ORIGINAL ARTICLE

Outcome of Hepatitis C Screen-and-Treat Program at a Drug Rehabilitation Centre in Perlis State

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ABSTRACT

Introduction: Hepatitis C virus (HCV) infection is prevalent among people who inject drugs globally and in Malaysia. Drug rehabilitation centres (PUSPEN) offer opportunities for intervention, but the feasibility of HCV care cascades in these settings requires evaluation. This study aims to evaluate the outcome of an integrated HCV screen-and-treat program implemented at PUSPEN Perlis, Malaysia.

Materials and Methods: This retrospective cohort study analysed data from an HCV screen-and-treat program conducted between October 2022 and December 2023 at PUSPEN Perlis. The program involved initial screening with rapid antibody testing, confirmatory HCV RNA testing, APRI-based fibrosis assessment, and Direct-Acting Antiviral (DAA) treatment, with Sustained Virologic Response at 12 weeks post-treatment (SVR12) as the primary outcome.

Results: Screening of 461 participants during study period identified 62 (13.4%) as HCV antibody positive. Significant attrition occurred before confirmatory testing, with 34 (54.8%) undergoing HCV RNA tests, of whom 33 (97.0%) were positive. Treatment initiation was also limited, with 17 (51.5%) starting DAA therapy, primarily due to anticipated short rehabilitation stays. One participant transferred during therapy; the remaining 16 completed the 12-week regimen, all achieving SVR12 (100%) without reported adverse effects.

Conclusion: HCV screen-and-treat programs are feasible in Malaysian drug rehabilitation centres but face challenges in linkage to confirmatory testing and treatment initiation, largely due to limitations imposed by the duration of stay. While DAA therapy is highly effective when completed, strategies addressing diagnostic streamlining, potentially shorter regimens, and continuity of care post-release are crucial to optimise HCV elimination efforts in this vulnerable population.

KEYWORDS:
hepatitis C, drug rehabilitation centre, injecting drugs, direct-acting antivirals, Malaysia

INTRODUCTION

Drug addiction stands as a widespread and concerning global health issue, impacting millions of individuals across the world. The World Health Organization (WHO) estimates that a substantial proportion of the global population grapples with substance abuse.[1] The ramifications of drug addiction extend beyond the individual, encompassing detrimental effects on physical and mental health, interpersonal relationships, and overall economic productivity. Furthermore, drug-related criminal activities, violence, and broader social problems are frequently intertwined with substance abuse.[2] Notably, the practice of injecting drugs presents a significant avenue for the transmission of the hepatitis C virus (HCV).[3,4]

As a blood-borne pathogen, HCV is readily transmitted through the sharing of needles and other contaminated injecting tool among individuals who use drugs. The prevalence of HCV infection among people who inject drugs (PWID) is alarmingly elevated on a global scale, including within the Asian region. In Malaysia, approximately 2.5% of the adult population is estimated to be living with HCV, with injection drug use accounting for a significant 59% of these infections.[5] Several local studies reported an alarmingly high prevalence of HCV among people who inject drugs, ranging from 40.5% to a staggering 89.9%.[6,7] This underscores the critical and immediate need for effective interventions aimed at both preventing and treating HCV infection within this particularly vulnerable demographic.

Malaysia has a long-standing and recognised commitment to addressing the challenges of drug addiction and its associated issues.[8] The National Anti-Drug Agency (NADA), a key governmental body operating under the purview of the Ministry of Home Affairs, plays a central role in the management and rehabilitation of individuals struggling with drug dependence. NADA oversees a network of 30 drug rehabilitation centres, known as PUSPEN, strategically located throughout the nation.[9] One such centre is situated in Bukit Chabang, within the state of Perlis.

Individuals undergoing rehabilitation at PUSPEN participate in a comprehensive and structured program that spans to a maximum period of 24 months. This prolonged engagement

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offers a valuable window of opportunity for medical teams to systematically screen and provide treatment to individuals who may be living with HCV infection. While HCV elimination programs have demonstrated considerable success and effectiveness in the general population,[10,11] there remains a relative lack of understanding regarding their feasibility and outcomes when implemented specifically within vulnerable populations residing in drug rehabilitation centres.

In order to bridge this critical knowledge gap, a collaborative initiative was established between the Ministry of Health and the Ministry of Home Affairs. This inter-ministerial partnership facilitated the implementation of a novel screen-and-treat program at PUSPEN Perlis, with crucial support provided by a nearby health clinic. The primary aim of this study was to evaluate the outcome of this newly implemented program in enhancing the continuum of HCV care within the unique setting of a drug rehabilitation centre.

MATERIALS AND METHODS

Ethics approval

This study received approval from the Medical Research and Ethics Committee, Ministry of Health Malaysia (NMRR-24-03922-JR4), in accordance with the ethical standards of the 1964 Helsinki Declaration. The requirement for informed consent was waived because the study used secondary data retrieved from the program database.

Study Design and Setting

This study employed a retrospective cohort design to evaluate the outcomes of an integrated HCV screen-and-treat program implemented at a drug rehabilitation centre (PUSPEN) in Perlis State, Malaysia. The program was conducted between October 2022 and December 2023. Data for this analysis were derived from secondary records of individuals who participated in the program, under the auspices of the Perlis State Health Department.

PUSPEN Perlis was established in 1987 with a maximum capacity of 150 clients/trainees. The main aim of its establishment is to provide treatment and rehabilitation to individuals recovering from drug addiction so they can return to their families and society, functioning as productive and accepted individuals. At the time the HCV screen-and-treat program was being implemented, the health of trainees at PUSPEN Perlis was managed by two resident Medical Assistants (MA). Trainees who require further medical attention are referred to either the Klinik Kesihatan Padang Besar (KKPB), a primary healthcare clinic, or to the Hospital Tengku Fauziah (HTF), a state tertiary hospital.

The Hepatitis C Screen-and-Treat Program Protocol

The HCV screen-and-treat program at PUSPEN Perlis was a collaborative effort involving the Perlis State Health Department, KKPB, Hospital Sultanah Bahiyah (HSB), Hospital Tuanku Fauziah (HTF), and PUSPEN Perlis. The HCV care cascade in the program was adapted from the Clinical Practice Guideline for Management of Chronic Hepatitis C in Malaysia.[12] The program incorporated the following key steps: To manage logistical constraints with a small medical team and ensure safety precautions were met, HCV screening was conducted over two separate sessions for program participants at PUSPEN Perlis. All eligible participants were gathered in the multipurpose hall in PUSPEN Perlis and briefed on the program. Subsequently, a medical team consisting of healthcare staff from PUSPEN Perlis and KKPB collected demographic data and relevant medical histories. Participants underwent an initial anti-HCV screening using a Rapid Diagnostic Test (RDT) performed on a finger prick. Those with a reactive anti-HCV result then proceeded to HCV confirmatory testing and pre-treatment assessment, which involved a venous blood draw for HCV RNA viral load, complete blood count, and liver function tests, all performed on the same day. These blood samples were subsequently sent to a designated hospital (HSB) laboratory for HCV RNA analysis. Other blood tests were managed by HTF laboratory.

Liver fibrosis status was assessed using the Aspartate aminotransferase to Platelet Ratio Index (APRI) score to determine the likelihood of cirrhosis.[13] Participants with APRI score ≥1.5 were considered to have high possibility of having liver cirrhosis. This non-invasive biomarker approach using APRI was selected as a practical and accessible method for determining the likelihood of cirrhosis in this resource-limited setting, helping to streamline Direct-Acting Antiviral (DAA) treatment initiation. Treatment with DAA medications was initiated for participants with detectable HCV RNA and either with non-cirrhotic liver or compensated cirrhosis. The medical officer and Family Medicine Specialist from KKPB performed a clinical assessment to check for any signs of liver decompensation before initiating DAA treatment. The duration of DAA therapy was determined based on the presence or absence of cirrhosis, typically 12 weeks for those without cirrhosis and 24 weeks for participants with compensated cirrhosis. Treatment initiation occurred within the PUSPEN facility. Participants identified with HCV co-infections (HIV/HCV or HBV/HCV) or those with decompensated cirrhosis were referred to the Gastroenterology team at HTF for specialised management.

Treatment completion was verified through self-reporting and medication refill records. Twelve weeks following the completion of antiviral therapy, participants were scheduled to provide blood samples for Sustained Virologic Response at 12 weeks post-treatment (SVR12) testing. Participants who did not achieve SVR12 were referred to gastroenterology clinic in HTF for further evaluation and management strategies. All data pertaining to participants enrolled in this program were systematically entered into a dedicated database maintained by the HIV/STD/HEPC Unit of the Perlis State Health Department.

Study Population and Eligibility Criteria

The study population comprised all individuals at PUSPEN Perlis who participated in the HCV screen-and-treat program between October 2022 and December 2023. The inclusion criteria for this study were: (i) adult aged 18 years or older who participated in the hepatitis C screen-and-treat program at PUSPEN Perlis, and (ii) having a confirmed diagnosis of hepatitis C based on a positive HCV RNA test result. Individuals were excluded if their anticipated duration of stay within the 6-month program was deemed insufficient for

Table I: Characteristics of participants with anti-HCV positive (N=62).

Characteristics	n	(%)
Age(mean, SD)	44.1	(6.64)
Age Group (years)		
20-29	2	(3.2)
30-39	14	(22.6)
40-49	34	(54.8)
50-59	12	(19.4)
Gender		
Male	62	(100.0)
Ethnicity		
Malay	57	(91.9)
Chinese	2	(3.2)
Indian	3	(4.8)
Risk Factor*		
People who inject drugs**	49	(79.0)
Previously in jail/prison	42	(67.7)
Tattooing	21	(33.9)
Partner who is HCV-infected	12	(19.4)
History of invasive medical procedures	10	(16.1)
Body piercing	8	(12.9)
Men who have sex with men	5	(8.1)
Sex worker	4	(6.5)
Recipient of blood/blood products before 1994	2	(3.2)
Number of risk factors		
1	21	(33.9)
2-4	37	(59.7)
>4	4	(6.4)
APRI score		
<1.5	62	(100)
≥1.5	0	(0)

* Participant can have more than one risk factor.
** People who inject drugs: Participants with any history of injection drug use (past or present).
Abbreviations: SD, standard deviation; APRI, Aspartate aminotransferase to Platelet Ratio Index.

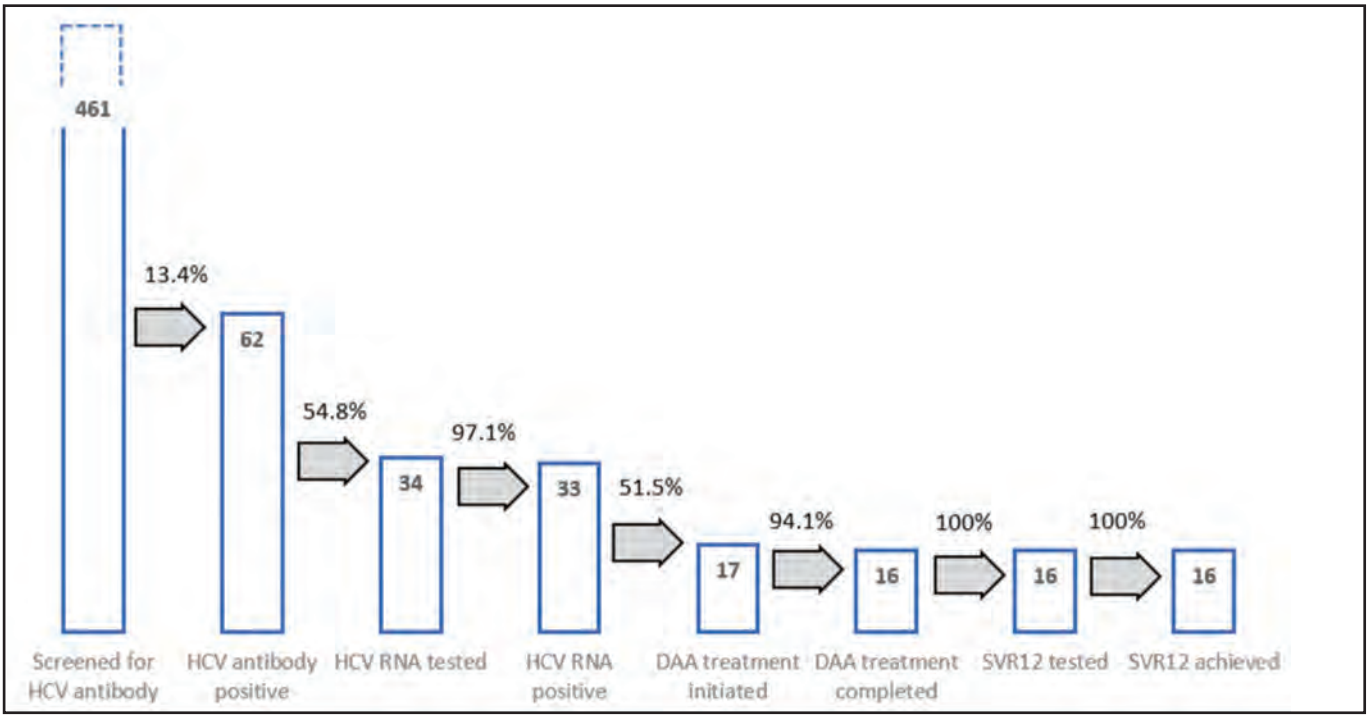

Fig. 1: Progression of participants in HCV screen-and-treat program at PUSPEN Perlis, Oct 2022– Dec 2023

the standard 12- or 24-week DAA treatment course and subsequent SVR12 follow-up assessment.

Data Collection

The relevant data for this study were retrospectively retrieved from the program's database. As the data were initially collected for program monitoring rather than research, the scope of information available for participants, particularly those undergoing initial screening, was limited. The information extracted included: (i) baseline characteristics of the program participants, such as age, gender, and documented history of exposure to HCV infection risk factors (e.g., injecting drug use); (ii) results of blood investigations pertinent to hepatitis C management (HCV RNA test results); (iii) DAA treatment history, including the date of treatment initiation, prescribed treatment duration, and treatment completion status; and (iv) treatment outcomes, specifically the achievement of SVR12, defined as an HCV RNA level below the limit of quantification (<15 IU/mL) at 12 weeks following the completion of antiviral therapy.

Statistical Analyses

The analysis of the study results primarily involves descriptive statistics to summarise the characteristics of the participants and the overall outcomes of the implemented screen-and-treat program. Categorical variables were presented as frequencies and percentages within each category. Numerical variables, including age, will be reported as means and standard deviations if the data are normally distributed, or as medians and interquartile ranges if the data exhibit a skewed distribution. The proportion of participants who underwent on-site anti-HCV RDT and subsequent HCV RNA testing were calculated. Further analysis of HCV RNA status was performed to those who underwent HCV RNA testing. Treatment uptake was analysed among participants with confirmed positive HCV RNA results. Treatment initiation and completion rates were determined for those who commenced antiviral therapy, and the SVR12 achievement rate were assessed for participants who completed treatment and underwent the post-treatment virological assessment.

RESULTS

Study population characteristics

During the study period, 461 participants who received drug rehabilitation at PUSPEN Perlis were screened, and 62 (13.4%) tested positive for HCV antibody. All those with positive HCV antibody were male, and the majority were Malay (91.9%). Their mean age was 44.1 years (SD=6.64), with over half (54.8%) aged 40-49 years. The majority reported at least two risk factors for HCV (66.1%), most commonly injection drug use (79.0%) and prior incarceration (67.7%). None of the participants had liver cirrhosis (APRI score ≥1.5), hepatitis B or HIV co-infection. Characteristics of participants underwent HCV screening test are summarised in Table I.

HCV screen-and-treat program's outcome

Among these 62 HCV antibody-positive participants, 28 (45.2%) did not proceed with confirmatory testing for HCV RNA detection, primarily due to anticipated short stays or difficulties in sample collection. Of those who underwent confirmatory HCV RNA testing, one (3.0%) had undetectable HCV RNA, while the vast majority (33, 97.0%) had positive HCV RNA, confirming active HCV infection (Figure 2). Subsequently, participants who tested positive for HCV RNA underwent pretreatment assessments, and none of them had liver cirrhosis (APRI score ≥1.5). However, only 17 (51.5%) initiated DAA treatment with sofosbuvir-daclatasvir combination for a planned duration of 12 weeks. The remaining 16 (48.5%) with positive HCV RNA did not commence treatment due to their anticipated short stays in the rehabilitation centre. During the treatment course, one participant who had started DAA therapy was transferred to another rehabilitation centre and was lost to follow-up for SVR12 assessment. The remaining 16 (94.1%) successfully completed the 12-week DAA treatment regimen and subsequently underwent SVR12 testing. Notably, all 16 participants (100%) who completed treatment had achieved SVR12 (100%). Furthermore, no adverse side effects were reported by any of the participants who received DAA treatment during the study period.

DISCUSSION

The implementation of a new screen-and-treat program for HCV within a drug rehabilitation centre in Perlis yielded notable insights into the feasibility and outcomes of HCV care delivery within this vulnerable population. Our study revealed a seroprevalence of HCV antibodies of 13.4% among individuals in PUSPEN Perlis during the study period, highlighting the significant burden of HCV infection within this setting, consistent with the elevated prevalence observed among people who inject drugs both regionally and globally.[5-7,14] Additionally, the significant burden of HCV infection within this rehabilitation centre is consistent with observations elsewhere.[15,16] For instance, a study in drug rehabilitation facilities in Japan reported a prevalence of 11.1% among residents.[15] This finding underscores the critical need for routine screening upon entry into drug rehabilitation facilities.

However, our findings also highlight several challenges in translating screening positivity into the full cascade of HCV care within this specific context. A substantial proportion (45.2%) of participants who screened positive for HCV antibodies did not proceed to confirmatory HCV RNA testing. This was primarily attributed to the screening activities being performed on existing residents, rather than on admission, which often led to an anticipated shorter duration of stay within the rehabilitation centre before participants completed their program. Additionally, practical difficulties in obtaining blood samples contributed to this gap. These factors emphasise the unique logistical constraints inherent in delivering healthcare within a residential rehabilitation setting, where the length of stay is predetermined, and medical procedures may face operational hurdles. To mitigate missed opportunities for treatment initiation due to short stays, it's crucial that HCV screening be conducted promptly upon admission to the centre. Streamlining the process for confirmatory testing and exploring alternative sampling methods that are less invasive and more readily implementable in this environment could potentially

improve the proportion of participants undergoing RNA testing. For instance, a 'one-stop-shop' model implemented in Australian prisons incorporated finger-stick point-of-care HCV RNA testing, which provided diagnostic results within one hour.[17,18] This approach was found to be beneficial, timely, and increased uptake of prisoners into the treatment pathway.

Among those who underwent confirmatory testing, the high rate of active HCV infection (97.0% of RNA-tested participants) further reinforces the necessity for targeted interventions. Despite this high prevalence of viraemic infection, only slightly more than half (51.5%) of those with detectable HCV RNA initiated antiviral treatment. The primary barrier to treatment initiation, similar to that observed for RNA testing, was the anticipated short duration of stay, deemed insufficient to complete the standard 12-week DAA regimen. This highlights a critical mismatch between the standard treatment duration and the typical length of stay for a significant portion of participants within the rehabilitation program. Exploring shorter duration DAA regimens, where clinically appropriate, or establishing robust referral pathways and linkages to care upon discharge, are crucial considerations to improve treatment uptake in this population. In line with exploring shorter options, an investigator-initiated trial has recently been completed for a potential 8-week DAA treatment combining sofosbuvir and ravidasvir (ClinicalTrials.gov ID: NCT04885855). The anticipated finding that this regimen is equivalent in efficacy and safety to the standard 12-week duration would be transformative for hepatitis C treatment, particularly in settings where shorter treatment windows are necessary, such as prisons and drug rehabilitation centres.

Despite the challenges in the initial steps of the care cascade, the treatment outcomes among those who initiated and completed therapy were highly encouraging. The 100% SVR12 rate achieved by the 16 participants who completed the 12-week DAA course is remarkable and consistent with the high efficacy of modern DAAs reported in various populations.[10,11] This finding demonstrates that when treatment can be initiated and completed within the rehabilitation setting, it can be highly successful in achieving viral eradication. This finding aligns with the notion to cure HCV among people incarcerated either in prison or a rehabilitation setting to achieve the WHO hepatitis elimination targets.[19,20] Furthermore, the absence of reported side effects among those treated suggests that DAA therapy was well-tolerated in this population.

The loss to follow-up of one participant due to transfer to another facility underscores the importance of inter-institutional communication and coordinated care for individuals within the rehabilitation system. Establishing mechanisms for seamless transfer of medical records and continuation of treatment across different facilities could help prevent attrition along the care pathway.

Our study has several limitations. The retrospective nature of the study and reliance on secondary data may introduce potential biases and limit the availability of detailed clinical information. Furthermore, the reasons for difficult blood taking were not systematically documented, which could provide valuable insights for future program improvements. The exclusion of participants with a stay of < 6 months also might have underestimated the overall impact of the program on the entire cohort of admissions. Importantly, the study population consisted exclusively of male participants (100%), which accurately reflects the current residents of this specific drug rehabilitation centre. This demographic constraint limits the generalisability of the identified psychosocial barriers and success factors to female PWID and the broader female high-risk population in Perlis State. Therefore, future HCV programs must actively seek tailored strategies and opportunities to engage female high-risk populations, possibly outside of single-gender centres, to ensure equitable progress toward national HCV elimination goals.

In conclusion, this study provides valuable real-world data on the implementation of an HCV screen-and-treat program within a drug rehabilitation centre in Malaysia. While the high HCV seroprevalence justifies the need for such programs, significant challenges remain in ensuring progression through the entire care cascade, particularly regarding confirmatory testing and treatment initiation, largely influenced by the duration of stay in the facility. The excellent treatment outcomes observed among those who completed therapy highlight the potential for HCV elimination within this population when these barriers can be overcome. Future efforts should focus on strategies to streamline diagnostic processes, particularly during the early phase of admission to the centre, explore shorter treatment durations, and establish effective linkages to care post-discharge to maximise the impact of HCV elimination programs within drug rehabilitation settings. Further research could also explore the cost-effectiveness of such integrated programs and the long-term impact on both individual health and public health outcomes within this marginalised population in Malaysia.

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