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SIMPLIFICATION OF THE VIRAL HEPATITIS CASCADE OF CARE IS REQUIRED TO REACH THE WHO 2030 ELIMINATION GOALS

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ABSTRACT

Hepatitis B virus (HBV) and hepatitis C virus (HCV) affect more than 320 million people globally. Elimination of HBV and HCV will, therefore, produce substantial public health and economic benefits. In many countries the national hepatitis response is either still in the early stages, or more mature, but with emerging challenges in case finding to identify and treat the remaining infected persons. Simplification is imperative as progress on attainment of the 2030 WHO service delivery target of 90% testing and 80% treatment coverage, is currently less than 20%. During the sixth International Viral Hepatitis Elimination Meeting (IVHEM), 22-23 November 2019, Amsterdam, the Netherlands, an expert panel of clinicians, virologists and public health specialists discussed the challenges in achieving elimination and the role of simplification at all steps along the care cascade.

INTRODUCTION

It is estimated that around 257 million people have chronic hepatitis B virus (HBV) and in 2015 accounted for 887,000 deaths^{1,2}. Additionally, an estimated 71 million persons are living with chronic hepatitis C virus (HCV) and there were 399,000 deaths in 2015². Elimination of HBV and HCV will, therefore, produce substantial public health and economic benefits. In 2016, the World Health Organization (WHO) global health sector strategy on viral hepatitis set global targets and priority actions for countries to achieve the goal of elimination of HBV and HCV as a public health treat by 2030². This was defined as a 90% reduction in the incidence of new chronic infections and a 65% reduction in liver-related deaths.

Considerable progress has been made towards achieving elimination of new HBV infections through scale-up of universal infant hepatitis B immunisation, which has been highly effective in reducing new HBV infections in children. The global coverage for the three-dose series of HBV vaccine in infancy in 2016 was estimated to be 84% (compared with 1% in 1990). However, there has been less progress in achieving goals morbidity and mortality due to chronic liver disease, through scale-up of testing and treatment. In 2015, less than 10% of HBV infected persons and 20% of HCV infected had been diagnosed, and less than 10% had been treated. Despite the enthusiasm and considerable progress to meet the WHO goals, few countries are on track to achieve elimination³.

In the past few years, the International Viral Hepatitis Elimination Meeting (IVHEM) has focused on various barriers and gaps in achieving hepatitis elimination goals. Topics extensively discussed have included the lack of epidemiological data to guide countries elimination efforts, the failure to include children in elimination plans, and the neglect of HBV treatment scale-up compared to HCV, and addressing specific barriers on linkage to care such as a lack of prioritisation of hepatitis, access to hepatitis care, and treatment outside tertiary facilities^{4,5}. Experts identified potential strategies for issues such as finding the 'missing' millions and specific interventions to improving linkage to care⁴. Most importantly, the positive return on investment in elimination of viral hepatitis has been extensively stressed^{4,6}. During the sixth IVHEM meeting, held on 22-23 November 2019 in Amsterdam, the Netherlands, the focus was on simplification across the cascade of care.

SIMPLIFICATION OF THE CASCADE OF CARE IS REQUIRED TO OBTAIN THE WHO 2030 ELIMINATION GOALS

As of the end of 2019, it is estimated that around 5 million persons had been treated for HCV infection. As many people including clinicians have the mistaken notion most patients with HCV are cured, treatment rates have declined in some high-income countries. However, the majority of treated patients are in a few champion countries, and particularly Egypt which has established the world's largest HCV testing and treatment program. In other countries, the national hepatitis response is either still in the early stages, or more mature, but with emerging challenges in case finding to identify and treat the remaining infected persons.

Simplification is imperative as progress on attainment of the 2030 WHO service delivery target of 90% testing and 80% treatment coverage is currently less than 20%². Several organizations have pledged a call for action to improve the uptake of testing that includes key good practice principles of simplified service delivery highlighted in the 2018 updated WHO guidelines for the care and treatment of persons with HCV infection⁷. These include decentralization of testing and treatment, integration of HCV care into other existing services such as HIV/ART clinics or harm-reduction services, and task-sharing to non-specialists.

As only 10% of HBV infected patients are diagnosed simplification is highly needed. In order to reduce new infections prevention strategies, including vaccination or harm reduction should be used to their full potential. Moreover, health systems should be strengthened to stop iatrogenic transmission. Apart from the technical solutions other elements required for both HBV and HCV to obtain elimination, the engagement of civil society, the government, international organisations, and funding should be included.

PREVENTION

HBV prevention in early life is important in avoiding chronic HBV infection with a higher chance of liver cancer and subsequently mortality^{15,16}. The best ways to prevent ongoing HBV transmission is by administration of the birth dose (vertical transmission) or infant immunization (horizontal transmission). Financial support is key in providing vaccines as a prevention strategy for low income countries. HCV is a major concern among persons who inject drugs (PWIDs). Global HCV prevalence among PWIDs is approximately 60% but varies per region. Therefore, epidemiological knowledge is key in strategy planning. Medication assisted therapy combined with syringe service programs have proven to be excellent interventions in reducing HCV transmission with over 70%¹⁷. HCV treatment of PWIDs further reduces transmission risks. Capacity is needed to assure equitable access to these interventions and operational research can accelerate progress toward the elimination goals.

GAVI, the vaccine alliance, has supported HBV vaccination among infants by providing funding to GAVI eligible countries. This resulted in the implementation of combination vaccines among infants in 73 countries and a global 84% coverage of the triple-dose vaccine. Due to the integration of HBV, in the already existing combination vaccines, vaccine coverage has increased. Overall the implementation of HBV vaccines resulted in a decrease in prevalence from 4.7% in pre-vaccine era to 1.3% in 2015². Unfortunately, the global birth dose coverage is low at 43% and lower at 4% in African countries. This is the result of the many home births on this continent, which is a challenge for implementation and delivering of the birth dose. Moreover, the follow-up of administering all three doses is hard as individuals are not engaged in care. High-income countries face a different problem with vaccine coverage due to an upcoming group of anti-vaxxers. Obtaining good successes with the birth-dose requires strategic planning. GAVI will start supporting the birth dose from 2021 onwards in GAVI eligible countries.

China was one of the countries with a high HBV prevalence, which received GAVI support for evaluation of the national HBV immunization program. Combined with governmental support they have accelerated HBV vaccine integration into the Expanded Program of Immunization and while also improving immunization injection safety. Key elements in this model were education of the community and providers, training of health care workers, data to monitor implementation, and creating incentives for hospital deliveries by establishing more birth clinics and providing financial benefit for the mothers.

DIAGNOSIS

The most important step in strategical monitoring and testing is defining the epidemic. A generalized epidemic needs a different approach than a more focussed epidemic. In a more focussed epidemic, micro-elimination is feasible and will eventually result in macro-elimination. Regardless of the type of epidemic, monitoring and testing programs should be integrated in already existing prevention, care, and treatment services. In that way, the functionality of the existing facilities is maximized. Furthermore, people should be engaged to get tested.

Case-finding for both hepatitis B and C is still a major challenge in many countries. In terms of who to test, the 2017 WHO testing guidelines, WHO recommended focussed testing in the most affected populations (PWIDs, people in prisons, men who have sex with men (MSM), sex workers, HIV-infected, tattoos, transfusions, some migrant populations from endemic countries, some indigenous populations, children of HBV/HCV +ve mothers), as well as those with a clinical suspicion of chronic viral hepatitis, family members/children, and sexual partners (HBV), and healthcare workers. In addition, WHO recommends consideration of general population testing, in settings with $\geq 2\%$ or $\geq 5\%$ (intermediate/high) HBsAg or HCV Ab prevalence, and routine antenatal clinic testing for HBV. Building on these recommendations, a framework has been developed for countries to use for an initial phase of testing scale-up focussing on well-defined higher risk populations, such as prisoners, HIV-infected, injecting drug users, etc.)¹⁴. Such testing can be implemented through integrated testing in HIV or other existing harm-reduction services.

The next phase might expand testing in the community, with prioritisation based on criteria as people who received a blood transfusion or certain age-groups with a higher prevalence due to past exposures. The 2017 WHO testing guidelines also recommend strengthening the linkage from testing to treatment by integrating testing at harm reduction sites, use of rapid diagnostic tests (RDT), and reflex sample collection for viral load following a positive RDT, and involvement of peer workers.

The reasons for inadequate testing are many. Most countries lack policies or programs to provide testing to populations at risk. Persons might not have regular access to a health clinical provider or other test provider. Patients can have reluctance to get tested because of concerns of stigma of risk-behaviour or of a hepatitis diagnosis. Easily accessible self-tests can be a good solution. Moreover, the testing algorithm should be simplified and standardized. This was more straightforward for the HCV algorithm where the removal of additional steps such as pre-treatment genotyping, liver biopsy, and on treatment viral load monitoring reduced the number of patient visits required.

Moreover, the capacity to undertake immediate sample collection or reflex lab testing for viral load following a positive HCV antibody test provides a further opportunity to reduce need for a return visit for viral load sample collection. For HCV diagnosis, ideally a one-step point-of-care (POC) test would greatly simplify testing reducing the time until the diagnosis and number of patients falling out of the care cascade⁸. Simplifying the HBV algorithm is, however, much more complex as the requirement for treatment cannot be determined by a single visit. After diagnosis, the stage of liver disease can be assessed with non-invasive methods such as a fibro scan or using the APRI score. Preferably, a pre-treatment work-up is minimized followed by a clear indication for therapy or a simple therapy regimen.

TREATMENT

Treatment is recommended for all persons with current HCV infection and HCV therapeutic regimens are relatively straightforward and curative. HBV guidelines are complicated with multiple tests needed for decisions when to start simple but long-term therapy to suppress HBV replication decreasing mortality risk. As a result, HCV care can be readily moved to a primary care setting⁹. For HBV, this move is also possible with training of primary care clinicians to determine when to start HBV therapy and how to monitor long-term therapy. Currently, the criteria for treatment initiation involve the use of both the HBV DNA level above a threshold (varying from >2000 IU/ml to above $20,000$ IU/ml) and presence of raised liver enzymes.

In all guidelines, the presence of cirrhosis is an indication for immediate treatment regardless of liver enzymes or HBV DNA level. It is recognised that this additional level of assessment is likely to result in many patients not completing a full treatment assessment and therefore failing to access therapy. There is an active debate about how access to HBV treatment can be further expanded by simplifying this initial assessment for treatment eligibility, and in particular lowering the HBV DNA threshold for treatment initiation. The use of existing care infrastructure such as HIV/ART clinic or harm reduction programs that are already providing opioid substitution therapy and other services for PWIDs is another important element of simplification.

THE COMMUNITY'S ROLE IN SIMPLIFICATION

Civil society and the affected patient groups play a crucial role in developing and implementing simplified care pathways as they bring a unique insight into the needs of patients and perspectives of end-user of services. Community involvement may also lead to a greater uptake of services along the cascade and better patient outcomes overall. Stigma is a major topic where the community can advise and ensure that patients are feeling heard and understood. Stigma either perceived (based on previous negative encounters) or experienced by patients seeking care, may make it less likely that they will attend key assessment visits at clinics for treatment initiation, or follow-up visits to assess treatment response.

The use of RDT for HCV antibody or HBsAG serological tests with results available in 15 minutes and POC viral load instruments, such as the GeneXpert, can overcome the inconvenience of multiple clinical visits especially for marginalized populations. Another community idea is the use of medication dispensers to avoid feeling stigmatized when visiting a pharmacist.

Gaining more insight into the key populations affected is important in establishing sustainable HCV and HBV elimination plans as the broader social and health requirements should be considered. Homeless people might, for example, be less interested in receiving HCV therapy but more in a structural change that improves housing. Combining HCV care with harm reduction and other services made available in response to the opioid epidemic increases the feasibility of a sustainable HCV prevention program.

In one of the HCV programs in British Columbia, patients who self-report or test positive for HCV antibodies can immediately consult with an on-site healthcare provider and book a follow-up appointment at a multidisciplinary care clinic¹¹. Not only are the medical issues addressed here but also the psychological, social, and addiction-related needs. This method is shown to be highly effective in obtaining people in care and is also associated with a reduction in opioid-related deaths and rates of recurrent HCV viremia¹¹. Learning to approach populations differently, decentralize care to more accessible settings, and provide multidisciplinary care can be beneficial to improve patient care and reaching elimination.

SUCCESSFUL MODELS FOR CARE

Georgia has a national HCV elimination program since April 2015. This program includes nationwide HCV screening, active case finding, and linkage to care. HCV screening is integrated with HIV and TB screening to combine efforts. Additionally, they used a decentralized approach. To tackle the financial barrier for patients to receive HCV treatment, all treatment is free of charge. Another challenge is still the scarcity of treatment centres in rural areas. Nevertheless, Georgia has made substantial progress towards eliminating HCV with over 50% of persons with chronic HCV infection diagnosed, most of whom have initiated treatment and high cure rates are being achieved. Integrated, decentralized HCV treatment has successfully improved linkage to care¹⁸.

Egypt did a great job with reducing the HCV prevalence in their country and their approach is a great example for other countries with limited resources. Their HCV program has been highly sustainable due to presidential support. In addition, most of the country was involved in the elimination program, including non-governmental organisations, the ministry, and army. To gain community awareness, a website was established, and text messages were sent to all citizens. Moreover, people could use the hotline to set up an appointment for testing. A successfully used model was a community-based educate, test-and treat project

established by the Egyptian Liver Research Institute and Hospital and out rolled in 73 villages across Egypt¹⁹. In this model, the community was mobilized by a network of village promoters who supported the campaign and raised fund in the community. Awareness was created by education and dissemination of messages through public events, promotional materials, and house-to-house visits. People were offered an “all-in one day model” including testing with HCV antibodies and HBsAg RDT with HCV PCR or HBV DNA confirmation in case of positivity¹⁹. As the price of diagnostics is often a barrier, mass purchases prices were negotiated to lower the overall price of testing. The majority of HCV screening occurred in hospital settings and around 10% in other facilities which included mobile teams. For marginalized populations, such as migrants, special screening programs were in place so this population would be reached. All teams were provided with a tablet to register screening information into a centralized system. This information was used for a verification workforce to establish reports. It is a lessons learned that a sustainable HCV elimination program includes awareness for the issue in which the media can provide major assistance.

Uganda focussed on plans for both HBV and HCV elimination. There is a prioritization of HBV due to the high level political commitment at a presidential level. Furthermore, the African minister supported the treatment of 1 million HCV infected individuals. Uganda has a large population of 41 million people with a limited number of doctors (ratio 1: 25,725). The HBV prevalence is around 4.3%, but the HCV prevalence remains unclear (estimated at 1-2%). The program included adult mass testing and vaccination in areas with high HBV prevalence. Additionally, childhood immunization is supported, however the introduction of the birth dose is needed. The country made great progress with increasing regional advocacy among policy makers and an increased population awareness regarding the HBV burden. Moreover, there is a widespread provision of RDT kits to the designated districts and HBV samples are transported leveraging on the already existing HIV systems. They have organized a first hepatitis summit which brought many stakeholders and policy makers together. To move forward, more engagement from the community is needed, advocacy must be strengthened, and screening tests should become more affordable. The latter is a challenge for both HCV and HBV as diagnostic tests are often expensive. Additionally, HBV follow-up is measured by ALT levels which individuals must pay for themselves. Another challenge is the lack of data as there is no data collection at a district or national level. Importantly, attention should be given to female patients to reduce MTC transmission²⁰.

Mongolia has the highest rate of liver cancer mortality in the world related to a high prevalence of both hepatitis B (11.1%) and C (8.5%)^{1,21}. Additionally, 60% of HBsAg positive persons are also positive for Hepatitis Delta virus, which is associated with more rapid progression²². A viral hepatitis elimination and control program was established. This plan resulted in a reduction of costs for diagnostics and eventually in fully subsidized testing programs. Additionally, almost 100% of HCV therapy costs are now being covered through national health insurance. Key challenges identified include a lack of access to prompt viral load confirmatory testing and treatment for those in the rural areas and the need to travel long distances to the hospital treatment sites in the major cities. Although testing is undertaken at the primary care sites, there have been recent discussions about expanding capacity to deliver treatment at these primary care facilities, under the supervision and with support from medical doctors at secondary and tertiary care facilities.

In 2005, Pakistan accounted for 2.5% of people being infected with HBV (4 million) and 5% with HCV (8 million) from which 2% were children. Most HCV infections have been attributed to exposures through unsafe injection practices, inadequate screening of blood products, and inadequate infection control practices in health care settings. Recent modelling work has shown that the plan to eliminate HCV in Pakistan will require reduction in all risk factors by 50% and active one-time screening of the whole population and linkage to care and treatment of >90%. The investment in proactive testing and treating combined with prevention is predicted to yield profitability within three years. To reduce risk factors, they have closed all private blood banks as screening was not properly provided. Unsafe injections are being tackled by locally producing auto disabling syringes. Currently, fourteen hospitals are used as patient friendly and safe model hospitals. The HCV model of care consists of public and private partnerships. Most care revolves around the District Headquarter Hospitals (DHQ), which mostly have fully automated HCV RNA machines. In basic health units, private doctors and private hospitals shall screen actively and passively using tests supplied by the government. Positive patients are then referred to the DHQ. The HCV cascade of care is simplified by skipping genotyping and fibro scans and patients receive immediate generic DAAs. In the slums, the community health workers (CHWs) have a great role in identifying new HCV infections. They are often selected from the same slums and go door-to-door daily to screen high-risk individuals. Using CHWs from the same community results in trust and engagement in the program. Rapid HCV testing is performed, and HCV positive patients are referred to a health facility located in the slums. This same day test and treat model decreases the drop out and is highly effective. All screening, testing, and treatment is free for all patients through the project. Data is collected in an excel sheet and is uploaded in a cloud, forming a robust information system, which can monitor progress and identify gaps.

Iceland has a population of approximately 300,000 people with a 0.3% HCV prevalence mainly focussed among PWIDs. In January 2016, they launched The Treatment as Prevention for Hepatitis C (TraP HepC) programme, offering treatment with DAAs to all infected individuals. The project is organized with several collaborations (infectious disease, addiction medicine, hepatology, and multiple other stakeholders) and nurses play a key role in the elimination efforts. Nurses provide counselling and improve adherence by providing advice, pill boxes, and phone messages, which lowers drop-out rates specifically seen among PWIDs. Patients can move freely from one place to another since there is an electronic program monitoring them over all the systems. Patients who discontinue treatment and remain viraemic as well as reinfected patients are reengaged in care and offered retreatment. Currently, 95% of patients in Iceland were initiated on therapy. Thus, several challenges occurred which learned that harm reduction must be strengthened, immediate retreatment of reinfections of active users is of importance, and that an increase of PWIDs results in an increase in homelessness and therefore political support is needed. Nevertheless, the TraP HepC programme showed that a flexible multidisciplinary approach with adherence support, and prompt treatment of reinfections has been highly successfully among PWIDs in Iceland.

CONCLUSION

Simplification of the care cascade is urgently needed to increase the number of diagnoses, linkage to care, people on therapy, and people cured with lower costs and is critical to reach the WHO elimination targets. The tools to simplify are largely available, however, these are not used to their full potential. For both diseases, community involvement can help by advocating for increasing political support, assist in the establishment of sustainable elimination plans, and increase access to marginalized populations.

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