Over-the-Counter Birth Control Study for American Indian Women and Adolescents in King County

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Abstract

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American Indians and Alaska Natives experience reproductive health disparities. Despite this, little is written regarding their perception and barriers to birth control (BC), including over-the-counter birth control pills. The study aimed to identify birth control preferences and acceptability of over-the-counter birth control; identify perceived barriers to birth control access; and identify favorable locations of over-the-counter birth control. A qualitative online study of 18 items about current birth control use, perceived barriers, potential benefits, and potential solutions of over-the-counter birth control was distributed to American Indian and Alaskan Native women of reproductive age by survey link. The 6 eligible participants were <32 years old; 83% had insurance coverage, 50% had issues with transportation, 83% use birth control. The majority (83%) of participants would consider switching to progestin-only over-the-counter birth control pills. Approximately, 67% percent would consider switching to over-the-counter birth control. Primary barriers were transportation and lack of knowledge on health care information. Eighty-three percent report online retailer or pharmacy as the preferred delivery mechanism. These preliminary findings suggest further research may provide more context to perceptions of over-the-counter birth control for American Indian/ Alaskan Native women across the United States.

I. Introduction

An over-the-counter (OTC) progestin-only birth control pill is pending approval by the U.S. Food and Drug Administration (FDA) to be available nationwide. This is the first time the U.S. will have cyclic over-the-counter birth control pill access, although other contraceptive methods are currently available. There are over 570 federally recognized tribes in the United States. There is little research of American Indian/Alaska Native (AI/AN) populations pertaining to reproductive health and family planning and, in particular, perceptions and preferences about over-the-counter birth control (BC). This research project responds to the gap in literature on information about American Indian attitudes and barriers in accessing birth control and their preferences for OTC BC. The research is a quantitative survey of women and adolescents in King County, Washington, and part of a bigger, multi-community mixed-methods research to understand the best ways to deliver the most acceptable and affordable over-the-counter birth control to AI/AN individuals in Washington State. To our knowledge this study is the first of its kind to address AI perceptions of OTC contraceptives and barriers.

II. Background

The potential precursors to the poor health outcomes in AI/AN communities are limited access to quality health services, difficulty accessing family planning resources, and violence. Many of these factors are social determinants of health. The health services gaps directly create, uphold, and perpetuate disparities in family planning. Family planning according to the World Health Organization "allows people to control their number of desired children and spacing of pregnancies. It is achieved through preferred use of contraceptives and infertility treatments."[1] There are several methods of birth control currently available in the United States. Examples of common and effective contraception are male and female condoms; cervical diaphragms; hormonal birth control pills (BCP); hormonal rings; hormonal patches: hormonal shot (Depo-Provera); long-acting reversible contraception (LARC); intra-uterine devices (IUDs); emergency contraception; and male and female sterilization. Domestically, birth control pills have the highest usage over any other contraceptives, but IUDS are steadily increasing.[2–4] A review on the disparities in contraceptive access, historical context on AI/AN communities, historical contexts on sterilization on AI/AN, over the counter (OTC) birth control pills, current reproductive context in the United States provided foundational knowledge to develop our research study and survey materials.

A. Disparities in Birth Control Access

The disparities in reproductive health access of AI/AN individuals lead to outcomes that are a public health issue. Timely access to effective and affordable contraception represents a major

barrier for American Indian/ Alaska Native (AI/AN) women in obtaining birth control. Unintended pregnancy accounts for nearly half of all pregnancies in the United States.[5] Unintended pregnancies are avoidable with access to safe and affordable contraception. The teen birth rate among AI/ANs is 1.6 times higher and the overall rates of unintended pregnancy and abortion are 1.5 and 2 times greater, respectively, compared to the rates among non-Hispanic white women.[6,7] The use of contraception for urban AI/AN teens is lower than non-Hispanic white teens.[7] 61% of urban AI/AN teens were not using a birth control method.[7] Contraceptive counseling has been observed to improved birth control utilization from 50% to 96% in AI/AN women.[4]

Possible factors contributing to these disparities are health literacy, access to reliable transportation, and affordability of family planning, all of which may reduce access to contraception, yet the existing research fails to adequately characterize access to contraception among AI/AN women and teens. Without empirical research, it is not possible to fully understand the access to, preferences for, satisfaction with existing contraception options among AI/AN women and teens. Upstream factors must be considered when learning from the population, including possible cultural and contextual factors which may support or impede access to meaningful contraception options for AI/AN women and teens.

B. Social Determinants and Historical Context

Collectively, American Indian, and Alaska Native (AI/AN) populations experience a higher burden of health disparities compared to the general United States population. Framing the observed disparities within the social determinants of health framework (SDH) underscores the importance of social structures that influence health. Common examples of SDH include- income, education, housing, food security, neighborhood conditions, employment, occupational conditions, childcare, social inclusion and non-discrimination, access to affordable health care, and quality of health care services. Additionally, the conditions of the social structures are shaped by the dark history of the United States with the displacement, forced assimilation, and extreme violence to AI/AN communities. Patrick Wolfe defined ‘settler colonialism’ as an on-going structure that is the removal and erasure of indigenous people and cultures from their lands for the use of the settler.[8] The domination of settler culture created an entitlement which allowed the dissolution of sovereign land and treaties to allow for the settlers to expand-simply allowing settlers to further take land regardless of previous treaty agreements.[8–10] The sovereign territories were forcefully reduced in size and deprived of quality social services and structures which lead to historical displacement of AI/AN communities.

Settler colonialism is on-going and impacts sovereign lands and reservations due to the hegemony of the settler culture and the abundance of resources outside of the sovereign lands.[8,11,12] Settler colonialism upholds ‘invisibility’ of indigenous people, cultural spaces, and issues by framing them as a part of the past. Urban dwelling AI/AN may encounter this

invisibility within local and state government via lack of recognition and support of contemporary indigenous community spaces and concerns.
The dispossession driven by settler colonialism on the social, political, geographical, and cultural environments further propels the marginalization of AI/AN populations. Each AI/AN community framework of the Social Determinants of Health varies based on the interactions within the community as well as the social environment outside of the community. The present study supports a more complex, nuanced understanding of the King County urban AI/AN population, presenting an opportunity to develop and implement programs tailored to support this population and the need for birth control access.

C. Historical Context of Birth Control

Voluntary sterilization is a good option for permanent birth control. However, involuntary sterilization in a community can affect the relationship between women and the health care system.[13] The United States has a long-documented history of involuntary sterilization, especially against Black American and AI/AN women in the 20th century.[14] The violence against AI/AN women continued through the 1970s. The Indian Health Services (IHS) involuntarily sterilized approximately 25% of their female patients.[15] The majority of the sterilizations were conducted on women under 21 years of age. The federal government conducted an investigation on over 4,000 sterilizations by IHS and though they could not determine if the sterilizations were forced, they did determine there was a lack of documentation of written consent for the procedure.[13–15] The results of the various AI/AN communities organizing and advocating for informed consent led to a new standard of procedures in the IHS in the mid 1970s. After 1976, American Indian women had an uptake of using IHS services, which is the leading health provider for AI people.[15] Arguably, the uptake occurred due to increased agency and advocacy for AI/AN women led by AI/AN women. The historical context of involuntary sterilization could influence individual perceptions of birth control.

D. Over-the-Counter Oral Contraceptive Pills

Over the counter (OTC) oral contraceptive pills (OCP) are available in over 100 countries without a prescription.[16] Since 2012, the American College of Obstetricians and Gynecologists has supported OTC OCP for birth control, without age restrictions.[17] The primary obstacle is getting the U.S. Food and Drug Administration (FDA) to approve OTC BCP nationwide. There is documented interest in OTC pills by American women and adolescents.[18–20] A recent study concluded nearly 62% of participants would be in favor of taking OTC combination birth control pills.[18] A subsequent study concluded 39% of adults and 29% of teens are interested in OTC progestin-only pills, and approval rates steadily increased from 39% to 46% of adults and 29% to 40% of teens if OTC progestin pills were covered by insurance.[19]

The Reproductive Parity Act in Washington State covers the cost of OTC contraceptives when billed for patients in community pharmacies with or without a medical prescription. Community

pharmacies in Washington State were the first in the nation to provide pharmacist-prescribed contraception. Covering the cost of OTC birth control may address otherwise burdensome financial barriers to improve access to birth control for AI women in WA state.

E. Current Reproductive Health Context in the U.S.

Abortions are a form of reproductive health service, and there are barriers in the United States to safe and affordable abortion services. Abortion rights in the United States are no longer federally protected. The 2022 U.S. Dobbs v. Jackson Women's Health Organization Supreme Court ruling ended abortion as a federally protected right. Guttmacher's Institute reported, "22 states have laws that could restrict abortion rights." Of the 22, "13 states have nearly all abortion bans" while "14 states have laws that protect abortion rights."[21] Thus, abortion access varies in each state. Washington state permits abortion until the point of viability, or about 24 weeks (about 5 and a half months) of gestation.

AI/AN women experienced barriers in abortion access before the overturn of Roe v Wade. Abortion rights for AI/AN women utilizing IHS have been virtually non-existent for the last 40 years. IHS is prohibited from using federal funds to provide abortion services due to the Hyde Amendment, which effectively bars many AI/AN women from accessing affordable abortion services.[22] It is assumed many AI/AN people seeking abortions would have to either pay out of pocket or find private clinics to receive abortion services.

Traveling to clinics that preform abortion services requires time, means of reliable transportation, and financial resources which prevent some women from accessing care. These abortion barriers are intricately linked to similar issues within health care access such as access to birth control. It is reasonable to assume if our study population reports barriers to birth control, they experience similar barriers to abortion. Given the current barriers to abortion, there is increased significance to affordable, timely, and accessible birth control, like OTC BCPs. The current FDA application for OTC BCP is still pending at the time of writing. The informed roll-out of OTC BCPs, we argue, will help close the gap of reproductive health inequities in WA state.

F. Call to Action

The call for reproductive health research designed and driven by AI/AN populations will fill existing gaps in the literature. The goal of this research is to collaborate with AI communities to hear directly from community members about their experience with contraceptives and their interest in OTC BC.

The research project conducted with Uplift International, a Seattle-based NGO, focused on over-the-counter (OTC) birth control (BC) in American Indian (AI) communities in Washington State. The research was a quantitative survey and part of a larger research project. The research is timely because the FDA received the first ever application for OTC birth control pills this year.

The survey and the other components of the research project will inform Washington State policymakers in the development of the OTC birth control program, in general, and for AI women and adolescents, in particular. The Washington State model may be used as a model throughout the U.S.

III. Study Aims

1. **Identify BC preferences and OTC birth control pill acceptability in King County Urban Indian community**
2. **Identify perceived and institutional barriers for women and adolescents to accessing birth control in the King County Urban Indian community**
3. **Determine favorable delivery mechanism ex. Vending machines**

IV. Methods

A. Study Design

The research is a quantitative survey nestled in a larger mixed-methods study to be conducted within King County, Washington. The survey was distributed to a convenience sample. The multiple-choice quantitative survey aimed to identify current birth control use, birth control preferences, attitudes about OTC BC and barriers to OTC BC. The complete electronic survey and all components, including the consent and assent were approved by the University of Washington institutional review board (IRB).

B. Study Setting

The site is King County in Washington State. King County has a population of 2.3 million, making it the most populous country in the state. Approximately, 40,000 people are AI/AN including those of mixed origin. King County is home to Duwamish, Muckleshoot, and Snoqualmie tribes. There is a wide array of other AI/AN tribes and communities in King County.

C. Study Subjects

Study participants included individuals who could become pregnant that self-identified as AI/AN and were of reproductive age (ages 15-49) who lived in King County, WA. Recruitment occurred from May 2022 to July 2022.

Eligibility for participation in the quantitative survey:

- Identify as an individual who can become pregnant
- Aged 15-49 at the time of the initial survey
- Willing and able to provide digital consent
- Self-identify as American Indian/ Alaska Native
- Be able to communicate in English
- Lived in King County, WA

D. Recruitment

Originally, the study used two primary strategies to recruit and enroll participants in this study:

1. Community Snowball Method. The survey team contacted community organizations and individuals that fall into the survey criteria and/or can invite individuals that fit the criteria. The survey materials were individually emailed to targeted populations. This

strategy allowed us greater confidence in the recruitment of our study population. Once the individual obtained the contact information, they were sent the pre-screening survey.

2. Flyers and print media. A publicizing effort placed print media in community centers, clinics, University campuses, and grocery stores. The flyers included a QR code for individuals to scan off their smartphone and tear off paper portions of the flyer with contact information and links for those who might not have a smartphone.
    a. Due to lack of access to internet capable devices, lack of access to the internet, and/or lack of familiarity with computers and other devices, some individuals might have preferred to complete the survey in a paper form. In these cases, a paper survey was mailed to respondents upon request, along with a pre-paid return envelope to support survey return.

As the project developed, there was a need to revise recruitment strategies to ensure participants met inclusion criteria. The survey was therefore distributed by individual contacts and paper flyers in common locations, such as libraries, community centers, grocery stores, community poster boards, and on University of Washington, Seattle, and Bothell campus.

Users who experienced interest via survey email or phone number were sent the URL to the pre-screening link. Researchers used a script when recruiting participants who contacted the study email. Users who expressed interest accessed the pre-screening via QR code were directed to the RedCap website on their mobile or personal devices. The RedCap pre-screening required participants to answer a series of questions to determine eligibility. (Appendix A)

Upon completion, participants were emailed an invitation to the survey along with their personalized study identification number. Informed consent was obtained after the pre-screener and was required to participate in the survey. (Appendix B) The initial launch of the survey yielded individuals with traditional male names and falsified contact information that did not meet study inclusion criteria. Hence those 29 responses were excluded from the present analysis. The initial recruitment method relied on social media. The team promoted the study via Facebook, Instagram, and Twitter using QR codes and hyperlinks. Unfortunately, the second launch of social media recruitment yielded artificial ‘bots’ participants responses that failed to meet inclusion criteria. The study team called to verify information and discovered the use of false contact information which led to low confidence for over 300 pre-screenings.

The survey was developed from a literature review on OTC BC, family planning, pharmacy, and emergency contraception. The 18-question survey covers Demographics (10 items), Birth control preferences (3 items), Barriers to Access (8 items), Potential Solutions (3 items), Possible Benefits of Over-the-Counter Birth Control Pills (10 items), and Future Options for of Over-the-Counter Birth Control Pills (2 items). (Appendix C). The IRB approved the recruitment of adults prior to teens, which lead the to the development of individual projects. Teen and adult data were stored separately in RedCap. The goal of the survey for 25 participants was not achieved due to a lack of confidence that the potential participants met the survey criteria.

E. Data Collection

Data collection occurred in a step-by-step format using two RedCap surveys, a screening survey, and the full survey with all measures. The survey was programmed in RedCap, an electronic secure HIPAA compliant data collection tool that allowed researchers to store participants' metadata on a secure drive. The quantitative survey data was collected and stored within RedCap.
The research team reviewed each participant pre-screening survey and survey data, surveys under 50% complete were not used in analysis. The research team member sent a reminder for impartial surveys to request completion.

The participants' contact information was kept separate from survey data on a password protected drive. Once a week, contact information was extracted from the drive to send $20 gift cards as incentives for survey participation.

The exported files were imported to Excel for data cleaning. The comma-separated values (csv) file was reviewed to remove outliers, errors, and redundancies. Both Teen and Adult survey data files were merged for analysis. After cleaning the survey data, eligible survey data was exported out of RedCap for analysis.

F. Data Analysis:

Independent variables included age, gender, history of pregnancy, parental status, health insurance coverage, and transportation difficulties. Dependent variables included current birth control use, OTC BCP preference, and perceived barriers. We controlled for race; participants were required to identify as AI/AN to meet inclusion criteria. Categorical variables included age range, parental status, interest in OTC birth control, and potential solutions OTC. Age is presented categorically in our study to group age cohorts.

Matrix questions asked participants to read a statement and select statements that best matched their agreement. Responses were recorded using a numeric value. For example, "Strongly Disagree" on the survey was assigned an ordinal response value of "0," while "Strongly Agree" was assigned the code value of "4." Data was analyzed via cross-tabulation to identify quantitative relationships with the variables and project trends within the responses. "Strongly Agree" and "Agree" responses were collapsed together for analysis. We dichotomized some variables for the purposes of analysis. Insurance was recoded in our analysis as "coverage." The five responses that reported coverage were grouped under "Yes" and the two responses that reported lack of insurance coverage or uncertainty were grouped under "No." Transportation was re-coded in a similar fashion, responses "Yes" and "Often" were recoded as "Yes," and responses "Sometimes" and "No" were recoded as "No."

Stata software version 17 (StataCorp, College Station, TX) was used to compute summary statistics to identify characteristics within the population with descriptive statistics. Due to the small sample size, regression analyses were not a possibility. Frequencies were calculated for all items including missing values, and cross tabulations were made with age group (Teen, Adult). Age subgroups are an important variable to analyze to illustrate how needs, perceptions, and barriers differ among the study populations. The results provide a preliminary description of the population of interest. The study relied on stratified sampling methods to obtain a larger sample size in fall 2023.

V. Results

The study sample for the survey was N=6. All participants identified as American Indian/Alaska Native because the study controlled for this demographic characteristic. Table 1 describes the characteristics of the study sample. One of the participants also identified as Hispanic or Latino. Our study sample was younger, between the ages of 18-31. Fifty percent of the sample had no history of pregnancy and were not parents. Eighty three percent of the study sample reported having insurance coverage. Fifty percent of the sample reported difficulty with transportation. Half of the responses to the questions on pharmacy were missing, with 16.7% reporting that they used pharmacies to obtain prescriptions.

Table 1. Demographic Characteristics of American Indian/Alaska Native Participants and Health Coverage (N=6)

Gender	% (n=6)
Female	100 (6)
Missing	0
Age	
15-17	33.3 (3)
18-24	33.3 (3)
25-31	16.7 (1)
Missing	16.7 (1)
Hispanic or Latino	
Yes	16.7 (1)
No	66.7 (4)
Missing	16.7 (1)
History of Pregnancy	
Yes	33.3 (2)
No	50.0 (3)
Missing	16.7 (1)
Parent	
Yes	33.3 (2)
No	50.0 (3)
Missing	16.7 (1)
Insurance Coverage	
Yes	83.3 (5)
No	0
Missing	16.7 (1)

Transportation Problems	
Yes	50.0 (3)
No	33.3 (2)
Missing	16.7 (1)
Pharmacy Used for Prescriptions / Care	
Yes	16.7 (1)
Sometimes	2 (33.3)
Missing	3 (50.00)

Table 2 describes the current birth control use of the study sample and attitudes towards OTC birth control. The majority of study participants reported current use of a birth control method. On average, study participants reported about 2.67 birth control methods used per person (SD=2.34). The most common birth control methods reported were condoms (male and female), the pill, and "pulling out." Approximately two thirds of study participants indicated they would prefer obtaining birth control over the counter and without a prescription. Additionally, 67% of study participants reported an interest in switching to OTC BCP, (33.3% selected "Definitely will Switch" and 33.3% selected "Will Consider"). When asked whether they would switch over to progestin-only pills, a majority of study participants (83%) reported that they would consider switching to progestin only, two thirds of study participants reported that they used another method of birth control at the time of participation and would consider switching.

Table 2. Current Birth Control Use and OTC Acceptability (N=6)	
Birth Control Use	% (6)
Yes	83.3 (5)
Missing	16.7 (1)
Current Method*	
Condoms	50 (3)
Female Condoms	50 (3)
The Pill	50 (3)
The Arm Implant	16.7 (1)
Pulling Out	50 (3)
Abstinence	33.3 (2)
Morning After Pill	16.7 (1)
Missing	16.7(1)
Prefer to Obtain Birth Control OTC and Without Prescription	
Yes	66.7 (4)
No	16.7 (1)
Missing	16.7 (1)
Prefer OTC BC if Available	
Definitely Switch	33.3 (2)

Consider Switching	33.3 (2)
Not Switch	16.7 (1)
Missing	16.7(1)

*This item was “check all that apply”. See Appendix for additional response options.

Table 3A describes the current barriers and perception of birth control. The population reported concern over side effects as a primary reason people do not take birth control (67%). Additional reported barriers included lack of transportation (33%), not feeling comfortable asking health providers for BC (17%), and tribal concerns (17%). A third reported they did not know why people do not use birth control.

Table 3B displays barriers to accessing care by age category (Teens 15-17 and Adults 18+). Two thirds of adults and half of teens reported it is easy to get birth control. All teens (100%) and most adults (67%) reported having friends who have difficulty getting birth control. Similarly, all teens (100%) and most adults (67%) reported religious leaders' view on BC as being a concern. The majority of adults (67%) reported that tribal leaders view on birth control was a minor concern. In comparison, half of teens reported tribal leaders' view as a moderate to major concern and half reported tribal leadership views on BC was not a concern. Nearly all study participants disagreed, reporting that adolescents in their community cannot easily access BC, 100% teens and 67% of adults, respectively. All (100%) of youth participants reported that they believed community members do not know where to get birth control if they want it. Thirty-three percent of adults agreed that everyone knows where to access BC, 33% reported neutral, and 33% disagreed. Sixty-seven percent of adults reported having knowledge on where to get emergency birth control, yet one hundred percent of teens disagreed with the statement. The majority of adults (67%) and half of teens (50%) agreed that health clinics in their communities respect their privacy about BC. In comparison, half of teens (50%) and a third of adults (33%) agreed that pharmacies in their community respect their privacy about BC. All participants (100%) agreed that more women and adolescents would use birth control if the method they want was free and easy to get. Trends in the participant responses reflected transportation issues, religious concerns, knowledge on where to access birth control and costs as perceived issues, and institutional barriers. Additionally, trends reflected that teens experienced greater perceived barriers than adults.

Table 3A. Barriers to Birth Control

Reasons Community Members Do Not Use BC	% (6)
Discomfort Asking a Health Care Provider for BC	16.7 (1)
Worried About Side Effects	66.7 (4)
Missing	16.7 (1)
Reasons Others Your Age Do Not Use BC	
Tribal concerns	16.7(1)
Lack of Access to Transportation	33.3(2)

Don't Know	33.3(2)
Missing	16.7(1)

Table 3B. Barriers for Birth Control for Teens and Adults

Statement	Strongly / Agree Agree		Neither Agree nor Disagree		Strongly Disagree / Disagree		Missing
	Teen (%)	Adult (%)	Teen (%)	Adults (%)	Teen (%)	Adult (%)	(%)
a. It is easy to get all types of birth control if you want it.	100	67				33	17
b. I have friends who have difficulty getting birth control	100	67		33			17
c. I am concerned that my peers view me negatively because I use birth control.	50	33		33		33	17
d. I am concerned what religious leaders think about using birth control	100	67		33			17
e. I am concerned about what tribal leaders think about using birth control	50	33		67	50		17
f. Adolescents in my community can easily get birth control		33			100	67	17
g. Over-the-counter birth control allows teenagers to access birth control easily without parental consent	50	67			50	33	17

Statement	Strongly / Agree Agree		Neither Agree nor Disagree		Strongly Disagree / Disagree		Missing
	Teen (%)	Adult (%)	Teen (%)	Adults (%)	Teen (%)	Adult (%)	(%)
h. Everyone knows where to get birth control if they want it		33		33	100	33	17
i. I know where to go to get emergency birth control / the morning after pill/ Plan B.		67		33	100		17
j. Health clinics in my community or nearby respect my privacy about birth control.	50	67			50	33	17
k. Pharmacies in my community or nearby respect my privacy about birth control.	50	33		33	50	33	17
l. More women and adolescents would use birth control if the method they want was free and easy to get.	100	100					17

Table 4 offers solutions that OTC BCP may solve to evade potential barriers. The majority of adults (67%) and all teens (100%) reported that easy access to OTC BCP would save them time and would make birth control access easier for them. Over half of adult participants expressed comfort with purchasing OTC BCP. In comparison, half of teen participants expressed being comfortable with purchasing OTC BCP, and 50% reported not feeling comfortable.

Table 4. Possible Solutions for Over-The-Counter Birth Control Pills

Statement	Strongly / Agree Agree		Neither Agree nor Disagree		Strongly Disagree / Disagree		Missing
	Teen (%)	Adult (%)	Teen (%)	Adults (%)	Teen (%)	Adult (%)	(%)
a. Having easy access to over-the-counter birth control pills would save me time.	100	67		33			17
b. Being able to access birth control over-the-counter pills would make it easier for me to access birth control.	100	67		33			17
c. I would feel comfortable buying over-the-counter birth control pills.	50	67		33	50		17

Table 5 describes potential benefits of OTC BCP. All participants reported within each age group that OTC BC would be beneficial in that it would save money (100%). Adults reported being more likely to take OTC BCP to avoid annual pelvic exams to access birth control (67%). Adults reported agreeing to routine cervical cancer screenings with OTC BCP use (67%), whereas teens reported (100%). Many teens and adults indicated that they believed OTC BC adherence would be improved if available. Teens reported they believed OTC BC availability would result in an increase in perception of control over family planning (100%). Adults reported higher interest in using OTC BCP as a long-term method than teens (67% v 50% respectively). The other 50% indicated they would not use OTC BCP as a long-term method. Additionally, all teens (100%) disagreed with using OTC BCP as a short-term birth control method and teens reported being more likely switch to OTC BCP if their insurance covered them. Adults were more ambivalent about being more likely to switch if insurance covered them with equal reports of agreement (33%), disagreement (33%), and neutrality (33%). Adults reported higher interest in OTC BCP use, yet 67% disagreed that they feel comfortable speaking to their pharmacist if they had any questions compared to 100% of teens. The financial benefits of OTC appeared to be an emerging trend.

Table 5. Barriers for Over-the-Birth Control

Statement	Strongly / Agree		Neither Agree nor Disagree		Strongly Disagree / Disagree		Missing
	Teen (%)	Adult (%)	Teen (%)	Adults (%)	Teen (%)	Adult (%)	(%)
a. Having access to over-the-counter birth control pills would save me money as I would not have to pay for additional doctor visits to obtain a prescription or a refill.	100	100					17
b. I would prefer over-the-counter birth control pills as I would not have to get a pelvic exam to access birth control.	50	67			50	33	17
c. I believe I would be more likely to take birth control pills on time if I had access to them over the counter.	100	67		33			17
d. I believe over-the-counter birth control pills are safe.	100	67		33			17
e. I would feel more in control of my family planning if I had access to over-the-counter birth control pills.	100	67		33			17
f. If over-the-counter birth control pills were available, I would use it as a long-term birth control method.	50	67		33	50	33	17

Statement	Strongly and Agree Agree		Neither Agree nor Disagree		Strongly Disagree and Disagree		Missing
	Teen (%)	Adult (%)	Teen (%)	Adults (%)	Teen (%)	Adult (%)	(%)
g. If over-the-counter birth control pills were available, I would use it as a short-term birth control method.		33		33	100	33	17
h. If over-the-counter birth control pills were available, I would continue to get pap tests and routine exams to prevent cervical cancer and other reproductive health problems.	100	67		33			17
i. I would be more likely to use over-the-counter birth control pills if my insurance covered them.	100	33		33		33	17
j. I would feel comfortable talking to my pharmacist about any questions I might have about over-the-counter birth control pills.	100	33				67	17

Table 6 displays locations participants preferred to have OTC BCP available. The participants were asked to select all that apply. The unanimous choice was online pharmacy or retail (83.3%), followed by community colleges (33.3%) and vending machines (33.3%).

Table 6. Preferred Locations for OTC BCP in King County

Location	% (6)
Online Retailer or Pharmacy	83.3(5)
Community College	33.3(2)
Vending Machines	33.3 (2)
Food Store	16.7(1)
Other (e.g., Seattle Indian Health Board pharmacy, other community center or central location)	16.7(1)
Missing	16.7(1)

VI. Discussion

While OTC BCP are pending in the United States, the preliminary data illustrates general interest in OTC BCPs. Eighty-three percent of the participants reported they would consider switching progestin-only OTC BCP, 67% would consider switching to OTC BC in general. Half of the study population reported transportation issues. Teens expressed higher barriers to accessing birth control than adults. Sixty seven percent of adults reported they would use OTC BCP as a long-term method. All teens (100%) and adults (100%) reported that access to OTC BCP would save them money. The most desirable delivery mechanism for OTC BCP is through an online retailer or pharmacy. Online options may reduce the reported discomfort teens experience within person purchasing in Table 4. Vending machines and community college locations offer easy and quick access to OTC BCPs. Online retail and vending machines would aid those who desire a discrete delivery mechanism. Due to the small nature of the sample size and descriptive survey, the findings are not representative of AI women and adolescents in King County. However, this data may suggest trends that may be confirmed when analyzing a larger population sample.

Study conclusions are limited due to the small sample size. This is explained by the length of time for recruitment of two months (May-July) and the online interface where the survey took

place. Recruitment efforts heavily relied on social media. Though social media yielded over 315 interested participants in the pre-screening survey, the data indicated these responses were likely generated through "bots." Upon further investigation, the majority of the responses used fraudulent numbers from across the country and fraudulent addresses (warehouses, restaurants, hotels) to meet the survey criteria. The growing concern with artificial participants or "bots" has impacted the data quality of online research.[23,24] The bots caused us to shift recruitment tactics several times and created several iterations of the survey to avoid bots. Nonetheless with each iteration, bots found creative solutions to beat measures to deter them from survey access. A survey recruitment through social media concluded 94.5% of cases were fraudulent.[23] A 2021 study concluded "enhanced data security mechanisms were not sufficient" as 62% of survey respondents were bots.[24] The research team conducted spot checks for the validity and integrity of the data. The consequence of this limitation yielded a small sample size.

The small sample size did not allow for tests of statistical significance, impairing our ability to assess the validity of the data and from drawing conclusions about the overall King County population of AIAN from the present sample. Our sample size did not meet the minimum number of responses necessary in each category in order to perform a t-test. Thus, the analysis is descriptive in nature.

Limitations also include a possible selection bias due to the sample selection technique used in the study. Due to low study participation using social media, the recruitment plan pivoted to an individualized snowball recruitment method. The research team sent invitations to personal connections and resources which can create a bias in our data, as respondents may be more likely to have similar characteristics, including health behaviors, health literacy, and perceptions.

Since participants have subjective experiences in their community, recall bias may be a factor in their responses to the quantitative questions in the survey. However, much of the data is consistent with other research.[3,7,18–20,25–27]

The interest in OTC BCP aligns with previous work conducted on women and adolescents in the United States. Our study reported 67% were interested in OTC BCP, which is similar to another study which reported 62%.[18] In comparison, our study population expressed higher interested in OTC progestin only (83%) than a 2018 study, which showed approximately 33% of study population expressed OTC BCP interest.[19] Insurance coverage yielded higher interest in OTC BCP.[18–20,25,27] Previous research observed that insurance coverage positively impacts health behaviors and impacts birth control use.[28,29]

Transportation access and insurance coverage are observed challenges for AI/AN women in accessing birth control in our study. Although 83% of the study population had insurance coverage, this is not comparable to AI/AN data in King County. AI/AN residents of King County uninsured rate was 4.7 higher than non-Hispanic Whites and approximately 25% are uninsured.[30] It is important to consider how the responses may vary for individuals without health insurance coverage.

Implications of these findings may highlight the need to prioritize interventions for AI/AN teens in King County. Teens experienced more barriers than adults in our study sample. Critically,

teens reported perceiving multiple social barriers (peers, tribal concerns, and religious considerations) to the use and adherence of birth control. The data also suggests that this population may also experience potential barriers from negative attitudes towards birth control. Arguably, positive social attitudes and support can act as facilitators to help teens access birth control. Several successful AI/AN health interventions involve community- and women-led programs.[31–33] which provide information and education for the community by fellow community members. A potential implication for future rollout of OTC BC could provide teens resources on where to access affordable BC. Future interventions may benefit from exploring additional factors related to teen perceptions that friends have difficulty accessing BC and they do not have knowledge of where to get emergency BC, as reported in Table 3B. Often, research focuses on deficits without looking for strengths to improve public health research for AI/AN populations. Additional research is necessary to fully explore potential strength-based approaches to ensuring AI/AN teen OTC BC access.

AI/AN reproductive health calls for more research that investigates beyond health disparities. Timely, affordable, and accessible birth control is a human right. The preliminary data provided in this study will help inform future efforts to mitigate health disparities in the population and work directly with AI/AN individuals to develop an informed roll-out of OTC BCP in WA State. Future research is needed to further unpack the barriers and potential benefits of OTC BCP in King County and outside WA state.

VII. Conclusions

The project sought to close the gap on research of OTC BC in AI/AN population of King County. This preliminary data will be used to continue an expanded research project in the urban Indian population and in other AI/AN communities in Washington State. Eighty-three percent of participants would switch to a progestin-only OTC BCP. One hundred percent of the study population agree that more people would use birth control if the method they want is free and easy to obtain. All participants (100%) state OTC BCP would save them money. The data trends suggest the need for improvement of birth control affordability, knowledge, and insurance of OTC BCP so King County AI/AN have timely and affordable access to OTC BC. The data suggests interest in the use of OTC BCP. We cannot confidently use this data alone to inform policy development for the roll-out of OTC BCP in King County.

VIII. Acknowledgements

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I would like to thank my committee- Beth, Myra, and Don for their support and their inputs on our research.

IX. Appendices

Appendix A. Pre-Screening

Pre-Screening Adult Tribal ABC Study

Thank you for your interest in our study. Please complete the survey below to determine eligibility. Please read the questions carefully and answer them all.

Thank you!

The University of Washington (UW), in collaboration with the non-governmental organization Uplift International, is conducting community research to understand American Indian birth control preferences, barriers, and acceptability of over-the-counter birth control. This research will allow American Indian communities to benefit from the availability of existing and new methods of birth control that do not require prescriptions.

This is a one-time research study survey that asks you whether or not you use birth control and whether you would prefer to take over-the-counter birth control.

Please answer the questions below to determine if you meet the study criteria. If you have any questions or concerns, please feel free to email indigenousphi@uw.edu or call us at (206)-685-0161.

Are you 18 years old or over?

- ◯ Yes
- ◯ No

(18+ Age)

Are you able to become pregnant?

- ◯ Yes
- ◯ No

Are you American Indian or Alaskan Native?

- ◯ Yes
- ◯ No

King County Map

Do you live in King County?

- ◯ Yes
- ◯ No

First Name

_____

Last Name

_____

Email

_____

Phone number

_____

Mailing Address

_____

Zip Code

_____

Appendix B. Consent Form

Informed Consent for Participation in Tribal Acceptability of Birth Control Study Survey

08/05/2022 5:39pm projectredcap.org

The University of Washington (UW), in collaboration with the non-governmental organization Uplift International, is conducting community research to understand American Indian birth control preferences, barriers, and acceptability of over-the-counter birth control. This research will allow the King County Urban Indian community to benefit from the availability of existing and new methods of birth control that do not require prescriptions.

Study Title: Tribal Acceptability of Birth Control Study Researchers

Dr. Myra Parker, Associate Professor, Department of Psychiatry and Behavioral Sciences, University of Washington School of Medicine; 206-258-1132, myrap@uw.edu

Dr. Beth Rivin, Clinical Associate Professor, Department of Global Health, University of Washington; brivin@uw.edu

Dr. Donald Downing, Clinical Professor, Department of Pharmacy, University of Washington School of Pharmacy;206 616-4587 dondown@uw.edu.

Bianca Graves, MPH Student Research Assistant, blg20@uw.edu

Researchers' Statement

We ask you to participate in a research study carried out by Dr. Beth Rivin, Dr. Myra Parker, Professor Don Downing, and Bianca Graves. We are asking you to participate in a survey. This consent form aims to provide the information you need to help you decide whether or not to participate in the survey.

Please read the form carefully. You may ask questions about the purpose of the study, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else you do not understand. When we have answered all your questions, you can decide if you want to participate in the study or not.
Your name and personal information will be de-identified by a unique code. That code will be used in lieu of your name for the research team. In other words, your name and personal information will not be associated with the survey information.

If you join the study, you can change your mind later about participating and quit at any time. You can refuse to answer any question. There will be no penalty or loss of services or benefits if

you decide not to participate in the study or quit later. This process is called 'informed consent.'

We will give you a copy of this form for your records. What is the purpose of the study? The research aims to learn from the community about women's birth control preferences and barriers to accessing it, including community pharmacy barriers. The study investigates the perception and acceptability of over-the-counter (OTC) methods.

What will I be asked to do if I am in this study? If you take part in the study, you will be asked to complete the paper or online survey (about 15-30 minutes).

Are there any benefits to me if I am in this study? There is no direct or intended benefit to you from being in this study. If you take part in this study, you will be sharing your experience to help guide better support to members of the King County community.

Are there any risks to me if I am in this study? The potential risks of taking part in this study are:

Loss of confidentiality. To minimize this risk, we will maintain the confidentiality of data as described below. Psychological/emotional discomfort or distress. To minimize this risk, we will assure participants that they do not have to answer any questions that make them uncomfortable. Will my information be kept private? The data for this study will be kept confidential to the extent allowed by federal and state law. Under certain circumstances, information that identifies you may be released for internal and external reviews of this project.

Data will be stored in a secure, password-protected UW server. The following people will have access to the data: the three principal investigators of the study, Dr. Rivin, Dr. Parker, Professor Downing, and their teams of researchers, and the Institutional Review Board (Ethics Review) at UW. The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous. The data for this study will be kept for seven years after the completion of the study. The data file with no identifying information, including the code, may be kept longer by the University of Washington.

Are there any payments for being in this study? There are no direct payments for being in the study. Each participant will have the opportunity to enter a lottery. We plan to give out three prizes to the winners of the lottery drawing. The lottery will take place at the end of survey data collection, which will be in early June 2022. The prizes will include items valued at about $50-$100, including small Native baby blankets, gift cards from tribal gift shops, and similar prizes.

Who is funding this research? The Vadon Foundation and Uplift International fund this research, a non-profit organization focused on reproductive rights.

Will the data be used for any future research? The information collected as part of this research will not be used or distributed for future research studies.

Who can I talk to if I have questions? If you have questions about this study or the information in this form, please contact the study number (206) 685-0161 or the researcher Dr. Myra Parker at myrap@uw.edu. If you have questions about your rights as a research participant or would like to report a concern or complaint about this study, please contact the University of Washington Human Subjects Division (HSD) at (206) 543-0098 or email hsdinfo@uw.edu.

What if I want to withdraw? To withdraw your previously collected data from the study, you must contact Dr. Myra Parker at myrap@uw.edu stating that you would like to have your data removed. There are no consequences for withdrawing from the research.

What are my rights as a research study volunteer? Your participation in this research study is completely voluntary. You may choose not to be a part of this study. There will be no penalty if you choose not to take part. You may choose not to answer specific questions or to stop participating at any time. You will be given a copy of the consent form for your records.

Acknowledgment

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have study-related questions, I can call (206) 685-0161. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

Consent to Participate in the Study I confirm the following:

I have read (or had read to me) this entire consent document. All my questions have been answered to my satisfaction. The purpose of the survey has been explained to me. I agree to let the study team use and share the health information and other information gathered for this focus group. I voluntarily agree to participate in the study. I agree to follow the study procedures as directed. I have been told that I can stop at any time.

Appendix C. Survey

Tribal Acceptability Of Birth Control Survey

Please complete the survey below.

Thank you!

Over The Counter Birth Control Preference Survey

We are asking you to complete this survey to learn about your birth control preferences, use and access in your community. Confidential - we will keep your personal identifiers separate from your responses. We will only use your personal information to send you a gift card for your participation.

Section I. Demographics

1. Are you able to become pregnant?	◯ Yes ◯ No (The study requires participants to be able to become pregnant.)
2. What is your gender identity?	◯ Female ◯ Male ◯ Non-binary ◯ Other
Please specify: "Other"	_____
3. How old are you today?	◯ 18-24 years old ◯ 25-31 years old ◯ 32-38 years old ◯ 39-45 years old ◯ 46 years old or older
4. Have you ever been pregnant?	◯ Yes ◯ No
5. Do you have any children?	◯ Yes ◯ No
6a. Are you American Indian/Alaskan Native?	◯ Yes ◯ No (The study requires participants to be of AI/AN descent)
6b. What is your race? (Check all that apply)	☐ American Indian or Alaskan Native ☐ Asian, including East Asian, South Asian, and Southeast Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White / Caucasian ☐ Other
7. Are you Hispanic or Latino/a?	◯ Yes ◯ No ◯ Don't know

8. Do you ever have problems with transportation to the clinic or grocery store?	◯ Yes ◯ No ◯ Sometimes
9. What is the name of the health clinic you usually go to for health care?	_____
10. Do you have health insurance? (Check all that apply)	☐ Yes, I have health insurance through my employer. ☐ Yes, I have Apple Health. ☐ Yes, I have other private health insurance. ☐ Yes, I have other coverage (e.g., Medicare or Medicaid) that covers my health care costs. ☐ I access health care through my tribal, Indian Health Service, or urban Indian health clinic. ☐ No, I do not have health insurance ☐ Not sure
11. Do you ever obtain prescription medications or other care from a pharmacy?	◯ Yes ◯ No ◯ Sometimes ◯ Often

Section II. Birth Control Preferences

12. What current method of birth control do you use? Check all that apply

- ☐ Condoms
- ☐ Female condoms
- ☐ The pill, oral contraceptive pill
- ☐ The patch (hormone skin patch)
- ☐ The ring (vaginal contraception ring)
- ☐ The sponge
- ☐ The shot (Depo-Provera)
- ☐ Diaphragm or Cervical Cap
- ☐ The IUD (intra-uterine device)
- ☐ The arm implant (long-acting reversible contraception or LARC)
- ☐ Pulling out
- ☐ Abstinence
- ☐ Emergency birth control / the morning after pill/Plan B
- ☐ I just had a baby and I'm still lactating/breast feeding
- ☐ I do not use any
- ☐ Other

Please Describe

_____

13. Would you like to get your birth control over-the-counter and without a prescription? Over-the-counter means available at a convenient location without going to the pharmacy counter and submitting a prescription. For instance, it could be in a vending machine or a convenience store or out front in a pharmacy.

- ◯ Yes
- ◯ No
- ◯ Not Sure
- ◯ I already get my birth control over-the-counter.

14. If birth control pills were over-the-counter, would you prefer to use them? (Please choose best answer)

- ◯ I already use oral contraceptives or birth control pills
- ◯ I would consider switching to birth control pills
- ◯ I would definitely switch to birth control pills
- ◯ I would not switch to birth control pills
- ◯ I have medical reasons not to use hormonal birth control pills as contraception

Section III. Barriers to Access

15. Think about people your age in your community. What are some reasons they DO NOT use birth control methods? Check all that apply.

- ☐ They do not believe they need it.
- ☐ They are not sure where to get it.
- ☐ They are not sure how to get it.
- ☐ They do not know what the options are.
- ☐ They do not feel comfortable asking a health care provider for birth control.
- ☐ They do not want to have a vaginal exam.
- ☐ They have heard female birth control options might have negative health effects.
- ☐ They are worried about side effects from the hormones in female birth control options (for example, weight gain, irregular periods, high blood pressure, etc.)
- ☐ They do not have insurance. It costs too much.

16. What are some other reasons people your age DO NOT use birth control methods? Check all that apply.

- ☐ Their partner is another female.
- ☐ Their partner does not want them to use it.
- ☐ Family members do not want them to use it.
- ☐ They are afraid their parents will find out.
- ☐ There are religious concerns.
- ☐ There are tribal concerns.
- ☐ They are not sexually active or are waiting until they get married.
- ☐ They want to become pregnant.
- ☐ They do not have transportation to access birth control.
- ☐ I don't know why people in my community don't use birth control.
- ☐ Other

Please specify "Other"

_____

Instructions: Please read the following statements and choose the option that you identify with most for each statement.

In this section, we would like you to think about some experiences and opinions you may have around birth control in your community.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Not Applicable
It is easy to get all types of birth control if you want it.	○	○	○	○	○	○
I have friends who have difficulty getting birth control.	○	○	○	○	○	○
I am concerned that my peers view me negatively because I use birth control.	○	○	○	○	○	○
I am concerned what religious leaders think about using birth control.	○	○	○	○	○	○
I am concerned about what tribal leaders think about using birth control.	○	○	○	○	○	○
Adolescents in my community can easily get birth control.	○	○	○	○	○	○

Section III: Continued

Instructions: Please read the following statements and choose the option that you identify with most for each statement.

In this section, we would like you to think about some experiences and opinions you may have around birth control in your community.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Not Applicable
Over-the-counter birth control allows teenagers to access birth control more easily without parental consent	○	○	○	○	○	○
Everyone knows where to get birth control if they want it.	○	○	○	○	○	○
I know where to go to get emergency birth control / the morning after pill/ Plan B.	○	○	○	○	○	○
Health clinics in my community or nearby respect my privacy about birth control.	○	○	○	○	○	○
Pharmacies in my community or nearby respect my privacy about birth control.	○	○	○	○	○	○
More women and adolescents would use birth control if the method they want was free and easy to get.	○	○	○	○	○	○

Section IV. Potential Solutions for OTC Birth Control

In this section, we would like you to think about some of the possible solutions of any birth control method that is over-the-counter. By "over-the-counter" we mean you would be able to purchase birth control pills without a prescription at a grocery store pharmacy or other location.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Not Applicable
Having easy access to over-the-counter birth control pills would save me time.	○	○	○	○	○	○
Being able to access birth control over-the-counter pills would make it easier for me to access birth control.	○	○	○	○	○	○
I would feel comfortable buying over-the-counter birth control pills.	○	○	○	○	○	○

Section V: Possible Benefits of Over-the-Counter Birth Control Pills

In this section, we would like you to think about some of the possible benefits of birth control pills that are over-the-counter.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Not Applicable
Having access to over-the-counter birth control pills would save me money as I would not have to pay for additional doctor visits to obtain a prescription or a refill.	○	○	○	○	○	○
I would prefer over-the-counter birth control pills as I would not have to get a pelvic exam to access birth control.	○	○	○	○	○	○
I believe I would be more likely to take birth control pills on time if I had access to them over-the-counter.	○	○	○	○	○	○
I believe over-the-counter birth control pills are safe.	○	○	○	○	○	○
I would feel more in control of my family planning if I had access to over-the-counter birth control pills.	○	○	○	○	○	○

Section V Continued: Possible Benefits of Over-the-Counter Birth Control Pills

In this section, we would like you to think about some of the possible benefits of birth control pills that are over-the-counter.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Not Applicable
If over-the-counter birth control pills were available, I would use it as a long-term birth control method.	○	○	○	○	○	○
If over-the-counter birth control pills were available, I would use it as a short-term birth control method.	○	○	○	○	○	○
If over-the-counter birth control pills were available, I would continue to get pap tests and routine exams to prevent cervical cancer and other reproductive health problems.	○	○	○	○	○	○
I would be more likely to use over-the-counter birth control pills if my insurance covered them.	○	○	○	○	○	○
I would feel comfortable talking to my pharmacist about any questions I might have about over-the-counter birth control pills.	○	○	○	○	○	○

SECTION VI: Future Options for Over-the-Counter Birth Control

17. There are different types of birth control pills and the most used are a combination pill with estrogen and progestin. In the future, there will likely be an over-the-counter safe and effective birth control pill that is progestin-only. When it becomes available, would you consider using the progestin-only birth control pill? (Please choose the best answer)

- ○ I use oral contraceptives and would try the progestin only over-the-counter birth control pill.
- ○ I use another method and would consider switching to progestin only over-the-counter birth control pills
- ○ I use another method and would definitely switch to progestin only over-the-counter birth control pills
- ○ I use another method and would not switch to progestin only over-the-counter birth control pills
- ○ I don't use birth control now and would consider using progestin only over-the counter birth control pills
- ○ I don't use birth control now and would not consider using progestin over-the counter only birth control pills
- ○ I have medical reasons not to use hormone birth control pills as contraception

18. We are interested in learning about the most convenient over-the-counter locations for you. Please choose all the locations that you would use to get over-the-counter birth control:

- ☐ Non-tribal no- or low-cost pharmacy
- ☐ Online pharmacy or retailer
- ☐ Central location on a tribal reservation
- ☐ Community College
- ☐ Convenience store at gas station
- ☐ Off reservation extension office
- ☐ Vending machine
- ☐ Food store
- ☐ over-the-counter purchase
- ☐ Other (e.g., Seattle Indian Health Board pharmacy, other community center or central location)

Other- Please fill in the option that works best for you:

_____

Name

_____
(Please enter your name for follow up.)

Mailing Address

_____
(Please enter your mailing address for followup.)

Email

_____
(Please enter your email address for compensation)

Phone Number

_____
(Please enter your phone number for followup)

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