



Introducing the Library of Guidance for Health Scientists (LIGHTS) A Living Database for Methods Guidance

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Abstract

IMPORTANCE Improving methodological quality is a priority in the health research community. Finding appropriate methods guidance can be challenging due to heterogeneous terminology, poor indexing in medical databases, and variation in formats. The Library of Guidance for Health Scientists (LIGHTS) is a new searchable database for methods guidance articles.

OBSERVATIONS Journal articles that aim to provide guidance for performing (including planning, design, conduct, analysis, and interpretation), reporting, and assessing the quality of health-related research involving humans or human populations (ie, excluding basic and animal research) are eligible for LIGHTS. A team of health researchers, information specialists, and methodologists continuously identifies and manually indexes eligible guidance documents. The search strategy includes focused searches of specific journals, specialized databases, and suggestions from researchers. A current limitation is that a keyword-based search of MEDLINE (and other general databases) and manual screening of records were not feasible because of the large number of hits (n = 915 523). As of September 20, 2022, LIGHTS included 1246 articles (336 reporting guidelines, 80 quality assessment tools, and 830 other methods guidance articles). The LIGHTS website provides a user-oriented search interface including filters for study type, specific methodological topic, research context, guidance type, and development process of the guidance. Automated matching of alternative methodological expressions (eg, enter *loss to follow-up* and find articles indexed with *missing data*) enhances search queries.

CONCLUSIONS AND RELEVANCE LIGHTS is a peer-supported initiative that is intended to increase access to and use of methods guidance relevant to health researchers, statisticians, methods consultants, methods developers, ethics boards, peer reviewers, journal editors, and funding bodies.

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Introduction

Systematic reviewers and meta-scientists often lament limitations in the methodological quality of health research. They frequently identify the need for better adherence to existing methods guidance,^{1,2} improved methods guidance,^{3,4} and stricter quality control through ethics committees,⁵ funding agencies,^{5,6} peer reviewers,⁷ and journal editors.^{4,6,8}

From the perspective of health researchers, however, finding appropriate and trustworthy methods guidance is not easy. Challenges include large variation in terminology,⁹ lack of methodological index terms (**Box**), inconsistent use of index terms in MEDLINE,⁹ and unstructured abstracts.⁹ These challenges make it difficult for health researchers and information specialists to

+ Supplemental content

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perform precise and sensitive searches for methods guidance (eg, when performing a systematic review of methods guidance¹⁰) and hinder the dissemination and uptake of methods guidance.

One approach to increase the access to a specific body of literature is to create a specialized database. Successful examples include the database of the Enhancing the Quality and Transparency of Health Research (EQUATOR) network for reporting guidelines,¹¹ the Online Resource for Research in Clinical Trials (ORRCA) database for recruitment and retention research,¹² and the Core Outcome Measures in Effectiveness Trials (COMET) Initiative database for core outcome sets.¹³ Such databases, if comprehensive, up-to-date, and easy to use, can render complex multidatabase searches unnecessary, save researchers time and resources, and increase both sensitivity and precision of systematic searches. In addition, specialized databases allow the use of content-specific indexing systems and search features. A database specifically for methods guidance was not available.

Herein, we introduce the Library of Guidance for Health Researchers (LIGHTS), a new searchable database for methods guidance in health research involving humans and human populations (ie, excluding basic and animal research). LIGHTS aims to improve the findability of methods guidance articles and revoke the burden of searching for methods guidance articles in MEDLINE, Embase, Google, and other general databases; to provide a comprehensive and up-to-date inventory of methods guidance; and, ultimately, to improve the uptake of methods guidance and the methodological quality of health research.

Box. Selected Methodological Topics for Which MEDLINE Provides No Specific Index Terms

- Methods guidance
- Subgroup analysis
- Applicability
- Diagnostic test accuracy
- Meta-research
- Prognostic research
- Literature search
- Causal inference
- Directed acyclic graphs
- Random error
- Qualitative data analysis
- Sensitivity analysis
- Hypothesis tests
- Individual participant data
- Familywise error
- Blinding
- Missing data

Methods

This Special Communication explains the development and maintenance of LIGHTS. Key methods include a diverse team of methodologists; explicit eligibility criteria for methods guidance; a regularly updated, multifaceted literature search; a process for eligibility assessment; a system for indexing the methods guidance; and a freely accessible online search portal (www.lights.science).¹⁴

Development Team

The development team consists of a core group including methods experts and information specialists (J.H., H.E., G.H.G., M.B., and S.S.) and an extended group of methodologically trained health researchers and students who work in a variety of areas of health research.¹⁴ We do not involve patients or members of the public in formulating the research objectives, designing the review, interpreting the results, or drafting the manuscript.

Eligibility Criteria

A document is eligible for LIGHTS if it satisfies all of the following criteria:

1. It is a peer-reviewed journal article (we may broaden this criterion in future versions of LIGHTS).
2. The document explicitly expresses the aim to provide guidance on a methodological topic. This could be stated in the journal section or article type (eg, *PLOS Medicine*'s "Guidelines and Guidance" or *Statistics in Medicine*'s "Tutorials in Biostatistics") or the article's title, abstract, or objective (typically provided in the abstract or at the end of the introduction). We accept any alternative expression for guidance (eg, guidelines, guide, step-by-step explanations, common mistakes and solutions, best practice statement, recommendations, tutorial, methodological framework, and other terms⁹).
3. The article is relevant for health-related research in humans and human populations as per judgment of the members of the LIGHTS team. We include guidance for any type of clinical or epidemiological research, including guidance for primary studies but also meta-analyses, health economics, implementation science, or clinical practice guidelines. We include methods guidance for any phases of a health research project, including planning, design, conduct, analysis, interpretation, and reporting but also postpublication considerations such as quality assessment and implementation.

Articles are excluded based on the following criteria:

1. The goal of the article is to propose a new method rather than recommend best research practice (those that suggest both a new method and best research practice may be eligible).
2. Guidance is focused on research content (eg, research priorities, interventions, or outcome variables) rather than research methods.
3. The article is a meta-study, simulation study, or other methodological study (unless they also explicitly state the aim to provide guidance).
4. The article is a methodological case study (eg, a “lessons learned” article in which primary researchers report on their experience with a specific methodology in a specific study).
5. The article is a research letter, editorial, or other type of commentary that does not contain original guidance (eg, for lack of a specific article type, editors may choose a commentary format for methods guidance).
6. The article illustrates the application of methods guidance to a specific study or medical area (eg, CONSORT applied to eHealth interventions¹⁵) without suggesting a modification.
7. The article describes a protocol for the development of methods guidance.

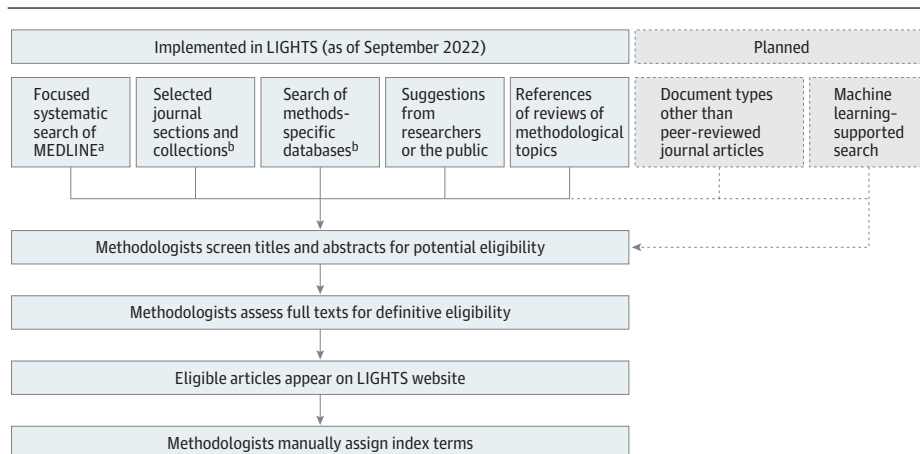
Literature Search

As of September 20, 2022, our search strategy consists of 5 sources (Figure):

1. A recent meta-study on methods guidance articles.⁹ This search was limited to specific journals indexed in MEDLINE in 2020 and yielded 105 methods guidance articles.
2. General and methods-specific journals, sections, or article types designed specifically for methods guidance without time limit (Table 1).¹⁶⁻²⁵ Since MEDLINE does not include index terms for sections and article types of individual journals, we searched—manually or supported through web-scraping software²⁶—sections denoting methods guidance on the websites of the journals.
3. Screening of databases specialized in methodological topics (Table 1).^{11,12}
4. Screening of reference lists of reviews of the methods literature that included methods guidance (eg, statistical guidance on regression analysis²⁷).
5. Suggestions from researchers in and outside our professional network.

A keyword-based search of MEDLINE and potentially other general databases was not feasible. In collaboration with an information specialist experienced in clinical research methods (H.E.), we have been working on a MEDLINE search strategy through the Ovid interface (eAppendix 1 in Supplement 1). Despite many iterations of systematic development (based on a seed sample of 1184 eligible methods guidance articles), the search yielded a very large number of records (915 523) that was not feasible to screen. The supplemental content shows the variant of the search that yielded the smallest number of records, included a time limit (2010 or later), and retrieved 77.8% of the seed

Figure. Process for Article Search, Eligibility Assessment, and Indexing



Abbreviation: LIGHTS indicates Library of Guidance for Health Scientists.

^a See Hirt et al.⁹

^b Table 1 provides a list of journal websites and databases that were screened.

sample. We tried other, more elaborate versions of the search strategy that retrieved a larger proportion of seed articles but at the cost of a substantial increase in the number of records because of unspecific search terms such as *key concepts*, *introduction to*, or *standards*.

Eligibility Assessment

Researchers of the core group apply the eligibility criteria to titles and, if available, abstracts of potentially eligible articles, resulting in a list of articles for full-text screening. Members of the extended group then select articles, preferably those matching their methodological expertise, and apply the eligibility criteria to the full text. To support the eligibility assessment, they collect a verbatim quotation expressing the article's aim to provide methods guidance. This quotation appears in LIGHTS as a subtitle. A second methodologist double-checks the full-text eligibility assessment, discusses disagreements, and, if necessary, approaches a third team member for arbitration. An instruction manual provides detailed explanations for the eligibility assessment (eAppendix 2 in Supplement 1).

Indexing Process

The systematic indexing of guidance articles serves 2 purposes: to group together guidance articles on the same topic and to facilitate a synonym search by linking together alternative expressions for the same methodological concept. Using a shared spreadsheet, researchers assign to each included guidance document 1 or more index terms for each of the following 5 categories:

1. Study type (eg, randomized controlled trial, case-control study, scoping review)
2. Methodological topic (eg, missing data, causal inference, patient-reported outcomes)
3. Medical context (eg, neurology, public health, infectious diseases)
4. Guidance type (eg, guidance for study planning, analysis, or reporting)
5. Guidance development process (eg, consensus study, meta-research, user testing)

We collect and organize the index terms in a controlled vocabulary²⁸ that we curate in a separate spreadsheet. We arrange the index terms in a hierarchical structure and, for each index term, record alternative terms (abbreviations, variations, synonyms, and opposites), the preferred term (ie, the term we use for indexing if ≥ 2 alternative terms are available), related terms, and clarifying comments following established standards for taxonomy data.²⁹ We plan to develop the emerging vocabulary into a separate resource (eg, for information specialists who are designing a search strategy for a systematic review of a methodological topic¹⁰) and make it accessible through the LIGHTS website.

Table 1. Methods-Specific Journal Sections, Article Types, Article Series, and Databases Screened for Methods Guidance

Resource	Type of resource	No. of records ^a
<i>BMJ</i> research methods & reporting ¹⁶	Article type	78
<i>PLoS Med</i> guidelines and guidance ¹⁷	Article type	63
Wiley Online Library Statistics in Medicine tutorials in biostatistics ¹⁸	Article type	133
<i>JAMA</i> User's Guide to the Medical Literature ¹⁹	Collection	45
<i>Ann Intern Med</i> research and reporting methods ²⁰	Article type	89
<i>BMJ</i> statistics notes ²¹	Series	68
<i>PLoS</i> ten simple rules ²²	Series	102
STRATOS initiative ²³	Guidance development group	40
<i>J Clin Epidemiol</i> GRADE guidance ²⁴	Guidance development group	33
EQUATOR Network library for health research reporting ¹¹	Collection of reporting guidelines	527
ORRCA ¹²	Collection of articles related to recruitment and retention	6012
TRIAL FORGE ²⁵	Guidance development group	3

Abbreviations: EQUATOR, Enhancing the Quality and Transparency of Health Research; GRADE, Grading of Recommendations Assessment, Development and Evaluation; ORRCA, Online Resource for Research in Clinical Trials; STRATOS, Strengthening Analytical Thinking for Observational Studies.

^a As of June 27, 2022.

A second team member double-checks the indexing. The 2 team members discuss disagreements and, if necessary, approach a third team member for arbitration. The instruction manual provides detailed explanations for the indexing process (eAppendix 2 in Supplement 1).

Results

As of September 20, 2022, LIGHTS (www.lights.science) included 1246 articles (336 reporting guidelines, 80 quality assessment tools, and 830 other methods guidance articles). Between August 1 and 31, 2022, the median number of unique visitors per day was 444 (range, 105-731).

The search interface provides 5 search facets corresponding to categories we use for indexing. Three additional search facets are based on the following metadata that we retrieved from the publisher's website, MEDLINE, or another bibliographic source: date of publication, authors (all authors), and journal. **Table 2** shows the most frequent categories for each of the 8 search facets as of September 20, 2022. The search features include automated synonym mapping. For instance, if users enter *loss to follow-up* (one of several alternative terms for missing data), LIGHTS will also show all guidance articles indexed with *missing data*, irrespective of whether the article's title, abstract, or keywords include the term *loss to follow-up*.

Discussion

LIGHTS is a new open-access database curated by researchers working in different areas of health research that is optimized for health researchers, including those concerned with assessing the quality of study proposals and reports, developers of methods guidance, and learners and educators in health research. We are planning to update LIGHTS every 6 months.

LIGHTS as a Resource

For Health Researchers

LIGHTS offers guidance for investigators at any stage of a study. In early stages, guidance for clarifying the need for new studies may be particularly useful (eg, for deciding whether a new systematic review is needed³⁰), as well as guidance on methodological concepts (eg, Prognosis Research Strategy [PROGRESS] framework for prognostic research³¹), types of adaptive trial designs,^{32,33} guidance for specific design considerations (eg, Difference Elicitation in Trials [DELTA²] guidance for sample size calculation³⁴), and reporting guidelines that often provide a well-structured overview of the key steps of a study (eg, a randomized clinical trial³⁵ or a systematic review³⁶). Over the course of a study, other types of guidance may become relevant, including guidance on trial process organization (eg, patient recruitment³⁷ or data collection³⁷), specific analytic issues (eg, handling missing data³⁸), presenting results (eg, creating figures³⁹), interpreting the strength on evidence (eg, regarding a prognostic factor^{40,41}), and structuring study reports (eg, of a randomized clinical trial³⁵ or a systematic review³⁶).

For Assessors of Study Quality

Funding agencies, ethics committees, journal editors, peer reviewers, systematic reviewers, meta-researchers, and others who assess the quality of health research can use LIGHTS to identify suitable quality assessment tools (eg, to assess risk of bias in a randomized clinical trial⁴² or the credibility of a subgroup claim made in a meta-analysis⁴¹). LIGHTS includes quality assessment instruments for various types of studies.

For Developers of Methods Guidance

Developers of methods guidance can use LIGHTS to identify previous methods guidance. Reviewing previous guidance helps avoid unnecessary duplication (eg, we are aware of >30 checklists for

assessing the credibility of subgroup analyses⁴³). In addition, review of previous guidance can identify experts in methodological areas, for example, to form an expert panel for a consensus study. Finally, LIGHTS provides a platform to disseminate newly developed methods guidance. Future

Table 2. Content of LIGHTS and 4 Most Frequent Categories of Each Search Facet

Search facet by most frequent categories ^a	Frequency, No. (%) (N = 1246)
Study type	
Nonspecific	293 (24)
Randomized controlled trials	206 (17)
Observational studies	128 (10)
Systematic reviews	98 (8)
Methodological topic (other than study type)^b	
Nonspecific	364 (29)
Bias and confounding	44 (4)
Certainty in evidence	38 (3)
Heterogeneity of effects	27 (2)
Guidance type^b	
Conduct (broad)	534 (43)
Reporting	336 (27)
Conceptual overview (broad)	200 (16)
Analysis	123 (10)
Development process^b	
Not reported	447 (36)
Stakeholder involvement	237 (19)
Consensus process	216 (17)
Systematic review of methodological literature	152 (12)
Medical context^b	
Nonspecific	648 (52)
Psychiatry or psychology	28 (2)
Oncology	24 (2)
Surgery	19 (2)
Publication date	
2020s	316 (25)
2010s	726 (58)
2000s	124 (10)
1990s	45 (4)
Author^c	
Altman D	107 (9)
Guyatt G	82 (7)
Moher D	64 (5)
Schünemann H	61 (5)
Journal^c	
<i>BMJ</i>	182 (15)
<i>J Clin Epidemiol</i>	161 (13)
<i>Stat Med</i>	135 (11)
<i>Ann Intern Med</i>	50 (4)

Abbreviation: LIGHTS indicates Library of Guidance for Health Scientists.

^a As of September 20, 2022.

^b Based on manual indexing.

^c Based on metadata, for example, from the publisher website or MEDLINE/PubMed.

features could include a registry for planned guidance development projects and feedback measures such as access statistics and user ratings.

For Health Research Learners and Educators

LIGHTS includes guidance for users at various levels of familiarity with a methods topic ranging from introductions to expert level. Many guidance documents start with conceptual overviews often written by leading experts, sometimes supported by systematic reviews and consensus panels, and may therefore provide excellent introductions on a given methodological topic.^{31,44} Another guidance format that may be useful for learners is “challenges and solutions.”^{45,46} Those articles, ideally informed by meta-research, can direct learners and educators to the most relevant methodological issues. Another group of users who may appreciate the varying levels of difficulty are methods consultants who are looking for methods guidance that matches their client’s level of understanding.

Relationship of LIGHTS With Other Databases

The EQUATOR network provides a searchable library for reporting guidelines.¹¹ Many reporting guidelines qualify for inclusion in LIGHTS. What may seem unnecessary overlap has a number of advantages. First, often a specific study design (eg, randomized clinical trial³⁵) defines the scope of a reporting guideline. We anticipate that users of LIGHTS will appreciate finding both reporting and nonreporting guidance on the same topic in a common database. Second, reporting guidelines often include consensus-based definitions and terminologies that help us calibrate our controlled vocabulary. Third, reporting guidelines, although designed primarily to support the writing of manuscripts, often provide a reasonable step-by-step structure for those who are planning research projects. Fourth, including reporting guidelines in LIGHTS can help promote their dissemination because LIGHTS may be attracting a broader audience (in particular those who are in an early stage of a research project).

There is little overlap of LIGHTS with other methods-specific databases (Table 1). For instance, the ORRCA database for recruitment and retention research includes more than 6000 articles, but only 20 currently qualify as methods guidance eligible for LIGHTS. This small proportion illustrates the potential value of LIGHTS: most methods articles do not aim to provide guidance.

Other methods-specific databases can serve as models for LIGHTS. For instance, the COMET database is based on a machine learning–supported search process.⁴⁷ We are currently developing a similar approach for LIGHTS. SAGE research methods—a website primarily for guidance books available from SAGE Publishing, therefore not overlapping with LIGHTS—provide a tool termed a *methods map*⁴⁸ through which users can browse the vocabulary used for indexing books. Similarly, we are planning to provide access to the vocabulary of LIGHTS.

Limitations

The main limitation of LIGHTS is that, for reasons of feasibility, it is currently not based on a systematic search of MEDLINE, Embase, and potentially other general databases. Machine learning—specifically learn-to-rank models—may provide a solution to facilitate the screening of the very large data sets produced by keyword-based searches for methods guidance articles.⁴⁷

We restricted our focus to journal articles to avoid increasing the complexity of this project. We have plans for gradually broadening the inclusion criteria. For instance, we are considering including guidance documents provided by regulatory authorities such as the US Food and Drug Administration⁴⁹ and the European Medicines Agency.⁵⁰ We excluded textbooks because they are organized in other catalogs and are typically much broader in scope than journal articles. Individual book chapters, while sometimes comparable in scope, are difficult to search and would have greatly complicated our search process.

Users of LIGHTS will often find multiple guidance documents for a given research task. Deciding which guidance documents are most appropriate can be a challenge. Although the search facets in

LIGHTS offer potential directions (eg, users may prefer guidance based on a systematic development process or those developed by prominent authors), formal quality criteria for methods guidance are currently not available. To inform the development of such criteria, more research is needed to better understand when a guidance document can be considered more or less appropriate.

For a small number of guidance documents, users will find different versions such as the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) reporting guidelines from 2009 and 2020³⁶ or the Cochrane risk of bias tool, versions 1.0 and 2.0.⁴² For now, we suggest keeping both updated guidance and previous versions, assuming that users of LIGHTS will naturally prefer the most recent version. If the number of updated guidance documents in LIGHTS increase—most guidance articles are one-time initiatives—we will develop a system for labeling different versions.

Future Directions

We conceptualized LIGHTS as a living resource and will implement improvements depending on available funding and suggestions from users. Our current plans include studying the suitability of machine learning to support the search for eligible methods guidance, developing a user interface for our controlled vocabulary, and including nonjournal articles (eg, methods guidance published by the US Food and Drug Administration⁴⁹ or European Medicines Agency).⁵⁰

As an area for future research, we suggest the development of formal guidance both for developing and reporting methods guidance. Such guidance would include recommendations for reviewing the methodological literature specifically to inform method guidance, for selecting and involving key stakeholders in the guidance development process, and for presenting methods guidance that optimizes researcher-friendliness and findability (eg, label it as “methods guidance” and provide a clear objective in a structured abstract).⁹

Conclusions

LIGHTS is a new peer-supported initiative and a publicly available database that may increase access to and promote the use of existing methods guidance and inform the development of future guidance. LIGHTS is intended to support health researchers in making methodological choices, support research evaluators in identifying methodological standards or quality assessment tools, help developers of methods guidance identify existing guidance, and serve as a resource for health research students, science educators, and methods consultants.

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Concept and design: Hirt, Ewald, Guyatt, Briel, Schandelmaier.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Hirt, Schandelmaier.

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Supervision: Guyatt, Briel, Schandelmaier.

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SUPPLEMENT 1.

eAppendix 1. Ovid MEDLINE Search Strategy (Not Part of the Current Search Process of LIGHTS), Yielding 915 523 Records on May 6, 2022, Covering 921 (77.8%) of a Sample of 1184 Seed Articles

eAppendix 2. Instructions for Team Members of LIGHTS Working Group for Full-Text Eligibility Assessment, Indexing, and Taxonomy Development for LIGHTS

SUPPLEMENT 2.

Data Sharing Statement