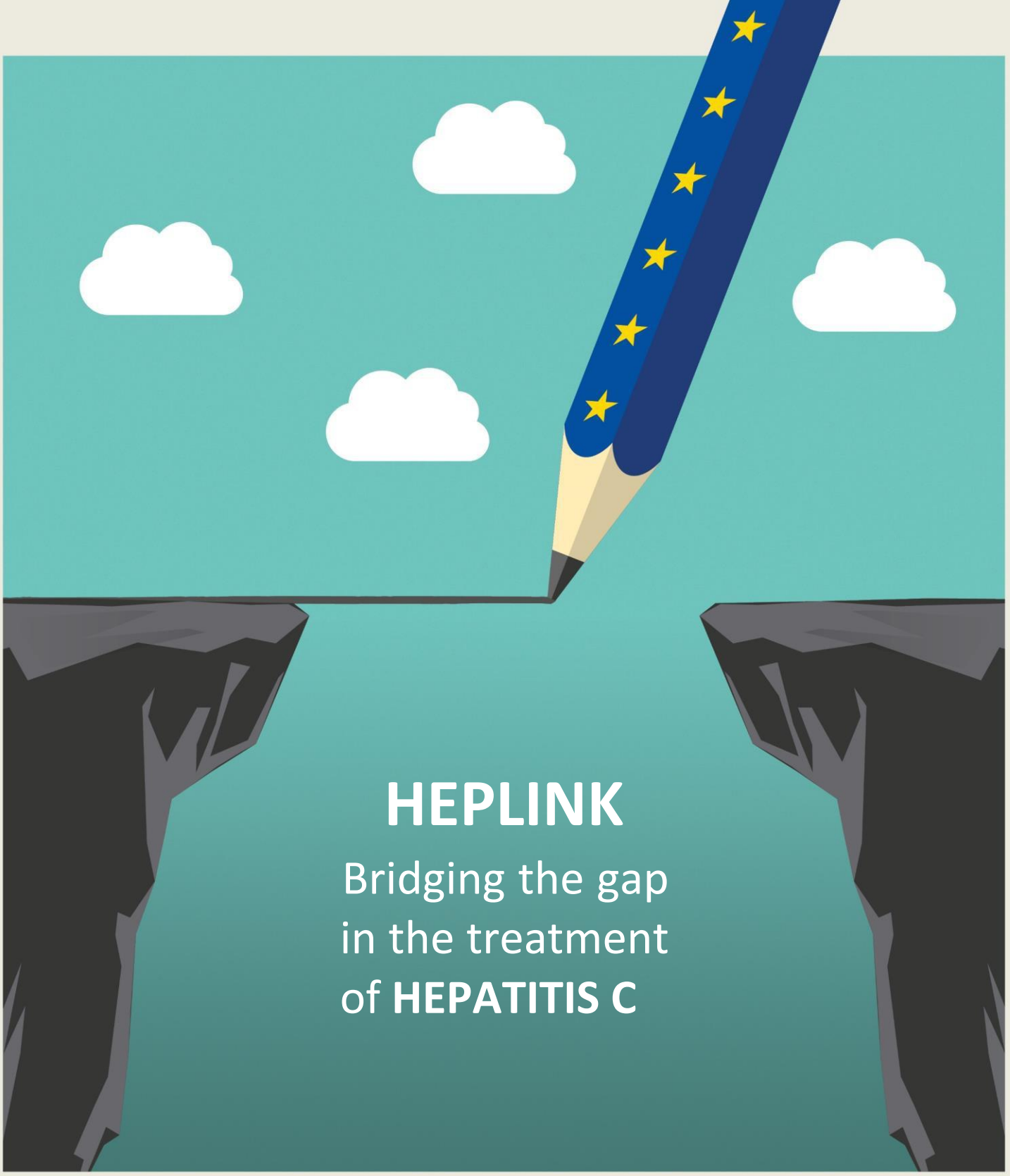

HEPLINK

Bridging the gap
in the treatment
of **HEPATITIS C**

HEPCARE EUROPE

Dublin | London | Bristol | Seville | Bucharest

Preface

Hepatitis C (HCV) infection is a major cause of chronic liver disease and death [1]. Injecting drug use remains the significant cause of new infections in the European Union, with estimates of HCV antibody prevalence among persons who inject drugs (PWID) ranging from 5% to 90% in 29 European countries [2]. In Ireland and the EU, primary care is a key area to focus efforts to enhance HCV diagnosis and treatment among PWID [3].

Recently developed HCV direct-acting anti-viral drugs (DAAs) are well tolerated, delivered for shorter courses (8–12 weeks), with trials reporting more than 90% cure rates among PWID [4]. Despite these highly effective and simplified therapeutic regimens, many people at risk are unaware of their infection and obstacles limit access to HCV care, resulting in many patients not being treated [5].

The HepCare Europe project [6] is an EU-supported service innovation project and feasibility study at four European sites (Dublin, London, Seville and Bucharest) to develop, implement and evaluate interventions to enhance identification and treatment of HCV among PWID. As part of the Hepcare Europe project, HepLink aims to improve HCV care outcomes among opiate substitution therapy (OST) patients in general practice by developing an integrated model of HCV care and evaluating its feasibility, acceptability and likely efficacy. The study is being conducted at each of the four Hepcare consortium sites.

The purpose of this training manual is to share intervention protocols along with study documentation and data collection instruments that were used in the HepLink study. The first part of the manual focuses on HepLink in Dublin, Ireland and provides an overview of the study protocol for the nurse intervention and the clinical assessment proforma used to collect patient data. The manual then presents a series of appendices that contain site-specific information and documentation germane to the Heplink study as operationalized at the other three sites: London, Seville and Bucharest. A final appendix is also provided containing resource materials for patients who attended Heplink in Dublin.

Acknowledgments

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HepLink

Outline

The HepLink study aims to improve identification of Hepatitis C (HCV) and linkage to specialist HCV evaluation and HCV treatment among methadone patients in general practice by developing an integrated model of HCV care and evaluating its feasibility, acceptability and likely efficacy.

The integrated model of care consists of: education of community practitioners, outreach of a HCV-trained nurse into GP practices, and enhanced access of patients to community- based evaluation of their HCV disease (including a novel approach to diagnosis, i.e. FibroScan).

Opiate substitution (i.e., methadone) prescribing general practices were recruited from the professional networks/databases of the research team. Patients were eligible to participate if ≥18 years of age, on methadone and attend the practice for any reason during the recruitment period. The researchers instructed participating GPs to recruit consecutively presenting patients who were eligible and interested to participate until they had attained a quota of 10.

The HepLink intervention

The intervention had been developed based on extensive preliminary work examining the barriers and enablers to HCV treatment conducted in Dublin[6] and consisted of:

- Outreach of a HCV-trained liaison nurse into GP practices (please see Figure 2)
- In-practice education for GPs/practice staff regarding developments in the diagnosis and treatment of HCV
- Enhanced access of patients to community-based evaluation of HCV disease, including a novel approach to diagnosis, i.e. transient elastography (i.e., FibroScan)
- Researcher-facilitated practice based clinical audit of HCV care processes and feedback to GP

HepLink outreached a HCV-trained liaison nurse into GP practices to optimise interaction and integration between primary and secondary care. She conducted on-site specialist evaluation of HCV disease (including FibroScan) in the general practice setting and assisted in referring HCV-infected patients to a Hepatology/Infectious Diseases service for HCV treatment (see Figure 3). She educated GPs, practice staff and patients on HCV and developments in its diagnosis and treatment and ensured that patients' HCV testing and other blood borne virus screening and vaccinations were up-to-date. A central component of the intervention was the staging of liver fibrosis among HCV-infected patients using a FibroScan.

HepLink evaluation

In addition to developing and delivering the intervention, the intervention's feasibility, acceptability and likely efficacy will be evaluated. An audit of patients' clinical records was

conducted at baseline and a further audit conducted at 6-months post-intervention to examine HCV care processes and outcomes following the intervention.

Information for participating doctors / healthcare professionals

Why is the study being done?
The aim of the HepLink study is to develop, deliver and evaluate an integrated model of HCV care to enhance access to HCV treatment for at-risk patients.

The study is part of a larger programme of work (HEPCARE EUROPE), funded by the EU Commission, to bridge primary and secondary care and outreach in the community to facilitate access to HCV testing and treatment among key risk groups including drug users and the homeless.

The HepLink study will bridge primary and secondary care, by:

- developing an integrated model of HCV care, to include education of GP/PN, nurse. specialist liaison, and enhanced access to specialist assessment, i.e. Fibroscan
- delivering this model of care
- examining the feasibility, acceptability and likely efficacy of this model

Who is doing the study?
HEPCARE EUROPE is a consortium led by Dr Jack Lambert and Professor Walter Cullen of UCD School of Medicine, with partners in University College London, University of Bristol, Servicio Andaluz de Salud (Seville), and Spitalul Clinic Dr Victor Babes (Bucharest). The HepLink study is being conducted by a team of investigators, including: Professor Walter Cullen, Dr Jack Lambert, Dr Davina Swan, Dr Geoff McCombe, Ms Eileen O'Connor, and Ms Carol Murphy.

Who should take part in the study?
We are seeking expressions of interest from practices prescribing methadone treatment for participation in the study.

What will I have to do?
Your involvement in the study would entail helping us recruit 10 consecutive patients who would be suitable for participation, permitting the researcher access to consenting patients' clinical records, addressing Hepatitis C issue with participants supported by the specialist liaison nurse, and completing a 10-minute interview with the researcher on your experience of the project.

What supports will I receive?
A researcher and a specialist liaison nurse will support you throughout the study. All participating practices will receive academic detailing (Internal CME eligible) on the HepLink project and will be supported by the specialist liaison nurse in the assessment (i.e., blood tests, fibroscan) and referral of patients to Hepatology/ID.

What are the benefits of the study?
This study has the potential to improve identification and treatment of HCV infection among at-risk patients which has considerable personal, social and economic benefits.

What if I have any questions?
If you or any of your colleagues would like more information or to discuss the study, please feel free to contact the research team:
Dr Davina Swan (Researcher) – 086 1796529; davina.swan@ucd.ie.

Professor Walter Cullen (Principal Investigator) – 086 8583585; walter.cullen@ucd.ie Dr Jack Lambert (Principal Investigator) – 087 2613778; jlambert@mater.ie

Information for participating patients

Aim of the study
The objective of this study is to improve the outcomes of Hepatitis C care by studying the effectiveness of a new care programme which will help GPs to diagnose and treat people who are at risk of hepatitis C infection by training and enhancing access for specialist assessment.

What will you have to do?
You will be asked to continue treatment with your GP, which include but are not limited to, regular assessment, medication, laboratory investigations, counselling sessions and referrals to secondary care. To help us evaluate the new care programme, we seek your permission to examine all of your medical records and for us to interview you about the care you receive during the programme. Your interview will be audio recorded and unidentifiable for confidentiality. The audio recording will be transcribed and then deleted. Your medical records will be examined by the research team at 1,3,5,7 & 9 years after consenting to the study. If you are Hepatitis C negative, you will not continue in the study.

What are the benefits for you?
Participation ensures that you will be tested for Hepatitis C. If tested positive, you will then be the recipient of a structured care programme for Hepatitis C. You will only be given treatment if you are deemed suitable for treatment. If deemed unsuitable for treatment at the time of screening you will be given support to make you a suitable participant so that you can have the best chance of receiving treatment. If you test negative education will be given to reduce the risk of acquiring Hepatitis C virus.

What are the risks to you?
There are no obvious risks to you as a result of taking part in this care programme. However, as a participant you may be tested positive for Hepatitis C which you never knew you had. This may be upsetting and result in emotional distress, the nurse/doctor will explain what Hepatitis C is, what impact it will have on you and your health, will answer any questions you may have and will explain what the next steps are in relation to your care. Also while this is not a trial of a new medicinal product it is possible that you may experience some side-effects from medication if you are tested positive and receive treatment. The risks will be discussed with you.

What if I do not want to take part?
There will be no consequences to you should you decline to take part. You may still continue your follow ups with your GP.

What if I change my mind during the study?
There are no consequences if you decide that you do not want to continue. You may still continue your follow ups with your GP

Who is taking part?
Participation is open to patients who attend their GP for any reason during our recruitment period and fulfil our inclusion criteria.

What happens to information about me?
The information collected will not bear the names of participants. It will be stored securely and analysed to highlight the prevalence of Hepatitis C and to evaluate new care initiatives to improve treatment service. Findings will be published to contribute to service improvement and development.

Who can I contact about the study?
You can contact the Principal Investigators for this study if you have any queries.

Dr John S Lambert
Email jlambert@mater.ie
Tel 01-716-4530

Dr Walter Cullen
Email walter.cullen@ucd.ie
Tel 01-716-6561

Hepatitis C Screening Guidelines for General Practice

Below are the Hepatitis C screening guidelines for general practice as recommended by the (UK) Hepatitis C Screening National Clinical Guideline No. 15[7].

Persons to whom screening should be offered include

- Injecting drug users.
- persons who use illicit drugs, (sharing drug paraphernalia, e.g. bongs, crack pipes etc).
- possible sexual exposure, (low or no risk with heterosexual exposure, higher risk with HIV, anal sex, MSM and chemsex, etc.).
- vertical transmission.
- receipt of blood or blood products (in Ireland prior to Oct 1991 who have not yet been tested) See section 3.1.14 of National Screening Guidelines for more details.
- tattoos or body piercings.
- Homeless who have a history of engaging in risk behaviours associated with HCV transmission, or who have potential HCV risk exposure.
- pregnant women who may be at risk (chance to intervene to prevent vertical transmission),
- persons with history of incarceration.
- household contacts/family members, (risk is low and no need to test unless there is HIV co-infection, exposure to blood i.e. razor, toothbrush sharing, current IVDU or also can test if patient requests same).
- persons from a country with high prevalence of HCV (countries with anti-HCV prevalence >2%, see Appendix 2 in Hep C Screening Guidelines).
- persons who received medical or dental treatment abroad (countries with poor infection control).

Blood tests to be performed

- Initially perform anti-HCV or antibody/antigen test and If positive this should be directly followed by testing for the detection of HCV-RNA to confirm current infection.
- Current infection should be confirmed on a second sample and HCV-RNA (Viral Load) should be performed (if not already performed).
- and HCV genotyping should be carried out.
- Those individuals with evidence of a resolved HCV infection (i.e. anti-HCV positive and antigen/ RNA negative) should have a further sample drawn after six to 12 months for HCV-RNA testing to confirm their resolved infection status.
- Persons who you have screened and are HCV antibody/antigen negative but have ongoing risk of infections should be retested every six months.
- Harm reduction information should be provided. (see guidelines on Harm Reduction related to Injecting drug use).
- If patient is HCV RNA positive they should be referred to Hepatology/Infectious Diseases in local hospital for assessment for treatment of Hepatitis C.
- Also consider HIV, Hepatitis B testing also.

Please refer to the following resources for further information

Ireland's National Hepatitis C Strategy:
https://www.hse.ie/eng/services/Publications/HealthProtection/HepCstrategy.pdf

(UK) Hepatitis C Screening Guidelines:
http://health.gov.ie/wp-content/uploads/2017/08/HepC-NCG-15_Summary_v8.pdf

Harm Reduction Guidelines:
http://www.drugsandalcohol.ie/5812/

HepLink nurse intervention

This is an outline of the HepLink nurse intervention carried out at the Dublin site, followed by a Flow Chart of the process (Figure 2).

- Nurse meets with General Practitioner and explains her role as the HCV liaison nurse. She discusses the study and what it entails, the assessment of the participants, organising testing if required, fibroscanning and assisting with referral to specialist services. The recruitment process is explained to the GP. 10 consecutive OST patients on opiate substitution therapy are to be recruited. Once informed consent is obtained the nurse arranges to return to the practice and meets with the participants.

- Nurse meets with the participants, explains her role as the HCV liaison nurse. The assessment and referral process is explained. All questions and queries that the participant may have are addressed. She then checks the participants medical record regarding their HCV status and assesses if the patient knows their status or not. Risk status is also assessed, checking whether the participant has been at risk in the past or currently at risk of contracting HCV.

  a) If HCV Ab is unknown or never tested the nurse arranges for HCV testing to take place with the GP.

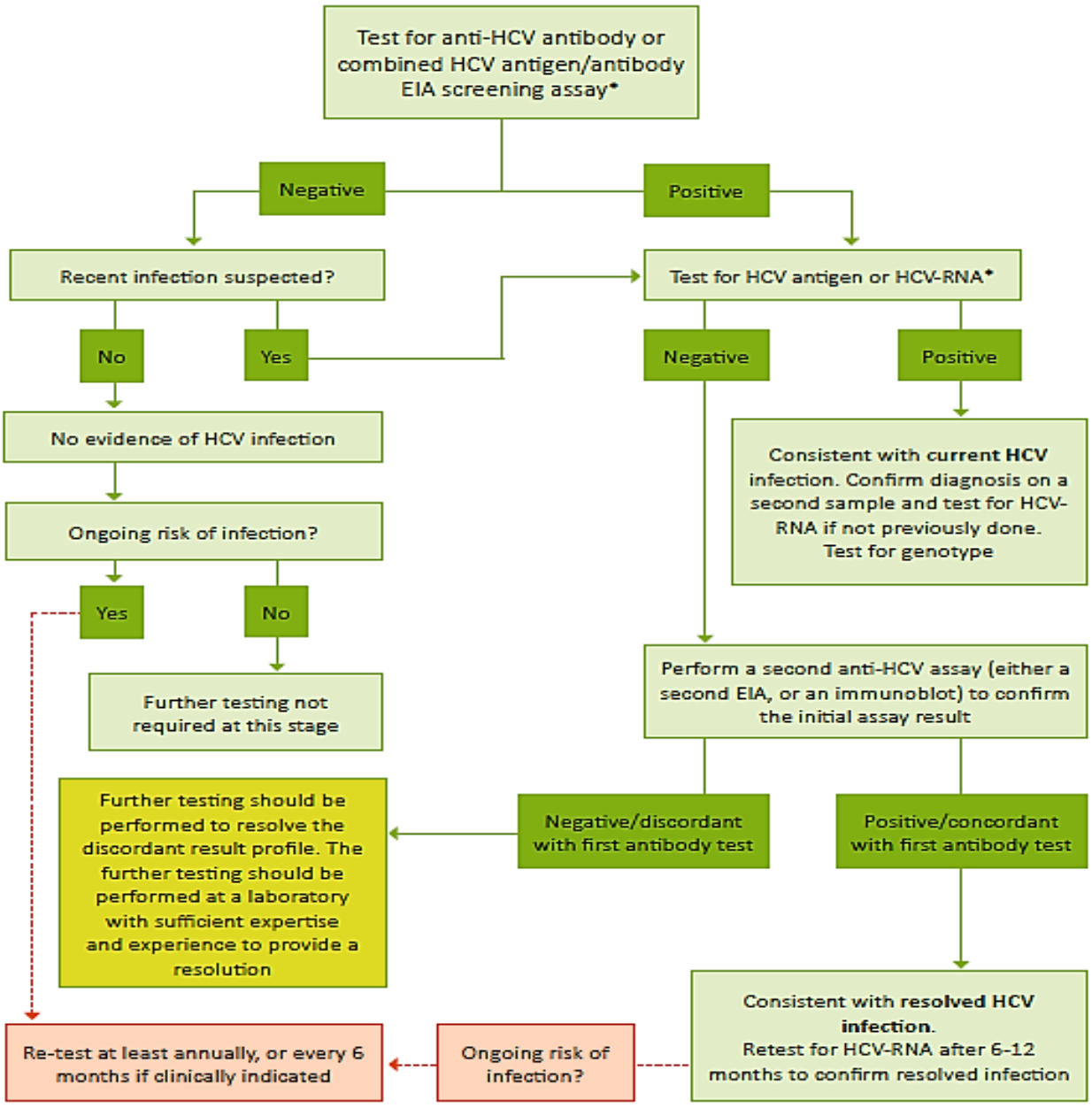
  b) If HCV Ab is negative the nurse carries out an addiction assessment including drug use, alcohol use etc. Information/education re HCV is given, including what HCV is, how it is transmitted and how to prevent transmission. Harm reduction strategies are addressed if required. If participant has engaged in practices which may have put them at risk of HCV since last tested re-testing is arranged with the GP, otherwise she advises the GP to carry out yearly HCV as per national HCV Screening Guidelines (Department of Health, July 2017). A handover of the nurse's assessment regarding these participants is given to the GP.

- If HCV Ab is positive and PCR (RNA) is negative process is as per section 3. (b). If HCV RNA is positive/unknown nurse carries out and addiction assessment including drug use, alcohol use etc. Fibroscan test is carried out and findings are explained in detail to the participant. Information/education re HCV is given including what HCV is, how it is transmitted and how to prevent transmission. Harm reduction strategies are addressed with the participant if required. RNA testing is arranged with GP if status is unknown. A handover of the nurse's assessment regarding these participants is given to the GP.

- Participants are referred to specialist services if they are HCV Ab+ and Ag/RNA+/unknown. This process is carried out by the GP with the assistance of the HCV liaison nurse. Referrals are submitted the Hepatology or Infectious Diseases department.

Figure 1: HCV National Screening Guidelines (UK)

Flow chart describing assessment pathway for HCV infection as recommended by the Hepatitis C Screening National Clinical Guideline No. 15[7].



*In certain patient groups, initial testing should routinely incorporate HCV antigen or HCV-RNA testing. Those are: immunocompromised individuals; individuals previously treated for HCV infection; and those at risk of recent infection in whom an antibody response might not yet have developed (HCV-RNA testing should be performed 6 weeks post-exposure).

Figure 2: HepLink - Nurse-led intervention clinical assessment flow chart

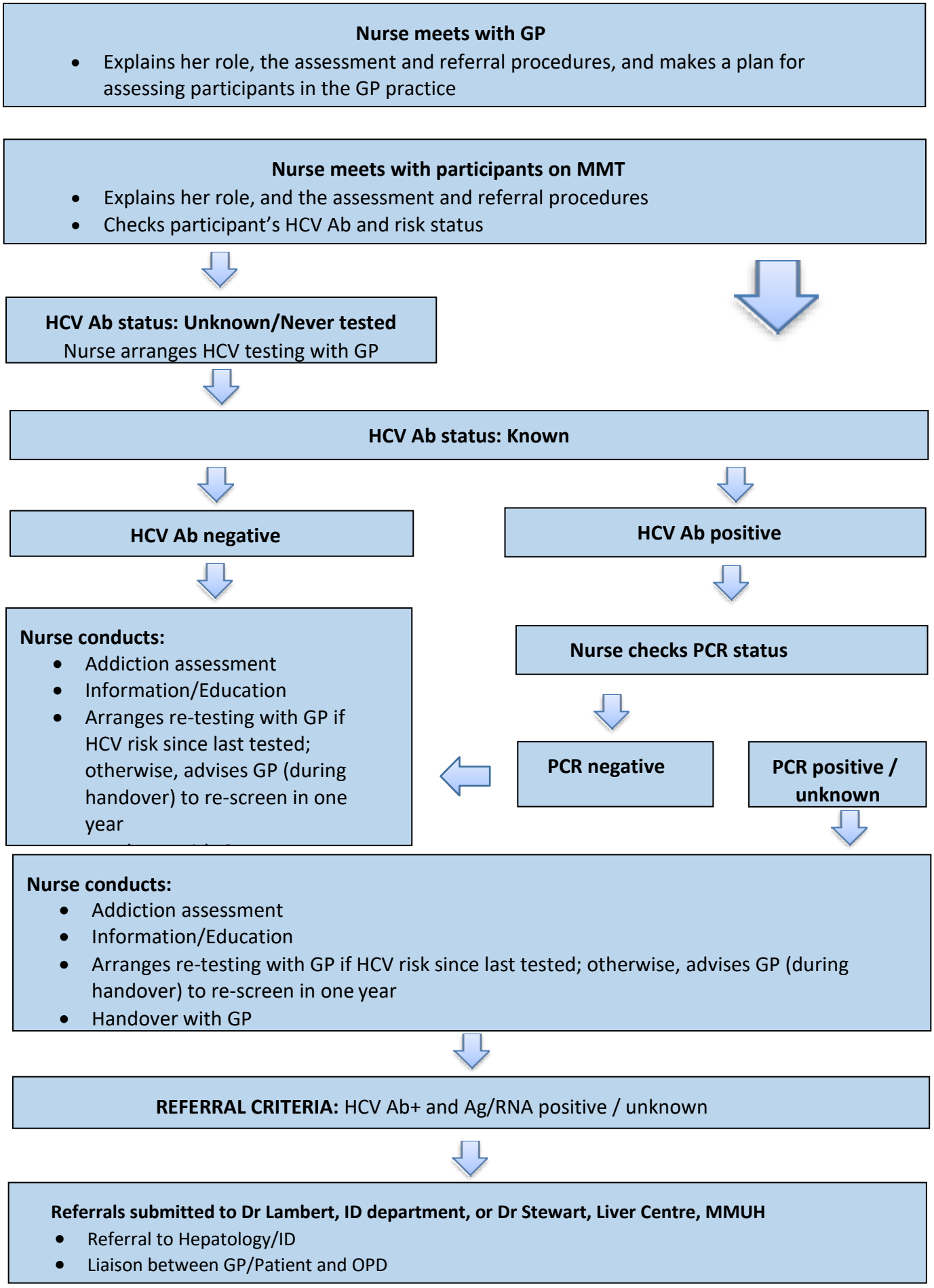


Figure 3: Clinical Assessment Proforma

This document was used by the liaison nurse to collect data on patient demographics and HCV care processes and outcomes when conducting clinical assessment in community settings / primary care.

PATIENT DETAILS	
First name	
Surname	
DOB (DD/MM/YYYY)	
Gender	☐ Male ☐ Female ☐ Unknown
Address	
Tel	
Email	
Key contact person	Name: Relationship to patient: Contact details:

For office use only: Participant ID:

(If assessment was completed over more than one visit, please complete date/time for each)

DATE OF ASSESSMENT:	**ASSESSMENT CONDUCTED BY:**	**START TIME:**	**FINISH TIME:**

RISK FACTORS	
Ever injected drugs? Circle No Not sure Yes → 	If *yes* - Age started: Age stopped (if applicable): Shared recent (past 12 months)? Please circle Y / N Shared ever? Y / N If injecting currently, specify frequency: _____ injections per day/week/month (please circle)
Ever incarcerated? Circle No Yes →	If yes – When last time incarcerated: How long for (months): Where: _____
Other risk factors? If *yes* for any of following, please specify *when* and *where*:	When/Where Tattoo Y / N _____ Piercing Y / N _____ High burden country Y / N _____ Needle Stick Y / N _____ Close contact Y / N _____ Blood transfusion Y / N _____ STI test Y / N _____
Current Housing status? Circle one	☐ Rough Sleeping ☐ Insecure ☐ Hostel ☐ Secure

ADDICTION TREATMENT	
On OST currently? Circle No Yes →	If *yes*, what OST (circle one): ☐ Methadone ☐ Diamorphine ☐ Buprenorphine ☐ Other (specify):_____ How long on OST (current episode)? _____ days/weeks/months/years (please circle)

ALCOHOL USE	**Scoring System**					
	0	**1**	**2**	**3**	**4**	**Score**
How often do you have a drink containing alcohol?	Never	Monthly or less	2-4 times per month	2-3 times per week	4+ times per week	
How many units of alcohol do you drink on a typical day when you are drinking?	1-2	3-4	5-6	7-9	10+	

How often have you had 6 or more units if female, or 8 or more if male, on a single occasion in the last year?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	

HEPATITIS C TESTING / TREATMENT	
Previous HCV Antibody test? Circle **NO** **NOT SURE** **YES** →	Date: Where (i.e. service): Result: ☐ HCV Ab **negative** ☐ Don't know ☐ HCV Ab **positive**
Previous HCV Antigen test? Circle **NO** **NOT SURE** **YES** →	Date: Where (i.e. service): Result: ☐ HCV Ag **negative** ☐ Don't know ☐ HCV Ag **positive**
Previous HCV RNA test? Circle **NO** **NOT SURE** **YES** →	Date: Where (i.e. service): Result: ☐ HCV RNA **negative** ☐ Don't know ☐ HCV RNA **positive** **If positive: HCV Viral Load:** **Genotype:**
Referred to secondary care for HCV assessment previously? Circle **NO** **YES** →	When: Where: Outcome: ☐ Currently attending/engaged ☐ Defaulted/Disengaged (i.e. never attended or stopped attending) ☐ Other (*specify*):
Treated for HCV previously? Circle **NO** **YES** →	When: Where: Outcome: ☐ On treatment currently ☐ SVR ☐ No SVR ☐ Unknown SVR ☐ Other (*specify*):

HIV TESTING	
Previous HIV Antibody test? Circle **NO** **NOT SURE** **YES** →	Date: Result: ☐ HIV Ab **negative** ☐ Don't know ☐ HIV Ab **positive**
HEPATITIS B TESTING	
Previous HBV Antibody test? (anti-HBs/anti-HBc) Circle **NO** **NOT SURE** **YES** →	**Anti-HBs** Date: Result: ☐ anti-HBs **negative** ☐ anti-HBs **positive** ☐ Don't know **Anti-HBc** Date: Result: ☐ anti-HBc **negative** ☐ anti-HBc **positive** ☐ Don't know
Previous HBsAg test? Circle **NO** **NOT SURE** **YES** →	Date: Result: ☐ HBsAg **negative** ☐ Don't know ☐ HBsAg **positive**
IMMUNIZATIONS	
HBV Immunization ever? Circle **NO** **NOT SURE** **YES** →	Date: Number of Doses (Circle): 1 2 3 Outcome: antibody titre levels:
HAV Immunization ever? Circle **NO** **NOT SURE** **YES** →	Date: Number of Doses (Circle): 1 2 3 Outcome: antibody titre levels:

FIBROSCAN	
	Previous fibroscan (ever)? Y / N If Yes: Previous fibroscan date: Previous fibroscan score:
	For Fibroscanning? Y / N Median stiffness (Kpa): Valid measures: IQR: IQR/med: Date done: Fibroscan Operator: ☐ **Patient declined scan** ☐ **Unable to scan**
	Notes:

FOR REFERRAL?	☐ Yes ☐ No If Yes, Date referral made: Where referred:
EDUCATION GIVEN?	☐ Yes ☐ No

RECOMMENDATIONS TO GP:

HCV Antibody test	Y / N	HIV Antibody test	Y / N
HCV Antigen test	Y / N	HBV Antibody test	Y / N
HCV RNA test	Y / N	HBsAg test	Y / N
Referral to secondary care for HCV assessment	Y / N	HBV vaccination	Y / N
		HAV vaccination	Y / N

NOTES:

FOLLOW-UP INTERVENTIONS CONDUCTED BY GP/PRACTICE	
HCV Antibody test Circle **NO** **YES** →	Date: Done by: Sample sent to: Date sample sent: HCV Antibody Result (please circle): □ Negative □ Indeterminate/unable to process □ Positive
HCV Antigen test Circle **NO** **YES** →	Date: Done by: Sample sent to: Date sample sent: HCV Antigen Result (please circle): □ Negative □ Indeterminate/unable to process □ Positive
HCV RNA test Circle **NO** **YES** →	Date: Done by: Sample sent to: Date sample sent: HCV RNA Result (please circle): □ Negative □ Indeterminate/unable to process □ Positive **If positive:** HCV Viral Load: Genotype:
Referral to secondary care Circle **NO** **YES** →	Date: Done by: Where referred:
HIV Antibody test Circle **NO** **YES** →	Date: Done by: Sample sent to:

	Date sample sent: HIV Antibody Result (please circle): □ Negative □ Indeterminate/unable to process □ Positive
HBV Antibody test Circle **NO** **YES** →	Date: Done by: Sample sent to: Date sample sent: HBV Antibody Result (please circle): **Anti-HBs** □ Negative □ Indeterminate/unable to process □ Positive **Anti-HBc** □ Negative □ Indeterminate/unable to process □ Positive
HBsAg test Circle **NO** **YES** →	Date: Done by: Sample sent to: Date sample sent: HBsAg Result (please circle): □ Negative □ Indeterminate/unable to process □ Positive
HBV vaccination Circle **NO** **YES** →	***Doses:*** ***Date:*** ***Done by:*** HBV Vacc 1 □ _____ _____ HBV Vacc 2 □ _____ _____ HBV Vacc 3 □ _____ _____
HAV vaccination Circle **NO** **YES** →	***Doses:*** ***Date:*** ***Done by:*** HAV Vacc 1 □ _____ _____ HAV Vacc 2 □ _____ _____ HAV Vacc 3 □ _____ _____

Appendix 1. References.

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6. *Swan D, Cullen W, Macias J, et al. Hepcare Europe - bridging the gap in the treatment of hepatitis C: study protocol. Expert Rev Gastroenterol Hepatol 2018;12(3):303-14.*
7. *Department of Health (2017). Hepatitis C Screening (NCEC National Clinical Guideline No. 15 Summary). Available at: http://health.gov.ie/national-patient-safety-office/ncec/national-clinical-guidelines.*

Appendix 2. Site specific information.

In this appendix, we present additional documentation that was used at each clinical site across the consortium, specifically:

- Department of Infection and Population Health, University College London, 406a, Mortimer Market Centre, London.

- Victor Babes Clinical Hospital for Infectious and Tropical Diseases, 281 Mihai Bravu Avenue, Bucharest, Romania.

- Unidad de Enf. Infecciosas y Microbiología; Hospital Universitario de Valme, Avda Bellavista, Seville, Spain.

Appendix 2.1. Additional documentation - London, UK

Recruitment
The HepLink model was adapted as part of the Find&Treat service which provides testing and linkage to care interventions for homeless and hard-to-reach populations in London.

Participants were recruited from OST-prescribing clinical sites based in the community and in primary care and other sites involved in the management of persons with high risk behaviour. Methadone prescribing services were recruited from the professional networks/databases of the outreach team.

Eligibility: Patients were eligible to participate if they were aged at least 18 years and were receiving OST or had a history of high-risk behaviour including prior or current injecting drug use and were engaged with the prescribing service. The team instructed participating services via case managers to recruit consecutively presenting patients who were eligible and interested to participate.

Intervention
The intervention consisted of:

- Outreach of a HCV-trained liaison nurse and peer support worker into prescribing services;
- In-practice education for service staff regarding developments in the diagnosis and treatment of HCV
- Enhanced access of patients to community-based evaluation of HCV disease, including a novel approach to diagnosis, i.e. POCTs, transient elastography (FibroScan), peer support
- Researcher-facilitated practice audit of HCV care processes and feedback to lead of service

HepLink Nurse Intervention

- Nurse meets with key workers in prescribing clinic and explains their role as the HCV liaison nurse. They discuss the intervention and what it entails, the assessment of the participants, organising testing if required, fibroscanning and assisting with referral to specialist services.
- Patients are identified by site staff and invited to attend to the service to meet with the recruitment nurse in a clinic at site. A patient information sheet was provided prior to baseline visit (see PIS attached).
- Once a patient attends clinic, informed consent is obtained by the outreach nurse. All questions and queries that the participant may have are addressed. They then check the participant's patient record regarding their HCV status and assesses if the patient knows their status or not. Risk status is also assessed, checking whether the participant has been

at risk in the past or currently at risk of contracting HCV. Information is collected on a baseline screening form.

HCV testing, baseline visit:

HCV Ab status unknown: HCV Ab POCT oral mouth swab: result given in 20 mins.

- If positive see next step.
- If negative: Information/education re HCV is given, including what HCV is, how it is transmitted and how to prevent transmission. Harm reduction strategies are addressed if required. Regular re-test recommended if at risk every 6 months.

HCV Ab positive / No HCV RNA result

- HCV RNA test via dried blood test (DBS)
- Fibroscan done

HCV RNA result (after approx. 1 week)

- HCV RNA positive
  - Site staff refer to local specialist service
  - Peer support from HepCare team helps recruit attend subsequent appointment.
- HCV RNA negative
  - Post-test education given regarding risk and importance of regular re-testing.

Follow-up data regarding patient engagement collected by peer support worker or nursing staff.

Appendix 2.2. Additional documentation - Bucharest, Romania

Recruitment

This study was performed across nine sites in Bucharest and the surrounding area including night shelters (n=3), centers for OST (n=3), prisons (n=2) and other health care facilities (n=1). Medical and social services were provided for patients at these sites.

215 participants were recruited and baseline data was collected between April 2016 and June 2018. Data was typically self-reported by patients. Medical records were also used, where available.

Patients were eligible to attend if:

- At least 18 years old
- High risk behaviour (e.g. active or past injecting drug use, homeless, prisoners, etc.)

Participants were recruited following invitation to screening at the relevant site. During screening a GP and research team member were present. Counselling and testing were performed and informed consent was gained. They were invited to engage in follow-up and scheduled for a hospital appointment. There were also 5 GPs who performed HCV screening during their practice and referred positive patient to hospital for linkage to care.

Baseline data was collected for all 215 patients on:

- Demographic characteristics: age, gender, ethnicity
- Medical services and outcomes related to their HCV status during lifetime and especially past 12 months (screening, follow-up, treatment, SVR)
- Screening, vaccinations (where vaccines are available) and outcomes related to others blood born and hepatotropic viruses (HIV, HBV, HVA)
- Access to medical services (emergency department) during past month
- Chronic illness

It is important to highlight that urinalysis for illegal drug use is not done routinely in our department. Screening for alcohol abuse is not a common practice in our department and there are few specialised services for this problem in Romania. There is also lack of adequately trained personnel who can initiate screening in such departments. OOH is also an uncommon practice in our country, so only the emergency department can be accessed by patients when they need medical services and the GP is not available.

Intervention

The “HepLink” intervention involves social workers from the hospital and from an NGO who helps the patients to solve their social problems related to identity and health cards, as well as the health insurance. Without these documents it is impossible for the patients to have access to adequate services. These social workers and the psychologist from the hospital

guide them to local authorities responsible for the release of identity documents and to the National House of Health Insurances and helps them to complete the necessary forms in order to obtain these documents. This is a very important step for linkage to care in our region, because without these eligible documents, our patients can't be followed up and can't have access to treatment.

Nine peer support sessions were organized in our setting, coordinated by social workers and psychologists from our HepCare team, as well as by social workers from NGOs.
Educational materials (flyers and booklets) for patients and social workers with brief information on chronic hepatitis C were created and distributed by the Hepcare team in waiting rooms of the hospitals, GPs practice, night-shelters, prisons, drug support centers and to people living on the streets.

Liver fibrosis was evaluated with a mobile Fibroscan (from Dublin) or by Fibromax (mainly during hospitalization). Fibroscanning was performed both in our hospital and in Rahova prison. Our HepCare team, including HCPs, nurse, social workers and psychologists, went to prison and performed both screening with OraQuick rapid oral tests and liver fibrosis evaluation using the mobile fibroscan.

HepLink Nurse Intervention

- Liaison nurse performed rapid oral tests at drug support and opioid substitution centers, prisons and night centers.
- Follow up with HCPs from these centers and scheduled positive patients for medical appointments at the hospital for further evaluation and linkage to care.
- Nurse directly contacted patients and scheduled them for medical appointments when their blood tests results were available.
- Nurse provided counseling and facilitated communication with the treating physician.
- Nurse involved in Fibroscan evaluation for patients who were referred to the hospital.

Appendix 2.3. Additional documentation - Seville, Spain

Recruitment

Four OST-prescribing primary care centres participated. Primary care centres were eligible to participate if they prescribed OST and were located in Seville health districts.

Patients were eligible to participate if they were receiving OST or at risk of HCV infection and attending one of the primary care centres. Practices were recruited from the professional networks/databases of the research team. In this way, 109 patients were recruited for the study.

Baseline (pre-intervention) data was collected between January 2017 and April 2018 on 96 patients via patients' medical records and patient self-report using a questionnaire purposively developed for this study.
Patients were eligible to participate if:

- ≥18 years of age,
- At risk of HCV infection
- On OST, and
- Attending the practice for any reason during the recruitment period

GPs provided eligible patients with a verbal explanation of the study and a written information leaflet outlining the study's purpose, procedures and how the findings would be utilised. Patients who were interested in participating were asked to sign a consent form which was witnessed by the GP and/or a member of the research team. While the initial approach to participate was from the GP, recruitment was facilitated by a member of the research team being 'on site' (where feasible) to support the practice during the recruitment phase and answer any questions potential participants might have.

Baseline data was extracted on:

- Demographic characteristics - age, gender
- Lifetime and past-12 month care processes/outcomes in relation to HCV (i.e. HCV screening and antibody status, Ag/RNA testing and status, referral to hepatology/ID, attendance at hepatology ID, fibroscanning scores, HCV treatment initiation, completion and SVR)
- Lifetime and past-12 month care processes/outcomes in relation to other blood borne viruses and hepatotrophic viruses (HIV and HBV)
- Problem alcohol use screening, in past year
- Health service utilisation (emergency department, GP out of hours) in past month

Intervention

The “HepLink” intervention involved outreach of a HCV-trained nurse into GP practices to provide clinical support to GPs/practice staff and to enhance referral of HCV-infected patients to hepatology/infectious diseases services for HCV treatment.

The HepLink nurse provided education to GPs and practice staff on developments in diagnosis and treatment for HCV. The nurse clinically assessed participating patients at the GP practice regarding HCV risk and HCV infection status and treatment history. In addition, she assessed their risk and infection status for other blood borne viruses and hepatotrophic viruses (HIV, HBV). The nurse also assisted the GP completing referrals of HCV-infected patients to secondary care for HCV treatment.

HepLink Nurse Intervention

- Nurse attendance at clinical site.
- Personal interview with the patient, involving HCV-related history and Anti-HCV Ab test on site.
- Determination of the status of HCV infection:
- Anti-HCV unknown: Anti-HCV determination in blood or saliva.
- Anti-HCV (-): Education on HCV infection and brief intervention on risk reduction.
- Anti-HCV (+): Report the situation and determine the HCV RNA; Education about contagion and prevention as well as the possible options after the result of the HCV RNA.
- HCV RNA (-): Report with results.
- HCV RNA (+): Direct appointment in outpatient clinics.
- Transport specimens to Microbiology laboratory.
- Follow-up of results.
- Initial on-site, HCV assessment in order to reduce visits to the hospital.
- Personalized appointments and reminder to patients.
- Completion of FibroScan.
- Direct contact with professionals from specialist centre.
- With the results of HCV viremia, if there is any evidence that an active infection exists, the nurse makes an appointment adapting it to:
- Availability of the patient to avoid loss of time in the hospital.
- Laboratory and imaging tests previously appointed for the same day of the 1st outpatient visit.
- Reminder to patients the day before their appointment.

Appendix 3. Patient information resource on Hepatitis C infection

Are you Hep C aware?

awareness

support

information

prevention

What is Hepatitis C?

Hepatitis C is a viral infection that affects the liver, causing it to become inflamed and not work as effectively in the body.

About Hepatitis C

- Hepatitis C is a serious chronic illness that requires treatment
- Hepatitis C is a curable disease for most
- Hepatitis C testing is free at public testing clinics
- You can get hepatitis C through contact with an infected person's blood
- The only way to know if you have hepatitis C is to get tested
- Untreated hepatitis C can cause serious health problems, such as liver disease
- Hepatitis C will not go away in about 4 out of every 5 people who become infected - it will become chronic and will require treatment

Signs and Symptoms

You can have hepatitis C and not have any signs or symptoms.

However, if symptoms exist they can include:

- Tiredness/fatigue
- Nausea
- Loss of appetite
- Vomiting
- Abdominal pain and discomfort
- Swelling of the abdomen
- Fever
- Jaundice (yellowing of the skin and the whites of the eyes)

These signs and symptoms can also be associated with other illnesses or infections.

Do You Know?

Most people will show no signs or symptoms of initial infection.

Are you at risk?

Hepatitis C is a blood-borne virus. You can get it through blood-to-blood contact with an infected person's blood.

Do You Know?

Hepatitis C can still be passed on to others even if a person has no symptoms.

You can get it through:

- Blood to blood contact
- Using/sharing drug injecting equipment (highest rate of transmission) and using/sharing contaminated snorting/smoking equipment
- In rare cases, it can be transmitted through certain unprotected sexual practices if blood is present
- Mother to child during childbirth although rare (breastfeeding is possible if nipples are not cracked and bleeding)
- Tattoos, body modifications and acupuncture if the tools used were not sterilised properly after being used on another person

Prevention

Use safer drug-using practices, safer sex practices, and get tested.

Hepatitis C is a preventable illness. You can avoid infection by:

- Safer drug using practices: avoid sharing any drug-using equipment.
- Do not share personal grooming items e.g. razors, tweezers, toothbrushes, nail scissors, with an infected person.
- If getting tattoos or body piercings ensure that the facility is licensed and the equipment used is sterilised.
- Use condoms for anal, vaginal and oral sex, and avoid sharing sex toys.
- Make informed decisions: talk to partner(s) about testing, drug-using practices and safer sex practices, and get informed about the risks.
- Use common sense when cleaning up spillages of human blood and body fluids – wear gloves for example. Take care to avoid needle stick injuries where needles and other skin piercing equipment are used.
- Get tested, and treated if required. Ask about free tests at public testing clinics.

Do You Know? Hepatitis C can live outside the body on surfaces for several days and is considered 10 times more infectious than HIV.

Who should go for a Hepatitis C test?

Anyone who thinks they may have had, at any time, a risky exposure to hepatitis C, should get tested.

- Anyone who has any symptoms
- Anyone who has ever injected drugs (including steroid and botox injectors)
- Anyone who has ever shared drug-using equipment including injecting, skin popping, smoking and snorting equipment
- People with sexual partners who have hepatitis C
- HIV-positive people
- Children born to mothers who have hepatitis C
- Health/social care workers that are exposed to infected blood or body fluids at work
- Anyone who received a tattoo with needles that were not sterilised properly
- Those travelling or residing in countries with high rates of infection

Testing

Hepatitis tests are simple, painless, confidential and free at public STI Clinics.

Tests for hepatitis C are free at public STI testing Clinics.
Ask for a free test if you think you have been at risk. For a list of clinics see **www.hepinfo.ie**.

The test for hepatitis C is two blood tests: one to check if a person has ever had hepatitis C, and a second to test if a person currently has hepatitis C. It is very important that a person gets both tests.

Treatment

The goal of new hepatitis C treatments is cure.

Do You Know?

There is currently no vaccine for hepatitis C.

There are two main phases of Hepatitis C infection: acute (short-term) and chronic (long-term).

Treatment for hepatitis C is dependent on:

- Whether it is an acute or chronic infection
- What genotype you are infected with; (there are currently 6 different genotypes of

More information

www.hepinfo.ie for information on hepatitis C and free testing.

Freephone the Hepatitis Helpline on **1800 459 459** for confidential support and information.

DEVELOPED BY:

Dublin AIDS Alliance

Community Response

HEPATITIS C PARTNERSHIP

INFORM · EMPOWER · SUPPORT

HEP C PEER SUPPORT GROUP

Health

Empathy

Prepare

Cure

Peer Support Group for People Living with HEP.C

This group is aimed at people who are experiencing difficulties with Hep C. It is a support group that aims to be informative and educational. It will be facilitated by Community Response workers.
(Every Thursday: 2.30pm – 4.00pm)

Community Response

Community Response
14 Carmans Court, Carmans Hall, Dublin