DISTRIBUTION OF HEPATITIS C TESTING IN PHILADELPHIA, 2012-2014

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by
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ABSTRACT

Background: Hepatitis C virus (HCV) is a widespread problem in the United States, but the disease's low screening rates mean that reported cases account for only a fraction of the population's antibody prevalence. In reality, chronic HCV is the most common chronic blood-borne infection in the country. While newer infections may be completely asymptomatic, the virus can lead to serious complications in the liver down the line, including hepatic fibrosis, cirrhosis, and hepatocellular carcinoma (HCC). Because HCV is a reportable disease, the Philadelphia Department of Public Health (PDPH) hepatitis surveillance registry has records of all of the positive tests performed in the city. Negative test results are not readily available, however, making it difficult to create an accurate picture of who is being tested for HCV. Our study used negative results collected from reference laboratories throughout the city to fill in many of the gaps and determine which neighborhoods were not sufficiently screening at-risk populations.

Methods: Our dataset included approximately 100,000 individuals, a little over 90% of whom were HCV negative. Negative test results were obtained from Quest and Lab Corp, two of the major reference laboratories in the area that account for approximately 80% of all of the results of tests performed in Philadelphia. The screening data were then combined with records from the PDPH hepatitis surveillance registry. ArcGIS geographic information software was used to create maps out of neighborhood and census tract data, providing a visual representation of HCV screening distribution in Philadelphia. We also explored differences in demographic characteristics and testing facility information by

test result. The data included anyone in the past 2 years who had undergone an antibody (Ab) or RNA test for HCV.

Results: We found that census tract poverty rate was positively associated with HCV screening rate. Also, the majority of testing occurred in either hospital networks or private practices. There were significantly more males testing positive for HCV, despite the fact that many more females were tested overall. Similarly, the "baby boomer" age range (50-69) had the highest proportion of HCV positive test results, yet those aged 30-49 had the highest HCV testing rates.

Conclusions: Negative test results for reportable diseases are rarely utilized, but can be extremely useful in identifying problem areas and focusing testing resources. Because so many people with HCV go undiagnosed, it is especially important that populations requiring additional attention be recognized and screened.

I dedicate this work to

my family, who have always supported

me in everything I have wanted

to accomplish.

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CHAPTER 1

INTRODUCTION

Hepatitis C virus (HCV) is a widespread problem in the United States, but the disease's low screening rates mean that reported HCV cases account for only a fraction of the population's antibody prevalence. In reality, chronic HCV is the most prevalent blood-borne infection in the country.[1-3] The latest data from the National Health and Nutrition Examination Surveys (NHANES) estimates that there are about 4.1 million people with HCV in the U.S., but many believe this to be a very conservative number.[4] While newer infections may be primarily asymptomatic, chronic HCV infection can lead to serious complications in the liver, including hepatic fibrosis, cirrhosis, and hepatocellular carcinoma (HCC).[5] The highest burden of HCV often occurs in populations that are difficult to track, such as injection drug users (IDU), homeless, and prison inmates. Great strides have been made in HCV treatments in the last few years, but the fact remains that not nearly enough of the people infected are screened and brought to care.[6,7] The 2010 Institute of Medicine Report (IOM) on Hepatitis and Liver Cancer estimates that up to75% of people with HCV are undiagnosed.[8]

Since HCV is a reportable disease, the Philadelphia Department of Public Health (PDPH) hepatitis surveillance registry has records of all of the positive HCV tests performed in the city. However, negative test results are not readily available, making it difficult to create an accurate description of who is and is not being tested for HCV. To address this, PDPH requested all 2012-2014 HCV test results (positive and negative) from Quest and LabCorp, the two major reference laboratories responsible for conducting

approximately 80% of all HCV test results in Philadelphia. With this data, many of the knowledge gaps regarding HCV screening practices and demographics in Philadelphia can be filled. The primary objectives of this study were to: 1)identify Philadelphia neighborhoods where HCV screening rates are lowest and 2)test whether the neighborhoods with high or low screening rates differ by poverty level. The secondary objective was to estimate the impact of the Centers for Disease Control and Prevention (CDC)'s 2012 recommendation that all adults born between 1945 and 1965 (i.e. "baby boomers") receive HCV screening.[9] In aim two, we tested for a difference in screening rate before and after August of 2012. Lastly, differences in gender, age group, and testing facility type were also assessed for individuals testing HCV positive and negative. Since these data include the large majority of HCV tests run in Philadelphia, the findings create an accurate and comprehensive picture of differences in HCV screening practices and positivity. These results can inform future outreach efforts to funnel screening and treatment resources to areas that most require additional attention.

CHAPTER 2

REVIEW OF LITERATURE

Background

Hepatitis C is not only a significant public health problem, but a disease that is often overlooked. Despite having relatively limited funding for research, roughly five times as many individuals are infected with HCV than are infected with human immunodeficiency virus (HIV) in the United States.[10] Due to the low HCV screening rates, surveillance of the virus is extremely difficult. Estimates of HCV prevalence in the United States vary from between 2.7-3.9 million as noted from the CDC to 4.1 million from NHANES surveys.[4,9] One study claims that the number of HCV positive individuals may be as high as 5-7 million.[11] The general elusiveness of HCV is due to several factors.

First, many infected individuals can remain asymptomatic for decades.[5] HCV infection comes in two forms, acute and chronic. Roughly 20-30% of acute cases exhibit symptoms, including nausea, jaundice, abdominal pain, and fatigue. Even if left untreated, 15-25% of acute cases may spontaneously clear acute HCV for reasons that are still unclear. The remainder of cases progress to chronic HCV. Chronic HCV cases represent the vast majority of undiagnosed cases. Most people with chronic HCV do not exhibit symptoms for 20 to 30 years until significant liver damage, liver cancer, or liver failure have already occurred. Chronic HCV will lead to liver cirrhosis in about 20% of cases and is the leading risk factor for liver transplants in the United States.[5]

Another reason that HCV so often goes undiagnosed is the nature of the populations that are at highest risk of infection. Recipients of blood transfusions, children

of chronically-infected mothers, individuals infected with HIV, patients on long term hemodialysis, and those who received organ transplants before 1992 or clotting factor concentrates before 1987 are all considered high-risk for HCV.[10] However, the virus also often manifests at a higher rate among injection drug users, homeless people, prisoners, and the severely mentally ill.[12,10] In fact, more than one-half of all new cases of HCV can be attributed to IDU, with an HCV prevalence of up to 93% among long-term injection drug users.[11,13] Studies among incarcerated individuals found HCV prevalence rates ranging from 23.1% to 39.4%, and among homeless individuals the HCV prevalence ranges from 19% to 69.1%. In comparison, the HCV prevalence rate in the general U.S. population is about 1-2%.[11]

Concrete prevalence and incidence rates from HCV surveillance efforts often do not include the homeless and the institutionalized, so it is understandable that published HCV prevalence rates can be severe underestimates. Additionally, even when high-risk populations are successfully identified and included, they do not progress through the standard treatment and continuum of care. About 1.6 million HCV positive individuals in the U.S. have received an HCV antibody screening test, which is less than one-half of even the most conservative estimates of total HCV prevalence. Of those being screened, only 1-1.2 million are referred to care to receive a confirmatory RNA test or liver biopsy, and even less, 220,000-360,000, are treated.[14]

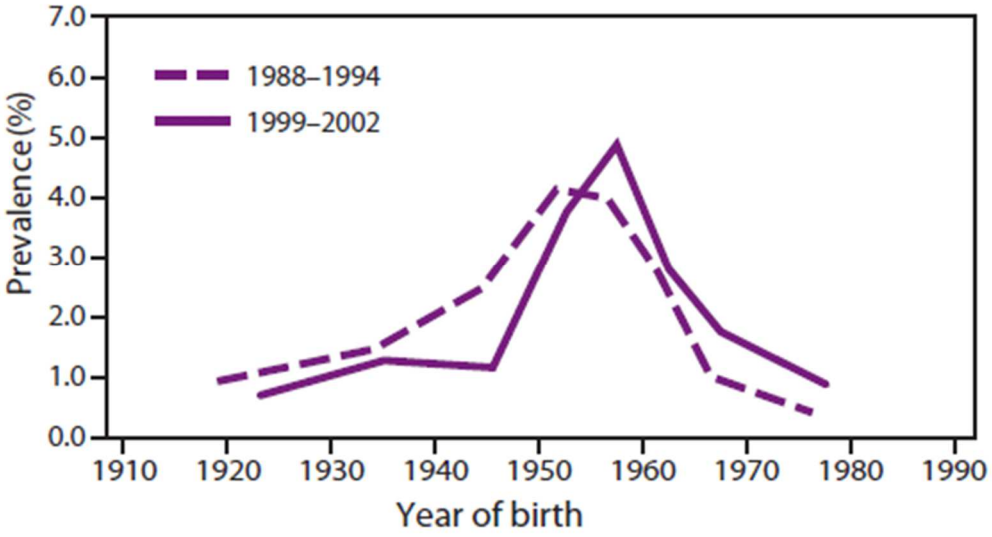
In the past, the CDC has recommended HCV testing for any individual who:

- Has injected drugs
- Received clotting factor concentrated before 1987

- Was on long-term dialysis
- Has abnormal alanine aminotransferase (ALT) levels
- Has HIV
- Received a blood transfusion or organ transplant before 1992[15]

The newest subpopulation that CDC recommends for HCV screening is individuals born between 1945 and 1965. These baby boomers, with an HCV antibody prevalence of about 3.25%, have risk factors and a distribution of HCV that is slightly different from those in younger populations. In the baby boomer population, men have twice the HCV infection rate of women, and non-Hispanic blacks have twice the HCV prevalence of non-Hispanic whites and Hispanics.[16] An extended birth cohort from 1945 to 1970, however, does not show these disparities.[16] Baby boomers are thought to have higher rates of HCV infection because they were at risk for receiving contaminated organs before 1992 or blood products before 1987 when routine HCV screening was implemented. This population will need special attention in the coming years, particularly once they reach an age when HCV complications begin to manifest in infected individuals. Thus, without treatment, higher hospitalization rates and prescription costs, along with higher rates of HCV-related mortality, are expected to occur. Figure 1 helps to demonstrate the extent of the hepatitis C problem among baby boomers.

Figure 1. Prevalence of hepatitis C virus antibody, by year of birth — National Health and Nutrition Examination Survey, United States, 1988–1994 and 1999–2002[9]



Studies have predicted that by the year 2030, hepatitis C-related end stage liver disease will reach all-time highs with an incidence of 38,600 cases per year.[17] The number of HCV-related deaths in the U.S. has already increased significantly in the last 10 years, exceeding the mortality rate of HIV. If HCV screening and treatment rates continue as they are, HCV-related mortality will continue to increase, peaking 36,000 deaths per year by 2030.[13,17]

Treatment

HCV treatment has been improving. In the recent past, HCV treatment could last for almost a year and involve debilitating side effects. Doctors have been recommending a combination treatment of the HCV protease inhibitors, boceprevir and telaprevir, along with peginterferon and ribavirin since 2002. Common reactions to this treatment include

flu-like symptoms, mood changes, rashes, chest pain, visual disturbances, thyroid dysfunction, hair loss, anemia, anorectal symptoms, thrombocytopenia, and neutropenia.[18] Depending on individual circumstances and response to the treatment, individuals must stay on these drugs for up to 48 weeks. In the last year, however, shorter, more effective treatments have become available. The combination of drugs simeprevir (Olysio) and sofosbuvir (Sovaldi), for example, result in viral clearance in up to 90% of individuals with the most common HCV virus genotype.[18] Now that new and effective treatments are reaching the market, this study's aim of identifying Philadelphia's screening needs is of particular importance. The more individuals that HCV testing efforts can identify, the more HCV positive individuals who can be treated and cured of their infection.

Specific Aims

The aims of this study were to:

1) Compare the poverty rates of Philadelphia census tracts with low and high HCV screening rates. We hypothesized that poverty rates will be higher in areas where HCV screening is low.
2) Compare HCV screening rates before and after the August 2012 CDC baby boomer HCV testing recommendation. We hypothesized that there will be an increase in HCV testing in the time period following the recommendation.
3) Assess demographic differences between individuals who test HCV negative and those who test HCV positive, as well as differences in the type of facility (hospital network, city health center, other health center, private practice, or other) in which

they were tested. We hypothesized that HCV positivity rates will differ by sex, age group and facility type.

CHAPTER 3

METHODS

Overview

This was a cross-sectional study using existing data from reference HCV lab records, the PDPH hepatitis surveillance registry, and the Philadelphia Census. Registry data was supplied by healthcare providers and laboratories as required by state and local guidelines on notifiable infectious disease reporting. Datasets from all sources were cleaned and merged together into one dataset using SAS statistical software. Individuals were included in the study if they received their first HCV antibody screening test or confirmatory RNA test during the study period, and were successfully geocoded by the ArcGIS mapping system. 118,494 observations were included in the analysis.

Study Variables

At the time of HCV testing, healthcare providers collect a variety of patient information. Individual-level study variables came from this data source, and census tract information came from Philadelphia census data. Variables used in this study include the following:

Individual Level Variables

- Gender

  - Male

- Female

- HCV Test Result

  - Positive

  - Negative

- Age Category

  - ≤ 19 years

  - 20-29 years

  - 30-49 years

  - 50-69 years

  - ≥ 70 years

- Facility Type

  - Hospital network

  - City health center

  - Other health center

  - Private practice

  - Other

Census Tract Level Variables

- Race

  - Percent White

  - Percent Black

  - Percent Asian

- Percent Hispanic
- Percent Other racial group

- Census Poverty Rate Category
  - ≤ 10% living in poverty
  - 11-30% living in poverty
  - ≥ 31% living in poverty

Individuals were considered HCV "positive" if they received at least one reactive HCV Ab or RNA test result. Individuals were defined as "negative" if all of their antibody or RNA tests were non-reactive for HCV. HCV screening rates were calculated by dividing the number of people tested per year by the total annual population in the Philadelphia census.

Analytic Method

SAS version 9.4 was used to conduct all of the analysis. For all statistical tests, individuals with missing data were excluded from the final analysis.

Specific Aim 1a:To map HCV testing rates in Philadelphia in order to visualize gaps in screening. Combined data from participating reference labs and the PDPH hepatitis surveillance registry were geocoded using ArcGIS mapping software. Population census data were added in order to provide a denominator for the screening rate calculations. Positivity rates were mapped by census tract using counts from the original merged

dataset. In order to examine HCV trends over time, changes in both positivity and overall screening rates from 2013 to 2014 were mapped.

Specific Aim 1b:To compare the poverty rates of Philadelphia census tracts with low and high HCV screening rates, poverty rates were analyzed as a categorical variable (≤10%, 11-30%, or ≥ 31% of the census tract living in poverty) and screening rates were assessed continuously. An ANOVA test was used to determine whether the calculated HCV screening rates varied between categories of poverty. A linear regression model was then created to assess the added impact of race on this relationship.

Specific Aim 2: To compare HCV screening rates before and after the August 2012 CDC baby boomer HCV testing recommendation. An ANOVA test was used to compare the averages of census tract screening rates from January 1 2012 to July 31 2012 and August 1 2012 to August 1 2013.

Specific Aim 3:To assess differences in gender, age, and testing facility type for individuals who tested HCV negative and those who tested HCV positive. This analysis included gender, age, and also the type of facility in which the individual received screening. Age was classified as a categorical variable, by ≤ 19 years, 20-29 year, 30-49 year, 50-69 years, and 70 + years. Facility type was a categorical variable, by hospital network, city health center, other health center, private practice, or other depending on what facility provided the HCV test. Significant differences in HCV positivity were assessed using Chi-square analysis. Logistic regression was used to create a model predicting HCV positivity by age and sex. Age category "20-29" was used as the reference for age and "female" was the reference for sex.

CHAPTER 4

RESULTS

As shown in the appendices, the maps revealed fascinating patterns in Philadelphia's HCV screening and positivity rates. The overall HCV screening rates (Appendix A) seem to be concentrated highest in the northern part of the city. The HCV screening rates decrease as they radiate out in a circular pattern from north Philadelphia. However, North Philadelphia is also the same part of the city that experienced decreases in HCV screening rates in the past year (Appendix C).

The HCV positivity rate map (Appendix B) does not have quite such a striking pattern, but still contains valuable information. Apart from a few stray census tracts, the highest rates of HCV positivity are concentrated in west Philadelphia. This is also the area where positivity rates have decreased in the past year, along with some places in north Philadelphia (Appendix D).

HCV screening rates differed significantly ($p = <.0001$) between each category of census tract poverty level. Census tracts with low levels of poverty had lower HCV screening rates (mean = 53.87 per 1000) compared to census tracts with a mid-range of poverty (mean = 69.87 per 1000). Census tracts with a mid-range level of poverty in turn had lower screening rates than census tracts with high poverty (mean = 99.67 per 1000). The box and whiskers plot shown in Figure 2 depicts a visual representation of these differences. Variance around HCV screening rates also seems to increase with increasing levels of poverty.

Figure 2. Variance in HCV screening rates by poverty rate category

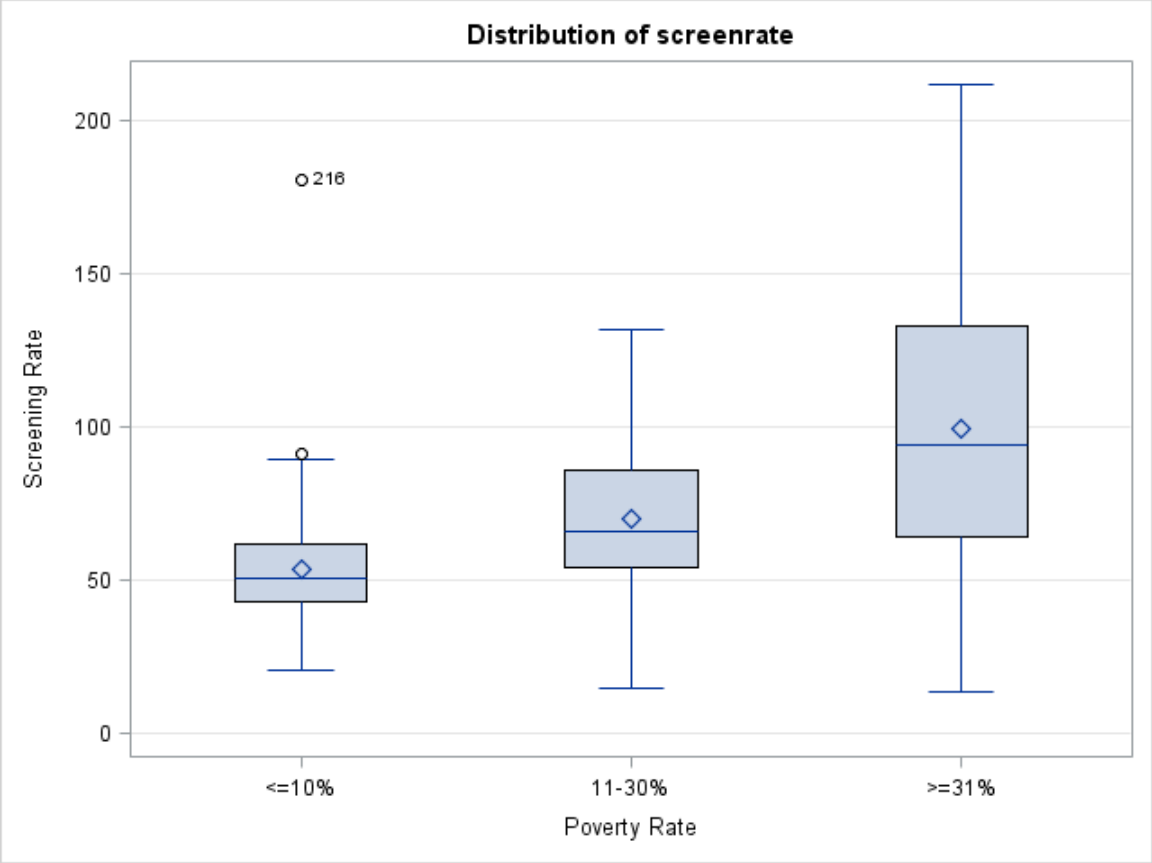


Table 1. Mean HCV screening rate by census tract poverty level category

Poverty Rate Category	N	Screening Rate	
		Mean	Std Dev
<=10%	61	53.867	22.153
11-30%	118	69.871	22.278
>=31%	81	99.675	44.257

Table 2. Analysis of variance (ANOVA) testing for significant difference of mean screening rate by poverty rate category

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	79622.6452	39811.3226	41.90	<.0001
Error	257	244210.6174	950.2359		
Corrected Total	259	323833.2626			

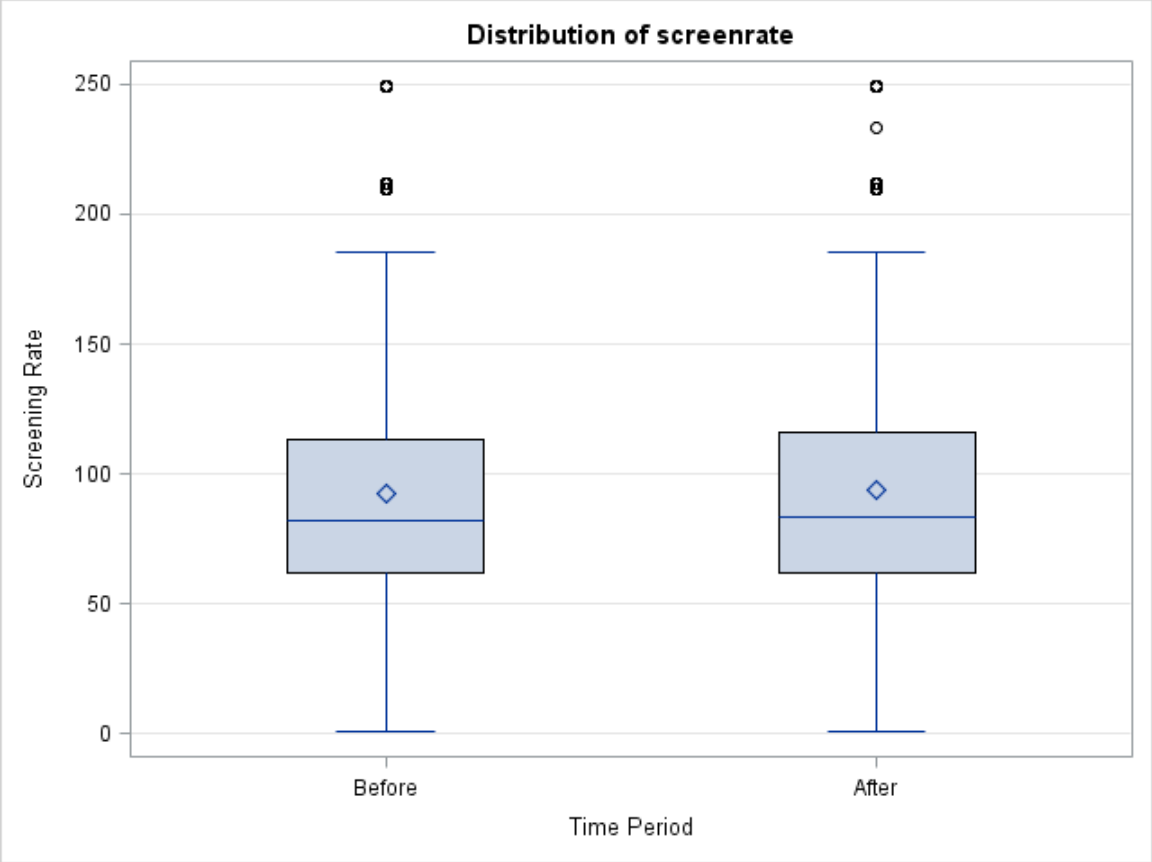
A linear regression model also revealed a significant, positive relationship between poverty rate and HCV screening rate (p = <.0001) even when race was added as a covariate using the proportion of non-white individuals by census tract population. This model had an adjusted R-square of 0.2921, meaning that 29% of the variance in screening rate is explained by poverty rate and race.

Table 3. Linear regression model for HCV screening rate by poverty category

Variable	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	1	38.11208	4.16134	9.16	<.0001
Poverty	1	14.64093	3.11426	4.70	<.0001
Race	1	32.87870	6.95798	4.73	<.0001

While HCV screening rates do not appear to have changed a large amount since August of 2012 (Figure 3), there was a significant increase in HCV testing in the year following the new screening guideline (p = <.0001). It is possible that the CDC's recommendation that all baby boomers be screened had a one-time impact on overall screening rates during that time period.

Figure 3. Variance in HCV screening rates before and after August of 2012



When comparing HCV positivity by individual-level demographic data, males tested positive for HCV significantly more often than females (p = <.0001) even though females appear be screened more often (Table 4). HCV positivity also differed significantly between age categories (p = <.0001). Nearly one-half of individuals who test positive for HCV were from the baby boomer age range of 50-69 (Table 5). 23.54% of individuals between 50-69 years tested for HCV were found to be HCV positive.

However, the age group 30-49 is the age group receiving the most HCV screening. Of all of the individuals screened for HCV, the vast majority were tested through either a hospital network or city health center (p = <.0001). Out of those receiving HCV positive results, almost one-half were tested through a hospital network (Table 6).

Table 4. Gender by HCV test result

Freq. **Row %** **Col. %**	**Result**	**Gender**		
		F	**M**	**Total**
	Negative	66304	35836	102140
		64.91	35.09	
		91.22	78.23	
	Positive	6379	9975	16354
		39.01	60.99	
		8.78	21.77	
	Total	72683	45811	118494

Table 5. Age category by HCV positive test result

Freq. **Row %** **Col. %**	**Result**	**Age Category**					
		<=19	**20-29**	**30-49**	**50-69**	**>=70**	**Total**
	Negative	8573	25101	37761	26320	4385	102140
		8.39	24.58	36.97	25.77	4.29	
		75.60	95.58	90.99	76.46	88.21	
	Positive	2767	1161	3738	8102	586	16354
		16.92	7.10	22.86	49.54	3.58	
		24.40	4.42	9.01	23.54	11.79	
	Total	11340	26262	41499	34422	4971	118494

Table 6. Facility type by HCV positive test result

Freq. Row % Col. %	Result	Facility Type						
		0	**1**	**2**	**3**	**4**	**9**	**Total**
	Negative	34853	37422	212	9670	19412	571	102140
		34.12	36.64	0.21	9.47	19.01	0.56	
		82.45	92.76	63.10	98.02	96.04	10.45	
	Positive	7419	2922	124	195	800	4894	16354
		45.37	17.87	0.76	1.19	4.89	29.93	
		17.55	7.24	36.90	1.98	3.96	89.55	
	Total	42272	40344	336	9865	20212	5465	118494

0 =Hospital network
1 = City health center
2 = Other health center
3 = Private practice
4 = Other
9 = Unknown

The logistic regression model predicting HCV positivity by sex and age category found that gender and age group remained significant in the model (Table 7). Males were 2.39 times more likely to test HCV positive than females (p = <.0001, 95% CI [2.305-2.483]. In addition, the model clearly elucidated the age categories with the highest HCV burden. Individuals age 30-39 tested HCV positive 1.92 times more often than those 20-29 (p = <.0001, 95% CI [1.796-2.058]), individuals aged 70+ tested HCV positive 2.50 times more often (p = <.0001, 95% CI [2.247-2.774]), and age 50-69 tested HCV positive 5.59 times more often (p = <.0001, 95% CI [5.239-5.962].

Table 7. Logistic regression model of gender and age category

Parameter		OR	95% Confidence Interval	
			Lower	Upper
Gender	M	2.393	2.305	2.483
Age	<=19	0.403	0.342	0.475
Age	30-49	1.923	1.796	2.058
Age	50-69	5.589	5.239	5.962
Age	>=70	2.497	2.247	2.774

CHAPTER 5

DISCUSSION

Many of the results of this study were surprising. The ArcGIS maps revealed that even though HCV screening rates seems to be concentrated in North Philadelphia, HCV positivity looks to be highest in West Philadelphia. This is possibly because individuals in North Philadelphia are living in close proximity to several large testing centers and seeking HCV screening is more convenient. If this is true, these maps may illustrate a need for more HCV testing facilities or screening outreach in West Philadelphia, where HCV screening needs do not appear to be sufficiently met. Comparing the maps in appendices A and B to the maps in appendices C and D raised additional questions. Even though West Philadelphia as shown in map B has the highest HCV positivity, map D showed that HCV positivity has been decreasing in West Philadelphia in the past year. Even more strange, the areas with the highest screening rates as shown in map A were the same areas where HCV screening has been decreasing in the past year. This may indicate that there was a push for HCV screening sometime in the past few years and now screening has tapered off. Perhaps this was because of the CDC's baby boomer screening recommendations in 2012 which seem to have had an immediate but not lasting influence on screening rates. Another possibility is that this difference is due to the limitations of HCV screening reporting. Some sites may have reported tests more reliably in 2012 or 2013, but dropped off in 2014. Other sites may have also ceased reporting patient addresses in recent years, which would have excluded individuals from this study.

HCV screening rate were related to census tract poverty rate, but in a way opposite than was expected. Screening rates were higher in areas of higher poverty, potentially meaning that screening outreach efforts in this population has been effective. The majority of efforts are most likely aimed toward the individuals living in the poorest areas of the city.

There was a significant increase in HCV screening in the year following the CDC baby boomer guideline announcement compared to the 7 months before the guideline was released. However, this may be a coincidence and is not necessarily attributable to the guideline itself. Furthermore, this was a measure of screening rates for all ages, not just individuals aged 50-69. The CDC announcement may have triggered an increase in overall HCV screening awareness and been responsible for the higher rates, but the trend may have also been due to another event or HCV screening outreach effort.

The analysis of predicting HCV positivity identified several risk groups in need of more screening efforts. For both gender and age category, the populations with the highest HCV positivity rates were not the individuals with higher screening rates. It is clear from past research that individuals who are age 50-69 have the highest burden of disease, and special attention needs to be given to this high risk age group. The CDC's screening recommendation was the first step, but providers need to be following this updated HCV screening guideline. It was also expected that males would be testing positive for HCV more often than females, but it is not clear why females have higher HCV screening rates than males. HCV testing for pregnant women is not currently recommended by the CDC, so that could not be the explanation.[19] Perhaps more HCV outreach efforts currently are directed more toward women, or perhaps outreach efforts

are just more effective in targeting and reaching women. The information that we gathered about HCV testing facility types, and the fact that hospitals and city health centers are reaching the most amount of people, can further direct future screening efforts toward greater efficiency.

There are several limitations in this study that need to be recognized. Primarily, we were only able to include individuals who had address information in the original datasets. Because much of the analysis was categorized by census tract, this information was necessary to determine the areas where individuals lived before the data were de-identified. Another potential problem is that data from negative HCV test results came from only two reference laboratories. While they account for a large proportion of testing in Philadelphia, smaller screening facilities are still not being included in our analysis. Lastly, because geocoding was performed using patient address instead of provider address, those who gave the address of a treatment or correctional facility were also excluded from the analysis. This may reduce the number of homeless people and inmates included in the study sample.

CHAPTER 6

CONCLUSION

To summarize, this study measured the current state of HCV screening and positivity in Philadelphia and came to three main conclusions. First, poverty rate is positively related to HCV screening rate. Second, an increase in HCV screening occurred in the year after the CDC's HCV screening guideline for baby boomers. Third, certain demographics are related to HCV positivity, and these groups may still not be targeted sufficiently for HCV screening efforts. Despite the limitations previously described, these results should show an accurate estimate of HCV distribution in Philadelphia.

Future research efforts should continue to include all HCV screening test results when conducting analysis or reporting descriptive data, not only positive HCV test results. While negative HCV test results are more difficult to acquire, it is important for disease surveillance to avoid leaving gaps in this assessment. Continuing to collect information on individuals who screen negative for HCV may reveal important trends over time and increase efficiency of public health resource allocation toward populations in the most need.

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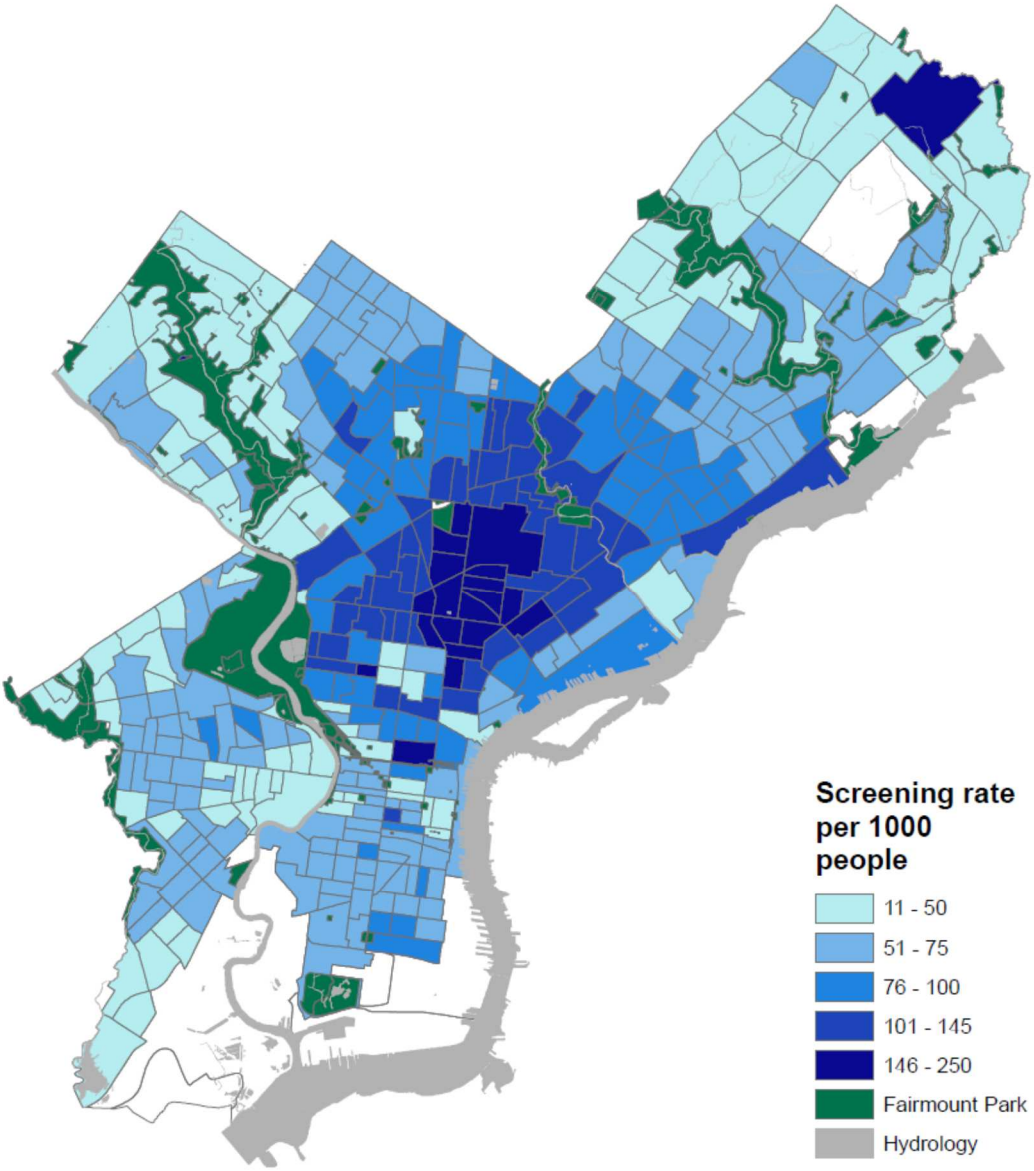
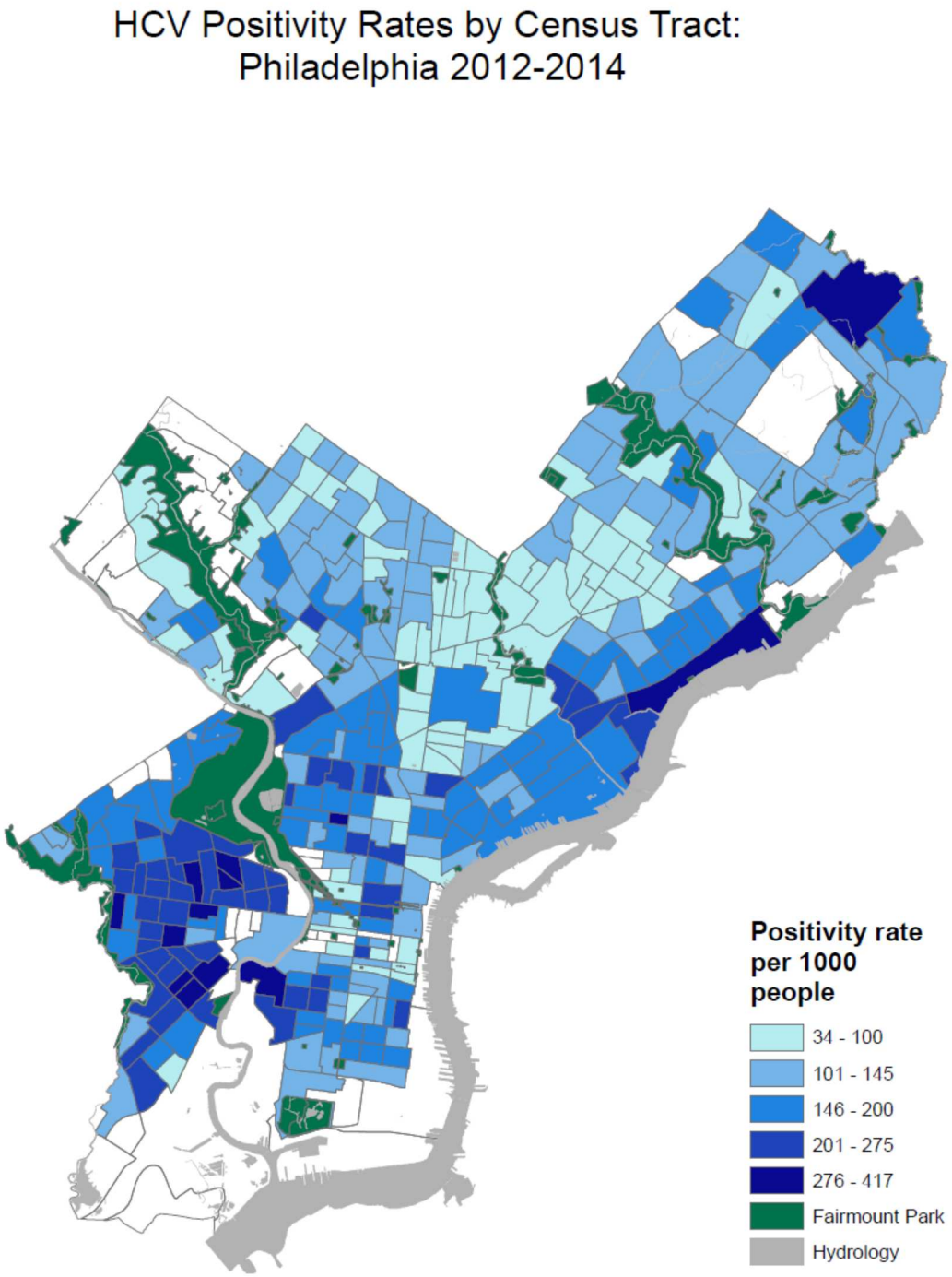
APPENDIX A

MAP OF CENSUS TRACT SCREENING RATES



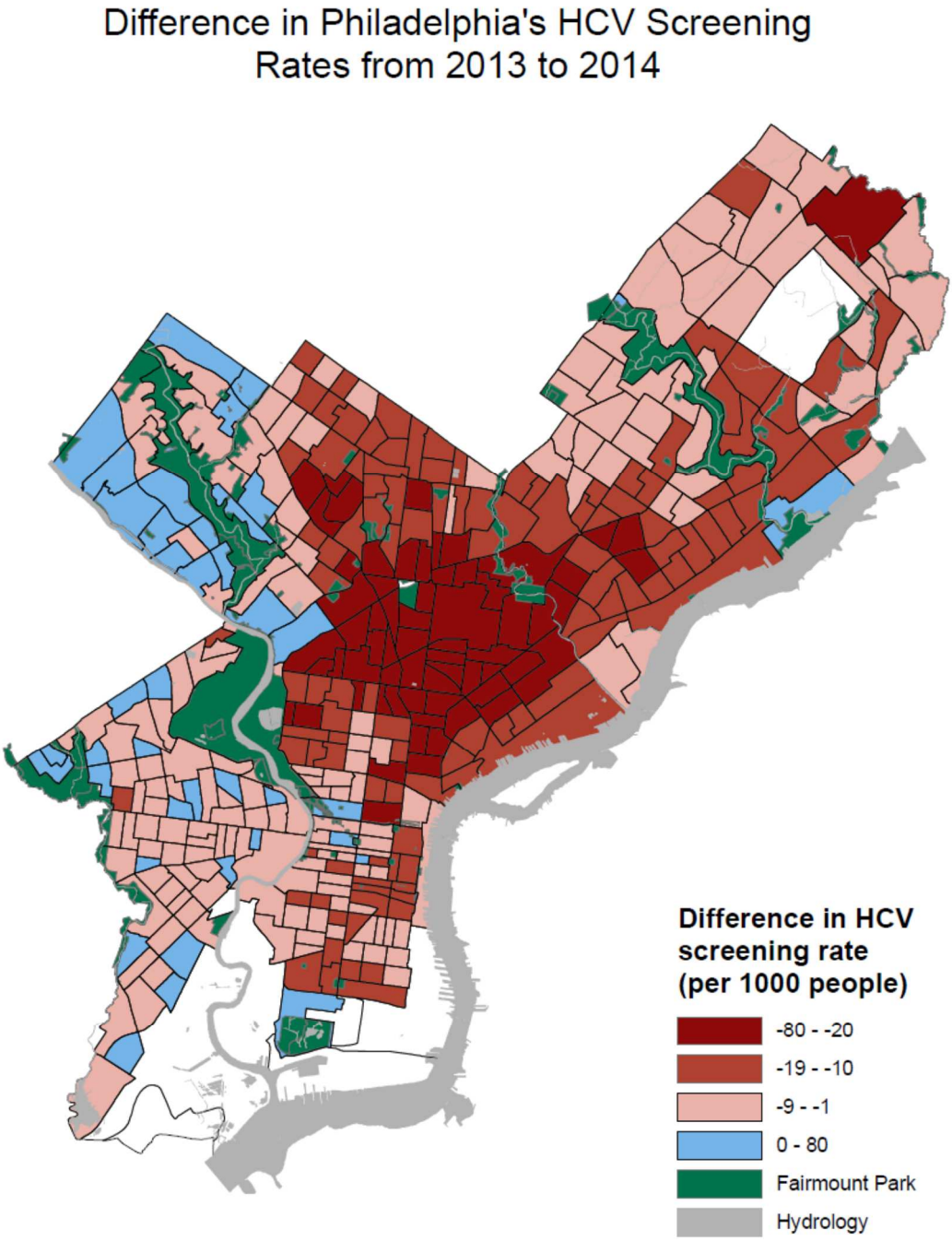
APPENDIX B

MAP OF CENSUS TRACT POSITIVITY RATES



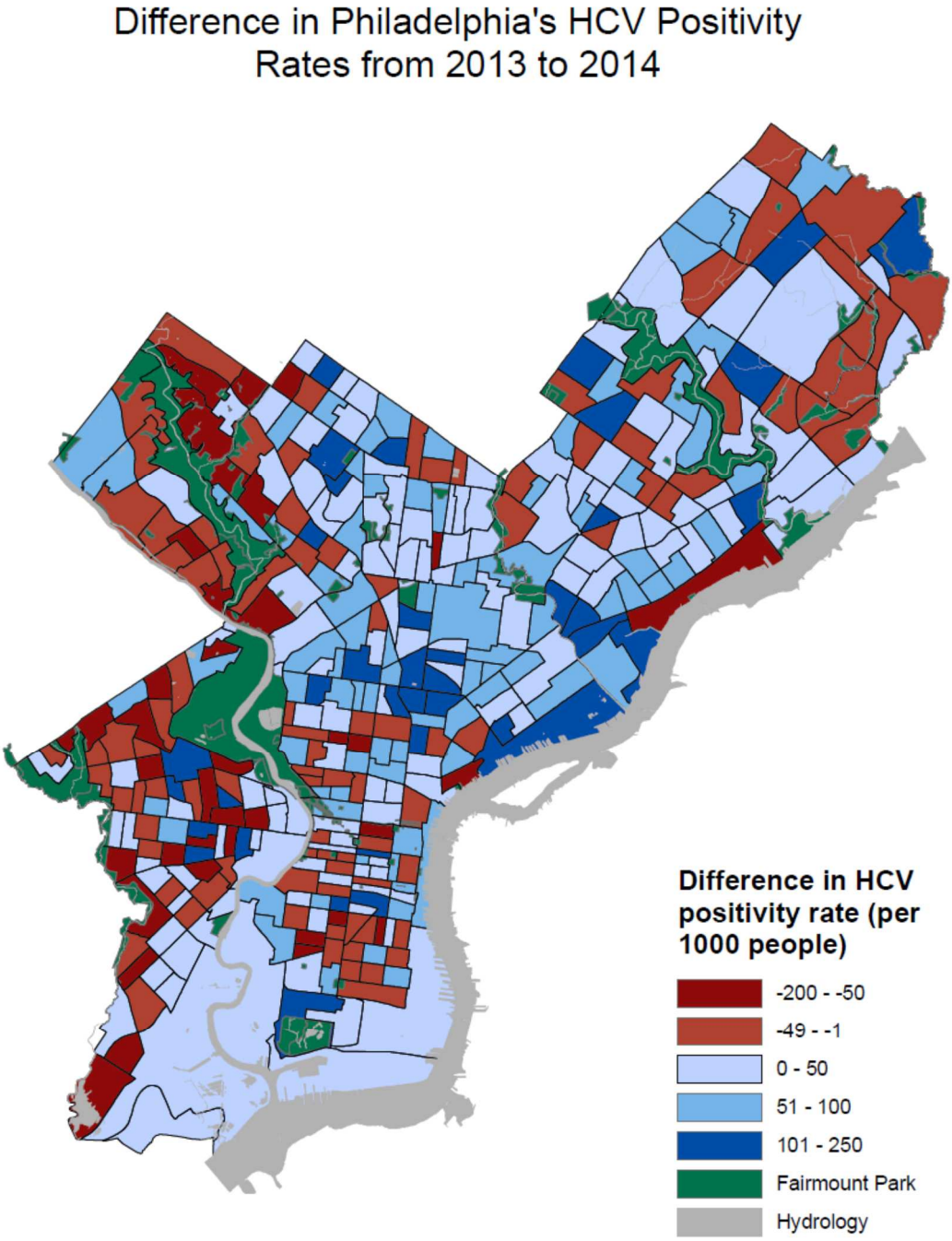
APPENDIX C

MAP OF DIFFERENCES IN SCREENING RATES FROM 2013-2014



APPENDIX D

MAP OF DIFFERENCES IN POSITIVITY RATES FROM 2013-2014



APPENDIX E

HUMAN RESEARCH TRAINING COMPLETION REPORT

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)

HUMAN RESEARCH CURRICULUM COMPLETION REPORT

Printed on 11/05/2013

LEARNER	Rachel Corrado (ID: 3856415)
PHONE	4848835819
EMAIL	tuf33013@temple.edu
INSTITUTION	Temple University
EXPIRATION DATE	11/05/2015

SOCIAL/BEHAVIORAL RESEARCH COURSE : Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.

COURSE/STAGE:	Refresher Course/2
PASSED ON:	11/05/2013
REFERENCE ID:	11695329

REQUIRED MODULES	DATE COMPLETED	SCORE
Temple University	11/05/13	No Quiz
SBE Refresher 1 – Defining Research with Human Subjects	11/05/13	2/2 (100%)
SBE Refresher 1 – Privacy and Confidentiality	11/05/13	2/2 (100%)
SBE Refresher 1 – Assessing Risk	11/05/13	2/2 (100%)
SBE Refresher 1 – Research with Children	11/05/13	2/2 (100%)
SBE Refresher 1 – International Research	11/05/13	2/2 (100%)
SBE Refresher 1 – History and Ethical Principles	11/05/13	2/2 (100%)
SBE Refresher 1 – Federal Regulations for Protecting Research Subjects	11/05/13	2/2 (100%)
SBE Refresher 1 – Informed Consent	11/05/13	2/2 (100%)
SBE Refresher 1 – Research with Prisoners	11/05/13	2/2 (100%)
SBE Refresher 1 – Research in Educational Settings	11/05/13	2/2 (100%)
SBE Refresher 1 – Instructions	11/05/13	No Quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI Program participating institution or be a paid Independent Learner. Falsified information and unauthorized use of the CITI Progam course site is unethical, and may be considered research misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Program Course Coordinator

APPENDIX F

PRACTICE RUNS TRAINING COMPLETION REPORT

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Rachel Corrado (ID: 3856415)
- **Email:** tuf33013@temple.edu
- **Institution Affiliation:** Temple University (ID: 926)
- **Phone:** 4848835819

- **Curriculum Group:** Human Research
- **Course Learner Group:** Practice Runs Training
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 15341815
- **Completion Date:** 02/18/2015
- **Expiration Date:** 02/18/2016
- **Minimum Passing:** 100
- **Reported Score*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Practice Runs Training	02/18/15	2/2 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

APPENDIX G

TEMPLE UNIVERSITY IRB APPROVAL LETTER

TEMPLE UNIVERSITY
Office of the Vice Provost for Research

Research Integrity & Compliance
Student Faculty Center
3340 N. Broad Street, Suite 304
Philadelphia PA 19140

Institutional Review Board
Phone: (215) 707-3390
Fax: (215) 707-9100
e-mail: irb@temple.edu

Certification of Approval for a Project Involving Human Subjects

Date: 24-Feb-2015

Protocol Number:	22770
PI:	NELSON, DEBORAH B
Review Type:	EXEMPT
Approved On:	24-Feb-2015
Approved From:	
Approved To:	
Committee:	B BEHAVIORAL AND SOCIAL SCIENCES
School/College:	HEALTH PROFESSIONS (0900)
Department:	CHP:PUBLIC HEALTH (09100)
Sponsor:	NO EXTERNAL SPONSOR
Project Title:	Distribution of Hepatitis C Testing in Philadelphia, 2012-2014

The IRB approved the protocol 22770.

If the study was approved under expedited or full board review, the approval period can be found above. Otherwise, the study was deemed exempt and does not have an IRB approval period.

If applicable to your study, you can access your IRB-approved, stamped consent document or consent script through eRA. **Open the Attachments tab and open the stamped documents by clicking the View icon next to each document**. The stamped documents are labeled as such.

Before an approval period ends, you must submit the Continuing Review form via the eRA module. Please note that though an item is submitted in eRA, it is not received in the IRB office until the principal investigator approves it. Consequently, please submit the Continuing Review form via the eRA module at least 60 days, and preferably 90 days, before the study's expiration date.

Note that all applicable Institutional approvals must also be secured before study implementation. These approvals include, but are not limited to, Medical Radiation Committee ("MRC"); Radiation Safety Committee ("RSC"); Institutional Biosafety Committee ("IBC"); and Temple University Survey Coordinating Committee ("TUSCC"). Please visit these Committees' websites for further information.

Finally, in conducting this research, you are obligated to submit modification requests for all changes to any study; reportable new information using the Reportable New Information form; and renewal and closure forms. For the complete list of investigator responsibilities, please see the Policies and Procedures, the Investigator Manual, and other requirements found on the Temple University IRB website: http://www.temple.edu/research/regaffairs/irb/index.html

Please contact the IRB at (215) 707-3390 if you have any questions

APPENDIX H

CITY OF PHILADELPHIA IRB APPROVAL LETTER

CITY OF PHILADELPHIA

DEPARTMENT OF PUBLIC HEALTH
INSTITUTIONAL REVIEW BOARD
HEALTH CENTER #5
1900 N 20th Street
Philadelphia, PA 19121
(215) 685-7630
FAX (215) 685-0867
http://www.phila.gov/health/Commissioner/IRB.html

James W. Buehler, MD
Health Commissioner

S. Gulino, MD
Chairperson

Judith Samans-Dunn, MSIA, CIP
Administrator

September 30, 2014

Rachel Corrado
13 Ridgewood Road
Malvern, PA 19355

RE: 2014-38 Distribution of Hepatitis C Testing in Philadelphia, 2012-2014

Dear Ms. Corrado:

The above noted proposed protocol has been determined to be exempt from Institutional Review Board review based upon the following Federal Regulation:

45 CFR 46 PROTECTION OF HUMAN SUBJECTS
Section 101 (b): Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy.

> Subsections (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects
>
> And
>
> (5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
> (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

NOTE: This study will require approval from the Health Commissioner's Office Review Committee.

Should any changes in the procedure be desired, they must be submitted to the IRB in advance in writing. I can be reached at 215-685-7630 or through e-mail at Judith.SamansDunn@Phila.Gov if you have any questions.

Sincerely,

Judith Samans-Dunn, MSIA, CIP
Administrator

CC: Correspondence file
2014-38
S. Gulino, MD
K. Viner
C. Johnson, MD