Form Approved

OMB No. 0920-New

Expiration Date: XX/XX/XXXX

Preferences for Longer-Acting Preexposure Prophylaxis (PrEP) Methods Among Persons in US Populations at Highest Need: A Discrete Choice Experiment

Attachment #6

Provider Screening & Consent

C4P Providers Screening Survey & Consent

Screening Survey & Consent link:
https://survey.rti.org/SE/1/ProviderScreenerDev

Note: text in blue indicate instructions for programming.

Specs:

- One question will be shown per screen.

- Response not required for all questions. Participants need to be able to skip questions that they prefer not to answer; if a question on screen is not answered and the participant selects to move forward in the survey, the survey will note to the participant that an item is not answered and confirm if they would like to move forward and leave the question unanswered. The survey will code this response as a refusal.

** Indicates item used to assess eligibility

U Indicates single response option only in question allowing multiple responses

The U.S. Centers for Disease Control and Prevention is conducting a survey to understand opinions on new HIV prevention options that may be available in the future. We thank you for your interest in this survey and appreciate your time.

[Page break]

S1. How old are you?

_____ years old [numeric response only; REQUIRE RESPONSE]

[if S1<18 à END SURVEY]

Consent to Participate in a Research Study

Title of the research study: Choices for Prevention (C4P)
Principal Investigator: Dr. Sarah Roberts, RTI International
Study Sponsor: The Centers for Disease Control and Prevention (CDC) Division of HIV Prevention

KEY INFORMATION

- You are invited to participate in a research study funded by the Centers for Disease Control and Prevention (CDC) and conducted by a non-profit research organization named RTI International.
- Participation in this study is completely voluntary. You may choose not to take part in the study or leave the study at any time without any consequences.
- The purpose of this research study is to understand provider preferences for several new long-acting PrEP, or pre-exposure prophylaxis, methods and how other factors related to PrEP care might influence the decision to prescribe long-acting PrEP. PrEP is an HIV medication that people without HIV can take to prevent getting HIV from sex or injection drug use.
- As part of the study, you will be asked to complete an online screening form that asks questions about your background characteristics (e.g., age, gender identity, race/ethnicity), your clinical practice, and your experience prescribing PrEP. The screening form takes about 5 minutes to complete.
- If the screening form shows that you are eligible for the study, you may be invited to participate in the online survey. In that survey, you will be presented with several scenarios where you are asked to compare two PrEP provision options with different characteristics and think about which one you would prefer to prescribe. We will also ask you some direct questions about your opinions of different PrEP products and some more detailed questions about your background and experiences with PrEP. The survey should take about 20 minutes to complete.
- All participants that complete the online survey will receive a $20 Visa gift card. The $20 gift card may be withheld if it is determined that you do not meet the eligibility criteria, you do not complete the survey, or there is evidence of fraud.
- You may be uncomfortable answering some questions about yourself. You do not have to answer any questions that make you uncomfortable.
- The study has a minimal level of risk. The key risk is small chance of a loss of confidentiality. To help minimize this risk you will be assigned a

unique research ID number. Additionally, your personally identifying information (e.g., name, email address) will be kept separate from your data and will only be accessible to the research staff at RTI International.

Introduction

You are being asked to participate in a research study. Before deciding if you want to take part, you need to read this Informed Consent form to understand what the study is about and what you will be asked to do. This form tells you who can be in the study and the risks and benefits of the study. This form explains how we will protect your information and who you can call if you have questions.

Purpose

The C4P Study is a research study paid for by the Centers for Disease Control and Prevention (CDC). The study is being led by researchers from CDC and from RTI International, a research organization in Research Triangle Park, North Carolina. The purpose of the study is to understand provider preferences for several new long-acting PrEP, or pre-exposure prophylaxis, methods and how other factors related to PrEP care might influence the decision to prescribe or administer long-acting PrEP. PrEP is an HIV medication that people without HIV can take to prevent getting HIV from sex or injection drug use. You are being asked to screen for this study because you prescribe PrEP as part of your practice. About 200 health care providers will participate in the study.

Procedures

If you agree to participate, you will be asked to complete a confidential online screening form. As part of this screening form, you will be asked questions about your background characteristics (e.g., age, gender identity, race/ethnicity), your clinical practice, and your experience prescribing PrEP. If you are eligible for the study, you may be invited to participate in the study's online survey.

If you are not selected to participate in the study's online survey, you will be notified by email or SMS and thanked again for completing the study's screening form. If you are selected to participate in the study's online survey, you will be invited by email or SMS. The invitation will include a link to the survey and your respondent ID. If you are invited for the study's online survey, you will be asked to complete the survey one time within 2 weeks after receiving the invitation. You may also have the option to complete the survey immediately after the screening form.

In the survey, you will be presented with several scenarios where you are asked to compare two PrEP provision options with different characteristics and think about which one you would prefer to prescribe. We will also ask you some direct questions about your opinions of different PrEP products and some more detailed questions about your background and experiences with PrEP. There are no wrong or right answers to any of the questions that we will ask you. All of your answers are confidential, which means your name will not be known to anyone other than the researchers.

Study Duration

The screening form is expected to take only 5 minutes to complete. If you are invited to participate in the study's online survey, it is expected that you will spend about 20 minutes on the survey.

Possible Risks or Discomforts

We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet. There are no physical risks involved in this study or costs involved in participation. It is possible that some questions may make you uncomfortable. You can refuse to answer any question. There is a small risk of a loss of confidentiality, meaning that people outside the study could find out that you joined the study or see your answers to the survey questions. Steps to protect your information are described in the next section, but this cannot be guaranteed. You should report any problems to the researcher (contact information is below).

Confidentiality

Many precautions have been taken to protect your information. We have procedures in place to limit who can connect you/your name to your answers. We will remove your name and any other information that could directly identify you from your survey responses. We will replace this information with a research ID number. We will create a master list linking your code number to your name. We will keep this list separate from your survey responses in a secure location. Only a few research staff from RTI International who are working on this study will know your name and your ID number. If findings from this study are presented at scientific meetings or published, your name will not be used.

This study has a Certificate of Confidentiality from the CDC. Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT protect your information if a federal, state, or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.

Sometimes there are opportunities for researchers to use data from previous studies or to share data with each other if they are conducting similar research. For these reasons, we may use or share your research data for future research. We will not ask

for your additional informed consent for those studies. Prior to using or releasing this data for future research, we will remove or code any personal information that could identify you to ensure that, by current scientific standards and known methods, no one should be able to identify you from the information we share. RTI International plans to destroy all of the study's records that contain the link between your identifying information and your research data before the study's end. We will do so unless legal or scientific reasons require us to keep the link beyond the study's end.

The Institutional Review Board (IRB) at RTI International has reviewed this research. An IRB is a group of people who are responsible for protecting the rights of research participants. The IRB may review study records to make sure that proper procedures were followed. A representative of the IRB may contact you about your experience with this research. This representative will be given your name, but not your confidential study data. You may refuse to answer any questions this person may ask.

Benefits

Your Benefits

There are no direct benefits to you for participating in this study. You may feel satisfaction from being part of project that will help determine how best to deliver HIV prevention services to people who are vulnerable to HIV across the United States.

Benefits for Other

The results of this study could help improve delivery of HIV prevention services and thereby increase uptake of PrEP among people who are vulnerable to HIV across the United States. Increasing uptake of PrEP could reducing the overall number of new HIV infections and reduce racial and ethnic disparities in HIV.

Payment for Participation

There is no payment for completion of the screening form. However, if you are invited to participate in the online survey, you will be sent a $20 Visa gift card after completing the survey.

Your Rights

Your decision to take part in this study is completely voluntary. You can refuse any part of the study. You can stop participating at any time. You can refuse to answer any question. If you decide not to participate, or you withdraw later, you will not lose any benefits or rights to which you are entitled. The $20 gift card may be withheld if it is determined that you do not meet the eligibility criteria, you do not complete the survey, or there is evidence of fraud.

Your Questions

If you have any questions about the study, you may contact Dr. Sarah Roberts by calling her at (510) 665-8255 or emailing her at sroberts@rti.org. If you have any

questions about your rights as a study participant, you may call RTI's Office of Research Protection at 1-866-214-2043.

Project Assurance of Consent

I understand what the study involves, and my questions so far have been answered. I am 18 years of age or older and I voluntarily choose to participate in this study. I am aware that I may choose not to participate or to withdraw from this study at any time without penalty or loss of benefits to which I am otherwise entitled. I understand that I may print a copy of the informed consent for my records.

Please indicate your decision about participating in the study.

- ☐ I have decided to participate in this study. On the next page, I will provide information about how to contact me about my participation in the study and my preference related to the gift card I may earn as part of the study. I consent for this information to be used as part of this study.

- ☐ I have decided NOT to participate in this study.

[page break]

Your name and contact information

Your First Name: _____

Your Last Name: _____

[page break]

Do you prefer to receive the survey link by email or SMS? If possible, we recommend selecting "email" and completing the survey on a computer or tablet instead of a smartphone.
 Email

 SMS

Your [email address/mobile phone number] for sending the online survey link:
_____

Confirm your [email address/mobile phone number] for sending the online survey link:
_____

[page break]

If you are selected to participate in the online survey, how to you prefer to receive your gift card?

- ☐ eGift card emailed to my email address below

Your email address for receiving the gift card: _____

Confirm your email address for receiving the gift card: _____

- ☐ Physical gift card mailed to my address below

Street Address: _____ Apartment Number: _____

City: _____ State: _____ Zip Code: _____

[page break]

Now we will move on to the screening survey questions.

S2. Pre-exposure prophylaxis (PrEP) is a strategy in which a person without HIV takes an HIV medication daily to prevent HIV infection.

Are you familiar with oral pre-exposure prophylaxis (PrEP) for HIV prevention? **

- Extremely (have expert knowledge) **
- Very (know a lot of information about PrEP, including details such as recent clinic trial results) **
- Somewhat (know what PrEP is and basic information about it) **
- A little (heard of PrEP but don't really know what it is) **
- Not at all (first time hearing about PrEP)

[page break]

S3. Have you ever prescribed PrEP? **

- Yes**
- No

[page break]

S4. [If S3 = “Yes”] When did you start prescribing PrEP?

Year __ __ __ __ [number 2012 - 2023]

[page break]

S5. [If S3 = “Yes”] How many patients did you prescribe PrEP for in the past year? **

_____ [numeric response only]

[page break]

S6. What is your profession?

- Nurse Practitioner
- Physician's Assistant
- MD
- DO
- Other prescribing health care provider, specify: _____ [max characters: 100]

[page break]

S7. What is your area of specialty? Please select all that apply

- ☐ Adolescent Medicine
- ☐ Emergency Medicine
- ☐ Family Medicine
- ☐ HIV/AIDS Medicine
- ☐ Internal Medicine
- ☐ Infectious Disease
- ☐ Obstetrics and Gynecology
- ☐ Pediatrics
- ☐ Preventative Medicine
- ☐ Other, specify: _____ [max characters: 100]

[page break]

S8. Which state and county or territory do you practice in? If you practice in more than one county, please select the county where you practice most often. **

State or Territory: _____

County : _____

[include drop down of states and then counties based on state. There are 3,143 county equivalents; target based on 57 EHE jurisdictions]

S9. Which best describes your principal practice setting? Please select one of the items on the drop-down menu [items will be in dropdown]

- Academic health center/ University health clinic
- Community health center
- Community based organization
- Family planning clinic
- HIV clinic
- HMO/Managed care organization
- Emergency room/Urgent care clinic
- Indian health service/Tribal clinic
- Infectious disease clinic
- Maternal/Child health clinic
- Mental/Behavioral health clinic
- Private practice
- Rural health clinic
- STD clinic
- State/Local health department clinic
- Substance abuse treatment center
- Other primary care site, please specify _____ [max characters: 100]
- Non-health setting

Thank you for taking the time to complete this survey. We truly value the information you have provided.

We may contact you to participate in a longer survey, where we will ask about your opinion of new HIV prevention options that may be available in the future.

If you are interested in learning more about prescribing PrEP, please visit

https://www.cdc.gov/hiv/clinicians/prevention/prep.html.

ELIGIBILITY CRITERIA: If S2 = 'Not at all' OR S3 = 'No' OR S5 <1 → respondent not eligible.

PLEASE CREATE VARIABLE ELIGIBLE 1=Yes, 0=No