

HCV testing in NSP (Needle and Syringe Provision) Community Pharmacies Pilot (Phase 2)

Report and Findings

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About LJWG

The London Joint Working Group on Substance Use and Hepatitis C (LJWG) is a group of expert clinicians and patient advocacy and voluntary sector leads, working in collaboration with a wide group of stakeholders with the common goal of implementing an integrated plan to drive improvements in the prevention, diagnosis, treatment and outcomes of hepatitis C in people who use drugs, and reduce the spread of the virus.

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Executive summary

Hepatitis C (HCV) is a 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 (PWID), with national data demonstrating PWID account for over 90% of all HCV infections.

Since 2014, direct-acting, all oral antiviral treatments have revolutionized the treatment of HCV as well as mitigating complications such as liver failure, liver cancer and the need for liver transplantation. Direct-acting antivirals (DAAs) are effective in curing the infection in more than 90% of those infected with HCV of all genotypes, thus making the HCV elimination targets of the World Health Organisation (WHO) by 2030 and NHS England by 2025 achievable.

Despite this, diagnosis and treatment rates in HCV positive people who are actively injecting remain low. This vulnerable group faces many barriers to access existing services and need more accessible testing and treatment pathways given their high risks of HCV transmission and acquisition. The LJWG's phase 1 pharmacy pilot offered HCV antibody testing to PWIDs accessing needle and syringe programmes (NSPs) at specific community pharmacies and provided pathways to secondary care for treatment.

The LJWG's pharmacy testing pilot, phase 2, builds on learning from phase 1 in order to increase testing and treatment for those most at risk of HCV acquisition and transmission. Phase 2 provides point of care capillary blood testing for HCV RNA to PWIDs accessing NSPs from community pharmacies in London, whereas phase 1 tests provided on-the-spot HCV antibody testing. This change enables those with chronic HCV infection to be identified directly in the pharmacies. Both pilots aimed to ensure transition to treatment with pathways from NSP community pharmacies to tertiary treatment centres.

Six pharmacies providing NSPs across London took part in the phase 2 pilot between April 2018 and March 2019. Key findings were:

- Of the 308 patients offered HCV testing across all sites, 57% accepted (n=176).
- 38% (n = 66) tested positive for HCV, of whom 21% completed treatment (n=14).

- 29% (n=51) of those tested did not know that interferon-free treatment was available.
- 78% (n=137) of those tested would prefer to receive HCV treatment in their community pharmacy, followed by 9% (n=16) reporting they would prefer to receive treatment from a GP practice.
- Over three-quarters (78%) of people reported having previously been tested for HCV, and 41% said they had been tested within the last year.
- 75% (n=132) of service users said they would recommend the pharmacy testing service to a friend.

Following on from the success of the phase 1 pilot conducted in 2017-18, this report confirms the feasibility and value of offering point of care HCV diagnosis to PWIDs attending community pharmacies for needle exchange services. This report provides valuable insights for future HCV testing programmes in pharmacies and recommends a broader roll-out.

Background

Hepatitis C is a blood borne virus that causes chronic liver disease. It is estimated that around 113,000 people live with chronic HCV infection in England. People who inject drugs carry the greatest burden of infection, with around half of all PWIDs in England and Wales estimated to have been infected with HCV (1).

The advent of direct-acting antivirals has revolutionised treatment of HCV, achieving virological cure or sustained virological response (SVR) in over 90% of patients. In the last few years, NHS England has expanded access to DAA treatment across the country, with patients being prioritised through Operational Delivery Networks (ODNs). To achieve elimination of HCV as a major public health threat by 2030, it is critical that treatment uptake is maximised in actively injecting PWIDs, the group most affected by this infection with the highest acquisition and transmission rates (1; 2).

Previous studies have demonstrated that the delivery of HCV testing through pharmacies is an effective method of engaging with this cohort (3; 4; 5). A recent phase 1 pilot by the LJWG involving point of care testing using oral fluid test (OFT) for HCV antibody had demonstrable success in increasing testing uptake by PWIDs accessing needle and syringe programmes (NSPs) through community pharmacies in London (6). However, the phase 1 pilot had considerable loss to follow-up after pharmacy testing, as further investigation of RNA status through secondary care was required to confirm the diagnosis before treatment could be initiated in secondary care (6).

Drawing upon learning from the phase 1 pilot, a phase 2 pilot was designed to evaluate chronic HCV diagnosis in this population using capilliary blood testing for HCV RNA instead of OFT used in phase 1. This was the first time worldwide that capilliary blood testing for HCV RNA was employed in a non-clinical setting. Enhanced peer support was also implemented to determine whether engagement with treatment services could be increased, and drop-out rates reduced.

Aims

The aim of the phase 2 pilot was to reduce the impact of hepatitis C in actively injecting PWIDs, by facilitating access to immediate chronic HCV diagnosis in NSP community pharmacies using point of care testing HCV RNA capillary blood test and ensuring enhanced support for transition into treatment for this vulnerable population.

The objectives of the analysis in this report are to:

- Ascertain the prevalence of hepatitis C among the tested pilot cohort.
- Determine uptake and loss to follow-up at each point in the care cascade.
- Explore whether the service delivery model was acceptable to service users and pharmacy staff.
- Identify barriers and facilitators to engagement with services.
- Compare uptake and engagement with the phase 1 pilot to determine which elements of the service models are most effective at improving uptake.

Methods

The testing model in phase 2 was similar to phase 1, with the major difference being the use of Cepheid capillary blood test for HCV RNA detection. This was the first study worldwide to use the Cephied test in a non-clinical environment. Further details of the methodology can be found in the phase 1 report (6).

Pharmacies were invited to take part in the phase 2 pilot on recommendation to the LJWG by the Local Pharmaceutical Committee and needle exchange commissioners. Pharmacy staff were trained in the methods of the pilot by the LJWG (see phase 1 report) and provided with a Standard Operating Procedure (SOP). Cepheid undertook a joint training session on use of the point of care testing machine for representatives from each pharmacy at an evening event. Company technicians made regular site visits and were contactable by telephone in case of any queries. The care pathway for phase 2 is summarised in Figure 1.

Quantitative data on service users' testing uptake and onward referral to secondary care was captured using a handwritten or electronic form, depending on pharmacy preference (appendix

2). A unique ID was generated for each patient and used to track outcome data in terms of attendance of secondary care appointments, uptake and completion of treatment.

Feedback questionnaires for pharmacy staff and service users were designed and tested prior to implementation (see appendix 2). For service users, the survey was completed over the counter at the point of care, and staff feedback was captured at a time convenient for them to complete the survey.

Following a request from the LJWG, the Public Health England (PHE) Field Service agreed to assist with analysis of the data and report writing. No patient-identifiable information was provided to or stored by PHE. Data was analysed in accordance with PHE policies on information governance and record keeping. All files will be processed by Field Services South East and London (FS SEaL) in accordance with PHE record retention policies.

Quantitative analysis was undertaken using STATA 15. Key themes from the qualitative survey were explored to gain further insight into the experiences of patients as well as pharmacy staff.

This pilot evaluated extending access to a standard hepatitis C testing practice that is already in use within other areas of the NHS. Care professionals and the service users themselves determined the choice of care accessed in line with professional guidance and user preference. The pilot was therefore deemed a service evaluation and so a Research Ethics Committee review was not required. All staff taking part in the pilot adhered to their respective professional codes of ethics in their conduct and actions.



Figure 1. Care pathway for hepatitis C testing in pharmacies, LJWG pilot phase 2, 2018-19

Results

Pharmacy engagement

Six pharmacies took part in the phase 2 pilot between April 2018 and March 2019. The period of activity for each pilot site ranged between 15 and 329 days, with a median of 173 days.

The total number of eligible population attending these six pharmacies could not be calculated as individuals could register at more than one pharmacy and did not need to provide their unique identifiable details such as date of birth or name to obtain NSP pharmacy services. Pilot sites reported that 308 patients were offered testing, of which 176 accepted the capillary test. Assuming that the data are reliable, this would give a test acceptance rate of 57% (95% confidence interval: 51.4% - 62.7%). Among those tested and reporting the reason for attending the pharmacy, 83% reported needle exchange and 17% reported both supervised consumption and needle exchange as the primary reason for attending the pharmacy.

The number of tests performed by each site during the total pilot period varied between 9 and 100 (Table 1 and Figure 2). Taking into account the range in activity periods between sites, the average number of tests per week ranged between 0.6 tests to 4.2 tests per week.

Further data presented relate to the 176 patients who accepted the offer of testing.

Table 1. Activity period and number of tests performed by pharmacies, LJWG pilot phase 2, 2018-19

			Activity	Number of	Average
Pharmacy	First Test	Last Test	Period	tests	tests per
			(in days)	conducted (%)	week
Portmans Pharmacy	25/04/2018	20/03/2019	329	100 (57%)	2.13
Junction Pharmacy	10/07/2018	18/12/2018	161	23 (13%)	1
St Georges Pharmacy	16/05/2018	16/11/2018	184	20 (11%)	0.76
Market Chemists	19/05/2018	22/11/2018	187	16(9%)	0.6
Hills Pharmacy	31/05/2018	15/06/2018	15	9 (5%)	4.2
Mintons Chemist	14/09/2018	24/10/2018	40	8 (5%)	1.4
Total				176 (100%)	

Figure 2. Activity period and number of tests performed by pharmacies, LJWG pilot phase 2, 2018-19



Demographic factors

The mean age of those accepting testing was 42 years (range 22 to 61 years) and the majority (82%) were male. The age and gender distribution of participants is summarised in the population pyramid in Figure 3.



Figure 3. Age-sex pyramid of those accepting HCV testing in pharmacies, LJWG pilot phase 2, 2018-19

Most participants described their ethnicity as White British (n=122; 69%). Other ethnic groups, including Asian, Caribbean and mixed backgrounds, constituted almost 19% (n=33), and the remaining 12% (n=21) were of other White ethnic background.

Number tested

Previous testing and treatment

Over three-quarters (78%; n=135) reported having previously been tested for hepatitis C. Among those reporting previous testing, 41% (n= 55) reported being tested within the last year and 56% (n=76) reported being tested more than one year ago.

As shown in Table 2 below, compared to those tested within the previous year, HCV RNA positivity was higher in those who did not report being tested in the previous year, although this was not statistically significant (p>0.05).

Table 2	Capillar	, tost	recult by	solf_ro	norted	nrovious	otch teat		nilot	nhasa 2	2018-1	۵
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Self-reported previous test date	Number of patients	Capillary test result			
		Positive	Negative		
Less than one year ago	55	18 (33%)	37 (67%)		
More than one year ago	78	30 (38%)	48 (62%)		
Not known	43	18 (42%)	25 (58%)		
Total	176	66	110		

Table 3 shows self-reported previous test result compared with capillary test results. Of note, 19% of those who reported a previous negative result had a positive result, whereas 63% of those who reported a previous positive result continued to be positive. HCV RNA positivity with the capillary test was 44% among those who did not know their previous test result.

Table 3. Self-reported previous test result compared to capillary test result, LJWG pilot phase 2,2018-19

Self-reported previous test result	Number of	Capillary test result			
	patients	Negative	Positive		
Negative	84	68 (81%)	16 (19%)		
Not known	41	23 (56%)	18 (44%)		
Positive	51	19 (37%)	32 (63%)		
Total	176	110	66		

Of the 22 participants who reported having previously received treatment for HCV, 15 reported having previously completed HCV anti-viral treatment (3 were HCV RNA capillary test positive) and the remaining five reported either partial or no treatment previously (2 were HCV RNA capillary test positive).

Viral load

The capillary blood test kit reported viral load for all positive HCV results. Five participants (6.58%) had a HCV viral load of 100 IU/ml or less in this cohort. The median viral load was 468,500 IU/ml (Q1: 62300 IU/ml and Q3: 2,210,000 IU/ml). All participants with a positive test, regardless of viral load, were referred to secondary care.

Use of vouchers and peer support

Among the 66 patients with HCV RNA positive results, contingency management vouchers for receiving their result were issued in pharmacies to 64 patients. Peer support was offered to 24 patients, of which nine who accepted attended secondary care. Of the 36 not offered peer support, 12 attended secondary care.

Treatment outcome

Among 66 patients, 60 patients were referred to secondary care for further investigation and treatment, of which 21 attended outpatient appointments. Among six patients who declined referral, three had a HCV viral load of <100 IU/ml and the rest had viral load of <300,000 IU/ml.

On genotyping, the majority were genotype 1a (10 patients) or genotype 3 (9 patients). None of the participants were HIV or HBV positive.

18 patients started treatment, of which 14 completed treatment and the other four discontinued treatment before completion. Among those who completed treatment, four were confirmed to have SVR at 12 weeks, eight were pending and two did not attend their appointment.

Among the 21 patients seen in secondary care, four patients were diagnosed as having cirrhosis. Of these, two completed treatment, one did not attend their clinic appointment after four weeks of treatment and another did not attend for treatment initiation.

Figure 4. Care cascade, LJWG pilot phase 2, 2018-19



Comparison with Phase 1

Outcome data was compared between phase 1 and phase 2 pilots for attendance of secondary care services and treatment completion. The proportion of patients testing HCV positive in phase 2 was 37.5%. There was no significant difference between phase 1 and phase 2 with regard to attendance at secondary care services (p>0.05) and treatment completion (p>0.05).

Table 4. Comparison of LJWG pilot phases 1 and 2, 2018-19

Eligible	Proportion positive	Attended	Number	Number
tests	(95% CI)	secondary	started	completed
		care (%)	treatment	treatment
	47.8%		16	
178	HCV antibody	22 (270/)		O*
	postive	23 (27 /0)	10	2
	(40%-55%)			
	37.5%			
176	HCV RNA postive	21 (32%)	18	14*
	(30.3-45.1%)			
	Eligible tests 178 176	Eligible testsProportion positive (95% CI)17847.8% HCV postive (40%-55%)17637.5% HCV RNA postive (30.3-45.1%)	Eligible testsProportion positive positive (95% CI)Attended secondary care (%)178 47.8% HCV postive (40%-55%) $23 (27\%)$ $23 (27\%)$ 176 37.5% HCV RNA postive $(30.3-45.1\%)$ $21 (32\%)$	Eligible testsProportion positive poswAttended secondary care (%)Number started treatment178 47.8% HCV postive $(40\%-55\%)$ 47.8% antibody $23 (27\%)$ 16 176 47.8% HCV RNA postive $(30.3-45.1\%)$ $21 (32\%)$ 18

* Numbers correct at the time of phase 1 and phase 2 report writing; likely to be an underestimate of actual numbers completing treatment

Service user feedback

Service users rated their HCV testing experience on a scale of 1 to 10, with 1 being "very poor" and 10 being "excellent". The mean rating was 9.3 (range 6 to 10). Three-quarters of service users reported that they would recommend the pharmacy testing service to a friend.

When asked where they would like to receive HCV treatment if found to be positive on testing, the majority (78%) reported they would like to receive it at the pharmacy, followed by 9% of service users preferring GP surgery for treatment. The remaining 13% of users were split between drug treatment service and hospital as preferred locations for accessing treatment. When asked if they were aware that current HCV treatment did not involve interferon injections and involved tablets only, 71% reported that they were aware and the rest reported not being aware.

Pharmacy feedback

All six pharmacies provided a feedback response on their experience of taking part in phase 2:

• Communication from the LJWG (1= very poor, 5= excellent) – mean 4.8

- Willingness of service users to participate (1= not willing to engage, 5= all willing to engage) – mean 3.3
- Ease of testing process (1= very difficult, 5= very easy) mean 4.5
- Ease of filling forms (1= very difficult, 5= very easy) mean 4.8
- Ease of referral process (1= very difficult, 5= very easy) mean 4.7
- Engagement of service users in having a conversation about testing/having the test (1= not engaged, 5= very engaged) – mean 3.75

Pharmacy staff reported that they had received generally good feedback from participants, appreciating that the service was quick, convenient and easy. The common reasons for declining testing reported by pharmacy staff was that the client stated they were busy, or had had the test done recently, or wanted to get it done the next time they attended the pharmacy. One pharmacist reported that test uptake was better if the pharmacy had developed a good relationship with the service user as part of opiate substitution therapy. Respondents suggested ways to improve uptake, including designing posters, leaflets, and working with other organisations to raise awareness (e.g. social services and other pharmacies).

Challenges reported by pharmacy staff included difficulties in taking blood, especially in cold weather. One pharmacy reported difficulties in working the testing machine.

Pharmacy staff requested confirmation of receipt of referral from secondary care services, as this was reported as currently variable. It was suggested that if pharmacy staff were informed of the clinic appointment date, they would be able to encourage and remind patients to keep their clinic appointment.

Discussion

Following on from the success of the phase 1 pilot conducted in 2017-18, this report confirms the feasibility and value of offering point of care HCV diagnosis to PWIDs attending community pharmacies for needle exchange services. Feedback from service users and pharmacy staff for HCV testing and referral service has been overwhelmingly positive. Pharmacies providing needle

exchange services for PWIDs are an important location to "diagnose the undiagnosed" HCV cases.

Engagement from pharmacy was suboptimal due to limitations in resources for the pilot, in terms of the number of pharmacies signed up to offer testing in phase 2, the activity period when the service was offered and the number of tests undertaken among the eligible population. Nevertheless, 176 service users were tested, of which 66 were diagnosed with HCV infection. Further work is needed to explore how best to improve the engagement of those pharmacies that performed less well in offering an HCV testing service.

The reasons for the substantial fall in secondary care attendance following referral are not clear. Only a third of patients who were referred went on to attend clinic appointment, suggesting barriers in accessing secondary care services. One of the positive findings is that the vast majority who attended clinic appointments in secondary care were able to start treatment with DAAs and over two-thirds completed treatment. Of note, over three-quarters of users stated pharmacies as their preferred location for accessing treatment if it were to be offered.

It is encouraging to note that most service users (78%) reported having been tested for hepatitis C previously, with over 30% of all service users being tested within the previous year. An important finding is that almost two-fifths of those who reported a previous negative result had a positive result, reaffirming the need for regular testing of this high-risk group regardless of previous test history. Additionally, self-reported positive previous test appears to be a useful marker for HCV infection, with almost two-thirds (63%) of those who reported a previous positive result confirmed as having HCV infection by capillary tests. Unsurprisingly, we found that positivity was higher in those who did not report being tested in the previous year although this was not statistically significant due to small sample size. This also demonstrated re-engagement of those previously known to have chronic HCV infection.

Contingency management vouchers were well-utilised in phase 2 and almost all patients diagnosed with HCV infection were offered and accepted this incentive. Although peer support was offered to some of those testing HCV RNA positive, more work needs to be done to identify why the offer and uptake was low. Peer support has been shown to be successful at engaging people using drug services in accessing treatment in secondary care (7), so perhaps an adapted model is needed in the pharmacy setting.

The prevalence of HCV in phase 2 among those tested was 37.5%, which, while lower than the phase 1 figure of 48%, needs to be interpreted with caution. The primary reason for this variation is that positivity was measured by HCV antibody alone in phase 1 thus identifying those with previous *exposure* to HCV who may not necessarily have chronic HCV infection. Whereas in phase 2 HCV RNA was used, providing a more reliable marker of chronic HCV infection. With regard to outcome data such as clinic attendance and completion of treatment, there were no substantial differences between phase 1 and 2, although the sample sizes were small in both phases to detect meaningful differences.

Analysis of the feedback from service users and pharmacy staff has provided further insights to inform wider implementation of this programme. It is important that relevant written materials including SOP and referral letters are developed and shared with pharmacies providing this service, and adequate training is provided to pharmacy staff on HCV, test counselling, use of testing equipment and the referral process. Secondary care providers should consider how best to acknowledge referral of new patients by community pharmacists if this is not routinely done. Almost 30% of patients were not aware that newer tablet treatments are available for HCV, suggesting scope for further development of resources to raise awareness, such as leaflets and posters, and holding engagement events.

There are several limitations to this study. First, while pharmacy staff received training on test counselling and use of the point of care machine, standardised practice between pilot sites cannot be guaranteed, and there may be some systematic differences in how the pilot was conducted at pharmacy level. Furthermore, differing levels of engagement of pharmacy staff could have had an impact on the number of people invited to take part in the pilot. Second, due to current service configuration and operational reasons, it was not possible to measure or estimate the overall population of PWIDs attending the six pharmacies who would have been eligible for testing in the phase 2 pilot. Third, data on previous testing and treatment was provided by service users and could not be verified for reliability. The use of free text and lack of data format requirements also led to poor quality information for certain variables (e.g. previous test date) and necessitated a degree of estimation to collapse into categories. Fourth, we were unable to adequately capture the reasons why two-thirds of those testing positive for HCV did not attend secondary care service for further assessment and treatment.

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Recommendations

1. HCV testing and treatment is necessary for PWIDs actively injecting. 37.5% of those tested had chronic HCV infection, which is higher than that seen in the prison population. This confirms the importance of testing and treating this vulnerable population.

2. HCV testing should be rolled out in selected pharmacies across the country. The recent *Community Pharmacy Contractual Framework for 2019/20 to 2023/24* provides an exciting opportunity to expand hepatitis C testing for people accessing needle exchanges in community pharmacies (8). With £4 million announced to fund hepatitis C testing in this setting, this report, alongside the phase 1 report (6), has provided key insights to delivering testing in pharmacies. To avoid duplicating efforts and to ensure people who are at risk of infection or re-infection through injecting drug use are targeted effectively, the SOPs developed for this and the previous pilot have the potential to be utilised in developing a testing programme.

3. A campaign targeting actively injecting PWIDs is needed to increase awareness that treatment for HCV is now all oral tablets. This may increase the uptake of both testing and treatment in this at-risk population.

4. The Government should overcome legislative barriers to support the roll-out of hepatitis **C** treatment in pharmacies. When asked where they would prefer to be treated for hepatitis **C**, the majority of people already accessing a hepatitis **C** test at a community pharmacy in both phase 1 (84%) and phase 2 (78%) of the pilot said they would like treatment in the same setting. This, together with the significant drop-out at the secondary care attendance level, requires a more patient centred approach to HCV treatment delivery. The Department of Health and Social Care needs to overcome the legislative barrier preventing hepatitis **C** treatment from being dispensed in pharmacies so that those most at risk can more readily access medication.

References

1. Public Health England. Hepatitis C in England 2019. London: PHE, 2019.

2. World Health Organisation. WHO Global Health Sector strategy for viral hepatitis 2016-2021q. Geneva : WHO, 2016.

3. Radley A, Tait J, Dillon JF. DOT-C: a cluster randomised feasibility trial evaluating directly observed anti-HCV therapy in a population receiving opioid substitute therapy from community pharmacy. s.l. : International Journal of Drug Policy, 2017. pp. 126-136.

4. **Radley A, Melville K, Tait J, et al.** A quasi-experimental evaluation of dried blood spot testing through community pharmacies in the Tayside region of Scotland. Frontline Gastroenterology, 2017. pp. 221-228.

5. Buchanan R, Hasan-Hicks P, et al. Integrating community pharmacy testing for hepatitis C with specialist care. s.l. : Clinical Pharmacist, 2016. p. Online.

6. Verma S, Leeman D. HCV testing in NSP (needle and syring provision) community pharmacies pilot (phase 1). London : London Joint Working Group on Substance Use and Hepatitis C, 2018.

7. **Stagg H, Surey J, et al.** *Improving engagement with healthcare in hepatitis C: a randomised controlled trial of a peer support intervention.* s.l. : BMC Medicine, 2019.

8. **Department of Health & Social Care.** The Community Pharmacy Contractual Framework for 2019/20 to 2023/24: supporting delivery for the NHS Long Term Plan. 2019.

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Appendix 1- HCV testing paperwork (Data collection form)

LONDON JOINT

WORKING GROUP ON SUBSTANCE USE

+ HEPATITIS C

Client Questionnaire										
1. Did you attend pharmacy for:										
Needle X 🔲 Supervised Consumption & Needle X 🔲 Other 🗖										
2. Do you attend a drug and alcohol service. Yes 🗆 No 🗖										
2. Were you aware of the Hepatitis C testing service before you came today?										
Yes No No If yes where did you hear about the testing service?										
3. If you require treatment where would you ideally receive this?										
Hospital 🗖 GP 🗖 Pharmacy 🗖 Drug Treatment Service 🗖										
Other 🗖 (Please Specify):										
4. How would you rate the test experience you received today?										
Very Poor 1 2 3 4 5 6 7 8 9 10 Excellent										
5. Would you recommend this test to a friend?										
Yes 🗆 No 🗖										
6. If No, why not?										
7. Are you aware current treatment does not involve interferon injections and is tablets only?										
Yes 🗆 No 🗖										

Pharmacy				GP N	ame ar	nd ac	dress		
					□ No ⁻	t registe	red w	ith a GP	
Date of test:									
Client Name:									
Date of Birth:									
Gender	Male 🗖	Ferr	nale						
Ethnic Origin:	White British Black British Black Other East Asian Other:			White Iri Black Afr Asian Bri Asian Otl	sh ican tish ner		Whi Blac Sout Mixe Rath	te Other k Caribbean th Asian ed ner not Say	
Contact Address:									
Post Code:									
Telephone No:									
Alternative No:					Conta Relati	act onship	:		
If we are unable t	o contact yo	u do ye	ou g yc	ive con our alte	sent to rnative	o speal e conta	cto ct?	Yes 🗖	No 🗖
Testing History									
Have you been teste Hepatitis C previous	ed for sly?	Yes 🕻]	No 🗖	Do	on't kn	ow E		
Approximate Date	of last test:								
	Location:	GP □ Other	Dru	g/Alcoh	ol Servi	ce 🗖 Se	exual	Health Serv	/ice 🗖
	Results:	Posit	ive [egativ	e 🗖 No	ot kn	own 🗖	
Have you been	treated for		-					-	

Yes 🛛 🛛 No 🗖

Hepatitis C previously?

Don't know 🗖

Hepatitis C Screening Service

London Pharmacies

Can you remember		
Did you complete treatment		
and informed you were cured?		
Pre-Test Check List		Done
Explained what GeneXpert proces	s will entail	
Explained how and when results v up for a positive RNA test, includin	vill be given and arrangements for follow- ng referral	
Explained possible 3 month windo	w period for re-testing if recently at risk	
Offered contingency managemen	t voucher of £5	
Explanation of the implications of	a positive result	Done
They may have difficulty securing with many chronic (long term) illn	Life / Health Insurance as is common esses	
Hepatitis C can lead to severe live However there is effective treatm	r damage and an increased risk of cancer. ent available.	
They have received a copy of the	hepatitis B and C information.	
Consent		
 I have had the GeneXpert exp and anonymous information Chelsea and Westminster How I consent to the specialist ser RNA test results. If the test result is positive I a Hepatitis C Trust who can pro- If you would prefer not to do I am happy for the test result have been diagnosed positive can receive the best care pos of current medications. If you do not collect your Gen you would prefer we don't do 	plained to me and I consent to the test bein being used by the LIWG, the local health se spital. wice at the hospital being given details of ar m happy for my contact details to be share ovide support to access treatment. In this please tick this box. □ s to be shared with my GP if blood tests sho e for a blood born virus – This is to ensure the sible if your test result is positive and the G meXpert results we will forward them to you to this please tick this box □	Ig taken Prvice and Prypositive Id with The ow that I hat you P is aware Ir GP. If
Client Signature:	Date:	

Test Results										
Hepatitis C RNA	🗖 Nega	ntive								
Unique identifier										
If test declined why? Already tested \Box already HCV positive \Box Not interested \Box Addition information -										
Results Appointment					Done					
Information about Hepatitis C, on treatment available and give client a copy of 'Hep C Info' or 'Hep C Care booklet										
Advice on how to prevent passing He	patitis C	to others								
Client referred on to appropriate local service for further assessment and treatment										
Contingency Management Voucher accepted?										
If referred on please state where they have been referred to:										
Peer support offered:	Acc	epted 🗖	Decline	d 🗖						
Peer assigned:	Yes		o 🗖							
Negative Results Checklist					Done					
Recommend re-test if at risk recently										
Advise on prevention in future and give negative test information										
If they are at risk of Hepatitis B or HI\ B vaccination	atitis									
If they remain at risk from Hepatitis B										
Declined Tests Checklist (fill in daily)	No inter	est	Already tes	ted (Other					

This document has been produced for the LJWG on Substance Use and Hepatitis C for use by pharmacies participating in the HCV testing pilots Phase 2.

This document has been adapted from a document provided by Graham Parsons from Turning Point and the Devon Local Pharmaceutical Committee. The LJWG would like to thank Graham and the Devon LPC for permission to adapt this paperwork for use within this pilot.

Appendix 2- Hospital referral form

Patient details									UID *		Refe date	rral	
Surname:	First Name												
Address:													
Telephone:	NHS Number:												
Alternative Contact	No.					R	elations	hip					
Date of Birth:						E	thnicity	:			Ge	nder:	
GP Surgery:													•
Country Of Birth:					Interpreter Ne	eded?	YES			Language	:		
Referrer Details													
Referrer name:	Referrer name: Email:												
Pharmacy:							Tel i	no:					
Job Role:							Fax	No:					
					Current	Subs	tance l	Jse	-				
Alcohol C	rack		Amp	hetan	nines 🗌	Det	ails:						
Opiates 🗌 Co	ocaine		Cann	abis									
					Curre	nt Tre	eatmen	t					
Is client currently in receipt of OST:	YE	s 🗌	NO		UNKNOWN		Whand	at OST is at what	s being p t dose:	rescribed			
How long have they OST in this treatment	been i ht episo	n recei de?	pt of										
Drug and Alcohol Tr	reatmer	nt Prov	ider:										
Keyworker:								Conta	ct No:				
					Те	st Re	sults						
Date of Test:						Posit	ive RNA	Test		IU/N	ЛL		
Have you been	YES		NO 🗌			Resu	lt of HI\	/					
tested for HIV? Have you been						Test: Resu	lt of HA	V					
tested for HAV?	YES					Test:	h (110						
Have you been tested for HBV?	YES]	NO 🗌			Resu Test:	It of HB	v					
					Additio	nal In	format	ion					
Any relevant medic	al/psyd	hiatric	history	' Any	special comm	unicat	ion nee	ds?					
* UID = Patient Unique Identification - each pharmacy will be provided with a UID letter and number													

Consent obtained for referral and the sharing of the patient information outlined above

Please attach any available results to this referral and send to the hepatology team at relevant hospital