OptTEST
OPTIMISING TESTING AND LINKAGE TO CARE FOR HIV ACROSS EUROPE

Tip Sheet 3
What are the new testing technologies and strategies and where are they working?

HIV Testing – what are the current options?

No medical test is perfect. Choices are made based on the available tests, the needs of the people being tested and our priorities.

Which is more important – that people who do have an infection are identified, or that some people without the infection are not falsely alarmed by the suggestion that they might be infected?

If a rapid and convenient option encourages more people to test, should it be offered even though it is slightly less accurate than another test?

All European health systems expect any initial positive HIV test result to be confirmed by a second, lab-based test.

Antibody-only tests

HIV tests most commonly used in the past tested for HIV antibodies only, as opposed to the virus itself, so they were known an 'indirect tests'. The earlier first- and second-generation types of tests are no longer used but third-generation HIV tests are still used in some parts of Europe. Although the accuracy of these third-generation tests is good, they are less able to detect early infection than newer (fourth-generation) tests. The typical time it takes for a third-generation test to detect HIV antibodies is around 20-25 days after infection, but it can be longer in some cases.

Antibody/antigen (fourth generation) laboratory tests

Fourth-generation tests are currently the best available for initial testing and are used in most European clinics. These tests can sometimes detect the virus just 10 days after infection, and most infections can be detected within a month. Antibody/antigen laboratory tests are extremely accurate.

Follow-up diagnostic testing

All HIV tests which show reactive ('positive') results should be confirmed with further tests. Most providers tell people who are testing that a negative result is definitive, but that a reactive result indicates the need for further laboratory testing. There are several types of follow-up or confirmatory test in use.

For a doctor, these tests done in clinics have advantages. They give the most accurate results and usually processes are automated and quality control can be assured. Because the person testing has to return for their results a few days or a week later, there is time to carry out additional tests to clarify any unclear result. Most clinics can also refer people directly into treatment and other health services, or have them in-house. All of these may be reasons that some doctors resist using other types of testing.

However, laboratory tests also have disadvantages. Getting the results usually means coming back on another day, but up to half of the people tested at publicly-funded clinics do not return for their HIV test results. Some may be less likely to test if a return visit is required, because the wait for the test result causes stress and anxiety. Some people dislike having blood taken with a needle.

Others do not think they have time to visit a clinic, or feel it will stigmatise them to do so.

Rapid (point-of-care) tests

'Point-of-care' (POC) tests do not require specialised laboratory equipment. They can be administered and interpreted in any setting. Most require a tiny sample of blood from a fingertip prick, while others involve swabbing around the outer gums in the mouth.

POC tests are also known as 'rapid' tests because the result can usually be given within 30 minutes. These tests are often used in community settings to encourage people to test for HIV at venues they go to anyway. Rapid tests can be performed by anyone with the appropriate training. However, reading the test result relies on subjective interpretation. If the result is borderline, experienced staff should be relied on to give accurate results.

Currently, with the exception of one test from *Alere*, all POC tests look for antibodies only. The window periods of these tests are usually a few days longer than those of antibody laboratory tests. It is important to verify that any test used is CE marked, which means that the test conforms to European health and safety legislation.

Rapid testing in clinical settings

The use of more convenient, less invasive rapid HIV tests within clinic settings, such as GP practices, hospitals and sexual health clinics, may improve HIV testing acceptability and uptake. Rapid testing kits are more expensive than the traditional tests, but are roughly equivalent in overall cost when laboratory time and labour are included. Confirmatory tests should be performed for all positive rapid test results. Such uses are acceptable to patients and shown to be effective but require ongoing effort to maintain.

For an example of successful usage in an emergency room setting, read Routine testing in the emergency department: tough lessons in sustainability.

The accuracy of some brands of rapid tests is slightly lower than traditional tests, which results in a small number of false-positive initial test results. Inaccurate test results can also be due to problems with staff training or quality control. Organisations using point-of-care tests should work with a pathology laboratory that provides support with clinical governance and quality assurance.

It is most effective to use point-of-care-tests in acute care settings in high-prevalence populations, such as gay men (as the proportion of true positives there will likely outnumber any false positives) rather than in low prevalence areas or populations. Rapid testing has been associated with higher entry into care through increased knowledge of HIV, particularly where these programmes had HIV counsellors on site.

Rapid testing in outreach/community settings

Community HIV testing is HIV testing in settings outside hospitals or health clinics. This reaches people who may not have contact with healthcare services, especially in hard-to-reach populations. This testing happens in two different types of settings: community-run clinics or other centres (e.g. young people's or drugs services) and outreach settings, such as bars and sex-on-premises venues.

Community based HIV testing services, usually but not always involving rapid tests, have existed in Europe since 2002 and are spreading rapidly. Such services are often labelled "Checkpoint" and targeted at gay men or other specific high-prevalence populations. They exist in a growing number

of countries and have been shown to be cost-effective and to reach undiagnosed people in key groups. Most successful community testing specifically targets one or more specific populations, such as men who have sex with men (MSM), migrants, or injecting drug users (IDU). The people offering testing are often from the same communities as those they offer the service to.

See Slide Set 2 for more data on Barcelona Checkpoint or read extensively about community based testing services at Euro HIV EDAT.

Many studies have found client satisfaction with community testing is high, and the availability of same-day testing and results influences the decision to test. Community testing services are particularly helpful in areas with a high prevalence of HIV or directly in venues where there may be high-risk sexual behaviour or where people at high risk gather.

Read a descriptive evaluation of a Spanish outreach initiative here.

Outreach testing presents specific challenges. It is important that the setting allows for privacy and safety, and that people agreeing to test are not intoxicated. Venues may fear that HIV testing could repel customers or expose the venue to police scrutiny. Those doing the testing must be trained and supervised, whether they are staff or volunteers, and proper records kept as in all testing options. Other challenges can include re-contacting patients with unclear rapid tests for later positive results and sustainability of programmes.

Self-sampling (Home sampling)

Self sampling kits are a recent development which combines the convenience and control of self-testing with the supportive diagnostic contact of a clinic or NGO. They often involve initial contact through internet or online outreach. Kits are distributed, usually to targeted populations, through community contact or by mail after online ordering. The saliva (swab) or blood (needle prick) sample is taken by the person testing and posted to a laboratory for analysis along with brief contact details. The individual is notified, usually within a few days, of the result. Negative results may be sent by email but reactive results are communicated by phone.

Studies have evaluated self sampling as a feasible HIV testing approach. Advantages include the ability to stay in contact with people and offer further testing or ongoing support. It is important to provide appropriate information with the kit. Online systems in particular offer opportunities for risk assessment and targeting of further information. Although self sampling has been shown to effectively reach people who have not tested before, it is best targeted to high-prevalence populations because of costs.

For more information on self sampling, see Slide Set 3 or read about a self-sampling pilot in the UK.

Internet outreach involves reaching a targeted population online through chat rooms, social networking sites, hook-up sites, and mobile apps. Agencies can promote HIV testing services through these approaches, provide information about HIV prevention, care, and treatment, or schedule appointments for people seeking testing. Internet-based outreach may be especially useful for reaching young people and MSM who do not identify as gay or cannot be found in traditional outreach settings.

Self-testing

HIV self-testing is increasingly common across Europe but is not legal in all countries yet. As of

November 2016, the product most commonly approved for HIV self-testing is the Biosure HIV Self Test. The person testing buys a kit, usually over the internet or at a pharmacy and collects their sample in the same way as described for home sampling above. However, with self-testing the kit enables the person to test the sample and read their own result within minutes, with or without help.

In HIV self-testing, like all initial tests, positive results should be confirmed by a further laboratory test. In accordance with the WHO HIV self-testing guidance, individuals who may have been exposed to HIV in the past 6 weeks are advised to retest a few weeks later (or regularly if the risk is ongoing).

When used as intended, CE marked self-test kits work properly and are acceptably safe. There is a risk of individuals performing their test or interpreting the result incorrectly and a small risk of false-positive results. Performance is slightly poorer when using swabs compared to finger-prick blood, resulting in a small number of people with HIV receiving a false negative result. A positive result requires the person testing to self-refer to healthcare services for a confirmatory test and further help.

There are ways of mitigating some of these concerns. They include:

- Providing easily understandable literature with the test kit, including links to video demonstrations of how to test and interpret the results and/or to telephone support, safer sex information and where to get further support
- Offering “assisted self-testing” in which the person testing is accompanied by a trained health worker or volunteer, often a peer, while they test and read the result
- How referrals are made from HIV self-testing to further testing for confirmation of test results and for linkages into care.

Assisted self-testing is particularly useful in meeting the concerns of many clinicians about allowing people to self-test and self-refer. An example of how it operates is in Case Study 9 about its use in Ukraine.

For more information on self-testing, see Slide Set 4 and Case Study 9.

Table 1 Self-testing support tools created by WHO for the *Guidelines on HIV self-testing and partner notification, supplement to consolidated guidelines on HIV testing services.*

Support tools	Directly assisted	Unassisted
Brief in-person, one-on-one or group demonstrations on how to correctly use the kit and how to interpret the results	✔	
Internet-based, virtual or social media demonstrations on how to correctly use the kit and how to interpret the results	✔	✔
In-person assistance during self-testing procedure	✔	
Instructions for use: • Pictorial/written • Brochures or flyers that include information on local HIV services and contact details, for example, health clinic, 24hr hotline • Multimedia instructions	✔	✔
Remote support via telephone, social media, text message, QR code, Internet-based or mobile messaging applications	✔	✔

Useful Links

European Centre for Disease Prevention and Control. *HIV testing: Increasing uptake and effectiveness in the European Union*. Stockholm: ECDC, 2010.
http://ecdc.europa.eu/en/publications/Publications/101129_GUI_HIV_testing.pdf

European Centre for Disease Prevention and Control. *Novel approaches to testing for sexually transmitted infections, including HIV and hepatitis B and C in Europe*. Stockholm: ECDC, 2012.
http://ecdc.europa.eu/en/publications/Publications/Novel_approaches_to_testing_for_STIs_.pdf

HIV Prevention England. *HIV testing technologies*. HPE, 2014.
http://www.hivpreventionengland.org.uk/wp-content/uploads/2016/04/HPE_briefing_HIV_testing_technologies.pdf

World Health Organization. *Consolidated guidelines on HIV testing services*. Geneva: WHO, 2015.
http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/

World Health Organization. *Guidelines on HIV self-testing and partner notification*. Geneva: WHO, 2016.
http://www.who.int/hiv/pub/vct/hiv-self-testing-guidelines/en/

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