.

Evidence-Based Practice and Systematic Review Study Selection Process

EBP involves the application of the *best available* evidence to practice, not just rigorous evidence. Completely rigorous or strong evidence often doesn't exist. Searches for published peer-reviewed articles in indexed bibliographic databases is a necessary and invaluable starting point for identifying quality studies.

Identification of evidence on a clinical topic begins with formulation of an answerable, specific clinical question. Vague questions (e.g., does it work?) lead to vague or professionally useless or misleading answers. Empirically answerable questions of intervention effectiveness need to be formulated in PICO terms: the relevant patient population (P), the intervention (I), a comparator (C), and expected outcomes (O) (Gronseth et al., 2017; Richardson et al., 1995; Sackett et al., 1996). Each of these

Figure 1. Steps for Systematic Review Study Selection



elements is potentially complex: Human populations vary in innumerable, potentially important characteristics; interventions in rehabilitation and health care often involve multiple-step considerations of dosage and variations depending on patient needs and response. Outcomes are often multiple, with some affected and others not; negative side effects and risks must be considered, and timing of outcomes measurement is generally relevant. The extent of outcome improvement is always dependent on the comparison group, and ethical, appropriate, calculably similar comparison groups are typically hard for researchers to find and study.

Searching for evidence on the topic. Systematic reviewers must evaluate the extent to which selected search terms and databases map to relevant constructs and identify relevant evidence. This understanding is necessary for searching and interpreting the peer-reviewed literature and is particularly valuable in evaluating the need for a grey literature search. When using overly narrow search terms and strategies, the systematic reviewer can easily overlook important evidence. Therefore, a broad search to identify good evidence is often the best initial approach. Reliance on MEDLINE or the Cochrane Database of Systematic Reviews alone, for instance, could bias a literature search toward the purely medical (e.g., medication) treatments, leading one to overlook allied health therapies and other topics important in disability and rehabilitation (e.g., behavioral, psychological, educational, and learning-based interventions; occupational therapy; economic, social, and community interventions). The important studies on these topics may be found only in CINAHL, PsycINFO, or other "non-medical" databases. The systematic review team must carefully develop their search algorithms and procedures and will benefit if their strategies are peer reviewed (Atkinson et al., 2015; Balshem et al., 2014; Booth, 2006; Kable et al., 2012; Niederstadt & Drost, 2010; Straus et al., 2018). Whether conducting a traditional or grey literature search, consulting with a research librarian who has expertise in health care literature searches can be invaluable in developing the search strategy and identifying the best evidence.

Grading the evidence. Detailed, standardized, empirically based methods for grading strength and nature of evidence have been developed—e.g., American Academy of Neurology (Gronseth et al., 2017), GRADE (GRADE Working Group, 2023; Guyatt et al., 2008a, 2008b), and Cochrane (Higgins et al., 2022). These criteria are very well developed and

influence national policy and health care delivery in many countries and organizations—e.g., the U.S. Veterans Administration (GRADE Working Group, 2023; Gronseth et al., 2017; Guyatt et al., 2008a, 2008b; Higgins et al., 2022). They need to be applied to appraise, weight, and select all studies on the topic of interest, whether traditional or grey. We strongly recommend use of one of these well-developed, structured evidence-grading checklists or computer programs, such as Cochrane's Review Manager (RevMan).

Note, however, that some of the best developed of these (e.g., RevMan) are applicable only to randomized clinical trials (RCTs). Reviews that focus only on RCTs are good for identifying rigorous evidence, but in the absence of strong, well-controlled RCTs, such reviews may not identify *best* extant evidence. Evidence from strong, quasi-experimental research methods (e.g., interrupted time series designs, regression discontinuity studies) has been excluded, perhaps because it is so common to confuse such studies with weak correlational and merely descriptive studies (Johnston & Dikers, 2012; Seel et al., 2012). Methodologies to develop more reliable, valid, and accurate measures and diagnostic procedures, or to identify the strongest and most applicable prognostic or predictive methods to employ, are quite different from the RCTs needed for intervention effectiveness studies (GRADE Working Group, 2023; Gronseth et al., 2017; Sackett et al., 1996).

Systematic reviews of the scientific literature, which identify two or more high quality studies—well-controlled studies with a well-defined, appropriate population; intervention; and equivalent (randomized) comparator, with clear positive outcomes in both studies—provide a sound basis for a strong treatment recommendation (GRADE Working Group, 2023; Gronseth et al., 2017; Higgins et al., 2022). Many potential biases need to be systematically considered and evaluated in this process, such as blinding when the outcome is subjective or if there is conflict of interest. Evaluation of strength and reliability of evidence and absence of definite biases are in principle more important than whether the source is "grey" or not.

Definition of Grey Literature

For the purposes of health care evidence reviews, we define *grey literature* as any study or report that has not undergone a scientific peer-review process and/or has not been published in a professional research journal that is indexed in one of the major bibliographic

databases. Grey literature includes unpublished reports on funded research, conference proceedings, doctoral theses, editorials, blogs, government reports, and reports by nongovernmental organizations—for instance, research institutes that may or may not be affiliated with universities. Grey literature also can refer to peer-reviewed articles not easily found through standard bibliographic databases, because the journal was not indexed in a major database or the article in question was skipped by the database indexers for one reason or another. It should be noted that

- some grey literature is easily found (e.g., dissertations in PsycINFO), and
- not every scientific or professional journal is peer reviewed.

Further, some non-journal literature *is* peer reviewed. For instance, committee members spend considerable time editing successive drafts of a student's dissertation. Typically, they spend far more time editing a series of drafts than journal peer reviewers spend making accept/reject decisions on submitted manuscripts. In addition, reputable Health Technology Assessment centers use internal peer review before posting reports.

Searching the Literature

While there are many circumstances in which searching the grey literature can be valuable in identifying best evidence, it is important to remember that most good evidence will be found by searching the world's primary health-related, scientific study databases. MEDLINE/PubMed currently includes over 29 million studies of health, disease, and medicine from peer-reviewed sources! Even so, the Cochrane Library and Cochrane Central Register of Controlled Trials include a great number of RCTs not found in MEDLINE/PubMed. Behavioral interventions are largely covered by PsychINFO (though it is substantial work to distinguish RCTs of interventions from other studies that mention the term *random*). Nonetheless, it is possible that searches of the main health-related databases will find few or non-completed RCTs, or other strong research studies for the topic of interest.

If you conduct a search using MEDLINE or another of the main health study databases and find very few or no studies, you should first try alternative or related search terms. Often, a change in terminology or framing of the question to include related interventions or

processes, or similar populations or outcomes, will identify relevant studies. We have frequently encountered students and clinicians who complain that there are no RCTs or relevant scientific studies, but when we did a competent search of MEDLINE on highly related topics, we found dozens or even hundreds of RCTs.

Read the strong studies and reviews first! A research librarian can be very helpful in conducting a high-quality search of the literature, whether peer reviewed or grey. Our experience is that there is often relevant (if not exact) research in related fields, using generically similar interventions, outcomes, or processes.

Supplementing limited indexed studies. Despite the wealth of information in databases that index peer-reviewed journal studies, there are many topics for which few or no well-controlled studies exist (e.g., niche research topics, rare or orphan diseases or populations). Health care fields with limited grant funding produce fewer quality RCTs. Multidisciplinary rehabilitation, for instance, has far fewer RCTs than internal medicine or other purely medical fields. Federal or industry funding may not exist or may be scarce for topics or treatments that are not "in vogue," cannot be patented, or are unlikely to be reimbursed or produce profits. Self-funded studies and small grants from universities typically result in small, short-term, or poorly controlled studies, which may end up in the grey literature even if they provide best or only evidence on a specific topic. Grey literature searches of preprints, dissertations, and research study findings reported in clinical trial or funded grant registries are then most helpful in identifying complete evidence. Nonprofit policy and government policy reports often include combinations of empirical data and consensus from experts on the state of the science regarding important topics emerging in health care.

Scoping reviews. It is not unusual to have insufficient knowledge to formulate the best possible focused PICO question: The relevant population details, intervention types, alternatives, and outcomes that result may be poorly understood. One needs understanding of them to develop the optimal PICO intervention question. When the scope of the literature is not well understood and may not include high-quality studies with definitive results, the relevant literature needs to be identified and characterized before one formulates the PICO question or questions necessary for an exacting, comprehensive, rigorous systematic review (Atkinson et al., 2015; Dijkers, 2015; GRADE Working Group, 2023; Kable et al., 2012; Tricco et al., 2018). Generalization of results requires multiple studies. Theories need to be

developed and improved. Broad and less well-understood topics need to be reviewed. Both traditional reviews and scoping reviews can be valuable in developing understanding of a topic and appropriate PICO questions, even If they do not yield clear, definitive results (Munn et al., 2018).

Emerging biomedical health care innovations. In addition, emerging biomedical health care innovations and technological advances may be in the stage of formulating insightful, focused hypotheses and conducting proof of concept, safety studies, or pilot efficacy studies rather than large clinical trials that draw conclusions broadly applicable to clinical practice. U.S. Food and Drug Administration (FDA) approval requirements for technology differ vastly from those for medications and other interventions that require efficacy data from RCTs (Van Norman, 2016). In the absence of strong evidence, reviewers should search for the *best* relevant literature, even if it is grey and includes advisory statements in lieu of formal practice guidelines. This type of evidence may be found in non-scholarly communications such as health care technology reports, industry updates, and new technology releases.

Growth of open-access internet publication. The tremendous growth of open-access publication on the internet strongly motivates searching of such sources by those who want a complete evidence review. However, given the uncertain presence or quality of peer review in these studies, evaluation of the strength and nature of evidence is especially needed for such publications. Grey literature databases that house or index open-access publications are good sources of preprints and other research studies that haven't been indexed in traditional bibliographic databases.

Various forms of reporting bias occur in the literature. Arguably the most important form of reporting bias, even when accessing studies from highly reputable journals, is suppression of data on negative findings and adverse events, often due to financial interests or conflict of interest of investigators (e.g., Fries & Krishnan, 2004). Even without financial interests, researchers may suppress data that do not support their theory, ideology, or advocacy. The effects of losses to follow-up are often ambiguous. Central tendency is often emphasized without commenting on the wide and unexplained variation in outcomes. To save effort and shorten the manuscript, secondary outcomes and outcomes in important subgroups may not be analyzed or reported. Sometimes the grey literature has information to fill in these blanks.

It is possible to check registries of RCTs (e.g., ClinicalTrials.gov, the EU Clinical Trials Register, European Medicines Agency) to identify studies that were planned but never published (a bad sign, often indicating bias or bad results). Sometimes one may find other studies on the topic. Occasionally, grey literature will provide information on limitations of claimed results, positive or negative. On the other hand, the internet is filled with studies claiming great results, without presenting any relevant data or controlled studies. Grey literature can be very biased too. The quality of studies and claimed results of internet studies need careful evaluation using extant, well-developed evidence-grading methods. If not done by peer review or a published systematic review, you will need to grade the strength and nature of evidence provided.

Methods for Searching the Grey Literature

Development of a search strategy for grey literature depends on the clinical (systematic review) question and the lack of quality evidence in traditional bibliographic database sources. The systematic reviewer should evaluate the clinical question for the presence of risk factors that drive lack of published evidence and then estimate whether a targeted search of the grey literature related to those risk factors has a medium to high likelihood of finding quality evidence. If so, then the reviewer should select and search the two or three grey literature sources that are most likely to generate relevant, quality evidence.

Information Sources for Grey Literature

There is a wide array of grey literature information and sources that can be used in systematic reviews. We recommend consulting with a university librarian with expertise in systematic review literature searches, including grey literature searches. Table 1 shows a list of grey literature evidence sources commonly used for intervention systematic reviews. These grey literature documents typically are accessed through web searches, specific websites, or email and telephone contact with known experts, key informants, or study authors.

Table 1. Common Grey Literature Evidence Sources

Clinical Trial Funding Source, Status, Protocol, and Results	
International Standard Randomized Controlled Trial Number (ISRCTN) clinical trial registry	https://www.isrctn.com/
U.S. Clinical Trials Registry	https://clinicaltrials.gov/
World Health Organization International Clinical Trials Registry Platform (ICTRP)	https://trialsearch.who.int/

Dissertations and Theses	
EBSCO OpenDissertations.org	https://biblioboard.com/opendissertations/
ProQuest	https://www.proquest.com/
Sherpa OpenDOAR institutional repositories	http://v2.sherpa.ac.uk/opendoar/

Conference Abstracts, Presentations	
Clarivate Conference Proceedings Citation Index	(Web of Science, subscription required)
Poster and presentation repositories: • SlideShare • FigShare • Zenodo	https://www.slideshare.net/ https://figshare.com/ https://zenodo.org/
Proceedings of relevant health and medical societies' specific conferences	Professional membership organizations' websites

Nonprofit Policy Reports	
National Academies of Sciences, Engineering, and Medicine	https://nap.nationalacademies.org/
National Institute for Health and Care Research (NIHR), Centre for Reviews and Dissemination (CRD)	https://www.crd.york.ac.uk/prospero/

Nonprofit Policy Reports (cont'd)	
Rand Corporation	https://www.rand.org/health-care.html

Government Reports	
Agency for Healthcare Research and Quality (AHRQ)	https://www.ahrq.gov/research/findings/index.html
Centers for Disease Control and Prevention (CDC)	https://www.cdc.gov/publications/index.html
Centers for Medicare & Medicaid Services (CMS)	https://www.cms.gov/research-statistics-data-and-systems/research-statistics-data-and-systems

Preprints, Other Open-Access Research Publications	
CADTH's Grey Matters	https://greymatters.cadth.ca/
medRxiv preprint server	https://www.medrxiv.org/
OpenGrey (multidisciplinary European database)	http://www.opengrey.eu/
Open Science Framework	https://osf.io/

Technology Updates, Reports	
Healthcare Technology Report	https://thehealthcaretechnologyreport.com/
Medgadget	https://www.medgadget.com/
National Technical Reports Library (NTRL)	https://ntrl.ntis.gov/NTRL/

Systematic Review Protocols	
Systematic Review Protocols and Protocol Registries	https://www.nihlibrary.nih.gov/services/systematic-review-service/systematic-review-protocols-and-protocol-registries

Study Evaluation and Synthesis

Searches of both published studies and the grey literature may identify studies with conflicting findings. When this occurs, look for indications of differences in

- The samples studied, particularly studies of groups with different prognoses. Randomized assignment with a sufficient sample size is required to make the experimental and control groups equivalent within calculable bounds.
- Interventions applied and in the comparison or control groups.
- Outcome measures employed, including dropout rates. Use of a subjective outcome measure in unblinded studies usually results in a bias toward the expected treatment, whether it works or not.

Statistical analysis for heterogeneity of results is possible with sufficient sample and variables characterizing possible sources of heterogeneity (see Higgins et al., 2022). Whether studies come from mainstream journals or the grey literature, a systematic process of evaluation and synthesis that employs sensible, well-developed criteria is needed. Actual systematic reviews have an evidence table describing key characterizes of the research, including the four elements in PICO. Generally, studies rated as having Class of Evidence (CoE) 1, 2, or 3 are retained for initial data synthesis and drawing of conclusions (see Gronseth et al., 2017). Class 4 studies are excluded for unacceptably high risk of biased conclusions. Balanced judicious conclusions about intervention effectiveness are drawn from quality, strength, consistency, and generalizability of the evidence provided by the studies for each outcome (and population) of interest. In formal evidence grading, overall strength of conclusions is typically graded using the lowest quality rating for any included study. Sensitivity analyses and weighting methods have also been employed, but they are more complex. Strong dose-response relationship or grouped effect sizes can increase strength of conclusions. The strength-of-conclusion rating can be downgraded one level for heterogeneity, imprecision, or indirectness (lack of generalizability) of findings.

Missing or ambiguous reporting of methods and data can lead to inaccurate evidence grading or to downgrading of studies. Contacting study authors or reading study design protocols can fill in some gaps. Scientific journals increasingly require authors to use reporting guideline checklists to screen their work before submitting an article for publication (Chan et al., 2014). The quality and completeness of study methods, reporting, and findings has tended to improve over the years.

Information needed to make usable clinical recommendations may require a grey literature search for detailed protocol information or unique circumstances not typically published in peer-reviewed studies (Balshem et al., 2014). Detailed, replicable descriptions of behavioral intervention (treatment manuals) often are not included in peer-reviewed publications due to word limits, and journals vary in their policies on publishing supplemental material. Qualitative studies may inform how people with lived experience understand the meaning of treatments, prioritize outcomes, and best adhere to protocols (though, absent control groups, they are not a reliable source of information on generalizable effective treatments).

Using established evidence-grading tools to review a study's methodologic quality and biases is highly recommended. CoE ratings may differ somewhat depending on the grading system selected. Evidence-grading systems such as the GRADE approach apply rigorous, bias-rating criteria initially designed for medication studies (GRADE Working Group, 2023). The American Academy of Neurology evidence-grading system, which is considered highly rigorous, provides quality ratings that are more forgiving of the challenges presented by behavioral rehabilitation interventions wherein treatment group or outcome assessment blinding is difficult or infeasible (Gronseth et al., 2017).

Summary

Recommendations for clinical practice and health care policy should be based on the best evidence. This is not a simple matter. Studies published in established scientific journals and indexed in major health-related databases in most cases provide access to the best evidence. In selected circumstances, e.g., when there are limited indexed studies or there

is emerging innovative technology, the grey literature can improve or supplement knowledge and sometimes can provide the best evidence. Independent of the source of evidence, pointed questions need to be asked about the population addressed, the intervention, the comparison group, the degree to which they are equivalent, and both desired and possible undesired outcomes. In general, evidence is either sufficiently rigorous or is not; it must be understood in terms of graded levels of strength, regardless of source of evidence.

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