Utility evaluation of Point-of-Care Tests in Non-Clinical Settings for the Screening of HIV and Syphilis in Men Who Have Sex with Men

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WHO initiative on STI POCT

World Health Organization Point-Of-Care Diagnostics Evaluation Scheme for Sexually Transmitted Infections (STI)

- **Overall objective:** to provide advice to WHO Member States and other relevant public health institutions on the performance and operational characteristics of commercially available STI diagnostic tests that can be used at the point-of-care.

- Comprises of three types of POCT evaluations:
  - Laboratory-based evaluations. Aim: providing data on the analytical performance of POCTs.
  - Clinic-based evaluation, aimed to determaine test performance when the test is performed by clinical personal who are not trained laboratory technicians.
  - **Non-clinical based assessment of the utility of POCTs in non-clinical settings, mainly CBVCTs.**
    - **(MSM – HIV/Syphilis) COBATEST network**

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Global Health Strategy STIs 2016-2021

World Health Organization

JUNE 2016

GLOBAL HEALTH SECTOR STRATEGY ON

SEXUALLY TRANSMITTED INFECTIONS 2016–2021

TOWARDS ENDING STIs

VISION

Zero new infections, zero sexually transmitted infection-related complications and deaths, and zero discrimination in a world where everybody has free and easy access to prevention and treatment services for sexually transmitted infections, resulting in people able to live long and healthy lives.

GOAL

Ending sexually transmitted infection epidemics as major public health concerns.[11]

Global Health Strategy STIs 2016-2021 (2)

OPTIMIZE SEXUALLY TRANSMITTED INFECTION DIAGNOSTICS

New and improved diagnostics technologies, strategies and approaches would lead to earlier and more accurate diagnosis, and strengthened patient monitoring.
A major barrier to advancing sexually transmitted infection control and prevention is the lack of reliable, low-cost, point-of-care tests. There are several opportunities for innovation.

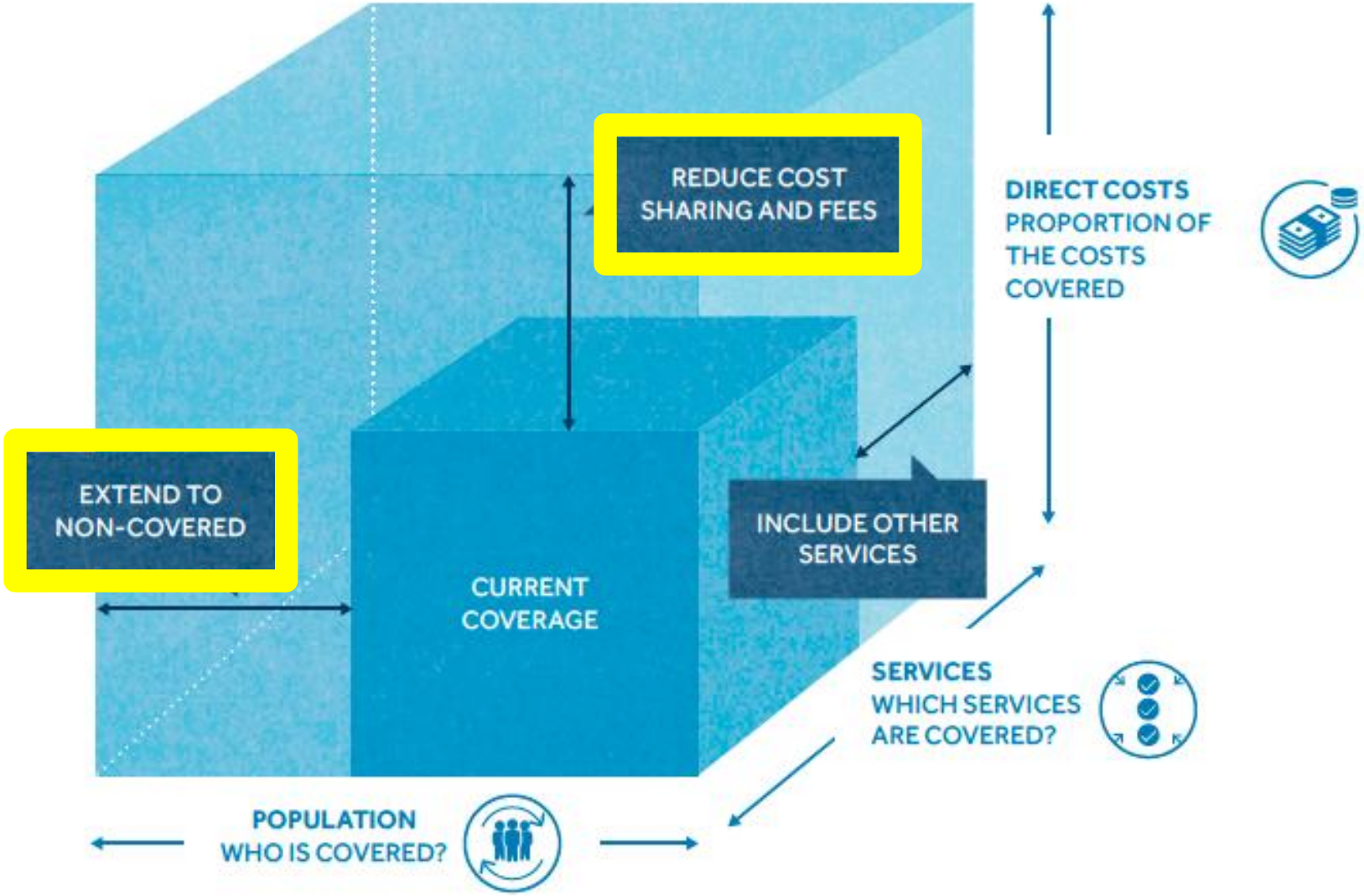
Global Health Strategy STIs 2016-2021 (3)

PRIORITY ACTIONS FOR WHO

Develop and support public–private partnerships to catalyse the development of new technologies, in particular point-of-care testing, multiplex platforms and the development of effective microbicides to prevent HIV and other sexually transmitted infections acquisition; and new treatment options.

Validation and standardization of innovative technologies and approaches, including: new and existing diagnostic technologies and operational research in implementing point-of-care tests for sexually transmitted infection screening; dissemination of best practices describing service delivery models; guidance to countries on creating an environment that is supportive of innovation; ensuring access to affordable point-of-care tests for sexually transmitted infections, particularly in low- and middle-income countries.

Global Health Strategy STIs 2016-2021 (4)



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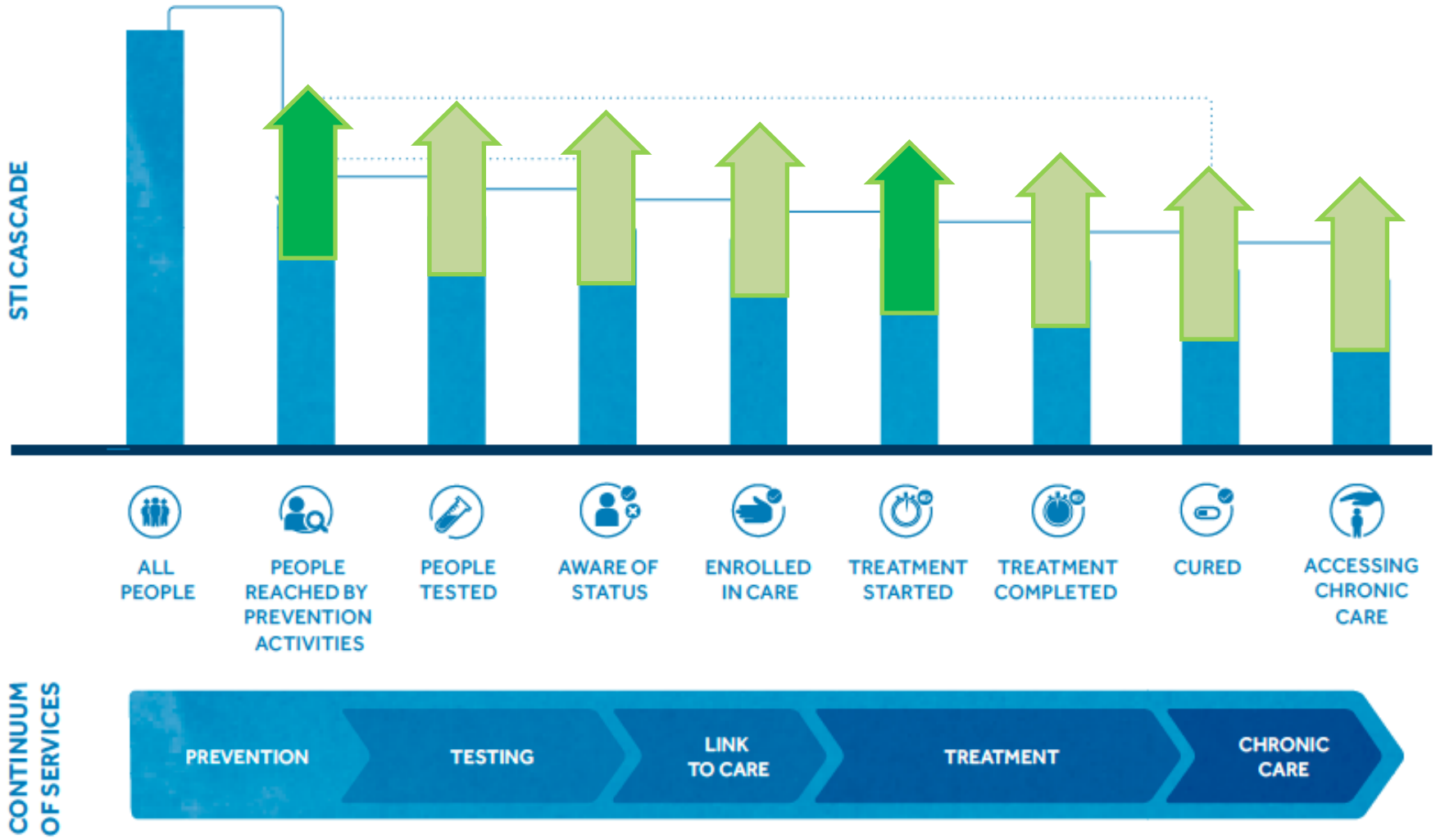


WHO/RHR STI POCT INITIATIVE

World Health Organization

Advancing STI control and prevention through new innovations for STI testing technology: Integrated Point-Of-Care Tests for Sexually Transmitted Infections.

Overall goal:
To support and facilitate universal access to high-quality STI-testing through the development and implementation of high-quality, low-cost POCTs for STIs.

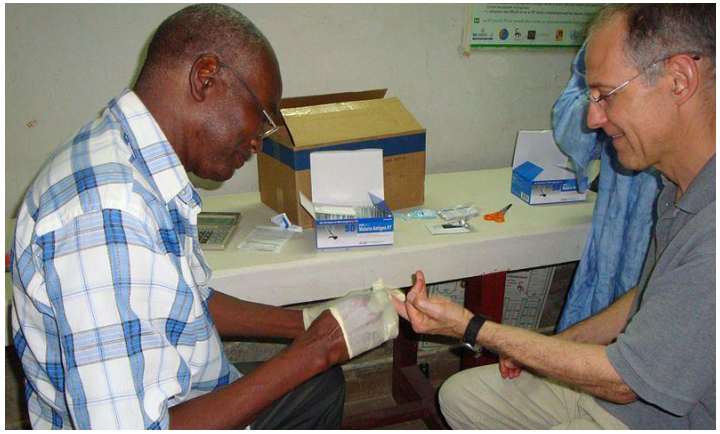
✓Research

✓Guidelines

✓Technical assistance

Promote standardized high quality laboratory, clinic-based and utility evaluations

- Priority setting: STIs and populations
- Study protocols for laboratory, clinic-based and utility evaluations
- evaluating
  - sensitivity and specificity
  - predictive values
  - optimal operational characteristics
- sample sets
  - high and low prevalence
  - variety of populations
  - screening for asymptomatic STIs and case management



POCT Initiative products

Systematic reviews

-> Landscape analysis of STI POCTs

-> Technical consultations (2014-2015)

-> Target Product Profiles

-> Core protocols evaluation studies

Available on public website

http://www.who.int/reproductivehealth/topics/rtis/pocts/en/

Core protocols evaluation studies

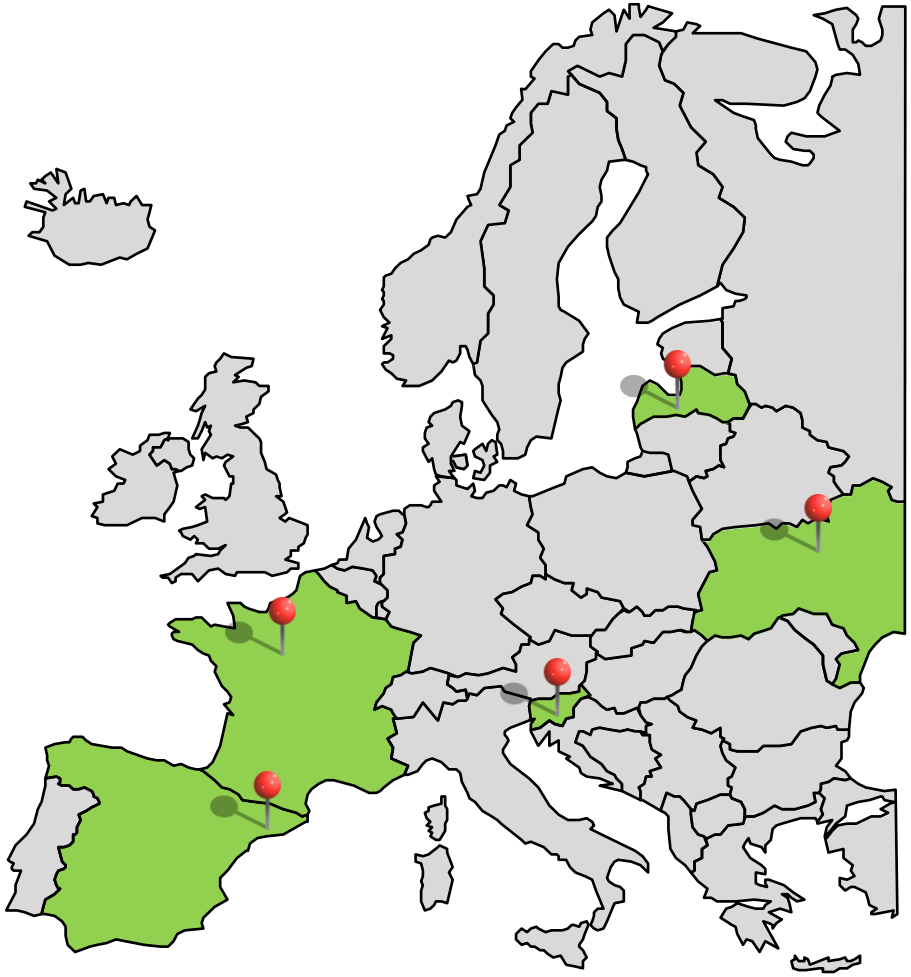
Validation	Population	STI	Test
Laboratory-based (performance)		Ng Ct Tv	
Clinic-based (performance & operational characteristics)	ANC (screening)	HIV/syphilis	Whole blood
	MSM & SW (screening)	HIV/syphilis	Whole blood
	Women with vaginal discharge (case management)	Ng Ct Tv	Vaginal (cervical) swab
	Women at high risk (screening)	Ng Ct Tv	Vaginal (cervical) swab
	MSM (screening)	CT NG	Urine (+pharyngeal & rectal swab)
Non-clinic based (utility & operational characteristics)	MSM	HIV/syphilis	

WHO protocols utility evaluations HIV/syphilis

5 participant sites:

- Gais Positius; Barcelona, Spain
- Legebitra; Ljubljana, Solvenia.
- Baltic HIV Association; Riga, Latvia.
- Alliance Global, Kiev, Ukraine.
- HF Prévention, Paris, France.

Coordinator centre: CEEISCAT



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Objectives

- **Aim:** to assess the utility and operational characteristics of POCTs for the dual screening of HIV/syphilis in men who have sex with men (MSM), who seek or receive dual testing in non-clinical settings.

- **Specific objective:** to evaluate the feasibility of introducing SD BIOLINE HIV/Syphilis Duo (Alere) and DPP® HIV-Syphilis Assay (Chembio) by assessing the acceptability and usability of performing both tests among MSM CBVCT service users and providers and to assess the operational characteristics and compare them, if possible, with the tests that are performed routinely by the CBVCTs.

Feasibility

Feasibility: process in which dual HIV/syphilis POCTs are deployed to CBVCT providers, leading to their acceptability and usability.

Divided into 2 interrelated domains:

- **Acceptability** comprises positive perceptions, beliefs, and attitudes towards dual HIV/syphilis POTCs among users and providers.
- **Usability** refers to the actions taken by the providers to apply the tool and its results to achieve specified outcomes, while among users refers to the actions taken to have the tests performed on themselves believing that the test is accurate and convenient.

If acceptability and usability are high among both providers and users, then implementation is feasible.

Feasibility

CBVCT providers

- These two domains, acceptability and usability, have been further broken down into 6 sub-domains:
  - Learnability
  - Willingness
  - Suitability
  - Satisfaction
  - efficacy
  - effectiveness

CBVCT users

- These two domains have been further broken down into 3 sub-domains:
  - Willingness
  - Suitability
  - Satisfaction

Study participants

- *Inclusion Criteria:*

  The target populations for this HIV-syphilis POCT evaluation are MSM. According to the UNAIDS Action Framework, the term 'men who have sex with men' is used to describe those males who have sex with other males, regardless of whether or not they have sex with women or have a personal or social identity associated with that behaviour, such as being 'gay' or 'bisexual'.

- *Exclusion criteria:*
  1. CBVCTs users who are not MSM
  2. CBVCTs users who are younger than 18 years old
  3. MSM, 18 years old or older who refuse to give written consent.

- There is no mention of transgender persons in this protocol for the utility validation of dual POCTs for the screening of HIV and syphilis, because there is no consolidated clinical definition of what constitutes a transgender person.

Sampling size calculations

Sample size for tested individuals

- Baltic HIV Association); Riga, Latvia: **150 participants**
- Gais Positius (GP); Barcelona, Spain. **300 participants**
- Legebitra Ljubljana, Solvenia. **300 participants**
- Alliance Global, Kiev, Ukraine. **300 participants**
- HF Prévention , Paris, France. **300 participants**

- In total for the five sites a total of **1,350 participants** will be recruited.

Sample size for providers

At least the 75% of the providers from the CBVTC service, who received the training and performed the dual POCTs for the screening of HIV and syphilis, answer the feasibility questionnaire.

Participants recruitment

Participants recruitment

Consecutive MSM presenting at the evaluation will be informed about the study by CBVCT provider 1 — **Provider 1**

Provider 1 will perform the CBVCT's routine tests — **Provider 1**

If the person is interested in participating (pre-consent), CBVCT provider 2 will evaluate whether he fits the inclusion criteria. — **Provider 2**

If the potential participant fits the criteria and agrees to participate in the study, the CBVCT provider 2 will take final consent — **Provider 2**

CBVCT provider 2 will perform the dual tests. — **Provider 2**

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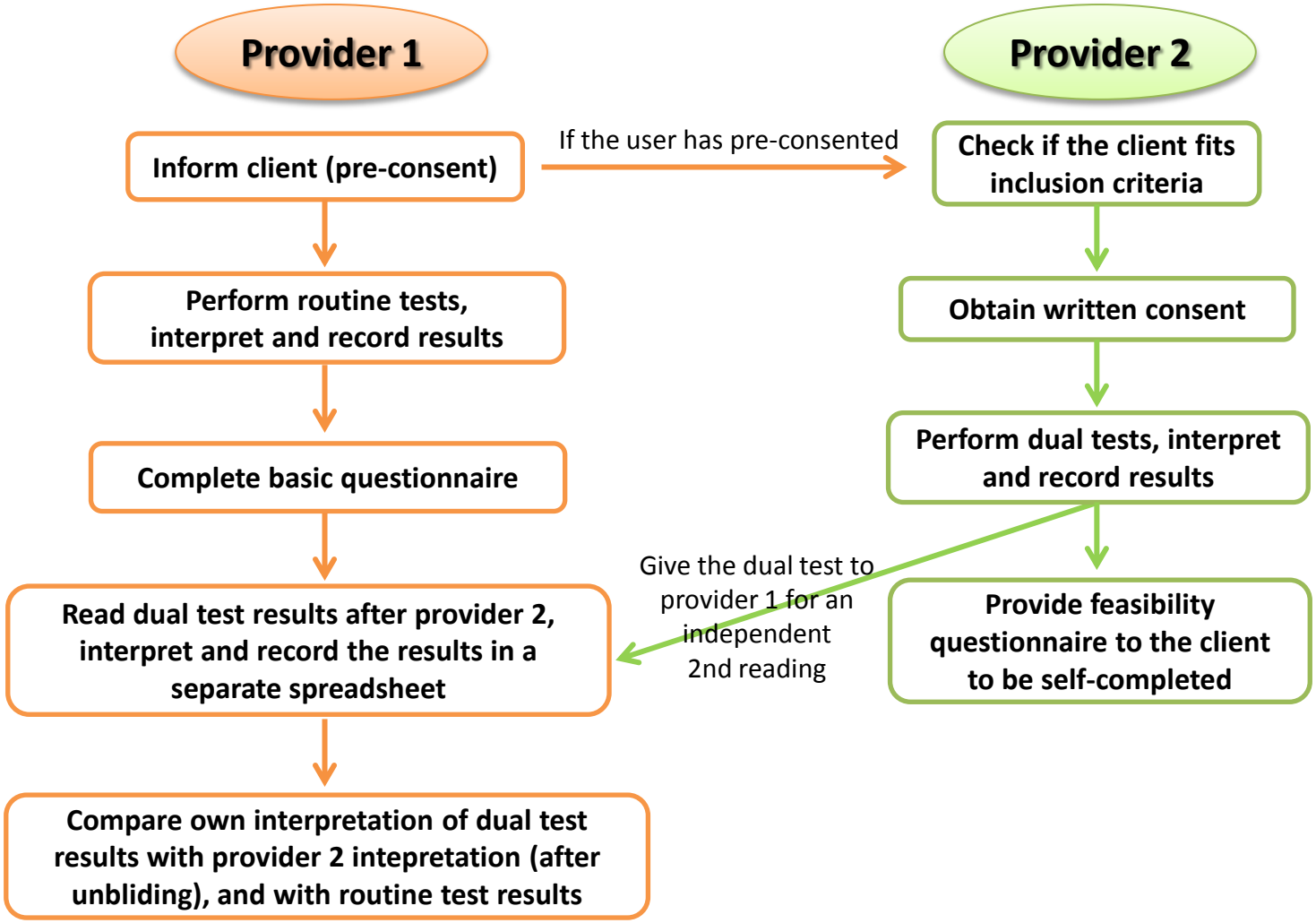
Admission procedures



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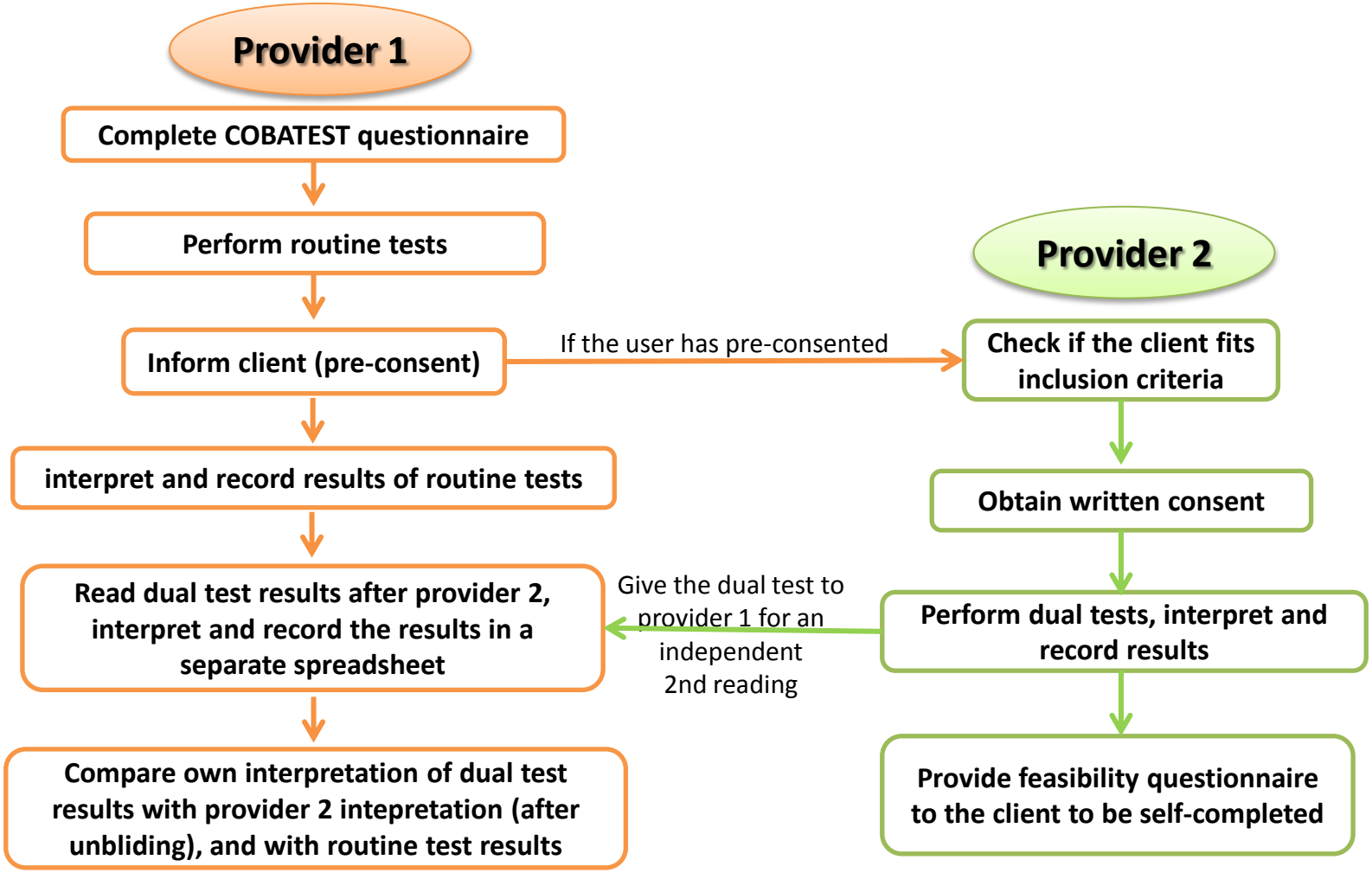

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Study instruments

- Appendix 1. Informed consent
- Appendix 2. Basic questionnaire (to be piloted)
- Appendix 3. Feasibility questionnaire for the CBVCT providers
- Appendix 4. Feasibility questionnaire for the CBVCT users