Analyzing Patient Characteristics Associated With Hepatitis C Follow-Up Care After Implementation Of A Pharmacy Technician-Driven Service

Ву

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Abstract

Background: Hepatitis C is a chronic, curable, infectious disease that can lead to substantial cost burden when left untreated. Previous studies have examined models of testing and connecting patients to care for hepatitis C and why patients do not follow-up for hepatitis C care. However, no studies have looked at characteristics of patients not connected to care and characteristics associated with follow-up with and without targeted intervention. A pilot program was created through a specialty pharmacy to work on connecting patients to care for hepatitis C, and these characteristics were analyzed.

Methods: Patients over the age of 18 with a positive hepatitis C RNA test from the inpatient or emergency department setting from Jan. 1, 2020 to Oct. 15, 2020 were contacted by a specialty pharmacy technician between Dec. 15, 2020 and Jan. 22, 2021. Data was retrospectively analyzed based on outcomes of technician calls and patient information from the EMR. Data points analyzed included patient demographics, test location, hospital site, time to contact, and history of HIV, substance use disorder, or any mental, behavioral, or neurodevelopmental disorder. Patient connection to care was recorded.

Results: A total of 231 patients were analyzed. 39 patients (16.9%) had established follow-up prior to the technician calling. 67% of patients were not able to be contacted. There was a statistically significant association between sex and being connected to care prior to the call ($\chi^2 = 7.534$, p=0.006). Sex was independently associated with connection to care, with males 2.6 times more likely to not be connected to care (p=0.007, 95% CI (1.298, 5.315)). 35 patients were reached that were not previously connected to care with 24 (68.6%) connected to care. There was a statistically significant interaction between insurance status and being connected to care (Fisher's Exact Test, p=0.004). Additionally the patients who were more likely to be connected to care were contacted in average 1.092 months later (6.38 +/- 2.98) compared to those who did not get connected to care (5.27 +/- 2.24 months) (t(33)=-1.092, p=0.029). Insurance status was significantly associated with not being connected to care (p=0.004).

Discussion: This study highlights that having a dedicated resource to care coordination helps to increase the proportion of patients connected to care. Additionally, pharmacy technicians have the skillset to effective be in this role. Limitations of the study include a small sample size, inability to contact many patients, and relying on accuracy of data entered into the EMR.

Conclusion: In the setting of a non-closed, large health system with multiple sites, a centralized resource to facilitate care coordination efforts may be beneficial in increasing the number of patients connected to care for hepatitis C. Based on the results, male patients should have an increased focus on connecting to care and tools need to exist to connect self-pay patients to care.

I. Background

Hepatitis C is a curable infectious disease that, when left untreated, can lead to recurrent and costly hospitalizations.¹ Across the United States, there has been an increase in recent years in the number of cases of acute hepatitis C, in part due to the opioid epidemic.² Given the burden of hepatitis C across the globe and the presence of efficacious treatment, the World Health Assembly has set a goal to eliminate hepatitis C by the year 2030.³

Previous studies have been conducted on connecting patients to care after having a positive hepatitis C test. One study evaluated screening patients in the "Baby Boomer" generation admitted to a hospital in a low-income area. In this study, 148 of 175 patients who tested positive for hepatitis C were able to be connected to care. Another study focused on patients in the emergency room setting born between 1945 and 1965. This study found 102 patients to be positive for hepatitis C, and of those, 24 were able to be connected to care. Coyle, et al, conducted another study of five health centers and was able to inform 90% of the patients who were positive for hepatitis C of their status and connect 62% of those to a specialist.

Most studies discuss the use of dedicated care coordinators to guide patients throughout transition of care. These coordinators assist the patient with overcoming barriers to receiving treatment by helping to schedule appointments with specialists and helping with other issues, such as transportation.^{4,5,7,8}

Although the above mentioned studies have noted that there is not complete follow-up, few studies have examined if there are different patient characteristics that contribute to a patient receiving follow-up care or not. One study interviewed patients who did not receive treatment after the implementation of a robust hepatitis C program; some reasons cited by patients included stigma associated with the disease and not thinking the disease was active. A study of patients in the VA, conducted when interferon-based treatment was the standard of care, found economic considerations and side effects of the medications kept patients from pursuing treatment. Another study of patients with hepatitis C found depression to be independently associated with patients not accessing hepatitis C care. However, these studies did not assess specifically the characteristics associated with seeking connection to care for hepatitis C.

Researchers studied patients with HIV who visited the Vanderbilt Comprehensive Care Clinic and analyzed various characteristics of patients who were retained in care and maintained viral suppression, including sex, age, race, and socioeconomic status. They found that younger patients, Black patients, and those that engaged in injection drug use were less likely to be retained in care over the study period. Another study analyzing a cohort of patients co-infected with HIV and hepatitis C in the Atlanta VA system found that barriers to care for hepatitis C in these patients included active substance use, unstable housing, and underlying psychiatric conditions. This is an important patient population as patients with both hepatitis C and HIV are at an increased risk of progressing to cirrhosis, hepatocellular carcinoma, and all-cause mortality. Given this association between HIV and hepatitis C, it will be important to include data on HIV status and study similar characteristics as seen in these studies.

About Memorial Hermann Health System

Memorial Hermann Health System is the largest not-for-profit healthcare system in southeast Texas, with 14 different hospitals. In addition, there are various outpatient specialty clinics, including the Ertan Digestive Disease Center in the Texas Medical Center. Within this clinic, there is dedicated care for patients with hepatitis C, including a pharmacist and pharmacy technician who are part of the Memorial Hermann Specialty Pharmacy team. However, Memorial Hermann is not a closed health care system, so

there is currently no set service in place to connect patients to this resource, while the clinic is open to strengthening the opportunity to connect with patients.

A study conducted within the Memorial Hermann Health System showed that there is limited evidence that patients receive follow-up after testing positive for hepatitis C in any encounter across the health system. This finding led to the implementation of a pharmacy-technician led referral program for patients testing positive across the health system. This pilot focused on patients with a positive hepatitis C RNA test between January 1, 2020 and October 15, 2020 from either an inpatient or emergency department encounter across the health system. The pharmacy technician selected to lead the project already worked as a program technician with the Memorial Hermann Specialty Pharmacy focused on the Ertan Digestive Disease Center. Additionally, a referral process was established with the clinic due to the relationship that already existed with the specialty pharmacy since 2017. For patients that were uninsured, appropriate steps to schedule at a local federally-qualified health center (FQHC) were provided. Patients unable to attend the clinic for other reasons were advised to connect with their primary care provider (PCP).

Based on this pilot, analysis was conducted on the patients included to determine if there is a specific subset of the population that benefitted from the technician's outreach to be able to improve efforts in the future. The purpose of this study is to determine if there are key differences in patient characteristics who test positive for hepatitis C and receive follow-up care compared to those who do not while using a pharmacy technician-led model to connect patients to follow-up care for their hepatitis C.

Objectives

The primary objective of this study is to determine if there are key differences in patient characteristics between patients who seek follow-up care for their hepatitis C and those who do not. Investigators hypothesize that differences exist in key patient characteristics between patients who receive follow-up care and those that do not after testing positive for hepatitis C during an emergency department or inpatient visit.

The primary endpoint of the study evaluated the differences between patients who do and do not follow-up for hepatitis C after a positive RNA test during an inpatient or emergency department visit. The secondary endpoint evaluated the differences in patients without connected to care that the pharmacy technician was able to connect and those they were not. (see Appendix, Figure 3)

II. Methods

Setting and Procedures

The study included patients who had a positive hepatitis C RNA test in an inpatient or emergency department visit between January 1, 2020 and October 15, 2020 and were attempted to have been contacted by the pharmacy technician. Patients included in the pilot to be contacted by the pharmacy technician were (1) over the age of 18 with (2) a positive hepatitis C RNA test from the inpatient or emergency department setting from January 1, 2020 to October 15, 2020. Patients were excluded from being called by the technician if (1) they were deceased during the encounter with the test, (2) were discharged to hospice, or (3) had an emergency department encounter at the Memorial Hermann – Texas Medical Center campus due to a conflicting study that began at the end of October.

The technician was trained on how to conduct the phone calls, HIPPA rules, and was provided a script. A list of eligible patients for the study was provided to the technician by the pharmacy resident leading the project. The pharmacy technician then incorporated the calls into their daily workflow between December 15, 2020 and January 22, 2021. Any questions or issues were triaged to the pharmacy resident. All calls and attempts were recorded in a log for tracking purposes. The pharmacy technician attempted to contact each patient twice, except for those with incorrect or disconnected phone numbers. (see Appendix, Figure 4 for workflow).

For this study, the patients included in the analysis includes those patients that were attempted to be contacted by the pharmacy technician between December 15, 2020 and January 22, 2021.

Data Collection

Table 1 shows the data points that were collected for analysis. Data points 1 through 14 were all collected from electronic medical record (EMR) data. HIV status was defined as having a record of ICD10 code B20 in their record. History of substance abuse disorder was defined as having any ICD10 code F10.1, F10.2, F10.9, F19.9. A history of mental, behavioral, or neurodevelopmental disorder was defined as any ICD10 code F01-F99 excluding the above ICD10 codes.

The patients were considered connected to care prior to the technician call if the patient verbalized they had already sought follow-up care for their hepatitis C or by evidence of follow-up in the EMR, including an encounter with a specialist or fill for a medication to treat hepatitis C. If the patients were not connected to care, the technician recorded if they were able to connect the patient to care or not. Connected to care after the technician call was defined as sending a referral message to the clinic in the EMR, getting the patient appropriate information to pursue care at FQHC, or connecting patient to their primary care physician for further referral.

Table 1: Data Points Collected

- 1. Birth Sex
- 2. Age at time of first call attempt
- 3. Ethnic Group
- 4. Race
- 5. Primary Language
- 6. Insurance status
- 7. Home Zip Code
- 8. Home County
- 9. Test Location (Inpatient or emergency department)
- 10. Hospital Site
- 11. Time from discharge to first call attempt
- 12. HIV Status
- 13. History of substance abuse disorder
- History of Any Mental, Behavioral, or Neurodevelopmental disorder
- 15. Patient connection to care prior to call
- 16. Patient connection to care after call

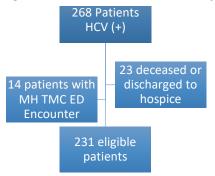
Data Analysis

Patients were divided into 2 groups for analysis – patients already connected to care at time of initial call and patients not connected to care or unable to reach and had no evidence of follow-up in the EMR. A sub-analysis was conducted on patients the pharmacy technician contacted and divided into two groups – those connected to care and those not (see Appendix, Figure 3). These patients were compared based on the ability of the pharmacy technician to connect them to care or not.

The statistics used to evaluate for differences in patient characteristics were chi-squared for all categorical variables, t-tests for the continuous variables, and a binomial logistic regression for the adjusted models.

III. Results

Figure 1. Patients Included in Study



Between January 1, 2020 and October 31, 2020, 268 patients tested positive for hepatitis C. Of those, 23 were not contacted by the technician as they were deceased or discharged to hospice from the encounter where they tested positive for hepatitis C. An additional 14 patients were excluded due to having an encounter at Memorial Hermann-TMC emergency department after October 24, 2020 (See Figure 1).

A total of 231 patients were included in the final analysis. Only 39 patients

(16.9%) had established follow-up prior to the technician calling. 67% of patients were not able to be contacted (see Figure 2).

The heat maps (Figure 3) below shows the geographic distribution of patients connected to care and those not connected to care by both zip code and county. Patients connected to care tended to be closer to the city of Houston whereas those not connected to care were more geographically dispersed. The vast majority of patients lived in Harris County.

Figure 2. Call Outcomes

Already connected to care 17%

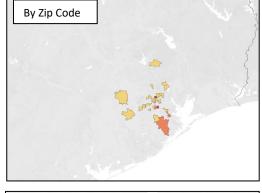
Assisted in connecting to care 11%

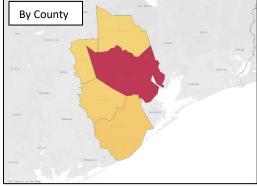
Unable to contact 67%

Refused help 5%

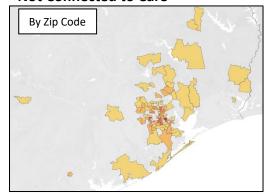
Figure 3. Geographic Distribution of Patients Based on Connection to Care

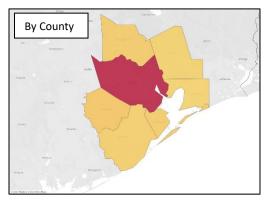






Not Connected to Care





When analyzing variables for association with connection to care, three variables were removed from analysis – test location, ethnicity, and language. Test location was eliminate as all of patients included in the analysis were tested during an inpatient encounter. Both ethnicity and language were found to be poorly collected variables based on the EMR data and would not contribute meaningfully to the results of the study.

Primary Outcome

A chi-square test for independence or t-test was conducted between the various patient characteristics and if the patient was connected to care prior to being contacted by the pharmacy technician (see Table 2). There was a statistically significant association between sex and being connected to care ($\chi^2 = 7.534$, p=0.006). Males are less likely to be connected to care than female. No other variables showed a statistically significant difference between those connected to care and those not.

Table 2. Comparison of Characteristics for Primary Outcome				
		Connected to Care*	Not Connected to Care*	p-value**
Sex	Male	20 (51.3)	141 (73.4)	p=0.006
	Female	19 (49.7)	51 (26.6)	
Mean Age (yrs)		60.05 +/- 10.48	57.91 +/- 10.80	p=0.784
	Non-Black	22 (56.4)	130 (67.7)	p=0.175
Race	Black	17 (43.6)	62 (32.3)	
Time to Contact Post- Discharge (months)		6.97 +/- 3.19	6.70 +/- 2.88	p=0.187
Hospital Location	Community Hospitals	25 (64.1)	128 (66.7)	p=0.758
	Academic Medical Center	14 (35.9)	64 (33.3)	
Insurance Status	Insured	33 (84.6)	139 (72.4)	p=0.111
	Self-Pay	6 (15.4)	53 (27.6)	
County	Harris	32 (82.1)	141 (73.4)	p=0.258
County	Not Harris	7 (17.9)	51 (26.6)	
HIV Status	HIV (-)	36 (92.3)	187 (97.4)	p=0.113
The Status	HIV (+)	3 (7.37)	5 (2.6)	
Substance Use Disorder	No	31 (79.5)	139 (72.3)	p=0.360
	Yes	8 (20.5)	53 (27.7)	
Mental, Behavioral, or	No	19 (48.7)	88 (45.8)	p=0.742
Neurodevelopmental Disorder	Yes	20 (51.2)	104 (54.2)	
	*Actual frequency (percent) **p-value for Chi Square Test of Independence for categorical variable and t-test for continuous variables Mean age: calculated at the time of first call attempt to the patient Time to Contact Post-Discharge: calculated from the discharge date to the first call attempt Community Hospitals: includes Memorial Hermann Pearland (8), Memorial Hermann Cypress (7), Memorial Hermann Greater Heights (24), Memorial Hermann The Woodlands (6), Memorial Hermann Memorial City (14), Memorial Hermann Northeast (15), Memorial Hermann Katy (6), Memorial Hermann Sugar Land (2), Memorial Hermann Southwest (33), Memorial Hermann Southeast (38) Insurance Status: "Insured" includes patients on Medicaid alone (58), Medicare (67), dual Medicare/ Medicaid enrollees (28), and commercial (19) County: Includes Brazoria (9), Chambers (1), Fort Bend (14), Galveston (7), Liberty (3), Montgomery (9), Waller (1), and other counties non-contiguous to Harris (14)			

A stepwise binomial logistic regression was conducted to determine if there was a statistically significant variable independently associated with patients not already connected to care (see Table 3). Sex was the only significant variable, demonstrating that males are 2.6 times more likely to not be connected to care after a positive hepatitis C test in the inpatient setting.

Table 3. Stepwise Binomial Regression for Primary Outcome			
	Odds Ratio (Expβ)	p-value	95% Confidence Interval
Malea	2.626	0.007	(1.298, 5.315)
a. As compared to Female for not being connected to care			

Secondary Outcome

The pharmacy technician reached 35 patients that were not previously connected to care. Of those patients, 24 (68.6%) were able to be connected to care. Each patient characteristic was tested for a significant relationship for connection to care after technician intervention (see Table 4). There was a statistically significant association between insurance status and being connected to care (Fisher's Exact Test, p=0.004). Additionally the patients who were more likely to be connected to care were contacted in average 1.092 months later (6.38 +/- 2.98) compared to those who did not get connected to care (5.27 +/- 2.24 months) (t(33)=-1.092, p=0.029). After technician intervention, there was not a significant relationship between sex and connection to care, indicating that the reaching out to patient impacts the differences in connection to care between males and females as seen prior to the intervention.

Table 4. Comparison of Characteristics for Secondary Outcome				
		Assisted in Connecting	Unable to Assist in	p-value**
		to Care*	Connecting to Care*	
Sex	Male	19 (79.2)	7 (63.6)	p=0.416
	Female	5 (14.7)	4 (36.4)	
Mean Age (yrs)		59.17 +/- 9.87	54.91 +/- 10.53	p=0.714
Race	Non-Black	15 (62.5)	9 (81.8)	p=0.435
Nace	Black	9 (37.5)	2 (18.2)	
Time to Contact Post- Discharge (months)		6.38 +/- 2.98	5.27 +/- 2.24	p=0.029
	Community Hospitals	14 (58.3)	7 (63.6)	p=1.000
Hospital Location	Academic Medical Center	10 (41.7)	4 (36.4)	
Insurance Status	Insured	21 (87.5)	4 (36.4)	p=0.004
	Self-Pay	3 (12.5)	7 (63.6)	
County	Harris	17 (70.8)	6 (54.5)	p=0.451
	Not Harris	7 (29.2)	5 (45.5)	
HIV Status	HIV (-)	23 (95.8)	11 (100)	p=1.000
THV Status	HIV (+)	1 (4.2)	0 (0)	
Substance Use Disorder	No	17 (65.4)	9 (34.6)	p=0.685
	Yes	7 (77.8)	2 (22.2)	
Mental, Behavioral, or	No	12 (50.0)	4 (36.4)	p=0.493
Neurodevelopmental Disorder	Yes	12 (50.0)	7 (63.6)	
	*Actual frequency (percent) **p-value for Fisher's Exact Test for Sex, Ethnic Group, Language, Hospital Location, Insurance Status, County, HIV Status, Substance Use Disorder, and Mental, Behavioral, or Neurodevelopmental Disorder; Chi Square Test of Independence for Race, and t-test for continuous variables Mean age: calculated at the time of first call attempt to the patient Time to Contact Post-Discharge: calculated from the discharge date to the first call attempt Community Hospitals: includes Memorial Hermann Pearland (2), Memorial Hermann Cypress (1), Memorial Hermann Greater Heights (4), Memorial Hermann The Woodlands (1), Memorial Hermann Memorial City (1), Memorial Hermann Northeast (2), Memorial Hermann Southwest (3), Memorial Hermann Southeast (7) Insurance Status: "Insured" includes patients on Medicaid alone (11), Medicare (7), and dual Medicare/ Medicaid enrollees (5), or with Commercial Insurance (2) County: Includes Brazoria (3), Chambers (1), Fort Bend (1), Galveston (3), Montgomery (1), and other counties non-contiguous to Harris (2)			

A stepwise binomial logistic regression was completed again for the secondary outcome to determine if there was a statistically significant variable associated with patients not getting connected to care. Of the independent variables only insurance status was independently associated. Self-pay patients were 12.2 times more likely to not get connected to care when contacted by the pharmacy technician.

Table 5. Stepwise Binomial Regression for Secondary Outcome			
	Odds Ratio (Expβ)	p-value	95% Confidence Interval
Insureda	0.082	0.004	(0.015, 0.458)
a. As compared to Uninsured for not being connected to care			

The geographic distribution of patients connected to care after the technician intervention are shown below in Figure 4. Patients who were connected to care tended to be more in the Greater Houston area as compared to those not. Additionally, patients connected to care appeared to have come from counties with more patients not connected to care initially.

IV. Discussion

The overall comparison of the proportion of patients connected to care without the intervention of the pharmacy technician and those with the intervention of the pharmacy technician echoes what other studies have shown — a dedicated resource to care coordination for hepatitis C leads to more patients receiving care. This is the first study of using a pharmacy technician as a care coordinator for this patient population. The ability of the technician to help a higher proportion of patients than not once contacted demonstrates that they have the skills to perform in this role.

Various challenges existed with reaching the patients. Some reasons patients were not able to be contacted include phone number being disconnected, patient deceased prior to contacting, or patient no longer living in the residence. In one case, a sibling stated that the patient had been missing for several

months, and the family could not contact them. This patient had struggled with drug use, and the family did not know where they could be.

The geographic groupings of the patient groups highlight the disproportionate impact on hepatitis C on lower income communities. Per Kinder Institute for Urban Research at Rice University, most of the most distressed zip codes in Harris County lie to the south, east, and west of downtown. Figure 3 clearly shows that patients lacking follow-up tended to be concentrated in that area. Additionally, the 4 zip codes with the highest concentrations of patients with a positive test for hepatitis - 77051, 77036, 77033, and 77017 – are all considered distressed zip codes. In fact, 77051 has the lowest median income. Still, the pharmacy technician connected patients to care from these distressed zip codes. These highlight the need to have continued focus in these lower income areas in connecting patients to care.

Sex was independently associated with connection to care. This relationship suggest that males are less likely to seek follow-up care for their hepatitis C after testing positive. However, there was no characteristic that seemed to suggest that a patient would be connected to care, indicating there is not a focused group of patients to not target for care coordination efforts.

The results of the secondary outcome showed that self-pay patients were less likely to be connected to care by the pharmacy technician. There were varying reasons for the pharmacy technician to be unable to connect these patients to care when they were reached. A couple of patients stated they had more severe health problems now they were struggling to pay for and did not want to pursue this diagnosis at this time. Three patients were not responsive to the calls and were very adamant they not be called again. Others cited transportation issues to get to care, which highlights a gap in our process that other models have previously had with ensuring all aspects of care could be provided more.^{4,5,7,8} Our pilot did not have the resources to support those services. Despite this, there were some uninsured patients connected to care. Per the report of the technician, multiple patients did not realize they realize they could receive care and treatment for their hepatitis C at an FQHC but were willing to take the information to work on scheduling an appointment.

Time to contact was also significantly longer in the group the technician assisted in connecting to care. This is an interesting contrast to previous studies that primarily focused on patients much more immediately compared to our retrospective model. This may indicate patients have had more resolution of acute issues and can now focus on this chronic disease state. More studies would have to be conducted with more patients to see if this continues to hold true.

Anecdotally, about 10 patients contacted by the pharmacy technician were unaware of their hepatitis C diagnosis, stating they had never been informed of their diagnosis. One patient expressed gratitude at being called as they had lost a sibling due to complications from hepatitis C and were glad they could get treatment now. Another patient was very distraught by the diagnosis, both over the time that it took to be contacted and feeling as though the diagnosis was an attack on his character. This patient was eventually grateful and connected for follow-up care. Cases like this highlight the importance of having some definitive way to not only test patients for hepatitis C to ensure early diagnosis but also ensure there is continuity of care for treatment.

Another consideration in this study is the potential impact of the ongoing COVID-19 pandemic. This may have impacted the study in multiple ways, including decreasing the number of patients to be studied and decreasing the likelihood of follow-up. A survey from the CDC published in September 2020 showed that an estimated 40.9% of patients avoided care, with 12.0% of those patients avoiding urgent or emergent

care.¹⁵ Given our selection criteria focused on the inpatient and emergency department settings, the sample size may have been smaller due to patients not seeking care in these settings. Additionally, for those who did seek care, there may have been a falsely high proportion of patients who did not seek follow-up care due to the ongoing pandemic. Given the timing of implementation, patients may have been more responsive to the technician to receive care as they felt more comfortable seeking care at the time rather than earlier in the pandemic.

Limitations

The primary limitation of this study is the small sample size of patients able to be analyzed. Of this small sample size, many patients not able to be contacted. Limitations in this study are that most of the data came from EMR, data relying on the accuracy of what was entered by others. For data analysis of patients that were unable to be contacted, it was assumed that the patient was not connected to care for their disease, which may have led to an overestimation of patients not connected to care. Although patient charts were reviewed to try to also determine connection to care, patients may have followed up for care outside of the health system, which is not readily reflected in the EMR. Additionally, researchers could only capture if a patient was referred for a follow up appointment but could not accurately capture if they attended the visit, particularly for those referred outside of the health system. In part, this is due to limited time passing since follow-up to care and not having definitive evidence for those connected outside of the system. The data also does not capture variations in testing practices for hepatitis C across the system as there is no system-wide standard criteria for testing patients.

V. Conclusions

In the setting of a non-closed, large health system with multiple sites, a centralized resource to facilitate care coordination efforts may be beneficial in increasing the number of patients connected to care for hepatitis C. Based on our results, male patients should have an increased focus on connecting to care and tools need to exist to connect self-pay patients to care. Furthermore, a pharmacy technician in the role of a care coordinator can successfully connect patients to care for hepatitis C.

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Patients with (+) HCV RNA Test in the emergency department or inpatient setting contacted by pharmacy technician Primary Outcome Subgroup 1: Patients already with follow-up scheduled as per EMR or patient report Subgroup 2: Patients who did not have follow-up scheduled when technician called OR Patients unable to be contacted by technician and no evidence of follow-up appointment in EMR

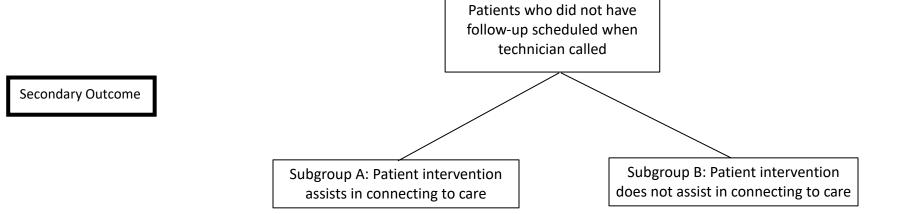


Figure 6. Technician Workflow

