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National treatment programme of hepatitis C in Egypt: Hepatitis C virus model of care

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Summary

Hepatitis C virus (HCV) infection is a major health problem in Egypt as the nation bears the highest prevalence rate worldwide. This necessitated establishing a novel model of care (MOC) to contain the epidemic, deliver patient care and ensure global treatment access. In this review, we describe the process of development of the Egyptian model and future strategies for sustainability. Although the magnitude of the HCV problem was known for many years, the HCV MOC only came into being in 2006 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. The strategy outlines best practices for patient care delivery by applying a set of service principles through identified clinical streams and patient flow continuums. The Egyptian national viral hepatitis treatment programme is considered one of the most successful and effective public health programmes. To date, more than one million patients were evaluated and more than 850 000 received treatment under the umbrella of the programme since 2006. The NCCVH has been successful in establishing a strong infrastructure for controlling viral hepatitis in Egypt. It established a nationwide network of digitally connected viral hepatitis-specialized treatment centres covering the country map to enhance treatment access. Practice guidelines suiting local circumstances were issued and regularly updated and are applied in all affiliated centres. This review illustrates the model and the successful Egyptian experience. It sets an exemplar for states, organizations and policy-makers setting up programmes for care and management of people with hepatitis C.

KEYWORDS

chronic HCV, Egypt, model of care, National Committee for Control of Viral Hepatitis

1 | BACKGROUND

In 2008, Egypt had the highest burden of hepatitis C virus (HCV) infection worldwide, where about 15% of the population were seropositive, 10% chronically infected, with 90% of patients infected with genotype 4.[1] In 2015, the seroprevalence of HCV infection in Egypt has declined to 6.3% among the studied population[2] with an overall estimated 30%

Abbreviations: DAAs, direct-acting antiviral agents; DAC, daclatasvir; HCV, hepatitis C virus; HIO, Health Insurance Organization; LED, ledipasvir; MOC, model of care; MOH, Ministry of Health; NCCVH, National Committee for Control of Viral Hepatitis; NNTC, National Network of Treatment Centers; RBV, ribavirin; SIM, simeprevir; SOC, standard of care; SOF, sofosbuvir; SVR, sustained virological response; US-CDC, US Centre for Disease Control and Prevention; VPN, virtual private network; WHO, World Health Organization.

decrease in HCV prevalence in Egypt between 2008 and 2015.[3] HCV transmission is still ongoing, and incidence rates have been estimated at 2.4 per 1000 person-years (close to 165 000 new infections annually). In some reports, prevalence rates were estimated at 6.9/1000 persons/yr based on a regression model using a national probability sample.[4]

The national campaign for the parenteral treatment of schistosomiasis that took place from the late 1950s to the 1980s is claimed to be responsible for the large pool of chronic HCV infection in Egypt.[5] Additionally, history of blood transfusion was identified in 24.3% and needle reuse in 20.6% of HCV-positive cases.[6,7] Nosocomial infection from medical procedures and household transmission continued to be a risk factors.[8,9]

Among patients with chronic HCV, 35%-45% will develop some level of progressive liver disease, and without treatment approximately 5%-10% will develop cirrhosis (10%-20% lifetime risk) and 1%-3% develop hepatocellular carcinoma (HCC).[10,11] An increase in incidence of HCC and other liver-related complications was expected, with estimated doubling of HCV-related mortalities between 2000 and 2020, reaching more than 35 000 deaths per year in 2020.[12]

Before the era of direct-acting antiviral agents (DAAs), the available therapeutic options for HCV were limited. The combination of pegylated interferon and ribavirin was the standard of care (SOC) leading to a sustained virological response (SVR) that did not exceed 60% of patients of genotype 4.[13] In addition, side effects of IFN and ribavirin were a major problem and the list of contraindications for HCV therapy was long, including decompensated cirrhosis and psychiatric disorders.[14] Hence, alternative therapeutic approaches were needed. Progress in the molecular virology of HCV identified optimum targets for antiviral intervention, and rapid progress in the field necessitated rapid action on part of the National Committee for Control of Viral Hepatitis (NCCVH) to ensure access to new effective medications at costs that suit the limited resources of the country. The guidelines for treatment had to change repeatedly in accordance with the rapidly changing international guidelines with the development of active drugs and effective treatment combinations.[15,16]

2 | THE VISION FOR THE HEPATITIS C VIRUS MODEL OF CARE IN EGYPT

The aim was to provide a framework for control of HCV infection, markedly reducing the prevalence and burden of HCV in Egypt, and targeting disease elimination by 2030. The NCCVH set its goal to enhance access to diagnosis and treatment, coupled by prevention of transmission to reduce the health and economic impact on the individual and the community.

3 | MISSION OF THE HEPATITIS C VIRUS MODEL OF CARE IN EGYPT

- Deliver equitable, safe and standardized medical evaluation and treatment services to all HCV patients, without discrimination, while considering cost-effectiveness to maintain sustainability in a limited-resource country like Egypt.
- Plan prevention strategies to reduce further risk of transmission including raising public awareness of modes of transmission and high-risk behaviours, providing safe blood products, improving infection control in healthcare facilities, adopting safer injection practices and strengthening surveillance.
- Establish approved evidence-based national guidelines for treatment of chronic HCV infection to be delivered by expert hepatologists.
- Training the healthcare professionals (hepatologists, infectious disease specialists, physicians and nurses) to deliver an efficient counselling, care and treatment programme for patients with chronic HCV in accordance with the updated national guidelines. Pharmacists and information technology specialists were also trained to coordinate dispensing medications and data management through a well-regulated system implemented on a nationwide basis.

4 | MAJOR STAKEHOLDERS CONTRIBUTING TO THE HEPATITIS C VIRUS MODEL OF CARE IN EGYPT

The process of developing and implementing the national programme was multidisciplinary, involving a number of stakeholders with varying roles and levels of contribution.

The cornerstone for the hepatitis C model of care (MOC) is the NCCVH. The committee is divided into an advisory board and an executive working group. The advisory board is responsible for planning and developing the strategy and implementation plan and for monitoring progress of the MOC. The executive team is responsible for implementation of the planned strategy.

The governmental stakeholders include the Ministry of Health (MOH), Ministry for Administrative Development and the Ministry of Communication. The MOH supports the development of specialized centres for care of viral hepatitis patients within existing nationwide MOH hospitals and healthcare facilities. It ensures allocation of necessary resources to maintain sustainable supplies of antiviral treatment for all registered HCV-infected patients within a time frame in accordance with the action plan, in addition to assigning a working multidisciplinary team for execution of the treatment plan. It sponsors the cost treatment for all those who do not have—or request—financial coverage. The other ministries contribute through development of a national web-based registration system and creation and maintenance of the database connecting the specialized treatment centres.

National and international pharmaceutical companies play a crucial role as stakeholders in implementing the national strategic treatment plan making medications available and at affordable cost.

The availability of a national infrastructure dedicated to HCV management, rigorous data collection, trained personnel, a committed government, as well as local production leveraged cost negotiations. An outstanding example was the local production of pegylated interferon

and ribavirin—the previous standard of care treatment—led to a sharp reduction in the price of the imported drug in the local market.

The media continues to be one of the main stakeholders raising public awareness about HCV infection, modes of transmission, risk factors, means of prevention and the importance of treatment. It informs the population about the national programme for control of viral hepatitis, NCCVH strategic plan and treatment programme, registration for treatment and location of treatment centres.

5 | STEPS OF DEVELOPING THE HEPATITIS C VIRUS MODEL OF CARE IN EGYPT

In 2001, the Egyptian MOH implemented a multitask strategic programme to reduce HCV transmission in Egypt. The first national guideline for infection control was published preceded by establishment of the first surveillance unit at the MOH. Improvements in infection control practices over the years resulted in a decrease in the annual incidence of new HCV infection among dialysis patients from 28% to 6% in 2008.[17]

In 2006, in recognition of the enormity of the HCV problem and burden of disease in Egypt, the Minister of Health established the NCCVH. The advisory board members are volunteering Hepatology and Public Health Professors in Egyptian Universities, a Ministry of Health representative, and included initially ad hoc experts from the Pasteur Institute in Paris, France, and the University of California in San Francisco, USA.

The NCCVH set several targets, including assessment of burden of disease, establishment of an infrastructure for a national treatment programme, development of a national strategy for control of viral hepatitis and management of advanced liver disease, while continuing performing clinical and epidemiological research activities. The initial target was to provide antiviral treatment for HCV-infected individuals at either minimum cost or totally free of charge (paid for on the expense of the state) for those who are not under health insurance coverage, and fully covered for those treated through the Health Insurance Organization (HIO).

The committee is responsible for preparing strategic and action plans, appropriate treatment protocols and clinical guidelines, centralizing electronic medical records from all treatment centres, analysing data and providing feedback to ensure provision of quality patient care. It is also responsible for establishing treatment centres and training the healthcare team on implementation of the programme, in addition to negotiating prices of medicines for the MOH-supported treatment programme.

In 2007, the NCCVH established its first specialized centres for treatment of viral hepatitis within MOHP (Ministry of Health and Population) healthcare facilities. Centres were planned to be geographically distributed in the most populous areas, so that eventually no patient will have to travel more than 50 km to a centre. This ensured better access to care and treatment for patients everywhere. These centres are managed through a well-trained team of specialized hepatologists providing a full spectrum of care for patients starting with initial screening for treatment legibility up to providing standard of care management according to the standardized protocols. More than 54 centres were established between 2007 and 2016 providing care and treatment to nearly 800 000 chronic HCV-infected persons.

In 2010, a closed virtual private network (VPN), the National Network of Treatment Centers (NNTC), was founded to connect the viral hepatitis treatment centres to the head office. Remote users in all the centres were connected real time to customized database on "Microsoft Dynamic CRM." The Academy of Scientific Research and Technology supported the development and operation of the database server where baseline and follow-up data of patients under treatment in all centres were recorded.

In 2014, with the availability of DAAs suitable for patients with HCV genotype 4, negotiations between the Egyptian Government, represented by the NCCVH and Gilead Sciences, Foster City, California, U.S.A. the US manufacturer of sofosbuvir (Sovaldi®) led to an agreement providing the medication for patients treated through the Government programme at the reduced price of $300 per bottle (a reduction from $28 000 per bottle in the USA market). The manufacturer had set a three-tier global pricing programme that sets the price of the product in each country depending on the country's income. Although Egypt is a "middle-income" or "low-middle-income" country according to its per-capita GDP, the set-up of the Egyptian national treatment programme infrastructure as a tightly supervised system preventing diversion of medication to other countries, the availability of outcome data in a national database, as well as the huge burden of HCV infection in the country, helped negotiate the price of medication down to that set for low-income countries ($300 per bottle instead of $5000 per bottle).

The deal with Gilead Sciences set the bar for the cost of introducing new DAAs to Egypt. Similar negotiations with the other manufacturers of DAAs resulted in equivalent reduction of prices of their medications or the national programme: simeprevir (Janssen Pharmaceutica, Beerse, Belgium.) and daclatasvir (Bristol-Meyers-Squibb, New York City, NY, USA) at $250 for a month's supply each, paritaprevir-ombitasvir (AbbVie, North Chicago, Illinois, USA) at $300 for a month's supply and sofosbuvir-ledipasvir (Gilead Sciences, Foster City, California, U.S.A.) for the equivalent of $400 for a month's supply. The prices are set in local currency equivalent, and with the devaluation of local currency, the current prices in US $ have decreased by 50%.

The agreements signed with the international pharmaceutical manufacturers of the original brands of the DAAs did not preclude the MOH and other official bodies from contracting with other companies to manufacture the drug locally. The local production of DAAs and the support given to generic production led to price competition and reduction in the Egyptian market.

With the first introduction of DAAs in Egypt, the initial administrative problem was organizing and streamlining patient evaluation, prioritization and treatment in the then-available 26 specialized centres. The NCCVH estimated that there were more than 750 000 patients diagnosed and waiting for the new medications (150 000 who had failed previous treatment with interferon and ribavirin over the previous years,

300 000-500 000 patients who were "not fit" for interferon therapy and around 150 000 who were previously diagnosed and preferred not to be treated with interferon). The initial demand and anticipated numbers were beyond the capacity of the centres. This necessitated a novel administration solution that was custom-developed for the first time in the healthcare setting in Egypt. The Ministry of State for Administrative Development developed a web-based online registration system website (www.nccvh.org.eg) once the first DAA was registered in Egypt. The system has an appropriate bandwidth that withstands the highest possible submissions per second. This portal was designed for registration of patients with HCV and scheduling appointments at the treatment centres. Inputs from patients' registry include their national ID, residence and a simple question for validation. Daily workload and appointments were set according to each centre's capacity. Patients' appointments were automatically set to the first time available in the treatment centre nearest to their residence. Scheduled lists were seen online at the treatment centres and included patients' national ID data.

With the initial wave of patient registration (more than 300 000 registered to be evaluated during the first week), wait times for first appointments reached 6 months or more in some centres (depending on the prevalence in the area and the centre capacity). This eased off with the opening of new centres and with treatment of the patients on the wait list. Eventually, by mid-2016, there is no wait time for the first appointment in any of the centres, and patients are evaluated on the same week of registration all-over Egypt.

The Ministry of Communication provided easy access for the appointment and reservation portal and offered mobile phone messaging service via SMS (in addition to the web-based service) for notification about appointment dates and its changes when needed. On the first day, the portal was launched, and 103 000 patients registered and were scheduled for their first visits. By the end of November 2016, around 1 500 000 patients registered and received appointments through the web-based system.

Helplines are available to answer patients' queries and receive complaints, if any. This patient support service provides sufficient information to make appointments and treatment decisions that best suit patients' lifestyles, occupational and social responsibilities, personal needs and preferences.

The viral hepatitis-specialized treatment centres are operating and treating patients through a financial programme that depends on "the governmental support funds" directed to those who do not have national insurance coverage through the HIO. This ensures full reimbursement for laboratory tests and treatment course expenses. During the past 2 years and since the introduction of DAAs to the hepatitis treatment protocol in Egypt, the Egyptian Government spent around 2.8 billion L.E. (350 million US dollars) for HCV national treatment programme. Almost 88% of treated patients were totally sponsored by the government (29% through the HIO and 56% through governmental support funds). The remaining 12% of patients were treated out of pocket at the reduced prices.

A series of programmes supported by the NCCVH followed including screening of high-risk population groups for early detection of hepatocellular carcinoma according to a timely plan, a programme to control HBV infection, in addition to a programme directed towards treatment of children with chronic HCV infection. The latter was implemented and financially endorsed through an NGO (the Egyptian Liver Care Society) within paediatric university hospital facilities. The NCCVH supervised the programme and the training and contributed to the advisory board with expert paediatric hepatologists.

6 | JOURNEY OF PATIENTS WITH CHRONIC HEPATITIS C VIRUS ACROSS THE MODEL OF CARE IN EGYPT

The patient first visits the website and registers providing the basic information needed according to his national ID. Following registration, the patient receives a reply on the same site with the scheduled time and place for his initial visit. The patient prints the feedback page and brings it to the appointment.

The print out includes the first visit date and location of the treatment centre corresponding to the patient's residence. It also includes instructions as for the required documents and list of laboratory investigations that are required for the evaluation. If these are available, the patient is expected to bring them to the visit. Alternatively, the patient may request that all investigations be performed at the expense of the state through the programme.

The initial assessment of a patient with chronic hepatitis C includes background information, medical history, transmission risks assessment, family history, a full clinical examination and evaluation of disease progression. The patient is informed about the treatment financial alternatives: whether governmental subsidy on the expense of the state, health insurance organization, contracts (for corporate sponsorship) or out-of-pocket (cash payment at reduced prices). No alternative leads to preferential treatment decision or shorter wait time till initiation of therapy.

Pre-treatment counselling is conducted in person in respect of the patient's emotional, social and psychological status. The patient is given ample time for a detailed discussion of treatment options and provides a written consent to use the outcome of his/her treatment for statistical analysis of the programme results. Physicians provide clear descriptions of the process of treatment and the meaning of test results. This counselling also addresses issues concerning confidentiality of test results. In addition, patients are referred to additional support services to make an informed decision about testing and treatment. Patients' assessment is summarized in Figure 1.

The specialized HCV treatment centres are supported by consultants in nephrology, rheumatology and endocrinology for consultation about extra-hepatic manifestations of HCV and cryoglobulinemia, a dietician for weight control, in addition to a psychiatrist, dermatologist and ophthalmologist for patient support and management of adverse events of treatment. The patient concomitant medications are carefully reviewed with clinical pharmacist for possible drug interactions and alternative therapies.

With the start of treatment, patients are informed about the treatment plan, duration of treatment, adverse events and the follow-up schedule. With the introduction of the DAAs, patients are only required to attend the HCV medical centres on monthly basis for

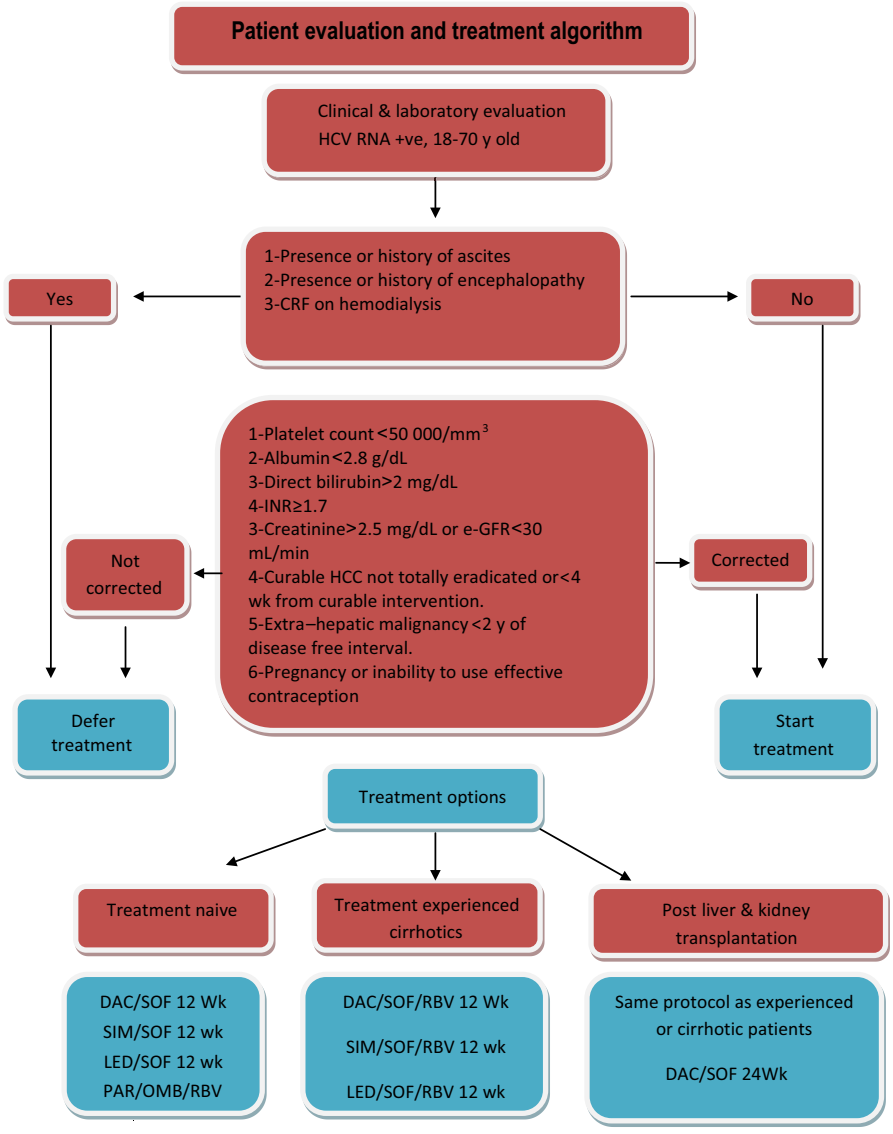

FIGURE 1 Journey of chronic hepatitis C virus (HCV) patients through the Egyptian HCV model of care. DAC, daclatasvir; SIM, simeprevir; LED, ledipasvir; SOF, sofosbuvir, RBV, ribavirin; PAR, paritaprevir; OMB, ombitasvir; RBV, ribavirin

clinical follow-up, laboratory tests and refill of their medication. They are required to return after completion of the course of treatment for evaluation of sustained virological response (SVR) according to the treatment protocol.

At the end of treatment, patients are informed and cautioned about prevention of HCV re-infection and advised for the importance of HBV vaccination. Cirrhotic patients are regularly monitored following treatment for detection of complications of cirrhosis or HCC, and they have liver tests, ultrasonography and alpha fetoprotein carried out every 6 months.

One of the major challenges following the introduction of DAAs was the failure of a significant number of patients (approximately 40%) to return for evaluation of SVR. Patients were motivated to come back 12-week post-therapy for clinical and laboratory results' follow-up through issuing a certificate of "cure from hepatitis C" for patients who remain HCV-RNA negative at 12 weeks after end of therapy. Patients who relapse are retreated according to the guidelines and protocols of managing treatment failures.

7 | PREVENTION

Prevention activities before 2011 were limited to awareness and education campaigns to university students (that reached close to 100 000 university undergraduates in different areas), and a vaccination campaign for hepatitis B that reached 30 000 persons, and limited media awareness campaigns. Acknowledging the urgent need to stop the ongoing transmissions of HCV, the NCCVH (representing the MOH) sought technical support from global partners in 2011 to develop a new action plan that addresses all components for control of viral hepatitis. The action plan addressed all aspects of viral hepatitis prevention and control: disease surveillance; infection control and injection safety; blood safety; vaccination; information, education and communication; screening, care and treatment; research; and governance. Experts from Egypt's multisectoral healthcare system for each component in addition to the World Health Organization (WHO), US Centre for Disease Control and Prevention (US-CDC) and the Pasteur Institute, Paris, launched an action plan for 2014-2018. This was

followed by the WHO selecting Egypt as one of the three countries to be supported for the global injection safety programme and celebrating the global world hepatitis day in 2015 in Egypt. The plan led to updating guidelines for infection control and blood safety, training programmes in infection control for physicians and undergraduate students, assessment of injection safety and blood safety, introduction of the HBV vaccine birth dose, a nationwide media awareness campaign and reallocation of resources to support prevention activities.

It is noteworthy that a programme for control of HBV was implemented providing subsidized HBV antiviral treatment through selected treatment centres and vaccinating all HCV-infected patients against hepatitis B.

Patients with HCV face significant discrimination within the community, and that can occur also within the healthcare settings. Calling for a legalization that prohibits discrimination against HCV-infected patients was addressed by the NCCVH in the National Council. It invited discussions to consider it illegal to discriminate against people on the basis of disability caused by an infectious disease, except where discrimination is necessary to protect public health. Similar laws exist in the UK and USA. People with hepatitis C are entitled to receive the same level of access to medical treatment as other members of the community.

8 | SUMMARY AND CONCLUSIONS

The HCV sustainable MOC in Egypt is considered a successful disease control programme serving up to 6 million patients. This model provides access to all HCV-infected individuals and an action plan and strategy for prevention of new infections. This control programme aims at elimination of HCV in Egypt in accordance with the WHO and global targets.

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