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1	Asking different questions: a call to action for research to improve the quality of care for
2	every woman, every child

#### 3

# Abstract

4 Despite decades of considerable economic investment in improving the health of families and 5 newborns world-wide, aspirations for maternal and newborn health have yet to be attained in 6 many regions. The global turn towards recognizing the importance of positive experiences of 7 pregnancy, intrapartum, postnatal care, and care in the first weeks of life, while continuing to 8 work to minimize adverse outcomes, signals a critical change in the maternal and newborn 9 health care conversation and research prioritization. This paper presents "different research 10 guestions" drawing on evidence presented in the 2014 Lancet Series on Midwifery and a 11 research prioritization study conducted with the World Health Organization. The results 12 indicated that future research investment in maternal and newborn health should be on 'right 13 care,' which is guality care that is tailored to individuals, weighs benefits and harms, is person-14 centered, works across the whole continuum of care, advances equity, and is informed by 15 evidence, including cost-effectiveness. Three inter-related research themes were identified: 16 examination and implementation of models of care that enhance both wellbeing and safety; 17 investigating and optimizing physiological, psychological and social processes in pregnancy, 18 childbirth, and the postnatal period; and development and validation of outcome measures that 19 capture short and longer term well-being. New, transformative research approaches should 20 account for the underlying social and political-economic mechanisms that enhance or constrain 21 the well-being of women, newborns, families and societies. Investment in research capacity and 22 capability building across all settings is critical, but especially in those countries that bear the 23 greatest burden of poor outcomes. We believe this call to action for investment in the three 24 research priorities identified in this paper has the potential to achieve these benefits and to 25 realize the ambitions of Sustainable Development Goal Three of good health and well-being for 26 all.

## 27 28 Keywords 29 Research priorities, maternal and newborn health, sustainable development goals, guality of 30 care 31 32 Introduction and Background 33 We are an alliance of global stakeholders, comprised of academics, researchers, clinicians, 34 policymakers, and service users who collaborated on a research prioritization study (1) with the 35 World Health Organization (WHO) in response to the Lancet Series on Midwifery (1-5). This 36 series started with a re-analysis of the evidence on quality care (1). Instead of examining the 37 evidence from the perspective of the health system or workforce, this critical synthesis of 38 quantitative and qualitative evidence examined the care and services that women and newborn 39 infants need. This process, described in more detail below, identified a serious imbalance in the 40 current evidence base; the great majority of existing research focuses on the treatment of 41 complications when they occur, with very little on their prevention or the support of women, 42 where most gains are to be made. This re-analysis demonstrated that care within the scope of 43 midwifery has a critical contribution to make, with the potential to improve survival, health, and 44 well-being, while reducing morbidity and resource use (1,2). Skilled midwifery was shown to be 45 not only a question of workforce, but to be core to the provision of quality care. There is an 46 urgent need to consider future research priorities in the light of these findings. 47 This paper reports on work that has followed on from that analysis, to identify research 48 priorities to improve the quality of care for women and newborns, including the implementation 49 of full scope midwifery. A research prioritization study was conducted to identify the most

51 newborn health, including the perspectives of what matters most to women themselves (1).

pressing research priorities aimed at addressing critical knowledge gaps in maternal and

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52 Since publication of this research prioritization study, we have formed a research alliance, 53 including funders and donors, to address and implement the priorities. Our aim is to improve 54 and expand the knowledge base to support the United Nations/WHO "survive, thrive, and 55 transform" agenda (6). The promotion of sustainable, context-specific, high-quality care holds 56 potential for optimal physical, psychological, and social well-being for women, newborn infants, 57 and families in both the short and longer term.

58 Despite decades of considerable economic investment of foundations, governments, and 59 individuals in improving the health of families and newborns world-wide, aspirations for maternal 60 and newborn health have yet to be attained in many regions (7). This may be explained in part 61 by the fact that only an estimated 7% of these funds have been invested in women and girls (8). 62 Additionally, the majority of studies have focused on reducing maternal and infant mortality and 63 treating short-term morbidity, rather than building the economies, infrastructures, and skilled 64 clinical workforces needed to reduce preventable death and suffering (9: 10). Some multicenter 65 studies have generated new knowledge and improved outcomes, yet contrary to anticipation 66 others have not demonstrated improvement. For example, one large multicenter trial found no 67 significant difference in maternal and newborn care outcomes after implementing a safe birth 68 checklist (11). In addition, there have been unanticipated consequences of implementing 69 technology across settings before long term health implications were known (12). The near 70 universal implementation of continuous electronic fetal monitoring in high resource settings has 71 contributed to the cesarean epidemic and elevated maternal mortality associated with over-72 intervention (13). Nonetheless, electronic fetal monitoring continues to be investigated via 73 funded randomized clinical trials, even though no benefit has been demonstrated in over 20 74 years of research (14-16).

Research resource waste and the length of time it takes for high-quality evidence to reach frontline health care and improve outcomes remain major concerns (17; 18). Many promising technological innovations in maternal and newborn care, such as video consultation in antenatal

78 clinics, are characterized by non-adoption or abandonment by individuals, or by failed attempts 79 to scale up locally, spread distantly, or sustain over the longer term at the organization or 80 system level (19). We contend that this reflects a lack of attention to implementation science, or 81 inquiry which accounts for "the act to carry an intention into effect, which in health research can 82 be policies, programmes, or individual practice" (20). Furthermore, what research gets funded 83 and what findings get implemented can reflect gendered, cultural, and other power-laden 84 hierarchies that privilege some voices and silence others (21; 22). Without understanding the 85 contexts in which research is implemented and adapted, sustaining or generalizing the findings 86 will be difficult and may too often result in what has been called the 'plague of pilots' wherein 87 most projects fail or never go to scale, despite their initial promise for improving health (23).

For these reasons, *the time has come to ask and answer different research questions*. The global turn towards recognizing the importance of prevention and of positive experiences of pregnancy, intrapartum, postnatal care, and care in the first weeks of life, while continuing to work to minimize adverse outcomes, signals what we see as a critical change in the maternal and newborn health care quality conversation and research prioritization (24-28).

93 The Quality Maternal and Newborn Care Framework (QMNC) (Figure 1) describes the full 94 scope of care that should be accessible to all women and newborns (2). The evidence for the 95 framework was drawn from data analyses presented in the Lancet Series on Midwifery (2-5). An 96 extensive review of evidence included 461 Cochrane reviews of practice, 7 systematic reviews 97 on workforce studies, and 13 meta-syntheses on women's views and experiences (2). Over 50 98 outcomes were improved by midwifery, including but not limited to decreased maternal and 99 newborn mortality, fetal loss, preterm birth, low birthweight, and interventions in labor. Women 100 were more likely to breastfeed, have improved psychosocial outcomes and birth spacing, 101 shorter hospital stays, and to be attended by a known midwife. All the components of the 102 framework, except the top right box (medical care for complications) are within the scope of 103 midwifery practice and reflect not only how care is organized and delivered, but also the skill of

the practitioner and the philosophy and values upon which it rests, much of which is focused on
prevention and strengthening women's capabilities. However, much of funding investment to
date has been targeted toward research on complications of pregnancy and birth (29).

107 Modeling analyses presented in the Lancet Series on Midwifery demonstrated that if the 108 model of care and philosophy described in the framework were widely applied, fewer women 109 and newborns would require referral and treatment services for serious complications. The 110 Lives Saved Tool was used to estimate the number of maternal and newborn deaths that could 111 be averted if quality care, as described in the framework, were scaled up in 78 countries that 112 bear the largest burden of maternal and newborn mortality (3). Scaling up midwifery care that 113 includes family planning, could prevent 83% of all maternal deaths, stillbirths, and neonatal 114 deaths. The third paper in the series presented extensive case studies of four countries that had 115 sustained decreases in maternal mortality over two decades while increasing access to 116 midwifery services, in order to understand interventions they used to strengthen their health 117 systems (4). Across the four countries, they found an expansion of health facility networks, 118 increased production of midwives and facility birthing, and decreased financial barriers. There 119 was political will and commitment to improving maternal and newborn health, and midwifery was 120 an integral part of the solution.

121 Collectively, the extensive body of good quality quantitative and qualitative evidence that 122 informed the QMNC framework demonstrates that care focused on knowledge, skills, and 123 positive interpersonal relationships results in optimal outcomes, especially when each level of 124 care is well integrated between and across health and social systems (30). These findings 125 support a system-level shift from the current primary focus on the identification and treatment of 126 pathology for the minority. The evidence calls, instead, for a 'both-and' approach, which 127 prioritizes skilled, tailored, respectful, preventive, and supportive care for all mothers and 128 newborns and strengthens women's capabilities for normal reproductive processes, as well as 129 identifies and treats pathologies for the minority requiring those services (Figure 2).

130 The QMNC Framework reflects the benchmarks of quality care needed by all childbearing 131 women and infants. Further analysis shows that the majority of this care is provided best by 132 midwives who are well educated, highly skilled in sexual and reproductive health, with effective 133 professional regulation, and are integrated and supported within health care systems and who 134 work in the context of interdisciplinary teams. However, a challenge in past research is the lack 135 of specificity around what constitutes skilled midwifery care in many workforce studies. This has 136 contributed to global confusion about the role and impact of midwives, in part because 137 numerous studies have conflated care by midwives with care by non-professional health 138 workers who not only lack adequate education and training, but sometimes must function in 139 isolation and in the absence of even the most basic of resources (2; 31; 32). Are poorer than 140 expected outcomes in some studies then a result of poverty, an under skilled workforce, a lack 141 of systems integration, or a combination of factors that lead to low quality care? Without clear 142 definitions and attention to a complexity of intersectional factors, outcomes of cross-country 143 research are challenging to interpret. Thus, there is a clear need to prioritize future research to 144 address these complexities.

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### 146 Method for Identification of the Research Priorities

147 The research prioritization study was undertaken in collaboration with WHO (1). Researchers 148 used a modified Child Health Nutrition Research Initiative method to ask global stakeholders 149 across disciplines and populations relevant to maternal and newborn health to identify and rank 150 future research priorities on quality maternal and newborn care, and the contribution of 151 midwifery to that care. Participants (N=271) ranked priorities across the continuum of 152 preconception, pregnancy, labor, birth, postnatal, newborn, and early weeks of life, taking into 153 account short and longer term outcomes. They were also asked to consider what questions and 154 approaches would matter most to childbearing women and families. Five criteria were used to

support the final scoring and prioritization of each of the topics (Table 1) See reference (1) for amore detailed description of the method.

Eleven top research priorities were identified (1). We have combined them into three broad, interconnected areas for future research (Figure 3). Below we discuss the relevance and key components of each priority and propose some next steps for initiating a research-driven approach to decreasing preventable global maternal and newborn death and suffering.

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162 **Research Priority A:** Evaluate the effectiveness of midwifery care as defined by the QMNC 163 framework and the contribution of its components, when compared to other models of care 164 across various settings, particularly on rates of maternal/fetal/infant death, preterm birth, and 165 low birth weight; and on access to and acceptability of family planning services. 166 This priority is underpinned by the following assumptions 167 a. The evidence-informed QMNC framework provides a conceptual foundation to examine 168 and compare operational elements and mechanisms across a range of models of care. 169 b. All future research on models of maternal and newborn care should involve women, 170 communities, advocacy groups and clinicians in study design and conduct, and 171 interpretation of the findings. 172 c. We have found no randomized trials of skilled midwifery or midwifery models of care in 173 low resource settings, rather the focus has been on birth attendants with highly variable 174 levels of training and access to essential supplies and resources. The study of models 175 and philosophies of care is urgently needed in low and middle resource countries where 176 the potential benefits are greatest. In high resource countries, the need is particularly to 177 reduce the iatrogenic risks of over-treatment. In all settings, there is a need to 178 understand prevention, how to strengthen women's own capabilities, and how to 179 enhance positive well-being for mother and newborn in the short and longer term.

d. Given the evidence of cost-effectiveness and high levels of acceptability of midwife-led
continuity of care from high-resource settings, and WHO recommendations for
implementation of this approach where the health system is able to support it, there is a
critical need to understand the mechanisms that underpin the effectiveness of these
models (33). This should include the short and longer term outcomes subsequent to
introducing these in low resource settings, and what underpins effective implementation
and sustainability in all settings, using the QMNC framework.

e. Place of birth is also of increasing interest to policy makers, and there is evidence that
community (home and birth center) settings are beneficial for some women and
newborns in high income settings (34-39). There is also a need to study alternative
models of care in settings where facility-based birth is problematic for those who cannot
attend for logistical reasons such as distance or economic constraints.

192 There is high quality evidence, based on trials conducted in high resource countries that 193 midwife-led continuity of care, compared to other models of care, improves a range of outcomes 194 for women and infants including lower rates of preterm birth and fetal loss, higher levels of 195 maternal well-being, and overall lower health care costs (40). However, similar data are lacking 196 in low resource countries, particularly about how midwife-led continuity of care is delivered and 197 in what settings. Despite the evidence on the benefits of planned home birth and community 198 and hospital birth centers for healthy women and newborns (37; 39; 41-43) in high resource 199 settings, these models have been minimally studied in middle or low resource settings, a gap 200 that urgently needs to be filled. As described above, the addition of family planning services as 201 part of the provision of quality maternal and newborn care has been estimated to markedly avert 202 maternal and neonatal mortality (3), yet there are few studies that have examined integration of 203 this component of care into the scope of midwifery practice.

204 Using the QMNC framework to design and inform analyses in future research will allow
205 some level of consistency across models of care being tested and compared with other models,

206	and maximize the potential for substantial impact on outcomes. Future research should attempt		
207	to examine the full scope of midwifery care within the QMNC framework, including family		
208	planning services and care across the continuum of preconception, pregnancy, labor, birth,		
209	postnatal, breastfeeding, and the first few weeks of life.		
210	We propose research designed to meet this priority should include, but not be limited to the		
211	following questions:		
212	1. Using the QMNC framework, what are the features of models of care that provide		
213	optimal clinical outcomes and positive antenatal, intrapartum, postnatal, and early		
214	life experiences for women and newborns across all resource settings and within		
215	specific sociocultural contexts, and how can these be replicated or scaled up?		
216	2. What are the short and longer term outcomes of different models of midwifery,		
217	including midwife-led care continuity of care based on the QMNC framework in		
218	middle and low resource settings?		
219	3. In all resource settings, what are the unique barriers or facilitators to implementing		
220	midwifery models of care, including midwife-led continuity of care as reflected in the		
221	QMNC framework?		
222	4. What strategies could be used to upskill midwifery workforces to provide the full		
223	scope of midwifery, including midwife-led continuity of care across settings through		
224	improvement and implementation science as determined by distinct contexts?		
225	5. What kinds of community birth places are optimal for healthy women and		
226	newborns, and how should these be embedded in the wider health system to		
227	ensure right sizing and appropriate delivery of obstetric resources?		
228			
229	Research Priority B: Identify and describe aspects of care that optimize, and those that disturb,		
230	the biological/physiological processes for healthy childbearing women and fetus/newborn infants		
231	and for those who experience complications.		

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232 This priority is underpinned by the following assumptions:

a. Health and well-being for childbearing women and their newborns and infants is acontinuum, with long term impacts, including for subsequent generations.

b. The health status of the mother from the preconception period and throughout

236 pregnancy can be protective or hazardous for the subsequent childbirth and postnatal

period and can impact the ability to breastfeed and care for the newborn and otherchildren.

c. The majority of women across resource settings and contexts (including some who have
 complications) have the potential to labor and to give birth safely as a result of naturally
 occurring biological and physiological processes (25).

242 d. Behaviors, attitudes, care processes, birth environment, and interventions enacted by 243 maternal and newborn care providers can actively optimize or disturb the naturally 244 occurring biological and physiological processes of pregnancy, labor and birth, postnatal, 245 breastfeeding and the early weeks of life, with short and longer term outcomes (44). 246 A woman's health and well-being before and during pregnancy, and how that has been 247 supported, sets the stage for the labor and birth and beyond. Further challenges in conducting 248 research include the interactions among psychological, emotional, and physical factors, 249 including cognitive and cultural beliefs about pregnancy, childbirth and breastfeeding, the 250 familial and social setting in which the childbearing woman lives, and where and how maternal 251 and newborn care takes place. These include social determinants of health such as poverty, 252 inequitable access to care, advertising, marketing, and social pressures, among many other 253 factors. A positive or traumatic experience in pregnancy, birth, or the postnatal period also has 254 the potential to affect future pregnancies; the woman's childbearing journey can have 255 cumulative physical and psychological effects over her reproductive life time and beyond. 256 Much of what we currently understand about the naturally occurring physiology of the 257 perinatal period and breastfeeding of the newborn, is based on animal models and population-

258 based studies. In the case of the latter, understanding of human physiological processes during 259 the entire childbearing continuum is heavily confounded by commonly used procedures and 260 interventions. Few studies have prospectively examined the effect of care models, procedures, 261 attitudes, behaviors, and settings on short and longer term biological and physiological 262 processes of pregnancy, birth, breastfeeding and the neonatal period. The Epigenetic Impact of 263 Childbirth Research Group (45) posits that the use of interventions during the intrapartum 264 period, such as synthetic oxytocin, antibiotics, and cesarean delivery, can impact epigenetic 265 remodeling, microbiomial integrity, and subsequent health of the mother and children. There is 266 also growing literature on the importance of breastfeeding on the microbiome and thereby on 267 the immune system (46; 47).

268 Buckley has compiled an impressive body of work that examines the hormonal physiology of 269 childbirth (44). She suggests that the perinatal period is a "window of heightened sensitivity, with 270 potential longer-term impacts," not only for the entire perinatal period, but also across the life 271 course. 'Optimality' during the perinatal period has been defined as the, "maximal perinatal 272 outcome with minimal intervention placed against the context of the woman's social, medical, 273 and obstetric history" (48). This suggests that in order to achieve best outcomes, there are 274 complex intersections to balance care practices with the woman's needs and those of her baby. 275 All of the components of the QMNC framework directly or indirectly reflect this research priority; 276 however, practice, philosophy, and values specifically address care that preserves normal 277 physiological processes and is respectfully tailored to the woman's individual needs.

We propose research designed to meet this priority should include, but not be limited to thefollowing questions:

What are the biological, physiological, psychological, sociological, and cultural features
 of physiological pregnancy, labor and birth, postnatal, breastfeeding, and the newborn
 period (hereafter referred to as the childbearing continuum), and how are they influenced
 across care settings and models of care?

284	2.	What specific practices, attitudes, and behaviors optimize or disturb biological and	
285		physiological processes across the childbearing continuum, in a range of health system,	
286		sociocultural, geographic, and commercial contexts?	
287	3.	How do organizational and birth environment factors, including setting, architecture,	
288		artifacts, policies, and access to care optimize or disturb biological and physiological	
289		processes across the childbearing continuum?	
290	4.	How do providers' attitudes and behaviors optimize or disturb biological and	
291		physiological processes across the childbearing continuum, and how are they influenced	
292		by disciplinary training and norms, experience, philosophy, and preparation?	
293	5.	How do the attitudes, behaviors, and pre-birth preparation activities of women, their	
294		partners, and families optimize or disturb biological and physiological processes across	
295		the childbearing continuum?	
296	6.	What are critical lifetime reproductive, life course, and inter-generational outcomes that	
297		are impacted by optimization or disturbance of naturally occurring biological and	
298		physiologic processes across the childbearing continuum?	
299			
300	Resea	rch Priority C: Determine which indicators, measures, and benchmarks are most	
301	valuable in assessing quality maternal and newborn care across settings, including the views of		
302	women; and develop new ones to address identified gaps.		
303	3 This priority is underpinned by the following assumptions:		
304	a.	Most outcomes and instruments currently used in maternal and newborn care research	
305		are focused on mortality, morbidity, and short-term assessments. There is increasing	
306		recognition of the connection between positive maternal and newborn care experiences	
307		and clinical outcomes and growing evidence on what matters to women. Taken together,	
308		these indicate that the focus to date on pathology and short term outcomes has	

309		excluded an extensive and critical area of outcomes assessment of positive childbearing
310		care and experiences.
311	b.	When involving trials research, we support the goals of the CROWN initiative (49);
312		however, it is likely that the metrics and measures used in traditional and established
313		research approaches, including randomized controlled trials, will fall short in capturing
314		the complexity of care during the childbearing continuum and first weeks of life; outcome
315		measures need to be tailored to individuals and their local context.
316	C.	Mixed method approaches that include quantitative and qualitative data, and the active
317		engagement of women and service users in the design and conduct of research, are
318		more likely to capture the complex interactions between health services and experience
319		of care and outcomes during the childbearing continuum and first weeks of life.
320	d.	Most nations, states, provinces, health systems, institutions, professional organizations,
321		and special interest consumer/service user groups have unique data needs that are
322		context-dependent.
323	e.	It is possible to develop shared data collection tools, databases, and analytic strategies
324		that identify existing measures and instruments for optimal maternal and newborn
325		outcomes in the short and longer term, and to address related gaps.
326	f.	Facilitating access to a pool of standardized, validated instruments and metrics that can
327		be tailored for local cultural, social and economic contexts, could promote cross-cultural
328		and cross-setting assessment, and appropriate locally-relevant and evidence-informed
329		recommendations.
330	This p	urpose of this priority is to optimize procedures and opportunities for identifying and
331	develo	pping indicators, measures, and benchmarks that may be used to assess and compare
332	quality	of care, as defined by service users, as well as by health systems (5). We propose that

333 facilitation of coordinated data collection and databases, and open access spaces that can serve

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334 as repositories for sharing validated measures, will substantially improve the ability of researchers 335 and decision-makers to examine maternal and newborn care across settings and populations. 336 It is critical that existing instruments, benchmarks, and metrics are assessed for a high 337 degree of context specificity. Funding could enable the synthesis of a set of methodologies for 338 the adaptation and validation of tools locally that could be made widely available by Open 339 Source type access. Where gaps exist, new instruments and methods should be developed, 340 with particular regard to understanding what matters in the short and longer term, especially for 341 underserved and vulnerable populations. 342 Transdisciplinary communities of colleagues with expertise on practice, philosophy, 343 organization of care/health systems, and policy can help to define concepts that have not yet 344 been adequately or reliably described and to create composite measures for complex 345 phenomena such as inter-professional collaboration or maternal perceptions of respectful care, 346 to name a few. Furthermore, it may be possible to develop an index to assess components of 347 care that promote or detract from quality of care at the institutional level. 348 Future work in this priority should identify significant gaps in validated instruments that can 349 assess the impact of models of care on maternal and newborn outcomes, measure quality and 350 experience of care from a service user perspective, and evaluate components of care that 351 optimize, or disturb, the biological/physiological processes of the childbearing continuum in the 352 short and longer term. 353 We propose research designed to meet this priority should include, but not be limited to the 354 following questions: 355 1. Can a culturally, linguistically, and socially relevant minimum data set be created to 356 evaluate the "different questions" proposed by the Lancet Series on Midwifery global

357 health stakeholders (1), taking into account positive experiences and short and longer

358 term outcomes? Can this minimum data set reflect what matters to women and service

359 users, including those most vulnerable and marginalized?

360	2.	How do we create and make more widely available an item bank of existing, validated	
361		measures and indicators that align with the QMNC framework?	
362	3.	How do we best evaluate existing models of care using the QMNC framework, including	
363		short and longer term health outcomes and cost effectiveness?	
364	4.	How do we best assess gaps in measures and indicators and support targeted	
365		development of new ones to capture all components of the QMNC framework across the	
366		childbearing continuum and in the first weeks of life in all resource settings?	
367	5.	How can we best ensure and support community-led design, development and validation	
368		of new measures of the impact of the lived experience of care on quality and safety, as	
369		defined by the person?	
370	6.	How can these measures be used most effectively to support quantifiable improvements	
371		in both clinical indicators and maternal experiences? Are they more applicable to	
372		research, evaluation or quality assurance/quality improvement programs in existing form,	
373		or do they have cross-cutting value?	
374			
375	Discu	ssion	
376	Over the past decade the survival and health of childbearing women and their newborns		
377	globally has improved, but rates remain unacceptably short of the United Nations Development		
378	Programme Sustainable Development Goals (50). There is a growing recognition that high		
379	levels of mortality and morbidity are co-existing with excessive rates of intervention and failures		
380	in the quality of care across the childbearing continuum and into the early weeks of life. This is		
381	associated with iatrogenic damage in the short term, and possibly into the longer term and even		
382	transgenerational (51). There is also a global turn towards valuing positive outcomes of		
383	maternal and newborn care, as well as the reduction of negative outcomes (24-26).		
384	Ne	ew insights into mechanisms of effect generated by critical and realist research	

385 philosophies suggest that the kinds of questions that have been asked for decades by funders

and researchers may not be suitable for the complex adaptive systems under examination, such
as maternal and newborn care (52-54). Researchers may not pay enough attention to the
issues of what works, for who, in what contexts, or short and longer term outcomes that matter
to stakeholders (20). They may focus on individual interventions and their effects, rather than on
the broader picture of preventive and supportive care for all.

391 We argue that future investment in maternal and newborn health should be focused on "right 392 care" - that is, care which is tailored to individuals, weighs benefits and harms, is person-393 centered, works across the whole continuum of care, advances equity, and is informed by 394 evidence, including cost-effectiveness (33). The challenge is to find the right care that will help 395 balance the "too little too late" phenomenon of poor access to safe, quality care, with care that is 396 "too much too soon" in settings which often results in unnecessary interventions (34). Along with 397 using well established research methods, we will need to evolve new, transformative 398 approaches that consider the underlying social and political-economic mechanisms that function 399 to enhance or constrain the well-being of women, newborns, families and societies within a 400 complex global network marked by resource inequity.

401 Policy decisions should be informed by evidence, and for this we need more investment in 402 implementation research to understand health systems and test solutions in a range of 403 situations and contexts. The involvement of end users, and particularly the political will within 404 system hierarchies in identifying problems and solutions provides vital insights and increases 405 the likelihood that they will be relevant and appropriate for large-scale implementation (4; 5; 55). 406 Policymakers' involvement should be part of the assessment criteria of any research proposal 407 and policy-level implementation should be considered in the dissemination of research findings 408 (20; 56; 57).

Future research programs must include new kinds of questions that involve local
communities and are co-designed with women and other stakeholders. The questions should be
designed to ensure that the resulting findings contribute to the achievement of health equity,

and therefore consider the needs of the most vulnerable. Ideally, studies should be undertaken
across a range of centers, including low, middle, and high resource settings. Research
programs should encompass biological, psychological, emotional, social, economic, cultural,
and life course aspects of the childbearing continuum and the first weeks of life and should
include settings where minimal intervention and optimal outcomes are the norm.

This effort will require a system-wide shift and a different lens. It will be critical to strengthen inter- and trans-disciplinary research capacity and capability building across midwifery, obstetrics, pediatrics and other fields, such as economics, epidemiology, engineering, architecture, and social sciences to fully examine the complexities of quality maternal and newborn care. This investment should be across all settings, but especially in those countries that bear the greatest burden of poor outcomes.

423

### 424 Conclusion

425 It is important to provide timely and effective treatment and interventions for the minority of 426 women and infants who experience pathology. However, it is also essential to provide high 427 quality skilled care for all women, infants, and families, and thereby to enhance health and well-428 being for all in the short and longer term. This can be done by the conduct of research and 429 ensuring the provision of skilled, respectful, preventive and supportive care for all and by 430 maximizing the benefits of physiological pregnancy, labor, birth and the postnatal and neonatal 431 period, to ensure positive motherhood, parenthood, and early years of health and development. 432 We believe this "call to action" for investment in the three research priorities identified in this 433 paper has the potential to achieve these benefits and to realize the ambitions of Sustainable 434 Development Goal 3 (50) and the "Every Woman Every Child Survive, Thrive, Transform" 435 agenda (6).

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### 594 Figure 2. Emphasis for future research



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598 Figure 3. Interconnection of the future research priorities to improve the quality of care for every 599 woman, every child

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Criterion	Definition	
Maximal Impact	Is it likely the research will lead to high quality care for women, infants, and families; improve the short- and/or long- term physical, social and emotional health and well-being of women, infants, and families; and/or have an impact on the broad social conditions of people's lives that influence health and well-being?	
Answerability	Can the new knowledge lead to an efficacious intervention or program?	
	Is the research question clear and transparent about process and outcomes and respects ethical principles that protect human rights?	
Community* Involvement	Does the research have the potential to engage communities	
*Community includes women, infants, girls, families, and the context in which	about topics important to them and/or include groups that are seldom heard, often excluded, or hard to reach?	
they live, but could also include clinicians; user groups of services, policymakers, etc.	Are the proposed interventions or programs deliverable and acceptable to the community?	
Sustainability	Is it likely that there will be adequate resources and commitment to the conduct of the research and/or that the implementation of the research results will be affordable over time in a variety of settings?	
	Can the interventions or programs improve maternal and newborn health substantially over time?	
Equity	Does the research have the potential to reduce inequities by including those most vulnerable to poor outcomes and/or enhancing the health and well-being of ALL childbearing women, infants, and families?	

Table 1. Definitions of criteria used for scoring research priorities (listed in order of rank)

Concept Paper Commentary – Response to Reviewers

Reviewer Comment	Response		
Reviewer 1:			
I am not an expert in Global Women's and Children's Health, but I have spent 6 months in the publically-underfunded obstetrical trenches in urban and rural Kenya. I find this commentary too general, naïve, and over-encompassing in scope to be an interesting read or helpful in setting a research agenda.	Thank you for your assessment. We have gone back over the manuscript to more thoroughly outline the findings from the Lancet Series on Midwifery and the gaps upon which the priorities were identified.		
<b>Precis:</b> We should study every physiological, psychological, social, familial, cultural, economic, and political factor at the local, regional, national, and international level that influences the continuum of pre-conceptual, antenatal, intrapartum, postpartum and newborn care in the context of a woman's life-cycle, with particular attention to the heretofore neglected areas of women's, children's and family's experiences and the expansion of a highly skilled midwifery care model to low-resource settings that currently struggle to pay for and provide basic, clean, obstetrical care for millions of poor women.	If we need a precis we would suggest the following: Future research investment in maternal and newborn health should be on 'right care,' which is tailored to individuals, weighs benefits and harms, is person-centered, works across the whole continuum of care, considers equity, and is informed by evidence, including cost-effectiveness. It should also address the relatively neglected study of women's, children's, and family experiences and the evidence gap around the implementation of skilled midwifery, particularly in low-resource settings.		
Reviewer 2			
I have a more favorable view of the article, which is well written and makes a good case for reframing research priorities to reflect a larger set of societal goals in childbirth.	Thank you.		
From an editorial perspective however, I think a midwifery journal would be a more appropriate venue as it is currently written as an interdisciplinary journal, I worry about Birth being perceived as a shill for any one professional interest. The authors and the working group that generated these priorities makes sweeping leaps in associating complex	We have added more specific data from the Lancet Series on Midwifery to support the justification for the system issues needed in future research. In addition, we have added clarification that the evidence supports that midwifery is core to quality, dignity, and equity.		

Reviewer Comment	Response
systemic challenges with "midwifery models of care." (I suspect this may be in part, the "over-encompassing scope" that Reviewer 1 is concerned with as well).	
E	ditor
I'm not quite sure what to do with reviews of this type. They are very general. I feel that setting an overall research agenda needs to be wide in scope, so reviewer 1's comment doesn't really bother me too much.	Great.
As far as reviewer 2's comment that the piece would be better placed in a midwifery journal, I disagree. Birth is at least in part about midwifery, and I want to keep it that way. We publish plenty of other articles more related to standard obstetrics, etc. As far as reviewer 2's comment about the "sweeping leaps in associating complex systemic challenges with midwifery models of care", I think the comment has some justification. Maybe some of the connections between systemic issues and midwife models of care need to be drawn more explicitly, particularly for readers less familiar with some of the midwifery literature on this.	See our comments above on how we approached this.
Bottom line - Please try to be responsive to the reviewers to the extent that you can.	