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Short Report

Harm reduction-based and peer-supported hepatitis C treatment for people who inject drugs in Georgia

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ABSTRACT

Backgrounds: Georgia faces high HCV rates (5.4% of chronic cases in general population) with an epidemic concentrated among people who inject drugs (PWID). A National HCV Elimination Program (NHCEP), was launched in April 2015, aiming to eliminate HCV by 2020. To succeed, this program must develop tailored interventions to enroll PWID in treatment.
Intervention: We implemented a pilot intervention to facilitate access to and retention of PWID in the NHCEP, and to prevent reinfection after treatment. Screening was offered at a harm reduction center. PWID with positive results were followed by peer-workers during medical assessment, which lasted 73 days in average, and throughout the treatment by Sofosbuvir and Ribavirin+/− PegInterferon for 12, 24 or 48 weeks delivered at a medical center. Additional prevention sessions and PCR checks were delivered to PWID 6 and 12 months after the confirmation of sustained virologic response.
Results: The pilot intervention screened 554 people in 5 months with 244 starting treatment. The majority of participants (98.0%, n = 239) completed the treatment. The intervention, initially implemented in the capital, was replicated in a rural area.
Conclusion: Peer-supported and strongly integrated, comprehensive HCV care will help PWID reach high uptake and adherence to care.

Background

Eliminating hepatitis C

The introduction of new highly effective direct-acting antiviral (DAA) therapies has created an opportunity for the global elimination of hepatitis C virus (HCV) (Hepatitis C: only a step away from elimination?, 2015).

People who inject drugs (PWID) account for 10% of HCV cases worldwide (Gower, Estes, Blach, Razavi-Shearer, & Razavi, 2014; Nelson et al., 2011) and 23% of new infections (WHO, 2017). Almost half of chronically infected PWID lives in East/Southeast Asia and Eastern Europe (Nelson et al., 2011), where there is overall limited access to HCV treatment due to the high prices of DAAs (Bailey, Turkova, & Thorne, 2017; Lim et al., 2017). In many Eastern European countries, these exorbitant prices lead to further exclusion of PWID, with reimbursement restrictions in case of drug use, masked as concern about treatment adherence (Marshall et al., 2017).

Interventions adapted to middle-income countries that overcome the barriers to HCV treatment in PWID urgently need to be developed to achieve the WHO targets of testing 90% and treating 80% of chronic HCV cases by 2030 (WHO, 2016).

The Georgian challenge

With 5.4% of chronic HCV infection in the general population (Gvinjilia et al., 2016), Georgia has one of the highest HCV burdens in the world. The country also has a high rate of injecting drug use, with 66.2%–92% of antibody carriers among PWID (Bouscaillou

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et al., 2014; Curatio International Foundation, 2015). PWID represent 25% of HCV cases in the country (Luhmann et al., 2015). A National HCV Elimination Program (NHCEP) was launched in April 2015 with strong stakeholders support and a donation of DAAs from Gilead Sciences. The initial phase (2015–2016) of the NHCEP focused on providing 7000 free courses of Sofosbuvir (with Ribavirin+/− PegInterferon) limited to persons with advanced liver fibrosis (F3 or more corresponding to elastometry above 10 kPa or FIB4 > 3.25). The ongoing second phase (2016–2020) intends to treat every person chronically infected with HCV (Gvinjilia et al., 2016). To succeed in eliminating HCV, PWID must be considered a priority target, with a more proactive approach to guarantee their access to treatment.

Intervention: a model of care for PWID to facilitate access and adherence to treatment

Aim of the project

To facilitate access to and retention of PWID in the NHCEP and to prevent reinfection after treatment, Médecins du Monde (an international, medical non-governmental organization), alongside New Vector (a Georgian self-support organization of PWID) and Neolab (a medical center) developed and implemented a peer-support intervention. The overall aim of the project was to provide a model to scale-up to other regions of Georgia in the framework of the NHCEP.

The project took place in Tbilisi, the capital of Georgia, during the initial phase of the NHCEP. During this phase and until recently, HCV treatment delivery was only possible in authorized medical centers (MC).

The project was evaluated in the context of an effectiveness-implementation research (Curran, Bauer, Mittman, Pyne, & Stetler, 2012) that received ethical clearance from the Georgian Institutional Review Board of the Health Research Union, Tbilisi. Each participant included in the project signed a written informed consent. Medical costs that were not included under NHCEP (e.g. management of the adverse events) were reimbursed by Médecins du Monde.

Conceptual framework

In addition to stigma, being denied social support, criminalization and discrimination, patient and provider-related barriers contribute to suboptimal hepatitis C treatment uptake and retention among PWID (Doyle et al., 2015; Harris & Rhodes, 2013; Rich et al., 2016). The intervention aims to overcome the following obstacles: (1) due to referral-associated delays, inflexible hours, geographical distance, waiting time, as well as the prejudiced attitudes of some health professionals, PWID are not likely to seek HCV testing if delivered only in specialized services; (2) in case of a positive result, linkage to care can be made difficult by the long medical assessment required before starting treatment (the PCR test, which confirms the infection, needs to be done in centralized laboratories, and until now, the choice of treatment combination is based on knowing the genotype and the level of liver fibrosis); (3) health providers are concerned that poor treatment adherence in PWID, related to their supposed instability and the occurrence of unusual side effects, will lead to suboptimal efficacy; and finally (4) the risk of reinfection due to continued injecting drug use after treatment that would negate the benefit of treatment is a major reason stated by health authorities for excluding PWID from treatment programs.

Intervention content (Table 1)

Screening within a harm reduction center (HRC)

The screening process was offered at a HRC usually delivering prevention services to about 2600 PWID in Tbilisi. Eligibility to treatment was defined for the initial phase of the NHCEP by a positive viral load and severe liver fibrosis (defined as fibrosis F3 or more according to FIB-4 score or liver elastometry). The usual clients were invited to the HRC to undergo a HCV rapid test (which can only identify people having HCV antibodies, not those who have actually confirm chronic infection) and a liver elastometry (which can be performed using a device that is highly mobile). People with HCV antibodies and liver fibrosis F3 or more were sent to the medical center (MC) for further assessment. To avoid missing cases eligible to treatment, PWID with F2-F3 or inconclusive

Table 1
Pathway of participants.

PROJECT STEP	HARM REDUCTION CENTER	MEDICAL CENTER
Throughout the project	Peer workers: - Are in contact with the patient and the navigator throughout the process - Deliver an individual support in addition to the regular appointments: mediation with medical staff, help with paperwork, etc. - Track the patients dropping out of medical follow-up	Navigator: - Schedules PWID medical appointments - Orientates PWID within the medical center - Relays relevant information from the medical staff to the peer workers and vice et versa
SCREENING	- Noninvasive screening: HCV rapid andibody test and liver elastometry - Initial interview with peer worker (general information and social assessment)	
MEDICAL ASSESSMENT		- HCV confirmation (PCR) - Pretreatment assessment (FIB4, genotype, ultrasonography, etc.)
TREATMENT	- Counseling by peer worker at treatment initiation: messages on adherence, side effects, drug interactions, etc. - Patients' group discussions (monthly) - Multidisciplinary meetings involving peer workers and medical staff	- Bi-monthly medical appointments
12 weeks POST-TEATMENT	- Counseling by peer worker at the end of treatment: messages on the risk of reinfection and liver disease progression after treatment - Reminders to get a PCR check on 12th week after the end of treatment	- PCR check on 12th week after the end of treatment
POST TEATMENT	- Counseling by peer worker regarding reinfection 6 and 12 months after the PCR check on 12th week after the end of treatment	- PCR checks 6 and 12 months (right after the counseling session with the peer worker)

elastometry results were also sent to the MC for a second assessment (elastometry performed by a different person and FIB-4 score) .

Besides facilitating the recruitment of PWID by offering screening in a low threshold HRC, the objective of this process was to avoid unnecessary invasive procedures (blood sampling for PCR) and related costs for the majority who would be ineligible for treatment and, at the same time, to be sufficiently sensitive so as not to miss any cases.

Case management through peer support and patient navigation

In this pilot, the medical assessment, treatment and follow-up were performed in a MC authorized to deliver HCV treatment (Sofosbuvir, Ribavirin+/− PegInterferon for 12, 24 or 48 weeks according to genotype, treatment experience and cirrhosis status). The peer-support intervention consisted of three mandatory face-to-face sessions and personalized support, plus the organization and moderation of patient group discussions at the HRC.

The initial interview with a peer took place at the time of the screening of each patient pre-assessed as eligible. The aim of this first meeting was to provide general information about the program (registration process, steps of the treatment program, etc.), to assess each patient's situation, in particular in terms of social support needs, and to organize a personalized follow-up. A second face-to-face was delivered by peers just after treatment initiation and addressed the questions of adherence, side effects and their management, as well as treatment contraindication and drug interactions. The last face-to-face was delivered just after the end of treatment. Individuals with negative results received information about liver disease progression and post-treatment follow-up (including the importance of a viral load check 12 weeks after the end of treatment), and concerning behaviors carrying a risk of reinfection. Additional meetings or phone calls with peers could also be arranged at the patient's request. Further support included helping with paperwork or mediating with medical staff, etc.

Patient group discussions were organized at least once a month at the HRC and were moderated by peers to enable patients to share information about their treatment experience (how to maintain adherence, how to deal with side effects, etc.) and to ask specific questions. Patients at different stages of treatment, including those who had not yet started, also participated.

Finally, the peer workers were responsible for tracking patients dropping out of the intervention. In the MC, a full-time navigator was in charge of scheduling PWID medical appointments and had a key role as a mediator between the medical staff and the team of peers. If needed, individual cases were reviewed by peer workers and medical staff during multidisciplinary meetings.

Six peers already working at the HRC were involved, each one followed approximately 40 PWID. Prior to the intervention, peer workers had received three-day training delivered by a medical doctor from the MC partner and a harm reduction specialist, and one-week on-the-job skill enhancement relating to counseling methods delivered by a professional social worker.

Standardized material was provided to guide the peer-support intervention. The tools (three check lists for the face-to-face sessions, a peer-worker file, a group discussions grid, and a notebook for PWID in treatment) were specifically developed by medical experts of Médecins du Monde, then tested and adapted by the peer workers (Supplementary material).

Reinfection prevention

Changing behaviors at risk of HCV transmission was part of the three face-to-face sessions described above, which were also used to deliver standardized messages regarding reinfection, as well as personalized advice based on practices reported. After treatment completion, PWID were invited to two additional visits 6 and 12 months after the confirmation of sustained virologic response. These visits were composed of a counseling session with a peer worker and a PCR check. Messages regarding reinfection were specifically developed for these sessions, following the analysis of behavioral questionnaires completed at treatment initiation. Specific drug consumption related risks were identified in the project population, as providing assistance to one another during drug preparation or drug injection, and purchase of ready to use pre-filled syringes.

Cascade of care in the project (Fig. 1)

In a five-months period (May to September 2015), 554 of the ~2600 of HRC usual clients (an estimated 21%) came to be screened to enter the NHCEP. Cascade of care was as follows:

- 97% (n = 338) of the 350 persons referred by the HRC (i.e. with positive rapid test, and elastometry result ≥F2-F3 or inconclusive) actually attended the MC for eligibility confirmation.
- 98% (n = 333) of these 338 patients completed the pre-treatment assessment, which took 73 days on average. Eligibility was confirmed for 244 who initiated treatment.

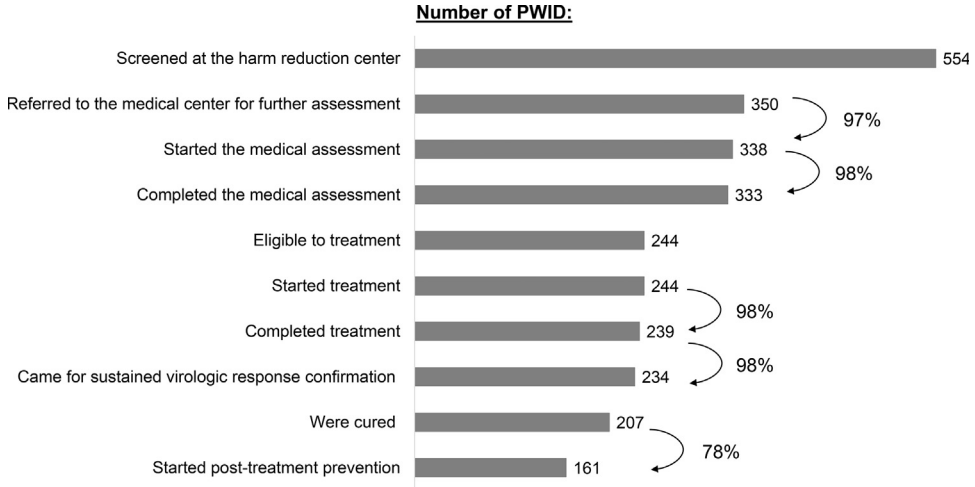

Fig. 1. Cascade of care.

- 98% (n = 239) of the 244 participants who started treatment completed the treatment
- 98% (n = 234) of them came for the PCR check 12 weeks after treatment (88.5% reached sustained virologic response, n = 207). Incarceration was one of the reasons for dropping out of the intervention at this step.
- Finally, 78% (n = 161) of those identified as cured at the end of treatment came for at least one post-treatment prevention session and PCR check
- The intervention, initially implemented in Tbilisi, capital of Georgia, is being replicated in another area of Georgia, in partnership with another local harm reduction organization .

Conclusion

Our findings demonstrated that a simple peer-support intervention implemented in a HRC produced excellent treatment uptake and retention among PWID based in Tbilisi, Georgia. Further, our work contributed to securing recognition of PWID as a priority group for prevention and treatment within the national program. Moving forward, we suggest additional key actions to increase equitable access to HCV treatment in Georgia. First, we advocate for further decentralization and integration of HCV care services, which would allow adoption of a multidisciplinary approach to PWID treatment that is fully integrated into HRC. This is likely to obtain even better results in terms of linkage to and retention in care and may appeal to the most vulnerable (Ho et al., 2015). In addition, ensuring that ongoing public-awareness campaigns incorporate messages to help PWID recognize their risk of HCV on the one hand and to improve public understanding of addiction on the other, would help reduce stigma. Also, drug addiction should be addressed as a health issue and not a crime: restrictive legislation towards PWID that applies in the country still represents a major obstacle to care and prevention in general (Grebely, Dore, Morin, Rockstroh, & Klein, 2017). Finally, access to effective interventions to prevent reinfection after treatment in PWID is crucial to reach elimination. In fact, the coverage of harm reduction services was still suboptimal when the NHCEP started (51% of PWID had access to needle and syringe programs and 9% to OST in 2015) (Alavidze et al., 2016).

Georgia, as the other middle-income countries developing their HCV control strategy, must prioritize PWID, with specific interventions for screening and support during treatment. Based on our findings, scaling up this model of care nationally appears to be a way to improve PWID access to treatment and to make progress towards the country's goal of eliminating HCV.

Conflict of interest

The authors have declared that no competing interests exist.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.drugpo.2017.11.014.

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