

# Challenges and Opportunities in Human Subjects Research: Assessing Glyphosate Exposure in Pregnant Women

MATRIX BIOLOGY



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The herbicide glyphosate has become the world's most popular agricultural chemical, the use of which has risen more than 12-fold in the last two decades. Recent epidemiologic research suggests that exposure to glyphosate may lead to adverse pregnancy outcomes. Despite the widespread use and potential toxicity, little research exists to quantify human exposure to glyphosate. This study aims to measure long-term glyphosate exposure in pregnant women and to attribute that exposure to agricultural and dietary sources. We recruited 40 women from whom we collected 1,395 urine samples throughout their pregnancies. We conducted quality assurance checks on the collected data and are working with the CDC to analyze glyphosate concentrations in a subset of the samples. Here, we aim to describe challenges and opportunities in conducting human subjects research in a vulnerable population – particularly during a global pandemic. Challenges included the need to revise protocols to eliminate "in-person" contact with hard-to-reach populations; and difficulties with accurately and consistently assessing and resolving database issues. Opportunities included the collection of real-world data; the chance to provide aid to study participants; and the potential to build unique connections with those participants.

### BACKGROUND

- Glyphosate is the most used agricultural chemical globally
- Previous research suggests exposure to glyphosate is linked with preterm birth, making pregnant women a particularly vulnerable population



Fig. 1: the chemical glyphosate is often used in weed-killers

1) Pregnant women who live closer to agricultural fields experience increased glyphosate exposure. 2) Consumption of an organic diet can reduce glyphosate exposure among pregnant women.

# METHODS OVERVIEW

This study included 40 pregnant women living in Southwestern and South Central Idaho. We collected weekly spot urine samples beginning in their first trimester, and daily samples during the dietary intervention, to estimate longitudinal glyphosate exposure.

Our methodology involved:

Recruitment Sample collection **Dietary intervention** Lab work

Fig. 2: the study's logo

# RECRUITMENT

- Participants were recruited through Women, Infant, and Children (WIC) clinics
- Informed consent was obtained
- Questionnaires determined demographics and general pesticide exposure

This process was hindered by the Covid-19 pandemic: Recruitment had to be conducted through phone calls made from a vehicle outside participants' houses as well as YouTube videos. 

What does this look like? Check out one of our YouTube videos here:

# SAMPLE COLLECTION

**Design:** Collect urine samples from participants living across Southern Idaho (Fruitland-Burley). This involved driving to participants' homes on a weekly basis to pick up urine samples left in coolers, and daily during the two-week dietary intervention.

#### Considerations

- Sudden heat waves may alter glyphosate levels in urine samples left in coolers
- Navigating real time communication with participants experiencing food/housing insecurity and high residential mobility
- Transporting samples across 100+ miles



agricultural areas might experience higher rates of glyphosate

- Participants consumed a conventional diet for one week and an organic diet for one week randomized to order
- Participants received an allowance of \$180/week and used Albertsons' accounts created by our research team to order their groceries
- Food purchases were approved and complications in orders/deliveries were resolved by our team
- Compliance was monitored with a "food diary"
- Sample collection was conducted daily



Fig. 4: one groceries intervention. as ordered by a participant

# LAB WORK

#### **Analysis and Storage**

- Various sample features were analyzed, such as specific gravity
- Sample collection was recorded on a chain of custody form
- All information was recorded in an electronic locked database
- Aliquots were stored in a -80 °C freezer for future analysis



Fig. 5: samples ready for analysis following a routine pickup

Fig. 6: labeling/storing aliquots after performing quality assurance checks

### **Quality Assurance Checks**

- Databases, spreadsheets, and stored aliquots were compared to ensure accuracy
- Aliquots were inspected for quality assurance and shipped to the CDC for glyphosate analysis
- Additional aliquots were either stored for future testing or sent to the CDC for further quality assurance

### Scoring Dietary Compliance Forms (DCFs)

- Compliance to the dietary intervention restrictions was determined through analysis of the DCFs
- A protocol was designed to translate the qualitative data recorded on the DCFs into quantifiable scores
- Inter-rater inconsistencies were addressed by the team

Fecha	Aproximadamente, ¿qué cantidad de los alimentos que comió hoy provienen de los alimentos proporcionados por el estudio? (Marque una casilla para cada día):	Tome nota de cualquier alimento o bebida que comió o bebió que no era de los alimentos proporcionados por el estudio, incluida la comida de los restaurantes:
Martes 22 de Junio	Todo lo que comí fue del estudio  La mayoría de lo que comí fue del estudio  Aproximadamente la mitad de lo que comí fue del estudio  Un poco de lo que comí fue del estudio  Nada de lo que comí fue del estudio	Fresas quesadillas jugos Y Camarones
Miércoles 23 de Junio	Todo lo que comí fue del estudio  La mayoría de lo que comí fue del estudio  Aproximadamente la mitad de lo que comí fue del estudio  Un poco de lo que comí fue del estudio  Nada de lo que comí fue del estudio	Jugos Fresas huevos con Jamon Cerezas
Jueves 24 de Junio	Todo lo que comí fue del estudio  La mayoría de lo que comí fue del estudio  Aproximadamente la mitad de lo que comí fue del estudio  Un poco de lo que comí fue del estudio  Nada de lo que comí fue del estudio	barras de fresa quesaditas Cerczas, frigoles

Fig. 7: a page from one of the food diaries, filled out by a participant during the dietary intervention

### SUCCESS REPORT

We collected 1,395 samples out of a max possible 1,450 samples (864/890 weekly samples and 531/546 daily samples). Overall, we had a 97% compliance rate among our participants. Follow this QR code to view a graph depicting the completion of the weekly sample collections:



## DISCUSSION

#### Challenges

- Changing various aspects of the study due to the Covid-19 pandemic and unexpected heat waves
- Resolving issues with missing or wrong items in grocery deliveries during dietary intervention
- Maintaining contact with populations dealing with housing insecurity, often meeting at remote or unusual locations to collect samples
- Navigating texting; maintaining participant engagement without overwhelming participants
- Comparing thousands of records and frozen sample vials to ensure accuracy and quality of the study
- Accurately and consistently assessing food diaries with cultural and nutritional factors in mind, and discussing parameters with others on the team

#### **Opportunities**

- Successfully recruited 40 study participants and collected 1,395 samples
- Provided food and financial aid to study participants in the form of gift cards and Albertsons' groceries
- Crafted unique human connections and relationships with study participants as well as other individuals involved in the process of this study
- Ensured all data gathered was accurately recorded and samples were preserved well, so the resulting findings will be accurate and useful

**Jun 27, 2021** 1:03 PM

Thank you so much for all the gift cards and the formula!! Really appreciate it, it's lot of help!! So greatful!!!

1:03 PM

Fig. 8: a text from a participant emphasizing the positive impact the study had on her

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