Raymond G. de Vries, Yasaswi Paruchuri, Kathleen Lorenz, and Saraswathi Vedam, "Moral Science: Ethical Argument and the Production of Knowledge about Place of Birth," *The Journal of Clinical Ethics* 24, no. 3 (Fall 2013): 225-38.

Moral Science: Ethical Argument and the Production of Knowledge about Place of Birth

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ABSTRACT

Ethical arguments about caregiver responsibility and the limits of client autonomy rely on best evidence about the risks and benefits of medical interventions. But when the evidence is unclear, or when the peer-reviewed literature presents conflicting accounts of the evidence, how are clinicians and their clients to recommend or decide the best course of action? Conflicting evidence about the outcomes of home and hospital birth in the peer-reviewed literature offers an opportunity to explore this question. We present the contrary evidence and describe the social and cultural elements that influence the production of the science of birth, including professional, publication, and critical bias. We then consider how the science of birth has been used an misused in making ethical arguments about preferred place of birth. We conclude with a number of recommendations about the responsible use of the evidence, arguing for an "ethics of information" that can be drawn on to guide caregivers and clients in the use of evidence for clinical decision making.

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The debate over place of birth is not new. Partisans in this debate—"home is safer," "hospital is safer"—support their position with opinion, anecdote, and scientific evidence. While the nature, content, and quality of the evidence used in the arguments over place of birth have changed over the years, one thing remains constant: both sides seek to frame the debate in a way that puts their opponent on the defensive. Those who favor birth at home ask, "Have hospitals stopped the flood of iatrogenic injuries suffered by healthy women who birth in hospitals?" And those who favor hospital birth begin with the question, "Have home birth providers stopped ignoring the lifesaving benefits of modern obstetrical technologies?" Both are classic examples of a loaded question, impossible to answer without incriminating oneself.

Consider the title of a session at the first European Congress on Intrapartum Care—sponsored by

European Association of Perinatal Medicine in 2013.[1] The program included several sessions on "controversies," one of which was titled, "Home Births: Are There Any Increased Risks?" The organizers did not recognize the biased nature of this question nor the way the question required proponents of home birth to assume a defensive posture. The session *could* have been called "Hospital Births: Are There Any Increased Risks?"—in which case, proponents of *hospital* birth would be placed on the defensive, required to prove there were no iatrogenic or nosocomial injuries associated with hospital birth. A more evenhanded approach would have been to organize a session called, "The Relationship Between Risks and Place of Birth," allowing both sides to muster evidence supporting their position.

In and of itself, this rhetorical strategy is not surprising: after all, we expect a good debater to create a frame that favors her or his side of the argument. What is surprising is that this framing also has shaped the production of the *science* that informs this debate. As we shall see, a researcher's preexisting beliefs about place of birth are almost never disconfirmed by their data. In an era when clinicians rely heavily on evidence-based medicine, the effect of framing on scientific research is troubling. If the frame in which data are generated and interpreted biases the evidence, how can a clinician provide patients with reliable information and advice? To help clinicians sort through conflicting evidence and to respond responsibly to patients' requests for information regarding place of birth, we review the literature on the safety of home and hospital birth, paying close attention to the ethical dimensions of the way the science on place of birth is produced and used.

COMPARING THE SAFETY OF HOME AND HOSPITAL BIRTH

Before we begin our review and analysis of the literature on the risks and benefits associated with place of birth, we must make a few important observations. Clearly, it is not appropriate to compare the outcomes of home birth attended by highly skilled, well-educated, and well-equipped midwives with outcomes of obstetrical care given by poorly trained staff in an inadequately equipped hospital. And the reverse also is true: it is not legitimate to compare the outcomes of home birth, when the qualifications of the attendant(s) are unknown, with birth in well-equipped hospitals with well-trained staff. Similarly, comparative studies of birthplace safety also must control for the health of the mother. It is not fair simply to compare home and hospital birth, because mothers with complications are far more likely to give birth in a hospital, skewing the rate of poor outcomes. Similarly, both prospective and retrospective studies must use an intention-to-treat design because *planned* place of birth is not synonymous with actual place of birth.

To fully understand the outcomes associated with place of birth, it is important to know where labor began, where the birth was intended to take place, and where it actually took place. The essential question of birth place safety is: Is birth such a risky and unpredictable event that it is dangerous for a healthy mother (and her baby) to labor and birth in an environment where the full complement of obstetrical technology is not immediately available?

The best place to begin our review is with the Cochrane Collaboration, an organization that generally is recognized as an unbiased source of information that can be used to guide clinical practice. This collaboration is, in its own words:

> . . . an international network of more than 28,000 dedicated people from over 100 countries . . . [who] work together to help healthcare practitioners, policy-makers, patients, their advocates and carers, make well-informed decisions about health care, by preparing, updating, and promoting the accessibility of . . . systematic reviews of primary research in human health care and health policy [which] are internationally recognised as the highest standard in evidence-based health care.[2]

The authors of the most recent review of the outcomes of planned hospital birth versus planned home birth, Olsen and Clausen, begin with an interesting historical note.[3] They point out that the origins of the Cochrane Collaboration—which reviews evidence on everything from anesthesia to urology—can be found in questions about birth place and safety: "one of the pivotal issues when Archie Cochrane laid out the ideological ground for The Cochrane Collaboration" was the "transfer of low-risk births from home to hospital in the 1960s, despite the lack of high-quality evidence" (p. 2).

The gold standard for generating clinically relevant evidence is a randomized double-blind trial (RCT), a standard that is difficult, if not impossible, to meet in the case of place of birth. Olsen and Clausen were able to identify only one RCT of place of birth, a study done in the U.K. that enrolled only 11 of the 71 women who were invited to participate.[4] A more recent effort in the Netherlands found only one woman who was willing to be randomly

placed in a home birth cohort or in a hospital birth cohort, in spite of the effort to recruit participants on the part of 35 midwives in 14 practices.[5] Olsen and Clausen point out that extremely large trials are required to discover differences in maternal and perinatal mortality (p. 15). The unwillingness of women to join an RCT for place of birth, and the likely negative effects of assigning women to give birth in a location they do not prefer, make it extremely unlikely a trial of that size will ever be done.

Given the near impossibility of an RCT, Olson and Clausen consider what can be learned from "observational studies"—that is, studies that cannot control for bias via randomization. They note that "the amount of observational evidence has grown tremendously" in recent years and that "the methods for assessing and including evidence from observational studies in systematic reviews have also improved" (p. 6). Drawing on their review of the observational studies of place of birth, they offer this "plain language summary" of the evidence (p. 2):

> Most pregnancies among healthy women are normal, and most births could take place without unnecessary medical intervention. However, it is not possible to predict with certainty that absolutely no complications will occur in the course of a birth. Thus, in many countries it is believed that the safest option for all women is to give birth at hospital. In a few countries it is believed that as long as the woman is followed during pregnancy and assisted by a midwife during birth, transfer between home and hospital, if needed, is uncomplicated. In these countries home birth is an integrated part of maternity care. It seems increasingly clear that impatience and easy access to many medical procedures at hospital may lead to increased levels of intervention which in turn may lead to new interventions and finally to unnecessary complications. In a planned home birth assisted by an experienced midwife with collaborative medical back up in case transfer should be necessary these drawbacks are avoided while the benefit of access to medical intervention when needed is maintained. Increasingly better observational studies suggest that planned hospital birth is not any safer than planned home birth assisted by an experienced midwife with collaborative medical back up, but may lead to more interventions and more complications. However, there is no strong evidence from randomised trials to favour either planned hospital birth or planned home birth for low-risk pregnant women.

Notice a few things about this summary: (1) the authors assert that most women with a healthy pregnancy do not require medical intervention, (2) the frame for their review is that planned hospital birth is an intervention that must demonstrate advantages if it is to replace the more traditional planned home birth, (3) the authors underscore the importance of collaboration between caregivers at home and in the hospital, and (4) the authors conclude that a planned hospital birth *may* lead to more interventions and complications, but they go on to acknowledge that, at present, there is no evidence from RCTs to favor either home or hospital birth for healthy women.

A CLOSER LOOK AT THE SCIENCE OF BIRTH PLACE

The scientific literature on place of birth and safety is substantial. In order to better understand what the Cochrane review characterizes as a "hot debate,"[6] we look at eight studies, chosen because they are the most cited or because they were published after the review by Olsen and Clausen. We begin by summarizing the articles, and we then consider how the science of place of birth is produced, looking at the professional identities of the researchers, the process by which their research found its way into the scientific literature, and the differences in the use of published studies.

Research on the Risk and Benefits Associated with Place of Birth

To the uninitiated, the most surprising aspect of studies of the outcomes associated with place of birth is the fact that they offer sharply conflicting conclusions. We use that fact to group the eight studies into four categories:

1. Studies questioning the safety of home birth,
2. Studies questioning the safety of hospital birth,
3. Studies finding no difference in outcomes, and
4. Studies that report varied benefit and risks associated with place of birth.

Some studies resist classification. As we will see, the study by van der Kooy and colleagues could be placed in category 1 or category 3.[7]

Category 1: Studies Questioning the Safety of Home Birth

J.R. Wax et al., "Maternal and newborn outcomes in planned home birth versus planned hospital births: a metaanalysis," *American Journal of Obstetrics & Gynecology,* 2010 (hereafter, the Wax study).[8]

This meta-analysis included 12 studies conducted between 1976 and 2006 and concluded that:

> Planned home births were associated with fewer maternal interventions including epidural analgesia, electronic fetal heart rate monitoring, episiotomy, and operative delivery. These women were less likely to experience lacerations, hemorrhage, and infections. Neonatal outcomes of planned home births revealed less frequent prematurity, low birthweight, and assisted newborn ventilation. Although planned home and hospital births exhibited similar perinatal mortality rates, planned home births were associated with significantly elevated neonatal mortality rates.

The authors concluded that "Less medical intervention during planned home birth is associated with a tripling of the neonatal mortality rate."

A. Evers et al., "Perinatal mortality and severe morbidity in low- and high-risk term pregnant women in the Netherlands: prospective study," *BMJ*, 2010 (hereafter, the Evers study).[9]

While this is not a study of home birth, it is often referred to in debates about home birth. The researchers combined data from a national perinatal register and data from prospective reports of all antepartum stillbirths, intrapartum stillbirths, neonatal deaths, and admissions to a level three neonatal intensive care unit (NICU) of term infants within the first seven days of life in the research area, to compare outcomes for women who began labor in primary care (that is, with midwives or general practitioners) at home or in the hospital, with women who began labor under the care of an obstetrician. The researchers found:

> Infants of pregnant women at low risk whose labour started in primary care under the supervision of a midwife had a significant higher risk of delivery related perinatal death than did infants of pregnant women at high risk whose labour started in secondary care under the supervision of an obstetrician (relative risk 2.33, 95 percent CI [confidence interval] 1.12 to 4.83). NICU admission rates did not differ between pregnancies supervised by a midwife and those supervised by an obstetrician. Infants of women who were referred by a midwife to an obstetrician during labour had a 3.66 times higher risk of delivery related perinatal death than did infants of women who started labour supervised by an obstetrician (relative risk 3.66, 95 percent CI 1.58 to 8.46) and a 2.5-fold higher risk of NICU admission (2.51, 95 percent CI 1.87 to 3.37).

Category 2: Studies Questioning the Safety of Hospital Birth

P.A. Janssen et al., "Outcomes of planned home birth with registered midwife versus planned hospital birth with midwife or physician," *Canadian Medical Association Journal*, 2009 (hereafter, the Janssen study).[10]

This is a prospective, five-year long cohort study with an "intention to treat" design, comparing outcomes among midwife-attended planned home births (n = 2,802), midwife-attended planned hospital births (n = 5,984), and physician-attended hospital births (n = 5,985). Women in all three groups of the study had comparable risk profiles measured in terms of their eligibility for home birth. The authors found no difference in the rates of perinatal death in the three cohorts. Women in the planned home birth group had significantly fewer intrapartum interventions, including narcotic or epidural analgesia, augmentation or induction of labor, and assisted vaginal or cesarean delivery. In addition, women in the home birth group were less likely to suffer from postpartum hemorrhage, pyrexia, and third or fourth degree tears of the perineum. Babies of women planning a home birth were less likely to have Apgar scores of less than five at one minute and the babies were less likely to need drugs for resuscitation.

E. Hutton, K. Reitsma, and K. Kaufman, "Outcomes associated with planned home and planned hospital births in low-risk women attended by midwives in Ontario, Canada, 2003-2006: a retrospective cohort study," *Birth*, 2009 (hereafter, the Hutton study).[11]

The authors used the Ontario Ministry of Health Midwifery Program (OMP) database to compare outcomes of all women planning a home birth from 2003-2006 (n = 6,692) with a matched sample of women planning a hospital birth (n = 6,692.) Women with contra-indications for home birth were excluded from the hospital sample. The researchers found, "The rate of perinatal and neonatal mortality was very low (1/1,000) for both groups, and no difference was shown between groups in perinatal and neonatal mortality or serious morbidity (2.4 percent versus 2.8 percent; relative risk [RR], 95 percent confidence intervals [CI]: 0.84 [0.68-1.03])." With regard to maternal outcomes, they report,

> Women in the planned home birth group experienced fewer intrapartum interventions for each specific intervention studied (induction, augmentation, pharmaceutical pain relief, episiotomy, assisted delivery), including an absolute decrease of 2.9 percent in the rate of cesar-

ean section (5.2 percent versus 8.1 percent, RR [95 percent CI]: 0.64 [0.56, 0.73]). Women in this group also had less perineal trauma and reduced incidence of blood loss greater than 1,000 ml.

A. de Jonge et al., "Severe adverse maternal outcomes among low risk women with planned home versus hospital births in the Netherlands: Nationwide cohort study," *BMJ*, 2013 (hereafter, the 2013 de Jonge study).[12]

The researchers used data from a national registry in the Netherlands to compare maternal outcomes for 92,333 (62.9 percent) healthy women who had a planned home birth and 54,419 (37.1 percent) healthy women who had a planned hospital birth. They found that the rate of severe acute maternal morbidity among planned primary care births was 2.0 per 1,000 births. For nulliparous women (women who would give birth for the first time), the rate for planned home versus planned hospital birth was 2.3 versus 3.1 per 1,000 births (adjusted odds ratio 0.77, 95 percent CI 0.56 to 1.06), relative risk reduction 25.7 percent (95 percent CI -0.1 percent to 53.5 percent), the rate of postpartum hemorrhage was 43.1 versus 43.3 (0.92, 0.85 to 1.00 and 0.5 percent, -6.8 percent to 7.9 percent), and the rate of manual removal of the placenta was 29.0 versus 29.8 (0.91, 0.83 to 1.00 and 2.8 percent, -6.1 percent to 11.8 percent). For parous women (women who have given birth one or more times), the rate of severe acute maternal morbidity for planned home versus planned hospital birth was 1.0 versus 2.3 per 1,000 births (0.43, 0.29 to 0.63 and 58.3 percent, 33.2 percent to 87.5 percent), the rate of postpartum hemorrhage was 19.6 versus 37.6 (0.50, 0.46 to 0.55 and 47.9 percent, 41.2 percent to 54.7 percent), and the rate of manual removal of the placenta was 8.5 versus 19.6 (0.41, 0.36 to 0.47 and 56.9 percent, 47.9 percent to 66.3 percent). The authors concluded, "there was no evidence that planned home birth among low risk [that is, healthy] women leads to an increased risk of severe adverse maternal outcomes in a maternity care system with well trained midwives and a good referral and transportation system."

Category 3: Studies Finding No Difference in Outcomes

A. de Jonge et al., "Perinatal mortality and morbidity in a nationwide cohort of 529,688 low-risk planned home and hospital births," *BJOG: An International Journal of Obstetrics & Gynaecology*, 2009 (hereafter, the 2009 de Jonge study).[13]

The authors used data from the Perinatal Registry Netherlands,[14] collected between 2000 and 2006, to conduct a retrospective cohort study of 529,688 low-risk women who were in primary midwife-led care at the onset of labor. They compared perinatal mortality and morbidity for planned home births (321,301; 60.7 percent), planned hospital births (163,261; 30.8 percent), and unknown place of birth (45,120; 8.5 percent), controlling for parity, gestational age, maternal age, ethnic background, and socio-economic status. Criteria for inclusion was that subjects were strictly low risk. The main outcomes were intrapartum death, intrapartum and neonatal death within 24 hours and seven days after birth, and admission to a NICU. No significant differences were found between planned home and planned hospital births for any of the main outcomes.

J. van der Kooy et al., "Planned home compared with planned hospital births in the Netherlands: intrapartum and early neonatal death in low-risk pregnancies," *Obstetrics & Gynecology,* 2011 (hereafter, the van der Kooy study).[15]

This study also used the Perinatal Registry Netherlands, but included an additional year (2000 to 2007), providing the records of 679,952 low-risk women. Using a retrospective cohort study, the researchers compared intrapartum and early neonatal mortality rates (zero to seven days after birth) for planned home versus planned hospital births attended by midwives. As we noted above, the results of this study are somewhat difficult to classify. When comparing *observed* intrapartum and neonatal death at zero to seven days, the researchers found fewer deaths in home births (crude relative risk 0.80, 95 percent CI 0.71-0.91). After adjusting for case mix, there was no significant difference in the risk of mortality for home birth compared to hospital birth (odds ratio [OR] 1.05, 95 percent CI 0.91-1.21). But after a third hypothetical comparison (using a model to estimate the potential consequences of one of the "big four" conditions associated with poor neonatal outcome—congenital abnormalities, intrauterine growth restriction, preterm birth, and low Apgar score—the research team concluded that additional mortality may arise at home births. It should be noted that women with preterm labor, a fetus who is known to have restricted growth, and a fetus with a known congenital anomaly were not included in the cohort who planned home birth with a midwife in the Netherlands.

Category 4: Studies that Report Both Benefits and Risks Associated with Place of Birth

Birthplace in England Collaborative Group, "Perinatal and maternal outcomes by planned place of birth for healthy women

with low risk pregnancies: The Birthplace in England national prospective cohort study," *BMJ* 2011 (hereafter, the "Birthplace in England" study).[16]

This prospective cohort study was done in England (April 2008 through April 2010) and compared perinatal and maternal outcomes and interventions by planned place of birth at the onset of care during labour (planned home birth, freestanding midwifery birth centers, alongside midwifery units, and obstetric units). The study included 64,538 low-risk women with a singleton pregnancy at term. The primary study outcome was a composite measure that combined intrapartum stillbirth, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, and birth-related injury including brachial plexus injury and fractured humerus or clavicle. The researchers found that the incidence of the composite outcome measure was low for the entire sample (4.3 incidents per 1,000 births). Overall there were no "significant differences" in the odds of the primary outcome in any of the midwifery-led care settings compared with planned birth in an obstetric unit. When mothers were stratified by parity, the odds of an adverse neonatal outcome among nulliparous women were higher for planned home birth than for planned obstetric unit birth. There was no evidence of a difference in adverse outcomes for nulliparous or multi-parous women birthing in freestanding or alongside midwifery units compared to obstetric units. Of women who started labor in an obstetrical unit, 20 percent had at least one complicating condition compared with less than 7 percent in other settings. For low-risk women birthing in an obstetric unit, the odds of receiving augmentation, epidural, spinal analgesia, general anesthesia, ventouse or forceps delivery, cesarean section, episiotomy, and active management of third-stage labor were significantly higher than for all other birth settings.

Producing the Science of Birth

What do we learn from these eight studies? Most obvious is that researchers do not agree about the safety of birth in the hospital and at home. How can scientists, striving to be objective, come to such drastically different conclusions? Even when studies agree, the researchers disagree on how to interpret the point they agree upon. For example, four of the eight studies summarized above found that women who birth their baby in the hospital are subject to more interventions, but the Janssen study and the Hutton study see increased intervention as injurious, while the Wax study concludes that a paucity of intervention in home birth results in increased incidences of neonatal death. Putting these studies in their social context and in the historical context of earlier research on the place of birth, we discover: (1) persistent professional bias, (2) bias in the publication process, and (3) what we call "critical bias," that is, systematic differences in the criticisms leveled against the studies.

Professional Bias

Social norms and expectations, as well as the nature of discussions with prenatal careproviders, can play a significant role in a woman's choice of birth place and other maternity care options including breast feeding.[17] Similarly, women's choice of elective cesarean versus vaginal delivery has been correlated with the opinions of their primary caregiver and the nature and length of discussion on mode of delivery.[18] A careprovider's education, experience, and location of practice may have an impact on which birth site options she or he will present to women.[19] The Canadian Birth Place Study evaluated the range of attitudes towards planned home birth among maternity careproviders and predictors of which place of birth was favored by physicians and midwives. The authors report that 84 percent of the variance in preference in place of birth was accounted for by profession alone, and that midwives had significantly more favorable attitudes than both family physicians and obstetricians toward home birth.[20]

Consistent with these findings, the direction of the conclusions of the studies on the safety of home birth coincide almost perfectly with the profession of the first authors. Studies done by midwives find no association between mortality and place of birth, while studies done by gynecologists-obstetricians find increased risk of perinatal/neonatal death associated with planned home birth. The exception among these eight articles appears to be the study by van der Kooy, a gynecologist (in training at the time of the research) and her colleagues. But recall that these researchers, who found no difference in mortality rates between planned hospital and planned home birth, nevertheless conclude, "In certain subgroups, additional mortality *may* arise at home if risk conditions emerge at birth (up to 20 percent increase)" (p. 1037, emphasis added). Interestingly, the "Birthplace in England" study team, a group with balanced representation from several maternity care professions, found that home was the best option for multiparous women (no difference in outcomes and a significantly higher rate of interventions and adverse outcomes for mothers in hospital), and that birth centers or hospital obstetric

units may be the best option for primiparous women (less adverse outcomes for the newborn). The only study that specifically examined the association of place of birth and outcomes for mothers (the 2013 de Jonge study) was led by a midwife researcher.

In the history of this debate, there is at least one researcher who allowed her study results to shape her conclusions. Majorie Tew, MD, an epidemiologist from the United Kingdom, began her research on the safety of birth settings serendipitously. Like most people, she assumed the shift to hospital birth that occurred in the first half of the 20th century (in England and elsewhere) was based on medical evidence. The wisdom of this shift seemed obvious, given the decline in morbidity and mortality at birth that accompanied the move from home to hospital. Finding no published studies that confirmed this common sense assumption, Tew assigned her students to do an epidemiological study of home and hospital birth. As the work of the class progressed, she was taken aback to learn that the data indicated that *home* birth was the safer of the two options. In the preface to her "critical history of maternity care," Tew describes her reaction to her surprising discovery:

> I was teaching students in the Department of Community Health in Nottingham University's young Medical School how much they could find out about various diseases from the available official statistics. As part of these epidemiological exercises, I discovered to my complete surprise that the relevant routine statistics did not appear to support the widely accepted hypothesis that the increased hospitalization of birth had caused the decline by then achieved in the mortality of mothers and their new babies. At first, it seemed hardly possible that I could be right in questioning the justification for what the medical world and everyone else apparently believed, but my further researches only served to confirm my initial discovery.[21]

Her findings are summarized in a report of a meeting of the Forum on Maternity and the Newborn, in December 1984:

> [Tew] examined the hypotheses on which the maternity service policies were currently based: namely, that high technology birth in hospital was safer than low technology birth in general practitioner maternity units (GPUs) or at home, and that the higher the degree of predicted risk, the more advantage there was to be gained from delivery in hospital. Both these hypotheses, she maintained, were translated into policy without any statistical evidence to support them and on investigation they were found to be completely undermined by the statistical evidence that was available—in particular by the evidence, published and unpublished, of the national survey of British Births 1970.[22]

Tew used a measure of risk—the antenatal prediction score (APS), devised for the 1970 British Births Survey[23]—to demonstrate that very little of the hospitals' excess perinatal mortality rate (PNMR) was the result of their greater numbers of births at high or moderate risk: "After standardization for the APS, the PNMR became 26.8 for hospital and 6.0 for GPU/home." She also refuted the second hypothesis, "the higher the predicted risk, the greater the benefit of hospital delivery," by showing that "not only was the PNMR higher [in the hospital] at each level of risk, but that the PNMR for the low-risk group in hospital was higher than for the high-risk group in GPU/home.[24]

Publication Bias

Tew's story is interesting for a second reason. Fascinated by her findings and impatient to get her research published, she encountered resistance within her department and from editors of scientific journals:

> My pursuit of the subject was not encouraged in the Department. My temporary contract of employment was not renewed. . . . Medical journals were not eager to publish an article presenting the results of my statistical analyses. I was dismayed that there was such formidable resistance to discussing openly honest, well founded criticism of the basis of established policies. . . . I became determined to break through the resistance and to fight against the false use of statistics to support a system that was actually harming its proclaimed beneficiaries.[25]

Others who have done research that challenged existing obstetrical practice—what everyone "knew" to be true in spite of the lack of evidence—have reported similar problems. Michael Klein submitted the first of his ground-breaking articles on the harm of routine episiotomy to the *Journal of the American Medical Association* (*JAMA*). *JAMA* refused the article, even though three of four reviewers recommended publication. The single critical review challenged Klein's results because they contradicted a 40-year-old study done with no controls for social, obstetrical, or demographic factors. When Klein

called the editor to ask for an explanation, he was told that the fourth reviewer was one of *JAMA*'s principal obstetrical consultants, and thus they would not publish the article.[26] Researchers in the Netherlands also have described editorial bias at home and abroad. Dutch researchers whose work documents the safety of home birth have had difficulty getting published in English language journals,[27] while colleagues whose work *challenges* the safety of home birth could not get their research published in Dutch language medical journals.[28]

Are Tew and Klein overly sensitive about the resistance to their research? Their reports are consistent with a pattern in the publication of research related to place of birth suggested by the eight studies described above: compared to articles that question the safety of hospital birth, articles questioning the safety of home birth typically appear in journals with higher impact factors, directed at physician audiences, with larger international audiences. The studies finding higher mortality rates at home birth (the Wax study and the Evers study) or questioning the safety of home birth (the van der Kooy study) were published in the *American Journal of Obstetrics & Gynecology* (*AJOG*), the *BMJ*, and in *Obstetrics & Gynecology* (*OG*), respectively. The article reporting mixed outcomes (the "Birthplace in England" study) was published in *BMJ.* The three articles questioning the safety of hospital birth (the Janssen study, the Hutton study, and the 2013 de Jonge study) were published in the *Canadian Medical Association Journal* (*CMAJ*), *Birth,* and *BMJ.* The article reporting no difference in outcomes (and concluding that home and hospital birth were equally safe) was published in *BJOG: An International Journal of Obstetrics & Gynaecology* (*BJOG*). The rank order of the impact factors of journals concerned with obstetrics (2012)[29] is: *OG* (4.8), *AJOG* (3.9), *BJOG* (3.8), and *Birth* (2.9). Spanning all medical specialties, *BMJ* and *CMAJ* have broader readership; their impact factors are 17.2 and 6.5 respectively.

It is interesting that *BMJ* has published articles that *support* and articles that *challenge* hospital birth. This may be the result of the more empirical orientation of British medicine—the Cochrane Collaboration originated in the U.K., and the U.K. is home to NICE, the National Institute for Health and Care Excellence, a governmental organization set up to produce evidence that would reduce variation in the availability and quality of NHS treatments and care[30]—but it also may signal a change in editorial orientation. The 2013 de Jonge study, which found no difference in perinatal outcomes by place of birth, was rejected by the *BMJ* the year before that journal published the Evers study, which reported a greater number of adverse outcomes among births attended by primary caregivers (that is, midwives and general practitioners). Although all of the reviews were positive, the editors told the lead author that her research offered nothing new to the readership of the *BMJ.*

Critical Bias

Another interesting aspect of these eight studies is the varied degree to which each has been criticized. The Wax study and Evers study have been subject to far more methodological criticism than the six other studies. The authors of the Cochrane Collaboration review describe the "intense critique" of the Wax study, listing 11 critical reviews.[31] The editors of *AJOG* responded to this criticism—some of which called for a retraction—by appointing three specialists in maternal fetal medicine (but no midwives) to review the article. The editors reported that the results of these reviews were "slightly different from the result in the manuscript," but the direction of association and levels of significance were not changed. The editors concluded no retraction was necessary, adding, "It is clear that we need more rigorous and better designed research on this important safety issue of home birth, given the many confounding factors."[32] The controversy over the Wax study drew the attention of the larger scientific community when *Nature* published a report describing "potential errors in the study's statistics" including use of a faulty online meta-analysis calculator and "inappropriately including or excluding studies"—most noticeably the exclusion of the large 2013 de Jonge study, that found no difference in mortality in the first seven days after birth.[33]

The Evers study attracted significant criticism over its method.[34] In a study published in *BMJ* in 2010, de Jonge and colleagues pointed out that the numerator and denominator in the study do not come from the same population:

> . . . although the title suggests that this is a prospective cohort study, the entire population at risk has been defined retrospectively and was based on postal codes of the catchment area of one university hospital. All intrapartum and neonatal deaths were included from hospitals and midwifery practices within this area, but potentially not all births. Midwives in practices at the periphery of the catchment area will also care for many women in neighbouring regions. These births have not been included in the study, unless the baby died. This will artificially inflate mortality rates in midwifery practices.[35]

Critics also commented on the fact that the reported intrapartum and neonatal mortality rates were twice as high as those found in previous national studies in the Netherlands. A team of researchers in Amsterdam[36] that is replicating the Utrecht study[37] discovered that, in cases of perinatal death, it was not easy to determine where labor began—the critical independent variable in the Evers study. The way careproviders register a birth in the Netherlands often makes it impossible to identify whether a death occurred antepartum or intrapartum. Given this uncertainty, the Amsterdam team decided to classify the cases "undefined." It would be surprising if the researchers in the Utrecht study did not face the same problem, but we are not told whether they did, or how they were able to reach consensus in such cases. A perinatal audit done in 2010 that examined the majority of at-term perinatal deaths in the Netherlands[38] casts further doubt on the conclusions of the Evers study. Using these audit data, and counting all of the deaths, when it is unclear where labor started, against primary care, the calculated perinatal death rate for labors begun in primary care is one-third lower than the rate reported in the Evers study.

It is reasonable to ask why the other studies—those showing no difference or more harm in hospital settings—have not drawn extensive methodological criticism. The obvious answer would be that the Wax study and the Evers study have flaws in method and the others do not. But it also may be that the community that supports home birth is more alert to studies that challenge its beliefs or feels it is more necessary to reject the concept that more technology at birth results in better outcomes. In addition, conclusions and publications by those who are acknowledged experts in the dominant culture (medicine) may be less suspect than those produced by a marginalized or minority health profession (midwifery).[39]

The problems associated with the science of birth place safety make it unlikely that we will ever have a definitive answer to the question of the relative safety of hospital and home birth. While the authors of the Cochrane review are optimistic about the possibilities of well-controlled observational studies, they nevertheless conclude that, even in these studies "observed differences (or lack of differences) may be due to uncontrolled confounding and bias. Thus, some of [the] findings . . . may be partly or entirely due to bias.[40] Commenting on the debate over the Wax study, Andrew Vickers, a statistician at the Memorial Sloan-Kettering Cancer Center in New York, agrees, adding a comment about the politics behind the disagreements: "The scientific debate about home birth has become extremely polarized and politicized. It is becoming hard to be anything but skeptical about anything but the most carefully conducted randomized trials."[41]

THE USE AND MISUSE OF THE SCIENCE OF BIRTH

Given the near impossibility of a randomized trial of place of birth and the uncertain quality of the findings of observational studies, what are the ethical responsibilities of clinicians who wish to use the best evidence to advise their clients? How should a clinician respond when there is pervasive doubt about the advisability of one approach over another? Often clinicians will rely on advice in the form of guidelines and opinion papers from their professional associations. But here, too, we find patterns of bias consistent with what we saw in the production of evidence: when offering advice, maternity professionals call on scientific evidence that is consistent with their interests/ideology and, for the most part, ignore or dismiss contrary evidence (see an article by Claire L. Wendland, MD, in this issue of *JCE*).[42]

Consider the 2013 article, "Planned home birth: the professional responsibility response." The authors, the majority of whom are members of departments of obstetrics, describe what they believe to be the proper professional response to "recrudescence" of home birth:

> We argue that obstetricians and other concerned physicians should understand, identify, and correct the root causes of the recrudescence of planned home birth; respond to expressions of interest in planned home birth by women with evidence-based recommendations against it; refuse to participate in planned home birth; but still provide excellent and compassionate emergency obstetric care to women transported from planned home birth. We explain why obstetricians should not participate in or refer to randomized clinical trials of planned home versus planned hospital birth.[43]

In making their case, where do the authors go for evidence? The Wax study. They cite this study with no mention of the critiques of the method or the sources of data used/not used in the meta-analysis. On occasion they also use anecdote, citing a journalistic account of a maternal death from the *Daily Mail*[44] to support their assertion, "For unpredictable, extremely sudden complications, even rapid transport may not prevent the fetus or pregnant woman

from death or severe harm, such as sudden cardiopulmonary arrest, shoulder dystocia, or maternal exsanguination" (p. 32). Furthermore, they make no reference to studies that might contradict their opinion—including the 2009 de Jonge study, the Janssen study, and the Hutton study. And when they refer to research that suggests birth at home may be safe, they simply dismiss that evidence. After citing the conclusion of the "Birthplace in England study" that the results "support a policy of offering healthy nulliparous and multiparous women with low risk pregnancies a choice of birth setting," the authors assert, "We contend that this view is irrational and cannot be supported in light of the reported adverse outcomes for birth outside of an obstetric service" (p. 32). They conclude their argument by citing Ab Klink, MD, former Dutch Minister of Health.[45] They list the seven topics that Klink understood to be "essential to improve perinatal care in the Netherlands," the last of which is "that a woman can be reassured that at any time of the day or night any intervention that is necessary can be initiated within 15 minutes," and go on to say, "This last goal cannot now or in the foreseeable future ever be met by a home delivery" (p. 36). Unfortunately for their argument, they took this piece of information out of context. The Dutch guidelines allow 45 minutes for transport from a primary care setting to hospital. In its report, *Een goed begin* (A good beginning), the Stuurgroep Zwangerschap en Geboorte (Steering Committee on Pregnancy and Childbirth)[46] reiterate the national policy governing hospitals and emergency care: "in acute situations, ambulances must be able to deliver a pregnant women to a hospital within 45 minutes from the time the call was made."[47] Klink was referring to the amount of time required for a hospital to ready its team to receive the incoming patient.

The authors of an article in this issue of *JCE* (Howard Minkoff, MD, and Jeffrey Ecker, MD)[48] exhibit the same bias when using evidence. Although they are more nuanced in their handling of the evidence and in their description of the ethical responsibilities of physicians vis-à-vis home birth, they accept the findings of the Wax study. They acknowledge the controversy around the Wax study, but they defend their use of the findings by referring to just one of the several outcomes of the "Birthplace in England" study:

> While the Wax meta-analysis has engendered much debate, subsequently published studies support its conclusion that home birth is associated with a small absolute risk of adverse neonatal outcomes, including mortality. For example, the Birthplace in England study, a large prospective cohort analysis of outcome by place of intended birth, concluded that for nulliparous women, . . . the odds of a composite adverse outcome . . . were higher for planned home births (adjusted odds ratio 1.75, 95 percent confidence interval 1.07 to 2.86).

The main finding of the "Birthplace in England" study is that "there were no significant differences in the adjusted odds of the primary outcome for any of the non-obstetric unit settings compared with obstetric units." Minkoff and Ecker cite only one of the outcomes—relating to primiparous women—and fail to mention other outcomes. They ignore, for example, the finding that there were no differences in primary outcome for multiparous women and the finding that for *all* women there were more interventions in the obstetric unit compared to midwife-led care.

This pattern of selective use of evidence also is found in the position statements and committee opinions of professional associations. In their position statement on home birth, the American College of Nurse Midwives (ACNM) assert:

- Every family has a right to experience childbirth in an environment where human dignity, self-determination, and the family's cultural context are respected.
- Every woman has a right to an informed choice regarding place of birth and access to safe home birth services.
- CNMs (Certified Nurse Midwives) and CMs (Certified Midwives) are qualified to provide antepartum, intrapartum, postpartum and newborn care in the home.
- An integrated system of health care that includes collaboration among all health care providers is essential and fundamental to supporting a safe, seamless, transfer of care from home and/or out of the hospital setting when necessary.[49]

ACNM supports its position with evidence from the 2009 de Jonge study, the Hutton study, and the Janssen study. The position statement refers to, but rejects, the evidence offered by the Wax study and the Evers study: "Unfortunately, some studies that have not differentiated between planned and unplanned home birth or attendance by qualified versus unqualified attendants, and/or have not used clearly defined appropriate inclusion criteria for analysis, have been used inappropriately to discredit all home birth."[50]

The American College of Obstetricians and Gynecologists (ACOG) issued a committee opinion on

planned home birth in 2011. Like ACNM, ACOG recognizes the right of women to make an informed choice about the manner and place of birth, but, unlike ACNM, ACOG emphasizes the risks of birth at home:

> Although the Committee on Obstetric Practice believes that hospitals and birthing centers are the safest setting for birth, it respects the right of a woman to make a medically informed decision about delivery. Women inquiring about planned home birth should be informed of its risks and benefits based on recent evidence. Specifically, they should be informed that although the absolute risk may be low, planned home birth is associated with a twofold to threefold increased risk of neonatal death when compared with planned hospital birth. Importantly, women should be informed that the appropriate selection of candidates for home birth; the availability of a certified nurse-midwife, certified midwife, or physician practicing within an integrated and regulated health system; ready access to consultation; and assurance of safe and timely transport to nearby hospitals are critical to reducing perinatal mortality rates and achieving favorable home birth outcomes.[51]

The ACOG committee opinion is informed almost entirely by evidence from the Wax study, which is used with no comment about method or the criteria used to include/exclude studies. The opinion does mention the 2009 de Jonge study, the Janssen study, and the Hutton study, pointing out—correctly—that the evidence of the safety of home birth found in these reports: (1) "describe planned home births within tightly regulated and integrated provincial health care systems, which may not be generalizable to current practice in the United States," and (2) where there exist "strict selection criteria for appropriate candidates [for home birth]." Interestingly, the authors of the ACOG opinion do not reflect on the implications of this observation for the generalizability of the Wax study, a meta-analysis that mixes together outcomes from care systems with widely varying degrees of regulation and cooperation between professionals. And as Wendland points out in her article in this issue of *JCE,* while the opinion calls attention to the lack of such systems in the U.S., it fails to take the next step, encouraging obstetricians to create systems that protect women who make an informed choice for home birth.[52]

The use of evidence evinces the same biases we found in the production of the science of birth place safety. It is, of course, legitimate to question evidence one finds discomfiting, but to dismiss or unfairly evaluate such evidence in formulating clinical advice or models for professional responsibility is unethical. The responsible use of evidence in healthcare requires considering all the evidence, including that which contradicts one's assumptions.

TOWARD RESPONSIBLE USE OF THE EVIDENCE ON PLACE OF BIRTH

How can we solve the conundrum of professional/publication/critical bias in the production and use of evidence about the risks associated with place of birth? Our review suggests several steps:

1. Because there is a predisposition to look for evidence that confirms one's point of view and to—consciously or unconsciously—design research in a way that favors that point of view, research in this area must be done by "frenemies," that is, those who share a common goal—in this case, healthy mothers and babies—but who hold conflicting perspectives on how best to achieve that goal. Given the concern over the influence of bias in even well-designed observational studies, it makes sense to begin research on place of birth with team members from differing points of view, rather than the current practice of waiting until results are published and then ignoring or trying to discredit that research. *The frenemies must be real frenemies and not "tokens" chosen to demonstrate that all sides are represented, but ineffectual in their ability to challenge the point of view of the lead researcher. The multidisciplinary Research and Data Collection Action coalition that was formed at the national Home Birth Summits in 2011 and 2013 is an effort to bring true frenemies together to improve the quality of research on place of birth.*[53]
2. Research on place of birth must begin with agreement on the appropriate conditions and operationalization of variables for comparative study. This is why we need frenemies: as we have seen, researchers eager to confirm what they already "know" may introduce bias into the definition of independent variables, outcome measures, and criteria for inclusion/exclusion.
3. It is important to find a location where the conditions for objective comparison of birth place setting safety can be done. This will be challenging. Both ACOG and ACNM recognize that the outcomes of birth, in home or hospital, depend on maternity care that is well organized, regu-

lated, and integrated. For example, ACNM calls for an "integrated system of health care that includes collaboration among all health care providers,"[54] and ACOG stresses the import of having "a certified nurse-midwife, certified midwife, or physician practicing within an integrated and regulated health system; ready access to consultation; and assurance of safe and timely transport to nearby hospitals."[55] Other medical and midwifery associations, including the American Academy of Pediatrics (AAP) and the Midwife Alliance of North America (MANA), echo this call for better integration of care.[56] In modern medical systems, this kind of maternity care can be hard to find. New Zealand, the Netherlands, Canada, the U.K., and certain places in the U.S. are promising venues to study the effects of birth setting and careprovider type on maternity care outcomes.

4. Reducing conflict and confusion among maternity care professionals about the interpretation and application of the science of home birth may allow for more ethical presentation of the "state of the science" to women. A precursor to this ideal will be developing modules for inter-professional education on birth place that describe evidence-based birth site selection, the requisite competencies and characteristics of care in each setting, and strategies for optimal inter-professional communication and collaboration across birth sites.
5. The Cochrane review begins by defining *hospital birth* as an intervention, a move that many will find odd. Is not hospital birth the norm, and the decision not to use the technology of the hospital the "experimental treatment"? In a society where technology is held in high esteem, careproviders and women assume that technology improves birth outcomes. This attitude can carry over into the design of research on place of birth, introducing bias in favor of technology—another reason to work in research teams with equal representation of all professional and client stakeholders.

Returning to the question about birth place safety that began our article—Is birth such a risky and unpredictable event that it is dangerous for a healthy mother (and her baby) to labor and birth in an environment where the full complement of obstetrical technology is not immediately available?—we now see the search for an answer is complicated by professional allegiance, peer review, and selective use of evidence. If we are to respect women's right to choose, and to provide them with the information they need to make an informed decision about where they will birth their child, we must strive to produce objective evidence, and we must use that evidence fairly. Lacking consideration of the ethics of information, work in the field of reproductive justice is incomplete. Given the as-yet uncertain and conflicting outcomes of studies of the safety of home birth, it is crucial that careproviders do not simply choose evidence that seems right to them, but cannot withstand scientific scrutiny.

NOTES

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