HepCare Europe

HOW TO REACH THE RISK GROUPS

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HEPCARE EUROPE is a €1.8M 3-year EU-supported project at 4 member state sites

**Consortium members:** UCD (Ireland); SAS (Spain); SVB (Romania); University of Bristol (UK); University College London (UK)

**Aims** to improve access to HCV testing and treatment among key risk groups, including drug users and homeless, through outreach to the community and integration of primary and secondary care services

‘HEPCARE’: A new user-friendly Hepatitis C Care service model

Co-funded by the Health Programme of the European Union
Issues that need to be addressed to make HCV a ‘rare disease’ in the EU:

* Community Education (preparing the at risk population for testing, assessment and treatment)
* Community Health Care worker education: to give them a better understanding of the new treatment regimes, and to prepare them to act as partners in treatment and support in a ‘shared care’ primary/secondary integrated partnership.
* Testing of the utility of point of care testing with HCV oral tests in diverse populations and different countries/settings and assessment of the cost effectiveness of such a strategy.
* Implementation of a community Fibroscan testing strategy and evaluation of the effectiveness of such a strategy; and for those identified with advanced disease, reasons for non-attendance.

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Issues that need to be addressed (2)

* Development of a community focused assessment for HCV disease in those identified as HCV positive utilising community nurse outreach and peer advocacy support, as vulnerable communities have not and do not access secondary care services.

* Development of educational tools and pathways for those who test negative for HCV, to ensure that their risk of subsequent risk of acquisition of HCV and other blood borne viruses are minimised.

* Linking up disease services, so that Drug and Alcohol Addiction, Primary Care, STD, blood borne virus testing, TB evaluation and treatment, Hepatitis B vaccination, are all addressed in vulnerable populations in a linked up fashion.
Advantages of Fibro Scan

* Rapid test that allows POCT: Entire scan 5-7 minutes to complete.
* Allows clinicians to arrange OGD or liver ultrasound urgently if evidence of cirrhosis on baseline fibro scan.
* Non invasive procedure/ No pain/No sedation required.
* No risk of bleeding or infection which are potential complications of liver biopsy.
* No requirement to admit as a day case.
* Inexpensive scan.
* 96% specificity when compared to liver biopsy staging

Helps stratification and prioritisation.
RESULTS from one Dublin OST Site

* The fibroscan scores ranged from 3.6- 75.0 kpa.
* 32% (n=62) of all patients scanned scored > 8.5 kpa (at that time current Irish DAA treatment eligibility criteria).
* 60% were HCV diagnosed more than 10 years ago.
<table>
<thead>
<tr>
<th>NON-ATTENDANCE</th>
<th>(n)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never Referred/unaware if referred.</td>
<td>20</td>
<td>32.7</td>
</tr>
<tr>
<td>Attended at least once but no f/up offered/received.</td>
<td>30</td>
<td>50</td>
</tr>
<tr>
<td>Fear (of illness and/or tx)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Prison/Incarceration</td>
<td>1</td>
<td>1.6</td>
</tr>
<tr>
<td>Chaotic lifestyle:drug/alcohol use</td>
<td>6</td>
<td>9.9</td>
</tr>
<tr>
<td>Told treatment / f/up not needed/Not ill enough</td>
<td>2</td>
<td>3.3</td>
</tr>
<tr>
<td>Encouraged to wait for new tx</td>
<td>4</td>
<td>6.6</td>
</tr>
<tr>
<td>Still engaging with secondary care/monitored at least annually.</td>
<td>12</td>
<td>20</td>
</tr>
<tr>
<td>Unaware of HCV pos status</td>
<td>2</td>
<td>3.3</td>
</tr>
<tr>
<td>Completed tx</td>
<td>2 (1 X DAA/ x1 INTERFERON)</td>
<td>3.3</td>
</tr>
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Primary Care Study N. Dublin: Heplink
Methods

- Methadone prescribing GP practices in North Dublin were recruited from the professional networks / databases of the research team.

- Patients were eligible to participate if:
  - ≥ 18 years of age
  - on MMT
  - attend the practice for any reason during the recruitment period

- Baseline data on HCV care processes / outcomes were extracted from the clinical records of participating patients.
GP Practices recruited n=13

Patients recruited n=91 (9 practices)

Baseline Data Collected n=73 (7 practices)

HCV positive patients undergone fibroscan n=15

Patients referred to secondary care n=7

GP Practices received HepLink model of care n=4
Patient Characteristics at Baseline (n=73)

* **Demographics**
  * Gender: Male 65.8% (n=48); Female 34.2% (n=25)
  * Age: Median 40 yrs (range 28-71 yrs)

* **HCV Testing**
  * 91.8% (n=67) of participants had been tested for HCV infection

* **HCV Status**
  * 71.6% (n=48) of those tested were HCV Antibody positive
Co-infection

- 6.3% (n=3) of HCV Ab+ participants were co-infected with HIV
- 4.2% (n=2) of HCV Ab+ participants were co-infected with HBV

Attendance at Hepatology/ID

- Less than half (47.9%; n=23) of HCV Ab+ participants had attended secondary care for specialist assessment
* The integrated model of HCV care has been piloted in 4 GP Practices to date

* 15 HCV Ab+ patients have undergone a fibroscan

* 8/15 (53.3%) scored above ≥8.5 kPa which until recently has been the threshold for access to the new DAA treatments in Ireland
All ‘identified’ cirrhotic patients with HCV have been treated

- The ‘unidentified’ ones count too
- Using pilot fibroscan data from Drug treatment Centres in Dublin 25% of HCV patients have high fibroscan scores
- Using pilot fibroscan scores from Methadone prescribing GP practices 30% have high fibroscan scores.
- Over 10,000 patient on registry for OST in Dublin
- Estimate 70% HCV positive, 70% viremic
- We still have 1600 in the community with advanced disease
- Dropping the ‘fibroscan score’ was a strategic decision to ensure the ‘tender quota was met’, not to ensure that those who were ill would access care.
- There are still many cirrhotics out there; and a ‘pilot’ study to enroll 100 in the community with HCV will not benefit them; they may not survive into 2018
Hepatitis C: the opportunity to make it a ‘rare disease’ in Ireland

* We can cure patients with HCV
* Drugs are safe to be given in the community with minimal monitoring
* The costs are currently prohibitive, but will come down with time
* Community Partnership is critical as most patients will not come to the Hospital Clinics
* Partnership with Primary Care is essential
* Partnership with the Community and Peer Support groups are essential
* To delay identification of HCV advanced disease in the community will result in unnecessarily patients presenting to tertiary care with decompensated liver disease and HCC
* Additional financial investment in the community will be needed to ensure that ‘vulnerable populations’ access treatment
Ireland’s Plan for the Future 2017

- Eliminate fibroscan criteria for DAA treatment (previously fibroscan score of 8.5 needed)
- Plans to treat 1600 patients in the hospital setting in 2017
- There are still 1600 out there in the community, not engaged in care, with high fibroscan scores based on initial projections from our community fibroscanning statistics. Who will provide their care?
- The Irish HSE plan is to pilot 100 community patients in drug treatment centres with community dispensed DAA therapies in 2017
- No additional monies/resources are being put into the community to assist ‘vulnerable populations to access testing, support and treatment
- More monies may be provided in 2017 to the ‘hospital based HCV services’.
Ireland’s Plan (2)

- There are currently 20,000+ in Ireland with HCV, 750 who have been treated in 2016, and a planned 1600 hospital based treatments budgeted for in 2017.
- However most of those who to be treated, with elimination of fibroscan score, will have no/minimal disease ie HCV infection but no disease
- HepCare teams’ priority is to treat disease first, not just infection
- How do we advocate for those 1500 out in the community, vulnerable populations (homeless, IDU) with advanced HCV related liver disease who are not accessing care in the hospital centres?
- How do we ‘seek and treat’ the additional 17,000+ in Ireland out there?
- Clearly more monies for community partnerships needed, and better coordinated efforts to link up hospital and community services
The hidden burden of hepatitis C related advanced liver disease in the community

Nadeem Iqbal, Carol Murphy, Tina McHugh, Aileen Singleton, Shay Keating, Des Crowley, Hugh Gallagher, Fidelma Savage, John Maloney, Jack Lambert, Stephen Stewart.

A total of 618 consecutive patients (75% male, mean age 38 ±7.2) were assessed. HCV status was known in 91% (561) of patients with 70% (391) being HCV +ve. The mean FS score was higher in the HCV +ve patients than the HCV –ve (11.0kPa ± 12.4 v 5.6kPa ± 4.0; p = 0.001). In the HCV +ve group, patients that drank alcohol (35 %) had a higher score than those that were abstinent (13.2kPa ±16.4 v 9.7kPa ±9.9; p = 0.02). There were 128 (33% of total cohort) HCV +ve patients with FS ≥8.5 kPa, 34 (9%) with FS ≥25 kPa and 21 (5%) with FS ≥35 kPa.

This community based study has identified a large number of HCV positive patients that do not attend specialist hepatology services yet qualify for DAA treatment. Within this group there are significant numbers of patients at high risk of decompensation. On-going alcohol use is associated with a significantly higher FS score. While these patients may have significant comorbidities, including addiction, which limits access to specialist hospital services, it is important to overcome these challenges if we are to make an impact on HCV-related mortality.
In 2008, 84 patients were scanned. Of these 77% were HCV Ab positive and 58% of this group were HCV viraemic. By 2016, all of the 2008 patients with TE scores > 13 Kilopascal (Kpa) had died (a total of 13 patients) and 11 of these patients died as a result of liver failure associated with hepatitis c viraemia and alcohol.

In 2016 105 scans were carried out on surviving patients from 2008 who still attended the clinic and on new patients attending the clinic. 16 patients (15%) of the 2016 population had TE scores > 13 Kpa, the previous threshold for death at eight years.

This longitudinal data demonstrates universal mortality at 8 years among OST patients with a TE reading of 13 Kpa or greater. Among surviving patients it demonstrated widespread progression of TE readings to levels indicating a requirement for early DAA treatment, and to levels previously associated with high mortality.
**Current Situation**: Plans being finalised Q1 2017?
- No community fiboscan capacity
- No ECG machines
- No clinical governance, pathways of care
- Who will prescribe? Indemnity issues
- Pharmacy and drug delivery issues
- Contingency plans for AE and hospital referral?
**Future Plans**: Look to Q2 of 2017
- Hepcare EU will provide fibroscan, ECG
- Clinical governance between Mater (Lambert, Stewart) and City Clinic drafted
- Pathways of care being developed by Jean Flanagan HCV Liaison Nurse
- Trainings at Mater 3rd week March, Trainings at City Clinic 4th week March
- First patient on treatment April 2, 2017
How do we guarantee that those in the community, vulnerable populations not accessing HCV care, will be able to attend the hospital and be on of the ‘chosen 1600’?

**Aims** to improve access to HCV testing and treatment among key risk groups, including drug users and homeless, through outreach to the community and integration of primary and secondary care services

‘**HEPCARE’**: A new user-friendly Hepatitis C Care service model

Hepcare Europe 2017

No One Left Behind

WP1 Coordination; WP2 Dissemination; WP3 Evaluation

WP4: HepCheck (screening)

WP5: HepLink (linkage to care)

WP6: HepED (inter-professional education)

WP7: HepFriend (peer advocacy support)

WP8: HepCost

Co-funded by the Health Programme of the European Union
HepFriend Project plan

• HepFriend is a proof of concept study in Dublin, Ireland, which aims to assess the efficacy of a peer support (also known as ‘buddying’) model to enable vulnerable people living with the hepatitis C to access specialist care and complete treatment.

• HepFriend is a collaboration between The Hep C Partnership, The Mater Hospital, and the following community organisations: Community response; Crysalis; SAOL and is supported by the pharmaceutical industry – Namely Gilead Sciences and Abbvie.

• The objective of the study is to provide an evidence base for the effectiveness of the HepFriend concept with a view of scaling up and exporting the model to other geographies through community partnerships.
HepFriend Project Timeline

- **10 March**
  - Project Plan Meeting – Documents finalised

- **Third stakeholder meeting**

- **27 March**
  - HepFriends Recruited

- **Initial Stakeholder meeting**

- **HepFriend Training**
  - 27 April Day 1: HCV
  - 4 May Day 2: HepFriend

- **10 March**
  - Project Plan Meeting – Documents finalised

- **27 March**
  - HepFriends Recruited

- **HepFriend Training**
  - 27 April Day 1: HCV
  - 4 May Day 2: HepFriend

- **24 March**
  - Community group ratification of plan and docs

- **6 April**
  - 1pm HepFriend Induction
  - 2-4pm HepFriend Stakeholders Meeting

- **11 May**
  - HepFriend HCV Masterclass

- **Monthly**
  - meeting with Volunteer coordinator and HepFriend Manager (progress report)

- **HepFriend Project commences**

Co-funded by the Health Programme of the European Union
HepFriend Role

- Each community group will recruit and manage a total of 12 HepFriend (4 HepFriends per community group)
- HepFriends will be certified after completing a 2 day training course, delivered by members of the stakeholder group in May 2017
- The project will run for 12 months from June 2017 - June 2018
- Each HepFriend will be assigned 10 patients over the course of the study
- There will be approximately 10 ‘one-to-one’ meetings between the HepFriend and patient (variable upon the needs of the patient)
- ‘one-to-one’ meetings may involve
  - Meeting the patient
  - Taking patient to hospital
  - Attending clinical appointment with the patient
  - Post appointment coffee where they can help the patient understand the care pathway and treatment
  - Calling/texting and reminding patient of upcoming appointments
Volunteer Coordinator

• Each Community organisation will provide a volunteer coordinator to manage to Hepfriends
• The will meet each hep friend month to discuss progress and collect data from previous month
• Volunteer coordinator will collate data for their 4 hep friends and submit data to HepFriend Manager

HepFriend Manager

• Will collate data for analysis
HepCare Europe 2017: ‘no one left behind’

- Partnership with HSE HCV programme, representation on the Community HCV committee (Professor Walter Cullen) so ‘the left hand knows………’
- Advocacy for ‘vulnerable populations’ migrants, homeless, PWID
- HepFriend will guarantee that PWID/ex-PWID are represented in the 2017 quota (as most of my patients now going to the clinic to access DAA’s have low risk disease and low/no risk of transmission)
- Prioritisation of those with advanced liver disease to be partnered with HepFriend
- Seek and Treat: Community Fibroscan of Country (not just Dublin), focusing on methadone prescribing facilities will target those at highest risk and stratify those who need ‘peer support’
- Advocacy for more community resources for 2018 and beyond.
- While Ireland was ‘the first’ to submit a plan for HCV ‘viral elimination’ it has failed to put its resources into where patients with HCV are residing and will finish last (one DAA treatment course = one fibroscan machine)