USF IRB Application
Section I

Name of Investigator:

Helene Holbrook FNP-C
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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:

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

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:

1. 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

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.

Chart review tool

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:

heleneholbrook@gmail

or

c/o Dr. Karen Burt

2500 Alhambra Ave.

Martinez, CA 94512

510 612-4630 cell for Helene Holbrook

from irbphs <irbphs@usfca.edu>
to Helene Holbrook <heleneholbrook@gmail.com>
date Wed, Jan 20, 2010 at 11:04 AM hide details Jan 20
subject Re: IRB consideration

Dear Ms. Holbrook:

If your project involves archival data and no patient contact, a USF IRB review is not necessary, This also assumes you have permissions from the proper authority to access the records.

Sincerely,

/s/

Terence Patterson, EdD, ABPP
Professor & Co-Chair, Institutional Review Board for the Protection of Human Subjects
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2130 Fulton Street
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irbphs@usfca.edu
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http://www.usfca.edu/humansubjects/

Chart Review Form

Practice Name: _____ Patient Log # _____

Data Submission Date: _____

1. Is this patient pregnant?	Yes	No (Stop here)
2. Is this a prenatal visit?	Yes	No (Stop here)
3. Is Spanish the patient's primary/preferred language?	Yes	No
4. Is this a first prenatal visit?	Yes	No
a. Is this an 8-12 week gestation visit?	Yes	No
b. Is this a 13-17 week visit?	Yes	No
c. Is this an 18-22 week visit?	Yes	No
d. Is this a 23-27 week visit?	Yes	No
e. Is this a 28-32 week visit?	Yes	No
f. Is this a 33-37 week visit?	Yes	No
g. Is this a 38-40+week visit?	Yes	No
5. Evidence of breastfeeding at birth	Yes	No

6. Evidence of breastfeeding at postpartum or reunion PP visit Yes No

7. Birth Weight of infant _____LB/KG/GRAMS

8. Total weight gain for pregnancy ____LB/KG

9. Total number of prenatal visits ____#

10. Weeks of gestation at delivery ____WKS

11. Evidence of complications related to preeclampsia/eclampsia Yes No

12. Diagnosis of Gestational Diabetes? Yes No

13. 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.				

e of ex visit	Patient Name	Medical Record or other ID #	Chart review date	Data entry complete?	Patient Referre
	18.				
	19.				
	20.				
	21.				
	22.				
	23.				
	24.				
	25.				
	26.				
	27.				
	28.				
	29.				
	30.				