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## Health Policy

## What China can learn from Malaysia to achieve the goal of “eliminate hepatitis C as a public health threat” by 2030 – a narrative review

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## ABSTRACT

**Background:** To discuss a range of strategic options for China to improve the accessibility of direct antiviral agents (DAAs) as the treatment for hepatitis C.**Methods:** We adopted a narrative review approach for comprehensive comparisons and in-depth analyses of the country context, and barriers of increasing the DAA treatment rate of hepatitis C in Malaysia and China, and how the two countries have been navigating the hepatitis C agenda.**Findings:** Malaysia adopted a series of successful strategies to scale up the diagnosis of hepatitis C and DAA treatment, which have valuable implications for China.**Interpretation:** The potential game-changing strategies for China to adapt from Malaysian experiences range from the stepping-up of political commitment and leadership, enhanced market competition, simplified and decentralized treatment at the strengthened primary care level, integrated healthcare services, coordinated government initiatives, to multi-organizational participation and civil society's active role in raising public awareness, and training of non-specialist physicians. Embarking on scale-up of hepatitis C treatment marks another contribution of China to improve the health of not only the Chinese citizens but also mankind, which is an important component for building healthy Chinese and global communities.**Funding:** No funding supported this study.

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## Research in context

## Evidence before this study

Although the number of people living with hepatitis C virus (HCV) is approximately 8 million and only less than 1.3% of the chronic hepatitis C patients had received treatment, China only took initial steps in response to this public health burden in recent

years. While, Malaysia made DAAs highly accessible in the country mainly by bringing in generic DAAs and staging a clinical trial on a new DAA combination in collaboration with the Drugs for Neglected Diseases initiative (DNDi) and access-oriented pharmaceutical industry partners.

## Added value of this study

The National Work Plan for Elimination of Hepatitis C as a Public Health Threat (2021–2030) of China is due to be launched and starting its implementation in 2021, which is a critical point for China to roll out the diagnosis and treatment of hepatitis C. This paper made comprehensive comparisons and in-depth analyses of

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the country context, and barriers of increasing the DAA treatment rate of hepatitis C in Malaysia and China, and summarized the successful strategies of Malaysia and critical points for China to follow to overcome the barriers.

### *Implications of all the available evidence*

The potential strategies for China to adapt from Malaysia include the stepping-up of political commitment and leadership, multi-organizational participation, enhanced market competition, advocacy and education to raise the public awareness, simplified and decentralized screening, diagnosis and treatment at the primary care level and integrated health services delivery approach.

## **1. Background**

Approximately 58 million people in the world are living with chronic hepatitis C virus (HCV). The epidemic continues to grow in both size and severity. Nearly 1.5 million new HCV infections are reported annually, and more than 290 000 deaths took place yearly due to the long-term complications of the infection, including advanced liver disease, cirrhosis and hepatocellular carcinoma in 2019. Despite its high prevalence and mortality, up until 2019, only 16% (9.4 million) of the HCV-infected individuals had received treatment worldwide [1, 2, 3]. Many factors contributed to the poor accessibility of treatment, including the limited awareness of the illness due to its asymptomatic nature, the lack of funding and infrastructures for large-scale screening and treatment programs, and the high cost and unfavourable safety profile of the conventional interferon-based treatment.

The introduction of the first direct antiviral agent (DAA) in the market in 2013 became a game-changer for hepatitis C treatment, marked the emergence of the highly effective new treatment. The World Health Organization (WHO) and its member states in the World Health Assembly have endorsed the target to eliminate viral hepatitis as a public health threat by 2030, with the aims to diagnose 90% of the HCV infections and treat 80% of those who would benefit from the treatment [4].

Individual countries need to overcome a wide range of challenges to meet such an ambitious public health goal, and improving the accessibility of DAAs is one of them. Ideally, the DAAs introduced under a nationwide hepatitis C program should be pan-genotypic and affordable to both individuals and the government [5]. However, today the efforts made under some national HCV programmes to scale up treatment are stalled, as high prices of DAAs in many countries have been withholding HCV-infected individuals from receiving treatment, especially the vulnerable population.

Malaysia stands out in the middle-income countries, as it successfully expanded hepatitis C treatment through a series of government-led initiatives. However, despite having a much higher disease burden, progress remained slow and only some initial steps have been taken in China to scale up the diagnosis and treatment of hepatitis C. Proactive testing, diagnosis and treatment mainly focus on the high-risk population and most patients were found to be infected with hepatitis C viral only when they progress to liver cirrhosis and hepatocellular carcinoma. This paper is jointly authored by the academicians and healthcare professionals from the two countries, together with the non-governmental organization—the Drugs for Neglected Diseases initiative (DNDi). It compares how Malaysia and China have been navigating the hepatitis C agenda, summarizes the strategies adopted by Malaysia to scale up the DAA treatment, and analyses the implications, challenges and opportunities for China to achieve the goal of elimination of hepatitis C as a public health threat by 2030.

## **2. Search strategy and selection criteria**

References for this policy paper were identified through searches the official websites of the national government agencies and their technical arms, the World Health Organization, and other relevant international and national organizations, including UN-ITAI, Clinton Health Access Initiative (CHAI), Drugs for Neglected Diseases initiative (DNDi), Intellectual Property Watch, Chinese Hepatitis Prevention and Treatment Foundation, From the Desk of the Director-General of Health Malaysia, Malaysia AIDS Council, American Association for the study of liver diseases (AASLD), as well as relevant medias and charities which have been actively involved in promoting access to DAAs, including The Star, NAM. Formal published literature was identified through searches of PubMed based on multiple sources of evidence recommended by authors and their organizations, and references in key papers. Grey literature was identified through solicitation from the authors' own files and their relevant organizations, including highly regarded reports, working documents suggested by peers and internal documents of government and international organizations. Only papers published in English were reviewed. The final reference list was generated on the basis of originality and relevance to the broad scope of this policy paper.

## **3. Overview of the situation of hepatitis C-common grounds and differences between Malaysia and China**

### *3.1. Health system*

Malaysia has a policy of universal health coverage. The government strives to provide subsidized healthcare at minimal charges, centrally administered by the Ministry of Health (MOH) through its federal, state and district offices, the healthcare services are delivered by a public and private two-tiered system at primary, secondary and tertiary levels. The public healthcare system funded through taxation is the main player in the Malaysian health system.

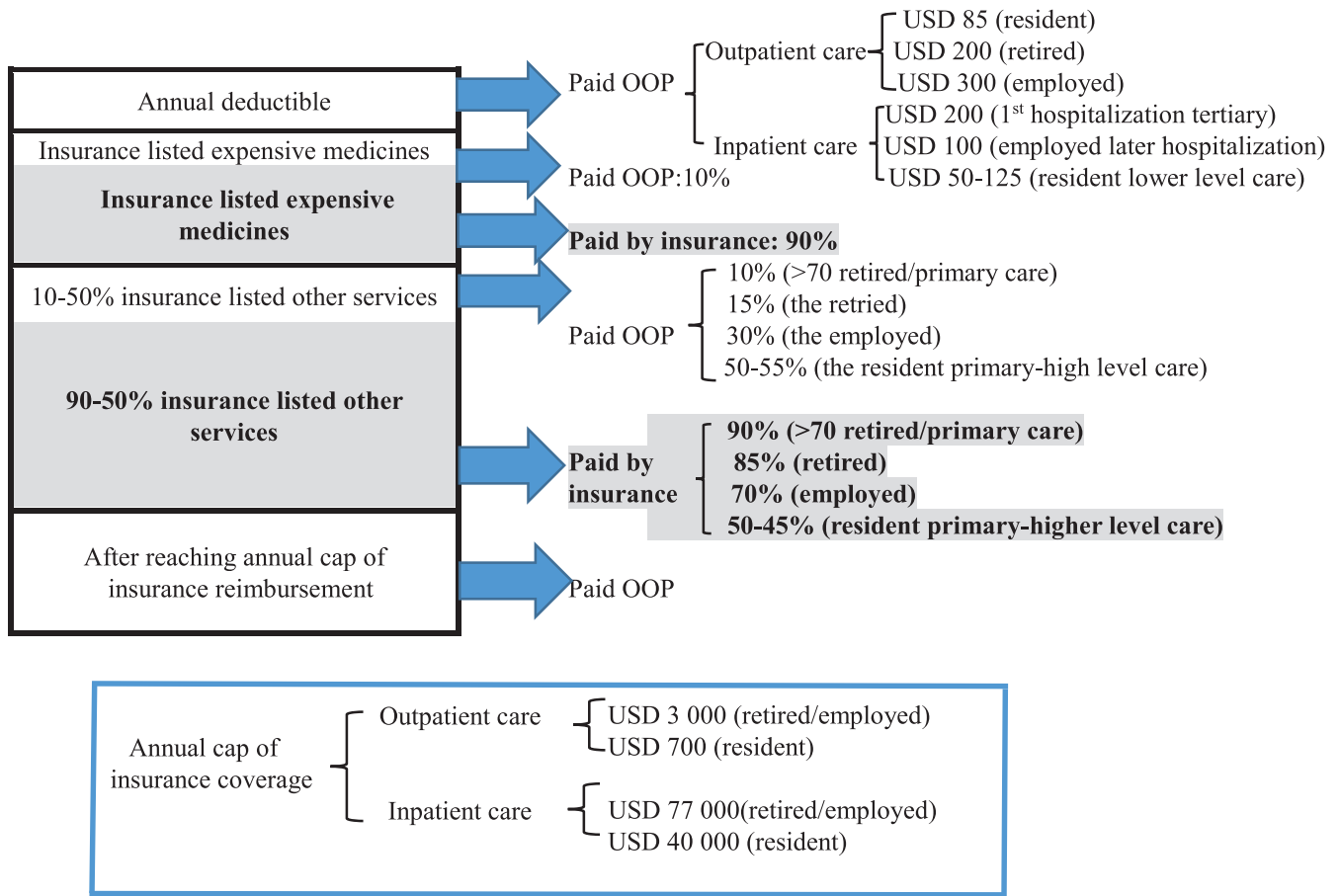
On the other hand, the centralized Chinese healthcare system has been experiencing transformations along with the rapid changes of the country's administrative system and economic policy. China also achieved universal coverage of a public basic health insurance system in 2012. The healthcare system is currently co-funded by the government, the society and individuals. The healthcare services are delivered by three-tiered system with tertiary, secondary and primary care, and the primary healthcare has been continuously strengthened its service delivery capacity through the national health system reforms since 2009.

### *3.2. Disease burden*

Approximately 2.5% of the Malaysian population (384 000 with a range of 272 000 to 443 000) were living with HCV infection [6]. The estimated adult viraemic prevalence of HCV for China is 0.8% (0.2%–1.2%). However, the number of people (adjusted for the adult population) living with hepatitis C in China is approximately 8 859 000 (2 658 000–13 356 000) [7], 20 times higher than that of Malaysia.

### *3.3. Accessibility of DAAs for the roll-out of hepatitis C treatment*

Malaysia used to have access to only patent-protected DAAs. The high cost of patent-protected sofosbuvir, the building block of many DAA combinations, had limited the roll-out of the DAA treatment. Less than 2% of the HCV-infected patients in Malaysia were treated from 2003 to 2017, and less than 600 patients were treated annually before the launch of a national HCV treatment program in



**Note:** “resident” included the non-formally employed population in both urban and rural areas.

**Figure 1.** Outpatient and inpatient benefits packages of patients enrolled in different basic health insurance programs in Beijing 2021.

2018 [8]. As most of them depend on the public health system to obtain free treatment, the high burden of hepatitis C posed a financial challenge to the government.

Due to a similar challenge, the treatment coverage of hepatitis C with DAAs has been low in China. It was estimated that 70% of hepatitis C patients received anti-HCV test only when they showed clinical symptoms of hepatitis C and sought medical advices [9]. Up until 2016, only 18% of the HCV-infected population in China were diagnosed, and only less than 1·3% of the chronic hepatitis C patients had received treatment [10]. Under the Chinese health system, financing of hepatitis C diagnosis and treatment has been integrated into the basic health insurance system. DAAs and combinations launched in the Chinese market since 2017 were either imported from multi-national pharmaceutical companies or developed locally [11, 12]. Before the health insurance coverage, the out-of-pocket (OOP) price of these new products in China was USD 2 800-3 800 [13] for a 3-month treatment course. Three original patent-protected DAAs were included into the basic health insurance scheme in 2019, including sofosbuvir/ledipasvir, elbasvir/grazoprevir and the pan-genotype sofosbuvir/velpatasvir. At the same time, coblopasvir, a locally developed novel DAA was also covered by the health insurance program through price negotiation in 2020. The agreed price under the insurance scheme for a 3-month treatment was US\$ 1 200 to 1 800 [14, 15], which is still too high compared with that of the generics used in Malaysia. Even though more alternative DAA options have been covered by the insurance, the OOP expenditure of a full treatment course after the insurance coverage is still not affordable for the patient with low ability-to-pay, due to both the high prices of the original

patent-protected products and the non-pro-poor benefits packages of the basic health insurance system. The diagnosis cost (around US\$ 40) for screening and confirmation tests are covered by the insurance, while genotype testing (around US\$ 70) is not. Annual deductible, OOP expenditure of expensive medicines, and OOP expenditure after reaching annual cap of insurance reimbursement, all these make the actual insurance coverage less than 50% of the total expenditure. Detailed outpatient and inpatient benefits packages of patients enrolled in different insurance programs in Beijing in 2021 were presented in Figure 1. Different cities set different amounts of annual deductibles and caps of insurance reimbursement, as well as the insurance co-payment based on the scale of the locally pooled insurance funds. A small number of civil servants are entitled to a waiver of deductible and cap of insurance reimbursement. The actual insurance coverage for a patient enrolled in the resident program with a lower insurance reimbursement cap for a 3-month DAA treatment in Tianjin in 2019 was only 45%. At least US\$ 700 to 1 000 had to be paid OOP [16], which is too high relative to the national average disposable income of the Chinese population (US\$ 366 per month in 2019) [17]. High prices of original patent-protected DAAs have limited the overall population-wide access. The affordability of DAA treatment for both the individuals and the government is still one of the key barriers for the low treatment rate.

### 3.4. Intellectual property (IP) barrier

In Malaysia, sofosbuvir, the core of many DAA combinations, was once not widely available due to its high cost. The cost did not

significantly drop following a two-year negotiation by the Ministry of Health Malaysia with the patent holder of sofosbuvir. This was similar to the situation in China, where the cost of sofosbuvir remained high. To overcome the IP barrier, China has an advantage as the local company has successfully developed a generic version of sofosbuvir, unlike Malaysia who had to import generic sofosbuvir from overseas. Most recently, the patent barrier of sofosbuvir was partially unblocked in China through the Patent Re-evaluation Committee of the National Intellectual Property Administration in 2020 [18] following an invalidation procedure initiated by the public health non-governmental-organization I-MAK. At the same time, the first generic sofosbuvir from the local manufacturer was registered by the regulatory authority of China in March 2020. However, the invalidation of sofosbuvir patent was associated with the process of preparation, different combinations and the formulation, etc. While, the patent holder was granted with multiple patent protections for sofosbuvir in China. This means that the generics of sofosbuvir cannot be formally marketed, due to the concerns of the remaining key patent on sofosbuvir pro-drug, which was initially rejected by the National Intellectual Property Administration in 2015 [19]. Furthermore, a re-examination of this decision was made in July 2021 upon Gilead's continuous requests since in 2017, resulting the likelihood of the sofosbuvir patent to be granted with an expiry date of 2028. Access to affordable DAA produced by local companies will likely be hampered if patent for sofosbuvir is to be granted by the Chinese authority.

### 3.5. Other barriers in the health systems

Before 2018, there was no national program to conduct proactive screening and tests and DAA treatment of hepatitis C patients in Malaysia. Patients could access DAAs only from the private sector or through clinical trial participation. Such a situation changed in 2018 when the national hepatitis C program was launched in Malaysia. HCV screening has becoming an increasing public health priority with a national stepwise approach under the central coordination. Such a large-scale screening program required further decentralization of HCV screening and treatment to primary health-care clinics in all states of Malaysia. Building this capacity nationwide required major investments in human resources and training [8].

Barriers to access to treatment are also compounded with many other hurdles in China, most notably the limited health system readiness with a very low rate of proactive screening and diagnosis [20]. The awareness of the disease among the general public has been low, many patients only receive a test after showing clinical symptoms [21]. The knowledge and understanding of the disease of non-specialist physicians, especially at the primary level of care, also becomes a barrier to treatment scale-up [22]. HCV management in China mainly concentrated at tertiary hospitals located in major cities. The screening, diagnosis and treatment algorithm is still complex and the disease needs to be managed by hepatologists and gastroenterologists as per the current treatment guideline [23]. Moreover, there is always an insufficient supply of diagnostic tools (laboratory, fibroscan, echo tomography, etc.) in resource-limited settings. Most importantly, the healthcare services are delivered dominantly by the public tertiary hospitals, which has weak linkages with the secondary and primary care in the health system. HCV patients need to travel far to seek HCV care and often default on their treatment due to socioeconomic challenges. Despite recommendations from the WHO to simplify and decentralize the screening and treatment of HCV, China is still far from integrating proactive HCV screening, diagnosis and treatment into universal health coverage. These are also key barriers that must be addressed even if the DAAs are available and affordable for individuals and the government.

## 4. Strategic responses-success of Malaysia and efforts made in China

### 4.1. Political commitment and leadership in using TRIPS flexibility to allow access to affordable generic DAA

Evidence proves that generic competition is associated with lower medicine prices [24, 25]. The WHO found that the most affordable DAA prices are widely available in countries which allowing generic competition in general [26]. Countries which failed to reduce prices of DAAs through price negotiations or pooled procurement schemes need a stronger political will to improve the access to affordable pan-genotypic DAAs with a policy change, notably by overcoming IP and regulatory barriers. One of the potential strategies is to capitalize on the flexibilities provided in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) [27], as Malaysia did.

Regardless of constant pressure brought by the multi-national pharmaceutical industry and the US government, Malaysia became the first country to invoke the TRIPS and issued a compulsory license (CL) to enable the government-use (public non-commercial use) of sofosbuvir imported from Egypt in September 2017 [28]. This decision prompted the patent holder to add Malaysia to the list of countries given the voluntary licenses which enable Malaysia to also obtain generic DAAs from Indian companies [29]. This meant that the patent holder of sofosbuvir allowed Indian companies to start registering generic sofosbuvir for sale in Malaysia [30]. However, the Malaysian government maintained its decision of using the CL to achieve the lowest possible price between 2017 and 2020, as sofosbuvir is the core of many DAA combinations [31]. By having more options with both compulsory and voluntary license, in about one year, Malaysia has obtained generic versions of sofosbuvir at the cost of US\$ 33-35 per 28-day course [32,33], which were much lower than the cost of US\$ 11 200 reported in 2017 for the original patent-protected sofosbuvir [26,32,33]. The price of imported generic sofosbuvir under the CL in Malaysia is even lower than the price of an Indian product under voluntary license in neighbouring countries [34]. Moreover, daclatasvir is not patent-protected in Malaysia. The combination of generic sofosbuvir, under the CL, and generic daclatasvir brought down the public procurement price from US\$ 11 000 to US\$ 300 per 12-week treatment, leading to a 99.5% reduction in the cost of the treatment for patients living with hepatitis C [35]. This price also has been used as a benchmark in the price setting of DAAs in future tenders. In an increasingly competitive environment created by the presence of more generic products, further reduction in the prices of DAAs in Malaysia is very possible. A nationwide scale-up of the screening, diagnosis and treatment was also made possible following the accessibility of treatment [28].

Different from Malaysia in which the government took the lead of a series of initiatives, the situation in China has been more relatively quiet. Much of the efforts have been made to develop alternative novel DAAs with independent intellectual right. While Malaysia overcame the financial barrier to DAA treatment through the CL, the IP barrier of marketing the generic core DAA to constitute China's locally made pan-genotype DAA combinations is still not fully addressed. The locally developed alternative novel DAAs could only be applied for the treatment of specific genotypes of hepatitis C. Only when they are combined with sofosbuvir, the core DAA, could they be applied as pan-genotype combinations. Without the cheaper generic sofosbuvir, local novel DAAs do not have a cost advantage when competing with the patent-protected original pan-genotype DAA. The last round of national health insurance price negotiation in 2019 proved this concern. During which, the locally developed novel DAA targeting specific genotypes failed in competing with the original patent-protected



pan-genotype DAA, and is still not covered by the health insurance program [14].

#### 4.2. R&D of alternative treatment options to enhance market competition

Countries that have a larger number of suppliers registering their DAAs can have more access options, ensure supply security in-country, and lower the price of DAAs by increasing competition among suppliers. A more extensive supplier network also allows for a more competitive tender process [25]. R&D for new hepatitis C treatment has been a central pillar to support Malaysia in implementing the DAA access strategy[5]. To develop more options for DAA, the Malaysian government has been actively engaging in a large-scale clinical trial of a potential new pan-genotypic DAA regimen (sofosbuvir/ravidasvir) since 2016 [36]. The trial has been driven by the Drugs for Neglected Diseases initiative (DNDi), an international non-profit organisation, which has been dedicated to developing a pan-genotypic, simple and affordable treatment of hepatitis C at less than US\$ 300 per 12-week treatment. Considering the access to treatment for hepatitis C will get a significant boost in the country with a drug to be produced locally, the Malaysian local pharmaceutical company Pharmaniaga collaborated with the access-oriented Egyptian Pharco Pharmaceuticals to register and potentially produce the new DAA combination in Malaysia [5]. The clinical trial result shows that the combination of sofosbuvir/ravidasvir is highly effective [37], which opens the door to affordable and yet more effective hepatitis C treatment in Malaysia, and forms the basis of the hepatitis C response in Malaysia. Currently, Malaysia is adopting a competitive tendering approach for registered products to set medicines price. In an increasingly competitive environment created by the presence of more generic DAAs and alternative treatment options, a further price reduction of DAAs in Malaysia is possible.

#### 4.3. Simplified DAA treatment model for hepatitis C with integrated healthcare delivery system

In China, the government has taken a strategy to emphasize on R&D as well to support the access to affordable DAA, by providing grants to the R&D based local companies to develop and market alternative novel DAAs in China. A dozen of local generic companies also developed and registered generic sofosbuvir in China. The increasing R&D capacities and outputs in the area of DAA treatment for hepatitis C benefited from the National Middle-to-Long Term Science & Technology Development Plan (2006–2020) and the huge public-private partnership investment in pharmaceutical R&D [38]. However, these advantages may not fully play its positive role in promoting the competitiveness of the Chinese pharmaceutical companies without resolving the IP barrier of the core DAA, sofosbuvir.

Fully committing to elimination requires investment in identifying the infections, and access to treatment alone is not sufficient to eliminate hepatitis C. The effectiveness of the screening, diagnosis and treatment strategies to identify the infections is a critical determinant of the speed at which elimination can be realized. There have been recommendations made by the professional liver study society and the WHO for countries to simplify the algorithm of hepatitis C diagnostic & treatment [39–43]. Simpler and innovative models of care must be established for a scale-up of treatment [44]. Access to affordable diagnostics, capacity building and support for primary care healthcare workers are also critical elements for scaling up hepatitis C management in the community.

Besides improving the access of DAA via a CL, Malaysia collaborated with The Foundation for Innovative New Diagnostics

(FIND) & DNDi to conduct decentralized screening in 25 community health clinics for HCV by using a pre-qualified rapid diagnostic test kit in an effort to expand the reach of screening initiatives. People who screened positive and were subsequently confirmed to have HCV were linked to DAA treatment. To date, more than 88 hospitals and 146 primary health clinics in Malaysia are providing HCV screening and diagnosis services and treatment in the country, from only 12 hospitals in 2017 [45–47]. With additional training and support, HCV were treated at the primary health care level by well-trained family doctors or medical officers.

The key barrier to implement the decentralized and simplified DAA-based treatment model in China is that the tertiary hospitals have weak linkages with the secondary and primary care in the health system, although the lower levels of care have been continuously strengthened through the national health system reforms.

#### 4.4. Multi-organizational participation

Civil society organizations in Malaysia have been playing a key role in both domestic policy dialogues and promoting awareness of medicines pricing and affordability. The support given by civil society organisations was an essential element in Malaysian's bid to expand access to hepatitis C treatment. Civil society groups advocated vigorously for the inclusion of Malaysia in the voluntarily licensed territory. The sustained advocacy from civil society was important to accelerate the roll-out of hepatitis C treatment, and support the government in ensuring access to affordable DAA to the people most in need in Malaysia [35, 48]. With the support of DNDi and FIND, MOH also staged a one-week nationwide free hepatitis C screening campaign in 105 participating health facilities (including both hospitals and clinics) for the general population. This campaign, for the first time, introduced a highly sensitive and specific rapid diagnostic test (RDT) for a population-based HCV screening in public health institutions, and served as a model to raise the public awareness and educate the general population about the disease. Malaysia launched the 5-year National Strategic Plan for Hepatitis B and C (2019–2023). A budget of over US\$50 million was proposed to realize this 5-year-plan made for the elimination of hepatitis C as a public health threat [49]. To ensure better coordination and to optimize resource utilization, Malaysia integrated the viral hepatitis programme into the existing national HIV programme under MOH since 2017. The civil society organizations (CSOs) played an active role in increasing the screening uptake among high-risk groups, particularly persons who inject drugs and persons living with HIV. Multi-organizational participation is of great significance in pushing the agenda of hepatitis C elimination in Malaysia [50–52].

Multi-organizational collaborations across sectors including the government, research institutes, professional associations, healthcare providers, pharmaceutical companies, and civil societies in China were not strong enough to integrate all resources to combat and eliminate HCV [21]. Such a situation has been improving especially during the ongoing formulation of the National Work Plan for Elimination of Hepatitis C as a Public Health Threat (2021–2030).

## 5. Reflections and lessons learned

There are several key factors of Malaysia's success in battling hepatitis C. The most important one is the strong political will demonstrated by the Ministry of Health, and its interactions with the pharmaceutical industry through an open platform, which included continuous discussions with the patent holders of DAA to reach an agreement. A coordinated multi-governmental action combined with a strong support network formed by the local and international CSOs were also critical to raise the public awareness

of the disease and make the DAAs and the diagnostic test kits affordable in Malaysia. Furthermore, the success of Malaysia also lies in the national strategy of promoting market competition by ensuring the availability and affordability of DAAs through CL and R&D, the market transparency through tenders, the increased financing options and the commitment of government funding. Last but not the least, the simplified and decentralised treatment model involving the primary care and integrated health service delivery system is another critical point. To date, more than 10 000 HCV-infected individuals in Malaysia had received sofosbuvir-based DAA treatment. The total number of hepatitis C patients treated annually was shown to increase by more than 10 times, from only 300 patients in 2017 to 3116 in 2019. However, the drug expenditure for hepatitis C care relative to the overall health expenditure did not significantly increase overtime. Timely decisions of the MOH and the judicious use of policy tools were shown to have transformed the landscape of hepatitis C management in Malaysia without considerably raising the budgetary pressure [53].

## 6. Future directions for China

Hepatitis C is unique in the sense that it is curable. Even if its burden is not as high as that of other diseases, its elimination will leave a massive impact on the health care system, mainly by saving patients from fatal complications. It would be a massive boost to the elimination goal of 2030 if China could overcome the barrier to HCV treatment. Both Malaysia and China have been showing a strong commitment to safeguard their people's health. With a strong political will as in Malaysia, China can achieve the elimination goal of 2030, as most of the accessibility elements are already in place in the country. Both the countries achieve the universal health coverage albeit via different health financing mechanisms. Both countries have also integrated the national hepatitis C programme into the existing HIV programme. China has more advantages in having locally developed alternative novel DAAs, local generics and multiple options of affordable diagnostic test kits, which will help ensure the affordability of the roll-out of the diagnosis and treatment. To take a leadership role for the rest of the world, China needs to optimize the use the resources of the civil societies to raise the public awareness of the disease and educate non-specialist physicians. It is also important to continue the efforts of strengthening the primary healthcare system and transform it from a centralized to an integrated and decentralized system.

To achieve the elimination of hepatitis C as a public health threat, multi-agency cooperation is very crucial, as lessons from the international experiences imply that central government-led strategies such as price negotiation and other policy tools like the TRIPS flexibility are essential to ensure affordability of medicines to both the patient and the government. The Chinese government has been funding local pharmaceutical companies to develop new hepatitis C treatment, and there has been an increasing number of locally developed alternatives available in the market, including sofosbuvir. It is important that the patent authority expedite the decision on the final patent dispute of sofosbuvir to enable the generic core DAA to be sold in the Chinese market without infringing patents. This is critical for the local companies to have their alternative novel DAAs combined with the cheaper generic sofosbuvir, to form their own pan-genotype DAA combinations with the reduced prices, which is critical for the local companies to compete with the international companies.

Although the diagnosis and treatment of hepatitis C are covered by the basic health insurance system in China, the hepatitis C program should still be managed with the public health strategies. Through which, the disease based public health programs identify the patient with proactive screening and testing, and the health

insurance programs ensure appropriate coverage of the diagnosis and treatment. These strategies are essential to ensure that patients benefit from the significant public R&D investment. To integrate the health services for hepatitis C into benefits packages of the universal health coverage, and to strengthen the safety net for the patient with financial hardship is essential, as it will save lives and reduce costs related to the long-term care of cirrhosis and liver cancer resulting from untreated hepatitis, giving a return on the public investment [54]. The pilot hepatitis C in Tianjin [16] to roll out proactive screening and diagnostic tests and DAA treatment with the capitated health insurance provider payment mechanism could be a model for the other areas in a nationwide hepatitis C program.

Accessibility of medicines is only one element to achieve the elimination goal. Optimize the resources of civil societies to raise the public awareness of the disease and to up-skill the non-specialist physicians at the primary care level would be an essential step for the efficient early detection of hepatitis C. An integrated approach to provide the services for screening, testing, diagnosis, treatment and patient management with a simplified procedure with the back-up of functioning primary care is also critical. The screening uptake of hepatitis C within the framework of the existing disease control programs like HIV program, and integration of the monitoring and evaluation of HIV and hepatitis C is also important to optimize resource utilization. This can only be done if the disease-based public health program coordinate with the healthcare service delivery system (hospitals, primary care clinics) and the health insurance programs. The health system reform by strengthening the primary care system and promoting an integrated healthcare delivery will be the key for China to achieve the elimination target by 2030.

## 7. Limitations

The limitation of this "narrative review" was that although the authors followed the principles of the "systematic review" method to perform the literature search, the nature of our research topic and associated existing evidence were largely not formally published. This review was based mainly on expert opinions developed from responses of both countries to hepatitis C to date and grey literature.

## 8. Conclusions

As highlighted by Dr Zhu Chen, the Vice Chairman of the National People's Congress, at the point when the Initiative of Elimination of Viral Hepatitis for Healthy China 2030 was launched in March 2021 [55], the elimination of hepatitis C as a public health threat by 2030 in China could have a global impact and is of historical significance. China had the experience of taking a lead in eradicating polio in the 20<sup>th</sup> century with very limited resources, and this set an excellent example for developing countries. Embarking on scaling up hepatitis C treatment marks another contribution of China to improve the health of not only the Chinese citizens but also mankind, which is an important component for building healthy Chinese and global communities.

## Contributors

Jing Sun and Hanchao Cheng were primarily responsible for manuscript preparation. Muhammad Radzi Abu Hassan, Huan Keat Chan and Jean-Michel Piedagnel made substantial contributions to the critical revision of the manuscript. All co-authors reviewed the manuscript before submission.

## Data sharing statement

All data referred to in this paper are available from the references, relevant information are available upon appropriate request from the corresponding author.

## Declaration of Competing Interest

All authors have nothing to declare.

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## Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.lanwpc.2021.100261.

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