

Statewide Needs Assessment of Dialysis Treatment for End Stage Renal Disease



**A Report to the Governor and General Assembly
of the State of Vermont
Pursuant to Act 40**

Respectfully submitted,

**Patrick Flood, Commissioner
Department of Aging and Disabilities
Agency of Human Services**

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Dialysis Needs Assessment Committee

In May 2003, a committee formed to address the legislative request for a statewide needs assessment of dialysis treatment. The committee includes the following individuals:

- ✦ **Rick Barry**, RN, BSN, CNN, Administrative Director of Nursing Operations, Fletcher Allen Health Care
- ✦ **Paul Bengtson**, Chief Executive Officer, Northeast Vermont Regional Hospital
- ✦ **Charles “Chip” Castle**, Executive Director, Central Vermont Council on Aging
- ✦ **Rick Cochran**, President, Chief Executive Officer, Mobile-Medical International Company
- ✦ **Pat Crocker**, MPA, CTPA, Executive Director, Vermont Public Transportation Association
- ✦ **Emily Gennari**, President, Vermont Kidney Association
- ✦ **Camille George**, Independent Living Program Administrator with the Division of Advocacy and Independent Living, Vermont Department of Aging and Disabilities
- ✦ **Sue Girouard**, RN, BSN, Public Health Nurse Surveyor, Vermont Department of Aging and Disabilities
- ✦ **Ken Gordon**, MSW, Executive Director, Northeast Vermont Area Agency on Aging
- ✦ **Ron Hallman**, Vice President Development and Public Relations, Porter Medical Center
- ✦ **Robert R. Holland**, MD, MS, North Country Hospital
- ✦ **Donna Jerry**, Health Policy Analyst, Department of Banking, Insurance, Securities & Health Care Administration
- ✦ **Janet Lumbra**, Senior Manager of Business Development and Marketing, Mobile-Medical International Company
- ✦ **Jackie Majoros**, State Long Term Care Ombudsman, Vermont Legal Aid, Inc.
- ✦ **Frank G. McDougall Jr.**, Director, Government Relations, Dartmouth-Hitchcock

Medical Center

- ✦ **Pauline Mosher**, Consumer, St. Johnsbury, Vermont
- ✦ **William Mroz**, RN, BSN, MBA, VP of Clinical Services, Dartmouth-Hitchcock Medical Center
- ✦ **Isabelle Sargeant**, RN, Nurse Manager for Renal Services, Fletcher Allen Health Care
- ✦ **Marie Saunders**, Executive Director, Council on Aging for Southeastern Vermont
- ✦ **Kim Taylor**, Vice President of Sales and Marketing, Mobile-Medical Corporation
- ✦ **Kathleen H. Templin**, LICSW, Renal Social Worker, Fletcher Allen Health Care

Executive Summary

Background

A total of 365 Vermont citizens are receiving dialysis treatment as of December 17, 2003. Approximately 70% are treated at six (6) locations in Vermont; the remainder receive treatment at dialysis centers in New Hampshire, New York, and Massachusetts (refer to tables on page 22 and 23). Appendix A is a detailed listing of patient origin by zip code and county as of December 17, 2003. Patients travel to a dialysis center 3 days per week to receive a 4-hour treatment. There are very few alternatives to this inconvenient and rigid schedule. Kidney transplantation and self-dialysis (home dialysis) are available but these modalities have a limited impact on the overall dialysis population. The chronic nature of the treatment and the burden of travel combine to make this an important regional service issue.

Concern has been raised about the distribution of dialysis centers throughout the state. The greater the travel distance to receive treatment, the greater the impact to personal finances and lifestyle. The economic impact of transportation extends beyond the individual patient to state agencies, family members, and volunteers who assist those who are unable to drive, or have no access to public transportation. The most visible example of the dialysis access issue is the ongoing discussion about the location of dialysis services in the Northeast Kingdom.

Act 40 (S.170) was passed during the 2003 legislative session. The Act directed the Vermont Department of Aging and Disabilities to conduct a statewide needs assessment of dialysis treatment and make recommendations to address gaps in renal dialysis service.

Key Findings of the Committee

- Nationally, the total number of dialysis patients at the end of 2001 was 292,000. The growth of new patients over the 5-year period from 1997 to 2001 (most recent data) has slowed. New patients increased 1.8% from 2000 to 2001.
- In Vermont, new patient growth rates closely follow national trends (see table, page 13). The odds of developing kidney failure vary significantly across the country. These variations are partially explained by race and ethnicity (higher in African American and Hispanic populations) and by complex interactions that involve regional variations in care.
- Nationally, the count of patients on dialysis (prevalence) continues to increase but at a slower rate. The number of patients on dialysis grew 4.2% between 2000 and 2001. Prevalence increases because new patients add to an existing base of patients who will receive care for the remainder of their lives. An average mortality rate of 20% and kidney transplants also influence prevalence.
- In Vermont, prevalence rates closely follow national trends. The number of patients on

dialysis grew from 327 to 357 (9%) from 2000 to 2001. From 2001 to 2002 the growth rate was -1%.

- Fletcher Allen Health Care currently provides all dialysis services in Vermont through a network of dialysis facilities in six locations around the state: Burlington (at the hospital itself), South Burlington, Bennington, Rutland, Berlin, and St. Albans. The facilities in Bennington and Berlin are presently running at capacity, and Fletcher Allen is in the midst of expanding the Berlin facility from six to nine stations in order to increase capacity there.
- Patients in Orleans, Lamoille, Caledonia, Addison and Essex counties have the longest travel times to receive care. Average one-way drive times in minutes are 78, 46, 44, 41, and 33 respectively. The total number of patients from each of these counties is 15, 9, 18, 21, and 10 respectively. (See Appendix B).
- Current Certificate of Need (CON) guidelines state that "In Vermont, kidney dialysis of non-acute patients should be provided only through Fletcher Allen Health Care, Dartmouth Hitchcock Medical Center, Albany Medical Center or other academic medical center, either directly or through a satellite service, for both in-home and in hospital dialysis". Roughly 15% or 60 Vermont patients receive care in for-profit dialysis facilities in New Hampshire (Keene), Massachusetts (Greenfield, Pittsfield), and New York (Glens Falls, Saratoga, Albany, Plattsburg).
- All CON applications that have been submitted to the Department of Banking, Insurance, Securities and Health Care Administration (BISHCA) since 1980 have been approved. In August 2001, Fletcher Allen Health Care submitted a CON application to build a new facility in St. Johnsbury and withdrew that application in December 2002 prior to approval. In October 2002, Dartmouth Hitchcock Medical Center (DHMC) was granted a CON to build a dialysis facility within Springfield Hospital in Springfield, Vermont. In October 2003, DHMC informed BISHCA that it had decided not to implement the Springfield Renal Dialysis program at that time due to financial considerations (See Recent Dialysis Facility Proposals, page 17).
- The Committee did not determine the cost of establishing a new dialysis facility due to multiple factors that impact the model. Variables such as location, new construction versus renovation, square footage, payer mix, reimbursement rates and staffing plans impact financial performance.
- In SFY 2003, the Vermont Public Transportation Association estimates that \$571,700 will be expended providing dialysis transportation in the Medicaid Program. This represents approximately 13.6% of the transportation costs in the Medicaid Program.
- From July 2002 to June 2003, the Section 5310 Program expensed \$406,000 or 11.2% of total program resources on dialysis transportation.
- In a survey to which 202 dialysis patients responded, 59% provided their own transportation

to dialysis and rated the financial burden as moderate (2) on a scale of 1 (low) to 4 (high).

- Mobile dialysis is currently in the concept phase of development at Mobile Medical International Company, located in St. Johnsbury, Vermont. The concept is modeled after their successful Mobile Surgery Unit that has been deployed in several states during hospital renovations. The Committee determined that mobile dialysis has not been proven and is currently not available for implementation.
- Home Dialysis. This therapeutic option is currently offered to all patients who meet clinical criteria. Since this is not a therapy suitable for all dialysis patients, it will not consistently reduce the travel burden for all patients who travel greater than 60 minutes.
- For-Profit Programs The Committee considered the difference between the Vermont dialysis environment and other areas of the country. In New Hampshire, for example, dialysis is provided predominantly by for-profit chains in population dense areas of the state (i.e., Concord, Manchester, Portsmouth, Somersworth and Nashua). A fundamental difference between this case and the case in Vermont is the distribution of private nephrology physician practices that typically partner with dialysis chain providers to establish facilities. (See discussion, page 20)

Recommendation #1

The Dialysis Needs Assessment Committee recommends that grants be sought to commission a Vermont specific study to understand the present and future incidence and prevalence rates of renal disease. This study should include, but not be limited to, exploration of variables such as the economic impact of transportation on patients, state agencies, family members and volunteers who assist those who are unable to drive or who have no access to public transportation as well as the impact of capital and operating expenses in building dialysis facilities.

Rationale:

The Committee determined that the methods utilized to understand the patient access issues were not robust. The method consisted of counts of patients at a given point in time with no forecasting methodology to predict growth based on population characteristics. Utilization of national rates of growth can be misleading since high rates of disease exist in Hispanic and African American populations. The Committee determined that a more scientifically rigorous assessment of the Vermont-specific trends must be developed to more accurately plan for growth of dialysis needs within the state. The economic impact of transportation extends beyond the individual patient to state agencies, family members, and volunteers who assist those who are unable to drive, or have no access to public transportation. The most visible example of the

dialysis access issue is in the Northeast Kingdom. At present, dialysis patients in Orleans, Lamoille, Addison, Caledonia, and Essex counties have the longest travel times to receive care. The Committee also agrees with the CON guideline that new facilities should be economically viable.

Recommendation # 2

The Committee supports a collaborative process to address the renal dialysis needs of Vermonters.

Rationale:

Vermont's CON program's statute and regulations specify that all projects be reviewed for efficiency, non-duplication of services, and cost-containment. In addition, the Public Oversight Commission, the public body that reviews all CON's and recommends approval or denial to the Commissioner of BISHCA, has placed an emphasis on the need for collaboration with and between entities that may have an interest in any future project. For example, citing a report to the Legislature, dated December 15, 2003, the Commissioner of BISHCA recommended that FAHC and DHMC utilize a collaborative approach for future projects, such as the development of a renal dialysis center for the Northeast Kingdom, similar to that established by DHMC and six community hospitals in developing the North Country Oncology Center.

Recommendation #3:

Evaluate the current CON Guidelines, as they relate to renal dialysis, to assure there are no barriers to establishing dialysis capacity in Vermont. Specifically, BISHCA should re-examine the current 60-minute travel guideline. Secondly, BISHCA should analyze the pros and cons of the limitation on which organizations are permitted to provide ESRD, including the possibility of utilizing for-profit ESRD providers.

Recommendation #4

The Committee recognizes that at this time funding is finite, creating tensions between the ability to provide special needs community transportation and transportation assistance to non-Medicaid dialysis clients. Working together, the Agency of Human Services (AHS) and VTrans will maximize access and coordination of all publicly funded transportation resources including services provided by Medicaid, Section 5310 and all other Federal Transit Administration (FTA) and Department of Health and Human Services (DHHS) funded services. Furthermore, within the Section 5310 Program, DA&D will continue to collect trip purpose data and use this information to develop and implement, in consultation with the Section 5310 Advisory Board, prioritization and coordination protocols for the use of these funds.

Legislative Background

In 2003, the Legislature passed Act 40 (S.170) directing the Vermont Department of Aging and Disabilities to conduct a statewide needs assessment of dialysis treatment, and make recommendations to address identified gaps in renal dialysis service.

The Legislature directed the Department of Aging and Disabilities to:

- Focus on cost, convenience, availability, accessibility and transportation issues;
- Identify funding mechanisms that currently pay for such services;
- Explore alternatives to the present delivery system including mobile dialysis units; and
- Report its finding and recommendations to the House and Senate Committees on Health and Welfare by November 15, 2003.

Introduction

This report represents a significant step toward resolving a very difficult and complex issue. Renal Dialysis is a life-saving medical treatment and access to it can be difficult in a rural state. The lives of people who require renal dialysis can be consumed by the need for this treatment three times a week. The further people have to travel, the more onerous the treatment becomes.

The Legislature asked DA&D to do a study of the supply of renal dialysis services, access to these services, and related transportation services. DA&D convened a group of knowledgeable people interested in the issue, which met many times over a period of months to examine the data and try to fashion suggestions for improvements. This study reveals how complex the issue is. There are no simple answers. This report does not answer the question of where additional renal dialysis sites, if any, should be located. This report advances the public discussion and lays the groundwork for further necessary study. The study envisioned will help direct future development of dialysis services statewide, taking all the factors into consideration in a new way. Given the available time and limited resources, this Committee was unable to accomplish such an undertaking.

With respect to transportation funding, there is no question that the high use of limited transportation funds for renal dialysis transportation results in less transportation money for other uses. In the short term, current transportation funds can be prioritized to free up money for renal dialysis and other crucial transportation needs. In the long term, travel time for dialysis services needs to be decreased while public transportation for all independent living activities needs to be increased.

Hopefully, the collaboration and cooperation exhibited by the Committee will continue until all the issues are resolved and a desirable system of dialysis services exists for all Vermonters.

Key Terms

- End Stage Renal Disease:** End stage renal disease (ESRD) refers to the late stages of kidney failure where the damage to the kidney is irreversible and permanent. Treatment for ESRD includes dialysis and transplantation. Without undergoing one of these treatments, the patient's only other choice is death.
- Transplantation:** The process of implanting a kidney from a cadaver or live donor into a recipient with ESRD to restore renal function. Nationally, 2.3% of patients receive transplants.
- Hemodialysis:** The process of filtering the patient's blood by pumping it through an artificial kidney machine that removes toxins and extra fluid. Nationally, 87% of patients receive hemodialysis.
- Peritoneal Dialysis:** This method involves implanting a permanent catheter into the abdomen. The process involves placing fluid into the peritoneal space to remove toxins and extra fluid. The patient performs this "exchange" process 4 to 5 times per day. Nationally, 10.7% of patients utilize peritoneal dialysis.
- Home Dialysis:** Patients who perform peritoneal or hemodialysis at home.
- In-center Dialysis:** Hemodialysis performed at a dialysis facility.

Overview

National and Regional Data

The End Stage Renal Disease (ESRD) Program was established in 1972 by federal legislation that extended Medicare coverage to all individuals with end stage renal disease regardless of age who require either dialysis or transplantation to sustain life. This legislation and subsequent regulations established health and safety standards applicable to providers of ESRD services. It also established ESRD Network Coordinating Councils to serve as liaisons between the federal government and the providers of ESRD services.

The United States has been divided into eighteen ESRD Networks. Network 1 consists of the states of Maine, New Hampshire, Vermont, Massachusetts, Connecticut and Rhode Island. Each network is required to participate in data collection, quality improvement, and the assessment of patient satisfaction. Data provided from the ESRD Networks is based upon all dialysis patients receiving hemodialysis in Medicare-approved facilities. Information from each network can be obtained by accessing the website for the ESRD Networks: www.esrdnetworks.org.

The United States Renal Data System (USRDS) is a national data system funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the Centers for Medicare and Medicaid Services (CMS), formerly HCFA. The USRDS collects, analyzes, and distributes information about end-stage renal disease from the ESRD Networks. The USRDS 2003 Annual Report is one of the sources of information used in preparation of this report. Data can be obtained directly from the USRDS through the Renal Data Extraction and Referencing Service (RenDER) on the website: www.usrds.org. Data available through the USRDS generally have a lag time of 3 years.

The following national statistics about the ESRD program are taken from the 2003 USRDS Annual Report:

- During the year 2001, 96,295 new dialysis and transplant patients started ESRD treatment.
- Diabetes was the primary cause of ESRD in 44% of these patients.
- The number of patients under ESRD treatment on December 31, 2001 was 406,081 including 292,215 dialysis patients and 113,866 patients with a functioning kidney transplant.
- Growth in incident population has slowed to 2-3 percent, while the prevalent population has increased 4 percent.
- Medicare costs for the ESRD program in 2001 were \$15.4 billion (almost 12 percent higher than costs in 2000), while non-Medicare spending increased 11.5 percent and accounted for \$7.4 billion. Expenditures for the entire program totaled \$22.8 billion, an increase of 11.4 percent from 2000.

National Incidence and Prevalence

A key variable to assessing the need for dialysis services is the rate of growth of newly diagnosed patients, and the number of patients currently being treated. The USRDS definitions of incidence and prevalence are:

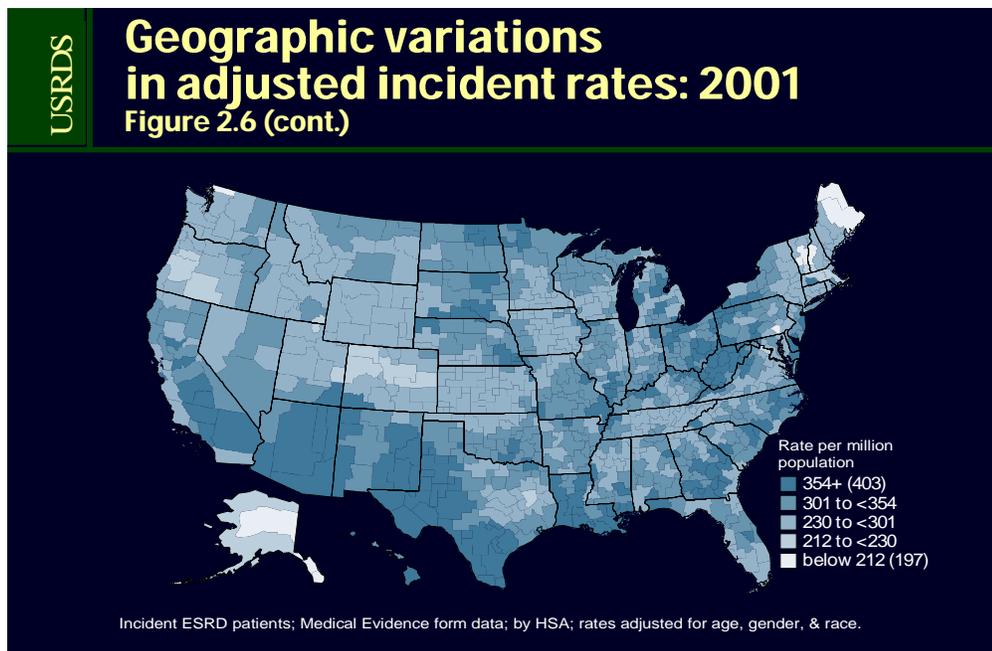
Incidence: Incident patients are those with new cases of ESRD during a given time period. A patient is considered incident at the time of first treatment (dialysis or transplantation) for chronic renal failure.

Prevalence: December 31 point prevalent patients, i.e. patients reported as receiving renal replacement therapy for ESRD on December 31 of a given year.

USRDS data shows that the odds of developing kidney failure and the incident and prevalent rates of ESRD vary significantly across the country. These variations are partially explained by race and ethnicity. There are, however, complex interactions that involve regional variations in care that may explain some of the differences. For example, the way patients are managed before they develop end stage renal disease may have an influence. The prevalence of patients receiving dialysis is also influenced by an annual mortality rate of 20% and the rate of transplantation.

The following national statistics about incidence and prevalence are taken from the 2003 USRDS Annual Report:

- The odds of developing ESRD are greatest in the southwestern states and the lowest in the Midwest and the northeastern states. Incidence rates vary 60% between the lowest and highest quintiles, even after adjustments for age, gender and race.



- The incident rate has slowed over the last five years, with the 2000-2001 increase at 1.8%. The rate of growth has varied considerably across the country, decreasing in some areas and continuing to rise in others. The overall incident rate in 2001, adjusted for age, gender, and race, was 334 patients per million population.
- The prevalent rates have continued to rise, but the rate of increase has slowed to 4.2% between 2000 and 2001. The overall prevalent rate in 2001, adjusted for age, gender, and race, was 1,392 patients per million population.
- The median age of the dialysis population has been fairly constant over the last five years, while the median age of the transplant population has continued to increase due to improved graft function and patient survival.
- Growth in incident rates of ESRD due to diabetes and hypertension has slowed, while rates of ESRD due to glomerulonephritis and other causes of renal failure remain virtually unchanged.

Regional Incidence and Prevalence

The table on the next page summarizes the unadjusted incidence and prevalence in Vermont. The trends are similar to the adjusted national data presented above. Incidence rate has changed minimally over the past five years. Prevalence has increased since 1998 but the growth has leveled between 2001 and 2002. At the end of calendar year 2002, there were 352 ESRD patients in Vermont receiving dialysis therapy.

**Incidence and Prevalence Counts for Vermont and
Network 1 (New England)**

		1998	1999	2000	2001	2002
Incidence	VT	118	120	118	107	123
	Network	3,502	3,408	3,726	3,664	3,502
Prevalence	VT	291	306	327	357	352
	Network	9,024	9,506	10,161	10,324	10,627

It is important to recognize that this report does not contain a predictive model that can forecast incidence and prevalence in Vermont. All data consists of counts of patients at specific points in time, and the time periods are not consistent.

Appendix A contains a listing of patient origin by zip code for all Vermont ESRD patients receiving dialysis therapy on December 17, 2003.

Structure of Renal Dialysis Programs

Facilities

Hemodialysis facilities are either hospital-based or freestanding. A hospital-based hemodialysis center is usually located in a hospital that provides the full spectrum of renal services including vascular access, pre-ESRD care, hemodialysis, acute dialysis, and peritoneal dialysis. A freestanding hemodialysis unit is not based in a hospital facility. Hemodialysis centers can be either for-profit or non-profit; chain-affiliated or independent. A chain-affiliated unit is one of a group of freestanding hemodialysis units that are owned by a common party and located in a single state or more than one state. A hemodialysis center must have an arrangement or affiliation agreement with a hospital-based hemodialysis center for the provision of inpatient care and other hospital services. The center must have documentation from the hospital-based hemodialysis center that patients from the hemodialysis center will be accepted and treated in emergencies.

Renal Dialysis Treatments

There are three treatment modalities available to replace renal function. They include transplantation, hemodialysis and peritoneal dialysis. This report focuses on hemodialysis therapy only. Dialysis treatments can be provided at dialysis centers or at home. In all cases, dialysis removes waste products and extra fluid from the blood. This occurs either by pumping blood through an artificial kidney (hemodialysis), or using the patient's abdominal area to slowly remove toxins across the peritoneal membrane (peritoneal dialysis). The decision about which treatment modality a patient chooses (transplant, hemodialysis or peritoneal dialysis) is made jointly between the patient and physician.

Peritoneal Dialysis

Peritoneal dialysis is the primary form of home dialysis. The method involves implanting a permanent catheter into the abdomen. The peritoneal membrane covers the abdominal organs and has a very high blood supply. The process involves placing 2 to 3 liters of fluid, or dialysate, through the catheter and into the space between the peritoneal membrane and the wall of the abdomen. The dialysate remains in the body for a period of 4 to 6 hours and waste products and fluid move out of the blood and into the fluid. The patient then drains the toxin-filled fluid out and replaces it with fresh fluid. This process must happen 4 to 5 times per day, every day of the week. During the time the fluid is in the abdomen, the patient can resume normal activity

The success of this modality requires careful patient selection. Not all patients are candidates for this independent therapy. The patient must be highly motivated to provide self-care, possess good fine motor coordination and vision. They must also have access to electric and/or water supply, have heated space for supply storage and an area that can be isolated for aseptic procedures. Approximately 10% of ESRD patients in the United States receive peritoneal dialysis.-

Hemodialysis

Hemodialysis requires access to the patient's blood. Prior to starting dialysis, the patient must undergo surgery to create a blood access that can accept large intravenous needles. In some cases, the patient must have a temporary catheter placed into one of their large blood vessels to allow access to the bloodstream. The hemodialysis process involves pulling blood from the patient, pumping it through an artificial kidney, and returning the blood to the patient. As the blood passes through the artificial kidney, toxins and fluid are removed. At a minimum, patients require hemodialysis 3 times per week. A typical schedule is Monday, Wednesday, Friday or Tuesday, Thursday, Saturday.

Patients receiving hemodialysis also require regular treatment with medications such as calcium, phosphorus, iron, and nutritional supplements. They also require medication to treat the chronic problems of anemia and hypocalcemia (low blood calcium).

A dialysis "station" consists of the dialysis machine and dialysis chair. The patient is attached to the dialysis machine for approximately 4 hours. An additional hour is required to initiate and discontinue the therapy. Upon completing the hemodialysis session, it takes an additional 30 minutes to prepare the dialysis station for the next patient. Hence, a single dialysis session requires approximately 5 hours. Some hemodialysis centers operate three days a week, on Monday, Wednesday, and Friday, while others operate six days per week. Typically, dialysis centers operate 16 hours per day beginning at 5:00 AM. Commonly, the center plans to treat three patients per day, per dialysis station. A facility with 6 stations has a maximum patient capacity of 36.

The majority of hemodialysis occurs at a dialysis center; however, some patients perform the treatment at home. Approximately 1.5% of patients nationwide perform home hemodialysis. Patients must be medically stable and motivated to take responsibility for their own care in order to be eligible for a home dialysis training program; otherwise this mode of treatment will not be recommended nor allowed. The patient also needs another person to either assist with the treatment and/or be available in the event of an emergency. The assistant must learn the complete dialysis procedure regardless of their eventual role. The patient is responsible for the costs of an assistant, as Medicare no longer covers this expense. Without a trained assistant, the patient must return to in-center dialysis. A home dialysis training program generally runs for 8 weeks.

In addition, the home environment must meet specific standards to perform home hemodialysis. Environmental, electrical, plumbing, sewer and water source are critical components of a successful installation. Patients are responsible for the costs of any renovations and upgrades to their home and for ensuring that work is completed and inspected by a licensed professional. Additional storage space for supplies is an important consideration.

Medicare and insurance companies will pay for the dialysis machine, reverse osmosis equipment (a component of the water treatment system), the dialysis chair and all the supplies necessary to perform the dialysis.

Overview of Regulatory Authority and Certificate of Need Process

Federal legislation authorizing the “Conditions of Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services” is under sections 1102, 1138, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act. The rules and regulations can be found in the Federal Register: 41 FR 22511, June 3, 1976; re-designated at 42 FR 52826, September 30, 1977. Each hemodialysis center must conform to these federal rules and regulations in order to participate in the Medicare reimbursement program. Some states may also have their own licensing laws regarding hemodialysis centers. Vermont does not have a licensure program for dialysis facilities.

The National Kidney Foundation has developed a set of guidelines entitled, “Kidney Disease Outcomes Quality Initiative” (K/DOQI) to improve clinical outcomes for people with all stages of kidney disease. These guidelines were released in the [American Journal of Kidney Diseases](#). The quality improvement activities known as the National Clinical Performance Measures (CPM) are based upon the K/DOQI. Each year CMS identifies categories of care to assess, the targeted ESRD patient population to study, and the clinical performance measures to be collected. A random sample of adult ESRD hemodialysis patients is identified. Clinical performance data for the identified quality indicators is collected on these patients from the networks. Results of the analysis are published in the End Stage Renal Disease (ESRD) Network Program Annual Report Summary.

Some states, Vermont included, have a Certificate of Need (CON) process. Adopted in 1979 by the Vermont Legislature, the CON review process establishes criteria to guide the development of most new health care projects in Vermont. The program exists to avoid unnecessary duplication, and contain or reduce increases in the cost of delivering services, while at the same time maintaining and improving the quality of and access to health care services. It also aims to promote rational allocation of health care resources in the state; and, the need, cost, type, level, quality and feasibility of providing any new health care project are subject to review and assessment prior to any offering or development. (See 18 V.S.A. §9431)

To facilitate these policy goals, the Legislature has required the Department of Banking, Insurance, Securities and Health Care Administration (BISHCA) to develop CON guidelines to assist in its decision-making. The current CON Guidelines for “access” indicate that renal dialysis services should be available to most Vermonters within 60 minutes travel time by ground transport from the center of town. (See page 5 of the *Certificate of Need Guidelines*.) The current CON Guidelines also state that “In Vermont, kidney dialysis of non-acute patients should be provided only through Fletcher Allen Health Care, Dartmouth-Hitchcock Medical Center, Albany Medical Center, or other academic medical center, either directly or through a satellite service, for both in-home and in-hospital dialysis.” (See page 7 of the *Certificate of Need Guidelines*.)

In 2003, the Legislature passed H-128 (Act 53), An Act Relating to Hospital and Health Care

System Accountability, Capital Spending and Annual Budgets that requires the Commissioner of BISHCA, in consultation with the Secretary of the Agency of Human Services to submit to the Governor on or before July 1, 2005, a Health Resource Allocation Plan for the state of Vermont. This plan will include identification of the current supply and distribution of a wide array of services and resources that may include renal dialysis units. Act 53 also requires that there be public input regarding this Plan and development of a mechanism for ongoing public comment regarding the Plan.

New renal dialysis units and the expansion of existing renal dialysis units are subject to CON review if they trigger the dollar thresholds specified in 18 V.S.A. §9434. As of the writing of this report, all CON applications that have been submitted since 1980 to create or expand a renal dialysis unit have been granted a CON.

Recent Dialysis Facility Proposals

On August 28, 2001, Fletcher Allen Health Care filed a CON application seeking approval to spend \$2.5 million to establish a six-station renal dialysis unit located adjacent to Northeast Vermont Regional Hospital (NVRH) in St. Johnsbury. The CON application was submitted after a lengthy analysis by Fletcher Allen, involving NVRH and North Country Hospital (NCH) in Newport, of the need for dialysis services in the Northeast Kingdom. That analysis led FAHC health planners to the conclusion that patient need in the Northeast Kingdom would support one dialysis unit. After reviewing a number of potential sites for the unit, and considering those sites in light of both clinical and financial criteria, FAHC determined that a St. Johnsbury location would be the most appropriate.

After the CON was submitted, NCH filed a letter of intent to establish a dialysis facility at NCH in Newport. As both NCH and NVRH are affiliated with the Hitchcock Alliance, FAHC invited Dartmouth Hitchcock Medical Center to join in the discussion of how best to serve patients needing renal dialysis in that region.

After several meetings in 2002, DHMC agreed to continue planning with NCH and NVRH to see if a mutually supported, financially viable plan could be identified to develop an initial renal dialysis site at NVRH followed by a second site at NCH as soon as the region could support two dialysis units. Accordingly, in late 2002, FAHC withdrew its pending CON application in the hope that DHMC, in collaboration with NCH and NVRH, would be able to develop a plan for the phased implementation of two renal dialysis sites in the Northeast Kingdom.

Unfortunately, DHMC, NCH and NVRH have not been able to finalize a mutually supported plan and a further CON application to provide renal dialysis services in the Northeast Kingdom has not yet been submitted. In response to the continued patient need for these services, however, FAHC is presently engaged in discussions with NCH about the possibility of establishing a renal dialysis unit in Newport.

Dartmouth Hitchcock Medical Center and Springfield Hospital began planning for a renal dialysis facility to be located at Springfield Hospital in 2000. The plan outlined the facility and staffing requirements to operate a 6-station facility that would treat a maximum patient census of

36 patients. A CON application for the project was submitted in October 2001 and approved in October 2002. In October 2003, DHMC made a decision not to pursue the project. The decision was influenced by two factors. First, the bid process documented that the cost of the project was higher than predicted. The increase was large enough to require that a new CON application would have been required. Second, during this process, DHMC began to experience significant financial challenges. Opening the Springfield Dialysis Unit required a large initial investment and an ongoing subsidy. The combination of the increased cost to build the unit and the financial challenges experienced by DHMC led to the decision not to implement the plan at this time.

Economic Considerations

Variables that Impact the Economic Viability of a Hemodialysis Center

The Dialysis Needs Assessment Committee did not model the cost of establishing a new dialysis facility in Vermont due to multiple variations as described below. Assumptions regarding critical variables such as location, new construction versus renovation, square footage, payor mix, reimbursement rates, growth rates, and staffing models have a major impact on the predicted financial performance. The Committee determined that making broad assumptions about financial performance leading to specific financial data would be misleading.

Estimating the financial performance for a hemodialysis center requires information on the number of patients covered by Medicare and by third-party payers, as well as the expected reimbursement per treatment for dialysis and drugs. To determine revenues, the financial performance is offset by the costs of providing dialysis per patient per treatment, facility and equipment costs, and annual operating costs. If eligible for Medicare coverage, all ESRD patients are entitled to coverage of their medical care through Medicare regardless of age or income.

If the patient has insurance through employment, that third-party payer will be billed by the center for 33 months of treatment, after which the patient is eligible for Medicare. Such patients are considered Medicare secondary payer patients. Reimbursement by a third-party payer may differ between insurance companies. In the event the patient does not have insurance, the hemodialysis center bills the patient and, if the patient is unable to pay, absorbs the cost of treatment for the first three months while the patient awaits Medicare authorization. Some patients may pay out of pocket for their hemodialysis treatments.

The total costs of establishing and operating a hemodialysis center consist of capital costs and annual costs. Capital costs include the acquisition and preparation of a suitable facility. Total annual costs consist of annual capital costs and operating expenses. Annual capital costs include the depreciation of all capital items in the facility and required investment in capital equipment and the facility. Operating costs are the daily costs incurred in the process of providing hemodialysis. Cost estimates will vary based upon the number of stations, number of patients treated, and number of treatment days per week.

The major components of capital costs for a hemodialysis center include land, building and parking lot, and equipment. The building or facility must be handicapped accessible. Capital costs will be different depending on whether a new facility is built or an existing building is renovated.

The viability of a hemodialysis center is dependent upon generating revenue to cover the total cost of the services. Revenue is dependent upon the number of treatments given and the payer mix. The payer mix will vary throughout the year as new patients begin treatment and others leave. Payment by third-party payers (insurance and managed care companies) will vary depending upon the specific policy. Payment is negotiated between the hemodialysis center and

the commercial payer. Self-pay will also vary depending upon the patient's ability to pay. The turn-around time for billing and receiving payment from Medicare usually takes several months. Additional revenues for the center may be generated through other charges including drugs. For example, the center may sell dialysis products to peritoneal dialysis patients who dialyze at home.

Medicare reimbursement is lower than reimbursement from third-party payers, therefore, a center with a larger percentage of Medicare patient enrollment will have lower revenues than would a center with a smaller percentage.

Hemodialysis equipment has an expected life of seven years. Operating costs for a hemodialysis center can vary greatly based upon whether the center is part of a large corporation and/or is hospital based. The cost per treatment depends upon several variables, including staffing, management costs, overhead, and patient mix.

Current CON guidelines state that "in Vermont, kidney dialysis of non-acute patients should be provided only through Fletcher Allen Healthcare, Dartmouth Hitchcock Medical Center, Albany Medical Center or other academic medical center, either directly or through a satellite service, for both in-home and in hospital dialysis." Fletcher Allen Healthcare is the single not-for-profit provider of dialysis services in Vermont. In neighboring New Hampshire, dialysis services are available at not-for-profit and for-profit dialysis providers. Roughly 15% or 60 Vermont patients receive care in for-profit dialysis facilities in New Hampshire (Keene), Massachusetts (Greenfield, Pittsfield), and New York (Glens Falls, Saratoga, Albany, Plattsburg).

Nationally, approximately 70% of the dialysis patient population is treated at for-profit facilities. Fresenius Medical Care, Baxter Healthcare, and Gambro Healthcare treat more than 50% of these patients. Other companies exist, but have less of a market presence. In New Hampshire, Fresenius Medical Care operates the Manchester Kidney Center, Fresenius Medical Services of Exeter, Monadnock Dialysis Center in Keene, New Hampshire Kidney Center in Concord, Seacoast Dialysis in Portsmouth, and Somersworth Dialysis in Somersworth. Gambro Healthcare operates a facility in Nashua. The Central New Hampshire Kidney Center in Laconia is not-for profit and independently owned. The Dartmouth Hitchcock Medical Center operates not-for profit hospital-based facilities in Lancaster and Lebanon.

In a typical for-profit arrangement, a physician group practice will partner with a dialysis chain provider to establish dialysis capacity. The for-profit company will build, equip, and operate the dialysis center. The group practice provides the physician service to the dialysis patients and medical direction for the facility. Revenue from the professional (physician) service accrues to the physician practice and the company receives revenue for the technical (dialysis) service. A medical direction fee is usually paid to the physician practice. The medical director is responsible for the overall quality of care and implementation of standards of clinical practice. The physician practice generally admits acutely ill dialysis patients to a local hospital for acute dialysis services.

Large providers of dialysis services have access to capital to expand into promising markets. Many but not all of the for-profit companies are vertically integrated, and manufacture their own dialysis equipment and supplies. This fact creates a cost advantage compared to smaller providers like FAHC and DHMC. Large providers have high leverage with pharmaceutical suppliers and payors based on their national presence and the number of treatments performed. As an example, at the end of 2002 (last full year available), Fresenius Medical Care was treating a total of 81,700 patients in 1,080 centers throughout the US. The total number of treatments performed was 16.3 million. By comparison, Dartmouth Hitchcock Medical Center is currently treating 160 patients in two centers. The annual treatment volume is 25,000. Medicare is the primary payor for more than 80% of dialysis patients. Reimbursement rates are low and not expected to rise.

Since large corporations continue to make a positive return providing dialysis treatments, there is no incentive for the federal government to raise reimbursement rates. All dialysis facilities are held to the same practice standards that are mandated in the Medicare Conditions for Coverage. Patients can examine the clinical performance of any dialysis center in the country by visiting www.medicare.gov and accessing the Dialysis Facility Compare function.

Renal Dialysis in Vermont

Brief History

Dialysis began in Vermont in the early 1970's with one patient who traveled to Ohio to receive training for home dialysis. Medical Center Hospital of Vermont (MCHV), now known as Fletcher Allen Health Care, opened its own home training program soon after. A hospital-based hemodialysis unit was opened in the mid-1970's at the hospital to provide hemodialysis treatments to patients who preferred in-center treatment or were unable to dialyze at home.

By the early 1980's, 25 patients were participating in the home program and approximately eighty patients were receiving dialysis treatments at MCHV. MCHV started a peritoneal dialysis program in 1981. In the early 1990's, FAHC opened its first satellite unit at the Central Vermont Medical Center with six stations.-

Distribution of Dialysis Centers within Vermont

Fletcher Allen Health Care is currently the only provider of dialysis services in the state. The table below summarizes the location of dialysis facilities, the current number of patients being treated, the maximum number of patients that can be treated at each center, and the number of patients being dialyzed elsewhere but waiting to transfer.

Fletcher Allen Health Care Dialysis Facilities in Vermont:

Facility	Number of Stations	Maximum Patient Capacity	Current Patient Census	Waiting List
Bennington	6	36	36	6
Berlin	6	36	36	14
Rutland	9	54	47	0
Burlington (MCHV)	10	60	42	0
So. Burlington	18	108	91	0
St. Albans	9	54	45	0

Currently the facilities located at Southwestern Vermont Medical Center in Bennington and Central Vermont Medical Center (CVMC) in Berlin are at capacity with patient waiting lists at both facilities. The capacity to accommodate additional patients (including home dialysis) exists at all other Vermont facilities. Construction is in progress at CVMC to increase the number of stations from six to nine, resulting in an increased capacity of 18 patients. No plans currently exist for expansion of any other Vermont facility.

Some Vermont patients travel to dialysis facilities in New Hampshire, Massachusetts, and New York for their treatments. The table on the next page summarizes the location of dialysis accessed outside of Vermont and the total number of Vermonters with their county of origin who utilized these facilities from January to October 2003.

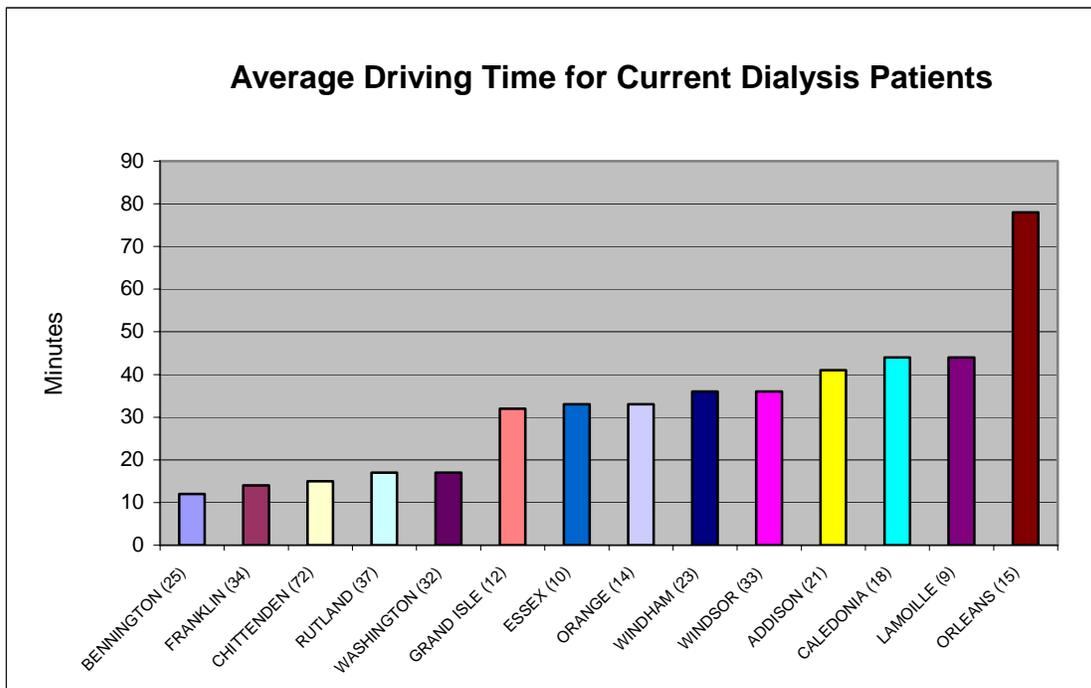
**Vermont Residents Receiving Dialysis at
Facilities Outside of Vermont
As of December 2003**

Facility Location	# of Dialysis Stations as of 2003	# of Vermonters Served (2003)	County of Residence Represented	Plans to Add Stations During Next 2 Years
Lebanon, NH	19	43 (plus 9 Dialysis Patients Performing Home Peritoneal Dialysis)	Caledonia County, Orange County, Windsor County.	Will expand to 33 stations in 2004.
Lancaster, NH	15	18	Caledonia County, Essex County, Orleans County.	None
Keene, NH	13	19	Windham County	None
Greenfield, MA	13	23	Windham County	None
Glens Falls, NY	24	2	Rutland County	None
Berkshire Medical Center/Pittsfield, MA	19	12 (treat Vermont patients on a short-term basis typically for 2-3 weeks and then transfer them to Bennington Renal site.	Bennington County	Will add 6 additional stations in 2004
Rubin Ctr./Saratoga, NY	18	1 (slow nocturnal home dialysis)	Bennington County	None
VA/Albany, NY	5 (acute facility)	2	Bennington County	None
Plattsburgh, NY	24	No In-center, but supports one person on home dialysis.	N/A	None

Patient Access

The average one-way driving time for current Vermont dialysis patients to the closest dialysis center (Vermont & New Hampshire) is 27 minutes. This does not take into account that the closest dialysis center may be at capacity and the patient may be required to travel to a more distant facility, nor is there any adjustment for inclement weather or less than ideal road conditions. Currently, 20 patients travel over 60 minutes in each direction to dialysis three times a week.

The following table documents the average one-way driving time for Vermont patients receiving dialysis therapy to the closest dialysis unit (Vermont & New Hampshire). The data was derived by information received on December 17, 2003 from the ESRD Network of New England and represents a single point in time. MapQuest.com was utilized to determine the driving times between the patient's zip code and the zip code of the closest dialysis unit.



Impact is greatest in Orleans County where 14 of the 15 patients travel over 60 minutes each way to dialysis with an average of 78 minutes. For the patients of Orleans County, this equates to 7.8 hours of travel each week to receive their dialysis treatments. At present, dialysis patients in Orleans, Lamoille, Caledonia, Addison and Essex counties have the longest travel times to receive care.

Average Driving Time for Current Dialysis Patients

		Average	Median	Standard
County	Patients	Drive Time	Drive Time	Deviation
Orleans	15	78	84	12
Lamoille	9	46	48	4
Caledonia	18	44	39	9
Addison	21	41	38	7
Essex	10	33	28	10

Source: Patient counts from Network of New England and driving time determined utilizing MapQuest.com

Patient Transportation

Transportation is one of the key issues facing dialysis users in Vermont. With dialysis units spread unevenly across the state, some dialysis patients have to travel significant amounts of time to access dialysis services. This section examines the transportation resources available in Vermont, funding and costs associated with transportation, and availability and accessibility of transportation services; and discusses the impact of dialysis transportation on other transportation needs. As part of this report, the task force compiled the results of a survey of consumers and their perceptions of the transportation options available to them.

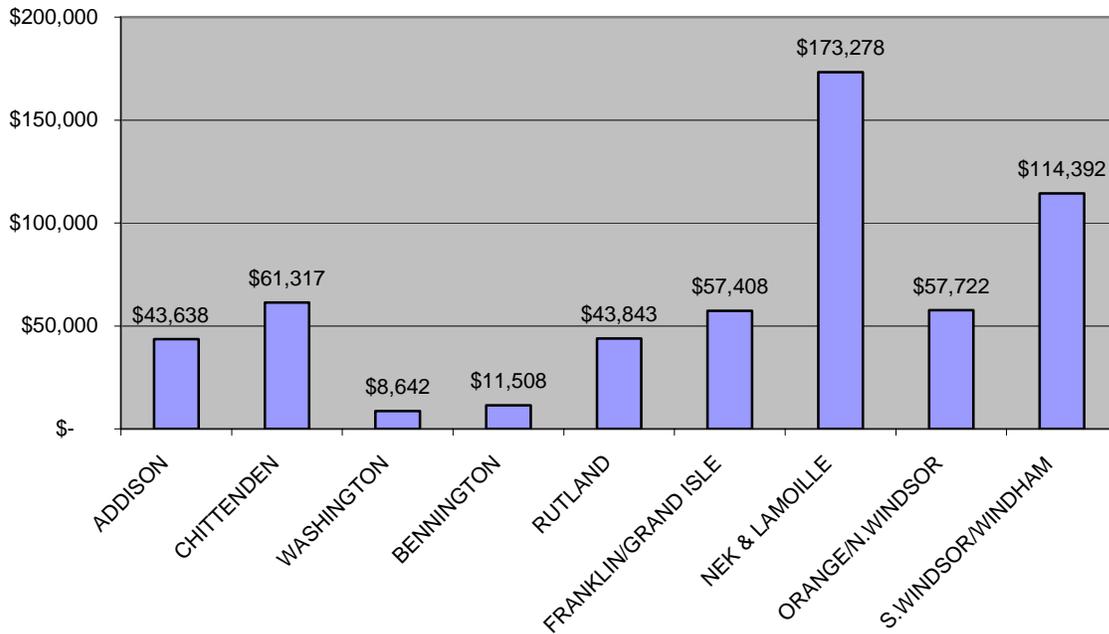
Current Transportation Resources

Medicare: Medicare coverage for transportation to dialysis centers is limited. Medicare beneficiaries can obtain Medicare coverage for their transportation to and from dialysis only if it is medically necessary for the beneficiary to travel by ambulance. Information from regional dialysis centers suggest that Medicare transportation for dialysis constitutes a small portion of the total transportation picture.

Medicaid Transportation: Medicaid Transportation to and from dialysis (and other Medicaid covered services) is available to Medicaid beneficiaries who have no other means of transportation. In order for an individual to become eligible for Medicaid, she or he must meet categorical and financial eligibility criteria. Within the Vermont Department of Prevention, Assistance, Transition and Health Access (PATH), the Office of Vermont Health Access (OVHA) is the State agency responsible for administering the Medicaid program. OVHA contracts with the Vermont Public Transportation Association (VPTA) to provide Medicaid transportation benefits. VPTA then subcontracts with transportation providers across the state to provide transportation benefits to Medicaid beneficiaries. All of VPTA's subcontractors are also the nine State-designated regional public transit providers. VPTA employs a brokerage system that includes volunteer drivers, local taxi companies, and specialized paratransit van services, both non-profit and for profit. The cost for all services is approximately \$4.2 million annually.

VPTA reports that from July 1, 2002 through April 30, 2003, Vermont Medicaid provided transportation benefits to 111 individuals to access dialysis services for the 10-month reporting period, at a cost of \$476,500. Projected to 12 months, Vermont Medicaid will spend approximately \$571,700 or 13.6% of the total Medicaid transportation budget to transport Medicaid eligible patients needing dialysis. The cost per region is illustrated on the next page, with the Northeast Kingdom (NEK) and Lamoille County experiencing the highest overall costs.

Medicaid Dialysis Transportation Costs by Region SFY 2003 est'd



The Medicaid transportation benefit for dialysis has no impact on the availability of other Medicaid transportation benefits. Once a beneficiary is found eligible and without another means of transportation, she or he is entitled to this service, within the limits and parameters of the Medicaid Program. However, as the number of beneficiaries needing this service grows, the increase in demand for transportation affects the overall State Medicaid budget.

The Medicaid transportation benefit requires prior authorization and limits the distance within thirty (30) miles of a beneficiary's residence, unless the beneficiary must travel out of that radius to receive necessary services. Transportation and costs to the overall Medicaid budget are impacted if a dialysis unit is not within that radius or the closest unit is full and beneficiaries need to travel out of range.

Subcontractors have access to lift-equipped vans, volunteer drivers and, if necessary, may contract with private taxis, ambulance companies and other transportation providers. Medicaid transportation will only be provided if the service is not available through other means, is to or from medically necessary services and is provided using the least expensive means suitable to the beneficiary's medical needs. Since this benefit is an entitlement to those Medicaid beneficiaries without another means of transportation, the State agreement with VPTA includes the expectation that their subcontractors provide the service. If a transportation provider does not have the capacity to provide the trip on the day or time requested, the beneficiary may be asked to reschedule their appointment to a time when the trip can be provided. Information from VPTA confirms that this does not occur frequently with respect to dialysis transportation, largely

due to the providers' understanding of the critical importance of dialysis as well as their knowledge of the limited flexibility in scheduling at many of the dialysis units across the state.

Section 5310 Transportation for Elders and Persons with Disabilities Program: The Vermont Department of Aging and Disabilities (DA&D) through a grant agreement with the Vermont Agency of Transportation, administers this Federal Transportation Administration (FTA) program designed to meet the special transportation needs of elders and persons with disabilities. Funding for this program is comprised of eighty percent federal totaling \$2.1 million that require a local match of twenty percent, or \$525,000 for a total program funding of \$2,625,000. However, actual costs in the Section 5310 Program exceeded \$3.6 million, largely due to substantial local support for the services in some regions of the state. The local match can be made with both cash and in-kind support. Presently, in-kind support is limited to the time spent by volunteer drivers transporting program participants. Through a formal Request for Proposal (RFP) process, DA&D enters into grant agreements with regional transit providers and/or human service agencies to purchase or provide transportation to elders and persons with disabilities. The local applicants must describe how they will meet the local match requirements for the program as part of the RFP process.

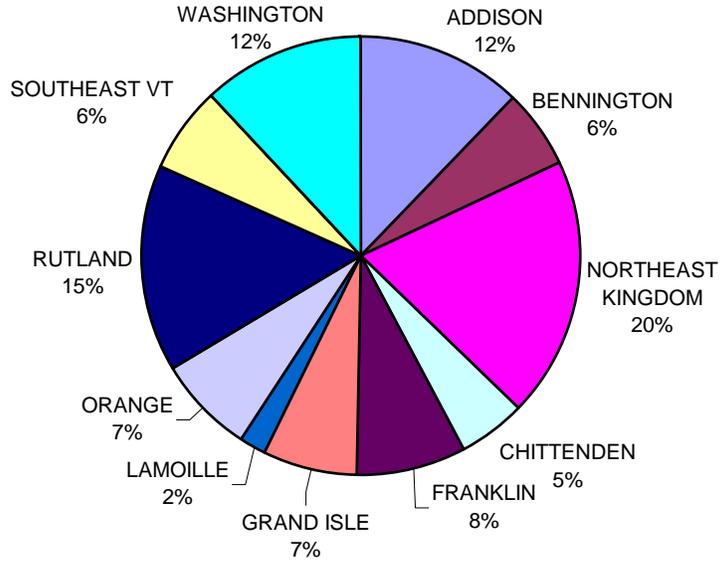
Unlike the Medicaid Transportation Program, there are currently no financial eligibility limitations for users of the 5310 program. The only eligibility requirement is that the participant is a Vermont resident age 60 or older, or an individual of any age with a disability as defined by the Americans with Disabilities Act (ADA). In addition, grantees are instructed to ensure that Section 5310 services are provided only when no other resource is available.

According to the Federal rules for this program, the range of trip purposes is not limited, but broadly defined, encompassing not only dialysis and other essential medical transportation, but transportation to community meals programs, adult day centers, vocational trips, personal quality of life trips and group trips. In addition, funding in this program is fixed and limited. Within each region, the various stakeholders involved in the transportation program must work together to plan and prioritize the services to be provided and to manage the program to ensure that the region does not run out of funding before the end of the year. The Regional Planning Commissions throughout the state have played a key role to facilitate this process and promote on-going communication and coordination.

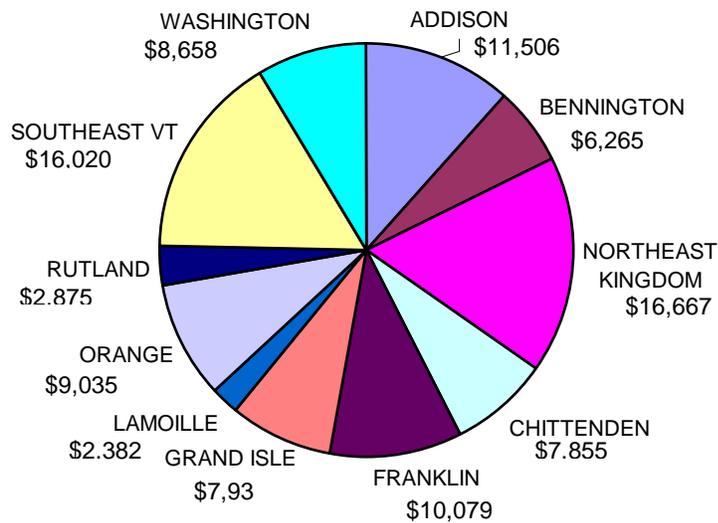
From July 2002 to June 2003, the Section 5310 Program is estimated to have provided 300,000 trips to approximately 4,500 eligible participants at an overall estimated total program cost of \$3,600,000. At least ninety participants used this program to access dialysis. Dialysis accounted for 19,300 of all program trips, at a cost of \$406,000 or 11.2% of total program resources. Data regarding the contribution of volunteer driver hours was not available for the first half of the fiscal year, hence the actual cost of this program could be higher, perhaps as much as \$48,000.

Regional data as provided by the Section 5310 grantees for the last six months of SFY 2003 shows that the Northeast Kingdom provided the highest volume of dialysis transportation in the Section 5310 Program and also experienced the highest costs for dialysis transportation:

Section 5310 Dialysis Trips by Region January - June 2003



Section 5310 Dialysis Costs by Region January - June 2003



The number of people accessing this program for transportation to dialysis can have a significant

impact on the ability of other individuals to utilize this program both for necessary medical transportation and other special needs purposes. Funding for the 5310 Program is fixed and limited. Grantees are expected to manage program funds to ensure that they are not exhausted before the end of the year. In order to do this, some grantees limit the number of trips or per person funds available in the grant year. For example, in one region, the human service agency may pay for some, but not all, of the dialysis trips. In another region, the provider may set a dollar limit for each person and then stop providing service to an individual once that limit has been met. In other regions, if more dialysis users request services, the grantee, working with the various regional stakeholders, may reduce transportation for other purposes in order to ensure sufficient funds for dialysis transportation. As the Department of Aging and Disabilities works with local providers to expand community-based services and promote consumer choice of long term care, it is becoming increasingly critical to ensure that adequate access to transportation to other vital services such as adult day centers and community meals programs is available. As the demand for dialysis transportation continues to increase in the Section 5310 Program, transportation to other community-based services and employment will need to be cut even further.

Like Medicaid Transportation, Section 5310 Program providers utilize lift-equipped vans or minibuses, volunteer drivers and taxis as primary modes of transportation. The vehicle fleet size and availability of volunteer drivers can affect the availability and accessibility of services. As with the Medicaid transportation, if a transportation provider does not have the capacity to provide the trip on the day or time requested, the participant may be asked to reschedule the appointment to a time when the transportation can be provided.

Consumer Survey: Consumer input regarding the burden of personal transportation costs as well as the convenience of their treatment schedule was sought as an important aspect of the study. A survey was conducted using a questionnaire, developed by members of the Dialysis Needs Assessment Committee, asking respondents to report the amount of time and distance they travel to dialysis. The financial burden of personal travel costs and the convenience of their dialysis schedule was measured on a scale of 1 (low/convenient) to 4 (high/inconvenient). The questionnaire was distributed to all patients at Vermont dialysis units and to Vermont residents dialyzing at units in New Hampshire and Massachusetts. Unit staff assisted patients, as needed, to complete the survey. (See Appendix C for a copy of the questionnaire.)

A total of 202 Vermont residents receiving dialysis participated in the survey. The age of participants ranged from 19 to 91 years of age with an average age of 66. The length of time on dialysis ranged from 1 month to 16 years with an average of 3 years. Travel time, as reported by the participants, from their residence to the dialysis unit ranged from 5 minutes to 2 hours with an average of 34 minutes. Mileage, one way from residence to the dialysis unit, as reported by the participant, ranged from 1 mile to 128 miles with an average of 23 miles.

One hundred fifteen or 59% of the respondents reported that they or a friend or relative drove them to dialysis. Forty-one percent of the respondents indicated that an agency or other type of transportation provided transportation. Fifty-nine percent (59%) of the respondents indicated that they or their family paid for the transportation while 43% reported that either a transportation agency (11%), Medicaid (25%) or other entity (7%) paid for transportation to dialysis.

The personal financial burden of transportation, rated by 115 respondents, was interpreted as moderate with an average rating of 2.0. Results also indicated that most of the 202 respondents were satisfied with their dialysis schedule with an average rating of 1.4.

Sixty-three participants (30%) indicated that they had to dramatically alter their lifestyle in order to access dialysis services. Nine participants (4.4%) reported moving to a new location to access dialysis services.

Respondents' written comments included appreciation for the treatment option itself as well as for the quality of the service, including transportation, provided them. Respondents from many of the units expressed the need for a unit "closer" to where they lived, citing travel time, winter travel conditions, and the cost of gas and vehicle maintenance as significant areas of concern. Few indicated a preference for a different schedule or time of dialysis. Several individuals commented on the "hassles" or inconvenience to family members who provide transportation to dialysis. Several wrote about the time away from home and family activities, due to the number of hours per week consumed by dialysis, which was extended for some by lengthy travel times and/or distance.

See Appendix D for a summary of the responses to travel time and distance by survey respondents.

Mobile Dialysis

The core concept of mobile dialysis is mobilizing a multi-station dialysis unit and bringing the treatment to patients in a geographic area of need instead of the patient traveling long distances to a fixed location for dialysis treatment. There are no mobile dialysis units in existence at this time.

Mobile Medical International Corporation (MMIC), a Vermont company located in St. Johnsbury, has designed a proposed mobile dialysis unit, using their Mobile Surgery Unit™ (MSU) as a prototype. Available and in use since 1996, the MSU, which is Medicare certified, has been successfully utilized during hospital renovations in California, Virginia, Florida, and Louisiana. A MSU allows for major surgical intervention ranging from cataracts and colonoscopies to hip replacement and general abdominal surgery. Each MSU has been designed and constructed with the same regulatory requirements of a hospital.

Configured in a hydraulically expandable, fifty-three foot trailer, the proposed self contained, self-sustainable dialysis unit includes a six station treatment area, a reception area, nurses' station, water treatment room and bathroom. Service connections for electricity, water and sewer are included as well. The floor plan and technical data sheet outlining the specifications of the proposed unit are located in Appendix E.

MMIC has conducted its own survey in order to determine dialysis needs and options in the Northeast Kingdom as well as the design requirements that would make a mobile project viable. Research included on-site visits to a satellite dialysis unit in Whitefield, New Hampshire (no longer in operation) and a Fletcher Allen Health Care satellite located in South Burlington, Vermont. The results of this MMIC survey and research indicated that a proposed mobile dialysis unit could be utilized in two different geographic locations located 40 miles apart in the Northeast Kingdom (St. Johnsbury and Newport) with local hospitals in each community serving as bases of operation.

Potentially, personal and public transportation costs could be reduced through direct and indirect cost savings by deploying a mobile unit. The indirect costs are to family and friends who support the dialyzed patient. Not included in the report is the opportunity costs for those individuals supporting the dialysis patient. MMIC's research found that this was a concern to families due to loss of income when the providing family member alters his/her lifestyle to accommodate a loved one.

MMIC's survey revealed three distinct regions within the Northeast Kingdom and Northern New Hampshire where the continuing change in demographics raises an important consideration. The patient base within these regions can be fluid due to the fact that many patients are elderly and attrition can change the demographics. Mobile service solves key concerns of patient access and transportation costs to the patient and family. As demographics shift, the mobile unit changes its location; services are brought to the region rather than the region traveling to the service.

MMIC has submitted a Small Business Innovation Research grant application in cooperation

with the National Institutes of Health that could support the pilot program. By having a beta site in close proximity to the manufacturing headquarters, support services will be readily available. Economic development will also benefit the area if the technology is exported to other states and nations.

The potential benefits to implementation of a mobile dialysis program include:

- Improved access;
- Potential for significant transportation cost savings; and
- Re-locatable resource in the event of a change in the patient base.

The potential barriers to implementation of a mobile dialysis program include:

- There is no mechanism for reimbursement by Medicare or other private insurers;
- A mobile dialysis unit has not yet been constructed and thus remains an unproven treatment modality; and
- Growth of the ESRD population to more than 18 patients at a single site would require capital for an additional mobile dialysis unit or a fixed site facility.

Recommendations and Rationales

Recommendation #1

The Dialysis Needs Assessment Committee recommends that grants be sought to commission a Vermont specific study to understand the present and future incidence and prevalence rates of renal disease. This study should include, but not be limited to, exploration of variables such as the economic impact of transportation on patients, state agencies, family members and volunteers who assist those who are unable to drive or who have no access to public transportation as well as the impact of capital and operating expenses in building dialysis facilities.

Rationale:

The Committee determined that the methods utilized to understand the patient access issues were not robust. The method consisted of counts of patients at a given point in time with no forecasting methodology to predict growth based on population characteristics. Utilization of national rates of growth can be misleading since high rates of disease exist in Hispanic and African American populations. The Committee determined that a more scientifically rigorous assessment of the Vermont-specific trends must be developed to more accurately plan for growth of dialysis needs within the state. The economic impact of transportation extends beyond the individual patient to state agencies, family members, and volunteers who assist those who are unable to drive, or have no access to public transportation. The most visible example of the dialysis access issue is the ongoing discussion of access to dialysis in the Northeast Kingdom. At present, dialysis patients in Orleans, Lamoille, Addison, Caledonia, and Essex counties have the longest travel times to receive care. The Committee also agrees with the CON guideline that new facilities should be economically viable.

Recommendation # 2

The Committee supports a collaborative process to address the renal dialysis needs of Vermonters.

Rationale:

Vermont's CON program's statute and regulations specify that all projects be reviewed for efficiency, non-duplication of services, and cost-containment. In addition, the Public Oversight Commission, the public body that reviews all CON's and recommends approval or denial to the Commissioner of BISHCA, has placed an emphasis on the need for collaboration with and between entities that may have an interest in any future project. For example, citing a report to the Legislature, dated December 15, 2003, the Commissioner of BISHCA recommended that

FAHC and DHMC and utilize a collaborative approach for future projects, such as the development of a renal dialysis center for the Northeast Kingdom, similar to that established by DHMC and six community hospitals in developing the North Country Oncology Center.

Recommendation #3:

Evaluate the current CON Guidelines, as they relate to renal dialysis, to assure there are no barriers to establishing dialysis capacity in Vermont. Specifically, BISHCA should re-examine the current 60-minute travel guideline. Secondly, BISHCA should analyze the pros and cons of the limitation on which organizations are permitted to provide ESRD, including the possibility of utilizing for-profit ESRD providers.

Recommendation #4

The Committee recognizes that at this time funding is finite, creating tensions between the ability to provide special needs community transportation and transportation assistance to non-Medicaid dialysis clients. Working together, the Agency of Human Services (AHS) and VTrans will maximize access and coordination of all publicly funded transportation resources including services provided by Medicaid, Section 5310 and all other Federal Transit Administration (FTA) and Department of Health and Human Services (DHHS) funded services. Furthermore, within the Section 5310 Program, DA&D will continue to collect trip purpose data and use this information to develop and implement, in consultation with the Section 5310 Advisory Board, prioritization and coordination protocols for the use of these funds.

Sources and Acknowledgments

The following sources were utilized to develop this report:

USRDS 2003 Annual Data Report: Atlas of End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2003

ESRD Network of New England, Inc., 30 Hazel Terrace, Woodbridge, Connecticut 06525

A Systems Development Guide for a Kidney Dialysis Center, Department of Agricultural Economics Oklahoma State University, Stillwater, Oklahoma Office of Rural Health, Oklahoma State University, OKC. Dr. Gerald Doeksen, Division of Agricultural Sciences and Natural Resources, Oklahoma State University. August 2003.

Certificate of Need Guidelines, Department of Banking, Insurance, Securities and Health Care Administration, March 15, 1999.

Report on Collaboration: Fletcher Allen Health Care and Dartmouth-Hitchcock Medical Center, December 15, 2003

APPENDICES

Appendix A: List of Vermont residents by zip code origin receiving dialysis in December 2003.

Appendix B: Driving Times by Zip Code to the Closest Dialysis Unit

Appendix C : Dialysis consumer survey questionnaire.

Appendix D: List of survey respondents sorted by dialysis with responses to questions of travel distance, travel time, burden of personal cost and convenience of current schedule.

Appendix E: Mobile Dialysis Program and Schematic