UNDER EMBARGO UNTIL MARCH 31, 2011, 12:01 AM ET

Study validity questioned

TO THE EDITORS: We read with some alarm the article by Wax et al entitled, "Maternal and newborn outcomes in planned home births vs planned hospital birth: a metaanalysis."[1] We agree with several researchers who point out that the method used to select studies for inclusion in this metaanalysis requires serious scrutiny.

But even if we accept the authors' flawed data, their main argument remains highly misleading. Of greatest concern is the conclusion that home birth is associated with a greater risk of neonatal death. This conclusion is an artifact of the authors' study design, in that the home birth data used for comparison include births not attended by a certified midwife.

The authors do inform us that when these studies are excluded from the analysis, the odds ratio for neonatal death between home and hospital births is no longer statistically significant. However, this information appears only in a complex sentence at the end of *Results*, opening the door to the publication of false reports on the safety of birth at home by the mass media. A more honest title for this study would be "Outcomes of unattended birth vs births attended by trained professionals." The misleading presentation of data begins in the title and continues in the abstract and virtually throughout the article.

This misrepresentation of data is contrary to what the public rightly expects from science.

Noam Zohar, PhD
Graduate Program in Bioethics
Department of Philosophy
Bar Ilan University
Israel
Currently: Visiting Scholar,
School of Social Science
Institute for Advanced Study
Princeton, NJ

Raymond De Vries, PhD
Bioethics Program/Medical Education/Sociology/Obstetrics and Gynecology
University of Michigan Medical School
300 North Ingalls St., Rm 7C27
Ann Arbor, MI 48109-5429
AVM University of Midwifery Education and Studies
Faculty of Health, Medicine, and Life Sciences
Maastricht University
Postbox 1256
6201 BG MAASTRICHT
rdevries@med.umich.edu

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REPLY

We are utterly dismayed by Drs Zohar and De Vries' citing unnamed detractors and nonspecific unreferenced criticisms of our study. Their characterization of the data as "flawed" is particularly interesting regarding a metaanalysis. We were especially taken aback by the proposed alternative title for our paper. Not only is it disingenuous considering the clearly stated objective, study inclusion criteria, and method of study identification, but it is also an affront to midwives with credentials other than the certified midwife (CM) or certified nurse-midwife (CNM) designation.

The writers contend that studies with planned home births attended by midwives other than CMs or CNMs should have been excluded. More than half of planned home births in the United States are conducted by midwives other than CMs and CNMs, typically certified professional midwives.[1] We therefore stand by the broader inclusions of the full metaanalysis and use of sensitivity analysis.

Drs Zohar and De Vries fail to appreciate several aspects of the analysis excluding planned home births by other than CMs or CNMs. First, this evaluation excluded most of the total included planned home and planned hospital births, opening the possibility of a type II effect. Second, the odds ratio (OR), although not reaching significance, is entirely consistent with the ORs for the full study and other sensitivity analyses. Third, as noted in the original manuscript, the OR is unadjusted for the often lower obstetrical risk among planned home births, likely underestimating the OR. This phenomenon is exactly what was observed in a recent report of planned home births by trained, regulated midwives in Australia when compared with planned hospital births.[2]

Recently, the American College of Obstetricians and Gynecologists stated, regarding a trial of labor after cesarean, that "respect for patient autonomy supports that patients should be allowed to accept increased levels of risk; however, patients should be clearly informed of such potential increase in risk and management alternatives."[3] We would extend the application of this statement to appropriately selected planned home births, consistent with our conclusion "that planned home compared to planned hospital births are associated with significantly less maternal and newborn medical intervention and morbidity, particularly among selected low risk women cared for by highly trained and regulated midwives who are integrated into the health care system."

It is indeed unfortunate that Drs Zohar and De Vries have apparently fallen victim to the very "false reports on the safety of home birth by the mass media" that they so decry.

Joseph R. Wax, MD
Michael G. Pinette, MD
Division of Maternal-Fetal Medicine
Department of Obstetrics and Gynecology
Maine Medical Center
887 Congress St., Suite 200
Portland, ME 04102
waxj@mmc.org

F. Lee Lucas, PhD
Maine Center for Outcomes Research and Evaluation
Maine Medical Center
Portland, ME 04102

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Home birth metaanalysis: does it meet AJOG's reporting requirements?

TO THE EDITORS: We challenge the conclusions of the metaanalysis by Wax et al,[1] which reported that planned home births had higher neonatal mortality rates than hospital births and were therefore less safe. The metaanalysis includes poor quality studies, has a high risk of methods bias, and does not meet the Journal's requirement to comply with metaanalysis of observational studies in epidemiology guidelines.[2] For example:

1. The outcome of a metaanalysis is highly dependent on which studies are included and excluded. In this case, there is no list of citations and of which studies were excluded and why.
2. The quality judgment for each individual study should have been reported. For example, the study that was based on routine data for Washington State contributed the largest numbers of neonatal deaths but was at high risk of misclassifying unplanned home births as planned home births because this information was not recorded in the dataset. This study has other methods problems.[3]
3. The assessment of confounding was inadequate. The authors reported that the sensitivity analysis by quality did not change the findings but gave no details.
4. All relevant available studies should have been included, and contact should have been made with authors where necessary. Funnel plots show that the decision to exclude studies that had not been published in peer-reviewed journals contributes to publication bias. This could explain the lack of heterogeneity that was reported. If the authors had chosen a random-effects model, this would have been more appropriate because of the high clinical heterogeneity in the included studies.
5. There is no graphic summarizing individual study estimates with overall estimates. The authors have not reported which individual studies contributed to which metaanalyses.

We identified 8 studies that had data on overall neonatal mortality rates, not 7. We also identified several different definitions of neonatal death in the included studies. Some studies used the same definition as the authors, but others did not. If Wax et al had contacted the authors of the very large Dutch study and included their neonatal mortality data, then no difference in neonatal mortality rates would have been evident.[4]

It is of particular concern that this study was published in this present form when it does not meet the criteria for publication set out by the Journal itself. We believe that the *American Journal of Obstetricians and Gynecologists* should withdraw this publication in view of the failure of the peer review process to pick up these fundamental and fatal flaws.[4] ■

Gillian M.L. Gyte, MPhil
Cochrane Pregnancy and Childbirth Group
Liverpool, UK
ggyte@cochrane.co.uk

Miranda J. Dodwell, PhD
BirthChoice UK
London, UK

Alison J. Macfarlane, BA
Department of Midwifery
City University London
London, UK

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Maternal and newborn outcomes in planned home birth vs planned hospital births: a metaanalysis

TO THE EDITORS: A recent metaanalysis by Wax et al[1] raises several methodologic and analytic concerns. Only 4 studies selected for analysis involved deliveries occurring in the present decade, 7 studies involved fewer than 3000 participants (one with n = 11), and only 1 study was US-based. That study[2] accounted for 59% of the neonatal deaths analyzed by Wax et al, and was based on birth certificates that did not explicitly indicate whether the place of birth was planned. Moreover, the analyses of intervention, maternal and infant morbidity involved different studies from those examined for perinatal and infant mortality. Results (Tables 2 and 3) derive from 5 or fewer of the 12 studies included for most outcomes reported, and only for cesarean section were data from as many as 10 studies included. We therefore have concerns about the generalizability of these results, especially in the current American context.

Despite variation in inclusion in specific analyses, the results are generally consistent–planned home birth results in significantly less obstetric intervention, and maternal peripartum morbidity. Although low birthweight and preterm birth were also significantly lower, no differences in large-for-gestational age and newborn ventilation were observed. We question the results for postdates delivery in Table 3; given similar crude frequencies (2.1% vs 2.2%) it seems unlikely that the multivariable analysis would yield a result of odds ratio, 1.87 (95% confidence interval, 1.50–2.32).

The analysis of perinatal and neonatal death raises more concern. A single study contributed most of the data for the perinatal mortality analysis,[3] yet this study fails the authors' case definition for perinatal death. Only intrapartum deaths, intrapartum death and death in the first 24 hours, and intrapartum death and death in the first 7 days were reported. Although these end points seem more appropriate than traditional definitions of neonatal death (death of liveborn infant within the first 28 days of life), the studies included had heterogeneous outcomes. Although the neonatal mortality analysis included more of the 12 studies, far fewer deliveries were analyzed. Had data from the de Jonge study been included,[3] Wax et al[1] would have observed no difference in odds of neonatal death between planned home and hospital births. We also dispute the notion that "nonanomalous" deliveries were identifiable in all the studies included in the mortality analyses (Table 3). Most birth defects registries worldwide identify major congenital anomalies in 3-5% of deliveries, which would yield a minimum of 10,000 anomalous infants among the home births and 5000 among hospital births in the perinatal death analysis. In actuality, less than 1% of births were so identified. Although the proportions are higher among the studies included in the neonatal death analysis, incomplete ascertainment likely occurred. The lengthy time interval across these studies occurred requires statistical control if not a stratified analysis by decade, as perinatal and neonatal mortality rates declined considerably since the 1970s.

Although we commend the efforts of Wax et al in addressing an important issue, we believe that, due to inconsistencies in the methodology and implementation of their study, its findings raise more questions than they answer, potentially giving rise to unfounded consumer fears toward a birthing choice that has otherwise been shown to result in safe and healthy outcomes for women with low obstetrical risk and their newborns.[2] ■

Russell S. Kirby, PhD, MS, FACE
Jordana Frost, BS, CLC
Department of Community Health and Prevention
College of Public Health
13201 Bruce B. Downs Blvd., MDC56
University of South Florida
Tampa, FL 33612
rkirby@health.usf.edu

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International data demonstrate home birth safety

TO THE EDITORS: The metaanalysis by Wax et al[1] resulted in misleading results and conclusions about the safety of home birth.

The authors appropriately found no difference in perinatal mortality rates between planned home and planned hospital births when they included all of the selected studies, which included the very large, high-quality Dutch study that represented >90% of the available data.[2]

However, when they summarized the risk for neonatal death separately, they chose to look only at combined early (0-6 days) and late (7-28 days) neonatal deaths. Because the Dutch study reported only on early neonatal deaths, Wax et al excluded it, thus ignoring neonatal mortality rates for 90% of the available home birth data. If early neonatal deaths had been examined separately, the Dutch study would have been included, and the conclusion would have been that the risk of early neonatal death in home births was no different than that for low-risk hospital births.

Across perinatal/neonatal studies in high resource countries, 2 of 3 to 4 of 5 of neonatal deaths consistently occur in the first 7 days.[3] There is no reason to expect that the rate of late neonatal mortality in the Dutch study would carry any difference in safety than the early neonatal mortality rates, had it been reported by or requested from the Dutch researchers.

Furthermore, when the high-quality Dutch study[2] is excluded from the neonatal analysis, the American study by Pang et al[4] consequently becomes the largest study that contributed to the neonatal risk estimate. Based on birth certificate records, this study does not meet the quality criteria of more sophisticated approaches of home birth research that, since the 1980s, have required home/hospital birth comparisons to be able to stratify explicitly for whether the home births in the studies were planned and had a midwife or physician in attendance,[5] as the Dutch study does.

Leaving out the study by Pang et al[4] or including the Dutch study[2] would have meant that the authors could not have jumped to the conclusion that less medical intervention or home births create higher neonatal risk. Rather, the more accurate conclusion of the metaanalysis would read, "planned home birth produces the same intrapartum and neonatal outcomes as planned hospital birth with far less intervention." The international media may not have picked it up so enthusiastically, but the public would not have been misled either. ■

Kenneth C. Johnson, PhD
Adjunct Professor
Department of Epidemiology and Community Medicine
Faculty of Medicine
University of Ottawa
Ottawa, Ontario, Canada
Ken47Johnson@gmail.com

Betty-Anne Daviss, MA, RM
Adjunct Professor
Pauline Jewett Institute of Women's and Gender Studies
Carleton University
Ottawa, Ontario, Canada

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"Home birth triples the neonatal death rate": public communication of bad science?

TO THE EDITORS: Current debate and commentaries about the paper by Wax et al[1] regarding outcomes of home births have focused on methodological flaws.[2] Another serious concern is the selective quoting of results and conclusions in the paper's abstract and the misleading press release from the *American Journal of Obstetrics and Gynecology* (AJOG) entitled "Planned Home Births Associated with Tripling of Neonatal Mortality Rate Compared to Planned Hospital Births," that stated ". . .of significant concern, these apparent benefits are associated with a doubling of the neonatal mortality rate overall and a near tripling among infants born without congenital defects."[3] The news story was picked up by the mass media, and reported uncritically in *BMJ* and *The Lancet*.

These practices are unethical, causing harm through unfounded confusion and fear, and misleading policymakers and the public. The Singapore statement on research integrity represents the first international effort to unify policies, guidelines, and codes of conduct for researchers worldwide.[4] Accordingly, the AJOG publication would fail on 2 counts: (1) poor quality of the study; and (2) author recommendations made beyond what the data support and outside of their professional expertise. Obstetricians are not the leading professional group in home birth and midwifery-led care, and should not reach policy conclusions in isolation. It is essential to use appropriate subject peer reviewers: in this case midwife and epidemiology experts in studies examining midwifery care and birth setting.

The AJOG needs to review its quality assurance procedures to ensure that standards of assessing and communicating science are improved. "Bad science" damages both the public and professionals. ■

Jane Sandall, PhD, MSc BSc RM, RN, HV
King's College London
10th Floor, North Wing, St. Thomas' Hospital
Westminster Bridge Rd.
London SE1 7EH, UK
jane.sandall@kcl.ac.uk

Susan Bewley, BA, MBBS, MRCOG, MD, MA, FRCOG
Guy's and St Thomas' NHS Foundation Trust

Mary Newburn, MSc BSc
National Childbirth Trust

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Perinatal mortality and planned home birth

TO THE EDITORS: We read with interest the recent systematic review of the safety of home birth.[1] The results were alarming, but closer examination revealed reason to suspend judgment.

The reported similarity in the perinatal death rate whether birth was planned to occur at home or in hospital, accompanied by an increased neonatal death rate when planned to occur at home, implies that there were fewer stillbirths in the planned home birth group. Analysis of the numbers provided in the paper indicates strong evidence that this is indeed the case, although this was not mentioned. Whether the death occurs before or after birth is not the primary criterion most would use to judge the safety of management of birth, rather the fact of the death. So the perinatal mortality should be the primary focus of the paper, not the neonatal mortality without also reporting fetal deaths.

The authors highlighted the consistency of findings related to neonatal deaths, but excluded papers (including the largest) that reported only perinatal deaths, not neonatal deaths separately. Is there some reasonable explanation for this?

The paper suggests that the true risk may be higher than reported due to the self-selection of low-risk women to planned home birth. This is a curious comment given that women in both groups in this systematic review were "low risk," or matched on risk factors.

A quick glance reveals a number of apparent errors in the tables. For example the odds ratio for postpartum hemorrhage is said to be 0.66, but using the numbers provided in the table results in an odds ratio of 0.99. There are several others. Whether these errors result from miscalculation, typographical errors, or some other factor, they have the unfortunate effect of lowering confidence in the accuracy of the paper as a whole. ■

Mary-Ann Davey, DPH
Margaret M. Flood, RN
Mother and Child Health Research
La Trobe University
215 Franklin St.
Melbourne 3000, Victoria, Australia
m.davey@latrobe.edu.au

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REPLY

Thank you for the opportunity to respond to the preceding authors. For most, these submissions simply represent their latest of a series of letters to various editors on the same paper.[1-4] At least one of the letters' clear intent is to discredit our study and force its retraction. This goal provides valuable interpretive context, calling the criticisms' severity and validity into question. Harboring no bias, we embarked on the study to examine an important clinical issue. Although our findings may be unpopular in certain quarters, they result from appropriate rigorous scientific methods that have undergone appropriate peer review. They are also consistent with the results of 2 subsequently published large, high-quality investigations.[5,6]

Common themes raised are the inclusion of one study and the handling of another.[7,8] The study by Pang et al[7] was designed and intended to examine outcomes by planned delivery location, thus was included. Data from de Jonge et al[8] were included in the evaluation of perinatal mortality as they included the important measure of intrapartum perinatal mortality.[5] However, they were excluded in the evaluation of neonatal mortality because they encompassed only early, and not late neonatal deaths. Because one-third of delivery-related neonatal deaths occur in the late neonatal period, excluding these subjects could introduce significant bias.[9,10] To the best of our knowledge, the late neonatal mortality data have not been published. Thus, the certainty with which several writers speculate that there would be no difference in overall mortality by planned delivery location is truly prescient. The centrality of this report to our study requires further critical exploration. The Netherlands has an unexpectedly high perinatal mortality rate (PMR) reflecting the significantly increased PMR observed among low-risk women entering labor under the care of midwives. The PMR in this group exceeds even that observed among high-risk women receiving hospital-based physician care. Low-risk women under the care of midwives during planned home birth and later requiring intrapartum transfer to hospitals contribute disproportionately to the PMR. Forty-nine percent of nulliparous and 15% of multiparous women planning home birth were transferred in this recent study.[6] Importantly, de Jonge et al[8] did not separately analyze low-risk women entering labor under the care of a midwife and subsequently requiring transfer to hospital-based physician care. Nor did they compare low-risk women entering labor under the care of a midwife with high-risk women entering labor in hospital under physician care. Thus the methods of de Jonge et al potentially obscured a true difference in neonatal mortality rate and PMR by delivery location.

We address the third letter from Gyte et al[1,3] to the editor regarding our publication. Their earlier authors' disclosed conflicts of interest indicating potential bias, absent here, raise more serious questions about their current criticisms, than do the criticisms regarding our study.[1,3] The MOOSE checklist includes 35 items and the authors suggest noncompliance with only 5.[11] We did not believe that an additional 225 bibliographic references were warranted. Publication bias is less of an issue in observational as compared with randomized trials. Moreover, other biases are likely to predominate, rendering funnel plots less useful in metaanalyses of observational studies.[12] The guideline does not require author contact, which was not our study's design, only its reporting if attempted. The random effects model was used in the presence of heterogeneity, as described. Furthermore, we openly cautioned readers with regard to the presence of heterogeneity when interpreting the results. Forest plots graphically expressing results have been provided to the editors. Finally, the referenced quality assessment tool does not result in a numerical score and, as per MOOSE recommendations, quality was accounted for by sensitivity analysis.

In response to Kirby and Frost, women carrying fetuses with known congenital anomalies are not typically considered home birth candidates and are therefore often excluded from study. Thus, a low prevalence of anomalous offspring in studies of home birth is to be expected. Sensitivity analysis evaluated temporal differences among included studies.

The concerns raised by Johnson and Daviss have been addressed yet were not surprising after reading their nearly identical previously published, unreferenced letter to the editor of the *British Medical Journal*.[4]

We completely agree with Sandall et al that focus should remain on the medical evidence. However, the authors' contention that only "midwife and epidemiology experts" possess, much less hold a monopoly on the training, knowledge, and skills to provide a quality review of home birth-related research is simply fallacious. A case in point follows from the comments of Davey and Flood.

These authors' criticisms reveal unfortunate fundamental knowledge deficits regarding metaanalysis and perinatal mortality. The results that Davey and Flood mischaracterize as erroneous based on simply adding all cells and taking a näive odds ratio, actually represent summary odds ratios reflecting the statistical weighting imparted to each study by the analysis.[13] The timing of perinatal death, completely discounted by the authors, is central to understanding, identifying, and modifying potentially causative factors.[5]

Given that the mortality rate among US term neonates without congenital anomalies is approximately 0.4/1000, a reasonable estimate of the excess neonatal mortality realized by planned home birth in this group would be 1 death per 1333 births (95% confidence interval, 1/476–1/7812).[14] This compares favorably with the risk of a severe adverse perinatal outcome associated with a trial of labor after cesarean.[15] However, reflexively denying the now consistently observed increased neonatal and perinatal mortality associated with planned home birth serves no conceivable good, particularly that of families choosing home birth.[5,6] Considering the decreased maternal intervention, and maternal and neonatal morbidity associated with planned home birth, it remains intriguing that the most vocal criticisms of our study demonstrating the relative safety of planned home births come from birth place choice advocates.

Joseph R. Wax, MD
Division of Maternal-Fetal Medicine
Department of Obstetrics and Gynecology
Maine Medical Center
Portland, ME
waxj@mmc.org

Michael G. Pinette, MD
Division of Maternal-Fetal Medicine
Department of Obstetrics and Gynecology
Maine Medical Center
Portland, ME

F. Lee Lucas, PhD
Maine Center for Outcomes Research and Education
Maine Medical Center
Portland, ME

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Editors' comment

We have received numerous letters to the editors regarding the article by Wax et al: Maternal and newborn outcomes in planned home birth vs hospital births: a metaanalysis, published in the September, 2010 edition of the Journal. Five of these letters are selected to be published here with the reply from the authors. In response to the concerns that were expressed in the letters, the *American Journal of Obstetrics and Gynecology* convened an independent review panel to (1) review the article that was published and these letters to the editors and (2) make recommendations to the Journal. The review panel consisted of 3 panelists who are all specialists in maternal fetal medicine, with expertise in metaanalysis and clinical research. The panel was provided a copy of the manuscript that had been submitted (Wax et al[1]) and all of the letters to the editors. In addition, after its initial review, the panel requested additional information from Dr Wax, the corresponding author of the article, that would include the individual summary graphs for each outcome that was presented in the manuscript. Each member of the panel reviewed the information independently, and consensus was reached in a conference call.

There were a number of issues raised in the letters, many of which the panel believed were subjective and should be debated openly. The issue that the panel focused on was the "numbers" that were included for each outcome in the metaanalysis. The panel reviewed several outcomes and attempted to reconstruct the results of the metaanalysis. In all 3 cases, the results the panel found was slightly different from the result in the manuscript, although there was no difference in (1) the direction of the point estimate of the pooled odds ratio or (2) the overall "statistical significance" of the result. The panel made the following recommendations: (1) The Journal should publish online full summary graphs for each outcome that was assessed in the study, which will allow readers to assess the study findings better, and (2) no retraction of the article is necessary.

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. ■

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