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The STROBE extensions: A protocol for a qualitative assessment of content and a survey of endorsement

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Abstract

Introduction: The STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) guideline was developed in response to inadequate reporting of observational studies. In recent years, several extensions to STROBE have been created to provide more nuanced field-specific guidance for authors. The content and the prevalence of extension endorsement has not yet been assessed. Accordingly, there are two aims: 1) to classify changes made in the extensions to identify strengths and weaknesses of the original STROBE checklist; and 2) to determine the prevalence and typology of endorsement by journals in fields related to extensions.

Methods and analysis: Two independent researchers will assess additions in each extension. Additions will be coded as "field-specific" (FS) or "not field-specific" (NFS). FS is defined as particularly relevant information for a single field and guidance provided generally cannot be extrapolated beyond that field. NFS is defined as information that reflects epidemiological or methodological tenets and can be generalized to most, if not all, types of observational research studies. Intra-class correlation (ICC) will be calculated to measure reviewers' concordance. Upon disagreement, consensus will be reached. Individual additions will be grouped by STROBE checklist items to identify the frequency and distribution of changes.

Journals in fields related to extensions will be identified through National Library of Medicine (NLM) PubMed Broad Subject Terms, screened for eligibility, and further distilled via Ovid MEDLINE search strategies for observational studies. Text describing endorsement will be extracted from each journal's website. A classification scheme will be created for endorsement types and the prevalence of endorsement will be estimated. Analyses will utilize NVivo 11 and SAS University Edition.

Ethics and dissemination: This study does not require ethical approval as it does not involve human participants. This study has been pre-registered on Open Science Framework.

Word count: 290

Keywords: Reporting guidelines, STROBE, observational studies, information dissemination/methods, bibliometrics

Strengths and limitations of this study

- Our systematic approach to qualitatively assess the content of the additions made in the STROBE extensions provides a comprehensive overview of the types of changes made and can identify redundancies and problem areas.
- Our method involves standardized search strategies in Ovid MEDLINE, ensured to capture a representative sample and circumvent issues of subjectivity in the identification of eligible journals
- This study will create an open source corpus of recent observational studies spanning seven fields which future researchers can utilize to assess completeness of reporting or other topics of interest.
- The bibliometric aspect of this study only focuses on 7 extensions and fields so results are not generalizable to other studies.

INTRODUCTION

The STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) guidelines were developed in 2007 in response to the pervasiveness of inadequate reporting of observational studies. STROBE provides a checklist of items that serve as a reference for how to report sufficient information for observational research involving cohort, case-control, and cross-sectional studies [1]. The guidelines have been endorsed by the International Committee of Medical Journal Editors (ICMJE) and the accompanying checklist is sometimes explicitly used as a requirement for manuscript submission [2]. However, there is no standard method of endorsement by journals and little is known about the most effective ways to apply the guidelines in practice [3–5].

Regarding the reporting of clinical trials, requiring a completed Consolidated Standards of Reporting Trials (CONSORT) checklist upon submission of a manuscript has been shown to lead to improvements in reporting [6]. However, some journals do not want to take responsibility for guideline enforcement and many overlook non-adherence to guidelines; editors have expressed beliefs that their journal's current policies are adequate or that they fear losing authors to other journals that have less strict requirements for publication [7–9]. Editors may also be unaware of the existence of guidelines, as demonstrated by low endorsement rates by journals in dentistry [10], veterinary medicine [7], and urology [11]. On the other hand, the evidence for the endorsement of STROBE is also mixed. Endorsement was not shown to be associated with better reporting for items related to confounding, regardless of strength [12].

Several field-specific extensions to STROBE have been designed in recent years in an effort to promote complete reporting, provide more nuanced guidance for authors, and perhaps address editor's concerns that STROBE is not focused enough for their journal. Extensions for

other reporting guidelines are common, however the creation of extensions for STROBE seems to outpace those for other reporting guidelines such as the CONSORT [13]. Since the publication of STROBE in 2007, 13 extensions have been published and indexed by the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) Network, an international collaboration that promotes transparent and accurate reporting and indexes reporting guidelines [14]. In contrast, CONSORT was first published in 1996, updated in 2001 and further revised in 2010, yet only 17 extensions have been published during that period [15]. The reason behind the difference in the pacing of publications of extensions is unclear. Perhaps the concept of field-specific extensions to reporting guidelines were pioneered by CONSORT, thus making the idea more commonplace for subsequent reporting guidelines. Alternatively, the complexity of the types of observational research studies may require more guidance due to the wide variety of methods employed in observational studies. Regardless of the reasoning, it is evident that authors are still perceiving a need to provide more guidance on how to report information about their studies. However, until now, many of these initiatives have not been evaluated.

Extensions to STROBE offer a potential new avenue for promoting more complete reporting but their use has been largely unassessed and, similar to STROBE, they may face implementation and usage problems [3,7]. An evaluation of the content of the extensions can identify both strengths and weaknesses in the original STROBE guidelines and can reduce waste in the process of extension creation. Currently, it is unclear if and how journals are encouraging or requiring authors to use STROBE extensions. As journals are key players influencing the use and uptake of extensions, the prevalence and typology of extension endorsement is needed to understand the variety of methods employed to encourage transparent reporting. Data collected

from this study can later be used as the groundwork for an evaluation of the impact of endorsement on the completeness of reporting.

Aims

The objectives of this study are twofold. Firstly, to qualitatively assess and classify the changes made in the extensions to help to identify the strengths and weaknesses of the original STROBE checklist; this will identify potential problem areas or deficiencies conveyed in extension additions. Secondly, we will estimate the prevalence of endorsement in journals that publish observational studies from extension-related fields and create an endorsement typology to provide a finer detailed view of the promotion of the STROBE extensions.

METHODS AND ANALYSIS

Qualitative Assessment and Analysis

The main focus of this phase will be on coding the additions that are made in each extension. Coded additions will help to identify the strengths, weaknesses and redundancies conveyed in the STROBE extensions in order to provide guidance for modifications to the original STROBE checklist and to identify target areas for future educational interventions.

STROBE extensions will be identified through the EQUATOR Network website as well as through a MEDLINE search for STROBE-related publications. Two independent reviewers (DH, MKS) will code the additions made in each STROBE extension; disagreement will be resolved by consensus. Each sub-item on an extension that is attached to a STROBE checklist item will be coded individually by the relevant content area (e.g., item 5 sub-item additions a, b, and c, will be counted and coded as three separate items). Each sub-item will also be coded as "field-specific" (FS) or "not field-specific" (NFS). FS is defined as information that is

particularly relevant for a single field and guidance provided cannot be generalized beyond that particular extension's field. Items which note phrases such as "including," "specifically," "for example," and "e.g." followed by a field-specific example, generally are considered to be field-specific as these items are adding additional information specific to a certain topic area. NFS is defined as information that reflects general epidemiological or methodological tenets and can be extrapolated to most, if not all, types of observational research studies.

For the subjective assessments of the field-specific or not field-specific nature of the additions (rated as binary yes or no), intra-class correlation (ICC) will be used to assess the inter-rater reliability (IRR). The ICC for the two raters will be calculated for ratings across all 13 extensions that involve the subjective assessment of an item as field-specific or not. This method was chosen because ICC does not take an all-or-nothing approach to agreement but rather it "incorporates the magnitude of disagreement to compute IRR estimates" [16]. Descriptive statistics such as counts, means, and percentages will be given.

Endorsement Survey

Eligibility Criteria

Extensions to the STROBE guidelines will be identified through the EQUATOR Network website as well as through a search on PubMed. Extensions will be eligible for assessment if at least one year has passed since publication as this allows for some time for endorsement and implementation. In the case of multiple publications of an extension, the earliest publication/availability date will be used to determine eligibility. As of March 1, 2017, eligible extensions are detailed in Table 1 while ineligible extensions are detailed in Table 2.

Table 1. Extensions Eligible for Assessment

Abbreviation	Title/Description	Publication Date
STREGA [4]	STrengthening the REporting of Genetic Association Studies	February 3, 2009
STROBE-EULAR [17]*	A EULAR extension of STROBE guidelines	June 4, 2010
STROBE-ME [18]	STrengthening the Reporting of OBservational studies in Epidemiology - Molecular Epidemiology	October 24, 2011
STROME-ID [19]	Strengthening the Reporting of Molecular Epidemiology for Infectious Diseases	March 13, 2014
STROBE-RDS [20]	Strengthening the Reporting of Observational Studies in Epidemiology for Respondent-Driven Sampling studies	May 1, 2015
RECORD [21]	REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement	October 6, 2015
STROBE-AMS [22]	Strengthening the Reporting of Observational Studies in Epidemiology for AntiMicrobial Stewardship	February 19, 2016

** This extension does not have an official acronym. For simplicity's sake, this will be used.*

Table 2. Extensions Not Eligible for Assessment

Abbreviation	Title/Description	Publication Date
MARE-S [23]	Medical Abortion Reporting of Efficacy - STROBE	April 23, 2016
STROBE-NUT [24]	Strengthening the Reporting of Observational Studies in Epidemiology-NUTritional epidemiology	June 7, 2016
ROSES-I [25]	CONSISE statement on the REporting of SEroepidemiologic Studies for influenza	July 17, 2016
STROBE-SBR [26]	Strengthening the Reporting of Observational Studies in Epidemiology for Simulation-Based Research	July 26, 2016
STROBE-NI [27]	Strengthening the Reporting of Observational Studies in Epidemiology for Newborn Infection	September 13, 2016
STROBE-Vet [28]	Strengthening the Reporting of Observational Studies in Epidemiology - Veterinary	November 1, 2016

Identification of Journals

Journals in fields related to extensions will be identified using the National Library of Medicine (NLM) Catalog which contains, among other things, "biomedical and health-related life sciences journals" indexed in MEDLINE. As of March 2017, there are over 5,600 journals indexed [29]. This database was chosen for two primary reasons: 1) Broad Subject Terms are

used which allows for easy identification and segmentation of research fields for journals and topic areas for articles; and 2) the segmentation of other search engines, namely Clarivate Analytics Web of Science Journal List [30], did not clearly align with extension fields and would result in more overwhelming searches with less certainty that potentially eligible journals would be identified.

Journals will be identified using the following search string in the NLM Catalog*: pubmed["Broad subject terms"]*. If an extension reports search terms in their publication, these will be considered as a starting point. All search strategies were developed in collaboration with a medical librarian. Further details listing the individual broad subject terms used for each extension are detailed in Table 3.

Table 3. Broad Subject Terms

STROBE Extension	**Broad Subject Term(s)**
STREGA	Genetics, Genetics, Medical
STROBE-EULAR	Rheumatology
STROBE-ME	Molecular Biology
STROME-ID	Molecular Biology, Anti-Infective Agents
STROBE-RDS	Public Health
RECORD	Health Services, Health Services Research
STROBE-AMS	Anti-Infective Agents, Drug Therapy

Screening

Journals will be manually screened to confirm that they publish in English, are in a relevant format (e.g., not a textbook, magazine, etc.), and are currently publishing. From the remaining list of journals that are indexed in MEDLINE, search strategies will be used to identify observational studies in the relevant topic areas (see Supplementary File 1). The filter for observational studies is a combination of a study design search filter for cohort and case-control studies by BMJ Evidence Centre information specialists, Fraser et al.'s work on

identifying observational studies in surgical interventions, and consultations with a medical librarian [31,32].

From the remaining list of journals that publish observational studies, field-specific search strategies (detailed in Supplementary File 1) will be used. Extensions were used as a starting point and extant systematic reviews provided additional guidance, particularly for RECORD and STROBE-AMS [33,34]. In the case of EULAR, a combination approach will not be used as this is the only extension where the broad subject term is the exact focus of the extension; the search strategy for observational studies will still be used.

The results of the OVID MEDLINE field-specific and observational search strategies will be compared to the list of journals that the search was run on to determine inclusion and exclusion. This combination approach will be used for several reasons. Firstly, journal information from NLM is given in more structured manner and allows for easy matching between sets with overlapping Broad Subject Terms. For example, both STROBE-AMS and STROME-ID use the term "Anti-Infective Agents" while both STROBE-ME and STROME-ID use "Molecular Biology." This approach is also less resource-intensive and allows us to more easily identify how many journals in each field publish observational studies, thus establishing the extent and importance of the issue.

Data Extraction

Eligible journals and their websites will be searched exhaustively for any mention of STROBE extensions in their instructions for authors, guidelines for reviewers, other guidance documents, or ethical policies. Primary data sources (i.e., website pages) will be downloaded in pdf format and relevant text describing guideline endorsement will be extracted and coded into a

standard data extraction sheet in Excel. Although STROBE and its extensions are the main focus of this investigation, we will also collect information about endorsement of other common guidelines such as CONSORT, PRISMA, ICMJE's Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals and mentions of organizations like EQUATOR and COPE [13,15,35–37]. This information will be gathered to see if journals that endorse other reporting guidelines or ethical reporting guidance, are more likely to endorse STROBE or an extension. Altman and Hopewell's classification schema will be used as a starting point for the development of a typology of endorsement for STROBE and extensions [6,38,39]. In addition to information regarding support for STROBE and its extensions, general information about the journal such as impact factor, publisher, and contact information for the editorial offices will be collected. For the purposes of future analyses focused on completeness of reporting, it will also be noted if journals have recently launched and have not been publishing for at least two years prior to the publication of its related extension; this will ensure the ability to establish baseline data on the completeness of reporting. For example, STREGA was published in 2009, therefore journals must have begun publishing by 2007 to be included in latter assessments.

As publishers often provide additional resources for authors, we will collect information from the websites of publishers about their methods of endorsement. Endorsement from publishers will be considered to be indirect methods of support as they require significant effort on the part of the user seeking the information. Information communicated directly through the journal's website will be considered to be direct if it is supplied in immediately available resources to authors.

Statistical Analyses

Endorsement, types of endorsement, and journal characteristics (e.g. Impact factor, publisher) will be expressed using descriptive statistics such as counts, means/medians, and percentages. For analyses comparing two binary variables (i.e., endorsement of extensions and endorsement of other reporting guidelines), unadjusted odds ratios and their associated 95% confidence intervals will be conducted. Differences in impact factors between endorsing and non-endorsing journals will be assessed with the Wilcoxon test of ranks, equivalent to the c-stat, c-index or area under the receiver operating characteristic (ROC) curve. All confidence intervals will be provided at the two-sided 95% level.

DISCUSSION

An evaluation of the extensions provides a deeper understanding of content areas that are adequately detailed or in need of elaboration. By identifying the content areas that authors have difficulties with, the groundwork will be laid for an assessment into how authors currently use and understand STROBE and what difficulties they encounter with its implementation.

Results from this study will also provide estimates of the frequency and typology of endorsement. This dataset will allow journals to be targeted in order to promote guideline usage and will establish a groundwork for follow-up studies on attitudes related to endorsement of STROBE and its extensions. Perhaps most importantly, this study will provide the foundation for assessing the impact that endorsement has on the completeness of reporting. The data collected through this study will generate important insights for the design of future studies such as feasibility or pilot studies to estimate the effects of endorsement. Perceived lack of tangible benefit due to a weak evidence-base can be a major barrier to guideline use. Testing a relationship between endorsement and an increase in completeness of reporting, can provide the

much-needed data to address skeptic's concerns about the tangible value of supporting STROBE and its extensions.

This study will solidify the scope of the problem of insufficient support and use of STROBE extensions, detail variability in endorsement typology, and establish data for future studies focused on the effects of endorsement on completeness of reporting and attitudes towards STROBE and its extensions.

SUPPLEMENTARY INFORMATION

Ethics and dissemination

Ethical approval was not needed or this study as there will be no human participants in this study. All data is publicly available.

Authors' contributions

All authors have made substantive intellectual contributions to the development of this protocol. MKS conceptualized the study and led the writing of the manuscript. DH led the supervision of the manuscript preparation. MKS and AU developed the search strategies. All authors provided detailed comments on earlier drafts and approved the final manuscript.

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Competing interests statement

The authors declare that they have no competing interests.

Data sharing statement

The final datasets supporting the conclusions of the research proposed in this protocol will be available in the Zenodo repository in the Methods in Research on Research (MiRoR) community [https://zenodo.org/communities/miror/]. This study has been pre-registered at the Open Science Framework (osf.io/u75gb).

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Supporting information

Supplementary File 1. Ovid MEDLINE Search Strategies

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Supplementary File 1. Ovid MEDLINE Search Strategies

All searches use the following database:
Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>

For each extension (except for EULAR), the observational strategy (14) is combined with the field-specific strategy (or/15-xx) and restricted to search only within the list of eligible journals ("journal name" or "journal name 2" ...or "journal name n"…).jn. within a certain time frame (limit xx to year="2 years prior to extension publication – 2017").

Identifying Observational Studies

1. Observational study/
2. (observational adj3 stud$).tw.
3. exp Cohort Studies/
4. cohort$.tw.
5. controlled clinical trial.pt.
6. Epidemiologic Methods/
7. exp case-control studies/
8. (case$ adj3 control$).tw.
9. Comparative Study/
10. prospective$.tw.
11. retrospective$.tw.
12. Cross-Sectional Studies/
13. prevalence/
14. or/1-13

Identifying Journal Publishing Studies in the Relevant Field

STREGA

15. exp Genetic Association Studies/
16. exp Polymorphism, Genetic/
17. exp Genetic Predisposition to Disease/
18. exp Genetic Research/
19. genome-wide association.tw.
20. genomewide association.tw
21. genetic research.tw.
22. gene$ polymorphism.tw.
23. gene$ association.tw.
24. or/15-23

STROBE-EULAR

No field-specific search strategy necessary due to specificity of broad subject term. The observational filter is still used in combination with the eligible journal pool.

STROBE-ME

15. exp molecular epidemiology/

16. exp Biomarkers/
17. Molecular epidemiolog$.tw.
18. Genetic epidemiolog$.tw.
19. Biomarker$.tw.
20. Bio-marker$.tw.
21. Or/15-20

STROME-ID
15. Molecular Epidemiology/
16. molecular epidemiolog$.tw.
17. exp Communicable Diseases/ep [Epidemiology]
18. exp Infection Control/
19. infection$.tw.
20. exp Molecular Typing/
21. molecular typing.tw.
22. molecular marker$.tw.
23. molecular clock.tw.
24. multiple-strain.tw.
25. or/15-24

RECORD
15. exp Records as Topic/
16. Registries/
17. database/ or dataset/
18. exp Information Systems/
19. (data or dataset or database or register or registry or registries or record$).tw.
20. or/15-19

STROBE-RDS
15. respondent driven.tw.
16. respondentdriven.tw.
17. participant driven.tw.
18. or/15-17

STROBE-AMS
15. exp Anti-Infective Agents/
16. exp Infection/
17. (antibiot$ or antimicrob$).tw.
18. exp Drug Resistance, Microbial/
19. Vancomycin/
20. exp Aminoglycosides/
21. exp Fluoroquinolones/
22. exp Carbapenems/
23. exp Cephalosporins/
24. (vancomycin or aminoglycosides or fluoroquinolones or carbapenems or cephalosporins).tw.
25. or/15-24

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The STROBE extensions: A protocol for a qualitative assessment of content and a survey of endorsement

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The STROBE extensions: A protocol for a qualitative assessment of content and a survey of endorsement

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Abstract

Introduction: The STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) Statement was developed in response to inadequate reporting of observational studies. In recent years, several extensions to STROBE have been created to provide more nuanced field-specific guidance for authors. The content and the prevalence of extension endorsement has not yet been assessed. Accordingly, there are two aims: 1) to classify changes made in the extensions to identify strengths and weaknesses of the original STROBE checklist; and 2) to determine the prevalence and typology of endorsement by journals in fields related to extensions.

Methods and analysis: Two independent researchers will assess additions in each extension. Additions will be coded as "field-specific" (FS) or "not field-specific" (NFS). FS is defined as particularly relevant information for a single field and guidance provided generally cannot be extrapolated beyond that field. NFS is defined as information that reflects epidemiological or methodological tenets and can be generalized to most, if not all, types of observational research studies. Intra-class correlation (ICC) will be calculated to measure reviewers' concordance. Upon disagreement, consensus will be sought. Individual additions will be grouped by STROBE checklist items to identify the frequency and distribution of changes.

Journals in fields related to extensions will be identified through National Library of Medicine (NLM) PubMed Broad Subject Terms, screened for eligibility, and further distilled via Ovid MEDLINE search strategies for observational studies. Text describing endorsement will be extracted from each journal's website. A classification scheme will be created for endorsement types and the prevalence of endorsement will be estimated. Analyses will utilize NVivo 11 and SAS University Edition.

Ethics and dissemination: This study does not require ethical approval as it does not involve human participants. This study has been pre-registered on Open Science Framework.

Word count: 290

Keywords: Reporting guidelines, STROBE, observational studies, information dissemination/methods, bibliometrics

Strengths and limitations of this study

- Our systematic approach to qualitatively assess the content of the additions made in the STROBE extensions provides a comprehensive overview of the types of changes made and can identify redundancies and problem areas.
- Our method involves standardized search strategies in Ovid MEDLINE, designed to capture a representative sample and circumvent issues of subjectivity in the identification of eligible journals
- This study will create an open source corpus of recent observational studies spanning seven fields which future researchers can utilize to assess completeness of reporting or other topics of interest.
- The bibliometric aspect of this study only focuses on 7 extensions and fields so results are not generalizable to other studies.

INTRODUCTION

The STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) Statement was developed in 2007 in response to the pervasiveness of inadequate reporting of observational studies. STROBE provides a checklist of items that serve as a reference for how to report sufficient information for observational research involving cohort, case-control, and cross-sectional studies [1]. The guidelines have been endorsed by the International Committee of Medical Journal Editors (ICMJE) and the accompanying checklist is sometimes explicitly used as a requirement for manuscript submission [2]. However, there is no standard method of endorsement by journals and little is known about the most effective ways to apply the guidelines in practice [3–5].

Regarding the reporting of clinical trials, requiring a completed Consolidated Standards of Reporting Trials (CONSORT) checklist upon submission of a manuscript has been shown to lead to improvements in reporting [6]. However, some journals do not want to take responsibility for guideline enforcement and many overlook non-adherence to guidelines; editors have expressed beliefs that their journal's current policies are adequate or that they fear losing authors to other journals that have less strict requirements for publication [7–9]. Editors may also be unaware of the existence of guidelines, as demonstrated by low endorsement rates by journals in dentistry [10], veterinary medicine [7], and urology [11]. On the other hand, the evidence for the endorsement of STROBE is also mixed. Endorsement was not shown to be associated with better reporting for items related to confounding, regardless of strength [12].

Several field-specific extensions to STROBE have been designed in recent years in an effort to promote complete reporting, provide more nuanced guidance for authors, and perhaps address editor's concerns that STROBE is not focused enough for their journal. Extensions for

other reporting guidelines are common, however the creation of extensions for STROBE seems to outpace those for other reporting guidelines such as the CONSORT [13]. Since the publication of STROBE in 2007, 13 extensions have been published and indexed by the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) Network, an international collaboration that promotes transparent and accurate reporting and indexes reporting guidelines [14]. In contrast, CONSORT was first published in 1996, updated in 2001 and further revised in 2010, yet only 17 extensions have been published during that period [15]. The reason behind the difference in the pacing of publications of extensions is unclear. Perhaps the concept of field-specific extensions to reporting guidelines were pioneered by CONSORT, thus making the idea more commonplace for subsequent reporting guidelines. Alternatively, the complexity of the types of observational research studies may require more guidance due to the wide variety of methods employed in observational studies. Regardless of the reasoning, it is evident that authors are still perceiving a need to provide more guidance on how to report information about their studies. However, until now, many of these initiatives have not been evaluated.

Extensions to STROBE offer a potential new avenue for promoting more complete reporting but their use has been largely unassessed and, similar to STROBE, they may face implementation and usage problems [3,7]. Being intended as general guidelines for observational studies, STROBE should include *necessary* information that is *sufficient* to most observational studies. For some fields, however, STROBE guidelines may not be sufficient due to specific requirements within the field. This gap is then covered by an extension for that field. However, when extensions include non-specific guidance that can be extrapolated to most observational studies (e.g. details about participants, settings, confounders, follow-up, biases or any other general epidemiological constructs), it suggests potential deficiencies in STROBE checklist. If

the content is already in STROBE, extension authors may have thought that it was not clearly communicated, or that it is necessary to include it in the checklist instead of being only in the explanation and elaboration document. Whilst, if the content is not already in STROBE, extension authors may have identified a gap or insufficiency which should be considered as an addendum to STROBE. Therefore, by identifying non-specific or redundant guidance suggested in the STROBE extensions, we will be able to identify perceived gaps and deficiencies in the current STROBE checklist and potentially reduce future waste in the process of extension creation.

A perceived lack of confidence in reporting guidelines can impact journal editors' willingness to endorse reporting guidelines. Currently, it is unclear if and how journals are encouraging or requiring authors to use STROBE extensions. As journals are key players influencing the use and uptake of extensions, the prevalence and typology of extension endorsement is needed to understand the variety of methods employed to encourage transparent reporting. Data collected from this study can later be used as the groundwork for an evaluation of the impact of endorsement on the completeness of reporting.

Aims

The objectives of this study are twofold. Firstly, to qualitatively assess and classify the changes made in the extensions to help to identify the strengths and weaknesses of the original STROBE checklist; this will identify potential problem areas or deficiencies conveyed in extension additions. Secondly, we will estimate the prevalence of endorsement in journals that publish observational studies from extension-related fields and create an endorsement typology to provide a finer detailed view of the promotion of the STROBE extensions.

METHODS AND ANALYSIS

Qualitative Assessment and Analysis

The main focus of this phase will be on coding the additions that are made in each extension. Coded additions will help to identify the strengths, weaknesses and redundancies conveyed in the STROBE extensions in order to provide guidance for modifications to the original STROBE checklist and to identify target areas for future educational interventions.

We will assess the content of 13 STROBE extensions which were identified through the EQUATOR Network website as well as through a PubMed search for STROBE-related publications. Two independent reviewers (DH, MKS) will code the additions made in each STROBE extension; disagreement will be resolved by consensus. Each sub-item on an extension that is attached to a STROBE checklist item will be coded individually by the relevant content area (e.g., item 5 sub-item additions a, b, and c, will be counted and coded as three separate items). Each sub-item will also be coded as "field-specific" (FS) or "not field-specific" (NFS). FS is defined as information that is particularly relevant for a single field and guidance provided cannot be generalized beyond that particular extension's field. Items which note phrases such as "including," "specifically," "for example," and "e.g." followed by a field-specific example, generally are considered to be field-specific as these items are adding additional information specific to a certain topic area. NFS is defined as information that reflects general epidemiological or methodological tenets and can be extrapolated to most, if not all, types of observational research studies.

For the subjective assessments of the field-specific or not field-specific nature of the additions (rated as binary yes or no), intra-class correlation (ICC) will be used to assess the inter-

rater reliability (IRR). The ICC for the two raters will be calculated for ratings across all 13 extensions that involve the subjective assessment of an item as field-specific or not. This method was chosen because ICC does not take an all-or-nothing approach to agreement but rather it "incorporates the magnitude of disagreement to compute IRR estimates" [16]. Descriptive statistics such as counts, means, and percentages will be given.

Endorsement Survey

Eligibility Criteria

Extensions to the STROBE guidelines were identified through the EQUATOR Network website as well as through a search on PubMed. Extensions are eligible for assessment if at least one year has passed since publication as this allows for some time for endorsement and implementation. In the case of multiple publications of an extension, the earliest publication/availability date will be used to determine eligibility. As of March 1, 2017, eligible extensions are detailed in Table 1 while ineligible extensions are detailed in Table 2.

Table 1. Extensions Eligible for Assessment

Abbreviation	Title/Description	Publication Date
STREGA [4]	STrengthening the REporting of Genetic Association Studies	February 3, 2009
STROBE-EULAR [17]*	A EULAR extension of STROBE guidelines	June 4, 2010
STROBE-ME [18]	STrengthening the Reporting of OBservational studies in Epidemiology - Molecular Epidemiology	October 24, 2011
STROME-ID [19]	Strengthening the Reporting of Molecular Epidemiology for Infectious Diseases	March 13, 2014
STROBE-RDS [20]	Strengthening the Reporting of Observational Studies in Epidemiology for Respondent-Driven Sampling studies	May 1, 2015
RECORD [21]	REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement	October 6, 2015

STROBE-AMS [22]	Strengthening the Reporting of Observational Studies in Epidemiology for AntiMicrobial Stewardship	February 19, 2016

* *This extension does not have an official acronym. For simplicity's sake, this will be used.*

Table 2. Extensions Not Eligible for Assessment

Abbreviation	Title/Description	Publication Date
MARE-S [23]	Medical Abortion Reporting of Efficacy - STROBE	April 23, 2016
STROBE-NUT [24]	Strengthening the Reporting of Observational Studies in Epidemiology-NUTritional epidemiology	June 7, 2016
ROSES-I [25]	CONSISE statement on the REporting of SEroepidemiologic Studies for influenza	July 17, 2016
STROBE-SBR [26]	Strengthening the Reporting of Observational Studies in Epidemiology for Simulation-Based Research	July 26, 2016
STROBE-NI [27]	Strengthening the Reporting of Observational Studies in Epidemiology for Newborn Infection	September 13, 2016
STROBE-Vet [28]	Strengthening the Reporting of Observational Studies in Epidemiology – Veterinary	November 1, 2016

Identification of Journals

Journals in fields related to extensions will be identified using the National Library of Medicine (NLM) Catalog which contains, among other things, "biomedical and health-related life sciences journals" indexed in MEDLINE. As of March 2017, there are over 5,600 journals indexed [29]. This database was chosen for two primary reasons: 1) Broad Subject Terms are used which allows for easy identification and segmentation of research fields for journals and topic areas for articles; and 2) the segmentation of other search engines, namely Clarivate Analytics Web of Science Journal List [30], did not clearly align with extension fields and would result in more overwhelming searches with less certainty that potentially eligible journals would be identified.

Journals will be identified using the following search string in the NLM Catalog*:* *pubmed["Broad subject terms"]*. If an extension reports search terms in their publication, these will be considered as a starting point. All search strategies were developed in collaboration with

a medical librarian. Further details listing the individual broad subject terms used for each extension are detailed in Table 3.

Table 3. Broad Subject Terms

STROBE Extension	Broad Subject Term(s)
STREGA	Genetics, Genetics, Medical
STROBE-EULAR	Rheumatology
STROBE-ME	Molecular Biology
STROME-ID	Molecular Biology, Anti-Infective Agents
STROBE-RDS	Public Health
RECORD	Health Services, Health Services Research
STROBE-AMS	Anti-Infective Agents, Drug Therapy

Screening

Journals will be manually screened to confirm that they publish in English, are in a relevant format (e.g., not a textbook, magazine, etc.), and are currently publishing. From the remaining list of journals that are indexed in MEDLINE, search strategies will be used to identify observational studies in the relevant topic areas (see Supplementary File 1). The filter for observational studies is a combination of a study design search filter for cohort and case-control studies by BMJ Evidence Centre information specialists, Fraser et al.'s work on identifying observational studies in surgical interventions, and consultations with a medical librarian [31,32].

From the remaining list of journals that publish observational studies, field-specific search strategies (detailed in Supplementary File 1) will be used. Extensions were used as a starting point and extant systematic reviews provided additional guidance, particularly for RECORD and STROBE-AMS [33,34]. In the case of EULAR, a combination approach will not be used as this is the only extension where the broad subject term is the exact focus of the extension; the search strategy for observational studies will still be used.

The results of the OVID MEDLINE field-specific and observational search strategies will be compared to the list of journals that the search was run on to determine inclusion and exclusion. This combination approach will be used for several reasons. Firstly, journal information from NLM is given in more structured manner and allows for easy matching between sets with overlapping Broad Subject Terms. For example, both STROBE-AMS and STROME-ID use the term "Anti-Infective Agents" while both STROBE-ME and STROME-ID use "Molecular Biology." This approach is also less resource-intensive and allows us to more easily identify how many journals in each field publish observational studies, thus establishing the extent and importance of the issue.

Data Extraction

Eligible journals and their websites will be searched exhaustively for any mention of STROBE extensions in their instructions for authors, guidelines for reviewers, other guidance documents, or ethical policies. Data will be extracted by the first author (MKS). To inspect reliability, another researcher (DH) will extract data from 10% of the sample and agreement will be calculated. Primary data sources (i.e., website pages) will be downloaded in pdf format and relevant text describing guideline endorsement will be extracted and coded into a standard data extraction sheet in Excel. Although STROBE and its extensions are the main focus of this investigation, we will also collect information about endorsement of other common guidelines such as CONSORT, PRISMA, ICMJE's Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals and mentions of organizations like EQUATOR and COPE [13,15,35–37]. This information will be gathered to see if journals that

endorse other reporting guidelines or ethical reporting guidance, are more likely to endorse STROBE or an extension.

Altman and Hopewell's classification schema will be used as a starting point for the development of a typology of endorsement for STROBE and extensions [6,38,39]. We anticipate that there will be several categories of endorsement ranging from strong to weak. Some examples include a requirement of a completed checklist with manuscript submission, a suggestion that authors "should" reference or follow a specific guideline, a vague suggestion that author should adhere to reporting guidelines, a vague suggestion that authors should adhere to certain standards which include reference to reporting guidelines, or not explicit mention at all.

In addition to information regarding support for STROBE and its extensions, general information about the journal such as impact factor, publisher, and contact information for the editorial offices will be collected. For the purposes of future analyses focused on completeness of reporting, it will also be noted if journals have recently launched and have not been publishing for at least two years prior to the publication of its related extension; this will ensure the ability to establish baseline data on the completeness of reporting. For example, STREGA was published in 2009, therefore journals must have begun publishing by 2007 to be included in latter assessments.

As publishers often provide additional resources for authors, we will collect information from the websites of publishers about their methods of endorsement. Endorsement from publishers will be considered to be indirect methods of support as they require significant effort on the part of the user seeking the information. Information communicated directly through the journal's website will be considered to be direct if it is supplied in immediately available resources to authors.

Statistical Analyses

Endorsement, types of endorsement, and journal characteristics (e.g. Impact factor, publisher) will be expressed using descriptive statistics such as counts, means/medians, and percentages. For analyses comparing two binary variables (i.e., endorsement of extensions and endorsement of other reporting guidelines), unadjusted odds ratios and their associated 95% confidence intervals will be conducted. Differences in impact factors between endorsing and non-endorsing journals will be assessed with the Wilcoxon test of ranks, equivalent to the c-stat, c-index or area under the receiver operating characteristic (ROC) curve. All confidence intervals will be provided at the two-sided 95% level.

DISCUSSION

An evaluation of the extensions provides a deeper understanding of content areas that are adequately detailed or in need of elaboration. By identifying the content areas that authors have difficulties with, the groundwork will be laid for an assessment into how authors currently use and understand STROBE and what difficulties they encounter with its implementation. This study will provide us with potential hypotheses for future survey for authors, focused both on the perceived sufficiency of STROBE and the extensions as this could be a barrier to use. For example, if we find non-specific additions in parts of STROBE, we may focus on those parts when inquiring authors' opinions about adequacy of STROBE. The qualitative assessment will also allow us to identify key areas (e.g., particular sections of the methods, results, conclusion) that may be commonly misunderstood to specifically probe authors about these points.

Results from this study will also provide estimates of the frequency and typology of endorsement. This dataset will allow journals to be targeted in order to promote guideline usage

and will establish a groundwork for follow-up studies on attitudes related to endorsement of STROBE and its extensions. Perhaps most importantly, this study will provide the foundation for assessing the impact that endorsement has on the completeness of reporting. The data collected through this study will generate important insights for the design of future studies such as feasibility or pilot studies to estimate the effects of endorsement. Perceived lack of tangible benefit due to a weak evidence-base can be a major barrier to guideline use. Testing a relationship between endorsement and an increase in completeness of reporting, can provide the much-needed data to address skeptic's concerns about the tangible value of supporting STROBE and its extensions.

This study will solidify the scope of the problem of insufficient support and use of STROBE extensions, detail variability in endorsement typology, and establish data for future studies focused on the effects of endorsement on completeness of reporting and attitudes towards STROBE and its extensions.

SUPPLEMENTARY INFORMATION

Ethics and dissemination

Ethical approval was not needed or this study as there will be no human participants in this study. All data is publicly available.

Authors' contributions

All authors have made substantive intellectual contributions to the development of this protocol. MKS conceptualized the study and led the writing of the manuscript. DH led the supervision of the manuscript preparation. MKS and AU developed the search strategies. All authors provided detailed comments on earlier drafts and approved the final manuscript.

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Competing interests statement

EW is a Fellow of the UK EQUATOR Centre. This is an unpaid position but she has been paid to run training courses associated with the EQUATOR Network, and by other organizations, which promote the use of reporting guidelines such as STROBE. The EQUATOR Network is also a member of the Methods in Research on Research Network, which MKS, DH, EW, LG, and EC are members of. MKS has a placement with the EQUATOR Network as part of her doctoral studies. The other authors declare that they have no competing interests.

Data sharing statement

The final datasets supporting the conclusions of the research proposed in this protocol will be available in the Zenodo repository in the Methods in Research on Research (MiRoR) community [https://zenodo.org/communities/miror/]. This study has been pre-registered at the Open Science Framework (osf.io/u75gb).

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Supporting information

Supplementary File 1. Ovid MEDLINE Search Strategies

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Supplementary File 1. Ovid MEDLINE Search Strategies

All searches use the following database:
Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>

For each extension (except for EULAR), the observational strategy (14) is combined with the field-specific strategy (or/15-xx) and restricted to search only within the list of eligible journals ("journal name" or "journal name 2" ...or "journal name n"…).jn. within a certain time frame (limit xx to year="2 years prior to extension publication – 2017").

Identifying Observational Studies

1. Observational study/
2. (observational adj3 stud$).tw.
3. exp Cohort Studies/
4. cohort$.tw.
5. controlled clinical trial.pt.
6. Epidemiologic Methods/
7. exp case-control studies/
8. (case$ adj3 control$).tw.
9. Comparative Study/
10. prospective$.tw.
11. retrospective$.tw.
12. Cross-Sectional Studies/
13. prevalence/
14. or/1-13

Identifying Journal Publishing Studies in the Relevant Field

STREGA

15. exp Genetic Association Studies/
16. exp Polymorphism, Genetic/
17. exp Genetic Predisposition to Disease/
18. exp Genetic Research/
19. genome-wide association.tw.
20. genomewide association.tw
21. genetic research.tw.
22. gene$ polymorphism.tw.
23. gene$ association.tw.
24. or/15-23

STROBE-EULAR

No field-specific search strategy necessary due to specificity of broad subject term. The observational filter is still used in combination with the eligible journal pool.

STROBE-ME

15. exp molecular epidemiology/

16. exp Biomarkers/
17. Molecular epidemiolog$.tw.
18. Genetic epidemiolog$.tw.
19. Biomarker$.tw.
20. Bio-marker$.tw.
21. Or/15-20

STROME-ID
15. Molecular Epidemiology/
16. molecular epidemiolog$.tw.
17. exp Communicable Diseases/ep [Epidemiology]
18. exp Infection Control/
19. infection$.tw.
20. exp Molecular Typing/
21. molecular typing.tw.
22. molecular marker$.tw.
23. molecular clock.tw.
24. multiple-strain.tw.
25. or/15-24

RECORD
15. exp Records as Topic/
16. Registries/
17. database/ or dataset/
18. exp Information Systems/
19. (data or dataset or database or register or registry or registries or record$).tw.
20. or/15-19

STROBE-RDS
15. respondent driven.tw.
16. respondentdriven.tw.
17. participant driven.tw.
18. or/15-17

STROBE-AMS
15. exp Anti-Infective Agents/
16. exp Infection/
17. (antibiot$ or antimicrob$).tw.
18. exp Drug Resistance, Microbial/
19. Vancomycin/
20. exp Aminoglycosides/
21. exp Fluoroquinolones/
22. exp Carbapenems/
23. exp Cephalosporins/
24. (vancomycin or aminoglycosides or fluoroquinolones or carbapenems or cephalosporins).tw.
25. or/15-24

BMJ Open

The STROBE extensions: A protocol for a qualitative assessment of content and a survey of endorsement

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Secondary Subject Heading:	Research methods
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The STROBE extensions: A protocol for a qualitative assessment of content and a survey of endorsement

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Abstract

Introduction: The STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) Statement was developed in response to inadequate reporting of observational studies. In recent years, several extensions to STROBE have been created to provide more nuanced field-specific guidance for authors. The content and the prevalence of extension endorsement has not yet been assessed. Accordingly, there are two aims: 1) to classify changes made in the extensions to identify strengths and weaknesses of the original STROBE checklist; and 2) to determine the prevalence and typology of endorsement by journals in fields related to extensions.

Methods and analysis: Two independent researchers will assess additions in each extension. Additions will be coded as "field-specific" (FS) or "not field-specific" (NFS). FS is defined as particularly relevant information for a single field and guidance provided generally cannot be extrapolated beyond that field. NFS is defined as information that reflects epidemiological or methodological tenets and can be generalized to most, if not all, types of observational research studies. Intra-class correlation (ICC) will be calculated to measure reviewers' concordance. Upon disagreement, consensus will be sought. Individual additions will be grouped by STROBE checklist items to identify the frequency and distribution of changes.

Journals in fields related to extensions will be identified through National Library of Medicine (NLM) PubMed Broad Subject Terms, screened for eligibility, and further distilled via Ovid MEDLINE search strategies for observational studies. Text describing endorsement will be extracted from each journal's website. A classification scheme will be created for endorsement types and the prevalence of endorsement will be estimated. Analyses will utilize NVivo 11 and SAS University Edition.

Ethics and dissemination: This study does not require ethical approval as it does not involve human participants. This study has been pre-registered on Open Science Framework.

Word count: 290

Keywords: Reporting guidelines, STROBE, observational studies, information dissemination/methods, bibliometrics

Strengths and limitations of this study

- Our systematic approach to qualitatively assess the content of the additions made in the STROBE extensions provides a comprehensive overview of the types of changes made and can identify redundancies and problem areas.
- Our method involves standardized search strategies in Ovid MEDLINE, designed to capture a representative sample and circumvent issues of subjectivity in the identification of eligible journals
- This study will create an open source corpus of recent observational studies spanning seven fields which future researchers can utilize to assess completeness of reporting or other topics of interest.
- The bibliometric aspect of this study only focuses on 7 extensions and fields so results are not generalizable to other studies.

INTRODUCTION

The STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) Statement was developed in 2007 in response to the pervasiveness of inadequate reporting of observational studies. STROBE provides a checklist of items that serve as a reference for how to report sufficient information for observational research involving cohort, case-control, and cross-sectional studies [1]. The guidelines have been endorsed by the International Committee of Medical Journal Editors (ICMJE) and the accompanying checklist is sometimes explicitly used as a requirement for manuscript submission [2]. However, there is no standard method of endorsement by journals and little is known about the most effective ways to apply the guidelines in practice [3–5].

Regarding the reporting of clinical trials, requiring a completed Consolidated Standards of Reporting Trials (CONSORT) checklist upon submission of a manuscript has been shown to lead to improvements in reporting [6]. However, some journals do not want to take responsibility for guideline enforcement and many overlook non-adherence to guidelines; editors have expressed beliefs that their journal's current policies are adequate or that they fear losing authors to other journals that have less strict requirements for publication [7–9]. Editors may also be unaware of the existence of guidelines, as demonstrated by low endorsement rates by journals in dentistry [10], veterinary medicine [7], and urology [11]. On the other hand, the evidence for the endorsement of STROBE is also mixed. Endorsement was not shown to be associated with better reporting for items related to confounding, regardless of strength [12].

Several field-specific extensions to STROBE have been designed in recent years in an effort to promote complete reporting, provide more nuanced guidance for authors, and perhaps address editor's concerns that STROBE is not focused enough for their journal. Extensions for

other reporting guidelines are common, however the creation of extensions for STROBE seems to outpace those for other reporting guidelines such as the CONSORT [13]. Since the publication of STROBE in 2007, 13 extensions have been published and indexed by the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) Network, an international collaboration that promotes transparent and accurate reporting and indexes reporting guidelines [14]. In contrast, CONSORT was first published in 1996, updated in 2001 and further revised in 2010, yet only 17 extensions have been published during that period [15]. The reason behind the difference in the pacing of publications of extensions is unclear. Perhaps the concept of field-specific extensions to reporting guidelines were pioneered by CONSORT, thus making the idea more commonplace for subsequent reporting guidelines. Alternatively, the complexity of the types of observational research studies may require more guidance due to the wide variety of methods employed in observational studies. Regardless of the reasoning, it is evident that authors are still perceiving a need to provide more guidance on how to report information about their studies. However, until now, many of these initiatives have not been evaluated.

Extensions to STROBE offer a potential new avenue for promoting more complete reporting but their use has been largely unassessed and, similar to STROBE, they may face implementation and usage problems [3,7]. Being intended as general guidelines for observational studies, STROBE should include *necessary* information that is *sufficient* to most observational studies. For some fields, however, STROBE guidelines may not be sufficient due to specific requirements within the field. This gap is then covered by an extension for that field. However, when extensions include non-specific guidance that can be extrapolated to most observational studies (e.g. details about participants, settings, confounders, follow-up, biases or any other general epidemiological constructs), it suggests potential deficiencies in STROBE checklist. If

the content is already in STROBE, extension authors may have thought that it was not clearly communicated, or that it is necessary to include it in the checklist instead of being only in the explanation and elaboration document. Whilst, if the content is not already in STROBE, extension authors may have identified a gap or insufficiency which should be considered as an addendum to STROBE. Therefore, by identifying non-specific or redundant guidance suggested in the STROBE extensions, we will be able to identify perceived gaps and deficiencies in the current STROBE checklist and potentially reduce future waste in the process of extension creation.

A perceived lack of confidence in reporting guidelines can impact journal editors' willingness to endorse reporting guidelines. Currently, it is unclear if and how journals are encouraging or requiring authors to use STROBE extensions. As journals are key players influencing the use and uptake of extensions, the prevalence and typology of extension endorsement is needed to understand the variety of methods employed to encourage transparent reporting. Data collected from this study can later be used as the groundwork for an evaluation of the impact of endorsement on the completeness of reporting.

Aims

The objectives of this study are twofold. Firstly, to qualitatively assess and classify the changes made in the extensions to help to identify the strengths and weaknesses of the original STROBE checklist; this will identify potential problem areas or deficiencies conveyed in extension additions. Secondly, we will estimate the prevalence of endorsement in journals that publish observational studies from extension-related fields and create an endorsement typology to provide a finer detailed view of the promotion of the STROBE extensions.

METHODS AND ANALYSIS

Qualitative Assessment and Analysis

The main focus of this phase will be on coding the additions that are made in each extension. Coded additions will help to identify the strengths, weaknesses and redundancies conveyed in the STROBE extensions in order to provide guidance for modifications to the original STROBE checklist and to identify target areas for future educational interventions.

We will assess the content of 13 STROBE extensions which were identified through the EQUATOR Network website as well as through a PubMed search for STROBE-related publications. Two independent reviewers (DH, MKS) will code the additions made in each STROBE extension; disagreement will be resolved by consensus. Each sub-item on an extension that is attached to a STROBE checklist item will be coded individually by the relevant content area (e.g., item 5 sub-item additions a, b, and c, will be counted and coded as three separate items). Each sub-item will also be coded as "field-specific" (FS) or "not field-specific" (NFS). FS is defined as information that is particularly relevant for a single field and guidance provided cannot be generalized beyond that particular extension's field. Items which note phrases such as "including," "specifically," "for example," and "e.g." followed by a field-specific example, generally are considered to be field-specific as these items are adding additional information specific to a certain topic area. NFS is defined as information that reflects general epidemiological or methodological tenets and can be extrapolated to most, if not all, types of observational research studies.

For the subjective assessments of the field-specific or not field-specific nature of the additions (rated as binary yes or no), intra-class correlation (ICC) will be used to assess the inter-

rater reliability (IRR). The ICC for the two raters will be calculated for ratings across all 13 extensions that involve the subjective assessment of an item as field-specific or not. This method was chosen because ICC does not take an all-or-nothing approach to agreement but rather it "incorporates the magnitude of disagreement to compute IRR estimates" [16]. Descriptive statistics such as counts, means, and percentages will be given.

Endorsement Survey

Eligibility Criteria

Extensions to the STROBE guidelines were identified through the EQUATOR Network website as well as through a search on PubMed. Extensions are eligible for assessment if at least one year has passed since publication as this allows for some time for endorsement and implementation. In the case of multiple publications of an extension, the earliest publication/availability date will be used to determine eligibility. As of March 1, 2017, eligible extensions are detailed in Table 1 while ineligible extensions are detailed in Table 2.

Table 1. Extensions Eligible for Assessment

Abbreviation	Title/Description	Publication Date
STREGA [4]	STrengthening the REporting of Genetic Association Studies	February 3, 2009
STROBE-EULAR [17]*	A EULAR extension of STROBE guidelines	June 4, 2010
STROBE-ME [18]	STrengthening the Reporting of OBservational studies in Epidemiology - Molecular Epidemiology	October 24, 2011
STROME-ID [19]	Strengthening the Reporting of Molecular Epidemiology for Infectious Diseases	March 13, 2014
STROBE-RDS [20]	Strengthening the Reporting of Observational Studies in Epidemiology for Respondent-Driven Sampling studies	May 1, 2015
RECORD [21]	REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement	October 6, 2015

STROBE-AMS [22]	Strengthening the Reporting of Observational Studies in Epidemiology for AntiMicrobial Stewardship	February 19, 2016

* *This extension does not have an official acronym. For simplicity's sake, this will be used.*

Table 2. Extensions Not Eligible for Assessment

Abbreviation	Title/Description	Publication Date
MARE-S [23]	Medical Abortion Reporting of Efficacy - STROBE	April 23, 2016
STROBE-NUT [24]	Strengthening the Reporting of Observational Studies in Epidemiology-NUTritional epidemiology	June 7, 2016
ROSES-I [25]	CONSISE statement on the REporting of SEroepidemiologic Studies for influenza	July 17, 2016
STROBE-SBR [26]	Strengthening the Reporting of Observational Studies in Epidemiology for Simulation-Based Research	July 26, 2016
STROBE-NI [27]	Strengthening the Reporting of Observational Studies in Epidemiology for Newborn Infection	September 13, 2016
STROBE-Vet [28]	Strengthening the Reporting of Observational Studies in Epidemiology – Veterinary	November 1, 2016

Identification of Journals

Journals in fields related to extensions will be identified using the National Library of Medicine (NLM) Catalog which contains, among other things, "biomedical and health-related life sciences journals" indexed in MEDLINE. As of March 2017, there are over 5,600 journals indexed [29]. This database was chosen for two primary reasons: 1) Broad Subject Terms are used which allows for easy identification and segmentation of research fields for journals and topic areas for articles; and 2) the segmentation of other search engines, namely Clarivate Analytics Web of Science Journal List [30], did not clearly align with extension fields and would result in more overwhelming searches with less certainty that potentially eligible journals would be identified.

Journals will be identified using the following search string in the NLM Catalog*:* *pubmed["Broad subject terms"]*. If an extension reports search terms in their publication, these will be considered as a starting point. All search strategies were developed in collaboration with

a medical librarian. Further details listing the individual broad subject terms used for each extension are detailed in Table 3.

Table 3. Broad Subject Terms

STROBE Extension	Broad Subject Term(s)
STREGA	Genetics, Genetics, Medical
STROBE-EULAR	Rheumatology
STROBE-ME	Molecular Biology
STROME-ID	Molecular Biology, Anti-Infective Agents
STROBE-RDS	Public Health
RECORD	Health Services, Health Services Research
STROBE-AMS	Anti-Infective Agents, Drug Therapy

Screening

Journals will be manually screened to confirm that they publish in English, are in a relevant format (e.g., not a textbook, magazine, etc.), and are currently publishing. From the remaining list of journals that are indexed in MEDLINE, search strategies will be used to identify observational studies in the relevant topic areas (see Supplementary File 1). The filter for observational studies is a combination of a study design search filter for cohort and case-control studies by BMJ Evidence Centre information specialists, Fraser et al.'s work on identifying observational studies in surgical interventions, and consultations with a medical librarian [31,32].

From the remaining list of journals that publish observational studies, field-specific search strategies (detailed in Supplementary File 1) will be used. Extensions were used as a starting point and extant systematic reviews provided additional guidance, particularly for RECORD and STROBE-AMS [33,34]. In the case of EULAR, a combination approach will not be used as this is the only extension where the broad subject term is the exact focus of the extension; the search strategy for observational studies will still be used.

The results of the OVID MEDLINE field-specific and observational search strategies will be compared to the list of journals that the search was run on to determine inclusion and exclusion. This combination approach will be used for several reasons. Firstly, journal information from NLM is given in more structured manner and allows for easy matching between sets with overlapping Broad Subject Terms. For example, both STROBE-AMS and STROME-ID use the term "Anti-Infective Agents" while both STROBE-ME and STROME-ID use "Molecular Biology." This approach is also less resource-intensive and allows us to more easily identify how many journals in each field publish observational studies, thus establishing the extent and importance of the issue.

Data Extraction

Eligible journals and their websites will be searched exhaustively for any mention of STROBE extensions in their instructions for authors, guidelines for reviewers, other guidance documents, or ethical policies. Data will be extracted by the first author (MKS). To inspect reliability, another researcher (DH) will extract data from 10% of the sample and agreement will be calculated. Primary data sources (i.e., website pages) will be downloaded in pdf format and relevant text describing guideline endorsement will be extracted and coded into a standard data extraction sheet in Excel. Although STROBE and its extensions are the main focus of this investigation, we will also collect information about endorsement of other common guidelines such as CONSORT, PRISMA, ICMJE's Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals and mentions of organizations like EQUATOR and COPE [13,15,35–37]. This information will be gathered to see if journals that

endorse other reporting guidelines or ethical reporting guidance, are more likely to endorse STROBE or an extension.

Altman and Hopewell's classification schema will be used as a starting point for the development of a typology of endorsement for STROBE and extensions [6,38,39]. The initial approach will be to codify endorsements into several categories of ranging from active, passive, and not-endorsing. Some examples include a requirement of a completed checklist with manuscript submission (e.g., active), a suggestion that authors "should" reference or follow a specific guideline (e.g., passive strong), a vague suggestion that author should adhere to reporting guidelines (e.g., passive moderate), a vague suggestion that authors should adhere to certain standards which include reference to reporting guidelines (e.g., passive weak), or no explicit mention at all (e.g., not endorsing).

In addition to information regarding support for STROBE and its extensions, general information about the journal such as impact factor, publisher, and contact information for the editorial offices will be collected. For the purposes of future analyses focused on completeness of reporting, it will also be noted if journals have recently launched and have not been publishing for at least two years prior to the publication of its related extension; this will ensure the ability to establish baseline data on the completeness of reporting. For example, STREGA was published in 2009, therefore journals must have begun publishing by 2007 to be included in latter assessments.

As publishers often provide additional resources for authors, we will collect information from the websites of publishers about their methods of endorsement. Endorsement from publishers will be considered to be indirect methods of support as they require significant effort on the part of the user seeking the information. Information communicated directly through the

journal's website will be considered to be direct if it is supplied in immediately available resources to authors.

Statistical Analyses

Endorsement, types of endorsement, and journal characteristics (e.g. Impact factor, publisher) will be expressed using descriptive statistics such as counts, means/medians, and percentages. For analyses comparing two binary variables (i.e., endorsement of extensions and endorsement of other reporting guidelines), unadjusted odds ratios and their associated 95% confidence intervals will be conducted. Differences in impact factors between endorsing and non-endorsing journals will be assessed with the Wilcoxon test of ranks, equivalent to the c-stat, c-index or area under the receiver operating characteristic (ROC) curve. All confidence intervals will be provided at the two-sided 95% level.

DISCUSSION

An evaluation of the extensions provides a deeper understanding of content areas that are adequately detailed or in need of elaboration. By identifying the content areas that authors have difficulties with, the groundwork will be laid for an assessment into how authors currently use and understand STROBE and what difficulties they encounter with its implementation. This study will provide us with potential hypotheses for future survey for authors, focused both on the perceived sufficiency of STROBE and the extensions as this could be a barrier to use. For example, if we find non-specific additions in parts of STROBE, we may focus on those parts when inquiring authors' opinions about adequacy of STROBE. The qualitative assessment will also allow us to identify key areas (e.g., particular sections of the methods, results, conclusion) that may be commonly misunderstood to specifically probe authors about these points.

Results from this study will also provide estimates of the frequency and typology of endorsement. This dataset will allow journals to be targeted in order to promote guideline usage and will establish a groundwork for follow-up studies on attitudes related to endorsement of STROBE and its extensions. Perhaps most importantly, this study will provide the foundation for assessing the impact that endorsement has on the completeness of reporting. The data collected through this study will generate important insights for the design of future studies such as feasibility or pilot studies to estimate the effects of endorsement. Perceived lack of tangible benefit due to a weak evidence-base can be a major barrier to guideline use. Testing a relationship between endorsement and an increase in completeness of reporting, can provide the much-needed data to address skeptic's concerns about the tangible value of supporting STROBE and its extensions.

This study will solidify the scope of the problem of insufficient support and use of STROBE extensions, detail variability in endorsement typology, and establish data for future studies focused on the effects of endorsement on completeness of reporting and attitudes towards STROBE and its extensions.

SUPPLEMENTARY INFORMATION

Ethics and dissemination

Ethical approval was not needed or this study as there will be no human participants in this study. All data is publicly available.

Authors' contributions

All authors have made substantive intellectual contributions to the development of this protocol. MKS conceptualized the study and led the writing of the manuscript. DH led the supervision of the manuscript preparation. MKS and AU developed the search strategies. All authors provided detailed comments on earlier drafts and approved the final manuscript.

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Competing interests statement

EW is a Fellow of the UK EQUATOR Centre. This is an unpaid position but she has been paid to run training courses associated with the EQUATOR Network, and by other organizations, which promote the use of reporting guidelines such as STROBE. The EQUATOR Network is also a member of the Methods in Research on Research Network, which MKS, DH, EW, LG, and EC are members of. MKS has a placement with the EQUATOR Network as part of her doctoral studies. The other authors declare that they have no competing interests.

Data sharing statement

The final datasets supporting the conclusions of the research proposed in this protocol will be available in the Zenodo repository in the Methods in Research on Research (MiRoR) community [https://zenodo.org/communities/miror/]. This study has been pre-registered at the Open Science Framework (osf.io/u75gb).

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Supporting information

Supplementary File 1. Ovid MEDLINE Search Strategies

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Supplementary File 1. Ovid MEDLINE Search Strategies

All searches use the following database:
Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>

For each extension (except for EULAR), the observational strategy (14) is combined with the field-specific strategy (or/15-xx) and restricted to search only within the list of eligible journals ("journal name" or "journal name 2" ...or "journal name n"…).jn. within a certain time frame (limit xx to year="2 years prior to extension publication – 2017").

Identifying Observational Studies

1. Observational study/
2. (observational adj3 stud$).tw.
3. exp Cohort Studies/
4. cohort$.tw.
5. controlled clinical trial.pt.
6. Epidemiologic Methods/
7. exp case-control studies/
8. (case$ adj3 control$).tw.
9. Comparative Study/
10. prospective$.tw.
11. retrospective$.tw.
12. Cross-Sectional Studies/
13. prevalence/
14. or/1-13

Identifying Journal Publishing Studies in the Relevant Field

STREGA

15. exp Genetic Association Studies/
16. exp Polymorphism, Genetic/
17. exp Genetic Predisposition to Disease/
18. exp Genetic Research/
19. genome-wide association.tw.
20. genomewide association.tw
21. genetic research.tw.
22. gene$ polymorphism.tw.
23. gene$ association.tw.
24. or/15-23

STROBE-EULAR

No field-specific search strategy necessary due to specificity of broad subject term. The observational filter is still used in combination with the eligible journal pool.

STROBE-ME

15. exp molecular epidemiology/

16. exp Biomarkers/
17. Molecular epidemiolog$.tw.
18. Genetic epidemiolog$.tw.
19. Biomarker$.tw.
20. Bio-marker$.tw.
21. Or/15-20

STROME-ID
15. Molecular Epidemiology/
16. molecular epidemiolog$.tw.
17. exp Communicable Diseases/ep [Epidemiology]
18. exp Infection Control/
19. infection$.tw.
20. exp Molecular Typing/
21. molecular typing.tw.
22. molecular marker$.tw.
23. molecular clock.tw.
24. multiple-strain.tw.
25. or/15-24

RECORD
15. exp Records as Topic/
16. Registries/
17. database/ or dataset/
18. exp Information Systems/
19. (data or dataset or database or register or registry or registries or record$).tw.
20. or/15-19

STROBE-RDS
15. respondent driven.tw.
16. respondentdriven.tw.
17. participant driven.tw.
18. or/15-17

STROBE-AMS
15. exp Anti-Infective Agents/
16. exp Infection/
17. (antibiot$ or antimicrob$).tw.
18. exp Drug Resistance, Microbial/
19. Vancomycin/
20. exp Aminoglycosides/
21. exp Fluoroquinolones/
22. exp Carbapenems/
23. exp Cephalosporins/
24. (vancomycin or aminoglycosides or fluoroquinolones or carbapenems or cephalosporins).tw.
25. or/15-24