





Evidence Used, Evidence Ignored: The case of home birth policy

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Overview

- Large prospective home birth study, found similar risk to the weight of home birth and low-risk hospital birth literature
- APHA resolution, legislators using the data, media, obstetric societies in other countries, midwifery models
- Reaction from ACOG, blogs
- Other precedents/models: Chiropractors



Early Development of Databases: Canadian Midwives Statistics/MANA/CPM and Understanding Birth Better Databases

- 1989-1990 - analysis of Ontario 1983-85 data
- 1991 - National Perinatal Epidemiology Unit (Oxford)
- 1991 – Created new Ontario form
- 1991-1993 – form adopted by Quebec, Manitoba, made revisions based on evaluation of other forms, 9 revisions, feedback from midwives, epidemiologists
- 1992-3 – form adopted by MANA; pilot completed
- 1994 - 1999 ongoing data collection > 16,000 births
- 1996 - 1999 Local studies completed in Minnesota, Oregon, Manitoba, Maine, Quebec preliminary



Theory divides, data unites.

Marshall Klaus



College of Physicians and Surgeons of Ontario and Alberta late 1990s

- ONTARIO: In 1994, “because of midwifery being regulated.... because home birth is becoming more common, and because there is no compelling evidence from the literature one way or the other
- Voted to rescind a 7-year policy that discouraged doctors from attending home births.
- ALBERTA: Created protocols for physicians attending home births. Midwives regulated but not government funded as in the other provinces



Prior to the Large Home North American Home Birth Study

- Substantial literature on intended homebirths and midwife-attended births, internationally and in North America
- Studies varied in quality
- Consistent findings of low perinatal mortality among low-risk women giving birth at home or in a birth centre with a midwife



Critical Piece – To Bring Together the Best Epidemiologic Design for Home Birth In One Study

- Systematic Prospective Design
- Defined time period (year 2000)
- Defined target population: clients of midwives who have the national/intercontinental CPM credential
- Mandatory participation for recertification
- Direct validation procedures
- Needed a large study from across North America rather than one jurisdiction



APHA Resolution on Increasing Access To Out-Of-Hospital Maternity Care Services

- Recognizing evidence that many women seek alternatives to hospital care for normal pregnancy and birth, and,
- Recognizing the evidence that births to healthy mothers, who are not considered at medical risk after comprehensive screening by trained professionals, can occur safely in various settings, including out-of-hospital birth centers and homes ([\[x\]](#),[\[xi\]](#),[\[xii\]](#),[\[xiii\]](#),[\[xiv\]](#)) and,
- Noting that an epidemiological study of Certified Professional Midwives (CPMs) is ongoing in order to further substantiate practice outcomes, safety, client satisfaction, and practitioner competency is in progress; ([\[xv\]](#))
- Recognizing that out-of-hospital settings have the potential for reducing the costs of maternity care; (7,12,[\[xvi\]](#))



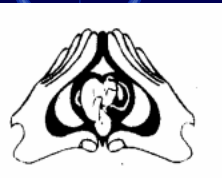
APHA Resolution passed 2001

➤ “APHA supports efforts to increase access to out-of-hospital maternity care services ...through recognition that legally-regulated and nationally certified direct-entry midwives can serve clients desiring safe, planned, out-of-hospital maternity services.”

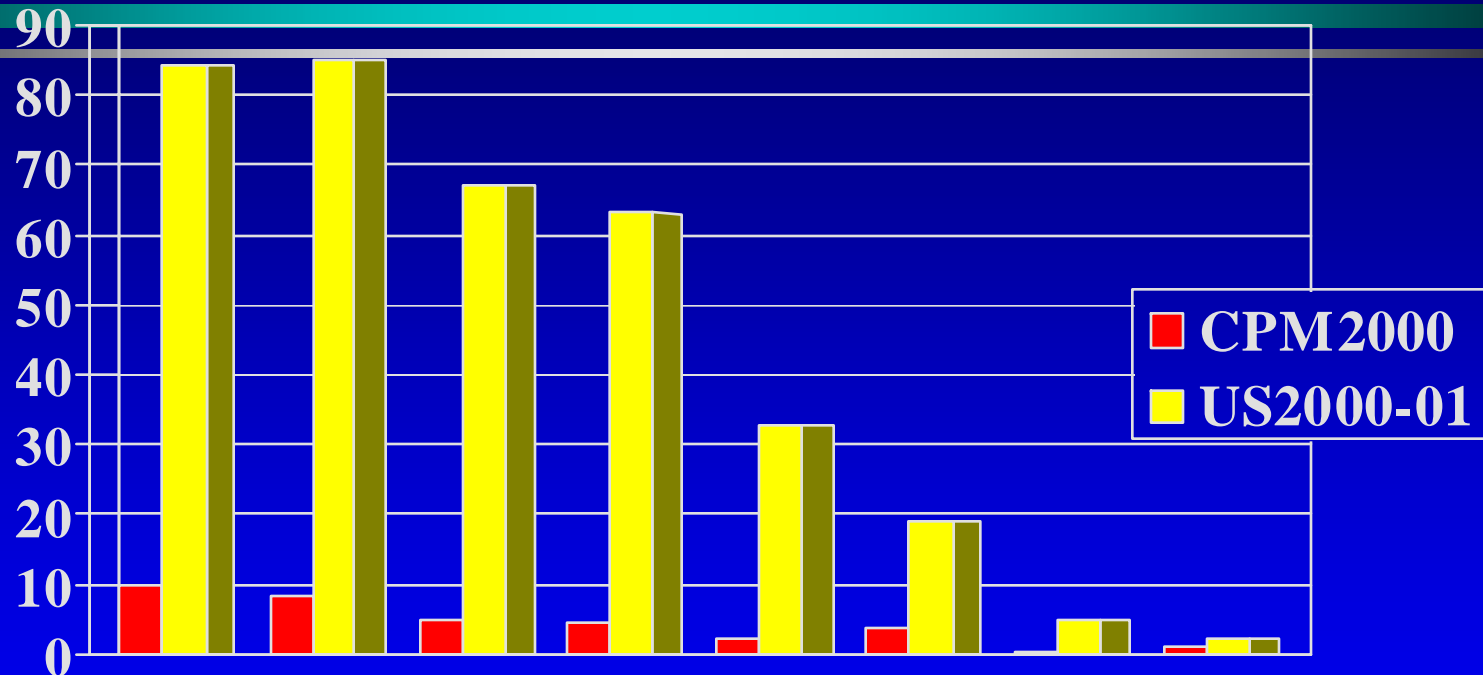


Publication

- Outcomes of planned home births with certified professional midwives: large prospective study in North America
Johnson, KC; Daviss, BA.
- British Medical Journal June 18th, 2005.
- BMJ Daviss
- Free download. Also 27 rapid responses (letters to the editor), are available online



Intervention Rates CPM2000 Compared to All US Women 2000-01



	EFM	IV *	AROM *	Epidural*	Episiotomy	C-Section	Vacuum	Forceps
■ CPM2000	9.6	8.4	5	4.7	2.1	3.7	0.6	1
■ US2000-01	84.3	85	67	63	33	19	5.2	2.2

Ref: U.S. Vital Statistics 2000. – singleton, vertex, ≥ 37 weeks

*Listening to Mothers – 1st National U.S Survey, October 2002



Intrapartal and Neonatal Mortality (low risk births)

- Intended homebirths at initiation of labour: 5,418

- antenatal deaths 4
- fatal birth defects (removed) 3
- intrapartum deaths 5
- neonatal deaths 6

- Intrapartum and neonatal deaths: 11/5,418
- = 2.0 / 1,000 intended homebirths
- After removal of breech and twins
- 1.7 / 1,000 intended homebirths



Conclusions

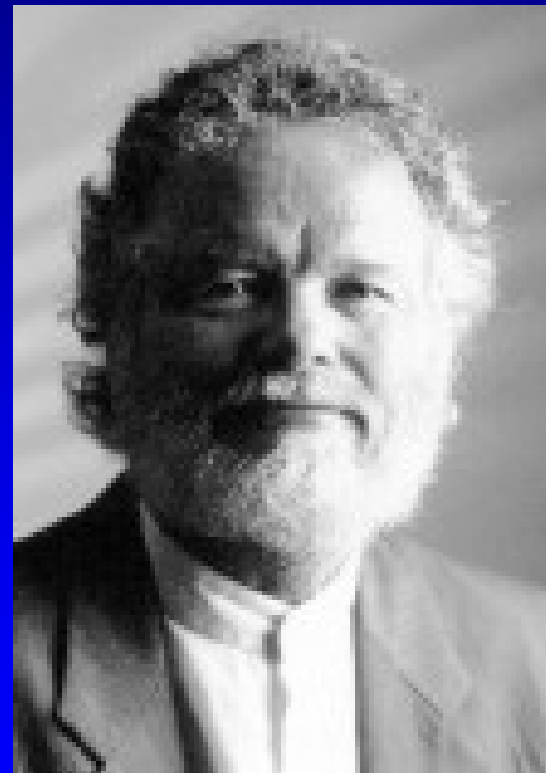
- Planned home birth for low risk women in North America using certified professional midwives was associated with **lower** rates of medical intervention but **similar** intrapartum and neonatal mortality to that of low risk hospital births in the United States.





Commentary On Responses to the BMJ home birth Study

➤ “When a study is published with scientifically valid evidence against an important position of a clinical group, clinicians have two common reactions: ignore the study and hope it goes away; torture the data until it confesses to what they want it to say.”



Dr. Marsden Wagner



Commentary On Responses to the BMJ home birth Study

- Demedicalization group:
“This group recognizes the excellence of the methodology, the importance of the findings and the consistency with the existing weight of evidence.”

➤ Dr. Marsden Wagner





Commentary On Responses to the BMJ home birth Study

- “The second largest group of responders is primary care physicians, some of whom are generally positive about the findings while others try to torture the data to justify running from the heresy of agreeing to health care which is not in some kind of medical setting: “this information does not change my practice.”



Dr. Marsden Wagner



The Silence of the Lions

- -- Only one American Obstetrician answered in BMJ responses
- -- Positive data but fear of litigation





Perinatal or Neonatal Deaths in Homebirth Studies (500 births +) (excluding lethal congenital anomalies)

Place	Study Years	Births	Neonatal and/or intrapartum mortality
North Carolina	1974-76	934	3.0 per 1,000 (- intra)
United States	1977	1,146	3.5 per 1,000
Missouri	1978-84	1,770	2.8 per 1,000
Washington State	1981-1990	6,944	1.7 per 1,000 (-intra)
Arizona	1983	1,243	2.4 per 1,000
Canada	1983-88	1,001	2.0 per 1,000
Kentucky	1985	575	3.5 per 1,000 (-intra)
Tennessee (Farm)	1972-1992	1707	2.3 per 1,000
United States (84 birth centres)	1985-1987	11,814	0.6 per 1,000



Perinatal or Neonatal Deaths in Homebirth Studies (500 births +) (excluding lethal congenital anomalies)

Place	Study Years	Births	Neonatal and (sometimes) intrapartum mortality
United States (90 home birth practices)	1987-1991	11, 081	0.9 per 1000
Washington State (Pang)	1989-1996	6,133	2.0 per 1000 (- intra)
California(Schlenzka)	1989-90	3,385	2.4 per 1,000
United States (Murphy & Fullerton)	1993-1995	1,350	2.5 per 1,000
Canada (Janssen)	1998-99	862	2.3 per 1,000
North America (Johnson & Daviss)	2000	5, 418	1.7 per 1,000



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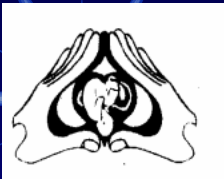
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Perinatal or Neonatal Deaths in Homebirth Studies (500 births +) (excluding congenital anomalies)

Place	Study Years	Births	Perinatal or Neonatal Mortality
Holland	1969-73	7,980	2.3 per 1,000
Britain	1979	5,933	4.1 per 1,000
Australia	1981-87	976	5.1 per 1,000*
Britain	1996	2,888	2.1 per 1,000

Key British reference – Campbell R, MacFarlane A, Where to be born: the debate and the evidence. 2nd edition, 1994.



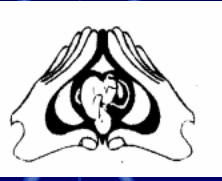
Perinatal or Neonatal Deaths in Low-Risk Hospital Births attended by physicians (500 births +) (twins, premature, congenital anomalies removed) * = minus intrapartum

Place	Study Years	Births	Neonatal & Sometimes Intrapartum Mortality
Boston (academic hospital)	1969-75	12,055	0.5-1.1 per 1,000*
Anato (community hospital)	1974-5	4,144	3.4 per 1,000*
Rooks et al (national natality survey)	1980	2,935	2.5 per 1,000 *
Adams (15 hospitals)	1983	10,521	1.7 per 1,000
Washington	1981-90	23,596	1.7 per 1,000*
Dallas (academic hospital)	1982-85	14,618	1.0 per 1,000
Illinois (12 hospitals)	1982-85	8,135	1.9 per 1,000
Washington (Pang)	1989-96	10,593	0.7 per 1,000*
California	1989-90	806,402	1.9 per 1,000
Canada	1998-99	733	1.4 per 1,000



Since 2005

- A few comments of obstetricians
- Not a randomized controlled trial
- Not a direct comparison
- Attempts to accuse “comparing apples to oranges”



California Study: Key Adjunct to the Certified Professional Midwife study

- PhD Thesis: Peter Schlenzka
- Large defined retrospective cohort of planned home and hospital births with similar low risk profiles



Results of Largest State Population in the Union

- When Schlenzka compared 3,385 planned home births with 806,402 low risk hospital births, he consistently found a non-significantly lower perinatal mortality in the home birth group.



Searching for a National Comparison Group

- **When we submitted for publication:** NIH published singleton, vertex, baby at term (which we could match)
- **After we submitted:**
- Vital stats retrospective assessment of gestation. Adjustment for different populations, published data for 2004 by gestational age and ethnic group



Flawed Comparison Made to Our Study

Neonatal Mortality for Non-Hispanic Whites at term for U.S. from birth certificate and infant deaths statistics, 2004 (NIH report)

0.76 deaths /1000 births



Neonatal mortality dropped by .15/1000 from 2000 to 2004 in the U.S.

- In 2000, 2500 gram plus NHW births
- 0.9 deaths per 1000 livebirths



CPM2000 neonatal death rate comparable to NIH Non-Hispanic White >37 weeks rate

<u>Description of Deaths</u>	<u>Total Deaths</u>
➤ 5 intrapartum, 9 neonatal deaths	14 deaths
- 5 intrapartum	9 deaths
- 3 birth defect deaths	6 deaths
- 1 death in 286 Hispanic/African-American/other births	5 deaths

5 deaths among 5,132 births =

0.97 neonatal deaths /1,000 births



High Prematurity Rate In NIH data compared to Home Birth Data

- Perinatal Mortality: all deaths from 28 weeks gestation till 6 weeks postpartum
- BMJ home birth study presented intrapartum plus neonatal death
- 11.3% of non-Hispanic white U.S. live births in hospital in the NIH are reported to have a gestation of less than 37 weeks (premature)
- BMJ home birth study has approximately 4% premature rate.



Popularity of BMJ home birth Article Continues

- Over 85,000 accesses to date
- Still being accessed at the rate of 1000 to 1500 different individuals per month



ACOG Statement 2006

➤ History of statement: came after Wisconsin's bill was passed, Missouri and Indiana about to follow suit, we presented testimony for legislators in California, Indiana





ACOG Statement 2006-7

- **October 2006** Studies comparing the safety and outcome of U.S. births in the hospital with those occurring in other settings are limited and have not been scientifically rigorous. The development of well-designed research studies of sufficient size, prepared in consultation with obstetric departments and approved by institutional review boards, might clarify the comparative safety of births in different settings. Until the results of such studies are convincing, **ACOG strongly opposes out-of-hospital births**. Although ACOG acknowledges a woman's right to make informed decisions regarding her delivery, ACOG does not support programs or individuals that advocate for or who provide out-of-hospital births.
- **May 4 2007** changed from “opposes out-of-hospital births” to “**opposes home births**” If freestanding, only those “**that meet the standards of the Accreditation Association of Birth Centers or the Joint Commission or the American Association of Birth Centers.**”



Reaction to the BMJ home birth study by obstetricians





Unanticipated Support for Home Birth





Society of Obstetricians and Gynecologists of Canada (SOGC) 1997

- Policy Statement on Home Birth
- SOGC is opposed to homebirths because of potential risks to mother and fetus. Women should be informed adequately about the risk of birth at home or in free-standing birthing centres, and especially about potential difficulty in emergency transport in a country with such diverse geography, population density, and weather as Canada. While recognizing that women wish to have different options for birthing, SOGC stresses that women and their families be informed correctly about the safety that childbirth in a hospital setting provides. The SOGC strongly advocates family-centred care, with provision of appropriate facilities for this care in the hospital setting.

The SOGC policy statement No. 66, September 1997



Change in SOGC Policy Statement

March 2003

-The SOGC recognizes and stresses the importance of choice for women and their families in the birthing process. The SOGC recognizes that women will continue to choose the setting in which they will give birth. All women should receive information about the risks and benefits of their chosen place for giving birth and should understand any identified limitation of care at their planned birth setting. The SOGC endorses evidence-based practice and encourages ongoing research into the safe environment of all birth settings....
- *This policy statement replaces Policy Statement No. 66 dated September 1997.*



Society of Obstetricians & Gynecologists of Canada





Royal College of Obstetricians and Royal College of Midwives

- {RCM & RCOG} “support home birth for women with uncomplicated pregnancies. There is no reason why home birth should not be offered to women at low risk of complications and it may confer considerable benefits... There is ample evidence showing that labouring at home increases a woman’s likelihood of a birth that is both satisfying and safe, with implications for her health and that of her baby.”



April 2007





Reality Defined by Cultural Paradigm



Debate





(Wilk vs. AMA)

- Five doctors of chiropractic filed antitrust lawsuit in 1976
- Rationale: The AMA had created a written goal to "contain and eliminate" a competitor, the chiropractic profession.
- Made it unethical for any MD to associate with a DC in any way, shape or form. It was unethical for an MD to refer a patient to (or even accept a referral from) a DC.
- MDs were not allowed to teach or address students at chiropractic colleges or chiropractors at gatherings of DCs, nor were DCs allowed to address medical students or gatherings of MDs.
- Referred to chiropractors as unscientific cultists and quacks.



ACOG Statement About “Lay Midwifery”

- CPMs were excluded from the list of midwives recognized



Essential Need

- Presently approximately 10 midwives under investigation
- 11-12 states going for legislation of Certified Professional Midwives





Chiropractor Victory

- On August 27, 1987, the judge issued a 101-page opinion finding the AMA guilty of long-term wrongdoing and illegally attempting to eliminate the chiropractic profession. In September of 1987, the judge issued a permanent injunction against the AMA and all of its members from ever trying to destroy the profession through such an illegal boycott again.
- On February 7, 1990, the Court of Appeals found the AMA guilty. On November 26, 1990, the U.S. Supreme Court upheld the trial court and the Court of Appeals' finding. In January of 1992, the final settlement took place between the AMA and the plaintiffs to complete all terms of the court order, thus ending one of the longest antitrust legal battles in the history of this country.



How Can We Help the Medical World Understand that Home birth, like Global Warming, Is Not Going to Go Away?





Conclusions



Typical delivery room



Answers to Questions Re the BMJ Article

- At UnderstandingBirthBetter.com
- E.g. “Home birth study is Comparing Apples to Oranges”