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Development and Validation of a National Data Registry for Midwife-Led Births: The Midwives Alliance of North America Statistics Project 2.0 Dataset

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Introduction: In 2004, the Midwives Alliance of North America's (MANA's) Division of Research developed a Web-based data collection system to gather information on the practices and outcomes associated with midwife-led births in the United States. This system, called the MANA Statistics Project (MANA Stats), grew out of a widely acknowledged need for more reliable data on outcomes by intended place of birth. This article describes the history and development of the MANA Stats birth registry and provides an analysis of the 2.0 dataset's content, strengths, and limitations.

Methods: Data collection and review procedures for the MANA Stats 2.0 dataset are described, along with methods for the assessment of data accuracy. We calculated descriptive statistics for client demographics and contributing midwife credentials, and assessed the quality of data by calculating point estimates, 95% confidence intervals, and kappa statistics for key outcomes on pre- and postreview samples of records.

Results: The MANA Stats 2.0 dataset (2004-2009) contains 24,848 courses of care, 20,893 of which are for women who planned a home or birth center birth at the onset of labor. The majority of these records were planned home births (81%). Births were attended primarily by certified professional midwives (73%), and clients were largely white (92%), married (87%), and college-educated (49%). Data quality analyses of 9932 records revealed no differences between pre- and postreviewed samples for 7 key benchmarking variables (kappa, 0.98-1.00).

Discussion: The MANA Stats 2.0 data were accurately entered by participants; any errors in this dataset are likely random and not systematic. The primary limitation of the 2.0 dataset is that the sample was captured through voluntary participation; thus, it may not accurately reflect population-based outcomes. The dataset's primary strength is that it will allow for the examination of research questions on normal physiologic birth and midwife-led birth outcomes by intended place of birth.

Keywords: birth center, cohort study, data collection, home childbirth, midwifery, parturition, registry, research design

INTRODUCTION

In 1982, the Midwives Alliance of North America (MANA) was established as an inclusive professional organization with the express goal of uniting and representing all North American midwives, regardless of educational background, credentials, or primary place of practice.[1] Over the last 30 years, however, MANA has become largely US-based due, in part, to the increasing number of professional midwifery organizations that have formed in Canada and Mexico.[2,3] Today, the mission of MANA is to work with other midwifery organizations, including the American College of Nurse-Midwives (ACNM), the National Association of Certified Professional Midwives, and the International Confederation of Midwives, to strengthen the midwifery profession and improve access to high-quality maternity care for all women and newborns both in the United States and globally.

Over the last decade, one of MANA's key initiatives has been the development of the MANA Statistics Project (MANA Stats), a data collection system that captures perinatal and process-of-care data for midwife-led births in all settings. This unique and comprehensive Web-based registry was designed to facilitate research on midwifery care and normal physiologic labor and birth. In this article, we describe the purpose and development of MANA Stats, provide an overview of data collection and review procedures, and present characteristics of the MANA Stats 2.0 sample (2004-2009). In addition, we report results from an analysis of the data quality wherein pre- and postreviewed samples were evaluated for differences across key benchmarking variables. We conclude with an overview of the strengths and limitations of the 2.0 dataset.

BACKGROUND

Following the World Health Organization's call for the elimination of unnecessary and costly interventions in childbirth,[4] explicit benchmarks and strategies for supporting safe, physiologic birth have emerged.[5–9] This emphasis on normal physiologic birth research stems at least in part from the poor maternal and infant health outcomes documented in the United States, despite the $98 billion spent annually on inpatient pregnancy, birth, and newborn care.[10–13] The negative health effects for mother and newborn associated with unnecessary interventions, and exacerbated by the simultaneous disruption of beneficial and protective effects afforded by

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Quick Points

- The Midwives Alliance of North America Statistics Project (MANA Stats) 2.0 dataset contains demographic characteristics and outcomes for 24,848 midwife-led births across all settings; 20,893 courses of care were for women who planned a home or birth center birth at the onset of labor.
- Midwives logged clients into the data collection system early in prenatal care and entered data throughout pregnancy, labor and birth, and the postpartum period.
- Data quality testing found near-perfect agreement between pre- and postreviewed variables, suggesting that midwives entered MANA Stats 2.0 data with a high degree of accuracy.
- The MANA Stats 2.0 dataset is a comprehensive data source for research on midwifery processes of care, normal physiologic birth, midwife-attended birth, and birth outcomes by intended place of birth.

physiologic labor and birth, are increasingly understood as root causes of poor maternal and infant health.[14–17]

The advancement of research on normal physiologic birth and the adoption of evidence-based recommendations that support undisturbed birth require information derived from large datasets comprised of births occurring with little or no technological intervention. These resources have proved difficult to develop in the United States where "high-tech, low touch" birth[18] has been normalized.[19] The MANA Stats database[20] and the American Association of Birth Centers' (AABC's) Uniform Data Set (UDS)[21,22] are the largest datasets in the United States, comprised of midwife-led births occurring in home and birth center settings with low rates of intervention. As such, these datasets are uniquely positioned to contribute to research on normal physiologic birth.

In 1993, a group of midwife researchers within MANA, called the MANA Statistics Committee at the time, developed and piloted a data collection tool designed to help track demographic characteristics and pregnancy- and birth-related outcomes for midwife-led births occurring primarily in the United States. User feedback over the next 7 years led to several modifications, and the MANA Stats 2.0 paper data collection form resulted. In 2000, this form was used for a year-long, prospective study of planned home births attended by certified professional midwives (CPMs) in North America. Data were collected on all CPM clients who consented to participate during the research year. Participation was mandatory for all CPMs, and results were published in 2005.[20]

In 2004, MANA restructured their Statistics Committee and renamed the resulting group the MANA Division of Research (DOR). Later that same year, the DOR developed an online data collection tool based on the 2.0 paper data form and incorporated a system of prospective logging of clients at the initiation of care. Data were collected using this Web-based form for all births logged between November 2004 and December 2009 (Table 1). These data have been exported and analyzed for key pregnancy, birth, and newborn outcomes.[23]

MANA Stats was developed for 3 purposes. First, it was designed to allow midwives to keep track of their practice demographics and outcomes via statistics reports autocalculated instantly for all contributors and accessible via their online accounts. Midwives are encouraged to use these data when describing their practice outcomes to prospective clients. Any type of midwife is welcome to contribute data to MANA Stats, including CPMs, certified nurse-midwives (CNMs), certified midwives (CMs), naturopathic midwives, and traditional midwives without formal credentials.

Second, data collected in MANA Stats provides key benchmarks to its contributors at the annual MANA professional meetings, as well as via the MANA newsletter and direct communications with contributors. Like the ACNM benchmarking project,[24,25] this service is designed to provide contributors with the tools and standards needed to evaluate their own practices as part of ongoing quality assurance and quality improvement.

Third, MANA Stats collects and maintains high-quality datasets that can be used by researchers to examine study questions related to normal physiologic birth and midwife-led care. Because the vast majority of births in the 2.0 dataset (>85%) occurred at home or in birth centers in the absence of common medical interventions such as epidural analgesia, synthetic oxytocin induction or augmentation, and continuous electronic fetal monitoring, this registry provides the rare opportunity to examine birth outcomes for a large, voluntary sample of births with minimal intervention.[5] The features of the Web-based tool were developed in accordance with the Agency for Healthcare Research and Quality guidelines for data registries.[26]

METHODS

Variables Collected

The MANA Stats 2.0 data collection tool allowed midwives to enter data on the basic demographic characteristics of participating women and families; pregnancy and general

Table 1. Summary of MANA Stats Data Collection Form Versions

Form Version	Dates in Use	Courses of Care
2.0	11/2004-12/2009	24,848
3.0	5/2009-1/2012[a]	15,660
4.0[b]	5/2011-Current	22,905[c]

Abbreviation: MANA Stats, Midwives Alliance of North America Statistics Project.
[a]Between May 2011 and January 2012, contributors were able to choose between the 3.0 form and the 4.0 form, constituting a period of overlap in form versions.
[b]This is the current form version in use by MANA Stats.
[c]This is the total number of courses of care completed by midwives using the 4.0 form at the time of this writing; new courses are being added at a rate of approximately 1000 per month.

Table 2. Variables Collected on the MANA Stats 2.0 Form

Form Section	Variables Included
Midwife credential	CPM, CNM, other
History	Woman and partner demographic characteristics; obstetric history; prepregnancy anthropometrics; method of conception; history of sexual abuse/assault
Current pregnancy	Maternal health; fetal health; emotional/social factors; prenatal care; payment source; use of controlled substances; diet; physical activity levels; perineal massage; use of herbs or homeopathy; breech after 28 weeks' gestation and version procedures
Birth data	Transfer of care; birth site intention and motivation; place of birth; length of gestation; weight gain
Labor	Induction or augmentation; length of labor by stage; rupture of membranes; number of newborns; date of birth; labor progress (plateaus, reversals, anterior lips, etc); presentation and position; woman's mobility and positions; monitoring methods; hydrotherapy and other low-intervention pain relief; oral intake; IV access; medications; herbs; homeopathy; perineal support
Complications and procedures	Transport, including timing and details; hospital or birth center procedures; cesarean birth; shoulder dystocia and resolution techniques; meconium; miscellaneous factors and complications
Third stage	Timing of cord clamping; maternal position; placental delivery method; blood loss; hemorrhage treatment
Newborn	Anthropometrics; Apgar scores; clinical evidence of gestational age; stillbirth; anomalies; immediate neonatal care; immediate neonatal complications and emergency treatment; newborn health problems; circumcision; infant hospital admittance (first 6 weeks); newborn death
Postpartum	Maternal hospital admittance; postpartum complications, including postpartum depression; maternal death; number of postpartum visits with midwife; number of postpartum visits with other provider; breastfeeding; overall health assessment

Abbreviations: IV, intravenous; CNM, certified nurse-midwife; CPM, certified professional midwife; MANA Stats, Midwives Alliance of North America Statistics Project.

health history; antepartum, intrapartum, neonatal, and postpartum events and procedures; and maternal and newborn outcomes. Data were also collected on antepartum, intrapartum, and postpartum maternal and neonatal transfers of care, as well as on intended and actual place of birth. In total, 182 variables were collected. Categories of variables are summarized in Table 2. A copy of the 2.0 data collection form and a demonstration of the system are available at http://demo.manastats.org.

Data Collection

The data collection design for MANA Stats hinges on preregistration, or prospective logging, of all clients. Each midwife contributor is given a password-protected account to use for secure access to the Web site. To minimize selection bias, the software requires contributing midwives to log clients early in prenatal care, before outcomes are known. If a midwife attempts to log a client after her due date, the midwife is blocked from doing so and must go through an appeals process with the DOR to explain the rationale for logging a client late. A total of 1211 (4.9%) late-added clients are included in the 2.0 dataset, even though the midwife did not prospectively log them per project protocols. These clients were allowed entry primarily because the woman transferred care to the midwife near term and gave birth before she was logged or her consent form was received, or because there was a software or consent problem with the MANA Stats system. Key outcomes for late-added clients and those added early in care were compared periodically throughout the study period to make sure there were no differences between groups.

A client consent form is required for every course of care entered; if the client declines consent, her birth data are not included in the dataset. The estimated rate of decline for MANA Stats is less than 3%, reflecting clients who either declined consent or who left care prenatally without returning a consent form. Most contributors report never having had a client who declined consent (B. Ackerman, MANA Stats Director of Data Collection, written communication, February 2013).

Midwife contributors completed the online 2.0 data form over the course of care through to the 6-week postpartum visit, or the final visit if earlier. Upon enrollment in the project, midwife contributors were provided with detailed instructions that included logging and data collection procedures, the use of the online data collection tool, variable definitions, and suggestions for effectively integrating MANA Stats into practice. The MANA DOR presented training workshops at national and regional conferences throughout the study period. Data collection team members, called data doulas, provided e-mail and phone support to all contributors, and the MANA newsletter and direct contributor communications were used to inform midwives when data quality concerns were identified during the data review process.

The MANA Stats data collection software is designed to flag courses of care when a data point is either missing or outside of an expected range. In this way, midwives are prompted to reexamine potential errors and to either correct the entry or to enter a brief explanation at the site of the flag. Once all flags on a course of care are explained or corrected, the form can be submitted to the database. Data are stored on a secure server with encryption software congruent with privacy and security measures defined by the United States Department of Health and Human Services.[27,28]

Data Review

All courses of care submitted by midwives using the 2.0 form were subjected to 3 postsubmission review processes. The software identified a data form for review if: 1) minor mistakes or inconsistencies remained in the form; 2) a midwife indicated that there was a transfer or hospital admission for mother or newborn; or 3) a miscarriage, stillbirth, or death of mother or newborn/infant was reported. Nearly half (42%) of all courses of care collected on the 2.0 form met at least one of these criteria and underwent some level of review.[29]

The first level of data review was designed to catch and correct inaccuracies or inconsistencies in a form. An example of this is when an estimated date of birth (EDB) was more than 30 days earlier or later than the original EDB, but there were no other indicators on the form that the newborn was preterm or postterm. The computer system flagged the entry for further verification by a data reviewer, who contacted the midwife to request verification of the newborn's date of birth, EDB, estimated gestational age, etc. The review process identified simple data entry errors, as well as possible flaws in form design or phrasing that led to recurring errors. Information on potential flaws was then used to modify the form through to its current iteration (Table 1). This phase of the data review process, combined with the presubmission flags, enabled correction of the majority of data entry errors.

In the second level of data review, records that indicated a transfer to the hospital or a hospital admission for mother or newborn were examined. Some of these cases did not require a call to a midwife because they had no internal inconsistencies or missing data points. However, many records contained errors that required contact with a midwife (eg, an intrapartum transfer from home to hospital was indicated, but the midwife had also indicated that the hospital was the intended place of birth at the onset of labor). These types of errors triggered a call or e-mail message from a data reviewer who, via consultation with the midwife and the medical record, clarified the intended and actual place of birth. Overall, 50% of all forms flagged for the first or second level of data review (21% of the total 2.0 forms) contained actionable errors such that the data reviewer initiated contact with the midwife and, via consultation with the medical record, either confirmed or corrected a potential error or inconsistency in a form.

In the third level of data review, forms indicating maternal, fetal, or newborn deaths underwent detailed case review. Using a modified Fetal–Infant Mortality Review approach,[30,31] 4 experienced midwife-researchers first identified all miscarriages and then conducted detailed interviews with midwives for all nonmiscarriage fetal and neonatal deaths and any maternal deaths. The objective was to clarify the gestational age at which the death occurred and to properly classify late miscarriages (some midwives listed fetal losses occurring at or around 20 weeks' gestation as miscarriages, while others used intrauterine fetal demise [IUFD] as the classification). The reviewers also collected as much qualitative data as possible on when, how, and why the death occurred, as well as data on whether an autopsy was conducted, and the official cause of death assigned via medical examiner or coroner's report. This step was essential because the 2.0 form was not designed to collect this level of detail; all subsequent versions of the data collection tool (Table 1) were enhanced to capture these data. The reviewer classified each case as a miscarriage (death occurring prior to 20 completed weeks' gestation), an IUFD (death occurring at or after 20 weeks' gestation but before birth), or a neonatal death (death occurring after a live birth but before 28 completed days of life).

To enhance comparability with other perinatal datasets, the reviewer also categorized each death, as per the coroner's and the midwife's assessments of the cause of death, into standard International Classification of Diseases-10 categories for fetal/infant deaths[32,33] and American College of Obstetricians and Gynecologists categories[34] for maternal deaths. All but one midwife was reachable and willing to discuss the demise. That single perinatal death remains in the sample, but lacks additional data on autopsy, cause of death, etc.

Assessing Data Quality

In March 2008, the DOR captured a snapshot of the 2.0 data that had not yet been reviewed, including 7 key benchmarking variables: rates of cesarean, preterm birth (based on clinical gestational age assessment), low birth weight (<2500 grams), intrapartum transfer, neonatal transfer, postpartum transfer, and low 5-minute Apgar score (<7). At the time of the prereview snapshot, 10,040 complete courses of care had been submitted. Of these, we limited the prereview/postreview comparison sample to those records where home or birth center was indicated as the intended place of birth at the onset of labor, for a total of 9932 courses of care. Out of these 9932, only 42% were actually prereview in the sense that they eventually went through the review process. The other 58% never triggered a review based on the criteria described above. Then in April 2011, after the data review process for 2.0 forms was complete, another snapshot of the same subsample

(n = 9932) was captured postreview. We evaluated selected benchmarking variables to determine if there were any significant differences between the pre- and postreviewed datasets. The reliability of the data collection methods was assessed by calculating point estimates, 95% confidence intervals, and kappa statistics for congruence of pre- and postreview datasets.[35]

Data Export and Analysis of Sample Characteristics

After the review process was complete, all data from the 2.0 dataset were exported from the SQL-based online data collection system as a comma-separated values (*.csv) file. Identifiers were removed, although enough details remain (eg, date of birth, rare events) that the dataset is, according to the Health Insurance Portability and Accountability Act criteria, a limited dataset rather than a fully de-identified dataset. Complete details can be found in the codebook for the 2.0 dataset, available upon request to interested researchers. Following approval by Oregon State University's institutional review board, this file was imported into SPSS Statistics[36] for calculation of pre- and post-review frequencies, proportions, and kappa statistics, as well as basic descriptive statistics for sample characteristics. We calculated 95% confidence intervals around the proportions, using the standard formula.

RESULTS

Sample Description

The 2004 to 2009 MANA Stats 2.0 dataset includes data from a total of 24,848 courses of care. The sample for the analyses reported here is restricted to 20,893 pregnancies in which women were planning a home or birth center birth at the onset of labor. These pregnancies included 66 sets of twins for a total sample of 20,959 newborns. Excluded from our sample are 521 women who were not planning a home or birth center birth at the onset of labor, 3434 women who transferred care to another provider prior to the onset of labor for either medical (eg, a complication requiring obstetric specialty care) or nonmedical (eg, woman moved during pregnancy) reasons.

The births in this sample were attended by 445 different midwives over the 6-year research period. Certified professional midwives were the primary attendant at 15,342 (73.4%) of these births. An additional 2621 (12.5%) births have CNMs/CMs listed as the primary attendant, and 502 of the births (2.4%) were attended by midwives who held both a CPM and CNM credential. The remaining births were attended by midwives who identified as licensed midwives (n = 1270, 6.1%), direct-entry midwives without licensure or certification (n = 166, 0.8%), or "other" (n = 48, 0.2%)—a heterogeneous category containing students, naturopathic doctors, and doctors of osteopathy. Because 48 contributors listed no credential on their enrollment forms, there are 966 (4.6%) births in the sample for which attendant type is unknown.

The majority of women in the sample are white, middle-income, college-educated, married, and multiparous, with 91.9% identified on the data form as Caucasian, 4.9% identified as Asian, 4.6% identified as Hispanic, 2.2% identified as African or Caribbean, and 1.2% identified as Native American. In addition, 5.6% of the sample (n = 1163) is comprised of Amish, Mennonite, or similarly religious women from Plain communities.[37] Mormon, Muslim, and Orthodox or Hassidic Jewish women make up 0.8% (n = 173), 0.08% (n = 17), and 0.7% (n = 138) of the sample, respectively. Most (90.7%) of the women had completed high school, and 49.4% had completed 4 years or more of college; 87.1% were married; and an additional 10.1% were unmarried, but partnered. The geographic distribution of the births included 35.7% in the Pacific states (Alaska, California, Hawaii, Oregon, Washington); 23.4% in the West (Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Oklahoma, Texas, Utah, Wyoming); 14.8% in the Midwest (Illinois, Iowa, Indiana, Kansas, Michigan, Minnesota, Missouri, North Dakota, Nebraska, Ohio, South Dakota, Wisconsin); 10.8% in the Southeast (Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, North Carolina, Kentucky, South Carolina, Tennessee, Virginia, West Virginia); 10.0% in the North Atlantic states (Delaware, New Jersey, New York, Maryland, Pennsylvania, Washington, DC); and 5.3% in New England (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont). The residency pattern was 49.4% urban, 15.2% suburban, 19.5% small town, and 15.9% rural; these designations were subjective because the midwives were not provided standardized definitions for these terms based on population densities. One-quarter of the sample was primiparous, and 8.2% were grand multiparas ($\geq$ 5 previous live births or stillbirths after 20 weeks' gestation).

Pre- and Postreview Comparison

Of the 9932 courses of care included in the prereview/postreview dataset, 4171 met at least one of the review criteria described previously. As Table 3 summarizes, the overlap of 95% confidence intervals for the estimated rates of the 7 key outcomes evaluated is near perfect. This is confirmed by an examination of the kappa statistics, all of which are above 0.98 indicating near perfect agreement between the pre- and postreview data. Taken together, these data indicate that on both the aggregate level (rates and confidence intervals) and the individual level (kappas), the data as originally entered into MANA Stats were highly accurate. Consultation of the medical record and correction of the form, when indicated, did not result in significantly improved data accuracy for key benchmarking variables postreview.

DISCUSSION

Strengths of the MANA Stats 2.0 Dataset

The MANA Stats 2.0 dataset includes data on complete courses of prenatal, birth, and postpartum care for 20,893 pregnant women who planned a midwife-led home or birth center birth. These data have some unique properties that will allow for the examination of research questions related to midwife-led births, normal physiologic birth, and birth outcomes by intended place of birth. In 2009, 62% of home births in the United States were attended by midwives: 19% by CNMs and 43% by "other midwives," including CPMs and other direct-entry midwives.[38] However, CPM practice and outcomes are understudied.[39] More than 70% of births in the

Table 3. Comparison of Key Outcomes Prereview and Postreview of the MANA Stats 2.0 Dataset for 9932 Women Who Were Planning a Home or Birth Center Birth at the Onset of Labor

	Prereview Sample		Postreview Sample		
	n (%)	95% CI around percent	n (%)	95% CI around percent	Kappa
Preterm birth[a,b]	124 (1.25)	1.03-1.47	123 (1.24)	1.02-1.46	0.995
Cesarean birth[c]	554 (5.58)	5.13-6.03	554 (5.58)	5.13-6.03	1.00
Birth weight < 2500 g[d]	82 (0.83)	0.65-1.01	81 (0.82)	0.64-1.00	1.00
Intrapartum transfer[e]	1172 (11.80)	11.17-12.43	1167 (11.75)	11.12-12.38	0.996
Neonatal transfer[f]	83 (0.84)	0.66-1.02	86 (0.87)	0.69-1.05	0.982
Postpartum transfer[g]	199 (2.00)	1.72-2.28	200 (2.01)	1.73-2.29	0.992
Apgar score < 7 at 5 minutes[h]	151 (1.57)	1.27-1.75	151 (1.57)	1.27-1.75	1.00

Abbreviations: CI, confidence interval; g, grams; MANA Stats, Midwives Alliance of North America Statistics Project.
[a]Data available for 9929 participants.
[b]These data come from one question on the 2.0 data form. The exact wording of the question is: "Any clinical evidence that baby is preterm?" Further instructions were not given to midwives.
[c]Data available for 9927 participants in prereview sample and 9926 in postreview sample.
[d]Data available for 9878 participants in prereview sample and 9876 in postreview sample.
[e]Intrapartum transfer: Mother and fetus are transported to the hospital during labor for additional care.
[f]Neonatal transfer: Birth is completed outside of the hospital, but the newborn is transported to the hospital for additional care.
[g]Postpartum transfer: Birth is completed outside of the hospital, but the mother is transported to the hospital for additional care.
[h]Data available for 9644 participants in prereview sample and 9643 in postreview sample.

MANA Stats 2.0 sample were attended by CPMs, allowing researchers a unique opportunity to study practices and outcomes associated with these providers.

In addition, interventions such as continuous electronic fetal monitoring, labor induction and augmentation with synthetic oxytocin, and epidural anesthesia are so ubiquitous in contemporary hospital settings[12,40] that it is challenging to find perinatal datasets that contain a large number of undisturbed births. The AABC's UDS and MANA Stats share a similar capacity for the collection of data on normal physiologic birth, and both include home and birth center births. However, the UDS draws data primarily from birth centers, while the MANA Stats 2.0 dataset predominantly contains courses of care for women who intended to give birth at home.

Most important, this dataset is valuable to researchers because it allows for the analysis of outcomes by intended place of birth. As has been noted in studies examining trends in birth setting in the United States,[38,41] it is currently impossible to reliably study outcomes by place of birth using vital statistics data alone because, to date, in most states, birth certificates collect only actual place of birth and not intended place of birth. Analysis of birth outcomes by setting are subject to misclassification bias because some intended home and birth center births actually occur in the hospital following intrapartum transfer, just as some planned hospital births accidentally occur at home in the absence of a professional birth attendant. Reliable evaluation of safety and efficacy of midwife-led birth across birth settings can only occur when women are correctly classified according to intended place of birth at the onset of labor.

Pre- and Postreview Analysis

An analysis of selected variables pre- and postreview revealed kappas ranging from 0.98 to 1.00, where kappa greater than 0.7 is considered good.[42] A 2012 systematic review of the quality of data in perinatal population health databases summarized sensitivity, specificity, and kappa ranges for 43 studies that compared perinatal data collected for research purposes against a gold standard, usually medical records.[34] While some data points (eg, mode of birth) had excellent agreement, many other variables showed much lower kappa ranges, revealing errors and inaccuracies in perinatal data collection. In comparison, the MANA Stats 2.0 data were accurately entered by participants, as evidenced by the perfect or near perfect agreement among pre- and postreview variables. This suggests that any errors in this 2.0 dataset are primarily random and not systematic, at least for the key outcomes assessed.

Limitations

There are several limitations of the MANA Stats 2.0 dataset for the purposes of research. The primary one is that the sample was captured through voluntary participation by providers; thus, it may not accurately reflect population-based outcomes. In addition, we are unable to quantify precisely what proportion of practicing midwives contributed data between 2004 and 2009 for a number of reasons. For example, a total of 54 CNMs contributed data between 2004 and 2009. According to the National Center for the Analysis of Healthcare Data, there were 7922 CNMs licensed in the United States in 2009. Given that the known proportion of CNMs attending home births is less than 4%,[43] we estimate that approximately 316 CNMs were attending home births in 2009, for a participation rate of about 17% for MANA Stats. In addition, only 12.5% of births in the MANA Stats 2.0 dataset were attended by CNMs. As such, this dataset captures a very small proportion of the total births attended by CNMs; thus, it cannot be used to reliably describe CNM practice outcomes—or even those outcomes for the subset of CNMs who attend home and birth center births.

Although a much larger proportion of the total number of active CPMs contributed data between 2004 and 2009, there are still barriers to estimating a participation rate for the 6-year period. The number of CPMs in the United States has increased sharply over the last decade. In the year 2000, there were only 624 CPMs. By 2009, this number had risen

to 1645 (I. Darragh, North American Registry of Midwives Chairperson, written communication, December 2012). In addition, 25% of contributors to the project did not participate continuously throughout the study period, enrolling and disenrolling as they temporarily or permanently exited project participation and/or clinical practice. The system in place between 2004 and 2009 did not allow us to track participation trends closely enough to provide further detail about how many or what types of midwives contributed data throughout the study period versus dropping out early or entering late. The credential of the midwife contributor is also unknown in 4.6% of cases. Although we diligently sought to identify credentials for all contributors who left this portion of the enrollment form blank (through communications with the North American Registry of Midwives, for example), the fact that more than 4% remain unknown limits our ability to describe the project's contributor base. Furthermore, in a recent survey of currently credentialed US CPMs, 13.8% of participants reported having attended no births as a primary midwife in the previous 3 years, despite maintaining a current credential (M. Cheyney, PhD, CPM, LDM et al, unpublished data, February 2013). A final limitation stems from the regulatory environments in some states that restrict midwifery practice, particularly for CPMs. In states without a mechanism in place to census such practitioners, the contributor denominator is unknown. Taken together, these factors make it difficult to calculate the captured proportion of all potentially eligible contributors. Based on examination of MANA Stats enrollment records and data from the North American Registry of Midwives on the number of CPMs by year, our best estimate is that between 20% and 30% of active CPMs contributed data between 2004 and 2009. Although not ideal, especially when vital statistics data are ineffective at capturing accurate outcomes,[41] this rate of participation is comparable to other recently reported midwife-led birth benchmarking projects.[24,25,44]

The data entered into the MANA Stats system come from medical records, which have some known limitations when used for research.[45,46] The main limitation is that medical records are kept to facilitate clinical care, as well as for billing and liability purposes, without thought to future research questions that may be asked of the data. If a given condition is not reported in the medical record, it does not necessarily mean that it was not present, but may be that it was not documented. However, we expect that nearly all of the variables reported here would have been accurately documented in client records because of their importance to clinical care. In addition, in most cases the midwives themselves, not a third-party records abstractor, entered the data, increasing accuracy. Furthermore, for mode of birth, intrapartum transfer to the hospital, etc, our prereview/postreview analysis showed no significant differences, suggesting that the key variables were initially entered into MANA Stats from midwives' medical records with a high degree of accuracy.

When the 2.0 research dataset was closed in 2011, it included some incomplete forms (2456 incomplete records out of a total of 27,304 logged, or 9.0%). Throughout the project, midwives received automated e-mails every 6 weeks reminding them to complete their forms. In addition, one year prior to closing the 2.0 dataset, all midwives with incomplete entries were contacted by the director of data collection for the DOR and encouraged to complete their records with the assistance of a data doula. While many did, a small number of midwives expressed the desire to leave the project rather than to complete data entry. It is possible that some selection bias was introduced by dropping all incomplete forms from the dataset, although our analyses of these forms suggest a pattern in which midwives simply stopped participating at some point after falling behind rather than a pattern of episodically uncompleted forms. There is no evidence that providers with incomplete records failed to complete those with adverse outcomes.

Finally, we have no way of assessing whether midwives who participated in this project logged every client who consented to participate. It is theoretically possible that some midwives intentionally excluded some courses of care from their reporting; however, the protocol and software required that clients be logged early in the pregnancy, and with a low-risk home birth population it would be difficult, if not impossible, for a midwife to predict ahead of time which births not to log.

Going forward, the quality of the data would be greatly improved if national or state regulations required mandatory participation in MANA Stats or AABC's UDS (now called the Perinatal Data Registry) for all midwives attending home and birth center births, as these are the only registries currently capturing data on planned place of birth and midwifery-led, process-of-care in the United States. Such regulations are already established for CPMs licensed in 2 states (Oregon, Vermont) and are under consideration in others (Arizona, California, Colorado, Texas, and Washington).

CONCLUSION

The MANA Stats 2.0 dataset is a unique and comprehensive source for research on midwifery care across all settings, including planned home birth, birth centers, and hospitals. These data, especially in combination with AABC's UDS,[22] have some unique properties that will allow for the examination of research questions that cannot be answered by existing data sources currently available in the United States. Because the vast majority of births (>85%) in the MANA Stats 2.0 dataset occurred at home or in birth centers without common medical interventions, this registry provides a rare opportunity to examine outcomes for a large cohort of women who experienced normal physiologic births.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

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