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Context of Clinical Care: The Case of Hepatitis C in Underserved Communities - A Report from the Primary Care Multi-Ethnic Network (PRIME Net) Consortium

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Abstract

Background—The importance of Hepatitis C (HCV) as a public and individual health concern is well-established. However, national groups differ in their recommendations to primary care clinicians about screening high-risk persons for HCV. The purpose of this study was to explore the context of care within which primary care clinicians decide to detect and initially manage HCV.

Methods—The Primary Care Multi Ethnic Network conducted a web and paper based survey of primary care clinicians who largely practice in low-income, medically underserved communities in three regions across the country.

Results—A total of 494 clinicians participated for a response rate of 61%. Most (68%) clinicians view HCV as an important problem; over half (59%) consider screening for HCV to be important when compared with other conditions they screen for in practice. In regard to reported screening habits for risk-factors, 54% of clinicians routinely ask new patients whether they have used intravenous drugs and 28% inquire about blood transfusions before 1992. Sixty one percent order an ALT when patients present with other risk factors for HCV. The majority of clinicians (54%) refer 75% or fewer of their patients with HCV for treatment; nearly one-fifth (18%) provide anti-viral treatment themselves. Key factors influencing clinician HCV decisionmaking are: patient comorbidities (74% reported as a factor), access to treatment (55%), and tolerance (44%) of treatment.

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Conflict of interest statement: Drs. Pace, Parnes, Fry-Johnson, Pathak, Skipper, Daniels, and Kroth state that they have no potential, perceived or real conflicts of interest. Drs. Williams and Leverence state that they are in discussions with the leadership of the hepatitis C treatment program referred to in references 20 and 29, a program operated within Dr. Leverence's academic department. These discussions could lead to a collaborative research project aimed at investigating the facilitators and barriers for primary care clinicians for participating in the program. While there will be no personal gain to either Dr. Leverence or Dr. Williams, the referenced program may in the future provide some salary support to staff of RIOS Net (of which Drs. Leverence and Williams are both leaders). While we believe this does not present a real conflict of interest, we bring this to your attention should there be a perceived potential conflict of interest.

Conclusions—In the face of conflicting national guideline recommendations about screening high-risk persons for HCV, clinicians have varied views and practice habits, influenced by multiple patient, access, and treatment issues.

Background

Hepatitis C (HCV) is the most common blood borne infection in the United States, the leading cause of liver transplantation, and responsible for 8,000-10,000 deaths annually.(1,2) Prevalence estimates in the United States indicate that 1.6% of the population have chronic HCV infection, with disadvantaged and stigmatized populations having a disproportionately increased prevalence.(3,4)

Despite the clear public and individual health implications of HCV infection, controversy exists over what actions primary care clinicians should take with regard to screening for the disease (Table 1). The Centers for Disease Control and Prevention (CDC) (5,6), the National Institutes of Health (NIH) (7), and the American College of Preventive Medicine (ACPM) (8) all advocate screening of individuals at high risk for having HCV infection. At the same time, the U.S. Preventive Services Task Force (USPSTF) finds insufficient evidence to recommend for or against routine screening of high risk persons (“I” recommendation). (9-11) In its recommendation statement, the USPSTF notes the lack of information about long-term outcomes of anti-viral treatment following screening, as well as insufficient information about the natural history of HCV infection and about potential harms from screening. In response and in support of screening of high-risk groups, representatives of the CDC and others have pointed out that: 1) definitive evidence of benefit from treatment of HCV would require longitudinal clinical trials of greater than 20-30 years, considering the protracted nature of the disease; 2) studies of up to 10 years have shown persistent virological response and improved hepatic measures following treatment; and 3) additional benefits beyond anti-viral treatment can result from screening of high-risk groups (immunization, counseling about transmission and risk reduction). (4,6)

In the face of inconsistent guidance from these major scientific bodies, it is likely that primary care clinicians will vary in their approach to screening and management of patients at high risk for HCV. Clinicians may choose their approach based on the NIH, CDC, ACPM or USPSTF recommendations, heuristics related to the treatment experience of their patients, competing demands for care within the patient encounter, or other factors that may vary across clinicians (12,13).

Several studies have in fact shown that screening and initial management of patients at high-risk for HCV by primary care clinicians varies widely.(14-20) Under the assumption that low levels of screening and referral for HCV management are due primarily to insufficient understanding of the problem by primary care clinicians, recommendations of the authors of some of these studies and of national panels have focused on providing increased education on HCV to primary care clinicians.(14,16,17) The underlying expectation is that reversing a knowledge deficit can lead to higher rates of HCV identification and entry into treatment.

We conducted this study to gather a more in-depth understanding about primary care clinicians' perspectives on the context within which HCV screening and initial management takes place. The goal was to gain a greater understanding of the multiple factors that impact on clinicians' decisions related to hepatitis C detection and management. The primary aims were to: 1) describe views about HCV among a sample of primary care clinicians caring mainly for medically underserved populations; 2) characterize these clinicians' reported HCV screening and management practices; and 3) describe primary care clinician perceptions of the context of care for HCV. The study was focused among clinicians working in medically underserved

communities in part because HCV is a particular concern in these communities where HCV prevalence may often be higher than in the general population.

Methods

Study design

A survey was conducted among primary care clinicians mostly practicing in low-income, medically underserved communities.

Sample

All clinicians from three primary care practice-based research networks were surveyed. These three networks are part of the Primary Care MultiEthnic Network (PRIME Net), a consortium of eight primary care practice-based research networks (Research Involving Outpatient Settings Network: RIOS Net; the Colorado Research Network: CaReNet; the Southeast Regional Clinicians' Network: SERCN; the Southern Primary Care Urban Research Network: SPUR-Net; the Collaborative Research Network: CRN; the Southernwestern Ohio Ambulatory Research Network: SOARnet; MetroNet; and LA Net) (<http://hsc.unm.edu/som/primenet/>). Clinicians in RIOS Net, CaReNet, and SERCN participated in this study. The majority of clinicians in these three networks practice in community health centers, Indian Health Service clinics, or academic practices serving low-income/underserved communities. Recruited clinicians are located in urban, suburban and rural settings and the patient populations seen in these practices present with patterns of diagnoses typical of primary care.(21) In addition, primary care clinicians from a fourth, non-research network – the University of New Mexico School of Medicine Preceptorship Network – were surveyed. This latter group consists of 160 practicing primary care clinicians throughout the state of New Mexico who precept University of New Mexico medical students. This group was included in the survey sample to provide perspectives of clinicians not in a research network; many also work in underserved communities.

Survey Instrument

The questionnaire focused on contextual factors that might influence clinician approaches to screening and initial management of HCV. It was developed through a review of the existing literature, consultation with the lead author of a prior HCV clinician survey, and iterative discussions with PRIME Net clinicians.(18) The survey contained 30 branching questions, with the opportunity for the clinician to provide additional narrative comments for several of the questions. The questionnaire was piloted among a sample of clinicians at a RIOS Net Annual Meeting and among University of New Mexico Family Medicine and Internal Medicine residents, resulting in minor revisions. Copies of the final survey instrument are available at: <http://hdl.handle.net/1928/3620>.

Data Collection

The HCV Clinician Survey was administered electronically by an initial email solicitation directing the clinician to a web-based questionnaire.(22) This was followed by four additional email solicitations with links to the questionnaire sent to non-responders at 7-10 day intervals. Additional reminder emails were sent between solicitations. After five e-mail solicitations, paper questionnaires were mailed to non-responders. These were followed two weeks later by reminder postcards and then two weeks later by another postal mailing of the questionnaire. Solicitations offered drawings for gift certificates as response incentives. The questionnaire took approximately 7 minutes to complete and respondents earned 0.5 unit of CME credit. The questionnaire included links (or references on paper-based questionnaires) to HCV educational activities as well.

Participant anonymity was assured through separation of the questionnaire distribution and data collection processes. The CaReNet team maintained identifying participant login codes, using these to guide solicitations. The RIOS Net team collected and analyzed the data without access to respondent identifiers. Each of the three network institutional review boards approved this study.

Data analysis

Responses from clinicians who used the web-based questionnaire were stored in a Microsoft SQL Server database. Paper-based responses were entered by RIOS Net staff into the web-based database. Analysis of all data was done using SAS version 9.1.3.(23) Chi-square tests were used to test for differences in distribution of responses for categorical variables across demographic characteristics, attitudes, and behavior patterns. Results were considered statistically significant if the p-value was <0.05.

Results

Sample

Four hundred and ninety four clinicians participated for a response rate of 61%. Table 2 presents data regarding these clinicians. Nearly half of the respondents were family medicine physicians. There was a wide range of practice experience, with clinicians coming from rural and small town practices as well as urban, inner city and suburban settings. Reflecting the nature of the PRIME Net consortium, most of the clinicians were in academic, community health center, or Indian Health Service practices. There were no significant differences in reported attitudes toward importance, screening, or practice habits among clinicians in the four networks (data not shown). Likewise there were no significant differences in attitudes by clinician specialty after controlling for number of HCV patients in the practice.

General views about HCV

Ninety percent of the clinicians agreed that the long-term consequences of untreated HCV can be serious for most people. As shown in Table 3, 68% reported that compared with other conditions they encounter in their daily practice, HCV is important/more important, though when they were asked to compare with other conditions they routinely screen for, the percent reporting important/more important dropped off to 59%.

Current approaches to detection of HCV and initial management

Almost all clinicians indicated primary care providers should be involved in the screening, diagnosis, and co-management of patients with HCV (Table 3). When clinicians were presented with a menu of common clinical circumstances, such as new or established patient visits, or visits with patients with other suspected HCV risk factors, inquiry about HCV risk factors varied by circumstance. For instance, just over half of clinicians (54%) routinely ask new patients whether they have used intravenous drugs (*"I ask new patients when the time is not consumed by other issues"*), 28% ask new patients about blood transfusions before 1992 (*"If they have surgeries or history of severe injuries, I ask about blood transfusion"*), and 61% of clinicians reported they would order an ALT when patients presented with risk factors for hepatitis (*"[When both] risk factors and nonspecific symptoms [are present]"*). (Table 3) Similarly, diagnostic evaluation with an HCV antibody test following identification of an HCV risk factor varied by risk factor (Table 3).

With regard to initial management of patients with HCV, 94% of clinicians advise their HCV patients to avoid alcohol, 79% advise acetaminophen avoidance, 90% recommend hepatitis B testing/vaccination, 84% recommend hepatitis A testing/vaccination, and 82% do HIV testing.

(Table 3) In their narrative comments, many clinicians also reported counseling about methods to reduce transmission to others, referring for substance abuse counseling, and focusing on management of comorbidities (e.g., depression).

Slightly more than half (54%) of these clinicians who have HCV patients in their practices refer three-quarters or fewer of their patients, including 24% of the clinicians who refer less than one-quarter of their HCV patients. There was a trend in the difference between rural clinicians (less likely to refer) and urban clinicians (more likely to refer) that did not reach statistical significance ($p=.08$) (“*My practice population is remote from specialist care*”; “*Closest hep C program is 100 mile travel for my patients*”). (Data not shown.) Nearly one-fifth (18%) of these primary care clinicians have themselves prescribed anti-viral therapy for HCV (Table 2). Compared to non-prescribers, these treating clinicians were more likely to practice in communities of 100,000 or less (28% vs. 13%, $P<0.001$).

Factors which influence the approach to detection and initial management of HCV

To further explore the dynamics affecting hepatitis C detection and initial management in these primary care practices in medically underserved communities, clinicians were asked about a variety of factors that might influence their decision making (Table 4). Almost three-quarters (74%) reported that the presence of comorbidities in the patient influenced their approach to screening (“*Don't refer those actively using alcohol or illicit drugs*”; “*Alcohol and depression comorbidities keep me from referring more patients*”; “*Most of my hepatitis C patients are medically non-compliant, drink alcohol, or have serious psychiatric issues*”). Over half the clinicians (55%) reported treatment availability and 39% reported financial barriers influenced their decisions about HCV assessment (“*Very difficult to get referrals for uninsured*”; “*Lack of insurance/funds/transportation*”; “*Lack of specialist accepting Medicaid and the uninsured*”; “*Lack of specialists and lack of funds*”). In addition to these access barriers, 44% reported competing clinical issues in the patient (i.e., multiple clinical problems to be addressed within the limited time of the patient encounter) influenced their approach, and 44% reported that HCV antiviral treatment intolerance influenced their decision-making (“*Low effectiveness and tolerance of treatment*”; “*Treatment intolerance*”). While 75% reported that clinical guidelines also impacted their approaches to HCV, 50% felt that antiviral treatment effectiveness was sufficient that it influenced their approaches (“*If treatment likely ineffective, I do not refer*”). Many of these same reasons were endorsed when we asked the clinicians why their patients who had not undergone treatment had not done so (Table 5). We also asked the clinicians about their confidence in their knowledge about HCV confirmatory/diagnostic tests and about current anti-viral therapy for HCV. With regard to diagnostic testing, most clinicians (79%) expressed some level of confidence in their understanding, although fewer (53%) were confident of their knowledge about current anti-viral therapy.

Discussion

Summary of findings

While national scientific groups differ in their recommendations to primary care clinicians about HCV screening in high-risk persons, it is clear that in clinical practice in medically underserved communities a complex set of factors influences decisions regarding the detection and initial management of patients with hepatitis C. We found some support for the need for increased clinician education in the clinicians' reports of their confidence in their knowledge about treatment of hepatitis C. However, the larger picture suggests that several key factors play a greater role in clinician decision-making about hepatitis C. These factors include:

1. Comorbidities:
 - that limit eligibility for antiviral treatment,

- that are a higher treatment priority, or
 - that make adherence to chronic antiviral treatment problematic;
2. Lack of access to treatment, including
 - lack of financial access to anti-virals,
 - lack of access to treating consultants, and
 - lack of geographic access to care;
 3. Intolerance to and inconsistent effectiveness of antiviral therapy.

Viewed together, these factors make clear that from the perspective of primary care clinicians in these high prevalence communities, if there are to be future efforts to increase detection and treatment of hepatitis C, the multiple barriers cited above must be addressed comprehensively.

Historically, comorbid mental health diagnoses, particularly depression and substance use disorders, have been considered to be relative contraindications for treatment of HCV, as a result of both mental health side effects and the challenges of adherence with interferon treatment. More recently, studies have shown that with appropriate monitoring and treatment of these comorbidities, many patients can enter and complete HCV treatment with comparable treatment outcomes. (24-28) However, the picture painted by the clinicians in this survey appears to both endorse and go beyond this issue of side effects and adherence to also describe the place of HCV and its treatment among multiple comorbidities competing for the patient's and clinician's attention. We furthermore found that the high cost of current treatments for HCV and the limited options for referral for treatment (if the primary care clinician does not treat) act to limit screening for HCV for a substantial portion of the clinicians in these communities.

Comparison with previously published studies

Previous studies have shown similar patterns of primary care clinician familiarity with established risk factors for HCV infection, and of routine inquiry for HCV risk factors. (16-18) Prior studies have also shown that rates of referrals of HCV patients are variable, similar to what clinicians in this sample report, and at least one study has noted high rates of ineligibility for treatment at HCV referral centers based on continued substance use and serious comorbid medical or psychiatric conditions. (14,16,18,29-31) In general, however, these studies have focused on measures of clinician behavior, rather than exploring in-depth the reasons for that behavior, or the context of care under which clinicians' decisions are made. Our study focuses on the broader complexity of care for HCV patients, such as the multifaceted access issues, problematic treatment adherence, and the higher prioritization given treatment for comorbidities.

Limitations

This study focuses on care of hepatitis C patients in medically underserved communities, and therefore may not be broadly generalizable to communities where access to care is more readily available. However, these low-income and minority communities, which often have higher rates of HCV than the general population, are precisely the communities for which issues related to screening and treatment of HCV may be most relevant. At the same time, we found that overall responses were similar across three geographically distinct regions; such consistency suggests the findings were indeed generalizable more broadly. Furthermore, our clinicians' reports of the frequencies that they undertake selected behaviors related to HCV are consistent with those reported in other studies (as above), further supporting generalizability.

Conclusions

National scientific groups differ in their recommendations about screening for HCV among persons at high risk for HCV infection. The composite picture painted by the results of this study is that for clinicians practicing in communities where HCV prevalence is likely to be higher than in the general population, decisions about screening and initial management of hepatitis C reflect the complex context of the illness and the health care environment. Competing demands in the primary care environment, patient comorbidities, lack of access to care, and difficulties with the anti-viral treatments available all influence clinicians' approaches to screening and referral for treatment for HCV. These factors would need to be addressed if there were any future efforts toward increasing HCV screening and treatment.

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Table 1
National guidelines for screening of high risk persons for hepatitis C

| Organization | Recommendation | Year of latest publication | References |
|--|---|----------------------------|------------|
| National Institutes of Health Consensus Conference | Promote the establishment of screening tests for all groups at high risk of HCV infection | 2002 | 7 |
| U.S. Preventive Services Task Force | Insufficient evidence to recommend for or against routine screening for HCV infection in adults at high risk for infection ("I" recommendation) | 2004 | 9,11 |
| Centers for Disease Control and Prevention | Testing should be offered routinely to persons most likely to be infected with HCV who might require medical management, and testing should be accompanied by appropriate counseling and medical followup | 1996,2004 | 5,6 |
| American College of Preventive Medicine | Individuals at high-risk for hepatitis C infection should be screened for anti-HCV | 2005 | 8 |

Table 2
Clinician Demographics and Practice Characteristics

| Variable | n | % |
|--|-----|------|
| Network Affiliation (N=494) | | |
| CaReNet | 217 | 43.9 |
| RIOS Net | 150 | 30.4 |
| SERCN | 31 | 6.3 |
| UNM Preceptor | 93 | 18.8 |
| Other | 3 | 0.6 |
| Practice type (N=484) | | |
| Community health center | 184 | 38.0 |
| Indian Health Service | 53 | 11.0 |
| University faculty | 122 | 25.2 |
| Veterans Administration | 4 | 0.8 |
| Solo practitioner | 16 | 3.3 |
| Other group practice | 105 | 21.7 |
| Specialty (N=485) | | |
| Family Medicine | 216 | 44.5 |
| Pediatrics | 71 | 14.6 |
| Internal Medicine | 81 | 16.7 |
| Nurse Practitioners/Physician Assistants | 43 | 8.9 |
| Family Medicine Resident | 64 | 13.2 |
| Resident Other | 10 | 2.1 |
| Years since Completing Primary Care Residency, among physicians not currently in residency (N=368) | | |
| Less than 10 | 139 | 37.8 |
| 10 – 20 | 115 | 31.2 |
| More than 20 | 101 | 27.4 |
| Not applicable | 13 | 3.5 |
| Community Size (N=491) | | |
| Town <= 25,000 people | 109 | 22.2 |
| Town > 25,000 but < 100,000 people | 60 | 12.2 |
| City of 100,000 to 500,000 people | 88 | 17.9 |
| Urban or suburban area in city of > 500,000 people(not inner city) | 138 | 28.1 |
| Inner city, > 500,000 people | 96 | 19.6 |
| Number of HCV patients currently in practice (N=491) | | |
| None | 94 | 19.1 |
| 1-5 | 180 | 36.7 |
| 6-20 | 139 | 28.3 |
| More than 20 | 78 | 15.9 |
| New diagnoses of HCV during past year, among clinicians with HCV patients in their practice (N=395) | | |
| None | 103 | 26.1 |

| Variable | n | % |
|---|-----|------|
| 1 – 5 | 246 | 62.3 |
| 6 – 15 | 34 | 8.6 |
| More than 15 | 12 | 3.0 |
| Prescribed anti-viral therapy for HCV patients, among clinicians with HCV patients in their practice (N=393) | | |
| Yes | 72 | 18.3 |

HCV = Hepatitis C

CaReNet = Colorado Research Network

RIOS Net = Research Involving Outpatient Settings Network

SERCN = Southeast Regional Clinicians' Network

UNM = University of New Mexico

Table 3
Clinician perspectives regarding the detection and management of hepatitis C (HCV)

| | More Important/Important % (n) |
|---|---|
| Compared to the common problems you face in practice, how important would you consider hepatitis C to be? (N=491) | 67.8 (333) |
| Compared to the common medical problems you screen for in practice, how important would you consider screening for HCV to be? (N=490) | 58.8 (288) |
| The extent to which you agree or disagree about whether primary care providers should be doing the following with respect to hepatitis C. (N=494*) | Strongly Agree/Agree % (n) |
| Screening | 87.5 (428) |
| Diagnosis | 93.0 (456) |
| Treatment with anti-viral therapy | 29.6 (144) |
| Monitoring and follow-up | 66.9 (327) |
| Referral for consultation and co-management of hepatitis C | 94.9 (463) |
| Referral for all hepatitis C management | 50.6 (247) |
| How do you assess patients for these concerns (N=490-494): | % (n) |
| Intravenous drug use - routinely ask new patients | 53.8 (266) |
| Intravenous drug use - ask patients who give a history of other illicit drug use | 54.0 (267) |
| Blood transfusion or solid organ transplant before July 1992 -routinely ask new patients | 28.4 (139) |
| Blood transfusion or solid organ transplant before July 1992 – ask patients who have abnormal liver function tests | 42.7 (209) |
| Under what circumstances do you order serum ALT levels? (N=487) | % (n) |
| Routine screen for new patients | 25.3 (123) |
| Patients with other risk factors for hepatitis C | 60.6 (295) |
| Patients with a history of hepatitis C | 56.3 (274) |
| How often do you order a hepatitis C antibody test? (N=494*) | Always/Frequently % (n) |
| Patient history of intravenous drug use | 75.9 (375) |
| Patient history of blood transfusion/organ transplant before 1992 | 52.8 (261) |
| Patient with an abnormal serum ALT | 79.6 (393) |
| What percent of patients in your practice with hepatitis C have you referred for treatment? (N=394=clinicians with hepatitis C patients in their practices) | % (n) |
| Less than 25% | 23.6 (93) |
| 25-75% | 30.2 (119) |
| More than 75% | 46.2 (182) |
| Do you routinely offer to patients with hepatitis C (N=397=clinicians with hepatitis C patients in their practices): | % (n) |
| Counseling about alcohol avoidance | 93.7 (371) |
| Counseling about acetaminophen avoidance | 78.6 (312) |
| Hepatitis A vaccination/testing | 84.4 (335) |
| Hepatitis B vaccination/testing | 89.7 (356) |
| HIV testing | 82.4 (327) |

* Minor differences in item responses, range 487-490.

Table 4
Factors that influence approach to screening for HCV risk factors (N=494*)

| | Yes % (n) | No % (n) | N/A % (n) |
|--|--------------|-------------|--------------|
| Consequences of untreated hepatitis C can be serious for most people | 89.5 (437) | 7.0 (34) | 3.5 (17) |
| Guideline recommendations | 75.0 (366) | 25.0 (122) | - |
| Presence of comorbidities in patient | 73.5 (358) | 26.5 (129) | - |
| Treatment availability | 54.8 (268) | 45.2 (221) | - |
| Treatment effectiveness (ability to improve outcome) | 50.0 (243) | 38.1(185) | 11.9 (58) |
| Other competing issues | 44.5 (216) | 55.5 (269) | - |
| High prevalence of hepatitis C among my patients | 44.5 (217) | 25.0 (122) | 30.5(149) |
| Treatment intolerance | 44.4 (216) | 55.6 (270) | - |
| Financial barriers | 39.3 (190) | 60.7 (294) | |

* Minor differences in item responses, range 484-489.

Table 5
Primary reason(s) patients have not undergone treatment for hepatitis C, as reported by clinicians with hepatitis C patients currently in their practices, (N=354*)

| | n |
|--|----------|
| Alcohol use, psychiatric morbidity, or other contra-indication | 267 |
| Lack of patient interest in treatment | 227 |
| Lack of insurance | 209 |
| Poor tolerance of treatment (recent or in past) | 197 |
| Poor access to treatment services or staff | 187 |
| Insurance companies will not cover treatment | 136 |
| My personal views of treatment | 78 |

* Clinicians could report more than one reason