

Strategies to Increase HCV Screening and Linkage to Care: The Experience of Bergamo SerD (Italy)

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INTRODUCTION

Drug use is one of the main risk factors for Hepatitis C Virus (HCV) infection. The prevalence of HCV serological positivity in people who inject drugs (PWID) is estimated to be over 80% in Italy (1). The first years after the start of injecting drug use determine a 40% risk of acquiring HCV infection (2). This population represents an important reservoir for the HCV epidemic and the absence of an effective vaccine to prevent HCV infection makes other prevention strategies, such as harm reduction strategies (e.g., education and provision of sterile syringes and screening campaigns for early diagnosis and treatment of infection) increasingly relevant (3-5). Targeting people who use drugs (PWUD) is key to achieving the World Health Organization (WHO) HCV elimination goal by 2030 (6). Different interventions are effective in increasing HCV screening and retention in care. For instance, integrated care, case management, contingency management, peer involvement, and telemedicine may be effective in the setting of the addiction community center (7). Addition community centers (called SerD in Italy) are key players for implementing these strategies. Capillary blood tests for the detection of HCV antibodies (Ab) and HCV RNA (GenExpert) represent valuable support for this group of people (8,9). Furthermore, the decentralization of specific antiviral treatment (direct-acting antiviral DAAs) from the hospital to the community, reduces barriers to treatment for this population. Different strategies have been implemented throughout Europe and Italy, such as the creation of "case managers" dedicated to HCV infection and the use of mobile units for testing and treatment distribution (10). This study aims to present the results of local initiatives at the SerD of Bergamo in response to the WHO call for HCV elimination. Bergamo SerD is one of the main addiction centers in northern Italy; around 1400 PWUD receive care at Bergamo SerD and 1/3 of them are PWID.

METHODS

1) Scaling up HCV screening:

Since 2022, the Italian government made capillary blood tests or finger tests (for HCV Ab and HCV RNA) available in each SerD in Italy. Finger tests allow to identify people who are positive for HCV antibodies and HCV RNA (GenExpert) in a short time range (minutes), without performing a phlebotomy. The algorithm for HCV diagnosis by the use of finger tests at SerD Bergamo is summarized in figure 1.

Figure 1. Algorithm for HCV screening at SerD Bergamo

Integrated care and contingency management strategies:
In 2023 the SerD of Bergamo implemented strategies to increase access to HCV screening and treatment for PWUDs. Intensive screening sessions were carried out during the weekends once a month, when PWUD accessed the center for other reasons, such taking opioid agonist treatment (OAT) or collect samples for toxicological analysis. *Incentives*, such as the distribution of food and condoms, were used on certain occasions to increase adherence to the screening.

Case management strategies:
In 2024 a HCV working group (HWG) including 2 medical and 2 nursing case managers, 1 nursing coordinator, and 1 quality expert, was created. The aims of this group were: coordinating HCV activities at Bergamo SerD, improving data collection from screening to completion of treatment, enlarging the number of professionals involved in HCV activities, integrating HCV initiatives into the regular activities of the center, and improving follow up of PWUD after HCV treatment.

2) Decentralization of DAAs treatment at SerD (*test and treat strategy*): HCV treatment requires a specific prescription procedure including data entry in the Italian Medicines Agency (AIFA) registry. Until 2022, prescription of such medications were exclusively performed by specialists in the main hospital. To improve the linkage to care for PWUD, in 2022, Bergamo SerD became a prescribing center for DAAs, making a "test and treat strategy" possible. The process required several steps:

- Regional authorization of SerD doctors for AIFA prescriptions (only in the northern region of Lombardy)
- simplified path for DAAs supply from the hospital to the SerD;
- creation of a dedicated space for people enrolled in treatment;
- creation of a database from screening to treatment at SerD.

Use of telemedicine for HCV treatment:
To further facilitate the linkage to care, the use of telemedicine was introduced. If the person is screened positive for HCV, the doctor carries out a telephone evaluation, based on blood tests, the person's medical history, and abdominal ultrasound when available. If eligible for treatment, DAAs prescription is sent to the central hospital pharmacy. DAAs are available at SerD pharmacy in 2 working days. On the day of the appointment, the person receives treatment for 28 days. A second appointment is scheduled to collect the second month of treatment and so on for the following months. After the treatment, the person only accesses the center once, to give blood sample to confirm the response to treatment (sustained virological response, SVR12, 12 weeks after the end of treatment). The SVR will then be monitored through an annual blood test for HCV RNA and a liver ultrasound per year is prescribed (figure 2).

Figure 2. Simplified journey from HCV screening to treatment at SerD Bergamo

RESULTS

➤ In 2022 most of the efforts were focused on the decentralization of treatment at SerD level: 42 PWUD were treated. 41 completed the treatment, while 1 died for comorbidities. Most of these people were already known to be HCV RNA positive, but they weren't able to access the treatment before, because it was available only in the central hospital.

➤ In 2023 and 2024 the focus of activities was: intensification of the screening and treatment of the "hard to reach" people. The availability of finger tests and the scheduled events for the screening made it possible to almost double the number of PWUD screened for HCV (343 in 2022 vs 588 in 2023, an increase of 42%).

❖ The events promoted in 2023 were:

- Sensitization and training of the healthcare professionals of SerD (1 session);
- HCV screening sessions during the access to SerD for toxicological analysis (3 sessions);
- HCV screening sessions during the administration of OAT (6 sessions);
- HCV screening and sensitization sessions one weekend per month, with distribution of condoms and breakfast (3 sessions).

In July 2023, an information leaflet was drawn up to raise awareness on the importance of diagnosis, prevention, and treatment of the different types of hepatitis among PWUD who accessed SerD.

The timetable was carried out effectively and all the planned activities were performed according to the schedule.

We highlight as a particularly successful event, the screening activities carried out during the opening hour of SerD over the weekend: more than 90% of the users were tested for HCV (around 100 throughout the weekend). Other harm reduction activities (distribution of condoms, counseling to users and family members, and distribution of food as incentives) were carried out during that session. In addition to capillary blood tests screening activities, regular screening activities via phlebotomy continued every week (2 mornings a week).

❖ In 2024 a HCV working group was established to respond to the increasing activities, especially in terms of screening and follow-up of treated PWUD. The group met once a month to monitor the activities and discuss strategies to improve the impact of our work.

The timetable for 2024 included:

- Liver ultrasound reservation and person's transportation to ultrasound department;
- HCV screening sessions during the access to SerD for toxicological analysis (6 sessions);
- HCV screening sessions during the administration of OAT (8 sessions);
- HCV screening and sensitization sessions one weekend per month, with offer of condoms and breakfast (once a month);
- On the 1st-2nd December for HIV/AIDS commemoration day, the screening was offered to people in the most deprived areas around the city. 17 people were tested, 2 of them were HCV positive, 1 HBV positive and 1 HIV positive. They were enrolled into treatment and sent to the central hospital for the follow up.

Figure 3 summarizes the results of HCV activities in the last 4 years and a half.

Figure 3. Summary of HCV screening and treatment at SerD Bergamo

Year	HCV Ab tests	HCV Ab pos	HCV RNA tests	HCV RNA pos	Pt enrolled into treatment	Completed treatments
2020	373	46	46	9	0	0
2021	516	399	110	151	0	0
2022	343	45	181	59	42	41
2023	588	140	143	35	23	23
2024	600	82	99	34	17	17

In 2021 efforts were focused to extend HCV screening to all the people who accessed SerD. In 2022, DAAs treatment was decentralized at the community level. As a result, 70% of HCV positive PWUD were treated. 30% represented a "hard-to-reach" population, because of homelessness, low compliance, presence of many comorbidities. In 3 cases, we adopted the directly observed therapy (DOT) strategy when the person accessed the center to take OAT.

In 2023 and the 2024 further efforts were done to maximize the access to HCV screening, as shown in the graph.

In 2023 and 2024, the number of treatments was lower because most of the PWUD accessed the treatment in 2022 when the DAAs became available in our center.

DISCUSSION AND CONCLUSION

The decentralization of DAAs treatment to the community and primary healthcare settings has proven to be highly effective when compared to the old linkage-to-care model with referral to specialist departments (11). Extending access to DAAs beyond hospital boundaries is necessary if we want to reach vulnerable groups. Community settings, such as SerD, are more accessible for PWUD who already access the center for other reasons (for example for taking OAT), as well as fostering a relationship of trust with healthcare providers (12,13).

Bringing DAAs treatment to SerD and introducing a simplified journey to access the treatment have certainly been effective strategies to reduce the risk of drop out in the critical phase of linkage to care and to improve the completion of treatment. Treatment adherence in SerD for PWUD is around 98%.

Furthermore, the *offer of agonist treatment* is itself a protective factor against blood-borne infections (14).

The cooperation between different stakeholders is essential to implement effective case identification and treatment enrolment strategies (12,15). In our experience, a collaboration between the pharmacy, gastroenterology, and Infectious Diseases department, SerD, and logistics service, has been key to making the whole process simple, practical, and effective.

The use of telemedicine for the evaluation of the person before starting DAAs treatment shortens the time and reduces the risk of drop out in the delicate phase of linkage to care, as well as strengthening the motivation and involvement of the person in the HCV pathway. Telemedicine approaches have already proven effective for the treatment of HCV in vulnerable groups in rural settings, or prison settings (16,17). Furthermore, it seems that telemedicine may be even more effective in promoting treatment adherence (18).

The administration of HCV treatment at the same time as opioid agonist therapy, according to a DOT scheme could promote treatment adherence (19), although our experience with this has been limited (only 3 cases). However, in these few cases, it has certainly allowed personalization of the treatment, which takes into account the health and social issues of the person.

Literature evidence shows how integrated care and the presence of a nursing case manager can facilitate the entire HCV care pathway, especially in vulnerable groups, with multiple needs (20-22). We found that creating a working group improved the quality of activities and data by sharing responsibilities. Integration with other activities has been useful to promote HCV screening more extensively and making it part of our routine.

In terms of strategies to increase HCV diagnosis among PWUD, the one-stop point-of-care model has certainly increased the access to HCV care for this population. The availability of rapid finger tests for the detection of HCV Ab and RNA must be constantly guaranteed since the effectiveness of this model largely depends on this.

There are still some critical aspects to be improved. For instance, the slow and poor supply of capillary blood tests for HCV RNA and the need to increase awareness HCV infection among healthcare professionals. Treating HCV in PWUD is a public health intervention because treating the individual reduces the risk of infection transmission. Furthermore, we realized that for a well-organized pathway, the presence of a case manager is essential, given the increasing number of treatments, infections and re-infections in this key population.

Finally, further activities, such as the use of incentives and the peers contribution to "word of mouth" could be successful.

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