

PROVIDER IDENTIFICATION OF HEPATITIS C VIRUS (HCV) RISK FACTORS AT
INMATE INTAKE TO PRISON

by

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A Doctor of Nursing Practice Project Submitted to the Faculty of the

COLLEGE OF NURSING

In Partial Fulfillment of the Requirements
For the Degree of

DOCTOR OF NURSING PRACTICE

In the Graduate College

THE UNIVERSITY OF ARIZONA

2015

THE UNIVERSITY OF ARIZONA
GRADUATE COLLEGE

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ABSTRACT

The hepatitis C virus (HCV) disproportionately affects the prison population. Studies demonstrate that healthcare provider knowledge of HCV risk factors is insufficient and many individuals are not aware that they are HCV positive. Early identification of HCV status can prompt early treatment and avoidance of complications that contribute to poor outcomes resulting in chronic disease progression. This doctor of nursing practice (DNP) project addresses provider identification of HCV risk factors at initial inmate intake to prison and whether providers obtained HCV testing based on guidelines from the Centers for Disease Control and Prevention (CDC). The principal investigator (PI) conducted a retrospective medical record review at Arizona State Prison Complex (ASPC) Lewis focusing on initial inmate intake forms identifying two of the CDC risk factors for HCV: drug abuse and tattoos; and ascertaining if a providers ordered a HCV test if inmates had one or both of these risk factors. The PI reviewed 51 randomly selected medical records; 40 records met inclusion criteria of 1) inmates who had an initial inmate intake evaluation occurring from 1 October 2013 to 1 October 2014 and 2) documentation of positive HCV risk factors.

Analysis of the records showed a mean inmate age of 26.78 years with a variable racial distribution. The risk factor of tattooing was present in 37 (92.5%) of records reviewed and the risk factor of intravenous drug use (IVDU) was present in 7 (17.5%). Only 4 (10%) records of inmates with positive risk factors had a HCV test ordered by the provider: One physician (n=2) and one nurse practitioner (n=2). This project demonstrated a gap in HCV testing in the presence of risk factors in the inmate population at ASPC Lewis which is consistent with studies in the general population. This study does not identify any reasons for this consistency, but

raises questions for future studies focused on provider knowledge, education and the institution of HCV testing protocols. This DNP project provides the foundation for a future full quality improvement Plan-Do-Study-Act based project aimed at educating providers about HCV testing according to CDC (2013a) guidelines and subsequently re-evaluating their HCV test ordering practices.

PROVIDER IDENTIFICATION OF HEPATITIS C VIRUS (HCV) RISK FACTORS AT INMATE INTAKE TO PRISON

Approximately 2 million people are incarcerated in correctional settings in the United States (U.S.). Prisoners bear a disproportionate burden of both physical and mental ailments compared to the general population. Many of these ailments are a result of individual behaviors. Hepatitis C virus (HCV) is of particular concern in the correctional setting owing to the high risk behaviors inherent in this population (Post, Arain, & Lloyd, 2013). The prison health care system bears a responsibility to inmates to identify HCV risk factors and test for HCV. The prison system can then provide adequate treatment and, thereby, decrease the spread of infection. To accomplish these actions, health care providers need to have an adequate knowledge of risk factors and the ability to identify them during prison inmate evaluation. The purpose of this doctor of nursing practice (DNP) project is to identify whether healthcare providers identify HCV risk factors at inmate intake to prison and if an HCV test was ordered based on these identified risk factors.

BACKGROUND

HCV was first identified in 1989 and is the cause of the most common chronic bloodborne infection in the U.S.—an estimated 4.1 million persons have been infected with HCV. Unfortunately, because HCV is typically asymptomatic, 75% of individuals with HCV do not know they are infected. Therefore, the estimated incidence could be considerably higher (CDC, 2013a). HCV infection causes liver damage through inflammation. Over a period of years, HCV leads to sustained oxidative stress that not only causes hepatic damage, but reduces the ability to treat or reverse this damage. Additionally, individuals with HCV have an 80%

chance of developing chronic liver disease leading to cirrhosis or hepatocellular carcinoma (HCC) compared to a 30% chance for those with hepatitis A, B and E (Paracha et al., 2013).

HCV has a tremendous impact on individual health, and the economic and public health burden is staggering as well. The annual cost of each new case of HCV is estimated at \$25,000 to \$30,000 (Jafari, Copes, Baharlou, Etminan, & Buxton, 2010). The total yearly costs associated with HCV infection were an estimated \$6.5 billion in 2007 and are projected to rise to \$9.1 billion by 2024. Additionally, if not diagnosed early, progressive disease leads to an added financial burden on community resources (Wenger, Rottnek, Crippin, & Parker, 2014). The HCV predicted death rate is 18,000 per year by 2020 and projected to increase to 35,000 per year by 2030 (Rein et al., 2012).

HCV is the most common communicable disease in the prison population (Post et al., 2013). The seriousness of HCV and its sequelae highlight the necessity for targeted HCV testing in this high-risk population (Post et al., 2013). Unfortunately, consistent with the general population, the majority of inmates do not know that they are infected. Identifying inmates at high risk for HCV could decrease the spread of HCV in the prison community through awareness and avoidance of high risk behaviors. Additionally, identification of HCV while in prison could lead to earlier supportive care, treatment and decreased morbidity associated with the late stages of HCV (Wenger et al., 2014).

Incidence, Prevalence and Risk Factors

The number of HCV cases declined rapidly from 1992-2003 with the availability of standard screening tests. However, the number of cases has increased since 2006, especially among younger persons who inject drugs (CDC, 2011). In 2011, the CDC reported 1,229 cases

of acute HCV which was a 44% increase from the previous year. The highest incidence was noted in persons aged 20-39 years, with higher rates in males than females. Approximately 60% of HCV transmission is through substantial or repeated percutaneous exposure to contaminated blood (e.g., injection drug use, tattoos). Receipt of contaminated blood, blood products or organs accounts for 15% of HCV transmission and occupational exposure through needle stick injuries is less than 2%. Additional infrequent exposure risks include sex with a HCV-infected partner and sharing personal care items (e.g., razors, toothbrushes) (CDC, 2014a).

Vulnerable populations, such as prison inmates, are at higher risk for HCV (Pena-Orellano, Hernandez-Viver, Caraballo-Correa, & Albizu-Garcia, 2011). Prison inmates make up 12%-35% of individuals infected with HCV compared to 1%-1.5% in the general population (CDC, 2013b). The CDC's Morbidity and Mortality Weekly Report (MMWR) (CDC, 2003) indicated 83% of state prisoners reported a past history of drug use and 55% admitted to drug use within the month prior to incarceration. The MMWR further identified intravenous drug use (IVDU) in 18% of jail inmates the month prior to incarceration but urine drug testing upon entry to jail revealed that inmates substantially underreported IVDU.

In 2003, the CDC consulted with specialists in the fields of corrections, correctional health and public health and developed a report for the planning and implementation of health care for incarcerated persons. The authors of this report cited case-control studies indicating tattooing was *not* a risk factor for acquiring HCV. However, they noted that the population of non-institutionalized individuals in their report may not have been generalizable to institutionalized populations (CDC, 2003). In contrast, this same report (CDC, 2003) cited one study by Samuel, Doherty, Bulterys and Jenison (2001) that reported an increased risk for both

HBV and HCV among individuals tattooed during incarceration. Despite this conflicting 2003 evidence, Jafari et al. (2010) and Pena-Orellano et al. (2011) reported a strong association between HCV and a history of tattooing even in the absence of a negative history of IVDU. These authors also found an association between tattooing and HCV for those tattoos performed in a non-professional setting or done by a friend. They concluded that tattooing was a *strong* indicator for HCV testing.

In 1998, the CDC recommended routine HCV testing for those persons most likely to be infected with the virus. Risk factors included:

- Persons who ever injected illegal drugs, including those who injected once or a few times many years ago and do not consider themselves as drug users.
- Persons with selected medical conditions, including:
 - persons who received clotting factor concentrates produced before 1987;
 - persons who were ever on chronic (long-term) hemodialysis; and
 - persons with persistently abnormal alanine aminotransferase levels.
- Prior recipients of transfusions or organ transplants, including:
 - persons who were notified that they received blood from a donor who later tested positive for HCV infection;
 - persons who received a transfusion of blood or blood components before July 1992; and
 - persons who received an organ transplant before July 1992.
- Persons who should be tested routinely for HCV-infection based on a recognized exposure:
 - Healthcare, emergency medical, and public safety workers after needle sticks,

sharps, or mucosal exposures to HCV-positive blood.

- Children born to HCV-positive women (CDC, 1998)

By 2012, results from the Chronic Hepatitis Cohort Study (CDC, 2012) reported that 45% of individuals who tested positive for HCV did not report any known risk factors. Study results showed that the prevalence of HCV infection among persons born from the mid-1940's through the mid-1960's was five times higher than adults born in other years. Males in this birth cohort were twice as likely to test HCV positive as females. Non-Hispanic black males had the highest prevalence followed by non-Hispanic white males and Mexican-American males. Therefore, the CDC amended previous testing recommendations to include one-time testing for HCV without prior ascertainment of HCV risk. The CDC also recommended testing for persons who had ever injected drugs or received a tattoo (CDC, 2012). The CDC specifically recommends that inmates reporting any risk factors during their medical intake should have their HCV status ascertained through HCV testing (CDC, 2013b).

HCV Testing

HCV testing is important to identify the HCV status of an individual and help providers make informed decisions regarding medical care and treatment options. A positive HCV test should prompt health care providers to counsel patients to limit behaviors (i.e. alcohol consumption, taking certain medications) that could advance disease progression. Knowledge of HCV status can also lead to other health promotion activities, such as vaccinations for hepatitis A and B (CDC, 2013a).

The enzyme immunoassay (EIA) is used to detect HCV antibody in the blood. A negative test indicates no HCV antibody present. A positive test can mean a current HCV

infection, resolution of a past infection or a false positive. Current EIA testing has 97% sensitivity. A positive result should be followed by a HCV ribonucleic acid (RNA) test to confirm a current HCV infection. A negative HCV RNA indicates a past infection that has resolved or a false positive (Firdaus, Saha, Biswas & Sadhukhan, 2015). HCV is a nationally notifiable condition and is subject to mandated reporting to state health departments (Gale, Dufour, Qazi & Kan, 2011).

The CDC (2013c) recommends HCV testing for all individuals who identify any of the above-mentioned risk factors. In addition, the CDC also recommends all adults born during 1945-1965 receive a one-time test regardless of exposure to any HCV risk factors. These guidelines form the framework for this project.

HCV Treatment

For many years, the standard therapy for HCV has been a 48-week course of pegylated interferon (PegIFN) and ribavirin which produced a 40-50% sustained viral response. This therapy is very difficult to tolerate because of the harsh side effects produced from the PegIFN. The most common side effects include fatigue, flu-like symptoms, anxiety, skin rash, depression, nausea, diarrhea, and anemia. Weekly to monthly monitoring of these side effects is critical to manage treatment efficacy. The poor tolerance of these side effects has led to high treatment discontinuation rates (U.S. Department of Veterans Affairs, 2013).

New drug regimens recently released are not only PegIFN-free, but also have shorter course durations of 12 weeks. Removal of the PegIFN from these new treatment regimens eliminates the unfavorable side effects. The new treatment regimens also have an improved sustained viral response of up to 90% (Lawitz & Membreno, 2014).

Role of the Nurse Practitioner in HCV Assessment, Testing and Treatment

Nurse practitioners (NPs) maintain national certification and practice autonomously as well as in collaboration with other healthcare providers. They are responsible for diagnosing and managing acute and chronic illness, with an emphasis on health promotion and disease prevention. Conducting research and applying findings to clinical practice promote NP accountability for health care outcomes (American Association of Nurse Practitioners (AANP), 2013). While there are no specific competencies addressing the NP role in the management of HCV, Olson and Jacobson (2011) noted that NPs play a pivotal role in providing supportive care and developing effective treatment strategies for persons with HCV. These authors also noted that NPs are in a position to conduct a thorough medical history including current social behaviors to identify HCV risk factors. These NP responsibilities are instrumental in HCV identification, education and management to maximize successful outcomes in persons with HCV.

REVIEW OF THE LITERATURE

The questions posed for this DNP project are: Are providers identifying inmates with HCV risk factors at the time of intake to the prison system, and, if so, do they order HCV testing based on those identified risk factors?

Search Strategy

The principal investigator (PI) searched three databases were utilized to search for evidence relating to the clinical questions: PubMed, CINAHL, and Web of Science. Search limits were "full text" and "within the last 5 years" to find the most recent literature in peer-reviewed journals, research or guidelines. The same key words "hepatitis C" and "risk factors" and "provider awareness" and "physician" and "nurse practitioner" and "physician assistant" were used in the search.

PubMed.

The keyword 'hepatitis C' generated 21,980 results. Adding 'risk factors' reduced that number to 3,484. The addition of 'provider awareness' reduced the results to 2. Adding 'screening' produced 3 results. Changing 'provider awareness' to 'provider knowledge' delivered 3 results and 'provider understanding' produced 1 result. The various levels of providers were also itemized including 'physician' with 23 results and 'nurse practitioner' and 'physician assistant' with zero results each. Adding 'prison' to the search yielded zero results.

CINAHL.

The keyword 'hepatitis C' generated 15,035 results. Adding 'risk factors' produced 12 results. Adding 'provider awareness' narrowed to 7 results. Changing the last keyword to 'provider knowledge' provided 3 results and 'provider understanding' provided zero results.

Again, itemizing of the provider levels produced zero results for 'physician', 3 results for 'nurse practitioner' and zero results for physician assistant. Adding 'prison' to the search yielded zero results.

Web of Science.

The keyword 'hepatitis C' generated 30,182 results. Adding 'risk factors' produced 3,913 results. Adding 'provider awareness' narrowed to 9 results and the addition of 'screening' produced 4 results. Changing 'provider awareness' to 'provider knowledge' provided 5 results. Changing 'provider knowledge' to 'provider understanding' produced 3 results. Itemization of provider levels produced 2 results for 'physician' and zero results for 'nurse practitioner' and 'physician assistant' respectively. Adding 'prison' to the search yielded zero results.

Overall Results

The results of the above literature search yielded six articles pertinent to the identified topic (see Table 1). Duplicate articles were deleted as well as studies not conducted in the U.S. and articles dealing specifically with management and treatment of HCV. All of the studies were completed in large primary care or community-based clinics. While none of the studies included prisoners in their sample, the Institute of Medicine (IOM) (2010) did include a review of information on correctional facilities and mid-level providers, e.g., NPs and physician assistants (PAs). The remainder focused on the physician (MD) level provider.

TABLE 1. Results of Literature Search of PubMed, CINAHL, and Web of Science databases

Author/s	Purpose	Method	Setting/Sample	Findings	Authors' Conclusions	Implications for Practice
Almario, Vega, Trooskin & Navarro (2012)	Determine actual HCV testing rate in patients with HCV risk factors and identify variables predictive of testing	Cohort study -survey on risk factors completed by patients at initial visit then completed by PCP	4 urban health care clinics in PA n=1848 pts	Only 8% of patients with +HCV risk factors were tested for HCV	HCV testing not a priority at PCP initial visit. May reflect PCP unfamiliarity with testing guidelines	Findings highlight need to focus on risky behaviors at initial visit and PCP awareness of testing guidelines
Institute of Medicine (2010)	Identify missed opportunities for addressing HCV	Independent review by CDC, National Viral Hepatitis Roundtable, DHHS, VA and open-session presentations by HCV experts	Comprehensive review of published literature Included healthcare providers and social services providers Also included correctional setting	Healthcare provider (MD, NP, PA) knowledge of HCV risk factors is insufficient, but no large scale controlled studies done	Recommended provider education on risk factors, prevention, and monitoring of HCV + individuals	Reinforces need for provider education on HCV risk factors
Jewett et al. (2014)	Develop understanding of limited success of provider identification of HCV testing based on CDC HCV testing recommendations	Qualitative study -Interviews re perceptions of PCPs & Hepatologists (HEPs)	4 large primary care systems (MI, NY,AL, TX) n= 6 PCPs, 8 HEPs	PCPs: No consistency with routine risk assessment HEPs: felt PCPs did not know HCV risk factors or follow established testing guidelines.	Barriers to HCV testing was lack of provider knowledge of HCV testing guidelines, comfort level, lack of time, fear that insurance would not pay for treatment, providers felt patients would not access treatment even if HCV+	Lack of provider knowledge of testing guidelines, time and comfort level can decrease identification of new cases. Discussion on risky behaviors at initial visit can decrease number of new cases of HCV

TABLE 1. Results of Literature Search of PubMed, CINAHL, and Web of Science databases

Author/s	Purpose	Method	Setting/Sample	Findings	Authors' Conclusions	Implications for Practice
Kallman et al. (2009)	To assess attitudes of HCV testing in primary care physicians (PCP), gastroenterologists (GE) and hepatologists (HEP)	Survey re knowledge and screening beliefs	Community-based primary care (DC) n=214 (103 PCP, 52 HEP, 59 Gastroenterologists (GE)	HEPs and GEs more knowledgeable of testing guidelines. HEPs endorsed appropriate testing scenarios more often than PCPs or GEs.	PCPs less aware of guidelines and tested inappropriately without +risk factors more often than HEPs	Need to educate PCPs to promote HCV testing according to guidelines
Roblin, Smith, Weinbaum & Sabin (2011)	To assess adherence to CDC HCV testing recommendations	Retrospective observational study x8yrs	Managed care organization (GA) n=557,056 pts	Only 4.31% with +HCV risk factors were tested at least once. Testing rates increased from previous study in 2004...reason unknown-possibly increased liver enzymes being noted at visit	Despite presence of +risk factors testing rates were low and many cases may have gone undiagnosed. PCPs felt computerized reminders to assess risk factors would be beneficial	Need for reminders to test for HCV and apply testing guidelines at each visit
Southern et al. (2014)	Measure adherence to CDC HCV testing recommendations after provider educational intervention	Cohort study -Computerized record review	3 community-based primary care clinics (NY) n= 8981 pts	HCV testing improved after the educational intervention but adherence to HCV testing guidelines declined over time with subsequent data collection	Provider barriers were lack of knowledge of HCV testing guidelines, time with patient, and comfort level with sensitive questions.	Educational reminders can improve adherence to HCV testing but provider barriers can still impede testing

TABLE 1. *Results of Literature Search of PubMed, CINAHL, and Web of Science databases*

Legend of abbreviations:

PCP= Primary Care Provider

HEP= Hepatologist

NP= Nurse Practitioner

GE= Gastroenterologist

HCV= Hepatitis C virus

CDC= Centers for Disease Control and Prevention

SYNTHESIS OF THE LITERATURE

Four consistent themes arose from the literature review to explain the lack of HCV testing: 1) Insufficient provider knowledge of HCV testing guidelines, 2) Insufficient knowledge of HCV risk factors, 3) Inconsistent use of provider type in the studies, and 4) Specific barriers resulting from provider concerns.

Insufficient provider knowledge of HCV testing guidelines was found in four of the studies (Almario et al., 2012; Jewett et al., 2014; Southern et al., 2014; and Kallman et al., 2009). However, only Southern et al., specifically evaluated provider knowledge of HCV testing guidelines. Southern et al. concluded that the educational intervention of HCV testing guideline reminders increased the HCV testing rates; however, the rate of testing compliance decreased with time. Almario et al. (2012) focused on the actual testing rate and not the reasons for deficiencies in testing. These investigators concluded that provider knowledge was the probable reason for the deficiency. Jewett et al. (2014) found a lack of provider knowledge of HCV testing guidelines, and concluded that this lack of provider knowledge specifically related to the lack of routine risk assessments being completed by primary care providers (PCPs).

Insufficient knowledge of HCV risk factors was noted in three of the studies (Jewett et al., 2014; Roblin et al., 2011; IOM, 2010). Jewett et al. (2014) concluded that providers lacked sufficient knowledge of HCV risk factors as demonstrated by the non-completion of routine risk assessments by providers. Roblin et al. (2011) found testing occurred in those with increased liver function tests which is not a risk factor according to the CDC testing guidelines (2013a). The comprehensive review done by the IOM (2010) specifically looked at knowledge of HCV

risk factors in PCPs and found insufficient knowledge of HCV risk factors. The IOM also identified no large scale controlled studies had been done.

Inconsistent provider type was found in three of the studies. Kallman et al. (2009) included not only primary care providers (PCPs), but hepatologists (HEPs) and gastroenterologists (GEs) as well. The authors concluded the lack of knowledge of HCV testing guidelines by PCPs was an opinion of the HEPs and GEs in the study. Both of these specialties have expert knowledge of HCV and were not sampled in any of the other studies. Jewett et al. (2014) also included HEPs in their study who felt that PCPs did not have adequate knowledge of HCV risk factors. The IOM (2010) included MDs, NPs and PAs in their studies and concluded that all had insufficient knowledge of HCV risk factors. Of note, the IOM found that physicians with more than 20 years in practice had less knowledge of HCV risk factors than physicians who had less than five years in practice. The IOM was the only study to include providers in the correctional setting.

Provider-specific barriers were noted in two of the studies. Both Jewett et al. (2014) and Southern et al. (2014) identified provider comfort level with sensitive questions and restricted amount of time spent with the patient as major barriers that resulted in the low rate of HCV testing. In addition, Jewett et al. added the additional aspect of provider fear that insurance would not pay for treatment or that patients would not access treatment even if HCV positive.

Interpretation of these studies should also take into account the strength or quality of evidence that they yield based on a rating system. Melnyk (2004) identifies a hierarchy of evidence (see Figure 1) that assists clinicians in being confident of the evidence provided by a study.

Level I	Systematic review or meta-analysis of all relevant randomized controlled trials (RCTs) or evidence-based clinical practice guidelines
Level II	Evidence from at least one well-designed RCT
Level III	Evidence from well-designed controlled trials without randomization
Level IV	Evidence from well-designed case-control and cohort studies
Level V	Evidence from systematic reviews of descriptive and qualitative studies
Level VI	Evidence from a single descriptive or qualitative study
Level VII	Evidence from the opinion of authorities or reports of expert committees

FIGURE 1. *Hierarchy of Evidence*

According to the rating system described by Melnyk (2004) above, the studies reviewed for this project represent three levels:

- Level 4:
 - Cohort studies: Almario et al. (2012), and Southern et al. (2014)
 - Qualitative and observational studies: Jewett et al. (2014) and Roblin et al. (2011)
- Level 5:
 - Single descriptive study: Kallman et al. (2009)
- Level 7:
 - Expert opinion: IOM (2010)

The lack of studies with higher levels of evidence (Levels 1-3) highlights the need for more rigorous research to increase the clinicians' confidence in incorporating this HCV risk factor-related evidence into their decision-making and practice preferences regarding patient care.

LOCAL PROBLEM

The high prevalence of HCV in the prison population makes identification of the virus a high priority to prevent and control further spread of the virus (CDC, 2003). Despite recommendations from the CDC for testing persons within the birth cohort of 1945 to 1965 and those with identified risk factors, HCV testing rates remain low (Almario et al., 2012; Southern et al., 2014). However, previous research did not focus on a local level or on prisoners.

The principal investigator (PI) for this DNP project is a NP employed by Corizon Health at the Arizona State Prison Complex (ASPC) Lewis in Buckeye, Arizona. Corizon Health is a private contractor providing healthcare services in correctional settings. Inmates are entitled to care for acute and chronic health issues, including a test for HCV if risk factors are present. The PI has observed anecdotally in this practice setting, a lack of testing for HCV at ASPC Lewis that is consistent with current literature. In addition, the PI has clinically evaluated a number of inmates who either became symptomatic or were noted to have elevated liver enzymes on routine blood tests that led to a positive HCV test. In reviewing their charts, the PI found positive risk factors for HCV were present at the time of initial inmate intake into prison.

There are currently 20 prison complexes in the state of Arizona. Ten are state operated, six are privately operated and four are federally operated (Arizona Department of Corrections, 2014; Federal Bureau of Prisons, n.d.). ASPC Lewis is a state-operated complex with 6,000 inmate beds that house minimum, medium and maximum security inmates. Inmates are provided an intake evaluation by medical providers which include two physicians (MDs), three nurse practitioners (NPs) and one physician assistant (PA). The initial intake form includes a medical history section filled out by the nurse during an inmate interview that elicits information

regarding drug abuse treatment and a history of hepatitis. The provider then reviews the medical history form and performs a detailed physical examination that includes documentation of any tattoos. The provider then documents any medical issues from the above on a master problem list. If one or more risk factors are present, the provider would then initiate HCV testing according to CDC HCV testing guidelines (CDC, 2013a). During incarceration medical care for acute and chronic medical conditions are paid for by Corizon under a contract with the Department of Corrections (DOC).

New HCV treatment protocols were released after the inclusion timeframe for this project; however, treatment is costly with new drug regimens estimated to cost up to \$150,000 per patient (Chhatwal, Kanwal, Roberts & Dunn, 2015). Corizon currently has strict inclusion criteria for approving inmate HCV treatment; however, testing in the presence of HCV risk factors and care of HCV and HCV-related conditions are budgeted and mandated for all inmates under the Corizon/DOC contract.

INTENDED IMPROVEMENT

This DNP project seeks to answer the question of whether healthcare providers at ASPC Lewis are identifying HCV risk factors in new inmates at their intake evaluation to the facility. Identifying a weakness in provider identification of HCV can lead to educational programs for providers. Eventually, this could lead to the establishment of local policies to promote the early identification of HCV at ASPC Lewis and, hopefully, prison systems in general throughout the state and beyond. Early identification of HCV can lead to early treatment as well as prevention of further liver damage. All of these factors will ultimately lead to a decrease in the future cost of managing HCV.

PURPOSE AND AIMS

The purpose of this DNP project is to identify whether health care providers address HCV risk factors on inmate intake evaluation at ASPC Lewis. The specific aims are to:

1. Determine whether healthcare providers are completing intake forms to assess risk factors;
2. Determine whether healthcare providers are ordering a HCV test for those inmates with at least one documented risk factor in accordance with CDC guidelines;
3. An exploratory aim to compare the ordering of HCV testing according to the CDC guidelines by provider type, i.e., MD, NP, PA who conduct inmate intake evaluations at ASPC Lewis.

ETHICAL ISSUES

According to Cislo and Trestman (2013), the inmate population is an overprotected and understudied group. The authors identified historical evidence of inmate research utilizing coercion, involuntary participation and introduction of disease or illness without the benefit of knowledge or consent. Prior to World War II, medical research utilizing inmates was rare. However, the war exposed soldiers to many understudied conditions. Inmates were seen as ideal for experimentation purposes in the study of these conditions through convenience and easy recruitment. Considering the priority of the war, medical ethics were often overlooked and inmates were viewed as paying a debt to society. Some were even compensated with early release for their participation.

In the 1960's, the focus shifted to a greater concern for civil rights. The general public became more aware of ethical breaches in studies involving inmates, like the Tuskegee Syphilis Project that followed black men with syphilis over four decades without intervention. Despite public awareness of such ethical breaches, research studies continued to utilize prisoners. In the late 1960's, 85% of all new drugs were still tested on inmates. This continued until 1980 when the US Food and Drug Administration (FDA) banned drug research involving prisoners. Regulations continued to be implemented which eventually led to inmates being an overprotected population in research (Cislo & Trestman, 2013).

As a result of protective research practices, few studies or trials have been conducted on inmate populations in recent years. In sharp contrast is the overabundance of health conditions, like HCV, that disproportionately affect the inmate population. Treadwell, Ortiz and McCoy (2014) point out that most health information data is derived from deinstitutionalized individuals

which creates a "missingness" of information from incarcerated individuals creating a gap in knowledge of the needs of this population (p. 452). The authors further note this lack of knowledge can put health care providers at a disadvantage regarding public health issues, like HCV. This lack of knowledge can have a detrimental effect on the special needs of this population and the communities they eventually return to. It is important to study HCV in the incarcerated population because of the potential impact on the public health of the community and its inhabitants (Treadwell et al, 2014).

Challenges faced by researchers can deter studies in the correctional setting. Health care and promotion are seen as secondary functions in corrections. Researchers are often seen as a burden in this rigid environment with requirements for authorizations, safety training, background checks, clearances and multiple identifications. Non-correctional staff require escorts or inmates are required to be transported utilizing additional security staff. The parallel between lack of research in the prison population and the dramatic increase of incarcerated individuals highlights the need to overcome these challenges (Cislo & Trestman, 2013).

The US Department of Health and Human Services (DHHS, 2009) and the National Institutes of Health (2011) have mandated guidelines for conducting research involving prisoners. These guidelines minimize risk to inmates by decreasing unfair advantage, benefit, coercion and risk. Permissible research must not provide advantage or compensation compared to the general conditions of other inmates and must not impair the prisoner's ability to evaluate the risks and benefits of the research. Studies with minimal risk and no more than inconvenience are allowed as long as a reasonable probability of improving health or well-being of the subject exists. Recruitment must be fair to all inmates and information must be presented in a language

understandable to the subject population. Lastly, there must be no benefit to participation, such as early release or parole.

Protection of subject's privacy and well-being in this DNP project is a primary concern, given the prison setting. As such, the PI conducted a retrospective record review which eliminated inmate contact, protected inmate privacy and identification as well as decreased the burden on the correctional staff. The PI is a current employee of Corizon Health at ASPC Lewis. This situation facilitated access to the facility because many of the identification and security barriers were overcome through employment. However, the PI's employment status also presented a potential conflict of interest to this project. To eliminate this potential, review of charts, documents or information created or authored by the PI were omitted from the project. This action served to promote the integrity of the data collected.

SETTING AND SAMPLE

ASPC Lewis has eight detached, self-contained inmate yards surrounding a central hub. The central hub area houses an emergency patient assessment area, supply and administrative areas and the medical records room. The first setting of the project was the medical records room which houses hard copy medical charts for all 6,000 inmates. The medical records room is manned by at least one person at all times and is accessible to all medical, nursing and supportive staff. There are no secure entry points to the medical records room and all personnel who are authorized entry into the medical hub have access to the medical records room.

For this project, the PI reviewed charts in the medical records room. The PI selected a random sample of 40 records from the 400 inmate charts that comprised currently incarcerated inmates with an initial intake into prison from 1 October 2013 to 1 October 2014. This sample size was determined based on the recommendations of Gearing, Mian, Barger and Ickowicz (2006) for sampling 10 charts for each variable in the study. Although this retrospective review does not have variables per se, there are four criteria being evaluated: a history of HCV, history of tattoos, history of drug abuse and whether an HCV test was ordered. The PI selected a random sample of 40 eligible medical records using a random numbers table (see Appendix A). This sampling provided the 40 cases necessary for this review, including the charts required for the pilot assessment described below. Inclusion criteria for this sample included newly incarcerated inmates with an inmate medical record number beginning after 284450 which represented new intakes beginning on or after 1 October 2013. Exclusion criteria included records of inmates with a previously documented diagnosis of HCV and records with documentation by the PI. Information obtained was transcribed onto a data collection form

utilizing pre-designated codes. This transcription was done by hand because the prison did not allow outside electronic devices (including laptops, tablets, etc.) were allowed to be brought onsite.

The PI then took the data collection form to the second setting of the project: her office in the prison hub area. The PI transferred the information onto a Microsoft Excel spreadsheet on her desktop computer and saved it to an external thumb drive. During data collection, this thumb drive was stored in the PI's locked office until data collection was complete. The PI then hand-carried the thumb drive to a statistician for analysis. The statistician had an office located at Arizona State University in the Department of Nursing.

PLANNING THE DATA COLLECTION

As an employee of Corizon Health at ASPC Lewis, the PI had authority to access inmate medical records, therefore, no specific prison authorization was required to access medical records after approval to begin the study. Initial site approval to conduct this project was obtained via email from Mark Jansen, Vice President of Operations at Corizon Health with subsequent Institutional Review Board, local medical and correctional site approval (see Appendices B, C and D). Data collection was focused on intake forms from new inmates (n=400) admitted to the facility from 1 October 2013 to 1 October 2014. The PI chose this time period to reflect medical intakes done by medical providers currently employed at the facility who would benefit most from the results of the data analysis. In addition, this time period gave the PI the ability to complete the project and compare findings to the most recent literature and iteration of the CDC guidelines.

Random sampling of medical records was achieved using a random numbers table (see Appendix A). The 400 medical records were divided into 40 groups of 10 by a colored sheet of paper for ease of counting. Each colored sheet of paper was marked as 10, 20, 30, etc., up to 400 to identify the general location of each group of records. The PI had permission from the medical records supervisor to leave these colored sheets of paper in place throughout the data collection process. The first record sampled was in row 1, column 1 of the random numbers table which was the 20th record. If this record was found to be ineligible, then the PI would proceed to column 2 and sample the 288th record and so forth through each column until finding an eligible record. Once the PI retrieved an eligible record, she moved down to the next row on

the random numbers table. The remaining 39 records were selected following this same procedure.

The PI developed a data collection tool (see Appendix E) with the assistance of a statistician at Arizona State University. This data collection tool used a code to protect inmate identity. Data collected were demographics (date of birth/age, ethnicity and education level), provider type, e.g., physician (MD), nurse practitioner (NP) or physician assistant (PA), history of HCV, tattoos or IVDU and identification of a lab result of HCV testing. The PI transferred hand collected data to an Excel spreadsheet for data analysis. The data were analyzed using SPSS Statistical Data Analysis Software Version 23.0. Descriptive statistics were utilized to provide nominal measurements of the data.

The PI reviewed the following intake forms (see Appendix F) which contained information that paralleled the CDC guidelines for HCV testing:

Health Services Problem List: This form identified any prior history of HCV, elevated liver enzymes or history of IDU

Medical History Form: Area of focus was a history of jaundice/hepatitis or drug abuse treatment

Physical Examination Form: Area of focus was item #20 identifying any tattoos

Lab Results: To indicate a HCV test was performed

Data collection took approximately 10 minutes for each medical record. A total of 51 records were reviewed with 40 eligible records completed in 6 hours.

METHODS OF EVALUATION

Due to the practical and ethical issues encompassing research involving inmates, the PI for this project selected a retrospective record review as the design for this DNP project. According to Vassar and Holzmann (2013), a retrospective record review utilizes patient-centered data to answer a study or project question. This methodology may identify valuable information, the results of which may serve to guide subsequent prospective studies.

The PI conducted a retrospective review with five records to identify feasibility of the project procedures and identify issues prior to initiating the full-scale project. The PI took these first five records from a convenience sample to test the data collection tool and data analysis procedures. No revisions of the tool or analysis procedures were necessary based on information from the pilot sample. These records were eliminated from the final analysis.

The main project with a sample of 40 records was then undertaken by random sampling as previously described. A minimum of 45 records were required for this project: Five records for the pilot sample and 40 records for the main project. The PI chose a maximum of 400 records basing this number on the approximate number of records of new inmate intakes from 1 October 2013 to 1 October 2014. There was also an expectation that some records would have incomplete forms, have inmates with a previous diagnosis of HCV or have inmates with no risk factors, thereby making the records ineligible. The PI reviewed a total of 51 records for this project to obtain the 40 eligible records. Records were categorized as meeting eligibility requirements with completed forms, eligible but with incomplete forms, eligible but already diagnosed with HCV and eligible but with no risk factors (See Figure 2). No data collection training was required in this project as the PI was the only data collector.

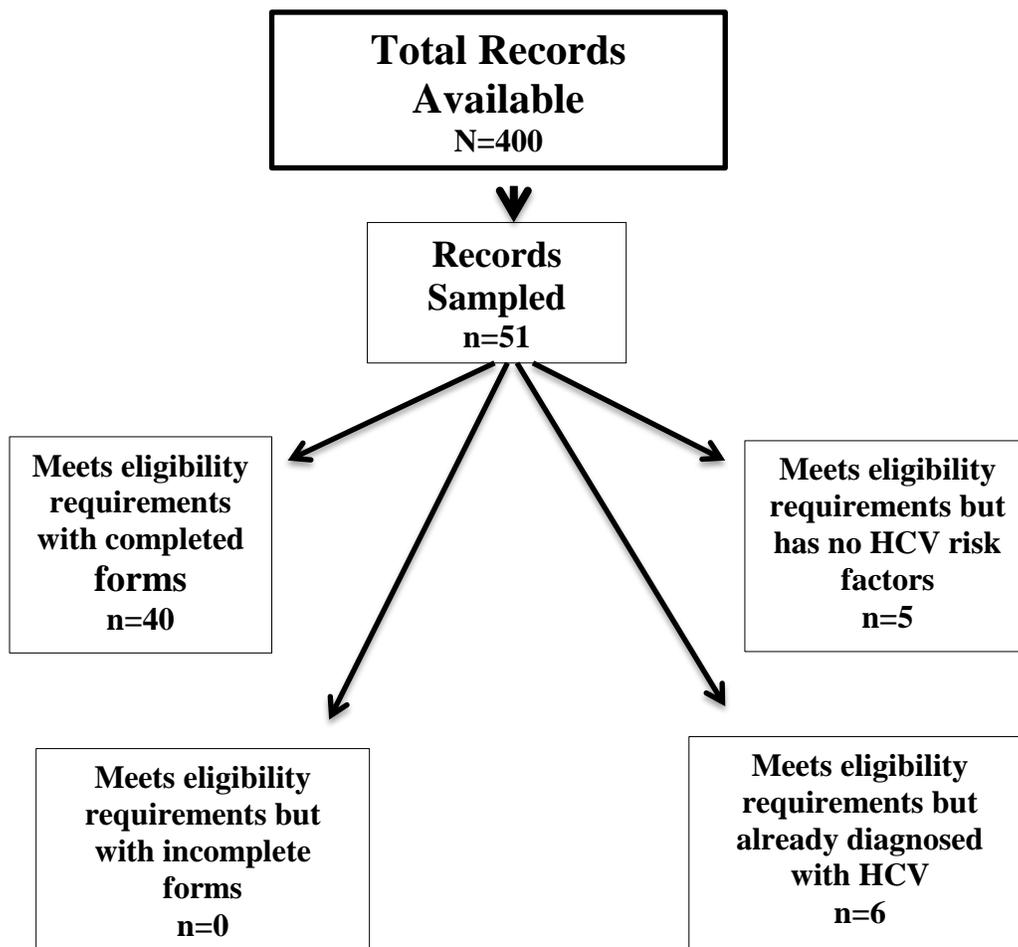


FIGURE 2. *Record Categories. Records categorized as meeting eligibility requirements with completed forms, eligible but with incomplete forms, eligible but already diagnosed with HCV and eligible but with no risk factors.*

ANALYSIS

This project was to identify if healthcare providers were completing inmate intake documents and whether HCV tests on new inmates were being ordered based on documented risk factors. This project was also to identify which healthcare providers, i.e., MDs, NPs or PAs are most consistently ordering HCV tests based on these risk factors. The aims of this study were analyzed as follows:

- Aim 1: Determine whether healthcare providers are completing intake forms to assess risk factors
 - This aim was analyzed using descriptive statistics assessing what proportions/percentages of the forms in the records are complete.
- Aim 2: Determine whether healthcare providers are ordering a HCV test for those inmates with at least one documented risk factor in accordance with CDC guidelines
 - This aim was analyzed using descriptive statistics assessing frequencies/percentages of the number of inmates with at least one risk factor who had a HCV performed.
- Exploratory Aim: Compare the ordering of HCV testing according to the CDC guidelines by provider type, i.e., MD, NP, PA who conduct inmate intake evaluations at ASPC Lewis
 - This aim was explored with a cross-tabulation using the dependent variable of the HCV test and the three practitioner factors.

RESULTS

Demographics

Table 2 summarizes selected demographic information collected from the medical records. The age of the inmates ranged from 19 to 48 with a mean age of 26.78 (6.96) years. Most inmates were Hispanic and did not have a high school diploma.

TABLE 2. *Demographics*

AGE	N	Minimum	Maximum	Mean	SD
	40	19	48	26.78	6.96

RACE/ETHNICITY	Frequency	Percent
White	12	30
Black	3	7.5
Hispanic	20	50
American Indian/ Alaska Native	3	7.5
Asian	1	2.5
Other	1	2.5

EDUCATION	Frequency	Percent
No high school diploma	21	52.5
High school diploma	14	35
Community college	4	10
University degree	1	2.5

Results of Aims

Aim 1: Determine whether healthcare providers are completing intake forms to assess risk factors

All 51 records reviewed (100%) had complete documentation. Tattoos were documented in 37 (92.5%) of the records. A history of IVDU was documented in 7 (17.5%) of the records. Tattooing was a predominant risk factor in this sample population.

Aim 2: Ordering of HCV Test for Inmates with at Least One Risk Factor

An HCV test was ordered in 4 (10%) of the records

Aim 3 (exploratory): Provider Type

Three provider types completed the inmate intake evaluations in this DNP project: MD, NP and PA. Table 3 shows the cross-tabulation, demonstrating that MDs performed the majority of intakes, whereas NPs performed the fewest intakes. One MD ordered a HCV test in 2 (5%) of the records and one NP ordered a HCV test in 2 records (5%). No records completed by PAs had a HCV test ordered.

TABLE 3. Cross-Tabulation of Provider Type and HCV Test Order

PROVIDER TYPE	Frequency	Percent	HCV Test Ordered
MD	n= 23	57.5	2
PA	n= 9	22.5	0
NP	n=8	22.0	2

DISCUSSION

Strengths and Limitations

This DNP project addresses a gap in knowledge with regard to HCV testing in the inmate population. Several studies from the literature review also identified incomplete provider identification of HCV risk factors and HCV testing in the general population (Almario et al., 2012; Jewett et al., 2014; Southern et al., 2014; Roblin et al., 2011; Kallman et al., 2009; IOM, 2010). All providers in this project completed the intake information pertaining to HCV risk factors; however, the findings confirmed that, similar to providers in the general population, providers at ASPC Lewis ordered insufficient HCV testing in the presence of HCV risk factors. Prior studies in the correctional setting were very limited, so no comparisons could be made with the literature.

One limitation to this DNP project was bias. Bias can occur at several stages of a project (Pannucci & Wilkins, 2010). The first potential for bias in this project was the study design. Record reviews depend on accuracy of the reporter or recorder of information and a record reviewer should confirm the presence or absence of a risk or exposure (Pannucci & Wilkins, 2010). Findings from this project depended on the integrity of the inmates to honestly report risk factors for HCV, as well as on the providers' accurate documentation of those risk factors. While some inmates may not have been forthcoming in disclosure of HCV risk factors (tattoos or IVDU) records from those inmates were excluded from the sample because those inmates did not meet inclusion criteria. Only those that did disclose HCV risk factors were included in the sample. Furthermore, confirmation of the presence of tattoos was documented on the physical exam form. There was no means available to confirm IVDU other than inmate report.

Another potential for bias was in the data collection phase. Pannucci and Wilkins (2010) recommended standardized protocols for data collection and training for study personnel to decrease any inter-rater variability. Data collected in this DNP project consisted of basic, general information that was either present or absent in the record. The PI was the only data collector; therefore data were collected consistently from each record.

A third potential bias was in the selection of the sample. Selection bias refers to the potential of a sample to not possess the risk or outcome of interest (Pannucci & Wilkins, 2010). This potential bias was eliminated by the inclusion criteria for this project. The sample was required to have positive risk factors for HCV, either tattoos or IVDU. Sample selection bias also was minimized by random selection of the medical records.

Other limitations included the small sample size which could affect generalizability to other correctional facilities. Generalizability could be strengthened with the inclusion of more records and expanded data collection at multiple correctional facilities. Increased sample size and settings would yield more providers (MD, NP, PA) to study further associations of provider knowledge of HCV risk factors and testing practices by a particular provider type.

Although no cost was incurred in the collection of data for this DNP project, of note is the reminder that collecting data in the corrections environment can be difficult given the extra security measures necessary to obtain entry to correctional facilities. Those providers currently working in corrections would be ideal future project developers having increased access to this protected population.

INTERPRETATIONS

This DNP project, although on a small scale, demonstrates the inmate population at ASPC Lewis has positive risk factors for HCV and is not being tested. The age of incarcerated individuals in this study was quite young. This age correlates with the CDC (2014b) findings wherein persons aged 20-29 years are noted to have had the highest increase in HCV rates. These young adults do not meet the birth cohort guidelines for one-time testing for those born between 1945 and 1965 (CDC, 2013a), which further highlights the need to focus HCV testing in persons with positive HCV risk factors. Persons diagnosed with HCV at a young age may be living longer with HCV which puts them at greater risk of developing chronic disease states including cirrhosis and HCC (Wenger et al, 2014).

Hispanic inmates comprised the majority of race/ethnic groups in this record review. According to the Arizona Department of Corrections Inmate Ethnicity Distribution by Unit (Arizona Department of Corrections, 2014), the Hispanic inmate population (38.4%) at ASPC Lewis exceeds that of any other ethnicity, followed by Caucasian (37.5%) and Black (11.3%). ASPC Lewis is the only prison complex in the state of Arizona, with the exception of ASPC Winslow, to have a higher percentage of Hispanics compared to other ethnicities. This ethnic distribution conflicts with the national statistics which show larger percentages of Black (37%) inmates followed by Caucasian (32%) and Hispanic (22%) (U.S. Department of Justice, 2014).

A literature review by Blessman (2008) identified Hispanics as the fastest growing minority in the U.S. She also noted that Hispanics have faster liver fibrosis progression rates, have a higher rate of cirrhosis, are infected with HCV at an earlier age and tend to be co-infected with human immunodeficiency virus (HIV) at a higher rate than other ethnicities. This disparity

in HCV chronic disease progression and co-morbidity highlights the importance of providers remaining culturally competent to the identification and care of the Hispanic population at ASPC Lewis as well as other Arizona correctional facilities.

The higher percentage of Hispanic inmates at ASPC Lewis is noteworthy when considering the potential for chronic disease states. A study by Younossi and Stepanova (2010) identified the majority of liver cancers are HCV-related HCC. The authors noted a 5-fold higher risk of HCC mortality in Hispanics than in other populations studied. The increased risk for HCC in the Hispanic population underscores the importance of HCV risk identification and testing in this population.

A report by Kirzinger, Cohen and Gindi (2012) noted young Hispanics (57.9%) aged 19-25 years were less likely to have a usual location for health care or a visit to a health care provider in the previous 12 months than Blacks (68.4%) or Caucasians (74.9%). This lack of health care visits in the Hispanic population underscores the need to identify HCV risk factors and test according to HCV testing guidelines at each provider visit.

The records reviewed in this DNP project further demonstrate that providers at ASPC Lewis did quite well with documentation of the presence or absence of HCV risk factors in this sample; however, no record audits were conducted during the inclusion timeframe for this project specifically identifying documentation compliance of risk factors on intake forms. Despite 100% compliance with documenting HCV risk factors on intake forms in this sample, providers did not consistently order HCV testing in the presence of HCV risk factors. This gap demonstrates a deficiency in HCV testing practices. This lack of recommended testing underscores the CDC (2013a) findings that 75% of individuals with HCV do not know they are

infected and the actual number of HCV cases could be much higher. This deficit of recommended testing also raises several questions for future study:

- Why are these providers who assess for risk factors not ordering the test?
- Are healthcare providers at ASPC Lewis not familiar with HCV testing guidelines or risk factors?
- Are providers limited on the time they spend with inmates at the initial intake evaluation?
- Do providers focus solely on current known health issues?
- Are they reluctant to test for HCV based on knowledge of cost or side effects of treatment?

These and other factors have been documented in the results of the literature review for this project (see Table 1) and should be further investigated in the correctional setting. Given the disproportionate number of inmates with HCV compared to the general population (Post et al, 2013), providers working in the prison environment need to be vigilant to identify HCV risk factors and order HCV testing.

CONCLUSIONS

Impact on Advanced Nursing Practice

Nurse practitioners in the state of Arizona have full practice status allowing them to practice independent of physician oversight (AANP, 2013). As leaders in primary care, Arizona NP's are accountable for health outcomes including the early identification of HCV. This accountability includes possessing knowledge of current HCV testing guidelines and applying them in their practice. Early identification of HCV could lead to earlier intervention and health promotion, thus minimizing the long-term damage of HCV (Wenger, et al, 2014).

While no statistics could be located for numbers of NPs working in the State of Arizona corrections environment, Corizon currently has 11 NP position openings at prisons throughout the state of Arizona. The utilization of NPs has been demonstrated to decrease direct and indirect healthcare costs and increase quality for consumers through increased work productivity and decreased work absenteeism (Blackmore et al., 2013). NP salaries are typically lower than MD salaries and appropriate utilization and workload allocation can provide cost-efficient care delivery (Liu & D'Aunno, 2012). These factors may make the utilization of NPs more desirable in most healthcare settings, including the prison setting.

The utilization of NPs in prison settings places them in a unique situation to effect policy change while keeping health care costs to a minimum. The unique education of the doctorally-prepared NP (DNP) provides tools to effect policy change. Applying change models (e. g. Lewin's change theory), incorporating quality improvement strategies (e. g., provider education and reminders on HCV risk factors and testing guidelines) and implementing evidence-based

practice guidelines (e. g., CDC HCV testing guidelines) can effect local policy change and practice improvement (Mauger et al., 2014).

Looking Toward the Future

Next steps should include studies to determine provider knowledge of HCV risk factors and HCV testing guidelines with a focus on the correctional population. A potential study could include a Plan-Do-Study-Act study of an educational intervention evaluating provider adherence to CDC (2013a) HCV testing guidelines in the prison setting (see Figure 3).

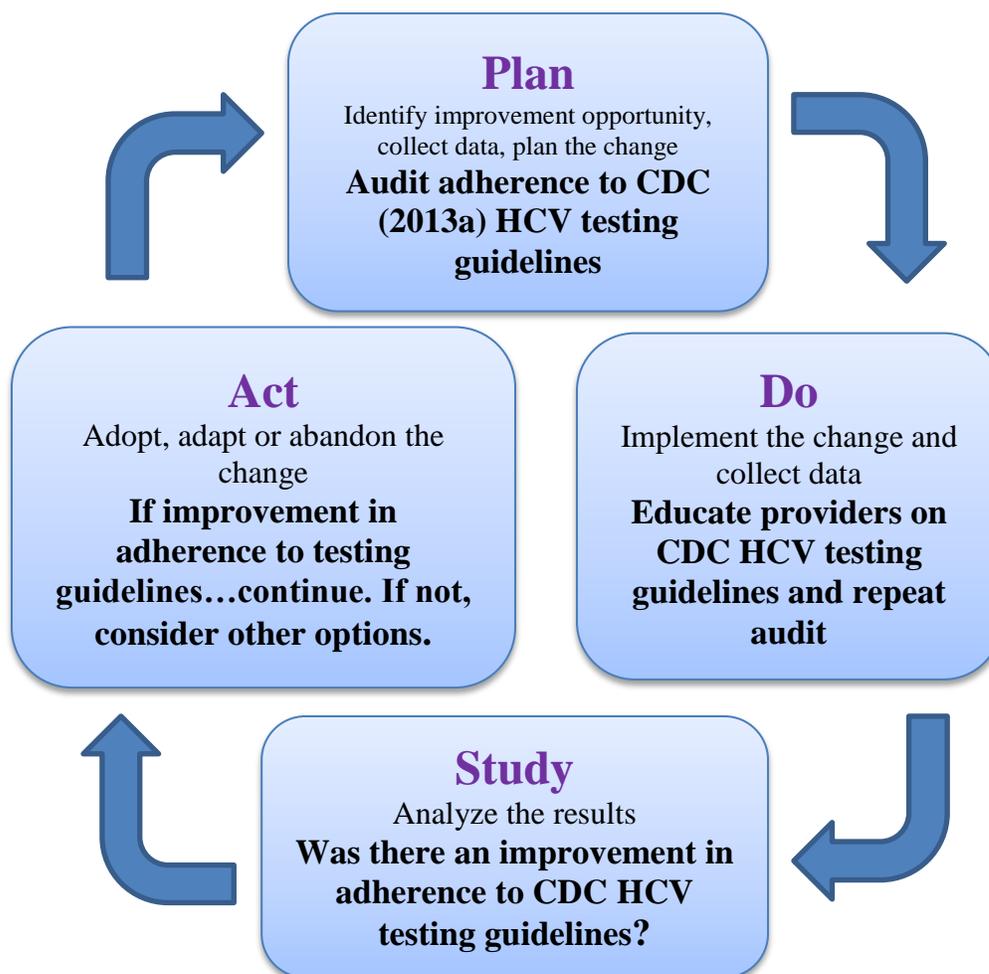


FIGURE 3. *Proposed Plan-Do-Study-Act of Proposed Educational Intervention.*

(Figure modified from diagram retrieved from <https://www.deming.org/theman/theories/pdsacycle>)

Additional studies could be done with inmate intake examinations focusing on HCV risk factors and HCV testing in the Hispanic population to further evaluate any disparity in this population. Lastly, future studies should include inmate education on HCV risk factors in order to halt the chain of infection.

As NPs, and healthcare providers in general, begin expanding their HCV testing practices to achieve compliance with guidelines, the incidence of documented HCV cases will undoubtedly increase. With new treatment protocols recently released, the eradication of this potentially deadly disease is a viable possibility (Kwong & Epstein, 2015). Decreasing a potentially deadly disease will not only decrease healthcare costs but improve health and quality of life.

APPENDIX A
RANDOM NUMBERS TABLE

APPENDIX A. *Random Numbers Table*

Row number	Column number											
	1	2	3	4	5	6	7	8	9	10	11	12
1	20	288	215	98	44	202	323	226	162	262	248	276
2	331	171	204	131	185	39	183	338	209	352	285	333
3	250	142	85	145	348	55	327	137	289	135	146	282
4	259	226	225	215	219	306	267	181	29	328	247	280
5	143	103	64	332	199	215	159	145	84	87	135	250
6	234	261	211	152	181	198	59	179	99	29	106	342
7	360	61	177	310	265	150	23	8	83	122	303	112
8	86	103	313	117	254	284	17	347	296	196	153	251
9	120	191	52	93	297	209	290	251	155	210	47	357
10	6	105	155	77	191	147	356	245	262	36	268	32
11	37	2	259	115	3	24	105	115	130	246	256	61
12	357	180	52	190	311	20	48	348	12	322	223	355
13	326	227	40	93	217	100	336	262	272	83	179	48
14	336	322	174	335	94	358	303	337	253	253	42	163
15	240	213	217	8	184	72	219	136	211	64	154	217
16	289	327	291	216	112	106	147	181	33	311	7	111
17	140	32	297	319	342	15	30	53	54	55	10	139
18	125	81	128	59	121	236	307	264	328	120	247	127
19	351	21	132	172	148	91	93	334	74	126	223	62
20	80	91	98	280	41	146	219	271	248	246	185	179
21	198	255	26	201	330	134	100	19	41	50	192	349
22	80	225	321	260	161	330	260	333	195	145	42	169
23	66	54	140	179	179	46	311	87	340	341	287	98
24	19	185	137	346	163	224	13	72	208	48	124	288
25	281	321	20	16	5	48	70	91	122	305	240	75
26	126	61	317	336	188	184	23	31	174	280	115	88
27	355	267	117	253	186	72	1	221	345	86	89	355
28	321	327	358	78	320	261	187	325	100	91	179	184
29	201	341	29	14	341	63	253	249	226	170	311	127
30	308	233	229	344	215	341	318	334	144	326	70	148
31	195	42	88	337	122	97	84	215	298	168	300	312
32	22	115	136	100	110	73	219	290	133	70	23	55
33	48	190	121	352	200	249	135	55	336	17	263	269
34	175	225	341	307	283	280	359	348	143	230	102	283
35	133	17	293	356	45	151	49	69	334	340	151	251
36	188	43	324	343	104	302	168	92	97	43	321	268
37	133	103	334	241	207	12	208	168	16	153	121	268
38	351	360	102	5	85	226	246	16	155	323	113	260
39	80	354	191	267	197	169	172	348	271	231	40	164
40	299	311	165	41	211	64	281	91	95	186	283	299

Select a row from 1 to 40 and a column from 1 to 12. Use the number at the intersection of the selected row and column.

APPENDIX B

INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

APPENDIX B. *Institutional Review Board Approval Letter*Human Subjects
Protection Program1618 E. Helen St.
P.O.Box 245137
Tucson, AZ 85724-5137
Tel: (520) 626-6721
<http://ocr.arizona.edu/hspp>

Date:	March 13, 2015
Principal Investigator:	Susan Lynn Thompson
Protocol Number:	1502702364
Protocol Title:	PROVIDER IDENTIFICATION OF HEPATITIS C VIRUS (HCV) RISK FACTORS AT INMATE INTAKE TO PRISON
Level of Review:	Expedited
Determination:	Approved
Expiration Date:	March 11, 2016
Documents Reviewed Concurrently:	Data Collection Tools: <i>Thompson Data Collection Tool.docx</i> Data Collection Tools: <i>Thompson Random Numbers Table.docx</i> HSPF Forms/Correspondence: <i>Signature page.pdf</i> HSPF Forms/Correspondence: <i>Thompson IRB Application EDIT 02_25_15.doc</i> HSPF Forms/Correspondence: <i>Thompson VOIF Form 107 EDIT.doc</i> Other Approvals and Authorizations: <i>Corizon Approval Dr M.pdf</i> Other Approvals and Authorizations: <i>Re Thompson DOC New Application.msg</i> Other Approvals and Authorizations: <i>Thompson DOC Approval.pdf</i>

This submission meets the criteria for approval under 45 CFR 46.110, 45 CFR 46.111 and/or 21 CFR 50 and 21 CFR 56.

- The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).
- All research procedures should be conducted in full accordance with all applicable sections of the Investigator Manual.
- The current consent with the IRB approval stamp must be used to consent subjects.
- The Principal Investigator should notify the IRB immediately of any proposed changes that affect the protocol and report any unanticipated problems involving risks to participants or others.
- For projects that wish to continue after the expiration date listed above please submit an F212, Continuing Review Progress Report, forty-five (45) days before the expiration date to ensure timely review of the project.
- All documents referenced in this submission have been reviewed and approved. Documents are filed with the HSPP Office. If subjects will be consented the approved consent(s) are attached to the approval notification from the HSPP Office.

This project has been reviewed and approved by an IRB Chair or designee.
No changes to a project may be made prior to IRB approval except to eliminate apparent immediate hazard to subjects.

APPENDIX C

DEPARTMENT OF CORRECTIONS APPROVAL LETTER

APPENDIX C. *Department of Corrections Approval Letter*DOUGLAS A. DUCEY
GOVERNOR**Arizona Department of Corrections**1601 WEST JEFFERSON
PHOENIX, ARIZONA 85007
(602) 542-5497
www.azcorrections.govCHARLES L. RYAN
DIRECTOR

February 12, 2015

Susan Thompson
College of Nursing
University of ArizonaVia email: Susan.Thompson@corizonhealth.com

Dear Ms. Thompson:

Thank you for your proposed research project entitled *Provider Identification of Hepatitis C Virus (HCV) Risk Factors at Inmate Intake to Prison*.

After review of your request by executive staff, I am pleased to inform you that your proposal has been approved. Since you are a Corizon employee and have received their approval for your project, no further Arizona Department of Corrections involvement is required. However, please do ensure compliance with all appropriate Arizona Department of Corrections and Corizon contract requirements when coordinating your activities.

Sincerely,

A handwritten signature in black ink that reads "Jacob Gable".

Jacob Gable
Bureau Administrator
Planning, Budget and Research

JCG/rlw

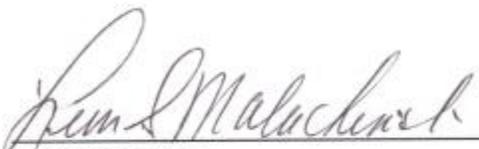
cc: Richard Pratt, Division Director, Health Services

APPENDIX D
CORIZON APPROVAL LETTER

APPENDIX D. *Corizon Approval Letter*

To Whom It May Concern:

This is to certify that I, Leon Malachinski, Site Medical Director at ASPC Lewis, have reviewed and approved the research proposal submitted by Susan Thompson titled, "PROVIDER IDENTIFICATION OF HEPATITIS C VIRUS (HCV) RISK FACTORS AT INMATE INTAKE TO PRISON." Ms Thompson has been granted access to our medical records room and all files identified in her proposal for purposes of this project.



Leon Malachinski
Site Medical Director ASPC Lewis



Date

APPENDIX E
DATA COLLECTION TOOL

APPENDIX F
INTAKE FORMS

ARIZONA DEPARTMENT OF CORRECTIONS

Physical Examination

Sex	Ethnic Group	Height	Weight
TPR		B / P	
Distant R 20 /	Corr. to 20 /	Near	Left
Vision L 20 /	Corr. to 20 /	Vision	Right
Hearing Right WV / 15			Gross Dental Defects
Left WV / 15			

CLINICAL EVALUATION Check each item in appropriate column: (Enter "NE" if not evaluated)		NOR MAL	ABNOR MAL	Notes: (Describe every abnormality in detail. Enter pertinent item number before each comment.)
1.	Normal, Face, Neck, and Scalp / Neck Thyroid			
2.	Nose			
3.	Sinuses			
4.	Mouth and Throat			
5.	Ears - General (Int. & Ext. Canals)			
6.	Drums (Perforation)			
7.	Eyes - General (Visual Acuity, Pupils, EOMS)			
8.	Ophthalmoscopic			
9.	Lungs and Chest (Include Breasts)			
10.	Heart (Thrust, Size, Rhythm, Sounds)			
11.	Vascular System (Varicosities, Femoral Pulse, etc.)			
12.	Abdomen and Viscera (Include Hernia)			
13.	Anus and Rectum (Hemorrhoids, Fistulae) (Prostate if Included)			
14.	Endocrine System			
15.	G - U System			
16.	Upper Extremities / Reflexes (Strength, Range of Motion)			
17.	Feet			
18.	Lower Extremities (Except Feet) (Strength, Range of Motion)			
19.	Spine, Other Musculoskeletal			
20.	Identifying Body Marks, Scars, Tattoos			
21.	Skin, Lymphatics, Parasites			
22.	Neurological			
23.	OB / GYN			
Summary of Physical Defects (or Diagnosis)				

RECOMMENDATIONS

Clinic Referrals	Laboratory Requests		
Work or Physical Classification			
Examiner Signature	Date	Approving Physician Signature	Date

Inmate Name (Last, First M.I.)	ADC Number
Date of Birth	Facility/Unit

ARIZONA DEPARTMENT OF CORRECTIONS

Medical History

Race	Religion	Education	Place of Birth	Age	Sex
Name of Next of Kin		Relationship	Address		
Date of Examination	Physician of Record		Address		

Family History: Has any blood relation (parent, brother, sister, other) or husband or wife had (Write in relationship next to items)

Relation	Age	State of Health	If dead, cause of death	Age of Death	Yes	No	(Check each item)	Relation(s)
Father							had tuberculosis	
Mother							had Syphilis	
Spouse							had Diabetes	
Brothers and Sisters							had Cancer	
							had Heart Trouble	
							had Asthma	
							had Hay Fever, Hives	
							had Epilepsy (fits)	
Children						been insane		

Have you ever had or have you now: (check Yes or No)

	Yes	No		Yes	No		Yes	No		Yes	No
Measles/Chicken Pox			Thyroid Problem			Cyst			Treatment for Nerves		
Diphtheria			Tuberculosis			Cancer			Alcohol Treatment		
Whooping Cough			Asthma			Rupture			Drug Abuse Treatment		
Mumps			Shortness of Breath			Appendicitis			Paralysis (inc. Infantile)		
Scarlet Fever			Pain or Pressure in Chest			Hemorrhoids/Rectal Disease			Gastrointestinal Disorder		
Rheumatic Fever			Chronic Cough			Kidney Stones			Depression		
Head Injury			Palpitation or pounding heart			Blood in Urine			Suicidal Attempt		
Swollen or Painful joints			Jaundice / Hepatitis			Frequent/Painful Urination			Menstrual Disorder		
Breast Pain or Lumps			Gall bladder trouble			Bone Deformity			Bed Wetting		
Frequent or severe headaches			Gall Stones			Joint or other deformity			Skin Rash		
Eye trouble			High blood pressure			Diabetes			Poor Vision		
Running ears			Low blood pressure			Venereal Disease			Hearing Problem		
Sinusitis			Tumor			Seizures			Head Lice		
Hay Fever			Growth			Loss of arm, leg, finger or toe			Other		

Operations	Allergies	Serum, Drugs or Medicine Reaction
Are you taking any medications now? (Including OTC's)		
Significant conditions (including hospitalization(s) in history)		

Staff Member's Signature	Inmate Name (Last, First M.I.)	ADC Number
Title	Date	Date of Birth
		Facility/Unit

ARIZONA DEPARTMENT OF CORRECTIONS NS

Medical History

Name	Religion	Education	Place of Birth	Age	Sex
Name of Next of Kin		Relationship	Address		
Date of Examination	Physician if Present		Address		

Family History: Has any blood relation (parent, brother, sister, other) or husband or wife had (Write in relationship next to items)

Relation	Age	State of Health	If dead, cause of death	Age of Death	Yes	No	(Check each item)	Relation(s)
Father							had tuberculosis	
Mother							had syphilis	
Spouse							had Diabetes	
Brothers and Sisters							had Cancer	
							had Heart Trouble	
							had Asthma	
							had Hay Fever, Hives	
Children							had Colic (if male)	
							been insane	

Have you ever had or have you now: (check Yes or No)

	Yes	No		Yes	No		Yes	No		Yes	No
Measles/Chicken Pox			Thyroid Problem			Cyst			Treatment for Nerves		
Diphtheria			Tuberculosis			Cancer			Alcohol Treatment		
Whooping Cough			Asthma			Rupture			Drug Abuse Treatment		
Mumps			Shortness of Breath			Appendicitis			Paralysis (inc. Infantile)		
Scarlet Fever			Pain or Pressure in Chest			Hemorrhoids/Rectal Disease			Gastrointestinal Disorder		
Rheumatic Fever			Chronic Cough			Kidney Stones			Depression		
Head Injury			Palpitation or pounding heart			Blood in Urine			Suicidal Attempt		
Swollen or Painful joints			Jaundice / Hepatitis			Frequent/Painful Urination			Menstrual Disorder		
Breast Pain or Lumps			Gall bladder trouble			Bone Deformity			Bed Wetting		
Frequent or severe headaches			Gall Stones			Joint or other deformity			Skin Rash		
Eye trouble			High blood pressure			Diabetes			Poor Vision		
Running ears			Low blood pressure			Veneral Disease			Hearing Problem		
Sinusitis			Tumor			Seizures			Head Lice		
Hay Fever			Growth			Loss of arm, leg, finger or toe			Other		

Cyanation	Allergies	Serum, Drugs or Medicine Reaction
Are you taking any medications now? (including OTC's)		
Significant conditions (including hospitalization(s)) in history		

Staff Member's Signature	Inmate Name (Last, First M.I.)	ADU NUMBER
Title	Date	Date of Birth
		Facility Unit

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