

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

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Abstract

Hepatitis C virus 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 the 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.

Keywords: Hepatitis C, Rural nursing, Nurse-managed clinics

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The Institute of Medicine (IOM), Committee on Prevention and Control of Viral Hepatitis Infections (CPCVHI) considers Hepatitis C (HCV) a major health problem and a major cause of liver disease (Colvin & Mitchell, 2010). Approximately 4.1-4.9 million people are affected with HCV in the United States (US), accounting for 1.8-2.0% of the general population (Calvert, Goldenberg, & Schock, 2005; Moore, Hawley, & Bradley, 2009; Rustgi, 2007) resulting in 8,000-10,000 deaths annually (Wolfe & Stowe, 2007; Albeldawi, Ruiz-Rodriguez, & Carey, 2010). Ranked as the 11th most prevalent disease in the world, (Pozza, 2008), there are 170 million cases of HCV responsible for 1.4 million deaths per year worldwide (Moore et al., 2009; Pozza, 2008; Rustgi, 2007; Wolfe & Stowe, 2007), but these numbers are difficult to obtain without a national Hepatitis C surveillance program (Colvin & Mitchell, 2010). These statistics are expected to triple in the next 10-20 years (Albeldawi et al., 2010), positioning HCV as a “global epidemic” in the new millennium (Gane, 2008), even as it has been termed the next “hidden epidemic” (“Hepatitis outbreaks outscore ongoing risk”, 2009).

A recent analysis showed a rapidly increasing number of deaths among HCV-infected persons, which now surpasses the deaths among HIV-infected persons in the US (Ly et al., 2012, p. 276). According to this new study from the U.S. Centers for Disease Control and Prevention (CDC) and Chronic Liver Disease Foundation recommends routine screening among those born between 1945 and 1965, not just for those at risk to for viral infection (Ly et al., 2012). HCV is the most common blood-borne infection in the US and is the leading cause of liver transplants (Albeldawi et al., 2010; Dienstag & McHutchison, 2006; Gane, 2008). The Organ Procurement

and Transplantation Network, located in the US, 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 (Sornmayura, 2010). 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) (Rustgi, 2007; Talley & Martin, 2006) and possible severe quality of life impairment. The risk of HCC is 1%-4% per year when cirrhosis of the liver has been established (El-Serag, 2012). HCC is expected to increase in this group over the next decade due to the slow progression of the disease. HCC is the third leading cause of cancer deaths worldwide, the fifth most common cancer among men and the eighth most common cancer among women (Sornmayura, 2010).

Antiviral therapy is considered standard of care even when eradication of the virus may not occur, as it reduces the risk of developing malignancy (Talley & Martin, 2006). Because of routine screening of blood products since 1992, the number of new HCV cases is declining, but the rates of HCV associated morbidity and mortality will continue to rise (Rustgi, 2007) for the next 20-30 years. Though the incidence of acute and chronic hepatitis A and B is diminishing in this country, and theoretically the 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 through the identification and testing of individuals with risk factors and public education on acquisition of HCV.

Rural Nursing and Quality of Life

Rural Nursing poses challenges and opportunities for unique care and is different from urban nursing due to the essential attributes and culture of this population. Rural nursing has

been identified as provision of health care by professional nurses to persons living in sparsely populated areas (McCoy, 2009) though these areas are not well defined. Rural can mean country, agriculture, or refer to attributes of rural culture. Sparsely populated can be defined anywhere between 3 and 1,000 persons per square mile. The term underserved has been used in association with rural nursing. Availability, accessibility, acceptability and affordability are all concerns for the rural nurse (Spencer, Van Dyke, & Swain, 2001). The general educational level of the rural population can be a challenge for the rural nurse. These factors compounded by a serious, chronic and potentially deadly virus must be included for the rural nurse's critical thinking. "After years of debate about universal health insurance legislation, it has not been enacted, leaving the most vulnerable members of society which includes the poor, those living in rural settings and children without comprehensive care" (Russell & Neff-Smith, 2001, p. 81). 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 (Poll, 2009) 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 expected of providers in the urban setting. Health and work beliefs, isolation, distance, outsider/insider concept, self-reliance, and lack of anonymity or familiarity are concepts identified with the rural community (Long & Weinert, 1998). Lack of health care 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 all must be considered before hepatitis treatment is considered (Bryant, Elliott, Hanson, Lobner, & Thomas, 2001). 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.

Rural areas may have few mental health clinics, thus primary care providers may be the only source of care. Side effects experienced by patients undergoing treatment may be minimal or quite severe. The most common reason to discontinue treatment is psychiatric side-effects such as depression (Hopwood & Treloar, 2005; Treloar & Hopwood, 2008) suicidal and homicidal thoughts. “Road rage” has been seen in some patients. Identifying the key family members for support for those experiencing depression during treatment can augment the rural nurse’s plan of care. The patient’s own coping skills that have been used successfully need to be utilized. Keeping the primary care provider aware of treatment and psychiatric concerns early in treatment may avoid disaster from treatment side effects. The DNP nurse should discuss with the collaborating hepatologist any emerging adverse side effects and discontinue treatment if necessary.

It is important to remember, that every patient identified with HCV, treated for the virus and who has successfully achieved a sustained viral response (SVR), reduces the chance of cirrhosis, HCC and have eliminated the potential spread of that virus to another person. This is imperative no matter where treatment occurs, thus the availability of a rural clinic with a DNP managing the HCV treatment can continue to reduce the morbidity and mortality of this virus.

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 Advanced Practice Nurses frequently offer services to

those 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 to 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 the DNP is made with evidence-based information and a theoretical base. The Effect theory brings together scientific facts and behaviors to deliver interventions and predict outcomes (Issel, 2009). This theory demonstrates a relationship between behavioral factors, disease causality, with moderating and mediating mechanisms, and disease outcomes. The identification of risk factors as described by the model will allow an accurate testing of possible disease and prediction outcomes (Estes, 2007). 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 may also appreciate the cultural complexities of the rural setting using this model.

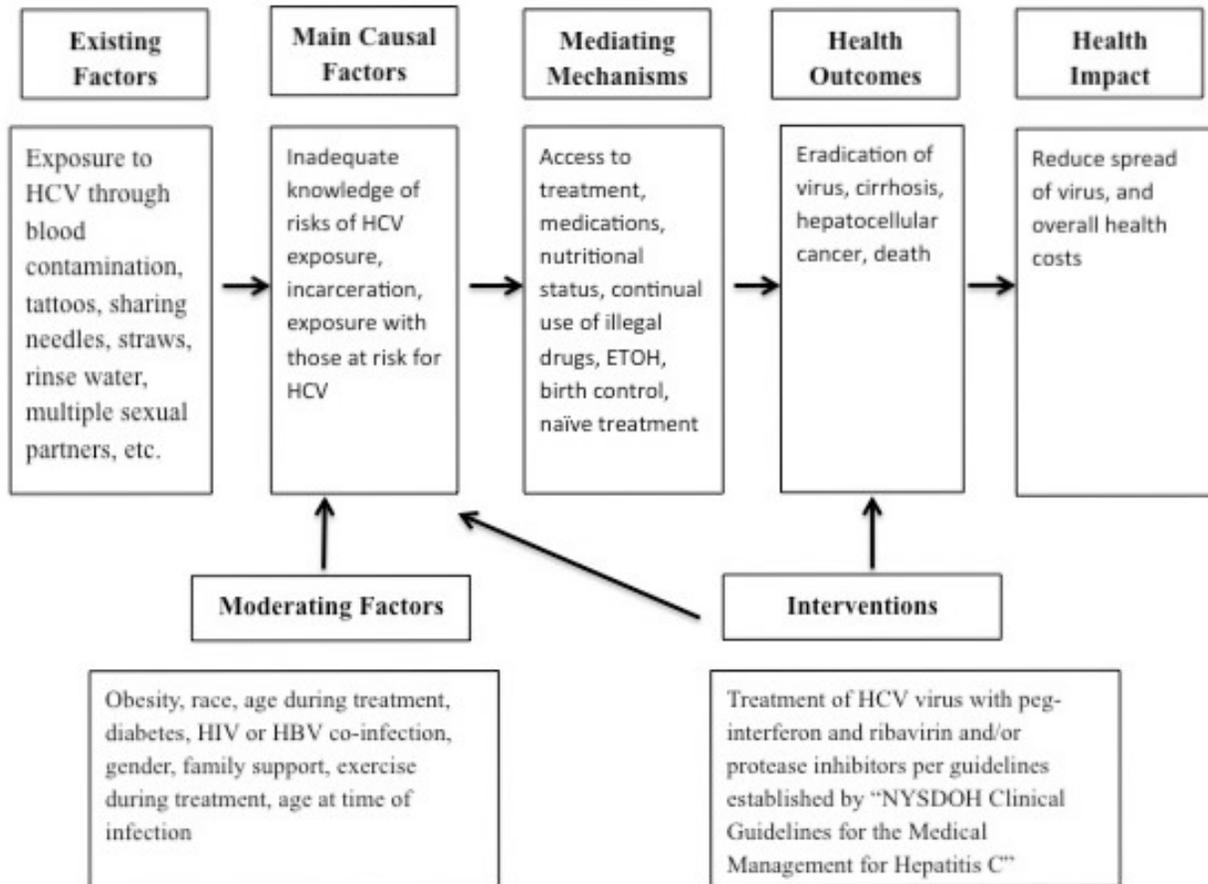
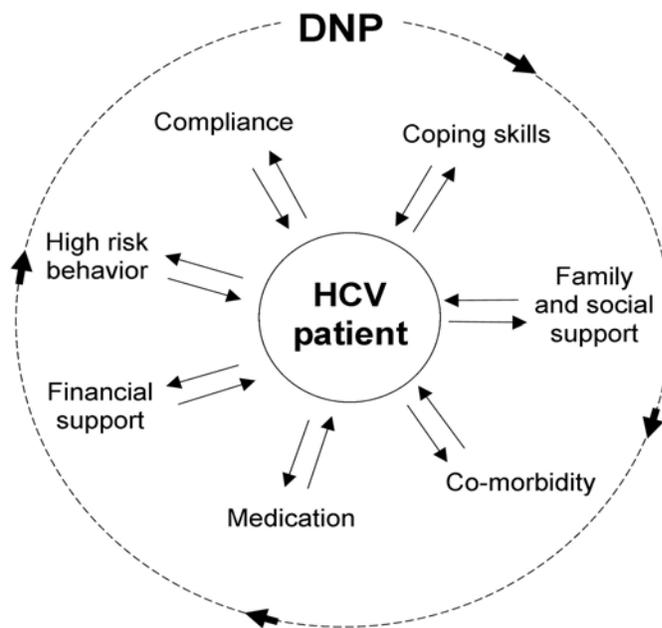


Figure 1 A Flow Chart showing using the Effect Theory with HCV using a linear chart. Adapted from *Health Program: Planning and Evaluation: A Practical Systematic Approach for Community Health*, by L. M. Issel, 2009, p. 181. Copyright 2010 by the American Psychological Association. Reprinted with permission. Guidelines for intervention (Ghany, Nelson, Strader, Thomas, & Seeff, 2011; Yee et al., 2012).

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 DNP 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 (Ehsani, Vu, & Karvelas, 2006), allows a rural clinic for Hepatitis C as an acceptable option for viral treatment. The concerns and challenges of the rural nurse as discussed above were used to develop the DNP Model of Care. 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 HCV. 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. The accessibility, availability, affordability and acceptability concerns were used to identify the factors affecting the treatment. In a rural setting these complicating concerns for the patient will be different than care within an urban setting, thus it is necessary to incorporate these factors into the surrounding boxes. These individual factors may complicate treatment and thus need to be monitored and managed by the DNP.



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Figure 2 Doctor of Nursing Practice Model of Care.

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 (Issel, 2009). Clinical Objectives will need to be established for a DNP managed HCV clinic.

These include to:

- increase awareness for the prevention of HCV to prevent new infections
- target lifestyle changes needed with HCV treatment
- improve access to HCV treatment
- provide services to those uninsured and underinsured
- provide a shorter time from diagnosis to treatment
- reduce the impact on health costs for treatment
- prevent the complications for cirrhosis associated with HCV
- 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, a Red Cross or similar blood donating organization 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, HAV and HBV antibody levels,

chemistries, autoimmune indices, and a ferritin level, TSH, HIV and HCG for female patients and for female 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 (Nazareth, Piercy, Tibbet, & Cheng, 2008). A baseline EKG is recommended (Yee et al., 2010). An informational packet that may be provided by the manufacturer of the treatment medication(s), is given to the patient at this first visit. These packets contain information on the treatment drugs including how they are to be taken with possible 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 to the provider. 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 presence of virus, 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 during treatment (McKenna & Blake, 2007), and any questions or concerns they may have throughout their time of care. A patient/provider contract for treatment is reviewed and signed by both parties. This contract contains patient and provider responsibilities, including appointment visits, laboratory times, and the importance abstinence of alcohol and non-prescribed drugs. Of significant importance is the understanding of not becoming pregnant or impregnating anyone

else during treatment or for 6 months following treatment, as treatment drugs for HCV have been determined to be teratogenic. An educational review of the medication side effects should be documented in the contract.

A dilated fundoscopic eye exam is important at the beginning of treatment to determine any baseline abnormalities, as some visual difficulties can but rarely occur as a result of the treatment drugs. These visual difficulties usually subside after treatment completion. Subsequent exams during treatment are at the discretion of the ophthalmologist performing the initial exam, and it is important to follow-up any finding of fundoscopic cotton-wool exudates. Retinopathy is common with pegylated interferon, one of the treatment medications, but most events that may occur clear after treatment is completed (Mehta, 2010).

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 influenza and other viruses during treatment may be difficult. It is contraindicated to immunize patients with live virus while undergoing treatment for HCV.

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 2, 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 (Suwantarat, Tice, Khawcharoenporn, & Chow, 2010).

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 American College of Gastroenterology (ACG), (Dienstag & McHutchison, 2006; Gane, 2008; Ghany, Nelson, Strader, Thomas, & Seeff, 2011, & Yee et al., 2012) which needs to be followed by the DNP. Any deviation from those protocols needs to be discussed and documented with the collaborating physician.

It is important for the patient to know how to self-administer these medications, especially those requiring subcutaneous injection. The start of treatment begins in the clinic office. The DNP or clinic nurse demonstrates to 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 cost of treatment with pegylated interferon and ribavirin is very high, about \$30,000 per patient for the medication alone (Calvert et al., 2005). 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 (Albeldawi et al., 2010). HCV screening and early treatment has the potential to improve average life-expectancy but in the past focused only on those at high risk for the virus (Sroczynski et al., 2009). With new concerns regarding the testing of all “baby boomers”, the diagnosis of those with chronic HCV will rise. 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 (Sornmayura, 2010).

The treatment for HCV changed May 2011 with the addition of protease inhibitors for the treatment for genotype 1. These additional medications have made a significant increase in the eradication rate of the HCV but treatment complications have increased (Stauber & Kessler, 2008). The identification of genetic variations with response to treatment may also influence viral eradication (Ge et al., 2009), but the use of genetic testing to determine treatment eligibility is controversial. The large tertiary clinics should be able to incorporate these treatment changes with little difficulty, but 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 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 and their expected changes, the measurable depletion of given medication, and lack of unacceptable behavior and legal involvement.

Clinical office conferences with the possible presence of 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 in care delivery, the creation of ideas and actions, creativity with energetic and committed followers (Bethel, 1990). This author advocates a “circle network” that allows and

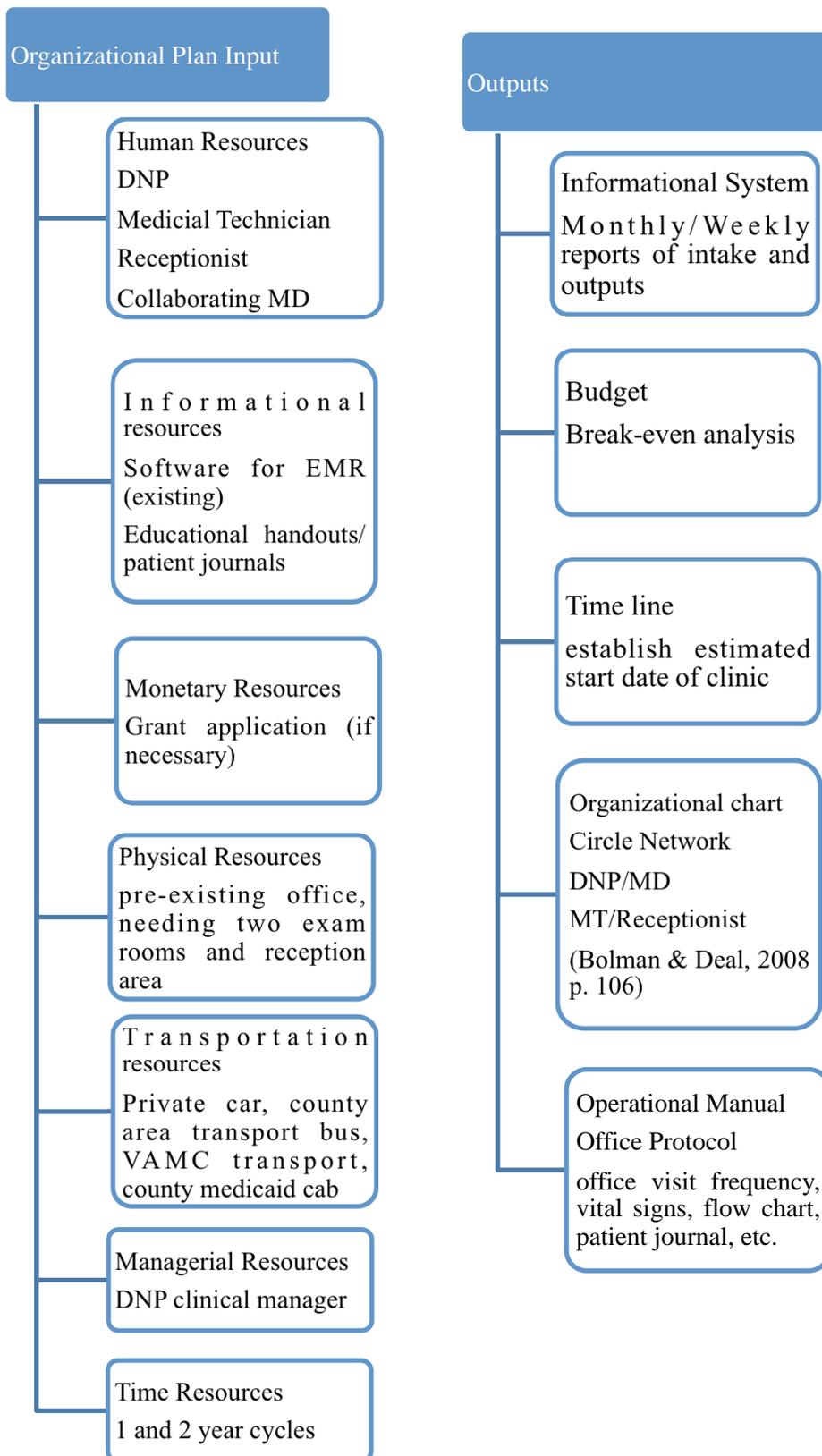
encourages information to move from one member to another equally. Communication is simplified and members have easy access to other member's thoughts (Bolman & Deal, 2008) with team members sharing responsibility for achieving the common goals of the clinic (Freund, & Drach-Zahavy, 2007). Familiarity among clinic staff members is also important for the patients. With a small group in a rural setting, this management structure should be effective.

A program evaluation plan must include operating costs of the clinic, with one method being a 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 (Issel, 2009). This analysis should be done before the opening of the clinic, 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. It is essential for patients without health insurance to apply for financial assistance for both their advantage and for the security of the clinic. A bill, H.R. 2754, to amend the Public Health Service Act to establish "the Nurse-Managed Health Clinic Investment Program", was at one time a possible option for those wanting to start an independent rural clinic (Capps, 2011) but unfortunately the bill did not become a law, although it may be offered at some future point. 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 (Arora, Thornton, Jenkusky, Paris, & Scalletti, 2007). 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).

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 (Colvin & Mitchell, 2010) and significant stigma surrounds this diagnosis (Butt, Paterson, & McGuinness, 2008). With an accepted and useful model of care and 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 Institute of Medicine's concern regarding the spread of HCV, rising death rates for those with HCV, the recent statement by the CDC regarding testing for the vulnerable age group, and Healthy People 2020 (U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, n.d.) including communicable disease a national concern, a DNP nurse-managed clinic can fill the gap and meet the need for addressing this "global epidemic".



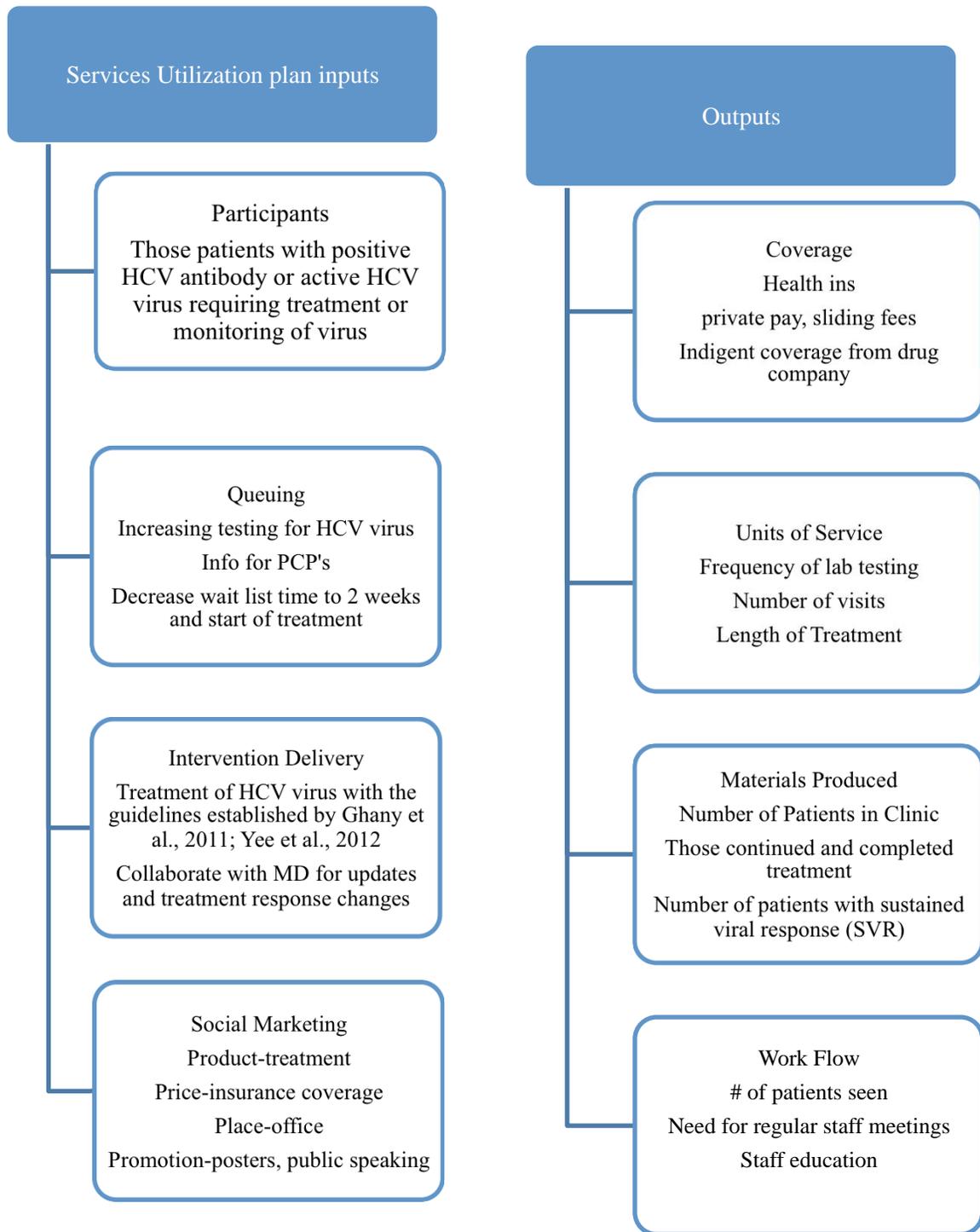


Figure 3: The Process Theory. Flow chart showing how a logic model as a tool for program evaluation may be used for HCV. Adapted from *Health Program Planning and Evaluation: A Practical Systematic Approach for Community Health*, by Issel 2009, p. 276. Copyright 2010 by the American Psychological Association. Reprinted with permission.

Acknowledgement

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