

1 **“Making stillbirths visible: A systematic review of globally reported causes of stillbirth”**

2 **Short title:** Global reporting of causes of stillbirth

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56 **Abstract**

57 ***Background***

58 Stillbirth is a global health problem. The World Health Organization (WHO) application of the
59 International Classification of Diseases for perinatal mortality (ICD-PM) aims to improve data on
60 stillbirth to enable prevention.

61 ***Objectives***

62 To identify globally reported causes of stillbirth, classification systems, and alignment with the ICD-
63 PM.

64 ***Search strategy***

65 We searched CINAHL, EMBASE, Medline, Global Health and Pubmed from 2009-2016.

66 ***Selection criteria***

67 Reports of stillbirth causes in unselective cohorts.

68 ***Data collection and analysis***

69 Pooled estimates of causes were derived for country representative reports. Systems and causes were
70 assessed for alignment with the ICD-PM. Data are presented by income setting (low, middle and high
71 income; LIC, MIC, HIC).

72 ***Main results***

73 85 reports from 50 countries (489,089 stillbirths) were included. The most frequent categories were
74 *Unexplained*, *Antepartum haemorrhage* and *Other* (all settings), *Infection* and *Hypoxic peripartum*
75 (LIC), and *Placental* (MIC, HIC). Overall report quality was low. Only one classification system
76 fully aligned with ICD-PM. All stillbirth causes mapped to ICD-PM. In a subset from HIC mapping
77 obscured major causes.

78 ***Conclusion***

79 There is a paucity of quality information on causes of stillbirth globally. Improving investigation of
80 stillbirths and standardisation of audit and classification is urgently needed and should be achievable

81 in all well-resourced settings. Implementation of the WHO Perinatal Mortality Audit and Review
82 guide particularly across high burden settings is needed.

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86 ***Keywords***

87 Stillbirth, classification, systems, cause of death, ICD

88 ***Tweetable Abstract***

89 Urgent need to improve data on causes of stillbirths across all settings to meet global targets.

90

91 **Introduction**

92 The global stillbirth rate (≥ 28 completed weeks' gestation) is estimated to be 18.4 per 1000 births¹ or
93 around 2.6 million stillbirths each year¹. The World Health Organization's (WHO's) Every Newborn
94 Action Plan aims to reduce the stillbirth rate to 12 or fewer per 1000 births by 2030 in every country,
95 and for countries already meeting this target to reduce equity gaps². However, with an estimated
96 annual reduction rate of 2.0% between 2000 and 2015¹, half that for neonatal deaths, progress has
97 been slow. Identifying interventions to achieve such a target would be facilitated by cross-country
98 and inter-country comparisons of the causes of stillbirth. Moreover, while national neonatal causes
99 of death are regularly published through the United Nations^{1,3}, there is currently no systematic global
100 reporting of causes of stillbirth. The WHO recommends use of the International Statistical
101 Classification of Diseases and Health Related Problems (ICD) for classification of perinatal deaths
102 for international reporting⁴. However, limitations in ICD for classifying stillbirths⁵ has resulted in
103 numerous disparate systems currently in use⁶, thus limiting global comparisons. In 2016, WHO
104 released ICD Perinatal Mortality (ICD-PM) as part of the WHO Perinatal Mortality Audit and Review
105 guide⁷. The ICD-PM is an application of ICD and holds promise as an important step in improving
106 global and local reporting of causes of stillbirths and neonatal deaths⁸. The ICD-PM aims to collect,
107 at a minimum, timing of death and clinically defined causes and associated conditions.

108 **Objectives**

109 Following on the introduction of the ICD-PM, we aimed to identify globally reported causes of
110 stillbirth in order to support progress toward the WHO Every Newborn Action Plan stillbirth rate
111 target. The specific objectives were to:

- 112 1. Describe the current status of global reporting of stillbirth causes, including reported causes
113 and classification systems used;
- 114 2. Pool results from country representative reports to identify commonly reported causes of
115 stillbirth, stratified by income setting (high-, middle-, and low-income); and

116 3. Assess alignment of systems used and reported causes of stillbirths with the ICD-PM for
117 country representative reports.

118 **Methods**

119 This systematic review was conducted and reported according to the PRISMA checklist⁹. The
120 protocol has not been published. Two authors independently undertook screening of reports,
121 selection, data extraction and quality assessment.

122 ***Eligibility criteria***

123 All published and unpublished cohort and cross-sectional reports from 1 January 2009 to 31
124 December 2016 which presented causes of stillbirth were eligible. Reports were excluded if they:
125 included non-consecutive or selected subgroups, e.g. preterm; aimed only to identify risk factors or
126 did not provide data on causes in an extractable format (for complete study selection see Figure S1).

127 ***Information sources***

128 We searched PubMed, Global Health, Cinahl, Medline and Embase without language restrictions.
129 We identified national reports through web-based systematic searches (Appendix S1) and cross-
130 referenced included reports.

131 ***Study selection***

132 Titles and abstracts of identified reports were screened for eligibility; full text papers were retrieved
133 if potentially eligible or unsure. All reports presenting causes of stillbirth were included to address
134 Objective 1. To address Objectives 2 and 3, the most recent national report for each country was
135 selected. If a national report was unavailable, a report was selected on criteria (in descending order):
136 1) population-based report with the largest number of stillbirths, 2) multi-centre health facility report
137 covering the largest population.

138 ***Data extraction***

139 A purpose built data extraction form was used. For details on data items and definitions used, see
140 Additional Information S2.

141 ***Grouping reported stillbirth causes***

142 The development of categories and mapping of reported causes of stillbirth to categories
143 were undertaken by a panel including Maternal Fetal Medicine Specialists (GG, BS, DE), pathologist
144 (RL) and epidemiologist (VF), with guidance from The Amsterdam Classification Workshop¹⁰
145 members. Categories were created by “clustering” reported causes into 15 clinically meaningful
146 groups for stillbirth prevention (“global categories”) (Table S1). With the addition of *Placental*
147 *conditions*, these categories generally coincided with previously suggested major causal groupings
148 by Lawn et al¹¹. We did not attempt to differentiate causes from associated conditions (Table S1).

149 ***Quality assessment***

150 Quality assessment of country representative reports included in the pooled analysis of reported
151 causes was performed using an adapted version of the Joanna Briggs Institute Critical Appraisal
152 Checklist for Studies Reporting Prevalence Data¹² (Appendix S3). An overall quality rating was
153 derived for each report (low, medium, or high quality). For subgroup analyses of “good” quality
154 reports, we combined data from reports assessed as high and medium quality.

155 ***Data presentation and analysis***

156 Data were presented by income setting using World Bank groupings¹³ of low and lower-middle (LIC;
157 Gross National Income (GNI) \leq \$3,955), upper-middle (MIC; GNI \$3,956- \$12,235) and high (HIC;
158 GNI \geq \$12,236). Categories of stillbirth causes were presented as proportions of the total number of
159 stillbirths classified. Results from country representative reports were statistically pooled to identify
160 commonly reported causes stratified by country groupings. Analyses were done in R using the meta
161 package¹⁴ with 95% prediction intervals (PI)¹⁵⁻¹⁷ (Appendix S4). Subgroup analyses by report quality
162 and type of system (ICD versus clinical classification systems) were planned *a priori*. See Appendix
163 S2 for definition of clinical classification systems⁶ and criteria for alignment of classification systems
164 with ICD-PM.

165 Each reported cause was mapped to the relevant ICD-PM major category. The ICD-PM includes five
166 major maternal condition categories (M1-5) and 13 fetal categories, six with antepartum timing (A1-
167 6) and seven with intrapartum timing (I1-7)⁴. For the Unknown (U) timing category we included the

168 categories: U1: *Congenital malformations, deformations and chromosomal abnormalities*; U2:
169 *Infection*; U3: *Other specified disorder*; U4: *Disorders related to fetal growth*; U5: *Death of*
170 *unspecified cause*. We added one category, *Other*, to all timings to accommodate the causes without
171 ICD-PM coding.

172 The proportions of stillbirths that could be mapped to a fetal cause and/or a maternal condition in
173 ICD-PM were calculated. Mapping of data from good quality HIC reports to ICD-PM was compared
174 descriptively with the 15 global categories.

175 **Results**

176 Of 7415 abstracts screened for eligibility, 909 full-text papers were reviewed for inclusion and 824
177 records were excluded: did not discuss stillbirth (396), no extractable data (217), sub-populations
178 only (145), risk factors only (12) (for complete study selection see Figure S1). Eighty-five reports
179 (LIC 28, MIC 20, HIC 37) with a total of 489,089 stillbirths were included in the review (LIC 13,197,
180 MIC 431,216, HIC 44,676). Thirty-three country representative reports classifying 454,533 stillbirths
181 were included in the pooled analysis of causes and mapping to ICD-PM.

182 ***Global stillbirth reporting***

183 *Description of included reports*

184 The 85 included reports originated from 50 countries. Reports were published in English (66) and
185 non-English (19; Table S2). Eleven reports excluded terminations of pregnancy. Half of the reports
186 (including 2.4% of all stillbirths) were from hospital settings (LIC: 19 reports/7419 stillbirths; MIC:
187 8 reports/1134 stillbirths; HIC: 16 reports/3240 stillbirths) (Table 1, for full details see Table S2).

188 *Definitions of stillbirth*

189 Stillbirth was defined in 71 reports (84%) using 34 discrete definitions (Figure S2). The majority of
190 HIC reports (78%) used a lower gestational age limit of 20-24 weeks while the majority of LIC reports
191 (68%) used 28 weeks (Table 1).

192 *Data available to classifiers*

193 Systematic prospective perinatal mortality audits were used in 21 reports (LIC 2, MIC 4, HIC 15), of
194 which 12 were hospital audits; seven used comprehensive investigation protocols (all from HIC)
195 (Table S2). In 40 reports, retrospective audit data were used; 18 of these (LIC 2, MIC 6, HIC 10)
196 sourced causes from Civil Registration and Vital Statistics (CRVS). Sixteen reports (LIC 13, MIC 3)
197 were prospective studies; eight of these, all from LIC, used verbal autopsy. Reported autopsy rates in
198 20 reports [MIC 3 (14%), HIC 17 (47%)] ranged from 2.7% to 100%. In over half of the reports
199 (55%) it was unclear whether autopsy had been performed. Placental pathology examination rates
200 were included in 15 reports (18%) (none in LIC) with rates ranging from 22% to 100%. For full
201 details on data available see Table S2.

202 *Classification systems*

203 Twenty-one clinical classification systems¹⁸⁻³⁸ were used in 41 of the 85 reports (LIC 15 reports/30%
204 of stillbirths, MIC 6 reports/5% of stillbirths, HIC 20 reports/27% of stillbirths). The ICD was used
205 more frequently in HIC (14 reports/72% of stillbirths) and MIC (7 reports/94% of stillbirths) than
206 LIC (3 reports/2% of stillbirths) (Table 1). The remaining 20 reports listed causes of death without
207 reference to any classification system. Areas of origin for the 21 clinical systems is shown in Table
208 S3. Three-quarters of the systems allow a single primary cause of death, and half the systems allow
209 associated factors to be recorded (Table S4). Five systems provide comprehensive definitions of
210 causes^{20,27,30-32} and 13 systems provide rules for assigning cause of death (See Table S4 for full details
211 on clinical classification systems).

212 *Globally reported categories of stillbirth*

213 The 85 included reports presented causes of stillbirth using 860 unique terms. These were grouped
214 into 15 global categories and 46 minor categories, of which eight major categories were common to
215 over half (53%) of the reports (Table S5).

216 *Congenital anomalies* was the most frequently reported category, included in 93% of all reports. The
217 proportion of stillbirths assigned to this category ranged from 1.4% in Nigeria³⁹ to 64.4% in China⁴⁰
218 (Figure 1, Table S5). The second category was *Unexplained*, included in 82% of all reports, ranging

219 from 0.3% in Turkey²⁵ to 82.0% in Japan⁴¹. *Maternal conditions* were included in 64% of all reports,
220 with frequency ranging from 0.6% in Ireland⁴² to 36.5% in Italy²⁸ (Figure 1, Table S5).

221 The proportions of categories also differed across type of classification system. The most commonly
222 reported categories for reports using the ICD included *Other unspecified condition* (68% of reports)
223 and *Hypoxic peripartum death* (64%), whereas for clinical systems these included *Antepartum*
224 *haemorrhage* (72%) and *Infection* (67%).

225 ***Country representative reports***

226 *Description of included reports*

227 Thirty-three reports classifying 454,533 stillbirths were included in the pooled analysis: seven LIC
228 (5,629 stillbirths), 11 MIC (429,666 stillbirths), and 15 HIC (19,238 stillbirths). Twenty-one reports
229 included $\geq 95\%$ of total stillbirths in the country during the reporting period, one report included 72%,
230 three included 6-49% and eight included $\leq 5\%$ (Figure S3). In two reports (6%), terminations of
231 pregnancy were excluded, and in 21 (64%), no reference was made to terminations. The ICD was
232 used mainly in HIC and MIC reports (60% and 64%, respectively, versus 14% of LIC reports; Table
233 1, Table S2).

234 Quality assessment identified 13 good quality reports (29% of all LIC reports, 36% of all MIC reports,
235 47% of all HIC reports); only one of these was high-quality⁴³. The remaining reports were assessed
236 as low-quality (Table S6, Figure S4).

237 *Pooled estimates of commonly reported causes of stillbirths*

238 The top five categories by frequency for each country grouping are shown in Figure 2. *Unexplained*
239 was the top category across all settings, with pooled estimated ranging from 31.2% to 43.7% (Tables
240 S7, S8). Two additional categories were amongst the top five across all settings: *Other unspecified*
241 *conditions* (9.3% to 11.6%) and *Antepartum haemorrhage* (8.4% to 9.3%; Tables S7, S9, S10). In
242 LIC, *Infection* (15.8%) and *Hypoxic peripartum death* (11.6%; Tables S7, S11, S12) were also
243 amongst the top five. In both HIC and MIC settings *Placental conditions* (14.4% and 13.7%,

244 respectively) ranked in the top five, with *Congenital anomalies* as the remaining category in HIC
245 (14.0%) and *Specific fetal/pregnancy pathology* in MIC (11.0%) (Tables S7, S13, S14, S15).

246 Details of pooled analyses of *Umbilical cord complications*, *Maternal conditions*, *Spontaneous*
247 *preterm*, *Hypertension*, *Fetal growth restriction* and *Terminations* are presented in Tables S16-S21.

248 *Sub-group analysis*

249 Due to insufficient data subgroup analysis by report quality was only possible for HIC. The proportion
250 of *Unexplained* (15.4% vs 31.6%) and *Other unspecified conditions* (1.6% vs 9.3%) was lower in
251 good quality reports versus all reports (Tables S8, S9). Subgroup analyses by system type showed
252 higher proportions of *Antepartum haemorrhage* using clinical systems (14.1%) than using ICD
253 (4.4%) in MIC (Table S10). Use of clinical systems resulted in lower proportions of *Other unspecified*
254 *conditions* (1.6%) and *Unexplained* (17.7%) than use of ICD (13.2% and 43.4%, respectively) in HIC
255 (Tables S9, S8).

256 *Alignment with the ICD-PM*

257 *Alignment of clinical classification systems with the ICD-PM*

258 Of 21 classification systems used, only Codac¹⁹ was fully aligned with the ICD-PM. Four systems
259 met two of the three criteria used to assess alignment, and 14 systems scored 0.5-1.5 out of a
260 maximum of 3 (Table S3, Figure S5).

261 *Mapping of reported causes to ICD-PM*

262 Nearly all the 454,533 stillbirths reported in the 33 country representative reports were mapped to an
263 ICD-PM fetal or maternal category, or both. Causes for 831 stillbirths (0.2%) mapped to ICD-PM
264 neonatal rather than fetal codes (for example “neonatal aspiration syndrome”). 264,480 stillbirths
265 (58%) were mapped to a fetal but not a maternal ICD-PM cause, and 140,319 (31%) to a maternal
266 but not a fetal ICD-PM cause; 49,734 stillbirths (11%) were mapped to both (Tables S22, S23).

267 Of the 204,545 stillbirths in the global category *Unexplained*, 113,558 (56%) were mapped to the
268 ICD-PM category *Unknown timing unspecified* (no maternal condition), 90,335 (44%) to *Antepartum*
269 *hypoxia* (no maternal condition), 602 (0.3%) to *Antepartum unspecified* (no maternal condition), and

270 50 (0.02%) to maternal condition *Other complications of labour and delivery* (no fetal cause) (Tables
271 S22, S23).

272 The global causes from best available data (good quality reports using clinical classification systems
273 in HIC, five reports; 6,194 stillbirths) were mapped to ICD-PM. The global categories reflecting
274 underlying placental causes of *Antepartum haemorrhage* and *Placental condition* (insufficiency)
275 accounted for 20%, and *Intrauterine growth restriction* 7% of stillbirths (Figure 3). When mapped to
276 the ICD-PM, these global categories are included within the major maternal category *Complications*
277 *of placenta, cord and membranes* and the fetal category *Disorders related to fetal growth*, accounting
278 for 30% and 17% of stillbirths, respectively (Figure 3).

279 **Discussion**

280 ***Main findings***

281 From 85 reports presenting causes of nearly half a million stillbirths from 50 countries and all income
282 settings, we identified 15 major causal categories from nearly 900 causal terms; eight categories were
283 common to the majority of reports. Despite this overarching commonality, we found wide variation
284 in frequency of stillbirth categories and in the systems used to classify them with generally poor
285 quality data. Underlining one of the key challenges of achieving the Every Newborn Action Plan
286 stillbirth target, are the high proportions of stillbirths without information to guide prevention
287 (*Unexplained* and *Other unspecified conditions*) in all income settings.

288 ***Strengths and limitations***

289 We sought to include the most detailed causes of stillbirth available to allow identification of common
290 groupings, and ultimately to enable consistent reporting across settings. In line with WHO
291 recommendations^{4,44} and to maximize the utility of the data for prevention strategies, we excluded
292 reports which assigned more than one cause of stillbirths and excluded all those reported as associated
293 only. This may have resulted in a loss of information and limited our ability to assess the full value
294 of the ICD-PM, which aim to record both a fetal and a maternal condition for every stillbirth. The
295 need to assign multiple causes for some stillbirths has been highlighted. Further, the distinction

296 between causes and associated conditions is often poorly defined²⁶ and in this review many reported
297 “causes” are not recognised as causal conditions. Further, although we imposed no language
298 restriction, we may have missed some reports due to English-language search terms.

299 *Interpretation*

300 *Data quality*

301 Data quality was generally poor with only a small number of reports based on high quality perinatal
302 mortality audit. Further, many reports did not provide sufficient detail to adequately assess quality.
303 Similar to others^{1,5,45}, we found global comparisons problematic due to differing definitions and
304 systems. The inability to identify termination of pregnancies in reporting of stillbirth causes is
305 problematic; many are terminated as a consequence of congenital anomalies⁴⁶, some of which may
306 not have resulted in stillbirth.

307 *Global causes of stillbirth*

308 Results of the pooled analysis enabled comparisons of stillbirth causes across settings, providing
309 additional evidence for key areas for prevention. The relatively high proportion of stillbirths attributed
310 to intrapartum hypoxia (*Hypoxic peripartum*) in LIC versus HIC and MIC is in line with recent
311 evidence from low- and middle-income countries (LMIC)^{47,48} and confirms the urgency of improving
312 care during labour and birth, when half of all global stillbirths occur^{1,3,47,49}. Further, similar to other
313 reports^{47,48} we identified infection as a top cause of stillbirths in LIC, confirming the importance of
314 infection prevention and management^{3,49,50}. Our findings clearly highlight the importance of placental
315 conditions as a major contributor to stillbirths in all settings, consistent with other recent studies^{47,51}.
316 However, many placental conditions were ill-defined and the causal link unclear (for instance delayed
317 villous maturation)^{52,53}. Many conditions that lead to stillbirth are also linked to neonatal deaths and
318 therefore both must be accommodated within a single system to ensure optimal pregnancy care and
319 outcomes⁵⁴.

320 *ICD-PM and progress towards global reporting*

321 We confirmed findings of other studies, showing numerous disparate systems for classification of
322 stillbirths in use globally^{5,45,55}, further highlighting the need for a globally effective classification
323 system. A recent consensus described user-identified characteristics for such a system⁵⁶, however no
324 existing systems meet these characteristics⁵⁷. Further, robust evaluation of system performance is
325 limited⁶. The ICD-PM is the first system intended for global use in classification of perinatal
326 deaths^{4,58-60}, aiming to facilitate comparisons by improving perinatal mortality data, particularly in
327 high burden settings. While evaluation of the performance of ICD-PM is currently limited,
328 retrospective application to datasets in the UK and South Africa highlighted its values and provided
329 insights to future improvements⁵⁹. In our dataset, all causes of stillbirths reported globally could be
330 accommodated within the ICD-PM. However, our mapping of causes from good quality reports in
331 HIC using clinical classification systems highlights that classification system needs differ across
332 settings. Meeting the needs of diverse settings is essential for global comparisons to identify important
333 variation and inform programmatic change to reduce deaths.

334 The WHO Perinatal Mortality Audit and Review guide⁷ provides a tool to initialize audits in low-
335 income settings using the ICD-PM for classifying perinatal deaths. The ICD-PM maps ICD-10 codes
336 to an underlying fetal cause of antepartum, intrapartum or unknown timing, and a maternal condition;
337 thus, data collection must include timing as well as fetal and a maternal condition. While this approach
338 aims to capture information on stillbirths from low resource settings (either cause and/or associated
339 conditions) the ICD-PM faces challenges due to its ICD-10 provenance, including insufficient
340 differentiation of causes from associated conditions, and insufficient detail on maternal conditions⁸.
341 Conditions noted as Maternal in the ICD-PM include not only fetal underlying causes (*Placenta, cord
342 and membranes*), but also maternal causes (*Maternal complications of pregnancy*) and maternal
343 associated conditions (*Maternal medical and surgical conditions*). Further, one-fifth of stillbirths in
344 the global category *Unexplained* mapped to ICD-PM *Antepartum asphyxia*. Classifying associated
345 conditions is important, particularly in data poor settings where assigning cause may be difficult.
346 However confusing causes from associated conditions or mechanisms of deaths (antepartum

347 asphyxia) while reducing the number of *Unexplained*, may obscure key areas for prevention. WHO
348 is currently working towards ICD-11 which provides an opportunity to alleviate some of these
349 issues[World Health Organization, #269].

350 Differences in proportions of causal categories across countries, were likely due to different
351 classification approaches. Codac¹⁹ was the only non-ICD system fully aligned with the ICD-PM.
352 Although Codac has previously been shown to be the best-performing system⁴⁵, the majority of
353 stillbirths classified using Codac were mapped to unknown timing and cause within the ICD-PM (data
354 not shown). Codac also resulted in a high proportion of *Unexplained* stillbirths, potentially influenced
355 by the categories included. Moreover, this system was only aligned with nine of the 17 user-identified
356 characteristics for an effective global system. Future enhancements to global classification of
357 stillbirths need to incorporate user-identified characteristics for an effective global system. Further,
358 optimisation of information from data-rich settings to incorporate recent advances in stillbirth
359 aetiology such as the consensus on placental pathology⁵³, and other detailed laboratory investigations
360 will serve to advance prevention of stillbirths globally. Implementation of any system must also be
361 accompanied by appropriate training to ensure high-quality data.

362 **Conclusion**

363 To achieve the Every Newborn Action Plan global stillbirth rate target, improving care of women in
364 labour and birth and preventing and treating infections and the quality of data on causes to drive
365 change are priorities. Implementation of ICD-PM as part of the WHO Perinatal Mortality Audit and
366 Review guide⁷ would be a major step forward. While the ICD-PM captures data from high-burden
367 settings by allowing for a minimum of timing and clinically defined causes and associated conditions,
368 a global system must also accommodate needs of data-rich settings to enable global comparisons.
369 Clearly ascertaining underlying causes separate from associated conditions and enabling capture of
370 more detailed information in data-rich settings will fully harness the ICD-PM's potential for global
371 reporting and prevention of stillbirths. Further research is needed to improve the classification of

372 placental causes of stillbirths. Enhancements to global classification of stillbirths and neonatal deaths
373 must be based on comprehensive testing across diverse settings.

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380 **Disclosure of Interests**

381 GS receives/has received research support from GE (supply of two diagnostic ultrasound systems),
382 from Roche (supply of equipment and reagents for biomarker studies, value £596,142) and from GSK
383 (£199,413 for in vitro studies on human myometrium). GS has been paid to attend advisory boards
384 by GSK and Roche. GS has acted as a paid consultant to GSK. GS has received support to attend a
385 scientific meeting from Chiesi. GS is named inventor in a patent submitted by GSK for a novel
386 application of an existing GSK compound for the prevention of preterm birth (PCT/EP2014/062602).
387 GS was a member of a GSK Data Safety Monitoring Committee for a trial of RSV vaccination in
388 pregnancy and infancy, 2016-2017.

389 **Contribution to Authorship**

390 HR was responsible for the conduct of the study. VF conceptualized the study and developed methods
391 and procedures with HR, MC and SHL. HR, VF, SHL, AW and ZT undertook searches, selection of
392 studies, data extraction and quality assessment. GG, DE, RL and VF created the global stillbirth
393 categories. MC oversaw all statistical aspects of the study and undertook the pooled analysis. VF and
394 SHL undertook the assessment of ICD-PM alignment with advice from RP, JG, ÖT and EA. HR and
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