

Service specification

Community pharmacy Hepatitis C Antibody Testing Service - Advanced Service

August 2020

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Introduction and background information

- 1.1. Hepatitis C virus (HCV) is an infectious, blood borne virus that affects the liver and is predominately transmitted by contact with infected blood. In the UK, those at highest risk of contracting HCV are people who inject drugs (PWIDs), i.e. any individual who injects illicit drugs, e.g. steroids or heroin, but who hasn't yet moved to the point of accepting treatment for their substance use.
- 1.2. National data demonstrates that this patient group accounts 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 sequalae of liver failure, death (20%-25% of patients) and hepatocellular carcinoma (1%-5%)¹.
- 1.3. The United Kingdom Government is a signatory to the World Health Assembly resolution and World Health Organization (WHO) goal of eliminating HCV² as a major public health threat by 2030.
- 1.4. In 2015, NHS England established 22 Operational Delivery Networks (ODN) to support treatment and testing efforts across the country and over 50,000 patients have been treated so far with around 95% being cured of the disease. NHS England and NHS Improvement plan to eliminate HCV in England by 2025, five years earlier than the World Health Organization goal³.
- 1.5. The Hepatitis C Direct Acting Antiviral (DAA) medicines are over 95% effective at achieving cure and have minimal side effects. As such, most individuals are cured with their first treatment.
- 1.6. There are also re-treatments available for the small number of patients where the first course of treatment is unsuccessful, which are also highly effective.

¹ London Joint Working Group on substance use and Hepatitis C (2018) HCV testing in NSP (Needle and Syringe Provision) Community Pharmacies Pilot (Phase 1). Available at: http://ljwg.org.uk/wp-content/uploads/2018/05/LJWG-Pharmacy-Testing-Phase-1-final-report-.pdf

² WHO (2016) Combating Hepatitis B And C To Reach Elimination By 2030. Available at: https://apps.who.int/iris/bitstream/handle/10665/206453/WHO HIV 2016.04 eng.pdf;jsessionid=23 B9A53C32594FF683037049096D8125?sequence=1

³ NHS England (2019) NHS England's plan to eliminate Hepatitis C decisively backed by High Court. Available at: https://www.england.nhs.uk/2019/01/nhs-englands-plan-to-eliminate-hepatitis-c-decisively-backed-by-high-court/

2. Service description

- 2.1. The Community Pharmacy Hepatitis C Antibody Testing Service ('the service') is an Advanced service commissioned under the NHS Community Pharmacy Contractual Framework.
- 2.2. PWIDS who are **not** engaged in community drug and alcohol treatment services, will be offered the opportunity to receive an HCV test from a community pharmacy of their choice (subject to the pharmacy being registered to provide the service).
- 2.3. Where the test produces a positive result, the PWID will be referred for appropriate further testing and treatment via the relevant ODN.

Aims and intended service outcomes

- 3.1. The aim of this service is to increase levels of testing for HCV amongst PWIDS who are not engaged in community drug and alcohol treatment services to:
 - a. increase the number of diagnoses of HCV infection;
 - b. permit effective interventions to lessen the burden of illness to the individual:
 - c. decrease long-term costs of treatment; and
 - d. decrease onward transmission of HCV.

4. Prerequisites for service provision

- 4.1. Prior to provision of the service, the pharmacy contractor must:
 - a. be satisfactorily complying with their obligations under Schedule
 4 of the Pharmaceutical Services Regulations (Terms of Service of NHS pharmacists) in respect of the provision of Essential services and an acceptable system of clinical governance;
 - notify NHS England and NHS Improvement that they intend to provide the service by completion of an electronic registration through the NHSBSA Manage Your Service (MYS) platform; and
 - c. be satisfied that all pharmacy staff involved in the provision of the service are competent to do so.
- 4.2. Pharmacy staff providing the service must have access to the pharmacy's shared NHSmail mailbox (the email address of which must be in the following format: nhspharmacy.location.pharmacynameODScode@nhs.net) and the Hepatitis C IT Registry⁴, provided by NHS England and NHS

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⁴ https://clinicalregister.gemcsu.nhs.uk/

Improvement. Signing up to provide the service via MYS will act as a 'trigger' for the pharmacy to be added to the registry's list of providers (please note that this may take several days). Once complete, members of staff will be able to request access to the registry, which will need to be approved via the pharmacy's generic inbox before access is granted.

- 4.3. Pharmacies must have a consultation room, where the point of care tests (POCT) will be undertaken, which complies with the following minimum requirements:
 - a. the consultation room must be clearly designated as an area for confidential consultations:
 - b. it must be distinct from the general public areas of the pharmacy premises;
 - c. it must be a room where both the person receiving services and the pharmacist or pharmacy technician providing those services are able to sit down together and talk at normal speaking volumes without being overheard by any other person (including pharmacy staff), other than a person whose presence the individual receiving the test requests or consents to (such as a carer or chaperone);
 - d. it must be a room where infection control measures can be maintained; and
 - e. handwashing facilities must be available in the room or nearby.
- 4.4. The pharmacy contractor must have a standard operating procedure (SOP) in place for this service, which includes procedures to ensure health and safety and infection control procedures are maintained in line with relevant guidelines⁵. Where the service is being provided during the COVID-19 Pandemic, members of staff performing the test must wear a fluid resistant (type IIR) surgical mask to protect both parties and any other personal protective equipment (PPE) recommended at that time by Public Health England (PHE)⁶ for any direct care of possible and confirmed COVID-19 cases in primary care. All staff involved in the provision of this service should ensure they are familiar with and adhere to the SOP.
- 4.5. The pharmacy contractor must ensure that pharmacists, pharmacy technicians and their teams providing the service are competent to do so. The core training requirement for any staff providing the service is to watch the NHS England and NHS Improvement training video⁷ and to ensure they are familiar with the manufacturer's instructions on how to use the POCT.

⁵ Health and Safety Executive (no date) 'Blood-borne viruses (BBV)' Available at: http://www.hse.gov.uk/biosafety/blood-borne-viruses/index.htm

https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/covid-19-personal-protective-equipment-ppe. At the time of publication, the PHE guidance on use of PPE in primary care, when providing direct patient care, such as Hepatitis C testing, with possible or confirmed cases of COVID-19, is that disposable gloves, a disposable plastic apron and eye/face protection should be used, in addition to a fluid resistant (type IIR) surgical mask (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/878750/T2_poster_Recommended_PPE_for_primary_outpatient_community_and_social_care_by_setting.pdf).

⁷ https://www.cppe.ac.uk/services/hep-c

- 4.6. The pharmacy contractor must ensure that staff are appropriately trained and made aware of the risks associated with the handling and disposal of clinical waste and that correct procedures are used to minimise those risks. A needle stick injury procedure must be in place.
- 4.7. The pharmacy contractor must ensure that staff involved in the provision of this service are advised that as there is a small risk that they could come into contact with blood borne viruses, they should therefore consider being vaccinated against Hepatitis B and be advised of the risks should they decide not to be vaccinated.

5. Service duration

- 5.1. The service will commence on 1st September 2020.
- 5.2. As the national Hepatitis C Programme is an elimination exercise, the service will be time limited. In the first instance it will run until 31st March 2022.
- 5.3. Prior to 31st March 2022, a review will be undertaken to ascertain whether the service is effective in testing this difficult-to-reach patient cohort and successfully directing those PWIDs who test positive towards further PCR testing and treatment. The review will be informed by PHE observational data and the NHS England and NHS Improvement registry. If the efficacy of the service model is suitably demonstrated, the service may be extended into 2022/23.
- 5.4. In line with the objectives of the Hepatitis C Programme Board, the service will not continue after 31st March 2025.

6. Service availability

- 6.1. The pharmacy contractor should seek to ensure that the service is available throughout the pharmacy's contracted opening hours. If they are also commissioned to deliver an NSP service, it will be particularly important to ensure that the testing service is offered at a time that PWIDs visit to exchange their injecting equipment.
- 6.2. The pharmacy's NHS website profile should be edited to indicate that a blood-borne virus testing service is provided. If the pharmacy temporarily or permanently ceases to provide the service, they should, as soon as possible, update their NHS website profile to reflect that the service is no longer available.
- 6.3. The pharmacy contractor must ensure the service is accessible, appropriate and sensitive to the needs of all service users. No eligible

PWID should be excluded or experience particular difficulty in accessing and effectively using this service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age.

- 6.4. The pharmacy contractor can refuse to provide the service to an eligible PWID if the PWID or any other person accompanying the PWID, threatens violence or commits or threatens to commit a criminal offence.
- 6.5. If the pharmacy contractor wishes to stop providing the service, they must notify NHS England and NHS Improvement that they are no longer going to provide the service via the MYS platform, giving at least one month's notice prior to cessation of the service, to ensure that accurate payments can be made.

7. Service provision

- 7.1. The pharmacy contractor must offer eligible PWIDs, aged 18 years and over, the opportunity of having a POCT, which tests for HCV antibodies, at the pharmacy. All POCTs must take place in the consultation room on the pharmacy premises, and the test is to be performed by an appropriately trained pharmacist or pharmacy technician.
- 7.2. People eligible for a POCT under this service, are PWIDs who are not engaged in community drug and alcohol treatment services. Eligible PWIDs should receive the test as soon as possible after they have consented, to reduce the possibilities of loss to follow-up and potential for further infection of other individuals.
- 7.3. PWIDs who are engaged in community drug and alcohol treatment services are not eligible to receive a test for HCV antibodies through this service, as testing will be offered to them via the drug and alcohol treatment service.
- 7.4. People who are not PWIDs who may, through another intervention, be identified as being at high risk of HCV should be referred into the relevant service. If the pharmacy contractor is unsure what the relevant service is, they should refer the individual to their GP or the local ODN (see appendix F).
- 7.5. A pharmacy contractor may determine a PWID's eligibility to receive the service on the basis that:
 - a. the PWID utilises needle and syringe programme (NSP) services from the pharmacy;
 - the PWID has been referred to the pharmacy for testing by another pharmacy or care provider which provides the individual with NSP services;
 - the individual is known to pharmacy staff, who know them to be a PWID; or

- d. the individual self-identifies to pharmacy staff as a PWID.
- 7.6. Appropriate efforts should be made to confirm that the PWID is **not** engaged in community drug and alcohol treatment services (e.g. supervised consumption of methadone), as they will have also been offered HCV testing through this service.
- 7.7. The DAAs are not recommended for treatment of pregnant women or breastfeeding mothers, however, if a pregnant or breastfeeding woman is an eligible PWID, they should still be offered a POCT as knowledge that a pregnant woman has acquired HCV infection may influence the technicalities of the delivery of the child.
- 7.8. The POCT to be used by pharmacy contractors is the InTec Rapid Anti-HCV Test. All POCT materials must be stored in accordance with the manufacturer's instructions.
- 7.9. Prior to a POCT being undertaken, a suitably trained pharmacist or pharmacy technician should carry out a pre-test discussion with the PWID, which will:
 - a. describe the test and how it is undertaken;
 - b. advise on what will happen if they test positive for HCV, including a referral being made to the local ODN for confirmatory RNA testing and treatment if the RNA test is positive;
 - explain that, with the individual's consent, positive test results will be notified in writing to their GP (where they are registered with a general practice). Refusal to consent to such data sharing does not exclude the PWID from being tested under the service;
 - d. explain that positive test results may have implications on life insurance and therefore mortgages, as is common with many longterm conditions;
 - e. explain that the provision of the test is confidential and that the information that they choose to provide will be managed in line with data protection legislation. The information will be recorded in an individual record for each PWID for reference and audit, held by the pharmacy. The PWID's personal information will only be accessible by staff providing the service. This information will be securely stored, to maintain strict confidentiality. This information will not be shared with the PWID's GP without their consent. Audit information will be compiled from records, but this data will be anonymous;
 - f. explain that, with the individual's consent, elements of the record held at the pharmacy will be added to the Hepatitis C Registry, provided by NHS England and NHS Improvement. Patient identifiable information in this record can be viewed by ODN clinical staff at treatment locations, where they have a need to access the information. Patient identifiable information can also be viewed by PHE staff undertaking monitoring of the prevalence of infectious diseases, as provided for in Section 251 of the National Health Service Act 20068, the Health

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⁸ http://www.legislation.gov.uk/ukpga/2006/41/contents

Service (Control of Patient Information) Regulations 2002⁹ and the Health Protection (Notification) Regulations 2010¹⁰. If the patient does not consent to their information being entered onto the register, an anonymous record must be made. Refusal to consent to inclusion on the register does not exclude the PWID from being tested under the service, or from being referred for confirmatory testing and (where the confirmatory testing indicates that the patient has active hepatitis C) receiving treatment; and

- g. answer any other questions they may have regarding the service.
- 7.10. Following the pre-test discussion, the pharmacist or pharmacy technician should confirm whether the PWID gives their consent to be tested; this can be gained verbally. Where consent is granted, the PWID can be asked to sign the service consent form (Appendix A) where the contractor wishes to maintain a written record of consent. If contractors do collect written consent, data retention rules need to be complied with. The consent form also notifies the individual of any necessary information flows as a consequence of receiving the service.
- 7.11. The pharmacist or pharmacy technician will advise the PWID of the outcomes of the test.
 - a. Where there is a negative antibody result, advice should be given relating to the risks of continuing to engage in risky behaviours, such as injecting illicit drugs, and where appropriate advice that they should consider being re-tested in 6 months' time.
 - b. Where there is a positive antibody result, the implications of that positive result should be explained to the PWID, with an explanation of what will happen next. They should be referred using the form in Appendix D to the relevant ODN (details of which are set out in Appendix F) for further testing and where appropriate suitable treatment. Where the PWID is registered with a general practice and they consent to their GP being notified of the positive test result, this notification should be made using the form in Appendix E. This notification should ideally be sent electronically, either by secure email or secure electronic data interchange. If necessary, the pharmacy should contact the GP practice for details of their secure email address. Where electronic notification is not possible, the pharmacy contractor should send the notification via post or hand delivery. The PWID should also be provided with the relevant literature (the hepatitis C pharmacy leaflet) which pharmacy contractors can order by following this link¹¹. The literature should be provided to the PWID in a manner that ensures it has not been handled by another person i.e. a fresh document straight out of the packaging and not previously stored in a leaflet rack.

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⁹ http://www.legislation.gov.uk/uksi/2002/1438/contents/made

¹⁰ http://www.legislation.gov.uk/uksi/2010/659/contents/made

¹¹ http://www.hepctrust.org.uk/pharmacy

- 7.12. The pharmacy contractor must have in place an escalation process, should the PWID fail to return for their results. As a minimum, this should include attempting to reach the patient via any known contact details (e.g. telephone/email/post) to request that they attend the pharmacy (however, patients should **not** be informed of their test results via this route, due to the risk of the information being seen/overheard by someone the patient does not wish to know their status). If this is not successful, or the pharmacy does not have any contact details for the patient, they should inform the ODN that the PWID has not returned for their results.
- 7.13. The pharmacy contractor is required to make arrangements for the removal and safe disposal of any clinical waste related to the provision of this service.

8. Records and data sharing

- 8.1. The pharmacy contractor must maintain appropriate records to ensure effective ongoing service provision and to support post-payment verification. Appendix B details the records that must be kept as part of provision of the service, set out in a clinical record form which contractors can use to create their clinical record for provision of the service. Contractors can also choose to record the same information in a secure IT system, should they have one available to them.
- 8.2. Appropriate records and documentation should be retained for an appropriate period of time, but for the purposes of post-payment verification, they should be kept for a minimum of two years after the test takes place. As pharmacy contractors are the data controller, it is for each contractor to determine what the appropriate length of time is, beyond two years. Decisions on this matter must be documented and should be in line with 'Records Management Code of Practice for Health and Social Care'12.
- 8.3. Where the PWID provides consent for their information to be recorded on the Hepatitis C Registry, provided by NHS England and NHS Improvement, the details set out in Appendix C must be entered by the pharmacy contractor into the Registry. Where the PWID does not provide consent for an identifiable record, an anonymous record must be entered by the pharmacy contractor into the Registry. This will enable the community pharmacy data to be collated alongside data from the other programmes commissioned by the Hepatitis C Programme Board.
- 8.4. Where there is a positive antibody result, the PWID is registered with a general practice and consents to information being shared, the GP should be notified of the test undertaken, the result and any onward referral, using the form in Appendix E.

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DHSC (2016) 'Guidance: Records management: code of practice for health and social care' Available at: https://www.gov.uk/government/publications/records-management-code-of-practice-for-health-and-social-care

9. Governance

9.1. The pharmacy contractor is required to report any patient safety incidents in line with the Clinical Governance Approved Particulars for pharmacies.

10. Reporting and Monitoring

10.1. Pharmacies may be required to provide reports for service evaluation and monitoring purposes. The data and evaluation periods will be agreed nationally with the Pharmaceutical Services Negotiating Committee (PSNC) and communicated to contractors when any submission is required.

11. Payment

- 11.1. Claims for payments for this service should be made monthly, via the MYS portal. Claims should reach the NHSBSA by the 5th day of the following month after completion of a POCT, in accordance with the usual Drug Tariff claims process. Later claims will not be processed.
- 11.2. The NHSBSA will make appropriate payments claimed by the pharmacy contractor as described above, in the same payment month as other payments for NHS Pharmaceutical Services and the payments will be separately itemised on the FP34 Schedule of Payments.
- 11.3. Payment will be £36 per POCT performed on an eligible PWID, plus the cost of the POCT (including VAT). Payments for this service include provision for expenses incurred by community pharmacies in providing this service. These include training, purchasing of POCTs and disposal of clinical waste.
- 11.4. The pharmacy contractor will not be reimbursed or remunerated, under this service, for POCTs provided to PWIDs or other members of the public outside of the eligibility criteria.
- 11.5. Pharmacy contractors will be required to purchase the POCTs in advance of starting to provide the service and will be reimbursed as set out in paragraph 11.3, once a claim for performing a POCT has been received.

Appendix A Consent Form

Co Co	mmunity phar	rmacy Hepat		y Testing Service	•
ı	Individual's name and address				
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Information for the person who is considering being tested for Hepatitis C antibodies

Referral for another test

If you test positive for Hepatitis C antibodies, this does not mean you have Hepatitis C. You may have had the virus in the past and it has cleared from your body.

If you test positive for Hepatitis C antibodies, we will refer you to the operational delivery network, which is the NHS organisation that tests and treats people with Hepatitis C.

Health professionals working for the operational delivery network will offer you another test which will confirm whether you currently have the virus.

If you do have the virus, they will also be able to provide you with treatment to clear your body of the virus.

Hepatitis C registry

If you consent to your identifiable data being entered onto the Hepatitis C registry, it can be viewed by the following members of staff:

- Operational delivery network staff who are directly involved in your care.
 They will also be able to update your record with additional information,
 including the results of the second test (where the original test result is
 positive), the genotype of Hepatitis C you have and your treatment plan.
- Public Health England staff, who will use it to monitor the number and location of Hepatitis C infections in England and any health issues resulting from Hepatitis C infection.

Sharing information with the NHS

We may send your completed consent form to NHS England & NHS Improvement or the NHS Business Services Authority if they need to check the payments to the pharmacy for providing this service to you.

If they need to, this will allow them to contact you to check that we carried out a test for Hepatitis C antibodies.

Any other questions?

If you have any questions about how we use your personal data or would like to exercise your rights under data protection law, please speak to a member of staff at the pharmacy.

Appendix B: Pharmacy Clinical Record Form

Individual'	s d	eta	ils								* inc	lica	tes s	ectio	ns th	at m	ust b	e cor	nple	ted	
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Surname*																					T
Address																					T
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																					t
Postcode																					_
Telephone											\Box									Π	Τ
Date of birth*							N	IHS	No.												T
Gender*		Ma	le				Fe	male										_		1	_
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	C – Asian or Asian British								D – Black or Black British												
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Country of																					Τ
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GP practice																					T
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Date of test*			/	/			_	_							_	_	_		_	-	_
Test used*	InT	ес	Rap	id A	nti-l	ICV	Tes	ŧ													
Test result*			sitive					gati													
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Where the	ind	ivid	ual (ons	ents	s to r	efe	rral,	whi	ch	_			_							
outreach c	linic	wo	uld t	hey	like	to b	e re	ferr	ed to	?											
(The individua	al shou	uld se	lect a	clinic			_			-											
						est ι		ertak echnic													

Appendix C: Information to be recorded on the Hepatitis C IT Registry

Where an individual provides consent for their information being recorded on the Hepatitis C IT Registry, provided by NHS England and NHS Improvement, the following information should be added to the Registry by pharmacy staff:

- First name
- Last name
- NHS Number or Local Patient Identifier
- Age range
- Date of birth
- Gender
- Ethnicity
- · Country of Birth
- Risk status
- Date of test
- Type of Test
- Has been tested for Hep C before
- Patient informed of test result
- Antibody test result
- Testing Location organisation type (Pharmacy)
- Testing Location organisation name

Appendix D: Referral to ODN Form

Individual's details:						
Name						
Address						
(If of no fixed abode, the pharmacy address can be used)						
Date of birth	1 1	NHS numbe	r			T
Phone number		, ,,				
They have previously hepatitis C Which outreach clinic referred to?	received treatment for would they like to be			□ No		
Pharmacy name		Telep	hone			
NHSmail address						

Appendix E: Notification to general practice form

Patient's details:							
Name							
Address							
(If of no fixed abode, the							
pharmacy address can be used)							
Date of birth	1	1		number	П		П
Phone number			(if knov	/n)			Ш
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No action is required by via the Hepatitis C Ope Pharmacy name NHSmail address				Telephone			

Appendix F: ODN contact details

ODN		Clinical Lead	Email for referrals, results queries, etc.
	Lead Provider	(Name and email)	
North East & North	The Newcastle Upon	Stuart MacPherson	nuth.necodn@nhs.net
Cumbria	Tyne Hospitals NHS	Stuart.McPherson@nuth.nhs.uk	
	Foundation Trust		
Greater Manchester		Javier Vilar	Mft.manchesterodn@nhs.net
& Eastern Cheshire		Javier.Vilar@pat.nhs.uk	
	Pennine Acute Hospitals	Martin Prince	
	NHS Trust	martin.prince@cmft.nhs.uk	
Cheshire &		Paul Richardson	rlb-tr.HCVEAPCM@nhs.net
Merseyside	Royal Liverpool & Broad	paul.richardson@rlbuht.nhs.uk	
	Green University Hospital	Libuse Ratcliffe	
	NHS Trust	Libuse.ratcliffe@liverpoolft.nhs.uk	
South Yorkshire	Sheffield Teaching	Ben Stone	sht-
	Hospitals NHS	Benjamin.Stone1@nhs.net	tr.SouthYorks.HCVNetwork@nhs.net;
	Foundation Trust		
Humberside and	Hull & East Yorkshire	Peter Moss	Peter.Moss@hey.nhs.uk
North Yorkshire	NHS Trust	Peter.Moss@hey.nhs.uk	
West Yorkshire	Leeds Teaching	Mark Aldersley	leedsth-tr.ViralHepatitis@nhs.net
	Hospitals NHS Trust	markaldersley@nhs.net	
Lancashire & South	East Lancashire	Ioannis Gkikas	HepatitisCTeam@elht.nhs.uk
Cumbria	Hospitals NHS Trust	ioannis.gkikas@nhs.net	
Leicester	University Hospitals of	Martin Wilselka	HepCODN@uhl-tr.nhs.uk
	Leicester NHS Trust	martin.wiselka@uhl-tr.nhs.uk	
Birmingham	University Hospitals	David Mutimer	s.bufton@nhs.net
	Birmingham NHS	dmutimer@nhs.net	angelie.moore@nhs.net
	Foundation Trust		

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St George's	NHS Foundation Trust		
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	Foundation Trust	<u></u>	
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	Foundation Trust	J -	
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