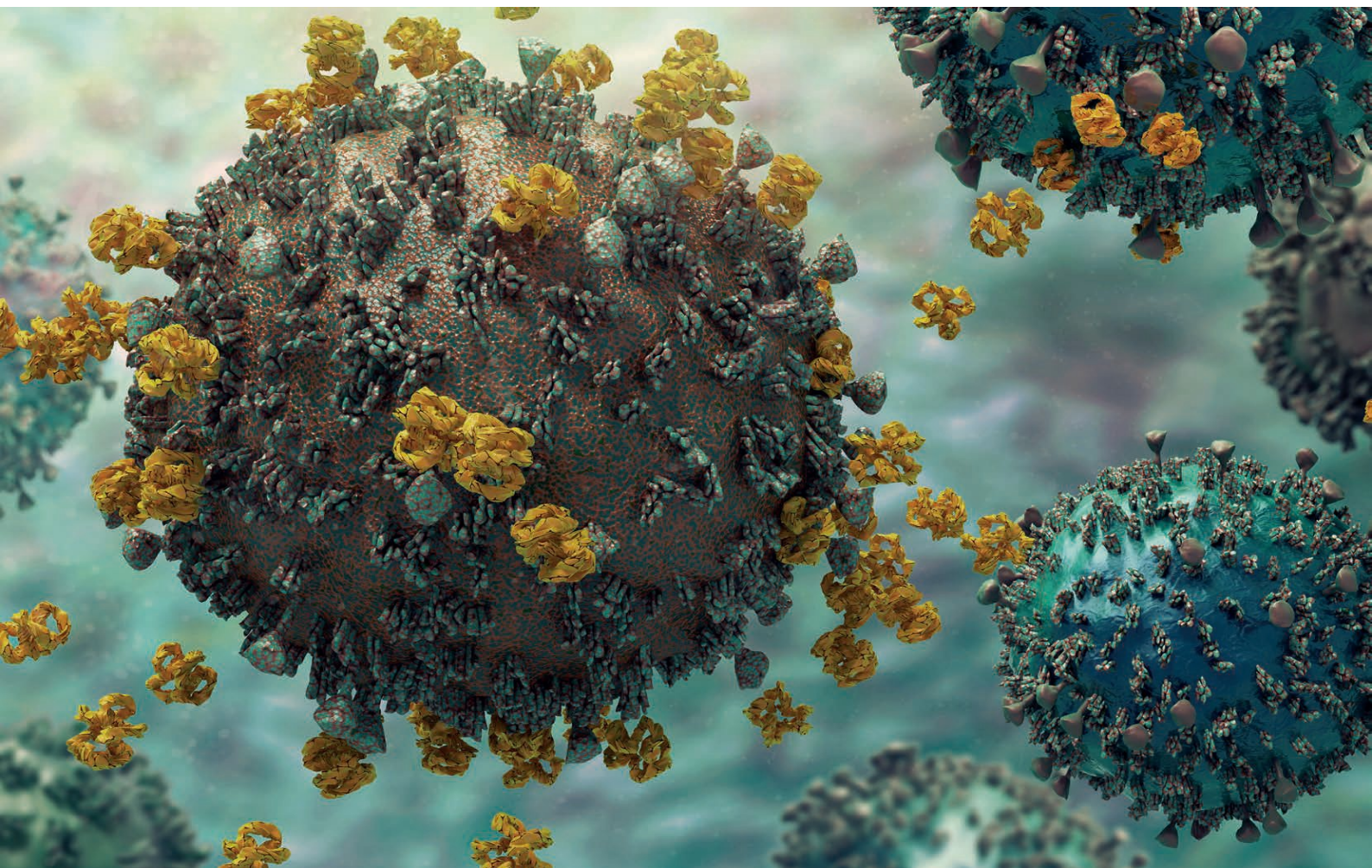


SUMMARY OF THE STRATEGY FOR THE ELIMINATION OF HEPATITIS C AS A PUBLIC HEALTH PROBLEM IN GALICIA



XUNTA
DE GALICIA

XUNTA DE GALICIA

Consellería de Sanidade
Dirección Xeral de Saúde Pública

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This document is a summary of the Strategy for the Elimination of Hepatitis C as a Public Health Problem in Galicia prepared by a large working group composed of different experts in the field. It has the scientific endorsement of the Alliance for the Elimination of Viral Hepatitis in Spain (AEHVE, in its Spanish acronym).

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DE GALICIA**

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1. BACKGROUND

In recent years, there have been significant advances in the field of hepatitis C treatment thanks to the new, more effective and safer direct-acting antivirals, which show excellent tolerance, are applicable to almost all patients and whose cure rates are greater than 95%. Therefore, the elimination of hepatitis C as a public health problem is possible, as WHO established a global strategy in 2016 to achieve this goal by 2030, which implies a 90% reduction in new chronic infections and a 65% reduction in mortality, compared to 2015 values (1).

2. CHARACTERISTICS OF HEPATITIS C

2.1. The infection

Hepatitis C is a liver inflammation caused by the virus with the same name, an RNA virus that is characterized by a high degree of genomic heterogeneity (genotype 1b is the most frequent in Spain) and by a high mutation rate that allows it to evade the host's immune defences and to induce low protection against reinfection.

The reservoir is the human being, and the main transmission routes are parenteral (85%), sexual, vertical and intrafamilial parenteral.

The incubation period ranges from two weeks to six months (average: two months). It is usually expected that alanine aminotransferase (ALT) levels rise between the sixth and ninth week. Anti-HCV antibodies become positive two to three months after infection (2) (3).

2.2. Diagnosis

Reflex testing has been used as a strategy. This testing method consists of determining the viral load or the hepatitis C virus core antigen after a positive serological result of anti-HCV antibodies, using the same sample and without requiring another extraction.

2.3. Treatment and Prevention

Current treatment for the infection, with pan-genotypic direct-acting antivirals, achieves a sustained viral response in more than 95% of cases. The duration of treatment can vary between 8, 12 or 24 weeks.

3. CURRENT SITUATION

3.1. Hepatitis C Situation Worldwide, in Spain and Galicia

The World Health Organization (WHO) estimates the prevalence of hepatitis C virus infection in the general population to be 0.8% (4).

In Spain, a seroprevalence study in 2018 (5) showed that the prevalence of antibodies against the virus in the general population aged 20 to 80 years was 0.85%, and that of active infection was 0.22%. No positive tests were detected in people under 20 years of age.

Table 1 shows an extrapolation of the seroprevalence study for Galicia according to the above study (5).

Table 1. Estimation of the number of cases of active hepatitis C virus infection in Galicia, 2021.

Age group	Population (IGE 01/01/2021)	Active infection prevalence	Estimated number of cases
40-49	443,148	0.14%	620
50-59	408,541	0.50%	2,043
60-69	353,142	0.34%	1,201
Total 40-69 (45% Galician population)	1.204,831	0.33%	3,864
Total 20-80	2.059,866	0.22%	4,532

This study indicates that globally there is an undiagnosed fraction of active hepatitis C virus infection of 29.4% between 20-80 years. According to this, based on the general population of Galicia of this age group, 1,332 people with active infection would be undiagnosed in this autonomous community.

4. JUSTIFICATION OF THE GALICIAN STRATEGY

Hepatitis C is a serious public health problem and one of the most important causes of chronic liver disease worldwide.

About a quarter of new diagnoses of hepatitis C virus infection involves advanced liver disease, resulting in an avoidable diagnostic delay which means a major impact on the patient's health and the health system.

On the other hand, treatment for hepatitis C using direct-acting antivirals achieves a sustained viral response after 12 weeks in more than 95% of people treated. In addition, it was shown to reduce the incidence of hepatocellular carcinoma substantially and accelerate the decline in hepatitis C mortality rates (*European Association for the Study of the Liver [EASL]*, *American Association for the Study of Liver Disease [AASLD]*).

As stated by WHO, it is essential to facilitate early access to diagnosis and treatment. That is why, since 2015, many countries have designed their own strategies against hepatitis C. In 2019, the *Spanish Association for the Study of the Liver* stated that the diagnosis rate of hepatitis C in our country was not satisfactory, estimating that 22,500 infected adults were unaware of their situation, so they could transmit the infection, being necessary to implement a strategy to eliminate hepatitis C as a public health problem.

With regard to the type of interventions that should be carried out, in addition to primary prevention actions, for the diagnosis and treatment of all cases of active infection, it is necessary to highlight the importance of population screening for this pathology.

Several international organizations recommend screening in priority populations, such as age cohorts with the highest hepatitis C viral loads (6-11).

In 2022, a systematic review was conducted on the clinical effectiveness, safety and economic evaluation of population screening for hepatitis C (12), concluding that screening of higher-risk subgroups would be the most efficient strategy, while population-based screening would be an efficient strategy in the medium and long term.

Based on the available scientific evidence, it is considered that the ideal strategy to achieve the elimination of hepatitis C as a public health problem in Galicia is the screening of people included in the groups with the highest risk of transmission, combined with the screening of the age groups with the highest prevalence of the hepatitis C virus (group of 40-69 years old), as well as the coordination of the largest number of professionals and entities involved, implementing active search measures

that facilitate the diagnosis and treatment of cases of hepatitis C virus infection not detected and all those cases of hepatitis C diagnosed, but not treated and/or cured.

The program will also address other improvements in the process of diagnosis and treatment of cases, such as reducing the time between diagnosis and treatment, improving the percentages of diagnosed patients who start treatment and follow it properly and monitoring patients to verify the obtaining of sustained viral response.

5. PURPOSE

The general objective of this Strategy is to promote and coordinate the necessary actions to eliminate hepatitis C as a public health problem in Galicia through the prevention of the disease, its detection, epidemiological surveillance, treatment and training and research.

The specific objectives are:

- Achieve an annual incidence of new hepatitis C diagnoses (in the general population) ≤ 5 cases per 100,000 population.
- Achieve an annual mortality rate related to hepatitis C virus ≤ 2 per 100,000 population.

By doing this, we want to contribute to achieving the WHO objectives, the Sustainable Development Agenda 2030 goals and those of the Alliance for the Elimination of Viral Hepatitis in Spain.

This Strategy will be valid for four years.

6. STRATEGIC AXES AND LINES OF ACTION

Table 2 presents the five axes and the strategic lines of action that will be developed in our community.

Table 2. Strategic Axes and Lines of Action

AXIS 1. Epidemiological surveillance	
Strategic line 1.1.	Surveillance and reporting of cases.
Strategic line 1.2.	Surveillance of morbidity and mortality due to hepatitis C sequelae
AXIS 2. Primary prevention and health promotion	
Strategic line 2.1.	Information for the general public
Strategic line 2.2.	Promotion and prevention in people who inject drugs ¹
Strategic line 2.3.	Promoting safe sex
Strategic line 2.4.	Prevention in tattooing, micropigmentation, piercing and other procedures performed with sharp material
Strategic line 2.5.	Prevention training for health and non-health professionals
AXIS 3. Secondary prevention: Detection of infection	
Strategic line 3.1.	Active search for patients who previously had a positive test, but no diagnostic confirmation/cure
Strategic line 3.2.	Infected patients who are unaware of their situation
	3.2.1. Active recruitment of people aged 40 to 69 and those of any age who belong to a risk group and who go to any healthcare centre of the Galician Health Network
	3.2.2. Active search for people who are difficult to attract
AXIS 4. Diagnosis and treatment	
Strategic line 4.1.	Facilitating diagnosis
Strategic line 4.2.	Treatment optimization
AXIS 5. Training and research	
Strategic line 5.1.	Training
Strategic line 5.2.	Research

¹ Due to gender language considerations, the former terminology (injecting drug users -UDI-, which in Galician and Spanish was usually used in its masculine form) has evolved to people who inject drugs (PID) in order to be more inclusive and gender-neutral.

AXIS.1. Epidemiological Surveillance

Hepatitis C is a notifiable disease, and its epidemiological surveillance is essential to know the status of hepatitis C infection. Following WHO recommendations (13), epidemiological surveillance will be based on three components: surveillance of newly acquired hepatitis C, estimation of the prevalence of chronic infection and surveillance of morbidity and mortality due to complications (cirrhosis and hepatocellular carcinoma).

STRATEGIC LINE 1.1. Surveillance and Reporting of Cases

The Spanish National Epidemiological Surveillance Network addresses hepatitis C surveillance based on the notification of new hepatitis C diagnoses, which will be investigated to identify those cases with recent infection.

Strategic objectives:

- Identify and report incident cases of hepatitis C virus infection and describe risk factors and practices to identify, prevent and control disease transmission.
- Detect, investigate and control outbreaks in the healthcare field and those related to risk practices.
- Identify and monitor the temporal evolution of diagnosed cases of hepatitis C virus infection and their basic epidemiological characteristics to have information to guide policies for preventing and controlling population diseases.

Actions:

- Regulate the mandatory reporting of cases from both public and private clinical microbiology services to guarantee their notification and develop a surveillance protocol that includes uniform criteria, and the actions that must be carried out in the event of an outbreak.
- Facilitate the electronic case notification by automating the necessary processes and integration into the epidemiological surveillance information system (VIXÍA).
- Investigate and classify cases as newly infected or newly diagnosed.
- Identify and investigate the occurrence of outbreaks.
- Investigate the presence of risk factors/practices to identify, prevent and control disease transmission and prepare an annual report with the results.
- Evaluate the relevance of conducting a seroprevalence study of the hepatitis C virus in Galicia in 2026.

STRATEGIC LINE 1.2. Surveillance of Morbidity and Mortality Due to Hepatitis C Sequelae

Knowing the fraction of cirrhosis, hepatocellular carcinomas and liver transplants that can be attributed to the hepatitis C virus is essential for evaluating activities aimed eliminating hepatitis C (13).

Strategic objectives:

- Determine liver complications attributable to the hepatitis C virus.

Actions:

- Establish, throughout the year 2023, a systematic approach to identify and follow the evolution of the fraction of cirrhosis, hepatocellular carcinomas and liver transplants that can be attributed to the hepatitis C virus.

AXIS 2. Primary Prevention and Health Promotion

Unlike other viral hepatitis, there is no vaccine against hepatitis C, so primary prevention, aimed at reducing the incidence of new infections, is based on reducing the risk of exposure to the virus.

STRATEGIC LINE 2.1. Information for the General Public

In addition to key messages on transmission routes and prevention measures for hepatitis C virus infection, the idea that hepatitis C is a curable disease will be emphasized, so early diagnosis is essential in order to establish treatment as soon as possible.

The information will include messages aimed at reducing stigma, marginalization and lack of solidarity with individuals infected with the hepatitis C virus.

Strategic objective:

- Carry out communication actions to increase the general population's knowledge about hepatitis C and reduce the population's risk.

Actions:

- Provide information on the problem of hepatitis C through the channels available in the Department for Health, including social networks (websites, Twitter, YouTube, etc.), with rigour, accuracy and credibility.

- Design informative materials to be distributed in healthcare centres, drug addiction treatment units, mental health units, non-governmental organizations and other collaborating entities, focusing on the benefits that people belonging to the groups with the highest prevalence of infection could obtain with their participation in the activities proposed in this Strategy.
- Engage the media's interest so that they commit to the goal of eliminating hepatitis C as a public health problem in Galicia, providing information through press releases, radio and television campaigns, etc.
- Through the Department for Health website, provide contact addresses and telephone numbers of the program and private non-profit entities that carry out preventive activities, health promotion and that offer various resources to the Galician society, especially to the most vulnerable people to hepatitis C.

STRATEGIC LINE 2.2. Promotion and Prevention in People Who Inject Drugs

The sharing of injection materials in intravenous drug use is a significant risk factor for hepatitis C virus transmission, so it is necessary to develop specific prevention and promotion actions in this population and harm reduction associated with consumption.

Strategic objective:

- Reduce the hepatitis C virus transmission in this group through specific actions.

Actions:

They are divided into two groups: preventive actions and harm reduction actions.

Preventive Actions:

- Develop continuous training and updating programs on drug abuse and other addictions for professionals of the Addiction Treatment Network, prevention technicians, healthcare and social professionals and other relevant groups involved in the prevention, treatment or social integration. These programs will be implemented through the Galician School of Public Health.
- Continue with the interventions carried out in events of high attendance of young people (festivals, parties or open-air gathering binge drinking places) regarding drug information and prevention.
- Continue with the periodic grant calls for drug addiction prevention projects in municipalities and private non-profit entities.

Harm Reduction Actions:

- Prevent sharing of injection materials by distributing hygienic injection kits with sterile material for injecting drugs. The distribution of this material is done through:
 - Free syringe exchange programme: through drug addiction treatment units, some pharmacies, social services of some municipalities and private non-profit entities that run specific prevention programmes.
 - Subsidized sale program of hygienic injection kits in pharmacies by the Directorate-General for Public Health.
- Facilitate cessation through opioid substitution therapy.

STRATEGIC LINE 2.3. Promoting Safe Sex

Actions aimed at preventing sexual transmission of hepatitis C are the same as those aimed at preventing other sexually transmitted infections. They are intended to raise awareness among the general population about safe sex, using condoms and other preventive measures, and avoiding the highest-risk practices involving blood contact without proper precautions.

Strategic objective:

- Reduce hepatitis C transmission in the group of individuals engaging in risky sexual practices by promoting safe sex.

Actions:

- Disseminate specific messages through the Department for Health website and the social networks of the Galician Plan against HIV/AIDS and other sexually transmitted infections, such as Sex Invaders on Facebook, Instagram, Blog and YouTube.
- Incorporate information on the prevention of hepatitis C on the websites and apps used in Galicia to facilitate connections among men who have sex with men (Grindr, Wapo, etc.), as well as in other communication forums used by them.
- Distribute condoms and prevention materials to groups or collectives engaging in high-risk practices through collaborating entities (Quérote+ Centers, social services, women's and youth attention services in municipalities, drug addiction treatment units, penitentiary institutions, midwives offices and various non-profit private entities implementing preventive projects for people with risk practices for the transmission of sexually transmitted infections).
- Periodic grant calls for projects in HIV/AIDS and other sexually transmitted infections carried out in Galicia by private non-profit entities.

STRATEGIC LINE 2.4. Prevention in Tattooing, Micropigmentation, Piercing and other Procedures Performed with Sharp Material

The performance of tattoos, micropigmentation, piercings and other procedures involving the use of sharp instruments (manicure, pedicure, acupuncture, etc.) is associated with the transmission of the hepatitis C virus, mainly when performed without the necessary safety conditions, such as sharing equipment without proper disinfection. In our community, the regulation of these activities is included in Decree 13/2004, dated January 15th (14).

Strategic objective:

- Reduce the transmission of hepatitis C in this group and the user population.

Actions:

- Verify the training provided to practitioners of these techniques, with special emphasis on asepsis, disinfection and sterilization methods. The minimum training requirements are established in Decree 51/2018, dated March 22nd.
- Inspect the facilities where these practices are carried out, by the Department for Health, through the Health Monitoring Program for tattoo, micropigmentation and piercing establishments (TMP).
- Publish a census of establishments of the Autonomous Community.
- Publish informative material on best practices.

STRATEGIC LINE 2.5. Prevention Training for Healthcare and Non-Healthcare Professionals

Contribute to the continuous education and training of professionals in primary healthcare centres and hospitals, drug addiction treatment units, non-governmental organizations, associations and support groups, etc.

Strategic objective:

- Update the knowledge on hepatitis C among professionals in healthcare centres and non-healthcare institutions.
- Prevent the transmission of hepatitis C in a healthcare environment.

Actions:

- Provide training and raise awareness among healthcare and non-healthcare professionals involved through the Galician School of Public Health (self-training

courses) and the management departments of the healthcare areas (training workshops, clinical sessions, etc.). Specific emphasis will be placed on activities to prevent hepatitis C virus infection and on the proactive identification of individuals at high risk of transmission.

- Maintain information and training of healthcare personnel on the prevention of biological accidents, safety devices and individual and collective protective equipment that reduce the risk of such accidents.
- Provide training for professionals in non-governmental organizations to disseminate preventive and healthcare promotion messages and facilitate access to the health system for people with risk exposures or suspected hepatitis C virus infection who are in socially marginalized or irregular situations. In addition, the necessary training for conducting rapid detection tests for this virus will be offered through the Galician School of Public Health (course directed: "Rapid tests for the detection of HIV and hepatitis C virus").

AXIS 3. Secondary Prevention: Detection of Infection

Identifying, treating and curing as many patients as possible with an active infection in Galicia is the strategy with the greatest impact on reducing the virus reservoir and, therefore, on reducing its transmission. This, in turn, will contribute reducing new infection cases.

Consequently, it is essential to diagnose as many infected individuals as possible, to facilitate their access to antiviral treatment and to monitor the achievement of sustained viral response.

STRATEGIC LINE 3.1. Active Search for Patients who Previously Had a Positive Test, but No Diagnostic Confirmation/Cure

In the studies carried out in Spain (15-17), patients with a positive anti-HCV result without subsequent confirmation or with confirmation but who did not undergo treatment or were not effectively treated have a significant common element: approximately 25% already have hepatic cirrhosis at the time of recapture, so they constitute a priority group to be addressed.

Strategic objectives:

- Recapture and evaluate previously detected hepatitis C virus infections as early as possible.
- Diagnostic evaluation of at least 50% of these cases, including viral load determination, and their inclusion in a treatment program.

Actions:

The Directorate-General for Public Health will carry out the following actions:

- In the first phase: active search, through the Platform for Information Exploitation and Management of Clinical and Epidemiological Data (HEXIN), for individuals with confirmed active infection but untreated (those with positive hepatitis C virus RNA).
- In the second phase: active search, through the Platform for Information Exploitation and Management of Clinical and Epidemiological Data (HEXIN), for individuals with a positive anti-HCV test who have not undergone determination of HCV-RNA to confirm or rule out active infection. 70-90% of these patients will have chronic hepatitis C.
- Finally, an active search will be conducted for people treated with interferon-based treatment regimens but do not have documented sustained viral response.

Once the data has been obtained and refined, each healthcare area will receive a list of candidates to be contacted to study their clinical situation and proposed treatment if appropriate.

STRATEGIC LINE 3.2. Infected Patients Who are Unaware of Their Situation

It is estimated that there are 4,532 people in Galicia between the ages of 20 and 80 with hepatitis C. 85% of them are concentrated in the age cohorts of 40 to 69 years. The cohort of individuals aged 50 to 59 has the largest number of cases (2,043).

Most of these individuals can be identified through the healthcare system. However, there is a percentage with social vulnerability-associated risk factors in which the prevalence of infection can be very high and require specific recruitment, diagnosis and treatment strategies.

Strategic objectives:

- Detect hepatitis C virus infections as early as possible in the 40 to 69-year-old age group.
- Perform hepatitis C virus antibody testing in at least 45% of individuals in the 40-69 age group.
- Detect hepatitis C virus infections in people at special risk as early as possible.
- Detect hepatitis C virus infections as early as possible in pregnant women.
- Detect hepatitis C virus infections as early as possible in hard-to-reach individuals through collaboration with non-governmental organizations, drug addiction treatment units, mental health units, prisons and social reintegration centres.

- Carry out hepatitis C virus antibody testing in at least 90% of new admissions to drug addiction treatment units each year.
- Carry out hepatitis C virus antibody testing in at least 80% of individuals imprisoned or in social reintegration centres and in at least 90% of new admissions.
- Implement rapid diagnostic tests (using a sample of oral fluid or capillary blood on dried blood spot cards) as an alternative for specific situations.

3.2.1. Active recruitment of people aged 40 to 69 and those of any age who belong to a risk group and who visit any healthcare centre of the Galician healthcare network

The objective is to perform opportunistic screening on those individuals who seek healthcare for any reason and are within the age group of 40 to 69 years and on individuals of any age with one or more risk factors for hepatitis C virus infection.

a) Primary Care Strategy

- **General population aged 40 to 69 years**

As a general recommendation, opportunistic screening will be conducted in Primary Care for all individuals seeking healthcare for any reason and who are between 40 and 69 years of age.

However, to ensure and facilitate this screening, the serological profile of hepatitis C will be included by default and in an automated way for those individuals in this age group who are requested any blood test for any reason².

This automatic request may be cancelled by the healthcare professional if, after providing appropriate information about the disease and the possibility of effective treatment, the required verbal consent is not obtained.

The implementation of this opportunistic population screening will be carried out sequentially with the following time scheme:

² **UPDATE 2023.** This strategic line was piloted in January 2023 in the Healthcare Area of Santiago de Compostela and Barbanza. Instead of the determination of hepatitis C virus antibodies, the determination of HCV-RNA was carried out using the sample pooling strategy for a size of 100 samples (Aguilera A, Fuentes A, Cena M, Carracedo R, Viñuela L, Ordóñez P, López-Fabal F, Sáez E, Cebrián R, Pérez-Revilla A, Pereira S, De Salazar A, García F. Real- life validation of a sample pooling strategy for screening of hepatitis C. Clin Microbiol Infect. 2023 Jan; 29(1):112.e1-112.e4. DOI: 10.1016/j.cmi.2022.09.006. Epub 2022 Sep 20. PMID: 36210627). Due to its efficiency, this procedure is being implemented in the rest of the healthcare areas of Galicia.

Year 2023:	Recruitment of the cohort group born between 1964-1973. This population is 408,541, and the prevalence of active infection is expected to be 0.50%.
Year 2024:	Recruitment of the cohort group born between 1954-1963. This population is 353,142, and the prevalence of active infection is expected to be 0.34%.
Year 2025:	Recruitment of the cohort group born between 1974-1983. This population is 443,148, and the prevalence of active infection is expected to be 0.14%.

- **Special risk population of any age**

At present, within this latter group of individuals, it is considered a priority to rule out hepatitis C virus infection in the following (not mutually exclusive) groups:

- People with elevated AST or ALT levels or acute or chronic liver disease in whom active hepatitis C virus infection had not been ruled out.
- People at high risk of hepatitis C virus infection through parenteral and/or percutaneous exposures:
 - Individuals with a history of tattoos, micropigmentation, piercings or procedures involving sharp instruments, performed without proper safety precautions.
 - People who inject or injected drugs in the past.
- People at high risk of sexual transmission:
 - Individuals who have or have had unprotected risky sex in the past, especially men who have sex with men.
 - Current or former sex workers.
 - Victims of sexual assault.
 - Individuals seeking or receiving pre-exposure prophylaxis.
 - Sexual partners of people with active hepatitis C virus infection.
- Children born to mothers infected with the hepatitis C virus, starting from 18 months of age, provided that they are not under follow-up for this reason in a specialized unit.
- Other groups for whom hepatitis C virus infection should be systematically ruled out:
 - Individuals who have been interned in penitentiary centres.
 - Individuals sentenced to non-custodial sentences.
 - People living with HIV and/or hepatitis B virus (HBV) infection.
 - People who have or have had sexually transmitted infections, particularly

syphilis, gonorrhoea, chlamydia, and *Mycoplasma genitalium* infections, especially in the anal area.

- People with severe mental disorders receiving care in mental health units.
- Immigrants from countries with high prevalence (in Spain, people from Romania, Ukraine, Russia, Pakistan, Nigeria, and Senegal).
- People who use inhalable drugs and share equipment.
- Homeless people currently or in the past.

All individuals identified with one or more of these high-risk factors or behaviours for infection will be requested to undergo a serology test for hepatitis C after their informed consent. It is important to note that an active search has to be carried out both for individuals currently at higher risk for the hepatitis C virus infection and also for those who were at high risk in the past.

In addition, sexually active individuals aged 20 to 59 years who seek healthcare for another reason and require a blood test should be offered an HIV test (18) after verbal consent.

- [Mental Health Units](#)

To strengthen the detection of people infected with the hepatitis C virus, an action protocol will be agreed upon in these units, establishing the frequency of tests and the conditions for their realization.

If the person belongs to the screening age group and is requested to undergo blood testing for any other reason, the hepatitis C serological profile will be included by default. Otherwise, this test should be requested proactively.

Those people who have difficulty and/or refuse venepuncture may be tested by using capillary blood samples on dried blood spot cards or saliva.

- [People requesting a test for hepatitis C virus infection](#)

Regardless of the person's age or belonging to a risk group, anyone requesting a test for hepatitis C antibodies will be provided with one since, in many cases, people may not want to disclose certain situations or risk practices that they perceive as stigmatizing.

- [Pregnant women](#)

A serology test for hepatitis C should be requested as part of the prenatal care program, and the woman should be referred to a specialized consultation if assessment and treatment are needed.

In the case of a mother being infected, the recommended action for the child is to carry out a test for antibodies against the hepatitis C virus after reaching 18 months of age.

Actions in hepatitis C screening:

- Disseminate a protocol for recruitment and follow-up in Primary Care that allows the identification of candidates (based on age groups or infection risk).
- Digitize the process through the integration into worklists in the electronic medical record to facilitate the recruitment of patients, as well as consider implementing an alert system in the medical history for specific risk situations with a CIAP code.
- Integrate the serological profile of hepatitis C by default in blood test requests for any other reason in the 40-69 age group. This profile can be unchecked if necessary.
- Establish a general control system of requests for hepatitis C serology to avoid redundant and unnecessary testing.
- Integrate the serological profile of hepatitis C by default in routine pregnancy care and, in case of active infection in women, generate an alert for clinical services to ensure proper monitoring and follow-up of both mother and child.
- Follow the strategy's processes (diagnosis in a single step, referral to the designated clinical service for people with active infection results, etc.) until the final outcome of the action is verified (treatment, obtaining the sustained viral response).

b) Hospital Care Strategy

It is also necessary to address in this setting the active recruitment of people who may be infected by the hepatitis C virus, as it is common for individuals belonging to high-prevalence groups to seek hospital care. In this regard, a decalogue for the elimination of the hepatitis C virus in hospitals was recently published and agreed upon by Spanish scientific societies (19).

Opportunistic screening, both based on age groups and risk factors, will be carried out, following the same protocol established for Primary Care within the hospital setting (including outpatient clinics, emergency units or hospitalized patients).

Concerning hospitalized patients, the request for a hepatitis C serology will be protocolized in the blood test carried out upon admission.

In addition, a specific protocol will be established for carrying out hepatitis C serology in those public or private hospitalization units that provide care to patients with severe mental disorders.

In the case of pregnant women who have not been previously screened for hepatitis C, the test must be requested upon admission for childbirth.

3.2.2. Active search for hard-to-reach individuals

- **Non-governmental organizations and other collaborating entities**

Some high-risk groups are characterized by their limited or no contact with healthcare services, making it difficult to access conventional screening and treatment measures.

Close collaboration with non-governmental organizations will be encouraged through the resources of the Galician Department for Social Policy and other collaborating entities at the municipal and supramunicipal levels that provide basic social and healthcare assistance.

As important factors that condition/hinder the achievement of the screening, diagnosis and treatment objective, we can highlight the following:

- The difficulty of recruitment.
- The need for decentralized treatment from the hospital setting.

Actions:

- Identify key entities in Galicia to offer them the necessary collaboration and the means for the recruitment and implementation of rapid tests to detect anti-HCV antibodies in oral fluid.
- Establish a healthcare referral centre for hepatitis C screening candidates.
- Protocolize rapid and alternative tests for HCV infection detection.
- Protocolize, together with the clinical services specialized in hepatitis C, the rapid clinical assessment and the implementation of treatment outside the hospital setting.

- **Drug addiction treatment units**

People with a history of past or current injecting drug use represent a group with a high prevalence and incidence of hepatitis C. A large part of these people are attended to and subsequently followed up by the units for drug addiction treatment.

Actions:

- Review and agree upon protocols for hepatitis C detection, establishing the periodicity of the tests and the conditions for their performance (verbal consent), etc. Include an annual serology follow-up for individuals with a negative serology

and an annual PCR for those with a history of cured hepatitis C but who continue to have risky practices or situations.

- Consider the integration of the serological profile of hepatitis C by default in the laboratory requests for any other reason within the age group of 40 to 69 years from these units.
 - Make alternative diagnostic tests available to these facilities, such as the collection of a capillary blood sample in dried blood spot cards or oral fluid for people who have difficulty with and/or refuse venepuncture.
 - Develop protocols, in collaboration with specialized clinical services for hepatitis C, for rapid clinical assessment and initiation of treatment outside the hospital setting.
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- [Penitentiary and social integration centres](#)

The actions proposed to achieve the elimination of hepatitis C in this group should include both individuals sentenced to imprisonment and those subject to non-custodial sentences serving centralized sentences in social reintegration centres.

[Prisons](#)

The actions of screening, diagnosis, indication of treatment and monitoring of hepatitis C virus infection will be carried out through the corresponding hospital services. Penitentiary institutions shall be responsible for dispensing the medicines used for treatment.

[Objectives:](#)

- Conduct a serological test on inmates in prisons and new admissions.
- Repeat the serological test at the time of the inmate's release to reduce the risk of transmission within the community.
- Establish treatment with direct-acting antivirals for all inmates with active infection and a stay longer than 30 days.
- Monitor antiviral treatment, as well as establish communication and coordination channels with other healthcare entities for people who leave the centre before completing treatment.

[Actions:](#)

- Adapt and coordinate the action lines outlined in this Strategy to the specific circumstances of inmates in prisons to ensure correct diagnosis and treatment.
- Perform the diagnostic test by means of a capillary blood sample on dried blood spot cards or oral fluid in specific situations.

- Designate a reference person in health districts and prisons to coordinate the necessary activities.
- Establish a system for inmates leaving the penitentiary centre to continue their treatment.
- Agree with penitentiary centre authorities on training and information activities aimed at inmates, informing them about the program, the disease and its consequences, the possibility of cure through pharmacological treatment, and the voluntary collaboration requested.
- Evaluate the achievement of objectives specifically in this population by analysing of the hepatitis C records.

Social reintegration centres

This population group is considered highly vulnerable and with limited access to the healthcare system, which poses additional challenges both in the diagnosis of hepatitis C and in the treatment, follow-up and adherence of identified cases.

Actions:

- Offer the diagnosis of hepatitis C virus infection through a dried blood spot test that, a priori, could improve acceptance and adherence to it.
- Implement the "diagnose and treat" strategy with direct-acting antivirals against the hepatitis C virus.
- Explore the possibility of implementing a telemedicine program through TELEA, a home care platform integrated with corporate information systems, that enables the patient's remote access to various healthcare services and allows the patients' healthcare control at home and asynchronous communication.
- Designate a Case Coordinator/Manager for the Hepatitis C Elimination Strategy in the corresponding healthcare districts, whose role will be to facilitate contact between patients diagnosed at the social reintegration centres and the relevant hospital services.
- Establish an action protocol that allows joint solutions to the problems detected in the process of diagnosis, treatment, monitoring and adherence.
- Agree with authorities at the social reintegration centres upon the training and informative activities for the people attended.

AXIS 4. Diagnosis and Treatment

This axis consists of two lines, which are described below.

STRATEGIC LINE 4.1. Facilitating Diagnosis

Strategic objectives:

- Optimise the diagnosis of all active infections.
- 100% of cases with positive anti-HCV serology will undergo a one-step diagnosis with a determination of the viral load indicative of active infection from the same sample.

Actions:

In order to speed up and facilitate the diagnosis avoiding the loss of patients during the process, the following actions will be developed:

- Establish the one-step diagnosis systematically, which consists of the investigation of viremia in the same sample for all patients newly diagnosed serologically.
- Include the investigation of sexual partners of newly diagnosed patients in clinical protocols, taking into account the increased risk of sexual transmission if the index case is coinfecting with HIV (20).
- Establish strategies for diagnosis in certain groups of patients characterised by limited or no contact with healthcare services.
- Design and implement communication channels that guarantee the daily notification of positive results to the hepatitis C referral service, as well as to the doctor requesting the analysis.

STRATEGIC LINE 4.2. Treatment Optimisation

In 2017, pan-genotypic direct-acting antivirals capable of eliminating all genotypes of the hepatitis C virus were approved. These new therapies are effective within 8 to 12 weeks and have the advantages of simplifying treatment, reducing patients' follow-up needs, increasing cure rates to over 95%, and delaying, if applicable, the onset of late and severe complications of the disease (21).

Strategic objectives:

- Treat and verify the effectiveness of treatment in cases of active hepatitis C infection.

- At least 95% of cases diagnosed with active hepatitis C virus infection will initiate treatment with direct-acting antivirals.
- The time between the diagnosis of active hepatitis C virus infection and the initiation of treatment will be less than 21 days in at least 95% of cases.
- Correct adherence to treatment will be found in at least 95% of cases with active hepatitis C virus infection who start treatment with direct-acting antivirals.
- Provide appropriate follow-up to patients treated for hepatitis C.
- Confirm the sustained viral response in at least 95% of cases that start treatment with direct-acting antivirals by means of a blood test 12 weeks after the end of the treatment.
- Perform annual serological retesting or determination of active infection, as appropriate, in individuals who persist with risky practices or exposure in the context of drug addiction care units, prisons, and social reintegration centres.

Actions:

- Improve information about the disease and its treatment: contents emphasising the importance of adherence will be published on the website of the Galician Department for Health, as well as information related to hepatitis C and its treatment (videos, infographics, leaflets, links to other websites and apps of interest). These contents will also be incorporated into the E-saúde app.
- Protocolise communication/coordination channels with social services, non-governmental organisations, drug addiction treatment units, etc., for dispensing treatment to patients with a special vulnerability.
- Collaborate with the Galician Subdirectorate-General of Pharmacy to study specific strategies for individual cases, such as providing personalised dosing systems (SPDs) or delivering medication to the patient's home.
- Monitor pharmacological treatment indicators through corporate information systems.
- Implement pharmaceutical care programs that facilitate adherence to antiviral treatment, detection of adverse reactions, medication reconciliation and review, etc.
- Develop programs that help assess the need for directly observed treatments and the verification of sustained viral response.

AXIS 5. Training and Research

Continuous training is an active and ongoing teaching-learning process aimed at updating and improving the knowledge, skills and attitudes of healthcare professionals and the population in response to scientific and technological evolution and the social demands and needs of the healthcare system itself.

STRATEGIC LINE 5.1. Training

There will be an internal and an external training program aimed at the general public.

Strategic objective:

- Achieve professional development.

Actions:

- Internal training: Training activities (two editions per year) available during the first two years of the Strategy through the Galician School of Public Health.
- External training: Design different contents depending on the age group to which the training is directed, as well as a hepatitis C expert patient program.

STRATEGIC LINE 5.2. Research

Research in the healthcare field is of utmost importance to improve population health, as it allows solving scientifically-based questions that help improve people's quality of life and provide comprehensive quality medical care, as well as the development of prevention programs.

Strategic objective:

- Promote research in the field of viral hepatitis.

Actions:

- Establish the Galician Hepatitis Research Network (ReGalHep), composed of researchers from the 14 healthcare districts, as well as from the Directorate-General of Public Health.
- Regulate the establishment and development of the ReGalHep through the corresponding regulatory framework.

7. EVALUATION

An annual and final evaluation of the results of the interventions proposed in this Strategy will be carried out to monitor progress in achieving its objectives and redesign any necessary actions. The first evaluation will occur in the first quarter of 2024 on the activities carried out in 2023.

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