



HCV Management in the Incarcerated Population: How Do We Deliver on This Important Front?

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Abstract

Purpose of Review In this review, the peculiarities of infection and treatment of HCV in the prison population are detailed. In addition, the barriers to HCV treatment and possible solutions are highlighted.

Recent Findings Several previous experiences of HCV treatment in prisons have been successful. In this manuscript, we detail the most relevant.

Summary We think that incarceration should be considered an opportunity to engage this population in health care. Therefore, we should encourage systematic screening of these patients and promote the access to treatment by supporting equity with the general population. Thus, inmates' care must involve a multidisciplinary team. To solve this matter, we propose telehealth to bring together all these services and overcome the geographical barrier(s) and improve costs. Then, to go further in hepatitis C elimination, harm-reduction programs should be added to treat with direct-acting antivirals.

Keywords Elimination · Direct-acting antivirals · Prison · Telemedicine · Harm reduction · Injecting drug use

Abbreviations

HCV Hepatitis C virus
PWID People who injects drugs
HBV Hepatitis B virus
HIV Human immunodeficiency virus

DAA Direct-acting antiviral
HRP Harm-reduction program
SVR Sustained viral response
OST Opioid substitution therapy
NSP Needle-syringe programs
DOT Direct observed therapy

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Introduction

Hepatitis C virus (HCV) is one of the main etiologies of liver-related morbidity and mortality worldwide, especially in Mediterranean countries. There, the prevalence ranges from 1 to 3% in the general population [1••].

In Spain, estimated rates of HCV-infected patients have been lower than expected; recent studies set the prevalence around 1.2%. The proportion of viremic patients is also surprisingly low, less than 50% of patients are anti-HCV positive [2, 3].

Around 30% of all patients infected with HCV have reported a prison stay at some point [4]. Therefore, prisons have become concentrated HCV microenvironments, indicating a great burden of disease, up to ten-fold that of the general population (previously reported 17–64%) [5]. Seroprevalence

in Western European and US prisons is 15.5% and 15.3%, respectively [5]. A recent observational study in 2011 that included 18 Spanish prisons demonstrated a prevalence of HCV infection of 22.7% [6].

This high prevalence combined with the high-risk behaviors in prison make the penitentiary setting an important site for blood-related infection transmission. A recent longitudinal study, including 10 years of follow-up, shows that prison is a high-risk location to contract HCV infection. Needle and syringe sharing were found to be the main factors related to HCV infection among continual inmates, regardless of the frequency of injecting or the type of drug used [7]. Regarding the penitentiary setting in Spain, HCV infection prevalence is ten times higher than in general population. This is due to risk behaviors of this special population (PWID, people who inject drugs). Last data available shows prevalence between 14.8% in prisons from the Ministry of Internal Affairs and 12% in prisons in Catalonia [8]. This prevalence is declining in the last years (in parallel with HIV prevalence reduction and the decrease in inmates that are PWID). This is due to prevention policies in prison and changes in risk behaviors, and recently, it is also due to treatment access.

The Spanish Ministry of Health published a national strategic plan to tackle HCV infection in April 2015 [9]. The document has changed HCV management and has transformed Spain into the country with the highest rate of treatment per million inhabitants. It has allowed the eradication of HCV seem an attainable reality. This plan establishes the penitentiary populations as a special priority setting to prevent, diagnose, and treat. This review is not intended to go through all the initiatives to eliminate Hepatitis C since the plan began; however, we would like to highlight the Spanish Alliance for Hepatitis C elimination (AEHVE, in Spanish; <http://aehve.org>). The main goal of this alliance is to coordinate efforts from clinicians, scientific societies, and patients' associations to fight against viral hepatitis.

Factors Affecting Treatment of HCV in Spanish Prisons

Features of HCV-Infected Patients in Prison

The prison and general populations are different. This is mainly due to a number of social and legal reasons [10, 11].

Inmates frequently are marginal individuals who usually have poor health despite their younger age. In addition, they have reduced access to health care before conviction [12]. This special setting usually has a history of high-risk sexual contacts, injection drug use, and tattooing [13, 14]. Thus, they may have multiple coinfections, including HBV (Hepatitis B virus) and HIV (Human immunodeficiency virus).

Furthermore, prison inmates commonly suffer from other comorbidities. More than 65% of inmates report psychiatric diseases [15], and substance abuse is reported in more than 50% of individuals studied [16]. In older prisoners, cardiovascular risk factors and disease are commonly seen. This is due in part to poor lifestyle (such as poor nutritional recommendations, smoking, and the absence of regular physical activity) [17].

Finally, legal and logistical factors should also be considered. The length of stay in the same prison can be very short, which makes it difficult to complete the circuit from screening to treatment and follow-up [18]. Other locations that restrict freedom such as jails, psychiatric wards, and pre-trial detention centers also likely add to the risk of HCV transmission to these vulnerable individuals.

These factors increase the HCV infection rate up to ten times the general population prevalence [19]. Intrinsic circumstances worsen the problem, particularly; there is an infection risk unawareness rate up to 25% which influences transmission during incarceration and after release [13].

Type of Penitentiary Health Care

In Spain, there is more than one model for financing penitentiary health care. There are models for penitentiary health care that depend on the Ministry of Internal Affairs and others that depend on the Ministry of Health Care. Thus, access to HCV care may depend on where Spanish prisoners may be serving their sentences.

The fundamental task that the Spanish Constitution and the General Penitentiary Law assigns to the prison system is to ensure the enforcement of the sentences imposed by judges, guaranteeing the custody of prisoners, and protecting their integrity. However, this task cannot be complete or effective if it is not also focused on the inmate's health recovery and social reintegration [20].

Non-custodial Sentences

International proposals to decrease reoffending and reduce prison population include community sanctions and measures to promote alternative sentences to imprisonment. In several settings, such as academics and public administration circles within the European Union, these alternatives are well received. Taking this into account, European Member States are improving measures to promote alternatives to imprisonment organizations. The "European Observatory on Alternatives to Imprisonment" project was created with the intention to design a functional network of partner countries that allows homogenizing various prison systems. The principal objective is to develop a comprehensive vision(s) of alternatives to detention. These visions would help us detect which alternative measures can lead to a reduction in detention rates and the deployment of rehabilitative programs [21].

Regarding this special setting in the penitentiary system, it is of paramount importance to engage offenders sentenced to non-custodial penalties with the health care available to them. In Spain, this sort of inmates is admitted to a site called *Social Insertion Centers*. These population’s features are similar to those found in prison: male, around 45 years old, mainly unemployed, low educational level, and 40% afflicted by severe psychiatric disorders and addictions (not only illicit drugs, but also alcohol and tobacco). Our group is designing a model of care in this setting—people sentenced to non-custodial penalties—to provide a microenvironmental elimination of hepatitis C and health engage to chronic disease/mental disorders programs available in our region.

HCV Treatment in Prisons

Barriers to HCV Treatment

Despite prisoners being a high-priority group to treat HCV infection and despite the availability of direct-acting antivirals (DAA) with high efficacy, low pill burden, few side effects, and reduced treatment duration, significant barriers to access treatment of HCV remain.

A recent systematic review identified 34 publications summarizing the effectiveness, cost-effectiveness, and acceptability of HCV treatment; this study also describes the barriers to care in prison settings [22••]. Nine studies included reasons for treatment discontinuation. The results are disappointing considering five out of the nine included first DAA regimens. In our hands, when using the most recently introduced interferon-free regimens, there were almost no discontinuations.

Despite the evident improvement of antiviral treatments, there are classical barriers that have limited the universality

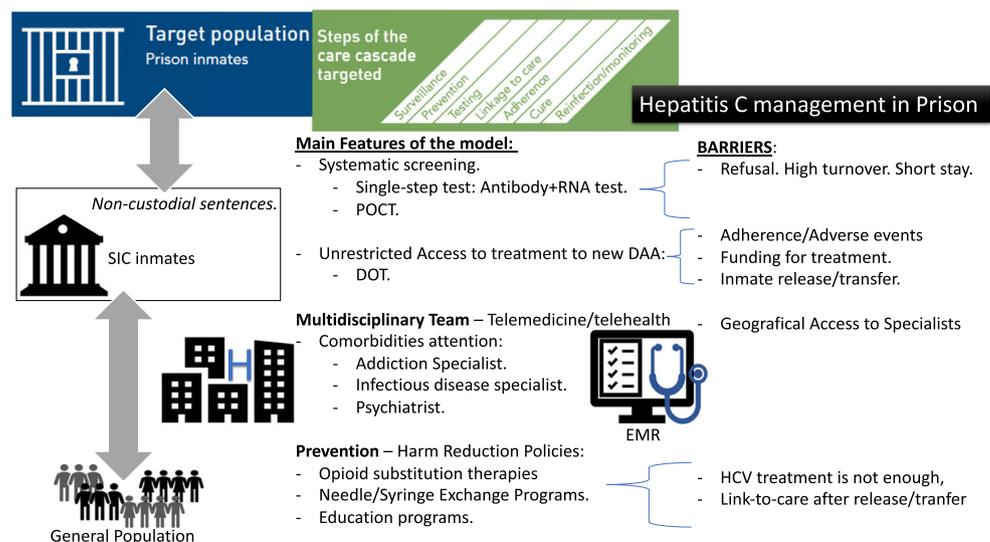
of these policies [23]. These are illustrated by Fig. 1 and include but are not limited to penitentiary health care managed within each country by public agencies with different sensitivity to the health problem posed by prisons. Additionally, persistence of internal risk practices favoring intraprisson transmission, limited capacity to access hospital-based hepatitis specialists and providers, complex health care needs of prisoners, high detainee turnover, facility lock-down days, and chronic prison staff shortages add to the limitations to treatment.

On the other hand, release and transfer are the most significant barriers to treatment adherence in the prison setting [24–30]. Incarceration duration can influence treatment starting [31–41]. Linkage to care post-incarcerations is very low, supporting the concept that treatment is best addressed during the period of imprisonment [42•]. Treatment limitations are not only occurring in a single country. A recent European study including 25 countries demonstrated a great variability and insufficient coverage at harm-reduction programs (HRP) [43•].

Treating HCV in prison is hampered by socio-political economic and prisoner-specific barriers. A recent Australian study [44] reported multiple barriers, such as prisoner’s priority on circumstances related to their incarceration, lack of perceived illness, unawareness of HCV treatments, misunderstandings on how HCV could be managed, inconvenience of treatment evaluation, lack of access to providers, frustration in treatment delays, stigma and fear of discrimination, fear of reinfection if they relapse into risk behaviors, and alcohol abuse.

Many HCV-exposed patients are incarcerated during their life. Incarceration can be seen as an opportunity to provide detection and treatment of HCV. Thus, when release occurs, in case of re-engagement in high-risk behaviors, there would be less risk of transmission. Another feature that is of

Fig. 1 Overview of hepatitis C management in prison. In the prison setting, treating inmates has to go through several barriers and it should be emphasized that harm-reduction policies and follow-up must be included. POCT, point-of-care testing; DOT, direct observed therapy; SIC, social insertion center (for non-custodial sentences); EMR, electronic medical records



paramount importance is linkage to care post-release. Effective connection to community care services in order to ensure HCV treatment compliance would decrease discontinuations, infection relapse, and reduction of new transmission [45–47].

Absence of Systematized Screening

Overall, in this special setting, inmates must be tested for HCV infection at admission and renewed at least annually [48]. However, up to 25% of inmates are unaware of the infection [49]. In Spain, at the time of imprisonment, inmates are offered to test for HCV and other infections. Exceptions are made for those with very short stays or who refuse to consent. Despite this opt-out policy, according to the General Sub-directorate for the Coordination of Prison Health screening rates in different Spanish facilities in 2015 varied widely (57–99%).

In countries like the USA, three-quarters of the state prisons either offer no screening or targeted testing of inmates reporting high-risk behavior, which will miss many potential patients [4, 50].

Experiences of Treatment in the Penitentiary Environment (See Table 1)

The available evidence demonstrates that there is no difference between prison-based and community-based treatment models regarding treatment outcomes.

In the study of Marco et al. [55•], they compare the effectiveness and rates of discontinuation of DAA treatment in inmates and non-inmates. This study included patients treated in 10 prisons of Catalonia and in 3 public hospitals in the Barcelona area between 1 January 2015 and 30 April 2016. They analyzed sustained viral response (SVR) and rates of discontinuation, rates through intention-to-treat and modified-intention-to-treat analyses; the latter excluding discontinuations due to release from prison. They found no differences when comparing these two populations. The only variation was the large number of missing cases among prisoners.

Our group has also led a treatment study in the prison environment, called Jailfree-C [51••], a global test-and-treat in a single Spanish prison “El Dueso”. Of 851 inmates held there, 847 (99.5%) agreed to testing and subsequent treatment if found to be viremic with HCV. Serological testing showed exposure in 110 patients (13% overall) and active viremia in 86 patients (10.2%). Among those with HCV viremia, HIV coinfection was found in 15.9%. For any positive viremia after treatment, phylogenetic analysis of HCV was available to distinguish between persistent infection, reinfection, and superinfection. SVR was achieved in 64 of 69 inmates (96.9%). At conclusion, two were lost to follow-up and three had initial treatment failures requiring salvage therapy. At the end of the intervention, all 409 currently imprisoned inmates were non-viremic, with no detected reinfections nor de novo infections.

Australia has recently implemented universal access to DAA therapy, including inmates. They recently reported results of HCV treatment in a single large facility microenvironment, wherein HCV viremia was decreased from 12 to 1% during the

Table 1 Summary of the experience in treating inmates with new direct-acting antiviral

Ref.	Sample size	Model of care	SVR	Treatment completion	Barriers
Cuadrado et al. [51••]	69	Test-and-treat strategy. DOT Telemedicine	96.9%	100%	Release/transfer to start or follow-up after treatment
Fernández-González et al. [52]	83	Prospective Usual care SAT	94.7%	–	–
Jiménez-Galán et al. [53]	50	Prospective Usual care. SAT	92%	–	–
Marco et al. [28]	212	Retrospective Usual care Retrospective	–	87.5%	Follow-up after release Patient refusal (12.5%)
Mínguez-Gallego et al. [54]	40	Usual care SAT Retrospective	85% ¹ 93.7–95% ²	–	Release or transfer to follow-up
Touzón-López et al. [30]	207	Usual care SAT Retrospective	91.1% ¹ 94.6% ²	95.5%	Release to follow-up after treatment

DOT, direct observed therapy; SAT, self-administered therapy

¹ Intention-to-treat rate of SVR

² Complete follow-up SVR (HIV-coinfected and monoinfected, respectively)

22 months of the study, including new admissions with HCV active infection [32].

Impact of Treatment on the Infection of Other Prisoners and the General Population

Treating chronic HCV in a “captive” microenvironment, such as prison, offers the opportunity to treat a high-risk population.

It is well known that high-risk behaviors persist in the inmate population, both inside the prison and after release [23]. Combining HRP with the treatment of hepatitis C can reduce the burden of disease in society. Several modeling studies suggest that treatment of PWIDs and inmates reduces global prevalence of HCV [49, 56]. A recent US-based report [57], using a dynamic model applied to 34 previously published studies, shows that to screen and treat in prison is a highly effective strategy to reduce HIV, HCV, and other infections among prisoners and the community.

Cost-Effectiveness

Several cost-effectiveness studies support the concept of universal treatment with DAAs in the prison system [58, 59]. One US cost-effectiveness study suggests that HCV treatment with DAAs is cost-effective for inmates compared with no treatment or treatment with older regimens [60].

A recent study of our group in collaboration with Dr. Chhatwal [61] demonstrated (1) scaling-up HCV treatment with DAAs to all prisons in Spain would reduce HCV disease burden, i.e., HCV-associated death, hepatocellular carcinoma, and decompensated cirrhosis; (2) among the strategies considered, prioritizing inmates by their disease stage, irrespective of the HCV prevalence or number of HCV-infected inmates in prisons, yielded the highest QALYs (quality-adjusted life year) and reduction in HCV disease burden; (3) prioritizing inmates by their health states is cost-effective, resulting in an ICER (incremental cost-effectiveness ratio) of € 9162 per QALY (using the commonly accepted willingness-to-pay threshold of €24,000 in Spain); and (4) sensitivity analysis showed that doubling the treatment capacity, i.e., 4000/year, will provide higher QALYs and lower cost. In conclusion, treating all HCV-infected inmates, i.e., with unlimited treatment capacity, will further reduce the HCV burden and is cost-effective, with the ICER of € 21,750 per QALY.

Good Clinical Practices in the Treatment of HCV in Prison

Universal Screening of Infection

In the prison setting, universal screening has been shown to be cost-effective. Overall, it is recommended that the serological

status of people in prison must be renewed at least annually [48]. In Spain, at the time of incarceration, opt-out HCV testing is offered and carried out except for extremely short stays.

Electronic Medical Records

In the era of internet and networking, electronic medical records should be implemented to share information in a safety manner between the prison and the general population health care system.

Single-Step Point-of-Care Diagnosis

Simplified strategies are needed to improve the diagnosis of HCV infection in people with difficult access, such as prisoners.

Robust evidence supports this approach and multiple studies show that it should be the standard of care for screening chronic HCV infection [62].

Some studies have evaluated the usefulness of point-of-care test (such as serology detection in capillary blood, dried blood samples, or saliva), and it seems to be a good way to increase screening rates in high-risk population [63].

Harm-Reduction Programs

Health education programs and the intensification and expansion of HRP to all inmates provide the control of infection inside and outside the prison.

Moreover, opioid substitution therapies (OST) have also played a role in the control of the infection. Education should be encouraged among inmates and their healthcare providers, therefore allowing a reduced risk of transmission. This approach should be of sufficient duration to maximize impact post-incarceration.

While provision of OST in prison is common in European countries, other measures such as needle-exchange programs are scarce, and when they are available the coverage are sub-optimal and difficult to assess [46, 64]. The Hep-CORE study surveyed liver patient groups in prisons of 25 European countries in 2016 and mid-2017 on national policies related to harm reduction, testing/screening, and treatment for HCV. This study concludes that in spite of the existence of evidence-based recommendations, infectious disease prevention measures such as HRP are inadequate [43] and they should be continued after release.

Another study revised existing data and evidence on HIV, HCV, and harm reduction in prisons, analysis of political barriers, and formulation of key policy recommendations, and it showed the effectiveness of HRP, however its availability is still inadequate in prison [65]. It is of paramount importance that governments lead and fund HRP in prisons. Authorities must also work to remove obstacles to improve these services

in the prison setting, enhance the monitoring and evaluation of laws, policies, and programs relating to HIV, HCV, and drugs in prison, and recognize HRP as a fundamental human right.

Administration of Treatment as Direct Observed Therapy

The use of DOT in prison allows daily communication with health services and takes advantage of other healthy interventions when needed.

New Healthcare Models: Telemedicine

In recent years, several new HCV elimination models have emerged.

One of the first was Project ECHO (Extension for Community Healthcare Outcomes) in New Mexico. This project aims to connect isolated communities with specialty care services by using telemedicine programs. This model has been used to deliver HCV treatment to the general community [66] and the imprisoned too [67]. Telemedicine is the use of medical information between different places through electronic communications to improve the health status of patients. Distance is a critical factor in the use of telematic tools for the improvement of health. However, telemedicine is not only used for geographical reasons, there are economic, social, security, and even privacy issues that can justify its use. Specifically, for prison populations, there are significant benefits for patients, no requirement for physical transportation, higher levels of privacy and self-esteem, fewer missed consultations for logistical reasons, and easier on-treatment monitoring.

Telemedicine is not an accessory health method; it is an ordinary method using a different channel with the same legal validity as any other medical intervention. Our group is also carrying out a novel program to eliminate HCV in El Dueso prison (Cantabria, Spain) since February 2015 [51]. The JailFree-C program is based on the work of a multidisciplinary team made up of hepatologists, prison doctors and nurses, specialized providers such as radiologists, infectious disease consultants, pharmacists, psychologists, addiction specialists, social educators, and telemedicine facilitators. Our aim was to create a permanent program of HCV elimination in a prison based on a test-and-treat strategy. Viremic patients were treated with a ledipasvir–sofosbuvir regimen (8–12 weeks) according to the 2015 Spanish Guidelines. A teleconsultation program was established to follow up patients from the hospital.

In this work, we have shown that a sustained test-and-treat strategy against HCV in prisons is feasible and beneficial. It also works including inmates with some neurocognitive impairment [68]. This experience has been successfully exported in Herrera de la Mancha Penitentiary, a prison with different characteristics, which demonstrates the possibility

of making this approach in different types of prisons (data not published).

We carried out a satisfaction assessment with the use of telemedicine through a satisfaction questionnaire. All treated patients who experienced teleconsultations were given the opportunity to answer the satisfaction questionnaire after each visit, with results showing a high level of satisfaction.

We also evaluated the cost-effectiveness of this strategy [69] (manuscript in process) highlighting that telemedicine is a very efficient strategy due to the savings in the costs derived from the transfers to the hospital and in indirect costs.

Challenges for the Future

This field faces significant challenges which include those regarding funding and potential ineffectiveness in stemming reinfection risk. The imprisoned population must have access to HCV treatment under the same principle of equity than the general population, and to achieve this goal in penitentiary health depends more than ever on public health models.

The risk of reinfection after successful antiviral treatment poses a challenge to reach the hepatitis C elimination, and this is especially high in the prison setting, where injection drug use constitutes the main transmission route. More comprehensive studies of HCV reinfection after achieving an SVR with DAA treatments are required, in order to accurately determine the current reinfection rate and to further understand the associated determinants to be able to ultimately diminish reinfection risk.

Conclusion

This review illustrates the importance of HCV management in prison.

We think that HCV elimination is achievable. Thus, we think that inmate admission in prison should be considered an *opportunity* to engage this population in the health care system.

We therefore should support systematic screening of these patients, promote treatment access in the same way as the general population. Taking this into account, HCV treatment is not the only issue to be managed. This special setting has other unmet needs, such as mental health disorders, addiction, or coinfections.

Thus, medical care of inmates must involve a multidisciplinary team. To solve this matter, we propose telehealth to join all these services and overcome the geographical and social barriers and improve costs.

Then, to go further in HCV elimination strategy, HRP should be added to treatment with DAA, such as OST and needle-syringe exchange programs, both inside the prison and after release.

Therapeutic models, such as JailFree-C, demonstrate that elimination is possible, thanks to the work of multidisciplinary teams, the use of new technologies and the support of all the institutions involved.

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Compliance with Ethical Standards

Disclaimer Gilead Sciences did not participate in the design, data analysis, and manuscript preparation.

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