



# Prevalence, estimated incidence, risk behaviours, and genotypic distribution of hepatitis C virus among people who inject drugs accessing harm-reduction services in Kenya: a retrospective cohort study

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## Summary

**Background** Sub-Saharan Africa has a large population of people with hepatitis C virus (HCV) infection, yet little is known about HCV among people who inject drugs this region. We assessed the prevalence of HCV mono-infection and HIV–HCV co-infection, and the estimated incidence, genotypes, and risk behaviours associated with HCV among people who inject drugs in Kenya.

**Methods** People aged 18 years or older who were living in Nairobi, coastal Kenya, or western Kenya, had a history of injection drug use, and had used any illicit drugs in the past 12 months were recruited at needle and syringe programme sites using respondent-driven sampling. Participants were screened for the presence of an anti-HCV antibody. Those who were anti-HCV positive underwent confirmatory HCV RNA testing, and those with detectable HCV RNA were genotyped. Participants were interviewed regarding parenteral risk behaviours and exposure to services received at the needle and syringe programme sites. We examined correlates of HCV infection and HIV–HCV co-infection using bivariate and multivariate regression, and estimated HCV incidence.

**Findings** Of 2188 enrolled participants, 291 (13%) were anti-HCV positive: 183 (22%) of 842 participants in coastal Kenya, 105 (13%) of 817 in Nairobi, and three (1%) of 529 in western Kenya. 284 anti-HCV-positive participants underwent successful HCV RNA testing, of whom 230 (81%) were viraemic. Estimated incidence rates of anti-HCV positivity per 100 person-years were 6·31 in coastal Kenya, 3·19 in Nairobi, and 0·22 in western Kenya. HCV incidence rate was greater in coastal Kenya compared with Nairobi (incidence rate ratio 1·97 [95% CI 1·35–2·93],  $p=0\cdot0001$ ) and the western region (28·17 [7·55–236·58],  $p<0\cdot0001$ ). In the coastal region, history of incarceration, more years injecting, more injections in the past month, and receptive cooker sharing were associated with increased risk of HCV, while female sex, more years injecting, more injections in the past month, and regular use of a syringe with a detachable needle were associated with HCV risk in Nairobi. HCV prevalence among HIV-positive participants was 50% (66 of 131 participants) in coastal Kenya, 35% (42 of 121) in Nairobi, and 4% (one of 23) in western Kenya. Risk factors for HIV–HCV co-infection were similar to those observed for HCV mono-infection. The prevailing genotypes were 1a (51%), 4a (47%), and mixed (2%; three 1a/4a and one 1a/2b).

**Interpretation** HCV prevalence, estimated incidence, and risk behaviours among people who inject drugs in Kenya vary with region, with the highest estimated incidence observed in coastal Kenya. These findings should be used to inform focused strategies to reduce HCV transmission, such as expansion of needle and syringe programmes, upscaling of opioid agonist therapy, and treatment as prevention in regions affected by injection drug use and HCV.

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## Introduction

Hepatitis C virus (HCV) infection is a global pandemic, with an estimated 71 million individuals infected worldwide.<sup>1,2</sup> Chronic HCV infection can result in liver cirrhosis, hepatocellular carcinoma, and liver failure, leading to 500 000 preventable deaths per year.<sup>3</sup> WHO has outlined global HCV elimination targets to be enacted by 2030.<sup>4</sup> People who inject drugs (PWID) are central to HCV elimination efforts, as they constitute the group with the highest HCV prevalence in many countries, and because these individuals often have risk factors for HCV

transmission.<sup>5</sup> Prevalence of the anti-HCV antibody varies widely among PWID, but is approximately 52% globally, amounting to roughly 8·2 million PWID who are anti-HCV positive.<sup>6</sup>

Sub-Saharan Africa is home to a large number of people living with HCV,<sup>2</sup> yet little is known about PWID—and specifically the prevalence of HCV among PWID—in this region. PWID in sub-Saharan Africa are one of the populations at highest risk for HCV and HIV infection, and comprise a growing proportion of the HCV and HIV transmissions in the region.<sup>7</sup> However, access to addiction

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### Research in context

#### Evidence before this study

We searched PubMed for studies published before June 1, 2018, with no start date restriction, with the search terms (HCV\*) AND PWID\* AND (Africa OR sub-Saharan Africa). We reviewed all study reports that described hepatitis C virus (HCV) prevalence, incidence, genotypes, and risk behaviours among people who inject drugs (PWID) in sub-Saharan Africa. Three articles described HCV prevalence among PWID. The single systematic review reported an HCV prevalence of 21.8% among PWID. There were no reports of estimated incidence. Reported genotypes included mostly 1a and 4. In the only study reporting specific risk behaviours beyond injection drug use, more years of heroin use, sharing of needles or other injection equipment, being arrested, and HIV co-infection were identified.

#### Added value of this study

This is the largest study to assess HCV prevalence among PWID in sub-Saharan Africa. To our knowledge, it is also the first

study to assess prevalence in several intra-country regions, to estimate HCV incidence, and to address specific injection risk behaviours among PWID in a sub-Saharan African country. The findings show regional variation in HCV prevalence and incidence among PWID in Kenya. We also identified specific demographic factors and injection practices that lead to increased HCV risk.

#### Implications of all the available evidence

Public health interventions to reduce HCV transmission—such as expansion of needle syringe programmes, upscaling of opioid agonist therapy, and treatment as prevention—are needed in the effort to eliminate HCV among PWID in sub-Saharan Africa.

treatment and prevention services, such as needle and syringe exchanges, has been insufficient among these individuals, who also face persecution and stigma from police and communities.<sup>8</sup> In Kenya, widespread use of heroin (particularly its more injectable forms) began during the tourism boom on the Kenyan coast in the 1980s, and has gradually made its way inland across the country.<sup>9</sup> To respond to the threat of blood-borne pathogens among PWID, the Kenyan Government introduced needle and syringe programmes in 2013 and methadone maintenance therapy in 2014 as part of a targeted strategy to engage the country's most at-risk populations.<sup>10</sup>

Although estimates of anti-HCV antibody prevalence among PWID in sub-Saharan Africa are limited in both quantity and quality, the available data suggest that this prevalence is similar to or lower than that in other settings worldwide.<sup>11,12</sup> In Kenya, reports have suggested that between 22% and 70% of PWID are anti-HCV positive.<sup>13,14</sup> HIV–HCV co-infection is also important among PWID because HIV infection can lead to reduced spontaneous HCV clearance, higher viral loads of HCV, and more rapid HCV disease progression.<sup>15</sup> Data on HIV–HCV co-infection among PWID in Kenya are scarce, but its prevalence appears to be 18–32%,<sup>13,16</sup> in contrast to a global prevalence of 82%.<sup>17</sup>

HCV mono-infection and HIV–HCV co-infection vary in prevalence by duration of injection drug use and by global geographical region.<sup>18</sup> To date, no comparative studies have been done to examine the associations between HCV prevalence and duration of injection drug use or geographical region in sub-Saharan African countries. Furthermore, to our knowledge, there have been no estimates of HCV incidence or assessments of the association between injection drug use-related risk behaviours and HCV transmission in sub-Saharan Africa.

The aim of this study was to report on the prevalence of HCV mono-infection and HIV–HCV co-infection, and the estimated HCV incidence, genotypes, and risk behaviours among PWID enrolled at needle and syringe programme service sites in Nairobi and coastal and western Kenya.

## Methods

### Study population and recruitment

Study participants were screened for HCV as part of a supplement to the Testing and Linkage to Care for Injection Drug Users (TLC-IDU) study (NCT01557998), a stepped-wedge cluster-randomised trial evaluating the effectiveness of a “seek, test, treat, and retain” approach to viral load suppression among people with HIV and who use injection drugs in Kenya.<sup>19</sup> Participants included in the TLC-IDU study met the following criteria: age 18 years or older; attending needle and syringe programme service sites; living in Nairobi or coastal or western Kenya; a lifetime history of injecting drugs; and reported use of any illicit, non-prescribed drugs by any route of administration within the past 12 months.

Respondent-driven sampling was used to recruit study participants. Initial seeds were selected through a nomination process by staff at the needle and syringe programme site, and were trained to recruit a small number of their peers for the research study, if they so chose, using coded recruitment coupons. These recruited peers became study participants and in turn had the opportunity to recruit their peers for the study, resulting in several waves of recruitment. All participants received training on recruiting peers, and participated in a brief interview to assess demographics and social network characteristics.

We used fingerprints to avoid duplicate enrolments within and between study timewaves, to ensure correct

identification of participants, to track repeat visits, and to protect subject privacy and information. The fingerprint software translated a fingerprint into a code containing numbers and letters; no image of the fingerprint was stored, and the code could not be used to recreate a fingerprint and thus was not personally identifiable information. The same finger yielded the same code on subsequent occasions in more than 99% of cases.

Individuals who were recruited through respondent-driven sampling were offered enrolment at four needle and syringe programme sites in Nairobi, six in coastal Kenya (two in Mombasa town, two in South Coast [one in Likoni and one in Ukunda], and two in North Coast [one in Mtwapa, Kilifi, and one in Malindi]), and three in western Kenya (one in Kisumu, one in Migori, and one in Kisii) between July 15, 2015, and April 28, 2017. Needle and syringe programme sites, which are run by non-governmental organisations and are partner sites of the Kenya National AIDS & STI Control Program (NASCO), provide PWID-specific services following the WHO recommended package (which includes needle and syringe programmes, HIV testing and counselling, HIV treatment and care, prevention and treatment of sexually transmitted infections, condom distribution, targeted information, education and communication, vaccination, diagnosis and treatment of viral hepatitis, and prevention, diagnosis, and treatment of tuberculosis). In addition, some sites provide food programmes and cleaning facilities, among other services, depending on fund availability.

This study was approved by the Ethics and Research Committee of Kenyatta National Hospital (University of Nairobi), and the Yale University Institutional Review Board. All participants provided written informed consent.

### Behavioural and virological assessments

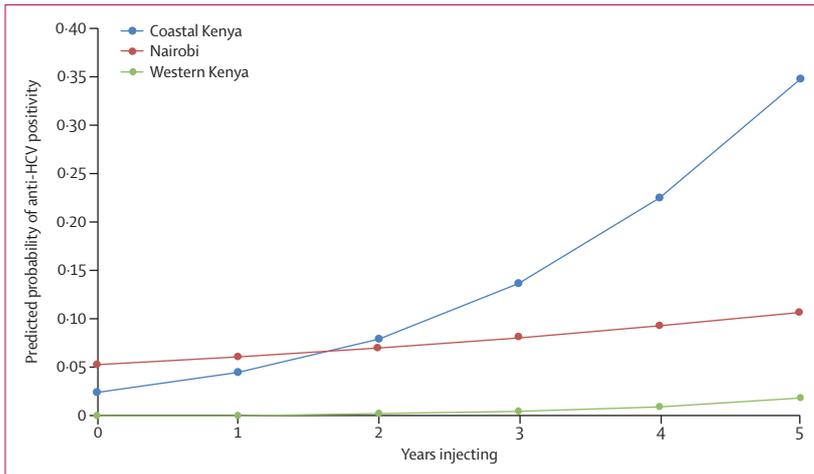
After obtaining informed consent, each participant completed a behavioural interview, which included questions on risk behaviours for parenteral transmission of infection, exposure to services received at the needle and syringe programme sites, and information on methods for preventing HIV and HCV transmission. HCV testing using the SD Bioline rapid anti-HCV test (Standard Diagnostics, South Korea) began in June, 2015, in Nairobi, and the last patient was tested in April, 2017, in western Kenya. For participants with reactive screening tests, we collected venous blood for confirmatory HCV RNA testing using the Abbott RealTime HCV Assay (Abbott Molecular, Des Plaines, IL, USA), which was done at the Kenya Medical Research Institute Centers for Disease Control laboratory in Kisumu, Kenya. Those with detectable HCV RNA were asked to return for a subsequent study visit to provide a venous blood specimen for genotyping. Venous blood specimens were stored at the Kenya National Blood Center Transfusion Service laboratory at -20°C, before being sent on dry ice to the US Centers for Disease Control and Prevention laboratory in

	Total (n=2188)	Coast (n=842)	Nairobi (n=817)	West (n=529)
Age, years	32 (28–36)	32 (29–37)	32 (27–37)	30 (27–33)
Sex				
Male	1984 (91%)	759 (90%)	711 (87%)	514 (97%)
Female	204 (9%)	83 (10%)	106 (13%)	15 (3%)
Ever incarcerated	1373 (63%)	613 (73%)	649 (79%)	111 (21%)
Age at first injection, years	27 (24–31)	28 (24–32)	27 (22–32)	26 (24–30)
Years injecting	3 (2–6)	3 (1–6)	3 (2–6)	3 (2–5)
Number of injections in the past month	60 (30–90)	90 (60–90)	60 (30–90)	30 (30–60)
Number of days injecting in the past month	30 (30–30)	30 (30–30)	30 (30–30)	30 (30–30)
Median number of injections per day in the past month	2 (1–3)	3 (2–3)	3 (2–3)	1 (1–2)
PWID social network size	20 (10–30)	20 (10–30)	15 (10–20)	20 (15–30)
Needle sharing at last injection				
Receptive	59 (3%)	35 (4%)	15 (2%)	9 (2%)
Distributive	66 (3%)	37 (4%)	20 (2%)	9 (2%)
Cooker sharing at last injection				
Receptive	216 (10%)	45 (5%)	162 (20%)	9 (2%)
Distributive	214 (10%)	45 (5%)	162 (20%)	7 (1%)
Cotton sharing at last injection				
Receptive	204 (9%)	35 (4%)	161 (20%)	8 (2%)
Distributive	204 (9%)	35 (4%)	163 (20%)	6 (1%)
Water sharing at last injection				
Receptive	216 (10%)	54 (6%)	154 (19%)	8 (2%)
Distributive	214 (10%)	51 (6%)	156 (19%)	7 (1%)
Regular use of syringe with detachable needle	1025 (47%)	761 (90%)	33 (4%)	231 (44%)
Used same syringe more than twice	100 (5%)	45 (5%)	35 (4%)	20 (4%)
NSP service use				
Accessed NSP in past year	1377 (63%)	716 (85%)	661 (81%)	354 (67%)
Main source of syringes neither NSP nor pharmacy	256 (12%)	45 (5%)	153 (19%)	58 (11%)
Number of needles received last visit	9 (3–10)	9 (3–10)	9 (0–12)	7 (0–30)
Number of needles returned last visit	3 (0–9)	6 (2–9)	0 (0–6)	0 (0–0)
Average number of NSP visits per week	7 (2–7)	7 (3–7)	7 (2–7)	7 (0–7)
Average number of exchanges per week	7 (0–7)	7 (7–7)	7 (0–7)	7 (0–7)
Anti-HCV positive	291 (13%)	183 (22%)	105 (13%)	3 (1%)
HIV positive	275 (13%)	131 (16%)	121 (15%)	23 (4%)

Data are median (IQR) or n (%). NSP=needle and syringe programme.

**Table 1: Demographic and serological characteristics by site**

Atlanta (GA, USA) for genotyping. Genotyping was done with Sanger sequencing of *NS5B* and next-generation sequencing of hypervariable region 1. Participants with detectable HCV RNA were brought back to the study site to receive their confirmatory HCV results, counselling per the Kenyan Government's standard of care, and referrals for future counselling, psychosocial support, harm reduction education, and HCV support groups. Those



**Figure:** Predicted probability of HCV infection based on number of years injecting by region  
HCV=hepatitis C virus.

with confirmed viraemic HCV were offered treatment with direct-acting antiviral therapy as part of a later substudy, and these data are not reported in this Article.

Participants in this study had already been tested for HIV with the Determine HIV-1/2 Ag/Ab rapid test (Alere, Waltham, MA, USA) and had HIV-antibody positivity confirmed with a second assay, Uni-Gold HIV-1/2 (Trinity Biotech, Wicklow, Ireland). Peer case managers with histories of injection drug use facilitated linkage to HCV, HIV, and injection drug use-specific services, and supported adherence and retention in care.

### Statistical analysis

We calculated population estimates of anti-HCV prevalence while taking into account social network sizes and patterns of recruitment using the RDS R package (version 0.8). We used version 3.42 of R statistical software for all other analysis. Demographic and regional differences were assessed with use of  $\chi^2$  tests. Firth's bias-reduced logistic regression was used to examine bivariate correlates of HCV infection.<sup>20</sup> Bias-reduced logistic regression was also used to estimate the unique effects of predictors in multivariate models of HCV infection and HIV-HCV co-infection.

Estimation of HCV incidence among PWID followed methods used by Des Jarlais and colleagues<sup>21</sup> and in other studies.<sup>22,23</sup> Two opposing factors were considered when deciding which PWID to include in estimates of incidence: including PWID with more years of injection drug use would increase sample size and allow for examination of the assumption that prevalence will systematically increase with increasing years injecting, whereas including PWID with fewer years of injection drug use reduces the likelihood of differential loss of people with (versus without) HCV infection from the pool of potential recruits. To balance these opposing factors, we included people who had been injecting for 5 years or fewer as new injectors, contributing to estimation of incidence. These

new injectors were defined as those whose age at the time of the survey was no more than 5 years greater than their reported age at first injection. The incidence estimate assumed the following: that all new injectors were uninfected when they began injecting, that the number of incident cases among new injectors was equal to the number who tested anti-HCV positive at the time of the survey, that HCV infection among those who tested positive occurred midway between the start of injecting and the time of the survey, that the time at risk for new injectors testing negative was the total time from first injection to the survey, and that there was no differential loss of HCV-positive participants versus HCV-negative participants in the PWID population in the periods between first injection and time of interview. For comparison of incidence rates by region, incidence rate ratios (IRRs) with CIs were calculated.<sup>24</sup> As a sensitivity analysis for incidence estimation, we plotted predicted prevalence in each region according to years injecting in logistic regression analysis. These predictions are a check on the assumption of zero prevalence at the start of injecting and provide an alternative approach to incidence estimation.

### Role of the funding source

The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

### Results

Between July 15, 2015, and April 28, 2017, 2212 PWID were screened and 2188 were enrolled. Of those enrolled, 291 (13%) were HCV antibody positive. Demographic characteristics are presented in table 1. 72% (n=1572) of all participants were classified as new injectors. Most participants were young men who had begun injecting less than 5 years previously. The frequency of anti-HCV positivity varied significantly between the coastal region (183 [22%] of 842), Nairobi (105 [13%] of 817), and the western region (three [1%] of 529;  $p<0.0001$ ). Women (45 [22%] of 204) were significantly more likely to be anti-HCV positive than were men (246 [12%] of 1983;  $p<0.0001$ ). Among the 291 participants who were anti-HCV positive, 284 underwent successful HCV RNA testing (three participants refused, one died, and three specimens were non-viable for RNA testing), of whom 230 (81%) had detectable and 54 (19%) undetectable viral loads.

Estimated incidence rates of anti-HCV positivity were 6.31 per 100 person-years in the coastal region, 3.19 in Nairobi, and 0.22 in the western region. The incidence rate in the coastal region was nearly twice the rate in Nairobi (IRR 1.97 [95% CI 1.35–2.93],  $p=0.0001$ ) and more than 28 times that in the western region (28.17 [7.55–236.58],  $p<0.0001$ ), while the incidence

	Coastal Kenya				Nairobi			
	Participants with HCV infection	Participants without HCV infection	OR (95% CI)	p value	Participants with HCV infection	Participants without HCV infection	OR (95% CI)	p value
Age, years*	35 (30–40)	32 (29–36)	1.55 (1.30–1.86)	<0.0001	34 (30–40)	32 (27–37)	1.19 (1.00–1.41)	0.0493
Sex								
Male	160 (87%)	599 (91%)	0.69 (0.42–1.16)	0.1597	83 (79%)	628 (88%)	0.50 (0.30–0.85)	0.0119
Female	23 (13%)	60 (9%)	1.00 (ref)	..	22 (21%)	84 (12%)	1.00 (ref)	..
Incarceration								
Ever	163 (89%)	209 (32%)	3.71 (2.33–6.20)	<0.0001	86 (82%)	563 (79%)	1.18 (0.71–2.04)	0.5367
Never	20 (11%)	450 (68%)	1.00 (ref)	..	19 (18%)	149 (21%)	1.00 (ref)	..
PWID social network size*	15 (7–30)	20 (10–30)	0.96 (0.77–1.15)	0.6936	20 (10–30)	15 (10–20)	1.21 (1.03–1.40)	0.0238
Age at first injection, years*	26 (22–30)	29 (25–32)	0.74 (0.61–0.89)	0.0012	26 (22–32)	27 (22–32)	0.98 (0.83–1.16)	0.8515
Years injecting*	7 (4.5–10.5)	3 (1–5)	2.37 (1.99–2.87)	<0.0001	6 (3–10)	3 (2–6)	1.31 (1.11–1.54)	0.0021
Number of injections in the past month*	90 (60–90)	60 (60–90)	1.46 (1.22–1.75)	<0.0001	90 (14–90)	60 (30–90)	1.26 (1.08–1.47)	0.0044
Days injecting in the past month*	30 (30–30)	30 (30–31)	0.90 (0.76–1.09)	0.2701	30 (25–30)	30 (30–30)	0.95 (0.83–1.10)	0.4944
Median number of injections per day in the past month*	3 (3–3)	3 (2–3)	1.91 (1.30–2.80)	0.0002	3 (2–4)	3 (2–3)	1.05 (0.91–1.18)	0.4329
Used same syringe more than twice								
Yes	19 (10%)	26 (4%)	2.83 (1.52–5.19)	0.0013	7 (7%)	28 (4%)	1.83 (0.74–4.00)	0.1777
No	164 (90%)	633 (96%)	1.00 (ref)	..	98 (93%)	684 (96%)	1.00 (ref)	..
Syringe type								
Regular use of syringe with detachable needle	167 (91%)	594 (90%)	1.12 (0.65–2.03)	0.6959	11 (10%)	22 (3%)	3.73 (1.72–7.71)	0.0013
Regular use of insulin syringe	16 (9%)	65 (10%)	1.00 (ref)	..	94 (90%)	690 (97%)	1.00 (ref)	..
Receptive needle sharing at last injection								
Yes	25 (14%)	10 (2%)	9.95 (4.88–21.74)	<0.0001	0	15 (2%)	0.21 (0.00–1.60)	0.1660
No	158 (86%)	649 (98%)	1.00 (ref)	..	105 (100%)	697 (98%)	1.00 (ref)	..
Receptive cooker sharing at last injection								
Yes	31 (17%)	14 (2%)	9.20 (4.90–18.04)	<0.0001	13 (12%)	149 (21%)	0.55 (0.29–0.97)	0.0381
No	152 (83%)	645 (98%)	1.00 (ref)	..	92 (88%)	563 (79%)	1.00 (ref)	..

Western Kenya was excluded from these analyses because the prevalence of HCV was too low to assess associations. HCV=hepatitis C virus. OR=odds ratio. PWID=people who inject drugs. \*For continuous variables, ORs are per standard deviation increase in that variable.

**Table 2: Correlates of HCV infection in coastal Kenya and Nairobi**

rate in Nairobi was more than 14 times that in the western region (14.23 [3.71–121.21],  $p < 0.0001$ ).

As shown in the figure, among new injectors, the prevalence of anti-HCV positivity increased with number of years injecting, reaching 10.7% in Nairobi and 34.7% in the coastal region after 5 years of injecting. In the western region, anti-HCV positivity increased to only 1.9% after 5 years of injecting. Averaging over the first 5 years of injecting and subtracting the estimated prevalence before injecting began suggests a HCV incidence rate of 1.1 per 100 person-years in Nairobi and 6.5 per 100 person-years in the coastal region. Incidence rate estimates based on the number of cases and person-time at risk are similar to those based on logistic regression for the coastal region, but are higher than those based on logistic

regression for Nairobi because of the higher estimated prevalence at the start of injecting in this region.

Bivariate analysis showed that older age, more years injecting, more injections in the past month, and receptive cooker sharing at last injection (positive association in coastal Kenya and negative association in Nairobi) were associated with HCV infection in coastal Kenya and Nairobi (table 2). Western Kenya was excluded from these analyses because the prevalence of HCV was too low to assess associations. Additionally, in the coastal region, history of incarceration, younger age at first injection, average number of injections per day, use of the same syringe more than twice, and receptive needle sharing at the last injection were associated with HCV infection. In Nairobi, there were associations with female

	Coastal Kenya		Nairobi	
	OR (95% CI)	p value	OR (95% CI)	p value
<b>HCV infection</b>				
Age, years*	1.02 (0.81–1.28)	0.8651	1.05 (0.85–1.29)	0.6459
Male (vs female)	0.65 (0.37–1.17)	0.1446	0.48 (0.27–0.86)	0.0138
Ever incarcerated (vs never incarcerated)	2.88 (1.70–5.13)	<0.0001	1.77 (0.92–3.61)	0.0871
PWID social network size*	0.94 (0.76–1.15)	0.0582	1.16 (1.00–1.32)	0.0534
Years injecting*	2.29 (1.86–2.86)	<0.0001	1.47 (1.19–1.82)	0.0004
Number of injections in the past month*	1.63 (1.33–2.01)	<0.0001	1.32 (1.11–1.58)	0.0016
Used same syringe more than twice (yes vs no)	1.30 (0.60–2.74)	0.4978	1.59 (0.57–3.88)	0.3532
Regular use of syringe with detachable needle (vs regular use of insulin syringe)	1.16 (0.61–2.30)	0.6564	3.47 (1.56–7.36)	0.0029
Receptive needle sharing at last injection (yes vs no)	3.12 (1.03–9.58)	0.0446	0.31 (0.01–2.59)	0.3461
Receptive cooker sharing at last injection (yes vs no)	4.55 (1.77–12.03)	0.0018	0.63 (0.32–1.18)	0.1521
<b>HIV-HCV co-infection</b>				
Age, years*	0.87 (0.59–1.24)	0.4410	1.00 (0.72–1.36)	0.9962
Male (vs female)	0.32 (0.16–0.70)	0.0048	0.44 (0.21–1.01)	0.0530
Ever incarcerated (vs never incarcerated)	2.69 (1.17–7.22)	0.0184	1.71 (0.68–4.83)	0.2625
PWID social network size*	0.76 (0.53–1.02)	0.0685	1.20 (0.99–1.40)	0.0635
Years injecting*	2.10 (1.58–2.80)	<0.0001	1.46 (1.09–1.97)	0.0122
Number of injections in the past month*	1.11 (0.85–1.45)	0.4412	1.05 (0.79–1.36)	0.7250
Used same syringe more than twice (yes vs no)	2.97 (1.23–6.77)	0.0165	2.51 (0.64–7.37)	0.1665
Regular use of syringe with detachable needle (vs regular use of insulin syringe)	0.78 (0.33–2.09)	0.6004	2.28 (0.59–6.62)	0.2074
Receptive needle sharing at last injection (yes vs no)	5.75 (1.74–19.97)	0.0040	0.53 (0.01–4.69)	0.6385
Receptive cooker sharing at last injection (yes vs no)	4.34 (1.43–12.33)	0.0108	1.17 (0.46–2.69)	0.7270

Western Kenya was excluded from these analyses because the prevalence of HCV was too low to assess correlates. HCV=hepatitis C virus. OR=odds ratio. PWID=people who inject drugs. \*For continuous variables, ORs are per standard deviation increase in that variable.

**Table 3: Predictors of HCV infection and HIV-HCV co-infection in multivariate logistic regression in coastal Kenya and Nairobi**

sex, PWID social network size, and regular use of a syringe with detachable needle.

Multivariate logistic regression analysis showed that history of incarceration, more years injecting, more injections in the past month, receptive cooker sharing at last injection, and receptive needle sharing were associated with increased odds of HCV infection in the coastal region (table 3). In Nairobi, female sex, more years injecting, more injections in the past month, and regular use of a syringe with a detachable needle were associated with increased odds of HCV infection.

The anti-HCV prevalence among HIV-positive participants (HIV-HCV co-infection) was 50% (66 of 131) in the coastal region, 35% (42 of 121) in Nairobi, and

4% (one of 23) in the western region. In the coastal region and Nairobi, multivariate models showed that more years injecting was associated with increased odds of HIV-HCV co-infection (table 3). Additionally, in the coastal region, female sex, a history of incarceration, use of the same syringe more than once, receptive needle sharing, and receptive cooker sharing were also associated with increased odds of co-infection (table 3).

From the 230 participants with detectable HCV RNA, 200 specimens were successfully obtained and sent for HCV genotyping (ten participants died, four were incarcerated, and 16 could not be traced). 175 (88%) specimens were able to be genotyped: 89 (51%) were genotype 1a, 82 (47%) were genotype 4a, and four (2%) were mixed genotype (three 1a/4a, and one 1a/2b).

## Discussion

This study is one of the first to report on HCV prevalence, estimated incidence, and risk factors for HCV transmission among PWID in sub-Saharan Africa. We showed that the HCV prevalence of 22% among PWID in Kenya is lower than global estimate of 52.3% among PWID.<sup>6,18</sup> Nevertheless, the prevalence in Nairobi and coastal Kenya was far greater than that in the general Kenyan population, which is estimated to be less than 1%.<sup>25</sup> Another notable finding was the gradation in HCV prevalence and estimated incidence from the coastal region to Nairobi and the western region. We believe that the low overall prevalence among Kenyan PWID and the geographic gradation are due, at least in part, to relatively new availability of access to heroin (especially injectable heroin) that began in the 1980s tourism boom in the coastal region and spread inland and westward.<sup>9</sup>

These variations suggest a need for rapid public health interventions, such as treatment as prevention and expansion of methadone and needle and syringe programmes in areas with higher prevalence, and prevention efforts in areas with lower prevalence of HCV infection. Without action, and if people who more recently initiated injecting continue, our results suggest that the prevalence of HCV infection with increased years injecting is likely to increase substantially, particularly in the coastal region. The Kenyan Government has been progressive in introducing methadone and needle and syringe programme services, which are well documented to be effective in preventing new infections.<sup>26,27</sup> In addition, the Kenya National AIDS/STI Control Programme is placing special emphasis on testing and treating HCV among PWID, with the goal of treating everyone at the national level. We initiated HCV direct-acting antiviral therapy as part of this supplement in the TLC-IDU cohort; however, expanded treatment coverage will be required at the national level for all PWID living with HCV. Treatment as prevention has been shown to be effective in reducing new infections, and to be cost-effective where HCV treatment is available.<sup>28</sup> Although HCV reinfection might limit the effectiveness of these strategies, reinfection rates have been low thus far

in the direct-acting antiviral era.<sup>29</sup> Therefore, rates of reinfection should be evaluated in this setting but should not limit treatment scale-up.

Our data show that anti-HCV positivity is associated with more years injecting, older age, and younger age at first injection. Similar trends have been observed elsewhere since low case fatality rates and long-lasting HCV serostatus result in a direct correlation between duration of injection drug use and HCV prevalence.<sup>30</sup> Conversely, younger PWID might have less knowledge regarding HCV risk behaviours than older PWID, increasing their probability of becoming infected.<sup>31</sup> Our findings signal a need to screen all PWID for HCV, but also suggest that extra resources might be required to educate younger individuals.

In our study, women were more likely to be anti-HCV positive than were men, and female sex was predictive of anti-HCV positivity in Nairobi and of HIV–HCV co-infection in the coastal region. Increased risk among women who inject drugs has been documented for HIV and HCV.<sup>32,33</sup> Although behavioural risk factors are likely to be significant drivers of this difference,<sup>34</sup> more data are needed on structural and biological mediators. Irrespective of mechanism, the heightened risk that women face has important implications for policy and implementation of gender-specific harm reduction programmes.

Several reported injection practices were associated with increased HCV risk. For example, in Nairobi, regular use of syringes with a detachable needle was associated with higher risk than use of insulin syringes. Syringes with detachable needles have larger dead space, leading to more residual fluid retention and greater risk for HCV transmission.<sup>35,36</sup> This finding highlights the need for harm reduction programmes to select syringes with the lowest risk for forward HCV transmission. Similarly, receptive cooker sharing was associated with increased risk of anti-HCV positivity in coastal Kenya. Whether cookers are true vectors for HCV transmission or surrogates for transmission resulting from contaminated syringes is debatable.<sup>37–39</sup> Until more evidence is available, PWID need to be educated about the risks of sharing all paraphernalia to reduce the risk of HCV transmission. Notably, HCV transmission risk is driven by more complex factors than individual behaviours alone, and is influenced by higher-level factors such as stigma, discrimination, and access to prevention services, which will also need to be addressed in future interventions.

Our data show that incarceration was associated with anti-HCV positivity in coastal Kenya. The relationship between HCV, injection drug use, and the criminal justice system is well known and should be taken into account during programme implementation.<sup>11,40</sup> Correctional settings can be strategic sites for screening and linkage to care. Moreover, when HCV treatment programmes commence, correctional settings could be used for treatment initiation and continuation if an individual is arrested while on HCV therapy.<sup>41</sup>

The global prevalence of anti-HCV antibody among HIV-infected PWID is estimated at 82%.<sup>17</sup> Data on the prevalence of HIV–HCV co-infection among PWID in Kenya are scarce, but the available data suggest that it ranges from 18% to 32%,<sup>13,16</sup> similar to the rates observed in our study. These prevalence estimates are lower than global estimates, and suggest a less well established HIV epidemic among PWID compared with that in other regions worldwide, which is similar to our finding for HCV. Our data also show that HIV–HCV co-infection among PWID appears to follow a similar geographical gradation to HCV mono-infection; this pattern runs counter to the increased HIV prevalence in western Kenya compared with Nairobi and coastal Kenya.<sup>42,43</sup> This increased HIV prevalence in the western region is due to sexual transmission,<sup>44</sup> and we suspect that HIV prevalence is lower among networks of PWID in the western than in the coastal region. Our finding among PWID suggests that regional prevention strategies similar to those for HCV mono-infection should be considered for HIV–HCV co-infection.

A strength of this study is the inclusion of confirmatory HCV RNA testing. Studies that do not show the prevalence of chronic HCV infection might overestimate HCV prevalence.<sup>45</sup> Previous studies among PWID in Kenya have shown the prevalence of viraemia to be around 56% among anti-HCV positive individuals.<sup>13</sup> Our results showed that 81% of anti-HCV positive participants were viraemic, which is similar to previously reported prevalence of chronic HCV infection among the general population.<sup>46</sup> We believe, however, that the true prevalence of chronic infection in our study might be lower because chronic HCV is marked by the persistence of HCV RNA for at least 6 months after the onset of acute infection.<sup>47</sup> The inability to genotype HCV in 12% of study participants might indicate viral clearance among a subset of study participants between the confirmation of chronic HCV viraemia and the collection of a second specimen for HCV genotyping.

The HCV genotypes observed in our study are compatible with the one other published study of HCV genotypes among Kenyan PWID, in which genotypes 1a (present in 73% of participants) and 4 (no subtype provided; 27%) were the circulating genotypes.<sup>13</sup> Our findings are also consistent with the prevailing genotypes observed regionally in eastern sub-Saharan Africa, where genotypes 1 and 4 are most common, although other genotypes (such as 2 and 3) are also observed.<sup>2,48</sup> In a study by Mwangi and colleagues,<sup>49</sup> 16 of 100 specimens from blood donors Kenya were anti-HCV positive, among which ten (63%) were viraemic. One (10%) of those ten participants had genotype 1a, and nine (90%) had genotype 2b.<sup>49</sup> One participant in our study was co-infected with HCV genotypes 1a and 2b, suggesting that genotype 2b might now be present among injecting networks, despite not previously being reported among Kenyan PWID.

Limitations of our study include the sampling strategy and methods used to estimate HCV prevalence and incidence. Specifically, we recruited participants using respondent-driven sampling and, when identified, these individuals were linked to needle and syringe programmes. However, individuals linked to needle and syringe programmes might not be representative of all PWID in those areas. Moreover, there might be PWID in areas that were not included in our sampling coverage area. Regarding prevalence, small sample sizes in some study sites decrease confidence in HCV prevalence estimates based on respondent-driven sampling. Additionally, it is unclear whether inability to genotype HCV in some participants was due to viral clearance or false-negative results. Genotyping is not currently available in Kenya, and the transnational shipment of study specimens could have resulted in complications related to specimen handling, such as temperature regulation. However, it is also possible that those with negative genotyping results cleared their infection before their specimens were collected for genotyping.

In summary, this is the largest cohort of PWID in sub-Saharan Africa to be tested for HCV to date and prevalence appears to be relatively low at present. The low HCV prevalence is promising in that it might present an opportunity for HCV elimination among PWID in Kenya. However, it is conservatively estimated that there are 16 000 PWID in Kenya,<sup>50</sup> and reports suggest that substance use has been increasing, especially in towns and cities in the coastal region, such as Malindi and Mombasa.<sup>9,51</sup> Despite new advances, including direct-acting antiviral therapies, HCV-related mortality is increasing and is expected to continue to climb for the next two decades, especially in low-income countries.<sup>48</sup> In sub-Saharan African, it is largely unknown what demographic factors and risk behaviours are associated with increased HCV transmission risk among PWID. Our data signal a need to screen all PWID for HCV. Needle and syringe programmes should select syringes with the lowest risk for forward HCV transmission, and PWID should be educated about the risks of sharing injecting drug paraphernalia to reduce the risk of HCV transmission. Additionally, urgency is needed in scaling up evidenced-based interventions centred on testing and linkage to affordable direct-acting antiviral HCV treatment coupled with needle and syringe programmes and methadone maintenance therapy among PWID in this setting.

#### Contributors

AEK, PC, MJA, and JAL conceived and designed the study. CMC, MJA, and JAL were responsible for analysis and interpretation of data. CMC was responsible for the statistical analysis. All authors contributed to drafting the manuscript and read and approved the final manuscript. MJA and AEK had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

#### Declaration of interests

We declare no competing interests.

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