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SUPPLEMENT ARTICLE



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Is elimination of hepatitis C virus realistic by 2030: Eastern Europe

Vasily Isakov¹ | Vladimir Tsyrkunov² | Dmitry Nikityuk^{1,3}

¹Department of Gastroenterology & Hepatology, Federal Research Centre of Nutrition, Biotechnology and Food Safety, Moscow, Russia

²Grodno State Medical University, Grodno, Belarus

³I.M.Sechenov First Moscow State Medical University

Correspondence

Vasily Isakov, Department of Gastroenterology & Hepatology, Federal Research Centre of Nutrition, Biotechnology and Food Safety, 21, Kashirskoe Shosse, Moscow 115446, Russia. Email: vasily.isakov@gmail.com

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Abstract

The WHO elimination goals (diagnosis of 90% of the cases of hepatitis C virus (HCV), treatment coverage in 80% and a 65% reduction in deaths from HCV) are set to be reached by 2030. Although these elimination programmes are extremely important in the Eastern European countries (Russia, Ukraine, Belarus and Moldova) with a high prevalence of HCV, limited economic resources prevent their development and implementation. Regardless of the decrease in the incidence HCV in all Eastern European countries, low diagnosis and treatment access, especially in high-risk populations, will not allow to achieve HCV elimination or even to control the infection by 2030.

KEYWORDS

Eastern Europe, elimination, HCV

Key points

- Nearly a half of all patients with hepatitis C virus (HCV) infection in Europe live in Eastern European countries (Russia, Ukraine, Belarus and Moldova).
- People who inject drugs will be the main source of new cases of HCV in Eastern European countries in the next 5-10 years as a result of the poor efficacy of harm reduction programmes and poor access to HCV treatment.
- Despite differences in the populations, economies and healthcare systems of the Eastern European countries, the barriers to elimination are similar (lack of awareness of HCV, underestimation of the economic burden, limited funds and resources for testing and universal treatment access).
- In 2020, none of the Eastern European countries was on track to reach WHO elimination goals by 2030.

1 | INTRODUCTION

The estimated prevalence of hepatitis C virus (HCV) in Europe is 1.7% representing over 13 million cases,¹ with nearly the half of them living in Eastern European (EE) countries. The prevalence of HCV infection varies (2%-5%) in EE countries as does the population densities, economies, healthcare systems and public awareness of the disease. Thus, it is logical to evaluate the perspectives of HCV

Abbreviations: CHC, chronic hepatitis C; DAAs, direct-acting antivirals; HCV, hepatitis C virus; IDU, intravenous drug use; PWID, people who inject drugs.

elimination in each country separately, focusing on the major factors that may negatively or positively influence the planning and implementation of the HCV elimination programme.

2 | RUSSIA

Russia is the largest country in EE with a population of more than 146 million people. The prevalence of HCV is high (4;1%), and Russia has the highest estimated number of cases of HCV infection (approx.

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5 million).¹⁻³ However, the real number of patients is unknown, although official statistics reported 591 830 registered patients with chronic hepatitis C (CHC) by the end of 2016.⁴ While the incidence of HCV infection is high, it has gradually declined in the last 10 years. Thus, the incidence of acute hepatitis decreased from 2.1/100 000 in 2010 to 1.0/100 000 in 2019.⁵

In 2019, 45 400 new CHC cases were registered and the incidence rate was 30.9/100 000, which is substantially lower than 10 years ago, 40.2/100 000. Nevertheless, the incidence was highly variable depending on the region.⁵ This high geographical variability in the prevalence of HCV was confirmed in a study of 4764 blood samples from 5 Russian regions obtained from the healthy population. Anti-HCV antibodies were found in 2.6% (126/4764) of samples, and the prevalence of HCV varied from 1.3% to 3.3% in different regions. However, HCV-RNA was only found in 1.1% (50/4764) of samples, and there was no HCV-RNA found in children (0-14 years old), but an increase in HCV-RNA positivity in older age groups.⁶ This long-term trend and a cohort phenomenon of a persistent annual decrease in the incidence of CHC were also found in a 20- to 29-year-old cohort, in which the incidence gradually decreased from 64/100 000 in 2011 to 38.3/100 000 in 2016.⁴ According to this analysis, nearly half of all CHC cases are found in the 30- to 49-year-old age group, which is a decade younger than in Western European countries. The most prevalent HCV genotypes in Russia are genotype 1b (48.9%-58%) and 3a (34%-39.6%), while genotypes 2 (7;8%) and 1a (3.7%) are rare.^{4,6} The distribution of HCV genotypes is also influenced by a cohort phenomenon. While HCV genotype 3a is extremely rare in older groups of patients, nearly half of the group of younger patients (30-39) was infected with this genotype⁶ and many of them were infected as a result of intravenous drug use (IDU). According to recent national statistics, the prevalence of drug abusers was high (1293.35/100 000 in 2019) and 44.1% of them still use drugs intravenously.⁷ Therefore, IDU is still one of the major modes of transmission of HCV in Russia (Table 1). According to a modelling study, 100% of new HCV cases associated with IDU from 2018 to 2030

could be prevented if the additional HCV transmission risk caused by IDU was removed.⁸ This suggests the need for extensive syringe exchange programmes, opioid substitution programmes and extensive treatment of high risk groups, with a special focus on people who inject drugs (PWID). However, in Russia, there are no specific programmes for the treatment of HCV in PWID, no opioid substitution programmes and only 20 centres for syringe exchange.⁸

Considering the estimated number of cases of HCV infection in Russia as well as the prevalence of cirrhosis and the associated mortality, one would expect the economic burden of HCV to be high. However, according to a national report chronic HCV infection is only ranked 14 among all infectious diseases, with an economic loss of 1.7 billion Russian rubles (USD 22.5 million) during 2019, which is much lower than for HIV, tuberculosis and many other infectious diseases.⁵

Although all known direct-acting antivirals (DAAs) combinations except SOF/VEL/VOX have been approved in Russia, access to treatment is restricted by the stage of liver disease (F3/F4) and the financial resources of the region where the patient lives. Infectious disease specialists or gastroenterologist/hepatologists usually prescribe treatment, and reimbursement is provided by the regional registry of hepatitis C patients and only in specialized centres. In 2019, 6.2 billion rubles (USD 83 million) was spent for reimbursement of HCV treatment, for the treatment of approximately 15 600 patients.⁹ There are no DAAs generics approved in Russia, but under Russian law, individual citizens can import non-registered medicines for their personal use. As a result of restricted access to the reimbursement of HCV treatment, increasing numbers of Russians are treating their HCV infection with generic drugs produced in India, China or Egypt at prices that are 10 times lower than the drugs approved in the country. Although the efficacy of these generics is expected to be the same as the original drugs,¹⁰ it is not possible to estimate the number of patients who treat themselves with these drugs because there are no statistical data.

The elimination of HCV by 2030 is not possible in Russia because of the high prevalence/incidence of HCV, as well as limited access to

TABLE 1 Key factors for the develo	ment of elimination programmes	in Eastern European countries
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	Eastern European countries			
	Belarus	Moldova	Russia	Ukraine
HCV prevalence, % /estimated number of patients ^{2,3}	2%-3%/250 000	4%/142 000	4,1%/4,5-5 000 000	5%/2 100 000
HCV prevalence in children, % (95% Cl) /estimated number of cases (95% Cl) ¹³	0,41% (0,01- 0,42)/7900 (120-8200)	0,44% (0,01- 0,46)/3600 (50-3700)	0,37% (0,26- 0,39)/118 000 (80 500-123 000)	0,54% (0,01-0,56)/46 500 (700-48 100)
HCV prevalence in PWID, % (95% CI)/ estimated number of PWID with active HCV infection (95% CI) ¹²	43,7 (32,3- 55,1)/18 000 (7000-31 500)	37,5 (25,5-49,7)/4500 (2500-7000)	51,6 (44,2- 58,9)/969 500 (463 000-1 570 500)	40,4 (36,3-44,6) 129 000 (54 000-222 000)
Estimated number of compensated cirrhosis patients/mortality per 100 000 ³⁰	231 686/17,5	137 489/55,6	3 913 270/24,3	1 289 123/31,7
Average number of HCV treatment courses reimbursed per year	6000	4500	15 600	2668

Abbreviations: HCV, hepatitis C virus; PWID, people who inject drugs.

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treatment (the number of patients who are reimbursed for treatment is 2.5 times lower than the number of new cases every year). Decision makers do not recognize HCV infection as a significant problem because of its low economic impact compared to other infectious (HIV and tuberculosis) or non-infectious diseases, which are on the top of a list of the most common causes of death in Russia. However, if this situation is not managed, the number of patients with HCV in Russia could double by 2030. Universal access to treatment should be the first step in preventing this scenario, but this is only possible if DAAs generics are approved and can be prescribed by all doctors. Also, universal diagnosis of HCV in high-risk groups such as IDUs is needed and treatment should be provided to all infected individuals as soon as possible to break the chain of transmission of HCV and markedly decrease its incidence, thus helping to control future infections. Although the 2019 national report stated that a programme for the prophylaxis and treatment of HCV should be created to reach the WHO target of eliminating HCV as a major public health threat by 2030,⁵ the start of this programme has still not been announced.

3 | UKRAINE

Ukraine is the second largest country in EE with a population of 42.7 million as well as a high estimated prevalence of HCV (5%) and a high number of patients with HCV infection (2.1 million).² Recent data reported that 470 new cases of acute hepatitis C were registered in 2017 and 5714 patients with CHC, and the incidence of acute hepatitis C/CHC was 1.1/13.42 per 100 000 inhabitants.¹¹ The incidence of CHC varies considerably in the different regions of the country, ranging from 3.0/100 000 to 28.37/100 000. These data are based on extensive testing of the population for HCV infection. Indeed, from 2013 to 2016, 4 976 448 individuals were tested and 205 449 (4.13%) were found to be HCV positive. Like other EE countries, the most prevalent HCV genotypes in the Ukraine are genotypes 1b (42.1%) and 3 (28.8%). It is interesting to note that the highest percentage of mixed genotypes (25.1%) was also found in Ukraine compared to Russia (0.6%) or to other EE countries (0%).³ IDU is an important source of transmission of infection because at least 40% of PWID are HCV positive and there are an estimated 129 000 PWID with HCV.¹² A large international modelling study¹³ showed that Ukraine had the highest prevalence of HCV in children among the EE countries (Table 1). However, local data showed that between 2013 and 2017 there was a decrease in the incidence of acute hepatitis C from 0.24 to 0.11 and in CHC from 0.62 to 0.55 per 100 000 children (0-17 years old) with a total of 600 cases registered by 2017.⁶ Illicit drug use has increased in the last 5 years in Ukraine in teenagers from 12% to 18%,^{14,15} which may be one explanation for the high prevalence of HCV in children. According to the modelling study, the estimated prevalence of HCV infection in teenagers (aged 12-18) was the highest of all the EE countries, 1.06% with up to 30 000 cases.¹³ The prevalence of CHC was found to be much lower than estimated. According to statistical forms, 51 848 patients with CHC were registered in Ukraine by 2017.¹¹ This publication showed

that the proportion of chronic viral hepatitis in the category "chronic hepatitis" increased persistently from 2013 to 2017 from 17.79% to 24.54%, and that this phenomenon could be explained by the increase in incidence as well as by better diagnostics. The prevalence of chronic HCV infection was 123.7 per 100 000 in 2017, with an average prevalence during the 5-year period of 112.7. There was a high variability in the different regions of the country from 44.86 to 314.22 per 100 000.¹¹ Only 15.5% of the patients were older than 55, therefore most chronic hepatitis patients are younger than in other EE countries.

All DAAs combinations except SOF/VEL/VOX are approved in Ukraine and, like in other EE countries, the access to treatment is mainly determined by the stage of liver disease and the cost of drugs. Between 2013 and 2017, a total of 13 340 courses of treatment were reimbursed from central or regional budgets as well as from different non-governmental sources of funding. However, at the beginning of 2018, 24 786 patients were still on the waiting list for treatment and 5873 needed immediate treatment because of the stage of disease.¹¹ In 2017, Gilead expanded their HIV and HCV licensing programme to include Ukraine and Belarus, granting access to the generics of sofosbuvir, SOF/LED and SOF/VEL. The generics were approved, and a recent publication stated that the project using generic drugs to treat hepatitis C in Ukraine, run by Médecins Sans Frontières, had been transferred to local authorities in July 2020 with hopes that it would be implemented across the country.¹⁶

Elimination of HCV in Ukraine by 2030 will not be possible because of the high prevalence/incidence of HCV, especially in teenagers as well as the limited access to treatment. However, a national strategy for the elimination of viral hepatitis was developed with the help of the CDA Foundation and World Hepatitis Alliance, which is now under review. There are several reasons to expect this national strategy to be successful. First, DAAs generics were approved, which is essential for programmes in low-income countries with a high prevalence of HCV, and also, the opioid substitution and syringe exchange programmes for PWID are well established, which is essential to begin universal testing and treatment to reduce the HCV transmission rate in this group of patients. However, all of these measures require both funds and human resources.

4 | BELARUS

The Republic of Belarus has a population of 9.4 million and a high prevalence of HCV infection similar to other EE countries.¹⁷ In 2019, 3420 cases of HCV infection were registered (incidence 36.09/100 000), including 72 cases of acute hepatitis C (0.8/100 000), 2889–CHC (30.5/100 000) and 159 (1.7/100 000) patients who were anti-HCV positive, but in whom the HCV-RNA test was not yet performed. There is a long-term trend towards a decrease in the incidence of acute and CHC in Belarus. The incidence of acute hepatitis was the lowest among EE countries 0.7/100 000 in 2017 and in the last 10 years it has never been higher than 1.1/100 000. A similar trend can be noted in CHC, with a marked decline between 2008 and 2017 from 71.5 to 45.9/100 000 with an average decrease of 3.2%.¹⁸ According to one international review, the estimated number of patients with HCV is around 250 000;² however, the most recent local publication reported that 33 830 patients with chronic HCV were officially registered at the end of 2018, and the estimated number of patients is 136 500.¹⁹

The distribution of HCV genotypes in Belarus is similar to that in Russia and Ukraine. The results of a study of 887 patients with HCV infection showed that HCV genotype 1b was found in 59.8% of patients, genotype 3a in 27.7%, genotype 1a in 7.1% and genotype 2 in 3.3%.²⁰ Like in other EE countries, the distribution of genotypes is dependent upon a cohort phenomenon (patients with HCV genotype 1b are older than those with genotype 3a) and also they differ in the mode of transmission of HCV. The main possible mode of transmission indicated by patients with HCV genotype 1b was a previous medical intervention or it was unknown, while it was IDU or non-medical events such as tattoos or piercing in patients with genotypes 3a or 1a.²⁰ IDU is expected to be the main mode of transmission of HCV in the next 5-10 years because the prevalence of drug abuse increased from 63/100 000 in 2005 to 100,7/100 000 in 2018, when drug dependence was diagnosed in 9593 persons.¹⁷ However, modelling studies have shown that the estimated number of PWID with HCV viraemic infection was 18 000, which only represents 43.7% of the total number of PWID, which is possibly 4 times higher than the official registers.¹² Although harm reduction programmes have been developed in Belarus, the number of distributed syringes (27 per PWID per year) is lower than in Ukraine or Moldova and only 2 of 100 PWID are provided with opioid substitution therapy.²¹ Analysis of the efficacy of the methadone substitution programme showed that by 2019 only 728 patients were on methadone substitution therapy in Belarus. In Minsk, the largest city in the country, 478 patients were enrolled into the programme between 2009 and 2019 and 339 dropped out, with an average number of active participants per year of only 149. During this period, the number of HIV-positive patients among these programme participants increased up to 26.3%, and all of them were receiving anti-HIV treatment. However, 100% were also HCV positive, but none of them was treated for viral hepatitis.²²

All known DAAs combinations, except SOF/VEL/VOX, have been approved in Belarus, but access to reimbursement is restricted, like in other EE countries.¹⁹ However, unlike Russia, where access to the treatment is highly dependent upon the region the patient lives in, the indications for and access to treatment in Belarus are regulated by order of the Ministry of Health (June 1, 2017), which determines which groups of patients have priority for reimbursement of treatment. Thus, reimbursement is provided to patients with advanced liver fibrosis (F3/F4), extrahepatic manifestations, post-transplant patients, advanced CKD/dialysis, HBV and HIV coinfection, women who plan pregnancy and medical workers. Major DAAs generics (SOF, DAC and SOF/LED) have been approved and are locally produced in Belarus, providing a better cost/efficacy ratio for antivirals and easier access to treatment. Their efficacy has been confirmed in local studies,²³ which have shown results similar

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to up-to-date real-world data. Treatment guidelines are regularly updated, with the last update published in 2019.¹⁹ In 2018, 2000 treatment courses (SOF/DAC and SOF/LED) were reimbursed by the government and this figure was multiplied by three times for 2019 (Table 1).¹⁹ It should also be mentioned that in 2018 more than 3000 treatment courses were bought by patients themselves through pharmacies. Like in Russia, individual citizens in Belarus can import non-registered drugs for their personal use, thus some patients may have obtained less expensive Indian or Chinese generics than the generics at local pharmacies. However, it is not possible to estimate the number of patients, as there is no statistical data. Therefore, from 9000 to 10 000 treatment courses were administered in Belarus in 2019, and at least 6000 of them were reimbursed.

Belarus is the only country in EE which has a good chance of if not eliminating than controlling HCV infection by 2030. Unlike other EE countries, it has a centralized state reimbursement system with a clear indication for priority treatment, and it can provide treatment yearly to at least twice the number of patients as the number of new cases registered per year. Local production of DAAs generics is the most important reason that the number of patients treated every year can be increased, as the prices of these drugs allow the government to reimburse more treatments. Second, when a certain number of treatment courses are provided per year (15 000-20 000), the healthcare system requires more doctors/nurses to prescribe and distribute drugs and, thus, actively looks for new patients in risk groups or certain cohorts. In EE countries, the modernization of the healthcare system has often caused a decrease in the number of beds in hospitals and in medical workers. However, the highest number of doctors in EE countries is found in Belarus (58.5/10 000),¹⁷ which makes it much easier to organize the treatment and distribution of DAAs than in other EE countries. One of the major difficulties of preparing and implementing national programmes for the elimination of HCV (once they have been developed and approved) will be the treatment of PWID. Although syringe-exchange programmes and opioid substitution programmes exist, they are not effective, while the prevalence of drug abuse is increasing, access to treatment for PWID is low and there is a lack of special programmes for HCV screening in this population. All of these factors could significantly reduce the effect of increased access to treatment to other groups of patients, by rapidly spreading HCV through the PWID population.

5 | MOLDOVA

The Republic of Moldova has a population of 2.68 million with a high prevalence of HCV infection that is similar to that in other EE countries, and an estimated 142 000 patients.² The incidence of acute hepatitis C has gradually decreased in the last 20 years from 3.72 in 2000 to 1.26/100 000 in 2017, but it is still the highest of all the EE countries. The incidence of CHC also decreased from 46.7 in 2011 to 34.6/100 000 in 2016, however, the officially registered number of patients (13 432) is much lower than estimated.²⁴ The distribution of HCV genotypes is different from other EE countries because there is

a majority of genotype 1b (95.5%), with a low per cent of genotypes 3a and 2.²⁵ This may be as a result of the modes of transmission of HCV in acute hepatitis patients. It is unknown in 70%, because of medical interventions in 12% and surprisingly only 4.2% are as a result of IDU, which is much lower than in other EE countries. By the end of 2018, the number of officially registered people who used drugs in Moldova was 11 805 and 3664 (31%) of them were PWID, ²⁶ which is a lower proportion than in other EE countries. However, it still represents one of the major modes of transmission of HCV in the population. Nosocomial transmission of HCV is still significant in Moldova as seen by the high seroprevalence of HCV in healthcare workers (4.4%), dentists (7.8%) and in haemodialysis patients (43.2%).²⁷

Although the major DAAs combinations have been approved in Moldova, access to reimbursement is restricted to generics (SOF, DAC and SOF/LED), which are provided by a national programme. Four national programmes for the diagnosis and treatment of viral hepatitis have been implemented since 1997 in Moldova. They included different measures to decrease transmission, vaccination programmes as well as improving diagnosis and treatment for patients and high-risk groups. The goal of the most recent national programme (2017-2021) was to reduce the incidence and prevalence of acute and chronic viral hepatitis B, C and D and cirrhosis caused these viruses by 50% by 2021.²⁴ In a recent report, a total of 15 754 patients received antiviral treatment with DAAs in the national programme before June 2020.²⁸ SOF/LED was used in 60.1% of treated patients, while the others received SOF/DAC. An SVR was achieved by more than 99% in all groups of patients except in those with HCV genotype 3 (SVR 93.6%). Patients had universal access to treatment independently of the stage of liver disease (26.2% F4, 16.5% F3, 19.1% F2, 26.6% F1 and 116% F0).28

Moldova has had extensive experience in the implementation of national programmes against viral hepatitis for more than 20 years, with success in decreasing the incidence of acute hepatitis, reducing the prevalence of chronic hepatitis especially related to HBV, but also in the incidence of CHC. The estimated economic loss prevented by these national programmes from 1997 to 2015 was 822.4 million lei (USD 48 million), while the cost to the National Budget was only 84.6 million lei (USD 4.9 million).²⁹ Although the number of patients with HCV treated every year exceeds the number of new cases registered per year, this is not enough to reach the WHO target for elimination of HCV by 2030. Moldova has a high rate of migration (at least 10% of population), thus, the real number of new cases of HCV is difficult to evaluate. Owing to the high total number of untreated patients in the population, the number of patients treated every year must be increased by at least three-fold to achieve the WHO goal by 2030. A significant nosocomial HCV transmission rate and a high proportion of PWID will also make it difficult to decrease the incidence of new CHC cases in the next 5-7 years.

In conclusion, it is obvious that none of the EE countries will be able to achieve elimination of HCV by 2030. Despite differences in economies, populations and healthcare systems, the difficulties

preventing the elimination of HCV are common to all EE countries. Many decision makers are still not convinced that the economic burden of HCV is significant enough in their countries because HCV infection is not highly ranked on the national lists of diseases with a high disability and mortality rate. The prevalence of HCV is high in all EE countries, therefore, even in countries with national programmes the aim is not to eliminate, but to control HCV infection by the end of the programme. Lack of funds and human resources for the decentralization of access to treatment is common to all EE countries, partly owing to the modernization of the healthcare system in the last 20 years, which has greatly reduced the total number of doctors and nurses. Not all countries have approved locally manufactured DAAs generics, which is essential for universal access to treatment. PWID will be the main source of HCV infection in the next 5-10 years in all EE countries and although most countries have harm reduction programmes, their efficacy is poor. Special programmes for extensive testing and treatment of HCV in PWID are badly needed because the number of PWID is increasing in all these countries and nearly half of them are HCV positive.

CONFLICT OF INTEREST

All authors have nothing to declare.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study

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