



## HHS Hep C treatment pathway

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## INTRODUCTION

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Viral Hepatitis C (HCV) treatment is more tolerable & effective than ever before, despite this untreated HCV remains prevalent within Bristol in a community of people with active and historic intravenous drug use. Untreated HCV can cause cirrhosis and hepatocellular carcinoma. There is unmet need focused among the most disadvantaged and work continues to reduce barriers to accessing treatment. All patients should be offered optimum treatment including specialist clinic appointments, fibro scanning and bloods. This community-based clinic aims to make gold standard HCV treatment more accessible to homeless people in Bristol.

## OBJECTIVES OF THE PROCEDURE

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This document provides a guide for clinicians to enable patients to access HCV treatment

## THE STANDARD OPERATING PROCEDURE

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### **Testing.**

People at risk of HCV infection should be offered testing at a minimum of twelve monthly intervals. If people present as concerned or having reported a potential exposure, they should also be offered testing for hep C. Patients can be testing any time after 2 weeks following exposure

Patients should also be offered screening for Hepatitis B (HBV) and Human Immunodeficiency Virus (HIV) at the same time

Patients who are considered most 'at risk' of HCV infection are currently injecting drugs (including intravenously, intramuscularly or subcutaneously) and people who have previously injected drugs (even if it was just once). Other 'at risk' groups are people who participate in sexual practices that lead to exposure to blood and people who received a blood transfusion prior to 1991. Vertical transmission from mother to baby is possible though rare. People sharing a household with someone with an active HCV infection have a marginally increased risk which can be further minimised through harm reduction advice .

Patients must be consented for testing and referral for treatment prior to testing.

There are number of ways of sampling bloods for testing

### **Venous blood sampling**

This is the most sensitive way to measure HCV antibody and viral load (qualitative Polymerase Chain Reaction (PCR)). It also offers the benefit of obtaining the additional samples needed for pre-treatment work up. However, amongst a population of people with a significant or traumatic injecting history this may not be the best option as many patients experience fear and shame associated from venous blood sampling.

Patients should be given all available options and supported to make the choice that is best for them and minimizes pain and distress.

### **Capillary blood sampling**

This type of sampling avoids the need to take venous bloods for part of the treatment workup; the sensitivity of the test is slightly lower than for venous blood samples. It is a good option where patients find venous blood sampling distressing or where venous access is very poor. It is not currently possible to request these samples on ICE so both labels and blood forms must be hand filled

(see How to guide)

### **Dried blood spot sampling**

This method of sampling allows a full screening for blood born virus using a capillary pin prick and a relatively small amount of blood. It can test for antibodies and detect the presence of RNA so is ideal for routine screening. The form must be hand filled. The samples must be sent with the silicone desiccant within the sample bag.

## **Diagnosis and Counselling**

Results of samples taken at HHS should be reported on ICE, where there are delays in reporting Virology can be contacted by phone for results 01174146222

Time between testing and reporting can vary significantly.

HCV carries a high level of stigma and so results should be delivered sensitively and ideally within a confidential setting however in outreach settings and where patients initiate conversations requesting results it may be appropriate to give results.

HCV results can be disclosed by any staff member who self assesses as competent to answer any patient questions about the implications of active HCV infection and the treatment pathway.

Many patients may be positive for HCV antibodies. This does not necessarily indicate there is an active HCV infection but does indicate that the patient has been exposed to HCV at some point in their life; they may have active infection, have previously been successfully treated, or have spontaneously cleared the virus. It is possible for a patient to have been infected with HCV and not to have known about it so this must be approached kindly & sensitively

If the results are RNA negative and the patient is still at-risk, harm reduction advice should still be given. Patients who remain at risk of blood born virus infection should be rescreened every 6 months.

## **Harm reduction advice**

The most important harm reduction principles for reducing HCV infection for people who are injecting drugs are to access new injecting equipment and not to share injecting equipment with people they are using alongside.

Locally Bristol Drugs Project provides the best range of injecting equipment alongside expert advice from harm reduction practitioners.

Injecting equipment can also be collected from most pharmacies locally.

BDP provide color coded equipment; this can be helpful for people sharing a household or using intravenously with another person.

Patients should be advised that not sharing equipment extends beyond just needles and syringes to all equipment used during the preparation of injectable drugs including spoons, water for injection and surface areas.

The sharing of personal items such as razors and toothbrushes must be avoided, manual toothbrushes can be provided from HHS stock if needed.

The risk of infection through sexual activity is low, however, where sexual activity involves practices where there may be an exchange of blood there is a risk. Patients should be informed of the risks and how to reduce them including the use of condoms and lubricants.

Clinicians can use the Hep C Trust website to aid conversations about risk and harm reduction and patients can be signposted to this website also. [Risk factors | Hepatitis C Trust \(hepctrust.org.uk\)](http://hepctrust.org.uk)

### **Pre-treatment assessment**

Pre-treatment assessment/ workup can take place as soon as the patient consents to treatment.

As a minimum the pre-treatment assessment EMIS template should be completed along with a viral load/genotype. This can be done as a capillary blood test (if not already completed). Where possible a Fib 4 score or a Fibro scan result should be available. A recent creatinine is required for safe prescribing; ideally this would be from within the last 6 months, but within the last 2 years is acceptable if there are no specific concerns about the patients' renal function.

Most patients are seen for a face to face pre-assessment appointment face to face by Dr Kate Robson in the Homeless Health Hepatitis C clinic (drop-in clinic every Wednesday). However it is also possible for other HHS clinicians to do the pre-assessment, if they feel competent to do so and are able to fill out the pre-treatment assessment EMIS template fully. The details of all patients undergoing pre-assessment should be passed onto Kate Robson to ensure continuity and progression of care.

### **Fibrosis**

Fibrosis and cirrhosis of the liver are the most serious long term health concerns for those living with HCV. Treating patients before they have developed fibrosis and cirrhosis is an important objective for this treatment pathway. Identifying and treating patients with concurrent alcohol use who are at increased risk of liver damaged is an important concern. Patients with fibrosis may not feel unwell and so may need education about how this may progress to severe illness if their HCV remains untreated. Cirrhosis may lead to serious morbidity and/or death as a result of decompensation; it also puts patients at high risk of developing hepatocellular carcinoma.

### **Fibroscanning.**

Fibroscans can be performed for patients at HHS through the Hep C outreach team. Alternatively they can be arranged at BDP or at the hospital (via emis referral).

Fibroscans are painless and give an immediate result.

The lack of an up-to-date fibroscan should not exclude patients from treatment, HHS staff should continue to support patients to access fibroscanning so liver surveillance can continue. Where possible a Fib 4 score can be calculated as an interim.

### **Fib 4**

The FIB-4 scoring system uses a combination of patient age, platelet count, AST and ALT. A score of  $<1.45$  has a negative predictive value of over 90% for advanced liver fibrosis of multiple aetiologies. The blood tests required to calculate a Fib-4 are Full Blood Count (FBC), Liver Function Test (LFT) and Aspartate Aminotransferase (AST); a venous blood sample is required for these tests.

### **Partners and people who inject together**

Where possible it is helpful for partners and people who inject together to be treated at the same time, this helps prevent reinfection following treatment and means patients can provide mutual support and encouragement to one another. Patients should be treated as individuals and should be offered individual assessment and counselling. It should not be assumed that patients' partners are aware of their BBV status and consent to share needs to be explicitly gained and documented.

### **Multi Disciplinary Team Meeting (MDTM)**

Patients will be presented at virtual MDTM on a Wednesday by Specialist HCV GP Dr Kate Robson. The meeting is attended by UHBW HCV clinicians and other HCV specialist practitioners working across the Severn Operational Delivery Network. Discussion at an MDT meeting prior to prescribing is a stipulation by NHSE and provides an important opportunity to ensure best practice is followed.

### **Prescribing**

Following the MDT, Dr Kate Robson will prescribe the DAA (direct acting antiviral) as dictated by the MDT outcome and will complete the Blueteq (compulsory national documentation for high cost drugs). The course of treatment is normally 8 or 12 weeks long and requires the patient to take one or three tablets a day. Kate Robson has an honorary contract with UHBW which allows her to prescribe these medications. Once dispensed these medications are available to collect at BRI Boots pharmacy; they are delivered to HHS, or sometimes directly delivered to the patient by Georgia Woodcock (BDP Hep C worker) or by a Hep C Trust peer support worker. The medication is also prescribed on EMIS as a 'hospital drug'.

### **Medication Storage**

Direct acting antivirals are stored in a designated drugs cupboard at HHS; the key for this is stored securely in a locked key box. Medications are labelled with patient details and are signed in and out using a controlled drugs book. HHS staff have had training on this process and there is an EMIS template 'Hep C med collection' to aid record keeping.

Daily ambient temperature monitoring required for storage room HHS nurses to manage this.,

## Documentation

All HCV related consultations will be recorded in EMIS. There are EMIS templates to aid record keeping and coding for pre-assessment and follow-up appointments. A UHBW Careflow clinic letter is generated for all pre-assessment, treatment start, treatment completion and SVR12 appointments; these letters are immediately available to view on Connecting Care. The BRI Hepatology clinic coordinators are informed of all HCV related consultations carried out by Dr Kate Robson.

## Follow up

All patients with untreated active HCV infection or who are on the HCV treatment pathway are followed up by Dr Kate Robson in the HHS Hepatitis C clinic. Patients can receive intensive peer support from the Hep C Trust if they consent and complete a Hep C Trust 'follow me' consent form, Keith Hathway is the Hep C Trust peer lead for Bristol, he is based at HHS on Wednesdays and where patients consent often joins Dr Robson for clinic appointments. Evidence shows that peer support improves treatment outcomes and patient experience.

## SVR12

Treatment outcome is determined by a blood test for HCV RNA 12 weeks after completion of treatment. A negative RNA result indicates successful treatment. A positive RNA result indicates treatment failure (either due to incomplete treatment or resistance) or reinfection. Patients who remain RNA positive will be seen again in clinic and are likely to be rediscussed at MDT. The SVR12 result is normally communicated to the patient by either Dr Kate Robson or Keith Hathway depending on the situation, however other HHS clinicians can also communicate the result if they feel competent to do so and have the knowledge to be able to answer any questions the patient may have

## Theseus

Dr Kate Robson has access to Theseus, the BDP record keeping system and uses this system to access the results of HCV tests performed by shared care.

## Side effects & counselling

DAA's have a good safety profile and side effects are uncommon but include headache, nausea, fatigue, GI disturbance, rash and worsening anxiety and depression. Patients must be counseled about side effects before commencing treatment and advised to return to HHS or contact their peer support worker if these occur. Symptom control medications such as antiemetics may be prescribed to enable patients to complete their treatment. Whilst serious side effects are very rare, patients should be counselled to seek urgent medical advice if there are any signs/symptoms of serious allergic reaction or anaphylaxis or any signs/symptoms of decompensated cirrhosis or liver failure.

## The Yellow Card scheme

The MHRA runs the Yellow Card scheme, which collects and monitors information on suspected safety concerns involving a healthcare product, The scheme relies on voluntary reporting of problems to a healthcare product by the public (including patients, parents and carer givers) as well as from healthcare professionals.

Suspected adverse reaction should be reported to the MHRA at <https://yellowcard.mhra.gov.uk/>

### Data sharing

Patients complete a data sharing agreement when registering at HHS. Patients who consent to Hep C Trust peer support have to sign a Hep C Trust 'follow me' form. Dr Kate Robson has an honorary contract with UHBW which allows her to access the hospital patient record. Patient confidentiality will be maintained at all times unless it is deemed that there is a risk of serious harm to the patient or others.

### Incentivisation

Voucher incentivization can be offered to patients in line with the policy at UHBW. UHBW have supplied HHS with Tesco vouchers of up to £50 per patient, The clinician can use their discretion as to how these are distributed, however a suggested program by UHBW is:

£10 for initial screening

£10 for treatment initiation

£10 at the mid treatment point

£20 on SVR12 testing.

This schedule is a guide only and can be adapted to motivate and meet the patient's individual need.

These vouchers are stored in the designated Hep C drugs cupboard. A record of the voucher serial number should be kept in the accompanying paperwork. The value of vouchers given must also be written into consultation notes on EMIS. A Hep C compensation claim form should be completed and signed by the patient as a receipt and these can be returned to UHBW via [Mike.Chapman-hill@uhbw.nhs.uk](mailto:Mike.Chapman-hill@uhbw.nhs.uk). Claim form master copy can be found Y:\Hepatitis C\vouchers stuff

**Please see appendix A for accompanying Delivery of Medications for the treatment of Viral Hepatitis C- Enabling equal access to treatment SOP for Medications, Storage and Delivery.**

## MONITORING

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## RELATED DOCUMENTS

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Medicines management

Hep C BDP storage sop

Guide to Hep C treatment at HHS



## CHANGE REGISTER

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Date	Version	Author	Change