BMJ Open

Reporting of methodological studies in health research: a protocol for the development of the METhodological study ReportIng Checklist (METRIC)

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-040478
Article Type:	Protocol
Date Submitted by the Author:	14-May-2020

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Keywords:	STATISTICS & RESEARCH METHODS, EPIDEMIOLOGY, EDUCATION & TRAINING (see Medical Education & Training)

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Reporting of methodological studies in health research: a protocol for the development of the METhodological study ReportIng Checklist (METRIC)

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Word count: 3798

ABSTRACT

Introduction: Methodological studies (i.e. studies that evaluate the design, conduct, analysis or reporting of other studies in health research) address various facets of health research including, for instance, data collection techniques, differences in approaches to analyses, reporting quality, adherence to guidelines, or publication bias. As a result, methodological studies can help to identify knowledge gaps in the methodology of health research, and suggest strategies for improvement in research practices. Differences in methodological study names and a lack of reporting guidance contribute to lack of comparability across studies, and difficulties in identifying relevant previous methodological studies. This paper outlines the methods we will use to develop an evidence-based tool—the METhodological study ReportIng Checklist (METRIC)—to harmonize naming conventions and improve the reporting of methodological studies.

Methods and analysis: We will search for methodological studies in the Cumulative Index to Nursing and Allied Health Literature, Cochrane Library, Embase, MEDLINE, Web of Science, check reference lists, and contact experts in the field. We will extract and summarize data on the study names, design, and reporting features of the included methodological studies. Consensus on study terms and recommended reporting items will be achieved via video conference meetings with a panel of experts including researchers who have published methodological studies.

Ethics and dissemination: The consensus study has been exempt from ethics review by the Hamilton Integrated Research Ethics Board. The results of the review and the reporting guideline will be disseminated in stakeholder meetings, conferences, peer-reviewed publications, in

requests to journal editors (to endorse or make the guideline a requirement for authors), and on the EQUATOR Network and METRIC websites.

Registration: We have registered the development of METRIC with the EQUATOR Network, and publicly posted this project on the Open Science Framework (www.osf.io/9hgbq).

STRENGTHS AND LIMITATIONS OF THIS STUDY

- To the best of our knowledge, this is the first study to design an evidence-based tool to support the complete and transparent reporting of methodological studies in health research.
- This project will help to highlight the current reporting practices of authors of methodological studies to outline a list of key reporting items.
- The stakeholders recruited for the consensus study will represent a diverse group of expert health research methodologists including biostatisticians, clinical researchers, journal editors, healthcare providers, and reporting guideline developers.
- Our study does not incorporate a blinded consensus process and this may impact the flow of discussions during the conference meetings.

INTRODUCTION

Concerns with the quality and quantity of research have sparked interest in the rapidly evolving field which has been called meta-epidemiology, meta-research, or research-on-research [1-3]. This field of research addresses the entire research process, from question development to design, conduct and reporting issues, and most often uses research-related reports (e.g. protocols, published manuscripts, registry entries, conference abstracts) as the unit of analysis. These studies have also been previously described as systematic reviews that "(1) describe the distribution of research evidence for a specific question; (2) examine heterogeneity and associated risk factors; and (3) control bias across studies and summarize research evidence as appropriate" [4]. For the purpose of this project, we will refer to these research outputs as "methodological studies", i.e. studies that evaluate the design, conduct, analysis (including bias), or reporting of other studies in health research. This definition does not include statistical methodological studies (e.g. studies testing new algorithms or analytical methods, simulation studies, and experimental studies in which the unit of analysis is not a research report). Methodological studies are important because they can identify gaps, biases, and inefficiencies in research practices, and propose improvements and solutions. A PubMed search performed in April 2020 for terms often used to describe methodological studies suggests that the rate of publication of methodological studies has increased over time, illustrated in Figure 1.

— Figure 1. Trends in methodological studies indexed in PubMed from 2009 to 2019. —

In the past 20 years, methodological studies have influenced the conduct of health research by informing many popular practices such as double data extraction in systematic reviews [5]; optimal approaches to conducting subgroup analyses [6]; and reporting of randomized trials, observational studies, pilot studies, and systematic reviews [7-10] to name a

few. Methodological studies have played an important role in ensuring that health research is reliable, valid, transparent and replicable. These types of studies may investigate: bias in research [11, 12], quality or completeness of reporting [13, 14], consistency of reporting [15], methods used [16], factors associated with reporting practices [17]; and may provide summaries of other methodological studies [18], and other issues. Methodological studies may also be used to evaluate the uptake of methods over time to investigate whether (and where) practices are improving and allow researchers to make comparisons across different medical areas [19, 20]. These studies can also highlight methodological strengths and shortcomings such as sample size calculations in randomized controlled trials [21, 22], quality of clinical prediction models [23], and spin and over-interpretation of study findings [24-26]. As such, methodological studies promote robust, evidence-based science and help to discard inefficient research practices [27]. A draft conceptual framework of the various categories of methodological studies that we have observed is outlined in Figure 2. Broadly, some categories of methodological studies include those investigating: bias and spin, methodological approaches to study design, or reporting issues.

— Figure 2. Draft conceptual framework of categories of methodological studies. —

Despite the importance of methodological studies, there is no guidance for their reporting. Murad and Wang have suggested a modification to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), a widely used reporting tool that is sometimes used for methodological studies because these studies often use methods that are also used in systematic reviews [28]. Although useful for reporting some aspects of methodological studies, the modified PRISMA approach does not fully address the many types of questions that methodological studies attempt to answer, and the specific methods and results of these studies.

Studies that include a random sample of research reports [29], or those structured as before-after investigations [19] are examples of methodological studies that would be a poor fit for the modified PRISMA tool, which is best suited for studies designed in the style of systematic reviews. Likewise, studies in which the unit of analysis is not the "study" require more specific guidance (e.g. when investigating multiple subgroup analyses or multiple outcomes within the same study) [30]. Thus, guidelines for transparent reporting of methodological studies are needed, and this need is widely acknowledged in the scientific community [31, 32]

Our work will address two main concerns:

1. There are no globally accepted names for methodological studies, making them difficult to identify. Methodological studies have been called 'methodological review', 'systematic review', 'systematic survey', 'literature review', 'meta-epidemiological study' and many other names. The diversity in names compromises training and educational activities [33], and it makes it difficult for end-users (e.g. clinical researchers, guideline developers) to search for, identify and use these studies [34, 35].
2. The reporting of methodological studies is inconsistent, which may relate to differences in objectives, and to differences in transparency and completeness. That is, some studies may be better reported than others. While the most appropriate approach to reporting will depend on the research question, explicit, user-friendly, and consensus-based guidance is needed to ensure that methodological studies are reported transparently and comprehensively [36].

Aims

The aims of this study protocol are to outline the procedures to define and harmonize the names describing methodological studies, and to develop reporting guidelines for methodological studies in human health research.

METHODS AND ANALYSIS

Study design

We have adopted the strategy for the development of reporting guidelines proposed by Moher et al. [37]. A visual overview of this approach, highlighting key components of the process, is presented in Figure 3. The three parts of the project which will be addressed using the above strategy are outlined in detail below (see Supplementary File for an outline of the data flow informing subsequent parts of the project).

— Figure 3. Project overview for the development of reporting guidelines for methodological studies in health research. —

Part 1: Methodological Review

The objectives of this part are to: a) identify names used to describe methodological studies, b) identify the various designs, analysis and reporting features of methodological studies, c) find any previous reporting guidance, and d) identify methodological study experts.

Search strategy

We developed a search strategy informed by our pilot work [38] targeting health-related sciences and biomedicine databases: Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Library, Excerpta Medica (Embase), MEDLINE, and Web of Science. We will limit our search to the last complete ten years (2009-2019). There will be no limits by publication type or language. We will perform searches for authors known to publish in this field, check reference lists of relevant studies, check existing methodological study repositories (Studies Within a Trial [SWATs] and Studies Within a Review [SWARs]), preprints (bioRxiv and medRxiv), setup Google Alerts for key words (e.g. meta-epidemiology, research-on-research), and contact experts (e.g. via email, meetings, following relevant journals, subscribing

to methods email newsletters including the Methods in Research on Research [MiRoR] and the National Institute for Health and Care Excellence [NICE] groups, and following researchers on social media platforms such as ResearchGate and Twitter) to identify additional methodological studies. We will also check the EQUATOR library to identify any published or under development reporting guidance. These approaches are informed by previous work and published literature [35, 38]. Two health sciences librarians at the Health Sciences Library (McMaster University) were consulted and reviewed the final search strategy (see Supplementary File) in line with the Peer Review of Electronic Search Strategies (PRESS) framework [39].

Eligible studies

Studies that investigate methods—design, conduct, analysis, or reporting—in other studies of health research in humans will be eligible. The 'other studies' (or research reports) refers to the unit of analysis of the methodological studies (e.g. abstracts, cohort studies, randomized trials, registry records, study protocols, systematic reviews). Only published protocols and final reports of studies that investigate methods will be eligible. Statistical methodological studies will not be eligible (e.g. studies testing new algorithms/analytical methods and simulation studies in which the unit of analysis is not another research report).

Screening

A team of reviewers led by DOL will screen titles and abstracts independently, in duplicate in *Rayyan* [40], and full-texts in standardized forms in *DistillerSR* [41]. Both are online collaborative platforms for screening and reviewing literature. We will measure agreement on screening and study inclusion using Cohen's Kappa statistic [42, 43]. Any discrepancies between reviewers will be resolved through discussion.

Data extraction

In order to document the current reporting practices we will extract data from included studies independently, in duplicate based on a standardized data collection form. Key data extraction fields for documenting methodological study features and reporting practices (e.g. study design name, databases search, any guideline use) are outlined in Table 1. All data will be compiled in *DistillerSR*. Any discrepancies between reviewers will be resolved through discussion.

Table 1. Overview of data extraction fields for the review.

Section	Data to be collected
Bibliometrics	• Corresponding or last author (first and last name) and contact information (email address). We will first verify whether the corresponding author has academic faculty status, and if not, we will contact the last author • Country of author • Publication year • Study design name in title (verbatim quotation/descriptor) • Type of article (protocol or final publication, and letter/brief report or full publication) • Journal
Methods	• Study design name in methods section (verbatim quotation/descriptor) • Objectives (verbatim quotation) • Outcomes (verbatim quotation) • Search strategy reported (yes/no) • Search time limits and justifications (yes/no and verbatim quotation) • Databases searched

	• Included research report types (e.g. randomized trials, systematic reviews, cohort studies) • Sampling method (where applicable) • Analysis type (e.g. correlation, descriptive, regression, time-series) • Reporting guidance used and justification (yes/no, name and verbatim quotation) • Prospective registration and existence of a published protocol (yes/no, where applicable)
Results	• Presence of flow diagrams (yes/no) • Total records screened and included • Type of final synthesis performed (qualitative, quantitative, both)
Discussion	• Intended use of findings (verbatim quotation) • Limitations (verbatim quotation)
Other	• Conflicts of interest (yes/no) • Funding type (e.g. industry, institutional, non-profit) • Provide access to data (yes/no)

All reviewers will undergo calibration exercises and pilot the screening and data collection forms (25 studies per reviewer). We will incorporate an emergent design in the data collection stage of the review, which is characterized by a flexibility in the methodology, allowing researchers to remain open to modifications [44]. Should any new information that is of interest arise during the full-text screen or data extraction, we will update the data collection form and collect this information for all studies retrospectively and going forward. Any modifications to the present protocol will be reported in the final published review. This iterative approach will allow for the capture of information as new methodological study design features

come to light during the full-text screening and data extraction phases. Based on this approach, data extraction will be updated accordingly for previously reviewed studies as needed. For example, we expect to see overlaps in methodological study names, some of which might be attributed to collaborating research groups. There also appear to be similarities in methodological study reporting styles that are borrowed from systematic review [4] or survey study designs, which have both been extensively developed and are omnipresent in health research literature. However, if the current data collection fields, listed in Table 1, are insufficient to capture the nuances of the varieties of methodological studies, we will revise our data collection forms accordingly and collect the data for all studies.

Generation of a list of candidate items

The generation of a list of candidate items will be informed by two sources. First, a list of reporting items will be compiled based on what has been reported by authors of the included studies in the methodological review (e.g. flow diagram, search strategy). We will also note the use of any reporting guidance as mentioned by authors (e.g. PRISMA, STrengthening the Reporting of OBservational studies in Epidemiology [STROBE]). Each item will be ranked from most frequently reported to those less frequently reported. Second, this list will be presented to expert user stakeholders alongside the proportion of methodological studies that report on each item. Stakeholders will be asked to propose additional relevant items to finalize the list of candidate reporting items for Part 2.

Data analysis

We will present the flow of articles retrieved and screened in a study flow diagram, and summarize data in tables with explanatory text. We will provide descriptive statistics, i.e. counts (percentage) for categorical data, and means (standard deviation [SD]) or medians (interquartile

range [IQR]) for continuous data. In addition to study names, we will synthesize and tabulate verbatim quotations for the study objectives, outcomes, and intended use of findings to provide context and clarification for methodological study rationales [48]. We will qualitatively group studies into categories based on similarities in reporting features. All statistical analyses will be done in *STATA version 15.1* [46]. We will identify additional potential stakeholders from the list of authors of included studies.

Part 2: Consensus Study

This part of the project will consist of consultation with expert user stakeholders in a consensus study. The objectives are to define methodological studies, and outline the recommended study name(s) and best reporting practices. The project steering group (DOL, GG, LM, LT), which includes members with expertise in health research methods, will oversee the consensus study and development of the reporting guideline.

Identification of stakeholders

The steering group will be responsible for identifying expert user stakeholders based on expertise with methodological studies and expertise with reporting guideline development [49]. Additional stakeholders will be identified from the list of authors (either corresponding or senior, with academic faculty-status) of methodological studies from the review. In our selection of stakeholders, we will seek individuals who will be committed to participating and providing feedback for the reporting guideline. We define expert user stakeholders as researchers involved in the design, conduct, analysis, interpretation, or dissemination of methodological studies. Approximately 20-30 stakeholders will be selected (including the protocol authors) as participants in the consensus exercises. We will track response rates to invitations to participate

in the consensus study. We will collect participant demographics (e.g. country, primary job title, academic rank, and methodological study publication history) to provide insight into the representation in this field of research based on sociocultural factors.

Measuring agreement and achieving consensus

The above definition of methodological studies (i.e. studies that evaluate the design, conduct, analysis, or reporting of other studies in health research) will be used during the online consensus exercises and video conference meetings. Participants will discuss the following: a) names for methodological studies, b) categories of methodological studies, and c) reporting requirements. These three components, outlined in Table 2, will be completed electronically through a McMaster Ethics Compliant service, *LimeSurvey* (https://reo.mcmaster.ca/limesurvey) for online surveys [50].

Table 2. Overview of consensus study activities and expected outputs.

Stage	Description of activities to be completed	Expected outputs
Online consensus exercise: categories of methodological studies*	• We will present the **proposed categories of methodological studies** (i.e. based on the aim, design, sampling strategy and unit of analysis) with rationale for each. For each category (e.g. methodological studies that evaluate study design; methodological studies that evaluate reporting practices) an example of studies that belong in each category will also be presented. An example of potential categories are outlined in Figure 2.	• List of 'appropriate' categories for methodological studies

	• Participants will be asked to rate and comment on the appropriateness of each category on a 3-point ordinal scale: 3-appropriate; 2- somewhat appropriate; 1-inappropriate • A validity ratio (VR) will be computed as follows: $\boldsymbol{VR} = \frac{(\boldsymbol{Ne} - \boldsymbol{N}/\mathbf{2})}{(\mathbf{N}/\mathbf{2})}$ where ***Ne*** is the number of participants who indicated that the category was appropriate (i.e., a rating of "3") and ***N*** is the total number of participants. This ratio will indicate the category that at least half of the participants consider appropriate. The VR will be interpreted based on a table of critical values [51]. For example, for 30 participants (N = 30), the critical value is 0.33 (i.e., at least 20 participants must deem the category appropriate). Only items based on a critical value greater than the set threshold will be considered further [52]. This approach allows consensus to be achieved remotely, and makes decision-making objective.	

Online consensus exercise: name(s) for methodological studies*	• We will present the **names of methodological studies** and for each name (i.e. meta-epidemiological study, systematic survey etc.), an example of a study using that name will be provided. • Participants will be asked to rate the appropriateness of each potential name on a 3-point ordinal scale, and VR will be computed: 3- appropriate; 2- somewhat appropriate; 1- inappropriate	• List of 'appropriate' names for methodological studies
Online consensus exercise: reporting items*	• We will present the **proposed reporting items** and participants will be asked to rate the usefulness of each item on a 3-point ordinal scale, and VR will be computed: 3- essential; 2- maybe essential; 1- not essential • Participants will be asked to indicate if each reporting item applies to each different methodological study category.	• List of 'essential' reporting items for methodological studies
First video conference meeting (two	• Participants will confirm the appropriate name(s) and categories for methodological studies, and agree on reporting items that should be included or excluded, and	• First drafts of the: a) reporting checklist b) user guide

calls†, 2 hours each)	discuss the rationales behind their selections. All participants will be required to come to a consensus to include an item. • Meeting minutes and summary of the discussion and decisions will be shared with participants to provide additional feedback after the meeting. • Based on these discussions and decisions, the steering group will develop a **first draft of the reporting checklist** (e.g. with a checkbox to indicate Yes/Reported, No/Not Reported, and a space to indicate on what page the information is reported). • The checklist will be divided into different reporting sections in a methodological study (e.g. Introduction, Methods, Results, Discussion). • Examples of how to report information for each item will be provided alongside the checklist as part of the **draft user guide**. This will be shared with participants for comment prior to the next meeting.	c) recommended methodological study name(s) and categories
Second video conference meeting (two	• Participants will agree on a structure and format for the checklist (e.g. general layout, decision tree to delineate the	• Revised drafts of the: a) reporting checklist b) user guide

calls†, 2 hours each)	category of the methodological study, core items for each category of methodological study, optional items). The group will also review the examples of reporting to be included in the user guide for each reporting item. • Meeting minutes and summary of the discussion and decisions will be shared with participants to provide additional feedback after the meeting. • Based on these discussions and decisions, the steering group will develop a **revised draft of the reporting checklist** and an **elaborated user guide**.	c) recommended methodological study name(s) and categories
Final video conference meeting (4 hours)	• Discussion with participants will focus on confirming rationales for the final selected items, and providing examples for each reporting item to be outlined in the consensus statement and elaboration.	• Final documents for the: a) reporting checklist b) user guide c) recommended methodological study name(s) and categories • Consensus statement and elaboration

* During the online exercises, participants can suggest additional categories, names, or items that they wish to discuss during the video conferences.
† Two calls will be scheduled to accommodate stakeholders in Eastern and Western time zones.

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All video conferences will be facilitated by two investigators (DOL and LM). Stakeholders will be consulted for the development of drafts, elaborations and explanations for specific items. All steering committee members and stakeholders will be required to participate and vote during the consensus meetings. Disagreements will be resolved through discussion, and if no consensus can be reached, the steering committee will convey the recommendations for the stakeholder group to approve. *Zoom*, or comparable video conferencing software, will be used to allow for the collection of recordings [53].

Data analysis

Findings from the consensus exercise will be summarized descriptively in tables that include counts (percentage) for categorical data, and means (SD) or medians (IQR) for continuous data. We will measure the levels of agreement (i.e. percentage increase in agreement for successive rounds, number of comments made for each successive round, and rounds with emergence of new themes) and instability (i.e. spread and SD of ranked responses for each item) for each round [54]. After the online exercises, one investigator (DOL) will qualitatively synthesize and code the suggestions for the methodological study names, categories and reporting items into common themes in *Dedoose*, a qualitative research software [55]. The steering committee will synthesize data from the participant discussions to revise each subsequent draft.

Part 3: Reporting Guideline

The objectives of this part are to develop, refine, publish, and disseminate the reporting guideline for methodological studies. We have registered the development of the reporting guideline—METhodological study ReportIng Checklist (METRIC)—with the EQUATOR Network [56]. This record may see updates to its name and acronym after deliberations during the consensus

study. We will also consider which reporting items are appropriate for different categories of methodological studies. This will include discussions about whether a decision tree may be useful to direct users to other existing reporting guidelines should they be more appropriate for specific categories of methodological studies (e.g. STROBE for methodological studies designed as cohort studies). Quantitative and qualitative findings from the consensus study will be incorporated into the final guideline document to include the: a) recommended methodological study name(s) and categories, b) recommended checklist with agreed upon reporting items, c) user guide and elaboration (e.g. an explanation of why it is important, rationales and an example of how it can be presented in a methodological study), and d) consensus statement. The draft document will be returned to the steering group and stakeholders to collect additional feedback. The checklist will be tested with end-users for face validity and clarity, and for additional fine-tuning as needed prior to publication. We will distribute the finalized checklist to a group of authors of methodological studies identified from the review (Part 1) to assess its usefulness and whether the checklist appropriately captures items relevant to the reporting of methodological studies [57].

Patient and public involvement

Although patients and the general public are not directly involved in this project, the findings of this research will be relevant to a broad range of knowledge users including methodological study authors, health researchers, methodologists, statisticians, and journal editors. We will seek recommendations from investigators for general public members and patients that could be recruited for this project.

ETHICS AND DISSEMINATION

This research has received an exemption (October 2019) from the Hamilton Integrated Research Ethics Board (HiREB) for the consensus study. Ethics committee approval and consent to participate is not required for any other component of this project since only previously published data will be used.

Data deposition and curation

All participant records and data will be stored in MacDrive, a secure cloud storage drive that is privately hosted and based in-house at McMaster University [58]. Only two researchers (DOL and LM) will have direct access to study related documents and source data. Qualitative data will be promptly coded and transcribed, and all audio files will be encrypted. As part of our knowledge translation (KT) strategy and a consequence of the difficulties we faced in retrieving methodological studies from literature databases during our pilot work, we have developed an open-access database of methodological studies (www.methodsresearch.ca). We will catalogue all included studies from the pilot and full reviews on this website such that end-users can easily retrieve these studies. We have also setup a submission portal for researchers to submit their studies to be catalogued in this database. Parallel research by our colleagues will use this database as well as explore the automation of retrieving and indexing methodological studies in a dedicated space [59]. Lastly, we will setup a complementary website to serve as the primary repository for the published reporting guideline document.

Dissemination

We will publish all manuscripts arising from this research and present the findings at conferences. We will setup a complementary website to serve as the primary repository for the published reporting guideline document. The inclusion of knowledge users and representatives from methodology journals and guideline groups on our core study team will aid the wide

dissemination of the reporting guideline. We continue to contact journal editors for their endorsement, and encourage researchers to reach out to us about this work, as we have done previously [34]. We will also encourage user feedback to inform future updates of the guideline as needed. These approaches are informed by our collective experience in developing and disseminating health research guidelines [7, 60-64].

DISCUSSION

Our work is contributing to reducing research waste by: 1) making methodological studies transparent through streamlining their reporting; 2) permitting researchers to appraise methodological studies based on adherence to proposed guidelines; 3) allowing end-users of methodological studies to be able to locate inaccessible research in a dedicated database and promoting its continued development; and in doing so 4) allowing end-users of methodological studies to better evaluate and identify issues with study design and reporting that influence patient health, enabling them to apply methodological study evidence to their own research practices. Many methodological studies are done to improve the design, conduct, analysis and reporting of primary and secondary research. We anticipate that, in reviewing this body of evidence on research methods, we will further highlight the importance of studies that aim to improve the design of health research [65].

Strengths and limitations

We acknowledge that there are inherent challenges in the search and retrieval of studies that lack consistent names, or dedicated indexing in common health research databases. As such, it is plausible that certain methodological studies that use terms not previously identified in the pilot or from our systematic database searches may be missed. To mitigate this limitation, we will

(and have already) contact(ed) experts in the field to identify additional studies, and screen references and citing articles of relevant studies. We have consulted extensively with librarians at the McMaster Health Sciences Library on optimal approaches to capture the maximum number of studies.

The uncertainty in the number of methodological studies that are currently available and published in the literature can present additional logistic and timing constraints to the review component and overall progress of this work. However, given the landscape of methodological studies, we believe it is essential to apply a comprehensive search. To help with the organization of screening and data extraction, we will use robust systematic review management software (*DistillerSR*) [41]. Further, we have designed all screening and data extraction prompts to ensure consistency and replicability of our work.

Lastly, our study does not incorporate a blinded consensus process and this may impact the flow of discussions during the video conference meetings. We will aim to regulate discussions such that dominant speakers do not steer the discussion and ensuring that all participants have a chance to speak. Additionally, we will share summaries of the discussion and decisions after the meetings. This will allow for participants to privately provide any additional written feedback to the steering group that may not have been addressed.

A key strength of this research is the diversity of our study team. We have brought together an international, multidisciplinary team with expertise in consensus activities and guideline development, and research methodology and synthesis. This gives us an advantage in the breadth of feedback and fruitful discussions to be had with a wide array of users of the forthcoming guideline. Given the rise in the conduct of methodological studies, a general call for guidelines in the scientific community, and the number of teams that have reached out to us with

interest in participating in this work, we are confident that the guideline will be used. However, we fully acknowledge the factors associated with implementation and use of guidelines, notably journal endorsement of the guidelines, the passage of time and other study level characteristics [20, 66-70]. Therefore, our stakeholders include editors from key journals that publish methodological studies such as the *Journal of Clinical Epidemiology*, *BMC Medical Research Methodology*, *BMC Systematic Reviews*, *The Campbell Collaboration,* and *Cochrane*. Stakeholders also include representatives from academic programs building capacity, at the master's and doctoral level, in conducting methodological research. To encourage better uptake, it has been suggested that researchers should work collaboratively with journals in the prospective design, knowledge translation, and evaluation of reporting guidelines [71], as well as following up on user feedback and incorporating a system to revise the reporting guidelines when necessary [72]. These strategies have been incorporated in our KT plan.

CONCLUSIONS

This research will improve the transparency of reporting of methodological studies, and help streamline their indexing and easier retrieval in literature databases. This work stands to make a substantial impact by informing research reporting standards for studies that investigate the design, conduct, analysis, or reporting of other health studies, and thereby improving the transparency, reliability and replicability of health research, and ultimately benefitting patients and decision makers. Future efforts will focus on field-testing the published checklist with authors of methodological studies, gathering feedback from end-users, and optimizing and adapting the checklist for different typologies of methodological studies as needed.

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AUTHORS' CONTRIBUTIONS

DOL and LM conceived the idea. DOL, GG, LM and LT contributed to the design of the study. DOL wrote the first draft of the manuscript. AKN, AWC, BDT, DBA, DM, DP, EMW, GG, GSC, JCJ, LM, LP, LT, MB, PT, RBP, SS, TY, VW and ZS contributed to the refinement of the study methods and critical revision of the manuscript. All authors read and approved the final version of the manuscript.

FUNDING

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors. This project is being carried out as part of a doctoral dissertation by DOL. DOL is supported by an Ontario Graduate Scholarship and the Queen Elizabeth II Graduate Scholarship in Science & Technology administered through McMaster University, and the Ontario Drug Policy Research Network Student Training Program. The funders had no influence over the design, data collection, analysis, interpretation, preparation of or decision to publish the manuscript.

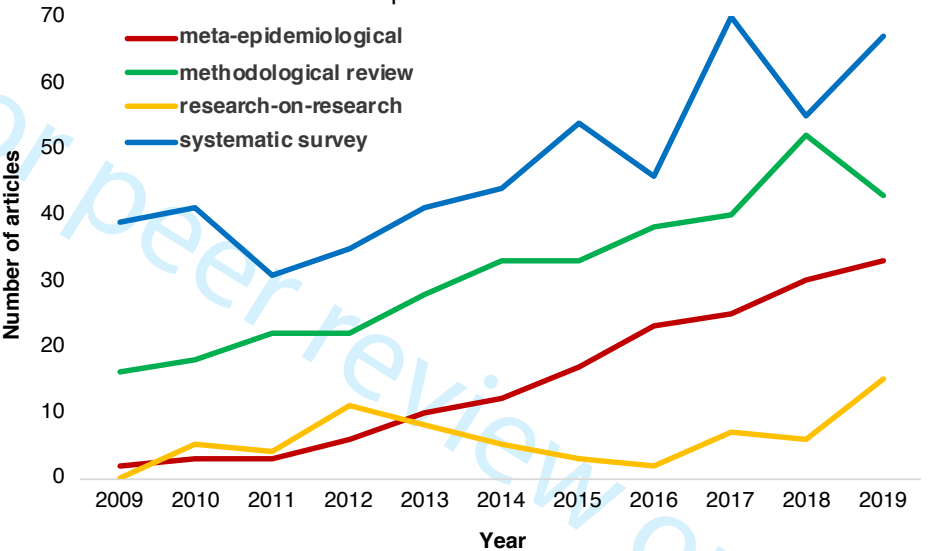
COMPETING INTERESTS

All study authors have published methodological studies.

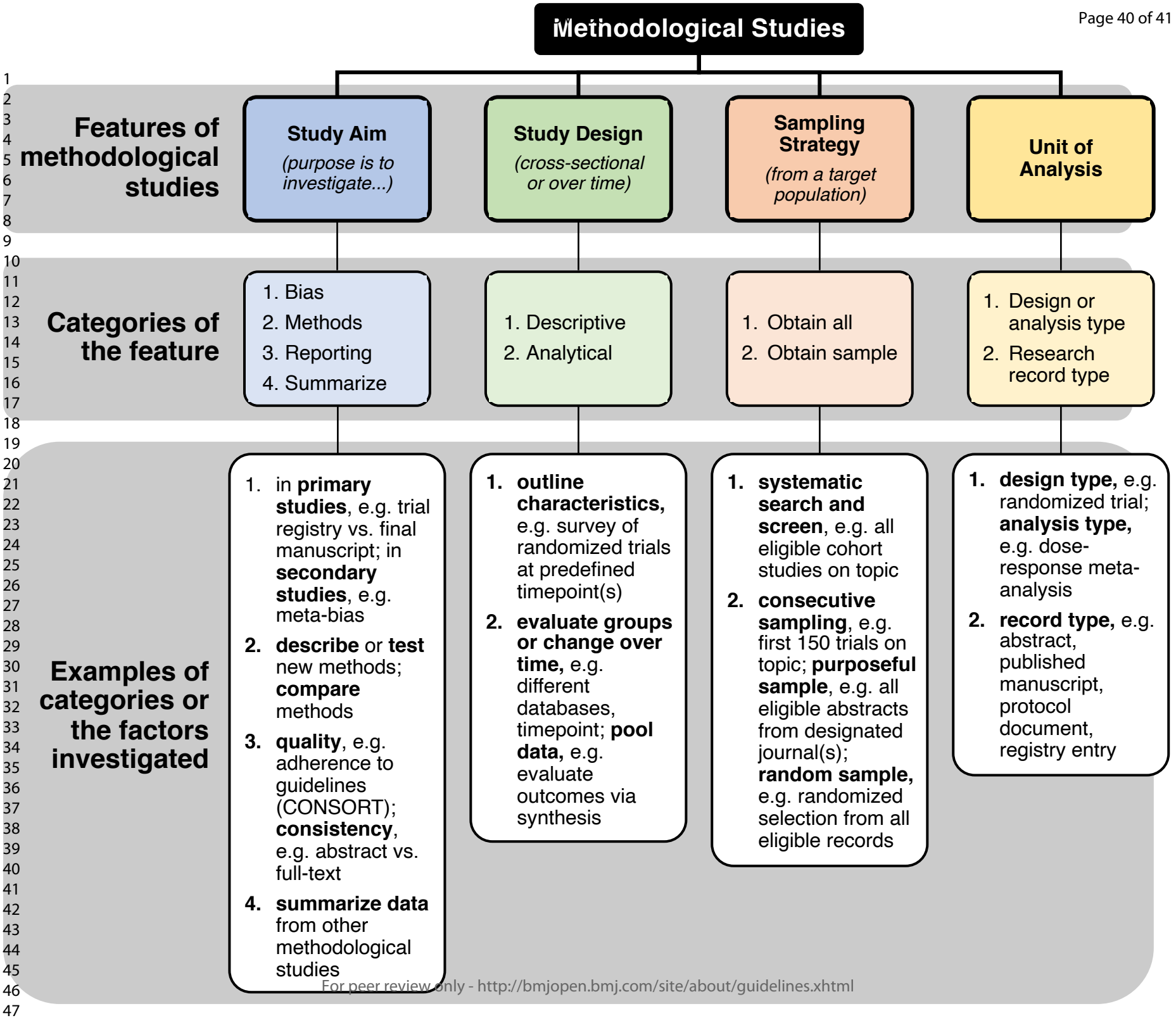
ACKNOWLEDGEMENTS

We would like to thank Denise Smith and Jack Young at the Health Sciences Library at McMaster University for their critical review of the search strategy. We would like to thank Dr.

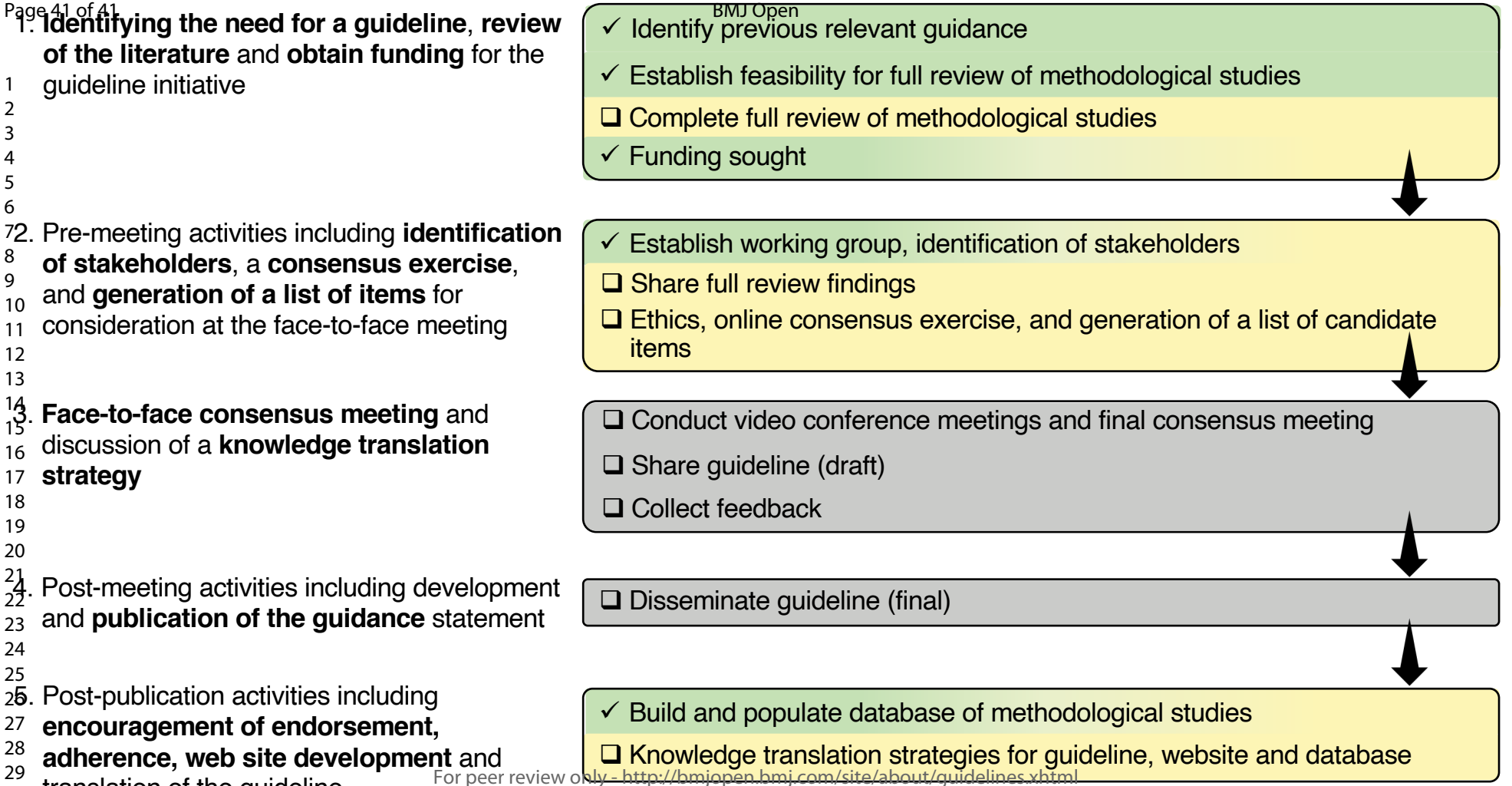
628 Susan Jack at the School of Nursing at McMaster University for sharing her expertise and
629 recommendations on qualitative and mixed methods research design.



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
meta-epidemiological	2	3	3	6	10	12	17	23	25	30	33
methodological review	16	18	22	22	28	33	33	38	40	52	43
research-on-research	0	5	4	11	8	5	3	2	7	6	15
systematic survey	39	41	31	35	41	44	54	46	70	55	67

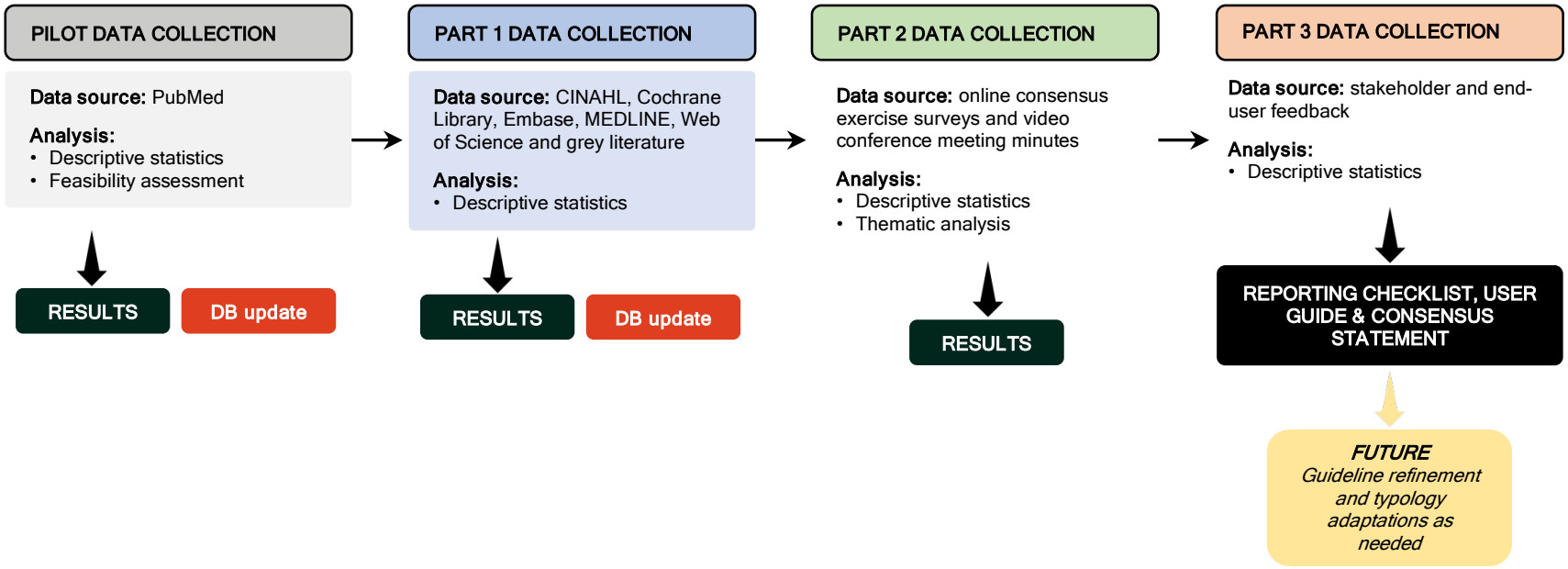


CONSORT: CONsolidated Standards of Reporting Trials.



SUPPLEMENTARY FILE

Flow of data for informing subsequent stages of the project:



CINAHL: Cumulative Index for Nursing and Allied Health Literature, DB: database (www.methodsresearch.ca)

Sample search strategy for MEDLINE:

	Concept: names of methodological studies
1	(meta-epidemiolog* OR metaepidemiolog* OR meta-research OR methodolog* analysis OR methodolog* evidence OR methodolog* investigation OR methodolog* literature OR methodolog* overview OR methodolog* report* OR methodolog* review OR methodolog* survey OR methodolog* synthesis OR method* overview OR systematic database review OR systematic literature survey OR systematic survey).mp.
2	(methodolog* study OR method* review OR method* survey)
	Concept: topics in methodological research (i.e. analysis, design and reporting)
3	exp Data Collection/
4	exp Data Interpretation, Statistical/
5	exp Epidemiologic Research Design/
6	exp Nursing Methodology Research/
7	exp Reproducibility of Results/
8	exp Research Design/
9	3 OR 4 OR 5 OR 6 OR 7 OR 8
10	2 AND 9
	Concept: methodological studies that are called 'systematic reviews'
11	systematic review.mp.
12	Cochrane Database of Systematic Reviews.jn
13	11 NOT 12
14	*Data Collection/
15	*Data Interpretation, Statistical/
16	*Epidemiologic Research Design/
17	*Nursing Methodology Research/
18	*Reproducibility of Results/
19	*Research Design/
20	14 OR 15 OR 16 OR 17 OR 18 OR 19
21	13 AND 20
22	1 OR 10 OR 21

BMJ Open

Reporting of methodological studies in health research: a protocol for the development of the MethodologIcal Study reporTIng Checklist (MISTIC)

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-040478.R1
Article Type:	Protocol
Date Submitted by the Author:	05-Nov-2020
Complete List of Authors:	Lawson, Daeria; McMaster University, Department of Health Research Methods, Evidence, and Impact Puljak, Livia ; Croatian Catholic University, Center for Evidence-Based Medicine and Health Care Pieper, Dawid; University of Witten/Herdecke, Institute for Research in Operative Medicine Schandelmaier, Stefan; McMaster University, Department of Health Research Methods, Evidence, and Impact; University and University Hospital of Basel, Institute for Clinical Epidemiology and Biostatistics, Department of Clinical Research Collins, Gary; University of Oxford, Centre for Statistics in Medicine Brignardello-Petersen, Romina ; McMaster University, Department of Health Research Methods, Evidence, and Impact Moher, David; Ottawa Hospital Research Institute, Centre for Journalology, Clinical Epidemiology Program; University of Ottawa, School of Epidemiology and Public Health, Faculty of Medicine Tugwell, Peter; University of Ottawa, Department of Medicine and School of Epidemiology and Public Health, Faculty of Medicine; Bruyère Research Institute Welch, Vivian A.; University of Ottawa, School of Epidemiology and Public Health, Faculty of Medicine; Bruyère Research Institute Samaan, Zainab; McMaster University, Department of Health Research Methods, Evidence, and Impact Thombs, Brett; McGill University, Faculty of Medicine; Jewish General Hospital, Lady Davis Institute for Medical Research Nørskov, Anders; Copenhagen University Hospital, Copenhagen Trial Unit Jakobsen, Janus; Copenhagen University Hospital, Copenhagen Trial Unit; University of Southern Denmark, Department of Regional Health Research, The Faculty of Heath Sciences Allison, David; Indiana University Bloomington School of Public Health, Department of Epidemiology and Biostatistics Mayo-Wilson, Evan; Indiana University Bloomington School of Public Health, Department of Epidemiology and Biostatistics Young, Taryn; Stellenbosch University, Centre for Evidence-based Health Care, Faculty of Medicine and Health Sciences Chan, An-Wen; University of Toronto, Department of Medicine, Women's College Research Institute Briel, Matthias; McMaster University, Department of Health Research Methods, Evidence, and Impact; University and University Hospital of

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Primary Subject Heading:	Research methods
Secondary Subject Heading:	Epidemiology, Evidence based practice, Medical publishing and peer review
Keywords:	STATISTICS & RESEARCH METHODS, EPIDEMIOLOGY, EDUCATION & TRAINING (see Medical Education & Training)

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Reporting of methodological studies in health research: a protocol for the development of the MethodologIcal Study reporTIng Checklist (MISTIC)

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Word count: 3823

ABSTRACT

Introduction: Methodological studies (i.e. studies that evaluate the design, conduct, analysis or reporting of other studies in health research) address various facets of health research including, for instance, data collection techniques, differences in approaches to analyses, reporting quality, adherence to guidelines, or publication bias. As a result, methodological studies can help to identify knowledge gaps in the methodology of health research, and strategies for improvement in research practices. Differences in methodological study names and a lack of reporting guidance contribute to lack of comparability across studies, and difficulties in identifying relevant previous methodological studies. This paper outlines the methods we will use to develop an evidence-based tool—the MethodologIcal Study reporTIng Checklist (MISTIC)—to harmonize naming conventions and improve the reporting of methodological studies.

Methods and analysis: We will search for methodological studies in the Cumulative Index to Nursing and Allied Health Literature, Cochrane Library, Embase, MEDLINE, Web of Science, check reference lists, and contact experts in the field. We will extract and summarize data on the study names, design, and reporting features of the included methodological studies. Consensus on study terms and recommended reporting items will be achieved via video conference meetings with a panel of experts including researchers who have published methodological studies.

Ethics and dissemination: The consensus study has been exempt from ethics review by the Hamilton Integrated Research Ethics Board. The results of the review and the reporting guideline will be disseminated in stakeholder meetings, conferences, peer-reviewed publications, in requests to journal editors (to endorse or make the guideline a requirement for authors), and on the EQUATOR Network and reporting guideline websites.

Registration: We have registered the development of the reporting guideline with the EQUATOR Network, and publicly posted this project on the Open Science Framework (www.osf.io/9hgbq).

STRENGTHS AND LIMITATIONS OF THIS STUDY

- To the best of our knowledge, this is the first study to design an evidence-based tool to support the complete and transparent reporting of methodological studies in health research.
- This project will help to highlight the current reporting practices of authors of methodological studies to outline a list of key reporting items.
- The stakeholders recruited for the consensus study will represent a diverse group of expert health research methodologists including biostatisticians, clinical researchers, journal editors, healthcare providers, and reporting guideline developers.
- Our study does not incorporate a blinded consensus process and this may impact the flow of discussions during the conference meetings.

INTRODUCTION

Concerns with the quality and quantity of research have sparked interest in the rapidly evolving field which has been called meta-epidemiology, meta-research, or research-on-research [1-3]. This field of research addresses the entire research process, from question development to design, conduct and reporting issues, and most often uses research-related reports (e.g. protocols, published manuscripts, registry entries, conference abstracts) as the unit of analysis. These studies may seek to "(1) describe the distribution of research evidence for a specific question; (2) examine heterogeneity and associated risk factors; and (3) control bias across studies and summarize research evidence as appropriate" [4]. For the purpose of this project, we will refer to these research outputs as "methodological studies", i.e. studies that evaluate the design, conduct, analysis (e.g. including bias, statistical plan and methods), or reporting of other studies in health research. This definition does not include statistical methodological studies (e.g. studies testing new algorithms or analytical methods, simulation studies), and experimental studies in which the unit of analysis is not a research report. Methodological studies are important because they can identify gaps, biases, and inefficiencies in research practices, and propose improvements and solutions.

A PubMed search performed in April 2020 for terms often used to describe methodological studies suggests that the rate of publication of methodological studies has increased over time, illustrated in Figure 1.

— Figure 1. Trends in methodological studies indexed in PubMed from 2009 to 2019. —

In the past 20 years, methodological studies have influenced the conduct of health research by informing many popular practices such as double data extraction in systematic reviews [5]; optimal approaches to conducting subgroup analyses [6]; and reporting of randomized trials,

observational studies, pilot studies, and systematic reviews [7-10] to name a few. Methodological studies have played an important role in ensuring that health research is reliable, valid, transparent and replicable. These types of studies may investigate: bias in research [11, 12], quality or completeness of reporting [13, 14], consistency of reporting [15], methods used [16], factors associated with reporting practices [17]; and may provide summaries of other methodological studies [18], and other issues. Methodological studies may also be used to evaluate the uptake of methods over time to investigate whether (and where) practices are improving and allow researchers to make comparisons across different medical areas [19, 20]. These studies can also highlight methodological strengths and shortcomings such as sample size calculations in randomized controlled trials [21, 22], quality of clinical prediction models [23], and spin and over-interpretation of study findings [24-26]. As such, methodological studies promote robust, evidence-based science and help to discard inefficient research practices [27]. A draft conceptual framework of the various categories of methodological studies that we have observed is outlined in Figure 2. Broadly, some categories of methodological studies include those investigating: bias and spin, methodological approaches to study design, or reporting issues.

— Figure 2. Draft conceptual framework of categories of methodological studies. —

Despite the importance of methodological studies, there is no guidance for their reporting. Murad and Wang have suggested a modification to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), a widely used reporting tool that is sometimes used for methodological studies because these studies often use methods that are also used in systematic reviews [28]. Although a modification of PRISMA may work well for the data collection components of some methodological studies, it would fail to appropriately

address the many different types of research questions that methodological studies attempt to answer. For example, if researchers were interested in changes in reporting quality of trials since the publication of the CONSORT guidelines, they could use an interrupted time-series design. Also, methodological studies that include a random sample of research reports [29], or those structured as before-after designs [19] would be a poor fit for the modified PRISMA tool, which is best suited for studies designed in the style of systematic reviews. Likewise, studies in which the unit of analysis is not the "study" require more specific guidance (e.g. when investigating multiple subgroup analyses or multiple outcomes within the same study) [30]. Thus, guidelines for transparent reporting of methodological studies are needed, and this need is widely acknowledged in the scientific community [31, 32]

Our work will address two main concerns:

1. There are no globally accepted names for methodological studies, making them difficult to identify. Methodological studies have been called 'methodological review', 'systematic review', 'systematic survey', 'literature review', 'meta-epidemiological study' and many other names. The diversity in names compromises training and educational activities [33], and it makes it difficult for end-users (e.g. clinical researchers, guideline developers) to search for, identify and use these studies [34, 35].
2. The reporting of methodological studies is inconsistent, which may relate to differences in objectives, and to differences in transparency and completeness. That is, some studies may be better reported than others. While the most appropriate approach to reporting will depend on the research question, explicit, user-friendly, and consensus-based guidance is needed to ensure that methodological studies are reported transparently and comprehensively [36].

Aims

The aims of this study protocol are to outline the procedures to define and harmonize the names describing methodological studies, and to develop reporting guidelines for methodological studies in human health research.

METHODS AND ANALYSIS

Study design

We have adopted the strategy for the development of reporting guidelines proposed by Moher et al. [37]. A visual overview of this approach, highlighting key components of the process, is presented in Figure 3. The three parts of the project which will be addressed using the above strategy are outlined in detail below (see Supplementary File for an outline of the data flow informing subsequent parts of the project).

— Figure 3. Project overview for the development of reporting guidelines for methodological studies in health research. —

Part 1: Methodological Review

The objectives of this part are to: a) identify names used to describe methodological studies, b) identify the various designs, analysis and reporting features of methodological studies, c) find any previous reporting guidance, and d) identify methodological study experts.

Search strategy

We developed a search strategy informed by our pilot work [38] targeting health-related sciences and biomedicine databases: Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Library, Excerpta Medica (Embase), MEDLINE, and Web of Science. There will be no limits by publication year, type or language. We will perform searches for

authors known to publish in this field, check reference lists of relevant studies, check existing methodological study repositories (Studies Within a Trial [SWATs] and Studies Within a Review [SWARs]), preprints (bioRxiv and medRxiv), setup Google Alerts for key words (e.g. meta-epidemiology, research-on-research), and contact experts (e.g. via email, meetings, following relevant journals, subscribing to methods email newsletters including the Methods in Research on Research [MiRoR] and the National Institute for Health and Care Excellence [NICE] groups, and following researchers on social media platforms such as ResearchGate and Twitter) to identify additional methodological studies. We will also check the EQUATOR library to identify any published or under development reporting guidance. These approaches are informed by previous work and published literature [35, 38]. Two health sciences librarians at the Health Sciences Library (McMaster University) were consulted and reviewed the final search strategy (see Supplementary File) in line with the Peer Review of Electronic Search Strategies (PRESS) framework [39].

Eligible studies

Studies that investigate methods—design, conduct, analysis, or reporting—in other studies of health research in humans will be eligible. The 'other studies' (or research reports) refers to the unit of analysis of the methodological studies (e.g. abstracts, cohort studies, randomized trials, registry records, study protocols, systematic reviews). Only published protocols and final reports of studies that investigate methods will be eligible. We will exclude simulation studies, studies testing new statistical methods (i.e. there is no specific unit of analysis) and experimental studies of methods (i.e. the unit of analysis is not a research report). These sorts of studies either already have reporting guidelines or can be reported in a commentary-style format.

Screening

A team of reviewers led by DOL will screen titles and abstracts independently, in duplicate in *Rayyan* [40], and full-texts in standardized forms in *DistillerSR* [41]. Both are online collaborative platforms for screening and reviewing literature. We will measure agreement on screening and study inclusion using Cohen's Kappa statistic [42, 43]. Any discrepancies between reviewers will be resolved through discussion.

Data extraction

In order to document the current reporting practices we will extract data from included studies independently, in duplicate based on a standardized data collection form. Key data extraction fields for documenting methodological study features and reporting practices (e.g. study design name, databases search, any guideline use) are outlined in Table 1. All data will be compiled in *DistillerSR*. Any discrepancies between reviewers will be resolved through discussion.

Table 1. Overview of data extraction fields for the review.

Section	Data to be collected
Bibliometrics	• Corresponding or last author (first and last name) and contact information (email address). We will first verify whether the corresponding author has academic faculty status, and if not, we will contact the last author • Country of author • Publication year • Study design name in title (verbatim quotation/descriptor) • Type of article (protocol or final publication, and letter/brief report or full publication) • Journal
Methods	• Study design name in methods section (verbatim quotation/descriptor) • Objectives (verbatim quotation)

	• Outcomes (verbatim quotation) • Search strategy reported (yes/no) • Search time limits and justifications (yes/no and verbatim quotation) • Databases searched • Included research report types (e.g. randomized trials, systematic reviews, cohort studies) • Sampling method (where applicable) • Analysis type (e.g. correlation, descriptive, regression, time-series) • Reporting guidance used and justification (yes/no, name and verbatim quotation) • Prospective registration and existence of a published protocol (yes/no, where applicable)
Results	• Presence of flow diagrams (yes/no) • Total records screened and included • Type of final synthesis performed (qualitative, quantitative, both)
Discussion	• Intended use of findings (verbatim quotation) • Limitations (verbatim quotation)
Other	• Conflicts of interest (yes/no) • Funding type (e.g. industry, institutional, non-profit) • Provide access to data (yes/no)

All reviewers will undergo calibration exercises and pilot the screening and data collection forms (25 studies per reviewer). We will incorporate an emergent design in the data collection stage of the review, which is characterized by a flexibility in the methodology, allowing researchers to remain open to modifications [44]. Should any new information that is of

interest arise during the full-text screen or data extraction, we will update the data collection form and collect this information for all studies retrospectively and going forward. Any modifications to the present protocol will be reported in the final published review. This iterative approach will allow for the capture of information as new methodological study design features come to light during the full-text screening and data extraction phases. Based on this approach, data extraction will be updated accordingly for previously reviewed studies as needed. For example, we expect to see overlaps in methodological study names, some of which might be attributed to collaborating research groups. There also appear to be similarities in methodological study reporting styles that are borrowed from systematic review [4] or survey study designs, which have both been extensively developed and are omnipresent in health research literature. However, if the current data collection fields, listed in Table 1, are insufficient to capture the nuances of the varieties of methodological studies, we will revise our data collection forms accordingly and collect the data for all studies.

Generation of a list of candidate items

The generation of a list of candidate items will be informed by two sources. First, a list of reporting items will be compiled based on what has been reported by authors of the included studies in the methodological review (e.g. flow diagram, search strategy). We will also note the use of any reporting guidance as mentioned by authors (e.g. PRISMA, STrengthening the Reporting of OBservational studies in Epidemiology [STROBE]). Each item will be ranked from most frequently reported to those less frequently reported. Second, this list will be presented to expert user stakeholders alongside the proportion of methodological studies that report on each item. Stakeholders will be asked to propose additional relevant items to finalize the list of candidate reporting items for Part 2.

Data analysis

We will present the flow of articles retrieved and screened in a study flow diagram, and summarize data in tables with explanatory text. We will provide descriptive statistics, i.e. counts (percentage) for categorical data, and means (standard deviation [SD]) or medians (interquartile range [IQR]) for continuous data. In addition to study names, we will synthesize and tabulate verbatim quotations for the study objectives, outcomes, and intended use of findings to provide context and clarification for methodological study rationales [45]. We will qualitatively group studies into categories based on similarities in reporting features. All statistical analyses will be done in *STATA version 15.1* [46]. We will identify additional potential stakeholders from the list of authors of included studies.

Part 2: Consensus Study

This part of the project will consist of consultation with expert user stakeholders in a consensus study. The objectives are to define methodological studies, and outline the recommended study name(s) and best reporting practices. The project steering group (DOL, GG, LM, LT), which includes members with expertise in health research methods, will oversee the consensus study and development of the reporting guideline.

Identification of stakeholders

The steering group will be responsible for identifying expert user stakeholders based on expertise with methodological studies and expertise with reporting guideline development [47]. Additional stakeholders will be identified from the list of authors (either corresponding or senior, with academic faculty-status) of methodological studies from the review. In our selection of stakeholders, we will seek individuals who will be committed to participating and providing

feedback for the reporting guideline. We define expert user stakeholders as researchers involved in the design, conduct, analysis, interpretation, or dissemination of methodological studies. Approximately 20-30 stakeholders will be selected (including the protocol authors) as participants in the consensus exercises. We will track response rates to invitations to participate in the consensus study. We will collect participant demographics (e.g. country, primary job title, academic rank, and methodological study publication history) to provide insight into the representation in this field of research based on sociocultural factors.

Measuring agreement and achieving consensus

The above definition of methodological studies (i.e. studies that evaluate the design, conduct, analysis, or reporting of other studies in health research) will be used during the online consensus exercises and video conference meetings. Participants will discuss the following: a) names for methodological studies, b) categories of methodological studies, and c) reporting requirements. These three components, outlined in Table 2, will be completed electronically through a McMaster Ethics Compliant service, *LimeSurvey* (https://reo.mcmaster.ca/limesurvey) for online surveys [48].

Table 2. Overview of consensus study activities and expected outputs.

Stage	Description of activities to be completed	Expected outputs
Online consensus exercise: categories of methodological studies*	• We will present the **proposed categories of methodological studies** (i.e. based on the aim, design, sampling strategy and unit of analysis) with rationale for each. For each category (e.g. methodological studies that evaluate study design; methodological studies that evaluate	• List of 'appropriate' categories for methodological studies

	reporting practices) an example of studies that belong in each category will also be presented. An example of potential categories are outlined in Figure 2. • Participants will be asked to rate and comment on the appropriateness of each category on a 3-point ordinal scale: 3- appropriate; 2- somewhat appropriate; 1- inappropriate • A validity ratio (VR) will be computed as follows: $\boldsymbol{VR} = \frac{(\boldsymbol{Ne} - \boldsymbol{N}/\mathbf{2})}{(\mathbf{N}/\mathbf{2})}$ where $\boldsymbol{Ne}$ is the number of participants who indicated that the category was appropriate (i.e., a rating of "3") and $\boldsymbol{N}$ is the total number of participants. This ratio will indicate the category that at least half of the participants consider appropriate. The VR will be interpreted based on a table of critical values [49]. For example, for 30 participants (N = 30), the critical value is 0.33 (i.e., at least 20 participants must deem the category appropriate). Only items based on a critical value greater than the set threshold will be considered	

	further [50]. This approach allows consensus to be achieved remotely, and makes decision-making objective.	
Online consensus exercise: name(s) for methodological studies*	• We will present the **names of methodological studies** and for each name (i.e. meta-epidemiological study, systematic survey etc.), an example of a study using that name will be provided. • Participants will be asked to rate the appropriateness of each potential name on a 3-point ordinal scale, and VR will be computed: 3- appropriate; 2- somewhat appropriate; 1- inappropriate	• List of 'appropriate' names for methodological studies
Online consensus exercise: reporting items*	• We will present the **proposed reporting items** and participants will be asked to rate the usefulness of each item on a 3-point ordinal scale, and VR will be computed: 3- essential; 2- maybe essential; 1- not essential • Participants will be asked to indicate if each reporting item applies to each different methodological study category.	• List of 'essential' reporting items for methodological studies

First video conference meeting (two calls†, 2 hours each)	• Participants will confirm the appropriate name(s) and categories for methodological studies, and agree on reporting items that should be included or excluded, and discuss the rationales behind their selections. All participants will be required to come to a consensus to include an item. • Meeting minutes and summary of the discussion and decisions will be shared with participants to provide additional feedback after the meeting. • Based on these discussions and decisions, the steering group will develop a **first draft of the reporting checklist** (e.g. with a checkbox to indicate Yes/Reported, No/Not Reported, and a space to indicate on what page the information is reported). • The checklist will be divided into different reporting sections in a methodological study (e.g. Introduction, Methods, Results, Discussion). • Examples of how to report information for each item will be provided alongside the checklist as part of the **draft user guide**.	• First drafts of the: a) reporting checklist b) user guide c) recommended methodological study name(s) and categories

	This will be shared with participants for comment prior to the next meeting.	
Second video conference meeting (two calls†, 2 hours each)	• Participants will agree on a structure and format for the checklist (e.g. general layout including appropriate sectioning such as 'Title', 'Abstract' and 'Body' of reports; a decision tree to delineate the category of the methodological study, core items for each category of methodological study, optional items). The group will also review the examples of reporting to be included in the user guide for each reporting item. • Meeting minutes and summary of the discussion and decisions will be shared with participants to provide additional feedback after the meeting. • Based on these discussions and decisions, the steering group will develop a **revised draft of the reporting checklist** and an **elaborated user guide**.	• Revised drafts of the: a) reporting checklist b) user guide c) recommended methodological study name(s) and categories
Final video conference meeting (4 hours)	• Discussion with participants will focus on confirming rationales for the final selected items, and providing examples for each reporting item to be outlined in the consensus statement and elaboration.	• Final documents for the: a) reporting checklist b) user guide

		c) recommended methodological study name(s) and categories • Consensus statement and elaboration

* During the online exercises, participants can suggest additional categories, names, or items that they wish to discuss during the video conferences.
† Two calls will be scheduled to accommodate stakeholders in Eastern and Western time zones.

All video conferences will be facilitated by two investigators (DOL and LM). Stakeholders will be consulted for the development of drafts, elaborations and explanations for specific items. All steering committee members and stakeholders will be required to participate and vote during the consensus meetings. Disagreements will be resolved through discussion, and if no consensus can be reached, the steering committee will convey the recommendations for the stakeholder group to approve. *Zoom*, or comparable video conferencing software, will be used to allow for the collection of recordings [51].

Data analysis

Findings from the consensus exercise will be summarized descriptively in tables that include counts (percentage) for categorical data, and means (SD) or medians (IQR) for continuous data. We will measure the levels of agreement (i.e. percentage increase in agreement for successive rounds, number of comments made for each successive round, and rounds with emergence of new themes) and instability (i.e. spread and SD of ranked responses for each item) for each round [52]. After the online exercises, one investigator (DOL) will qualitatively synthesize and code the suggestions for the methodological study names, categories and reporting items into common themes in *Dedoose*, a qualitative research software [53]. The steering committee will synthesize data from the participant discussions to revise each subsequent draft.

Part 3: Reporting Guideline

The objectives of this part are to develop, refine, publish, and disseminate the reporting guideline for methodological studies. We have registered the development of the reporting guideline—MethodologIcal Study reporTIng Checklist (MISTIC)—with the EQUATOR Network [54]. This record may see updates to its name and acronym after deliberations during the consensus study. We will also consider which reporting items are appropriate for different categories of methodological studies. This will include discussions about whether a decision tree may be useful to direct users to other existing reporting guidelines should they be more appropriate for specific categories of methodological studies (e.g. STROBE for methodological studies designed as cohort studies). Quantitative and qualitative findings from the consensus study will be incorporated into the final guideline document to include the: a) recommended methodological study name(s) and categories, b) recommended checklist with agreed upon reporting items, c) user guide and elaboration (e.g. an explanation of why it is important, rationales and an example of how it can be presented in a methodological study), and d) consensus statement. The draft document will be returned to the steering group and stakeholders to collect additional feedback. The checklist will be tested with end-users for face validity and clarity, and for additional fine-tuning as needed prior to publication. We will distribute the finalized checklist to a group of authors of methodological studies identified from the review (Part 1) to assess its usefulness and whether the checklist appropriately captures items relevant to the reporting of methodological studies [55].

Patient and public involvement

Although patients and the general public are not directly involved in this project, the findings of this research will be relevant to a broad range of knowledge users including methodological

study authors, health researchers, methodologists, statisticians, and journal editors. We will seek recommendations from investigators for general public members and patients that could be recruited for this project.

ETHICS AND DISSEMINATION

This research has received an exemption (October 2019) from the Hamilton Integrated Research Ethics Board (HiREB) for the consensus study. Ethics committee approval and consent to participate is not required for any other component of this project since only previously published data will be used.

Data deposition and curation

All participant records and data will be stored in MacDrive, a secure cloud storage drive that is privately hosted and based in-house at McMaster University [56]. Only two researchers (DOL and LM) will have direct access to study related documents and source data. Qualitative data will be promptly coded and transcribed, and all audio files will be encrypted. As part of our knowledge translation (KT) strategy and a consequence of the difficulties we faced in retrieving methodological studies from literature databases during our pilot work, we have developed an open-access database of methodological studies (www.methodsresearch.ca). We will catalogue all included studies from the pilot and full reviews on this website such that end-users can easily retrieve these studies. We have also setup a submission portal for researchers to submit their studies to be catalogued in this database. Parallel research by our colleagues will use this database as well as explore the automation of retrieving and indexing methodological studies in a dedicated space [57]. Lastly, we will setup a complementary website to serve as the primary repository for the published reporting guideline document.

Dissemination

We will publish all manuscripts arising from this research and present the findings at conferences. We will setup a complementary website to serve as the primary repository for the published reporting guideline document. The inclusion of knowledge users and representatives from methodology journals and guideline groups on our core study team will aid the wide dissemination of the reporting guideline. We continue to contact journal editors for their endorsement, and encourage researchers to reach out to us about this work, as we have done previously [34]. We will also encourage user feedback to inform future updates of the guideline as needed. These approaches are informed by our collective experience in developing and disseminating health research guidelines [7, 58-62].

DISCUSSION

Our work is contributing to reducing research waste by: 1) making methodological studies transparent through streamlining their reporting; 2) permitting researchers to appraise methodological studies based on adherence to proposed guidelines; 3) allowing end-users of methodological studies to be able to locate inaccessible research in a dedicated database and promoting its continued development; and in doing so 4) allowing end-users of methodological studies to better evaluate and identify issues with study design and reporting that influence patient health, enabling them to apply methodological study evidence to their own research practices. Many methodological studies are done to improve the design, conduct, analysis and reporting of primary and secondary research. We anticipate that, in reviewing this body of evidence on research methods, we will further highlight the importance of studies that aim to improve the design of health research [63].

Strengths and limitations

We acknowledge that there are inherent challenges in the search and retrieval of studies that lack consistent names, or dedicated indexing in common health research databases. As such, it is plausible that certain methodological studies that use terms not previously identified in the pilot or from our systematic database searches may be missed. To mitigate this limitation, we will (and have already) contact(ed) experts in the field to identify additional studies, and screen references and citing articles of relevant studies. We have consulted extensively with librarians at the McMaster Health Sciences Library on optimal approaches to capture the maximum number of studies.

The uncertainty in the number of methodological studies that are currently available and published in the literature can present additional logistic and timing constraints to the review component and overall progress of this work. However, given the landscape of methodological studies, we believe it is essential to apply a comprehensive search. To help with the organization of screening and data extraction, we will use robust systematic review management software (*DistillerSR*) [41]. Further, we have designed all screening and data extraction prompts to ensure consistency and replicability of our work.

Lastly, our study does not incorporate a blinded consensus process and this may impact the flow of discussions during the video conference meetings. We will aim to regulate discussions such that dominant speakers do not steer the discussion and ensuring that all participants have a chance to speak. Additionally, we will share summaries of the discussion and decisions after the meetings. This will allow for participants to privately provide any additional written feedback to the steering group that may not have been addressed.

A key strength of this research is the diversity of our study team. We have brought together an international, multidisciplinary team with expertise in consensus activities and guideline development, and research methodology and synthesis. This gives us an advantage in the breadth of feedback and fruitful discussions to be had with a wide array of users of the forthcoming guideline. Given the rise in the conduct of methodological studies, a general call for guidelines in the scientific community, and the number of teams that have reached out to us with interest in participating in this work, we are confident that the guideline will be used. However, we fully acknowledge the factors associated with implementation and use of guidelines, notably journal endorsement of the guidelines, the passage of time and other study level characteristics [20, 64-68]. Therefore, our stakeholders include editors from key journals that publish methodological studies such as the *Journal of Clinical Epidemiology*, *BMC Medical Research Methodology*, *BMC Systematic Reviews*, *The Campbell Collaboration,* and *Cochrane*. Stakeholders also include representatives from academic programs building capacity, at the master's and doctoral level, in conducting methodological research. To encourage better uptake, it has been suggested that researchers should work collaboratively with journals in the prospective design, knowledge translation, and evaluation of reporting guidelines [69], as well as following up on user feedback and incorporating a system to revise the reporting guidelines when necessary [70]. These strategies have been incorporated in our KT plan.

CONCLUSIONS

This research will improve the transparency of reporting of methodological studies, and help streamline their indexing and easier retrieval in literature databases. This work stands to make a substantial impact by informing research reporting standards for studies that investigate the

design, conduct, analysis, or reporting of other health studies, and thereby improving the transparency, reliability and replicability of health research, and ultimately benefitting patients and decision makers. Future efforts will focus on field-testing the published checklist with authors of methodological studies, gathering feedback from end-users, and optimizing and adapting the checklist for different typologies of methodological studies as needed.

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AUTHORS' CONTRIBUTIONS

DOL and LM conceived the idea. DOL, GG, LM and LT contributed to the design of the study. DOL wrote the first draft of the manuscript. AKN, AWC, BDT, DBA, DM, DP, EMW, GG, GSC, JCJ, LM, LP, LT, MB, PT, RBP, SS, TY, VW and ZS contributed to the refinement of the study methods and critical revision of the manuscript. All authors read and approved the final version of the manuscript.

FUNDING

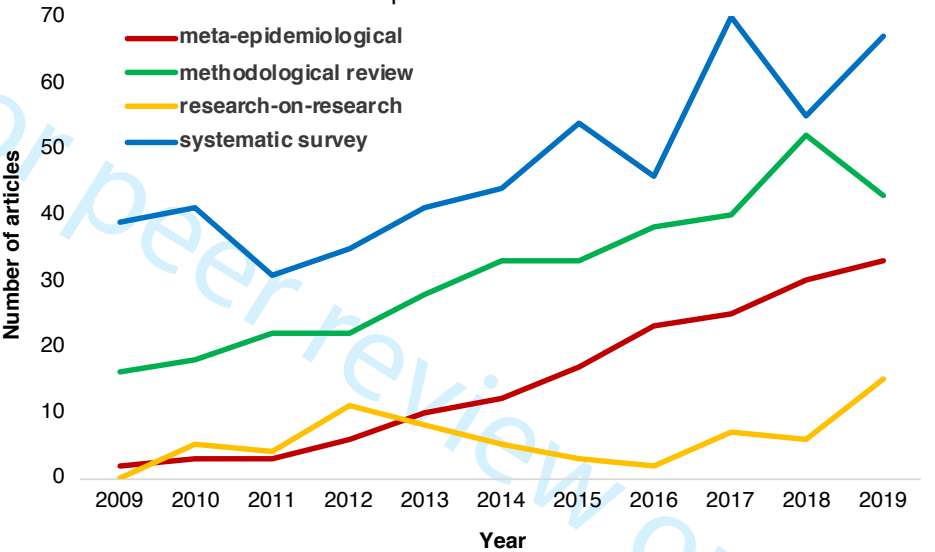
This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors. This project is being carried out as part of a doctoral dissertation by DOL. DOL is supported by an Ontario Graduate Scholarship and the Queen Elizabeth II Graduate Scholarship in Science & Technology, and the Ontario Drug Policy Research Network Student Training Program. The funders had no influence over the design, data collection, analysis, interpretation, preparation of or decision to publish the manuscript.

COMPETING INTERESTS

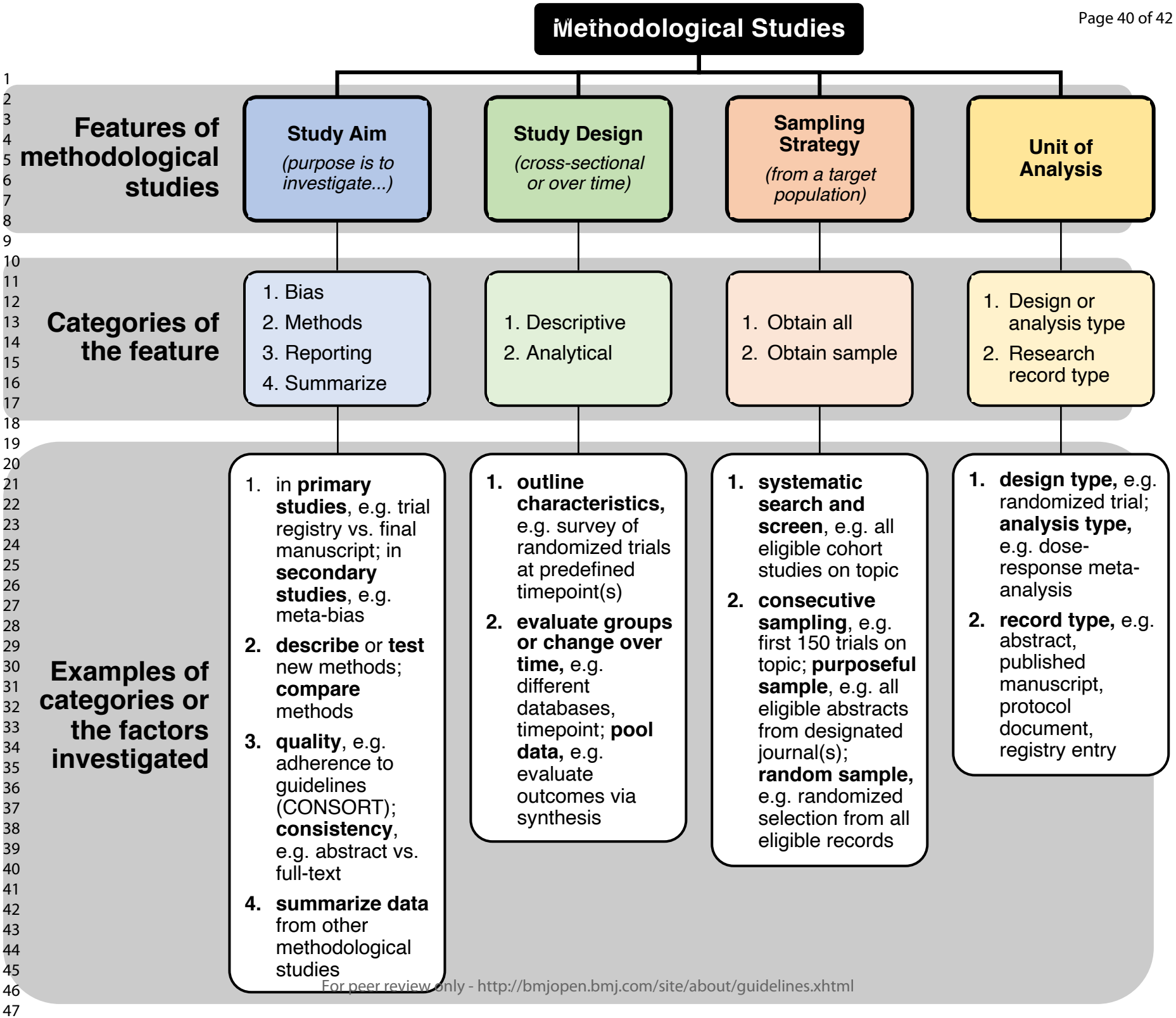
All study authors have published methodological studies.

ACKNOWLEDGEMENTS

We would like to thank Denise Smith and Jack Young at the Health Sciences Library at McMaster University for their critical review of the search strategy. We would like to thank Dr. Susan Jack at the School of Nursing at McMaster University for sharing her expertise and recommendations on qualitative and mixed methods research design.



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
meta-epidemiological	2	3	3	6	10	12	17	23	25	30	33
methodological review	16	18	22	22	28	33	33	38	40	52	43
research-on-research	0	5	4	11	8	5	3	2	7	6	15
systematic survey	39	41	31	35	41	44	54	46	70	55	67



CONSORT: CONsolidated Standards of Reporting Trials.

1. **Identifying the need for a guideline**, **review of the literature** and **obtain funding** for the guideline initiative

- ✓ Identify previous relevant guidance
- ✓ Establish feasibility for full review of methodological studies
- ✓ Funding sought
- ❑ Complete full review of methodological studies

2. Pre-meeting activities including **identification of stakeholders**, a **consensus exercise**, and **generation of a list of items** for consideration at the consensus meeting

- ✓ Establish working group, identification of stakeholders
- ❑ Share full review findings
- ❑ Ethics, online consensus exercise, and generation of a list of candidate items

3. **Consensus meeting** and discussion of a **knowledge translation strategy**

- ❑ Conduct video conference meetings and final consensus meeting
- ❑ Share guideline (draft)
- ❑ Collect feedback

4. Post-meeting activities including development and **publication of the guidance** statement

- ❑ Disseminate guideline (final)

5. Post-publication activities including **encouragement of endorsement, adherence, web site development** and translation of the guideline

- ✓ Build and populate database of methodological studies
- ❑ Knowledge translation strategies for guideline, website and database

Completed *In progress* *Not started*

SUPPLEMENTARY FILE

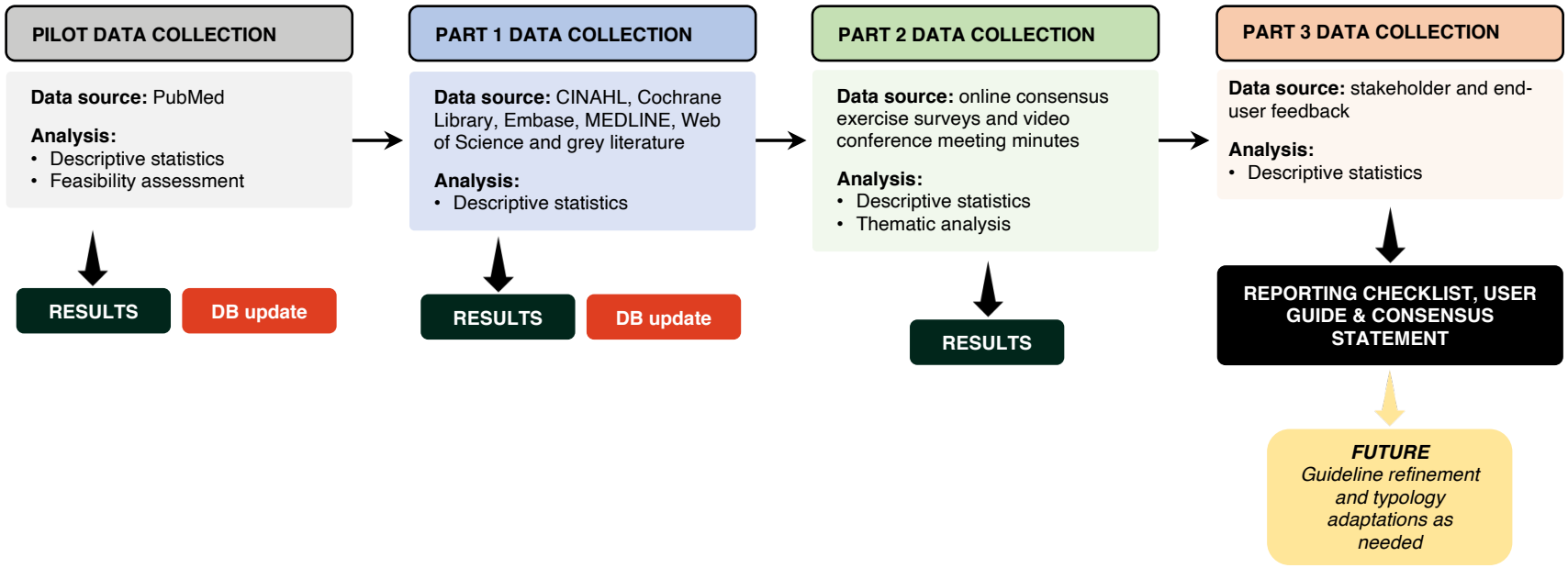
Timeline of the development of reporting guidelines:

	OBJECTIVES & STEPS	DURATION (MONTHS)	YEAR 1 (2021)				YEAR 2 (2022)			
			Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
1	**Methodological review** of the literature	8	●	●						
2	Development of an **electronic database** for methodological studies	8		●	●					
3	**Consensus study** and development of a **reporting guideline**	6			●	●	●	●		
4	Knowledge translation activities	—	●	●	●	●	●	●	●	●

Q: quarter.

SUPPLEMENTARY FILE

Flow of data for informing subsequent stages of the project:



CINAHL: Cumulative Index for Nursing and Allied Health Literature, DB: database (www.methodsresearch.ca)

SUPPLEMENTARY FILE

Sample search strategy for MEDLINE:

	Concept: names of methodological studies
1	(meta-epidemiolog* OR metaepidemiolog* OR meta-research OR methodolog* analysis OR methodolog* evidence OR methodolog* investigation OR methodolog* literature OR methodolog* overview OR methodolog* report* OR methodolog* review OR methodolog* survey OR methodolog* synthesis OR method* overview OR systematic database review OR systematic literature survey OR systematic survey).mp.
2	(methodolog* study OR method* review OR method* survey)
	Concept: topics in methodological research (i.e. analysis, design and reporting)
3	exp Data Collection/
4	exp Data Interpretation, Statistical/
5	exp Epidemiologic Research Design/
6	exp Nursing Methodology Research/
7	exp Reproducibility of Results/
8	exp Research Design/
9	3 OR 4 OR 5 OR 6 OR 7 OR 8
10	2 AND 9
	Concept: methodological studies that are called 'systematic reviews'
11	systematic review.mp.
12	Cochrane Database of Systematic Reviews.jn
13	11 NOT 12
14	*Data Collection/
15	*Data Interpretation, Statistical/
16	*Epidemiologic Research Design/
17	*Nursing Methodology Research/
18	*Reproducibility of Results/
19	*Research Design/
20	14 OR 15 OR 16 OR 17 OR 18 OR 19
21	13 AND 20
22	1 OR 10 OR 21