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Hepatitis C Virus Testing Perspectives Among Primary Care Physicians in Four Large Primary Care Settings

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Abstract

Background—In 1998, the Centers for Disease Control and Prevention (CDC) published Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease, recommending HCV testing for populations most likely to be infected with HCV. However, the implementation of risk-based screening has not been widely adopted in health care settings, and 45% to 85% of infected U.S. adults remain unidentified.

Objectives—To develop a better understanding of why CDC's 1998 recommendations have had limited success in identifying persons with HCV infection and provide information about how CDC's 2012 Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965 may be implemented more effectively.

Design—Qualitative data were collected and analyzed from a multidisciplinary team as part of the Birth Cohort Evaluation to Advance Screening and Testing for Hepatitis C project.

Respondents—Nineteen providers were asked open-ended questions to identify current perspectives, practices, facilitators, and barriers to HCV screening and testing. Providers were affiliated with Henry Ford Hospital, Mount Sinai Hospital, the University of Alabama, and the University of Texas Health Science Center.

Results—Respondents reported the complexity of the 1998 recommendations, and numerous indicated risk factors were major barriers to effective implementation. Other hindrances to

hepatitis C testing included physician discomfort in asking questions about socially undesirable behaviors and physician uncertainty about patient insurance coverage.

Conclusion—Implementation of the CDC’s 2012 recommendations could be more successful than the 1998 recommendations due to their relative simplicity; however, effective strategies need to be used for dissemination and implementation for full success.

Keywords

delivery of health care; guidelines; hepatitis; screening

INTRODUCTION

Approximately 3.2 million Americans are chronically infected with the hepatitis C virus (HCV; Davis, Alter, El-Serag, Poynard, & Jennings, 2010; Ly et al., 2012), and 45% to 85% of infected adults remain unidentified (Spradling et al., 2012). HCV-related morbidity and mortality are forecasted to grow exponentially over the next decade (Rein et al., 2011). In 2007, more than 15,000 HCV-associated deaths were recorded. Chronic HCV infection is the leading cause of end-stage liver disease, and HCV-related medical costs are expected to exceed \$6 billion annually by 2019 (Ly et al., 2012; National Center for HIV/AIDS, Viral Hepatitis, STD, & TB Prevention, 2010; Shehab, Orrego, Chunduri, & Lok, 2003). Studies have demonstrated the cost-effectiveness of testing to increase identification of persons living with HCV followed by treatment, if indicated (McEwan, Ward, Yuan, Kim, & L’Italien, 2013; McGarry et al., 2012; Rein et al., 2012). In 2012, the Centers for Disease Control and Prevention (CDC) recommended that all individuals born during 1945 to 1965 (the birth cohort with the highest prevalence of HCV) receive a onetime test for HCV, assessment for alcohol use and intervention as indicated, and linkage to care and treatment as appropriate (Smith et al., 2012).

CDC’s 2012 recommendations supplement the 1998 recommendations, which indicated HCV testing of those with risks of exposure (Ghany, Strader, Thomas, & Seeff, 2009; Kaplan, Masur, & Holmes, 2002; National Center for Infectious Diseases, 1998; see Table 1). CDC’s 1998 recommendations were subsequently supported and endorsed by The National Institutes of Health (2002) and the American Association for the Study of Liver Diseases (Strader, Wright, Thomas, & Seeff, 2004). To understand the potential challenges in implementing CDC’s new birth cohort recommendations, it is instructive to consider the degree to which CDC’s prior recommendations resulted in changes in HCV testing in clinical settings.

HCV infection typically presents without symptoms; therefore, risk assessments and HCV antibody testing in primary care are necessary to identify asymptomatic, chronically infected patients. Evidence suggests that the 1998 recommendations did not result in the widespread identification of HCV infection in the United States. In a sample of 208,752 primary care patients, only 26.2% of those with elevated liver enzymes, 33.7% of those who reported injection drug use, 33.3% of those who had received a blood transfusion before 1992, 61.8% of people with HIV, 24.1% of people with hemophilia, and 76.0% of those who had undergone hemodialysis had received an antibody test for HCV (Rein et al., 2012).

Furthermore, primary care providers do not appear to routinely conduct behavioral risk assessments that are needed to implement CDC's 1998 recommendations (Almario, Vega, Trooskin, & Navarro, 2012; Clark, Yawn, Galliher, Temte, & Hickner, 2005; Navarro, St Louis, & Bell, 2003; Shehab et al., 2003). One study found that only 8% of patients who acknowledged having an HCV-related risk factor via an intake questionnaire in a primary care waiting room had been tested for HCV within 2 months of disclosing that risk (Almario et al., 2012). Although many primary care physicians (PCPs) test for HCV infection appropriately when patients volunteer risk information, few proactively elicit risk factor information (Navarro et al., 2003). A survey of active members of the American Academy of Family Physicians found that 37% of respondents reported not routinely asking patients about HCV risk factors (Clark et al., 2005).

Published studies suggest that the 1998 recommendations had attributes of other successfully implemented guidelines. For example, systematic reviews of the impact of clinical guidelines on quality of care found that successful change in care practice is based on strong evidence, addresses an area of uncertainty in clinician knowledge, is supported by an authoritative local or national professional body, is implemented during routine or chronic care, and is designed with extensive clinical input (Bazian Ltd., 2005; Grimshaw & Russell, 1993). Gross (2001) found that engaging physicians and stakeholders, actively disseminating recommendations to physicians, and using local consensus conferences to build support for changes in practice were strategies that led to greater levels of implementation.

These studies also suggest barriers to implementation. Specifically, guidelines were more difficult to implement when physicians did not believe that benefits of implementation were significant, when physicians felt that following the guidelines was more difficult or time-consuming than providing usual care, and when hospital administration viewed the guidelines as increasing costs (Bazian Ltd., 2005). Gross (2001) described approaches that were generally ineffective in changing physician behavior (e.g., dissemination of guidelines with limited to no follow-up). Finally, Burgers (2003) identified complex recommendations and the subsequent need for physician education and skill acquisition as principal barriers to the successful implementation of clinical recommendations.

CDC's 1998 recommendations may have been viewed by providers as unlikely to result in patient benefit given the relatively low effectiveness of clinical therapy for HCV prior to 2012 or uncomfortable to implement because they involved an explicit discussion of socially undesirable behavior (Modabbernia, Poustchi, & Malekzadeh, 2013) with patients. Practice administrators may have viewed the guidelines as likely to raise the cost of health care, with little benefit in terms of immediately offsetting costs or patient satisfaction. In addition, the CDC's 1998 recommendations required physicians to remember multiple risks of exposure and clinical indicators and interview patients to elicit risk. Adoption of the recommendations may have been limited by these informational and skill acquisition barriers.

CDC's 2012 birth cohort recommendations are intended to augment the 1998 recommendations and should mitigate some of the barriers noted above because the focus is identification of a targeted group for HCV testing. However, addressing other systemic

problems, such as achieving institutional acceptance of the recommendations, may be as important as guideline simplification for expanding testing in primary care settings.

This article examines the perceptions of three groups of health professionals regarding implementation of CDC's 1998 recommendations and the anticipated challenges to implementation of the birth cohort recommendations. Specifically, we seek to understand the extent to which PCPs, administrators, and hepatologists are familiar with CDC's 1998 recommendations, as well as how these health professionals view the benefits and impacts of the recommendations on patient well-being and clinical practice. The intended use of this study is to understand why the 1998 recommendations have had limited effectiveness in identifying a broader population of those infected with HCV and how CDC's 2012 birth cohort testing recommendations can be effectively implemented in the future.

METHOD

Interviews

We collected data from four large primary care systems (Henry Ford Hospital, Detroit, Michigan; Mount Sinai Hospital, New York, New York; University of Alabama at Birmingham, Birmingham, Alabama; and University of Texas Health Science Center at Houston, Houston, Texas) as a component of the Birth Cohort Evaluation to Advance Screening and Testing for Hepatitis C. The study was approved by each primary care systems' institutional review board. Informed consent was received from each participant. We conducted 19 interviews (six PCPs, eight hepatologists, and five administrators). Interviews were semistructured and lasted approximately 45 minutes.

We interviewed PCPs because the guidelines target providers to conduct hepatitis C testing; we interviewed administrators under the assumption that they could exert influence over the implementation of guidelines; and we interviewed hepatologists to understand better the barriers to linking patients diagnosed in primary care settings to specialist services.

Data Analysis

Interview data were analyzed to address research questions for PCPs, hepatologists, and administrators (see the appendix). Data coding and quality assurance were performed by a multidisciplinary team including research analysts, a project manager, the CDC project officer, a qualitative specialist, and a data research assistant. Intercoder reliability was 83.0%. Data were organized and indexed by four of the authors using qualitative software (NVivo 9, QSR International). Employing grounded theory (Strauss, 1990), themes and subthemes were identified and validated by peer triangulation.

RESULTS

PCPs

All PCP respondents reported having been the provider of someone at risk for HCV. Providers identified the characteristics or behaviors used most commonly to identify patients for testing: history of injection drug use, multiple sexual partners, history of hepatitis B, positive test for HIV, and the presence of tattoos. Physicians placed the highest priority on

patients infected with HIV, patients with a history of injection drug use, and patients infected with hepatitis B.

A majority of the respondents reported conducting verbal assessments of the risk factors for HCV, without the aid of intake questionnaires or automated prompts from electronic record systems. One respondent reported that patients are presented with an intake questionnaire; however, the form does not include drug use history, and patients may choose not to fill out the form in its entirety. Another reported that the electronic record system prompts the physician to conduct behavioral assessments, such as drug use history.

Four of six respondents reported having prior knowledge of CDC's 1998 recommendations for HCV testing. However, several inaccurately described the recommendations, such as recommended testing of those with multiple sex partners and those with tattoos. One respondent tested patients who received transfusion of blood or blood components before 1990 instead of 1992. Another provider reported an awareness of the guidelines' existence but was unfamiliar with their contents.

Overall, PCP respondents identified risk behavior assessment as the largest barrier to identifying patients for testing. They explained that PCPs do not routinely conduct behavioral assessments due to lack of time, lack of HCV knowledge among PCPs, and discomfort in asking patients about risk factors. Two PCPs cited discomfort of both the physician and the patient as a barrier to assessing patient risks, whereas two others reported confusion about clinical indications for testing.

All respondents reported ordering HCV testing on determining that a patient should be tested, before referring the patient to a specialist. Four reported conducting the process of referral to specialist care themselves, whereas two others used referral coordinators who assisted them with linking patients to specialist care. With the exception of one respondent, who stated that contacting a representative from the liver clinic treatment facility can sometimes be a problem, none of the others identified the referral procedure as a hindrance or a barrier to the testing of patients for HCV infection.

Respondents reported delays in scheduling appointments at the liver clinic, lack of insurance for uninsured or underinsured patients, patient resistance, and poor patient follow-through as the main barriers in linking patients to specialist care.

Hepatologists

Hepatologists reported having patients referred to them at various stages of the patients' hepatitis C disease but only after they receive a positive HCV antibody test. Hepatologists listed delays in appointments at a liver clinic as the most common challenge of linking patients to specialist care. Three respondents reported wait times of 6 to 8 weeks to be seen by a hepatologist, once referred. Respondents reported receiving referrals from within their own hospital systems and from external sources; two stated that their hospital practices are not equipped to absorb large numbers of new patients.

Five of the eight hepatologists expressed concern about the lack of proper testing for hepatitis C by PCPs. They were concerned that physicians did not have adequate knowledge

about hepatitis C risk factors and felt uncomfortable discussing hepatitis C risk factors with patients. Hepatologists thought that physicians sometimes attempted to care for patients diagnosed with hepatitis C infection themselves instead of referring these patients to specialist care and that physicians did not test for hepatitis C because they prioritized testing for other health concerns such as cholesterol or cancer. One respondent stated that PCPs usually conduct hepatitis C testing only when they observe an abnormal alanine aminotransferase level.

Although hepatologists acknowledged that patients often face financial barriers to treatment, three described alternate methods for patients to obtain treatment. Two hepatologists reported that when their hospitals receive patients who lack insurance they are steered into clinical trials to receive treatment. Two hepatologists reported that patients without insurance can use drug companies' charitable access or compassionate treatment programs to receive care. Thus, hepatologists did not necessarily view lack of insurance as a barrier to clinical treatment.

Administrators

Five administrators reported varying levels of involvement with hepatitis C testing. Three respondents stated their only involvement with HCV testing was through their normal primary care practice. One reported having no experience with HCV testing. Four respondents described supervising the operations and quality of care provided in their health care organization. One reported taking an active educational role in disseminating risk guidelines for hepatitis C testing.

Administrators reported having the influence to change hospital practices, including standardizing primary care practices and improving systemic adherence to practice guidelines. Three administrators specifically indicated that they have considerable influence over hospital residents, who are responsible for a large percentage of the primary care provided to patients.

Prospectively, the administrators interviewed suggested a number of different dissemination methods that could be used to promote adherence to CDC's HCV testing recommendations, such as the use of educational media, grand rounds and other talks or academic conferences, yearly newsletters, and resident-training protocols. One respondent reported that although he was aware of CDC's 1998 recommendations, the guidelines had not been distributed to physicians at his hospital. Two administrators reported that their hospital had not had any educational efforts related to hepatitis C guidelines in the past 5 years. Three reported having educational efforts related to hepatitis C during grand rounds and lunch conferences. One administrator reported that educational efforts at his hospital focused "more on treatment and less on testing."

Four administrators reported that their clinic did not have a formal system for hepatitis C testing, and the decision to test for HCV was dependent on the individual PCP. Two administrators, however, expressed interest in the possibility of implementing a systematic testing procedure. One administrator reported that his clinic used the hepatitis C testing

guidelines issued by his municipality's health department in place of the 1998 CDC recommendations.

Overall, administrators reported that the complexity of CDC's 1998 recommendation was a hindrance to effective implementation. They commented that CDC's 1998 recommendations include too many criteria and that PCPs lack the time to conduct behavioral assessments during appointments with patients. Two administrators specifically expressed enthusiasm for birth cohort testing; one commented, "Universal screening of an age cohort" would "make screening practices more formal and structured" and another concurred, "Screening by age group would be a much simpler process to follow." One administrator reported, "Doctors don't know what to follow" because of conflict between different sets of guidelines for the same clinical practice.

Administrators commented on the strengths and weaknesses of the referral system from PCPs to hepatologists. Two administrators expressed concern that referral systems did not allow PCPs to follow up with patients and ensure the referral appointment was completed. Administrators reported issues with insurance as a considerable barrier to effective testing and treatment. Two administrators reported that hepatologists may not be on an insurance provider list; in those cases, the clinic or the hospital needs to secure insurance preauthorization, which can be time-consuming and burdensome.

DISCUSSION

CDC's 1998 recommendations have not identified a larger percentage of persons infected with HCV as anticipated. PCPs, hepatologists, and administrators provided institutional knowledge of HCV testing and the barriers that exist to identifying and caring for those infected with HCV. Research suggests four main reasons why the CDC's 1998 recommendation might not be fully implemented (Bazian Ltd., 2005; Burgers, 2003; Gross, 2001; Solà et al., 2014). First, the large number of risk factors included in the recommendations requires physicians to acquire new knowledge, and their disinclination or lack of time to do so would inhibit testing. Second, providers are reluctant to elicit information that would call for testing because they are uncomfortable discussing socially stigmatizing behaviors with their patients, or lack time. Third, providers hesitate to test for HCV because they fear that patients' insurers would not reimburse costs for testing or clinical treatment among newly diagnosed patients. Finally, some physicians believe that implementation of the guidelines will not benefit patients because patients will not access care and treatment or treatment might be ineffective.

The data revealed a number of misconceptions among PCPs about the contents of the 1998 recommendations. Although the PCPs correctly identified two indications for testing— injection drug use and HIV status—they inaccurately stated that individuals with multiple sex partners, hepatitis B infection, and a history of tattoos should also be tested for HCV. Other risk factors, such as a history of hemodialysis or hemophilia or a history of blood transfusions prior to 1992, were rarely mentioned. Respondents stated that the sheer number and complexity of the risk factors indicated in the 1998 recommendations served as a deterrent to physicians' use of the guidelines.

The current study also found evidence of physician discomfort with eliciting risk information from patients. Many providers denied that they were uncomfortable asking their patients about their past exposure history, even stigmatizing behavior, but rather stated that they lacked the time needed to collect patient histories during their primary care interactions, given the large number of recommendations that they were already expected to implement. Although PCPs reported little discomfort in asking patients about risk information, hepatologists almost universally perceived physician awkwardness and discomfort as the main reason that PCPs avoided taking patient history information.

Similarly, there was a difference in the attitudes displayed by PCPs, administrators, and hepatologists about the role of insurance coverage for HCV treatment. PCPs and administrators cited locating a hepatologist or a liver clinic that falls within the patients' insurance provider list as a primary barrier to referral for care, and each group of respondents stated that this problem was greater for uninsured patients. Although hepatologists acknowledged that insurance coverage can sometimes act as a hindrance, only a few cited lack of insurance as a barrier to patient care and treatment, and several explicitly commented on the alternate options available to patients without insurance, such as enrollment in clinical trials or assistance from drug companies' patient assistance programs. This suggests the need for clearer communication between PCPs, administrators, and hepatologists, to ensure that each group is fully informed about the options available for patients to receive care and treatment.

Finally, our data suggested reluctance among PCPs and hepatologists to treat patients for HCV with the expectation that more effective treatments would soon be available. Although skepticism of the efficacy of clinical treatment could have played some role in limiting HCV testing the reluctance applied only to treatment and not to testing.

Simpler recommendations with fewer indications requiring less knowledge and skill acquisition are likely to be more widely adopted as a routine element of clinical practice. In this regard, this evidence supports CDC's birth cohort screening recommendation as a parsimonious method to target a population with a disproportionately high prevalence of unidentified HCV infection.

Strategies that public health advocates could pursue to encourage broader implementation of HCV testing include leveraging the authority of administrators within their organizations. This could greatly facilitate the dissemination of, and adherence to, birth cohort testing recommendations. The administrators reported having the authority to implement organization-wide policies on the use of clinical guidelines or having a significant influence over the clinical practices of medical residents in their organizations. However, they did not indicate a strong familiarity with the 1998 recommendations or that the 1998 recommendations were particularly suited for implementation by PCPs (complexity of the guidelines, large number of risk factors, and conflict with other sets of guidelines). Given the enthusiasm that some of the administrators expressed for hepatitis C testing by birth cohort, it is possible that this group could be effective in advancing linkage to care by effectively disseminating and implementing the 2012 recommendations issued by the CDC.

Last, additional medical personnel with the skills to evaluate and treat patients with HCV may be needed if the birth cohort strategy of case identification proves successful. Hepatologists revealed routine delays of 6 to 8 weeks between initial diagnosis and initial evaluation. Although hepatologists advocated for better testing by PCPs, several of them admitted that their current facilities were already operating at close to, if not beyond, maximum capacity.

It is worthwhile to note two major limitations. First, all interview subjects were aware, ahead of their scheduled interview, that they would be asked questions about hepatitis C and that a representative from the CDC would be observing the interview. The interview results may therefore overestimate respondents' actual knowledge of and interest in HCV and CDC's 1998 recommendations. Second, the primary care systems that participated are large, integrated systems with practicing hepatologists; findings about the processes at these organizations may not be generalizable to all primary care settings.

CDC's additional recommendations may be easier to implement than the 1998 recommendations, as they do not require physicians to ask about a number of HCV risk factors and could make it feasible for physicians to identify persons at risk for HCV infection (based simply on birth year), even during short appointments. Overcoming the PCP's limit on time is necessary for effective implementation, as other studies have reported (Katz et al., 2014). However, if the new recommendations are not disseminated and implemented effectively, they may not achieve their intended goal of identifying a greater proportion of the HCV-infected population. Administrators seem to have considerable authority over their institutions' adoption of policies pertaining to clinical guidelines and thus should be more involved in the dissemination and implementation of the new recommendations. In addition, the shortage of specialist care needs to be addressed if patients are to receive timely and adequate treatment after receiving a diagnosis of HCV infection.

If CDC's birth cohort screening recommendations are adopted widely by physicians, it is probable that there will be a considerable increase in the number of individuals identified as being infected with HCV; however, success is dependent on the availability of care to provide patients with treatment and medical support. There needs to be clearer communication between clinical and administrative staff to facilitate a comprehensive understanding of reimbursement options available to patients for HCV testing and treatment. In conclusion, the CDC birth cohort testing recommendations are likely to be more effective than the 1998 risk-based recommendations due to their relative simplicity, and efforts should be made to adopt and implement them broadly in primary care settings.

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APPENDIX. Research Questions Presented to Respondents for Each Health Professional Category

Primary Care Physicians (PCPs)

1. What risk factors do PCPs consider when testing patients, and to what extent do these risk factors align with those recommended in CDC's 1998 guidelines?
2. From the perspective of PCPs, what are the main barriers to effective testing of patients at risk for HCV infection?

Hepatologists

1. What is the relationship between PCPs and hepatologists, and how does this relationship facilitate or hinder the testing of patients and the linkage of infected patients to clinical services?
2. Are hepatologists able to provide clinical care to the current HCV-infected patients referred to them in a timely and effective manner, and are they able to accommodate additional patients should the number referred to them increase?

Administrators

1. What emphasis do health system administrators place on the dissemination of CDC's 1998 guidelines?

2. What influence do administrators have to disseminate and encourage adherence to screening and testing guidelines for medical practice?

TABLE 1**Persons Who Should be Tested routinely for HCV Infection based on Their risk for Infection**

Persons who ever injected illegal drugs^a

- Those who injected once or a few times many years ago and do not consider themselves as drug users

Persons with selected medical conditions^a

- Persons who received clotting factor concentrates produced before 1987
- Persons who were ever on chronic (long-term) hemodialysis
- Persons with persistently abnormal alanine aminotransferase levels

Prior recipients of transfusions or organ transplants^a

- Persons who were notified that they received blood from a donor who later tested positive for HCV infection
- Persons who received a transfusion of blood or blood components before July 1992
- Persons who received an organ transplant before July 1992

Persons who should be tested routinely for HCV infection based on a recognized exposure^a

- Health care, emergency, medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV- positive blood
- Children born to HCV-positive women

Persons who are HIV infected should be tested routinely for evidence of chronic HCV infection^b

NOTE. HIV = human immunodeficiency virus.

^aNational Center for Infectious Diseases (1998); Ghany, Strader, Thomas, and Seeff (2009).

^bKaplan, Masur, and Holmes (2002).