5-29-2019

Increasing the identification of Hepatitis C and referral to treatment in primary care through a medical assistant driven workflow

Inga Giske

Increasing the Identification of Hepatitis C and Referral to Treatment in Primary Care Through a Medical Assistant Driven Workflow

Inga Giske, MSN, PMHNP-BC, RN-BC, NE-BC

University of Portland School of Nursing

Abstract

Purpose/Background: The purpose of this quality improvement (QI) project was to increase Hepatitis C Virus (HCV) screening and identification through the implementation of universal screening for HCV with a Medical Assistant (MA) workflow as provider prompt. This QI project evaluated the effectiveness of universal HCV screening in a federally qualified health center (FQHC), community health center (CHC), patient centered medical home serving primarily Medicaid, Medicare and uninsured patients. HCV is a major cause of chronic liver disease throughout the world. It now causes more deaths than any other infectious disease in the United States (US). Costs associated with its treatment are significant and increasing. Therefore, early identification through screening and referral to treatment are essential in preventing the spread of the disease and reducing disease related morbidity and mortality.

Methods: Implementation of universal screening for HCV through an MA driven workflow to identify the need for screening and as a provider prompt.

Results: The number of HCV at-risk patients screened increased from 1,144 to 1,393, ($x^2 = 7.96$, $p = .0048$), representing 21.8% increase in the eight weeks post implementation. The screening rate for all clinic patients increased from 27.1% to 32.2% ($x^2 = 26.598$, $p < .00001$). Additionally, referrals to HCV treatment increased from 314 to 442 ($x^2 = 5.507$, $p = .0189$), representing a 40.8% increase.

Conclusion: This MA driven universal HCV screening workflow demonstrated the effectiveness of a simple, cost-effective practice change in improving the identification of HCV and referral to treatment.

Keywords: hepatitis C, screening, referral, linkage to care, primary care

Increasing the Identification of Hepatitis C and Referral to Treatment in Primary Care Through a Medical Assistant Driven Workflow

Hepatitis C Virus (HCV) infection is a major cause of chronic liver disease in the United States (US) and throughout the world (Coyle & Kwakwa, 2016; Heil et al., 2018). HCV is frequently categorized as either acute or chronic. For most individuals, infection with HCV results in a chronic lifelong illness if left untreated (Centers for Disease Control and Prevention [CDC], 2018). It is estimated that at least 2.4 million individuals in the US are living with HCV with infection rates increasing due to the national opioid crisis (CDC, 2018; Oregon Health Authority [OHA], 2017). Moreover, most individuals with HCV are unaware of their infection as they remain asymptomatic until advanced liver disease occurs (Coyle & Kwakwa, 2016; Ford et al., 2018). Early identification of the disease through screening is essential to preventing the spread of the disease and the referral of individuals to effective treatment to reduce costs to the healthcare system and save lives. The financial costs associated with chronic HCV to the healthcare system are significant and increasing. In 2011, the lifetime cost of care for an individual with chronic HCV was $64,490 while the US spent $6.5 billion on HCV care that year (Razavi et al., 2013). Deaths from HCV reached record high in 2014, with 19,659 individuals dying from HCV in the US (Ly, Hughes, Jiles, & Holmberg, 2016). HCV now causes more deaths than any other infections disease in the US (Ly et al., 2016).

Early identification, referral to effective treatment and quality care are key in fighting the HCV epidemic (Department of Health of Health and Human Services [DHHS], 2017). Current HCV screening recommendations from the CDC include: 1) the baby boomer cohort (adults born between 1945 and 1965); 2) current intravenous drug users; 3) individuals with any history of injection drug use; 4) individuals with medical conditions which include a history of receiving

clotting factors before 1987, long-term hemodialysis, long term alanine aminotransferase levels (ALT), and human immunodeficiency virus (HIV) infection; 5) prior recipients of blood transfusions or organ transplants; and 6) individuals with a recognized exposure to HCV (CDC, 2015).

A quality improvement (QI) project to increase the screening rates for HCV took place at a clinic which is a designated healthcare for the homeless clinic, a federally qualified health center (FQHC), community health center (CHC), and patient centered medical home located in Portland, Oregon serving approximately 5,000 Medicaid, Medicare and uninsured patients annually (Central City Concern [CCC], 2016). HCV positive patients are able to receive their care within the clinic as there is an embedded HCV treatment program.

Clinical Problem

HCV is the most commonly reported blood born virus in both Oregon and the US (OHA, 2017). Furthermore, both chronic HCV and HCV mortality rates for Oregon are over twice that of the national average (OHA, 2017). Oregon has the third highest chronic HCV rate in the nation and the second highest mortality rate (HepVu, n.d.; OHA, 2017). In the US, baby boomers, minorities, injection drug users, individuals living in households with annual incomes less than $25,000 and those without a high school education are disproportionately affected by HCV (Coyle & Kwakwa, 2016). As the clinic serves those at the highest risk for HCV in the community, a robust screening program is essential to help stop the spread of HCV while ensuring access to treatment and potential cure to minimize the long-term health effects of chronic HCV such as cirrhosis, liver failure and hepatocellular carcinoma (HCC).

Prior to this project, HCV screening at the clinic was ordered at provider discretion. Providers receive annual HCV education covering CDC screening recommendations, treatment

recommendations, and how to refer patients to HCV treatment program in the clinic. It was the general expectation that those at risk were screened and referred to treatment if appropriate, however there was no supporting policy or practice guideline. Additionally, there was no systematic method to ensure screening for at risk patients such as a flag in the electronic health record (EHR), or through a chart review by the Medical Assistant (MA). Despite knowledgeable providers and the availability to refer patients to HCV treatment within the clinic, the lack of a standardized process to ensure HCV screening resulted in a gap in screening those at risk for HCV. Analysis of baseline data demonstrated only 53% (1,144 of 2,157) of at-risk patients being screened for HCV. Furthermore, the determination of screening rates for at-risk patients is limited by EHR reporting. EHR reporting defines those at risk as patients in the baby boomer cohort and patients with opiate use disorders. When looking at the entire clinic patient population, only 27% (1,144 of 4,227) of patients are screened for HCV. Due to the demographic of patients served by the clinic, patients are disproportionately more likely to be at risk of HCV than the general US public. Therefore, effective screening, diagnosis and referral to treatment is essential in managing the long-term health needs of the patients as well as helping prevent further spread of HCV.

Additionally, in working with the HCV program team, clinic care team managers (CTM) and MA a lack of standardization and training delivering HCV results to patients was identified. Baseline data analysis along with team member interviews demonstrated that the clinic had opportunities to improve screening rates for all clinic patients, increase referrals of HCV positive patients to treatment, to standardize the result notification process by ensuring the most appropriate team members were providing patients with their results and were trained to do so.

Through stakeholder engagement, review of current clinic practices and analysis of baseline HCV data, the project team concluded that the QI project would focus on achieving the following goals: (1) increase HCV screening of clinic patients; (2) increase referral to HCV treatment; and (3) standardize the HCV result notification process.

Methods

Project Development

Literature Review

A literature review was conducted searching CINAHL and MEDLINE was conducted using the search terms: hepatitis C, screening, and primary care with the Boolean connector and. The review was limited to the years 2013 through 2018 with publication in the English language only. A five-year timeframe was chosen due to advances in HCV treatment availability. Twenty-two articles were identified in the initial literature search, one additional article was found through review of identified articles. Articles were excluded through review, or title, abstract and full-text review resulting in a total of five articles included in this paper. See Appendix A: Literature Review Process. The literature review demonstrated that screening in primary care settings is an effective way to identify HCV (Coyle & Kwakwa, 2016; Ford et al., 2018; Heil et al., 2018; O'Kelly, Byrne, Naughten, Bergin, & Williams, 2016; Wolffram et al., 2015). Furthermore, both risk-factor based and universal HCV testing with linkage to care was shown to be effective in FQHCs and CHCs with similar patient populations as OTC (Coyle & Kwakwa, 2016; Ford et al., 2018). See Appendix B: Evidence Table and Appendix C: Synthesis Table.

Theoretical Framework

The Quality Implementation Framework (QIF) guided project design and implementation (Meyers, Durlak, & Wandersman, 2012). The QIF was chosen as it provides a structure with clearly identified steps to follow and key questions to consider at each step throughout all stages of project design, implementation, and evaluation. Additionally, the QIF provides a large area on the assessment and preparation steps to ensure the organization is ready for change and build capacity for change, if needed (Meyers et al., 2012). Lastly, the QIF recognizes that change is a cyclical process and allows for bi-directional movement within the framework. The project manager utilized the QIF to ensure key steps were completed during each phase of the project design, implementation and evaluation process.

Stakeholder Engagement

Clinic providers were surveyed via an online survey distributed through email asking the following questions: (1) Do you screen all patients for HCV? (2) If not, how do you determine who to screen?, (3) What barriers do you have with screening your patients for HCV?, and (4) What would make it easier for you to screen your patients for HCV?. Providers reported barriers to HCV screening including the inability to confirm patient's HCV screening status, unfamiliarity with screening recommendations, unfamiliarity with HCV screening labs, lack of time, and other priorities. Providers frequently have to comb through past medical records to find screening results, a time-consuming task. Additionally, patients frequently recall neither past screening nor past behaviors that put them at risk of contracting HCV. MAs and CTMs were interviewed from each care team within the clinic to identify challenges with screening and seek feedback as how to improve the process.

Screening Workflows

Based on recommendations from the literature, the HCV team and clinic leadership supported moving to a model of universal HCV screening with annual screening for patients with ongoing risk factors, such as IV drug use. The clinic is well situated to have a positive impact on HCV rates and treatment outcomes due to its ability to identify HCV in a high-risk population group through universal screening and subsequently link them to treatment with the embedded HCV program. While the CDC recommends screening patients in high risk groups, in Oregon half of all new HCV infections occur in persons 30 years of age or younger (OHA, 2017). Therefore, a universal screening program which offers one-time screening to all clinic patients and annual screening for those at continued risk will help to ensure identification of those with HCV infection. Through referral of patients who test positive for HCV to the embedded HCV program, access to effective care can be ensured, helping to prevent new infections and decrease HCV mortality in Oregon. Clinic providers, CTMs and MAs agreed that adding HCV screening status to the clinic's "huddle prep process" would be an effective method to identify the need for screening.

Huddle Prep Process

Prior to all patient visits, MAs prepare for the visit by using a huddle prep document. See Appendix D: HCV Huddle Prep and Resource Initial. Through this review MAs are able to prompt providers for necessary screenings and procedures, such as a capillary blood glucose (CBG) or hemoglobin A1C lab draw for diabetics, or HIV screening. Portions of the necessary info for huddle prep pull into the EHR for MAs to review, but other key sections do not, such as HCV screening status. The Huddle Prep document was revised with Clinic Operations Manager and MA input to better reflect the actual workflow of MAs as to how they navigate within the EHR. Components of huddle prep were grouped to correspond with where the information is

found in the EHR. See Appendix E: HCV Huddle Prep and Resource Final. All clinic MAs were trained through an MA staff meeting and individual follow-up by clinic operations manager. Additionally, all MA's completed a competency assessment of their ability to find the information listed on the HPRD in the EHR and provider notification of their findings to allow the provider to consider screening if appropriate.

Result Notification Workflows

In addition to adjusting the MA workflow to prompt screening, the team standardized the result notification process by having health assistants notify patients of negative results, and CTMs notify patients of positive results and schedule follow-up care simultaneously. See Appendix F: Result Notification Process. CTMs were trained on the positive result notification process and HCV counseling by the project coordinator at a team meeting using recommendations form the CDC and the Harm Reduction Coalition (CDC, n.d.; Ellendon, 2003).

Project Implementation Timeline

Project development utilizing provider, MA and CTM interviews along with huddle prep form revisions and trials occurred in September and October of 2018. The project was proposed and approved by the HCV program team in early November 2018. CTM training on the new HCV result notification process was completed in November of 2018. MA training and competency validation on the revised huddle prep process was completed in December 2018. The revised huddle prep process using the new huddle prep document was implemented mid-December 2018. See Appendix D: HCV Huddle Prep and Resource Final.

Data Collection and Evaluation

Both process and outcomes measures were tracked to measure efficacy of the project. Process measures included MA and CTM training completion rates. Outcome measures tracked

were screening rate of at-risk patients, screening rate of all clinic patients and number of referrals to HCV treatment. Training and competency completion rates were gathered upon implementation by the project manager and clinic operations manager using competency validation forms. Eight weeks post implementation, HCV screening and referral numbers were gathered and compared to baseline data. Due to reporting challenges the total number of screenings and referrals were tracked and compared to the baseline data, rather than using screening and referral rates over separate timeframes. A chi square analysis was conducted to determine the association between the new screening workflow and the increase in HCV screening for both at risk and all clinic patients. Chi square analysis was completed using Social Science Statistics (Stangroom, 2019).

Ethical Considerations

Institutional Review Board (IRB) approval was sought and granted for this project by the University of Portland IRB committee. Informed consent to allow their training and competency data to be included in the project outcomes was reviewed with MAs and CTMs to include their competency and training data in the results of this project. Patients maintained the right to refuse HCV screening and/or referral to treatment. All project team members were free from relevant conflicts of interest.

Results

Project outcomes were tracked using a metric tracker table. See Appendix G: Metric Tracker for more detail. All 19 clinic MAs competed the huddle prep training and competency validations and all six clinic CTMs completed the HCV counseling training. The number of active patients, defined as patients who saw a provider at least once in the last two years, increased during the project timeframe from 4,227 to 4,332, an increase of 2.2%. Furthermore,

the number of patients at risk for HCV at the clinic increased from 2,157 to 2,436, representing a 12.9% increase (x^2= 23.30 p < .00001). The number of at-risk patients screened increased from 1,144 to 1,393, representing 21.77% increase ($x^2 = 7.96$, $p < .004787$). The screening rate for all clinic patients increased from 27.06% to 32.16% (x^2= 26.60, $p < .00001$). Additionally, referrals to HCV treatment increased from 314 to 442 ($x^2 = 5.51$, $p = .0189$), representing a 40.8% increase. The screening rate of all clinic patients increased more than the rate of HCV at-risk patients, and 18.9% increase as compared to a 7.8% increase.

Discussion

These findings suggest that the MA driven workflow to prompt provider consideration of the need for HCV screening using a model of universal screening was successful in increasing screening for both patients identified as at-risk for HCV and those who were not defined as at risk of HCV per CDC recommendations. The project was optimistically accepted by clinic staff, providers, and patients. As anticipated, the project proved effective in increasing screening for both patients identified as at-risk and those who were not, and resulted in an increase in referrals to treatment. Moreover, the rate of increase in referrals rose at a steeper rate than the increase in both patients identified at risk, and patients screened, indicating increasing rates of patients identified as having HCV. Screening of patients not traditionally deemed as at-risk is known to be effective in identifying chronic HCV as not all patients accurately recall or disclose their at-risk behaviors (Coyle & Kwakwa, 2016). The project data is consistent with this finding as the total screening rate and referrals to treatment both increased at a higher rate than the HCV at-risk screening rate.

Project Limitations

Due to EHR and reporting limitations it was not possible to gather HCV screening, identification and referral rates for discontinuous timeframes. Therefore, all data was analyzed beginning February 1, 2017. February 1, 2017 was chosen as the HCV treatment program began at that time resulting in HCV program data available for the total timeframe between February 1, 2017 and the end of the project data collection timeframe, but not at different intervals. Additionally, current EHR reporting does not fully identify all HCV risk factors. A patient is only classified as at-risk if they are in the baby boomer age cohort and if they have "problem" history of opiate use disorder. Therefore, the data analysis does not fully capture all patients at risk for HCV.

Additionally, the data collection timeframe was limited to eight weeks. During this timeframe, HCV screening was fresh in the minds of both MAs and providers. Ongoing evaluation of the project will need to be done by the clinic operations manager and HCV program team to continue to assess ongoing effectiveness in increasing HCV screening and referrals as a proxy for HCV infection.

EHR changes to support more rapid identification of HCV screening needs, such as clearer identification of risk factors, pulling in HCV screening status to the EHR huddle prep, along with improved reporting would have allowed for cleaner data analysis in both the gathering of baseline data and post-practice change data.

Lessons Learned

This QI project proceeded smoothly as designed with outcomes as expected. Utilizing the QIF, engaging stakeholders early, identifying potential barriers and developing mitigation strategies for those barriers allowed for a successful project which can be sustained utilizing the clinic's existing structures.

Conclusion

HCV screening has been demonstrated to be cost-effective as the early identification and treatment of HCV decreases the overall economic burden to the individual and health system through the prevention of healthcare related costs and potential disability from liver disease (Joshi, 2014). The current project, intentionally designed to be embedded within current clinic structures and workflows at no organizational cost and requires no ongoing additional resources in terms of committee structures, time, or staffing for sustainability. Clinic HCV data will be tracked moving forward by the HCV team program coordinator and standard clinic quality assurance processes. The revised MA huddle prep process proved to be a cost-effective means to improve HCV identification and linkage to treatment, thus improving the health of clinic patients and the community overall.

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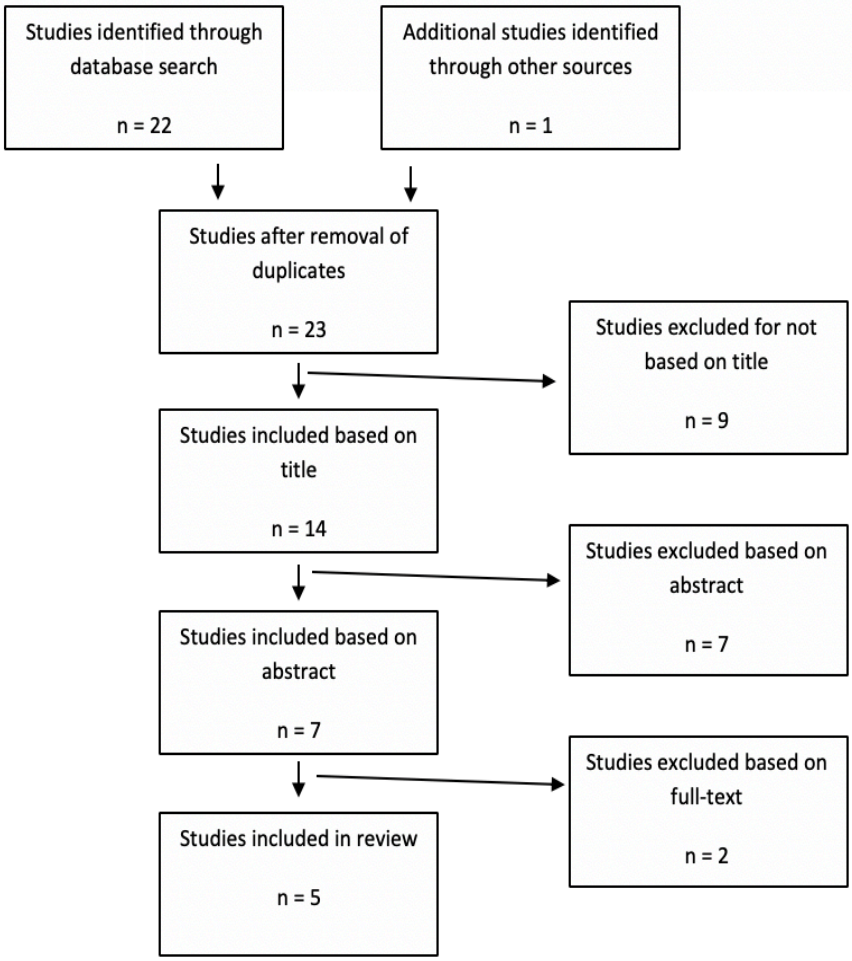
Appendix A: Literature Review Process



Appendix B: Evidence Table

Citation (author, title, year)	CF or TF	Study Design/ Method	Setting/ Sample	Major Variables (and their definitions)	Metrics	Data analysis (stats)	Results	Strengths Limitations Applicability
Coyle, et al. *Pub Hlth Rep* 2016: 131(S1) 41-52	None	Multicenter, prospective study • MA initiated routine HCV and opt-out HIV testing for all CHC pt with known risk factors and/or baby boomer cohort • Team and provider training • Linkage to ongoing care and tx	4 CHC/FQHCs in Philadelphia, PA caring for low-income and homeless patients n = 9035 ≥ age 18 pt unaware of their HCV or HIV status	IV – routine HCV and opt-out HIV testing DV – pts screened for HCV and HIV	# pt tested for HCV # pt tested for HIV % increase of HCV and HIV testing after implementation of routine testing # pts anti-HCV + # pt received RNA	%ages, no statistical analysis	Post implementation: • 1,888 pt tested for HCV • 3,890 pt tested for HIV Representing a: • 23.7% increase in HCV testing • 124.7% increase in HIV testing Testing Discovered: • 101 HCV + pt • 13 HIV + pt	Strengths: • Multiple test sites with experience working with and tx pt at high risk for HCV • Free testing • Diverse pt sample in terms of gender, race • Include both pt and provider education • Used reflexive testing to prevent additional lab draws • Demonstrated efficacy and feasibility of opt-out HCV and HIV screening as part of routine primary care Limitations: • No statistical analysis to determine if outcomes were statistically significant changes • During study timeframe, two test sites moved to

		for those who test positive			confirmatory test # pt with chronic HCV infection # pt HIV +		Linkage to Care for: • 39 HCV + pt • 9 HIV + pt	universal HCV screening for all clients due to high rates of HCV outside of the baby boomer birth cohort and known risk factor pts Applicability: • Applicable to OTC due to: • Similar pt populations served • All test sites were CHC/FQHC like OTC • Demonstrates importance of screening with confirmatory testing, linkage to care and availability of tx in one site, which OTC has
Ford, et al., *JPHMP* 2018; 24(1) 41-48	None	Multicenter, prospective study • Targeted outreach with rapid HCV ab screening in the field	12 test sites comprised of: • 6 CHCs • 4 FQHCs • 2 SEPs In low-income neighborhoods of NYC with high	IV – targeted outreach to encourage rapid HCV screening DV – • Pts screene	# pts anti-HCV + # pt received RNA confirmatory test # pt with chronic	%ages for outcomes %ages with 95% CI for pt demographics	880 (19%) pt anti-HCV ab positive Of, anti-HCV ab + pts 678 (77%) received RNA confirmatory testing	Strengths: • Numerous test sites with experience working with and tx pt at high risk for HCV • Free testing • Diverse sample in terms of gender, race and testing site • Used rapid HCV ab testing in the field

		• Lab draw for confirmatory testing
		• Pt navigators for linkage to care
		• Medical provider training
			rates of HCV infection
			
			n = 4751
				d for HCV	HCV infection
					
					# chronic HCV pt with linkage to care
					
					# chronic HCV pt who are tx candidates
					
					# chronic HCV pts who initiated tx
						and testing site
						
						Chi square test to assess difference between pt who received confirmatory testing and those who did not
							Of the 678 seropositive pt, 512 (76%) had chronic HCV infection
							
							435 (85%) pt with chronic HCV had linkage to care
							
							Of pt who were linked to care, 47 (30%) were deemed tx candidates
							
							14 pts (30) of those deemed tx candidates initiated tx
								• Include both pt and provider education
								
								Limitations:
								• Did not include total # pts outreached to
								• No CI analysis for outcomes
								• Included pts who already knew HCV positive status
								• At the time of the study tx restrictions included fibrosis levels and active IV drug use – these are no longer in place
								
								Applicability:
								• Applicable to OTC due to:
								  • Similar pt populations served
								  • 10 of the test sites were CHC or FQHCs. OTC is both a CHC and FQHC
								  • Demonstrates importance of screening with confirmatory testing, linkage to care and availability of tx in

								one site, which OTC has
Heil, et al., *Ann Fam Med* 2018; 16(1) 21-27	None	Multicenter, prospective study Invited pts between age 40 and 70 to participate in HBV and HCV testing over a 3-day period for no charge Screening testing covered HBV and HCV antibodies. If screening +, blood sent for confirmatory testing	11 family practices is the Netherlands serving 2 areas of high HVC prevalence n = 6743	IV – invitation of HBV and HCV testing to all pts between age 40 – 70 at primary care clinics DVs • Pt opt in to testing • Pt opt out of testing	Total test uptake (# pt who tested) # positive tests for HBV # positive tests for HCV	%ages with 95% CI	3,434 (50.9%) [95% CI = 49.7% to 52.1%] opted in to HBV and HCV testing 0 active HCV infections 7 past HCV infections 9 active HBV infections • 2 known diagnoses • 7 new diagnoses 142 past HBV infections	Strengths: • Simple implementation strategy • Testing was free • High test uptake • Demonstrated efficacy of primary care/public health approach to HBV/HCV screening • First study assessing public health/primary care testing strategy in Europe • Demonstrated importance of birth cohort screening in addition to risk factor prevalence Limitations: • Did not rule out selection bias as HCV pts tend to have lower health literacy, a letter outreaching for testing may not be effective • Risk factor data for HBV and HCV reported by pt may be inaccurate due to recall bias or social desirability bias

								• No questions on sexual risk factors were included in questionnaire
								• Lack data pts who did not test
								• Data from pts who did not test may not be generalizable to general public
								
								Applicability:
								• Applicable to OTC due to:
								  • Primary care setting
								  • Known HCV hot spot
								  • Implementation through provider invitation to testing
								  • No adjustment to EHR needed
								  • Suggested that testing be done as part of routine lab work to increase test uptake, rather than having a pt come in for solely HBV and HCV testing

O'Kelly, et al., *Br J Gen Pract* 2016;	Non e	Multicenter, prospective study	Four primary care centers in Dublin Ireland serving an	IV - offer of BBV testing to all adult pts who	# pt opt in to BBV testing	%ages with 95% CI	1063 (89.5%) [95% CI = 87.7% to 91.2%] opted	Strengths: • Simple implementation strategy with education of all pertinent care team members

66(647): e392-396		Offered BBV testing to all adults age 18 and over who presented to the sites for routine blood tests over a six-month period.
		
		BBV testing screened for HBV surface antigens, HCV antibody, and HIV antigen-antibody combination.
			impoverished area.
			
			n = 1188 pts
			
			Represented 8% of practice populations.
			• 753 female
			• 453 male
			• Median age = 54
				present for routine blood testing
				
				DVs
				• pt opt in to BBV testing
				• pt opt out of BBV testing
					# pt opt out of BBV testing
					
					# positive tests for HBV
					
					# positive tests for HCV
					
					# positive tests for HIV
							in to BBV testing
							
							125 (10.5%) opted out of BBV testing
							
							10 pt had positive results
							
							2 new diagnoses of HBV
							
							2 new diagnoses of HCV
							
							0 new diagnoses of HIV
								• Educational hand outs and signs for pts
								• High rate of pts who opt in confirms that opt-out testing for BBV is viable in primary care
								• Adds to limited existing literature regarding opt-out BBV screening in primary care
								
								Limitations:
								• Relatively small study with four study sites
								• Limited number of pts
								• Conducted over short time-frame (six months)
								
								Applicability:
								• Quite applicable to OTC due to:
								  • Primary care setting
								  • Impoverished area
								  • Implementation through care team and pt education
								  • No adjustment to EHR needed

Wolffram, et al., *J Hepatol* 2015: 62	None	Multicenter, prospective study	51 primary care private practices in Germany	IV: • include ALT, HBsAG, and	# HBsAg + pts # anti-HCV + pt	T test with Welches approxi	20,864 pts screened for HBV	Strengths: • Large sample size • Large testing uptake

1256-1264		Implemented routine ALT, HBV and HCV testing as part of Check Up 35+, a standard preventative medical exam for pt who are at least 35 and is covered by insurance along with a 16-question questionnaire assessing risk factors for HCV and HBV	n = 21,008 with an avg of 412 pt at each practice 780 pts were <35 and included in study Mean age – 57.5 years 11,766 (56%) female 2,740 (13.9%) pt were immigrants	anti-HCV testing in routine lab work of Check-Up 35+ • 16 question pt question naire assessin g risk factors for HCV and HBV DV – pts opt out of testing	# pt with elevated ALT	mation to compar e the two means Odd ration with 95% CI testing for risk factors identifie d by question naire	20,917 screened for HCV Prevalence rates as follows: • HBsAG – 0.52% • Anti-HCV – 0.95% • HCV-RNA – 0.43% Infection previously unknown in: • 85% of HBV + pt • 65% of HCV + pt Risk factors most associated with HBV: • Immigration (4.4 [2.9, 6.7]) • Infection in household (2.5 [1.2, 4.5])	• Thorough statistical analysis of pt demographics and risk factors associated with HBV and HCV infection • First prospective study evaluating routine HBV and HCV testing in primary care in Germany • Identified a higher disease burden than had been previously described by the national health authority Limitations: • Age distribution of sample not representative of German population • Sample size likely didn't include a representative number of high-risk patients • Data on study participation rates not collected Applicability: • Applicable to OTC due to:

							• Male gender (1.6 [1.1, 2.4]) Sexual risk factors for HBV underreported Risk factors most associated with HCV: • IV drug use (384 [233, 644]) • Blood transfusion before 1992 (5.3 [3.5-7.9]) • Immigration (2.4 [1.5, 3.6])	• OTC's patient population contains patients identified at high risk with this study • Demonstrates ability to complete routine HCV and HBV testing in a primary care setting with a large sample size

Notes: % = percent, + = positive, ab = antibody, ALT = alanine aminotransferase, BBV = blood borne virus, CF = conceptual framework, CHC = community health center, CI = confidence interval, DV = dependent variable, EHR, electronic health record, FQHC = federally qualified health center, IV= independent variable, HBsAG = hepatitis B surface antigen, HBV = hepatitis B virus, HCV = hepatis C virus, HIV = human immunodeficiency virus, MA = medical assistant, NYC = New York City, New York, USA, pt = patient, SEP = syringe exchange programs, TF = Theoretical framework, tx = treatment

Appendix C: Synthesis Table

Study Citation	Population & Number of Participants	Duration of Study	Study Design	Intervention	Impact of Intervention and Recommendation	Level of Evidence
Coyle, et al. *Pub Hlth Rep* 2016: 131(S1) 41-52	Pts served by 4 CHC/FQHCs in low-income areas of Philadelphia, PA n = 9035 ≥ age 18 pt unaware of their HCV or HIV status	9 months (9/1/2013 – 5/31/2014)	Multicenter, prospective	Implementation of MA driven routine HCV and opt-out HIV testing as part of primary care visits	HCV Screening ⇑ HIV Screening ⇑⇑ HCV Diagnosis ⇑⇑ HIV Diagnosis ⇑ HCV Linkage to Care ⇑⇑ HIV Linkage to Care ⇑ Universal screening for HCV/HIV as part of routine primary care with opportunity to opt out	Level 4
Ford, et al., *JPHMP* 2018; 24(1) 41-48	Pts served by 6 CHCs, 4 FQHCs, and 2 SEPs in high HCV prevalent areas of NYC n = 4751	1 year (May 2012 – Apr 2013)	Multicenter, prospective	Rapid HCV screening with availability for confirmatory testing, linkage to care and tx	HCV ab + ⇑⇑⇑⇑⇑ HCV infection confirmation ⇑⇑⇑ HCV linkage to care ⇑⇑ HCV tx initiated ⇑ Universal screening for HCV with availability of co-located care navigation, and HCV tx	Level 4

Heil, et al., *Ann Fam Med* 2018; 16(1) 21-27	Pts age 40-70 in 11 family practices in 2 known HCV hot spots of the Netherlands personally invited to come in HBV and HCV testing by PCP n = 6743	3 testing days over 8 months	Multicenter, prospective	PCP personal invitation to pts between age 40 and 70 to come in for free HBV and HCV testing on one of three testing days. Pt who did not show for testing after initial invitation were sent reminder invitations	HBV/HCV test uptake ⇑⇑⇑ HCV Diagnosis ⇑ HBV Diagnosis ⇑⇑ Birth cohort testing in addition to risk factor prevalence for HBV and HCV Suggested that testing with routine blood work would be more effective than having pts come in solely for HBV and HCV testing	Level 4
O'Kelly, et al., *Br J Gen Pract* 2016; 66(647):e392-396	Adult pts in primary care centers in Dublin, Ireland who presented for routine blood screening n = 1188	Six months	Multicenter, prospective	Offer BBV testing which included HBV, HCV, and HIV screening to all adult pts who presented for routine blood testing	BBV opt in to testing ⇑⇑ HBV Diagnosis ⇑ HCV Diagnosis ⇑ HIV Diagnosis ⇔ Implement opt-out screening for BBV in primary care	Level 4
Wolffram, et al., *J Hepatol* 2015: 62 1256-1264	51 primary care private practices in Germany	16 months	Multicenter, prospective	Included ALT, HBsAG, and anti-HCV ab testing in the	HBV Screening ⇑ HCV Screening ⇑	Level 4

	n = 21,008 with an avg of 412 pt at each practice 780 pts were <35 and included in study Mean age – 57.5 years 11,766 (56%) female 2,740 (13.9%) pt were immigrants			Check-Up 35+ annual visit along with a 16-question questionnaire focusing on risk factors for HBV and HCV	HBV Diagnosis ⇑⇑ HCV Diagnosis ⇑ Include HBV and HCV screening as part of routine primary care visits with the ability to opt-out	

Notes: ab = antibody, BBV, blood-borne virus, HBsAg = hepatitis B surface antigen, HBV = hepatitis B virus, HCV = hepatis C virus, HIV = human immunodeficiency virus, MA = medical assistant, NYC = New York City, New York, USA, PCP = primary care provider, pt = patient tx = treatment

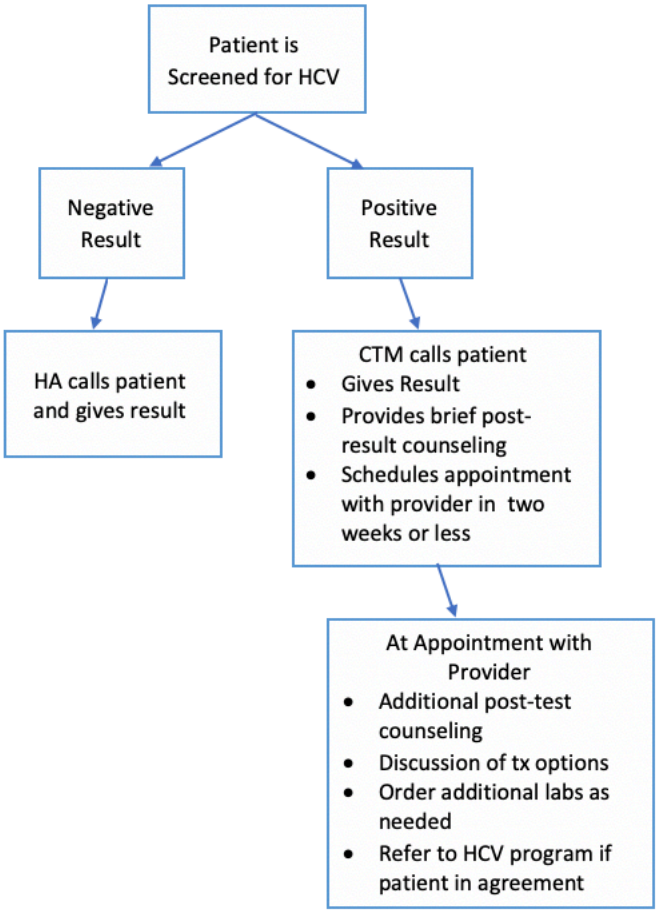
Appendix D: HCV Huddle Prep and Resource Initial

Test	**frequency**	**Male**	**Female**	**Diabetic**	**50-74**	**18-50**	**65+**	**smoker**
SBIRT	Initial visit and annual	x	x					
PHQ 3		x	x					
PHQ 9	Initial visit and when PHQ 3 is +	x	x					
CBG		x	x	x				
A1C	Controlled q 6 months Uncontrolled q 3 months	x	x	x				
Foot exam	Annual	x	x	x				
UA urine dip	Annual	x	x	x				
Eye referral	Annual	x	x	x				
Flu vaccine	Annual	x	x					
Pneumococcal	One dose	x	x				x	x
Pap	Q 3 years		x			24-64		
Mammogram	Q 2 years		x		x			
Colonoscopy	Once (unless abnormal)	x	x		x			
Fit kit	annual	x	x		x			
TSH	Annual if normal, q 6 m if abnormal							
TDaP	Q 10 years	x	x					
Last pain Rx/last UDS? Evaluate refill potential (28 day)		x	x					
Pain medication orders		x	x					
Open orders		x	x					
Effective contraceptive use	Annually and q visit if not on problem/med list		x			x		
Hep C	Once and prn risk factors	x	x	x	x	x	x	
HIV	Once and annually with risk factors	x	x		x	x	x	

Appendix E: HCV Huddle Prep and Resource Final

Task/Test	Frequency	Male	Female	Diabetic	50-74	18-50	65+	smoker	Opiate RX/Use
Print provider schedule									
Reason for appointment	Every visit	x	x						
Pop ups/behavior agreements	Every visit	x	x						
Interpreter Needed	Every Visit	x	x						
VACCINES:									
Flu vaccine	Annual	x	x						
Pneumococcal	One dose	x	x	x			x	x	
TDaP	Q 10 years	x	x						
CENTRICITY HUDDLE INFO:									
Open orders	Every visit	x	x						
Hep C test	Once and annually with risk factors	x	x						
SBIRT	Initial visit and annual	x	x						
A1C	Controlled q 6 months Uncontrolled q 3 months	x	x	x					
Foot exam	Annual	x	x	x					
Urine microalbumin/creat	Annual	x	x	x					
Eye referral	Annual	x	x	x					
Pap	Q 5 years		x			24-64			
Mammogram	Q 2 years		x		x				
Colonoscopy	Once (unless abnormal)	x	x		x				
Fit kit	Annual	x	x		x				
Problem/Med List:									
Injections/LAI due	Every visit	x	x						
CBG	Every visit	x	x	x					
Effective contraceptive use**	Annually or with each visit if not on problem/med list		x			x			
Dx of COPD: oxygen level	Every visit	x	x						
LABS:									
Last UDS	Every visit	x	x						x
HIV test	Once and annually with risk factors	x	x						

Appendix F: Result Notification Process



Appendix G: Metric Tracker

	Pre-Implementation	Post-Implementation	Percent Change
MA competency validation rate	0	100%	
CTM training completion rate	0	100%	
Total Number of Clinic Patients	4227	4332	2.2%
Identified HCV At-Risk Patients	2157	2436	12.9%
Patients Not Identified as HCV At-Risk	2070	1896	-8.4%
Patients Screened	1144	1393	21.8%
Identified HCV At-Risk Patients Screening Rate	53.0%	57.2%	7.8%
Total Clinic HCV Screening Rate	27.1%	32.2%	18.9%
Referrals to HCV Treatment	314	442	40.8%