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BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-019043
Article Type:	Protocol
Date Submitted by the Author:	08-Aug-2017
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Primary Subject Heading:	Medical publishing and peer review
Secondary Subject Heading:	Research methods
Keywords:	Reporting Guidelines, STROBE, observational studies, information dissemination/methods, bibliometrics

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Manuscripts

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9 4 The STROBE extensions: A protocol for a qualitative assessment of content and a survey of
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51 28 **Word Count:** 2276
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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 reached. Individual additions will be grouped by
45 STROBE 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

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3 57 **Strengths and limitations of this study**
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- 5 58
- 6 59 • Our systematic approach to qualitatively assess the content of the additions made in the
7 60 STROBE extensions provides a comprehensive overview of the types of changes made
8 61 and can identify redundancies and problem areas.
 - 9 62 • Our method involves standardized search strategies in Ovid MEDLINE, ensured to
10 63 capture a representative sample and circumvent issues of subjectivity in the identification
11 64 of eligible journals
 - 12 65 • This study will create an open source corpus of recent observational studies spanning
13 66 seven fields which future researchers can utilize to assess completeness of reporting or
14 67 other topics of interest.
 - 15 68 • The bibliometric aspect of this study only focuses on 7 extensions and fields so results
16 69 are not generalizable to other studies.
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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

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3 92 other reporting guidelines are common, however the creation of extensions for STROBE seems
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6 93 to outpace those for other reporting guidelines such as the CONSORT [13]. Since the publication
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8 94 of STROBE in 2007, 13 extensions have been published and indexed by the Enhancing the
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10 95 QUALity and Transparency Of health Research (EQUATOR) Network, an international
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12 96 collaboration that promotes transparent and accurate reporting and indexes reporting guidelines
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14 97 [14]. In contrast, CONSORT was first published in 1996, updated in 2001 and further revised in
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16 98 2010, yet only 17 extensions have been published during that period [15]. The reason behind the
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18 99 difference in the pacing of publications of extensions is unclear. Perhaps the concept of field-
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20 100 specific extensions to reporting guidelines were pioneered by CONSORT, thus making the idea
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22 101 more commonplace for subsequent reporting guidelines. Alternatively, the complexity of the
23
24 102 types of observational research studies may require more guidance due to the wide variety of
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26 103 methods employed in observational studies. Regardless of the reasoning, it is evident that authors
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28 104 are still perceiving a need to provide more guidance on how to report information about their
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30 105 studies. However, until now, many of these initiatives have not been evaluated.
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37 106 Extensions to STROBE offer a potential new avenue for promoting more complete
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39 107 reporting but their use has been largely unassessed and, similar to STROBE, they may face
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41 108 implementation and usage problems [3,7]. An evaluation of the content of the extensions can
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43 109 identify both strengths and weaknesses in the original STROBE guidelines and can reduce waste
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45 110 in the process of extension creation. Currently, it is unclear if and how journals are encouraging
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47 111 or requiring authors to use STROBE extensions. As journals are key players influencing the use
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49 112 and uptake of extensions, the prevalence and typology of extension endorsement is needed to
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51 113 understand the variety of methods employed to encourage transparent reporting. Data collected
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3 114 from this study can later be used as the groundwork for an evaluation of the impact of
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6 115 endorsement on the completeness of reporting.
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8 9 116 **Aims**

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11 117 The objectives of this study are twofold. Firstly, to qualitatively assess and classify the
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14 118 changes made in the extensions to help to identify the strengths and weaknesses of the original
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16 119 STROBE checklist; this will identify potential problem areas or deficiencies conveyed in
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19 120 extension additions. Secondly, we will estimate the prevalence of endorsement in journals that
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21 121 publish observational studies from extension-related fields and create an endorsement typology
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24 122 to provide a finer detailed view of the promotion of the STROBE extensions.
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26 27 123 **METHODS AND ANALYSIS**

28 29 30 124 **Qualitative Assessment and Analysis**

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33 125 The main focus of this phase will be on coding the additions that are made in each
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35 126 extension. Coded additions will help to identify the strengths, weaknesses and redundancies
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37 127 conveyed in the STROBE extensions in order to provide guidance for modifications to the
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40 128 original STROBE checklist and to identify target areas for future educational interventions.
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43 129 STROBE extensions will be identified through the EQUATOR Network website as well
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45 130 as through a MEDLINE search for STROBE-related publications. Two independent reviewers
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47 131 (DH, MKS) will code the additions made in each STROBE extension; disagreement will be
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50 132 resolved by consensus. Each sub-item on an extension that is attached to a STROBE checklist
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52 133 item will be coded individually by the relevant content area (e.g., item 5 sub-item additions a, b,
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55 134 and c, will be counted and coded as three separate items). Each sub-item will also be coded as
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57 135 “field-specific” (FS) or “not field-specific” (NFS). FS is defined as information that is
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3 136 particularly relevant for a single field and guidance provided cannot be generalized beyond that
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6 137 particular extension's field. Items which note phrases such as "including," "specifically," "for
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8 138 example," and "e.g." followed by a field-specific example, generally are considered to be field-
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11 139 specific as these items are adding additional information specific to a certain topic area. NFS is
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13 140 defined as information that reflects general epidemiological or methodological tenets and can be
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15 141 extrapolated to most, if not all, types of observational research studies.
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18 142 For the subjective assessments of the field-specific or not field-specific nature of the
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20 143 additions (rated as binary yes or no), intra-class correlation (ICC) will be used to assess the inter-
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22 144 rater reliability (IRR). The ICC for the two raters will be calculated for ratings across all 13
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24 145 extensions that involve the subjective assessment of an item as field-specific or not. This method
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26 146 was chosen because ICC does not take an all-or-nothing approach to agreement but rather it
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28 147 "incorporates the magnitude of disagreement to compute IRR estimates" [16]. Descriptive
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30 148 statistics such as counts, means, and percentages will be given.
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35 149 **Endorsement Survey**

36 37 38 150 Eligibility Criteria

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41 151 Extensions to the STROBE guidelines will be identified through the EQUATOR
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43 152 Network website as well as through a search on PubMed. Extensions will be eligible for
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45 153 assessment if at least one year has passed since publication as this allows for some time for
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47 154 endorsement and implementation. In the case of multiple publications of an extension, the
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49 155 earliest publication/availability date will be used to determine eligibility. As of March 1, 2017,
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51 156 eligible extensions are detailed in Table 1 while ineligible extensions are detailed in Table 2.
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56 157 **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

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3 167 used which allows for easy identification and segmentation of research fields for journals and
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5 168 topic areas for articles; and 2) the segmentation of other search engines, namely Clarivate
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8 169 Analytics Web of Science Journal List [30], did not clearly align with extension fields and would
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10 170 result in more overwhelming searches with less certainty that potentially eligible journals would
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13 171 be identified.

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15 172 Journals will be identified using the following search string in the NLM Catalog:
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18 173 *pubmed["Broad subject terms"]*. If an extension reports search terms in their publication, these
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20 174 will be considered as a starting point. All search strategies were developed in collaboration with
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22 175 a medical librarian. Further details listing the individual broad subject terms used for each
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24 176 extension are detailed in Table 3.

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27 177 **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

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45 180 Journals will be manually screened to confirm that they publish in English, are in a
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47 181 relevant format (e.g., not a textbook, magazine, etc.), and are currently publishing. From the
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49 182 remaining list of journals that are indexed in MEDLINE, search strategies will be used to
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52 183 identify observational studies in the relevant topic areas (see Supplementary File 1). The filter
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54 184 for observational studies is a combination of a study design search filter for cohort and case-
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56 185 control studies by BMJ Evidence Centre information specialists, Fraser et al.'s work on
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3 186 identifying observational studies in surgical interventions, and consultations with a medical
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6 187 librarian [31,32].
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8 188 From the remaining list of journals that publish observational studies, field-specific
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10 189 search strategies (detailed in Supplementary File 1) will be used. Extensions were used as a
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12 190 starting point and extant systematic reviews provided additional guidance, particularly for
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14 191 RECORD and STROBE-AMS [33,34]. In the case of EULAR, a combination approach will not
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16 192 be used as this is the only extension where the broad subject term is the exact focus of the
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18 193 extension; the search strategy for observational studies will still be used.
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22 194 The results of the OVID MEDLINE field-specific and observational search strategies will
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24 195 be compared to the list of journals that the search was run on to determine inclusion and
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26 196 exclusion. This combination approach will be used for several reasons. Firstly, journal
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28 197 information from NLM is given in more structured manner and allows for easy matching
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30 198 between sets with overlapping Broad Subject Terms. For example, both STROBE-AMS and
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32 199 STROME-ID use the term “Anti-Infective Agents” while both STROBE-ME and STROME-ID
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34 200 use “Molecular Biology.” This approach is also less resource-intensive and allows us to more
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36 201 easily identify how many journals in each field publish observational studies, thus establishing
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38 202 the extent and importance of the issue.
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46 204 Data Extraction 47

48 205 Eligible journals and their websites will be searched exhaustively for any mention of
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50 206 STROBE extensions in their instructions for authors, guidelines for reviewers, other guidance
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52 207 documents, or ethical policies. Primary data sources (i.e., website pages) will be downloaded in
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54 208 pdf format and relevant text describing guideline endorsement will be extracted and coded into a
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3 209 standard data extraction sheet in Excel. Although STROBE and its extensions are the main focus
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6 210 of this investigation, we will also collect information about endorsement of other common
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8 211 guidelines such as CONSORT, PRISMA, ICMJE's Recommendations for the Conduct,
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10 212 Reporting, Editing, and Publication of Scholarly work in Medical Journals and mentions of
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12 213 organizations like EQUATOR and COPE [13,15,35–37]. This information will be gathered to
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15 214 see if journals that endorse other reporting guidelines or ethical reporting guidance, are more
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17 215 likely to endorse STROBE or an extension. Altman and Hopewell's classification schema will be
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20 216 used as a starting point for the development of a typology of endorsement for STROBE and
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22 217 extensions [6,38,39]. In addition to information regarding support for STROBE and its
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24 218 extensions, general information about the journal such as impact factor, publisher, and contact
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27 219 information for the editorial offices will be collected. For the purposes of future analyses focused
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29 220 on completeness of reporting, it will also be noted if journals have recently launched and have
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31 221 not been publishing for at least two years prior to the publication of its related extension; this
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34 222 will ensure the ability to establish baseline data on the completeness of reporting. For example,
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36 223 STREGA was published in 2009, therefore journals must have begun publishing by 2007 to be
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38 224 included in latter assessments.

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41 225 As publishers often provide additional resources for authors, we will collect information
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43 226 from the websites of publishers about their methods of endorsement. Endorsement from
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46 227 publishers will be considered to be indirect methods of support as they require significant effort
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48 228 on the part of the user seeking the information. Information communicated directly through the
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50 229 journal's website will be considered to be direct if it is supplied in immediately available
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53 230 resources to authors.

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3 232 Statistical Analyses
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6 233 Endorsement, types of endorsement, and journal characteristics (e.g. Impact factor,
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8 234 publisher) will be expressed using descriptive statistics such as counts, means/medians, and
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10 235 percentages. For analyses comparing two binary variables (i.e., endorsement of extensions and
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12 236 endorsement of other reporting guidelines), unadjusted odds ratios and their associated 95%
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14 237 confidence intervals will be conducted. Differences in impact factors between endorsing and
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16 238 non-endorsing journals will be assessed with the Wilcoxon test of ranks, equivalent to the c-stat,
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18 239 c-index or area under the receiver operating characteristic (ROC) curve. All confidence intervals
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20 240 will be provided at the two-sided 95% level.
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27 242 **DISCUSSION**
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29 243 An evaluation of the extensions provides a deeper understanding of content areas that are
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31 244 adequately detailed or in need of elaboration. By identifying the content areas that authors have
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33 245 difficulties with, the groundwork will be laid for an assessment into how authors currently use
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35 246 and understand STROBE and what difficulties they encounter with its implementation.
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38 247 Results from this study will also provide estimates of the frequency and typology of
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40 248 endorsement. This dataset will allow journals to be targeted in order to promote guideline usage
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42 249 and will establish a groundwork for follow-up studies on attitudes related to endorsement of
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44 250 STROBE and its extensions. Perhaps most importantly, this study will provide the foundation for
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46 251 assessing the impact that endorsement has on the completeness of reporting. The data collected
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48 252 through this study will generate important insights for the design of future studies such as
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50 253 feasibility or pilot studies to estimate the effects of endorsement. Perceived lack of tangible
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52 254 benefit due to a weak evidence-base can be a major barrier to guideline use. Testing a
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54 255 relationship between endorsement and an increase in completeness of reporting, can provide the
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3 256 much-needed data to address skeptic's concerns about the tangible value of supporting STROBE
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6 257 and its extensions.
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8 258 This study will solidify the scope of the problem of insufficient support and use of
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10 259 STROBE extensions, detail variability in endorsement typology, and establish data for future
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12 260 studies focused on the effects of endorsement on completeness of reporting and attitudes towards
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15 261 STROBE and its extensions.
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3 262 **SUPPLEMENTARY INFORMATION**

4 263 **Ethics and dissemination**

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6 264 Ethical approval was not needed for this study as there will be no human participants in this
7 265 study. All data is publicly available.

8 266
9 267 **Authors' contributions**

10 268 All authors have made substantive intellectual contributions to the development of this protocol.
11 269 MKS conceptualized the study and led the writing of the manuscript. DH led the supervision of
12 270 the manuscript preparation. MKS and AU developed the search strategies. All authors provided
13 271 detailed comments on earlier drafts and approved the final manuscript.
14 272

15 273 **Funding statement**

16
17 274 This work was supported by the European Union's Horizon 2020 research and innovation
18 275 programme under the Marie Skłodowska-Curie grant agreement No 676207.

19 276
20 277 **Competing interests statement**

21 278 The authors declare that they have no competing interests.
22 279

23 280 **Data sharing statement**

24 281 The final datasets supporting the conclusions of the research proposed in this protocol will be
25 282 available in the Zenodo repository in the Methods in Research on Research (MiRoR) community
26 283 [<https://zenodo.org/communities/mirror/>]. This study has been pre-registered at the Open Science
27 284 Framework (osf.io/u75gb).
28 285

29 286 **Acknowledgements**

30 287 The authors would like to acknowledge the Methods in Research on Research (MiRoR)
31 288 consortium for their support and guidance
32 289

33 290 **Supporting information**

34 291 **Supplementary File 1.** Ovid MEDLINE Search Strategies
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For peer review only

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3 **Supplementary File 1. Ovid MEDLINE Search Strategies**
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5
6 All searches use the following database:

7 Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations,
8 Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>
9

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

15
16 *Identifying Observational Studies*
17

- 18 1. Observational study/
19 2. (observational adj3 stud\$.tw.
20 3. exp Cohort Studies/
21 4. cohort\$.tw.
22 5. controlled clinical trial.pt.
23 6. Epidemiologic Methods/
24 7. exp case-control studies/
25 8. (case\$ adj3 control\$.tw.
26 9. Comparative Study/
27 10. prospective\$.tw.
28 11. retrospective\$.tw.
29 12. Cross-Sectional Studies/
30 13. prevalence/
31 14. or/1-13
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35 *Identifying Journal Publishing Studies in the Relevant Field*
36

37 STREGA

- 38 15. exp Genetic Association Studies/
39 16. exp Polymorphism, Genetic/
40 17. exp Genetic Predisposition to Disease/
41 18. exp Genetic Research/
42 19. genome-wide association.tw.
43 20. genomewide association.tw
44 21. genetic research.tw.
45 22. gene\$ polymorphism.tw.
46 23. gene\$ association.tw.
47 24. or/15-23
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50 STROBE-EULAR

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

- 56 15. exp molecular epidemiology/
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3 47 16. exp Biomarkers/
4 48 17. Molecular epidemiolog\$.tw.
5 49 18. Genetic epidemiolog\$.tw.
6 50 19. Biomarker\$.tw.
7 51 20. Bio-marker\$.tw.
8 52 21. Or/15-20
9 53
10 54 STROME-ID
11 55 15. Molecular Epidemiology/
12 56 16. molecular epidemiolog\$.tw.
13 57 17. exp Communicable Diseases/ep [Epidemiology]
14 58 18. exp Infection Control/
15 59 19. infection\$.tw.
16 60 20. exp Molecular Typing/
17 61 21. molecular typing.tw.
18 62 22. molecular marker\$.tw.
19 63 23. molecular clock.tw.
20 64 24. multiple-strain.tw.
21 65 25. or/15-24
22 66
23 67 RECORD
24 68 15. exp Records as Topic/
25 69 16. Registries/
26 70 17. database/ or dataset/
27 71 18. exp Information Systems/
28 72 19. (data or dataset or database or register or registry or registries or record\$.tw.
29 73 20. or/15-19
30 74
31 75 STROBE-RDS
32 76 15. respondent driven.tw.
33 77 16. respondentdriven.tw.
34 78 17. participant driven.tw.
35 79 18. or/15-17
36 80
37 81 STROBE-AMS
38 82 15. exp Anti-Infective Agents/
39 83 16. exp Infection/
40 84 17. (antibiot\$ or antimicrob\$.tw.
41 85 18. exp Drug Resistance, Microbial/
42 86 19. Vancomycin/
43 87 20. exp Aminoglycosides/
44 88 21. exp Fluoroquinolones/
45 89 22. exp Carbapenems/
46 90 23. exp Cephalosporins/
47 91 24. (vancomycin or aminoglycosides or fluoroquinolones or carbapenems or cephalosporins).tw.
48 92 25. or/15-24
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BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-019043.R1
Article Type:	Protocol
Date Submitted by the Author:	12-Sep-2017
Complete List of Authors:	Sharp, Melissa K; Universite Paris Descartes, Pierre Louis Doctoral School: Epidemiology and Biomedical Sciences; Sveuciliste u Splitu, Department of Psychology, Faculty of Humanities and Social Sciences Utrobičić, Ana; Sveuciliste u Splitu, School of Medicine Gómez, Guadalupe; Universitat Politecnica de Catalunya, Departament d'Estadística i Investigació Operativa Cobo, Erik; Universitat Politecnica Catalunya, Departament d'Estadística i Investigació Operativa Wager, Elizabeth; Sideview; Sveuciliste u Splitu, School of Medicine Hren, Darko; Sveuciliste u Splitu, Department of Psychology, Faculty of Humanities and Social Sciences
Primary Subject Heading:	Medical publishing and peer review
Secondary Subject Heading:	Research methods
Keywords:	Reporting Guidelines, STROBE, observational studies, information dissemination/methods, bibliometrics

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14 7 Melissa K. Sharp^{1,2}, Ana Utrobičić³, Guadalupe Gómez⁴, Erik Cobo⁴, Elizabeth Wager^{5,3}, Darko
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30 Abstract

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

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

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

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

55 **Word count:** 290

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

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3 58 **Strengths and limitations of this study**
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- 5 59
- 6 60 • Our systematic approach to qualitatively assess the content of the additions made in the
7 61 STROBE extensions provides a comprehensive overview of the types of changes made
8 62 and can identify redundancies and problem areas.
 - 9 63 • Our method involves standardized search strategies in Ovid MEDLINE, designed to
10 64 capture a representative sample and circumvent issues of subjectivity in the identification
11 65 of eligible journals
 - 12 66 • This study will create an open source corpus of recent observational studies spanning
13 67 seven fields which future researchers can utilize to assess completeness of reporting or
14 68 other topics of interest.
 - 15 69 • The bibliometric aspect of this study only focuses on 7 extensions and fields so results
16 are not generalizable to other studies.
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70 INTRODUCTION

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

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

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

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3 93 other reporting guidelines are common, however the creation of extensions for STROBE seems
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6 94 to outpace those for other reporting guidelines such as the CONSORT [13]. Since the publication
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8 95 of STROBE in 2007, 13 extensions have been published and indexed by the Enhancing the
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10 96 QUALity and Transparency Of health Research (EQUATOR) Network, an international
11
12 97 collaboration that promotes transparent and accurate reporting and indexes reporting guidelines
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15 98 [14]. In contrast, CONSORT was first published in 1996, updated in 2001 and further revised in
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17 99 2010, yet only 17 extensions have been published during that period [15]. The reason behind the
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20 100 difference in the pacing of publications of extensions is unclear. Perhaps the concept of field-
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22 101 specific extensions to reporting guidelines were pioneered by CONSORT, thus making the idea
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24 102 more commonplace for subsequent reporting guidelines. Alternatively, the complexity of the
25
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27 103 types of observational research studies may require more guidance due to the wide variety of
28
29 104 methods employed in observational studies. Regardless of the reasoning, it is evident that authors
30
31 105 are still perceiving a need to provide more guidance on how to report information about their
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34 106 studies. However, until now, many of these initiatives have not been evaluated.

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37 107 Extensions to STROBE offer a potential new avenue for promoting more complete
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39 108 reporting but their use has been largely unassessed and, similar to STROBE, they may face
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41 109 implementation and usage problems [3,7]. Being intended as general guidelines for observational
42
43 110 studies, STROBE should include *necessary* information that is *sufficient* to most observational
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45 111 studies. For some fields, however, STROBE guidelines may not be sufficient due to specific
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47 112 requirements within the field. This gap is then covered by an extension for that field. However,
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49 113 when extensions include non-specific guidance that can be extrapolated to most observational
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51 114 studies (e.g. details about participants, settings, confounders, follow-up, biases or any other
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54 115 general epidemiological constructs), it suggests potential deficiencies in STROBE checklist. If
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3 116 the content is already in STROBE, extension authors may have thought that it was not clearly
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5 117 communicated, or that it is necessary to include it in the checklist instead of being only in the
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8 118 explanation and elaboration document. Whilst, if the content is not already in STROBE,
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10 119 extension authors may have identified a gap or insufficiency which should be considered as an
11
12 120 addendum to STROBE. Therefore, by identifying non-specific or redundant guidance suggested
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14 121 in the STROBE extensions, we will be able to identify perceived gaps and deficiencies in the
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16 122 current STROBE checklist and potentially reduce future waste in the process of extension
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18 123 creation.
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23 124 A perceived lack of confidence in reporting guidelines can impact journal editors'
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25 125 willingness to endorse reporting guidelines. Currently, it is unclear if and how journals are
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27 126 encouraging or requiring authors to use STROBE extensions. As journals are key players
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29 127 influencing the use and uptake of extensions, the prevalence and typology of extension
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31 128 endorsement is needed to understand the variety of methods employed to encourage transparent
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33 129 reporting. Data collected from this study can later be used as the groundwork for an evaluation of
34
35 130 the impact of endorsement on the completeness of reporting.
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40 131 **Aims**

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43 132 The objectives of this study are twofold. Firstly, to qualitatively assess and classify the
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45 133 changes made in the extensions to help to identify the strengths and weaknesses of the original
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47 134 STROBE checklist; this will identify potential problem areas or deficiencies conveyed in
48
49 135 extension additions. Secondly, we will estimate the prevalence of endorsement in journals that
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51 136 publish observational studies from extension-related fields and create an endorsement typology
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54 137 to provide a finer detailed view of the promotion of the STROBE extensions.
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138 **METHODS AND ANALYSIS**

139 **Qualitative Assessment and Analysis**

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

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

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

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3 160 rater reliability (IRR). The ICC for the two raters will be calculated for ratings across all 13
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5 161 extensions that involve the subjective assessment of an item as field-specific or not. This method
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8 162 was chosen because ICC does not take an all-or-nothing approach to agreement but rather it
9
10 163 “incorporates the magnitude of disagreement to compute IRR estimates” [16]. Descriptive
11
12 164 statistics such as counts, means, and percentages will be given.

165 **Endorsement Survey**

166 Eligibility Criteria

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

173 **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
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174 * This extension does not have an official acronym. For simplicity's sake, this will be used.

175

176 **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

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178 Identification of Journals

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

188 Journals will be identified using the following search string in the NLM Catalog:

189 *pubmed*["Broad subject terms"]. If an extension reports search terms in their publication, these
 190 will be considered as a starting point. All search strategies were developed in collaboration with

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

193 **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

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195 Screening

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

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

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3 210 The results of the OVID MEDLINE field-specific and observational search strategies will
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6 211 be compared to the list of journals that the search was run on to determine inclusion and
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8 212 exclusion. This combination approach will be used for several reasons. Firstly, journal
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10 213 information from NLM is given in more structured manner and allows for easy matching
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13 214 between sets with overlapping Broad Subject Terms. For example, both STROBE-AMS and
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15 215 STROME-ID use the term “Anti-Infective Agents” while both STROBE-ME and STROME-ID
16
17 216 use “Molecular Biology.” This approach is also less resource-intensive and allows us to more
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20 217 easily identify how many journals in each field publish observational studies, thus establishing
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22 218 the extent and importance of the issue.
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25 21926
27 220 Data Extraction

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30 221 Eligible journals and their websites will be searched exhaustively for any mention of
31
32 222 STROBE extensions in their instructions for authors, guidelines for reviewers, other guidance
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34 223 documents, or ethical policies. Data will be extracted by the first author (MKS). To inspect
35
36 224 reliability, another researcher (DH) will extract data from 10% of the sample and agreement will
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39 225 be calculated. Primary data sources (i.e., website pages) will be downloaded in pdf format and
40
41 226 relevant text describing guideline endorsement will be extracted and coded into a standard data
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44 227 extraction sheet in Excel. Although STROBE and its extensions are the main focus of this
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46 228 investigation, we will also collect information about endorsement of other common guidelines
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49 229 such as CONSORT, PRISMA, ICMJE’s Recommendations for the Conduct, Reporting, Editing,
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51 230 and Publication of Scholarly work in Medical Journals and mentions of organizations like
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53 231 EQUATOR and COPE [13,15,35–37]. This information will be gathered to see if journals that
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3 232 endorse other reporting guidelines or ethical reporting guidance, are more likely to endorse
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6 233 STROBE or an extension.
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8 234 Altman and Hopewell's classification schema will be used as a starting point for the
9
10 235 development of a typology of endorsement for STROBE and extensions [6,38,39]. We anticipate
11
12 236 that there will be several categories of endorsement ranging from strong to weak. Some
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15 237 examples include a requirement of a completed checklist with manuscript submission, a
16
17 238 suggestion that authors "should" reference or follow a specific guideline, a vague suggestion that
18
19 239 author should adhere to reporting guidelines, a vague suggestion that authors should adhere to
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21
22 240 certain standards which include reference to reporting guidelines, or not explicit mention at all.
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25 241 In addition to information regarding support for STROBE and its extensions, general
26
27 242 information about the journal such as impact factor, publisher, and contact information for the
28
29 243 editorial offices will be collected. For the purposes of future analyses focused on completeness
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31 244 of reporting, it will also be noted if journals have recently launched and have not been publishing
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34 245 for at least two years prior to the publication of its related extension; this will ensure the ability
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36 246 to establish baseline data on the completeness of reporting. For example, STREGA was
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38 247 published in 2009, therefore journals must have begun publishing by 2007 to be included in latter
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41 248 assessments.
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44 249 As publishers often provide additional resources for authors, we will collect information
45
46 250 from the websites of publishers about their methods of endorsement. Endorsement from
47
48 251 publishers will be considered to be indirect methods of support as they require significant effort
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50 252 on the part of the user seeking the information. Information communicated directly through the
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53 253 journal's website will be considered to be direct if it is supplied in immediately available
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55 254 resources to authors.
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256 Statistical Analyses

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

265

266 DISCUSSION

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

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

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3 279 and will establish a groundwork for follow-up studies on attitudes related to endorsement of
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5 280 STROBE and its extensions. Perhaps most importantly, this study will provide the foundation for
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8 281 assessing the impact that endorsement has on the completeness of reporting. The data collected
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10 282 through this study will generate important insights for the design of future studies such as
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12 283 feasibility or pilot studies to estimate the effects of endorsement. Perceived lack of tangible
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14 284 benefit due to a weak evidence-base can be a major barrier to guideline use. Testing a
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16 285 relationship between endorsement and an increase in completeness of reporting, can provide the
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18 286 much-needed data to address skeptic's concerns about the tangible value of supporting STROBE
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20 287 and its extensions.
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25 288 This study will solidify the scope of the problem of insufficient support and use of
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27 289 STROBE extensions, detail variability in endorsement typology, and establish data for future
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29 290 studies focused on the effects of endorsement on completeness of reporting and attitudes towards
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31 291 STROBE and its extensions.
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3 292 **SUPPLEMENTARY INFORMATION**

4 293 **Ethics and dissemination**

5 294 Ethical approval was not needed for this study as there will be no human participants in this
6 295 study. All data is publicly available.

7 296

8 297 **Authors' contributions**

9 298 All authors have made substantive intellectual contributions to the development of this protocol.
10 299 MKS conceptualized the study and led the writing of the manuscript. DH led the supervision of
11 300 the manuscript preparation. MKS and AU developed the search strategies. All authors provided
12 301 detailed comments on earlier drafts and approved the final manuscript.

13 302

14 303 **Funding statement**

15 304 This work was supported by the European Union's Horizon 2020 research and innovation
16 305 programme under the Marie Skłodowska-Curie grant agreement No 676207.

17 306

18 307 **Competing interests statement**

19 308 EW is a Fellow of the UK EQUATOR Centre. This is an unpaid position but she has been paid
20 309 to run training courses associated with the EQUATOR Network, and by other organizations,
21 310 which promote the use of reporting guidelines such as STROBE. The EQUATOR Network is
22 311 also a member of the Methods in Research on Research Network, which MKS, DH, EW, LG,
23 312 and EC are members of. MKS has a placement with the EQUATOR Network as part of her
24 313 doctoral studies. The other authors declare that they have no competing interests.

25 314

26 315 **Data sharing statement**

27 316 The final datasets supporting the conclusions of the research proposed in this protocol will be
28 317 available in the Zenodo repository in the Methods in Research on Research (MiRoR) community
29 318 [<https://zenodo.org/communities/mirror/>]. This study has been pre-registered at the Open Science
30 319 Framework (osf.io/u75gb).

31 320

32 321 **Acknowledgements**

33 322 The authors would like to acknowledge the Methods in Research on Research (MiRoR)
34 323 consortium for their support and guidance

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36 325 **Supporting information**

37 326 **Supplementary File 1.** Ovid MEDLINE Search Strategies

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For peer review only

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/

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- 47 16. exp Biomarkers/
48 17. Molecular epidemiolog\$.tw.
49 18. Genetic epidemiolog\$.tw.
50 19. Biomarker\$.tw.
51 20. Bio-marker\$.tw.
52 21. Or/15-20
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54 STROME-ID
55 15. Molecular Epidemiology/
56 16. molecular epidemiolog\$.tw.
57 17. exp Communicable Diseases/ep [Epidemiology]
58 18. exp Infection Control/
59 19. infection\$.tw.
60 20. exp Molecular Typing/
61 21. molecular typing.tw.
62 22. molecular marker\$.tw.
63 23. molecular clock.tw.
64 24. multiple-strain.tw.
65 25. or/15-24
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67 RECORD
68 15. exp Records as Topic/
69 16. Registries/
70 17. database/ or dataset/
71 18. exp Information Systems/
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75 STROBE-RDS
76 15. respondent driven.tw.
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81 STROBE-AMS
82 15. exp Anti-Infective Agents/
83 16. exp Infection/
84 17. (antibiot\$ or antimicrob\$.tw.
85 18. exp Drug Resistance, Microbial/
86 19. Vancomycin/
87 20. exp Aminoglycosides/
88 21. exp Fluoroquinolones/
89 22. exp Carbapenems/
90 23. exp Cephalosporins/
91 24. (vancomycin or aminoglycosides or fluoroquinolones or carbapenems or cephalosporins).tw.
92 25. or/15-24

BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-019043.R2
Article Type:	Protocol
Date Submitted by the Author:	27-Sep-2017
Complete List of Authors:	Sharp, Melissa K; Universite Paris Descartes, Pierre Louis Doctoral School: Epidemiology and Biomedical Sciences; Sveuciliste u Splitu, Department of Psychology, Faculty of Humanities and Social Sciences Utrobičić, Ana; Sveuciliste u Splitu, School of Medicine Gómez, Guadalupe; Universitat Politecnica de Catalunya, Departament d'Estadística i Investigació Operativa Cobo, Erik; Universitat Politecnica Catalunya, Departament d'Estadística i Investigació Operativa Wager, Elizabeth; Sideview; Sveuciliste u Splitu, School of Medicine Hren, Darko; Sveuciliste u Splitu, Department of Psychology, Faculty of Humanities and Social Sciences
Primary Subject Heading:	Medical publishing and peer review
Secondary Subject Heading:	Research methods
Keywords:	Reporting Guidelines, STROBE, observational studies, information dissemination/methods, bibliometrics

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14 7 Melissa K. Sharp^{1,2}, Ana Utrobičić³, Guadalupe Gómez⁴, Erik Cobo⁴, Elizabeth Wager^{5,3}, Darko
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30 Abstract

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

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

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

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

55 **Word count:** 290

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

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3 58 **Strengths and limitations of this study**
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- 5 59
- 6 60 • Our systematic approach to qualitatively assess the content of the additions made in the
7 61 STROBE extensions provides a comprehensive overview of the types of changes made
8 62 and can identify redundancies and problem areas.
 - 9 63 • Our method involves standardized search strategies in Ovid MEDLINE, designed to
10 64 capture a representative sample and circumvent issues of subjectivity in the identification
11 65 of eligible journals
 - 12 66 • This study will create an open source corpus of recent observational studies spanning
13 67 seven fields which future researchers can utilize to assess completeness of reporting or
14 68 other topics of interest.
 - 15 69 • The bibliometric aspect of this study only focuses on 7 extensions and fields so results
16 are not generalizable to other studies.
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70 INTRODUCTION

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

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

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

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3 93 other reporting guidelines are common, however the creation of extensions for STROBE seems
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6 94 to outpace those for other reporting guidelines such as the CONSORT [13]. Since the publication
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8 95 of STROBE in 2007, 13 extensions have been published and indexed by the Enhancing the
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10 96 QUALity and Transparency Of health Research (EQUATOR) Network, an international
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12 97 collaboration that promotes transparent and accurate reporting and indexes reporting guidelines
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15 98 [14]. In contrast, CONSORT was first published in 1996, updated in 2001 and further revised in
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17 99 2010, yet only 17 extensions have been published during that period [15]. The reason behind the
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20 100 difference in the pacing of publications of extensions is unclear. Perhaps the concept of field-
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22 101 specific extensions to reporting guidelines were pioneered by CONSORT, thus making the idea
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24 102 more commonplace for subsequent reporting guidelines. Alternatively, the complexity of the
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27 103 types of observational research studies may require more guidance due to the wide variety of
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29 104 methods employed in observational studies. Regardless of the reasoning, it is evident that authors
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31 105 are still perceiving a need to provide more guidance on how to report information about their
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34 106 studies. However, until now, many of these initiatives have not been evaluated.

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37 107 Extensions to STROBE offer a potential new avenue for promoting more complete
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39 108 reporting but their use has been largely unassessed and, similar to STROBE, they may face
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41 109 implementation and usage problems [3,7]. Being intended as general guidelines for observational
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43 110 studies, STROBE should include *necessary* information that is *sufficient* to most observational
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45 111 studies. For some fields, however, STROBE guidelines may not be sufficient due to specific
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47 112 requirements within the field. This gap is then covered by an extension for that field. However,
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49 113 when extensions include non-specific guidance that can be extrapolated to most observational
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51 114 studies (e.g. details about participants, settings, confounders, follow-up, biases or any other
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54 115 general epidemiological constructs), it suggests potential deficiencies in STROBE checklist. If
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3 116 the content is already in STROBE, extension authors may have thought that it was not clearly
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6 117 communicated, or that it is necessary to include it in the checklist instead of being only in the
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8 118 explanation and elaboration document. Whilst, if the content is not already in STROBE,
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10 119 extension authors may have identified a gap or insufficiency which should be considered as an
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12 120 addendum to STROBE. Therefore, by identifying non-specific or redundant guidance suggested
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14 121 in the STROBE extensions, we will be able to identify perceived gaps and deficiencies in the
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16 122 current STROBE checklist and potentially reduce future waste in the process of extension
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18 123 creation.

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23 124 A perceived lack of confidence in reporting guidelines can impact journal editors'
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25 125 willingness to endorse reporting guidelines. Currently, it is unclear if and how journals are
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27 126 encouraging or requiring authors to use STROBE extensions. As journals are key players
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29 127 influencing the use and uptake of extensions, the prevalence and typology of extension
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31 128 endorsement is needed to understand the variety of methods employed to encourage transparent
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33 129 reporting. Data collected from this study can later be used as the groundwork for an evaluation of
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35 130 the impact of endorsement on the completeness of reporting.

36 37 38 39 40 131 **Aims**

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43 132 The objectives of this study are twofold. Firstly, to qualitatively assess and classify the
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45 133 changes made in the extensions to help to identify the strengths and weaknesses of the original
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47 134 STROBE checklist; this will identify potential problem areas or deficiencies conveyed in
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49 135 extension additions. Secondly, we will estimate the prevalence of endorsement in journals that
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51 136 publish observational studies from extension-related fields and create an endorsement typology
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53 137 to provide a finer detailed view of the promotion of the STROBE extensions.
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138 **METHODS AND ANALYSIS**

139 **Qualitative Assessment and Analysis**

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

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

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

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3 160 rater reliability (IRR). The ICC for the two raters will be calculated for ratings across all 13
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5 161 extensions that involve the subjective assessment of an item as field-specific or not. This method
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8 162 was chosen because ICC does not take an all-or-nothing approach to agreement but rather it
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10 163 “incorporates the magnitude of disagreement to compute IRR estimates” [16]. Descriptive
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12 164 statistics such as counts, means, and percentages will be given.

165 **Endorsement Survey**

166 Eligibility Criteria

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

173 **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
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174 * This extension does not have an official acronym. For simplicity's sake, this will be used.

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176 **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

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178 Identification of Journals

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

188 Journals will be identified using the following search string in the NLM Catalog:

189 *pubmed*["Broad subject terms"]. If an extension reports search terms in their publication, these
 190 will be considered as a starting point. All search strategies were developed in collaboration with

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3 191 a medical librarian. Further details listing the individual broad subject terms used for each
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6 192 extension are detailed in Table 3.

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8 193 **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

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195 Screening

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

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

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3 210 The results of the OVID MEDLINE field-specific and observational search strategies will
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6 211 be compared to the list of journals that the search was run on to determine inclusion and
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8 212 exclusion. This combination approach will be used for several reasons. Firstly, journal
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10 213 information from NLM is given in more structured manner and allows for easy matching
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13 214 between sets with overlapping Broad Subject Terms. For example, both STROBE-AMS and
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15 215 STROME-ID use the term “Anti-Infective Agents” while both STROBE-ME and STROME-ID
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17 216 use “Molecular Biology.” This approach is also less resource-intensive and allows us to more
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20 217 easily identify how many journals in each field publish observational studies, thus establishing
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22 218 the extent and importance of the issue.
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27 220 Data Extraction

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30 221 Eligible journals and their websites will be searched exhaustively for any mention of
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32 222 STROBE extensions in their instructions for authors, guidelines for reviewers, other guidance
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34 223 documents, or ethical policies. Data will be extracted by the first author (MKS). To inspect
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36 224 reliability, another researcher (DH) will extract data from 10% of the sample and agreement will
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39 225 be calculated. Primary data sources (i.e., website pages) will be downloaded in pdf format and
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41 226 relevant text describing guideline endorsement will be extracted and coded into a standard data
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44 227 extraction sheet in Excel. Although STROBE and its extensions are the main focus of this
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46 228 investigation, we will also collect information about endorsement of other common guidelines
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49 229 such as CONSORT, PRISMA, ICMJE’s Recommendations for the Conduct, Reporting, Editing,
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51 230 and Publication of Scholarly work in Medical Journals and mentions of organizations like
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53 231 EQUATOR and COPE [13,15,35–37]. This information will be gathered to see if journals that
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3 232 endorse other reporting guidelines or ethical reporting guidance, are more likely to endorse
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5 233 STROBE or an extension.
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8 234 Altman and Hopewell's classification schema will be used as a starting point for the
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10 235 development of a typology of endorsement for STROBE and extensions [6,38,39]. The initial
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12 236 approach will be to codify endorsements into several categories of ranging from active, passive,
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14 237 and not-endorsing. Some examples include a requirement of a completed checklist with
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16 238 manuscript submission (e.g., active), a suggestion that authors "should" reference or follow a
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18 239 specific guideline (e.g., passive strong), a vague suggestion that author should adhere to
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20 240 reporting guidelines (e.g., passive moderate), a vague suggestion that authors should adhere to
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22 241 certain standards which include reference to reporting guidelines (e.g., passive weak), or no
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24 242 explicit mention at all (e.g., not endorsing).
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29 243 In addition to information regarding support for STROBE and its extensions, general
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31 244 information about the journal such as impact factor, publisher, and contact information for the
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33 245 editorial offices will be collected. For the purposes of future analyses focused on completeness
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35 246 of reporting, it will also be noted if journals have recently launched and have not been publishing
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37 247 for at least two years prior to the publication of its related extension; this will ensure the ability
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39 248 to establish baseline data on the completeness of reporting. For example, STREGA was
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41 249 published in 2009, therefore journals must have begun publishing by 2007 to be included in latter
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43 250 assessments.
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48 251 As publishers often provide additional resources for authors, we will collect information
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50 252 from the websites of publishers about their methods of endorsement. Endorsement from
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52 253 publishers will be considered to be indirect methods of support as they require significant effort
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54 254 on the part of the user seeking the information. Information communicated directly through the
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10 258 Statistical Analyses

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13 259 Endorsement, types of endorsement, and journal characteristics (e.g. Impact factor,
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15 260 publisher) will be expressed using descriptive statistics such as counts, means/medians, and
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17 261 percentages. For analyses comparing two binary variables (i.e., endorsement of extensions and
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19 262 endorsement of other reporting guidelines), unadjusted odds ratios and their associated 95%
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21 263 confidence intervals will be conducted. Differences in impact factors between endorsing and
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23 264 non-endorsing journals will be assessed with the Wilcoxon test of ranks, equivalent to the c-stat,
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25 265 c-index or area under the receiver operating characteristic (ROC) curve. All confidence intervals
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27 266 will be provided at the two-sided 95% level.
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34 268 **DISCUSSION**

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36 269 An evaluation of the extensions provides a deeper understanding of content areas that are
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38 270 adequately detailed or in need of elaboration. By identifying the content areas that authors have
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40 271 difficulties with, the groundwork will be laid for an assessment into how authors currently use
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42 272 and understand STROBE and what difficulties they encounter with its implementation. This
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44 273 study will provide us with potential hypotheses for future survey for authors, focused both on the
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46 274 perceived sufficiency of STROBE and the extensions as this could be a barrier to use. For
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48 275 example, if we find non-specific additions in parts of STROBE, we may focus on those parts
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50 276 when inquiring authors' opinions about adequacy of STROBE. The qualitative assessment will
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52 277 also allow us to identify key areas (e.g., particular sections of the methods, results, conclusion)
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54 278 that may be commonly misunderstood to specifically probe authors about these points.
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3 279 Results from this study will also provide estimates of the frequency and typology of
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6 280 endorsement. This dataset will allow journals to be targeted in order to promote guideline usage
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8 281 and will establish a groundwork for follow-up studies on attitudes related to endorsement of
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10 282 STROBE and its extensions. Perhaps most importantly, this study will provide the foundation for
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12 283 assessing the impact that endorsement has on the completeness of reporting. The data collected
13
14 284 through this study will generate important insights for the design of future studies such as
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16 285 feasibility or pilot studies to estimate the effects of endorsement. Perceived lack of tangible
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18 286 benefit due to a weak evidence-base can be a major barrier to guideline use. Testing a
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20 287 relationship between endorsement and an increase in completeness of reporting, can provide the
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22 288 much-needed data to address skeptic's concerns about the tangible value of supporting STROBE
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24 289 and its extensions.
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29 290 This study will solidify the scope of the problem of insufficient support and use of
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31 291 STROBE extensions, detail variability in endorsement typology, and establish data for future
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33 292 studies focused on the effects of endorsement on completeness of reporting and attitudes towards
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35 293 STROBE and its extensions.
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3 294 **SUPPLEMENTARY INFORMATION**

4 295 **Ethics and dissemination**

5 296 Ethical approval was not needed for this study as there will be no human participants in this
6 297 study. All data is publicly available.

7 298

8 299 **Authors' contributions**

9 300 All authors have made substantive intellectual contributions to the development of this protocol.
10 301 MKS conceptualized the study and led the writing of the manuscript. DH led the supervision of
11 302 the manuscript preparation. MKS and AU developed the search strategies. All authors provided
12 303 detailed comments on earlier drafts and approved the final manuscript.

13 304

14 305 **Funding statement**

15 306 This work was supported by the European Union's Horizon 2020 research and innovation
16 307 programme under the Marie Skłodowska-Curie grant agreement No 676207.

17 308

18 309 **Competing interests statement**

19 310 EW is a Fellow of the UK EQUATOR Centre. This is an unpaid position but she has been paid
20 311 to run training courses associated with the EQUATOR Network, and by other organizations,
21 312 which promote the use of reporting guidelines such as STROBE. The EQUATOR Network is
22 313 also a member of the Methods in Research on Research Network, which MKS, DH, EW, LG,
23 314 and EC are members of. MKS has a placement with the EQUATOR Network as part of her
24 315 doctoral studies. The other authors declare that they have no competing interests.

25 316

26 317 **Data sharing statement**

27 318 The final datasets supporting the conclusions of the research proposed in this protocol will be
28 319 available in the Zenodo repository in the Methods in Research on Research (MiRoR) community
29 320 [<https://zenodo.org/communities/mirror/>]. This study has been pre-registered at the Open Science
30 321 Framework (osf.io/u75gb).

31 322

32 323 **Acknowledgements**

33 324 The authors would like to acknowledge the Methods in Research on Research (MiRoR)
34 325 consortium for their support and guidance

35 326

36 327 **Supporting information**

37 328 **Supplementary File 1.** Ovid MEDLINE Search Strategies

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For peer review only

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/

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- 47 16. exp Biomarkers/
48 17. Molecular epidemiolog\$.tw.
49 18. Genetic epidemiolog\$.tw.
50 19. Biomarker\$.tw.
51 20. Bio-marker\$.tw.
52 21. Or/15-20
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54 STROME-ID
55 15. Molecular Epidemiology/
56 16. molecular epidemiolog\$.tw.
57 17. exp Communicable Diseases/ep [Epidemiology]
58 18. exp Infection Control/
59 19. infection\$.tw.
60 20. exp Molecular Typing/
61 21. molecular typing.tw.
62 22. molecular marker\$.tw.
63 23. molecular clock.tw.
64 24. multiple-strain.tw.
65 25. or/15-24
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67 RECORD
68 15. exp Records as Topic/
69 16. Registries/
70 17. database/ or dataset/
71 18. exp Information Systems/
72 19. (data or dataset or database or register or registry or registries or record\$.tw.
73 20. or/15-19
74
75 STROBE-RDS
76 15. respondent driven.tw.
77 16. respondentdriven.tw.
78 17. participant driven.tw.
79 18. or/15-17
80
81 STROBE-AMS
82 15. exp Anti-Infective Agents/
83 16. exp Infection/
84 17. (antibiot\$ or antimicrob\$.tw.
85 18. exp Drug Resistance, Microbial/
86 19. Vancomycin/
87 20. exp Aminoglycosides/
88 21. exp Fluoroquinolones/
89 22. exp Carbapenems/
90 23. exp Cephalosporins/
91 24. (vancomycin or aminoglycosides or fluoroquinolones or carbapenems or cephalosporins).tw.
92 25. or/15-24