

Incremental Cost of Hepatitis C Screening, Diagnosis and Treatment among People who Inject
Drugs in Kenya

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Abstract

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Hepatitis C virus infection is a global public health threat, and has potential to progress to chronic liver disease, liver cancer and preventable deaths, if left untreated. Among people who use injecting drugs, the prevalence of HCV is 52% globally and 13-40% in Kenya, which is higher than in the general population, where the prevalence is 0.7% globally and 0.9% in Kenya. Injectable drug use accounts for 1 in 3 HCV related deaths globally. While Direct Acting Antiviral treatment has been known to eradicate the virus by 95%,¹⁵ only 23% people were diagnosed with the virus and 5% initiated treatment globally, by 2020. In Africa, of 10% diagnosed with the virus, 0.4% initiated treatment. In Kenya, there is limited data of the proportion of people diagnosed with the virus and initiated on treatment. Additionally, there is no cost data for screening, diagnosis and treatment among people who inject drugs in Kenya. This is the first cost study in Kenya. The two

aims of the study were: 1. To estimate the annual incremental costs, using a micro-costing approach and payer (Ministry of Health) perspective over 5-year time horizon and 2. To determine human and other resources use by analyzing monitoring and evaluation data from time and motion surveys and health care provider interviews. The study analyzed secondary data collected from 123 clients who underwent screening, diagnosis and treatment in 8 needle syringe program and methadone treatment centers in Kenya. The total annual incremental costs were \$48,996. Total annual incremental costs per client were \$398 and the biggest cost drivers were personnel, \$285 (73%) and lab, stationery and supplies accounting for \$83 (21%). The overall time taken for screening, diagnosis and treatment was 55 min (IQR 40, 103), out of which screening took the longest time, 20 min (18, 42). With an understanding of these costs, there is need for scale up these services to increase access to this priority population. Provision of treatment by the Ministry of Health and focus on this population, provides a valuable opportunity for Hepatitis C virus micro-elimination.

Introduction

Hepatitis C virus (HCV) infection is a global public health threat. HCV is a blood borne virus, whose infection, if left untreated has potential to progress to chronic liver disease, liver cancer and preventable deaths, which estimate at 1.4 million annually. By 2020, there were 56.8 million (0.7%) people infected with HCV globally, 7.8 million (0.7%) in Africa and 482,000 (0.9%) in Kenya. In Kenya, HCV is higher prevalence in the Nairobi and Coast regions. Among people who use injecting drugs (PWID), the prevalence of HCV is 52% globally and 13-40% in Kenya, and this is higher than the general population, where the prevalence is 0.7% globally and 0.9% in Kenya. Injectable drug use accounts for 1 in 3 HCV related deaths globally and PWID account for 23-39% of the 7.5 million new infections globally.^{1,2} As PWID are at a higher risk of HCV infection, due to unsafe needle and syringe practices, they comprise a growing proportion of HCV transmissions. Additionally, PWID face multiple barriers to accessing HCV management at needle and syringe programs (NSPs) and methadone treatment centers (MAT), at individual, provider and systems levels, resulting in low rates of testing, engagement in care and completion of treatment. Therefore, focusing on this population, in HCV management, provides a valuable opportunity for HCV micro-elimination. As there is no protective vaccine currently, HCV treatment with Direct Acting Antivirals (DAAs), which work by blocking HCV replication, has been known to eradicate the virus by 95%, which is defined as sustained virologic response (SVR) and reduce HCV relapse, with minimal adverse events.¹⁵ In 2016, when HCV was declared a public health threat, the WHO introduced global 2030 targets for the management of HCV. These included: >90% diagnosed and >80% treated. However, by 2020, of 12.9 million (23%) people with HCV diagnosed globally, 641,000 (5%) were initiated treatment. In Africa, of 10 % who were diagnosed, 0.4% were initiated on treatment.^{3,4,5} In Kenya, results from a prospective study, conducted among 100 PWID in

Kenya, indicated that out of 92% diagnosed and initiated on treatment, 86% completed treatment and achieved SVR-12. However, there is no cost data available for HCV management.^{6,7}

This was the first cost study, with the largest cohort of PWID treated in Kenya. It sought to estimate the total financial and economic incremental cost per client for HCV screening, diagnosis and treatment. The goal of this was to inform the design of a systematic treatment approach to achieve micro-elimination of HCV among PWID in Kenya. Our specific aims were: 1. To estimate the annual incremental costs, using a micro-costing approach and payer (Kenya Ministry of Health) perspective over 5-year time horizon. 2. To determine human and other resources use by analyzing monitoring and evaluation data from time and motion surveys and health care provider interviews.

Regional Context

A micro-costing study of a randomized control trial conducted in 2017 in 8 hospitals in the United States (US), among PWID, showed total health care costs for HCV care facilitation per client as \$11,940 and \$11,150 in the treatment as usual arm, an incremental cost per client of \$790 (p=0.75).¹⁶ After randomization, 51 of them received HCV care facilitation, which included motivational interviewing to help clients progress along the HCV continuum of care, and 62 of them received treatment as usual, which encouraged clients to maintain or re-enter HIV care and receive referrals to social services for 6 months. The results highlighted the importance of HCV specialized care for PWID, to facilitate tracking their progress along the HCV care continuum. In a model-based cost effectiveness analysis for HCV screening, and treatment with DAAs conducted between 2016 and 2018 in Nairobi, Kenya among 64 PWID found that the total cost per client of screening, diagnosis and treatment was \$5011. This was excluding the cost of DAAs, which were \$ 727 for 12 weeks treatment.³ This was higher than the cost of HCV care facilitation in the US, which could indicate differences in care delivery. There is also evidence of HCV treatment success

among PWID in Kenya from a prospective study, conducted between 2017 and 2018, among 100 PWID in 9 NSPs in Nairobi and Coast regions. Among the 92 PWID who initiated the 12 weeks treatment, 85 (92.4%) completed treatment and 79 (85.9%) achieved a positive SVR-12.^{6,7} Despite the success of DAA treatment, there is limited cost data on HCV management among PWID in Kenya. As HCV micro-elimination strategies among PWID has been prioritized in Kenya, this cost analysis is the first in Kenya. It sought to fill the gap in costing data, which is important for financial planning and designing efficient, affordable and scalable programs nationally.

Methods

Study setting and participants

The costing study uses secondary data collected from two parent studies: 1. A prospective cohort study of HIV, Hepatitis C, Assisted Partner Notification Services and Phylogenetics among PWID in Kenya (SHARP study), conducted between 2018-2022 and funded by NIH R01-DA043409 and 2. A follow-up observational cohort study Optimizing HCV Treatment for PWID to Achieve Micro-elimination (GILEAD study), conducted between 2020-2021 and funded by Gilead Sciences, Inc. Our study analyzed cost data collected from the GILEAD study, in 8 NSP and MAT centers, in Nairobi and Coast regions, which have the highest PWID in Kenya.^{10,11}

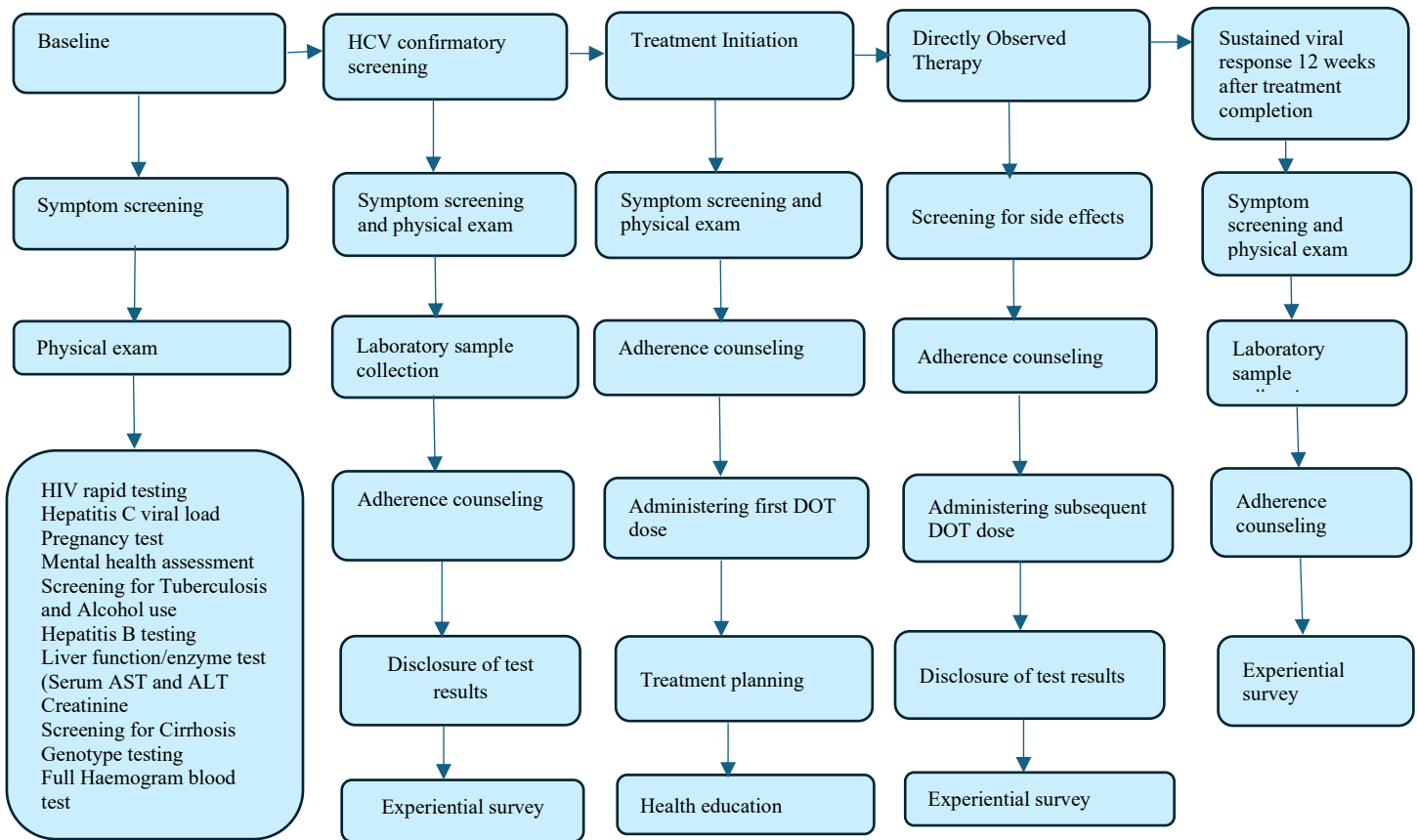
Sampling strategy

The study used data for 123 clients (men and women) who were screened, found eligible and consented to be enrolled in HCV treatment out of a total of 500 clients, who had been purposively sampled from the 8 NSP and MAT centers and included in the study if they: injected drugs at least once in the past 3 years and enrolled in NSP/MAT centers; were a sexual or injecting drug partner of someone who injected drugs and was enrolled in the treatment program; at least 18 years; had

no liver fibrosis; women who were not pregnant or planning to become pregnant in the next 6 months; gave informed consent. Clients were excluded from the study if they had: drug-drug interactions with previous HCV treatment medication; liver disease; confirmed pregnancy or breast feeding; cohabiting behaviors, with a regular sexual partner who was pregnant; unwilling or unable to return for required clinic visits.

We analyzed costs and resource use associated with the HCV management (see Figure 1).

Figure 1: HCV care cascade (Adapted from: Gilead study protocol)¹¹



A total of 123 clients underwent four HCV management procedures: 1. Screening with HCV rapid diagnostic tests (antibody testing) using SD Bioline, to detect antibodies produced by the body in response to HCV, which shows past or present (active) HCV infection. Positive test results were

confirmed using HCV Polymerase Chain Reaction – (PCR) testing, which detects the virus’ genetic material (RNA) and confirms active infection. Clients also underwent clinical review for signs and symptoms of advanced liver disease prior to treatment initiation; 2. Treatment initiation with DAA (Harvoni, a generic drug combination of Ledipasvir/Sofosbuvir, taken 1 oral tablet daily for 12 weeks; 3. Directly observed treatment, where clients were given treatment under the observation of the health care provider; 4. Sustained virologic response 12 weeks after treatment completion, which was identified through viral load. testing. An undetectable viral load signified HCV cure. Out of these, 123 clients who were initiated on HCV treatment with DAA, 104 (85%) completed the treatment and 86 (83%) achieved SVR-12, confirmed by a negative HCV test, indicating no detectable HCV in blood, which showed that HCV was successfully cleared in the blood and that the clients had achieved HCV cure.^{12,13} Out of 123 clients, majority, 78 (63%) received HCV management at MATs and the rest at NSPs. Other client characteristics include: median age was 38 years (IQR 31, 44) and majority, 101 (82.1%) were male.¹³

Data collection

We obtained financial and economic costs for inputs used in Gilead study from invoices, expenditure reports, administrative records, published literature, Kenya MOH published personnel salaries. We obtained data for personnel type, time and cost from monitoring and evaluation reports from time and motion survey and personnel interviews. We used an excel-based costing method to input, calculate and summarize cost data categorized for start-up and recurrent inputs. To ensure accuracy of data entry, we had online discussions with the study coordinator and administrator.

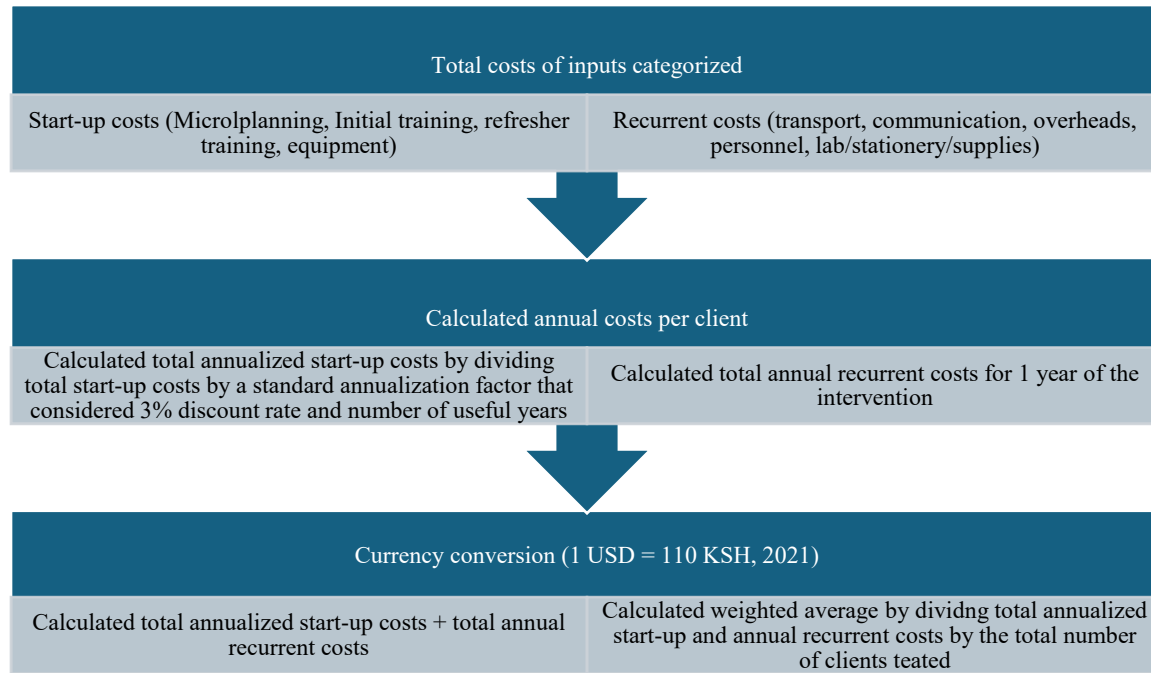
Estimating cost

We conducted prospective micro-costing analysis, using a bottom-up approach, considering all inputs, activities, personnel and duration of time included in HCV screening, diagnosis and treatment. We used the payer perspective, considering the MOH bore the costs of the HCV services for PWID, and applied a 5-year time horizon, assuming that these costs would reduce with time, as health outcomes improved. The objective of the costing was to analyze costs of established HCV activities in order to identify potential cost savings and implications for increasing access to and sustainability of HCV management among PWID. By analyzing costs by inputs, we ascertained which activities were high or low spending and improvements needed for potential efficiency. Using Microsoft Excel-based costing, we estimated the total and unit financial and economic costs for 12 months HCV intervention period, for direct medical and non-medical and indirect costs by following 3 steps: 1. We categorized input costs into start-up (capital) costs, which were used for more than 1 year and included: microplanning, initial training, refresher training and equipment; and recurrent costs, which were used for the duration of the study, which was 1 year. These included: transport, communication, overheads, personnel and laboratory, stationery and supplies (see Table 1). 2. For start-up costs, we calculated the annualized total start-up costs or economic costs, by dividing total start-up costs by a standard annualized factor, which factored a 3% discount rate to account for depreciation over time and the number of useful years of the start-up inputs (see Figure 2).

Table 1: Classification of cost by inputs

Cost categories	Description
Capital/Start-up costs	Needed to set up HCV screening, diagnosis and treatment and their value lasts for >1 year
Microplanning	Standard operating procedures and material development
Initial training	Training workshops providing an overview of the HCV study protocol describing the role of for peer educators, site advisors, clinicians, health advisors and study personnel
Refresher training	Follow-up training workshops to ensure compliance to the study protocol by peer educators, site advisors, clinicians and study personnel
Equipment	Capital inputs of \$100 or more used for one time and which last for more than one year. These include: equipment such as: micro-planning, initial and refresher training and equipment such as mobile phones and tablets, for which we assumed some of which we assumed 5 useful years. For other equipment such as laptops, label printers, metallic cabinets, routers, hard drives, office desks and chairs, we assumed 10 useful years and for metallic filing cabinet, we assumed 20 useful years.
Recurrent costs	Needed to maintain HCV screening, diagnosis and treatment and their value lasts for the period of intervention
Transportation	Fare reimbursement for peer educators for follow-up of clients and transport of laboratory samples for testing and dry ice to laboratory in Nairobi
Communication	Cost of internet data bundles for electronic medical records, airtime cost for making client follow up phone calls and sending short text messages for clinic and lab appointment
Overheads	Clinic collaboration fees and indirect costs such as management, office building maintenance, support staff, utilities (internet, rent, electricity, water, solid waste including sharps disposal) and stationery.
Personnel (Service delivery)	Costs for salaries, benefits and allowances of human resource involved in HCV screening, diagnosis and treatment, including laboratory testing and data management
Personnel (Supervision)	Human resource involved in supervising personnel, coordinating and monitoring implementation of HCV screening, diagnosis and treatment
Laboratory procedures	Blood draws and laboratory tests for HCV PCR confirmatory and viral load testing, liver function/enzyme level tests (serum aspartate aminotransferase (AST) and alanine aminotransferase (ASL)), creatinine and full hemogram tests
Stationery	Items used for recording clinical and laboratory procedures, including pens, note books, labels, photocopy paper, multi punch pocket
Supplies	Items used in clinical and lab procedures, including Diluent Isotonic, Cleanac, Hemolinac, vacutainer tubes, serum vials, transfer pipettes, cryo boxes, vacutainer needles and needle holders, Lumiquick Hep B kit, biohazard autoclave bags, sharps container, examination gloves, cool box, alcohol swabs, cotton wool, Elastoplast, urine collection bottles, pregnancy test strips, hand sanitizers, surgical face masks

Figure 2: Steps in calculating costs



Calculating start-up costs

Annualizing costs for start-up inputs averages their value, and allows for depreciation and opportunity cost over the lifetime of their services. It reflects the net present value in use of the capital items, rather than reflecting when they were purchased. In using the 3% discount rate, we considered the different number of useful years for the inputs. These include: 5 years for microplanning, initial and refresher training (non-recurrent), phones and tablets, 10 years for laptops, label printers, metallic cabinets and internet routers and 20 years for metallic filing cabinet, which we discounted and expressed in terms of their present value. We assumed that start-up costs were incurred at the beginning of HCV activities and that these costs would reduce with time as their use spreads beyond the duration of the intervention. Annualization involved calculating the present value of the start-up inputs, as this takes into account their opportunity cost, which is the value of alternative opportunities for using these items. In another words, the

alternative to spending money on the inputs in year 1, would be that the money could be invested elsewhere and gain a rate of interest. For recurrent costs, the purchase and use of the inputs was reflected in the current year's costs. The annualization factor is calculated using the formula: $[(1+r)^n - 1] / [r(1+r)^n]$, Where r = discount (rate), n = number of useful years. In this study, we did not calculate the annualization factor. Rather, we used standard tables for annualization factors and used 4.58 for 5 useful years, for 10 useful years and for 20 useful years.^{8,9} From literature, the choice of discount rate significantly influences that relative costs and cost effectiveness of HCV interventions, when they are compared. Recommended discount rates are between 3% and 5%.⁸

Calculating recurrent costs

For recurrent costs, we calculated financial costs of recurrent inputs, assuming their opportunity cost was their own cost. We calculated the total incremental costs by adding the annualized capital costs to the annual recurrent costs and converted local KSH currency to the US Dollar at the exchange rate of 1USD to 110 KSH in 2021. We made the following exclusions and assumptions:

1. We excluded research costs associated with the parent studies.
2. Considering some clinical staff may not be employed by the government, we valued personnel time for clinicians, health advisors, peer educators, data manager and laboratory technologists, using the Kenya MOH salary scale as recorded on the staff payroll.

2. The treatment of HCV was not part of the study procedures as it was provided by the MOH through the Global Fund, as part of the MOH initiative to expand HCV treatment in Kenya. The market cost of DAAs is between \$68-\$136 for the 12-week treatment. However, we did not factor this cost, as it was covered by the MOH, which also incurred personnel time and costs to procure the drugs. In our costing procedures, we followed the principles of best practices based on the global health cost consortium reference case for estimating the costs of global health services and interventions.¹⁴

Time and motion survey

We analyzed data collected from interviews and time and motion surveys. Study staff directly observed service time spent by health advisors and clinical officers during clients' 4 encounters with them (Figure 1). These included: 1. Screening: symptom screening, physical exam, counseling, sample collection and laboratory testing, results dissemination, experiential survey; 2. Treatment initiation: health education, counseling on adherence, symptom screening and physical exam, treatment plan options and administering the first dose by Directly Observed Therapy (DOT); 3. Subsequent daily DOT: screening for side effects, counseling on adherence and administering subsequent DOT dose; and 4. SVR-12: screening, physical exam, lab sample collection, viral load testing and liver function tests, counseling on adherence and prevention, and an experiential survey. Study staff also conducted semi-structured interviews with facility in-charges to understand facility characteristics. We summarized the time actively spent by health providers per client encounter using the median and interquartile range (IQR) in Microsoft Excel and calculated personnel costs based on this time and their annual salary.

Results

Total annual incremental costs per client for HCV screening, diagnosis and treatment

From table 2 and figures 3, 4 and 5, the total annual incremental costs were \$ 48,996. The total annual incremental costs per client were \$398. The biggest cost drivers were personnel, which was \$292 (73%), followed by laboratory, stationery and supplies, which was \$83 (21%).

Table 2: Total annual incremental costs per client for HCV screening, testing and treatment

Input	Total annual incremental costs (USD)	Total annual incremental costs per client (USD)	Cost drivers (%)
Start-up costs			
Micro-planning	905.77	7.36	1.84
In-person training	95.80	0.78	0.19
Online training	63.64	0.52	0.13
Equipment	1,330.55	10.82	3.12
Sub-total start-up costs	2,395.76	19.48	5.28
Recurrent costs			
Transportation	190.77	1.55	0.39
Communication	104.55	0.85	0.21
Overheads	295.91	2.41	0.60
Personnel	35,835.50	291.35	72.84
Lab, stationery, supplies	10,173.67	82.71	20.68
Sub-total recurrent costs	46,600.41	378.87	94.72
Total costs	48,996.16	398.34	100.00

Figure 3: Total annual incremental costs (USD)

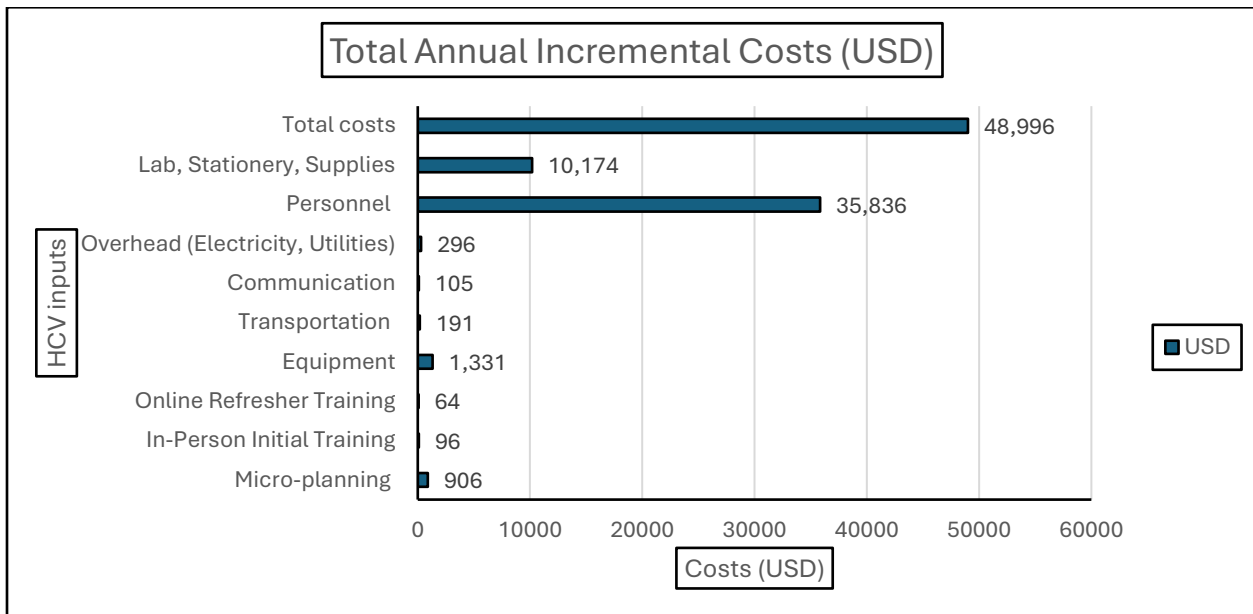


Figure 4: Total annual incremental costs per client (USD)

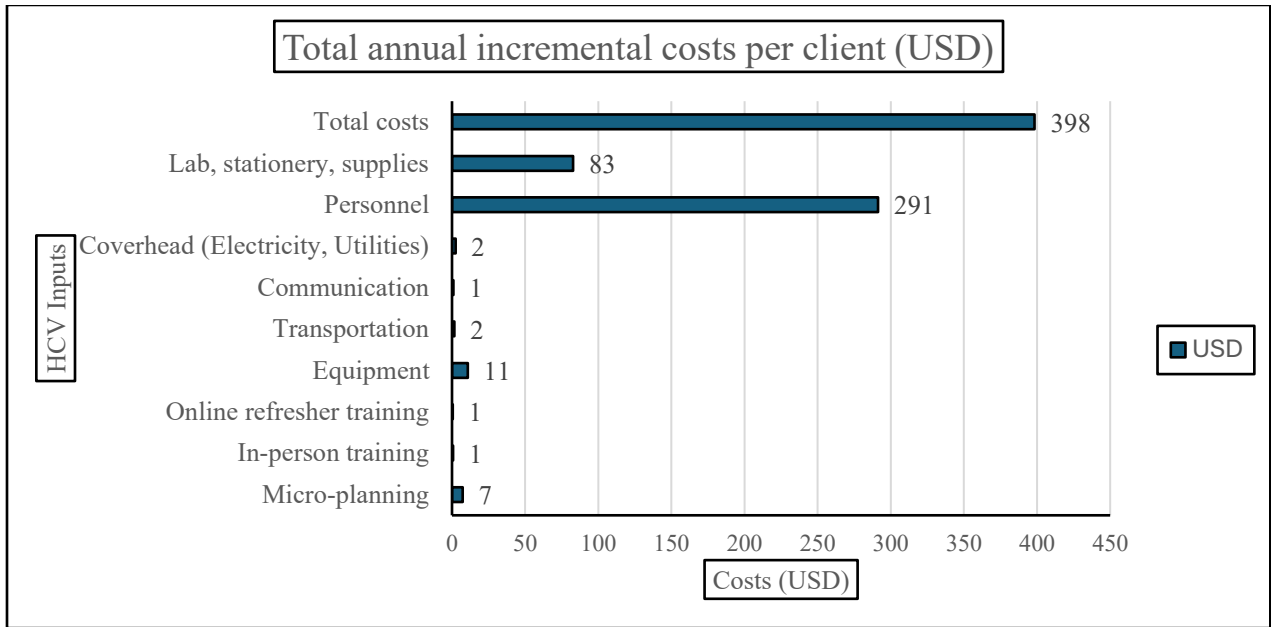
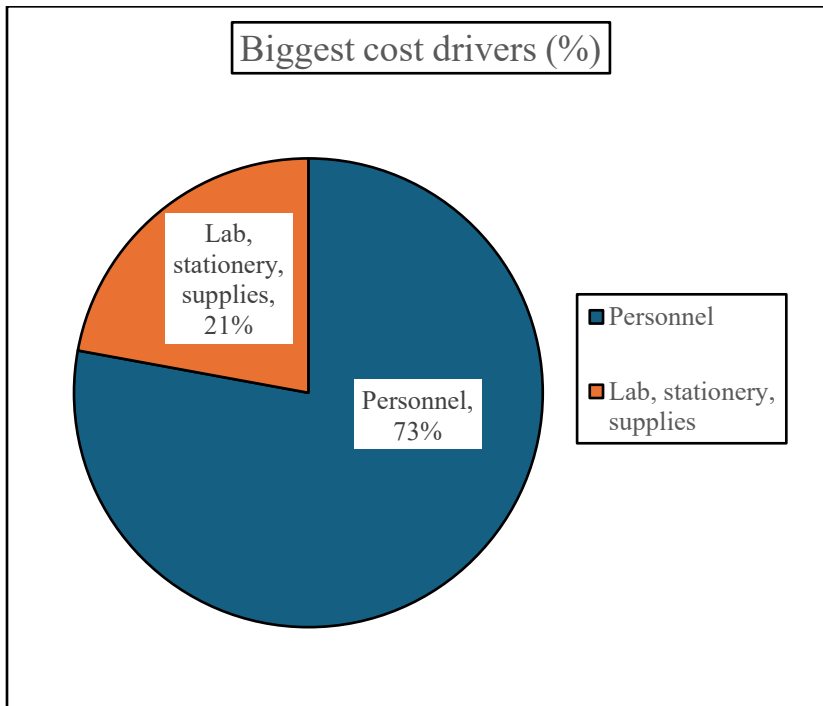


Figure 5: Cost drivers



Human and other resource use

From table 3, the median time personnel took for HCV screening, diagnosis and treatment was 55 min (IQR 40, 103). Out of this, the longest time was taken in screening was, 20 min (18, 42).

Table 3: Median time, min (IQR) per client for screening, treatment initiation, directly observed treatment and sustained viral response 12 weeks after treatment completion

Screening	Symptom screening and physical exam (Clinician)	Lab sample collection (Clinician)	Adherence counseling (Clinician)	Disclosure of test results (Health Advisor)	Experiential Survey (Health Advisor)
20 (18, 42)	7 (5, 10)	8 (7, 13)	9 (5,10)	10 (5, 14)	4 (3, 5)
Treatment Initiation	Symptom screening and physical exam (Clinician)	Adherence counseling (Clinician)	Administering first Directly Observed Therapy (DOT) dose (Clinician)	Treatment planning (Clinician)	Health Education (Clinician)
15 (10, 25)	3 (1, 8)	4 (4, 9)	3 (1, 8)	6 (5, 10)	4 (2, 5)
Directly observed treatment	Screening for side effects (Clinician)	Adherence counseling (Clinician)	Administering subsequent DOT dose (Clinician)	Total	
3 (2, 4)	2 (1, 3)	2 (1, 3)	1 (1, 2)	5 (3, 8)	
Sustained virologic response 12 weeks after treatment completion	Symptom screening and physical exam (Clinician)	Laboratory sample collection (Clinician)	Adherence counseling (Clinician)	Adherence counseling (Health Advisor)	Experiential survey (Health Advisor)
19 (11, 33)	4 (0, 7)	10 (6, 16)	4 (0, 7)	2 (1, 4)	6 (4, 9)
Total 55 (40, 103)					

Discussion

The study has provided evidence for the total annual incremental costs of HCV screening, diagnosis and treatment among PWID in Kenya, which were \$48,996. Unit costs, that is the total annual incremental costs per client were \$ 398. The biggest cost drivers were personnel, which was \$292 (73%) and laboratory, stationery and supplies, which were \$83 (21%). Additionally, the total time it took per client for HCV screening, diagnosis and treatment was 55min (IQR 40, 103).

Comparing these findings to the costs per client for 51 clients, randomized to HCV care facilitation a randomized control trial, conducted in the US in 2017, which were \$11,940 and the costs per client for HCV screening, diagnosis and treatment for 64 clients in a model-based cost effectiveness study, conducted in Kenya between 2016 and 2018, which was \$5011, where the costs of DAA was excluded, our findings were much lower. This difference could be attributed to differing modes of HCV care delivery.

The results of this study also underscore the importance of scaling up HCV management in NSP an MAT centers in Kenya, to increase access and sustainability for PWID. This would facilitate uptake of HCV management, minimize stigma and track their progress along the HCV care cascade, towards HCV micro-elimination.

Limitations

The following were limitation of the study:

- 1) Unavailability of cost data for some inputs, omission of indirect costs such as lost productivity, medical costs averted and costs incurred by loss to follow-up, may have led to under-estimation of total incremental costs per client.

- 2) While cost data was obtained from the regions in Kenya with the largest prevalence of PWID, rendering the cost data useful for informing policy and practice on HCV management among PWID in Kenya, these findings may not be generalizable to other settings outside Kenya.

Conclusion

From our micro-costing analysis, the total annual incremental costs were \$48,996 and unit costs were \$398. The biggest cost drivers were personnel, \$291 (73%) and lab, stationery and supplies, \$83 (21%) were the biggest cost drivers. From our analysis of time and motion surveys and interviews, the total time taken for HCV screening, diagnosis and treatment per client was, 55min (IQR 40, 103). As DAAs are effective in curing HCV, additional research to inform policy and practice, involving multiple sites with high prevalence of PWID is needed to estimate total costs of HCV screening, diagnosis and treatment at population level. As the MOH provides DAA treatment, HCV micro-elimination can be achieved with continued political will, national planning and appropriate resources allocation.

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