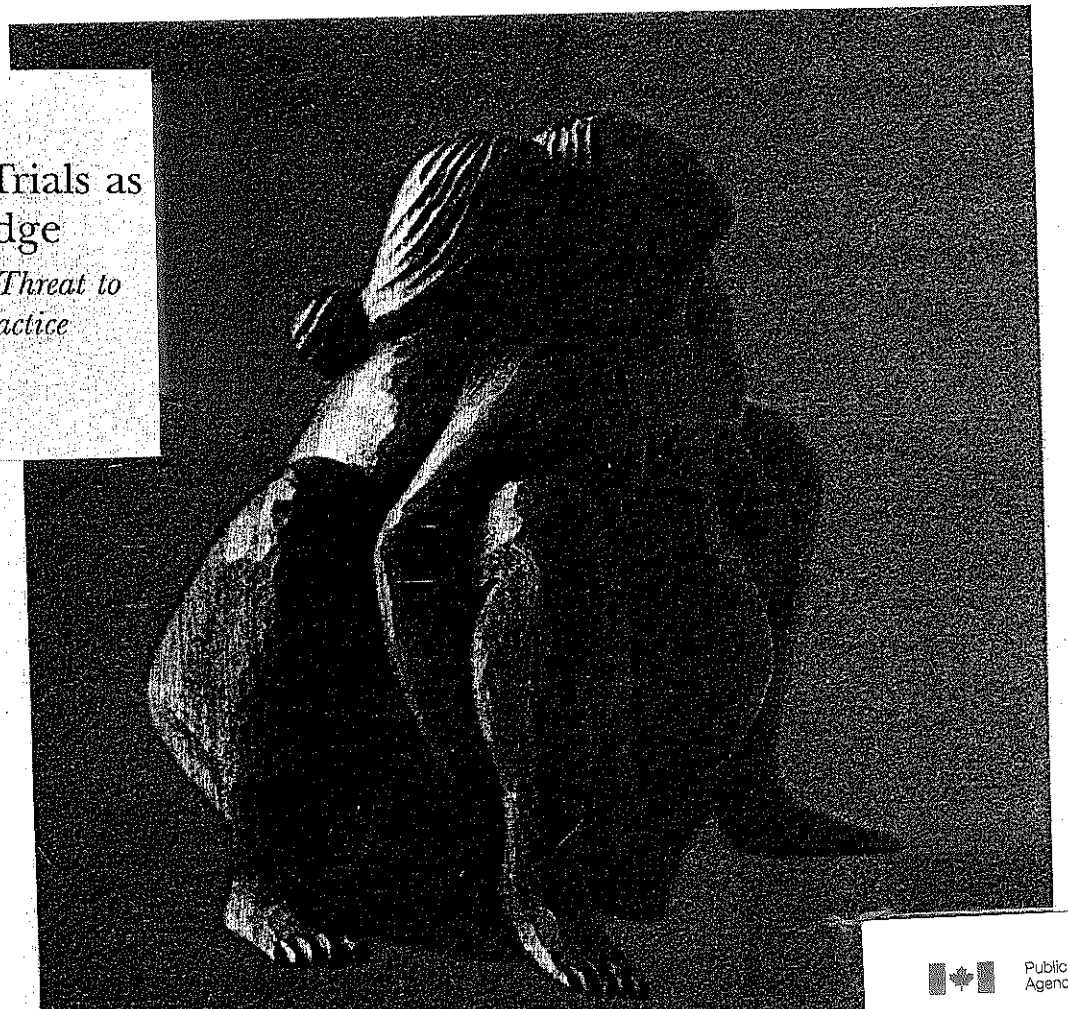
THIRTEEN

Randomized Controlled Trials as Authoritative Knowledge

Keeping an Ally from Becoming a Threat to North American Midwifery Practice

Kenneth C. Johnson



CHILDBIRTH *and* AUTHORITATIVE KNOWLEDGE

Cross-Cultural Perspectives

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Randomized Controlled Trials as Authoritative Knowledge

Keeping an Ally from Becoming a Threat to North American Midwifery Practice

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A welcome movement away from belief- and tradition-based "current medical opinion" toward evidence-based care and intervention is occurring in obstetrics. Central to this development have been the increased use of and respect for the randomized controlled trial (RCT) as a research method and the use of meta-analysis as a tool for systematic quantitative summarization of existing RCT research. While RCTs in many instances have provided strong support for the midwifery model of woman-centered care, there are important limitations on their ability to assess certain aspects of midwifery care. This chapter discusses the strengths and limitations of the RCT as a tool for evaluating alternative birth practices and presents an example of an observational epidemiologic study of midwifery care that can address issues not amenable to RCT evaluation.

In 1989 a watershed in the development of evidence-based care in obstetrics was reached with the publication of *Effective Care in Pregnancy and Childbirth* (Chalmers, Enkin, and Keirse 1989), which presented systematic, scientific summaries (meta-analyses) focusing on the available RCT-based epidemiologic research concerning almost three hundred care issues in obstetrics. This scientific approach to evaluating care has proven strongly supportive of many aspects of the woman-centered, low-intervention type of midwifery care that has developed in North America over the last quarter century. Highly interventive approaches to the care of high-risk pregnant women and infants have a place. Intensive care of low birth weight infants, in particular, has contributed to substantial reductions in neonatal mortality (deaths in live-born infants in the first twenty-eight days of life) over the last few decades (Paneth 1990). However, it is less clear that this high-intervention approach is optimal for pregnant women without special medical risks or for infants in the normal birth weight range.

Although the RCT-based research has proven generally supportive of midwifery care, there is a danger in depending almost exclusively on RCT-based evidence. The limitations of RCTs need to be understood: there can be scientific, clinical, ethical, and political problems that make it difficult, if not impossible, to use RCTs to evaluate some important components of midwifery practice, particularly practices that are outside the pharmacologic interventionist medical paradigm. Other epidemiologic methods, in particular prospective observational studies, have different strengths than the RCT. They have played and will continue to play an important role in understanding what constitutes effective care.

In this chapter I first describe the important work that has been done using RCTs and meta-analysis to study perinatal management. Then I address various limitations of the RCT for evaluating effective birthing practice. Finally, a Midwives' Alliance of North America (MANA) research project that involves collecting detailed information on midwife-attended births is discussed as an example of a non-RCT epidemiologic study. The research is anticipated to be a valuable complement to the RCT work, particularly for addressing issues beyond the RCT's scope.

THE OXFORD ACCOMPLISHMENT: STRENGTHS OF THE RCT

Effective Care in Pregnancy and Childbirth was a landmark in the development of an authoritative knowledge of birthing practice. The 1,500-page two-volume tome was the culmination of a vision and a decade of work by three obstetricians, Marc Keirse from the Netherlands, Iain Chalmers from England, and Canadian Murray Enkin, in collaboration with a large number of dedicated colleagues. For the first time in any field of medicine, a thorough, systematic review of available research evidence on the effects of care was assembled. The medical literature was systematically and exhaustively searched from 1950 onward, and more than forty thousand obstetricians and pediatricians worldwide were contacted to locate unpublished research. More than one hundred epidemiologists, obstetricians, midwives, and other birth researchers were recruited to evaluate the more than 275 birthing practice issues for which research, in particular, RCTs, had been undertaken.

The overall results of the analyses were the identification of 99 currently used forms of care that reduce negative outcomes of pregnancy; 38 forms of care that appear promising but require further evaluation; 88 forms of care with unknown effects that require further evaluation; and 61 forms of care that should be abandoned in light of available evidence. An inexpensive paperback presenting only the main conclusions of the analyses was also published to allow access to the information by pregnant women, midwives, physicians, and other clinicians (Enkin, Keirse, and Chalmers

1989). The analyses were extended to include care of the newborn and culminated in the publication of *Effective Care of the Newborn Infant* (Sinclair and Bracken 1992).

Science-based evaluation of care has proven strongly supportive of many aspects of the woman-centered, low-intervention midwifery care that has developed in North America over the last quarter century. These evaluations have provided support for midwifery practices such as allowing women to birth in the position of their choice, promoting vaginal birth after cesarean, restricted use of episiotomy, not automatically inducing labor in women who have gone past their due dates, avoiding arbitrary time limits in the second stage of labor, and placing importance on the woman's input to medical decisions.

Associated with this initial evaluation is another innovation, the Cochrane Database, an electronic database that provides a mechanism for regular updating of the existing evaluations as new research is completed. For each meta-analysis, the database contains a concise, consistently formatted summary of the key issues, including limitations, findings, conclusions, graphic presentations summarizing the results of the individual studies, and references for all studies included in the meta-analysis. As well, addresses and telephone numbers are listed for the individual researchers responsible for the review and for keeping it current. The Cochrane Database runs on IBM personal computers or clones, is updated twice yearly, and is available on diskette by subscription.[1]

Remarkably, to date this remains the only field of medicine that has received a systematic scientific evaluation of existing research. Recently, the Cochrane Collaboration was formed by Iain Chalmers, who was a driving force in the original effective care collaboration, with the express intent of facilitating similar reviews of research in other clinical medicine fields. The importance of this new authoritative knowledge, based for the first time on the available scientific research and evaluated using the procedures of meta-analysis (a systematic search of the literature, setting criteria for individual study quality that must be met for inclusion, numerical summarization of results, and statistical evaluation of effect), should not be underestimated. The use of meta-analysis has gone a long way toward alleviating the subjectivity of conclusion and lack of quantification associated with the traditional literature review that it replaces. Meta-analysis is particularly useful when the available research suffers from any of the following limitations: (1) the number of individuals enrolled in the individual studies is small, so that the conclusions of individual studies have large statistical uncertainty associated with them; (2) individual studies vary in research quality, so that conclusions from poor research may dilute the conclusions of more carefully undertaken studies; (3) numerous studies have been

completed, so that systematic summarization is necessary to see the bigger picture.

The Oxford accomplishment has helped raise the profile of the RCT in birth issues. The RCT provides an extremely valuable framework for careful evaluation of much clinical practice. First, by randomly allocating subjects to the standard treatment or the experimental treatment, a new treatment can usually be compared to an existing one "without bias that can result from people at different prior risk selectively receiving one of the alternative forms of care being compared" (Enkin, Keirse, and Chalmers 1989). The idea of randomization in a clinical trial is that it will make it likely that the subjects in each group are so similar overall that the observed effects (or lack of them) are the result only of the treatment(s) or lack of them. Second, by carefully controlling who will be allowed into the trial to make sure they are appropriate candidates for the planned interventions, by describing carefully the procedures for how and when interventions will be carried out, and by making explicit the outcome measures that will be used to evaluate the relative success of a new intervention, a well-designed trial provides an opportunity for concise evaluation of a specific treatment question.

LIMITATIONS OF THE RCT

Although the RCT is an extremely useful clinical research tool for evaluating many specific obstetric practices, like all research methods, it has its limitations. David Grimes (1991) has commented on the need to perform and report RCTs properly, Judith Lumley (1987) describes the many stumbling blocks to performing perinatal RCTs, and Samuel Helman and Deborah Helman (1991) address various ethical dilemmas that can arise. Here I focus on a number of important technical and logistic issues that need to be considered in the debate about appropriate birthing practice, particularly in the context of evaluating several central components of woman-centered midwifery care.

Scientific Method

The gold standard in RCTs is the double blind trial, where both the patient and the practitioner are unaware (i.e., blinded) of whether the patient is receiving the standard or experimental intervention. This ideal is most readily attained in a drug trial in which individuals in a study are randomly allocated to receive a drug or an identical-looking placebo and neither patient nor prescriber knows who gets which. This is rarely possible with regard to birth intervention issues; for example, both the practitioner and

the patient know when a woman has been induced or a fetal monitor is being used.

Furthermore, just because a study employs randomization does not mean that the research is good. The question asked may be inappropriate or irrelevant. The study may be unethical (e.g., the use of placebo controls when an effective treatment is proven and available). The advantages of randomization may be undermined by unblinding of allocation or outcome assessment, cointervention(s), biased dropouts or losses to follow-up, or subjective responses. Although the RCT generally minimizes the chance of problems with bias, there are no guarantees—just as is the case in non-RCT research.

Clinical Judgment

When RCTs are used to evaluate birth practices, the criteria for judging outcomes or the need for intervention often depend on practitioners' perception or judgment: Is there fetal distress? Is there a need for intervention in a long second stage of labor? Is there failure to progress? What is the amount of blood loss? What is the newborn infant's physical status? When combined with a lack of blinding, it is possible that the systematic bias that the RCTs have labored to eliminate may creep in. If practitioners participating in the trial are overly optimistic about the new treatment or, conversely, disagree or are uncomfortable with it, it is possible that the observation of the outcome or the pressure to intervene may be skewed. For example, one of the first RCTs in Britain to evaluate active versus physiologic management of the third stage of labor instructed accoucheurs to try to leave the cord attached to the baby until the placenta was delivered. They were unable to comply with this directive in 51 percent of cases, probably because they were unaccustomed to and thus uncomfortable with this procedure. In a recent trial of restricted use of episiotomy (Klein et al. 1992), physicians in the study, when told to do episiotomies only when "absolutely necessary," still perceived a need for them in 25 to 90 percent of the births. In contrast, North American midwives find episiotomies necessary less than 5 percent of the time (Johnson, Daviss, and the Midwives' Alliance of North America Research and Statistics Group 1994).

Evaluating Emotional/Social Issues

The RCT is best suited to study very specific, technical issues with specific, easily measured outcomes (e.g., which type of suture material results in the lowest infection rate). The RCT is much more difficult to undertake for broader and less specific interventions and outcomes such as "satisfaction with care." Ann Oakley (1989) describes in detail the trials, tribulations, and ethical dilemmas for researchers and care providers alike of undertaking an RCT involving randomized allocation of emotional/social support during pregnancy. Furthermore, it is not always clear that evaluating one aspect of care in isolation, removed from the larger context, will provide generalizable or appropriate answers. For example, trying to isolate exactly which components of supportive, personalized, and woman-centered care create a feeling of safety is unlikely to be amenable to RCT evaluation.

Finding Willing Subjects and Practitioners

The RCT can only be used to answer questions when one can get a group of pregnant women and practitioners to agree to choice of intervention based solely on random selection. Important issues like the safety of home versus hospital birth and the short- and long-term benefits of breastfeeding versus formula feeding are not amenable to RCTs.

Efficacy versus Effectiveness

The RCT answers the question, Does a new treatment work better than the existing treatment in an experimental setting? Thus it attempts to answer the question, *Can* it work? This is referred to as the efficacy of the treatment. Equally important is the question, When a new treatment is actually used in the real world, does it result in the expected improvement in outcome—that is, *Does* it work? This is referred to as the treatment's effectiveness. Just because a treatment has been shown to be efficacious does not guarantee that it will necessarily be particularly effective. Evaluations of effectiveness require observational epidemiologic studies, not RCTs. In observational studies data are collected on a specific population—for example, all communities in a certain geographic region, or all infants with a specific birth defect in a state and a comparable sample of healthy babies—and then comparisons of health outcomes within subsets of the study population are made.

RCTs generally involve well-trained and interested practitioners, often in research-oriented progressive teaching hospitals. The subjects eligible for receiving the treatment are carefully selected and are willing to participate, the interventions are performed according to a strict set of rules, and the whole process is carefully documented. In the real world the interventions may be applied incorrectly or by practitioners without the requisite skills, in settings where there is resistance to or undue confidence in the intervention, and thus the interventions may be applied to subjects for which the interventions were never intended or overlooked for subjects who might benefit. Furthermore, the cost of the intervention may not be justified by the derived benefits.

Expense and Funding

RCTs tend to be expensive and therefore can often only be done where significant research resources are available and the question to be resolved would justify the effort to the funding body. Research resources are rarely made available for any therapy not within the Western medical paradigm. If medical research funding is more readily obtained for studies addressing questions considered important within the highly technical, highly interventive approach to childbirth, research into midwifery care will not be readily funded. The situation parallels that of research funding for alternative cancer therapies. Almost all of the extensive resources committed to finding effective cancer therapies continue to be spent on the radiation/chemotherapy/surgery medical model of cancer therapy. Research into alternative therapies has rarely received funding. As a result there is usually no track record of research, proper studies are not undertaken, and the alternatives remain unevaluated and unaccepted.

"The Gold Standard"

Perhaps of more concern is that when RCTs are considered the gold standard of epidemiologic research, other well-respected types of epidemiologic research may be inappropriately devalued. Applied dogmatically, this notion will undermine established research methods that often are the only methods available to address basic, important issues. Furthermore, RCTs always require that prior descriptive epidemiology studies have been performed. It is from these that the RCT study questions often arise. Why are cesarean section rates going up? The postsection infection rate is too high; what interventions are effective in reducing risk? The framing of the study questions, sample size calculations, estimation of potential recruitment, duration and costs of studies, and ultimate feasibility often depend on such data.

Authority

The idea that the RCT is a "medical" technology should be dispelled. Although it has been popularized recently in a medical context, it is a general study design strategy developed in agricultural research and applicable to many fields, including midwifery. It is one of the most powerful designs but has distinct limitations. A much more rational approach to choice of designs is required. One should start with a clearly stated question, examine the literature and anecdotal experience, and then choose the most powerful and feasible design available. This might be a qualitative study, a case-control analysis, a cohort study, a clinical audit, a utilization study, a quality of life assessment, or an RCT.[2]

When authoritative knowledge becomes based almost exclusively on RCT research, then only techniques or approaches that have been subjected to RCT may be taken as authoritative. Alternative approaches (ones that do not depend on medical technology or prescription drugs) are far less likely to be well studied. For example, there have been a large number of studies evaluating the effectiveness of fetal monitoring (Thacker and Banta 1983) the benefits of which have been shown to be questionable (Leveno et al. 1986; Prentice and Lind 1987; Shy et al. 1990), whereas there have only been five studies reporting on the effectiveness of the "doula" (a woman who provides labor support), whose presence has been shown in the populations studied to result in shortened length of labor, reduced number of medical interventions, and increased maternal satisfaction (Klaus et al. 1992). Furthermore, because of the expense of RCTs and the limited amount of public research money available, more research is likely to become corporately funded, with the likely consequence that funding will be increasingly directed toward marketable, profitable technical interventions such as RCTs of drug interventions funded by drug companies.

AN EXAMPLE OF NON-RCT EPIDEMIOLOGIC RESEARCH: THE MIDWIVES' ALLIANCE OF NORTH AMERICA STUDY

The Midwives' Alliance of North America[3] is currently undertaking a large epidemiologic study that could prove useful for furthering knowledge about the details and outcomes of low-intervention midwifery practices in North America. In 1992, MANA adopted a dataform that elicits detailed information about an individual mother's pregnancy, labor, and birth and the midwifery care she receives through pregnancy, birth, and follow-up of mother and baby to six weeks postpartum (see fig. 13.1 at end of this chapter). The form is being used to collect data in a consistent way from more than two hundred midwives from across North America. In the main part of the study, midwives send a registration form listing births they expect to attend in the following three months and then provide complete dataforms for those births as they occur. As of the summer of 1996, midwifery associations in over a dozen states and provinces including California, Oregon, Alaska, and Quebec had adopted the form; more than six thousand midwife-attended home and birth center births have been reported on the dataform and entered into a database for evaluation.

MANA is uniquely placed to carry out such research. First, a number of midwifery practices differ from those found in the regulated and restricted technomedical system. Home birth midwifery practice has evolved over the last quarter century outside of the control of medical authorities, because until recently midwifery has enjoyed an alegal status in much of the United

States and Canada. Second, MANA provides a neutral forum for data collection because it is an organization that has no disciplinary function. Midwives can feel safe about reporting the truth about their management of birth without fear of repercussions or disciplinary action. With a greater respect for and patience with variations in women's laboring, an expanded view of what is normal during birth has developed. Thus this forum also provides an opportunity to document the range of what "normal birth" may actually be.

The care provided by these midwives is focused on being "with women." It includes continuity of a caregiver or caregivers through pregnancy, labor, and the postpartum period, an emphasis on the development of a caring and trusting relationship between mother and midwife, patience during labor, and the use of modern low-tech intervention tools such as sterile gloves, uristicks, and Pinard horns.[4] Labor and delivery take place in an environment in which a woman feels safe and are attended by midwives who believe in a woman's ability to deal with pain and successfully labor with little intervention. High-quality high-tech obstetrical backup care is available when required.

As an observational study, this research project provides an opportunity to efficiently investigate many different aspects of care and their effects on outcome. Whereas an RCT can be used only to study the practice that has been randomized, an observational study can be used to evaluate many aspects of care. Midwives practice independently and in a variety of ways (e.g., differing methods of perineal support, of using water during labor and birth, of management of second-stage labor, of dealing with delivery of the placenta, of use of herbs during pregnancy, labor, and postpartum, etc.). It should be possible to examine midwifery practices and their relation to pregnancy outcome for issues including the following: the overall approach of woman-centered midwifery care and perinatal mortality rates; not setting arbitrary time limits on the various stages of labor; differing approaches to delivery of the placenta and complications; differing approaches to perineal stretching during the third trimester and perineal tear rates; home versus hospital vaginal birth after cesarean; differing approaches to shoulder dystocia; and restricted use of episiotomy in relation to third- and fourth-degree perineal tear rates. With a database representing several thousand births, a variety of situations that occur rarely such as shoulder dystocia, long second-stage labor, and retained placenta, as well as practices that are not required often such as episiotomy, external cephalic version,[5] and emergency transport can be evaluated in a systematic way not possible through individual or informal observation.

Because the subjects are not randomized to different forms of care, one can never be positive that results do not reflect a bias introduced by some unmeasured factor that is associated with both the choice of practice and the outcome. Cautious evaluation is required as biased information might result because the caregiver is also the observer. However, as with a formally randomized sample, characteristics of mothers (age, parity, prenatal problems, socioeconomic status, ethnicity, etc.) can be compared (and controlled for in analysis if necessary) to increase the likelihood of unbiased evaluation. Furthermore, the development of epidemiologic knowledge, theory, and tools over recent decades has provided a strong backdrop for careful evaluation, and it is likely that considerable useful information can be obtained from observation of the outcomes of different forms of care used by different midwives. As with any study, suitable caution in the interpretation of results will be exercised.

Although no one study is conclusive, this work should be helpful in describing the outcomes of variations of care based on an approach dominated by a belief in women's ability to give birth with little or no intervention. The study analyses should provide a number of leads as to which forms of care may be effective, which may not be useful, and which may be detrimental. Some results may suggest areas in which RCTs would clarify or validate observational data. Because a number of states will be collecting data with the same form (reproduced at the end of this chapter), it should be possible to compare outcomes in different parts of North America, and in different settings, for consistency and reproducibility.

CONCLUSION

Epidemiology, in the form of both the RCT and the observational study, is an important ally for supporting and further developing low-intervention woman-centered midwifery care. The recent meta-analysis work done in the field of obstetrics is giving a new profile to evidence-based care, particularly that gained through RCTs, and is beginning to change obstetrics. The movement of authoritative knowledge away from "current medical opinion" toward evidence-based care has proven strongly supportive of many aspects of the woman-centered low-intervention type of midwifery that has developed in North America over the last quarter century. Armed with a balanced understanding of the strengths and limitations of RCTs and other types of epidemiological studies, we will be better able to assess the efficacy of alternative birth practices.

NOTES

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1. The address of the Cochrane Pregnancy and Childbirth Database is Manor Cottage, Little Milton, Oxford OX44 7QB, U.K. In the United States and Canada, contact Canadian Perinatal Clinical Trials Network, Local Do-705, Hospital St.-François d'Assise, 10 rue de l'Espinay, Quebec, Canada G1L 3L5 (418-525-4455; fax 418-525-4481; e-mail 3028wfra@vmi.ulaval.ca). The database is available on disk and CD-ROM for IBM and Apple Macintosh computers.

2. *Case-control studies* involve comparing a set of subjects with a disease or health outcome of concern (cases) with a sample of healthy subjects from the same population (controls) to look for factors that may have contributed to the disease condition. *Cohort studies* involve following large groups of individuals (cohorts) until disease outcomes of interest occur and then examining how the rates of disease differ within subgroups with and without factors of interest.

3. For a description of MANA, see Davis-Floyd and Davis, this volume.

4. The uristick is a small plastic strip with a number of small chemically reactive blotters used to evaluate the constituents of urine. A pregnant women tests her urine on the stick, and color changes of the chemical blotters will indicate normal or abnormal levels indicating the need for more detailed investigation of potential problems. The Pinard horn, a hollow cone about 8 inches long and generally made of wood, was invented in the nineteenth century by the French physician Pinard. When placed against the pregnant woman's belly, it assists the midwife in monitoring the baby's heartbeat by amplifying the heart tones. Its use requires a high degree of tactile and sensory closeness between mother, baby, and midwife.

5. Most babies adopt a head-down position a number of weeks before delivery; this is the safest positioning for delivery. External cephalic version is the procedure of gently moving a baby who is in the breech position (bottom or feet down) to a head-down position in the uterus through positioning of the mother and by the practitioner pushing gently with the hands on the woman's belly in a specific way (see Jordan [1978] 1993).

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Fig. 13.1 appears on the following four pages.

MANA STATISTICS FORM Version: 1.3

Revision: APRIL 1993

Please note: in general code: 1=yes, 0=no, ?=don't know; blank=does not apply

DEMOGRAPHIC

Midwife Code

Midwife's Code for Identifying This Birth

Client's Municipality

Population (1=city >1,000,000), 2=city >250,000, 3=town >10,000, 4=small town (<10,000), 5=rural)

Postal (ZIP) Code

Mother's: Age

Last grade of high school completed

Post secondary education (years)

Occupation

Ethnic Origin (1=Caucasian, 2=African or Caribbean, 3=Native American, 4=Asian, 5=Other)

Special group (1=Hispanic, 2=Amish, 3=Francophone, 4=other)

Natural hair colour (1=brown, 2=black, 3=red, 4=blond)

Partner status at time of birth (1=married couple, 2=unmarried couple, 3=female partner, 4=separated/divorced, 5=single, 6=couple, marital status not known, 7=other)

Partner's: Age

Last grade of high school completed

Post Secondary education (years)

Occupation

Family socio/economic level (midwife's evaluation) (1=low, 2=medium, 3=upper)

PREVIOUS PREGNANCY AND DELIVERY HISTORY

Number of previous: pregnancies

miscarriages

induced abortions

stillbirths

live births

Number of previous: home births

caesarean sections

VBAC's*

episiotomies

postpartum hemorrhages

Other previous pregnancy or delivery concern(s): (1=gest <37 wks, 2=gest>42 wks, 3=hypertension, 4=breech, 5=pre/eclampsia, 6=IUGR, 7=birth defect, 8=shoulder dys, 9=other)

PRESENT PREGNANCY CONCERNS

Maternal problems: (1=pregnancy-induced hypertension,2=chronic hypertension,3=pre-eclampsia, 4=eclampsia, 5=gestational diabetes, 6=diabetes mellitus, 7=persistent anemia (Hct<30 or Hb<10 g/dl), 8=Rh sensitized,9=other)

Infection (1=genital herpes, 2=chlamydia, 3=urinary tract infection, 4=yeast, 5=gonorrhea, 6=other)

Bleeding in trimester: (1=light, 2=heavy) 1st 2nd 3rd

Fetal problems: (1=suspected IUGR, 2= birth defect diagnosed in utero( ), 3=intrauterine death, 4=other)

Midwife perceives emotional/social problems <---- (specify and describe in margin of form)

BREECH AFTER 28 WEEKS GESTATION

1st time breech noticed (week of gest. from LMP)

Last time breech (week of gest. from LMP)

Breech turning exercises (# of times)

External cephalic version (attempts: sucesses) by midwife : by physician :

Other procedures (1=)

** 1,2,3 etc. are footnotes; see page 4 for clarifications*

PRENATAL CARE

Week (from LMP) any prenatal care began

Week (from LMP) midwife prenatal care began

Prenatal classes (1=this preg, 2=other preg, 3=both)

Two most important reasons for choosing intended place of birth (as stated by mother) (1=desire for natural birth, 2=effect on baby, 3=control, 4=social pressure, 5=cost, 6=safety, 7=family unity, 8=atmosphere, P=partner preference, H= "high risk", 9=other)

Number of prenatal visits: with a midwife

estimated with G.P.

estimated with obstetrician

Payment (1=client paid, 2=Blue Cross/Shield, 3=commercial insurance, 4=HMO (other prepay), 5=Champus,6=Medicaid,7=universal government health insurance, 8=other)

PRENATAL DETAILS

Mother's height (or estimate) feet inches

Mother's prepregnancy weight (pounds)

Weight gain during pregnancy (pounds)

Method of conception (1=coitus, 2=artificial insemination, 3=in vitro, 4=other) 1st 2nd 3rd

Ultrasound (# of times each trimester)

Other prenatal testing (1=triple screen, 2= chorionic villus sampling, 3=AFP, 4=amniocentesis, 5=biophysical profile, 6=non stress test, 7=GTT, 8=random glucose, 9=other)

Tobacco, Alcohol or Recreational Drugs

Mother smoked cigarettes during pregnancy

Number of months

Average # of cigarettes per day

Alcohol during pregnancy

Average number of drinks per month

Marijuana/THC/hashish (1=occasional, 2=regular)

Other illegal drugs (1=occasional, 2=regular)

Drug type (1=cocaine, 2=other)

Prescription drugs in pregnancy (1=antibiotics, 2=antifungals, 3=antiemetics, 4=antihypertensives, 5=other (specify))

Mother's overall nutrition in pregnancy (midwife's assessment)(1=excellent, 2=good, 3=fair, 4=poor)

Diet during pregnancy (1='meat & potatoes', 2=whole foods and meat, 3=junkfood, Secondary 4=ovo-lacto vegetarian, 5=vegan vegetarian, 6=macrobiotic, 7=other) Primary

Mother restricted calorie intake to limit weight gain

Herbs to ease labour(last 6 wks)(1=daily, 2=less often)

Activity level during majority of pregnancy (1=very active, 2=active, 3=sometimes active, 4=sedentary)

Perineal Massage or Stretching

Estimated # of times during 3rd trimester

Mother reports a history of sexual abuse (1=yes before puberty, 2=yes after puberty, 3=before and after puberty, 4=mother prefers not to answer, 5=midwife did not ask)

Risk Factors Why a Home Birth Was Not or Could Not Have Been Initiated, Or Was Outside of Home Birth Protocol (Answer for All clients)

Reasons: (1=preterm/post-term, 2=breech or malpresentation, 3=multiple birth, 4=hypertension, 5=anemia, 6=diabetes, 7=pre-eclampsia/eclampsia, 8=placenta previa/abruptio, 9=other(specify))

Woman Stopped Using This Midwife For Primary Care Before Labour Began

Reasons:(1=miscarriage, 2=referral for complications, 3=client moved, 4=client chose birth centre, 5=client chose hospital, 6=changed midwives, 7=cost, 8=stillbirth, 9=other)

Gestation when midwife primary care stopped

** Code will be added later*

Revision: APRIL 1993

Please note: in general code: 1=yes, 0=no, ?=don't know; blank=does not apply

INTENDED BIRTH PLACE, GESTATION, ATTENDANTS

Midwife Code

Birth Number

Planned during pregnancy to have: (1=home birth, 2=birth centre birth, 3=hospital birth)

Began labour intending to deliver: (1=at home, 2=in birthing centre, 3=in hospital)

Referral after first assessment in labour

Gestation -- midwife's best estimate before birth based on all available information Weeks Days

Mother certain about dates (1=yes ,2=fairly, 3=not)

Attendants at labour and birth

Attendants during labour

Attendants at birth (1=mother's partner, 2=midwife, 3=2nd midwife, 4=midwife apprentice, 5=friends, 6=children age 1-4, 7=children 5+, 8=other family members, 9=FP or GP, N=nurse, B=obstetrician, S=other)

LABOUR SUMMARY

Date of birth Day Month Year

Place of birth (1=home, 2=freestanding birth centre, 3=hosp birth room, centre or "LDR", 4=hosp separate lab/del/rec, 5=hosp OR, 6=other)

Midwife's role in hospital (if applicable) (1=primary care giver, 2=doctor's assistant, 3=labour coach, 4=midwife's assistant, 5=not present, 7=)

Length of Labour:

Total time:	Days	Hours	Minutes
Early Labour		:	:
1st stage		:	:
2nd stage (full dilation)			:
3rd stage			:

Approximate total time the woman in labour had a:

midwife present before birth		:	:
apprentice only before birth		:	:
midwife present after birth			

Amount of time before birth membranes ruptured	Hour	Minute	AM/PM
Actual time of birth		:	

Plateaus, Reversals, Anterior Lip or Pushing Before Full Dilation:

	Dilation	Hours	Minutes
1st stage plateau	cm	:	:
(stayed at same centimetre	cm	:	:
assessment for > 2 hours)	cm	:	:
	cm	:	:

Cervical reversal (from what cm to what cm) to

	Hours	Minutes
Anterior lip longer than 1 1/2 hours	:	:
Pushing before full dilation	:	:
2nd stage plateau(full dilation & no pushing)	:	:

Positions and Mobility

Positions of potential concern occurring during active labour Stage 1 Stage 2 (1=posterior, 2=breech, 3=head deep transverse, 4=tranverse lie, 5=acyncliism, 6=face & brow)

Baby's position at delivery (1=anterior, 2=posterior, 3=frank breech, 4=footling breech,5=complete breech, 6=head deep trans, 7=transverse lie, 8=face, 9=brow)

Mother's mobility during labour Stage 1 Stage 2 (1=mother changed positions frequently, 2=mother didn't choose to take many positions 3= movement restricted by anaesthetic or attachments, 4=movement restricted by staff)

Mother's final delivery position (1=semi-sitting, 2=hands & knees, 3=squatting, 4=standing,5=on side, 6=on back, 7=stirrups, 8=birthing stool, 9=deBy birth stool, M=McRoberts(high hyperflexion), 0=other)

Underwater birth

LABOUR AND BIRTH PROCEDURES

Induction, Augmentation or IV

Induction (1=pitocin, 2=prostag, 3=nipple stimulation, 4=castor oil, 5=art rupture of membs < 5 cm, 6=art rupture of mem >= 5cm, 7=stripping of membranes, 8=intercourse, By midwife

9=other) By physician

Time until labour started (hours)

Augmentation By midwife

(use induction codes) By physician

I.V. initiated (stage)

Other Procedures During Labour

Number of vaginal examinations

Doppler use (1=1st stage, 2=2nd stage, 3=1st and 2nd)

Use of water (0=none,1=bath, 2=shower, 3=jacuzzi, 4=other) Stage 1 Stage 2

Drugs (1=analgesics, 2=tranquilizers, 3=sedatives, 4=alcohol, 5=other)

Medicinal herbs (specify) (1=)

Other procedures (1=body massage, 2=enema, 3=catheterization,4=other)

Nourishment during active labour (0=nothing, 2=only clear fluids or jello, 3=other fluids, 4=solid food)

Perineal Care

Active perineal guidance in 2nd stage (0=midwife remained passive,1=manual support, 2=massage,3=compresses,4=oils/lubricants, 5=verbal guidance,6=other)

Episiotomy (1=medio lateral by physician,2=median, physician,3=medio lateral,midwife,4=median,midwife)

Perineal tear & degree (0=no tear,1=1st, 2=2nd, 3=3rd(into anal sphincter), 4=4th (into rectal mucosa))

Episiotomy or tear repair (0=no repair)

Local anaesthetic for repair

Labial tear(1=slight, 2=required suture)

Clitoral/urethral tear (1=slight, 2=required suture)

Cervical laceration (2=required suture, 3=extensive)

Hospital or Birth Centre Procedures

Electronic fetal monitoring:(1=internal,2=ext,3=both)

Fetal scalp sample

Cord blood gases

Anaesthesia (1=epidural,2=general,3=pudendal,"+ block,4=entonox,5=other)

Forceps (1=outlet,2=low,3=mid,4=rotation,5=other)

Vacuum extraction

Caesarean section

Reason(s) for C-section (1=failure to progress, 2=fetal distress, 3=meconium, 4=not vertex lie, 5=maternal exhaustion, 6=other)

Midwife considers C-Section necessary (0=no, 1=yes, 2=possibly, 3=probably)

Apgars (hospital staff assessment) 1 minute 5 minute

TRANSPORT FROM PLANNED HOME BIRTH OR PLANNED BIRTH CENTRE BIRTH

Did the midwife consider transport an emergency?

Transport by- (1=car, 2=ambulance, 3=other)

Labour stage at transport (1=first, 2= second, 3=third, 4=postpartum)

Length of time before or after birth that decision to transport was made (hrs/mins)

Minutes from decision to arrival at hospital

Reason(s) for transport Primary reason Secondary reason (1=failure to progress, 2=sustained fetal distress, 3=malpresentation, 4=thick meconium, 5=abruptio/praevia, 6=hemorrhage, 7=retained placenta, 8=maternal exhaustion, 9=baby's condition, 9=other)

Midwife and clients reception at hospital (1=supportive,2=indifferent,3=unsupportive,4=hostile)

LABOUR, BIRTH AND POSTPARTUM SUMMARY Page 3 of 3

Revision: APRIL 1993

Please note: in general code: 1=yes, 0=no, 7=don't know; blank=does not apply

LABOUR AND DELIVERY FACTORS

Midwife

Birth Number

Delivery Factors

Preterm labour (< 37 weeks)

Compound presentation

Shoulder dystocia (1=minor, 2=moderate, 3=severe)

# of resolution techniques tried

Most effective tech(_____)

Fetal bradycardia (prolonged FHT < 110)

Fetal tachycardia (prolonged FHT > 160)

Late or deep decels (1=1st stage,2=2nd,3=1 & 2)

Midwife thinks emotional or social factors may have affected course of labour(<—— write details in margin)

Cord problems (1=only 1 or 2 vessels, 2=very short, 3=around neck tightly, 4=around neck 2+ times, 5=cord prolapse, 6=other_____)

Other complications (1=shock, 2=uterine prolapse, 3=placenta previa, 4=abruptio placenta, 5=hematoma, 6=embolism, 7=ruptured uterus, 8=anesthesia complications, 9=other_____)

Meconium

Stage when meconium noticed

Density (1=thin, 2=moderate, 3=thick)

Consistency (1=particulate, 2=well dissolved)

Colour (1=yellow,2=light green,3=dark green, 4=brown, 5=colour darkened during labour

Blood Loss

Prophylatic to avoid hemorrhage (1=oxytocin, 2=shepherd's purse, 3=other_____)

Estimated blood loss millilters

or cups (use 2 decimals – e.g. 1.00, 2.25)

Postpartum hemorrhage(> 500 ml or 2 1/4 cups)

Action(s) taken for blood loss (1=fundal massage, 2=nipple stimulation, 3=external bimanual compression, 4=internal bimanual comp, 5=IV fluids, 6=blood transfusion, 7=other_____)

Drugs (1=pitocin,2=methergine(ergotrate),3=_____)

Herbal(1=_____)

D&C

NEWBORN DATA (first 4 hours)

Number of babies (complete this page for each baby)

Sex (1=girl, 2=boy)

Birthweight grams

OR lbs. ozs

Apgar (midwife's assessment) 1 minute

5 minute

Any clinical evidence that baby is preterm

Any clinical evidence that baby is postterm

Stillbirth(1=death before labour, 2=during labour)

Birth defects(1=minor,2=serious,3=life threatening)

Specify_____

Procedures

Resuscitation: (1=suction on the perineum, 2=DeLee, 3=bulb suctioning, 4=tactile stim, 5=oxygen, 6=ambubag, 7=mouth to mouth, 8=chest compressions, 9=intubation, R=respirator, W=wall)

Eye prophylaxis (1=silver nitrate, 2=erythromycin (llotycin), 3=sterile water, 4=other_____)

Vitamin K given (1=oral, 2=IM)

Immediate neonatal complications

Complications: (1=respiratory distress, 2=meconium aspiration, 3=IUGR, 4=metabolic (hypoglycemia,hypocalcemia), 5=prematurity, 6=seizures, 7=birth injuries_____, 8=other_____)

Transfer to neonatal intensive care unit

DELIVERY OF PLACENTA AND MEMBRANES

Cord clamped (1=immediately (before pulsing stopped), 2=after pulsing stopped, 3=after placenta delivered, 4=other_____)

Cord clamped –# of minutes after birth

Mother's postion waiting to deliver placenta (1=lying down, 2=standing, 3=squatting, 4=sitting, 5=hands & knees, 6=several positions)

Method: (1=maternal effort, 2=controlled cord traction,3= manual removal, 4=D&C)

Membranes appear: (1=complete, 2=incomplete)

Placenta appears: (1=complete, 2=incomplete)

Anatomical variations of placenta (1=infarcts, 2=calcium deposits, 3=succenturiate, 4=accreta, 5=other_____)

POSTPARTUM CARE AND BREASTFEEDING

Number of postpartum visits with midwives

Estimated postpartum visits: other caregivers

Final midwife postnatal visit or contact (week)

Number of weeks breastfed in first 6 weeks

Number of weeks before any supplement (7= >6 weeks)

Circumcision in first 6 weeks

INFANT'S HEALTH IN FIRST 6 WEEKS

Newborn health problems in first 6 weeks (1=jaundice beyond normal physiologic level, 2=sepsis/infection, 3=respiratory distress, 4=failure to thrive,5=premature/immature,6=seizures,7=birth trauma, 8=other (specify)_____)

Jaundice level if measured (mmol/litre)

Newborn hospitalized in first 6 weeks

Number of days in neonatal intensive care unit

Number of days newborn hospitalized in first 6 weeks

Reason(1=born there,2=baby's cond,3=mother's cond)

Baby's problem(s) (use newborn health problems)

Newborn died in first 6 weeks of life

No. of days after birth that death occurred

Underlying cause of death (1=birth defects, 2=prematurity, 3=other(specify)_____) (Provide details about death in margin ——>)

MOTHER'S HEALTH IN FIRST 6 WEEKS

Postpartum infections (1=yeast, 2=delayed perineal healing/infection, 3=breast, 4=urinary tract, 5=uterine, 6=febrile episode(>100.4 after first 24 hours))

Other Postpartum Complications (1= late hemorrhage(after 24 hrs), 2=hypertension, 3=cervical/uterine prolapse, 4=hematoma, 5=pulmonary embolism, 6= thrombophlebitis, 7=eclampsia, 8=anemia (<10 mg), 9=other (Specify)_____)

Postpartum depression (1=moderate, 2=severe)

# of days mother hospitalized in first 6 weeks

Maternal Death Underlying cause_____ (Please provide details about death in margin ——>)

INFANT'S & MOTHER'S HEALTH at 6 WEEKS

Infant (1=good,no problems, 2=residual problems)

Mother (1=good,no problems, 2=residual problems)

FORM COMPLETION

Form filled out by: (initials)

Date majority of form filled out Day Month Year

MANA thanks you for spending the time to contribute to its data collection by carefully filling out this form.

Form developed by Kenneth C. Johnson, PhD and Betty-Anne Daviss-Putt. Many thanks to 26 midwives, 5 epidemiologists, 2 psychologists and 1 graphic artist who provided invaluable feedback.

Contact: Betty-Anne Daviss-Putt
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FOOTNOTES (Further Information About Specific Data Items)

(The numbers refer to footnotes as specified to the right of certain boxes on the form.)

1. If you haven't yet been assigned a code, use your initials here. Some midwives have a number for each birth. What we need here is an identifying code so that should those analyzing the data have questions about the way in which the form was filled out they can feed back the code to you and you can dig up that particular file. The important thing is that you have a different code for each birth that you have attended.

2. The client's municipality, population and postal code are used for demographic comparison to other birth datasets.

3. Please indicate which professions, vocations, or trades the mother has engaged in besides motherhood.

4. Miscarriage:WHO: Death before 20 weeks of gestation from LMP.
Stillbirth: Death at 20 weeks or more. Baby did not take a breath.

5. Chronic hypertension (1) is defined by Williams Obstetrics as "A diastolic blood pressure of at least 90 mm Hg. or systolic pressure of at least 140 mm Hg, or a rise in the former of at least 15 mm Hg or in the latter of 30 mm Hg. The blood pressure cited must be manifest on at least two occasions six or more hours apart...Before the 20th week of gestation in the absence of hydatiform mole or extensive molar change, or persistent hypertension beyond six weeks postpartum."
Pregnancy-induced hypertension (2) is defined by Williams Obstetrics as "The development of hypertension in pregnancy after the 20th week of gestation and sometimes earlier when there are extensive hydatidiform changes in the chorionic villi...It may also occur during the first 24 hours after delivery."

6. Describe serious personal, emotional or family problems that may be adversely affecting the woman during pregnancy.

7. You must ask the mother about these or put a ?. Do not prompt with categorized answers.

8. One of the purposes of this form is to study outcomes of low risk women in all settings. This question, therefore, needs to be answered even for the births that were not planned at home to develop a comparison group of low risk women in hospital and birthing centre settings who could have had their babies at home.

9. Time when care was transferred to other provider even if you continued to provide support.

10. If this client at any time during her pregnancy planned to have a home birth please respond positively.

11. Latent or early labour is the beginning of contractions that are regular or irregular up to the point where dilation begins to progress. It is the period in which there is no dilation of the cervix beyond 3-4 cm. Most midwives do not feel that if a woman has had contractions for several hours or days, that this should be dismissed or be unaccounted for merely because the midwife has not been able to recognise any change in the cervix or lower uterine segment. We therefore think that the presence of contractions should be acknowledged no matter how long it has been going on and whether or not there has been cervical change, and it should be included under the title "early labour."

12. First stage of labour begins when contractions are of sufficient frequency, intensity, and duration to bring about progressive dilatation of the cervix (greater than 3 cm.), and ends when the cervix is sufficiently dilated to allow passage of the presenting fetal part (complete dilation).

13. Anterior lip sometimes persists when the rest of the cervix has been "taken up". It may be caused by pushing or continue when the woman begins to push before she is completely dilated. A woman may begin to push but if the pushing is not effective because she is not fully dilated and the anterior lip is still there, second stage has not begun.

14. Some women do not experience the plateau phase of 2nd stage. Others experience this break in which they are neither dilating nor pushing. Although this plateau stage of 2nd stage usually begins at complete dilatation of the cervix and ends at the point at which the mother begins to actively push her baby out, some women have already begun to push when they suddenly stop or fall asleep before they resume pushing. This would be considered plateau phase as well.

15. In a compound presentation, an extremity prolapses alongside the presenting part with both entering the pelvis simultaneously.

16. Birth defects are often difficult to categorize. Give enough detail, in the margin, of the nature of the defect and the need for treatment, etc. so we can evaluate severity if in doubt.

Questions or comments contact: Betty-Anne Daviss-Putt, Co-chair of MANA Research and Statistics Committee, 36 Glen Avenue, Ottawa, Ontario, CANADA K1S 2Z7; Phone (613) 730 0282 or 432 5701.

Midwives' Alliance of North America