



SCIENTIFIC ADVICE

Public health guidance in brief on HIV, hepatitis B and C testing in the EU/EEA

An integrated approach

Scope and purpose of guidance

The ECDC guidance on integrated testing of hepatitis B (HBV), hepatitis C (HCV) and HIV supports countries in the global effort to combat viral hepatitis and eliminate HIV as public health threats by 2030. At present, reaching and testing those at risk of infection with HIV, HBV or HCV is still a public health challenge across Europe.

Figure 1. The case for integrated testing

Why do we need to improve testing for HIV and viral hepatitis?

One in two people living with HIV are diagnosed late in the course of their infection. A large proportion of the estimated nine million Europeans living with chronic hepatitis B or C are unaware that they are infected.

Why integrated testing for HIV and viral hepatitis?

The three viruses have common modes of transmission, and integrated HBV, HCV and HIV testing allows synergies to be created in times of constrained resources.

What are the benefits of testing and early diagnosis?

Testing is an entry point to treatment and care. Effective treatment either eliminates or suppresses the viruses = it improves the health of those tested and prevents further transmission.

Suggested citation: European Centre for Disease Prevention and Control. Public health guidance in brief on HIV, hepatitis B and C testing in the EU/EEA – An integrated approach. Stockholm: ECDC; 2018.

Stockholm, December 2018

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Increasing testing coverage and uptake, especially for those most at risk, is an essential element of any strategy to eliminate HIV, HBV and HCV in the European Union and European Economic Area (EU/EEA). In order to interrupt existing transmission chains and prevent further infections, Europe needs a stronger focus on working closely with vulnerable populations. This will improve efforts to identify those who are infected but not diagnosed and link them to appropriate healthcare services.

This guidance provides EU/EEA countries with the latest scientific evidence to help develop, implement, improve, monitor and evaluate national or local HIV, HBV and HCV testing guidelines and programmes. It offers a range of evidence-based options for the design of testing interventions in different settings and populations and supports the variation and integration of testing services¹.

Why integrated testing?

The three viruses have common modes of transmission, with significant overlaps in affected population groups and high levels of co-infection. Integrated testing also reflects existing patterns of service delivery in EU/EEA countries and a growing movement to integrate HIV, HBV and HCV testing, prevention and linkage-to-care efforts.

To maximise the benefits of individual treatment for all three infections, it is critical to test and diagnose people as soon as possible in the course of the infection, which is challenging since these infections can typically be asymptomatic for years.

The ECDC guidance advocates for the development of an integrated national testing strategy or programme for HIV, HBV and HCV. Such integrated testing strategies or programmes should apply the six core testing principles, respect the individual needs of those tested and incorporate evidence-based interventions. Success in increasing the testing uptake should contribute considerably to the elimination of HIV and combat viral hepatitis as public health threat by 2030.

There are six overarching principles for HIV, HBV and HCV testing programmes in this context:

- An effective national testing strategy, including a monitoring and evaluation framework, is critical in responding to HIV, HBV and HCV infection.
- Testing should be accessible, voluntary, confidential and contingent on informed consent.
- Appropriate information should be available before and after testing.
- Linkage to care is a critical part of an effective testing programme.
- Normalising HIV, HBV and HCV testing in all healthcare settings; and
- Those carrying out HIV, HBV and/or HCV testing should receive appropriate training and education.

Who to test?

The guidance identifies the following population groups suitable for targeted HIV, HBV and HCV testing due to higher risk of infection and suggest to offer tests to:

- men who have sex with men (MSM)
- trans* people
- people who inject drugs (PWID)
- migrants²
- household contacts of people diagnosed with HBV
- homeless people
- sex workers
- people in prison
- pregnant women
- haemodialysis patients
- people who have received blood products, organs or surgical interventions before adequate safety and quality regulations were enforced; and
- sexual or injecting partners of people diagnosed with HIV, HBV and HCV.

¹ The *Guidance in brief* is based on the comprehensive guidance document that examines the rationale of all key interventions and provides the evidence base for this guidance. Available from: <u>http://ecdc.europa.eu/en/publications-data/public-health-guidance-hiv-hepatitis-b-and-c-testing-eueea</u>.

² Migrants defined here as individuals who originate from a country of intermediate or high endemicity for HBV/HCV/HIV or belong to local migrant communities known to have high prevalence or incidence of HBV/HCV/HIV.

Normalising testing

Making the testing offer a routine and with that making the process similar to those for other diagnostic test, helps to reduce stigma and increases testing uptake.

The implementation of indicator condition-guided HIV testing provides a useful complement to targeted HIV testing of groups at higher risk. By providing a clinical rationale for testing, this strategy can also help normalise testing and reduce barriers to it, including issues around stigma among healthcare providers and patients alike.

Where to test?

The ECDC guidance outlines where, how and when to test for viral hepatitis and HIV by providing evidence-based options of testing strategies that are applicable to all healthcare settings, as well as testing strategies specifically for:

- primary healthcare settings
- hospital settings
- other healthcare settings (e.g. STI clinics, pharmacies, prisons and some drug and harm reduction services)
- community settings (including drug and harm reduction services); and
- self-sampling and self-testing.

Frequency of testing

The suggested frequency of testing is³:

- For those at risk of HIV infection at least once a year and up to every three months depending on
 ongoing risk, sexual behaviour, history of sexually transmitted infections, use of pre- or post-exposure
 prophylaxis (PrEP, PEP) and local HIV prevalence or incidence.
- For those at risk of HBV infection test those at risk who have not had a complete course of HBV vaccinations based on vaccination history. Retesting up to every 6 to 12 months is only suggested if there is an ongoing risk for either unvaccinated people or vaccine non-responders.
- For those at risk of HCV infection consider testing all sex workers, people who inject drugs, trans* people, prisoners and migrants, and other populations at risk every 6 to 12 months depending on risk profile.

Testing strategies for all settings

Focus

In areas of intermediate (HBV/HCV) or high prevalence (HBV/HCV/HIV)⁴:

- Consider identifying those who are unaware they are infected through geographically targeted routine testing.
- Consider birth cohort or universal one-time testing as option to increase HCV testing coverage, taking into account local epidemiology, affordability and the availability of effective linkage-to-care pathways.

³ Consult the full overview on suggested frequencies for all groups in the long version of the Guidance.

⁴ Intermediate HBV and HCV prevalence: When HBsAg seroprevalence or HCV antibody seroprevalence in the general population is between 2% and 5%. For both HBV and HCV, high prevalence is ≥5%. High HIV prevalence: When HIV prevalence consistently exceeds 1% in general population. Consult the full version of the ECDC guidance.

In addition:

- Test all patients diagnosed with either HIV, HBV and HCV infection for the other two viruses as per guidelines from the European AIDS Clinical Society (EACS)⁵ and European Association for the Study of the Liver (EASL)^{6,7}.
- As per the ECDC antenatal screening guidance⁸: offer pregnant women HBV and HIV tests during the first two trimesters of pregnancy. Offer an HCV test depending on the pregnant woman's risk profile.
- Only for women at-risk: repeat HIV testing during pregnancy and HBV testing for those who decline HBV vaccination or are non-responders.
- When a woman tests negative for HIV or HCV and has a partner at higher risk, facilitate testing of her partner. If the partner remains untested or risk factors are unknown, consider retesting the mother later in pregnancy.
- Voluntary partner notification following a positive diagnosis helps to achieve earlier diagnosis and treatment of exposed (sexual) partners.

Testing in primary healthcare settings

Evidence shows that HIV, HBV and HCV testing in primary care (PHC) is acceptable and may effectively contribute to increase testing coverage and case detection.

Focus

Offer integrated testing to any person attending primary care if they:

- identify as members of certain risk groups
- present with clinical symptoms suggestive of one of three infections; or
- show laboratory markers (including elevated liver enzymes) compatible with acute or chronic hepatitis or an HIV indicator condition, including a sexually transmitted infection.

Rapid testing, dried blood spot testing and testing using venepuncture are all acceptable in primary care.

• Consider offering all patients who were diagnosed with HBV, HCV or HIV a test for the other two viruses.

Considerations

- Although limited, evidence on general population testing in these settings is also encouraging, at least in intermediate- and high-prevalence regions and birth cohorts.
- Available evidence suggests testing coverage in primary care settings is often suboptimal and caused by factors that discourage healthcare professionals from offering tests. Consider interventions to increase test offers, including educational interventions for healthcare staff and clinical decision-making tools.
- For testing in PHC settings, appropriate clinical care pathways and referral systems need to be established to ensure better linkage to care for people newly diagnosed with HBV, HCV or HIV in primary care.

⁵ European AIDS Clinical Society. HIV guidelines version 9.0. Brussels: EACS, 2017.

⁶ European Association for the Study of the Liver. EASL Recommendations on Treatment of Hepatitis C 2016. J Hepatol. 2017;66(1):153-94.

⁷ European Association for the Study of the Liver. EASL 2017 Clinical Practice Guidelines on the management of hepatitis B virus infection. J Hepatol. 2017;67(2):370-98.

⁸ European Centre for Disease Prevention and Control. Antenatal screening for HIV, hepatitis B, syphilis and rubella susceptibility in the EU/EEA – addressing the vulnerable populations. Stockholm: ECDC; 2017. Available from: http://ecdc.europa.eu/publications-data/public-health-guidance-antenatal-screening-hiv-hepatitis-b-syphilis-and-rubella.

Testing in hospital settings

Testing for HIV, HBV and HCV in hospital settings is generally accepted by patients and staff and can contribute to better testing coverage and case detection among risk groups or people presenting with HIV indicator conditions.

Focus

Offer integrated testing to any person attending a hospital if they:

- identify as members of certain risk groups
- present with clinical symptoms suggestive of one of three infections; or
- show laboratory markers (including elevated liver enzymes) compatible with acute or chronic hepatitis or an HIV indicator condition, including a sexually transmitted infection.

Studies indicate that routine testing in emergency departments, including universal testing and integrated testing, is also acceptable to patients and staff in hospitals even though it is currently supported by limited evidence on its effectiveness.

Considerations

- Test all patients diagnosed with an HIV, HBV and HCV infection in hospital settings for the other two viruses, despite little current evidence on effectiveness.
- Even though there is little evidence of the effectiveness of any specific intervention over any other, education and training programmes for healthcare staff, campaigns and clinical decision-making tools can support the offer and uptake of integrated testing strategies.

Testing in other healthcare settings

These settings include formal healthcare services (outside hospitals and primary care practices) such as STI, genito-urinary medicine, dermato-venereology and low-threshold clinics, pharmacies, antenatal, prison health, drug and harm reduction and tuberculosis services.

Focus

Based on available evidence for integrated testing in these specific settings:

- Consider offering all patients diagnosed with an HBV, HCV or HIV infection a test for the other two viruses.
- Ensure that people who are newly diagnosed with HBV, HCV or HIV are linked to care given that efficient testing strategies in these surroundings need appropriate pathways to care and effective referral systems.

Considerations

- Testing for HIV, HBV and HCV, including integrated testing, in such healthcare settings results in varying degrees of effectiveness regarding the increase of testing coverage and case detection. Limited evidence suggests that rapid diagnostic tests and dried blood spot tests are acceptable and may help to increase testing coverage in such sites.
- Pharmacies generally offer HIV, HBV and HCV testing under the same quality standards that apply to healthcare settings despite very limited evidence currently on the effectiveness of this activity.
- Harm reduction services offer and suggest HBV and HCV testing to everyone attending drug and harm
 reduction services and during their initial assessments. Repeat this offer in case of indicated ongoing risk.
- Sites serving migrant populations can look into offering relevant testing to people who come from countries with intermediate (HCV) or high HIV, HBV and HCV prevalence.
- Prison settings can look into offering HIV, HBV and HCV testing to all people in prison as per ECDC guidance on active case finding in prison settings given the higher prevalence of blood-borne viruses in many prison settings. See also the ECDC/European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) guidance on prevention and control of blood-borne viruses in prison settings⁹.

⁹ European Centre for Disease Prevention and Control and European Monitoring Centre for Drugs and Drug Addiction. Public

- STI/genito-urinary/dermato-venereology clinics can consider offering HIV testing to anyone seeking care
 regardless of symptoms or risk factors as part of the initial screening for STIs according to the International
 Union against Sexually Transmitted Infections' European guidelines. This includes offering HIV testing to
 those who:
 - have a high likelihood of exposure to HIV
 - are pregnant regardless of risk factors; or
 - voluntarily seek testing, especially if never tested before.

Based on geographic prevalence and risk group, it may be appropriate to suggest HBV testing.

Testing in community settings

Community-based testing services refers to programmes and services that offer voluntary HIV and/or HBV, HCV testing outside formal healthcare facilities. They are designed to target specific population groups and clearly adapted and accessible to those communities.

Focus

There is a role for community-based testing to target groups at higher risk in any national testing strategy. They are acceptable and effective in increasing HIV, HBV and HCV testing coverage and case detection among these groups.

Integrated testing and rapid testing may be offered for everyone accessing drug and harm reduction services in a community or outreach testing activities. Rapid testing in the community is acceptable and contributes to increased testing coverage when implemented in such settings.

Options based on available evidence for integrated testing in these settings:

- Linkage to care after HBV and HCV testing in community settings may currently be suboptimal, at least for certain risk groups. If testing in community settings is considered within a national testing scheme, clear pathways into care and other services have to be developed. This includes differentiated care pathways for the three infections and other services.
- Testing services offered by lay providers help to increase testing opportunities, uptake and coverage.

Self-sampling and self-testing

Self-sampling and self-testing are additional options that give people the flexibility and privacy of performing an initial HIV, HBV and HCV test in their own homes or a place they consider convenient.

To date, there is little scientific evidence on the effectiveness of self-sampling, especially relating to HCV and HBV, to reach any firm conclusions regarding inclusion in a national testing strategy. There is limited evidence that kits distributed to people attending an STI clinic may increase test coverage and frequency.

Focus

Self-sampling for HIV, HBV and HCV, including possible integrated sampling, is likely acceptable among those most at-risk and may contribute to increased testing coverage and case detection.

Limited available evidence suggests that self-testing for HIV among men who have sex with men is acceptable and may increase testing coverage, frequency and case detection.

Self-sampling kits can be effectively distributed through a variety of channels, such as pharmacies, healthcare settings, outreach activities and online platforms, but should be based on local circumstances and target populations.

health guidance on prevention and control of blood-borne viruses in prison settings. Stockholm: ECDC and EMCDDA; 2018. Available from: <u>http://ecdc.europa.eu/publications-data/public-health-guidance-prevention-control-bloodborne-viruses-prison-settings</u>.

Considerations

To ensure effective linkage to care after self-sampling and/or self-testing as part of a testing strategy, clear pathways to care and other services need to be in place or developed, including differentiated care pathways for the three infections.

Contact tracing (includes voluntary partner notification)

Contact tracing, including partner notification, implies that people who may potentially have been exposed to an infection are informed of this possibility and are offered a test. This can also include other interventions depending on the specific infection.

Partner notification is a voluntary process in which a trained provider asks a person diagnosed with HIV, HBV and HCV about details of their sexual partners, at-risk drug injecting partners and household contacts as indicated by the diagnosis and then offers to invite them for a test. The identity of the diagnosed person remains anonymous to the contact unless consent is given.

Focus

Even though there is currently limited evidence on the effectiveness of partner notification in increasing testing coverage and case detection, mainly related to HIV, it follows public health logic in response to other communicable diseases to offer voluntary anonymous partner notification to every patient with a newly confirmed diagnosis.

There are various strategies to implement partner notification, including passive notification, assisted anonymous notification using a web-based platform and assisted notification with the direct involvement of the service provider.

Considerations

Current implementation of partner notification processes appears to be suboptimal across Europe. While the success of interventions to increase the coverage of partner notification may depend on local factors, including organisational and legal circumstances, educational interventions targeting healthcare workers may prove to be beneficial.

Monitoring integrated national testing strategies or programmes for HBV, HCV and HIV

Monitoring and evaluation is an essential component of any effective testing programme. While strategic information should guide the design of testing initiatives, monitoring and evaluation data permit continuous reevaluation of targets as well as assessment of programme effectiveness, efficiency and impact. Such data can prove invaluable in planning improvements.

Figure 2. Main elements of a monitoring framework for viral hepatitis and HIV testing



More comprehensive guidance on monitoring and evaluation of testing programmes will be published separately.