Grant Instructions pp.27-36

Sigma Theta Tau International
RESEARCH GRANT

Proposal Number:
Applicant Name: Helene M. Holbrook
Reviewer Name:

I. Appendix A
   A. Letters
      1. Support from colleagues (2 minimum) — Yes — No — ***X Not Applicable***
      2. Research advisor/committee (if dissertation) — ***X*** ***Yes*** — No — Not Applicable
      3. Agreement letters from consultants — ***X*** ***Yes*** — No — Not Applicable
      4. Collaborating Institutions — Yes — No — ***X Not Applicable***

   B. Co-investigator(s) Biosketch(es) — Yes — No — ***X Not Applicable***

   C. Human or animal subject approval by the institutional review board received — ***X*** ***Yes*** — No — Not Applicable

II. Appendix B
   A. Copies of paper/pencil instrument, interview format or other instruments, scoring instructions and documentation of copyright permission — ***X Yes*** — No — Not Applicable

III. Research Grant Agreement Signed — ***X Yes*** — No

IV. Application Form
   A. Budget and funding sources:
      1. Other funding sources involved? — Yes — ***X No***
      2. Research depends on obtaining other funding? — Yes — ***X No***
      3. Appropriate/reasonable match between proposal and request for funds? — ***X Yes*** — No
      4. Prior and current extramural funding? — Yes — ***X No***
      5. Budget adequately justified? — ***X Yes*** — No

   B. Investigator/Team
      1. Indicate research career stage of Principal Investigator (PI):
         Check <u>one</u> of the following categories:

Master's Prepared
Pre-Doctoral (Dissertation)
X Pre-Doctoral (Non-Dissertation)
Doctorally Prepared
Experienced researcher entering new area
Other (Please specify)

2. Multidisciplinary Yes ***X No***
   If yes, identify disciplines represented.

3. International
   Is population studied outside the United States? Yes ***X No***
   If yes, indicated population(s) to be studied.

   Is PI International? Yes ***X No***
   If yes, identify country of residence.

   Does PI's research team have international representation? Yes ***X No***
   If yes, identify countries represented

I. Abstract

A pilot project using a retrospective chart review is conducted to determine if the CenteringPregnancy model for group appointments offered to Spanish- speaking prenatal women can affect pre and post delivery conditions when compared to traditional visits in same population. There are no published prenatal guidelines for group-based prenatal care as there is in other conditions, such as management strategies in diabetes or low back pain. (Yehle, 2009) The pilot study may support practice changes, including group visits, to improve care by providing patients, their partners and families with ongoing education, promoting improved patient comprehension of their pregnancy with risk reduction and improved self-care .(Yehle, 2009)

Variables include: a) the incidence of preterm births (gestational age at birth), b) adequate prenatal care (# of prenatal visits), c) birth weight. And d) breastfeeding retention (breastfeeding at delivery and Postpartum check). The group appointment is a model of care utilized in pregnancy, pediatrics, geriatric and chronic conditions management. These models of care have demonstrated evidence based applications in

reducing utilization of acute care services, reduction in delivery costs, improved quality of life, knowledge, health behaviors, improved self-esteem and patient and provider satisfaction. (Beck, 1997; Trento, 2005; Trento, 2001)

II. Body of Proposal

Narrative:

A. Purpose/Specific Aims:

The chart review will locate the variables associated with pre and post pregnancy outcomes.

Aim #1:

Evaluate available chart data from a subset of women seeking pregnancy care at the Contra Costa County medical clinics.

Aim #2

Determine how closely aligned the chart data are with current evidence that has shown success in reducing health disparities other populations (The Life Course Initiative, 2005). Disparity in health outcomes are influenced by socioeconomic factors that may include access to important healthcare information in a culturally sensitive way. Can a group appointment model like the CenteringPregnancy model provide a more effective means for engaging Spanish-speaking pregnant women? Clinical trials using the group prenatal

appointment model show increased pregnancy knowledge, readiness for labor, and higher satisfaction compared with individual prenatal appointments. This article discusses the importance of reducing disparities in birth outcomes using a CenteringPregnancy group appointment model.

B. Significance of Project

1. Potential for leading to further research or development of methodology or theory

Comparing past practice with current evidence may lead to changes in practice with the healthcare systems and further quasi-experimental research questions.

2. Potential contribution to nursing knowledge or knowledge in other fields

A pilot project has the ability to guide larger, more sophisticated and randomized studies.

3. Statement on direction of research

A pre and post intervention study will be designed as a result if these findings.

C. Conceptual/Theoretical Framework

The structured chart review tool builds on an established outpatient method of quality review, based on the Academy of Pediatrics Association chart review tool done to assess whether "Well Child" checks met current evidence-based guidelines, including outcomes for measurement associated with education, growth and development, immunization, safety, and nutrition.

Evaluating actual practice through retrospective audit will be based on the general guidelines set forth by the Academy of Obstetrics and Gynecology for prenatal care that minimizes the risk of complications, maximizes the likelihood of a good outcome, and maximizes the humane care of the patient at a level achievable by group or traditional prenatal practice.

Section Mean:

D. Literature Review

Include information about the variables you will look at in chart review….example: why is it important to avoid early birth, what are the mechanisms for success in breast feeding (immunologic, etc for baby)

Literature review

Author Year	Point A Objective	Point B Study Design	Point C Results	Point D Conclusion
Ickovics 2007	Group vs. trad Prenatal care	RCT	Group Less likely: preterm birth, additional	+Group outcome of preterm delivery

			content on HIV and STI reduction, initiate more breastfeed		
Ickovics 2003	Group vs. prenatal trad	Prospective matched cohort study	Higher bw, increased gestational age in group appt	+Group appt outcome for BW	
Rising 1998	Group prenatal vs. trad	Convenience sample	96% preference for group appt. Less 3rd trimester ED visits	Perceived satisfaction with group appt	
Grady and Bloom 2006	Group adolescent Prenatal vs. indiv.	Retrospective study of birth outcomes	CP patients had less likely to be preterm or low wt	+group experience on gestation and bw	
Baldwin 2006	Prenatal Group vs. Trad care	Prospective longitudinal study	Higher levels of pregnancy knowledge	Less ED visits, more healthy practices regarding not smoking, eating well	

E. Design and Methods

Study Design and Methods:

This is a retrospective chart review of patients treated for prenatal course through group appointments or traditional care. A convenience sample of the most recent 100 prenatal patients, with expected date of

delivery by 12/31/09 (so post partum breastfeeding retention can be gathered), divided evenly between traditional and group prenatal care, gathered from prenatal rosters listing Spanish speaking patients, date entered for care, and participation in group versus individual prenatal care. A chart review tool (Table 1) used by the Academy of Pediatrics will be modified to fit the variables of interest in this population; the tool has been used in other populations to conduct pilot studies allowing researchers to assess feasibility of the planned investigation, reliability of the data abstraction instrument, effectiveness of the protocol, availability of the data, and address any sampling concerns. (Gearing, 2006) The reliability and validity has not been established in this population. Sample obtained through rosters of patients registered for the CenteringPregnancy group appointments and traditional prenatal appointments, limited to Spanish speaking prenatals in a time frame to gather approximately 50 patients from each group, available through Healthy Start. Patients will not be contacted. A waiver of HIPAA authorization has been obtained from IRB at Contra Costa County.

Each selected patient's medical records and prenatal registry information will be reviewed by the investigator for demographics, attendance in group or traditional prenatal visits, birth weights of baby, weeks of gestation at birth, breastfeeding at birth and at 6 week postpartum visit, and course of pregnancy. Additional information requested are who saw patient for prenatal care and the age of the patients. Information will be collected on individual data collection sheets and stored in a password-protected database on a spread sheet. A code will be used to protect patient confidentiality. The key to the code will be kept separate for the data. At the completion of the data analysis, the key to the code will be destroyed.

The project review by the IRB requests an exempt status type of review but understands the IRB makes the final determination. Most student projects qualify for exempt status or expedited review because they are of no more than minimal risk. I understand the IRB reserves the right to send any study to the full board for review.

The project could be considered as:

Category 4 - A retrospective chart review for which all of the information already exists in the chart prior to starting the study and all information extracted from the chart does not contain any identifiers, even though you may see identifiers in the course of gathering your information.

Eligibility Criteria

- Treated at CCHP Hospital and Clinics between 2008 and 2009
- Subject will be included in the study based on gender, racial or ethnic origin due to the focus on Spanish speaking prenatal patients.

Sample test:
Chart reviews will be conducted by one principal investigator, Helene Holbrook, documenting:

1. Spanish speaking patient as participating in group or traditional care appointments.
2. Patients EDC and actual gestational age in weeks at delivery.
3. Baby birth weight.
4. Is baby breast feeding at birth?
5. Is baby breast feeding at postpartum visit approximately 6 weeks?
6. Number of actual prenatal/postnatal visits per patient
7. Who is identified as prenatal provider?
8. Age of the prenatal at start of care.

Possible benefits of proposed study are to see any advantage of one type of prenatal care versus another.

No known identifiable risks to subjects participating in study.

We keep confidential (and secure) names and associated data pertaining to studying in a HIPPA controlled chart review environment.
Any secondary data analysis or restricted/limited data (including HIPAA):
No names or identities of subjects in the data base can be deducted from the data fields.
There is no human tissue involved.
The data set is restricted access.
Datasets will not be available to anyone but Administrative supervisor, Dr. Karen Burt.
Information from data revealing outcomes will be submitted for publication in a peer reviewed professional journal, data set information will remain secure.

Number of subjects for study will be 100+, about 50 prenatals from traditional care and 50 from group appointments.
The subject sample will be Spanish speaking prenatal patients who received prenatal care at CCHS in traditional or group prenatal appointments.

Subjects will not be compensated for their participation.

Additional sources of data will be census/public records, medical records, and registries Pre/ante-natal birth statistics.

appointments and traditional prenatal appointments, limited to Spanish speaking prenatals in a time frame to gather approximately 50 patients from each group, available through Healthy Start. Patients will not be contacted. A waiver of HIPAA authorization will be requested from IRB.

F. Data Analysis
   1. Adequately described (Results are pending)
   2. Appropriate to specific aims and hypotheses or research questions

What will be measured?	Goal: To reduce [what] by [number,%] within [timeframe]
1. Breast Feeding Retention Rate: Definition: Percentage of patients in Group Vs. Individual prenatal care who have documentation of ongoing breast feeding at the 4-6 week post-partum visit.	Goal: to compare the percentage of patients who continue to breastfeed after DC from the hospital between the Group Prenatal patients and the patients receiving Individual prenatal care. You could also measure farther out than 4-6wks. Our Well Child forms ask about breast feeding up until the age of 12mos, although I'm not sure how often it is assessed or documented by providers after 6 mos.
2. Birth Weight: Definition: Average of Documented Weight at birth as listed in the Delivery Record for infants born to patients attending the each group (Group appt patients and Traditional Prenatal patients).	to look at the rate of ELBW infants in each group or the Percentage of prematurity in each group as defined by GA < 2500 Gms. An average of BW at delivery for each group. An average and range will be culled from chart data for comparison to see if this pilot project finds any differences.
3.Gestational Age at Delivery: Average Gestational age at birth documented on the Newborn H & P between each group Group Class vs. Traditional	Goal: Goal for the Gestational age. preterm is GA less than 37 weeks; low birth weight is BW less than 2,500 grams; and small for gestational age (SGA) is BW less than the tenth percentile weight for the infant's GA. An average and range will be culled from chart data for comparison to see if this pilot project finds any differences
4.Weight Gain for Pregnancy Average Wt gain by the date of delivery documented in the OB H & P for each group.	Current guidelines recommend that you gain somewhere between 25-35 pounds during your pregnancy if you are an average-size person. If a woman already is overweight when she becomes pregnant, most practitioners suggest that she gain between 15-20 pounds. An average and range will be culled from chart data for

	comparison to see if this pilot project finds any differences

G. Time Frame: Proposed research can be carried out within the support period? ***X Yes*** No

Submission Confirmation

ID and Password
Application ID#: 5267
Password : 853570
Applicants

Helene Holbrook, FNP - Principal Investigator

Home Address:
528 Jean St
Oakland, CA 94610
USA
Phone Number: 510 612-4630
Email: heleneholbrook@gmail.com
Degree sought: DNP
Expected Date Of Completion: 2010-05-21
University/College/School: University of San Francisco
Department: Nursing
Majors: FNP
Minors:
Research Advisor/Chairperson: Judith Lampton

Biographical Sketch

Education

#	Institution and Location	Inclusive Dates of Attendance	Degree	Date Degree attained	Major

Professional experience

#	Title of Position	Employer Name	Employer Address	Inclusive Dates
1	Family Nurse Practitioner	Contra Costa County	2500 Alhambra Ave. Martinez, CA	1978-1998, 2009-present
2	Family Nurse Practitioner	Kaiser	2238 Geary Blvd San Francisco CA	1998-2009
3	Family Nurse Practitioner	Yukon Kuskoquen Health Corp	St Marys, AK	2007-2008

Honors

Sigma Theta Tau International, Chapter San Francisco

Publications or Papers Presented

AANP Poster presentation

CANP Education Committee

Previous Research Experience

N/A

Previous Grant(s) Received

N/A

Research Specialty

Clinical Practice: Evidence-Based Practice, Healthcare Delivery, Practice Environments, Practice Models
Evidence-Based Practice
Family Health
Health of Diverse Populations: Health Disparities
Health-Related Behaviors
Models and Mechanisms

Abstract Text

I. Abstract A pilot project using a retrospective chart review is conducted to determine if the group appointments offered to Spanish- speaking prenatal women can affect pre and post delivery conditions when compared to traditional visits in same population. There are no published guidelines for group-based prenatal care as there is in other conditions, such as management strategies in diabetes or low back pain. The pilot study may support practice changes, including group visits, to improve care. Variables include: a) the incidence of preterm births (gestational age at birth), b) adequate prenatal care (# of prenatal visits), c) birth weight. And d) breastfeeding retention (breastfeeding at delivery and Postpartum check). The group appointment is a model of care utilized in pregnancy, pediatrics, geriatric and chronic conditions management. These models of care have demonstrated evidence based applications in reducing utilization of acute care services, reduction in delivery costs, improved quality of life, knowledge, health behaviors, improved self-esteem and patient and provider satisfaction. (Beck 1997, Trento 2005, Trento 2001)

Project Description
Title of project: Exploring the value of group and traditional obstetrical appointments to reduce health disparity
Requested Grants: Sigma Theta Tau International/Midwest Nursing Research Society Research Grant
Start Date: Monday, 1 February 2010
Proposed Completion Date:
Human subjects involved?: no
Animal subjects involved?: no

Institutional Review Board Action

Comments:
Cleared to progress
Approval Date: 01/22/2010

Letters of Support

References have been contacted. You may resend a letter of support request by clicking the resend button below.

- judith lampton lamptonj@usfca.edu : No Response yet

Other sources of support

n/a

Proposal Text

Exploring the value of group and traditional obstetrical appointments to reduce health disparity
Helene M. Holbrook, FNP-C
University of San Francisco
Abstract:
Disparity in health outcomes are influenced by socioeconomic factors that may include access to important healthcare information in a culturally sensitive way. Can a group appointment model provide a more effective means for engaging Spanish-speaking pregnant women? Clinical trials using the group prenatal appointment model show increased pregnancy knowledge, readiness for labor, and higher satisfaction compared with individual prenatal appointments. This article discusses the importance of reducing disparities in birth outcomes through the use of a group appointment model. Socioeconomic status, race and racism, health care, disease status, stress, nutrition and weight status, birth weight, and a range of behaviors are some of the key protective and risk factors that may affect health outcomes, including reproductive and birth outcomes. The group appointment model creates opportunities to build protective factors and reduce risk factors. (Lu, 2003)
Introduction Raphael (2008) reinforces the social concept of need: in the position that social determinants of health are the economic and social conditions that shape the health of individuals, communities, and jurisdictions as a whole. Social determinants of health are the primary determinants of whether individuals stay healthy or become ill (a narrow definition of health) and can determine the extent to which a person possesses the physical, social, and personal resources to identify and achieve personal aspirations, satisfy needs, and cope with the environment (a broader definition of health). Social determinants of health are about the quantity and quality of a variety of resources that a society makes available to its members. Debate exists over the factors that contribute to health disparities between ethnic and racial groups; it is generally accepted

that disparities can result from three main areas a) personal, b) socioeconomic, and c) environmental characteristics among ethnic and racial groups. Evidence continues to evolve about the confluence of the social determinants of health on community health (Goldberg, 2004); both with respect to the barriers certain racial and ethnic groups encounter when trying to enter into the health care delivery system; and from the quality of health care different ethnic and racial groups receive (Kaiser Foundation, 1999). Group prenatal appointment may be a "just" way to address racial and ethnic health disparities and is in alignment with Healthy People 2010, an important Federal guideline to promote improvement of health and access to care, in increasing pregnancy knowledge and rates of breastfeeding in the United States (USDHHS, 2000). Group appointments can be a model for information flow, peer collaboration, and culturally sensitive communication. (WHO, 2008) Education and management strategies in a group model could focus on important variables associated with positive outcomes that include a) normal infant weight for gestation, b) weeks of gestation at birth, and c) degree of breastfeeding retention, which serve as markers associated with both pregnancy knowledge, and pregnancy outcomes. While women cannot often alter some of the risk factors that are associated with adverse perinatal outcomes (e.g. race/ethnicity and past obstetric history), they can adjust their activities to decrease the possibility of poor birth outcomes (USDHHS, 2000). Improved self-management practices can be positively influenced by prenatal education and group dynamics (Walker, 2008). Lu's life-course perspective sees socioeconomic status, race and racism, health care, disease status, stress, nutrition and weight status, birth weight and a range of behaviors as some of the key protective and risk factors that may affect health outcomes (Lu, 2009). The community health center setting , by law , is located in medically underserved communities and plays a critical role in providing care to people of color. Although people of color represent one-third of the U.S population, half the patients who receive care at community health centers are persons of color. (Rosenbaum, 2009). The community setting could serve as a ready venue for the establishment of group appointments that provide care for underserved communities by employing "kinship" relationships that broaden the strict definition of pure genealogy.

A Model for Equity

In a formal CenteringPregnancy group prenatal model, eight to 10 women with similar gestational ages begin their group care after their initial obstetric exam, usually around 12 to 16 weeks. There are 10 two-hour sessions following the usual prenatal visit schedule of four-week visits until the 28th week of pregnancy, followed by bi-weekly visits until the last session. During the last month of pregnancy, healthy women can be seen every other week according to the Guidelines for Prenatal Care (ACOG) or may be seen individually, if needed. During each session, women complete self-care activities, including checking their blood pressure using digital wrist or arm cuffs, measuring their weight, and determining their gestational age using a standard gestational age wheel. The educational component is guided by an extensive curriculum developed by the Centering Healthcare Institute (CHI) based upon the educational needs of pregnancy, current recommendations of leading health care groups and organizations, and current research. A facilitative leadership style is used to guide the discussion of the group, and self-assessment sheets help to guide discussions about common pregnancy topics like nutrition, contraception, labor, birth, and parenting issues. Patient centered group facilitation training is offered nationwide for prenatal group appointments. Women in the group share their concerns and develop supportive relationships with one another throughout the six to 10 sessions. Women often exchange contact information, thereby creating opportunities for mutual support during and after pregnancy. Knowing the community culture that is being served allows for gathering and sharing information, as a means of enhancing a familiar and open environment. Baldwin (2006) comments on the effect of traditional prenatal care versus a group model of care, CenteringPregnancy, on maternal knowledge of pregnancy, social support, health locus of control and satisfaction. (CenteringPregnancy, 2005) The group appointment is a model of care utilized in pregnancy, pediatrics, geriatric and chronic conditions management. These models of care have demonstrated evidence-based applications in reducing utilization of

acute care services, reduction in delivery costs, improved quality of life, knowledge, health behaviors, improved self-esteem and patient and provider satisfaction (Beck, 1997; Trento, 2005; & Trento, 2001). The needs of a population in a specific area in Northern California could be met by the group appointment model. Both the feasibility of data collection and outcomes for consideration were discussed with a champion of group appointment methods who agree that additional data would serve to advance practice.

Confirming the value

In order to determine the value of the group and traditional methods of appointments, a pilot chart review will be done. A thorough retrospective chart review can compare prenatal and infant outcomes of birth weights, number of prenatal visits and breastfeeding retention in Spanish-speaking women, by reviewing those who received instruction and care via group appointments and those who engaged in traditional, one-on-one prenatal appointments (figure 1) A convenience sample of 100 patients will be evenly divided between traditional and group prenatal care. A chart review tool (Figure 2) used by the Academy of Pediatrics will be modified to fit the variables of interest in this population; the tool has been used in other populations to conduct pilot studies allowing researchers to assess feasibility of the planned investigation, reliability of the data abstraction instrument, effectiveness of the protocol, availability of the data, and address any sampling concerns. (Gearing, 2006) The reliability and validity has not been established in this population. The prenatal charts will be limited to Spanish-speaking patients who form the population of interest. Subjects will be retrospectively identified using “language preference” which is listed in the chart demographics that can be obtained from the billing codes, which list the prenatal patients as “in-group” and “traditional” prenatal settings. Patient names were verified by prenatal clinic rosters kept in clinic. Prenatal and infant outcomes will be defined as: a) the number of prenatal visits attended, b) maternal weight gain, c) infant birth weight, d) gestational age at delivery and) breastfeeding retention. The birth weights, gestational weeks at delivery, and breastfeeding retention results will provide an understanding of pregnancy knowledge gained from the group appointment information compared with traditional prenatal appointments. Previous studies comparing group prenatal appointments and traditional care reflect improved infant birth weights, even those born prematurely, lower preterm delivery rates, increased rates of breast feeding initiation, and adequate prenatal care. (Ickovics, 2003; Grady, 2004)

Discussion and Conclusion

The proposed chart reviews will begin to identify a method by which comparison of pregnancy trajectory and birth outcomes in-group versus traditional appointments can be explored. Group prenatal care is an innovative model of care and limited data is available for review. The data of the randomized control trial (RCT) by Ickovics in 2007 and the cohort study by Ickovics in 2003 support the protective effect of group prenatal care against preterm delivery for women at increased risk of adverse outcomes. More study that is extensive will be needed to define the optimal population for group care. The study is going forward with significant community interest in looking at results and including future topics of improved pregnancy knowledge, readiness for labor, parenting readiness and high levels of satisfaction with group prenatal care with pre- and post-testing as tools to offer data. The more data and understanding of what improves prenatal knowledge, satisfaction and access to care will improve the pregnant woman and infants outcomes. The group prenatal appointment model may be an important way to address racial and ethnic disparities and is in alignment with Healthy People 2010 in increasing pregnancy knowledge and rates of breastfeeding in the country. (United States Department of Health and Human Services {USDHHS}, 2000)

References

Baldwin, K. (2006). Comparison of selected outcomes of CenteringPregnancy versus traditional prenatal care. Journal of Midwifery & Women's Health, 51(4): 266-272.

Beck, A., Scott, J., Williams, P., et al. (1997). A randomized trial of group outpatient visits for chronically ill older HMO members: The cooperative health care clinic. Journal of American Geriatric Society, 45, 543-549.

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World Health Organization. (2008). Commission on the Social Determinants of Health. Retrieved January 12, 2010, from http://www.who.int/social_determinants/en/

Yehle,K., Rhynders,P., Newton, G. (2009) The effect of shared medical visits on knowledge and self-care in patients with heart failure: A pilot study.*Heart & Lung: The Journal of Acute and Critical Care*.38(1) 25-33.

Appendices

- 2-13chart review tool.doc - Instrument

Project Budget

All values are in U.S. Dollars.

Categories	Amount Requested	Total Budget Amounts
Personnel *(Requests for Investigator salaries may be included. Include hourly rate for personnel.)*	1500	1500
Secretarial staff	0	0
Typing Costs *(must be those directly related to the research. Typing of dissertations will not be funded.)*	0	0
Research Assistants	0	0
Consultants *(Limit to $50 per*	0	0

hour)		
Supplies	0	0
Computer Costs *(software only)*	0	0
Travel Expenses *(data collection only)*	1000	1000
Other	0	0
TOTAL	2500	2500

Justification

A

Personnel Costs (e.g., stipends or honoraria for staff, faculty, student assistants, invited speakers, and benefits where applicable). Call the Office of Student Employment at 422-6770 for the current student pay rate.

Describe the responsibilities of each person listed, and justify costs:

150 hours of student time devoted to chart review and data collection, IRB and proposal development.

$10.00 hour x 150 hr hours=$1500

B

Catering & Supplies. e.g., photocopying costs, refreshments, books; include justification for each item listed. *Any catering requests must include a separate itemized budget estimate from Bon Appétit/USF Catering.*

CenteringPregnancy (CP) Institute offers group facilitator training and workbooks

$150.00 Centering Pregnancy Workbook

C

Hotel Accommodations & Per Diem. Include length of stay and calculate cost per day according to *http://policyworks.gov/org/main/mt/homepage/mtt/perdiem/travel.shtml*.

2 days stay at Sheridan Springfield MA. Hotel $99/day x 2 day 12/4-5 for 2 day CP workshop for training as group facilitator.

$30/day food x 2=$60.00

$198.00

$60.00

D

Airfare. (Printed estimate from *Expedia.com* or *Travelocity.com* must be attached)

Southwest Air $99 fare from SFO-Hartford CN each way ($198 RT)

$198.00

E

Other expenses. Itemize and include a brief statement justifying each expense.

Fees for Centering Pregnancy Group Facilitator Training $500.

$500.00

Total Cost of Project:

$2606.00

Amount requested :

$2500.00

If you have applied for other sources of support, how will the conduct of this study be affected, if the other funding is not obtained?

n/a

IRB Application
Section I

Name of Investigator:

Helene Holbrook FNP-C
Email address: heleneholbrook@gmail.com
Address: 528 Jean Street Oakland CA 94610
Phone: 510 612-4630
Administrative Manager: Karen Burt MD
Academic Supervisor: Judith Lampton PhD, RN Associate Professor USF

Status: FNP-C, Affiliate Medical Staff CCCMS,
Doctorate in Nursing Practice (DNP) candidate expected 2010
University of San Francisco (USF)

Title of Project:

Exploring the Value of Group and Traditional Obstetrical Appointments to Reduce Health Disparity

Start of Project:
2/4/2010

Estimated End Date of Project:
4/1/2010

An external sponsor does not fund research.

Research is being conducted in conjunction with DNP doctoral dissertation.

Summary description of hypothesis:

The trials with CenteringPregnancy model show increased birth weights, increased numbers of women breastfeeding at 6-12 weeks post-partum, heavier birth weights at preterm delivery, plus increased pregnancy knowledge, readiness for labor, and higher satisfaction compared with individual prenatal appointments. Evaluating the data collected from CenteringPregnancy group prenatal appointment experiences in busy CCHP county medical clinics Health Services will give information about effectiveness of the group appointment model as a means of documenting actual pregnancy outcomes. This reflects the mission of the Contra Costa health organization Life Course Initiative (Life Course 2005) to reduce disparities in birth outcomes and change the health of the next generation in Contra Costa County by achieving health equity, optimizing reproductive potential, and shifting the paradigm of the planning, delivery and evaluation of maternal, child, and adolescent health services. (Lu 2009)

Objectives:

Primary objective:
To determine outcome variables to include birth weight, gestational weeks at delivery, breastfeeding at delivery and at 6 weeks.

Secondary objective:
To evaluate compliance, satisfaction with services.

Background and Rationale:

The Centering Pregnancy model may be an important way to address racial and ethnic disparities and is in alignment with Healthy People 2010 in increasing pregnancy knowledge, and rates of breastfeeding in the country. (USDHHS 2000)

The birth weights, gestational weeks at delivery, and breastfeeding results will document understanding of pregnancy knowledge gained from the group appointment information, in hopes of eventually reflecting a reduction in risks that adversely affect the pregnancy outcomes. Low birth weight, prematurity, and infant mortality are important outcomes to be reduced by improved quality and frequency of prenatal care. The pre/postnatal patients cannot alter some of the risk factors that are associated with adverse perinatal outcomes (e.g. race/ethnicity and past obstetric history); however, it is in her ability to adjust her activities to decrease the possibility of poor birth outcomes. (USDHHS, 2000)

Design of research and planned use of human subjects:

Study Design and Methods:

This is a retrospective chart review of patients treated for prenatal course through group appointments or traditional care. Sample obtained through rosters of patients registered for the CenteringPregnancy group appointments and traditional prenatal appointments, limited to Spanish speaking prenatals in a time frame to gather approximately 50 patients from each group, available through Healthy Start. Patients will not be contacted. A waiver of HIPAA authorization will be requested from IRB.

Each selected patient's medical records and prenatal registry information will be reviewed by the investigator for demographics, attendance in group or traditional prenatal visits, birth weights of baby, weeks of gestation at birth, breastfeeding at birth and at 6 week postpartum visit, and course of pregnancy. Information will be collected on individual data collection sheets and stored in a password-protected database or spread sheet. A code will be used to protect patient confidentiality. The key to the code will be kept separate for the data. At the completion of the data analysis, the key to the code will be destroyed.

The project review by the IRB requests an exempt status type of review but understands the IRB makes the final determination. Most student projects qualify for exempt status or expedited review because they are of no more than minimal risk. I understand the IRB reserves the right to send any study to the full board for review.

The project could be considered as:

Category 4 - A retrospective chart review for which all of the information already exists in the chart prior to starting the study and all information extracted from the chart does not contain any identifiers, even though you may see identifiers in the course of gathering your information.

Eligibility Criteria

- Treated at CCHP Hospital and Clinics between 2000 and 2009
- Subject will be included in the study based on gender, racial or ethnic origin due to the focus on Spanish speaking prenatal patients.

Sample test:

Chart reviews will be conducted by one principal investigator, Helene Holbrook, documenting:

9. Patient as participating in group or traditional care appointments.

10. Patients EDC and actual gestational age in weeks at delivery.
11. Baby birth weight.
12. Is baby breast feeding at birth?
13. Is baby breast feeding at postpartum visit approximately 6 weeks?
14. Number of actual prenatal/postnatal visits per patient

Possible benefits of proposed study are to see any advantage of one type of prenatal care versus another.

No known identifiable risks to subjects participating in study.

We keep confidential (and secure) names and associated data pertaining to studying in a HIPPA controlled chart review environment.
Any secondary data analysis or restricted/limited data (including HIPAA):
No names or identities of subjects in the data base can be deducted from the data fields.
There is no human tissue involved.
The data set is restricted access.
Datasets will not be available to anyone but Administrative supervisor, Dr. Karen Burt.
Information from data revealing outcomes will be submitted for publication in a peer reviewed professional journal, data set information will remain secure.

Number of subjects for study will be 100+, about 50 prenatals from traditional care and 50 from group appointments.
The subject sample will be Spanish speaking prenatal patients who received prenatal care at CCHS in traditional or group prenatal appointments.

Subjects will not be compensated for their participation.

Additional sources of data will be census/public records, medical records, and registries Pre/ante-natal birth statistics.

This study has not been reviewed by any other institution.

This investigator has donated her time to gather and compile the information. The time donated would not be in lieu of working in clinic.

There is no financial conflict of interest

Descriptive statistics will be performed using SPSS statistical software.

Protocol Review
The protocol and all subsequent modifications must be reviewed and approved by the CCHP Clinical Research Review Committee (CRRC) and CCHP Institutional Review Board (IRB) prior to any patient data collection.
Administration Approval

show details Jan 28 2010

ddunnbow@hsd.cccounty.us

to me

Helene,
Everything looks to be in order. Please proceed and have fun. dianne

Dianne Dunn-Bowie, Chief Executive Officer
Contra Costa Health Centers

Chart review tool

CONTRA COSTA
HEALTH SERVICES

CONTRA COSTA REGIONAL MEDICAL CENTER
AND HEALTH CENTERS
2500 Alhambra Avenue
Martinez, CA 94553
Ph: 925-335-7474, ext. 4027
Fax: 925-370-5251

To: Helene Holbrook, FNP.
Principal investigator

Date: 1-28-2010

From: Shideh Ataii, Pharm.D.
Chair, Institutional Review Committee

Re: Prenatal group appointments compared to traditional prenatal appointments as a means to increase prenancy knowledge and improve outcomes in Spanish speaking patients

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The Contra Costa Regional Medical Center and Health Centers Institutional Review Committee has met and approved the following study: "Prenatal group appointments compared to traditional prenatal appointments as a means to increase pregnancy knowledge and improve outcomes in Spanish speaking patients".

Please notify this Committee of any concerns you may have in relation to this study, promptly.

In addition, the investigator is to submit a request for study renewal on an annual basis. To maintain a formal cycle to match our quarterly meetings, future dates would be 1-2011, 1-2012, etc....

If you have any questions, please contact me at 925-335-7474 ext. 4027.

Data Collection Strategies

*(For **this** research purpose, a chart review will be conducted retrospectively)*

Prenatal

- Visit was for a prenatal/postnatal check

- Record the prenatal's date of visit, name, your practice's medical record number, and today's date in the spaces provided on the *Chart Review Log Sheet* (*Note: this form is for your office's internal use only, to aid you in tracking your chart reviews. To protect patient confidentiality, please do not submit the Chart Review Log Sheet to us!)*
- Locate the number to the left of the prenatal's name on the *Chart Review Log Sheet*. This is the *Patient Log Number*. Please write this number in the space indicated on the upper right hand side of the *Chart Review Form*.
- Review the chart and complete the *Chart Review Form*. See specific question instructions on the next page.
- Compile data collected on the *Chart Review Forms* and include a summation of this data on the *Monthly Data Reporting Form*.
- Submit your *Monthly Data Reporting Form* by email or mail to:

Helene Holbrook FNP-C, DNP expected 2010
heleneholbrook@gmail
or
c/o Dr. Karen Burt
2500 Alhambra Ave.
Martinez, CA 94512
510 612-4630 cell for Helene Holbrook

References

U.S. Department of Health and Human Services. *Healthy People 2010*. 2nd ed. With Understanding and Improving Health and Objectives for Improving Health. 2 vols. Washington, DC: U.S. Government Printing Office, November 2000.

Table 1

Chart Review Form

Practice Name: _____ Patient Log # _____

Data Submission Date: _____

1.	Is this patient pregnant?	Yes	No (Stop here)
2.	Is this a group prenatal visit? (Stop here, sort separately from nongroup appointments)	Yes	No
3.	Is Spanish the patient's primary/preferred language?	Yes	No
4.	Evidence of breastfeeding at birth	Yes	No
5.	Evidence of breastfeeding at postpartum or reunion PP visit	Yes	No
6.	Birth Weight of infant	_____LB/KG/GRAMS	
7.	Total weight gain for pregnancy	____LB/KG	
8.	Total number of prenatal visits	____#	
9.	Weeks of gestation at delivery	____WKS	
10.	Evidence of eclampsia	Yes	No
11.	Diagnosis of Gestational Diabetes?	Yes	No

12. Diagnosis of Intrauterine growth retardation (IUGR) Yes No

Tally Method

After each chart review insert a tally mark on the *Monthly Data Reporting Form* in the appropriate boxes. At the end of the review, add all of the tally marks for each question and include that number on the *Monthly Data Reporting Form*.

Administrative Systems Reports/EHR

This method of data collection allows you to pull data from your administrative system or electronic health record. The system will need to be set up in a way that allows all of the questions on the *Monthly Data Reporting Form* to be answered. Discussion about this with system's technical support staff to determine if this is a possibility.

Every effort to maintain the confidentiality of all patient data is addressed. Confidentiality is crucial – no documents that have unique identifiers on them, such as patient names, hospital record numbers, date of visit, Medicaid ID#s, etc will be disclosed

D-PIP Chart Review Log Sheet
[INTERNAL OFFICE USE ONLY-DO NOT SUBMIT]

e of ex visit	Patient Name	Medical Record or other ID #	Chart review date	Data entry complete?	Patient Referre
	1.				
	2.				
	3.				
	4.				
	5.				
	6.				
	7.				
	8.				
	9.				
	10.				
	11.				
	12.				
	13.				
	14.				
	15.				
	16.				
	17.				
	18.				
	19.				
	20.				
	21.				
	22.				

e of ex visit	Patient Name	Medical Record or other ID #	Chart review date	Data entry complete?	Patient Referre
	23.				
	24.				
	25.				
	26.				
	27.				
	28.				
	29.				
	30.				