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Progress Towards Hepatitis C Elimination: Perspectives from Egypt, EU/EEA, and the European Neighbourhood Partnership countries

26-28 November 2024, Cairo, Egypt

Background

All countries globally are aiming to achieve the Sustainable Development Goal (SDG) target 3.3 'End the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases and combat hepatitis, waterborne and other communicable diseases' in addition to the World Health Organization (WHO) hepatitis elimination targets by the year 2030. To support exchange between Egypt, European Union and European Economic Area (EU/EEA) countries and European Enlargement and Neighbourhood Policy partner countries, the European Centre for Disease Prevention and Control (ECDC) and Egypt's Ministry of Health and Population (MoHP) organised a meeting on 26-28 November 2024.

The "Progress Towards Hepatitis C Elimination" meeting, held in Cairo, Egypt, brought together public health experts, policymakers, and key stakeholders from the Mediterranean, Europe, and Africa. Organised under the framework of the [EU Initiative on Health Security](#), the meeting focused on sharing experiences, discussing challenges, and identifying pathways to achieving the elimination of hepatitis C.

This meeting provided a unique opportunity to learn lessons learnt from the Egyptian success as the first country to achieve WHO "gold tier" status on the path to elimination of hepatitis C and allowed the exchange of experiences of good practices between countries. Furthermore, the meeting identified pragmatic strategies and programmes to accelerate the progress towards viral hepatitis C elimination. The key areas of interest were an overview of progress towards elimination, strengthening of screening strategies, capitalising on lessons learned for hepatitis C to eliminate hepatitis B, addressing hepatocellular carcinoma, and addressing remaining challenges in viral hepatitis elimination.

The three-day event featured a series of plenary sessions, panel discussions, and presentations addressing various aspects of hepatitis C elimination. Regional and local perspectives were explored, with participants discussing progress in Egypt, the EU/EEA, and other European Neighbourhood Policy partner countries, highlighting best practices and lessons learned.

Key factors for achieving the pathway to elimination of hepatitis C in Egypt

The unique epidemiological situation of hepatitis C in Egypt was reported to be related to poor injection safety practices during efforts to treat schistosomiasis that led to the mass transmission of hepatitis C across the population during the 1960s and 1970s. In 2008, Egypt's first demographic survey found an estimated anti-HCV prevalence of 14.7%. In 2008, it was estimated that 10% of the Egyptian adult population (15-59 years of age) was HCV RNA positive. A study in 2015, reported an HCV RNA prevalence of 7% with the decline attributed to the scale up of infection prevention control (IPC) measures and aging of the population included in the first survey and the entry of younger population with low. Prevalent disease in the second survey. Modelling found that increased screening and

treatment combined with no reduction in HCV incidence would result in an 80% reduction in population prevalence. Economic analyses in 2015 indicated that national spending by the Egyptian government on HCV was around 3.8 billion Egyptian pounds. In terms of direct costs, it was estimated that if there had not been any campaign, the direct costs would have been 19 billion. The return was 3.59 Egyptian pounds for each Egyptian pound spent on the campaign, and the savings were estimated to be 23 billion Egyptian pounds and 1.1 million life years saved over 25 years.

In tackling the large burden of HCV in the country, pegylated interferon treatment was initially launched in 2006, with 300,000 people treated between 2006-2014, although the success rate was relatively low during this period with a 40% sustained viral response rate (SVR). In 2014, treatment with the brand new direct acting antivirals (DAAs) was started, facilitated through a web-based registration system. The National Committee for Control of Viral Hepatitis (NCCVH) developed a national treatment guideline with exclusion and inclusion criteria to be used by clinicians to define the appropriate treatment for each patient. In the first 30 days of the system, 550,000 people were registered for evaluation. After three months of DAA treatment, mainly Sofosbuvir (SOF) and Daclatasvir (DA), 95% of patients were reaching SVR.

In 2016, Egypt started production of generic DAAs, which allowed wider treatment availability. The efficacy of the generic DAAs was critical to Egypt in being able to reduce the high number of infected people, which decreased the national prevalence significantly. A local Egyptian company applied for a non-proprietary process patent for the production of SOF and for a new polymorph shape (alpha). A plant was built in Alexandria for local production. The local production was enabled by political will and by WHO pre-qualification of the manufacturing site. The production scale was high, and it was also eventually possible to export locally-produced DAAs to other countries.

In 2017, Egypt started to see a drop in the number of patients with known HCV status treated and it was understood that there needed to be a widescale screening programme to identify undiagnosed individuals. A decree was issued by the Prime Minister in 2017 indicating the need for wider targeted screening and, through this approach, 3.3 million citizens were screened. Eventually, 290,400 cases were identified through screening campaigns in 2017. In 2018, Egypt initiated the "100 million healthy lives" campaign, to reach 70 million people with a much more widespread screening approach for multiple chronic diseases, including using finger prick rapid testing to test for hepatitis C. Those who registered positive through initial screening were registered for appointment with further virological evaluation and assessment of liver status. The majority (77%) of screening was done in primary health centres, but also in hospitals (7%), mobile clinics (2%), youth centres (4%) and other facilities. For this population-based screening to succeed, it was emphasised that it had been essential to train frontline healthcare workers, to improve test turn-around time to 20 minutes and to improve lab capacity. A multi-modal mass media was used to inform the population about the campaign.

There were other critical factors noted in relation to the scaling up of screening including update of machines for better performance and digitalisation was key with all labs connected to the treatment centres. Training was also essential with training conducted in line with WHO, CDC and the MoHP. Increasing training capacity impacted positively at improving the performance of the personnel and keeping workers up to date. Limitations with use of the data were that there were pools of data that were not connected and patient drop-out. In response to these issues a database was developed that connected patients with hepatitis B and C, HCC patients, pregnant patients and blood banks and patients with HIV. A dashboard was developed to allow monitoring of real time data at the national level, to enable the production of statistics and to monitor the progress of each patient. A key factor underlying the success of the system was the availability of national identification numbers.

Egypt succeeded to screen more than 60 million people in the campaign and to scale up treatment services. This has resulted in a prevalence of 4.5% in people aged over 18 years with varying prevalence in other groups. Egypt initiated a system to ensure that people would return after treatment for a test of cure by providing hepatitis-free certificates. Egypt worked to ensure that costs for hepatitis screening tests declined from over 20 USD to 5 USD and were also able to reduce the cost of DAAs from more than 600 USD per treatment to 50 USD per full treatment course.

In relation to harm reduction programmes for persons who inject drugs (PWID), Egypt implemented the updated WHO HIV prevention guidelines including needle and syringe programmes (NSP), opiate agonist therapy (OAT), naloxone for overdose management under a comprehensive package of evidence-based interventions. Egypt's NSP programmes expanded in 2020 through a signed agreement between the MoHP and community-based organisations. Syringes were then provided through the community-based organisations and currently the estimated needle and syringe provision per PWID is 250 annually. One reported major challenge of the programme was the limited numbers of people working in community-based organisations. HCV testing is also carried out in these settings, and it was noted that HCV prevalence among PWID tested in these settings has declined from 7.4% in 2021 to 0.9% in 2023. In relation to OAT, the MoHP, plus the Ministry of Justice and the Ministry of Interior have endorsed the OAT programme, as one of the evidence-based treatment approaches for addiction. Implementation was also supported by national guidelines on OAT and Standard Operating Procedures, along with capacity building. Study visits to countries already implementing OAT supported Egypt's implementation. The project was launched in March 2023, in the context of a psychiatric and addiction hospital and has now been expanded to several regions of the country.

In 1997, Egyptian Swiss project modernised and unified all aspects of the blood transfusion system. blood transmission and blood products are an important pillar in Egypt response to HCV infection. Nucleic acid testing (NAT) was introduced in 2008 and a comprehensive quality control system was also activated to safeguard the whole system. The MoHP also established the Egyptian Transfusion Medicine Fellowship, strengthening training and continuous training program.

Egypt proceeded to get a certification for HCV elimination from the WHO between 2021 and 2023, reaching 'gold tier' status on the Path to Elimination in October 2023 by showing that 87.7% of people living with chronic HCV were diagnosed and that 93.7% of those diagnosed were treated.

In terms of critical factors underpinning the success of this achievement, the importance of political will and leadership in Egypt's path towards hepatitis C elimination were highlighted. This leadership extended from the level of the President, who instructed the government to put forward sufficient resources towards fighting HCV. It was reported that this focus and the allocation of resources were instrumental to the success achieved. The price reductions were also considered essential, as was the provision of diagnosis and treatment to the population for free. The important role of training across all sectors from primary care to tertiary care was highlighted with tailored trainings for different groups delivered through a wide range of media, including online. The role of media was also important with a carefully crafted media campaign to gain the trust of the population. This campaign included a range of awareness raising approaches including the use of celebrities as well as real testimonials of people who had gone through screening and treatment.

In terms of the sustainability of viral hepatitis elimination and Egypt's journey towards full validation, there are ongoing plans to continue with the expansion of the blood monitoring system into a unified electronic platform and expansion of NAT services to the private sector; a scaling up local capacity to produce safety-engineered syringes; and an expansion of NGOs carrying out NSP and OAT services. Screening programmes will continue, focusing on younger populations and will include school children and pre-marital screening and also the key populations. Many treatment centres opened originally to

treat large numbers of people no longer have large numbers of patients, but they are shifting their tasks to other topics like surveillance among cirrhotic patients and management of people chronically infected with hepatitis B virus, and ensuring the sustainability of access to HCV treatment in all parts of the country. Finally, Egypt's MoHP is also developing "sequelae surveillance" through an ongoing project with WHO and IARC that is focusing on sentinel sites to collect data on the HCV related mortality attributable fractions in order to calculate mortality estimates and ensuring the proper reduction of HCV related mortalities.

Two spin-off effects of Egypt's work on hepatitis are that it prompted the government to create a national non-communicable disease programme and the work resulted in an electronic health database for all adult citizens.

The role of external organisations in Egypt's pathway to elimination

The "100 million Healthy lives campaign" was backed by \$250 million USD World Bank financing as well as with technical support from the WHO. The role of the WHO in the campaign was as an independent verification agency and included a team of 11 verifiers who spent over 10,000 hours working on the validation of elimination of HCV in Egypt. This was mainly done through site visits to carry out field verification on the process of screening, as well as to assess service quality, verify data collected, measure satisfaction of service beneficiaries, and measure compliance with WHO guidance and principles.

The World Bank conducted an analysis of the indirect and direct costs of "no-action" on HCV and estimated that there would be a 7.5% productivity decline in HCV-positive workers, meaning that HCV-positive workers would have 5-times higher odds of falling into poverty; this resulted in an estimated overall projected 1.5% loss of GDP if no action had been taken. The Egyptian government requested support from the World Bank, which modelled multiple scenarios and found that the fiscal savings from an aggressive HCV screening and treatment programme were high, and this was championed by the MoHP. Negotiations on medication costs, local production, and competition dramatically lowered prices for treatment (from 80,000 USD in the end of 2013 to 50 USD/full course in 2018), allowing more to be treated.

Addressing hepatocellular carcinoma

In Egypt, HCV is the leading cause of liver cancer. The national programme for early detection of hepatocellular carcinoma (HCC) has complemented the HCV programme since 2019. The main outcome of the programme is early detection of HCV related cancer and the implementation of the HCC systemic therapy for patients suffering from advanced stages of HCC. Presidential initiatives helped to deploy the HCC programme in 22 centres. A protocol for systematic therapy was developed relying mainly on immunotherapy and tyrosine kinase inhibitors (TKIs). The number of enrolled patients declined over time as the screening enabled early detection of cases. Efforts to enhance the surveillance programme have had a great impact at improving patient outcomes. However, loss-to-follow-up is a concern for patients diagnosed at a late stage of HCV infection. Cirrhotic patients once cured of HCV had lower adherence rates for Surveillance program and follow-up. In response to this, different modalities were created to keep patients in care including a patient hotline, TV advertising and a national information campaign. Additionally, enhanced surveillance, including AI machine learning, has improved the diagnostic capacity and quality.

Key steps on the pathway to validation of elimination for hepatitis C in Georgia, Pakistan and Morocco

Georgia: In Georgia a seroprevalence study in 2015 found HCV RNA prevalence to be 5.4%, finding a variety of populations affected including key populations and the wider population group. The spread of HCV in Georgia was likely attributed to poor blood safety and infection control, combined with injecting drug use dating back to the 1990s. A national HCV elimination plan was published in 2016 along with the establishment of a technical advisory group. Georgia updated their plan in 2021 to include HBV. In 2021, a second serosurvey was conducted and Georgia found that the population prevalence had reduced to 1.8% (a 64% reduction).

As part of the Georgia plan, HCV treatment was enabled by a 10-year agreement with a pharmaceutical company. HCV diagnostics, care and treatment services were decentralised, a registry was created and screening and diagnostics were made free-of-charge. In 2020, Georgia initiated a linkage-to-care programme and increased NAT testing on the blood supply. Georgia has screened more than 6 million people and found 101,000 who needed to initiate treatment.

Key lessons for success in Georgia include strong political commitment, aided by public-private partnerships and strong intersectoral collaboration. This was inspired by Egypt's experience where Georgia officials visited Egypt and learned from their experience and then adapted it to the Georgian context. Additional lessons from Georgia for other countries include international partnerships (medication donated, a technical advisory group of international experts, externally funded serosurveys), decentralisation and simplification of access to testing and treatment (free of charge, point of care testing, simplified patient management to reduce tests and medical visits needed), electronic registries for reach time data to target interventions quickly and effectively (screening database as well as HCV treatment registry, unique identifier to link databases), mass awareness campaigns which also address stigma. Georgia also found collateral benefits of HCV elimination programme in Georgia including improvements to blood safety and infection control, health infrastructure and harm reduction services. Next steps for Georgia include strengthening linkage to care, raising awareness, increasing vaccination and application for validation of elimination, including improved measurement of the programmatic and impact targets.

Pakistan: Pakistan is the country with the highest current burden of hepatitis C globally (4.4% in the general population) combined with high HBV burden (1.6%). A programme was announced by the Prime Minister for HCV elimination by 2027 based on Egypt's experience. Pakistan modelled the impact that elimination will have on morbidity and mortality reduction, finding a positive return on investment by 2037. Due to Pakistan's devolved health system, a province level generation of returns on investment were produced to show provinces how the partial funding from the central level would accelerate progress in their provinces if co-funding and implementation was ensured from the provincial level.

Morocco: Morocco has a low national prevalence of HCV (0.5%) and HBV (0.5%), but the country aims to eliminate HCV as part of an integrated approach with HIV and STI. An integrated strategic plan has been developed, with national and regional steering committees. Morocco is establishing screening sites, integrating screening for the three disease areas. Micro-elimination is also a goal for Morocco, where they aim to focus on eliminating HCV among PWID. There is also an aim to expand their electronic medical record system to include HCV

Key issues for success across Egypt, Georgia, Pakistan and Morocco: These include high-level political leadership, partnerships, tailored approaches driven by good epidemiological data with strong data systems and indicators for validation, building investment cases early on to show the return on investment, scaling-up models based on lessons learned, sustainability (domestic financing, innovative

financing and long-term visions for impact). The validation process for elimination is considered useful to help improve programming and maximise impact.

Hepatitis B elimination- Capitalising on lessons learned from hepatitis C

There are several key lessons from the experience with hepatitis C elimination that are relevant for countries in their work to reach the elimination targets for hepatitis B. Georgia, the hepatitis C programme served as a blueprint for hepatitis B, although the hepatitis B programme is still referred to as a “management” programme rather than an “elimination” programme. In Egypt, there has been some leverage of the comprehensive approach to screening of HCV for HBV, but based on the epidemiological data the country is focusing more closely on key risk groups for HBV. The importance of data for informing policy is as relevant for HBV as it is for HCV but remains one of the key barriers to the effective scaling up of services as up-to-date estimates of the epidemiological burden are lacking or outdated. The decentralisation of services and the training of staff who are non-specialists to support in the scale up of testing and treatment was highlighted as a key consideration for countries. A shift towards indicator disease testing is one approach to promote diagnosis of HBV and offer opportunistic testing for specific groups.

Strengthening screening strategies

Several barriers still exist among EU/EEA countries in relation to the testing of populations for HCV. These include a need to strengthen communications to ensure hepatitis is pushed higher up the political agenda and greater funding is allocated to services involved in testing, especially those based in the community. In some countries, high-threshold, hospital-based approaches to testing still dominate and there is a greater need for decentralised services that are well integrated with community programmes, such as harm reduction services. A further issue across the European region is the lack of health insurance in many countries that disproportionately affects many of the key populations that should be targeted for testing. Stigma remains an ongoing concern that can have a major impact on the effectiveness of different screening approaches and needs addressing at the healthcare professional level and in communities.

In overcoming these barriers and strengthening screening programmes, the importance of good data to inform policy is critical. As the epidemiological situation varies across all countries, each testing programme needs to be carefully tailored to the local situation. There are many examples of good practices in relation to scaling up testing including the use of mobile testing services, access to point of care tests and access to fibro-scanning in drug consumption rooms. A shift to decentralisation of services and testing in community settings, including primary care and prisons, is important to reach the populations that need testing. Adding additional work onto services in the community requires a review of funding allocations to ensure that the additional workload is properly funded.

Awareness-raising initiatives among key populations for testing, such as specific migrant populations, are important. Messaging in relation to the risk of cancer associated with hepatitis is important in providing populations with information to enable them to make informed decisions.

Recent changes to international guidance around testing for hepatitis, such as that from EASL or WHO, have helped to simplify the diagnostic pathway. The sustainability of screening initiatives over time is important to ensure all the populations at risk of having HCV infection get tested and to retest those who have been treated but remain at ongoing risk.

Conclusions

The meeting provided a detailed account of Egypt's experience on the path to hepatitis C elimination, what challenges were faced and how these were tackled. Importantly, the information presented at the meeting highlighted what can be achieved with ambition and collaboration. Several of the factors that helped Egypt's success included strong political commitment, the national strategy that included funding, good data and interlinked data systems to guide the elimination programme, decentralisation and task-shifting, a multi-media campaign, the mass screening, and the reduced costs of HCV treatment.

As the HCV situation is quite different in many European countries from that of Egypt, the experiences and key lessons learnt from the Egypt experience need to be contextualised locally. Indeed, many European countries have HCV epidemics that are driven by injecting drug use and thus prevention, testing and treatment needs to be focused on these populations. For prevention, testing and treatment to be successful in any setting however, it was recognised that efforts to tackle stigma and discrimination remain crucial. Going forward, some of the lessons learned from HCV elimination can also be applied to HBV.