A DNP Nurse-Managed Hepatitis C Clinic, Improving Quality of Life in a Rural Area

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Abstract
Hepatitis C is quickly becoming a national threat, involving 2% of the nation’s population, ranking this as the 11th most prevalent disease in the world. Traditionally, treatment for hepatitis C has been conducted in tertiary care settings, limiting access to care for those residing in rural areas. Improving access to care through the development of a Doctor of Nursing Practice (DNP) nurse-managed clinic in a rural setting will improve health outcomes and quality of life for those treated outside the traditional setting. Caring for those living in less densely populated areas requires an understanding of rural culture. This paper will discuss the development and implementation of a DNP Model of Care for rural patients being treated for hepatitis C. The model of care starts with identifying hepatitis C, treating the patient following established medical guidelines, using the nursing model to monitor clinical progress and managing side-effects caused by the treatment medications. Using the DNP Model of Care, a patient-focused clinic can successfully treat rural patients utilizing the principles of the Effect Theory for management and the Process Theory for ongoing evaluation. Collaboration with other key resources, utilizing a multidisciplinary approach allows the DNP nurse to care for those requiring treatment for chronic hepatitis C, where they live and work with the assistance of family and social support.

Document Type
Dissertation

Degree Name
Doctor of Nursing Practice

First Supervisor
Vivian Cunningham
A DNP Nurse-Managed Hepatitis C Clinic, Improving Quality of Life in a Rural Area

By

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A Clinical Scholarship Project
Submitted in partial fulfillment of the requirements for the
Doctor of Nursing Practice (DNP) Program

Supervised by

Dr. Vivian Cunningham

Wegmans School of Nursing
St. John Fisher College

June 2011
Title: A DNP Nurse-Managed Hepatitis C Clinic, Improving Quality of Life in a Rural Area

Student Signature: Date: June, 2011

The above student has successfully completed this thesis is partial fulfillment of the requirements for the Doctor of Practice Nursing degree from the Wegmans School of Nursing at St. John Fisher College.

Advisor Signature: Date:

This project/thesis fulfills the requirements of thesis/ seminars and assists in meeting the program outcomes for the Doctor of Nursing Practice Nursing degree from the Wegmans School of Nursing at St. John Fisher College.

Second Reader Signature: Date:
ABSTRACT:

Hepatitis C is quickly becoming a national threat, involving 2% of the nation’s population, ranking this as the 11th most prevalent disease in the world. Traditionally, treatment for hepatitis C has been conducted in tertiary care settings, limiting access to care for those residing in rural areas. Improving access to care through the development of a Doctor of Nursing Practice (DNP) nurse-managed clinic in a rural setting will improve health outcomes and quality of life for those treated outside the traditional setting. Caring for those living in less densely populated areas requires an understanding of rural culture. This paper will discuss the development and implementation of a DNP Model of Care for rural patients being treated for hepatitis C. The model of care starts with identifying hepatitis C, treating the patient following established medical guidelines, using the nursing model to monitor clinical progress and managing side-effects caused by the treatment medications. Using the DNP Model of Care, a patient-focused clinic can successfully treat rural patients utilizing the principles of the Effect Theory for management and the Process Theory for ongoing evaluation. Collaboration with other key resources, utilizing a multidisciplinary approach allows the DNP nurse to care for those requiring treatment for chronic hepatitis C, where they live and work with the assistance of family and social support.

Key Words: hepatitis C, rural nursing, nurse-managed clinics
The Institute of medicine (IOM) considers hepatitis C a major health problem and a major cause of liver disease.\textsuperscript{1} Approximately 4.1-4.9 million people are affected with hepatitis C (HCV) in the United States, accounting for 1.8-2.0\% of the general population,\textsuperscript{2,3,4} resulting in 8,000-10,000 deaths annually.\textsuperscript{5,8} Ranked as the 11\textsuperscript{th} most prevalent disease in the world,\textsuperscript{6} there are 170 million cases of HCV responsible for 1.4 million deaths per year worldwide,\textsuperscript{3,4,5,6} but these numbers are difficult to obtain without a national hepatitis C surveillance program.\textsuperscript{1} These statistics are expected to triple in the next 10-20 years,\textsuperscript{8} positioning HCV as a “global epidemic” in the new millennium,\textsuperscript{9} even as it has been termed the next “hidden epidemic”.\textsuperscript{10} HCV is the most common blood-borne infection in the United States and is the leading cause of liver transplants.\textsuperscript{8,11,12,13} The Organ Procurement and Transplantation Network located in the U.S., states that 6,320 patients underwent liver transplantation in 2009 for treatment of end-stage liver failure, with nearly 17,000 patients currently waiting for a donor liver.\textsuperscript{14} Approximately 75\%-85\% of acutely infected individuals progress to chronic infection with up to 20\% developing cirrhosis over 20-30 years, putting them at risk for end-stage liver disease and hepatocellular carcinoma (HCC)\textsuperscript{4,15} and possible severe quality of life impairment. The risk of HCC is 1\%-4\% per year when cirrhosis of the liver is present,\textsuperscript{13} and this is expected to increase over the next decade due to the slow progression of the disease. HCC is the third leading cause of cancer deaths in the worldwide, the fifth most common cancer among men and the eight most common cancer among women.\textsuperscript{14} Antiviral therapy is considered standard of care even when eradication of the virus may not occur, as it reduces the risk of developing malignancy.\textsuperscript{15} Because of routine screening of blood products, the number of new HCV cases is declining, but the rates of HCV associated morbidity and mortality will continue to rise\textsuperscript{4} for the next 20-30 years. Though the incidence of acute and chronic hepatitis A and B are diminishing in this country, and theoretically eradication of these diseases could occur over the next 20 years through standard
vaccination, HCV has multiple types and subspecies with a high rate of mutation, making vaccine development very difficult. Until a vaccine is developed, reducing the spread of the HCV needs to be continued though the identification of risk factors.

**Rural Nursing and Quality of Life**

Rural Nursing poses challenges and opportunities for unique care and is different from urban nursing due the essentials attributes and culture of this population. This nursing has been identified as providing health care by professional nurses to persons living in sparsely populated areas, though these areas are not well defined. Rural can mean country, agriculture, or just in terms of assumed culture. Sparsely populated can be defined anywhere between 3 and 1,000 persons per square mile. DNP nurses working in any setting require a model of care with a theory base by which to practice and rural nursing is no exception. Once diagnosed with HCV, rural patients may not start treatment due to inconvenient access to specialist care, which is traditionally available in tertiary care settings located in urban areas. Rural health care providers are expected to do more with less and accept responsibilities not usually seen by providers in the urban setting. Health and work beliefs, isolation, distance, outsider/insider concept, self-reliance, and lack of anonymity of familiarity are concepts identified with the rural community. Lack of health accessibility is a major factor with the rural patient. Transportation, distance, isolation, weather, finances, time of year (including planting and harvesting of crops, and hunting season), attitudes toward health and patient education may be barriers to care and all must be considered before hepatitis treatment is considered. Seasonal agricultural farm workers who are transient and are of a different culture may be included as a subset population. Understanding these concepts of rural nursing will require the DNP to create an evidence-based plan of care for the HCV patient undergoing treatment.
Side effects experienced by patients may be minimal or quite severe. The most common reason to discontinue treatment is psychiatric side-effects such as depression, suicidal and homicidal thoughts. “Road rage” has been seen in some patients. Rural areas may few mental health clinics, thus primary care providers may be the only source of care. Keeping the primary care provider aware of treatment any psychiatric concerns early in treatment may avoid disaster from side effects. Do not hesitate to discuss with the collaborating hepatologist and discontinue treatment if necessary.

**Theoretical Framework**

Nursing case management, provided by public health nurses and social workers, has been in practice since the 1800’s to improve health care to immigrants and those who could not afford health care. Nursing clinics that include APN’s offer services to the uninsured and underserved that have chronic illnesses. The DNP with advanced preparation will add diagnostic skills and, clinical management to those with chronic illness and in need of patient-focused care. The Doctor of Nursing Practice Model of Care focuses on the patient, allowing the DNP to oversee the hepatitis C treatment while managing response to treatment and monitoring any side effects of care. The office visits, laboratory monitoring and documentation by both the patient and managing nurse allow improved compliance and success rates in treatment. Critical thinking and decision making by APN’s are made with evidence-based information and a theoretical base. The Effect Theory brings together scientific facts and behaviors to deliver interventions and predict outcomes. This theory demonstrates a relationship between behavioral factors, disease causality, with moderating and mediating mechanisms, and disease treatment outcomes. The identification of risk factors as described by the model will allow an accurate testing of possible disease and prediction of outcomes. The theoretical framework used to implement this model
of care for the treatment of HCV is the Effect Theory, see Figure 1. This combination theory provides the reader with an understanding of the complexity of HCV in the rural setting and its impact for treatment outcomes. The DNP nurse practicing in a rural setting can best understand the needs of the HCV patient as this is where the patient is living and where primary intervention occurs. The DNP also appreciates the cultural complexities of the rural setting. (Figure 1.)

**Figure 1. The Effect Theory**

<table>
<thead>
<tr>
<th>Existing Factors</th>
<th>Main Causal Factors</th>
<th>Mediating Mechanisms</th>
<th>Health Outcome</th>
<th>Health Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure to HCV through blood contamination, tattoos, sharing needles, straws, rinse water, multiple sexual partners, etc.</td>
<td>Inadequate knowledge of risks of HCV exposure, incarceration, exposure with those at risk for HCV</td>
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<td>Eradication of virus, Cirrhosis, hepatocellular cancer, death</td>
<td>Reduce spread of virus, and overall health costs</td>
</tr>
<tr>
<td><strong>Moderating Factors</strong></td>
<td><strong>Interventions</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obesity, race, age during treatment, diabetes, HIV or HBV co-infection, gender, family support, exercise during treatment, age at time of exposure</td>
<td>Treatment of HCV virus with peg-interferon and ribivirin per guidelines established by “NYSDOH Clinical Guidelines for the Medical Management for Hepatitis C”</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Flow Chart showing how HCV can be used in an Effect Theory using a linear chart. Adapted from “Health Program: Planning and Evaluation: A Practical Systematic Approach for Community Health,” by L. M. Issel, 2009, pg. 181.

**DNP Model of Care for a Rural Clinic**

Although traditional treatment for hepatitis C is carried out in tertiary/hospital settings, a rural clinic managed by a Doctor of Nursing Practice nurse, working in collaboration with a hepatologist, can successfully evaluate and manage the multiple complications and side effects commonly seen with hepatitis C treatment. Patient-centered availability, access to treatment with cost savings benefits seen by nurse-managed clinics, allows a rural clinic for hepatitis C an acceptable option for viral treatment. Below (Figure 2.) is the DNP Model of Care developed by the author for those with chronic illness in a rural setting and used for the patient being treated with hepatitis C. The patient is the focus of care with the DNP surrounding the outer circle of the model as the manager of the care. Surrounding the patient are factors that influence treatment outcomes, such as quality of life or completion of treatment, and failure to eradicate the virus. In a rural setting the complicating factors for the patient will be different than care within an urban setting, thus it is necessary to incorporate these into the surrounding boxes the individual factors that may complicate treatment. (Figure 2.)
A mission statement needs to be made for any clinic development. This should state the purpose of the clinic, how it will be developed and how it will be evaluated. Clinical Objectives also need to be established for a DNP managed HCV clinic. These include:

- To increase awareness for the prevention of HCV to prevent new infections
- To target lifestyle changes needed with HCV treatment
- To improve access to HCV treatment
- To provide services to those uninsured and underinsured
- To provide a shorter time from diagnosis to treatment
- To reduce the impact on health costs for treatment
- To prevent the complications for cirrhosis associated with HCV
To obtain a sustained virological response early in treatment and 6 months following completion of treatment

Once the mission statement and objectives for the clinic have been established, implementing the plan of care for the patient with HCV will be followed using the guidelines of the model of care and the theoretical framework which is consistent with the program purpose and objectives. The patient is referred to the clinic from their primary care provider, OB/GYN or from recent incarceration. On the first visit, the patient enters the clinic with a definite diagnosis for HCV or may be referred to the clinic with abnormal liver function tests. The DNP will either establish the diagnosis of HCV or confirm the presence of chronic active HCV through the identification of active virus with a RNA quantitative viral load and genotyping of the virus. Supplemental baseline laboratory testing is done at this first visit. These tests include a CBC, chemistries, autoimmune and viral indices (HAV and HBV), ferritin level, TSH, HIV and HCG for female patients and for partners of male patients if they are of child-bearing age. An abdominal ultrasound is obtained on all patients to observe the contour of the liver. This may give the DNP an indication if cirrhosis is already present. If any question exists, then an ultrasound guided liver biopsy may be obtained, but mandatory liver biopsy is no longer necessary prior to treatment. An informational packet is given to the patient at this first visit. These packets contain information on the treatment drugs including how they are used with side effects and cautions regarding their use. These drugs have a “black box warning”, meaning they may have dangerous side effects under certain circumstances. It is important not to overwhelm the patient at this point as they have received an extreme amount of information on this first visit. Allowing an hour of time for this visit is not unusual.
The second visit is about 2-3 weeks later, allowing the results of all testing done to this point to return. The DNP will review all the previous testing including the result of the viral quantitative count. If confirmation of HCV is determined with a positive number, then a more detailed discussion regarding the treatment is made. The patient is given a journal for recording laboratory results, documenting exercise/physical activity done,24 and any questions or concerns they may have. A patient/provider contract for treatment is reviewed and signed by both parties. This contract contains patient responsibilities, including appointment visits, laboratory times, and the importance of alcohol abstinence and the use of non-prescribed drugs. Of significance importance is the understanding of not becoming pregnant or impregnating anyone else, as treatment drugs for HCV are teratogenic. A dilated fundoscopic eye exam is important at the beginning of treatment to determine any baseline abnormalities, as some abnormalities rarely occur as a result of the treatment drugs but usually subside after treatment completion. An influenza immunization is recommended during the season and vaccination for HAV and HBV are important if the patient has not had established immunity. Avoiding exposure to and combating these other hepatitis viruses during treatment may be difficult.

Regular office visits occur at 1,2,4,6,8,12 and every 4 weeks thereafter until treatment is completed. Laboratory testing is obtained at these times to assure no serious consequences are occurring. Calculating and documenting serial absolute neutrophil counts (ANC) is important when monitoring for serious side effects. Following medical protocol regarding these values is essential. It is important to obtain a quantitative viral load at weeks 4,12,24,36, and 48, then 1, 3, and 6 months post-treatment. Testing yearly thereafter has not been established. The patient is weighed at each visit to monitor any loss. Some weight loss is expected but should not be excessive.25
Treatment and Screening for Hepatitis C

The standard treatment of care for HCV is well-documented by the American Gastroenterological Association (AGA), American Association for the Study of Liver Diseases (AASLD) and the New York State Department of Health (NYSDOH), which needs to be followed by the DNP. Any deviation from those protocols needs to be discussed with the collaborating physician first.

It is important for the patient to know how to administer these medications. The start of treatment begins in the clinic office. The DNP or clinic nurse shows the patient how to administer the medications with an emphasis on technique and hygiene. Safe disposal of the used needles and syringes is essential for safety of the patient and any household members.

The baseline eye exam and subsequent exams during treatment are at the discretion of the ophthalmologist performing the initial exam, and are important to follow any cotton-wool exudates. Retinopathy is common with pegylated interferon, one of the treatment medications, but most events clear after treatment is completed. The cost of treatment with pegylated interferon and ribavirin is very high, about $30,000 per patient for the medication alone. The National Surveillance Program calculated the cost of screening for HCV to be $1,246 per case detected, though other studies have shown the cost between $374 and $1,047 per case detected. HCV screening and early treatment has the potential to improve average life-expectancy but should focus only on those at high risk for the virus, as screening those without risk factors has not been proven to be cost-effective. Approximately 30% of patients identified with chronic HCV have normal liver tests but upon liver biopsy, have some degree of liver damage, thus it remains very important to screen for those with current or past risk behavior for the virus.
The future treatment for HCV will soon change. The addition of protease inhibitors are currently being evaluated by the Federal Drug Administration (FDA) and will be added to standard treatment, but their exact role is yet to be determined. The identification of genetic variations with response to treatment may also influence viral eradication. These changes are expected to occur mid to late 2011. The large tertiary clinics should be able to incorporate these changes with little difficulty, but the rural areas may find resources and funding difficult to manage. Despite this, the management of HCV treatment in a rural setting should be reasonable with a workable model of care and a collaborating health team.

**Evaluation Plan**

Evaluating this model of nursing care needs to include both quantitative and qualitative outcomes. Mentioned previously are quality of life concerns regarding HCV. Observation by the DNP during office visits, conversation with patients and families with review of journal entries are all forms of qualitative measurements. Quantitative measurements may include compliance with office appointments, medication adherence and successful eradication of the virus at completion of the treatment contract. Some of these measurements can be seen through the monitoring of laboratory values, the expected depletion of medication, acceptable with changes and lack of legal involvement.

Clinical conferences with collaborators involved in those patients undergoing HCV treatment will be essential for the success of the clinic. Effective leadership by the DNP manager will require a strong support staff with those wanting to make a difference, the creation of ideas and actions, creativity with energetic and committed followers. This author advocates a “circle network” that allows and encourages information to move from one member to another equally. Communication is simplified and members have easy access to other member’s
thoughts\textsuperscript{32} and team members share responsibility for achieving the common goals of the clinic.\textsuperscript{33} Familiarity among staff members of the clinic is also important for the patients. With a small group in a rural setting, this management structure should be very effective.

An evaluation plan of the program must include operating costs of the clinic. One method to do this uses the break-even analysis tool. This mathematical calculation divides the fixed cost of operation of the clinic into the cost per patient equaling the number of patients needed to be seen.\textsuperscript{21} This analysis should be done before the operational of the clinic begins, early in its operation and throughout its management. Unfortunately, lack of health insurance can be a critical factor in treating this potentially vulnerable population. Medicare and Medicaid can underestimate actual costs for providing services which can greatly affect operational costs. If patients have no health insurance, it is essential for them to apply for financial assistance for both their advantage and for the security of the clinic. At one point a potential solution for those looking to start an independent, rural clinic was H.R. 2754, to amend the Public Health Service Act to establish the Nurse-Managed Health Clinic Investment Program, and other purposes, may have been an option,\textsuperscript{34} but unfortunately the bill did not become a law, but may be presented again with the next session of Congress. Another solution is to incorporate the nurse-managed clinic into an existing gastroenterology or primary care practice to help defray the costs. Sharing of office equipment and staff with the DNP providing care to those with HCV along with patients with other health problems may need to be done until the clinic is financially secure. A third method to provide cost-effective care is the use of telemedicine. Its use in rural and prison settings allows providers to effectively manage patients with chronic illness.\textsuperscript{35} The Process Theory showing the components of the organizational and service plans may be used for a nurse-managed clinic as shown below. (Figure 3.)
Flow chart showing how a logic model as a tool for program evaluation may be used for HCV. Adapted from “Health Program” Planning and Evaluation: A Practical Systematic Approach for Community Health”, by Issel, LM. 2009, pg. 276.
Conclusion

As health care becomes more complex, evidence-based practice with collaboration among multiple health disciplines needs to be implemented. Cost effective care with positive outcomes and individualized care with innovation will be necessary. The IOM suggests knowledge about this disease is poor and significant stigma surrounds the diagnosis. With an accepted and useful model of care, theoretical framework with an ongoing evaluation tool, a hepatitis C clinic within a rural setting can be successfully managed by a DNP prepared nurse. Using the Effect and Process Theory, with the DNP Model of Care, patients with HCV can be provided quality, culturally sensitive and cost-effective care. With the IOM’s concern regarding the spread of HCV and Healthy People 2020 including communicable disease a national concern, a DNP nurse-managed clinic can fill the gap and meet the need for addressing this “global epidemic”.
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Treatment of HCV virus with peg-interferon and ribivirin per guidelines established by “NYSDOH Clinical Guidelines for the Medical Management for Hepatitis C”
Figure 2. Krebbeks Doctor of Nursing Practice Model of Care
Figure 3. The Process Theory, Evaluation Flow Chart

Organizational plan input
- Human resources
  - DNP
  - Med tech
  - Collaborating MD
  - Receptionist
- Informational resources
  - Software for EHR (existing)
  - Educational handouts/Roche pt journals
- Monetary resources
  - Grant Application (if nec)
- Physical Resources
  - Pre-existing Office, needing two exam rooms and reception area
- Transportation
  - Private Car
  - CATS bus
  - VAMC transport
- Managerial resources
  - DNP clinic manager
- Time resources
  - 1 and 2 year cycles

Services utilization plan
- Participants
  - Those patients with positive antibody or active HCV virus requiring tx or monitoring of virus
- Queuing
  - Increase testing for HCV virus info PCPs
  - Decrease wait list time to 2 weeks and start of tx
- Intervention Delivery
  - NYSDOH Guidelines 2005 with collaborating MD with constant update as tx changes
- Social marketing
  - Product-treatment
  - Price-ins coverage
  - Place-exist office
  - Promotion-posters/speaking

Outputs
- Informational System
  - Monthly/Weekly reports of intake and outputs
- Budget
  - Break-even analysis
- Time line
  - Anticipated start date 7/1/11
- Organizational chart
  - Circle Network
  - DNP/MD
  - MT/Receptionist
  - (Bolman & Deal, pg 106)
- Operational Manual
  - Office Protocol
  - visit times/freq/vital signs, flow chart, patient log

Coverage
- Ins
- Private pay, sliding fees
- Indigent Coverage from drug manufacturer

Units of Service
- Frequency of Lab testing,
- Number of Visits
- Length of Treatment (Patient flow sheet)

Materials produced
- Number of pts in tx
- Continued and completed tx
- Number of pts with SVR

Work Flow
- % of pts seen
- Need for regular staff meetings
- Staff education