HANDBOOK FOR RESEARCHERS INTERESTED IN OBTAINING ACCESS TO THE MANA STATS DATASET

The Midwives Alliance of North America, Division of Research (DOR) Coordinating Council has created specific procedures for requesting access to MANA Stats data, which are available for research purposes only. These documents are contained in this Handbook and the related forms are available on the Midwives Alliance website: http://www.mana.org/research-main

Midwives Alliance Division of Research

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Introduction

Thank you for your interest in the Midwives Alliance of North America Statistics Project (MANA Stats). The MANA Stats datasets contain tens of thousands of records describing the pregnancy, birth and postpartum processes and outcomes for families who choose midwife-led care. Data collection is ongoing; at this time, over 1100 new records are entered each month. The vast majority of the records within MANA Stats describe births that took place in the United States; however, midwives practicing in any location are able to contribute their data to MANA Stats. Most mothers in MANA Stats plan either a home or birth center birth.

The MANA Stats data collection system is web-based, and data are entered by midwives, based on their medical records. The system has a high level of data security, and meets the HIPAA legislation standards set by the US Department of Health and Human Services. When midwives enroll in the project as a *contributor*, they sign written informed consent and provide demographic information about themselves and their practice.

Contributing midwives then ask each of their clients (patients) for permission to enter data. This inquiry occurs early in pregnancy, before outcomes are known; this helps to reduce selection bias for the study population. A record for a given client must be started in the system before the expected date of birth. If such "prospective logging" does not happen, that birth is not included in the research dataset.[1] *Mothers* also give informed consent for their data to be entered into MANA Stats, which includes explicit permission for the data to be used in research.[2] Over 95% of mothers have agreed to allow their data to be entered into the system (Cheyney et al., "Development and validation…" *JMWH,* 2014). Midwives are expected to complete the data form for a given client within 6 weeks of the final postpartum visit; all forms from a given year *must* be completed by May 5 of the following year.

A demonstration version of the current iteration of MANA Stats is available at: http://demo.manastats.org. This site operates exactly as the real site operates for midwife contributors, except that records created are not entered into the MANA Stats dataset and are erased periodically.

History of changes to the MANA Stats Datasets

The web-based data collection system was launched in 2004, and, because it was based on a paper form developed by the organization in previous years, was dubbed "the 2.0 dataset." The 2.0 dataset can be viewed on the demo site by logging in as "guest20."

The DOR periodically assesses the content of the form, and makes minor changes based on user feedback or updated literature searches. These minor changes—usually a slight change in the wording of a question, including adding additional answer options, or adding/removing a

[1] The midwife has the option of appealing, and if she contacts the DOR and provides an acceptable explanation (usually, that the mother chose home birth late in her pregnancy and midwife did not have a chance to pre-log the client), then the record is included in the research dataset. This applies to fewer than 5% of records in the dataset.
[2] Prior to 2014, pregnant women provided written informed consent. After consultation with our IRB, we transitioned to a verbal consent process, and this has been used since.

question—are recorded in the codebook, but do not constitute a new "version" of the dataset. New/revised questions are pilot tested before full implementation. This process is ongoing, throughout the 2.0, 3.0, and 4.0 data collection forms (see below).

In May 2009, the DOR launched a completely revised data collection form, dubbed "3.0 long form." This form was designed to collect extensive detail about midwifery practice and many more details about the pregnancy and birth. For these reasons, it was much longer than the previous 2.0 form, and many contributors stopped participating in the project because of the time involved to enter data on each birth. The DOR recognized, at this point, that major revisions were necessary; a shorter version ("3.0 short form") containing only necessary items was issued as a temporary stopgap measure. These forms can be accessed on the demo site by logging in as "guestlong" and "guestshort," respectively.

Then in May 2011, the 4.0 form was launched as the new primary data collection form. The 4.0 form design drew from experience with the 2.0 and 3.0 versions, though questions have been extensively re-worked based on the latest midwifery, home and birth center literature. Shortening the form had the desired effect, and the number of contributors has been steadily increasing since implementation of the 4.0 form.

At this time, both the 2.0 and 3.0 forms have been "closed"; ongoing data collection occurs using the 4.0 form only. Datasets based on each form are currently available to researchers. We encourage early consultation with the DOR regarding your research question to determine which dataset(s) will best suit your needs.

Data Review Procedures

As the midwife enters data, the MANA Stats system automatically 'checks' for impossible or inconsistent values. Midwives are required either to fix the offending value(s), or to enter a free-text explanation for each.

Once the midwife has completed and submitted the entire record (this happens usually at 6-12 weeks postpartum), some forms are then automatically selected for Data Review. For the 2.0 dataset, these selected forms included:

- any form in which an inconsistent value remained (i.e., the midwife entered an explanation, as above, when prompted about inconsistent or missing values)
- any form on which a transport to the hospital was noted

A Data Reviewer--paid staff members (usually midwives), trained by the DOR and supervised by the Data Review Coordinator--viewed each of these selected forms. Data reviewers follow pre-specified (revised as necessary, on an ongoing basis) protocols for reviewing the data with extensive software support to guide review to the areas needed. In many cases (58% of cases for 2.0 data), the data reviewer examined the record, determined that either no changes were necessary (i.e., the midwife's explanation was sufficient and reasonable, or the hospital transport was straightforward and correctly entered) or that only minor changes were necessary and sufficient information existed within the record for the data reviewer to make the changes

herself (e.g., the midwife listed a miscarriage at 24 weeks; data reviewer corrected to an IUFD). In the remaining 48% of cases in the 2.0 dataset, the data reviewer contacted the midwife, and asked her to verify details by going back to her chart. For the 3.0 and 4.0 datasets, data review is less extensive because more automatic checks are in place, catching simple errors. Additionally, our analysis of 2.0 pre- and post-reviewed samples revealed that, on an aggregate level, the Data Review procedures did not substantially alter the data (Cheyney et al., "Development and validation…" *JMWH*, 2104).

For all versions of the MANA Stats data collection form, if a fetal or neonatal death after 20 weeks, or a maternal death at any time, is noted, the record undergoes extensive review using a modified Fetal-Infant Mortality Review (FIMR) procedure. Specially-trained data reviewers interview each midwife via telephone to ask additional questions about the circumstances of the death and categorize the death according to current ICD-10 codes (for fetal/newborn deaths) or ACOG categories (maternal deaths). These additional variables are entered directly into the data form for all cases involving a death.

Datasets available for research

Each of the MANA Stats datasets are available for research; each has unique characteristics and variables. We encourage researchers to contact the DOR early to discuss which datasets will best suit their needs.

Please note that, because of the way the data are collected, the following topics cannot be studied using the MANA Stats datasets: miscarriage, IUFD, and antenatal transfers of care from midwives to obstetricians[3]. It would also be difficult to study inductions, because many times these women are marked as an antenatal transfer (as Pitocin inductions cannot be done at home) and we are not confident that we have captured complete data for all such cases, leaving the research subject to unquantifiable selection biases.

There are additional topics that would be difficult to study because of low numbers of events (e.g., some racial/ethnic minority groups, rare outcomes); please contact the DOR's Research Review Committee (researchapplications@manastats.org) if you have power/sample size inquiries for specific variables. We recommend doing this early in your planning process, so that you do not spend time developing a non-feasible research question.

Data Access Fees

There is a cost to researchers for using MANA Stats data; these fees are used to cover the ongoing costs of data collection (server space, programmer time for changes to the form, data reviewer salaries and contributor support, etc.) and data cleaning/processing (maintenance of the research datasets and codebooks, creating datasets for individual researchers). All fees discussed below include the $50 application fee.

[3]Depending on the research question, the antenatal transfers data might be useful to some researchers to provide parameters for sensitivity analyses—please contact us if this applies to you.

The fee for students is $100 ($50 application fee, then $50 once your application is approved and you obtain your dataset). Proof of student status is required (an email from your advisor is sufficient, or a copy of your current student ID).

The fee for faculty at large research institutions (defined as those ineligible for NIH AREA grants—a list of such institutions can be found at http://grants.nih.gov/grants/funding/area-ineligible.htm) is $1000.

The fee for faculty at smaller institutions (defined as those who would be eligible for an AREA grant), or for independent researchers[4], is $250.

Data Access Application Process

The Midwives Alliance of North America Division of Research (DOR) is responsible for the reliability, integrity, privacy and security of the data contained within the MANA Stats dataset. The dataset is made available to researchers outside the DOR through an application process. All requests for data must be received and approved through the application process. The DOR does not provide data for political, commercial, or advocacy purposes.

A summary of the steps involved:

1. Applicant contacts the Research Review Committee (RRC) (researchapplications@manastats.org) to inquire about the feasibility of the potential research question.
    a. "Feasibility" has two components. One, the research question must be able to be answered using MANA Stats data—considering study population, power/sample size, etc. Two, the research question must not be under investigation by another group of researchers using MANA Stats data. This is to ensure that two research groups, each using the same data set, aren't "scooping" each others' publications. Once a research question is approved, the Applicant has 2-3 years (see below for more details) of "protected time", during which time they are the only researcher(s) allowed to be working on that particular analysis.
2. Once a research question has been approved, the DOR will provide the Applicant with the most current version of the codebook (data dictionary) to assist with preparation of the IRB packet and the MANA Stats Application.
3. Applicant seeks IRB (ethics review board) approval from their home institution. The IRB application must request a waiver of informed consent; this should be approved since data are pre-existing and de-identified, and mothers signed consent for their data to be included in MANA Stats.

[4] Because of the requirements for IRB approval, it is easier if independent researchers to collaborate with researchers at colleges, universities, or academic medical/clinical centers. If you are a potential independent researcher, the DOR will put you in touch with potential academic collaborators through the ConnectMe program: http://www.mana.org/research/midwives-participating-in-critical-research/#connectme

4. Once IRB approval is secured, the Applicant completes the application packet (see below for a list of components) and submits it to the Research Review Committee[5] along with the $50 application fee.
    a. The application fee will eventually apply towards the data access fees, above.
    b. Once a research question is approved, Applicants have 6 months from the date of the email confirming approval of the research question (formal completion of step 1) to submit the rest of their application (step 4, above).[6]
5. The Research Review Committee reviews the application for completeness, feasibility, scientific soundness, and ethical compliance.
6. If errors are found, the application is returned to the Applicant for revision (revised applications do not require additional application fees).
7. Once the Research Review Committee approves the application, it is forwarded to the DOR, and then the MANA Board of Directors, who must give final approval for all applications. Historically, the MANA Board has approved all applications when so advised by the Research Review Committee & DOR.
8. If an application is denied (not including 'returned for revision') and the Applicant wishes to appeal the decision, then the complete application packet, including a summary review by the Research Review Committee, would be reviewed by a committee of external, independent researchers. The decisions reached by the external committee are final.
9. Once MANA Board approval has been issued, the applicant must pay the data access fees (see above) and sign the data access/non-disclosure and confidentiality agreements.
10. The DOR's Data Quality Coordinator will then be in touch with the applicant regarding creation of the necessary dataset. Datasets will be transferred in SPSS format.
11. From the date of dataset receipt by the Applicant (formal completion of step 10), the Applicant has two years to submit an article for publication. Following the two-year moratorium, if a paper has not been completed, other applicants would again be able to use this particular research question.
12. Per the data use agreement, please keep the MANA DOR informed of all accepted conference presentations and publications. Keeping track of productivity helps us obtain grant funding to sustain MANA Stats.

Components of the Application packet:

1. Applicant Information Cover Page – available for download at http://mana.org/research/for-researchers
2. Documentation of Institutional Review Board/Ethics Board approval
3. Copy of the approved IRB protocol, to include, in any order, the following:
    a. Description of project and research questions
    b. Project background, review of the relevant literature and significance

[5] Electronic submission preferred; please contact us if this is not possible and alternate arrangements will be made
[6] Deadline can be extended for extenuating circumstances, such as prolonged IRB review. Some proof of attempt to comply with the deadline (copy of submission email to the IRB, dated several months' previously, for instance) will be required.

c. Methods and procedures, including details of planned statistical analyses
d. Risks/benefits assessment
e. Research dissemination plan
f. Project timeline
g. Funding summary
h. Works cited

If the IRB protocol template for your institution does not contain one or more of the above components, please provide the missing piece(s) separately when you apply for access to MANA Stats.

4. Detailed list of variables requested for analysis (including any time or geographic limits), referenced by variable name as listed in the appropriate Codebooks
5. CVs for Applicant and all co-investigators
6. Documentation of completion of CITI human subjects research ethics course or NIH-approved equivalent for Applicant and all co-investigators
7. Application fee (see above)

E-mail all documents as attachments to:
Research Review Committee
researchapplications@manastats.org

Receipt will be acknowledged by email.

$50 application fee:

These fees get sent directly to the current MANA treasurer; we will provide the current correct address during correspondence prior to your application.

Make check payable to "Midwives Alliance" with 'data access application' in the memo line. Receipt will be acknowledged by email and the Division of Research will be notified.

All questions regarding data access should be directed to the Research Review Committee (researchapplications@manastats.org)

References

Cheyney, M., Bovbjerg, M., Everson, C., Gordon, W., Hannibal, D., & Vedam, S. Development and Validation of a National Data Registry for Midwife-Led Births: The Midwives Alliance of North America Statistics Project 2.0 Dataset. *Journal of Midwifery & Women's Health, 59*(1): 8-16. DOI: 10.1111/jmwh.12165