HEPATITIS C VIRUS DIAGNOSTICS ADVOCACY WORKSHOP

SUMMARY REPORT

COPTHORNE ORCHID HOTEL

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Positive Malaysian Treatment Access and Advocacy Group (MTAAG+) and Treatment Action Group (TAG) prepared the workshop summary report for public dissemination. The views and opinions expressed in this report are those of the workshop participants and do not necessarily reflect the official policy or position of the convening organizations. This report was written by Noel Solomon and Bryn Gay and edited by Jeremy Kwan.[1]

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Positive Malaysian Treatment Access & Advocacy Group

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Treatment Action Group

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INTRODUCTION

We have a cure for hepatitis C, yet less than 5% of people in low- and middle-income countries have been diagnosed. Malaysia's extensive history for expanding generic access to HIV and hepatitis C virus (HCV) medicines includes the issuing of a compulsory license on the breakthrough direct-acting antiviral (DAA), sofosbuvir, for combinations with daclatasvir and ravidasvir. To maximize the affordable generics availability in the public health sector, screening and testing campaigns need to be scaled up to diagnose and link people to treatment, care, and support services. Strengthening technical knowledge of providers, advocates, and community members on HCV treatment and diagnostics builds our empowerment to mobilize and meaningfully participate in national hepatitis elimination planning processes.

The summary report captures the exchanges and advocacy strategizing that took place during a three-day workshop focused on HCV diagnostics in Penang, Malaysia. A total of 41 participants from across different districts attended, including four family medicine providers and other specialists, 12 resource people, and 25 community leaders working with or representing people living with HIV and/or HCV (PLHIV and/or PLHCV), people who use drugs, men who have sex with men, incarcerated people, transgender people, and sex workers. As it was a community-focused meeting and to strengthen solidarity, government officials, donors, and the pharmaceutical industry were not invited. It was important to exchange experiences from different districts and clinical settings, ensure presence of medical expertise, and break down the silos between medical professionals, advocates, and community members in order to build a coalescent yet diverse and active coalition.

The workshop preceded the National Hepatitis Conference (NHC), held in Kuala Lumpur on 7-8 March 2019. The NHC was the first time civil society and community members from across Malaysia participated. The workshop was an opportunity to hone diagnostics advocacy plans and prepare community participation in the high-level, medical convening.

The report outlines each session's learning objectives and key information shared by presenters. The first day set the scene for the national viral hepatitis epidemic and reviewed basic treatment and diagnostics concepts. The second day explored the various obstacles to obtaining a HCV diagnosis, from the health systems, legal, sociocultural, and financial angles. Much of the second and third day facilitated participants to strategize about different campaigns and compile a list of recommendations to present to the Ministry of Health. Key action points and

outcomes conclude the report. All workshop materials are compiled in the Appendices.

DAY 1 SUMMARY: *Strengthening Relationships & Building Momentum to Catalyse Diagnostics Advocacy*

MTAAG+ started the workshop with welcoming remarks, provided rationale for the convening, and outlined the objectives and anticipated outcomes.

Objectives:

- Strengthen treatment, harm reduction, and other healthcare advocates' capacity and technical knowledge on HCV diagnostics;
- Foster advocates' leadership skills and prepare their meaningful community engagement in high-level national decision-making processes associated with timely regulatory approval, guidance development, and scale up of diagnostic technologies.

Anticipated outcomes:

- Community leaders at the workshops will provide country-specific recommendations and advocacy priorities related to diagnostics access and coverage, screening, testing and treatment scale up that inform national elimination planning processes.

- Following the workshops, the outcomes would be for advocates to form, strengthen, and regularize coalitions for advocacy and accountability with a view towards HCV elimination and implementation of recommendations.

- Community leaders gain increased visibility by government counterparts, and—using technical knowledge on diagnostics—more effectively engage in national elimination summits, regulatory processes, and guidelines bodies.

Following introductions and reviewing the learning evaluation form, it became apparent that hepatitis C was relatively new to almost all participants because community leaders were mostly from HIV and harm reduction nongovernmental organizations (NGOs). The health care provider (HCP) participants mentioned that hepatitis C was a relatively new area of clinical management for them, and it had not received much attention in Malaysia until now. The hepatitis C direct-acting antivirals, which can effectively cure the disease by achieving sustained virological response for over 95% of patients, have become available in the country and the hepatitis response is accelerating. To ensure a safer space for open and dynamic

discussion on these issues, participants were asked to suggest their own ground rules, which remained visible throughout the workshop (see Appendix 1).

"Diagnostic Burnout"

- Introduce concept of "diagnostic burnout" and highlight global "Missing Millions" campaign.

"Diagnostic burnout" is the phenomenon in which governments are treating people who are *already* diagnosed with HCV ('warehouse patients'). Not enough people with new infections are being diagnosed every year to keep up with the treatment rates. Modelling by Andrew Hill (University of Liverpool) suggests that for every new infection, five people need to be cured. Globally, it's estimated that we need to treat 5 million each year to achieve WHO elimination targets by 2030.[2] In this projection, only nine countries[3] are forecasted to meeting HCV elimination.

"Diagnostic burnout" frames the work set out for advocates to increase the number of people diagnosed. "Find the Missing Millions" is one campaign that can be adapted as "Find the Missing Thousands" in Malaysia to raise HCV awareness, educate the public about the importance of prevention, testing, and treatment, encourage people to get tested, and urge the government to adopt national testing policies.

Setting the Scene

- Provide an overview of HCV in Malaysian context, including the greatest unmet needs in HCV testing.

Globally, there are an estimated 71 million people living with active/viremic HCV and an average of 400,000 people die from HCV-related deaths each year.[4] In Malaysia, there are an estimated 380,000 people living with chronic HCV, with an alarmingly high prevalence of 67% among people who inject drugs (PWID).[5] The Ministry of Health (MoH) estimates 78% of PLHCV are aged 26 to 50 years and 90.8% are males.[6] Demographic data on transgender and non-binary gender people would give a more accurate picture of the national epidemic and inform service delivery.

Due to participants' limited technical knowledge on hepatitis a short review was provided. The progression of liver disease is same for the five other known types of

[2] Hill A. The road to elimination of Hepatitis C: Analysis of SVR versus new HCV infections in 91 countries. Poster presented at AASLD, 2017 October 20-24; DC.

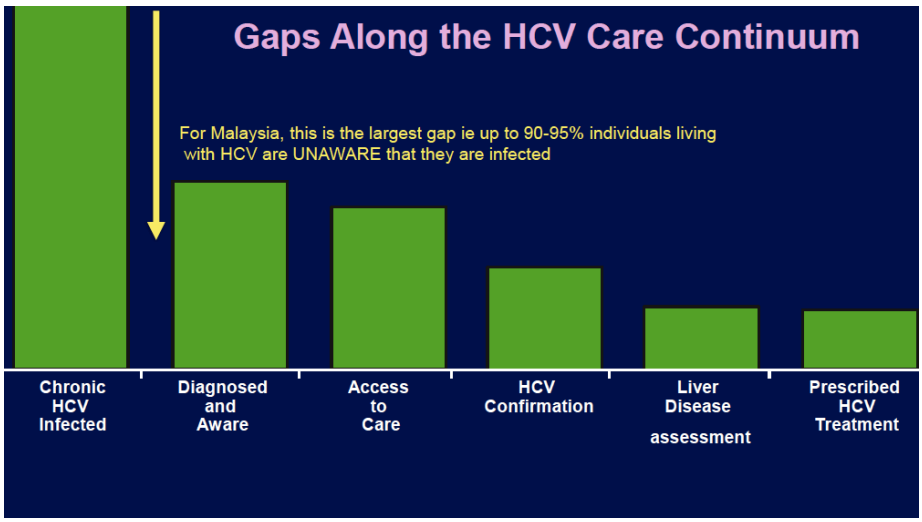
[3] Egypt, US*, Japan, Spain, Canada, Portugal, Israel, Iceland, Qatar. *Based on 2016 data, the year which had the most significant treatment scale up in the US.

[4] Global hepatitis report 2017. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/handle/10665/255016, accessed 30 May 2019).

[5] Mohamed R. Malaysia HCV Epidemic, Transmission, Targets, Current Care Cascade. Presented at HCV Diagnostics Advocacy Workshop; 2019 March 1; Penang, Malaysia.

[6] *Ibid*.

hepatitis (A, B, D, E, G) and it is important to prevent coinfection with other types to prevent rapid disease progression and liver (*hepatocellular*) cancer. HCV is a blood-borne virus and risk factors related to blood and blood products were highlighted.[7]



The largest gap in the HCV care continuum is the number of people living with HCV who are diagnosed and aware of their status, followed by those who obtain their HCV confirmation tests.[8] To scale up diagnosis and linking more people to treatment requires expanding and strengthening harm reduction programs, disseminating awareness and information on correct preventive steps, increasing the identification of new infections, and increasing HCPs' capacity to test and treat patients. HCV advocacy efforts in Malaysia are based on the 4C's: "Connect, Communicate, Collaborate and Campaigns", which have been ongoing since 2011.[9] We can learn from previous campaigns in the pre-DAA era to improve and ramp up community outreach going forward.

Diagnostics Basics & What Advocates Need to Know

- Give participants an understanding of the basic tools and steps required to diagnose someone with HCV and examples of questions to ask healthcare providers.

An overview of hepatitis C advocacy and the current landscape was supplemented by real world examples from four countries where FIND supports diagnostics-related projects: Malaysia, India (3 projects), Georgia, and Myanmar. Diagnostics is a precursor to treatment and we need to become familiarized with the terminology to effectively talk to policy-makers, funders, the private sector, and other stakeholders. The hepatitis C response must be people–centered: communities need to be aware and have access to accurate information to become empowered activists and, in turn, policy advocates. The workshop materials covered the basic terminology and concepts of HCV diagnostics and were based on a curriculum aimed for training

[7] *Ibid*.
[8] *Ibid*.
[9] *Ibid*.

other colleagues, HCPs, treatment activists, and affected communities. The different types of diagnostics used for antibody screening and confirmation of hepatitis C infection were discussed. HCV diagnosis also involves tests for genotyping to determine treatment options, Liver Disease Staging to see the extent of damage to the liver, and confirming Sustained Virology Response (SVR)—or when the virus is no longer detected in the blood and the patient is essentially cured.

Updated WHO Testing Guidelines & What is in Practice in Malaysia?

- Review WHO guidelines for HCV diagnosis, explore the advocacy needed for changes to the diagnostics algorithm in Malaysia, and understand the types of tests used in the country.

The 2018 WHO guidelines[10] provide a simpler diagnostics pathway. HCV diagnosis is a **two-step process** and requires an **antibody screening** to detect the virus and a second **confirmation test**, either by RNA or core antigen testing, to confirm active infection. When patients are diagnosed, they can receive counselling, discuss treatment options with their providers, and start treatment on the same day. The duration of treatment depends on the extent of liver damage, comorbidities, or other health issues. A viral load test needs to be taken at the end of the treatment course, usually at 12 weeks after the treatment is finished. This viral load test checks whether the patient achieved SVR. Liver function tests and post-treatment monitoring for people with more advanced liver disease can screen for liver cancer.

However, there are major differences in how HCV testing is conducted in Malaysia. Costs may be one factor in the types of tests used (see Table 1), yet ensuring the safety, efficacy, and quality are important for procurement agencies to consider. Confirmation tests are centralized at the hospital (see Table 2). Patients are referred to liver (*hepatologist* or *gastroenterologist*) specialists for further testing, which often has long waiting times—the need to shift and integrate HCV care to other medical providers is a barrier to be overcome.

Table 1. Comparisons of HCV Confirmation Test Costs in Malaysia[11] [12]

Roche Qualitative HCV RNA COBAS® AmpliPrep/COBAS® TaqMan®	1/3 cost of COBAS® Quantitative HCV RNA
Roche Qualitative HCV RNA COBAS® AmpliPrep/COBAS® TaqMan®	Similar cost to Cepheid GeneXpert HCV RNA
Abbott HCV core antigen	1/3 to 1/2 cost of Roche Qualitative

[10] Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C infection. Geneva: World Health Organization; 2018 (https://apps.who.int/iris/handle/10665/273174, accessed 30 May 2019).

[11] Not all diagnostics platforms available in the country are compared. Some platforms, which can also run HCV RNA, are only licensed for HIV or TB.

[12] *Ibid*.

	Cepheid GeneXpert HCV RNA

Qualitative RNA tests are cheaper than quantitative; core antigen is cheaper than qualitative but requires central laboratories in hospitals, which have larger volumes than community clinics.

Table 2. Availability of HCV Confirmation Tests in Malaysia[13]

Roche Qualitative HCV RNA	Hospital Kuala Lumpur Hospital Sultanah Bahiyah, Alor Setar (Kedah) Hospital Umum Sarawak Hospital Selayang (Selangor) Hospital Sungai Buloh (Selangor) Institute for Medical Research (Kuala Lumpur)
Cepheid GeneXpert HCV RNA* (*Several other hospitals have GeneXperts but they are used only for HIV or TB)	Hospital Tengku Ampuan Afzan (Pahang) Hospital Pulau Pinang (Penang) Hospital Melaka (Malacca) Hospital Sultanah Nur Zahirah (Terengganu)
Qiagen QIASymphony	Hospital Kuala Lumpur Hospital Raja Perempuan Zainab II (Kelantan) Hospital Sultanah Bahiyah (Kedah)
Abbott m2000 HCV RNA	Hospital Kuala Lumpur (but not in use for HCV viral load)
Abbott HCV core antigen	Hospital Kuala Lumpur Hospital Ampang (Selangor) Hospital Selayang (Selangor) (for reflex HCV confirmation) Hospital Sultanah Bahiyah (Kedah) Hospital Raja Perempuan Zainab II (Kelantan) Hospital Sultanah Aminah (Johor Bahru) Hospital Queen Elizabeth (Sabah)

In 2016, Family Medicines Specialist (FMS) providers detected 3449 patients with positive HCV antibody tests yet only 458 (13.3%) people were referred for confirmatory tests because they were not available in the government-run community clinics (KK) clinics. FMS were not sure which patients needed to be referred and access to the DAAs was not widely available in the country.

Several diagnostics platforms in the hospitals can run multiple tests, but are licensed for HIV and/or TB, not HCV. Additional mapping of the available diagnostics is needed to inform bundled procurement, which can increase volume and help reduce

[13] *Ibid*.

prices when negotiating with diagnostics companies. Furthermore, while the cost of test kits, cartridges, and reagents are important factors for national diagnostics strategies, it is important for advocates to push government counterparts for access to high quality tests that align with recommendations by the WHO testing guidelines and the Essential Diagnostics List. Tests that have already been prequalified by the WHO or meet other international quality standards (FDA-approved, CE-IVD, ISO certifications) can be considered for fast-tracked regulatory approval by national regulatory bodies, in order to ensure accurate HCV diagnoses.

We need to further decentralize both antibody and confirmation tests whereby FMS can immediately order the confirmation tests at the KKs as soon as they detect a positive HCV antibody. Discussions with the Ministry of Health on how to decentralize so that testing processes align with WHO guidelines continue, yet putting this into practice is still several years away.

What happens after HCV antibody diagnosis & confirmation?

- Provide examples for improving liver disease assessment and linkage to treatment and care.

Assessing the extent of liver scarring (*fibrosis*) and damage is essential prior to HCV treatment. People with liver disease (*cirrhosis*) can be more difficult to cure. They might need ribavirin or to be treated for a longer duration.

WHO guidelines reconfirm that invasive liver biopsies should no longer be used. Non-invasive methods that check liver enzymes (such as *AST or ALT enzymes*) are safer and less expensive. These include the AST to Platelet Ratio Index (APRI) or FIB-4 tests. APRI can be taken at the primary care level. In resource-limited settings, the WHO recommends APRI or FIB-4 for liver function tests, but they require labs and can add wait time for results. The more tests, the more costs. Alternatively, transient elastography (such as Fibroscan or FibroTest) uses ultrasound imaging to detect the extent of liver scarring. WHO 2018 guidelines recommend treatment regardless of liver disease progression.

However, in Malaysia, with DAA access just becoming more widely available, providers are prioritizing patients to treat based on whether they have cirrhosis. In the near future, providers will treat people regardless of liver damage. There is still a need to get more people tested, particularly people who inject drugs (who have a 64-67% prevalence of active HCV infection). Community plays a vital role, for example, to reach out to people taking methadone maintenance treatment (MMT) in the private sector and at harm reduction sites, which is in line with the midterm review by the MoH Disease Control Division.

Finally, HCV RNA tests are recommended at the end of treatment to confirm that patients have been cured. People with cirrhosis or people at risk of infection should

be monitored for liver cancer with ultrasound or blood tests (*alpha fetoprotein* tests) at least every six months.

Visioning Exercise

The first part of the workshop gave everyone similar information about hepatitis C treatment and diagnostics in order to generate discussions and ask participants to design strategies that would improve and scale up diagnoses in Malaysia. We reviewed the Malaysia Status Paper on HCV diagnostics availability and accessibility, to help frame the visioning exercise. Two breakout groups focused on how to increase HCV screening in the community and one group discussed how to decentralize HCV confirmatory testing outside hospital settings, keeping in mind the simpler HCV diagnostic algorithm and liver disease assessments (See Appendix 8).

What screening strategies work most effectively in linking people to care in your community?

- Show that different populations require different outreach, screening, and HCV antibody testing strategies. Explore different approaches that may work in key affected populations.

Following the visioning exercise, leaders from different communities exchanged experiences and expertise on how we could scale up HCV testing. For PWID, we can build on the prolific evidence and success of HIV prevention and harm reduction interventions, such as expanding needle and syringe exchange programs (NSEP) and MMT. In the transgender community, awareness and the dissemination of tailored, health-specific information was the main gap—pertinent for other key populations. In general, there is a lack of an enabling environment and support groups for our communities. We need to be more inclusive in substance user health programs, which do not cater to transgender women sex workers (TGWSW) and female sex workers (FSW) who use drugs. A peer-based approach would be the most effective to encourage more transgender people and men who have sex with men (MSM) get tested.

Regarding incarcerated people, a pilot project that conducted screening in three prisons in Malaysia, showed an estimated 45% antibody detection rate in the prison setting.[14] It is important to provide education on preventative techniques and to support people at risk during their sentences. There is a need to connect people who may have been exposed or who have tested positive for HCV to healthcare, including harm reduction services, when they reintegrate into the community. With the high incarceration rate of people for drug-related offences, there are many people at risk for hepatitis C and other infectious diseases, who may have

[14] Unofficial figures, subject to approval and validation by the Prisons Department.

interconnected networks, which engage in practices that could transmit hepatitis C. We need to better understand the overlapping networks of people who use drugs, their sexual partners, and peers in order to more effectively reach out to them and to see them as peers in prevention education and linkage to care.

DAY 2 SUMMARY: *Practices in Malaysia & Barriers to Diagnostics*

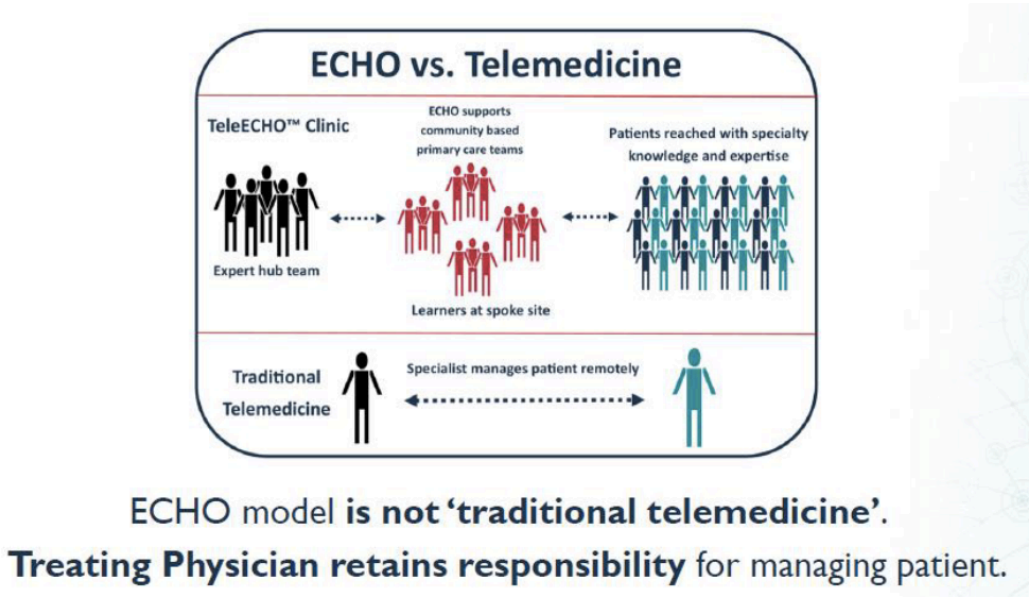
The second day focused on health system and other barriers that prevent people, particularly those from key populations, from accessing HCV treatment, diagnostics, and care.

Project ECHO Model: One example of scaling up diagnosis and treatment

- Give an overview and explain the Extension for Community Healthcare Outcomes (ECHO) model to providers and advocates, as a potential way to address diagnostics barriers.

In 2018 Malaysia treated 1,501 people with hepatitis C (less than 1%), mainly using sofosbuvir/daclatasvir (SOF/DAC). Given the population size estimate of 380,000 people living with chronic HCV, we should aim to treat 10,000 people in 2019, 20,000 people by 2020, and the same number annually going forward, in order to achieve the 2030 national elimination target.

The ECHO model is one example that could facilitate the training of HCPs to enable them to treat HCV using a shared, case-based learning model. In this way, the treating physician retains responsibility of managing the patient, unlike in the traditional telemedicine model, in which specialists manage patients remotely. Training is enhanced by web-based tele-mentoring, which would collect data and monitor outcomes centrally. ECHO can also assess the costs and effectiveness of healthcare programs. It is seen as an innovative certified medical education (CME) model and enables continuous professional interaction with colleagues across borders who share similar interests. This can be a boon for HCPs in isolated locations where it is too remote to travel easily for CME trainings. The model has the potential to reshape healthcare delivery, beyond viral hepatitis, in resource-limited countries and is pivotal for geographically isolated and underserved populations. The ECHO model aims at building capacity of FMS and General Practioners (GP) to treat patients with hepatitis C outside hospital settings; bringing this model to Malaysia has been discussed with the MoH. The development of the CME for viral hepatitis and options for remote healthcare service delivery, which build on and support the existing health system, are under discussion.

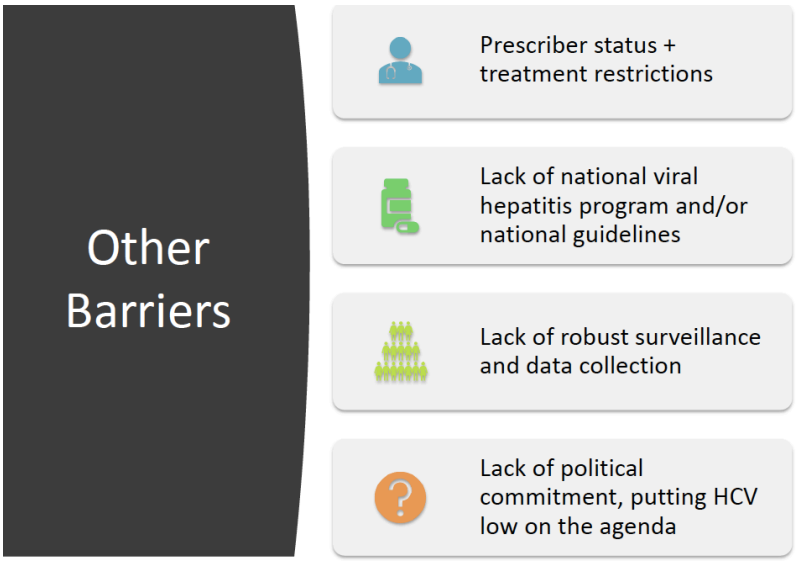


Health System Barriers to Diagnosis

- Understand and discuss fundamental health system barriers that people face when trying to access HCV diagnostics.

There is a global estimate of 290 million people unaware that they are living with viral hepatitis, of which only 5% of people living with HCV in low- and middle-income countries (LMIC) have been diagnosed. Barriers include a lack of knowledge about viral hepatitis among the general public as well as medical providers, lack of easily accessible testing, stigma and discrimination experienced by patients, limited trainings and implementation of cultural competency and respect for some affected communities by medical providers, high costs of procuring tests for public and private labs, patient out-of-pocket costs, lack of dedicated hepatitis funding, lack of social supports (e.g., prevention/harm reduction counselling, employment, housing, transportation assistance, etc), and poor surveillance and data collection in some settings.

Other barriers include[15]:



To overcome these barriers, necessary measures include raising public awareness, designing and developing quality trainings for HCPs as well as the implementation of service delivery—in partnership with community members—and decentralizing testing. Lifting treatment restrictions, shifting tasks to expand prescriber status to non-specialists, raising visibility and including community in the development and implementation of the national hepatitis program and guidelines, and holding the government accountable for its political and funding commitments are simultaneous moving parts that would help actualize hepatitis elimination in Malaysia.

[15] Hoe CH. Health System Barriers to Hepatitis C Diagnosis. Presented at HCV Diagnostics Advocacy Workshop; 2019 March 1; Penang, Malaysia.

Additional strategies to overcome these barriers include[16]:

Review of the HCV Treatment Landscape (Pangenotypic Era)

[16] *Ibid.*

- Briefly review the latest all genotype-treating (*pangenotypic*) DAAs, understand the safety and efficacy of DAAs with opioid substitution therapy (OST) and certain antiretroviral therapies (ARTs).

After a review of how DAAs work and the major milestones in their development, we discussed the main treatment regimens available in Malaysia. Sofosbuvir/daclastasvir (SOF/DAC) is the most used regimen, procured under the compulsory license arrangement. The WHO recommends SOF/DAC for 12 weeks for most patients, unless they have compensated cirrhosis, in which case they can be treated for 24 weeks. Ribavirin should be avoided in treatment regimens because it has several intolerable side effects and can cause birth defects or miscarriage. RBV should not be used by pregnant women or by women's male sexual partners. Thus, a priority for treatment activism in Malaysia is to push for ribavirin-free treatment options and starting patients on early treatment and for all stages of fibrosis.

Sofosbuvir/velpastasvir (SOF/VEL) does not need RBV for compensated cirrhosis, so we need to stratify our approach to HCV treatment. In Malaysia, we should use SOF/DAC for patients without cirrhosis and consider SOF/VEL for patients with compensated cirrhosis also as a first line of treatment. The SOF/RAV regimen which is also a RBV-free regimen, is the first non-profit drug developed through a partnership with the MoH and Drugs for Neglected Diseases *initiative* (DNDi). SOF/RAV is in the pipeline and could be a cornerstone in expanding affordable treatment in Malasyia and other resource-limited countries. Looking ahead, SOF/RAV's STORM-C-1 trials show a 97% SVR at week 12 among the 300 enrolled patients[17]. There were a few treatment failures due to *non-compliance*, or patients not exactly following providers' instructions. Ravidasvir will need to be registered in Malaysia, so when the study trials conclude it can be made available on the market as soon as possible.

We also highlighted AbbVie's pan genotypic DAA, glecaprevir/pibrentasvir ([G/P], also known as Mavyret). This DAA can achieve SVR in 8 weeks for people without cirrhosis, making it the shortest treatment regimen available. AbbVie provided a voluntary license on G/P to the Medicines Patent Pool, which would allow generics under licensed manufacturers for 99 low- and middle-income countries (LMICs).

Studies show that DAAs have similar curative rates for active and former PWID, as for people who do not use drugs. Treatment efficacy for people taking OST is nearly the same as people not taking OST, as long as they are not lost-to-follow up (LTFU). **There is no scientific evidence for denying the hepatitis C cure for people who use drugs (PWUD).**

[17] DNDi. New affordable hepatitis C combination treatment shows 97% cure rate. Press release. Paris; 2018 April 12. https://www.dndi.org/2018/media-centre/press-releases/new-affordable-hepatitis-c-combination-treatment-shows-97-cure-rate/

There are some drug-drug interactions (DDI) between DAAs and ARTs, so patients need to tell their doctors about any medications they are taking. Studies do not indicate compromised efficacy; dosage may need to be adjusted to take into account potential DDI. Patients coinfected with HIV/HCV should not take some DAAs with **efavirenz**, which is a common HIV regimen in Malaysia. It's possible for people to be triply infected with HIV/HBV/HCV, and patients taking **tenofovir** could reactivate HBV. To look for drug-drug interactions the following resource is useful:

www.hep-druginteractions.org

Update from DAA registration meetings[18]

Since 2017, the Egyptian manufacturer, Pharco, with local distributor Pharmaniaga, provides sofosbuvir for government hospitals in Malaysia, under the compulsory license. Sofosbuvir, combined with daclatasvir (accessed as a generic medication), is procured at RM 1,225 (US$300) per 12-week treatment course. This is a massive reduction from the Gilead-offered price of RM 45,000 (US$11,000) per 28-tablet bottle.

On 7 March 2019, Malaysia registered the first generic sofosbuvir, which is manufactured by the Indian company, Strides Pharma Sciences Limited and distributed by Unimed. Then on 2 May 2019, the government registered the first generic daclatasvir, manufactured by an Egyptian company, Pharco, and also distributed by Pharmaniaga.

An estimated 50% of patients receive care in university and private hospitals, which are excluded under the compulsory license. Additional options are being explored to expand treatment access. On 25 February, 2019, 20 advocates, many of whom participated in this workshop, met with the National Pharmaceutical Registration Agency (NPRA) and two generic companies, Mylan and Hetero, about the status of registering generic DAAs. Malaysia has very high standards for registration of both originator (branded) and generics. This is to ensure that safe, effective, and quality medicines are procured in the country, but advocates see that some of the stringent requirements are difficult for companies to meet and pose barriers to treatment access, particularly when there are "pre-qualified" DAAs by the WHO.

The MoH more than doubled the budget from RM 3.7 million to 7 million (roughly US$835,000 to 1.7 million) to buy DAAs yet regulatory hurdles remain. NPRA is committed to fast-tracking the registration and approval of generic DAAs in 90 days for complete dossiers. Generic companies provided feedback that completing a dossier is difficult and can be costly. NPRA reassured that they expected at least

[18] Based on Ling CY. Update. Presented at HCV Diagnostics Advocacy Workshop; 2019 March 1; Penang, Malaysia; Malaysia HCV Advocates WhatsApp Group. Personal communications. 23 February to 31 May 2019.

one generic sofosbuvir to be registered within Quarter 1 2019—(in March 2019, Unimed, under the Indian voluntary license holder, Stridsarcolab, was approved). Potentially, the two generic companies could enter the market. It is not known for which DAAs each company applied.

Ongoing community engagement and monitoring of the treatment and diagnostics pipeline with the NPRA should be explored to ensure timely updates on the registration process and vigilance on the availability of medicines critical to saving lives.

Ideal HCV Test & HCV Diagnostics Pipeline[19]

- Examine the characteristics of the ideal HCV test, highlight different tests in the research and development pipeline, and the related advantages and disadvantages.

The "ideal" HCV test:

- Uses either HCV RNA or HCV core antigen, either taking blood samples from fingerstick or dried blood spots (DBS)
- Confirms diagnosis in 20 minutes
- Costs less than US$5 per test (including the chemical *reagent* cost)
- Enables a person to initiate a pangenotypic treatment immediately, then return for test-of-cure at 12 or 24 weeks (SVR12 or SVR24) after completion of DAA treatment.

However, this ideal test is still several years away and we lack simple, affordable tests in LMICs. New types of tests are being created to improve the quality, effectiveness, and simplicity of diagnosing a person. Some of the tests may not work or meet regulatory approval, but there are several products to highlight.

The diagnostics company, Molbio, is developing a credit card-size HCV testing device that can be used in point-of-care (PoC) settings (e.g., community health clinics, mobile vans, urgent care). FIND and another research firm are developing HCV self-testing kits. Advocates need to consider whether HCV self-testing would improve diagnosis in communities which are most at risk for infection. Counseling components, like in HIV, need to be an essential part of any self-testing kit. FIND is supporting partners to develop an HIV/HCV combined serology test that could potentially detect coinfection cases and could be important for healthcare providers and other people who are higher risk of infection to use.

[19] Foundation for Innovative New Diagnostics. High-priority target product profile for hepatitis C diagnosis in decentralized settings: Report of a consensus meeting; 2015 April 22; Vienna, Austria: Forum for Collaborative HIV Research, https://www.finddx.org/wp-content/uploads/2019/03/HCV-TPP-Report_FIND-2015.pdf (accessed 2019 July 1).

In addition to treatment costs, there are high costs for diagnostics, liver assessment tests, healthcare equipment, as well as human resources, staffing, and training costs.

Information on treatment pricing and availability is relevant for our advocacy. mapCrowd (www.mapCrowd.org) is an advocacy tool and database that crowd-sources information from advocates in over 50 countries. The database is free, open to the public, and allows users to create country and regional comparisons for a range of issues, including treatment and diagnostics pricing. Maps, graphics, and tables can be generated for advocates to use in their own, localized campaign materials. Historically, one example of using pricing transparency to leverage in procurement negotiations is how India compared ARV and DAA prices in different countries and across their different states. India pooled together the vast demand for treatment to buy them in bulk, which has been proven to effective to lower prices.

Patent and licensing barriers to diagnostics

- Highlight current patent and licensing barriers on treatments, potential implications of monopolies on diagnostics, and treatment activism needed to address HIV/HCV treatment access in Malaysia and further considerations to address patent and licensing barriers.

Many policy-makers see intellectual property as a form of property that should be protected like any other property. However, pharmaceutical companies that are granted patents on medicines are given 20 years of minimum protection, whereby non-licensed manufacturers cannot produce the medicines without permission. Pharmaceutical companies set high list prices during those 20 years and may offer different prices to different countries according to economic/income status.

Malaysia was offered prices that exceeded its healthcare budget and tiered pricing structures do not accurately reflect the economic reality on the ground. See comparative prices by country below.[20]

[20] Médecins Sans Frontières. Not even close. Issue Brief. 2017 October 29. In Yong K. Hak Harta Intelek. Intellectual Property Rights. Presented at HCV Diagnostics Advocacy Workshop; 2019 March 1; Penang, Malaysia.

TABLE 1: PRICES FOR AVAILABLE ORIGINATOR AND GENERIC DAAS IN SELECTED MIDDLE-INCOME COUNTRIES (IN $US PER 28-TAB BOTTLE)

COUNTRY* (Income Classification)	GILEAD SOF[25]	GENERIC SOF	GILEAD SOF/LDV[25]	GENERIC SOF/LDV	GILEAD SOF/VEL[25]	GENERIC SOF/VEL	BMS DCV 60MG	GENERIC DCV 60MG
Brazil[1] (UMIC)	$2,292						$850	
Egypt (LMIC)	$250	$51[4]	$300	--†			$167[1]	$7[4]
India (LMIC)	$250	$22[4]	$300	$65[4]		$283[26]	$167[27]	$13[4]
Jordan[28] (UMIC)			$22,220				$11,800	
Malaysia[29] (UMIC)	$11,053		$14,212		$18,239		$3,746	
Pakistan (LMIC)	$250	$15[1]		--†				
Thailand[23,‡] (UMIC)	$1,200		$2,000				$1,500[30]	
Ukraine (LMIC)	$250		$300				$300[31]	

* Included in both BMS and Gilead voluntary licences: Egypt, India, Pakistan; included in Gilead voluntary license only: Malaysia, Thailand, Ukraine; excluded from both BMS and Gilead voluntary licenses: Brazil, Jordan.

† Generic SOF/LDV available; price not reported.

‡ SOF and SOF/LDV prices are for the private market. Thailand was recently added to Gilead's VL, but reduced price is not yet available.

Boxes shaded in grey indicate that the DAAs are not available in that country. All prices converted to USD using Oanda: https://www.oanda.com

UMIC = upper middle-income country; LMIC = lower middle-income country.

While 20 years is the standard protection, there are "permissive laws" and "secondary patents" that can extend patents longer, e.g., for sofosbuvir the patent was supposed to be until 2024 but has been extended to 2032. A pre-grant patent opposition system allows governments to block a patent before it is granted; this mechanism is lacking in Malaysia. We can only challenge a patent after it has been granted, which would end up as a prolonged court case. There needs to be a mechanism in Malaysia that allows pre-grant patent opposition.

Malaysian advocates are familiar with policy mechanisms under the international Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. A compulsory license (CL) allows a government or manufacturer to obtain a patented technology for non-commercial uses, while still paying royalty compensation. CLs include the use of technology (e.g., medicines) as a measure to protect public health. A compulsory license can be used until the end of the patent period (in sofosbuvir's case until 2032), but Malaysia has issued a two-year CL. Malaysia was initially excluded from Gilead's voluntary license (VL) for HIV and HCV medicines, and only obtained a VL when Malaysia decided to invoke a CL. Gilead refused to voluntarily reduce the price of sofosbuvir from US$11,000 per 28-tablet bottle (three bottles are generally needed to achieve SVR), leading the government to invoke a CL. TRIPS provisions also allow countries to put more stringent patent requirements in their national laws. This calls for legislative changes in Malaysia because current patent requirements are too broad and allow for patent extensions beyond the end of the patent period.

There may be patent issues on components or parts related to diagnostics platforms, such as reagent chemicals. However, data is scarce on relevant patent and licensing

barriers for diagnostics. It is important to monitor the pipeline to inform regulatory approval procedures and procurement negotiations and to ensure that a monopoly of one diagnostics platform is not created in the country. A recommended model would be to ensure that any research and development on diagnostics that is publicly funded (e.g., with government grants) is issued a non-exclusive (open) license to safeguard access.

Review of harm reduction principles

- Emphasize harm reduction principles, approaches, and applicability in Malaysia.

Malaysia has a successful track record of harm reduction for responding to HIV, which can be applied to HCV. We should design a comprehensive, holistic package of services that address substance user health. Until now, there has been a lack of emphasis on HCV in harm reduction programs, which is a missed opportunity. Advocates questioned whether a separate Malaysian Hepatitis Council should be established or to use existing governing bodies. It is generally agreed that if there is a costed, national strategic plan that includes a national task force, the hepatitis elimination work can fall under the MoH HIV Unit. NGOs that apply for MoH HIV grants should integrate HCV into their proposals to ensure they are providing the outreach, training, and service delivery needed for the response.

Social determinants of health: Stigma and discrimination

- Report back from the Malaysia AIDS Council (MAC) workshops on stigma and discrimination (S&D).

S&D remains one of the most significant barriers for community members to trust and seek healthcare services. MAC conducted workshops in Kuala Lumpur and Johor Bahru in November and December 2018, respectively. FMS and key CSOs strategized on how to decentralize all HCV services, including testing. The MoH is developing a learning module on S&D for HCPs, largely focusing on HIV services but HCV can be integrated. Going forward, MAC will be taking the lead on interventions for HCV with funding from UNITAID/Coalition PLUS. MTAAG+ is included to undertake several activities (Refer to Appendix 9).

Ending the war on drug users & addressing myths about DAAs for PWID

- Understand how the criminalization of drugs in Malaysia creates barriers for people to access healthcare, including HCV services.

Studies show that drug decriminalization does not increase drug use or increase crime and must be paired with sufficient public health, mental health, and other support services. We need to mobilize resources and find the funding for creating community empowerment and constructing an enabling environment for people to want to seek healthcare and treatment. This video highlights the failures of the war

on drugs and examines alternative best practices to address substance use as a public health—not a criminal justice—issue:

https://www.youtube.com/watch?v=wJUXLqNHCaI

Addressing Health System Barriers to Diagnosis

A panel discussion covered different health system barriers including: poor nationwide data collection and surveillance, lack of funding and dedicated budget allocations for HCV, and limited community inclusion in national elimination planning. We need to ensure that community is part of the National HCV Task Force, under the national action plan for HCV, so that any decision-making process for budgeting and allocation for hepatitis C is done inclusively.

Recap from Visioning Exercise & Key Themes.
(Refer to Appendices 5 and 6).

Mapping Our Advocacy
(Refer to Appendix 7).

DAY 3 SUMMARY: *Advocacy Strategies for Overcoming Diagnostics Barriers*
The final day facilitated participants to strategize about different campaigns, action steps, and compile a list of recommendations to present to the Ministry of Health.

Lessons from other countries and jurisdictions
A panel discussion with representatives from different key populations presented initiatives from other countries and jurisdictions. The discussion on other initiatives helped informed the advocacy strategizing.

FIND has a multi-year hepatitis C project in India (Punjab, Delhi and Manipur), as well as projects in Malaysia, Georgia, and Myanmar. In India, comprehensive test-and-treat programs, or “One Stop Shops”, are being rolled out that would decentralize and integrate HCV services into other clinical settings. Punjab is a conflict-affected state, with a high HCV prevalence and high number of people who inject drugs. In July 2016, the Government of India partnered with FIND to initiate the test-and-treat programs and to raise the profile of hepatitis C in India. Several capacity-building workshops for advocates/providers and trainings for journalists on how to cover HCV without using stigmatizing language have been conducted under this project.

MTAAG+ shared information about a pilot project for HCV screening in prisons (as well as HIV at the prison authorities’ request). MTAAG+ provided educational health talks among inmates and conducted antibody testing on a voluntary basis. This was

a joint project with the Prisons Department, in which the Human Rights Commission of Malaysia SUHAKAM is informed. SUHAKAM was established by Parliament under the Human Rights Commission of Malaysia Act 1999, Act 597, which is Malaysia's initiative to set up a national human rights institution. This took place under Malaysia's active participation in the United Nations Commission on Human Rights (UNCHR) in 1993-1995 and when it was elected as a member of the Commission by the United Nations Economic and Social Council.

The testing in three prisons was agreed as a pilot project. A full report has been sent to the Prisons Department with SUHAKAM in the loop. MTAAG+ expects an official meeting with the Prisons Department on how to respond to the screening results in the first half of 2019.

LOCATION	Inmates	Total Tested	HCV	HIV	Co infection
Prison A*	Mixed	60 (Male 44, Female 16)	27	22	15
Prison B* (initially refused)	Mixed	60 (Male 36, Female 24)	26	5	2
Prison C* (oiginally supposed to be at another location)	Men only	60 (All Male)	21	1	1
		TOTAL	**74**	**28**	**18**

*Unofficial figures, subject to approval and validation by the Prisons Department.

Opportunities for advocacy to overcome diagnostics barriers
Themes arising from the previous presentations, breakout groups, and discussions were presented to help frame how CSOs can raise awareness for World Hepatitis Day (28 July) and how representatives from key populations can be involved in the national strategic plan and national task force on hepatitis elimination. (Refer to Appendices 5 and 6).

Breakout group discussions and action plans
Participants returned to the same groups as as for the Visioning Exercise, in which they would focus on a particular strategy and discuss more detailed action plans and next steps. Each group selected a representative to present their outputs to everyone. (Refer to Appendix 8).

KEY ACTION POINTS AND OUTCOMES

Participants compiled the following priorities for advocacy based on breakout group discussions:

1. In the immediate and short-term, enhance meaningful CSO participation at the National Hepatitis Conference on 7-8 March, through the preparation of:

a. A list of potential questions to be raised during appropriate sessions at the upcoming National Hepatitis Conference. (Refer to Appendix 10).
b. A "CSO wishlist" (call for action) to present at the separate community dialogue with the Ministry of Health (MoH) on 7 March, 2019. The checklist can serve as a reference to be ticked off or added to, for community delegates to use when raising questions and participating in other conference sessions. (Refer to Appendix 11).

2. In the medium to long-term, the CSO wishlist will be further developed into a further detailed plan of action for implementation, taking into account:
   a. Input from the National Hepatitis Conference and CSO dialogue (Refer to Appendix 11).
   b. Follow and communicate other developments related to treatment access and testing decentralization through a regular communication channel (e.g., WhatsApp group, email, conference calls, meetings).

3. Immediate action steps after the workshop: Modify and update the advocacy and partner mapping list (see Appendix 7) to include:

   a. CSOs and private sector stakeholders, which were not represented at this workshop, which can offer community-friendly options for testing and treatment.
   b. Cover other relevant information like contacts, location, geographical coverage, strengths and weaknesses of the organizations, as well as their levels of influence versus interest.

Outcomes:

- Clearer overview of the hepatitis C situation in Malaysia and basic understanding of challenges related to hepatitis C diagnostics and treatment.
- Basic knowledge of hepatitis C, in which participants felt more prepared to share with their respective community members and CSOs and to use the information in their further advocacy efforts.
- A renewed sense of solidarity and confidence in being advocates for hepatitis C issues, with a focus to ensure that there will always be civil society representation and input moving forward in national planning.
- Participants who would be attending the National Hepatitis Conference felt more prepared to present a unified stance based on the exchange of information and advocacy strategizing.

CONCLUSION

The workshop provided a space for community advocates and medical providers alike to explore the complexity of HCV diagnostics. Overall, participants felt that they

gained relevant knowledge for sharing with their colleagues and peers and to become stronger HCV advocates. The workshop materials can supplement existing and forthcoming HIV/HCV community outreach training curricula in Malaysia. The outcomes of the workshop feed into broader advocacy to expand affordable medicines and accelerate generic DAA registration in the country, including for use outside public health settings, as well as initiatives to protect the human rights of people from key affected populations. They also align with government efforts to decentralize antibody screening and HCV treatment and care outside hospital settings, which will need massive awareness and testing campaigns designed and led by affected communities.

APPENDICES

APPENDIX 1: Participants' Ground Rules

1. Handphones to be placed on silent.
2. Punctuality to be practiced for all sessions.
3. No personal attacks—address the issue not the person.
4. Privacy and confidentiality must be respected. Respect people's openness to share real experiences—all such discussions to stay within these walls.
5. No interrupting (One Diva, One Mic). Raise hands and talk one at a time.
6. Agree to disagree. Respect each other's opinion.
7. Step Up, Step Back. Allow people who are more quiet or shy to have a chance to speak up. Don't dominate or monopolize the discussions.
8. Bilingual language allowed and encouraged. Use local slang and ask questions in Malay, if more comfortable.
9. Use participants' correct gender pronouns.
10. Use people-centered language (e.g., people who use drugs, people living with HIV/HCV). Avoid stigmatizing language.

APPENDIX 2: AGENDA

Friday, 1 March 2019 *Strengthening Relationships & Building Momentum to Catalyse Diagnostics Advocacy*

Time	Topic	Speaker/Facilitator
7.45-8.30am	Registration & Pre-Workshop Learning Evaluation Form	
8.30-8.40am	Welcoming Remarks & Workshop Objectives	Edward Low (MTAAG+)
8.40-9.30am	Introductions, Rationale & Learning Needs	Manis Chen (MTAAG+)
9.30-10.00am	Setting the Scene: Malaysia HCV Epidemic, Targets, Current Care Cascade and Routes of Transmission	Dr Rosmawati (University Malaya Medical Centre) *Facilitator:* Han Yang (DNDi)
10.00-10.30am	*Coffee break*	
10.30-12.00pm	Diagnostics Basics & What Advocates Need to Know	Bryn Gay (TAG) and Navneet Tewatia (FIND) *Facilitator:* Dr Ruziatun Hashim (FMS, KK Pandamnaran)
12.00-12:10pm	Updated WHO Testing Guidelines, Essential Diagnostics List & Simplifying the Diagnostics Algorithm	Dr Rosmawati (University Malaya Medical Centre) Input from Bryn Gay (TAG) & Navneet Tewatia (FIND) *Facilitator:* Jeremy Kwan (MTAAG+)
12.10pm-12.20pm	What is in practice in Malaysia? Examining Malaysia Status Report	Dr Rosmawati (University Malaya Medical Centre) *Facilitator:* Jeremy Kwan (MTAAG+)
12.20pm - 1.00pm	Visioning Exercise Start by showing the Status Report on availability and accessibility of HCV diagnostic tools in Malaysia Ask each group to each address one strategy to improve access to HCV testing based on issues framed in the Status Report	*Facilitators:* Manis Chen (MTAAG+) and Han Yang (DNDi)
1.00-2.30pm	*Lunch and Friday prayers*	

Time	Topic	Speaker/Facilitator
2.30-2.45pm	"Diagnostic Burnout": Finding the Missing Thousands Cost effectiveness of universal screening	Bryn Gay (TAG) *Facilitator:* Dr Ruziatun Hashim (FMS, KK Pandamaran)
2.45-3.10pm	What happens after HCV antibody diagnosis? How to improve HCV confirmation and liver disease assessment?	Dr Rosmawati (University Malaya Medical Centre)
3.10-4.30pm	What screening strategies work most effectively in linking people to care in your community?	4 community member presenters (5-10 min each): Mohd Hafiz (SAHABAT - PWID setting) Syariana Jane Kasim, (KOPEK - Transgender community) Adzrin Bin Mumin (TAPS – MSM community) Ed Low (Prison setting) *Facilitator:* Mohd Razali
4.30-5.00pm	*Coffee break*	
5.00-6.00pm	Wrap up & Pre-dinner Break	
6.00-8.00pm	*Group photo, dinner & evening activity*	

***END DAY 1 ***

Saturday, 2 March 2019 *Practices in Malaysia & Barriers to Diagnostics*

Time	Topic	Speaker/Facilitator
8.00-8.30am	Health Systems Barriers in Malaysia	Dr Hoe (Penang Hospital) *Facilitator:* Dr Rosmawati
8.30-9.00am	Project ECHO Model: One example of scaling-up treatment	Dr. SS Tan (Selayang Hospital) *Facilitator: Ed Low*

Time	Topic	Speaker/Facilitator
9.00-9.30am	Review HCV Treatment Landscape (Pangenotyic Era)	Dr SS Tan (Selayang Hospital) *Facilitator:* Ed Low
9.30-10.00am	Update from DAA registration meetings	Chee Yoke Ling (Third World Network)
11.15-11.30am	*Coffee break* *Participants can opt to attend World Cancer Day event; participants prepare their own transport logistics* *Rapporteur can prepare summary of following sessions to report back*	
11.30-12.00pm	Patent and licensing barriers to diagnostics	Karina Yong (Third World Network) *Facilitator:* Edward Low (MTAAG+)
12.00-1.30pm	*Lunch*	
1.30-2.00pm	Review of harm reduction principles	Kamal Pilos *Facilitator:* Yatie Jonet
2.00-2.45pm	Ending the war on drug users & addressing myths about DAAs for PWID	Yatie Jonet (Independent Consultant) *Facilitator: Mohd Razali*
2.45-3.00	Social Determinants of Health: Stigma & discrimination	Anushiya Karunanithy (MAC) *Facilitator: Mohd Razali*
3.00-3.45pm	Addressing Health System Barriers to Diagnosis: Improving nationwide data collection and surveillance Ways community can be involved and monitor surveillance Financial barriers to diagnosis	*Facilitators:* Han Yang (DNDi) and Mohd Razali (10 min) Dr. Roziaton (FMS) (10 min) Bryn Gay (TAG) (10 min) Kamal Pilos (Community representative to Global Fund CCM) (10 min) Anushiya Karunanithy (MAC)

Time	Topic	Speaker/Facilitator
3.45-4.15pm	*Coffee break*	
3.15-3.45	Recap from Visioning Exercise, key themes, and break out group discussions	Noel Solmon (Rapporteur)
3.45-5.00pm	Mapping Our Advocacy Update from FIND/DNDi projects	*Facilitators*: Han Yang (DNDi) + Yatie Jonet Han Yang (DNDi)
Evening	World Cancer Day – Jade Ribbon Dinner (optional)	

***END DAY 2 ***

Sunday, 3 March 2019 *Advocacy Strategies for Overcoming Diagnostics Barriers*

Time	Topic	Speaker/Facilitator
8.30-9.15am	Panel: Lessons from other countries and jurisdictions 'One stop shops' in India & media advocacy Malaysia prison pilot project	*Facilitator:* Jaafar Daud Navneet Tewatia (FIND) Manis Chen (MTAAG+)
9.15-10.15am	Opportunities for advocacy to overcome diagnostics barriers One Prick, One Visit: Uniting medical providers and building effective, targeted awareness campaigns Malaysia Action Plan	*Facilitators:* Han Yang (DNDi) & Yatie Jonet Dr Rosmawati – (University Malaya Medical Centre)
10.15-10.45am	*Coffee break (and check out)*	
10.45-11.00am	Report back and summary	*Facilitators:* Dr Rosmawati and Noel Solomon (Rapporteur)
11.00am-12.00pm	Mapping diagnostics advocacy strategies and priorities	Facilitators: Han Yang (DNDi) and Dr Rosmawati
12.00-1.00pm	Group discussion on recommendations for devising community platform, monitoring, and metrics on diagnostics in elimination plan	*Facilitators:* Han Yang (DNDi) and Dr Rosmawati

Time	Topic	Speaker/Facilitator
1.00-2.00pm	*Lunch*	
2.00-3.00pm	Identify key action plans and follow up activities	*Facilitators:* Khartini Slamah (APNSW) and Noel Soloman (Rapporteur)
3.00-3.30pm	Wrap up and post- workshop learning evaluations	Manis Chen (MTAAG+)

End of workshop

APPENDIX 3: List of Participants

No	Name	Organization	Pronouns & Comments
1	Ms. Manis Chen	Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)	She/Her
2	Noel Solomon Ponniah	Rapporteur	Pronouns don't matter for him/her
3	Zack (Mr. Mohd, Nadzir Bin Mohd. Nordin)	Persatuan Cahaya Harapan Negeri Kedah/Perlis	Just call me Zack
4	Effa (Ms. Latifah Binti Mat Haji)	Persatuan Cahaya Harapan Negeri Kedah/Perlis	Volunteer (Came at own expense)
5	Am (Ms. Maslinah Binti Zainal)	Independent (Persatuan Kebajikan Karisma Malaysia (KARISMA)	Volunteer (Came at own expense)
6	Fitri (Mr. Mohd. Nor Fitri Bin Mat Berahi)	Persatuan Kebajikan Karisma Malaysia (KARISMA)	He/Him
7	Anu (Ms. Anushiya Karunanithy, TGW)	Hep-C Project Program Manager (coalition plus funding) Malaysian AIDS Council (MAC)	She/Her
8	Han @ Han Yang (Mr. Chung Han Yang)	Drugs for Neglected Diseases Initiative (DNDi)	
9	Dr. Ruzi (Dr. Ruziatun Hashim)	FMS, KK Pandamnaran	
10	Mr. Thilak	Drugs for Neglected Diseases Initiative (DNDI)	
11	Dr. Anita	FMS, KK Macalister	
12	Dr. Jenizah	AIDS Officer (AO) Penang State, JKNPP (DOH Penang)	
13	Dr. Azlina	FMS KK Butterworth	
14	Hafiz (Mr. Mohd Hafiz Afendi Abdul Rahman)	SAHABAT Kota Bahru	
15	Yatie (Ms. Yatie Jonet @ Haryati Binti Jonet)	Independent, Patient advocate groups. (Former MAC DU program & SHIFT program staff)	
16	Khariul (Mr. Md Khairul Bin Che Imran)	SAHABAT Kota Bahru	
17	Afiq @ Apek (Mr. Mohd Afiq Bin Mohamad Khairi)	Program Manager, Persatuan Insaf Murni Malaysia	Call me "Apek"
18	Raja Azizan (Mr. Raja Azizan Suhaimi Bin Raja Abd. Latiff)	Malaysian Substance Abuse Council (MASAC)	Abang Raja, He/Him
19	Reduwan (Mr. Muhd. Redduwan Bin Zairu Kaperi)	Penang Family Health Development Association (FHDA)	
20	Dave (Mr. Davaraj A/L Veerakesery)	Komited Malaysia (KM), ISMA	He/him
21	Adzrin (Mr. Adzrin Bin Mumin)	Treatment Adherence Peer Supporter (TAPS) under Dept. of Health (JKN/DOH) Sabah "FACE" CBO founder (MSM PLHIV peer support group)	He/him (cisgender)

22	Razali (Mr. Mahd. Razali Bin Ayub)	Wadhu founder, Senior Citizen, Welfare association of recovering DU	
23	Mr. Jegathesan	AIDS Action And Research Group (AARG)	
24	Ferdaus (Mr. Mohd Ferdaus Bin Hussain)	AIDS Action And Research Group (AARG)	
25	Kamal (Mr. Kamal Pilos)	Persatuan Kebajikan Komuniti Ikhlas Malaysia & Malaysia CCM (Country Coordinating Mechanism)* Community Rep for PWUD	
26	Khalid (Mr. Khalid Hashim)	Malaysian Substance Abuse Council (MASAC) Founder of Komited Malaysia (KM)	
27	Rashid (Mr. Mohd. Rashid Hashim)	Persatuan Kebajikan Komuniti Ikhlas Malaysia	
28	Dr. Syed	University Malaya Medical Centre (UMMC) & Hepatitis Free Malaysia	
29	Sazura (Ms. Sazura Sarif)	Komited Malaysia (KM)	
30	Ms. Rohayu	Malaysian Human Rights Commission @ Suruhanjaya Hak Asasi Manusia (Suhakam)	
31	Dr. Rosmawati (Prof. Ros)	University Malaya Medical Centre (UMMC) President of Hepatitis Free Malaysia	She/her
32	Dr. Navneet Tewatia	Advocacy Officer Foundation for Innovative New Diagnostics (FIND), New Delhi, India	From HIV background, new to Hepatitis C over a year
33	Jane (Ms. Syariana Jane Kasim)	Independent working mainly in Taiping Perak, helps with NGOs for TG Women in Perak: Kopek and Pekasih	Does work all over Malaysia also
34	Tini (Ms. Khartini Slamah)	Asia Pacific Network of Sex Workers (APNSW) Founder & Asia Pacific Transgender Network (APTN) Founder	“Mama”, 31yrs in HIV, Hepatitis C new to us…need to share experience
35	Bryn (Ms. Bryn Gay)	Director, Hepatitis C Project Treatment Action Group (TAG), NYC, USA	
36	Ms. Karina Yong	Third World Network (TWN)	Diagnostics is new to everyone
37	Ms Chee Yoke Ling	Third World Network (TWN)	She/her
38	Dr Tan Soek Siam	Consultant in Gastronterology and Hepatology, Hospital Selayag Ministry of Health Malaysia	She/her
39	Dr Hoe Chee Hoong	Consultant in Gastronterology, Hospital Pulau Pinang Pulau Pinang	He/him
40	Edward Low	Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)	He/him
41	Jeremy Kwan Wing Kien	Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)	

APPENDIX 4: Learning Evaluation Form

Pre Test : HCV Diagnostics Advocacy Workshop, Penang. 1st – 3rd March 2019

Instruction : Please circle all the correct answers.

1. **Which of the following statements is NOT correct?**
   A. The majority of HCV infected persons will have persistent infection.
   B. Persons with acute HCV infection are often asymptomatic.
   C. Once HCV is cleared from the body (resolved infection), the antibody to HCV (anti-HCV) usually disappears and will no longer be positive.
   D. HIV/HCV-coinfected patients have faster progression to cirrhosis.

2. **Which of the following statements is NOT correct?**
   A. A positive HCV antibody test does not confirm the presence of active HCV infection
   B. Qualitative HCV RNA or Quantitative HCV RNA testing can be used to confirm active infection.
   C. The definition of chronic HCV infection is the persistence of detectable virus or active infection over six months after the estimated time of infection.
   D. We can assess the degree of liver fibrosis by testing ALT/AST, albumin, INR and bilirubin.

3. **We know the value of AST and Platelet of a patient. By which test can we assess liver fibrosis?**
   A. FIB-4
   B. APRI
   C. FibroTest
   D. Fibroscan

4. **A patient has Anti-HCV (+) and HCV RNA (-). What is the interpretation?**
   A. Recent infection
   B. Chronic or persistent infection
   C. Never infected
   D. Infection resolved or cured

5. **Which person does NOT have screening for HCV?**
   A. A 24 year-old pregnant woman (the HCV seroprevalence is 1.2% in her country).
   B. A 52 year-old man with liver cancer.
   C. A 47 year-old woman who received blood transfusion in 1990.
   D. A 62 year-old woman with kidney failure on regular haemodialysis.

6. **Which is NOT correct regarding assessment and monitoring of HCV treatment?**
   A. HCV genotyping is recommended for everyone before treatment.
   B. Non-invasive tests to assess for the presence of cirrhosis are recommended before treatment.
   C. Cure is assessed 12 weeks after treatment completion.
   D. In a patient with cirrhosis, surveillance for liver cancer should be done for even if after cure is achieved.

7. **Which of the following is NOT correct?**
   A. Reflex testing with HCV Core Antigen can be considered for those with positive HCV antibody to confirm whether or not there is ongoing active HCV infection.
   B. Sustained virological response is equivalent to a cure.
   C. HCV Core Antigen can be used to assess cure.
   D. Reflex HCV genotyping should not be considered for anyone with a positive HCV RNA test prior to treatment initiation.
   E. Either Qualitative HCV RNA or Quantitative HCV RNA testing can be used to assess cure.

8. **Which of the following is NOT true for HCV treatment?**
   A. All adults and children aged 12 years and above with chronic hepatitis C infection should be offered treatment with DAAs
   B. For people aged 18 years and above, “pangenotypic” DAA regimens should be used.
   C. 12 weeks of treatment is usually recommended for adults with chronic hepatitis C infection who do not have cirrhosis.
   D. DAA treatment duration is exactly the same for both hepatitis C mono-infection and HIV co-infection.
   E. 24 weeks of “pangenotypic” DAA regimen is recommended for all adults with chronic hepatitis C infection who have cirrhosis.

APPENDIX 5: Day 1 Breakout Group Outputs and Discussion Points

	Group 1	Group 2	Group 3
MEMBERS	**1.** Dr Janizah **2.** Effa **3.** Khartini **4.** Adzrin **5.** Rashid **6.** Hafiz **7.** Jega **8.** Fitri **9.** Khairu **10.** Siti	**1.** Dr Syed **2.** Reduwan **3.** Anu **4.** Am (Maslinah) **5.** Sazura **6.** Ferdaus **7.** Afiq (Apek) **8.** Razali **9.** Jane	**1.** Dr Tan **2.** Dr Anita **3.** Dr Azlina **4.** Dr Ruzi **5.** Dr Navneet **6.** Thilak **7.** Prof Ros **8.** Jaafar **9.** Kamal **10.** Yatie
TOPIC	Increase HCV screening in the community (2 groups created)		Decentralize HCV confirmatory testing; simpler HCV diagnostic algorithm and liver assessment (staging of liver disease)
OUTPUT	**a. Capacity Building** - Training to equip NGOs/ community based organizations (CBOs) with hep C knowledge - Ensure outreach workers are well versed in hep C; Provide Training of Trainers - Materials must be far more simplified and created in local languages **b. Public & Key Population Awareness Events** - Broad contexts: Outreach at shopping malls, public events - Personal testimonies and sharing by PLHCV **c. Scale up** of existing NGO HIV activities to include hep C as part of their outreach - Screening part linked to Key Population Indicators - Leverage on existing NSEP programs	**a. Awareness campaign for public and Key Populations** - For public: use KKs - For peers and community members: use simplified materials **b. Training of Trainers for Outreach workers** **c. Prioritize Community Based Testing (CBT), on site** - Leverage on existing HIV outreach programs to roll out CBT **d. Mobile Testing** - Use vans - Can be part of public campaigns such as on family testing days	**a. Make diagnostics a single step from the patients' point of view** - Whether or not there is RDT available - Take blood straightaway for lab tests and implement reflex testing for confirmation so patient does not have to return to clinic **b. Request all Community Clinics (KK) to have database for antibody positive cases** - Some may be HCV RNA negative…if positive send for next step immediately - Determine who should be prioritized and sent for treatment first **c. Include AST and Platelets Testing at KK level** - Include as part of their budget - Must have effective history of taking these tests

APPENDIX 6: Arising Strategies and Themes

1. Increase awareness among people at risk (KP) to get them to go for testing

- Must ensure testing facilities are ready and community friendly— can tie in to existing efforts to sensitize HCP for HIV
- Should leverage on existing HIV service delivery mechanisms for HIV, e.g., Outreach workers (ORW) to be trained to also cover hepatitis C awareness for peer outreach.
    - MAC has a simplified toolkit for this training and ORW can be trained under Global Fund and MoH funded trainings.
    - MTAAG's HCP toolkit in Malay can be the detailed "textbook" for their more detailed knowledge.
    - Pocket booklet on hepatitis C in simplified Malay with graphics has been produced by MAC for distribution to KP and the public.

2. Increase decentralization of HCV health services

- For example, simplify the steps for diagnostics to make it a single step for the patient (despite the two tests needed for screening and confirmation). Blood samples should be taken for confirmation at primary care when screening is done (whether or not Rapid Diagnostic Tests are available).
- Faster lab results and increasing decentralization of all related lab tests.

3. Collect more comprehensive HCV-specific data

- Common questions: What is the exact number of PLHCV because two figures are used. The correct national total estimate is 380,000 PLHCV, which reflects people with active (or chronic) infection, rather than 453,700 of people who have postive HCV antibody tests. Nearly 20% of people spontaneously clear the virus and do not require treatment.
- Collect the number of HCV antibody positive tests in the total number of people tested at all KKs.
- Ensure collection of RNA negative test results as well for comprehensive picture of the national epidemic.
- Compare and monitor the full cascade of HCV care for proper surveillance.
- Collect the number of people who may be actively injecting drugs and who access materials at NSEPs. These people may need to be tested.

- Examine diagnostics prices/costing for comparison. Collect information on the overall HCV care cascade costs (not just treatment costs), such as costs of diagnostics, liver staging, equipment, human resources, training, etc.

4. Strengthen and escalate advocacy for treatment availability

- For example, align advocacy with better patent controls and more stringent patentabilty criteria in Malaysian laws.
- Advocate for transparency (e.g., prices, registration filings) by pharmaceutical sector, including generics.

<u>Themes identified by Han Yang after Prof Rosmawati's presentation</u>:

(To keep in mind when developing activity/action plans).

a. Campaigns (online and 'old school' in-person)
b. Data and evidence is crucial for advocacy
c. NSP/National Action Plan/WHO strategy needs to be taken into account
d. Policy & Political Advocacy: Need to lobby MP and other decision makers
e. Financial & Budget
f. National and high-level discussions as platforms, e.g., National Hepatitis Conference; NSP finalization working group
g. Training/support for both HCPs and CBOs/Staff/Peers
h. Defining roles is crucial (who does what?)

APPENDIX 7: Advocacy and Partner Mapping

Organization/ Individual	Main Scope	Activities (especially in relation to hepatitis C, if any)
DNDI	HCV & research	Clinical trial for ravidasvir + FIND Study on testing (Sg Buloh , Ampang, Selayang, KB, Alor setar and the surrounding KKs)
Karisma	HIV & Drug Use	No specific HCV program Shelter, Peer support, Mainly in Kg Lamir
MAC	HIV all KP	HCV program funded by Coalition Plus - Projek Teman for 3 Prisons (to be opened to POs for implementation) not just for HCV/HIV but also psycho-social support - 2 Multiple Stakeholder Forum for HCV this year and next year - S&D sensitization for HCP (3 in 2019 and 4 in 2020) - Chemsex community care model, study on baseline (3 sites targeted) Training of HCV for ORW will be integrated into existing HIV programs
ECHO	HCV	ECHO To start out in UMMC as it is difficult to put directly under MOH as a foreign source program (not limited to hep C) Need help of community to trace default cases
FMS Dr Ruzi		Screened patients
Cahaya Harapan	HIV, Drug Use (TG/SW/MSM)	NSEP, MMT referral which includes hep C screening, TAPS (applying for sexual transmission pilot project)
Sahabat	HIV, Drug Use	NSEP, Shelter, TAPS, no direct focus on hep C but have referred TAPS and shelter clients for hep C
MASAC	Council for Substance Use	40 NGO members under them, training for NGO members, not well versed with hep C, open to doing training for hep C
Ikhlas	HIV, Drug Use	Support groups (NA), Outreach, NSEP Staff are ready to roll out a hep C program but not yet have the structure/funding to do so
DIC / KM	Drug Use, HIV	NSEP, TAPS, Shelters, Outreach, community burial Available and ready to do for hep C, just call them
Suhakam	Human rights for all	Covers health scope Awareness and research Advise and recommendation to government
Pengasih	HIV Drug Use	Rehab, outreach, shelter, NA support group, prison, affected families. Public awareness
FHDA	SRHR, HIV all KP	Outreach, VCT, CBT Clinic, PrEP & PEP
JKN Sabah	HIV MSM, TG, SW	Outreach, TAPS
AARG	HIV research, Drug Use	CBT, NSEP, MMT, Workshops for HIV awareness (even in schools), have fishermen Du clients - No update on hep C data for MMT clients, this needs to change

Organization/ Individual	Main Scope	Activities (especially in relation to hepatitis C, if any)
KOPEK	TG (Taiping, Perak)	Train community peer for outreach and stakeholder dialogue, volunteer based, Whatsapp based communication
TAG	HCV research, policy and advocacy	Can provide technical assistance and advocacy materials, if needed
FIND	HCV diagnostics development	Can provide technical assistance, if needed

APPENDIX 8: Day 3 Breakout Group Activity Plans

Group 1 : Capacity Building (Training of Outreach Workers)

Activities	Key Milestone + Timeline (July 2019)	Who involving + lead	What support needed
1. Capacity Building	- Training & equip NGO with knowledge - Communication skills - Healthcare tool kit	Outreach Worker (ORW) + Leady by MTAAG+, MAC & MOH	Part of existing HIV outreach worker training (Twice a year: May & Sep 2019)
	- Identify trainers e.g. Hepatitis Free Malaysia, DNDi, MTAAG+, MAC & MOH FMS	Management staffs	- Funding * Trainers - IEC Materials
	- Confirm suitable NGO & venue for training		
	- Follow up (Whatsapp group) - Training - Feedback		

Group 2 : Community Based Testing*

Activities	Key Milestone + Timeline (July 2019)	Who involving + lead	What support needed
1. Community Based Testing	1. Training / Knowledge to ORW - HCV toolkit (Q2 2019) 2. Integrate HCV into HIV CBT module - Timeline: April - June 2019	ORW, MAC, FHM, & MOH	1. MOH/MAC funding, trainer, HCV toolkit for community (integrate into NSEP training)
	2(a). Discussion with MOH on HCV – HIV integrated CBT module - Timeline: Q3 2019	MOH, MAC & NGO	2. Meeting venue – Putrajaya (or any venue) with funding
	2(b). HCV CBT Training (Training for Testing) - Timeline: Q1 2020	MOH, MAC & NGO (send participants)	- Screening toolkit - FMS - Clinic / Healthcare setting as training venue

* Need to ensure there is proper linkage to care before actual roll out so for now just plan up to training

Group 3 : Diagnostics (Screening/Confirmation)

Activities	Key Milestone + Timeline (July 2019)	Who involving + lead	What support needed
1. KK – FMS Keen to participate - Methadone Clinic - STD Clinic - HIV Clinic	1. Retrieve List & Confirmation - Decentralization (Sample to Hospital) - After discussed with Gastro Team, $$$ budget - Timeline: March / April 2019 * Keen for treatment: - Select those keen - If keen them proceed - If not keen then STOP	Team I/C Methadone (FMS)	Funded * National Policy - Done by National Technical Working Group
2. Assessment of Liver (only for HCV confirmed cases)	*** One Visit & One Prick** 2. Inclusion of AST Level (as part of APRI score) - Timeline: July 2019	Team I/C Methadone (FMS)	
3. Community Engagement for HCV Screening	*** One Visit & One Prick** - Timeline: July 2019	– mainly by NGO (case workers)	

APPENDIX 9: Malaysian AIDS Council Background Documents for Health Care Providers

(Highlights in yellow are points identified by a leader from Hepatitis Free Malaysia as important points to focus on that align with the workshop's focus).

Note: This proposed action plan is the product of output from the 2 workshops below which were organized by MAC:

- Held in Kuala Lumpur on 22nd & 23rd November 2018
  - "Collaborative Efforts with MOH of Malaysia and NGOs: Enhancing Surveillance: Increasing Awareness and Eliminating HCV"
- Held in Johor Bahru on 3rd December 2018
  - "Improving Awareness on key population health needs and Hepatitis C (HCV) among health care workers and communities"

Output from the abovementioned workshops includes draft proposed action plans which have been combined into a single plan using the 5 "National Strategic Plan for Hepatitis C" Priority Areas for categorization. The timeframe discussed was 2019 but these activities can be ongoing beyond 2019.

National Strategic Plan for Hepatitis C Priority Areas

Strategy 1 : Advocacy, communication and social mobilization
Strategy 2 : Improving quality and coverage of prevention
Strategy 3 : Improving access to diagnostic, treatment and care
Strategy 4 : Ensuring quality strategic information and its use by policy makers and planner through monitoring evaluation and research
Strategy 5 : Capacity Building and Enhancement

ACTION PLAN

Strategy 1 : Advocacy, communication and social mobilization

Activity	Parties involved
1.1 Produce and distribute IEC materials for public awareness & education on importance of testing and treatment of hep C • printed • online via social media • Talk shows or Public service announcements on radio/TV	MOH, MAC, MTAAG
Note : *MAC has produced 2 IEC materials in Malay* 1. *Community friendly toolkit for outreach workers which is made available online and promoted on social media* 2. *Pocket booklet targeted at KP* *Both of these can be used for promoting public awareness as well*	

Activity	Parties involved
1.2 Campaigns and events for world hepatitis day July 28th • Should be month long for the whole month of July • Hospital and district based for public, set up booths at popular malls or other public spaces as well o Clinic and NGO based for at risk populations	MOH, MAC, all NGOs
1.3 Raising awareness and interest among other organizations and agencies relevant to key populations at risk of hep C • Dialog sessions and Common Memorandum of Understanding or guidelines o Eg : employers most affected by hep C (fishermen association, FELDA) to include hep C etc through KOSPEN (Komuniti Sihat Perkasa Negara) Plus Model's screening component • Promotes healthy and productive workforce via better working environment	MOH and relevant agencies/organizations

Strategy 2 : Improving quality and coverage of prevention

Activity	Parties involved
2.1 Raise awareness among prisoners, drug rehab inmates, drug use shelter residents and other high risk key population groups • Talks and Kem Kesihatan (health camps) • Outreach programs leveraging on existing HIV efforts o Utilize tablet/smart phone educate KP at risk as well as PLHCV on hep C and its treatment (Promote IEC materials under 1.1) ▪ eg MAC community friendly printed booklet and online toolkit with graphics/pictures showing hep C complications and flow of hep C treatment ➢ need to emphasize how to avoid reinfection of hep C if KP is still involved in at risk activities	MOH, MTAAG, AADK, Prisons Dept, DU NGOs
Note: *MAC's existing network of outreach/case workers and peer supporters for HIV to be trained using the community friendly online toolkit to enable them to educate Key Populations when they distribute the printed pocket booklet. (MTAAG's toolkit for HCP which is more detailed can be used an additional reference for the outreach/case workers)*	
2.2 Research to identify who are the at risk populations in each state • small scale/state level research, survey or data analysis for better understanding of the situation locally	MOH,MAC, MTAAG, NGOs

Activity	Parties involved

2.3 Dialogue with relevant authorities governing guidelines to places that are potentially risky for hep C transmission
• ensure proper awareness of as well as compliance with legislation/regulation/guidelines
• produce any necessary legislation/regulation/guidelines for this if there are none in existence
• places that are potentially risky for hep C transmission may include centres that perform services for
  ○ bekam (cupping)
  ○ tattoo
  ○ acupuncture
  ○ shaving/hair removal with razors
  ○ manicure/pedicure and foot scraping
	MOH, relevant enforcement authorities

Strategy 3 : Improving access to diagnostic, treatment and care

Activity	Parties involved

3.1 Widen testing of hep C not just via KK clinics but also through community based testing by NGOs
• Supply of rapid test kits (RTK) needs to be expanded to ensure availability at clinics & other testing sites
  ○ provide training to outreach workers in NGOs on how to use them for community based testing
• Target Prisons, rehab centres (AADK) and shelters for DU
  ○ Need to target rural areas as well so needs to be done on site along with outreach programs
  ▪ can combine with existing HIV efforts by NGOs
• Integrate into school and PMTCT (Ante natal) programs
	MOH, MAC, MTAAG all NGOs

Note: *MTAAG has been conducting hep C awareness sessions combined with offering voluntary hep C testing at prisons and shelters for people who use drugs*	
3.2 Produce and disseminate hep C clinical practice guidelines (CPG) to facilitate & simplify the understanding of hep C testing algorithm (& treatment) • Sustainable Lab testing with better coordination • easily accessible and quicker hep C serology (confirmation test) ○ ensure necessary infrastructure/equipment in place at confirmation centers • Need for Hepatologist in each state • Decentralize treatment (refer strategy 5.1)	MOH
Note: • *Target for CPG by MOH is end of 2019* • *MTAAG has reference material for HCW which can is available online and can be distributed as additional reference*	

Activity	Parties involved

3.3 Support group for treatment adherence (clinic based or at NGOs)
• Support from case workers and peer supporters from NGOs (can be leveraged on existing HIV case workers/peer supporters)
  • Assist with PLHCV defaulter tracing
• Education of PLHCV on hep C and its treatment using MAC community friendly toolkit online resource in Malay
  ○ Indirectly spread good "rumors" that hep C is curable
  ○ Discuss ongoing revision on allocation of funds to treat PLHCV
	MOH, MAC, MTAAG

Note - *MTAAG already has a group of PLHCV meeting regularly* - *MAC to train existing case workers and peer supporters to add hep C treatment adherence as part of their skills/knowledge as a service for clients*	
• In high volume clinics have a dedicated HCW team with person-in-charge to manage PLHCV appointments and follow-up for more personalized care for PLHCV • Start with pilot at selected KK and replicate to other STI friendly KKs with high number of PLHCV • Ensure sufficient Lab resources for treatment and surveillance • Collaborate with peer supporters from NGOs for PLHCV defaulter tracing	
3.4 More effective Drug procurement and treatment availaibity • Better Strategy for Licensing • Allow Voluntary license for generic medicines • For Better drugs availability and more Information on new drugs • advocacy to make more meds available and minimize waiting list for treatment	MOH, MTAAG, DNDI, TWN

Strategy 4: Ensuring quality strategic information and its use by policy makers and planner through monitoring evaluation and research

Activity	Parties involved
4.1 Better Data surveillance via proper notification practices as SOP under new clinical practice guidelines (CPG)	MOH
4.2 Establish proper hep C separate registry • for full case details ○ Case investigation	MOH
4.3 More research trials on newer drugs to fast track registration	MOH, DNDI, MTAAG

Strategy 5 : Capacity Building and Enhancement

Activity	Parties involved

5.1 Training of FMS and other ID unit HCW (Mom SN, MA) on hep C service provision
• including FMS training to handle treatment to enhance decentralization of treatment
• Need CPG and related Training modules
• CME and echo trainings/knowledge sharing sessions
  ○ Online module
  ○ Clinic attachment (rotation)
• Include
  ○ overcoming stigma & discrimination,
  ▪ how to be more caring/sensitive towards KPs and PLHCV
  ○ appropriate counselling approaches and techniques as well as ensuring privacy confidentiality
  ○ Risks vs Benefits of starting treatment, latest treatment options and availablity
  ○ importance of and techniques for defaulter tracing including cooperation with NGOs
refer strategy 3.2 on CPG
	MOH, MAC, MTAAG

Note (added on after MTAAG workshop in March 2019) *UMMC is taking the lead to bring the ECHO model here for capacity building of HCP and this can be leveraged upon for this strategy*	

5.2 Raise awareness about hep C among all other (non ID unit) HCW
• CME and echo trainings/knowledge sharing sessions
  ○ Online module
• Include
  ○ overcoming stigma & discrimination,
  ▪ how to be more caring/sensitive towards KPs and PLHCV
	MOH, MAC, MTAAG

APPENDIX 10: List of Questions Raised at 4th National Hepatitis Conference

Testing (Diagnostics)

- Is decentralization and simplification of hep C diagnosis at government community clinics (KK) possible and what would be the timeline for this?
- If so, we would propose for screening and confirmation to be done via only one visit to the KK FMS—whereby enough of the blood sample is taken during the screening visit to also do a confirmation test (if detected HCV antibody positive) without requiring the patient to be referred to a hospital or to return for another visit to take another blood sample (satu kunjungan, satu pemeriksaan untuk saringan dan konfirmasi/"one visit, one prick for screening and confirmation).

Treatment availability

- Are the DAAs that are allocated for the 2,000 people, who need to be treated for hep C in 2019 under the government budget, readily available (Is there already enough stock of the meds in the treating hospitals)? There are many of our clients on the waiting list for treatment. Can the allocation be increased if fully utilized within the year?
- Are there plans to increase the allocation for DAA meds under the government in 2020 especially if more generics are available and pricing goes down?
- *(Note: We know generic companies are trying to get registered here under NPRA for generics to be available in Malaysian market. NPRA expects a successful registration of a hep C generic DAAs within Q1 2019. The generic companies seeking registration are confident to be able to supply generics at much lower prices to make it more affordable once they do get registered.*
- In the longer term, will treatment be decentralized to the KK under FMS providers? If so, is there any proposed timeline for this?
- What is the timeline for training under the hepatitis C treatment training module? Who will be trained under this module? Is it part of the decentralization of treatment efforts by MoH?
- *(Note: Parts of the training module were launched during the NHC's morning session on 8 March, 2019.)*

Patents and licensing

- Does the government plan to tighten our legislation for patent requirements, as allowed under TRIPS Agreement, because Malaysia is comparatively lenient in our patent registration requirements/specifications?

HCV specific surveillance data

- Is the data captured for infectious disease, like the current hep C "e-reporting" system, sufficient to produce the statistics for monitoring the full HCV treatment cascade, so that we can track our progress towards the 2030 elimination goals?

National Strategic Plan for Hepatitis C

- Overall, what is the government budget allocation for hep C?
- What is the timeline for finalization of the national strategic plan for hep C and how has civil society's input been incorporated into the draft, so far? What is the finalization process? Will the plan be fully costed?
- Will a National Task Force be set up for hep C and how will civil society representatives be included?
- Will the MoH have a specific allocation for hep C in upcoming government budgets for 2020 and onwards? If so, is there any possibility for allocation for NGO/CSO based interventions?

APPENDIX 11: CSO "Wishlist" (Call for Action) Presented at CSO Dialogue

1. Testing (Diagnostics)

- Scaled up targeted screening of high risk clients:
  - NSEP clients not yet screened
  - Prison inmates
  - Residents of rehab centres and shelters for people who use drugs (both Agensi Antidadah Kebangsaan/National Anti-Drug Agency [AADK] and NGO-run)
  - Clients enrolled in private sector MMT/MAT or other drug substitution therapy services. (Ensure continued screening of clients under government-funded MMT programs when they start treatment as well as routine re-screening if people tested negative).

- Decentralization and simplification of hep C diagnostics at government clinics (KK).
- Screening and confirmation can be done via one visit to the KK FMS—whereby enough of the blood sample is taken during the screening visit to also do a confirmation test (if detected HCV antibody positive) without requiring the patient to be referred to a hospital or to return for another visit to take another blood sample (satu kunjungan, satu pemeriksaan untuk saringan dan konfirmasi/"one visit, one prick for screening and confirmation).

- Speedier results for lab-based tests, e.g., confirmation, liver assessment/staging.
  - Ensuring shorter waiting periods which is crucial to minimize loss-to-follow up of patients.

- Community-friendly hep C-related service delivery, such as outreach and testing conducted by both CSO peer-to-peer intervention workers and government/private sector healthcare providers.

2. Treatment availability

- Increased allocation for free DAA meds in government healthcare settings.
- Reduction of prices for DAA meds for patients who opt for private sector treatment.
- Waiting list (warehouse) of patients waiting for treatment cleared as soon as possible with the availability of both free government-based treatment and affordable private sector treatment.

- Decentralization of treatment to KKs under the care of FMS.

3. Regulatory initiatives

- Registration of as many generic DAAs as possible which comply with NPRA standards for registration.

- More stringent patent requirements/specifications, as allowed under the TRIPS Agreement, to be incorporated into our legislation.

- Enforcement of regulations to ensure safe service delivery by centres which provide acupuncture, tattooing, ear/body piercing, cupping (bekam) and other procedures which are potentially risky for hep C.

4. National Strategy & Public awareness

- A fully costed national strategy plan for hep C which includes civil society input.

- Specific allocation for hep C in upcoming government budgets for 2020 and onwards, including allocation for NGO/CSO based interventions.

- National Task Force for Hepatitis C to be set up as soon as possible.
  - Meaningful engagement and representation from key affected populations in the National Task Force. The necessary support and resources for the representatives to fulfil their functions must be allocated accordingly.

- Regular updates with community on the hep C treatment cascade in order to monitor progress towards the 2030 elimination goals.

- Public awareness campaigns first and foremost targeted at higher risk populations, then the public in general, with emphasis on the importance of early detection to ensure effective treatment.