

September 2020

## PSNC Briefing 029/20: Guidance on the Community Pharmacy Hepatitis C Antibody Testing Service

This PSNC Briefing provides guidance for community pharmacy contractors and their teams on the Community Pharmacy Hepatitis C Antibody Testing Service.

Information and resources to support the service are also available at [psnc.org.uk/Hep-C](https://psnc.org.uk/Hep-C).

### a) Introduction

The Community Pharmacy Hepatitis C Antibody Testing Service is the second new Advanced Service to be added to the NHS Community Pharmacy Contractual Framework (CPCF) in 2020/21. The service was originally trailed as part of the [5-year CPCF agreement](#) and its launch was delayed in response to the COVID-19 pandemic outbreak.

The service offers a Hepatitis C antibody test in the pharmacy to people who inject drugs (PWID) who are not currently accessing treatment services (e.g. for the management of addiction to opioids). Where people test positive for hepatitis C antibodies, they will be referred for a confirmatory test, followed by treatment, where appropriate.

Any pharmacy that meets the service requirements can provide the service, but it will be of most interest to contractors that provide a locally commissioned needle and syringe programme (NSP) service, with a sufficient number of clients, to make the investment in provision of the service worthwhile.

### b) Background and aims of the service

The Hepatitis C virus (HCV) is an infectious, blood-borne virus that affects the liver and is predominately transmitted by contact with infected blood. In the UK, those at highest risk of contracting HCV are people who inject drugs, e.g. steroids or heroin; national data shows that PWIDs account for 90% of all new HCV infections.

Following infection with the virus, there is a first acute phase followed in many cases by a chronic infection. During the acute phase, which is normally the first six months of infection, the individual may not have any perceivable symptoms. In about 20% of cases the body will naturally clear the virus within the acute phase. Of the 80% that do not clear the infection naturally, a long-term infection develops. Of these, 10%-20% progress to cirrhosis within 20 years and the associated sequelae of liver failure, death (20%-25% of patients) and hepatocellular carcinoma (1%-5%).

It is estimated that around 215,000 people in the UK have Hepatitis C. On the world stage, the United Kingdom Government is a signatory to the World Health Assembly resolution and World Health Organization (WHO) goal of eliminating HCV as a major public health threat by 2030. NHS England and NHS Improvement (NHSE&I) plans to eliminate HCV in England by 2025, five years earlier than the World Health Organization goal.

Driving the success of treatment, the Hepatitis C Direct Acting Antiviral (DAA) medicines are over 95% effective at achieving cure and have minimal side effects. As such, most individuals are cured with their first treatment. For the small number of patients that are not successfully cured with their first treatment, there are also re-treatments available which are also highly effective.

The overall aim of this service is to increase levels of testing for HCV amongst PWIDS who are not engaged in community drug and alcohol treatment services to:

- a. increase the number of diagnoses of HCV infection;
- b. permit effective interventions to lessen the burden of illness to the individual;
- c. decrease long-term costs of treatment; and
- d. decrease onward transmission of HCV.

### c) The service specification

Before deciding whether to provide the service, contractors should read the [service specification](#), which describes the full requirements for provision of the service. It should also be read and understood by all pharmacists and pharmacy technicians providing the service.

### d) Assessing the viability of the service for your pharmacy

Contractors are advised to carefully consider the likely viability of this service in their pharmacy before confirming they will provide the service. The service is an important part of the national effort to eliminate Hepatitis C, but the number of people eligible to be tested is relatively small and hence the overall budget for the service (circa £2m) is also not very large in comparison to overall NHS community pharmacy funding.

As the service can only be provided to PWIDs who are not currently accessing treatment services, it is most likely to be financially viable to provide for contractors:

- that provide a locally commissioned needle and syringe programme service, with a good number of clients; and
- their staffing levels and workflow will allow them to provide the service when clients present to make an exchange.

The upfront setup costs, including the cost of buying an initial supply of test kits (sold in packs of 10) will also need to be considered when assessing the likelihood that the service will be financially viable to provide.

### e) Commencement and duration of the service

As the national Hepatitis C Programme is an elimination exercise, the service will be time limited. It commenced on 1st September 2020 and it will run until 31st March 2022. If the efficacy of the service model is suitably demonstrated, the service may be extended into 2022/23, but in line with the objectives of the NHSE&I Hepatitis C Programme Board, the service will not continue after 31st March 2025.

Contractors must notify NHSE&I that they intend to provide the service by completion of an electronic registration through the NHSBSA [Manage Your Service \(MYS\) platform](#).

### f) Availability of the service

Following notification through the MYS platform that a contractor intends to provide the service, contractors should seek to ensure that the service is available throughout the pharmacy's contracted opening hours. If they are also commissioned to provide an NSP service, it will be particularly important to ensure that the testing service is offered at a time that PWIDs visit to exchange their injecting equipment.

The pharmacy's [NHS website profile](#) should be edited to indicate that a blood-borne virus testing service is provided. If the pharmacy temporarily or permanently ceases to provide the service, they should, as soon as possible, update their NHS website profile to reflect that the service is no longer available.

Contractors providing the service must ensure the service is accessible, appropriate and sensitive to the needs of all service users. However, contractors can refuse to provide the service to an eligible PWID if the PWID or any other person accompanying the PWID, threatens violence or commits or threatens to commit a criminal offence.

## g) Eligibility to receive the service

People eligible for a test under this service are PWIDs who are 18 years and over and are not engaged in community drug and alcohol treatment services.

PWIDs who are engaged in community drug and alcohol treatment services are **not** eligible to receive a test for HCV antibodies through this service, as testing will be offered to them via the drug treatment service.

People who are not PWIDs who may, through another intervention, be identified as being at high risk of HCV should be referred into the relevant service. If the pharmacy contractor is unsure what the relevant service is, they should refer the individual to their GP or [the local Operational Delivery Network \(ODN\)](#). The role of ODNs is to support Hepatitis C treatment and testing efforts across the country.

A contractor may determine a PWID's eligibility to receive the service on the basis that:

- a. the PWID utilises needle and syringe programme (NSP) services from the pharmacy;
- b. the PWID has been referred to the pharmacy for testing by another pharmacy, or care provider which provides the individual with NSP services;
- c. the individual is known to pharmacy staff, who know them to be a PWID; or
- d. the individual self-identifies to pharmacy staff as a PWID.

The DAAs are not recommended for treatment of pregnant women or breastfeeding mothers, however, if a pregnant or breastfeeding woman is an eligible PWID, they should still be offered a test as knowledge that a pregnant woman has acquired HCV infection may influence the technicalities of the delivery of the child.

## h) The test to be used in the service

The test to be used by contractors to provide this service is the [InTec Rapid Anti-HCV Test](#). All test materials must be stored in accordance with the manufacturer's instructions.

[Access the manufacturer's instructions here](#)

The test also has a [one-page user guide](#) and short [product demonstration digital media guide](#) that can be used to complement the NHSE&I service training video.

Where the test is not available through mainline wholesalers, contractors can order test kits directly from the manufacturer. Test kits are distributed in the UK by [Matrix Diagnostics](#) (01992 762678). Further information on ordering the kits can be found on the PSNC website.

## i) Training and related requirements

The service is only to be provided by pharmacists or pharmacy technicians and the core training requirement is for them to watch the [NHSE&I training video](#) and to ensure they are familiar with the manufacturer's instructions on how to use the test.

In addition, contractors must ensure staff are appropriately trained and made aware of the risks associated with the handling and disposal of clinical waste, and that correct procedures are used to minimise those risks. A needle stick injury procedure must be in place at the pharmacy.

The pharmacy contractor must ensure that staff involved in the provision of this service are advised that as there is a small risk that they could come into contact with blood borne viruses, they should therefore consider being vaccinated against Hepatitis B and be advised of the risks should they decide not to be vaccinated.

Contractors will also need to ensure staff have been appropriately trained in the donning and doffing of the personal

protective equipment (PPE) necessary for provision of the service.

## j) Providing the service

The service must be provided in a consultation room on the pharmacy premises, which complies with the following minimum requirements:

- a. the consultation room must be clearly designated as an area for confidential consultations;
- b. it must be distinct from the general public areas of the pharmacy premises;
- c. it must be a room where both the person receiving services and the pharmacist or pharmacy technician providing those services are able to sit down together and talk at normal speaking volumes without being overheard by any other person (including pharmacy staff), other than a person whose presence the individual receiving the test requests or consents to (such as a carer or chaperone);
- d. it must be a room where infection control measures can be maintained; and
- e. handwashing facilities must be available in the room or nearby.

The pharmacy contractor must have a standard operating procedure (SOP) in place for this service, which includes procedures to ensure health and safety and [infection prevention and control procedures](#) are maintained in line with relevant guidelines.

### *Pre-test consultation*

Prior to a test being undertaken, a suitably trained pharmacist or pharmacy technician, should carry out a pre-test discussion with the PWID, which will:

1. describe the test and how it is undertaken;
2. advise on what will happen if they test positive for HCV, including a referral being made to the local ODN for confirmatory RNA testing and treatment if the RNA test is positive;
3. explain that, with the individual's consent, positive test results will be notified in writing to their GP (where they are registered with a general practice). Refusal to consent to such data sharing does not exclude the PWID from being tested under the service;
4. explain that positive test results may have implications for life insurance and therefore mortgages, as is common with many long-term conditions;
5. explain that the provision of the test is confidential, and that the information that they choose to provide will be managed in line with data protection legislation. The information will be recorded in an individual record for each PWID for reference and audit, held by the pharmacy. The PWID's personal information will only be accessible by staff providing the service. This information will be kept securely stored, to maintain strict confidentiality. This information will not be shared with the PWID's GP without their consent. Audit information will be compiled from records, but this data will be anonymous;
6. explain that elements of the record held at the pharmacy will be added to the Hepatitis C Registry, provided by NHSE&I. This will include patient identifiable information, if the PWID consents to this being added to the registry. If the patient does not consent to patient identifiable information being entered into the registry, an anonymous record will be made. Refusal to consent to inclusion of patient identifiable information in the registry does not exclude the PWID from being tested under the service, or from being referred for confirmatory testing and (where the confirmatory testing indicates that the patient has active hepatitis C) receiving treatment.

Patient identifiable information in the registry can be viewed by ODN clinical staff at treatment locations, where they have a need to access the information. Patient identifiable information can also be viewed by Public Health England (PHE) staff undertaking monitoring of the prevalence of infectious diseases, as

provided for in Section 251 of [the National Health Service Act 2006](#), [the Health Service \(Control of Patient Information\) Regulations 2002](#) and [the Health Protection \(Notification\) Regulations 2010](#); and

7. answer any other questions they may have regarding the service.

### Consent

As with the provision of any pharmacy service, the patient must consent to the service. Following the pre-test discussion, the pharmacist or pharmacy technician should confirm whether the PWID gives their consent to be tested; this can be gained verbally.

Where consent is granted and the contractor wishes to maintain a written record of consent, the PWID can be asked to sign the service consent form (the form can be downloaded from the PSNC website). The consent discussion needs to determine the individual's decision on three elements:

- A. consent to be tested for Hepatitis C antibodies;
- B. consent or otherwise for the result of the antibody test to be share with the patient's GP practice so that the patient's health record can be updated; and
- C. consent or otherwise for the patient's information and test results to be entered onto the Hepatitis C registry in an identifiable form.

For both points B and C, where the PWID chooses not to give consent, this can be indicated on the consent form. In both these situations, the PWID can still be tested in the pharmacy, as long as they consent to point A.

The information sheet appended to the consent form can be printed and given to the individual to confirm the necessary information flows that occur because of receiving the service.

### Information for PWIDs & referrals

The pharmacist, or pharmacy technician, will advise the PWID of the outcomes of the test.

Where there is a negative antibody result, advice should be given relating to the risks of continuing to engage in risky behaviours, such as injecting illicit drugs, and where appropriate advice that they should consider being re-tested in 6 months' time.

Where there is a positive antibody result, the implications of that positive result should be explained to the PWID, with an explanation of what will happen next. They should be referred using the ODN referral form (the form can be downloaded from the PSNC website) to the relevant ODN (details of which are set out in the service specification) for further testing and where appropriate, suitable treatment. These referrals will normally be sent via NHSmail, which is why pharmacy staff providing the service must have access to the pharmacy's shared NHSmail mailbox.

Where the PWID is registered with a general practice, and they consent to their GP being notified of the positive test result, this notification should be made using the GP notification form (which can be downloaded from the PSNC website). This notification should ideally be sent electronically, either by NHSmail or secure electronic data interchange. Where electronic notification is not possible, the pharmacy contractor should send the notification via post or hand delivery.

The PWID should also be provided with the relevant literature ([the hepatitis C pharmacy leaflet](#)) which pharmacy contractors can order via the above link. During the COVID-19 pandemic, the literature should be provided to the PWID in a manner that ensures it has not been handled by another person, i.e. a fresh document straight out of the packaging and not previously stored in a leaflet rack.

Contractors must have in place an escalation process, should the PWID fail to return for their results. As a minimum, this should include attempting to reach the PWID via any known contact details (e.g. telephone/email/post) to

request that they attend the pharmacy (however, PWIDs should **not** be informed of their test results via this route, due to the risk of the information being seen/overheard by someone the PWID does not wish to know their status). If this is not successful, or the pharmacy does not have any contact details for the PWID, they should inform the ODN that the PWID has not returned for their results.

### **Personal Protective Equipment**

Pharmacy professionals providing the service will need to ensure they follow the current [PHE guidance on the use of personal protective equipment \(PPE\)](#). The [COVID-19: infection prevention control guidance](#), at the time of publication of this guidance, states where there is direct contact, staff providing the test are advised to wear disposal gloves, an apron, fluid resistant Type IIR face mask and eye or face protection.

### **Clinical waste**

The pharmacy contractor is required to make their own arrangements for the removal and safe disposal of any clinical waste related to the provision of this service.

## **k) Records and Data sharing**

Contractors must maintain appropriate records to ensure effective ongoing service provision and to support post-payment verification. Appendix B in the service specification details the records that must be kept as part of provision of the service, set out in a clinical record form which contractors can use to create their clinical record for provision of the service; copies of the form can be downloaded from the PSNC website.

Contractors can also choose to record the same information in a secure IT system, should they have one available to them.

Where the individual provides consent for their information to be recorded on the Hepatitis C Registry provided by NHSE&I, the details set out in Appendix C of the service specification will be entered into the Registry.

Where the PWID does not consent to identifiable data being recorded in the Hepatitis C Registry, an anonymous record should instead be created in the registry. This will enable the community pharmacy data to be collated alongside data from the other programmes commissioned by the Hepatitis C Programme Board.

NHSE&I will publish guidance on how to access, register for and use the registry.

### **Post-payment verification**

Relevant information from the contractor's service records may be shared, on request, with NHSE&I and the NHSBSA for the purpose of post-payment verification. Appropriate records and documentation should be retained for an appropriate period of time, but for the purposes of post-payment verification, they should be kept for a minimum of two years after the test takes place.

As pharmacy contractors are the data controller, it is for each contractor to determine what the appropriate length of time is, beyond two years. Decisions on this matter must be documented and should be in line with [Records Management Code of Practice for Health and Social Care](#).

## **l) Payments and the process for claiming payments**

Claims for payment for this service should be made monthly, via the MYS portal. Claims should reach the NHSBSA by the 5th day of the following month after completion of a test, in accordance with the usual Drug Tariff claims process.

Payment will be **£36** per test performed on an eligible PWID, **plus** the cost of the test (including VAT).

Contractors will be required to purchase the tests in advance of starting to provide the service and will be reimbursed

as set out above, once a claim for performing a test has been received.

### m) Discontinuation of service provision

If contractors wish to stop providing the service, they must notify NHSE&I that they are no longer going to provide the service via the MYS platform, giving at least one month's notice prior to cessation of the service, to ensure that accurate payments can be made.

### n) Promoting the service to patients

Promotion of the service is first and foremost about having a conversation with PWIDs.

- Ensure all staff are aware of the service, particularly those that provide the NSP service.
- Target your NSP service clients first. The Hepatitis C Trust advise the following when having these conversations:
  - **Appeal to the person's human nature.** Ask if they would like to help you implement the service and be tested. Mention that it could provide them with health benefits and could also support to improve the health of their local community;
  - **Demonstrate that you care about the person's wellbeing.** Be attentive and show you care about them as an individual. This service is about them and the benefits to them;
  - **Be patient and consistent.** If a person refuses, continue to offer the service to them each time they visit. A continued and caring approach will help;
  - **Explore reasons behind the refusal.** Some people will be operating under misconceptions of the condition, the risks, the test, and the treatments. Providing new information to dispel the myths and raise awareness will help.
- Use the [hepatitis C pharmacy leaflet](#) to provide clients with information to consider and take away.
- Raise awareness in the local area that you are providing the service. Flag it to support workers, outreach groups and charities that support the homeless or people that use substances in the area; this would also support your collation of evidence for meeting some of the Healthy Living Pharmacy requirements.
- Encourage Peer to Peer promotion by those who have used the service.
- Highlight the service to those clients who are already in treatment and ask them to mention it to friends or relatives who may not be in treatment but are injecting drugs.
- Flag your provision of the service to the other pharmacies in your area that are not providing the service, to encourage signposting of PWIDs to your pharmacy for testing. Provide them with a briefing and literature that they may find useful to use when signposting PWIDs.

### o) Further information and resources

The PSNC website contains Frequently Asked Questions (FAQs) and answers and these will be updated on an ongoing basis. The following links provide further information on Hepatitis C and related topics.

[Royal College of General Practitioners Hepatitis C Toolkit](#)

[Hepatitis C infection and its management in primary care \(RCGP\)](#)

[Centre of Pharmacy Postgraduate education - Substance use and Misuse learning module](#)

[Hepatitis C Trust](#)

[NHS website information about Hepatitis C, including lifestyle risks and associated health concerns](#)

If you have queries on this PSNC Briefing or you require more information, please contact the [PSNC Services Team](#).

## Appendix - Checklist for the Community Pharmacy Hepatitis C Antibody Testing Service

Preparing to provide the service – checklist for pharmacists and pharmacy technicians		✓
1.	Read the <a href="#">service specification</a> and visit <a href="https://psnc.org.uk/Hep-C">psnc.org.uk/Hep-C</a> to familiarise yourself with the resources available there.	
2.	Watch the <a href="#">NHSE&amp;I training video</a> and read the manufacturer’s instructions on how to use the test.	
3.	Consider getting vaccinated against hepatitis B if you have not previously had the vaccination. PHE’s advice in <a href="#">the Green Book</a> is that hepatitis B vaccination is recommended for healthcare workers who may have direct contact with patients’ blood, blood-stained body fluids or tissues. This includes any staff who are at risk of injury from blood contaminated sharp instruments.  The <a href="#">Health and Safety Executive guidance on blood borne viruses</a> provides further advice on this issue.	
4.	Read and sign the standard operating procedure (SOP) for the service: <ul style="list-style-type: none"> <li>ensure you know what role support staff will have in providing the service;</li> <li>review your working practices to ensure that the Hepatitis C Antibody Testing Service can be built into your routine work as well as continuing to be able to offer other services; and</li> <li>ensure you know whether an appointment system for the service will be used, or whether the pharmacy will provide testing immediately on request (‘walk ins’).</li> </ul>	
5.	Familiarise yourself with relevant service documents, for example, the pharmacy’s: <ul style="list-style-type: none"> <li>chaperone policy;</li> <li>needle stick injury procedure; and</li> <li>guidance on infection control procedures, including hand hygiene guidance, donning and doffing PPE.</li> </ul>	
6.	Make sure NHSE&I have been notified that your pharmacy wishes to provide the service via a declaration in the MYS portal.	
7.	Check whether an IT system is available to support record keeping and notification of GP practices of test results. If so, ensure you have the required logon credentials for the system and are familiar with how to use it. If not, make sure you are familiar with the paper forms for use in the service.  Additionally, get login details for the Hepatitis C Registry.	
8.	Ensure you have the necessary equipment/supplies needed for provision of the service, for example: <ul style="list-style-type: none"> <li>test kits;</li> <li>service consent &amp; referral forms and copies of the <a href="#">hepatitis C pharmacy leaflet</a>;</li> <li>required PPE; and</li> <li>clinical waste bin.</li> </ul>	
9.	Update your pharmacy’s NHS website profile to indicate that a blood-borne virus testing service is provided.	
10.	Brief all staff on the service and train them on how to promote it to suitable people.	