

Certification program of Addiction Centres for hepatitis C virus elimination in Spain. HepCelentes Project

Programa de certificación de Centros de Adicciones para la eliminación del virus de la hepatitis C en España. Proyecto HepCelentes

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Abstract

Microelimination strategies for the hepatitis C virus (HCV) in vulnerable populations, such as users of Addiction Centres (AC), are key for the elimination of hepatitis C. The aim of the HepCelentes project was to design a certification program for AC from the generation of a guide with the criteria to favour the prevention, diagnosis, control, and treatment of HCV in Spain. The project was

Resumen

Las estrategias de microeliminación del virus de la hepatitis C (VHC) en poblaciones vulnerables, como los usuarios de los centros de adicciones (CA), son fundamentales para lograr la eliminación de la hepatitis C. El objetivo del proyecto HepCelentes fue diseñar un programa de certificación para los CA, a partir de la generación de una guía con los criterios para favorecer la prevención, diagnóstico, control

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structured in 4 phases: normalisation, implementation, certification, and communication. In the first phase, developed between July and December 2020, a Steering Committee was created (formed by representatives of scientific societies, healthcare professionals from AC, primary care centres and hospital units, and patient associations) that, from of an exhaustive bibliographic review, generated by consensus an accreditation guide for AC. The guide consists of 22 criteria (15 mandatory and 7 recommended) structured based on the requirements to be met by AC, justification for the selection, level of action (management, prevention, diagnosis and treatment/follow-up), measurement of the indicator, objective level to be achieved, evidence of compliance, clarifications to improve understanding, and mandatory / recommendation (depending on their relevance to achieve HCV elimination and its feasibility for implementation in real practice). The development of a certification system for the AC, based on consensus and coordination of multidisciplinary teams, is intended to favour the management of hepatitis C and its elimination in AC users, supporting the international, national, and regional elimination strategies.

Key words: Addiction Centres; vulnerable population; hepatitis C virus; elimination; certification; quality.

y tratamiento del VHC en España. El proyecto se estructuró en 4 fases: normalización, implementación, certificación y comunicación. En la primera fase, desarrollada entre julio y diciembre de 2020, se creó un Comité de Normalización (formado por representantes de sociedades científicas, profesionales sanitarios de CA, centros de atención primaria, unidades hospitalarias, y asociaciones de pacientes) que, a partir de una revisión bibliográfica exhaustiva, generó por consenso una guía de certificación de los CA. La guía consta de 22 criterios (15 obligatorios y 7 recomendados) estructurados en base a la definición del criterio, justificación de su selección, nivel de actuación (gestión, prevención, diagnóstico y tratamiento/seguimiento), fórmula de medición, nivel objetivo a alcanzar, evidencias de su cumplimiento, aclaraciones para mejorar su comprensión y obligatoriedad/recomendación (en función de la relevancia en la eliminación y capacidad de implementación). El desarrollo de un sistema de certificación para los CA, a partir del consenso y la coordinación de equipos multidisciplinares, pretende favorecer el manejo de la hepatitis C y su eliminación en los usuarios de los CA, apoyando las estrategias de eliminación internacionales, nacionales y autonómicas.

Palabras clave: Centros de Adicciones; población vulnerable; virus de la hepatitis C; eliminación, certificación; calidad.

Hepatitis C represents a high burden of disease associated with the development of liver complications and mortality and its economic impact (Turnes, Domínguez-Hernández & Casado, 2017), especially in people receiving treatment for addictive disorders due to substance use (Lozano, Domeque, Perálvarez, Torrellas & Gonzalo, 2019). In 2016, the World Health Organization (WHO) set 2030 as a target for the universal elimination of the hepatitis C virus (HCV), with elimination considered to be an 80% reduction in the incidence of new infections and a 65% reduction in HCV mortality (World Health Organization, 2016). One year earlier, Spain implemented the strategic plan for tackling hepatitis C (PEAHC) through its national health system (Ministry of Health, 2015, 2020a); this was aligned with other plans for the prevention, control and elimination of hepatitis C developed by the Autonomous Communities, highlighting the involvement of doctors and health professionals in achieving the elimination of hepatitis C. As a result of these actions, Spain could be one of the first countries to meet this target (Polaris Observatory Collaborators, 2021).

To achieve the elimination of hepatitis C, micro-elimination strategies have been implemented in recent years; these are focused on specific subgroups, such as those with the highest prevalence and at-risk or vulnerable populations. These measures have been aimed primarily at screening for HCV infection, simplifying diagnosis, linking diagnosis and early treatment, periodic assessment

of people at risk of reinfection, improving health policy measures and defining indicators (Alianza para la Eliminación de las Hepatitis Víricas en España, AEHVE, 2021; Crespo et al., 2019a; Grupo técnico de cribado de la infección por el VHC, 2021; Ministerio de Sanidad, 2020b).

Despite a decrease in recent years largely due to the use of direct-acting antivirals (DAAs) of high effectiveness, easy administration, less need for follow-up and efficiency compared to previous therapies (American Association for the Study of Liver Diseases, 2021; Calleja et al., 2018; Crespo et al., 2020; Ghany, Morgan & AASLD-IDSA Hepatitis C Guidance Panel, 2020; Mennini et al., 2021; Pawlotsky et al., 2020; Turnes et al., 2017), the prevalence of hepatitis C remains high in vulnerable populations (1.02%) (Rodríguez-Tajes et al., 2020). While a great effort has been made in Spain, and a large number of people have been diagnosed and treated, there are still barriers to approaching the most vulnerable groups, such as drug users, who have greater exposure to contracting infectious diseases and, for the most part, reject health care, thus making it difficult to detect and monitor the disease (Parés-Badell et al., 2017; Roncero, Vega, Martínez-Raga & Torrens, 2017). It is estimated that the prevalence of active HCV infection in this population is between 50% and 56% (Grebely et al., 2019), with undiagnosed infection at around 35.8% (Saludes et al., 2019). Furthermore, risky behaviours among drug users, even after effective treatment, result in high rates of reinfection (4.76%) and are an important route of HCV transmission (Midgard et al., 2016; Pineda

et al., 2015). On the other hand, compared to the general population, this group presents suboptimal diagnosis, less linkage to care and, in some cases, use of hepatotoxic substances, essentially alcohol, which implies a greater risk of fibrosis progression (Folch et al., 2021; Morales-Arráez et al., 2020).

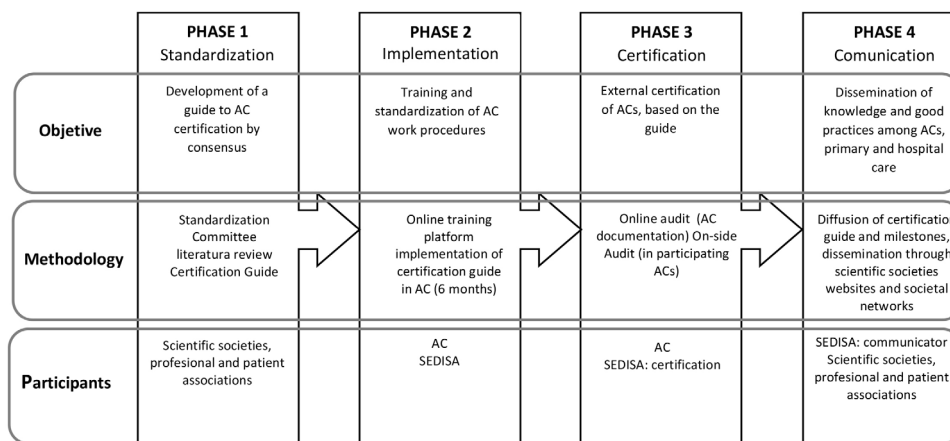
Addiction centres offer socio-health care and comprehensive treatment, with teams of multidisciplinary professionals, to people with addiction problems. Drug users regularly go this centres, becoming a key point of action for the management of users with hepatitis C. The centres are integrated differently in each Autonomous Community, through the primary care network, mental health network, social resources, etc. (Ministry of Health, 2021), so there is variability in the care process for hepatitis C, which leads to heterogeneous management of users. Therefore, it is important that addiction centres are involved in effective and efficient ways, promoting strategies or actions for the development and improvement of care circuits to facilitate the diagnosis, treatment and follow-up of users with hepatitis C, as well as the establishment of coordination and interaction mechanisms between the different levels of care (addiction centres, primary care centres and hospital units). The development of a certification system for these centres to normalize and systematize their work in a multidisciplinary framework that accredits their commitment to the elimination of hepatitis C and that recognizes and gives visibility to the work of the addiction centre professionals would help to promote these strategies. Thus, the objective of this paper was thus to describe the HepCelentes project, aimed at designing a certification program for addiction centres for the elimination of HCV in Spain and to show the criteria for the guide developed in the first phase of the project.

Method

Description and phases of the HepCelentes Project

The aim of the HepCelentes project is to establish a certification program for addiction centres, based on consensus and the creation of a guide comprising objective, specific and measurable criteria, to standardize the procedures of these centres, and promote prevention, control and monitoring of users with hepatitis C. Along these lines, it aims: a) to establish a series of criteria, agreed by a group of experts in the management of HCV infection, representatives of scientific societies and health management to improve care for users with hepatitis C in addiction centres; b) to standardize the working procedures in addiction centres, promoting the creation and improvement of circuits that facilitate the diagnosis of infection, treatment and monitoring of patients and the creation of coordination mechanisms between addiction centres, primary care centres and hospital units; c) to develop a system of certification for addiction centres committed to the elimination of hepatitis C; d) to share knowledge and best practices among addiction centres; and e) to support the strategy of the Ministry of Health and the regional plans to prevent, control and eliminate hepatitis C, establishing working guidelines focused on the benefit of patients that strengthen integration between levels of care and can be maintained for good disease control.

The HepCelentes project was developed in four differentiated and sequential phases following qualitative research methods: standardization, implementation, certification and communication (Figure 1).



Note. AC: Addiction centres. Soc.: society. SEDISA: Sociedad Española de Directivos de la Salud.

Figure 1. Diagram of the phases of the HepCelentes project: objective, methodology and participation of the actors in the process.

First phase: normalization

In the first phase, carried out between July and December 2020, a Steering Committee was created, led by the Sociedad Española de Directivos de la Salud (SEDISA), made up of representatives selected by their respective scientific societies with extensive experience in their practical fields, and health professionals from addiction centres, primary care centres and hospital units, as well as patient associations. This was followed by an exhaustive and structured review of the available scientific literature, with a search strategy based on the PICO methodology to locate relevant information on the handling, management and treatment of users of addiction centres in databases such as PubMed, Medes, Google Scholar, Web of Scientific Societies and review of grey literature in official bodies. This was completed with a free search.

Subsequently, based on the review of the located information, several deliberative meetings were held with the Steering Committee using nominal group methodology and complemented in the inter-meeting periods with discussions by email to define, agree on and prioritize the criteria to be included in the certification guide for addiction centres. These criteria were defined to standardize the work procedures of these centres and improve the provision of care to users with hepatitis C and were mainly based on the creation of circuits to facilitate infection diagnosis, treatment and follow-up of these patients and the creation of coordination mechanisms between addiction centres, primary care centres and hospital units. After the SEDISA technical team prepared several working drafts, a final deliberative meeting was held with the Steering Committee to validate and agree on the final version of the certification guide for addiction centres committed to HCV elimination.

Subsequent phases: implementation, certification and communication

The following phases of the project are currently underway.

The aim of the second phase, implementation, is to standardize addiction centre work procedures. To this end, a project presentation meeting will be held, coordinated by SEDISA, in which all centres interested in joining the program will participate. This will be followed by a 6-month period for implementing the indicators in the addiction centres. In addition, a web platform will be developed to provide online documentation of the certification guide, a training area on the approach to liver diseases and the elimination of hepatitis C, guidelines for the certification process and technical assistance.

In the third phase, with SEDISA acting as an external certifying entity, the certification process for the addiction centres will be established. This will include a documentary audit to assess compliance with the criteria in which

the centres will have to show evidence of meeting the requirements on the web platform enabled for this purpose. In addition, there will be a random face-to-face audit in 20% of the centres at their facilities. The centres that want to apply for certification must meet all the mandatory criteria and, in the event that any of these criteria cannot be met, this must be justified in due course.

The fourth phase, communication, will focus on the dissemination of knowledge and best practices among all the centres involved, in addition to delivering the certification guide and the project itself. Different levels of communication have been established, promoted mainly by scientific societies, associations of health professionals, and patient associations. The aim is to achieve wider dissemination through inclusion on the web pages of these organisations and on social networks.

Workgroup

The Steering Committee was based on the selection and incorporation of a multidisciplinary panel of experts in the management of hepatitis C and addiction centres, of recognized professional prestige, led by the Sociedad Española de Directivos de la Salud (SEDISA).

The following organisations have collaborated on the HepCelentes project: Asociación Española para el Estudio del Hígado (AEEH), Alianza para la Eliminación de las Hepatitis Víricas en España (AEHVE), Federación Nacional de Enfermos y Trasplantados Hepáticos (FNETH), Grupo de Estudio de Hepatitis Víricas (GEHEP) de la Sociedad Española de Enfermedades Infecciosas y Microbiología Clínica (SEIMC), Sociedad Científica Española de Estudios sobre el Alcohol, el Alcoholismo y las otras Toxicomanías (Socidrogalcohol), Sociedad Española de Directivos de la Salud (SEDISA), Sociedad Española de Médicos de Atención Primaria (SEMERGEN), Sociedad Española de Médicos Generales y de Familia (SEMG), Sociedad Española de Patología Digestiva (SEPD) and Sociedad Española de Patología Dual (SEPD).

Results

The certification guide with the requirements to be met by addiction centres committed to eliminating HCV, as prepared in the first phase of the HepCelentes project and agreed by the experts of the Steering Committee, comprises 22 criteria with a common structure based on the following elements: a) definition of the criterion; b) justification for criterion selection; c) level of action (management, prevention, diagnosis and treatment/monitoring); d) measurement formula; e) target level to be achieved; f) evidence of compliance; g) clarifications to enhance understanding; and e) mandatory/recommended status.

Depending on the level of action, six criteria were related to management, two to prevention, seven to diagnosis, and

seven to treatment and patient follow-up. As a whole, a total of 15 criteria were considered mandatory and seven recommended, according to their relevance to elimination and their implementation capacity. Regarding the criteria based on diagnosis and treatment/monitoring, in which a formula was established as an indicator for measurement, the target level to be achieved was set at between 80% and 90%. Evidence of compliance was established with two types of audits, documentary and face-to-face (the latter in 20% of the participating centres, randomly selected).

The management criteria were based on the commitment, coordination and collaboration between centres, provision of information and training of professionals. Those related to prevention were based on plans and programs for health promotion and risk reduction. The diagnostic

criteria focused mainly on screening and access to HCV testing and one-step diagnosis for addiction centre users. The treatment/monitoring criteria were defined taking into account the coordination between the physicians at the addiction centres and the gastroenterology, hepatology and infection services, the ease of application in the patient care circuit, the possibility of dispensing drugs at the addiction centre and telemedicine, among others.

Table 1 specifies all the certification guide criteria, classified by the level of action: management, prevention, diagnosis and treatment/monitoring, and with information on their mandatory status. The detailed characteristics of each of the guideline criteria are shown in Tables 2, 3, 4 and 5.

Table 1. Summary of criteria, by action level, mandatory and recommended status.

Performance level (A-D) Criterion (1-22)	Mandatory (M) / Recommended (R)
A. Management	
1. Development of a hepatitis C elimination policy in addiction centre	M
2. Appointment of a project coordinator in addiction centre	M
3. Multidisciplinary committee with area professionals	R
4. Shared access to clinical history and patient registration	M
5. Training of professionals in hepatitis C	M
6. Adequate information systems	M
B. Prevention	
7. Health promotion plans and preventive programs	M
8. Risk reduction programs	M
C. Diagnosis	
9. Screening for HCV infection (in first consultation)	M
10. Screening for HBV and HIV coinfection	M
11. Annual HCV screening (users with risky habits)	M
12. Access to rapid serological diagnostic tests (anti-HCV)	R
13. One-step diagnosis (OSD)	R
14. Determination of virological markers (if no OSD available)	M
15. Annual detection of reinfections (users with risks habits)	M
D. Treatment and follow-up	
16. Patient journey with the hospital specialist	M
17. Consensus protocol with gastroenterology/infectious disease services	M
18. Coordination/monitoring between addiction centre and hospital specialist	M
19. Adherence control (users with poor adherence)	R
20. Promoting the use of telemedicine	R
21. Documentary record of the process	R
22. Promoting hospital or peer accompaniment	R

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

Table 2. *Criteria related to management level.*

Criteria related to management level.	Hepatitis C Elimination Policy in addiction centre (1)	Project coordinator in addiction centre (2)	Multidisciplinary committee with area professionals (3)	Shared access to clinical history and patient registration (4)	Training of professionals in hepatitis C (5)	Information systems (6)
Criterion definition	The centre must develop and approve a policy that demonstrates the commitment of the centre management to the elimination of hepatitis C.	The centre must designate a project coordinator, the reference person for primary and hospital care.	Establishment of a multidisciplinary committee with area professionals is recommended.	Maintenance of clinical history, if possible electronic, with shared access for addiction centres, primary care centres and specialized consultations, as well as patient registry, are recommended.	Addiction centre professionals must receive training in hepatitis C.	Appropriate information systems must be established to avoid loss of continuity between diagnosis, treatment and follow-up and also allow rapid problem solving.
Justification	By approving this policy, the centre commits in writing to start the project and provide the necessary resources. This commitment must be signed by the centre coordinator or director.	The centre must appoint a project coordinator to improve coordination with primary and hospital care, establishing direct communication mechanisms and facilitating problem solving.	The creation of a multidisciplinary committee (pharmacist, microbiologist, hepatologist, infectious disease specialist, psychiatrist, psychologist, family doctor, social worker, etc.) favours coordination between area professionals and improves patient follow-up.	The aim is for the centres to have an electronic medical record and for part of this data to be shared with the addictions, primary care and specialized consultation centres. In addition, the centres must maintain an updated registry of patients with hepatitis C.	Addiction centre professionals should receive training on advances in hepatitis C knowledge for management of their patients based on the best available medical evidence.	The centre must establish adequate information systems to guarantee the continuity of patient care and facilitate rapid problem solving.
Formula	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.
Target level	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.
Compliance evidence	The centre will have a policy that evidences the commitment to the elimination of hepatitis C, made available to users and other interest groups.	Identification of the responsible person through a record of appointment.	Committee meeting minutes will be reviewed.	<i>Documentary audit:</i> The centre will attach to the platform a brief description of the characteristics of the clinical history and the registry, uploading an image of these, in which personal data protection is guaranteed. In the event that access is shared, the type of access will be reported and an image evidencing it will be attached. <i>In-person audit:</i> In the centre, the clinical history, the patient registry and the shared access will be evidenced in situ.	Certificates of completion of courses, attendance at congresses, etc., are considered evidence.	Evidence that the centre has an established information system will be reviewed.

Clarifications	If the centre already has an approved policy, this will be considered valid to evidence commitment, making it unnecessary to prepare another document.	Not applicable.	Not applicable.	Not applicable.	Certificates of completion of courses, attendance at congresses, etc., are considered evidence. It is recommended that all professionals in the addiction centre receive training regardless of their professional category. Only the training of physicians is considered mandatory. The project website will include a training section, completion of which will serve to meet this criterion.	Not applicable.
Mandatory / Recommended	Mandatory.	Mandatory.	Recommended.	Clinical history in any format: Mandatory. Electronic medical record with/without external communication: Recommended. Hepatitis C patient registry: Mandatory.	Mandatory.	Mandatory.

Table 3. Criteria related to the level of prevention.

Criterion (criterion number in the certification guide)	Health promotion plans and preventive programs (7)	Risk reduction programs (8)
Criterion definition	The addiction centre must establish health promotion plans and preventive programs for its patients.	The centre will implement risk reduction programs that reduce the possibility of new infections and reinfections. In addition, it will have informative materials aimed at the target population on HCV transmission and risk and harm reduction strategies, as well as information on treatments. It will also inform cohabitants and relatives about the risks, advising them not to share sharp objects, razor blades or toothbrushes that may come into contact with the blood of the person infected with HCV.
Justification	It is necessary that the centre has established health promotion plans and preventive programs for its patients.	Information, education and communication actions towards the target population will reduce the percentage of infected people. This makes it essential to provide information and stress the risks to avoid contagion.
Formula	Not applicable.	Not applicable.
Target level	Not applicable.	Not applicable.
Compliance evidence	<i>Documentary audit:</i> The centre will post the plans and programs that it has established in its centre on the platform. <i>On-site audit:</i> The centre's preventive plans and programs and their follow-up will be reviewed.	<i>Documentary audit:</i> The risk reduction programs and the informative material available to the centre will be reviewed. <i>Face-to-face audit:</i> Risk reduction programs, informative material and records of informative meetings will be reviewed in situ.
Clarifications	Not applicable.	It is recommended to include advice in the informative materials on NGOs or patient associations that can provide support to the patient. In addition to information, educational and communicative actions, it is recommended that the centres provide users with sterile needles and hygiene kits (and condoms).
Mandatory / Recommended	Mandatory.	Mandatory.

Note. HCV: Hepatitis C virus. NGO: Non-governmental organization.

Table 4. *Criteria related to diagnostic level.*

Criterion (criterion number in the certification guide)	Screening for HCV infection (first consultation) (9)	Screening for HBV and HIV coinfection (10)	Annual HCV screening (users with high-risk habits) (11)	Access to rapid serological diagnostic tests (anti-HCV) (12)	One-Step Diagnosis (OSD) (13)	Determination of virological markers (if no OSD available) (14)	Annual detection of reinfections (at-risk users) (15)
Criterion definition	All drug users must be screened for HCV infection at first consultation.	All drug users must be screened for HBV and HIV infection. The diagnostic record must be documented.	Screening must be repeated annually for drug users whose results were negative if they maintain risky habits.	It is recommended that the centre have access to serological diagnostic tests (anti-HCV) through dried blood or saliva, or that they can perform blood tests by extraction in the centre.	One-step diagnosis is recommended to characterize active HCV infection.	In the event that one-step diagnosis is not available, the virological markers (HCV-RNA or HCV core antigen) must be determined in patients with positive serology and the centre must have a care circuit defined for it.	The necessary means will be made available for monitoring plasma HCV RNA every 12 months in patients already treated to detect reinfection against new exposures to HCV in patients who maintain risky habits.
Justification	It is important to screen for HCV infection in the patient's first consultation at the centre to identify those users not known to be infected or with unavailable information.	The goal is to discard HBV and HIV coinfection in all patients.	The goal is to detect those patients whose previous year result was negative and re-evaluate them in case they have become infected with HCV.	The centre should have access to serological diagnostic tests using dried blood or saliva, or should be able to do blood tests by extraction in the centre.	Carrying out the diagnosis in a single step is recommended as it significantly reduces the patient drop-out for both diagnosis and follow-up.	In those patients with positive serology, virological markers (HCV-RNA or HCV core antigen) must be determined. The centre must have a patient journey defined.	Elimination of infection does not confer protection against new exposures to HCV. For this reason, patients who have already been treated and who maintain risky habits must be monitored to detect reinfections.
Formula	$(\text{Number of users who have undergone the HCV test in the first consultation} / \text{Number of first consultations carried out}) * 100.$	$(\text{Number of users screened for HBV and HIV infection} / \text{Number of first consultations made}) * 100.$	$(\text{Number of users who have been screened after a negative result the previous year if they maintain risk habits} / \text{Total number of users with negative screening the previous year}) * 100.$	Not applicable.	Not applicable.	$\text{Number of viremias performed} / \text{Number of users with positive serologies. Number of users with positive viremia.}$	$(\text{Number of patients monitored} / \text{Number of patients treated}) * 100.$ Percentage of reinfections.
Target level	90%	90%	80%	Not applicable.	Not applicable.	80%	80%
Compliance evidence	<i>Documentary audit:</i> The centre's screening protocol will be reviewed. <i>Face-to-face audit:</i> The screening protocol will be reviewed and clinical records will be audited to check that screening was carried out in the first consultation.	<i>Documentary audit:</i> The screening protocol will be reviewed. <i>Face-to-face audit:</i> The screening protocol will be reviewed and the medical records will be audited to check that screening was carried out in the first consultation.	<i>Documentary audit:</i> The protocol that the centre has implemented will be reviewed. <i>Face-to-face audit:</i> The protocol will be reviewed and medical records will be audited to check that screening was carried out.	<i>Documentary audit:</i> Documentation will be reviewed to check that the centre has access to serological diagnostic tests using dried blood or saliva, or that they can perform blood tests by extraction in the centre. <i>Face-to-face audit:</i> Documentation showing that the centre has access to serological diagnostic tests using dried blood or saliva, or that they can perform blood tests by extraction in the centre, will be reviewed. In addition, clinical records in which these diagnostic tests have been carried out will be audited.	<i>Documentary audit:</i> The protocol in which includes the information on one-step diagnosis will be reviewed. <i>Face-to-face audit:</i> The protocol will be reviewed and clinical records will be audited to check one-step diagnosis is used.	<i>Documentary audit:</i> The care circuit defined by the centre will be reviewed. <i>In-person audit:</i> the patient journey will be reviewed and clinical records will be audited to check that virological markers (HCV-RNA or HCV core antigen) are determined in patients with positive serology.	<i>Documentary audit:</i> The protocol of the centre will be reviewed. <i>Face-to-face audit:</i> The protocol will be reviewed and medical records will be audited to check for monitoring.

Clarifications	This requirement is considered met if the centre offered the test, even if the user did not accept it. A record of the offer must be included in the patient's clinical history. When referring to all drug users, alcohol users are also included.	This requirement is considered met if the centre offered the test, even if the user did not accept it. A record must be included in the patient's clinical history.	In the event of patient drop-out, the annual period from readmission to the most recent treatment will be counted. In the event of a negative screening result (anti-HCV), the test must be repeated annually.	The indicator refers to access to diagnostic tests. The whole blood analysis must incorporate the variables to have a liver profile and to calculate the fibrosis indices. In addition, the centres may optionally measure the following indicators: a) Number of saliva tests carried out / number of people screened. b) Number of dry drop tests carried out / number of people screened. c) GeneXpert number performed/number of anti-HCV positive people tested. d) Number of people screened by point of care test/ number of people screened.	Not applicable.	Patient journey is understood as the algorithm or protocol used by the centre.	Monitoring will be carried out on patients who continue in the centre.
Mandatory / Recommended	Mandatory.	Mandatory.	Mandatory.	Recommended.	Recommended.	Mandatory.	Mandatory.

Nota. HBV: Hepatitis B virus; HCV: Hepatitis C virus; HIV: Human immunodeficiency virus.

Table 5. *Criteria related to treatment level and follow-up.*

Criterion (criterion number in the certification guide)	Patient journey with the hospital specialist (16)	Consensus protocol with gastroenterology/ infection services (17)	Coordination/ monitoring between addiction centre and hospital specialist (18)	Adherence control (users with poor adherence) (19)	Promoting the use of telemedicine (20)	Documentary record of the process (21)	Promoting of hospital or peer support (22)
Criterion definition	All patients diagnosed with hepatitis C must be informed about assessment by the hepatologist or infectious disease specialist and the centre must have a care circuit defined for this.	The centres must have an agreed protocol with the gastroenterology/ infection services and a reference physician.	The addiction centre physician and the viral hepatitis specialist treating the HCV infection must be coordinated and must closely monitor the patient.	In patients whose profile suggests poor compliance, it should be possible to facilitate that the administration of the treatment be directly observed by the health professional of the addiction centre.	The use of telemedicine should be encouraged, both for the relationship between professionals and for the follow-up of patients with difficulties in accessing the hepatologist (consultation with the specialist / patient - doctor of the addiction centre).	Maintenance of a documentary record of the process is recommended from the start until the sustained virological response (SVR) and communication with the addiction centre of the SVR registry are documented.	It is recommended that the figure of hospital companion, facilitator or peer accompaniment be promoted, with the aim of facilitating the care journey of patients who do not normally use classic patient journey.
Justification	The centre must have a defined patient journey with the hospital specialist to refer patients diagnosed with HCV infection for staging and treatment.	In order to improve patient follow-up, the presence of an agreed protocol and reference physician(s) in the gastroenterology/ infection service is recommended.	The objective is that both specialists are coordinated to guarantee treatment and follow-up of the patient.	The objective is to guarantee that patients with poor adherence take medication in the addiction centre.	Telemedicine can make it easier for patients with difficulties in accessing the specialist to be treated in the addiction centre with the virtual support of the specialist doctor.	The purpose of this registry is to facilitate the follow-up of referred and treated patients.	The ultimate goal is to treat the patient. To this end, the centres may promote the figure of hospital companion, facilitator or peer accompaniment, with the aim of facilitating access to the specialist, reducing the isolation of the patient and improving treatment adherence.
Formula	Number of users referred to a hepatologist or infectious disease specialist.	Not applicable.	Number of patients who receive a consultation with the viral hepatitis specialist and are treated.	Number of treatments administered in the centre.	Not applicable.	Not applicable.	Not applicable.
Target level	90%	Not applicable.	80%	Not applicable.	Not applicable.	Not applicable.	Not applicable.

Compliance evidence	<i>Documentary audit:</i> It will be checked that the centre has a defined patient journey. <i>Face-to-face audit:</i> It will be checked that the centre has a documented patient journey and clinical records will be audited to evidence its implementation.	The agreed protocol with the gastroenterology/ infection services and a document that identifies these doctors as the reference ones will be reviewed.	The centre must indicate the means by which the doctors of the addiction centre and the hepatologist coordinate.	<i>Documentary audit:</i> the centre must post the designated dispensing protocol on the platform. <i>Face-to-face audit:</i> The designated dispensing protocol will be reviewed and the patient's medical records will be audited.	<i>Documentary audit:</i> The protocol that includes remote monitoring of patients will be reviewed.	<i>Documentary audit:</i> The evidence of the registry documenting the negative viral load or sustained viral response and communication of the SVR to addiction centre will be reviewed.	The documentation showing that the centre has some figure for patient accompaniment will be reviewed.
Clarifications	This criterion would not apply in those centres that have implemented a protocol in which the hepatitis C specialist is not referred, but rather the patient is treated directly.	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.
Mandatory / Recommended	Mandatory.	Mandatory.	Mandatory.	Recommended.	Recommended.	Recommended.	Recommended.

Note. SVR: Sustained Virological Response.

Discussion

Recent years have seen important advances in the management of addiction centre users with hepatitis C, but there are still a series of barriers to access and a lack of structured tools, agreed upon and endorsed by experts, that certify the correct operation of programs and strategies aimed at reducing HCV infection and reducing unmet needs in this group (Corma-Gómez & Pineda, 2019; Pericàs et al., 2019).

At the international level, a series of studies have reviewed the most important barriers in managing users of addiction or harm reduction centres. A study published in 2017, for example, established an action framework based on a series of epidemiological, health and social indicators and the definition of best practice in harm reduction centres for patients with opioid use disorder or in needle exchange programs, through consensus among a broad group of experts, members of civil society, and associations of users with a history of injecting drug use (Wiessing et al., 2017). In addition, in 2017 the *International Network of Hepatitis in Substance Users* (INHSU) hosted an international panel of experts in drugs and alcohol, infectious diseases and hepatology to discuss an action plan and recommendations regarding the management of people who inject drugs, focused on the elimination of hepatitis C. Six key pillars were established, focused on the provision of services, strengthening of health personnel structures, health information systems, access to technologies with proven quality, safety, efficacy and efficiency, financing of health systems, and leadership/governance (Day et al., 2019).

In the other hand, the C-SCOPE study, by means of an electronic questionnaire, assessed the barriers perceived by health professionals related to the diagnosis and treatment of HCV infection in patients with opioid use disorder in substitution treatment, some of which were not applicable in our environment. The most relevant obstacles among them related to the management of hepatitis C were: lack of funding for diagnostic tests for liver disease and access to antiviral treatment, considerable waiting times for accessing specialists in the management of the infection, restrictions regarding reimbursement, lack of peer support programs, problems in referring people with opioid use disorder to specialists, and difficulty in linking diagnosis and health care at the point of patient care (Litwin et al., 2019).

The HepCelentes project has designed a certification program for addiction centres to standardize the management of HCV and improve the care provided to patients with the disease, in line with existing clinical guidelines and recommendations (American Association for the Study of Liver Diseases, 2021; Calleja et al., 2018; Ghany et al., 2020; Pawlotsky et al., 2020), the strategy of the Spanish Health Ministry (Ministerio de Sanidad 2015; 2020a), existing regional plans (Comunidad de Madrid, 2017; Generalitat de Catalunya, 2018; Gobierno de Aragón, 2019; Gobierno de Cantabria, 2020) and the objectives established by the WHO (World Health Organization, 2016). In addition, it aims to contribute to the acquisition of knowledge and the development of best practices among the affiliated centres. The criteria developed in the certification guide for addiction centres

were fundamentally based on the recommendations made by scientific societies for the micro-elimination of hepatitis C (Alianza para la Eliminación de las Hepatitis Víricas en España -AEHVE-, 2021; Crespo et al., 2019a; Pineda et al., 2020) at the different levels of action: management, prevention, diagnosis and treatment/monitoring.

Management of drug users mainly takes place in addiction centres. However, most of these centres do not have a specific elimination policy and the necessary means to carry out a complete assessment of patients with hepatitis C, making it necessary to decentralize certain tests and refer these patients to hospital care (Crespo et al., 2019a; Guerra Veloz et al., 2021; Roncero et al., 2017). During this process, some patients are lost on their care journey (Del Pino Bellido et al., 2021). To avoid such patient drop-out, it is necessary to promote the creation of agreed circuits of care that enable patients to be linked to the health care system, coordination mechanisms to be established between addiction centres, primary care and hospital units, and effective information systems to be developed (Macías et al., 2019). Moreover, the possibility of using shared information systems between healthcare centres, such as having a shared clinical history, would help the joint registration of patients and would allow optimal follow-up with updated data on risk groups (Litwin et al., 2019). Similarly, it is necessary that health professionals in addiction centres receive optimal information on the latest clinical evidence in the management of hepatitis C (Samuel, Martinez, Chen, Markatou & Talal, 2018).

Due to the risky habits of the population attending addiction centres, the incidence, transmission of the virus and reinfection among them are high (Antuori et al., 2021; Midgard et al., 2016). To prevent this, it is important to promote information and health education for this group through the implementation of preventive and health promotion plans and programs aimed at reducing risks and avoiding new infections (Alianza para la Eliminación de las Hepatitis Víricas en España -AEHVE-, 2021; Crespo et al., 2019a).

Diagnosis plays a key role in the elimination of hepatitis C. The limited linkage between addiction centre users and the general health care system increases undiagnosed HCV infection (Folch et al., 2021). These risk populations thus need to be screened to provide early diagnosis of the infection. Furthermore, as mentioned above, many patients are lost in the care process meaning that HCV-RNA may not be confirmed after their initial serology for the diagnosis of HCV (Morales-Arráez et al., 2019). In recent years, the management of hepatitis C has undergone important changes related to the simplification of one-step diagnosis (Crespo et al., 2019b) and the development of new diagnostic techniques for the detection of antibodies or HCV viremia or even the standardization of existing ones by integrating them into the normal hospital diagnostic

process (Gómez et al., 2020). All this has facilitated infection screening in outpatient settings, thereby avoiding patient drop-out (Crespo et al., 2021; Gómez et al., 2020; Saludes et al., 2019, 2020). Nevertheless, the risk behaviours associated with this population, as well as the possibility of reinfection or suffering from other infections, indicate that these patients should undergo periodic diagnostic tests (Saludes et al., 2018), not only for the re-assessment of hepatitis C, but also HIV and HBV (in unvaccinated patients) (Martínez-Sanz et al., 2021; Tucker et al., 2017).

The ultimate goal of the process is that users of addiction centres with hepatitis C have access to antiviral treatment, but the lack of defined healthcare circuits or coordination between centres and agreed protocols leads to patients becoming disconnected from health care, thus making access to specialists and subsequent treatment with DAAs difficult (Roncero et al., 2017). In addition, many of these patients, even despite accessing treatment, have poor treatment adherence (Roncero et al., 2012). Linking the diagnosis to an early treatment start directly in the addiction centre (Morales-Arráez et al., 2021) and establishing hospital or peer support programs would thus facilitate access to specialists in the gastroenterology, hepatology or infectious disease services, would reduce patient isolation and improve treatment adherence and persistence (Litwin et al., 2019). Interaction between health professionals, and the lack of access to specialists by addiction centre users, could also be improved through the implementation of regular telemedicine use (Cuadrado et al., 2021; Mateo et al., 2019; Morales Arráez et al., 2021).

Recently, during the early stages and development of the COVID-19 pandemic, it was shown that the delay in diagnosis and treatment of patients with hepatitis C can have a significant impact on the appearance of complications and the increase in hepatic mortality (Butí, Domínguez-Hernández & Casado, 2021). The involvement and collaboration of all the health agents involved in comprehensive care for addiction centre users with hepatitis C through the establishment and definition of standardized quality indicators are thus essential elements for achieving the goal of eliminating hepatitis C in Spain. In this sense, one of the strengths of the HepCelentes project has been the leadership of an organization such as SEDISA as a reviewing and certifying entity on behalf of the managers of social health centres; which has achieved a high degree of consensus among associations, health professionals and other agents involved in dealing with hepatitis C, including the patients themselves, for improving the care provided to addiction centre users with hepatitis C and defining the criteria of the certification guide.

Nevertheless, the project development has a number of limitations. One of these is related to the selection of Steering Committee members. Although the panel

comprised a selection of professionals and decision-makers from all fields, based on their scientific and technical knowledge, there was a predominance of health professionals, since they are directly responsible for the management of addiction centre users; other sectors, such as patients, were however also represented. In addition, like any instrument for managing the quality of clinical care, the certification guide will need to demonstrate its value and effectiveness in the control and elimination of HCV infection in addiction centres in routine clinical practice. The HepCelentes project could thus be the starting point for developing a national plan to eliminate hepatitis C in patients with addictions.

Conclusions

In conclusion, addiction centres are a cornerstone in the development of a comprehensive plan for the elimination of hepatitis C. The development of a certification system for these centres that contributes to improving the quality of care for users with hepatitis C, based on the consensus and coordination of multidisciplinary work teams, aims to promote standardization, best practice, management, prevention, diagnosis, treatment, and monitoring of users, supporting international, national and regional strategies aimed at the elimination of hepatitis C.

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Conflict of interests

All participants in the development of the project were supported by SEDISA, independently of results. Joan Colom declares that he has no conflicts of interest. Marta Torrens has received consultant and/or speaker fees from Gilead, MSD, Servier, Lundbeck and Rovi. Ángeles Rodríguez-Cejas has received fees for presentations from Exeltis, Gilead and Lundbeck and grants to attend training activities from Lundbeck and Gilead. Ignacio Aguilar declares that he has no conflicts of interest. Rocío Álvarez-Crespo has received grants to attend training activities from Gilead and Janssen and fees for participating in Gilead presentations. Lorenzo Armenteros declares that he has no conflicts of interest. Victoria Ayala and Helena Cantero are employees of Gilead Sciences. Miguel Ángel Casado is an employee of Pharmacoeconomics & Outcomes Research Iberia (PORIB), an independent consultancy specializing

in the evaluation of health interventions that has received funding from Gilead Sciences. Javier Crespo declares that he has no conflicts of interest. Joaquín Estévez declares that he has no conflicts of interest. Javier García-Samaniego has received scholarship fees and for participating in Gilead presentations. Manuel Hernández-Guerra has received consultancy fees and grants from Gilead, Abbvie, Bayer, Orphan, and Intercept. Carlos Mur has received consultancy fees from LUG Healthcare Technology and as a contributor to BD, BMS, Otsuka, Lundbeck and Gilead. Eva Pérez-Bech declares that she has no conflicts of interest. Mercedes Ricote declares that she has no conflicts of interest. Juan A. Pineda has been a beneficiary of grants for research projects from Abbvie, Janssen, Gilead, MSD and ViiV, has received presentation fees from Abbvie, Janssen, Gilead, MSD and ViiV, has received grants to attend training activities from Janssen and Gilead and has done advisory work for Abbvie, Janssen, Gilead and MSD.

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