HCV testing in NSP (Needle and Syringe Provision) Community Pharmacies Pilot (Phase 1)

Report and Findings
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Executive Summary

Hepatitis C (HCV) is an infectious blood borne virus that affects the liver and is pre-dominately 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 90% of all new HCV infections. Of those infected with HCV 70%-90% do not clear the virus and go on to develop chronic hepatitis C infection. 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%)\(^1\).

Since 2014 the new direct-acting, all oral, antiviral treatments have revolutionized the treatment of HCV, as well as reducing complications such as liver failure, need for liver transplantation and liver cancer. They can eradicate HCV in more than 95% of people infected with HCV of all genotypes, thus making the World Health Organisation (WHO) and NHS England targets of elimination of HCV by 2030\(^2\) and 2025 achievable. However, diagnosis and treatment rates in patients living with HCV and concurrent intravenous drug use remain low, as this vulnerable group faces many barriers to accessing existing services.

Aims of Pilot

The aim of the pilot was to provide point of care HCV testing to PWID accessing needle and syringe programmes (NSP) based at community pharmacies in London. Comprehensive testing and referral routes already exist within community drug treatment services. However, for those not currently engaging in community drug treatment services but actively injecting drugs, HCV testing and referral into treatment provision is sparse. Engagement with healthcare services by these socially isolated patients is sporadic. NSP provision in community pharmacies provides a potential point of contact to offer opportunistic HCV testing, education and referral into treatment.

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Hence the LJWG community NSP Pharmacy testing pilot aimed to:

(i) Develop effective point of care patient-centred HCV testing and supported pathways into treatment for patients actively injecting drugs
(ii) Determine the prevalence of HCV within this population
(iii) Provide information and education to this population regarding HCV, antiviral therapy and safe injecting practices.

Methodology

The LJWG Pharmacy-Based HCV Testing Pilot provided point of care HCV antibody testing using the OraQuick HCV oral fluid test (OFT) across nine NSP community pharmacies in London, north and south of the River Thames, from October 2017 to March 2018. PWID actively injecting drugs and collecting needles and syringes as part of the NSP provision were included in the pilot HCV point of care testing. Whilst some of these service users were also receiving opioid substitution therapy (OST), others were not. Service users were provided with information on HCV, current HCV treatment and safer injecting practices. Additionally, all PWID tested were provided with a £5 contingency voucher upon receipt of their result. If they tested HCV antibody positive, in accordance with their wishes, referral to secondary care services for further assessment and treatment was instigated. Peer support was also offered to all patients on receipt of a positive result and, if accepted, provided to support patients through further assessment and treatment in secondary care. Whilst a total of 216 tests were undertaken 178 fulfilled the inclusion criteria and are included within this report.

Prior to commencement of testing a standard operating procedure was developed. Referral pathways into secondary care for further assessment and treatment were established, together with an education programme and assessment for participating pharmacies. Referral pro formas and patient questionnaires were created to ensure all pharmacies were equipped with adequate knowledge of HCV to approach and counsel patients for opportunistic HCV testing, provide facilities to ensure patient confidentiality and were aware of points of contact in and the newly established referral pathways into secondary care.
Key findings

- 53% tested positive for HCV antibodies and 47% of these were told for the first time that they were HCV antibody positive.
- 78% of those engaging with further assessment in secondary care had chronic HCV and were HCV RNA positive (18 service users).
- 57% of those tested did not know that interferon-free treatment was available.
- 27% of those referred to secondary care for further assessment and treatment attended secondary care appointments (23 service users).
- 15 patients have commenced HCV antiviral therapy.
- 84% of those tested would prefer to receive HCV antiviral therapy in their NSP community pharmacy.
Recommendations from Phase 1

• Pharmacy training is essential prior to HCV testing going live in order to maintain momentum and confidence in conducting the test.
• Pharmacy training should include practical demonstrations on using the test and undertaking the pre- and post-test counselling with a service user.
• Pharmacies need all counter staff to attend the pharmacy training programme in order to offer the test to service users rather than depend entirely on those who have been trained to recruit all the service users.
• Site visits and/or teleconferences are essential to ensure that sites are on target for conducting tests and identify any issues early to ensure solutions can be implemented.
• Integrated IT systems (as developed for Phase 2) would assist in referral to secondary care and collection, validation and evaluation of data.
• Educating service users regarding HCV treatments and safer injection practices should be integral to any pharmacy testing programme.
• Signposting and publicising the HCV testing by other pharmacies in the area is beneficial to education and uptake of the service.
• Treating with HCV antiviral therapy directly in NSP pharmacies has the potential for higher uptake of treatment by service users testing positive for HCV.

Future work

Phase 2 will utilise point of care HCV RNA testing using the Cepheid testing system in NSP pharmacies with integrated IT referral pathways and enhanced peer support as well as assessing the transferability of this model to other cities (Birmingham and Manchester) and exploring the potential to treat HCV in the NSP setting.
Background

The Public Health England Report on Hepatitis C in London identifies over 60,000 people have been infected with hepatitis C and are HCV antibody positive. Of this 60,000 estimates suggest that 69% (41,511) are RNA positive\(^5\). PWID are by far the most at risk group and national data shows that PWID account for 90% of all new HCV diagnoses\(^3\). PWID are a heterogeneous population with those engaged fully in community drug services; those actively injecting but intermittently engaged into community drug services; and those actively injecting but not engaging in any community drug services. Whilst testing and referral routes already exist within community drug treatment services for those engaging, those partially or not engaging have inadequate provision.

The London Joint Working Group (LJWG) was established in 2009 as a collaboration of individuals and organisations spanning the healthcare network, to drive improvement in prevention, diagnosis and treatment of hepatitis C in the vulnerable, socially isolated patients living with intravenous drug use. LJWG has been working to increase testing and treatment rates in order to achieve the World Health Organisation (WHO) target of elimination by 2030\(^4\) and the NHS England target of 2025. In order to achieve this aim, novel patient-centred approaches to testing and treatment for those at risk of HCV need to be explored and this pilot represents one new approach to offering rapid testing to those most at risk from IV drug use (i.e. those actively injecting drugs and either engaging partially or not at all with community drug services).

In 2014, a revolution in HCV treatment with the development of direct-acting antivirals (DAAs) enabled virological cure rates of more than 95%. NHS England funded DAA therapy for 10,011 patients across the UK in 2016, with planned increases to 12,500 in 2017 and 15,000 by 2021\(^5\). UK surveys of PWID suggest that numbers of new hepatitis C infections have not reduced over recent years; both estimated rates of infection

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\(^5\) Dr Faye Kirkland, Hepatitis C patients go abroad for drugs -15th December 2016. (Quoting a statement from NHS England)
and prevalence of infection in recent initiates to drug use, were similar in 2015\textsuperscript{6,7}. Needle/syringe provision was found to be suboptimal, with only around one half of those surveyed reporting adequate provision for their needs. If the prevalence levels do not reduce and if needle exchange provision does not improve, the WHO call to reduce new cases of chronic hepatitis C by 30\% by 2020 and 80\% by 2030 will represent a significant challenge for UK health services\textsuperscript{8}.

As most new infections are acquired via injecting drug use, the prevalence of infection among recent initiates to injecting drugs have been used as a proxy measure of incidence by PHE. There is no accurate incidence data available and the published data available is for incidence of hepatitis C in England alone, London specific data has not been extracted from the Unlinked Anonymous Monitoring Data\textsuperscript{4}. More needs to be done to reduce the persistently high proportion of people who inject drugs and remain undiagnosed, if levels of avoidable premature mortality are to be reduced. Considering that approximately 40\% of people with hepatitis C are undiagnosed\textsuperscript{9}, the current number receiving treatment is low, and even with the projected increases, when compared to the estimated 160,000 people with chronic hepatitis C infection in England, very little progress will be made towards elimination.

Previous studies have been undertaken to assess the take-up of HCV testing within pharmacies. These studies show that this is an effective method of providing tests to PWID\textsuperscript{10,11,12}. The cohorts studied within these trials, however, have been clients in receipt of opioid substitution therapy (OST) who have been attending the pharmacy to collect prescriptions and were included if they had injected within 6 months to a year or the HCV testing had been provided within a wider range of diagnostic tests being


\textsuperscript{9} LJWG, Public Health Report on Commissioning of HCV services in London for People who Inject Drugs, 2013.


\textsuperscript{11} 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; 8:221-228

\textsuperscript{12} Buchanan, R., Hasan-Hicks, P., et al, Integrating Community Pharmacy testing for Hepatitis C with Specialist Care, Clinical Pharmacist, August 2016, Vol 8, No 8, online
offered by a pharmacy. As many pharmacies provide needle and syringe provision, an opportunity was identified to offer testing specifically to PWID who are accessing the NSP provision and currently injecting but not engaged or intermittently engaged with OST or any community drug service.

**Pilot Design**

The aim of the pilot was to provide point of care testing to PWIDs accessing needle and syringe programmes based at community pharmacies in London. Comprehensive testing and referral routes already exist within community drug treatment services. However, for those not currently engaging in treatment, the NSP provision provides an opportunistic point of contact HCV testing. The specific aim of the first phase of the pilot was to see if HCV testing would work within this setting and provide an initial estimate of the prevalence of HCV within the client group. Future phases will build on this to provide different forms of diagnostic testing and potentially treatment within pharmacies.

Nine pharmacies were identified by the local pharmacy committees (LPC) and were formally invited to join the pilot by the LJWG. Criteria for being involved in the pilot included:

- Have a designated area/consulting room for pre- and post-counselling discussion and test procedure.
- Commitment to attend evening training session and evening post-project meeting.
- Commitment to completion of RCGP on-line module.
- Experience of engaging and communicating health education messages with a variety of customer types.
- Needle Exchange provision.
- Appropriate systems in place to capture data, share with Public Health lead and follow up on positive results.
- Commitment to refer positive tests directly into treatment services via clear referral pathways.
- For Haringey, pharmacies had to be accredited Healthy Living Pharmacies (HLP).

The nine pharmacies identified and recruited into the pilot were;
• AR Chemist, Bermondsey
• Cadge Pharmacy, Haringey
• Chana Chemist, Ladbroke Grove
• Green Light Pharmacy, Shepherd’s Bush
• Caregrange Pharmacy, Shepherd’s Bush
• Hills Pharmacy, Kennington
• Junction Pharmacy, Brixton
• Portmans Pharmacy, Pimlico
• St George’s Pharmacy, Southwark

Once pharmacies were identified and agreed to take part in the pilot, pharmacy staff were required to undertake online training provided by the Royal College of General Practitioners (RCGP) and attend a face-to-face training session. This training ensured that all staff involved had sufficient knowledge of hepatitis C, the need for testing, how to approach clients, how to deliver pre- and post-test counselling, how to complete the diagnostic test and the referral routes for positive tests.

Point of care oral fluid tests (OFT) were selected to be used in this pilot (there are plans for future pilots to use Cepheid capillary test for RNA). The OFT provides a quick point of care test for HCV antibodies; these antibodies indicate that the person has at some point been exposed to the HCV virus. Further testing is then necessary to ascertain if the virus is still present within the body (chronic infection), stratification of the level of liver fibrosis and if treatment is required. Oral swab tests were selected as they are a simple and quick way to ascertain if a service user has had contact with HCV. Test results from OFT are available within 20-40 minutes and service users were able to wait for their results or return for them at a later time.

In order to encourage return for the HCV OFT test results, service users were offered a contingency management incentive in the form of a £5 voucher for a high street supermarket. All those who accepted a test were provided with pre-test counselling and literature on HCV. On receiving test results, those who tested positive were
provided literature on HCV treatment and referred on to a local service for further RNA testing and treatment if required. Those who tested negative were advised to be tested again in 3-6 months’ time and to continue regular testing while engaged in high risk activities such as intravenous drug use. For those requiring onward referral, the option of a peer supporter was offered to assist in accessing secondary services.

Direct referral routes to secondary care services were established for the pilot. For pharmacies based in south London, referrals were sent to Kings College Hospital while those in the north were sent to either St Mary’s Hospital, Chelsea and Westminster Hospital or Mortimer Market Centre. Hospitals kept a record of patients that were referred so that further testing and treatment could be tracked through the hospital system.

Each pharmacy was initially allocated 50 tests (400 tests in total) and asked to complete their 50 tests within a three-month timeframe. As the pilot progressed it became clear that some of the pharmacies would not use all of their allotted tests and these were re-distributed to pharmacies that were achieving a higher rate. The pilot ran for a four-month period from October 2017 to March 2017.

Test Results
A total of 216 tests were completed from 18th October 2017 to 20th March 2018. Of these, 38 tests were excluded from the analysis for the following reasons:

- Ten were from the wrong cohort and not using the pharmacy for needle exchange.
- Twenty-eight tests undertaken at one pharmacy were excluded due to concerns about data validity.
- Ninety-five tests were positive for HCV antibodies which accounted for 53% (46%-61%) of tests. Of these 95, 85 were referred on for further testing and treatment while nine declined a referral and one did not return to collect their results.
The breakdown of tests performed by each pharmacy is recorded in Table 1; these range from fewer than 5 to 75. Univariate analysis was carried out on sex, age and previous testing status which is also shown in Table 1. This analysis showed that there was no variation in test results based on gender (OR 1.05 p=0.91), and weak evidence to suggest those who had not been tested previously had a higher odds of testing positive (OR 1.71 p=0.11). There were very few service users tested who were under the age of 29, which is in line with the national picture of an ageing population of IV drug users. There was no pattern observed in relation to risk of a positive result with an ageing population; however, the data does suggest some evidence that those aged 50-59 had the highest odds of having a positive result. This group had 4.57 times the likelihood of testing positive compared to 18-29 year olds (0.92-22.62 p=0.041). These results should be interpreted with caution and as suggestive only, particularly as the pilot study was not designed or powered to measure these variables.

<table>
<thead>
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<th>Variable</th>
<th>No. Individuals (%)</th>
<th>No. Positive Test Results (%)</th>
<th>Crude OR</th>
<th>95% Confidence Interval</th>
<th>p-value</th>
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<td>Greenlight Pharmacy</td>
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<td>&lt;5</td>
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<table>
<thead>
<tr>
<th>Variable</th>
<th>No. Individuals (%)</th>
<th>No Positive Test Results (%)</th>
<th>Crude OR</th>
<th>95% Confidence Interval</th>
<th>p-value</th>
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<tr>
<td>18-29</td>
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<td>&lt;5</td>
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<tr>
<td>30-39</td>
<td>52 (30.2)</td>
<td>32 (61.5)</td>
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<td>40-49</td>
<td>52 (30.2)</td>
<td>25 (48.1)</td>
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<td>0.17 - 2.77</td>
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Table 1  Crude odds ratios, 95% confidence intervals and p-values for positive test result by sex, age and previously tested. Values <5 suppressed for confidentiality.

There was a wide range of ethnicities included within the data with inconsistent recording, but the majority of clients recorded were either white British or British (66%). The majority (64%) were unaware of the test being available before attending the pharmacy which indicates a high level of opportunistic testing. Seventy percent of those tested reported having a previous test and 120 of these knew the result of that test. Of those who had had a previous test and could remember the result, half (60 service users) had previously tested positive, 16 service users who had previously tested negative tested positive on OFT testing, while six service users who had previously tested positive (three of whom reported having treatment) tested negative with OFT testing. Twenty-five clients who had previously not been tested or could not remember being tested previously, tested positive. Therefore this pilot advised 41 people that they were HCV antibody positive for the first time.

All service users were asked to rate their experience of receiving the test within the pharmacy and also if they were aware that current HCV treatment does not require
interferon injections. Ninety four percent of those who responded (n=160) rated the service at nine or ten out of ten and the lowest score received was a six. Only 70 of 161 (43%) respondents were aware that current treatment does not require interferon.

**Onward Referrals**

Eighty five people were referred onto secondary care for further testing and treatment if required. Those with an antibody positive result were sent to the following:

- St Mary's Hospital (36)
- Kings College Hospital (37)
- Chelsea and Westminster Hospital (9)
- Mortimer Market Centre - Sexual Health (1)
- GP (1)

Whilst the data regarding engagement into treatment at the level of secondary care is still being compiled, at the time of publication the key findings were:

- Only 27% (23 service users) attended their appointment at the referral secondary care centre.
- 78% (18 service users) were HCV RNA positive.
- Of these, 33% (six service users) were found to have advanced end-stage liver disease and cirrhosis.
- Sixteen service users with HCV were approved for treatment and commenced HCV DAA therapy, with to date one service user achieving virological cure at 12 weeks post-treatment and two dropping out from treatment.
- The interval of time between referral to secondary care and approval of HCV DAA therapy was up to eight weeks.
Discussion

This pilot has demonstrated that providing opportunistic HCV tests within NSP community pharmacies can be an effective tool in identifying PWID with HCV and referring these clients for further testing and treatment in secondary care. There were, however, a number of operational challenges encountered in setting up and running the pilot.

No referral pathways into secondary care from NSP pharmacies existed and needed to be established. Significant stakeholder commitment from a number of organisations was necessary for this, and was challenging to achieve within the timeframe for pilot completion. In order to be successfully implemented, the pilot needed to be supported by commissioners, public health departments, operational delivery networks, secondary care and pharmacists. Seeking to agree the pilot with all of these stakeholders, agree aims, establish operational pathways and ensure appropriate evaluation caused delay at the beginning of the pilot and resulted in fewer than the original target of 400 tests being completed.

Recommendations from Phase 1:

- Pharmacy training is essential prior to HCV testing going live in order to maintain momentum and confidence in conducting the test.
- Pharmacy training should include practical demonstrations on using the test and undertaking the pre- and post-test counselling with a service user.
- Pharmacies need all counter staff to attend the pharmacy training programme in order to offer the test to service users rather than depend entirely on those who have been trained to recruit all the service users.
- Site visits and/or teleconferences are essential to ensure that sites are on target for conducting tests and identify any issues early to ensure solutions can be implemented.
- Integrated IT systems (as developed for Phase 2) would assist in referral to secondary care and collection, validation and evaluation of data.
- Educating service users regarding HCV treatments and safer injection practices should be integral to any pharmacy testing programme.
- Signposting and publicising the HCV testing by other pharmacies in the area is beneficial to education and uptake of the service.
• Treating with HCV antiviral therapy directly in NSP pharmacies has the potential for higher uptake of treatment by service users testing positive for HCV.

Pharmacies who were enthusiastic and motivated in engaging this client group had much higher rates of opportunistic testing, and the highest performing pharmacy was not on a main road or the highest needle exchange dispenser. This best practice has the potential to be replicated across other sites resulting in a significantly higher number of tests being completed and an attempt was made to do this, although some pharmacies did not inform the project team of barriers they came across at the earliest opportunity. This could be further aided by a pharmacy network to share best practice and to provide further motivation, ensuring that pharmacies receive some feedback from their referrals. One member of staff reported that patients who had been referred on for treatment had come back to thank them and looked visibly healthier, whilst a few other patients were reported to have had new engagement with community drug services post treatment. This type of feedback acts as a strong encouragement for staff involved so a systematic way of receiving feedback from referrals should be considered.

As this was a pan-London pilot, it became quickly apparent that the referral pathways varied significantly across the city and by each hospital. For a population that is often transient and with so many PWID recorded as “No fixed abode”, it was important to ensure that pathways are made as simple and efficient as possible in order to remove barriers to treatment. Peer support was offered to all those being referred but uptake was not high and so further consideration is needed as to how to utilise peers more effectively in assisting service users on the referral pathway to HCV treatment access.

Despite the challenges, the pilot has successfully tested over 200 people for HCV in a four-month window. Approximately 40 of these tests revealed new positive results and therefore 40 people were referred for treatment for the first time. It seems clear from this pilot that providing point of care tests within pharmacy-based needle exchanges to PWID can successfully identify HCV positive individuals and refer them into treatment. Importantly, given a large percentage of service users had been previously tested for HCV, the NSP point of care HCV testing allows re-engagement of this “lost” population and education regarding treatment now being interferon-free.
Whilst the data regarding engagement into treatment at the level of secondary care is still being compiled, at the time of publication only a small proportion of service users (27%) attended the secondary care referral centre for further testing and, of these, 78% were found to be HCV RNA positive and 33% were found to be cirrhotic. This lends further support to the need for more widespread opportunistic HCV testing in the NSP pharmacies to detect HCV at the early stages of liver disease. Outcome data will be compiled at a later date to determine the number of service users who achieve virological cure.

Next Steps

Following this pilot there are plans for two further phases. Phase 2 will move from OFT testing to Cepheid capillary testing which will provide an RNA test rather than just an antibody test. This will provide point of care testing for HCV viral load to determine whether service users have a current chronic HCV infection quickly and prevent unnecessary referral to secondary care. Additionally, there will be more comprehensive peer support and a shorter interval between referral from NSP pharmacy and approval of DAA therapy as this is a likely barrier to engagement with secondary care. This model will also run concurrently in Birmingham and Manchester to determine its transferability.

There is potential for pharmacies that have been successful in recruiting and testing patients who have hepatitis C to start offering treatment within the pharmacy itself. This setting was identified by service users themselves as the place where they would most like to receive treatment on the pilot questionnaire (84% of service users in the pilot). Further exploration of this, to enable service users to access treatment closer to home, with a pharmacist they have built a relationship with (sometimes over many years) provides a more patient-centred approach for this vulnerable population. As this pilot has demonstrated, there are many people who test positive for HCV who do not access treatment. By moving HCV treatment into NSP pharmacies the rates of those in this high-risk group receiving treatment should increase, moving the UK closer to the NHS England and WHO targets to eliminate hepatitis C as a public health risk.
Phase 2 will launch in mid-May 2018 and run for six months.

The LJWG Steering Committee are:

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Dr Emily Finch, Consultant Addictions Psychiatrist, South London and Maudsley
Dr Kosh Agarwal, Consultant Hepatologist, Kings College Hospital
Dr Ashwin Balabhadra, GP with Special Interest, Haringey
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Janet Catt, Nurse Consultant, Kings College Hospital
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Charles Gore, CEO, The Hepatitis C Trust
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John Jolly, Chief Executive, Blenheim
Prof William Rosenberg, University College London

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CGL Drug and Alcohol Service
Chana Chemist, Kensington and Chelsea
Greenlight Pharmacy, Hammersmith and Fulham
Groundswell
Haringey Public Health
Health Inclusion Team, Adult Community Health 3 Boroughs Team (GSTT)
The Hepatitis C Trust
Inclusion Health, Kings Health Partnership
Invitech (Orasure)
Kensington, Chelsea & Westminster LPC
Kensington, Chelsea & Westminster, Hammersmith and Fulham Local Pharmaceutical Committee
Lambeth CCG
Lambeth Public Health and Health Protection
Lambeth, Southwark & Lewisham Local Pharmaceutical Committee;
London Joint Working Group on Substance Use and Hepatitis C (LJWG)
Lorraine Hewitt House Drug and Alcohol Service, Lambeth (SLAM)
Middlesex Local Pharmacy Committee
MSD
North Central London ODN
PHE Colindale
PHE Health Protection
PHE London: North East and North Central London Health Protection Team
Portmans Pharmacy Westminster
Public Health Department, Westminster, Hammersmith and Fulham, Kensington and Chelsea
Public Health England Colindale
Public Health England National Infection Service
SLAM Pharmacy Needle Exchanges
South Thames (HepNet) ODN
Southwark Public Health and Health Protection
The Grove Drug and Alcohol Service BEH NHS Trust
Turning Point
West London ODN

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Katayoon Bamdad, West London Hepatology Operational Delivery Network Manager
Kate Bowgett, Director of Advocacy, Groundswell
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Kar Man, Chung Hills Pharmacy
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Professor Kevin Fenton, Director, Health and Wellbeing, London Borough of Southwark
Melanie Getty, CEO, Aurora Project Lambeth
John Gibbons, Groundswell
Dr Indrajit Ghosh, Specialty Doctor, Camden Provider Services
Rachel Halford, Deputy CEO, The Hepatitis C Trust
Amy Harmsworth, Data and Performance Manager, Drug and Alcohol Action Team
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Sarah Hodgson, Hepatology Specialty Nurse, Kings College London
Jade Holvey, Lead Commissioner – Community Safety and Substance Misuse, London Borough of Lambeth
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