PROTOCOL OF THE

CBVCT SERVICES NETWORK

December 2012

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1. Introduction

Early diagnosis of HIV infection is essential to decrease mortality, morbidity and transmission rates, allow counselling and assess suitability for treatment. The Community-based voluntary counselling and testing (CBVCT) services are commonly recognized as a good model to improve access to most-at-risk populations (MARP) by promoting its early HIV diagnosis and linkage to care. These centres are in excellent position to improve all aspects of the HIV testing and counselling for those vulnerable and hard to reach [1-4]. Most of the European countries have universal access to health care. Nevertheless, most of the vulnerable groups, such as IDUs, MSM and migrants, because of lack of risk perception, marginality, stigma or illegality, do not have active seeking behaviours for HIV testing or face important barriers to testing within the formal health care system.

The European project co-funded by the Executive Agency for Health and Consumers (EAHC), "HIV community-based testing practices in Europe" (HIV-COBATEST) (Grant Agreement N° 2009 12 11) aims to promote early diagnosis of HIV infection in Europe by improving the implementation and evaluation of community-based testing practices. This objective has been highlighted as well in the European public health agenda [5]. The European Commission has included access to HIV testing as a priority in their "Community Action in the Field of Public Health Work Plan 2009" [6]. Several proposals and actions related to HIV testing have been conducted or are currently being conducted in Europe: the expert meeting held in Stockholm on January 2008, organised by European Centre for Disease Prevention (ECDC) and the International Centre for Reproductive Health (ICRH); Ghent University, produced the report: "HIV testing in Europe: from policies to effectiveness" [7], addressing the plan of action for the surveys on testing and counselling practices.

The HIV-COBATEST project will contribute to the creation of a network of CBVCT that will monitor and evaluate HIV testing activity and will conduct operational research.

In 1994, in Catalonia a project to collect epidemiological information of people tested in VCTs started. Since then, a CBVCT network in Catalonia has been consolidated (currently comprised by 12 CBVCT) that offer voluntary, free, anonymous and confidential HIV testing, together with pre-test and post-test counselling. Data on sociodemographic characteristics, reasons for testing, previous HIV test history, measures of HIV risk, hepatitis B and hepatitis C virus infection history and diagnoses of HIV after testing have been systematically collected in each CBVCT. The CBVCT network has allowed providing data about HIV testing activity, to describe epidemiological characteristics of people tested and has laid the bases for evaluating of

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specific interventions, such as the introduction of rapid testing in these centres [8].

To share the best practices between the different CBVCT of the network across Europe will improve these services, helping to get the objective of universal access to HIV testing and counselling. To guide the future actions, to perform monitoring and evaluation of these practices is needed.

To share a common data collection instrument and a common data base will allow the analysis of global data and the comparison of data between the different CBVCT.

The results obtained in the HIV-COBATEST project could be used by European stakeholders to improve the implementation of CBVCT, and strengthen capacity in the European countries, improving access to testing, early diagnosis and care for hard-to reach Groups.

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2. Network objectives:

2.1. Purpose

To promote HIV testing and linkage to care and treatment by means of consolidating a European network of CBVCT services using similar data collection instruments and procedures.

2.2. Objectives

- **To develop and implement standardized questionnaires and procedures for monitoring and evaluation of CBVCT activity.**
  - To field test the CBVCT core and optional indicators to monitor and evaluate CBVCT testing activity (developed in the COBATEST project WP6).

- **To evaluate the potential impact of CBVCT services in the improvement of HIV early diagnosis and access to treatment.**
  - **To describe and monitor the HIV testing activity and practices of CBVCT.**
    To reach this objective, the information related to the number of clients tested for HIV, the number of clients with a reactive test and the number of clients with a counselling session have to be collected.

  - **To describe and monitor epidemiological profile of people tested for HIV in CBVCT.** To reach this objective, CBVCT services have to collect some information about their clients: transmission group, age, gender, HIV testing history, risk behaviour, etc.

  - **To estimate the percentage of clients with a reactive test who were confirmed and to estimate the percentage of clients with a positive confirmation who are linked to care.** To reach this objective, CBVCT services have to collect the information related to the confirmation of the clients with a reactive test, and the linkage to care of those positives.

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- **To consolidate a network of CBVCT services in which to perform operational research.**
  - **To assess the acceptability, feasibility and impact of the introduction of oral rapid tests in CBVCT.** This example of operative research is part of HIV-COBATEST project (WP8). Only some of the CBVCT services members of the network will take part of this study. A specific protocol research has been developed for this study.

Objectives to be developed in a second phase:

- **To describe the counselling practices of each CBVCT service**
- **To analyze the acceptability and the feasibility of the Code of Good Practices developed also in COBATEST project (WP5)**

To monitor and evaluate the CBVCT screening activity, the Core Indicators to monitor Voluntary Counselling and testing for HIV developed in the COBATEST project (see annex x) will be used. For all members of the HIV-COBATEST network it will be mandatory to report the monitoring and evaluation data for the core group of indicators (CBVCT1 to CBVCT16) at least once during the HIV-COBATEST Project. All necessary data items for these indicators can be collected at the HIV-COBATEST level, and are included in the common data collection form developed for the network,

To reach some of these objectives it is very important that the participating CBVCT services have a unique Client Identification Code that ensures the anonymity of the client and also allows the identification of repeat testers. It will allow to eliminate duplicates and to link the information obtained at different visits from the same client and the information of the client received from other services (e.g. HIV testing laboratory). It must to be highlighted that the unique client identification code is very important to improve the service, to allow the CBVCT to count clients tested and not only tests performed.

If some centre doesn't have their own unique coding system can adopt a code suggested by the network, see section 5.2 of this protocol. This suggested code can be used simultaneously with the code usually used in the CBVCT service. For all CBVCT services where to use a unique Client Identification Code will be not possible, some kind of arrangement should be agreed upon. Each case will be directly discussed between the network coordinator and the CBVCT service.

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2.3. Benefits

To become a member of the HIV-COBATEST network will allow them to have the possibility of sharing and applying good practices and capacity building. Sharing a standardized protocol for monitoring and evaluation will allow them to compare their data with other European CBVCT services. The participating CBVCT services will dispose of a website tool to enter their data, and they will have the digitized data available if they want to analyze it. Moreover, they will participate in a research project and they will take profit of all benefits related to the participation in a European initiative, with more visibility and more options to get funding.

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3. CBVCT services participating in the network.

3.1. Local mapping of screening services and recruiting a selected subset

In order to select the CBVCT centres that will become members of the network, a specific questionnaire (see annex 1) has been submitted to all potential CBVCT network members, requesting basic information about their activity and organization.

All CBVCT centres that best fit the criteria for becoming a member of the network will receive a follow-up questionnaire to obtain relevant information about the ability to execute the network protocol.

The topics covered by the initial questionnaire include:

- Organization and functioning of the CBVCT
- Target groups reached
- City and reference area
- HIV testing activity and HIV positives detected by target group
- Counselling
- HIV Test used
- Confirmation of reactive tests (in case of rapid test)
- Kind of setting where the programme is implemented
- Anonymity
- Referrals to Health care facility of those with a HIV positive result
- Information collected
- Instrument to collect information
- Information digitized

The CBVCT definition agreed by all partners in COBATEST project was included in the questionnaire, asking to the CBVCTs if their service can be considered a CBVCT according our definition:

> "CBVCT is any programme or service that offer HIV counselling and testing on a voluntary basis outside formal health facilities and that has been designed to target specific groups of the population most at risk and is clearly adapted for and accessible to those communities. Moreover, these services should ensure the active participation of the community with the involvement of community representatives either in planning or implementing HIV testing interventions and strategies."

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3.2. Inclusion criteria

The CBVCT services candidates will be evaluated upon topics covered in the CBVCT selection questionnaires.

The inclusion criteria established to select the CBVCT services for the network are:

- To fit the CBVCT definition
- To accept the network's protocol and to be able to achieve the objectives of the network
- To agree to collect data on agreed list of variables.
- To agree to fill the CBVCT core and optional indicators to monitor and evaluate CBVCT testing activity (developed in the COBATEST project WP6)
- To have a referral system to health care for those detected positive
- To have financial support that ensures continuity of the screening activity of the centre during the HIV COBATEST project.

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4. Management Plan

4.1. Network structure

The COBATEST structure will be used for the CBVCT network. The network will be managed following the HIV-COBATEST management structure.

The network structure will be as follows:

- Principal investigator (Jordi Casabona)
- 2 project managers (Laura Fernàndez and Cristina Agustí)
- Steering committee: PI, Field Coordinators, ULSS20 (Italy): Luigi Bertinato; Association AIDES (France): JEAN-MARIE LE GALL; STOP AIDS (Denmark): Per Slaaen Kaye; AIDS-Hilfe (Germany): Michael Wurm; Projecte dels NOMS-Hispanosida (Spain): Félix Pérez; Institute of Sexology (Czech Republic): Ivo Prochazka; Institute of Public Health of the Republic of Slovenia: Irena Klavs; National AIDS Centre of Poland: Anna Marzec.
- CBVCT services members

4.1.1. Principal Investigator

The network Principal Investigator (PI) is the leader of the network and chairs the Steering Committee (SC) and:

- Coordinates and facilitates SC responsibilities.
- Schedules and chairs regular and special meetings and conferences calls of the SC and communicates the decisions and action items to network members.
- Ensures the efficient development and implementation of the network research agenda by the SC.

The network PI works in coordination with the 2 project manager of the network.

4.1.2. Steering Committee.

A Project Steering Committee (SC) will be established. The SC is composed of one duly authorised representative of each CBVCT service from the network and the 2 field coordinators of the network. The SC is chaired by the Principal Investigator of the project (Jordi Casabona) or its deputy (Laura Ferrnàndez or Cristina Agustí). Each representative has a deputy. The deputy can participate in SC meetings in replacement of the authorised representative or together with the latter. Authorised representatives and deputies shall both receive notifications of SC meetings, agendas, minutes and

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any other communications concerning the SC. Each Beneficiary has the right to invite to the SC meetings the members of staff whom they consider appropriate to invite in consideration of the topics in the agenda. Independently from the number of representatives participating in a meeting, each Beneficiary shall have the right to one and only one vote.

After having informed the others in writing, each CBVCT shall have the right to replace its representative and/or its deputy, although it shall use all reasonable endeavours to maintain the continuity of its representation.

The SC shall decide all fundamental questions and issues regarding cooperation during the Project implementation and ensure the evaluation of the project activities.

4.1.3. Working group.

A working group has been established to work in the protocol, in the list of variables to be collected and in the data collection form,

The working group will work also in the analysis of the data collected and in the development of reports.

The working group will work under the direction of the PI and the Steering Committee.

Members of the working group: the CBVCT core and optional indicators to monitor and evaluate CBVCT testing activity (developed in the COBATEST project WP6)

- Jordi Casabona (CEEISCAT, Catalonia)
- Laura Fernàndez (CEEISCAT, Catalonia)
- Cristina Agustí (CEEISCAT, Catalonia)
- Irena Klavs (Institute of Public Health of the Republic of Slovenia)
- Daniela Rojas (AIDES, France)
- Per Slaaen Kaye (Stop-AIDS, Denmark)
- Ricardo Fuertes (Checpoint LX, Portugal)
- Galina Musat (ARAS, Romania)
- Maria Meliou (PRAKSIS, Greece)
- Niki Voudouri (PRAKSIS, Greece)

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4.2. Decision making

All decisions concerning the project implementation are taken by the SC by voting. In voting, each member of SC shall have one vote. Only members of SC attending the meeting may vote. The chair will have just one vote. In case of a tie, the chair will have the casting vote.

All decisions shall be taken by the majority of the votes of the present member of SC.

Any decision requiring a vote at a SC meeting must be identified as such on the pre-meeting agenda, unless there is unanimous agreement to vote on a decision at that meeting and all SC members are present or represented.

Any decision required or permitted to be taken by the SC as set out above may be taken:

(i) in meetings,

(ii) via teleconference, and/or

(iii) via email

Provided it is confirmed in writing by the representatives of the SC members having not less than the minimum number of votes that would be necessary to take such a decision at a meeting at which all SC members entitled to vote on such a decision were represented and voted.

4.3. Establishing information circuits and the organizational aspects of the network.

Each participating CBVCT service will be in charge of monitoring data collection of its own service. They have to collect all the relevant data items of each client tested (which will be provided in the variable list). A consensus data collection form is provided to collect all this data of each client tested and a common application for data entry will be accessible from the COBATEST website. The project coordination will send a login and a password to access to the web based tool for data entry. For those CVBCT services that want to use the data collection form but are not able to fill it completely, a core group of questions of the data collection form will be defined, allowing those CBVCT services to use also the data collection form and the application for data entry.

Alternatively, for those CBVCT services that are not able to use the consensus data collection form, and use their own data entry system CBVCT site could submit a minimum common data to the common HIV COBATEST data set according to the data file specification that will be provided by the HIV-COBATEST coordinator.

For those CBVCT services that are not able to neither use the consensus data collection form nor to provide the data set according the data file specification, have to provide at least the CBVCT core indicators to monitor and evaluate CBVCT testing activity (developed in the COBATEST project WP6),

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completing online the form that will be available on the HIV-COBATEST website.

One data analysis is planned in the first semester of 2013. Each CBVCT service participating in the network should have entered the data corresponding to the established period of time. After this initial period, the frequency of data analysis would be once a year.

4.4. Network communication.

Internal communication among the network coordination and the participating CBVCT services will be made by weekly or monthly contacts by email, telephone conferences and fax.

A mailing list to exchange documents with CBVCT partners of the network will be developed and the HIV-COBATEST project website (www.cobatest.org) will be used to share information and documents between members.

4.5. Ensuring the application of the code of good practices.

One of the deliverables of the HIV-COBATEST project is a Code of Good Practices in the implementation of CBVCT programmes and services. The final version of the Code will be ready in the first trimester of 2013. The objectives of this document are: to identify and describe CBVCT practices in Europe, to facilitate implementation and development of CBVCT programs, to inspire organizational change, to provide a framework for collaborative partnerships, to inform about the development, implementation and evaluation of evidence-based programs and advocacy, and to help to monitor and improve the quality of CBVCT programs.

All CBVCT members are strongly encouraged to subscribe the code of good practices. In this way all CBVCT network members will have a shared vision of principles for good practices in HIV testing activity.

4.6. Human subjects considerations (ethical issues, confidentiality, informed consent process, …)

It is important to remark that most CBVCT services don't make a diagnosis of HIV, because, in fact, most of them do not have physicians performing the tests, but they do an HIV screening, and if reactive the client is referred to the health system, where physicians will apply the appropriate testing algorithm for the diagnosis of HIV. Each country follows the testing algorithm according to their national testing guidelines, which, at the same time, are based on the recommendations of UNAID-WHO-CDC testing guidelines.

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A referral system in each participating CBVCT service will be ensured, so the availability of ARV treatment for those diagnosed HIV positive will be warranted.

Regarding the rest of ethical issues: confidentiality and informed consent process; all CBVCT services members are strongly encouraged to subscribe the code of good practices produced in the context of the HIV-COBATEST project.

4.7. Letter of agreement between partners.

All CBVCT services members of the network will sign a letter of agreement with the Network Coordination, with the purpose of specifying the distribution of tasks among the members and the roles and responsibilities of each one.

4.8. Publications policy.

Global data

Peer-reviewed articles on global data have to be announced and authorized by the SC. The SC must be given the opportunity to provide critical input or revision of the paper, by being asked to read and contribute to any draft paper.

A list of publications in progress will be maintained by the Main Partner.

Significant contribution to the design and implementation of HIV-COBATEST Project and the CBVCT network warrants authorship on papers written from the global data. This was supplied by 3 people: Jordi Casabona (PI of the Project), Cristina Agustí and Laura Fernàndez (project mamgers). These 3 people warrant authorship on any paper from the global data.

The following authorship is proposed:

- Up to 3 representatives of the leaders of the paper, up to 3 representatives of the Main Partner, the Writing Committee or the Working Group and the HIV-COBATEST project study group.

4.9. Addition of new sites on the ongoing network.

Increasing number of CBVCT sites enrolled in the network and a major geographical coverage is expected in the future, increasing its contribution to the global surveillance of HIV testing.

The inclusion of each new member in the network will be decided by the SC. The same procedures described in 3.1 section will be followed in order to include new members in the network: a specific

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questionnaire will be sent to candidate CBVCT centre in order to obtain relevant information. The SC will evaluate the CBVCT candidate upon topics covered in the CBVCT selection questionnaire.

4.10. Operational research.

One of the main objectives of the network is to consolidate a structure of CBVCT services in which to perform operational research. In the WP8 of the COBATEST project a first operational research study will be performed. The aim of this study will be to assess the acceptability, feasibility and impact of introducing oral rapid test technologies at community-based VCT.

To provide new operational research ideas are encouraged in the network. Concepts may be generated by network SC or by CBVCT centres members of the network. The scientific agenda of the network will be decided by the SC. All study concept plans developed within the Network must be reviewed and approved by the SC.

4.11. Future of the network. Sustainability strategy after the end of the EAHC co-funding.

In order to consolidate the network, external funding is being sought. Financial support from Gilead Science SL has been received with the aim to expand the HIV-COBATEST activities adding new partners to become members of the network.

It is planned to prepare and to submit another proposal to European Commission (Call 2013) with some new ideas of operational research in the network, pending on the topics of the Call.

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5. Methodology

5.1. Data collection

All participating CBVCT services will collect 2 different types of data:

- Data about each client tested: To collect these data, there will be a consensus data collection form and a web based tool for data entry. A core group of questions of the data collection form will be defined, for those CBVCT services that want to use the data collection form but are not able to full fill the entire questionnaire. Alternatively variables list and data file specification will be provided to those CBVCT services that will be not able to use the consensus data collection form and use their own data entry system so that they will be able to submit their CBVCT site data to the common HIV VOBATEST dataset.

- Indicators for monitoring and evaluation of CBVCT activities: A report form for sending the results of monitoring and evaluation to HIV-COBATEST coordinator will be available in the HIV-COBATEST website. For those CBVCT services that use the data collection form and for those that send the disaggregated data according to the variable list and data file specifications, the completion of the indicators form will not be necessary as the indicators will be computed automatically.

5.2. Client Identification Code

The client identification code has to be unique, it has to ensure the anonymity of the client and it also has to allow the identification of repeat testers in order to eliminate duplicates. On the other hand it has to allow linking the information obtained at different visits from the same client and the information of the client received from other services (e.g. HIV testing laboratory).

The Client Identification Code suggested for the network is:

- **Gender (0 male, 1 female), month (2 digits), day (2 digits) and year of birth (4 digits), nº of older brothers, nº of older sisters, initial letter of mother's first name.**

This code can be used simultaneously with the code used usually in the CBVCT. If some centre doesn't have a unique code can adopt the code suggested in the network. For all CBVCT services where to use a unique Client Identification Code will be not possible, some kind of arrangement should be agreed upon. Each case will be directly discussed between the network coordinator and the CBVCT service.

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5.3. Consensus data collection form.

A consensus data collection form will be developed to collect data about each client tested. An early draft has been developed by the WP7 leader. The variables included in the data collection form were discussed during at the Workshop on the European Network of CBVCT services in Barcelona on May 25th 2012.

After the Workshop, the draft protocol and the questionnaire has been discussed among the members of the WP7 working group.

Each partner will be in charge of the translation of the protocol and the questionnaires (Spanish, Catalan, Italian, French, Danish, German, Slovene, Czech and Polish), if they consider that is necessary.

5.4. Development of a database and a web based tool for data entry.

A web based tool for data entry in the HIV-COBATEST project website will be developed. Each CBVCT centre will have a password to accede to the tool in order to enter data from each questionnaire. Data sent through the tool won't contain personal data identification (an anonymous code will be used) and will be stored in a centralized database. Only the network's coordinators and the Working Group will have access to the whole database. Each CBVCT centre will be only able to visualize and to access to their own data.

5.5. Collection of data about each centre

A questionnaire will be sent to each CBVCT service member of the network to describe their centre. The questionnaire will include questions about the kind of setting, their activities, the kind of test used, the algorithm used for testing, capacity of performing follow-up of all its clients, etc.

5.6. Data analysis and reports.

Periodically data analysis and reports will be performed. During all the period of the HIV-COBATEST project 1 data analysis will be performed.

Statistical analysis of the whole sample will be carried out by WP7 leader, whereas local data analysis could be lead independently by partners accordingly to their specific needs. Stratification according to gender, age and nationality is important at least by patients groups.

Development of periodically reports will be carried out also by the field coordinators, with the WP7 working group. This will continue after the ending date of the HIV-COBATEST project, and then one

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data analysis will be performed per year.

5.7. Indicators for monitoring and evaluation.

CBVCT services that will be part of the network have to integrate the core CBVCT indicators suggested in the document generated in WP6 of COBATEST project.

These indicators will be used to monitor and evaluate the CBVCT service and activity. To collect these indicators the core CBVCT indicators data collection form generated in WP6 will be used (see annex x).

This will be part of the ongoing evaluation process.

The first indicators data collection will be in the first semester of 2013 (January-June). Each CBVCT have to send the indicators data collection form filled to the coordinator of the network. Another data collection will be made before the end of COBATEST project. When COBATEST project ends, then data base sending could be once a year.

All necessary data items for these indicators can be collected at the HIV-COBATEST level, and are included in the common data collection form developed for the network.

5.8. Calendar

- Start collecting data (1st January)
- First deadline to enter data (30th June)
- Report of results (31 August)

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6. References

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HIV TESTING DATA COLLECTION FORM

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Name of the CBVCT site: _____

City of the CBVCT site: _____

Testing site: ☐ CBVCT office ☐ Public venue (pharmacy, library, ...) ☐ Outdoors/Van ☐ Amusement venue (coffe, bar, ...) ☐ Sex work venue ☐ Needle exchange venue ☐ Sauna/sex venue ☐ Other:_____

Date of visit: ☐☐ Day ☐☐ Month ☐☐☐☐ Year

User's unique identifier (used by the CBVCT service): _____

OR

User's unique identifier (COBATEST): ☐ Gender (0 male, 1 female. 2 trangender) ☐☐ Day ☐☐ Month of birth ☐☐☐☐ Year ☐ Nº of older brothers ☐ Nº of older sisters ☐ initial letter of mother's first name

Client's characterisitics data:

Gender: ☐ Male ☐ Female ☐ Transgender

Date of birth ☐☐ Day ☐☐ Month ☐☐☐☐ Year

Foreign national: ☐ Yes → Country of birth: _____ → Year of arrival to this country: *(if migrant)* ☐☐☐☐ Year

☐ No

☐ Don't know

Is the client a: ☐ Resident ☐ Tourist

Municiapality or home town: _____

Reasons for HIV testing: (multiresponse)

☐ **Risk exposition**

- ☐ Unprotected vaginal sex
- ☐ Unprotected anal sex
- ☐ Unprotected oral sex
- ☐ Broken condom
- ☐ Unprotected sex with sex worker
- ☐ My partner has tested positive recently
- ☐ Episode of sharing injection material
- ☐ Other:_____

☐ **For control/screening**

- ☐ My partner asked to me
- ☐ Before dropping using condom with my partner
- ☐ I wish to have a baby
- ☐ Prenatal screening: before delivery
- ☐ Regular control
- ☐ Only to know my health status
- ☐ Other:_____

☐ **Window period in the last test**

☐ **Clinical symptoms**

☐ **Other:** _____

Reasons for come to this CBVCT service to be tested: (multiresponse)

☐ I've come here before ☐ I've seen this CBVCT in a pamphlet ☐ Other:_____

☐ A friend told me about this CBVCT ☐ I've found this CBVCT in internet

Previous HIV tests:

HIV test in the past? ☐ Yes ☐ No ☐ Don't know → Date of last test: ☐☐ Month ☐☐☐☐ Year

Result of last test: ☐ Positive ☐ Negative ☐ Don't know

HIV test in the last 12 months in this CBVCT facility? ☐ Yes ☐ No ☐ Don't know

Risk behaviour/factors:

Sex in the last 12 months with: ☐ men ☐ women ☐ women and men ☐ I haven't had sex ☐ Don't know

Condom use in the last sexual relation with penetration ?	☐ Yes	☐ No	☐ Don't know
Exchange of sex for drugs or money in the last 12 months?	☐ Yes	☐ No	☐ Don't know
STI diagnosed in the last 12 months?	☐ Yes	☐ No	☐ Don't know
Ever in jail?	☐ Yes	☐ No	☐ Don't know

Unprotected sex with penetration in the last 12 months with:

Sex workers:	☐ Yes	☐ No	☐ Don't know
IDU:	☐ Yes	☐ No	☐ Don't know
Known HIV positive partner:	☐ Yes	☐ No	☐ Don't know
MSM:	☐ Yes	☐ No	☐ Don't know

Intravenous drug use? ☐ Yes ☐ No ☐ Don't know → Date of last time: ☐☐ Month ☐☐☐☐ Year

Share of materials of injection in the last 12 months, as:

Syringes or needles?	☐ Yes	☐ No	☐ Don't know
Spoons, filters, water, ...?	☐ Yes	☐ No	☐ Don't know

Pre-test counselling:

Pre-test/pre-result counselling performed? ☐ Yes ☐ No ☐ Don't know

Screening HIV test :

Date of specimen collection: ☐☐ Day ☐☐ Month ☐☐☐☐ Year

Type of test used: ☐ Blood rapid test ☐ Oral rapid test ☐ Conventional blood test (Elisa)

Screening test result: ☐ **Reactive** ☐ **Non reactive**

Did the client receive the screening HIV test result? ☐ Yes ☐ No ☐ Don't know → Date of receiving screening test result: ☐☐ Day ☐☐ Month ☐☐☐☐ Year

Post-test counselling:

Post-test HIV counselling performed? ☐ Yes ☐ No ☐ Don't know

Confirmatory HIV test:

Confirmatory test performed? ☐ Yes ☐ No ☐ Don't know → Date of specimen collection: ☐☐ Day ☐☐ Month ☐☐☐☐ Year

Confirmatory HIV test result: ☐ **Positive** ☐ **Negative** ☐ **Inconclusive**

Did the client receive the confirmatory HIV test result? ☐ Yes ☐ No ☐ Don't know → Date of receiving confirmatory test result: ☐☐ Day ☐☐ Month ☐☐☐☐ Year

Access to health system for those HIV positive:

Patient linked to healthcare system? ☐ Yes ☐ No ☐ Don't know → Date of linkage: : ☐☐ Day ☐☐ Month ☐☐☐☐ Year

First CD4 count result: ---------- → Date of the first CD4 count: ☐☐ Day ☐☐ Month ☐☐☐☐ Year

MODULE B

Syphilis test:

Previous syhpilis diagnosis? ☐ Yes ☐ No ☐ Don't know → Date of last syphilis diagnoses: ☐☐ Day ☐☐ Month ☐☐☐☐ Year

Syphilis test performed? ☐ Yes ☐ No ☐ Don't know → Date of specimen collection: ☐☐ Day ☐☐ Month ☐☐☐☐ Year

Type of test used: ☐ Rapid test ☐ Conventional test

Rapid test result: ☐ **Reactive** / ☐ **Non reactive** → Diagnosis test performed? ☐ Yes → Date of specimen collection: ☐☐ Day ☐☐ Month ☐☐☐☐ Year / ☐ No / ☐ Don't know

Syphilis diagnosis: ☐ **Active infection** ☐ **Serological scar (old or cured infection)** ☐ **Not known**

HCV test:

Previous HCV diagnosis? ☐ Yes ☐ No ☐ Don't know → Date of last HCV diagnoses: ☐☐ Day ☐☐ Month ☐☐☐☐ Year

HCV test performed? ☐ Yes ☐ No ☐ Don't know → Date of specimen collection ☐☐ Day ☐☐ Month ☐☐☐☐ Year

Type of test used: ☐ Rapid oral test ☐ Rapid blood test ☐ Conventional test

Rapid test result: ☐ **Reactive** / ☐ **Non reactive** → HCV RNA test performed? ☐ Yes → Date of specimen collection: ☐☐ Day ☐☐ Month ☐☐☐☐ Year / ☐ No / ☐ Don't know

HCV diagnosis: ☐ **Active infection** ☐ **Serological scar (old or cured infection)** ☐ **Not known**

Hepatitis A and B vaccination:

Vaccination for Hepatitis A (with all required dosis)? ☐ Yes ☐ No ☐ Don't know

Vaccination for Hepatitis B (with all required dosis)? ☐ Yes ☐ No ☐ Don't know

Comments: ----------

ANNEX 2

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Instructions to fill the data collection form:

This data collection form is part of the CBVCT services network developed by the COBATEST project.

Objective:
To provide data on the dynamics of HIV voluntary testing as well as information that describes the demographic characteristics of people who are diagnosed.
The data collection form has to be included in the practice of counselling before and after the performing of the test, and has to be filled by the counsellor or the person who are performing the test to the user.
A core group of questions has been defined. These questions are very important to obtain the minimum basic information to perform the analysis. In the data collection form this questions are marked in a grey colour.

- **Name of the CBVCT:** Name of the CBVCT that perform the test. This question is a core question.
- **City of the CBVCT:** City of the CBVCT that perform the test.
- **Testing site:** The kind of site where the CBVCT service is performing the test.
- **Date of visit:** The date of client visit. This question is a core question.
- **Clients' unique identifier**: This unique identifier is a suggestion for the CBVCT services, to preserve the anonymity of the client, but to allow the identification of repeat testers. This code use the gender (0 male, 1 female, 2 transgender), the date of birth (dd/mm/yyyy), the number of older sisters, the number of older brothers and the initial letter of mother's first name.
- **Clients' unique identifier (used by the CBVCT service):** The identifier used for the CBVCT, used to identify duplicates. If the CBVCT doesn't use a unique identifier for each client, then they have to use the client's unique identifier suggested.

One of the two Unique identifiers has to be indicated (it can be both of them).

Client's characteristics data:

- **Gender:** The gender of the client, male, female or transgender. This question is a core question.
- **Date of birth:** The date of birth of the client in the format dd/mm/yyyy. This question is a core question.
- **Foreign national:** If the client has been born in another country. This question is a core question.
- **Country of birth:** If migrant, the country of birth of the client should be indicated. This question is a core question.
- **Year of arrival to this country:** If migrant, it should be indicated also the year of arrival to the country.
- **Is the client a resident or a tourist:** If migrant, it should be indicated if the client is a resident of a tourist.
- **Municipality or home town:**

Reasons for testing: In this section it should be indicated the reason or reasons of the client to ask for the test. The different options are not excluding, so it can be marked more than one. Is mandatory to indicate one or more of these categories: Risk exposition, For control, Window period* in the last test, Clinical symptoms, or Other. It can be indicated also one of more of the more detailed reasons.
In the case of outreach activities, it can be indicated always the reason "For control/screening".
* *The 'window period' for an antibody test is estimated to be three months after exposure to HIV infection. A negative test at three months will almost always mean a person is not infected with HIV.*

Previous HIV tests: This section refers to if the applicant has been tested previously independent of the currently test results. If that is the case, it is important to specify, if possible, the date of the last time (dd/mm/yyyy), the result of the last test, and if in the last 12 months the client has been tested in the same CBVCT facility. In the section the core questions are: "Have you ever had an HIV test in the past" and the "result of the last test".

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Risk behaviour / factors:

- Information about the sexual behaviour of the client.
  - **Did you have sex in the last 12 months with men, women, women and men, transgender?** This question is a core question.

    If the client hasn't had sex in the last 12 months, it should be indicated.
- **In the last sexual relation with penetration did you use a condom?** The use of the condom during the last sexual relation with penetration independent of the kind of partner. This question is a core question.
- **Have you exchanged sex for drugs or money in the last 12 months?** If the client has practiced commercial sex. This question is a core question. If some CBVCT doesn't want to ask this question, it can be indicated "not know".
- **Have you been diagnosed with a STI in the last 12 months?** If the client had a diagnosed STI during the last 12 months.
- **Have you ever been in jail?** The client has been held in prison ever, independent of time.
- Epidemiological information about the sexual partners of the client: This section refers to the possible sexual partners, stable and / or occasional that the client has or may have had in the last year.
  - **Did you have unprotected sex with penetration in the last 12 months with sex worker?**
  - **Did you have unprotected sex with penetration in the last 12 months with IDU?**
  - **Did you have unprotected sex with penetration in the last 12 months with known HIV positive?**
  - **Did you have unprotected sex with penetration in the last 12 months with MSM?**
- **Have you ever used intravenous drugs?** If the answer referring to consumption is yes, the month and the year of the last consumption have to be indicated (mm/yyyy). It has to be indicated also if the client has shared any injection material in the last 12 months. The question of using intravenous drugs is a core question.. If some CBVCT doesn't want to ask this question, it can be indicated "not know".

Pre-test counselling: This section refers to if the client has received the pre-test counselling*.

**It can be consider a pre-test counselling if at least a shorter pre-test information has been done. The new recommendations advocate moving away from in-depth pre-test counselling towards shorter pre-test information. This should at least cover the benefits of and practical arrangements for the test and its results (ECDC, 2010;.Poljak, Smit, & Ross, 2009; World Health Organization, 2010)*

Screening HIV test: This section refers to the screening HIV testing performed. It has to be indicated the date of the realization of the test (dd/mm/yyyy), the type of test used (if is a blood rapid test, an oral rapid test or the conventional test), the result of the screening test performed, and if the client had received the result, and the date of receiving the result. The marked issues are core questions.

Post-test counselling: This section refers to if the client has received the post-test counselling, independent of the result of the screening test and the confirmation test.

Confirmatory HIV test: This section has to be filled when the screening HIV test performed is reactive, and refers to the confirmation HIV test. It has to be indicated if the confirmatory test was performed, if this is the case, it is important to specify the date of the confirmatory test realization (dd/mm/yyyy), the result of the confirmation test and if the client received the results of the confirmation test, and the date of receiving the results. The marked issues are core questions.

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Access to health system: This section refers to the access to the health system if the HIV reactive test is confirmed. This information might not be available at the CBVCT service, but some CBVCT services could obtain such information from local health care services to which the clients who tested positive were referred to or from the national HIV surveillance system.

- **Patient linked to health care system?** Linkage to health care is defined as entry into health care or follow-up by an HIV specialist or in an HIV unit after HIV diagnosis at CBVCT facility and the linkage was facilitated by the CBVCT facility.
- **Date of linkage:** the date of entry into health care or follow-up by an HIV specialist or in an HIV unit (dd/mm/yyyy).
- **First CD4 count result:** the first CD4 counts at entry into health care or follow-up by an HIV specialist or in an HIV unit.
- **Date of the first CD4 count:** the date of the first CD4 count.

MODULE B: This is an optional module for those CBVCT services that perform also Syphilis and Hepatitis C tests.

Syphilis test: This section refers to the realization of screening syphilis test, the date of realization (dd/mm/yyyy) the type of test used (rapid or conventional), the result of the rapid test, and if reactive, the confirmatory test realization, and the date of the confirmation test realization (dd/mm/yyyy). If the confirmatory test is performed or if the conventional test is used, the syphilis diagnoses by the doctor has to be indicated.
It has to be indicated also if the client has had a previous syphilis infection, and if yes, the date of the last infection.

HCV test: This section refers to the realization of screening hepatitis C test, the date of realization (dd/mm/yyyy) the type of test used (rapid or conventional), the result of the test, and if reactive, the confirmatory test realization, the date of the confirmation test realization (dd/mm/yyyy), and the confirmatory test result.
It has to be indicated also if the client has had a previous HCV infection, and if yes, the date of the last infection.

Hepatitis A and B vaccination: This section refers to if the client has been vaccinated for Hepatitis A and Hepatitis B.

Comments: In this section you can add any comment you consider interesting to take it into account for the analysis.

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