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LETTER TO THE EDITOR

Comment on: "Projections of the Healthcare Costs and Disease Burden due to Hepatitis C Infection Under Different Treatment Policies in Malaysia, 2018–2040"

Muhammad Radzi Abu Hassan[1] · Huan-Keat Chan[2]

Dear Editor,

We read with interest the work of McDonald et al. published in *Applied Health Economics and Health Policy* in 2018, which proposed a wide range of potential strategies to address the increasing burden of hepatitis C in Malaysia and compared their economic implications [1]. We completely agree with the authors that governmental commitment is essential in pursuing the World Health Organization's goal of eliminating viral hepatitis by 2030. In fact, following the advent of highly effective direct-acting antivirals (DAAs), the Ministry of Health (MOH) in Malaysia has made a multipronged push to combat hepatitis C over the last few years.

Approximately 2.5% of the Malaysian population, as estimated by McDonald et al. in their previous work [2], is currently living with hepatitis C virus (HCV) infection. The number of HCV infection cases notified to the MOH also continued to rise from 3.71 to 9.54 per 100,000 between 2009 and 2017 [3]. As patients are heavily dependent on public health institutions for free treatment, the high burden of hepatitis C undoubtedly poses a financial challenge to the Malaysian Government.

HCV infections in Malaysia are predominantly of genotypes 3 and 1 [4], and are thus highly curable with DAAs. Nevertheless, the access to patent-protected sofosbuvir, the backbone of most DAA regimens, was once restricted by its prohibitively high cost, which did not considerably change after rounds of negotiation between the MOH and its patent holder. In September 2017, despite the pressure received from the pharmaceutical industry, the Malaysian Government invoked the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to issue a compulsory license [5]. This has since then enabled the use of generic sofosbuvir in an upper-middle income country like Malaysia, marking a milestone in the history of hepatitis C treatment. Immediately following this decision, the patent holder of sofosbuvir also allowed the MOH to start acquiring locally registered generic products from companies to which voluntary licenses were granted. Consequently, in less than 2 years, more than 3000 HCV-infected patients in Malaysia had received sofosbuvir-based DAA treatment at a cost of less than US$300 per 12-week course. In an increasingly competitive environment created by the presence of more generic products, we foresee a further reduction in the prices of DAAs in Malaysia.

Malaysia, together with Thailand, has also actively engaged in a large-scale clinical trial of a new pan-genotypic DAA regimen (sofosbuvir/ravidasvir) driven by the Drugs for Neglected Diseases *initiative* (DND*i*), an international non-profit organization. This trial opens the door to less costly and yet more effective hepatitis C treatment in Malaysia. Its first phase yielded promising results, with the sustained viral response achieved in 97% of the 301 patients receiving the treatment [6]. Apart from that, the ongoing collaboration with the Foundation for Innovative New Diagnostics (FIND) to introduce the use of rapid diagnostic test kits in public health clinics represents one of the initial steps taken by the MOH to decentralize hepatitis C management [7]. Hepatitis C screening services and treatment are currently available in 49 public hospitals and 38 public health clinics, and are planned to be extended to all the public and private health institutions across the country by 2023. With the support of the DND*i* and FIND, the MOH also recently staged a 1-week nationwide hepatitis C screening campaign in the general population [8], in which nearly 2% of the 11,382 individuals screened in the 87 participating hospitals

✉ Muhammad Radzi Abu Hassan
drradzi91@yahoo.co.UK

[1] Gastroenterology Unit, Department of Medicine, Sultanah Bahiyah Hospital, Ministry of Health, Alor Setar, Kedah, Malaysia

[2] Clinical Research Center, Sultanah Bahiyah Hospital, Ministry of Health, Alor Setar, Kedah, Malaysia

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and clinics were found to be positive for the HCV antibody. These patients were subsequently referred to onsite medical departments or nearby hospitals for confirmatory testing. In addition to enhancing the public awareness of the disease, the success of the campaign suggests that the decentralization of hepatitis C management is feasible in Malaysia.

The MOH also acknowledged the need for leadership and a supportive policy to harmonize hepatitis C management throughout the country. For better coordination in planning, hepatitis C has been integrated into the human immunodeficiency virus (HIV) infection program under the MOH since 2017. Recently, the MOH also launched the National Strategic Plan on Hepatitis B and C 2019 to 2023 [3]. It covers several key aspects of viral hepatitis management, ranging from public education, harm reduction programs, screening, treatment, monitoring and evaluation, and staff training to capacity building. A budget of approximately US$50 million is also proposed to realize the 5-year plan made for hepatitis C elimination [3].

Although the public healthcare services are accessible for nearly 95% of the Malaysian population [9], it is also important to ensure that future plans to promote hepatitis C screening and treatment go beyond health institutions. In this context, the MOH will capitalize on its partnership with civil society organizations and inter-ministerial collaborations to reach out to key populations, including HIV-infected individuals, people who inject drugs, men who have sex with men, sex workers, prisoners, and refugees. The aim is to ensure universal coverage, providing treatment to all patients with HCV in the key populations by 2025.

We truly appreciate the continuous efforts made by the authors to present the whole picture of hepatitis C and its complications in Malaysia. We also concur with the authors that the uptake of hepatitis C treatment needs to be massively scaled up to avert or at least reduce the projected disease burden, and we are certainly paving a path toward this goal.

Compliance with Ethical Standards

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Conflict of Interest Muhammad Radzi Abu Hassan and Huan-Keat Chan have no conflicts of interest that are directly relevant to the content of this letter.

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