Audit of Hepatitis C Testing and Referral 2016

Addiction Treatment Centres, Community Health Organisation Area 7

Introduction

Hepatitis C is a notifiable disease in Ireland. There has been a steady downward trend in notifications in recent years, with 645 notifications received in 2016 compared to a high of 1,538 in 2007.[1] Where risk factor information was reported, 66% of the cases notified in 2016 had a history of injecting drug use. The proportion of hepatitis C cases attributed to injecting drug use has decreased in recent years (80% in 2014, 72% in 2015), but risk factor data completeness varies from year to year so this trend must be interpreted with caution.[3]

Studies of people who inject drugs (PWID) in Ireland, published between 1992 and 2011, have found hepatitis C antibody prevalences of between 52% and 84% in this population.[2] However, there have been no recent, large-scale, representative hepatitis C prevalence studies in drug users in Ireland. Given the recent decrease in hepatitis C notifications and reports from drug treatment services indicating that the proportion of drug users who inject is decreasing, it is probable that the prevalence of hepatitis C in this cohort has changed, particularly amongst those who have started using drugs in more recent years. Thus, there is a need for recent prevalence data in this cohort.

The contract of service (Appendix 1) for all GPs working in addiction treatment centres in Ireland specifies that they are required to "Screen patients for relevant viral diseases, evaluate the results, treat and refer to specialist services where appropriate". This also applies to level 1 and 2 GPs. Therefore, drug users attending treatment services should be routinely tested for hepatitis C and it should be possible to report the prevalence of blood-borne viruses in patients attending each treatment centre. However, these test results are not recorded electronically in most clinics, so it is not possible to readily determine the prevalence of hepatitis C in drug users in treatment.

An audit of hepatitis C testing and referral was carried out in 2014-2015 in addiction treatment centres in HSE Community Health Organisation (CHO) Area 7.[3] This area covers Dublin 2, 4 (part of), 6, 6W, 8, 10, 12, 16 (part of), 22, 24. The audit was not carried out in the satellite clinics or in West Wicklow or Kildare as services there are in community-based (dispensed in community pharmacies). The purpose of the audit was to inform the Audit Sub-Group of the Addiction Treatment Clinical Governance Committee of CHO7 of compliance with the expected standard of care in relation to hepatitis C and to make recommendations for improvement where necessary. A secondary aim of the audit was to collect and collate data on the prevalence of hepatitis C infection in this cohort of patients.

This audit was repeated in 2016-2017, with a slightly modified data collection form (Appendix 2), and this second audit is the subject of this report.

Standard of care in addiction treatment centres

The standard of care for patients presenting for treatment at addiction treatment centres in Ireland had not changed since the previous audit. This includes offering an antibody test for hepatitis C to determine if a

client has ever been infected with hepatitis C. If the antibody test is positive, a test for hepatitis C antigen or RNA (PCR test) is carried out to determine if the client is currently infected with hepatitis C. Genotyping should then be carried out for all patients who are currently infected and they should be assessed for treatment, either in the addiction treatment centre, or in a specialist hepatology or infectious disease clinic.

If the patient initially tests negative for hepatitis C, a repeat test should be offered every 6-12 months if the patient continues with risk-taking behaviour. This standard of care is outlined to all doctors working in the Addiction Treatment Centres in CHO7 in an algorithm which has been circulated to them (Appendix 3).

Hepatitis C infection and the benefit of screening

Hepatitis C infection is initially asymptomatic in most cases, but approximately 75% of those infected fail to clear the virus and develop chronic infection with associated morbidity. Between 5 and 20% of chronically infected individuals develop cirrhosis of the liver after 20 years of infection. Of those with cirrhosis, 1.5% to 2.5% will go on to develop hepatocellular carcinoma each year.[4] Screening at-risk populations for hepatitis C allows earlier diagnosis and treatment. There have been major advances in the treatment of hepatitis C in recent years with the development of oral direct acting antiviral regimens that are interferon-free. Sustained virological response (SVR) rates of over 95% have been reported with the latest generation of direct-acting antivirals. SVR is regarded as a virological cure and is associated with significantly improved morbidity and mortality.[5]

Methods

A customised audit form was developed (Appendix 2). A letter (Appendix 4) accompanied by the audit form was sent by Dr Margaret Bourke as Chairperson of the Audit Sub-Group to 20 GPs in 11 addiction treatment centres in CHO7, outlining the audit project and requesting their assistance in completing the forms. The letters were sent on 12 May 2016. Audit forms were returned to Dr Margaret Bourke.

One form was to be completed for every patient attending each centre. Data were requested on age, sex, whether or not the patient was tested for hepatitis C, and their hepatitis C status if tested. Information on risk factors for hepatitis C infection, HIV status, referral to a specialist clinic (hepatology or infectious diseases) and alcohol dependence was also requested. No personally identifiable information was collected on patients. In order to encourage cooperation and to avoid making comparisons between centres, the form did not contain the name of the doctor or the treatment centre.

Data entry and analysis was carried out by the HSE Health Protection Surveillance Centre (HPSC). An MS Access database was developed and the data were entered by an administrator. Once entered, the data were then validated and analysed by a surveillance scientist at HPSC.

Results

Response

A total of 383 audit forms were returned. This represents 40.4% (383/948) of the patients attending addiction treatment centres dispensing on-site services in CHO7. It is not possible to determine how many doctors or treatment centres participated as the study was anonymous, as stated above.

Age and sex

Where data were available, 67% (249/374) of the study population were male. Ninety six percent (363/379) were aged between 25 and 54 years, with ages ranging from 24 to 67 years. The overall median age was 39 years (males 40 years, females 38 years).

Risk factors

Data on possible risk factors for hepatitis C infection were available for 99% (379/383) of patients. Seventy nine percent (298/379) had a history of injecting opiates/opioids, 15% (n=44) of whom were currently injecting at the time of the audit and 85% (n=254) of whom had injected in the past. Eighteen percent of patients (68/379) reported that they had never injected drugs (64 opiate/opioid users and 4 patients who used other drugs) and the remaining 3% (n=13) of patients were opiate/opioid users for whom injecting status was not known. A significant proportion (79%) of patients used cocaine and/or benzodiazepines in addition to opiates/opioids (table 1).

Table 1. Number of patients by injecting status and types of drugs used

Injecting status	Patients with risk factor information	Opiates or opioids	Cocaine	Benzodiazepines	Novel psychoactive substances	Z-drugs
Current injecting drug use	44	44 (100%)	26 (59%)	31 (70%)	10 (23%)	17 (39%)
Past injecting drug use	254	254 (100%)	144 (57%)	153 (60%)	7 (3%)	39 (15%)
Non-injecting drug use	68	64 (94%)	35 (51%)	31 (46%)	2 (3%)	8 (12%)
Unknown injecting status	13	13 (100%)	9 (69%)	9 (69%)	0	4 (31%)
	379	**375 (99%)**	**214 (56%)**	**224 (59%)**	**19 (5%)**	**68 (18%)**

Hepatitis C testing

Hepatitis C antibody results

Hepatitis C antibody testing was carried out for 95% (365/383) of patients for whom forms were completed. Results were available for 98% of these (358/365). Sixty six percent (235/358) of patients with antibody results tested positive for hepatitis C. This varied by injecting status, with 79% of patients who ever injected drugs testing positive compared to 8% of those who never injected (chi square p-value <0.001) (table 2). Of the 235 patients who tested positive for hepatitis C, 95% (n=222) had either injected opiates/opioids in the past or were currently injecting, 2% (n=5) used opiates/opioids in addition to other drugs but had not injected (3 of whom reported intranasal cocaine use) and injecting status was not

reported for 3% (n=8). All of those with unknown injecting status used opiates/opioids in addition to other drugs.

HCV antibody positivity did not vary significantly by sex, but there were differences by age, with older patients significantly more likely to have tested positive for hepatitis C. Seventy six percent of patients who were 40 years or older tested hepatitis C antibody positive compared to 56% of those aged less than 40 years (chi-square p-value <0.001). The mean age for patients who tested positive was 41 years compared to 38 years for those who were hepatitis C negative, t-test p-value 0.005). The association between older age and HCV antibody positivity was also observed when the analysis was limited to patients with a history of injecting drugs. Eighty nine percent of patients who had a history of injecting drugs and who were 40 years or older tested hepatitis C antibody positive compared to 69% of those aged less than 40 years (chi-square p-value <0.001). Figure 1 shows the percentage of all patients, and percentage of those with a history of injecting, who tested positive for hepatitis C antibody by age group.

Of the 18 patients with no record of hepatitis C antibody testing, 5 had declined testing and no information was available for the remaining 13.

Table 2. Hepatitis C antibody results (current or past infection), by risk factor for infection

Hepatitis C antibody test result	Current injecting drug use	Past injecting drug use	Non injecting drug use	Unknown injecting status	All
Positive	31	191	5	8	235
Negative	9	51	58	5	123
Tested, results not in records	2	4	1		7
Not tested	2	8	4	4	18
Total	**44**	**254**	**68**	**17**	**383**
% positive where results reported	**77.5**	**78.9**	**7.9**	**61.5**	**65.6**

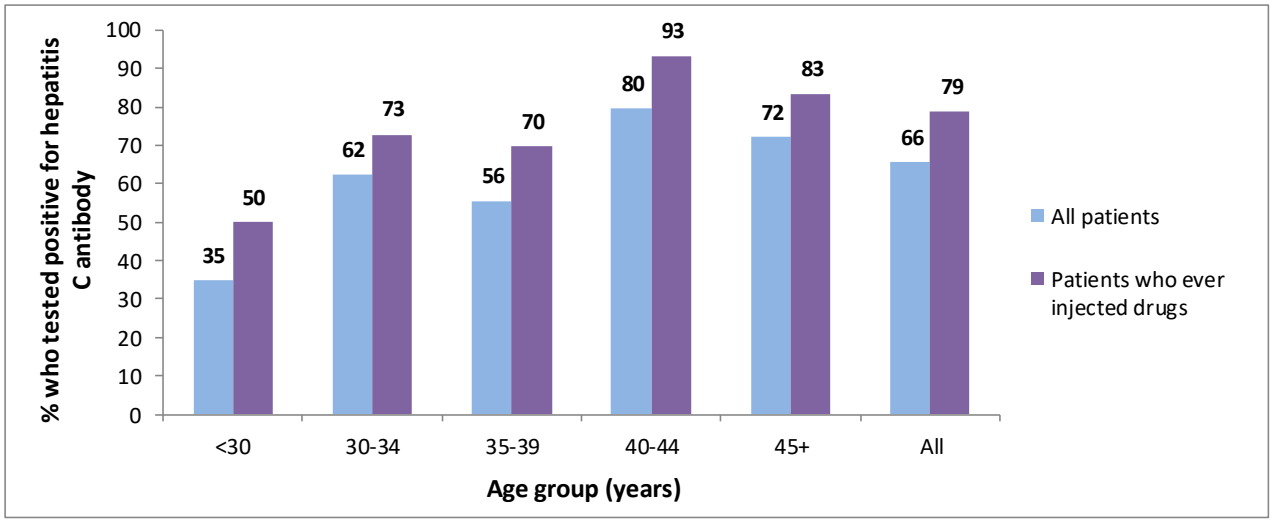

Figure 1: Percentage of all patients, and patients with a history of injecting, who tested hepatitis C antibody positive by age group

Note: there were only 20 patients in the <30 years age group

Year of most recent hepatitis C antibody test

The year of most recent hepatitis C antibody test is shown for patients who tested negative for hepatitis C (figure 2). Patients who test negative and are at continuing risk of infection should be re-tested every 6-12 months. In this cohort, date of most recent test was reported for 93% (115/123) of patients who had tested negative for hepatitis C antibody. Of these, only nine were reported as continuing to inject. Four had been tested in 2015 or 2016 and the most recent test for the remaining 5 was between 2009 and 2013.

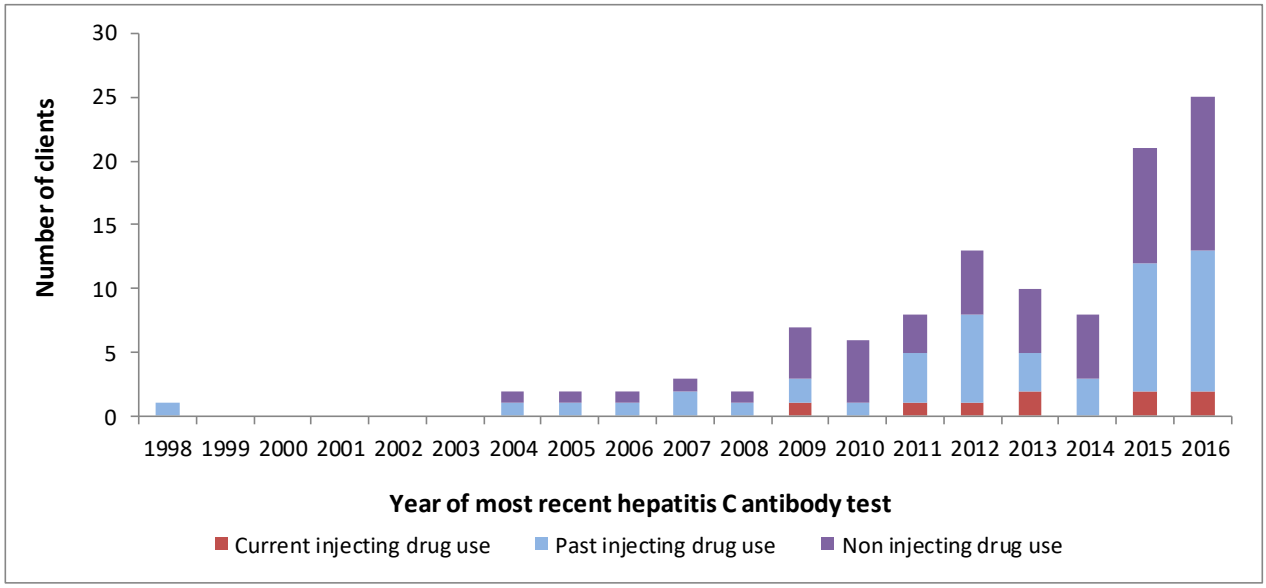

Figure 2: Year of most recent hepatitis C antibody test for patients who tested negative for hepatitis C, by risk factor for hepatitis C infection

Hepatitis C antigen or RNA results

Hepatitis C antigen or RNA results were reported for 89% (208/235) of patients who had tested positive for hepatitis C antibody. Overall, where results were available 41% of all patients (136/331) and 50% of patients with a history of injecting (128/256), were currently infected with HCV at the time of the audit (table 3, figure 3).

Of those who had tested HCV antibody positive, 65% (136/208) remained viraemic (table 3). Females were more likely than males to have cleared the virus, with just 54% of antibody positive females also testing positive for HCV antigen or RNA, compared to 72% of males (chi square p-value 0.013).

Of the 27 HCV antibody positive patients with no antigen or RNA results, 20 had been referred to infectious disease or hepatology specialists, 2 were tested elsewhere and results were not available, 2 had been tested recently and results were awaited, 2 declined testing and no information was available on the reason for not testing for the remaining client.

Table 3. Hepatitis C antigen or RNA results (current infection), by risk factor for infection

Hepatitis C antigen or RNA result (current infection)	Current PWID	Past PWID	Non injecting drug use	Unknown IDU status	All
Positive	15	113	4	4	136
Negative	14	54	1	3	72
Result awaited		2			2
Unknown	2	22		1	25
Total	**31**	**191**	**5**	**8**	**235**
% of antibody positive patients currently chronically infected*	**51.7**	**67.7**	**80**	**57.1**	**65.4**
% of all patients currently chronically infected†	**39.5**	**51.8**	**6.3**	**33.3**	**41.1**

*Percentage of patients who were ever infected with hepatitis C who remain chronically infected.
†Percentage of all clients with hepatitis C results who are currently chronically infected with hepatitis C.

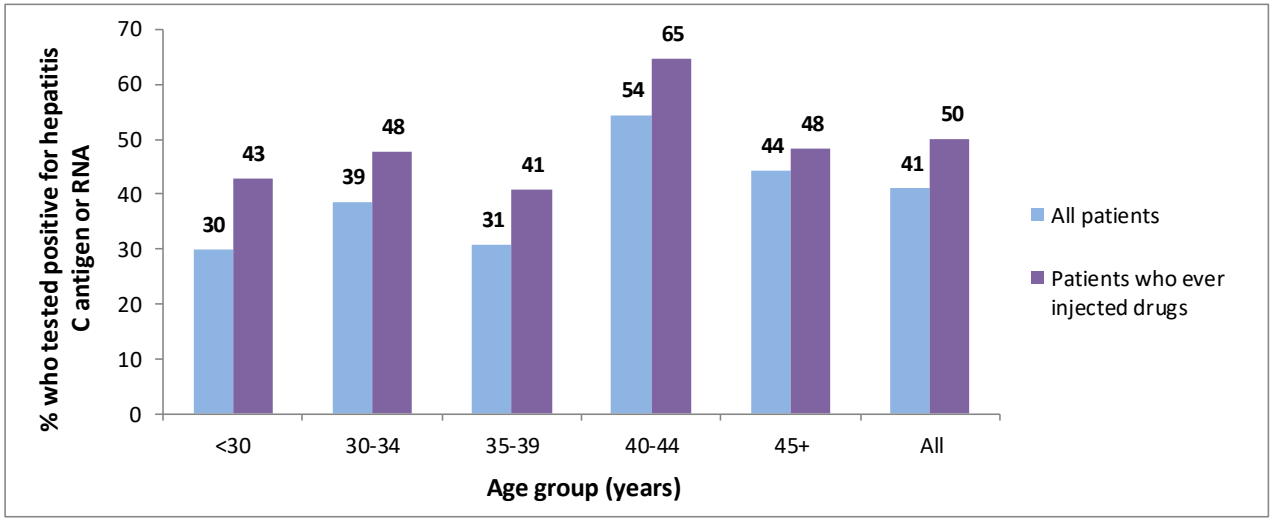

Figure 3: Percentage of all patients, and patients who ever injected, who tested hepatitis C antigen or RNA positive by age group (denominator includes HCV antibody negative patients – reflects % of patients with current infection)
Note: there were only 20 patients in the <30 years age group

HIV Infection

HIV status was recorded for 349 patients, of whom 49 (14%) were HIV positive. Of the 49 HIV positive patients, 39 had injected drugs in the past, 7 were currently injecting drugs and injecting status was not known for 3 patients. Seventeen percent (46/274) of patients with a known history of injecting drugs were HIV positive. Ninety six percent (47/49) of HIV positive patients were also hepatitis C antibody positive. Hepatitis C antigen or RNA results were available for 70% of these patients and almost three quarters (73%, 24/33) were positive.

Fifty eight percent of HIV positive patients were male, but the difference in HIV positivity by sex was not statistically significant. The median age of HIV positive patients was 42 years (range 27 to 58 years). HIV status did vary by age, with patients aged 40 years or older significantly more likely to be HIV positive (18% compared to 10% of those aged less than 40 years, chi-square p-value 0.025). Figure 4 shows the HCV and

HIV status by age group for patients with both HCV and HIV results and figure 5 shows the same information for patients with a history of injecting.

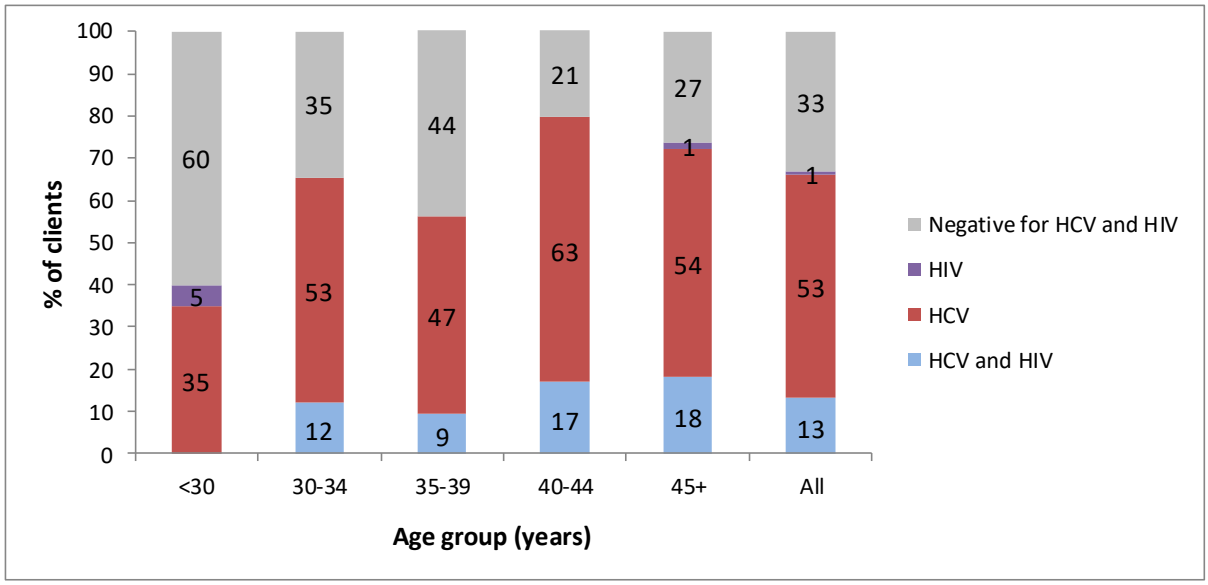

Figure 4. HCV antibody status and HIV status for **all patients** by age group (where both HIV and HCV results available only)

Note: there were only 20 patients in the <30 years age group

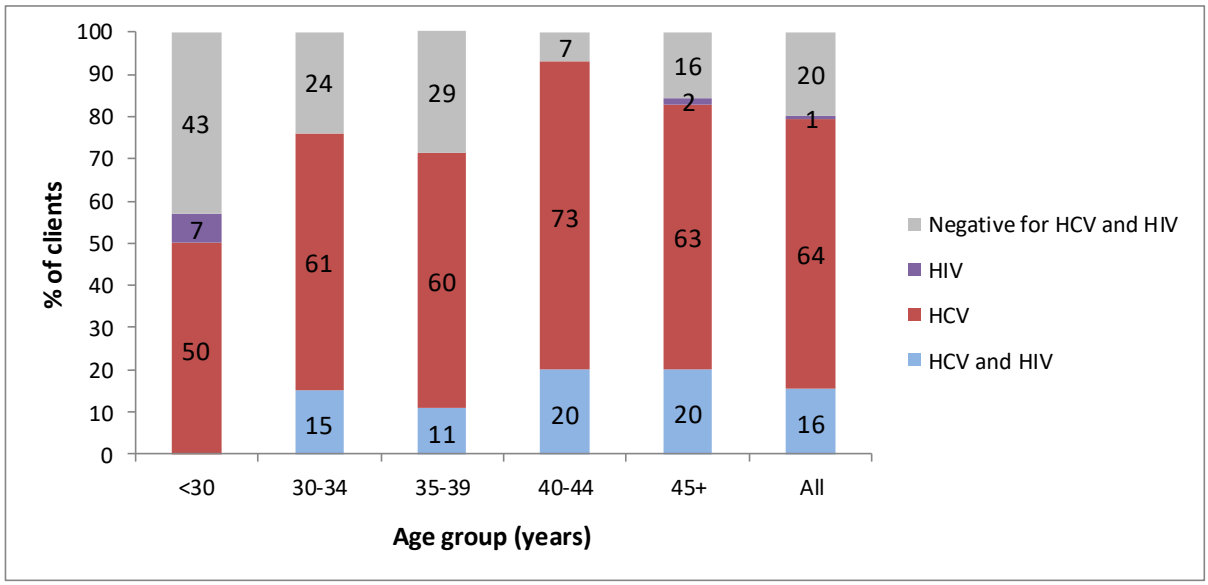

Figure 5. HCV antibody status and HIV status for **patients who ever injected drugs** by age group (where both HIV and HCV results available only)

Note: there were only 14 patients in the <30 years age group

3.6 Referral and attendance at hepatology or infectious diseases clinics by sex

Where data were available, 98% (131/133) of hepatitis C antigen or RNA positive patients had been referred to a specialist clinic. Of those referred, 19% (25/131) did not attend. Attendance did not differ significantly by age and sex.

3.7 Alcohol dependence

Information on alcohol dependence was available for 88% (338/383) of patients included in the audit. Almost one fifth (19%, 65/338) were reported as alcohol dependent. Alcohol dependence increased with increasing age: 9% of patients who were under 40 years of age were alcohol dependent compared to 27% of those aged 40-49 years and 45% of those aged 50 years and older (chi-square p-value <0.001).

Alcohol dependence did not differ significantly by sex, injecting status, HIV status or hepatitis C status after taking account of age.

4. Discussion

The primary purpose of this study was to audit hepatitis C screening in addiction centres and referral to hepatology with a view to identifying areas for improvement. The response rate was 40%. This was a considerable improvement on the previous audit, which had a response rate of just under one third. However, the findings may not be representative of the entire patient population in addiction treatment in CHO7. The sub-optimal response was understandable given that most of the addiction treatment clinics are not computerised and all data extraction had to be done manually.

Where audit forms were completed, there was a very high level of compliance with the recommendation to test for hepatitis C (95%). Almost all of those who were antibody positive were either tested for hepatitis C antigen or RNA (as per standard of care) (89%) or were referred to other specialist services (10%) where further testing was likely to have occurred. Compliance was also very high, at 98%, with referral of antigen/RNA positive patients for specialist assessment.

Repeat testing for those who tested antibody negative was indicated for only a minority of patients as most were no longer engaged in risk-taking behaviour. However, a small number of patients who were still injecting drugs (7/9) were not tested as recommended.

A secondary aim of the study was to provide information on the prevalence of hepatitis C infection in patients attending addiction treatment clinics. Almost two thirds (66%) of all patients and 79% of patients who ever injected drugs tested positive for current or past hepatitis C infection. This figure is in keeping with previous studies among injecting drug users which found the hepatitis C antibody prevalence to be 52% to 84%.[2] It is also similar to the results of the previous audit in CHO area 7, in which 67% of all patients and 72% of those with a history of injecting drug use were reported to be positive for HCV antibody.[3] Almost two thirds (65%) of patients who had tested antibody positive remained infected with hepatitis C. This was slightly higher than in the previous audit (60%).[3]

The prevalence of hepatitis C markers was significantly higher in older patients. This could reflect their longer injecting history and opportunity for exposure to hepatitis C, but is likely to be primarily due to a

reduction in hepatitis C incidence in recent years. Data from nationally collated notifications of hepatitis C infection show a substantial downward trend in notifications in PWID and rising age at diagnosis since peak levels in 2007, indicating that the incidence of hepatitis C in this cohort is likely to be decreasing in Ireland.[1] A strong emphasis has been placed on better education and harm reduction through the use of needle exchange in the addiction services, and these measures are likely to have contributed to the observed decline in hepatitis C notifications and the lower prevalence of hepatitis C in younger PWID found in this study.

The prevalence of HIV in this cohort was higher than expected, with 14% of all patients, and 17% of those with a history of injecting, testing positive. A similarly high prevalence was found in the 2014/2015 audit (16% of all patients and 19% of those who had injected). However, this may reflect a particularly high-risk cohort who have been HIV positive for some time, as published estimates have generally been lower than this. Studies in Irish drug users published between 1991 and 2005 found HIV prevalences ranging from 1.2% to 17%, but most of these reported prevalences of less than 10%.[6]

The incidence of HIV infection in PWID is likely to have declined in recent years. Since 2009, there were less than 30 HIV notifications per year among PWID, apart from in 2015 (n=49) when there was an outbreak of HIV among homeless PWID living in Dublin.[7] At the time of this outbreak, addiction services encouraged all service users who fit the profile of outbreak associated cases (homeless and chaotic PWID) to be tested for HIV. Of 347 service users tested, only 1.15% were positive for HIV. However, only those not already known to be HIV positive were tested, so the HIV prevalence in this cohort is likely to be higher than this (personal communication: Dr Margaret Fitzgerald, HSE E).

The high level of compliance with hepatitis C testing and referral found in this study is reassuring at a time when there is a strong impetus to diagnose and treat hepatitis C. National hepatitis C screening guidelines were published by the Department of Health in July 2017.[8] These recommend HCV screening for anyone who has ever injected illicit drugs or used illicit drugs by a route other than injecting where there is a possibility of transmission of HCV. They also recommend re-testing of those with negative results at least annually if they remain at risk of infection. This is consistent with the policies and practices currently in place in the addiction services. Highly effective treatments using Directly Acting Antivirals (DAAs) are now available for hepatitis C. The HSE has established a National Hepatitis C Treatment Programme to ensure that patients with hepatitis C in Ireland are offered effective antiviral drug regimens in a structured way, based on clinical need. The ultimate goal of this programme is to treat all infected patients and eliminate hepatitis C in Ireland (https://www.hse.ie/eng/about/Who/primarycare/hepcprogramme%20.html).

5. Conclusions and recommendations

1. A computerised patient management system for addiction treatment clinics is urgently needed. This would improve the efficiency of the clinics, improve quality of care for patients and facilitate data analysis for audits and reports as needed.

2. The under-resourcing of clinics is a serious ongoing concern and should continue to be highlighted on the HSE Risk Register.

3. All patients who test positive for chronic hepatitis C infection should be assessed for anti-viral treatment, either in an addiction treatment centre or in specialist hepatology or infectious disease

services. All patients who test positive for HIV should be referred to specialist HIV services. Where patients are referred to other services they should be supported to facilitate their attendance. If they do not attend, the reasons for non-attendance should be investigated.

4. If a further re-audit is being done, questions on hepatitis C treatment uptake and outcomes, and possible re-infections, should be added.

5. The results of this audit will be sent to
   - The Clinical Governance Committee of CHO7
   - All doctors who participated in the audit
   - HSE National Clinical Lead, Addiction Services
   - Programme Manager, National Hepatitis C Treatment Programme
   - Local primary care management and local addiction services management
   - The HSE Directorate for Primary Care
   - Local senior CHO management
   - Hepatitis C Strategy Implementation Committee
   - HSE Social Inclusion

Acknowledgements

Sincere thanks to the following:

All doctors who responded to the audit.

Ciara Nolan, Administrative Officer, Castle St Clinic.

Margaret McIver, HSE Health Protection Surveillance Centre

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Date: February 2018

Appendix 1
GP Service Contract

Appendix 2
Hepatitis C Audit Form

Appendix 3
Hepatitis C Testing and Referral Algorithm used in CHO7

Appendix 4
Letter to GP re Audit

Appendix 1: GP Service Contract

HSE, Dublin Mid-Leinster
Employment Agreement – GPs Specialising in Substance Abuse

This employment agreement is between the HSE, Dublin Mid-Leinster, Addiction Services and Dr _____ of _____.
Dr. _____is employed as a GP specialised in the treatment of substance abuse problems.

1. Qualification

The GP must be registered other than provisionally on the General Register of the Medical Council. In the event that for whatever reason the GP ceases to be registered, the contract will as a consequence cease to have effect. Training in addiction treatment will have been completed in the service to a minimum standard of Level 2 GP under the Methadone Protocol Scheme and will take place over a period of at least one year.

2. Service

The GP will ensure that provision of service under this agreement with the HSE, Dublin Mid-Leinster, Addiction Services is carried out to a satisfactory standard and complies with HSE, Dublin Mid-Leinster policies, procedures and standards.

The GP shall not sign, transfer or sub contract, this agreement or any portion thereof without the prior consent in writing of the HSE, Dublin Mid-Leinster, Addiction Services.

3. Principal Duties

The GP will be required to:

- As part of a multidisciplinary team, provide treatment for addiction to clients who present or are referred to HSE, Dublin Mid-Leinster, Addiction Services clinics with substance use problems. Locations, times, dates and duration of clinic to be agreed between the GP, GP Co-ordinator and Area Operations Manager.
- Assess clients on presentation (medical and addiction assessment), prescribe a course of treatment and monitor that treatment for its duration.
- Screen clients for relevant viral diseases, evaluate the results, treat and refer to specialist services where appropriate.
- Provide appropriate vaccination programs to clients under their care.
- Provide primary medical care in emergency situations to clients who do not yet have medical card cover. 24 hr primary care cover is not provided
- Be wholly responsible for the medical treatment he/she initiates and carry medical indemnity to cover his/her practice.
- Address issues such as absenteeism, punctuality, and IR issues through the GP Co-ordinator.
- Attend clinical team meetings where clients' cases will be discussed and treatment plans developed with the care team.
- Participate in quarterly meetings of GPs working in the service at which GPs' views on policy, operational issues and service development will be discussed and consensus positions developed.
- Participate in continuing medical education to update skills in treating addiction problems.
- Participate in peer review of his/her practice on a regular basis.

Appendix 2: Hepatitis C Audit Form

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Drug treatment centres

Audit of hepatitis C testing 2016

Please complete one form for each of your current clients

Date form completed ____ **Local ID** (for your own purposes) ____

Age: ____ **Sex:** Male ☐ Female ☐

Hepatitis C testing practice and test results

Was the client ever tested for hepatitis C?	Yes ☐	No ☐	Unknown ☐
If yes, date of most recent HCV antibody test	____		
Result of most recent **HCV antibody** test	Positive ☐	Negative ☐	Unknown ☐
If positive, was a HCV antigen or RNA (PCR) test done?	Yes ☐	No ☐	Unknown ☐
Result of most recent **HCV antigen or RNA(PCR)** test	Positive ☐	Negative ☐	Unknown ☐

Referral to Hepatology or Infectious Disease specialist?

If HCV antigen or RNA positive, was the client referred?	Yes ☐	No ☐	Unknown ☐
	Yes, but client refused or did not attend ☐		

Risk factors for HCV infection

Injecting drug use	Current ☐	Past ☐	Never ☐
Intranasal drug use	Current ☐	Past ☐	Never ☐
Unprotected sex with HCV positive person	Yes ☐	No ☐	Unknown ☐

Types of drugs used (tick all that apply)

- Opiates/opioids ☐
- Cocaine ☐
- Benzodiazepines ☐
- Novel psychoactive substances ☐
- Z-drugs ☐

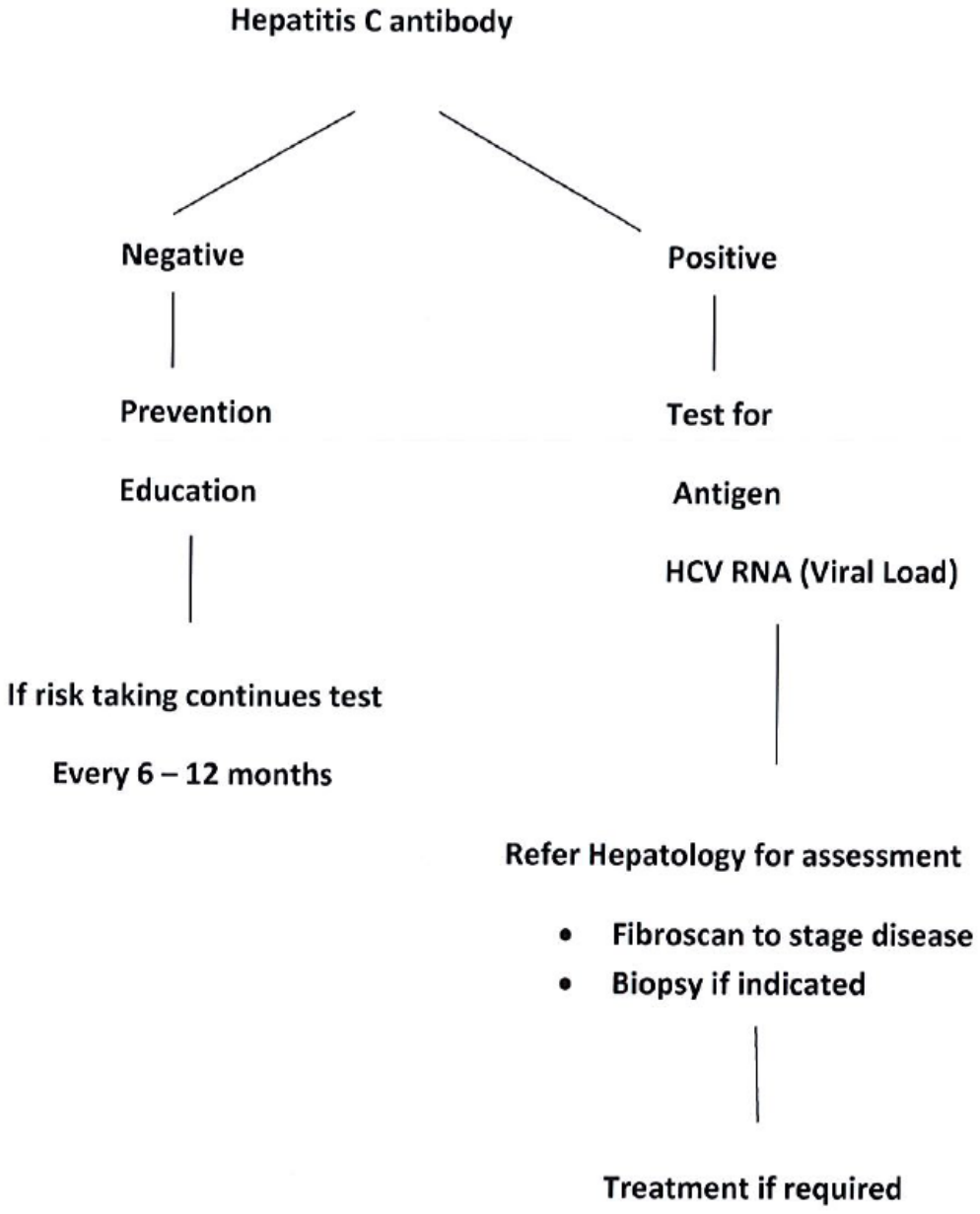
Is patient alcohol-dependent?	Yes ☐	No ☐	Unknown ☐

HIV status

Positive ☐ Negative ☐ Unknown ☐

Comments

Appendix 3: Hepatitis C Testing and Referral Algorithm, CHO7



Appendix 4: Letter to GP re Audit

To: **GPs**

From: **Dr Bourke, GP Coordinator**

Date: **12th May 2016**

Re: **Repeat Audit of Hepatitis C Testing**

As you are aware we have previously done an audit on hepatitis C testing and while the "buy in" was low only 25% the statistics that emerged where extremely encouraging. These statistics where done by the HSPC so are completely accurate.

We are anxious to repeat this audit and on this occasion hope to get much higher numbers.

The questionnaire has been modified and simplified. I do plan to attend the Clinical Team meetings to explain to people and respond to any questions. The audit is completely anonymous; it does not identify the clinic, the doctor or the patient.

I would be grateful if you could help us with improving our input on this occasion

Thank You

Margaret