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## Physician Nonadherence With a Hepatitis C Screening Program

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### Abstract

**Background**—Testing for patients at risk for hepatitis C virus (HCV) infection is recommended, but it is unclear whether providers adhere to testing guidelines. We aimed to measure adherence to an HCV screening protocol during a multifaceted continuous intervention.

**Subjects and Methods**—Prospective cohort design to examine the associations between patient-level, physician-level, and visit-level characteristics and adherence to an HCV screening protocol. Study participants included all patients with a visit to 1 of the 3 study clinics and the physicians who cared for them. Adherence to the HCV screening protocol and patient-level, physician-level, and visit-level predictors of adherence were measured.

**Results**—A total of 8981 patients and 154 physicians were examined. Overall protocol adherence rate was 36.1%. In multivariate analysis, patient male sex (odds ratio [OR] = 1.18), new patient (OR = 1.23), morning visit (OR = 1.32), and patients' preferred language being non-English (OR = 0.87) were significantly associated with screening adherence. There was a wide variation in overall adherence among physicians (range, 0%–92.4%). Screening adherence continuously declined from 59.1% in week 1 of the study to 13.7% in week 15 (final week). When implementing complex clinical practice guidelines, planners should address physician attitudinal barriers as well as gaps in knowledge to maximize adherence.

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The authors declare no conflicts of interest.

## Keywords

clinical practice patterns; community-based participatory research; guideline adherence; hepatitis C; intervention studies; mass screening

Chronic hepatitis C virus (HCV) infection affects an estimated 3.2 million persons in the United States,<sup>1</sup> and it is responsible for 40% of chronic liver disease<sup>2</sup> and the majority of hepatocellular carcinoma.<sup>3</sup> Effective treatment of HCV infection is available,<sup>4–10</sup> but the majority of those infected are unaware of their status.<sup>11–15</sup> Testing for patients at risk is recommended,<sup>2,7,8,16–18</sup> but guidelines are complex, and it is unclear whether providers adhere to these guidelines and what factors are associated with adherence. We implemented a multifaceted intervention to improve adherence to guidelines for HCV testing. The purpose of this analysis was to report on adherence to guidelines during the intervention and factors associated with adherence.

Evidence-based therapeutic targets are often not met,<sup>19,20</sup> a situation known as the “therapeutic gap.” Although poor patient adherence has been well documented,<sup>21,22</sup> physician nonadherence to guidelines contributes substantially to the therapeutic gap as well.<sup>23,24</sup> Despite evidence demonstrating that adherence to guidelines is associated with improved outcomes,<sup>25,26</sup> physician adherence to guidelines is often poor.<sup>23,27</sup> In the present study, we sought to synthesize complex guidelines for HCV testing into a single screening protocol and examine physician adherence to the protocol and barriers to adherence.

The guidelines for HCV screening and testing suggest testing patients with a history of transfusion or organ transplant prior to 1992, persons using injection drugs,<sup>2,7,16,17</sup> those with HIV infection,<sup>2,7,8</sup> those receiving hemodialysis,<sup>2,7,16,17</sup> children of HCV-infected mothers,<sup>18</sup> and persons with unexplained elevated alanine transaminase (ALT) levels.<sup>2,7,17</sup> In addition, it has been noted that prevalence of HCV infection is very high among patients with a history of alcohol abuse,<sup>28,29</sup> sexually transmitted diseases,<sup>30–32</sup> psychiatric disease,<sup>33–36</sup> tattoos,<sup>18</sup> and homelessness and incarceration.<sup>18</sup> Because one barrier to adherence might be awareness and understanding of the guidelines, we synthesized the existing guidelines and literature on HCV infection risk into a single protocol for screening and testing. We then conducted an intervention that included educational sessions for providers and used chart stickers that included risk questions and reminders to test those with risk.

To inform the implementation of clinical practice guidelines, we examined adherence to our HCV screening protocol and barriers to adherence. Barriers to adherence with clinical practice guidelines have been classified into 3 categories: (1) knowledge-based (eg, lack of awareness or familiarity with guidelines), (2) attitudinal (eg, lack of agreement with guidelines or lack of motivation), and (3) external (eg, time or environmental barriers).<sup>27</sup> We sought to minimize knowledge-based barriers to adherence with HCV testing with the intervention and determine whether attitudinal and/or external barriers remained. We hypothesized that in the setting of our continuous intervention that focused on knowledge barriers to adherence, attitudinal and external barriers would continue to limit adherence to screening and testing guidelines.

## METHODS

### Study setting

The study was conducted at 3 community-based primary care (family medicine or internal medicine) clinics affiliated with Montefiore Medical Center, a university-affiliated teaching hospital. The 3 participating primary care clinics are large, urban clinics located in Bronx, New York. Each year, 54 000 adults make more than 150 000 primary care visits to the 3 clinics. The clinic sites are located in economically depressed areas of Bronx and serve patients with high rates of poverty and substance use.

### Study design

The study occurred during the risk-based screening phase of the Hepatitis C Assessment and Testing Project (HepCAT), a serial cross-sectional intervention study investigating the effectiveness of strategies to improve HCV screening. The study sites underwent a continuous intervention during the 15-week intervention phase. The study used a prospective cohort design with retrospective electronic medical record (EMR) review to examine the associations between patient-level, physician-level, and visit-level characteristics and adherence to guidelines.

### Study population

Study patients included all patients with a primary care visit to 1 of the 3 study clinics from November 24, 2008, to March 6, 2009, who had not been previously tested for HCV. Study physicians included all physicians who cared for study patients during each of the study visits, including residents and attendings.

### The intervention

At the beginning of the 15-week intervention phase, all providers and site staff participated in on-site educational sessions focused on HCV infection risk and the screening protocol. In addition, project staff visited each clinic twice weekly to place stickers on all progress notes, encourage adherence to the screening protocol, and elicit feedback from clinic staff. A risk-based screener sticker was placed on top of each progress note (Figure 1). The screener prompted the physician to ask the patient 9 questions related to HCV risk. In addition, the physician was asked to indicate whether patients ever had an elevated ALT level (defined as 20 IU/mL for female or 31 IU/mL for male).<sup>20</sup> These risks were chosen on the basis of the Center for Disease Control and Prevention's HCV testing recommendations, American Association for the Study of Liver Diseases guidelines, and other associations' guidelines reported in the literature.<sup>13,14,21</sup> Physicians were asked to complete the sticker at every patient visit, unless previously completed, and to order an HCV antibody test if any risk was identified. Patients who were already positive for HCV antibody or who had been tested within the last 12 months were not asked to be tested. Spanish translations of the sticker were available in every medical office, and laminated versions were placed in each provider's mailbox. Physicians were supplied with a script (available upon request in English and Spanish) to help standardize and normalize the introduction of the screening questions. This phase was conducted from November 24, 2008, to March 6, 2009 (15

weeks). After the first 6 weeks of the intervention, a second educational session for physicians and staff was held to increase adherence with the screening protocol.

### Data extraction

For research and quality improvement purposes, Montefiore Medical Center maintains a data replicate of its computerized Clinical Information System containing patient demographics, outpatient visit records, hospital records, *International Classification of Diseases, Ninth Revision*, codes, prescriptions, and laboratory test results. From this replicate, we extracted demographic and clinical information for each patient and the gender and number of patients seen for each physician. Because the data set contains only de-identified records, informed consent was not obtained from patients or physicians; instead, a HIPPA-approved data use agreement<sup>37,38</sup> was signed by all participating investigators.

### Outcome variables

The primary outcomes were (1) adherence to the screening protocol and (2) accuracy of the information recorded on the screener. “Adherence” was defined as a nonblank screener submitted with any screening information recorded.

An additional aim of the study was to measure the accuracy of information recorded on the screener. Accuracy of information recorded on the screener was ascertained by comparing information recorded from the screener with data extracted from the EMR. Because we had both screener and EMR data on ALT levels, liver disease, and hemodialysis, the proportion of patients in whom the screener correctly identified a history of elevated ALT levels, liver disease, and hemodialysis was examined.

### Independent variables/definitions

The major independent variables included patient-level, physician-level, and visit-level characteristics that might be associated with adherence to the screening protocol.

- Patient-level variables:
  - *Age*. For analysis, age was dichotomized as less than 65 years versus 65 years or more.
  - *Sex*. Dichotomized as male and female.
  - *Race/ethnicity*. For analysis, race/ethnicity was collapsed into 4 categories: non-Hispanic white; non-Hispanic black or African American; Latino or Hispanic; and other/unknown.
  - *New patient*. The patient was considered a new patient if the visit being studied was the first visit to 1 of the 3 clinics included in the study.
  - *Preferred language*. Each patient’s preferred language is recorded in the EMR. For analysis, preferred language was dichotomized as English versus non-English.
- Physician-level variables:

- *Physician sex*. Dichotomized as male and female.
- *Physician volume*. The total number of patients seen by each physician during the study period was recorded. Physicians were defined as high-volume if the total number of patients seen was greater than the mean for all physicians (85 patients).
- Visit-level variables:
  - *Gender concordance*. A visit was defined as gender concordant if the sex of the patient and the physician were the same and discordant if they were not the same.
  - *Morning visit*. A visit was defined as a morning visit if the visit time was before 1 PM. All visits that occurred after 1 PM were considered afternoon visits.
  - *Busy session*. A visit was defined as having occurred during a busy session if the physician saw more than the number of patients defined by the 75th percentile for all physicians' sessions ( 9 patients for a morning session; 7 patients for an afternoon session).

### Statistical analysis

The proportion of eligible patients screened is reported. Univariate and multivariate associations between patient-level factors (age, sex, race/ethnicity, new patient vs non new patient, English preferred vs non-English preferred), physician-level factors (sex, high-volume vs low-volume), and visit-level factors (patient physician gender concordance, morning vs afternoon session, busy vs nonbusy session) and the primary outcome, successful screening, were determined. First, we constructed univariate mixed-effects logistic regression models to assess the associations between each factor and successful screening, with a physician random effect, to account for clustering of patients within physician. Next, we constructed a multivariable mixed-effects logistic regression model, in a forward stepwise fashion retaining each factor associated with the outcome (Wald statistic:  $P < .20$ ), with a physician random effect, to account for clustering. Candidate variables for the multivariate model included each factor associated with the outcome on univariate analysis (Wald statistic:  $P < .20$ ).

To assess the variability of adherence among physicians, the proportion of patients screened for each physician who saw 20 or more patients during the study period was determined. To assess the trend of screening adherence over the 15-week study period, the rate of screening adherence was calculated for each week. The analysis of the trend of screening adherence over time was repeated, after stratifying physicians into quartiles of overall adherence.

To determine the accuracy of screener information in patients who were screened, screener-reported ALT elevation and hemodialysis were compared with the corresponding EMR measures. To determine the variability of accuracy of elevated ALT reporting among physicians, the proportion of screeners in which ALT elevation was accurately recorded, for each physician with 20 or more patients with ALT elevation, was determined.

STATA/IC software, version 10.0 (StataCorp, College Station, Texas), was used for all data management and statistical analyses. The institutional review boards of Boston University Medical Center and Montefiore Medical Center approved the study.

## RESULTS

### Study population/proportion screened

Data on 8981 patients and 154 physicians were examined. Overall, 3250 were screened for an adherence rate of 36.1%. Demographics and clinical information for the study population and the subset of patients who were screened are summarized in Table 1. The mean age was 47.8 (range, 18–102) years. The study population was predominantly female (74.1%) and predominantly Latino (52.7%) or African American (30.4%). The physician population was predominantly female (64.2%) and included both residents (52.0%) and attendings (48.0%).

### Factors associated with screening protocol adherence

Univariate and multivariate analyses of factors associated with screening protocol adherence are given in Table 2. In univariate analysis, factors associated with an increased likelihood of screening protocol adherence included patient male sex (odds ratio [OR] = 1.23; 95% confidence interval [CI], 1.11–1.38), being a new patient (OR = 1.30; 95% CI, 1.12–1.50), and morning visit (OR = 1.35; 95% CI, 1.22–1.50). Factors associated with a decreased likelihood of screening included patients' preferred language being non-English (OR = 0.90; 95% CI, 0.81–1.00), gender concordance between patients and physicians (OR = 0.87; 95% CI, 0.78–0.96), and a busy session (OR = 0.86; 95% CI, 0.75–0.97). In multivariate analysis, patient male sex (OR = 1.18; 95% CI, 1.05–1.32), being a new patient (OR = 1.23; 95% CI, 1.07–1.43), and morning visit (OR = 1.32; 95% CI, 1.19–1.47) were significantly associated with an increased likelihood of screening protocol adherence and patients' preferred language being non-English (OR = 0.87; 95% CI, 0.80–0.99) was independently and significantly associated with decreased odds of screening protocol adherence.

### Variation among physicians with respect to screening protocol adherence

There was a wide variation among physicians with respect to screening protocol adherence. Among physicians who saw at least 20 patients during the study period, the median of physicians screened 31.8% of their patients (range, 0%–92.4%). The top quartile of physicians accounted for 41.8% of screens submitted ( $n = 1342$ ), whereas the bottom quartile of physicians accounted for 7.3% of screens submitted ( $n = 235$ ). Heterogeneity of adherence to the screening protocol among physicians is depicted in Figure 2.

### Trend of screening protocol adherence over time

Screening protocol adherence declined from 59.1% in week 1 of the study to 34.6% in week 8 (midpoint) to 13.7% in week 15 (final week; Figure 3A). Screening protocol adherence increased slightly from week 6 to week 7 (from 34.3% to 37.0%) after a second educational session designed to increase adherence, but it declined in every other week of the study period. After stratifying the physicians into quartiles of overall adherence, adherence for each quartile declined over time (Figure 3B).

### Accuracy of screening information

Of 1560 patients with elevated ALT levels documented in the EMR, and for whom a screener was submitted, the screener correctly identified 209 patients (13.4%). Among physicians who saw at least 20 patients with elevated ALT levels documented in the EMR, the median of physicians correctly identified 7.1% using the screener (range, 0%–70.3%; Figure 4).

Of 10 patients on hemodialysis documented in the EMR, and for whom a screener was submitted, the screener correctly identified 9 (90%). In addition, the screener identified an additional 12 patients as being on long-term hemodialysis.

## DISCUSSION

Despite educational sessions to promote adherence, continuous presence at the study sites, and chart reminders placed on all charts, adherence with an HCV screening and testing protocol was low: 36.1% overall. In addition, we found that adherence dramatically declined over the 15-week intervention, from 59.1% in the first week to 13.7% in the last week of the intervention period. Adherence was more likely with male and new patients, as well as during morning visits. Adherence was less likely with patients whose preferred language was not English. We found a considerable variation among physicians with respect to overall adherence and the accuracy of screening information recorded.

Phase 3 translational research focuses on the movement of evidence-based guidelines into clinical practice. To tailor intervention strategies to maximize the uptake of guidelines, it is important to understand the barriers to adherence. Cabana et al<sup>27</sup> have framed these barriers as (1) lack of knowledge, (2) attitudinal, or (3) external. In the present study, although we directly addressed lack of knowledge by using an educational intervention that synthesized existing literature, overall adherence was low, suggesting that attitudinal and external barriers were playing a role. We were able to measure several external factors such as patient-level and visit-level characteristics and found small associations between external factors and adherence. But these associations were small compared with the large variation among physicians, suggesting that attitudinal barriers predominated.

Lack of time is often cited as a barrier to following clinical guidelines.<sup>39,40</sup> It has been estimated that it would take 7.4 hours per day for a primary care physician to satisfy the US Preventative Services Task Force recommendations.<sup>41</sup> Despite this, we found only a modest association between a busy session and decreased odds of adherence to our screening protocol, which was not significant after adjustment for other factors. Instead, we found a wide variation in adherence among physicians who all worked in the same clinics and presumably had the same time constraints, suggesting that individual physician's attitudes about the screening protocol were the primary drivers of adherence or nonadherence.

It is worth noting that there were many questions on our screener that may have been uncomfortable for physicians to ask their patients, including questions about intravenous drug use, intranasal drug use, sexual partners, homelessness, and incarceration. It is possible that physicians' discomfort with these questions may have led to negative attitudes about the



screening protocol and decreased adherence. Our finding that male patients were associated with increased adherence and that physician-patient gender concordance was associated with decreased adherence may be evidence of this discomfort. To address this, a more parsimonious list of screening questions might be used. It may be, for example, that after assessing intravenous and intranasal drug use, further assessment of homelessness or incarceration does not add to the overall risk assessment. Research that examines multiple risk assessments simultaneously to determine which factors confer independent risk is warranted.

Our study also sheds light on what types of risk assessment are appropriate to ask of physicians during the physician-patient visit. One question on the screener asked whether the patient had ever had an elevated ALT level. If the physician did not know, answering this question would have required logging on to a clinical information system and reviewing laboratory results. In our study, physicians successfully performed this task only 17.3% of the time, with about a third of physicians never completing this task. This suggests that multistep tasks to assess risk are unlikely to be completed by physicians and should be placed elsewhere in the workflow outside of the physician-patient visit.

In conclusion, although we addressed knowledge-based barriers to implementing an HCV screening and testing guideline, overall adherence to the guideline was low, suggesting that attitudinal and external barriers remained. When implementing complex clinical practice guidelines, planners must address attitudinal and external barriers to maximize adherence.

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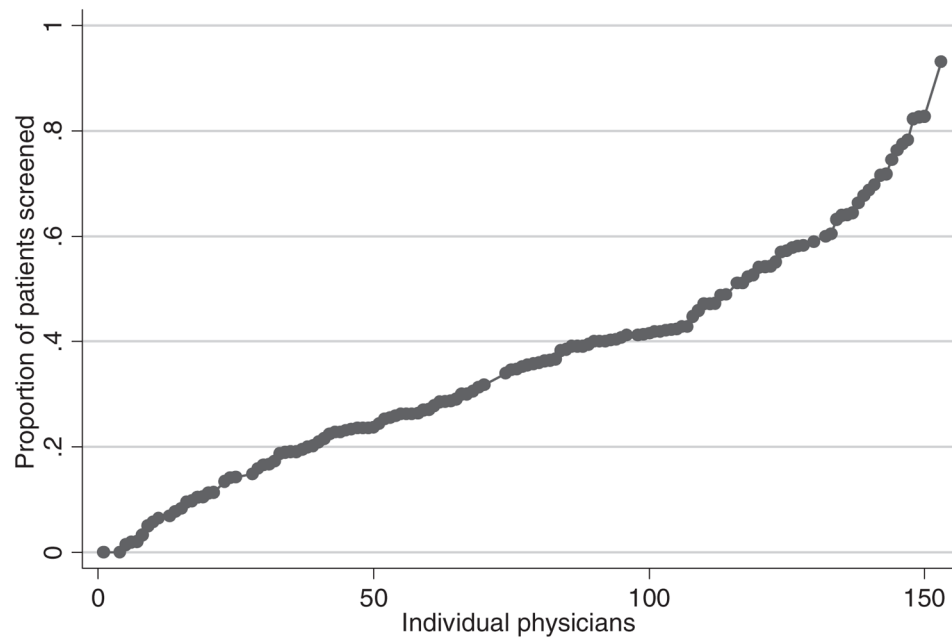


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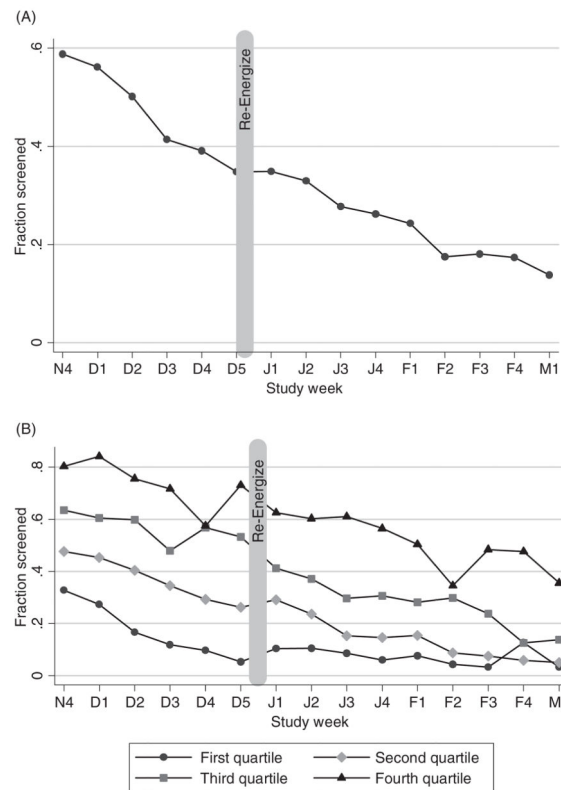
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Hepatitis C screening				
PLACE LABEL HERE	<b>History/risk factors</b>	Yes	No	DK
	EVER homeless	<input type="checkbox"/>	<input type="checkbox"/>	
	EVER incarcerated	<input type="checkbox"/>	<input type="checkbox"/>	
	EVER snorted ANY drug	<input type="checkbox"/>	<input type="checkbox"/>	
	EVER injected ANY drug	<input type="checkbox"/>	<input type="checkbox"/>	
	≥20 lifetime sexual partners	<input type="checkbox"/>	<input type="checkbox"/>	
	Liver disease (told by MD)	<input type="checkbox"/>	<input type="checkbox"/>	
	Chronic hemodialysis	<input type="checkbox"/>	<input type="checkbox"/>	
	Organ transplant pre-1992	<input type="checkbox"/>	<input type="checkbox"/>	
	Transfusion pre-1992	<input type="checkbox"/>	<input type="checkbox"/>	
	Maternal hepatitis C	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Labs: Elevated LFT (ALT: F ≥ 20, M ≥ 31)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Country of birth: if US specify PR _____			
	Other reason for HCV test (specify) _____			
<hr/>				
<b>Plan</b>	Yes	No	N/A	
Recent HCV test?	<input type="checkbox"/>	<input type="checkbox"/>		
HCV test ordered? (N/A = HCV+)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

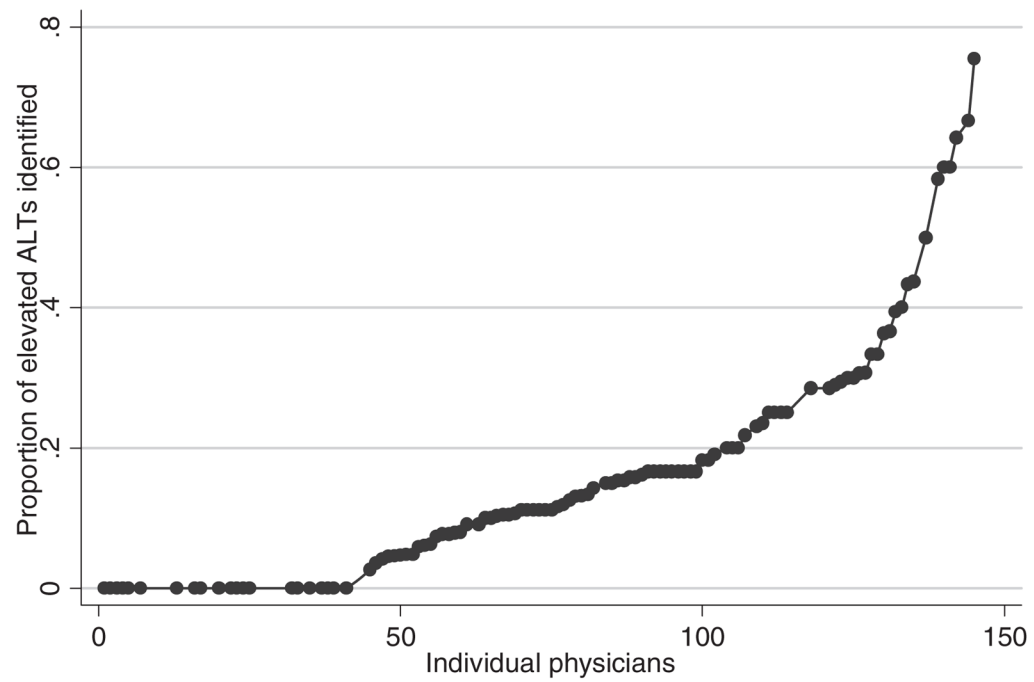
**Figure 1.**  
Hepatitis C screening.



**Figure 2.**  
Variation in screening among physicians.

**Figure 3.**

(A) Fraction screened each study week. (B) Fraction screened each study stratified by physician quartile.



**Figure 4.**  
Proportion of elevated alanine transaminase levels correctly identified on screener.

**Table 1****PATIENT POPULATION NOT PREVIOUSLY TESTED FOR HEPATITIS C VIRUS**

	<b>Entire Population (n = 8981)</b>	<b>Screened Population (n = 3250)</b>
Age, mean $\pm$ SD	47.8 $\pm$ 17.7	48.1 $\pm$ 17.1
Male sex, n (%)	2330 (25.9)	906 (27.9)
Race/ethnicity, n (%)		
White	389 (4.3)	117 (3.6)
Black	2733 (30.4)	1035 (31.8)
Latino	4734 (52.7)	1709 (52.6)
Other/unknown	1125 (12.5)	389 (12.0)
Insurance, n (%)		
Medicare	1029 (11.5)	384 (11.8)
Medicaid	4609 (51.3)	1628 (50.1)
Self	1272 (14.2)	453 (13.9)



**Table 2****FACTORS ASSOCIATED WITH SCREENING ADHERENCE**

	<b>Odds Ratio (95% CI)</b>	
	<b>Univariate Analysis</b>	<b>Multivariate Analysis</b>
Patient-level		
Age ≥ 65 y	0.93 (0.82–1.06)	...
Male sex	1.23 (1.11–1.38)	1.18 (1.05–1.32)
Nonwhite race	1.16 (0.91–1.49)	1.19 (0.93–1.53)
New patient	1.30 (1.12–1.50)	1.23 (1.07–1.43)
Non-English	0.90 (0.81–1.00)	0.87 (0.80–0.99)
Physician-level		
Male sex	1.01 (0.68–1.49)	...
High-volume MD <sup>a</sup>	1.42 (0.98–2.07)	1.38 (0.94–2.03)
Resident	1.18 (0.81–1.71)	...
Visit-level		
Morning visit	1.35 (1.22–1.50)	1.32 (1.19–1.47)
Gender concordance	0.87 (0.78–0.96)	0.90 (0.81–1.01)
Busy session <sup>b</sup>	0.86 (0.75–0.97)	0.90 (0.79–1.03)

Odds ratio calculated using mixed-effects modeling with physician random effect.

<sup>a</sup>Greater than or equal to mean among MDs (85 over study period).

<sup>b</sup>Nine or more patients if morning visit or 7 or more patients if afternoon visit (75th percentile)