A. AWHONN FACE PAGE



AWHONN RESEARCH GRANT APPLICATION PROPOSAL FACE SHEET

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AWHONN Member # (Membership of selection for funding)	o must be current at time of application AND at time
RESEARCH AREA (please check one only):	
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	Women's Health Nursing Novice Researcher
TITLE OF PROPOSAL: Birthing Quality: A Ground	ded Theory Study of Chinical Excellence
Please check the appropriate box for the next	t two questions before signing and dating.
I am currently a principal investigator o	n a federally funded research grant.
I have previously received an AWHONN	Research Grant.
Neither of the above.	
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Signature: CNM, PhD Desix, CA Que email-adeleved Deter 2010.081	ley@gmail.com, c=US 9/30/11 Date:

BIOSKETCH

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CERTIFICATION: Certified as a Nurse-Midwife (#4378) by the American College of Nurse-Midwives (ACNM), 1983;

Continuing Competency Cycle completed 1993, 1999, 2004, 2009

Certified as a Childbirth Educator (#6214) by Lamaze International (formerly ASPO/LAMAZE), 1981;

Recertified 1985, 1988, 1991, 1994, 1997, 2000, 2003, 2006, 2009

EDUCATION						
YEAR	INSTITUTION	FIELD OF STUDY	DEGREE			
Sept, 1970	Temple College	General Studies	A.A.			
-May, 1972	2600 So.1st St.					
	Temple,Texas 76501					
May,1972	University of Texas	Nursing	B.S.N.			
- June,1975	1700 Red River					
	Austin, Texas 78701					
Aug., 1976	University of Texas	Maternal-Child	M.S.N.			
- Dec, 1978	1700 Red River Austin,	Nursing; Adult				
	TX 78701	Education				
Sept., 1982	University of Illinois	Nurse-Midwifery	Post-Master's Certification			
- Dec, 1983	845 So Damen					
	Chicago, IL 60612					
	Master's Project: "A comparison of two methods of measuring bearing-down efforts: the reliability					
	of manual extrapolation as compared to computerized reproduction of graphic data." Chair: J.					
0 1 1000	Engstrom, CNM, PhD	0 1 1000	DI D			
Sept., 1983	University of Illinois	Sept., 1983	Ph.D.			
-Dec, 1988	845 So Damen	-Dec, 1988				
	Chicago, IL 60612	. () ()	Control of the Contro			
			technique on the fetal heart rate during the			
0004	second stage of labor". Cha		MDII			
Sept., 2004	Emory University	Public Health:	MPH			
-Dec, 2011	1518 Clifton Rd NE	Outcomes				
	Atlanta, GA 3032	Measurement	ity A Crounded Theory Study of Clinical			
			ity: A Grounded Theory Study of Clinical			
	Excellence". Chair: R. Osbu	IIIe, MD				

PERSONAL STATEMENT:

The goal of the proposed research is to investigate the definition and exemplars of quality of care by professionals who work in a birth center that is widely recognized as providing excellent labor care. The PI is an experienced nurse and nursemidwife, as well as nurse researcher who has access to the desired subject pool and the motivation and training to carry out the research. In particular, the PI has completed a program of study leading to the degree of Master in Public Health with an emphasis on Health Care Outcomes. The purpose of this education was to prepare the PI to use assessment tools and research expertise to investigate the quality of health care. In this program, the PI specifically sought out course work in qualitative research to expand her skill set and prepare her for this and similar studies. As indicated in the section below on research support, the PI has prior experience writing and conducting research, as well as publishing the results of those projects. One project in particular was recognized by the American College of Nurse-Midwives as the "Best Research Paper" in the year it was presented. The PI has affiliations with Dr. Susan Schaeffer Jay, an experienced qualitative nurse researcher, and Dr. Robert Osburne, a physician experienced with quality assessment in health care, both of whom are available as pro bono consultants for this project. The transcriptionist is also known to the PI as a highly professional and dependable worker who has agreed in advance to take on this project, should it be funded. To summarize, the PI has experience with research both alone and with colleagues, and has specifically sought training and opportunity to maximize the potential for success with the proposed project. The manuscript for publication will be submitted to JOGNN, in the hope that the lessons learned will enable other maternity professionals to offer the best possible care to childbearing women.

POSITIONS AND HONORS:

Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN):

Chapter Coordinator, Austin, Texas, 1978;

Chapter Treasurer, Austin, Texas, 1977

American College of Nurse-Midwives (ACNM):

Co-chair: Publicity and Public Relations Committee, Denver, CO, 1990

Site Visitor, Division of Accreditation, 1991-1997

Section Chair, Ad Hoc Committee on Consumer Education, Division of Education, 1996

Educational Program Director (Denver, 1990-1994; Chicago 1994-1997)

Reviewer, Journal of Midwifery and Women's Health, 2009-present

Coalition for the Improvement of Maternity Services (CIMS)

Charter Member, 1996

Co-author, Mother-Friendly Childbirth Initiative, 1996

Chair, Editorial Committee, 1996-2000

Treasurer, CIMS Council, 1998-2000

Co-Chair, CIMS Council, 2000-2003

Chair, CIMS Council, 2003-2005

Member, CIMS Council, 2005-2008

Lamaze International [formerly ASPO/LAMAZE]

Member, Board of Directors, Provider Coalition (1990-1993; Re-elected 1993-1996)

Chair, National Conference Planning Committee, 1991-94

Vice-President, Board of Directors, 1992-1993; Re-elected 1993-1994

Member, Educational Council, 1992-1994

President, Board of Directors, 1994-1995; Re-elected 1995-1996

Board Advisor, 1996-1997

Reviewer, <u>Journal of Perinatal Education</u>, 1995-present

Member, Certification Council, 1997-2006

Sigma Theta Tau, 1978-present

SELECTED PEER-REVIEWED PUBLICATIONS:

- Shaw-Battista, J., Fineberg, A., Boehler, B, Skubic, B., Woolley, D., & Tilton, Z. (2011.) Obstetrician and Nurse-Midwife collaboration: Successful public health and private practice partnership. Obstetrics and Gynecology, 118(3), 663-674
- Leslie, M.S., Romano, A., & Woolley, D. (2007.) Step 7: Educates staff in nondrug methods of pain relief and does not promote use of analgesic, anesthetic drugs. <u>Journal of Perinatal Education</u>, 16(1), 65S-73S.
- Hill, P.D., Humenick, S.S., Brennan, M.L. & Woolley, D. (1997.) Does early supplementation affect long-term breastfeeding? Clinical Pediatrics, 36(6), 345-350.
- Roberts, J., & Woolley, D. (1996.) A second look at the second stage of labor. <u>JOGNN</u>, 25(5), 415-423.
- Woolley, D. & Roberts, J. (1995.) Second stage pushing: A comparison of valsalva-style with "mini" pushing. <u>J Perinatal</u> Education, 4(4),37-43.
- Perlis, D.W. (May, 1992). The influence of bearing-down technique on the fetal heart rate during the second stage of labor. In J.E. Roberts (Chair), <u>The Childbirth Experience: Physiological, and Social-Psychological Factors</u>. Symposium conducted at the meeting of International Sigma Theta Tau, Columbus, Ohio, Abstract No. 376.
- Penney, D.S., & Perlis, D.W. (1992). The Use and Abuse of Manual Extrauterine Pressure during Shoulder Dystocia. MCN, The American Journal of Maternal Child Nursing, 17(1),34-36.
- Perlis, D.W., Engstrom, J.L., van Lier, D., & Mendez-Bauer, C. (April,1988). The concurrent validity of manual extrapolation of maternal bearing-down efforts during the second stage of labor. In J.L. Engstrom (Chair), Reporting the reliability and validity of physical measures. Symposium conducted at the meeting of the Midwest Nursing Research Society, Wichita. Kansas.
- Perlis, D.W. & van Lier, D. (1985). A comparison of two methods of measuring bearing-down efforts: the reliability of manual extrapolation as compared to computerized reproduction of graphic data. <u>The Measurement of Clinical and Educational Nursing Outcomes Conference Program and Abstracts</u>, 85, Abstract No. U.4.
- Perlis, D.W. & Brucker, M.C. (1983). Malpractice: A professional risk. Journal of Nurse-Midwifery, 28(2), 3-8.

RESEARCH SUPPORT:

Principal Investigator, "Redefining Physiologic Norms for Second Stage Labor." AREA Grant Submitted to the U.S. Department of Health and Human Services, National Institute of Nursing Research, Rockville, MD. \$75,000 direct costs. Proposal approved and funded, 7/1/96-6/30/99

Principal Investigator, "Establishing a Baseline for Physiological Variables in the Second Stage of Labor: Calibration and Pilot Testing of the Instrument." Internal Research Support Program, UIC College of Nursing, Chicago, IL. \$6700 requested. Approved and funded; completed 1997.

Research Associate, "Supportive Vs. Directive Care in Second Stage Labor". Public Health Service, Department of Health and Human Services, #1846002597A1, funded 1985-1989. Principal Investigator: Joyce Roberts, CNM, Ph.D.

Primary investigator, "The influence of bearing-down technique on the fetal heart rate during the second stage of labor". Doctoral dissertation, The University of Illinois at Chicago, 1988.

Co-Investigator, "A comparison of two methods of measuring bearing-down efforts: The accuracy of manual extrapolation as compared to computer reproduction of graphic data," The University of Illinois at Chicago, 1985.

Data Collector, dissertation research of D. van Lier, R.N., C.N.M., Ph.D., entitled "Effect of maternal position of the second stage of labor", University of Illinois at Chicago, 1985.

Training Support:

Principal Investigator, "The University of Colorado Nurse-Midwifery Education Program." Submitted to the U.S. Department of Health and Human Services, Public Health Service, Rockville, MD. 10/01/92-9/30/95. \$314,420; \$311,595; \$339,246. Approved, funded 10/01/92-9/30/95.

HONORS AND AWARDS

March of Dimes Outstanding Nurse Recognition Award, 28th Annual Perinatal Nursing Conference, Chicago, IL, March 3, 2003.

Board Recognition Award, Lamaze International, Dallas, Texas, Oct.5, 1996.

Fellow, American College of Childbirth Educators, 1990.

"Best Scientific Paper" at the 34th Annual Convention of the American College of Nurse-Midwives, San Diego, June 8, 1989.

Inducted into Sigma Theta Tau, National Honor Society for Nursing, 1978

C. ABSTRACT

The overarching purpose of this research project is to develop a theory of how clinical excellence is generated and maintained in a Birth Center long recognized for its quality of care and excellent outcomes, specifically their low cesearean section rate. The proposed research is, in essence, seeking to "deconstruct" or "reverse engineer" the successful system at Sutter Davis Hospital in Davis, California. The specific outcome of interest in this study is the primary cesarean section rate – that is, the proportion of live births delivered by Cesarean section to mothers with no previous history of a Cesarean section, since a cesarean section represents failure to achieve a "normal, i.e., physiologic" birth. The ultimate goal is to understand the system, its context and contributors with the hope that this knowledge could be applied in other sites; and by so doing provide an opportunity to make major inroads into the "cesarean epidemic" that is impairing the short- and long-term health of women and babies, and unnecessarily depleting the scarce resources of the American medical system.

The proposed project is a case study of the Sutter Davis Midwifery Service (SDH), which is comprised of a public and private arm, both of which have contractual back-up from the same five obstetricians. In this study the whole "service" is considered the case. This will be a "key informant" study, although the definition of key informant will be very broad. The time required to do the study, as indicated in the timetable below, is a reflection of the large number of interviews anticipated.

The grounded theory analysis will be done using the constant comparative method in the computer program MAXQDA.

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E. BUDGET



RESEARCH GRANTS PROPOSED BUDGET & BUDGET JUSTIFICATION

Funded period:	From	7	2012	To ⁶	2013
•			(yr)	(mo)	(yr)

1. Salaries (no investigators may receive a salary):

Personnel (Title)	Salary
1. ^{PI}	none
2. professional transcriptionist	\$8750
3.	
(Please list additional personnel on a separate	sheet).

2. Project Costs:

	AWHONN Grant	Other Sources	Totals
Total Salaries	\$8700	\$50	\$8750
Consultation		donated	
Instruments			
Data Analysis	\$1000		\$1000.00
Equipment/Facilities	\$299.98		\$299.98
Printing/duplication			
Telephone			
Supplies			
Travel			
Miscellaneous			
TOTALS	\$9,999.98	\$50	\$10,049.98

3. Include you	ir budget justification addressing all costs listed above.
Total Salaries:	professional transcriptionist: \$8750, of which \$50 exceeds the limits of the grant. This will be paid by the PI.
	The fee to the transcriptionist is calculated as follows: estimated N of 35 @ 10 pages of text per subject interviewed. With approximately 50 lines on each page of text, the total number of lines expected is 17,000. At a fee of \$0.50 per 65 characters of rotating text per line, the salary to the transcriptionist would be \$8750.
Consultation:	Susan Shaeffer Jay, PhD, RN is an experienced qualitative researcher who has agreed to donate consultative services to this project as appropriate.
Instruments:	The interview guide is attached in the Appendices. Since this guide was developed by the PI, there is no cost other than duplication, which is possible using equipment and supplies already owned by the PI.
Data Analysis:	Data will be analyzed using the qualitative program MAXQDA, which can be downloaded online for a fee of \$1000.
Equipment/Fac	Lilities:
	A Sony ICD PX 820 Digital Voice Recorder is available from Amazon.com for \$49.99. This device downloads directly into a file on a computer, and then made available to the transcriptionist. She already owns compatible transcription equipment, so no additional expense is required.
Printing/Duplic	eation:
	The PI owns a copier and reams of paper, so no expenses for printing or duplication will be required.
Telephone:	
•	There will not be expenses, as the PI has unlimited service.

Supplies:	Supplies for printing and duplication are discussed under that category.
	To facilitate note-taking and coordination of field notes with the audio recording, a Livescirbe 8 GB Smartpen Pro Pack (\$249.99) will be used.
	o GB Smartperi P10 Pack (\$245.55) will be used.
Travel:	
114.4.	No travel expenses are being requested.
"	
Miscellaneous:	Name
	None
Total:	
	\$9999.98 requested of the grantor, plus \$50 paid by the PI to the transcriptionist, supplies and equipment already owned by the PI, and consultation time donated by an interested colleague who is an experienced qualitative researcher

BIRTHING QUALITY:

A GROUNDED THEORY STUDY OF CLINICAL EXCELLENCE

F. NARRATIVE

"...[T]he quality of birth is a vital element in public health. The message is that maternity care is not exclusively a woman's issue, but has life-long effects, for each individual and family, and for society as a whole." (Kitzinger, 2005, p. 52)

Problem Statement/Specific Aims

Maternity care in the United States is in crisis. The media abound with reports of failures in our health care system, both before and after the Institute of Medicine at the National Institutes of Health began to emphasize the need for quality improvement (2001). What is quite *uncommon* is to find a report on a system that works, and examine it as an exemplar and source of ideas and inspiration for other sites.

The overarching purpose of this research project is to develop a theory of how clinical excellence is generated and maintained in a Birth Center long recognized for its quality of care and excellent outcomes, specifically their low cesearean section rate. (CaliforniaWatch, 2010; Schimmel, Hogan, Boehler, DiFelice, Cooney & Schimmel, 1992; Schimmel, Lee, Benner & Schimmel, 1994; Schimmel, Schimmel & DeJoseph, 1997; Shaw-Battista, Fineberg, Boehler, Skubic, Woolley, & Tilton, 2011). The proposed research is, in essence, seeking to "deconstruct" or "reverse engineer" the successful system at Sutter Davis Hospital in Davis, California. The specific outcome of interest in this study is the primary cesarean section rate – that is, the proportion of live births delivered by Cesarean section to mothers with no previous history of a Cesarean section, since a cesarean section

represents the ultimate failure to achieve a "normal, i.e., physiologic" birth.. The ultimate goal is to understand the system, its context and contributors with the hope that this knowledge could be applied in other sites; and by so doing provide an opportunity to make major inroads into the "cesarean epidemic" that is impairing the short- and long-term health of women and babies, and unnecessarily depleting the scarce resources of the American medical system.

Research questions

The research questions or hypotheses to be tested are:

- 1. How do the key informants define clinical excellence?
- 2. What factors do the key informants see as exemplars of clinical excellence, in general and at their facility?
- 3. What quality processes do the key informants identify as in place/desirable?
- 4. What factor(s) emerge from interviews with key informants as influencing the primary cesarean section rate (a nation-wide indicator of clinical quality)?
- 5. Can a theory be proposed, using constructs from the data as well as from evidence-based practice and quality assurance literature, which offers an explanation for the findings, with the primary outcome of interest being the primary cesarean section rate?

Background and Significance

One of the major indicators of the problems in American maternity care is the primary cesarean section rate (Healthy People, 2010; Joint Commission, 2010; National Quality Forum, 2010; Zhang et al, 2010). In and of itself, it contributes significantly both to maternal and newborn morbidity and mortality (Sakala & Corry, 2008). A

parturient who has a cesarean is more likely to develop complications, more of which are lethal (compared to women delivering vaginally), either in this or subsequent pregnancies (Yang et al, 2007; MacDorman, Menacker & Declercq, 2008). A neonate delivered by cesarean section is three times more likely to die (MacDorman, Declercq, Menacker & Malloy, 2006). Time in hospital is extended, cost of care is increased, and family bonding and breastfeeding are often negatively influenced. Thus, any "abdominal delivery" has both short- and long-term health consequences for the mother, and social as well as financial considerations both for her family as well as for society as a whole (Sakala & Corry, 2008).

In 1985, the World Health Organization (WHO) produced a recommendation that the cesarean rate in any country/region not exceed 15%, with 10% being the preferable rate (Wagner, 1994). In 2007, another group from WHO (Betran et al.) maintained that rates above 15% actually are associated with increased maternal and newborn mortality. In the US, current rates are hovering around 33% (Menacker & Hamilton, 2010) of 2.29 million births (2008 data) (Livingston & Cohn, 2010), virtually guaranteeing that approximately 755,700 mothers and newborns are suffering as a result of needless surgeries.

A review of the literature revealed only one agency that did make a specific connection between high cesarean rates and poorer outcomes, and sought to identify factors which might aid them in resolving the problem. In 2000, the Ontario (Canada) Women's Health Council (OWHC) did a mixed methods survey (multi-site, including document review and key informant interviews of providers and administrators), in which they identified the following categories of "Critical Success Factors in Attaining and Maintaining Low Caesarean Section Rates":

Attitude, Organization, Knowledge and Information, Network Development, Change Management, and Adequate Funding (See Appendix A, Figure 1). The OWHC then gave each of the 4 hospitals in the survey \$10,000-\$15,000,

which most of them chose to apply to either upgrading staffing ratios (to 1:1 labor support) or CQI related to nurse-managed issues (such as training in the use of intermittent fetal monitoring) (OWHC, 2002). The authors of this report felt this information was very significant, as it spoke to the importance that nurses --via their knowledge and their care – contribute to the success of the physiologic birth process. Unfortunately, no similar study of such highly successful facilities in the US has been located in the literature. There is a need to see whether the same or similar factors would be identified as "critical" to reducing the primary cesarean section rate in the US, and to look at a model which details a mechanism through which that might be accomplished.

Four critical conditions come together to produce the impetus for this project. First, maternity care outcomes in the US are deteriorating. For example, maternal mortality doubled in the 20 year period between 1987 and 2006, "near misses" doubled, and adverse events of some variety affected more than 1/3 of all women who give birth in the US (Amnesty International, 2010). Second, as suggested by these statistics, there is a need for improving the quality of maternity care throughout the US – since no single regional, ethnic or SES group is exempted from these problematic outcomes (Amnesty International, 2010; Institute of Medicine, 2001). Third, there is minimal representation of the voices of the actors – patients, providers, administrators, i.e., the human inputs and throughputs of the system who might offer insight into solutions. Evidence based practice would deride us for ignoring such obvious sources of data. Finally, few <u>national</u> measures of the quality of intrapartum care as it relates to the promotion of physiologic birth are found in the literature (Bingham, 2010; Joint Commission, 2010; Main, 2009). While the overall number is large, those that are specific to labor care are relatively few, and only those that are monitored by the National Quality Forum and the Joint Commission have much organizational enforcement power. Even the Healthy People measures are goals, not requirements.

The contribution of primary cesarean sections to deteriorating maternal/newborn outcomes in the US has been well documented (Sakala & Corry, 2008.) As a member of the audience at the NIH Consensus Conferences on "Cesarean Section on Demand" and "VBAC", this writer has both witnessed and shared the frustration, the despair and occasionally the anger of those who wish to decrease the "epidemic" rate of cesareans. Instead of simply railing at all of the failed systems, however, the proposed case study of the Sutter Davis Hospital (SDH) Nurse-Midwifery System would provide a rare in-depth look from the point of view of providers and administrators at a model that works. Once the critical components of such a system were identified, they could be tried in other sites and systems, offering an opportunity to make specific, positive changes and, hopefully, reverse the decades-long trend of increasing cesarean surgery and its concomitant short- and long-term contribution to diminishing maternal and neonatal health.

Rationale/framework.

This study is grounded in a quality assurance technique called Failure Mode Effects Analysis (FMEA). (See APPENDIX A., Figure 2). FMEA is defined as "the design, manufacturing, operation or maintenance of a component, ... or overall system. It is used to determine potential reliability problems through identification of: What might go wrong (failure mode)...possible results of that failure mode...[and] what action is, therefore, desirable." (Berger, 2007, p.1). It has a component called the criticality analysis that is used to quantify the likelihood and severity of a given failure. Another component, the Root Cause Analysis (RCA), is intended to identify and eliminate the cause of a failure after the fact. Its proactive twin is called root cause maintenance (RCM) (Berger, 2007). Since the situation to be studied in the proposed research is working well, the techniques to be used will be similar, but they will be directed at discerning the elements that contribute to the successes observed.

A very common technique used to get to the essential cause of a situation is called the "5 Whys", indicating that one asks the informant "Why did that happen?" over and over until one has drilled down to the ultimate trigger. The data thus obtained are displayed in an Ishikawa or fish-bone diagram (see example, APPENDIX A., Figure 3.). (Ransom, Joshi, Nach & Ransom, 2008). As the fish-bone diagram example indicates, there are already some hypotheses about what processes can contribute to a healthy birth outcome. These are grounded in the "Lamaze" Six Steps to a Healthy Birth": 1: Let labor begin on its own; 2: Walk, move around and change positions throughout labor; 3: Bring a loved one, friend or doula for continuous support; 4: Avoid interventions that are not medically necessary; 5: Avoid giving birth on your back and follow your body's urges to push; 6: Keep mother and baby together. (Appendix A. Figure 4.) These suggest what themes may emerge from the interviews regarding the nature of care that promotes normal birth. As can be seen, these practices are similar in many ways to the essential elements identified by the Ontario Women's Health Council, and the fact that two such disparate groups would develop such similar lists of essentials speaks to the credibility of the underlying concept of promoting normal ("physiologic") birth as the desirable outcome of labor – a step far away from the comment implying that if Mom and baby are alive and well at the end of the day, then the rest is just 'icing on the cake' (Amelink-Verberg & Buitendijk, 2010). Grounded theory, however, builds from the interviews up, so that while it is tantalizing to project that the themes will be consistent, the picture of the situation at the study facility will emerge only after careful analysis of the thoughts of the informants interviewed.

Research Design and Methods.

Design: The proposed project is a case study of the Sutter Davis Midwifery Service (SDH) which is comprised of a public and private arm, both of which have contractual back-up from the same five obstetricians. In

this study the whole "service" is considered the case. Specifically, it will be 'an empirical inquiry that investigates a contemporary phenomenon....within its real life context, defined by Yin as especially important "when the boundaries between phenomenon and context are not clearly evident. [It] relies on multiple sources of evidence (2009, p.18). Marshall and Rossman (2011) add to this definition the idea that both the researcher's and the participants' worldviews are incorporated into the emerging data.

The specific methods to be used in the proposed study will be grounded theory techniques, which differ substantially from the positivistic techniques of typical "Western" science. Corbin (Corbin & Strauss, 2008), one of the early nurse researchers using these techniques describes them as follows:

The science aspect of qualitative research is not "science in the traditional sense. The science comes from "grounding" concepts in data. Then, it systematically develops concepts in terms of their properties and dimensions and at the same time validates interpretations by comparing them against incoming data....When we use the term "validate," we don't mean to imply that we are testing hypotheses in a quantitative sense. Validating here refers more to a checking out of interpretations with participants and against data as the research moves along." (p48.)

Sample: This will be a "key informant" study, although the definition of key informant will be very broad. The SDH midwifery service sees its success as attributable to a stable "family triad" composed of the midwives themselves, the physicians, and the nurses at the Birth Center (Blanche Skubic CNM, personal communication, Nov.4, 2010) Consequently all of the midwives with delivery privileges who regularly cover call (n = 8) and the 5 obstetricians will be interviewed. Interviews are also planned with the Director of the Midwifery Service, and the physician who founded the service. In addition, interviews will be requested with each of the nurses who work in

the Birth Center, including charge and floor nurses from both the day and night staff, and their 2 supervisors until redundancy is reached. This is a group of approximately 30 women. The Director of the public clinic has already expressed an interest in the study, and an interview with her is anticipated, as well as one with the Hospital Administrator. The time required to do the study, as indicated in the timetable below, is a reflection of the large number of interviews anticipated. If the study resources are not exhausted by this sample, a few interviews with patients will also be sought. If such patient interviews are not possible with this study, funding will be sought in future proposals.

Instruments: A series open-ended questions derived from the literature has been developed and will be pilot tested with 1 RN who just left the SDH Birth Center (to move for her husband's job), 1 former SDH CNM (who left to take an academic position), and 1 physician who occasionally covers for the regular obstetricians. The questions are structured along the lines of the "5 Why's" of a Root Cause Analysis (IHI, 2010). More focused probes about the constructs of interest may be added if required to assist the interviewee to elaborate on a given topic. (Charmaz, 2006; Namey & Lyerly, 2010)

As the nurse/midwife herself is the "instrument" of care in birth, in qualitative research, the "researcher is the instrument" (Marshall & Rothman, 2011). It is recommended, consequently, that the researcher understand 7 things about herself and her study: (1) the nature of the research – which in the proposed study is somewhat controversial, as it is motivated by what is perceived as a current problem in the delivery of obstetric care; (2) the relationship with participants – all in this study are known to and work with this researcher, with the exception of the SDH Administrator, (3) the "direction of gaze" – both inward and outward, as the researcher works with all of the providers as well as provides care herself within this system; (4) the purpose of the research – useful to both the

participants and the site; (5) intended audience – both the scholarly community and the community of patients and providers; (6) the researcher's political position – explicitly focused on improving maternity care; and (7) the researcher's views on agency – an employee as well as an observer, actively engaged in improving her own care and understanding how the system as a whole might change to improve maternity outcomes (Marshall & Rossman, 2011).

Methodological rigor. As noted by Firestone (1990) "The major justification for the research enterprise is that we have the time and the skills to develop approximations of the truth that have a firmer warrant than common sense." (p. 123, cited in Miles and Huberman, 1994, p. 277). In qualitative studies, this is done through reliability and validity analogs called credibility and trustworthiness. Credibility is defined by Miles and Huberman (1994) as the "truth value", akin to the internal validity of the study. It is concerned with whether the data included are complete, and the interpretation of the data is accurate. It is achieved through rich and "thick" description, which will be achieved in this study through the number and varieties of the informants interviewed. Trustworthiness has dependability as its primary concern (Lincoln & Guba, 1985). Dependability is a factor that can be affected by the passage of time during the study, a sort of historical effect. If a long period of time is required to collect data, it is possible that the situation at the site of study will change, thereby affecting the informants' thoughts and comments. This is unlikely, as the site was established 15 years ago, and is considered stable, at least at this point in time. A second source of change is in the design itself, as the research adapts both questions and interpretation of data as the study progresses. In part, this is a component of the constant comparison method of grounded theory development, and is therefore desirable to some extent.

Procedure. Subject selection: This will be a key informant study, as detailed above.

Data analysis: The grounded theory analysis will be done using the constant comparative method in the computer program MAXQDATA favored by Corbin (Corbin & Strauss, 2008). This requires the researcher to begin analysis with the first interview, and then read each subsequent interview with an eye to patterns, themes, "holes", and areas of convergence and divergence. It may also suggest modifications or redirection of some questions, depending on the "story" as it develops (Corbin & Strauss, 2008).

Tentative Time-table

May, 2012	June, 2012 – Feb, 2013	Mar/Apr, 2013	June, 2013	Nov, 2013	June, 2014
Obtain hospital IRB approval					
Contact potential interviewees	Interview 5 people per month (until saturation is reached)				
Confirm transcriptionist & purchase equipment	Tapes to transcriptionist immediately after interviews				
	Ongoing analysis of transcriptions	Complete analysis	Present findings at conference	1st manuscript submitted	2nd manuscript submitted if appropriate

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APPENDIX A. Figures

<u>Figure 1. Conceptual Framework Example:</u> Organizational Factors related to Success from Ontario Project

CRITICAL SUCCESS FACTORS



ATTITIDE:

- 1. Pride in a low cesarean section rate;
- 2. A "culture" of birth as a normal physiological process;
- 3. A commitment to one-to-one supportive nursing care during active labor;

ORGANIZATION:

- 4. Strong team leadership;
- 5. Effective multidisciplinary teams;
- 6. Timely access to skilled professionals;

KNOWLEDGE AND INFORMATION:

- 7. Strong commitment to evidence-based practice;
- 8. Program to ensure continuous quality improvement (CQI);
 - 9 Accessible, interactive database;

NETWORK DEVELOPMENT:

10. Ability to coordinate labor and delivery services with other maternal/newborn programs; (continuity of care);

11. Ability to network with peers and organizations;

CHANGE MANAGEMENT: 12. Ability to manage change;

FOUNDATION OF: 13. Adequate funding.

Figure 2. Failure Mode Effects Analysis

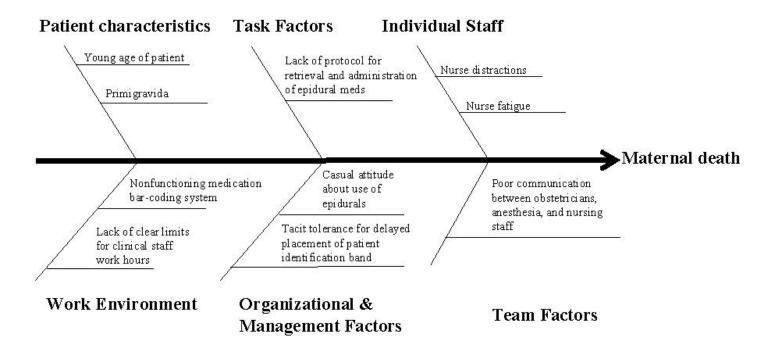
Conceptual Framework of Total Project Process+



⁺ Adapted from Team Problem Solving Quick Reference Guide G8D. Quality Associates International.

Accessed 11/20/10 from: www.quality-one.com

Figure 3. Example of RCA/Ishikawa "fish bone" Diagram



Accessed 11/21/10 from Science and Sensibility; info@Lamaze.org

Lamaze Six Practices for Promoting Normal Birth**

Figure 4. Conceptual Framework for Clinical Focus of Root Cause Analysis:



^{**}Modeled after the Lamaze Six Healthy Birth Practices. http://www.lamaze.org Accessed 11/09/10.

APPENDIX B. Solicitation of Participation

Robin Affrime, MPH, Chief Executive Officer Communicare Health Centers 2051 John Jones Road Davis, CA 95616 June 22, 2011

Dear Ms. Affrime:

As you know, I am one of the Certified Nurse-Midwives on staff at Communicare, and one of the co-authors of the award winning paper documenting the excellent outcomes of the collaborative model used by the midwives and the physicians in the Sutter and Communicare systems.

When I was first hired, you and I spoke about my interest in using my training as a researcher to study our model and try to understand better the means through which we obtain our remarkably good patient outcomes. I have now designed a study that I wish to submit for funding to do just that. The prospective funding agency is the Association for Women's Health, Obstetric and Neonatal Nursing, i.e., AWHONN, and a copy of the grant is attached to this letter. AWHONN restricts the grant to 10 pages plus appendices, so I am hoping you will have the time to review it and give me your thoughts.

I am planning for this to be the first in a series of projects that will examine the CommuniCare model, with the ultimate goal of understanding the bases for its successes well enough to assist others in duplicating both the model and its high quality of care and excellent outcomes.

Thank you for your consideration of my request.

Sincerely yours,

Deborah Woolley, CNM, PhD, MPH

Brian Wilson, MD Medical Director Sutter West Women's Health 2020 Sutter Place #203 Davis, CA 95616 June 22, 2011

Dear Dr. Wilson:

As you know, I am one of the Certified Nurse-Midwives on staff at Communicare, and one of the co-authors of the award winning paper documenting the excellent outcomes of the collaborative model used by the midwives and the physicians in the Sutter and Communicare systems.

Since we have been working together, you and I have spoken about my interest in using my training as a researcher to study our model and try to understand better the means through which we obtain our remarkably good patient outcomes. I have now designed a study that I wish to submit for funding to do just that. The prospective funding agency is the Association for Women's Health, Obstetric and Neonatal Nursing, i.e., AWHONN, and a copy of the grant is attached to this letter. AWHONN restricts the grant to 10 pages plus appendices, so I am hoping you will have the time to review it and give me your thoughts.

I am planning for this to be the first in a series of projects that will examine the CommuniCare model, with the ultimate goal of understanding the bases for its successes well enough to assist others in duplicating both the model and its high quality of care and excellent outcomes.

Thank you for your consideration of my request.

Sincerely yours,

Deborah Woolley, CNM, PhD, MPH

Carolyn Campos, RN, MS Unit Manager, Birth Center Sutter Davis Hospital 2061 John Jones Road Davis, CA 95616 June 22, 2011

Dear Ms. Campos:

As you know, I am one of the Certified Nurse-Midwives on staff at Communicare, and one of the co-authors of the award winning paper documenting the excellent outcomes of the collaborative model used by the midwives and the physicians in the Sutter and Communicare systems.

When we first met, you and I spoke about my interest in using my training as a researcher to study our model and try to understand better the means through which we obtain our remarkably good patient outcomes. I have now designed a study that I wish to submit for funding to do just that. The prospective funding agency is the Association for Women's Health, Obstetric and Neonatal Nursing, i.e., AWHONN, and a copy of the grant is attached to this letter. AWHONN restricts the grant to 10 pages plus appendices, so I am hoping you will have the time to review it and give me your thoughts.

I am planning for this to be the first in a series of projects that will examine the CommuniCare model, with the ultimate goal of understanding the bases for its successes well enough to assist others in duplicating both the model and its high quality of care and excellent outcomes.

Thank you for your consideration of my request.

Sincerely yours,

Deborah Woolley, CNM, PhD, MPH

APPENDIX C. Sample Site Permission Letter

To be placed on agency letterhead

Date

AWHONN, Association for Women's Health, Obstetric and Neonatal Nursing Research Committee
Regarding the Hill-Rom, Celeste Phillips Family-Centered Maternity Care Award

To Whom It May Concern:

Deborah Woolley, CNM, PhD, MPH has requested permission to conduct the research project named below with employees and providers associated with the Sutter Davis Hospital Birth Center during the period of May, 2012 to April, 2013. This letter notifies you that I/we grant permission to Dr. Woolley to conduct this research at the location listed below.

Research Project Title: "Birthing Quality: A Grounded Theory Study of Clinical Excellence"

Principal Investigator: Deborah Woolley, CNM, PhD, MPH

Study Site Location: Sutter Davis Hospital Birth Center

2061 John Jones Road, Davis, CA 95616

Permission granted by:	
Name of Individual (print) and Title	
Name of Individual (Signature)	Date

Cc:Robin Affrime, CEO, Communicare Health Centers Cc:Carolyn Campos, Manager, SDH Birth Center

Cc:Brian Wilson, MD, Medical Director, Sutter West Women's Health

APPENDIX D. Recruitment Bulletin

DEB WOOLLEY WANTS TO TALK

TO YOU

about "Birthing Quality: A Grounded Theory Study of Clinic Excellence"

Deb is studying the care we provide in the Birth Center by talking to the nurses, midwives and doctors here to get their thoughts about how our individual and collective efforts result in our great patient outcomes.

Every RN, CNM, and MD who works in the Sutter Davis Hospital Birth Center providing obstetric care is invited to participate in an individual one-hour interview with Deb.

Please contact Deb directly when she is at work,

Or by phone: xxx-xxxx or e-mail: xxx@gmail.com

to ask more questions and/or discuss when you might share approximately one hour of your time to talk. She will meet you at a place of your convenience and an hour of your choosing.

There is no payment for participating in this study, nor is there any penalty for not participating. There is no risk to you. Your remarks will be recorded and transcribed, but you will not be named in the report. You will benefit from having contributed to the understanding of our successes here, and from the satisfaction of knowing that this may help other providers and their clients to duplicate our success.

The results of the research will be presented at the AWHONN Annual Conference, and submitted for publication to JOGNN. The study is funded by AWHONN and approved by the Sutter Institutional Review Board.

APPENDIX E. Consent

BIRTHING QUALITY: A GROUNDED THEORY STUDY OF CLINICAL EXCELLENCE

INTRODUCTION

Communicare Health Centers and Sutter Davis Hospital support the practice of protection for human subjects participating in research. The following information is provided for you to decide whether you wish to participate in the present study. You may refuse to sign this form and not participate in this study. You should be aware that even if you agree to participate, you are free to withdraw at any time. If you do withdraw from this study, it will not affect your relationship with this unit, the services it may provide to you, or your employment. All responses are confidential.

PURPOSE OF THE STUDY

This study is intended to develop a theory of how clinical excellence is generated and maintained in a Birth Center recognized for its quality of care and outcomes. The specific outcome of interest in this study is the primary cesarean section rate.

PROCEDURES

If you consent to participate in this study, you will be asked to spend approximately one hour with the investigator, answering questions regarding your professional or personal experience and thoughts about quality of care in birthing centers, both at SDH and in other facilities where you might have worked or delivered. The investigator will audiotape these interviews and transcribe those tapes for analysis. The tapes will be stored in a locked cabinet, and used only by the investigator.

RISKS

There are no risks to the safety of participants. The identity of participants will be protected by the assignment of a random number to each person interviewed. Given the small number of participants, however, there is some risk that comments from individuals will be recognizable by other persons who are familiar with the various interviewees.

BENEFITS

There are no direct benefits to participants. The intended benefit is to the obstetric community, both professionals and patients, who stand to learn more about what type of care results in excellent outcomes.

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PAYMENT TO PARTICIPANTS

There is no payment to participants.

PARTICIPANT CONFIDENTIALITY

Your name will not be associated in any publication or presentation with the information collected about you or with the research findings from this study. Instead, the researcher(s) will use a study number or a pseudonym rather than your name. Your identifiable information will not be shared unless required by law or you give written permission.

Permission granted on this date to use and disclose your information remains in effect indefinitely. By signing this form you give permission for the use and disclosure of your information for purposes of this study at any time in the future.

REFUSAL TO SIGN CONSENT AND AUTHORIZATION

You are not required to sign this Consent and Authorization form and you may refuse to do so without affecting your right to any services you are receiving or may receive from either Communicare or Sutter Davis Hospital. However, if you refuse to sign, you cannot participate in this study.

CANCELLING THIS CONSENT AND AUTHORIZATION

You may withdraw your consent to participate in this study at any time. You also have the right to cancel your permission to use and disclose further information collected about you, in writing, at any time, by sending your written request to: Deborah Woolley, CNM, PhD, MPH, Communicare Health Center, 2060 John Jones Rd., Davis, CA., 95616.

If you cancel permission to use your information, the researchers will stop collecting additional information about you. However, the research team may use and disclose information that was gathered before they received your cancellation, as described above, unless you specifically direct them not to do so.

QUESTIONS ABOUT PARTICIPATION

Questions about procedures should be directed to the researcher(s) listed at the end of this consent form.

PARTICIPANT CERTIFICATION:

I have read this Consent and Authorization form. I have had the opportunity to ask, and I have received answers to, any questions I had regarding the study. I understand that if I have any additional questions about my rights as a research participant, I may call (530) 753-3498, write the Human Subjects Committee, Sutter Davis Hospital, 2000 Sutter Place, Davis, CA 95616 or write debw@communicarehc.org.

I agree to take part in this study as a research participant. By my signature I affirm that I am at leas and that I have received a copy of this Consent and Authorization form.				
Type/Print Participant's Name	Date			
Participant's Signature				
Researcher Contact Information				

Deborah Woolley, CNM, PhD, MPH Principal Investigator Communicare Health Center/Sutter Davis Hospital 2060 John Jones Rd. Davis, CA 95616 530.753.3498

APPENDIX F. Instrument: Guiding Questions for Clinical Interviews

1.	Demog	graphics:
	a.	Age
	b.	Professional Credential:
		i. RN/Associate's
		ii. RN/Bachelor's
		iii. RN/Master's
		iv. CNM
		v. MD
		vi. Other
	C.	Years in professional practice
	d.	How long have you worked at SDH?
	e.	Before you came to work here, based on information you had about SDH from other sources
		(friends, media, relatives etc.) what did you expect your experience to be like? Has that been what
		you found, if not how has it been different?
	f.	What is your prior experience?
		i. Number of Level I facilities worked at:
		ii. Years worked at Level I birthing facility:
		iii. Number of Level II facilities worked at:
		iv. Years worked at other Level II birthing facility:
		v. Number of Level III facilities worked at:
		vi. Years works at Level III birthing facility:
	g.	Incorporating both your education and your experience, what would you say is your definition of
		"quality of care"?
2.	What do you like most about the care that women and their families receive here?	
3.	How does that compare with other places that you have worked?	
4.	Please describe your experience at the facility that you believe provides the best quality of care you have ever seen.	
	a.	What made that care "the best ever"?
	b.	Did that "best ever" care translate into a low cesarean section rate? Why or why not?

- 5. Providing optimal care at SDH
 - a. Can you describe a situation that you feel typifies the way(s) in which SDH assures a high quality of labor and birth care for its clients?
 - b. What factors in that situation most contributed to the good care?

Probe: These could be factors present in the moment, and/or less direct factors like policies or administrative support.

- 6. Thinking specifically about the excellent (low) cesarean section rate at SDH, please talk about your impression of the various factors that produce that rate, Probe: such as:
 - a. Prenatal preparation
 - b. Care in labor
 - c. Provider characteristics
 - d. Professional interactions
 - e. Administration
 - Othe
- 7. Please talk in detail about your personal approach to patients and how you believe that contributes to the low cesarean section rate.
- 8. Group action directed at quality of care
 - a. What ongoing group activities are directed at maintaining and/or improving the quality of care at SDH, particularly the low cesarean section rate?
 - b. Are you aware of any quality assessment tools that are used?

Probe: benchmarking, statistical Charts, root cause analysis, Failure Mode Analysis...

- c. If so, please talk about the role they play in maintaining/improving the quality of care at SDH,
 - i. Both in general, and
 - ii. Regarding the cesarean section rate.
- d. In which if any of these activities do you participate?
- e. How do you believe your individual contribution influences:
 - i. the overall quality of care?
 - ii. The cesarean section rate?

Ending Questions

- 9. Is there anything else you think I should know to understand better:
 - a. The overall quality of care at SDH?
 - b. The low cesarean section rate at SDH?
- 10. Is there anything you would like to ask me?
- 11. Do you have any general thoughts about this interview or the overall project you would like to share?