A REPORT ON THE MULTI-STAKEHOLDER FORUM ON

NATIONAL HCV RESPONSE 2019

Closing the gaps in HCV Response: Strategy on the Hard-to-Reach Populations

A JOINT INITIATIVE

Malaysian AIDS Council | The Ministry of Health, Malaysia
Drugs for Neglected Diseases Initiative (DNDi) |
Civil Society Organisations

11 November | Hotel Tamu & Suites, Kuala Lumpur

CONTENTS

List of Terms and Abbreviations

CL	Compulsory Licensing
CSO	Civil Society Organisation
CW	Case Workers
DAA	Direct-Acting Antivirals
DBS	Dried Blood Spot
DNDi	Drugs for Neglected Diseases Initiative
FIND	Foundation for Innovative New Diagnostics
FRHAM	Federation of Reproductive Health Associations, Malaysia
HCV	Hepatitis C Virus
HCW	Health Care Worker
HEAD-START	Hepatitis C Elimination through Access to Diagnostics
IEC	Information, education and communication
KK	*Klinik Kesihatan* (Government Health Clinics)
MAC	Malaysian AIDS Council
MPD	Malaysian Prisons Department
MTAAG+	Positive Malaysian Treatment Access & Advocacy Group
MOH	Ministry of Health, Malaysia
MOHA	Ministry of Home Affairs, Malaysia
MPP	Medicine Patent Pool
MSM	Men who have sex with men
MyIPO	Intellectual Property Corporation of Malaysia
ORW	Outreach Workers
PKKUM	Pertubuhan Kebajikan dan Kesihatan Umum Malaysia
PLHCV	People Living with Hepatitis C
PLHIV	People Living with HIV
PWID	People Who Inject Drugs
RDT	Rapid Diagnostic Test
SEED	Pertubuhan Kebajikan dan Persekitaran Positif Malaysia
SVR	Sustained Virologic Response
TB	Tuberculosis
TG	Transgender
WHO	World Health Organization

EXECUTIVE SUMMARY

In 2016, a global strategy to eliminate viral hepatitis C (HCV) by 2030 was adopted by WHO member states, including Malaysia. The following year, the Malaysian government issued a compulsory licensing (CL) to a generic version of HCV medicine called Sofosbuvir despite facing pressures by the U.S. government and patent-based pharmaceutical companies. This was seen by many as an admirable decision to make life saving medicine available for the estimated 450,000 people living with HCV (PLHCV) in the country with an HCV viraemic prevalence that is estimated to be 1.8% of population aged 15 to 64 years old. Subsequently, in conjunction with the National Hepatitis Day on 27th August 2019, the Ministry of Health had launched the first ever National Strategic Plan on Hepatitis B (HBV) and Hepatitis C (HCV) (2019 – 2023) to combat the hepatitis epidemic in the country.

This report summarises the findings from a landmark event – the 1st Multi-stakeholder Response on HCV Response – themed "Closing the gaps in HCV response: Strategy on the hard-to-reach populations" that was attended by representatives from the Ministry of Health, Prisons Department, Non-Governmental Organisations (NGOs) and Civil Society Organisations (CSOs) that was held on the 11th November 2019 in Kuala Lumpur. An Action Plan to improve the gap in accessing HCV diagnostic and treatment was conceived.

Objectives of the Forum

To share experiences and results from the current program approaches

To discuss opportunities and challenges in the current program implementation in accessing to diagnostics and treatment

To generate common understanding on the current situation of national HCV response and the National Strategic Plan on Hep B & C

To build network and strengthen the collaboration and the roles of service providers with local CSOs and ensure for the future monitoring response and feedback

The 1st Multi-Stakeholder Response on HCV Forum consisted of two sections. In Part 1, the current national HCV response in Malaysia was presented. This was followed by a panel and group discussion that had resulted in the conceptualisation of an action plan in Part 2. This one-day forum was attended by stakeholders from the NGO (MAC); government agencies (MOH, AADK, Prison Department); international NGOs (WHO, DNDi, TWN); as well as CSOs and KPs, (MTAAG+, Insaf Murni, PKKUM, FRHAM, SEED, Sahabat, Cahaya Harapan, KOMITED, KARISMA, and AARG).

In summary, participants were briefed on the Malaysian government's efforts in HCV elimination by obtaining Sofosbuvir through CL that had begun in 2015; subsequently, the formation of the National Strategic Plan on HCV Elimination (2019 – 2023) at the national level; as well as at the local level, i.e. upscaling HCV screening initiatives through the FIND Study and decentralisation of HCV services in *Klinik Kesihatan* (KK). Besides that, key population (KP) representatives had also presented the gaps in accessing HCV services in community settings.

The forum provided the platform for stakeholders to identify gaps and challenges, as well as opportunities and best practices to screen, diagnose and treat individuals with HCV infection, and to ensure that they are provided a continuum of care based on the HCV Treatment Cascade. Based on the sub-themes below, an action plan was developed to improve gaps in accessing HCV diagnostic and treatment with the resources required or currently at disposal.

WELCOMING & OPENING REMARKS

Prof. Dato' Dr. Adeeba Kamarulzaman, Chairperson of the Malaysia AIDS Foundation (MAF) and Vice President of the Malaysian AIDS Council (MAC) welcomed the participants to the multi-stakeholder forum. She shared that with safer drugs, the government's action to obtain Sofosbuvir through CL, and better diagnostic lab facilities and technologies, many will be able to benefit from the HCV treatment very soon. She encouraged the CSOs to assist the MOH in the expansion of treatment.

Next, Datuk Dr. Christopher K. C. Lee, Deputy Director of General Health, Research & Technical Support (MOH) in his opening speech stressed on the importance of this forum as a platform to ensure that HCV treatment reaches the population that needs it.

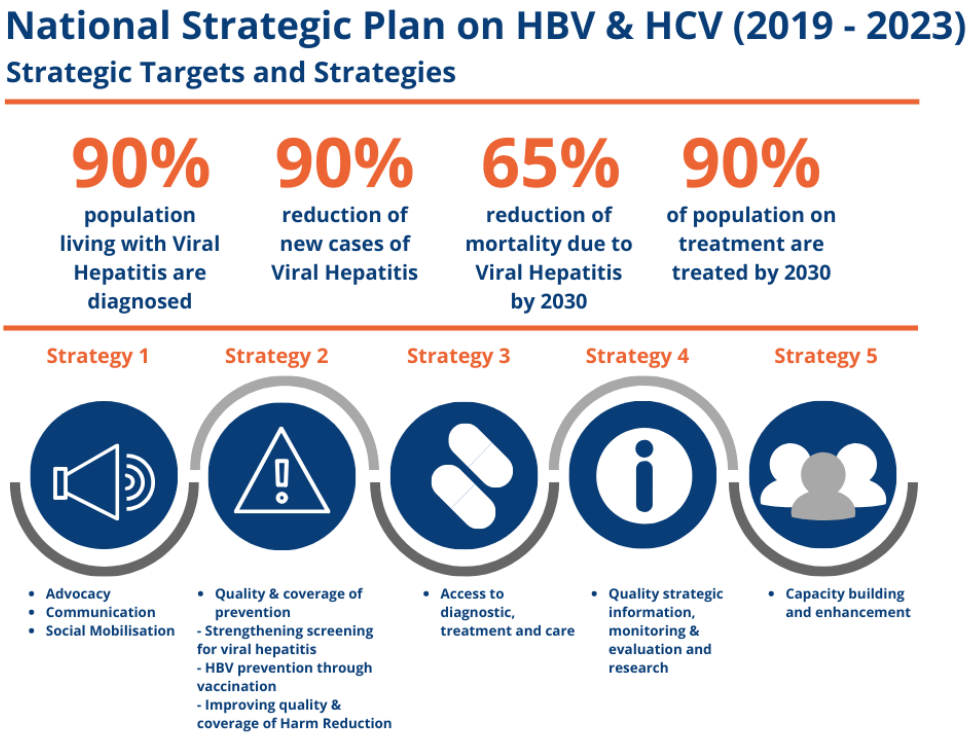
He shared that the government has taken a courageous step to push for CL despite foreign pressure and threat on our trade, and encouraged the participants to make this effort worthwhile. He reiterated that much lessons can be learned from the HIV experience in scaling up HCV services. He shared that the participants should utilise this platform to strengthen networking with each other, and have frank, precise, accurate, realistic and pragmatic discussions.

UPDATES ON THE HCV SITUATION IN MALAYSIA

Overview of HCV Situation in Malaysia and the National Strategic Plan on Hepatitis B & C (2019 – 2023)

This session was presented by Head of HIV/STI/Hep C Unit, Dr. Anita Suleiman. Below are the summary points from her presentation:

- 453,700 PLHCV (2.5% population 15 – 64 years old) (McDonald etc., 2015)
- A National Strategic Plan (NSP) for Viral Hepatitis is needed due to the disease burden in our country. Moreover, HCV is preventable, treatable, and curable.
- The NSP provides a framework for structured, comprehensive, and extensive programme on viral hepatitis.
- The objectives, strategic targets, and five core strategies were elaborated.

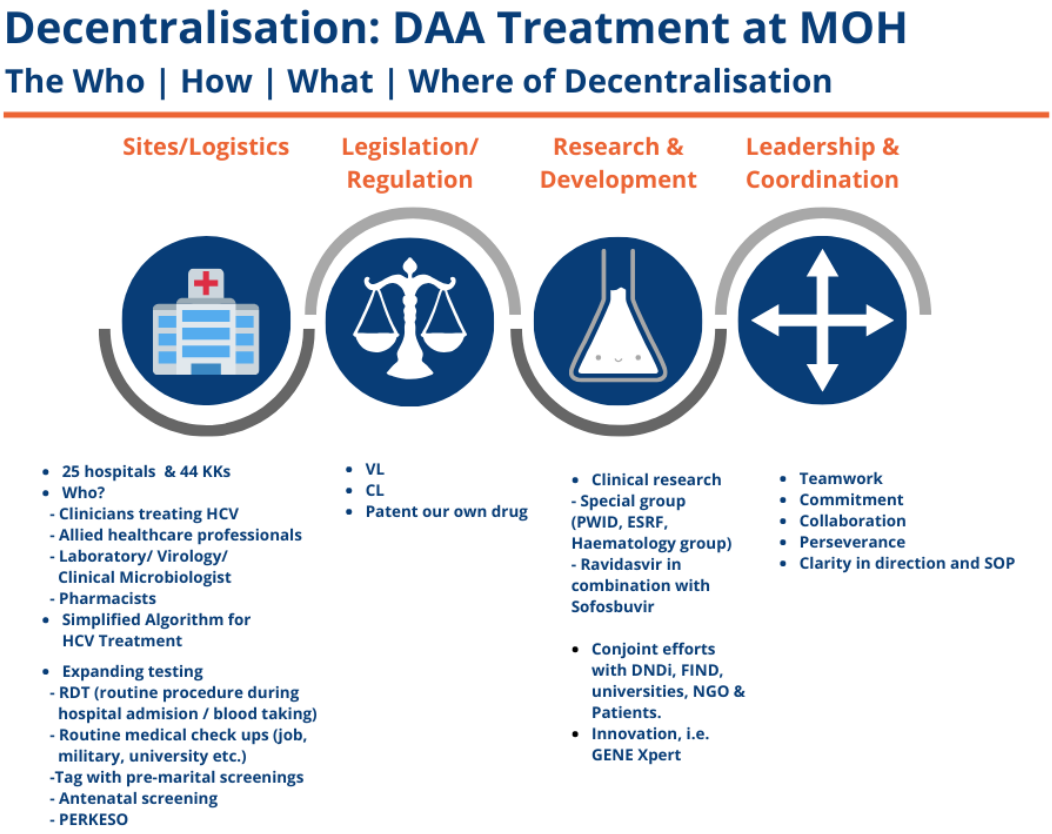


Decentralisation of HCV Services: Direct Acting Antivirals (DAA) Treatment at MOH

This session was presented by Dr. Hajah Rosaida Hj. Md. Said, Senior Consultant Gastroenterologist and Hepatologist from Hospital Serdang. Below are the summary points from her presentation:

- Decentralisation involves the following 4 aspects:
    i. Sites/Logistics
    ii. Legislation/Regulation of Medicine
    iii. Research and Development
    iv. Leadership/Coordination

- DAAs are medications targeted at specific steps within the HCV life cycle.
- DAAs started in March 2018 in 14 hospitals and expanded to 44 hospitals and 25 KKs in 2019[1]

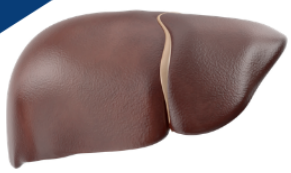


[1] Under the HEAD-Start FIND Project, a total of 5 hospitals and 25 KKs are involved in the study. Please see the related section on page 9 for more information.

KEDAH CASE STUDY

Achievements

HCV Positive : 136
No. treated : 34
SVR : 9



High Risk Client

HCV Serology

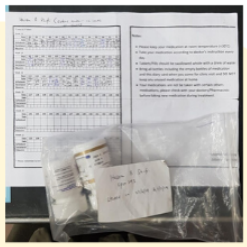
Negative → Health Education/ Discharge

Positive → Send for VL & Genotyping

HCV RNA

Positive → 1. Assessment for Cirrhosis 2. Other assessments, e.g. renal profile, HIV/HBV etc.

Negative → Health Education/ Discharge



- Ticking done by Pharmacist after DAAs served

Liver Cirrhosis

Yes → Refer to Gastroenterologist

No → Start Treatment x 12 weeks

Viral Load after 12 weeks upon treatment completion

Positive → Refer to Gastroenterologist

Negative → Health Education/ Discharge

Inclusion Criteria

- HCV Positive serology & HCV RNA
- No co-infection HBV/HIV/TB
- Renal function eGFR >30
- No cirrhosis
- Agree to treatment

81% of active MMT clients are HCV Positive

Why? Decentralisation improves access to treatment through existing health clinic system

Best Practices

Currently running in 6 *Klinik Kesihatan*

KK Bandar Sg Petani
KK Bandar Alor Setar
KK Bakar Arang
KK Kuala Kedah
KK Pendang
KK Ayer Hitam

Start with existing High Risk Clients

- Methadone Clinic - Clients who are on Methadone Replacement Therapy
- STI-friendly clinic
- Out-patient clinic
- Referral by NGO, i.e. Cahaya Harapan

Klinik Kesihatan with FMS as CENTRE OF TREATMENT

TEAM
FMS
MOs
Pharmacists
Paramedics
Lab technician

Easy to dispense during Methadone DOTS

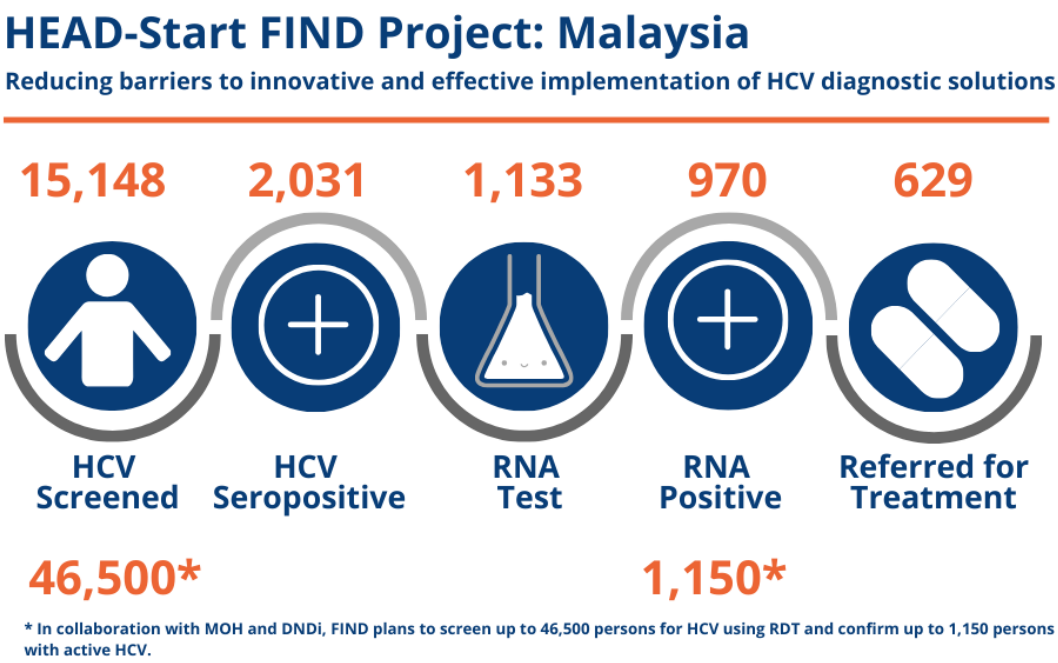
Ensure completion of therapy

TRAINING
The existing team in charge of Methadone Replacement Therapy can be trained on HCV Management

**Extracted from Dr Habshoh Binti Hat's presentation entitled "Decentralisation of Hepatitis Treatment: The Kedah Experience". She is the Family Medicine Specialist from KK Bandar Sg Petani.*

Sharing findings from the FIND HEADS-Start Project & Next Steps

This session was presented by Ms Sem Xiao Hui, the Country Manager of this project. The Hepatitis C Elimination through Access to Diagnostics (HEAD-Start) project aims to improve diagnosis of HCV by making it more affordable and widely available to those in need, with a focus on serving people co-infected with HIV. This project involves 5 hospitals, 25 KKs, 1 central laboratory, 157 registered investigators, and over 300 staff.



The capacity of our health care provides were improved through the activities conducted under this project. These include:

- Training workshops for health clinic staffs[2];
- Refresher training workshops for health clinic staffs[3];
- Site trainings at KKs on RDT demonstration by FIND Geneva-based lab coordinator;
- HCV and diagnostic training for CSO representatives;
- Grants for PWID CSOs to educate and refer clients to KK for RDT screening, as well as follow up on HCV positive clients;
- Cross learning trip[4];
- GeneXpert POCT training;
- Organising the National Hepatitis Conference and World Hepatitis Day 2019.

[2] Topics: HCV RDT testing, disease biology and infection control, testing technologies, pre and post-test counselling.
A total of 170 persons were trained, including 116 health workers and 24 lab workers.

[3] Topics: HCV training module in primary care setting, DAA MTAC, special populations, sharing by CSO representatives.
A total of 125 persons were trained, including 92 health workers and 8 lab workers.

[4] To Georgia

Sharing of findings from the Community

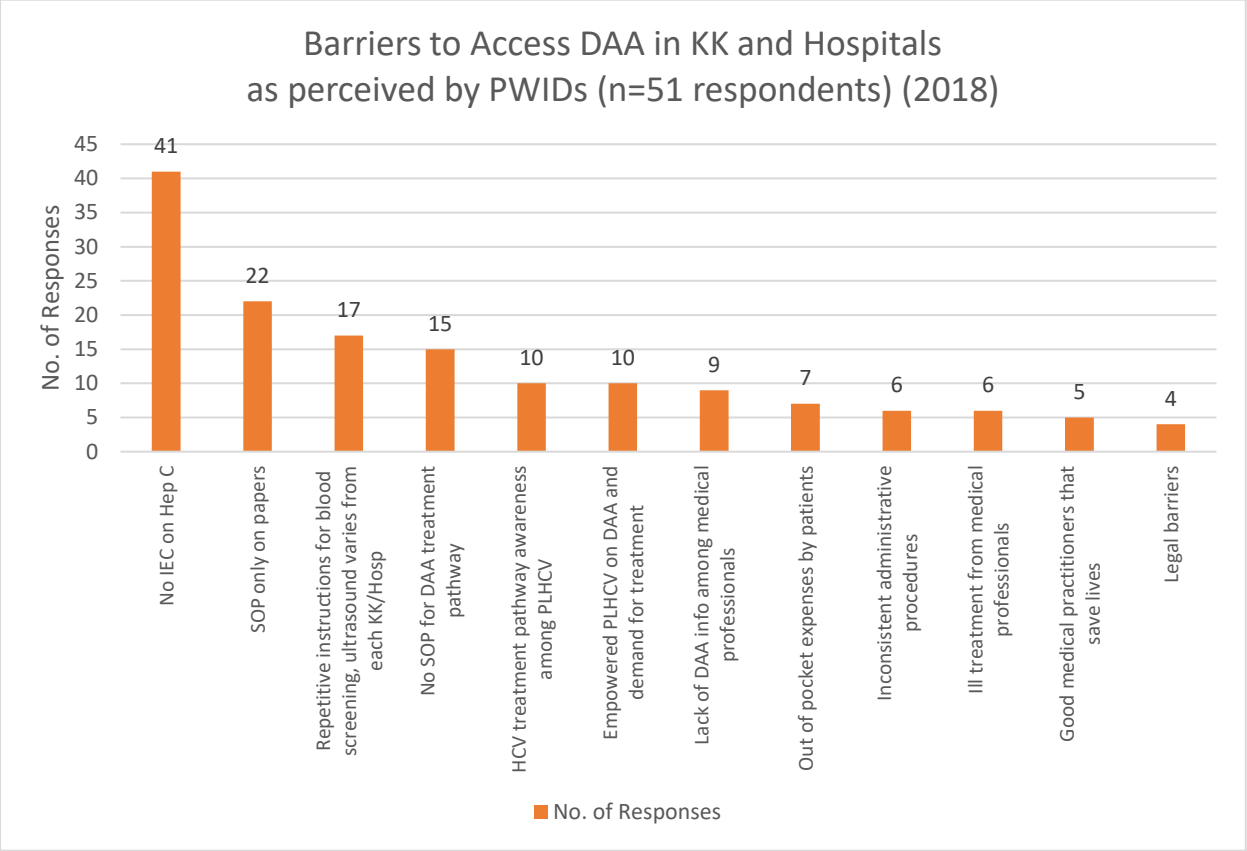
This sub-section comprises two presentations of findings from the community.

The first presentation was on the findings from the CPLUS/FIND community consultations in accessing to HCV diagnostics and treatment by Ms Anushiya Karunanithy from MAC, summarised below:

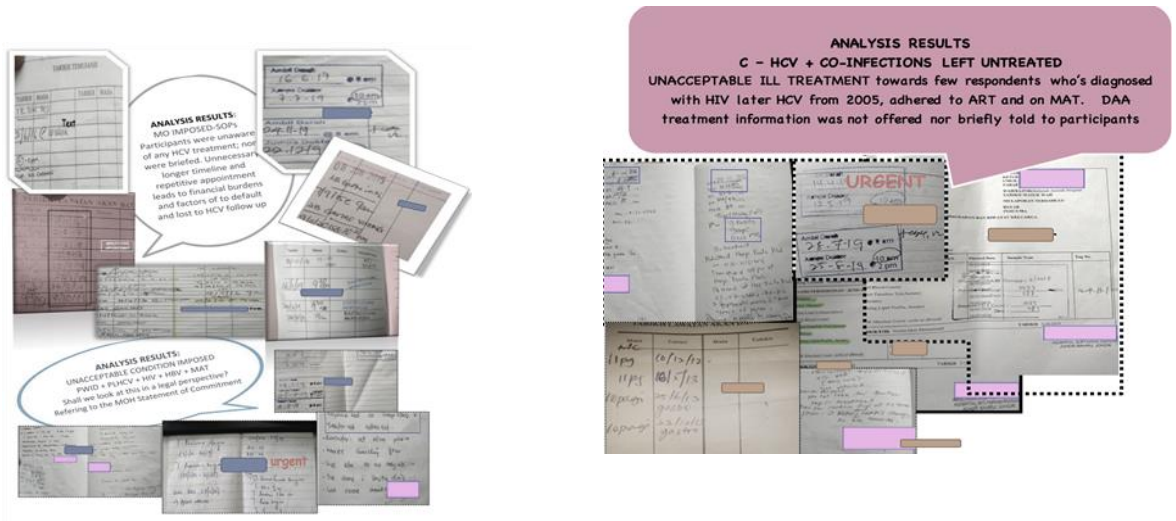
Strategy	Closing The Gap	Proposed Activity/Action
1. ADVOCACY, COMMUNICATION & SOCIAL MOBILISATION	How to properly target KP in awareness campaign to increase screening and treatment demand	Increase awareness through social media and simplified IEC materials
	How to reach communities that are the most marginalised	Joint collaboration between CSO and KK/AADK/Prison
	How to ensure participation of communities in the continuous medical education program of the MOH	Monthly talk at KKs/NGO Drop-in centres
2. QUALITY & COVERAGE OF PREVENTION PROGRAMMES	How to gain common support from both MOH and MOHA to obtain budget for access to treatment in prisons	MoU between MOH & MOHA (Prison Health Settings to ensure supplies of medical person & medicines)
	How to decentralise treatment in prisons without clinics and doctors	Training for MOs in the prison (Echo model), Training the NGO as para-counsellors and compulsory screenings at entry point
	How to ensure continuous availability & accessibility to treatment	Advocate to policy makers through cost effectiveness study and return of investment (ROI)
3. ACCESS TO DIAGNOSTIC, TREATMENT & CARE SERVICES	How to motivate KK to express interest to join decentralisation efforts	Training FMS and increase knowledge of HCWs at KKs
4. QUALITY STRATEGIC INFORMATION, M&E AND RESEARCH	How to ensure adequate geographical coverage of screening and treatment efforts (i.e. adequate resources)	Standardised SOP (confirmatory test at KK level, long waiting follow-up process)
	How to advocate to obtain an increased budget for HCV diagnostic and treatment to reach the 2030 targets	Advocate to influence policy makers (i.e. MPs) to increase budget for Hep C (PEKA B40)
5. CAPACITY BUILDING	To reduce stigma and discrimination	Using the HOPE module to train more healthcare workers at KKs
	KP approach to test and treat	Training ORWs/CWs on Hep C and train Hep C champions among CSOs
	Specific key pop needs (illiterate population and other hard to reach key pop)	Community based testing/Health camp

Next, findings from a community-led study on the barriers faced by PWIDs to access DAA at primary health care settings was presented by Ms Yatie Jonet, consultant with MTAAG+ and PLUS.

A total of 51 respondents were recruited for this study. Majority of the respondents cited that there was a lack of IEC materials on HCV. Although almost half cited that available SOP is only on papers, almost a third (29%) also cited that there was a lack of SOP for DAA treatment pathway, whereas one fifth (20%) mentioned that PLHCV were unaware of the HCV treatment pathway.



One of the major challenges identified is that **PWIDs with HIV and HCV Co-infection were left untreated.**



Snapshot of findings obtained from the presentation.

The HOPE Module: An Anti-Stigma & Discrimination Training Module on HIV-HCV for Health Care Workers and Key Populations

This section was presented by En. Azman Mohamed, Psychology Officer from the HIV/STI/Hep C Sector under the Disease Control Division.

HOPE = *Hentikan Stigma dan Diskriminasi kepada Orang yang Hidup dengan HIV/AIDS (ODHA) dan Key Populations*

It is inline with the NSP for Ending AIDS (2016 - 2030) Strategy 3: Reduction of Stigma and Discrimination

The #MYMissingMillions and #AkuJanjiUbatiHepC are two campaign initiatives by the MOH and MAC to increase awareness on HCV and reduce stigma and discrimination related to it.

TOPIK-TOPIK DARI MODUL HOPE

Sesi 1: Stigma Walk
Sesi 2: Pengenalan Bengkel
Sesi 3: Perkongsian dari KP
Sesi 4: Penerokaan Sistem Kepercayaan, Corak Pemikiran dan Sikap yang Menyumbang kepada Komunikasi Stigma
Sesi 5: Terma & Definisi
Sesi 6: Pengenalan kepada Orientasi Seksual, Identiti dan Ekspresi Gender
Sesi 7: Pengenalan kepada Populasi Tertumpu (Key Population) dan ODHA
Sesi 8: Carousel of HIV
Sesi 9: Pengenalan kepada Stigma dan Diskriminasi
Sesi 10: I AM YOU (Saya sebagai KP)
Sesi 11: Syok dan Sweet
Sesi 12: Isu-isu lain

PANEL DISCUSSION ON THE CURRENT SITUATION IN ACCESSING HCV DIAGNOSTICS & TREATMENT

This sub-section of the report summarises the overview provided by representatives from the government agencies, i.e. the Ministry of Health, the Prisons Department, and AADK on the current situation in accessing HCV diagnostics and treatment, with regards to hard-to-reach populations such as PWIDs and inmates; followed by a Q&A session with the participants. The session was moderated by DNDi Project Manager, Mr. Chung Han Yang.

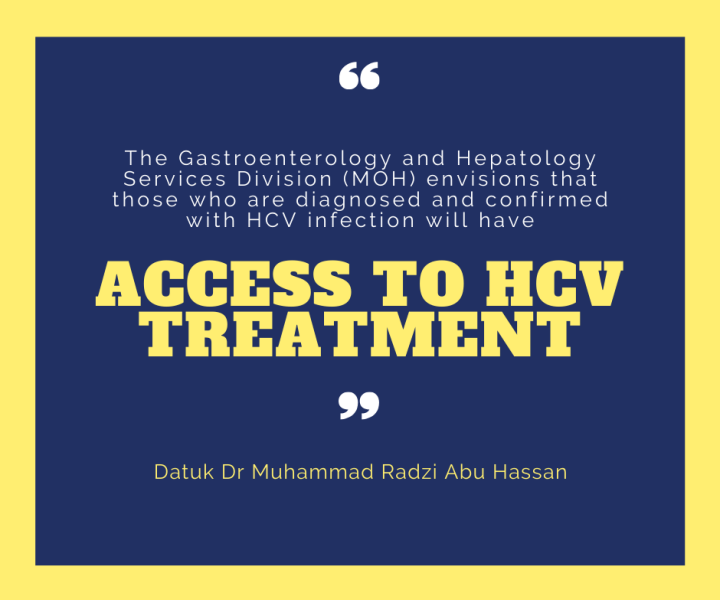
From left: Mr Chung Han Yang (DNDi) (Moderator) and the five panellists* - Puan Fatimah Bt Abdul Rahim (Deputy Director, Pharmaceutical Services Division, MOH), Dr Anita Suleiman (Head of HIV/STI/Hep C Unit, MOH), Datuk Dr Muhammad Radzi Abu Hassan (National Head, Gastroenterology and Hepatology, MOH), Dr Ravi Ramadah, Senior Principal Assistant Director,Treatment & Rehabilitation (AADK), and Dr Muhammad Nor Hayat Mamat (Medical officer, Prisoners Management Department, Malaysia Prisons Department)

In the order of the statements provided by the panellists, here are the points that they have elaborated:

DATUK DR. MUHAMMAD RADZI ABU HASSAN
National Head, Gastroenterology and Hepatology, MOH

Introduction

- Access to HCV diagnostics and treatment cannot be done within six months or a year, but there will be challenges and it requires much planning.
- The approval of Sofosbuvir for use in Malaysia was only completed in March 2018, therefore time is needed to streamline HCV screening, diagnostics and treatment processes by MOH.



Opportunities

- The Malaysian public health care system is the "best ecosystem" at the moment. We have over 10 years of experience in managing HIV at the community level.
- We can learn from the management of HIV to be implemented in addressing the HCV epidemic.
- HCV treatment is one-off as compared to HIV treatment that is life-long. Therefore, the treatment algorithm is comparatively simpler.

- By January 2020, there are 6,000 slots of HCV medication for those who are eligible for treatment. It is hoped that this will be increased to 10,000 slots by the end of 2020.
- Currently, via central purchasing, the DAAs are distributed to the hospital, and subsequently to KKs. But from next year, apart from central purchasing, the hospitals can also purchase additional DAAs. This will increase the update of HCV treatment for those who are eligible.

Challenges

- Even though we have obtained Sofosbuvir through CL, acquiring Daclastavir takes time too.
- The availability of labs and transportation of blood for HCV diagnostic tests are logistic challenges that we are currently facing.

Success Factors

- The MOH has been generous and supportive to allocate budget to purchase medication.
- Task-shifting of HCV treatment cascade from the hospital to KKs. In other words, HCV patients are treated by FMS at the KKs instead of the hepatologist, gastroenterologist or ID physicians at the hospital level unless they require referral due to complications, e.g. cirrhosis.
- Task-shifting to NGOs and CSOs who have community workers to screen and refer HCV patients to the health care system.
- Decentralisation promotes treatment within the community setting and it is one of the key features of the Malaysian public health care systems. It increases accessibility of HCV treatment to the public.
- There is a training module and clinical practice guideline that has a defined, simplified algorithm.

PN FATIMAH BT ABDUL RAHIM

Deputy Director, Pharmaceutical Services Division, MOH

Introduction

- The HCV treatment initiative begun in December 2015 when the MOH agreed that it was a public health issue that required intervention.
- The first meeting with the Ministry of Domestic Trade and Consumer Affairs and the Intellectual Property Corporation of Malaysia (MyIPO) was held on 15 December 2015. It was held to discuss about an HCV treatment clinical trial with DNDi.
- Subsequently, several meetings were held to advocate to the relevant ministries on the importance of addressing the HCV epidemic in Malaysia. This has resulted in the commencement of the CL that has culminated to the availability of DAA in Malaysia today.

Opportunities

- As the HCV epidemic is highlighted by the MOH as a public health issue, it was easier to obtain approval for the budget for diagnostic tests and medication requested by the Pharmaceutical Services Division.
- With the availability of generic versions of Sofosbuvir and Daclastavir that has been recently registered in Malaysia through VL, the HCV medication will also be available in University hospitals and other private hospitals.

Challenges

- Even though Sofosbuvir is currently available through CL, the Pharmaceutical Services Division needs to also ensure that the budget to purchase the medication is requested according to the estimated number of patients to be treated, and for all financial requirements and processes are followed accordingly.

Success Factors

- Networking and continuous advocacy across ministries are important steps that has ensured the success of the HCV initiative.
- The government's perseverance in going forward with CL despite pressure from foreign governments and MNCs has proven to be fruitful when treatment is now more widely available.
- The pharmacists conduct the dispensing of the medication and provide counselling to HCV patients to ensure adherence.

DR RAVI RAMADAH

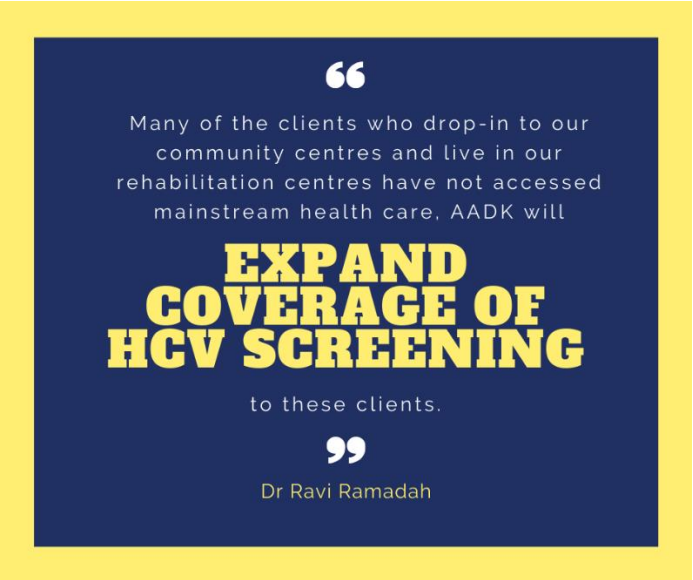
Senior Principal Assistant Director, Treatment & Rehabilitation (AADK)

Introduction

- The AADK provides HIV, HBV and HCV health services to its clients with the assistance from the MOH.
- There are 107 District Offices (DOs) and 28 Rehabilitation Centres (RCs) under the purview of AADK. A total of 26,000 clients report to the DOs and 6,000 clients are currently living in the RCs.
- Since July 2019, a total of 2,000 clients have been referred to KKs for HCV screening. It was found that 5% (100) were found to be HCV positive.
- In a separate screening, 12 out of 60 clients (20%) who were screened were HCV positive.

Opportunities

- In 2015, the AADK officers have been trained in managing HIV among its clients. This makes it easier for the agency to conduct HCV-related programmes.
- The FIND study provided an avenue to start screening AADK clients for HCV.
- With data generated from screening, it serves as evidence on the need to implement HCV-related programmes in AADK.



Success Factor

- The clients who report themselves at DOs and check-in to its RCs for rehabilitation serve as the high-risk target populations that are available for screening.
- Advocacy meetings are held with counsellors who are encouraged to include HCV-related information in their counselling sessions with clients.
- The FMS have allocated designated days and waiting areas in KKs to reduce waiting time for clients.

Challenges

- The primary objective of AADK is on crime prevention and ensure the safety of the country and its people is preserved. Majority of staff in AADK were attached with the Ministry of Home Affairs (MOHA) and involved in law enforcement instead of health-related work.
- The HCV treatment cascade is fairly new in this agency, therefore it takes time to establish a screening, diagnostics, and treatment workflow.
- Currently, the agency focuses on screening HCV patients. When more HCV positive clients are identified, then the agency could make further arrangement on diagnostics and treatment.

DR MUHAMMAD NOR HAYAT MAMAT

Medical officer, Prisoners Management Department, Malaysia Prisons Department

Introduction

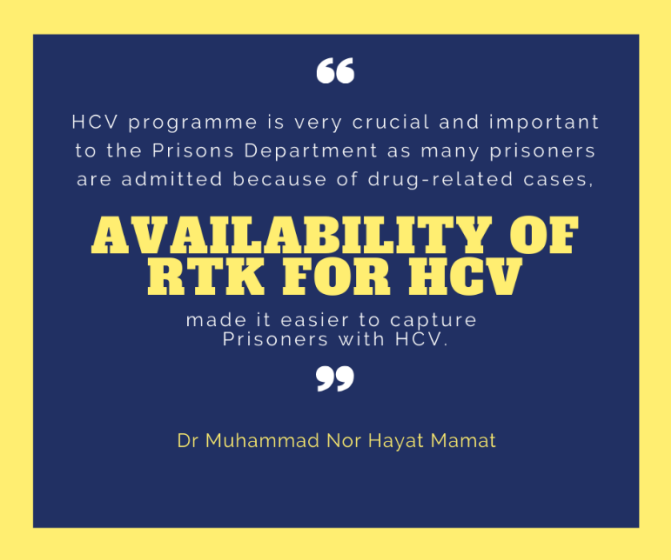
- The MPD acknowledges that HCV programme is very crucial and important to the department.
- It is estimated that 60% of prisoners are serving sentences related to drug use.
- Currently, there is no systematic programme on HCV in prisons.

Opportunities

- There is an existing systematic programme on HIV and TB.
- The availability of RTKs makes it easy to screen the prisoners.

Success Factors

- The MOH had meetings with the MPD to advocate on the importance of having HCV-related programmes in the prison. This has prompted the latter to begin screening by using RTKs.
- MTAAG+ works with the MPD to conduct screenings and managed to detect cases with positive HCV antibody.



Challenges

- The MPD focuses on security and safety of the country, therefore health is not always the priority. Advocacy initiatives are needed to transform the mindsets of prison officers to be health-oriented within the department and prison settings.
- Once a prisoner is detected to be positive HCV antibody, proper workflow between MPD and MOH (i.e. clinic or hospital) for diagnosis and treatment is needed.
- To escort one prisoner out of prison facility to the health clinic or hospital, it takes up to three prison officers. Moreover, there are other health conditions that require follow up too, such as HIV and TB.

DR ANITA SULEIMAN

Head of HIV/STI/Hep C Unit, MOH

Introduction

- Since the first HIV case was reported over 30 years ago in 1986, the MOH has established a platform for HIV that include prevention through screening among the incarcerated, antenatal, and premarital couples.

Opportunities

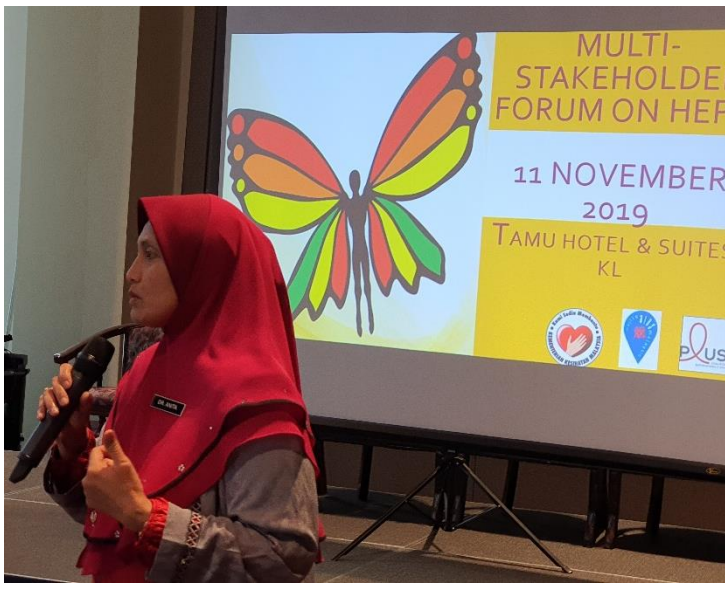
- In the 1990s, the formation of MAC was mooted by the MOH as a strategy to bridge health care services between KPs, including PWIDs, MSM, TG as well as sex workers, and health service providers.
- As we have successfully achieved the target of 90% of PWIDs to know their HIV status, it should be easy to do so for HCV as well. Additionally, as HCV is treatable and its treatment is short term, achieving 90% of PLHCV on treatment by 2030.
- Since we have good coverage for HIV testing, it is convenient to add the HCV test to pre-existing sets of test in for inmates in drug rehabilitation centres and prisons, as well as pregnant women attending antenatal care in KKs.

Success Factors

- The Malaysian model of Government-Non-Government social contracting is well-known regionally and globally in developing a strong network to reach out to KPs.

Challenges

- From the previous study, it was estimated that there are 450,000 PLHCV in Malaysia. This denominator when compared with notification rate would make it a difficult to reach the target of 90% of PLHCV who know their status. Therefore, there is definitely a need to re-estimate the HCV prevalence in Malaysia.
- The approval to include HCV screening to pre-existing screening tests, such as HIV require approval from the MOH.
- Ideally, we need more budget to screen and diagnose more people. We definitely need more budget to treat them too.



After the panellists provided their views, the moderator continued the session by asking the following questions.

How do we reach out to more PWIDs and prisoners to come forward for testing, diagnosis and treatment?

DATUK DR MUHAMMAD RADZI

- The initiative has to "be out of the hospital to the community".
- Decentralisation is the way to go to address the HCV epidemic. This requires training to be done for KK health care team, including pharmacists, lab technicians, clinicians, and NGO community workers.
- This has been proven to be possible, as during World Hepatitis Day, 11,000 people were screened within 1 week. A total of 1.9% were found to be positive for HCV. All those who are positive had been linked to care.
- It is important to increase the point-of-care management, including KKs, extending to AADK's Cure and Care clinics and prisons.

What are the challenges that AADK and MPD face in the screening, diagnostic and treatment of at-risk populations, and what are the support that are needed?

DR RAVI RAMADAH

- The AADK has two types of facilities:

Type of facility	District Offices (DOs)	Rehabilitation Centres (RCs)
What is it?	• Community-based • Clients are free to move around. • Under supervision and they need to report to the office.	• Residential-based • Clients live in-house, usually for 1 to 2 years • Total: 28 centres
Health care worker	• There are no health care workers.	• In-house MAs
Screening	• Cases are referred to KK for screening since July 2019.	• MAs are trained to conduct HIV testing are also skilled to conduct HCV screening.
Diagnostic/ Confirmatory	• Clients need to follow up at KK. • AADK has negotiated for "fast lanes", e.g. designated days and time to ensure clients are not loss to follow-up at KKs.	• For a resident to leave the RC, he/she has to be escorted. This may pose a challenge as AADK is under-staffed. • Alternatively, drawing blood at RCs to be sent to KK or the lab for diagnostic/confirmatory is a challenge.
Treatment	• Adherence may be an issue if the client does not come to the clinic for treatment and follow-up testing.	• MAs are trained to dispense TB medication and HAART. They can be trained to provide HCV medication.

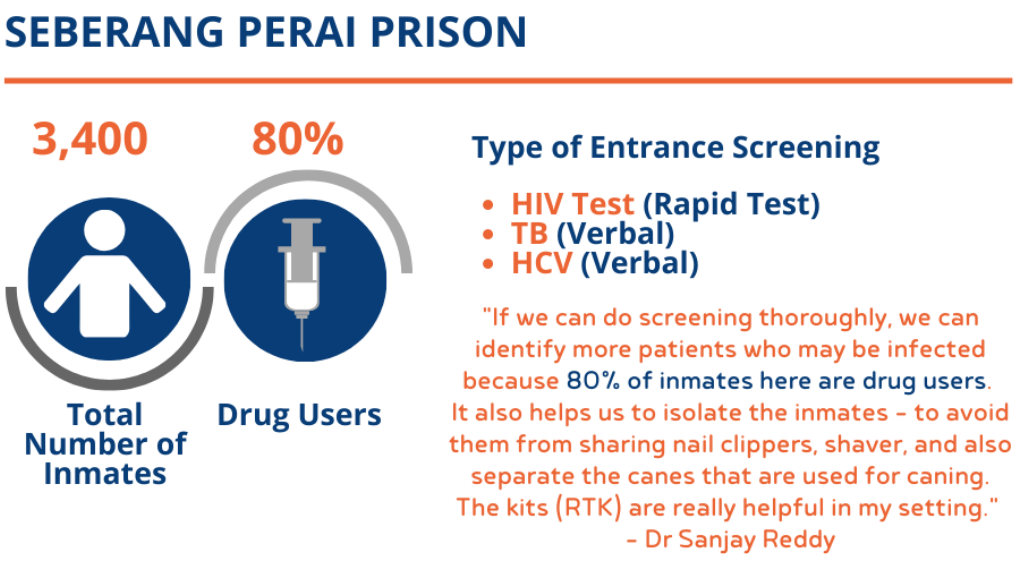
DR MUHAMMAD NOR HAYAT MAMAT

- The MPD has its designated doctors and MAs.
- Currently, there is no set criteria for treatment, especially in terms of the duration of incarceration of inmates who are screened and diagnosed HCV positive.
- The prison has two types of facilities:

Type of facility	*Penjara Reman*	*Penjara Sabitan*
What is it?	Shorter incarceration period	Longer incarceration period
Screening	Screening can be done.	Screening can be done.
Diagnostic/ Confirmatory	Clients need to follow up at KK. AADK has negotiated for "fast lanes", e.g. designated days and time to ensure clients are not loss to follow-up at KKs.	For a resident to leave the RC, he/she has to be escorted. This may pose a challenge as AADK is under-staffed. Alternatively, drawing blood at RCs to be sent to KK or the lab for diagnostic/confirmatory is a challenge.
Treatment	As the duration of incarceration or lock-up is shorter, it may not be sufficient to provide treatment within the prison setting.	The duration is incarceration is known, therefore treatment within the prison setting can be provided.

DR ANITA SULEIMAN

- With regards to the criteria, screening can be done on inmates in *Penjara Sabitan* who are incarcerated for at least 3 months to ensure that treatment can be completed within the prison setting;
- Screening is not an issue because RTKs are fairly affordable. Apart from that, logistics is not an issue as the blood can be drawn in the prison setting and sent to the regional labs. However, it is important to ensure that budget for diagnostic tests is available. In other words, there needs to be a meeting between the MPD and MOH on how many screenings, diagnostics and treatment required to ensure that there is sufficient budget available.



Is the supply of HCV medication sufficient for PWIDs and prisoners?

PN FATIMAH BT ABDUL RAHIM

- Recently, the Pharmaceutical Services Division has submitted and presented their budget. The division will be notified how much is allocated by January 2020.
- The MOF knows that this is one of the country's top health agenda and we have committed to achieve the HCV screenings, diagnostic and treatment targets. Therefore the ministry will prioritise budget for this purpose.
- However, it is important to deliver the results. When more are screened, it will also increase the need for diagnostic tests and treatment. This way, the budget can also be increased phase by phase.

This was followed by a Q&A session with members of the floor.

Q: Should we use HCV RNA or HCV antigen as the confirmatory test?

A: DATUK DR MUHAMMAD RADZI & DATIN DR SALBIAH HJ NAWI

- HCV screening tests include ELISA by blood or RTK by finger prick. These tests check for antibody and does not confirm the status of viraemia.
- HCV confirmatory tests include Hep C RNA test and Hep C Core-Antigen test.

Type of Confirmatory Test	HCV RNA	HCV Core-Antigen
Cost	• More expensive • Used to cost RM 100 – RM 300; for now, it is around RM 70 – RM 80	• Relatively cheaper compared to HCV RNA.
Transportation	• Cold chain	• Labs are available across Malaysia
Labs	• 12 labs, including 3 in Klang Valley	• 8 centres, 3 in Klang Valley (except Perlis, Negeri Sembilan and Perak) • Perlis – send to Alor Setar (Kedah) • Perak and NS – send to Sg Buloh (Selangor)

- It was discussed that "Dried Blood Spot" that is also used in resource-scarce settings be used as a method of getting blood samples for confirmatory tests to address logistics issues. To pilot test this initiative, it was suggested that a project to obtain dried blood spot for testing at the nearest health labs is initiated with AADK or the MPD.
- The MOH recommends using the Hep C Core-Antigen test for due to its cost and practicality in terms of public health approach.

If a patient is tested positive for HCV antigen, can we register in e-Notis?

A: DATUK DR MUHAMMAD RADZI

- Once a patient is screened HCV positive for antibody, notification must be done.
- If a patient is diagnosed to be HCV positive, a second notification can be done.
- These information are crucial to map out and estimate the prevalence and incidence of HCV.

Can NGO or CSO representatives enter prison or AADK settings to conduct HCV screening?

A: DR RAVI RAMADAH, DR MUHAMMAD NOR HAYAT MAMAT & DR ANITA SULEIMAN

- AADK allows the public, especially NGOs into its RCs for education and peer support purposes, but not to conduct any medical screening or procedures. However, NGO can come to the DOs to provide HCV testing.
- The MPD allows public into prisons but strictly dependent on their backgrounds. For example, an ex-prisoner is not allowed into the prison until after a certain period. The public, especially NGOs can conduct health education, but they are not allowed to do any medical screening or procedures in the prisons. However, there is a designated team of doctors and MAs in each prison who can conduct these procedures.
- Under the Prisons Act (*Akta Penjara*), the health services provided in prisons is under jurisdiction and responsibilities of the MOH. Therefore, only MOH certified doctors and health care professionals are allowed to screen, diagnose, and treat patients in these settings.
- However, the MPD representative shared that training needs to be done to ensure that the prisoners are screened, diagnosed and treated according to procedures.

Other issues and comments

- **ESTIMATED POPULATION WITH HCV IN MALAYSIA**
  One of the participants from MTAAG+ shared that from a separate study, experts have projected that there are 15,000 instead of 450,000 PLHCV in Malaysia.

- **CL FOR ARV DOLUTEGRAVIR**
  One respondent asked whether there is an update on the CL for ARV Dolutegravir.

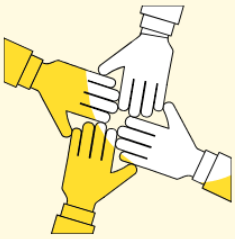
  ### A: PN FATIMAH BT ABDUL RAHIM
  The Director General (DG) has written to the Medicine Patent Pool (MPP) on the interest to obtain VL for ARV Dolutegravir. The MOH is currently negotiating and hope for positive results.

Group Discussion and Findings

The session was moderated by Dr Karina Razali from the World Health Organization. The participants were divided into three groups, based on the themes listed below.

Multi-Stakeholder Linkages	Key Populations	Testing to Treatment Cascade
• Experience and Best Practices • Barriers and Solutions	• PWIDs (and other subpopulations of PWUD) • People in incarceration / prison settings	• Decentralisation and task shifting • Integration and differentiation - the HIV experience

Multi-Stakeholder Linkages



Who are the Stakeholders?

- Ministry of Health, including *Sektor HIV/HBV/HCV*, Pharmacy, BPKK, Lab, NPRA)
- Ministry of Home Affairs (Prisons Department and AADK)
- Malaysian Organisation of Pharmaceutical Industries (MOPI), locally - Pharmaniaga
- Ministry of International Trade and Industry (MITI)
- Ministry of Education
- Non-governmental organisations
- Community-based organisations
- Royal Malaysia Police
- Religious authorities

Experiences and Best Practices

- Adopt and adapt HCV Decentralisation Programme from Kedah State
- Dispense MMT and DAAs through Direct Observation with current MMT clients.

  This will ensure better compliance, detection of defaulters, monitoring of side effects, and ensure completion of treatment by monitoring SVR.

- Linkages with Gastroenterology and Hepatology Department to refer complicated cases
- Linkages with laboratory to ensure diagnostic tests can be done
- Role of pharmacy to ensure that patients receive counselling, prevent drug interactions, and monitor for adverse effects.

Barriers

- Accessibility
  i) Not all KKs are treating HCV, for example in Penang, there are no KKs that have started HCV treatment.

  ii) Unable to treat people in incarceration (during remand)

- Availability
  i) Limited DAAs
  ii) Limited lab facilities to conduct diagnostic tests.

Solutions

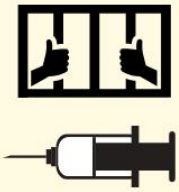
- Increase number of DAA slot **per State** and **per KK** so that more patients can benefit from treatment
- Downgrade DAAs from A* to AKK - learning from the HIV experience, this enables FMS to treat more cases
- Train NGO workers to do Community-based Testing (CBT) - learning from the HIV experience, as mode of testing for HCV is the same as HIV.
- Train more FMS and MOs to initiate treatment
- Promote Comprehensive Sexuality Education that includes lessons on HCV.

Other lessons

- In Spain, the testing, diagnostic and treatment of HCV in Prisons is under the direct supervision of MOH.

- In the short term, it is important to ensure that budget provided to the Prisons by MOF should include testing, diagnostics, and treatment since the current health budget is separated from the MOH.

Strategies to Ensure Accessibility for Key Populations



Who are the Key Populations?

- People who inject drugs (and other subpopulations of PWUDs)
- People in incarceration / prison settings

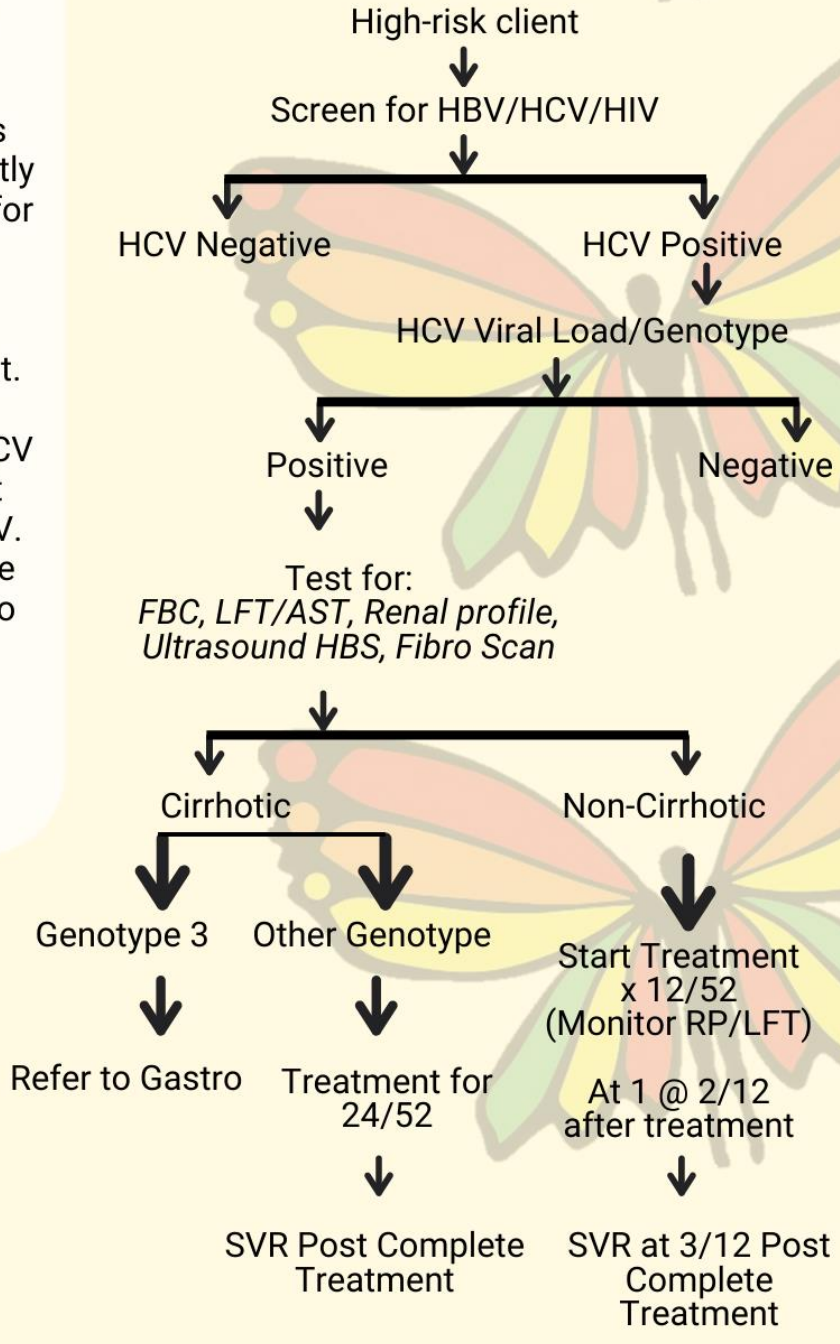
How to reach out?

PWIDs and other subpopulations of PWUDs

- Awareness campaign to the public, society and stakeholders (i.e. AADK and Police).
- Empower health care workers in KKs to start HCV services. That is currently being done throughout the country, for FMS and health care workers.
- Train NGO workers on HCV to promote about testing and treatment.
- Train outreach worker to conduct HCV testing based on the CBT concept at outreach points, that is similar to HIV. Once a client is detected positive, the outreach worker can bring him/her to the KK.
- NSEP / MMT as an entry point

People in incarceration / prison settings

Suggestion of Flowchart for HCV Case Management in Prison Setting



** Monitor Renal Profile 4 weeks later*
Cannot prescribe Sofosbuvir if eGFR<30

Challenges

- To sustain clients from being re-infected with HCV
  i) Monitor through MMT programme
  ii) Educate them to use drugs safely, use clean needles etc.
- MO reluctant to start treatment

Work Procedure in Prison Clinic Setting

Activity	Action
Health screening on new inmates	MO/MA
Conduct health screening, i.e. TB, HIV, HCV and others on new inmates	MO/MA
Further examination on the health status of clients	MO/MA
If client is screened HCV positive, draw blood for HCV viral load and genotyping to be sent to the nearest KK	MO/MA
If HCV viral load is positive, run further tests on other HCV co-infections. Ensure client's readiness and eligibility to receive treatment.	MO
If client is ready and eligible for treatment, draw blood to rule out cirrhosis: FBC/LFT/AST/RP (to inspect for concomitant illness), apt ultrasound / fibroscan	MO/MA
Examine client and check lab results, initiate treatment	Gastroenterologist/ FMS/MO
Medication is given daily for 3 months	MO
Follow up once per month	MO
Refer to KK or hospital if complications arise	
Follow up, send blood for HCV viral load/FBC/LFT/RP after 12 months of treatment initiation	MO
HCV viral load **Negative**: Client has recovered HCV viral load **Positive**: Refer to Gastroenterologist	MO

Other issues

- The MPD can work with CBOs to ensure that SVR is achieved for clients who are released earlier.

- According to a doctor based in the Seberang Perai Prison, HCV blood screening is not part of the entrance screening test. However, usually inmates will be asked verbally on whether they have HCV. The inmates will not usually admit because they will not be given jobs, especially tasks involving sharp equipment. They are also not allowed to be on parole due to health reasons. Therefore, screening is the best way to determine their HCV status. Once their status is known, it is easier to manage or segregate them.

  With regards to this, the AO from Penang has responded that she will provide RTKs to Seberang Perai Prison.

Testing-to-Treatment Cascade

WHAT IS THE CURRENT NUMBER OF PWID AND PLHCV IN MALAYSIA?

To effectively plan for the Testing-to-Treatment Cascade, we need reliable and accurate data.

The current number of PLHCV in Malaysia is unknown as the last Estimation Study was done in 2019. Therefore, an accurate estimation is important. This makes it easier to project quantity of DAAs needed.

The logistics of this new study includes:
- Who will conduct the study?
- What is the budget?
- Where is the source of data?

REEVALUATE ADMINISTRATION AND PROTOCOL BY GOVERNMENT, NGOS AND CSOS

The effectively implement decentralisation and task shifting, unnecessary bureaucracy within and between ministries and agencies need to be addressed.

Opportunities

- **The Malaysian Health Care System consists of Public and Private sectors.**
- **Both sectors should play their role in Decentralisation and Task Shifting.**

Decentralisation & Task Shifting Strategies

Break the "Monopoly" in Testing & Diagnosis
- MKA can support testing and diagnosing of new clients, whereas the hospitals can test existing patients.
- Decentralise according to regional MKA for VL testing using DBS.
- This allows for "centralised tender" to reduce the cost of diagnosis since bulk of it will occur in MKA labs.
- It will also reduce the burden and workload of hospitals.

Break the "Monopoly" in Treatment
- Availability and sustainability of drugs is currently restricted by quota. Once quota is finished, then a person may need to wait for new slots.
- To expand treatment coverage, if a patient is willing to pay, he/she should be able to purchase these drugs from public health care system, e.g. KKs. This will solve the quota issue.

Integration & Differentiation - The HIV Experience

Integration - Ministry of Health
- Employ and deploy MOs as MOH team to visit AADK, Prisons, CnC and other institutions.
- This serves as a good training ground for them.
- Let them be the "Champions" to ensure sustainability.
- Mentor-Mentee programme to train young doctors on the ground and pair them with senior doctors
- The stigma and discrimination is not to the diseases, but to the KPs.
- Direct network between Gastroenterology and Hepatology department with the KKs where patients are initially screened and seen, to ease referral and reduce dropouts.

What is Integration?

- To "piggy back" on existing programme, e.g. Combos (for example TB merge with HIV, STI, HCV, and other communicable diseases)

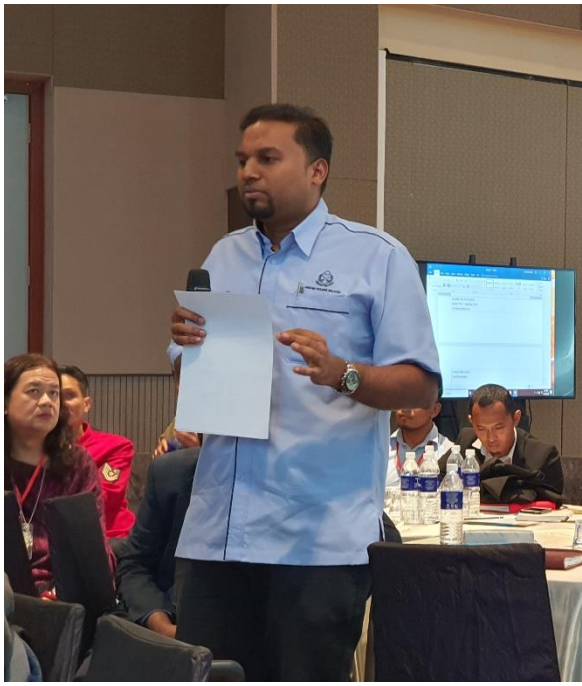
What is Differentiation?

- Fitting health services to the needs of KPs

Integration - Non-MOH with NGOs and CSOs
- AADK work closely with doctors in KKs so that patients' whereabouts can be identified.
- Education and awareness, including *Jabatan Penerangan, Kementerian Wanita, Keluarga dan Pembangunan Masyarakat.*

Other issues

- One of the doctors from KKKL shared that as her clinic is involved in the FIND studies, it has screened up to 800 patients of which approximately 100 are HCV positive. She shared that although it is convenient to start MMT patients on DAA, it is also important to look at non-MMT patients, for example those who have stopped taking drugs (cold turkey) who are ready and eligible to start DAA.
- Another respondent shared that she has heard from FMS that even though there are many patients who are not ready to take HAART treatment, they are willing to take up DAA as the treatment algorithm is simpler, i.e. only for 3 months.



Summary Recommendations

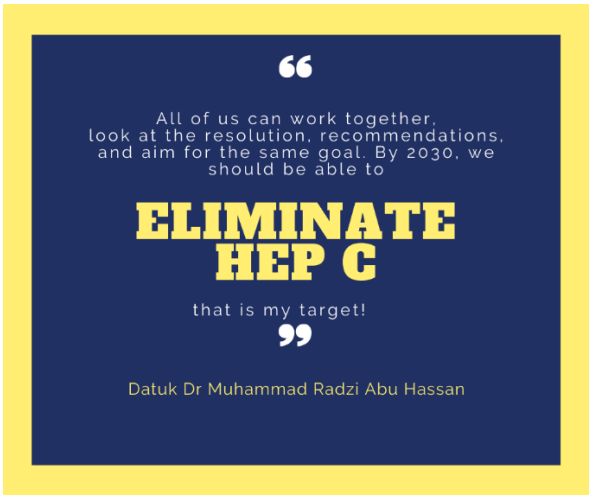
This sub-section summarises the recommendations by the Forum, specifically actions to be taken.

Phase / Cascade	MOH / Government agencies	AADK	Prison	CSOs
Testing	• Availability of test kits, including budget • Increase testing for high risk populations • Integration, "combo" tests that includes HCV with other tests, e.g. HIV, STIs, HBV etc. • Identify "entry points" for screening, e.g. MMT, NSEP, etc.	• Screen residents in Rehabilitation Centres • Refer clients who walk in to District Offices to KK • Screening criteria and eligibility	• Review criteria of entrance health screening test	• Community-based testing • Training of HCs and ORWs
Diagnostics	• Budget for diagnostic tests • Type of confirmation test • Dried Blood Spot (DBS)	• Pilot test on DBS • Logistics, i.e. diagnostic tests to be done in facility or sent to KK	• Pilot test on DBS • Logistics, i.e. diagnostic tests to be done in facility or sent to KK	• Ensure clients go for diagnostics
Treatment	• Budget for treatment • Criteria for treatment, consider MMT and non-MMT patients based on readiness and eligibility • KKs/FMS to provide designated day and time for KPs • Provide option for patients to purchase medication in KK setting if quota for free medication has finished	• Refer for treatment • Ensure completion of treatment	• Estimate budget for, testing, diagnostics, and treatment	• Ensure clients go for treatment
Awareness on HCV and Prevention of Re-infection	• Train health care team to provide counselling • Anti-stigma and discrimination module for health care providers	• Increase awareness of public and high-risk KPs on HCV through social media and IEC materials • Train staff in HCV issues, including safe drug use		

		▪ Ensure clients are equipped with HCV information before they return into the community ▪ Educate clients on HCV treatment cascade. ▪ Anti-stigma and discrimination module for KPs		
Others	▪ Initiate decentralisation and start more KKs on HCV treatment services ▪ HCV training for medical team ▪ New estimation studies ▪ Standardise / update treatment algorithm or flowchart of treatment ▪ Referral flowchart for clients with HIV, HBV etc. co-infections.	▪ Standardise flowchart of treatment especially with KKs	▪ Standardise flowchart of treatment especially with KKs	▪ Include HCV in comprehensive sexuality education modules

WRAP UP & CLOSING REMARKS

Datuk Dr Muhammad Radzi Abu Hassan, National Head Gastroenterology and Hepatology Department, MOH wrapped up the session. He shared that he is glad to see the enthusiasm of all participants from the MOH, NGOs, CSOs and the community coming together. He cited that as we are currently in the best health care ecosystem, he look forward to increasing HCV treatment from 4,000 slots to double or triple the number next year.



Next, Dr Anita Suleiman gave a closing remark. She took consensus that all stakeholders were in high spirit to decentralise, and reiterated the importance of doing so in ending the HCV epidemic in Malaysia. She also shared that we have much to learn from our experiences in managing the HIV epidemic, and encouraged all stakeholders to work together, especially in training more FMS and increase coverage for screening. She said that when the MOH streamlines the NSP on HBV/HCV elimination, the recommendations from this forum will be considered. Finally, she wished all members the best of luck, Happy World AIDS Day, and a happy 2020.


MULTI-STAKEHOLDER FORUM ON HEP C
11 NOVEMBER 2019
TAMU HOTEL & SUITES, KL


Groups/Topics