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Relationship of hepatitis C risk to hepatitis C test acceptance among adult patients participating in an ED hepatitis C screening programme

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ABSTRACT

Background It is possible that adult ED patients consider their hepatitis C virus (HCV) risk factor history when deciding whether to accept HCV screening. To help address this question, we examined whether self-reporting any HCV risk was more common among ED patients who agreed than who declined HCV screening. Among ED patients who agreed to HCV screening, we also assessed if self-reporting any HCV risk was more common among those whose HCV antibody (Ab) and HCV viral load (VL) test results were positive.

Methods This study was conducted among adult patients ≥ 18 years old participating in a universal, ED-based HCV screening programme in New York City between 22 January 2019 and 9 April 2020. Participants were surveyed about their HCV risk factors. Differences in the frequencies of self-reporting any HCV risk were compared according to HCV screening acceptance and by HCV Ab and VL status.

Results Of the 4658 ED patients surveyed, 2846 (61%) accepted and 1812 (39%) declined HCV screening. Among these participants, 38% reported at least one HCV risk factor, most commonly injection drug use. Self-reporting any HCV risk was not more common among those who accepted versus declined HCV screening (40% vs 37%, $p < 0.7$) but was more common among those with HCV Ab positive versus negative test results (36% vs 6%, $p < 0.001$) and HCV VL positive versus negative results (95% vs 5%, $p < 0.001$).

Conclusion HCV risk factors were self-reported by more than one-third of ED patients but were not more commonly present among those who accepted HCV screening.

INTRODUCTION

Hepatitis C virus (HCV) is the most frequently reported bloodborne infection in the USA and causes significant morbidity and mortality and profound financial burden every year.¹ Incident HCV infections have increased annually in the USA since 2009.² As of 2018, there were approximately 50 300 new HCV infections, resulting in an estimated 2.4 million people living with HCV in the USA.¹ Recent increases in incident HCV infections among individuals aged 20–39 years old in the USA are particularly notable, given that this age group previously had not been included in HCV screening recommendations.

In April 2020, the US Centers for Disease Control and Prevention (CDC) expanded its HCV screening

WHY IS ALREADY KNOWN ON THIS TOPIC

⇒ Hepatitis C virus (HCV) is one of the most prevalent chronic viral infections in the world. Many individuals with HCV are unaware of their serostatus, and it is unknown if self-reported risk is associated with HCV test acceptance.

WHAT THIS STUDY ADDS

⇒ This study examined self-reported risk among a cohort of ED patients and determined if that risk was associated with HCV test acceptance. Self-reported HCV risk was common, being present in 38% of participants, but was not associated with HCV test acceptance.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ These data suggest that, in adult ED patients, HCV screening acceptance might not be related to self-assessment of HCV risk and support the practice of offering HCV screening without regard to self-reported HCV risk.

recommendations to recommended that all US adults aged ≥ 18 years be HCV tested at least once in their lifetime, regardless of HCV risk, and that all pregnant women be tested during every pregnancy, except in settings where the prevalence of HCV infection is $< 0.1\%$.¹ This expansion was a significant change from prior CDC recommendations that were based on age cohorts, notably screening advised for 'baby boomers' (born from 1945 to 1965), and for those with HCV risk factors.³ According to the CDC, people with HCV risk factors are those who have HIV/AIDS; currently or formerly injected drugs; received hemodialysis, underwent transfusions or organ transplants prior to 1992; had prior percutaneous injuries or mucosal exposures to HCV in the healthcare setting; or were children born to mothers infected with HCV.^{4 5}

EDs in the USA and elsewhere have recently reported experience with providing HCV screening.^{6 7} Screening efforts in US EDs have mirrored changes in CDC recommendations, moving from risk-based to non-risk-based HCV screening. Despite these changes in policy and practice, ED patients themselves could still connect acceptance of HCV screening to self-perceived HCV risk, which could affect their willingness to



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be screened if they believed they were not at risk for HCV. If ED patients are more likely to accept HCV screening based on their perceived or actual HCV risk-taking, then non-risk-based HCV screening efforts could be hampered, and interventions to increase HCV screening regardless of risk need to be developed and used.

To assess the relationship between HCV risk and willingness to accept HCV screening in EDs, we conducted this investigation at an ED in an urban, high-HCV incidence setting that has a non-targeted HCV screening programme. As a primary aim, we examined whether patients who agreed to HCV testing were more likely to have any self-perceived HCV risk compared with those who declined testing. In addition, we examined whether HCV screening acceptance was related to membership in the baby boomer birth cohort, which previously had been isolated as an age cohort needing HCV testing.³ As a secondary aim, among ED patients who agreed to HCV screening, we explored if self-reporting any HCV risk was more common among those whose HCV antibody (Ab) test result was positive or whose HCV viral load (VL) was positive.

METHODS

Study design

This study enrolled participants from a non-targeted HCV screening programme at a US urban academic ED, between 22 January 2019 and 9 April 2020. The Mount Sinai Beth Israel ED in New York City has an annual census of approximately 85 000 adult visits, drawing from a large urban catchment area. HCV incidence in this catchment area is very high, ranging between 73.7 and 108.1 newly reported and chronic HCV infections per 100 000 people.⁸

HCV programme

Details of the HCV programme have been previously published.^{9 10} In brief, to be eligible for HCV screening, ED patients needed to be age 18 years old and older, medically stable (as determined by their primary registered nurse (RN)), and capable of providing informed consent for testing (opt-in). Programme eligible patients were offered both HCV and HIV testing by their primary RN. For patients who accepted testing, the RN generated a testing order, performed phlebotomy and sent a blood sample to the hospital laboratory for HCV testing. As per standard practice in our screening programme, patients who declined the RN testing offer were approached by an ED-based health educator (HE) who provided a brief educational session and encouraged the patient to accept testing. For patients who accepted HCV screening after this brief educational session, phlebotomy was performed if the patient did not already have a blood specimen obtained. If a blood specimen had already been obtained, the HCV test was added to existing testing orders. All HCV Ab tests were automatically reflexed to HCV VL testing. The ED HEs followed up on all VL tests, which result between 3 days and 5 days after the patient's ED visit. Patients who were HCV VL+ were linked and navigated by the HEs to the hepatology clinic proximate to the hospital.

Study eligibility criteria

Eligibility criteria for participation in this study mirrored those for the HIV screening programme. English-speaking and Spanish-speaking ED patients 18 years of age and older were potentially eligible for study participation regardless of their HCV status and testing history. Patients had to have the capacity

to provide verbal consent for study participation, as determined by the research associate (RA) collecting the study data.

Study procedures

RAs were present during the study period in the ED 16 hours/day, 5 days/week, collecting data for this investigation. During these times, the RA would review the ED electronic health record (EHR) tracking board for potentially study-eligible patients. Once identified, the RA would approach the potential study patient, explain the study in detail and ask for verbal consent for participation. Patients who agreed to participate were administered a 17-item questionnaire about HCV status, treatment history and risk factors (online supplemental material 1). The HCV risk factor portion of the questionnaire was derived from existing literature on the topic and the CDC's published list of HCV risk factors, which include injection drug use, sharing injection-drug needles and receipt of blood transfusions before 1992.^{4 11} The RAs administering the questionnaire were blinded to whether or not the patient had accepted or declined HCV testing from the RN. In addition to the surveys conducted by the RAs, ED patients whose test was HCV Ab+ were asked by an HE to complete the same HCV risk factor questionnaire if it had not been completed prior to testing.

Analytical dataset creation

The analytical dataset was created by linking three separate data sources: (1) HCV risk factor questionnaire collected by the RA/HE, (2) sociodemographic data from the hospital EHR collected as part of the non-targeted HCV screening programme and (3)

Table 1 Demographic characteristics of study participants

Demographic characteristics	Study participants	ED patients presenting for care during the study period
	n=4658	n=45783
Age, mean (SD)	49.41 (17.66)	45.84 (21.11)
'Baby boomer' birth cohort, n (%)		
Not a cohort member	3059 (65.7)	33 872 (74.0)
Cohort member	1591 (34.2)	11 610 (25.4)
Unknown	8 (0.2)	301 (0.7)
Sex, n (%)		
Female	2309 (49.6)	22 252 (48.6)
Male	2316 (49.7)	22 593 (49.3)
Unknown	33 (0.7)	938 (2.0)
Race, n (%)		
Asian	146 (3.1)	2391 (5.2)
Black	805 (17.3)	7288 (15.9)
Other	1318 (28.3)	11 521 (25.2)
Unknown	1193 (25.6)	13 699 (29.9)
White	1196 (25.7)	10 884 (23.8)
Hispanic/Latino ethnicity, n (%)		
Hispanic/Latino	849 (18.2)	6461 (14.1)
Not Hispanic/Latino	1503 (32.3)	12 487 (27.3)
Unknown	2306 (49.5)	26 835 (58.6)
Healthcare insurance type, n (%)*		
Commercial	1740 (37.4)	20 279 (44.3)
Medicaid	1621 (34.8)	13 920 (30.4)
Medicare	1076 (23.1)	8831 (19.3)
Self-pay	132 (2.8)	1113 (2.4)
Unknown	89 (1.9)	1640 (3.6)
Baby boomer birth cohort: born between 1945 and 1965.		
*Commercial includes private insurance; Medicaid and Medicare include governmental insurance; self-pay denotes uninsured.		

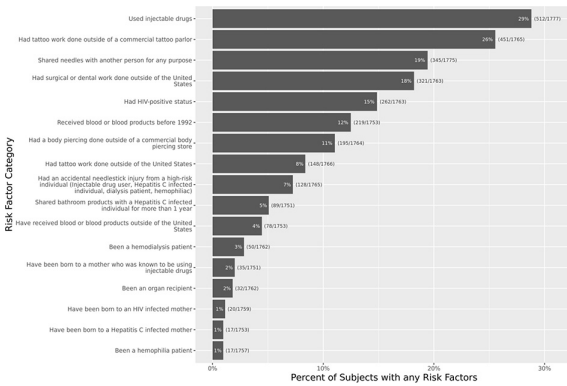


Figure 1 Study cohort's hepatitis C risk factors.

HCV test results from laboratory reports collected by the HCV screening programme. These three data sources were merged using the patient's medical record number as the unique identifier. The merged dataset was then stripped of identifiers to create a deidentified analytical dataset.

Statistical analysis

No a priori sample size was calculated because we did not have frequency estimates of self-reported HCV risk factors among ED patients who had accepted or declined HCV screening. Our goal was to collect 5000 risk factor questionnaires, which we believed would allow for a robust comparison between those

who accepted and declined HCV screening; however, data collection ended early due to COVID-19 restrictions. Demographic characteristics of study participants were summarised. We compared demographic characteristics of study participants to the larger population of patients who received care in the ED during the study period using Fisher's exact or Chi-square testing, as appropriate for categorical variables and t-tests to compare continuous variables. We used similar methods to compare demographic characteristics of participants who reported no versus any HCV risk factor, and presence of no versus any HCV risk factors according to those who accepted versus declined HCV screening, and by HCV Ab test result (HCV Ab+ vs Ab-) and detectable versus non-detectable HCV VL. Simple logistic regression was performed to evaluate univariate associations between sociodemographic variables of interest and HCV test acceptance. Three multivariable logistic regression models were constructed to assess the association of HCV screening acceptance and (1) any versus no self-reported HCV risk factors, (2) being a member versus not a member of the baby boomer birth cohort (born from 1945 to 1965), (3) being in the combined HCV risk group (ie, either reporting any HCV risk, being a member of the baby boomer birth cohort or both). All models were adjusted for participant demographic characteristics (age, sex, race, Hispanic/Latino ethnicity, and healthcare insurance type (commercial, Medicare, Medicaid, other). Statistical analysis was performed using R statistical software (R Core Team 2020, Vienna, Austria). An $\alpha=0.05$ level of significance was used for all statistical testing.

Patient and public involvement

Patients were not involved in the design, conduct, reporting or dissemination plans of our research.

RESULTS

Participant population demographic characteristics

Between 22 January 2019 and 9 April 2020, risk factor surveys were obtained for 4658 ED patients and thus comprised the study sample. Of these 4658, 365 patients (142 HCV Ab+ and 223 HCV Ab-) completed a risk factor survey after receiving their HCV test results. Study enrolment was stopped prior to our targeted enrolment goal due to the declaration of public health emergency for COVID-19. Of the 4658 participants, the majority were not members of the baby boomer birth cohort, most had healthcare insurance, and men and women were represented in similar percentages (table 1). As compared with the rest of the patients presenting to the ED during the study period, those from whom a risk factor questionnaire was obtained were slightly older and more likely to be in the baby boomer birth cohort (table 1).

HCV risk factors among study participants

Among the 4658 participants, 2865 (61%) self-reported no HCV risk factors and 1793 (38%) reported at least one HCV risk factor. Among participants who reported a risk factor for HCV, 874 (49%) reported one risk factor; 338 (19%) reported two risk factors; 228 (13%) reported three risk factors and 353 (20%) reported more than three risk factors. The most commonly reported were use of injectable drugs, tattoos received at a location other than a commercial tattoo parlour and sharing injection-drug needles with another person (figure 1). As compared with those who did not report any HCV risk factor, those reporting any HCV risk factor were slightly older, more often a member of the baby boomer birth cohort, male, black or

Table 2 Participant demographic characteristics, any self-reported HCV risk versus no self-reported HCV risk

Demographic characteristics	No HCV risk factors	Any HCV risk factor	P value
	n=2865	n=1793	P<
Age, mean (SD)	48.68 (18.55)	50.58 (16.07)	0.001
'Baby boomer' birth cohort, n (%)			
Not a cohort member	1984 (69.2)	1075 (60.0)	0.001
Cohort member	878 (30.6)	713 (39.8)	
Unknown	3 (0.1)	5 (0.3)	
Sex, n (%)			
Female	1565 (54.6)	744 (41.5)	0.001
Male	1285 (44.9)	1031 (57.5)	
Unknown	15 (0.5)	18 (1.0)	
Race, n (%)			
Asian	104 (3.6)	42 (2.3)	0.001
Black	452 (15.8)	353 (19.7)	
Other	772 (26.9)	546 (30.5)	
Unknown	798 (27.9)	395 (22.0)	
White	739 (25.8)	457 (25.5)	
Hispanic/Latino ethnicity, n (%)			
Hispanic/Latino	502 (17.5)	347 (19.4)	0.011
Not Hispanic/Latino	895 (31.2)	608 (33.9)	
Unknown	1468 (51.2)	838 (46.7)	
Healthcare insurance type, n (%)			
Commercial	1192 (41.6)	548 (30.6)	0.001
Medicaid	871 (30.4)	750 (41.8)	
Medicare	659 (23.0)	417 (23.3)	
Other	85 (3.0)	47 (2.6)	
Unknown	58 (2.0)	31 (1.7)	
HCV, hepatitis C virus.			

Table 3 Logistic regression models assessing relationship of HCV screening acceptance versus decline by HCV risk models

HCV risk factor groupings and demographic characteristics	Univariable models	Any self-reported HCV risk factor model	'Baby boomer' birth cohort model	Combined HCV risk group model
	OR (95% CI)	aOR (95% CI)	aOR (95% CI)	aOR (95% CI)
Any versus no self-reported HCV risk factors	1.12 (0.99 to 1.26)	1.09 (0.96 to 1.23)	N/A	N/A
Member versus not a member of the baby boomer birth cohort	0.99 (0.88 to 1.12)	N/A	1.00 (0.86 to 1.16)	N/A
Combined HCV risk group versus no HCV risk	1.17 (1.04 to 1.32)	N/A	N/A	1.19 (1.04 to 1.35)
Age	1.00 (1.00 to 1.00)	1.00 (0.99 to 1.00)	1.00 (0.99 to 1.00)	1.00 (0.99 to 1.00)
Sex				
Female	Reference	Reference	Reference	Reference
Male	1.07 (0.95 to 1.20)	1.12 (0.99 to 1.26)	1.10 (0.98 to 1.25)	1.09 (0.97 to 1.24)
Unknown	1.15 (0.57 to 2.42)	0.88 (0.40 to 2.05)	0.87 (0.39 to 2.02)	0.87 (0.39 to 2.01)
Race				
White	Reference	Reference	Reference	Reference
Asian	1.37 (0.96 to 1.97)	1.34 (0.94 to 1.93)	1.35 (0.94 to 1.95)	1.35 (0.94 to 1.95)
Black	1.26 (1.05 to 1.52)	1.29 (1.07 to 1.56)	1.28 (1.07 to 1.55)	1.28 (1.06 to 1.50)
Other	1.40 (1.19 to 1.64)	1.27 (1.06 to 1.51)	1.26 (1.06 to 1.51)	1.26 (1.06 to 1.50)
Unknown	1.14 (0.96 to 1.34)	1.10 (0.92 to 1.31)	1.10 (0.92 to 1.31)	1.11 (0.93 to 1.33)
Hispanic/Latino ethnicity				
Non-Hispanic/Latino	Reference	Reference	Reference	Reference
Hispanic/Latino	1.46 (1.22 to 1.74)	1.41 (1.16 to 1.72)	1.41 (1.16 to 1.72)	1.40 (1.15 to 1.71)
Unknown	1.07 (0.93 to 1.22)	1.07 (0.92 to 1.25)	1.07 (0.92 to 1.25)	1.07 (0.92 to 1.25)
Healthcare insurance				
Commercial	Reference	Reference	Reference	Reference
Medicaid	1.09 (0.95 to 1.25)	1.03 (0.89 to 1.19)	1.02 (0.88 to 1.18)	1.02 (0.88 to 1.17)
Medicare	1.02 (0.87 to 1.19)	1.06 (0.87 to 1.29)	1.06 (0.87 to 1.28)	1.08 (0.88 to 1.31)
Other	0.90 (0.63 to 1.30)	0.92 (0.64 to 1.32)	0.92 (0.64 to 1.32)	0.92 (0.64 to 1.32)
Unknown	0.44 (0.28 to 0.67)	0.36 (0.22 to 0.57)	0.36 (0.22 to 0.57)	0.36 (0.22 to 0.57)

aOR, adjusted OR; HCV, hepatitis C virus.

other race and more likely to have Medicaid healthcare insurance (table 2).

Self-report of any HCV risk among those accepting versus declining HCV screening

Of the 4658 participants, 2846 (61%) accepted and 1812 (39%) declined HCV testing. Of the 2846 tested, 519 (11%) were Ab+ and 117 (4%) were HCV VL+. The 2846 participants who accepted HCV screening were not more likely to report any HCV risk than the 1812 who declined HCV screening (40% vs 37%, $p=0.7$). Among the 2846 tested for HCV, self-reporting any HCV risk was more common among those who were HCV Ab+ versus HCV Ab- (37% vs 6%, $p<0.001$) and HCV VL+ (95% vs 5%, $p<0.001$).

Table 3 provides the results of the multivariable logistic regression models assessing the association between acceptance versus decline of HCV screening and HCV risk factor groupings, as adjusted for participant demographic characteristics. For both the any self-reported HCV risk model and the baby boomer birth cohort model, only black race and 'other' race compared with white race, and Hispanic/Latino ethnicity compared with not Hispanic/Latino ethnicity were associated with greater acceptance of HCV screening. For the combined HCV risk group model, being in the combined HCV risk group (ie, either reporting any HCV risk, being a member of the baby boomer birth cohort or both) was associated with greater HCV screening acceptance, along with black race and other race compared with white race, and Hispanic/Latino ethnicity compared with not Hispanic/Latino ethnicity.

DISCUSSION

We report on self-reported HCV risk among a convenience sample of ED patients participating in a non-targeted HCV screening programme in an attempt to ascertain if HCV risk is associated with HCV test acceptance. Among those surveyed, self-reported HCV risk was common, with 38% reporting at least one HCV risk factor. Much of this risk was secondary to practices associated with injection drug use and tattoos not performed at a commercial parlour. Unfortunately, we cannot know if these HCV risks, particularly those associated with injection drug use, were ongoing at the time of the ED visit. Regardless, given the recent increase in injection drug use associated with the ongoing opioid epidemic, it is not surprising that two of the top three risk factors reported were using injection drugs and sharing needles.¹²

The frequency of injection drug use as an HCV risk found in this study is higher than what has been reported in similar non-targeted ED-based HCV screening programmes.^{6 13} This finding, as well as the higher frequency of any HCV risk, undoubtedly is related to those included in the study. HCV risk assessments were included from two populations: (1) anyone whose HCV Ab test was positive and (2) those who agreed to complete a survey when approached by the research coordinator, regardless of whether or not agreeing to be tested for HCV. As a consequence, the HCV risk frequency is likely higher in this study, and distribution of types of risk could differ from that of other populations. Furthermore, because patients approached to be surveyed was a convenience sample rather than a random sample, and patients could decline participation, we cannot claim to have estimated the true prevalence of HCV risk in this population.

In addition, direct comparison to other ED-based HCV screening programmes is challenging because most only report the prevalence of injection drug use among those who accepted HCV testing.

As compared with those surveyed without self-reported HCV risk, those with any self-reported HCV risk tended to be slightly older. This distinction is not surprising, given that opportunities for engaging in HCV risk accumulates over time. Those reporting any HCV risk were predominantly men, which could be secondary to the higher prevalence of opioid use disorder in men, a significant risk factor for HCV infection.¹⁴ Our finding that more patients with any self-reported HCV risk had Medicaid (state administered insurance programme for low income adults, children, pregnant women, elderly and people with disabilities) is commensurate with other studies showing that a high proportion of people with HCV are either uninsured or have public healthcare insurance.^{15 16} We are unable to accurately comment on differences in HCV risk by race and Hispanic/Latino ethnicity, given missing data on these elements.

With regard to the primary aim, we found no association between any self-reported HCV risk and HCV test acceptance. There also was no association between being in the baby boomer birth cohort and HCV test acceptance. However, when having any self-reported risk and being a member of the baby boomer birth cohort were combined, there was an association; participants in this combined risk group were more likely to accept HCV screening. Although the reason for this finding cannot be known from this type of study, one possibility includes there being a synergistic effect of having any HCV risk and being in the baby boomer birth cohort. Baby boomers with any HCV risk might be more cognisant that HCV screening is recommended for them or might be more aware of the association of HCV risk and need for testing. Another possibility is that combining risk groups made the marginal associations of the baby boomer cohort and having any HCV risk with HCV screening acceptance become statistically significant. Regardless of the reason, the absence of an association between any self-reported HCV risk and HCV test acceptance suggests that non-targeted HCV screening can achieve the intended objective of routinising and increase HCV testing among all populations regardless of perceived or actual risk. Furthermore, we cannot explain why blacks and Hispanic/Latino ED patients were more likely to accept HCV screening.

It was expected that any HCV risk was more common among those who were HCV Ab+ and VL+, given that many of these risk behaviours indicate known methods of HCV transmission, for example, injection drug use, sharing of injection drug needles, receipt of blood products before HCV screening of blood products was available and mandatory. However, significant proportions of HCV Ab+ and VL+ patients reported no HCV risk or were not members of the baby boomer birth cohort. We have previously shown that baby boomer birth cohort screening alone would miss more than 50% of ED patients who ultimately were found to be HCV VL+.⁹ These findings have been corroborated by multiple other ED-based HCV screening studies.^{6 17 18} We believe our findings provide further support for current CDC testing recommendations that hepatitis C screening be performed at least once in a lifetime for all adults aged ≥ 18 years, except in settings where the prevalence of HCV infection is $< 0.1\%$.²

This study had a number of limitations. It was conducted in a single urban ED that provides care to a large number of patients who inject drugs. This ED also employs full time HEs who perform structured re-engagement for patients who refuse the RN offer of testing. Because our programme uses re-engagement to convince patients to accept testing, our comparison is between those who accepted HCV testing (or who could be convinced to accept it) versus those who could not be convinced to accept HCV testing. Thus, our results might not generalise to sites not using re-engagement. HCV

risk profiles of patients in other EDs could be different, depending on the population served and surveyed. As noted previously, the study sample was not randomly chosen, included those with an HCV Ab+ test result, and thus might not reflect the true HCV risk prevalence in this population. Furthermore, some patients with positive HCV Ab tests may have been asked about their HCV risk after being informed of their test results, which could have resulted in recall bias. It is also possible that those who refused HCV screening did so because they recently had been tested, which was not reflected in the data. Patients with ongoing HCV risk might have been more likely to have been offered HCV testing in other settings, and thus declined the HCV test offer, thereby affecting the observed results. In addition, data were missing for race and ethnicity. These characteristics are recorded in the EHR and are often incomplete. The missing data made it challenging to estimate associations of race and ethnicity with HCV test acceptance.

CONCLUSIONS

Among patients surveyed in this ED HCV screening programme, self-reported HCV risk was common, being present in 38% of participants. There was no association between any self-reported HCV risk and HCV test acceptance, nor was test acceptance related to membership in the baby boomer birth cohort. These data suggest that in adult ED patients, HCV screening acceptance might not be related to self-assessment of HCV risk, and support the practice of offering HCV screening without regard to self-reported HCV risk.

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Contributors EC designed the study, interpreted the data and drafted the manuscript. SB, BA and CO'B-L acquired the data and assisted with manuscript preparation and critical revision. DGB created the data analysis plan and analysed the data. RM helped draft the manuscript and assisted with the analyses. EE and YC helped in the design of the study. All authors assisted with critical review and revision of the manuscript and approval of the final draft. EC takes responsibility for the paper.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the Icahn School of Medicine at Mount Sinai institutional review board (study number 18-01337), which granted an alteration of informed consent to allow for verbal rather than written informed consent. The participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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