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Evaluating Hepatitis C Screening in Primary Care

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Final DNP Project Report

Evaluating Hepatitis C Screening in Primary Care

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Dedication

My DNP Practice Improvement Project is dedicated to all patients who benefit from recommended screenings in the primary care setting. As a result of this project, I have a heightened awareness for various screening needs and the understanding that primary providers must be the catalyst to ensure patients receive recommended screenings.

EVALUATING HEPATITIS C SCREENING IN PRIMARY CARE

Acknowledgements

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My family is owed overwhelming appreciation for supporting me throughout the past three years. Your patience, understanding, and love are treasured.

EVALUATING HEPATITIS C SCREENING IN PRIMARY CARE

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Abstract

Purpose: The purpose of this study was to evaluate primary care provider screening for hepatitis C virus (HCV) in three high risk populations. The specific aims were to determine the percentage of patients born between 1945-1965 who had a one-time screening for HCV, to determine what proportion of patients with a history of human immunodeficiency virus (HIV) or intravenous drug use (IVDU) have been screened for HCV, and to examine providers' thoughts on their HCV screening practices.

Methods: A retrospective chart review of patient electronic medical records (EMR's) from 2015 was conducted in an urban primary care site. SPSS was used to analyze the data. A provider survey was conducted to assess comfort, familiarity, and adherence with screening recommendations.

Results: The sample demographics were very similar to the total population of the practice. Of the birth cohort, it was determined that 6.1% were screened per the USPSTF recommendations. The HIV positive and IVDU groups were very small and either were not screened at all or were screened by a specialist. Of the individuals screened, 16.7% were positive for HCV. The provider survey demonstrated belief that screenings were done per recommendations. Barriers to screening according to the recommended guidelines included coding and insurance denials for screenings. The provider survey suggested acknowledged an EMR trigger would assist in prompting more screenings.

Conclusion: The study demonstrates there is opportunity to improve screening rates of the birth cohort. There is insufficient evidence to determine if there are gaps in screening HIV and IVDU. Future studies should focus on additional high risk groups with larger sample sizes.

Keywords: HCV, screening, recommendations

Evaluating Hepatitis C Screening in Primary Care

Introduction

The World Health Organization (2014) estimates that over 180 million people worldwide have been infected with the hepatitis C virus (HCV). The disease is the most common blood-borne infection in the United States (U.S.; Armstrong et al., 2006). Affecting approximately 2.7-3.9 million Americans, HCV represents 1.8% of the population (Centers for Disease Control and Prevention [CDC], 2014). Further estimates suggest that two-thirds of all HCV infections are found in individuals born between the years of 1945-1965 (Institute of Medicine [IOM], 2010). These persons have been given the description the "birth cohort" by researchers who have recognized the significance of the disease burden facing this population. The CDC (2013) and the United States Preventative Services Task Force (USPSTF; 2013) recognize the heightened risk facing the birth cohort and have both issued moderate to strong recommendations for providers to perform a one-time antibody screening to assist in identification of HCV. These recommendations were born of the realization that HCV can go for decades without producing obvious signs of illness, yet it can silently cause irreversible liver damage. Further, research has demonstrated up to 75% of those infected were unaware of their disease state (Southern et al., 2011).

Chronic HCV results in a slow progressive inflammatory response causing liver fibrosis and hepatic infrastructure deterioration. As fibrosis worsens, the patient becomes at risk for cirrhosis, hepatocellular carcinoma and a host of hepatic related complications that may take decades to evolve (CDC, 2012). HCV leads to a number of chronic health conditions, unexpected medical costs, disability, decline in quality of life, and in many cases death (USPSTF, 2013). HCV was estimated to generate U.S. healthcare costs in excess of $6.5 billion

in 2012, with further estimates that the burden of cost will peak in the year 2024 at an annual

$9.1 billion dollars (Razavi et al., 2013). Over the past decade, use of direct acting antivirals has

produced strong evidence that morbidity and mortality associated with HCV can be controlled

(Thomas, 2013). Successful treatment leading to a sustained virological response (SVR), has

recently gained significant strides in clearing the host of the virus entirely. Lack of knowledge

of infection status is the number one impediment to reduced transmission and treatment of HCV.

The CDC model of risk-based screening estimated that the U.S. birth cohort testing would reveal

over a million new cases of chronic HCV, opening the opportunity to treat the disease, improve

quality of life, reduce deaths, and lower the costs associated with the virus (Rein et al., 2011).

Despite the evidence-based guidelines released by the American Association for the

Study of Liver Diseases (AASLD) in conjunction with the Infectious Diseases Society of

America (IDSA; 2014) and supported by recommendations from the CDC and USPSTF, recent

studies show that primary care providers have low efficacy in HCV cohort screening rates

(Southern et al., 2011). A study performed in New York City assessed the screening practices of

three large primary care clinics and found an overall adherence rate of 36.1%. Another five-year

screening study, observing primary care providers in Maryland, Virginia, and the District of

Columbia, found the high risk birth cohort were screened at a rate of 14.4% (Linas, Hu, Barter,

& Horberg, 2014).

The CDC (2013) reported that the state of Kentucky's statistics for new cases of HCV

increased by 357% between the years of 2007 and 2011 and in 2013 the state had the largest

number of new HCV cases in the nation (CDC, 2013). One leading health system (2015) is a

prominent provider of inpatient and outpatient health services serving a large portion of

Kentucky and the surrounding areas. The primary care medical group focuses on preventative

medicine with an emphasis on maintaining wellness. Primary care providers had over 480,000 outpatient encounters in 2015 (Norton Healthcare Report to Our Community, 2015).

Objectives

Purpose of the Project

Taking into account the background and importance of HCV screening practices for identification and treatment of active disease, a retrospective study was planned to examine screening of the birth cohort and other high risk groups in one of the health systems primary care practices. The aim of the study was to evaluate primary care provider screening practices and survey providers' perceptions of HCV testing related to compliance with current recommendations.

Clinical Questions

In a primary care setting, do providers follow the recommendations established by the CDC and USPSTF for HCV screening in high risk groups? Do certain high risk factors determine if HCV screening is considered with any higher degree of frequency? Do providers ask questions that would determine high risk status? Do providers feel that there are barriers in HCV screening? Do providers believe an electronic medical record (EMR) trigger would improve their ability to screen the birth cohort? If providers note high risk behavior, do they document having done so in the EMR?

Literature Review

The birth cohort is currently experiencing an increase in HCV associated mortality and morbidity (Ward, 2013). As the birth cohort ages, if they are unaware of their infection status and the disease is allowed to silently evolve, they will begin to suffer irreversible and devastating health effects from liver fibrosis (Ly et al., 2012). The CDC, USPSTF, IDSA, AASLD, and the

American College of Gastroenterology (ACG) have all recommended additional risk based HCV screenings. The recommendations include screening anyone with a history of using intravenous drugs (IVDU), as well as anyone who has received clotting factor concentrates produced before 1987, had a consistently elevated alanine aminotransferase (ALT), received blood transfusion or organ transplant prior to 1992, infected with human immunodeficiency virus (HIV), received long-term dialysis, or received a blood transfusion from someone who later tested positive for HCV (Afdhal et al., 2013). The recommendations also include screening men who have sex with men (MSM), children born to HCV positive mothers, and anyone with known exposure to needle sticks, sharps, or mucosal contact with HCV-positive blood. For the purposes of this study, the focus on HCV screening will be limited to individuals born between 1945-1965, HIV positive individuals, and anyone with a history of IVDU.

Greenfield (2002) defines the purposes of a literature review as discovering gaps in current knowledge, exposing opposing viewpoints, discovering applicable research methods, and revealing inconsistencies and unanswered questions regarding the subject. The purpose of this literature review was to identify relevant studies regarding primary care provider's efficacy in screening for HCV in three high risk populations. The databases that were searched included Cochrane, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, EBSCOhost, National Guideline Clearinghouse, and UpToDate. The USPSTF and the CDC websites were also referenced for relevant research and updated statistics. The searches were conducted using the keywords "hepatitis C", "HCV", "chronic hepatitis C", and "hep C" in combination with the following phrases, "screening", "primary care", "diagnosis", "identification", "barriers", "recommendations", "high risk", and "guideline". A goal of including articles five years old or less was established. However, it was found that original

research that is still being referenced was outside of this window and was included in the evidence. Further inclusion criteria included published, peer-reviewed and evidence-based research, recognized by accredited medical organizations.   National and international agencies including the World Health Organization (WHO), USPSTF, and CDC were utilized for their guidelines and recommendations. Additional specialty groups, including the IDSA, AASLD, and ACG were also used as expert recommendations and research findings. Exclusion criteria included research conducted that focused greater than fifty percent of the study on treatment, screening for HCV was not primary in study, screening for disease other than HCV also included in research, study focus on HCV disease progression, focus on atypical subcultures not representative of the U.S. population, and main focus on cost effectiveness. Once the articles were appraised and duplicates removed, a total of thirty-one articles remained. Of these articles, one was a meta-analysis, three were systematic reviews, four were clinical guidelines, twenty-one were cohort studies, and two were expert opinion.

The literature review was focused on determining primary care provider screening of HCV in pre-determined risk groups and identifying barriers research found limiting screening practices. Overall the findings were consistent in concluding that HCV screening per the recommendations is done less than fifty percent of the time. One study found that once an intervention to improve screening rates among the birth cohort was implemented, identification of new cases of HCV was significant versus any other risk based screening (Southern et al., 2015). A study looking at the prevalence of HCV in a community-based health setting, found that beyond the birth cohort the next strongest association with carrying HCV antibodies was a history of injection drug use (Porter, Lusk, & Katz, 2014).   Another study looked at four large primary care settings to determine provider knowledge regarding the recommendations of which

populations should be tested for HCV (Jewett et al., 2015). Six primary care providers were

interviewed regarding their knowledge and application of the recommendations. One of which

reported awareness of existence of guidelines, but lacked familiarity of the details. Several of

the primary care providers incorrectly stated content of the guidelines. Further investigation

found risk behavior assessments were not routinely performed due to a perceived lack of time

and discomfort with discussing situational risks. Some providers reported overall discomfort and

confusion in testing, and many did not test unless there were symptoms to suggest hepatic

dysfunction.

McGowan and Fried (2012) found patient HCV screening barriers included deferral of

testing due to lack of patient awareness of recommendations, economic fears due to lack of

insurance, social pressures and fear of stigmatization, underlying psychiatric disease, and

disregard for provider recommendations. After the birth cohort, the two populations with the

highest incidence of HCV disease are IVDU and those with HIV (CDC, 2015). The co-infection

rates of HIV and HCV are between 50-90% in the U.S. A study published in 2014 found that

individuals with history of IVDU were more likely to have been tested for HCV by their primary

care provider if the provider knew of a history of IVDU (Barocas et al., 2014). The study also

found that patients who had high risk behaviors were reluctant to initiate a conversation with

their provider due to fear of being negatively judged. However, the authors determined that if

the provider asked about high-risk behaviors with a non-judgmental approach, the result was an

increase in individuals tested.

Sidlow and Msaouel (2015), implemented a targeted intervention using the EMR to

trigger a reminder to perform a one-time HCV screening of the birth cohort if not previously

tested. Screening rates pre-implementation were found to be 11% or 851 out of 7,764 of the

individuals eligible for HCV screening. Post-implementation of the EMR trigger screenings were found to improve significantly, as 46% or 3012 out of 6,577 of eligible patients were screened. The benefit of adding the technological aid yielded a 254% increase in screenings. Throughout the appraisal of the evidence, one element was consistently repeated: there is opportunity to improve the knowledge base of existing primary care providers and improve screening rates among the at-risk populations.

In 2013 the CDC recognized Kentucky as having the highest number of new HCV cases in the country. A more recent study to identify the most HCV and HIV vulnerable counties in the U.S., found 25% of these counties are in Kentucky (Van Handel et al., 2016). During the first six months of 2013, the Kentucky inpatient billing cost for HCV related care was over $174,000,000 for 5,387 individuals (Kentucky Cabinet for Health and Family Services, 2014). Razavi et al., (2013) estimated that current costs to the U.S. to care for HCV related illness are between $6.4-$13.3 billion dollars annually with yearly increases and a peak expected in 2025. While there have been studies regarding HCV screening of pregnant women and their children in Kentucky, there has not been a study to examine primary care providers' screening of other high risk groups. The background and literature review support the need to determine if primary care providers in Kentucky are screening high risk patients per the recommendations of the CDC and USPSTF. This study will specifically address the screening rates of high risk groups by one group of primary care providers affiliated with a large hospital system in Kentucky.

Methods

Study Permission

Permission for this study was first obtained from the Norton Healthcare Office of Research Administration (NHORA) #16-N0066 and then the University of Kentucky's

Institutional Review Board (IRB) #16-0282-P1G. IRB approval for this DNP Final Project was

issued on May 6, 2016.

Study Demographics and Setting

The practice site was located in an urban location in Louisville, Kentucky. Provided by

the healthcare system the 2015 demographics for the practice were 85% Caucasian, 8% African

American, less than 1% Hispanic, 6% classified as unanswered or other, 45% were male, and

55% female. Of the adult individuals identified for the study, 1990 out of 4608 were born

between the birth cohort years of 1945-1965, four were HIV positive, and five admitted to

IVDU. Patients who had any of these three pre-determined risk factors were randomly selected

for retrospective analysis of their EMR.   The study design was set to analyze 100 charts fitting

the search criteria. Cross-sectional data were collected on selected patient demographics. These

included age, gender, ethnicity, birth year, HIV status, IVDU history, and HCV screening

history. Provider notes were also evaluated to determine if additional interventions were

implemented at the time of the visit to suggest HCV screening or high risk behavior was

discussed. There were several medical doctors (MD) and one advanced practice nurse

practitioner (APRN) who worked at the practice during the time the data were collected. The

second portion of the study focused on the practice's providers and took place during the

summer of 2016.

Inclusion and Exclusion Criteria

Inclusion criteria for the study included patients 18 years and older with one of the

following: born in the birth cohort years, ever IVDU, or HIV positive. Exclusion criteria

included pregnant women, patients previously diagnosed with HCV, patients born outside the

birth cohort years of 1945-1965, and no history of IVDU or HIV.

Instruments Used

An Excel dataset was supplied by Norton Healthcare containing demographic data allowing the PI (principal investigator) the ability to identify subjects in the three high risk groups. A data collection tool in the form of a spreadsheet was created in a Microsoft Word document by the PI. SPSS statistical software was downloaded from the University of Kentucky. Statistical assistance from the University of Kentucky was provided by Dr. Amanda Wiggins, who assisted in creating meaningful results of data.

Study Procedures

Medical records that met the inclusion criteria for the study were requested from the healthcare organizations data support. All patient encounters taking place between January 1, 2015 and December 31, 2015 were requested in randomized order. The PI was then able to identify targeted populations by using the Excel file built by the organization. There was no active recruitment for participants for this portion of the study. Per a randomized computer number generator, the number 10 was produced and further randomization was implemented by pulling every 10th medical record to achieve the sample size of 100. The medical records chosen for the sample were then de-identified by using a crosswalk table and unique identifications to protect patient confidentiality. The data collection tool built for the study contained no patient identifiers. Both the crosswalk table and the data collection tool with responses were stored on a password protected H drive.

The second portion of the study was a survey given to providers which included six short answer questions to determine providers' level of comfort and familiarity in screening for HCV in at risk populations. The PI presented each of the providers with a questionnaire and consent form. Each provider was given a brief explanation of the purpose of the questionnaire and how

the information they provided would be anonymously used in evaluating how primary care

providers screen for HCV. The questionnaires were separate from the consents and no

identifying information was observable on the questionnaires. The consents were stored in the

PI's locked office safe and the questionnaires were loaded into the password protected and

encrypted Norton Healthcare H drive.

Data Analysis

The data collection tool developed by the PI included demographic and clinical data that

would later be separated into categorical variables. Demographics included gender, race, age,

and birth cohort status. Detailed clinical information included if they were HIV positive,

acknowledged IVDU, or were screened for HCV in 2015. A more detailed chart review was

required by the PI to determine if the provider offered HCV screening, but the patient declined or

if the provider placed a note in the record regarding discussion of high risk behaviors that could

place the patient at risk of having HCV. The PI also looked at HIV positive patients to

determine if the provider acknowledged the need to monitor for co-existing diseases or that the

patient was managed by another service. This was done by examining each provider note in

2015 for a given medical record and examining for details to answer the aforementioned

questions.

Once the data were collected, SPSS was used to create outputs to allow the PI to analyze

and interpret the results. A continuous variable was used to assess the sample's age range, mean

and standard deviation (See Table 1). Frequency distributions were used to describe categorical

variables the sample population (See Table 2). It was determined that further software analysis

to assess for associations was not of value due to the low screening rates across the sample

population. The determination was made to observe the small population of screened patients to

determine if there were any notable conclusions. The six that were screened were all female and predominantly Caucasian.

Results

Sample Characteristics

One hundred charts that met the inclusion criteria were reviewed. The mean age of the patients was determined to be 60.5 years, with a potential range of 36-71. The mean being skewed to the right was determined to be due to 98% of the sample being of the birth cohort status, making their ages between 50-70 years old at the time the data were created. The sample was noted 39% male, closely representative of the entire office demographic. The sample was found to be 90% Caucasian, 8% Black or African American, 1% Hispanic, and 1 % unanswered or other. Again, the race distribution of the sample was closely representative of the total demographic.

HCV Screening per USPSTF Recommendation

The largest part of the sample represented the birth cohort of patients born between 1945 and 1965. A one-time HCV screening for all people born during this time has been a grade B recommendation since 2013 (USPSTF, 2013).   The findings in the sample concluded that 6.1% of the 98 patients in the birth cohort were screened per the recommendations. The patients who were positive for HIV or had a history of IVDU, were not tested for HCV in the primary care setting. There also lack of documentation of discussion regarding high risk behaviors and exposures in these charts. There was one notation regarding a HIV positive patient being monitored for HCV by their infectious disease provider.

Additional Findings

Of the six patients that were screened all were women, one was African American and five were Caucasian. Of the sample that was screened for HCV, one patient had positive HCV antibodies. Of the entire sample, 23 were not asked if they ever participated in illicit drug use including IVDU.

Provider Survey

The providers at one office location were surveyed with a short open-ended questionnaire regarding their thoughts on HCV screening. One provider was willing to complete the survey. Response included that they routinely screen patients the born between 1945-1965. They felt all patients are screened for high risk behaviors, but are not always honest in their responses to the provider, therefore limiting the provider's ability to make appropriate recommendations. There were also noted barriers in HCV screening that included denial for payment if the lab was coded "screening" and the patient did not have Medicare. It was suggested that a meeting for all providers explaining how to code the screenings would be helpful. It was also noted they did not screen HIV positive patients for HCV, but acknowledged that they probably should. They stated that all of their HIV positive patients report seeing a specialist in infectious disease to manage their combination therapies. In answering whether they thought an EMR trigger would help prompt in screening the birth cohort, the response was "yes it does, it started this summer."

Discussion

The study outcomes regarding actual screenings of at risk patients demonstrated significant gaps in provider practice. In 2013 the USPSTF and CDC updated their recommendations to support expanding HCV screening practices in high risk populations. With providers missing 93.9% of the screenings recommended for the birth cohort, there is evidence to

suggest that alternative methods of alerting providers could be of benefit. There is also a need to

address the requirement of screening patients who have a history of IVDU. The 23% of the total

sample missing screening for substance abuse of any kind also represents an opportunity for

improvement to ensure that providers are capturing all history that could alert them to increased

risk factors and the need to screen. Accuracy of social history is essential to clinical decision

making. Overall provider education regarding the 2013 recommendations by the USPSTF and

CDC could assist in bringing awareness to which patients need screening for HCV. The provider

survey demonstrated that they felt they screened the birth cohort per the recommendation;

however, only one provider was willing to complete the survey.

Limitations

Study limitations included an inconsistent provider practice due to turn over. Providers

retired, left the country, switched to in-patient only, and changed practice locations during the

year of focus in the retrospective analysis. The sample size was likely limiting to the study. A

larger sample may have uncovered a greater frequency of testing. Analysis of the HIV positive

and IVDU population was limited due to single digit representation within the practice. The

providers' limited exposure to HCV positive patients may have effected their judgement to

screen. Of the 4608 patients' visits in 2015, only 17 were known to have HCV, and of those 12

were in birth cohort. After randomization only one of these known subjects appeared in the

sample and did account for the HCV positive case.

Further limitations occurred with the provider survey. In May of 2016, the healthcare

organization created a trigger in their EMR to alert providers that the patient needed HCV

screening due to birth cohort status. The provider survey, previously created without knowledge

of this trigger, asked a question regarding the benefit of an EMR in assisting with identifying

when screening is needed. The survey also questioned if providers were screening for HCV if

they had defined risk factors. At the time the survey was administered, there were only three

providers practicing from the previous six. The PI believed the wording of the survey in

conjunction with the newly implemented EMR trigger may have created a barrier in provider

willingness to participate. The question was asked, "do you perform a one-time screening on all

patients born between 1945-1965," may have been interpreted as if the provider was being

challenged regarding their individual screening practices. The question "do you feel patients are

adequately assessed for high risk behavior, specifically IVDU," may also have been interpreted

as assessing individual provider practice. A greater number of responses may have been gained

if the question was asked, "what populations do you screen for HCV?" If the PI had known

about the emergence of the EMR trigger, the survey would have been administered prior to

implementing the trigger and after implementation.

Conclusion

The retrospective chart analysis assessed provider adherence to the current HCV

screening recommendations. Frequency distributions were analyzed to determine population

characteristics and HCV risk based screenings. Due to the high percentage of unscreened

subjects statistical analysis was not of value to determine significance. The larger focus was on

the birth cohort, as they represent approximately 70% of all HCV cases (CDC, 2013). The low

frequency of screening in this sample added to the evidence suggesting additional measures are

needed to prompt provider screenings (USPSTF, 2013). The 6.1% screening adherence that was

evaluated is much lower than a larger study completed in 2011, which found screening rates of

the birth cohort at 36.1 % (Southern et al., 2011). Due to having only one patient with HIV and

one with a history of IVDU in the study, it was difficult to determine if the providers would have

been more inclined to screen if other risk factors were present. The patient that did admit to

IVDU but was never screened for HCV does provide insight that more provider education could

be beneficial to improve appropriate screenings. The patient with HIV told his provider that he

is monitored for HCV by his infectious disease provider.

        The recommendations by multiple accredited agencies are conclusive in the need to

screen at risk patients for HCV to identify disease and reduce progression and transmission of a

now treatable infection (Aspinall et al., 2015). It will be of future value to evaluate cases of

HCV that have been diagnosed post EMR trigger to determine the significance of the

implementation. Going forward it would also be advisable to create a method of communicating

all new guidelines to providers to ensure they have been apprised of and have full understanding

of the content. Since efforts to improve birth cohort screenings have been addressed, future

studies could focus on the effectiveness of assessing additional HCV high risk groups. These

groups would include those having a history of blood transfusion or solid organ transplant before

1992, any history of IVDU, received clotting factor prior to 1987, long-term dialysis patients,

known blood exposure from patient known to have HCV, patients with lab work demonstrating

signs of liver disease, and any individual born to a HCV positive mother (CDC, 2014). While

persons with other risk factors contribute a smaller percentage of HCV cases, the total cost of the

disease from all factors is overwhelming. Any means to improve screening can affect the long-

term consequences on the health care system as a whole, and on individual lives.

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Table 1.

Mean, Standard Deviation and Range for Continuous Variables: Evaluating Hepatitis C Screening in Primary Care (N=100).

Variable	Mean	Standard Deviation	Actual Range	Potential Range
Subject Age	60.5	6.8	36-71	18+

Table 2.

Frequency Distributions for Selected Categorical Variables: Evaluating Hepatitis C Screening in Primary Care (N=100).

Variable	Frequency/Percent (%)
Gender	
Male	39
Female	61
Race	
Caucasian	90
Black or African American	8
Hispanic	1
Unanswered	1
Born between 1945-1965	
Yes	98
No	2
HIV Positive	
Yes	1
No	99
History of IVDU	
Yes	1
No	76
Unanswered	23
Screened for HCV	
Yes	6
No	94
HCV positive	
Yes	1
No	99

Table 3.

2015 Practice Population Verses Sample Population Demographics; Subjects 18 years and Older.

	Practice population (4608)	Sample population (100)
<u>Gender</u>		
Male	45%	39%
Female	55%	61%
<u>Race</u>		
Caucasian	85%	90%
African American	8%	8%
Hispanic	<1%	1%
Other/Unanswered	6%	1%
<u>Born between 1945-1965</u>	43%	98%
<u>HIV Positive</u>	.09%	1%
<u>History of IVDU</u>	.1%	1%