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Barriers to effective management of hepatitis C virus in people who inject drugs: Evidence from outpatient clinics

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Abstract

Introduction and Aims. *People who inject drugs (PWID) constitute the largest reservoir of hepatitis C virus (HCV). Although effective medications are available and access to care is universal in Italy, the proportion of PWID receiving appropriate care remains low.* ***Design and Methods.*** *To identify the major barriers for PWID to HCV treatment we surveyed a large sample of practitioners working in outpatient addiction centres (SerDs). The survey was conducted in two stages and involved 30.3% of SerDs operating in Italy. In the first, SerD physicians completed a questionnaire designed with a Delphi structure. In the second, SerD practitioners completed a targeted questionnaire to identify barriers to four SerD services in HCV management: screening, referral, treatment and harm reduction.* ***Results.*** *The first-stage questionnaire, in which a Delphi and RAND-UCLA method was used, revealed a lack of agreement among the physicians about barriers to health care. The more detailed second-stage questionnaire indicated the barriers to delivering specific SerD services. As regarded the delivery of all four services, the major reasons for treating <50% of patients were: physician and nurse understaffing, technical, economic and logistic issues. In contrast, the practitioners who responded that they follow protocol recommendations often deliver all four services to >50% of patients.* ***Discussion and Conclusions.*** *HCV treatment remains out of reach for many PWID attending a drug treatment centre in Italy. To meet the World Health Organisation (WHO) target, there is a need to increase economic, technical and staff support at treatment centres using the protocols and the universal health care already in place.* [Molinaro S, Resce G, Alberti A, Andreoni M, D'Egidio PPF, Leonardi C, Nava FA, Pasqualetti P, Villa S. Barriers to effective management of hepatitis C virus in people who inject drugs: Evidence from outpatient clinics. *Drug Alcohol Rev* 2019]

Key words: hepatitis C virus, infection, drugs, people who inject drugs management.

Introduction

Globally, 71.1 million people have chronic hepatitis C virus (HCV) infection [1]. Annually, more deaths are attributable to viral hepatitis than to human immunodeficiency virus (HIV), malaria or tuberculosis [2]. An estimated 5.6 million people are chronically infected with HCV in Europe and this number is predicted to increase as HCV continues to spread [3]. The prevalence of HCV in developed countries is

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consistently higher in people who inject drugs (PWID) [4,5]. Some 67% of PWIDs are anti-HCV positive in Europe [6] compared to the 70% in Italy [7,8]. Drug injection accounts for 23% of new infections [9,10], since a PWID infected with HCV is likely to infect at least 20 other people [11,12].

The World Health Organisation (WHO) has set a goal for the elimination of viral hepatitis as a major public health threat by 2030 [9,13]. A unique opportunity for HCV treatment has come about with the advent of direct-acting antivirals (DAAs), owing to their high rates of sustained virological response (SVR) and good tolerability [14–16]. DAAs not only provide a therapeutic tool but also a preventive measure for limiting the spread of HCV infection [17]. Regardless of disease severity, access to health care in Italy is delivered to individuals with HCV [18]. Management of PWID is performed in specialised outpatient centres (SerD) that also carry out prevention, treatment and rehabilitation [19]. In 2016 there were 638 SerDs treating 143 271 patients, at least 27% of which were PWID. Nine percent of nearly 30% of PWID tested for HCV at SerDs were found to be positive [20]. A study conducted in 21 SerDs involving 543 patients reported that 63.9% of substance users are anti-HCV+ [7] and that an estimated 90 000 of the 150 000 users treated in SerDs are HCV positive. The proportion of HCV+ drug users currently treated in Italy is unknown. To facilitate uptake of the population at risk for HCV, algorithms have been developed and published for the main services delivered at the centres: screening, referral, treatment and harm reduction [19]. Overall, the Italian National Health System (NHS) has given SerDs a clear mandate on the delivery of services:

- Screening: HCV screening must be offered to all substance users (Figure 1(a)).
- Referral: All patients eligible for treatment must be referred to a specialist (infectivologist/hepatologist/gastroenterologist) (Figure 1(b)).
- Treatment: All HCV-ribonucleic acid (RNA)-positive patients are eligible for treatment (Figure 1(c)).
- Harm reduction: The measures for limiting harm, as suggested by the WHO, should be offered to all substance users (regardless of whether they are active and /or receiving DAA treatment) (Figure 1(d)).

Although access to care is guaranteed to all persons with HCV, the proportion of HCV patients receiving DAA therapy in Italy remains low. The lack of HCV treatment among PWIDs in high-income countries is due to several factors [21–31]. Some barriers to care persist even after the advent of DAAs [32,33].

This study contributes to the literature by addressing three main questions:

1. How much agreement is there among physicians working in drug treatment centres in Italy on the barriers to HCV treatment for drug users?
2. How many drug users are actually treated according to the protocol for intervention by practitioners working in SerDs?
3. What are the reasons SerDs practitioners most often give for treating <50% of patients according to protocol?

To answer these questions, we surveyed health-care providers working at SerDs (30.3% of centres) and developed a two-stage study using a Delphi method in the first and a more targeted questionnaire in the second. The results offer a framework to inform health-care providers, managers, policymakers and other stakeholders about improving the management of HCV in PWID.

Methods

Participants were recruited from the national network of outpatient addiction centres (SerD). The first questionnaire was sent out in April 2018 to more than 900 physicians working in 638 SerDs. In total, 193 centres (30.3%) participated in the survey, with good national representativeness (North 44.0%, Centre 23.3%; South, Sicily and Sardinia 32.6%). The study was carried out in two stages. In the first, a questionnaire (Q1) with a Delphi structure was sent to SerD physicians; in the second, a more targeted Questionnaire (Q2) was sent to all practitioners working in the SerDs.

Questionnaire 1—Delphi method

Using the principles of the Delphi Method, a scientific board consisting of nine experts (hepatologists, infectivologists, pharmacoeconomist, epidemiologist) was created to review the literature on the subject and to prepare a draft questionnaire. The board identified the key topics to be evaluated by SerD operators via a structured questionnaire (Q1). For each question in which a topic was investigated, the board also defined possible response options. The second questionnaire (Q2) was developed by the board after having analysed the responses to the first questionnaire. The Q2 refined certain topics that had generated ambiguous responses. In addition, the Q2 asked the SerD operators to evaluate the effective practical application and applicability of the algorithms operated at their centre to manage the population at risk for HCV [19].

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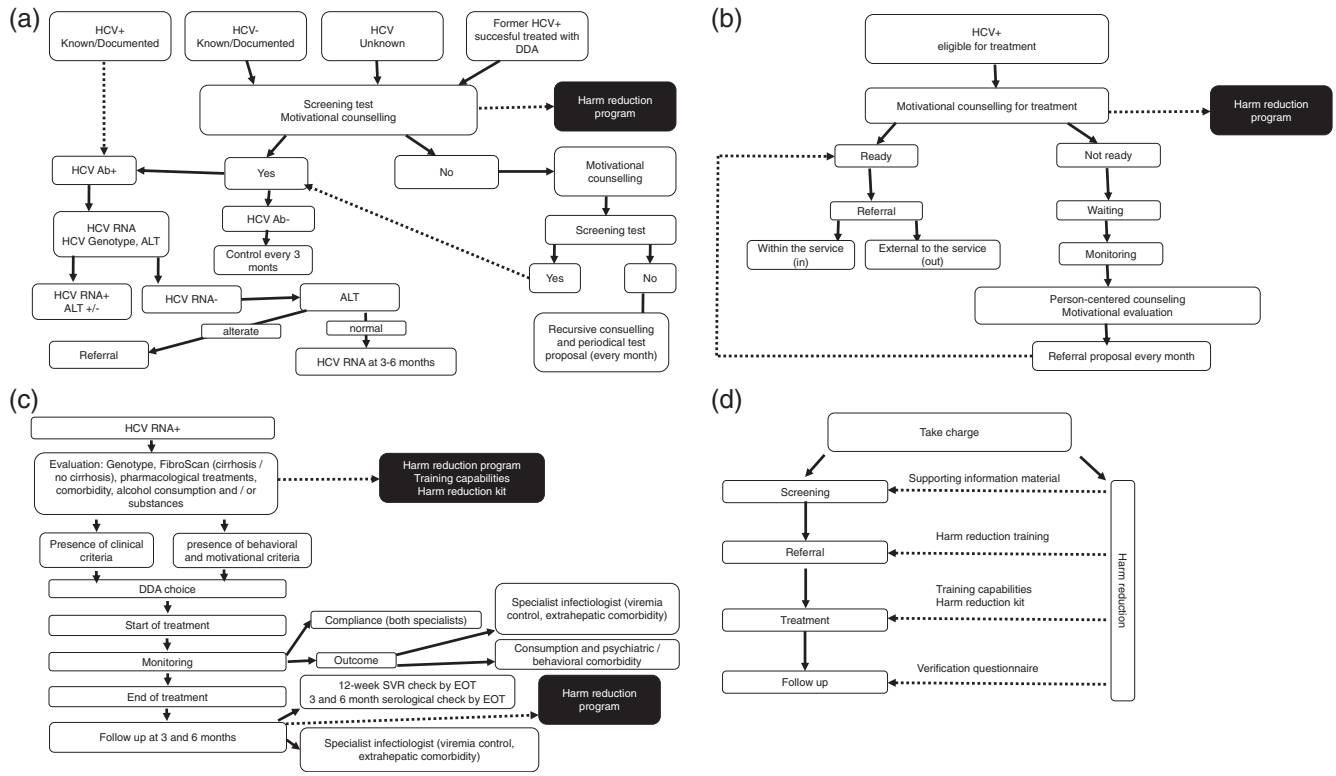

Figure 1. *Algorithm for screening, referral, activity, treatment and harm reduction services (adapted from Ref. [19]).*

To assess agreement among the practitioners, the Delphi method (developed by the RAND Corporation) was applied that uses a scale from 1—maximal disagreement to 9—maximal agreement, with five corresponding to a neutral opinion on a given statement. The practitioners′ responses were scored and statistically analysed to obtain an 'index of consensus'. The interpercentile range adjusted for symmetry (IPRAS) scores, which are a measure of score dispersion adjusted for panel symmetry, were used to determine the level of agreement on each item. The rationale behind this is that when ratings are symmetric, the interpercentile range (IPR) needed to label an indication as 'disagreement' is smaller than when they are asymmetric. Asymmetry was defined as 'the distance between the central point of the IPR and the central point on the scale from 1 to 9, i.e. 5'. Since the more asymmetric the ratings, the larger the IPR needed to say that there is disagreement, the following function was applied: IPRAS = IPRr + (AI × CFA), where IPRr is the interpercentile range needed for disagreement when perfect symmetry exists; AI is the asymmetry index; and CFA is the correction factor for asymmetry. A statement or indication is rated as disagreement if IPRi > IPRASi. Based on IPR and IPRAS computation, each statement is classified according to the appropriateness of a given diagnostic/therapeutic strategy for the following categories: Appropriate (panel median of 7–9, without disagreement), Uncertain (panel median of 4–6 or any median with disagreement), Inappropriate (panel median of 1–3, without disagreement).

Questionnaire 2—targeted questions

To identify specific barriers to access to HCV treatment, we sent a more targeted questionnaire (Q2) to all practitioners working in the SerDs. The Q2 was structured so that responders could report the proportion of their patients treated according to protocol for the four services in HCV management: screening, referral, treatment and harm reduction (Figure 1). After reporting the proportion of patients they treat, the practitioners could select the reasons why they feel they are unable to treat 100% of their patients.

Screening. Screening was investigated via six questions: General; Motivational counselling; Information; Periodical repeat for HCV-negative patients; Monthly repeat for declining patients; Periodical repeat for treated patients.

Referral. Referral was investigated via three questions: General; Motivational counselling; Harm reduction.

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Treatment. Treatment was investigated via six questions: General; Use of DAA; Harm reduction; Outcome assessment; Follow-up; Provision of harm reduction kits.

Harm reduction. Harm reduction was investigated via three questions: General; In all services; Provision of harm reduction kits.

Analysis of Q2 responses

After reporting the proportion of patients they treated in each service, the practitioners stated the reasons for their responses by selecting from the following statements: (i) 'We do not feel that it is appropriate'; (ii) economic reasons; (iii) technical reasons; (iv) logistic reasons; (v) physician understaffing; (vi) nurse understaffing; (vii) 'We know that adherence is low'; (viii) 'We select only a few categories'; (ix) 'We follow the protocol recommendations'; (x) time reasons; (xi) staffing; (xii) 'We can do it on a different schedule'.; (xiii) 'We do not have specialised staff'. By collecting data in this way, we were able to define as an outcome the proportion of patients treated, and the practitioners′ responses as the explanatory variables. Technically, for each stage the proportion of treated patients (binary <50% = 1 and >50% = 0) is the dependent variable, and the reasons that impede SerDs from treating 100% of patients are the explanatory variables. Given the intersect between a specific stage of treatment and practitioners′ response to an item, three outcomes are attainable:

1. All the practitioners who gave that response treat <50% of patients;
2. None of the practitioners who gave that response treat <50% of patients;
3. Some of the practitioners who gave that response treat <50% of patients.

In the first outcome, the response can be considered a relevant reason for being in the category with <50% of patients treated; in the second, the response cannot be considered a relevant reason for being in the category with <50% of patients treated; and in the third, there is uncertainty. To resolve this uncertainty, logistic regression was performed to obtain a measure of significance.

We used odds ratios (ORs) with a 95% confidence interval of the determinants (responses given) for treating <50% of patients (Table A1, Appendix). The interpretation of the resulting ORs is the extent to which there are significant differences between practitioners who treated more or less than 50% of patients. For a specific response option, an OR > 1 means that the practitioner′s response and the fact that the practitioner treats <50% of patients are positively associated (significantly when the lower limit of 95% confidence interval is >1); while an OR < 1 means that the practitioner′s response and the fact that practitioner treats <50% of patients are negatively associated (significantly when the upper limit of 95% confidence interval is <1).

The backward stepwise selection method was used to keep only the significant variables in the final model. All statistical analyses in this stage were performed using R [34].

Results

Descriptive statistics

In total, 193 out of a total of 638 drug treatment centres were included in this study, accounting for 30.3% of the overall number of SerDs operating in Italy [20]. By region, a higher proportion of responders (≥50%) were SerDs located in Abruzzo, Umbria and Trentino, whereas none of the six SerDs operating in Basilicata took part in the study. In 2017, >80% of the SerDs involved in the study had 200 or more patients,20% had a team specialised in infectious diseases, 10% had a team specialised in HIV, and 18% had a team specialised in hepatitis. The first section of questionnaire 1 (S1 Q1) focused on the SerD as a whole and was completed by physicians (N = 193). The second (S2 Q1) was addressed to all practitioners working in a SerD (N = 263) and encompassed a wide range of specialist areas, including psychiatry (25%), pharmacology, toxicology (23%) and infectious diseases (10%). The majority (86%) of practitioners surveyed had >10 years of professional experience. There was no agreement among practitioners on the estimated prevalence of HCV; most gave an educated guess that the national and regional prevalence was about 1.5–2.0%.

How much agreement is there among physicians working in a drug treatment centre on the barriers to HCV treatment for drug users?

There was a certain degree of agreement among practitioners about the high-risk of HCV infection in polydrug users, heroin users, PWID, sex workers, men who have sex with men and users of psychotropic substances (Table 1). In contrast, there was a certain degree of consensus that persons with alcohol dependence have a low-risk of HCV infection. In the first

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Table 1. *Practitioners' assessment of barriers to HCV screening and intervention by RAND-UCLA analysis*

Question	Median	IQR	IPRAS	Assessment
Risk of HCV infection among substance consumer types				
Youth (<21 years)	5	3	3.1	Uncertain
Polydrug users	7	2	5.35	High-risk
Occasional substance users	4	3	3.85	Uncertain
Persons with alcohol dependence	3	3	3.85	Low-risk
Cocaine users	5	3	2.35	Uncertain
Heroin users	8	2	6.1	High-risk
Users of injective substances (PWID)	9	1	7.6	High-risk
Users of inhaled substances	4	3	3.1	Uncertain
Sex workers	7	3	5.35	High-risk
Men who have sex with men	7	3	4.6	High-risk
Users of psychotropic substances	7	2	5.35	High-risk
Barriers to HCV screening in PWID				
Lack of knowledge	3	4	5.4	Inappropriate
Lack of symptoms	6	4	4.6	Uncertain
Logistic	3	4	4.6	Inappropriate
Technical	2	3	6.1	Inappropriate
Staff	3	4	4.6	Inappropriate
Lack of specialised services	3	4	4.6	Inappropriate
Lack of staff training	2	4	6.1	Inappropriate
Too much work at the SerD	3	5	4.6	Inappropriate
Lack of coordination	4	5	3.9	Uncertain
Lack of new patients	3	3	5.4	Inappropriate
Lack of specialisation	1	2	7.6	Inappropriate
Barriers to referral				
Low adherence	5	3	3.1	Uncertain
Lack of references	5	4	3.9	Uncertain
Lack of guidelines	5	5	2.4	Uncertain
Waiting list too long	4	5	3.9	Uncertain
Difficulty of access to specialist centres	4	4	3.1	Uncertain
Specialist centres do not take PWID	4	5	3.9	Uncertain
Lack of coordination	5	4	2.4	Uncertain
Lack of collaboration	5	5	3.1	Uncertain
Different objectives among centres	5	5	2.4	Uncertain
Barriers to treatment				
Patient fears starting treatment	6	4	3.1	Uncertain
Patient fears being stigmatised	3	3	4.6	Inappropriate
Patient is PWID	5	5	3.1	Uncertain
Patient is in OST	3	3	4.6	Inappropriate
Patient has a severe mental disorder	4	3.75	3.1	Uncertain
Low adherence	5	3	3.1	Uncertain
Treatment can be initiated only for SerD patients	2	3	6.1	Inappropriate
Restrictive criteria	4	4	3.1	Uncertain

(Q1 S2) questionnaire based on the Delphi and RAND-UCLA modified method, nine of the 11 barriers to screening were considered inappropriate, while two (lack of symptoms and lack of coordination) were uncertain (Table 1). As for referral, all nine barriers were uncertain. For treatment, three of the eight barriers were judged inappropriate, and the remaining five where uncertain (Table 1). Overall, Table 1 shows that, except for high-risk groups, there was a complete lack of consensus among the physicians about barriers to screening, referral or treatment. To overcome these unsatisfactory results, the board developed a more targeted questionnaire (Q2) to determine for each single practitioner the proportion of patients s/he treated in each stage of HCV treatment, and the reasons why s/he was unable to treat 100% of patients. The following results refer to the 158 practitioners who responded to the Q2.

How many drug users are actually treated according to the protocol for intervention by the practitioners working at a SerD?

The first part of Q2 asked each practitioner how many patients does s/he screen, refer, offer treatment and

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provide harm reduction (the general category in Tables 2 and 3). The answer options are grouped in five classes (<10%, 10–25%, 25–50%, 50–75% and 75–100%). Overall, except for harm reduction (53%), the majority of practitioners did offer screening (85%), referral (89%) and treatment (81%) over 50% of their patients. However, when all elements of the protocol in each of the four specific services were taken into account (Figure 1), the percentages were lower: 4.5% of the practitioners follow all the protocol recommendations for screening, 60.6% for referral, 14.3% for treatment and 20.9% for harm reduction (These percentages were estimated by means of a dummy indicator for each of the four services; the indicator is 1 only if all the elements of the protocol within the service are offered to more than 50% of patients).

Screening. Analysis of responses showed that 85% of practitioners performed HCV screening in more than 50% of their patients (134/157 responders, see Table 2). Furthermore, 77% of practitioners offered screening with motivational counselling, 27% with information, 17% with periodical repeat for patients testing negative, 37% with monthly repeat for patients who declined screening and 37% with periodical repeat for treated patients (Figure 1(a) and Table 2).

Referral. In total, 89% of practitioners reported that they referred their patients for specialist treatment in more than 50% of cases but only 73% coupled this with motivational counselling and 72% with harm reduction (Figure 1(b) and Table 2).

Treatment. Although 81% of practitioners were able to initiate treatment in at least 50% of HCV-positive parents, only 78% did so with DAAs, 55% with harm reduction, 61% with outcome assessment, 59% with follow-up and 22% with a harm reduction kit (Figure 1(c) and Table 2).

Harm reduction. Only 52% of practitioners stated that they were able to offer harm reduction measures in at least 50% of cases, 46% offered harm reduction measures in all services (screening, referral, treatment and follow-up), and 23% provided a harm reduction kit to at least 50% of patients currently or previously receiving DAA therapy (Figure 1(d) and Table 2).

What are the most common reasons practitioners state for treating less than 50% of their patients according to protocol?

Table 3 presents the percentage of reasons the practitioners gave for their responses and the proportion of patients treated in each service. Overall, the response 'We do not feel that it is appropriate' was the least frequent, on average, while the answer 'We follow the

Table 2. *Percentage of practitioners who reported performing a service in different proportions of patients*

	<10%	10–25%	25–50%	50–75%	75–100%
Screening					
General	2.5	2.5	9.6	15.3	70.1
Motivational counselling	4.5	2.5	15.9	18.5	58.6
Information	42.7	12.7	17.2	9.6	17.8
Periodical repeat for HCV-negative patients	38.9	22.3	22.3	7.0	9.6
Monthly repeat for declining patients	20.3	20.9	21.6	14.4	22.9
Periodical repeat for treated patients	32.9	14.8	14.8	14.2	23.2
Referral					
General	1.9	2.6	6.4	14.7	74.4
Motivational counselling	6.4	7.0	13.4	20.4	52.9
Harm reduction	7.1	8.3	12.8	19.2	52.6
Treatment					
General	2.6	5.9	10.5	17.0	64.1
DAA	7.2	5.9	9.2	14.5	63.2
Harm reduction	16.4	8.6	20.4	21.7	32.9
Outcome assessment	13.1	9.2	16.3	24.8	36.6
Follow-up	12.5	8.6	20.4	26.3	32.2
Provision of harm reduction kits	56.9	6.5	15.0	8.5	13.1
Harm reduction					
General	16.2	10.4	21.4	23.4	28.6
Follow-up	17.0	12.4	24.8	20.9	24.8
Provision of harm reduction kits	55.8	7.8	13.0	10.4	13.0

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Table 3. *Percentage of practitioners affirming reasons (a….k) for their responses in relation to the proportion of patients treated in a specific step of the protocol, and significant association between reasons given and treating <50% of patients (ORs in Table A1)*[a,b]

	a	b	c	d	e	f	g	h	i	j	k
Screening											
General	1.9	3.2	2.5	4.4	6.3	5.7$^{(A)}$	3.2*$^{(+)}$	3.2*$^{(+)}$	81.6*$^{(-)}$	n.p.	n.p.
Motivational counselling	0.6$^{(N)}$	3.2$^{(A)}$	3.8*$^{(+)}$	7.0	13.9*$^{(+)}$	9.5*$^{(+)}$	2.5*$^{(+)}$	5.7*$^{(+)}$	72.8*$^{(-)}$	n.p.	n.p.
Information	1.3	29.7*$^{(+)}$	31.0*$^{(+)}$	10.8*$^{(+)}$	n.p.	7.0$^{(A)}$	1.3$^{(A)}$	7.0	31.0*$^{(-)}$	13.3	n.p.
Periodical repeat for HCV-negative patients	19.0	16.5	8.2$^{(A)}$	11.4$^{(A)}$	19.6$^{(A)}$	17.7$^{(A)}$	10.8$^{(A)}$	17.1*$^{(+)}$	1.9*$^{(-)}$	n.p.	n.p.
Monthly repeat for declining patients	4.4$^{(A)}$	5.7$^{(A)}$	4.4$^{(A)}$	7.0$^{(A)}$	20.3	16.5	10.1	44.3*$^{(+)}$	29.7*$^{(-)}$	n.p.	n.p.
Periodical repeat for treated patients	4.4$^{(A)}$	13.3	8.9*$^{(+)}$	11.4	19.0*$^{(+)}$	16.5	n.p.	n.p.	n.p	19.6	n.p.
Referral											
General	0.6$^{(N)}$	0.6$^{(N)}$	2.5	3.8	9.5*$^{(+)}$	8.2*$^{(+)}$	5.7	n.p.	80.4*$^{(-)}$	n.p.	5.1*$^{(+)}$
Motivational counselling	0.0$^{(N)}$	3.2	6.3*$^{(+)}$	10.1*$^{(+)}$	15.2*$^{(+)}$	12.0*$^{(+)}$	1.9	n.p.	66.5$^{(-)}$	3.2*$^{(+)}$	n.p.
Harm reduction	1.9	5.1*$^{(+)}$	2.5	15.2*$^{(+)}$	12.0*$^{(+)}$	8.9*$^{(+)}$	3.2	n.p.	63.9*$^{(-)}$	15.8*$^{(+)}$	n.p.
Treatment											
General	2.5	1.9	2.5	4.4	7.6*$^{(+)}$	7.0*$^{(+)}$	11.4*$^{(+)}$	1.3$^{(A)}$	70.3*$^{(-)}$	n.p.	n.p.
Use of DAA	0.6$^{(N)}$	5.1*$^{(+)}$	3.8	7.0*$^{(+)}$	10.8*$^{(+)}$	8.2^{a} $^{(+)}$	7.0	n.p.	70.9*$^{(-)}$	n.p.	n.p.
Harm reduction	1.9	7.6*$^{(+)}$	6.3	12.0*$^{(+)}$	18.4*$^{(+)}$	15.8*$^{(+)}$	4.4	n.p.	45.6*$^{(-)}$	20.9*$^{(+)}$	n.p.
Outcome assessment	0.6$^{(A)}$	4.4	8.2*$^{(+)}$	15.2*$^{(+)}$	19.6*$^{(+)}$	14.6*$^{(+)}$	5.1*$^{(+)}$	n.p.	48.7*$^{(-)}$	20.9*$^{(+)}$	n.p.
Follow-up	0.0$^{(N)}$	5.1	10.1	14.6	20.3*$^{(+)}$	16.5*$^{(+)}$	5.7	n.p.	48.1*$^{(-)}$	21.5*$^{(+)}$	n.p.
Provision of harm reduction kits	5.1$^{(A)}$	36.1*$^{(+)}$	24.7*$^{(+)}$	26.6*$^{(+)}$	15.8*$^{(+)}$	12.7*$^{(+)}$	2.5*$^{(+)}$	n.p.	21.5*$^{(-)}$	22.8*$^{(+)}$	n.p.
Harm reduction											
General	1.3	20.9*$^{(+)}$	18.4*$^{(+)}$	18.4*$^{(+)}$	22.8*$^{(+)}$	14.6*$^{(+)}$	4.4	n.p.	38.6*$^{(-)}$	23.4*$^{(+)}$	n.p.
Follow-up	0.6$^{(A)}$	17.7*$^{(+)}$	16.5	19.6*$^{(+)}$	27.2*$^{(+)}$	18.4*$^{(+)}$	5.1	n.p.	34.8*$^{(-)}$	26.6*$^{(+)}$	n.p.
Provision of harm reduction kits	2.5$^{(A)}$	39.9	25.9*(+)	25.3*(+)	17.1$^{(A)}$	15.2$^{(A)}$	1.9	n.p.	20.3*$^{(-)}$	25.3*$^{(+)}$	n.p.

[a]*N* = 158; n.p. = the answer option for the specific question was not included in the Q2 questionnaire. [b]**Summary of logistic regression presented in Table A1**: $^{(N)}$ = None of the practitioners who gave that response treat <50% of patients; $^{(A)}$ = All the practitioners who gave that response treat <50% of patients; * = Response and treat <50% of patients are associated; $^{(+)}$ = Significant difference between practitioners who treated more or less than 50% of patients; $^{(-)}$ = response and treat <50% of patients are negatively associated. a = 'We do not feel that it is appropriate'; b = Economic reasons; c = Technical reasons; d = Logistic/time reasons; e = Physician understaffing; f = Nurse understaffing; g = 'We know that adherence is low'; h = 'We select only a few categories'/'We can do it on a different schedule'; i = 'We follow the recommendations'; j = Staff reasons/'We do not have specialised staff'; k = 'We do not have contact with specialised centres'.

recommendations' was the most frequent. Higher percentages in all stages are also found in responses involving staff issues (Physician understaffing; Nurse understaffing; staff reasons/'We do not have specialised staff'). This general trend remained substantially unchanged for each of the four stages (Screening, Referral, Treatment and Harm Reduction) (Table 3). However, these response options cannot be considered barriers unless they are combined with information about the share of patients treated. We estimated the odds ratios (ORs) with 95% confidence interval between responses given and treating <50% of patients. The odds ratios and confidence intervals are reported in Table A1. Table 3 presents the outcomes of logistic regressions annotated with the following four symbols:

$^{(N)}$—None of the practitioners who gave that response treat < 50% of patients;

$^{(A)}$—All the practitioners who gave that response treat < 50% of patients;

*—Significant differences between practitioners who treat more or less than 50% of patients;

$^{(+)}$—Response and treat < 50% of patients are associated;

$^{(-)}$—Response and treat < 50% of patients are negatively associated.

As regards the reasons associated with treating <50% of patients, physician and nurse understaffing were associated with treating <50% of patients, respectively, in 15 and 16 of the 18 steps of the services, while the other reasons were significantly associated with treating <50% of patients in less steps of services (5–12). The answer 'We follow the recommendations' was negatively associated with treating <50% of patients in all the services and the steps in which the answer option was included. Among the four services,

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the difference in the number of significant reasons to treat <50% of patients was smaller: from three in screening-periodical repeat for treated patients, to nine in Treatment—Provision of harm reduction kit (Table 3). This signals that many barriers are probably equally relevant to all stages of all services in the SerDs and that they mainly regard understaffing. Specific barriers to each service are described below.

Screening. Screening was investigated via six items (Figure 1(a)). Recurrent reasons for treating <50% of patients were: technical reasons, nurse understaffing and 'We know that adherence is low'. For both items regarding periodical repeat of screening, all the practitioners with <50% of patients treated stated: 'We do not feel that it is appropriate' (response a).

Referral. For the referral service, none of the practitioners with <50% of treated patients stated 'We do not feel that it is appropriate' or economic reasons. Significant reasons for treating <50% were: technical, physician understaffing, nurse understaffing and 'We don′t have contact with a specialist health-care centre'. Significant reasons for referring <50% of patients associated with motivational counselling and harm reduction (Figure 1(b)) were related to: logistics, physician understaffing, nurse understaffing and 'We do not have a specialist staff'.

Treatment. For the treatment service, all practitioners responding 'We select only a few categories' treated <50% of patients. Moreover, significant reasons for treating <50% of patients were: physician understaffing, nurse understaffing, and 'We know that adherence is low'.

Harm reduction. Significant reasons for providing harm reduction measures in <50% of patients were: economic, technical, logistical, physician understaffing, nurse understaffing and 'We do not have specialist staff'. Considering the recommendations in the algorithm (Figure 1d) (in all services and harm reduction kit), all the practitioners who offered harm reduction measures to <50% of patients stated, 'We do not feel that it is appropriate'.

Discussion

Improving the management of HCV in PWID attending a substance abuse centre is a necessary step towards the elimination of HCV at both the population and the individual level. The Italian NHS provides universal health care to individuals diagnosed with HCV infection. Management is carried out by SerDs, which are responsible for primary/secondary prevention and rehabilitation. Although guidelines are broadly inclusive, the proportion of patients with HCV attending a SerD and having access to DAA treatment is <50% in many cases. Management of HCV in a SerD is delivered via four main services: screening, referral, treatment and harm reduction.

Overall, except for harm reduction, the large majority of practitioners (>80%) reported that they offer screening, treatment, and referral to 50% or more of their patients. Nevertheless, the proportion of practitioners who follow all the protocol recommendations in >50% of their patients was substantially lower—4.5% of practitioners follow all the protocol recommendations for screening, 60.6% for referral, 14.3% for treatment and 20.9% for harm reduction. In total, 85% of practitioners responded that they provide HCV screening to >50% of their patients. The major barriers they cited were related to economic, technical, logistic factors and understaffing. The lack of adequate nursing staff was the reason many practitioners stated why they were unable to treat 100% of their patients. Moreover, the significantly low rate of motivational counselling was often associated with the practitioner′s perspective that this service is largely inappropriate. In the delivery of referral services, the significant barriers to referring 100% of patients were technical in nature and related to understaffing and/or lack of staff training. Furthermore, many practitioners stated that they do not have contact with a specialist centre for referral of patients for advanced, targeted care.

Treatment is provided to more than 50% of HCV patients in 89% of the SerDs involved in this survey. All practitioners stated that monitoring of treatment and evaluation of infectious, toxicological, and behavioural outcomes are inadequate. In addition, provision of harm reduction kits is suboptimal. Nonetheless, no practitioner stated that follow-up monitoring, *per se*, was inappropriate. Finally, technical and economic reasons were significantly associated with a low proportion of patients receiving adequate care in many steps of the treatment pathway.

Harm reduction was the service least often offered. Many practitioners stated that they did not feel that offering it was appropriate in all stages of treatment and that a harm reduction kit was not appropriate for patients receiving DAA. In contrast, studies using a multipronged approach have, in fact, demonstrated successful treatment in PWID [35–40]. This signals a lack of knowledge among practitioners, which contributes to poorer health outcomes [27]. In addition to this relevant barrier, staff reasons were recurrently

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cited as the reason why a SerD does not provide harm reduction to all its patients.

Overall, the practitioners who follow protocol recommendations are more likely to deliver services to >50% of patients in all the stages of treatment. Physician and nurse understaffing were associated with treating <50% of patients in most of the steps and services, while other reasons were less frequently associated with treating <50% of patients. Recurrent barriers were also economic and technical in nature. Among the services, the difference in the number of significant reasons to treat <50% of patients was smaller, which signals that many barriers are probably equally relevant to all stages of all services in a SerD. Oddly, the low response rate to the questionnaires in this study, which may reflect the scarce interest among practitioners for this issue, may in itself represent one of the most relevant barriers. Another factor that may limit comprehensive HCV treatment in SerDs is the pronounced lack of agreement among practitioners who responded to the first questionnaire designed using the modified Delphi method. In order to meet the WHO targets for eliminating HCV, improved health services for PWID are needed to enhance HCV prevention, with efforts focusing not only on improving care for HCV infection but also on the overall health of PWID [28].

This study has several limitations. First, the practitioners self-reported their characteristics. Furthermore, due to the small size of the sample, some of the odds ratios have extremely wide confidence intervals, which limits the interpretation of some findings. Moreover, the findings are peculiar to Italy and may not be applicable to other countries with different substance abuse services and/or identification of HCV patients. Potential co-infection with HBV and HCV or other co-morbidities was not considered. Additionally, this study did not assess whether integrated HCV treatment is offered in the SerD system. This study focused on the situation in Italy; nevertheless, it may provide a useful framework for further studies. Moreover, the strength of our study is that the participating centres came from the national network SerDs attended by about 30% of the total population. Further analysis is needed to compare the responses from the 18% of SerDs where a specialised HCV care team is present versus the SerDs that operate without one.

Conclusions

Here we report on the responses of a large cohort of practitioners to questionnaires designed to identify potential barriers to the improvement of HCV management in PWIDs. The study was carried out in two main steps. In the first, a Delphi questionnaire was sent to all substance abuse treatment centres (SerDs) to investigate their perspective on the barriers to HCV treatment in PWIDs. In the second, all practitioners working in a SerD completed a more targeted questionnaire; the questionnaire was so structured that responders could report the proportion of patients treated at each stage of the HCV care pathway and select the reasons why they felt unable to treat all of their patients attending the SerD.

The results from the first questionnaire showed large disagreement on identifying the barriers to HCV treatment for PWID. The responses to the more targeted questionnaire underlined that the reasons for treating <50% of patients were mainly related to economic issues, physician and nurse understaffing, and sometimes coordination and communication between a SerD and specialised facilities in the uptake of HCV patients. In contrast, the SerDs that follow protocol recommendations were more likely to provide HCV care services to a greater proportion of patients.

From a policy perspective, our findings show that HCV treatment remains out of reach for many PWIDs attending a substance abuse treatment centre in Italy. To meet the WHO target, there is a need to increase economic, technical and staff support at the centres in combination with the universal health care already in place in Italy.

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Conflict of Interest

The authors have no conflicts of interest.

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APPENDIX A

Table A1. *Barriers to screening referral, treatment and harm reduction*[a]

	0-50% = 1	50-100% = 0	a	b	c	d	e
Screening							
General	*N* = 23	*N* = 134	n.s.	n.s.	n.s.	n.s.	n.s.
Motivational counselling	*N* = 36	*N* = 121	None	All	19.35 (2.98-378.07)	n.s.	5.55 (2.16-14.64)
Information	*N* = 114	*N* = 43	n.s.	13.37 (3.84-84.58)	6.36 (2.36-22.26)	6.86 (1.33-125.75)	n.p.
Periodically repeat for HCV -negative patients	*N* = 131	*N* = 26	n.s.	n.s.	All	All	All
Monthly repeats for refusing patients	*N* = 96	*N* = 57	All	All	All	All	n.s.
Periodically repeat for treated patients	*N* = 96	*N* = 57	All	n.s.	3.95 (1.03-26.02)	n.s.	11.36 (3.22-72.28)
Referral							
General	*N* = 17	*N* = 139	None	None	n.s.	n.s.	11.47 (3.42-39.02)
Motivational counselling	*N* = 42	*N* = 115	None	n.s.	13.29 (3.15-90.92)	11.10 (3.58-42.01)	8.23 (3.27-22.31)
Harm reduction	*N* = 44	*N* = 112	n.s.	21.00 (3.57-399.36)	n.s.	12.11 (3.54-55.92)	16.27 (5.92-52.96)
Treatment							
General	*N* = 29	*N* = 124	n.s.	n.s.	n.s.	n.s.	8.80 (3.03-27.04)
Use of DAA	*N* = 34	*N* = 118	None	12.43 (2.70-87.99)	n.s.	7.39 (2.08-29.94)	8.93 (3.08-28.28)
Harm reduction	*N* = 69	*N* = 83	n.s.	6.86 (1.73-45.74)	n.s.	5.49 (1.87-20.06)	4.10 (1.73-10.54)
Outcome assessment	*N* = 59	*N* = 94	All	n.s.	4.05 (1.25-15.56)	6.44 (2.50-18.87)	4.64 (2.04-11.20)
Follow-up	*N* = 63	*N* = 89	None	n.s.	n.s.	n.s.	3.54 (1.59-8.30)
Provision of harm reduction kits	*N* = 120	*N* = 33	All	13.11 (3.74-83.29)	6.91 (1.94-44.07)	7.75 (2.19-49.37)	3.67 (1.01-23.71)
Harm reduction							
General	*N* = 74	*N* = 80	n.s.	7.08 (2.88-20.15)	4.41 (1.83-11.86)	3.57 (1.516-9.14)	4.53 (2.02-11.01)
Follow-up	*N* = 83	*N* = 70	All	9.63 (3.17-41.91)	n.s.	3.66 (1.53-9.78)	3.36 (1.58-7.62)
Provision of harm reduction kits	*N* = 118	*N* = 36	All	n.s.	5.22 (1.73-22.67)	8.07 (2.29-51.38)	All

	f	g	h	i	j	k
Screening						
General	All	9.90 (1.55-78.76)	9.90 (1.55-78.76)	0.03 (0.01-0.09)	n.p.	n.p.
Motivational counselling	3.41 (1.11-10.28)	3.41 (1.11-10.28)	14.36 (3.27-99.88)	0.10 (0.04-0.24)	n.p.	n.p.
Information	All	All	n.s.	0.04 (0.02-0.11)	n.s.	n.p.
Periodically repeat for HCV-negative patients	All	All	3.01 (1.26-7.80)	0.05 (0.02-0.13)	n.p.	n.p.
Monthly repeats for refusing patients	n.s.	n.s.	2.35 (1.20-4.76)	0.05 (0.02-0.12)	n.p.	n.p.
Periodically repeat for treated patients	n.s.	n.p.	n.p.	n.p.	n.s.	n.p.
Referral						
General	10.29 (2.88-36.71)	n.s.	n.p.	0.05 (0.01-0.14)	n.p.	18.89 (4.15-101.77)

(Continues)

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Table A1. *(Continued)*

	f	g	h	i	j	k
Motivational counselling	8.14 (2.95-24.94)	n.s.	n.p.	0.05 (0.02-0.13)	6.87 (2.274-23.444)	n.p.
Harm reduction	13.97 (4.67-51.95)	n.s.	n.p.	0.04 (0.01-0.09)	5.28 (2.172-13.352)	n.p.
Treatment						
General	6.21 (1.73-23.23)	13.88 (4.76-44.68)	All	0.08 (0.03-0.19)	n.p.	n.p.
Use of DAA	3.40 (1.02-11.03)	n.s.	n.p.	0.08 (0.03-0.19)	n.p.	n.p.
Harm reduction	3.83 (1.55-10.47)	n.s.	n.p.	0.05 (0.02-0.11)	19.33 (6.38-84.20)	n.p.
Outcome assessment	3.66 (1.48-9.73)	5.21 (1.15-36.42)	n.p.	0.05 (0.02-0.11)	3.78 (1.71-8.68)	n.p.
Follow-up	2.69 (1.14-6.60)	n.s.	n.p.	0.05 (0.02-0.11)	11.07 (4.47-31.75)	n.p.
Provision of harm reduction kits	n.s.	0.08 (0.01-0.68)	n.p.	0.04 (0.02-0.11)	3.64 (1.19-15.89)	n.p.
Harm reduction						
General	6.56 (2.31-23.60)	n.s.	n.p.	0.06 (0.02-0.14)	5.48 (2.40-13.84)	n.p.
Follow-up	5.29 (2.04-16.50)	n.s.	n.p.	0.04 (0.02-0.10)	13.27 (4.91-46.59)	n.p.
Provision of harm reduction kits	All	n.s.	n.p.	0.02 (0.01-0.06)	8.07 (2.29-51.38)	n.p.

[a]Odds ratios with a 95% confidence interval the determinants (responses given) for treating <50% of patients. $N = 158$; n.p. = the answer option is not present; n.s. = the odds ratio is not significant. a = 'We do not feel that it is appropriate'; b = Economic reasons; c = Technical reasons; d = Logistic/time reasons; e = Physician understaffing; f = Nurse understaffing; g = 'We know that adherence is low'; h = 'We select only a few categories'/'We can do it on a different schedule'; i = 'We follow the recommendations'; j = Staff reasons/'We do not have specialised staff'; k = 'We do not have contacts with specialised centres'.

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