Identification of Risk Factors for Testing of Hepatitis C in Non-Birth Cohort Patients

Amanda Smart
GUSOM M2019
aes242@georgetown.edu
Funding: Gilead FOCUS

Amanda Smart[1], Alexander Geboy[2], Peter Basch[2,3,4], Whitney Nichols[2], Alexander Zeymo[2], Idene Perez[2], Maria Hafeez[2], Ilan Fleisher[2], Stephen Fernandez[2], Dawn Fishbein[2,5]

[1]Georgetown University School of Medicine, [2]MedStar Health Research Institute, [3]MedStar Institute for Innovation, [4]MedStar Quality and Safety Institute, [5]MedStar Washington Hospital Center

BACKGROUND

- Substantial emphasis has been placed on hepatitis C (HCV) infection screening of patients in the Birth Cohort (born 1945-65, BC) due to high prevalence in this population. However, initiating widespread, automated, risk factor-based (RF) screening outside this population is challenging as RFs that warrant screening are often unstructured data and therefore not always searchable in the Electronic Health Record.
- The CDC currently recommends screening outside of the BC (non-BC) in those who: currently inject drugs, ever injected drugs, received clotting factor concentrates before 1987, are/were on long term hemodialysis, have persistently abnormal ALT levels, have HIV, had blood transfusions or organ transplants before 1992, had a recognized exposure such as a needle stick, or were born to a HCV positive woman.
- CDC data from a national health survey in 2012 indicated that 45% of people infected with HCV reported no known exposure risks. Therefore, testing non-BC patients solely based on RFs has the potential to miss a substantial number of HCV positive patients.
- This study examines the prevalence and associated factors in: (1) those non-BC HCV tested, and (2) non-BC HCV antibody positive (Ab+) patients with no documented RFs, compared to those HCV Ab+ with documented RFs.

METHODS

- In January 2015, with Gilead FOCUS funding, a MedStar-Wide HCV Linkage to Care Navigation program was established; a primary care EHR-based BC HCV testing protocol went live in July 2015, which included risk-based testing language but no actual filter. Data was collected for all including the non-BC as a presumptive marker for high risk.
- The study design was 1:3 case-control retrospective nested chart review of 329 of the total 4,741 non-BC patients tested from July 1, 2015 through June 30; 80 (1.7%) HCV Ab+ or indeterminate patients were compared to 249 randomly selected HCV Ab negative (Ab-) controls.
- Controls were not matched for age, sex or race so that differences could be evaluated. Data was manually abstracted for HCV RFs and opiate prescriptions; other variables were collected using Explorys. Univariate and multivariate logistic regression models were utilized for HCV Ab+ predictors.

Author Disclosures: Dawn A. Fishbein, MD has served on an Advisory Board for BMS, Gilead and serves as a Medical Advisor for Hepatitis Foundation International; Alexander G. Geboy has served on an Advisory Board for Gilead Sciences, LLC. Both have grant funding from Gilead Sciences. Dr. Fishbein has stock ownership in Abbvie and Gilead.

Table 1. Demographic Characteristics by Risk Factor and HCV Ab Test Result

	HCV Ab Negative (N = 249)		HCV Ab Positive or Indeterminate (N = 80)		Total (N = 329)		
	RFs	No RFs	RFs	No RFs	HCV Ab -	HCV Ab +/Ind	*p**
Characteristic	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Total	126 (50.6)	123 (49.4)	62 (77.5)	18 (22.5)	249 (100)	80 (100)	
Mean Age ± SD							*0.002*
Below BC	33±8	35±9	38±9	38±9	34±8	38±9	
Above BC	76±4	78±4	74±2	77±4	77±4	74±3	
Sex							
Female	62 (24.9)	77 (30.9)	25 (31.3)	11 (13.8)	139 (55.8)	36 (45.0)	
Male	64 (25.7)	46 (18.5)	37 (46.3)	7 (8.8)	110 (44.2)	44 (55.0)	
Race							*0.014*
Black	55 (22.1)	65 (26.1)	21 (26.3)	8 (10.0)	120 (48.2)	29 (36.3)	
White	38 (15.3)	40 (16.1)	34 (42.5)	7 (8.8)	78 (31.3)	*41 (51.3)*	
Unspecified/Other	33 (13.3)	18 (7.2)	7 (8.8)	3 (3.8)	51 (20.5)	10 (12.5)	
Ethnicity							
Non-Hispanic	109 (43.8)	112 (45.0)	58 (72.5)	16 (20.0)	221 (88.8)	74 (92.5)	
Hispanic	9 (3.6)	7 (2.8)	2 (2.5)	1 (1.3)	16 (6.4)	3 (3.8)	
Unspecified	6 (2.4)	4 (1.6)	2 (2.5)	1 (1.3)	10 (4.0)	3 (3.8)	
Primary Insurance							*< 0.001*
Medicare	20 (8.0)	9 (3.6)	11 (13.8)	1 (1.3)	29 (11.6)	12 (15.0)	
Medicaid	23 (9.2)	16 (6.4)	25 (31.3)	5 (6.3)	39 (15.7)	*30 (37.5)*	
Private	80 (32.1)	92 (36.9)	25 (31.3)	12 (15.0)	172 (69.1)	37 (46.3)	
Self Pay	3 (1.2)	3 (1.2)	-	-	6 (2.4)	-	
Unspecified/Other	-	3 (1.2)	1 (1.3)	-	3 (1.2)	1 (1.3)	
Opiate Rx	32 (12.9)	18 (7.2)	27 (33.8)	5 (6.2)	50 (20.1)	*32 (40.0)*	*0.001*
No Opiate Rx	93 (37.3)	106 (42.6)	35 (43.8)	13 (16.2)	199 (79.9)	48 (60.0)	

*Comparing total HCV Ab positives to HCV Ab negatives

Figure 1. Age Distribution by HCV Ab Test Result

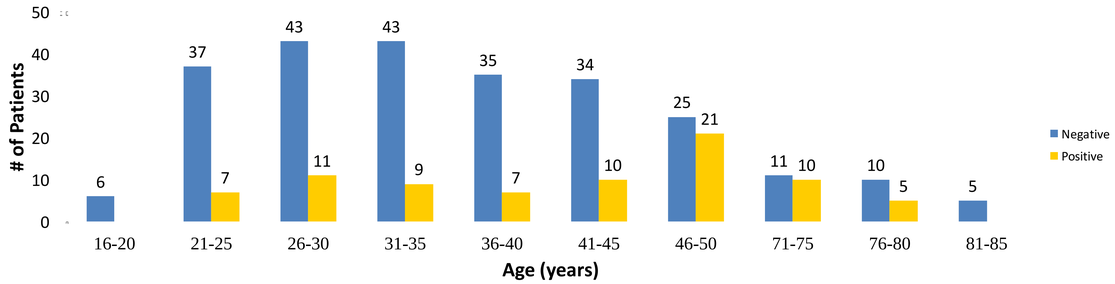

Table 2. Documented EHR Risk Factors

	Negatives (N = 249)	Positives (N = 80)	
Risk Factor	n (%)	n (%)	OR [CI]
Elevated LFTs	36 (14.5)	14 (17.5)	
Drug use	4 (1.6)	28 (35)	35 [12,105]
High risk sexual behavior	42 (16.9)	5 (6.3)	0.3 [0.1, 0.9]
Renal disease	5 (2.0)	2 (2.5)	
Occupational	4 (1.6)	1 (1.3)	
Country of origin	-	3 (3.8)	
Tattoos	4 (1.6)	4 (5)	
Blood transfusion	-	1 (1.3)	
Piercings	-	1 (1.3)	
Incarceration	-	5 (6.3)	
STI	25 (10.0)	8 (10.0)	
HIV	7 (2.8)	4 (5.0)	
Hx of HCV	-	16 (20.0)	
Cirrhosis	-	2 (2.5)	
Alcohol abuse	1 (0.4)	2 (2.5)	
Opiate Rx	50 (20.1)	32 (40.0)	

Note: does not total to 100% due to presence of multiple risk factors

RESULTS

- In multivariate logistic regression (not shown) of this non-BC cohort, persons were more likely to be HCV Ab+ if they: reported drug use (OR_{adj}26, CI_{95}6.1-109.8), had Medicaid v. private insurance (3.4, 1.6-7.7), and were white v. other races (3.4, 1.5-7.9), adjusting for demographic factors and opiate prescriptions; sex behavior was no longer significant (ROC = 0.823).
- There was a significant interaction for age and opiate prescription use with those over 40 with an opiate prescribed 11x more likely to be HCV Ab+ (CI_{95} 1.6-74.8).
- In bivariate analysis, patients with at least one documented RF were more than twice as likely to have Medicaid and more than three times as likely to have Medicare than patients without RFs (p = 0.005, p = 0.0034 respectively).
- 18 (23%) of those HCV Ab+ and 123 (49%) HCV Ab- had no identified RFs; 6 (33%) of the HCV Ab+ reported RFs only after a positive test result, 3 of whom had multiple RFs, 1 reported IV drug use, 1 reported tattoos, and 1 reported a previous history and treatment of HCV.

CONCLUSION

- In non-BC patients, drug use remained a significant predictor of HCV positivity, as in the BC. However, white race is now more significant than black race, which is reversed compared to the BC.
- There are increased CDC reports of HCV in opiate abusers, and our data shows some signal for increased risk as well.
- Additionally, there was a clustering within the 5 year age groups above and below the BC (46-50 and 71-75 years) whereby nearly 50% of the individuals tested in this sample were positive.
- 23% of the HCV Ab+ patients would not have been identified if providers had tested based on RF recommendations alone; and 1/3 of them reported RFs only after receiving a positive test.
- Testing non-BC patients only on the basis of RFs has the potential to miss a significant number of HCV Ab+ patients. Given that patients may not understand HCV RFs or are possibly unwilling to disclose them, and that providers may not be eliciting accurate reporting, universal HCV Ab testing may be warranted.