

Hepatitis B and C testing:

why?
who?
how?

**A guidance paper on testing in community
and harm reduction settings**

Colophon

**This paper is a product of the
Correlation Hepatitis C Initiative.**

You can access the paper at www.hepatitis-c-initiative.eu

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**Eberhard Schatz
Correlation Hepatitis C Initiative
Amsterdam, December 2016**

“The Hepatitis C Initiative aims to enhance the momentum of current HCV treatment opportunities and strives for universal access to essential HCV prevention and treatment for the most affected and under-served communities: people who use drugs.”

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1: Introduction

The shorter treatment periods of the new hepatitis C direct antivirals with almost no side effects and high cure rates shift the focus of the HBV and HCV treatment cascade to non-medical settings.

That many of those infected with HBV and HCV are unaware of their infection has significant consequences, both for the health of the individual and the continued transmission of the viruses. This underlines the importance of raising public and professional awareness around the need for diagnosis and increased access to testing for viral hepatitis. Identifying if someone has hepatitis B or hepatitis C can be the first step to accessing healthcare, treatment and support.

People who use drugs are the main risk group for hepatitis c with infection rates up to 90%.¹

why?

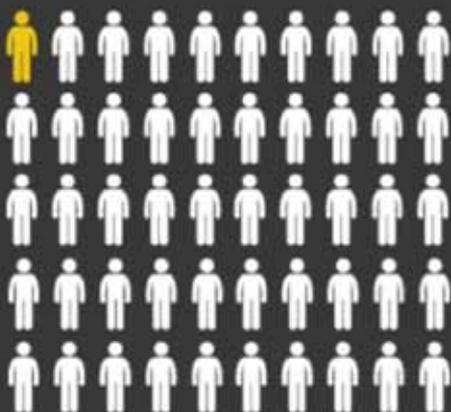
Community centres, harm reduction and low threshold services have to play a crucial role in order to link potential patients to testing and treatment in the future. The Correlation Manifesto¹⁷ strongly recommends the scale-up of harm reduction and community-based programs ensuring high quality, effective and sustainable coverage. Research showed that a combination of integrated interventions in low threshold settings such as needle distribution programmes, opioid substitution therapy, access to medicalised heroin and community based, peer led harm reduction programs are not only cost effective regarding HCV prevention, but also ensure that marginalised populations stay connected to direly needed services¹⁷. Moreover - considering the easier transmission of HCV when compared to HIV - it is crucial to ensure even higher quality standards for harm reduction services in order to prevent HCV infections.

This paper aims to stimulate services to engage in HCV and HBV awareness raising and in particular to inform community members, social and health care practitioners about current HBV/HCV testing and diagnosis methods, screening technologies and other aspects around the issue.

HEPATITIS

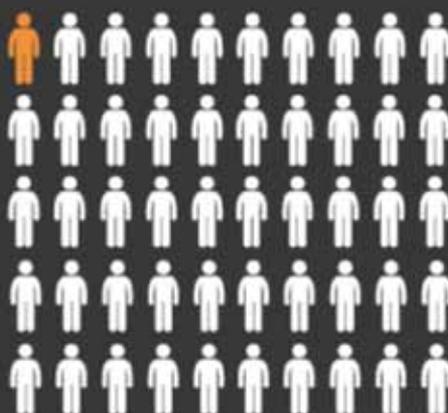
In the WHO European Region

Hepatitis C affects



**1 IN 50
PEOPLE**

Hepatitis B affects



**1 IN 50
PEOPLE**

co-infection may occur

why?

1.1 Hepatitis B and C infect one in fifty adults in European Region

Over 13 million adults are living with hepatitis B and 15 million with hepatitis C in the WHO European Region 1 – indicating a huge burden of treatment and care. New estimates suggest that almost one in fifty adults is infected with hepatitis B and a similar amount of people have chronic hepatitis C and yet most people infected with hepatitis B or C are unaware of their infection. ^{2,3}

1.2 Higher rates of hepatitis among vulnerable groups

People who inject drugs are the most affected (15% for hepatitis B and 44% for hepatitis C), but infection is also common in other vulnerable population groups such as men who have sex with men (8.7% and 4.2%, respectively), and sex workers (3.3% and 11%, respectively).

By comparison, rates in the general population of countries in the European Region outside the European Union and European Free Trade Association are 3.8% for hepatitis B and 2.3 % for hepatitis C.⁴

1.3 A public health approach to hepatitis

For decades hepatitis has been largely ignored as a health and development priority. In recognition of the public health burden – comparable to other major communicable diseases, including HIV, tuberculosis and malaria - the WHO published its Global Health Sector Strategy on Viral Hepatitis ⁵, calling on specific action to combat and eliminate viral hepatitis.

The strategy calls for a reorientation of hepatitis programmes towards a comprehensive public health approach. This approach requires people-centred health services that can reach populations most affected, an appropriately trained health workforce, adequate public funding for essential harm reduction services, testing and treatment interventions and active involvement of affected communities including people who inject drugs (PWID).

1.4 Harm reduction as prevention

A package of harm reduction services for people who inject drugs can be highly effective in preventing the transmission and acquisition of viral hepatitis as well as HIV and other blood-borne infections. Current coverage of these interventions and the hepatitis strategy calls for a major increase in interventions and services that should be integrated into a comprehensive package for PWID.

As part of the comprehensive package of care for PWID, WHO, UNODC and UNAIDS⁶ have defined a set of five intervention areas that will have greatest impact on hepatitis epidemics:

- sterile needle and syringe programmes,
- opioid substitution therapy for opioid users,
- risk reduction communication,
- hepatitis B vaccination,
- treatment of chronic hepatitis infection.

Although available across Europe, current coverage of these interventions is too low to have a significant impact on hepatitis epidemics and there is wide variation in their implementation across the European region.⁷ Combined harm reduction approaches, in particular needle and syringe exchange, opioid substitution therapy

and hepatitis B vaccination programmes, are all well evidenced and established as central components in effective hepatitis B and hepatitis C prevention strategies.^{8, 9, 10, 11}

Studies have highlighted that there are grounds for greater optimism in preventing and treating viral hepatitis in PWID.^{12, 13, 14, 15, 16} Recent advances in hepatitis C treatment and increasingly effective hepatitis B medications, in line with adequate prevention, vaccination and harm reduction measures, can have a significant impact in reducing hepatitis B and C transmission.

However, while the coverage of these approaches for PWID remains variable and suboptimal, hepatitis B and C continue to affect millions of people every year across Europe - with most people unaware of their infection.^{17, 18}

1.5 Diagnosing hepatitis B and C

Early testing and diagnosis of hepatitis infection is the gateway for access to both treatment and prevention services.¹⁹ It is critical for effective treatment and care and crucial for an effective hepatitis epidemic response.

why?

However, awareness around viral hepatitis is universally lacking and there is a need for education and awareness training among policy makers, the general public, healthcare workers and affected communities to overcome this deficit.

Certainly, although there are exceptions such as England, Austria, Scotland and France which have viral hepatitis plans, most European countries are yet to develop targeted, locally relevant policies or the tools to implement them.²⁰

1.6 Awareness raising - key recommendations

(From Hepatitis B and C – an action plan for saving lives in Europe)

- Secure government funding for awareness campaigns
- Use mass media campaigns to raise awareness among the general population
- Provide stigmatised groups such as people who inject drugs, migrants, homeless people and men who have sex with men, with appropriate knowledge and support to help them overcome stigma
- Improve awareness of healthcare professionals working in areas of high prevalence
- Raise awareness among the prison population
- Involve civil organisations at a national level
- Involve civil society in World Hepatitis Day

Hepatitis B and C – an action plan for saving lives in Europe, 2016

In contrast to HIV, where awareness and policy development has led a more systematic approach to testing, hepatitis testing remains fragmented and limited to a few countries. In Europe the number of undiagnosed people is high. Around 90 per cent of an estimated 10 million people who have hepatitis B and C, are unaware of their condition. Without diagnosis, millions of people are at risk of developing serious and potentially life threatening liver disease.

Although technologies are advancing, reliable diagnostics that can work well in community settings are not sufficiently available or targeted to reach affected populations. Increasing early diagnosis requires efforts to overcome these shortcomings, using effective testing approaches, quality-assured diagnostics, and linking the results of testing to treatment.^{21,22}

Testing for viral hepatitis is not only advantageous for people who are affected, but also benefits national healthcare systems, the economy and society. Detection and treatment at an early stage can reduce the spread of the virus and both the cost and duration of treatment, as well as increasing the chances of recovery. Indeed, most liver cancer cases could be prevented with appropriate management of viral hepatitis B and C.²³

Increased political will, increased focus and specific policy measures can ensure earlier and more active testing and improved diagnosis of viral hepatitis and will benefit individuals, communities and improve health outcomes resulting in significant savings in financial resources.

why?

1.7 Testing and diagnosis - key recommendations

- Set up local screening, referral and treatment facilities for the general population, and specially for high-risk groups
- Ensure early identification of chronically infected pregnant women
- Implement routine testing for blood donors, with referral to a specialist for those testing positive
- Provide free-of-charge, anonymous testing for all
- Deliver targeted, low-barrier testing activities for high-risk groups
- Develop standard protocols
- Include liver enzyme testing in routine medical check ups

Hepatitis B and C – an action plan for saving lives in Europe, 2016

2: who should be tested

Hepatitis C testing should be offered to:

- Anyone who has ever injected drugs
- People born or who have lived in a country of high prevalence, predominantly, Asia, Eastern Europe and Africa ²⁴
- Everyone who has been diagnosed with HIV or hepatitis B
- People who may have had unsterile medical or dental treatment abroad, or treatment in countries where infection control procedures are sub-standard
- People who have had an tattoo or piercing (i.e. in unlicensed premises, in prison or home)
- Those who have elevated Liver Function Tests (LFTs)
- Men who have sex with men
- Pregnant women, if other risk factors are present
- Prisoners, if other risk factors are present
- Children of women known to be infected
- Any healthcare worker following occupational needle-stick injury

who?

Hepatitis B testing should be offered to:

- Anyone who has injected drugs (in community and prison settings)
- People born or who have lived in a country of high prevalence ²⁵, predominantly, Asia, Eastern Europe, Africa and the Caribbean
- Men who have sex with men
- Everyone who has been diagnosed with HIV or hepatitis C
- People who may have had unsterile medical treatment abroad, or treatment in countries where infection control procedures are sub-standard
- People who may have had unsterile body piercing or tattoos
- Those who have elevated Liver Function Tests (LFTs)
- The sexual partners and close contacts of those diagnosed with hepatitis B
- Prisoners, if other risk factors are present
- Pregnant women
- Children of women known to be infected
- Any healthcare worker following occupational needle-stick injury

2.1 Barriers to testing

Institutional discrimination and lack of governmental or political will to invest in the treatment and care of people who inject drugs is common across Europe. It is widely recognised that stigmatised, marginalised and socially excluded groups, such as PWID, face barriers accessing healthcare services. Understanding these barriers can determine the responses needed to overcome them and increase access to hepatitis B and hepatitis C testing.

However, although some barriers may be common to those at risk of both hepatitis B and C, there are notable differences in the way in which different communities can be perceived and stigmatised.

2.2 Barriers to testing and treatment may include:

For people at risk:

- Fear of stigma from healthcare professionals, family, friends and the wider community
- Lack of awareness of hepatitis transmission, their natural histories and consequences, and treatment options
- Fear of disclosure and breach of confidentiality
- Normalisation - where disempowerment can lead to repositioning of risk behaviours, an acceptance that infection is inevitable
- Fear of venepuncture for testing, and invasive monitoring procedures
- Fear of cultural or community isolation following a positive test
- Fear of a positive diagnosis
- Fear of negative impact on employment prospects, life insurance and mortgage, from both testing and a positive diagnosis
- Limited healthcare and punitive responses to PWID in custodial settings
- Fear of judgement from healthcare professionals around injecting drug use and risk behaviours
- Lack of insurance (a huge number of PWIDs do not have health insurance in certain countries)

who?

For the healthcare workers:

- Lack of knowledge among healthcare professionals of the risk factors for hepatitis B and C, the transmission of the infections, their natural histories and consequences, and the potential for treatment
- Fear of limited competency to support effective and sensitive engagement central to pre- and post- testing discussion
- Inaccurate beliefs that continued drug use is a barrier to treatment for hepatitis C
- Limited understanding of the potential benefits of treatment, which include the potential for elimination of the virus in hepatitis C and control of the infection in hepatitis B
- Lack of clarity about local referral pathways and procedures
- Lack of confidence in raising questions of sexual behaviours, drug use behaviours, ethnicity and cultural beliefs

2.3 Overcoming barriers to testing

Overcoming hepatitis-related health inequalities and barriers requires enhanced knowledge, skills and competency in regard to the differences between hepatitis B and C.²⁶ Given the prevalence among PWID, healthcare workers require an understanding of how injecting can be optimised to prevent hepatitis transmission and other risks. The development of supportive healthcare cultures, providing hepatitis B vaccination and evidence based harm reduction responses including hepatitis B vaccination, can significantly contribute to the reduction of infections and increase diagnosis and access to treatment.

Effective testing and treatment of both hepatitis B and C requires a high level of interpersonal and communication skills. For example, healthcare workers should be able to effectively and respectfully engage service users in conversations about sexual behaviours and injecting drug use, in a way that is individualised, sensitive to cultural diversity and needs. The fear for many people - of being diagnosed with hepatitis - and the implications for their future health and for the health of others cannot be underestimated. Effective, considered and respectful engagement may be the first essential step to effective management.

2.4 Testing as standard practice

In most cases hepatitis B can be effectively treated and with the advent of new drugs, hepatitis C can be treated and cured. However, while many people continue to be unaware of their infections, significant consequences remain for the long-term health of the individual and also for the continued transmission of viral hepatitis. This underlines the importance of raising public and professional awareness around the need for diagnosis and increased access to testing.

It is regarded as good practice to offer testing to all PWID and all other people identified as at risk of contracting hepatitis B and C. As a standard, treatment services²⁷ should provide voluntary blood borne virus testing, support to reduce blood-borne virus risks and facilitate access to hepatitis care and treatment, while respecting ethical principles, human rights, confidentiality, cultural and social characteristics, gender and health inequalities.

There are multiple benefits for people being tested for hepatitis B and C - for many the process can be the first step to accessing essential healthcare, treatment and support and **all people identified with chronic hepatitis B or hepatitis C infection should be offered**

referral to specialist treatment services for possible treatment and care or long term monitoring^{28, 29}. People with chronic hepatitis C infection should be offered vaccination against hepatitis A and hepatitis B if they are already immunized.

The most important reason to testing is for the person to establish their status and gain access to treatment. Even without hepatitis treatment, there are enormous benefits in people knowing if they are infected. Knowing they have hepatitis allows people to take informed steps to protect themselves. Avoiding viral transmission, making lifestyle choices, including reducing alcohol consumption, losing weight, avoiding obesity and diabetes, can all slow down the progression of liver disease.

Diagnosis can also help people recognise hepatitis symptoms they may have experienced; such as fatigue or 'brain fog' which may have been incorrectly attributed to ageing, drug use or other issues.

who?

2.5 Pre- and post- test discussion

Hepatitis B or C testing should always be voluntary, confidential and done with informed consent. Testing should be accompanied with a discussion about the test, its benefits, and the implications for both positive and negative test results.³⁰

Although a small number of people may not need it, for most, pre- and post- test discussion provides a necessary opportunity to provide clear and up-to-date information about

hepatitis B and hepatitis C. Ideally, the same person should provide both pre- and post test discussion as this helps to build trust and rapport.

These discussions provide important preventive and health promotion information and should encourage continued engagement with healthcare services. Individualised to the person's needs, pre and post-test discussions ensures the individual receives appropriate support, before, while waiting and when receiving their result.

Pre- and post- test discussion checklist

- Have issues of confidentiality and anxiety been addressed?
- Has the offer been accompanied by an agreed mechanism for providing the result?
- Has the offer been phrased in a way that suits the person's age, culture and literacy level and is respectful and non-judgmental and avoids stigmatisation and blaming language?
- Has the offer taken into account potential barriers to testing such as the stigma associated with hepatitis B and C or lack of access to services?
- Is the person aware of the legal requirements for notifying hepatitis B and hepatitis C?
- Has the offer included information to enable people to make informed choices about their care should they test positive?
- Has the offer included guidance and practical harm reduction support to reduce their risk of hepatitis B and C infection including access to NSP and OST?
- Has the offer been accompanied by details of support available for clinical and non-clinical needs, both while waiting for test results and following diagnosis?

2.6 Serological testing for viral hepatitis

Chronic hepatitis is often incorrectly described as asymptomatic – that is most people display no obvious symptoms of infection. However, people do typically present with common symptoms, such as fatigue, nausea, brain fog and depression. These can significantly impact an individual’s quality of life and are easily overlooked or wrongly attributed to other things such as drug use or ageing.

Symptoms may begin months or years after getting hepatitis and can come and go but **serological testing** is needed for the accurate diagnosis of type-specific hepatitis and to differentiate between acute hepatitis and chronic infection.³¹

Common symptoms, such as fatigue, nausea, brain fog and depression, can be easy to overlook or attribute to something else. Symptoms may begin months or years after getting hep C and can come and go.

The diagnosis of either hepatitis B or hepatitis C infection and the different phases of infection are established through **serological testing** using laboratory tests, commonly **ELISA and EIA**

immunoassays. Subsequent tests are used, in the case of hepatitis C, to confirm infection.

Serological tests are blood tests that look for **antibodies** or other markers of viral infection (**antigens**). There are several serology techniques that can be used depending on the antibodies being looked for – different types of serological tests can diagnose various disease conditions. Hepatitis B and Hepatitis C first line diagnostic tests are used to determine if a person has ever been infected with either virus and in the case of hepatitis B, if they have an acute or chronic infection or immunity from infection. **As the risks for hepatitis B and C and HIV overlap it is always good practice to test for all viruses both at the same time.**

Antibodies, also called immunoglobulins, are proteins made by a person’s immune system, the body’s natural defense mechanism. They are a part of the immune system’s response to viruses, bacteria and other harmful substances, which are known collectively as **antigens**.

who?

When an antigen enters the body, it stimulates the immune system to produce antibodies. The antibodies attach or bind themselves to the antigen in an attempt to inactivate it. Antibodies and antigens are known as serological 'markers'.

ELISA and EIA immunoassays are both reliable laboratory tests commonly used to detect hepatitis B and C. EIA stands for "enzyme immune assay" while "ELISA" stands for "enzyme linked immunosorbent assay."

The window period. After infection with a virus it can take up to several months before the body makes detectable antibodies to the infection. The **window period** describes the period of time after an individual has been infected until the point where the body makes enough antibodies that can be detected through testing. Although there are individual variables, the window period for hepatitis B and hepatitis C is 3 to 6 months.

While the range of tests varies, serological testing for hepatitis B and hepatitis C usually involves venous blood sampling or **venapuncture** and increasingly **dried blood spot testing**.

3: Screening technologies and development of non-invasive techniques

There are huge opportunities to improve viral hepatitis diagnostics technologies, strategies and approaches, essential for rapidly expanding viral hepatitis testing services and ensuring accurate and reliable diagnosis, clinical assessment and patient monitoring.

Global Health Sector Strategy on Viral Hepatitis 2016 -2021. WHO (2016)

how?

3.1 Venapuncture

Venapuncture or venipuncture is the process of obtaining intravenous access – through a vein - for the purpose for blood sampling. This procedure is usually performed by medical practitioners, phlebotomists or nursing staff. Venipuncture is one of the most routinely performed invasive procedures and is routinely carried out in clinical settings to obtain blood for diagnostic purposes.

Although other veins can and are often used, blood is most commonly obtained from the median cubital vein. This vein lies close to the surface of the skin on the inside of the elbow and in most people, readily accessed.

However venous access for people with a history of injecting may be compromised making venipuncture unsuitable and a barrier to testing.

Recent technological advances in diagnostic testing and the use of less-invasive techniques including dried blood spot testing (DBST) and other rapid diagnostic tests (RDTs) is becoming more established. These newer technologies^{32, 33} are being increasingly used to overcome barriers to testing, improving access to affected communities through both healthcare and community outreach settings and potentially, through peer delivered interventions.



3.2 Dried blood spot testing

Dried blood spot testing (DBS), which requires a much smaller sample of capillary blood to be taken using a finger prick to filter paper, can improve testing uptake, particularly among hard to reach (e.g. PWID) populations.

Collection of blood spots is a relatively simple and nearly painless procedure and can be performed by trained, supervised non-clinical personnel making testing easier in non-clinical (e.g. drug treatment/harm reduction/pharmacy) settings.³⁴

DBS, as well as being used to collect whole blood specimens in order to perform EIA detection of antibodies to hepatitis B and C in a central laboratory, is now increasingly being used as a reliable alternative to venepuncture sampling for point of care screening and confirmation of current hepatitis B and C infection.³⁵



how?

3.3 Rapid diagnostic tests (RDTs)

Innovations in viral hepatitis testing and RDTs now include point-of-care assays for nucleic acid testing (NAT) and **core antigen**, which avoid the need for expensive laboratory processing. These newer testing technologies don't require extensive training to deliver and are now sufficiently sensitive, specific and convenient to offer a time and cost-saving alternative to conventional tests.

RDTs which provide same-day point of care results are recommended for use by EASL³⁶ in settings with limited access to laboratory services, and in particular to improve access in hard to reach and rural populations.

The sensitivity and specificity of some of the latest generation of RDTs can be comparable to those of EIAs. However, the quality of assays is variable. A variety of RDTs are under evaluation and/or are currently in use in low- and middle-income countries for screening, diagnostic and surveillance purposes.³⁷



3.4 Benefits of RDTs ³⁸

- The simplicity, relatively low cost and rapid turn-around time of RDTs, can substantially improve access to HCV testing, enhance linkage to care and reduce loss to follow-up.
- RDTs provide same-day results and do not require complex equipment or advanced training. They can be performed outside of a traditional laboratory setting by persons without a laboratory background who have been trained to conduct the testing process using an RDT.
- Affected populations and health workers show strong support for the use of RDTs delivered at the point-of-care to overcome barriers associated with conventional testing methods and promote access to care.
- RDTs can be performed by readily trained non-medical practitioners and can be used in outreach programmes (e.g., prison services, substance use/treatment services) to increase the uptake of hepatitis screening.
- RDTs are likely to be cost-effective and may mitigate the difficulties of inefficient specimen collection, processing and transportation to laboratory services, and allow for the simplification and decentralisation of testing.
- Systematic reviews of RDTs have shown high sensitivity and specificity across a wide range of settings and different populations which compare highly with laboratory-based reference EIAs.
- RDTs that used oral fluid (of particular value where collection of venous or capillary whole blood is challenging) also had adequate sensitivity and specificity.

how?

Simple technologies are required to ensure that testing services can reach remote areas and hard-to-reach populations. Priority should be given to the development of rapid diagnostic tests for diagnosing viral hepatitis B and C infection, point-of-care tests for monitoring hepatitis B and hepatitis C viral load (and hepatitis C virus antigen) to guide treatment decisions.

Global Health Sector Strategy on
Viral Hepatitis 2016 -2021. WHO (2016)

3.5 Self testing

New assays have been developed that in the future will also give the potential for home or self-testing of blood borne viruses. Self-testing is a process in which a person who wants to know their status collects a specimen, performs a test and interprets the result themselves, discreetly and conveniently. The experience with hepatitis self-testing is currently very limited, but, based on experiences with HIV self-testing, represents a potentially important approach to optimise viral hepatitis testing in the future and to facilitate increased access to comprehensive viral hepatitis testing, treatment and care for hard to reach populations.

3.6 Interpreting hepatitis C serology

Hepatitis C liver disease caused by the hepatitis C virus (HCV) can be **acute or chronic**. Although most people with newly acquired hepatitis C infection will have no obvious symptoms, up to 85% will go on to have chronic infection.

Those that spontaneously clear the virus on their own are said to have resolved the infection. Since anti-viral treatment is intended for people with current hepatitis C infection

it is important to distinguish those with chronic infection from those whose infection is resolved. Hepatitis C testing is a two-stage process that begins with **serological testing**, usually requiring a blood sample.

Acute Hepatitis C virus infection is a short-term illness that occurs within the first 6 months after someone is exposed to the Hepatitis C virus. For most people, acute infection leads to chronic infection.

Chronic Hepatitis C virus infection is a long-term illness that occurs when the Hepatitis C virus remains in a person's body. Hepatitis C virus infection can last a lifetime and lead to serious liver problems, including cirrhosis (scarring of the liver) or liver cancer.

The first stage is a hepatitis C antibody (Anti-HCV) test.

When the hepatitis C virus enters a person's bloodstream, it triggers an immune response and makes antibodies to the virus. Antibodies to hepatitis C can be detected in the blood, usually within two or three months but sometimes up to six months or more after exposure to the virus. The Anti-HCV test detects the presence of **antibodies** to the hepatitis C virus.

Using an **enzyme immunoassay (EIA)** or similar testing technologies, Anti-HCV antibodies are detectable in the vast majority of people with hepatitis C infection.

how?

3.7 Anti HCV negative (non-reactive)

If the anti-HCV test is negative it usually means that the person has not been infected with hepatitis C. However, results may be negative in early acute hepatitis C and during the '**window period**' or in people with weakened immune systems. In these situations, and where a person has been exposed to risk of infection during the window period, ongoing monitoring and follow up testing should always be offered.

People with suppressed or **weakened immune systems**, including those with HIV, or those receiving certain medications including immunosuppressant drugs, are not always able to produce antibodies.

3.8 HCV antibody positive (reactive)

A positive hepatitis C antibody test means that the person has, at some time, been exposed to the hepatitis C virus. It does not necessarily mean a person is currently infected and a

confirmatory test will be needed to determine if the person is currently infected or not. After infection, the hepatitis C antibodies stay in the blood permanently, even if the virus is no longer present.

All people with a positive HCV antibody test should have a confirmatory **HCV RNA test** to determine the presence of active infection. It is recommended that the confirmatory test should be taken from the same sample (either through venapuncture or dried blood spot testing (DBS) is used for the antibody test.

Roughly one in five people who are infected with hepatitis C spontaneously clear the virus completely without needing any treatment.

However, it is important to note that even if someone has previously cleared the virus any future exposure to the virus could cause infection – having hepatitis C antibodies does not give immunity against reinfection.

3.9 The second stage is a confirmatory (HCV RNA) test

Both venipuncture or DBS samples that are positive for hepatitis C antibody should automatically be tested for the presence of the hepatitis C virus. Samples should be of sufficient quantity to allow for this and prevent the need for additional sampling.

Using **nucleic acid tests (NAT)** or **antigen** techniques, the **HCV RNA test** will detect the presence or absence of virus. Usually using a subset of the specimen used³⁹ for Anti-HCV testing, the PCR tests looks for genetic material – ribonucleic acid - of the hepatitis C virus (HCV RNA). This test will be reported as either negative (no virus present) or positive (virus present) confirming the person has hepatitis C infection and at risk of developing serious liver disease.

All people with a positive HCV RNA test should be offered a referral to a specialist service to have their liver health monitored and to discuss treatment options.

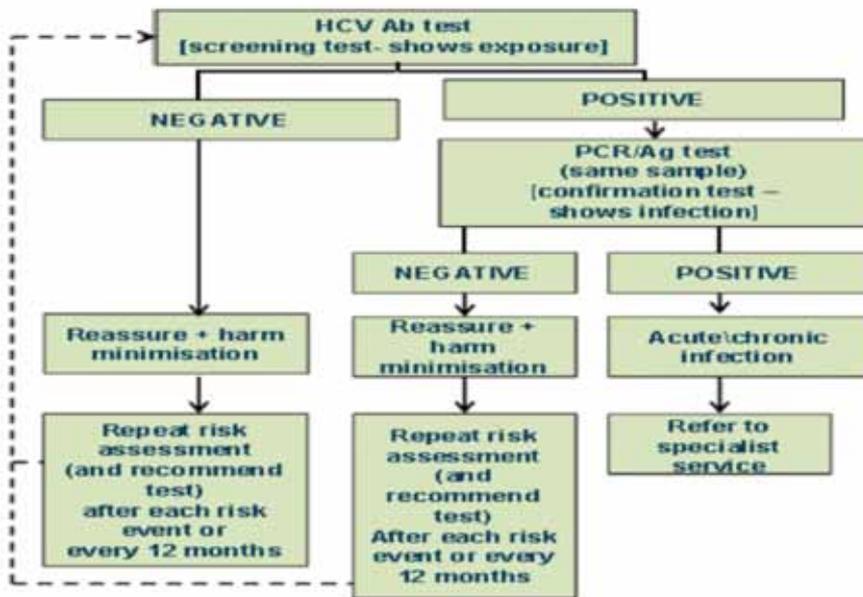
3.10 Antigen test - HCV Core Antigen as a serologic marker

HCV antigen testing also has the potential to reduce the cost of diagnostic testing, and of treatment monitoring and could eventually replace the current two-step procedure for diagnosing chronic hepatitis C infection in lower- and middle-income countries, speeding up access to treatment and improving retention in care.

EASL Guidelines on the Treatment of Hepatitis C recommend that although core antigen assays are slightly less sensitive than HCV RNA assays for detection of viral replication, HCV core antigen tests should be used if HCV RNA assays are not available or not affordable to identify patients with on-going infection.⁴⁰

how?

3.11 Hepatitis C testing pathway



3.12 Interpreting hepatitis B serology

Hepatitis B serology is generally accepted to be more complex and more difficult to interpret than hepatitis C serology. The aim of hepatitis B testing is to establish whether the hepatitis B virus is present, whether the person has immunity to the virus from either a previous infection or hepatitis B vaccination, or whether the person may be susceptible to the virus.

As with hepatitis C, the sample for determining a person's hepatitis B status can be obtained reliably through whole blood venipuncture or through less invasive dried blood spot. Only one sample of blood is needed for a hepatitis B blood test.

There is more than one test for hepatitis B. Screening and determining the immune status of people at risk of chronic hepatitis B infection is done by detecting several markers and a combination of test results are needed to fully understand if a person is infected or not and to determine the appropriate management:

Hepatitis B surface antigen (HBsAg) is a protein on the surface of the virus. HBsAg can be detected in high levels in the blood during acute or chronic hepatitis B infection. A 'positive' or 'reactive' test result means the person has a current hepatitis B infection, which may either be acute or chronic.

Hepatitis B surface antigen-specific antibody (HBsAb or anti-HBs). A 'positive' or 'reactive' HBsAb test result indicates the person has immunity to the virus. Immunity can develop either through successfully recovering from previous hepatitis B infection or through being protected successfully by the hepatitis B vaccine.

Hepatitis B core antibody (HBcAb or anti-HBc) can be detected and is a marker for infection. A 'positive' or 'reactive' HBcAb test result indicates previous or ongoing infection.

how?

Hepatitis B can be a complicated liver infection to understand, so additional blood tests, including further hepatitis B markers and Liver Function Tests (LFTs) may be required to get a better understanding of what kind of care and follow-up might be needed. Some clinical guidelines recommend that all people who test positive for HBsAg, and especially people with any signs of advanced fibrosis or cirrhosis, or pregnant women⁴¹ are referred to specialist treatment for a more comprehensive assessment.

However, many people with chronic hepatitis B infection have inactive disease and may not require referral to a specialist and can be well supported and monitored by their general practitioner. It is therefore essential under these circumstances that general practitioners and other non-specialist medical health providers understand the clinical course of chronic infection, which may change over time as a result of the relative balance between viral replication and the person's immune response to the infection.⁴² Without specialist care, people with hepatitis B should be monitored at least once a year for any changes in liver health.

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why?
who?
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