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REVIEW

Hepatitis C virus: Current steps toward elimination in Germany and barriers to reaching the 2030 goal

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Abstract

Hepatitis C virus (HCV) affects over 70 million people globally, with an estimated 399 000 HCV-related deaths in 2016. The World Health Organization (WHO) has set a goal to eliminate HCV by 2030. Despite the availability of direct-acting antivirals—highly effective and well-tolerated therapies for HCV—many patients infected with HCV in Germany have not initiated treatment, including a majority of those who are aware of their positive diagnosis. Barriers to screening, diagnosis, and treatment are major factors taking many countries off track for HCV elimination by 2030. Identifying country-specific barriers and challenges, particularly in at-risk populations such as people who inject drugs or men who have sex with men, has the potential to create tailored programs and strategies

Abbreviations: AIDS, acquired immune deficiency syndrome; CI, confidence interval; DAA, direct-acting antiviral; DDI, drug-drug interactions; DHC-R, German Hepatitis C Registry; EACS, European AIDS Clinical Society; ECDC, European Centre for Disease Prevention and Control; EU, European Union; FSU, former Soviet Union; HBV, hepatitis B virus; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; HIV, human immunodeficiency virus; IfSG, Infection Protection Act; MSM, men who have sex with men; NEP, needle exchange program; OR, odds ratio; OST, opioid substitution therapy; PWID, people who inject drugs; SVR, sustained virologic response; WHO, World Health Organization.

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to increase access to screening or treatment and engage at-risk populations. This review aims to report the current steps toward HCV elimination in Germany, the country-specific barriers and challenges that will potentially prevent reaching the 2030 HCV elimination goal and describe good practice examples to overcome these barriers.

KEYWORDS

barriers, elimination, Germany, Hepatitis C, high-risk groups

1 | INTRODUCTION

It is estimated that 71 million people worldwide are chronically infected with hepatitis C virus (HCV),¹ including 5.6 million people in Europe.² If left untreated, chronic HCV infection can lead to life-long and life-threatening complications such as liver cirrhosis, hepatic decompensation, and hepatocellular carcinoma (HCC).¹

Since 2014, the availability of direct-acting antivirals (DAA) has revolutionized HCV treatment, with sustained virologic response (SVR) rates reflecting definitive cure in >95% of treated patients.³ Compared with former interferon-based therapies, all-oral DAA regimens require a shorter duration of treatment (8–12 weeks in most cases), are very well tolerated, highly effective and can even be administered to patients with well-known contraindications to interferon-based treatment, for example, patients with decompensated liver cirrhosis or neuropsychiatric comorbidities.³

The availability of DAAs makes HCV elimination a real possibility. The World Health Organization (WHO) has set a goal to eliminate viral hepatitis as a major public health threat by 2030 by reducing new hepatitis B and C infections by 90% and mortality from hepatitis B and C by 65%.¹ However, many countries are not on track to meet these goals by 2030.⁴ The WHO's strategy for HCV elimination includes prevention interventions, increased access to testing and treatment, expanded treatment for patients coinfecting with human immunodeficiency virus (HIV), an information system based on surveillance data and sustainable financing.¹

Due to the scale and complexity of global HCV elimination, a more practical approach that breaks down the overall goal into smaller goals for patient sub-populations, known as micro-elimination, is needed.⁵ Micro-elimination works to achieve the WHO goals in specific sub-populations, settings, generational cohorts, or geographic areas.⁵ This approach has already begun in most high-income countries for at least one patient sub-population and shows promise; for example, progress to HCV micro-elimination was seen in the United Kingdom when targeting patients with HCV and HIV coinfection, where a significant decline in the incidence of HCV infection was observed following access to DAA treatment.⁶

2 | AIMS OF THIS REVIEW

This review aims to report the status quo of HCV elimination in Germany, describe barriers and challenges to potentially preventing the

goal of HCV elimination by 2030, and present good practices from other countries which could serve as examples of how Germany might overcome these barriers. The principle of identifying country-specific barriers and learning from good practice can be generalized and applied to other countries to overcome barriers to HCV elimination.

3 | CURRENT STATE OF HCV ELIMINATION IN GERMANY

In 2011, the Study on the Health of Adults in Germany (DEGS1) tested 7047 participants aged 18–79 years for HCV and determined an anti-HCV antibody prevalence of 0.3% in the German general population.⁷ However, the true prevalence is likely to be higher as the study included patients already cured and cleared of HCV and did not include populations at increased risk for HCV, such as former or active drug users, prisoners, and migrants from regions with high HCV prevalence. Although the HCV screening rate in Germany's general population is unknown, a 2018 report estimated that approximately 57% of patients with HCV are diagnosed.⁸ Despite this relatively high rate of diagnosis, data show that from 2014 to 2019 approximately 69 000 patients with statutory health insurance were treated with DAAs in Germany, with approximately 7000, 20 100, 13 200, 11 600, 9900, and 8100 patients treated in 2014, 2015, 2016, 2017, 2018, and 2019, respectively.⁹ The low rate of treatment initiation combined with the fact that there were 5891 newly diagnosed cases of HCV in 2018, indicates clear gaps in the care cascade.^{8–10}

Despite these gaps, in 2016, Germany ranked in the top eight countries for treating patients with HCV infection (7%), and in the top 10 countries for net cure rate (5%), defined as the number of patients with SVR, minus new HCV infections, plus HCV-related deaths.¹⁰ The German Hepatitis C Registry (DHC-R), a prospective multicenter non-interventional study, gathers real-world data on HCV treatment throughout Germany. The study found that, since DAAs became available in 2014, the number of treated patients with cirrhosis decreased from 35.1% in 2014 to 16.5% in 2018 and SVR rates increased from 92.8% to 97.4%.¹¹ In addition, the number of patients who were former or active drug users increased from 26.9% in 2014 to 43.1% in 2018.¹¹ The DHC-R also shows that an increasing number of registered patients have a migration background from the Commonwealth of Independent States.¹¹

The HCV elimination strategy in Germany (BIS 2030), an integrated strategy for HIV, hepatitis B and C and other sexually

transmitted infections, aligns to the WHO's strategy and aims to sustainably contain the aforementioned infections.¹² This strategy aspires to improve the health of the German population by preventing serious diseases such as acquired immune deficiency syndrome (AIDS), liver cirrhosis and HCC.¹² BIS 2030 focuses on creating an environment accepting of sexual orientations and different lifestyles to avoid stigma, expanding services for at-risk and affected populations, developing integrated services, promoting networking and cross-sectoral cooperation and collecting strategic information and data for the planning and implementation of interventions.¹² However, it is important to note that the BIS 2030 strategy includes only advice and implementation through non-government organizations and companies rather than governmental-initiated or organized projects.¹²

The healthcare system plays a crucial role in HCV elimination strategies. The German healthcare system is notable for two essential characteristics, first, the decision-making powers are shared between the state, the federal government, and self-regulated organizations of payers and providers, and second, two types of health insurance exist in Germany: statutory health insurance (insures 90% of the population) and private health insurance (insures 10% of the population). Statutory health insurance is based on a benefit-in-kind principle, a contract exists between the sick fund and the service providers, patients are not involved in the financial process, copayment is kept to a minimum, and drug costs are a maximum of €10 ensuring all patients have access to drug therapy regardless of financial status. Private insurance is based on a refund-of-expenses principle, patients pay the service providers and are reimbursed by their insurer which can sometimes be difficult, and they pay higher fees and normally have better access to drugs. HCV testing and treatment are covered by statutory health insurance. All German residents can access the healthcare system through statutory health insurance and have the option to take out private health insurance.

4 | DETERMINING HCV PREVALENCE AND INCIDENCE IN GERMANY

Determining the prevalence and incidence of HCV is methodologically difficult. HCV infections are often undetected, with 80% of infected patients unaware of their infection status.¹ As the time between infection and diagnosis differs widely, it is difficult to generate an accurate incidence rate of HCV infection. In addition to these general issues encountered when estimating HCV incidence, barriers specific to Germany also exist when generating accurate epidemiological data. In 2015, the HCV case definition changed, allowing for a more precise analysis of active infections (ie, HCV RNA-positive patients). This allows an approximation of the true incidence of HCV to be obtained, with 5891 newly diagnosed patients reported in 2018; however, the date of actual infection and route of transmission is unknown in the majority of cases.⁹ Another barrier to accurate epidemiological data in Germany is the historic requirement to delete HCV records after 3 years, which existed until the Infection Protection Act (IfSG) amendment in 2017. This requirement meant that multiple tests from the

same patient could not always be identified, leading to double counting. As such, reported case figures generated in recent studies are only partially comparable to those of previous years, before the change in the case definition in 2015 and IfSG amendment in 2017.⁹ Trend analyses should be carried out with appropriate restrictions and considerations. Despite the difficulty determining the prevalence and incidence of HCV prevalence, it was estimated that in 2016 Germany had over 200 000 cases of HCV, although the rate of newly diagnosed infections was low relative to the overall population.¹³⁻¹⁵ Furthermore, in 2019, 5940 cases of HCV were reported to the Robert Koch Institute, which corresponds to a nationwide incidence of 7.1 reported infections per 100 000 inhabitants.^{9,13}

5 | BARRIERS AND CHALLENGES TO ELIMINATION

5.1 | Screening and diagnosis

As the early stages of HCV infection are asymptomatic in most cases, people are often unaware of their infection, therefore they do not seek medical attention, and a lack of screening is a major gap in the HCV care cascade.¹ As such, a high proportion of people, potentially infected with HCV, do not know their infection status. In 2015, it was estimated that less than 30% of people with HCV had been screened and less than 5% had been treated in the European Union (EU).¹⁶

An extract of the German HCV screening guidelines is shown in Table 1. Currently, there is no universal screening strategy in Germany but a nationwide screening program will be implemented by the middle of 2021, which will include one-time testing as part of a routine health check for people over 35 years of age. A study analyzing the clinical relevance of guideline-based screening demonstrated that risk-based screening identified most unknown HCV infections (83%).¹⁸ Furthermore, cohort modeling of different screening strategies has suggested that screening the total population of people who inject drugs (PWID) would be the most effective means to reducing HCV infection.¹⁹ However, cooperation of the PWID community, a group that may be difficult to engage, would be critical to the success

TABLE 1 German HCV screening guidelines (extract)

German HCV screening guidelines (extract)¹⁷

- Patients with abnormal liver blood values/transaminases
- Patients with a history of, or current, drug use
- HIV or HBV infected patients
- Patients with high-risk sexual behaviour
- Migrants from countries with high HCV prevalence or conflict
- Healthcare workers
- Prisoners
- Children of HCV-positive mothers
- Hemodialysis patients
- Patients living with or sexual partners of patients with HCV

Abbreviations: HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus.

of such a strategy.¹⁹ Overall, it is agreed that an effective screening strategy is vital for the elimination of HCV in Germany; however, the initiation of a reimbursed screening program does not automatically lead to an increased number of patients tested. To successfully initiate a national screening program, an accompanying program to increase awareness is required.

The most common initial test for HCV infection is the detection of anti-HCV antibodies in patient serum.²⁰ In Germany, physicians can receive a financial bonus from statutory health insurances if they do not spend the entire budget available for laboratory diagnostics. Initially, the test for anti-HCV antibodies was excluded from the budget calculation but, in April 2018, a nationwide budget-reform removed the extra-budgetary funding for this test.^{9,20} A study evaluating the impact of this reform on HCV testing in 510 656 patient data sets demonstrated that, although anti-HCV testing declined after the reform, so had anti-hepatitis B virus (HBV) testing, which remained extra-budgetary, suggesting the reduction in HCV testing was not parameter-specific, but most likely a surrogate of the intention of the laboratory reform to generally lower the demands of blood samples and laboratory costs.²⁰ In response to this, the German hepatology community made a statement demanding the removal of this hurdle brought by the budget-reform.²¹ This is an important example of how policy changes have the potential to impact healthcare, and how policy reform is required in order to meet the WHO's HCV elimination goal.²⁰

5.2 | Healthcare provider initiation of HCV therapy

Almost all countries (94%) require a specialist to prescribe DAA therapy, such as a gastroenterologist, hepatologist or infectious disease specialist.¹¹ Even in countries that allow drug and alcohol specialists, and primary care providers to prescribe DAAs, restrictions exist through managed care networks, and there may be concerns with medical liability claims.¹¹ Germany, however, allows non-specialists to prescribe DAAs without network restrictions. Studies have shown that, following a 3-hour training session, non-specialists, such as nurses and primary care providers, can safely and effectively administer treatment.²² Expanding the number of providers able to give HCV treatment could increase the number of patients who are screened, diagnosed and treated for HCV.

5.3 | Elimination in high-risk groups

5.3.1 | PWID/opioid substitution therapy (OST) patients

Of the 71 million people infected with HCV, 5.6 million (8%) currently inject drugs.¹ Globally, it is estimated that 52.3% of PWID are anti-HCV positive,²³ and in the EU injection drug use is the most common route of HCV transmission (44% of cases).²⁴ DAA therapy achieves similar results in PWID and patients on OST compared with those

observed in the general population, with no impact on treatment completion, adherence, efficacy, or safety.²⁵ HCV reinfection rates vary among current and former PWID, as well as in different countries, and although they are often higher than in non-PWID patients, HCV reinfection rates in PWID may be considered low with regard to the high HCV prevalence in this population.²⁶ Frequent testing, as well as education about the risk of reinfection, should be continued in PWID following successful HCV treatment to minimize reinfections. While the costs of repeat testing are covered by health insurance, the real problem is linkage to care in this high-risk group. Strategies to reach these patients need to be implemented to ensure that they are receiving tests for HCV and treatment if they are positive.

In Germany, PWID account for approximately 80% of new HCV infections with information on the mode of transmission.²⁷ Additionally, the number of patients who currently or previously used drugs increased from 26.3% in 2014 to 43.1% in 2018.¹¹ A German study of 2077 PWID showed a HCV seroprevalence of 42%-75%, that 41% of patients had chronic HCV, that 85% of the patients indicated for treatment had had a positive HCV antibody test at least once, and only 19% had been successfully treated with interferon-based therapy.²⁸ Furthermore, just a fifth of study participants were unaware that sharing filters, spoons and water can transmit HCV.²⁸ Another German study estimated the reinfection rate among current PWID and those with a history of injection drug use to be 8.4 and 3.94 per 100 patient-years, respectively.²⁹ Gaps between PWID being tested, knowing their infection status, and starting treatment are evident. Education of both HCPs and patients will play a critical role in increasing the number of PWID who are tested, treated, and who begin to take preventive measures.²⁸

In a study evaluating physician perception, most physicians who offered OST perceived HCV testing and treatment among PWID to be important (82% and 85%, respectively).³⁰ However, self-perceived competency was below average for advising patients (28%), knowledge of new treatments (37%), and the treatment and management of HCV (40%).³⁰ This highlights the importance of improving HCV education and training particularly among physicians offering OST.

Although DAA treatment is highly effective and well tolerated in PWID and patients receiving OST, these populations are often harder to reach than the general population, thereby creating a barrier to successful treatment initiation (Table 2).²⁵ HCV counseling and testing should be offered to these often stigmatized groups in settings accessible to PWID, such as via OST-providers, hospitals, prisons, and needle/syringe exchange sites.¹ Key recommendations to eliminate HCV in PWID globally include reforming drug and healthcare policies, scaling up and improving access to OST, harm reduction services, avoiding stigma and discrimination, creating community-based programs, and improving access to affordable diagnostics and medicines.³¹

Across Europe, several positive examples of initiatives designed to increase treatment rates in PWID and OST patient populations have been described. Iceland is successfully addressing HCV with an initiative called Treatment as Prevention for Hepatitis C (TraP Hep C) which provides increased nurse counseling, linkage to other health services, travel reimbursements, incentives and encourages patients

TABLE 2 Barriers PWID may encounter when accessing HCV care and treatment**Barriers PWID may face accessing HCV care and treatment³¹**

- Poverty
- Homelessness
- Illicit drug dependency
- Fear of imprisonment
- Needle and syringe access
- Childcare and possible child removal
- Stigma
- Self-stigma
- Social isolation
- Distrust of police and healthcare services

Abbreviation: HCV, hepatitis C virus.

TABLE 3 Barriers prisoners may encounter when accessing HCV care and treatment**Barriers prisoners may face accessing HCV care and treatment**

- Short imprisonment duration
- Lack of access to NEPs in prison³⁹
- Lack of access to screening and treatment in prison¹⁷
- The transfer of health insurance after release⁴⁰
- Lack of post-release care⁴⁰

Abbreviations: HCV, hepatitis C virus; NEPs, needle exchange program.

to bring friends, and injection partners to visits.³² The impact of the program is demonstrated by an 82.3% reduction in the prevalence of HCV viremia among PWID currently injecting at Vogur Addiction Hospital.³³ Another country demonstrating effective strategies toward HCV elimination in PWID is the Netherlands, who, through providing OST in combination with social-medical care and needle exchange programs (NEPs), have reduced the incidence of HCV in PWID since 1986 to almost zero.²

Examples of similar initiatives have also been described in Germany, such as the PLUS health initiative, which aims to reach people who use drugs or substitutes and those with a history of drug use but now abstain, by taking a comprehensive account of their living conditions and providing addiction support for people with HCV.³⁴ The program has a participatory peer approach to ensure effective support is given and to motivate people to become more involved with the program.³⁴ A German HCV awareness program, “bist du Chris?,” which translates to “are you Chris?,” is a campaign initiated by “Die Initiative pro Leber” (Initiative for the Liver) and aims to increase awareness and fight the stigma surrounding HCV by encouraging people to reflect on their lives and consider if they may have contracted HCV.^{35,36} Chris is a common first name for both men and women in all social classes, showing that hepatitis C can affect anybody. The main focus of the campaign was a website (www.bist-du-chris.de) that included educational information, a personal hepatitis C risk checklist developed by the Die Initiative pro Leber, and a physician locator as well as a TV commercial that showed various life situations of “Chris” that can be associated with a risk of infection.^{35,36} Another German program, from the association for innovative drug help (Vision e.V.)

offers personal support throughout treatment.³⁷ People from the community, called buddies, are trained to be companions of people affected by HCV.³⁷ Vision e.V. is a non-profit association and a state drug counseling center and is based on the idea of self-help. The association offers, among other things, the possibility of contact, syringe exchange, and a mobile medical service. This unique approach aims to motivate vulnerable people and connect them through the different stages of the care cascade, offering personal support throughout treatment.³⁷

5.3.2 | Prisoners

Globally, the anti-HCV prevalence in prisoners is 26%, with the incidence of infections in prisons estimated at 1.4 per 100 people annually and at 16.4 per 100 people annually in prisoners with a history of drug use.³⁸ Living in an environment with a high HCV prevalence, unsafe drug injection, non-professional tattooing, and condomless sex puts prisoners at particularly high risk of infection.³⁸ The average length of stay in some prisons can be weeks or a few months only, creating a barrier to complete HCV management from screening to follow-up (Table 3). A German study investigating the association between prison history and HCV status found the proportion of participants reporting risk factors, including injection drug use and receiving non-professional tattoo/piercing, increased significantly with both total duration and frequency of imprisonment.⁴⁰ The overall HCV seroprevalence, defined as positive for HCV antibodies, RNA, or both, was significantly associated with the duration and frequency of imprisonment: odds ratio (OR) 1.35 (95% confidence interval [CI] 1.04-1.74) for short and rare experience, and OR 4.01 (95% CI 3.05-5.27) for long and frequent experience, compared with those with no imprisonment history.⁴⁰

Modeling studies have shown that HCV testing and treatment in prison could be cost effective and that this environment offers a good opportunity to study the feasibility of HCV treatment as a prevention strategy.⁴¹ Prisons may provide a controlled environment for the screening and treatment of high-risk populations such as PWID or others, who can otherwise be difficult to reach.⁴¹

PWID are over-represented in prison populations globally.³⁸ Drug use can also continue or begin in prison; however, access to sterile injecting equipment is rarely available.³⁸ Despite the recommendations from the United Nations Office on Drugs and Crime and the WHO to provide NEPs for inmates, only four countries in Western Europe currently offer NEPs in selected prisons (Luxembourg, Spain, the Netherlands, and Switzerland).³⁹

In 2009, the prevalence of HCV in 31 German prisons was 14.3%.⁴² It is estimated that approximately 30% of sentenced inmates in Germany are current or historic drug users.⁴³ According to German guidelines, HCV screening should be performed on all prisoners. Furthermore, prevention (NEPs, condoms), testing, counseling, OST, HCV treatment, and prevention of reinfection should be available to all imprisoned PWID.¹⁷ Healthcare in German prisons is covered by a separate federal prison health system (budgeted by the 16 federal

state ministers of justice) and, when released, the transfer of detainees back into the regular health insurance system should occur automatically.⁴⁰ However, due to administrative barriers this transfer is often delayed, leaving newly released individuals uninsured, without access to OST and other healthcare services, and therefore unable to continue HCV therapy.⁴⁰ Newly released individuals may also face challenges such as finding a home and a job, which may deprioritize HCV treatment. Post-release care is necessary to support prisoners following release to maintain HCV treatment and post-treatment surveillance.⁴⁰

Portugal is taking measures to increase healthcare in prisons, with a goal of eliminating HCV from prisons by 2020. The model adopted brings healthcare providers to prisons to increase the number of people with access to care and to avoid the necessity for multiple trips to a hospital.⁴⁴

In Germany, there is a federal state government agreement that aims to reduce the risk of infection, including HCV, in prisons through substitution therapy, NEPs and safer sex programs, and access to modern treatments that are the standard of care outside of prison.⁴⁵

5.3.3 | Migrants

Migrants account for approximately 14% of patients with HCV in Europe; however, HCV prevalence in migrant populations varies greatly depending on the countries of origin.¹ The migrant population in the EU carries a disproportionate burden of HCV, representing over 50% of cases in some countries,¹⁶ with migrants from Romania and Russia reported to harbour the highest number of cases.⁴⁶ The migrant population faces additional difficulties accessing care and treatment as a result of patient, practitioner and healthcare system barriers (Table 4).¹⁶ To reach this high-risk population, HCV screening needs to include people originating from countries with intermediate and high HCV prevalence ($\geq 2\%$ and $\geq 5\%$, respectively)¹⁶ and be tailored to their specific needs.

In Germany, between 23% and 37% of reported HCV cases occur in patients of a foreign nationality.⁴⁷ One study investigated the country of birth and citizenship for patients with HCV in Germany and found that Germany was the country of birth in 65% (1397/2141) of patients, and 76% (1542/2039) had a German citizenship.⁹ The other most common countries of birth included the Russian Federation ($n = 117$), Kazakhstan ($n = 64$), and Poland ($n = 61$) and the other most common nationalities of patients were the Russian Federation ($n = 54$), Georgia ($n = 42$), and Poland ($n = 40$).⁹ HCV and HIV seroprevalence with related risk behaviors in first-generation former Soviet Union (FSU) migrants and native Germans using drugs has been investigated by the DRUCK study, which used data from a sero-behavioral survey of PWID.⁴⁸ HCV seroprevalence was 74.5% in FSU migrants vs 64.6% in native Germans ($P = 0.006$) with a higher proportion of FSU migrants reporting injection-related risk behaviors than native Germans.⁴⁸ This highlights the need for access to, and acceptance of, harm reduction measures, together with HCV treatment in this high-risk subpopulation of FSU migrants.

TABLE 4 Barriers migrants may encounter when accessing HCV care and treatment

Barriers migrants may face accessing HCV care and treatment¹⁶

- Lack of awareness of risk factors
- Fear
- Stigma of blood-borne diseases
- Language barriers
- Cultural differences
- Negative national attitudes
- Lack of entitlement to healthcare
- Socioeconomic factors
- Provider lack of awareness of migrant risk factors
- Lack of screening guidelines

Abbreviation: HCV, hepatitis C virus.

TABLE 5 Barriers MSM may encounter when accessing HCV care and treatment

Barriers MSM may face accessing HCV care and treatment

- Perceived risk of drug-drug interactions⁵¹
- Late treatment initiation⁵²
- Stigma surrounding reinfection⁴⁹

Abbreviations: HCV, hepatitis C virus; MSM, men who have sex with men.

5.3.4 | Men who have sex with men (MSM)

HCV prevalence in MSM varies widely depending on other risk factors, with anti-HCV prevalence ranging from 1% to 7% in MSM without a history of injection drug use compared with 25%-50% in MSM with a history of injection drug use, including chemsex.⁴⁹ HCV infection is also more common in MSM coinfecting with HIV (3%-39%) compared with those without (0%-19%).⁴⁹ Although HCV is more prevalent in HIV-coinfecting individuals, DAA therapy demonstrates similarly high efficacy in this population compared with those without HIV coinfection.⁵⁰ Drug-drug interactions (DDIs) are a potential problem when combining HIV and HCV treatment; however, studies have demonstrated effective and well-tolerated management of DDIs as long as care providers are aware of the risk.⁵¹

HCV diagnosis is often not the limiting factor in this high-risk group. Most MSM are aware of their risk of infectious diseases and tend to be tested regularly. One of the main barriers (Table 5) is late treatment initiation, which results in the spread of HCV, as in many countries, including Germany, acute HCV infection (the first 6 months of infection) does not qualify for treatment as there is no increased risk of mortality and therefore treatment expenses may be hard to rationalize, despite some guideline recommendations to treat acute HCV.^{17,52} However, this may lead to a further spread of HCV infections. With the known risk of HCV spread in MSM, it is recommended that HIV centers practice the evidence-based European AIDS Clinical Society (EACS) guidelines, these state that DAA-therapy should be initiated if the HCV viral load has not decreased by $>2 \log_{10}$ after 4 weeks.⁵³ A study in the Netherlands examining the feasibility and cost-effectiveness of early treatment of acute HCV in HIV-positive

TABLE 6 Examples of the initiatives and actions taken in Germany to overcome barriers and help achieve HCV elimination

Initiative/action	Overall aims
The integrated strategy for HIV, Hepatitis B and C and other sexually transmitted infections (BIS 2030) ¹²	To sustainably contain HIV, Hepatitis B and C and sexually transmitted infections, which can improve the overall health of the German population through preventing serious disease, and may result in societal and healthcare expenditure benefits ¹²
Non-specialist prescription of DAAs without network restrictions	To increase the number of patients who are screened, diagnosed and treated for HCV
The PLUS health initiative ³⁴	To engage PWID and patients on OST in HCV care ³⁴
Bist du Chris?	To increase awareness and fight the stigma surrounding HCV
Vision e.V. ³⁷	To motivate vulnerable people and link them to HCV care ³⁷
The federal state government agreement to provide substitution therapy, NEPs, safer sex programs and access to modern treatments in prisons ⁴⁵	To reduce the risk of HCV infection in prisons ⁴⁵

Abbreviations: DAA, direct-acting antiviral; HCV, hepatitis C virus; HIV, human immunodeficiency virus; NEPs, needle exchange program; OST, opioid substitution therapy; PWID, people who inject drugs.

MSM found that immediate treatment lowered the incidence and prevalence rates of HCV, as well decreasing the cost on society by €30.1 million over a lifetime, compared with treatment delayed until F2 fibrosis stage.⁵²

In addition to early HCV therapy, prevention of reinfection is another key factor in HCV elimination. A high incidence of HCV reinfection has been reported in HIV-coinfected MSM. A retrospective analysis of 606 HIV-positive MSM who had cleared HCV spontaneously or been successfully treated, found that 24.6% became reinfected.⁵⁴ Of those, 43% presented with a second reinfection following spontaneous clearance or successful treatment, 5 had a third and 1 had a fourth reinfection.⁵⁴ The risk of reinfection should be considered as part of the care cascade for every person for whom HCV treatment is considered, with surveillance after viral cure as a critical step to prevent reinfection.⁵⁴ Education, counseling, linkage to services, and behavioral interventions will help to reduce the risk of reinfection.⁵⁴ Increasing rates of reinfection should be expected and acknowledged without stigma or judgment and constructive preventative measures should be put in place to reduce the risk of, and rapidly treat, reinfections.⁴⁹

In Germany, data on HCV prevalence in MSM are still lacking. In 2015, the European Centre for Disease Prevention and Control (ECDC) estimated HCV prevalence in MSM in Germany as 8.2%; however, these data only included HIV-coinfected MSM so may be an

overestimate.²⁴ A study of MSM successfully treated with DAAs in Germany found a high rate of reinfection (9.02 per 100 patient-year; 95% CI 6.48-12.26), which was higher than that found in the PWID population (1.14 per 100 patient-year; 95% CI 0.56-2.09).⁵⁵

In 2015, the Netherlands introduced unrestricted access to DAA therapy for all patients newly infected with HCV. This led to a 51% reduction of new HCV infections in MSM, the first reduction in new infections in MSM for over 10 years.¹⁰ NoMoreC, another Dutch initiative, was created in collaboration with the gay community to reduce HCV through online and offline interventions to increase knowledge and home-based HCV RNA testing.⁵⁶

6 | DISCUSSION

To meet the 2030 elimination goal in Germany, changes need to be made with regards to almost all aspects of the elimination strategy. The gaps in the care cascade are evident, with most HCV-positive patients not receiving treatment, despite high cure rates. It is also apparent that at-risk groups contribute to most of the HCV infections; however, guidelines and strategies are not adequately tailored to suit the specific needs of these populations. Previously described initiatives and actions aimed to help achieve HCV elimination in Germany are summarized in Table 6. Across many countries, different approaches have been made in an attempt to engage these at-risk groups. It is possible that, by learning from these individual strategies and harmonizing good practice, HCV elimination in Germany may be a more achievable goal.

Across Europe, there are multiple projects that aim to increase HCV treatment and awareness. One example is Hepcare, a peer-based project, which focuses on the joint participation of primary and secondary care providers to allow more people to be treated with the limited resources available.⁵⁷ Community-based peers are trained to provide support and access to care.⁵⁷ This project has the potential to reach at-risk populations at a community level and decrease the number of patients who are lost in the care cascade through liaison links.

Individual countries have also made advances in reducing HCV infection at a national level. In 2011, Portugal faced many difficulties in trying to address HCV elimination, including low investment in public health, an inadequate hospital referral network and high costs of DAA regimens.² However, a group of stakeholders prepared a literature review on the needs for HCV elimination that resulted in a fully funded patient registry.² All identified patients with HCV were included, and this led to a reduction in time between treatment request and authorization.² This program has helped reduce the incidence of HCC by 73% and reduce the development of cirrhosis by 93.2%, as well as saving approximately €30 000+ euros per patient in lifetime healthcare costs.² Another country making rapid advances toward HCV elimination is Iceland, through their nationwide TraP Hep C program. The aim of this program is to provide universal access to DAAs, diagnose early and treat patients at high risk for transmitting HCV.³² With these measures, Iceland is predicted to achieve HCV

elimination before the 2030 goal.³² Many programs, such as the one in Iceland, are government-supported programs. Such initiatives are currently missing, or have only recently been started in Germany.

Measures to remove barriers in the care cascade, such as initiating treatment at the point of diagnosis, may be particularly important for hard to reach populations. This approach is recommended by the WHO for the treatment of HIV and has the potential to overcome barriers such as patient transport costs, parental or employment responsibilities and loss of motivation through treatment without delay.⁵⁸

7 | CONCLUSION

HCV elimination in Germany is possible with the availability of DAAs and may lead to widespread significant savings for both society and the economy.² The barriers preventing elimination do not include treatment itself but reaching people, in particular at-risk populations, and engaging them at every aspect of the care cascade, from diagnosis to post-cure surveillance.² To address these barriers, tailored, people-centered, health-system-wide programs that increase disease awareness and knowledge, link patients to care, and prevent reinfections are needed.² These principles of identifying and addressing country-specific barriers can be generalized and tailored to other countries to help eliminate HCV. Adopting and adapting such good practices and learning from success stories may help Germany and other countries reach the 2030 elimination goal.

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CONFLICT OF INTEREST

Christoph Sarrazin: Honoraria for consulting/speaking: AbbVie, Gilead, Merck Sharp and Dohme; Christoph Boesecke: Honoraria for consulting/education lectures: AbbVie, Bristol-Myers Squibb, Gilead, Merck Sharp and Dohme, and ViiV; Solmaz Golsabahi-Broclawski: Honoraria for consulting/education lectures: AbbVie; Gero Moog: Honoraria for consulting/speaking: AbbVie; Francesco Negro: Honoraria for consulting/speaking: AbbVie, Gilead, Merck Sharp and Dohme. Grant support from Gilead; Carmina Silaidos, Polly Patel and Kristina Lohmann: Employee of AbbVie and may hold stock/share options; Christoph D. Spinner: Honoraria for consulting/speaking/travel grants: AbbVie, Gilead, Janssen-Cilag, Merck Sharp and Dohme, and ViiV; Stephan Walcher: Nothing to disclose; Heiner Wedemeyer: Honoraria for consulting/speaking: Abbott, AbbVie, Bristol-Myers Squibb, Gilead, Janssen, Merck Sharp and Dohme, and Roche; Marcus-Alexander Wörns: Honoraria for consulting/speaking: AbbVie, Bayer, Bristol-Myers Squibb, Celgene, Eisai, Gilead Sciences, Incyte, Ipsen, Janssen-Cilag, Merck Sharp and Dohme, and Roche Pharma.

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TRANSPARENCY STATEMENT

The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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