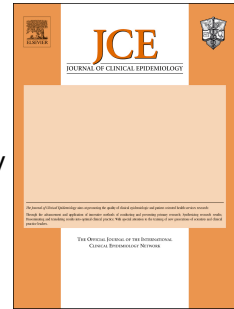


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A scoping review establishes need for consensus guidance on reporting health equity in observational studies

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A scoping review establishes need for consensus guidance on reporting health equity in observational studies

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92 **Abstract**

93 **Objective**

94 To evaluate the support from the available guidance on reporting of health equity in research for
95 our candidate items and to identify additional items for the STROBE (Strengthening Reporting of
96 Observational studies in Epidemiology)-Equity extension.

97 **Study design and setting**

98 We conducted a scoping review by searching Embase, MEDLINE, CINAHL, Cochrane
99 Methodology Register, LILACS, and Caribbean Centre on Health Sciences Information up to
100 January 2022. We also searched reference lists and grey literature for additional resources. We
101 included guidance and assessments (hereafter termed “resources”) related to conduct and/or
102 reporting for any type of health research with or about people experiencing health inequity.

103 **Results**

104 We included thirty-four resources, which supported one or more candidate items or contributed to
105 new items about health equity reporting in observational research. Each candidate item was
106 supported by a median of six (range: 1 - 15) resources. In addition, 12 resources suggested 13 new
107 items, such as “report the background of investigators”.

108 **Conclusions**

109 Existing resources for reporting health equity in observational studies aligned with our interim
110 checklist of candidate items. We also identified additional items that will be considered in the
111 development of a consensus- and evidence-based guideline for reporting health equity in
112 observational studies.

113 **Keywords:** health equity; observational studies; reporting guideline; scoping review;
114 STROBE_Equity

115

116 **Running title:** Consensus guidance on reporting health equity in observational studies is needed

117

118 **Word count:** 199

119

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What is new?**Key findings**

- All candidate items proposed to extend STROBE (Strengthening Reporting of Observational studies in Epidemiology) for equity were supported by at least one resource.

We identified 13 additional items related to defining health equity terms; these described the role of racism and discrimination, composition and training of the researcher(s), considering relevant factors in the study methods, and data sharing specific to and across equity factors.

What adds to what is known?

- Through the current resources, we confirmed the support of the interim checklist of items and identified new items for reporting health equity in observational studies. This adds an important tool for observational studies, including those underpinning public health, and health systems and services research.

What is the implication and what should change now?

- Researchers designing observational studies could refer to the items from this review when designing and reporting their studies.
- These items will be used for the consensus process to develop a research reporting guideline on health equity to extend STROBE.

125 **1. Introduction**

126 Health inequities are defined as “differences which are unnecessary and avoidable, unfair and
127 unjust” [1]. Health inequities exist across numerous dimensions such as income, education,
128 geographical setting, age, ethnicity and gender; these factors are well documented in influencing
129 health outcomes [2-4]. These health disparities have persisted despite global efforts to reduce them
130 by organizations such as the World Health Organization (WHO) and United Nations International
131 Children's Emergency Fund (UNICEF) [5-8]. Addressing the health needs of populations
132 experiencing inequities requires conducting research merging scientific standards and their
133 sociocultural contexts.

134
135 Observational studies predominate in health-related research[9] and are well-suited to answer
136 research questions of health inequity such as access, implementation, treatment adherence, and
137 public health interventions[10-12]. We defined observational studies as those relevant to the
138 STROBE reporting guideline, including case-control, cohort and cross-sectional studies[13].
139 Compared with some randomized controlled trials (RCTs), observational studies have inherently
140 stronger external validity because they provide insight about healthcare delivery to all patients in
141 routine practice, the health impacts of policy and practice interventions, and of potentially harmful
142 exposures, including among those populations at risk of disadvantage due to inequities[14,
143 15]. Evidence suggests that strong observational studies such as discontinuity designs, produce
144 estimates which are statistically identical to RCTs[16]. During the COVID-19 pandemic,
145 observational studies highlighted the inequities in the direct and indirect consequences of SARS-
146 CoV-2 infection and attempts to control it[17-19], thus playing a critical role in informing public
147 health responses[20-22]. In addition, in cases where conducting a RCT would be unethical,
148 observational studies become the most reliable source of evidence[23].

149

150 Despite the predominance of observational studies in health research, many such studies do not
151 adequately report information such as clear eligibility criteria, reliability and validity of
152 measurements, and details on data gaps[24-28]. The reporting guideline for observational studies
153 (STROBE, Strengthening Reporting of Observational Studies in Epidemiology) [15] released in
154 2007, has been widely used by journals and authors of observational research [29] and has been
155 cited 29,276 times according to Google Scholar as of November 28, 2022[30]. Nonetheless, the
156 reporting of intervention effects across health equity determinants in observational studies is far
157 from ideal. For example, researchers consistently found a lack of integration and reporting of sex
158 and gender in observational studies[31-33]. This gap may be partly because STROBE lacks items
159 tailored for health equity; for example, in describing equity seeking populations, evaluating
160 outcomes across PROGRESS (i.e., place of residence, race/ethnicity/culture/language, gender/sex,
161 religion, education, socioeconomic status, social capital) factors, appraising applicability. As such,
162 it is necessary to develop, endorse, and implement reporting guidelines to improve the reporting
163 of health equity in observational studies [34-36].

164

165 In response to this gap, we established a global, multi-disciplinary team that includes academics,
166 policymakers, participants with lived experience, practitioners, advisors and regular peer reviewers
167 to journals, funder, and other knowledge users[37] across a range of disciplines including
168 Indigenous health, knowledge translation, equity, social science, epidemiology, biostatistics, and
169 other health sciences. We aim to develop the STROBE_Equity extension to encourage transparent,
170 concise and comprehensive reporting of health equity in observational studies [38]. As described
171 in a previous study[17], the team formulated an interim checklist of 36 candidate items by

172 reviewing existing checklists related to equity such as the CONSORT (Consolidated Standards of
173 Reporting Trials)-Equity, the SAGER (Sex and Gender Equity in Research) reporting guidelines
174 and the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses)-Equity,
175 and convened a citizen panel (HE, JT, RG) with lived experience of health inequities to seek their
176 feedback. The interim checklist could be found in the **Supplemental Table B1** [17].

177

178 This scoping review aims to describe the extent to which the available guidance on reporting of
179 health equity in research supports our candidate items (interim guidance) and to identify new items
180 that could be used for the STROBE-Equity extension guideline.

181

182 **2. Methods and analysis**

183 **2.1 Protocol and registration**

184 We set up a governance structure of an executive team of four principal investigators (PIs) (VW,
185 LM, JJ, SF) and a lead for each of three steering committees (Indigenous, Knowledge user and
186 Patient/Public) and a Technical Oversight committee to ensure all the team members participated
187 in an integrated knowledge translation process to develop the protocol of this review. The steering
188 committees and Technical Oversight committee are consulted for input on design and delivery of
189 all the relevant studies under the STROBE_equity project, and for feedback on the research results.

190 The executive team meets monthly with a research coordinator and leaders of the studies to consult
191 on study methods and issues arising during the conduct. The executive team, the Technical
192 Oversight Committee and the steering committees meets quarterly by video conference for project
193 updating and consultation as needed [39]. Following the JBI method [40], we conducted this study

194 in adherence with a peer reviewed protocol published in BMJ Open [41] and reported according
195 to the PRISMA reporting guideline for Scoping Reviews[42].

196

197 **2.2 Eligibility criteria**

198 We included the following types of resources: 1) guidance related to conduct or reporting for any
199 type of research on, with or about people experiencing health inequity; 2) methodology reviews
200 assessing reporting of equity-related issues of research; 3) summary reports of recommendations
201 on reporting for equity issues in research; and 4) relevant guidance from ethics boards, funders
202 and journal policies on the conduct or reporting of research related to health equity. We excluded
203 resources without recommendation (a statement explaining why specific information is important
204 or recommending reporting specific information in research of health) related to health equity
205 reporting. There was no restriction on language of the publication. As described in the protocol,
206 we decided to conduct two scoping reviews (one for Indigenous and one for ‘global’ stream) based
207 on the available data and consultation with Indigenous researchers [39, 41]. Here we only included
208 resources that considered non-indigenous populations; resources tailored for research with
209 Indigenous Peoples were designated to the scoping review led by Miranda Lesperance, Sarah
210 Funnell and Andrea Martel to avoid double use. The results of the two scoping reviews will be
211 used together to inform the global and Indigenous STROBE-equity reporting guideline [39].
212 Indigenous Peoples was defined as “... distinct social and cultural groups that share collective
213 ancestral ties to the lands and natural resources where they live, occupy or from which they have
214 been displaced.”[43]

215

216 Although there are unique aspects on reporting health equity information in observational studies,
217 we did not restrict the focus to observational studies since guidance for other types of studies, such
218 as randomized clinical trials (RCTs), could also provide important and relevant information that
219 is shared by observational studies. For example, even though the CONSORT equity reporting
220 guideline is focused on RCTs, it has some items that are relevant for observational studies [17, 36].

221

222 **2.3 Search strategy**

223 We searched for both peer and non-peer reviewed published guidance on the reporting and conduct
224 of health equity-related research. The search was conducted in MEDLINE via OVID, LILACS via
225 BIREME–PAHO–WHO Latin American and Caribbean Centre on Health Sciences Information
226 (<http://lilacs.bvsalud.org/en/>), the Cochrane Methodology Register (Wiley), Embase via OVID,
227 and CINAHL via EbscoHost in January 2022. A full search strategy was developed in MEDLINE
228 using the following concepts: (1) health equity (using PROGRESS-Plus [44] characteristics); (2)
229 reporting, analysis and design of research; and (3) guidelines or guidance articles. We assessed
230 relevance of the search results through testing with a set of 11 target articles and modified the
231 search until all these were identified. Searches were limited to records published in 2005 and later
232 considering that: 1) we are interested in recent guidance and conceptualizations of health equity in
233 research; and 2) the establishment of the Commission on Social Determinants of Health by the
234 WHO was in 2005. No language limit or study design limit was applied. Search strategies are
235 presented in **Supplementary Table B2**. Searches were designed and conducted by a librarian (TR)
236 experienced in systematic reviews, using a method designed to optimize term selection[45]. After
237 identifying eligible full texts from databases, we checked the reference lists for additional eligible
238 studies or documents.

239
240 We classified grey literature into five categories and searched for guidance within each: journal
241 guidance from Journal Citation Reports[46], publisher policies from the Joint commitment for
242 action[47], ethics guidance from the International Compilation of Human Research Standards[48],
243 generic research guidance from funding agencies[49], and reporting guidance from interest groups
244 across PROGRESS-Plus factors in consultation with the technical committees. We sampled
245 randomly from these five categories in intervals of 20 documents at a time, stratified by country
246 income setting (i.e., high-income countries (HICs), middle-income countries and low-income
247 countries (LIMCs) as defined by the World Bank to get more representative information from the
248 entire research world (<https://data.worldbank.org/country/XD>). We decided the information as
249 saturation if no new recommendation was found per category of the grey literature, and we stopped
250 searching further in this case. Detailed methods and results of grey literature are presented in
251 **Supplementary Table B3.**

252

253 **2.4 Study selection process**

254 Search results from databases were imported into Covidence (<https://www.covidence.org/>). Pairs
255 of reviewers (PD, JH, RD, OD, AR) screened titles and abstracts and full texts in duplicate and
256 independently. All disagreements were resolved through team discussions.

257

258 **2.5 Data items and extraction**

259 In this scoping review, we developed the data extraction form based on the interim
260 STROBE_Equity guidance and the 36 candidate items[17] using Microsoft Excel 2022 (Version
261 16.58). We tested the form three times with 2-3 included resources each time and modified as

262 required based on feedback from the team. We considered the different publication types and scope
263 of the studies (e.g. we tested our form with reports of different study designs). After three rounds
264 of pilot-testing, we started the formal data abstraction.

265

266 Pairs of reviewers (XW, JH, PD, RD, OD, EG) extracted data for each included study
267 independently and discussed for consensus. A third reviewer (VW) was consulted for a final
268 decision where necessary. All extractions were verified as an additional data cleaning step (XW).
269 We collected characteristics on the source, type of organization, scope of the document (e.g.,
270 population, setting, and type of study design), and methods of development. The extraction form
271 can be found in **Supplementary Appendix A**.

272

273 For judgments on whether or not the guidance supports the preliminary STROBE_Equity
274 extension items, we selected from options “support (i.e., suggest reporting)” or “nothing relevant”.
275 We also collected the supporting verbatim text and captured any potential new items as free text
276 with verbatim quotes from the source document.

277

278

279 **2.6 Methodological quality appraisal**

280 Consistent with the JBI guidance on scoping review conduct, we did not appraise methodological
281 quality or risk of bias of the included studies[50].

282

283 **2.7 Data analysis and presentation of the evidence**

284 We used the principles of framework synthesis to analyse the data[51]. First, we mapped the
285 recommendations to the preliminary STROBE_Equity checklist of 36 candidate items as our *a*
286 *priori* framework. Online meetings among team members (XW, OD, EG, VW, RD, JH, PD) were
287 held to evaluate the support for each item of the interim checklist and identify any new items. For
288 recommendations that did not match the items in the checklist, we applied an inductive thematic
289 analysis to develop new items or categories as needed[52]. We also assessed the new items for
290 overlapping concepts then combined and drafted wording based on the existing guidance. The
291 wording of the candidate items was then clarified as necessary and finalized with the writing team
292 and the wider STROBE_Equity team.

293

294 Data synthesis included: 1) descriptive quantitative analysis (frequencies and proportions) of the
295 characteristics for included resources and the supporting recommendations for the preliminary
296 STROBE_Equity checklist of candidate items; and 2) qualitative analysis (i.e., content analysis)
297 of supporting recommendations for each candidate or new item.

298 We presented the results as a map of the extracted data in tabular form based on the *a priori*
299 framework according to the STROBE structure (e.g., introduction, methods, results, discussion).

300 The unit used when counting the number of sources was the study; thus, if a study was published
301 in more than one report, the reports associated with the study were collectively counted as a single
302 source. For example, the GRADE equity guidelines were published as a series of four reports: the
303 first provided a preamble and rationale, and the other three focused on guidance for health
304 guideline developers [53-56].

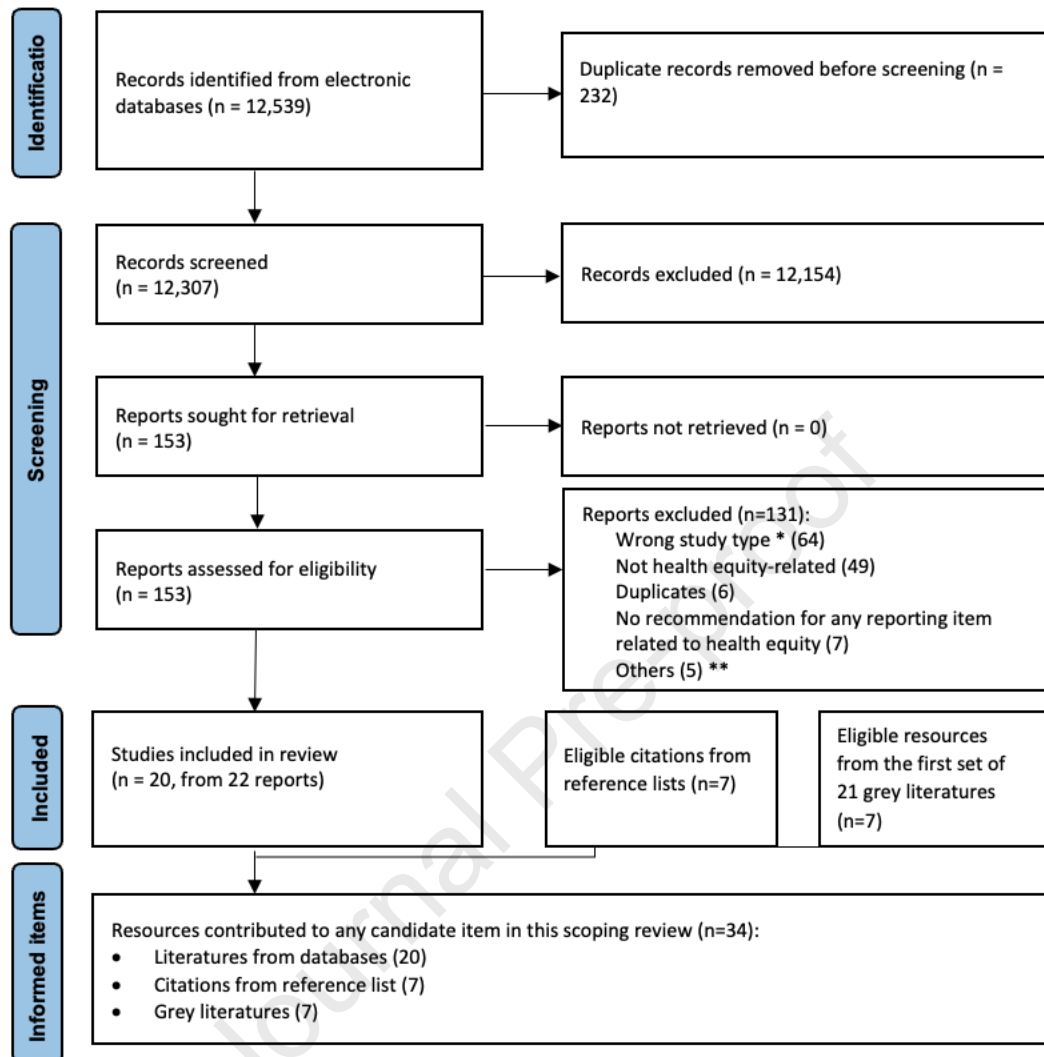
305

306 **3. Results**

307 **3.1 Literature search**

308 The electronic database literature search resulted in 12,539 records (**Figure 1**). We retained 153
309 relevant full-text papers after title and abstract screening. After reviewing the full texts, we found
310 20 eligible studies from academic databases. In addition, we identified seven eligible citations
311 through screening reference lists of included studies and seven eligible resources from the first set
312 of 21 grey literatures. In total, we included 34 eligible resources supporting at least one candidate
313 item or suggested a new item (**Supplementary Table B4**). **Supplementary Table B5** presented
314 the 33 excluded reports that met all the other criteria but did not make recommendations related to
315 reporting health equity.

316



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Note

* “Wrong study type” was applied to any report that did not provide guidance on reporting equity in research (e.g., clinical practice guideline)

** One was the interim Guidelines for Reporting Health Equity in Observational Studies [17], which was part of this STROBE_Equity project; Four studies [57-60] about Indigenous Peoples were separated out for the parallel scoping review led by the Indigenous steering committee.

Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow

diagram

Characteristics of included resources that informed any candidate item or new item

329 Of the 34 included resources, the majority of those informing candidate items were journal articles
 330 ($n = 24$, 71%). Other resources included documents or webpages from research ethics guidance,
 331 government, journal editor and non-governmental organizations. The types of resources included
 332 varied but were primarily methodology guidelines (11, 32%), reporting guidelines (7, 21%) and
 333 research ethics guidance (7, 21%). Of the 17 methodology and reporting guidelines, only five (15%)
 334 were developed through consensus. All the resources were published in English and 19 (55%)
 335 were published since 2015.

336
 337 **Table 1 General characteristics of included resources that informed any reporting items**
 338 **(N=34)**

Document publisher	<i>N</i> (%)
Academic journal	24(71)
Research ethics guidance	5(15)
Government	3(9)
Journal editor	1(3)
Non-governmental organization	1(3)
Document type	
Methodology guidelines	11(32)
Reporting guidelines	7(21)
Research ethics guidance	7(21)
Methodology review	5(15)
Editorial/commentary	3(9)
Journal instruction	1(3)
Publication year	
2005-2009	6(18)
2010-2014	9(26)
2015-2019	10(29)
2020-2022	9(26)
Demographic focus	
General population	25(74)
Focused on specific population *	9(26)
Clinical area focus	
Non-specific	27(79)

Specific [§]	7(21)
PROGRESS-Plus #	
Gender or Sex	9(26)
Race/ethnicity/culture/language	6(18)
Place of residence	4(12)
Plus: Personal, time-dependent or relationship dependent factors, such as pregnancy, reproductive capacity	1(3)
Broad focus [¥]	17(50)
What study design is this document for	
No statement on scope of study design	16(47)
Any type of primary research	7(21)
Clinical trials	4(12)
Any type of evidence synthesis (e.g., systematic review, scoping review)	4(12)
Observational studies	2(6)
Clinical practice guidelines	1(3)

339 *Including transgender health, underserved population, women aged 45–55, people who live in
340 rural and remote area, and resource poor setting.

341 [§] Including oral health, covid 19, psychiatric Anesthesia, women's health, orthopedics, preventative
342 medicine.

343 [#] Each document could cover more than one factor.

344 [¥] Broad focus means that the focus is on health equity, but not about specific PROGRESS-Plus
345 factor (e.g., CONSORT-Equity)

346

347

3.2 Scope of resources that informed any candidate items or new items

348 Of the 34 resources, 9 (26%) focused on specific populations who may experience health inequity,
349 including transgender individuals [61-63], those in remote/ rural/ underserved/ low-socioeconomic
350 settings [64-67], women and minorities[68], and women aged 45–55 years[69]; 25 (74%) were
351 focused on health equity with no population restriction. Most (27; 79%) of the resources were non-
352 specific to a certain clinical or public health area, while seven (21%) focused on specific clinical
353 or public health areas, including oral health [70], psychiatry [71], COVID-19[72], anesthesia [73],
354 orthopedics [74], preventative medicine [75] and gynecology [69]. Half of the resources had no
355 restriction on PROGRESS-Plus factors; another half focused on one or more specific PROGRESS-
356 Plus factors, where 9 (26%) focused on Gender or Sex[62, 63, 68, 69, 73, 74, 76-78], 6 (18%) on
357 Race/ethnicity/culture/language[68-71, 79, 80], 4 (12%) on Place of residence[64-67] and 1 (3%)

358 on personal, time-dependent or relationship-dependent factors (i.e., menopausal symptoms among
359 women)[69]. (**Table 1**)

360

361 For documents targeting specific study designs, 7 (21%) were for all types of primary research, 4
362 (12%) for any type of evidence synthesis, 4 (12%) for clinical trials and 2 (6%) for observational
363 studies. (**Table 1**) There were two resources focused on observational studies. One included
364 consolidated criteria for reporting qualitative research (COREQ) including interviews and focus
365 groups[81], and the other was the guidelines for strengthening the reporting of menopause and
366 aging (STROMA) in cross-cultural comparisons study[69].

367

368 **3.3 Supporting recommendations**

369 For the 34 resources informing any candidate item, each resource supported a median of five
370 candidate items (range 1-22). For the 36 candidate items, the median number of resources
371 supporting an item were six (range 1 to 15); all candidate items were supported by at least one
372 resource. Six candidate items (one for rationale, four for methods and one for results) were
373 informed by more than 10 resources and 21 were informed by more than five resources. (**Table 2**
374 **and Supplementary Table B6**) Of the candidate items, rationale for focus on health equity in
375 *Background* (15, 44%), involvement of patients or community experiencing health in equity in
376 *Study design* (13, 38%), sampling/recruitment methods designed to reach populations across
377 PROGRESS-Plus characteristics in *Setting* (16, 47%), and details of informed consent and ethical
378 clearance (13, 38%) were the top four items suggested.

379

380 In addition, 11 resources suggested 13 new items. (**Table 2 and Supplementary Table B7**). These
381 items included one for *Title* and suggested using a health equity term; two for *Background* on
382 defining health equity terms and describing the role of racism and discrimination; seven applicable
383 to *Methods*, including topics on reporting the health-equity logic model, composition and training
384 of the researchers considering equity-related factors, reaching people experiencing health inequity,
385 communicating on discontinuation, and describing comparator and technique validation across
386 equity factors; two for *Discussion* on reporting limitations and implications related to health equity;
387 and one for *Data sharing* on reporting the access to raw data across equity.

388

389 **4. Discussion**

390

391 We performed a scoping review of available research guidance and relevant documents across
392 dimensions of health equity from a diverse and comprehensive range of resources to evaluate
393 support for proposed items for a STROBE_Equity extension.

394

395 Our findings show that existing resources for reporting equity in health research are spread across
396 various document types and formats that may be challenging for authors to access and implement
397 in practice. This review provides a contemporary collation of health equity reporting guidance
398 established from a comprehensive review of literature and serves as an important resource for the
399 field.

400

401 All candidate items were supported by at least one resource with more than half being supported
402 by more than five resources; suggesting a good alignment of our proposed framework with the

403 current health research landscape. Of these candidate items, rationale for focus on health equity in
404 *Background*, involvement of patients or community experiencing health inequity in *Study design*,
405 sampling/recruitment methods designed to reach populations across PROGRESS-Plus
406 characteristics in *Setting*, and details of informed consent and ethical clearance were the top four
407 items suggested in the resources we included. Additionally, the 13 new items provided more
408 important information on novel intersections, such as describing the role of racism and
409 discrimination in the experience of health inequity in relation to the problem or intervention,
410 reporting the background and research area of the team members considering relevant experience,
411 and providing information on accessing raw data across equity factors. With all these items
412 suggested, our review provides a comprehensive, evidence-based set of reporting items covering
413 all dimensions of reporting health equity in observational studies, including title, abstract,
414 background, methods, result, discussion and other information (e.g. data sharing).

415
416 We identified two resources designed for observational studies, one for qualitative research
417 including interviews and focus groups[81], the other for guidelines for strengthening the reporting
418 of menopause and aging (STROMA) in cross-cultural comparisons study[69]. Neither of these
419 covers the breadth of reporting of health equity in observational studies from design to
420 interpretation. Further, we did not identify any reporting guidance that covers all important aspects
421 of reporting health equity related information in observational studies. Instead, the research
422 guidance related to health equity was fragmented -- existing resources for reporting equity in
423 research are spread across various document types and formats that may be challenging for authors
424 to access and implement in practice. Such findings underscore the need for comprehensive
425 reporting resource drawing on such guidance.

426
427 Including equity reporting guidance for other study designs gave us a broad view of potential
428 important items. Compared to CONSORT-Equity[36] for clinical trials and PRISMA-Equity[35]
429 for systematic reviews, some of our proposes items are shared across different study designs, such
430 as reporting rationale for focus on health equity, sampling methods designed to reach populations
431 across relevant PROGRESS items, and discussing external validity to populations across relevant
432 PROGRESS-Plus characteristics. Some, however, are unique to observational studies, such as
433 “whether the comparator is considered more advantaged or to have less barriers to health
434 opportunities”. Further, some items are not covered by CONSORT-Equity and PRISMA-Equity,
435 but may also be relevant for those study designs, such as report the research area (e.g. personnel
436 with unique professional and cultural backgrounds on equity related issues) and social location
437 (i.e., gender, race, etc.) of investigators, describe any process to ensure that the research is reaching
438 the people experiencing health inequity, and report the definitions of health equity related terms.

439
440 This review, along with other studies that are part of the larger STROBE Equity project, will be
441 used to inform the development of the Equity extension to the STROBE reporting guideline. We
442 will present and discuss the results with technical committees and circulate the checklist using a
443 global online survey, together with findings from a methodological survey of observational studies
444 [13]. These studies and surveys will be used to reach consensus on a STROBE_Equity extension.
445 The protocol for the overall project is available on Open Science Framework[38].

446

447 **Strengths and limitations**

448 We used the JBI scoping review methodology [50] to map resources on health equity reporting in
449 research from multiple information sources in an attempt to capture guidance produced and used
450 by relevant stakeholders, including from academic journals, journal policies, research ethics
451 boards, publishers, research funding agencies and interest groups. Another strength is that we used
452 multidisciplinary team and multiple knowledge users with defined roles and governance strategy
453 to engage diverse perspectives in designing and study, and analyzing and interpreting the results
454 [41]. One limitation of our approach is that we were not able to review all available guidance from
455 all sources in every setting. Instead, we employed the principle of saturation such that no new
456 items were identified. We also used a structured approach by seeking different sources and
457 balancing between sources (i.e. HICs and LMICs) as well as across PROGRESS-Plus
458 characteristics[82]. This helped to identify evidence for all PROGRESS-Plus elements and from
459 different countries or settings. Another limitation is that the checklist is currently draft for
460 consultation, and some of the items need further elaboration, which are expected to be completed
461 as a justification document for the checklist after consensus and global survey [39]. Two examples
462 will be: 1) the item on reporting a contextual factor used in adjustment needs elaboration on that
463 the adjustment may hide important differences that could inform health policy [83] and authors
464 should transparently report on this if conducted; 2) for effort to avoid selection bias, further
465 elaboration could be used to describe whether selection bias is related to outcomes as particular
466 outcomes may be affected by systemic discrimination.

467 As expected, the included resources varied across publication type, publisher, scope, levels of
468 detail and format, which posed a challenge for comprehensive and consistent data extraction. To
469 ensure accuracy of the data extraction, we did all the data extraction in duplicate, with at least one
470 reviewer experienced in equity research for more than 3 years. Each pair of reviewers discussed

471 the results periodically and any questions were presented and solved in weekly team meetings.
472 Furthermore, a senior reviewer verified every supporting recommendation for each item and all
473 the results presented were based on agreement among the review authors.

474

475 **5. Conclusions**

476 Existing resources for reporting health equity in research are fragmented and only two included
477 resources were focused on any PROGRESS-Plus factors in observational studies. However, we
478 found a strong agreement of the candidate items of our draft checklist with the current research on
479 reporting of health equity. Based on this review, we have supplemented the checklist with an
480 additional 13 items related to use and define health equity terms, describe the role of racism and
481 discrimination, report background and experience of team members, provide information on logic
482 model, describe process used to reach people experiencing health inequity, describe quality of the
483 comparator (e.g. more advantaged or not), describe the validation of measurements across patients
484 with different backgrounds, report limitations and implications relevant to health equity, and state
485 way to access raw data across PROGRESS-plus factors. This comprehensive, evidence-based set
486 of reporting items will inform the development of the STROBE_Equity extension.

487

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504
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513
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Table 2 Number of sources identified supporting each of the 36 candidate items and 13 new items.

Topic	STROBE checklist	Proposed Item for an Equity Focused Extension in Observational Studies	N (%) of resources
Title and abstract			
Title	1a Indicate the study's design with a commonly used term in the title or the abstract	<ul style="list-style-type: none"> If health equity is a major focus, consider using "health equity" or relevant terms in the title. ^{§#} 	2 (6)
Abstract	1b Provide in the abstract an informative and balanced summary of what was done and what was found	<ul style="list-style-type: none"> Describe population according to PROGRESS-Plus 	8 (24)
		<ul style="list-style-type: none"> Describe extent/limits of applicability to populations of interest across PROGRESS-Plus characteristics 	6 (18)
Background/rationale			
	2 Explain the scientific background and rationale for the investigation being reported	<ul style="list-style-type: none"> If equity is a focus, what is the rationale for focus on health equity? [#] 	15 (44)
		<ul style="list-style-type: none"> Describing role of racism, discrimination and exclusion in health inequities across one or more PROGRESS-plus factors in relationship to the research questions. ^{§#} 	1 (3)
	None	<ul style="list-style-type: none"> Report the definitions of health equity related terms. ^{§#} 	1 (3)
Objectives	3. State specific objectives, including any pre specified hypotheses	-	
Method			
Study design	4 Present key elements of study design early in the paper	<ul style="list-style-type: none"> Report who was involved/engaged/consulted with experience in health equity/inequity in study design (e.g. patients, community, industry, government, etc.) [#] 	13 (38)
		<ul style="list-style-type: none"> Report the background and research area (e.g. personnel with unique professional and cultural backgrounds on equity related issue) and social location (i.e., gender, race, etc.) of investigators. [§] 	4 (12)
		<ul style="list-style-type: none"> If applicable, describe whether research staff were selected for or trained with particular skills and experience on working with groups experiencing health inequity (e.g., age inclusion training, disability inclusion training)? ^{§#} 	2 (6)
		<ul style="list-style-type: none"> Report whether a theory of change related to equity was described for the study to design analysis [#] 	1 (3)
		<ul style="list-style-type: none"> If applicable, provide the information or link to the logic model developed which shows how equity is important ^{§#} 	1 (3)

Setting	5 Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	• Report whether methods of sampling/recruitment were designed to reach populations across relevant PROGRESS-Plus characteristics	16 (47)
		• Is there possibility of self-selection bias across PROGRESS-Plus factors?	2 (6)
		• If applicable, describe any process in place to monitor and ensure that the research is reaching the people experiencing health inequity appropriately. ^{.\$#}	1 (3)
		• If applicable, describe how pauses or discontinuation across equity factors were managed as well as how to communicate with participants. ^{.\$#}	1 (3)
Participants	6a. Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	• Give inclusion and exclusion criteria across relevant PROGRESS-Plus characteristics	9 (26)
	Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	• Report context and relationship to health equity. [#]	8 (24)
	Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	• Report details of partnerships with populations and communities, where applicable. [#]	11 (32)
	6b. Cohort study—For matched studies, give matching criteria and number of exposed and unexposed	• Report whether any PROGRESS-Plus factors used for matching, how categories were determined and why	1 (3)
	Case-control study—For matched studies, give matching criteria and the number of controls per case		
	None	• If applicable, describe whether the comparator is considered more advantaged or to have less barriers to health opportunities. ^{.\$#}	1 (3)
Variable	7 Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	• Report whether outcomes were identified as relevant and important to populations across PROGRESS-Plus	10 (29)
		• If applicable, report whether to measure inequity as an outcome. [#]	4 (12)
Data sources/ measurement	8 * For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe	• Report the method of obtaining population characteristics (e.g., age)	7 (21)
		• If applicable, describe whether the techniques, especially those developed as diagnostic or quality of life measures	1 (3)

	comparability of assessment methods if there is more than one group	were validated or operate similarly across participants regardless of patients' background (e.g., ethnic/linguistic). ^{,\$#}	
Bias	9 Describe any efforts to address potential sources of bias	• Report efforts to reduce selection bias across PROGRESS-Plus	6 (18)
		• Report whether dimensions of context might influence the study (e.g., bias in response/participation)	5 (15)
Study size	10 Explain how the study size was arrived at	• Report whether PROGRESS-Plus characteristics of interest were considered in determining the study size	7 (21)
Quantitative variables	11 Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	• Report how decisions were made about analyses related to PROGRESS-Plus, including whether any categories were defined, and how they were decided	9 (26)
		• Report whether dimensions of context were collected for analysis	3 (9)
Ethical concerns	None	• Report details of informed consent and ethical clearance	13 (38)
Statistical methods	12a Describe all statistical methods, including those used to control for confounding	• If PROGRESS-Plus factors used to control for confounding, describe how they were defined and rationale. #	3 (9)
		• Report whether contextual factors were used in adjustment for confounding. #	1 (3)
	12b Describe any methods used to examine subgroups and interactions	• Report details of additional analyses related to health equity if applicable. #	9 (26)
		• Report whether context or systems were explored.	2 (6)
	12c Explain how missing data were addressed	• Explain whether missing data was related to individual or contextual factors associated with health inequities.	2 (6)
Results			
Participants	13a.* Report numbers of individuals at each stage of study—e.g. numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study,	-	
	13b Give reasons for non-participation at each stage	• Describe the losses and exclusions of participants across PROGRESS-Plus.	5 (15)
		• Describe non-response/nonparticipation across PROGRESS-Plus.	2 (6)
	13c.* Consider use of a flow diagram	-	
Descriptive data	14a Give characteristics of study participants (e.g., demographic, clinical,	• Present characteristics across relevant PROGRESS-Plus characteristics.	11 (32)

	social) and information on exposures and potential confounders		
	14b Indicate number of participants with missing data for each variable of interest	<ul style="list-style-type: none"> Describe whether data on PROGRESS-Plus factors are missing (e.g., ethnicity data in some settings has a high level of missingness). 	3 (9)
	14c.* Cohort study—Summaries follow-up time (e.g., average and total amount)	-	
Data	15.* Cohort study—Report numbers of outcome events or summary measures over time	-	
	Case-control study—Report numbers in each exposure category, or summary measures of exposure		
	Cross-sectional study—Report numbers of outcome events or summary measures		
Main result	16a Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included	<ul style="list-style-type: none"> Report if confounders were defined for contextual or PROGRESS-Plus factors that are associated with health inequities 	2 (6)
		<ul style="list-style-type: none"> Justify why certain categories of PROGRESS-Plus are not disaggregated for analysis 	2 (6)
	16b. Report category boundaries when continuous variables were categorized	-	
	16c. If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-	
Other analysis	17 Report other analyses done (e.g. analyses of subgroups and interactions, and sensitivity analyses)	<ul style="list-style-type: none"> Report other analyses to address health equity questions, if the study had objectives related to health equity.[#] 	6 (18)
Discussion			
Key results	18. Summaries key results with reference to study objectives	-	
Limitations	19. Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	<ul style="list-style-type: none"> Report any limitations related to assessing effects on health equity.^{S#} 	3 (9)

Interpretation	20 Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	<ul style="list-style-type: none"> Consider importance of context in interpretation of health equity. # 	7 (21)
Generalizability	21 Discuss the generalisability (external validity) of the study results	<ul style="list-style-type: none"> Discuss external validity to populations across relevant PROGRESS-Plus characteristics, considering issues of possible self-selection, healthy volunteer bias, losses across PROGRESS-Plus 	6 (18)
		<ul style="list-style-type: none"> Consider implications of exclusion of people across PROGRESS as well as differential participation and/or loss to follow-up 	3 (9)
		<ul style="list-style-type: none"> Consider context in discussion of generalizability 	9 (26)
Implications for research [§]	None	<ul style="list-style-type: none"> Provide implications for research, practice or policy related to health equity where relevant (e.g., types of research needed to address unanswered questions). ^{§#} 	1 (3)
Other information			
Funding	22. Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based		
Data sharing [§]	None	<ul style="list-style-type: none"> Describe where the raw data across PROGRESS-plus factors could be accessed. [§] 	1 (3)
<p>*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies. [§] New items suggested based on resources identified in this review. [#] Some items are more generic for all observational studies, while some (with #) maybe more specific to observational studies related to health equity.</p>			

Highlights

- All candidate items proposed to extend STROBE (Strengthening Reporting of Observational studies in Epidemiology) for equity were supported by at least one resource.
- We identified 13 additional items related to defining health equity terms; these described the role of racism and discrimination, composition and training of the researcher(s), considering relevant factors in the study methods, and data sharing specific to and across equity factors.
- These items will be used for the consensus process to develop a research reporting guideline on health equity to extend STROBE.

Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Vivian A Welch reports financial support was provided by Canadian Institutes of Health Research. Luis Gabriel Cuervo is an official of the Pan American Health Organization, but the views expressed in this publication are his sole responsibility and do not necessarily represent the decisions or policies of the Pan American Health Organization (PAHO/WHO).

Author statement

XW, OD, AR, LM, and VW conceptualised this review. TR conducted the literature search. XW, OD, MM, AR, JH, PD, RJD, and EG screened the references and extracted the data. XW analyzed the data and drafted the manuscript. OD, AR, EG, TR, SGN, AA, BS, BJH, CC, CSW, CF, DOL, EAO, EK, EE, HW, HE, CJP, HSW, JR, JGR, JJ, JT, JL, LM, LW, LLN, LGC, LW, MK, MTA, MKS, MJM, MN, OM, PC, PT, SF, SGN, TK, TH, TY, TP, ZB, AM and VW revised the manuscript. All authors reviewed and edited the manuscript and approved the final draft. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.