THE ARAB REPUBLIC
OF EGYPT

MINISTRY OF HEALTH
AND POPULATION

VIRAL HEPATITIS C

PATH TO ELIMINATION DOSSIER

August 2023

Table of Contents

List of abbreviations

A	
ALT	Alanine Transaminase
ART	Antiretroviral Therapy
AST	Aspartate Transaminase
B	
BB	Blood Banks
BMS	Blood Management System
C	
CAPMAS	Central Agency for Public Mobilization and Statistics
CCO	Curative Care Organization
CHE	Current Health Expenditure
CPHL	Central Public Health Laboratories
D	
DAA	Direct Acting Antiviral
DBBs	District Blood Banks
DCV	Daclatasvir
DDM	Data for Decision Making
DH	District Hospitals
E	
EDA	Egyptian Drug Authority
EDHS	Egyptian Demographic and Health Survey
EHIS	Egypt Health Issues Survey
ELISA	enzyme-linked Immunosorbent Assay
EMRO	Eastern Mediterranean Regional Office
EMTCT	Elimination of Mother-to-Child Transmission
ENBTS	Egyptian National Blood Transfusion Services

EQA	External Quality Assessment
ESRD	End Stage Renal Disease
F	
FDA	Food and Drug Administration
FIB-4	Fibrosis-4
G	
GDB	Global Disease Burden
GDP	Gross Domestic Product
GFATM	Global Fund to Fight AIDS, TB and Malaria
GGHE	General Government Health Expenditure
GH	General Hospitals
GHSS	Global Health Sector Strategy
GLOBOCAN	Global Cancer Observatory
GoE	Government of Egypt
GOTHI	General Organization for Teaching Hospitals
H	
HAI	hospital-Acquired Infections
HBBs	Hospital Blood Banks
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HCWs	Health Care Workers
HIO	Health Insurance Organization
HIS	Dealth Information System
HIV	Human Immunodeficiency Virus
I	
IARC	International Agency for Research on Cancer
IBBSS	Integrated Bio-Behavioral Surveillance Survey
IFN	Interferon

IMS	Information Management System
IPC	Infection Prevention and Control
IVA	Independent Verification Agency
K	
KPI	Key Performance Indicator
M	
MENAHRA	Middle East and North Africa Harm Reduction Association
MOHP	Ministry of Health and Population
MoU	Memorandum of Understanding
MTCT	Mother-to-Child Transmission
N	
NAP	National AIDS Program
NAT	Nucleic Acid Testing
NBRA	National Blood Regulatory Authority
NBTC	National Blood Transfusion Center
NCCVH	National Committee for Control of Viral Hepatitis
NCDs	Noncommunicable Diseases
NCRP	National Cancer Registry Program
NCSI	National Centre for Statistics and Information
NEDSS	National Egyptian Disease Surveillance System
NGO	Non-Governmental Organization
NNTC	National Network of Treatment Centers
NSP	Needle Syringe Program
NVTF	National Validation Taskforce
O	
OAT	Opioid Agonist Therapy
OOP expenditure	Out-of-Pocket Expenditure
P	

PCR	Polymerase Chain Reaction
PEG	Pegylated Interferon
PHC	Primary Health Care
PLHIV	People Living with HIV
PMR	Proportionate Mortality Rate
PoA	Plan of Action
PrO	Paritaprevir-Ritonavir-Ombitasvir
PSE	Population Size Estimate
PTE	Path to Elimination
PWIDs	People who Inject Drugs
Q	
QMS	Quality Management System
R	
RBTC	Regional Blood Transfusion Center
RBV	Ribavirin
RDT	Rapid Diagnostic Test
S	
SMCs	Specialized Medical Centers
SMV	Simeprevir
SOF	Sofosbuvir
SVR	Sustained Virological Response
T	
TASE	Treatment at State’s Expense
TTI	Transfusion-Transmitted Infection
U	
UHC	Universal Health Coverage
UHI	Universal Health Insurance
UPA	Egyptian Authority for Unified Procurement

V	
VCTS	Voluntary Counseling and Testing Services
W	
WHO	World Health Organization

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Executive summary

Egypt has long been considered one of the countries with the highest hepatitis C virus (HCV) prevalence in the world. Although HCV infection can remain asymptomatic in most cases, if left untreated it can cause hepatic decompensation, hepatocellular carcinoma, and eventually death. Thus, HCV infection is a serious public health problem that can impose not only a health burden, but also financial stress on the patients, as well as creating a burden for the health system.

Since 2006, Egypt has made great leaps in combating HCV, starting with the establishment of the National Committee for Control of Viral Hepatitis (NCCVH) to set up and implement a national control strategy for the disease and other causes of viral hepatitis. In 2012, the Ministry of Health and Population (MOHP), in collaboration with relevant stakeholders, developed the "Plan of Action (PoA) for the Prevention, Care, and Treatment of Viral Hepatitis – Egypt, 2012-2018" which focused on the seven main components of viral hepatitis prevention and control: surveillance, infection control, blood safety, hepatitis B virus (HBV) vaccination, care and treatment, communication, and research. This PoA was a significant governing step to highlight and implement the goals and objectives of MOHP's viral hepatitis program and reflect MOHP's commitment to controlling the viral hepatitis epidemic by preventing new infections and effectively managing the present cases, thus paving the way towards elimination.

The NCCVH has successfully established a strong infrastructure for controlling viral hepatitis in Egypt. The introduction of direct acting antivirals (DAAs) to the treatment protocols was a milestone with high promises of cure rates. The NCCVH established a nationwide network of digitally connected viral hepatitis-specialized treatment centers, starting with a few centers in 2006 and rapidly expanding to cover the whole country to enhance treatment access. Also, practice guidelines were developed according to the available resources, are regularly updated, and are still used in all affiliated centers.

The Government of Egypt (GoE), represented by MOHP, not only concentrated its efforts in the therapeutic and diagnostic areas but also devoted considerable attention to the preventive aspect of the disease. Throughout the years, the infection prevention and control (IPC) programs, including injection safety and blood safety, have shown significant progress. The umbrella of services was expanded to include people living with HIV (PLHIV) and strengthening the National AIDS Program (NAP), which benefited from the country's interest in eliminating viral hepatitis that presents a risk to key populations. Thus, more organized and integrated efforts to promote harm reduction have gained a political push in recent years.

Since 2016, the GoE has encouraged Egyptian pharmaceutical manufacturers to begin production of generic HCV and HBV medications, utilizing the country's strong infrastructure and human capacities in the pharmaceutical field. This has resulted in the production of millions of anti-HCV DAAs, allowing for the smooth deployment of these medications throughout the Egyptian governorates and facilitating the expansion of access to therapy in both the public and private sectors.

The "100 Million Healthy Lives" mass screening program, which began in 2018 and which the WHO Director-General recognized as the largest campaign in the world in terms of performance, quality, and speed, was the culmination of the Egyptian efforts. This presidential campaign aimed to screen and treat Egyptian citizens for HCV and noncommunicable diseases (NCDs) such as diabetes, hypertension, and obesity, which are risk factors for even more severe diseases. In accordance with the WHO's Global Health Sector Strategy (GHSS) for viral hepatitis, Egypt decided to accelerate all the pillars in order to achieve HCV elimination status more quickly.

This report sheds light on the evolution of the national response to viral hepatitis in general and HCV in particular, which was guided by WHO's GHSS for viral hepatitis (2016) as a map, WHO's recent interim guidance for country validation of viral hepatitis elimination (2021), and the background document for global consultation to update the 2021 interim guidance and define the Path to Elimination (PTE) of the framework for validation of the elimination of viral hepatitis. The report showcases Egypt's current achievements towards PTE of viral hepatitis C in comparison to WHO global targets.

MOHP has established a National Validation Taskforce (NVTF) consisting of 130 members from different MOHP departments, in addition to independent national experts and researchers of different specialties from different institutes. The NVTF collected the required data with the support of the WHO country office in Egypt. After months of hard work and shared effort, MOHP decided to present the dossier, choosing option C which focuses on hepatitis C elimination criteria.

Egypt has made some noteworthy achievements in the elimination of mother-to-child transmission (EMTCT) of HBV, syphilis, and HIV (triple elimination). However, further steps are still needed to achieve the full MTCT targets, which is the reason for choosing option C (elimination of viral hepatitis C as a public health problem - Path to Elimination).

Table i. Programmatic indicators for achieving the gold tier target necessary for *Path to Elimination of HCV* as a public health threat

Indicator	Gold tier target	Achieved target
HCV cascade of care indicators		
HCV diagnosis proportion	80% of people living with chronic HCV are diagnosed	**86.7%**
HCV treatment proportion	70% of people diagnosed with HCV are treated	**93.7%**
Blood safety indicators		
Blood units screened for blood-borne diseases	100% of blood units screened for blood-borne diseases	**100%**
Injection safety indicator	100% injection safety	**100%**
Harm reduction	150 needles/syringes/year in PWIDs (OR a demonstrated 100% coverage increase in NSP coverage within the past 2 years)	100% coverage increase in NSP coverage within the past 2 years

Country context

The Arab Republic of Egypt is a transcontinental country, located in the northeast corner of Africa and the southwest corner of Asia. It lies primarily between latitudes 22° and 32°N and longitudes 25° and 35°E, with a total area of 1 million km^2 (Figure 1).

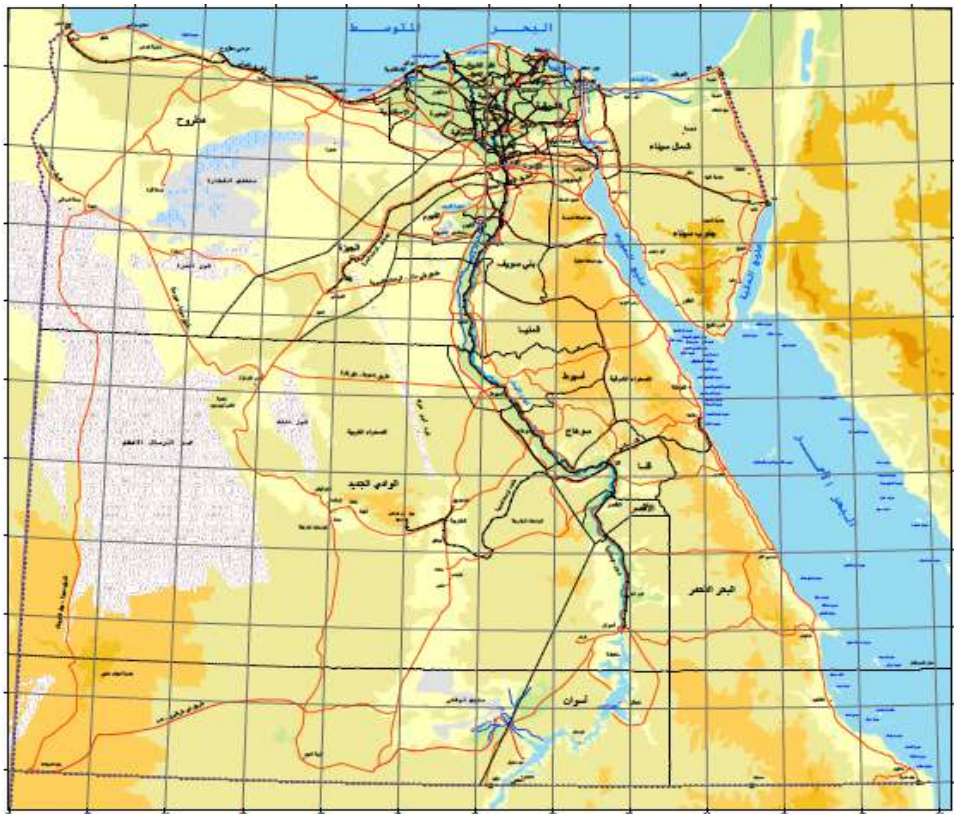

Figure 1. Map of Egypt

Administratively, the country is divided into 27 governorates. The governorates can be classified in four categories: four cosmopolitan (urban) governorates, nine lower Egypt governorates (north of Cairo), nine Upper Egyptian governorates (south of Cairo), and five frontier governorates located along the eastern and western desert borders.

The total population of Egypt in the 2017 census year was 94,798,827 million people, as reported by the Central Agency for Public Mobilization and Statistics (CAPMAS), the main statistical agency in the country. The current population, as of June 2023, is estimated at 105,108,249 people.[1]

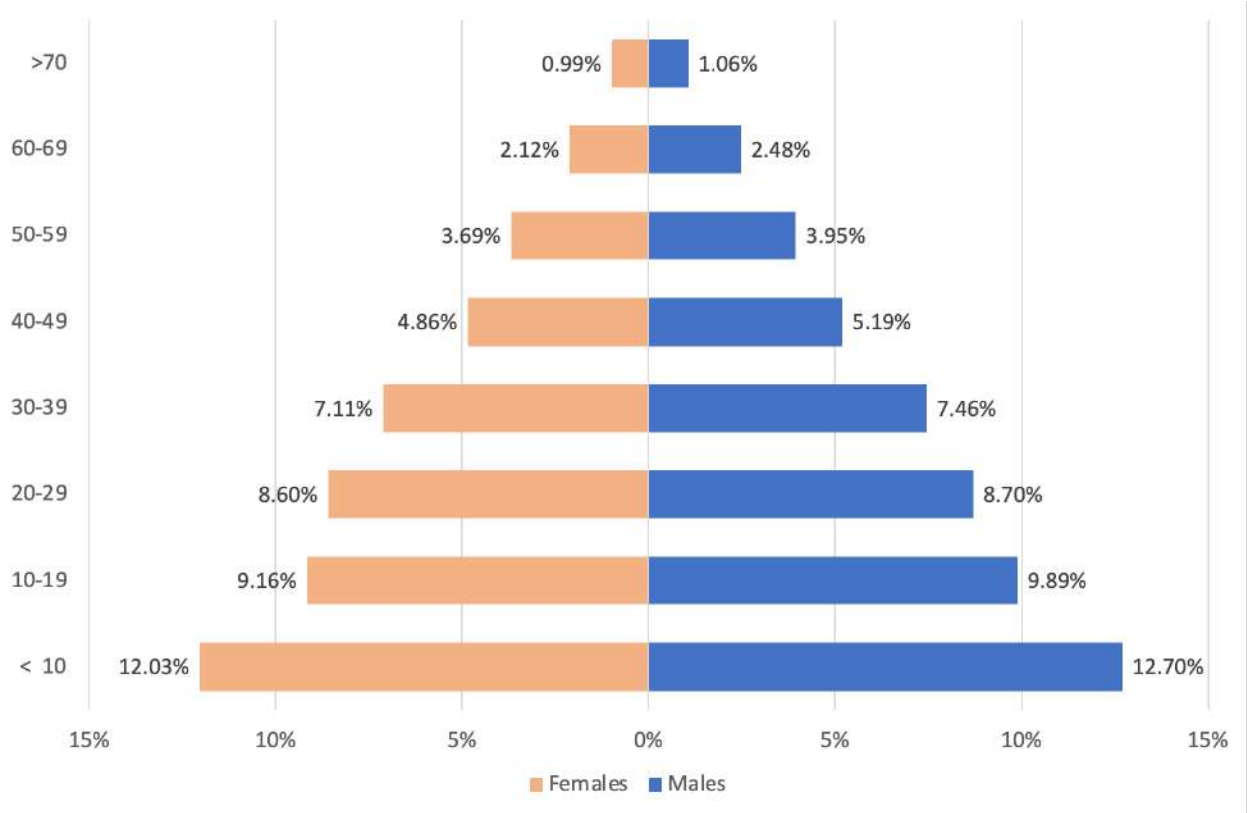

Figure 2. Population pyramid of Egypt (CAPMAS 2022)

1.1. Description of the National Validation Taskforce and summary of review goals

MOHP established the National Validation Taskforce comprised of 130 members from different MOHP departments, as well as experts and researchers from other parts of the country and some international experts. The decree detailing the establishment of the NVTF is available in Annex I.

The NVTF collected the required data with the support of the WHO country office in Egypt. Based on the WHO interim guidance for country validation of elimination options for viral hepatitis C in 2021,[2] and the guidance for country validation of viral hepatitis elimination and PTE of July 2023,[3] MOHP decided to present the dossier, choosing option C out of the certification options for the PTE of viral hepatitis B and C as a public health problem. This option is concerned with HCV elimination only as a public health problem (Table 1). Egypt has prioritized addressing the disease with the recognized health burden, aiming to attain optimal health gains for the largest segment of the population by effectively utilizing the available national resources.

Table 1. Options for validation of Path to Elimination of HBV and HCV as a public health threat

Options	PTE options	Impact indicators	Program indicators
Option A	HBV PMTCT	Already established	Already established
Option B	HBV as a public health problem (including HB PMTCT)	N/A	Coverage of prevention, testing and treatment
Option C	HCV as a public health problem (PTE)	N/A	Coverage of prevention, testing and treatment
Option D	Elimination of both HBV and HCV (including HB PMTCT) PTE	PTE of A, B and C above	PTE of A, B and C above

HBV, hepatitis B virus; HCV, hepatitis C virus; N/A, not available; PMTCT, premarital mother-to-child transmission.

The PTE of HCV focuses only on achieving the key programmatic targets, including prevention services coverage, diagnosis, and treatment; adding to these is the establishment of a simple tool to monitor the reduction of the trends of HCV related mortalities at several sentinel sites having the capacity to determine the attributable fractions of liver-related mortalities, as shown in Table 2.

Table 2. Programmatic indicators for achieving each of the three tiers necessary for *Path to Elimination of HCV* as a public health threat

PTE tier	Impact target	Program target
GOLD TIER	N/A	The gold level recognizes where a country has implemented: ● 100% blood safety ● 100% injection safety ● 150 needles/syringes/year in PWID (OR a demonstrated 100% coverage increase in NSP coverage within the past 2 years) ● 80% of people living with chronic HCV are diagnosed ● 70% of people diagnosed with HCV are treated ● Establishment of sentinel surveillance program for hepatitis sequelae
SILVER TIER	N/A	The silver level recognizes where a country has implemented: ● 100% blood safety ● 100% injection safety ● NSP and OAT present in country ● 70% of people living with chronic HCV are diagnosed ● 60% of people diagnosed with HCV are treated
BRONZE TIER	N/A	The bronze level recognizes the attainment of the 2025 milestones in the GHSS 2022-2030 ● 95% blood safety ● 95% injection safety ● NSP is present in the country ● 60% of people living with chronic HCV diagnosed ● 50% of people diagnosed treated for HCV

GHSS, Global Health Sector Strategy; HCV, hepatitis C virus; N/A, not available; NSP, needle syringe program; OAT, opioid agonist therapy; PTE, Path to Elimination.

Egypt has made some notable achievements in the elimination of mother-to-child transmission (EMTCT) of HBV, syphilis, and HIV (triple elimination), especially regarding HBV vaccination coverage for newborns and infants. HepB-BD was introduced in 2015 and later established within the compulsory infant vaccination schedule nationwide in 2016. Reported national vaccination coverage for HepB-BD was 93.2% in 2022, with coverage for the vaccine at 2, 4, and 6 months reaching 96%. However, further steps are still needed to achieve the full EMTCT targets, which is the reason why option C was chosen.

1.2. Demography and basic health indicators

According to CAPMAS, the country's population was 105,108,249 by the end of June 2023. Egypt has the fastest growth rate worldwide, with the population increasing by 1.6 million from 2021 to 2022. About half of Egypt's residents live in urban areas, with most spread across the densely populated centers of Greater Cairo (Cairo, Giza, Qalyubia), Alexandria, and other major cities in the Nile Delta. The annual growth rate of Egypt's gross domestic product (GDP) was 3.3% in 2021, at an estimated US$ 3,699 per capita.[1]

The crude death rate in Egypt is almost 5.8 per 1,000 population, while the crude birth rate is 25.7 per 1,000 population. The total fertility rate has decreased from 3.2 to 2.85 per woman in 2021 according to the Egypt Family Health Survey. Maternal and under-5 mortality rates are estimated at 33 and 23 per 1,000 live births, respectively.[2]

Egypt hosts approximately 300,000 registered refugees and asylum seekers. Most live in urban areas of Greater Cairo and the north coast. They come from over 60 countries but are predominantly from Sudan, the Syrian Arab Republic (Syria), and Yemen. The GoE grants refugees and asylum seekers of all nationalities access to primary and secondary health care on par with Egyptian nationals. Moreover, Syrian, Sudanese, and Yemeni refugees and asylum seekers are granted full access to public education.[3]

1.2.1. Egypt's epidemiological profile for hepatitis

For a long time, Egypt was considered one of the countries with the highest HCV prevalence in the world. The most common HCV RNA genotype in Egypt is genotype 4, representing more than 85% of all HCV cases in Egypt.[4]

1.2.1.1. Trends of infection

According to the results of the Egypt Health Issues Survey (EHIS) in 2015, the national prevalence rates for positive HCV antibody (Ab) and RNA among individuals aged 1-59 years were 6.3% and 4.4%, respectively. The HCV RNA prevalence appears to have declined in the group aged 15-59 years from an estimated 9.8% in the 2008[5] E-DHS survey, to 7% in the EHIS of 2015.[6] Adults over the age of 40 and those living in rural areas have a significantly higher prevalence.

A presidential initiative to conduct a nationwide mass screening and treatment campaign for HCV and NCDs, "100 Million Healthy Lives," was implemented between October 2018 and the second quarter of 2019. This campaign was a major drive to reach out to chronic HCV cases and successfully link them to treatment. The campaign

screened over 49 million adults over the age of 18. Results of rapid testing for hepatitis C Ab through the campaign showed a further decline in HCV prevalence to reach 4.6%.

In addition, screening of adolescents and children (12-17 years) in years 2020, 2021, and 2022 revealed an HCV Ab prevalence of 0.15%, 0.12%, 0.09%, and 0.08%, respectively.[7]

In 2022, MOHP conducted a household survey in 27 governorates via a multistage cluster sampling technique. A sample of 20,881 household members, aged 1-70 years, available during the visit were interviewed by the survey team using a standardized data collection tool that covered demographic and risk factors for HCV infections. The hepatitis testing component of the 2022 survey involved the collection of blood samples for anti-HCV testing by chemiluminescence technique at the Central Public Health Laboratories (CPHL). Positive anti-HCV specimens were then confirmed by reverse transcription (RT) PCR. Positive laboratory results were reported to patients through phone calls to refer them to MOHP hospitals for medical care and treatment. The preliminary results of this survey are found in this report in the indicators section.

1.2.1.2. Drivers of infection

The origins of the HCV epidemic in Egypt can be traced back to the 1950s through the 1980s, during a mass treatment campaign for parasitic schistosomiasis. During this mass treatment scheme, there were three main causes for the transmission of HCV, as well as other blood-borne diseases. First, patients were exposed to multiple injections over the time period, which increased the likelihood of pathogen transmission. Second, sterilization techniques were extremely poor, which led to a high frequency of HCV transmission. Finally, the mass scale of the anti-schistosomal eradication campaign led to widespread mistakes, including the reuse of equipment, which was not considered important until the advent of the HIV epidemic in the early to mid-1980s.

Acute clinical symptoms are not present in about 80% of HCV infections. Hence, the infection spread quickly and largely went unnoticed. These campaigns were hypothesized to have led to the high HCV seroprevalence rates currently observed in the Nile Delta. The clustering effect between HCV infections in households with schistosomiasis patients who received parenteral treatment further supports this theory. Toward the end of the campaign in the 1970s, oral drugs to treat schistosomiasis were developed, which slowly replaced the tartar emetic injections as the gold standard of treatment. Over the last two decades, most new HCV cases in Egypt have been attributed to HCV transmission in health care facilities related to blood transfusions and suboptimal infection control techniques.

1.2.1.3. Health system in Egypt

The health system in Egypt is considerably fragmented, with many different public and private providers and financing agents. Health services in Egypt are managed, financed, and provided by agencies in all three sectors of the economy: government, parastatal, and private. In addition to MOHP, other sectors that provide health care include the ministries of defense, interior, transport, aviation, and electricity; non-governmental organizations (NGOs); and private hospitals and clinics (Figure 3).[8]

MOHP is the major provider of preventive and curative care programs through its affiliated health facilities. It delivers primary, secondary, and tertiary levels of medical care. Primary health care (PHC) facilities represent the frontline of the Egyptian health care system. The number of PHC facilities has increased, reaching 5,468 in 2020. About 95% of Egyptians live within 5 km of a PHC facility.

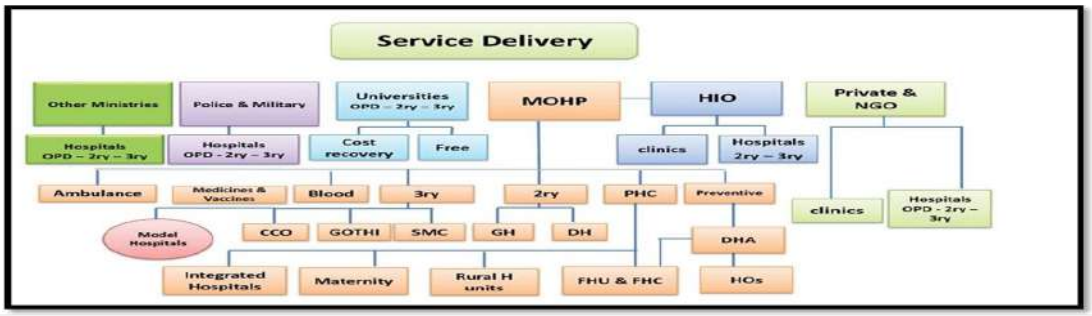

Figure 3. Health system in Egypt: Three sectors in health service delivery

GOTHI, General Organization for Teaching Hospitals; GH, general hospitals; DH, district hospitals; SMCs, Specialized Medical Centers; CCO, Curative Care Organization.

The Health Insurance Organization (HIO) provides medical services to citizens who are covered by health insurance. According to an MOHP report, 68.7 million citizens are covered by HIO. Medical facilities related to the ministries of defense, interior, transportation, civil aviation, and electricity and energy offer medical services to their employees. Other citizens can seek medical services through MOHP, and services are funded by the government through the Specialized Medical Boards.

Through the National Electronic Disease Surveillance System (NEDSS), established in 2002, both the public and private sectors report 41 diseases (including acute viral hepatitis) to the nearest governmental medical facility.

Nonetheless, Egypt is currently pursuing an ambitious vision to restructure the health system. In December 2017, Egypt approved the Universal Health Insurance (UHI) law to accelerate progress towards universal health coverage (UHC). The new law replaced several laws, ministerial decrees, and other directives governing insurance coverage.[9] Under the new law, all Egyptians will be covered through family membership, with the state subsidizing the poor and vulnerable.

Separation of financing from the provision and quality control of health services was established through three new organizations, namely, the Universal Health Insurance Agency as a payer, the Egypt Healthcare Authority as a public health care provider, and the General Authority for Healthcare Accreditation and Regulation for setting quality standards, monitoring quality, and granting accreditation. The new insurance coverage, which will be mandatory for all Egyptians once finalized, is being rolled out in six phases over 15 years, starting with a rollout in Port Said governorate launched in July 2019. The aim is to cover all Egyptian governorates by 2032.

Working towards developing a system of universal health coverage and insurance, MOHP seeks to define adequate health care standards that are part of the internal performance culture of the organizations, e.g. different elements of patient-centered standards like patient safety goals, access and continuity of care, patient and family rights, assessment and care of patients, and patient and family education. A major challenge facing the new system is the deficiency and high turnover rate of qualified personnel in MOHP. Additionally, major transformations in the health sector are leading to profound institutional, functional, and regulatory changes, creating several technical, legal, and institutional challenges that require substantial technical expertise and process management.

In 2016, health expenditure as a share of GDP for Egypt was 4.6%. Health expenditure as a share of the GDP of Egypt fell gradually from 5.5% in 2002 to 4.6% in 2016. According to the latest National Health Accounts data, around 59% of the Current Health Expenditure (CHE) comes from out-of-pocket payments, thus dropping from 71.8% in 2008. General Government Health Expenditure (GGHE) accounted for 32% of CHE and the rest were from firms and NGOs. Government expenditure on health per capita of Egypt increased from US$ 17 in 2003 to US$ 35 in 2017, growing at an average annual rate of 6.25%. The current health financing system architecture is shown in Figure 4.[1]

Through the period 2006-2018, the funding of the hepatitis program was purely domestic, including the financing of prevention, diagnosis, and treatment in all its subdivisions. In 2016, the GoE negotiated with the World Bank to receive a specific health-related loan to improve different health care systems in Egypt, including an ambitious plan to support hepatitis C elimination activities. The loan was under the “Transforming Egypt's Healthcare System” project, a 5-year project that commenced in 2018. The total budget of the project was US$ 530 million, of which US$ 129.6 million was assigned to HCV screening, US$ 130.6 million to HCV treatment, and US$ 50 million to the National Blood Transfusion Services system to improve the screening of blood products for transmissible infections and enhance the nucleic acid testing (NAT) chain.

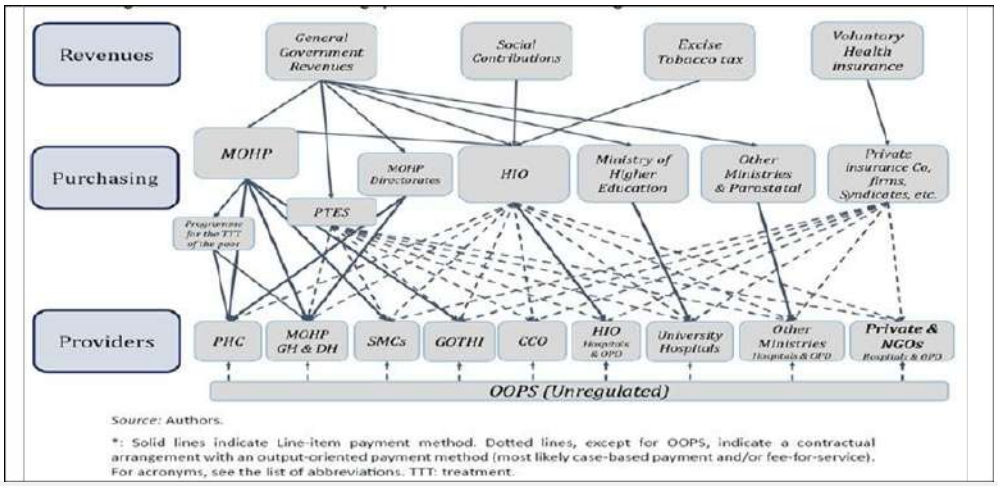

Figure 4. Current health financing system architecture and funding flows

GGHE, General Government Health Expenditure; GOTHI, General Organization for Teaching Hospitals; OOP expenditure, out-of-pocket expenditure; GH, general hospitals; DH, district hospitals; SMCs, Specialized Medical Centers; CCO, Curative Care Organization; HIO, Health Insurance Organization.

Viral hepatitis policies and programs

Since 2001, Egypt has made great leaps in combating HCV, starting with performing the first surveillance for hepatitis,[12] followed by the launch of the first IPC guidelines in 2003 aiming to control hospital acquired infections. In 2006, the NCCVH was established to set up and implement a national disease control strategy. In 2012, MOHP, in collaboration with relevant stakeholders, developed the "Plan of Action (PoA) for the Prevention, Care, and Treatment of Viral Hepatitis, Egypt" 2012-2018, which focused on the seven pillars of viral hepatitis prevention and control namely; surveillance, infection control, blood safety, HBV vaccination, care and treatment, communication, and research.

1.3. First surveillance for hepatitis

In 2001, surveillance for hepatitis started in five fever hospitals in diverse areas of Egypt.[12]

In most governorates, there is one infectious disease hospital to which patients with acute viral hepatitis are referred for care. Hospitals participating in this sentinel surveillance network were selected by MOHP to represent diverse regional ecologies that might influence hepatitis risk: Alexandria, Mahalla, Abbasia, Qena, and Aswan.

Through this network, surveillance protocols were developed, and one surveillance coordinator was assigned to each sentinel site. The surveillance site coordinators were trained and were responsible for interviewing patients, handling logistical issues such as drawing blood, sending samples to the laboratory, and completing data forms. This surveillance system was useful in understanding the epidemiology of HCV infection in the country.

1.4. Development of national guidelines for infection control

In December 2003, the first edition of the national IPC guidelines was developed. In 2005, the WHO adopted the guidelines as a reference for IPC in the EMRO region and distributed it to EMRO countries. It was revised and updated in 2008, as were the national IPC policies for health care facilities. This was a major turning point in the history of Egyptian infection control, since it included all policies related to standard precautions for infection control in health facilities, from hand washing, personal protective equipment, aseptic technique, reprocessing equipment, medical waste management, handling textiles and sheets inside a washing machine, and safe disposal of waste.

1.5. Establishment of the National Committee for Control of Viral Hepatitis

In December 2006, MOHP established the NCCVH. The objectives of the NCCVH include studying the situation of viral hepatitis in Egypt, creating an efficient unified treatment and follow-up program based on the most recent treatment guidelines (the latest HCV guidelines

are available in Annex II), training junior physicians, increasing awareness in both fields of prevention and management, creating a national plan for the prevention of viral hepatitis infections, and building a strong database for research. The advisory board of the NCCVH is in charge of overseeing various divisions in the organization chart. The executive team of the NCCVH is responsible for administrative and operational issues and the monitoring of treatment centers.

1.5.1. The first specialized centers for treatment of viral hepatitis

In 2007, the NCCVH established its first specialized center for the treatment of viral hepatitis. It was located within MOHP health care facilities. The number of comprehensive treatment centers across the 27 governorates increased over time to 26 centers in 2014. By 2018, there were 295 centers nationwide. When allocating treatment centers, it was intended that they be geographically distributed in the most populous areas, so that no patient would have to travel more than 50 km to receive treatment. This ensured better access to care and treatment for patients nationwide.

1.5.2. Before the direct-acting antiviral era (first phase, 2006-2014)

The NCCVH offered treatment to 350,000 Egyptian patients using interferon-based regimens in 26 treatment centers all over Egypt. Treatment started with standard interferon (IFN) injections, then was replaced later by pegylated IFN plus ribavirin for 48 weeks. IFN is known for its high adverse events profile, and the long list of contraindications for HCV therapy, including decompensated cirrhosis and psychiatric disorders. Therefore, only a small proportion of patients were eligible to be treated using these regimens. Furthermore, sustained virological response (SVR) did not exceed 60%.

1.5.3. The First Egyptian National Control Strategy for Viral Hepatitis

In 2008, the NCCVH published the first Egyptian National Control Strategy for Viral Hepatitis.

The strategy comprised several goals for 2008-2012:

- Detect the prevalence and incidence of HCV and HBV infections.
- Reduce the prevalence of chronic HCV and HBV infections in the 15-30 age group by 20% from 2008 levels by 2012.
- Expand access to treatment to within 100 km for all Egyptians and treat 50% of individuals needing treatment by 2012.
- Continue to produce high-quality scientific research.
- Ensure programmatic sustainability.

The plan achieved several goals:

1. The GoE acknowledged the magnitude of the HCV problem in Egypt, as supported by the 2008 Egypt Demographic and Health Survey, which showed an HCV RNA prevalence of 10% among Egyptians aged 15 to 59 years.
2. National guidelines for the treatment of chronic HCV were established.
3. Between 2007 and 2010, 21 specialized HCV treatment centers were established.
4. Governmental funding for HCV treatment programs exceeded 90%.

   However, the strategic plan was a modest success; only about 191,000 Egyptians had started treatment. At the time, treatment modalities included a combination of pegylated IFN and ribavirin given over an extended period. The underlying investment of US$ 80 million in subsidized HCV treatment over 4 years was inadequate. From 2008 to 2012, MOHP emphasized HCV treatment more than prevention of transmission among high-risk groups.
5. The National Network of Treatment Centers

   The National Network of Treatment Centers (NNTC) is the database of the NCCVH which was established in 2010. It succeeded in connecting the NCCVH with 26 units by the end of 2014. Users were connected to a real-time database on Microsoft Dynamic CRM. Currently, all NCCVH treatment centers are connected to the central database using a cloud server.
6. PoA for the Prevention, Care, and Treatment of Viral Hepatitis, Egypt, 2014-2018

   Egypt's second HCV national strategy, covering 2014-2018, is referred to as the Plan of Action (PoA) for the Prevention, Care, and Treatment of Viral Hepatitis The plan aimed to build on the success of clinical trials for DAAs, to overcome the limitations of the previous strategy by emphasizing reduced HCV transmission via increased prevention and education, and to ensure access to safe and effective care and treatment for all Egyptians.

The two main goals of this plan were to:

1. Prevent HCV transmission and treat HCV patients on the treatment waitlist.
2. Offer treatment to 300,000 patients annually.

These goals were implemented along five predefined axes:

- Axis 1: Strengthening surveillance to detect viral hepatitis transmission and disease.
- Axis 2: Improving blood products safety to reduce transmission of viral hepatitis.
- Axis 3: Promoting infection control practices to reduce transmission of viral hepatitis.
- Axis 4: Educating providers and communities to increase awareness about viral hepatitis and its prevention.
- Axis 5: Improving care and treatment to prevent liver disease and cancer.

1.5.4. Evolution of the direct-acting antiviral era (second phase, 2014-2018)

The dream of HCV elimination became more feasible after the introduction of highly potent DAAs in 2014. Newer generations of DAAs are characterized by the pangenotypic effect with a high safety profile, significant effectiveness, and short duration of the treatment course. The second phase depends on DAAs as a cornerstone of management. The NCCVH treatment registration website portal was launched (http://www.nccvh.org.eg/) for reservation and electronic scheduling of visits. This made the registration process easier and more organized, allowing for monitoring of the best results for both service providers and patients.

1.5.5. The DAA treatment program

The national DAA treatment program started in October 2014.[13] More than 700,000 patients with a known diagnosis (>200,000 IFN treatment failures and 300,000 deferred treatments for the presence of cirrhosis or no fibrosis, and a few hundred thousand who had opted not to receive interferon because of the adverse events and low efficacy) were waiting eagerly for the start of the DAA treatment program. The administrative problem of lining up these patients to be evaluated and start treatment was enormous and needed novel solutions.

The NCCVH set up a web-based registration and appointment management system (Figure 5) where patients could register their names, national ID numbers, and residence, in order to be assigned an appointment at the first available time in the nearest center to their residence. Daily workload and appointments were set according to each center's capacity. Patients would receive the appointment details online and by text message to their mobile phones.

Figure 5. Online NCCVH reservation portal

Patients were evaluated for treatment in centers managed by the NCCVH or the Health Insurance Organization where they had a clinical examination, blood counts, biochemical tests, viral load test, and abdominal ultrasound. Initially, the supply was limited to 50,000 patients in the first three months. At that time, it was necessary to prioritize treatment for those patients with advanced fibrosis or cirrhosis. It was decided to limit treatment to patients with F2-F4 fibrosis if patients with cirrhosis were compensated. Initially, a liver stiffness measurement by Fibroscan was mandated to evaluate fibrosis and select patients for treatment. With the initial massive flow of patients and limited availability of Fibroscan machines in the country, patients had to wait several weeks (and in some areas several months) for a Fibroscan appointment. It became apparent that this was a major bottleneck in the program. The fibrosis evaluation method was changed to use FIB-4 as a measure to evaluate fibrosis, where patients with FIB-4 values >3.25 were considered to have cirrhosis, and patients with FIB-4 <1.45 were considered not to have significant fibrosis and were deferred until the availability of more medications.

The treatment pathway was as follows: registration for treatment in the DAAs program using a widely publicized URL (www.nccvh.org.eg) which was made available in September 2014. All persons aged above 18 years who were diagnosed with hepatitis C were eligible to register for treatment. An appointment was then assigned, usually within 24 hours, and the patient then logged on to the website to open a standard form indicating the clinic location, time, and date of the appointment. The assignment was usually to a treatment center in the governorate of residence, and the waiting period for an appointment varied by treatment site and governorate. An initial assessment followed by appropriate treatment was initiated. The patient was then followed up until the end of the treatment regimen, and PCR was done to detect viral load at the end of treatment and after 12 weeks to establish a complete cure.

Almost all patients were treated with different combinations of SOF-containing regimens (only a small minority [3%] with paritaprevir-ritonavir-ombitasvir [PrO], which was reserved mostly for patients with renal impairment). All DAA-treatment failures were re-treated with a SOF-containing regimen (SOF-SMV-DCV or SOF-PrO with or without RBV). The real-life SVR rates for treatment with SOF-containing regimens were 94% with SOF-PEG-RBV, 83% with SOF-RBV, 97% with SOF-SMV, and 98.5% with SOF-DCV.

Table 3. First line treatment options in the national HCV program

Time interval	First line therapies
2006-2014	PEG-IFN + RBV
2014-2015	PEG-IFN + RBV + SOF / SOF + RBV
2015-2016	SIM+SOF / SOF+DCV
2016-2018	SOF+DCV ± RBV / PrO +RBV
2018-present	SOF+DCV ± RBV

By 2018, more than 2 million patients had started treatment. They were almost all those who were living with the diagnosis. The program started losing momentum, and the number of patients registering for treatment monthly decreased to less than 10,000, much less than the necessary number to sustain the elimination targets, which necessitated treating at least 350,000 patients per year.

1.6. Screening program

There have been several focused attempts to discover hidden chronic HCV cases in Egypt, as described in the following waves:

1.6.1. Wave 1: Focused screening

In September 2016, following a cabinet decree, Egypt began screening for HCV using ELISA testing for six categories (prisoners, hospital in-patients, blood donors, university freshmen students, governmental employees, and pre-employment screening for those traveling abroad). This program succeeded in screening 1.5 million people in less than a year.

1.6.2. Wave 2: Field screening

In 2017, the first field screening was conducted in 3 governorates in Upper Egypt and succeeded in screening 1.8 million people using rapid salivary tests. This was associated with many campaigns for screening in many rural areas (Figure 6).

Figure 6. Mobile clinics for screening (2017)

1.6.3. Wave 3: Mass screening, nationwide HCV and NCD screening and testing campaign “100 Million Healthy Lives” (A step closer to viral hepatitis elimination)

In 2018, MOHP launched a massive screening campaign, which began on 1 October 2018. The objective was to identify all individuals with HCV who were to be treated at the expense of the state. The screening was performed by a WHO-prequalified finger-prick-based rapid test (SD Bioline HCV, Abbott, Abbott Park, IL, USA) for individuals in outreach and rural areas (which included most of the target population) (Figure 7), and blood-based immunoassay for screening done in hospitals and central facilities.

Seropositive individuals were referred for HCV-RNA testing in 350 hospital facilities; those found to be positive were referred for evaluation and treatment in 172 specialized HCV treatment centers. Referral was done to the nearest treatment center using the national ID as a unique identifier for the patient.

At the same time, a simultaneous screening program screened adolescents (between the ages of 12 and 18) in middle and high schools. They were screened in their schools if their parents signed a consent from agreeing that their child would be tested for HCV and treated if indicated. Although screening was carried out in schools to prevent stigmatization, the results were not given to the students or the school staff but were instead mailed to the parents, with an appointment at Health Insurance Organization clinics nationwide for positive children to be evaluated and treated away from their schools. This was the first teenage screening and treatment program for hepatitis C to be conducted worldwide.

Figure 7. Screening and testing sites, "100 Million Healthy Lives"

MOHP applied ***WHO's core testing principles*** during this national mass testing, including voluntary consent, confidentiality, counseling, correct test results, and connection (linkage to prevention, treatment, and care, and support services), to maximize both individual and public health benefits while ensuring client confidentiality.

The country was divided into three screening phases, as displayed in Table 4. Each phase was finalized over a period of 2 or 3 months and included seven to eleven governorates, 100 to 150 administrative divisions, and a screening target population of 17.9 million to 23.3 million. A detailed description of the screening sites, process, and verification can be found in Annex III.

Table 4. Phases of the presidential initiative campaign, 2018-2020

Phase	Frontier governorates	Delta	Urban governorates	Upper Egypt
I. Oct-Dec 2018	South Sinai	Damietta	Port Said	Fayoum
	Matrouh	Beheira	Alexandria	Assiut
		Qalyubia		
II. Dec 2018 - Feb 2019	North Sinai	Kafr El-Sheikh	Cairo	Sohag
	Red Sea	Menofia	Ismailia	Beni Sweif
			Suez	Luxor
				Aswan
III. Mar-Apr 2019	New Valley	Gharbia	Giza	Minia
		Sharqia		Qena

1.7. HCV elimination programs for special populations and age groups

MOHP has started screening and treatment programs for special populations and age groups, aiming to control and eliminate HCV in these populations.

1.7.1. Screening campaign for children and adolescents

Screening of 3,024,325 adolescents (15-17 years) and 3,807,260 children (12-14 years) revealed HCV Ab prevalence of 0.38% and 0.22%, respectively. Moreover, there was continuous screening every year of 12-year-old school students, covering 1,750,425 children in 2020, 1,321,660 in 2021, 1,785,833 in 2022, and 1,665,899 in 2023, and revealing an HCV Ab prevalence of 0.15%, 0.12%, 0.09%, and 0.08%, respectively.[14]

1.7.2. Screening program for hospital in-ward patients

Screening patients prior to medical intervention is recommended for better infection control. From August 2023 in 2016, 721,029 inpatients were screened for HCV with anti-HCV seroprevalence (1.4%). These patients were linked to care using the same electronic system as the initiative, to proceed with further steps of assessment. In 2020, MOHP began to use the triple test kit (HCV, HIV, and HBV) in this project to cover the most common blood-borne pathogens.

1.7.3. Screening program for people living with HIV

Due to shared risk factors, HCV co-infection is common in PLHIV. The prevalence of the hepatitis C virus seropositivity in PLHIV increased from 10% among those with high-risk sexual behavior to 90% with injection drug use. Combined infections accelerate disease progression. Treatment decisions are always complicated due to a poor immune state and drug-drug interactions with antiretroviral therapy (ART); therefore, the elimination of HCV ensures a better disease course and outcome for people with HIV. A long-term care program has been designed for HCV/HIV co-infected patients.[15] Linkage between all HIV and HCV treatment centers was done with a conjoint protocol for the management of co-infection. Among 19,501 known PLHIV in Egypt, 5,084 (26.1%) were discovered to be seropositive for HCV through screening. All of them have been linked to care for HCV.

1.7.4. Screening program for end stage renal disease patients

Managing an HCV patient with end stage renal disease (ESRD) is always challenging. Limitations in treatment options as well as dose modifications remain the main obstacles to HCV elimination in ESRD patients. Frequent screening is also highly recommended due to their high susceptibility to re-infection, especially for those who use hemodialysis machines. The treatment protocol used ombitasvir/paritaprevir/ritonavir, which were later replaced by sofosbuvir-containing regimens after the published safety reports regarding its usage in ESRD.[16]

A periodic screening program was launched to provide regular testing every 6 months, either by Anti-HCV for HCV-naive patients or by HCV RNA for those who had previously received HCV treatment. Patients who test positive will be linked to care through the same mechanism as the screening program for hospital in-patients.

Among dialysis patients, the annual HCV incidence rate declined from 28% in 2001 to 6% in 2012 and just 1.6% in 2015.

1.7.5. Screening program for chronic blood disease patients

A program of periodic screening for chronic blood disease patients (sickle cell anemia, hemophilia, thalassemia) was launched. The target population of this program is 9,611 patients.

1.7.6. Screening program for people attending mental health and addiction treatment clinics

Through the cooperation between the NCCVH, National AIDS Program and General Secretariat of Mental Health and Addiction Treatment, MOHP, 20 centers for screening and treatment of viral hepatitis and HIV were established in the centers for mental health and addiction treatment. Through August 2023, 70,282 were screened and 2,804 (4%) patients were discovered to be seropositive.

1.7.7. Screening program for blood donors

As a continuation of previous efforts, an electronic link was established between the blood bank network, which connects 135 blood banks throughout Egypt, and the NCCVH database for electronic referral to treatment centers for patients who tested positive for anti-HCV antibody testing. Through August 2023, 1,182,794 were screened and 14,578 (2%) were discovered to have positive anti-HCV antibodies.

1.7.8. Screening program for refugees and asylum seekers

A special program of free testing and treatment for HCV in refugees and asylum seekers was launched in 2019. According to UNHCR, as of March 2023, 291,578 refugees were registered in Egypt. Screening was done for 68,843 with only 495 (0.06%) testing positive for anti-HCV antibodies.

1.7.9. Screening program for prisoners

Through the mass screening campaign, prisoners were offered through mobile teams HCV testing and treatment services. Through August 2023, 105,606 prisoners were screened. Anti-HCV antibodies were positive in 15,007 (14.2%). Treatment has started for 74% of eligible patients.

1.7.10. Screening program for people with deaf-mutism

A whole parallel model of care was optimized and modified for people with hearing or speech disabilities among the activities of the mass screening campaign for HCV. The health care workers (HCWs) were trained on sign language, interactive video call systems were used, and informative videos using sign language to raise health awareness made. Several meetings were held with societies of people with hearing or speech disabilities in all governorates to raise awareness, spread knowledge, and address comments.

1.8. Social engagement and NGOs' role in HCV elimination

1.8.1. MOHP program for infection control in barbershops and beauty salons

MOHP launched a program designed to control the transmission of HCV and other blood-borne diseases through beauty salons and barbershops. This campaign aimed to raise awareness about how to prevent the spread of hepatitis and eliminate possible routes of infection. Shared grooming items for hair or nails could be a source of infection if not well disinfected. Hence, beauty salons and barbershops were encouraged to adopt single-use disposable tools and these tools were dispensed to barbershops. Safety practices in these beauty centers were legalized in cooperation with the Ministry of Local Development.

1.8.2. NGOs' role in HCV elimination

The Tahya Misr Fund participated efficiently in the elimination of HCV by establishing a center of excellence for HCV in Luxor, where they provided all care services free of charge and successfully treated more than 10,000 HCV patients. Additionally, they donated HCV medications to the presidential initiative campaign as a part of their social role in HCV elimination.

Bait Al Zakat Foundation also shared in HCV elimination through their treatment center at Al-Azhar specialized hospital, where they treated more than 2,000 HCV patients. Additionally, medications for more than 30,000 patients were donated to MOHP.

The Society for the Care of Liver Patients in Dakahlia specializes in supporting patients with chronic liver disease. It has many treatment centers in Egypt, especially in the Nile Delta region. All these centers participated in the first two stages of the presidential initiative campaign.

Programmatic targets for being on the *Path to Elimination of HCV*

1.9. HCV cascade of care indicators

The achievement of programmatic targets for being on the *Path to Elimination of HCV* as a public health entails addressing both diagnostic and treatment targets (Tables 5, 6, 7) (Figures 8, 9, 10, 11) as well as prevention targets, as per WHO interim guidance for country validation of viral hepatitis Path to Elimination (PTE), 2023.

The variation among governorates regarding the proportion of patients diagnosed and treated could be due to the internal migration between governorates, as some governorates have growing populations (e.g. New Valley) and others are shrinking (e.g. Matrouh).

Table 5. HCV cascade of care indicators

Indicator	Gold tier target	Achieved target
HCV diagnosis proportion	80% of people living with chronic HCV are diagnosed	**86.7%**
HCV treatment proportion	70% of people diagnosed with HCV are treated	**93.7%**

1.9.1. Methodology of assessment of HCV cascade of care indicators

1.9.1.1. Method of person identification and follow-up

Each Egyptian citizen has a 14-digit national ID number. This ID number is linked to an array of information, including the holder's date of birth, gender, and birth governorate. The screening for HCV using Ab, confirmation of diagnosis, treatment, and treatment response are recorded using the national ID. This can help accurately identify citizens across different national databases.

1.9.1.2. Baseline assessment of disease burden

To assess the HCV disease burden in Egypt, we used the national Egyptian Health Issues Survey (EHIS) in 2015 as a starting point for our cascade of care.

In EHIS, the multistage stratified sampling method was used to ensure a nationally representative sample. Stratification and primary sampling units (PSUs) were based on the most recent census carried out by the Egyptian Central Agency for Public Mobilization and Statistics (CAPMAS) at that time. EHIS enrolled a sample of 614 PSUs with a total sample size of 16,671 participants aged 1-59 years old.

1.9.1.3. Epidemiological profile at the national and governorate levels

1.9.1.3.1. Prevalence

The national screening, which started in October 2018, targeted the population above the age of 18. The overlap between the EHIS and the national screening lies in the age group 15-59 years.

The population size of the 15-59 age group through 2015-2022 was based on official reports from CAPMAS, both on the national or governorate levels.

Estimation of the targeted HCV positive patients in the age group (15-59 years) was based on the 3 time points of national HCV RNA prevalence in:

- EHIS 2015: 7%
- National screening campaign 2019: 3.1%
- MOHP survey 2022: 0.38%

As the prevalence followed a continuous downtrend, the yearly HCV RNA prevalence was estimated as if it declined at a gradual yearly rate. The annual decline in prevalence was estimated by dividing the difference between each two time points by the interval between them. For example, based on the prevalence in 2015 (7%) and 2019 (3.1%), the prevalence reduction was 3.9%, and the estimated annual decline = prevalence in 2019 - prevalence in 2015 / 4 years = 0.975 per year. The same estimations were used for the prevalence at the level of governorates.

1.9.1.3.2. Incidence

The annual incidence at the national level was estimated using the same methods of prevalence estimation in the same age group (15-59 years) based on the two following time points:

- Meta-analysis of the available studies for HCV incidence 2015: 0.003
- MOHP survey 2022: 0.000092

HCV RNA incidence in each governorate was weighted according to the national prevalence and the prevalence in this governorate.

1.9.1.3.3. Deaths

Annual deaths were estimated based on the prevalence, incidence, and crude death rate reported by the CAPMAS for the same age group (15-59 years) from 2015 to 2022.

1.9.1.3.4. Diagnosis coverage

The total number of HCV RNA positive patients who were diagnosed was calculated by the following equation: (total treated + total ineligible for treatment).

Data sources:

- Patients treated in the public sector: MOHP databases (NCCVH, HIO).
- Ineligible to treatment: MOHP database (Specialized Medical Boards).
- Patients treated in the private sector: Egyptian Drug Authority (EDA) report (Anti-HCV drug dispensed in the private market).
- Patients treated in NGOs: Reports from NGOs.

Table 6. HCV cascade of care in Egypt through the period 2015-2022 (age 15-59 years)

	N	%
Estimated number of patients with positive HCV RNA, 2015-2022	3,867,964	
Number of diagnosed patients (cumulative), 2015-2022	3,351,734	86.7
Number of treated patients (cumulative), 2015-2022	3,139,983	93.68
Sustained virologic response	3,096,651	98.62
Estimated number of people living with HCV in 2022	221,613	

Data source: MOHP databases (NCCVH, HIO)

Table 7. Patients treated in Egypt through the period 2015-2022

	Patients treated in MOHP according to age groups (n)	
	12-17	18,477
	18-29	253,037
	30-39	455,208
	40-49	608,783
	50-59	941,435
	60-69	665,289
	70-79	202,665
	80-89	35,864
	90+	2,223
1	Total patients treated in MOHP (n)	3,182,981
2	Patients treated in public sector outside MOHP (n)	94,116
3	Patients treated in NGOs (n)	159,368
4	Patients treated in private sector (n)	628,037
5	Total patients treated outside MOHP (n) = 2 + 3 + 4	881,521

MOHP, Ministry of Health and Population; NGOs, non-governmental organizations.

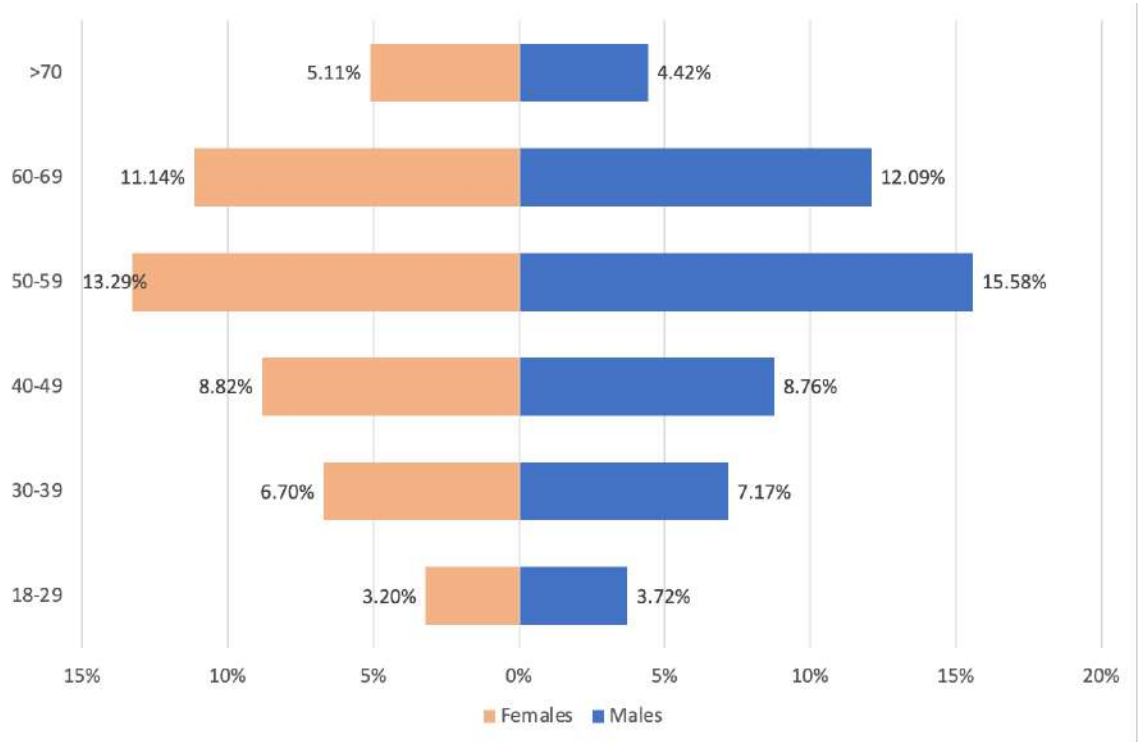

Figure 8. Diagnosis distribution by gender and age group

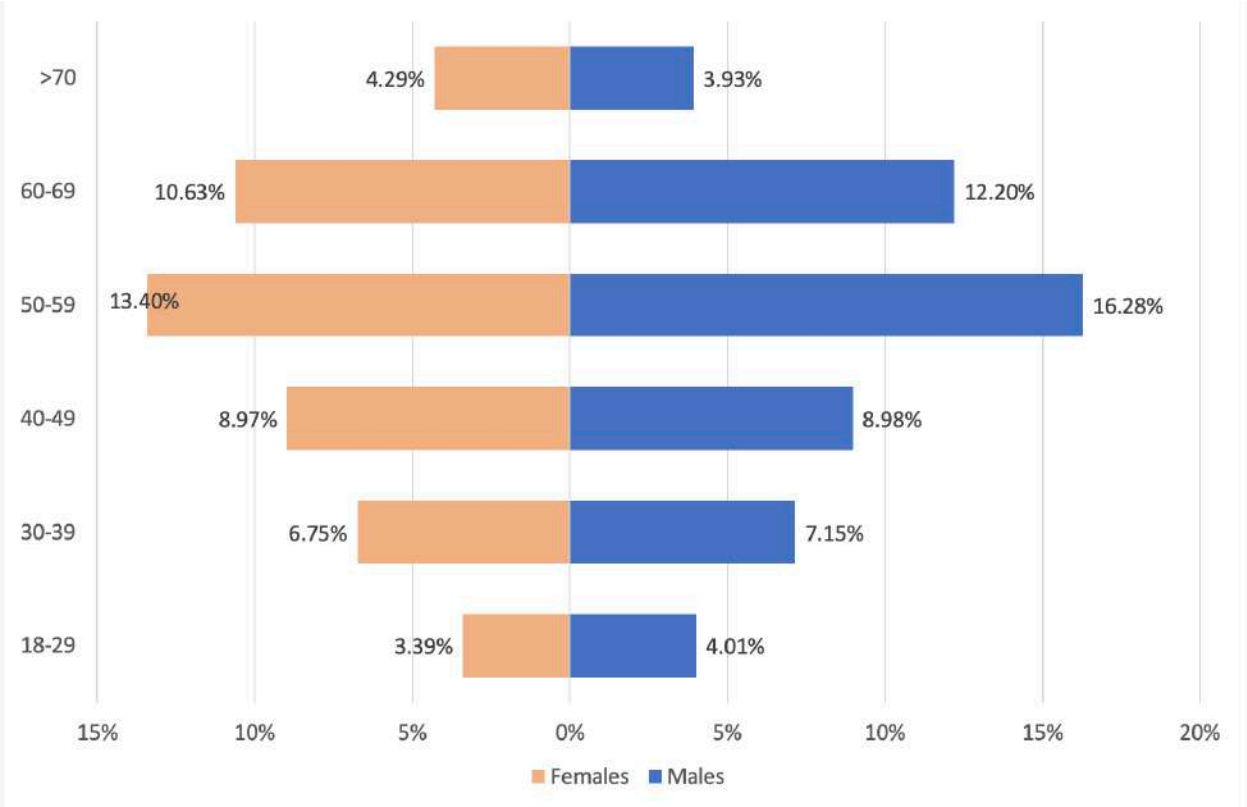

Figure 9. Treatment distribution by gender and age group

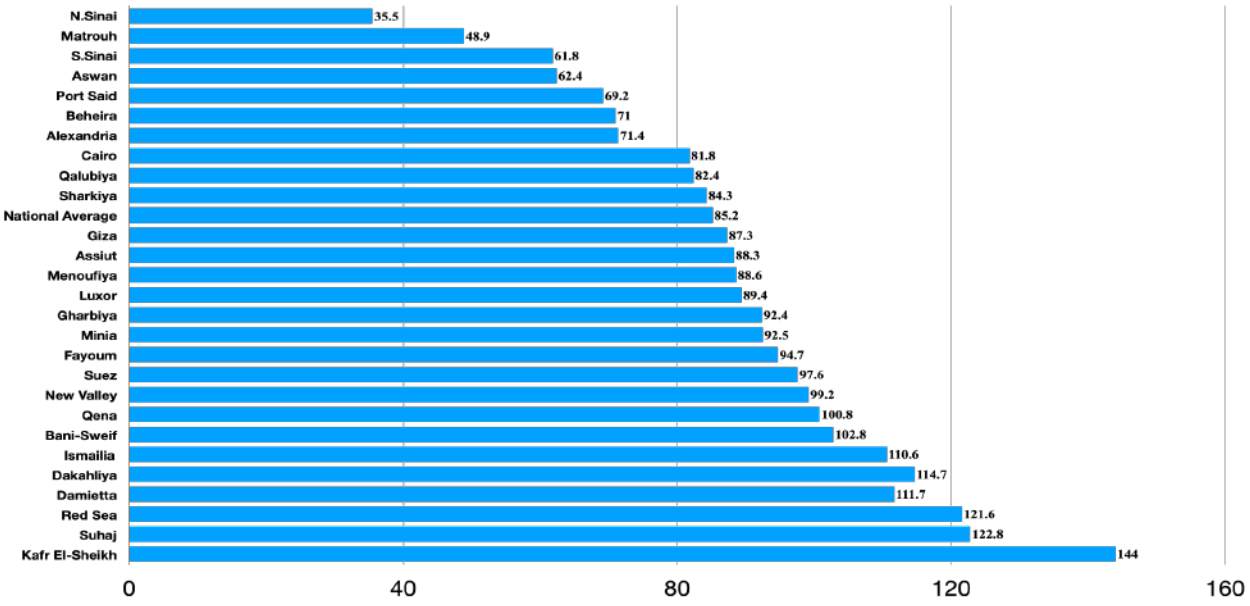

Figure 10. Proportion of patients with chronic HCV diagnosed by governorate, Egypt 2022

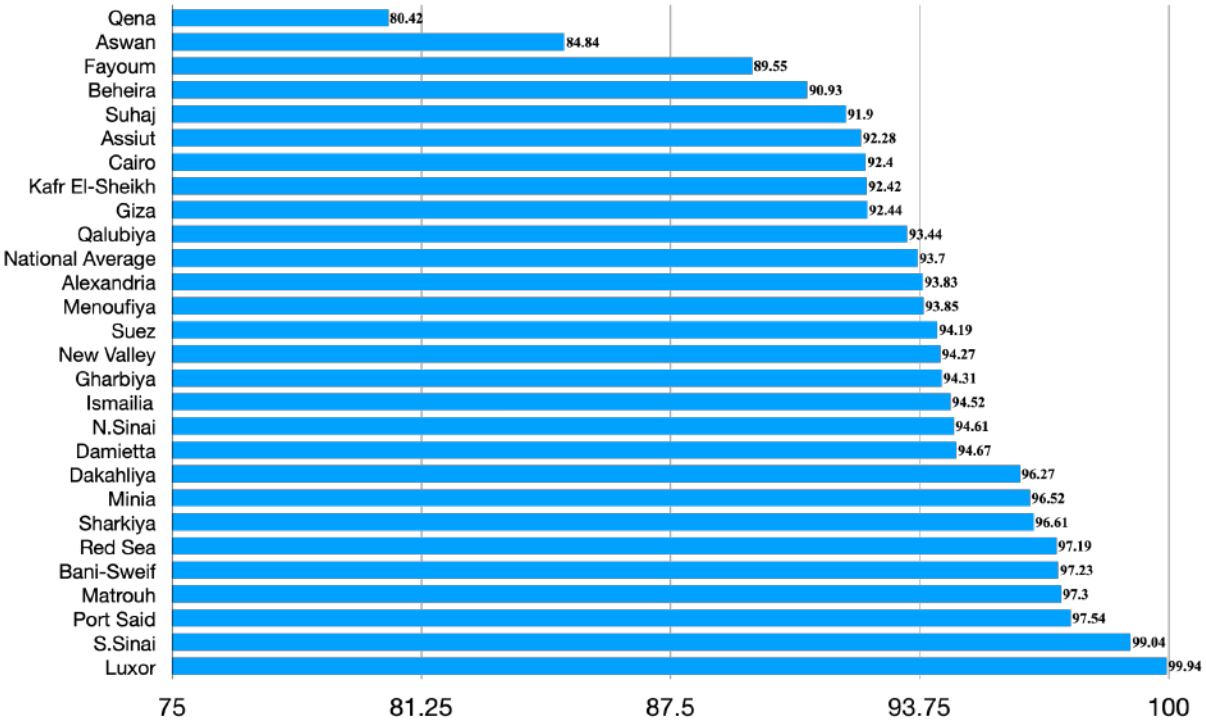

Figure 11. Proportion of those with chronic HCV treated by governorate, Egypt 2022

The detailed table of the HCV cascade of care for the age group 15-59 by governorate is available in Annex IV.

1.10. Blood safety indicators

Blood transfusion is an essential part of modern health care systems. When performed correctly, it saves lives or rapidly improves serious clinical conditions. However, blood transfusion carries a potential risk of immediate or delayed complications and transfusion-transmitted infections (TTIs), hence its presence as in the programmatic indicator in the Path to Elimination criteria is crucial (Table 8).

The Egyptian National Blood Transfusion Services (ENBTS) is a network of appropriately equipped blood transfusion centers. After the National Blood Transfusion Center (NBTC) was inaugurated in November 2000, the network was expanded to include 21 Regional Blood Transfusion Centers (RBTCs) and six district blood banks (DBBs) in the remote governorates to satisfy the needs of safe blood and blood components in Egypt.

The ENBTS is dedicated to a system of quality management to ensure that its blood products and services satisfy the needs and expectations of Egyptians and Egyptian health-care providers. Its quality systems program relentlessly pursues a customer-focused, management-driven, prevention-based quality system using performance measures that are challenging,

visible, and understandable, where all employees actively contribute to the continuous improvement process.

In addition, the university hospitals are a large chain of hospitals with a parallel network of blood banks that offer hundreds of thousands of units of blood products to their patients and are distributed in almost all the Egyptian governorates. The first university hospital blood bank started offering services in 1960 at Alexandria University, and they have since expanded to 25 universities, including nearly 106 hospitals and specialized institutes.

Table 8. Blood safety programmatic targets and current status in Egypt, 2022

Indicator	Gold tier target	Achieved target
Blood units screened for blood-borne diseases	100% of blood units screened for blood-borne diseases	100%

1.10.1. Governance, structure and composition and the network of blood banks in Egypt

- MOHP has 306 blood banks (188 storage banks and 118 collection banks).
- University hospitals have 46 blood banks (6 storage banks and 40 collection banks).
- Private hospitals have 98 blood banks (69 storage banks and 29 collection banks).
- NGOs have 3 blood banks (57357 Hospital, Red Crescent, and Orman).
- The total units of blood collected are estimated to be 1,600,000 per year.

1.10.1.1. The Blood Regulatory Council

Egypt has a national Blood Regulatory Council that is responsible for setting national policies and strategies to ensure homogeneity and governance in function and workflow for all stakeholders. It is regulated by Egyptian Law No. 8/2021. The roles and responsibilities of the Blood Regulatory Council are detailed in Annex V.

1.10.1.2. National blood transfusion policy in Egypt

It is an important principle of the national blood transfusion policy that adequate, safe, and effective blood products and services for Egypt are ensured in the entire country (including remote areas). This policy therefore sets out the intention and commitment

of the GoE to develop a modern blood transfusion service which has the responsibility for the collection, testing, processing and distribution of blood and blood products to the entire country. This policy also identifies the responsible regulatory body for blood transfusion activities in Egypt.

The goal of MOHP regarding the safety of blood and related products is to provide a comprehensive national system that ensures:

1. The provision of an adequate supply of safe and effective blood and related products to all patients.

2. The appropriate use of blood and related products.

3. Equal access to safe blood transfusions across all of Egypt.

4. The sustainability and cost-effectiveness of the NTBS.

5. Adoption and strict implementation of the national policy for blood and blood products.

1.10.1.3. Voluntary non-remunerated blood donor program

The basis of the blood donor program is the recruitment and retention of voluntary, non-remunerated blood donors from low-risk population groups.

1.10.2.Operation and quality management of the network of blood banks in Egypt

1.10.2.1. Laboratory testing

All blood donations are screened for transfusion-transmissible diseases as defined in the Egyptian national standards for blood transfusion in a quality-assured manner.

1.10.2.2. Storage and distribution of blood and blood products

MOHP and the NBTS shall procure and make available the equipment needed to ensure that all blood and blood products are stored and transported at the correct temperatures at all points throughout the transfusion chain.

1.10.2.3. Appropriate clinical use of blood and blood products

National guidelines for appropriate clinical use of blood and blood products (ACUB) are continuously updated and promoted by the NBTS to suit the health needs of the country.

1.10.2.4. Hemovigilance

The NBTS shall establish a hemovigilance system for Egypt covering all transfusion activities, from the collection of blood and its components to the follow-up of its recipients, wherever they are performed.

1.10.2.5. Quality management system

The NBTS and National Blood Regulatory Authority (NBRA) ensure the quality of all blood and related products through the development of a comprehensive and appropriate national quality management system (QMS).

The NBRA appoints a national secretary for both the NBTS and the NBRA who will have the responsibility and authority for ensuring the overall functioning and effectiveness of the systems in their respective organizations.

The NBRA includes all the quality requirements as described in WHO's Quality Management Program for Blood Transfusion Services.

The NBRA ensures that there is a regular review of all the QMS activities of the respective organizations.

The NBRA in conjunction with other experts ensures that appropriate national standards for blood transfusion practice are implemented.

MOHP and the NBRA ensure that it is fully and appropriately licensed and accredited to function as the responsible body for the regulation of blood transfusion activities within Egypt.

1.10.2.6. National information management system

The NBTS is responsible for the initial development, implementation, and ongoing development of a comprehensive information management system (IMS) covering all the activities of the NBTS.

A blood management system (BMS), which is a software system that connects 17 regional blood banks belonging to the National Blood Transfusion Services, has been implemented. It also connects the blood banks belonging to MOHP's public hospitals. The BMS helps to ensure complete control over the selection of blood donors and a complete tracking system for blood and blood products.

1.10.3. National efforts for optimization of blood safety

1. Increasing awareness and culture about the importance of blood donation includes increasing donors' knowledge of the importance of blood donation as well as encouraging voluntary, non-remunerated blood donation. Additionally, organizing blood donation campaigns with the participation of NGOs that have a significant contribution to make in the recruitment of blood donors and organizing lots of regular successful blood campaigns and awareness campaigns.
2. Implementation of the strategic plan for screening the donated blood and ensuring that it is free from blood-borne infectious diseases by using validated techniques and reagents. This includes:
    - **Serological screening of donors' samples.** This is to ensure that all blood donations are non-reactive to TTIs (hepatitis B and C, HIV, and syphilis), using the most recent technologies in screening platforms and assays, as well as performing evaluation and validation of the used kits and reagents. In addition, nucleic acid testing (NAT) for HCV, HBV, and HIV has been introduced in the screening of blood units since 2008 as a modern technology to detect the DNA and RNA of the viruses, which helps to reduce the window period for the detection of reactive cases.
    - **Implementing a counseling system for serologically reactive blood donors** as another sample is withdrawn from donors after 2 weeks for confirmatory testing, to ensure that the donor is notified appropriately of any laboratory test results and that appropriate education, counseling, and referral are offered to the donor.
    - Confirmed sero-reactive donors are **registered on the portal of the National Committee for Control of Viral Hepatitis** so that the donor is referred for further evaluation and treatment at the nearest treatment center.
3. Implementation of the centralization plan for virology screening of the collected units by the blood banks of MOHP hospitals, to be screened in the nearest regional blood transfusion center. This step was implemented to standardize the methodology of screening for TTIs using validated kits and reagents with the highest technology to ensure the safety of blood. The ENBTS performs screening for an average of 900,000 blood donors annually for the blood units collected in the NBTS and hospital blood banks using the chemiluminescence/EIA technique. A quality control system is followed. Participation in external quality assessment schemes with approved and accredited proficiency testing providers is implemented in some blood banks to ensure that screening of blood units is implemented in a quality-assured manner.

4. The Egyptian National Blood Transfusion Services has an important role in the Middle East and Africa as a training facility in the field of blood transfusion. WHO acknowledges the NBTC as a training center for quality management training courses, and its curriculum covers all aspects of blood banks.
5. MOHP established an Egyptian Transfusion Medicine Fellowship in 2005 for physicians working in blood banks. It is a four-year on-the-job training program.
6. Implementation of a local hemovigilance system in each blood center that has a therapeutic unit for transfusion of blood or blood components for patients. The blood management system allows for the recording and management of adverse events.
7. Issuing several updates of the Egyptian National Standards for Blood Transfusion, relying on international standards and recommendations of WHO in line with the traditions and laws of Egyptian society, taking into account endemic diseases and how to limit their spread. The first edition was issued in 2007, the second in 2010, the third in 2015, and the fourth in 2023.
8. Egyptian National Blood Transfusion Services has issued many publications to help establish the basics of transfusion medicine for workers in this field:
    - Appropriate Clinical Use of Blood (Third Edition, 2011)
    - Technical Manual for National Blood Transfusion Services (First Edition, 2010)
    - A Guide to Occupational Health and Safety (First Edition, 2007)
    - National Strategy for Blood Testing (First Edition, 2010).

Through our Corporate Quality Systems Program, we shall relentlessly pursue a customer-focused, management-driven, prevention-based quality system using performance measures that are challenging, visible, and understandable and where all employees actively contribute to our continuous improvement process.

The NBTS' quality policy objectives include:

- Maintain customer satisfaction and increase the number of customers receiving our services.
- Establishment of a nationally coordinated blood transfusion service.
- Collection of blood only from voluntary, non-remunerated blood donors from low-risk populations.
- Testing of all donated blood, including screening for TTIs, blood grouping and compatibility testing.

- Reduction in unnecessary transfusions through the effective clinical use of blood, including the use of simple alternatives to transfusion (crystalloids and colloids) wherever possible.
- Integrating quality with overall business and strategic plans and carefully specifies our requirements to our suppliers (donors and manufacturers), our processes (collection, laboratory, distribution), and our blood component unit users.
- Ensure that, under the guidance of trained quality management, each member of our staff recognizes their responsibility for quality improvement.
- Ensure that the education and training of staff are sufficient to maintain and improve quality.
- Adhering to current good laboratory and manufacturing practice and Egyptian national standards for the practice of blood transfusion.

9. The National Blood Transfusion Center is internationally accredited by the American Association of Blood Banks, which is the highest accrediting body in the field of blood banks and transfusion medicine. The NBTC was first accredited in 2014, followed by three successive successful assessment visits until 2019.
10. The ENBTS performed NAT screening for blood donations for early detection of HBV, HCV and HIV for 157,660 blood units in 2019, 237,086 blood units in 2020, 390,912 blood units in 2021, and 425,383 blood units in 2022. It was found that total NAT yield blood units constitute 0.1% of the blood units that are NAT tested, as displayed in Figure 15, which indicates the necessity of NAT screening to enhance blood safety.

1.10.4. Utilizing the national database for viral hepatitis in strengthening blood safety measures

As a routine first step prior to blood donation, every donor is checked using their national identification number on the national database of the NCCVH, as well as on the database of the donor management system. This process ensures that the donor is not registered as reactive for HCV or any TTIs before being accepted as a blood donor. This helps to reduce the waste of testing for these donors that appeared to be positive on the database of the NCCVH; this initiative reduced the waste of screening tests by 2.6%.

All reactive blood donors are counseled to withdraw new samples to perform confirmatory testing in the Microbiology Reference Laboratory. Confirmed reactive blood donors and NAT reactive blood donors are registered with the portal of the NCCVH so that these patients can be contacted to be referred for further investigations and treatment.

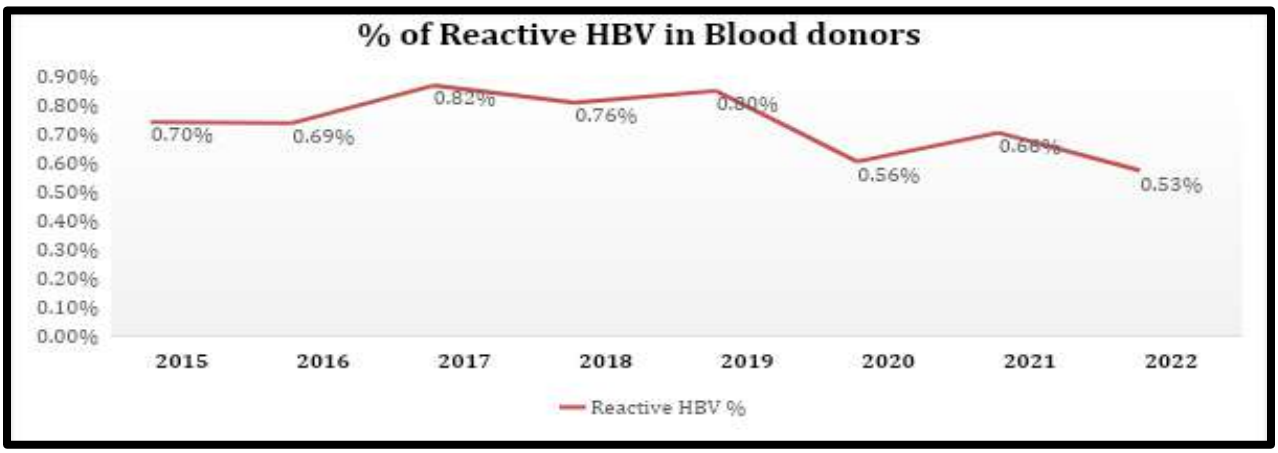

Figure 12. Trends of HBV reactive tests among blood donors, 2015-2022

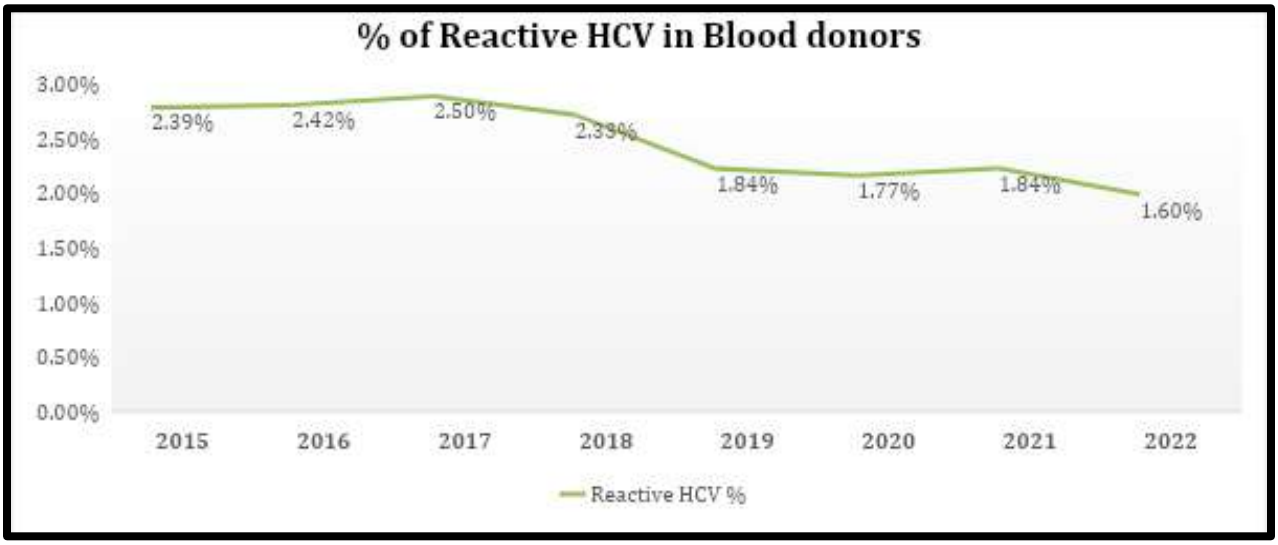

Figure 13. Trends of HCV antibodies reactive tests among blood donors, 2015-2022

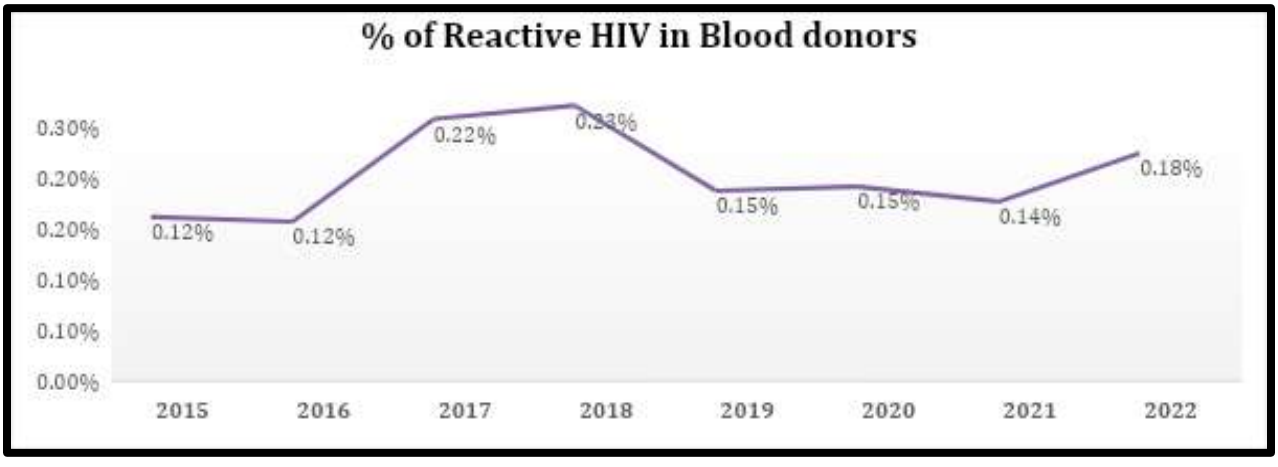

Figure 14. Trends of HIV reactive tests among blood donors, 2015-2022

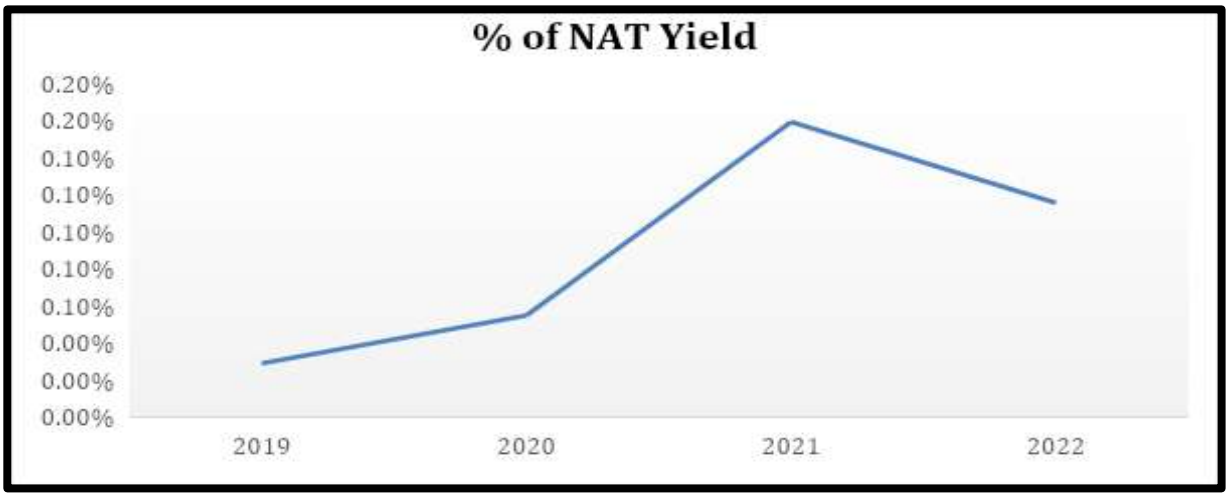

Figure 15. NAT yield samples is average 0.1% from total tested NAT samples

1.11. Injection safety indicators

Egypt is considered to be one of the countries that suffered from the unsafe injection sequelae that caused the largest historical spread of the hepatitis C virus among millions who received tartrate-emetic injections as a treatment for bilharziasis during the 1970s.

Infection prevention and control (IPC) measures, including injection safety, are considered one of the most important pillars in the prevention of infections from all pathogens, especially those that are blood-borne.

Egypt's adoption of IPC measures is a cornerstone of efforts to prevent new infections and sustain its path towards the elimination of hepatitis viruses (Table 9).

Table 9. Injection safety programmatic targets and current status in Egypt, 2022

Indicator	Gold tier target	Achieved target
Injection safety	100% injection safety	100%

1.11.1. National policy for infection control programs

In 2002, a ministerial decree (Nos. 99 and 100) issued on 4/2002 to create the National Advisory Group for Infection Control headed by H.E. Minister of Health, and to create the Infection Control Department (centrally and in all governorates), district-level committees, and facility-level committees and teams.

The National Program for Promotion of Infection Control has been concerned with the development of organizational structure, national guidelines for infection control, training

and capacity building, occupational safety and health programs, supervision and monitoring, surveillance for nosocomial infections, and advocacy.

The first edition of the IPC guidelines was developed in 2003, followed by a series of updates through 2007. In 2008, the national IPC policies for health care facilities were issued. This was considered to be a major turning point in the history of Egyptian infection control, as they included all policies related to standard precautions for infection control in health facilities.

Adherence to these policies in recent times has led to an impressive progress in infection control in Egypt. This was followed by the release of the IPC guidelines in isolation (2010), manual in hospital acquired infections (HAI) surveillance (2012), and national guidelines for IPC (2016, 2020) (Figure 16).

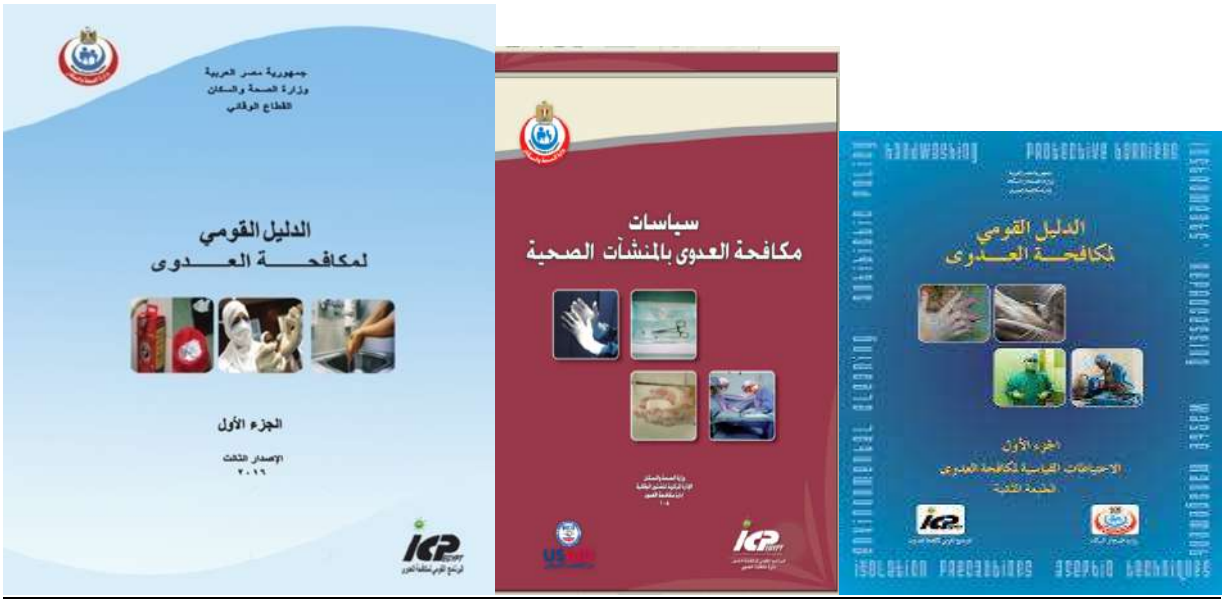

Figure 16. National IPC guidelines

Since the implementation of the IPC's first national guidelines and until the current period, a non-stop process of training and evaluation has been conducted on different levels to ensure adequate performance, follow-up, progress, gaps, and areas for improvement. Serial facility level surveys to assess the HCWs' compliance with policies and procedures were conducted.

1.11.2. Facility level injection safety: Supply and procurement

Since 1980, a series of landmark steps promoting injection safety have been implemented. On 25 August 2019, Law No. 151 of 2019 was issued for the establishment and regulation of the Egyptian Authority for Unified Procurement (UPA). The UPA is established as the sole authority for medical procurement and as a public economic authority reporting directly to H.E. the Prime Minister. The UPA is an exclusive authority that carries out purchase transactions of medical equipment, including safety syringes, on behalf of all governmental and public entities in Egypt, and its activities can also include the private sector if requested. According to the law, government and public entities will be prohibited from making any direct purchase of medical equipment, including safety syringes, except in cases of emergency and after obtaining the approval of the cabinet. They are also prohibited from taking any loans to purchase pharmaceutical products or medical equipment without obtaining the approval of the cabinet.

The cabinet published its resolution (cabinet meeting number 71/2019) on 26 December 2019, mandating the use of safety syringes instead of standard syringes in all health care facilities in Egypt by June 2020. Currently, the UPA portal for purchasing only allows the purchase of boxes of all types of safety syringes, without the presence of any boxes of regular syringes. All the health care facilities in Egypt have direct access to the portal to carry out their own procurement plans; every facility has its own login details, which allow for tracking and tracing of every order. Table 10 shows the supply of safety syringes during the period from January 2021 to December 2022.

Table 10. Safety syringes procured, January 2021 to December 2022

Item	MOHP health facilities	Supreme Council of University Hospitals	Military hospitals	General Authority for Health Insurance
3 cm^3 safety syringe	148,782,090	23,923,469	1,464,400	5,799,339
5 cm^3 safety syringe	105,575,476	24,386,298	1,358,000	5,029,516
10 cm^3 safety syringe	72,696,202	30,617,027	1,128,700	3,753,708
Insulin syringes	33,084,050	8,079,175	824,000	1,242,214
0.5 cm^3 syringes for routine immunization programs	82,000,000			
0.05 cm^3 syringes for routine immunization program	5,000,000			
0.5 cm^3 syringes for COVID-19 immunization program	77,912,833			
0.3 cm^3 syringes for COVID-19 immunization program	26,539,884			
Total	**551,590,535**	**87,005,969**	**4,775,100**	**15,824,777**
Grand Total	**659,196,381**			

1.11.3. Needle-stick injuries among health care workers

1.11.3.1. Traditional paper-based reporting system

MOHP has an established reporting system for HCWs' accidental occupational exposure to blood-borne pathogens. Reporting is usually to the authorized medical attendant in the health care facility, who will record the circumstances and details of the injury, order baseline investigations of the HCW and source, and carry out counseling. Post-exposure prophylaxis (PEP) is then started, in consultation with the physician, parallel with reporting to the higher administrative level.

1.11.3.2. Electronic web-based reporting system

MOHP has developed a parallel electronic web-based reporting system (Figure 17) for these incidents. Through this electronic system, the following information will be documented: date, time, and details of exposure; type and amount of biological material; severity of exposure; details about the exposure source; other medical conditions or current medications, if any; pregnancy or breastfeeding status; hepatitis B vaccination status; and, if vaccinated against HBV, antibody status.

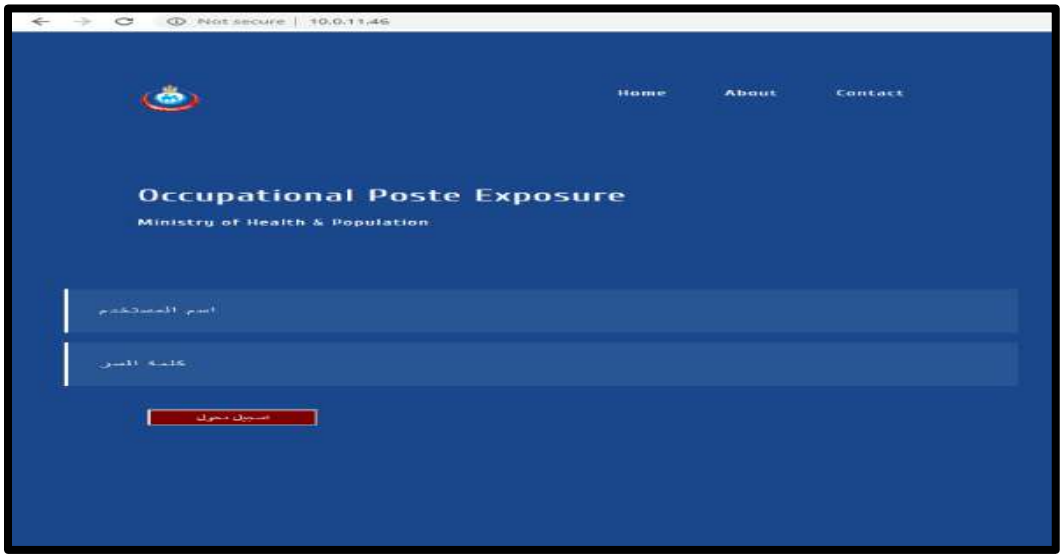

Figure 17. Occupational exposure electronic reporting system: Home and registration screens

1.12. Harm reduction indicators

Harm reduction refers to policies and programs that aim to reduce the harms associated with the use of drugs. They constitute a pragmatic approach that acknowledges the fact that, despite all prevention and control efforts, there will always be a population that uses illegal drugs.

People who inject drugs (PWID) are at high risk of transmission of blood-borne viruses such as HIV, hepatitis B, and hepatitis C through the sharing of contaminated needles, syringes, and other injecting equipment. Therefore, harm reduction focuses on preventing drug-related harm rather than preventing drug use per se, with an immediate focus on proactively engaging individuals, target groups, and communities to address their most pressing needs. Given the frequent contact between drug users and the ongoing epidemics of blood-borne viruses linked to problem drug use, we urgently need harm reduction activities.

In its latest consolidated key population guidelines, WHO calls on countries to prioritize HIV and viral hepatitis prevention, particularly through NSP and OAT for PWID as an important pillar in the Path to Elimination criteria (Table 11). Egypt recognizes the importance of scaling up NSP and OAMT and has taken pragmatic steps to ensure availability and accessibility of those services for PWID, with major steps to increase their coverage.

Table 11. Harm reduction programmatic targets and current status in Egypt, 2022

Indicator	Gold tier target	Achieved target
Harm reduction	150 needles/syringes/year in PWIDs (OR a demonstrated 100% coverage increase in NSP coverage within the past 2 years)	100% coverage increase in NSP coverage within the past 2 years

1.12.1. Estimated size of key populations

In Egypt, there are 33,784 people living with HIV, as per the latest UNAIDS estimates for 2022. Of this group, 25,498 are officially registered as PLHIV. A total of 14,759 officially registered cases were newly detected to be HIV positive, meaning withing the last five years.

About 37% of the cases detected in the last 5 years were attributed to injecting drug use, meaning it is one of the main epidemic drivers for HIV infection in Egypt.

As Egypt currently is about to finalize the mode of transmission study that is being conducted with the support of UNAIDS and is launching the PSE and IBBSS for HV, HBV HCV the epidemic pattern among key populations will be clearly identified for HIV and hepatitis.

The latest population size estimate (PSE) survey for the key population was conducted in 2014. This survey presented a best national-level estimate of 93,314 male PWID **(range: 86,142-119,412)** across both urban and rural areas. As a percentage, this comprises 0.37% **(range: 0.35%-0.48%**) of the male population aged 18-59. Reported estimates of men having sex with men (MSM) reached a total of 64,000 (range: 16,000-91,000) and 23,000 female sex workers (FSWs; range: 6,500-27,000) in urban areas of Egypt, representing 0.62% **(range: 0.15-0.87%)** and 0.24% (range: 0.07-0.28%) of the urban household population of adult males aged 18-59 and females aged 15-49, respectively.[1]

Only two rounds of the HIV Integrated Bio-Behavioral Surveillance Survey (IBBSS) have been conducted in Egypt. The first round conducted in 2006 and the second round conducted in 2010 sampled PWID, MSM, and FSW (as well as male and female street children).

MOHP, supported by the Global Fund to Fight AIDS, TB, and Malaria (GFATM), is currently working on updating the population size estimate and the Integrated Bio-Behavioral Surveillance Survey. The two studies address the three key populations (PWIDs, MSM, and FSW), and the IBBSS will go beyond HIV to include assessing the prevalence of HBV and HCV among the three key populations and will include syphilis among MSM and FSWs. The results of those studies are expected to be available by the first quarter of 2024.

The IBBSS Egypt 2023 intends to collect data to inform the Global AIDS Monitoring (GAM) Indicators, HIV modes of transmission (MOT), the AIDS Cascade for reaching the UNAIDS

95-95-95 targets to end HIV by 2030, the pre-exposure prophylaxis (PrEP) Cascade, and the HIV National Strategic Plan 2022.

Data collected from the IBBSS will be used to:

- Evaluate the effectiveness of implemented program activities.
- Enhance advocacy and policy making.
- Provide input for the National AIDS Program and the National Committee for Control of Viral Hepatitis for configuring the national HIV and hepatitis strategies.
- Model HIV infection and incidence.
- Develop the AIDS and PrEP cascades.
- Provide the country's GAM indicators for national reporting.

The IBBSS Egypt 2023 surveys among PWID, FSW, and MSM will be conducted in 4 locations for PWID, 3 locations for FSW, and 5 locations for MSM (total of 12 locations, 14 sites) (Table 12). The locations were selected based on several criteria, including HIV prevalence, the existence of some organizations working with the key populations, and whether the HIV IBBSS had been carried out previously. The final selection of survey locations was agreed upon by consensus during an HIV IBBSS planning session that included numerous stakeholders, including WHO, UNDP, UNAIDS, UNODC, NGOs, NAP-MOHP, and academia.

Table 12. Selected governorates in the IBBSS based on key population type

Type of key population	PWID	FSW	MSM
Selected governorate	Cairo, Alexandria, Fayoum and Minia	Cairo, Alexandria and Red Sea	Cairo, Alexandria, Minia, Gharbia, and Luxor

FSW, female sex workers; MSM, men who have sex with men; PWIDs, people who inject drugs.

1.12.2. Needle-syringe distribution

Needle and syringe programs (NSP) provide sterile injection equipment to PWIDs, aiming to reduce the transmission of blood-borne viruses such as HIV, HBV, and HCV via the sharing of used syringes. Nationally, from 2014 to 2016, limited NSP programs were conducted through NGOs funded by GFATM and Middle East and North Africa Harm Reduction Association (MENAHRA) organizations, which were implemented on a small scale, passing all the challenges in implementation at that time.

1.12.2.1. Launching and expansion of the NSP program in Egypt

MOHP, through the National AIDS Program, signed an official memorandum of understanding (MoU) in August 2020 with the two largest NGOs (Caritas and Al Shehab) working within the scope of NSP and HIV prevention in Egypt. These two NGOs receive dedicated funding for prevention activities. Caritas is the subrecipient for the regional multi-country grant of the global fund, which includes two subrecipient NGOs (Friends in Minia governorate in Upper Egypt and Freedom in Cairo). Al Shehab is the principal recipient of the 5% French initiative as well as one of the subrecipients of the Global Fund NFM3 grant.

The NSP was a cornerstone in this MoU for the first time in Egypt through joint (government-NGOs) responsibilities. In the initial phase of this MoU, MOHP started to supply the NGOs with enough sterile syringes, and the NGOs started to expand their activities in the proper distribution to PWIDs to mitigate the risk of acquiring HIV, HCV, and HBV infections. The following phase witnessed the supply of the syringes through the GFATM and UNODCS, and the National AIDS Program has included a forecasting plan for the syringe needs until 2025 through the GFATM NFM3 grant.

1.12.2.2. Geographical coverage expansion of the NSP program

The NSP was launched officially in August 2020, covering three governorates (Cairo, Alexandria and Minia). Currently it is scaled up to cover 9 governorates (Cairo, Alexandria, Minia, Sharqia, Fayoum, Ismailia, Gharbia, Sohag and Giza) (Table 13).

Table 13. Geographical coverage expansion of the NSP, 2020-2023

Year of enrollment	Responsible NGO	Governorate
2020	Al Shehab	Cairo
	Caritas	Alexandria
	Friends	Minia
2021	El Nour	Gharbia
	Freedom	Cairo
	Befriends	Giza
2022	Adel Zein	Ismailia
	Sehaty Mn Be2aty	Cairo
	Al Nouran	Fayoum
	Abna Al Daheyrya	Alexandria
2023	Al Tamyooz	Sharqia
	Heya	Sohag

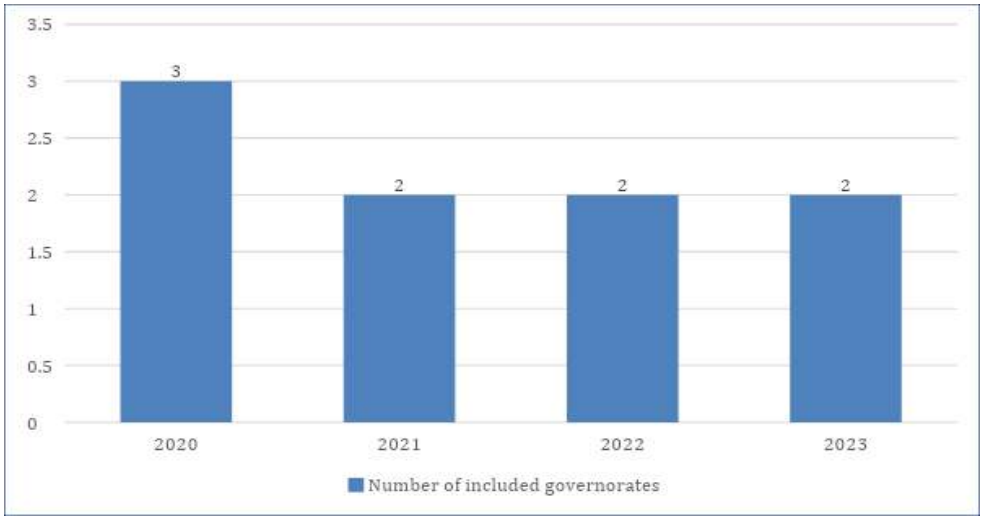

Figure 18. Geographical coverage expansion of the NSP, 2020-2023

Number of newly added governorates

The trend graph shows the annual number of new governorates that are included in the needle and syringe program as part of the harm reduction activities implemented by NGOs in those governorates (Figure 18). Although progress has been achieved in the geographical expansion of the program, there are still challenges that we are working to address through including more NGOs in the harm reduction program, which can enable us to expand in more governorates and in more geographical areas in the governorates where the NSP is currently being implemented.

1.12.2.3. Institutional expansion

This NSP program in Egypt started with only 3 NGOs working in this area. However, the National AIDS Program worked with partners to include more NGOs to enroll the NSP in the provided harm reduction package for PWID. Currently, 12 NGOs are working closely with the NAP to provide sterile syringes for PWID.

1.12.2.4. Human capacity expansion

This expansion of the working NGOs in harm reduction necessitates a comprehensive capacity building program to ensure the existence of qualified capacities from outreach and drop-in center teams that can provide an adequate harm reduction package with proper case follow-up and linkage to other services.

The National AIDS Program has collaborated with partners including UN agencies, Caritas, and Al Shehab to conduct a series of comprehensive workshops to train the teams working in NGOs. A group of 150 outreach workers were provided with training, including the HIV basic course, counseling skills, outreach modalities, the harm reduction and prevention package, NSP, and the monitoring and evaluation framework.

1.12.2.5. Procurement and supply channel expansion

At the beginning phase of the program, MOHP provided syringe supply for NGOs; however, a great challenge was faced when Egypt adopted the use of safety-engineered syringes, which were not welcomed by beneficiaries from PWID, as these types of syringes are hard to deal with and need special training. This also matches the WHO recommendations to use conventional syringes in the NSP program implementation. This highlights the need to explore other channels for syringe supply. The National AIDS Program has set up a procurement plan with UNDP to provide the 3 ml conventional syringes through the GFATM grant and through UNODC as well.

1.12.2.6. Funding resources and collaborating partners

Since the launching of the NSP program in Egypt, MOHP has been working extensively to expand and diversify the stakeholders and mobilize resources to enhance the program's implementation and maximize its outcomes:

- Monitoring and evaluation framework for the NSP was developed in collaboration with UNAIDS.
- Prevention tool guidance and standard operating procedures were designed in collaboration with UNAIDS.
- Capacity building programs for NGOs and outreach teams in partnership with UNDP, UNODC, and experienced NGOs.
- Procurement and supply plan supported by UNDP and GFATM.
- Exchanging experiences and training programs in collaboration with MENAHRA.

Table 14. Number of distributed syringes at the community level, 2022

Governorate *	Estimate of PWIDs (2014 PSE)	Distributed syringes (n)	Distribution (n/PWID/y)	Actual PWID beneficiaries (n)	Distribution (n/PWID/y)**	NGOs working in NSP (n)
Cairo & Giza	22,701	63,027	2.77	3,414	18.4	4
Minia	1,005	134,700	134	1,900	70.8	1
Alexandria	6,969	73,478	10.5	3,533	20.7	3
Total	30,675	271,205	8.84	8,847	30.65	8

* Those four governorates are where the latest 2014 PSE was conducted.
**The number of syringes distributed /1 PWID (adherent, regular) has reached an average of 300 syringes annually; this is calculated considering PWIDs who are enrolled in the program and adhere to receiving and using sterile syringes (continuum of services and beneficiary follow-up). The National AIDS Program, in collaboration with UNAIDS, developed a monitoring and evaluation framework to ensure accurate measurement and effective assessment of this implemented project.
NGOs, non-governmental organizations; NSP, needle syringe program; PWIDs, people who inject drugs; y, year.

In conclusion, the NSP showed a demonstrated expansion and coverage increase over the last 2 years as well as distributing 150 syringe/1 PWID calculated for PWID who are enrolled in the program and not lost to follow-up (Table 14).

1.12.2.7. Challenges and limitations

- The limited numbers of NGOs working in harm reduction and specifically the needle syringe program are considered a main challenge that affects the reach to PWID as well as the geographical coverage. On this issue, the National AIDS Program is working with partners to scale the umbrella of NGOs that can include harm reduction as part of their activities, and more outreach teams are also enrolled each quarter and capacitated to implement those activities.
- The national adoption of the safety-engineered syringes within the health settings since 2020 was not welcomed by PWID as they are more comfortable using the conventional syringes. This affected the rate of distribution of syringes for 8 months and was overcome by securing another window to provide these conventional syringes (GFATM, UNODC, etc.).
- The NSP is an evidence-based program, but its effectiveness is dependent upon two points: firstly, outreach to the beneficiaries among PWIDs, which requires a wide geographical distribution of civil society organizations working in harm reduction; and secondly, proper case management and follow-up to ensure the use of sterile syringes every time. We are exerting efforts to address those factors and reach more PWIDs with a quality NSP program. The National AIDS Program was keen at the start of the program to have a monitoring and evaluation framework in place that enables assessing the outcomes of the program. We are focusing not only on the distribution rates but also the follow-up with the beneficiaries to ensure that they are adhering to the program and use sterile syringes every time drugs are injected. This quality service is very challenging as it relies mainly on the outreach workers' competencies and good knowledge of the program, as well as building channels with beneficiaries to link to the package of services that are an attractive element to increase utilization of the program and support the continuum of services.
- In Egypt, as in similar countries, numerous factors affect access to syringe exchange services and therefore coverage, in terms of what services can be provided and what individuals can achieve. These factors can be broadly classified as institutional (e.g. government policy), environmental (e.g. difficulty reaching needle and syringe programs), and individual barriers (e.g. different injecting frequencies, different drug preferences). Multiple barriers may exist in a given location and may be beyond the control of PWIDs as individuals. While the barriers to service use and provision, and therefore coverage, cannot be eliminated entirely, the more they can be planned for and mitigated, the greater the potential to maximize coverage. It is worth mentioning that these barriers are the same in all countries and are more significant in countries in the MENA region with conservative cultures and communities.

- The challenges of implementation, however, extend beyond the practicalities of data collection. For example, individual-level coverage can only describe coverage among the specific group of users being surveyed and cannot give the overall estimates provided by population-level coverage calculations. For this reason, we believe that the results of the current PSE and IBBSS studies provide significant information about the NSP program and PWIDs' patterns and characteristics in Egypt. It is also very important to focus on the follow-up of the clients and what is known as the case management dossier, where we can ensure that more clients adhere to the harm reduction program and minimize the rates of cases lost to follow-up (LTFUs).

1.12.3. Opioid agonist therapy

1.12.3.1. How opioid agonist therapy is delivered

As mentioned above, injecting drug use as one of the main epidemic drivers for HIV and hepatitis. There was a crucial need and priority measure to target injecting drug users with harm reduction services, trying to provide a one-stop shop wherever this can be applicable. A model has been adopted since 2020 in the governmental addiction hospitals through operationalizing virology clinics that provide HIV, HCV and HBV testing for clients as well as ART, HCV and HBV treatment for infected PWIDs to minimize the rates of lost to follow-up that are faced due to many referrals for positive cases.

The HBV vaccination is also provided for PWID in the addiction treatment hospitals, considering that all those services are main pillars of the harm reduction interventions that are recommended to be provided for PWID as per WHO, UNODC and UNAIDS recommendations.

A main harm reduction intervention was added to this package in the governmental addiction hospitals in March 2023, namely opioid agonist therapy (OAT).

In Egypt, the current implementation model for the OAT program is adopting the OAT service delivery within the public sector as a first phase to ensure a properly controlled launching phase. The MOHP chain of mental health and addiction hospitals is the current implementing and governing body.

As per the ministerial decree, there is a plan to expand the OAT program to be implemented in other modalities where health services are provided for injecting drug use, such as:

- University hospitals
- Addiction fund hospitals (associated with the Ministry of Social Solidarity)
- Military hospitals
- Closed and correctional settings
- Private addiction treatment and rehabilitation centers.

As the program has only recently been launched, the implementation is being closely monitored to provide timely improvements to the program's performance and make any needed updates, whether to the clinical guidelines or the standard operating procedures, so as to ensure quality expansion.

1.12.3.2. Opioid agonist therapy coverage

Egypt's MOHP calls high-level meetings of the tripartite committee, including the ministries of health, interior, and justice to advocate for the OAT program implementation. This tripartite committee is responsible for allowing the usage of any narcotic substances for medical use upon technical recommendations from MOHP. The committee has agreed on authorizing the use of OAT as one of the addiction treatment approaches and one of the harm reduction interventions. In September 2020, H.E. Minister of Health and Population issued an official decree to authorize the introduction of OAT in Egypt for the first time to be used in addiction treatment strategies and one of the harm reduction interventions.

In 2021, a ministerial decree was issued on the formation of the National Scientific Committee for Harm Reduction and OAT. The scientific committee includes members from the mental health and addiction hospitals, the hepatitis program, NAP, UNODC, UNAIDS, WHO, the Addiction Fund (Ministry of Social Solidarity), the Egyptian Authority for Unified Procurement, and the Egyptian Drug Authority. This scientific committee developed scientific guidelines for OAT implementation with technical support from UNODC, following the international guidelines adapted to align with the national context and profile of drug use in Egypt.

A major step was taken through MOHP's commitment to provide for all the needs of the OAT program for the first 3 years of implementation, funded totally from domestic funding with a budget of US$ 27,000,000. This procurement was done through UNICEF as a procurement agency as the OAT medications are still not registered in Egypt.

All the required infrastructure to implement this program for the first time in Egypt was considered following the guideline recommendations. A tour visit was conducted in May 2022 to Morocco with the support of UNODC and UNAIDS, and another study visit to Madrid, Spain, took place in June 2023, to explore the countries' experience in OAT implementation.

A series of capacitating programs were held for the teams of physicians, pharmacists, and nurses who are assigned to this program in the governmental hospitals; also, an international consultant was recruited for a training of trainers (ToT) to ensure comprehensive understanding of the use of OAT medications (prescribing phases, dosage, adverse effects, case management, follow-up, etc.).

To ensure proper data capture, utilization, and processing, a specified electronic health information system for the OAT program, including stock management, inclusion forms, and case follow-up, is used in the implementing centers.

All the process standard operating procedures are in place, starting from those related to the procurement process, storage, transportation, case inclusion, follow-up, and divergence as well.

The procurement order includes both methadone and buprenorphine plus naloxone. The implementation of the national OAT program was launched on 1 March 2023 in Al Matar Hospital (one of the public mental health and addiction hospitals).

1.12.3.3. Current opioid agonist therapy program situation

Currently, the implementation of the OAT program has been expanded to four hospitals in three different governorates:

- Cairo: Al Matar and Al Abbasia hospitals
- Alexandria: Maamoura addiction hospital
- Sohag: Sohag addiction hospital.

It is planned to extend the program to five more hospitals during 2023 and 2024. There is also a vision to include OAT in some ART HIV care centers for more coverage of people living with HIV among PWIDs, as they are considered the most recommended priority group for such a harm reduction intervention.

A total of 82 patients have been enrolled in the OAT program since its launch in March 2023, and it is expected that more will be enrolled with the expansion in the geographical coverage of the program.

Moreover, the inclusion of civil society organizations in the implementation of an effective OAT program is considered crucial to building a pathway and referral mechanism for the outreach program beneficiaries among PWIDs.

In conclusion, the OAT program was started in 2021 and launched in early 2023, and it is aiming for gradual expansion through more recruitment of PWIDs during the next 2 years.

1.12.3.4. Combating stigma and discrimination

Egypt is moving forward on mitigating stigma and discrimination; key populations do not face stigma and discrimination in HIV voluntary counseling and testing centers (VCT) and treatment centers. However, stigma toward PLHIV is still observed in relation to other health services. The National AIDS Program is planning to conduct a stigma index in the GC7 NFM4 in collaboration with GFATM, UNDP, and UNAIDS. A recent exploratory study using a qualitative approach was conducted among 46 PLHIV who were seeking HIV counseling and treatment from two HIV centers in the Cairo governorate using a purposive sampling technique, showed that most of the study participants were not satisfied with HIV services in the participating centers and had also experienced stigma.[17]

Egypt has taken major steps toward mitigating stigma in health care settings through the following:

- A stigma-free health services policy was endorsed by H.E. Minister of Health and Population and will be disseminated to be followed by all health facilities by Q4 2023. This policy secures a systematic pathway for providing health services for PLHIV and key populations with a complaint platform to deal with any situations where confidentiality and privacy are breached or when health services are not provided with the desired quality.
- Since 2021, a series of comprehensive stigma-free workshops have been implemented for health care providers targeting different categories of health facilities (general, specialized care, university, mental health, and addiction hospitals, etc.). Since 2021, about 1,000 HCPs have been targeted by these workshops.

1.12.3.5. Challenges and limitations

- Scaling up the attraction of new beneficiaries.
- Maintaining patient adherence, especially with the mandated daily visit to the dispensation center, the daily costs of the visit, and the expected loss of the beneficiary's working hours.
- The program's sustainability under economic hardship, especially with the relatively high procurement costs

1.12.4. Future directions (2024-2025)

- Updating the PSE and IBBSS data.
- Expansion of the NGO activities and inclusion of new NGOs to maximize the NSP program coverage, and supporting their capacity building programs and fund-raising activities.
- Expansion of the OAT coverage and inclusion of more beneficiaries.
- Patients' awareness program aiming at improving knowledge of existing programs, their core values, and ways to participate.
- Community awareness aiming at reducing stigma, providing proper patient employment, and supporting human rights.

3.5 Establishment of sentinel surveillance program for hepatitis sequelae

For many years, Egypt has issued death certificates as a declaration of death. Death certificates are issued by a network of 5,300 health offices distributed throughout the governorates.

Since October 2017, the issuing of death certificates has been modified and upgraded to a fully digital system depending on the ICD-10 codes and using the unique national ID number, through collaborative work between the ministry of health and the ministry of planning.

Continuous training has been undertaken of the responsible persons on the best methods for registration of any death incident, using the best available data, and trying to identify the primary, secondary, and tertiary causes of death. Since September 2022, the country has been progressively moving toward ICD-11 coding, which will enable to capture the underlying cause of death in a more efficient, consistent, and digitalized way.

Mortality from HCV can occur rarely during the acute stage of the infection, or much more frequently from long-term complications such as liver failure and hepatocellular carcinoma (HCC). HCV-related mortality is multifactorial, including individual factors and health system-related factors. Table 15 and Figure 19 show annual HCV mortality in Egypt in comparison to all-cause mortality and the proportionate mortality rates by year.

Table 15. Annual all-cause mortality and HCV mortality, 2018-2022

Year	Cause of death			Total HCV mortality	Total all-cause mortality	Proportionate mortality rate*
	Acute HCV	Liver failure	HCC			
2018	999	7,285	5,571	13,855	501,467	2.76 %
2019	902	5,235	5,644	11,781	511,872	2.30 %
2020	711	3,921	5,383	10,015	610,333	1.64 %
2021	517	2,654	5,109	8,280	682,083	1.21 %
2022	436	1,879	4,966	7,281	540,583	1.35 %
Cumulative total	**3,565**	**20,974**	**26,673**	**51,212**	**2,846,338**	
Relative reduction (%)**				**- 47.45**		**- 51.25**

The proportionate mortality rate was calculated as follows:

$$\frac{Total\ mortalities\ from\ HCV\ and\ its\ complications}{Total\ all-cause\ mortality\ in\ the\ same\ year\ and\ locality}\ X\ 100$$

**Percentage of relative reduction in mortalities from HCV complications was calculated as follows:

$$\frac{(Total\ HCV\ mortality\ in\ a\ given\ year\ -\ Total\ HCV\ mortality\ in\ the\ baseline\ year)}{Total\ HCV\ mortality\ in\ the\ baseline\ year\ (2018)}\ X\ 100$$

**Percentage of relative reduction in proportionate mortality rate (PMR) was calculated as follows:

$$\frac{(PMR\ in\ a\ given\ year\ -\ PMR\ in\ the\ baseline\ year)}{PMR\ in\ the\ baseline\ year\ (2018)}\ X\ 100$$

- Total mortalities from HCV complications decreased by (- 47.45%) between 2018 and 2022.
- The proportionate mortality rate decreased from 2.76% in 2018 to 1.35% in 2022.
- The proportionate mortality rate decreased by (- 51.25%) between 2018 and 2022.
- Figure 19 shows the reduction of mortality related HCV complications over 5 years from 2018 to 2022. Liver failure shows the most evident reduction, while HCC shows a less evident reduction in mortalities over the past 5 years.

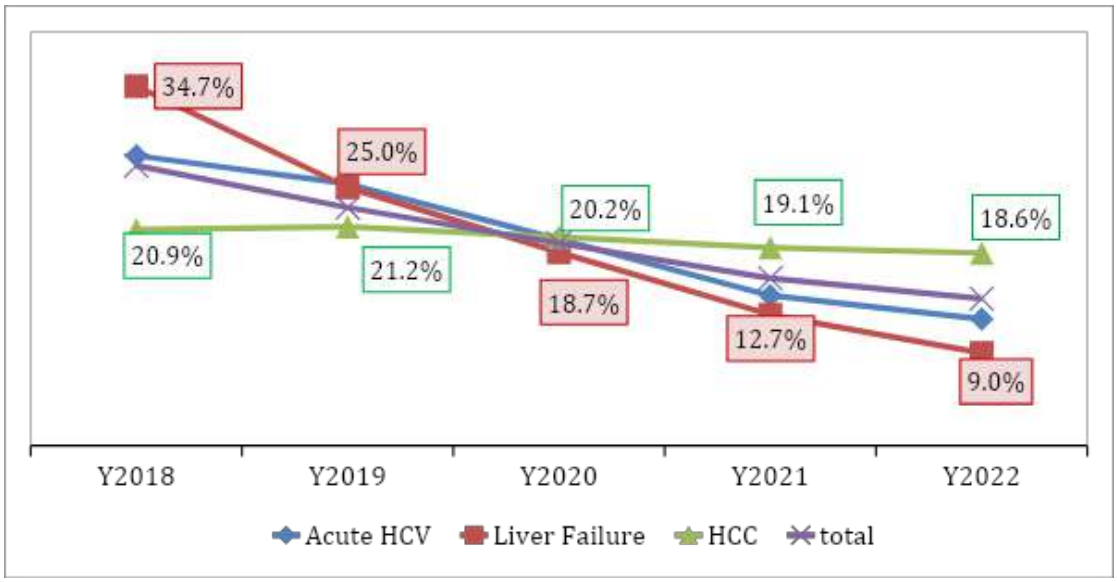

Figure 19. Trend in total mortalities from specific HCV complications across 5 years, 2018-2022

Although all these efforts have been made, many challenges remain, including the incomplete and sometimes inaccurate registration of liver-related causes of death through vital statistics and the inability to directly determine the actual proportions that are attributable to variable diseases, including chronic viral hepatitis.

MOHP, in collaboration with WHO, is now working to scale up implementation of ICD-11 in early 2024, together with the setup of an interfacing model between the sites of death (hospital HIS) and the death registry system in health offices, to reduce errors and inaccuracies in the death registration process. This will greatly improve estimation of the overall liver-related mortality envelope.

In addition, WHO has proposed a simple tool aimed at monitoring the mortality from HBV and HCV over time at the national level, promoting the development of a long-term surveillance system in the country. WHO is encouraging many countries to adopt this tool, aiming for accurate determination of the hepatitis sequelae attributable fraction among the annual mortality envelope related to hepatitis. The full protocol can be found in Annex VI.

MOHP, in collaboration with the International Agency for Research on Cancer (IARC), is providing technical support to help Egypt adapt this templated protocol to local settings, and start implementing it in 5 representative sites, including:

1. Greater Cairo (National Hepatology and Tropical Medicine Research Institute)

2. Upper Egypt governorates (Heart and Liver Center in Sohag, Qena Fever Hospital in Qena)

3. Nile Delta governorates (National Liver Institute in Menofia, Damanhour National Institute in Beheira).

The selection of these primary sites was based on their geographical locations, population density, disease burden, and availability of data sources, aiming to provide a fully representative sample that can give accurate estimates for disease mortality trends and the change in their attributable fractions.

Ethical approval to start applying the protocol was issued from the research ethical committee of the National Hepatology and Tropical Medicine Research Institute on 5 April 2023.

The responsible health care providers in these 5 centers received a one-day training focused on protocol implementation on 8 June 2023, and the centers have now started to apply the protocol and collect the needed data. In the next few months, the working team will retrieve the data from 2017 in the selected centers, followed by data processing, analysis, and interpretation, to acquire the bottom line for hepatitis-related mortalities and their time-related changes.

Implementation considerations for elimination of viral hepatitis

Implementation considerations for validation of elimination are those health systems and related criteria that can be used to determine the feasibility of achieving or sustaining the elimination of viral hepatitis, including the pathway to elimination.

1.13. Data quality

1.13.1. Egypt has a standard mechanism/system in place to collect and report on the WHO programmatic indicators

Egypt has a national health information system (HIS) that can generate and analyze reliable data necessary for monitoring and assessing progress against the hepatitis elimination criteria, impact, and programmatic targets. The NNTC is the database of the NCCVH which was established in 2010. It succeeded in connecting the NCCVH with 26 units by the end of 2014.

Users are connected to a real-time database on Microsoft Dynamic CRM. Currently, all NCCVH treatment centers are connected to the central database. In 2018, NNTC upgraded to a cloud database to comply with the increasing number of centers. Each treatment center has its own team of data entry personnel. Each center has unique access to the database for uploading patient data and follow-up investigations. The PCR hubs are connected electronically through the laboratory information system (LIS) to the NNTC to upload PCR results automatically to the system. The unique national ID number is used as the unique identifier in all screens throughout the electronic system of HCV management. A central team from the NCCVH is responsible for data verification and analysis for all treatment centers.

As for the private sector, the estimation of the number of patients treated came from the annual report of drug dispensation in the private market by the EDA.

A national registry for chronic hepatitis patients has been established. In addition, MOHP launched a homegrown health information system with numerous screening and referral treatment sites to support the presidential initiative screening campaign. It was essential to sustain the integrity of the work by linking peripheral screening sites with a central monitoring and governing body. Work was facilitated using an electronic registration system; tablets for data entry were distributed at a large number of screening sites, which resulted in a large database that was easily accessible for policymakers on a central dashboard, which helped to utilize Data for Decision Making (DDM).

Referring to the Egyptian example, the data from the "100 Million Healthy Lives" campaign was very beneficial as baseline data and as a starting point for strategic data integration in many subsequent campaigns, like the nationwide campaign to support women's health, a

follow-up NCDs screening campaign, and the GoE's response to the COVID-19 emergency. In these instances, the database of the "100 Million Healthy Lives" campaign was integrated and used for better service provision. In addition, the generated mega-data can act as a nucleus for many beneficial research projects, which will give policymakers insight for more evidence-based actions.

During the national campaign, efficient information technology support with user-friendly applications and integration with national databases facilitated planning and patient flow during screening, evaluation, and treatment. Immediate results and immediate linkage to care resulted in smooth evaluation and treatment of patients.

1.13.2. Ability of the national information system to provide disaggregated and representative data

The national HIS can provide disaggregated and representative data relating to hepatitis impact indicators. The mandatory national ID made it possible for the registry to include more complete demographic information, including accurate age and birth date, detailed address, place of birth, and gender. And for more information, like occupation or religion, we refer to the electronic medical records at both MOHP and the Ministry of Planning and Economic Development.

In addition, the national HIS can capture service delivery and outcome data from both the public and private health sectors through the Egyptian Drug Authority and the IQVIA Medical Data Index.

1.13.3. Viral hepatitis case reporting is included in the national surveillance system

Public health surveillance is an essential tool in the prevention and control of infectious and chronic diseases and for medical management. Cases of hepatitis A, B, and C are reported monthly by the National Egyptian Disease Surveillance System.

Between January 2014 and June 2017, sentinel surveillance for acute viral hepatitis was conducted in a network of five infectious disease hospitals (Abbasia, Alexandria, Helwan, Menouf, and Aswan) representing the different Egyptian geographic regions. Abbasia, Alexandria, and Helwan hospitals represented the main urban regions, while Menouf and Aswan represented the rural regions. MOHP chose the hospitals that would take part based on geographic and population diversity, the ability of hospital labs to do routine blood chemistry, such as alanine transaminase (ALT), aspartate transaminase (AST), and testing for viral hepatitis markers, and the ability of the hospitals to manage data.

Adequate laboratory capacity is an important component of any surveillance system. Currently, most laboratories in Egypt can conduct serological tests for viral hepatitis. Each Egyptian governorate has a central laboratory, in addition to numerous other laboratories

affiliated with both the public and private sectors, in addition to the Central Public Health Laboratory in Cairo governorate. The national surveillance system can differentiate between acute and chronic viral hepatitis cases. These case definitions are for the purpose of reporting and surveillance and may differ from criteria to be used for the management of patients.

1.13.4.Registry for liver cancer in place

The National Cancer Registry Program (NCRP) in Egypt started in 2007 as a population-based cancer registry and a collaboration between three Egyptian ministries: MOHP, the Ministry of Communication and Networking, and the Ministry of Higher Education. This registry was accredited by the WHO's International Agency for Research on Cancer, and the data derived from it is used by the WHO's GLOBOCAN. Currently, there are 11 active centers for registration: Damietta (2), Minia, Aswan, Tanta, Damanhour, El-Salam, Nasser, Kabbary, Dar El-Salam, and Mit Ghamr.

1.14. Laboratory quality

Meeting laboratory standards is an important requirement for the validation of hepatitis C elimination. Laboratories contribute data points to the surveillance system and for validation, including seroprevalence surveys, and for clinical diagnosis and program implementation. In Egypt, hepatitis tests and molecular diagnostics are quality-assured and WHO-prequalified. MOHP applies a quality assurance mechanism routinely and consistently to laboratories and verifies that they participate in a domestic external quality assessment (EQA) program. HCWs have been trained in accordance with the manufacturers' instructions and nationally recommended algorithms.

1.15. Medicine quality

All local manufacturers make great efforts to comply with all the quality standards in production of DAAs. One Egyptian factory (Pharco), which is the main supplier of the NCCVH, is WHO-prequalified. Generally, most local DAA manufacturers import their active pharmaceutical ingredients (APIs) from Optimus company in India. All APIs of sofosbuvir and daclatasvir were imported from the same origin in India, which complies with good manufacturing practice (GMP) and has been inspected by the EDA's technical experts. The EDA has full access to ensure all the measures for good production, starting from importation of APIs until lot release. This is followed by post-marketing follow-up on efficacy and pharmacovigilance level. Locally manufactured generic DAAs were compared to original DAAs and have proven to have comparable safety and efficacy.[18,19]

1.16. Quality hepatitis programming, policy, and practice

1.16.1. National infection control and blood safety policies are consistent with WHO recommendations and implemented accordingly

The area of infection prevention and control in Egypt has changed drastically over the years. Egypt has a national policy in place for infection control programs; this policy is supported by national IPC guidelines, which have been updated numerous times through the years to address scientific advances and the dynamic national context. The last version was published in 2021. MOHP is very concerned with raising the capacity of its human resources regarding the application of IPC guidelines; thus, periodic training is carried out and a monitoring and evaluation plan is in place to ensure the integrity of the system. One hundred percent of therapeutic injections in health care facilities are given with new, disposable, single-use injection equipment. Through the support of the Egyptian Authority for Unified Procurement (UPA), MOHP ensures that health care facilities do not face stockouts of quality-assured needles and syringes or mismatched quantities of safety boxes and essential supplies, in order to maintain IPC measures across all health care facilities. A national injection safety policy was launched in 2019, and accordingly, there is a plan for a gradual shift from conventional needles to safety syringes.

1.16.2. Evidence-based harm reduction interventions (including needle and syringe programming) are implemented consistent with WHO recommendations

Harm reduction gained national recognition and support in recent years as one of the core indicators for viral hepatitis elimination. The current estimate of the number of PWIDs in Egypt is 18,839. Needle and syringe programs (NSP) provide sterile injection equipment to PWIDs. Nationally, from 2014 to 2016 limited NSP programs were conducted through NGOs which were implemented on a small scale with distribution of 89,000 syringes passing all the challenges in implementation in this period. The National AIDS Program has signed an official MoU with the largest NGOs (Caritas and Al Shehab) working in the scope of HIV prevention in Egypt. These two NGOs receive dedicated funding for prevention activities; Caritas is the principal recipient of the regional GFATM grant including 2 subrecipient NGOs (Friends in Minia in Upper Egypt and Freedom in Cairo), while Al Shehab is the principal recipient of the 5% French initiative. Unfortunately, the outreach activities were hampered due to the COVID-19 situation. Last year, 43,550 syringes were distributed (2.3 syringe/PWID). Condoms are also distributed to PLHIV, a key population, through voluntary counseling and testing services (VCTS), either governmental or non-governmental, and also through ART centers. However, the main challenge is ensuring the effective use of condoms to prevent HIV infection. This should always be guaranteed by continuous education programs.

1.16.3. National hepatitis B and C testing and treatment protocols are consistent with WHO recommendations and implemented accordingly

National hepatitis testing and diagnosis algorithms are consistent with WHO recommendations and implemented accordingly. Treatment for HCV affiliated with the public sector falls under two main systems supervised by the NCCVH, which are treatment centers affiliated with the NCCVH itself and the Health Insurance Organization (HIO). By the end of 2019, there were around 126 treatment clinics affiliated with the NCCVH across the 27 governorates. In addition, there were 41 central HIO organization clinics with an HCV medical assessment committee across the 27 governorates.

1.16.4. Evidence of liver cancer screening and hepatitis workforce training

Patients with diagnosed liver cirrhosis due to HCV are linked to the NCCVH and are followed up by visits with AFP and abdominal ultrasound every 6 months. However, after the EASL 2018 guidelines for management of HCC were published, MOHP issued an updated decision that the follow-up would be every 4 months.

Hepatitis workforce training (in-person/online training, curriculum, and mentorship) is included in national health policies.

1.16.5. Programmatic indicators and program quality are reported from the lowest-performing subnational unit

About 5,400 primary health care units (the lowest-performing subnational unit) offer prevention services through vaccinations and screening services through premarital screening and mass screening. All units are connected to the national central database. Once a positive case is detected, there is an immediate notification of the higher level to take decisions.

1.17. Human rights

1.17.1. Voluntary viral hepatitis C testing and treatment

MOHP applied WHO's core testing principles during this national mass hepatitis testing, including voluntary consent, confidentiality, counseling, correct test results, and connection (linkage to prevention, treatment, and care, and support services), to maximize both individual and public health benefits while ensuring client confidentiality. Participation in screening was voluntary, with no financial or in-kind incentives for participating and no punitive consequences for not participating. The same applies to the school children screening campaign; children who have reached the age of 12 on admission

to the first year of preparatory schools all over Egypt can be screened with written consent from their parents.

1.17.2. Confidentiality and privacy of hepatitis C status and treatment

To maintain the confidentiality and privacy of hepatitis C status and treatment, all data are stored securely in a national database using national ID. The patient is the only one who knows their results. In the national screening campaign, WHO was selected by MOHP as the independent verification agency (IVA) for the verification of the work done through the campaign. As the IVA, WHO monitored whether MOHP was respecting WHO's core testing guiding principles. This was carried out through an audit and a verification team of experts who started their work with the launch of the mission in October 2018.

1.17.3. Absence of legal discrimination

Article 53 of the Egyptian Constitution states that citizens are equal in rights, freedoms and public duties, without discrimination on grounds of religion, gender, origin, race, color, language, disability, social level, political or geographical affiliation, or for any other reason. Discrimination and incitement to hatred are crimes punishable by law.

1.17.4. Stigma-free access to health care and treatment for those with HCV

People were tested for HCV antibodies with the use of a finger-prick rapid diagnostic test, with results available within 20 minutes. Seropositive patients had appointments immediately scheduled electronically for a date within 2 to 15 days at the closest assigned center for evaluation and treatment. At the center, patients received clinical evaluation, underwent abdominal ultrasonography, and had blood drawn for HCV RNA and liver-function tests. The time between screening and the dispensing of medication was usually 10 days but ran to 4 weeks for some patients who were delayed in scheduling or attending follow-up appointments. The shortest time to dispense treatment was 6 days, while the longest was 30 days.

Turnout for evaluation was continuously monitored. A call center contacted seropositive persons who did not show up for their evaluation appointments and patients with viremia who did not return for treatment in order to inquire about reasons for no-shows and to assign new appointments if necessary.

1.17.5. Absence of drug use, sexual orientation status, incarceration experience, immigration status or profession as a criterion for exclusion from hepatitis treatment

MOHP has started special screening and treatment programs for certain populations and age groups, aiming to control disease and micro-eliminate HCV in these populations (young adolescents [school and university students], in-patients, people living with HIV, end-stage renal disease patients, chronic blood disease patients, people attending mental health and addiction treatment clinics, blood donors, and refugees and asylum seekers).

1.18. Equity

1.18.1. Testing and treatment service decentralization and integration

HCV testing and treatment services were decentralized. Trained MOHP screening teams screened participants at different health care facilities, including primary health care units, government hospitals, and health offices. Also, to ensure they left no one behind, screening teams reached out to the participants through mobile clinics. Mobile screening teams in specially outfitted vehicles augmented the screening efforts by visiting crowded areas on special occasions (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.

In addition, citizens were reached out to at government institutions and private companies, and the screening sites operated 12 hours per day, seven days per week, to make it as easy as possible for people to access screening. Persons could be screened in any phase and at any site, regardless of their residence. Mobile teams went to where people were rather than relying on people to come to health facilities, and nearly every health center was engaged in the process.

1.18.2. Gender equity

Gender equity is an additional important aspect of public health and elimination of viral hepatitis. Article 53 of the Egyptian Constitution states that citizens are equal before the law, and they are equal in rights and freedoms. and public duties, without discrimination on grounds of religion, creed, gender, origin, race, color, language, disability, social level, political or geographical affiliation, or for any other reason. Discrimination and incitement to hatred are crimes punishable by law. The state shall take the necessary measures to eliminate all forms of discrimination. The law regulates the establishment of an independent commission for this purpose.

Full details related to implementation considerations for elimination of viral hepatitis are available in the implementation checklist in Annex VII.

Outline of the potential risks and accompanying strategies for sustaining elimination of viral hepatitis

The GoE realizes the importance of maintaining the optimal level of prevention and early detection of hepatitis viruses to maintain the achievement that occurred during the past few years to declare Egypt a hepatitis C-eliminated country. MOHP is currently operating a series of early detection services meant to maintain the discovery of blood-borne viruses and the timely link to care for the cases that have been identified, to maximize containment power and reduce the rate of community spread.

These series include the following:

1.19. School children screening program

In parallel to the mass screening campaign in 2018 and 2019, and because until 2019, there was no approved HCV medication for children below the age of 12, MOHP decided to screen children nationwide who had reached the age of 12 on admission to the first year of preparatory school. In the school year 2022-2023, the program is in its fourth consecutive year and is conducted in nearly 13,300 schools (Table 16).

Table 16. Child screening activities and results by year in Egypt

Anti-HCV test	Sites (n)	Year	Tested students (n)	Positive anti-HCV (n)	Prevalence (%)
RDT	13,300	2019/2020	1,750,425	2,701	0.15%
		2020/2021	1,321,660	1,619	0.12%
		2021/2022	1,785,833	1,613	0.09%
		2022/2023	1,639,436	1,441	0.09%

RDT, rapid diagnostic test.

1.20. Fixed sites for voluntary screening

During the countrywide mass screening program in 2018, 2019, and early 2020, MOHP deployed about 6,000 sites capable of screening approximately 60 million individuals. After passing the COVID-19 pressure, MOHP announced in early 2022 the reactivation of 70 fixed screening locations in all Egyptian governorates for people who need to get tested voluntarily. These networks of screening stations are digitally networked with the NCCVH platform to validate the results and expeditiously reserve the positive patients for further examination and treatment if they are eligible (Table 17).

Table 17. Voluntary screening activities in the fixed sites, 2022

Anti-HCV, HBsAg & anti-HIV tests	Sites (n)	Tested people (n)	Positive anti-HCV (n)	Positive HBsAg (n)	Positive anti-HIV (n)
RDT	70	31,540	2,777	1,170	12
Prevalence (%)			8.80	3.70	0.03

HBsAg, hepatitis B surface antigen; HCV, hepatitis C; HIV, human immunodeficiency virus; RDT, rapid diagnostic test.

It is noted that once this service was available, the rate of positive tests was significantly high compared to the known national statistics. This relatively high percentage of infections among those tested was attributed to the fact that expressing a wish to be tested was likely linked to known exposure to risk factors (e.g. they may be PWIDs).

1.21. Fixed sites for voluntary screening at addiction clinics

Since early 2021, MOHP has established 20 fixed screening sites permitting biannual testing for PWIDs, their relatives, and even patients addicted to non-IV drugs. These sites are also digitally networked with the NCCVH platform. Those who are tested positive are referred to be evaluated and treated by specialized health care personnel within the same premises to avoid the probable drop-out of patients from this important group if referred to different places (Table 18). Although this program has been running since 2015, the expansion of its activities by 2021 and its link to the national program have greatly affected its recruitment rate.

Table 18. Voluntary screening activities at addiction clinics in Egypt, 2021-2022

Anti-HCV, HBsAg & anti-HIV tests	Sites (n)	Tested people (n)	Positive anti-HCV (n)	Positive HBsAg (n)	Positive anti-HIV (n)
RDT	20	73,699	3,815	348	777
Prevalence %			5.17%	0.47%	1.05 %

HBsAg, hepatitis B surface antigen; HCV, hepatitis C; HIV, human immunodeficiency virus; RDT, rapid diagnostic test.

1.22. Screening for pre-intervention beneficiaries

This type of hospital-based screening was offered to all hospital admissions for those prepared to do any surgical or non-surgical interventions (e.g. cardiac catheterizations). This program has been running since 2020 and includes a chain of 539 hospitals, which are also digitally networked with the NCCVH platform (Table 19).

Table 19. Hospital-based screening activities in Egypt, 2022

Anti-HCV, HBsAg & anti-HIV tests	Sites (n)	Tested people (n)	Positive anti-HCV (n)	Positive HBsAg (n)	Positive anti-HIV (n)
RDT*	539	686,491	9,281	2,447	483
Prevalence %			1.35%	0.35%	0.07%

HBsAg, hepatitis B surface antigen; HCV, hepatitis C; HIV, human immunodeficiency virus; RDT, rapid diagnostic test.

1.23. Double way connection with the national network for blood donation:

In May 2019, after having generated an enormous amount of data on HCV testing, a very fruitful digital solution was created by the NCCVH platform and the electronic system of the national blood donation network (Table 20) aiming at:

1. Identification of those who tested positive for either HCV or HBV prior to starting the process of blood donation and exempting those who are known to be positive from proceeding with donation.
2. Linking those who tested positive after screening of the blood bags to proper care based on their evaluation results.

Table 20. Screening activities in the national network for blood donation in Egypt, 2021-2022

Anti-HCV, HBsAg & anti-HIV tests	Sites (n)	Shared records (n)	Positive anti-HCV (n)	Positive HBsAg (n)	Positive anti-HIV (n)	Rejected*
Chemiluminescence	194	1,005,873	12,911	6,230	NA	21,493
Prevalence %			1.28%	0.61%	NA	-

*Rejected from blood donation due to previous positivity for HBV or HCV.
HBsAg, hepatitis B surface antigen; HCV, hepatitis C; HIV, human immunodeficiency virus; RDT, rapid diagnostic test.

1.24. Double way connection with the Central Public Health Laboratory network

Using the methodology of connection with the blood banking network, a similar program is currently running and connecting a chain of labs, including 27 labs in the 27 governorates. The testing beneficiaries are Egyptian citizens who are seeking employment in the Gulf countries which mandate negative virology testing as a prerequisite for employment (Table 21).

Table 21. Screening activities in the Central Public Health Laboratory network in Egypt, 2021-2022

Anti-HCV test	Sites (n)	Year	Tested samples (n)	Positive anti-HCV (n)	Prevalence (%)
Chemiluminescence	27	2020	150,596	399	0.26
		2021	245,351	677	0.27

HCV, hepatitis C.

1.25. Premarital screening

Starting from 26 February 2023, MOHP has included HBV, HCV and HIV screening among the health service package offered at premarital examinations (Table 22). This ambitious program targets nearly 1.8 million people/year.

Table 22. Premarital screening activities in Egypt, 2023

Anti-HCV, HBsAg & anti-HIV tests	Sites (n)	Tested people (n)	Positive anti-HCV		Positive HBsAg		Positive anti-HIV	
			Known*	New	Known*	New	Known*	New
RDT	320	648,779	7,039	315	120	308	24	104
Prevalence %			**1.08%**	**0.04%**	**0.01%**	**0.04%**	**0.003%**	**0.01%**

*Cases that were previously tested positive and referred to care in any previous year.

HBsAg, hepatitis B surface antigen; HCV, hepatitis C; HIV, human immunodeficiency virus; RDT, rapid diagnostic test.

Potential risks to sustaining elimination efforts

Egypt is finally on the path to eliminating hepatitis C. Various surveys and evaluations prove that infection rates are decreasing, but a variety of risks continue to threaten this progress, including the following:

1. Egypt is not only a populous country but also hosts hundreds of thousands of refugees, asylum seekers, and migrants from countries suffering from instability.
2. The COVID-19 pandemic and its impacts on health care systems globally affected all hepatitis elimination activities worldwide to a great extent, including those in Egypt, which suffered from a reduction in the activities of the viral hepatitis treatment centers with a lot of task shifting for HCWs and premises to confront the multiple COVID-19 peaks. Additionally, there was a reduction in screening and early detection activities due to the country's lockdown measures, including the school closures, and effects on the HCV surveillance system, including challenges in keeping patients to regular visits and in recruiting more targeted patients.
3. The current global economic crisis and its effects on health care systems and the stability of the supply chains for diagnostics and medicines.

The Government of Egypt is determined to pursue and sustain all efforts to finally achieve HCV elimination as a public health problem in the country.

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Proud of my country

Fière de mon pays

فخورة ببلدي

Annexes:

Annex I	HCV elimination National Validation Taskforce
Annex II	National Committee for Control of viral hepatitis (NCCVH) guidelines for management of adult patients with HCV infection (2020)
Annex III	Nationwide Hepatitis C and NCDs screening & testing campaign “100 Million Healthy Lives: a step closer towards HCV elimination
Annex IV	HCV cascade of care
Annex V	National Regulation of blood and blood components in Egypt
Annex VI	Draft Concept note for estimating and monitoring the mortality from cirrhosis and hepatocellular carcinoma attributable to viral hepatitis B and C at a national level (WHO, 2022)
Annex VII	Implementation Checklist

ANNEX 1: HCV elimination National Validation Taskforce

Description of the National Validation Taskforce (NVTF)

Background

The Egyptian national validation task force for viral hepatitis C elimination consists of a team of 130 experts and stakeholders responsible for supervising and coordinating the validation process in their country. According to the interim guidance provided by the WHO for the validation of viral hepatitis elimination at the country level, the roles and responsibilities of this task force include the following:

- Crafting a national validation plan that delineates the goals, activities, schedules, budget, and collaborators involved in the validation process.
- Establishing a national validation secretariat that offers administrative and technical support to the national validation task force while also serving as a liaison with the WHO regional office and headquarters.
- Conducting a thorough evaluation of the national hepatitis C program, encompassing an assessment of the quality and accessibility of strategic information, laboratory procedures, diagnostic tools and medications, healthcare programs, and adherence to principles of fairness, human rights, and community engagement.
- Gathering and scrutinizing data to gauge the impact and programmatic objectives for hepatitis C elimination, utilizing the methods and criteria specified in the WHO guidance.
- Drafting and submitting a national validation report summarizing the findings and conclusions of the assessment and data analysis, providing evidence of having met the criteria for validating the elimination of hepatitis C as a public health concern.
- Addressing any inquiries or requests for clarification from the WHO regional validation committee or the global validation advisory committee.
- Implementing any recommendations or corrective measures proposed by the WHO regional or global validation committees to enhance or sustain the performance and outcomes of the hepatitis C program.
- Celebrating and disseminating the achievement of eliminating hepatitis C as a public health issue, while upholding strong political commitment and public awareness to prevent the resurgence of hepatitis C infections.

Mission

Collect data, develop and submit the national elimination/Path to elimination report to the national committee for control of viral hepatitis (NCCVH).

NVTF members

The NVTF is a multidisciplinary team comprising a wide cross-section of professionals from various MOHP sectors. programs, and Ministries.

Chairman: Dr. Mohamed Hassany, Executive director of NCCVH

Secretariat: National Committee for Control of Viral Hepatitis (NCCVH)

1- MOHP Sectors and programs

- Primary Health Care and Nursing Sector
- Preventive Sector
- The General Secretariat of Mental Health and Addiction Treatment
- National AIDs Program
- Egyptian National Blood Banks

2- **Egyptian Drug Authority**

3- Unified Procurement Authority

4- National Experts

5- Two International experts

6- Civil Society

7- Other Ministries such as Ministry of Education

Responsibilities

- Collect the required data for verification with the support of the WHO country office in Egypt based on the WHO interim guidance for country validation of elimination options for viral hepatitis C in 2021 and the guidance for country validation of viral hepatitis elimination and PTE of July 2023.
- Collaboration and coordination with the other existing national health programs, e.g. Immunization Program; Injection Safety, Blood Safety and, the National AIDS Program.
- Arrange for Dossier Review meetings and provide technical guidance.
- Writing the national Path to elimination report and submitting it on behalf of the Ministry of Health and addressing any queries or clarifications regarding the report, including from the regional validation taskforce (RVTF).

Ways of Communication

- Virtual/offline meetings at least once every month (examples of meeting minutes are present at https://drive.google.com/drive/folders/1NnSHiz6XkbE3nIalydkS_XVj_R3SNYIA)
- Emails

Output

After months of hard work and compiled efforts, MOHP decided to present the dossier, choosing option C which focuses on hepatitis C elimination criteria.

Ministry Of Health And Population
Assistant Minister For Public Health
Projects And Initiatives

وزارة الصحة والسكان
مساعد الوزير لشئون مشروعات
ومبادرات الصحة العامة

قـــرار

رقم (7) لسنة 2023

مساعد وزير الصحة لشئون مشروعات ومبادرات الصحة العامة

- بعد الاطلاع على قانون الخدمة المدنية الصادر بالقانون رقم 81 لسنة 2016.
- وعلى قرار رئيس الجمهورية رقم 242 لسنة 1996 بتنظيم وزارة الصحة والسكان
- وعلى قرار وزير الصحة والسكان رقم (449) لسنة 2006 بإنشاء اللجنة القومية لمكافحة الفيروسات الكبدية.
- وعلى قرار وزير الصحة والسكان رقم (646) لسنة 2012 بالقواعد التنظيمية للجنة القومية لمكافحة الفيروسات الكبدية ووحدات العلاج التابعة لها.
- وعلى قرار وزير الصحة والسكان رقم (155) لسنة 2022 بشأن تكليفي للعمل مساعد وزير الصحة لشئون مشروعات ومبادرات الصحة العامة.
- وعلى قرار وزير الصحة والسكان رقم (498) لسنة 2022 بشأن تكليفي للقيام بأعمال المدير التنفيذي للجنة القومية لمكافحة الفيروسات الكبدية.

تقـــــــرر

المادة الأولى: -يتم تشكيل اللجنة الوطنية لمتابعة لملف الإشهاد للقضاء على الفيروسات الكبدية طبقا للكشف المرفق بالأسماء والتخصص.

المادة الثانية: – على جميع الجهات المختصة تنفيذ هذا القرار من تاريخ صدوره.

وتفضلوا بقبول فائق الاحترام،،،

مساعد الوزير
لشئون مشروعات ومبادرات الصحة العامة
د. محمد حسانى

مساعد الوزير
لشئون المشروعات ومبادرات الصحة العامة
د/محمد حسانى

تحريراً في: 8 / 3 /2023

3 ش مجلس الشعب – ص ب : 11516 – القصر العينى- القاهرة

- **Egyptian Ministry Of Health and Population (MOHP):**

1. **Central:**

Mohamed Hassany	Assistant Minister for Public Health Projects, and Initiatives, MoHP. Associate Professor of Hepatology and Gastroenterology, National Hepatology and Tropical Medicine Research Institute, Cairo. Executive Director of the National Committee for Control of Viral Hepatitis (NCCVH)
Wael Abdel-Razek	Professor of Hepatology and Gastroenterology, National Liver Institute, Menofia University Head of Primary Health Care and Nursing Sector, MOHP Deputy Executive Director of the National Committee for Control of Viral Hepatitis, MOHP
Ehab Kamal	Assistant Professor of Tropical Medicine, National Research Center Minister's Advisor for Continuous Medical Education, MOHP
Mohamed Alboraie	Assistant professor of Medicine and gastroenterology, Al-Azhar University, Cairo, Egypt, Executive Director of the Presidential initiative for treating one million African hepatitis C patients,
Mohamed Abdallah	Lecturer of Tropical Medicine, National Research Center Head of Central Administration for Integrated Healthcare, MOHP General Coordinator of the National Committee for Control of Viral Hepatitis, MOHP
Galal Elshishiney	Associate Minister for Public Health and Health Policies, MoHP
Ramy Galal	Director of the Technical Office of the Assistant Minister of Health and Population for Public Health Projects and Initiatives
Mona Khalifa	Technical Officer, Assistant Minister of Health and Population for Public Health' Projects and Initiatives Office
Kadry Mohamed	Technical Officer, Assistant Minister of Health and Population for Public Health Projects and Initiatives Office
Alaa Abdelfattah	Technical Officer, Assistant Minister of Health and Population for Public Health Projects and Initiatives Office
Bassant Tawfik	Technical Officer, Assistant Minister of Health and Population for Public Health Projects and Initiatives Office

Fatma Abo Elella	Technical Officer, Assistant Minister of Health and Population for Public Health Projects and Initiatives Office
Noha Assem	Assistant Professor of Public Health, Cairo University Former Minister Advisor for Clinical Research
Sahar ElSonbaty	Former Head of the National Council for Childhood and Motherhood
Soaad Abd El Mageed	Head of the Central Administration for Family Planning Monitoring and Evaluation
Mohamed Dahy	Head of General Authority of Health Insurance
Mohamed Zidan	General Director of Specialized Medical Councils
Maha Ibrahim	Head of Secretariat of Specialized Medical Centers
Mohamed Zaki Elsodany	Head of Curative Organization
Mohamed Mostafa Abdel Ghaffar	Head of the General Organization of Teaching Hospitals and Institute (GOTHI)
Samah Abd Elhafiz	Consultant Infectious Disease Director of the combined infections program
Sohair Abd Elhameed	Former Head of the General Authority of Health Insurance
Emad Kazem	Former General Director of Specialized Medical Councils

2. **National Committee for Control of Viral Hepatitis (NCCVH)**

Wahid Doss	Professor of Hepatogastroenterology and Endemic Medicine, Cairo University Head of the National Committee for Control of Viral Hepatitis
Khaled Kabeel	General Assistant to the Head of the National Committee for Control of Viral Hepatitis
Yahya Elshazly	Professor of Medicine, Ain Shams University
Gamal Esmat	Professor of Hepatogastroenterology and Endemic Medicine, Cairo University
Manal Hamdy	Professor of Pediatrics, Ain Shams University
Imam Waked	Professor of Medicine, National Liver Institute, Menofia University
Magdy El-Serafy	Professor of Hepatogastroenterology and Endemic Medicine, Cairo University
Maha Elrabbat	Professor of Public Health, Cairo University Former Minister of Health and Population
Nasr Mohamed Elsayed	Former Minister Advisor for Preventive and Primary care and Family Planning, MoHP
Yasser Omar	Medical Coordinator of the National Committee for Control of Viral Hepatitis, MOHP
Eslam Ammar	Medical Coordinator of the National Committee for Control of Viral Hepatitis, MOHP
Ramy Saeed	Medical Coordinator of the National Committee for Control of Viral Hepatitis, MOHP

Kadry Elsaeed	Former Executive Director of the National Committee for Control of Viral Hepatitis, MOHP
Sohair Shouman	Former Deputy Executive Director of the National Committee for Control of Viral Hepatitis, MOHP

3. **Primary HealthCare (PHC) Sector:**

Hanaa Sorour	Former Head of Primary Health Care and Nursing, MOHP
Samir Eldemiry	Director of the Technical Office of Head Primary Health Care and Nursing Sector
Mohamed Hassan	Technical Officer, Head of Primary Health Care Sector Office
Sameh Samir	Technical Officer, Head of Primary Health Care Sector Office

4. **Preventive Medicine Sector:**

Amr Kandeel	Head of the Preventive Medicine Sector
Alaa Eid	Former Head of the Preventive Medicine Sector
Rehab Mohamed	Head of the Extended Program for Immunization
Essam Othman	Former Head of the Extended Program for Immunization
Amal Nageeb	Virology Consultant, Central Public Health Laboratories
Shaymaa Shawky	Virology Consultant, Central Public Health Laboratories
Ehab Elbasha	Former Technical officer of the Extended Program for Immunization Office
Radi Hammad	Former Head of General Administration for Viral Hepatitis
Shymaa Abdelaziz	Technical Officer of the Head of Preventive Medicine Sector
Elshymaa Galal	Technical Officer of the Head of Preventive Medicine Sector
Hanaa Abo El Sood	Former Head of General Administration for Surveillance
Manal Fahim	Head of General Administration for Surveillance
Mohamed Baiumi	Consultant of Infection Control
Hanem Abdel Rauof	Head of General Administration for Infectious Diseases
Shymaa Abo Kamar	Coordinator of Evidence-Based Surveillance Program

5. **Curative Care Sector:**

Hazem Elfeel	Head of Curative Care Sector
Magda Tantawy	Former Head of Curative Care Sector
Mostafa Ghonema	Former Assistant Minister of Curative Care Affairs
Mohsen Taha	Former Head of Curative Care Sector

Ministry Of Health And Population
Assistant Minister For Public Health
Projects And Initiatives

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مساعد الوزير لشئون مشروعات
ومبادرات الصحة العامة

Ahmed Mohy	Former Head of Curative Care Sector

6. **Information Technology Center:**

Eng. Tarek Saad	Minister's Advisor for Automation of the Oncology Centers
Eng. Aysam Salah	Minister's Advisor for Information Technology
Eng. Akram Samy	Associate Minister for Information Technology

7. **National AIDS Program**

Heba Abdelkawy	Head of the National AIDS Program

8. **Mental Health Program**

Menan Abdelmaksood	Head of the General Secretariat of Mental Health and Addiction Treatment
Raghda El Gamil	Director of Addiction Treatment Administration Executive Director of OAT Program

9. **Egyptian National Blood Bank:**

Nehad Mosaad	General Director of Egyptian National Blood Bank
Ihab Serag Eldin	Former Head of the National Blood Banks
Marwa Mohsen	Deputy of General Director of Egyptian National Blood Transfusion Services Quality Director of NBTS and National Plasma Collection Project

- **Unified Procurement Authority (UPA)**

Bahaa Zidan	Chairman of the Egyptian Unified Procurement Authority
Mohamed Abdelkawy	Deputy of the Director of the Egyptian Unified Procurement Authority
Ahmed Abdelwahab	Advisor to the Head of UPA
Nermeen Samir	Head of Unified Procurement Central Administration
Mohamed Elsayed	Medical Supply Director

- **Egyptian Drug Authority (EDA)**

Tamer Essam	Chairman of the Egyptian Drug Authority
Rasha Zyada	Deputy Chairman of the Egyptian Drug Authority
Anas Mostafa	Technical Officer at the Head of EDA Office

➢ **Civil Society:**

Tahya Misr Fund	Tamer Abdelfattah, Executive Director of Tahya Misr Fund.
Egyptian Zakat and Charity House	Ahmed Tarek, Secretary General
Liver Patients Care Association	Gamal Shiha, Professor of Medicine, Mansoura University Chairman of the Board of Directors

➢ **Dossier Experts:**

Madiha Said	Professor of Public Health and Community Medicine, Cairo University
Doaa Saleh	Professor of Public Health and Community Medicine, Cairo University
Marwa Rashad	Assistant Professor of Public Health, Cairo University

➢ **National Experts:**

1. **Diagnosis & Treatment Group**

Aisha El Sharkawy	Professor of Tropical Medicine, Cairo University
Tamer El Baz	Professor Of Tropical Medicine, Cairo University
Naglaa Allam	Professor of Medicine, National Liver Institute, Menofia University
Magdy El Dahshan	Professor of Medicine, Azhar University
Fatheya El Raey	Professor of Tropical Medicine, Azhar University
Samy Zaki	Professor of Tropical Medicine, Azhar University

2. **HCC & Mortality Group**

Mohamed Kamal Shaker	Professor of Tropical Medicine, Ain Shams University
Ashraf Omar	Professor Of Tropical Medicine, Cairo University
Basem Eysa	Assistant Professor of Tropical Medicine, National Hepatology and Tropical Medicine Research Institute
Ehab Fawzy	Professor of Tropical Medicine, Assuit University
Amin Abdel Beki	Professor of Tropical Medicine, National Hepatology and Tropical Medicine Research Institute
Wagida Anwar	Professor of Public Health, Ain Shams University

3. **Incidence Group:**

Mohsen Gad Allah	Professor of Public Health, Ain Shams University
Mohamed El Kassas	Professor of Tropical Medicine, Helwan University
Maysa Abdullah	Professor of Tropical Medicine, Zagazig University
Mohamed Omar	Professor of Tropical Medicine, Assuit University
Gasser El Azzab	Professor of Hepatology, National Liver Institute, Menofia University
Maysaa El Raziky	Professor Of Tropical Medicine, Cairo University

4. **Injection Safety & Infection Control Group:**

Hanaa Shalaby	Consultant of Infection Control, National Hepatology, and Tropical Medicine Research Institute
Amal Sayed	Director of the Committee for Control of Blood Born Pathogens, Cairo University
Ilham Ezzat	Director of the Infection Control Department, GOTHI
Ola Ahmed	Director of the Infection Control Department, HIO
Saadia Mousa	Director of Infection Control Department, Specialized Medical Centers

5. **Blood Safety & Availability Group:**

Heba Karam	Director, HIO

6. **Harm Reduction Group:**

Walid Kamal	UNAIDS
Tarek Sonan	UNODC
Mahmoud El Habibi	UNODC

➢ **International experts**

John Ward	Coalition for Global Hepatitis Elimination, Professor, Hubert Department of Global Health. The Taskforce for Global Health Rollins School of Public Health, Emory University, Atlanta, Georgia Director, Coalition for Global Hepatitis Elimination Professor, Hubert Department of Global Health, Rollins School of Public Health, Emory University, Atlanta Georgia
Homie Razavi	Founder and Director at the Center for Disease Analysis Foundation

- **Other Ministries:**

1. **Ministry Of Planning:**

Eng. Ashraf Abdelhafeez	Minister Assistant for Digital Transformation
Eng. Mohamed Abdel Azeem	Director, Information Technology Projects
Eng. Rofida Mahmoud	"Rapid Pro" Project Manager
Eng. Ahmed Youssef	Health Sector Projects Manager
Eng. Heba Masoud	Software and applications Developer

2. **Ministry Of Higher Education and clinical research:**

Hossam Abdel Ghaffar	Secretary-General of the Supreme Council of University Hospitals
Reem Jan	Professor of Clinical Pathology, Cairo University Director of Blood Banks at the Supreme Council of University Hospitals

3. **Ministry Of Education and Technical Education:**

Reda Hegazy	Minister Of Education and Technical Education

Annex II: National Committee for Control of viral hepatitis (NCCVH) guidelines for management of adult patients with HCV infection (2020)

NCCVH Guidelines for the Management of Adult Patients with HCV Infection August 2020

Inclusion criteria

Positive HCV RNA within the past 6 months. If the patient has received HCV therapy during that period, a new test should be performed.

Exclusion criteria

- Child C cirrhosis.
- Manifest liver decompensation: uncontrolled ascites, history of hepatic encephalopathy, hepatorenal syndrome.
- Serum albumin less than 2.8 g/dl, total bilirubin more than 3 mg/dl and INR 1.7 or more.
- Platelets count less than 50,000/mm^3.
- HCC, except 6 months after concluding an intervention aiming at cure with no evidence of activity by dynamic CT or MRI.
- Extra-hepatic malignancy except after two years of disease-free interval. In lymphomas and chronic lymphatic leukaemia, treatment can be initiated immediately after remission based on the treating oncologist's report.
- Pregnancy or inability to use effective contraception.

Precautions before starting treatment

- Check HCV treatment history.
- Ladies in the childbearing period should have a recent negative pregnancy test and should be counselled for effective contraception especially with the use of ribavirin.
- Check medications received by the patient especially cardiovascular disease therapy (particularly amiodarone), antipsychotic therapy and statins.
- Family counselling for the risk of transmission and prevention of infection.

Management of HCV treatment-naïve patients

Patients are categorized into "easy" or "not easy" to treat groups according to pre-treatment tests:

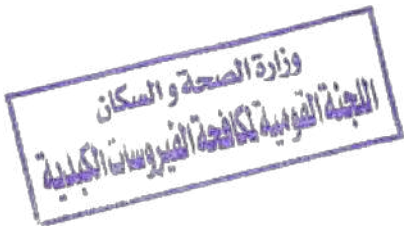
	Easy to treat group	Not easy to treat group
Criteria	• Total serum bilirubin ≤ 1.2 mg/dl • Serum albumin ≥ 3.5 g/dl • INR ≤ 1.2 • Platelets count ≥ 150,000/mm^3	• Total serum bilirubin > 1.2 mg/dl • Serum albumin < 3.5 g/dl • INR > 1.2 • Platelets count < 150,000/mm^3
Treatment regimen	SOF + DCV for 12 weeks	• SOF + DCV + RBV* for 12 weeks • SOF + DCV for 24 weeks if cases of RBV ineligibility or intolerance

*Ribavirin cannot be given if the patient's hemoglobin is less than 10 g/dl, in case of depression, or cardiac dysfunction. A drop of hemoglobin of 2 g, or less than 10 g/dl necessitates intervention either by dose reduction, possible use of erythropoietin or possible discontinuation. Ribavirin dose starts by 600 mg/day and is raised gradually to 1,000 mg/day according to tolerance.
DCV, daclatasvir; LDV, ledipasvir; RBV, ribavirin; SOF, sofosbuvir.

Management of HCV treatment-experienced patients

Previous Regimen	Child-Pugh class A	Child-Pugh class B
• IFN + RBV • INF+ SOF + RBV • SOF + RBV • SOF + SIM ± RBV • OBV/ PTV/r + RBV	SOF + DCV + RBV for 24 weeks	
• SOF + DCV for 12 weeks	SOF/VEL/VOX for 12 weeks	SOF/VEL + RBV (initial dose 600 mg daily) for 24 weeks ***(Treatment in special centers)***
• OBV/ PTV/r + SOF ± RBV for 12/24 weeks • SOF + SIM +DCV ± RBV for 12 weeks	SOF/VEL/VOX for 12 weeks	
• SOF/VEL/VOX for 12 weeks	SOF/VEL/VOX + RBV for 24 weeks	
• SOF/VEL + RBV for 24 weeks		

DCV, daclatasvir; IFN, interferon; LDV, ledipasvir; OBV, ombitasvir; PTV, paritaprevir; r, ritonavir; RBV, ribavirin; SIM, simeprevir; SOF, sofosbuvir; VEL, velpatasvir; VOX, voxilaprevir.



Patients with chronic kidney disease

- As described above for HCV treatment-naïve and experienced patients.
- Sofosbuvir-containing regimens could be used without dose adjustment in patients with renal disease, including those with an eGFR ≤30 ml/min and those on dialysis.
- RBV dose adjusted according to eGFR and hemoglobin level:
    - eGFR > 50: 600-1,200 mg daily as tolerated
    - eGFR 30-50: 400 mg alternating with 200 mg
    - eGFR < 30, not on dialysis: 200 mg daily to be reduced if not tolerated to 200 mg, 3 times weekly
    - eGFR <30, on dialysis: 200 mg, every other day given on dialysis day, 4 hours before dialysis.
    - Should be discontinued if hemoglobin level declines by more than 2 g/dl despite the use of erythropoietin.

Patients post-liver transplantation ***(Treatment in special centers)***

- As described above for HCV treatment-naïve and experienced patients.
- Voxilaprevir is not recommended in patients receiving cyclosporine.

Dual HBV and HCV infection

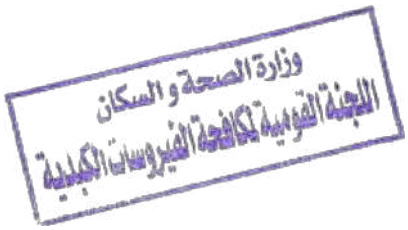
- HCV therapy should be started immediately, following the same rules as in patients with HCV mono-infection.
- HBsAg positive patients are treated if the treatment requirements are present, as in patients with HBV mono-infection. In case these criteria are not met (like an inactive carrier state), the following 2 options are available:
    - Initiate prophylaxis, to be continued until 12 weeks after end of treatment.
    - Monitor HBV DNA levels every 4 weeks, during and immediately after end of treatment for HCV. Nucleos(t)ide therapy is initiated if HBV DNA rises by 10-fold (one log), or if HBV DNA exceeds 1,000 IU/ml if it was previously undetectable.

Combined HCV/HIV Infection and HCV/HBV/HIV **(*Treatment in special centers)***

According to the special protocol for these co-infections.

Precautions after the end of treatment

- Confirmatory PCR test for the sustained virologic response should be performed 12 weeks after the end of treatment.
- Patients with advanced liver fibrosis (FIB4 ≥ 3.25) should be enrolled in the HCC surveillance program using AFP and abdominal ultrasonography every 4 months.
- HBV vaccination should be initiated if not already received.



Annex III: Nationwide Hepatitis C and NCDs screening & testing campaign “100 Million Healthy Lives: a step closer towards HCV elimination

Nationwide Hepatitis C and NCDs screening & testing campaign, "100 million Healthy lives": a step closer towards viral hepatitis elimination

Finally, in 2018, the Ministry of Health announced a massive screening effort , which began on October 1, 2018 . Its objective was to identify all individuals with HCV to be treated at the expense of the state. The screening was performed by a WHO-prequalified finger-prick-based rapid test (SD Bioline HCV, Abbott, Abbott Park, IL, USA) for individuals in outreach and rural areas (which included most of the target population), and blood-based immunoassay for screening done in hospitals and central facilities. Seropositive individuals were referred for HCV-RNA testing in 350 hospital facilities; those found to be positive were referred for evaluation and treatment in 180 specialized HCV treatment centers.

During the same time, a simultaneous screening program screened teenagers (between the ages of 12 and 18) in middle and high schools. They were screened in their schools if their parents signed a consent agreeing that their child be tested for HCV and treated if infected. Although screening was carried out in schools, to prevent stigmatization, the results were not known to the students or the school staff and were mailed to the parents, with an appointment in a health-insurance clinic for positive children to be evaluated and treated away from their schools. Of a target of 12 million teenagers, 7 million participated in screening, and 20,000 (0.3%) seropositive children were identified and evaluated. The SVR rate for treated children was 100%. This was the first teenage screening and treatment program for hepatitis C anywhere.

Figure (1) Hepatitis C screening & testing sites, "100 million Healthy lives

The MoHP applied the ***WHO's core testing principles*** during this national mass testing, including voluntary consent, confidentiality, counselling, correct test results, and connection (linkage to prevention, treatment, and care, and support services), to maximise both individual and public health benefits while ensuring client confidentiality.
The country was divided into three screening phases, as displayed in Table 3, each to be screened over a period of 2 or 3 months. Each phase included seven to eleven states, 100 to 150 administrative divisions, and a screening target population of 17.9 million to 23.3 million.

Table (1). Phases of the presidential initiative campaign

Phase	Frontiers Gov.	Delta	Urban Gov.	Upper Egypt
One	South Sinai	Damietta	Port Said	Fayoum
	Matrouh	Behira	Alexandria	Asuit
		Qalyubia		
Two	North Sinai	Kafr Elsheikh	Cairo	Sohag
	Red Sea	Menofia	Ismailia	Beni Sweif
			Suez	Luxor
				Aswan
Three	New Valley	Gharbia	Giza	Elmina
		Shariqa		Qena
		Dakahlia		

Screening sites and staff

Screening was conducted in all Ministry of Health hospitals, all primary and rural health units, the Egyptian Health Insurance Organization–managed clinics, university hospitals, and military and police hospitals, and all youth centres in all screened areas. Mobile screening teams in specially outfitted vehicles augmented the screening efforts by visiting crowded areas on special occasions (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, as displayed in Fig. 2.

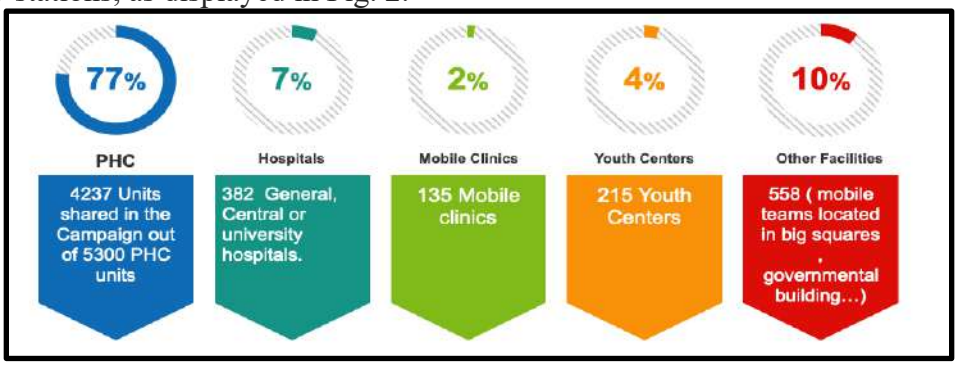


Figure (2). Types of screening sites

Each screening phase had 5800 to 8000 screening teams, each including a physician, a nurse, and a data entry person. Screening sites were open 12 hours per day, seven days per week. Training started two months before screening launched 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 the database, and to set further appointments electronically.

Screening process

Population data at the national, state, and district levels were obtained from the Central Agency for Public Mobilization and Statistics 2017 national census.[12,13] The names and national identification numbers of persons 18 years of age or older who were registered in each electoral district were obtained from the National Elections Authority,[14] which automatically registers everyone 18 years of age or older for voting in the district of his or her residence and has a comprehensive database of all persons 18 years of age or older.

Coverage

Figure 3 illustrates the flow of individuals reached by the 100 million healthy lives campaign. Patients diagnosed with but not treated for HCV registered at a website (stophcv.eg). Within 24 hours of registering, the person received a call from an operator to schedule an appointment at a nearby care centre within the NNTC. Individuals with no known history of HCV could also be screened for HCV without an appointment at any of the 5,820 testing sites (including 1,079 mobile units) throughout the country. [35] These individuals were tested onsite and typically received their results within 20 minutes. Individuals with positive screening tests were referred to the nearest NNTC member for confirmatory testing. Confirmed HCV cases were referred for treatment, which was typically approved within one week. All patients who were treated for HCV were asked to return to the treatment centre after completing the 12-week therapy to evaluate their sustained virologic response (cure status) for HCV.

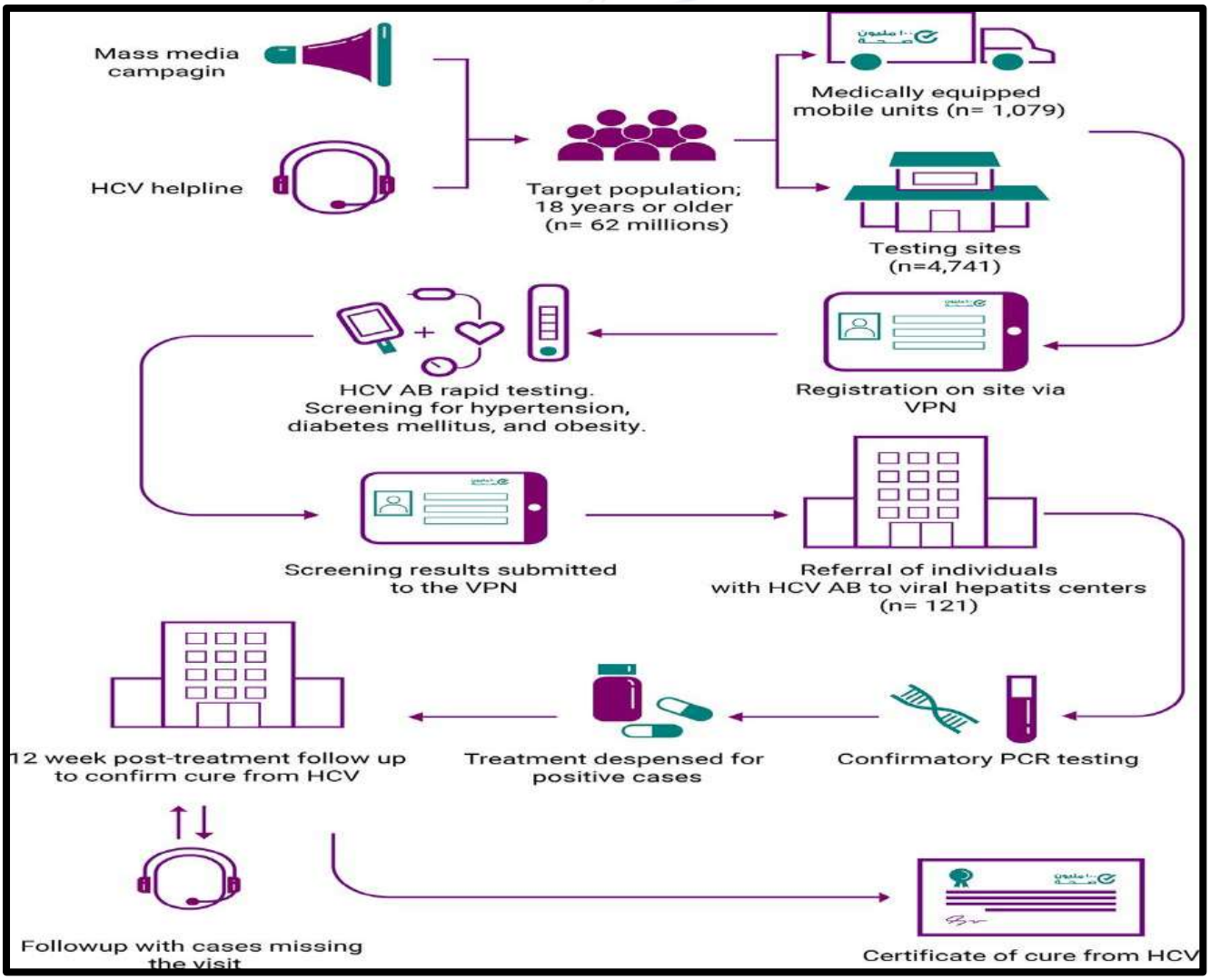


Figure (3) Hepatitis Screening process

Persons could be screened in any phase and any site, regardless of their residence. Participation in screening was voluntary, with no financial or in-kind incentives for participating and no punitive consequences for not participating. Participation in screening was encouraged and emphasized through a massive national advertisement campaign. Television advertisements ran on all channels throughout the screening period, several popular movie and music stars were contracted for the advertising campaign, and television and radio talk shows repeatedly had the national HCV screening program as their main theme. Newspaper advertisements and billboards on many roads were part of the advertising campaign, and millions of text messages were sent to cell phones in each phase.

Immediately before screening, the person's national identification number was electronically checked against the NCCVH database (which includes data on patients previously treated for HCV

infection with direct-acting antivirals since 2014). Patients who had been previously treated were not tested for HCV antibodies.

Persons were tested for HCV antibodies with the use of a finger-prick rapid diagnostic test, with results available within 20 minutes. Seropositive patients had appointments immediately scheduled electronically for a date within 2 to 15 days in the closest assigned center for evaluation and treatment. At the center, patients received clinical evaluation, underwent abdominal ultrasonography, and had blood drawn for HCV RNA and liver-function tests. Patients returned for results after 5 days, and treatment was prescribed for those with viremia. All patients were treated with sofosbuvir (400 mg daily) plus daclatasvir (60 mg daily) with or without ribavirin for a duration of 12 or 24 weeks, depending on the presence or absence of cirrhosis and the stage of cirrhosis. The time between screening and the dispensing of medication was usually 10 days, but it ran to 4 weeks for some patients who were delayed in scheduling or attending follow-up appointments. The shortest time for dispensing treatment was 6 days, and the longest time was 30 days.

The turnout for evaluation was continuously monitored. A call centre contacted seropositive persons who did not show up for their evaluation appointments and patients with viremia who did not return for treatment to inquire about reasons for no-shows and assign new appointments if necessary.

Continuous political support from the Egyptian presidency helped make all necessary resources available. The WHO, through its local office, monitored the campaign as an independent verification agent.

Verification of the work done through the campaign

To ensure the success of the national screening campaign, the World Health Organization was selected by the MoHP as the independent verification agency (IVA) for the verification of the work done through the campaign. WHO, as IVA was monitoring that the MoHP was respecting the WHO's core testing guiding principles, which are consent, confidentiality, counseling, correct test results, and connection to care, is also being monitored through the increased confirmation testing post-HCV treatment (Sustained Virological Response, or SVR), to monitor the HCV cure rates. These were carried out by an audit and verification team of experts, who began their work in October 2018 and continued until the mission's official end in May 2019. By May 2019, screening services continued at 313 sites nationwide, ensuring the sustainability of the screening services. http://www.stophcv.eg/

Annex IV:

Nationwide Hepatitis C and NCDs screening & testing campaign “100 Million Healthy Lives: a step closer towards HCV elimination

Annex IV: HCV Cascade of Care

		2015	2016	2017	2018	2019	2020	2021	2022	Diagnosis coverage (%)	Treatment coverage (%)	SVR %
General data	RNA Prevalence (%)	7	6.025	5.294	4.7	3.1	2.2	1.6	0.38			
	Incidence	0.003000	0.002585	0.002169	0.001754	0.001338	0.000923	0.000507	0.000092			
	Crude death rate (15-59 y)	0.0029	0.0027	0.0026	0.0035	0.0035	0.0040	0.0030	0.0025			
Cairo	Population 15-59 y (n)	5,855,237	5,991,944	6,187,083	6,282,054	6,361,758	6,430,586	6,493,855	6,557,634	81.8	92.4	98.0
	HCV RNA prevalence (%)	4.7	3.9	3.7	3.6	1.65	1.3	1.0	0.54			
	HCV RNA prevalence (n)	275,196	235,933	230,662	224,338	104,969	82,312	67,103	35,411			
	Weighted incidence	0.002014	0.001689	0.001528	0.001320	0.000712	0.000539	0.000330	0.000131			
	New cases (n)		9,722	9,099	7,995	4,457	3,419	2,121				
	Patients treated in MOHP cumulative (n)	12,207	15,204	19,026	90,888	142,603	144,967	145,692	146,120			
	Patients treated in MOHP (n)	12,207	2,997	3,822	71,862	51,715	2,364	725	428			
	Patients reated outside MOHP cumulative (n)	57,033										
	Patients reated outside MOHP (n)	4,765	1,170	1,492	28,049	20,185	923	283	167			
	Total treated (n)	16,972	4,167	5,314	99,911	71,900	3,287	1,008	595			
	Ineligible to treatment cumulative (n)		1,396	3,255	5,470	7,751	9,994	13,322	16,794			
	Crude death rate (15-59 y)	0.0046	0.0044	0.0045	0.0062	0.0063	0.0069	0.0056	0.0047			
	HCV deaths (n)	1,265	1,077	1,079	1,434	684	594	211	87			
Giza	Population 15-59 y (n)	4,828,890	4,941,502	5,156,493	5,254,042	5,342,527	5,427,592	5,499,832	5,576,768	87.3	92.44	99.10
	HCV RNA prevalence (%)	4.4	3.8	3.6	3.5	1.8	1.3	0.9	0.21			
	HCV RNA prevalence (n)	212,471	185,306	184,989	182,085	96,165	68,930	50,415	11,711			
	Weighted incidence	0.001886	0.001609	0.001470	0.001281	0.000777	0.000534	0.000293	0.000051			
	New cases (n)		7,651	7,308	6,496	4,077	2,863	1,595				
	Patients treated in MOHP cumulative (n)	14,584	18,390	27,286	37,853	119,434	120,751	121,235	121,505			
	Patients treated in MOHP (n)	14,584	3,806	8,896	10,567	81,581	1,317	484	270			
	Patients reated outside MOHP cumulative (n)	47,426										
	Patients reated outside MOHP (n)	5,692	1,486	3,472	4,125	31,843	514	189	105			
	Total treated (n)	20,276	5,292	12,368	14,692	113,424	1,831	673	375			

	Ineligible to treatment cumulative (n)		1,244	2,676	4,362	6,145	7,689	10,678	13,818			
	Crude death rate (15-59 y)	0.0030	0.0027	0.0025	0.0036	0.0036	0.0045	0.0033	0.0026			
	HCV deaths (n)	632	530	489	674	360	320	172	31			
Qalyubia	Population 15-59 y (n)	3,240,432	3,316,030	3,393,504	3,451,766	3,503,361	3,552,387	3,595,137	3,641,520	82.4	93.44	98.70
	HCV RNA prevalence (%)	5.7	4.9	4.5	4.1	2.7	1.9	1.3	0.27			
	HCV RNA prevalence (n)	184,705	164,061	152,220	142,876	94,240	66,903	48,375	9,832			
	Weighted incidence	0.002443	0.002122	0.001838	0.001530	0.001161	0.000792	0.000430	0.000065			
	New cases (n)		6,690	5,958	5,062	3,959	2,762	1,524				
	Patients treated in MOHP cumulative (n)	18,422	22,285	27,917	94,101	97,068	100,016	100,542	100,936			
	Patients treated in MOHP (n)	18,422	3,863	5,632	66,184	2,967	2,948	526	394			
	Patients reated outside MOHP cumulative (n)	39,397										
	Patients reated outside MOHP (n)	7,190	1,508	2,198	25,833	1,158	1,151	205	154			
	Total treated (n)	25,612	5,371	7,830	92,017	4,125	4,099	731	548			
	Ineligible to treatment cumulative (n)		1,010	2,176	3,583	4,970	6,366	7,969	9,846			
	Crude death rate (15-59 y)	0.0026	0.0024	0.0023	0.0032	0.0032	0.0039	0.0029	0.0023			
	HCV deaths (n)	475	417	363	471	312	275	144	23			
Menoufia	Population 15-59 y (n)	2,509,628	2,568,156	2,522,124	2,570,000	2,612,983	2,655,068	2,689,770	2,728,428	88.6	93.85	97.80
	HCV RNA prevalence (%)	11.4	9.6	8.0	6.8	4.3	3.0	2.2	0.47			
	HCV RNA prevalence (n)	286,098	246,864	201,376	173,816	111,052	79,387	57,830	12,824			
	Weighted incidence	0.004886	0.004124	0.003272	0.002499	0.001835	0.001258	0.000687	0.000114			
	New cases (n)		9,572	7,593	5,989	4,590	3,240	1,807				
	Patients treated in MOHP cumulative (n)	29,640	39,428	52,402	132,524	163,171	168,267	168,755	169,105			
	Patients treated in MOHP (n)	29,640	9,788	12,974	80,122	30,647	5,096	488	350			
	Patients reated outside MOHP cumulative (n)	66,005										
	Patients reated outside MOHP (n)	11,569	3,820	5,064	31,273	11,962	1,989	190	137			
	Total treated (n)	41,209	13,608	18,038	111,395	42,609	7,085	678	487			
	Ineligible to treatment cumulative (n)		1,872	3,849	6,107	8,339	10,351	12,711	15,419			
	Crude death rate (15-59 y)	0.0026	0.0024	0.0023	0.0032	0.0031	0.0038	0.0028	0.0022			
	HCV deaths (n)	734	626	479	579	357	313	169	29			

Gharbiya	Population 15-59 y (n)	3,014,808	3,085,138	3,008,112	3,060,539	3,107,711	3,151,639	3,185,300	3,224,355	92.4	94.31	98.40
	HCV RNA prevalence (%)	9.8	8.1	6.9	5.9	3.0	2.1	1.4	0.09			
	HCV RNA prevalence (n)	295,451	250,128	206,225	181,083	94,164	64,609	44,488	2,902			
	Weighted incidence	0.004200	0.003478	0.002809	0.002187	0.001308	0.000863	0.000446	0.000022			
	New cases (n)		9,860	7,871	6,296	3,942	2,663	1,401				
	Patients treated in MOHP cumulative (n)	39,984	51,768	64,593	97,808	177,840	181,746	182,299	182,811			
	Patients treated in MOHP (n)	39,984	11,784	12,825	33,215	80,032	3,906	553	512			
	Patients reated outside MOHP cumulative (n)	71,355										
	Patients reated outside MOHP (n)	15,607	4,600	5,006	12,964	31,238	1,525	216	200			
	Total treated (n)	55,591	16,384	17,831	46,179	111,270	5,431	769	712			
	Ineligible to treatment cumulative (n)		1,856	3,825	6,179	8,238	10,480	12,757	15,343			
	Crude death rate (15-59 y)	0.0029	0.0028	0.0027	0.0037	0.0036	0.0042	0.0030	0.0023			
	HCV deaths (n)	871	726	580	695	357	280	136	7			
Beheira	Population 15-59 y (n)	3,710,977	3,797,467	3,635,180	3,716,544	3,789,947	3,859,734	3,917,833	3,973,932	71.1	90.93	98.60
	HCV RNA prevalence (%)	8.8	7.2	6.2	5.4	2.3	1.7	1.2	0.29			
	HCV RNA prevalence (n)	326,566	272,848	224,063	200,612	88,685	63,943	47,058	11,524			
	Weighted incidence	0.003771	0.003082	0.002526	0.001995	0.001010	0.000697	0.000384	0.000070			
	New cases (n)		10,864	8,615	7,014	3,739	2,646	1,485				
	Patients treated in MOHP cumulative (n)	34,196	39,784	48,169	145,183	148,198	149,192	149,804	150,365			
	Patients treated in MOHP (n)	34,196	5,588	8,385	97,014	3,015	994	612	561			
	Patients reated outside MOHP cumulative (n)	58,690										
	Patients reated outside MOHP (n)	13,347	2,181	3,273	37,866	1,177	388	239	219			
	Total treated (n)	47,543	7,769	11,658	134,880	4,192	1,382	851	780			
	Ineligible to treatment cumulative (n)		2,009	4,261	6,916	9,722	12,991	16,551	20,851			
	Crude death rate (15-59 y)	0.0025	0.0024	0.0022	0.0029	0.0028	0.0033	0.0026	0.0019			
	HCV deaths (n)	801	672	508	607	261	218	124	22			
Kafr El Sheikh	Population 15-59 y (n)	2,021,892	2,069,032	1,989,947	2,030,357	2,067,155	2,107,395	2,134,227	2,162,300	144.1	92.42	98.50
	HCV RNA prevalence (%)	5.5	4.7	4.3	4.0	2.4	1.8	1.4	0.52			
	HCV RNA prevalence (n)	111,204	97,710	85,904	81,471	49,405	37,231	28,836	11,244			
	Weighted incidence	0.002357	0.002026	0.001769	0.001483	0.001032	0.000743	0.000431	0.000126			

	New cases (n)		3,994	3,368	2,890	2,082	1,539	908				
	Patients treated in MOHP cumulative (n)	22,804	35,750	41,111	84,043	101,890	104,525	104,824	105,171			
	Patients treated in MOHP (n)	22,804	12,946	5,361	42,932	17,847	2,635	299	347			
	Patients reated outside MOHP cumulative (n)	41,050										
	Patients reated outside MOHP (n)	8,901	5,053	2,093	16,757	6,966	1,028	117	135			
	Total treated (n)	31,705	17,999	7,454	59,689	24,813	3,663	416	482			
	Ineligible to treatment cumulative (n)		1,151	2,306	3,901	5,465	7,189	9,249	11,993			
	Crude death rate (15-59 y)	0.0026	0.0024	0.0023	0.0030	0.0030	0.0035	0.0026	0.0019			
	HCV deaths (n)	289	249	205	257	153	135	77	22			
Alexandria	Population 15-59 y (n)	3,040,602	3,111,582	3,201,197	3,250,781	3,292,816	3,333,745	3,362,677	3,393,328	71.4	93.83	98.50
	HCV RNA prevalence (%)	3.6	3.0	3.0	3.0	1.2	1.0	0.9	0.64			
	HCV RNA prevalence (n)	109,462	93,581	97,016	99,083	40,502	34,449	30,339	21,717			
	Weighted incidence	0.001543	0.001290	0.001242	0.001126	0.000531	0.000435	0.000288	0.000155			
	New cases (n)		3,894	3,855	3,550	1,727	1,434	960				
	Patients treated in MOHP cumulative (n)	5,986	7,407	9,441	48,586	51,031	51,333	51,495	51,740			
	Patients treated in MOHP (n)	5,986	1,421	2,034	39,145	2,445	302	162	245			
	Patients reated outside MOHP cumulative (n)	20,195										
	Patients reated outside MOHP (n)	2,336	555	794	15,279	954	118	63	96			
	Total treated (n)	8,322	1,976	2,828	54,424	3,399	420	225	341			
	Ineligible to treatment cumulative (n)		424	959	1,627	2,352	3,028	3,836	4,734			
	Crude death rate (15-59 y)	0.0036	0.0035	0.0033	0.0046	0.0046	0.0055	0.0041	0.0033			
	HCV deaths (n)	389	341	331	475	196	197	127	71			
Matrouh	Population 15-59 y (n)	294,235	301,070	237,053	248,974	260,214	272,237	282,532	292,392	48.9	97.30	99.10
	HCV RNA prevalence (%)	3.6	3.1	3.1	3.1	1.4	0.9	0.6	0			
	HCV RNA prevalence (n)	10,592	9,183	7,260	7,648	3,643	2,541	1,758	0			
	Weighted incidence	0.001543	0.001308	0.001255	0.001135	0.000604	0.000393	0.000199	0.000000			
	New cases (n)		382	288	274	155	106	56				
	Patients treated in MOHP cumulative (n)	105	131	157	3,414	3,551	3,563	3,573	3,574			
	Patients treated in MOHP (n)	105	26	26	3,257	137	12	10	1			

	Patients reated outside MOHP cumulative (n)	1,395										
	Patients reated outside MOHP (n)	41	10	10	1,271	53	5	4	0			
	Total treated (n)	146	36	36	4,528	190	17	14	1			
	Ineligible to treatment cumulative (n)		10	21	39	56	79	107	138			
	Crude death rate (15-59 y)	0.0028	0.0028	0.0028	0.0041	0.0035	0.0040	0.0039	0.0034			
	HCV deaths (n)	29	27	21	32	13	11	7	0			
Dakahlia	Population 15-59 y (n)	3,773,536	3,861,565	3,821,592	3,887,168	3,946,078	4,002,420	4,044,306	4,090,624	114.7	96.27	99.00
	HCV RNA prevalence (%)	7.8	6.5	5.6	5.0	2.5	1.8	1.2	0.20			
	HCV RNA prevalence (n)	294,336	250,422	215,490	194,516	100,230	70,443	50,149	8,181			
	Weighted incidence	0.003343	0.002782	0.002311	0.001849	0.001097	0.000741	0.000396	0.000048			
	New cases (n)		10,046	8,332	6,829	4,217	2,912	1,582				
	Patients treated in MOHP cumulative (n)	61,342	73,673	87,164	124,222	224,158	227,589	229,314	230,801			
	Patients treated in MOHP (n)	61,342	12,331	13,491	37,058	99,936	3,431	1,725	1,487			
	Patients reated outside MOHP cumulative (n)	90,086										
	Patients reated outside MOHP (n)	23,943	4,813	5,266	14,464	39,007	1,339	673	580			
	Total treated (n)	85,285	17,144	18,757	51,522	138,943	4,770	2,398	2,067			
	Ineligible to treatment cumulative (n)		1,401	2,916	4,448	5,999	7,667	9,700	12,431			
	Crude death rate (15-59 y)	0.0030	0.0030	0.0026	0.0037	0.0036	0.0041	0.0030	0.0024			
	HCV deaths (n)	885	773	587	749	375	298	156	20			
Sharkiya	Population 15-59 y (n)	4,130,700	4,227,014	4,193,444	4,275,589	4,350,534	4,422,155	4,482,120	4,549,703	84.3	96.61	98.90
	HCV RNA prevalence (%)	10.4	8.6	7.3	6.2	3.3	2.4	1.7	0.40			
	HCV RNA prevalence (n)	429,593	365,003	304,077	265,661	145,308	104,363	76,495	18,199			
	Weighted incidence	0.004457	0.003704	0.002971	0.002296	0.001442	0.000993	0.000545	0.000097			
	New cases (n)		14,306	11,556	9,208	6,063	4,287	2,401				
	Patients treated in MOHP cumulative (n)	52,124	62,214	76,095	110,264	243,241	247,226	248,084	248,810			
	Patients treated in MOHP (n)	52,124	10,090	13,881	34,169	132,977	3,985	858	726			
	Patients reated outside MOHP cumulative (n)	97,115										
	Patients reated outside MOHP (n)	20,345	3,938	5,418	13,337	51,903	1,555	335	283			
	Total treated (n)	72,469	14,028	19,299	47,506	184,880	5,540	1,193	1,009			

	Ineligible to treatment cumulative (n)		1,278	2,643	4,134	5,672	7,299	9,513	12,139			
	Crude death rate (15-59 y)	0.0028	0.0026	0.0024	0.0033	0.0032	0.0037	0.0028	0.0022			
	HCV deaths (n)	1,183	999	769	897	481	406	220	40			
Damietta	Population 15-59 y (n)	845,031	864,746	891,146	906,206	919,196	931,427	940,850	950,158	111.8	94.67	99.20
	HCV RNA prevalence (%)	8.2	6.8	5.9	5.2	2.5	1.9	1.5	0.70			
	HCV RNA prevalence (n)	69,293	58,608	52,204	46,838	23,072	17,759	14,155	6,651			
	Weighted incidence	0.003514	0.002907	0.002400	0.001910	0.001084	0.000802	0.000480	0.000169			
	New cases (n)		2,344	2,014	1,642	971	733	445				
	Patients treated in MOHP cumulative (n)	14,100	18,780	22,931	49,969	51,482	51,742	51,866	51,961			
	Patients treated in MOHP (n)	14,100	4,680	4,151	27,038	1,513	260	124	95			
	Patients reated outside MOHP cumulative (n)	20,281										
	Patients reated outside MOHP (n)	5,504	1,827	1,620	10,553	591	101	48	37			
	Total treated (n)	19,604	6,507	5,771	37,591	2,104	361	172	132			
	Ineligible to treatment cumulative (n)		354	716	1,091	1,551	2,068	2,761	4,065			
	Crude death rate (15-59 y)	0.0033	0.0032	0.0029	0.0040	0.0040	0.0043	0.0035	0.0026			
	HCV deaths (n)	229	196	155	193	95	79	51	18			
Port Said	Population 15-59 y (n)	420,706	430,524	468,750	474,419	479,262	483,817	487,132	490,336	69.1	97.54	98.80
	HCV RNA prevalence (%)	4.1	3.4	3.4	3.3	1.5	1.0	0.7	0			
	HCV RNA prevalence (n)	17,249	14,832	15,744	15,628	7,093	4,774	3,204	0			
	Weighted incidence	0.001757	0.001478	0.001376	0.001217	0.000639	0.000415	0.000210	0.000000			
	New cases (n)		614	623	559	302	199	102				
	Patients treated in MOHP cumulative (n)	1,449	1,659	1,911	7,632	8,164	8,245	8,251	8,252			
	Patients treated in MOHP (n)	1,449	210	252	5,721	532	81	6	1			
	Patients reated outside MOHP cumulative (n)	3,221										
	Patients reated outside MOHP (n)	566	82	98	2,233	208	32	2	0			
	Total treated (n)	2,015	292	350	7,954	740	113	8	1			
	Ineligible to treatment cumulative (n)		57	111	164	221	257	276	289			
	Crude death rate (15-59 y)	0.0027	0.0026	0.0023	0.0036	0.0035	0.0037	0.0029	0.0022			
	HCV deaths (n)	46	40	37	58	26	18	9	0			

Ismailia	Population 15-59 y (n)	753,338	770,898	763,848	780,717	795,817	810,105	822,334	834,664	110.6	94.52	98.60
	HCV RNA prevalence (%)	4.3	3.7	3.6	3.5	2.0	1.3	0.9	0			
	HCV RNA prevalence (n)	32,394	28,697	27,246	26,936	15,837	10,747	7,273	0			
	Weighted incidence	0.001843	0.001597	0.001462	0.001275	0.000859	0.000558	0.000282	0.000000			
	New cases (n)		1,185	1,077	961	670	446	230				
	Patients treated in MOHP cumulative (n)	3,713	4,338	5,076	17,417	23,737	23,873	23,915	23,951			
	Patients treated in MOHP (n)	3,713	625	738	12,341	6,320	136	42	36			
	Patients reated outside MOHP cumulative (n)	9,349										
	Patients reated outside MOHP (n)	1,449	244	288	4,817	2,467	53	16	14			
	Total treated (n)	5,162	869	1,026	17,158	8,787	189	58	50			
	Ineligible to treatment cumulative (n)		257	525	789	1,071	1,357	1,679	1,930			
	Crude death rate (15-59 y)	0.0033	0.0030	0.0029	0.0041	0.0039	0.0042	0.0034	0.0027			
	HCV deaths (n)	107	90	82	114	64	47	25	0			
Suez	Population 15-59 y (n)	395,698	404,930	441,795	449,318	456,179	462,594	467,853	473,445	97.6	94.19	98.80
	HCV RNA prevalence (%)	3.8	3.3	3.2	3.2	1.7	1.1	0.8	0			
	HCV RNA prevalence (n)	15,037	13,251	14,267	14,365	7,709	5,212	3,514	0			
	Weighted incidence	0.001629	0.001404	0.001323	0.001182	0.000730	0.000474	0.000240	0.000000			
	New cases (n)		550	566	514	327	217	111				
	Patients treated in MOHP cumulative (n)	1,766	2,015	2,365	6,696	9,580	9,721	9,744	9,769			
	Patients treated in MOHP (n)	1,766	249	350	4,331	2,884	141	23	25			
	Patients reated outside MOHP cumulative (n)	3,813										
	Patients reated outside MOHP (n)	689	97	137	1,690	1,126	55	9	10			
	Total treated (n)	2,455	346	487	6,021	4,010	196	32	35			
	Ineligible to treatment cumulative (n)		95	204	314	422	537	682	838			
	Crude death rate (15-59 y)	0.0032	0.0033	0.0028	0.0036	0.0037	0.0042	0.0034	0.0028			
	HCV deaths (n)	49	46	42	53	30	23	12	0			
N.Sinai	Population 15-59 y (n)	277,166	283,630	257,621	262,263	266,061	276,526	280,411	284,325	35.3	94.61	98.50
	HCV RNA prevalence (%)	3.6	3.1	3.1	3.1	1.4	0.9	0.6	0			
	HCV RNA prevalence (n)	9,978	8,651	7,890	8,056	3,725	2,581	1,745	0			
	Weighted incidence	0.001543	0.001308	0.001255	0.001135	0.000604	0.000393	0.000199	0.000000			

	New cases (n)		360	313	289	159	108	55				
	Patients treated in MOHP cumulative (n)	109	130	145	1,050	2,331	2,349	2,354	2,362			
	Patients treated in MOHP (n)	109	21	15	905	1,281	18	5	8			
	Patients reated outside MOHP cumulative (n)	922										
	Patients reated outside MOHP (n)	43	8	6	353	500	7	2	3			
	Total treated (n)	152	29	21	1,258	1,781	25	7	11			
	Ineligible to treatment cumulative (n)		15	39	50	67	83	126	187			
	Crude death rate (15-59 y)	0.0033	0.0032	0.0038	0.0026	0.0023	0.0025	0.0023	0.0020			
	HCV deaths (n)	33	29	31	22	9	7	4	0			
S.Sinai	Population 15-59 y (n)	105,189	107,648	58,704	60,030	61,190	63,421	64,558	65,816	61.8	99.04	98.30
	HCV RNA prevalence (%)	3.6	3.3	3.2	3.2	2.3	1.5	1.0	0			
	HCV RNA prevalence (n)	3,787	3,525	1,897	1,920	1,407	972	660	0			
	Weighted incidence	0.001543	0.001405	0.001324	0.001182	0.000993	0.000645	0.000326	0.000000			
	New cases (n)		146	75	69	59	40	21				
	Patients treated in MOHP cumulative (n)	7	12	17	1,278	1,635	1,638	1,638	1,638			
	Patients treated in MOHP (n)	7	5	5	1,261	357	3	0	0			
	Patients reated outside MOHP cumulative (n)	639										
	Patients reated outside MOHP (n)	3	2	2	492	139	1	0	0			
	Total treated (n)	10	7	7	1,753	496	4	0	0			
	Ineligible to treatment cumulative (n)		1	3	6	12	15	20	22			
	Crude death rate (15-59 y)	0.0031	0.0028	0.0054	0.0061	0.0065	0.0067	0.0065	0.0062			
	HCV deaths (n)	12	10	11	12	10	7	4	0			
Fayoum	Population 15-59 y (n)	2,039,293	2,086,780	1,984,358	2,033,717	2,077,482	2,117,683	2,156,059	2,199,164	94.7	89.55	98.60
	HCV RNA prevalence (%)	8	6.8	5.9	5.2	3.3	2.6	2.1	1.21			
	HCV RNA prevalence (n)	163,143	142,475	116,990	105,687	68,765	55,272	46,212	26,610			
	Weighted incidence	0.003429	0.002929	0.002416	0.001921	0.001429	0.001098	0.000684	0.000293			
	New cases (n)		5,695	4,511	3,703	2,870	2,265	1,444				
	Patients treated in MOHP cumulative (n)	20,471	27,553	43,547	92,710	95,908	97,635	98,165	98,625			
	Patients treated in MOHP (n)	20,471	7,082	15,994	49,163	3,198	1,727	530	460			

	Patients reated outside MOHP cumulative (n)	38,495										
	Patients reated outside MOHP (n)	7,990	2,764	6,243	19,189	1,248	674	207	180			
	Total treated (n)	28,461	9,846	22,237	68,352	4,446	2,401	737	640			
	Ineligible to treatment cumulative (n)		1,496	3,368	5,443	7,669	9,951	12,741	15,997			
	Crude death rate (15-59 y)	0.0020	0.0018	0.0017	0.0021	0.0022	0.0026	0.0020	0.0016			
	HCV deaths (n)	326	273	211	235	160	147	95	42			
Bani-Sweif	Population 15-59 y (n)	1,837,155	1,879,934	1,767,272	1,811,235	1,852,335	1,892,555	1,927,224	1,966,773	102.8	97.23	98.80
	HCV RNA prevalence (%)	8	7.0	6.0	5.3	4.0	2.8	1.9	0.18			
	HCV RNA prevalence (n)	146,972	131,783	106,611	95,984	74,834	52,108	36,532	3,540			
	Weighted incidence	0.003429	0.003007	0.002472	0.001958	0.001744	0.001158	0.000605	0.000044			
	New cases (n)		5,257	4,105	3,359	3,100	2,132	1,145				
	Patients treated in MOHP cumulative (n)	18,114	23,982	33,908	84,035	102,663	103,766	104,236	104,587			
	Patients treated in MOHP (n)	18,114	5,868	9,926	50,127	18,628	1,103	470	351			
	Patients reated outside MOHP cumulative (n)	40,822										
	Patients reated outside MOHP (n)	7,070	2,290	3,874	19,566	7,271	431	183	137			
	Total treated (n)	25,184	8,158	13,800	69,693	25,899	1,534	653	488			
	Ineligible to treatment cumulative (n)		587	1,018	1,494	2,009	2,489	3,205	4,142			
	Crude death rate (15-59 y)	0.0022	0.0021	0.0020	0.0025	0.0024	0.0029	0.0022	0.0017			
	HCV deaths (n)	320	285	221	252	188	155	81	6			
Minia	Population 15-59 y (n)	3,311,983	3,389,119	3,126,894	3,210,307	3,287,375	3,362,928	3,440,756	3,516,304	92.5	96.52	99.00
	HCV RNA prevalence (%)	10.5	8.7	7.3	6.2	3.2	2.4	1.9	0.86			
	HCV RNA prevalence (n)	347,758	294,176	227,794	200,283	105,853	81,831	65,680	30,240			
	Weighted incidence	0.004500	0.003723	0.002985	0.002306	0.001390	0.001024	0.000610	0.000208			
	New cases (n)		11,524	8,654	6,940	4,423	3,359	2,058				
	Patients treated in MOHP cumulative (n)	46,918	61,953	100,296	130,520	217,240	219,900	220,894	221,564			
	Patients treated in MOHP (n)	46,918	15,035	38,343	30,224	86,720	2,660	994	670			
	Patients reated outside MOHP cumulative (n)	86,481										
	Patients reated outside MOHP (n)	18,313	5,868	14,966	11,797	33,848	1,038	388	262			
	Total treated (n)	65,231	20,903	53,309	42,021	120,568	3,698	1,382	932			

	Ineligible to treatment cumulative (n)		1,570	2,871	4,393	5,964	7,303	9,026	11,119			
	Crude death rate (15-59 y)	0.0020	0.0018	0.0018	0.0023	0.0022	0.0026	0.0018	0.0016			
	HCV deaths (n)	702	563	419	479	246	224	125	49			
Assiut	Population 15-59 y (n)	2,719,338	2,782,695	2,521,041	2,590,368	2,654,407	2,716,844	2,774,884	2,836,055	88.3	92.28	98.50
	HCV RNA prevalence (%)	4.2	3.6	3.5	3.4	1.7	1.3	1.0	0.44			
	HCV RNA prevalence (n)	114,212	99,412	87,086	87,186	44,859	34,594	27,626	12,479			
	Weighted incidence	0.001800	0.001533	0.001415	0.001244	0.000730	0.000536	0.000318	0.000107			
	New cases (n)		4,112	3,445	3,114	1,904	1,437	873				
	Patients treated in MOHP cumulative (n)	13,347	16,414	23,727	62,871	64,817	65,921	66,035	66,099			
	Patients treated in MOHP (n)	13,347	3,067	7,313	39,144	1,946	1,104	114	64			
	Patients reated outside MOHP cumulative (n)	25,800										
	Patients reated outside MOHP (n)	5,210	1,197	2,854	15,279	760	431	44	25			
	Total treated (n)	18,557	4,264	10,167	54,423	2,706	1,535	158	89			
	Ineligible to treatment cumulative (n)		632	1,337	2,178	3,061	4,197	5,759	7,691			
	Crude death rate (15-59 y)	0.0027	0.0025	0.0025	0.0032	0.0032	0.0035	0.0025	0.0021			
	HCV deaths (n)	305	255	228	292	148	125	72	27			
Suhaj	Population 15-59 y (n)	2,952,961	3,021,757	2,799,978	2,874,724	2,945,654	3,015,201	3,075,535	3,141,972	122.8	91.90	98.40
	HCV RNA prevalence (%)	3.3	2.9	2.9	3.0	1.6	1.0	0.7	0			
	HCV RNA prevalence (n)	97,448	86,649	81,917	85,357	46,247	31,559	21,460	0			
	Weighted incidence	0.001414	0.001230	0.001199	0.001097	0.000678	0.000440	0.000223	0.000000			
	New cases (n)		3,610	3,258	3,061	1,965	1,314	681				
	Patients treated in MOHP cumulative (n)	20,807	24,718	32,608	64,675	77,084	77,717	77,988	78,242			
	Patients treated in MOHP (n)	20,807	3,911	7,890	32,067	12,409	633	271	254			
	Patients reated outside MOHP cumulative (n)	30,539										
	Patients reated outside MOHP (n)	8,121	1,527	3,080	12,516	4,843	247	106	99			
	Total treated (n)	28,928	5,438	10,970	44,583	17,252	880	377	353			
	Ineligible to treatment cumulative (n)		895	1,781	2,800	3,858	5,207	7,159	9,583			
	Crude death rate (15-59 y)	0.0023	0.0021	0.0020	0.0026	0.0025	0.0027	0.0021	0.0017			
	HCV deaths (n)	225	188	166	227	120	89	46	0			

Qena	Population 15-59 y (n)	1,950,588	1,996,036	1,842,617	1,890,357	1,934,375	1,984,615	2,022,408	2,065,534	100.8	80.42	97.90
	HCV RNA prevalence (%)	4.3	3.5	3.4	3.3	1.1	1.0	0.9	0.63			
	HCV RNA prevalence (n)	83,875	70,061	62,787	62,961	22,052	19,251	17,325	13,013			
	Weighted incidence	0.001843	0.001506	0.001396	0.001231	0.000492	0.000408	0.000274	0.000153			
	New cases (n)		2,900	2,485	2,249	941	802	549				
	Patients treated in MOHP cumulative (n)	11,980	13,717	18,398	26,613	47,682	48,043	48,255	48,434			
	Patients treated in MOHP (n)	11,980	1,737	4,681	8,215	21,069	361	212	179			
	Patients reated outside MOHP cumulative (n)	18,905										
	Patients reated outside MOHP (n)	4,676	678	1,827	3,206	8,224	141	83	70			
	Total treated (n)	16,656	2,415	6,508	11,421	29,293	502	295	249			
	Ineligible to treatment cumulative (n)		854	1,939	3,633	5,644	8,075	11,763	16,390			
	Crude death rate (15-59 y)	0.0021	0.0020	0.0020	0.0026	0.0026	0.0030	0.0022	0.0018			
	HCV deaths (n)	175	147	132	172	59	59	39	24			
Luxor	Population 15-59 y (n)	730,428	747,463	763,023	779,391	795,217	810,254	822,152	836,337	89.3	99.94	98.70
	HCV RNA prevalence (%)	4.2	3.4	3.3	3.3	0.9	0.6	0.4	0			
	HCV RNA prevalence (n)	30,678	25,246	25,242	25,378	7,236	4,916	3,325	0			
	Weighted incidence	0.001800	0.001449	0.001356	0.001203	0.000393	0.000255	0.000129	0.000000			
	New cases (n)		1,046	1,000	907	310	206	106				
	Patients treated in MOHP cumulative (n)	0	0	0	3,947	5,704	5,705	5,705	5,705			
	Patients treated in MOHP (n)	0	0	0	3,947	1,757	1	0	0			
	Patients treated in NGOs cumulative (n)	0	2,615	8,670	16,371	19,153	19,153	19,153	19,153			
	Patients treated in NGOs (n)	0	2,615	6,055	7,701	2,782	0	0	0			
	Patients reated outside MOHP cumulative (n)	2,227										
	Patients reated outside MOHP (n)	0	234	542	1,043	407	0	0	0			
	Total treated (n)	0	2,849	9,212	17,414	19,560	19,153	19,153	19,153			
	Ineligible to treatment cumulative (n)	16										
	Crude death rate (15-59 y)	0.0025	0.0024	0.0024	0.0032	0.0032	0.0040	0.0030	0.0022			
	HCV deaths (n)	76	63	63	84	24	20	10	0			
Aswan	Population 15-59 y (n)	913,021	934,308	886,555	907,212	925,403	943,319	957,923	974,658	62.4	84.84	98.60

	HCV RNA prevalence (%)	5.7	4.6	4.2	4.0	1.4	0.9	0.6	0			
	HCV RNA prevalence (n)	52,042	43,212	37,623	35,906	12,956	8,804	5,960	0			
	Weighted incidence	0.002443	0.001984	0.001739	0.001463	0.000604	0.000393	0.000199	0.000000			
	New cases (n)		1,768	1,476	1,274	551	367	189				
	Patients treated in MOHP cumulative (n)	3,781	4,333	6,048	16,980	20,289	20,402	20,448	20,483			
	Patients treated in MOHP (n)	3,781	552	1,715	10,932	3,309	113	46	35			
	Patients reated outside MOHP cumulative (n)	7,995										
	Patients reated outside MOHP (n)	1,476	215	669	4,267	1,292	44	18	14			
	Total treated (n)	5,257	767	2,384	15,199	4,601	157	64	49			
	Ineligible to treatment cumulative (n)		292	641	1,141	1,664	2,166	2,779	3,659			
	Crude death rate (15-59 y)	0.0024	0.0022	0.0022	0.0032	0.0033	0.0039	0.0031	0.0026			
	HCV deaths (n)	127	100	88	118	44	36	19	0			
Red Sea	Population 15-59 y (n)	220,292	225,436	213,846	218,357	222,598	227,052	230,775	234,621	121.5	97.19	98.70
	HCV RNA prevalence (%)	2.1	1.9	2.2	2.4	1.3	0.9	0.6	0			
	HCV RNA prevalence (n)	4,626	4,283	4,705	5,295	2,894	1,968	1,333	0			
	Weighted incidence	0.000900	0.000815	0.000901	0.000896	0.000561	0.000365	0.000185	0.000000			
	New cases (n)		180	189	191	123	82	42				
	Patients treated in MOHP cumulative (n)	82	94	135	2,308	3,825	3,837	3,843	3,853			
	Patients treated in MOHP (n)	82	12	41	2,173	1,517	12	6	10			
	Patients reated outside MOHP cumulative (n)	1,504										
	Patients reated outside MOHP (n)	32	5	16	848	592	5	2	4			
	Total treated (n)	114	17	57	3,021	2,109	17	8	14			
	Ineligible to treatment cumulative (n)		10	20	34	57	77	110	155			
	Crude death rate (15-59 y)	0.0032	0.0029	0.0033	0.0040	0.0039	0.0037	0.0039	0.0034			
	HCV deaths (n)	15	13	16	22	12	8	5	0			
New Valley	Population 15-59 y (n)	143,459	146,807	144,704	147,641	150,189	153,070	154,936	157,274	99.1	94.27	98.70
	HCV RNA prevalence (%)	2.1	1.9	2.2	2.4	1.2	0.8	0.5	0			
	HCV RNA prevalence (n)	3,013	2,753	3,156	3,560	1,802	1,225	826	0			
	Weighted incidence	0.000900	0.000804	0.000894	0.000891	0.000518	0.000337	0.000170	0.000000			

	New cases (n)		116	127	128	77	51	26				
	Patients treated in MOHP cumulative (n)	100	124	143	227	1,980	1,993	1,995	1,999			
	Patients treated in MOHP (n)	100	24	19	84	1,753	13	2	4			
	Patients reated outside MOHP cumulative (n)	780										
	Patients reated outside MOHP (n)	39	9	7	33	684	5	1	2			
	Total treated (n)	139	33	26	117	2,437	18	3	6			
	Ineligible to treatment cumulative (n)		7	22	41	59	74	114	169			
	Crude death rate (15-59 y)	0.0022	0.0020	0.0020	0.0025	0.0022	0.0030	0.0026	0.0018			
	HCV deaths (n)	7	6	7	9	4	4	2	0			
Total	Population 15-59 y (n)	56,036,583	57,343,211	56,277,881	57,424,076	58,457,824	59,466,369	60,313,379	61,218,420	86.7	93.7	98.6
	HCV RNA prevalence (n)	3,922,561	3,454,928	2,979,210	2,724,952	1,812,193	1,304,296	958,313	232,630			
	New cases (n)		139,278	115,612	95,927	75,808	53,675	30,118				
	Patients treated in MOHP cumulative (n)	448,138	565,856	744,616	1,537,814	2,206,306	2,241,662	2,250,949	2,258,462			
	Patients treated in MOHP (n)	448,138	117,718	178,760	793,198	668,492	35,356	9,287	7,513			
	Other Public Sector cumulative (n)	94,116										
		18,675	4,906	7,449	33,055	27,858	1,473	387	313			
	Patients treated in NGOs Cumulative (n)	159,368										
		31,623	8,307	12,614	55,972	47,172	2,495	655	530			
	Patients treated in the private cumulative (n)	38,510	92,528	127,120	147,386	268,811	599,965	628,037				
		124,619	32,735	49,710	220,574	185,895	9,832	2,583	2,089			
	Total treated outside MOHP cumulative (n)	881,521										
	Total treated outside MOHP (n)	174,917	45,948	69,773	309,600	260,925	13,800	3,625	2,932			
	Total treated (n)	623,055	163,666	248,533	1,102,798	929,417	49,156	12,912	10,445			
	Ineligible to treatment cumulative (n)	211,751										
	Ineligible to treatment (n)	42,017	11,037	16,760	74,369	62,677	3,315	871	704			
	HCV deaths (n)	11,248	9,772	8,043	9,934	6,557	5,457	3,014	572			
	People living with HCV (n)								221,613			

Annex V: National Regulation of blood and blood components in Egypt

قانون رقم ٨ لسنة ٢٠٢١

بإصدار قانون تنظيم عمليات الدم وتجميع البلازما لتصنيع مشتقاتها وتصديرها

باسم الشعب

رئيس الجمهورية

قرر مجلس النواب القانون الآتى نصه ، وقد أصدرناه :

(المادة الأولى)

تسرى أحكام القانون المرافق على عمليات الدم ، وتجميع البلازما وتصنيع مشتقاتها وتسفيرها واستيرادها وتصديرها .

(المادة الثانية)

يُلغى القانون رقم ١٧٨ لسنة ١٩٦٠ بتنظيم عمليات جمع وتخزين وتوزيع الدم ومركباته بالإقليم الجنوبى ، كما يُلغى كل نص يخالف أحكام القانون المرافق .

(المادة الثالثة)

يلتزم المخاطبون بأحكام القانون المرافق بتوفيق أوضاعهم طبقًا لأحكامه وذلك خلال مدة لا تجاوز ثلاثة أشهر من تاريخ صدور اللائحة التنفيذية للقانون المرافق .

(المادة الرابعة)

يصدر رئيس مجلس الوزراء اللائحة التنفيذية للقانون المرافق خلال ثلاثة أشهر من تاريخ العمل بهذا القانون بناءً على عرض الوزير المختص بالصحة ، وإلى أن تصدر هذه اللائحة يستمر العمل بالقرارات القائمة بما لا يتعارض مع أحكامه .

(المادة الخامسة)

يُنشر هذا القانون فى الجريدة الرسمية ، ويُعمل به من اليوم التالى لتاريخ نشره .

يُبصم هذا القانون بخاتم الدولة ، ويُنفذ كقانون من قوانينها .

صدر برئاسة الجمهورية فى ٣ رمضان سنة ١٤٤٢هـ

(الموافق ١٥ أبريل سنة ٢٠٢١م) .

عبد الفتاح السيسى

قانون تنظيم عمليات الدم
وتجميع البلازما لتصنيع مشتقاتها وتصديرها

(الفصل الأول)
التعريفات

مادة (١) :

يُقصد فى تطبيق أحكام هذا القانون بالكلمات والعبارات التالية المعنى المبين قرين كل منها :

الوزارة المختصة : الوزارة المختصة بشئون الصحة .

الوزير المختص : الوزير المختص بشئون الصحة .

عمليات الدم : جمع الدم ومركباته ومشتقاته ، أو فحصه أو تخزينه أو توزيعه أو نقله عدا البلازما لغرض التصنيع .

البلازما : هى إحدى مشتقات الدم ، وتشمل البلازما العلاجية والبلازما المجمعة لغرض التصنيع .

مشتقات البلازما : مستحضرات حيوية مشتقة من مكونات بلازما الدم البشرى ، منها على سبيل المثال الألبومين وعوامل التجلط وغيرها من مشتقات البلازما .

مركز تجميع البلازما : مركز مرخص له بعمليات تبرع أو تجميع أو تخزين أو تحليل أو توزيع البلازما لأغراض التصنيع .

تسفير البلازما : إرسال بلازما الدم بغرض تصنيعها خارج جمهورية مصر العربية وإعادتها فى صورة مشتقات بلازما .

المتبرع المنتظم : كل متطوع للتبرع بالبلازما بشكل منتظم طبقًا للقواعد الطبية .

هيئة الشراء الموحد : الهيئة المصرية للشراء الموحد والإمداد والتموين الطبى وإدارة التكنولوجيا الطبية .

(الفصل الثانى)

تنظيم عمليات الدم

مـادة (٢) :

مع عدم الإخلال بأحكام ترخيص مراكز عمليات الدم فى أى قانون آخر ، لا يجوز القيام بأى من عمليات الدم إلا فى مركز متخصص ثابت أو متنقل بعد الحصول على ترخيص من الوزارة المختصة .

ولا يمنح هذا الترخيص إلا للجهات الحكومية وغير الحكومية التى يدخل فى اختصاصها القيام بعمليات الدم .

ويحدد الوزير المختص المواصفات والاشتراطات التى يجب أن تتوافر فى المركز ، بناءً على عرض مجلس مراقبة عمليات الدم .

مـادة (٣) :

يؤدى طالب الترخيص الرسوم الآتية :

ما لا يجاوز عشرين ألف جنيه مقابل الفحص عند تقديم طلب الترخيص .

ما لا يجاوز مائة ألف جنيه مقابل إصدار الترخيص .

ما لا يجاوز خمسين ألف جنيه مقابل تجديد الترخيص .

على أن يتم سداد هذه الرسوم بأى وسيلة من وسائل الدفع الإلكترونى المحددة قانونًا ، ويُعفى من أداء هذه الرسوم الجهات الحكومية .

وتحدد اللائحة التنفيذية لهذا القانون فئات هذه الرسوم ، وبيانات وإجراءات تقديم طلب الترخيص وتجديده ، وإجراءات التظلم من القرار الصادر بشأنه .

مـادة (٤) :

على الطبيب المرخص له بإدارة مركز عمليات الدم أخذ كمية الدم المتبرع بها من المتبرعين بمعرفته وتحت إشرافه ومسئوليته .

وفى جميع الأحوال ، يجب أن يكون التبرع بالدم تطوعًا وبغير مقابل .

مادة (٥) :

يُعد بكل مركز لعمليات الدم سجل إلكترونى أو ورقى يدون به أسماء المتبرعين اللائقين طبيًا الذين يسمح لهم بالتبرع فى هذا المركز ، ويتعين على هذه المراكز الربط فيما بينها بما يحقق إتاحة الأسماء المقيدة فى السجلات الخاصة بها لجميع المراكز .

ويصدر ببيان طريقة القيد بالسجلات والتحقق من شخص المتبرع وقواعد تغيير مركز التبرع قرار من الوزير المختص ، وتصرف بطاقة لكل متبرع تحدد اللائحة التنفيذية لهذا القانون شروط صرفها وبياناتها .

مادة (٦) :

يُنشأ بالوزارة المختصة مجلس لمراقبة عمليات الدم برئاسة الوزير المختص أو من ينيبه ، وعضوية كل من :

مدير عام خدمات نقل الدم القومية بالوزارة المختصة (مقرراً) .

ممثل عن وزارة الدفاع والإنتاج الحربى ، يرشحه وزير الدفاع والإنتاج الحربى .

ممثل عن وزارة الداخلية ، يرشحه وزير الداخلية .

ممثل عن وزارة التعليم العالى والبحث العلمى ، يرشحه وزير التعليم العالى والبحث العلمى .

أمين المجلس الأعلى للمستشفيات الجامعية .

ممثل عن هيئة الشراء الموحد ، يرشحه رئيس الهيئة .

ممثل عن هيئة الدواء المصرية ، يرشحه رئيس الهيئة .

ممثل عن الهيئة العامة للتأمين الصحى ، يرشحه رئيس الهيئة .

ممثل عن الهيئة العامة للرعاية الصحية ، يرشحه رئيس الهيئة .

ممثل عن الهيئة العامة للاعتماد والرقابة الصحية ، يرشحه رئيس الهيئة .

مدير الإدارة المركزية للمؤسسات العلاجية غير الحكومية والتراخيص الطبية بالوزارة المختصة .

مدير الإدارة العامة لشئون الدم ومشتقاته بالوزارة المختصة .

ممثل عن الجمعيات الطبية الخاضعة لأحكام قانون تنظيم ممارسة العمل الأهلى الصادر بالقانون رقم ١٤٩ لسنة ٢٠١٩ ، يرشحه وزير التضامن الاجتماعى .

ممثل عن مراكز الدم الخاصة ، يختاره الوزير المختص .

اثنين من ذوى الخبرة ، يختارهما رئيس مجلس الوزراء بعد عرض الوزير المختص .

ويصدر رئيس مجلس الوزراء قراراً بتسمية مجلس مراقبة عمليات الدم .

مادة (٧) :

يختص مجلس مراقبة عمليات الدم بما يلى :

١ - الإشراف الفنى على مراكز عمليات الدم ، والتفتيش على استيفاء هذه المراكز للاشتراطات والمواصفات المقررة .

٢ - توحيد أسلوب وطريقة العمل والمواد المستخدمة فى مراكز عمليات الدم دون تقييد أغراض البحث العلمى .

٣ - إنشاء قاعدة بيانات مركزية إلكترونية مرتبطة بجميع مراكز عمليات الدم وهيئة الدواء المصرية وهيئة الشراء الموحد لبيان مقدار ما تم تجميعه وما تم صرفه والمخزون المتاح لدى جميع المراكز .

٤ - تقييم البحوث الفنية المتعلقة بالنواحى المتصلة بعمليات الدم ، وتقييم أعمال مراكز عمليات الدم المرخص بها سنويًا مع عدم الإخلال بحرية البحث العلمى .

٥ - وضع المواصفات والاشتراطات الواجب توافرها فى المراكز المختصة بعمليات الدم .

٦ - وضع قواعد تحديد أثمان الدم ومركباته ومشتقاته ، وأسعار خدمات الدم فى القطاع الحكومى والخاص ، وتحديد سعر مقابل خدمات نقل الدم فى القطاع الخاص للمواطنين ، وذلك كله استرشاداً بالمعايير الدولية المعمول بها .

٧ - مراجعة لوائح عمليات الدم وتطويرها .

٨ - إعداد اللائحة الداخلية لمجلس مراقبة عمليات الدم ونظام العمل بها ، ويصدر بهذه اللائحة قرار من الوزير المختص .

(الفصل الثالث)

تجميع البلازما لتصنيع مشتقاتها وتصديرها

مادة (٨) :

لا يجوز القيام بتجميع بلازما الدم بغرض تصنيع مشتقاتها إلا عن طريق مركز مرخص له .

كما لا يجوز القيام بتصنيع مشتقات بلازما الدم إلا عن طريق مصنع مرخص له .

وذلك كله مع الاسترشاد بالمعايير الدولية المعمول بها .

مادة (٩) :

يصدر بترخيص تشغيل مركز تجميع بلازما الدم وتجديده قرار من هيئة الدواء المصرية ، كما يصدر بترخيص التشغيل الفنى للمصنع وتجديده قرار من هيئة الدواء المصرية بعد التنسيق مع هيئة الشراء الموحد .

ويؤدى طالب الترخيص رسم فحص لا يجاوز أربعين ألف جنيه حال تقديم الطلب ، وعند الترخيص يحصل رسم لا يجاوز مائتى ألف جنيه ، كما يحصل رسم لا يجاوز مائة ألف جنيه عند تجديد الترخيص ، على أن يتم سداد هذه الرسوم بأى وسيلة من وسائل الدفع الإلكترونى المحددة قانونًا ، ويعفى من أداء هذه الرسوم الجهات الحكومية .

وتحدد اللائحة التنفيذية لهذا القانون فئات ذلك الرسم ومواصفات واشتراطات الترخيص ، وبيانات وإجراءات تقديم طلب الترخيص ومدته وتجديده ، ومواعيد البت فيه والتظلم من القرار الصادر بشأنه .

مادة (١٠) :

يحظر الحصول على بلازما الدم إلا من متبرع لائق طبيًا .

وتحدد اللائحة التنفيذية لهذا القانون شروط التبرع وعدد مراته وفقًا للمعايير المتعارف عليها دوليًا ، ووفقًا للحالة الصحية والعمرية للمتبرعين والشروط والأوضاع التى يصير فيها المتبرع منتظمًا .

مادة (١١) :

يلتزم مركز تجميع بلازما الدم أن يمنح المتبرع عوضًا يتناسب مع نفقات الانتقال ومقابل التغذية وساعات العمل وأى نفقات أخرى يتحملها المتبرع فى سبيل تبرعه ، وتحدد اللائحة التنفيذية لهذا القانون قواعد احتساب هذا العوض .

مادة (١٢) :

لمركز تجميع بلازما الدم التصرف فيما يجمعه منها إلى أى من المصانع الخاضعة لأحكام هذا القانون ، وتسفيرها ، وتصدير مشتقات البلازما منتهية التصنيع بعد تحقيق الاكتفاء الذاتى منها وفقًا للضوابط التى تضعها هيئة الدواء المصرية بالتنسيق مع هيئة الشراء الموحد .

مادة (١٣) :

للمصنع الخاضع لأحكام هذا القانون التصرف فى مشتقات البلازما ، وذلك عن طريق البيع أو التصدير .

وله استيراد بلازما الدم أو تصديرها كمشتقات منتهية التصنيع .

وذلك كله وفقًا للأحكام والقواعد والإجراءات التى يصدر بها قرار من هيئة الدواء المصرية بعد التنسيق مع هيئة الشراء الموحد بعد تحقيق الاكتفاء الذاتى من مشتقات البلازما .

مادة (١٤) :

يكون مركز تجميع بلازما الدم مسئولاً عن الأضرار التى تلحق بالمتبرع أثناء عملية التبرع أو بسببها .

(الفصل الرابع)

أحكام عامة

مادة (١٥) :

مع مراعاة حكم المادة (١١) من هذا القانون ، يجب أن يكون التبرع بالدم أو بلازما الدم تطوعًا وبغير مقابل .

وفى جميع الأحوال يكون التبرع صادراً عن إرادة حرة خالية من عيوب الرضا على النحو الذى تحدده اللائحة التنفيذية لهذا القانون .

ولا يقبل التبرع من الطفل ولا يعتد بموافقة أبويه أو من له الولاية أو الوصاية عليه ، كما لا يقبل التبرع من عديم الأهلية أو ناقصها ، ولا يعتد بموافقة من ينوب عنه أو من يمثله قانونًا .

ويكون استبعاد المتبرع لأسباب طبية دون غيرها من أسباب التمييز الأخرى ، وذلك بعد إجراء الفحوصات والتحاليل الطبية .

مادة (١٦) :

تلتزم كافة الجهات العاملة فى مجال عمليات الدم وتجميع البلازما بسرية بيانات المتبرع والمتبرع إليه وعدم الإفصاح عنها إلا بموجب أمر على عريضة يصدر من قاضى الأمور الوقتية بالمحكمة الابتدائية التابع لها تلك الجهات ، أو بقرار من جهة التحقيق المختصة .

مادة (١٧) :

يجب على كافة المراكز المعنية بتجميع الدم والبلازما إجراء الفحوصات الطبية اللازمة التى تحددها اللائحة التنفيذية لهذا القانون قبل استخدام الدم ومكوناته والبلازما ومشتقاتها ، فيما عدا ما تتطلبه أغراض البحث العلمى .

مادة (١٨) :

يُحظر الإفراج الصحى عن أى وحدات دم أو مكوناته أو البلازما أو مشتقاتها المستوردة أو المهداة إلا بعد التأكد من خلوها من كافة الأمراض والفيروسات المعدية التى يصدر بتحديدها قرار من الوزير المختص بالتنسيق مع هيئة الدواء المصرية ، وذلك بتحليل عينات من جميع التشغيلات الواردة بالرسائل وإصدار شهادة رسمية معتمدة تفيد خلوها من هذه الأمراض والفيروسات وفقًا للضوابط والقواعد الأخرى التى تحددها اللائحة التنفيذية لهذا القانون فى هذا الشأن .

مادة (١٩) :

يُصرف الدم أو مكوناته والبلازما بغرض علاجى بالمجان لمرضى أقسام العلاج المجانى بجميع المستشفيات التابعة للدولة وفقًا للضوابط التى يصدر بها قرار من الوزير المختص .

مادة (٢٠) :

يُصدر وزير العدل بالاتفاق مع كل من الوزير المختص ووزير الدفاع والإنتاج الحربى ووزير الداخلية ووزير التعليم العالى والبحث العلمى ورئيس مجلس إدارة هيئة الدواء المصرية ، كل فيما يخصه ، قراراً بمنح صفة الضبطية القضائية للموظفين الذين يتولون الإشراف والرقابة والتفتيش على المنشآت الخاضعة لأحكام هذا القانون .

(الفصل الخامس)

الجـزاءات

مادة (٢١) :

مع عدم الإخلال بأية عقوبة أشد ، يعاقب بغرامة لا تقل عن مائة ألف جنيه ولا تجاوز مليون جنيه كل من ارتكب أيًا من الأفعال الآتية :

١ - أدار مركز عمليات الدم بدون ترخيص بالمخالفة لأحكام هذا القانون ولائحته التنفيذية .

٢ - أدار مركز تجميع بلازما الدم أو مصنعًا لتصنيع مشتقاتها بدون ترخيص بالمخالفة لأحكام هذا القانون ولائحته التنفيذية .

٣ - صدّر أو استورد بلازما الدم بالمخالفة لأحكام هذا القانون والقرارات الصادرة تنفيذاً له أو شرع فى ذلك .

٤ - حصل على دم أو بلازما من متبرع غير لائق طبيًا بالمخالفة لأحكام هذا القانون ولائحته التنفيذية .

٥ - خالف أحكام المادتين (١٥، ١٦) من هذا القانون .

٦ - امتنع عن إعطاء دم عمداً رغم توافره أو قام ببيعه بسعر مخالف للأسعار المحددة .

ومع عدم الإخلال بحقوق الغير حسن النية ، للمحكمة فضلاً عن العقوبة المنصوص عليها فى الفقرة السابقة مصادرة الأجهزة والأدوات والمهمات موضوع المخالفة ، وغلق المركز أو المصنع .

وتضاعف الغرامة فى حالة العود .

مادة (٢٢) :

يعاقب المسئول عن الإدارة الفعلية للشخص الاعتبارى بذات العقوبات عن الأفعال التى تُرتكب بالمخالفة لأحكام هذا القانون متى ثبت علمه بها وكان إخلاله بواجبات الإدارة قد سهل وقوع الجريمة .

ويكون الشخص الاعتبارى مسئولاً بالتضامن عن الوفاء بما يُحكم به من عقوبات مالية وتعويضات إذا كانت المخالفة قد ارتكبت من أحد العاملين به باسم ولصالح الشخص الاعتبارى .

مادة (٢٣) :

للجهة المختصة بإصدار الترخيص غلق المركز أو المصنع إداريًا إذا أدير دون ترخيص أو دون إشراف طبيب بشرى على المركز أو دون مراعاة المواصفات والاشتراطات التى تحددها اللائحة التنفيذية لهذا القانون .

وتحدد اللائحة التنفيذية لهذا القانون مدة الغلق وإجراءاته ، وأحوال إلغاء قرار الترخيص ومواعيد التظلم منه والبت فيه .

Annex VI: Draft Concept note for estimating and monitoring the mortality from cirrhosis and hepatocellular carcinoma attributable to viral hepatitis B and C at a national level (WHO, 2022)

DRAFT VERSION – not yet IRB approved

Concept note for estimating and monitoring the mortality from cirrhosis and hepatocellular carcinoma attributable to viral hepatitis B and C at a national level

Background

In 2016, the World Health Organisation (WHO) published the Global Health Sector Strategy (GHSS) for hepatitis that aims at the elimination of hepatitis B and C as public health threats by 2030. A reduction of mortality due to the hepatitis B (HBV) and C (HCV) virus infections is one of the two criteria that the GHSS uses to define elimination. Indeed, one of the two impact targets outlined in the GHSS is related to hepatitis mortality. The GHSS for HIV, viral hepatitis and sexually transmitted infections for the period 2022 – 2030 and the supporting WHO guidance for country validation of hepatitis elimination includes the use of absolute impact targets to validate elimination at the national level, instead of, although equivalent to, the relative reduction targets originally defined in the 2016 GHSS. (1, 2)

While the WHO and the Global Burden of Disease (GBD) project have estimated mortality from viral hepatitis at the global level based on modelling approaches using data from published studies, most countries have not yet established a clear system for generating national estimates of mortality due to long term sequalae from chronic HBV and HCV infections. Deaths related to hepatitis C infections are mostly due to decompensated cirrhosis and hepatocellular carcinoma, but accurately measuring mortality is challenging as death certificates often do not capture the underlying disease (e.g., viral hepatitis infection). Here we propose and describe two independent collection of data that are complementary to support countries in monitoring mortality from HBV and HCV over time at the national level. The overarching goal is to set up a long-term surveillance system in the country.

1. The first is to estimate the proportions of sequelae (cirrhosis and HCC) that are attributable to hepatitis B and C viruses or to other risk factors that are known to cause these sequelae. These proportions, also referred to as **attributable fractions (AFs)**, vary greatly between countries due to differences in the scale and progression of HBV and HCV epidemics over time and to the presence of other risk factors (alcohol, NAFLD, or other rarer conditions) in the country population. Up to date attributable fractions are best estimated in selected sentinel centres that diagnose, follow-up and treat representative populations of patients with cirrhosis and HCC.
2. The second is to estimate the "**mortality envelope**" from chronic liver disease (i.e., cirrhosis and HCC). This "mortality envelope" is a term that has been developed to define all the different possible causes of death (e.g., HCC) that are potentially related to HBV or HCV as defined by ICD coding or other criteria (e.g., clinical). National mortality data are usually available from vital statistics registries, but their quality need to be assessed to ensure that all (or an acceptable proportion of) deaths occurring as a consequence of decompensated cirrhosis or primary liver cancer, namely HCC, are captured, whatever the underlying cause. This assessment should be done by the country as the accuracy of vital statistics strongly depends on the challenges faced locally.

   To assess the quality of vital statistics, one may consider the following options (non-exhaustive):

   a. Mortality from cirrhosis and HCC in selected sentinel sites can be measured and compared to data corresponding to the same geographical area as reported in the national vital statistic database.
   b. Unexpected or unexplained geographical or temporal variations in cirrhosis/ HCC mortality could be investigated.
   c. Triangulation with strong available other robust data sources such as cancer registries or cohorts of patients (if available) may be undertaken.

Applying AF estimates to the mortality envelope derived from vital statistics will enable calculation of national mortality due to viral hepatitis sequelae over time.

In 2019, WHO developed a protocol to support countries in implementing simple studies to collect the data needed to generate national estimates. This protocol, available at: https://www.who.int/publications/i/item/9789241515191 (Annex 2), provides a standardised method to estimate the proportion of patients with cirrhosis and HCC that have HBV and HCV infection in sentinel centres. This template protocol needs to be adapted to a country specific setting.

An amended and simplified methodological approach is outlined in this short concept note. Two departures from the original protocol need to be highlighted:

- One of the key suggested changes to the initial protocol is that the attributable fraction should be only based on the proportion of patients diagnosed with **decompensated cirrhosis (DC)** (by opposition to all cirrhotic patients) **and HCC**. The rational for this change is that decompensated patients are more likely to die at the cirrhosis stage than patients with compensated cirrhosis. Therefore, the estimated AF in these two groups (DC and HCC) will better reflect the underlying cause of death when applied to the mortality envelope.
- A further suggestion is that **a surveillance system** should be ultimately developed to allow **periodical or continuous collection of data** over the years to monitor AF changes due to health policy measures or, in the absence of public health measure, to the natural course of the epidemic in a given country.

Main steps in measuring hepatitis related mortality

1. To carefully select one or several sentinel centres (see below).
2. To recruit or assess a representative and large enough sample of **consecutive** patients with **decompensated cirrhosis and HCC** over a predefined period.
3. To assess for these patients the underlying cause of the disease: HBV (also ideally HDV) and HCV chronic infection, as well other non-viral causes, through a review of medical records supplemented, where appropriate, by direct contact (interview/questionnaire) with care givers.
4. To calculate the proportion of patients that have HBV and HCV infection, or other non-viral causes (attributable fractions, AFs);
5. To apply theses AFs to the mortality envelope derived from vital statistics, in order to estimate national mortality due to viral hepatitis sequelae.

Design

A **prospective** or **cross-sectional** study design that follows up patients over time and collects real-time information may be easiest to implement as opposed as to a retrospective approach that requires a search through different sources to identify data relating to previous patients who may have died, and their records be hard to locate or for whom information may have been lost. However, in some instances, a **retrospective** approach may be quicker to undertake and may therefore be more feasible, especially if there are challenging ethical considerations (e.g., consent forms for the prospective recruitment of patients), lack of funding, or large sample sizes.

Sentinel centres

The selection of the sentinel sites requires careful consideration and should include centres that see patients with **both decompensated cirrhosis and HCC in sufficient numbers** for the required sample size. The selection of sentinel sites should include a prior assessment of the underlying characteristics of patients attending the centre through discussion with local clinicians to **avoid centres with major source of referral bias that would affect the AF** and to ensure that data can be collected from all the various departments where patients with decompensated cirrhosis and/or HCC are cared for. Whilst it may be easier and more feasible to collect data from just one sentinel site, representativeness is likely to be improved if data were collected from a few different clinical sites across the country.

Population

Any patient with decompensated cirrhosis or HCC seen during the study period. Patients seen several times should be included only once. The inclusion of patients in departments other than hepatology and gastroenterology is important as patients with decompensated cirrhosis or HCC may present with a range of untypical complications (e.g., sepsis, haemorrhage, encephalopathy…).

Investigators

Participating centres will identify a team of investigators for the purpose of the data collection. A lead will be identified who will be the liaison point for the country lead investigator.

Case definitions

Cases are broadly defined using the clinical criteria below, but these criteria should be **refined and adapted to the country health care specificity**:

Decompensated cirrhosis

- case of decompensated cirrhosis defined by clinical symptoms (e.g., recurrent or refractory ascites, portal hypertension-related bleeding, hepatic encephalopathy, acute kidney injury and hepatorenal syndrome,)

Hepatocellular carcinoma

- Case defined using imaging criteria or pathological evidence.

Sample size considerations

The sample size will depend upon the **highest expected viral AF** in the sentinel centre and the desired precision for the estimate. The sample size calculation will need to be undertaken for decompensated cirrhosis and HCC separately. For an absolute precision of 5%, it may roughly vary between 70 and 400, depending on the expected highest AF. A local decision may need to be made around the desired level of precision for the estimate and the size of the sample that is reasonable to collect.

Sample sizes have been estimated below for a range of values for the expected highest AF using absolute precision values of 5% (table 1).

Table 1: Example of sample size calculations based on an absolute precision of 5%.

Estimated AF*	Estimated sample size	Estimated AF*	Estimated sample size
50%	384	50%	384
40%	369	60%	369
35%	350	65%	350
30%	323	70%	323
25%	288	75%	288
20%	246	80%	246
15%	196	85%	196
10%	138	90%	138
5%	73	95%	73

*Highest expected AF (for HBV or for HCV) in the sentinel centre (use 50% if not sure)

Data collection

- For each case, investigators will extract information from the patients' records using a case report form (See enclosed template table that can be locally adapted as necessary).
- Data extracted should include at least age, sex, serological testing showing HBV (possibly HDV) and/or HCV chronic infection, as well as excessive alcohol consumption, and metabolic syndrome components (diabetes, obesity). Other rare risk factors for cirrhosis or HCC will be aggregated under 'other cause'.
- As this information is normally collected as part of the assessment of a patient with cirrhosis or HCC under normal clinical practice, no additional data need to be collected for the purpose of the surveillance activity.

Expected outcomes

- Improved national mortality estimates (after applying the attributable fraction data to the mortality envelope);
- Capacity building for the ongoing surveillance of HBV and HCV infection among patients with cirrhosis and HCC;
- Creation of a community of practice/partnership with clinicians, laboratory, and public health specialists, that could be used for other data collections or research initiatives.

References

1. World Health Organization. Interim guidance for country validation of viral hepatitis elimination. Geneva, 2021.
2. World Health Organization. Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022-2030. Geneva, 2022.

Minimum set of data to be extracted

General characteristics				
Centre:				
Case ID:				
Date of inclusion (dd/mm/yyyy):		_____ /_____/ _____		
Age:				
Gender:		☐ Male ☐ Female ☐ Other		
Sequelae				
Decompensated cirrhosis ☐		***Hepatocellular carcinoma** ☐		
Optional: Clinical main symptom (see case definition), and/or APRI score, Fib-4 index		*Optional*: Diagnosis tool (see case definition)		
Possible risk factors/exposures for cirrhosis or hepatocellular carcinoma				
Chronic infection with viral hepatitis viruses (HBV and/or HCV)				
HBV	HBsAg	☐ Positive	☐ Negative	☐ Unknown
	HBV DNA (last available) (IU/ml)			☐ Unknown
	Optional: Currently under treatment	☐ Yes	☐ No	☐ Unknown
	Optional: Treatment regimen			☐ Unknown
	Optional: HDV test (RNA or Ab)	☐ Positive	☐ Negative	☐ Unknown
HCV	Anti-HCV	☐ Positive		☐ Unknown
	HCV RNA (last available)	☐ Detectable	☐ Undetectable	☐ Unknown
	HCV core antigen	☐ Positive	☐ Negative	☐ Unknown
	Optional: Received treatment with DAA	☐ Yes	☐ No	☐ Unknown
	Optional: Treatment regimen			☐ Unknown
	Optional: Treatment date (dd/mm/yyyy)	Start: ___/___/_____	End: ___/___/_____	☐ Unknown
Other risk factors				
Excessive alcohol consumption, as per local definition		☐ Yes	☐ No	☐ Unknown
Arterial hypertension		☐ Yes	☐ No	☐ Unknown
Fatty liver disease		☐ Yes	☐ No	☐ Unknown
Diabetes, as per local definition		☐ Yes	☐ No	☐ Unknown
Obesity (BMI>25)		☐ Yes	☐ No	☐ Unknown
Other causes (e.g. Wilsons disease, Hemochromatosis, Auto-immune hepatitis etc…)		☐ Yes	☐ No	☐ Unknown

*If a patient presents with both decompensated cirrhosis and HCC, the patient will be considered as having HCC for the analysis.

Case definitions: To be refined and adapted to the country health care specificity. *Examples provided below*

Decompensated Cirrhosis

Cases defined by clinical symptoms such as

- Recurrent or refractory ascites
- Portal hypertension-related bleeding,
- Hepatic encephalopathy
- Acute kidney injury
- Hepatorenal syndrome

Hepatocellular Carcinoma

Cases defined using clinical criteria, imaging criteria or pathological evidence.

Annex VII: Implementation Checklist

ANNEX IV – IMPLEMENTATION CHECKLIST

Implementation component	Present (Y/N)	Detailed information on component (e.g. when developed/updated, etc.)	Evidence of statement and references
1.Data quality			
1.1 Country has a standard mechanism/system in place to collect and report on the WHO 10 core programmatic indicators	Y	Egypt has a national health management information system that can generate and analyse reliable data necessary for monitoring and assessing progress against the hepatitis elimination criteria and impact and programme targets. The national network of treatment centers (NNTC) is the database of the NCCVH, which was founded in 2010. It succeeded in connecting NCCVH with 26 units by the end of 2014. Users are connected to a real-time database on "Microsoft Dynamic CRM". Currently, all NCCVH treatment centers are connected to the central database. In 2018, NNTC upgraded to a cloud database to comply with the increasing number of centers. A national registry for chronic hepatitis patients has been established. In addition, the MoHP launched a homegrown health information system with numerous screening and referral treatment sites to support the Presidential Initiative Screening Campaign. It was essential to sustain the integrity of the work by linking peripheral screening sites with a central monitoring and governing body. Work was facilitated using an electronic registration system; tablets for data entry were distributed at a large number of screening sites, which resulted in a large database that was easily accessible for policymakers on a central dashboard, which helped to utilize the 'Data for Decision Making' (DDM). This database can act as a seed for a more holistic health information system. Referring to the Egyptian example, the data from the "100 million healthy lives campaign" was very beneficial as baseline data and as a starting point for strategic data integration in many subsequent campaigns, like the nationwide campaign to support women's health, a follow-up NCDs screening campaign, and the government's response to the COVID-19 emergency, where the database of 100 million healthy lives was integrated and used for better service provision. In addition, the generated mega-data can act as a nucleus for many beneficial research projects, which will give policymakers insight for more evidence-based actions. During the national campaign, efficient information-technology support with user-friendly applications and integration with national databases facilitated planning and patient flow during screening, evaluation, and treatment. Immediate results and immediate linkage to care resulted in smooth evaluation and treatment of patients.	Management Information System: (1) Incidence: *Premarital Screening, *Blood Bank Screening, *Neonatal screening, *CPHL system for detection of new infections, *Hospital Screening (2) Mortality: *Electronic Death Registry (3) Harm Reduction *Needle Syringe Program, *OST (4) Diagnosis and Treatment: fully electronic NCCVH and connected with both the PCR chain and treatment centers. (5) Prevention: Full electronic automated immunization system (EPI); UPA (Unified Procurement Authority) supervises the procurement of registered AD syringes; and NEDSS (National Egyptian Disease Surveillance Systems)

1.2 Programmatic indicators are well defined at the country level and data inputs regularly checked	Y	Programmatic indicators are well defined at the country level, and data inputs are regularly checked and reported through the governmental quarterly reports.	- MoHP reports
1.3 National information system is able to provide disaggregated and representative data relating to hepatitis impact indicators	Y	The National Information System can provide disaggregated and representative data relating to hepatitis impact indicators. The mandatory national ID made it possible for the registry to include more complete demographic information, including accurate age and birth date, detailed address, place of birth, and gender. and for more information like occupation or religion, we refer to the electronic medical records at both MOHP and the Ministry of Planning and Economic Development.	- National ID - Electronic medical records at both MOHP and the Ministry of Planning and economic development.
1.4 National information system is able to capture service delivery and outcome data from both the public and private health sector	Y	A national information system can capture service delivery and outcome data from both the public and private health sectors through the Egyptian Drug Authority (EDA) and the IQVIA Medical Data Index.	- Through the Egyptian Drug Authority (EDA) and the IQVIA Medical Data Index
1.5 National capacity to undertake or commission mathematical modelling using country data for viral hepatitis is available	Y	We use direct estimates for viral hepatitis	- Management Information System (Same as 1.1)
1.6 Viral hepatitis case reporting is included in the national surveillance system	Y	Public-health surveillance is an essential tool in the prevention and control of infectious and chronic diseases and for medical management. Cases of hepatitis A, B, and C are reported monthly from the National Egyptian Disease Surveillance System (NEDSS). Between January 2014 and June 2017, sentinel surveillance for acute viral hepatitis was conducted in a network of five infectious disease hospitals (Abbasia, Alexandria, Helwan, Menouf, and/Aswan) representing the different Egyptian geographic regions. Abbasia, Alexandria, and Helwan hospitals represented the main urban regions, while Menouf and Aswan represented the rural regions. Participating hospitals were selected by the MoHP based on geographic and population representation, hospital laboratory capacity to perform routine blood chemistry, including alanine transaminase (ALT), aspartate transaminase (AST), and testing for viral hepatitis markers, and capacity for data management. This network was expanded in the year 2019 to include nine other sentinel surveillance sites at: Fayoum, Damietta, Assuit, el Menia, Kafr el Sheikh, Qalyubia, Adequate laboratory capacity is an important component of any surveillance system. Currently, most laboratories in Egypt can conduct serological tests for viral hepatitis. Each Egyptian governorate has a central laboratory in addition to numerous other laboratories affiliated with both the public and private sectors. In addition to the central public health laboratory (CPHL) in Cairo governorates	1. There are sentinel sites for acute viral hepatitis recording. 2. HCV is included in routine screening before medical intervention. 3. HCV is a component of the NADES database.
1.7 Surveillance system can differentiate between acute and chronic viral hepatitis	Y	The surveillance system can differentiate between acute and chronic viral hepatitis cases through well-defined case definitions. These case	Surveillance System Documents

cases		definitions are for the purpose of reporting and surveillance and may differ from criteria to be used for the management of patients.	
1.8 Attributable fraction of HCC and cirrhosis are estimated on a national level	In progress	MoHP is working with WHO to implement the sequel survey to be able to calculate the attributable fraction.	
1.9 Registry for liver cancer in place	Y	The national cancer registry program (NCRP) in Egypt started in the year 2007 as a population-based cancer registry and a collaboration between three Egyptian ministries: MOHP, the Ministry of Communication and Networking and, the Ministry of Higher Education. This registry was accredited by the WHO's International Agency for Research on Cancer (IARC), and the data derived from it is used by the WHO's Globecan. Currently, there are 11 active centers for registration at: Damietta (2), Minia, Aswan, Tanta, Damanhour, Elsalam, Nasser, Kabbary, Dar el Salam, and Mit Ghamr.	Centers that are linked to Globocan (1) Demitta Oncology Center (2) Aswan Oncology Center (3) Tanta Oncology Center (4) National Cancer Institute
1.10 Registry for cirrhosis and/or decompensated cirrhosis in place	Y	The NCCVH primary data base includes all the data of the cirrhotic patients diagnosed and treated in the public sector , the data defines the cirrhosis status based on either (liver biopsy, fibroscan , FIB-4) The registry of the department concerned with the state covered expenses contains the registry of those followed in the public sector and having decompensated cirrhosis .	- NCCVH registry - "On state expenses" department
1.11 National registry for chronic hepatitis patients established	Y	Sound and reliable information is the foundation of decision-making across all health system building blocks. Egypt has a standard mechanism and system in place to collect and report on the WHO's 10 core programmatic indicators. The national network of treatment centers (NNTC) is the database of the NCCVH, which was founded in 2010. It succeeded in connecting NCCVH with 26 units by the end of 2014. Users are connected to a real-time database on "Microsoft Dynamic CRM". Currently, all NCCVH treatment centers are connected to the central database. In 2018, NNTC upgraded to a cloud database to comply with the increasing number of centers. A national registry for chronic hepatitis patients has been established. In order to support the Presidential Initiative Screening campaign, the MoHP launched a homegrown health information system with numerous screening and referral treatment sites in action, it was essential to sustain the integrity of the work by linking peripheral screening sites with a central monitoring and governing body. It can give an instant reservation for discovered cases. Work was facilitated using an electronic registration system; tablets for data entry were distributed at a large number of screening sites, which resulted in a large database that was easily accessible for policymakers on a central dashboard, which helped to utilise the 'Data for Decision Making' (DDM). This database can act as a	Management Information System: (1) Incidence: *Premarital Screening, *Blood Bank Screening, *Neonatal screening, *CPHL system for detection of new infections, *Hospital Screening (2) Mortality: *Electronic Death Registry (3) Harm Reduction *Needle Syringe Program, *OST (4) Diagnosis and Treatment: fully electronic NCCVH and connected with both the PCR chain and treatment centers. (5) Prevention: Full electronic automated immunization system (EPI); UPA (Unified Procurement Authority) supervises the procurement of registered AD syringes; and NEDSS

		seed for a more holistic health information system.	(National Egyptian Disease Surveillance Systems)

Implementation component	Present (Y/N)	Detailed information on component (e.g. when developed/updated, etc.)	Evidence of statement and references
2. Laboratory and medicines quality			
2.1 Laboratory quality management system is in line with existing WHO laboratory guidance	Y	Hepatitis tests and molecular diagnostics are quality-assured and WHO-prequalified. All DAAs are registered inside EDA. DAAs were selected to comply with recent international guidelines. There is one registered factory (WHO Prequalified)	- Lab accreditation certificates
2.2 Internal and external quality assessment (EQA) programme present	Y	MoHP apply a quality assurance mechanism routinely and consistently to laboratories and verify that they participate in a domestic external quality assessment (EQA) program	- Accreditation certificates
2.3 National hepatitis reference laboratory oversees the domestic laboratory network and laboratory quality management (including procurement, staff proficiency, etc.)	Y	Health care workers have been trained in accordance with the manufacturers' instructions and nationally recommended algorithms. In terms of ensuring that quality standards are met for medicines, it is important that national testing and treatment guidelines	- Training Modules - List of trainees
2.4 Hepatitis tests and molecular diagnostics are quality assured and WHO prequalified or approved by a relevant regulatory authority	Y	To ensure that hepatitis tests are procured, stored, and used in accordance with the manufacturer's protocol; - Testing kits were WHO-prequalified. - HCV PCR was according to the WHO Standards	- "Abott HCV certificate - Roche HCV certificates
2.5 Hepatitis B antivirals for treatment are domestically registered and are WHO prequalified or approved by a relevant regulatory authority	NA		
2.6 Hepatitis C direct-acting antivirals are domestically registered and WHO prequalified or stringent regulatory authority (SRA) approved	Y	All DAAs are registered inside EDA. DAAs were selected to comply with recent international guidelines. There is only 1 registered factory (WHO Prequalified).	- Documents
3. Quality hepatitis programming, policy and practice			
3.1 National infection control and blood safety policies are consistent with WHO recommendations and implemented accordingly	Y	The infection prevention and control (IPC) domain in Egypt shaped drastically across the years. Egypt has a national policy in place for infection control programs; this policy is supported by national IPC guidelines, which	The latest national infection prevention and control guidelines

		have been updated numerous times through the years to cope with scientific advances and the dynamic national context; the last version was published in 2021. MoHP is very concerned with raising the capacity of its manpower regarding the application of IPC guidelines; thus, periodic trainings are sustained, and a monitoring and evaluation plan is in place to ensure the integrity of the system. 100% of therapeutic injections in health-care facilities are given with new, disposable, single-use injection equipment. Through the support of the UPA, MoHP ensures that all healthcare facilities won't face stockouts of quality-assured needles and syringes or mismatched quantities of safety boxes and essential supplies to maintain IPC measures across all healthcare facilities. In the year 2019, a national injection safety policy was launched, and accordingly, there is a plan for a gradual shift from conventional needles to safety syringes.	
3.2 National vaccination programme is consistent with WHO recommendations and implemented accordingly (including assessment of rationale if targeted timely birth dose)	NA		
For elimination of mother-to-child transmission (EMTCT) of hepatitis B, there is evidence of comprehensive antenatal care (ANC) services and timely birth-dose vaccination of their newborns as well as hepatitis B testing and treatment prophylaxis, preferably integrated with HIV and syphilis testing	NA	.	
3.3 Evidence-based harm reduction interventions (including needle and syringe programming) are implemented in consistence with WHO recommendations	Y	Harm reduction gained national recognition and support in the recent years as one of the core indicators for viral hepatitis elimination. Needle and syringe programs (NSP) provide sterile injection equipment to PWIDs, aiming to reduce the transmission of blood-borne viruses, such as human immunodeficiency virus (HIV) and hepatitis B and C virus (HCV) via the sharing of used syringes. Nationally, from 2014 to 2016 limited NSP programs were conducted through NGOs funded by GFATM and MENAHRA which was implemented on small scale passing all the challenges in implementation at this period. National AIDS Program has signed official MoU	Harm reduction documents Validation Report (Harm reduction)

		with the largest non-governmental organizations (Caritas & ElShehab) working in the scope of HIV prevention in Egypt. These two NGOs are receiving dedicated funding for prevention activities, Caritas is the sub recipient for the regional multi- country grant of the global fund including 2 sub-sub recipient NGOs (Friends in El Menia in Upper Egypt and Freedom in Cairo), Al shehab is the principle recipient of the 5% French initiative. The MoU was drafted to organize all the joint work between those NGOs and NAP to ensure that all the activities implemented by those NGOs are in line with the National HIV response, assigning clear reporting mechanism, Moreover the needle syringe program was included in this MoU officially for the first time in Egypt stating that MoHP will assist in providing those NGOs with the syringes and testing kits for HIV, HBV &HCV , also the National AIDS Program has included a forecasting plan for the syringes needs till 2025 through the GFATM NFM3 grant. This MoU was endorsed by official and security approvals from concerned authorities to ensure security coverage umbrella for the field work in this program. The NSP was launched officially in December through 3 NGOs working in 3 governorates and now it is scaled up to cover 8 governorates through 11 NGOs. **The number of syringes distributed /1 PWID (adherent, regular) has reached average 300 syringes annually this is calculated considering PWIDs who are enrolled in the program and adhere to receive and use sterile syringes (Continuum of services and beneficiary follow up). National AIDS Program in collaboration with UNAIDS developed monitoring and evaluation framework to ensure accurate measurement and effective assessment of this implemented project**	
3.4 National hepatitis testing and diagnosis algorithms are consistent with WHO recommendations and implemented accordingly	Y	National hepatitis testing and diagnosis algorithms are consistent with WHO recommendations and implemented accordingly	
3.5 National hepatitis B and C treatment protocols are consistent with WHO recommendations and implemented	Y	National hepatitis testing and diagnosis algorithms are consistent with WHO recommendations and implemented accordingly	The NCCHC Guidelines for the Management of Adult Patients with HCV Infection

accordingly			
3.6 Hepatitis B vaccination is available for health workers and high-risk and vulnerable populations	NA		
3.7 Hepatitis B testing, and treatment are available across the country (all regions and districts) and to vulnerable and high-risk populations (including in prisons) through public health systems	NA		j-
3.8 Hepatitis C testing and treatment are available across the country (all regions and districts) and to vulnerable and high-risk populations (including in prisons) through public health systems	Y	Treatment for HCV affiliated with the public sector falls under two main systems supervised by the NCCVH, which are treatment centers affiliated with the NCCVH itself and health insurance organizations (HIOs). By the end of 2019, there were around 126 treatment clinics affiliated with the NCCVH across the 27 Egyptian governorates. On the other hand, there were 41 central HIO organization clinics with an HCV medical assessment committee across the 27 Egyptian governorates.	Testing and treatment centers Lists
3.9 There is evidence of liver cancer screening for eligible persons living with chronic viral hepatitis	Y	Patients with diagnosed liver cirrhosis due to HCV are linked to the NCCVH underwent a follow up visit with AFP and Abdominal Ultrasound every 6 months. However, after the EASL 2018 guidelines for management of HCC were published; the ministry of Health & Population Issued an updated decision that the follow up would be every 4 months.	Documents
3.10 Hepatitis workforce training (in person/online training, curriculum and mentorship) is included in national health policies	Y	Hepatitis workforce training (in person/online training, curriculum and mentorship) is included in national health policies	- List of trainees - Training modules
3.11 Programmatic indicators and programme quality have been reported from the lowest-performing subnational unit	Y	The primary health care units are the lowest-performing subnational units which have been the main reporters in the screening activities for HBV, HIV, and HCV through several programs.	Screening e-platform modules

Implementation component	Present (Y/N)	Detailed information on component (e.g. when developed/updated, etc.)	Evidence of statement and references
4. Human rights			
4.1 Evidence of voluntary viral hepatitis B and C testing and treatment	Y	The MoHP applied the WHO's core testing principles during this national mass hepatitis testing, including voluntary consent, confidentiality, counselling, correct test results, and connection (linkage to prevention, treatment, and care, and support services), to maximize both individual and public health benefits while ensuring client confidentiality. Participation in screening was voluntary, with no financial or in-kind incentives for participating and no punitive consequences for not participating. The same applies to the school children screening campaign, where the children who reached the age of 12 at their new admission to the first year of preparatory schools all over Egypt can be screened if their parents signed a consent agreeing that their child be tested for HCV and treated if infected..	- Verification Report - Consent form
4.2 Evidence of confidentiality and privacy of hepatitis B and C status and treatment	Y	To maintain the confidentiality and privacy of hepatitis C status and treatment, all data are stored securely in a national database using national ID. The patient is the only one who knows his results. In the national screening campaign, the WHO was selected by the MoHP as the independent verification agency (IVA) for the verification of the work done through the campaign. WHO as IVA was monitoring that the MoHP was respecting the WHO's core testing guiding principles. These were carried out through an audit and verification team of experts	- Verification Report

		that started their work since the launch of the mission in October 2018. For school children. although screening was carried out in schools, to keep confidentiality, the results were not known to the students or the school staff and were mailed to the parents, with an appointment in a health-insurance clinic for positive children to be evaluated and treated away from their schools.	
4.3 Evidence of absence of legal discrimination (for employment status, access to education, housing, social benefits)	Y	No of legal discrimination (for employment status, access to education, housing, social benefits) Article 53 of the Egyptian Constitution states that citizens are equal in rights and freedoms. and public duties, without discrimination on grounds of religion, gender, or origin, race, color, language, disability, or level social, political, or geographical affiliation, or for any other reason. Discrimination and incitement to hatred are crimes punishable by law.	Article 53 of the Egyptian Constitution
4.4 Evidence of stigma-free access to health care and treatment for those with HBV and HCV	Y	Persons were tested for HCV antibodies with the use of a finger-prick rapid diagnostic test, with results available within 20 minutes. Seropositive patients had appointments immediately scheduled electronically for a date within 2 to 15 days in the closest assigned center for evaluation and treatment. At the center, patients received clinical evaluation, underwent abdominal ultrasonography, and had blood drawn for HCV RNA and liver-function tests. The time between screening and the dispensing of medication was usually 10 days but ran to 4 weeks for some patients who were delayed in scheduling or attending follow-up appointments. The shortest	Verification Report (Programmatic Indicators)

		time to dispensing treatment was 6 days, and the longest time was 30 days. Turnout for evaluation was continuously monitored. A call center contacted seropositive persons who did not show up for their evaluation appointments and patients with viremia who did not return for treatment, in order to inquire about reasons for no-shows and to assign new appointments if necessary.	
4.5 Evidence that people living with hepatitis are informed of their status and provided adequate counselling	Y	All the discovered cases with positive infections were given a specific referral card containing their personal data and the name, location, and date of referral to the nearest viral hepatitis treatment center.	Training on patient counselling Referral card Electronic referral system (appointment reservation)
4.6 Evidence of the absence of drug use, sexual orientation status, incarceration experience, immigration status or profession as a criterion for exclusion from hepatitis treatment		MOHP has started special screening and treatment programs for certain populations and age groups, aiming to control disease and micro-eliminate HCV in these populations. (Young adolescents (school and university students), in-patients, people living with HIV (PLHIV), end-stage renal disease (ESRD) patients, chronic blood disease patients, people attending mental health and addiction treatment clinics, blood donors, and refugees and asylum seekers).	
5. Equity			
5.1 Evidence of testing and treatment service decentralization and integration	Y	HCV testing and treatment services were decentralized. Trained MoHP screening teams screened participants at different healthcare facilities, including primary healthcare (PHC) units, government hospitals, and health offices. Also, to ensure they left no one behind, screening teams reached out to the participants through mobile clinics. Mobile screening teams in specially outfitted vehicles augmented the	Testing and treatment centers list

		screening efforts by visiting crowded areas on special occasions (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. In addition, citizens were reached out to at government institutions and private companies, and the screening sites operated 12 hours per day, seven days per week, to make it as easy as possible for people to access screening. Persons could be screened in any phase and at any site, regardless of their residence. 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.	
5.2 Evidence of disaggregation of program and epidemiological data by gender and other equity stratifiers[i]	Y	All program and epidemiological data are disaggregated by gender and other equity stratifiers.	Validation Report
6. Gender equality			
6.1 Evidence of the presence of national policy that includes specific reference to addressing the gender needs of those living with or at risk for viral hepatitis, including access and stigma/discrimination	Y	Article 53 of the Egyptian Constitution states that citizens are equal in rights and freedoms. and public duties, without discrimination on grounds of religion, gender, or origin, race, color, language, disability, or level social, political, or geographical affiliation, or for any other reason. Discrimination and incitement to hatred are crimes punishable by law. Epidemiological data and programmatic data on hepatitis prevention, diagnosis and treatment services disaggregated by gender MOHP has started special screening and treatment programs for certain populations and age groups, aiming to control disease and micro-	Article 53 of the Egyptian Constitution

		eliminate HCV in these populations. (Young adolescents (school and university students), in-patients, people living with HIV (PLHIV), end-stage renal disease (ESRD) patients, chronic blood disease patients, people attending mental health and addiction treatment clinics, blood donors, and refugees and asylum seekers).	
6.2 Evidence of efforts to address stigma/discrimination of men and women living with hepatitis	NA	Hepatitis C is an endemic health problem in Egypt, and hence it has been for several years a common problem among Egyptians. Therefore, there is no community stigma or discrimination.	
7.Community engagement			
7.1 Evidence of affected community representatives in the national hepatitis task force	NA	Hepatitis C is an endemic health problem in Egypt, and hence it has been for several years a common problem among Egyptians. Therefore, there is no community stigma or discrimination.	
7.2 National hepatitis policy documents explicitly state the active participation of affected community in hepatitis prevention, diagnosis and treatment services	NA		
7.3 Evidence of peer-led navigation in hepatitis service delivery for hard-to-reach, rural and marginalized populations	NA		
7.4 Evidence of government support or funding for representative groups of the hepatitis-affected community	NA		

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