

The Donor HIV Risk Questionnaire Study (HRQ)

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Agency Principles Moving Forward for MSM Policy

- FDA is committed to ongoing evaluation of the MSM deferral policy and to potentially advancing policy based on the available scientific evidence.
- FDA is also committed to maximizing the transparency of the process through stakeholder engagement and use of public advisory committees.
- The process will be based on gathering the necessary scientific evidence while ensuring the continued safety of the blood supply.



HIV Risk Questionnaire Pilot Study

- This presentation will cover the HIV Risk Questionnaire (HRQ) pilot study to gather population-specific risk behavior evidence.
- The FDA Office of Acquisitions and Grants Services is currently finalizing the solicitation package for this HRQ pilot study and anticipates posting the Sources Sought notice to FBO.gov within the next two weeks.

Background

- MSM deferral background
- Non-compliance with lifetime MSM deferral
 - 2.6% reported in U.S.
- Need for population-based evidence upon which to base regulatory decisions to ensure blood safety



Donor High Risk Questionnaire (HRQ) Pilot Study Overview

- Background
- Purpose and Objectives of Study
- Study Design
- Questionnaire
- HIV Testing and Follow-up
- Data Analysis
- Reporting Requirements
- Timing

Pilot Study Background

- Pilot study
 - Was designed through a collaborative process to assess potential risk of alternative MSM donor deferral strategies.
 - May help determine the feasibility and size of a larger study to assess whether reduction or elimination of the donor deferral interval for MSM is possible.
- Larger study criteria:
 - Identification of a set of behavioral questions/ responses that are associated with the absence of detection of recent HIV infection.



Pilot Study Purpose & Objectives

Purpose: To provide FDA with evidence by which to consider potential changes in MSM deferral policy while maintaining the safety of the blood supply.

Primary Objective:

- Assess the discriminant function of a list of behavioral history questions for predicting recent infection with HIV in MSM who wish to donate blood.

Secondary Objectives:

- Evaluate the recency of HIV infection in those individuals by individual NAT and/or antibody testing;
- Identify risk factors associated with recent HIV infection in individuals who are antibody negative yet HIV NAT positive.

Pilot Study Endpoints

Primary Endpoint

- The number of individuals who are HIV NAT positive but antibody negative.

Secondary Endpoints

- The number of overall HIV infections
- The number of recent HIV infections
- Correlation of responses to questions with HIV status

Pilot Study Design: Subjects and Population

- Subjects: 2,000 men who have had sex with men (MSM) at least once during the past 3 months
 - Sample size chosen to increase likelihood that a recent HIV infection will be identified
- Subjects will be enrolled from 8-12 geographically distributed sites with high risk of HIV transmission among LGBTQ
- The sites may be a combination of clinical facilities and venue-based locations (e.g. vans at bars)

Pilot Study Design: Site Selection

Pilot sites shall be selected from locations in states and cities with the highest new HIV diagnosis rates based on 2017 CDC HIV epidemiology reports¹, such as:

- States/Districts:
 - District of Columbia, Georgia, Louisiana, Florida, and Maryland (rates above 20/100,000 adults and adolescents);
 - Nevada, Texas, Mississippi, South Carolina, New York, Alabama, Delaware, and North Carolina (rates between 15-20/100,000 adults and adolescents).
- Cities:
 - Miami FL, Orlando FL, Atlanta GA, New Orleans LA, Baton Rouge LA, Jackson MS, Jacksonville FL, Memphis TN, Columbia SC, Las Vegas NV, and Baltimore MD.

¹<https://www.cdc.gov/hiv/statistics/overview/geographicdistribution.html>

Pilot Study Design: Eligibility Criteria

Inclusion criteria

1. Male
2. ≥ 18 years of age
3. Interest in donating blood
4. Oral sex or anal intercourse with a male partner at least once during the past 3 months
5. Answer the study questionnaire, provide a blood sample, and follow the study protocol
6. Provide informed consent

Exclusion criteria

1. Prior use of injection drugs ever
2. Exchange of sex for money or drugs ever
3. Prior documented history of HIV infection
4. Diagnosis of syphilis, gonorrhea, or chlamydia during the 3 months prior to enrollment

Pilot Study Outline

- Eligible subjects will have two study encounters.
 - Encounter 1: Initial enrollment materials, questionnaire, and provide a 7 mL blood sample for testing
 - Encounter 2 (within 14 days): Second interview; counseling and referral provided, as appropriate.
- Study questionnaire must be translated into Spanish
- OMB and IRB approvals required
 - 9 subject pilot allowed to identify issues
 - Questionnaire
 - In-person delivery
 - Data collection methodology.

Pilot Study Design: Questionnaire



1. How many different sexual partners have you had sex with (defined as oral sex or anal intercourse) during the past
 - a) 1 month (number_____)
 - b) 3 months (number_____)
 - c) 12 months (number_____)

2. What kind of sex have you had during the past month?
 - a) Oral sex
 - b) Anal penetrative or receptive intercourse
 - c) Both oral sex and anal intercourse
 - d) Not sexually active during the past month



Pilot Study Design: Questionnaire (2)

3. To your knowledge, have you had sex with an HIV positive partner during the past 12 months?
(Yes/No)
4. Do you
 - a) Always use condoms
 - b) Use condoms sometimes
 - c) Never use condoms
5. Do you take pre-exposure prophylaxis (PrEP)?
(Yes/No)

If yes, when was the last time that you took PrEP? _____

HIV Testing and Follow Up by Investigator

- Blood screening for HIV
 - Antibody and individual donor NAT testing for HIV
 - If HIV positive, recency testing for HIV
- Follow-up visit within 14 days
 - Interview to collect HIV risk exposure from those with positive HIV tests
 - Counseling and referral to be provided for HIV+ subjects
- Sample repository shall be established and maintained.

Pilot Study Data Analysis

- Investigator shall submit an analysis plan to FDA, including
 - Proposed analyses
 - Data specifications
 - Data and Table structures
 - Statistical plan to include modeling
 - Data QC procedures



Pilot Study

FDA Reporting Requirements

- Monthly progress reports
- Study site selection report
- 9 Subject pilot report
- Regular test result reports
- Data analysis reports (mid-point, draft, and final)
- Draft and final study reports

Pilot Study Timing

- RFP posted May - June 2019
- Award expected in FY 2019
 - OMB and IRB approvals must be obtained
- Initiate enrollment of MSM
 - Late 2019 to early 2020
- Full enrollment within 6 months
 - Mid to late 2020
- Data Analysis to be completed
 - Early 2021

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