The Art and Science of Eliminating Hepatitis: Egypt’s Experience
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Foreword

Making hepatitis C elimination a global reality.

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More than 1.1 million people die from hepatitis B and C every year. An estimated 296 million people worldwide are living with hepatitis B, but only 2% of those are receiving treatment. For hepatitis C (HCV), which is curable, only 21% of the 58 million people worldwide affected by the disease are diagnosed, and fewer than two-thirds of those are on treatment.¹

Nonetheless, despite the scale of the problem, remarkable progress is being made against viral hepatitis. The number of people receiving treatment for HCV increased ninefold between 2015 and 2019.² Since 2014, Egypt, which prior to launching its HCV elimination campaign had the highest rates of hepatitis globally, has screened 60 million people, has treated 4 million people and is now poised to eliminate HCV within its borders.³ This white paper details how this feat was achieved and the transferable lessons for other countries on the same journey.

We recognize that viral hepatitis is one of the few major endemic diseases worldwide for which the 2030 targets to eliminate it as a public health threat could be realized. In doing so, according to estimates from the World Health Organization (WHO), 4.5 million deaths could be prevented in just the next nine years.⁴

The World Economic Forum is working with partners from across the hepatitis community to find ways to support countries to deliver on their plans to eliminate hepatitis. We bring together public, private and non-profit stakeholders to unlock new financing and design public-private partnerships to help eliminate the disease as a public health threat. We hope this paper will support these efforts by sharing the practical steps that can make HCV elimination a reality.
For all the amazing advances in medical science in the last century, only one human disease has ever been eliminated: smallpox. Little more than a decade ago, the idea of eliminating hepatitis C (HCV) would have been inconceivable. Today, the country that once had the highest prevalence of HCV in the world, Egypt, could be the first to eliminate the disease entirely.

This short report outlines some of the critical components of Egypt’s elimination campaign to date. From its inception, through major price discounts, to a screening programme on a scale rarely seen before anywhere in the world, and then to 4 million people being cured, the Egyptian effort to eliminate viral hepatitis can and should be an inspiration to public health leaders around the world.

These insights can be divided into key areas for decision-makers and resourcing institutions interested in accelerating the efforts towards eliminating HCV.

- Political commitment is key.
- Significant resourcing is available from the public and private sectors.
- The reduction of barriers to access screening and treatment is critical.
- Return on investment is demonstrable, and elimination pays for itself quickly.
- Overall public health improves because of the infrastructure and innovation fostered in the elimination programme.

Although some components of the Egyptian programme are unique to Egypt, there is no reason why these lessons could not be adopted by any other country seeking to eliminate HCV.
Introduction

Egypt has made unprecedented progress against HCV, having screened and treated 60 million and 4 million people respectively in the six years following the programme’s launch.

Chronic hepatitis C virus (HCV) infection is one of the world’s leading infectious killers. The World Health Organization (WHO) estimates that 58 million people globally have chronic HCV infection and 1.5 million are newly infected each year. In 2019, 290,000 people worldwide died from HCV, with most dying from cirrhosis and liver cancer.

HCV was first introduced in *The Lancet* in 1975, where it was described as “non-A, non-B hepatitis”. For most of the following fifty years, HCV infection was chronic – the disease could be managed but not cured. In 2013, sofosbuvir, a direct-acting antiviral (DAA) with a 95% cure rate for HCV, was approved by the US Food and Drug Administration. Sofosbuvir, and subsequent DAA, transformed the outlook for patients and health systems, making the elimination of HCV a genuine possibility. DAA are a relatively new approach to treating HCV. They target specific steps in the HCV life cycle that previous treatments could not interrupt. DAAs have shorter treatment times, fewer side effects, and last longer in the body than the previously used drugs.

When sofosbuvir became available, Egypt had the highest number of cases of HCV in the world. A high prevalence of schistosomiasis (also known as bilharziasis) – an acute and chronic disease caused by parasitic worms – led to a mass treatment campaign using intravenous injections between the 1950s and 1980s. The consequence of these injections, however, was to unwittingly spread HCV throughout the population. A survey of the Egyptian population in 2015 found that 10% of people between 15 and 59 years of age had HCV – a huge health problem and associated economic burden. In 2014, Egypt launched an ambitious national hepatitis screening and treatment programme, which, in the following years, grew into a world-leading national strategy to eliminate HCV as a public health threat by 2020.

As the Egyptian programme was accelerating in 2015, the Sustainable Development Goals (SDG) adopted by the United Nations General Assembly included combatting viral hepatitis as one of its targets. Similarly, in May 2016, the World Health Assembly (WHA) set targets for eliminating viral hepatitis, including reaching 90% diagnosis, 80% treatment coverage, and a 65% reduction in related mortality by 2030. The WHA highlighted key barriers to achieving HCV global elimination targets, including finding patients without symptoms, linking them to care, and providing access to affordable treatments.

The Egyptian programme has been a huge success. In the six years, following the launch of the programme, Egypt screened more than 60 million people and treated more than 4 million, resulting in Egypt being well-positioned to become the first country to eliminate HCV entirely. This paper will highlight the seven key elements that contributed to Egypt’s successful HCV elimination programme.
Increased affordability, improved access

The government fully funded all testing and treatment as a result of generic drug competition and negotiating lower costs of screening kits.

Sofosbuvir first appeared on the US market under the brand name Sovaldi. Developed by Gilead Sciences, Sovaldi carried a price tag of $84,000 for a 12-week course of treatment, which, at the time, was one of the most expensive prescription drugs in the US. A series of voluntary licensing arrangements between Gilead and manufacturers brought the price down in some countries. In Egypt, however, the Egyptian Patent Office rejected an application to patent Sovaldi in 2014, opening the door to generic competition and local domestic production.

The lower prices afforded by generic drug production proved to be an important component of Egypt’s elimination efforts. With the introduction of DAA treatments, Egypt’s National Committee for Control of Viral Hepatitis (NCCVH) set a national strategy to make treatment, paid for by the Egyptian government, available to all. However, with a burden of potentially 5 million people, the 2015 price of treatment per patient ($1,650) set mass treatment beyond reach, even though calculations of the economic burden of HCV infection in Egypt estimated that the lifetime direct medical costs, plus the indirect costs of disability and death for a patient with HCV infection, were more than $100,000 per person.

Generic drug production enabled the cost of treatment to fall to $85 per person by 2018. However, another challenge impeded progress. By late 2017, the number of new patients who routinely presented for treatment had fallen below 5,000 a month. In contrast, the economic model making the elimination of the disease by 2030 cost effective required diagnosing and treating six times that number of patients.

Consequently, in 2018, the Egyptian government decided that a more active outreach programme was needed. It negotiated costs as low as $0.60 for HCV screening kits (Abbott’s SD Bioline HCV test) and negotiated the cost of quantitative polymerase chain reaction assays COBAS AmpliPrep/COBAS TaqMan HCV Test, Roche Diagnostics) to $4.80 per test. This, along with the cheaper treatments, meant that the total cost of identifying a patient as positive with HCV fell to $85.41 and the cost of treatment was only $45.24. As a result, testing and treatment could be fully funded by the government for every patient.

Of all patients treated, 58% were covered by the NCCVH and a further 24% were covered by the Egyptian Health Insurance Organization. The testing and treatment component had a total direct cost of $207.1 million. In 2017, the World Bank’s projections estimated the excess cost of HCV elimination incurred by the Egyptian healthcare sector at $530 million but, over time, this would generate savings of $60 million a year for every subsequent year up to 2030.

Several lessons could apply to other countries pursuing HCV elimination. First, mass procurement through a single negotiating body ensured low prices. The costs of diagnostics and treatment in the Egyptian screening campaign could be benchmarks that other low- and middle-income countries could use to reach lower prices. Second, providing tests and treatment at no cost to patients was a major factor driving adherence and programme success – there was no economic reason not to get treated. Third, generic competition played a major role in bringing down the cost of treatments to the level that the Egyptian government could afford. Without that situation, it is hard to imagine that the scale-up necessary to make such progress against the disease could have been achieved.
Political commitment

The launch of the 100 Million Healthy Lives campaign had the highest level of support from senior political leaders.

A mass screening and treatment campaign of the kind conducted by Egypt requires a cross-governmental effort, the support of the private sector. Egypt experienced several years of political upheaval between 2011 and 2013, and had a new government and president in 2014. As HCV was a major health challenge, tackling it was considered by the new administration as a way to bring the country together. However, the cost of treatment limited the government’s ambitions concerning mass screening.

In May 2015, Egyptian President Abdel-Fattah el-Sisi formally asked the pharmaceutical industry to participate in manufacturing cheaper HCV treatments. The request was part of the inauguration of the campaign 100 Million Healthy Lives, which included tackling other health challenges such as noncommunicable diseases. The campaign’s launch by the president demonstrated that the full force of the Egyptian government was behind it.

The HCV elements of the 100 Million Healthy Lives campaign included:

- Senior political leaders participating in the campaign and getting screened themselves, generating coverage of the campaign and setting social norms related to getting screened.
- Screening sites operating 12 hours per day, 7 days per week, to make it as easy as possible for people to access screening.
- A media campaign that helped reduce stigma and educated the public about HCV.
- Free screening and treatment for every patient, as well as free follow-up visits.

A transferable insight for other countries is that without political support at the highest level, it is unlikely that the diverse elements of the campaign – cross-governmental coordination, media, private sector and public engagement – would have come together as successfully.
As referenced in the previous section, the successful outcome of HCV screening and treatment in the national campaign was the result of the collaboration of a variety of organizations and groups who came together to support Egypt’s Hepatitis C Virus Elimination Programme:

- **Senior political leadership:** While the campaign was planned and executed largely by the Ministry of Health and Population, the support of the president, driving cross-governmental efforts, was critical. The effort involved screening millions of people and building training programmes for thousands of healthcare workers, which could not have been achieved without sustained political commitment.

- **The National Committee for Control of Viral Hepatitis (NCCVH):** The NCCVH was established in 2006 and is responsible for monitoring the prevalence of HCV. It is also responsible for the overarching strategy to tackle the disease and played a role in establishing many specialist centres to provide high-quality care for patients, the backbone of their efforts.

- **Non-profit providers:** Screening was not exclusively the domain of the public sector. Several NGOs contributed to the efforts and offered support with the cost of medication for uninsured patients and the anti-stigma programmes.

- **International organizations:** Although led by the Ministry of Health and the NCCVH, the strategy for eliminating hepatitis in Egypt benefited from considerable support from a range of international partners, including the US Centres for Disease Control and Prevention and the Pasteur Institute, headquartered in France.

- **Multilateral institutions:** The WHO played a key role in supporting the initiative and verifying progress, while the global health sector strategy on viral hepatitis served as a key blueprint. The World Bank provided loans to the government to support elimination, as well as assisting with the initial studies to determine the feasibility of the elimination programme.

- **Private sector:** As discussed, the private sector worked intensively with the government, helping reduce the cost of essential supplies and medicines, while a local company, Pharco Pharmaceuticals, played a key role in producing cheap and effective DAAs.

A transferable insight for other countries is that elimination campaigns require multistakeholder coalitions, in addition to political will. The end-to-end process of marshalling data, building awareness, crafting an implementation plan based on the best available science, securing funding, reaching patient populations, deploying screening and treatment, and conducting follow up requires a serious and sustained coalition of actors.
External funding

Egypt received $530 million in funding from the World Bank as a result of prioritizing health resources for addressing HCV.

In 2016, the World Health Assembly saw the global community commit to eliminating viral hepatitis as a public health threat by the end of the SDG period in 2030. Also, in 2016, the World Bank and the Egyptian government began collaborating on modelling scenarios for the elimination of HCV.

The base scenario was a continuation of the existing programme, treating patients who presented for treatment and screening 5% of the population per year on average. A second, more ambitious scenario focused on covering the entire population by 2022, including screening 20% of at-risk individuals each year.  

The World Bank estimated that the more ambitious elimination scenario would be much more expensive in the short term, but the long-term benefits would be considerable – an estimated $420 million saved between 2023 and 2030. Most of these savings were forecast to come through preventing HCV-related complications such as liver cancer.  

Based on these findings, and thanks to the development of cheaper treatments and screening tools, the government shifted from control to elimination and committed to providing care for free. The World Bank committed $530 million from the International Bank of Reconstruction and Development as part of a project that included the hepatitis elimination campaign, but also targeted broader efforts to strengthen primary and secondary care and enhance demand for health and family planning services. The Egyptian government contributed an additional $442.5 million to the project.  

A transferable insight for other countries is that the Egyptian government chose to prioritize health programming within the funds that it could borrow from a financing institution such as the World Bank and focused a large proportion of that funding on HCV elimination. Egypt could equally have not focused on health, but on infrastructure or other aspects of development. Resources may be available for similar projects in other countries if governments choose to prioritize health.
Innovative scientific research

Pharco manufactured a generic form of sofosbuvir after establishing the bioequivalence between the generic drug and the innovator drug, Sovaldi.

The discovery of sofosbuvir was a major breakthrough, turning a chronic disease into a curable one. DAAs, often based on sofosbuvir, are associated with more than 90% success rates, even in “difficult-to-treat” patients such as people with liver cirrhosis and those with a prior null response to other treatments such as interferon and ribavirin. Cheap DAAs were critical to the success of Egypt's hepatitis campaign.

However, prior to treatment, patients must first be screened and diagnosed. Diagnostics partners that supported the screening components of Egypt's programme devoted considerable resources to the effort, including the price negotiations referenced above. Roche, for example, supported local teams with installation and training and made new agreements with third-party logistics companies to provide mobile testing facilities.

The strengthening of infrastructure and trained staff helped expand Egypt's healthcare system capacity, which has subsequently been deployed during the COVID-19 pandemic.

As discussed above, Egypt’s Patent Office had already rejected a patent for sofosbuvir as a drug. However, a patent was pending for the active pharmaceutical ingredient (API) production process and polymorph shape. One of the largest Egyptian pharmaceutical companies, Pharco Pharmaceuticals, applied for a patent to produce the sofosbuvir API by a non-infringement process with a new polymorph shape. This API was manufactured in Egypt through the non-infringement process and therefore not affected by the patent status of the innovator's API. Pharco built a state-of-the-art API production facility in Alexandria, Egypt, to produce the sofosbuvir API using the non-infringement process and conducted a study on the bioequivalence of the sofosbuvir API to the original sofosbuvir under the guidance of the WHO. This study established the bioequivalence between the innovator drug (Sovaldi) and the generic drug, which allowed Pharco to start producing a generic version of sofosbuvir for Egypt.

Pharco also licensed ravidasvir, a drug used in combination with sofosbuvir, from a US research company Presidio Pharmaceuticals for the Middle East and North Africa region and sponsored a clinical trial to see if it would effectively treat the strain of HCV found in Egypt. Based on the clinical trial results, in 2015, Egypt started using ravidasvir as an innovative treatment to be administered in combination with the generic sofosbuvir.

Via subsequent collaborations with the Drugs for Neglected Diseases initiative (DNDi), generic sofosbuvir and ravidasvir clinical trials were conducted in Malaysia and Thailand. Pharco Pharmaceuticals subsequently supplied the Malaysian government with generic sofosbuvir as part of a Malaysian hepatitis elimination initiative.

A transferable lesson for other countries is the value of governments in supporting local innovation initiatives by local pharmaceutical companies by creating clear registration guidelines for innovative products. In Egypt, what accelerated the registration process of the innovative drug ravidasvir was the issuance of a new Clinical Trials Law, and the establishment of a department for the registration of innovative drugs in the Egyptian Central Administration of Pharmaceutical Affairs under the Ministry of Health. The Egyptian Drug Authority was established in February 2020. These regulatory and policy institutions have helped create the necessary guidelines for registering innovative drugs submitted by local pharmaceutical companies.
Outreach and engagement

Mobile screening units and the involvement of nearly every health centre in the screening process meant it was much easier for people to engage.

The 100 Million Healthy Lives campaign was extremely ambitious in its scope. Sixty-two million people fell under the criteria for free HCV screening – every Egyptian over 18 years of age. To service the screening requirements – and subsequent treatments – 60,000 healthcare personnel were trained in just six months between October 2018 and April 2019. This training was spread over more than 5,000 HCV screening or treatment sites.40

Planning started in May 2018. The country was divided into three screening areas, each to be screened for two to three months. Each phase involved 7 to 11 states, 100 to 150 administrative divisions, and a screening target population of between 17.9 million and 23.3 million people.41 Specific programmes were built for high-risk groups, including the prison population. Screening was conducted in nearly every health centre in the country, including police and military hospitals. Mobile screening teams in specially outfitted vehicles augmented the screening efforts by targeting large crowds (such as mosques for Friday prayers, churches for Sunday mass, soccer stadiums during game times, and picnic areas and shopping malls on holidays), as well as factories, office buildings, train stations and subway stations.42

Each screening phase had 5,800 to 8,000 screening teams, with each team comprising a physician, a nurse, and a data-entry specialist. Screening sites were open 12 hours per day, 7 days per week. Staff training started two months before the screening launch in each phase, in which 800 trainers were taught how to train the screening teams to use the rapid diagnostic test for the detection of HCV antibodies, to record data and results in a central patient record database created by the Ministry of Health, and to set further appointments electronically.43

The importance of the communications campaign that ran alongside the screening and treatment processes has already been referenced, but it is also important to note that a key aspect of the success of the 100 Million Healthy Lives campaign was the concerted effort to make it as easy as possible for people to engage. Mobile teams went to where people were, rather than the health system relying on people to come to it, and nearly every health centre was engaged in the process. Without these outreach efforts, it is unlikely that such a large number of people could have been screened in such a short period.
Sufficient and reliable epidemiologic data

The Health Map created by the Egyptian Ministry of Health tracked health outcomes for 50 million people.

The mass screening and treatment effort was underpinned by a robust computer system, integrated with a range of national databases. As part of the efforts, the Egyptian Ministry of Health created a Health Map, which monitored the health status of 50 million citizens and helped identify prevalent diseases in different areas to catch outbreaks and hotspots. These databases, in turn, linked to the national health insurance system, which allowed for more accurate cost estimates.

The underpinning data was drawn from the 2017 national census, which captured population data at the national, state, and district levels. This data was connected to the electoral register, which registers everyone over 18 years of age.

As a result of this infrastructure, Egyptian citizens could be screened in any phase and at any site, regardless of where they lived. Immediately before the screening, the person’s national identification number was electronically checked against the NCCVH database (which includes data on patients who had been previously treated for HCV infection with DAAs after 2014). Patients who had been previously treated were not tested for HCV antibodies. People were tested for HCV antibodies using a finger-prick rapid diagnostic test, with results available within 20 minutes. If a person was found with antibodies to HCV, they were considered infected. Treatment appointments were immediately scheduled electronically for 2 to 15 days later at an assigned centre. The immediate scheduling reduced the likelihood of patients being lost to follow-up. At the follow-up appointment, patients received a clinical evaluation, underwent abdominal ultrasonography, had liver function tests and were tested for the presence of HCV RNA.

With a delay, on average, of five days to receive results, the time between initial contact and screening and initiation of treatment was approximately ten days. The shortest time to dispense treatment was six days and the longest time was 30 days. Turnout for evaluation was continuously monitored. A call centre contacted patients who did not attend their evaluation appointments and those with viremia (the presence of viruses in the blood) who did not return for treatment.

Although participation in screening was voluntary, turnout was very high, with 49.6 million people participating over seven months.
Next steps in Egypt

Egypt has made unprecedented progress towards HCV elimination and is planning to sustain this achievement through continuing the screening programme, particularly in high-risk populations. Screening and successfully treating these groups are priorities. The government has therefore outlined plans to support harm-reduction programmes to reduce the risk of transmission and follow up with 400,000 people identified as having liver cirrhosis, who are more difficult to successfully treat for HCV.

In parallel, there are plans to include those under the age of 18, who were not covered by the initial screening programme. The NCCVH has outlined that it intends to screen children starting school and students about to begin university.

Lastly, a major route of hepatitis B transmission is from mother to child. Expectant mothers are now systematically being screened for HCV and the hepatitis B virus to ensure that no child is born with either of these diseases.

These ongoing efforts will ensure the successful elimination of HCV continues by treating identified HCV patients after screening and thus, preventing the risk of transmission.

Insights from Egypt’s experience tackling HCV

- **Political commitment is key**: A mass screening campaign to target rapid elimination requires cross-governmental and cross-sectoral engagement and effort and needs to be driven from the very highest level of government.

- **Resourcing is available**: The World Bank and other development partners are prepared to make resources available to support hepatitis elimination if a country chooses to prioritize their available funds in this way.

- **Engage with the private sector**: Low commodity costs are critical to an efficient and effective campaign. Egypt negotiated successfully with diagnostics companies and has worked extensively with generic medicine providers.

- **Reduce barriers**: Egypt’s success has been built on a dedicated effort to make screening, testing and treatment for HCV as easy as possible by going into the community to engage with people where they are. Similarly, all aspects of the programme were free to the end user.

- **Return on investment**: Each individual with HCV infection in Egypt was estimated to carry a lifetime cost of $100,000. The World Bank estimated the elimination campaign would cost $530 million but would generate savings of $60 million per year once accomplished. This represents a remarkable return on investment for a public health intervention.

- **Elimination is possible**: For many major infectious diseases, elimination is not possible, especially by the SDG deadline in 2030. In contrast, hepatitis can be eliminated worldwide by 2030. In Egypt, the main screening campaign reached 50 million people in just seven months.
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Endnotes

2. Ibid.
22. Ibid.
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