
Protocol of Evaluation for Cluster Randomized Controlled Trial of Integrated Interventions to Reduce HIV Incidence Among MSM in China

The effectiveness evaluation of the "Cluster Randomized Controlled Trial of Integrated Interventions to Reduce HIV Incidence Among MSM in China" will be launched through MSM natural Cohort Study. A natural cohort of MSM will be established through the "Happiness Check" appointment-based testing platform in the 20 cities and tracked via MSM-focused social platforms to understand the incidence of new HIV infections. The planned duration for this natural cohort is from Feb.1, 2019 – Jan. 31, 2021 (24 months).

I. Work Platforms

The field work for the cohort study is conducted through three platforms, including:

- 1.The project team at the municipal Centers for Disease Control and Prevention in the project cities;
- 2.Testing clinics/community-based organizations designated by the project team (hereinafter referred to as "project sites");
- 3.The HIV confirmation laboratory of the municipal CDC or other HIV confirmation laboratories designated by the project team (hereinafter referred to as the "confirmation laboratory").

II. Work Flowchart

Natural cohort flowchart for the evaluation are as follows:

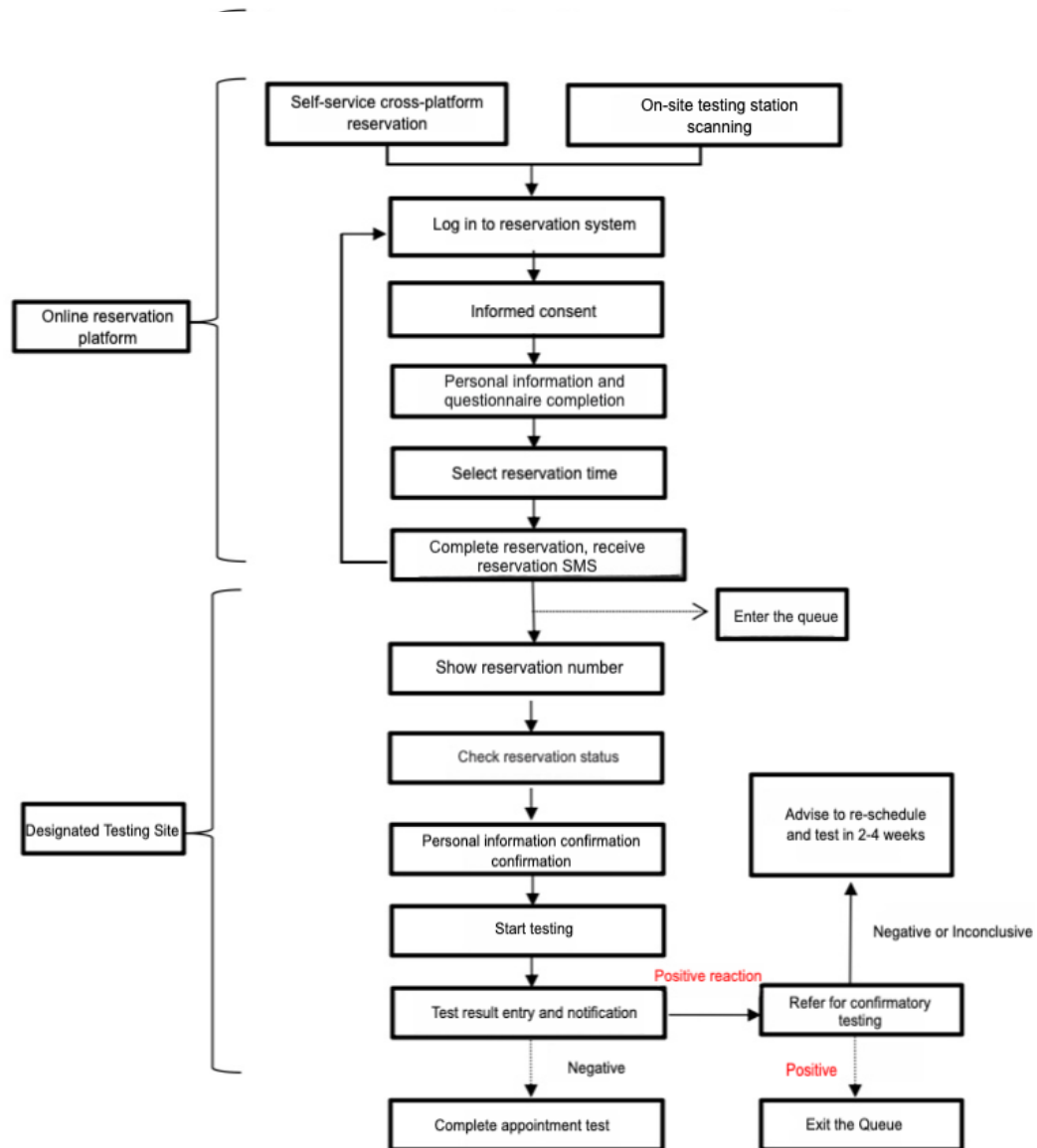


Figure 1: Cohort Flowchart

III. On-site task allocation and teamwork

1. Responsibilities of the Municipal CDC Project Team

(1) Organize personnel from project sites and confirmation laboratories within the city to assist the national research team in conducting project training.

(2) Carry out data collection, reporting, feedback, and coordination of workflow and communications.

(3) Organize training on the online appointment and testing information system for project sites within the city, and assist in establishing and maintaining the natural cohort.

(4) Communicate regularly with the national project office to carry out quality control and management of data collection for the city's natural cohort.

2. Responsibilities of Project Sites

(1) Each project site shall be staffed with one medical personnel or MSM community volunteer during working hours.

(2) A dedicated computer shall be provided.

3. Responsibilities of the Confirmation Laboratory

Work related to individuals with an initially reactive HIV screening result shall proceed according to the laboratory standard procedures.

IV. Natural Cohort Construction

1. Training on the Appointment and Testing Information System

Technical staff from the appointment and testing system platform will conduct training for doctors at testing points and group volunteers.

2. MSM Population Appointment System Login

(1) The MSM population accesses the appointment and testing system via social platforms, Weibo, WeChat, or other online platforms. They can search for the nearest HIV testing facility

to schedule an appointment, confirm the time and location. Individuals who visit the testing site without a prior appointment can log in to the appointment system by scanning a reserved code at the testing site to fill in the required information.

(2) Informed Consent

The platform automatically displays an informed consent form, which explains the content of the survey and emphasizes the confidentiality and safety of the testing process. After reading the form, participants must click "Agree" to proceed.

(3) Personal Information and Questionnaire Completion

After providing informed consent, participants use their mobile phones to fill in personal information and a basic questionnaire. They then verify the appointment time and location, submit the information to complete the appointment, receive an SMS notification confirming the appointment, and obtain an appointment number.

3. Appointment Verification and On-Site Guidance

(1) Investigators at the testing site are responsible for checking participants' appointment SMS, reviewing their personal information and questionnaire completion. For participants without prior appointments, investigators guide them to complete the online appointment on-site.

(2) Investigator Assessment of Eligibility

Investigators determine whether participants meet the inclusion criteria. Participants must be voluntary counseling and testing individuals registered on the appointment and testing platform in the study area between Feb.1, 2019, and Jan.31, 2021. Inclusion criteria: aged 18 or above; have engaged in male-to-male sexual behavior (anal or oral intercourse); voluntarily

participate in the survey and sign the informed consent form. Eligible participants proceed to the next step.

(3) Personal Information Confirmation

Before testing, staff verify the accuracy of participants' information and the completeness of the online questionnaire. Refusal to participate in the online questionnaire does not affect the participant's eligibility to receive normal offline testing services.

4. Preliminary Screening Test

On-site HIV rapid testing or blood sample collection for testing is conducted. For those with negative preliminary screening results, inform them of the next testing time and encourage follow-up testing. For those with positive preliminary screening results, provide post-test counseling, collect venous blood for confirmation laboratory testing, or advise them to visit the local CDC for confirmatory testing.

5. Data Management

Investigators enter the test results into the appointment platform information system. For details, refer to the user manual of the appointment platform information system online.

VI. Supervision and Quality Control

The National Center for AIDS/STD Control and Prevention (China CDC) and provincial CDCs will strengthen on-site supervision of project teams at municipal CDCs, HIV confirmation laboratories, and project sites. The municipal CDC project teams and HIV confirmation laboratories will enhance personnel training at project sites, conduct random checks on testing quality, and supervise documentation standardization, ensuring timely verification of reported data and consistency between submitted samples and original records. Specific quality control evaluation indicators are as follows:

1. Monthly/Quarterly/Annual Cohort Enrollment Rate:

Number of individuals enrolled in the cohort / Number of local Blued account users. Specific target levels will be determined based on actual conditions.

2. Cohort Matching Rate:

Number of individuals successfully matched before and after cohort coding within six months / Number of individuals in the cohort. Specific target levels will be determined based on actual conditions.

Appendix 1. Informed Consent Form for MSM Population Health Survey (For Dating App Appointment-Based Testing Platform)

1. Survey Introduction

Hello! The National Center for AIDS/STD Control and Prevention (China CDC) is conducting a survey on the incidence of new HIV infections among men who have sex with men (MSM) through dating app appointment-based testing platforms in select cities. We are staff involved in this project. We now invite you to participate in a survey, which includes a questionnaire and an HIV rapid test. The purpose is to understand the health status of the MSM community in our city, thereby improving health services for this population.

2. Survey Content

The questionnaire covers general personal information, HIV testing history, sexual behaviors, healthcare-seeking, and sexually transmitted disease status, and will take approximately 15 minutes to complete via the "Happy Testing" platform (computer/mobile device). For the HIV rapid test, we will collect a fingertip blood sample, oral mucosal transudate, or venous blood. We strictly adhere to operational procedures and will inform you of the results as soon as possible.

3. Confidentiality

All information related to your participation in the survey will be kept strictly confidential. The questionnaire is anonymous, and the form containing contact information is stored separately from the questionnaire under the supervision of designated personnel. We will not disclose your privacy or personal information, and unauthorized individuals will not have access to any research data or information. Research institutions and the dating platform will apply strict de-identification measures to any personal information included in research publications or result descriptions.

4. Important Notes

This survey provides an opportunity for you to learn about your health status and receive professional consultation and support. However, some questions in the survey may cause discomfort, and blood collection may cause mild discomfort. If your test result is positive, you may experience worry or anxiety.

Upon completion of the survey, we will provide you with health education materials and free condoms. If your test result is positive, the CDC will offer follow-up services and information on treatment options.

5. Other Information

Participation in this survey is entirely voluntary. If you have any questions regarding this survey, you may contact the local CDC project lead:

(Name) (Organization) (Contact Number)

(Address)

If you have understood the above information and agree to participate in this survey, please sign your name (or pseudonym) and the date on the lines below:

Participant Signature: _____ Date: _____ Year ____ Month ____ Day

Investigator Signature: _____ Date: _____ Year ____ Month ____ Day