PERSPECTIVE ARTICLE

Pakistan's national hepatitis strategic framework (2024-2030)

Hassan Mahmood[1], Ahmed Sabry Alaama[2], Muhammad Shahid Jamil[3], Shabana Saleem[4], Safdar Kamal Pasha[5], Atiya Aabroo[6], Saeed Akhter[7], Ammara Naveed[8], Saeed Hamid[9], Aamir Ghafoor Khan[10], Abid Ghori[11], Zulfiqar Dharejo[12], Tariq Hayat[13], Mehreen Awan[14], Shoaib Kurd[15], Muhammad Salman[16], Shah Zaman[17], Muhammad Farooq[18], Zaeem Zia[19], Muhammad Khawar Aslam[20], Ambreen Arif[21], Huma Qureshi[22]

Abstract

Objective: The framework sets ambitious targets to reduce new chronic hepatitis C virus infections, lower hepatitis B virus prevalence among children, and decrease hepatitis-related mortality.

Method: The framework outlines five strategic objectives:

1. Strengthening leadership and governance.
2. Improving prevention and access to care.
3. Building laboratory capacity.
4. Enhancing strategic information use.
5. Improving access to testing, care and treatment services.

Results: By implementing these strategic objectives, the framework aims at driving progress towards global health goals, and reduce the burden of hepatitis B and C.

Conclusion: The National Hepatitis Strategic Framework 2024-30 provides a comprehensive roadmap for national efforts to combat hepatitis, leveraging evidence-based strategies to achieve meaningful impact.

Key Words: Hepatitis strategy, Viral hepatitis strategy.

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Introduction

In 2022, an estimated 304 million people worldwide were living with viral hepatitis B and C. Of these, approximately 254 million had hepatitis B virus (HBV) and 50 million had hepatitis C virus (HCV).[1] Half of the burden of chronic hepatitis B and C infections fell on individuals aged 30-54 years, with men comprising 58% of all cases. Around 12% of this burden affected children, primarily due to hepatitis B transmission.[1] The World Health Organisation (WHO) estimated a decline in new viral hepatitis infections from 2.5 million in 2019 to 2.2 million in 2022. Of these new infections, approximately 1.2 million were attributed to hepatitis B, and nearly 1.0 million to hepatitis C. Deaths from viral hepatitis rose from 1.1 million in 2019 to 1.3 million in 2022.[1]

Recognising viral hepatitis as a global public health issue, the World Health Assembly (WHA) in 2016 adopted the first Global Health Sector Strategy (GHSS) 2016-21 for viral hepatitis, marking the first global call to eliminate hepatitis B and C infections as public health threats by 2030.[2] This target aims for a 90% reduction in incidence (95% for HBV and 80% for HCV) and a 65% reduction in mortality compared to 2015 levels.

Subsequently, the GHSS on human immunodeficiency virus (HIV), viral hepatitis and sexually transmitted infections (STIs) for 2022-30, endorsed by the WHO in 2022, share a unified goal to end these epidemics while advancing universal health coverage (UHC), primary healthcare (PHC), and health security. These strategies align under five strategic directions that synergise

[1]World Health Organization (WHO) & Country Lead, Integral Global, Pakistan. [2,3]Department of Communicable Diseases, WHO Regional Office for the Eastern Mediterranean, Egypt. [4,6,22]Ministry of National Health Services, Regulations and Coordination, Pakistan. [5]WHO Country Office, Pakistan. [7]Pakistan Kidney and Liver Institute and Research Center, Lahore, Pakistan. [8]Department of Hepatology, Pakistan Kidney and Liver Institute and Research Center, Lahore, Pakistan. [9]Department of Medicine, Aga Khan University, Karachi, Pakistan. [10]Department of Gastroenterology, Hepatology and Nutrition, Lady Reading Hospital, Peshawar, Pakistan. [11]Hepatitis Control Programme Punjab, Pakistan. [12]Deputy Director General Health and Director Communicable Disease Control Department, Pakistan. [13,14]Hepatitis Control Programme Khyber-Pakhtunkhwa, Pakistan. 15Hepatitis Control Programme Balochistan, Pakistan. [16]National Institute of Health, Islamabad, Pakistan. [17]Hepatitis Focal Person Gilgit Baltistan, Pakistan. [18]Hepatitis Focal Person Azad Jammu Kashmir, Pakistan. [19]Islamabad Capital Territory, Pakistan. [20]Project Medical Referent, Medecins Sans Frontieres, Doctors Without Borders, Pakistan. [21]Department of Hepatology, Doctors Plaza, Karachi, Pakistan

Correspondence: Hassan Mahmood

Email: hassanmahmood1@hotmail.com

ORCID ID: 0000-0001-6493-3625

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responses across HIV, viral hepatitis and STIs. For viral hepatitis, the approach builds upon the 2016 framework, envisioning a world where transmission is halted, and everyone affected has access to safe, affordable and effective prevention, diagnosis, care and treatment. This vision emphasises a public health approach and aims at achieving UHC. The strategy aims at reducing the incidence of chronic viral hepatitis infection from the current 6-10 million cases to 0.9 million, and to reduce the annual deaths from chronic viral hepatitis from 1.4 million to less than 0.5 million by 2030.[2]

In the Eastern Mediterranean Region, the WHO Regional Office for the Eastern Mediterranean developed a regional action plan for the implementation of the GHSS 2022-30 (RAP-GHSS 2022-30), tailored to the cultural and epidemiological context, needs and challenges of the region. The RAP has five strategic directions, with recommended shared and disease-specific actions. These five directions are: delivering high-quality evidence-based, people-centred services; optimising health systems, sectors and partnerships for impact; generating and using data to drive decisions for action; engaging empowered communities and civil society; and fostering innovations for impact. The regional action plan sets out a monitoring and evaluation (M&E) framework with targets and milestones to ensure accountability and measure progress towards ending HIV and eliminating viral hepatitis and STI epidemics by 2030.[3]

Pakistan's demography and socioeconomic profile

Pakistan is situated in the northwestern part of the South Asian subcontinent, comprising a total land area of 796,096 square kilometers.[4] Administratively, Pakistan has four provinces along with the federating areas, including Islamabad Capital Territory (ICT), Azad Jammu and Kashmir (AJ&K) and Gilgit-Baltistan (GB). The country has 169 districts, including 10 in AJ&K5 (Figure 1) and 14 in GB, and excluding ICT. Punjab is the most populous province (56%), followed by Sindh (23%), Khyber Pakhtunkhwa (KP) (17%) and Balochistan (4%).[6-10]

Population Growth in Pakistan: Pakistan's population in 2023 reached 241.5 million, showing a significant increase of 33.82 million from 2017.[11,12] Punjab recorded the highest population increase with 17.7 million, followed by Sindh 7.8 million, KP 5.36 million, Balochistan 2.55 million, and ICT 0.36 million.[11-13]

Updating the National Hepatitis Strategic Framework (NSHF) 2024-30: A steering committee was formed, comprising representatives from the Ministry of National Health Services, Regulations and Coordination (M/o NHSR&C), the national hepatitis focal point, and WHO regional and country offices. This committee oversaw the development of the National Hepatitis Strategic Framework (NHSF) 2024-30.

The development process started with a thorough desk review to analyse national epidemiological data, assess

Figure-1: The map of Pakistan.

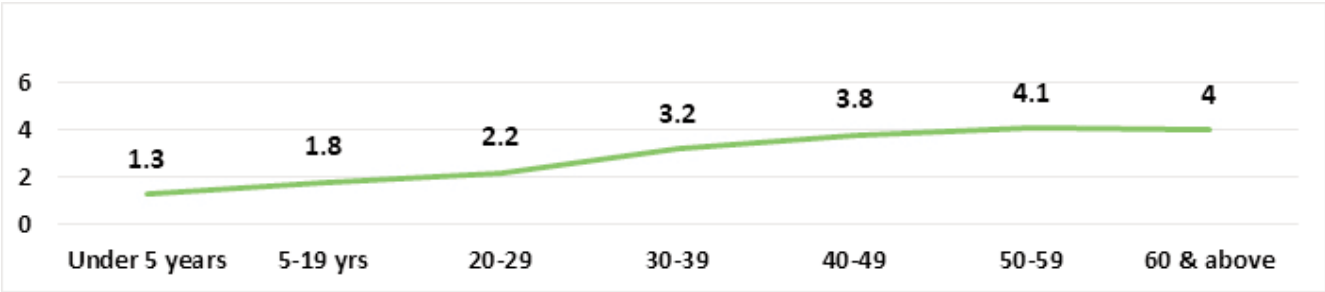

Figure-2: Prevalence of Hepatitis B surface antigen (HBsAg) in Pakistan by age group in 2008.

current progress, and identify challenges and opportunities, including a review of the previous national strategic framework 2016-22. Draft priorities for the NHSF 2024-30 were initially formulated based on these insights and refined with input from key stakeholders, including the National Technical Advisory Group (TAG) on Viral Hepatitis. An initial draft was then shared with key stakeholders in Pakistan, including M/o NHSR&C technical teams, Aga Khan University (AKU), Pakistan Kidney and Liver Institute (PKLI), and international partners, such as the Centres for Disease Control and Prevention (CDC) and Médecins Sans Frontières (MSF).

Feedback gathered from these stakeholders informed the development of the first draft, which was subsequently presented at a National Consultative Workshop held on July 11, 2024, in Islamabad. Further inputs from national and international participants were incorporated into the final draft of NHSF.

The epidemiology of hepatitis in Pakistan: In Pakistan, all five hepatitis viruses (A, B, C, D and E) are endemic. Most of the population are infected with hepatitis A (childhood) or E (adulthood) as acute infection. Both viruses have relatively low to moderate morbidity and mortality.[13] On the other hand, the country is facing an epidemic of hepatitis B, C and D.[14] This strategy will only be focused on HBV and HCV.

Prevalence of hepatitis B infection (2008 national seroprevalence survey): In 2008, a national survey revealed a 2.5% prevalence of hepatitis B surface antigen (HBsAg) in the general population, with 0.1% co-infected with both HBV and HCV. Broken down by provinces, the prevalence rates were 2.5% in Sindh, 2.4% in Punjab, 1.3% in the North-West Frontier Province (NWFP) (since renamed Khyber Pakhtunkhwa), and 4.3% in Balochistan.[15]

Overall hepatitis B e-antigen (HBeAg) prevalence was 14.5%, with highest results of 17% from Balochistan, followed by 15.4% from Sindh, 14.2% from Punjab and 8.5% from the NWFP.[16] Higher prevalence of HBsAg was observed among older individuals compared to younger populations (Figure 2) Males had a higher prevalence than females, at 2.9% compared to 2.0%. The 2008 survey showed that prevalence in children aged <5 years was 1.3%.[16]

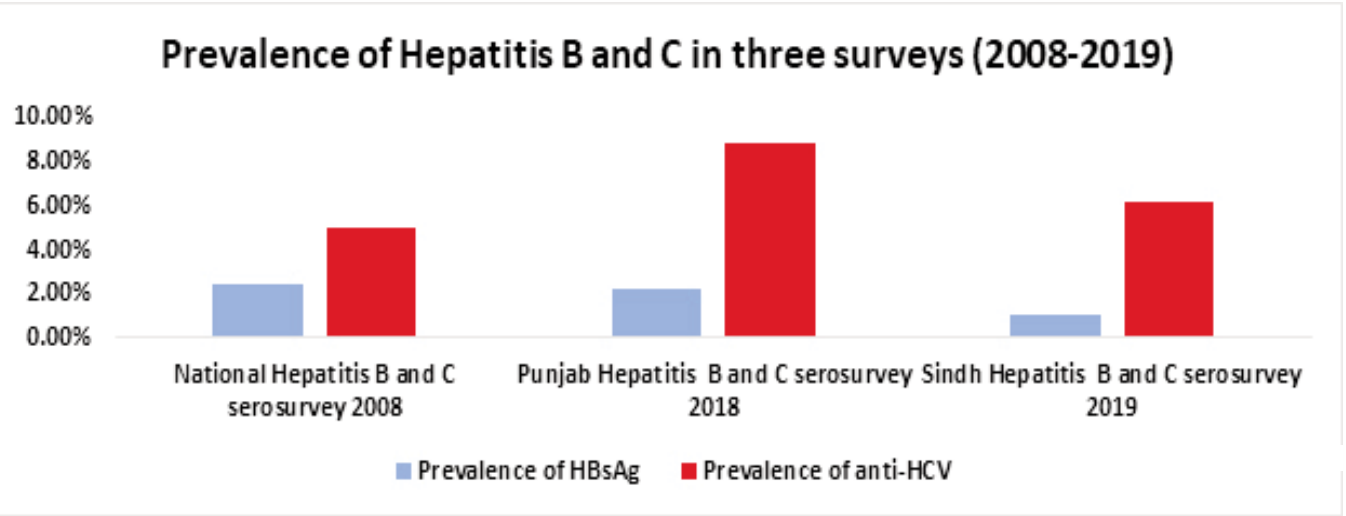

Figure-3: Prevalence of Hepatitis B surface antigen (HBsAg) and anti-Hepatitis C virus (HCV) in the national and two provincial surveys (2008-2018, 2019).

Serosurveys 2018 and 2019 in Punjab and Sindh: In 2018 and 2019, two provincial surveys were carried out in Punjab and Sindh, respectively, to understand the prevalence of HBV and HCV infections in the two provinces.[16,17] In 2018, the overall prevalence of HBV in Punjab was 2.2%, a slight decrease from 2.4% observed in 2008 (Figure 3). HBV prevalence was nearly evenly distributed between rural and urban areas. However, it was higher among males (2.9%) than females (1.6%), and prevalence rates were generally higher in older age groups compared to younger populations.[17]

Furthermore, among HBV-positive cases, the overall prevalence of hepatitis delta virus (HDV) was 17.7%. Urban areas showed a higher prevalence at 19.6% compared to rural areas at 17.0%. Notably, HDV prevalence was more pronounced among males (19.4%) than females (15.1%).[17]

In 2019, the overall prevalence of HBV in Sindh was 1.09%, marking a decrease from 2.5% reported in the 2008 serosurvey. Males showed a higher prevalence of HBsAg at 1.3% compared to 0.8% among females. HDV was seen in 32.8% people.[18]

Prevalence of hepatitis C infection (2008 national seroprevalence survey): In 2008, the overall prevalence of HCV in Pakistan was 4.9%.[16] Among the provinces, Punjab had the highest prevalence at 6.7%, followed by Sindh at 5%. The prevalence in Balochistan was 1.5%, and in the NWFP it was 1.1%. Prevalence rates were similar among males and females and no gender differences in HCV prevalence were observed across Pakistan. Further, the prevalence of HCV infection across Pakistan increased by age, rising steadily from age 20, peaking at 10.4% among 50-59-year-olds. This was attributed to the higher chances of exposure to the virus through injections for common ailments, dental treatments, communal shaving, and more frequent visits to healthcare facilities.

Provincial surveys 2018 and 2019 in Punjab and Sindh: In Punjab in 2018, the overall prevalence of HCV was 8.9%.[17] The rural population showed a higher prevalence at 9.3% compared to 7.8% in urban areas. Among females, the prevalence of HCV was slightly higher at 9.1% compared to 8.8% among males. In Sindh in 2019[18], the overall prevalence of HCV infection was 6.1%. Among males, the prevalence was 5.8%, whereas among females it was slightly higher at 6.6%. The prevalence of anti-HCV antibodies increased with age: from 1.3% in those aged 12-17 years to 2.6% in individuals aged 18-24 years, and notably rose to 14% among those aged 45 years and above (Figure 3).

Centre for Disease Analysis modelling in 2023: The national survey was conducted in 2008, followed by two provincial surveys in 2018 and 2019 in Punjab and Sindh, respectively. The data, along with other data sources, like publications and programmatic data, was utilised by the Centre for Disease Analysis (CDA) to project the national disease burden for HBV and HCV for 2022, providing insights into the trajectory of those epidemics in Pakistan (Table 1).[18]

In 2022, the projected prevalence of HBV infection among the general population (all ages) was 1.6% and among children aged <5 years, the prevalence was estimated at 0.2%, showing a decline from 2.5% and 1.3% in the groups, respectively. This corresponds to a total number of HBV infections across all age groups to be 3.8 million. While for HCV, in Pakistan, as of the beginning of 2022, the prevalence of HCV infection among the general population was 4.4%. At the provincial level, the actual anti-HCV prevalence figures were taken; for Punjab, it was 8.9%, and for Sindh, 6.2%. As no provincial surveys were done in two provinces, therefore, after consultation with experts, a consensus was reached, suggesting Balochistan to have an estimated prevalence of 5.2%, and KP 6.5%, corresponding to an estimated 9,775,000 viraemic infections. It was estimated that in 2022, there were an estimated 15,068 new incident cases of HBV and 110,000 new incident cases of HCV, respectively. The model also suggested that a total of 35,107 deaths were caused by HBV and HCV infections combined. [19]

Table1: CDA modelling analysis for hepatitis burden in Pakistan in 2022.

Prevalence					Incidence				Mortality	
Prev. of HBV among the general population (all ages) in 2022	Prev. of HBV among children > 5 in 2022	Prev. of HCV among the general population	Total HBV Infections (all ages) in 2022	Total HCV Infections (all ages) in 2023	HBV incident cases 2022	HCV incident cases in 2022	HCV incidence among PWID	PWID population size estimates in 2018	No. of deaths caused by HBV 2022	No. of deaths caused by HCV 2022
1.6%	0.2%	4.4%	3,796,372	9,850,374	15,068	110,000	TBR	TBR	10,260	24,847

CDA: Centre for Disease Analysis, HBV: Hepatitis B virus, HCV: Hepatitis C virus, PWID: People who inject drugs.

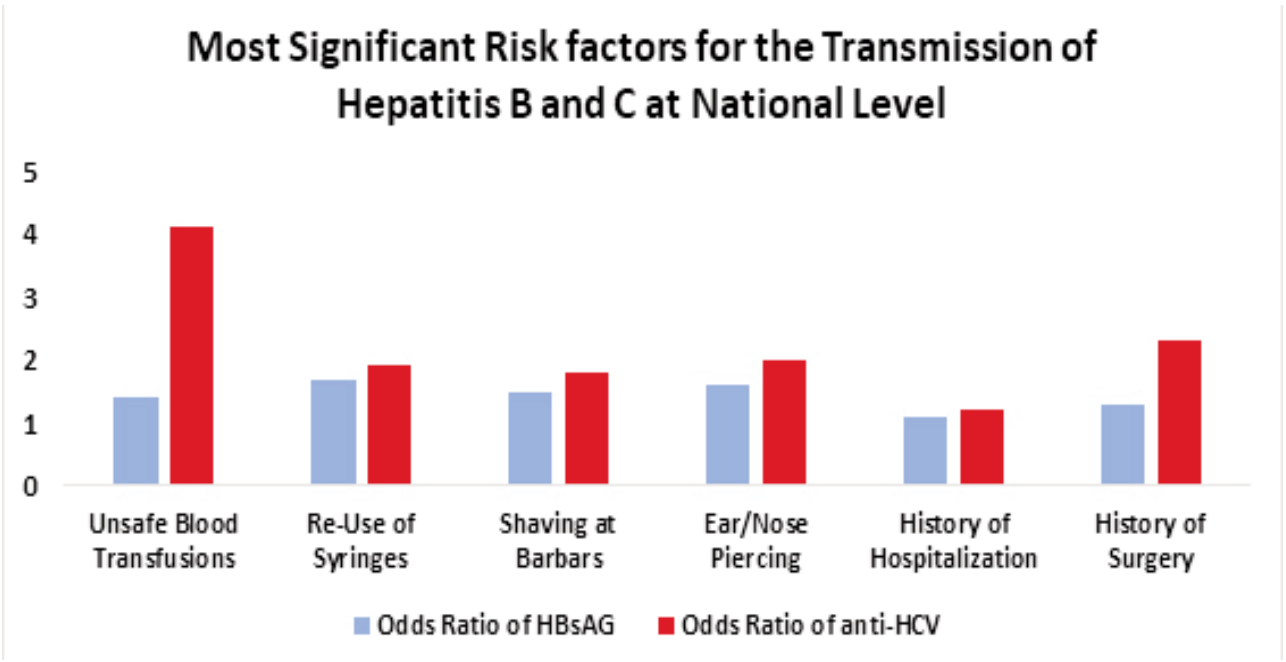

Figure-4: Risk factors for the transmission for both hepatitis B virus (HBV) and hepatitis C virus (HCV) in Pakistan.

Prevalence of HCV and HBV in key populations: It is estimated that there are 113,776 People Who Inject Drugs (PWIDs) in Pakistan.[20,21] Studies among PWIDs in Pakistan report a high prevalence of HCV. A meta-analysis of [17] studies from Pakistan concluded that the mean HCV prevalence among PWIDs was 61.8%.[22] Additionally, prevalence >90% was reported from certain areas of Karachi (94%).[23] A study conducted by the Association of People Living with HIV/acquired immunodeficiency syndrome (AIDS) reported 92% prevalence of HCV among PWIDs in Pakistan.[23,24] Prevalence of HBV in PWIDs was reported to be 28.5% in 2007.[23-25]

A review of HBV and HCV in high-risk groups was conducted in 2010.[14] It reported HBsAg infection in 12% of the commercial sex workers (women) in Lahore, while it was only 3.4% among transvestites in Karachi who acknowledged having commercial sex with men. In multiple transfused populations, like thalassemia, the HBV figures ranged 7.5-8.4%, and for HCV they ranged 36-56%. Figures in haemophilia were similarly high (HBsAg 5%, HCV 25%). In dialysis population, HBV figures were 12.4% and HCV 20%. Among the healthy individuals who were screened prior to their induction in the armed forces, HBsAg ranged 3-7.3% and HCV 2.2- 5.2%. Blood screening data showed higher prevalence of HBsAg (0.8-8%) and HCV (0.2-10%) in blood donors.[14]

Risk factors for the transmission of HCV and HBV in Pakistan: In Pakistan, several risk factors contribute to the transmission of HCV and HBV. These include unsafe medical practices, such as contaminated needles and syringes, inadequate sterilisation of medical equipment, and the reuse of disposable syringes.[26] Additionally, unsafe blood transfusions and organ transplantation procedures without proper screening for HCV and HBV contribute to their transmission.[25] The National Hepatitis Survey of 2008 identified significant risk factors for the transmission of hepatitis B and C (Figure 4).[16]

Pakistan's national response to hepatitis

National hepatitis response: In 2005, the government launched the nationwide Prime Minister's Programme for the Prevention and Control of Hepatitis (2005-10)[27] with clear goals: preventing new hepatitis transmissions, implementing hepatitis B immunisation, ensuring injection safety, infection control services, and providing standardised diagnosis, testing and treatment across the country. Following the devolution of health responsibilities in 2011, the programme transitioned to the provinces as the Provincial Hepatitis Prevention and Control Programme.[28] In June 2013, the TAG on viral hepatitis was established to offer guidance and policy decisions. Chaired by the Secretary of M/o NHSR&C, TAG included leading gastroenterologists and experts from national and international organisations, such as WHO and CDC's Division of Viral Hepatitis (DVH). TAG also comprised members from the private sector, civil society organisations and patient groups. Notably, TAG played a crucial role in introducing new Direct Acting Antivirals (DAAs) in the country at the world's most affordable rates. The national response aligned with the GHSS 2016, aimed

at eliminating viral hepatitis as a public health issue. The strategy proposed five key interventions: hepatitis B vaccination, prevention of mother-to-child transmission of HBV, ensuring blood and injection safety, promoting harm reduction, and scaling up testing, treatment, surveillance, in addition to surveillance and data systems.

Hepatitis surveillance, monitoring and evaluation: Monitoring, evaluation and surveillance for hepatitis is lacking at national and provincial levels. Only Punjab has an Electronic Medical Record (EMR) system, while the rest of the country still has paper-based data entry systems. Field Epidemiology and Lab Training Programme (FELTP)[29] with the support of CDC, United States, established the sentinel sites for the surveillance of acute hepatitis in one major public-sector hospital of each province and one in the federal capital of the country, but this does not capture the data from the whole province and from private-sector healthcare facilities. Besides, its case definition is different from WHO's definition, causing issues of usage of the data by international organisations.

Prevention

Vaccination: In Pakistan, the Federal Directorate of Immunisation (FDI), formerly the Expanded Programme on Immunisation (EPI), began in 1978[30], ensuring all vaccines were administered with auto-disable syringes. The hepatitis B vaccine, initially introduced in 2002 with the Global Alliance for Vaccines and Immunization (GAVI) support as a monovalent vaccine, transitioned to a tetravalent vaccine in 2006 (Diphtheria, Tetanus and Pertussis- DTP3-Hep B). By 2008, a pentavalent vaccine containing DPT plus Hepatitis B and Hemophilus influenzas (DTP-Hep B-Hib) was adopted for infants at 6, 10 and 14 weeks, achieving 56% coverage for all three doses.[29-31] To date, birth-dose (BD) of HBV vaccine is not implemented nationwide. There is a policy for preventing hepatitis B infection among healthcare workers, but, as per the latest data, 20% of healthcare staff are not vaccinated against HBV.[31] According to EPI medical information system (MIS) of FDI in 2022, Punjab had a hepatitis B BD coverage of 70%, followed by Sindh 15% and Balochistan 14%. There was no data available for KP, ICT and other federating units.[32]

Injection safety and infection control: In Pakistan, high rates of therapeutic injections, including unnecessary ones, contribute significantly to blood-borne infections, such as hepatitis B and C, largely due to syringe reuse. Studies have reported that 20% of therapeutic injections administered annually in Pakistan in healthcare settings are unnecessary.[14,16] Modelling by Bristol University estimated that 8% of healthcare injections in Pakistan are unsafe.[33] In the 2008 seroprevalence survey, therapeutic injection usage due to various ailments was high and showed strong positivity to HCV prevalence. About 30% of the screened population was taking >5 injections per person per year.[16] Since 2008, at least three HIV outbreaks in Pakistan among rural communities have been linked with unsafe injection. The first one occurred in Jalalpur Jattan in Punjab in 2008,[34] where 88 patients were found HIV-positive and exposed to unsafe injections. The second one was in Kot Imrana in Sargodha district in 2018[35] where 699 patients were confirmed HIV-positive. The third one happened in Ratodero, a small town in Sindh's Larkana district, in 2019,[36] which resulted in more than 1,500 infections among children. In 2019, M/o NHSR&C and EPI initiated the National Campaign to Address Unsafe Injection Practices and Promote a Safe Environment in Pakistan, launching a national action plan aimed at tackling unsafe injection practices across the country.[37]

Blood transfusion safety: In Pakistan, approximately 3 million units of blood are transfused annually, distributed among 170 public and 450 private blood banks.[38,39] Alarmingly, about 40% of these transfusions are conducted without proper screening, with the remaining 60% are often screened using substandard methods.[26,40] The country heavily relies on family/replacement donors, accounting for nearly 99% of blood donations.[7,28,41,42] Furthermore, a significant portion of the blood supply comes from unregulated private blood banks, where quality standards are frequently compromised.

The government of Pakistan, with support from the German government, has initiated the Safe Blood Transfusion Programme (SBTP) in ICT and four provinces. In this project, a network of fully equipped regional/divisional blood centres shall be established throughout the country[29-31,43-45] It is envisaged that a safe blood transfusion programme would lead to prevention of new HBV and HCV cases in the country through promotion of voluntary non-remunerated blood donation, optimal use of blood and blood products, quality-assured blood collection and its component separation, and development and practice of standards in blood banking.[30,34-36,39,43-45]

Harm reduction: The national and provincial AIDS control programmes and some civil society organisations are playing a major role in providing harm-reduction services to PWIDs in Pakistan. The primary focus of such services is to prevent transmission of HIV, HBV and HCV through syringe exchange services, and linkages have been developed for referral to public and private health sectors. However, there is no HBV vaccination and HBV and HCV testing and treatment services for the PWIDs.

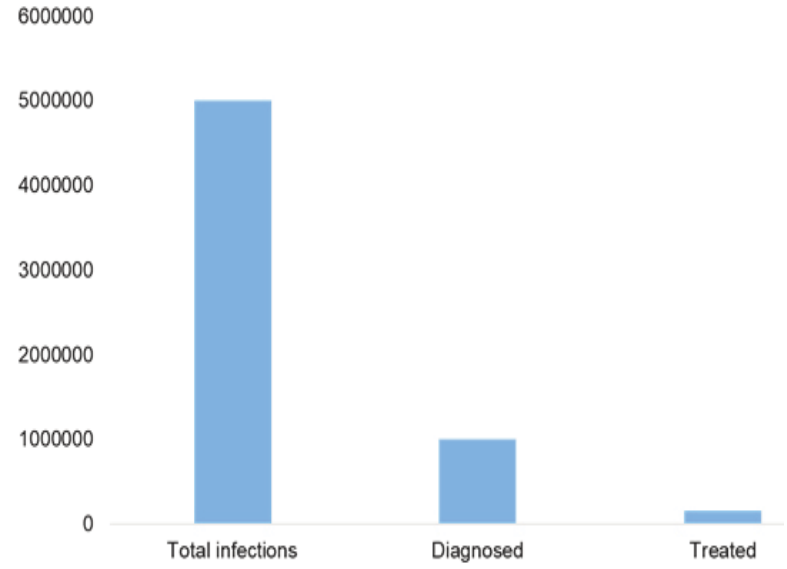

Figure-5 National hepatitis B virus (HBV) Cascade of Care data up to 2022.

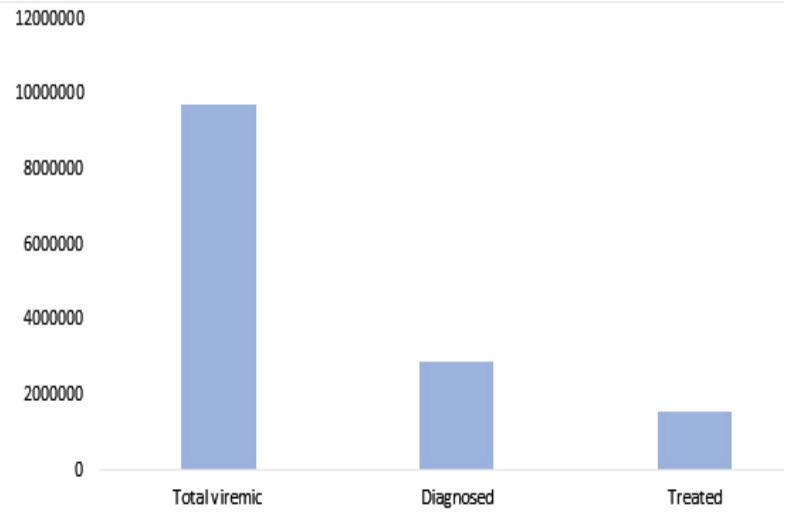

Figure-6 National hepatitis C virus (HCV) Cascade of Care data up to 2022.

Work is being done with provincial and district administrations in health, law-enforcement and social sectors for medical care, rights-based services and an enabling environment for PWIDs.

Testing and treatment: In Pakistan, a significant public health challenge persists, with 86% of individuals infected with HBV or HCV unaware of their infection status and the potential risks of transmission to their families, partners and communities. By the end of 2022, it was estimated that 20% of the HCV-infected population (approximately 1,962,000 individuals) had been diagnosed with HCV-ribonucleic acid (RNA), using provincial diagnosis rates weighted by prevalence.19 For HBV, about 25% people, or about 1 million individuals, had been diagnosed by the same period (Figure 5).

Access to HCV treatment has seen notable improvement in recent years, marked by significant expansions. Initially, from 2005 to 2010, an average of 60,700 patients annually received treatment through the Prime Minister's Programme for the Prevention and Control of Hepatitis.[46] Subsequently, with the launch of provincial programmes in 2011, treatment numbers rose to 230,000 in 2015 and further to 354,000 in 2018. This increase coincided with the adoption of direct-acting antiviral (DAA) oral drugs, replacing older interferon and combination therapies.[47] DAAs offer shorter treatment durations (typically 12 weeks or less), minimal side-effects, and high efficacy in preventing advanced liver disease, cancer and mortality.

The introduction of branded DAAs in 2014, followed by generic versions from 2015 onwards, led to substantial local production and a significant reduction in treatment costs, with three months of treatment now costing as low as $1547. Various micro elimination projects across Pakistan have demonstrated the feasibility and cost-effectiveness of integrating HCV testing and DAA treatment within primary healthcare facilities.[48-55]

Despite these advancements, challenges remain in achieving HCV elimination goals. By the end of 2022, less than 200,000 individuals were receiving treatment for HBV, while cumulative treatment initiations for HCV since 2015 totalled 2,224,486 individuals (Figure 6). Findings highlight areas for continued improvement in hepatitis care and management.[56]

Prime Minister's Programme for the Elimination of HCV Infection: The Prime Minister's Programme for the Elimination of Hepatitis C Infection is a comprehensive initiative aimed at combating the widespread HCV prevalence in Pakistan.[57] The primary objective of the project is to ensure that 100% of the eligible population (aged 12 years and above) undergoes screening, testing and treatment for HCV. By achieving this objective, the project aims at significantly reducing the disease burden, improving the quality of life, and contributing to economic productivity by eliminating the health hazards associated with HCV infection. The plan entails universal

Table-2: Screening, testing and treatment targets of PCI of Prime Minister's Programme for the Elimination of HCV Infection Phase-I (2024-27).

Estimation of Screening, Testing and Treatment Costs for Elimination of HCV in Pakistan, 2024-27									
Province/Area	Population								
	Project 2024* (Million)	Eligible (age ≥ 12 Yrs.) (65%)	Targeted (Phase I = 50% of Eligible)	RDTs + Commodities Cost**	HCV Prevalence	Population for PCR (Million)	PCR Cost	Population PCRs +ive (60%)	Total Cost of Treatment **
	N	N	N	PKR	%	N	PKR	N	PKR
Punjab	131	85	42.500	2.98	10.0	4.250	8.500	2.550	33.660
Sindh	57	37	18.500	1.30	6.9	1.278	2.557	0.767	10.125
KP	42	27	13.500	0.95	1.8	0.248	0.497	0.149	1.967
Balochistan	15	10	5.000	0.35	2.4	0.120	0.240	0.072	0.950
ICT	2	2	1.000	0.07	6.4	0.064	0.128	0.038	0.505
AJ&K	5	3	1.500	0.11	6.4	0.096	0.191	0.057	0.757
GB	2	1	0.500	0.04	6.4	0.032	0.064	0.019	0.252
PMU									
Total	254	165	82.500	5.775		6.088	14.611	3.653	48.217

HCV: Hepatitis C virus, RFT: Rapid diagnostic test, PCR: Polymerase chain reaction, KP: Khyber Pakhtunkhwa, ICT: Islamabad Capital Territory, AJ&K: Azad jammu and Kashmir, GB: Gilgit-Baltistan.

screening using WHO-certified rapid diagnostic tests (RDTs), followed by confirmatory polymerase chain reaction (PCR) testing, and subsequent treatment for those diagnosed with HCV. The project is budgeted at PKR67.77 billion, with funding sourced from the Public-Sector Development Programme (PSDP). The financial burden is shared equally between the federal and provincial/regional governments. The allocated funds cover the costs of screening, testing, treatment, operational expenses, social mobilisation and the establishment of a project management unit (PMU). In July 2024, first principal component (PC1) was approved and implementation of the PM initiative for elimination would start soon. The screening, testing and treatment targets for the elimination of HCV infection in the next three years 2024-27 (Phase-I) have been identified (Table 2).[57] Pakistan can achieve HCV elimination if it follows the same targets during years 2027-30 (Phase-II), but it will be preferred if the government scale up the targets immediately after the successful implementation of first phase.

Conclusion

Pakistan has a high disease burden of viral hepatitis B and C. Blood safety, injection safety and poor infection control practices challenge efforts to combat the diseases, and cause continuous transmission. The high prevalence rates, coupled with various risk factors, necessitate a comprehensive approach to prevention and control. Strengthening immunisation programmes, improving blood safety, enhancing infection control practices, coupled with large-scale efforts related to diagnosis and treatment, and raising awareness are crucial steps towards eliminating HBV and HCV infections by taking their spread as a major public health issue in Pakistan.

Key health system challenges and opportunities for an effective response in Pakistan

Key Challenges

➢ Unregulated blood transfusions and inadequate screening are the main challenges in a safe blood supply.

➢ Unsafe therapeutic injection practices, especially within the community.

➢ Low coverage of hepatitis B vaccination, in particular the hepatitis B BD.

➢ Low coverage of testing and treatment. Many chronically infected persons are unaware of their infection and its consequences, and are at a risk of transmitting the disease to their families and partners.

➢Very low coverage of harm-reduction services for PWIDs

➢ Weak collaboration and coordination of viral hepatitis

prevention, testing and treatment services at federal and provincial levels.

➢ Weak surveillance and data systems.

Key Opportunities: Opportunities exist for enhancing and expanding the national hepatitis response by investing more in the following:

➢ **HCV elimination:** In 2023, the government launched a national flagship initiative to eliminate hepatitis C from Pakistan by 2030.

➢ **Strategic information:** The existence of Punjab Hepatitis EMR covering almost 52% of the country's population. The same EMR can be adopted/adapted by other provinces and regions of the country to capture good-quality real-time data electronically.

➢ **Vaccines:** The FDI needs to be strengthened to improve vaccination coverage. Significant public health benefits can be achieved by focusing efforts on reducing deaths by introducing and rapidly scaling up HBV BD and childhood vaccination.

➢ **Oral DAAs:** Pakistan has made commendable strides in providing access to oral DAAs, significantly reducing their prices to $55 for a three-month treatment course. The same is the case with hepatitis B antiviral therapy.

National strategic framework and expected results of the national response 2024-30: The framework outlines the vision, goals and a set of targets that are aligned with the WHO global goals and targets and with the 2030 Agenda for Sustainable Development. It also outlines the country's priority interventions and actions to contribute to the WHO global elimination targets by 2030.

Guiding principles: The following guiding principles will direct the implementation of the NHSF to achieve the greatest impact of the national response to viral hepatitis (VH).

➢ **Guiding principle 1:** Data for decision-making.

➢ **Guiding principle 2:** Universal health coverage (UHC).

➢ **Guiding principle 3:** The continuum of hepatitis services.

➢ **Guiding principle 4:** Public health approach.

➢ **Guiding principle 5:** Equitable access to services and conservation of human rights.

➢ **Guiding principle 6:** Partnership and multi-sectoral approach.

➢ **Guiding principle 7:** Accountability.

Vision, goal, targets and strategic objectives: These are shown in the table 3)

Vision: In Pakistan, viral hepatitis transmission is halted and everyone living with VH has access to safe, affordable and effective prevention, care and treatment services.

Key priority goals and actions for NHSF 2024-30
Strategic Objective 1: Strengthening the leadership, governance and advocacy for a coordinated and integrated hepatitis response.

Goal: Enhanced coordinated and integrated hepatitis response

1. Strengthen the national TAG under NHSF leadership by refining roles and enabling direct reporting to the Prime Minister via the M/o NHSR&C secretary.

2. Foster synergies among VH vaccination (FDI), common

Table-3: Goals, targets and strategic objectives

Goal	The goal is to eliminate viral hepatitis as a major public health threat by 2030.
Targets	The NHSF targets by 2030 are aligned with the GHSS 2022-30 and the Regional Action Plan (RAP) targets for impact and service coverage targets. • Reduce new chronic HCV infections to ≤5 per 100 000 in the general population, • Reduce chronic HBV prevalence among 1-5-year-olds to ≤0.1%, • Reduce HBV and HCV related mortality to ≤6 per 100 000.
Strategic Objectives	The analysis of the epidemiological situation and the national response to VH revealed five main priority areas that will be considered as five strategic objectives to achieve NHSF targets by 2030: ➢Strategic objective 1: To strengthen leadership, governance and advocacy for a coordinated and integrated hepatitis response. ➢Strategic objective 2: Improve the quality, and scale up coverage of the hepatitis B and C prevention. ➢Strategic objective 3: To improve access to the viral hepatitis B and C testing, care and treatment services. ➢Strategic objective 4: Build laboratory capacity to support diagnosis and strengthen surveillance for HBV and HCV. ➢Strategic objective 5: To increase the availability and use of strategic information that will enable the development and monitoring of the implementation of evidence-based strategies.

management unit (CMU), national AIDS programme, blood transfusion services, infection control, thalassemia and haemophilia programmes, haemodialysis services, sexual and reproductive health, maternal and child health, and cancer care across federal, provincial and district levels.

3. Establish linkages of hepatitis programmes with prevention, testing, care, and treatment services at federal, provincial and district levels.

4. Establish provincial TAGs on VH in all provinces and federating areas, with defined responsibilities and links to the national TAG for planning, resource mobilisation and progress monitoring.

5. Establish district coordination committees to facilitate planning, resource mobilisation, and implementation monitoring at the district level.

6. Appoint a dedicated focal unit or person in each district to oversee the implementation of district hepatitis plans, varying in size based on provincial needs.

7. Develop and implement a partnership policy involving civil society, private sector, and patient organisations to enhance community involvement and support for hepatitis initiatives.

8. Strengthen institutional, organisational and managerial capacities of partner associations.

9. Engage people living with hepatitis in strategy development and implementation through participatory approaches.

10. Form partnerships with government agencies, development agencies, and donors to implement NHSF initiatives at federal, provincial and district levels.

11. Craft a tailored communication strategy for effective public engagement.

12. Advocate for priority interventions through an investment case to prevent new cases and manage chronic diseases.

13. Utilise national and international events, like World Hepatitis Day, to raise awareness and accelerate hepatitis response efforts aligned with NHSF targets.

14. Conduct economic analyses to demonstrate the return on investment in viral hepatitis elimination efforts.

Strategic Objective 2: Improve the quality, and scale up coverage of the HBV and HCV prevention.

Goal 1: Improving HBV vaccination coverage (Hepatitis B birth dose (HepB- BD), Hepatitis B third dose-Hep- B3)

1. Vaccinate the population groups who are at increased risk of getting HBV infection, such as healthcare workers, family members of people having hepatitis B, people who inject drugs, people on haemodialysis, people with haemophilia, men who have sex with men, sex workers, prisoners and prison personnel.

2. Ensure implementation and universal access to Hep BD vaccination for all infants.

3. Develop strategies to timely administer the Hep BD vaccine to newborns delivered either at health facility or at home.

4. Introduce routine screening of pregnant women for HBsAg to ensure detection of infection and linkage to care and treatment of women positive for HBsAg as per WHO recommendations.

5. Ensure that all infants born in health facilities receive Hep BD within 24 hours of birth. The immunisation programme must work with maternal and child healthcare and obstetric staff to integrate the BD into essential neonatal care. The discharge certificate of the mother/infant should be linked to Hep BD certification.

6. Conduct targetted awareness campaigns across communities to educate about the importance of hepatitis B vaccination.

7. Collaborate with community leaders, religious institutions, and schools to promote vaccination as part of routine health practices.

8. Train healthcare providers on the administration, storage and handling of hepatitis B vaccines to maintain efficacy and safety.

9. Implement robust monitoring and evaluation systems to track vaccination coverage at national, provincial and district levels.

10. Conduct regular assessments to identify barriers to vaccination uptake, and implement corrective measures as needed.

Goal 2: Strengthening infection prevention and control practices, including safe injections.

1. Ensure the adoption of standard infection control precautions in all healthcare facilities, including training and monitoring of healthcare workers on adherence to standard precautions.

2. Develop strategy for reducing unnecessary injections in Pakistan.

3. Utilise the already developed training programmes on infection prevention and control (IPC) to prevent the transmission of all infections, including VH in all healthcare settings.

4. Implement protocols for the safe handling and disposal of sharps and medical waste to prevent needle-stick injuries and contamination.

5. Establish/strengthen national infection control regulating authority with the ability to:

o Investigate infection outbreaks in healthcare settings.

o Oversee the implementation of safe therapeutic injection practices.

o Ensure compliance with correct sterilisation procedures and medical waste management in both public and private sectors and the informal healthcare sector.

o Promote injection safety through exclusive use of safety-engineered devices or reuse-prevention devices.

o Ensure adequate funding for single-use disposable injection equipment (safety-engineered devices or reuse-prevention devices) in all public health facilities and adherence measures to prevent the re-use of such equipment.

o Promote IPC/injection safety practices with a learning culture.

Goal 3: Ensuring 100% blood safety

1. Strengthen regulatory frameworks to enforce stringent guidelines and accreditation standards for both public and private blood banks.

2. Conduct regular inspections and audits of blood banks to ensure compliance with quality assurance protocols, including proper storage, handling, and testing of blood and blood products.

3. Promote voluntary non-remunerated donation of blood and blood donor care, including referral of blood donors with reactive HBV and HCV screening results for confirmatory testing, evaluation, treatment and care.

o Launch awareness campaigns to promote voluntary non-remunerated donation among the general population, emphasising the importance of donating safe blood voluntarily without any financial incentive.

4. Ensure quality-assured screening for all blood collected from voluntary unpaid donors.

Goal 4: Strengthen harm-reduction programme.

1. Conduct needs assessment and resource mapping.

o Conduct a needs assessment to identify areas with high prevalence of drug use and associated harms.

o Map existing resources and capacities of non-governmental organisations (NGOs) working in harm-reduction to understand gaps and opportunities for collaboration in view of expansion.

2. Capacity-building and training.

o Provide training and capacity-building workshops for NGO staff on harm-reduction strategies, including opioid substitution therapy (OST), and needle and syringe programmes (NSPs).

o Equip NGOs with skills in community outreach, peer education, and advocacy to effectively engage with drug users and key populations.

3. Expansion of outreach services.

o Expand outreach activities to reach PWIDs, including setting monthly and yearly targets to reach those populations.

o Establish mobile harm-reduction units to provide services in underserved areas, offering HIV, hepatitis testing, counselling, distribution of clean needles and syringes, and linkage to treatment and care services.

4. Advocacy and policy engagement.

o Collaborate with government agencies, policymakers and healthcare authorities to integrate harm-reduction into national health strategies and policies.

5. Monitoring and evaluation.

Develop robust monitoring and evaluation frameworks to assess the impact of harm-reduction interventions implemented by NGOs.

Regularly collect data on service utilisation, and behavioural changes among target populations to inform programmatic adjustments and improvements.

Strategic Objective 3: Improve access to the viral hepatitis B and C testing, care and treatment services.

Goal 1: Develop clear guidance for viral hepatitis prevention, diagnostic and treatment.

1. Update hepatitis B and hepatitis C screening, diagnosis and management guidelines in line with new WHO recommendations.

2. Simplify treatment and management guidelines to

enable better treatment adherence and wider implementation.

3. Conduct training workshops and educational sessions for healthcare providers to ensure understanding and implementation of the guidelines in clinical practice.

Goal 2: Increase the number and proportion of persons with HBV and HCV infection who are tested, diagnosed and receiving treatment.

1. Revisit and revise national targets in the light of the government initiative for 2024-27.

2. Develop detailed provincial testing strategies to implement the programme for the elimination of HCV and linkage to treatment.

3. Integrate screening for HBV and HCV with primary care screening for HIV, tuberculosis (TB), and non-communicable diseases (NCDs).

4. Expand innovative models for VH testing in a range of settings, such as community-based organisations (CBOs), mobile units, substance use disorder (SUD) treatment programmes, correctional facilities, syringe services programmes, HIV clinics, STI clinics, refugee health centres, and homeless shelters.

5. Educate people who are newly diagnosed about recommended assessments, vaccination, treatments, and the benefits of treatment adherence and completion, including in SUD and correctional settings.

6. Dedicated strategy for under-privileged and marginalised populations living in slums and remote areas. Being at a high risk for infection because of limited access to healthcare, they can serve as the hotspot of blood-borne infections, including HBV/HCV.

7. Establish linkage to care between CBOs, correctional facilities, syringe services programmes, alcohol and other SUD treatment programmes, and VH treatment providers.

8. Integrate HBV and HCV treatment within the existing healthcare services (decentralisation of services to primary healthcare centres and harm-reduction centres).

9. Advocate for governmental support, and continue negotiating pricing agreements with pharmaceutical companies to reduce the cost of hepatitis B and C medications.

10. Expand insurance coverage and financial assistance programmes to ensure affordability for all patients, including marginalised groups. Monitor people with chronic hepatitis B or chronic hepatitis C related to treatment status, fibrosis and risk for hepatocellular carcinoma (HCC), to prevent morbidity and mortality from HCC, end-stage liver disease (ESLD), and other hepatitis-related sequelae.

11. Study risk factors for hepatitis B reactivation in persons with inactive disease or resolved infection, and make recommendations for prophylaxis, monitoring and use of vaccination to boost immunity in people with antibody to hepatitis B who are receiving immunosuppressive therapy.

12. Study risk factors for hepatitis C reinfection or reactivation in persons with documented sustained virological response after completing treatment, and make recommendations.

Strategic Objective 4: Build laboratory capacity to support diagnosis and surveillance for HBV and HCV.

Goal: Improve hepatitis B and hepatitis C laboratory diagnostics.

1. Develop and implement standardised testing protocols. Create and disseminate standardised testing algorithms and protocols for HBV and HCV diagnostics across all healthcare facilities and laboratories.

Ensure guidelines include sample collection, storage, processing, and interpretation of test results to maintain consistency and accuracy.

2. Enhance training and capacity-building. Conduct comprehensive training programmes for laboratory technicians and professionals on advanced techniques and best practices in HBV and HCV testing. Include

training modules on quality assurance, proficiency testing, and adherence to international standards for laboratory diagnostics.

3. Establish quality assurance and control measures. Implement stringent quality assurance and control measures to monitor and improve the accuracy and reliability of HBV and HCV testing. Develop

internal quality control protocols and participate in external quality assessment programmes to validate testing procedures and ensure consistency.

4. Upgrade laboratory infrastructure and equipment. Ensure laboratories are

equipped with necessary facilities for sample handling, storage and analysis as per the standardised protocols. Optimise the GeneXpert machines introduced through coronavirus disease-2019 (COVID-19) and with other

programmes, such as HIV and TB.

5. Develop national reference laboratories and networks. Establish a national reference laboratory dedicated to VH diagnostics and monitoring. Foster collaboration and networking among laboratories at regional and national levels to share resources, expertise and best practices in HBV and HCV testing.

Strategic Objective 5: Strengthen VH surveillance, and increase the

availability and use of strategic information.

Goal 1: Develop and implement integrated hepatitis information system.

1. Define a set of national indicators tailored to the capacity of the national surveillance system to monitor epidemiological trends of hepatitis B and C.

2. Expand the Punjab EMR hepatitis information system to interface with national and provincial health dashboards for real-time data access.

3. Implement the hepatitis information system nationwide to ensure uniform data collection, reporting and analysis.

Goal 2: Enhance surveillance and monitoring capabilities.

1. Develop standardised case definitions for acute and chronic HBV and HCV infections, ensuring consistency in reporting.

2. Train healthcare workers on case investigation procedures and reporting protocols for VH cases.

3. Establish sentinel surveillance sites for better measurement of the mortality and implementation of WHO protocol on sequalae surveillance.

Goal 3: Strengthen data utilisation and dissemination.

1. Conduct routine analysis of VH data to inform public health actions and policy decisions.

2. Enhance data analytics and informatics capacity to monitor trends over time and among key populations.

3. Disseminate findings through national and local epidemiological profiles and indicators for VH elimination.

4. Utilise VH programme data to evaluate interventions, conduct seroprevalence surveys, and establish registries for liver cancer and related morbidity/mortality.

Implementation of the national hepatitis strategic framework

Effective implementation of NHSF 2024-30 depends on concerted federal and provincial actions from all stakeholders in healthcare and other sectors to respond to VH. Success requires strong partnerships to ensure policy and programme coherence. Within the healthcare sector, linkages across different disease-specific and cross-cutting programmes need to be established and strengthened. Implementation of the strategic framework needs the development of the provincial action plan and a strong monitoring and evaluation system to generate the best possible data on the VH situation, trends and responses, and to monitor the hepatitis response through a set of standard and measurable indicators.

Development of the hepatitis provincial action plans: The NHSF will be translated into provincial hepatitis action plans with a well-defined governance and management structure that can ensure a coordinated and efficient response and clear accountability.

Provincial action plans will help to mobilise political commitment, define budget for tailored packages of interventions and services at the provincial level, define responsibilities and allocate resources through PC1s across the different levels of the healthcare system, and identify potential and reliable sources of funding. Regular reviews of the provincial action plans are essential in order to ensure that the provincial plans are current and fit for the purpose.

Collaboration with other public health programmes and partners: Hepatitis prevention, control and elimination is not the only responsibility of the hepatitis control programme. It needs a holistic approach and a collaborative coordinated response from all the stakeholders. Responses to hepatitis can learn from successful public health programmes in other areas, including those for HIV, TB and immunisation. Innovative HIV service delivery approaches can be adapted to reach specific populations. Quality improvement and price-reduction strategies that have enabled rapid expansion of HIV treatment coverage provide lessons for increasing access to affordable HCV treatment. Immunisation programmes can demonstrate how a range of strategies can be used to reach all communities and ensure access to effective, safe and affordable vaccines.

Communities as well as leveraged public and private sectors should be engaged in the response to focus interventions for maximum impact.

Ensuring long-term viability of hepatitis programming through integration: VH prevention and control should be continuously supported by the federal

and provincial health ministries with appropriate allocation of funds, followed by their timely release. Integration of policies for the prevention and control of blood-borne diseases, like HIV, hepatitis and STIs, and service delivery is required at different levels of the healthcare system, with the relative contributions and roles of primary healthcare, referral care and hospital care well defined.

Coordination mechanisms: This hepatitis programme will be implemented through a multi-sectoral approach. Public sector, civil society, media, private sector and all stakeholders will be involved in the implementation of the programme.

The responsibilities of the various stakeholders for the NHSF implementation will be clearly defined, and can be reviewed and reorganised during the whole process of the implementation.

National and Provincial Technical Working Groups

The national TAG and the provincial Technical Working Groups (TWGs) will play a key role in the implementation of the federal and provincial policies in the public sector. TAG will develop policies and technical guidelines necessary for the implementation of the hepatitis response in Pakistan. It will coordinate activities among the various stakeholders at the federal and provincial levels.

Table-4: Four strategies to include the private sector in hepatitis elimination in Pakistan.

Strategy 01: Case notification by private laboratories/ blood banks		
Mechanism	**Activities**	**Output**
• Non-monetary data sharing service agreements • Start with COVID designated private laboratories• Service charges as per usual	• Reporting into National Hepatitis Information System/EMR • Training on the use of EMR & e-reporting access• Refer positive cases to treatment sites	• Number of private laboratories reporting• Number of screened cases received • Number of HCV PCRs conducted•Number of confirmed HCV cases
Strategy 02: Expanding testing with private laboratories		
Mechanism	**Activities**	**Output**
• Non-monetary service-agreement with commodity supply + negotiatedsubsidized service chargesOR • Priced volume basedc ontracts / diagnostic vouchers, commodity purchase on negotiated rateby private providers	• Geotag areas needing support • Accredited laboratories + pre-qualify other laboratories • QA training + EMR training• Active & passive screening referrals from programs• E- report into E-HepEMR • Private provider refers positive cases to treatment sites• 3rd party payment • Periodic independent verification	• No of private laboratories reporting• No of screened cases received • No of HCV PCRs conducted• No of confirmed HCV cases
Strategy 03: Expanding testing & treatment with medium sized private hospitals/ medical charities		
Mechanism	**Activities**	**Output**
• Non-monetary service-agreement with commodity supply + negotiatedsubsidised service charges OR • Priced volume based contracts/ testing & Rx vouchers, with commodity purchase by private providers on negotiatedrates	•Geotag areas needing support •Pre-qualification•Quality Assurance training•Active & passive screening referrals from programmes •E-Reporting access into EMR/Hepatitis information system • 3rd party payment•Periodic independent verification	• No of private laboratories reporting • No of positive screened cases received• No of HCV PCRs conducted • No of confirmed HCV cases• No of HCV cases initiated on treatment• No of HCV cases completed treatment
Strategy 04: Expanding screening, testing & treatment with private hospitals/ medical charities + neighborhood clinics		
Mechanism	**Activities**	**Output**
• Contract with intermediary providers • Priced volume based contract + commodity supply • Priced volume based contract with direct purchase of commodity supply on negotiated rates	• Geotag areas needing support• Pre-qualification, training etc. • Intermediary provider enrols private clinics• E-Reporting access into electronic medical record (EMR) or hepatitis medical information system(HepMIS) • 3rd party payment• Periodic independent verification	• No of private clinicsrecruited• No of cases screened• No of HCV PCRs conducted • No of confirmed HCV cases• No of HCV cases initiated on treatment• No of HCV cases completed treatment

HCV: Hepatitis C virus, PCR: Polymerase chain reaction, COVID: Coronavirus disease, EMR: Electronic medical record, HepMIS: Hepatitis medical information System

➢ **NGOs**

Leadership in the healthcare sector needs to foster partnerships with the civil society to advocate supportive policies. NGOs will be involved in the implementation of community activities, particularly interventions for the most affected populations. Organisational and operational mechanisms will be developed for the contribution of NGOs in the national hepatitis response.

➢ **Private sector**

The private sector is playing an important role in Pakistan, especially in terms of VH treatment. The share of the private sector in healthcare is 59.7%, while public sector and others contribute 40.3%. Out-of-pocket health expenditure by private households is 88.6%, and 10% is through local NGOs.1 All NGO/primary care physicians who meet the NHSF requirements should be engaged and incorporated as active hepatitis treatment centres that shall comply with the EMR requirements and guidelines set out by the respective hepatitis control programmes. Mechanisms for enhancing coordination and collaboration with the private sector will be put in place, including those inherent in advocacy and data collection on the hepatitis patients managed by the private sector. In 2022, the Aga Khan University and M/o NHSR&C, with the support of the Asian Development Bank (ADB), carried out an exercise to find out the best possible strategies to engage the private sector, and identified four strategies on engaging the private sector in the fight against hepatitis in Pakistan (Table 4).

Monitoring and evaluating the hepatitis response: Progress in implementing the hepatitis response to VH should be assessed at the federal and provincial levels with impact and coverage targets that are set at the federal and provincial levels for the period between 2024 and 2030 (Table 5).

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Table-5: Impact and coverage targets 2024-30.

Indicator		Baseline (2024)	2025/2026	2027/2028	2030
Impact	Hepatitis B surface antigen (HBsAg) prevalence among children younger than 5 years old	0.23	0.2	0.15	0.1
	Number of new hepatitis B infections per year	15,068 {6 per 100,000}	5 per 100,000	4 per 100,000	2 per 100 000
	Number of new hepatitis C infections per year	110,000 {45 per 100,000}	20 per 100,000	10 per 100,000	5 per 100 000
	Number of people dying from hepatitis B per year	10,260	15 per 100,000	10 per 100,000	6 per 100,000
	Number of people dying from hepatitis C per year	24,847			
Coverage	Hepatitis B vaccine coverage among children (third dose)	3%	30%	70%	90%
	Hepatitis B vaccine coverage - Birth dose	70%	80%	90%	90%
	Number of needles and syringes distributed per person who injects drugs	130	200%	250%	300
	Blood safety - proportion of blood units screened for blood-borne diseases	NA	100%	100%	100%
	Safe injections - proportion of safe health-care injections	92%	95%	100%	100%
	Hepatitis B – percentage of people living with hepatitis B diagnosed	25%	60%	80%	90%
	percentage of people living with hepatitis B treated	4%	50%	70%	80%
	Hepatitis C – percentage of people living with hepatitis C diagnosed	30%	60%	80%	90%
	percentage of people living with hepatitis C cured	15%	50%	70%	80%

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HM, ASA, MSJ, SS, SKP, AA, SA, AN, SH, AGK, AG, ZD, TH, MA, SK, MS, SZ, MF, ZZ, MKA, AA & HQ: Concept, design, data acquisition, analysis, interpretation, drafting, revision, final approval and agreement to be accountable for all aspects of the work.