Clinicaltrials.gov cover page

Official Title of the study

Evaluation of Driscoll Health Plan's Nurture program on nutrition education and food support for pregnant women

NCT number

To be assigned

Date of the document

January 24th, 2024

Unique Protocol ID:

STUDY00005622 (IRB Review Exempt)

Principal Investigator:

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STUDY INFORMATION

Submit this form when seeking determinations for human subject research using secondary data or biospecimens.

1 Confirmation of Secondary Use of Data or Specimen

Click on the following check box (or double click and type an "X" if using Google Docs).

☒ **The data or specimens have been or will be collected for purposes unrelated to the purpose of this study.**

If this is not the case, please complete HRP-UT901 IRB Proposal Standard Submission or HRP-UT902 IRB Proposal Exempt Submission form.

2 Study Information

Describe the purpose of the research, study background, and hypotheses.

To input text click in the light grey area below.

Purpose:
To assess the impact of Driscoll Health Plan's Nurture program on pregnancy outcomes among participating members.

Background:
Driscoll Health Plan (DHP) is a non-profit, community-based health insurance plan that provides coverage to South Texas and the Rio Grande Valley communities. Their insurance products include STAR Medicaid, STAR Kids, CHIP, and CHIP Perinatal. Affiliated with Driscoll Children's Hospital, DHP offers healthcare services at specialty centers and clinics in various locations, including McAllen, Harlingen, Brownsville, Laredo, Rio Grande City, Eagle Pass, Edinburg, Victoria, and Weslaco.

Maternal health has gained increasing attention. Senate Bill (S.B.) 750, 86th Legislature, Regular Session, 2019, Section 3, for example, mandates the Texas Health and Human Services Commission (HHSC) to develop or enhance statewide initiatives for improving the quality of maternal health care services (Kolkhorst, 2019). It specifies initiatives that contracted managed care organizations (MCOs) must implement and requires progress reporting to the legislature MCOs are also encouraged to incorporate their own initiatives to enhance maternal healthcare services.

In response, DHP, with input from our Factor Health lab at Dell Medical School, introduced the Nurture program for its members as a quality improvement initiative, designed to expand members' access to nutrition education and food purchase support to improve health and pregnancy outcomes.

DHP's Nurture Program:

The *Nurture* program focused on promoting healthy eating through nutrition education and food purchasing support with monthly gift cards for a main local grocery store at the Corpus Christi area. Specifically, the program includes the following components:

1. **Nurture Monthly Packages:** Sent every four weeks until the member reaches the end of pregnancy (delivery or other reasons, e.g., miscarriage), with a maximum of eight packages. Each package includes:
    - A US$40 gift card (2 x $20 each) to a grocery store.
    - A healthy eating information sheet selected from Brighter Bites project (https://brighterbites.org/).
    - A set of three recipes.
    - Nutrition-related Frequently Asked Questions (included in four out of the eight packages).

2. **Two 30-Minute Nutritional Consultations over the phone:** Designed by a Registered Dietitian Nutritionist (RDN) who trained a bilingual nutrition specialist to deliver the consultations. Topics revolved around healthy eating during pregnancy, such as food choices, portion sizes, budget-friendly shopping, food safety, and food preparation. No nutrition therapy advice to manage diseases was provided.

Members had the flexibility to opt out of the program at any time and discontinue receiving packages. Consultations were optional. If they opted out, they continued to receive the DHP benefits as part of their regular coverage.

Secondary Data Analysis Proposal: With funding from the Episcopal Health Foundation, we will conduct a secondary data analysis to evaluate the DHP's Nurture program using their existing administrative data from claims.

Kolkhorst (2019). *Relating to maternal and newborn health care and the quality of services provided to women in this state under certain health care programs*. (S.B. 750). 86th Legislature, Regular Session. https://capitol.texas.gov/BillLookup/History.aspx?LegSess=86R&Bill=SB750.

3 Design, Methodology, and Data Analysis

Provide information regarding study design or data collection methodologies. Describe the data analysis plan, including any statistical procedures or power analysis.

To input text, click in the light grey area below.

We will evaluate the impact of DHP's quality improvement pilot program (called, *Nurture*), which included nutrition education and food support offered to a subset of pregnant women aged 30 years and above and were covered by the Medicaid Managed

Care Organization (MCO) plan in their “STAR” and “CHIP” programs during October 2022 and July 2023.

From this population, DHP randomly selected a subset of approximately 500 women during that period, from which approximately 200 were in the program, the “exposed group.” The women who were covered during the same period but were not selected were not exposed to the program and will compose the “comparison group.”

The objective is to compare maternal and neonatal outcomes between those who participated in the program (exposed group) and those who did not (comparison group).

Analysis Plan:
Claims data will be pulled retrospectively from the insurer's database and other administrative sources. Information will include healthcare utilization, maternal outcomes during pregnancy, and neonatal outcomes at and post-delivery. The primary analysis involves comparing the outcomes of the exposed group with the comparison group. Statistical methods appropriate for this type of administrative data will be employed to assess the differences between the two groups, adjusting for potential confounders.

The *Nurture* program’s impact will be evaluated using claims data received from DHP concerning two composite outcomes: adverse maternal health outcomes (Composite 1) and adverse neonatal outcomes (Composite 2), as shown in Table 1 below. In addition, we will explore single outcomes, such as delivery mode (vaginal vs c-section), cost data, and birthweight, adding nuance to our understanding of the program's impact.

We will primarily use logistic regressions to predict the primary, binary composite outcomes for mothers and newborns, adjusted for risk factors such as maternal age, gestational age at the time of enrollment, pre-existing diabetes, hypertension, and being overweight pre-pregnancy (shown in Table 2). The program “dose” variables are anticipated to be continuous predictors that include both ‘usual care’ (i.e., prenatal care visits) and *Nurture* program elements (the dollar value of the gift cards spent up to 30 days after stopping the program, total number of nutrition consult minutes); see Table 3.
Because we expect cost data to be continuously distributed, linear regressions are expected to be more appropriate. The predictors will remain the same in all models irrespective of outcome, including the “dose” variables.

Table 1. Program outcomes from health claims

Composite outcome 1: Adverse health events during pregnancy	Composite outcome 2: Adverse health events at birth and newborn-related	Exploratory outcomes:
• Gestational Diabetes Mellitus • Excessive weight gain during pregnancy • Pregnancy-associated hypertension	• Pre-term birth (<37 weeks) • Neonatal Intensive Care Unit (NICU) • Small for gestational age • Large for gestational age • Stillbirths	• Emergency Department visits • Cost (outpatient, inpatient, pharmacy, total) • Delivery mode (vaginal, c-section) • Birthweight collected from hospitals

Table 2. Population descriptors and demographics from health claims

Demographics	Health history (dichotomous)
• Age (years) • Ethnicity • Location (Nueces/Hidalgo) • Gestational age at enrollment • Gestational age at delivery	• Family history of diabetes mellitus • Pre-pregnancy diabetes mellitus • Pre-pregnancy overweight/obesity • History of gestational diabetes • Chronic hypertension

Table 3. "Dose" variables from program implementation tracking and health claims

Nurture Program uptake	Care Received
Gift card usage (dollar amount) Packages received (counts) Nutritional consults (duration)	Prenatal visits (counts) Referral to Case Management (dichotomous)

DHP's Nurture enrollment:

1. DHP receives daily new health plan enrollees from the TX State. Their data analytics team identified new pregnant members aged 30 or older in bi-weekly "cycles" and ran an algorithm to randomly select a list of names to be notified and contacted by DHP's Community Health Workers (CHWs).
2. Notifications: Members on the roster to be called received an SMS text with a URL to an informational page, which was also mailed as a hard copy to the member's address on file.
3. Welcome calls: DHP's CHWs called up to 3 times on consecutive days to welcome the women to the *Nurture* program, explain what to expect, confirm address for mailing out the packages, and book two phone nutritional consultations.
    - Individuals who could not be reached by the CHW did not receive the packages and the consultations but continued to receive their regular benefits as part of their DHP membership.

The end of participation in the program is marked by the termination of pregnancy (in the form of a claim to the health plan that would flag delivery or a miscarriage/abortion/stillbirth). If such a claim does not reach DHP's system in a timely manner, the woman in the *Nurture* program could receive up to 8 mailout packages.

The Texas Health and Human Services Commission (HHSC) reviewed and approved key member-facing materials, such as SMS text and the informational letter, as part of their regular review process of member-facing materials.

Third group: The women who were selected to be offered the program, but DHP staff could not connect during telephonic outreach, compose a third group. Administrative data on this group will enable us to explore how they compare with the other two groups in terms of their population descriptors and demographics shown in Table 2 above. Answering evaluation questions such as how do those who were reached by the CHWs differ from those who weren't, helping to assess reach from an equity perspective.

4 Data or Specimen Information

Provide information about where the data or specimens will come from (e.g., pathology lab, commercial sources) and what type of data or specimens you will obtain.

To input text click in the light grey area below.

DHP data analysis team will leverage internal databases to compile the required administrative data for analyses, which will be shared as Excel spreadsheets via secured File Transfer Protocol (sFTP).

DHP also contracted the Dell Med lab (Factor Health) services for the delivery of the nutritional consultations and to track gift card balances. These data are owned by Driscoll, who will receive the full data set, de-identify and anonymize it, and merge it to the other relevant sets they will generate for analysis.

The staff involved in the delivery of the nutrition consultation service will not be involved in the data analysis in any way.

5 **Identifiers**

List all identifiers the researcher will obtain even if the researcher plans to make the data or specimens anonymous. Include information that can be linked directly or indirectly to the subject.

To input text click in the light grey area below. List all identifiers collected.

No identifier will be shared for this data analysis. Only basic demographics information (age, ethnicity, and service location [Nueces/Hidalgo]) will be shared.

DHP analytics team will anonymize and de-identify the data before sharing them with our team for the analysis. Anonymization will be done in a way so that no information can be linked back to the individuals.

Re-identification and DUAs

Review all statements and check those that apply.

Click on the following check box (or double click and type an "X" if using Google Docs).

6 ☐ **The researcher will receive/collect directly identifiable data or specimens with identifiers.**

7 ☒ **The researcher will only receive/collect coded or pseudonymized data or specimens.**

8 ☐ **The researcher will have the ability to re-identify participants.**

9 ☐ **The researcher will sign a DUA or MTA with the entity(ies) providing the data or specimens.**

9a ☐ **If so, the DUA(s) or MTA(s) prohibit the researcher from ever receiving identifiers from the entity(ies) providing the data or specimens and prohibit the researcher from seeking to learn the identities of participants.**

If available, upload a copy of the DUA(s) or MTA(s) to the RMS system under "Other Documents."

10 ☐ **The secondary data or specimens are publicly available.**

11 ☒ **The secondary data or specimens are not publicly available.**

12 **Describe the restrictions (if any) that apply to this data source (e.g., access to data requires log in, one must join an online community to access the data, one must sign a data use agreement)**

To input text click in the light grey area below.

A secured File Transfer Protocol via UT Box will be put in place for the data transfer. Only the individuals directly involved in the analysis will have access to the transfer folder.

The administrative data belong to Driscoll Health Plan and are not publicly available.

13 ☐ **Subjects provided consent for their participation in research when the data or specimens were originally collected.**

13a ☐ **If so, the consent form authorizes researchers to share data or specimens for future research.**

If available, upload a copy of the original consent forms to the RMS system under "Other Documents."

14 **Research Participant Information**
Provide information regarding the participant population (e.g., age, gender, inclusion/exclusion criteria, disease state).

To input text click in the light grey area below.

Members of the Driscoll Health Plan could be enrolled in the program if they were pregnant and aged 30 years or older at the time of DHP enrollment.

15 **Total Sample Size**

To input text click in the light grey area below.

We expect to receive data from approximately 1700 DHP members broken down as the following (approximate numbers):

- Exposed group: DHP selected 511 members between October 2022 and July 2023, of whom 224 were contacted and opted into the Nurture program.
    - CHWs could not reach the remaining 287 women on the list and, therefore, could not confirm address and book consultations. We will receive the demographic data on this group to explore how they compare with the other two groups in terms of their population descriptors (Table 2 in section 3).
- Comparison group: approximately 1200 women who were 30 years old or older and pregnant during the same enrollment period and were not selected during the DHP's enrollment process.

16 **Sample Size Rationale**

Provide justification for the sample size and its adequacy for answering the research question.

To input text click in the light grey area below.

Data coming from claims are mostly binary, which is characterized by limited variability and increased uncertainty in proportions. This fact makes detecting statistically significant differences more challenging, requiring larger sample sizes to ensure the reliability of the findings in such studies using these binary outcomes—which is the case of Nurture.

Statistical power is critically dependent on the base rate of the outcome metrics among the comparison subjects. But, when the comparison group is composed of unmatched subjects that is at least four times the size of the exposure group, statistical power tends to be maximized.

That being said, the analysis needs to include all women as described in the previous section.

Because we do not know the incidence rate of the outcomes of interest, we estimated the effect sizes we can capture at 80% power with alpha = 0.05 assuming different rates among comparison subjects (30% and 35%) and four different rates among exposed subjects (25%, 23%, 20%, 18%).

Table 4 demonstrates the statistical power to detect differences between the exposed and comparison groups, assuming *Nurture* produces certain effects. If the composite outcome rate is around 30% among comparison subjects, we have enough power to

detect rates of 20% or lower among exposed subjects (yellow highlight). If the rate is closer to 35% among comparison subjects, we have enough power to detect rates of 25% or lower among exposed subjects (blue highlight).

Table 4. Statistical power at alpha = 0.05 to detect the program effects of interest assuming two different base rates among comparison subjects.

		% rate among exposed			
		25%	23%	20%	18%
% rate among comparison subjects	35%	78	90	98	99
	30%	28	46	80	93

17 Confidentiality and Data Security Plan

Describe how you will protect confidentiality of the subjects and the security of the data or specimens. Describe where you will store the data or specimens, who will have access to data or specimens; and the data and specimen retention and destruction timelines.

To input text click in the light grey area below.

DHP's data analysis team will anonymize and remove all PHI from all data sets prior to sharing in a way so that no information can be linked back to the individuals.

Data for analysis will be saved as Excel files and, subsequently, in formats specific for analyses using specialized statistical software, in a UT Box folder accessible only to team members involved in the data analysis, such as the PI and the biostatistician.

Data sets will be destroyed (permanently deleted) 3 years after all analyses are completed.

WAIVER OF INFORMED CONSENT

Complete this section if you are seeking a waiver of informed consent for the collection of identifiable data or biospecimens.

To approve a waiver or alteration of informed consent all of the following criteria below must be justified by the researcher.

Only complete the sections below if requesting a waiver of informed consent for the use of readily identifiable data or specimens and the data use is not regulated by HIPAA.

If research solely involves HIPAA protected data, skip this section and complete the Waiver of HIPAA Authorization section below.

18 **The research involves no more than minimal risk to the subjects.**

To input text click in the light grey area below. Provide protocol specific rationale as to how this study meets this requirement.

19 **The waiver or alteration will not adversely affect the rights and welfare of the subjects.**

To input text click in the light grey area below. Provide protocol specific rationale as to how this study meets this requirement.

20 **The research could not practicably be carried out without the waiver or alteration (it is impracticable to perform the research if obtaining informed consent is required and not just impracticable to obtain consent).**

To input text click in the light grey area below. Provide protocol specific rationale as to how this study meets this requirement.

21 **If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.**

To input text click in the light grey area below. Provide protocol specific rationale as to how this study meets this requirement.

PROTECTED HEALTH INFORMATION

Complete this section if you need to attest to the first (21) question.

22 ☐ **As part of this research, the research will obtain, use, or disclose Protected Health Information (PHI).**

23 **Type of Authorization(s) Requested**

Select only those waivers being sought.
Click on the following checkboxes (or double click and type an "X" if using Google Docs).

a ☐ **Obtaining participant authorization for access to PHI**

b ☐ **Waiver or alteration of HIPAA authorization**

c ☐ **Partial waiver for subject identification or recruitment**

24 **Health Information Use Request**

To input text click in the light grey area below. List covered entities providing PHI

25 **HIPAA Defined Identifiers Recorded**

Select all identifier associated with the PHI.
Click on the following checkboxes (or double click and type an "X" if using Google Docs).

☐	**Names**	☐	**Dates (including month/year): Admission, birth, death, or procedure date, ages over 89**
☐	**Telephone numbers**	☐	**Vehicle identifiers and serial numbers**
☐	**Facsimile numbers**	☐	**Web universal resource locators (URLs)**
☐	**Electronic mail addresses**	☐	**Internet protocol (IP) address numbers**
☐	**Medical record numbers**	☐	**Biometric identifiers, including fingerprints and voiceprints**
☐	**Health plan beneficiary numbers**	☐	**Geography subdivisions** *E.g. (addresses, census block, zip codes, city, state)* *To input text, click in the light grey area below.*

☐ **Account numbers**

☐ **Certificate/license numbers**

☐ **Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification**

To input text, click in the light grey area below.

List the data points or attach a list of the data to be collected about each subject from their medical records or other HIPAA protected data sources.

Select either question 26a or 26b and provide additional information as requested.

Click on the following checkboxes (or double click and type an "X" if using Google Docs).

26a ☐ **Attach a list of all data points collected from PHI.**

Upload a document with data points collected from PHI to the UT RMS system under "Local Site Documents"

26b ☐ **Or, list the data points.**

To input text click in the light grey area below.

-

Waiver or Partial Waiver of HIPAA authorization (as required)

Complete this section if seeking a waiver of HIPAA authorization or a partial waiver to identify potential participants.

27 **Describe why the research could not practically be conducted without access to and use of the PHI**

To input text, click in the light grey area below.

Date Range of Records

28 **Start Date**

To input text, click in the light grey area below.

29 **End Date**

To input text, click in the light grey area below.

30 **State why obtaining written authorization is impracticable**

To input text click in the light grey area below.

Data Retention and Security

Attest to question 31 and select either question 31a or 31b and provide additional information as requested.

Click on the following checkboxes (or double click and type an "X" if using Google Docs).

31 ☐ **Attest that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research where the use or disclosure of protected health information meets IRB and HIPAA requirements**

31a ☐ **Identifiers will be destroyed at earliest opportunity**

Describe the destruction plan and timeline

To input text click in the light grey area below.

31b ☐ **Identifiers will be retained indefinitely**

State rationale for retaining identifiers indefinitely

To input text click in the light grey area below. Complete the repository supplemental form.

Partial Waiver of HIPAA Authorization For Activities Preparatory to Research and Subject Identification

Attest to questions 32 and 33 if seeking a partial waiver of HIPAA authorization to identify potential participants and collect their contact information to obtain authorization at a later date.

32 ☐ **Attest that PHI will be accessed only by individuals who have authorization to access the records outside of the research context.**

33 ☐ **Attest that researchers will not move or transmit identifiable PHI from the covered entity.**

CONFLICTS OF INTEREST

*This section is **required** for all studies. Please confirm that all research personnel who meet the definition of "covered individuals" are designated as such in the Local Study Team Members section of the SmartForm application in UTRMS-IRB.*

34 **Financial Conflicts of Interest**

Financial interest includes utilizing your licensed intellectual property in the study; serving as a paid consultant, or advisory board member, or officer/director with a related entity; and equity or business ownership in a company that is related to this project. Additional guidance on financial conflicts of interest is available on the COI website

A or B must be checked.

A ☐ **The PI and/or other covered individual(s) has/have a financial interest related to this study**

i **If A is checked above, please provide the name(s) of the covered individuals involved, and briefly describe the interest:**

To input text, click in the light grey area below.

B ☐ **To the best of your knowledge, no one on the study team has financial interest related to this study**

35 **Non-financial Conflicts of Interest**

Non-financial Interests could include such things as:
- utilizing your unlicensed intellectual property in the study,
- serving as an unpaid advisory board member or officer/director with a related entity,
- equity or business ownership in a company that has yet to make a profit and is related to this project,
- conflict of time/effort,
- personal and professional relationships/affiliations,
- intellectual passions or personal beliefs
- other factors that could create bias in the study

A or B must be checked.

A ☐ **The PI and/or other covered individual(s) has/have a non-financial interest related to this study**

i **If A is checked above, please provide the name(s) of the covered individuals involved, and briefly describe the interest:**

To input text, click in the light grey area below.

B ☐ **To the best of your knowledge, no one on the study team has non-financial interest related to this study**