

1 Reporting Guidelines for Health Care Simulation Research:
2 Extensions to the CONSORT and STROBE Statements
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4 Cheng A¹, Kessler D², Mackinnon R³, Chang T⁴, Nadkarni V⁵, Hunt EA⁶, Duval-Arnauld J⁶, Lin Y⁷, Cook
5 DA⁸, Pusic M⁹, Hui J¹⁰, Moher D¹¹, Egger M¹², Auerbach M¹³ for the International Network for
6 Simulation-based Pediatric Innovation, Research and Education (INSPIRE) Reporting Guidelines
7 Investigators*
8

9 **Corresponding Author:**

10
11 ¹Adam Cheng, MD, FRCPC
12 Associate Professor, University of Calgary
13 KidSim-ASPIRE Research Program, Division of Emergency Medicine
14 Department of Pediatrics, Alberta Children's Hospital
15 2888 Shaganappi Trail NW
16 Calgary, Alberta, Canada T3B 6A8
17

18 Email: chenger@me.com
19 Phone : 403 955 2633
20 Fax : 403 955 7552 (attention – Keely Piscopo)
21

22 **Authors:**

23
24 ²David Kessler, MD, MSc
25 Columbia University College of Physicians and Surgeons
26 Email: dk2592@cumc.columbia.edu
27

28 ³Ralph Mackinnon, BSc, MBChB, FRCA
29 Royal Manchester Children's Hospital
30 Central Manchester University Hospitals NHS Foundation Trust
31 Email: ralph.mackinnon@cmft.nhs.uk
32

33 ⁴Todd P Chang, MD, MAcM
34 Children's Hospital Los Angeles, University of Southern California
35 Email: dr.toddchang@gmail.com
36

37 ⁵Vinay M. Nadkarni MD
38 The Children's Hospital of Philadelphia,
39 University of Pennsylvania Perelman School of Medicine
40 Email: nadkarni@email.chop.edu
41

42 ⁶Elizabeth A. Hunt, MD, MPH, PhD, Jordan Duval-Arnauld, MPH, CPH, DrPH[c]
43 Johns Hopkins University School of Medicine
44 Email: ehunt@jhmi.edu; jordan@jhu.edu
45

46 ⁷Yiqun Lin MD, MHSc
47 Alberta Children's Hospital,
48 Cumming School of Medicine, University of Calgary
49 Email: jeffylin@hotmail.com
50

51 ⁸David A. Cook, MD, MHPE
52 Multidisciplinary Simulation Center, Mayo Clinic Online Learning, and Division of General Internal
53 Medicine
54 Mayo Clinic College of Medicine
55 Email: cook.david33@mayo.edu
56

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108
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111

⁹Martin Pusic MD, PhD
Institute for Innovations in Medical Education, Division of Education Quality & Analytics,
NYU School of Medicine
Email: martin.pusic@nyumc.org

¹⁰Joshua Hui, MD, MSc
Department of Emergency Medicine,
David Geffen School of Medicine at UCLA
Email: joshhui@gmail.com

¹¹David Moher, PhD
Ottawa Methods Centre, Clinical Epidemiology Program,
Ottawa Hospital Research Institute
Email: dmoher@ohri.ca

¹²Matthias Egger MD, MSc
Institute of Social and Preventive Medicine
University of Bern
matthias.egger@ispm.unibe.ch

¹³Marc Auerbach, MD, MSc
Department of Pediatrics, Section of Emergency Medicine,
Yale University School of Medicine
Email: dr.auerbach@gmail.com

*INSPIRE Network Reporting Guideline Working Group: Dylan Bould, MBChB, MRCP, FRCA, Med,
University of Ottawa, dylanbould@gmail.com; Ryan Brydges, PhD, University of Toronto,
r.brydges@gmail.com; Michael Devita, MD, FCCM, FACP, Harlem Hospital Center,
mdevita06@gmail.com; Jonathan Duff, MD, MEd, University of Alberta,
jon.duff@albertahealthservices.ca; Sandeep Gangadharan, MD, Hofstra University School of Medicine,
gangadsa@gmail.com; Sharon Griswold-Theodorson, MD, MPH, Drexel University College of Medicine,
Sharon.griswold-theodorson@drexelmed.edu; Pam Jeffries, PhD, RN, FAAN, ANEF, George Washington
University, pjeffries@gwu.edu; Lindsay Johnston, MD, Yale University School of Medicine,
Johnston.lindsayc@gmail.com; Suzan Kardong-Edgren, PhD, RN, ANEF, CHSE, Robert Morris
University, kardongedgren@rmu.edu; Arielle Levy, MD, MEd, University of Montreal,
arielle.levy007@gmail.com; Lori Lioce, DNP, FNP-BC, CHSE, FAANP, The University of Alabama in
Huntsville, liocceb@uah.edu; Marco Luchetti, MD, MSc, A. Manzoni General Hospital,
m.luchetti@fastwebnet.it; Tensing Maa, MD, Ohio State University College of Medicine,
tensing.maa@nationwidechildrens.org; William McGaghie, PhD, Northwestern University Feinberg
School of Medicine, wmcgaghie@luc.edu; Taylor Sawyer, DO, MEd, University of Washington School of
Medicine, tlsawyer@uw.edu; Dimitrios Stefanidis, MD, PhD, FACS, Carolinas HealthCare System,
dimitrios.stefanidis@carolinashelathcare.org; Kathleen Ventre, MD, Children's Hospital Colorado,
Kathleen.ventre@ucdenver.edu; Barbara Walsh, MD, University of Massachusetts School of Medicine,
bwalshmd1@gmail.com; Mark Adler, MD, Feinberg School of Medicine, Northwestern University, m-adler@northwestern.edu; Linda Brown, MD, MSCE, Alpert Medical School of Brown University,
lbrown8@lifespan.org; Aaron Calhoun, MD, University of Louisville, aaron.calhoun@louisville.edu;
Aaron Donoghue, MD, MSCE, The Children's Hospital of Philadelphia, Donoghue@email.chop.edu; Tim
Draycott, MD, FRCOG, Southmead Hospital, tdraycott@me.com; Walter Eppich, MD, MEd, Feinberg
School of Medicine, Northwestern University, weppich@gmail.com; Marcie Gawel, MSN, BSN, MS, Yale
University, Marcie.gawel@yale.edu; Stefan Gisin, MD, University Hospital Basel, Stefan.gisin@usb.ch;
Lou Halamek, MD, Stanford University, halamek@stanford.edu; Rose Hatala, MD, MSc, University of
British Columbia, rhatala@mac.com; Kim Leighton, PhD, RN, ANEF, DeVry Medical International's
Institute for Research and Clinical Strategy, kleichton@devrygroup.com; Debra Nestel, PhD, Monash
University, debra.nestel@monash.edu; Mary Patterson, MD, MEd, Cincinnati Children's Hospital,
marydpatterson84@gmail.com; Jennifer Reid, MD, University of Washington School of Medicine,

112 Jennifer.reid@seattlechildrens.org; Elizabeth Sinz, MD, FCCM, Penn State University College of
113 Medicine, esinz@psu.edu; G. Ulufer Sivrikaya, MD, Antalya Training and Research Hospital,
114 ulufers@gmail.com; Kimberly Stone, MD, MS, MA, University of Washington School of Medicine,
115 Kimberly.stone@seattlechildrens.org; Anne Marie Monachino, MSN, RN, CPN, Children's Hospital of
116 Philadelphia, monachino@email.chop.edu; Michaela Kolbe, PhD, University Hospital Zurich,
117 mkolbe@ethz.ch; Vincent Grant, MD, FRCPC, University of Calgary,
118 Vincent.grant@albertahealthservices.ca; Jack Boulet, PhD, Foundation for Advancement of International
119 Medical Education and Research, jboulet@faimer.org; David Gaba, MD, Stanford University School of
120 Medicine, gaba@stanford.edu; Peter Dieckmann, PhD, Dipl-Psych, Danish Institute for Medical
121 Simulation, mail@peter-dieckmann.de; Jeffrey Groom, PhD, CRNA, Florida International University,
122 groomj@flu.edu; Chris Kennedy, MD, University of Missouri Kansas City School of Medicine,
123 ckennedy@cmh.edu; Ralf Krage, MD, DEAA, VU University Medical Center, r.krage@vumc.nl; Leah
124 Mallory, MD, The Barbara Bush Children's Hospital at Maine Medical Center, mallol@mmc.org; Akira
125 Nishisaki, MD, MSCE, The Children's Hospital of Philadelphia, nishisaki@email.chop.edu; Denis Oriot,
126 MD, PhD, University Hospital of Poitiers, denis.oriot@gmail.com; Christine Park, MD, Feinberg School of
127 Medicine, Northwestern University, csparkmd@gmail.com; Marcus Rall, MD, InPASS Institute for Patient
128 Safety and Teamtraining, marcus.rall@inpass.de; Nick Sevdalis, PhD, King's College London,
129 n.sevdalis@kcl.ac.uk; Nancy Tofil, MD, MEd, University of Alabama at Birmingham,
130 ntofil@peds.uab.edu; Debra Weiner, MD, PhD, Boston Children's Hospital,
131 debra.weiner@childrens.harvard.edu; John Zhong, MD, University of Texas Southwestern Medical Center,
132 john.zhong@childrens.com; Donna Moro-Sutherland, MD, Baylor College of Medicine,
133 donnamsutherland@gmail.com; Dalit Eyal, DO, St. Christopher's Hospital for Children,
134 dalit.eyal@drexelmed.edu; Sujatha Thyagarajan, DCH, FRCPC, PediSTARS India, sujadoc@gmail.com;
135 Barbara Ferdman, MD, University of Rochester Medical Center, brferdman@gmail.com; Grace Arteaga,
136 MD, FAAP, Mayo Clinic (Rochester), arteaga.grace@mayo.edu; Tonya Thompson, MD, MA, The
137 University of Arkansas for Medical Sciences, thompsonTonyam@uams.edu; Kim Rutherford, MD, St.
138 Christopher's Hospital for Children, kim.rutherford@drexelmed.edu; Frank Overly, MD, Alpert Medical
139 School of Brown University, foverly@lifespan.org; Jim Gerard, MD, Saint Louis University School of
140 Medicine, gerardjm@slu.edu; Takanari Ikeyama, MD, Aichi Children's Helath and Medical Center,
141 taqary@gmail.com; Angela Wratney, MD, MHSc, Children's National Medical Center,
142 awratney@cnmc.org; Travis Whitfill, MPH, Yale University School of Medicine, travis.whitfill@yale.edu;
143 Nnenna Chime, MD, MPH, Albert Einstein College of Medicine, nnenna_chime@yahoo.com; John Rice,
144 PhD(c), US Department of the Navy (retired), john.rice@noboxes.org; Tobias Everett, MBChB, FRCA,
145 The Hospital for Sick Children, tobias.everett@sickkids.ca; Wendy Van Ittersum, MD, Akron Children's
146 Hospital, wenvan@gmail.com; Daniel Scherzer, MD, Nationwide Children's Hospital,
147 Daniel.scherzer@nationwidechildrens.org; Elsa Vazquez Melendez, MD, FAAP, FACP, University of
148 Illinois College of Medicine at Peoria, eluciav@uic.edu; Chris Kennedy, MD, University of Missouri
149 Kansas School of Medicine, ckennedy@cmh.edu; Waseem Ostwani, MD, University of Michigan Health
150 System, waseem@med.umich.edu; Zia Bismilla, MD, MEd, The Hospital for Sick Children,
151 zia.bismilla@sickkids.ca; Pavan Zaveri, MD, MEd, Children's National Health System,
152 pzaveri@childrensnational.org; Anthony Scalzo, MD, FACMT, FAAP, FAACT, Saint Louis University
153 School of Medicine, scalzoaj@slu.edu; Daniel Lemke, MD, Baylor College of Medicine,
154 dslemke@texaschildrens.org; Cara Doughty, MD, MEd, Baylor College of Medicine,
155 cbdought@texaschildrens.org; Modupe Awonuga, MD, MPH, MRCP(UK), FRCPC, FAAP, Michigan
156 State University, awonuga@msu.edu; Karambir Singh, MD, Johns Hopkins University School of Medicine,
157 ksingh14@jhu.edu; Melinda Fiedor-Hamilton, MD, MSc, Children's Hospital of Pittsburgh,
158 fiedml@ccm.upmc.edu

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167 **Abstract**

168 **Introduction:** Simulation-based research is rapidly expanding but the quality of reporting needs
169 improvement. For a reader to critically assess a study, the elements of the study need to be clearly
170 reported. Our objective was to develop reporting guidelines for simulation-based research by creating
171 extensions to the CONSORT (Consolidated Standards of Reporting Trials) and STROBE (Strengthening
172 the Reporting of Observational Studies in Epidemiology) Statements.

173 **Methods:** An iterative multi-step consensus-building process was used based on the recommended steps
174 for developing reporting guidelines. The consensus process involved: (1) Developing a steering
175 committee; (2) Defining the scope of the reporting guidelines; (3) Identifying a consensus panel; (4)
176 Generating a list of items for discussion via online pre-meeting survey; (5) Conducting a consensus
177 meeting; and (6) Drafting reporting guidelines with an explanation and elaboration document.

178 **Results:** Eleven extensions were recommended for CONSORT: item 1 (title/abstract), item 2
179 (background), item 5 (interventions), item 6 (outcomes), item 11 (blinding), item 12 (statistical methods),
180 item 15 (baseline data), item 17 (outcomes/estimation), item 20 (limitations), item 21 (generalizability), and
181 item 25 (funding). Ten extensions were drafted for STROBE: item 1 (title/abstract), item 2
182 (background/rationale), item 7 (variables), item 8 (data sources/measurement), item 12 (statistical
183 methods), item 14 (descriptive data), item 16 (main results), item 19 (limitations), item 21
184 (generalizability), and item 22 (funding). An elaboration document was created to provide examples and
185 explanation for each extension.

186 **Conclusions:** We have developed extensions for the CONSORT and STROBE Statements that can help to
187 improve the quality of reporting for simulation-based research.

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189

190 **Introduction**

191 Simulation has seen growing use in health care as a “tool, device and/or environment (that)
192 mimics an aspect of clinical care”¹ in order to improve health care provider performance, health care
193 processes, and ultimately, patient outcomes¹⁻⁵. The use of simulation in health care has been accompanied
194 by an expanding body of simulation-based research (SBR) addressing both educational and clinical issues⁶⁻
195 ¹⁵. Broadly speaking, SBR can be broken down into two categories: (1) research addressing the efficacy of
196 simulation as a training methodology (ie. simulation-based education as the subject of research); and (2)
197 research using simulation as an investigative methodology (ie. simulation as the environment for
198 research)^{16,17}. Many features of SBR overlap with traditional clinical or educational research. However,
199 the use of simulation in research introduces a unique set of features that must be considered when designing
200 the methodology, and reported when publishing the study¹⁶⁻¹⁹.

201 As has been shown in other fields of medicine²⁰, the quality of reporting in health professions
202 education research is inconsistent and sometimes poor^{1,11,21-23}. Systematic reviews in medical education
203 have quantitatively documented missing elements in the abstracts and main texts of published reports, with
204 particular deficits in the reporting of study design, definitions of independent and dependent variables, and
205 study limitations²¹⁻²³. In research specific to simulation for health care professions education, a systematic
206 review noted many studies failing to “clearly describe the context, instructional design or outcomes”¹.
207 Another study found that only 3% of studies incorporating debriefing in simulation education reported all
208 the essential characteristics of debriefing¹¹. Failure to adequately describe the key elements of a research
209 study impairs the efforts of editors, reviewers, and readers to critically appraise strengths and
210 weaknesses^{24,25} or apply and replicate findings²⁶. As such, incomplete reporting represents a limiting factor
211 in the advancement of the field of simulation in health care.

212 Recognition of this problem in clinical research has led to the development of a growing number
213 of reporting guidelines in medicine and other fields, including the Consolidated Standards of Reporting
214 Trials (CONSORT) Statement for randomized trials²⁷⁻³⁰, the Strengthening the Reporting of Observational
215 Studies in Epidemiology (STROBE) Statement for observational studies^{31,32}, and the Preferred Reporting
216 Items for Systematic Review and Meta-Analyses (PRISMA) Statement³³⁻³⁵, amongst more than 250
217 others³⁶. Transparent reporting of research allows readers to clearly identify and understand “what was

218 planned, what was done, what was found, and what conclusions were drawn³¹. In addition to these
219 statements, experts have encouraged³⁷ and published extensions to existing statements that focus on
220 specific methodological approaches^{38,39} or clinical fields^{40,41}. In this study, we aimed to develop reporting
221 guidelines for SBR by creating extensions to the CONSORT Statement and the STROBE Statement
222 specific to the use of simulation in health care research. These reporting guidelines are meant to be used by
223 authors submitting manuscripts involving SBR, and to assist editors and journal reviewers when assessing
224 the suitability of simulation-based studies for publication.

225

226 **Methods**

227 The study protocol was reviewed by the Yale University Biomedical Institutional Review Board
228 and was granted exempt status. We conducted a multi-step consensus process based on previously
229 described steps for developing health research reporting guidelines⁴². These steps involved: (1) Developing
230 a steering committee; (2) Defining the scope of the reporting guidelines; (3) Identifying a consensus panel;
231 (4) Generating a list of items for discussion; (5) Conducting a consensus meeting; and (6) Drafting
232 reporting guidelines and an explanation and elaboration document.

233

234 ***Development of the Steering Committee***

235 A steering committee was formed consisting of 12 members with expertise in simulation-based
236 education and research, medical education research, study design, statistics, epidemiology, and clinical
237 medicine. The steering committee defined the scope of the reporting guidelines, identified participants for
238 the consensus process, generated a pre-meeting survey, planned and conducted the consensus meeting and
239 ultimately, drafted and refined the final version of the reporting guidelines and the explanation and
240 elaboration document.

241

242 ***Defining the Scope of the Reporting Guidelines***

243 To clarify the scope of the reporting guideline extensions, we defined simulation as encompassing
244 a diverse range of products including computer-based virtual reality simulators, high fidelity and static
245 mannequins, plastic models and task trainers, live animals, inert animal products, human cadavers, and

246 standardized or simulated patients (ie. individuals trained to portray a patient). Our definition excluded
247 research using computational simulation and mathematical modeling, as the guidelines were developed for
248 research using human participants, either as learners or health care providers¹. The steering committee
249 determined to create reporting guidelines encompassing two categories of SBR: (1) studies evaluating
250 simulation for educational use; and (2) studies using simulation as investigative methodology¹⁶. We
251 identified the CONSORT²⁸ and STROBE^{31,32} statements as reflecting the current reporting standards in
252 health care research and aimed to develop extensions of these two statements for quantitative simulation-
253 based research. The CONSORT Statement and extensions were developed for randomized trials, and the
254 STROBE Statement and extensions were developed for observational studies (cohort, case-control, and
255 cross-sectional study designs). Our guideline extensions are not intended for qualitative research, mixed-
256 methods research or for validation studies.

257

258 ***Identification of Consensus Panel Participants***

259 The steering committee aimed to identify a consensus group with a broad range of expertise in
260 SBR, including experience in conducting single and multicenter simulation-based studies, expertise in
261 educational research, statistics, clinical epidemiology, and research methodology, and with varying clinical
262 backgrounds. We invited the Editor-in-Chief and editorial board members of three health care simulation
263 journals: *Simulation in Healthcare*, *BMJ Simulation and Technology-Enhanced Learning*, and *Clinical*
264 *Simulation in Nursing*, and editorial board members from two medical education journals: *Medical*
265 *Education* and *Advances in Health Sciences Education*. In total, 60 expert participants were invited to
266 complete the online survey.

267

268 ***Generating a List of Items for Discussion***

269 Prior to the consensus meeting, we surveyed the expert participants via a pre-meeting survey
270 (www.surveymonkey.com) to identify items in the CONSORT and STROBE Statements that required an
271 extension for SBR. The survey included all items from both the CONSORT and STROBE Statements, and
272 was pilot tested amongst steering committee members before being posted online. Participants were asked
273 to provide suggested wording for the items they identified as requiring an extension. Participants were also

274 given the option of suggesting new simulation-specific items for both the CONSORT and STROBE
275 Statements. Based on methods previously used to develop extensions to the CONSORT Statement⁴⁰, we
276 used a cutoff of endorsement by at least 1/3 of respondents to identify high priority items for discussion
277 during the consensus meeting.

278

279 *Consensus Meeting*

280 A five-hour consensus conference was conducted January 2015 in New Orleans, USA during the
281 annual International Network for Simulation-based Pediatric Innovation, Research and Education
282 (INSPIRE) meeting. The initial 60 consensus panel participants were invited to attend the consensus
283 conference as well as INSPIRE network members (i.e. clinicians, researchers, educators, psychologists,
284 statisticians and epidemiologists). The INSPIRE network is the world's largest health care simulation
285 research network with a proven track record of conducting rigorous simulation-based studies in health
286 care⁴³⁻⁵⁰.

287 The results of the online survey were circulated to each member of the steering committee, who
288 was then assigned to review specific items from the CONSORT and STROBE statements based on their
289 expertise. The consensus meeting started with a brief didactic presentation reviewing the CONSORT and
290 STROBE Statements, followed by a description of the study objectives and consensus process. In small
291 groups, each steering committee member led a discussion with 4 or 5 individuals tasked with determining if
292 a simulation-specific extension was required for their assigned items, and if so, to recommend wording for
293 the extension. Consensus panel participants were evenly distributed amongst small groups and specifically
294 assigned to review items based on their area of expertise. High priority items were discussed at length, but
295 all other checklist items were also discussed in the small groups.

296 Following small group discussion, the recommended simulation-specific extensions for both the
297 CONSORT and STROBE Statements were presented to the entire group of participants. Each proposed
298 extension was discussed before recommended wording was established. Minutes from the small and large
299 group discussions were used to inform the development of the explanation and elaboration document⁴².

300

301 *Drafting Reporting Guidelines*

302 The proposed extensions were circulated for comment amongst all meeting participants and
303 consensus panel participants who could not attend the meeting. The steering committee used the comments
304 to further refine the extension items. To evaluate these items in practice, four members of the steering
305 committee independently pilot tested both the CONSORT and STROBE statements with simulation-
306 specific extensions. They used two published SBR studies (i.e. one for each type of SBR), while ensuring
307 one study was a randomized trial and the other an observational study. Feedback from pilot testing
308 informed further revisions. The final reporting guidelines with extensions were circulated to the steering
309 committee one last time to ensure the final product accurately represented discussion during and after the
310 consensus conference. An explanation and elaboration document was developed by the steering committee
311 to provide further detail for each item requiring a simulation-specific extension⁴².

312

313 **Results**

314 *Pre-meeting Survey*

315 There was a 75% response rate for the survey, with 45 of the 60 participants completing the entire
316 survey. An additional 12 (20%) other participants partially completed the survey. Of the 57 participants
317 who responded to the survey, 17 were medical journal editors or editorial board members, 24 had advanced
318 degrees (Masters, PhD), 16 with advanced degrees in medical education or educational psychology, six
319 were nurses, one was a psychologist, and 54 were physicians (representing anesthesiology, critical care,
320 emergency medicine, pediatrics, and surgery). Of the 3 participants who did not complete the survey, two
321 were physicians and one was a scientist. The results of the survey are described in Supplemental Digital
322 Content (See Table, Supplementary Digital Content 1, Survey Responses).

323

324 *Consensus Meeting*

325 In total, 35 consensus panel participants who completed the pre-meeting survey attended the
326 consensus conference. An additional 30 attendees were INSPIRE network members. Of the 65 total
327 attendees at the consensus conference, 12 were medical journal editors or editorial board members, 18 had
328 advanced degrees (Masters, PhD), four were nurses, one was a psychologist, and 60 were physicians
329 (representing anesthesiology, critical care, emergency medicine, pediatrics, and surgery).

330 Eleven simulation-specific extensions were recommended for the CONSORT Statement: item 1
331 (title and abstract), item 2 (background), item 5 (interventions), item 6 (outcomes), item 11 (blinding), item
332 12 (statistical methods), item 15 (baseline data), item 17 (outcomes and estimation), item 20 (limitations),
333 item 21 (generalizability), and item 25 (funding). Participants agreed upon the importance of describing
334 the rationale for and design of the simulation-based intervention. As many simulation-based studies use
335 assessment tools as an outcome measure, participants thought it was important to report the unit of analysis
336 and evidence supporting the validity and reliability of the assessment tool(s) when available. In the
337 discussion section, participants thought it was important to describe the limitations of simulation-based
338 research, and the generalizability of the simulation-based outcomes to clinical outcomes (when applicable).
339 Participants also agreed it was important to identify the simulator brand used in the study and if conflict of
340 interest for intellectual property existed amongst investigators. The group did not feel that modifications to
341 the CONSORT flow diagram were required for simulation-based research. See Table 1 for CONSORT
342 extensions for SBR.

343 Ten extensions were drafted for the STROBE Statement: item 1 (title and abstract), item 2
344 (background/rationale), item 7 (variables), item 8 (data sources/measurement), item 12 (statistical
345 methods), item 14 (descriptive data), item 16 (main results), item 19 (limitations), item 21
346 (generalizability), and item 22 (funding). A similar emphasis was placed on the importance of describing
347 all simulation-specific exposures, confounders and effect modifiers, as was discussed for the CONSORT.
348 Other extensions for the STROBE were under similar categories as the proposed extensions for the
349 CONSORT. See Table 2 for STROBE extensions for SBR.

350 For both the CONSORT and STROBE Statements, extensive discussion occurred in the consensus
351 meeting related to the educational intervention and controlling for simulation-specific variables that pose as
352 potential threats to the internal validity of simulation studies. A group of consensus panel participants with
353 expertise in simulation-based education and instructional design utilized their knowledge of educational
354 theory, existing educational research guidelines⁵¹ and systematic reviews of simulation-based research^{1,5-8,11}
355 to address this issue (Table 3). Table 3 offers an additional checklist of key elements specific to SBR, for
356 item 5 (Interventions) on the CONSORT Statement and item 7 (Variables) on the STROBE Statement, that
357 should be reported for all simulation studies, for both the intervention and control groups (if applicable).

358 In modeling the explanation and elaboration document after other similar documents published in
359 conjunction with reporting guidelines^{28,32}, we provide a specific example for each item requiring a new
360 extension coupled with the background and rationale for including that information for that item. We
361 encourage readers to refer to the explanation and elaboration document to seek further detail about the
362 nature and type of recommended reporting for each new extension (see text, Supplemental Digital Content
363 2, Explanation and Elaboration of the Simulation-Specific Extensions for the CONSORT and STROBE
364 Statements).

365

366 **Discussion**

367 We have developed reporting guidelines for SBR by creating extensions to both the CONSORT²⁸
368 and STROBE³¹ Statements. These new extensions were developed via a consensus building process with
369 multiple iterative steps involving an international group of experts with diverse backgrounds and expertise.
370 By creating extensions to both the CONSORT and STROBE Statements that can be applied to studies in
371 both categories of SBR, we have developed reporting guidelines that are applicable to the majority of
372 studies involving simulation in health care research. To further assist authors in reporting SBR studies, we
373 have published an explanation and elaboration document as an appendix that provides specific examples
374 and details for all the new simulation-specific extensions for both the CONSORT and STROBE
375 Statements.

376 The CONSORT and STROBE Statements with accompanying SBR extensions are meant to serve
377 as a guide to reporting. As with other CONSORT and STROBE Statements, the items are not meant to
378 “prescribe the reporting... in a rigid format”, but rather the “order and format for presenting information
379 depends on author preferences, journal style, and the traditions of the research field”^{28,31}. We encourage
380 authors to refer to the explanation and elaboration document that provides details regarding specific
381 elements related to individual items that should be reported for SBR. The use of reporting guidelines can
382 have positive effects on various health care simulation stakeholders, including funders of SBR and those
383 applying for funding (ie. use as a template for grant applications), educators (ie. use as a training tool), and
384 students (ie. use to develop protocols for coursework or research)³³. The application of these reporting
385 guidelines will help to enhance quality of reporting for quantitative SBR and assist journal reviewers and

386 editors when faced with assessing the strengths and weaknesses of simulation-based studies in health
387 care^{24,52,53}. We encourage journals publishing SBR to consider endorsing the simulation-specific
388 extensions for the CONSORT and STROBE Statements and adding these to their 'Instructions for
389 Authors'.

390 SBR has several unique factors that prompted us to develop simulation-specific extensions for
391 both the CONSORT and STROBE Statements. First, there are a wide variety of simulators and simulation
392 modalities available for use in research¹⁶. This, coupled with a plethora of instructional design features in
393 simulation-based educational research make describing the simulation intervention a critically important
394 component of any educational study involving simulation (Table 3)^{6,8,54}. Second, SBR provides
395 opportunity for the investigator to standardize the simulated environment and/or simulated patient
396 condition. Standardization of the environment and patient condition allows the investigator to account for
397 many of the potential threats to internal validity that are associated with simulation. Clear reporting of
398 standardization strategies helps the reader understand how the independent variable was isolated (Table
399 3)¹⁶. Third, many simulation studies involve capturing outcomes from a variety of data sources (eg.
400 observation, video-review, simulator data capture). When assessment instruments are used (eg. expert
401 raters assessing performance) it is imperative to discuss the psychometric properties of these instruments⁵.
402 Existing guidelines fall short in this regard, and these new guidelines help to address this issue. Lastly,
403 simulation-based studies assessing outcomes in the simulated environment only (eg. clinical performance)
404 should attempt to provide evidence to support how the findings in the simulated environment translate to a
405 valid representation of performance in the real clinical environment³. By doing so, authors help to convey
406 the relevance and importance of their findings.

407

408 *Limitations*

409 Our consensus process has several limitations. Although we had a 75% response rate for our
410 survey, an additional 20% of participants only partially completed the survey. This may have potentially
411 introduced a selection bias, although the survey represented only one step in our consensus building
412 process. We include a wide variety of experts in our consensus meeting, but many of them had a pediatric
413 clinical background. We minimized this potential bias by ensuring that each breakout group had at least

414 one expert participant with a background outside of pediatrics. Furthermore, the principles of SBR are
415 common across specialties and professions, and INSPIRE network members represent researchers who are
416 recognized internationally for being leaders in SBR. We based our reporting guidelines on the CONSORT
417 and STROBE guidelines developed by clinical researchers. Other guidelines could have been used as a
418 starting point such as the American Education Research Association (AERA) standards developed in
419 2006⁵⁵. Our logic was to start with reporting guidelines that were applicable to all types of research, thus
420 providing us more flexibility in generating extensions for both types of SBR. Cross-checking against the
421 AERA guideline does not reveal areas we might have missed⁵⁶. While we tried to develop reporting
422 guidelines for all types of SBR, we recognize there may be specific types of research that may require new
423 items or different extensions. For example, studies designed to evaluate the validity of simulation-based
424 assessments vary in their reporting requirements. The STAndards for Reporting of Diagnostic Accuracy
425 (STARD) Statement⁵⁶ addresses these points, and a recent review operationalized these standards and
426 applied them to SBR⁵⁷. Other reporting guidelines that might be amenable for simulation-specific
427 extensions include the Consolidated criteria for reporting qualitative research (COREQ)⁵⁸, and the
428 Standards for Quality Improvement Reporting Excellence (SQUIRE)⁵⁹ guidelines for reporting quality
429 improvement studies. As the field of SBR grows, the simulation-specific extensions for the CONSORT
430 and STROBE Statements may need to be revised or refined. We encourage authors, reviewers and editors
431 to visit our website (<http://inspiresim.com/simreporting/>) and provide feedback that will be used to inform
432 subsequent revisions to these reporting guidelines.

433

434 **Conclusions**

435 The unique features of SBR highlight the importance of clear and concise reporting that helps
436 readers understand how simulation was used in the research. Poor and inconsistent reporting makes it
437 difficult for readers to interpret results and replicate interventions, and hence less likely for research to
438 inform change that will positively influence patient outcomes. The use of standardized reporting guidelines
439 will serve as a guide for authors wishing to submit manuscripts for publication, and in doing so, draw
440 attention to the important elements of SBR and ultimately improve the quality of simulation studies
441 conducted in the future.

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499 Akron Children's Hospital; Daniel Scherzer, MD, Nationwide Children's Hospital; Elsa Vazquez
500 Melendez, MD, FAAP, FACP, University of Illinois College of Medicine at Peoria; Chris Kennedy, MD,
501 University of Missouri Kansas School of Medicine; Waseem Ostwani, MD, University of Michigan Health
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Table 1: Simulation-based Research Extensions for the CONSORT Statement

Item	Item no	CONSORT Description (Randomized, controlled trials)	Extension for Simulation-based Research
Title and abstract	1a, 1b	1a: Identification as a randomized trial in the title 1b: Structured summary of trial design, methods, results, and conclusions	In abstract or key terms the MESH or searchable keyword term must have the word “simulation” or “simulated”.
Introduction			
Background	2a, 2b	2a: Scientific background and explanation of rationale 2b: Specific objectives or hypotheses	Clarify whether simulation is <i>subject of research</i> or <i>investigational method for research</i> .
Methods			
Trial Design	3a, 3b	3a: Description of trial design (such as parallel, factorial) including allocation ratio 3b: Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a, 4b	4a: Eligibility criteria for participants 4b: Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow for replication, including how and when they were actually administered	Describe the theoretical and/or conceptual rationale for the design of each intervention. Clearly describe all simulation-specific exposures, potential confounders, and effect modifiers.
Outcomes	6a, 6b	6a: Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed 6b: Any changes to trial outcomes after the trial commenced, with reasons	In describing the details of methods of assessment, include (when applicable) the setting, instrument, simulator type, timing in relation to the intervention, along with any methods used to enhance the quality of measurements. Provide evidence to support the validity and reliability of assessment tools in this context (if available).
Sample size / Study size	7a, 7b	7a: How sample size was determined 7b: When applicable, explanation of any interim analyses and stopping guidelines	
Randomization: Sequence generation	8a, 8b	8a: Method used to generate the random allocation sequence 8b: Type of randomization; details of any restriction (such as blocking and block size)	
Randomization: Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence	

		until interventions were assigned	
Randomization: Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding (masking)	11 a, 11 b	11 a: If done, who was blinded after assignments to interventions (for example, participants, care providers, those assessing outcomes) and how 11 b: If relevant, description of the similarity of interventions	Describe strategies to decrease risk of bias, when blinding is not possible.
Statistical Methods	12 a, 12 b	12 a: Statistical methods used to compare groups for primary and secondary outcomes 12 b: Methods for additional analyses, such as subgroup analyses and adjusted analyses	Clearly indicate the unit of analysis (e.g. individual, team, system) and identify repeated measures on subjects, and describe how these issues were addressed.
Results			
Participant flow (a diagram is strongly recommended)	13 a, 13 b	13 a: For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome 13 b: For each group, losses and exclusions after randomization, together with reasons	
Recruitment	14 a, 14 b	14 a: Dates defining the periods of recruitment and follow-up 14 b: Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics of each group	In describing characteristics of study participants, include their prior experience with simulation and other relevant features as related to the intervention(s).
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether analysis was by original assigned groups	
Outcomes and estimation	17 a, 17 b	17 a: For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) 17 b: For binary outcomes, presentation of both absolute and relative effect sizes is recommended	For assessments involving more than one rater, inter-rater reliability should be reported.
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	

Adverse Events	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Specifically discuss the limitations of simulation-based research.
Generalizability	21	Generalizability (external validity) of the trial findings	Describe generalizability of simulation-based outcomes to patient-based outcomes (if applicable).
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other Information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	List simulator brand and if conflict of interest for intellectual property exists.

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Table 2: Simulation-based Research Extensions for the STROBE Statement

Item	Item No	STROBE Description (Observational studies)	Extension for Simulation-based Research
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract. (b) Provide in the abstract an informative and balanced summary of what was done and what was found.	In abstract or key terms the MESH or searchable keyword term must have the word "simulation" or "simulated".
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported.	Clarify whether simulation is <i>subject of research</i> or <i>investigational method for research</i> .
Objectives	3	State specific objectives, including any pre-specified hypotheses.	
Methods			
Study Design	4	Present key elements of study design early in the paper.	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.	
Participants	6	(a) Cohort study: Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up. 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. Cross-sectional study: Give the eligibility criteria, and the sources and methods of selection of participants. (b) Cohort study: For matched studies, give matching criteria and number of exposed and unexposed. Case-control study: For matched studies, give matching criteria and the number of controls per case.	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and	Describe the theoretical and/or conceptual rationale for the design of the intervention / exposure.

		effect modifiers. Give diagnostic criteria, if applicable.	Describe the intervention / exposure with sufficient detail to permit replication. Clearly describe all simulation-specific exposures, potential confounders, and effect modifiers.
Data sources / measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group.	In describing the details of methods of assessment, include (when applicable) the setting, instrument, simulator type, timing in relation to the intervention, along with any methods used to enhance the quality of measurements. Provide evidence to support the validity and reliability of assessment tools in this context (if available).
Bias	9	Describe any efforts to address potential sources of bias.	
Study size	10	Explain how the study size was arrived at.	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why.	
Statistical Methods	12	(a) Describe all statistical methods, including those used to control for confounding. (b) Describe any methods used to examine subgroups and interactions. (c) Explain how missing data were addressed. (d) Cohort study: If applicable, explain how loss to follow-up was addressed. Case-control study: If applicable, explain how matching of cases and controls was addressed. Cross-sectional study: If applicable, describe analytical methods taking account of sampling strategy. (e) Describe any sensitivity analyses.	Clearly indicate the unit of analysis (e.g. individual, team, system) and identify repeated measures on subjects, and describe how these issues were addressed.
Results			
Participants	13	(a) Report the numbers of individuals at each stage of the study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed.	

		(b) Give reasons for nonparticipation at each stage. (c) Consider use of a flow diagram.	
Descriptive data	14	(a) Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders. (b) Indicate the number of participants with missing data for each variable of interest. (c) Cohort study: Summarize follow-up time—e.g., average and total amount.	In describing characteristics of study participants, include their prior experience with simulation and other relevant features as related to the intervention(s).
Outcome 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 results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence intervals). Make clear which confounders were adjusted for and why they were included. (b) Report category boundaries when continuous variables were categorized. (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period.	d) For assessments involving more than one rater, inter-rater reliability should be reported.
Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions and sensitivity analyses.	
Discussion			
Key results	18	Summarize 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.	Specifically discuss the limitations of simulation-based research.
Interpretation	20	Give a cautious overall interpretation of results	

		considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	
Generalizability	21	Discuss the generalizability (external validity) of the study results.	Describe generalizability of simulation-based outcomes to patient-based outcomes (if applicable).
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.	List simulator brand and if conflict of interest for intellectual property exists.

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Table 3: Key Elements to Report for Simulation-based Research

Elements*	Sub-elements**	Descriptor
Participant Orientation	Orientation to the simulator	Describe how participants were oriented to the simulator (eg. method, content, duration).
	Orientation to the environment	Describe how participants were oriented to the environment (eg. method, content, duration).
Simulator Type ¹⁶	Simulator make and model	Describe the simulator make and model.
	Simulator functionality	Describe functionality and/or technical specifications that are relevant to the research question. Describe modifications, if any. Describe limitations of the simulator.
Simulation Environment ¹⁶	Location	Describe where the simulation was conducted (eg. in situ clinical environment, simulation center etc)
	Equipment	Describe the nature of the equipment available (eg. type, amount, location, size etc)
	External stimuli	Describe any external stimuli (eg. background noise)
Simulation Event / Scenario ¹⁶	Event description	Describe if the event was programmed and/or scripted (eg. orientation to event, scenario progression, triggers). If a scenario was utilized, the scenario script should be provided as an appendix.
	Learning objectives	List the learning objectives and describe how they were incorporated into the event
	Group vs individual practice	Describe if the simulation was conducted in groups or as individuals.
	Use of adjuncts	Describe if adjuncts (eg. moulage, media, props) were used.
	Facilitator / operator characteristics	Describe experience (eg. clinical, educational), training (eg. fellowship, courses), profession.
	Pilot testing	Describe if pilot testing was conducted (eg. number, duration, frequency).
	Actors / Confederates / Standardized/Simulated Patients ¹⁶	Describe experience (eg. clinical, educational), training (eg. fellowship, courses), profession, gender. Describe various roles, including training, scripting, orientation, and compliance with roles.
Instructional Design (for educational interventions) ⁵³ or Exposure (for	Duration	Describe the duration of the educational intervention. If the intervention involves more than one segment, describe the duration of each segment.

simulation as investigative methodology) ¹⁶	Timing	Describe the timing of the educational intervention relative to the time when assessment / data collection occurs (eg. just-in-time training).
	Frequency / Repetitions	Describe how many repetitions were permitted and/or the frequency of training (eg. deliberate practice).
	Clinical Variation	Describe the variation in clinical context (eg. multiple different patient scenarios).
	Standards / Assessment	Describe pre-defined standards for participant performance (eg. mastery learning) and how these standards were established.
	Adaptability of Intervention	Describe how the training was responsive to individual learner needs (eg. individualized learning)
	Range of Difficulty	Describe the variation in difficulty or complexity of the task
	Non-simulation interventions and adjuncts	Describe all other non-simulation interventions (eg. lecture, small group discussion) or educational adjuncts (eg. educational video), how they were used, and when they were used relative to the simulation intervention.
	Integration	Describe how the intervention was integrated into curriculum
Feedback and/or Debriefing ¹¹	Source	Describe the source of feedback (eg. computer, simulator, facilitator).
	Duration	Describe the amount of time spent.
	Facilitator Presence	Describe is a facilitator was present (yes / no), and if so, how many facilitators.
	Facilitator Characteristics	Describe experience (eg. clinical, educational), training (eg. fellowship, courses), profession, gender.
	Content	Describe content (eg. teamwork, clinical, technical skills and/or inclusion of quantitative data etc).
	Structure / Method	Describe the method of debriefing / feedback and debriefing framework utilized (ie. phases).
	Timing	Describe when the feedback and/or debriefing was conducted relative to the simulation event (eg. terminal vs. concurrent).
	Video	Describe if video was used (yes / no), and how it was used.

	Scripting	Describe if a script was used (yes / no) and provide script details as an appendix.
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* These elements may apply for the simulation intervention (eg. RCT or observational study with simulation as an educational intervention) or when simulation is the environment for research (eg. RCT or observational study utilizing simulation as an investigative methodology). Elements should be described in sufficient detail to permit replication.

**Description required only if applicable