Strengthening the Monitoring and Evaluation Capacity

EGYPT'S VIRAL HEPATITIS PROGRAM

THE WORLD BANK

Egypt's Viral Hepatitis Program

Strengthening the Monitoring and Evaluation Capacity of the Egyptian Viral Hepatitis Program 2017

This report is developed as part of the World Bank's Technical Assistance on Strengthening Egypt's Response to Viral Hepatitis.

Comments and suggestions concerning the report contents are encouraged and could be sent to emassiah@worldbank.org

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Table of contents

List of Figures

List of Abbreviations

CDC	Center for Disease Control and Prevention
DAAs	Direct Acting Antivirals
DHS	Demographic Health Surveys
EPI	Expanded Program of Immunization
GOE	Government of Egypt
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HCWs	Health care workers
HIO	Health Insurance Organization
KAP	Knowledge, Attitude and Practice
IPC	Infection prevention and control
M&E	Monitoring and Evaluation
MOHP	Ministry of Health and Population
NAMRU-3	Naval Medical Research Unit-3
NBTS	National Blood Transfusion Services
NCCVH	National Committee for the Control of Viral Hepatitis
NEDSS	National Egyptian Disease Surveillance System
NGO	Non-governmental Organization
NTCs	National Viral Hepatitis Treatment Centers
NTP	National Treatment Program
PWIDs	People Who Inject Drugs
VHA	Viral Hepatitis Administration
WHO	World Health Organization

Acknowledgement

This paper was co-authored by Mostafa Hunter and Amr Elshalakani (Health Specialist). We are grateful for the leadership, guidance and encouragement from Ernest Massiah (Practice Manager for the Middle East, North Africa). We are also thankful for the operational and leadership support provided by Asad Alam (World Bank Director for Egypt, Yemen & Djibouti).

We gratefully acknowledge the support received from the incumbent Minister of Health and Population, His Excellency Dr. Ahmed Emad Rady This report was written at their direct request and we greatly valued their continuous support, input, and leadership.

The content of the four reports series was enriched by discussions with Ministry of Health and Population (MOHP) leadership and staff, whom we thank for their time and expertise. These include: i) the honorable Leadership and staff of the Preventive Sector, MOHP; ii) the honorable members of the national committee for combating Viral Hepatitis; iii) the team of the Viral Hepatitis Unit, MOHP and iv) the team of the Loans and Grants Administration (MOHP).

This appreciation is extended to the leadership and staff at the Regional Health Directorates, especially to the viral hepatitis teams working in the field to combat the disease.

We thank health experts in Egypt who shared their candid views to help strengthen the format and recommendations of the paper through multiple engagements. This includes but is not restricted to a spectrum of academicians, senior health professionals, policymakers, and representatives of professional associations.

We appreciate the inputs of our World Bank colleagues: Patrick Osewe (Lead Health Specialist), Andreas Seiter (Lead Health Specialist) and Moustafa Abdalla (Health Specialist,) for their insightful views, and for their overall support of the activities culminating in this paper. Very warm thanks go to Mohammed Duban and Mirna Mehrez who assisted with typesetting of this document, and to Rana Elgazzaz for doing a meticulous graphics job in a very expedient time frame.

Executive Summary

Viral hepatitis is a global health problem affecting millions of people worldwide. Globally, approximately 1.4 million persons die annually from all types of viral hepatitis. Egypt has one of the highest global burdens of hepatitis C virus (HCV) infection, with an estimated 10%, or over 6 million people, between 15-59 years chronically infected. Tragically, an estimated 150,000 Egyptians are newly infected annually, and thousands die every year.

In recognition of the enormity of the problem, in 2012, the Ministry of Health and Population (MOHP), in collaboration with stakeholders, developed the "Plan of Action for the Prevention, Care & Treatment of Viral Hepatitis, Egypt" (referred to in this report as the Viral Hepatitis Plan of Action), which focuses 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. The plan highlights the important goals and objectives of the MOHP's viral hepatitis program and reflects the MOHP's commitment to controlling the viral hepatitis epidemic by preventing new infections. The plan was later updated in 2016 to reflect the changing dynamics in the field.

With the arrival of Direct Antiviral Agents (DAAs), treatment became the main focus of Egypt's viral hepatitis activities. This has led to massive outreach, with more than 800,000 patients treated since January 2016. To sustain this success, the focus is expanding to support the other six components of the Plan of Action to eventually achieve the vision of a country free from HCV by 2020. Moreover, as demand for the treatment and flow of patients to treatment centers is gradually decreasing, there is growing pressure for the first component of the plan to go beyond surveillance to include screening as well.

Consequently, updating and revising the Viral Hepatitis Plan of Action became essential for achieving MOHP's new vision. Similarly, the importance of having a well-established coordination mechanism and a monitoring and evaluation plan assigned to a specific body became a cornerstone for the success of the Plan of Action. Hence, this task was assigned to the Viral Hepatitis Unit, which was transformed into an administration under the directorate of preventive medicine (Viral Hepatitis Administration VHA) based on ministerial decree, providing the agency with the mandate it needs to carry out its responsibilities.

Given the complexity of the task at hand and the multiple sectors involved in the implementation of the plan of action, the current monitoring mechanisms available for VHA and required interventions to strengthen monitoring capacity needed to be assessed. This report addresses this need as part of a series of reports undertaken by the World Bank, based on the request of the Government of Egypt (GOE) for technical assistance, to inform policies to strengthen the country's response to Viral Hepatitis situation. The President of Egypt specifically requested the Bank's technical assistance during his bilateral negotiations with the Bank's President at the latter's visit to Egypt in July 2015. Further, the Ministers of Health and Population, International Cooperation, and the Deputy Minister of Finance reaffirmed this request during a health sector mission to the country in October 2015.

I- Introduction

Over the past several years, the importance of monitoring and evaluation (M&E) has grown increasingly in the development sector. With greater demand for accountability and the adoption of Result Based Management approach in projects/program management, M&E has become an indispensable tool for managers and policy makers alike to decide on the effectiveness, efficiency, and sustainability of different programs and projects. This need is accentuated by limited resources and the ever increasing demand for better quality of services from the public.

In 2016, the Government of Egypt undertook an ambitious endeavor to eliminate HCV by 2020, but this vision has brought great challenges in terms of monitoring progress. The current Viral Hepatitis Plan of Action entails multiple pillars, including surveillance, infection control, blood safety, hepatitis B virus (HBV) vaccination, care and treatment, communication, and research. Each of these pillars has a specific set of outcomes, outputs and activities that are required to for the strategy to achieve the expected impact on reducing the prevalence of HCV and associated morbidities and mortalities.

Given the multiplicity of the actors within each pillar, it is pivotal to unify monitoring tools and mechanisms of data collection for similar activities conducted within different sectors and entities. Also, activities must be coordinated to avoid duplication, redundancy, and missed opportunities for pooling resources when applicable. Accordingly, it is crucial to have a single entity capable of pooling data from different sources to provide decision makers with a comprehensive view on all seven pillars of the Plan of Action, hence the critical role of the VHA.

The VHA has a central office in Cairo and affiliated focal points in each governorate and in treatment centers. Within the central office there is a specific staff member assigned as the key responsible person for one or more of the Viral Plan of Action pillars. The director of the unit coordinates and supports the staff in addition to being the key responsible person for treatment and research.

Objectives of this document

This report aims to analyze and evaluate the distribution of roles, responsibilities, and mechanisms for monitoring and evaluation as defined by the Plan of Action. Based on the analysis, key findings and recommendations are presented for building capacity of the MOHP regarding incorporating M&E mechanisms for the implementation of the Action Plan. This document is envisioned to act as a reference point for the mandate of the VHA in M&E functions and sets forth capacity development activities for the VHA to be able to achieve those functions.

Methodology of data collection

This report relied on two main sources of data:

1. Desk review for documents related to the Viral Hepatitis Plan of Action.

2. Guided with the suggested objectives and set of activities under six[1] components of the Plan of Sction, a set of in-depth interviews were conducted with VHA director and staff that aimed to:

- Identify progress achieved with regards to the objectives and activities of the plan
- Understand the challenges and pressures faced during the implementation and discuss how to overcome these challenges
- Examine the monitoring systems in place for the different activities in terms of an existing monitoring plan, monitoring tools, staff, and frequency of reporting
- Discuss the feasibility and level of collaboration among different players involved in different components of the plan

The results are organized according to all seven components of the viral hepatitis action plan. Key findings and recommendations for each component are presented at the end.

(1) Findings and conclusions for component seven of the action plan "Strategy for promoting viral hepatitis Health Research and information technology" is not included in this report due to technical difficulty in setting up the interview. However, it will be added in the coming period.

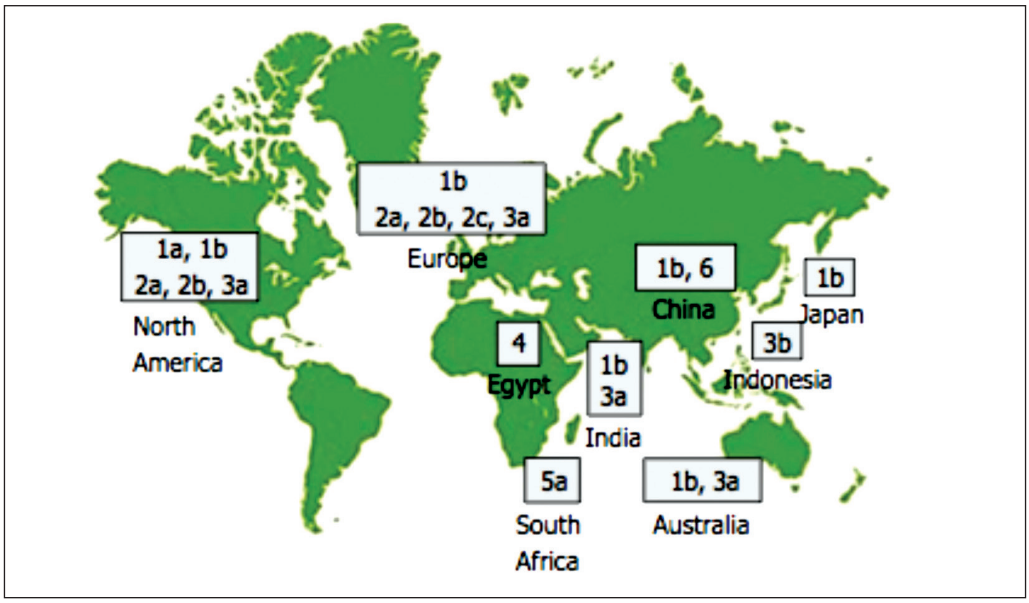
II- HCV: Current Situation

Hepatitis C (HCV) is one of the most common liver diseases in the world and is caused by a blood-borne virus with the same name. It can be transmitted by sharing syringes (e.g. for drug use), reuse and inadequate sterilization of medical equipment, or transfusion of unscreened blood and blood products ("Hepatitis C", 2016). Moreover, less common modes of transmission are sexual transmission and from mother to child. It can take form of an acute or chronic infection varying in symptoms. Between 15 to 45% infected individuals clear the virus from their system thanks to their immunological response, with no treatment needed ("Hepatitis C", 2016). The remainder develop chronic HCV, which accounts for 55-85% of cases ("Hepatitis C", 2016). From the most recent WHO estimates, there are 3-4 million new infections each year globally.

Currently, there are 130-150 million people globally infected with chronic HCV, accounting for 2-3% of the world's population (Abdel-Ghaffar, Sira, & al., 2015). Unfortunately, this number has been increasing in the last 15 years (Abdel-Ghaffar, Sira, & al., 2015). Moreover, HCV leads to more serious liver disease. HCV causes 25% of hepatocellular carcinoma (HCC) and 27% of cirrhotic cases worldwide (Mohamed, Elbedewey, & al., 2015). According to most recent WHO statistics, 500,000 people die each year from HCV related diseases ("Hepatitis C", 2016). Although there is no vaccine for hepatitis C on the market, there are now treatments that can cure even up to 95% of cases ("Hepatitis C", 2016).

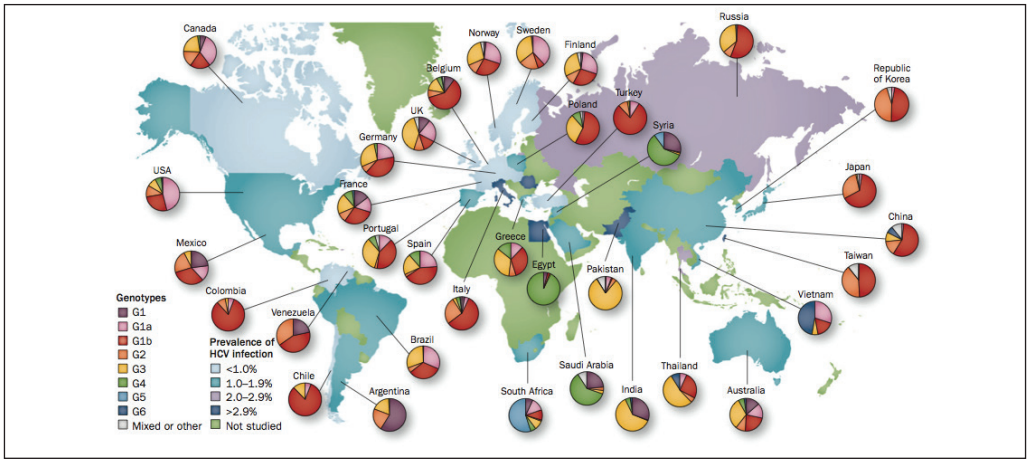
HCV is a global epidemic; however, the distribution and characteristics of the disease vary between regions and countries. Africa and Central and East Asia are most affected. Egypt, Bolivia, Mongolia and Cameroon have the highest HCV prevalence (above 10%) (Kim, Hutton, & al., 2015). The genotype of the virus also varies among regions and countries. Europe and North America are mostly affected by the genotype 1, 2 and 3 of the virus, whereas Africa suffers from genotype 5a in South Africa and genotype 4 in Egypt. One can also see disparities between genotypes in Central and East Asian countries (Abdel-Ghaffar, Sira, & al., 2015). The figure below presents a map with global hepatitis C virus genotype distribution.

Figure 1: Global Hepatitis C Virus Genotype Distribution



(Abdel-Ghaffar, Sira, and al., 2015)

Figure 2: Estimated prevalence of HCV infection and the distribution of HCV genotypes across the world



(Hajarizadeh and al., 2013)

Clearly, HCV is a significant problem for health systems and decision makers worldwide. The World Health Assembly recognized the magnitude of this problem and adopted a resolution recognizing viral hepatitis as a global public health problem. Moreover, in 2014, WHO published "Guidelines for the screening, care and treatment of persons with hepatitis C," the first international guideline concerning HCV issues. These guidelines provide recommendations for developing screening, care and treatment programs in low- and middle- income countries. However, with HCV therapies changing rapidly, the 2014 guidelines should be updated continuously ("Hepatitis C", 2016).

III- HCV: Case of Egypt

Egypt has the highest HCV incidence and prevalence rates in the world, at about 1 percent and 10 percent of its adult population (15-59 years), respectively, with the latter going up to 15 percent in some geographic areas. Close to 70 percent of new infections occur in persons less than 25 years of age. Nearly 4.5 million adults are chronically infected; an estimated 150,000 people are newly infected annually; and about 40,000 die every year, making HCV the third leading cause of death in Egypt after heart disease and cerebrovascular disease.

Although the young population does not entirely escape the burden of HCV, with 4% of 15-19 year-olds infected each year (Ministry of Health and Population, 2014), the prevalence rate is significantly higher in older population aged 40-60 (Kim, Hutton, & al., 2015). Based on that estimation, the prevalence of HCV in Egypt was expected to double in the next 20 years (El-Zanaty & Way, 2009) prior to the advent of the new DAA medications. Overall men are more likely than women to be infected with HCV, and people from rural areas more prone to infection than those from urban areas (El-Zanaty & Way, 2009).

Moreover, HCV prevalence was lower among populations with increased education level and wealth (Abdel-Ghaffar, Sira, & al., 2015). The highest HCV prevalence was found in rural upper and rural lower Egypt, and lowest in the Frontier Governorates and Urban Governorates (El-Zanaty & Way, 2009).

Additionally, the probability of HCV infection decreased with higher level of education and higher wealth quintile (Abdel-Ghaffar, Sira, & al., 2015).

The reasons for the high prevalence of HCV in Egypt are likely multifactorial. One of the most popular hypotheses is that the epidemic was caused by the parenteral anti-schistosomal therapy (PAT) campaigns to control endemic schistosomiasis during the 1960s and 1970s, which were carried out with very low standards of hygiene (Ministry of Health and Population , 2014). Multiple-use glass syringes were used even though disposable syringes were available. Syringes were not sanitized properly, so in the process of fighting one epidemic, the campaign unwittingly spread another blood borne disease, HCV.

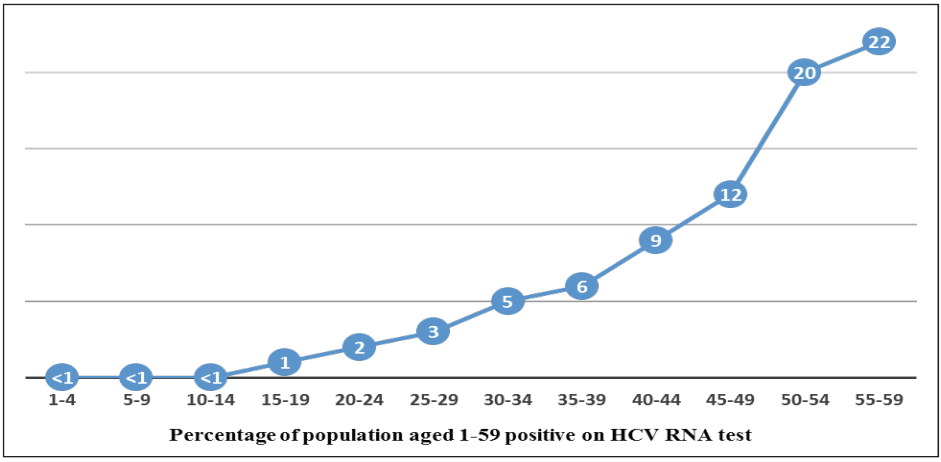
This unfortunate situation is considered the world's largest iatrogenic transmission of blood-borne disease to this date (Miller FD1, 2010). Having

infected Egyptian population with HCV, the disease spread further as many cases were not detected until years later. Other significant modes of transmission in Egypt currently include blood transfusion, sexual transmission, accidental occupational needle sticks. Moreover, mother to newborn transmission play a significant role in Egypt, where 5000 newborns are infected with HCV annually (Miller, Elzalabany, & al., 2015).

These findings signify the role of iatrogenic infections behind such high incidence and prevalence rates, owing to unsafe therapeutic injections of parenteral anti-parasitic drugs with reusable glass syringes to control schistosomiasis, and later on, bad infection control practices in health care facilities, public and private alike, coupled with suboptimal screening for transfused blood.

Another reason for the high rates of new infections in Egypt is the cultural and sociological position of its citizens. Egyptians are known for their preference of drug administration through injection rather than oral treatment. Therapeutic injection in Egypt accounts for more than 4% of treatments, where in other low-income countries it is 1.5% (Ministry of Health and Population , 2014). It has been calculated that 8% of medical injections are not safe, and many medical professionals do not follow hygiene guidelines for syringes (Ministry of Health and Population , 2014). Additioanlly, the awareness level about HCV is low (Kim, Hutton, & al., 2015).

Figure 3: HCV prevalence in the population age 1-59, by age, Egypt 2015



Source: Egypt Health Issues Survey 2015

IV- Health Sector in Egypt

The Egyptian health system faces multiple challenges in improving and ensuring the health and wellbeing of the Egyptian people. The system faces not only the burden of combating illnesses associated with poverty and lack of education, but it must also respond to emerging diseases and illnesses associated with modern, urban lifestyles. Emerging access to global communications and commerce is raising the expectations of the population for more and better care and for advanced health care technology. In addition, the crude high birth rate combined with a longer life expectancy increases pressure on the health system. The tremendous evolution in technology and infrastructure forces service providers to continuously upgrade. This must be understood in the context of the economic situation over the last several years which, as mentioned, combined with the political turbulence, has created pressures on the public fiscal space.

Public health facilities are not considered responsive to patients, leading patients to pay for private sector care. Inequities persist by income, across governorates, and by gender. Supply-side payment mechanisms along with low wages for physicians and other healthcare staff provide little incentive for better performance. Dual practice remains a pressing problem, with almost 80 percent of doctors working simultaneously in both the public and private sectors.

Service Provision

Egypt has a highly complex and pluralistic health care system, with many different public and private providers as well as financing agents. Health service providers are currently managed and financed by agencies in all three sectors of the economy: public, private business and not-for-profit non-governmental organizations.

For the public sector, MOHP is considered the main provider of healthcare services. Moreover, there are other affiliate bodies, including quasi-governmental organizations in which the MOHP has a controlling share of decision-making. In addition to the MOHP, the Ministry of Higher Education plays a crucial role in service provision through university hospitals and research institutes.

Most of the other ministries, such as Defense, Internal Affairs, Transport, Aviation, and Public Business Sector, own and run their own facilities. These are

mainly directed to offer services to their own beneficiaries, namely employees and their families.

The private sector also manages private clinics as well as hospitals and pharmacies where people pay relatively high fees for what they consider better service than the public sector. Most private hospitals are small and medium enterprises or small practices. Recently, there has been a growing trend of mergers and acquisitions of hospitals with a relative increase in investment in the sector.

There are a large number of nongovernmental organizations (NGOs) providing services, including religiously affiliated and other charitable organizations, all of which are registered at the Ministry of Social Affairs (MOSA). These hospitals are funded through donations.

In addition to that, professional syndicates also own a number of hospitals and health care units, which offer services mainly to their members.

Because government-owned hospitals mostly provide services in principle free of charge, they attract the wide segment of marginalized and less privileged groups of the society, increasing the social and moral obligation to provide care for these patients. This huge demand for healthcare services puts tremendous pressures on these hospitals and challenges the government might to keep up with demand. Efforts undertaken to enhance the sector performance are hampered by the escalating costs, financial shortages, and inefficient use of available resources, poor governing structures and incompetency of hospital management. Over time, these factors have led to deteriorating healthcare facilities with unsatisfactory services, thereby eroding public trust and prompting patients to turn to alternatives, such as private sector facilities. The gap of service provision to the poor has been mainly covered through university hospitals, a group of MOHP or affiliated hospitals with high quality, as well as hospitals and polyclinics run by charitable, non-governmental/not-for-profit organizations, and religious groups.

Determining which sector provides better quality care is a difficult task. However, many prevention and infection control strategies include only public sector, leaving the private sector unregulated. Moreover, the fragmentation of health care in Egypt poses many challenges for data collection and surveillance and therefore limits the evidence available for effective decision-making. Very often, decisions are made based on the data from the public sector, which can

misrepresent the actual situation by taking into an account patients using private providers. The MOHP decision-making process has been criticized as subjective and rarely based on real data or information (WHO, 2006). Management information systems are under-developed, and data gathered from public system must be analyzed cautiously while controlling for population characteristics.

Finance

The public governmental sector represents activities of ministries that receive funding from the Ministry of Finance (MOF). As in many low- and middle-income countries, the governmental health services in Egypt are organized as an integrated delivery system in which the financing and provider functions are part of the same organizational structure. This means that government providers receiving budgetary support from the government general revenues (MOF) are also subject to the administrative rules and regulations that govern all civil service organizations. For example, admin staff is subject to the Civil Service Employment Law, and remuneration is based on the civil service salary scale determined by the Central Agency for Organization and Administration (CAOA). The governmental providers who receive funds primarily from MOF include MoHP, the Ministry of Higher Education (MoHE), ministries that provide some health services for their employees (agriculture, teachers, railway, electricity, and others), and facilities of the other organizations (e.g. General Organization of Teaching Hospitals and Institutes)[2]. Government budgets are mainly provided through line budget items with no clear link to performance. Government providers are permitted to generate their own income through various means, including charging user fees in special units or departments known as economic departments. Income from these non-budgetary sources is classified as "self-funding."

Significant centralization, line item budgeting, and lack of service costing mechanisms have made providers unresponsive to local needs. There is no strategic purchaser in Egypt and most public providers lack the ability to interact with that purchaser. There are no clear referral processes within the Egyptian healthcare system, where most patients prefer to go directly to specialized and university hospitals.

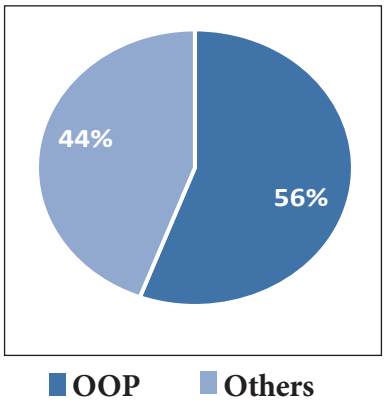
(2) The Ministry of Defense and the Ministry of Interior also receive a budget to provide health services to their staff, but they are not included in the discussion because of their limited targeting.

There are multiple forms of financial health coverage in Egypt. The Health Insurance Organization (HIO) covers almost 50 percent of the population; however, most services are restricted to its own hospitals, and it has a coverage ceiling. Many of those insured, in fact, refrain from using their insurance, which makes its contribution to healthcare expenditures in Egypt less than 5% despite the wide range of coverage. Egypt has a small but growing market for private healthcare insurance. Moreover, syndicates offer forms of coverage to their members, and some public and private organizations and corporates offer financial protection schemes to their employees.

Some not-for-profit NGOs also offer financial coverage schemes for the poor and some governmental programs offer additional protection.

The high incidence of out-of-pocket expenditure combined with poverty puts poorer Egyptians under extreme financial pressure when it comes to illness. However, at the same time, the privileged high and middle income segments of the population, combined with regional medical tourists, represent a major attraction for revenue generation. This makes the healthcare sector in Egypt both needy for subsidy and for-free-services, but at the same time attractive for revenue generation.

Figure 4: OOP expenditure as % of total expenditure on health, 2014

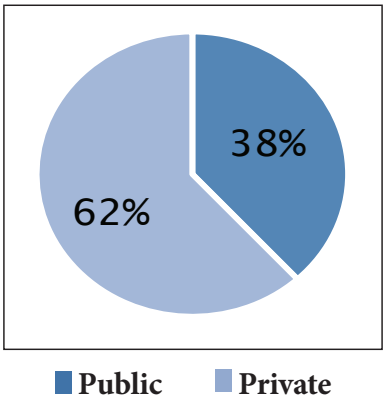


Source: Constructed by the authors using World Bank data

Egypt spends less on healthcare than its regional peers, resulting in high out of pocket expenditures[3]. Even with the different financial systems explained above, the largest part of the total healthcare expenditure is out of pocket payments (OOP expenditures comprise 56% of total expenditure on healthcare and 90% of private expenditure on healthcare). Despite the presence of multiple public insurances, around half of the population does not enjoy any type of formal coverage, especially those who are poor or working in the informal sector. In recent years, the MoHP introduced interventions aiming to provide better access to healthcare services targeted to disadvantaged groups, but they have yet to materialize into effective financial protection. Egypt is also moving in the direction of a new law for universal social health insurance.

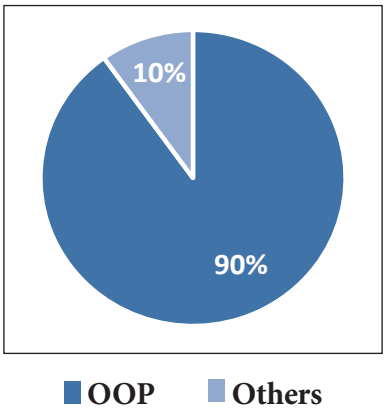
(3) Total expenditure on health as a percent of total government expenditure was 5.5% in 2013. General expenditure on health as a percentage of the total expenditure on health is 40.7 % for the public and 59.3% for the private expenditure.

Figure 5: General expenditure on health. 2014



Source: Constructed by the authors using World Bank data

Figure 6: Out-of-pocket expenditure as a % of private expenditure on health, 2014



Source: constructed by the authors using World Bank data

V- Actions taken by the government to reduce the burden of HCV

Current approach to treatment of viral hepatitis and potential future trends

With the discovery and development of a new category of drugs against Hepatitis C (Direct Acting Antivirals, DAA), HCV treatment has become shorter, better tolerated, and more successful, with cure rates close to 100 percent in early stages of the disease. The latest generation of DAAs against Hepatitis C includes molecules such as Sofosbuvir, Ledipasvir, Daclatasvir, Grazoprevir, Elbasvir, Velpatasvir, Ravidasvir, used in combination with each other or with older antivirals such as Ribavirin.

The national treatment program for control of Hepatitis C started before the era of DAA drugs, under which each governorate had one treatment center providing interferon treatment. However, the cost and long duration of interferon treatment limited the number of patients benefiting from the program. Since DAAs became available, the country has moved quickly to scale up treatment in collaboration with various stakeholders in the National Committee for the Control of Viral Hepatitis (established in 2006).

The roles for defining treatment protocols, setting up treatment centers, procuring medicines and enrolling patients are now defined. The number of treatment centers has been scaled up: The National Committee currently counts 56 centers and plans to open additional ones until 100 centers are reached. HIO has 37 centers and 90 dispensaries at which patients can receive medication for their prescriptions.

A web based enrollment tool has been launched and, as of 2016, 1.8 million Egyptians had registered for treatment. Once registered, they receive a list of lab tests required for their first appointment, instructions for payment (patient copayment is EGP 20, about USD 1, which finances the administration costs and overtime payment for the treatment center staff – physicians and nurses volunteer their time). They also get an appointment at the treatment center and a list of lab tests needed to confirm the diagnosis and status of disease.

As this procedure can be challenging for illiterate people or those without internet access, enrollment is also possible at treatment centers. Internet cafes offer assistance to people who otherwise do not have access. Waiting lists to get an appointment have resolved, but temporary drug shortages have delayed

treatment for some patients, although the delays are said to be no more than one month (HIO).

According to estimates of the National Committee, at least 800,000 patients received treatment in 2016 (after 200,000 in 2015), which is in line with the target number needed to reduce Hepatitis C prevalence to under 1 percent in 2030. Included are about 100,000 patients treated in HIO facilities. The total does not include those treated in the private sector (estimated at 200,000 for 2016), where there is no mandatory registration or follow up. A system to register patients and refill drug prescriptions only when they bring the originally dispensed bottle back empty[4] was in place as long as treatment had to rely on discounted originator drugs, but has since been abandoned.

Currently, only 50 percent of patients show up for the final lab test scheduled one month after end of treatment, which is needed to confirm complete viral clearance or "sustained response." This is a problem as it will be difficult to calculate the cure rate with the current treatment if patients do not get the final test.

Fragmentation of the treatment efforts is an issue. MOHP treatment centers, university hospitals, NGOs and facilities under the HIO each offer treatment centers but not all of them feed into a single monitoring system. The private sector also offers diagnosis and treatment in many facilities, some of which are of low standards and may use substandard lab reagents or medicines. This can negatively impact cure rates and lead to resistance against the first line medicines that are now available at low cost.

Action Plan for the Prevention, Care and Treatment 2014 -2018

In 2014, a new strategy document was developed for 2014 to 2018 covering a comprehensive set of actions under essential pillars with defined goals to control the epidemic. Prevention was emphasized, as preventing new infections is obviously cost-effective and will lead to a faster elimination of the virus reservoir and save long-term treatment costs. The strategy document set prevention goals focusing on educating and empowering the population to demand safe medical practice (Ministry of Health and Population , 2014). Another goal was to increase

(4) The main purpose was to prevent patients from selling Sofosbuvir (initially provided by Gilead, at a price of about 1% of the official US price) outside the countries in non-discounted markets.

infection control in the primary and secondary healthcare setting, as well as promotion of the use of disposable items in medical and other setting at risk of HCV transmission (Ministry of Health and Population , 2014).

Because this strategy document was drafted prior to the arrival of the DAAs in Egypt, it gave relatively less weight to treatment efforts. Nonetheless, it did task the MOH with preventing chronic HCV cases from progressing to liver diseases like cancer and cirrhosis by providing treatment (Ministry of Health and Population , 2014).

Mathematical modeling was used to predict what would need to be done if the government's aim is to eradicate HCV in Egypt in 10 years. First, the treatment effectiveness must be established on 90% or higher level. Moreover, between 250000 and 300000 patients would have to be effectively treated for HCV each year (Ministry of Health and Population, 2014).

Today, the Egyptian government faces multiple challenges regarding the implementation of the Action Plan as written. (Estes, Abdel-Kareem et al. 2015). Recent studies show that economic and logistical constraints have limited treatment outreach for patients (Obach, Yazdanpanah et al. 2015).

More significantly, there have been many developments in the field of HCV treatment as new, effective, and less expensive drugs have emerged on the market. In the light of these events, updating and revising the Viral Hepatitis Plan of Action came as an essential step towards achieving MOHP's new vision. Similarly, the importance of having a well-established coordination mechanism and a monitoring and evaluation plan with a specific body responsible for these functions, appeared to be a cornerstone for the success of the Plan of Action to ensure the best possible outcomes.

VI- Baseline Assessment of Capacity to Undertake Monitoring and Evaluation Functions

This section summarizes the key findings of a baseline assessment of the capacity of the VHA to undertake monitoring and evaluation (M&E functions for the plan of action). The information gained through interviews with key informants and findings of this assessment will identify existing gaps and propose recommendations for implementing the most appropriate interventions to address these gaps. This is the first step in an endeavor to establish a capacity-strengthening program for monitoring and evaluation functions to maximize effectiveness of the VHA and hence, the outcomes of the action plan implementation.

1- Strengthening surveillance and screening to detect Viral Hepatitis transmission and detection

As stated in the Action Plan, the Egyptian surveillance system consists of two main entities, the Sentinel Surveillance system and the National Egyptian Disease Surveillance System (NEDSS). The Sentinel Surveillance currently consists of five MOHP fever hospitals (Abbasia, Alexandria, Aswan, Helwan, Menof) under the supervision of Department of Epidemiology and Surveillance and funded by NAMRU-3 and CDC. These sites are responsible for acute case surveillance in Egypt. On the other hand, the NEDSS is responsible for reporting suspected cases of viral hepatitis admitted to any of the MOHP public sector hospitals. The NEDSS has a common portal where hospital administrators from different locations can enter data and generate reports on different diseases including Hepatitis.

Accordingly, the action plan identifies two strategies to strengthen the viral hepatitis surveillance system; the first focuses on strengthening the existing sentinel surveillance systems (Goal 1.1), while the second focuses on conducting regular surveys including bio-behavioral surveys for high risk populations e.g. PWIDs. Also, this goal includes soliciting data from other sources, e.g. dialysis units, antenatal clinics, VCT and blood donors (Goal 1.2).

From a structural point of view, the surveillance department at the MOHP receives reports on potential positive cases of Hepatitis from the national health offices and the five fever hospitals. Suspected cases are reported through the NEDSS. However, there is no unified format for the reports.

Findings from the semi-structured interviews reveal a significant gap in reporting positive cases. HCV positive cases from MOHP hospitals are not reported to the surveillance department, but rather to the Directorate for Curative Care. Other positive cases from the remaining public hospitals (MOHP-affiliate organizations such as Health Insurance Organization) as well as university hospitals, private and NGO hospitals are not reported to the surveillance department or any other body at MOHP.

In addition, information related to newly-detected positive cases is not regularly shared with VHA and confirmed cases of HCV are not formally reported to the VHA unit. This is a critical gap due to the significance of surveillance data for enabling the VHA to monitor the impact of the viral hepatitis Plan of Action.

Regarding the reporting process, the VHA has no established protocol for data sharing and exchange with either Sentinel Surveillance or the NEDSS. Findings confirmed that there is no unified template for data gathering neither for the surveillance nor for screening functions.

According to the Plan of Action, the NEDSS should undergo continuous capacity building and strengthening. To date, steps towards this end have not been fully undertaken.

On the national level, screening activities are becoming more and more significant over the past year in addition to sentinel surveillance activities. It is worth mentioning that the Action Plan does not include a specific pillar assigned for screening activities. However, this oversight has been corrected by including screening activities under the surveillance pillar where the VHA is the key responsible body appointed for performing the screening function. The VHA is responsible for supervising the national screening program targeting age group > 18 years. The VHA is currently involved in screening activities in Upper Egypt governorates. These activities run directly under the supervision of the VHA and with its own teams. Positive cases are referred to the nearest center for HCV

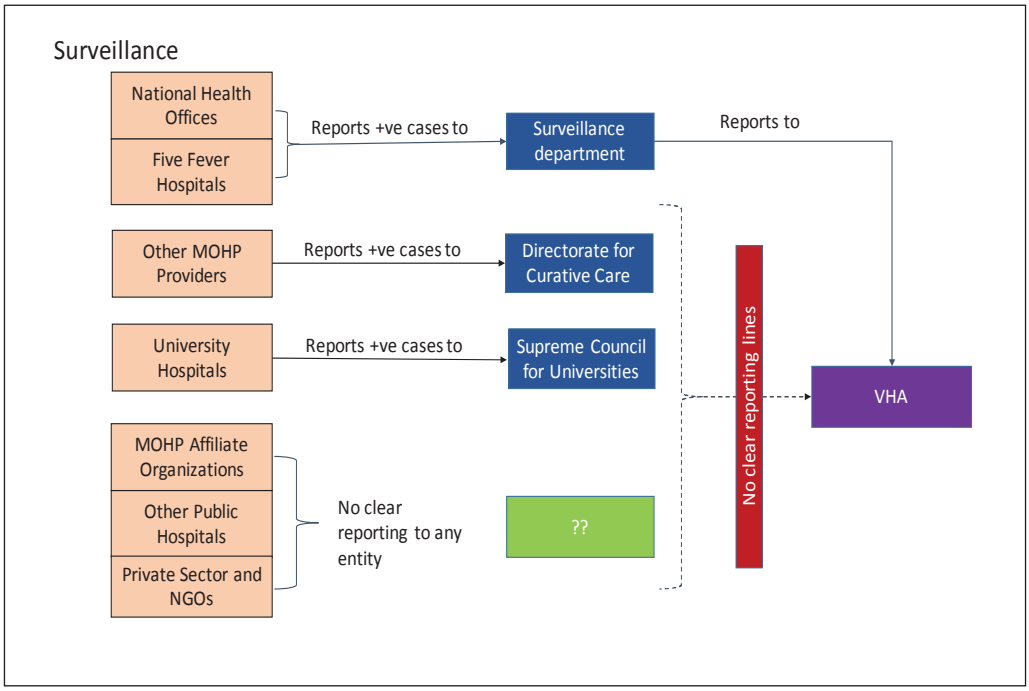
treatment. However, there is no back reporting, i.e., if the cases actually went for the treatment, completed it and/or were cured.

In line with the national call for community mobilization against Hepatitis C, many NGOs and community active groups are taking initiatives towards providing screening services in universities and other locations with higher potential for risk groups. However, there is no evidence of a clear process that ensures the involvement of VHA in supervising the quality of the screening process, such as monitoring the screening kits, which may have a high false negative rate. There are also no clear data collection tools for the screening area and screened persons, and no assurance of reporting these activities.

At the governorate level, there are two personnel who act as focal points for the VHA in the Directorate for Health Affairs in each governorate. They are presumably responsible for coordinating the VHA activities at a directorate level. However, they are not yet formally assigned with a clear mandate that is linked to their remuneration. Thus, their role is not yet fully effective and operational.

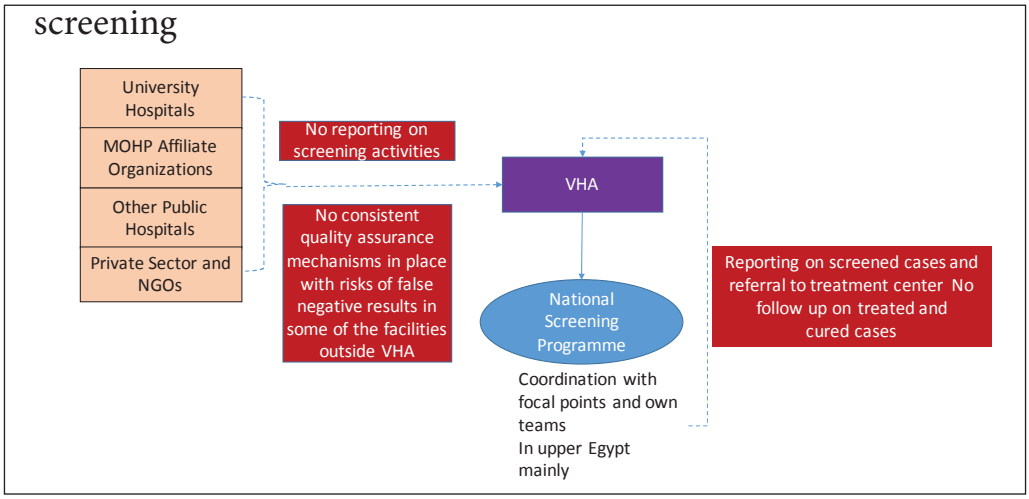
In summary, coordination and communication between different surveillance and screening activities are lacking. The absence of proper communication and coordination mechanisms leads to unnecessary duplication of efforts, waste of valuable resources and inability to utilize important data for monitoring and evaluation, control and planning functions. More important, there is no reporting on treated cases and if they were actually cured. This puts the screening program under the risk that after completion of the screening there will be a need to repeat it again as there is not clear data on how much and who of the screened cases was actually cured.

Figure 7: Illustration of gaps in the surveillance activities



Source: Ministry of Health, Egypt (n.d.)

Figure 8: Illustration of gaps in screening activities



Source: Ministry of Health, Egypt (n.d.)

Recommendations

Based on the abovementioned findings, the following recommendations will strengthen the surveillance pillar of the Action Plan and enable the VHA unit to better perform its surveillance and screening functions:

■ **Develop a unified protocol for data sharing**. This includes developing a data-sharing protocol among the VHA, the Sentinel Surveillance Unit, and NEDSS and creating a link that ensures surveillance department reporting of all positive cases to the VHA unit through a unified format.

■ **Establish a surveillance and screening taskforce.** The taskforce should include representatives for surveillance and screening partners. The taskforce should conduct regular meetings and follow up on all the activities related to monitoring the surveillance and screening functions. This taskforce should also identify standardized data collection tools, set the report formats and reporting frequency, and select the appropriate training material needed to strengthen M&E functions of surveillance and screening in the other units.

■ **Integrate the surveillance and screening functions in more public hospitals.** This should be done in coordination with the main players in the public sector that do not fall directly under the MOHP, e.g. HIO, university hospitals etc. The curative care department (receiving cases from MOH hospitals) and the Supreme Council of Universities (receiving cases from university hospitals) should report positive cases to the surveillance department. In addition, reporting mechanisms for other public hospitals to the respective organization should be established, and these organizations should report positive cases to the surveillance department.

■ **Strengthen reporting from the private sector.** This is aimed at extending the outreach of the screening and surveillance function to the private sector and NGOs. Private hospitals should regularly report positive cases to the surveillance department either directly or through the representative bodies such as the union for NGOs and the chamber for private sector providers.

■ **Coordinate all surveillance data to the VHA.** The surveillance department should coordinate with the VHA to make sure that all cases detected within health facilities are reported.

■ **Empower governorate VHA focal points**. This is approached through formally incorporating tasks that relate to the VHA as part of their working time and appraisal. In addition, an official administrative policy should be developed at the health directorate level indicating VHA focal points as the reference point for any screening activity request received by the health directorate in the respective governorate. It is important to have a legal mandate stating that any screening activity requires involvement of the VHA and clearance by the focal points.

■ **Strengthen the coordination role of the VHA for screening activities.** This would empower the VHA to act as the national coordinating body for screening activities. Towards this goal, the VHA should have a national plan for screening that is coordinated between the different stakeholders and parties conducting screening. Data should be gathered in a unified format and reported to the VHA. The taskforce should be used as the platform for such coordination. The VHA focal points should act a regional hub.

■ **Legally mandate the coordination role of the VHA**. This would be achieved by establishing a legal obligation to all institutions that aim to do any screening activity to coordinate with the VHA on the quality assurance process, methods, and tools used for screening. In addition, these institutions should be legally responsible for reporting all data including areas screened, positive cases, treated cases, and cured cases to the directorate in a unified reporting format.

Monitoring on the progress of all activities and areas related to this goal rely on the existence of a partnership between VHA and different players and should be achieved by strengthening data sharing and pooling from them to the VHA.

2- Promoting infection prevention and control practices to reduce transmission of Viral Hepatitis

According to the Plan of Action, promoting infection prevention and control practices to reduce the transmission of viral hepatitis should be achieved through four main goals: establishing government commitment to and support of policies that ensure infection, prevention, and control practices in Egypt; reducing transmission of viral hepatitis in primary, secondary, and tertiary healthcare facilities; promoting safe injection practices in healthcare; and strengthening monitoring and evaluation programs for ensuring implementation of infection, prevention, and control programs.

From a structural point of view, infection control falls under the directorate for preventive medicine at the MOHP. Findings from the interviews indicate that the directorate has a very strong and robust system for infection control within the hospitals of the MOHP. In addition, regular auditing visits and a strong regular reporting system are in place. The placement of the VHA under the directorate facilitates its oversight of MOHP facilities. However, hospitals affiliated to MOHP, other ministries, private and NGO hospitals are outside of its scope.

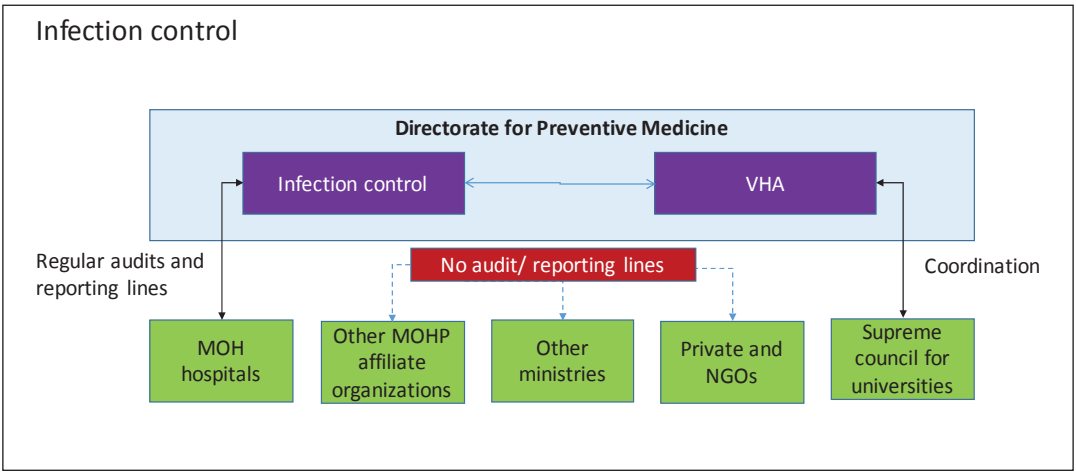
Current insights show that the infection control in such hospitals is run through their own infection control departments with no coordination mechanisms with VHA. Updated guidelines for infection control in hospitals are in place; however, their enforcement among health sector players not under direct authority of the MOHP infection control administration is absent.

Currently, the VHA has ensured commitments from the infection control unit at the Supreme Council of Universities. However, this partnering has not expanded to other players and is not strongly reflected at the university hospital level yet.

Over the past one and a half years, there has been a task force for infection control at the ministry level, joining partners along with the key responsible person for infection control within the VHA. Lately, however, this taskforce has been idle and hence progress towards a "National Infection Control Steering Committee" is lacking. Consequently, several activities on infection control remain currently on hold.

It is important to note that the rate of HCV/HBV infection cannot be used as an outcome indicator for effective infection control practices except in case of reducing occupational exposure and in seroconversion for dialysis patients. Otherwise, it is impossible to track the source of infection for a newly diagnosed case given the long incubation period and symptom free stage of infection. Instead, monitoring should rely on standard infection control indicators, e.g. rate of surgical wound infection.

Figure 9: Illustration of gasps in reducing infection control function



Source: Ministry of Health, Egypt (n.d.)

Recommendations

■ **Activate the taskforce for infection control.** This taskforce should comprise representatives from the broader stakeholder arena including all public hospitals, private hospitals (Chamber for Private healthcare providers) and NGO hospitals (Union for NGOs) in addition to representation from the regulatory arm of the MOHP, namely the Directorate for Private Treatment.

■ **Support the taskforce for infection control**. The VHA would provide technical support to the taskforce and act as an administrative secretariat to support the task force and support the coordination and information sharing between the representative bodies.

■ **Develop standard guidelines for infection control**. Taking into consideration the diversity of service providers in the Egyptian health care system, it is essential to standardize guidelines for infection control and create a national plan for unified infection control implementation and reporting mechanisms

■ **Create a set of indicators for monitoring the infection control activities**, their efficiency, and their progress. It is worth mentioning that these indicators will measure the infection control activities rather than the incidence of HCV infection.

■ **Regulate infection control activities within the private sector and NGOs**. This should be achieved through regulatory oversight by the licensing and inspection units in the Ministry of Health and the Directorates for Private Treatment.

3- Improving blood safety to reduce transmission of Viral Hepatitis

The Plan of Action includes two distinct goals regarding improving blood safety to reduce transmission of viral hepatitis in Egypt. These goals entail establishing government commitment and support of policies that ensure the safety and adequacy of national blood supply and building a sustainable base of safe blood donors to maintain adequate and safe national blood supplies.

Findings from interviews show that the NBTS is responsible for controlling the standards for blood screening activities within its own banks. However, these banks represent only approximately 30% of all blood products available in Egypt. All other blood products fall under the control of public hospital banks, university hospital blood banks, and private sector banks. This fragmentation leads to the absence of clear lines for coordination and control in addition to the lack of clear unified reporting mechanisms from the banks to the NBTS.

Currently, the NBTS shares information with the VHA key responsible person regarding the number of HCV and HBV positive cases from the total screened blood bags on a monthly basis. The data shared is cumulative and lacks information for identification. However, it is worth mentioning that starting June 2016 and based on a ministerial decree, sharing identifying information of blood donors to the VHA is now formally mandated. This decree has been successfully implemented and has enabled the VHA to contact positive cases and provide them with information on treatment options and facilities.

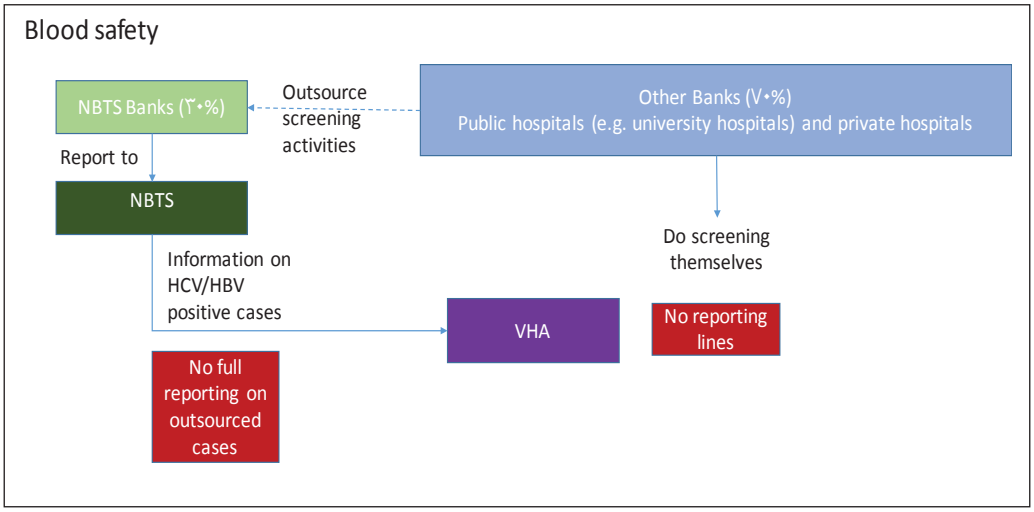
Since the NBTS provides only 30% of blood and blood products in Egypt, the sampling process of the majority of the cases (70%) takes place at the other remaining organizations. The NBTS has no access to information regarding these other sties; consequently, positive detected cases are not reported.

Findings reveal that a number of private and public entities decide to outsource their screening activities to the NBTS, thus ensuring a rigorous screening process. However, the NBTS does not have access to their personal identifying information. Thus, the NBTS and consequently the VHA do not have access to

the information of HCV-positive cases to be able to outreach them.

According to the plan of action, a National Blood Authority should be established to ensure standardization of all policies and procedures related to national blood supply. However, there is no progress detected regarding the establishment of such an entity.

Figure 10: Illustration of gaps in blood safety function



Source: Ministry of Health, Egypt (n.d.)

Recommendations

■ **Initiate the establishment of the national blood authority**. This would support regulating the screening of blood products particularly those provided by organizations other than the NBTS blood banks.

■ **Standardize the screening procedures**. This would ensure the enforcement of screening activities and reporting of all confirmed positive viral hepatitis cases to the VHA. This should be achieved through setting a clear unified reporting process and a unified format for the report.

■ **Grant access to information to the NBTS**. This should be achieved through authorizing the NBTS to access information of HCV positive cases detected during the screening of blood samples which are sent by other blood banks. At

the end, this information should be regularly reported to the VHA.

■ **Include the demographic information in the report.** The current report format lacks patient demographic data. Including such data in the report is essential to track the progress of the epidemic across the population.

■ **Enforce the reporting process to the national blood authority**. This includes requiring the private blood banks and blood banks in other public hospitals to report all positive cases to the national blood authority.

4- Eliminating transmission of Vaccine-Preventable Viral Hepatitis

According to the Plan of Action, eliminating the transmission of vaccine-preventable viral hepatitis will be achieved through two main goals. The first is to achieve universal hepatitis B vaccination for populations at high risk for infection or complications. The second is to ensure all newborns receive hepatitis B birth dose as soon as possible following birth (<24 hours).

Findings from interviews confirmed that the VHA is the main supplier of HBV vaccine and has managed to cover high percentage of healthcare workers (HCWs) in the public sector as well as universities and other sectors. However, it is worth mentioning that coverage of other high risk group e.g. people who inject drugs (PWIDs), is still not yet in progress.

The Expanded Program for Immunization for Egypt (EPI) has successfully established zero dose for HBV among their program. EPI is collaborating closely with the VHA and continuously sharing information and updates on the achieved vaccination target. They were expected to achieve the target coverage in all governorates by the end of 2016.

Reporting on the target and achieved vaccination is done rigorously and regularly through collaboration with different entities. Although this data lack disaggregation on basic demographics, it is complete for location and governorate. The VHA does not require reporting on other information related to training, logistics and cold chain management.

Recommendations

■ **Standardize the report format.** The unified report format should include demographic data for all reports whether for EPI or for HCWs.

■ **Initiate coordination and collaboration mechanisms between the VHA and actors** working with high-risk groups including, Mental Health Authority, National AIDS program and Ministry of Interior.

5- Role of Care and Treatment in Reducing Transmission of Viral Hepatitis

According to the plan of action, the treatment pillar will be achieved by providing safe, effective, and affordable treatment to patients with chronic Hepatitis B and C.

According to current estimates of the National Committee, at least 800,000 patients will receive treatment in 2016 (after 200,000 in 2015), which is in line with the target number needed to reduce Hepatitis C prevalence to under 1 % in 2030. Included are about 100,000 patients treated in HIO facilities. The total does not include those treated in the private sector (estimated at 200,000 for 2016), where there is no mandatory registration or follow up. A system to register patients and refill drug prescriptions only when they returned the originally dispensed bottle empty was previously in place when treatment entailed discounted originator drugs, but has since been abandoned.

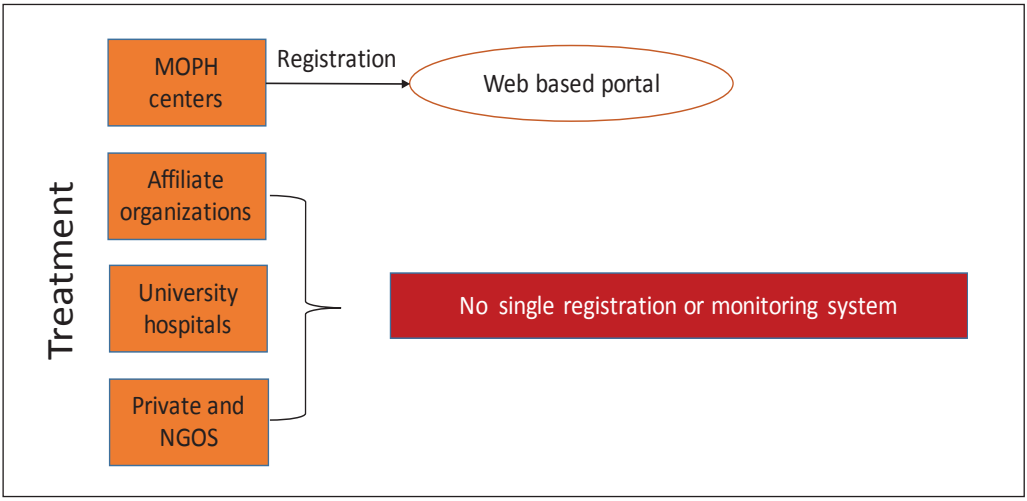
Currently, only 50% of patients show up for the final lab test scheduled one month after the end of treatment, which is needed to confirm complete viral clearance "sustained response." This low figure is a problem, as it will be difficult to calculate the cure rate for the current treatment if patients do not get the final test. The VHA has no reporting lines that indicate the actual rate regarding cure of cases.

Fragmentation of the treatment efforts is also an issue. MOHP treatment centers, university hospitals, NGOs and facilities under the HIO each offer treatment centers but not all of them feed into a single monitoring system. The private sector also offers diagnosis and treatment in many facilities, some of which are of low standards and may use substandard lab reagents or medicines.

This practice can negatively impact cure rates and lead to resistance against the first line medicines that are now available at low cost.

While the Ministry of Health relies upon a web-based portal to register patients for treatment, other sectors (e.g. university hospitals, HIO treatment centers, private sector) do not follow the same system nor do they have a unified monitoring system of their own. Hence, access to information on patients treated in sectors other than the Ministry of Health is quite challenging.

Figure 11: Illustration of gaps in viral hepatitis treatment prorgram



Source: Ministry of Health, Egypt (n.d.)

Recommendations

■ **Develop an information sharing protocol with the VHA.** This entails establishing clear reporting mechanisms between the different treatment programs and centers and the VHA. Data on the number of treated cases, cured cases and no show up cases should be shared with the VHA on a regular basis. This is of special importance for the cases referred from screening activities.

■ **Coordinate between treatment programs and screening activities in the VHA**. This would allow better planning for establishing new treatment centers in accordance with the amount of screening activities taking place and potential

numbers of detected cases in different regions. This includes number, geographical distribution, and capacity of the treatment centers that matches the demand for treatment.

6- Educating providers and communities to reduce transmission of Viral Hepatitis

Based on the Plan of Action, educating providers and communities to reduce transmission of viral hepatitis will be achieved through three main goals: increasing the inter-sectorial coordination for effective public awareness in viral hepatitis, educating healthcare workers to increase awareness about transmission of viral hepatitis in Egypt, and increasing public awareness in viral hepatitis control.

According to findings, a national public awareness campaign was successfully launched in 2016. It was clear that different activities identified in the plan of action were successfully completed. However, the impact of this campaign has yet to be rigorously assessed; it requires a knowledge, attitude and practice (KAP) study to compare the findings to the baseline preceding the campaign, which was not indicated as a budgeted activity in the action plan.

Currently, the VHA is informed on an ad-hoc basis with regards to awareness activities among different age groups e.g. universities and school children. However, the quality of the awareness campaigns and the information delivered is not greatly under control of the VHA key responsible person. In addition, the level of outreach of these campaigns is not well communicated to VHA.

No progress is yet achieved regarding the establishment of a hotline to provide information on HCV testing and treatment services.

The counseling services for hepatitis patients identified through testing centers for visa application and blood banks are being conducted through VHA via telephone. It was highlighted that this is a voluntary effort from the team and it is not yet formalized to include other potential catchment areas e.g. cases identified in hospitals.

Recommendations

■ Develop a reporting system. This is aimed at capturing the different health education activities conducted on the national level (estimated outreach, material distributed and geographical coverage).

■ Establish a hotline for counseling. Initiating and promoting a VHA hotline to facilitate access to counseling information and follow up on cases initiating treatment. This would help ensuring patients follow through with treatment.

■ Empower governorates VHA focal points. This will be achieved through an official policy at the health directorate level indicating VHA focal points as the referral point for any request for community based awareness campaign received by the health directorate. This would ensure the standardization of the quality of health messages delivered, facilitate access to health education material, and ensure reporting of the outputs and outcomes of these activities.

■ Improve coordination and collaboration between the School Health Department at the MOHP and the VHA. Similarly, this is needed with the Supreme Council of Universities and with the university deputies for community services and environment affairs.

■ Set a specific day as annual advocacy event. It is suggested to set the World Liver Day as an annual advocacy event around which a campaign can be launched annually, as is the case with other programs e.g. World AIDS Day and Breast Cancer Day. This will allow reinforcing community awareness and bring all partners together to identify the pressing challenges and celebrate successes. Such a strategy ensures continuous national buy-in to the program and supports its success.

7- Strategy for promoting viral hepatitis health research and information technology

According to the Plan of Action, the strategy for promoting viral hepatitis research and information technology should involve the following six goals: defining a participatory viral hepatitis health research plan, building capacities in research, developing central research warehouse concerning viral hepatitis in Egypt, capitalizing on different stakeholders' collaboration, supporting the conduction of experimental studies (e.g. clinical trials and community intervention studies), and reinforcing viral hepatitis prevention and control in Egypt.

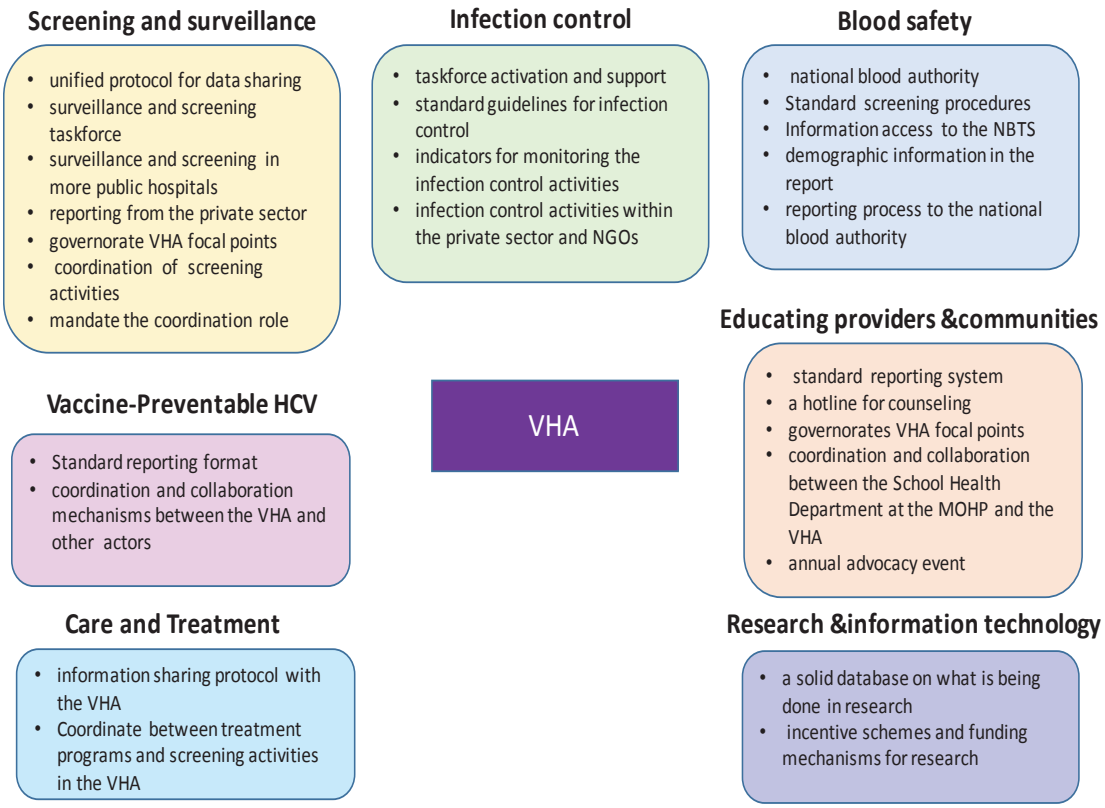
Research activities on viral hepatitis are widely undertaken across the country by public and private universities, research institutes and centers. There are no clear lines of coordination and information sharing among these entities nor with the ministry of health and many entities operate with no clear research objectives. To date, there are no precise data that indicate the number, type and the scope of published research. This sporadic and diverse nature of the research function makes it difficult to undergo monitoring and evaluation. Most of research around the treated cases focuses on clinical research.

Recommendations

■ **Establish a solid database on what is being done in research.** This is achieved through systematic and regular compilation of all national research activities on viral hepatitis conducted on the national level. The data should be compiled in an annual list that includes all the published research on viral hepatitis conducted by researchers in all public and private universities and research centers. This should also help in guiding researchers towards topic in need.

■ **Establish incentive schemes and funding mechanisms for research.** This can be achieved through several approaches. For example, by establishing solid networks and cooperation with international partners and organizations.

Figure 12: Summary recommendations of interventions to improve the M&E function



Source: Ministry of Health (MOH)

VII- The way forward

With the arrival of the recent Direct Antiviral Agents, treatment became the new focus of viral hepatitis programs across the country. This led to a massive outreach, with more than 800,000 patients being treated since January 2016. Following this outreach, however, demand for treatment and the flow of patients to treatment centers is now gradually decreasing. In order to sustain this massive success and achieve the vision of a country free from HCV by 2020, focus needs to be directed towards ensuring the early detection of existing positive cases, treating them, and preventing the infection of new ones and reinfection of treated patients. This can be achieved by establishing robust systems for screening activities, surveillance and blood testing. It will require reporting on all the screened individuals and positive cases. It means ensuring that all positive cases are referred for treatment, that they show up for the treatment, and that they complete the treatment and all cured cases are proted. In addition, there should be strong quality assurance mechanisms in place for all activities to ensure utmost sensitivity and avoid false negative results.

To achieve those objectives, the VHA must be empowered to act as the national coordinating body for the implementation of the above-mentioned areas of focus. A robust M&E system and capacity should be developed within the VHA with the respective resources and linked to the indicators mentioned in the plan (see tables in the annex). Finally, the VHA should be granted the authority and necessary capacity to achieve the following objectives effectively:

Early detection of existing positive cases

■ The established surveillance and screening taskforce should develop a national screening program through coordination and with administrative support of the VHA. Screening activities under the program could be either directly implemented through the MOHP teams under the leadership of the VHA and in coordination with the directorate for health affairs. Moreover, screening activities can be conducted through other entitles like NGOs. However, the focal points in the directorate should be authorized and empowered to provide clearance and

perform quality assurance for screening activities. All screened cases should be systemically reported to the VHA either directly or through VHA focal points at the directorate.

■ A robust reporting system for surveillance from all public, private and NGO hospitals should be in place. All respective organizations should regularly report positive cases to the appropriate surveillance department in a unified reporting format. This needs to be coordinated and enforced through the national taskforce. The surveillance department should communicate the cases to the VHA.

■ Once established, the national blood regulatory authority should enforce quality assurance mechanisms for all blood banks and ensure that a strong system for reporting positive cases to the VHA is in place. The national blood authority will report positive cases detected from its own banks and the outsourced samples screened by it. Other blood banks will report their own screening activities to VHA either directly or through the VHA focal points at governorate level.

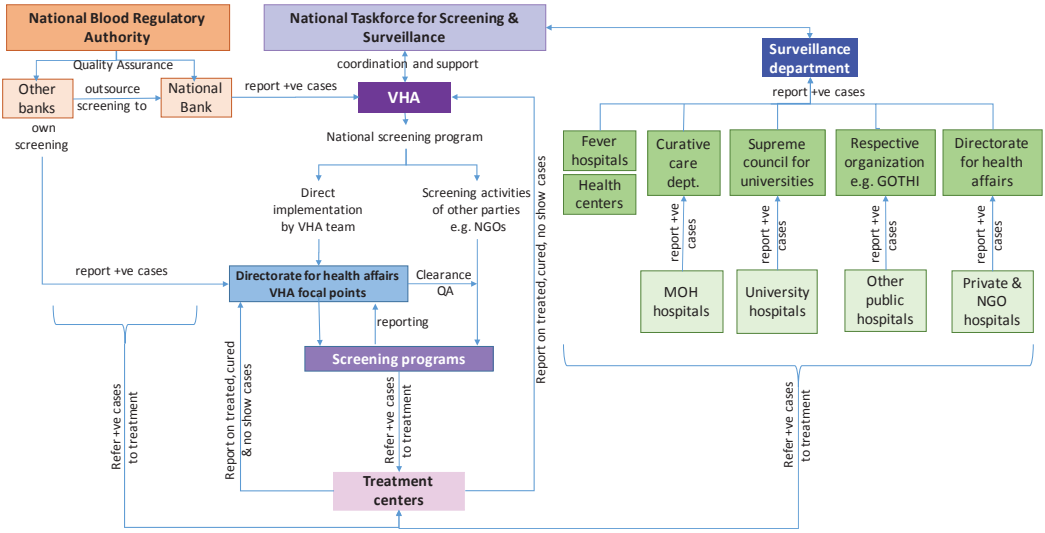
■ For all screened cases, a system for referring all positive cases to treatment centers should be implemented. There should be a process for reporting back all cases that showed up and received treatment, those who completed the treatment and those who got cured. This is a crucial step to a successful screening program.

Prevention of infection of new cases and reinfection of previous ones

■ A robust infection control system should be in place. This would be achieved by developing standard guidelines for infection control and ensuring compliance by all hospitals and health centers including public, private and NGOs with high focus on particularly vulnerable settings such as dentist clinics.

■ All existing vaccination programs should strengthen their reporting systems. Unified reports should include demographic data of the cases and be reported regularly to the VHA.

Figure 13: VHA as a hub for M &E of key areas



Source: Ministry of Health, Egypt (n.d.)

Annexes

The M&E framework for viral hepatitis will attempt to assess the success of the national plan action for prevention, care and treatment of viral hepatitis since 2014, making the most of the gathered data to initiate a road map for the time ahead till 2020 guided by clear Key performance indicators. The KPIs are listed in the below tables.

I- Context and needs

I-A Prevalence of chronic HBV infection	
Definition	Number and proportion of people living with chronic HBV infection (hepatitis B surface antigen [HBsAg] positive)
Numerator	Number of persons with chronic HBV infection defined by HBsAg-positive serological status
Denominator	Number of persons (total population)
Measurement method, sources of data	Information for this indicator is derived ideally from surveys, but can be derived from program data, special studies and modelling.

I-B Prevalence of chronic HCV infection	
Definition	Number and proportion of people living with chronic HCV infection (HCV RNA positive or HCV antigen [Ag] positive)
Numerator	Number of persons with chronic HCV infection defined as positive for HCV RNA or positive for HCV Ag
Denominator	Number of persons (total population)
Measurement method, sources of data	Information for this indicator is derived ideally from surveys, but can be derived from program data, special studies and modelling. Modelling may be used initially, if data are available only for anti- HCV.

I-C Experience with discrimination against people living with viral hepatitis	
Definition	Number and proportion of people infected with viral hepatitis who have experienced discrimination
Numerator	Number of people living with viral hepatitis who experienced discriminatory attitudes or actions towards them in the past 12 months.
Denominator	Number of people living with viral hepatitis.
Measurement method, sources of data	Population interviews.

II- Inputs

II-A Infrastructure for HBV and HCV testing	
Definition	Ratio of facilities with capacity to test individuals for chronic hepatitis HBV and/or HCV per 100 000 population according to the following testing methods: - molecular methods (HCV RNA, HBV DNA) - serological methods (HBsAg, anti-HBc, anti-HCV)
Numerator	Number of facilities with capacity to test for chronic hepatitis - Tests to be used depend on national recommendations based on WHO guidelines. - Facilities include health workers using point-of-care (POC) testing, health facilities, and laboratories.
Denominator	Number of persons (total population)
Measurement method, sources of data	Information for this indicator is derived from program data. Tests to be used depend on national recommendations based on WHO guidelines.

II-C Equitable access to hepatitis treatment	
Definition	Ratio of treatment access between high-risk / -burden populations and the general population.
Numerator	Number of persons from high-risk/ -burden populations receiving HBV treatment / initiated on HCV treatment during the reporting time (i.e. C.7.a and C.7.b indicators in high-risk/ -burden populations)
Denominator	The number of persons from the general population receiving HBV treatment/ initiated HCV treatment at a specified date.
Measurement method, sources of data	Program records or surveys depending on the subpopulation group being compared Data in high-risk /-burden populations such as PWID, are often collected through surveys. The type of high-risk/ - burden populations is to be chosen according to epidemic patterns.

II-D Availability of essential medicines and commodities	
Definition	Hepatitis C direct-acting antiviral (DAA) agents and hepatitis B medicines in the national essential medicines list (EML)
Numerator	Presence of the medicines needed for the treatment of viral hepatitis B and C that are included in the WHO model EML in the national EML.
Denominator	Not applicable
Measurement method, sources of data	Program data Review of documents.

III- Outputs and outcomes:

Prevention:

III- A Coverage of timely hepatitis B vaccine birth dose (within 24 hours) and other interventions to prevent mother-to-child transmission of HBV	
Definition	Proportion of newborns who have benefited from timely birth dose of hepatitis vaccine (within 24 hours) or from other interventions to prevent mother-to-child transmission of HBV percentage.
Numerator	Number of newborns receiving timely birth dose of hepatitis vaccine within 24 hours (HepB_BD) or benefiting from other interventions to prevent mother-to-child transmission of HBV (e.g. testing of the mother followed by immunoprophylaxis,1 or in the future, treatment)
Denominator	Number of live births
Measurement method, sources of data	Routinely collected from program data (vaccine administrative coverage data, facility information systems) or through periodic immunization validation surveys (household surveys).

III- B Coverage of third dose of hepatitis B vaccine among infants	
Definition	Proportion of infants (<12 months of age) who received the third dose of hepatitis B vaccine (HepB3) (percentage)
Numerator	Number of infants (<12 months of age) who received the third dose of hepatitis B vaccine (HepB3).
Denominator	Number of infants (<12 months of age in a year) surviving to age 1 year.
Measurement method, sources of data	Routinely collected from program data (vaccine administrative coverage data, facility information systems) or through periodic immunization validation surveys (household surveys).

III-C Facility-level injection safety	
Definition	Proportion of health-care facilities where all therapeutic injections are given with new, disposable, single-use injection equipment
Numerator	Number of sampled health-care facilities where all therapeutic injections are given with new, disposable, single-use injection equipment
Denominator	Number of facilities sampled
Measurement method, sources of data	- This indicator is measured through health facility surveys (facility data).

III-D Needle-syringe distribution	
Definition	Number of needles–syringes distributed per person who injects drugs
Numerator	Number of sterile needles–syringes distributed in the past 12 months by needle–syringe programs (NSPs)
Denominator	Number of people who inject drugs
Measurement method, sources of data	Numerator: program records, e.g. NSP logbooks Denominator: population size estimation exercises.

Testing

III- E People living with HCV and/or HBV diagnosed	
Definition	Proportion of people living with chronic HBV and/or HCV infection who have been diagnosed with HBV and/or HCV
Numerator	Number of persons with chronic HBV and/or HCV infection who have been diagnosed
Denominator	Estimated number of persons with chronic HBV and/or HCV infection
Measurement method, sources of data	Two measurement methods are possible: 1) Counting persons reported with chronic infection and dividing this number by the estimated size of the population infected. In that case, the numerator is the number of persons reported with chronic HBV and/or HCV infection from health-care facilities (case reporting) and/or laboratories, while the denominator is the estimated size of the population infected (modelled or estimated from a biomarker survey). This method estimates the number of persons newly identified or newly reported, which, after identification of duplicates, may be cumulated over time. 2) Using survey data where persons are asked if they are aware of their viral hepatitis infection status in population surveys. In that case, the numerator is the number of persons reporting that they are aware of their chronic HBV and/or HCV infection during the survey, while the denominator is the number of persons identified as infected during the survey

III- F HCV genotyping	
Definition	Proportion of chronic HCV infections with genotyping information.
Numerator	Reported cases of chronic HCV infection that have been genotyped.
Denominator	Reported cases of chronic HCV infection
Measurement method, sources of data	- Program data, or - Laboratory information systems, or - Special studies.

Care and treatment

III-G Treatment coverage for Hepatitis B	
Definition	Proportion of HBV-infected persons who are currently on treatment
Numerator	Number of persons with chronic HBV infection (defined by HBsAg-positive serological status) who are currently receiving treatment
Denominator	Number of persons with chronic HBV infection
Measurement method, sources of data	Numerator: program records (clinical records of health-care facilities providing hepatitis treatment and care) Denominator: modelling estimates of the number of HBV-infected persons

III-H Treatment Initiation Virus C	
Definition	Proportion of persons diagnosed with chronic HCV infection started on treatment during a specified time frame (e.g. 12 months)
Numerator	Number of persons already diagnosed with chronic HCV infection (defined as positive for HCV RNA or positive for HCV Ag) who initiated treatment during a specified time frame (e.g. 12 months)
Denominator	Number of persons already diagnosed with chronic HCV infection (defined as positive for HCV RNA or positive for HCV Ag) for the specified time period (12 months) Note: All those already diagnosed to date but treated and cured would be excluded.
Measurement method, sources of data	Numerator: program records (clinical records of health-care facilities providing hepatitis treatment and care) Denominator: program records and/or modelling estimates

Cure/suppression

III-I Viral suppression for chronic hepatitis B patients treated	
Definition	Proportion of patients with chronic HBV infection on treatment in whom HBV viral load (VL) is suppressed
Numerator	Number of patients with chronic HBV infection on treatment who have a suppressed VL (HBV DNA not detectable), based on VL measurement in the past 12 months
Denominator	Number of patients with chronic HBV infection on treatment and assessed for VL in the past 12 months
Measurement method, sources of data	Program records, cohort studies, patient records, combined with estimates for the population with no VL data

III- J Cure for hepatitis C patients treated	
Definition	Proportion of patients with chronic hepatitis C cured among those who completed treatment
Numerator	Number of patients who completed hepatitis C treatment and had a sustained virological response (SVR) based on VL measurement 12–24 weeks after the end of treatment (in the past 12 months)
Denominator	Number of patients who completed hepatitis C treatment and were assessed for SVR 12– 24 weeks after the end of treatment (in the past 12 months)
Measurement method, sources of data	Program records, cohort studies, patient records, combined with best estimates for the population with no VL data

V- Impact

V-A Cumulated incidence of HBV infection in children 5 years of age	
Definition	Proportion of children 5 years of age with serological evidence of past or present HBV infection (anti-HBc positive) and/or chronic infection (HBsAg positive).
Numerator	Number of survey children 5 years of age living with biomarkers of past or present infection and/or chronic infection
Denominator	Number of children aged 5 years of age in surveys (35)
Measurement method, sources of data	HBsAg biomarker prevalence survey in children 5 years of age (immunization coverage surveys and administrative vaccination coverage data)

V-B Incidence of HCV infection	
Definition	Number and rate of new infections with HCV (anti-HCV positive)
Numerator	Total number of new infections with HCV defined as anti-HCV positive per year
Denominator	Total population minus people living with hepatitis C
Measurement method, sources of data	Modelled with inputs from repeated surveys of HCV infection: - general population (in selected countries with a high prevalence) at least every 10 years - people who inject drugs (PWID), at least every 3 years - antenatal care (ANC), at least every 3 years - other relevant groups.

V- C Deaths attributable to HBV and HCV infection	
Definition	Deaths from hepatocellular carcinoma (HCC), cirrhosis and chronic liver diseases attributable to HBV and HCV infections
Numerator	Number of deaths from HCC, cirrhosis and chronic liver diseases attributable to HBV and HCV infection: - number of hepatocellular carcinoma (ICD-10 code C22.0) deaths multiplied by the proportion of HCC with chronic HBV and HCV infections - number of cirrhosis deaths (ICD-10 codes K74.3, K74.4, K74.5, K74.6) multiplied by the proportion of cirrhosis with chronic HVB and HCV infections - number of chronic liver disease deaths (ICD-10 codes K72–K75) with chronic HBV and HCV infections
Denominator	Not applicable
Measurement method, sources of data	• Cancer registry files • Including mortality registers • Hospital-/clinic-based registers. • Global databases (aggregated data): • WHO mortality databank (liver cancer ICD-10 code C22 only) • IARC Cancer Incidence in Five Continents (CI5) databases (liver cancer and HCC data) • Global estimated data (modelling) • IARC GLOBOCAN database (liver cancer ICD-10 code C22 only) • Prevalence of HBV and HCV infections among patients with HCC, cirrhosis and chronic liver diseases in sentinel sites

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