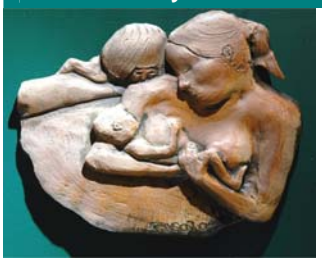

Answers to Questions About: Outcomes of planned home births with certified professional midwives: large prospective study in North America British Medical Journal 330, 1416. June 18th, 2005

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SUMMARY

This piece responds to questions that have been posed about our study and provides additional details that could not be accommodated in the original BMJ article which had a 2,000 word limit. The 8 questions concern the following:

1) The choice of the BMJ for publication;
2) The choice of intrapartum and neonatal mortality rate as the key risk measure;
3) The basis for concluding that planned home birth and low-risk hospital birth have similar safety but homebirth has much lower intervention;
4) Why did the Washington home birth study have different conclusions?
5) Are you comparing apples to oranges?
6) Why there are no confidence intervals for mortality rates?
7) What about reporting on other outcomes? and
8) Could the funders have biased the study?

Clearly understanding the article and its history is useful because it has attracted enormous attention not just in North America but worldwide, partly due to the fact that it is the largest prospective home birth study done to date, possibly because it is largely based in the U.S, and contextually because the debate over home birth and hospital birth has grown in sophistication since the early eighties and the article captures the best available methodology for a national study of the U.S. (with a glimpse of Canadians who have the same certification.)

1. Why did you choose to publish this study in the British Medical Journal?

There was great interest in our study as it was drawing to a close, and we received advice from several different parties about the best strategy for publication. One of the obstetricians/epidemiologists who had originated Effective Care in Pregnancy and Childbirth at the National Perinatal Epidemiology Unit (NPEU) in Oxford, suggested we send the article to the British Medical Journal because of their web-based system and prestigious reputation. However, American colleagues wanted us to submit to the Journal of the American Medical Association (JAMA), to see if it would spark some interest among American physicians. Therefore, we submitted first to JAMA. The article was returned quickly without being sent out to reviewers, and comment from only one editor—that the JAMA readership would not be interested in an article on home birth. This was regardless of the calibre of the methodology and size of the study.

We turned to our advisory council, including obstetric, public health, epidemiology, and nurse midwifery consultants, to debate the relative merits of submitting a home birth article to the Lancet, the New England Journal of Medicine (NEJM), the American Journal of Public Health (AJPH) or the British Medical Journal (BMJ). It was thought that there was high probability that the NEJM and the Lancet, even if they sent the article on for review, would respond to this topic with similar lack of interest as a priority item to publish. We assumed that the American Public Health Association's journal would be interested because the study's methodology was approved and applauded by epidemiologists in the organization, and subsequent to presentation of the preliminary findings at the APHA conference in 2001, a resolution was passed in the Maternal Child Health Division to increase out-of-hospital birth done by direct entry midwives (American Public Health Association 2001). However, at that time it took more than a year to reach print in the APHA journal and it does not have the same distribution or reputation as the BMJ.

We returned to the original decision to submit to the BMJ because:

1) It is one of the most highly respected medical journals with high standards for study acceptance and is a preferred place for publication (the BMJ publishes less than 10% of the papers it receives).
2) It publishes articles it thinks are important and timely, and had previously published on home birth without apparent concern their readers would lack interest;
3) The BMJ reviews and publishes manuscripts quickly;
4) The BMJ is one of the few journals that provides articles freely on the web to everyone, allowing anyone to get a copy to review it;
5) The BMJ is one of a small number of journals that maintains the Rapid Response feature which allows the readership to post letters to the editor quickly – this is a great benefit to the readership of an article, compared to the traditional average of 6 months before letters to the editor appear in print. (See *Note 1 at the end of this question)
6) Rapid Responses also allow for a greater diversity of opinion than traditional letters because the BMJ posts all letters of substance whereas rarely are more than 3 or 4 letters to the editor chosen to be published in print and the choices are totally at the editors discretion about which if any letter will be published.

In the end, it appears the BMJ was the best place to publish it because the article has been accessed by over 25,000 individual readers and according to the BMJ continues to be accessed at the rate of about 1500 times per month (Personal correspondence with British Medical Journal). It was the third most accessed article in the first week of publication in the BMJ for the year 2005 (Top Ten List for 2005, BMJ).

*NOTE 1: For example, consider the NEJM publishing of the Lydon-Rochelle *et al.* study (2001) of VBAC and the accompanying editorial. It was six months before 6 letters to the editor were published in the NEJM and 2 in the BMJ (Daviss 2001; Johnson and Gaskin 2001) – all highly critical of the study and/or editorial – but only after hospital protocols had changed as result of the original publication and had caused considerable damage to choice of VBAC for women in America. Furthermore, when we presented on the information in the letters to the NEJM, in our tertiary care setting in Ottawa, none of the obstetricians, midwives or obstetrical nurses were even aware of the letters, let alone knowledgeable of their content, yet our hospital had based their informed consent for patients on the this and one other article alone. VBAC at our hospital as well as the majority across North American appear to have similarly acted on the information from this article, evidenced by another drop on the graph in the downward trend away from offering VBAC in North America.

2. Why did you choose to compute an intrapartum and neonatal mortality rate rather than a perinatal mortality rate (PMR)? How were birth defects, premature births, and stillbirths reported?

Perinatal mortality rate (PMR) refers to the sum of deaths of fetuses and neonates per thousand births, but there are variations in the definition because jurisdictions can include or exclude early fetal death (22 weeks to 28 weeks) and/or late neonatal death (7 to 28 days after birth). Thus the WHO's definition "Deaths occurring during late pregnancy (at 22 completed weeks gestation and over), during childbirth and up to seven completed days of life" is not universally used.

The perinatal mortality rate (PMR) debate – how and whether to use it to compare practitioners and place of birth – ensued at the NPEU in Oxford when we were there in 1991, on the tail of the Australian home birth studies. PMR is relevant if one wants to compare the effectiveness of midwifery vs. physician care or the difference in care between jurisdictions both during the prenatal period as well as during the intrapartum and postpartum period. However, it is not the most relevant measure for examining the risk associated with place of birth, which was the focus of our article in the BMJ.

Intrapartum and neonatal mortality better address the clinical question of risk associated with planned out-of-hospital and hospital birth, by isolating the risk related to delivery itself. Therefore, while we collected PMR, we reported in this particular article on intrapartum and neonatal mortality. We chose deaths up to 6 weeks of age, because this includes both early and late neonatal death (up to seven and 28 days respectively) and it is possible to tally this information because 6 weeks is the common time of the last visit with the midwife. Unfortunately, this information is not captured consistently among physician-attended births because of the fragmentation of care subsequent to birth in hospital. Mothers generally go to family physicians, general practitioners, and pediatricians after their birth for baby care rather than obstetricians. However, the subsequent difficulty in finding comparison groups does not suggest it is not important.

The focus was home births, and therefore low-risk, normal births. It is not standard to count premature babies in mortality computations for low-risk women. Premature births are considered high risk for the newborn and therefore generally ruled out for the option of home birth. However, some premature births did occur at home and were included in the study, on the rare occasions when mothers slightly premature chose to remain at home, or there were doubts about the gestation.

While stillbirths prior to labour are eliminated from comparisons of home birth vs. hospital outcomes because they are not part of intrapartum or neonatal mortality, we did report stillbirths after 20 weeks in Figure 1. We also reported the four women who chose to deliver at home in spite of learning prior to the delivery that they had had a pre-labour stillbirth. However, they were not included in calculations of intrapartum and neonatal mortality as they do not fall into that category.

The occurrence of fatal birth defects is not associated with place of birth, and is not standardly reported when making comparisons among differing practices and so those deaths were reported in the article, but removed from final calculations just as they were from comparison studies.

3. What was the basis of your conclusion about the safety of home versus low risk hospital birth?

We came to the conclusion that "Planned home birth for low risk women in North America using certified professional midwives was associated with lower rates of medical intervention but similar intrapartum and neonatal mortality to that of low risk hospital births in the United States." (BMJ abstract). This was based primarily on our study results, as we had chosen the most refined methodology possible for a study across the U.S. –a large enough sample size, a prospective methodology with required accountability for recertification (with inclusion of Canadian midwives with the same certification),and incorporation of a validation study. It became evident that our study expanded the weight of evidence that already existed and we were careful to include an examination of the pertinent literature, both American studies of low risk hospital birth and other North American studies of out of hospital birth. Our findings are also consistent with the international literature on home birth. Consistency in results across studies with different designs and in different settings yields more confidence in results.

We used the term "similar" to describe how our findings measured up to the weight of evidence of other intrapartum and neonatal outcomes and "lower" to describe our study's rates of medical intervention for the following reasons:

"SIMILAR" Intrapartum and Neonatal Mortality

The term "similar" risk was appropriate to use with regard to intrapartum and neonatal death in our study because our results were "alike but not identical" to outcomes in other studies of low risk hospital births and other out-of-hospital births. It is not surprising that they were not identical, and only similar, because of the random variation that occurs when you are dealing with relatively small studies comparing rare outcomes, differences in study design, different populations, and hospital studies that are rarely able to collect neonatal mortality beyond a week. As Judith Rooks says in "The Safety

of Out of Hospital Birth in America" from the book, Midwifery and Childbirth in America, one of the best treatises of home birth/hospital birth comparisons:

The studies of low-risk births attended by physicians in hospitals {see our BMJ article Table 4}…provide a general frame of reference for making judgments about the mortality rates reported in the studies of out-of-hospital births. Each of the comparison studies created a low-risk pregnancy data set by excluding women with certain characteristics or outcomes from a larger database. (Rooks 1997:370)

Because we had seen how difficult it is to obtain a direct comparison, even within a provincial/state jurisdiction, and other studies had tried to create comparisons, but they inevitably ended up not having comparison groups that were collected with the same methodologies, we decided instead to present all the studies of greater than 500 births for a general frame of reference.

We carefully reviewed Rooks 40 page chapter which we had contributed to back in the 1990's at the request of the author (Rooks 1997), investigating a variety of issues related to establishing the relative safety of home versus hospital birth. She also reviews each of the studies listed in Table 4 of our BMJ article published up to 1997 when her book was published, focusing on the aspects of the design of each study and their implications for the evaluation and comparison of intrapartum and neonatal mortality. For anyone with an interest in more deeply understanding the safety of home birth issue, this is highly recommended reading and will help one to understand more clearly the considerations that go into evaluating the perinatal risks observed and why we came to our conclusion in the BMJ report.

The need for the same careful consideration of each study that Judith Rooks provides in her Chapter on home birth is noted in our footnote to Table 4 of our BMJ article on home birth:

"Table is presented for general comparison only. Direct comparison of relative mortality between individual studies is ill advised, as many rates are unstable because of small numbers of deaths, study designs may differ (retrospective versus prospective, assessment and definition of low risk, etc.), the ability to capture and extract late neonatal mortality differs between studies, and significant differences may exist in populations studied with respect to factors such as socioeconomic status, distribution of parity, and risk screening criteria used. For example, see the study by Schlenzka. Although the crude mortality for low risk babies weighing over 2500 g intended at home was 2.4 per 1000 and intended in hospital was 1.9 per 1000, when standard methods were employed to adjust for differences in risk profiles of the two groups (indirect standardization and logistic regression), both methods showed slightly lower risk for intended home births."
Since the article was submitted for review to the BMJ, the NIH has published a report that provides neonatal death data categorized by ethnicity for which we adjusted our data in order to do a crude comparison. In doing the analysis, we came to the same conclusion as we did in the original article but added the NIH as a crude comparison for neonatal mortality.

"LOWER" Medical Interventions

We had the good fortune to conduct our study coincidentally during the overlapping time period that the first nation-wide Listening to Mothers (Declercq ER *et al.* 2002) survey was also carried out. This enabled us not just to obtain the standard data reported by health care professionals to the National Center for Health Statistics (NCHS) for relatively low risk women (Martin JA 2002) , but the data reported by women across the U.S. in all risk categories with the exception of multiples. For comparative purposes, obviously we found the low risk births as reported by the NCHS were better for comparing to our study largely of low risk women than the data from Listening to Mothers. The latter reported on only singleton births but included risk categories such as breech and premature births, but we laid them side by side on Table 3 to show the differences.

In the case of the NCHS data, the interventions rate for low risk (single vertex babies at 37 weeks) were

twice to ten times higher in planned hospital births compared to home births, even when isolating the single, vertex babies at term, which could have been spared the interventions in hospital. The interventions rates are so overwhelmingly lower, it justified our use of the term "lower" without need for further discussion. When looking at such large differences in such common events, the same precision required for intrapartum and neonatal mortality (both rare occurrences in either setting), is less necessary for adequate intervention comparisons.

4. Why does the Washington home birth study have different conclusions than almost all other articles on home birth?

The highly publicized birth-certificate-based study in Washington State, (Pang JWY *et al.* 2002), reported increased risk for births in the home setting based on analysis of birth and death certificates. These findings are not only inconsistent with our study, but also unlike the weight of evidence of home birth articles in North America and worldwide.

Several studies conducted in the 1970s and 1980s established the wide variance in outcomes between planned vs. unplanned and attended vs. unattended home births: in North Carolina researchers found a neonatal mortality of 3/1000 for planned home deliveries attended by a lay midwife, 30/1000 for unattended planned homebirths, and 120 neonatal deaths/1000 for unplanned homebirths (Burnett *et al.* 1980); in Kentucky they found a neonatal death rate of 3.5/1000 for planned vs. 72.7 per 1000 for unplanned homebirths (Hinds *et al.* 1985); and Indiana found an estimated perinatal mortality of 18/1000 live births for the whole state compared to 45/1000 for women who received no prenatal care and gave birth at home without trained attendants (Kaunitz *et al.* 1984). It has also been known since those early studies on home birth were done, that in almost all jurisdictions, birth certificates do not include any information about the intended site of birth, and their use creates the potential for inclusion of high-risk unplanned and unattended home births. The concern that this was the case with this study was highlighted when the study reported a transfer rate to hospital during labour from planned home births of 4.5% (279 transfers among 6,133 births). This is about half the transfer rate one would expect in a cohort of planned home births with trained midwives in North America. The carefully conducted studies in the U.S.A. which include detailed data on each birth, consistently report hospital transfer rates of 8-10%. (Murphy and Fullerton 1998, Anderson 1995 and our BMJ article) during labour and low intrapartum and neonatal mortality. The low transfer rate of the Washington study hospital transfer rate suggests that many of the births identified by Pang *et al.* as "planned" may in fact not have been attended by health care professionals, as they generally have standards for transfer, and thus may not have been planned home births. (See Johnson K and Daviss BA, "Letter to the editor re Outcomes of Planned Home Births in Washington State: 1989-1996. The Journal of the American College of Obstetricians and Gynecologists (101), 1. Jan. 2003.)

To create a doubling of mortality from unplanned unattended home births, it would require only 15% of such births with a death rate of 12/1000 in unplanned or unattended home births and a death rate of 1.7/1000 in planned home births. Given the experience in North Carolina, Kentucky, Indiana, and considering the risks involved with those who do not seek any form of care (Rooks 1997:390-391), and the religious and self-sustenance culture of this particular state on the West Coast, this may well be an underestimate of risk associated with unplanned homebirth. With an intrapartum and neonatal death rate like that found in the CPM2000 study of 1.7/1000 in planned home births, here is the math on 1000 births:

Example

850 planned home births with 1.7/1000 death rate	= 1.6 deaths
150 unplanned with 12/1000 death rate	= 1.8 deaths
Total deaths for 1000 births	= 3.4 deaths

In this example with 15% of the out of hospital births unplanned an observed home birth risk could be observed that was doubled from 1.7 to 3.4 deaths/1,000 births.

For more details critiquing the Washington home birth study, see a thorough commentary on the Pang *et al.* study by Saraswathi Vedam (2003). Her comments include the following:

"In fact there is no way to determine from the birth certificate if a birth recorded as having occurred at home or attempted at home was a planned home birth (of a preselected woman who had qualified attendants and access to consultation and referral), a precipitous or unattended home birth, or an intended home birth outside the health care system." (page 58)

"To add to the confusion, the investigators included all births occurring between 34 and 37 weeks gestation in their initial analysis, although prematurity is a universal exclusion from planned home birth. They later restricted the analysis to babies of at least 2500 g and 37 weeks, but their abstract, tables, results, and conclusions are primarily based on the larger group." (page 58)

Under a "Truth in Reporting" subsection Vedam notes:

"The authors noted controversy in literature concerning the safety of home deliveries, but cited only 4 studies that they claim support their findings of increased risk of neonatal mortality and adverse outcomes. They failed to mention or discuss findings from the bulk of the recent national and international literature, which concluded that planned home birth is a safe and reasonable option (8, 16, 20, 26–31). More importantly, they misrepresented the literature that they did cite." (page 60)

"Furthermore, Pang *et al* noted the study limitations of reliance on birth certificate data, inability to ensure assignment of study subjects to correct study groups (planned home versus planned hospital), and possible differences related to attendant type. They concluded that the results suggest increased risk of adverse neonatal and maternal outcomes, particularly among nulliparous women. Nonetheless, more light needs to be shed on this controversial topic before practitioners and expectant parents can be fairly counselled about the safety of planned home births__ (p 259). Yet, they still represented their findings in an alarming manner. Throughout the article they warned that planned home births presented twice the risk of neonatal death—a risk amounting to a difference of 1 in 1000 for the study, which is a worst-case scenario given the weakness of the study design" (page 61)

5. Are you comparing apples to oranges?

The science of "comparing apples to oranges" had a breakthrough in the same year that we began to collect our data for the study on home birth by Certified Professional Midwives. Refuting the outdated belief that a fruit comparison was impossible, "Comparing apples and oranges: a randomized prospective study," was published in the BMJ issue of 23-30 December 2000. With its important conclusion, that apples and oranges are not only comparable but similar, the article begins by stating:
"Many authors use the analogy of the putative inability to compare apples and oranges as a means of scornfully reviewing the work of others."

a) Why the Randomized Controlled Trial Is NOT the Gold Standard for Home Birth Research

The phrase "comparing apples to oranges" has become a cliché increasingly used in the health sciences when attempting to categorize research as "invalid" if the methodology has not been a Randomized Controlled Trial. While convenient because it avoids the need to understand comparison in epidemiology on a more sophisticated level, the attempt to put all studies in one fruit basket of methodology in this kind of research reductionism ignores some important research realities.

When searching for excellence by using RCTs, it is quickly forgotten that the true gold standard is a randomized controlled trial which is double-blinded, where neither the clinician nor the subject know which treatment is being received. While useful for randomly and blindly allocating patients in studies of drugs, to receiving either the medication or a

placebo envelope, such double-blindedness can rarely be applied in obstetric or midwifery research. This is because the performance of episiotomies, rupturing of the membranes, induction, or caesarean section, are impossible to do without both the recipient and the practitioner painfully aware when the patient has been randomly assigned to treatment. Furthermore, such important research as whether caesareans cause more maternal mortality than vaginal birth is simply better carried out by methodology other than the RCT.

Enter the complicated politics of doing home birth research. As we have known for many years, and stated in the article in the BMJ, to date it has been impossible to randomly assign women to either home or hospital birth. If you could actually find women who didn't care enough about planning where they would have one of the most important events of their life to participate in such a trial, there would be high suspicion that they were psychological outliers. As we said in the article, this had already been attempted in Britain without success (Dowswell T 1996), a country where home birth is not a foreign concept and the health care system embraces the skills of midwives without question. It would also be extremely costly to create a trial large enough to have enough perinatal mortality to do comparison and finding funding even for retrospective studies is not easy to come by. A practice such as home birth that cuts down on intervention is not popular among companies selling pharmaceuticals and medical instruments. For further discussion about the strengths and limitations of RCTs for obstetrics and midwifery see Johnson 1997.

As well, even in the future if it were possible to find a society in which it was possible to carry out an RCT for out-of-hospital research compared to in-hospital, the complexities of clinical judgement and decision-making around home birth would make it inappropriate for similar reasons to those that have presented themselves with the use of the RCT to compare vaginal to caesarean section for breech delivery has fallen into question. (See Kotaska 2004.)

b) Finding National Comparisons

The principles of comparative analysis have to be well understood before claims are made about the legitimacy of any study. As mentioned above in question #3, Judith Rooks describes the difficulties of comparing home and hospital birth in an eloquent treatise. Only one state to date and one province have been able to do cohort studies of home birth with a defined, direct comparison group – Schlenzka in California (see details below) and Janssen in B.C. However, as we stated in the article, the other national home birth studies –and the low risk hospital studies for that matter (see our Table 4 and read Rooks 1997: 370-371) – did not have direct comparison groups that were collected with the same methodologies. There are practical reasons for this.

With the introduction of the CPM credential, we knew that we would be able to accomplish the task of a cross-the-country study on a defined group over a defined time period. We sought out comparisons from other studies for the most important comparable group between home and hospital – the group of low risk mothers in each setting. Data were secured through the NIH statistics for intervention and all other studies on out-of-hospital birth or low risk hospital birth that had at least 500 births (see Table 4 in the BMJ article). However, to directly compare our international study of all CPMs to a directly comparable group of hospital births in North America using the same prospective methodology as for the CPMs would have been extraordinarily difficult logistically, if it would even have been possible to get buy in from hospitals across the USA. Even if it would ever be possible, it would be extremely costly and large scale funding for studying home birth is not readily available in the United States. We carefully detailed the difficulties and shortcomings of using existing administrative records, particularly birth certificates, to form a directly-comparable national group, and decided against such comparison, with the comfort that Schlenzka in 1999 had managed it with one of the largest states in the union and would provide an important adjunct to what we had found nationally (see "c" below).

Just as apples and oranges are both grown in orchards or groves, have flowering trees, are considered a fruit, may be eaten and made into juice, are subject to damage by disease and insects, so too, the births in the cohorts to which we compared our cohort of home births were all births that occurred in the year 2000, all involved women living in North America (98% in the U.S.), and all fit into the category of "low risk" for intrapartum and neonatal considerations as defined by the accepted definition of singleton, head down, and > or = 37 weeks.

It should not really be considered remarkable that each study that we found that was carried out on low risk births fell into a similar pattern of 1 to 3 deaths per thousand births despite fluctuations in the definitions of intrapartum and neonatal death. Refer to question #3 to understand why that it is a respectable way to compare home and hospital birth and how we came to our conclusions.

c) The Important Adjunct to Our Study, as described in our BMJ article – A Direct Comparison Group in One of the Largest States in the Union With Ample Home Birth

The Stanford PHD thesis (Schlenzka P, Safety Of Alternative Approaches To Childbirth, [Unpublished Dissertation]. Palo Alto, CA: Department of Sociology, Stanford University, 1999), provided a rare opportunity to have a homebirth study with a directly comparable group of low risk hospital births as we noted in the Discussion in the BMJ. The Stanford PHD is an important compliment to our study, finding similar intrapartum and neonatal death rates as the CPM2000 study did for more than 3,000 planned home births and more than 800,000 low risk hospital births. Schlenzka was able to establish a large defined retrospective cohort of planned home and hospital births with similar low risk profiles, because birth and death certificates in California include intended place of birth and these had been linked to hospital discharge abstracts for 1989-90 for a caesarean section study through a contract with the Rand Corporation. When the author compared 3,385 planned home births with 806,402 low risk hospital births, he consistently found a non-significantly lower perinatal mortality in the home birth group. The results were consistent regardless of liberal or more restrictive criteria to define low risk, and whether or not the analysis involved simple standardization of rates or extensive adjustment for all potential risk variables collected.

The Schlenzka study is available for use at Stanford, through Interlibrary Loan to Shares partners (www.rlg.org/en/page.php?Page_ID=634) and for purchase from UMI/Proquest. UMI has the thesis available for download; the copy at the Interlibrary Loan is paper.

6. Why did you choose not to provide confidence intervals for the intrapartum and neonatal death rates?

We did not provide confidence intervals for the rates, taking guidance from other published studies, including the National Birth Center study (Rooks JP *et al.* 1989). As in the birth centre study, our study represents the risk for CPMs for the defined period – not an estimate of it, but the actual rate for CPMS for the year 2000, so a confidence interval is not required, as the rate is not an estimate, based on a sample, but the actual rate for the year 2000.

7. Why did you choose not to provide details about other outcomes?

We were limited to 2,000 words when we submitted our article for publication in the BMJ. We chose to focus on interventions and mortality figures because those appeared to be most critical to legislators and public health interests. We did not have the space to discuss perinatal mortality in sufficient depth. We will discuss other outcomes in future articles.

8. Could the funders have biased the study in any way?

Initial and primary funding was obtained from the Benjamin Spencer Fund, a small, private foundation with program interests in the environment, women and families and reproductive rights. The Fund had no advance review of the BMJ article, receiving a copy of the published article as part of the final grant report.

The study was not commissioned by any national or state midwifery group. However, we are greatly indebted to the North American Registry of Midwives for their role in requiring all CPMs to participate in the data collection as a requirement for renewal of their CPM credential. Without NARM's facilitation of CPM participation, we could not have met a key research requirement – participation by midwives with the same credential. This is important because the conclusions of the study would have been less compelling if the midwives were a diverse group with no commonality of credential, education, skills and site of practice.

NARM was not involved in the design or analysis of any of data collected and did not participate in editing the final article but to clarify the description of the CPM credentialing process. In fact, the risk to NARM, should the outcomes reflect negatively on the care by CPMs, was substantial and significant. The NARM Board realized that their organization was taking a risk, especially since as researchers we were very transparent in our process and made it very apparent to the epidemiologists at the APHA what we intended to do and how we intended to carry it out. However, NARM was at a point in its development where a study of the outcomes of CPMs was essential to demonstrate the safety of out-of-hospital birth with credentialed direct-entry midwives.

To further enhance the independent verification of the data, the mothers involved in the study were contacted independently and directly about outcomes and transfers to compare them to what the midwives had reported. Finally, the obstetrician on the Advisory Council for the study wanted to be assured that autopsy or hospital reports would be obtained where possible so that causes of intrapartum and neonatal deaths would not be assessed only through the eyes of the midwives in attendance, but a separate professional party. We were obliged to strictly follow all these processes for the credibility of the study as professional researchers.

The Foundation of the Advancement of Midwifery (FAM), a 501(c) (3) public charity was formed after the data for our study had already been collected, the preliminary analysis had been done and we had presented the draft findings to the American Public Health Association. FAM provided a small grant to fund the gathering of the remaining client satisfaction survey data, phone for autopsy reports and make sure any stragglers were accounted for. FAM had no role in the analysis of the data.

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