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Integrating hepatitis C treatment into multidrug-resistant TB care

O. Kirakosyan,[1] N. Melikyan,[1,2] J. Falcao,[2] N. Khachatryan,[1,3] H. Atshemyan,[1] I. Oganezova,[1] A. Aznauryan,[1] L. Yeghiazaryan,[3] N. Sargsyants,[1,4] A. Hayrapetyan,[3] S. Balkan,[5] C. Hewison,[5] H. Huerga[2]

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BACKGROUND: Direct-acting antivirals (DAAs) are not widely used for patients with chronic hepatitis C virus (HCV) infection and multidrug- or rifampicin-resistant TB (MDR/RR-TB). We describe the implementation aspects of a new integrated model of care in Armenia and the perceptions of the healthcare staff and patients.

METHODS: We used qualitative methods, including a desktop review and semi-structured individual interviews with healthcare staff and with patients receiving HCV and MDR/RR-TB treatment.

RESULTS: The new integrated model resulted in simplified management of HCV and MDR/RR-TB at public TB facilities. Training on HCV was provided for TB clinic staff. All MDR/RR-TB patients were systematically offered HCV testing and those diagnosed with HCV, offered treatment with DAAs. Treatment monitoring was performed by TB staff in coordination with a hepatologist. The staff interviewed had a positive opinion of the new model. They suggested that additional training should be provided. Most patients were fully satisfied with the care received. Some were concerned about the increased pill burden.

CONCLUSION: Integrating HCV treatment into MDR/RR-TB care was feasible and appreciated by patients and staff. This new model facilitated HCV diagnosis and treatment among people with MDR/RR-TB. Our results encourage piloting this model in other settings.

The twin epidemics of multidrug or rifampicin-resistant TB (MDR/RR-TB) and hepatitis C virus (HCV) infections have led to almost half a million cases of MDR/RR-TB yearly and 71 million people living with HCV.[1,2] The prevalence of HCV infection among MDR/RR-TB patients has been reported to be 12% in a multi-country study.[3] Drug-induced liver injury (DILI) is one of the most common adverse events during MDR/RR-TB treatment,[4–6] and is more likely to develop in MDR/RR-TB patients co-infected with HCV.[4] The 2014 introduction of direct-acting antivirals (DAA) has transformed the treatment landscape for chronic HCV.[7] However, despite existing effective treatment for HCV, DAAs are not widely used for patients with MDR/RR-TB.

Armenia has a high MDR/RR-TB incidence (5.8 per 100,000 people).[1] Prior to 2016 MDR/RR-TB patients in Armenia were not systematically tested for HCV infection and the prevalence of HCV among MDR/RR-TB patients was unknown. Diagnostic confirmation of HCV was not funded by the state, and there was no national protocol to treat HCV.[8] There was an overall lack of HCV treatment, and interferon analogues were the only treatment options available to patients.

During 2016–2018, a model of care integrating chronic HCV diagnosis and treatment for MDR/RR-TB patients was introduced in the country. The Armenian Ministry of Health (MoH), with the support of Médecins Sans Frontières (MSF), introduced systematic HCV testing for MDR/RR-TB patients and treatment with DAAs (which, until this time, were largely unavailable) for MDR/RR-TB patients with chronic HCV. The safety and efficacy of concomitant HCV and MDR/RR-TB treatment in Armenia has been previously reported.[9] However, to our knowledge the evaluation of an integrated HCV and MDR/RR-TB treatment model has not been reported elsewhere. We describe the implementation and healthcare worker and patient perspectives of the Armenian integrated treatment model of care.

METHODS

Study design

We used qualitative methods to assess the implementation of the integrated treatment model and the health worker and patient perspectives. The assessment was conducted from December 2017 to January 2019 in Armenia.

Setting

Armenia is an upper middle-income country with a population of around 3 million. The country is divided into 11 provinces with Yerevan, the capital, considered as an additional separate administrative unit. In Armenia, as in many post-Soviet countries, TB and HCV were considered two separate disciplines and managed by different specialists. Health personnel specialised in TB, including phtysiologists (TB physicians), nurses, social workers and counsellors, provide TB care. Ambulatory level care for MDR/RR-TB patients is provided in approximately 60 primary healthcare centres, which have separate consultation rooms for TB care. The National Tuberculosis Control Centre (NTCC) in Yerevan, the only hospital with a drug-resistant TB department in the country, provides hospitalisation care when required. HCV care is generally provided by infectious diseases physicians or by hepatologists (as required by Armenia's national HCV regulations), either in primary healthcare facilities or in specialised infectious diseases centres. Therefore, prior to the implementation of the integrated model of

AFFILIATIONS
1 Médecins Sans Frontières (MSF), Yerevan, Armenia;
2 Epicentre, Paris, France;
3 National Tuberculosis Control Centre, Ministry of Health, Yerevan,
4 Ministry of Health, Yerevan, Armenia;
5 MSF, Paris, France

CORRESPONDENCE
Correspondence to: Helena Huerga, 34 Ave Jean Jaurès, 75019 Paris, France. email: helena.huerga@epicentre.msf.org

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care, hepatitis C diagnosis and treatment was totally separated from MDR/RR-TB care.

Study procedures

To assess the implementation aspects of the integrated treatment model, two Armenian research associates conducted a desktop review of supervision notes, meeting minutes, training reports, treatment guidelines and other project documents. In addition, they also conducted semi-structured individual interviews with staff to assess their perspectives on the new model of care and obtain further information about its implementation, and with patients to assess their perspectives on the medical care received.

Interviews with staff included open questions adapted to the participant's role. Questions were related to trainings received, workload, human resources' management, procurement procedures for supplies and equipment, clinical and laboratory examinations, timeframe for receiving results, changes in patient flows, as well as strengths and challenges of the new model of care. Interviews with patients included closed and open questions and were focused on their perceptions of and satisfaction with the medical care they received, as well as their level of HCV knowledge. The interviews were held in Armenian or English, depending on participant's preference.

Sampling

Purposive sampling was used to select 16 staff members from MSF and NTCC directly involved in the integrated MDR/RR-TB-HCV programme. Staff members included doctors, nurses, laboratory managers, logisticians, pharmacists, and program managers. All MSF staff members involved in the integrated program were interviewed. NTCC staff was selected based on their degree of involvement in the programme and their availability to be interviewed.

Exhaustive sampling was used to select all patients who started HCV treatment with DAAs during the period planned for the patients' interviews (May–December 2018). Of the 18 patients who fulfilled these criteria, three could not be interviewed: one each due to prison rules, mental health illness and loss to follow-up. Finally, 15 patients were interviewed.

Data collection and analyses

Paper tools were used to collect and summarise the information obtained through the desktop review. All interviews were recorded and transcribed verbatim, using MS Word (MicroSoft, Redmond, WA, USA). The transcription was summarised with notes taken during the interviews. The summarised text was analysed and coded thematically. Data analysis was performed by the same research associates. No identifying information was used in notes or recordings, and audio-recordings were destroyed after transcription. Descriptive analyses were conducted using MS Excel (Microsoft).

Ethical aspects

The study protocol was approved by the MSF Ethics Review Board and the Yerevan State Medical University Ethics Committee, Yerevan, Armenia. All participants provided written informed consent (in Armenian or English) prior to the interview. Participants were not remunerated for their participation.

RESULTS

Integrated model of care

The new model of care was first introduced in Yerevan, the capital, and later expanded to all of Armenia. Prior to implementation, training on HCV-DAA treatment was organised for staff of the TB hospital and 30 TB clinics (TB specialists, nurses, laboratory technicians, counsellors, and social workers). Training was 1.5 hours long and included epidemiology, diagnosis, clinical manifestations, prevention, diagnostics, treatment with DAAs, side effects, concomitant use, potential drug–drug interactions, tools in use. Further on-the-job training was organised at the TB hospital and TB clinics while patients were undergoing treatment.

Once the new model of care was implemented, all MDR/RR-TB patients were systematically offered HCV serological testing and given general information about HCV infection. Patients with positive HCV serological results were counselled and received qualitative HCV RNA polymerase chain reaction. Patients diagnosed with chronic HCV infection, were counselled, underwent genotyping and fibrosis grading using Fibroscan® (Echosens, Paris, France) and were offered HCV treatment with DAAs (Figure 1).

The new model offered simplified management for both pathologies within the same system. Consultations prior to DAA initiation were done by a TB specialist and the hepatologist in coordination. Together they provided patients with information about their medical condition, the need for treatment, the proposed treatment and its duration, and the importance of treatment adherence. An educational session was also conducted by a nurse and a counsellor. This session included information about transmission, prevention, clinical symptoms, treatment, adverse events, follow-up consultations and monitoring procedures. DAA treatment follow-up consultations were done by TB specialists in the ambulatory TB centres at the same time as MDR/RR-TB follow-up consultations without any additional need of specialised consultations. In case of adverse events or difficulties with treatment, additional support was provided by the hepatologist. TB nurses also ensured treatment continuation by providing educational and counselling during follow-up appointments.

HCV and MDR/RR-TB treatment initiation and monitoring

Table 1 shows the eligibility criteria defined for HCV treatment with DAAs. Due to limited DAA availability, patients prioritised for treatment were initially those with frequent TB treatment interruption (due to hepatotoxicity), advanced liver fibrosis (F3/F4), HIV or hepatitis B (HBV) co-infection, or injectable drug use (Table 2). Once sufficient DAA supplies were acquired, this prioritisation system was stopped.

Patients treated with DAAs received 12 or 24 weeks of a combined regimen based on their genotype and fibrosis grade (per WHO recommendations). At first, the combinations available at the site (ledipasvir/sofosbuvir [LDV/SOF], daclatasvir/sofosbuvir [DCV/SOF] or daclatasvir/sofosbuvir/ribavirin [DCV/SOF/RBV]) were used. Some of them were recommended for specific genotypes. Later, the combination DCV/SOF was used for all genotypes. All treatment regimens and recommendations were discussed and approved by the Armenian National DR-TB Committee. DAA treatment for patients on MDR/RR-TB treatment was initially administered as directly observed therapy (DOT) at the hospital, with a mandatory 7-day hospitalisation to initiate the HCV treatment component. The rationale for hospitalisation was to monitor for any adverse reactions or drug–drug interactions from concomitant use of DAAs and anti-TB treatment. As staff became more experienced and HCV services became more integrated into routine TB care, mandatory hospitalisation requirements were revised and DAA treatment was initiated in ambulatory clinics and administered as DOT or self-administered therapy (SAT).

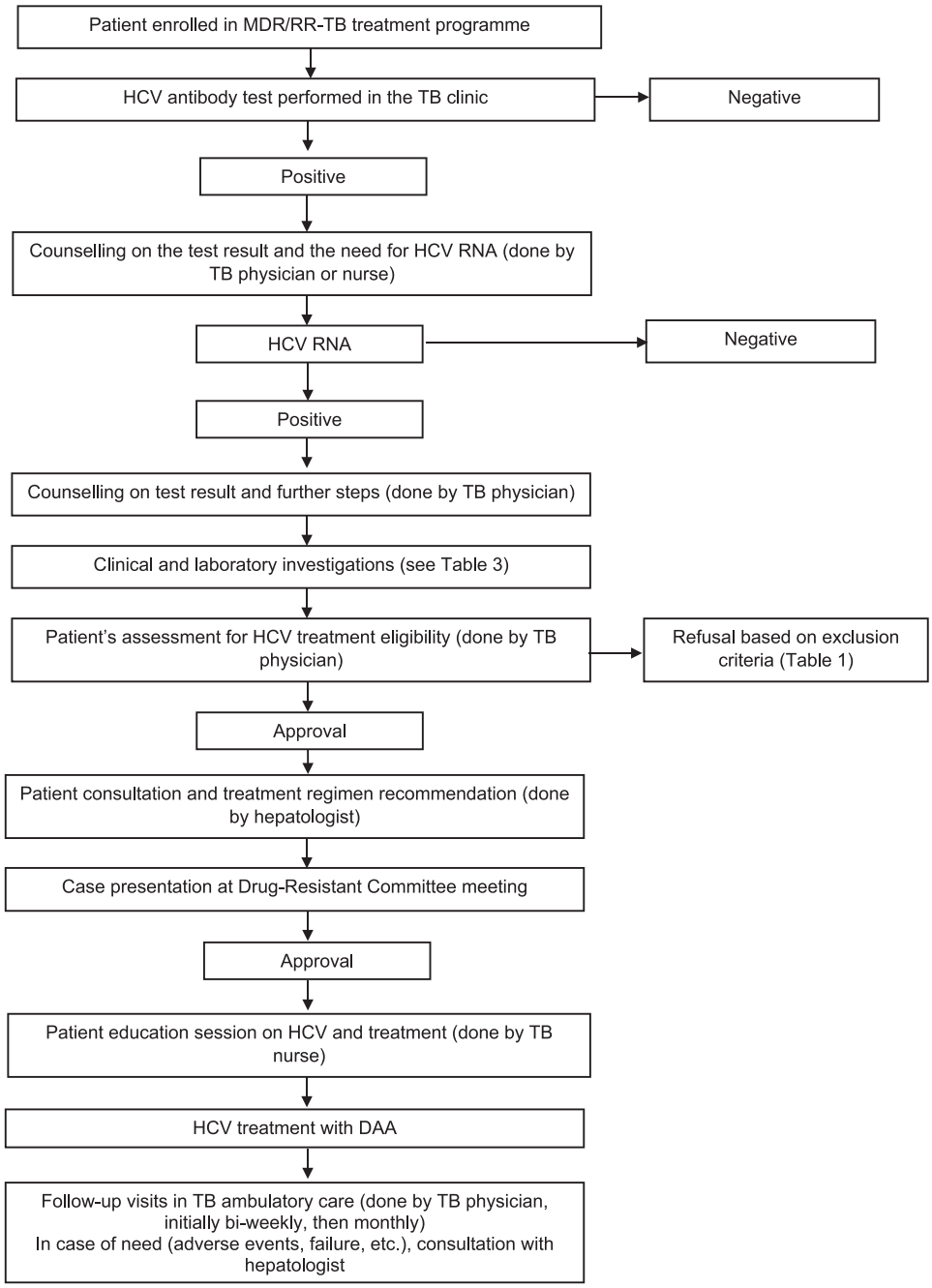

FIGURE Hepatitis C and MDR/RR-TB patient's pathway from the initial diagnosis up to the end of the care. MDR/RR-TB = multidrug-resistant/rifampicin-resistant TB; HCV = hepatitis C virus. NTCC = National Tuberculosis Control Centre; DAA = direct-acting antiviral.

Table 3 describes patient monitoring during DAA treatment. Adverse events and serious adverse events, occurring from the first dose of DAA until 12 weeks after treatment completion, were reported using a well-established system of pharmacovigilance (PV).

Staff perspectives on integrated treatment

In total, 16 staff members were interviewed for an average of 25 min each. The interviewed individuals had worked in their positions for an average of 6 years; 10 were women. The staff interviewed viewed the new model very positively. Participants described the following as positive aspects of integrated treatment: the possibility to continue MDR/RR-TB treatment in patients with hepatoxicity, improvement in their quality of life, the provision of free DAAs and the systematic collection of data on HCV infection among MDR/RR-TB patients. As stated by a participant:

> Many could not continue their TB treatment due to hepatotoxicity connected with Hep C. Thus, treatment of Hep C gives a chance to continue and complete TB treatment.

Another participant observed:

> Besides the access to hepatitis C treatment allowing continuation of TB treatment, which was impossible due to hepatotoxicity, it also improves the quality of life.

TABLE 1 Eligibility criteria for treatment with direct-acting antivirals among MDR/RR-TB patients with chronic hepatitis C

Eligible population	Adults with confirmed chronic hepatitis C disease and MDR/RR-TB
Exclusion conditions	Evidence of hepatocellular carcinoma or any other neoplasia in the terminal stage or being treated with chemotherapy; Advanced/terminal heart/pulmonary/renal or other disease; HIV viral load >1000 copies/ml; Advanced and uncontrolled HIV disease with repeated ART failures and impossibility of designing a new and effective ART regimen; Unwillingness of the patient to adhere to HCV treatment and ART and all appointment requirements; Pregnancy or planning pregnancy in following months, unwillingness to use contraception; breastfeeding women; Uncontrolled or severe psychiatric diseases; Baseline haemoglobin <9 g/dL for regimens containing ribavirin (treatment may be considered on a case-by-case basis depending on chronicity of anaemia + if systemic symptoms or not; blood transfusions will be decided on a case by case basis); Age below 18 years

MDR/RR-TB = multidrug- or rifampicin-resistant TB; HCV = hepatitis C virus; ART = antiretroviral therapy.

TABLE 2 Prioritisation criteria for treatment with direct-acting antivirals among MDR/RR-TB patients used at the beginning of the programme

Liver fibrosis F3/F4
HIV-positive on antiretroviral treatment with CD4 count >50/μL and HIV viral load <1000 copies/mL regardless of stage of liver fibrosis
Hepatitis B infection regardless of stage of liver fibrosis
Frequent TB treatment interruptions due to hepatotoxicity (risk of poor TB treatment outcome)
Injecting drug users regardless of stage of fibrosis (potential risk of transmission)
Men who have sex with men regardless of stage of liver fibrosis (potential risk of transmission)

MDR/RR-TB = multidrug- or rifampicin-resistant TB.

TABLE 3 Monitoring schedule for the patients on treatment with direct-acting antivirals

	Monitoring								
	Baseline	Week 2	Week 4	Week 8	Week 12*	Week 16	Week 20	Week 24†	12 weeks after treatment completion
Medical history	X								
Clinical evaluation and adverse events assessment	X	X	X	X	X	X	X	X	X
Body mass index	X				X			X	X
HCV RNA	X							X	
HCV genotype	X								
HBsAg	X								
IgM-anti-HBc-total	X								
HIV test	X								
HIV viral load	X								
CD4 count	X							X	
Pregnancy test‡	X								
Complete blood count	X		X	X	X	X	X	X	X
PT-t, Pt%, INR	X								X
ALT	X		X	X	X	X	X	X	X
AST	X		X	X	X	X	X	X	X
GGT	X								X
Bilirubin, total	X		X	X	X	X	X	X	X
Creatinine	X		X	X	X	X	X	X	
Albumin (only if F4)	X								
Glucose§	X		X	X	X	X	X	X	
Fibroscan	X								
Alpha feto protein (F3/F4)	X								
Abdominal Ultrasound (only F4)	X								
Gastroscopy¶	X								

* For patients on 12 weeks DAA treatment.
† For patients on 24 weeks DAA treatment.
‡ Should be performed up to 6 weeks after the end of ribavirin-containing therapy.
§ During follow-up only for patients with diabetes mellitus.
¶ Only if Fibroscan >20 kPa and platelets <150 000.
HCV = hepatitis C virus; HBsAg = Hepatitis B surface antigen; IgM = immunoglobulin M; HBc = hepatitis B core; Pt-t = partial thromboplastin-time; INR = international normalised ratio; ALT = alanine transaminase; AST = aspartate aminotransferase; GGT = gamma-glutamyl transpeptidase; F3/F4 = fibrosis stage 3 or 4.

In addition, participants viewed the programme as an example for other programmes, demonstrating that treating concomitantly MDR/RR-TB, HCV, and HIV for some patients, was feasible. One participant commented:

> Hep C programme is very important for Armenia and for the world. This programme shows that two, even three co-infections can be successfully treated simultaneously.

TB specialists did not feel that their workload was substantially increased. As stated by one doctor:

> Since patients with hep C also have MDR-TB, the patients' visits are conducted in a rational way to combine the treatment procedures for two infections. There is some workload but not much.

Some challenges were reported such as the lack of prior HCV surveillance data and information on DAA drug interactions with MDR/RR-TB drugs, TB physicians' inexperience treating chronic active HCV, and difficulties in organising medical examinations for smear-positive or imprisoned patients. According to some participants, MDR/RR-TB patients usually had many comorbidities besides hepatitis C. One of the fears was the co-administration of DAAs with other drugs in addition to anti-TB drugs. As stated by a participant:

> DAAs were new, and there was not enough information on their interaction with other drugs. Fortunately, within the framework of this programme no major drug interactions have been observed.

The clinical staff also suggested that additional training should be provided. All staff participants recommended the expansion of the HCV diagnosis and treatment to the entire population. Some participants stated that HCV treatment should at least be expanded to those with risk factors, creating links between the HIV, TB and hepatitis C vertical programmes, as one participant explained:

> It would be better to treat hep C in the entire population. But due to scarce resources, the priority population can be risk groups: medical workers, drug users, patients under haemodialysis.

Another participant emphasised the importance of political will and engagement to start or sustain any programme:

> Any health programme implemented in Armenia needs the approval of the government. If the government approves a specific programme, then the society accepts it and takes particular steps for its implementation.

Patients' perspectives on integrated treatment

Fifteen patients were interviewed. All were men and their average age was 51 years (range: 31–71); 4 (26.7%) were HIV-positive. The majority (13/15) received HCV and MDR-TB treatment concomitantly, and two received HCV treatment after the completion of the MDR-TB treatment (Table 4). The patients stated that they had little knowledge of HCV transmission prior to receiving care in the programme. The majority were fully satisfied with the HCV diagnostic information (11/15), treatment (12/15) and support (13/15) they received during the treatment. Participants stated that there were no issues during the treatment, and that they received the care they needed. One participant declared: "…the drugs were supplied and the examinations were done." Medical staff were praised as they were reported to carry out their job with responsibility and a very caring attitude. One participant said:

> The doctors' and nurses' attitude was indescribably better compared with the attitude which I had encountered for example 10 years ago. They weren't indifferent.

TABLE 4 Characteristics of the interviewed patients (n = 15)

Characteristics	n (%)
Age, years, median (range)	52 (31–71)
Male	15 (100)
HIV-positive	4 (26.7)
Concomitant MDR/RR-TB and HCV treatments	13 (86.7)

MDR/RR-TB = multidrug- or rifampicin-resistant TB; HCV = hepatitis C virus.

As they did not feel neglected, patients felt encouraged by the medical staff support. One of the participants admitted:

> If it was not [for] these staff I would not have taken the treatment. Their attitude was good.

Participants knew that they could contact their TB doctor and nurses without any problems, although the majority did not have to use this service. Patients also reported satisfaction with their experiences of the benefits of the treatment, as expressed by one participant:

> I am satisfied that I have been treated. Many people dream of such treatment.

Patients did not report financial, social or distance-location problems. Moreover, one patient pointed out the convenience of receiving the drugs for both diseases concomitantly:

> There were also no financial and distance issues because I visited the TB cabinet to receive TB treatment and I received Hepatitis C treatment in parallel.

In terms of challenges and obstacles, some issues were reported regarding long waiting times before initiating HCV treatment. Furthermore, some patients reported that they did not appreciate the increase in the daily pill burden required by the integrated treatment and the fact that DAAs have to be taken on Sunday while MDR/RR-TB was not. They requested that drug provision be adapted so that SAT was possible on more days.

> The only problem was the limitations for the self-administered treatment (SAT), which is uncomfortable when you are absent from the city. If the drugs are given for the SAT during the Sundays, they could be provided [by SAT] for the other days also. This is the only suggestion from my side – to make easier the provision of the drugs by SAT.

Other challenges included encountering discrimination from family members, neighbours or acquaintances regarding their HIV and TB status.

DISCUSSION

In Armenia, integrating HCV-DAA treatment into MDR/RR-TB care was feasible and well accepted by providers and patients. By allowing patients to be diagnosed and treated for HCV and MDR/RR-TB in TB facilities, the programme created a simple, sustainable and patient-centred model of care for concomitant treatment of both diseases. Success was made possible through the willingness of the Armenian Ministry of Health to try a new model, and the substantial training investment made to upskill TB programme staff. The project was even able to further simplify care when pan-genotypic DAA regimens were adopted. The fact that the piloted approach was adopted by the MoH and expanded further confirms its suitability and sustainability. Integrating this type of programme into community health centres is plausible.[10]

For community health centres with limited funding and resources, creating an HCV "test and treat" model within their existing clinic infrastructure is not only beneficial for the patient population but also fiscally sustainable.[11,12]

Overall, the staff interviewed were positive about their experience in the integrated treatment programme. The model of care did not appear to negatively impact TB specialists' workload, although some staff members asked for more training. Patient-participants were highly appreciative overall, the only complaint reported being the increase in the daily pill burden.

The success of this novel HCV-MDR/RR-TB project was as a huge accomplishment for Armenia. The MoH overcame significant barriers as they learned how to procure DAAs and effectively integrate them into routine care for all HCV patients. The MoH is now prepared to procure DAAs in the future and has ordered them using Global Fund support. Tests and examinations are also now provided by the state without private sector involvement. The positive experience of integrating TB-HCV care led the government to donate DAAs directly to the NTCC and re-routed some HCV care and management to the NTCC. Armenia's success shows the world that integrating HCV treatment into MDR/RR-TB care is possible. Findings described by Tunesi et al. in a multicentre, retrospective cohort study, showed coherent results and found that concomitant treatment of HCV and MDR-TB was effective and well-tolerated, and achieved undetectable and sustained virological responses.[13] Another study from rural Cambodia showed that a highly simplified, decentralised model of HCV care can be integrated into a rural public health system in a low- or middle-income country, while maintaining high patient retention, treatment efficacy and safety.[14]

This evaluation is limited by the fact that interviews were held with staff at their place of work and with patients in the clinics where they were under follow-up, so a social desirability effect cannot be excluded. To minimise this risk, confidentiality was repeatedly assured. To address challenges faced by patients, healthcare systems need to integrate HIV, TB and HCV services in one place and provide person-centred rather than disease-centred care.[15] Integrated HCV-MDR/RR-TB care increases access to DAAs therapy and makes HCV treatment possible for MDR/RR-TB patients. We believe our results encourages piloting this model in other settings.

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CONTEXTE : Les antiviraux à action directe (DAA) sont peu prescrits aux patients atteints d'hépatite C (HCV) chronique et de TB multirésistante ou résistante à la rifampicine (MDR/RR-TB). Nous décrivons la mise en place d'un nouveau modèle de soins intégrés en Arménie, ainsi que l'opinion du personnel soignant et des patients.

MÉTHODES : Nous avons utilisé des méthodes qualitatives, comprenant un examen électronique de la documentation et des entretiens individuels semi-structurés avec le personnel soignant et les patients sous traitement pour HCV et MDR/RR-TB.

RÉSULTATS : Le nouveau modèle intégré a permis de simplifier la prise en charge du HCV et de la MDR/RR-TB dans les centres de soins publics de la TB. Une formation sur le HCV a été dispensée au personnel des centres antituberculeux. Tous les patients atteints de MDR/RR-TB se sont vu systématiquement proposer un test de dépistage du HCV, et un traitement par DAA a été proposé à ceux dont le résultat était positif. Le suivi du traitement a été réalisé par le personnel des centres antituberculeux, conjointement à un hépatologue. Les membres du personnel interrogés avaient une opinion positive du nouveau modèle et suggéraient de dispenser d'autres formations. La plupart des patients étaient pleinement satisfaits des soins reçus, mais certains étaient inquiets au vu du nombre accru de comprimés à prendre.

CONCLUSION : L'intégration du traitement du HCV aux soins de la MDR/RR-TB s'est avérée possible et a été appréciée par les patients et le personnel soignant. Ce nouveau modèle a facilité le diagnostic et le traitement du HCV chez les patients atteints de MDR/RR-TB. Ce modèle devrait être testé dans d'autres contextes.

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