IMPLEMENTATION HANDBOOK

HARM REDUCTION-BASED AND PEER-SUPPORTED HEPATITIS C TREATMENT FOR PWID IN GEORGIA

MÉDECINS DU MONDE

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INTRODUCTION

This document describes the HCV treatment project targeting people who inject drugs (PWIDs) implemented in Tbilisi, Georgia, and shares information about how to scale-up the model to other regions of Georgia, or countries with a similar situation to Georgia in terms of HCV and national policies. The document offers basic operational guidance to program planners and governmental and non-governmental organization implementers. However, replication of this project in other settings will require an assessment of local context, and careful consideration of key stakeholders, including the program's beneficiaries – PWIDs.

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1. WHY THIS HANDBOOK?

The development of simple, tolerable and highly effective directly acting antiviral (DAA) therapies has become a game changer in the fight against HCV. More and more Low and Middle Income Countries (LMICs) are developing national programs to control the epidemic. As PWIDs carry a huge part of the HCV burden in LMICs, in order to succeed, these programs should consider them a priority target for prevention and treatment. However, the issue remains that HCV treatment uptake is extremely low among PWIDs. The main obstacles to HCV treatment for PWIDs are exorbitant prices; criminalization and systematic discrimination; health authorities' and providers' concerns regarding their adherence to treatment and risk of reinfection; and non-supportive national policies.

This handbook is designed to help implementers successfully include PWIDs in HCV treatment programs, through a simple and affordable peer-support intervention aiming to:

- **Improve the uptake, linkage to and retention in HCV treatment;**
- **Guarantee good adherence to treatment;**
- **Improve behaviors to lower the risk of reinfection after treatment.**

2. BACKGROUND

The intervention described and the tools shared in this document have been designed, implemented and evaluated in practice in the framework of an implementation research project conducted by Médecins du Monde France and its partners New Vector and the medical center Neolab in Tbilisi, Georgia. A total of 554 beneficiaries were screened for HCV. Of this number, 244 were included in the treatment.

The Georgian case

HCV and PWID in Georgia: HCV is a major health issue in Georgia. A population-based sero-survey conducted in 2015 by the National Center for Disease Control, working in collaboration with the US CDC, revealed that out of 6,012 study participants (reflecting 9.4% of the urban HCV infected population and 5.5% of the rural population), 7.1% were anti-HCV antibody positive and 5.16% were HCV RNA positive (giving Georgia the world's third highest prevalence of hepatitis C after Egypt and Mongolia).

Georgia also faces an epidemic of injecting drug use with around 50,000 PWID in the country. A recent study conducted among PWID in 2012 found that 92% had HCV antibodies and 82% of people were chronically infected, including 20% with advanced liver fibrosis (F3 or more according to Fibroscan) (Bouscaillou et al., 2014). The proportion of PWID among HCV carriers is estimated to be between 19% and 25.6% (Vickerman, 2015; Luhmann et al., 2015), and 34% of new cases can be ascribed to injecting drug use. According to the PWID Population Size Estimation Survey (Curatio International Foundation, Tbilisi, Georgia 2014), of 49,700 Georgian injecting drug users, around 8,000 require immediate treatment. Meanwhile, access to harm reduction services still remains limited. Prevention interventions targeting PWID are not widely accessible, with only 10% having access to opioid substitution therapy (OST) and around 28% to needle and syringe exchange programs (NSP) (Georgian Harm Reduction Network, 2015).

For many years, access to hepatitis C treatment in Georgia was restricted because of the high cost of treatment. However, since 2011, with support from the Global Fund, free antiviral treatment using a combination of Pegylated interferon and Ribavirin (dual therapy) became accessible for all HIV/AIDS and hepatitis C co-infected patients in Georgia. As part of this program, which was the first of its kind in Eastern Europe, 475 HIV/AIDS patients received free treatment (as of October 2014).

National HCV Elimination Program: The context in terms of national policies greatly evolved after the Georgian Ministry of Labor, Health and Social Protection recognized HCV as a main public health problem in 2011. Community mobilization, and the advocacy work conducted by civil society was central to this evolution. After the release of Sofosbuvir, Georgian authorities opened discussions with the American biopharmaceutical company and producer Gilead about providing treatment as part of a huge elimination plan, supported by the US CDC. These discussions eventually paid off. In May 2015, the Georgian government launched an HCV national elimination program, with the assistance of Gilead and the US CDC. The program aims to reduce HCV-related morbidity, mortality and prevalence in the country. The first stage gave priority to the treatment of patients with advanced hepatic disease and serious extrahepatic manifestations of the disease and 5,000 free courses of Sofosbuvir were reserved for people with advanced liver fibrosis. The second phase of the elimination plan (occurring in 2016-2020) has the objective of making Georgia an HCV-free zone through universal access to prevention, diagnosis and treatment.

Médecins du Monde in Georgia: Since 2011, MdM has run a harm reduction project in Georgia, in partnership with the self-support organization New Vector. On the one hand, the partners provide harm reduction and medical services to injecting drug users in Tbilisi, with an important focus on HCV, including counseling, screening, and secondary prevention with a mobile Fibroscan. On the other hand, advocacy work is undertaken to improve PWID's access to healthcare and to fight against their criminalization.

Since May 2015, MdM and New Vector have implemented peer-support intervention to facilitate access to and retention of PWIDs in the National HCV treatment program, and to prevent reinfection after treatment. MdM's program has been piloted in the framework of the National HCV Elimination Program.

INTERVENTION CONTENT

I. OVERVIEW

In this model, medical assessment, treatment and follow-up is delivered in an authorized medical center according to the HCV national treatment guidelines. In addition, the peer-support intervention relies on the following elements:

- A noninvasive affordable screening process within a harm reduction service used as entry point in the HCV national treatment program;
- A peer-support intervention delivered by social workers/peers before and throughout the treatment period;
- The coverage of costs not supported by the HCV national treatment program (for example, pretreatment diagnostic and side effects management).

The conceptual framework of this intervention is described in figure 1.

FIGURE 1 (page 9)

II. NON INVASIVE AFFORDABLE PRESELECTION PROCESS

The preselection process aims to facilitate the treatment uptake of PWIDs and avoid the costs related to wide screening. The selection process is designed to:

- Avoid unnecessary invasive procedures (blood withdrawal for PCR, liver biopsy for fibrosis assessment) and the related costs for the majority of those who will be ineligible for treatment;
- Be sufficiently sensitive to avoid missing cases;
- Be offered in the framework of PWID-friendly services, or services already used by the target population (harm reduction services).

Eligibility to treatment was defined in the Georgian context during this phase of the elimination plan by a positive viral load and severe liver fibrosis: F3 or more according to FIB-4 score or Fibroscan[1]. To identify PWIDs eligible for treatment, the following screening process was conducted in a harm reduction center *(please refer to FIGURE 2 on page 9)*

Experience & Evidence

Uptake

Information that screening and access to HCV treatment was available at the New Vector center rapidly spread in the community. From May to September 2015, 554 of the ~2,600 New Vector users came to be screened for the national treatment program (21%). Eventually, 244 of them were eligible for treatment, out of the ~470 people estimated to be eligible among all New Vector users[2]. *It was estimated that 51% of those in urgent need of treatment were reached in a few weeks.*

Process

Only participants with a positive HCV rapid test and an elastometry result of F2-F3 or more (or unclear results) were sent to the medical center (Neolab) for further evaluation. SD bioline® HCV rapid tests were performed by a VCT counselor, along with HIV and HBV testing. Elastometry tests were performed by a trained physician, with a Fibroscan (Echosens®). Before being referred, PWIDs eligible for medical assessment were sent for a face-to-face interview with a peer worker at the drop-in center (see below). Appointments at the medical center were taken at the same time.

Performances of screening algorithm

Sensitivity:

According to the data from prevalence survey conducted in 2012, this screening algorithm has a sensitivity of 96% for identifying PWID eligible to treatment under the criteria of phase 1 of the national elimination plan.

Positive predictive value

About 65% of the patients screened at New Vector were eligible for medical assessment (RDT+ and FS >F2-F3 or unclear). Eligibility for treatment was confirmed for 68% of them, and more precisely for:

- 94.4% of those with a Fibroscan of F3 or more (positive PCR);
- 19.5% of those with a Fibroscan of F2-F3 (positive PCR AND a second Fibroscan of F3+ or Fib4>3.25);
- 41.0% of those with an unclear Fibroscan result (positive PCR AND a second Fibroscan of F3+ or Fib4>3.25).

[1] As was clarified earlier, during the first phase of the elimination program when MdM's peer support intervention was undertaken, the eligibility criteria was higher liver fibrosis (F3 and F4). However, during the second phase of the program (from 2016 to 2020), everyone with a HCV viral load can be involved in the elimination program, regardless of liver fibrosis.

[2] From an estimated 18% of people chronically infected with HCV, with fibrosis level of F3 or more among PWIDs in Tbilisi (Bouscaillou & al.)

FIGURE 1 - CONCEPTUAL FRAMEWORK

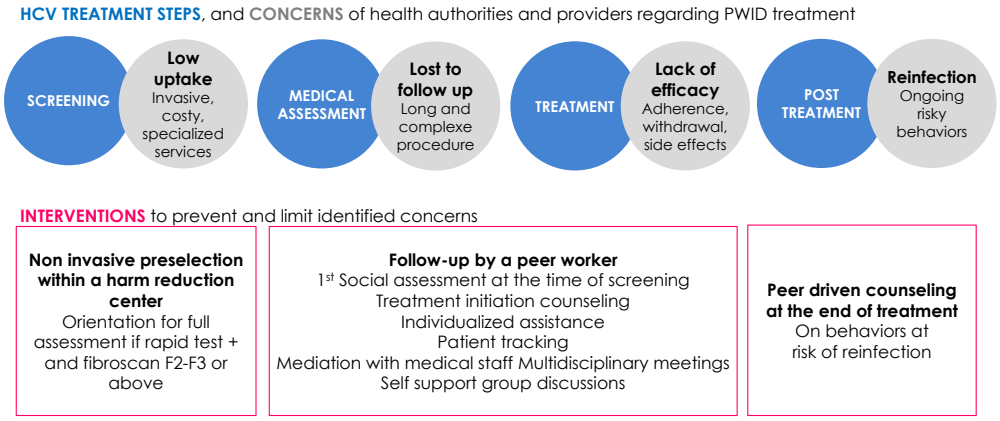
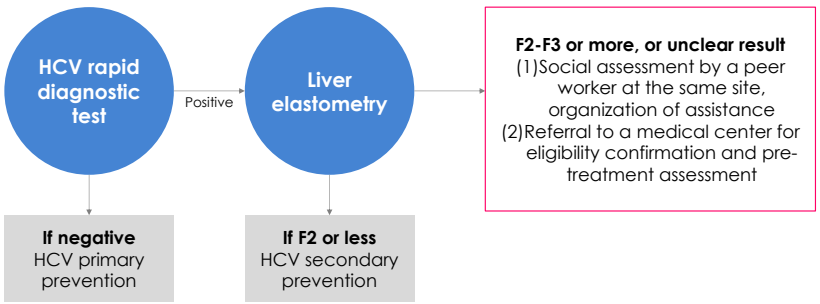


FIGURE 2 - SCREENING ALGORITHM

This screening algorithm may evolve when eligibility criteria are changing within the elimination plan. After screening, awareness-raising activities are conducted for regular users of the service.




Amethyst
COTTON MEDICAL
ВАТА МЕДИЦИНСКАЯ
ВАТА МЕДИЦИНА
MEDIZINISCHE WATTE
zigzag zurzar
100% cotton
Amethyst
Dettol
Dettol
Alcohol Swab
SURE
SURE
SURE


თუ აქვს ვინმეს „პერედოზი",
გაუკეთე ნალოქსონი!!!
MÉDECINS DU MONDE
HEPA+
NGO NEW VECTOR
STERILE SINGLE USE

III. PEER SUPPORT

First face-to-face assessment with peer-worker

An initial interview with a peer/social worker takes place at the time of the screening for each pre-eligible patient (with positive RDT and elastometry of F2-F3 or more, or unclear). This face-to-face meeting aims to inform the patient about the registration process and the different steps of the treatment program in general (medical assessment, overview of medical follow-up, peer support offered at the harm reduction service), and to deliver general information about HCV and its treatment. More importantly, this interview intends to assess the patient's needs in terms of social support, and to organize an individualized follow-up that will be conducted by the same peer/social worker throughout the patient's participation in the project. In addition, the peer/social worker provides general information on HBV and offers HBV vaccination at NeoLAB.
At this stage, the peer/social workers fill out the "assessment" part of the social worker file (Annex II), which they will subsequently use during patient follow-ups. A screening check list (Annex I) is also available to guide the social workers at the time of the first face to face.

Counseling

The first individual counselling session is delivered just after the initiation of treatment. The objectives are to assess the beneficiaries' understanding and knowledge of HCV and its treatment, to increase the retention in the project, to ensure adherence to treatment (and a fortiori the effectiveness), and to bring up the question of reinfection. The first individual counselling session specifically addresses the questions of adherence, side effects and their management, and treatment contraindication and interaction. The session is conducted in a private and friendly environment to enable the patient to talk freely about their requirements and concerns, and to ask questions. To conduct this session, the social worker uses the first check list for counselling (Annex III) and the patient's notebook (Annex VI) designed for the patient to plan his/her treatment intakes and medical visits, and to help manage any adverse events. These meetings last around half an hour, which enable the peer supporter to identify the needs of the beneficiary and try to address them.

Counselling sessions in groups are organized on at least a monthly basis and are moderated by social workers to enable patients to share information about their treatment experience (how to stay adherent, how to deal with side effects, etc.) and ask specific questions. According to a patient's needs identified during the project, some sessions will be organized with special contributors to address specific issues (for example, a nurse for a session on peginterferon injection, etc.). A standardized group session grid (Annex VII) can be used to collect the main issues and misconceptions of patients, and be used to adapt the counselling messages.

A second individual counselling session is delivered just after the end of treatment. It addresses specific messages depending on the viral load at the end of treatment. People with negative results receive information about the liver disease progression and medical follow-up after treatment (including the importance of viral load control at 12 weeks), and concerning behaviors that risk reinfection. Patients with positive results receive information about opportunities for retreatment, and secondary prevention messages. The second check list for counselling can be used to guide this session (Annexes IV & V).

Individualized assistance and patient tracking

Additional face-to-face meetings or phone calls with social workers can be arranged anytime (during the medical assessment, the treatment or after) based on the demands of the patient. Individualized interventions can be organized according to patient needs (help with paperwork, escort to the medical center, mediation with medical staff, etc.). In addition, social workers are responsible for the diligence of their patients. They try to contact them in the event of delayed visits, to understand the reasons for any problems and to offer solutions if possible. The circulation database (see for more detail Annex VIII) can be used to extract the list of patients who missed a medical or social visit.

FIGURE 3 (page 14)

Experience & Evidence

Process.

Follow-up

The whole process from counseling to treatment follow-up was conducted by six peer supporters. Each peer followed roughly 40 beneficiaries through the 12 to 48 weeks' long treatment period. After the completion of the treatment, they also contacted beneficiaries to remind them about the date of SVR12. Where necessary (if a patient was unable to walk due to overall poor

health coordination), physical follow-up from a peer supporter was also provided. Such assistance also involved purchasing and delivering medicines.

Counselling sessions in group

The most commonly discussed issues during the counselling sessions mainly related to treatment with interferon regimes because of certain misconceptions regarding its side effects. To address these concerns and to share first-hand information, counselling sessions involving both beneficiaries in treatment and those about to commence treatment were organized. Other issues commonly discussed included alcohol consumption, special dietary requirements, interactions between methadone therapy and HCV treatment, dealing with general fatigue and handling dry skin.

Multidisciplinary meetings

Multidisciplinary sessions between peer supporters and specialized doctors providing care to project beneficiaries were conducted where necessary and in certain problematic cases. This enabled peers to receive first-hand advice from doctors on how to effectively assist their patients in terms of side effects management.

Cascade of care and adherence to treatment.

Before treatment

Throughout the implementation of the model, only 3.4% of people were lost between the screening at the harm reduction center, and the reference to the medical services (half refused to go, the other went to another clinic or had to take care of a supplementary comorbidity before starting treatment). Only 2.0% of people were lost during pre-treatment follow-up, even though the medical assessment and the administrative process before starting treatment took 73 days in average.

During treatment

Of the 244 people who started a treatment, five had to stop prematurely due to serious medical events. Among those who completed the treatment, 81.3% never missed any dose, and 90.4% never delayed nor missed one of the bi-monthly medical appointments.

Sustained virologic response at 12 weeks

As of September 2016, all patients completed the treatment and 208 received SVR12 results. As of September 2016, 89% of patients who reached the SVR12 stage had sustained virologic response. This result is especially good with regards to the regimens of treatment used in the framework of the national program (sofosbuvir + ribavirin +/- pegylated interferon), and the genotype distribution among PWIDs of the pilot project (51.9% of genotype 3, 26% of genotype 2, 18.5% of genotype 1, and 3.7% of mixed genotypes).

Behavior changes.

Behaviors at risk of HCV transmission and knowledge regarding HCV assessed at the start and the end of treatment using a standardized questionnaire significantly improved during the treatment.

Peer Supporters Experience.

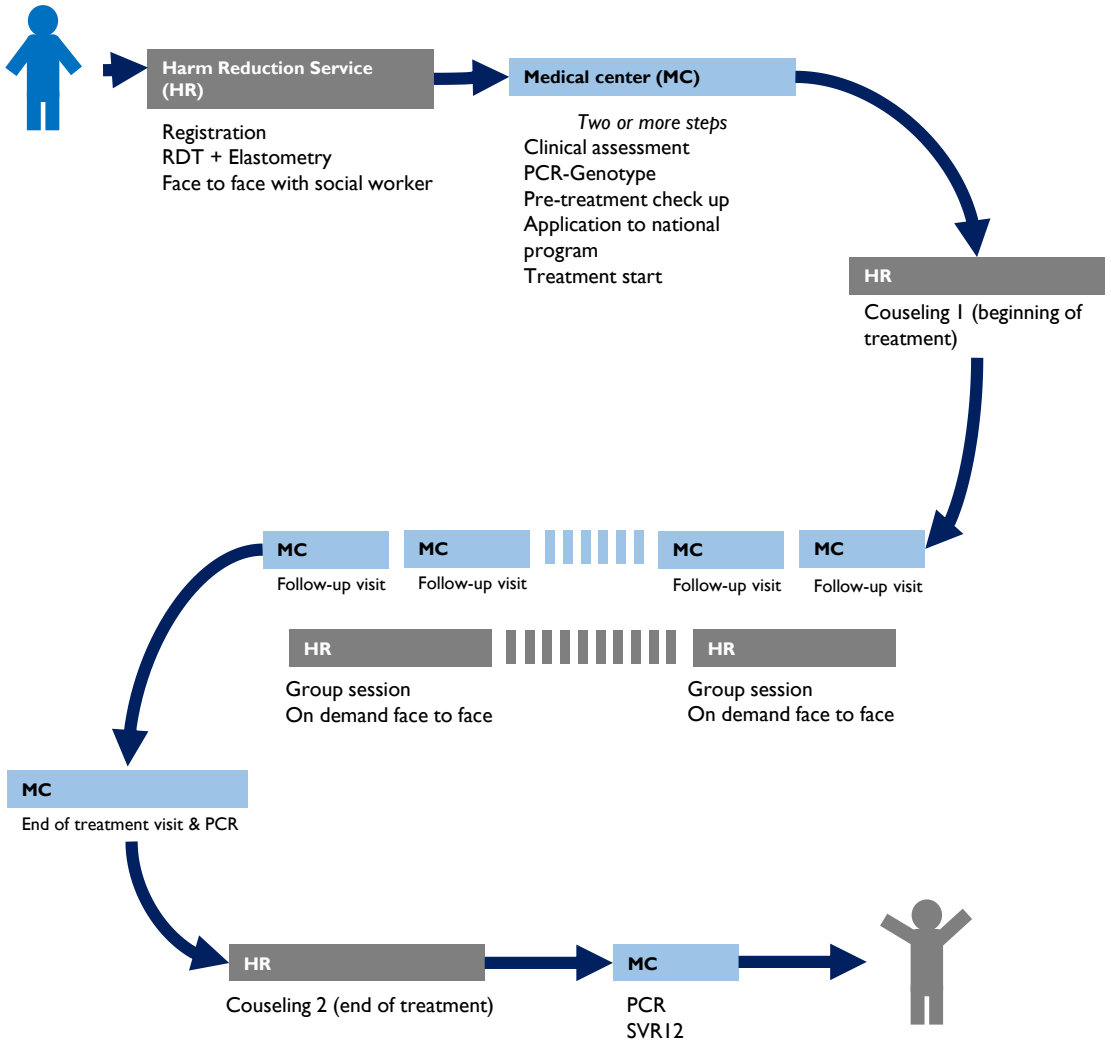
Throughout the implementation of the program, peer supporters acquired knowledge regarding HCV diagnosis and treatment, identification of the specific needs of beneficiaries, and follow-up. According to them, their knowledge of HCV was very limited before the project commenced. However, after intensive training-sessions and workshops, they acquired crucial medical knowledge about the disease that enabled them to conduct efficient consultations and follow-ups with beneficiaries to better assist them during their treatment.

Face-to face consultations, multidisciplinary sessions, case management and other features of the program required proactive communication with beneficiaries and dedicated follow-up to ensure a high rate of retention and completion of treatment. All this was achieved by the very close contact maintained between the peers and their beneficiaries. Throughout the treatment, peer supporters also had close relations with the family members of beneficiaries.

'I was really freaking out in the beginning of the project because there were a lot of things to be taken into consideration. Lots of documents needed to be filled and there were many beneficiaries to be followed. It was quite hard to keep up with everything. However, gradually we became more efficient in every direction and now we can use this knowledge in our daily work. This project gave us self-confidence and, more importantly, encouraged us to grow as social workers' – noted one of the peer-workers.

One of the more important tasks in the project was to identify the needs of beneficiaries to enable the peer supporters to provide adequate harm reduction packages and HCV prevention information. Intensive training sessions that emphasized harm reduction interventions and effective dissemination of key information for avoiding reinfection were underlined by peer supporters as one of the important directions that guided them in their work.

FIGURE 3 - PATIENT PATHWAY



IV. COORDINATION

The success of the intervention relies on the project coordinator. In particular, individual patient tracking through multiple interlocutors (social workers and physicians of the medical center) is meticulous work requiring endurance and solid organization. Good communication between the project coordinator at the harm reduction service and the medical center is crucial. Appointing a representative at the medical center is necessary for managing the scheduling of medical appointments, and the transmission of information regarding missed appointments. Finally, the coordinator must arrange multidisciplinary meetings, gathering both workers from the harm reduction service and from the medical center, to address any individual or general issues that emerge during the project.

Experience & Evidence

Project coordinator
Liaison officer - Peer supporter triangle.
A well-functioning triangle consisting of the project coordinator, liaison officer and peer supporter is a crucial element for the smooth and effective implementation of the program. For this purpose, quarterly meetings and workshops were organized to resolve any issues that arose during the implementation. Workshops were also dedicated to planning future activities and resolving any coordination issues.

At the initial stage of the program, the project coordinator was required to be available at the drop-in center (DIC) to oversee peers and ensure effective coordination. After a while, once the project became fully operational, this type of supervision gradually decreased.

The liaison officer, who was employed in the clinic and served as a mediator between the doctor and peer supporters, helped in data collection about the treatment progress of beneficiaries. The officer kept track of doctor appointments and gave prior notice to the peer supporters to help prevent any missed appointments or delays.

The project coordinator oversaw the whole process of the implementation of the project. With active engagement with peers, the coordinator supervised data collection and ensured the confidentiality of beneficiaries, and provided medical guidance and advice when necessary.

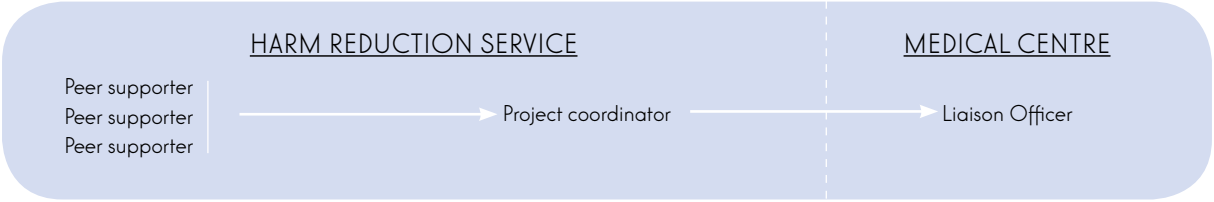
Special quota.
Because the elimination program put a lot of pressure on the authorized clinics in terms of number of patients, for the smooth functioning of the program a special quota was negotiated with a drug-user friendly clinic (NeoLab). This was an important prerequisite in order to avoid any impediments or long queues during the treatment process.

PROGRAMMATIC CONCERNS

I. STAFF AND TRAINING

Team composition

FIGURE 4. TEAM COMPOSITION



The project coordinator, who is largely based at the harm reduction service, is in charge of the project organization in general. He/she

- supervises the work of peer/social workers, and organizes weekly team meetings;
- ensures good communication between the harm reduction service and the medical center;
- manages the schedule of the harm reduction service (centralizes and validates the appointment dates for counseling sessions, and checks if they are kept);
- supervises the work of the liaison officer and data manager;
- tracks patients through the circulation database.

Within the harm reduction service, peer/social workers are the main operators of the project. They

- conduct the assessment at the screening step and identify patients' specific needs in term of support;
- follow the same patients during the whole project, from screening to the SVR12 measurement;
- are in charge of patient tracking and give reminders in case of missed appointments;
- escort people, where necessary, to medical services and undertake mediation with medical staff;
- conduct individual counselling sessions at the beginning and end of treatment, and deliver additional advice and reassurance where necessary;
- organize and deliver group counselling sessions.

The liaison officer is the focal point of the project at the medical center. He/she

- manages the schedule at the medical center (decides appointment dates for medical visits and checks if these are kept);
- welcomes the patients at the medical center and provides them with specific information about the organization of the center and patient pathways in general;
- relays relevant information from the medical center to the coordinator and/or the social workers (potential issues with a patient, need for mediation or other specific support, treatment discontinuation for medical reasons, missing appointments, etc.);
- passes relevant information from the harm reduction service on to physicians if needed.

Confidentiality

Personal data of beneficiaries are kept confidentially under the personal responsibility of the project coordinator and the physicians. However, it is recommended that a special confidentiality charter is developed and signed by peer supporters to ensure better maintenance of beneficiaries' privacy and confidentiality during their medical follow-up.

Training

Training sessions target all staff involved in the project, including the liaison officer and, if possible, other staff at the medical center. Each training session is delivered by different professionals: sessions about HCV diagnosis and treatment are covered by a medical doctor, the harm reduction sessions are introduced by a harm reduction specialist, while information about how to conduct counseling is provided by a professional social worker.

Different teaching methods, such as lectures, group discussions, hands-on activities and roleplaying games, are used for the training sessions. The modules and topics covered during these sessions are as follows:

TRAINING MODULE	TOPICS COVERED
ABOUT HCV	• Viral hepatitis • Liver performance and HCV • HCV transmission: how you get it, how you prevent it • Acute and chronic HCV • HIV/HCV confection
HCV DIAGNOSTICS	• HCV screening tests • What the results mean • Pre- and post-diagnostic counselling
TREATMENT AND SIDE EFFECTS BASICS OF THERAPEUTIC EDUCATION	• HCV treatment and drugs • HCV treatment regimes in Georgia • Monitoring of HCV treatment • Side effects of HCV treatment • Treatment for people who use drugs and risks of alcohol consumption
HOW TO CONDUCT COUNSELLING	• Methods of interviewing • Active listening • Collecting necessary information from a patient • Conducting individual and group counselling
HARM REDUCTION GOOD PRACTICES	• What is harm reduction? • Good practices in harm reduction • Prevention messages for HCV • Methadone and treatment of HCV • Preventive message dissemination during treatment • Reinfection
BASICS OF SOCIAL WORK	• Idea of social work • Social work principles • Case management

Experience & Evidence

The peer supporter/social workers involved in the HCV prevention program targeting PWID gained advanced knowledge of the topic. They received a three-day-long training session before the start of the project, and two refresher courses afterwards (regarding counselling sessions). Finally, a one-week on-the-job skill enhancement intervention regarding counselling methods was organized after the beginning of the project. The training materials, especially those related to medical issues, were adapted to make them easily understandable for a non-specialized audience.

II. MONITORING

The following indicators can be used to follow the project performance:

INDICATOR	CALCULATION AND SIGNIFICATION	SOURCE	RESULTS IN THE PILOT PROJECT
TREATMENT UPTAKE	Proportion of people in need of treatment in the target population who are reached by the project Number of patients starting the treatment / Estimated number of people needing treatment (in a given population) (Need an estimation of the prevalence of chronic infection with advanced liver fibrosis in the target population to calculate the denominator)	Circulation database (numerator), population based estimate (denominator)	51% of those estimated to need treatment, were included in in treatment
RETENTION IN CARE	Proportion of patients who completed the treatment Number of patients completing the treatment / Number of patients that started the treatment	Circulation database	98% of those who started treatment, completed it
ADHERENCE TO TREATMENT	Proportion of patients who did not miss any medical appointments Number of patients who did not miss any medical appointments / Number of patients that started the treatment	Circulation database	81% of those who started the treatment, did not delay any medical appointment
CURE RATE	Sustained virological response rate at 12 weeks Number of patients with undetectable viral load (<25 IU/ml) at week 12/ Number of patients that completed the treatment	Circulation database	89% of those who completed the treatment reached sustained virological response on week 12

Data collection:

Circulation database

This database should show which stage each patient is at (screening, medical assessment, treatment stage, etc.). It must be used to (1) organize patient flow, (2) track patients who missed a medical or other appointment, and (3) assess the care retention rate.
The database is filled on a weekly basis by the project coordinator, from information collected at the harm reduction center and the medical center. This database contains the following variables for each patient:

- Social worker in charge
- Date of screening
- Results of screening (RDT and elastometry result)
- Date of medical assessments: theoretical and actual dates
- Results of medical assessment (PCR, second elastometry if relevant, eligibility confirmation)
- Treatment regimen and theoretical treatment duration
- Date of first counseling session: theoretical and actual date
- Date of medical visits: theoretical and actual date
- Date of second counseling session: theoretical and actual date
- Date of SVR12: theoretical and actual date
- Result of SVR12
- Date and reason for premature treatment discontinuation

SUMMARY OF TOOLS

The following tools have been designed for the Georgian context, and must be adapted in the event of use in other settings.

Peer support

- Peer supporter checklist for screening (Annex I)
- Social worker file (Annex II)
- Peer supporter check list for first (Annex III) and second counseling sessions (Annexes IV and V)
- Patients' notebook (Annex VI)
- Group session grid (Annex VII)

Monitoring

- Circulation database (Annex VIII)


FIGHT
HIV & HCV
NOT
PEOPLE
USING
DRUGS

ANNEXES

ANNEX I

PEER SUPPORTER CHECKLIST FOR SCREENING

HARM REDUCTION-BASED AND PEER-SUPPORTED HEPATITIS C TREATMENT FOR PWID

OBJECTIVE

- Guidance for the first meeting with the beneficiary: social assessment and important information not to forget

CONTENT

1- To provide a general overview of the program to beneficiary verbally

2- To redirect beneficiary to data registry

3- To redirect beneficiary to testing

4- To redirect beneficiary to Fibroscan

5- To fill out the history about beneficiary and to do individual counselling/ evaluation

6- To provide beneficiary with the list of documentations (printed version) that he/she needs to submit for inclusion in the state healthcare program

7- To give addresses of social agencies

8- To provide information regarding Interferon injection (brochure)

9- To provide information about patient's responsibilities

10- To provide information to beneficiary related to group information sessions

11- To make an appointment for beneficiary in Neolab

12- To give the telephone number to beneficiary

13- To request beneficiary's and/or his/her representative's contact information

14- To redirect beneficiary to the data registry for discharge process

ANNEX II

SOCIAL WORKER FORM

PEER SUPPORT INTERVENTION FOR PWID UNDER HCV TREATMENT

OBJECTIVE

- To detect potential barrier to adherence to the program or the treatment through a social assessment of the beneficiary
- To follow the process (pre-screening, screening, treatment period, including counseling sessions) for each beneficiary
    - Decrease the risk of loss-to-follow up
    - Help in reporting side effects to the medical center

NB: the goal is not to collect and enter these data but for the social worker to have these information available when needed

CONTENT

- General information
- Medical information
- Social assessment
- Injecting drug and alcohol use
- Need for multidisciplinary meeting and related decisions concerning the beneficiary
- Individual counseling
- Participation to group session counseling
- Follow-up of the process: dossier submission, treatment period (adverse events, referencing…)

1- General information

Social worker

Name and surname: _____

Beneficiary

Name and surname: _____

ID in the program: _____

Date of birth: /__/__/ / /__/__/ / /__/__/__/__/

Sex: ☐ Male ☐ Female

Telephone number: _____

Address: _____

Date of last visit to NV Tbilisi: /__/__/ / /__/__/ / /__/__/__/__/

Support person/ legal representative/ family member

Name and surname: _____

Telephone number: _____

Comments and additional information

_____
_____
_____
_____
_____

2- Medical information

Pre-screening results

Date of HCV antibody test: /__/__/ / /__/__/ / /__/__/__/__/

Result: ☐ Positive ☐ Negative

Date of HIV test: /__/__/ / /__/__/ / /__/__/__/__/

Result: ☐ Positive ☐ Negative

Fibrosis level assessed by: ☐ Elastography ☐ Fib-4 test

Date of Fibroscan or Fib-4 test: /__/__/ / /__/__/ / /__/__/__/__/

Degree of fibrosis:

☐ F0 to F2 (<8) ☐ F2-F3 (8-10) ☐ F3 (10-12.5)
☐ F3- F4 (12.5-14) ☐ F4 (>14) ☐ Cannot be measured

Screening results

Date of PCR analysis (day / month / year): /__/__/ / /__/__/ / /__/__/__/__/

Result (number of copies): _____

Date of Genotype analysis (day / month / year): /__/__/ / /__/__/ / /__/__/__/__/

Result: _____

Date of abdominal ultrasound exam (day / month / year): /__/__/ / /__/__/ / /__/__/__/__/

Result:_____

Comments

_____
_____
_____
_____
_____

3- Social assessment (1/2)

Date of evaluation (day, month, year) /__/__/ / /__/__/ / /__/__/__/__/

Place of residence

☐ At your own private place ☐ At your parents' house ☐ At some relatives' or friends' place ☐ Renting a flat

☐ In the street, homeless, no fixed place ☐ In a hosting centre ☐ Other, please specify_____

Marital status

☐ Married ☐ Single ☐ Divorced

☐ Widowed ☐ In a relationship ☐ Other, please specify_____

Employment status

☐ Unemployed ☐ Temporarily unemployed ☐ Temporarily employed

☐ Employed ☐ At the expense of friends or relatives ☐ Other, please specify_____

Do you have health insurance?

☐ Yes, universal insurance ☐ Yes, private health insurance

☐ No ☐ Other, please specify_____

Do you receive any form of social assistance?

☐ No

☐ Assistance for below poverty line population, please specify _____

☐ Assistance for internally displaced persons, please specify _____

☐ Assistance for people with disabilities, please specify _____

How often do you usually have a drink containing alcohol?

☐ Never ☐ Once a month ☐ 2 to 4 times a month

☐ 2 to 3 times a week ☐ 4 or more times a week ☐ No response

What kind of alcohol do you drink most often?

☐ Beer ☐ Wine

☐ Vodka / Cognac/ whiskey and other high alcohol content drinks ☐ Other, please specify_____

3- Social assessment (2/2)

Are you enrolled in a methadone program?

□ No, I have never been enrolled □ Yes and I left □ Yes I am currently enrolled

If you are currently enrolled, for how long are you involved in the program? _____ (months)

If you are currently enrolled, in which program?

□ Paid methadone program □ Free methadone program

□ Paid Buprenorphine program □ Other, please specify_____

What dosage are you on now? _____ (mg)

Have you undergone detoxification course? □ No □ Yes, please specify the last time _____ (months ago)

Which product do you <u>inject</u>?

□ Heroine/ "Siret" □ Buprenorphine □ Opium □ Tropicamide

□ Methadone □ Home-made drug: Krokodil, Vint, Jeff □ Other, please specify_____

What is on average your frequency of injection?

□ Once per week □ Once to several times per week □ Everyday

□ Once per month □ Other, please specify_____

Which <u>non-injection</u> drugs do you take?

□ Marijuana, Hashish □ Psychotropic (pharmacy) substances

□ New psychoactive substances □ Other, please specify_____

Did you have any risky behaviors during last month? (e.g. sharing a syringe or drug equipment (Filter, cotton, spoon, tourniquet)

□ No □ Yes □ I don't remember

Do you have any health related problems? □ No □ Yes, please specify _____

Global evaluation by the social worker, specific needs before or during the treatment

_____

_____

_____

_____

_____

4- Individual counseling

Individual counseling 1 (after the start of treatment) : ☐ No ☐ Yes

Date : /__/__/ / /__/__/ / /__/__/__/__/

Questions discussed with the beneficiary

_____

_____

_____

_____

Individual counseling 2 (after having the result of the End Of Treatment PRC) : ☐ No ☐ Yes

Date individual counseling 2: /__/__/ / /__/__/ / /__/__/__/__/

Questions discussed with the beneficiary

_____

_____

_____

_____

5- On demand individual counseling

	Date	Questions	1 phone/ 2 face to face
1	/__/__/ / /__/__/ / /__/__/__/__/		
2	/__/__/ / /__/__/ / /__/__/__/__/		
3	/__/__/ / /__/__/ / /__/__/__/__/		
4	/__/__/ / /__/__/ / /__/__/__/__/		
5	/__/__/ / /__/__/ / /__/__/__/__/		
6	/__/__/ / /__/__/ / /__/__/__/__/		
7	/__/__/ / /__/__/ / /__/__/__/__/		
8	/__/__/ / /__/__/ / /__/__/__/__/		
9	/__/__/ / /__/__/ / /__/__/__/__/		
10	/__/__/ / /__/__/ / /__/__/__/__/		
11	/__/__/ / /__/__/ / /__/__/__/__/		
12	/__/__/ / /__/__/ / /__/__/__/__/		

6- Group session counseling

1- Date: /__/__/ / /__/__/ / /__/__/__/__/

Session topic:_____

2- Date: /__/__/ / /__/__/ / /__/__/__/__/

Session topic: _____

3- Date: /__/__/ / /__/__/ / /__/__/__/__/

Session topic: _____

4- Date: /__/__/ / /__/__/ / /__/__/__/__/

Session topic: _____

5- Date: /__/__/ / /__/__/ / /__/__/__/__/

Session topic: _____

Comment

_____

_____

_____

_____

_____

7- Multidisciplinary meeting (1/2)

1- Date: /__/__/ / /__/__/ / /__/__/__/__/

Decision(s):

_____

_____

_____

2- Date: /__/__/ / /__/__/ / /__/__/__/__/

Decision(s):

_____

_____

_____

3- Date: /__/__/ / /__/__/ / /__/__/__/__/

Decision(s):

_____

_____

_____

4- Date: /__/__/ / /__/__/ / /__/__/__/__/

Decision(s):

_____

_____

_____

7- Multidisciplinary meeting (2/2)

5- Date: /__/__/ / /__/__/ / /__/__/__/__/

Decision(s):

_____

_____

_____

6- Date: /__/__/ / /__/__/ / /__/__/__/__/

Decision(s):

_____

_____

_____

7- Date: /__/__/ / /__/__/ / /__/__/__/__/

Decision(s):

_____

_____

_____

Comment

_____

_____

_____

_____

_____

8- Treatment (1/3)

Treatment initiation

Date: /__/__/ / /__/__/ / /__/__/__/__/

Regimen: _____

Duration: _____ (weeks)

Missed consultations for HCV treatment at medical center

1- Date: /__/__/ / /__/__/ / /__/__/__/__/

Reason for absence: _____

Consultation rescheduled: ☐ No ☐ Yes

Date: /__/__/ / /__/__/ / /__/__/__/__/

Transmission to DOT: ☐ No ☐ Yes

Date: /__/__/ / /__/__/ / /__/__/__/__/

2- Date: /__/__/ / /__/__/ / /__/__/__/__/

Reason for absence: _____

Consultation rescheduled: ☐ No ☐ Yes

Date: /__/__/ / /__/__/ / /__/__/__/__/

Transmission to DOT: ☐ No ☐ Yes

Date: /__/__/ / /__/__/ / /__/__/__/__/

3- Date /__/__/ / /__/__/ / /__/__/__/__/

Reason for absence: _____

Consultation rescheduled: ☐ No ☐ Yes

Date: /__/__/ / /__/__/ / /__/__/__/__/

Transmission to DOT: ☐ No ☐ Yes

Date: /__/__/ / /__/__/ / /__/__/__/__/

8- Treatment (2/3)

Side effects and referral

1- Date: /__/__/ / /__/__/ / /__/__/__/__/

Short description: _____

_____

_____

Referral for specialist consultation: □ No □ Yes

Date:/__/__/ / /__/__/ / /__/__/__/__/

Doctor's name and surname:

Facility where the patient underwent counselling

Which insurance policy was utilized? □ Private □ Universal □ Other, specify

Hospitalization needed? : □ No □ Yes

Date: /__/__/ / /__/__/ / /__/__/__/__/

Facility

Which insurance policy was utilized? □ Private □ Universal □ Other, specify

2- Date: /__/__/ / /__/__/ / /__/__/__/__/

Short description: _____

_____

_____

Referral for specialist consultation: □ No □ Yes

Date:

Doctor's name and surname:

Facility where the patient underwent counselling

Which insurance policy was utilized? □ Private □ Universal □ Other, specify

Hospitalizaion needed? : □ No □ Yes

Date:

Facility

Which insurance policy was utilized? □ Private □ Universal □ Other, specify

8- Treatment (3/3)

Ceasing the treatment

Ceasing the treatment: ☐ No ☐ Yes

Date: /__/__/ / /__/__/ / /__/__/__/__/

Reason for ceasing the treatment: _____

Comment

_____

_____

_____

_____

_____

9- Closing the form

Reasons for closing the form

Date of termination: /__/__/ / /__/__/ / /__/__/__/__/

Social worker's name and surname: _____

Signature of the social worker

Comment

_____

_____

_____

_____

_____

ANNEX III

CHECK LIST COUNSELING I

HARM REDUCTION-BASED AND PEER-SUPPORTED HEPATITIS C TREATMENT FOR PWID

OBJECTIVE

- Assessment of the beneficiaries' understanding and knowledge of the disease and the treatment
- Increase retention in the program, adherence to treatment and effectiveness of the treatment
- Decrease risk of reinfection

PRACTICAL ASPECTS

- Done just after a patient started treatment for chronic hepatitis C
- Provided within the Harm Reduction (HR) service

KEY POINTS

This document is not entirely exhaustive and is designed to guide the counselling process: other topics can certainly be discussed, in particular according to beneficiaries' questions.

1- General assessment of the beneficiaries' understanding and knowledge of the disease and the treatment
2- Treatment: goals, disease progression, follow-up
3- Treatment: importance of adherence
4- Treatment: side effects
5- Treatment: interactions
6- Reinfection

CONTENT

1- GENERAL ASSESSMENT OF THE PATIENT

- Assess (i) what the patient understands about his condition and (ii) his knowledge, representations and perceptions regarding the disease and the treatment

- Identify and (re)evaluate factors with possible negative or positive impact on disease and treatment outcome:
    - Working conditions, economic resources, social integration
    - Living conditions (access to refrigerator, stable place, access to healthy food sources,…)
    - Potential stress factors : causes (significant personal or professional event,…), how to deal with this
    - False beliefs, fears
    - Alcohol and drug consumption, other at risk behaviors
    - Possible family support (or support through friends)
    - Etc.

- Identify patients with more personal and social difficulties to reinforce help

- Be sure that the patient has the phone contact of a peer social worker and of the medical center in case of problem

- Inform about other counselling offer : individual on demand counselling and group session counselling (meeting and exchange with other patients under treatment ; increase knowledge in HCV disease, treatment and side effects, reinfection)

2- TREATMENT : GOALS, DISEASE PROGRESSION, FOLLOW-UP

Goals of treatment

(1) Cure from the viral infection
(2) Minimize liver damage, prevent liver failure, minimize the chance of developing a cancer
(3) Improve quality of life
(4) Decrease the likelihood of HepC transmission from one person to another

Disease progression

- Despite treatment, advanced fibrosis and cirrhosis are not reversible: patients will need a follow up for their liver disease and avoid continuous liver damage (alcohol, certain illicit and licit drugs)

- Explain to the patient things to do to support the health of the liver:
    - Avoid alcohol use or heavy alcohol drinking
    - Avoid taking medicines that might cause further harm to the liver (if possible; discuss with physician)
    - Have a balanced diet, have exercise

Follow-up

Importance of follow-up exams to detect side effects and to assess treatment efficacy

3- TREATMENT: IMPORTANCE OF ADHERENCE

General information

Treatments work better when they are taken exactly as prescribed, in the right amount and at the right time for the entire time that your treatment lasts:

- Skipping doses or stopping treatment altogether means that the treatment may not work as well and the chance of being cured is lower
- With some Hep C medications, there is also a chance that the virus can become resistant to the medication : it will not be effective any more

Assessment of the knowledge of the treatment plan

- Assess knowledge of the schedule and of the frequency of each molecule (treatment plan) and give a written copy of this treatment plan to the patient
- If the patient will/has planned to go away, plan ahead the treatment and forecast regular visits

Tips to give to the patient

- Tips to help patients remember to take the medicines on time:
    - Choose the best moment to take pills (during a meal), that fits both with the prescription and the personal schedule of the patient
    - Select a regular day and time that is convenient for the weekly PEG IFN injections
    - Put an alarm on a mobile phone or a clock to provide reminders
    - Ask occasional reminders by the family members
    - Circle dates in a calendar
    - Keep a medication diary
- Find allies in their relatives/friends: schedule treatment together
- In case of travel:
    - Plan ahead the treatment
    - Use a pill box to take extra doses with you when the patient is out
    - Use a cooler with an icepack for IFN if the patient is going away
- Follow the prescription:
    - Do not take more pills than prescribed by the physician
    - Do not decide to stop / decrease doses alone – for example in case of side effects

Explain what to do if missing a treatment dose

(1) Of sofosbuvir

- If you miss taking a dose of sofosbuvir, take it as soon as possible
- But if it is close to the next time when you would take sofosbuvir, wait and take the next tablet at your regular time: do not take a double dose

(2) Of IFN

- If you miss taking a dose and remember <u>within two days</u> of when you were supposed to take it, take it as soon as possible
- If it is <u>more than two days after</u> you were supposed to take your dose, ask your doctor what you should do

(3) Of ribavirin

- <u>Within 6 hours of the scheduled dose</u>: take the missed dose as soon as possible
- <u>More than 6 hours have passed</u>: take only the next dose, do not take a double dose

4- TREATMENT : SIDE EFFECTS

Emergency: consult the physician in case of occurrence of the following symptoms

- Breathlessness
- Chest pain
- Thoughts about harming oneself
- Swelling around ankles or abdomen
- Confusion
- Rapid weight loss

In case of occurrence of side effects, it is very important that the patient

- Doesn't stop the treatment by himself
- Mentions the side effects to the physician and the peer social worker
    - Never adapt the dose by himself : the physician will do it;
    - Prescription of other treatment
- Writes side effects in the patient notebook

NB: Some of the side effects from hepatitis C medications can feel a lot like drug withdrawal : it is important to prevent these side effects and consult with physician/don't change dosing yourself

Main side effects

(1) Of Peg Interferon

Some of the side effects occur mainly 24 – 48 hours after interferon injection and do disappear after that

Symptoms	Detection	Advices for management by social workers
Influenza-like syndrome during the first weeks (fever, shivers, fatigue, myalgia (muscular pains))	Symptoms	Take paracetamol 30 minutes to 1 hour before the injection (max 3g/day, max 1g/dose) and after if necessary
Reduced appetite, loss of weight	Symptoms, clinical examination	Eat a balanced diet, take nutritional supplements
Loss of hairs	Symptoms	
Fatigue, decrease in concentration, depressed mood, anxiety	Symptoms	Adapt the daily life, ask help/organize with relatives, eat a balanced diet DO NOT HESITATE TO MENTION TO YOUR PHYSICIAN
Skin reactions at the injection site	Symptoms	Moisturizing cream, do not inject in this place, change place of injection every week
Drop in white blood cells → increase risk of infections	Symptoms, blood collection	Pay attention to infections (no contact with infected children/persons, pay attention to what is eaten…), healthy lifestyle
Drop in platelets → increase risk of bleading	Symptoms, blood collection	Avoid traumas/injuries

(2) Of ribavirin

Symptoms	Detection	Advices for management by social workers
Decrease in red blood cells, anemia	Symptoms, blood collection	Eat food rich in iron (read meet, vegetables, …)
Cough/and temporary difficulty to breath	Symptoms	

Ribavirin can cause as well more general side effects, similar to interferon, such as: headache, fatigue, nausea, pruritus.

Examples of management of main side effects

- *Fatigue* : ask help/organize with relatives and have a healthy lifestyle - eat balanced diet and nutritious foods, get regular exercise and enough sleep, avoid or reduce alcohol and drug use;
- *Loss of weight*: possibility to eat nutritional supplements;
- Influenza like syndrome: take paracetamol 30 minutes to 1 hour before injection (max 3g/day, max 1g/dose) and after if necessary;
- *Dry skin* : moisturizing cream;

5- TREATMENT: CONTRAINDICATIONS AND INTERACTIONS

Contraindications

- Pregnant and breastfeeding women cannot take treatment
- Couples with one of the partners (or both) being treated need to consider an efficient contraceptive method until 6 months after treatment, as severe birth defects may occur in the unborn child

Interactions with Opiate Substitute Treatment

- Minor interactions with methadone: tell to physician if methadone is not working the same after the start of hepatitis C treatment
- In case of start of a new treatment, the patient has to inform the physician

6- REINFECTION

People are not immune to hepatitis C after clearing the virus and it is possible to get re-infected. Taking steps to stay safe will help people continue to live well once they have finished hepatitis C treatment.

- Assess at risk behaviours of the patient
- Explain the importance of avoiding them
- Importance of absence of reinfection during and after the treatment period
- Explain measures to avoid the transmission, in particular through blood exchanges/contacts – razors, toothbrush, piercing exchanges, tattoos, sharing of injection/sniff material
- Possibility of infection with a second type of virus (in this case the treatment would be less effective)

ANNEX IV

CHECK LIST COUNSELING 2

- Positive PCR at EOT -

HARM REDUCTION-BASED AND PEER-SUPPORTED HEPATITIS C TREATMENT FOR PWID

OBJECTIVE

- Answer to beneficiaries' questions
- Reassurance
- Avoid fast evolution to liver cancer

PRACTICAL ASPECTS

- Done **after** the patient received the result of the PCR at the end of the treatment and **after** the beneficiary has completed the second questionnaire with the interviewer
- Provided within the Harm Reduction (HR) service

KEY POINTS

This document is not entirely exhaustive and is designed to guide the counselling process: other topics can certainly be discussed, in particular according to beneficiaries' questions.

1- Answer to beneficiaries' questions, reassurance
2- Information on liver disease follow-up
3- Information on drug use and reinfection
4- Information on OST program

CONTENT

1- BENEFICIARIES' QUESTIONS, REASSURANCE

Open questions and discussion

- Identify patients with more personal and social difficulties to reinforce help
- Experience of the treatment:
    - Occurrence of side effects?
    - Missed doses?
    - Complete treatment?
    - Difficulties encountered?
    - Reasons of early stop of the treatment if it is the case?
- Satisfactory with the overall program, including counselling sessions? Suggestions?

Explanation of the PCR result and reassurance

- The treatment hasn't worked: hepatitis C virus is still detected in the blood
- Reassurance ; inform on further opportunities (possibility to be treated again with sofosbuvir)
- Re-explain measures to avoid the transmission by blood contacts: (i.e. through razors, toothbrush, piercing exchanges, tattoos, sharing of injection/sniff material)
- Importance of reducing liver damage and the progression of liver fibrosis (see point 2).

2- EVOLUTION OF THE LIVER DISEASE

- Explain the progression of the liver disease
    - In most of the cases, advanced fibrosis and cirrhosis are not reversible
    - The risk of developing a liver cancer is important

- Importance to have a follow-up of the liver disease
    - At least abdominal US + liver function six months after the end of the treatment and then every 6 months to every year
    - Fibroscan in the framework of the harm reduction program, if available

- Explain what to do to support the health of the liver
    - Avoid alcohol use or heavy alcohol drinking
    - Avoid taking medicines that might cause further harm to the liver (if possible; discuss with physician)
    - Follow a balanced diet, make exercise, and avoid overweight

3- INFORMATION ON DRUG USE AND REINFECTION

- Assess behaviors at risk of reinfection
- Explain the importance of avoiding them

To assess the perception of the beneficiary concerning his/her personal risk(s) given his/her current behaviors, a graduated rule could be used (as the visual analogue pain scale), in addition of the usual counselling.To use it the social worker shows the colored part to the beneficiary and reads on the other side the corresponding value; red and 10 are "sure to be reinfected", green and 0 are "no risk of reinfection". It can be done for example regarding his/her last injection, asking to the beneficiaries which were the risks; after the beneficiary has assessed the risk it can open to questions such as: which risk (infectious, overdose, …), what is a safe injection if the beneficiary grade 0, why is it or not really a safe injection, different risks in different situations, how to improve the injection to decrease specific risks assessed... It can be a mean of guiding the counselling.

4- INFORMATION ON OST PROGRAM

If the beneficiary is not currently enrolled in an OST program, discuss the reasons and the opportunities to do it

ANNEX V

CHECK LIST COUNSELING 2

- Negative PCR at EOT -

HARM REDUCTION-BASED AND PEER-SUPPORTED HEPATITIS C TREATMENT FOR PWID

OBJECTIVE

- Answer to beneficiaries' questions
- Decrease the risk of loss to follow-up until SVR12 visit
- Decrease the risk of reinfection
- Avoid fast evolution to liver cancer

PRACTICAL ASPECTS

- Done **after** the patient received the result of the PCR at the end of the treatment and **after** the beneficiary has completed the second questionnaire with the interviewer
- Provided within the Harm Reduction (HR) service

KEY POINTS

This document is not entirely exhaustive and is designed to guide the counselling process: other topics can certainly be discussed, in particular according to beneficiaries' questions.

1- Answer to beneficiaries' questions
2- Inform on the follow-up of the hepatitis C disease
3- Inform on the evolution of the liver disease
4- Inform on risk of reinfection : people are not immune to hepatitis C after clearing the virus
5- Information on OST program

CONTENT

1- BENEFICIARIES' QUESTIONS

Open questions and discussion

- Identify patients with more personal and social difficulties to reinforce help
- Wellbeing of the beneficiary
    - Changes before/after the treatment?
    - *If Yes*, which are the differences?
- Experience of the treatment
    - Occurrence of side effects?
    - Missed doses?
    - Complete treatment?
    - Difficulties encountered?
    - Reasons of early stop of the treatment if it is the case?
- Satisfactory with the overall program, including counselling sessions? Suggestions?

Explanation of the PCR result and reassurance

- At this point, cure cannot be confirmed: sustained virological response (SVR) is the criteria to talk about cure; and it is assessed around 3 months after the end of the treatment
- A negative PCR means that the hepatitis C virus can not be detected in the blood anymore
    - If the beneficiary has completed the treatment, the probability of cure is very high
    - If the beneficiary has stopped earlier the treatment, there is a probability of relapse
- People are not immune to hepatitis C after clearing the virus and it is possible to get re-infected

2- FOLLOW-UP OF THE HEPATITIS C DISEASE

- Treatment effectiveness is assessed 3 months after the end of the treatment
- It can be said that treatment is effective if a person still has an undetectable hepatitis C viral load 3 months after the end of the treatment: this is called sustained virological response (SVR)
- It is very important not to miss this assessment at the medical center

3- EVOLUTION OF THE LIVER DISEASE

- Explain the progression of the liver disease
    - In most of the cases, advanced fibrosis and cirrhosis are not reversible
    - The risk of developing a liver cancer is important

- Importance to have a follow-up of the liver disease
    - At least abdominal US + liver function six months after the end of the treatment and then every 6 months to every year
    - Regular fibroscan in the framework of the harm reduction program, if available

- Explain what to do to support the health of the liver
    - Avoid alcohol use or heavy alcohol drinking
    - Avoid taking medicines that might cause further harm to the liver (if possible; discuss with physician)
    - Follow a balanced diet, make exercise, and avoid overweight

4- INFORMATION ON DRUG USE AND REINFECTION

People are not immune to hepatitis C after clearing the virus and it is possible to get re-infected

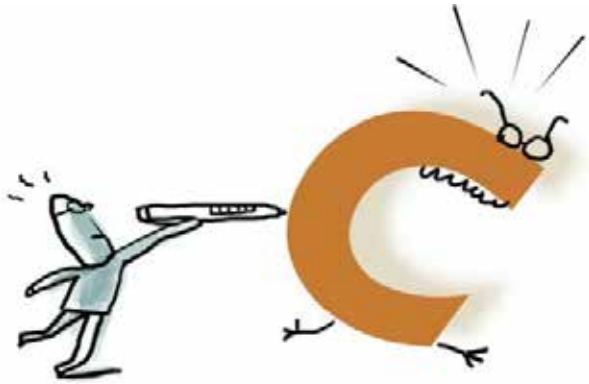
- Assess behaviors at risk of reinfection
- Explain the importance of avoiding them

To assess the perception of the beneficiary concerning his/her personal risk(s) given his/her current behaviors, a graduated rule could be used (as the visual analogue pain scale), in addition of the usual counselling.To use it the social worker shows the colored part to the beneficiary and reads on the other side the corresponding value; red and 10 are "sure to be reinfected", green and 0 are "no risk of reinfection". It can be done for example regarding his/her last injection, asking to the beneficiaries which were the risks; after the beneficiary has assessed the risk it can open to questions such as: which risk (infectious, overdose, …), what is a safe injection if the beneficiary grade 0, why is it or not really a safe injection, different risks in different situations, how to improve the injection to decrease specific risks assessed... It can be a mean of guiding the counselling.

5- INFORMATION ON OST PROGRAM

If the beneficiary is not currently enrolled in an OST program, discuss the reasons and the opportunities to do it

ANNEX VI



Treatment notebook

Image credit : SOS Hépatites Fédération

1

Here is a notebook that is given to you in the framework of the study that you recently agreed to take part in.

It should help you to manage your medical HCV treatment: not to forget pills of sofosbuvir and ribavirin, nor PEG-IFN injection.

You can fill with nurses or physicians in Neolab your treatment plan, and use the calendar page 4 to plan your PEG-IFN injections.

Don't hesitate to write in this notebook the side effects that occur and the timing compared with treatment intake and injections. This will facilitate the discussion with the physician.

Contacts

Patient name: _____

Patient phone number: _____

Social worker name: _____

Social worker phone contact: _____

New Vector: _____

Neolab: _____

Treatment plan

PEG-IFN alpha 2a - 180microg/1ml

Initial dose 180 mcg
Once-weekly injection volume 1,0 mL

Dosing adjustment 1 __ __ __ mcg
Once-weekly injection volume __ , __ mL
Date __ __ / __ __ / __ __ __ __

Dosing adjustment 2 __ __ __ mcg
Once-weekly injection volume __ , __ mL
Date __ __ / __ __ / __ __ __ __

What you have to do if you miss a dose

1- If you remember within two days of when you were supposed to take it

→ take it as soon as possible

2- If you remember more than two days after you were supposed to take your dose

→ ask your doctor what you should do

Ribavirin – 200 mg pills

Take the pills during the meals

	Every morning	Every evening
Initial dosage		
Dosage adjustment 1 Date 1 __/__/____		
Dosage adjustment 1 Date 2 __/__/____		

Nurse to circle prescribed ribavirin dosage

What you have to do if you miss a dose

1- If you remember within the 6 hours of the scheduled dose

→ take it as soon as possible

2- If more than 6 hours have passed since the scheduled dose

→ take only the next dose, **DO NOT DOUBLE !**

Sofosbuvir – 400 mg pills

Take the pills during the meals

400 mg each day

What you have to do if you miss a dose

1- If you remember within

→ take it as soon as possible.

2- If you remember close to the next time when you would take sofosbuvir

→wait and take the next tablet at your regular time, do not take a double dose

Calendar for PEG-IFN injections

June 2015						
Mon	Tue	Wed	Thu	Fri	Sat	Sun
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

July 2015						
Mon	Tue	Wed	Thu	Fri	Sat	Sun
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

August 2015						
Mon	Tue	Wed	Thu	Fri	Sat	Sun
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

September 2015						
Mon	Tue	Wed	Thu	Fri	Sat	Sun
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

October 2015						
Mon	Tue	Wed	Thu	Fri	Sat	Sun
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

November 2015						
Mon	Tue	Wed	Thu	Fri	Sat	Sun
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30						

December 2015						
Mon	Tue	Wed	Thu	Fri	Sat	Sun
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

January 2016						
Mon	Tue	Wed	Thu	Fri	Sat	Sun
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

February 2016						
Mon	Tue	Wed	Thu	Fri	Sat	Sun
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29						

March 2016						
Mon	Tue	Wed	Thu	Fri	Sat	Sun
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

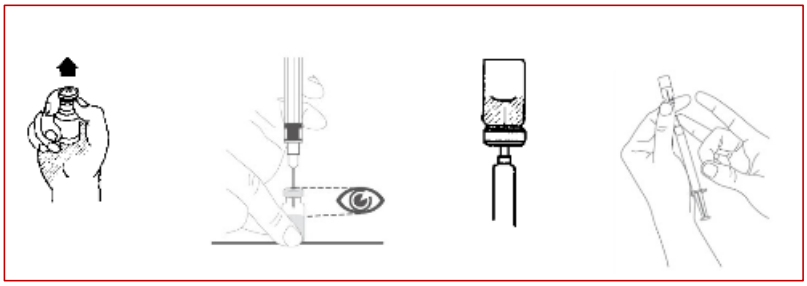
April 2016						
Mon	Tue	Wed	Thu	Fri	Sat	Sun
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

May 2016						
Mon	Tue	Wed	Thu	Fri	Sat	Sun
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

Mark a circle ◯ for dose planned and a cross X when injection has been done.

4

Advices for IFN injections



- ✓ PEG-IFN must be kept in a refrigerator (2-8°C) but not frozen.
- ✓ You can remove it about 15 minutes before the injection.
- ✓ It is advisable to do Change injection site each week and to avoid 2 inch area around your belly-button and waistline as sites of injection.

5

Advices and tips not to forget the treatment

Treatments work better when they are taken **exactly as prescribed**

- in the right amount
- at the right time
- for the entire time that your treatment lasts.

If you skip doses or stop the treatment, the treatment may not work as well and the chance of being cured is lower; there is also a chance that the virus can become resistant to the medication: it will not be effective any more.

- Choose the best moment to take pills (during a meal), **that fits both with the prescription and the personal schedule of the patient**
- Select a regular day and time **that is convenient** for the weekly PEG IFN injections
- Choose a reminder
  - Put an alarm on a mobile phone or a clock;
  - Circle dates in a calendar
  - Ask for occasional reminders to your the family members
- If you are going away
  - Use a pill box to take extra doses with you
  - Use a cooler with an icepack for IFN
  - Plan ahead to take enough pills/IFN for the duration of your stay
- Keep a medication diary
- Find allies in your relatives and/or friends: to schedule treatment together for example

General tips for your everyday life

- Eat nutritious foods
- Drink water (>2-3 liters a day)
- Get regular exercise
- Get enough sleep
- Avoid or reduce alcohol and drug use

Potential side effects

A variety of side effects can occur in patients under PEG-IFN and/or ribavirin.
Some of the main side effects are mentioned here below. They occur mainly 24 – 48 hours after interferone injection and do disappear after that.
As a general rule side effects should always be discussed with the physician, especially if they persist.

Symptoms
Influenza-like syndrome (fever, shivers, fatigue, myalgia (muscular pains))
Reduced appetite, loss of weight
Loss of hairs
Fatigue, decrease in concentration, depressed mood, anxiety
Skin reactions at the injection site
Drop in white blood cells → increase risk of infections
Drop in platelets → increase risk of bleading
Decrease in red blood cells, anemia
Cough/and temporary difficulty to breath

Some symptoms can be related to **urgent problems**: breathlessness, chest pain, dark urine, confusion, swelling around ankles or abdomen, rapid weight loss, thoughts about harming oneself **→consult the physician**

If you/your partner get pregnant or if you took too much treatment by error **→ call the physician**

Importance in case of occurrence of side effects

- ✓ **Do not stop the treatment!**
- ✓ Mention the side effects to the social workers and the physician: it can be possible to adapt the dose (**but do not do it by yourself**) and/or to prescribe other treatments
- ✓ Write in this notebook the side effects that occur so you can remember them
- ✓ Some of the side effects can feel a lot like withdrawal : it is important to prevent them and consult a physician

Side effects

Here you can write the side effects that occur, describe them and precise the moments when they occured (date, time since IFN injection, or ribavirin/sofosbuvir intake).

Type of side effects and description	Timing

8

Type of side effects and description	Timing

9

Type of side effects and description	Timing

10

Notes

ANNEX VII

GROUP SESSION GRID

HARM REDUCTION-BASED AND PEER-SUPPORTED HEPATITIS C TREATMENT FOR PWID

OBJECTIVE

- Document group session: difficulties encountered by beneficiaries, solutions adopted, questions related to HCV infection and coinfection

PRACTICAL ASPECTS

- During group sessions counseling, in Harm Reduction services
- Moderation and answers by a social worker and/or the project coordinator
- Someone else to take notes +/- audio recording after requesting permission to each participant
- "Check in" : participants registered in the circulation database

CONTENT

I- GENERAL INFORMATION

Date	
Number of participants	
Number of participants at the beginning of the treatment	
Number of participants at the end of the treatment	
Number of participants who ended/completed the treatment	
Number of women	
Thematic of the session	
Duration of the session	

2- HCV DISEASE AND COINFECTIONS (HBV++)

HCV	Mistaken beliefs (infection, virus, transmission, progression of the disease)	
	Questions	
HBV	Questions	

3- TREATMENT UPTAKE

Issues (difficulties in taking treatment /injecting PEG-IFN; problems related to OST, limitations in professional activities and/or personal everyday life activities)	
Misconceptions	
Questions	

4- SIDE EFFECTS

Side effects mentioned	
Issues	
Misconceptions	
Questions	

5- REINFECTION

Misconceptions	
Behaviors at risk of infection mentioned	
Questions	

CIRCULATORY DATABASE

STAGE	Identification					Screening				Medical assessment								
Variable	**Program code**	**Center**	**DOB**	**Sex**	**Social worker**	**date_s**	**HIV_RDT_s_res**	**HCV_RDT_s_res**	**FS_s_level**	**date_plan_ma**	**date_act_ma**	**PCR_baseline**	**geno**	**FS_ma_level**	**Eligibility**	**Date_elig**	**Reason**	**Preparation**
Definition	Individual ID	distinguish each center	dd/mm/yyyy	1 M/2 F	Name of social worker	Date screening dd/mm/yyyy	1 Pos/0 Neg	1 Pos/0 Neg	1 F0-F1/ 2 F1/ 3 F1-F2/ 4 F2/ 5 F2 F3/ 6 F3/ 7 F3-F4/ 8 F4	Expected date of medical assessment	Actual date of medical assessment	1: Positive / 0 :Negative	Genotype 1 gen 1 2 gen 2 3 gen 3 4 gen 4	(If necessary) 1 F0-F1/ 2 F1/ 3 F1 F2/ 4 F2/ 5 F2-F3/ 6 F3/ 7 F3-F4/ 8 F4	1 confirmed/0 N0	Date of eligibility confirmation	If not eligible	Need of preparation before treatment (alcohol detoxification, TB treatment, etc.)
Exemple	*X1111*	*1*	*06/06/1980*	*1*		*06/06/2015*	*0*	*1*	*6*	*12/06/2015*	*12/06/2015*	*1*	*3*	*NA*	*1*	*18/06/2015*		

Next colmuns

STAGE	Treatment follow-up													
Variable	**date_tx_start**	**tx_regimen**	**tx_duration**	**Date_W2**	**W2_att**	**Date_W4**	**W4_att**	**...**	**...**	**DOT**	**tx_disc**	**reason_disc**	**Date_comp**	**date_svr12**	**SVR12**
Definition	Date of treatment start	1 Sof+riba 2 Harvoni+Riba 3 Harvoni etc.	1 12 weeks 2 20 weeks 3 24 weeks	Expected date of week 2 visit	Attendance at week 2 visit 1 Yes/0 No	Expected date of week 4 visit	Attendance at week 4 visit 1 Yes/0 No	Expected date of week ... visit	Attendance at week ... visit 1 Yes/0 No	Patient in DOT 1 Yes / 0 No	Treatment discontinuation 1 Yes / 0 No	Reason of treatment discontinuation 0 Serious adverse event 1 Death 2 Drop out 3 Other	Date of treatment completion	Actual date of svr12 control	Sustaiend virologic response 1 Yes / 0 No
Exemple	*05/07/2015*	*1*	*3*	*19/07/2015*	*1*	*03/08/2015*	*1*	*...*	*...*	*0*	*0*		*27/11/2015*	*03/03/2016*	*1*

Medecins du Monde, **France**
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NeoLab, **Georgia**
Patients' community

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