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

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30 **Abstract**

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

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

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

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

54 **Word count:** 290

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

57 **Strengths and limitations of this study**

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

69 **INTRODUCTION**

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

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

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

92 other reporting guidelines are common, however the creation of extensions for STROBE seems  
93 to outpace those for other reporting guidelines such as the CONSORT [13]. Since the publication  
94 of STROBE in 2007, 13 extensions have been published and indexed by the Enhancing the  
95 QUALity and Transparency Of health Research (EQUATOR) Network, an international  
96 collaboration that promotes transparent and accurate reporting and indexes reporting guidelines  
97 [14]. In contrast, CONSORT was first published in 1996, updated in 2001 and further revised in  
98 2010, yet only 17 extensions have been published during that period [15]. The reason behind the  
99 difference in the pacing of publications of extensions is unclear. Perhaps the concept of field-  
100 specific extensions to reporting guidelines were pioneered by CONSORT, thus making the idea  
101 more commonplace for subsequent reporting guidelines. Alternatively, the complexity of the  
102 types of observational research studies may require more guidance due to the wide variety of  
103 methods employed in observational studies. Regardless of the reasoning, it is evident that authors  
104 are still perceiving a need to provide more guidance on how to report information about their  
105 studies. However, until now, many of these initiatives have not been evaluated.

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

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

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

### 130 **Aims**

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

137 **METHODS AND ANALYSIS**

138 **Qualitative Assessment and Analysis**

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

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

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

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

164 **Endorsement Survey**

165 Eligibility Criteria

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

172 **Table 1.** Extensions Eligible for Assessment

| <b>Abbreviation</b> | <b>Title/Description</b>                                                                                    | <b>Publication Date</b> |
|---------------------|-------------------------------------------------------------------------------------------------------------|-------------------------|
| 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

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

192 **Table 3.** Broad Subject Terms

| <b>STROBE Extension</b> | <b>Broad Subject Term(s)</b>              |
|-------------------------|-------------------------------------------|
| 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       |

193

194 Screening

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

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

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

218

#### 219 Data Extraction

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

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

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

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

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

254

## 255 Statistical Analyses

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

264

## 265 **DISCUSSION**

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

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

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

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

291 **SUPPLEMENTARY INFORMATION**

292 **Ethics and dissemination**

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

295

296 **Authors' contributions**

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

301

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305

306 **Competing interests statement**

307 The authors declare that they have no competing interests.

308

309 **Data sharing statement**

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

314

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318

319 **Supporting information**

320 **Supplementary File 1.** Ovid MEDLINE Search Strategies

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