National Strategy for the

Elimination of Hepatitis C Virus

OFFICE OF THE DEPUTY PRIME MINISTER
MINISTRY FOR HEALTH

A NATIONAL STRATEGY FOR THE ELIMINATION OF HEPATITIS C VIRUS AS A PUBLIC HEALTH THREAT IN THE MALTESE ISLANDS 2018-2025

OFFICE OF THE DEPUTY PRIME MINISTER
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FOREWORD

I am pleased to launch this strategy to eliminate Hepatitis C as a public health threat in Malta. This follows on my promise last November to meet WHO targets for elimination when, on behalf of the Maltese Government and people I signed the São Paulo Declaration on Viral Hepatitis at the World Hepatitis Summit 2017.

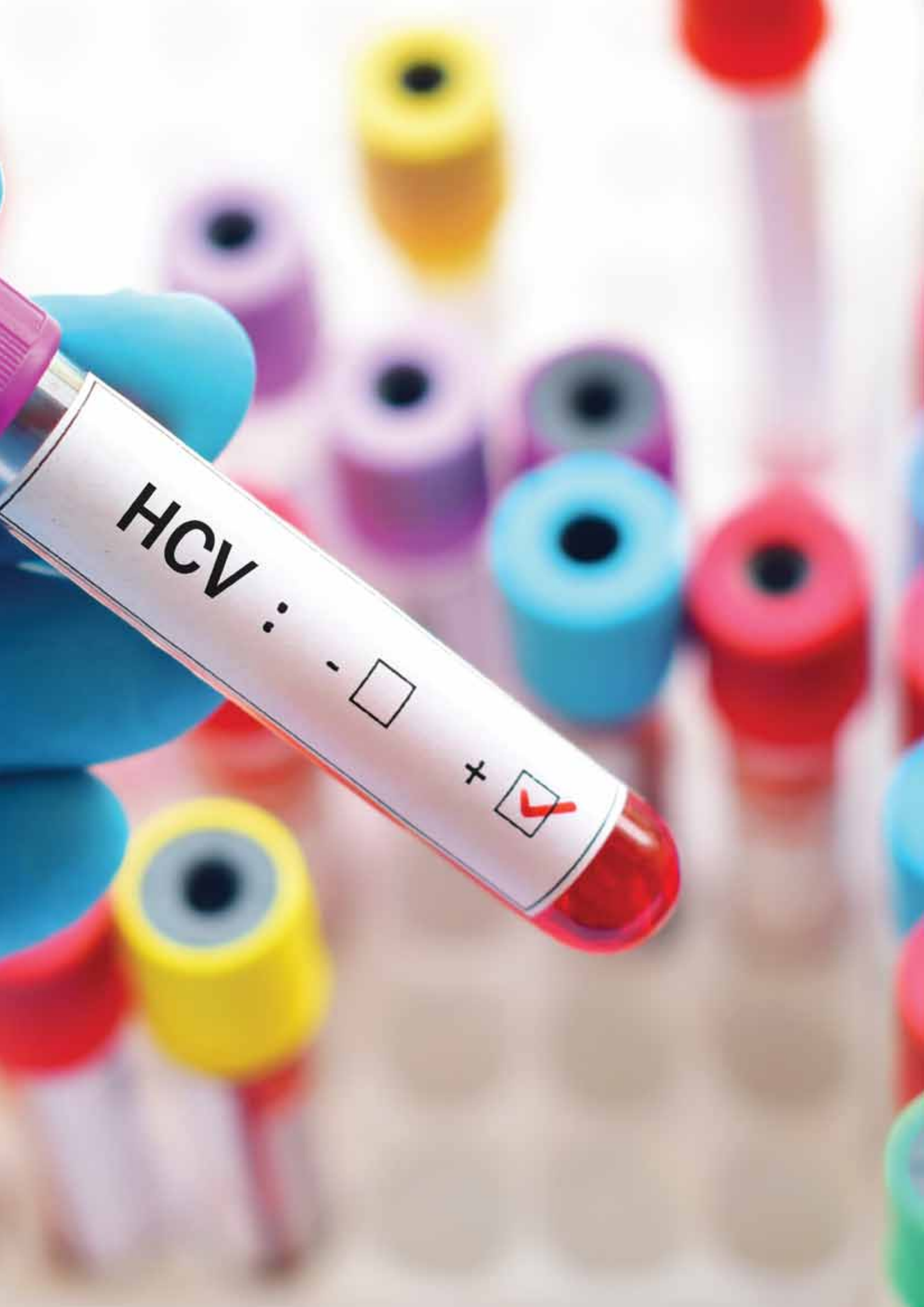
I am confident that Malta will be one of the first countries in the world to achieve this target. Through a combination of prevention, screening, and treatment, we will be aiming to reach all those who might be infected, and offer them curative therapy.

Over 1,000 persons in Malta have Hepatitis C who, so far, have had little hope of cure. Treatments were not very effective, complicated, and involved many side-effects, leading many to go on to have complications such as liver disease and liver cancer, eventually requiring liver transplants. New treatments are now available which are much more effective, and therefore offer a very reasonable possibility of cure for our patients.

Apart from providing these revolutionary medicines, we will also be stepping up prevention and screening efforts to prevent new infections. Mindful of key populations who might be at a higher risk of getting infected, we will be focusing our efforts to make sure no one is left behind.

This strategy represents an investment for health, which will reduce suffering in our society caused by chronic Hepatitis C infection. It is also an investment in the future, since the more successful we are now at curing Hepatitis C, the less we will have new infections and complications in the future.

Chris Fearne
Deputy Prime Minister
Minister for Health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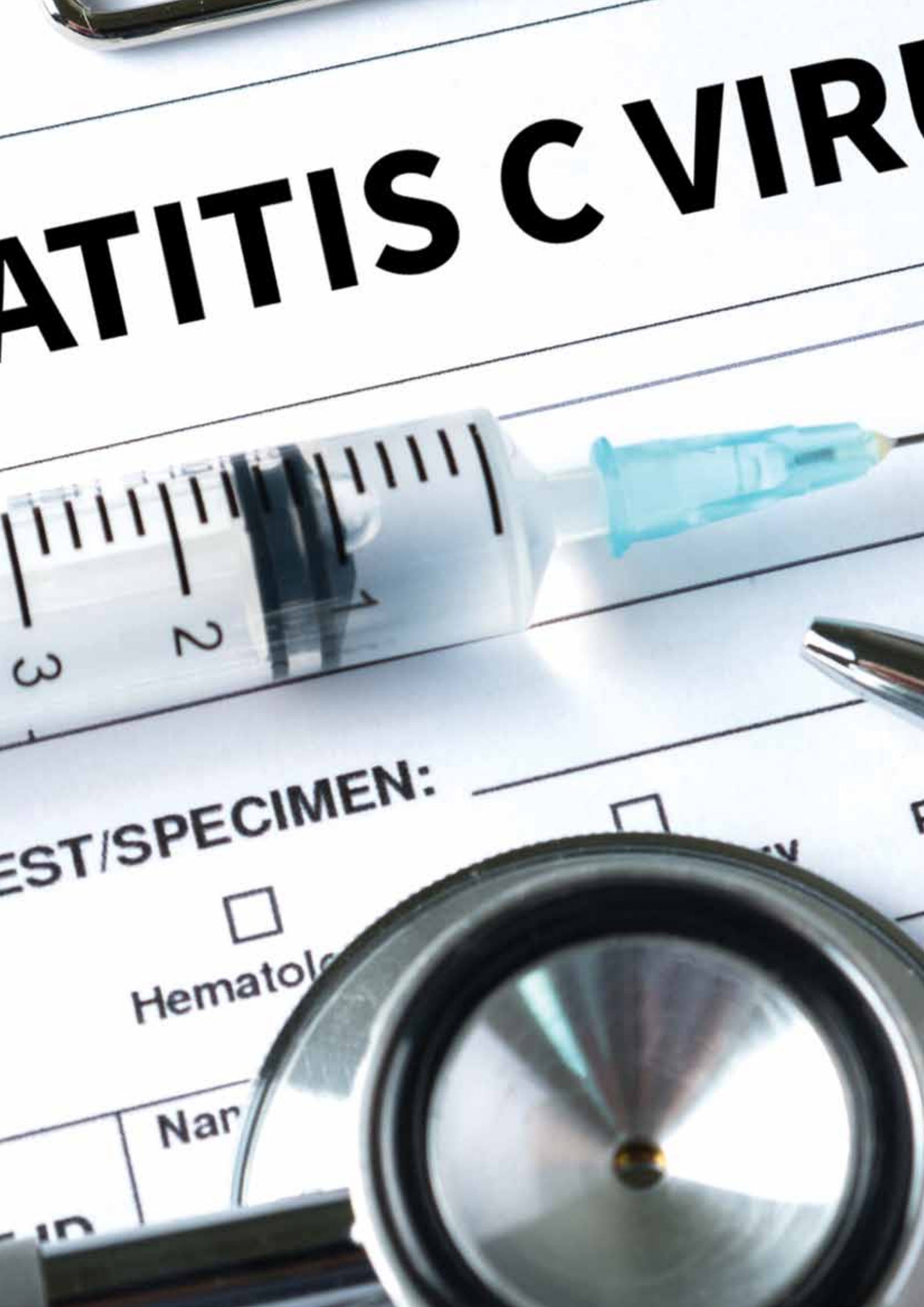
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INTRODUCTION

Hepatitis C is a liver disease caused by the Hepatitis C Virus (HCV). It is one of the most important causes of chronic liver disease worldwide posing a serious public health problem. Whilst some people manage to fight off the virus, the majority end up with a chronic infection which is a serious, lifelong illness unless treated. The risk of cirrhosis of the liver is between 15-30% within 20 years and has a mortality rate of 85% in 1-2 years if left untreated.

Infection with HCV is usually asymptomatic, and hence people go on living their lives not knowing that they are infected, until they develop complications such as liver disease and cancer, with poor survival rates.

HCV is a bloodborne virus, most commonly transmitted:

- during injecting drug use, through the sharing of injection equipment such as syringes and drug solutions
- in health care settings, due to reuse or inadequate sterilization of medical equipment, especially syringes and needles
- in some countries, via transfusion of unscreened blood and blood products HCV can also be transmitted sexually and can be passed from an infected mother to her infant; however, these routes are less common.

There is no vaccine to prevent HCV infection, and until recently it was not possible to cure the disease. Over the past few years however, new treatments have been developed which have a high chance of curing the disease with minimal side-effects and toxicity. By improving prevention efforts and with this new effective treatment, it will be possible to dramatically reduce the number of people infected with HCV, reduce the number of people who get infected, and prevent complications such as liver disease and liver cancer.

Vision

The vision is to reach a state where transmission of HCV is halted in Malta by 2025, and everyone living with HCV has access to safe, affordable and effective prevention, testing, care and treatment services.

By improving prevention efforts and with this new effective treatment, it will be possible to dramatically reduce the number of people infected with HCV

Epidemiology

International

Globally, an estimated 71 million people have chronic hepatitis C infection. In the WHO European Region, around 2% of adults, 15 million people are estimated to be living with the disease. The global burden has been increasing rapidly, and viral hepatitis (including other hepatitis viruses) is a leading cause of death globally with a toll exceeding that of HIV, tuberculosis and malaria.

A significant number of those who are chronically infected will eventually develop cirrhosis and/or liver cancer, and approximately 399 000 people die each year from Hepatitis C worldwide, mostly from cirrhosis and hepatocellular carcinoma.

Local

It is estimated that in Malta there are in the region of 1000 patients currently infected with HCV, 60% of whom are between 30-60 years old. Around 10-15 new cases are notified to the Infectious Disease and Control Unit per year. There might be an element of underreporting however, since the number of positive tests per year at the MDH laboratories is higher than this. In a 9-year span between 2008 and 2016, an average of 105 unique new cases were detected per year. It is important to highlight however, that a proportion of these presumed new cases might have been diagnosed before 2008, and re-tested, which would reduce the incidence calculated in this way.

Only approximately 250 persons with HCV are currently being cared for by hospital specialists, mainly because of them having complications. This is because up to now there was no effective treatment. Once the new treatment is available, referrals to these specialists will need to increase to be able to start treating all persons with HCV, before complications occur.

Policy Context

The strategy is based on a public health approach that is concerned with preventing infection and disease, early diagnosis and treatment, promoting health, improving the quality of life, and prolonging life among the population. It will require simplification and integration of care pathways among all relevant health and non-health services to ensure equitable access. Partnership with civil society and other Ministries will be essential.

The development of new curative treatment has brought Hepatitis C on the global agenda, since there is a real possibility now of eliminating Hepatitis C on a global scale. The new drugs can achieve viral clearance within eight weeks, with minimal side effects or toxicity.

In 2010 and 2014 two World Health Assembly resolutions first mentioned viral hepatitis as a global priority. Subsequently, combating viral hepatitis epidemics was included in the list of communicable diseases which are considered a health challenge critical for development in the 2030 Sustainable Development Goals. The World Health Assembly aligned its targets with the 2030 Agenda for Sustainable Development in 2016 when it adopted the Global Health Sector Strategy (GHSS) on viral hepatitis for the period 2016-2021. The elimination of hepatitis as a public health threat by 2030, namely a 90% reduction in new infections and a cut in mortality of 65% over the 15-year period leading up to 2030, are the core targets which is estimated to result in preventing 2.1 million HCV-associated deaths by 2030.

There is now a growing movement around Hepatitis with patients demanding access to curative treatment, and an increasing number of national plans. WHO has also prepared an action plan for the health sector response to viral hepatitis in the WHO European Region.

Malta has endorsed the São Paulo Declaration on Viral Hepatitis, committing to take a broad and coordinated approach to support implementation of the core interventions outlined in WHO's Global Hepatitis Strategy.

Addressing this epidemic will also impact other health targets such as reducing maternal mortality, reducing mortality from non-communicable diseases, preventing and treating substance use disorders, achieving universal health coverage, access to affordable medicines and vaccines, health financing, and health workforce.

Financial case

Investing in eliminating hepatitis is cheaper than not doing anything since the costs of dealing with the complications of hepatitis such as advanced liver fibrosis and hepatocellular carcinoma are very high. The sofosbuvir/ledipasvir combination to treat hepatitis C genotype 1 patients for example has been shown to be cost-effective compared to prior standard of care in all patient groups considering international costs per QALY thresholds. In many other countries, other cost-effectiveness analyses have shown that due to the very high cure rates, treating persons with HCV early on in the disease will result in cost-savings by preventing expensive complications such as liver cirrhosis, hepatocellular carcinoma and liver transplants, despite the high cost of treatment. Liver transplants alone cost close to €100,000 per patient who need to spend around 5 months in the UK.

If all new cases were to be treated immediately and cured, the incidence and cost of complications will be reduced. Decreasing the incidence will also have the effect of reducing costs of treatment in the future, since fewer people will get infected.

Social determinants of health

Hepatitis C is an example of how social determinants can affect health and wellbeing. Since HCV is transmitted most commonly during injecting drug use, through the sharing of injection equipment, the population most commonly at risk are people who inject drugs. Action needs to be taken to ensure that this population has access to all the necessary screening and treatment, to make sure no one is left behind.

Stigma

Persons infected with viral hepatitis are often ashamed of their condition, due to the fact that hepatitis B and C viruses are commonly acquired through sexual contact or drug use and because liver disease in general is associated with substance use. Since these are infectious, patients fear social rejection if their diagnosis becomes widely known. Furthermore, people with HCV can experience discrimination within the healthcare system, in their workplaces and in the community.

This results in fear of getting tested, and discourages effective prevention strategies to reduce onward transmission or minimise complications from long-term infection. Stigma might result in failure of HCV elimination, and needs to be addressed.

Comorbidities

Hepatitis C is commonly associated with other infectious diseases such as HIV, and non-communicable diseases such as renal impairment and alcoholism. Treatment plans will need to be tailored accordingly to deal with such patients, since different treatment regimens might be required, and patients might have additional medical and non-medical needs.

To deal with Hepatitis C adequately, a comprehensive, integrated and multisectoral approach will be required, encompassing four major areas which include prevention, screening and diagnosis, treatment, and monitoring and governance.

These measures will be addressed through a number of actions which will be implemented by various stakeholders. To ensure implementation, all actions will be monitored and reviewed regularly.

Prevention

Since no vaccination for HCV is available, preventive efforts focus on eliminating all sources of contagion. HCV is a bloodborne virus and the most common modes of infection are through exposure to small quantities of blood. This may happen with drug use with unsterilized or shared injecting equipment, sexual intercourse with a person with HCV, and the transfusion of unscreened blood and blood products. Despite best efforts to reduce the prevalence of persons with HCV, there will always remain a risk of infection, if not to HCV, then to other bloodborne viruses, and hence the following preventive measures which are basic and universal need to continue to be applied and improved over time.

As part of this strategy, measures to prevent the infection or reinfection with HCV include:

- Improving the safety of drug injection practices including safe disposal
- Improving the safety in health care settings
- Improving the safety of blood and blood products
- Reducing infections through sexual contacts
- Reducing infections through tattoos and piercings
- Increasing awareness and developing skills on prevention among key populations

Preventive efforts focus on eliminating all sources of contagion. HCV is a bloodborne virus and the most common modes of infection are through exposure to small quantities of blood.

Screening and diagnosis

Due to the fact that acute HCV infection is usually asymptomatic, few people are diagnosed during the acute phase. In those people who go on to develop chronic HCV infection, the infection is also often undiagnosed because the infection remains asymptomatic until decades after infection when symptoms develop secondary to serious liver damage. Early diagnosis through targeted screening of key populations will ensure early referral and treatment, reducing the chances of onward transmission, and the onset of complications.

The following measures will be implemented to improve the rates of diagnosis:

- Performing contact tracing on all persons with a new diagnosis of HCV

- Targeted screening of key populations
  - Persons who use drugs intravenously or nasally
  - Children born to mothers infected with HCV
  - Persons with HIV
  - Corradino Correction Facility inmates

Treatment

New drugs are available that can cure HCV within 8 weeks with minimal side effects and toxicity. This means that the traditional approach of dealing with complications as they arise can be discarded, while focusing on treating everyone with a diagnosis of HCV with curative intent. This will be particularly effective if all persons with HCV will have access to these medications, and not only those with complications of HCV.

Curing persons with HCV will shrink the pool of HCV in the community, reducing the chances of infection and re-infection, eventually reaching a stage where the number of people who need to be treated will reduce significantly. A significant initial investment is required however, until all persons known to have HCV are treated.

The measures that will be taken to ensure access to treatment for all include:

- Ensuring laboratory and clinic capacity to deal with the surge in new diagnoses and referrals due to screening

- Establishing treatment and care guidelines, plans and protocols to ensure fast linkage to care on diagnosis, and provision of required treatment

- Finding innovative ways of reducing the financial burden of providing treatment
- Engaging a specialist nurse in infectious diseases who will act as a focal point for all persons waiting for treatment, and who will assist in the monitoring and follow-up of those persons undergoing treatment
- Addressing comorbid conditions and common co-infections such as HIV and HBV

Monitoring & Governance

The aim of this strategy is to eliminate HCV infections in Malta. In order to make sure that the abovementioned measures and actions are effectively contributing towards this aim, their impact needs to be monitored.

An internal Action Plan which details all the actions under the different measures has been prepared which lists who needs to do what. These are tied to indicators which will be reviewed regularly to flag any issues. The measures can then be adjusted according to need to ensure that we remain headed towards our goal of eliminating HCV as a public health threat in Malta.

The core indicators that will matter the most are the rate of new HCV infections, and the rate of HCV-related morbidity and mortality, which we aim to bring down as close to zero as possible by 2025.

It is very likely that the number of new diagnoses of HCV infection will rise in the first couple of years due to increase in awareness and screening. Once these people are treated, the number of people with HCV is expected to drop drastically, reducing the number of new infections.

The number of HCV-related morbidity and mortality are expected to decrease after a few years, since the source of the chronic liver disease would have been treated.

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