A Description of Hepatitis C Infection on Prince Edward Island

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Table of Contents

List of Tables

List of Figures

List of Abbreviations

ALT	Alanine aminotransferase
Anti-HCV	HCV antibodies
CD	Communicable disease
CPHO	Chief Public Health Office
DAA	Direct-acting antivirals
EIA screen	Enzyme immunoassay screen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human immunodeficiency virus
IDU	Injection drug use
IV	Intravenous
LAC PHN	Los Angeles County Public Health Nursing
MRN	Medical records number
MSM	Men who have sex with men
PCR	Polymerase chain reaction
PEI	Prince Edward Island
PHAC	Public Health Agency of Canada
PHAS	Population Health Assessment and Surveillance
PO	Prescription opiates
PWID	Persons who inject drugs
RIBA	Recombinant immunoblot assay
RNA	Ribonucleic acid
SVR	Sustained viral response
WHO	World Health Organization

Abstract

In Prince Edward Island (PEI), it was estimated that there were up to 800 people infected with Hepatitis C Virus (HCV) since testing began in 1991; however, the exact number of those still actively infected was not known. The purpose of this study was to determine (a) the prevalence of active HCV cases; (b) the number of acute/chronic cases at diagnosis; (c) the demographic/risk profile of HCV cases; and (d) the risk factors significant to the diagnosis of acute cases on PEI. This study used a descriptive, correlational, quantitative design using retrospective chart review data and laboratory data for all laboratory confirmed HCV cases living on PEI from 1991 to 2016. Approximately 430 cases remain actively infected on PEI. Intravenous drug use was the most prevalent risk factor, 65% of cases were diagnosed between 30 and 59 years of age, more males were diagnosed than females, and females (34 years) were diagnosed at a significantly younger age than males (37 years). Limited laboratory data allowed 388 cases to be diagnosed into acute and chronic cases. Eighteen percent were acute; 68% were chronic. The younger the case was in age the greater the probability of the case being acute. There are still many people on PEI who would benefit from HCV treatment. Development of a broader case definition for acute cases in PEI may improve the information available to identify at-risk people and plan action for prevention of HCV.

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CHAPTER 1

The Research Problem

In this first chapter, the research problem is described, risk factors are presented, and the relevance to nursing is discussed. Lastly, the study purpose and research questions are introduced.

Background

Hepatitis C virus (HCV) is a global public health concern. The World Health Organization (WHO) estimates that 71 million people globally have chronic HCV infection (WHO, 2017). It is estimated that approximately 250,000 Canadians are infected with HCV (Trubnikov, Yan, & Archibald, 2014; Wong & Lee, 2006). Up to 20% of people who have contracted HCV will go on to clear the virus without treatment. Those who do not clear the virus may eventually develop cirrhosis, end-stage liver disease, and hepatocellular carcinoma (Wong & Lee, 2006). As the early signs and symptoms of HCV are not easily recognised, it is estimated that up to 44% of Canadians infected with HCV may not be aware (Trubnikov et al., 2014). Myers et al. (2014) estimated, in their modelling study, that in 2035, Canadian health care costs related to HCV will reach close to 260 million dollars. Along with this significant financial burden, persons with HCV may suffer loss of employment productivity, decreases in mental health, and overall quality of life (DiBonaventura et al., 2014; Myers, Liu, & Shaheen, 2008; Sievert et al., 2014; Stewart, Mikocka-Walus, Harley, & Andrews, 2012; Werb et al., 2011). The future impact of HCV on the health care system on Prince Edward Island (PEI) and the burden to persons with HCV has yet to be determined. Canada signed on to the World Health Organization (WHO)'s Global Viral Hepatitis Strategy, with the goal of eliminating viral hepatitis as a public health threat by 2030. This study provides some data that may help predict the present burden

and future impact that HCV will have on the PEI health care system, as well as the burden to persons with HCV.

In PEI, it was estimated that there are up to 800 people infected with HCV; however, due to successful treatment of cases, and some cases having cleared the virus, the exact number of those still actively infected is not known. In 2014, PEI had the highest number of new cases of HCV on record in PEI, however, in 2015, PEI's rate of new HCV cases decreased by almost half compared to the previous year. Prior to 2015, PEI had seen an upward trend in the number of new HCV cases, where nationally this trend was decreasing (Morrison, 2014). It was unknown if new cases testing positive were due to recent transmissions or if they were infections that occurred in the past and were now being identified. In 2011, the Public Health Agency of Canada (PHAC) introduced a national case definition separating acute or recently acquired cases of HCV from chronic or cases acquired in the past; this definition is described in detail in Chapter 3. Based on this case definition, provinces can use a standardised approach to differentiate the recently acquired cases from those acquired in the past. PEI was one of several provinces that did not apply the definition to differentiate acute cases from chronic cases (Dr. C. Sanford, personal communication, July 15, 2016; PHAC, 2017a). Information regarding the number of cases that are due to recent transmission, the risk factors associated with this transmission, as well as the cases who have been infected for a period of time, can be used to make decisions regarding health policy for prevention and treatment of HCV on PEI (Hajarizadeh, Grebley, & Dore, 2012). Informed policy decisions regarding HCV are intended to decrease the burden on individuals, as well as the health care system.

Risk Factors

The major risk factors for HCV have not changed significantly since the virus was discovered in 1989 (Mahajan, Liu, Klevens, & Holmberg, 2013; PHAC, 2009; Tillmann &

Manns, 1996). Blood transfusion was initially one of the most common risk factors until the screening of blood products was introduced in 1992 (Mahajan et al., 2013). In a study by the PHAC (2009), the most common risk factor in Canada was identified as the use of intravenous (IV) drugs. A study by Stratton, Sweet, Latorraca-Walsh, and Gully (1997) described the cases of HCV on PEI from 1990-1995. At that time, the use of IV drugs and blood transfusions were the most common risk factors on PEI as well (Stratton et al., 1997). Several studies have identified other risk factors that must be considered when assessing clients for risk of acquisition of HCV. These include: (a) being 20-59 years of age; (b) being male; (c) having a history of IV drug use (DU) and snorting drugs; (d) having household contact or sexual contact with an HCV-infected person; (e) being born to a mother who was HCV-infected; (f) receiving hemodialysis; (g) having a history of hemophilia; (h) receiving a blood transfusion or organ transplant prior to 1992; (i) having a history of incarceration; (j) receiving tattoos or piercing from an unregulated source; (k) being a health care worker with an occupational needle stick; and (l) having a history of dental surgery or major surgery prior to 1992 or in a country with poor infection control practices (Mahajan et al., 2013; Mast et al., 2005; Myers, et al., 2008; Porter, Lusk, & Katz, 2014; Wenger, Rottnek, Parker, & Crippin, 2014). In PEI, the risk profile of HCV cases who had acquired the virus recently (acute) versus those who acquired the virus in the past (chronic) was not known. Applying the PHAC (2016b) case definition in this study made it possible to compare these risk profiles.

Relevance for Nursing

The goals of public health practice are to prevent disease and promote health with the ultimate goal of prolonging the life of the population as a whole (WHO, 2015). Public health professionals, including nurses, are focused on preventing the transmission of HCV along with promoting health for those who are infected. Nurses provide access to care that includes

prevention services, as well as health promotion activities (WHO, 2015). Nurses have the potential to affect transmission by being knowledgeable about HCV in their area and being able to counsel and educate clients at point-of-care (Frazer, Glacken, Coughlan, Staines, & Daly, 2011; Keats et al., 2015; Krebbeks & Cunningham, 2013; Lewis et al., 2010; Nyamathi et al., 2013; Nyamathi et al., 2015; Olson & Jacobson, 2011). Nurses may be the only point of contact with the health care system for clients at risk of acquiring HCV including those living in rural areas with limited health resources (Krebbeks & Cunningham, 2013). Screening or testing for HCV can be initiated by nurses and ordered by nurse practitioners who identify a client at risk for HCV. With new treatments that can cure the disease, nurses will provide guidance through the treatment process for those infected with HCV.

To provide interventions effectively and efficiently, data relevant to the particular population must be used in planning. This study created a complete retrospective electronic dataset for HCV on PEI which can aid in analysis to make informed, evidence-based decisions.

Purpose and Research Questions

The purpose of this study was to create an electronic dataset from the charts of all HCV positive cases living on PEI and diagnosed on PEI since testing began in 1991, and included laboratory data from Health PEI (HPEI) for each case, to determine (a) the prevalence of active HCV cases; (b) the number of acute and chronic cases at diagnosis; (c) the demographic profile and risk factors of those infected with HCV; and (d) the risk factors significant to the diagnosis of acute cases on PEI.

The research questions for this study were:

1. How many people living on PEI have active HCV infection (acute and chronic) diagnosed by positive laboratory tests (polymerase chain reaction [PCR] or viral load)?

2. According to the Public Health Agency of Canada's (2011) case definition for HCV acute and chronic cases, how many of PEI's HCV cases were diagnosed when they were acute and how many were chronic?
3. (a) What were the risk factors and demographics for all HCV cases diagnosed on PEI (acute, chronic, and resolved)? (b) Which demographics/risk factors have a significant association with the diagnosis of acute HCV?

CHAPTER 2

Literature Review

Chapter 2 includes a review of the literature regarding various aspects of HCV as they pertain to the current study. The search strategy and the natural history are described and then, the risk factors, testing methods, and treatment are discussed. Lastly, the conceptual model that provides context and a framework for the study is presented.

Search Strategy

There has been extensive literature generated about hepatitis C infection since it was discovered in the 1980s. A review of the literature was conducted to examine the state of knowledge regarding HCV related to acute and chronic infections, risk factors, up-to-date testing and treatments, and the current surveillance data for HCV infections in Canada and Prince Edward Island. Studies were limited to those that were peer-reviewed and written in the English language.

The following computerized databases were searched: CINAHL, PubMed, and Medline as well as the UPEI Library Onesearch tool. The search was limited to the years 1990 to 2018, with the most up to date references utilized for each topic. Also, references in the retrieved literature added to the review. The search strategy involved combining the following terms: (“hepatitis C OR HCV OR hepatitis C infection OR hep C”) AND "case definitions" OR "acute" OR " chronic" OR " risk factors" OR "location" OR "drug use" OR "IVDU" OR "intravenous drug use" OR "PWID" OR "persons who inject drugs" OR "blood and blood products" OR "blood transfusions" OR "gender" OR "race" OR "rural" OR "sexual partner" OR sexual contact" OR "sexual transmission" OR "family member" OR "household contact" OR "vertical transmission" OR "dialysis" OR "hemodialysis" OR "hemophilia" OR " prison" OR "jail" OR "occupational" OR "health care worker" OR "needle stick" OR " tattoo" OR " surgery" OR

"dental surgery" OR "homelessness" OR "mental health" OR "mental illness" OR "testing" OR "screening" OR "lab testing" OR "treatment" OR "medication" OR "cost" OR "burden" OR " quality of life" OR "impact" OR "nursing" OR "public health" OR "policy" OR "Canada" OR "Prince Edward Island". Due to a large amount of literature in this area, the search was narrowed to the studies and literature that related most to the research questions and the proposed study.

Hepatitis C Infection

Hepatitis is a viral infection that causes inflammation of the liver. Hepatitis C virus was identified in the late 1980s (Wong & Lee, 2006). Before it was discovered as HCV, the virus was called hepatitis non-A non-B and identified as an acute hepatitis infection related to blood transfusions (Trepo, 2014). There are seven genotypes of HCV. The most predominant genotypes around the world and in Canada are type 1, which includes 1a and 1b, with approximately 75% of cases in Canada, and genotype 3 and 3a at between 10 and 25% of cases in Canada. Genotypes 2 and 4 are also seen in Canada but in much smaller numbers. Genotypes 5 and 6 are found in South sub-Saharan Africa and East Asia respectively. In the recent past, identification of genotypes was necessary for treatment, as some therapies were more effective for some genotypes than others. With new pan-genotypic medication, the genotype is becoming less important for treatment; however it is still useful in identifying transmission patterns (Messina et al., 2015).

HCV Infection Natural History

Worldwide it is estimated that 2.8% of the population is infected with HCV (Hanafiah et al., 2013). In Canada, this estimate is lower at .5% to1% of the population infected with HCV (PHAC 2017a; Remis, 2009; Rotermann, Langlois, Andonov, & Trubnikov, 2013; Trubnikov et al., 2014).

There are varying percentages used in the literature, but approximately 15 to 45% of persons infected with HCV will spontaneously clear the virus within the first 6 months of infection (Myers, Shah, Burak, Cooper, & Feld, 2015; PHAC, 2017a; Wong & Lee, 2006; WHO, 2014). Those who do not clear the virus and remain HCV PCR/viral load positive, become chronically infected. A case of HCV infection is considered chronic when the virus is detectable in the blood for longer than 6 months; however, clearance has been known to happen up to 2 years after infection (Micallef et al., 2006). Several studies have looked at the host factors that contribute to clearing the HCV virus. These factors are still not well understood; however, many recent studies examining the different genotypes and host immunity factors have been completed to better understand this occurrence (Deterding et al., 2013; Deutsch, Papadopoulos, Hadziyannis, & Koskinas, 2013; Funk, Kottilil, Gillam, & Talwani, 2014; Grebely et al., 2013, 2014; Hoffmann et al., 2015; Ishikane et al., 2014; Lai et al., 2013; Maor et al., 2013; Noureddin et al., 2013; Osburn et al., 2014; Rebbani et al., 2014; Riva et al., 2014; Sacks-Davis et al., 2015; Xiao et al., 2015). Other host factors such as being female and the occurrence of acute symptoms of illness upon infection with HCV have also been found to be related to viral clearing (Micallef et al., 2006). Persons who are co-infected with Human Immunodeficiency Virus (HIV) at the time of infection with HCV are less likely to clear the virus. They may also have poor outcomes related to their HCV infection (Bräu et al., 2007; Lin, Weinberg, & Chung, 2013).

For persons who do not clear the virus, it is estimated that up to 85% will become carriers and could go on to develop liver disease. Liver disease includes various symptoms and outcomes including extrahepatic morbidities, cirrhosis, liver failure, and hepatocellular carcinoma (Cacoub et al., 2016; Chen & Morgan, 2006; Negro et al., 2015).

Hepatitis C virus is thought to lead to liver disease in approximately 30% of those who have persistent infection (Wong & Lee, 2006). However, there are longitudinal studies over

several decades that have not shown this level of morbidity. In fact, Allison et al. (2012) and Seeff et al. (2000) have stated that the full impact of HCV morbidity and mortality may not be realized until a person has been infected 30 to 40 years. Thus, the full impact of HCV in the population that is infected is yet to be seen. Recent studies have also discussed that HCV may not only affect the liver, but may have extra hepatic effects such as cardiovascular disease, renal disease, and diabetes, as well as having an impact on mental and neurological health. It is thought that these extra hepatic effects may be related to inflammation and the immune system response (Cacoub et al., 2016; Negro et al., 2015; Petta et al., 2016; Yarlott, Heald, & Forton, 2017; Younossi et al., 2014).

Risk Factors

Hepatitis C virus is transmitted by direct blood-to-blood contact. It has also been documented to be transmitted by other less efficient modes. Percutaneous transmission, either through blood transfusions or sharing of IV paraphernalia, has been demonstrated to be the most effective means of transmission (Hanafiah et al., 2013; Kwong et al., 2012; Loayza & Schumann, 1999; Micallef et al., 2014). Additional factors that impact the acquisition of HCV include: gender/sex, age, race, postal code (region), having household/sexual contact, being born to a mother who is HCV infected, receiving hemodialysis, having a history of hemophilia, having a history of incarceration, being a health care worker with an occupational needle stick, receiving a tattoo or piercing from an unregulated source, having a history of dental surgery or major surgery, and being homeless/having mental health issues.

Received blood transfusion or organ transplant before 1992. Before 1992, there was no screening mechanism for HCV (Engle et al., 2014; Macdonald, O'Brien, & Delage, 2012; O'Brian, 2015). Donahue et al. (1992) found the risk of becoming infected after a blood transfusion before the screening of blood for HCV to be 3.84%. According to O'Brian, the

present risk of acquiring HCV from receipt of a unit of blood in Canada is 1 in 6.2 million. This risk is due to donor testing that may take place while the donor is in the window period of HCV infection. During the window period of 1 to 2 weeks from infection with the virus, a person may be infected; however, it is undetectable in the laboratory testing (O'Brian, 2015).

When HCV infection is discovered in a blood donor, a trace back procedure is initiated in order to contact and test any recipients who may have been exposed. There is still debate regarding the use of organs from donors who are HCV positive. However, because it is now an era of organ shortage and new medications can provide cures for HCV, organs from infected donors may be utilised more readily than in the past (Coilly & Samuel, 2016). In 2007, the prevalence of those in Canada who were HCV positive due to blood transfusion was 11%. Each year this number is expected to decrease and by 2030 is projected to be zero (Remis, 2009).

History of IV drug use and snorting drugs. Since HCV screening of the blood supply was introduced in 1992, the leading cause of HCV transmission has become sharing of drug paraphernalia such as needles, syringes, and other equipment (Remis, 2009). The I-track Study Phase III (PHAC, 2014) predicted that the lifetime risk of exposure to HCV for persons who inject drugs (PWID) in Canada is 68%. Injection drug equipment has been the focus of harm-reduction activities such as needle syringe programs that provide clean equipment to reduce the risk of transmitting HCV and other blood-borne diseases (Strike et al., 2015). Hepatitis C virus can be transmitted efficiently and easily by blood-to-blood contact; thus not only needles but the other equipment used to prepare drugs for injection, such as the cookers, wash, and filters can also become contaminated when reused (PHAC, 2016b; Strike et al., 2015). In recent harm reduction guidance documents, there has been a focus on the risk of smoking and snorting drugs as well. The mucosa of the mouth and nose are also areas that may crack and bleed; therefore sharing equipment can be a risk for transmission of the virus (Strike et al., 2015).

Bruneau, Roy, Arruda, Zang, and Jutras-Aswad (2012) performed a study to determine if the type of drug injected influences the risk of acquiring HCV. They found that those injecting prescription opiates (PO) as opposed to other drugs, were at a higher risk of becoming infected with HCV. They hypothesised that this might be due to the increased amount of manipulation required to prepare PO for injection such as crushing and filtering. Multiple injections are required to receive one dose of PO which provides opportunity for infected blood to be introduced into the filter. After injecting a dose, the residual in the filter may contain enough opioid substance to produce a minimal effect. Filters with residual may be kept for later use and shared among injection partners providing an opportunity for HCV transmission. Another group injecting illegal drugs are persons who use anabolic steroids or those using other performance-enhancing drugs (Ip, Yadao, Shah, & Lau, 2016). Ip et al. note that anabolic steroid users are at approximately 3.5 times greater risk for acquiring HCV than the general public, but have less than 2.5 times the risk of those who use other types of illicit drugs.

Even though PWID know that they may become infected when sharing needles and equipment with someone who is infected with blood borne pathogens, their daily concerns include other factors that often accompany drug use such as homelessness, poverty, mental illness, and potential incarceration. The impacts of HCV infection may be seen as too far in the future to be an immediate priority (Fitzgerald, Lundgren, & Chassler, 2007).

Remis (2009) reported that approximately 60% of all new hepatitis C cases with known risk factor information in Canada were PWID. Injection drug use is now the leading cause of transmission in developed countries. In developing countries, injection drug use (IDU) is also a major risk factor, as is the use of improperly sterilized or reused equipment during medical procedures (Lavanchy, 2009; Mahboobi, Porter, Karayiannis, & Alavian, 2013; Norma, 2007; Pereira et al., 2013; Tillmann & Manns, 1996).

Gender/Sex. Canadian HCV statistics compiled by PHAC reported that from 2005 to 2012 males had higher rates of HCV than females. This rate is consistent in each year of this study (PHAC, 2016b). However, there are other studies that describe a higher prevalence in women (Amin-Esmaeili, Rahimi-Movaghar, Razaghi, Baghestani, & Jafari, 2012; Sweeting et al., 2009). The Public Health Agency of Canada (2009) studied acute cases of HCV in Canada and found that females tended to be infected at a younger age than males. Fitzgerald et al. (2007) and Scheidell et al. (2015) looked at IV drug use sharing behaviours of females and found that women are more likely introduced to drug use by men, usually men with whom they are having a relationship. Power dynamics may interfere with the ability of females, especially those who are younger in age, to engage in harm reduction activities and therefore they may share injecting equipment. Sweeting et al. also hypothesised that women might not have as much control over their injecting environment and may be more likely to inject with older men. There is little discussion in the literature regarding the impact of being transgender on the risk of acquiring HCV. However, in one study carried out in Italy, Luzzati et al. (2016) found the rate of HCV was higher in people who transitioned male to female and were also HIV positive.

Age. All age groups are at risk of acquiring HCV. In Canada in 2014, the highest rate of HCV was found in males in the 40 to 59 year age category. The second largest rate was in the 25 to 29 years of age category. Females tend to be younger when diagnosed. The largest female group was in the 20 to 24 year age group, followed closely by 25 to 29 year olds (PHAC, 2017a).

Race. Indigenous Canadians and immigrants who come from HCV endemic countries are more at risk of HCV infection than the general population in Canada (Chen & Krahn, 2015; PHAC, 2009; PHAC, 2017a). Areas of the world that have endemic rates of HCV include Eastern Europe; Sub-Saharan Africa; Central; East and South Asia; North Africa; the Middle East; and Oceania, which includes Australia and some islands in the Central and South Pacific

Ocean (PHAC 2016a). All immigrants are not screened for HCV upon entry into Canada, so it is possible that they may be infected and are not aware. Immigrants from endemic areas may have a greater impact on the Canadian health care system, as many are infected as children; therefore, complications from the disease that can occur 10 to 30 years after infection may begin at a much younger age. Consequently, this group may have more years of morbidity due to HCV than someone who was infected in Canada at an older age due to risk behaviours such as IV drug use (Chen & Krahn, 2015).

Indigenous peoples in Canada, as in other parts of the world, experience both social and health inequities; consequently, there is a higher burden of acute and chronic diseases. In several studies done in large Canadian centres, Indigenous peoples have been found to have a disproportionately higher rate of IV drug use and HCV infection (Firestone, Tyndall, & Fischer, 2015; Turnbull, Muckle, & Masters, 2007). The Enhanced Hepatitis Strain Surveillance System (PHAC, 2009) found that Indigenous peoples had 5.5 times the rate of acute HCV infection than the general Canadian population. The reason for this is not totally clear, although the rate of homelessness and IV drug use in this population is reported to be greater than the general population in Canada (Firestone et al., 2015; Turnbull et al., 2007). A higher rate of harm from IV drug use, including HCV infection, was also found in Indigenous populations in other countries such as the United States, Australia, and New Zealand (Firestone et al., 2015; Suryaprasad et al., 2014).

Postal code (region). It is possible to generally identify where people with HCV are living at diagnosis using the Canadian postal code, specifically urban versus non-urban areas. In general, it is thought that the majority of those infected with HCV live in larger urban areas. In many studies in Canada, areas targeted for study include Vancouver, Montreal, and Toronto (PHAC, 2009, 2014). However, Suryaprasad et al. (2014) conducted a study between 2006 and

2012 and examined the incidence of acute HCV among young persons. They identified that the annual incidence was greater than 2 times higher in non-urban compared to urban jurisdictions in the areas of the United States of America that were studied. They hypothesised that those who inject drugs in rural areas might have less access to testing and harm reduction programs. They may also face greater stigma and lack of anonymity than those in an urban centre. Persons who inject drugs in non-urban areas may be harder to reach with harm reduction and educational programs than urban centres due to lack of public transportation and programs within walking distance. In urban centres, harm reduction programs may be more easily accessed, and HCV risk activities can be reduced (Havens, Oser, & Leukefeld, 2011).

Household contact or sexual contact of an HCV-infected person. The risk of household contacts and sexual contacts of HCV cases remains controversial (Gorgos, 2013; Napoli, Fiore, Vella, Fera, & Schiraldi, 1993; Neumayr, Propst, Schwaighofer, Judmaier, & Vogel, 1999; Norma, 2007; Orlando & Lirussi, 2007; Tohme & Holmberg, 2010). However, it is generally accepted that these contacts have a low but real risk of contracting HCV, and these groups are considered to have risk factors for acquiring HCV (Loayza & Schumann, 1999; Myers et al., 2015; Payne et al., 2014; PHAC, 2016a). Household contacts can reduce or eliminate their risk by not sharing personal-care items such as razors, toothbrushes, and nail-care instruments or other items that pose a risk of percutaneous exposure (PHAC, 2016b).

In a study by Neumayr et al. (1999), it was found that spouses and long-term sexual partners of those with HCV had a 2.5% risk of infection with the virus. The length of the sexual contact and cohabitation did not appear to increase the risk of acquisition of the virus. However, the risk will increase with sexual contact in the presence of "high risk" activities, which include sex with multiple partners, sex during menses, anal sex, and other types of sexual activities that cause damage to the anal, vaginal, or oral mucosa. In comparison to other percutaneous

exposures to HCV-infected blood, household and low-risk sexual contacts are considered inefficient methods of transmission (Moyer, 2013). In studies of men who have sex with men (MSM) who are HIV positive, there has been evidence of an increased risk of HCV infection in this population (Fierer et al., 2011; Le Talec, 2013; Myers et al., 2009; Schmidt et al., 2011; Tohme & Holmberg, 2010).

Being born to a mother who was HCV infected. Vertical transmission of HCV can occur from a pregnant mother who is infected with HCV to her unborn child. It is estimated that mothers who are infected with HCV at the time of birth have a 4% to 6% chance of transmitting the virus to their child. Transmission can occur in utero, during childbirth, and after birth (Garcia-Tejedor et al., 2015). The greatest risk of transmission is related to the viremic level of the mother at the time of childbirth, particularly in mothers who are co-infected with HIV (Benova, Mohamoud, Calvert, & Abu-Raddad, 2014; Garcia-Tejedor et al., 2015; Mast et al., 2005; Thomas, Newell, Peckham, Ades, & Hall, 1998). The use of intrauterine monitoring of the infant or the exposure of the infant's mucous membranes to the mother's blood during childbirth may also increase the risk for infection (Garcia-Tejedor et al., 2015; Mast et al., 2005). Infants should not be tested before 2 months of age, as the mother's antibodies may still be detected in the infant's blood before this time. As well, it may take up to 18 to 24 months before infection can be detected. If early testing is done, it should be repeated at 24 months to allow for the possibility of late seroconversion or clearance (Micallef et al., 2006). In most cases, children will not have symptomatic disease; however, it has been observed that their liver enzymes may be slightly elevated (Healy et al., 2001; Mast et al., 2005).

Receiving hemodialysis. Persons receiving hemodialysis are at an increased risk of infections of the blood due to the vascular access points required to perform hemodialysis. In the past, the prevalence of HCV in the dialysis population has been anywhere from 10 to 65%

(Griveas et al., 2007). Improvements in infection prevention and control processes in the dialysis units, screening of blood, and the use of recombinant human erythropoietin to decrease the need for blood transfusions have caused a significant decrease in the rate of HCV in dialysis clients (Griveas et al., 2007; Szücs et al., 2009).

History of haemophilia. People suffering from haemophilia lack certain clotting factors. Clotting factors are isolated from plasma and given to these individuals to treat this disorder. The clotting factors, which were isolated in the 1980s and 90s, were created from pooled donations of plasma from 20,000 to 30,000 donors. At this time, there was no test for HCV and only screening for hepatitis B virus (HBV) was available. In 1985, methods were introduced to inactivate all viruses in the plasma pools used to create the clotting factors. This development dramatically reduced the risk of contracting HCV. Unfortunately, the rate of HCV infection for those who received the clotting factors in the early 1980s was almost 100% (Lassila & Makris, 2016).

History of incarceration. There are federal and provincial correctional facilities throughout Canada. Inmates who serve a sentence greater than 2 years are housed in federal facilities. Inmates whose sentence is less than 2 years are in the provincial facilities (Correctional Service Canada, 2013). In Canada, approximately 19.2% to 39.8% of the population in the correctional system is HCV positive (Skoretz, Zaniewski, & Goedhuis, 2004). This rate is similar to numbers noted in the US and other parts of the world (Crofts et al., 1995; Wenger et al., 2014). Many of the risk factors in the correctional facilities are similar to those for the general public; however, inmates are 10 times more likely to be HCV positive than the general public (Wenger et al., 2014). Previous incarceration increases the odds of HCV infection, and the risk increases with each month spent in a correctional facility (Skoretz et al., 2004).

Approximately 25% of inmates report using IV drugs while incarcerated (Larney et al., 2015; Poulin et al., 2007; Skoretz et al., 2004; van der Meulen, 2017; Webster, 2012; Wenger et al., 2014). Even though drugs are available in correctional facilities, paraphernalia is scarce; therefore, inmates are more likely to share equipment regardless of HCV status (Skoretz et al., 2004). It is estimated that 45% of inmates in Canada receive tattooing performed in correctional facilities. These tattoos are not likely to be done with properly sterilised equipment and HCV is readily transmitted through contaminated tattooing equipment (Larney et al., 2015; Poulin et al., 2007; van der Meulen, 2017; Webster, 2012). In other countries, there are very effective programs to provide clean equipment for drug use and tattooing in some correctional facilities; however, this type of programming is controversial as it can be seen as the correctional system condoning illegal behaviours (Skoretz et al., 2004; Webster, 2012)

Health care worker with an occupational needle stick. Health care workers (HCW) provide care to a range of patients in many different settings. During the care of patients, there are risks of contact with blood and body fluids. If a health care worker sustains a percutaneous injury with a contaminated instrument or needle from a person who has active HCV, he/she has about a 2% chance of becoming infected with HCV (Ramsay, 1999; Rischitelli, Lasarev, & McCauley, 2005). There are various factors that increase this risk, such as being injured with a large gauge hollow bore needle that was in the patient's blood vessel, a deep tissue injury, and a patient with a higher viral load. The HCW will be at higher risk of infection if he/she has had multiple exposures in a high HCV prevalence population (Medeiros et al., 2012; Memon & Memon, 2002; Rischitelli et al., 2005; Yazdanpanah et al., 2005). The risks involved with providing care to people with blood borne pathogens like HCV have been mitigated by infection prevention and control practices such as Routine Practices (previously called Universal

Precautions) and sharps safety programs, which are the standard of care in Canada (Medeiros et al., 2012; Montella et al., 2002; PHAC, 2017b).

Tattoo or piercing from an unregulated source. Tattooing by unregulated sources, such as in correctional facilities and homes where unsterilized and reused equipment and ink are utilised, has been shown to be an independent risk factor for acquisition of HCV (Carney, Dhalla, Aytaman, Tenner, & Francois, 2013; Tohme & Holmberg, 2012). There does not seem to be a connection between HCV infection acquisition and regulated tattooing establishments, who use sterilised, or single use equipment and ink (Tohme & Holmberg, 2012).

History of dental surgery or major surgery. Hepatitis C infection is found in immigrants as well as others who have had dental or medical surgeries or procedures in countries where instruments may be reused or not properly sterilized (PHAC, 2011). The acquisition of HCV by dental or major surgery is highest in the Middle East, South-East Asia, and the Western Pacific (Lavanchy, 2009; Mahboobi et al., 2013). In a review by Hatia, Dimitrova, Skums, Teo, and Teo (2015), it was noted that nosocomial transmission does happen in developed countries as well, particularly through HCWs infected with HCV who are using IV drugs in the workplace, tampering with injectable opioids, and contaminating the vial.

Homelessness and mental health issues. New HCV infections often occur in subpopulations that are difficult to target with traditional prevention programs, including those with multiple co-morbid conditions such as mental health disorders and other addictions (PHAC, 2011). Many authors have shown the relationship between unstable housing and HCV acquisition (Corneil et al., 2006; Gelberg et al., 2012; Kim et al., 2009; Wright, Tompkins, & Jones, 2005). Those who are living on the street only have the belongings they can carry. If they cannot carry clean supplies which, depending on how often they inject, may be voluminous they must use what they can access (Roy, Nonn, Haley, & Cox, 2007)

Serious mental health issues and homelessness are often associated. Those with serious mental health issues are more likely to use drugs and alcohol and be homeless or have unstable housing. With mental illness comes the potential for compromised judgement and the possibility of using contaminated injection equipment. Providing sex for drugs, or having unprotected risky sex, are also more prevalent in this population (Carmo, Campos, Melo, Guimarães & Crosland, 2013; Lewis, Allen, & Warr, 2010; Matthews, Huckans, Blackwell, & Hauser, 2008; Paylor & Mack, 2010; Sockalingam, Shammi, Powell, Barker, & Remington, 2010). It has been recommended by Freudenreich, Gandhi, Walsh, Henderson, and Goff (2007) and Sockalingam et al. (2010) that screening for HCV for all those with severe mental illness should be considered.

Screening

It is estimated that 21% to 45% of those infected with HCV may not know their diagnosis (Myers et al., 2008; Myers et al., 2014; Trubnikov et al., 2014; Werb et al., 2011). The United States' Center for Disease Control has recommended screening the entire population born between 1945 and 1965 to discover those who may be infected but are not aware (Moyer, 2013; Wray & Davis, 2015). It is thought that people in this cohort may have been exposed years ago through recreational drug use, medical procedures, or tainted blood or blood products (Smith et al., 2012).

Recently in Canada, the Canadian Task Force on Preventive Health Care (2017) released a screening guidance document for HCV and at this time, recommended voluntary adult screening only for those who have the risk factors previously outlined; however, this continues to be debated. Screening for people at risk for HCV may not be occurring, as many of those at risk are in marginalized populations who may not access the health care system regularly (Ha, Totten, Pogany, Wu, & Gale-Rowe, 2016; Martinello & Matthews, 2015; Schackman et al., 2015; Wray & Davis, 2015).

Testing Methods

Present testing methods for HCV are more sensitive and specific than they were when the disease was discovered in the late 1980s. The recommended testing now involves an enzyme immunoassay (EIA) screen that detects HCV antibodies. The detection of antibodies demonstrates that the body has been in contact with the virus and has generated an immune response. The EIA screening tests have evolved since HCV was discovered. The first generation had a 70% to 80% sensitivity and poor specificity, which increased the number of false positives. The first generation EIA could detect HCV approximately 16 weeks after infection. The EIA screen that is presently being used has a 99% specificity and sensitivity and can detect infection within 4 to 6 weeks of being infected (Villar et al., 2015).

When the EIA antibody screen is positive, it must then be confirmed with a test for the hepatitis C virus. This can be done with a qualitative or quantitative testing method that identifies HCV RNA. All confirmatory testing for HCV on PEI is performed at the QEII Hospital laboratory in Halifax, Nova Scotia. The qualitative polymerase chain reaction (PCR) test was routinely utilized in PEI from 2002-2014 to confirm active infection with HCV. This test is either positive for RNA or negative. In 2014, the testing for PEI changed to a quantitative testing method involving real-time reverse transcriptase PCR (qRT-PCR) which is used to measure viral loads for HCV. If there is a sufficient level of RNA detected, further testing to determine the genotype of the virus can be done. The genotype can determine treatment methods and guide investigations into the transmission of HCV such as when a nosocomial transmission is suspected (Grebely et al., 2015; Villar et al., 2015).

In early infection (within 1 to 3 weeks), viral load is detectable. Generally, RNA testing is done only after the antibody is detected. Thus when someone is tested in the window period of the first 4 to 6 weeks after being infected, they may not screen positive. As noted, the window

was much larger in the early days of EIA testing (up to 4 months), so some who were tested early in their infection in the past may actually be positive and unaware (Villar et al., 2015). On PEI, when the EIA screen is positive but there is no viral load detected, a recombinant immunoblot assay (RIBA) test is done to confirm the EIA screen. The HPEI Provincial Laboratory uses the same blood sample for all testing required for HCV diagnosis. If the EIA screen is positive, the same blood sample is then sent for confirmatory testing. In many other provinces, people are screened and then have to return for a second time to have a confirmatory tested performed (CATIE, *n.d.*).

Villar et al. (2015) noted that there is room for improvement in testing for HCV. New methods are being developed that take less time for results and can be done at the point of care. This would make testing possible for those who do not have contact with the traditional health care system such as persons who are homeless and those in remote locations. As well, education, counseling and early testing can be done in areas where other care is being provided and at-risk individuals may be located such as addiction treatment centres, jails, soup kitchens, and outreach centres (Bajis et al., 2017).

Acute and Chronic HCV

The definition for acute HCV is inconsistent in the literature; in fact, the name acute is not consistently used. There are several other terms that describe acute HCV cases including recently acquired HCV, incident HCV, newly acquired HCV, and early HCV (Hajarizadeh et al., 2012). Unfortunately, there is no test that can distinguish acute HCV infection from chronic infection. Instead, various factors are used to identify acute infection. In a systematic review of the literature, Hajarizadeh et al. found that clinical symptoms along with an increase in liver enzymes and recent conversion from HCV seronegative to HCV-positive are used most commonly to differentiate an acute case from a chronic case. The timeframes and levels for these

criteria differ among the studies reviewed. The most common criterion used to define an acute case was seroconversion from negative HCV antibody to positive HCV antibody within a short timeframe; the timeframe between a negative test converting to a positive test across the studies range from 4 weeks to 4 years. Secondary criteria used by some studies to define acute cases include physical symptoms of hepatitis such as jaundice and elevated liver enzymes. They are considered secondary criteria, as few cases of acute HCV are actually symptomatic (Hajarizadeh et al., 2012; Loayza & Schumann, 1999; Myers et al., 2015; Wong & Lee, 2006), and elevated liver enzymes can occur with a flare-up of chronic HCV infection (Hajarizadeh et al., 2012). The liver enzyme that is assessed is serum alanine aminotransferase (ALT). This enzyme is used to detect liver injury and disease. Hajarizadeh et al. revealed that authors used levels from 2 times greater than the upper normal level of ALT up to 20 times greater than the upper normal level of ALT as the significant value to diagnose acute HCV. Some definitions include three criteria to be an acute case (recent conversion, PCR/viral load positive, and increased ALT level); whereas others only require the recent conversion to HCV antibody positive (Hajarizadeh et al., 2012).

The PHAC has developed a case definition to differentiate acute cases of HCV from chronic cases, but until now PEI has not used it to assess the cases of HCV being reported (Dr. C. Sanford, personal communication, July 28, 2015; PHAC, 2017a). Chronic cases of HCV infection, those infections that have been present for a longer period of time, present the most challenge to the health care system, as the sequelae of HCV infection on the liver and elsewhere in the body occur over time (Duberg et al., 2015; Hajarizadeh et al., 2012; McCombs, Yuan, Shin, & Saab, 2011; Myers et al., 2008; PHAC, 2016b). There are differing definitions of chronic HCV infection in the literature. Chronic HCV can be defined as HCV infection that is present greater than 6 months, or as PHAC's surveillance case definition states, chronic cases are those who have active disease but do not meet the definition for an acute case (PHAC, 2012).

However, detection of acute, recently transmitted HCV infection can provide information on current trends in the transmission of HCV that can guide policy for prevention and management of the disease (Hajarizadeh et al., 2012). Furthermore, there is evidence that early treatment of HCV can produce a greater chance of viral clearance in certain populations such as those who are co-infected with HIV (Boesecke & Rockstroh 2012; Lo, Rsai, Sun, Hung,& Chuang, 2015). In Canada, the majority of national data consist of cases of HCV that are not separated into acute and chronic categories. Provinces report all cases of HCV that have had a positive EIA antibody screen, which includes those who may have since cleared the virus or never shown active infection with PCR/ viral load. This reporting method does not provide a true picture of the burden of illness that chronic HCV presents (Myers et al., 2014; Remis, 2009; Roterman et al., 2013).

Since the case definition (see Methods) was released to the provinces and territories for use in 2011, there has not been a consistent adoption of the case definition across the country. Many provinces are not using the case definition to differentiate between acute and chronic cases, and Ontario is differentiating but using different criteria than those employed by the PHAC (2016b). The PHAC is using many of the commonly used criteria identified in the literature (Hajarizadeh et al., 2012). These include symptoms of HCV that have occurred in the 6 months before laboratory confirmation of HCV, serum ALT greater than 2.5 times the upper normal limit, and seroconversion within 12 months of the previous negative test (Hajarizadeh et al., 2012; PHAC, 2016b). Prince Edward Island has reported only the overall numbers of positive laboratory results for anti-HCV that have been confirmed with a RIBA or PCR/viral load follow up test. All cases for PEI, according to the PHAC case definition, have been reported as “Confirmed Cases- Unspecified” (PHAC, 2016b; PHAC, 2017a). The current study categorises each case so that numbers for PEI can be differentiated at the national level.

It appears that in Canada, the rate of new cases of persons with HCV is on the decline (PHAC, 2016b). In PEI, the trend between 2000 and 2014 appeared to be increasing (Morrison, 2016). We cannot be sure if this is due to new acute cases occurring or the discovery of old or chronic cases that have been acquired in the past and are now just being tested. Hajarizadeh et al. (2012) noted that the use of a consistent case definition for acute HCV allows the evaluation of transmission patterns for HCV infection, the development of prevention measures, and the evaluation of cases for timely treatment.

Treatment

There are many recent and ongoing developments in the treatment of HCV. Until very recently, the best treatment for hepatitis C was pegylated interferon combined with ribavirin. This treatment was usually required for 9 to 12 months and the success rate varied depending on the HCV genotype. The side effects of treatment were debilitating to the extent that self-care and working were often not possible. The duration of treatment combined with the side effects made treatment impossible for many with HCV (Arora et al., 2010; Meyer et al., 2015).

Health Canada approved the first direct-acting antiviral (DAA) in 2011. These early DAAs were used with pegylated interferon and ribavirin. The rate of sustained viral response (SVR), which is the measure used to determine the cure for HCV, increased; however, the side effects caused by the pegylated interferon and ribavirin remained. In 2014, new DAAs that are used alone were approved in Canada. These treatments involve a shorter duration of treatment of 8 to12 weeks and have minimal side effects (Abbvie Corporation, 2017; Gilead Science Inc., 2017; Grebely et al., 2015; Harris, Albers, & Swan, 2015; Martin et al., 2015; Meyer et al., 2015; Wolfe et al., 2015).

In PEI, the newest DAA pan genotypic drug has been available and funded by the provincial program since the fall of 2017. Now, people infected with all HCV genotypes have

the potential to be cured, as well, new medication has been approved for use on those whose treatment had previously failed. (Abbvie Corporation, 2017; Gilead Science Inc., 2017). New HCV treatments are very expensive. In Canada, treatment for one HCV patient can be up to $93,000 (Harris et al., 2015; Leidner et al., 2015).

Several authors have examined the cost versus the benefit of these treatments and found that until the cost decreases, treatment of all HCV-infected clients will not be possible (Grebely et al., 2015; Harris et al., 2015; Innes, Goldberg, Dillon, & Hutchinson, 2015). Innis et al. modelled two scenarios with different goals for treatment direction. Scenario one was to decrease incident or acute HCV infection. Scenario two was to treat those who have the most advanced liver damage. Decreasing incident infection such as in PWID would have the end goal of decreasing the spread of HCV in the future. This approach is also called treatment as prevention. On the other hand, scenario two targets the high morbidity and mortality associated with HCV infection. If treated, persons who have sustained the most liver damage can live healthier lives and will not experience declining health associated with ongoing HCV infection, thus saving the health care system money and improving the quality of life for those infected. This group has been the initial target of treatment in Canada as it has the most imminent cost impact on the health care system (Innes et al., 2015). The age of these two groups is very different. The age of PWID is generally younger; whereas those who experience the liver effects have had HCV infection for 20 to 30 years and are older.

There is a general reluctance to treat PWID who continue to inject actively. This is due to the lack of support and stability in this population, as well as the possibility of re-infection for those actively using drugs. However, studies have shown that PWID may have similar outcomes from treatment as those not injecting (Aspinall et al., 2013; Midgard et al., 2017). Decisions will

have to be made regarding the risk group that will be targeted for treatment in each area of the country. Risk factors specific to each province should be examined (Martin et al., 2015).

Economic/Personal Burden

Several authors have modelled the potential financial and health impacts of HCV infection in Canada and in other countries (Duberg et al., 2015; McCombs et al., 2011; Myers et al., 2008; Myers et al., 2014; Remis, 2009; Sievert et al., 2014; Werb et al., 2011). Myers et al. (2014) modelled the Canadian impact of HCV infection in the population through to 2035. They predict that the prevalence of HCV-infected individuals alive in the population will continue to decline and reach approximately one-third of present infections by 2035. A consideration in the Myers et al. (2014) model is that as those who are infected with the disease continue to age, the amount of morbidity and mortality is expected to increase thereby causing increased stress and expense for the health care system. Myers et al. (2014) revealed that the lifetime cost in dollars in 2013 for an HCV case was $64, 649. However, this projection was made using costs related to treatment with pegylayed interferon and ribavirin. New treatments with DAAs will at least double this cost (Harris et al., 2015; Leidner et al., 2015), but there is expectation with new curative treatment medications, that those progressing to morbidity related to long term infection will be decreased and costs to the health care system will be prevented.

The quality of life and life-years lost is also considered when looking at the burden of HCV in Canada. There is a significant impact on the physical and mental functioning for those with HCV infection (Kwong et al., 2012). The use of sick days and short-and long-term disability have been shown to be higher in those with HCV than those without HCV infection. The decreased ability of those infected with HCV to be productive citizens in society is a negative impact of HCV that is harder to measure (Abdo, 2008; DiBonaventura et al., 2014; Foster, 2009; John-Baptiste et al., 2009; Su, Brook, Kleinman, & Corey-Lisle, 2010; Vietri,

Prajapati, & Khoury, 2013; von Wagner et al., 2006). The introduction of new DAAs for the treatment of HCV may change the bleak outlook that was predicted in these studies (Sievert et al., 2014).

Presently, PEI provides new DAA pan-genotypic treatment to HCV patients at no cost to the patient. Recently, through a body called the pan-Canadian Pharmaceutical Alliance (pCPA) that represents provinces, territories, and federally funded drug plans, a deal was reached with several pharmaceutical companies agreeing to charge lower prices for HCV medications (CATIE, 2017). As a result, other provinces (British Columbia and Ontario) have begun to offer DAA treatment through provincially funded programs (CATIE, 2017).

Relevance to Nursing Practice

Nursing is a holistic practice that looks at the entire client situation to provide evidence-based care. The more nurses caring for HCV at-risk populations know about the particular risks for those they provide care for, the better targeted the interventions and care can be (Krebbeks & Cunningham, 2013; Wilkie, 2013). One of the core competencies of public health nursing practice is to assess the characteristics of a population or sub-population by analysing the epidemiological data and recognising trends as well as gaps in services (Canadian Association of Schools of Nursing [CASN], 2014). Public health nurses educate and counsel new HCV cases and provide harm reduction services. For example, in PEI, public health nursing provides seven needle exchange sites where clients can receive clean needles and injection equipment as well as immunizations, wound care, naloxone kits, and referrals to other agencies. Nurses may be the only point of contact with the health care system for clients at risk of acquiring HCV. Nurses working in other settings such as the emergency room, primary care, and mental health and addictions treatment programs also have an important role with HCV clients.

Screening or testing for HCV can be initiated by nurses and ordered by nurse practitioners who identify a client at risk for HCV. When the risk profile for HCV clients is available for their population, nurses will have greater accuracy in offering screening and testing to those most in need. Nurses have the potential to affect transmission by being knowledgeable about HCV in their area and being able to counsel and educate clients at point-of-care. This is particularly important in the PWID population, who may not have the resources to access health care and social services regularly (Frazer et al., 2011; Keats et al., 2015; Krebbeks & Cunningham, 2013; Lewis et al., 2010; Nyamathi et al., 2013; Nyamathi et al., 2015; Olson & Jacobson, 2011). Nurses who work in rural areas can enhance their effectiveness by knowing more about the population that is at risk in their areas. Rural clients tend to have fewer services available at close proximity, and transportation and poverty can be issues that impede access to HCV services (Krebbeks & Cunningham, 2013).

With new treatments being approved for HCV that have fewer side effects and shorter duration of treatment, but with increased financial cost, nurses are going to be involved with assessment for treatment and providing direction on policy for administration of these treatments. The prevalence of HCV in the population and the characteristics of the HCV population must be used to inform these policy decisions. The Canadian Nurses Association (CNA), *Nursing Code of Ethics* (2017) discusses that nurses have the responsibility to advocate for access to safe, compassionate, and ethical care for their clients. The population at risk for HCV, particularly clients who have HIV, persons who are homeless, and PWID are vulnerable populations that require this important nursing function.

Summary

Information regarding HCV acquisition, diagnosis, treatment, and risk factors have greatly improved in the past 20 years; however, some gaps still exist. The impact of gender and

heterosexual sex on the acquisition of HCV is still not clear (Amin-Esmaeili et al., 2012; Gorgos, 2013; PHAC, 2016b; Sweeting et al., 2009; Tohme & Holmberg, 2010). More research is required related to the extra hepatic health outcomes of HCV to measure the real impact on the health care system and the lives of those infected with HCV. The new direct acting antiviral treatments that have been approved in Canada in the past 2 years have the potential to change the future effect of HCV on the health care system (Grebely et al., 2015; Harris et al., 2015; Innes et al., 2015; Martin et al., 2015; Meyer et al., 2015; Wolfe et al., 2015). Due to these new developments in treatment and ideas regarding screening cohorts, several issues have yet to be resolved in the literature and implemented in public health policy. These include who to screen for disease and who should receive treatment. Harris et al. (2015) discuss the potential to use the new DAA treatment as prevention for HCV transmission, particularly in the PWID population. As it may not be possible to treat everyone initially, the evaluation of the cost of early treatment and cure versus the financial impact of chronic HCV cases to the health care system in the future should be explored.

It is apparent in the literature that information regarding the characteristics of the population that is infected with HCV is imperative to guide policy decisions regarding testing and treatment (Duberg et al., 2015; Grebely et al., 2015; Harris et al., 2015; Leidner et al., 2015; McEwan, Ward, Yuan, Kim, & L'Italien, 2013; Schackman et al., 2015; Wolfe et al., 2015). Nurses have a role to play in planning the future of HCV care, treatment, and prevention through harm reduction programs. This planning must be based on evidence and epidemiologic data particular to the local population (PHAC, 2008).

This study provides information regarding the characteristics of the HCV-infected population of PEI and by applying the PHAC case definition can help identify the risk characteristics of recent cases. Governments and health policy makers may use this information

to make the best decisions possible regarding screening, testing, and harm reduction activities for the health of the HCV positive population.

Conceptual Model

The Los Angeles County Public Health Nursing Practice Model (LAC PHN Practice Model) (Smith & Bazini-Barakat, 2003) has been chosen for use in this study to place the research into the context of public health practice. This model outlines the process by which public health practitioners make decisions and implement programs. This study focuses on the first two steps of this model: Assess and Diagnose. However, the model provides guidance regarding the use of the study results for policy and program development, as well as public health action, and therefore also serves as an organizational framework. The model uses American documents to support its development; however, Canadian documents are identified that align conceptually with the documents used in this model; thus, this model is suitable for use in the Canadian context.

Los Angeles County Public Health Nursing Practice Model

Smith and Bazini-Barakat (2003) developed a practice framework for public health professionals. The Los Angeles Public Health Nursing (LA PHN) Department provided an update in 2007, with a new narrative to accompany the model; however, the model remains unchanged. Smith and Bazini-Barakat's purpose of creating the model was to bring the public health nurses' focus from simply action and implementation to the important steps that come before and after public health action. This model can be generalised to all public health professionals and populations. The authors recognized that public health practice is multidisciplinary, and that a team approach is required. The public health team may include but is not limited to nurses, physicians, dieticians, speech-language pathologists, social workers, and environmental health inspectors.

The model is based on the standards outlined in the document *Public Health Nursing: Scope and Standards of Practice* (American Nurses Association [ANA], 2007). The standards closely align with the steps of the nursing process (assessment, diagnosis, planning, implementation, and evaluation). Smith and Bazini-Barakat's (2003) model is built on American nursing and public health standards, and although the concepts are not the same, the intent is similar to *Canadian Community Health Nursing Professional Practice Model and Standards of Practice* (Community Health Nurses of Canada [CHNC], 2011) and *Core Competencies for Public Health in Canada* (PHAC, 2008). Both the Canadian and American documents stress the need for high-quality data and research to plan programs and provide health promotion services.

The goal of the LAC PHN Practice Model is "healthy people living in healthy communities" (Smith & Bazini-Barakat, 2003, p. 45). The focus of the model is population-based practice involving individuals/families, communities, and systems. The model acknowledges that population-based care may be directed at one, or in many cases, all three levels of the population. Figure 1 provides a diagram of the model.

In the following section, the assumptions of the model are reviewed, and an overview of the model is provided. Lastly, the specific steps relevant to this study are discussed in detail.

Assumptions. The LAC PHN practice model is based on five assumptions. Smith and Bazini-Barakat (2003) assume that: (a) the model is relevant for other public health disciplines, as well as nursing; (b) the population (individual/family/community) is an active participant in all aspects of the model; (c) all public health nurses perform three functions: assessment, policy development, and implementation/evaluation; (d) public health nursing has interventions as described in the Minnesota Public Health Nursing Interventions (PHI) Model, which was published in an article by Olson Keller, Strohschein, Lia-Hoagberg, and Schaffer (1998), that can

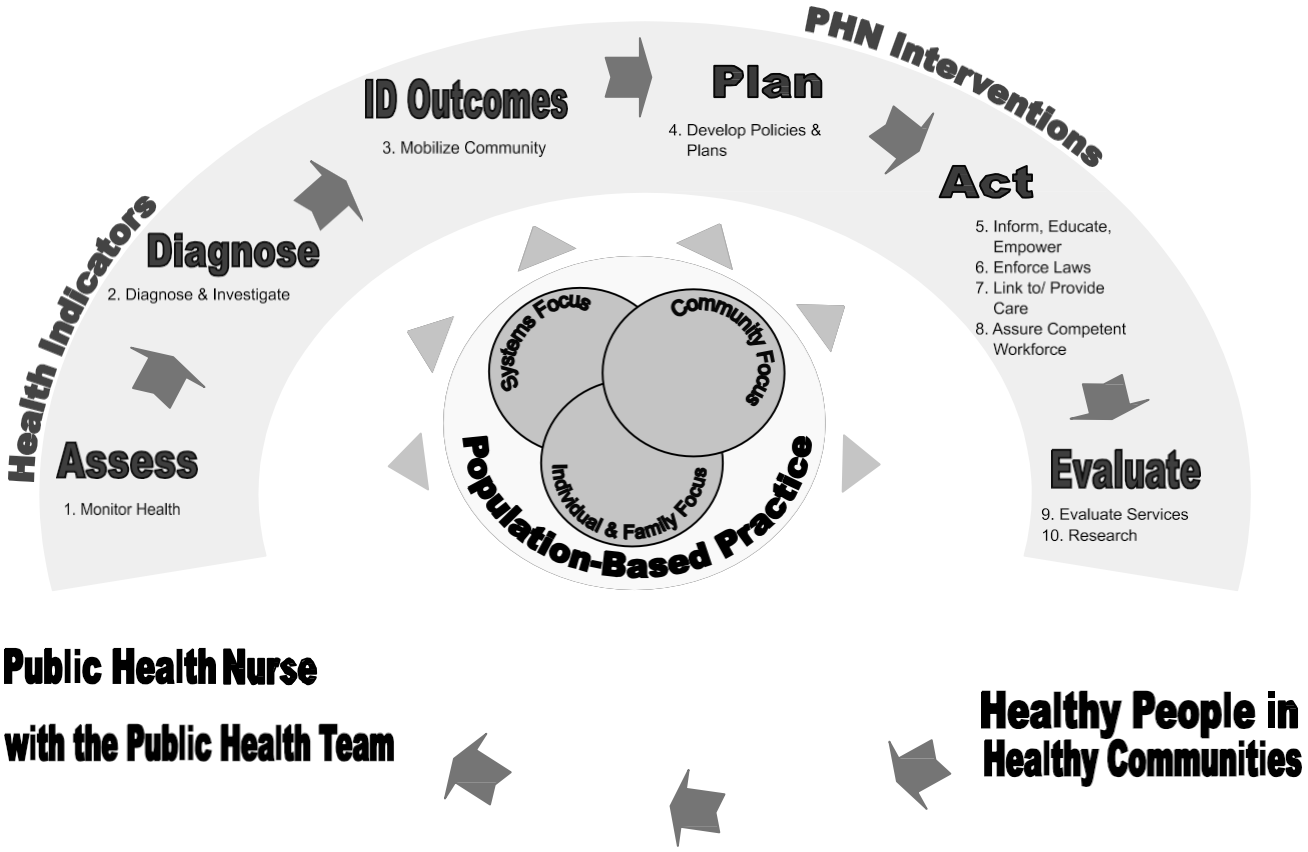

Figure 1. Diagram of the Los Angeles County Public Health Nursing Practice Model by K. Smith and N. Bazini-Barakat, 2003, *Public Health Nursing*,*20*(1), p. 45. Copyright 2003 by Blackwell Publishing, Inc.

be employed when implementing the nursing process. The interventions noted in the PHI Model are similar conceptually to the Canadian Community Health Nursing *Professional Practice Model* (CHNC, 2013) and include interventions such as collaboration, counselling, health teaching, screening, surveillance, and policy development; and lastly, (e) the model is based on the principles of population-based practice.

Model overview. The diagram of the practice model created by Smith and Bazini-Barakat (2003) demonstrates public health practice originating with the public health nurse and the public health team. The clients/population of interest are active participants throughout the framework. The inner ring of the model illustrates the six PHN standards as outlined in the

Public Health Nursing: Scope and Standards of Practice: Assess, Diagnosis, ID Outcomes, Plan, Act and Evaluate (American Nurses Association [ANA], 2007). These standards are referred to as ‘steps’ of the model as they follow a progressive sequence of actions. Aligned with the 6 steps in the models are 10 essential PHN functions. The functions provide the actions that are involved with each component. The outer ring of the model shows that ‘Health Indicators’ should be involved in the ‘Assess’ and ‘Diagnose’ steps of the model. The Health Indicators are meant to align the work of the PHN with the direction being given nationally, and during the ‘Assess’ step should be part of data gathering, as the indicators include useful data for creating a diagnosis. Health indicators such as “substance abuse, responsible sexual behaviour, mental health and access to health care" (Smith & Bazini-Barakat, 2003, p. 44) are considered in the present study.

Assess. The first step in the model ‘Assess’ (Smith & Bazini-Barakat, 2003) involves monitoring the health status of the population of interest. The goal of this component is to collect data that can be used to identify community or population health problems and to create plans to address these health problems. Once this information is gathered and studied, a problem or diagnosis can be identified (Smith & Bazini-Barakat, 2003).

Diagnose. The next step, ‘Diagnose’ (Smith & Bazini-Barakat, 2003) involves further investigation of the problem. This step includes diagnosing and investigating the specific health problems for the population of concern that were identified in the previous step, and the development of a broad plan to address the issue is created (Smith & Bazini-Barakat, 2003).

ID outcomes and planning. The next two steps in the model are ‘ID Outcomes’ and ‘Planning’ (Smith & Bazini-Barakat, 2003). The nursing process usually combines these two steps; however, the model, separates ‘ID Outcomes’ and ‘Planning’ to stress the importance of ensuring the outcomes that are identified are meaningful to the community of interest. When identifying outcomes, it is essential to identify and mobilise community partners who can aid in

identifying and addressing the needs of the identified population (Smith & Bazini-Barakat, 2003). 'Planning' uses the information that has been collected and developed in the first three steps of the model. The 'Planning' step considers the information collected, the objectives set by the affected community, and the roles of all partners who can impact the population under study. The development of policies and action plans begins in this step of the model (Smith &Bazini-Barakat, 2003).

Planning is the beginning of 'PHN Intervention' as shown in the outer ring of the model. The authors refer to 17 public health interventions that align closely with Canadian Community Health Nursing *Professional Practice Model* (CHNC, 2013). 'PHN Interventions' in this model have underlying assumptions. Upon beginning 'PHN Intervention', it is assumed that the 'Assess', 'Diagnose', and 'ID Outcomes' steps have been completed, and the interventions are grounded in the assessment of the communities' health (Smith & Bazini-Barakat, 2003). Interventions may be singular or several interventions may be required.

Act. The policies and action plans are then put into practice in the 'Act' step of the model (Smith & Bazini-Barakat, 2003). This step stresses the importance of informing, educating, and empowering people in the population or community about the health issues identified in previous steps. This step will require individuals who are involved in the intervention to be aware of their role, which can include public health activities such as enhanced surveillance, community education, health promotion, or harm reduction and prevention activities. The 'Act' step may also include enforcing laws that protect the health of the public and linking people in the population or community at risk to health services. It is imperative that there is a competent public health care workforce directing these interventions, and this can be accomplished through education and ensuring awareness of the issues or problems that have been discovered in the previous steps of the model (Smith & Bazini-Barakat, 2003).

Evaluation. Lastly, the model shows that once the new policy or intervention(s) has been implemented 'Evaluation' must occur (Smith & Bazini-Barakat, 2003). However, it is important for 'Evaluation' to occur at every juncture of the process, and planning for 'Evaluation' should occur during the 'Planning' step. Smith and Bazini-Barakat (2003) note that the model is cyclical and 'Evaluation' will identify further areas for study and lead back to 'Assess' and the process begins again. They also acknowledge that the 10 Essential Public Health Services have been loosely assigned under each step of the model and may take place throughout the model as many of the Essential Services apply to more than one step (Smith & Bazini-Barakat, 2003).

Population-based practice. The joined inner circles of the model include population-based practice. The principles of population-based practice, as outlined by Smith and Bazini-Barakat (2003), include: (a) having a focus on populations that have similar health concerns or characteristics; (b) being guided by an assessment of the population's health status, and is considerate of the determinants of health for the particular population; (c) having a focus on prevention at all levels particularly primary prevention; (d) being considerate of all levels of practice including individuals, communities, and systems; (e) reaching out to those in the population and not only serving those who present for care; (f) having a focus on the greater good where the interest of the whole comes before that of the individual or group; (g) striving to create a healthy environment including physical, social, and economic where people can thrive; (h) distributing health resources and supporting improvements for the maximum population; and lastly, (i) collaborating with other members of the profession and other organizations.

Model Application and Adaptation

The LAC PHN practice model, as it applies to this study, focuses mainly on the first two steps of the Model (Smith & Bazini-Barakat, 2003): 'Assess' and 'Diagnose'.

Assess. This step involves monitoring the health status of the population of interest with the goal of identifying community or population health problems and creating plans to address these health problems. *Core Competencies for Public Health in Canada* (PHAC, 2008) defines assessment as "a formal method of evaluating a system or a process, often with both qualitative and quantitative components" (p.9). The model uses the *Public Health Nursing Scope and Standards of Practice* (American Nurses Association, 2007) as the guiding document for the six nursing standards (steps) used in the model. This document discusses assessment for public health nursing as being a process where data are collected from multiple sources that relate to the health of the general public or a specific population. Data should be collected using models and principles of epidemiology, as well as social, behavioural, and physical sciences. This document also discusses that the advanced public health practitioner will partner with the population of interest, other health professionals, and stake holders, to interpret the data to make it meaningful to the population of interest. This process is carried on through the next step of the model, 'Diagnose' (Smith & Bazini-Barakat, 2003).

The current study involved the collection of data from case report forms as well as laboratory data to provide information regarding the risk factors, demographics, and the health status of HCV cases at diagnosis. The laboratory data were assessed to provide information that helped to determine acute cases and chronic cases and also identified those that have resolved the infection. Assessment of the data was completed to investigate and determine the characteristics and needs (Diagnosis) of the HCV cases occurring on PEI.

Diagnose. The next step 'Diagnose' involves further investigation of the problem of interest. In this step, diagnosis and investigation of a specific health problem for the population of concern, identified in the previous step, and the development of a broad plan to address the issue should be created. In the ANA *Public Health Nursing Scope and Standards of Practice*

(2007) document, diagnosis includes organising complex data and information that have been collected in the ‘Assess’ step. This information may include sociocultural, demographic, health status, and risk data, as well as information on geographical and environmental influences. The data collected are systematically analysed to create a diagnosis that can then be validated with the population of interest as well as other stakeholders. During this step, priorities are set that will be brought to the population in the next step of the model, which is ‘Outcomes ID’.

In the Canadian context, the *Core Competencies for Public Health in Canada* (PHAC, 2008) do not discuss diagnosis as such. Instead, they discuss the process of "analysis” (p.4) where the public health practitioner uses collected information to determine implications, appropriate uses, gaps, and limitations of the population of interest. Here a determination of the meaning of information is made with consideration of the current ethical, political, scientific, socio-cultural, and economic contexts. A recommendation of specific actions is based on the analysis of information. Although a different term is used, ‘Diagnose’ and analysis are similar processes.

In the current study, the laboratory data were reviewed and a diagnosis of acute or chronic HCV was made. With this determination, risk factors during the time of infection were assessed. Based on the risk factor and demographic data, identification of assets and needs, as well as areas of vulnerability for HCV cases can be analyzed and differential diagnosis/priorities can be identified. Using this same laboratory data, HCV cases who have resolved their HCV infection and no longer have circulating virus were identified and differentiated from those cases who had active disease and could benefit from treatment (acute and chronic).

Summary

The nursing process and public health practice rely on evidence to inform practice. The data collected through the first two steps of the model used indicator data such as HCV

surveillance information collected at the national level. This allowed the PEI rates to be compared to the national rates, and rates from other provinces, which grants a relative perspective of the local situation. As with the goal of the LAC PHN Practice Model (Smith & Bazini-Barakat, 2003), "healthy people living in healthy communities"(p.45), the goal of this study was to provide data that can be used to improve the health of the population of those living with HCV. It is the intention that the remaining steps will be followed upon completion of the current study.

CHAPTER 3

Methods

This chapter presents a review of the study design, population, and sample. The process of data analysis is described according to the research questions. This includes a description of the dependent and independent variables. Lastly, ethical considerations for the study are discussed.

Study Design

The study was a descriptive, correlational, quantitative study using retrospective chart review and laboratory data. The study involved the creation of a data set with input of secondary data that had been collected in case files from the PEI Chief Public Health Office (CPHO) and laboratory data from the Health PEI Provincial Laboratory. Although the data were previously collected by others, this study provided a primary analysis of the complete dataset.

Population/Sample

The study population included all positive cases of HCV on PEI since testing began in 1991. The conclusions drawn from this study will apply to the population of PEI infected with HCV; however, some of the results may be applied to the population of PEI as a whole for harm reduction activities.

The study sample was a census of the HCV cases on PEI that consisted of 856 paper charts (Dataset A) located in the Communicable Disease (CD) Coordinator's office in the CPHO on the second floor of the Sullivan Building in Charlottetown, PEI. The inclusion criterion was: all HCV EIA screen antibody positive cases that also had a positive confirmatory test that includes RIBA, PCR, or viral load. Cases diagnosed before January 1, 2017 were included. Expired cases up until the end of 2016 had been previously removed from the paper chart files.

The literature describes 24 months as the point where clearing the virus becomes unlikely (Healy et al., 2001; Mast et al., 2005); therefore, children born to a mother with HCV were included if they had a positive PCR or viral load after 24 months of age (Healy et al., 2001; Mast et al., 2005).

A second smaller dataset (Dataset B) excluded cases initially diagnosed in another province but living on PEI. They are not counted as PEI cases and are considered case management cases. It was also decided to exclude cases diagnosed while under the age of 15 years from this dataset. The risk profile of these cases was very different than the adult population of HCV positive cases, in that only two risk factors existed for those less than 15 years of age: blood transfusion and being born to a mother with HCV. Dataset B was created for the questions requiring an analysis of only cases that were diagnosed on PEI. This second smaller Dataset B was a subset of the first dataset and consisted of 784 cases.

The first test date for the laboratory data available for export was March 27, 2008. Diagnosis of acute and chronic HCV requires 1 year of laboratory information prior to the diagnosis date. Using the data back to March 27, 2008, cases diagnosed on or after March 27, 2009 were able to be categorized as acute and chronic. The cases with a diagnosis date up to December 31, 2016 were included. The limited laboratory data required the creation of a third dataset (Dataset C) which was a subset of Dataset B and consisted of 388 cases. The three datasets are illustrated in Figure 2.

Setting

Data collection took place at the CPHO in the CD Coordinator's office, as noted above. All charts were stored in this office in a locked filing cabinet. Data were retrieved and entered in the same office as the charts were stored.

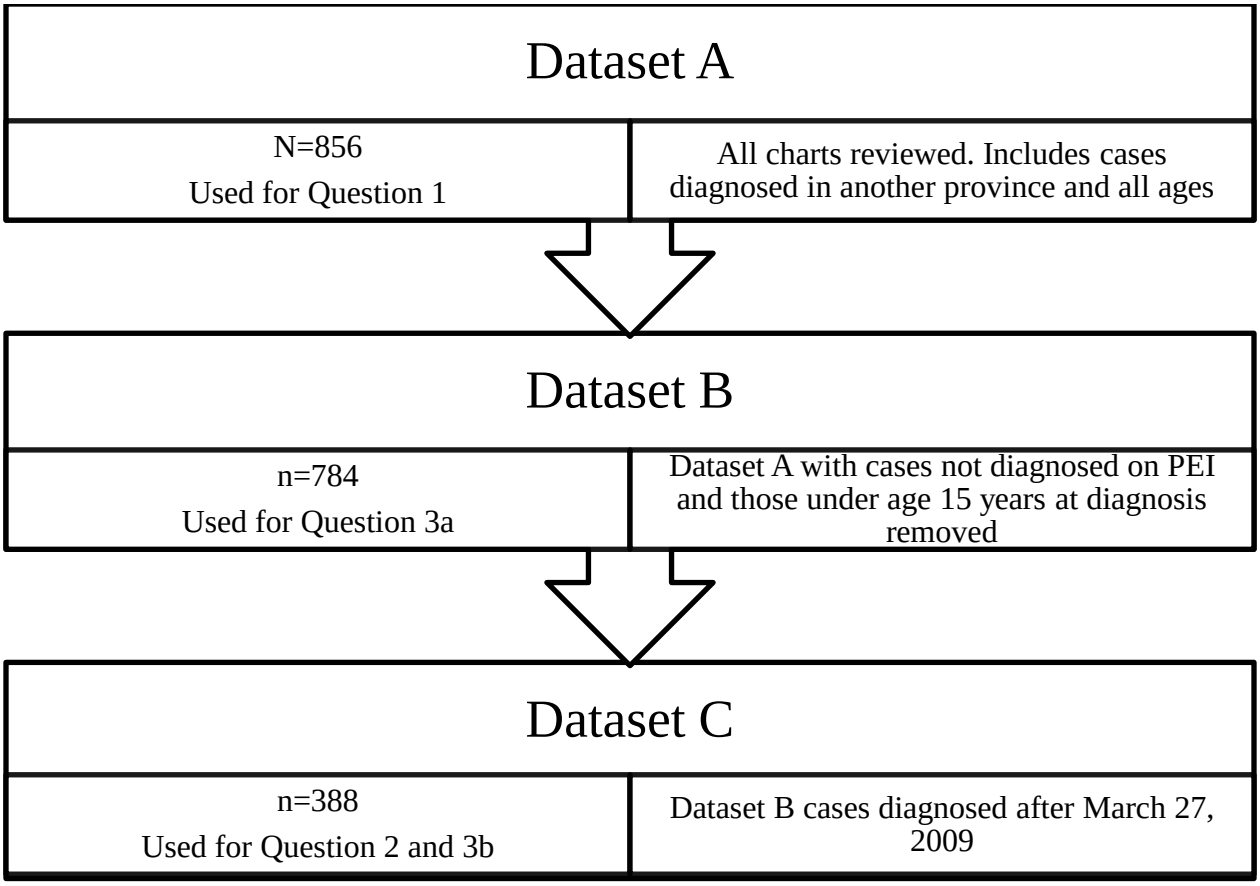

Figure 2. Flow chart of datasets used in study.

Data Collection/Procedure

Chart review. Permission for access to the paper charts was given by the PEI Chief Public Health Officer, Dr. Heather Morrison, and was also endorsed by the Provincial Epidemiologist at the time, Dr. Carolyn Sanford. Letters of support can be found in Appendix A.

The CPHO collects surveillance data on all notifiable diseases on PEI. These diseases are listed in the *PEI Public Health Act* and regulations (2015). Hepatitis C is one of these reportable diseases. Some data elements are kept in the electronic Communicable Disease (CD) Database. The data collected from the CD Database include: name, medical record number/provincial health number (MRN/PHN), laboratory accession number, sex, date of birth, and date of the positive test. In June of 2017, this system was expanded to include electronic case report forms broadening the analysis capabilities of this system, but these data were not available for this

study. Once data are entered and saved, a case number is generated. The case is then referred to by a 4-digit number that is meaningful only to those with access to the CD Database. This case number or case ID is used during the case investigation by employees of the CPHO and public health nurses who are involved in the investigation of the case.

In this study, the case ID was used to identify each case during the analyses of the data. The data from the paper charts were collected using a data collection tool, which was created in Microsoft *Access* (Microsoft Office 2003, Microsoft Corporation, version 11.0.5614.0) by the researcher. This tool included all variables that were available in the charts including demographic information and risk factors. This tool provided consistency in data gathering and included the variables noted in Table 1 and Table 2. After data entry was complete, all elements were visually reviewed to check for data entry errors, and 25 charts were selected in a non-random manner and reviewed a third time to confirm the accuracy of data entry by the researcher. As expected, there were missing data, primarily due to the evolving versions of the case report forms used by health care providers and the difficulty contacting some of the cases after diagnosis.

Health PEI Laboratory data. The Population Health Assessment and Surveillance (PHAS) Unit at the CPHO requested the laboratory data from the Health Information Unit of Health PEI, which included all previous HCV EIA screens and HCV confirmatory tests, HBV and HAV infection results, as well as all ALT test results. The laboratory data were only available from March 27, 2008. Data prior to March 27, 2008 were stored in a different data system and were inaccessible for export. This affected the sample analyzed for each question and will be discussed in more detail in the methods for answering each research question later in this chapter.

Table 1

Independent Variables (Risk Factors and Demographic at Diagnosis)

Variable	Type	Values
Urban/rural	Dichotomous	Postal Code C1 Urban C0 Rural
Age	Continuous	Numerical in years
Sex	Dichotomous	Male/Female
Born in Canada	Dichotomous	Yes/No
Race	Categorical	White, Asian, Black, Aboriginal Peoples, Latin American, South Asian/West Asian/Arab
IV drug use	Categorical	Current, Past, Never
Snorting drugs	Categorical	Current, Past, Never
Shared drug paraphernalia	Categorical	Current, Past, Never
Blood Transfusion or organ transplant before 1992	Dichotomous	Yes/No
Dental or major surgery	Dichotomous	Yes/No
Household or sexual contact with HCV (+)	Dichotomous	Yes/No
Born to mother HCV (+)	Dichotomous	Yes/No
History of incarceration	Dichotomous	Yes/No
Tattoo or piercing	Dichotomous	Yes/No
Occupational needle stick	Dichotomous	Yes/No

Table 2

Variables for Application of Case Definition to Determine Acute/Chronic Status

Variable	Type	Values
RIBA positive	Dichotomous	Yes/No
PCR or viral load positive	Dichotomous	Yes/No
Date of diagnosis	Discrete	Year-month-day Numerical
Date of last negative HCV antibody test	Discrete	Year-month-day Numerical
ALT above 2.5 times upper normal level	Dichotomous	Yes/No
Report of acute viral hepatitis symptoms within six months before (+) test	Dichotomous	Yes/No
Date of symptom onset	Discrete	Year-month-day Numerical
Negative anti-HAV IgM, and negative anti-HBc IgM or HBsAg tests	Dichotomous	Yes/No

The PHAS unit linked the chart review data with the laboratory data using the DOB, sex, and medical records number (MRN) as a unique identifier. Once the datasets were merged, all identifying information including the MRN was removed from the new dataset and each case was identified by the 4-digit case number only. Case names were not used in any part of this study and were not part of the data analyses. However, they were visible to the researcher when reviewing the paper case charts at the CPHO. This was necessary, as the paper charts are stored in alphabetical order by last name. The study data and analysis results were stored on an

encrypted external hard drive that was kept in the locked CD Coordinator's office in a locked drawer. Access was available only to the CD Coordinator/researcher. The study data and chart review database created for the study will be retained for at least 5 years by the researcher and will remain stored in the same secure location. After 5 years all the study data and *Access* database will be deleted from the external hard drive. The CPHO will retain the data as per their records retention policy.

Variables. The variables of this study consisted of the risk factors for HCV, the laboratory data that determined the category of the dependent variable, and the demographic data for each case. The process of collecting the variables for this study were the function of the 'Assess' step in the conceptual model.

Dependent variable for risk factor analysis. The dependent variable in this study was the timing of the diagnosis of HCV infection. The case definition issued by the PHAC (2016b) was used to categorize the HCV infection (Table 3). In this case definition, infection is divided into two categories Acute and Unspecified. The Unspecified category is then divided into Chronic and Resolved. This categorization is diagrammed in Figure 3. This study differentiated between the two possible reasons for being unspecified so that an accurate case count for those who are actively infected could be undertaken. By identifying which cases are acute and which are chronic, a description of those who may contribute to the health burden of HCV on PEI could be created.

The case definition for Acute HCV infection is well defined by the PHAC as shown in Table 3. The Unspecified category in Table 3 does not describe the differences between a Chronic Case of HCV and a Resolved Case. A Chronic Case has a positive EIA screen and positive viral load or PCR, but does not meet the other criteria for an acute case (PHAC 2016b).

Table 3

Hepatitis C Case Definitions Used Under the CNDSS - Updated 2011

Infection Status	Case Definition
Confirmed case - Acute or recent infection. Any one of the 3 of the options would constitute an acute case.	**Option 1** Detection of hepatitis C virus antibodies (anti-HCV) or hepatitis C virus RNA (PCR/viral load) in a person with discrete onset of any symptom or sign of acute viral hepatitis within 6 months preceding the first positive HCV test AND negative anti-HAV IgM, and negative anti-HBc IgM or HBsAg tests AND serum alanine aminotransferase (ALT) greater than 2.5 times the upper normal limit **Option2** Detection of hepatitis C virus antibodies (anti-HCV) in a person with a documented anti-HCV negative test within the preceding 12 months **Option 3** Detection of hepatitis C virus RNA (viral load) in a person with a documented viral load negative test within the preceding 12 months
Confirmed case – Unspecified (including chronic and resolved infections)	Detection of hepatitis C virus antibodies (anti-HCV) OR Detection of hepatitis C virus RNA (viral load)

Note. If diagnosis is based on anti-HCV alone, it should be confirmed by viral load, immunoblot, a second manufacturer's EIA, or based on an EIA signal to cut-off ratio predictive of a positive immunoblot. Adapted from Report on hepatitis B and C in Canada: 2012. By the Public Health Agency of Canada, 2016 (No. 150071). Ottawa, ON: Author.

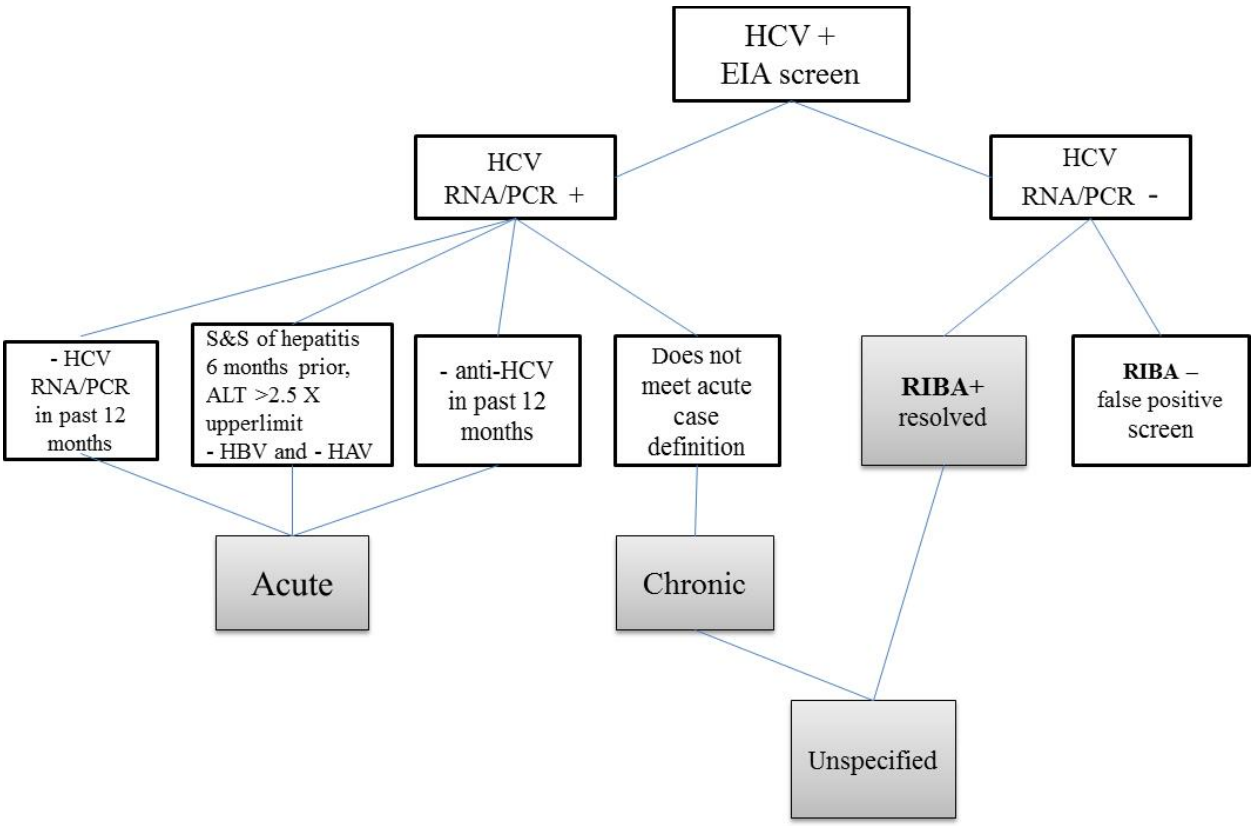

Figure 3. Categorization algorithm for the dependent variable. The PHAC case definition places chronic and RIBA + resolved cases in the unspecified category. Acute and chronic cases are both infected with the virus (viral load/PCR+). A RIBA + resolved case has antibody but is not infected with the virus (viral load/PCR -).

A Resolved Case of HCV has a positive EIA screen but negative viral load or PCR. The EIA screen then requires a confirmatory test. The HPEI Provincial Laboratory uses the RIBA test for confirmation. Resolved cases do not have virus circulating in their blood; therefore, there is no active infection and these cases do not require treatment for HCV.

Independent variables. The independent variables in the study included risk factors and demographics of the cases. Table 2 outlines the variables that were used to categorise the dependent variable as Acute, Chronic, or Resolved.

Data Analysis

The data analysis was performed using Stata© SE Statistical Software, version14.2, 2016 unless otherwise noted. The 'Diagnose' step of the conceptual model begins with the analysis of the data collected in the 'Assess' step. The analysis is presented according to the research question.

Question 1. "How many people on PEI have active HCV infection diagnosed by positive laboratory results?" This question was answered using Dataset A (N=856), which included all cases of HCV living on PEI. This question was asked to determine the prevalence of active cases on PEI at the time of analysis, regardless of where they were diagnosed.

The laboratory data were analyzed for each case and those whose most recent laboratory result was a positive PCR or viral load were included in this analysis. Those whose most recent test was a positive RIBA were not included in this group because the RIBA is only run after a negative PCR or viral load and these cases do not have measurable virus circulating in their blood and do not require treatment. Since laboratory data, were only available for testing done on or after March 27, 2008, those cases who were diagnosed prior to March 27, 2008 and did not have recent testing, were categorized using laboratory information captured from the chart review. When a new case of HCV is detected in the HPEI Provincial Laboratory, a paper copy of the positive laboratory results are sent to the CPHO and placed into the case file. During the chart review the researcher recorded the most recent laboratory results for each case as either RIBA or PCR/viral load positive and those whose most recent laboratory result was a positive PCR or viral load result were included in this analysis. These data were added to the laboratory data to determine the most accurate number of cases with active HCV infection.

Question 2. "How many PEI HCV cases were diagnosed when they were acute and how many were chronic?" Dataset C (n=388) was used to answer this question. This question was

answered when the researcher applied the PHAC (2012) case definition (Table 3) to each case, as described in the data collection section of this chapter. A case could be categorised as acute using two sets of criteria. If the date of the last negative HCV screen or PCR/viral load testing and the date of the positive test are assessed to be within 12 months of each other, the case could be categorised as acute (options 2 and 3). As well, if within the 6 months before the positive HCV screen and PCR/viral load test the person experienced a discrete onset of symptoms of the disease and had a laboratory ALT value 2.5 times higher than the upper normal limit for their age and sex, and other infectious hepatitis infections have been ruled out with laboratory testing, they were categorised as acute (option 1). If they did not meet these criteria, but did have a positive EIA antibody screen plus a positive PCR/viral load, they were categorised as a chronic case. They would be considered a chronic case for one of two reasons, either it could not be determined when they became positive, or they became positive more than 1 year before their diagnosis (PHAC, 2012). Cases with a positive EIA screen confirmed by a positive RIBA test were considered resolved and these cases are not included for this question.

The laboratory data received from the Health PEI Provincial Laboratory included all tests positive and negative for HCV for the cases specified. Therefore, time parameters were required to determine what PCR and viral load tests to include for the determination of the diagnosis of HCV infection. It was determined that the PCR or viral load result date should fall within 14 days prior to or 14 days after the date of diagnosis in order to be considered diagnostic for the case. The 14 day parameter was chosen by reviewing the time it took for the laboratory to complete the confirmatory tests, as well as by reviewing individual cases to explore plausible time frames. Sensitivity testing was carried out to confirm that the chosen time frame was appropriate by expanding the time lines past 14 days and decreasing the timelines to 0 days. The results for Question 2 are expressed as a frequency of acute and chronic cases and the proportion

of each. The results for Question 2 illustrate the number of cases of HCV who had circulating virus and were infectious when they were diagnosed with HCV.

Question 3 (a). "What are the risk factors and demographics for all HCV cases diagnosed on PEI (acute, chronic, and resolved)?" Part (a) of this question involves risk factors for those who were diagnosed while living on PEI therefore; Dataset B (n=784) was used to answer part (a) of this question. All cases who had a positive EIA screen regardless of how they have been confirmed (RIBA, PCR, or viral load) were included in the analysis for part (a) of this question (acute, chronic, and resolved). The frequency and percentage for each demographic and risk factor variable was calculated.

Several risk factors required special consideration and adjustment during data collection. In order to determine the general area, urban or rural, where cases were living when diagnosed, this study used postal codes to differentiate those who live in urban areas and those who live in rural. Postal codes beginning with "C1" are assigned to Charlottetown, Stratford, and Summerside; C0 is assigned to the areas of PEI considered rural. As many services are centred in Charlottetown and Summerside, and a postal code was a readily available way to determine general rural/urban area, postal code was used.

The risk factor "snorting drugs" was not asked in a direct way on the case report forms throughout the years and this risk factor question was mostly unanswered. A positive result for snorting was recorded if it was noted in the chart that straws were shared or if snorting was specifically recorded. If it was not mentioned, then it was recorded as "no answer".

There were three variables that had three possible answers to the question; "IV drug use, snorting drugs, and sharing paraphernalia" all had the answers of "current, past, and never". During analysis when the variable had an answer current or past, a new variable was created to combine these two answers. These new variables were called "ever IV drug, ever snort, and ever

share". These new variables were used when the analysis was looking for a history of the risk factors but did not require the differentiation of current or past.

Question 3 (b) "Which demographics/risk factors have a significant association with the diagnosis of acute HCV?" Dataset C (n=388) was used to answer this question. This question required analysis using chi-square for categorical variables and t-test for continuous variables to determine their relationship to the dependent variable. Multivariable logistic regression modelling was then completed to assess the combined influences of the independent variables on the diagnosis of acute HCV infection. The initial analysis using chi-square and t-test determined the significance of each independent variable on the occurrence of an acute case HCV on PEI. All independent variables with an association of $p<0.20$ were retained for multivariable logistic regression.

To start the multivariable analysis, all retained variables were put in the logistic regression model. The model was run in a backward approach with each step removing the variable with the highest p value until only the variables with a p value of <0.05 remained. When running the logistic regression model, there were variables that had significant Wald's test p-values, however, the number of responses was very low. These variables that did not have a high response rate were evaluated individually and removed from the model accordingly. The final model was then checked by using a forward logistic regression model approach to confirm the results. This forward approach began by including the most significant variable and adding second most significant variable until a variable was reached that did not have a p value <0.05. The model was then checked for variable confounding by looking at the significant variables in the model and adding variables that could be confounding by noting a change in the coefficient greater than 30% (Polit & Beck, 2012). There was only one variable that remained significant in the final model. As it was a continuous variable, the probability risk was calculated for the

dependent variable with each increase in this independent variable (UCLA: Statistical Consulting Group, 2017). The odds ratio and relative risk were calculated for other variables, to be able to express their relationship with the dependent variable.

Ethical Considerations

As the treatments, testing methods, and harm prevention interventions rapidly change and improve for people with HCV, the health system must make decisions regarding adoption of these new interventions. The PEI Public Health Act (PEI Legislative Assembly, 2014) outlines that information gathered from a person who is infected with a notifiable disease such as HCV should be collected systematically, analysed, published, and distributed in order to facilitate public health research and planning. This information is meant to anticipate, assess, and monitor changing health needs of the public.

To follow the remaining steps in the LAPHN model, accurate information collected through the 'Assess' and 'Diagnose' steps is extremely important. Making informed decisions regarding the number of HCV cases and the characteristics of and risk factors for this population are imperative. This study posed little if any risk to the cases being analysed as their confidentiality was strictly protected, and the study was intended to provide information to improve the quality of life for those living with HCV. A waver of consent was submitted to the research ethics boards, as obtaining consent was not possible due to the large number of HCV infected persons in the paper charts and the lack of recent contact information. The study did not involve direct contact with HCV positive persons, instead it used pre-existing case file information, pre-existing HPEI Provincial Laboratory data, and pre-existing CPHO CD Database information. The identity of all cases was highly protected. In the CPHO the CD Coordinator had a locked office in a secure provincial government building where the paper HCV case charts were stored. The researcher collected data from the paper charts in the office where they were

located, and all collection and analysis of electronic data were performed and stored in this same location. The data were stored on an external hard drive in a locked drawer in this office. The data on the hard drive were encrypted so that the researcher was the only person with access. These electronic data will be stored in the CPHO with the HCV charts in the locked file cabinet for a minimum of 5 years and will then be destroyed by erasing the external hard drive.

During the data collection from the paper charts, the researcher had access to the case names, birthdates, and MRN/PHNs. Once the data from the HPEI Provincial Laboratory and the chart review data were linked by the PHAS unit of the CPHO, the data were stripped of all identifiers. Each case was coded using the 4-digit code generated when previously entered into the CD Database at the CPHO. The code can only be connected to the client name by those with access to the CD database within the CPHO. Those with access included the Provincial Epidemiologist, three advanced practice nurses, one being the researcher, and the administrative support for the Chief Public Health Officer. To protect anonymity, the 'Provincial Small Numbers Policy' (CPHO, 2016) was strictly followed to prevent the possibility of identification of cases. Any categories that contained a small number of cases (<5) were reported for sex and age range only. No further breakdown of the case's identifiers were allowed. Previous to this policy, all numbers less than five were totally suppressed. This limited the information available for many diseases such as HIV and Hepatitis B. Presently, PEI does not suppress these numbers, and does not allow further breakdown of the cases' characteristics beyond sex and age range, in order to protect the identities of cases in this small province.

Ethics approval for the study was granted from the Health Research PEI Ethics Board and the UPEI Research Ethics Board. A copy of the Ethics certificate can be found in Appendix B.

Summary

Three datasets were created in order to answer the three questions asked in this study. Laboratory data were not available for all HCV cases diagnosed since 1991 so other data sources were combined with laboratory data to determine the number of cases actively infected on PEI. Risk factor and demographic information were analysed to determine their significance to the occurrence of the dependent variable, acute HCV. Ethics approval was obtained and the CPHO small numbers policy was used to protect the confidentiality of all cases in the study.

CHAPTER 4

Research Findings

This chapter describes the results of the statistical analyses for data collected during the chart review and collected from the HPEI Provincial Laboratory. Descriptions of the study sample, followed by the results related to each research question are presented.

Sample

The sample for this study included all people with HCV on PEI since testing began in 1991 (Dataset A, N=856). The mean age of persons infected with HCV living on PEI was 36 years of age, with 65% of the cases between 30 years of age and 59 years of age. Fifty-nine percent lived in an urban area, and the majority of cases were male (65%). Sixty-seven percent of cases were born in Canada, 5% were born outside of Canada, and 30% did not have an answer to this question. Although the race question was answered poorly, 89% of those who answered were White. Further discussion of sample demographics is presented for cases diagnosed on PEI (Dataset B, n=784) in the results for Question 3a.

Results by Research Question

Question 1. "How many people on PEI have active HCV infection diagnosed by positive laboratory results?" Dataset A (N=856) was used to answer this question. There were 362 cases of laboratory confirmed HCV actively infected cases on PEI at the time of the analysis (December 13, 2017). These cases were found by reviewing the most recent test for all HCV cases. Anyone who had a positive result for PCR/viral load after March 27, 2008 is included in this number. Cases who did not have laboratory results after March 27, 2008 were assessed using data from the chart review. The HPEI Provincial Laboratory reports all new positive HCV infections with paper laboratory reports to the CPHO. Data from the chart review for cases not counted in the 362 cases noted above revealed that 19 cases had a positive PCR/Viral Load noted

in their chart as the most recent laboratory result. It should be noted that there were 61 cases diagnosed from 1991-2002 when generally, the only confirmatory test was a RIBA, and it was not possible to determine if they were actively infected. During these years, most cases were not tested for PCR or viral load. If we estimate that 80% of these cases diagnosed between 1991 and 2002 were PCR/viral load positive, as the literature suggests, 49 of the early cases could be included in the prevalence (Myers, Shah, Burak, Cooper, & Feld, 2015; PHAC, 2017a; WHO, 2014; Wong & Lee, 2006). Combining the three data sources, the laboratory testing, the chart review laboratory data and the estimate for RIBA + cases prior to 2002, approximately 430 cases were actively infected with HCV on PEI at the time of analysis. The results for this question are illustrated in Table 4.

Analysis to ascertain the cases infected with HCV greater than or equal to 20 years ago, was carried out to further determine the imminent burden of illness of HCV on PEI. It was determined that 62 people were diagnosed with HCV on PEI greater than or equal to 20 years ago.

Question 2. "How many PEI HCV cases were diagnosed when they were acute and how many were chronic?" This question was answered by applying the PHAC case definition (PHAC, 2012), as described in Chapter 3, to cases with available laboratory data, diagnosed between March 27, 2009 and December 31, 2016 (Dataset C, n=388). In only three cases, was case information available for symptoms such as jaundice, fatigue, or abdominal pain, increased ALT 2.5 times the normal level for the case's age and sex (the normal levels for each case were provided in the HPEI Provincial Laboratory data), and negative Hepatitis A and Hepatitis B infection screens (anti-HAV IgM, HBsAg, anti-HBc IgM). Negative HCV screening tests, PCR or viral load in the past 12 months prior to the date of diagnosis, was the evidence available for the majority of the cases who were categorized as acute.

Table 4

Summary of Data Used to Calculate Prevalence of Active HCV Cases on PEI

Date of Last Test	Data Source	Result	Number
1991-2002	Chart review data	80% of total RIBA +	49[a]
1991-Mar 26, 2008	Chart review data	PCR/ VL + as their most recent test	19
Mar 27, 2009-Dec 31, 2016	HPEI laboratory	PCR/ VL + as their most recent test	362
Total			430

Note. [a]Estimated using unknown infection status cases at 80% actively infected.

As illustrated in Table 5, of the 388 cases that were able to be categorized, approximately 18% of cases were diagnosed when they were acute, 68% were chronic, and 14% were resolved cases. Cases who have been treated and are being tested for cure do not have a RIBA confirmatory test performed, as they are known to screen positive and do not need this confirmation once their viral load becomes negative. Thus the 14% noted are considered resolved cases. Any cases with irregularities in the timing of testing were reviewed on a case-by-case basis.

Question 3 (a). "What are the risk factors and demographics for all HCV cases diagnosed on PEI (acute, chronic, and resolved)?" The smaller chart audit dataset, with the case management and under 15 year old cases removed (Dataset B, n=784), was analyzed to answer this question. Table 6 illustrates the frequencies and percentages of the occurrence of each demographic variable found in the case chart reviews. As noted in the methods section, there was

Table 5

Number Cases Diagnosed when they were Acute, Chronic, and Resolved

Definition	Frequency	Percent
Acute	69	17.8
Chronic	264	68.0
Resolved	55	14.2
Total	388	100.0

Note. This table was calculated using cases diagnosed between March 27, 2009 and December 31, 2016 and excludes case management cases and children under 15 yrs.

missing information in the charts, due to evolving case report forms and cases that could not be located after diagnosis. The number of questions not answered is noted in Table 6 and 7.

The data revealed that the majority of those diagnosed with HCV were living in urban areas of PEI (60%) and less in rural PEI (34%); 6% did not have an answer to this question. More than 65% of cases were diagnosed with HCV between the ages of 30 and 59 years, and PEI had more males diagnosed than females. Further analysis showed a significant difference in the median age of females and males at diagnosis ($p<0.000$). Females were found to be younger at diagnosis (34 years) than males (37 years).

The majority of people with HCV diagnosed in PEI were born in Canada. Unlike some other blood borne pathogens such as Hepatitis B, HCV appears to be contracted by Canadians in PEI as opposed to people already infected from endemic countries immigrating to PEI. Although the question of race was answered poorly, of those who answered, 90% were White.

Table 6

Demographic Characteristics of HCV Cases Diagnosed on PEI 1991-2016 (n=784)

Variable	Frequency	Percent
Urban/rural		
C0 (rural)	267	34.0
C1 (urban)	471	60.1
Unknown	46	5.9
Age at diagnosis		
15-19	18	2.3
20-24	96	12.2
25-29	141	18.0
30-39	243	31.0
40-59	264	33.7
60+	22	2.8
Sex		
Male	506	65.3
Female	278	34.7
Born in Canada		
No	27	3.4
Yes	524	66.9
Unknown/no answer	233	29.7
Race		
White	145	x[b]
Asian[a]	<5	x
Black[a]	<5	x
Aboriginal Peoples	12	x
Latin American[a]	<5	x
South Asian/West Asian/Arab[a]	<5	x
Unknown/no answer	623	x

Note. [a]Data supressed for any results less than 5 in accordance with the CPHO (2016) *Small Numbers Policy*. [b]Percentages not available for the variables affected to maintain anonymity.

Table 7

Risk Factors for HCV Cases Diagnosed on PEI 1991-2016 (n=784)

Variable	Frequency	Percent
IV drug use		
Current	387	49.4
Past	218	27.8
Never	144	18.4
No answer	35	4.4
Snorting drugs		
Current	73	9.3
Past	44	5.6
Never	161	20.5
No answer	506	64.6
Shared drug paraphernalia		
Current	233	29.7
Past	153	19.5
Never	186	23.7
No answer	212	27.1
Blood Transfusion or organ transplant before 1992		
Yes	69	8.8
No	621	79.2
No answer/unknown	94	12.0
Dental or major surgery before 1992		
Yes	69	8.8
No	462	58.9
No answer/unknown	253	32.3
Sexual or household contact		
Yes	176	22.5
No	459	58.5
No answer/unknown	149	19.0

Table 7 (continued)

History of incarceration		
Yes	191	24.4
No	64	8.1
No answer	529	67.5
Tattoo or piercing		
Yes	165	21.1
No	55	7.0
No answer/unknown	564	71.9
Occupational needle stick		
Yes[a]	<5	x[b]
No	170	x
No answer/unknown	610	x

Note. [a]Data supressed for any results less than 5 in accordance with the CPHO (2016) *Small Numbers Policy*. [b]Percentages not available for the variables affected to maintain anonymity

Table 7 illustrates the occurrence of each risk factor found in the case chart reviews. Seventy-seven percent of all cases had a history of or were currently using IV drugs. In some cases, the use of IV drugs was in the remote past and may have been for a short time. Sharing needles was reported by almost half of all cases. Blood transfusions or organ transplant prior to 1992 was a cause for acquisition of HCV in 9% of cases and approximately the same number of cases reported major surgery or dental procedures as risk factors. These cases were generally seen in the early days of diagnosing HCV, as blood was not screened for HCV prior to 1992 (Engle et al., 2014; Macdonald, O'Brien, & Delage, 2012; O'Brian, 2015). There were a few cases who were diagnosed in recent years that appear to be related to blood transfusions that occurred prior to the screening of blood and blood products, but these cases were not identified until being investigated for other medical issues.

Twenty-three percent of cases reported a household or sexual contact who was HCV positive. Twenty-four percent of cases had a history of incarceration; however, it is important to note that this was not a question on the case report form for many years, and 67% of cases did not have an answer to this question. Similarly, having a tattoo or piercing was introduced to the case report form in recent years and over 70% of cases did not have an answer to this question. There were less than five HCV positive cases who suffered an occupational needle injury. In some cases the injury was sustained many years prior, but was the only risk factor identified. There were less than five cases of vertical transmission of HCV from mother to child. Child cases who did not have testing after 24 months of age were not counted.

Eleven cases were under the age of 15. These cases were dropped from the dataset for the analysis of questions two and three. Three cases were not included in the analysis of this group as they were tested at birth or within the first 23 months and either had no further testing after 2 years of age or the screening test was negative after 2 years of age. As noted, the literature describes 24 months as the point where clearing the virus becomes unlikely (Healy et al., 2001; Mast et al., 2005). Less than five of the cases under 15 years of age had the risk factor of blood transfusion before 1992, and less than five were born to a mother who was infected with HCV. Less than five cases were females and less than five were males; most cases lived in the urban postal code. The ages ranged from just over 2 years of age to 11 years of age, with the mean being 6 years of age.

Question 3 (b). "Which demographics/risk factors have a significant association with the diagnosis of acute HCV?" Each risk factor and demographic variable as described in part (a) of this question was tested for its significance related to the occurrence of acute HCV infection on PEI using chi square and t-test. Table 8 illustrates the results of the analysis. In the initial evaluation of the risk factor and acute status, only two variables were significant with a p value <

Table 8

Results for the Association of Demographics/Risk Factors of the Diagnosis of Acute HCV on PEI

Variable	Number of responses (n= 333)	P value	Used for logistic regression model
Postal code	324	.685	no
Sex (M or F)	333	.068	yes
Age at diagnosis	333	<.001	yes
Race	120	.552	no
Born in Canada	199	.061	yes
Ever-used IV drugs	312	.022	yes
Ever-snorted drugs	117	.953	no
Ever-shared paraphernalia	213	.135	yes
Blood transfusion/organ receipt before 1992	383	.162	yes
Having surgery or dental surgery before 1992	197	.167	yes
Sex with an HCV+ partner	250	.459	no
History of incarceration	160	.140	yes
Having a tattoo or piercing	139	.109	yes
Having an occupational needle stick	136	.448	no

Note. The variable "being born to a mother of HCV" has no positive answers as children under the age of 15 were removed from the dataset. There were only two variables that had a significant relationship of $p<0.05$: age and IV drug use.

0.05: age and IV drug use. However, two variables approached significance: sex and being born in Canada, with p values of 0.068 and 0.061 respectively. The risk factor and demographic variables that had a p value <0.2 were included in the regression analysis modelling to determine the most important independent variables that influenced being an acute case. The variables included in the regression analysis were: (a) sex, (b) age at diagnosis, (c) being born in Canada, (d) ever using IV drugs, (e) ever sharing paraphernalia, (f) ever having a tattoo or piercing, (g) ever being incarcerated, (h) having a blood transfusion/organ receipt before 1992, and (i) having surgery or dental surgery before 1992. In the final regression model, only age at diagnosis was found to be predictive of being an acute case of HCV on PEI. This result is illustrated in Figure 4. Of the cases that were acute, 72% were between the ages of 20 and 30 years. To further illustrate the impact of age on recently acquiring the HCV infection, the predicted probability was analyzed at different ages. Figure 5 shows the modelled probabilities of being an acute case by age. The odds ratio was also calculated for age. For each decreasing decade of age, the odds of being acutely HCV positive increase by 2.3 times (95% confidence interval 1.6-3.3).

Even though not statistically significant in the final regression model, the relative risk of using IV drugs to being an acute case of HCV was calculated. If a person used IV drugs, that person was 3 times more likely to be acutely infected with HCV than if they didn't use drugs. The odds ratio for age and relative risk for IV drug use are further illustrated in Table 9.

Summary

In summary, the prevalence of active HCV cases on PEI was estimated to be 430 cases. Intravenous drug use is the most prevalent risk factor for those who were infected with HCV and diagnosed on PEI. More than 65% of cases were diagnosed with HCV between the ages of 30 and 59 years, and PEI had more males diagnosed than females. Further analysis showed a significant difference in the median age of females and males at diagnosis (p<0.000). Females

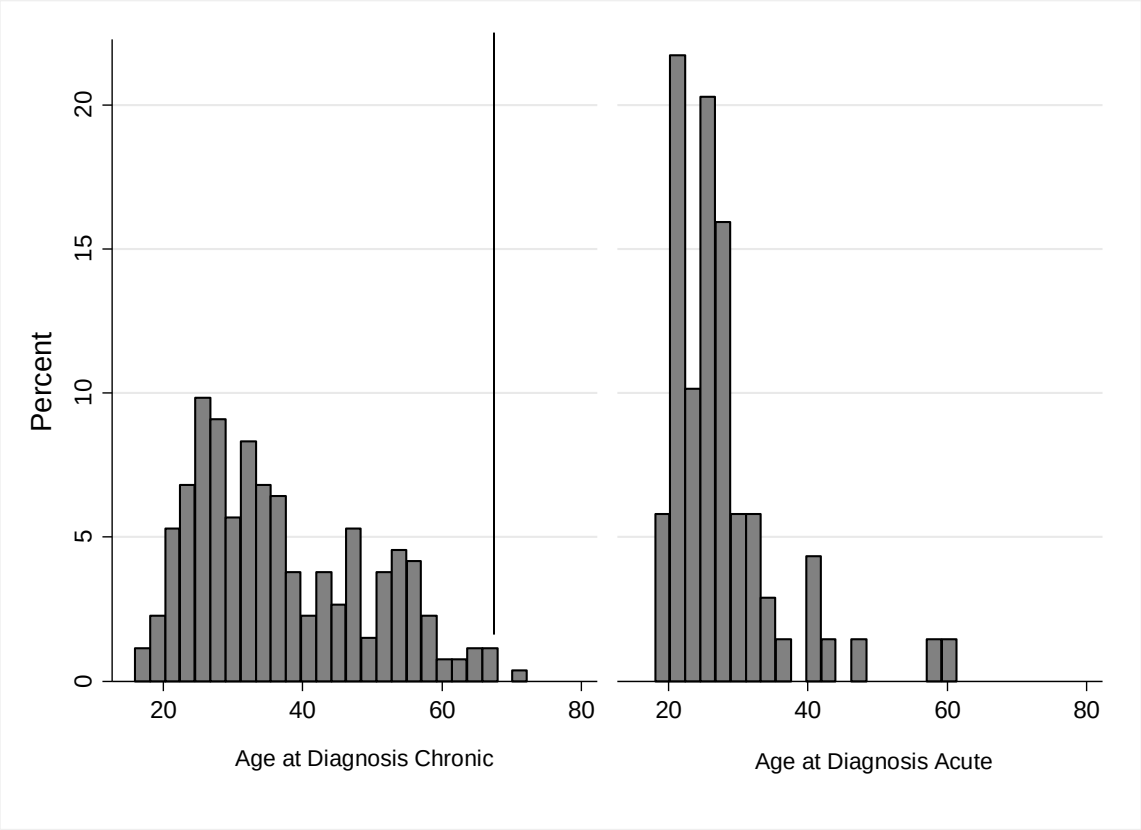

Figure 4. Percent of cases for years of age for chronic cases and acute cases.

were found to be younger at diagnosis (34 years) than males (37 years). The study was limited by only having the laboratory data for cases diagnosed after March 27, 2009; therefore, the case definition for acute and chronic cases was applied to 388 cases. Of these, 18 % were acute, 68% were chronic, and 14% were resolved. In these cases, people who used IV drugs were 3 times more likely to be acute. As well, the younger the case was in age, the greater the probability of the case being acute.

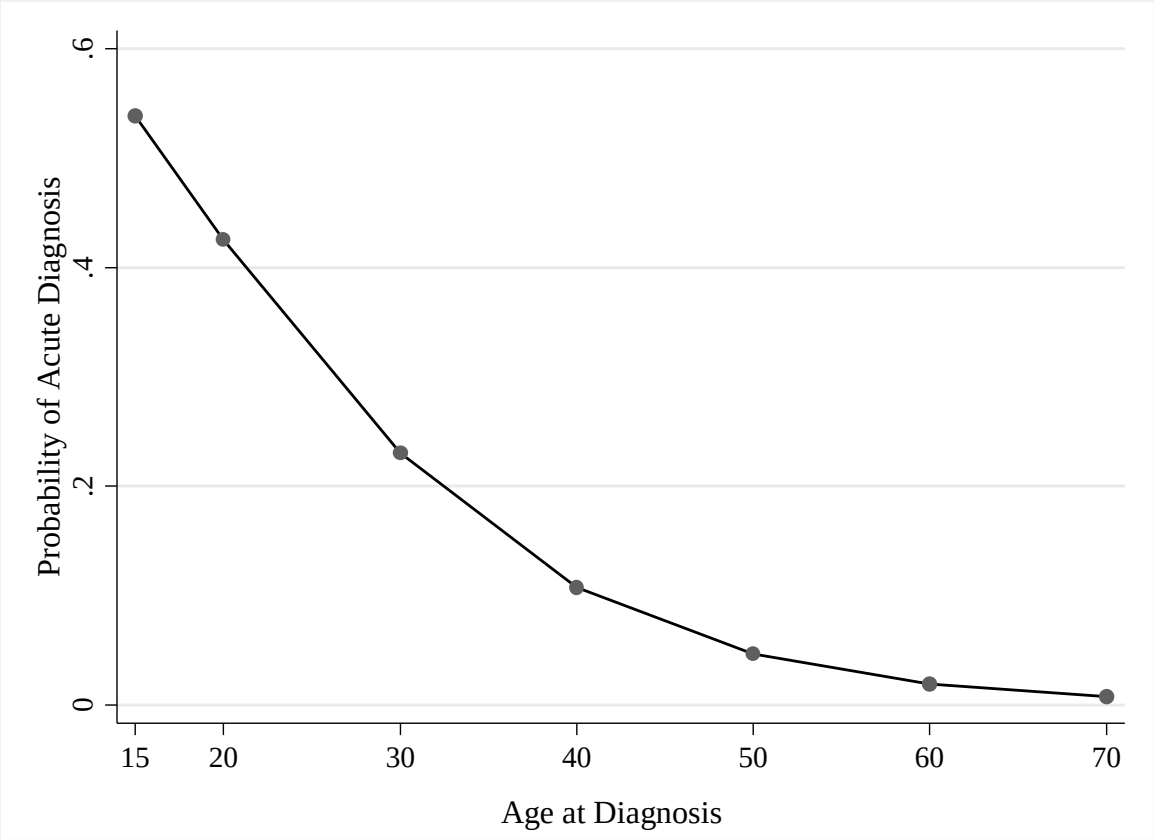

Figure 5. The modelled probability of being acute by age at diagnosis.

Table 9

Results for Risk Factors with P Value of <0.05

Risk Factor	Level	OR/RR (CI)	p-value
Age	-10 years	OR 2.3 (1.6-3.3)	<0.001
Ever-used IV drugs	Yes	RR 3.1	0.022

CHAPTER 5

Discussion

This chapter presents a discussion and interpretation of the results presented in Chapter 4. The discussion proceeds according to the research questions and compares the findings to the literature. The discussion begins with a review of the LAC PHN Practice Model, how the results can be used according to the model, and how they can be used moving through the next steps of the model.

LAC PHN Practice Model

Smith and Bazini-Barakat (2003) created the LAC PHN practice model to bring the focus of public health nursing from simply action and implementation of nursing practice to the important steps that come before and after public health action. The first two steps of the model "Assess and Diagnosis" were carried out in the data collection and analysis sections of this study. In the discussion, the information gathered will be interpreted and will begin to generate the direction for the planning for public health action. The focus of the model is population-based practice involving individuals and families, communities, and systems, with public health practice originating with the public health nurse and the public health team. The clients/population of interest are active participants throughout the framework. The public health practice of HCV data collection on PEI throughout the years is an example of this focus.

The data used in this study were originally collected by the Chief Public Health Officer, from physicians caring for the people infected with HCV, or from the people infected with HCV themselves. The researcher is a nurse working in CD in the CPHO and data were merged by public health epidemiologists. Thus collection of the data, assessment, and diagnosis of the HCV cases was, as the framework states, a public health team effort. The results of this study can be used in the next steps of the model, ID Outcomes and Planning which will lead to the final steps

of the model, Act and Evaluation. The next steps of the model are discussed further throughout this chapter according to the research questions.

Question 1

By answering Question 1, "How many people on PEI have active HCV infection diagnosed by positive laboratory results?" the researcher hoped to be able to provide a snapshot of the potential health burden of HCV infection on PEI. People who have the virus present in their blood, will eventually have some level of damage to the liver (Cacoub et al., 2016; Chen & Morgan, 2006; Negro et al., 2015).

It was estimated that almost half of the cases diagnosed on PEI still have active infection. The laboratory data available provided most of this information. For those not tested after 2008, it was possible to use laboratory information from the paper charts which contain paper copies of laboratory results; these were recorded and were available for analysis. Unfortunately, cases tested in the 1990's and early 2000's were generally not tested for PCR or viral load, so many of these cases would have been actively infected but no record is available. To account for this it was estimated that 80% of the cases who were RIBA positive from 1991 to 2002 would actually have had a positive PCR/viral load. This was added to the total which then became the estimate of cases actively infected. We know that the answer to this question would be an estimate even if we had these test results as we cannot be certain how many cases have moved from PEI since they were last tested and if any HCV positive cases have moved to PEI and have never been tested here. As well, the HCV provincial treatment program has cured numerous people living with HCV. There are at least 155 people who have participated in the HCV treatment program and been cured in the past 3 years (personal communication D. Lewis Fleming, December 5, 2017). Most of the treated cases should be reflected in the laboratory data

when they were tested for sustained viral response; however, those completing treatment after December 13, 2017 will not be reflected in the results.

There are no national acute and chronic rates to compare with PEI. However, we know that PEI's overall rate of HCV infection was higher than the national average in 2014, but is now close to the national average and is showing a declining trend similar to the rest of the country (PHAC, 2016).

The literature states that complications from HCV such as cirrhosis and hepatocellular carcinoma are seen 30 to 40 years after acquiring the disease (Cacoub et al., 2016; Chen & Morgan, 2006; Negro et al., 2015). There are cases whose risk of acquiring the disease occurred in the distant past, which could imply they had been infected much longer than their diagnosis date indicates. It would have to be assumed, even though 62 cases were diagnosed greater than 20 years ago that some people were infected greater than 30 years ago but testing to identify HCV infection was not available. However, as most cases have been infected less than 30 years, treatment has the potential to drastically reduce the burden of illness and the future health care implications and costs caused by HCV infection as predicated by Myers (2015). With the recent availability of pan-genotypic treatment, all HCV genotypes are now able to be treated and in almost all cases, cured of HCV. In studies by the company that supplies HCV treatment to PEI, 97% of cases of HCV (with cirrhosis and without) treated with the new pan-genotypic medication have been cured (Abbvie Corporation, 2017). The definition of cure is a sustained viral response meaning, no detectable viral load, for 12 weeks post treatment (Abbvie Corporation, 2017). There is great potential for treatment to decrease or even eliminate the burden to the health care system and those infected with HCV. Case finding and reaching cases who were diagnosed in the distant past will be important when working toward minimizing the impact of HCV in the Province.

Question 2

The PHAC case definition for acute and chronic HCV was used to answer Question 2 "How many PEI HCV cases were diagnosed when they were acute and how many were chronic?" Question 2 was asked so that the PHAC case definition for national surveillance of HCV in Canada could be applied retrospectively for PEI HCV cases. Janjua et al. (2016) discuss prevalent or chronic HCV infections as being representative of infections acquired in the distant past and these individuals are usually not involved in ongoing risk activities. New or acute infections represent ongoing transmission usually occurring in people with high risk activities such as injection drug use. These two groups would have varying levels of onward transmission risk and would have differing needs for engagement in prevention and care. Surveillance activities created around these ideas might serve public health purposes.

As noted in the literature review, internationally there are many definitions used to identify acute cases of HCV (Hajarizadeh et al., 2012). Oreland, Wright, and Cooper (2001) state that the majority of cases of acute HCV do not show symptoms and thus do not present clinically, which makes estimating the incidence of recent infection a challenge.

The literature indicates that approximately 80-85% of those diagnosed with HCV will go on to have a viral load for longer than 6 months (Myers et al., 2015; Wong & Lee, 2006; WHO, 2014). This was the case for PEI, as 14% of cases with positive antibody screens were noted to have resolved or cleared their infection. The data also showed that at diagnosis 86% of cases were active cases with 18% identified as acute and 68% as chronic. In both acute and chronic cases there was viral load as discussed in Question 1, but those classified as chronic did not have information available to meet the case definition for an acute case, including a previous negative screen within the past year. This is not necessarily an accurate picture of acute cases, as those who were not tested in the recent past and did not experience symptoms do not make it to the

acute category, even if the risk factor that may have exposed them to the disease occurred recently. As shown in the results for Question 3, many of those infected with HCV have had past use or are currently using IV drugs. Those currently using IV drugs may not have the resources to seek or access testing for HCV and other blood borne diseases on a regular basis (Frazer et al., 2011; Keats et al., 2015; Krebbeks & Cunningham, 2013; Lewis et al., 2010; Nyamathi et al., 2013; Nyamathi et al., 2015; Olson & Jacobson, 2011). Thus, in many cases there are no previous HCV screens to provide information regarding the timeframe for the occurrence of the infection.

In the past, PEI reported all cases of HCV as unspecified, meaning the cases were not differentiated using the case definition (PHAC, 2017a). Cases diagnosed within 1 year of acquisition of their infection were grouped with those diagnosed later in the disease process, or those that the timing of infection acquisition could not be determined. Nationally in Canada, acute case information is not reported consistently by the provinces so there is no available comparator. Even though it is possible that acute cases may have been misclassified as chronic cases due to the lack of data available, the information collected from cases that are acute can offer insight into the current transmission trends and patterns and chronic cases of HCV provide information regarding the potential burden of disease (PHAC, 2017a). The information required to classify cases as acute, chronic, or resolved going forward will be available to the CPHO, and will be collected on the case report form. It will be possible to report classified cases to the PHAC. This study provides case definition data for previous cases and this information can also be provided to PHAC.

Onofrey et al. (2015) note that changing the requirements that define acute cases and including variables such as being younger in age, looking at the date of risk onset, and removing the requirement for negative HAV and HBV screens, along with adopting a wider window

between the new positive and previous negative test results would provide more cases in the acute category with which to collect risk information. Another alternative would be a tiered categorization of acute cases such as confirmed cases that could be reported to PHAC and probable cases and possible acute cases which could include the less stringent timelines and consideration of other variables as mentioned. This type of tiered case definition is used for other reportable diseases, and PEI has approached other diseases in this manner to enhance risk analysis. PEI could consider adopting an evidence-based, local tiered case definition to create a more robust profile of recently acquired cases to guide policy decisions. Information from surveillance data, local studies, and the literature can provide a basis to move to the planning stage of the LAC PHN model which might then lead to the implementation of a new provincial case definition that would provide richer surveillance data to plan and implement programming.

Question 3 (a)

The question "What were the risk factors and demographics for all HCV cases diagnosed on PEI (acute, chronic, and resolved) ?" was interested in the risk factors for all those who had been infected with HCV while on PEI, whether they cleared the virus or not. The only cases not included were those diagnosed outside of the province and cases under the age of 15 for reasons previously discussed.

More than 65% of cases on PEI were diagnosed with HCV between the ages of 30 and 59 years and more males were diagnosed with HCV than females. These are consistent with national trends (PHAC, 2017a). Further analysis showed that the median age of females at diagnosis is younger (34 years) than males (37 years), which is also consistent with national trends (PHAC, 2017a).

On PEI, the majority of HCV cases were in residents of urban areas (60%). The first two characters of the postal code used to determine urban and rural only included Charlottetown,

Stratford and Summerside as urban “C1” areas. Thirty-four percent of cases occurred in rural or for this study the “C0” postal code. Statistics Canada (2011) showed that on PEI, the percentage of people living in urban areas was 47% and in rural areas was 53%. Statistics Canada defines urban centers as those with greater than 1000 people (Statistics Canada, 2011). This would not only include the two cities on PEI but also include smaller towns such as Montague, Souris, Tignish, and Alberton; however, this study considered Montague, Souris, Tignish and Alberton rural areas. As Statistics Canada included the smaller towns of the Island in their urban designation, the population infected with HCV is markedly different from the general Island population, as HCV cases are clustered in the urban areas. However, there may be cases not being tested in rural areas as the majority of services are concentrated in the more urban areas of the province. To use these data following the LAC PHN practice model (Smith & Bazini-Barakat, 2003) the next step would be to use this information in policy and program planning. Promotion of rural outreach as well as harm reduction in urban areas could be assessed.

In the 2014 surveillance report for HCV in Canada, it was estimated that 54% to 70% of hepatitis C infections between 2005 and 2010 were a result of injection drug use (PHAC 2017a). The present study showed that 77% of HCV cases on PEI have a current or past history of using IV drugs, which is higher than the national average. However, in some cases there may also have been other risk factors such as living with or having sex with an HCV positive person; therefore, assigning the cause directly to IV drug use would not always be possible.

As nursing is a holistic practice, and public health nursing as noted in Smith and Bazini-Barakat's (2003) LAC PHN practice model involves the process of systems change, it is important to consider the root cause for HCV transmission at this point in time. Mental health is not assessed as a risk factor on the present case report forms for HCV on PEI but as IV drug use is the most common risk factor, attention to mental health and addictions, and homelessness must

be given if it is hoped to eventually eliminate HCV on PEI. This is a much larger issue outside the scope of this study, and a systems level change is required to address these much larger community and population-based issues.

Question 3 (b)

Due to the poor response rate for many of the questions on the case report forms, significance for most risk factors and demographic variables was low. However, four of the most significant variables for the occurrence of HCV infection on PEI will be discussed: age, sex, being born in Canada, and IV drug use.

While performing the analysis to determine the risk factors which contributed to the occurrence of acute cases, it became clear that due to the likelihood of acute cases being diagnosed as chronic cases, the analysis results would not be as clear as expected. The regression model was not successful in finding multiple variables that were significant to the occurrence of acute cases; it did show that age was very significant to the diagnosis of acute HCV. Logic would dictate that the younger you are, the more likely you are to be diagnosed early in your disease. It was demonstrated in this study that if you are 20 years old, you are 40 times more likely to be acute than at age 70 years. When looking at the probability graph (Figure 5), going below 15 years of age would continue to show increased probability of being acute, however, this would not be accurate as we know for instance, IV drug use would not be as prevalent a risk factor in the under 15 year old population.

Interestingly, all cases not born in Canada were categorized as chronic. This may be due to the structure of the case definition itself, as cases may be categorized as chronic due to not having access to previous negative testing done prior to immigration. It may also be that immigrants were infected previously in the country from where they immigrated. In Canada in 2002, 20% of HCV cases were found in immigrants from countries where healthcare infection

control practices that would prevent the transmission of HCV, are not used consistently (PHAC, 2017a). This was not demonstrated in the PEI cases, as only 37 of 784 cases or approximately 5% of cases were not born in Canada.

Through the course of this study information that is lacking in order to easily make the diagnosis of acute and chronic HCV has been identified. As a result, these data have been added to the latest version of the HCV case report form. With the evolution to electronic case reporting in the CPHO, all risk factor questions are now required to be answered on the case report form. These improvements are examples of the results of the evaluation step in the LAC PHN model. These improvements will increase the data available for analysis in the future. With the assessment and analysis of this new data, the model cycle begins again.

Summary

In answering the research questions proposed by this study it was revealed that like the rest of Canada, IV drug use is the most significant risk factor for transmission of HCV. More males are infected than females and Canadians instead of immigrants are being infected on PEI. The national case definition adopted by the PHAC (2016b) has proven problematic in that there is risk of misclassification of acute cases as being chronic due to the laboratory data required to make the diagnosis of an acute case. Development of a new tiered case definition for PEI that expands the definition of “recently acquired” may improve the data collected and information available to identify at-risk clients, and plan action for the prevention of disease.

CHAPTER 6

Summary

This chapter presents a summary of the study limitations, the study implications for nursing theory, education and future research, and finally a study conclusion.

This study provided a synthesis of the information from the charts of all previously diagnosed cases of HCV on PEI. Intravenous drug use was the most prevalent risk factor for those who are infected with HCV on PEI. Females were diagnosed at a significantly younger age (34 years) than males (37 years). Although the significance cut off p value was <0.05, the demographic factors of being born in Canada and sex approached significance with a p value of 0.061 and 0.068 respectively. The study was limited by only having the laboratory data for cases diagnosed after March 27, 2009. The case definition for acute and chronic cases was able to be applied to 333 cases. In these cases, people who used IV drugs were 3 times more likely to be acute. As well, the younger the case was in age the greater the probability of the case being acute.

Limitations

There were several limitations in this study related to the data collection process, laboratory data availability, and limitations of the case definition. In this section, the risks of bias in the study will also be discussed.

Data collection. A common issue when doing a retrospective chart audit, as noted by PHAC (2015), is that case report forms used through the years for data collection evolve. Questions change, are added, and taken away as knowledge of a condition advances. In the early 1990's, when HCV was discovered and considered a virus related to blood transfusion, the focus of the case report form was blood services trace backs. The case report forms had other risk factor questions that may or may not have been answered. As evidence of other risk factors for

acquiring HCV infection were provided in the literature, they were added to the case report forms. As the main risk factor for HCV infection is IV drug use, contacting cases to obtain health history can be difficult as they may not have a stable address, cell phone number or be able to reliably attend appointments.

The numbers of cases of HCV on PEI may not be entirely accurate as it is possible that cases diagnosed on PEI have since moved to another province. As well, there may be people who are positive for HCV who live on PEI but were not diagnosed in this province and have not been re-tested since they moved. It is also possible that some people included in the study have expired during the course of the data collection.

Health PEI Laboratory data. As discussed throughout the study, the laboratory data required to determine the case definition assignment were not available for cases prior to March 27, 2009. This decreased the sample size by more than half.

Case definition. Many cases infected with HCV were placed into the chronic classification due to lack of laboratory data such as a test for HAV infection. Due to the parameters of the national case definition, only those who are tested routinely or had symptoms within the prescribed time frame would be identified as acute cases, thus acute cases are under represented by the numbers expressed in this study due to the limited data available (PHAC, 2017a)

Bias. There is a risk of bias in this study for several reasons. In retrospective studies, it is common to have missing data. In this study, there were several variables that were missing a large number of data. It was not possible to eliminate the cases that had missing data, as the sample size would become too small and other useful data from these cases would be lost. Instead, establishing the significance of the relationship of each variable to the occurrence of

acute HCV infection provided an illustration of the important risk factors and demographics in our province.

The case report form information is generally obtained by interviewing the clients who are infected with HCV. There is a potential for social desirability bias, as they may answer some questions such as “sharing paraphernalia” with an answer that would be more socially acceptable. Thus, the risk factor information may not be totally accurate.

Due to the availability of new treatments for HCV on PEI in the past few years, there may have been an increase in testing as compared to other provinces that had not yet made this new treatment available. As well, the availability of testing in the province may influence the type of population being tested, such as living in urban areas, having access to transportation or being in the process of substance use recovery. As well, the cases that were lost to follow-up could not be assessed for their impact on the outcome which could result in selection bias (Bajas et al., 2017). The researcher did attempt to measure for confounding and influence within the variables, however, factors outside the control of the study may still bias the results.

Implications for Nursing Practice

Collection of case report form data is presently the responsibility of the HPEI public health nurses. The quality of this data is dependent on the assessment skills, the interpersonal communication skills, and the thoroughness of the nurses performing the HCV follow up. As the LAC PHN practice model outlines, the data collection and diagnosis of a health issue, lay the foundation for the planning and implementation of practices to reduce the impact of the health issue for the population (Smith & Bazini-Barakat, 2003). Disseminating surveillance results and discussing the rationale for gathering complete data will help nurses generate appropriate probing questions and be equipped to educate their clients with HCV.

Considering the number of cases who were actively using drugs at their diagnosis, reaching this population is extremely important for harm reduction activities such as Opioid Replacement Therapy and the Needle Exchange Program in order to decrease the spread of the infection and provide support to those who are vulnerable. Nurses are the cornerstone of harm reduction activities for at-risk clients. Pain management as well as mental health and addiction treatment must also be considered to aid in the reduction of IV drugs as a risk factor for HCV acquisition. Nurses are instrumental in assessment, counseling, and education in these areas. Further study in HCV treatment and elimination can be carried out by nurses involved in this project.

Implications for Theory

The Los Angeles County Public Health Nursing Practice Model describes the process by which public health practitioners make decisions and implement programs. This study focused on the first two steps of this model: Assess and Diagnose. This model provides guidance regarding the use of the study results for policy and program development, as well as public health action, and serves as an organizational framework for use of the results of this study. If treatment for HCV infection is to become more accessible to people infected with HCV, planning for primary health care providers, the role of community pharmacies, and establishing criteria for treatment will need to occur. As well, evaluation of programs that are initiated can be completed using the data collected in the assessment and diagnosis steps of the model. The model outlines how the individual, family, community, and systems interact.

Health Indicators are meant to align the work of the PHN with the direction being given nationally and during the ‘Assess’ step, were used as part of data gathering, as they include useful data for creating a diagnosis. Health indicators "substance abuse, responsible sexual

behaviour, mental health, and access to health care" (Smith & Bazini-Barakat, 2003, p. 44) were considered in this study.

This study has shown that at the individual level, IV drug use is the main risk factor for acquisition of HCV. However, as the model identifies, population-based care may be directed at not only the individual, but communities and systems. At the systems' level the case definition used for the diagnosis of acute HCV may require modification to provide more robust data for PEI to continue to direct planning and policy development. Intravenous drug use must also be addressed at the community and systems' level by partnering with law enforcement and re-evaluating how the law views drug use and increasing community supports for those who use drugs. In planning for public health action, all levels of the population must be addressed in order to obtain the goal of "healthy people in healthy communities" (Smith & Bazini-Barakat, 2003, p. 45).

Implications for Education

The results of this study highlight the need to have complete, accurate data. The researcher can use the findings and experience of carrying out this research, to plan improvements in the case report forms and provide guidance to nurses collecting the data.

This study identified risk factors, demographics, and applied case definitions to the HCV cases on PEI. Providing the number of acute and unspecified cases to PHAC provides information not previously known. In time, it is hoped that all provinces will provide the same information and national data will be available for provinces to use as benchmarks regarding current infection trends.

It is important for health care providers to know the risk population for the Province so that targeted screening based on risk profile can be offered and implemented. This is particularly important now that there is a cure for HCV.

Recommendations for Future Research

As additions to the case report form are instituted and data are gathered over time, further analysis on the poorly answered risk factors of this study can be carried out to determine the significance of incarceration, tattoo and piercing, and occupational needle sticks in our population.

With a picture of what our HCV positive population looks like on Prince Edward Island, future research examining health care providers' knowledge about HCV and their attitudes towards those at risk could be undertaken to guide education efforts. Identifying the health care providers who test for HCV most frequently and more importantly areas where testing is not routinely done can also help to target education and information so that all those at risk have access to testing.

It will be important moving forward that the HCV treatment program and the CPHO collaborate and share data in order to have up-to-date data on active cases in the province. Moving forward, chart data will be collected electronically, which will provide easier access for analysis. Prince Edward Island is a unique province due to its size and population. Further research into screening protocols most appropriate for the province, based on the risk factors and demographics noted in this study could be undertaken. Being such a small province, it is feasible that many of PEI's HCV cases could be treated and cured over the next several years.

The definition of cure is a sustained viral response 12 weeks post treatment. Future research to follow cases in the years posttreatment for recurrences and reinfections will be important to determine further actions required to support those who have received treatment to remain free of the virus.

Conclusion

Hepatitis C infection continues to be a significant public health issue affecting certain segments of the Canadian and Island population. Hepatitis C infection has mental health and physical health implications with new cases continuing to occur on PEI. Gathering information on risk factors and demographics of newly acquired cases provides the best data with which to plan and implement programs for prevention, education, and treatment. This study provided information from all previously diagnosed cases of HCV on PEI. It was not surprising that IV drug use was the most prevalent risk factor for those who are infected with HCV on PEI. Sixty five percent of cases who are HCV positive on PEI were diagnosed between the ages of 30 and 59, with females being diagnosed at a younger age than males. Islanders who use IV drugs are 3 times more likely to be acutely infected with HCV.

Moving forward, an examination of the case definition used to differentiate acute and chronic cases for analysis of risk should be undertaken. Martinello and Matthews (2015) discuss the diagnosis of acute HCV infection as a means to estimate the annual incidence rates and transmission patterns at a population level, which can guide the planning and implementation of prevention programs. At an individual level, identifying acute cases can encourage early linkage to multidisciplinary care, including education and counselling to attempt to reduce high-risk behaviours and further virus transmission. The concept of treatment as prevention will rely on early diagnosis and treatment to make a significant impact on the prevalence of chronic HCV infection.

Utilizing current population data and capitalizing on opportunities to improve public health policy and process will move forward the goal of the LAC PHN Practice Model “healthy people living in healthy communities” (Smith & Bazini-Barakat, 2003, p. 45).

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Appendix A

Letters of Support

Prince Edward Island CANADA

Health and Wellness

Santé et Mieux-être

Île-du-Prince-Édouard CANADA

Chief Public Health Office
16 Fitzroy Street
PO Box 2000, Charlottetown
Prince Edward Island
Canada C1A 7N8

Bureau du médecin hygiéniste en chef
16, rue Fitzroy
C.P. 2000, Charlottetown
Île-du-Prince-Édouard
Canada C1A 7N8

To whom it may concern,

I am writing to provide my full support for the study, "A Description of Hepatitis C Infection on Prince Edward Island", to be conducted by Stacey Burns MacKinnon, a student in the Masters of Nursing Program at UPEI.

As the treatments, testing methods, and harm prevention interventions rapidly change and improve for people with HCV, the public health system and health care may need to make decisions regarding adoption of these new interventions. Further detailed information regarding risk factors and characteristics may help provide direction for future HCV policy and program planning for PEI. I support Ms. Burns MacKinnon in the proposed study.

[redacted]

Dr. Heather Morrison
Chief Public Health Officer

Tel/Tél. : 902 368 4996 www.gov.pe.ca Fax/Téléc. : 902 620 3354

Prince Edward Island CANADA

Health and Wellness

Santé et Mieux-être

Île-du-Prince-Édouard CANADA

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16 Fitzroy Street
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C.P. 2000, Charlottetown
Île-du-Prince-Édouard
Canada C1A 7N8

To whom it may concern,

I am very pleased to write this letter of support for Stacey Burns MacKinnon, a student in the Masters of Nursing Program at UPEI.

In order to gain an understanding of the factors involved in the cases of Hepatitis C virus (HCV) infection occurring each year in PEI, the cases must be identified as being recently acquired or acquired in the past. The Public Health Agency of Canada (PHAC) has requested the provinces and territories categorize hepatitis C virus (HCV) cases using a case definition that was issued in 2011. The application of the PHAC case definition to HCV cases on PEI will provide more information for national surveillance and context for the cases occurring in our province.

The proposed study by Stacey requires access to data that have been collected in hard copy case files at the Chief Public Health Office (CPHO). As the provincial epidemiologist and the manager of the Public Health Assessment and Surveillance (PHAS) unit at the CPHO, I support this study and am willing to provide assistance in accessing laboratory data from Health PEI. I also support granting Stacey access to approximately 850 paper charts located in the Communicable Disease Coordinator's office in the CPHO. The PHAS unit will also assist by linking the lab data with data from the CPHO CD database and the data collected by Stacey, which will then be extracted into an *Excel* database. All identifiers will then be removed. The study has been designed to protect the privacy of the cases and complies with the policies of the CPHO. I fully support Stacey in conducting this study.

[redacted]

Carolyn Sanford
Provincial Epidemiologist

Tel/Tél. : 902 368 4996 *www.gov.pe.ca* Fax/Téléc. : 902 620 3354

Appendix B

Ethics Certificates

Health PEI
One Island Health System

PEI Research
Ethics Board
16 Garfield Street
PO Box 2000, Charlottetown
Prince Edward Island
Canada C1A 7N8

Santé Î.-P.-É.
Un système de santé unique

Comité d'éthique de la
recherche de l'Î.-P.-É.
16, rue Garfield
C.P. 2000, Charlottetown
Île-du-Prince-Édouard
Canada C1A 7N8

FULL APPROVAL FORM

Date: April 20, 2017

Project Title: ***Description of Hepatitis C Infection on PEI***
Principal Investigator: **Stacey Burns MacKinnon**

Document(s) Reviewed:

- Protocol Submission Form (UPEI) (Dated January 2017)
- Table 1: Case Definitions
- Table 2: Independent Variables
- Table 3: Variables for Application of case Definitions
- Figure 2: Categorization Algorithm for the dependent variable
- Letter of Support from Dr. Heather Morrison, Chief Public Health Officer (Not Dated)
- Letter of Support from Carolyn, Provincial Epidemiologist (Not Dated)
- CV for Stacey Burns MacKinnon
- TCPS2 CORE Certificate (Dated 9 September 2012)
- PEI REB Confirmation of Supervisors Review Form (Dated February 5, 2017)
- Full Submission (Not Dated)
- REB Request for Waiver of Consent Form (Not Dated)

Full approval has been granted for the above noted study. This study was reviewed according to ICH GCP Guidelines and will require an annual report and request for re-approval to be in place prior to April 20, 2018.

Notification of closure is required once the study is completed or terminates early. The "Continuing Review Reporting Requirements"; the "Reporting Study Closure and/or Early Termination"; and the "Request for Annual Approval" forms are attached.

ATTESTATION: This Research Ethics Board complies with Division 5 of the Food and Drug Regulations, the ICH Harmonized Tripartite Guidelines: Good Clinical Practice, and the Tri-Council Policy Statement.

Signature: [redacted]

Name: Kathryn Bigsby, MD, FRCPC
Title: Chair, PEI Research Ethics Board

Tel/Tél. : 902 569 0576 healthpei.ca Fax/Téléc. : 902 368 4969

REB Approval: File #6007047 Inbox x

mknight@upei.ca 5/3/17

to Stacey, Jo-Ann, Carol, Janet, MoffattLyndsay

May 03, 2017

RE: A Description of Hepatitis C Infection on Prince Edward Island

FILE #: 6007047

Dear Ms. Burns MacKinnon,

We have received notification that the PEI Research Ethics Board has approved this application. Congratulations and good luck with your research!

Joy Knight
Research Compliance and Awards Coordinator
Office of Research Services
reb@upei.ca
620-5104