# Process Paper

Swiss Hepatitis Strategy 2014 – 2030



Process Paper
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## 1 Executive Summary

The 5th Swiss Hepatitis Strategy updates us on where we stand with elimination efforts in Switzerland today. The burden of disease caused by viral hepatitis is still relevant. While incidences of newly acquired infections are decreasing, newly diagnosed chronic infections have been on the rise since the end of the SARS-CoV-2 pandemic, both for hepatitis B and for hepatitis C. At the same time, sales of DAAs for the treatment of chronic hepatitis C are stagnating and not reflecting the pace of the newly diagnosed chronic cases. New publications show that Switzerland has made some progress throughout the last few years. However, essential gaps in the cascade of care for hepatitis B and C still exist.

After intensive discussions, we have decided to keep the elimination targets 2030 from the 4<sup>th</sup> version of the Swiss Hepatitis Strategy. Furthermore, we have slightly updated the vision and aims. However, we have introduced strategic approaches based on the new Global Strategy by the World Health Organisation. These are the following: Continuum of Care, Strengthen Partnerships, Surveillance Response, Community Involvement and New technology. Despite essential gaps in the cascades of care, we are convinced that eliminating viral hepatitis by 2030 is realistic.

Our flagship projects are rooted in the network: Network members develop an idea for a new project. They are then conceptualised and implemented by Swiss Hepatitis. Their purpose is to fill the existing gaps on the way to elimination. For this reason, they are essential in the whole strategic process. Our flagship projects are growing despite setbacks during the years of the coronavirus pandemic. Four projects are running, one is completed, and two are in development.

The steering groups of the Swiss Hepatitis Strategy developed the core chapters of this process paper. The board of Swiss Hepatitis approved this version at its meeting on 4 September 2023. It was approved by the network members at the 2<sup>nd</sup> meeting in 2023, on 27 November 2023.

## 2 Introduction

This document is the 5<sup>th</sup> update of the Swiss Hepatitis Strategy. The first one appeared as early as 2014, the last in 2019. Many things on the policy level happened since the previous update. The Federal Commission for Issues relating to Sexually Transmitted Infections (FCSTI/EKSI) published a Roadmap to eliminate HIV and hepatitis in Switzerland. The Swiss Hepatitis Strategy informed this roadmap. Several initiatives in the Swiss parliament revealed how underfunded the fight against viral hepatitis in Switzerland is. (1) A motion was passed in parliament in 2020, which demanded the inclusion of elimination goals for viral hepatitis into the next national HIV programme. (2) This was due for 2022. However, the Federal Office for Public Health (FOPH) postponed the programme to 2024 because of the SARS-CoV-2 pandemic.

Last but not least, the World Health Organisation (WHO) published a new and joint strategy to end the epidemics of HIV and viral hepatitis in 2022, setting the ground for a combined national programme in Switzerland (see also the timeline in chapter 14).

The coronavirus pandemic was a setback to the elimination strategy. Many of our network members were at the forefront of tackling the pandemic. Resources for hepatitis were scarce. Our projects came to a standstill or were delayed. With the end of the pandemic and due to the favourable conditions on the political level, we are looking optimistically into the future. Suppose Switzerland manages to draft a coherent and well-funded elimination plan for viral hepatitis, HIV and other sexually transmittable infections. In that case, the chances are that we will achieve the ambitious elimination goals.

This updated Strategy has slightly revised goals. Furthermore, it strengthens measures for the elimination of hepatitis B. Also, it takes into account hepatitis D as another chronic form of viral hepatitis, which only appears as a co-infection with hepatitis B. As in the previous strategies, the focal point is on the chronic forms of viral hepatitis, which include hepatitis B, C and D. Nevertheless, it is also essential to monitor the situation regarding hepatitis A and E, which are also notifiable infections and to include wherever possible vaccination campaigns for hepatitis A together with hepatitis B.

While joint strategies of HIV and viral hepatitis are something we have promoted for many years and will be put into reality hopefully by the Swiss Government in 2024, we still felt that we wanted to publish another update of our "single disease" strategy. We want to take into account the changes in the political environment. Our Strategy is an important document that guides our work and makes it effective. The Strategy remains a "process paper", meaning we implement it while we draft it. There is no final version, as a process paper is updated on a regular basis.

## 3 Background

3.1 Viral hepatitis: Burden of Disease

#### 3.1.1 The world

Worldwide, viral hepatitis is taking a high toll on morbidity and mortality. The World Health Organisation WHO estimates that globally, 296 million people live with hepatitis B and 58 million with hepatitis C. 1.5 million new infections occur both with hepatitis B and C each year. Approximately 820'000 died from hepatitis B and 290'000 from hepatitis C in 2019, mostly from chronic liver disease or cancer caused by the infection. (3)(4) This is similar to deaths caused by HIV, TB or malaria annually. (5)(6)(7) Early treatment and prevention would avoid many deaths and would reduce the high burden of disease: A safe vaccine is available to protect from hepatitis B infection. Hepatitis C can be cured in over 96% of the cases with antiviral treatment.

According to WHO, improvements have been made since the release of the first Strategy to eliminate viral hepatitis in 2016. (8) However, as the figures above show, significant gaps remain.

#### 3.1.2 Switzerland

The burden of disease caused by viral hepatitis is significant in Switzerland. Currently, approximately 62'000 people live with chronic hepatitis B and 30'000 with chronic hepatitis C. About 58% of hepatitis B and 40% of hepatitis C infected persons are not diagnosed. (9) A recent publication estimates the HCV prevalence data to be much lower and that elimination goals are reached. (10) However, most experts consider that the authors fail to provide enough evidence to draw such conclusions. (11)(12) We need more data and a better-functioning surveillance response to revise prevalence estimates. (13) A study which analysed routinely collected data from patients in a university hospital in Switzerland shows that hepatitis C infection is associated with elevated morbidity and mortality. (14) In 2022, 1107 cases of hepatitis B and 1043 of hepatitis C were newly notified to the FOPH. The vast majority of these cases are chronic infections. (15)

#### 3.2 Surveillance and Cascade of Care

#### 3.2.1 Hepatitis B and Hepatitis D

For hepatitis B, the number of people is estimated at 62'000 in Switzerland in the year 2020. (16) 58% are diagnosed, and 8'600 of the diagnosed would be eligible for treatment. Of these, 3'050 are under treatment (see Figure 1).

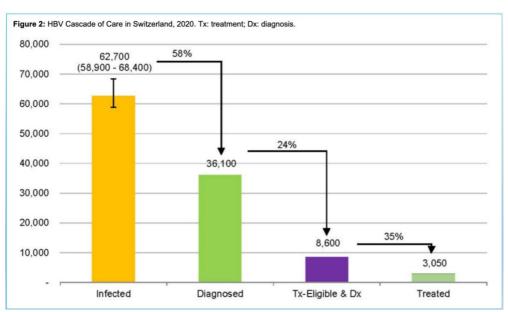


Figure 1: Cascade of Care for chronic hepatitis B in Switzerland in 2020 (16)

The incidence of acute hepatitis B cases has been decreasing for many years. (17) However, since 2022, an increasing number of newly diagnosed cases have been reported to the FOPH/BAG. (18) New infections, as well as diagnosed chronic infections, affect mainly individuals who were born abroad in high-endemic countries. The majority of transmissions were reported as sexually acquired. (17) However, no data is available for most of the notified cases. Vaccine coverage is 74% among adolescents aged 16 (19) and lower among adults. (20) For vulnerable populations such as sex workers and MSM, the vaccination rate is low. (20)(21)

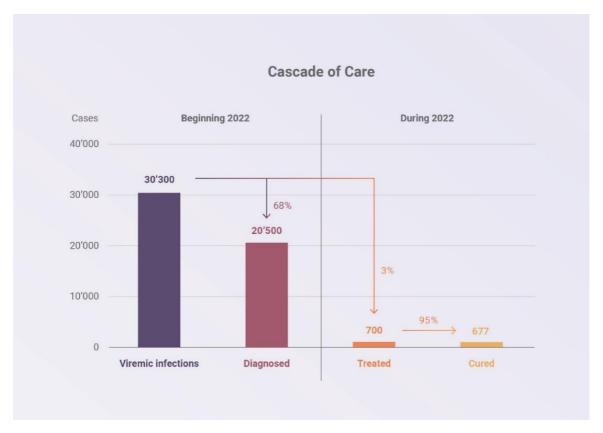
The US Center for Disease Control (CDC) has released new recommendations for testing, screening, and vaccination against hepatitis B. The CDC is now recommending that every adult 18+ of age, regardless of risk factors, is tested once in a lifetime for hepatitis B. (22) The CDC justifies this with the cost efficiency of universal screening. (23) Furthermore, universal vaccination against hepatitis B is also recommended to improve vaccination coverage. (24) In Switzerland, risk-based testing is recommended. Vaccination has been included in the vaccination schedule and reimbursed for all infants since 2019. Before, recommendations were in place for adolescents older than 11 years. For adults, recommendations restrict hepatitis B vaccination to risk groups. (25)

The hepatitis D virus only occurs together with hepatitis B and increases the risk of morbidity and mortality. The prevalence of hepatitis D among people with chronic hepatitis B in Switzerland has been assessed at 5.9% in a study from 2011. This is a relatively low number compared to other countries in Europe. However, underreporting is estimated to be substantial. (26) Today, hepatitis D infection is not a notifiable disease in Switzerland.

#### 3.2.2 Hepatitis C

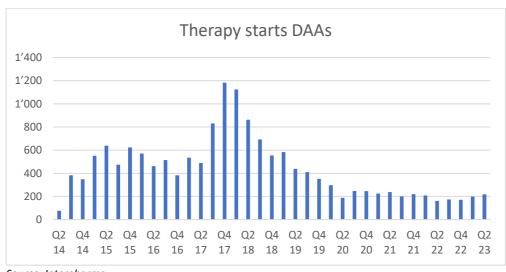
Similarly to hepatitis B, the incidence of newly acquired hepatitis C cases is decreasing. However, the last two years have seen an increase in reported chronic cases. There is uncertainty about the absolute number of chronic cases, as the notification system also contains cases reported only on the base of confirmed antibody positivity (without an RNA or Antigen test). (27) Therefore, it is very likely that the number of viremic cases is lower than reported since cases with a positive antibody test could also include cured individuals.

Figure 2. Cascade of Care for Hepatitis C (9)(24)



While we still have over 1000 newly detected cases of chronic hepatitis each year, sales of direct-acting antiviral agents are decreasing. The number of newly diagnosed yearly is about the same as the number of treatment starts (1066 cases and 714 treatment starts, respectively. (15)(28)

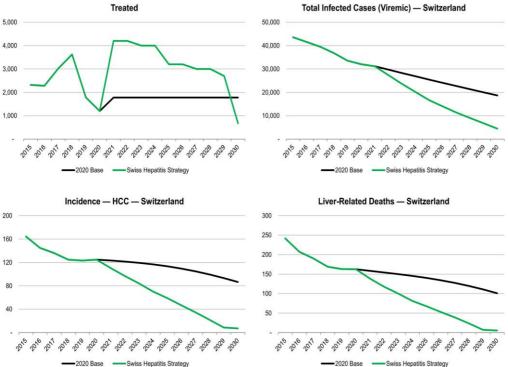
Figure 3. Sales of DAAs between 2014-mid-2023



Source: Interpharma

A modelling study showed that increased efforts in diagnosing and treating HCV are necessary to reach the elimination goals of the Swiss Hepatitis Strategy. The fact that increasing the number of patients treated is cost-effective supports the elimination strategy. (29)





From 2007 to 2017, the number of conducted HCV-antibody-tests tripled, while the number of positive HCV-antibody-test results showed a 75% increase over the same time. The person-level HCV AB tested positive rate decreased from 2.2% to 1.7% from 2012 to 2017. (30)

Figure 5. Total numbers of positive HCV antibody tests and all HCV antibody tests 2007-2017 from 13 laboratories in Switzerland (26)

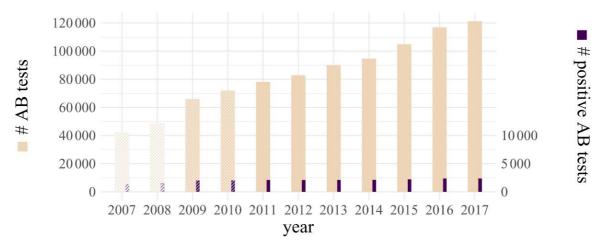
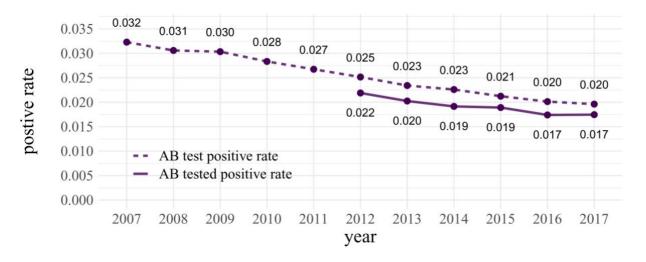


Figure 6. HCV antibody test positive rate and tested positive rate (corrected for multiple testing) (26)



## 4 Recommendations and Policies

The Federal Office for Public Health (FOPH), together with Infodrog, published new recommendations regarding hepatitis C care for people who use drugs (PWUD). (31) Treatment is recommended for all PWUD with chronic hepatitis C. PWUD with continuing injecting drug use should be tested annually for hepatitis C. These recommendations apply to different settings. A concept for implementation is currently underway.

Furthermore, the vision of the next HIV programme will fully include viral hepatitis. The programme will be implemented at the beginning of 2024.

## 5 Key populations

Persons most at risk for viral hepatitis are very similar to those populations that are at risk for HIV and other STIs. This is mainly because of similar transmission routes: HIV infection and hepatitis B/D and C are both blood-borne diseases and diseases that are sexually transmittable (this is less the case for hepatitis C, for which sexual transmission is observed to a critical extent only for the group of HIV positive MSM).

Persons at risk for viral hepatitis infection in the following named "key populations" are:

- Men having sex with men MSM (including PrEP users),
- Migrant populations from high-endemic countries,
- People who use drugs (by injection or nasal, sniffing),
- Sex workers,
- Prison inmates (current or former),
- People with piercings, tattoos or manicures and pedicures that were applied under non-hygienic conditions,
- People who have received blood before the year 1992 in Switzerland or any time in countries without RNA-testing of blood products
- People with a history of surgical or dental interventions in countries with low hygienic standards.

There are overlaps between these population groups.

Testing strategies should – apart from these "key populations" – always include pregnant women to avoid mother-to-child transmission.

## 6 Vision, Mission, Aims

#### 6.1 Vision

The vision of the Swiss Hepatitis Strategy is the elimination of viral hepatitis in Switzerland by 2030

#### Mission

The mission of the Swiss Hepatitis Strategy is to establish and maintain a network in Switzerland with stakeholders from all areas involved with viral hepatitis. The network has a lean structure and uses existing channels, systems and institutions to eliminate viral hepatitis efficiently and cost-effectively. The Strategy is initiating and carrying out projects and studies to eliminate viral hepatitis.

#### 6.2 Aims

1. Reducing the socio-economic impact of viral hepatitis on the individual and the community

The high morbidity and mortality rates of viral hepatitis are accompanied by relevant public health, social and economic costs. Viral hepatitis is still associated with **stigma and discrimination**. Raising awareness, improving detection rates, increasing treatment uptake, and stepping up education in healthcare settings could help ease the burden. A well-functioning **surveillance-response system** is necessary to detect epidemiologic changes rapidly and respond promptly and targeted.

2. Reducing transmission of hepatitis B and hepatitis C

Still, many individuals infected with the virus have not been tested and are unaware of the disease. Undiagnosed individuals are at risk of developing potentially life-threatening sequelae. Furthermore, there is a potential to pass the virus on to others. Significantly improving detection and treatment rates, stepping up prevention in those population groups most affected by ongoing transmissions and finding and treating undetected infections in the general population must be a primary goal of the Strategy. In addition, HBV and HDV transmissions can be reduced by a maximum HBV vaccination coverage in the general population.

New and qualitatively good data are needed in order to assess the situation and document the progress of the activities of the Swiss Hepatitis Strategy.

3. Reducing the burden of disease caused by viral hepatitis

Among infected individuals, hepatitis-related morbidity and mortality are unacceptably high for a preventable and curable disease. Successful treatment can prevent disease progression, extrahepatic manifestations, and death. The systemic character of HCV infections, causing non-liver-related morbidity and mortality, should also be considered. With the availability of highly efficient and safe HCV medicines with high cure rates and HBV medicines that control a chronic infection, a feasible test-and-treat approach should be envisaged. All HBV patients should be screened for co-infection with hepatitis D and referred to treatment. Treatment access for everyone should be ensured. This involves reducing drug prices and/or the availability of generics. A broadly planned detection strategy accompanied by an awareness campaign for health professionals, key populations and the general public must be implemented.

## 7 Target Values

Target values vs. a baseline from 2016 are:

## 1. Impact targets

- New cases of HBV and HCV will be reduced by 60% in 2025 and 95% in 2030.
- HBV and HCV-related mortality will be reduced by 50% in 2025 and 95% in 2030.
- Viremic cases of HCV will be reduced by 60% in 2025 and 95% in 2030.
- Liver transplants due to viral hepatitis-induced end-stage liver disease will be reduced by 60% in 2025 and by 95% in 2030.
- Liver cancer due to viral hepatitis will be reduced by 60% in 2025 and 95% in 2030.

#### 2. Service coverage targets

- HBV vaccine coverage at the age of 16 will be increased to 85% in 2025 and 95% in 2030.
- HBV and HCV diagnoses: increased to 80% in 2025 and 90% in 2030.
- HCV treatment: 80% of those diagnosed are treated in 2030.

Figure 7. Swiss Hepatitis Targets 2030 for Incidence, Mortality, Viraemia, Liver transplants and cancer, as well as HBV vaccination coverage and diagnosed cases of HCV

Target Area	Baseline 2016	2025 Targets	2030 Targets	WHO TARGETS 2030**		
	Impact Targets					
Incidence (new cases of chronic Hepatitis B and C)	40-50 cases/year	60%	95%	90% Reduction		
Mortality	200/year	50%	95%	65% Reduction		
Viremic cases Hep C	40'000 chronic infections	60%	95%	-		
Liver transplants	40-70 cases/year	60%	95%	-		
Liver cancer	600 cases/year	60%	95%			
	Service Coverage Targets					
HBV vaccination coverage	70%	85%	95%	90% (childhood vaccine coverage)		
HCV cases diagnosed	24'000	80%	90%	90% Reduction		

The WHO has also released targets for injection safety, blood safety, and transmission from mother to child. As Switzerland has for many years reached these targets, we will not set new targets here. However, it is of utmost importance that the level of injection safety and blood safety is secured in the future and that no transmission from mother to child occurs for viral hepatitis. Each of these transmissions is preventable.

The Swiss Hepatitis Strategy targets are based on the WHO targets. However, as a high-income country with one of the best health systems in the world, Switzerland should be able to surpass the WHO targets, especially regarding the target for HCV of 90% tested and 80% cured. For HIV, Switzerland has already, for many years, surpassed the 90/90/90 goals (90% diagnosed, 90% under treatment, 90% virally suppressed).

## 8 Strategic Approaches

For the strategic approaches, we orientate ourselves on the context of the new Strategy of WHO.(4)

These are the following 5:

- 1. Deliver high-quality, evidence-based, people-centred services (see chapter "continuum of care")
- 2. Optimise systems, sectors and partnerships (see chapter "Strengthen Partnerships")
- 3. Generate and use data to drive decisions for action (see chapter "Surveillance Response")
- 4. Engage empowered communities and civil society (see chapter "Community Involvement")
- 5. Foster innovations for impact (see chapter "New diagnostic technologies and testing approaches")

#### 8.1 Continuum of Care

The continuum of care for patients with viral hepatitis has to be ensured to make the elimination a success. The gaps in the Cascade of Care are still significant; too many patients get lost on the way to treatment. Furthermore, the settings where key populations for viral hepatitis are present are often challenging. E.g. the prison setting or asylum reception centres. In settings like this, the cascade of care is often disrupted. Physicians and health care workers don't start treatments of diagnosed individuals, as they fear that it cannot be continued in another setting. People at risk are not offered a test as treatment options are limited.

These challenges have to be addressed by providing people-centred services. Test and treatment services must be easily accessible, especially for key populations, and continuation of therapies, even when patients change the setting, is paramount. Rapid tests should be offered, and services that allow to start treatment in non-medical settings should be fostered.

## 8.2 Strengthen Partnerships

Partnerships and strong networks are crucial in ensuring good care for patients with viral hepatitis. On the one hand, a network of primary care providers and hepatitis specialists has to be well developed. Primary care includes the field of stationary psychiatric centres, prisons and centres for addiction medicine. Furthermore, services in the area of sexual

health, e.g. organisations that address Chemsex in the critical population of MSM, must be part of such a network. Also, pharmacies should be integrated into this system of partners, especially the ones caring for opioid-agonist treatment (OAT)-patients.

On the other hand, strengthening partnerships also means using existing services and integrating services that provide care for patients with chronic viral hepatitis. These can be services in the field of sexual health, in migrant-specific services, in the setting of harm reduction services or in prisons.

In the field of improving awareness and education and fighting stigma, a close collaboration between the hepatitis field and existing structures (e.g. the Swiss AIDS Federation, the Swiss Competence Centre for the Correctional System, or medical specialist societies) already reaching the key populations and their specific health system has to be achieved. In the sense of a patient-centred approach, the critical population should be accessed in an integrative way using a multi-disease method, covering whenever possible HIV, viral hepatitis and STIs.

## 8.3 Surveillance Response

The epidemiological data on viral hepatitis in Switzerland is relatively weak. Hepatitis B and hepatitis C are notifiable diseases. However, data on transmission and clinical outcomes are missing. A good database is a prerequisite to guide elimination efforts. Surveillance Response means that the progression should not only be monitored but changes should be detected rapidly, followed by timely specific measures, wherever and whenever necessary. A Surveillance Response concept allows one to act upon the available data and, if required, correct the direction of the course.

Hepatitis D, which appears only in patients with a chronic hepatitis B infection, should also be included in the notification system. This is in order to be able to monitor the epidemiology. Furthermore, Hepatitis D co-infected patients have a more severe disease progression and should receive treatment accordingly.

## 8.4 Community involvement

"Nothing about us without us" is an essential slogan in the HIV advocacy movement. It means that no decision should be made without involving representatives of groups that are affected most by the decision. This should guide us also in the course of our work. Patient organisations and organisations representing key populations of viral hepatitis should be involved in all steps of the elimination strategy. Patient groups and representatives of key groups have been part of the network Swiss Hepatitis Strategy from the start of the strategy process.

Furthermore, stigma and discrimination must be addressed to facilitate access to tests and treatment.

## 8.5 New Technology

A key measure to improve the cascade of care among the key population is "simplification": Developments and innovations in diagnostics and treatments allow more straightforward care provision and must be integrated into viral hepatitis care as soon as possible. The — sometimes complicated — drug and diagnostics approval process in Switzerland and the fact that our country is not a part of the European Union can be a barrier. Nevertheless, new technologies such as rapid tests, home testing, dried blood spot testing and others should be approved and implemented as soon as possible. New diagnostics and drugs help to lower the threshold to access testing services and treatment. Thus, they are essential tools to improve the continuum of care. With the smart inclusion of new technologies into services, fewer patients are lost on the way to treatment and cure.

## 9 Organisation

## 9.1 Network Swiss Hepatitis Strategy

The network Swiss Hepatitis Strategy, a civil society initiative, was founded in 2014. Eighty personalities from different fields, among other doctors, nurses, patient representatives, politicians, and representatives of key groups, agreed on elimination goals and drafted a first process paper regarding the elimination of viral hepatitis in 2014.

Network members meet twice a year to discuss gaps and progress of the Strategy. The members are organised into five steering groups: Prevention & Awareness, Testing & Surveillance Access to Treatment, High-risk Groups, and Financing. The network members contribute to 1,000 hours of voluntary work every year.

#### 9.2 Swiss Hepatitis

The non-profit association Swiss Hepatitis was founded in 2017 and is the successor organisation of the Swiss Experts in Viral Hepatitis SEVHep. Its primary mission is to coordinate the network Swiss Hepatitis Strategy and facilitate the implementation of the Strategy. Swiss Hepatitis is a non-profit organisation. Funds from national and cantonal health authorities, private companies and foundations finance the work of Swiss Hepatitis.

The goal is to keep lean structures and collaborate with other organisations in the field to reach the elimination goals for viral hepatitis by 2030.

## 10 Media and Awareness

Since 2015, the Swiss Hepatitis Strategy has been conducting an awareness campaign on viral hepatitis targeting the general population, key groups, as well as healthcare workers and decision-makers.

Relations with journalists are being cultivated. Primarily, World Hepatitis Day on 28 July is used as a platform to raise awareness. Regularly, articles in medical journals are being published.

## 11 Networking and politics

Relations with politicians who showed interest in the issue of viral hepatitis are cultivated. From the beginning, politicians were involved in the Strategy, both on the cantonal and national levels. Also, networking with organisations that have similar visions and goals is essential. The network also advocates for improving access to tests and treatment by removing all restrictions in prescribing direct-acting antiviral agents DAAs for treating HCV and for removing barriers in diagnostic (e.g. reflex-testing for HCV) and the introduction and reimbursement of rapid tests.

Networking with organisations in the fields of liver disease, HIV and sexual health, cancer, addiction medicine, prison health, migrants, as well as patient representative organisations, is essential.

## 12 Flagship projects

Flagship projects are closing the gaps on the way to elimination. At the network meetings, it is worked out where there is a need for a flagship project and the basis for a project start is defined.

In a next step, a steering group with network members and external experts is created. Swiss hepatitis is mandated to check the feasibility and to work out a first concept. After that, the financing will be secured. Swiss hepatitis will then be in charge of the project management and implementation.

The following projects are currently running:

- HepCare hepatitis C at the general practitioner (hepcare.ch)
- SHiPP Swiss Hepfree in Prisons programme (shipp.ch)
- Bel Paese awareness campaign directed at first-generation migrants from Italy over 60 years of age (bel-paese.ch)

• HCV Screening Strategies – feasibility and acceptance of different screening strategies for HCV by general practitioners

## In the making:

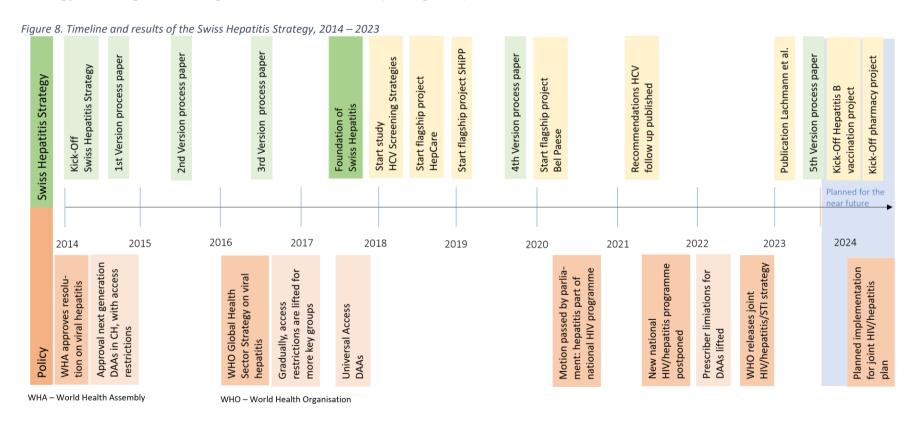
- Pharmacy Project: Testing and vaccination services for clients in an OAT programme
- Hepatitis B vaccination campaign among sex workers

## Past projects:

• HCV Follow-Up

## 13 Timeline & results

The initiative Swiss Hepatitis Strategy met for the first time in January 2014. Since then, the initiative has started many activities. The most important are: A Swiss Hepatitis Strategy with five updates (this one being the 5<sup>th</sup> version), 2017 the foundation of the association Swiss Hepatitis, the conception and implementation of four flagship projects, one of which is already completed, three are still running. Two more projects are in the making. There were also important developments on the policy level with the release of the WHO Global Health Sector Strategy and the gradual lifting of restrictions for DAAs (see Figure 8).



Additionally, every year, the following activities take place:

- ⇒ Two network meetings, where network members gather, discuss the progress of the Swiss Hepatitis Strategy and develop ideas for future activities and projects.
- ⇒ Furthermore, the yearly Swiss Hepatitis Symposium is today an important platform for knowledge transfer and exchange in the field of viral hepatitis with a focus on public health.

## 14 Outlook

Over the years, we can observe some progress concerning awareness and policies promoting the elimination of viral hepatitis. There seems to be a shift of attitude towards viral hepatitis and more awareness among decision-makers. (32) With the new joint HIV and hepatitis programme on the horizon, we see a good chance for the integration of elimination efforts into existing programmes and services in the field of HIV and STIs.

However, there are still many gaps in viral hepatitis care. Especially regarding the numbers of diagnosed and treated patients, but also regarding surveillance: Lack of data is a big problem as it makes it difficult to monitor progress in terms of elimination.

We have to speed up diagnosis, linkage to care and treatment of patients with hepatitis B and C if we want to reach the elimination goals by 2030. We are convinced that we have everything that is needed to achieve these goals. With joint efforts of all stakeholders, with close collaboration of actors in the field of viral hepatitis, HIV and STIs and with integration and coordination of the activities on a national and cantonal level, elimination is feasible.

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