SCIENTIFIC ADVICE

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

An integrated approach

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Abbreviations

AIDS	Acquired immune deficiency syndrome
ALT	Alanine aminotransferase
Anti-HB	Antibody to hepatitis B surface antigen
Anti-HCV	Antibody to HCV
ART	Antiretroviral therapy
BBV	Blood-borne virus
CD4	Cluster of differentiation 4
CDC	Centers for Disease Control and Prevention
DAA	Direct-acting antiviral
DBS	Dried blood spot
DNA	Deoxyribonucleic acid
EACS	European AIDS Clinical Society
EASL	European Association for the Study of the Liver
EATG	European AIDS Treatment Group
EU/EEA	European Union/European Economic Area
GP	General practitioner
HA-REACT	Joint Action on HIV and Co-Infection Prevention and Harm Reduction
HBV	Hepatitis B virus
HBsAg	Hepatitis B surface antigen
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
IC	Indicator condition
IFN	Interferon
INTEGRATE	Joint Action on Integrating Prevention, Testing and Linkage to Care Strategies Across HIV, Viral Hepatitis, TB and STIs in Europe
IUSTI	International Union Against Sexually Transmitted Infections
MSM	Men who have sex with men
NAT	Nucleic acid test
NICE	National Institute for Health and Care Excellence
NSP	Needle and syringe programme
OptTEST	Optimising Testing and Linkage to Care for HIV Across Europe
OST	Opioid substitution treatment
PEP	Post-exposure prophylaxis
PHC	Primary healthcare
PLHIV	People living with HIV
PrEP	Pre-exposure prophylaxis
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PWID	People who inject drugs
QALY	Quality-adjusted life year
RCT	Randomised controlled trial
RDT	Rapid diagnostic test
RNA	Ribonucleic acid
SACC	Shared Addiction Care Copenhagen
STI	Sexually transmitted infection
TasP	Treatment as prevention
TB	Tuberculosis
TESSy	The European Surveillance System
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

Glossary

Acceptability. Degree to which given intervention is acceptable to target population in relation to effect of intervention.

Accessibility. Degree to which given intervention is accessible to target population (availability of good health services within reasonable reach and when needed).

Audit: Quality improvement process that aims to improve care of patients by reviewing practices against criteria such as existing policy or guidelines and modifying practices where necessary.

Campaign: Series of activities and efforts to increase awareness and/or to promote initiatives. Campaigns can be conducted nationally or locally. For HIV testing, national campaigns generally focus on increasing awareness, while local campaigns generally advertise local testing activities.

Checkpoint: Community-based centre for detection of HIV and other sexually transmitted infections targeted at gay men, other men who have sex with men and transgender women [1].

Clinical decision-making tool: Clinical decision-making uses a combination of experience, knowledge and assessment tools to make effective clinical decisions. Clinical decision-making tool for HBV, HCV or HIV testing is any strategy that aids staff in deciding who should get tested, e.g. patient-completed risk-assessment questionnaire or reminding staff to offer testing.

Community-based testing services: Programmes and services that offer voluntary, free and anonymous HBV, HCV and/or HIV testing outside formal health facilities designed to target specific communities. For this guidance, such services include the following:

- **Community-based drug and harm-reduction service facilities:** Provide community-based testing in fixed location and specifically target people who use drugs. Typically, though not universally, they maintain low threshold for attendance and adopt client perspective on service provision to make user access as simple as possible. Services at these facilities may include needle and syringe exchange programmes, opioid substitution therapy and other forms of drug treatment, as well as additional services such as HBV, HCV and HIV testing, health-promotion activities and social services.
- **Community-based outreach activities:** Generic term covering several types of service delivery in community that do not occur at fixed site. They include services provided by mobile units and vans, street outreach by community health workers and regular satellite services sited in community-based facilities. Outreach services are often able to reach people who are not in contact with other health services by targeting them where they live or places they access. Such services play important role in identifying their needs and referring them to community-based facilities or public healthcare services.
- **Community-based testing facilities:** Provide client-initiated (voluntary) testing services at fixed location outside formal health facilities. These sites may also provide additional services, such as counselling and health-promotion activities. Community-based testing sites in EU/EEA are mainly focused on MSM and typified by peer-driven services (e.g. checkpoints).

Comparative study: Study designed to compare two or more groups or interventions (e.g. types of testing offered or test timings); statistical measure often provided for comparison.

Cost-effectiveness: Cost-effectiveness analysis is an aide to decision making that measures ratio of costs of programme or intervention to effects it has on a defined outcome. For HIV testing, this is defined as threshold for HIV screening associated with favourable cost-effectiveness ratios when undiagnosed HIV prevalence rates are ≥0.1% [2].

Emergency department: Treatment facility specialising in providing medical and/or surgical care to patients who present to hospital often in need of immediate/urgent care. Most are open access with no requirement for referral.

Feasibility: Degree to which it is possible to implement an intervention in terms of time, money or other circumstances.

Homelessness: A homeless person is an individual without permanent housing who may live on the streets, stay in a shelter, mission, single-room occupancy facility, abandoned building or vehicle or live in any other unstable or non-permanent situation.

Incremental cost-effectiveness ratio (ICER): Measure used in cost-effectiveness studies to represent value of intervention compared against an alternative (comparator). ICER is calculated by dividing difference in total costs of two interventions by measure of health outcome, e.g. quality-adjusted life year (QALY, see below). ICER determines whether new intervention is efficient use of resources.

Indicator condition guided-testing: For HIV, testing approach where HIV tests are routinely offered to all patients presenting with AIDS-defining illness or HIV indicator condition including STI, malignant lymphoma, cervical/anal dysplasia or cancer, herpes zoster infection, hepatitis B or hepatitis C infection, ongoing mononucleosis-like illness, unexplained leukocytopenia or thrombocytopenia and dermatitis/exanthema [3].

Inpatient department: Hospital department where patients stay while they receive treatment.

Integrated testing: Provision of testing for more than one infection at the same time. For example, HIV testing may be provided alongside testing for infections such as hepatitis B, hepatitis C, STIs or TB.

Key populations: Include both most at-risk and vulnerable groups of people in a given population.

Late presentation: Occurs when person is tested and diagnosed too late to either prevent avoidable harm or for treatment to be fully effective. For hepatitis, late presentation is defined as persons presenting for care with chronic hepatitis B and C and significant fibrosis (≥ F3 assessed by either APRI score > 1.5, FIB-4 > 3.25, Fibrotest > 0.59 or alternatively transient elastography (FibroScan) > 9.5 kPa or liver biopsy ≥ METAVIR stage F3) with no previous antiviral treatment [4]. For HIV, late presentation is defined as persons presenting for care with CD4 count below 350 cells/mL or presenting with an AIDS-defining event regardless of CD4 cell count [5].

Lay provider: Person providing healthcare in a community setting trained to deliver specific services, such as blood-borne testing services, but has not completed formal professional healthcare training.

Low-threshold service: Service that places few restrictions on access and adopts client perspective on service provision to make utilisation as accessible as possible for users.

Migrants: Individuals who change their country of usual residence irrespective of reason for migration or legal status. Generally, a distinction is made between short-term or temporary migration, covering movements between three and 12 months, and long-term or permanent migration, referring to change of country of residence for one year or more [6]. For this guidance, migrants are 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.

Opt-out testing: Testing modality where patients are informed they will be tested as part of routine care, but may decline testing by raising an objection to the test.

Outpatient department: Hospital department that diagnoses and treats patients without requiring an overnight stay.

Outreach: Type of health service that mobilises health workers to provide services to a population away from location where providers usually work [7].

Partner notification/contact tracing: Process where individuals potentially exposed to infection are informed of exposure and offered testing and other interventions dependent upon specific infection. When contact is of sexual or injecting nature, this process is also referred to as partner notification. Partner notification is voluntary process in which trained provider asks person diagnosed with HBV, HCV or HIV about their sexual partners, at-risk drug-injecting partners and household contacts as appropriate for diagnosis. With individual's consent, provider then offers, facilitates or provides advice on testing for relevant infections to these partners and contacts, as well as linking them to preventive interventions such as vaccination (HBV) or post-exposure prophylaxis (PEP) for HIV. Identity of diagnosed person is not revealed to contact by provider unless consent has been given to do so. Web-based partner notification is approach delivered via websites that allow users to send emails, e-cards or text messages to inform partners anonymously.

Post-exposure prophylaxis (PEP): Use of antiretroviral therapy following exposure to HIV infection to try to prevent establishment of infection.

Prevalence: Prevalence measures proportion of individuals in defined population with specific disease (or specific characteristic) at certain point in time. High, intermediate and low prevalence rates may be defined for HCV, HBV and HIV to guide testing strategies after taking local epidemiology and other circumstances into account. Present guidance applies following definitions of prevalence rates based on several published thresholds:

- **Intermediate HBV and HCV prevalence:** When HBsAg seroprevalence or HCV antibody seroprevalence in general population is between 2% and 5%. For both HBV and HCV, high prevalence is ≥5% [8].
- **High HIV prevalence:** When HIV prevalence consistently exceeds 1% in general population [9].

Pre-exposure prophylaxis (PrEP): Antiretroviral therapy-based HIV prevention strategy to prevent or at least reduce risk of HIV infection in adults who have not been infected with virus, but are at high risk of infection.

Primary care: Healthcare provided by general practitioners (GPs), nurses and ancillary healthcare workers and first point of contact for healthcare for majority of population.

Provider-initiated testing: Voluntary testing offered to eligible individuals by healthcare providers.

People who inject drugs (PWID): People who inject non-medically sanctioned psychotropic (or psychoactive) substances. These drugs include but are not limited to opioids, amphetamine-type stimulants, cocaine, hypnosedatives and hallucinogens. Injection may be through intravenous, intramuscular, subcutaneous or other injectable routes [10].

Quality-adjusted life year (QALY): Composite measure of health adjusted to reflect length and quality of life. One QALY equates to one year of life in perfect health. For an individual requiring an intervention, QALY would be the weighted value of each year remaining to the patient with a quality of life score (on a 0 to 1 scale). In cost-effectiveness studies, QALYs are used to assess the effectiveness of a new intervention against baseline intervention.

Rapid diagnostic test (RDT): Test that provides result with a short turnaround time, typically with oral fluid or finger prick blood sample. RDTs are employed for point-of-care rapid tests and self-testing.

Reflex testing: Occurs when positive test automatically initiates performance of another test, typically to improve diagnostic sensitivity or presence of active infection. For this document, reflex testing refers to performing HCV nucleic acid test (NAT) on same sample as positive antibody screening test in order to detect active HCV infection.

Retesting: People who should be retested after defined period of time. This includes HIV, HBV and HCV-negative people with recent (to cover the window period) or ongoing risk of exposure and people with inconclusive HBV/HCV/HIV status.

Risk group testing: Testing strategy targeted at groups identified as being at higher risk of infection. Identification of these groups depends on local epidemiology and typically includes men who have sex with men (MSM), prisoners, sex workers, people who inject drugs (PWID) and migrants.

Self-sampling: When individual collects a blood or saliva sample from themselves, typically outside healthcare setting, using suitable kit. Sample is then delivered to designated laboratory for processing. Results are usually delivered by phone, text message or online, with referral mechanisms in place to ensure linkage to treatment and care as appropriate.

Self-testing: When individual collects blood or saliva sample, then uses rapid diagnostic kit to process sample, obtain results and interpret them according to instructions provided with kit. Kit typically includes information on linkage to care as appropriate.

Sex workers: Individuals who receive money or goods in exchange for sexual services and consciously define those activities as income-generating even if they do not consider sex work to be their occupation.

Task sharing: Rational redistribution of tasks and increased scope of work among different cadres of healthcare providers, including trained lay providers.

Testing coverage: Extent to which testing program covers potential need, usually measured as proportion of persons tested in a given population.

Testing uptake: Rate of acceptance of testing by individuals offered a test in a given population.

Testing strategy: Describes testing approach to attain a specific objective that takes into consideration prevalence in population tested.

Traditional and non-traditional settings: For HIV testing, traditional settings are specialist healthcare settings where HIV testing is provided, including dedicated STI and sexual health clinics, antenatal services and infectious disease units. Non-traditional settings are non-specialist for HIV testing such as general practice, community settings and hospital outpatient departments.

Trans* people: Trans is an overarching term referring to those people whose internal perception of their own gender (gender identity) and/or a gender expression differs from sex they were assigned at birth. The term trans includes but is not limited to men and women with transsexual pasts and people who identify as transsexual, transgender, transvestite/cross-dressing, androgyne, polygender, genderqueer, agender, gender variant or with any other gender identity and/or expression that is not standard male or female and express their gender through their choice of clothes, presentation or body modifications, including undergoing multiple surgical procedures [11].

Treatment as prevention (TasP): The impact of antiretroviral therapy to reduce the HIV viral load to undetectable levels, effectively preventing onward transmission.

Universal testing: Strategy of offering HIV test to everyone regardless of individual risk. Settings where this strategy may be particularly relevant include hospital departments and general practice. In certain settings, such as antenatal services, universal testing may be opt-out (see above).

Window period: For test designed to detect a specific disease, window period is the between first exposure to infection and point in time after when test can give definitive (accurate and reliable) result.

Executive summary

Reaching and testing those at risk of infection with human immunodeficiency virus (HIV), hepatitis B virus (HBV) or hepatitis C virus (HCV) is still a public health challenge across Europe. One in two people currently living with HIV is diagnosed late in the course of their infection and an even larger proportion of the estimated 9 million Europeans living with chronic hepatitis B or C are not aware that they are infected. In order to interrupt existing transmission chains and prevent further infections, Europe needs a stronger focus on working closer with vulnerable populations to help better detect those with undiagnosed infections, then link them to appropriate healthcare services. Increasing testing coverage and uptake, especially for those most at-risk, is an essential element of any strategy to eliminate HBV, HCV and HIV in the European Union and European Economic Area (EU/EEA). To support Member States in their efforts to improve case detection and uptake of testing programmes as part of the global effort to eliminate viral hepatitis and HIV as public health threats by 2030, ECDC is providing this evidence-based guidance on integrated testing of hepatitis B (HBV), hepatitis C (HCV) and HIV.

Why integrated testing?

While HIV and often HBV infection require lifelong treatment, HCV infection is now curable within a few weeks. 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 – in itself a challenge given that these infections can typically be asymptomatic for years. Early diagnosis of HBV, HCV or HIV is vital as it allows people to access treatment, which significantly reduces associated long-term morbidity and mortality. Effective treatment either eliminates or suppresses the viruses, which in turn also prevents onward transmission – a benefit known as 'treatment as prevention'. In many cases, those most at risk of one of these infections are also more vulnerable to infection with one or both of the other viruses, making the argument for integrated testing even stronger. Similarly, efforts to integrate HBV, HCV and HIV testing, prevention and linkage-to-care strategies enable countries to use a synergistic approach to combat all three infections more effectively and efficiently, particularly given growing resource constraints.

All countries can benefit from comprehensive testing policies and guidelines. Recent surveys revealed that not all countries in the EU/EEA have clear national testing policies. Even if such policies do exist, they do not always reflect what is generally accepted to be best practice. This includes the need to focus on population groups at highest risk of infection, the promotion of testing in a wide range of settings and the use of self-testing and permission for lay providers to administer tests.

This guidance aims to provide EU/EEA countries with an evidence-based framework to help develop, implement, improve, monitor and evaluate national or local HBV, HCV and HIV testing guidelines and programmes. It offers a range of evidence-based options for the design of testing interventions for different settings and populations and supports the diversification and integration of testing services.

The guidance strongly advocates for the development of an integrated national testing strategy or programme for HBV, HCV and HIV – one that incorporates the six core principles outlined below, taking into consideration the client point of view and incorporating the evidence-based interventions described within this document. Such a testing strategy or programme should contribute significantly to the elimination of viral hepatitis and HIV as public health threats by 2030.

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

- 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.
- Testing in healthcare settings should be normalised.
- Those carrying out HIV, HBV and/or HCV testing should receive appropriate training and education.
- An effective national testing strategy, including a monitoring and evaluation framework, is critical in responding to HBV, HCV and HIV infection.

When applying these principles in practice, it is important to bear in mind the client's viewpoint.

Who to test?

The guidance identifies several population groups suitable for targeted HBV, HCV and/or HIV testing (due to higher infection risk):

- men who have sex with men (MSM)
- trans* people
- sex workers
- people who inject drugs (PWID)
- people in prison
- migrants[1]
- homeless people
- pregnant women
- haemodialysis patients
- people who received blood products, organs or surgical interventions before adequate safety and quality regulations were enforced
- sexual or injecting partners of people diagnosed with HBV, HCV or HIV; and
- household contacts of people diagnosed with HBV.

In addition, 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 stigma concerns among healthcare providers and patients alike.

Where to test?

In addition, 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 settings (e.g. STI clinics, pharmacies, prison and some drug and harm-reduction services)
- testing in the community, including some drug and harm reduction services and
- self-sampling and self-testing.

There are certain testing strategies that strategies that are appropriate in all healthcare settings. In areas of intermediate (HBV/HCV) or high prevalence (HBV/HCV/HIV), geographically targeted, routine testing will help identify people who are unaware they are infected. Similarly, birth-cohort or universal one-time testing may be considered as an option to increase HCV testing coverage considering local epidemiology, affordability and availability of effective linkage-to-care pathways. Voluntary partner notification should be considered for all individuals found positive, to achieve earlier diagnosis and treatment of other exposed individuals.

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

1 Introduction

1.1 Rationale

A global effort is under way to eliminate viral hepatitis and human immunodeficiency virus (HIV) as public health threats by 2030. To achieve this goal, the World Health Organization (WHO) and UNAIDS have identified several targets along the continuum of care for hepatitis B virus (HBV), hepatitis C virus (HCV) and HIV. These include promoting early diagnosis, scaling up treatment and reducing disease-related mortality [12,13]. Highly effective treatments have been developed that not only significantly improve patient outcomes, but also prevent the onward transmission of all three blood-borne viruses. While HIV and often HBV infection require lifelong treatment, HCV infection can now be cured in a few weeks, though the drugs are not yet affordable in many settings. To maximise the benefits of treatment for all three, it is critical that people be tested and diagnosed as soon after infection as possible – a major challenge, as these infections typically have long asymptomatic phases.

In the European Union (EU)/European Economic Area (EEA), an estimated 4.7 million people are chronically infected with HBV and 3.9 million with HCV [14]. Groups with high prevalence of HBV and HCV infection include migrants born in endemic countries, men who have sex with men (MSM), people who inject drugs (PWID) and people in prison for HCV [14]. Estimates for the undiagnosed fraction of HBV cases in the general population are scarce and range from 40% to 85% in certain countries of the EU/EEA where available, while corresponding estimates for HCV in general or proxy populations range from 20% to 91% [15].

In 2015, there were an estimated 810 000 people living with HIV (PLHIV) in the EU/EEA, including 120 000 people (14.8% of all PLHIV) who were unaware of their status [16]. Forty per cent of new diagnoses in 2016 were among MSM and 40% of all reported cases were among migrant populations [17]. While the number of new HIV diagnoses has remained fairly steady at around 30 000 annually, 2016 saw the first clear decline in a decade [16]. Despite this encouraging development, half of all persons diagnosed in 2016 presented at a late stage and therefore did not benefit from early treatment or measures to decrease the risk of passing on HIV to their partners [17].

Increasing testing offer and uptake, particularly among those most at risk of infection, is an essential element of any strategy to curb HBV, HCV and HIV in Europe. It can be achieved by strengthening existing interventions while devising new strategies for testing and promoting opportunities for an integrated approach to the three infections.

All countries can benefit from comprehensive testing policies and guidelines. Recent surveys reveal that not all countries in the EU/EEA have clear national testing policies. Furthermore, when such policies do exist, they do not always reflect what is generally accepted to be best practice, including the need to focus on population groups at greatest risk, promotion of testing in a wide range of settings, use of self-testing and permission for lay providers to administer tests [18–20].

1.2 Integrated guidance on HBV, HCV and HIV testing

As the EU agency tasked with strengthening Europe's defences against infectious diseases, ECDC published its first evidence-based guidance on HIV testing in 2010 [21]. In consideration of the rapid developments in the field of HIV diagnostics and testing, ECDC commissioned an evaluation of this guidance in 2015 [22]. Encouragingly, stakeholders stated that they referenced and used the ECDC guidance extensively in developing national policies, guidelines and testing strategies. They favoured an update of the guidance to ensure that it included the most up-to-date testing strategies and diagnostic developments, such as self-testing and self-sampling, neither of which are addressed in the 2010 guidance. The evaluation also conveyed the need for including examples of best practice to help foster effective testing implementation. As a result, in 2016, ECDC launched a project to update the 2010 guidance on HIV testing to support Member States in developing and improving their national testing policies.

In parallel, in 2015, ECDC undertook an exercise to assess and identify gaps in HBV and HCV testing policies and practices in the EU/EEA [18]. Few countries had national HBV and HCV policies and where they did exist, they did not always target people most at risk. This finding led ECDC to commission a project to develop evidence-based guidance to support Member States in developing and improving national testing policies for hepatitis B and C.

Although initially planned as two independent processes, the development of guidance for hepatitis and HIV testing were integrated to produce a single testing guidance document, which also reflects patterns of service delivery in the countries of the EU/EEA. This strategic decision was made in the context of a growing movement to integrate HBV, HCV and HIV testing, prevention and linkage-to-care efforts. The case for integration is strengthened by the three viruses having common modes of transmission, leading to significant overlaps in the risk groups affected and high levels of co-infection. By joining testing and prevention efforts, countries can use a synergistic approach to combat all three infections more effectively and efficiently, particularly given growing resource constraints. The move towards greater integration is also found in the European Parliament's call for 'a comprehensive EU Policy

Framework addressing HIV/AIDS, tuberculosis and viral hepatitis' and the EU's Joint Action on Integrating Prevention, Testing and Linkage to Care Strategies Across HIV, Viral Hepatitis, TB and STIs in Europe (INTEGRATE) [23,24].

This document marks the first time that testing guidance for HIV and viral hepatitis has been combined at the EU level. This guidance provides unified setting-based advice on HBV, HCV and HIV while complementing and strengthening the suggestions given in various WHO guidance (Annex 6), making them more specific to the European context. It supports achievement of the United Nations Sustainable Development Goals, specifically by promoting good health and well-being, in particular Goal 3.3, which includes ending the AIDS epidemic and combating hepatitis by 2030, and Goal 10, reducing inequalities [25]. Furthermore, the guidance supports the 2016 WHO hepatitis elimination agenda, European action plan on viral hepatitis, UNAIDS/WHO 90–90–90 goals for HIV and EU minimum quality standards for the reduction of drug demand [26–29].

1.3 Objective and scope

This guidance aims to provide EU/EEA countries with an evidence-based framework to help develop, implement, monitor and evaluate their own national HBV, HCV and HIV testing guidelines and programmes. It offers a range of evidence-based options for the design of testing interventions for different settings and populations and supports the concepts of diversifying and integrating testing services.

The overarching objective of this guidance is to support efforts to increase the coverage and uptake of HBV, HCV and HIV testing, while encouraging the integration of testing interventions for all three viruses. Ultimately, this guidance seeks to help reduce the number of persons unaware of their infection by promoting early diagnosis and prompt linkage to care, thereby reducing further ill health and onward transmission.

1.4 Target audience

The target audience for this guidance document is public health professionals in the EU/EEA who coordinate the development of national guidelines or programmes for HBV, HCV and HIV testing in consultation with key stakeholders including:

- policymakers, policy advisors and programme managers
- clinicians and other healthcare providers
- community activists and advocates
- commissioners or funders of testing services; and
- members of civil society in relevant fields.

This guidance may also serve as a reference for public health professionals operating in countries beyond the EU/EEA to help them develop national guidelines and programmes.

2 Background

2.1 Burden of disease

2.1.1 Hepatitis B and C

HBV and HCV can both cause acute and chronic hepatitis, potentially leading to the development of cirrhosis, liver cancer and death. In the EU/EEA, an estimated 4.7 million people are chronically infected with HBV and 3.9 million with HCV [14]. Many of these infections go undiagnosed, as chronic infection is frequently asymptomatic.

Both viruses are transmitted through contact with infected blood, blood products and other bodily fluids. Transmission in the EU/EEA occurs primarily through sexual contact or injecting drug use, with some countries still reporting high levels of nosocomial transmission. In recent decades, various factors have led to changes in the epidemiology of HBV and HCV in Europe, including improvements in blood transfusion safety and stricter healthcare standards, HBV vaccination programmes, HBV antenatal screening, harm reduction programmes for PWID and changing patterns of injecting drug use and migration. Although marginal in Europe, vertical transmission, mainly of HBV, is a major route for the acquisition of chronic infections among people originating from countries with high prevalence.

In the EU/EEA, 29 307 cases of HBV and 33 860 cases of HCV were reported in 2016, corresponding to a rate of 5.5 and 7.4 cases per 100 000 population respectively. HBV vaccination efforts have led to a steady decrease in the number of acute HBV cases reported. In contrast, the annual number of chronic HBV notifications has increased while there is no clear trend in the incidence of acute or chronic HCV cases over time [30,31]. Due to the mainly asymptomatic nature of hepatitis infections, notification data do not give an accurate picture of disease burden and notifications of chronic cases of HBV and all cases of HCV are strongly influenced by local testing practices.

A recent systematic review undertaken by ECDC shows that the burden of viral hepatitis is higher in southern and eastern Europe. Again, due to the mainly asymptomatic nature of hepatitis infections as well as inadequate local testing practices, the number of people living with these infections in the EU/EEA who are unaware of their HBV and HCV status is likely to be substantial [32]. According to a recent systematic review undertaken by ECDC, the estimated proportion of people with undiagnosed HBV infections in the national population ranged from 40% in Italy to 85% in Germany [33]. The estimated fraction of undiagnosed HCV infections in general or proxy populations ranged from 20% in Denmark to 91% in Greece [15].

In the same systematic review, prevalence data for specific population groups were compared to general population data and/or the 2% threshold for intermediate prevalence to identify groups at higher risk or with a higher disease burden, as suggested by the latest WHO guidelines on HBV and HCV testing [8].

For HBV, EU/EEA population groups considered to be at higher risk or to have a higher disease burden include migrants from countries with high HBV seroprevalence, people living with HIV and haemodialysis recipients. Populations who have a higher risk or burden of HBV in certain circumstances or specific countries include PWID, MSM and people in prison [15].

For HCV, the population groups deemed likely to be at higher risk or have a higher burden of disease are PWID, people in prison, people living with HIV, haemodialysis recipients, recipients of blood transfusions and human tissue and diabetics. Populations identified as being at higher risk or burden of HCV only in certain circumstances or certain countries include MSM, healthcare workers and specific migrant groups [15].

The systematic review looked into the HBV and HCV burden of disease and transmission risk for other population groups, including sex workers, recipients of tattoos, recipients of medical and dental interventions, waste workers, people who use anabolic steroids, people engaging in high-risk sexual behaviour, people with a sexually transmitted infection (STI), people who use intranasal drugs, travellers, trans* people, the homeless and public safety workers, but found very limited data. Nonetheless, people belonging to these groups may have exposure that put them at higher risk or lead to a higher burden of HBV or HCV [15]. It should be emphasised that the significance of specific transmission routes and risk groups varies significantly from country to country, underscoring the importance of tailoring national response to the local epidemic and targeting those who are at higher risk of infection.

2.1.2 HIV

Over the past decade, approximately 30 000 new HIV diagnoses have been reported each year in the EU/EEA, approximately 6 new cases per 100 000 population annually [17]. Recent modelling suggests that the actual incidence rate has declined to an estimated 3.6 new infections per 100 000. In 2015, the number of people living with HIV in the EU/EEA was 810 000, corresponding to a prevalence of 0.2% of the population age 15 and older [34]. According to one recent study, the estimated number of undiagnosed cases of HIV in the EU/EEA and

median time from infection to diagnosis have decreased since 2012. However, it still took 2.9 years on average in the EU/EEA to be diagnosed with HIV following infection in 2016 [16]. During the last decade, the number of new AIDS cases dropped steadily due to increases in the coverage of effective antiretroviral therapy [17].

Nonetheless, HIV continues to pose a major public health challenge in the EU/EEA. In 2015, the proportion of people living with HIV in the region who were undiagnosed was estimated to be 15%. Several population groups are at increased risk for infection. Three-quarters of new diagnoses in 2016 were men. The most common transmission route was sex between men, attributed to 40% of all new cases, while heterosexual sex was reported for 32% of new cases and injecting drug use for 4%. Forty per cent of all new cases were also diagnosed in people born abroad regardless of transmission mode. The most important population groups to target for HIV prevention and testing are thus MSM, migrants (especially those from high-prevalence countries) and PWID [17].

Other groups previously identified as risk groups in parts of Europe include prisoners and sex workers [35]. It should be emphasised that the significance of specific transmission routes and risk groups varies significantly from country to country, underscoring the importance of tailoring national response to the local epidemic and targeting those who are at higher risk of infection [17].

Despite current testing strategies, many people are still diagnosed at an advanced stage of disease. In the EU/EEA, the percentage of late presenters among new diagnoses has declined slightly in recent years. In 2016, an estimated 48% of new cases presented late, defined as having a CD4 cell count of less than 350 cells/mm^3 [17]. Older people, PWID and people who have acquired HIV through heterosexual contact have all been shown to be more likely to be diagnosed late [36,37].

2.2 Continuum of care for HBV, HCV and HIV

The continuum of care is a simple and widely accepted conceptual framework that countries have used to set targets and monitor the effectiveness of their efforts. The sequential nature of the stages in the continuum clearly indicates where countries need to focus their efforts [38]. It has become an essential tool for ECDC in monitoring the HIV response of the entire WHO European Region. A recent ECDC report highlighting that linkage to care is a particular challenge [38].

The continuum of care for a viral infection typically has four indicators, corresponding to four critical moments in the journey from infection to viral suppression/cure:

- number of people who are infected
- number of infected people who are aware of their infection
- number of people who have completed or are receiving antiviral/antiretroviral treatment; and
- number of people who are virally suppressed or cured.

While the continuum of care provides an invaluable overview of a country's progress in fighting disease, its real purpose is to identify gaps in care and stimulate action, as demonstrated by the success of the UNAIDS 90–90–90 targets [28]. Testing services are a key component of the continuum. Not only do they serve as the gateway to the remainder of the continuum, but by providing access to effective prevention interventions and linkage to care, they also reduce the number of people who are infected in the first place and ensure that as many people as possible receive treatment.

2.3 Individual and public health benefits of early diagnosis

Early diagnosis provides people infected with HBV, HCV or HIV a variety of benefits while also contributing to better public health. Most immediately, it enables them to access treatment. Lifelong hepatitis B treatment suppresses HBV replication in 70% to 80% of recipients, as well as slowing down progression to cirrhosis and development of hepatocellular carcinoma. HCV treatment for 8 to 12–24 weeks can now cure HCV infection in more than 90% of cases [26,39]. In 97% to 98% of people living with HIV, antiretroviral therapy results in viral suppression, decreased rates of co-morbidities and prevention of future opportunistic infections acquisitions [40,41]. For details on treatment, consult the latest treatment guidelines from the European Association for the Study of the Liver (EASL), European AIDS Clinical Society (EACS) and WHO [41–44].

In all three instances, successful treatment eliminates or suppresses the virus in the body, preventing onward transmission – a benefit known as 'treatment as prevention', or TasP.

People who test positive are advised on how to prevent onward transmission, while those who test negative and are at continuing risk may be offered various prevention interventions, such as behavioural advice, harm reduction services, HBV vaccination and HIV pre- and post-exposure prophylaxis (PrEP and PEP). In addition, through partner notification and/or contact tracing, testing can be offered to a diagnosed individual's sexual partners, injecting partners and, for HBV, household contacts (Section 4.5).

2.4 Diagnostics for HBV, HCV and HIV infection

While presenting the full range of diagnostic options for HBV, HCV and HIV is beyond the scope of this guidance, in recognition of the issue's importance, a brief outline of the various diagnostic options available for HBV, HCV and HIV testing is provided. The latest WHO testing guidelines should be consulted for more detailed descriptions of the different approaches [8,45].

The method of sample collection is dictated by the choice of diagnostic test and the site of analysis (laboratory, near patient, etc.). The sample may be venous or capillary blood or oral fluid. When samples are obtained outside healthcare facilities and need to be transported to a laboratory, the use of dried blood spot (DBS) samples can facilitate testing by decreasing potential technical, training and health and safety obstacles to site selection.

All rapid diagnostic tests (RDT) should be confirmed prior to provision of a diagnosis and initiation of treatment. In certain instances, some aspects of care may be initiated prior to a confirmed diagnosis, e.g. partner notification to enable timely access to PEP, behavioural advice etc. Regardless of the type and location of the testing site, it is important to assure there is minimal delay in the delivery of a confirmatory test result to the individual being tested in order to facilitate access to treatment and care in a timely manner. The increasing evidence for TasP, particularly for HIV, reinforces the need for a degree of urgency.

Prior to the delivery of a negative result, consideration needs to be given to the window period, which is determined by the specific infection and diagnostic test employed. Information on the latter should be included in the test manufacturer's instructions.

2.4.1 HBV and HCV diagnostics

An overview of current diagnostic technologies for HBV and HCV adapted from EASL guidelines [43,44] is provided in Table 1. WHO guidelines provide detailed recommendations on the detection of HBsAg and anti-HCV using a single quality-assured serological in vitro diagnostic test employing either a laboratory-based immunoassay or RDT. Rapid tests should meet minimum performance standards and be performed at the point of care (i.e. 'near patient' testing). Following a positive HBsAg serological test result, WHO testing guidelines recommend an HBV DNA nucleic acid test (NAT) to help guide treatment decisions in the absence of cirrhosis and monitor the response. Following a positive anti-HCV serological test result, WHO recommends an RNA NAT to diagnose viraemic infection; detection of core HCV antigen may be considered as an alternative [8]. Reflex testing should be prioritised where available to increase linkage to care [43].

WHO guidelines provide algorithms for diagnosing, treating and monitoring chronic HBV and HCV infections [8]. Published literature and expert consensus also provide simplified HCV diagnostic algorithms [46].

Table 1. Overview of existing technologies for HBV and HCV testing

Technology	Description
Laboratory-based immunoassay	A serological assay that detects antibodies (e.g. anti-HCV), antigens (e.g. HBsAg, HCV core antigen) or a combination of both. Typically used as the front line in testing. Relatively low cost compared to NATs.
Alternative to laboratory-based immunoassays	
Rapid diagnostic test (RDT)	RDTs using serum, plasma, finger stick whole blood or oral (crevicular) fluid can be used instead of classical immunoassays. A single-use immunoassay that detects antibodies or antigens can give same-day results (generally in less than 30 minutes). Most RDTs can be performed with blood collected by finger stick sampling. RDTs are quick and simple to perform. They can be useful in settings where access to laboratory infrastructure is limited and with populations for which access to rapid testing can facilitate linkage to care, e.g. in outreach programmes. Disadvantages include lower sensitivity/specificity and more subjective interpretation of results compared to other tests. For anti-HCV antibody testing, whole blood sampled from dried blood spots can be used as an alternative to serum or plasma obtained by venepuncture.
Nucleic acid test (NAT)	Test using molecular technology, such as polymerase chain reaction, to detect viral RNA or DNA, either qualitatively or quantitatively. An NAT is typically used to detect the presence of the virus, active infection, whether treatment is required and monitor the course of disease. Laboratory-based NATs are expensive and require highly trained staff to perform.
Alternative to laboratory-based NAT	
Point-of-care NAT	Anti-HCV antibody screening can be replaced by a point-of-care HCV RNA assay with a lower limit of detection (<1000 IU/mL) or HCV core Ag assay if available. Consideration given to cost effectiveness and affordability.

Anti-HBs: antibody to hepatitis B surface antigen
Anti-HCV: antibody to HCV
DNA: deoxyribonucleic acid
HBsAg: hepatitis B surface antigen
RNA: ribonucleic acid.

2.4.2 HIV diagnostics

HIV testing may take place at any level of the healthcare system or in the community. Fourth-generation serological assays are the typical diagnostic test employed in most healthcare settings. As these assays can detect both HIV antigens and antibodies, they have the potential to diagnose acute infection before antibody response becomes detectable. A number of RDTs using capillary blood or saliva are also currently on the market. While these rapid tests do not provide a definitive diagnosis, they are included as part of a 'test for triage' approach, which requires a confirmatory test to be performed in the presence of a reactive test. A diagnosis can usually be established on the same day. The WHO testing guidelines recommend retesting anyone with inconclusive results orabout to start antiretroviral therapy, although the latter is not required in all countries. Table 2 summarises the major classes of HIV tests.

Table 2. Overview of the most significant technologies for HIV testing

Technology	Description
Immunoassay	Serological assay that detects antibodies (e.g. anti-HIV), antigens or combination of both. There are several major kinds of HIV immunoassays. Best suited to settings with many clients, dependable infrastructure and skilled staff.
Nucleic acid test (NAT)	Utilise molecular techniques that permit monitoring of disease progression and response to antiretroviral therapy. Often used for early infant diagnosis and acute infection where designed to do so.
Simple assay	Like rapid tests, simple assays are appropriate for community and primary care settings, but require cold chain storage and precision pipetting. Simple assays based on agglutination, immuneDOT, immunochromatographic and/or immunofiltration techniques.
Rapid diagnostic test (RDT)	Involve the collection of either oral fluid or a blood sample by finger stick and provides results immediately. Rapid testing can be quickly performed by trained lay testing providers, healthcare workers and laboratory professionals in a variety of settings irrespective of infrastructure. For HIV, they are in vitro diagnostic medical devices using either an immunochromatographic or immunofiltration format for detection of HIV-1/2 antibodies and/or HIV p24–1 antigen in HIV context.
Western blot (immunoblot)	Used primarily to verify other tests. Laboratory-based, needs basic explanation, used as confirmatory test in some settings.

For more details on the characteristics of different diagnostic tests for HIV, as well as testing algorithms, consult the latest WHO HIV testing guidelines [45].

2.5 Core principles

European countries differ greatly from each other in the way they address viral hepatitis and HIV epidemics politically and socially, services available to at-risk groups, national and local healthcare structures and legal and regulatory frameworks.

Several of the six core principles shown in Figure 1 and described below are evidence-based, but others are aspirational and founded instead on accepted best practice and expert consensus. They also build upon overarching principles already established in previous ECDC HIV testing guidance and hepatitis technical reports [18,21], as well as reflecting principles articulated in other international publications, notably WHO guidelines for hepatitis B and C testing and for HIV testing [8,45]. As Figure 1 highlights, it is important to take into account the centrality of an individual's point of view when putting these principles into practice.

Principle 1. Testing should be accessible, voluntary, confidential and contingent on informed consent

Everyone should have easy access to voluntary HBV, HCV and HIV testing. Special efforts need to be made to ensure that is applied to all risk groups.

Confidentiality is a fundamental principle of healthcare, but it is especially important for hepatitis and HIV testing because of the stigma attached to these infections and their associated risk groups. For certain populations, such as scertain migrants and socially vulnerable groups, fear of incarceration or deportation due to lack of confidentiality can dissuade them from being tested and, if they subsequently test positive, accessing treatment and care [47–49].

Breaches in confidentiality can result in people not accessing testing services. Evidence shows that people who partake in anonymous testing have a high HIV prevalence [50].

Within the field of blood-borne virus testing, expert consensus is that written consent is no longer necessary and removing this requirement has shown to be effective in increasing testing rates [18,51,52].

Principle 2. Appropriate information should be available before and after testing

While concise pretest information is acceptable to people taking a test [53], a requirement for intensive pretest counselling may discourage both health professionals from offering a test and people from accepting the offer, especially people who would benefit from testing more often [54–57]. As a result, individual risk assessment and individualised counselling during the pretest information session is no longer considered standard practice in many countries. It may suffice to provide pretest information through materials such as posters, information leaflets or videos displayed in waiting rooms. It is recognised that certain people may require additional support and information before they are tested [41].

After testing, relevant information on health education, prevention options, linkage to care and care pathways should be available as appropriate for the individual test result. Test results need to be communicated promptly and privately [41]. People who test positive, including those who self-test, should be provided with information that will enable them to make informed choices about their care [58], as well as prompt linkage to any further diagnostic confirmation that is necessary.

Principle 3. Linkage to care is a critical part of an effective testing programme

Ensuring that people diagnosed with HBV, HCV or HIV are transferred to treatment and care services is an essential element of any testing programme. Testing services need to include a well-defined referral pathway to link people diagnosed to both clinical care and support services. This pathway should be communicated and made easily accessible to all staff within the service. Linkage to care need to occur in a timely manner and processes introduced to enable follow-up on any non-attendees.

Principle 4. Testing in healthcare settings should be normalised

As highlighted in previous ECDC guidance on HIV testing [21] and demonstrated in various subsequent studies, when the offer of testing is routine and the testing process is similar to that for other diagnostic tests, it reduces stigma and increases testing uptake. There is a benefit to having viral hepatitis and HIV tests available on request in all general medical settings and healthcare providers prepared to offer them.

Principle 5. Those carrying out HIV, HBV and/or HCV testing should receive appropriate training and education

One important way to make testing more routine and reduce the barriers to test offer is through education and training of healthcare workers. As detailed in Section 4, a variety of European studies have found that educational interventions targeting healthcare providers can improve testing coverage, improve linkage to care and increase partner notification and testing coverage [59–72].

Relevant education and training needs to be made available to staff members, including, but not necessarily limited, to healthcare professionals, in all HBV, HCV and HIV testing settings. Everyone who works in such settings, including administrative and support staff, should receive training on combating stigma and discrimination associated with these infections for groups at higher risk.

Principle 6. A national testing strategy is critical in responding effectively to HBV, HCV and HIV

Successful development and integration of HBV, HCV and HIV testing services require political commitment, removal of regulatory and financial barriers and engagement with risk groups and other stakeholders. Accordingly, testing services are more effective if supported by a national testing strategy, which can also be integrated or at least coordinated with any national STI strategies. The expert panel supporting this guidance strongly advocates the development of an integrated national testing strategy for these conditions: one incorporating the preceding principles will safeguard not only the health of a country's inhabitants, but also their human rights. ECDC published two reports on its assessment of existing national HBV, HCV and/or HIV testing policies in the EU/EEA and the WHO European Region and identified significant gaps in testing and a lack of monitoring at the national level [18,20]. Evidence-based suggestions for implementation presented within this guidance will be most effective if delivered in settings where these core principles are in place.

National testing strategies should consider prioritising access to testing and promote it in a wide range of settings and modalities in accordance with local epidemiology, infrastructure and healthcare systems. To assess progress, strategies could also address the monitoring and evaluation of testing services, including the dedicated funding it requires.

Figure 1. Core principles of integrated testing of HBV, HBC and HIV

3 Guidance development

3.1 Systematic reviews

In preparing this guidance, systematic literature reviews were performed to collect and synthesise recent evidence on strategies to improve HBV, HCV and HIV testing in the EU/EEA. The evidence was comprehensively collected, reviewed and appraised in a transparent and systematic way, covering peer-reviewed and grey literature and following international standards, including Cochrane and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). Pre-identified databases and websites were searched for relevant articles, reports and conference abstracts published since 2008 (HBV and HCV) and 2010 (HIV).

The systematic reviews addressed the following questions, always focusing on the EU/EEA:

- What approaches to increase coverage and uptake of HBV, HCV and HIV testing have been implemented and how (cost-)effective are they?
- How feasible and acceptable are implemented testing approaches?
- What are barriers to testing at the individual, healthcare provider and institutional level?
- What strategies for linkage to care (and prevention) have been implemented for people who have been tested for HBV and HCV in the EU/EEA and how effective are they?

The systematic reviews are described in extensive detail in two reports: Hepatitis B and C testing strategies in healthcare and community settings in the EU/EEA – A systematic review [73] and Strategies to increase HIV testing outside of healthcare settings in Europe [74]. HBV and HCV systematic review searches generated 10 895 results and 8 331 studies were reviewed for relevance after the removal of duplicates. Ultimately, the review included 108 papers on HBV/HCV testing. HIV systematic review searches generated 23 393 results and 15 504 studies were reviewed for relevance after the removal of duplicates. In the end, the review included 368 papers on HIV testing.

In early 2017, a separate second systematic review on linkage to care following HIV diagnosis in the WHO European Region was carried out by Optimising Testing and Linkage to Care for HIV Across Europe (OptTEST) project [75]. The aim of the review was to assess current levels of linkage to care and identify factors for poor linkage to care. This evidence was also incorporated into Section 4.

3.1.1 Evidence synthesis and grading

The quality and risk of bias of included studies were assessed as described in the detailed systematic review reports [73,74]. In brief, the HBV and HCV systematic review used Scottish Intercollegiate Guidelines Network (SIGN) checklists [76] for publications with appropriate study designs and assigned the quality ratings low (–), acceptable (+) and high (++). For publications with study designs no checklist available, a modified checklist was used to quantitatively describe the quality of each study and list the criteria that it did not fulfil adequately, but a quality rating was not applied. The two systematic reviews on HIV used adapted National Institute for Health and Clinical Excellence (NICE) checklists [77] and the Appraisal Tool for Cross-Sectional Studies (AXIS) [78] to assess the quality of the peer-reviewed literature included. They assigned the quality ratings low (+), medium (++) and high (+++) on the basis of seven standard quality-assessment questions. In all three systematic reviews, grey literature documents were included only if they reported clear methods for compiling data.

The systematic reviews did not include specific search terms on 'partner notification' or 'contact tracing'. However, when analysing the evidence, these terms were repeatedly raised as strategies used to increase testing uptake. It was decided that although not the result of a full systematic review, evidence on 'partner notification' or 'contact tracing' in these papers was valuable enough to be collated into a decision-making table for use in this guidance.

Findings from the hepatitis and HIV systematic reviews were integrated for the purpose of evidence synthesis using a pragmatic approach. To structure the evidence synthesis, the evidence base from the systematic reviews was compiled by developing separate decision-making tables, one for partner notification and one for each of the following settings: primary healthcare, hospitals, other healthcare settings, community settings, self-testing and self-sampling. For each decision-making table, the evidence was analysed for the following characteristics:

- Virus – HBV, HCV and HIV
- Study population (e.g. general population, migrants, PWID, MSM and the homeless)
- Study setting (e.g. emergency departments, drug services, STI clinics, migrant clinics, prison health services and outreach)
- Outcomes
  - Testing outcomes: sample size, test offer, number of people tested or number of tests performed, testing coverage, positivity rate, missed opportunities, testing outcomes before and after intervention
  - Acceptability measures – acceptance rates, patient and provider indicators
  - Barriers to testing at the individual, healthcare provider and institutional levels
  - Economic evaluation – cost per diagnosis
  - Linkage to care – referral rate, proportion linked to care; and
- Type of approach – testing implementation, campaigns, education, clinical decision-making tools, communication technology, audits

The hepatitis and HIV systematic reviews were carried out in parallel, but were not designed to be identical, which may have introduced some limitations in the ability to align and interpret the issues arising from each review. A quantitative approach in the final assessment of the evidence was not possible due to the lack of shared thresholds for analysis (e.g. for uptake, coverage and positivity rates) and heterogeneity of the studies. In this guidance, the evidence is referred to as 'limited' when, after assessing the size of the evidence base and its coherence, only a small number of coherent studies were identified for a particular topic, as 'conflicting' when studies differed in the positioning of their findings and 'robust' when there were a large number of supportive studies. These subjective judgements were made separately by the individual teams.

3.2 Role of ad hoc expert scientific panel

A multisectoral ad hoc panel of experts was established to contribute to the gathering, analysis and interpretation of the evidence on HBV, HCV and HIV testing strategies. The panel members were selected based on their expertise on viral hepatitis, HIV and guidance development and consisted of experts from various countries in Europe and different professional backgrounds. The panel included people from national institutions, international organisations, civil society, service providers and EU-funded projects (e.g. HA-REACT, INTEGRATE and HepCare Europe). The work of the panel was overseen by a writing consortium. See Annex 1 for the names and affiliations of the expert panel and consortium members.

Panel members were invited to provide their opinions based on their professional and scientific experience in their individual capacity and not representing the interests of any professional or commercial body or Member State. All panel members signed a declaration of interest that was reviewed by the ECDC compliance officer. None of the

members of the panel declared any interests that were considered to present a conflict of interest with regard to the topic and their participation in the panel.

The panel convened for a face-to-face meeting at ECDC headquarters in Stockholm on 5–7 February 2018 where the findings of the systematic reviews were presented and discussed in detail in separate topic sessions. Each session was chaired by one of the panel members (independent from ECDC) who facilitated the discussion. Panel members provided input and, using a consensus-building approach, agreed on the formulation of evidence-based guidance statements to be included in the guidance document by discussing draft advice, options for implementation and other predetermined issues. The panel members also later contributed to the drafting of the guidance and reviewed subsequent versions of it throughout 2018.

3.3 Guidance statement development

Following a systematic review of the evidence, evidence tables were produced and discussed by the expert panel together with the ECDC experts. The ad hoc expert panel then formulated its opinions based on both the evidence base (of peer-reviewed and grey literature) and the expert members' own views and experience. The expert panel also considered the following in developing their conclusions:

- population subgroups
- linkage to care and treatment uptake
- pre- and post-test discussions
- equity, ethics and human rights
- risks and benefits; and
- implementation.

The strength of consensus statements was similarly based on both the evidence base and expert opinion and agreed upon through a consensus-building approach.

3.4 Case studies

ECDC sought to collect good-practice examples for HBV, HCV and HIV testing services in EU/EEA Member States to support the collected evidence and exemplify the suggestions for testing implementation. These case studies demonstrate how testing strategies discussed in the guidance can be implemented using the lessons learned from successful interventions and testing programmes.

The case studies in Annex 2 were selected through the systematic reviews and in response to two published calls. To be included, the case studies needed to highlight approaches used in the EU/EEA to scale up or increase the effectiveness of HBV, HCV and/or HIV testing.

During the data extraction process for the systematic reviews, 9 journal articles were identified as potential case studies for HBV/HCV and 34 journal articles and 19 conference proceedings for HIV. Among the HIV candidates, 19 targeted MSM and 18 the general population.

To address gaps in the coverage of these sources in terms of geography, test service settings and targeted subpopulations, a call for best practice examples from EU/EEA countries was issued in December 2017 (see Annex 3) and disseminated through relevant European networks and initiatives, including European HIV-Hepatitis Testing Week, HIV in Europe and the European AIDS Treatment Group (EATG). The consortium also approached relevant contacts directly via email to encourage submissions. Twenty-two good practice examples from 13 countries were submitted in response to this initial call. Most of the case studies were from community and healthcare settings such as drug treatment centres and STI clinics.

In preparation for the expert panel review, the consortium reviewed and assessed 84 collected case studies on their methods for increasing HBV/HCV/HIV testing and the availability and quality of data. This review resulted in 38 case studies being selected for review by members of the expert panel. The experts were asked to grade the case studies on the following criteria:

- clarity of the service model description
- transferability of the service model across different countries, regions, practice models, etc.
- history of internal or external evaluations (indicator of quality assurance)
- presence of clearly described linkage-to-care pathway; and
- integration of HIV and viral hepatitis testing.

An online grading form was developed for the review using a five-point scale. All case studies with an average score of 4 or higher were considered for inclusion in the guidance. Since none of the case studies from hospital settings met this threshold, the two highest scores from that category were also considered. The results were then presented and discussed during the panel meeting in February 2018.

During their discussion, the panel decided to issue a second call (Annex 4) targeting the remaining geographical gaps and encouraging the submission of pragmatic examples (e.g. of how to develop monitoring and evaluation strategies). In March 2018, this call was disseminated through several networks, including EATG and the International Union Against Sexually Transmitted Infections (IUSTI), as well as direct contact with relevant organisations. The template employed was also redeveloped using a narrative format that anticipated how the case studies would be presented in the guidance. Eight case studies were submitted to the second call and assessed by the consortium on quality, testing setting or modality and how they could best complement and support the body of evidence.

In the end, the consortium selected 15 case studies to support the guidanceidentified through the systematic review (8) and first (4) and second calls (3).

4 Conclusions

This section aims to present the most effective testing modalities and interventions for HBV, HCV and HIV, with the ultimate objective of increasing testing uptake and coverage in the EU/EEA and, where possible, promoting integration of testing activities. It draws on evidence from three systematic reviews complemented by expert opinion and insights from country-specific case studies that exemplify the evidence.

To facilitate the selection of testing approaches and policies that are best suited to incorporate in national testing policies and programmes, the section has been organised by setting: primary healthcare (PHC), hospitals, other healthcare settings, community settings and other non-healthcare settings (self-sampling and self-testing). These sections are bookended by discussion of two overarching topics: first, the identification of whom to test and the optimal testing frequency, and second, the implementation of partner notification (contact tracing).

4.1 Who to test for HBV, HCV and HIV

This section focuses on the population groups that should be considered for targeted HBV, HCV and HIV testing. These groups have been selected on the basis of two criteria: high burden of infection or the likelihood of ongoing transmission. The assessment is based on epidemiological data collected from three complementary sources: the European Surveillance System (TESSy), scientific literature and country reports from the Dublin Declaration monitoring framework. Available data were presented and discussed with the expert panel and integrated with expert opinion. For HBV and HCV, relevant data were derived primarily from two systematic reviews conducted by ECDC on the prevalence and incidence of infection in the general population and selected risk groups, including those with overlapping risks [15,33] and complemented with national surveillance data reported to TESSy [79]. For HIV, epidemiological data were largely derived from national surveillance data reported to TESSy [79] and the latest Dublin Declaration monitoring reports [20]. The identified population groups are presented in Table 3 alongside the rationale for testing and suggested testing frequencies. It is generally accepted that robust evidence on testing frequency is scarce, especially for HBV and HCV, and the suggested frequencies presented in the table below are largely based on the opinion of the expert panel supported by existing guidance documents [8,42– 45,80,81] and findings from recent studies [82].

This section is intended to support the identification of target groups for national and subnational testing programmes and serve as an overarching guide to testing frequency across all settings. It should be noted that the classification of population groups is indicative and potential overlap and/or coexistence of risk factors also need to be considered. For that reason, there should be an individual assessment in all settings in order to inform the decision to offer an initial or repeat test. Finally, it is advisable to adapt the suggestions in the table to national and local epidemiological data when defining specific target groups for testing interventions.

Table 3. Population groups to be considered for targeted HBV, HCV and HIV testing and suggested testing frequencies (all settings)

Population group[a]	Rationale for testing	Who and how often to test		
		HBV	HCV	HIV
Men who have sex with men (MSM)	Disease burden: elevated prevalence of HBV and HCV in some countries; high incidence rate and prevalence of HIV Ongoing risk: sexual transmission of HBV and HIV; higher risk of sexual transmission of HCV, at least among individuals living with HIV, PrEP users and MSM who engage in sexualised drug use ('chemsex')	All MSM who have not had a complete course of HBV vaccinations based on vaccination history Frequency: retesting, up to every 6–12 months; only required if at ongoing risk and either unvaccinated or vaccine non-responder	When indicated by individual risk assessment (e.g. sexual behaviour, sexualised drug use, PrEP or PEP use, HIV infection, history of rectal bacterial STI) Frequency: up to every 6–12 months depending on ongoing risk, sexual behaviour, HIV PrEP use, history of STIs, injecting drug use and local HCV prevalence/incidence	All MSM Frequency: at least yearly and up to every 3 months depending on ongoing risk, sexual behaviour, history of STIs, PrEP or PEP use, local HIV prevalence/ incidence
Trans* people	Disease burden: limited epidemiological data available Ongoing risk: sexual transmission of HBV, HCV, HIV; increased likelihood of overlapping risk factors (e.g. condomless anal sex, injecting drug use, sex work)	All trans* individuals who have not had a complete course of HBV vaccinations based on vaccination history Frequency: retesting, up to every 6–12 months; only required if at ongoing risk and either unvaccinated or vaccine non-responder	All trans* individuals Frequency: up to every 6–12 months depending on ongoing risk, sexual behaviour, HIV PrEP use, history of STIs, injecting drug use and local HCV prevalence/incidence	All trans* individuals Frequency: at least yearly and up to every 3 months depending on ongoing risk, sexual behaviour, history of STIs, PrEP and PEP use, local prevalence/ incidence
Sex workers[b]	Disease burden: limited epidemiological data available; significant geographic variation Ongoing risk: sexual transmission of HBV, HCV, HIV; increased likelihood of overlapping risk factors (e.g. injecting drug use, male or trans*)	All sex workers who have not had a complete course of HBV vaccinations based on vaccination history Frequency: retesting, up to every 6 to 12 months; only required if at ongoing risk and either unvaccinated or vaccine non-responder	All sex workers Frequency: up to every 6–12 months depending on ongoing risk, sexual behaviour, history of STIs, HIV PrEP use, injecting drug use and local HCV prevalence/ incidence	All sex workers Frequency: at least yearly and up to every 3 months depending on ongoing risk, sexual behaviour, history of STIs, injecting drug use, PrEP and PEP use and local HIV prevalence/ incidence
People who inject drugs (PWID)	Disease burden: high prevalence of HBV and HCV; high incidence rate and prevalence of HIV Ongoing risk: current injecting drug use, sharing of injecting paraphernalia	All PWID who have not had a complete course of HBV vaccinations based on vaccination history Frequency: retesting, up to every 6–12 months; only required if at ongoing risk and either unvaccinated or vaccine non-responder	All PWID Frequency: up to every 6 months for those at ongoing risk or more frequently depending on local HCV prevalence/ incidence	All PWID Frequency: up to every 3 months depending on ongoing risk and local HIV prevalence/incidence
People in prison[c]	Disease burden: high prevalence of HBV, HCV and HIV Ongoing risk: increased likelihood of overlapping risk	Everyone in prison who has not had a complete course of vaccinations based on vaccination history Frequency: retesting	Everyone in prison Frequency: up to every year depending on individual risk assessment	Everyone in prison Frequency: up to every year depending on individual risk assessment

Population group[a]	Rationale for testing	Who and how often to test		
		HBV	HCV	HIV
	factors, including injecting drug use, sex between men, blood mingling[d], percutaneous injuries with unsterile equipment (e.g. tattooing)	up to every 6 to 12 months; only required if at ongoing risk and either unvaccinated or vaccine non-responder		
Migrants (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[e])	Disease burden: high prevalence of HBV, HCV and HIV Ongoing risk: possible presence of other risk factors (e.g. sexual behaviour, injecting drug use, household contact with others at risk for HBV)	All migrants (as defined in Column 1) who have not had a complete course of vaccinations based on vaccination history Frequency: retesting only required if at ongoing risk and either unvaccinated or vaccine non-responder	All migrants (as defined in Column 1) Frequency: once; re testing based on individual risk assessment and local epidemiology	All migrants (as defined in Column 1) Frequency: once; retesting based on individual risk assessment and local epidemiology
Homeless people	Disease burden: limited epidemiological data available Ongoing risk: possible presence of other risk factors (e.g. injecting drug use, sex work)	When indicated by individual risk assessment Frequency: once; retesting only required if at ongoing risk and either unvaccinated or vaccine non-responder	When indicated by individual risk assessment Frequency: once; repeat testing based on individual risk assessment and local epidemiology	When indicated by individual risk assessment Frequency: once; retesting based on individual risk assessment and local epidemiology
Pregnant women	Disease burden: low prevalence Ongoing risk: for foetus, high risk of vertical transmission from an infected mother	All pregnant women who have not had a complete course of vaccinations based on vaccination history Frequency: once during first two trimesters of pregnancy	To be considered based on individual risk assessment	All pregnant women Frequency: once during first two trimesters of pregnancy. Retesting only for women at ongoing risk (or with a partner at ongoing risk or at risk and untested)
Haemodialysis recipients	Disease burden: high prevalence of HCV, HBV and HIV Ongoing risk: ongoing haemodialysis; recipients of haemodialysis in settings with suboptimal infection control standards	All individuals in this group Frequency: once; retesting only required if unvaccinated or vaccine non-responder	All individuals in this group Frequency: once; retesting every 6 months or more often if required (e.g. in case of an outbreak, or if an individual receives haemodialysis in a setting with substandard infection control)	All individuals in this group Frequency: once; retesting only required if additional risks are present
People who received blood products, organs or surgical interventions before 1992 or in settings with suboptimal infection control standards	Disease burden: elevated prevalence of HCV Ongoing risk: none	All individuals in this group Frequency: once	All individuals in this group Frequency: once	All individuals in this group Frequency: once
Sexual partners and injecting partners of people diagnosed with HBV, HCV or HIV and household contacts of people diagnosed with HBV	Disease burden: Elevated prevalence of disease among sexual partners of HIV-positive individuals and injecting partners	All sexual partners, injecting partners and household contacts of people diagnosed with HBV when partners/contacts have not had	All sexual and injecting partners of people diagnosed with HCV Frequency: once. Retesting dependent upon window period and type of test used	All sexual and injecting partners of people diagnosed with HIV Frequency: once. Retesting dependent upon window period and type of test used

Population group[a]	Rationale for testing	Who and how often to test		
		HBV	HCV	HIV
	of HIV- and/or HCV-infected individuals; limited other epidemiological data available Ongoing risk: risk of HBV transmission to household contacts of infected individuals; risk of HBV/HCV/HIV transmission to sexual and injecting partners of infected individuals	complete course of HBV vaccinations based on vaccination history Frequency: once. Retesting dependent upon window period and type of test used		

a: Other groups of particular importance include people presenting with clinical symptoms suggestive of viral hepatitis, people presenting with an HIV indicator condition (Section 4.2.1) and patients diagnosed with HBV, HCV or HIV infection.
b: Includes female, MSM and transgender sex workers.
c: Refer to the joint ECDC and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) evidence-based guidance for the prevention and control of communicable diseases in prison settings in the EU/EEA [83].
d: Blood mingling is the sharing of body fluids, particularly blood, between two or more individuals as a result of violence or rituals (e.g. blood oaths).
e: While countries may determine their own thresholds for intermediate and high prevalence rates to guide their testing strategies, taking local epidemiology and other circumstances into account, the following definitions have been used in this guidance based on several published thresholds. Intermediate HBV and HCV prevalence refers to when HBsAg or HCV antibody seroprevalence in the general population is ≥2% and <5%. and for both HBV and HCV, high prevalence is when it is ≥5% [8]. High HIV prevalence is defined as when HIV prevalence consistently exceeds 1% in the general population [9].

In addition to population groups to consider for targeted HBV, HCV or HIV testing, testing can be considered for heterosexuals who report behaviours that put them at increased risk, such as having multiple serial or concurrent sexual partners or a history of STI. Among such individuals, adolescents and youth are a subgroup of particular importance, particularly if they are members of any of the population groups identified above. An individual risk assessment and sexual health history within the context of the local epidemiology are essential to determine risk and appropriately offer HBV, HCV and/or HIV testing alongside risk-reduction advice and interventions. For individuals using PrEP, more frequent routine HIV testing needs to be offered (every 3 months) and annual HCV testing need to be offered to specific groups at increased risk (e.g. MSM) in line with existing guidance [42,84].

Other groups of particular importance in addition to the populations covered in Table 3 include people presenting with clinical symptoms suggestive of viral hepatitis, people presenting with HIV indicator conditions, including STIs (Section 4.2.1) and patients diagnosed with HBV, HCV or HIV infection. Considerations for testing members of these groups are discussed in greater detail in the following sections.

The general population may also be considered for testing initiatives, such as universal testing in high-prevalence geographical areas or birth-cohort testing. These approaches are subject to country-specific assessment based on epidemiological and financial considerations and have been introduced in some countries, both in the EU/EEA and elsewhere. More details are provided in Section 4.2.1 below.

4.2 Testing in healthcare settings

Testing strategies to date have primarily been risk-based and overall not very effective both in identifying all those infected and significantly impacting epidemics. Increasing testing in healthcare settings is a strategy that has the potential to increase coverage and normalise testing. Given that it is frequently opportunistic, such testing is likely to do so at a relatively lower cost than other strategies. Opportunistic testing refers to when a healthcare provider takes the opportunity to offer a test to a patient who is presenting with another indication or healthcare need. Such a patient is typically already undergoing venepuncture for another reason. In these instances, the add-on cost for testing for HCV, HBV and HIV is relatively small and this strategy is likely cost-effective even when it yields a low positivity rate. To determine affordability, local factors need to be taken into account. Furthermore, the routine offer of a test to everyone attending a healthcare service can help reduce stigmatisation and improve testing access for vulnerable populations.

The first three testing strategies described below – population prevalence-based testing, birth-cohort testing and indicator condition-guided HIV testing – can be applied across all healthcare settings. The remainder of Section 4.2 addresses testing in primary care, hospitals and other healthcare settings.

4.2.1 Testing strategies for all healthcare settings

There are three testing strategies that can be delivered in all healthcare settings to effectively increase testing coverage and diagnose infection. For more specific strategies, see Sections 4.2.2 (PHC), 4.2.3 (hospitals) and 4.2.4 (other healthcare settings). They include universal test offers in areas of intermediate or high prevalence, birth-cohort testing and indicator condition-guided testing for HIV.

Generalised testing in areas of intermediate or high prevalence

Geographically targeted testing needs to be determined by the local diagnosed seroprevalence of an infection and it is recommended in areas where the rate is intermediate (HBV/HCV) and high (HBV/HCV/HIV). It is predicated on the high levels of undiagnosed infection typically seen across Europe for all three infections. Areas with high diagnosed prevalence are often associated with high levels of undiagnosed infection and generalised testing strategies, meaning routinely testing everyone in contact with the healthcare system, are likely to be effective. This strategy has the additional benefit of overcoming the need to target specific population groups, thereby reducing the stigmatisation of these groups. Many regions and countries cannot easily determine or estimate their undiagnosed prevalence; this strategy removes the need to do so. Where the undiagnosed prevalence is known or can be accurately estimated, it can be used to further finesse this strategy by mapping out specific areas where a universal test offer is also likely to be cost-effective. This particular strategy requires even more careful consideration of national conditions, including epidemiology, infrastructure and cost affordability as well as effectiveness thresholds than the other strategies.

The current recommended general-population thresholds for this strategy are based on WHO classifications of intermediate (HBV/HCV) and high prevalence (all three viruses). Those thresholds are 2% and 5% for both HBsAg seropositivity for HBV and HCV antibody seropositivity for HCV [8] and 1% positivity for HIV [9].

While this strategy may be applicable to all three viral infections, evidence from the EU/EEA suggests it has only been implemented for HIV in a few countries, including the United Kingdom. Public Health England used cluster analysis of national HIV surveillance data to stratify regions into those it has defined as having low (<2 per 1000 population), high (2–5 per 1000) and very high (>5 per 1000) diagnosed prevalence. The National Institute of Clinical Excellence (NICE) in the United Kingdom has used this approach to expand HIV testing beyond antenatal and sexual health settings. Its guidelines now recommend offering everyone an HIV test in areas of high and very high prevalence upon hospital attendance/admission and upon registration with a general practice [85].

To date, there is no evidence of such an approach being implemented for HBV or HCV testing. However, developing testing strategies for HBV or HCV targeting geographical areas at intermediate or high prevalence for HCV (≥2% and ≥5% respectively) may be considered [8].

Birth cohort testing for HCV

Birth cohort testing can be an effective testing strategy when prevalence rates are markedly higher among people of a given birth cohort. In 2012, the United States Centers for Disease Control and Prevention (CDC) [8] recommended one-time testing for everyone born in the years 1945–1965, a population with a disproportionately high prevalence of HCV infection and related disease [86]. Since then, the feasibility of birth cohort testing for HCV has been studied in several European countries, including Ireland, Italy, and Spain [87–89]. In the studies in Ireland and Spain, the authors concluded that to effectively implement birth cohort testing for HCV, each country must determine its own HCV seroprevalence by year in order to successfully develop screening recommendations because risk factors, particularly injecting drug use, can affect the selection of birth cohort. In Italy, authors found that the anti-HCV screening program had an acceptable expenditure increase for the National Health Service compared to the cost per quality-adjusted life year (QALY) of other approved interventions or treatments in Italy.

Birth cohort or universal one-time testing could be considered as an option to increase HCV testing coverage, taking into account local epidemiology, affordability and the availability of effective linkage-to-care pathways.

While birth cohort testing for HIV is not usually considered, age-based testing has been proposed in the United States. The Preventive Services Task Force has recommended that clinicians screen people between the ages of 15 and 65 for HIV [90]. Within the EU/EEA, the feasibility of HIV age-based testing has been assessed in Spain, where study authors found that once-in-a-lifetime HIV testing may be worth considering there in people aged 15–65 [89].

Indicator condition-guided testing for HIV

Previous ECDC guidance on HIV testing suggested offering HIV tests in 'services for the clinical diagnosis and management of HIV indicator conditions' [21]. These HIV indicator conditions can be divided into three categories:

- AIDS-defining illness
- condition associated with an undiagnosed HIV prevalence of at least 0.1% (individuals presenting with these conditions when tested for HIV have a positive testing rate of at least 1/1000); and
- condition where not identifying the presence of HIV infection may have significant adverse implications for the individual's clinical management (e.g. for conditions requiring chemotherapy or biologics).

HIV in Europe's guidance on implementing indicator condition-guided testing in healthcare settings draws on a large body of evidence and expert opinion to recommend HIV testing for patients presenting with 60 different indicator conditions [91]. The evidence now includes two large European studies (HIDES I and II) [3,92]. See Annex 5 for the entire list of indicator conditions, as well as a shorter list, drawn up by the expert panel, of the most significant ones to address in primary care.

The implementation of indicator condition-guided HIV testing provides a useful complement to targeted testing of most at-risk groups. By providing a clinical rationale for testing, this strategy can also help normalise HIV testing and reduce barriers to it, including stigma concerns, among both healthcare providers and patients [93].

ECDC scientific advice

There are several general options for testing for HIV/HBV/HCV applicable to all healthcare settings:

- Geographically targeted testing can be considered in areas where the local diagnosed seroprevalence of an infection is intermediate (HCV) or high (HBV/HCV/HIV).
- Birth cohort testing or universal one-time testing can be an effective testing strategy when prevalence rates are markedly higher among people of a given birth cohort and should be considered as an option to increase HCV testing coverage.
- Birth cohort testing or universal one-time testing can be an effective testing strategy when prevalence rates are markedly higher among people of a given birth cohort and should be considered as an option to increase HCV testing coverage.
- Indicator condition-guided HIV testing can complement targeted testing of most at-risk groups and should be adopted.

4.2.2 Testing in primary healthcare settings

Primary healthcare (PHC) is defined as healthcare provided by general practitioners (GPs) and ancillary healthcare workers. It is the first point of contact with the healthcare system for most people.

Evidence base

The systematic review on HBV and HCV testing identified 8 intervention studies (1 HBV, 5 HCV and 2 both) [59,60,71,94–98] and 2 clinical practice audits (1 HBV and 1 HCV audit) [99,100] that provide evidence on testing in primary care settings.[2] An additional 4 studies address barriers to testing (2 HBV/HCV and 2 HCV) [94,95,99,101] and 8 linkage to care (1 HBV, 2 HBV/HCV and 5 HCV) [70,71,94,96,102–105]. The systematic review on HIV testing identified 36 studies [3,59,61,62,92,106–136] and 8 clinical practice audits [137–144] that provide evidence on HIV testing in primary care. Another 19 studies include information on barriers to HIV testing in this setting [3,116,123,145–160].

Despite some guidelines recommending HBV, HCV and HIV testing in PHC, audits highlight many missed opportunities for HCV and HIV testing in this setting (1 HCV and 8 HIV studies) [99,137–144], with the one possible exception being high levels of HBV testing for pregnant women (1 study) [100]. Evidence suggests that this suboptimal coverage may be due to factors that discourage healthcare professionals from offering tests, including a lack of knowledge and training, time restrictions and concerns related to perceived stigma or the potential impact of offering tests on the patient–provider relationship (1 HBV, 3 HCV and 17 HIV studies) [3,94,95,99,101,116,123,140,148–160].

The body of evidence on the effectiveness of interventions to improve HBV and HCV testing coverage in PHC is very limited[3] (3 HBV studies and 6 HCV studies) [59,71,94–98], restricted to four studies from the United Kingdom and one each from France, Ireland and Italy, focusing on targeted test offers to members of risk groups such as migrants, PWID and the homeless. Testing and positivity rates vary across studies.

While the evidence on the effectiveness of testing interventions to improve HIV testing coverage in PHC is somewhat greater (30 studies) [3,59,92,106–132], it is also restricted to a small number of countries, chiefly Spain

[2] Studies examining testing for more than one virus are sometimes listed as combination studies, as in this section, and sometimes as separate studies for each virus being investigated.

[3] Evidence referred to as 'limited' for a particular topic when a small number of consistent studies were found.

and the United Kingdom, with no studies available from eastern European countries in the EU/EEA. Where data are available, HIV testing in PHC resulted in high positivity rates of up to 6% among risk groups (4 studies) [59,108,109,112] and people with HIV indicator conditions (10 studies) [3,92,110,112,118,125–127,129,131,161].

There have been a number of other strategies to improve testing coverage, including education programmes (1 HBV, 2 HCV and 4 HIV studies) [59–62], campaigns (2 HCV studies) [60,97] and clinical decision-making tools (3 HIV studies) [134,135,162]. There is limited evidence that educational interventions targeting GPs and campaigns targeting the public, GPs or risk groups may be beneficial for HBV and HCV testing (1 HBV and 3 HCV studies) [59,60,97]. In addition, based on the body of evidence, it is not possible to recommend clinical decision-making tools for HIV testing in PHC settings (3 studies) [134,135,162], though one study suggests they may be beneficial [134]. In addition, there were few studies that demonstrated that education and training programmes can improve GP attitudes and address their concerns about HIV testing (2 studies) [61,62].

HIV testing, both rapid testing and venepuncture, has been found to be highly acceptable to patients in a PHC setting (12 studies) [106,111,112,116,120,123–125,146,149,150,163], but less acceptable to GPs who were concerned about insufficient training and the stigmatising potential of offering tests (17 studies) [3,116,123,140,148–160]. Offering an HCV test was also considered acceptable among patients (2 studies) [59,94], but limited evidence, particularly from two studies targeting migrants, suggests the existence of barriers to PHC service access and the uptake of HBV and HCV testing (2 HBV and 4 HCV studies) [94,95,99,101].

Integrating HIV testing with viral hepatitis testing does not affect the acceptability of GP test offers for patients, but there is limited evidence that it improves the rate of testing by GPs by minimising the perceived stigma of offering an HIV test alone (4 HIV studies) [59,110,164,165]. There is also limited evidence showing that patient-completed risk assessments are acceptable in PHC settings (1 HIV study) [162].

Linkage to care, variably defined, following an HBV or HCV diagnosis may be suboptimal, particularly for vulnerable groups such as the homeless and PWID (1 HBV and 5 HCV studies) [94,96,102–104]. There is limited evidence to show that the existence of clinical care pathways and educational interventions for healthcare staff may result in better linkage to care (more than 80% attendance in specialist care; 1 HBV and 1 HCV study) [70,71]. While linkage to care was not covered in the HIV systematic review for the current guidance, a separate systematic review on linkage to HIV care following diagnosis in 2017 found no studies from primary care [75].

Case study example of testing in primary healthcare settings

To encourage GPs to offer HIV testing, the HIV European Research on Mathematical Modelling and Experimentation of HIV Testing in Hidden Communities (HERMETIC) project in Belgium developed a GP-friendly intervention tool to provide advice on HIV screening and complementary training to promote implementation of the advice. The tool recommends proposing an HIV test proactively and routinely to patients at increased risk of HIV acquisition and those with an HIV indicator condition.

The intervention was implemented by making the advice available on a GP website listing all GP guidelines and using GP networks for training and quality improvement to disseminate it to GPs in Flanders. To promote uptake of the advice, complementary training was developed based on a simplified intervention mapping protocol. The training addresses the GPs' main barriers to provider-initiated HIV testing as identified in a focus group study. The training approach is interdisciplinary: a public health specialist provides information on the hidden HIV epidemic and the advantages of early diagnosis and contextualises HIV risk in the groups at increased risk, an HIV specialist from a local HIV specialised care centre discusses the HIV indicator conditions and the role of GPs in HIV care and a sexual health communication specialist offers practical communication tips on sexual risk assessment and motivations to test for HIV.

A total of 672 GPs attended the training and reported sincere intentions to implement the advice among patients. The impact of the interventions on the number of HIV diagnoses and tests performed by GPs will be assessed through national HIV surveillance. By using the GPs' individual social and health insurance codes, the intervention results can be compared to the control results. The involvement of policymakers and the GP umbrella organisation in intervention development and their endorsements facilitated the sustainability of the intervention.

—from Case Study PHC1 in Annex 2

The evidence for HBV and HCV is more limited than that for HIV. This is primarily from studies conducted in western Europe for all three infections. Testing in PHC is effective and acceptable to patients, while suboptimal linkage to care and a number of clinician-related barriers to testing have been identified, although certain the clinician barriers are somewhat reduced by integrated testing. The evidence for effective interventions to increase testing is also geographically restricted and for HBV and HCV, it is focused mainly on risk groups.

Opinion from the expert panel

Based on the above evidence and their own experience in the field, as well as existing European and international guidelines (Annex 5), the expert panel reached consensus on the following conclusions.

All patients diagnosed with HBV, HCV or HIV infection in PHC need to be tested for the other two viruses as per EACS and EASL guidelines [42,43].

All patients presenting with clinical symptoms or laboratory markers (including elevated liver enzymes) compatible with acute or chronic hepatitis need to be offered and recommended testing for HBV and HCV in accordance with national and international guidelines [8]. All patients presenting to primary care with an HIV indicator condition (Section 4.2.1), including an STI, need to be offered and recommended for an HIV test as described in the European guidance on HIV indicator condition-guided testing [91]. See Annex 5 for a list of indicator conditions to be focussed on in primary care.

In addition, people who are known to be or identify themselves as members of certain risk groups need to be offered HBV, HCV and HIV testing, once local epidemiology has been taken into consideration. Those at ongoing risk should have this offer repeated. (Table 3). For HBV testing, this needs to be done in the context of previous vaccination history.

In areas known to have intermediate (HBV/HCV) or high (HBV/HCV/HIV) prevalence or incidence rates (Table 3 footnote), testing for the relevant virus needs to be offered and recommended to anyone attending PHC who has never tested before and is having a blood test for another indication (i.e. opportunistic testing). Those at ongoing risk need to have this offer repeated.

Pregnant women should be offered and recommended HBV and HIV tests during the first two trimesters of pregnancy as per ECDC antenatal screening guidance [166].[4] An HCV test could also be offered and recommended as indicated by their risk profile. Repeat HIV testing during pregnancy and HBV testing for those who decline HBV vaccination or are non-respondent is not recommended for women who are not at ongoing risk. When a woman tests negative for HIV or HCV and has a partner at higher risk, her partner needs to be offered a test and such testing ought to be facilitated. If her partner remains untested or if his risk factors are unknown, retesting of the pregnant woman needs to be considered later in pregnancy.

Rapid diagnostic (RDTs) and dried blood spot (DBS) tests could be considered to increase uptake among risk groups and those who decline venepuncture as per ECDC HIV testing guidance, EASL HCV guidelines from 2018 and WHO hepatitis testing guidelines [8,21,43].

In addition, relevant education and training should be made available to PHC staff members, including but not necessarily limited to healthcare professionals, to improve HBV, HCV and HIV test offer rates.

Finally, appropriate clinical care pathways and referral systems need to be established to ensure optimal linkage to care for people newly diagnosed with HBV, HCV or HIV in primary care, in addition to linkage to preventive services (such as HBV vaccination or PrEP for HIV) for those who test negative and are at ongoing risk. These referral systems ought to include linkage to other support services, including psychological and social services, to provide additional support and help address any inequities in access.

[4] Where there is shared antenatal care with other services, testing in PHC may not be necessary if there are local agreements in place on who undertakes testing.

ECDC scientific advice

There are several options for testing for HIV/HBV/HCV in primary healthcare settings:

- Available evidence shows that HBV, HCV and HIV testing in PHC settings is acceptable and may effectively contribute to increase testing coverage and case detection among higher risk groups and other specific population groups, such as people presenting with HIV indicator conditions. Although limited, evidence on general population testing in these settings is also encouraging in intermediate- and high-prevalence regions and birth cohorts.
- Any person attending PHC settings known to be or identify as members of certain risk groups or have clinical symptoms or laboratory markers (including elevated liver enzymes) compatible with acute or chronic hepatitis or an HIV-indicator condition, including an STI, should be considered for integrated HBV, HCV and HIV testing (see Table 3 for suggested frequency).
- In areas with intermediate (HCV) or high (HBV/HCV/HIV) prevalence or incidence rates (Table 3 footnote), testing for the relevant virus should be considered for anyone attending PHC who has never tested before and is having a blood test for another indication (i.e. opportunistic testing).
- Available evidence suggests that testing coverage in PHC settings is often suboptimal and attributable to factors that discourage healthcare professionals from offering tests. Several interventions may be considered to increase test offers (e.g. educational interventions for healthcare staff and clinical decision-making tools), although the volume of evidence for the effectiveness of any specific intervention over any other is small. When considering testing in PHC settings, locally agreed clinical care pathways and referral systems should be established to ensure better linkage to care for people newly diagnosed with HBV, HCV or HIV in primary care.
- According to the evidence, integrated HBV/HCV/HIV, rapid, dried blood spot and venepuncture testing are all acceptable in primary care, at least to patients. All patients diagnosed with an HBV, HCV or HIV infection in PHC should be considered for testing of the other two viruses.

4.2.3 Testing in hospital settings

The term 'hospital settings' covers all hospital departments, both inpatient and outpatient, including medical admissions units, infectious disease units, hepatology units and emergency departments.

Evidence base

There is limited evidence from audits of clinical practice that indicate suboptimal coverage of HBV testing for patients diagnosed with HCV or HIV, and of HCV testing for patients diagnosed with HBV or HIV (1 HBV, 1 HCV and 2 HBV/HCV studies) [167–170].

There is limited evidence on testing interventions aimed at improving HBV and HCV testing in hospital settings (5 HBV and 7 HCV studies) [97,98,171–175]. In most of these studies, as well as others drawn from the HIV systematic review, some form of combined testing was offered for HBV, HCV and/or HIV (9 studies) [171–173,175–180].

Viral hepatitis testing targeting individuals from certain population groups (migrants and psychiatric patients) has been implemented in various hospital departments, with varying levels of testing uptake and generally high positivity rates (up to 7.8% for HBV and 8.7% for HCV; 3 HBV/HCV studies) [171,174,175].

There is also limited evidence on the effectiveness of testing for HBV and HCV in emergency departments, showing lower positivity rates of up to 0.7% for HBV and 5% for HCV, compared to risk group targeting (2 studies) [172,173].

Available evidence from audits of HIV testing in hospital departments show that people with HIV indicator conditions are often not offered an HIV test and doctors working in hospital settings are not always aware of the relevant testing guidelines (23 studies) [140,181–202].

There is a body of evidence on testing interventions aimed at improving HIV testing coverage in hospital settings (41 studies) [3,64,65,68,92,124–126,131,171–173,175–180,203–225]. However, there is limited evidence on the effectiveness of these interventions in increasing HIV testing. In addition, the majority of studies are from a small number of countries (notably the United Kingdom, Spain and France), with only one study available from eastern Europe (Poland). Where data are available, testing in hospitals has resulted in generally high HIV positivity rates (up to 5%), though it is lower in emergency departments (up to just over 1%; 34 studies) [64,65,68,124,126,172,173,175–178,180,203–224].

Aside from the simple provision of testing, there have been a number of other strategies to improve testing coverage in hospitals, including education programmes (1 HBV, 1 HCV and 9 HIV studies) [63–69,174,226], campaigns (2 HBV, 3 HCV and 5 HIV studies) [97,133,173,174,208,217] and clinical decision-making tools (3 HIV

studies) [135,190,227]. There is evidence showing that the education of clinicians in hospital settings can improve testing rates, at least for HIV (7 studies) [63–69], though the majority of studies are not yet peer-reviewed (picked up during grey literature search). Campaigns may contribute to improving testing rates, but given the available evidence, it is not possible to recommend clinical decision-making tools in hospital settings.

Universal HIV (6 studies) [125,204,206,207,214,219] and rapid HIV testing (6 studies) [179,180,209,216,222,225] are highly acceptable to patients and staff in hospital departments according to peer-reviewed evidence.

Barriers to testing in hospitals have only been studied for HIV. Hospital staff barriers include competing priorities, lack of time to confidence in offering testing and an expressed need for training (10 studies) [3,63,159,195,202,228–232]. The obstacles reported for patients include a lack of awareness of testing consent procedures and concerns about confidentiality (8 studies) [216,224,228,230,231,233–235].

Four cost-implication studies of HIV testing in hospital settings have been conducted in the United Kingdom. They show that universal-offer testing is highly cost-effective if future healthcare costs and QALYs are incorporated into calculations [236–239].

Limited evidence on linkage to care exists for people testing positive for HBV or HCV, indicating that it is often suboptimal both for vulnerable groups (e.g. PWID) and the general population (5 HBV and 10 HCV studies) [70,104,171–175,240–243]. Evidence on linkage to care after HIV diagnosis made in hospital settings is also limited. A systematic review in 2017 [75] found only one study that examined linkage to care following diagnosis at a hospital in Spain and found thee proportion within one month of diagnosis at 63%.

The majority of the evidence on testing in hospital settings is for HIV and primarily from studies from a small number of western European countries. There is strong evidence on the acceptability (HIV) and effectiveness (all) of testing in hospitals, but not on integrated testing. However, the evidence on interventions to improve testing is less robust. The evidence for the cost-effectiveness of hospital testing (HIV), although geographically restricted, is relatively good.

Opinion from the expert panel

Based on the above evidence and their own experience in the field, as well as existing European and international guidelines (see Annex 6), the expert panel reached consensus on the following conclusions.

All patients diagnosed with HBV, HCV or HIV in hospital settings need to be tested for the other two viruses, as per current EACS and EASL guidelines [42,43].

Patients presenting with clinical symptoms or laboratory markers (including elevated liver enzymes) compatible with acute or chronic hepatitis need to be offered and recommended testing for HBV and HCV, in accordance with national and international guidelines. In addition, any patient who presents to a hospital department with an HIV indicator condition need to be offered and recommended HIV testing as described in the European guidelines for such testing [91].

People who are known to be or identify themselves as members of certain risk groups need to be offered HBV, HCV and HIV testing when they are undergoing venepuncture for another indication (i.e. opportunistic testing). See Table 3 above for risk groups and suggested testing frequencies. Those who are not undergoing routine venepuncture could be offered testing by venepuncture or alternative testing methods (e.g. finger stick and/or oral fluid testing) or information on how to get tested. Those at ongoing risk need to have this offer repeated. For HBV testing, this ought to be done in the context of previous vaccination history.

In areas of intermediate (HBV/HCV) or high (HBV/HCV/HIV) prevalence or incidence, testing should needs to be offered to anyone who is attending an emergency department or is admitted to hospital, has never tested before and is having a blood test for another indication. The offer needs to be repeated to those at ongoing risk (Table 3 footnote).

Case study examples on emergency department testing

Two HIV case studies from France and the United Kingdom show that routine testing in emergency departments can be feasible and cost-effective, with positivity rates of 3.9% in 6 emergency departments in Paris and 0.3% at the Chelsea and Westminster Hospital in London. In France, staff were trained on how to inform, propose and perform a rapid test in addition to their usual responsibilities and relevant posters and brochures were provided in waiting rooms or given to eligible patients.

In London, emergency department staff were prompted to offer a test by an electronic prompt and asked to document whether the test was accepted, declined or not offered. A weekly meeting was held with the sexual health team to evaluate the effectiveness of the testing service. In Paris, the offer rate was 6.2% and in London 14%, where it varied from 6% to 54% per month. The test acceptance rate was 69.6% in Paris and 63% in London. The United Kingdom study reported significant improvements in coverage when testing was switched from oral fluid to blood and nursing staff were incorporated into the testing service. Other interventions, including identifying 'testing champions' and providing regular teaching and newsletter updates, also had positive effects on the London outcomes.

The French study found that it is critical to emphasise the benefits of the testing strategy to emergency department staff during training, including its cost-effectiveness. The London study demonstrated that HIV testing can be delivered in emergency departments for a sustained period of time, but that constant innovation and attention are required to maintain it as a routine part of emergency department care and it requires additional staff training and infrastructure.

—from Case Studies HS1 and HS2 in Annex 2

All pregnant women should be offered and recommended HBV and HIV tests during the first two trimesters of pregnancy (as per ECDC antenatal screening guidance [166]). An HCV test could be offered and recommended to a pregnant woman if indicated by her risk profile. Repeat HIV testing during pregnancy and HBV testing for those who decline HBV vaccination or are non-respondent is not recommended for women who are not at ongoing risk. If a pregnant woman tests negative for HIV and HCV and has a partner at higher risk, then her partner ought to be offered a test and this offer facilitated. If such a partner remains untested or his risk is unknown, retesting needs to be considered later in pregnancy.

Both primary and secondary care staff should be adequately educated and trained in offering HBV, HCV and HIV testing.

ECDC scientific advice

There are several options for testing for HIV/HBV/HCV in hospital settings:

- According to available evidence, testing for HBV, HCV and HIV in hospital settings is acceptable to patients and staff and is likely to contribute to increasing testing coverage and case detection among risk groups and other specific population groups, such as people presenting with HIV indicator conditions. Routine testing in emergency departments, including universal testing and integrated testing, is also acceptable, but supported by limited evidence.
- Although supported by limited evidence, all patients diagnosed with an HBV, HCV or HIV infection in hospital settings should be considered for a test for the other two viruses.
- Any person attending a hospital department and known to be or identify as members of certain risk groups or having clinical symptoms or laboratory markers (including elevated liver enzymes) compatible with acute or chronic hepatitis or having an HIV indicator condition, including an STI, should be considered for integrated testing of HBV/HCV/HIV (Table 3).
- In areas of intermediate (HCV) or high (HBV/HCV/HIV) prevalence or incidence, testing should be considered for anyone attending an emergency department or admitted to hospital, has never tested before and is having a blood test for another indication. The offer should be repeated to those at ongoing risk.
- Strategies to improve HBV, HCV and HIV testing coverage in hospitals may include education and training programmes for healthcare staff, campaigns and clinical decision-making tools, although the evidence of the effectiveness of any specific intervention over any other is small.

4.2.4 Testing in other healthcare settings

'Other healthcare settings' in this guidance is used to designate formal healthcare services other than hospital departments and primary care practices. For the purpose of this document, they include STI clinics, genito-urinary

medicine clinics, dermato-venereology clinics, antenatal services, pharmacies, prison health services, drug and harm-reduction services within formal healthcare facilities, tuberculosis (TB) services and low-threshold clinics.

Evidence base

Several guidelines recommend expanding HBV, HCV and HIV testing across a variety of healthcare services. Studies auditing current HBV and HCV testing practices show that coverage of HBV testing in antenatal settings is high, but may be suboptimal in services targeting migrants (5 studies) [244–248], while missed testing opportunities have been reported for STI clinics (2 HBV and 2 HCV studies) [249–251]. Studies auditing current HIV testing practices show that coverage is high for patients who present to TB and STI services (10 studies) [181,191–193,252–257]. HIV testing coverage in antenatal settings is also high (3 studies) [258–260]. However, there is also evidence in the category of other healthcare settings, including STI clinics and prison health services, of missed opportunities to test members of HIV risk groups (4 studies) [261–264].

Though there have been various interventions based in other healthcare settings to implement HBV, HCV and HIV testing and improve coverage (8 HBV, 19 HCV and 34 HIV studies) [97,98,121,122,131,179,180,265–306], only a few studies have been carried out in any specific type of setting. These settings include prison health services [83], pharmacies and drug and harm-reduction services. Where reported, HBV and HCV testing coverage in these studies has been found to be variable and often suboptimal. The positivity rate for HBV and HCV has varied according to the setting and the targeted population. Within the category of other healthcare settings, STI clinics are the setting where HIV testing has been studied most frequently. There is overall limited evidence for the effectiveness of HIV testing implementation interventions in increasing uptake. Where data are available, they show that HIV positivity varies by setting, from 0.9% in pharmacies to 3.9% in prisons (24 studies) [121,122,131,179,266,268,270–278,280,281,283,285,287–290].

Despite limited evidence, the implementation of novel HBV and HCV testing approaches, including rapid tests, DBS tests and point-of-care NATs, has been associated with increased testing coverage in several settings, including drug and harm-reduction services, pharmacies, STI clinics and clinics targeting migrant populations (3 HBV and 12 HCV studies) [97,98,179,291,293,294,297,298,300,302–304,306]. RDTs and DBS tests have both been found to be highly acceptable to users (1 HBV and 2 HCV studies) [179,304].

Case study example of testing and care in drug treatment centres

Through a shared care model, drug users affiliated with drug-treatment centres in Copenhagen are now offered screening for viral hepatitis and HIV at the treatment centres instead of being referred to another facility. In order to improve access to health services for this vulnerable group, Shared Addiction Care Copenhagen (SACC) was developed as a cross-sectoral collaboration between 11 municipal drug treatment centres and two specialised infectious disease clinics.

An average of around 2 000 people are inscribed at the 11 drug treatment centres, some for shorter periods others for near-lifelong treatment. Data at baseline showed that 44% of the clients had previously been tested for HIV and hepatitis. During the 3-year project period, 700 clients were tested for HIV and hepatitis. By the project closure, 66% of clients had a previous HIV and hepatitis test. Five people tested positive for HBV, 207 for HCV and 1 for HIV.

A joint database maintained by the infectious disease clinics and drug treatment centres has allowed for better monitoring of infected patients. For instance, users who test positive for HCV are assessed with a mobile FibroScan device and receive treatment at the centres, monitored by the hospital.

The SACC project has helped break down barriers between different sectors in the healthcare system by establishing a cohesive treatment and care model for drug users with hepatitis C, while also providing a better overview of the number of HCV infections in Copenhagen. The key to the success of the SACC model is the close collaboration and investment of multiple stakeholders. It should be noted that the project required extensive human resources and involved training and educating staff at the drug treatment centres, in addition to coordination of tests, fibroscans, treatment and care.

—from Case Study DT1 in Annex 2

Integrated testing for HBV, HCV and HIV has been reported in several settings (12 studies) [179,266,270,272,277,278,281,288–292], with comparable positivity rates for the three infections and largely influenced by the underlying epidemiology in the target population.

Besides the simple implementation of a blood-borne virus testing policy, additional strategies to improve testing coverage in other healthcare settings have also been studied. Campaigns encouraging people to test in prison health services, STI clinics and drug and harm reduction services have been shown to improve testing coverage (2 HCV and 6 HIV studies [97,267,275,285,307–310]. There is insufficient evidence for the effectiveness of education

and training (1 HBV, 2 HCV and 3 HIV studies) [72,289,293,311], communication and technology (1 HIV study) [312] and clinical decision-making tools (1 HBV, 1 HCV and 1 HIV study) [292], although one study has shown a positive effect on HBV and HCV testing uptake following computer-assisted interviews at STI clinics [292].

Very limited findings were retrieved for the acceptability of HBV and HCV testing in other healthcare settings (1 HBV and 1 HCV study) [179,304]. The effectiveness and acceptability of universal HIV testing is well established for women as part of antenatal care as discussed in previous ECDC guidance on HIV testing [21]. However, evidence for the acceptability of HIV testing in pharmacies is variable (3 studies) [269,271,274]. There is evidence that rapid HIV testing may be preferable to venepuncture in certain settings in the category of other healthcare settings (5 studies) [124,180,270,271,285].

The systematic reviews found no studies examining the cost effectiveness of testing in healthcare settings outside hospitals and primary care.

Barriers to HCV testing reported by PWID in drug services include stigma related to drug use (1 study) [303]. Documented barriers to HIV testing in other healthcare settings among specific groups of patients include lower educational levels (pregnant women), low risk perception (expectant fathers in antenatal services and clients of drug and harm-reduction services), concerns about confidentiality (STI clinic attendees), lack of knowledge on where to obtain a test (expectant fathers and STI clinic attendees) and stigma (expectant fathers and STI clinic attendees; 7 studies) [258,266,313–317].

According to the body of evidence, linkage to care following an HBV or HCV diagnosis is generally suboptimal in the category of other healthcare settings, with the notable exception of antenatal care services after HBV diagnosis (9 HBV and 9 HCV studies) [104,179,248,250,290,291,298,300–302,306,318–322]. Limited evidence shows improved linkage to care when a clinical care pathway is in place (1 HBV and 6 HCV studies) [70,299,304,323–325]. The offer of outreach treatment for HCV may also be considered as an additional intervention to improve linkage to care (1 study) [326].

There is limited evidence on the levels of linkage to care after diagnosis with HIV in other healthcare settings (1 systematic review) [75]. However, in the few settings that have been studied, linkage after HIV diagnosis has been found to be high (more than 78% within 1 month of diagnosis and more than 87% within 3 months; 4 studies) [327–330].

The evidence for acceptability and effectiveness varies among the different settings considered under other healthcare settings, with more robust evidence available for antenatal care and STI services than for pharmacies and prison health service settings. Similarly, there is more evidence focussed on HIV testing than HBV and HCV testing for other healthcare settings. There is evidence to support the use of novel testing approaches (such as RDTs and DBS tests) and campaigns in various settings, with several barriers to testing identified, raising some concerns about linkage or transfer to care.

Opinion from the expert panel

Based on the above evidence and their own experience as specialists, as well as existing European and international guidelines (Annex 6), the expert panel reached consensus on the following conclusions.

All patients diagnosed with HBV, HCV or HIV need be tested for the other two viruses as per EACS and EASL guidelines [42,43].

For people attending community-based TB services, those who are known to have TB or show clinical indications of TB ought to be offered and recommended HIV testing. They could also be considered for HBV and HCV testing.

In addition, HBV, HCV and HIV testing need to be provided through pharmacies based in the community, under the same quality standards that apply in healthcare settings generally.

All who attend drug and harm reduction services need be offered and recommended HBV, HCV and HIV testing during their initial assessments. The offer needs to be repeated if indicated by ongoing risk.

Furthermore, healthcare settings serving migrant populations ought to offer and recommend testing for relevant viruses to people who come from countries with intermediate (HBV/HCV) or high HBV, HCV or HIV prevalence (Table 3 footnote)

RDTs and DBS tests could be made available in accordance with patient preferences to increase testing acceptance. In some settings, such tests may be the preferred option.

Pregnant women attending these settings and their partners need be tested as described for the previous two settings [166].

Given evidence of high prevalence of blood-borne viruses in prison settings and the lack of access to effective prevention and control measures there, HBV/HCV/HIV testing needs to be offered to all people in prison as per

ECDC guidance on active case finding in prison settings [83]. For HBV testing, this ought to be done in the context of previous vaccination history.

ECDC scientific advice

There are several options for testing for HIV/HBV/HCV in other healthcare settings:

- There is some evidence to show that testing for HBV, HCV and HIV, including integrated testing, may be implemented in a variety of other healthcare settings, including pharmacies, STI and dermato-venereology clinics, harm reduction services, prison health services and antenatal care services, with varying degrees of effectiveness in increasing testing coverage and case detection.
- Limited evidence suggests that RDTs and DBS tests are acceptable and may help to increase testing coverage in these settings.
- Although supported by limited evidence, all patients diagnosed with an HBV/HCV/HIV infection should be offered a test for the other two viruses.
- Available evidence suggests that implementation of testing in other healthcare settings is often suboptimal. While several interventions to increase test offer may be considered (e.g. campaigns, educational interventions for healthcare staff and clinical decision-making tools), the amount of evidence for the effectiveness of any specific intervention over any other one is very small.
- When considering testing in other healthcare settings, locally agreed care pathways and referral systems need to be established to ensure effective linkage to care for people newly diagnosed with HBV, HCV or HIV in other healthcare settings.
- Assessment related to specific settings:
  - Despite very limited evidence, HBV, HCV and HIV testing could be made available through pharmacies based in the community, provided the same quality standards that apply in all healthcare settings are met.
  - Everyone attending drug and harm reduction services needs to be offered and recommended HBV, HCV and HIV testing during their initial assessments. The offer should be repeated if indicated by ongoing risk.
  - All healthcare settings serving migrant populations should consider offering and recommending testing as appropriate to people who come from countries with intermediate (HCV) or high HBV, HCV or HIV prevalence.
  - Given the higher prevalence of blood-borne viruses in many prison settings, offering HBV, HCV and HIV testing should be considered to all people in prison, as per ECDC guidance on active case finding in prison settings.
  - IUSTI European guidelines for HIV testing among those who seek care in STI/genito-urinary/dermato-venereology clinics should be applied. They recommend offering everyone an HIV test regardless of symptoms or risk factors as part of the initial screening for STIs. They also recommend offering HIV testing to all attendees who have a high likelihood of exposure to HIV, are pregnant regardless of risk factors, or voluntarily seek testing, especially if never tested before.
  - IUSTI European guidelines for HBV and HCV testing among those who seek care in STI/genito-urinary/dermato-venereology clinics should be applied. These are based on an assessment of individuals' risks and on prevalence in the region or country of origin.

IUSTI guidelines for HBV and HCV testing in STI clinics and other sexual health settings need to be consulted and applied where appropriate, particularly the guidelines' recommendation for HBV testing based on geographic prevalence, risk group definitions and recommendations for risk group testing [81]. The same guidelines recommend that where the local general prevalence of HBV carriage is below 2%, a risk assessment should guide HBV testing. Where the local general prevalence of hepatitis B carriage is above 2%, all attendees need to be offered HBV testing unless known to be immune. The guidelines also recommend that HCV testing in sexual health settings ought to be conducted using a risk-based approach.

Finally, IUSTI European guidelines for HIV testing recommend offering everyone who seeks care in STI/genito-urinary/dermato-venereology clinics an HIV test regardless of symptoms or risk factors as part of the initial screening for STIs. These same guidelines also recommend offering HIV testing to all attendees who have a high likelihood of exposure to HIV, are pregnant regardless of risk factors, or voluntarily seek testing, especially if never tested before [331].

4.3 Testing in community settings

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

and accessible to those communities. As a rule, target populations covered by these services are at increased risk for infection, vulnerable or hard to reach. Common target groups for community-based testing include MSM, migrants, PWID, the homeless and sex workers. For the purpose of this document, such services include community-based testing facilities, community-based drug and harm-reduction service facilities and community-based outreach activities [332].

Evidence base

There is a large body of evidence from EU/EEA countries generally supporting the implementation of community-based testing services. According to the available evidence, community-based testing services generally result in high positivity rates, although the rates are influenced by the underlying epidemiology (15 HBV, 22 HCV and 52 HIV studies) [97,104,121,122,130,161,270,282,285,291,306,333–395].

Descriptive evidence indicates that community-based HIV testing services contribute to a sizeable proportion of new HIV diagnoses in countries that are able to monitor community-based diagnoses as part of national HIV surveillance [332]. No corresponding information is available for community-based HBV and HCV testing.

Community-based testing is effective in reaching populations that are at increased risk of infection, vulnerable or hard to reach, including MSM, migrants, PWID, the homeless and sex workers (16 HBV, 20 HCV and 34 HIV studies) [104,161,270,282,291,306,333–337,341,345,347–349,351,353–360,362,363,365,366,368–372,374–395].

There is a large body of evidence indicating that HIV testing services at community-based facilities result in high testing and positivity rates among MSM and migrants (22 studies) [104,282,334–337,341,347–349,353–356,358–360,362,363,365,372,375].

Many studies also support outreach testing for HBV, HCV and HIV in risk groups and hard-to-reach populations (11 HBV, 10 HCV and 23 HIV studies) [130,161,270,334,335,340,343,345–347,349,351,352,354,356,357,361,362,364–366,368,371,373,376,378,380,381,383,385,388,391–394]. Available evidence indicates that outreach activities targeting MSM, migrants, the homeless, PWID and sex workers can result in high testing coverage and positivity rates. On the other hand, limited evidence shows that outreach activities targeting populations with low HIV prevalence and risk, such as the general population, students or young people, have low yields (3 HIV studies) [122,346,361].

Case study example

CheckPoint Zagreb has served as an important supplement to blood-borne virus testing services provided by the Croatian healthcare system and was the first non-institutional centre for testing HCV and HIV in Croatia.

Since the launch of the checkpoint, the number of tests in Croatia has tripled. Positivity rates for both HCV and HIV at the checkpoint exceed 1%. Since 2013, 7 100 have been tested at CheckPoint Zagreb, with 4 300 people tested for HCV and 5 300 for HIV. Around 60%–70% of all visitors to the centre have never been tested before. Of the new positive test results, 50 were HCV tests (1.15%) and 61 were HIV (1.13%). The diagnosed patients are linked with appropriate specialist services.

Every person who receives a preliminary reactive test at CheckPoint Zagreb is referred to an infectious disease specialist who provides post-counselling and conducts a confirmatory test. Staff at CheckPoint Zagreb can schedule these appointments immediately. Support is offered to people who have had a reactive test by psychologists affiliated with the checkpoint, both during treatment and follow-up.

—from Case Study COM3 in Annex 2

A limited body of evidence supports HBV, HCV and HIV testing services at community-based drug and harm-reduction service facilities (2 HBV, 8 HCV and 3 HIV studies) [97,270,291,306,333,365,377,379,382,387]. Evidence indicates that such settings can achieve high testing coverage and positivity rates.

Available evidence indicates that community-based testing is associated with earlier HIV diagnoses among MSM (1 study) [344].

In addition, two studies have found that in community settings, DBS tests for HCV and rapid HIV tests result in a significant increase in testing uptake, tests performed and new diagnoses (1 HCV and 1 HIV study) [97,342]. Further evidence suggests that oral fluid and DBS tests result in higher testing uptake than venepuncture and that both are acceptable in community-based services (1 HBV, 3 HCV and 6 HIV studies) [270,285,333,342,354,358,365,386].

Studies have shown that integrated testing for HBV, HCV, HIV and other STIs does not affect the acceptability and uptake of testing services (6 studies) [270,349,357,361,368,396].

Research indicates that health promotion activities targeting groups at higher risk, such as European HIV-Hepatitis Testing Week, may be effective in increasing testing for HBV, HCV and HIV (4 HBV, 2 HCV and 7 HIV studies) [97,285,307,376,383,391,392,395,397–399].

Evidence addressing the economic aspects of community-based testing services is very limited. While operating costs may be higher for such testing than for testing in healthcare settings, especially when it involves outreach, community-based testing services can provide hard-to-reach populations with better access than traditional healthcare services (1 HCV and 1 HIV study) [387,400].

Suboptimal linkage to care has been reported after community-based testing of populations such as PWID and the homeless (4 HBV and 5 HCV studies) [104,291,306,361,376,378,388,391,392], with the exception of one study reporting 100% linkage to care for MSM who test positive for HBV or HCV [393]. For HIV, a systematic review indicates a high level of linkage to care for MSM following a reactive or confirmatory HIV test performed in a community setting [75].

Community-based HIV testing services delivered by non-medical staff (i.e. appropriately trained lay providers of testing services) have been authorised in 9 EU/EEA countries and prohibited in 10. HIV testing by lay providers has been implemented extensively in three countries of the EU/EEA (Denmark, France and Spain) and moderately in four (Finland, Luxembourg, Portugal and United Kingdom) [20]. According to one study, lay provider testing has resulted in increased HIV testing coverage among MSM in community-based testing services [355].

There is evidence on the acceptability and effectiveness of testing for all three infections across Europe, especially in specific groups, for both community-delivered and outreach services. Novel testing approaches are also well supported, including oral fluid and DBS.

Opinion from the expert panel

On the basis of the above evidence and their own experience in the field, as well as existing European and international guidelines (Annex 6), the expert panel reached consensus on the following conclusions.

Community-based HBV, HCV and HIV testing services targeting groups at higher risk (Table 3) need to be developed, including both services provided in facilities as well as those provided through outreach.

Community-based testing ought to be an integral part of national testing strategies for the three viruses.

Structures need be established to ensure the active participation of relevant communities by involving community representatives in the planning, implementation and governance of these testing interventions and strategies.

Community-based testing services ought to consider offering integrated testing of HBV, HCV and HIV, taking into account target populations and the underlying epidemiology. Where available, integrated testing needs to be offered and recommended to everyone accessing drug and harm-reduction services in a community setting for the first time and the offer needs to be repeated as appropriate (Table 3).

To establish appropriate linkage-to-care pathways for individuals receiving a positive HBV, HCV or HIV test result, whether reactive or confirmed, in a community-based testing service, there ought to be formal collaboration with local healthcare services. In particular, these need to include differentiated care pathways for the three infections and for other services, such as preventive services, social support services and harm-reduction services, as appropriate.

Despite the current limited research evidence on testing services offered by lay providers (including peer testing), there was consensus that their use ought to be considered as an option to increase testing rates and uptake among population groups at risk for HBV, HCV or HIV infection.

Suitable monitoring and evaluation of community-based testing services could be implemented (Section 5).

ECDC scientific advice

There are several options for testing for HBV/HCV/HIV in community settings:

- There is a sound body of evidence to suggest that there is a role for community-based testing and these are acceptable and effective in increasing HBV, HCV and HIV testing coverage and case detection among groups at higher risk.
- There is evidence that DBS testing for HCV, rapid HIV tests and oral fluid tests are acceptable strategies in community-based services and may increase testing uptake, tests performed and new diagnoses.
- Available evidence suggests that integrated testing among groups at higher risk, including those accessing community-based drug and harm reduction services, outreach testing activities and rapid testing in the community, are acceptable and contribute to increased testing coverage when implemented there.
- Evidence suggests that linkage to care after HBV/HCV testing in community settings may be suboptimal, at least for certain risk groups. Appropriate care pathways and referral systems need to be established to ensure effective linkage to care for people newly diagnosed with HBV/HCV/HIV in community settings, including differentiated care pathways for the three infections.
- Despite limited research evidence available from EU/EEA countries, testing services offered by lay providers should be considered to further increase testing opportunities, uptake and coverage.

4.4 Testing in other settings – self-sampling and self-testing

Self-sampling and self-testing are two additional options that provide individuals the flexibility and privacy of performing an initial HBV, HCV or HIV test in their own homes or anywhere else they consider convenient. Self-sampling occurs when an individual collects a blood or saliva sample from themselves, typically outside a healthcare setting, using a suitable kit. The sample is then posted or delivered to a designated laboratory for processing. Results are usually delivered by phone, text message or online, with referral mechanisms in place to ensure linkage to treatment and care as appropriate.

Self-testing occurs when an individual not only collects his or her own blood or saliva sample, but also uses a rapid diagnostic kit to process the sample, obtain the result and interpret them according to instructions provided with the kit.

4.4.1 Self-sampling

Evidence base

Self-sampling for HIV has been authorised and implemented in a limited number of countries in the EU/EEA [20]. No evidence is available for self-sampling of only HBV/HCV at the European level.

Evidence is available for self-sampling of HBV/HCV/HIV simultaneously (1 study) [393], HBV/HIV simultaneously (1 study) [401] and HIV alone (11 studies) [280,282,402–410]. The first two rely on DBS collection.

Self-sampling kits may be distributed through a variety of channels. For instance, they can be provided to clients during visits to healthcare settings such as STI clinics or HIV services (1 HBV/HCV/HIV and 2 HIV studies) [280,282,393] and outreach activities (1 HBV/HCV/HIV and 2 HIV studies) [393,403,405] or by ordering them directly through an online platform (1 HBV/HIV and 8 HIV studies) [401–404,406–410]. MSM have been the main population group targeted by these three modalities, followed by migrants. Very limited evidence is availabe for the targeting of other population groups.

The proportion of kits returned by users varies among studies reporting this information, but it has exceeded 50% in most (4 of 7 HIV studies) [402,406,409,410]. The existing body of evidence reports high positivity rates among those who returned the kits (1 HBV/HCV/HIV and 9 HIV studies) [280,393,402–407,409,410].

According to available evidence, self-sampling kits distributed to people attending an STI clinic may increase test coverage and frequency compared to testing performed in other facilities (1 HBV/HCV/HIV and 1 HIV study) [282,393].

A systematic review carried out by the OptTEST project in 2017 found very limited evidence describing linkage to care following HIV self-sampling [75,406].

Self-sampling is considered acceptable by users (1 HBV/HIV and 10 HIV studies) [280,282,401–405,407–409,411], though some have found obtaining a blood sample to be challenging (1 HBV/HIV and 1 HIV study) [401,411]. The main barriers reported by users are concerns about confidentiality and test accuracy and lack of support from healthcare workers (1 HIV study) [412].

There is still very limited evidence on self-sampling for any of the three viruses. The few available studies focus on MSM and migrants and suggest high positivity rates and acceptability.

Case study example

The aim of the Swab2know project was to detect new HIV cases among MSM in Belgium, a group at high risk for HIV. Before outreach activities, a secure and encrypted website was designed specifically for the project with the aim of providing a platform where visitors could find information and prevention messages, order test kits and collect test results. The oral fluid samples in the kits were self-collected by the participants under the remote supervision of study staff.

Within the project, the number of MSM tested for HIV was 898. A total of 17.1% reported they had never been tested for HIV before. Among those tested, the positivity rate was 2.2%. All new cases were successfully linked to HIV care. Despite a high yield and considerable number of false reactive results, satisfaction was high among participants.

To sustain the intervention, the Swab2Know team concluded that an emphasis on Internet-based testing and repeated testing for participants would be needed, as well as strong collaboration with community-based and prevention organisations to guide MSM to the project. Additionally, the online counselling tool should be refined to support participants with an increased emphasis on those with a reactive result. There should also be increased efforts to reduce the number of false reactive tests and expand the types of tests offered to STIs. Another priority was to develop the legal framework for self-testing and self-sampling, as neither are officially recognised in Belgium.

—from Case Study ST2 in Annex 2

Opinion from the expert panel

On the basis of the above evidence and their own experience in the field, as well as existing European and international guidelines (Annex 6), the expert panel reached consensus on the following conclusions.

Self-sampling needs to be promoted to increase testing coverage among people at risk for HBV, HCV and HIV infection. Doing so may necessitate legal and regulatory changes in certain countries.

The choice of distribution/dissemination channels for self-sampling and whether to provide it free or at a cost ought to be based on local circumstances and target populations.

In addition, the provision of integrated HBV, HCV and HIV self-sampling ought to be considered depending on the local populations being targeted, underlying epidemiology and HBV vaccination coverage.

Appropriate testing implementation strategies and linkage-to-care pathways need to be established for people who self-sample.

Suitable monitoring frameworks for self-sampling initiatives ould be implemented.

ECDC scientific advice

There are several options for self-sampling for HIV/HBV/HCV:

- Scientific evidence on the effectiveness of self-sampling, particularly for HBV/HCV, is still very limited. This precludes provision of strong advice on the effectiveness of this modality in a national testing strategy.
- There is limited evidence to suggest that self-sampling for HBV/HCV/HIV, including possible integrated sampling, is likely to be acceptable among those most at risk and may contribute to increasing testing coverage and case detection. In addition, limited evidence suggests that HIV self-sampling kits distributed to people attending STI clinics may increase test coverage and frequency. Self-sampling kits have shown to 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.
- Limited evidence is available on linkage to care after self-sampling in community settings. When considering self-sampling implementation, appropriate care pathways and referral systems need to be established to ensure effective linkage to care for people newly diagnosed with HBV/HCV/HIV, including differentiated care pathways for the three infections.

4.4.2 Self-testing

Evidence base

Self-testing for HIV has been authorised and implemented in very few countries of the EU/EEA [20]. No corresponding information is available on self-testing for HBV and HCV at the European level.

The body of evidence on the provision of self-testing is very limited and focuses exclusively on testing for HIV (5 studies) [265,413–416].

HIV self-testing kits using either oral fluid or blood samples have been primarily distributed via dedicated online platforms (3 studies) [414–416] or outreach activities (2 studies) [265,413]. Where reported, the positivity rate has been high (2 studies [413,415] and 3 from additional evidence gathered after the systematic reviews [417–419]).

According to existing evidence from countries outside the EU/EEA, HIV self-testing is associated with increased coverage and frequency of testing among MSM and men in general (2 studies from additional evidence) [418,419].

There is evidence indicating high acceptance of HIV self-testing and a high level of satisfaction among users (12 studies, plus 1 from additional evidence) [265,414–417,420–427]. The perceived benefits of HIV self-testing have been reported variously as privacy, convenience, immediacy, discretion, confidentiality and anonymity (12 studies, plus 1 from additional evidence) [265,414–417,420–427]. Perceived barriers reported are largely related to lack of immediate support in case of a positive result and the individual's ability to perform a self-test (5 studies) [422,423,426–428].

To date, there is very limited evidence on linkage to care after HIV self-testing (1 study from additional evidence) [75].

Evidence on the provision of self-testing is very limited and focuses only on testing for HIV. The few available studies suggest that it is an acceptable strategy and provides the benefits of privacy and confidentiality, but raises concerns related to the lack of immediate support.

Opinion from the expert panel

On the basis of the above evidence and their own experience in the field, as well as existing European and international guidelines (Annex 6), the expert panel reached consensus on the following conclusions.

HIV self-testing needs to be made available in order to increase testing uptake, frequency and coverage among MSM and other groups at risk for HIV infection. Doing so may necessitate legal and regulatory changes in certain countries.

Local circumstances and target populations need to be taken into account before deciding upon distribution channels and whether to charge a user fee.

In addition, appropriate linkage-to-care pathways need to be established for people who self-test.

It was not possible for the panel to reach any further conclusions on HBV and HCV self-testing based on the evidence currently available. However, if these testing modalities become available and evidenced (Section 5.2), their adoption ought to be considered to help increase testing coverage and uptake.

Suitable monitoring frameworks for self-testing initiatives ought to be implemented.

ECDC scientific advice

There are several options for self-testing for HIV/HBV/HCV:

- Scientific evidence on the effectiveness of HIV self-testing is still very limited and largely restricted to HIV self-testing among MSM. The available evidence suggests self-testing for HIV in this population group is acceptable and may increase testing coverage, frequency and case detection.
- Based on the body of evidence and their current availability in Europe, it was not possible to develop any firm advice on the effectiveness of HBV/HCV self-testing.
- There is very limited evidence on the effectiveness of linkage to care following self-testing. When considering self-testing implementation, appropriate care pathways and referral systems need to be established to ensure effective linkage to care for people newly diagnosed, including differentiated care pathways as needed.

4.5 Partner notification (contact tracing)

Contact tracing is a process where individuals potentially exposed to an infection are informed of exposure and offered testing and other interventions dependent upon the specific infection. When contact is of a sexual or injecting nature, this process is often referred to as partner notification. Partner notification is a voluntary process in which a trained provider asks a person diagnosed with HBV/HCV/HIV about their sexual and drug-injecting partners and household contacts as indicated by the diagnosis. If the person consents, the provider then offers, facilitates or provides advice on testing for relevant infections to these partners and contacts, as well as providing them with subsequent linkage to preventive interventions such as vaccination (HBV) and PEP (HIV). The identity of the diagnosed person is not revealed to the contact by the provider unless consent is given to do so.

Partner notification can be done by the diagnosed person alone (passive notification), with the help of a trained provider (assisted notification) or a combination of the two [80]. Regardless of approach, it is important to respect the core principle of confidentiality (Section 2.5). It should be noted that legal circumstances pertaining to partner notification vary from country to country and can constrain how it is implemented.

Risk network tracing is another modality of contact tracing where sexual and injection networks of recently infected individuals can help to identify sites for testing interventions, health promotion and prevention [429].

Partner notification is seen as a strategy that could be applied in all settings where a trained provider is in attendance, including in interventions such as birth cohort testing and indicator condition testing.

Evidence base

Evidence on partner notification presented in this section is not the result of the findings of a systematic review (page 32) and should not be considered as comprehensive as the other sections. The systematic reviews did not initially cover partner notification and did not include specific search terms for partner notification; hence some studies may have been missed.

No recent information is available on whether partner notification is currently implemented to also improve uptake of HBV/ HCV testing and diagnosis in the EU/EEA. However, it has been implemented for HIV in several European countries [20]. Available evidence from audits of clinical practice in providing partner notification after an HIV diagnosis indicates that it is only partially implemented and only a limited proportion of identified contacts are subsequently tested (11%–82%, 4 studies) [430–433].

The body of evidence identified for the effectiveness of partner notification is limited, focussing on HBV/ HIV, and primarily derived from healthcare settings, including antenatal services, STI clinics, HIV services, PHC and hospitals. However, it does suggest high positivity rates among contacts who are tested (1 HBV and 4 HIV studies) [72,128,219,298,434]. Limited evidence was found on partner notification following a reactive or diagnostic test performed in community settings (1 HIV study) [435].

There are several different methodologies for partner notification, including passive notification, assisted anonymous notification using web-based platforms and assisted notification with direct involvement of the service provider. Based on the studies identified, it is not possible to identify the most effective method (1 HBV and 4 HIV studies) [72,128,219,298,434]. Assisted anonymous notification using a web-based platform has been used successfully in both healthcare and community-based settings (2 HIV studies) [434,435].

Following notification of household contacts and children of HBV-positive women, evidence indicates very high linkage to care (e.g. vaccination; 2 studies) [298,319].

According to limited evidence from healthcare settings, educational interventions targeting healthcare workers may result in increased proportions of partners notified and tested (1 HIV study) [72].

The systematic reviews did not identify any evidence on partner notification and barriers, stigma, acceptance or potentially adverse effects.

Evidence on partner notification is quite limited. However, the small number of available studies, mostly on HIV, suggest high positivity rates may be possible with good partner notification delivery. There is little evidence on the effectiveness of different methodologies of partner notification or the effect of educational interventions on staff.

Opinion from the expert panel

On the basis of the evidence above and their own experience in the field, as well as existing European and international guidelines (Annex 6), the expert panel reached consensus on the following conclusions.

All testing providers, regardless of setting, need to initiate a discussion of partner notification with people who test positive for HBV/HCV/HIV. This discussion needs to be held in a timely manner, particularly for acute HBV/HCV infections and HIV reactive tests. If there is a likelihood of a significant delay in confirming the diagnosis, the

discussion may need to be undertaken before the initial test results are confirmed. Once a diagnosis is confirmed, the provider needs to inform the positive person of the purpose and utility of effective partner notification: namely, that it contributes to both individual and public health by facilitating access to measures such as protective vaccination, PEP and early treatment.

In addition, voluntary anonymous partner notification ought to be offered to every patient with a newly confirmed diagnosis. While there are various modalities for providing partner notification, ultimately the choice of method ought to be based on patient preference.

Suitable methods of partner notification could be further defined and implemented in accordance with the national legal framework and local procedures. Such efforts need to be coordinated carefully with different kinds of testing service providers. National legal frameworks that pose barriers to partner notification need to be revised, possibly by permitting data collection platforms and databases to be used to help facilitate the process, prohibiting mandatory or coercive partner notification and amending laws and policies that stigmatise, discriminate, criminalise and impose punitive actions as appropriate.

It is likely that ongoing interventions to educate healthcare workers on the utility and methods of partner notification may be beneficial.

ECDC scientific advice

There are several options for HBV/HCV/HIV partner notification:

- There is limited evidence on the effectiveness of partner notification in increasing testing coverage and case detection, with available evidence mainly relating to HIV. However, in line with the public health goal to promote early diagnosis and linkage to care, voluntary anonymous partner notification should be considered to offer to every person with a newly confirmed diagnosis.
- There is evidence of the benefit of various strategies to implement partner notification, including passive notification, assisted anonymous notification using a web-based platform (growing in poularity) and assisted notification with the direct involvement of the service provider.
- According to available evidence, implementation of partner notification may be suboptimal in the EU/EEA. While the success of interventions to increase coverage of partner notification may depend on local factors, including organisational and legal circumstances, there is limited evidence that educational interventions targeting healthcare workers may prove to be beneficial.

5 Implications for public health practice and research

5.1 Public health practice

This section covers specific considerations related to the implementation of HBV/HCV/HIV testing interventions that need to be considered in planning testing programmes, ranging from legal and organisational barriers to modalities of service delivery, monitoring and evaluation and other disease and population-specific issues. This section is intended to complement Section 4 and practice-based information to support the design and planning of testing programmes in the EU/EEA.

5.1.1 Considerations for designing and implementing national testing programmes

Reducing the undiagnosed fraction of infected populations and promoting prompt linkage to care for diagnosed individuals are critical to achieving global and regional goals for tackling the HBV, HCV and HIV epidemics. Designing appropriate national and subnational testing programmes that are well-tailored to the local epidemic is essential in ensuring success and the desired impact.

A number of points need to be considered and assessed in the development of testing programmes, including structural, financial, epidemiological and operational factors. While most of these elements are country-specific, Figure 2 presents overarching considerations that may be useful in guiding and supporting those considering developing a national or subnational testing programme. The major elements of the figure are all discussed briefly in the pages that follow. The indicator parameters listed in the 'Monitoring and evaluation' boxes in Figure 3 should be regarded as indicative only. ECDC plans to develop a more comprehensive monitoring framework on testing for viral hepatitis, HIV and STIs. This framework will build on the experience and lessons learned during Dublin Declaration monitoring work and include recommended standardised indicators that cover testing for these infections.

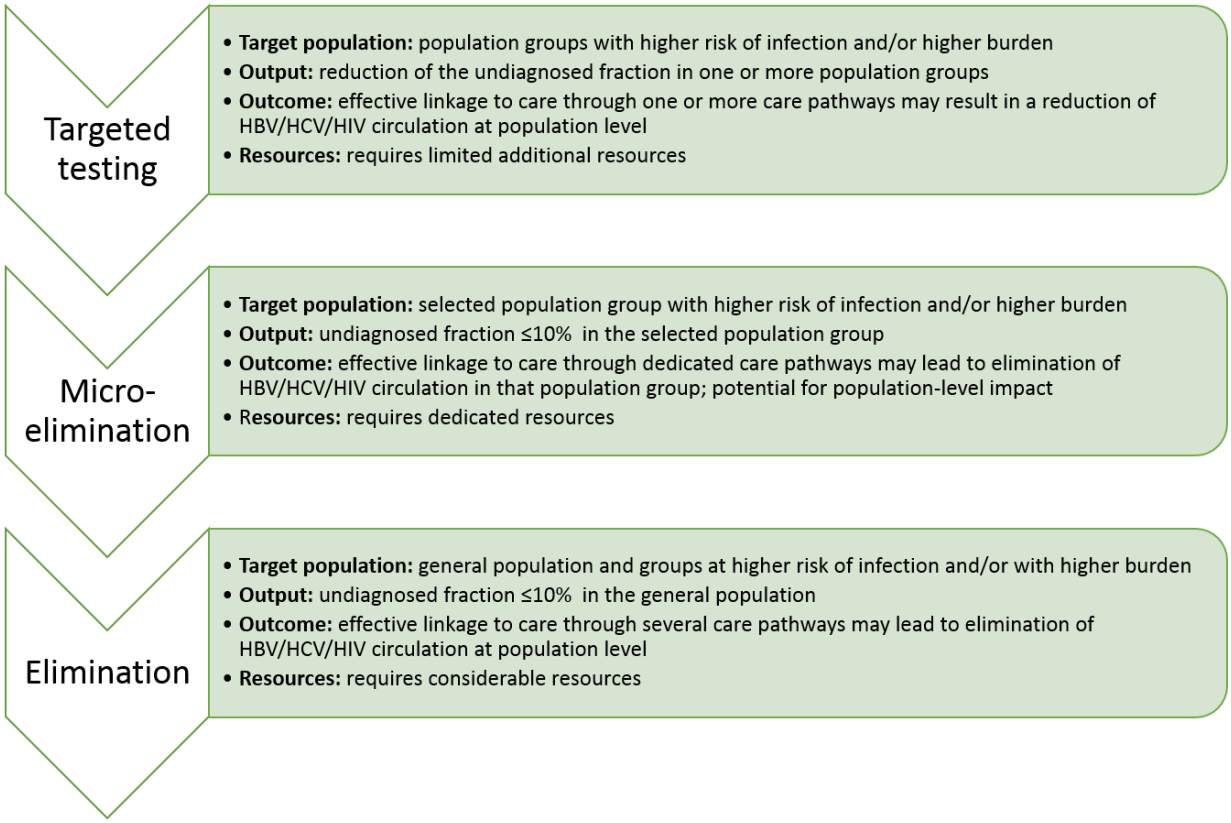
Table 4. Key considerations in developing a national testing programme

	Considerations	Strategic information	Monitoring and evaluation
Who?	Which populations should be targeted for testing? Are there any particular groups who are disproportionately affected by the infection? Are there legal barriers to targeting these groups (e.g. criminalisation of transmission or risk behaviours)? Are there any barriers for these groups to access care and treatment after testing positive?	National surveillance/ prevalence studies: undiagnosed fraction rate of late diagnosis infection prevalence/ incidence number of recently acquired/acute infections number newly diagnosed	Overall and for each target group: people living with HBV, HCV or HIV who know their status testing coverage rate positivity rate number/proportion of first-time testers number/proportion diagnosed late
What?	Which infections will be covered by the testing programme? Does the testing programme offer opportunities for other public health interventions or case-finding/ contact tracing?	National surveillance/ prevalence studies: prevalence of co-infections overlapping risks	Number/proportion of new diagnoses and rates of co-infection detected
Where?	In which setting(s) will the testing take place? Is there evidence of the acceptability and feasibility of testing in this setting for the target population? Are there any restrictions on who can carry out testing in this setting (e.g. legal or regulatory)? What will the geographical coverage of the testing programme be (e.g. local, regional or national)? Is there an established clinical pathway for those testing positive in this setting?	Acceptability and feasibility of testing in this setting (for staff and clients) Legal environment Structural/organisational barriers to testing in this setting Accessibility of setting for the target population	Number of individuals tested by setting and risk group Positivity rate by setting Return rates of testing kits (self-sampling) Rate of linkage to care
When?	What is the timescale for implementing the programme? How long will the testing programme last? Are there any barriers that may delay implementation (e.g. changes to testing guidelines)?	Review of relevant case studies Possibility of a pilot to inform cost, resource and positivity rate projections	Programme sustainability, as measured by specific success indicators over time Spread of programme Integration of testing implementation into guidelines
How?	How will the testing programme be implemented? What funding is available to implement the testing programme, and is the funding sustainable? Which stakeholders need to be involved to ensure the testing programme is successful (clinicians, nurses, community organisations)? Who will carry out the testing (e.g. clinicians, nurses, lay providers)? Are there any legal or regulatory barriers as to who can carry out testing tasks (e.g. offering tests, obtaining samples, carrying out point-of-care tests)? Is education or training required for the people who will perform the test or be tested? Which diagnostic technologies will be used? How will the target population be recruited to the testing programme? How frequently should the target population be tested? Will the testing be integrated into existing services, or will additional infrastructure be required? How will the testing programme be promoted? How will timely linkage to care be ensured if an individual tests positive? How and where will reactive results be confirmed? How will programme results be disseminated (local/national engagement)?	Review of relevant case studies and evidence of successful implementation of similar programmes OptTEST tools for implementing indicator condition-guided testing (HIV), addressing legal and regulatory barriers to testing, addressing stigma and assessing cost–effectiveness Financial assessment Possibility of a pilot to inform cost, resource and positivity rate projections	Cost per new diagnosis Cost per positive test Overall cost of programme Coverage of the programme Acceptability of the testing programme Testing uptake and offer rate, overall and by risk group Testing positivity rate Scope of HIV testing programme interventions (includes community-based testing, self-testing, lay provider testing)

Who?

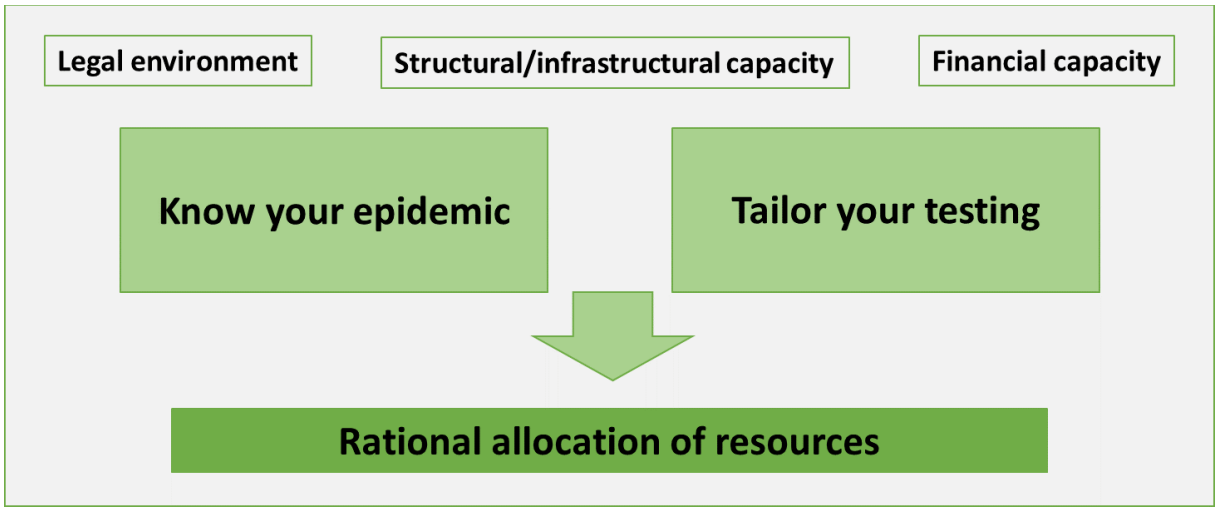
Where resources are limited, prioritisation is necessary to identify which population groups to target with testing programmes and interventions (Figure 3). In turn, the process of prioritisation ought to include an evaluation of factors, such as epidemiological data, including the prevalence and incidence of infection and co-infections, current testing rates and access to services (including post-testing services). Global, regional and national elimination targets may also be considered in the process.

Figure 2. Prioritising population groups to achieve elimination targets



An appraisal of the epidemiology of HBV/HCV/HIV is highly relevant when designing testing programmes (Figure 2), often described as the 'know your epidemic' approach (Figure 4). An overview of population groups that may be considered as possible targets for testing programmes is provided in Table 3.

Figure 3. Know your epidemic – Tailor your testing



What?

Consideration needs to be given to which conditions will be covered by the testing programme. Based on strategic information available on the prevalence of co-infections and overlapping risks, opportunities for the integration of HBV/HCV/HIV testing ought to be considered, including their integration with other health initiatives such as needle exchange points, in combination with STI and TB testing where appropriate.

Many successful testing programmes are typically focused on targeting a specific at-risk population and often embedded within or growing out of the community they serve. Several case studies in Annex 2 provide examples of integration of testing into community settings (Case Studies CS3, CS4 and CS5).

Where?

In Section 4, the presentation of the evidence for testing is structured according to different settings where testing can take place. Once target populations are identified, venues for testing need to be agreed upon. Testing needs to be available across a variety of both healthcare and community settings. As evidence shows, the integration of routine testing into the healthcare system is a key component of successful testing programmes. The findings presented in Section 4 also suggest that specialised community settings provide opportunities to better reach certain target populations. In addition, it is important to consider the geographical coverage of any testing programme so that testing is easily accessible throughout a country.

When?

In deciding the timescale for a testing programme, one needs to consider the objectives of implementing the proposed programme. How long will it take to see the desired effects (e.g. a 70% reduction in rates of late diagnosis)? The length of time an intervention lasts will also depend on resource availability.

If the testing programme involves implementation at a national level or a structural change in the way testing is carried out, there may be delays in rolling out the programme, due to factors such as the need for extensive stakeholder consultation or changes in testing guidelines. Such potential delays must also be considered in planning.

How?

As outlined in Figure 2 above, there are also many questions to consider when determining how to develop and implement a national testing programme. Annex 2 includes various case studies that provide concrete examples of implementation.

One of the key considerations for testing programme implementation is whether specific education or training needs to be developed for the people who will provide the testing services. As evidence from healthcare settings in Section 4 shows, training testers can increase staff confidence and ultimately improve offer rates.

Another consideration is how the testing programme will ensure that people who test positive are linked to clinical care. Clear clinical care and support pathways need be developed and mapped out in advance of implementation to reduce loss to follow-up. For community-based programmes, linkage to the health system for care and treatment after a positive diagnosis can be supported by a healthcare coordinator in collaboration with a social worker and a psychologist (see Case Study CS3).

5.1.2 Strategic information

A variety of resources are available to inform testing programme planning and implementation(Figure 2). First and foremost, it is important to become familiar with the epidemiological context in which the testing intervention is implemented. Official case-based surveillance figures for HBV/HCV/HIV are available online in the ECDC Surveillance Atlas of Infectious Diseases (http://atlas.ecdc.europa.eu) [79]. However, due to the largely asymptomatic nature of hepatitis infections, routine notification data do not provide a very accurate picture of disease burden and notifications of chronic HBV cases and all HCV cases are strongly influenced by local testing and reporting practices. Data from other sources, in particular prevalence surveys, are needed to complement case-based surveillance data. ECDC has carried out a systematic review of published peer reviewed prevalence surveys conducted in all EU/EEA countries for HBV and HCV during the past 10 years and has made the data available online [14,33,436]. These prevalence data will be updated periodically and will include HIV in the future.

In addition, an awareness of the legal and regulatory environment is crucial. The OptTEST project (http://www.opttest.eu) has developed an overview of common legal and regulatory barriers that might impede access to HIV testing [437], as well as a searchable database where one can search for legal and regulatory testing barriers in individual countries throughout the WHO European Region [19]. OptTEST has also produced several case studies demonstrating how regulatory restrictions and legal barriers to testing can be challenged and

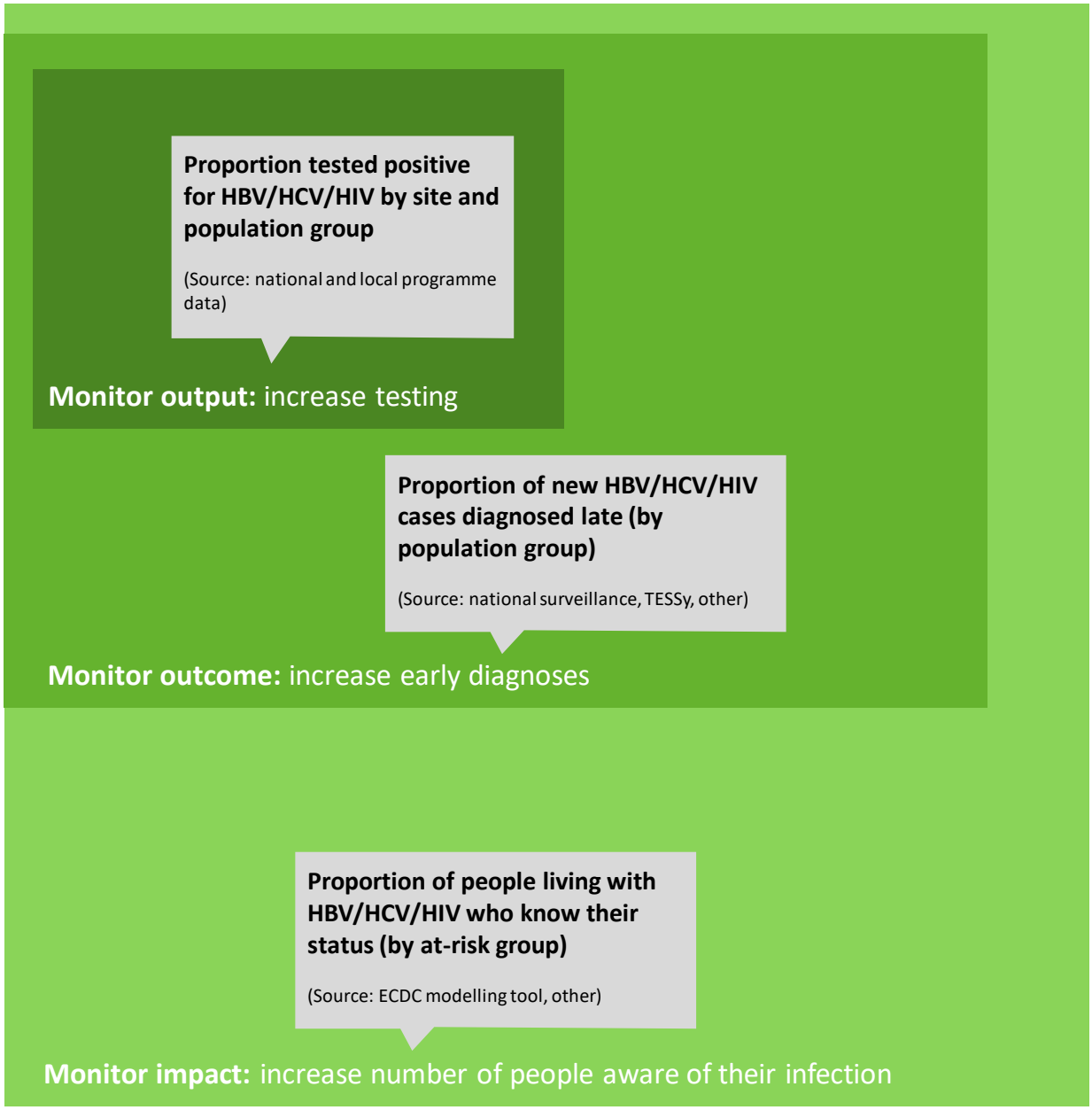
changed. For example, one case shows how a compromise was reached in Slovenia to allow a community testing service to perform outreach testing of MSM by hiring a nurse to perform the blood tests [438].

Monitoring and evaluation of testing initiatives

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 re- evaluation of targets as well as assessment of programme effectiveness, efficiency and impact. Such data can prove invaluable in planning improvements. While a monitoring and evaluation framework was embedded in previous ECDC guidance on HIV testing [21], the subsequent development of global and regional targets for HBV/HCV/HIV (e.g. for the reduction of the undiagnosed fraction for all three diseases) and resulting monitoring requirements have led to renewed efforts to develop appropriate EU/EEA frameworks [439–441]. ECDC, in collaboration with WHO and other national and international stakeholders, is currently developing and implementing EU/EEA monitoring frameworks for HBV/HCV and/HIV. The development of a European HBV/HCV-response monitoring framework began in 2017 and is designed in alignment with goals and targets defined by WHO for viral hepatitis elimination [27]. It covers domains such as prevention, treatment and the continuum of care [439,440]. Since 2010, ECDC has also coordinated monitoring the implementation of the Dublin Declaration on the Partnership to Fight HIV/AIDS in Europe and Central Asia [20], which covers domains such as prevention, continuum of care, access to care and leadership. While monitoring of testing activities for HBV/HCV/HIV is an integral part of these frameworks, ECDC recognises that a standardised set of metrics is needed to allow the assessment of testing programme performance for each virus across the EU/EEA region. ECDC therefore plans to develop a more comprehensive monitoring framework for viral hepatitis and HIV testing, building on the experience and lessons learned during Dublin Declaration monitoring work.

Acknowledging the difficulty of monitoring the performance of HIV testing programmes at all levels due to significant gaps in data available on testing services, ECDC convened an expert consultation in 2016 with representatives from a range of constituencies, including national institutions, community organisations and healthcare workers. Representatives from 14 Member States and international organisations met to explore how to strengthen the monitoring of HIV testing in the EU/EEA. The consultation's aims were to review current HIV testing monitoring, describe the need, scope and feasibility of a common approach to monitor HIV testing and formulate recommendations on how to improve the monitoring of HIV testing in the EU/EEA. The outcome of this meeting [441] has informed the approach for monitoring HBV/HCV/HIV testing outlined here. This outline (Figure 5) is structured along the key dimensions of output, outcome and impact and designed to include a core set of variables that can be monitored from the level of service provision to the subnational, national and supranational levels. A principle consideration for the future monitoring framework and metrics considered is that as far as possible, the data should be easily available through the appropriate integration of existing surveillance and programmatic data sources, including reference and primary laboratories, hospitals, national health insurance databases, cross-sectional and ad hoc studies, and national and international networks of community-based testing sites that collect monitoring data through online platforms [441].

Figure 4. Monitoring and evaluation of testing programmes



The expert consultation also developed key recommendations on the metrics and data sources to use in monitoring testing, including four key metrics for monitoring and evaluation:

- number of tests
- basic demographic data of the person tested (e.g. age, sex and population group)
- location/setting of the test; and
- number of reactive/positive tests.

In addition, the consultation recommended that indicators for monitoring HBV/HCV/HIV programmes capture core metrics that can be easily and widely tracked without overburdening frontline staff. These metrics should be measurable at the site level and capable of scaling up to national and international levels. Moreover, the metrics should be compatible with other national surveillance systems to allow for cross-country comparison of testing strategies and their impact on the epidemiology of HBV/HCV/HIV. Finally, core metrics should also be adaptable for collecting data from different testing settings and risk groups. All of these recommendations will be taken into account in the development of the new monitoring framework.

Other metrics for collection and monitoring could also be considered and prioritised if the monitoring system has the capacity and ability to capture and report data without negatively affecting the basic model. The ones recommended by the expert consultation include linkage to care, site/setting of first reactive test/diagnosis and

reason for test. Where available, estimates of risk group size and relative undiagnosed fractions were also identified as valuable metrics for monitoring. However, the consultation raised concerns about the accuracy of the current tools that could collect these data. Data on and the proportion of late diagnosis in different risk groups were also considered as complementary metrics.

The consultation identified community testing as an area with unique challenges, particularly with regard to monitoring testing activity and linkage to care. These data need to be systematically collected and reported and integration with national information systems is essential. Adequate data sharing is another challenge specific to community settings, particularly with regard to linkage to care given confidentiality requirements and data protection, both of which can limit data sharing; a collaborative approach will be required. Two European projects, HIV Community-Based Testing Practices in Europe (HIV-COBATEST) and the European HIV Early Diagnosis and Treatment Project (Euro HIV EDAT), have also recommended a group of core indicators [350] to monitor and evaluate community HIV testing, some of which have been incorporated into the Dublin Declaration monitoring process.

5.2 Knowledge gaps and future research

The outcome of the systematic reviews shows there are a number of gaps in the evidence base that need to be filled to improve the understanding of which options or strategies are most appropriate for each setting and Member State.

The value and cost-effectiveness of the various testing initiatives and early diagnosis are well established. However, the evidence is lacking on what are the effective interventions for initiating and sustaining a successful integrated testing programme, and indeed, on determining where integrated testing is indicated.

Future research is also needed on the implementation, sustainability and scale-up of acceptable and effective testing programmes that deliver integrated testing. Benchmarking and transferability may be complicated by the variation in healthcare systems among different countries, so such work may need to be carried out across the region.

As noted above, testing programmes should be tailored to local epidemiology and responsive to both changes in epidemiology and the results of programme evaluations to ensure they are effective in case finding and performing as intended. Much of the knowledge gap in this regard lies in the fields of implementation science and improvement methodology. Except where clearly unanswered scientific questions exist, formal research studies are no longer required to establish the benefits of testing programmes in either healthcare or community settings.

The expert panel has identified several specific areas, in addition to integrated testing and programme implementation, where it suggests further research may be directed:

- diagnostics, especially in relation to remote sampling and testing, rapid diagnostics (including HCV antigen testing) and test sensitivity
- self-sampling and self-testing, specifically in relation to results governance, case ascertainment and linkage to clinical care particularly for HBV and HCV
- effective interventions to increase coverage of HBV and HCV testing in eastern Europe; and
- setting-specific patient barriers to testing.

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Members of the writing consortium

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Annex 2. Case studies for increasing testing for hepatitis and/or HIV in the EU/EEA

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Introduction

These case studies were selected through the systematic reviews and in response to two published calls. To be included, the case studies needed to highlight approaches used in the EU/EEA to scale up or increase the effectiveness of HBV, HCV and/or HIV testing.

During the data extraction process for the systematic reviews, 9 journal articles were identified as potential case studies for HBV/HCV and 34 journal articles and 19 conference proceedings for HIV. Among the HIV candidates, 19 targeted MSM and 18 the general population.

To address gaps in the coverage of these examples in terms of geography, test service settings and targeted subpopulations, a call for good practice examples from EU/EEA countries was issued in December 2017 and disseminated through relevant European networks and initiatives, including European HIV-Hepatitis Testing Week, HIV in Europe and the European AIDS Treatment Group (EATG). The writing consortium also contacted relevant stakeholders directly via email to encourage submissions. Twenty-two good-practice examples from 13 countries were submitted in response to this initial call. Most of the case studies were from community settings and healthcare settings such as drug-treatment centres and STI clinics.

The consortium reviewed and assessed the collected case studies on their methods for increasing HBV/HCV/HIV testing and the availability and quality of data. It selected 38 case studies for review by members of the expert panel. The experts were asked to grade the case studies on the following criteria:

- clarity of the service model description
- transferability of the service model across different regions and practice models
- a history of internal or external evaluations (as an indicator of quality assurance)
- presence of a clearly described linkage-to-care pathway; and
- integration of HIV and viral hepatitis testing.

An online grading form was developed for the review, using a five-point scale. All case studies with an average score of 4 or higher were considered for inclusion in the guidance. Since none of the case studies from hospital settings met this threshold, the two highest-scoring examples from that category were also considered. The results were then presented and discussed during the expert panel meeting in February 2018.

During the discussion, the panel decided to issue a second call targeting the remaining geographical gaps and encouraging the submission of pragmatic examples (e.g. of how to develop monitoring and evaluation strategies). In March 2018, this second call was disseminated through several networks, including EATG and the International Union against Sexually Transmitted Infections (IUSTI), as well as through direct contact with relevant organisations. The template employed was also redeveloped using a narrative format that anticipated how the case studies would be presented in the guidance. Eight case studies were submitted to the second call.

In the end, the consortium selected 15 case studies to support the guidance described here: 8 identified through the systematic review, 4 through the first call and 3 from the second.

Primary healthcare settings (PHC)

PHC1: HIV testing within general practice in Europe: a mixed research synthesis (Belgium)

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Affiliation(s): Institute of Tropical Medicine; [2]Scientific Institute of Public Health[1]

Country: Belgium

Setting: Primary healthcare

Source: Open call

Background

The HIV epidemic in Belgium is concentrated in two groups: men who have sex with men (MSM) and people of sub-Saharan African (SSA) origin. Mathematical models on Belgium's surveillance data conducted within the European HIV-ERA project HERMETIC estimated an undiagnosed prevalence of 82.6 per 10 000 MSM aged 18 to 64 years and 173 and 93 per 10 000 among female and male heterosexuals respectively from SSA aged 18 to 64 years [1]. Despite Belgium's high testing rates [2], HIV patients are diagnosed on average 22 months after their infection [1]. This means that diagnostic opportunities continue to be missed, particularly in primary care settings [3–5]. Although general practitioners (GPs) play a pivotal role in HIV testing for early case finding, they mostly test in response to a patient request. A literature review revealed different barriers prevent GPs from effectively adopting provider-initiated HIV testing, including lack of communication skills in relation to sexual health and knowledge on HIV testing recommendations and epidemic specificities, difficulties with using the full list of clinical HIV indicator diseases and a lack of experience in delivering test results or communicating a diagnosis of HIV infection [6]. In Belgium, national HIV testing guidelines are currently under development, but are not yet in place.

Description of good practice

To exploit the full potential of GPs to reduce undiagnosed HIV, a participatory formative study was set up. A multidisciplinary advisory board of 22 experts was established, including GPs, GP umbrella organisations, policy makers, HIV care, public health, prevention and lab specialists. They reviewed existing GP-based HIV-testing interventions in terms of their potential for upscaling and sustainability in Flanders. Two strategies were selected for further qualitative assessment among a larger group of GPs: pro-active HIV testing of key populations and HIV testing based on HIV indicator conditions [7]. At the end of 2016, 122 GPs from Flanders participated in 16 focus group discussions (FGDs) and provided feedback on these strategies. In a second step, a GP-friendly intervention tool, 'Advice HIV screening by GPs', [8], was developed based on their input. It recommends proactively and routinely proposing an HIV test to patients at increased risk of HIV acquisition and with an HIV indicator condition. The list of patients to prioritise for HIV testing is based on the results of mathematical modelling of undiagnosed populations. It is therefore advised to screen MSM, people from SSA and other high prevalence countries and injecting drug users at least annually or more frequently depending on risk behaviour. For people who have had sexual contact with one of these groups, the GP is advised to make a behaviour-based assessment together with the patient. The advice also presents a limited list of 14 indicator conditions based on which GPs are advised to offer an HIV test. This reduced list was obtained based on the results of the FGDs and the advisory board's input, where the original 64-item list of the HIDES I study was discussed. The tool also contains a map of the world indicating countries with high HIV prevalence as an aid for GPs to propose an HIV test to people originating from highly endemic regions in a non-discriminatory way.

The intervention was implemented by making the advice available on a GP website that hosts all GP guidelines and has spread to GPs in Flanders using the channels of the GP circles (e.g. GP networks for training and quality improvement). To promote uptake of the advice, complementary training was developed based on a simplified intervention mapping protocol [9]. The training addresses GPs' main barriers to provider-initiated HIV testing as identified in the FGD study. The training approach is interdisciplinary: a public health specialist gives information on the hidden epidemic and advantages of early HIV diagnoses and contextualises HIV risk among target groups, an HIV specialist from the local HIV specialised care centre discusses HIV indicator conditions and the role of GPs in HIV care and a sexual health communication specialist offers practical communication tips on sexual risk assessment and motivation to test for HIV.

Evidence of impact

To evaluate the intervention, a modified stepped wedge design [10] was set up. All GP circles in Flanders in northern Belgium were randomly assigned to one of three intervention levels: no intervention for one third of the GP circles (control condition), delivery of the advice without further training for 25 circles (information condition) and delivery of the advice and complementary training offered to 25 circles (information and training condition).

In March 2017, a total of 4 475 GPs received 'Advice HIV screening by GPs'. Between September and December 2017, 23 of the 25 selected GPs circles accepted the training offer and a total of 672 GPs attended the training (attendance rate 36%). In an additional process evaluation, the training's overall satisfaction rate was 8.5/10 and the advice was rated 8.2/10. Participants found it feasible (7.8/10) and acceptable (7.6/10) to implement the advice and had high intentions to do so among patients at increased HIV risk (100%), as well as among patients presenting with an HIV indicator condition (99.5%).

The impact of the interventions on the number of HIV diagnoses and HIV tests performed by GPs will be assessed via national HIV surveillance. By using the GPs' individual social and health insurance code, intervention conditions can be compared to the control condition. Data are being collected from 2016 (historical control) to December 2018. Final results will be available in 2019.

Additionally, to better understand how these interventions have been used in day to day practice, an evaluation study adopting telephone interviews and online survey will evaluate the interventions' acceptability and feasibility and their perceived effectiveness. Data were collected in May and June 2018 and the results will be available in 2019.

Decisions on the overall evaluation strategy have been based on the findings of the FGD study and advisory board input.

Sustainability of practice

From the start, the HERMETIC project aimed at developing sustainable intervention, so a multidisciplinary advisory board was installed and extensive formative research was conducted. Formative research enabled the development of an intervention tailored to the reality of busy GP practices. The involvement of policymakers and GP umbrella organisation in the process of intervention development and their endorsement will facilitate the sustainability of this intervention. The evaluation will identify potential need for adaptation, which in turn may increase sustainability.

PHC2: Promotion of rapid testing for HIV in primary care (RHIVA2): a cluster-randomised controlled trial (United Kingdom)

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Country: United Kingdom

Setting: Primary healthcare

Source: Journal article [11]

Background

In 2016, Public Health England reported an estimated 89 400 people (0.16% of the adult population) in the United Kingdom were living with HIV and 5 164 patients were newly diagnosed [12,13]. The epidemic is disproportionally distributed among certain key populations, including men who have sex with men (MSM) (54% of new cases) and heterosexual men and women who identified as being of African Sub-Saharan origin (39% of new cases) [13].

Since 2008, the British HIV Association has recommended that there should be universal screening in general practices in areas with high diagnosed HIV seroprevalence (>2/1000 population) [14]. Although this recommendation was widely accepted and shown to be feasible, it was not widely adopted in primary care given there was no data at the time indicating that adoption of this practice led to a significant increase detecting the undiagnosed [15].

Description of good practice

A cluster-randomised controlled trial was setup in 2010, targeting general practices in multi-ethnic, high risk and socio-economically deprived communities in the London borough of Hackney. The intervention consisted of a practice-based educational outreach programme with follow-up training for a nominated HIV lead nurse or healthcare assistant in each practice, integration of rapid HIV testing with the new registration health check, management of reactive rapid HIV tests, provision of free rapid HIV test kits and payment of £10 per test

completed. Control practices provided standard care, which included opportunistic and diagnostic HIV testing and on patient request.

The educational training programme was based on clinician behaviour change strategies, together with input from lessons learned by the researchers in implementing similar interventions [16]. Ninety-minute training sessions were held at individual practices, targeted the whole practice team and included didactic and interactive elements. Session leaders were trained to ensure intervention fidelity and rapid HIV test operators completed competency-based training. The nominated HIV lead coordinated rapid testing and quality assurance.

Forty general practices participated in the study and were randomly organised in two groups: intervention practices that were exposed to the educational training programme and control practices that received no training. Registration health checks were performed by a nurse or healthcare assistant who followed HIV testing prompts on an electronic template in computerised patient health records. Prompts were added to offer rapid HIV testing and were linked to bespoke Read codes [17] to record the following test outcomes: non-reactive, reactive, indeterminate, invalid and test declined. Read coding enabled remote data collection for testing activity by the Clinical Effectiveness Group at Queen Mary University of London.

Core components of the intervention included an offer of a rapid HIV test as part of the new registration health check, followed by a post-test discussion for patients with a non-reactive test result and immediate notification by the rapid test operator to the general practitioner of any patient with a reactive, indeterminate or twice-invalid test result for confirmatory serology sampling. The intervention was adaptable to each practice, which had the option to additionally offer rapid HIV testing in sexual health or contraception consultations.

Evidence of impact

In the intervention group, 44 971 patients registered, of whom 11 487 were offered rapid HIV testing from 2010 to 2012. Of the 4 978 patients who accepted rapid testing (45% uptake), 11 were newly diagnosed with HIV. In addition, 2 728 patients had a serology HIV test as part of routine care, resulting in 18 additional new diagnoses by opportunistic testing and three new diagnoses via antenatal screening. In the control group, 38 464 patients newly registered, of whom 2 645 had a routine serology test for HIV, resulting in 21 new diagnoses. The mean CD4 count at diagnosis was 356 cells per µl in intervention versus 270 in control practices and the percentage of patients with a CD4 count less than 350 cells per µl was 55% in intervention practices, and 73% in control.

All patients diagnosed by rapid testing were transferred to the HIV clinic, showing that the links established between general practice and specialist services were safe and effective. Some patients who had previously defaulted on HIV specialist care re-engaged with specialist services following retesting in the intervention group, suggesting that primary care can play an important part in supporting individuals to re-engage with treatment and care.

The results support the hypothesis that an education programme promoting rapid HIV testing in general practice leads to increased and earlier HIV diagnosis.

Furthermore, a recent health economic analysis of the RHIVA2 trial demonstrated that HIV testing in general practices located in high-prevalence areas is cost-effective and may be cost-saving in countries with less efficient health services [18].

Sustainability of the practice

This study used a quality assurance scheme, which included competency-based training for rapid HIV testing, regular electronic monitoring of point-of-care test results and a quality control assessment every two months using external control serum samples, enhancing patient safety by reducing the chances of incorrect rapid test results. Despite this, three intervention practices discontinued testing as a consequence of the pragmatic study design. Therefore, continued training and encouragement to test may be needed in order to ensure sustainability.

PHC3: Comparison of two HIV testing strategies in primary care centres: indicator condition-guided testing vs. testing of those with non-indicator conditions (Spain)

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Country: Spain

Setting: Primary care centres

Source: Journal article [20]

Background

In Spain, health services are universal and free and primary healthcare centres are where most HIV tests are performed [21,22]. European guidelines recommend healthcare professionals should conduct indicator-condition (IC) guided testing as a method of increasing HIV diagnosis at an earlier stage of the disease and decreasing the level of undiagnosed infection [23].

In this context, a multidisciplinary pilot unit called the Unit of HIV Care Sharing was developed, linking hospital clinic and four primary care clinics (PCC) with the aim of cooperation in patient care, research and training in the field of HIV medicine. The aim of this initiative was to improve the detection of HIV infection in the general population through a prospective study to compare IC-guided testing versus testing of those with non-indicator conditions (NIC). The choice to restrict the study to PCCs was because most STI prevention, diagnosis and treatment in Spain occur in these centres.

Description of good practice

Before the study, PCC staff members were trained to perform the rapid test (Determine® HIV-1/2 Ag/Ab Combo, Alere Medical Company, Chiba, Japan). The cost for every rapid test performed was EUR6. The four selected ICs for the screening in the study included herpes zoster, seborrhoeic eczema, mononucleosis syndrome or leucopenia/thrombocytopenia (L/T). From October 2009 to February 2011, patients aged 18 to 65 years old who attended a PCC for the four ICs were included in the IC group and one in every 10 randomly selected patients consulting for other reasons were included in the NIC group. Consecutive patients between 18 and 65 years who were not already known to be HIV positive attending any of the four selected PCCs were offered an HIV test. If they gave written consent, they were interviewed using a standardised set of questions and a rapid HIV test was performed at the same time.

Evidence of impact

During the study period, 775 patients attended the PCCs with one of the four selected ICs, while 66 043 patients presented with an NIC. HIV screening was offered to 89 patients with ICs (offer rate 11.5%), of whom 85 agreed to and completed testing (94.4 and 100% acceptance and completion rates respectively). In the NIC group, an HIV test was offered to 344 persons (offer rate 5.2%), of whom 313 accepted (90.9%) and 304 completed (97.1%) testing. HIV tests were positive in four persons (prevalence 4.7%, 95% confidence interval (CI) 1.3–11.6%) in the IC group and one person in the NIC group (prevalence 0.3%, 95% CI 0.01–1.82%). These patients were referred to a specialised centre for further assessment.

In the IC group, all four patients diagnosed with HIV infection were male and their median age was 34 years. All had at least one visit to a PCC before study entry. Two of the patients presented with MNS and two with L/T. Three were Caucasian men who have sex with men (MSM), had at least four partners per year, had visited an STI clinic and had previously tested for HIV. Notably, the remaining patient was 58 years old and heterosexual with a single female sexual partner, had never used condoms and had no history of HIV serology.

The HIV-positive person in the NIC group was a 32-year-old male attending the PCC for a dermatological condition. He was a Caucasian MSM with at least four sexual partners per year and one to three coitus per week. He always used condoms and had had a previous HIV test.

If every eligible person had taken an HIV test, EUR 4 650 would have been spent in the IC group and EUR 396 258 in the NIC group and an estimated 36 (95% CI 25–49) and 198 persons (95% CI 171–227) respectively, would have been diagnosed with HIV infection. The estimated cost per new HIV diagnosis would have been EUR 129 (95% CI EUR 107–153) in the IC group and EUR 2 001 (95% CI EUR 1 913–2 088) in the NIC group.

Sustainability of the practice

This screening study found that it mimicked real-life implementation of routine HIV screening in PCCs. The number of HIV tests performed in individuals presenting with these four ICs in the same PCCs was examined retrospectively. A total of 704 patients attended the PCCS with these ICs, 68 HIV tests were performed (9.6% offer rate) and four were positive (HIV prevalence 4.7%; CI 1.3–11.6%). These results suggest that barriers to routine testing may still exist in the attitudes and practices of clinicians and this needs to be addressed urgently through collaboration and the provision of relevant information.

Although the number of patients included in the study was small and the results ought to be treated with caution, IC-guided HIV testing based on four selected ICs in PCCs seems to be a more feasible and less expensive strategy to improve diagnosis of HIV infection in Spain than a non-targeted HIV testing strategy. Patients who tested positive were referred to a specialised centre for further assessment.

Hospital settings (HS)

HS1: Twelve months of routine HIV screening in 6 emergency departments in the Paris area: results from the ANRS URDEP study (France)

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Country: France

Setting: Emergency departments

Source: Journal article [24]

Background

An estimated 25 000 to 30 000 persons in France have undiagnosed HIV infection (approximately 7 per 10 000 inhabitants) [24]. The French National Authority for Health 2009 HIV screening guidelines recommended systematic HIV screening to be offered at least once to all people aged 15 to 70 years regardless of signs, symptoms and risk profile, in addition to targeted HIV screening for key at-risk groups [25].

Public hospital emergency departments (EDs) receive 15 to 17 million visits every year and appear suited to implement non-targeted HIV screening [26]. However, EDs are overwhelmed with increasing activity over recent years, with a 2.5–3.5% increase in attendances per year in the Paris area [26].

The aim of this study was to examine whether routine HIV screening using a rapid test in emergency departments was feasible without dedicated staff and newly diagnosed persons would be linked to care. Because of contemporary French regulations, this study took the form of a formal research project requiring written informed consent (opt-in approach).

Description of good practice

Before the beginning of the study, ED staff members (nurses and physicians) were trained on providing information on offering and performing a rapid HIV test and counselling. During the one-year study, all participating EDs displayed posters and brochures in waiting rooms and registration areas advertising the availability of free rapid HIV screening. Patients could ask to participate in the study and ED staff members, whether triage or other nurses, senior physicians or interns, could offer testing to eligible persons on any day of the week at any time, obtain written consent, provide pre-test information and administer the HIV test in addition to their usual responsibilities. Patients with negative results were informed by the person who performed the test and given written information

on HIV prevention. Positive and invalid results were only given by senior physicians. All tested patients also received a dated and signed written result. No additional staff were provided for the study.

A delocalised biology station was established in each ED with a register to record the performed tests under the supervision of the virology laboratory of each participating hospital.

Evidence of impact

Among 183 957 eligible persons, 11 401 were offered HIV testing (6.2%), of whom 7 936 accepted (69.6%) and 7 215 (90.9%) were tested (overall screening rate 3.9%). Additionally, 1 857 non-eligible persons were also tested. Fifty-five new diagnoses of HIV infection were confirmed by Western blot (0.61%). There was one false-positive rapid test result. Among the newly diagnosed persons, 48 (87%) were linked to care, of whom 36 were not lost to follow-up at month 6 (75%). An appointment was made with a specialist in HIV/AIDS within 72 hours of all positive rapid tests.

Of the new diagnoses, 85% were MSM or from sub-Saharan Africa. The median CD4 cell count at diagnosis was 241/mm^{3,} and 44% of newly diagnosed persons had never previously been tested for HIV.

This study was able to test for HIV infection in 3.9% of eligible persons presenting to 6 emergency departments in the Paris area, representing one-third of all ED attendees in this area, with no additional staff and with obligatory written informed consent (opt-in approach).

Screening rates were similar to those reported in opt-in studies with no dedicated staff. The rate of new diagnoses was similar to that observed in free anonymous test centres in the Paris area and well above the prevalence (0.1%) at which testing has been shown to be cost-effective.

Sustainability of practice

In the context of reducing financial and human resources, a screening study with no additional staff mimicked real-life implementation of routine HIV screening in emergency departments. This research study required written informed consent. An opt-out approach without written consent is recommended in most settings and would be best suited to the emergency department, especially if utilising existing staff.

Although this study found good acceptability of HIV screening with rapid tests in the ED setting, the test proposal rate varied across the six centres and decreased over time. This was attributed to ED teams not being convinced of the program's utility and the lack of reinforcement during the study. The study also found that it is critical to emphasise during training to ED staff the benefits of the testing strategy, including its cost-effectiveness.

HS2: Routine HIV testing in the emergency department: tough lessons in sustainability (United Kingdom)

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Country: United Kingdom

Setting: Emergency department

Source: Journal article [27]

Background

In 2011, the United Kingdom HIV epidemic was characterised by a high proportion of late-stage diagnoses and of a persistently high proportion of undiagnosed infections [28]. Based on these findings, the National Institute for Health and Clinical Excellence (NICE) called for more widespread testing, including routine HIV testing in general medical settings in areas where HIV prevalence exceeds 0.2% [29]. The HIV in Non-Traditional Settings (HINTS) pilot study has shown that routine HIV testing services offered in general medical settings in high-prevalence areas is an efficient and feasible practice [19]. The challenge identified in the study was how best to maintain and sustain testing services beyond the confines of a pilot study. An assessment within the pilot identified the major barriers to sustainability, including training needs for non-specialist staff in HIV testing resource implications and the burden of results management.

The aim of this implementation and evaluation study was to develop and deliver a sustainable model of HIV testing in the emergency department (ED) of Chelsea and Westminster Hospital with the aim of producing a model of testing that replicated the success of the HINTS study model, but with provision of testing by ED staff themselves.

Moreover, the authors employed sustainability methodology to refine the service in an iterative fashion in response to key outcome measures.

Description of good practice

A routine HIV testing service defined by consultation between key stakeholders (ED staff and local sexual health staff) in an ED was delivered by staff as part of routine clinical care. ED staff were prompted by an electronic pop-up on the patient record to offer an HIV test and asked to document the outcome of the test offered (accepted/declined/not offered). All attending patients fulfilling the following inclusion criteria were to be offered an HIV test by ED staff:

- not known to be HIV-positive
- accessing the ED for the first time after the initiation of testing
- aged 16–65 years; and
- ability to give consent to a test.

An information leaflet was provided to eligible patients and provided in multiple languages. All staff delivering testing received competency-based training from sexual health staff and the ED and sexual health teams met weekly to evaluate the effectiveness of the testing service. The local sexual health service managed results and their delivery and patients with a reactive HIV test were recalled to undergo confirmatory testing. A helpline was also established where patients could access their results by telephone or email and a sexual health counsellor was available upon request.

The ED and sexual health teams met weekly to evaluate the effectiveness of the testing service. Additionally, sustainability methodology comprising process mapping and plan-do-study-act (PDSA) cycles were employed to identify significant trends in the outcome measures and evaluate the impact of interventions to improve the model [30]. Furthermore, the intervention included training exercises, identifying key staff (or 'testing champions'), incentivisation, information technology solutions and changes to the testing pathway and methodology.

Evidence of impact

Over 30 months, 44 582 eligible patients visited the ED. The mean HIV test offer rate was 14%, varying from 6% to 54% per month over the testing period. The mean test acceptance rate was 63% (range 33–100% a month). A total of 4 327 HIV tests were performed and 13 patients were diagnosed with HIV infection (0.30%).

The study reported significant impacts in coverage when testing switched from oral fluid testing to serology and the incorporation of nursing staff into the testing service. Additionally, other interventions including identifying 'testing champions' and the regular provision of teaching and newsletter updates had positive effects on the outcomes, albeit smaller. Overall patient uptake remained high over the 30 months the study was conducted, suggesting acceptability and feasibility, but the authors concluded it would require more time before HIV testing was fully embedded into routine clinical practice.

Sustainability of practice

This study proved that HIV testing can sustainably be delivered in EDs, but constant innovation and attention is required to maintain it. Key elements of the intervention that helped sustainability was the use of sustainability methodology and PDSA cycles: examining key outcome measures in real time and interventions based on stakeholder input, audit and patient feedback. Frequent communication, including weekly meetings between the ED staff and the sexual health team, helped to sustain momentum, facilitate best practice and maintain commitment to the project. The study concluded HIV testing in ED settings is acceptable and operationally feasible. However, if HIV testing is to be included as a routine part of patient care in EDs, additional staff training and infrastructural resources will be required.

Drug treatment/harm reduction settings (DT)

DT1: The SACC model: screening for viral hepatitis and HIV in drug treatment centres (Denmark)

Author(s): Bruun, Tina and Peters, Lars.

Affiliation(s): CHIP, Rigshospitalet, University of Copenhagen.

Country: Copenhagen, Denmark

Setting: Other healthcare settings

Source: Open call

Background

In Denmark, HBV prevalence is low, with most chronic cases found among immigrants from high-endemic countries. [31] However, an estimated 17 000 people live with chronic HCV (0.38% of the population over 15 years of age) [32]. Most HCV patients in Denmark are former or current people who inject drugs (PWID) and only one-third of have been in contact with a specialised hospital department responsible for HCV care [33]. Additionally, in 2016, injecting drug use (IDU) was the third-most reported mode of transmission of HIV. However, this is a relatively small and declining occurrence in Denmark [34]. To improve access to health services for this vulnerable group, the Shared Addiction Care Copenhagen (SACC) project was developed as a cross-sectoral collaboration between 11 municipal drug treatment centres and two specialised infectious disease clinics. The drug treatment centres offer a range of services, including drop-in services for counselling, opiate substitution therapies and needle exchange distribution. The aim was to develop a generic model for decentralised testing for HBV/HCV/HIV and evaluation and treatment of HCV at the drug treatment centres.

Description of good practice

In the SACC model, staff at drug treatment centres and infectious disease departments closely collaborated and conducted preliminary steps before launching intervention. The first step was to develop an online database to give both infectious disease clinics and drug treatment centres a complete overview of the patient's previous and current hepatitis and HIV test results, FibroScan results and other relevant blood tests, vaccinations and treatment status. Initially, these data needed to be keyed in manually, but once entered, the shared database prospectively collects and merges data from other sources in real-time. Additionally, staff at the 11 drug treatment centres received training in hepatitis, HIV and venepuncture, including viral hepatitis and HIV epidemiology, treatment and vaccination. Additionally, as part of training, staff were educated on their role in the SACC project and how both facilities, who normally operate separately, needed to work together to ensure SACC's effectiveness.

Drug treatment centres in Denmark are obliged to counsel and offer testing for HIV and viral hepatitis to all clients. However, prior to SACC, clients who accepted a test would be referred to a separate laboratory for testing. The aim of SACC was to offer screening for viral hepatitis and HIV on-site at the drug treatment centre, as well as a FibroScan to assess the degree of liver injury and further blood tests for those who test HBV- and/or HCV-positive. Subsequent treatment and care would then continue at the drug treatment centre in close collaboration with staff from the infectious disease clinic. Staff from the infectious disease clinics are responsible for prescribing and monitoring HCV treatment according to national HCV treatment guidelines, but within SACC, all counselling and dispensing of HCV treatment took place at the drug treatment centres. To enhance the likelihood of treatment success and minimise the risk of reinfection after treatment, the decision whether to initiate HCV therapy was based on a thorough evaluation of compliance and risk behaviour performed by both healthcare and social care staff at the drug treatment centre. Those who tested HIV-positive were referred to the infectious disease clinic for further treatment and care. Additionally, those who tested positive for HBV and/or HCV with cirrhosis were offered further evaluation for oesophageal varices and screening for hepatocellular carcinoma according to national guidelines.

Evidence of impact

Within the project period, an average of around 2 000 people were enrolled at the 11 drug treatment centres, some for shorter courses of therapy and others for near-lifelong treatment (approximately 25% of the 2 000 patents each year). Data at baseline showed that 44% of the clients had previously tested for HIV and hepatitis. During the project period from June 2014 to June 2017, the drug-treatment centres tested 700 clients for HIV and hepatitis. By project closure, 66% of clients had had a previous HIV and hepatitis test. During the project period, 207 people tested HCV-positive. All who tested HCV-positive were offered a FibroScan at their respective drug treatment centre by a staff member from the infectious disease clinic. Those with a high FibroScan score were evaluated for treatment and if indicated, treatment was distributed at the drug treatment centre. During the project period, due to the strict criteria for starting HCV treatment in Denmark (FibroScan score above 10 kPa), 26 individuals met the criteria and completed HCV treatment and all have been cured. One individual tested positive

for HIV and was linked to care at the infectious diseases department, while the five who tested positive for HBV were either treated at the drug treatment centre or referred to the infectious disease clinic.

The SACC project has helped break down barriers between different sectors in the healthcare system by establishing a cohesive treatment and care model for PWID with hepatitis C. By using a mobile FibroScanner at the drug treatment centres, the project was able to get a better assessment of the burden of liver fibrosis at both the individual and population levels.

Through establishing an online database, SACC has generated a better overview of the number of HCV infections in Copenhagen and of the extent to which the municipality meets its obligation to offer testing for HBV/HCV/HIV to all newly referred PWID. SACC can provide solutions that can be extended to other municipalities and hospitals, but also to other diseases areas and municipal institutions.

Sustainability of practice

The model for hepatitis C care developed during the SACC project period is now offered as part of routine clinical care for PWID with hepatitis C in Copenhagen. The key to the success of the SACC model is the close collaboration and investment of multiple stakeholders, including 11 municipal drug treatment centres, 2 infectious diseases clinics and a research facility that provided IT support to develop the online database. Key personnel, including dedicated nurses and doctors at clinics, need to be identified and act as resources to support the intervention. The project required extensive human resources and involved training and education of staff at the drug treatment centres in addition to coordination of tests, FibroScans, treatment and care. Additionally, a substantial financial investment for a mobile FibroScanner is an important consideration when implementing a similar model. However, by making diagnostics, treatment and care accessible at drug treatment centres, it may result in improved treatment success and the potential elimination of HCV.

DT2: Increasing the uptake of hepatitis C virus testing among injecting drug users in specialist drug treatment and prison settings by using dried blood spots for diagnostic testing: a cluster randomised controlled trial (United Kingdom)

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Country: United Kingdom

Setting: Other healthcare settings and prisons

Source: Journal article [31]

Background

It is estimated that 214 000 people live with chronic HCV infection in the United Kingdom [32]. Injecting drug use continues to be the leading risk factor associated with contracting HCV [32]. HCV disproportionally affects vulnerable minority groups, with higher incidences reported amongst Black-African populations and/or people who inject drugs (PWID) (54%) [32]. Current efforts focus on targeted HCV case finding, which is cost-effective and sustainable [33]. HCV testing is typically offered through venous blood collection and poor uptake may be attributed to the difficulty in finding a suitable vein or a lack of trained staff willing and able to take blood through venepuncture or femoral stab.

Unlike venous blood collection, dried blood spots (DBS) require less training and use single-use disposable sterile lancets that minimise the risk of a needle stick injury and do not require refrigeration prior to testing. The objective of this study was to assess whether introducing DBS testing in specialised drug clinics and prisons could increase uptake of HCV testing.

Description of good practice

A cluster-randomised trial was conducted in 28 (14 pairs) specialist drug clinics and six (three pairs) prisons throughout England and Wales. The specialist drug clinics offered a range of services, including counselling, drop-in services, opiate substitution therapies and syringe distribution and ranged in size from an average caseload of 50–60 to over 1 000 patients. The prisons were all local male facilities with an average inmate size of 260–270 to over 900.

A brief half-day introduction to the intervention (DBS for diagnostic HCV antibody testing) and updated staff training on HCV pre- and post- test discussion were given. Staff were given referral information on infection control contact personnel, participating laboratories and locally agreed HCV referral pathways. Local HCV specialist nurses provided ongoing support to drug clinic workers as needed.

The pairs were split randomly into intervention (using DBS testing) and control groups (using conventional testing method). HCV antibody tests were carried out by 14 laboratories. Testing of DBS was conducted by the Sexually Transmitted and Blood-Borne Viruses Laboratory at the Health Protection Agency Centre for Infections). Specimens were sent to the Centre for Infections via each intervention site's local laboratory and results were sent back to the laboratory and testing site within 10 days.

Control sites continued with their current HCV testing practice: either testing patients on request or at selected times each week when specialist staff were available or referring patients elsewhere.

Evidence of impact

Introducing DBS testing correlated with a positive effect on diagnostic HCV testing in all but one matched pair of specialist drug agencies and prisons, with an average increased uptake of 14.5%. During the trial, 791 patients (21%) accepted and were tested for HCV at the intervention sites, with 529 (67%) using DBS, leading to an increase in the average difference between the sites of 12.2% and a doubling of the total number of HCV antibody tests compared with the preceding 6 months. In the control sites, the average percentage difference declined by 2.3%. Overall, from both intervention and control sites, HCV positive antibodies were detected in 320 of the 1 034 (30.9%) patients during the trial.

Sustainability of the practice

The findings of this trial suggest that DBS testing is a feasible and promising practice and indicates the need for additional follow-up trials with a larger number of sites in other countries to strengthen evidence. Ideally, as recommended by the site participants, such a trial would take place against a background of drug and treatment policies that gave greater priority and clear targets to infection control and testing at agencies managing current and ex-PWID.

Community settings (COM)

COM1: The COBATEST network: Monitoring activities of CBVCTs across Europe in order to promote HIV testing, early diagnosis and care for hard-to reach groups (European-wide)

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Country: Europe-wide

Setting: Community

Source: Open call

Background

Although HIV can be prevented through effective public health measures, HIV transmission continues in Europe. In 2015, 29 747 people were diagnosed with HIV in the 31 countries of the EU/EEA, with a rate of 6.3 per 100 000 [34)].

Early diagnosis is beneficial both to the infected individual, allowing for early treatment, and in preventing onward HIV transmission. However, late presentation remains high in Europe: 47% of people diagnosed with HIV have a CD4 cell count of less than 350 cell/mm^3 and 28% are diagnosed with advanced HIV infection (CD4 < 200 cells/mm^3) (34). Moreover, 15% of people living with HIV are unaware of their infection [34,35].

The HIV care continuum is an internationally recognised framework that models the dynamic stages of HIV care from testing to suppression of the virus. In order to measure the HIV care continuum in Europe, it is recommended to measure four stages according to the 90-90-90 targets advocated by the Joint United Nations Programme on HIV/AIDS (UNAIDS): the number of PLWH, number/proportion diagnosed, number/proportion on antiretroviral therapy (ART) and number/proportion virally suppressed [36–38].

In order to reach the 90-90-90 targets, the first step – by 2020, 90% of all people living with HIV will know their HIV status – is critical. Nevertheless, testing rates among key populations are below 50% in many EU countries [39]. New strategies are required to expand targeted HIV testing services, focusing on reaching the most affected population groups in local and national epidemic contexts. Community-based voluntary counselling and testing (CBVCT) services are recognised as an effective model to improve access to HIV testing for key populations [40].

Description of good practice

The COBATEST network [41] is a network of community-based voluntary counselling and testing services (CBVCTs) created in the context of the HIV-COBATEST project (HIV Community-based testing practices in Europe). This network was established in 2009, scaling–up the Catalan DEVO network, with the purpose of sharing similar procedures to monitor the activity of CBVCTs across Europe in order to promote HIV testing, early diagnosis and care for hard-to reach groups. Currently the network is comprised by 48 CBVCT services from 21 different countries (Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, the former Yugoslav Republic of Macedonia, France, Germany Hungary, Italy, Latvia, Lithuania, Moldova, Poland, Portugal, Serbia, Slovenia, Spain, Switzerland and Ukraine).

A standardised protocol to monitor HIV testing activities in the network has been defined [42–44]. Core indicators to monitor voluntary counselling and testing for HIV developed by the HIV-COBATEST project are used to monitor and evaluate CBVCT screening activity in the network. CBVCT service members of the network share a common data collection tool and database that allow the analysis of global data and direct comparisons. Alternatively, participating CBVCTs that are unable to use the common data collection form collect data through their own data entry system, then submit a minimum set of data or send aggregated CBVCT core indicators.

Evidence of impact

In 2016, 72 916 people tested for HIV with a screening test in 38 CBVCT services. The proportion of clients with an HIV-reactive screening HIV test result varied between individual CBVCT services/networks from 0% to 8.4%, with a mean of 1.8% and a median of 1.3%.

The standardised data collection and data entry system permitted more detailed analyses of the data collected in CBVCT services using the common tools. In 2014, 20 CBVCT centres from the COBATEST network used common data collection tools, increasing to 25 in 2015 and 29 in 2016.

During the study period, 30 329 HIV tests were performed on 27 934 individuals, of which 1.8% were reactive. Of these results, 75.8% had a confirmatory test and 92.2% were confirmed as positive and 90.4% of the confirmed positives were linked to care. The total number of tests performed over the study period increased 19.3%. The proportion of confirmatory tests increased from 63.0% to 90.0% and proportion linked to care increased from 84.1% to 93.8%.

Most of the tested individuals were men (70.6%) aged 21 and 35 years (58.5%) and non-foreign born (68.1%). A high proportion of individuals tested were men who have sex with men (MSM; 42.2%). The percentage of reactive screening tests was particularly high among trans* people (8.37%) and male sex workers (6.38%). Repeat testers had a higher proportion of reactive tests (2.02%) than first-time testers (1.1%).

The results indicate that CBVCT services are successful in diagnosing and linking previously undiagnosed HIV-infected individuals to care in key populations, especially among MSM, male sex workers, trans* people and PWID.

Sustainability of practice

Standardised information collected through the CBVCT services strengthens the case for community-based service delivery models as an integral part of the HIV strategic investments. The data is also an important source of information to ensure quality services along the HIV care cascade.

In addition, monitoring and evaluation results from the COBATEST network prove the feasibility of collecting standardised data from CBVCT services in different countries across Europe, as well as demonstrating the usefulness of such data.

The COBATEST network is an example and a motivation for some countries to start national networks of community-based service delivery.

COM2: Increasing coverage of HIV prevention by providing services and linkage to care for key vulnerable populations. (Lithuania)

Author(s): Svetlana Kulšis

Affiliation(s): Association of HIV affected women and their families 'Demetra'

Country: Lithuania

Setting: Hospital and community settings

Source: Open call

Background

From 2010 to 2014, Lithuania recorded a steady decline in the annual HIV incidence rate, with 141 new diagnoses by the end of 2014 [45]. However, since 2015, there has been an increase in the number of new HIV diagnoses, up to 263 in 2017 due to significant increases of HIV diagnoses among PWID, comprising more than half of all diagnosed (51.7%) [46]. Every fourth HIV diagnosis was attributed to heterosexual intercourse and 6.8% were due to sex between men who have sex with men (MSM) [13].

The Demetra association (an association of women and their families affected by HIV) is a non-governmental organisation founded in Vilnius in 1998. The main objective is to deliver preventive interventions to key populations affected by HIV, including MSM, PWID, sex workers (SW) and ex-prisoners. The package of interventions is heavily dependent on available funding. but it typically consists of testing, counselling and information provision on HIV, other STIs and other related issues, behaviour change communication, promotion of safe sexual behaviour, exchange of syringes and needles, condoms and lubricants, rapid HIV testing and referrals to other health-care specialists. It also provides the possibility of peer-to-peer consultation for people living with HIV. The work also includes advocacy activities for those living with HIV and key populations to improve services and availability of treatment, educational activities to improve knowledge and reduce stigma and discrimination for healthcare professionals as well as for the general population. Service delivery is provided through stationary points and outreach work. Staff are trained and provide assisted self-testing.

Description of good practice

The Demetra 'Test and Treat' project started in 2011 with financial support from AIDS Healthcare Foundation (AHF). The main objective of the project was to provide rapid HIV diagnosis to key vulnerable populations (MSM, PWID, SWs, ex-prisoners) and link the newly diagnosed to healthcare institutions providing HIV services. The project covered four cities in 2011 and was gradually expanded. By 2017, it covered 17 cities and included 30 sites, which included healthcare institutions and the Red Cross, which provided access to rapid HIV testing and counselling. The service was mainly delivered at stationary sites except in the capital city, where an outreach and mobile unit was used to reach major events in the country.

Activities of the 'Test and Treat' project were monitored by collecting information about clients (age, gender), their reason for testing and their testing history. It also included additional information and follow-up results in cases of a positive HIV test result, including the date of positive test result confirmation, last CD4 count and possible HIV transmission risk factor.

Linkage to the healthcare system was ensured by the healthcare coordinator at testing sites, who together with a social worker and psychologist assessed individual cases and prepared individual integration plans for patients who tested positive. In order to maintain patient confidentiality, newly diagnosed individuals were given a unique identification code to confirm their status in the reference laboratory and link to HIV care and support site.

Evidence of impact

During the implementation period, more than 80 000 people were tested for HIV, with more than 1 000 who were found to be HIV positive, and of those who tested positive, more than 85% were linked to the healthcare system. The positivity rate was 0.9% at the beginning of the project in 2011 and increased to 1.8% in 2017.

Demetra, with support from AHF, conducted a HIV/AIDS care and treatment cascade study in 2017. The study collected HIV/AIDS cascade information from government institutions and doctors providing HIV treatment and care in Lithuania in 2015 and 2016. The study found there were three major gaps in HIV cascade coverage: low proportion of people aware of their HIV status, low level of patients retained in the healthcare system and low number of patients on antiretroviral therapy, with only 56% of patients retained in care [47], while the 'Test and Treat' program had more than 85% of patients linked into the healthcare system.

Sustainability of practice

In Lithuania, there is limited financial support for HIV prevention programmes, compounded by limited funds to support services for vulnerable populations. Therefore, the 'Test and Treat' programme relies heavily on external funding from international resources such as AHF. Other key stakeholders for the 'Test and Treat' project are local healthcare institutions and the Red Cross, serving as an entry point for people who wish to be tested for HIV. There is efficient collaboration established with reference laboratories, where confirmatory tests are done free of charge within the frame of this project. Additionally, there is a support network of doctors who treat HIV patients across the country. At the national level, there is increasing interest in service delivery models and active participation in relevant working groups from the Ministry of Health.

Among other barriers for sustainability and access to healthcare for vulnerable populations, there is low community capacity and limited active participation in the planning, monitoring and implementation of programmes. Furthermore, legal barriers including constraints on rapid HIV testing in non-medical facilities and the recent re-criminalisation of drug possession and use both hinder community-based HIV service settings in Lithuania.

COM3: Closing the gaps in HIV coverage through the first non-institutional centre for testing on HIV and HCV in Croatia

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Affiliation(s): Croatian Association for HIV and Viral Hepatitis (CAHIV)[1]; City Office for Health of the City of Zagreb[2]

Country: Croatia

Setting: Community setting

Source: Open call

Background

Although Croatia has a low HIV incidence rate of 2 per 100 000 persons, recent increases in MSM transmission are of concern [48]. In Croatia, most new HIV/AIDS cases are male (88%) and almost 90% of all people infected with HIV in Croatia are infected as a result of sexual contact, with only 5% as a result of injecting drug use [48].

The overall prevalence of HBV/ HCV in Croatia is less than 1% in the general population, rendering Croatia a low-prevalence country for these infections [48]. However, estimates of prevalence in high-risk populations are higher. For people who inject drugs, HBV prevalence is 3% and 40% for HCV (range: 30–65% [48]).

HIV and HCV testing services in Croatia have been based on free anonymous testing in healthcare settings within the Clinic for Infectious Diseases in Zagreb, a network of 10 centres in public health institutions and hospitals. Prior to establishing decentralised community-based voluntary testing, the response rate to voluntary HIV testing in healthcare settings was below 2% of sexually active populations [48]. The reason for this is high levels of associated stigma and discrimination, insufficient awareness by health professionals and lack of individual commitment in recognising people's needs and concerns.

CheckPoint Zagreb was established to make testing services available in a community setting in response to the country's inadequate facilities with regards to existing testing services in health institutions and high levels of late diagnosis. The main aim of CheckPoint is to provide testing services in community settings to increase HIV/HCV testing in Croatia, lower the rate of late diagnosis and link those who are infected directly to care, with a targeted focus on subpopulations.

Description of good practice

Decentralised access to voluntary counselling and testing (VCT) centres offers strong preventive solutions in response to the HIV epidemic, especially for youth and adolescents. Operating within the Croatian Association for HIV and Viral Hepatitis (CAHIV), CheckPoint Zagreb is a health education centre for young people, offering counselling, psychosocial support and voluntary, anonymous, confidential and free testing for HIV and HCV. Counsellors from CAHIV and medical professionals deliver services. The centre provides healthcare counselling and education for youth (e.g. HBV, HCV, HIV, STIs and HPV vaccination), testing and early detection of HIV and HCV, linkage to care and early treatment. CheckPoint Zagreb is a valuable addition to the existing network of 10 VCT centres in Croatia collaborating with the National Institute of Public Health and University Hospital for Infectious Diseases Dr. Fran Mihaljević.

The CheckPoint centre aims to increase voluntarily testing uptake in the number people at increased risk of infection who are hard to reach and not responding to testing offers in healthcare settings, reduce the proportion of late diagnosis, decrease the number of undiagnosed HIV/HCV-positive persons who are not in care, minimise risk behaviours and offer prevention interventions by counselling and education.

Services are provided three working days a week for four hours at the centre and are anonymous and free. All who access services are provided with pre-counselling, where they can ask questions about sexual health and infections and are educated on HIV, viral hepatitis and STI prevention. Pre-counselling is provided by professional counsellors and psychologists trained in a certified professional education program for HIV/STI counsellors by the Croatian Institute of Public Health. A risk assessment is conducted based on real people's needs, including adapted individual education, support and recommendations for health protection, HIV and/or HCV rapid testing provided by healthcare professionals (HCP) and referral to other appropriate services (e.g. testing for other STIs, psychosocial services, mental health support and addiction prevention support). In this way, a comprehensive individual approach is achieved for people in various needs or at high risk of exposure to infections based on their history of risk behaviour. A comprehensive approach to preventing disease and promoting healthy lifestyles is thus achieved by combining the areas of mental, physical, sexual and social health.

Every person with a preliminary reactive/positive test at CheckPoint Zagreb is counselled post-test by an infectologist who conducts an initial rapid test. The individual then receives psychosocial support from a psychologist and is directly linked to the Croatian care system for confirmatory testing and further care. Staff at CheckPoint Zagreb can schedule appointments for confirmatory testing and follow-up care for patients immediately or they can choose to do it themselves. However, CheckPoint staff ensures that they are provided with all necessary information and an explanation of the process of linking to care. Those who have a reactive test typically stay in contact with CheckPoint Zagreb-affiliated psychologists and receive support in the process and follow-up.

Evidence of impact

Since the establishment of CheckPoint Zagreb in 2013 through the end of 2017, over 7 100 individuals have been counselled individually, over 5 300 people have been tested for HIV and 4 300 for HCV, averaging between 150–200 persons per month. Of all CheckPoint users, 80% were recommended for testing based on a standardised risk assessment and 20% of all users have had a history of STIs when presenting for testing. Of those testing, 61 were preliminarily HIV-positive (1.13%) and 50 preliminarily HCV positive (1.15%). Those with a positive test result were referred to the University Hospital for Infectious Diseases for diagnostic confirmation, linkage to care and support for partner notification. Additionally, two licensed psychologists who specialise in HIV and STI psychosocial support provide offer further psychological counselling.

More than 50% of CP users were informed about their health status and directed to other specialised health services (STI screening, mental health, psychosocial support and addiction prevention support). This approach provides comprehensive access to health with positive indicators, such as the high percentage of individuals tested for the first time at between 60–70%.

The number of newly diagnosed cases of HIV and HCV at CheckPoint represents about one fifth of the total diagnoses in Croatia annually while offering a safe haven for users to feel respected and valued.

CheckPoint has become an important addition to existing testing services as an upgrade of the health system in Croatia, managed to reach at-risk populations and gained trust from health workers who also come for advice and testing. The number of tests in Croatia has tripled, with about 50% of the newly diagnosed being first-time testers, services effectively attract individuals at real risk of infection, stigma has been reduced and there is an increase in regular testing of high-risk populations.

Sustainability of practice

The success of CheckPoint Zagreb is attributed to the close collaboration of many stakeholders who support and have publicly recognised the importance of the service. The Ministry of Health has established a national cooperation program for NGOs that supports the CheckPoint workforce, the city office for health of Zagreb supports CheckPoint's resources as part of its health development strategy, close collaboration with the Croatian National HIV/AIDS Prevention Programme and Croatian Institute of Public Health provides training and professional support and the University Hospital for Infectious Diseases 'Dr. Fran Mihaljević' provides HCPs, professional protocols, quality assurance and confirmatory testing and care.

COM4: HIV and other STIs testing for key populations in a community-based setting (Greece)

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Affiliation(s): Positive Voice (the Greek Association of People Living with HIV/AIDS – PLWHA) [1]; Athens Checkpoint and Thess Checkpoint[2]

Country: Greece

Setting: Community setting

Source: Open call

Background

In Greece, approximately 13 800 people were living with HIV in 2017 and the country experienced a significant increase of HIV infection among people who inject drugs (PWID) in the period 2011–2013. [31] Since then, a downward trend has been reported and most new HIV infections are now among men who have sex with men (MSM). In the first 10 months of 2017, MSM accounted for 45.93% of new infections, followed by heterosexual transmissions (22.56%) and infections attributed to PWID (13.41%) [49].

The community-based organisation Positive Voice (the Greek Association of People Living with HIV/AIDS) has run the Athens (Ath) Checkpoint since 2012 and Thessaloniki (Thess) Checkpoint since 2014. The services provided follow a holistic approach to HIV prevention and testing services for key populations in order to facilitate early diagnosis and optimal access to treatment and care while also providing support to people diagnosed with HBV/HCV/HIV. Additionally, outreach street work activities are conducted four times a week to meet the key group's needs.

Description of good practice

The Ath and Thess Checkpoints aim to reduce the number of people living with HIV (and/or HBV, HCV and syphilis) who are undiagnosed and reduce the number of MSM who have never tested. Adopting a holistic approach (e.g. personalised risk assessment for every individual accessing the service, provision of pre- and post-test counselling, testing, reminder service to retest, referral to other services and linkage to care in cases of reactive test results), Checkpoint staff promote routine testing habits for HIV and STIs (every 3/6/12 months) for sexually active individuals and focus on raising awareness of the beneficial impact of early treatment, thus encouraging early diagnosis among key groups. A main focus area is providing information on risk minimisation of sex practices and also minimising stigma effects and myths around HIV, especially within the MSM community. There is also the dispensing of free condoms, informative material and injecting drug use material in the framework of street work activities.

To support a professional service, Checkpoint staff receive continuous education. Every second week, Checkpoint staff receive supervision and evaluation by the scientific staff from the Hellenic Center for Disease Control & Prevention (HCDCP). Staff members also participate in yearly training and seminars provided by the HCDCP. Moreover, they are trained on different HIV prevention programme evaluation tools from the Quality Action project for improving HIV prevention in Europe (e.g. Quality in Prevention, Succeed and Participatory Quality Development) and participate in numerous national and EU training projects and conferences. Testing activities are monitored through the use of a data collection form prompting information on a range of indicators (demographics, past testing history, sexual practices, alcohol and drug use, reason for getting tested, testing results and if positive, referral information, HIV knowledge level of the client, reminder for retest and others).

Evidence of impact

The national HIV/AIDS epidemiological reports issued by HCDCP found that more than 30% of new HIV cases in 2015, 2016 and 2017 had been screened at and referred from the Checkpoints. These services thus contribute considerably to Greece's HIV and HCV prevention strategy.

In 2016, 15 465 clients at the Checkpoints were offered an HIV test and 15 300 accepted. Of the 15 300 tests performed, 176 were reactive (approximately 1.15% general seropositivity and 3.6% in MSM). Of the clients with a reactive test, 95% were successfully linked to care for a confirmatory test.

Since the launches in 2012 and 2014 respectively, the Ath and Thess Checkpoints have performed more than 75 000 tests for over 58 000 unique beneficiaries, of whom 45% had never tested before. For the beneficiaries with reactive tests, the linkage to care rate for a confirmatory test is 95%. In terms of prevention, more than 4 million free condoms have been dispensed and over 300,000 leaflets and informative material have been distributed.

Sustainability of practice

Taking into consideration the non-existence of state funding and the fact that Ath and Thess Checkpoints provide free services for no profit, sustainability issues always constitute a challenge. The Checkpoint project of Positive Voice thus relies entirely on charitable foundations at national, European and/or international levels. The main partner and funding body is AHF Europe, while other private for-profit and non-profit organisations and companies contribute to Checkpoint's innovative (for Greek standards) holistic prevention project for HIV and other STIs. The goal is to build strong, stable and efficient partnerships by implementing projects with specific goals and deliverables that offer mutual benefit to both parties and add value to the research and development segment. More specifically, one salient aspect to consider regarding sustainability issues is the continuous expansion of collaborations through the evolution of its network, mainly with partners and foundations from abroad.

COM5: Community-based testing for HIV, hepatitis and sexually transmitted infections through a mobile testing caravan (Poland)

Author(s): Magdalena Ankiersztejn-Bartczak

Affiliation(s): Foundation for Social Education

Country: Poland

Setting: Community

Source: Open call

Background

Poland has a very low prevalence of HIV (1%), but the percentage of late presenters is very high, representing more than 50% of new diagnoses [50]. Highly active antiretroviral therapy is available in Poland and the proportion of virologically suppressed patients is in line with the WHO treatment target [51]. Despite HIV testing available free of charge in voluntary counselling and testing centres (VCTs), within the general population, only 5% have ever tested for HIV [52], with 87% of Poles not seeing themselves or their social environment as being at risk for HIV [52].

The perception of low risk, high percentage of late presenters, untested key groups (including PWID and sex workers) and low levels of HIV diagnosis by medical testing are the key barriers to tackling the HIV epidemic in Poland. Despite higher testing rates among populations with a higher risk of exposure to HIV (MSM), the rates still remain low, which indicates the existence of barriers to testing [52]. Additionally, there has been an increase in the number of infections in the MSM population in recent years [52].

Poland has 30 VCTs funded by he National AIDS Centre Agenda of the Ministry of Health providing free anonymous HIV testing. The HIV testing programme consists of non-governmental organisations under standards created by the National AIDS Centre. Every test is provided with pre- and post-test counselling, but only 31 000 persons per year access this method of testing and the number has not increased substantially over recent years. Testing is also offered in public and private care, but very often without counselling [53].

Description of good practice

The Foundation for Social Education (FES) coordinates two VCTs in Warsaw, both of which provide free testing for HIV, hepatitis and sexually transmitted infections (STIs) with linkage to care assessment [54]. In 2017, FES executed a pilot programme, the first of its kind in Poland, called Mobile Testing Service for Harm Reduction. The main aim of this intervention is to provide access to testing outside testing centres. Mobile testing provides access to people at high risk, but in their local communities. It also provides an insight into current user needs and the challenges they face in order to access harm reduction programmes. This programme is dedicated to the most at-risk populations in Poland: psychoactive substance users and sex workers. The fully equipped van offers professional facilities for rapid HIV, HCV and syphilis tests (finger prick rapid blood tests), injection equipment, condoms and lubricants. Users can benefit from free medical and therapeutic guidance. The programme also provides referrals for legal and social consultation at FES premises in Warsaw.

The FES Mobile Testing Service employs 10 specialists in harm reduction who have pre- and post- counselling training and are experienced in outreach work (exchanging injection equipment). The specialists include HIV counsellors and medical staff (nurses and doctors) who offer and provide tests for HIV, HCV, and syphilis to anyone who requests it. The FES Mobile Testing Service is open 12 hours per week (3 days, 4 hours each) and 4 workers: a counsellor, medical staff (nurse or doctor), an outreach worker and a driver, work on each shift.

The Mobile Testing Service for Harm Reduction is the first of its kind in Poland, reaching out to users who have never before used this kind of public testing service. People who are tested for HIV, HCV and syphilis can receive support for starting and continuing suitable treatment.

Evidence of impact

In 2017, the project provided 584 tests to 234 PWID through mobile units. Of these, 29 tested positive for HIV, with 22 already aware of their HIV status, 109 tested positive for HCV, with 69 already aware of their HCV status, and 6 tested positive for syphilis. Of the non-testing services provided, 286 people exchanged injection equipment, 40 received social help and 40 people took advantage of the offer for legal help. Everyone who tested positive was sent to a specialist clinic, infectious disease hospital, dermatologist, or hepatitis specialist. The mobile testing units helped to reach and test PWID in Poland and the local community better understand the situation in this group.

Sustainability of the practice

The project was founded in 2017 by the National Bureau for Drug Prevention Agenda of the Ministry of Health and secured funding in 2018 from the Warsaw city government for a 3-year project and private companies.

Providing harm reduction and integrated testing services through a mobile unit requires a long-term financial programme and open collaboration with stakeholders and partners. A professional team of staff tracking the changing epidemiological situation is also needed. Steps to consider when establishing this type of service include exchanging experiences with other countries who already use mobile testing, securing funding for resources (e.g. staff, testing kits, training and car), selecting staff and training, assuring stakeholders and community support, monitoring and evaluation and presenting results at a local and international level.

Self-sampling/self-testing (ST)

ST1: Identifying undiagnosed HIV in men who have sex with men (MSM) by offering HIV home sampling via online gay social media: a service evaluation (United Kingdom)

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Affiliation(s): HIV/GUM directorate, Chelsea and Westminster Hospital, London, United Kingdom

Country: United Kingdom

Setting: Community

Source: Journal article [55]

Background

In 2013, 16% of the estimated 43 500 HIV-infected MSM in the United Kingdom were considered to be undiagnosed and of the newly diagnosed MSM in 2013, 31% were diagnosed late [56]. Early diagnosis is crucial to improved outcomes, both for the individual the public health in terms of epidemic control. Home sampling is an HIV testing modality that may increase testing due to convenience in terms of time and anonymity.

Over the past 10 years, social media has been increasingly used by MSM to meet sexual partners [57], but social media also offers a platform for online educational interventions and offering HIV testing. This intervention targeted MSM on social media where sexual partners can be found. Online gay social media was chosen as a platform to offer HIV home sampling in order to try to reach men who have sex with men (MSM) who may live with undiagnosed HIV. The service was launched under the name 'Dean Street at Home' (DS@H) by the testing service 56 Dean Street run by the HIV/GUM Directorate at the Chelsea and Westminster Hospital, London.

Description of good practice

Through a personal message or promotional banner, the service invited MSM to order a free postal HIV home sampling kit via intermittent campaigns on MSM partner-finding social media websites (Gaydar, Grindr, Recon and Facebook pages of gay magazines and sex-on-premise venues). The project initially focused on London, but expanded nationally in May 2013.

Respondents were asked to answer a brief risk assessment survey (condom use, timing of last unprotected intercourse and HIV test and number and HIV status of partners), then feedback related to their responses was provided on HIV transmission risks, risk reduction and recommendations for post-exposure prophylaxis. A postal HIV oral fluid self-sampling kit (Orasure) was then offered to all regardless of risk and from August 2013, the choice of a blood sampling kit (Microtainer) was added. Users were required to answer a simple question demonstrating they understood the positive predictive value (0.95) of their chosen test before proceeding ('If my postal test reacts, the chance of me having HIV is' followed by three choices).

Within 24 hours of ordering, a pack containing the sampling kit, instructions and prepaid envelope for return was dispatched by next-day delivery. Samples were analysed using previously validated Abbott Architect platforms. Negative results were sent by text message within 24 hours of sample reception and experienced sexual health advisors delivered reactive results by phone arranging confirmatory testing and follow-up care.

Evidence of impact

During the two years of the programme, 66 579 individual users visited the website. Of these, 17 362 (26%) completed the online risk assessment, 45% were at 'identifiable risk for HIV' and 36% had never previously tested for HIV. A total of 11 127 (64%) clicked through for info on tests and of these, 10 323 (93%) ordered a sample kit. The return rate was 55% (N=5 696) in the evaluation period.

Of the 5 696 returned samples, 122 (2%) were reactive. To support adequate linkage to care, reactive results were delivered by experienced sexual health advisers by phone and arrangements for confirmatory testing and follow-up care were made. There were 82 confirmed new diagnoses, a 1.4% positivity rate among the returned samples. The project's confirmed linkage-to-care rate was 88% (82/93 potential new positives).

After two years, the service was evaluated to determine the HIV risk behaviour of users (with an online risk assessment), uptake of offer of home sampling and acceptability of the service. An anonymised acceptability user survey was also conducted to monitor user experience.

With a prevalence of 1.4%, the project demonstrated cost-effectiveness. Additionally, 23% of new diagnoses were made at CD4<350 cells/μL (compared to the 32.5% national average in 2012–13), which suggests that people diagnosed by this service may be at an earlier stage of infection with all its attendant advantages.

Sustainability of practice

The service was the first of its kind in the United Kingdom and provides evidence to inform the potential roll-out of further online strategies to enhance community HIV testing. Online test ordering and home sampling was shown to be an acceptable and welcome method for HIV testing in the acceptability survey. Although home sampling risks the potential for lack of immediate linkage into care or the opportunity to test for other sexually transmitted infections, this method has the potential to eliminate key barriers to testing and reach MSM who may not otherwise test for HIV while still offering online education and engagement with services.

ST2: Swab2know: An HIV testing strategy using oral fluid samples and online communication of test results for men who have sex with men in Belgium

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Country: Belgium

Setting: Community

Source: Journal article [58]

Background

In Belgium, 915 people were newly diagnosed with HIV in 2016, a rate of 8.1 per 100 000 inhabitants. [2] There is a concentrated epidemic among men who have sex with men (MSM; 52% of new diagnoses) and men and women originating from sub-Saharan Africa (SSA; 45% of new diagnoses). [2] In recent years, a decline in new HIV diagnoses has been observed (down 9.8% from 2015 and 25.1% from 2012) in both key groups. [2] A third of newly diagnosed people living with HIV (33%) were diagnosed late, indicating the importance of increased HIV testing among key populations [2].

The Swab2know project aimed primarily at detecting new HIV cases among MSM and men and women originating from SSA in Belgium, both groups at high risk for HIV/STI acquisition. The online approach was more successful among MSM, but results for SSA were published separately. [59] The secondary objective was to assess the acceptability and feasibility of an HIV testing strategy with the use of self-administered oral fluid samples collected through outreach and online activities and web-based delivery of test results. This project combines two strategies to increase HIV testing uptake among MSM: outreach HIV test sessions and free online testing. In both strategies, samples are collected using oral fluid collection devices and test results are communicated via secured website.

Description of good practice

A secure and encrypted website was specifically designed for the project with the aim to provide a platform where visitors can find information, prevention messages, order test kits and collect test results.

The intervention targeted MSM aged 18 years and older who were recruited in two ways: through outreach sessions and online. During the outreach sessions, the Swab2know team collected informed consent and baseline data through a self-administered pen-and-paper questionnaire and helped set up an online account on the secure website. All materials were available in Dutch, English and French. The oral fluid samples were self-collected by participants under the supervision of study staff. All samples were identified by a unique sample code that linked the sample with the personal account, indicator condition (IC) and baseline data.

Online recruitment occurred on the website by occasional visitors who created an account and provided their email address and phone number. The project was advertised by prevention organisations through articles and announcements in dedicated media. Participants who provided consent and ordered a sampling kit were sent one with a unique sample code to the Belgian address of their choice. Participants took the oral fluid sample after having seen a short educational video on the website. Samples were sent to the laboratory using a prepaid envelope. The participants could also opt to collect their results during a face-to-face consultation.

Once the results were known in the laboratory, they were uploaded onto the website and the participant was informed via email that his or her result was available. Participants who did not check their results were contacted by phone or email. In the case of a reactive result, a mobile phone number was provided for emergency counselling by a trained paramedic. Additionally, all participants with a reactive result were contacted by phone within 24 hours of having read their results to offer counselling, arrange a further confirmation test and guarantee linkage to care. If the confirmation did not take place at the organising healthcare centre, participants were contacted after the confirmation procedure to collect the final result.

Evidence of impact

Within the project, 898 people tested for HIV and the positivity rate was 2.2%. All new cases were successfully linked to HIV care, which is a crucial aspect of the HIV treatment cascade and a great asset of the project compared to self-testing. Moreover, with a yield of 2.2% of participants newly diagnosed with HIV in this project, it can be considered cost-effective, having surpassed the threshold of 0.1%. Furthermore, of the 898 people tested, 154 (17.1%) reported they had never previously tested for HIV.

Despite a high yield and a considerable number of false reactive results, satisfaction was high among participants. The project helped to reach the target population, both in numbers of tests executed and newly diagnosed HIV infections. Further optimisation should be considered in the accuracy of the test, functionalities of the website (including an online counselling tool) and studying the cost-effectiveness of the methodology.

Sustainability of the practice

In order to sustain the intervention, the Swab2Know team recognised that an emphasis on Internet-based testing and repeated testing for participants, as well as strong collaboration with community-based and prevention organisations to guide MSM toward the Swab2know project, was needed. Additionally, the online counselling tool would be refined to support participants: with an increased emphasis on those with a reactive result, there would be increased efforts to reduce the amount of false reactive tests. Another consideration for the practice is to develop the legal framework for self-testing and self-sampling, as neither are officially recognised in Belgium.

To attract new members from key populations and reduce the focus from being solely on HIV, expansion to testing additional STIs should be considered. Sustainability in Belgium requires a paying service, unlike the current system. However, several other HIV testing approaches directed towards key populations are free of charge. Accordingly, the impact of these adaptations (expanding the offer and paying service) should be monitored closely.

Partner notification (PN)/Contact tracing

PN1: Assessing impact of a nurse-delivered home dried blood spot service on uptake of testing for household contacts of HBV-infected pregnant women across two London trusts (United Kingdom)

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Country: United Kingdom

Setting: Home testing

Source: Open call/journal article

Background

In the United Kingdom, a low HBV prevalence country, the majority of chronic HBV infection occurs among migrant populations who acquired their infection outside the country [60]. Although rates vary between individual communities, prevalence rates are around 0.4% in the general population and higher in certain inner city areas where a greater proportion of the population originate from endemic countries [61]. Whereas in the past, most reports of acute infection in the United Kingdom were associated with injecting drug use, due to vaccination policies, they now occur most commonly due to heterosexual exposure, followed by sex between men. Transmission to infants from infected mothers has been largely attributed to exposure during or after delivery, with trans-placental infection being apparently rare [62].

As part of the universal antenatal screening for infectious diseases programme, pregnant women are routinely recommended screening for HBV infection (plus HIV and syphilis) in the United Kingdom [63]. National guidance recommends testing and vaccination of household contacts of HBV-infected pregnant women, but provision and uptake remain suboptimal. As an alternative approach to conventional primary care follow-up for household contacts of HBV-infected pregnant women, the unit for Immunisation, Hepatitis and Blood Safety Department, Centre for Infectious Disease Surveillance & Control (CIDSC) at Public Health England launched an intervention using in-home dried blood spot (DBS) testing to increase testing and vaccination of household contacts. The study was conducted across two London maternity trusts (North Middlesex and Newham). All HBV surface antigen-positive pregnant women identified through these trusts were eligible for inclusion.

Description of good practice

For the intervention, women whose household contacts were eligible for home DBS testing were identified by weekly meetings with the trust's antenatal screening coordinator and study nurse. The single study nurse made direct contact with the case to arrange an appointment with the family at their home for screening and vaccination of contacts. At the time of the visit, DBS samples were taken from all household contacts present who consented and had not previously been tested or vaccinated. Follow-up arrangements were made to obtain samples from those not at home at the time of the visit. The first dose of vaccine was administered by the study nurse to all contacts aged ≤16 years. Those aged >16 years were referred to their GP in line with local commissioning arrangements.

Evidence of impact

In the study, 169 household contacts of HBV-infected pregnant women participated. Of these, 90 were children, 56 were partners and 23 were other adults in the household. These household contacts were offered in-home dried blood spot (DBS) HBV testing and 167 (99%) accepted testing.

Contact testing showed an overall positivity rate of hepatitis B among household contacts of 31.7%. For children, the positivity rate was 5.6%, for partners it was 62.5%, and for other adults, the positivity rate was 56.5%.

In terms of the impact of this home-delivered DBS testing service on the uptake of HBV testing and vaccination in household contacts of HBV-infected pregnant women identified through antenatal screening, the study found a significantly increased testing uptake for all ages ($P<0{\cdot}001$), with the biggest impact seen in partners. In partners, testing increased from 30.3% during the baseline period to 96.6% during the intervention period. The provision of nurse-led home-based DBS may be useful in areas of high prevalence [64].

Sustainability of practice

This nurse-led provision of home-based DBS has shown to increase testing uptake for all ages, with the biggest impact seen in partners, and it may be useful to implement in areas of high HBV prevalence. However, the DBS approach has proven to be more resource-intensive and therefore may not be appropriate in lower-prevalence areas. A combined approach of a nurse-led clinic/home approach may be more affordable without compromising access to services for hard-to-reach groups. For the service to be sustained, it needs to be funded by local commissioners of NHS primary care services.

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Annex 3. First call for case models

Good-practice example on HIV and/or hepatitis testing scale-up	
Main person of contact of project (name and email)	
Name of organisation	
City, country or European region where intervention took place	
Testing service setting (e.g. healthcare setting: outpatient, primary care/general practitioner, STI/sexual health clinic, emergency department, pharmacy; community setting; Home testing/sampling)	In which setting did the intervention take place?
Targeted subpopulation (e.g. PWID, migrants, MSM, youth, partner contacts, general population, prisoners, sex workers, healthcare workers)	Which population group was targeted?
Main aim of project/service	What was the main aim of the intervention?
Denominator (e.g. total number of patients offered testing, total number of people who accessed services)	
Test uptake (i.e. how many that were offered a test accepted the offer)	
Positivity rate (i.e. of the tested how many positives were found)	
Other tests (e.g. Did you also offer tests for sexually transmitted infections, TB?)	
Linkage to care (e.g. If a person had a reactive test, were they referred to confirmatory testing or HIV care?)	
Monitoring (e.g. Were there any quality assessments conducted?)	
Conclusions (e.g. main outcomes of service or project)	
Other comments or additional information	

Annex 4. Second call for case models

Good practice example on HIV and/or hepatitis testing scale-up		
Section	**Guidelines**	**Examples**
Background (300 words)	In this section, we ask you to please include available information on the following: Available national and local epidemiological information on the targeted disease, population and setting Current screening guidelines/practices for your targeted disease and population	Our country has had relatively low national prevalence rates of HCV, however, within our local community we have seen a recent increase in prevalence of HCV in pregnant women late in pregnancy. Our National Hepatitis Screening guidelines do not require universal screening of HCV in antenatal care but in practice, physicians in our community screen depending on the perceived patient's risk for HCV
Description of the good practice (500 words)	In this section, we ask you to please include available information on the following: Rationale for the intervention Main aim of the intervention Description of the intervention (e.g. preparation, activities implemented, collaborations)	Due to the recent increase of HCV in pregnant women in our antenatal clinic, we decided to work with the hospital administrators and key physicians to introduce universal HCV screening. The main aim of our intervention was to introduce new policy for our clinic to require universal HCV screening for pregnant women.
Evidence of impact (300 words)	In this section, we ask you to please include available information on the following: Available results from your intervention How your intervention has improved testing practices/care at your site	
Sustainability of the practice (100 words)	In this section, we ask you to please provide information on what needs to be done in order for your organisation to sustain the intervention and considerations for other organisations who would like to implement a similar intervention	
Links	Please provide links to any available publications regarding your intervention.	

Annex 5. List of HIV indicator conditions and specialties to consider

Definitions of indicator conditions and recommendations for HIV testing [96]

1. Conditions which are AIDS defining among PLHIV*

Strongly recommend testing:

Neoplasms:
- Cervical cancer
- Non-Hodgkin lymphoma
- Kaposi's sarcoma

Bacterial infections
- Mycobacterium Tuberculosis, pulmonary or extrapulmunary
- *Mycobacterium avium* complex (MAC) or *Mycobacterium kansasii*, disseminated or extrapulmonary
- *Mycobacterium, other species or unidentified species, disseminated or extrapulmunary*
- Pneumonia, recurrent (2 or more episodes in 12 months)
- Salmonella septicaemia, recurrent

Viral infections
- Cytomegalovirus retinitis
- Cytomegalovirus, other (except liver, spleen, glands)
- Herpes simplex, ulcer(s) > I month/bronchitis/pneumonitis
- Progressive multifocal leucoencephalopathy

Parasitic infections
- Cerebral toxoplasmosis
- Cryptosporidiosis diarrhoea, > 1 month
- Isosporiasis, > 1 month
- Atypical disseminated leismaniasis
- Reactivation of American trypanosomiasis (meningoencephalitis or myocarditis)

Fungal infections
- Pneumocystis carinii pneumonia
- Candidiasis, oesophageal
- Candidiasis, bronchial/ tracheal/ lungs
- Cryptococcosis, extra-pulmonary
- Histoplasmosis, disseminated/ extra pulmonary
- Coccidiodomycosis, disseminated/ extra pulmonary
- Penicilliosis, disseminated

2a. Conditions associated with an undiagnosed HIV prevalence of ≥0.1

Strongly recommend testing:
- Sexually transmitted infections
- Malignant lymphoma
- Anal cancer/dysplasia
- Cervical dysplasia
- Herpes zoster
- Hepatitis B or C (acute or chronic)
- Unexplained lymphadenopathy
- Mononucleosis-like illness
- Community-acquired pneumonia
- Unexplained leukocytopenia/thrombocytopenia lasting >4 weeks
- Seborrheic dermatitis/exanthema
- Invasive pneumococcal disease
- Unexplained fever
- Candidaemia
- Visceral leishmaniasis
- Pregnancy (implications for the unborn child)

2b. Other conditions considered likely to have an undiagnosed HIV prevalence of >0.1%

Offer testing:
- Primary lung cancer
- Lymphocytic meningitis
- Oral hairy leukoplakia
- Severe or atypical psoriasis
- Guillain–Barré syndrome
- Mononeuritis
- Subcortical dementia
- Multiplesclerosis-like disease
- Peripheral neuropathy
- Unexplained weightloss
- Unexplained oral candidiasis
- Unexplained chronic diarrhoea
- Unexplained chronic renal impairment
- Hepatitis A
- Candidiasis

3. Conditions where not identifying the presence of HIV infection may have significant adverse implications for the individual's clinical management

Offer testing:
- Conditions requiring aggressive immuno-suppressive therapy:
  - Cancer
  - Transplantation
  - Auto-immune disease treated with immunosuppressive therapy
- Primary space occupying lesion of the brain.
- Idiopatic/Thrombotic thrombocytopenic purpura

* Based on CDC and WHO classification system

Indicator conditions and specialties involved
Blue: conditions that are AIDS defining among PLHIV – strongly recommend testing
Tan: conditions associated with an undiagnosed HIV prevalence of >0.1% - strongly recommend testing and other conditions considered likely to have and undiagnosed HIV prevalence of >0.1% - offer testing
Green: conditions where not identifying the presence of HIV infection may have significant adverse implications for the individual's clinical management despite that the estimated prevalence of HIV is most likely lower than 0.1% - offer testing

Respiratory/pulmonology
Tuberculosis
Pneumocystis *P. jirovecii* pneumonia
Pneumonia, recurrent
MAC lung disease
Histoplasmosis, disseminated/extrapulmonary
Herpes simplex bronchitis/pneumonitis
Candidiasis, bronchial/lungs
Community-acquired pneumonia
Neurology and neurosurgery
Cerebral toxoplasmosis
Cryptococcosis, extrapulmonary
Progressive multifocal leucoencephalopathy
Reactivation of American trypanosomiasis (meningoencephalitis or myocarditis)
Guillain–Barré syndrome
Mononeuritis
Subcortical dementia
Multiple sclerosis-like disease
Peripheral neuropathy
Primary space occupying lesion of the brain
Dermatology/dermatovenereology/genito-urinary medicine
Kaposi's sarcoma
Herpes simplex ulcer(s)
Atypical disseminated leishmaniasis
Penicilliosis, disseminated
Seborrheic dermatitis/exanthema
Herpes zoster
Sexually transmitted infections
Hepatitis B or C (acute or chronic)
Severe or recalcitrant psoriasis
Candidaemia
Candidiasis
Gastroenterology/hepatology
Cryptosporidiosis diarrhoea, > 1 month
Microsporidiosis, > 1 month
Isosporiasis, > 1 month
Candidiasis, oesophageal
Hepatitis B or C (acute or chronic)

Unexplained chronic diarrhoea
Oncology
Lymphoma, non-Hodgkin
Kaposi's sarcoma
Primary lung cancer
Anal cancer/dysplasia
Cancer requiring aggressive immunosuppressive therapy
Gynaecology/obstetrics
Cervical cancer
Sexually transmitted infections
Hepatitis B or C (acute or chronic)
Pregnancy (implications for unborn child)
Cervical dysplasia
Haematology
Lymphoma, non-Hodgkin
Malignant lymphoma
Unexplained leukocytopenia/thrombocytopenia lasting >4 weeks
Thrombotic thrombocytopenic purpura
Infectious diseases/internal medicine
Tuberculosis
Mycobacterium tuberculosis, pulmonary or extrapulmonary
Mycobacterium avium complex (MAC) or *Mycobacterium kansasii*, disseminated or extrapulmonary
Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
Pneumonia, recurrent (2 or more episodes in 12 months)
Pneumocystis carinii pneumonia
Cryptococcosis, extrapulmonary
Salmonella septicaemia
Cytomegalovirus, other (except liver, spleen, glands)
Herpes simplex ulcer(s) >1 month/bronchitis/pneumonitis
Candidiasis, bronchial/tracheal/lungs
Candidiasis, oesophageal
Histoplasmosis, disseminated/extrapulmonary
Coccidiodomycosis, disseminated/extrapulmonary
Atypical disseminated leishmaniasis
Reactivation of American trypanosomiasis (meningoencephalitis or myocarditis)
Penicilliosis, disseminated
Sexually transmitted infection
Hepatitis B or C (acute or chronic)

Mononucleosis-like illness
Invasive pneumococcal disease
Herpes zoster
Lymphocytic meningitis
Visceral leishmaniasis
Unexplained weight loss
Unexplained fever
Unexplained chronic diarrhoea
Unexplained lymphadenopathy
Unexplained leukocytopenia/thrombocytopenia lasting >4 weeks

Rheumatology

Autoimmune disease treated with aggressive immuno-suppressive therapy

Ophthalmology

Cytomegalovirus retinitis

Ear, nose and throat

Candidiasis tracheal/oesophageal
Mononucleosis-like illness

Nephrology

Unexplained chronic renal impairment

General practice

Symptomatology fitting any of the listed conditions

Emergency medicine

Symptomatology fitting any of the listed conditions

Dentistry

Candidiasis, oral and oesophageal
Kaposi's sarcoma
Oral hairy leucoplakia

Primary healthcare

Anal dysplasia
Candidiasis
Cervical dysplasia
Cytomegalovirus
Herpes simplex ulcers
Kaposi sarcoma
Recurrent pneumonia (2 or more episodes in 12 months)

Tuberculosis
Unexplained oral candidiasis
Community-acquired pneumonia
Hepatitis B
Hepatitis C
Herpes zoster
Mononucleosis-like illness
Multiple sclerosis-like syndrome
Oral hairy leukoplakia
Peripheral neuropathy
Pregnancy
Seborrhoeic dermatitis/exanthema
Severe or atypical psoriasis
STI
Unexplained chronic diarrhea
Unexplained fever (> 38 C for 3 weeks or more)
Unexplained leuko-/thrombocytopenia lasting >4 weeks
Unexplained lymphadenopathy
Unexplained weight loss (> 5% of body weight in 6 – 12 months, unintentional)

Annex 6. Major European and international guidelines for HBV, HCV and HIV testing

1. European AIDS Clinical Society. HIV guidelines version 9.0. Brussels: EACS; 2017.
2. 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.
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11. World Health Organization. Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection. Recommendations for a Public Health Approach. Geneva: WHO; 2016.
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13. World Health Organization. Guidelines on hepatitis B and C testing. Geneva: WHO; 2017.

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