

HCV testing and linkage to care for hepatitis C virus infection for marginalized drug user populations attending a harm reduction service in Bologna, Italy

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SUMMARY

Our aim was to estimate the prevalence of HCV in a highly vulnerable population of substance users living with social difficulties and marginality who came into contact with the mobile harm reduction service in the city of Bologna (Northern Italy).

Testing was offered in a van (mobile unit) by using a point-of-care HCV antibody test. For the HCV RNA test, the Xpert HCV Viral Load Fingerstick Test was used.

Participants with a detectable HCV RNA were accompanied within two weeks to the Infectious Diseases Department Sant' Orsola Hospital Bologna to start HCV treatment.

With regard to the main study findings, 54% reported

having never been HCV tested before; a prevalence of HCV RNA of 6% among all participants and 22% among those injecting drugs was found; among the HCV RNA positive participants, 80% were accompanied to treatment.

Our study suggests that mobile harm reduction services, in networks with healthcare facilities, are able to offer a continuous HCV screening service and linkage to care for people with drug use living in socially marginalized conditions.

Keywords: HCV antibody test, HCV RNA test, mobile harm reduction service, vulnerable population; injecting drugs.

INTRODUCTION

Hepatitis C virus (HCV) infection is one of the leading causes of liver-related death and disability worldwide. Globally, 56.8 million people live with HCV [1]. The prevalence rate in the European Union (EU) region is 1.5%, with the

highest rates existing in the Eastern Mediterranean (2.3%) [2].

A history of injecting drug use is the most frequently reported risk factor for newly diagnosed acute and chronic HCV infections in the EU [3], and the main viral reservoir consists of people who inject drugs (PWID) [4]. The burden of HCV infection among PWID is considerable, and transmission continues as a result of ongoing risk behaviours, such as sharing needles/syringes and paraphernalia [5].

Globally, 14.8 million people aged 15–64 years

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were estimated to inject drugs: 15.2% are living with HIV, 38.8% have current HCV infection, 18.5% have recently overdosed, and 31.7% have had a recent skin or soft tissue infection [6]. Among PWID, experiences of homelessness [7, 8], arrest [9], incarceration [10], and sex work [11] can increase exposure to blood-borne viruses and elevate the risks of harm to physical and mental health.

The World Health Organization aims to significantly reduce the number of new viral hepatitis infections and related deaths by 2030 [12]. One of the main barriers to HCV elimination is the large number of people who are unaware of their HCV infection status. General population testing has limited utility while a focus on settings attended by people with increased HCV risk is more feasible [13]. Therefore, screening campaigns are critical to detecting new infections, especially in high-risk groups such as PWID [14].

Globally, many people with hepatitis C virus (HCV) infection are marginalized and have very limited access to traditional healthcare services, including HCV testing and treatment [15]. In marginalized populations, point-of-care testing has been found to increase testing and treatment and shortens time from diagnosis to treatment initiation [16]. Furthermore, community-based point-of-care testing has been reported as the preferred setting for PWID [17].

The HCV RNA prevalence in studies conducted among marginal populations in comparable settings ranged from between 9% and 37% among PWID and between 2% and 11% among the total study population [15, 18-20].

In Italy, it has been estimated that nearly 280,000 HCV patients have yet to be diagnosed and half of this patient group are substance users. The Italian government has recently provided HCV rapid tests to those enrolled in the health registry (born between 1969 and 1989), patients followed by drug addiction centres (in Italy, SERDs), and individuals detained in prison [21]. Unfortunately, there is still a lack of/a paucity of interventions for people with drug use who live in marginalized conditions, screening campaigns, and point-of-care-based approaches. In 2022, only 25.6% of all patients attending SERDs were screened for HCV (of these, 41.4% were positive). Furthermore, only 25.9% of social private services (therapeutic communities, mobile units, drop-ins, harm

reduction, and emergency services) offered screening tests and pharmacological treatments for HCV [22].

From Italian studies, while a significant higher prevalence of HCV-positive subjects among PWIDs was observed, a high proportion of SERD patients were unaware of being HCV-positive or with other parenteral infections (i.e. HIV and HBV) [22, 23]. Furthermore, high rates of linkage-to-care and anti-HCV treatment initiation for patients receiving DAAs in their SERD were reported as well as a high level of retention in care for drug users and homeless individuals in DAA treatment in an out-of-hospital setting [24, 25].

In this study, our aim was to estimate the prevalence of HCV in a highly vulnerable population of substance users living with social difficulties and marginality who met the mobile harm reduction service in the city of Bologna (Italy).

■ PATIENT AND METHODS

Study design

In this cross-sectional study, the process of enrolling participants, conducting enrolment, HCV testing, making referrals, and collecting data were conducted by street workers (SWs – professional educators, cultural mediators, expert counsellors in sexual health and harm reduction) within a van (mobile unit) and inside a fixed headquarters located near the Bologna train station called “off track”.

Both the mobile unit and off track are operated on behalf of the ASP (a public personal services company) municipality of Bologna by Open Group, a non-governmental organization, which is a part of regional paid staff, delivering harm reduction services in the community. The activities regarding harm reduction in each provincial capital city of the Emilia Romagna region are coordinated by the regional health service.

In this study, from March 2022 to June 2023, the SW team scheduled appointments, coordinated patient support, kept stock of testing equipment, and oversaw the study’s data collection.

The inclusion criteria were:

- 1) age ≥ 18 years and using substance;
- 2) belonging to a marginalized population;
- 3) the capacity to provide informed consent in Italian or in English.

Marginalization was defined as experiencing one or more of the following criteria: a history of injecting drug use; an unstable housing situation; a history of moderate to severe mental illness; and migrant status [15]. Testing was not denied to individuals who did not meet the defined criteria. Testing and enrolment were available regardless of nationality or legal status.

Setting and study procedures

The respondents took part in the research voluntarily and were not paid; consent was collected in written form. Everyone had the aims and goals of the study explained to them and anonymity was guaranteed along with the possibility of being excluded in the case of second thoughts.

Participants answered a questionnaire at the time of enrolment enquiring about demographics (age class, gender, nationality), education, occupation, housing, a history of drug use and risk behaviours practised in the last 6 months. The questionnaire was administered by SWs. All data were self-reported except for the test results.

Screening for HCV and starting DAA treatment

Testing was offered in the van by using a point-of-care HCV antibody test (In-Tech, Xiamen, Fujian, China) providing a result in 15 min. For the HCV RNA test (inside off-track), the Xpert HCV Viral Load Fingerstick Test (Cepheid, Sunnyvale, United States) was used (test results in one hour). Patients also received face-to-face counselling on HCV treatment, prevention, and reinfection risk. Participants with a detectable HCV RNA were accompanied within two weeks by a SW to a specialized health centre (Infectious Diseases Department Sant' Orsola Hospital Bologna), where transient elastography (Fibroscan® by Echosens, Paris, France) and liver ultrasound were performed.

Patients were tested through standard blood tests for liver and kidney function and HCV genotype, and they were scheduled to start HCV treatment within two to three weeks [25].

Outcomes

The primary outcomes of this study were the number of participants never previously tested for HCV, the number of participants with HCV RNA positive, the proportion of persons accompanied to treatment.

Statistical analysis

Categorical variables were summarized with count and proportion (n, %). To analyze the profiles of people tested positive for HCV RNA, a multivariate analysis was carried out using logistic regression and the odds ratio was calculated along with the respective 95% confidence intervals. Stata 17.0 was used for the statistical analyses.

The study was conducted following the Declaration of Helsinki, and participants gave their written informed consent before any data collection or testing commenced.

■ RESULTS

Eligibility and participation

In total, screening was offered to 248 people, and of those, 233 (94%) were enrolled in the study and received their results. The main reasons for not including all 248 persons in the study were language barriers and because some were fearful of knowing the result.

All participants with a positive antibody test took an RNA test. Twenty-nine (13%) had HCV antibodies, 15 (6%) tested positive for HCV RNA.

Participant characteristics of the total population

Among the 233 people enrolled, 38% were younger than 30 years old and 31% were older than 40 years old, 74% were male, and 34% were born outside Italy. Fifty-five per cent did not finish a high school degree, 67% were unemployed and 66% reported being in unstable housing. Fifty-four per cent reported having never been HCV tested before, 98% reported having been HIV tested before. All participants were tested for HIV, and 3 (1.3%) tested positive for HIV (Table 1).

Sixty-four per cent used cocaine, 46% crack, 43% heroin, 37% cannabis, 20% alcohol, 8% ketamine, 6% MDMA, 2% LSD, 2% amphetamines and 1% speed. Twenty-five per cent reported having injected drugs, 23% injected cocaine and 19% injected heroin, 17% injected both cocaine and heroin. All crack users smoked crack (Table 2).

As for risk behaviors practiced in the last 6 months, 65% have had experiences of penetrative sex without condom use, 55% shared inhalation material, 18% had got a tattoo or piercing in non-certified laboratories, 11% shared injection materials (Table 2).

Table 1 - Characteristics of the study population - Univariate analysis.

	Overall (n=233)	HCV negative (n=218)	HCV RNA positive (n=15)	Odds Ratio	95% CI	p-value
Female	58 (24.9)	56 (25.7)	2 (13.3)	1	REFERENT	0.6116
Male	173 (74.2)	160 (73.4)	13 (86.7)	1.40	0.38-5.16	
<30 years	89 (38.2)	86 (39.5)	3 (20.0)	1	REFERENT	0.107
31-40 years	71 (30.5)	64 (29.4)	7 (46.7)	3.14	0.78-12.60	
>40 years	73 (31.3)	68 (31.2)	5 (33.3)	2.11	0.49-9.13	
Native	153 (65.7)	143 (65.6)	10 (66.7)	1	REFERENT	0.9328
Non-native	80 (34.3)	75 (34.4)	5 (33.3)	0.95	0.31-2.90	
None/Primary/Secondary school	129 (55.4)	121 (55.5)	8 (53.3)	1	REFERENT	0.8703
High school diploma/University	104 (44.6)	97 (44.5)	7 (46.7)	1.09	0.38-3.12	
Unstable housing	153 (65.7)	139 (63.8)	14 (93.3)	7.96	1-63.45	0.0199
Unemployed	155 (66.5)	142 (65.1)	13 (86.7)	3.48	0.76-16.02	0.09
<i>Previously been tested for HCV</i>						
No	107 (45.9)	104 (47.7)	3 (20.0)	1	REFERENT	0.0377
Yes	126 (54.1)	114 (52.3)	12 (80.0)	3.65	1-13.49	
<i>Previously been tested for HIV</i>						
No	5 (2.1)	5 (2.3)	–	1	REFERENT	
Yes	228 (97.9)	213 (97.7)	15 (100.0)	–		
<i>HIV test</i>						
Negative	230 (98.7)	216 (99.1)	14 (93.3)	1	REFERENT	0.0566
Positive	3 (1.3)	2 (0.9)	1 (6.7)	7.71	0.64-91.62	

Table 2 - Substance used and risky behaviours - Univariate analysis.

	Overall (n=233)	HCV negative (n=218)	HCV RNA positive (n=15)	Odds Ratio	95% CI	p-value
<i>Substance</i>						
Cocaine	148 (63.5)	135 (61.9)	13 (86.7)	4.0	0.87-18.44	0.0547
Crack	108 (46.4)	103 (47.3)	5 (33.3)	0.56	0.18-1.70	0.2969
Heroin	101 (43.4)	90 (41.3)	11 (73.3)	3.91	1.19-12.90	0.0156
Cannabis	87 (37.3)	83 (38.1)	4 (26.7)	0.59	0.18-1.93	0.3780
Alcohol	46 (19.7)	44 (20.2)	2 (13.3)	0.61	0.13-2.81	0.5200
Ketamine	18 (7.7)	17 (7.8)	1 (6.7)	0.84	0.10-6.85	0.8741
MDMA	13 (5.6)	12 (5.5)	1 (6.7)	1.23	0.15-10.17	0.8499
LSD	5 (2.1)	4 (1.8)	1 (6.7)	3.82	0.39-36.97	0.2126
Amphetamines	4 (1.7)	3 (1.4)	1 (6.7)	5.12	0.49-53.33	0.1279
Speed	3 (1.3)	2 (0.9)	1 (6.7)	7.71	0.64-92.62	0.0566
Any injecting	59 (25.3)	46 (21.1)	13 (86.7)	24.99	4.81-129.83	<0.0001
<i>Behaviors practiced in the last 6 months</i>						
Penetrative sex without condom use	152 (65.2)	141 (64.7)	11 (73.3)	1.50	0.46-4.89	0.4969
Sharing inhalation material	127 (54.5)	119 (54.6)	8 (53.3)	0.95	0.33-2.72	0.9250
Tattoo or piercing in non-certified laboratories	41 (17.6)	38 (17.4)	3 (20.0)	1.18	0.32-4.41	0.8009
Sharing injection materials	26 (11.2)	20 (9.2)	6 (40.0)	6.60	2.05-21.21	0.0003

HCV RNA positive individuals

Forty-seven per cent of the 15 HCV RNA positive participants were aged from 31 to 40 years old, 33% were born outside Italy and 47% had a high school diploma/a university degree. The data are reported in Table 1 and Table 2. A larger proportion of the HCV RNA positive population were male (87% vs 73%), unemployed (87% vs 65%), had unstable housing (93% vs 64%), used cocaine (87% vs 62%) or heroin (73% vs 41%), and injected substance (87% vs 21%) compared to HCV negative participants. In the last six months, more people in the HCV RNA positive group had penetrative sex without condom use (73% vs 65%) or shared injection materials (40% vs 9%) than among the HCV negative participants.

Regarding access to testing, 48% of the HCV negative participants reported having never been tested before compared to 20% in the HCV RNA positive population.

From the univariate analysis, a history of injecting drugs (OR 24.99, 95% CI 4.81-129.83), using heroin

(OR 3.91, 95% CI 1.19-12.90) and sharing injection materials (OR 6.60, 95% CI 2.05-21.21) was significantly more common among the HCV RNA positive group compared to HCV negative participants.

From the multivariate analysis, higher statistically significant ORs were found in people injecting any substance (OR 26.43, 95% CI 4.59-152.14).

HCV treatment uptake

Among the 15 HCV RNA positive participants, 12 (80%) were accompanied to the hospital infectious diseases department for treatment (2 moved abroad, 1 disappeared).

Among the 12 participants who started treatment, 7 (58%) completed therapy and 5 did not (2 refused therapy, 1 died, 1 had viremia levels too low to be treated, 1 did not have healthcare insurance). Table 3 describes the main characteristics of the subjects treated with DAA, divided into "did not start treatment", "completed therapy", and "not completed therapy".

Table 3 - Characteristics of the HCV RNA positive individuals.

	HCV RNA positive (n=15)	Did not start treatment (n=3)	Completed therapy (n=7)	Not completed therapy (n=5)
Female	2 (13.3)	–	1 (14.3)	1 (20.0)
Male	13 (86.7)	3 (100.0)	6 (85.7)	4 (80.0)
<30 years	3 (20.0)	1 (33.3)	2 (28.6)	–
31-40 years	7 (46.7)	1 (33.3)	2 (28.6)	4 (80.0)
>40 years	5 (33.3)	1 (33.3)	3 (42.8)	1 (20.0)
Native	10 (66.7)	3 (100.0)	4 (57.1)	3 (60.0)
Non-native	5 (33.3)	–	3 (42.9)	2 (40.0)
None/Primary/Secondary school	8 (53.3)	1 (33.3)	4 (57.1)	3 (60.0)
High school diploma/University	7 (46.7)	2 (66.7)	3 (42.9)	2 (40.0)
Unstable housing	14 (93.3)	2 (66.7)	7 (100.0)	5 (100.0)
Unemployed	13 (86.7)	3 (100.0)	6 (85.7)	4 (80.0)
Any injecting	13 (86.7)	2 (66.7)	6 (85.7)	5 (100.0)
Penetrative sex without condom use	11 (73.3)	2 (66.7)	5 (71.4)	4 (80.0)
<i>Previously been tested (self-reported) for HCV</i>				
No	3 (20.0)	–	1 (14.3)	2 (40.0)
Yes	12 (80.0)	3 (100.0)	6 (85.7)	3 (60.0)
<i>Previously been tested (self-reported) for HIV</i>				
Yes	15 (100.0)	3 (100.0)	7 (100.0)	5 (100.0)
<i>HIV test</i>				
Negative	14 (93.3)	3 (100.0)	7 (100.0)	4 (80.0)
Positive	1 (6.7)	–	–	1 (20.0)

■ DISCUSSION

This is the first study carried out in Italy on the prevalence of HCV in a highly vulnerable population of substance users living with social difficulties and marginality who came into contact with a mobile harm reduction service: seven out of ten were in unstable housing; one in three were non-natives; two in three used cocaine or heroin or crack; one in four injected drugs; one in five was without healthcare; one in ten shared injection materials.

As for the main study findings, 54% reported having never been HCV tested before; a prevalence of HCV RNA of 6% among all participants and 22% among PWID was found; among the HCV RNA positive participants, 80% were accompanied to treatment.

The prevalence of chronic HCV infection among PWID in our study is lower compared to the average among PWID globally, in Western Europe and in Italy [6, 21-23, 26].

A comparison with studies conducted in Europe among marginal populations in comparable settings, shows that differences emerge due to some characteristics of the populations tested. Among the 728 people enrolled in Copenhagen, the median age was 46 years, 78% were male, and 44% were born outside Denmark. Sixty per cent reported being in unstable housing, 40% reported a history of injecting drugs [15]. Among the 529 people enrolled in Madrid, the median age was 42 years, 79% were male, 21% were migrants, 20% were homeless, and 50% reported a history of injecting drugs [20].

The study conducted on 296 injecting drug users in Oslo reported only the characteristics of the 102 HCV RNA positive individuals (median age 51 years, 77% male, 6% had unstable housing) [18]. It should be noted that both the prevalence of HCV RNA among PWID (22% in Bologna, 40% in Madrid, 37% in Copenhagen, 34% in Oslo) and the percentage of HCV RNA positive individuals who started treatment (47% in Bologna, 88% in Oslo, 70% in Copenhagen, 51% in Madrid) are lower in our study than reported results [15, 18, 20].

Most likely, the high percentage of HCV RNA positive individuals who were accompanied to treatment in our study was due to the presence of a territorial network, the execution of the tests in the

same context as the contact, the low time elapsed between antibody testing and RNA tests for positive results, to the consultancy with and support activities by the operators, and to the use of SW to accompany participants to the specialized health centre for treatment.

A weakness of the study is the elapsed time between the initial HCV-RNA positive test and treatment, and the delay in treatment might be a cause of missing treatments. Indeed, in our study participants with a detectable HCV RNA were accompanied within two weeks to a specialized health center where they started HCV treatment within two to three weeks. From other studies in comparable setting, the time from sample collection to availability of test results was 19 days in Madrid [20], the time to start treatment was within 30 days in Copenhagen, while all HCV RNA positive individuals were offered immediate DAA treatment and follow-up in Oslo [15, 18].

Studies reveal a high impact of models designed to increase access to testing and therapy based on an educational approach and networking. Point-of-care testing has been found to increase tests and shorten the time from diagnosis to treatment initiation both in marginalized populations [16] and in SERD patients [24]. The main barriers to accessing rapid tests are the lack of personnel and financing, not having legal access to healthcare, geographical origin, and lack of knowledge of the language of the host country. Moreover, in our study some people had not undergone testing because they were fearful of knowing the result.

In conclusion, our study suggests that mobile harm reduction services, in network with healthcare facilities operating in the area, could offer a continuous HCV screening service and linkage to care for people with drug use living in socially marginalized conditions.

Conflict of interest

The authors declares that they have no conflicts of interest.

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