SERVICE SPECIFICATIONS

Service	**Hepatitis C dried blood spot testing service in Community Pharmacies**
Commissioner Lead	**Pharmacy Services North East Ltd**
Provider Lead	**Pharmacies**
Period	**1 February 2019 to 31 October 2019**

Purpose

1.1 National Picture

It is well known that there is a high prevalence of Hepatitis C (HCV) in the injecting drug community. However, BBV testing rates within drug treatment services are low and as a result there are many missed opportunities of diagnosing HCV and other BBVs. Moreover, treatment rates for those known to have HCV are low. With the recent development of direct acting antiviral (DAAs) drugs, which have high rates of cure and are well tolerated, there is an unprecedented opportunity to eliminate HCV from the UK. In order to do this, we must increase the diagnosis and treatment of HCV.
Community pharmacies that dispense opiate substitution therapy (OST), such as Methadone, offer an excellent place in which to offer BBV testing as clients attend the pharmacy frequently (often daily) to receive their treatment. Clients often build a good rapport with staff in the pharmacy and as a result this offers an excellent platform to perform testing and ensure a good linkage to care for HCV treatment should they be diagnosed as HCV positive on screening.

1.2 Local Picture

Public Health England data from 2016 suggested that there are approximately 6000 HCV RNA positive patients in the region and 40% of these remain undiagnosed. In 2017/18, 459 new cases of HCV were detected. Since 2007, approximately 2500 patients have received treatment for HCV in the region and it is estimated that 1800-2000 of these have been cured following treatment. Our region has an active case tracking team of 2 hepatology assistants whose role is to track patients with known HCV (previously tested HCV positive but not treated or newly diagnosed) and link them into care. It is estimated that there are approximately 4000 patients in the region left to treat.

1.3 Aims

The primary aim of this 1 year pilot project is to implement an HCV testing program in 7 community pharmacies in Newcastle to assess its impact on HCV testing and treatment rates. The data generated from this project will be used to develop a case for a larger project for implementation across the whole ODN. This programme will assess the feasibility of testing for HCV (and HBV and HIV) via dried blood spot (DBS) testing in community pharmacies that dispense OST.
Pharmacy staff will complete a comprehensive training programme on DBS testing, pre- and post- test counselling and harm minimisation. Robust referral to treatment pathways will ensure there is a high rate of linkage to care. All Individuals with a positive test will be offered treatment through an outreach or hospital clinic of their choice. Hepatology assistants will track the HCV positive patients from diagnosis through the treatment pathway to minimise loss to follow up. Throughout the project data will be collected on testing rates, HCV (and other BBVs) positivity rates, linkage to care and treatment outcomes. Moreover, an assessment of overall costs of the project will be conducted so that future business cases can be developed. Ultimately a “toolkit” will be developed to

allow implementation of the testing program to other pharmacies in our ODN and further afield.

1.4 Evidence Base

The NUTH team has a strong track record of delivering service improvement projects in viral hepatitis. Competed projects include:
Elsharkaway A et al. Improving access to treatment for patients with chronic hepatitis C through outreach. Frontline Gastroenterology 2012: 4; 125-12
McPherson S et al. Targeted case finding for hepatitis B using dry blood spot testing in the British–Chinese and South Asian populations of the North-East of England. Journal of Viral Hepatitis 2013; 20(9): 638-44
Darke J et al. Hepatitis C in a prison in the North East of England: what is the economic impact of the universal offer of testing and emergent medications? Journal of Public Health 2016; 38 (4) e554-e562
Morey S et al. Increased diagnosis and treatment of hepatitis C in prison by universal offer of testing and use of telemedicine. International liver Congress 2018 and submitted to Journal of Viral Hepatitis 2018
Dyson JK et al. Improving testing for hepatitis B before treatment with rituximab. European Journal of Gastroenterology and Hepatology 2016 Oct; 28(10):1172

1.5 General Overview

There are an estimated 160,000 HCV infected individuals in England and currently approx. 12,000 of these receive antiviral treatment each year. In the last few years treatment for HCV has been revolutionised with the development of the direct acting antiviral drugs (DAAs) which have high rates of sustained virological response (SVR= cure; 94% in “real world” cohorts) with an 8-12 week course of tablets and minimal side effects. This offers an unprecedented opportunity of eliminating HCV from England, and the UK Government has committed to achieving the World Health Organisation goal of HCV elimination by 2030.
In order to achieve elimination of HCV from the region a significant increase of testing in those at highest risk of HCV is needed to help diagnose the estimated 40% undiagnosed individuals. It is well known that the prevalence of HCV is high in people who currently use or have previously injected drugs (PWIDs), with estimates in the UK suggesting approximately 50% are anti-HCV ab positive (current or past infection) and approximately 35% are HCV RNA positive (current infection) (PHE report 2017). In England more than 200,000 individuals attend drug treatment centres and over 60% of these are PWIDs. Despite the known high prevalence of HCV individuals attending drug services, testing for HCV is suboptimal, with only 36% of newly registered clients in England accepting a test for HCV (PHE 2017). In order to achieve elimination testing rates for HCV in this population must be increased.
In England and Wales an estimated 149,000 individuals are prescribed opiate substitution therapy (OST) which is intended to replace the consumption of heroin. OST, in the form of methadone or buprenorphine, is frequently dispensed daily from community pharmacies as part of supervised OST consumption programs. Community pharmacies therefore have regular contact with individuals at high risk of HCV; this offers an excellent opportunity of providing HCV testing to these clients. This regular contact may also be advantageous by helping to ensure that those with a positive test are linked into care so they can receive appropriate treatment.

1.6 Expected Outcomes

Overall objective: Develop and implement a testing program for HCV (and other BBVs) using dry blood spot testing in 7 community pharmacies in Newcastle.
Specific objectives:

1. Develop a standard operating procedure for DBS testing in pharmacy.

2. Develop a comprehensive pharmacy staff-training program on DBS testing, pre- and post- test counselling and harm minimisation.
3. Implement dry blood spot testing for HCV (and other BBVs) in 7 high volume OST dispensing pharmacies in Newcastle. The 7 pharmacies have been identified already and are committed to the project.
4. Develop robust referral pathways for individuals with a positive BBV test to ensure all are offered further assessment and treatment.
5. Assess the number of tests undertaken (number of tests undertaken compared with the total number of OST clients attending the pharmacy) and any barriers to test uptake.
6. Assess the prevalence of HCV in the population tested (HCV Ab positivity rates and rates of HCV RNA positivity).
7. Assess the proportion of patients with a positive test attending for further investigation and treatment.
8. Assess the proportion of patients commencing treatment and rates of sustained virological response to treatment.
9. Conduct an assessment of overall actual cost of the project to assess the" testing cost per positive test" and the "testing cost per treated case".
10. Conduct a simple questionnaire to assess client satisfaction with the testing process.
11. Conduct a simple questionnaire for community pharmacy staff about their views on the testing program.
12. Develop a "toolkit" to allow this testing program to be implemented elsewhere.

- Scope

2.1 Service Description

Stages of the service

<u>Pre-implementation of BBV testing programme</u>

1. Identify 7 high volume OST pharmacies to conduct the pilot – these have been identified already and are highly committed to the service.
2. Develop robust standard operating procedure for conducting dry blood spot testing for HCV (and other BBVs) in community pharmacy.
3. Develop a training package for conducting the dry blood spot tests in the community pharmacies including: testing technique, pre and post test patient information, handling the test and transport to the lab, harm minimisation.
4. Develop referral pathways for assessment and treatment.
5. Develop a patient satisfaction questionnaire for the testing.
6. Develop a data collection tool, apply for approval from our clinical audit department and obtain Caldicott approval.

<u>Implementation of the BBV testing program</u>

1. Conduct training in the 7 pharmacies and begin the testing programme with the aim of conducting 750 tests. Training will be conducted by the ODN HCV specialist nurses.
2. Pharmacies will be paid £25 per patient tested to cover their costs of conducting the test, communicating the test result, making an onward referral for positive cases and any associated administration.
3. Individuals who have a test will be given a £5 voucher as an incentive for having the test to try and maximise uptake of the test.
4. Monthly review of progress to identify areas that require optimisation.
5. Review patients with a positive test in a HCV clinic (outreach clinic or hospital clinic depending on patient preference) and conduct further investigations as per the ODN

management guidelines.
6. Initiate treatment with an NHS England approved regimen for those confirmed HCV RNA positive, with follow up as per the hepatitis C management guidelines.

Post implementation review of the programme

1. A complete review of the outcomes of the service will be conducted 1 year into the project or after all 750 tests have been completed (whichever is sooner; if less than 750 clients tested then testing will continue but a review will be written at 1 year to develop a business case for expansion).
2. Complete data analysis.
3. Prepare the project report.
4. Prepare abstracts for submission to National and International meetings.
5. On-going collection of data to ensure complete dataset for sustained virological response results.
6. Develop a "toolkit" so the programme can be implemented elsewhere.

Equipment

The Newcastle upon Tyne Hospitals NHS Trust (NUTH) will supply the dried blood spot testing kits for all participating Community Pharmacies. NUTH will also provide the £5 vouchers to pharmacies to be passed to patients who return to receive their test result.

PSNE Ltd will provide a service claiming module on PharmOutcomes and will manage payment to the Community Pharmacies.

2.2 Accessibility/acceptability

The service provider will ensure that all patients within the target group, irrespective of culture, ethnicity, language and disability will be offered testing. An appropriate and confidential location should be made available for the delivery of the service.

2.3 Whole System Relationships

The pharmacy will complement the existing services provided in the community and secondary care services to ensure that patients receive a holistic approach.

3. Service Delivery

3.1 Staff training

The NUTH team will ensure that the recipient organisation and individuals receive training on the use of the dried blood spot testing kit. This will include the safe use of the lancet, collecting the blood sample correctly, completion of the patient details and harm minimisation.

Training will also equip staff with the skills to support patients pre and post testing and to refer patients with a positive result into treatment.

3.2 Consent

Consent is implied when patients agreed to provide a blood sample for testing. If referral is needed, it is good practice to keep patients informed throughout this process.
It is good practice to keep a record of the referral on the patients PMR if a regular patient of the pharmacy.

4. Referral, Access and Acceptance Criteria

- **Geographic Coverage/Boundaries**
  Pharmacies within Newcastle
- **Location(s) of Service Delivery**
  Within the pharmacy setting
- **Days/Hours of Operation**
  Dried blood spot testing to take place during normal business hours
- **Inclusion Criteria**
  Patients receiving prescriptions for OST will be offered testing
- **Referral Route**
  Patients with positive results will be offered referral for treatment at a location of their choosing.
- **Exclusion Criteria**
  Patients not receiving prescriptions for OST

5. Discharge Criteria & Planning

N/A

6. Self-Care and Patient and Carer Information

Offer participants information about HPC.

7. Activity

Activity Performance Indicators	***Method of measurement***	***Baseline Target***	***Frequency of Monitoring***
Number of patients screened	Monthly submission	100 maximum	Monthly

8. Prices & Costs

Fee structure

Fee per test: **£25.00**
The target is to screen 750 patients across 7 community pharmacies.

PSNE will monitor the service as per the specification and the pharmacy will receive payment for the activity carried out each month reported via PharmOutcomes. Data will be submitted monthly with payment following on a monthly basis.

PSNE will review uptake and reallocate resources each month if not all pharmacies participate in the scheme. PSNE reserve the right to reallocate the equipment if pharmacies do not provide any service within the first month.

Pharmacies will record details of patients tested using the template below, which can be used for post-payment verification.

Hepatitis C dried blood testing service Log

	Date	Initials	M	F	Date of Birth			Date	Initials	M	F	Date of Birth
1							26					
2							27					
3							28					
4							29					
5							30					
6							31					
7							32					
8							33					
9							34					
10							35					
11							36					
12							37					
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21							46					
22							47					
23							48					
24							49					
25							50					