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Evidence *in* Context

Health research — synthesized and contextualized for use in Newfoundland and Labrador

The Provision of Dialysis Services in Rural and Remote Populations in Newfoundland and Labrador

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Disclaimer

This contextualized HTA synthesis report was prepared by the Newfoundland and Labrador Centre for Applied Health Research (NLCAHR), Memorial University. It was developed from analysis, interpretation and synthesis of scientific research and/or health technology assessments conducted by other groups and organizations. It also incorporates information provided by experts in the subject area and methodologies. This document may not fully reflect all the scientific evidence available. Other relevant scientific findings may have been reported since completion of this synthesis report.

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About NLCAHR

The Newfoundland and Labrador Centre for Applied Health Research, established in 1999, contributes to the effectiveness of the health and community services system of the province and the physical, social, and psychological wellbeing of the population. The Centre accomplishes this mandate by building capacity in applied health research, supporting high-quality research, and fostering more effective use of research evidence by decision makers and policy makers in the province's health system. In 2007, the Centre launched the Contextualized Health Research Synthesis Program (CHRSP) to provide research evidence to help guide decision makers in the provincial health system on issues of pressing interest to Newfoundland and Labrador. CHRSP focuses on two types of issues – health technologies, and health services/health policy issues.

About CADTH

The Canadian Agency for Drugs and Technologies in Health is a national body that provides Canada's federal, provincial, and territorial health system decision makers with credible, impartial advice and evidence-based information about the effectiveness and efficiency of drugs and other health technologies. Established in 1989, CADTH is one of Canada's leading sources of health technology information and a significant, trusted contributor to the effectiveness and efficiency of Canada's health system.

About the Contextualized HTA Synthesis Project

The contextualized HTA synthesis project is one arm of CHRSP and is funded by CADTH through a grant to NLCAHR. The objective is to identify, in partnership with key decision makers in the province, HTA materials that are of relevance to their organizations, synthesize the evidence into a comprehensive set of findings, contextualize the results so that they are attuned to the characteristics and the capacities of their organizations and populations, and formulate them in terms that will maximize their uptake into the local decision-making process.

Who Should Read This Report?

This report is intended to inform and assist those making decisions about provision of dialysis services, particularly to rural and remote populations. The report is specifically aimed at the Province of Newfoundland & Labrador, Canada, but decision makers from other jurisdictions may find the content helpful. The full report includes explanations of terms and techniques such that a specialized medical background in the field is not needed to understand the content. The report assumes that a decision has already been made to provide dialysis services in some form to treat irreversible kidney failure. The report seeks to inform the next step in the decision-making process that asks how this should be done.

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The Provision of Dialysis Services in Rural and Remote Populations in NL

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Contents

Glossary of Acronyms

AETMIS	Agence d'évaluation des technologies et des modes d'intervention en santé
AHFMR	Alberta Heritage Foundation for Medical Research
CADTH	Canadian Agency for Drugs and Technologies in Health
CAPD	continuous ambulatory peritoneal dialysis
CHRSP	Contextualized Health Research Synthesis Program
CIHI	Canadian Institute for Health Information
CINAHL	Cumulated Index to Nursing and Allied Health Literature
CORR	Canadian Organ Replacement Register
CRD	Centre for Reviews and Dissemination
DACEHTA	Danish Centre for Evaluation and Health Technology Assessment
DHD	daily hemodialysis
EMBASE	Excerpta Medica Database
ESRD	end-stage renal disease
HD	hemodialysis
HNHD	home nocturnal hemodialysis
HTAi	Health Technology Assessment International
IHD	in-centre hemodialysis
IHE	Institute of Health Economics
INAHTA	International Network of Agencies for Health Technology Assessment
InfoPOEMs	Patient-oriented Evidence that Matters
MRU	main renal unit
NCCHTA	National Coordinating Centre for Health Technology Assessment
NHD	nocturnal hemodialysis
NHS	National Health Service
NLCAHR	Newfoundland and Labrador Centre for Applied Health Research
PATH	Program for Assessment of Technologies in Health
PD	peritoneal dialysis
PRAC	Provincial Renal Advisory Committee
QALY	quality adjusted life year
RCT	randomized controlled trial
RRT	renal replacement therapy
RSU	renal satellite unit
SDHD	short daily hemodialysis
TWSHD	thrice weekly sustained hemodialysis

The Research Question

The incidence of end-stage renal disease (ESRD) is increasing worldwide, especially among the elderly. In Newfoundland and Labrador, in particular, the number of patients aged 65 years and older with ESRD on renal replacement therapy is the highest in the country. Limited human and financial resources coupled with demographic predictions of an aging population who have underlying chronic diseases strongly associated with ESRD, all point to the need for evidence-based decision making on the provision of dialysis services in this province. Decisions about the provision of dialysis services are further challenged by the geographic dispersion of small clusters of patients with ESRD living in rural and remote locations.

Currently, the primary modality of renal replacement therapy in Newfoundland and Labrador is in-centre hemodialysis. Approximately 65 % of patients are being treated in main hospital-based dialysis units, centralized in St. John's and Corner Brook, and in Grand Falls-Windsor, a satellite of St. John's that operates much like a main unit. There has been a push from the interested public to develop satellite units throughout the province, in both hospital and non-hospital settings, despite the challenges associated with these service modalities. These challenges include changes in the medical stability of patients, unpredictable demands on the main dialysis units, and human resource requirements and maintenance of competencies, to name a few. Home-based therapies, including both hemodialysis and peritoneal dialysis, reduce the burden of travel and relocation, but the number of patients choosing these modalities is low at present, possibly because of issues of informed patient choice and the acceptability and feasibility of these modalities particularly for older patients with high co-morbidity living in isolated communities.

The purpose of this contextualized HTA synthesis is to answer the question: in meeting the needs for dialysis services in rural and remote populations, what are the differences among the available treatment options with regards to efficacy/ effectiveness, cost, acceptability, and feasibility in Newfoundland and Labrador.

Overview and Background

The Issue

End-stage renal disease (ESRD) is the irreversible loss of kidney function whereby the kidneys are no longer able to support life. Patients with end-stage renal disease undergo renal replacement therapy (RRT) in the form of renal transplantation or dialysis (Mowatt et al., 2003; Roderick et al., 2005). Renal transplantation, while possibly the treatment of choice (Vale et al., 2004), may not be an option for all patients and, with the limited availability of donor kidneys, many patients with ESRD require lifelong dialysis (Barrett et al., 2003; Mowatt et al., 2003; Vale et al., 2004).

According to a 2006 report from the Canadian Organ Replacement Register (CORR), the incidence of patients with ESRD on renal replacement therapy (RRT) rose 41% in Canada from 112 per million population in 1995 to 158 per million population in 2004, and this growth is in line with similar increases globally. By December 31, 2004, a total of 30,924 Canadians were registered in the database with ESRD. The growth in newly diagnosed patients was highest among those 75 years of age and older, with the incident rate for that age cohort having more than doubled in that same time period (CIHI, 2006). Newfoundland and Labrador had the highest rate of new patients aged 65 years or older with ESRD on RRT in the country. This is particularly significant since population projections for Newfoundland and Labrador suggest that, in the 15 years between 2001 and 2016, there would be an over 50% increase in the number of people aged 65 years or older, and an almost 20% increase in those between 45 and 64 years (Barrett et al., 2003). These changes in demographics and the resulting aging population with underlying chronic diseases associated with ESRD need to be considered when anticipating the needs for renal services throughout the province.

Every regional health authority in Newfoundland and Labrador offers some kidney care services, ranging from full services

(excluding renal transplantation, which is provided out-of-province) to traveling nephrology clinics. The ideal is for each geographic region, where feasible, to have the full range of services on the continuum of care from early detection and prevention of kidney disease to dialysis services with various modalities. This ideal is not attainable for both economic and practical reasons because, in large part, of the geographic dispersion of the relatively small population of individuals with ESRD. Putting services in place without sufficient demand can have an impact on quality. The alternative approach has historically been to centralize service delivery in major centers such as St. John's and Corner Brook. This approach limits the in-person follow-up of patients in rural and remote locations and often forces patients and families to relocate to areas of the province that offer the necessary or preferred form of RRT. Home-based dialysis services are also possible and are offered in all parts of the province; however the uptake of this modality has been declining.

In Newfoundland & Labrador the responsibility for provision of dialysis within each health region presently lies with the relevant Regional Health Authority. Regional Authorities who wish to expand current dialysis services generally send a proposal to this effect to the Provincial Department of Health and Community Services where a decision as to whether to allocate the additional funding is made. A Provincial Kidney Program within the Department provides advice to the Department on such matters. At the management level, the Kidney Program, with the help of the Program Coordinator, facilitates coordination between regions to ensure seamless service development, delivery and evaluation.

This report addresses the question of how best to meet the needs for dialysis services of patients with ESRD in rural and remote populations in Newfoundland and Labrador. A research team, under the leadership of Dr. Brendan Barrett, a nephrologist at Eastern Health and Professor of Medicine at Memorial University, has taken the novel approach of 'contextualized research synthesis' in order to answer this question. Using published Health Technology Assessments and systematic reviews, the team has synthesized the available evidence and has contextualized the results and recommendations so that they are as closely attuned as possible to the characteristics and capacities of the local populations and health organizations of Newfoundland and Labrador.

Overall, we have found no persuasive evidence to suggest that any of the available modalities of dialysis service is either more or less appropriate, for either clinical or economic reasons, in rural and remote populations. However, it is not likely to prove economically feasible to develop a full-fledged main dialysis unit in a rural or remote location. Since there are many scientifically acceptable ways to provide dialysis services for rural and remote populations in Newfoundland and Labrador, the decision-making process can focus on the specific contextual factors in a given community that might favour one or another modality. In particular, our review suggests that, all things being equal, home-based delivery of either peritoneal or hemodialysis is worthy of consideration for rural communities, given its lower requirements for infrastructure and professional resources.

About Dialysis

Dialysis is a treatment for kidney failure that removes waste and excess water from the body either by passing blood through an artificial kidney machine (hemodialysis) or by instilling fluid into the abdominal cavity whereby substances can be exchanged with the blood flowing through nearby blood vessels (Barrett et al., 2003). Dialysis may be used as a temporary or as a long-term measure when kidneys have failed, and patients with ESRD will likely move through different modalities of treatment during their lifetime.

Table 1: Number and location of patients in NL receiving dialysis services[1]

Site		Hemo-		Home HD	Home HD Nocturnal
St. John's: HSC		38	NA*	NA	NA
St. John's: Waterford		108	37	2	8
St. John's Satellites	Burin	6	NA	NA	NA
	Carbonear	28	NA	NA	NA
	Clarenville[2]	12	NA	NA	NA
	Gander	25	NA	NA	NA
	St. Anthony	1	NA	NA	NA
	Grand Falls-Windsor[3]	52	NA	NA	NA
Corner Brook		49	2	NA	NA
Corner Brook Satellite	Stephenville	12	NA	NA	NA
Total		**331**	**39**	**2**	**8**

* NA= Service not available. **Note: People on home-based PD or HD are located throughout the province but are counted as St. John's or Corner Brook depending on the location of their follow-up care.** 1: Source: Provincial Statistics, Provincial Kidney Program Coordinator, personal communication January 2008; 2: Clarenville has the only community-based site; 3: Grand Falls-Windsor is a satellite of St. John's but functions more independently than the other satellite units in the province and more closely resembles a main hospital-based dialysis unit.

Table 1 summarizes the number of patients in Newfoundland and Labrador, as of January 2008, receiving various dialysis services in various locations throughout the province. Details about the framework of the NL Provincial Kidney Program can be found in the Provincial Renal Advisory Committee Report (Barrett et al., 2003) and the Provincial Kidney Program 2005/06 Annual Report (Harding & Barrett, 2006).

Types of Dialysis Services and Interventions

Table 2 provides an overview of the various dialysis services and interventions available to patients with ESRD. Though the frequency and duration of treatment may vary slightly in different jurisdictions, the general treatment options are as outlined in the table.

Table 2: Types of dialysis services

<table>
<tr><th colspan="5">Hemodialysis (HD)</th><th colspan="2">Peritoneal Dialysis (PD)</th></tr>
<tr><td colspan="3">Conventional:
4-6hrs/day, 3 days/week</td><td colspan="2">Frequent</td><td rowspan="2">Continuous Ambulatory Peritoneal Dialysis (CAPD)

3-5 times/day</td><td rowspan="2">Continuous Cycler-Assisted Peritoneal Dialysis (CCPD)

2 times/day at most</td></tr>
<tr><td rowspan="2">Hospital-Based (Main Renal Unit)</td><td colspan="2">Satellite Unit</td><td rowspan="2">Home</td><td rowspan="2">Short daily, 1.5-3hrs 4-6 days/ week</td><td rowspan="2">Long nocturnal 6-8 hours 4-6 days/ week</td></tr>
<tr><td>Hospital-Based</td><td>Community-Based</td></tr>
</table>

Hemodialysis

Though kidney transplantation and peritoneal dialysis (PD) are acceptable interventions in the treatment of kidney failure, in-center hemodialysis (HD) is the predominant form of renal replacement therapy in North America (CIHI, 2006; Kliger, 2007). In Newfoundland and Labrador, in 2004, over 90% of patients received HD as their initial modality of treatment (CIHI, 2006).

Hemodialysis is the removal of waste products from the blood using a dialysis machine. A vascular access to the patient's blood circulation is surgically created, often as an arterio-venous fistula in the arm (Vale et al., 2004). Blood is then taken from the patient and passed through a dialyser containing a thin semi-permeable membrane (filter). As dialysis takes place, water and waste products in the blood pass into a specially formulated dialysis fluid (dialysate) and are discarded (Barrett et al., 2003; Mowatt et al., 2003).

There can be many variations in the delivery of HD, including variations in the setting in which it is carried out, the type of machines used, the duration and frequency of the sessions, and the types of membranes and dialysate used in the treatment (Mowatt et al., 2003; Vale et al., 2004). In the succeeding pages, the importance of these variations in the delivery of HD for the economic assessments of treatment modalities will become evident.

Hemodialysis requires specialized team support including interventional radiology, surgery, nephrology, nursing, biotechnology, social work, and dietetics (Barrett et al., 2003). Conventional HD takes place in a dialysis unit, either in a hospital or in a satellite unit, and patients are generally treated for 4 to 6 hours at a time, three days a week. More frequent HD regimes are available worldwide, particularly since the mid-1990s. These programs are either short daily HD regimes (e.g., 1.5 – 3 hour sessions, usually 4-6 days per week) or long nocturnal HD regimes (e.g., 6 - 8 hour sessions, usually 4-6 days per week), performed either in-center or at home (Suri & Garg, 2006).

As of January, 2008, 331 patients with ESRD in Newfoundland and Labrador were receiving in-centre hemodialysis, 2 patients were on conventional home HD, and 8 patients were on home nocturnal HD (see Table 1) (C. Harding, Coordinator of the Provincial Kidney Program, personal communication, 2008). There were no patients on short daily dialysis in this province.

The total number of patients on HD in January, 2008, was 341 as compared with only 39 patients on peritoneal dialysis. In this province, despite the challenges created by a geographically disperse population and historically centralized services, the primary mode of RRT is hemodialysis, located primarily in hospital-based main renal units and in a growing number of satellite units (97%), with a small percentage being dialyzed at home (3%).

Peritoneal dialysis

Peritoneal dialysis (PD) is another form of dialysis treatment for patients with ESRD. In preparation for this modality, a plastic catheter is placed through the patient's abdominal wall into the peritoneal cavity, the space around the bowels. Intermittently, throughout the day, the patient connects the catheter to a source of dialysis fluid (dialysate), which is then instilled into the peritoneal cavity via the catheter where it remains for several hours while dialysis occurs across the peritoneal membrane (Barrett et al., 2003). The human peritoneal membrane is semi-permeable and acts as a dialysis membrane or filter. The fluid is then drained out of the peritoneal cavity and fresh dialysate is instilled to continue dialysis.

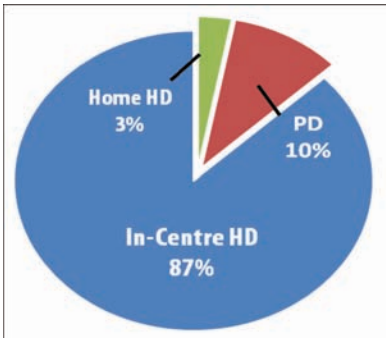
There are two common forms of PD, and the predominant modality is known as Continuous Ambulatory Peritoneal Dialysis (CAPD). CAPD uses gravity to deliver and drain the dialysate, and is performed anywhere from four to six times per day, every day of the week. PD can also be assisted by a simple machine called a 'Cycler', which automatically performs fluid exchanges while the patient is asleep at night (Continuous Cycler-assisted Peritoneal Dialysis). Patients using the Cycler may require just one or two additional exchanges throughout the day (Barrett et al., 2003; Mowatt et al., 2003). In Canada, in 2004, only 19% of newly diagnosed patients with ESRD began RRT with peritoneal dialysis compared with the over 78% who started with hemodialysis (CIHI, 2006). In Newfoundland and Labrador, in January, 2008, 39 patients were treated with PD (C. Harding, personal communication, 2008).

Trend from PD toward HD

There is wide variation in the uptake of various modalities of dialysis services. If there are no medical limitations to the type of dialysis, the modality chosen is largely left to the patient in consultation with a health professional (Vale et al., 2004). Historically, in Newfoundland and Labrador, geography has influenced the choice of dialysis treatment and, in places where HD facilities were not available and home-based PD therapy was, a large proportion of patients chose PD (Barrett et al., 2003).

There has been a decline in the proportion of patients with ESRD choosing PD. Anecdotal evidence indicates that this decline is due, in part, to a misperception that PD is a 'second-class treatment' and that it is not conducive to long-term RRT. Historically PD was the usual mode of therapy for most regions in Newfoundland, with up to 50% of the dialysis population treated by this means prior to 1998 (Barrett et al., 2003). In Newfoundland and Labrador, in 2004, over 90% of patients received HD as their initial modality of treatment, compared with less than 10% who began on PD (CIHI, 2006). In fact, in 2004, when compared to other provinces, Newfoundland and Labrador had the highest percentage of patients initiating RRT with hemodialysis (CIHI, 2006). Reducing geographic barriers by introducing satellite units that offer HD in smaller communities in the province may have also contributed to this trend (Barrett et al., 2003). Similarly, in England, Wales and Scotland, in the five years preceding the 2003 publication of a systematic review, there was a reported decline in the proportion of patients receiving PD, and a growth in the number of people receiving HD in satellite units (Mowatt et al., 2003).

Patients with ESRD on various dialysis modalities (Jan. 2008)



Informed patient choice is an important requirement for the successful operation of a dialysis program, especially one that supports the option of PD (Barrett et al., 2003). Target populations of patients with chronic kidney disease and advanced kidney disease who are preparing for dialysis or transplantation can be reached at interdisciplinary nephrology clinics. These clinics, commonly known as Progressive Renal Insufficiency Clinics, provide education about primary and secondary prevention of kidney disease, and prepare patients and families to consider the various treatment options available to them, including dialysis and transplantation (Barrett et al., 2003). Early dialysis education and predialysis attendance is associated with greater likelihood of planned dialysis initiation (Buck et al., 2007).

Clinics currently exist in St. John's, with an estimated 500 patients, Grand Falls-Windsor with 300 patients, and Corner Brook with about 200 patients (C. Harding, personal communication, 2008). For other regions of the province, patient education must be coordinated with visits by nephrology specialists and supported by well-trained nursing staff. As this is not always the case, and since some patients only come to the attention of the nephrology service just prior to initiating dialysis, patients, especially those in rural and remote populations, may lack information with regard to modality choice. This has contributed to the tendency to place patients on in-centre HD which requires much less patient education than PD (Barrett et al., 2003).

Where Dialysis Service is Provided

Dialysis services can be delivered through different service models and in a variety of settings.

Home-based dialysis - without staff support

Peritoneal dialysis is usually a home-based therapy. The technique, although technically complex, is not as complex as HD, and almost all patients on PD can be managed at home (Barrett et al., 2003).

Once a decision has been made to treat a patient with ESRD using peritoneal dialysis, a peritoneal catheter is inserted into the abdomen which, in Newfoundland and Labrador, has traditionally been done by surgical technique in the operating room, although catheters can also be placed in specially equipped procedure rooms by either a nephrologist, interventional radiologist or surgeon with the requisite training.(Barrett et al., 2003). Subsequently, patients and family members/caregivers undergo a training period which has generally taken five days, usually offered by specially trained PD nurses, to enable them to carry out the technique safely. At present, catheter placement and patient and family training are limited to centres in St. John's and Corner Brook. When the patient and/or family members are unable to perform the procedures necessary for PD, another option is to train home-care workers to provide support for patients in the home.

On average, about 25 % of patients on home PD in this province avail themselves of trained workers in the home, paid for by the health system and subsidized in rare instances by the patient. The trained worker must be available throughout the day for all or most PD exchanges, seven days a week. Anecdotal reports indicate that the low rate of pay (just above minimum wage) combined with the level of continuous responsibility required to perform the work, makes other job options with similar pay more attractive. Not surprisingly, the turnover rate for home-care workers is high in some cases, and this can be further complicated by personality differences between the patient and worker (C. Harding, personal communication, 2007).

The necessary disposable supplies for PD are delivered to the patient's residence by supply vendors. All patients on home-based dialysis therapy are generally followed through telephone outreach by specially trained nurses. Patients may contact these nurses for answers to questions about their dialysis and their overall health needs. The main complication of PD, usually arising from poor technique, is abdominal or exit wound infections which are usually treatable. All patients on PD are reviewed in-person by a nephrologist, approximately every three months, and more often depending on their health needs. The geographic dispersion of patients in rural and remote populations prevents this from being done in patients' homes. Instead, nephrologists have held periodic outreach clinics in all major centers of the province for many years (Barrett et al., 2003).

Home-based hemodialysis, including nocturnal HD, is another treatment option for selected patients. The number of people on home HD is small, perhaps related to the fact that today's patients with ESRD are typically older with greater co-morbidity and may not have a suitable person in the home who is willing to take the role of care-giver, thus affecting their ability to cope with the requirements of home HD (Mowatt et al., 2003). In Canada, in 2004, almost three-quarters of all patients on HD received conventional treatment in full care hospital settings, just over 22 percent were dialysed in community or other independent health care facilities, while only 2.3 per cent were on home HD (CIHI, 2006).

Nocturnal HD, which has gained popularity in North America and Europe since the mid-1990s, combines all the clinical benefits of frequent and prolonged HD in the home setting (Kooistra, 2003). Under this regime, patients undergo HD

at home four to six days a week while sleeping. Some patients may experience anxiety associated with conducting this relatively complex treatment in the home. In recent years, however, the technique has become much safer, in that automation and better delivery systems, dialysers, dialysate, and alarm and control systems have all led to a decline in the frequency and severity of complications during dialysis (Barrett et al., 2003).

In order to avail themselves of home HD, patients must be considered medically suitable for this modality. However, experience elsewhere suggests that nephrologists often underestimate people's ability to do hemodialysis at home and indeed the nephrologist's attitude may be one of the barriers to the use of this form of therapy. Patients usually have a family member or friend who is willing to undergo an intense training period necessary to support them in the home and to set up and maintain the dialysis machine. There are also service requirements for home HD including adequate space and water supply, machines and supplies, nursing and medical support by distance, biomedical technical backup, emergency response capabilities, and communication with in-centre dialysis units (Barrett et al., 2003; Kooistra, 2003). If the condition of a patient on home HD changes or support is no longer available in the home, patients must be referred back to the main dialysis unit, a practice that introduces unpredictable demands on the main unit. Home HD requires an initial high capital investment on the part of the patient in terms of possible home adjustments and there are associated training costs for caregivers (Suri & Garg, 2006). Home HD does, however, offer the advantages of maximizing flexibility, reducing patient travel for treatment, improving accessibility, and eliminating the requirement for patients in rural and remote areas to relocate to another part of the province that offers staff-supported HD.

Hospital-based satellite unit dialysis – with staff support

Secondary and tertiary care hospital units such as those found in Corner Brook and St. John's are not a realistic option in rural and remote areas of this province; hence the need for satellite units that provide dialysis services in local hospitals, health centres, and other locations in the community. In 1999, based on a report by the Provincial Renal Advisory Committee (PRAC) supporting the need for decentralized dialysis services and a great deal of public advocacy to the same effect, a decision was made to develop satellite units in the province. The PRAC report provided evidence suggesting that the numbers of dialysis patients in several regions of the province could sustain satellite dialysis services (Barrett et al., 2003; Panacea Research and Evaluation, 2003).

According to the 2005/06 Annual Report of the NL Provincial Kidney Program (Harding & Barrett, 2006), there are nine dialysis sites in this province. There is a site for the acute care of patients with ESRD in St. John's at the Health Sciences Centre, and a site for chronic care at the Waterford Hospital. St. Clare's Hospital in St. John's provides dialysis services, but only to those admitted to that site. There are four satellite units associated with the St. John's sites, and these are located in Carbonear, Clarenville, Gander, and Grand Falls-Windsor. Grand Falls-Windsor has ongoing input in the form of monthly visits from St. John's nephrologists. This input, coupled with the expertise of local medical specialists, enables the unit to function more independently and to provide some dialysis care beyond that of the other hospital-based satellite units. Clarenville has the only community-based satellite unit (see details below), while the others are hospital-based. Ten nephrologists provide service and support to these four sites. There is a hospital-based unit in Corner Brook at Western Memorial Hospital that has one nephrologist, and there is an associated satellite unit in Stephenville. Since the release of the 2005/06 Annual Report, two additional sites have opened in Newfoundland, one in Burin and another in St. Anthony, both satellites of St. John's. A third new satellite unit of St. John's is expected to open in early spring, 2008, in Happy Valley-Goose Bay, Labrador (C. Harding, personal communication, 2008) (See Map, Appendix 1). In total, excluding Grand Falls-Windsor, 72 patients (22% of patients on in-centre HD) were being treated in hospital-based satellite units in January, 2008.

Patients with ESRD receiving dialysis in a satellite unit commence HD in a hospital unit (Mowatt et al., 2003) and, once stabilized, are transferred to a satellite unit. All patients must be assessed initially by a nephrologist and deemed appropriate for treatment in a satellite unit based on established criteria. Specially trained nursing staff work in these satellite units. Other professionals such as dieticians or social workers are generally not available, or are available on a very limited basis. The absence of on-site nephrologists, interventional radiologists and surgeons, even in hospital-based satellite units in the province, imposes restrictions on the kind of patient that is able to use these services (Barrett et al., 2003). Patients in satellite units in this province are regularly reviewed in person by a traveling nephrologist. The availability of review by telehealth may extend the possibility for care delivery by nephrologists to smaller and even more remote satellite units in the future. In fact, weekly review of patients on hemodialysis in Burin and St. Anthony is now occurring via interactive videoconferencing equipment.

The service requirements for hospital-based satellite units include specially prepared hospital space with a suitable water-treatment system, dialysis machines and supplies that are the same as those used in the main dialysis units for ease of trouble shooting, biotechnical support and related support from other in-hospital departments (e.g., laboratory, pharmacy, emergency, supplies, clerical, etc.), specially trained nurses available in acceptable nurse-patient ratios (e.g., 1 nurse for 3, 4, or 5 patients; a minimum of two nurses per site), access to interventional radiologists and surgeons, some support from the departments of social work and dietetics, and emergency response capabilities and backup for electrical outages and voltage variations. Regular medical input by a nephrologist, either on-site or through telehealth, is imperative to allow for patient follow-up and direction regarding medical care (Barrett et al., 2003). The NL Provincial Renal Advisory Committee has recommended that each satellite unit serve 10 to 12 medically stable patients (Barrett et al., 2003).

The advantages of hospital-based satellite units are that they allow for access to institution-level support services and medical care in the event of an emergency (Panacea Research and Evaluation, 2003). For this reason, there is a perception among staff that it may be possible to treat patients in this type of satellite unit who are slightly less stable than those treated in a community-based satellite unit. Nurses from other units in the hospital may be cross-trained for dialysis care and this will provide a larger pool of specially trained nurses to draw from for relief staffing (e.g., sickness, annual leave). Maintenance of competency levels in nurses working in this specialized field, however, is extremely important and remains a challenge in all smaller dialysis units in particular (Barrett et al., 2003).

Other challenges involved in providing dialysis services in hospital-based satellite units include achieving staffing efficiencies while maintaining competencies, especially when patient volumes are low and fluctuating (Panacea Research and Evaluation, 2003); maintaining appropriate backup medical and nursing support and a strong collaborative relationship with the main dialysis unit; providing a unit manager who has dialysis experience and dedicated time for the unit; coordinating the unpredictable fall-back on the main renal unit resulting from changes in the patient's condition; and, managing sometimes unrealistic expectations on the part of patients and families that very ill patients can safely receive dialysis in a hospital-based satellite unit (Barrett et al., 2003).

Community-based satellite unit dialysis – with staff support

An alternative model for the provision of dialysis services is a community-based satellite unit. Community-based satellite units operate under the medical direction of a hospital-based unit but are located outside the confines of a hospital. The only health professional staff on site is specially trained nursing staff; hence, only medically stable patients can be treated in this service modality. The size of the satellite unit may vary depending on the needs of the population it serves. The NL Provincial Kidney Program has recommended that a geographic area must have a minimum of 10 to 12 medically stable patients in order to be considered for satellite HD service (Harding & Barrett, 2006). The only existing community-based satellite unit at present in Newfoundland and Labrador is located in Clarenville and it falls under the administrative structure of Eastern Health and under the medical direction of the main dialysis unit in St. John's (Barrett et al., 2003). As of January, 2008, 12 patients were receiving HD in the Clarenville satellite unit.

The service requirements for community-based satellite units include a specially prepared non-hospital space with direct access to the outside, a suitable water system, and a computer link with the main in-centre dialysis unit. Given the need for technical support from the main dialysis units in this province, it has been seen as advantageous to have machines and supplies that are the same as those used in the main dialysis units for ease of trouble shooting. Human resource requirements include specially trained nurses with nurse-patient ratios sufficient to ensure quality care and patient safety, and periodic in-person patient review by a nephrologist, completed either on-site, through telehealth, or by requiring patients to periodically attend a clinic at the regional hospital site. Access to interventional radiologists and surgeons is by referral, when necessary. Routine medical support (e.g., for prescriptions or treatment regimes) is usually by distance, and may also be possible through telehealth. There is no biotechnical support on site, so technicians are required to make periodic visits for preventive and corrective maintenance. In the absence of the usual supports found in a hospital-based unit, such as laboratory, pharmacy, laundry or housekeeping, these services must be contracted out. Dietetic and social work staff is usually not available on site, but the patients either access these services within their community or through distance support from the main nephrology program. There is limited clerical support at community sites. Emergency response usually relies on the local emergency room staff supported by discussions with a nephrologist, including transfer to the main hospital unit by ambulance when necessary (Barrett et al., 2003).

The advantage of a community-based satellite unit, as with hospital-based satellite units, is that patients on dialysis can be managed closer to home which may improve accessibility, especially for the elderly. An environment outside a hospital setting may also be more acceptable to patients who would not have to interact with severely ill patients. In addition, patient and family expectations of care in a non-hospital setting are often more realistic and manageable, as they understand that medically unstable patients cannot be treated there. The same does not hold true when patients are treated in a hospital-based satellite unit (Barrett et al., 2003; Panacea Research and Evaluation, 2003).

The treatment of patients in a community-based satellite unit is limited to very stable patients because of the absence of on-site medical backup. Patients are made aware that they may have to go to the local Emergency Department if they become ill. A minimum of two nurses is required at all times for patient safety, but achieving staffing efficiencies is a real challenge. While it may be possible to consider the utilization of community nurses as 'casual' relief for holiday/sick time, this creates other concerns such as maintaining dialysis nursing competency in this highly specialized area, and adhering to collective agreements and rates of pay (Barrett et al., 2003).

In-person visits to patients in community-based satellite units by a nephrologist can be infrequent (Panacea Research and Evaluation, 2003). Most patients prefer not to have to travel regularly to the main nephrology centre for review as, in many instances, this would require either many hours of driving in sometimes hazardous conditions, or a flight for which they would likely have to bear much of the cost. The intended expansion of the telehealth network is currently limited to hospitals and will not make community-based satellite units accessible. The coordination of care between staff at local hospitals and the distant nephrology team, should the patient become suddenly ill, continues to pose challenges. A signed Memorandum of Understanding with the main hospital unit to ensure adequate nursing and medical support is advisable

Table3: Criteria for patients receiving various dialysis services in NL

Home Hemodialysis	Home Peritoneal Dialysis	Community-Based Satellite Unity Dialysis
Interest of patient and family in pursuing home HD	Suitability of the abdomen for PD	Absence of frequent severe symptomatic hypotensive episodes
Informed consent for home HD	Patient education and understanding of PD	Absence of the need for supplementary oxygen
Reliable water source of sufficient flow and that meets standards of microbiological purity and chemical composition	Training of family member/significant other	Absence of uncontrolled or unstable angina
Sufficient and appropriate space for the delivery system, equipment and supplies	Home environment i.e. separate room, running water, heating system	Absence of frequent episodes of uncontrolled pulmonary edema
Availability of person willing to be trained to supervise each dialysis session and who will be trained and assessed for competence in HD initiation, maintenance and discontinuation, and in the immediate management of common emergencies	Education level (of patient or caregiver)	
Stable vascular access	Manual dexterity (of patient or caregiver)	
Clinically stable in terms of other co-morbid illnesses	Visual ability (of patient or caregiver)	
Ability to access a hospital with HD facilities within 24 hours in the event of illness	Hearing ability (of patient or caregiver)	
A written request for equipment		
A contract signed by the patient and partner before training begins. This contract asks that patients acknowledge their comfort with their knowledge and skills after training has been completed, and acknowledge their own and the program's responsibilities.		

Sources:

Home hemodialysis: Adapted from 'Home Dialysis Unit Criteria', Eastern Regional Integrated Health Authority, 2007

Home peritoneal dialysis: While there are no formal criteria for the treatment of patients on home peritoneal dialysis, these criteria were included in an assessment tool adapted with assistance from B. Barrett from the 'Peritoneal Dialysis Assessment Tool', Health Sciences Centre, Eastern Regional Integrated Health Authority, 2007

Community-based satellite units: Barrett et al., 2003; C. Harding, personal communication, 2007

(Barrett et al., 2003). The report by Panacea Research and Evaluation comparing hospital-based and community-based satellite units for HD, suggested that anxiety regarding the stability and well-being of patients would be lessened if dialysis services were provided in a hospital setting (Panacea Research and Evaluation, 2003).

About Dialysis Patients

The profile of patients undergoing RRT has changed over time, resulting in an increase in the frequency with which older and more medically frail patients are offered dialysis (CIHI, 2006). The specific modality of dialysis service chosen by the patient is partly dictated by medical criteria. For example, patients who are unable to achieve a vascular access are unsuitable for hemodialysis, while those who have had extensive abdominal surgery may not be eligible for peritoneal dialysis (Vale et al., 2004). Other factors to consider in choosing the modality of dialysis are psychosocial, biotechnical, and personal patient preference. The setting in which dialysis is provided also places limits on those who meet the criteria for safe treatment (Barrett et al., 2003). Table 3 is a summary of the criteria considered when placing a patient on various modalities of dialysis in Newfoundland and Labrador. Patients move from one modality to another as their condition changes, a phenomenon that is not uncommon or easily predicted. For example, patients being treated in a satellite unit whose condition deteriorates such that they no longer meet the required stability criteria must be prepared to return to the main in-centre unit for dialysis (Barrett et al., 2003).

Review of the Literature

What did we look at?

From January to June, 2007, an in-depth search of the published and unpublished literature on the provision of dialysis services was carried out by a research assistant at NLCAHR, under the direction of the senior research officer for this project. The methods included an electronic search of literature published in the last 10 years and accessed through PubMed, Web of Science, The Cochrane Library, EMBASE, CINAHL, and InfoPOEMs. An Internet search for Health Technology Assessments was conducted through various agency databases including the CRD, INAHTA, HTAi Vortal, CADTH, AHFMR, AETMIS, PATH, NCCHTA, DACEHTA, IHE, and the Technology Assessment Unit at McGill University Health Centre. The search terms and relevant limits are listed in the Appendix 2.

The search was limited to full health technology assessments and systematic reviews of the literature on dialysis, rather than on individual clinical trials or studies, and focused primarily on research reviews that compared the various dialysis modalities and the options for location of dialysis services. The outcomes considered in this review were clinical, economic, quality of life and patient satisfaction. Single studies that were published after the date of the most recent relevant systematic review were also considered for inclusion. Each of the studies analysed by each of the systematic reviews and health technology assessments was also hand searched by the research assistant to identify references to relevant studies that focused specifically on the provision of dialysis services in 'rural or remote locations'. The search results were recorded in a RefWorks database and were shared with all members of the research team.

Through a consultative process, members of the research team jointly assessed the quality and relevance of the HTAs and systematic reviews to be included in this report. The senior research officer read and synthesized the findings, which were further reviewed by the team leader for the project and the academic co-investigator.

In assessing the quality of the studies included in this synthesis report, it is worth noting the paucity of randomized trials on the modalities of service for dialysis. Improving the quality and quantity of randomized controlled trials has been, and continues to be, a challenge in the field of nephrology (Strippoli et al., 2004). The choice among modalities of dialysis is often a matter of personal choice on the part of the patient, and randomization in a clinical trial is unacceptable to most patients and families. The end result is that most of the studies to date are observational in design, and are limited by the usual methodological weaknesses, such as non-ideal control groups and selection bias (Suri & Garg, 2006). As well, the study participants are often a highly select group of patients and may not be representative of the general population of patients with end-stage renal disease, thus limiting the generalisability of the study findings.

The Canadian Society of Nephrology first published its Clinical Practice Guidelines in 1999. These guidelines, updated in 2003, were primarily evidence-based and intended to reflect the current available resources, both human and financial, across Canada. Although the experts graded the available evidence, many of the workgroups were forced, in the absence of randomized trial data within several clinically important areas, to make limited opinion-based recommendations (Jindal et al., 2006). This approach, however, can be problematic as it has been shown in the past that the availability of new, higher grades of evidence, such as that provided by well-designed randomized trials, has often reversed the consensus of informed opinion on treatment efficacy, as occurred recently in the case of hormone replacement therapy (Kliger, 2007).

Researchers in the Frequent Hemodialysis Network Trial Group are currently addressing ongoing uncertainties in the efficacy and cost-effectiveness of various modalities of dialysis by conducting multi-centered randomized trials in Canada and the US comparing conventional thrice weekly HD with (1) in-center daily HD and (2) home nocturnal HD (Suri et al., 2007). The objectives of the trials include examining the feasibility of randomization, the capacity to deliver the intervention, and patient adherence to the regime. The primary outcomes being studied include measures of efficacy, safety, feasibility and cost-effectiveness. The results of these trials are not expected, however, until 2009 (ClinicalTrials.gov, 2007).

Research domains reviewed for this synthesis

1. Clinical efficacy and effectiveness
   - 1.1. Studies comparing modalities of dialysis treatment
   - 1.2. Studies comparing the frequency and/or duration of dialysis treatment
   - 1.3. Studies comparing the settings where dialysis services are provided

2. Cost-effectiveness
   - 2.1. Studies on economic outcomes of modalities of dialysis
   - 2.2. Studies comparing home-based and hospital-based dialysis
   - 2.3. Studies comparing satellite-based HD and home- or hospital-based HD
   - 2.4. Studies comparing cost-effectiveness of HD and PD

3. Other Outcomes
   - 3.1. Studies that report on other outcomes (e.g., quality of life or patient satisfaction) for patients on dialysis. The evidence for these outcomes is included in the above.

What did we find?

The following research synthesis is based primarily on the evidence gathered from two Health Technology Assessments (Mowatt et al., 2003; Roderick et al., 2005), four systematic reviews (Greneche et al., 2005; Suri et al., 2006; Vale et al., 2004; Walsh et al. , 2005), two economic evaluations (McFarlane et al., 2006; Mohr et al., 2001), and three recent individual studies from Canada (Culleton et al., 2007; Lee et al., 2002; Prakash et al., 2007). The literature search revealed a lack of studies that specifically addressed the question of the provision of dialysis services in remote or rural populations. In its absence, the research team chose to synthesize the available evidence in several related domains.

1. Clinical Efficacy and Effectiveness

1.1 Studies comparing modalities of dialysis treatment

A systematic review by the Cochrane Collaboration, first published online in 2004, assessed the benefits and harms of continuous ambulatory peritoneal dialysis (CAPD) versus home or hospital HD for adults with ESRD (Vale et al., 2004). The authors of this review considered only randomized controlled trials (RCTs) or quasi-RCTs comparing CAPD with home or hospital HD. Out of the 11,800 studies reviewed and assessed for methodological quality, only one RCT was reported and it showed no significant differences in survival or quality-adjusted life-year scores at two years between patients on CAPD and those on HD. The quality of this RCT was questioned by Vale and colleagues, however, and in the absence of other high quality randomized trials the authors were unable to draw conclusions about the relative effectiveness of CAPD and hospital or home HD. Similarly, a critical appraisal of the literature on peritoneal dialysis and hemodialysis, published in French and available only in abstract form, concluded that, up to 2005, there had been no convincing evidence from randomized trials that demonstrated that one technique was superior over the other (Greneche et al., 2005).

From a policy perspective, the issue is one of balancing the provision of the two modalities as complementary, not

competing, treatments. For patients with ESRD for whom either modality may be initially acceptable, the decision about which modality to start with depends largely on the relative costs, benefits, and risks of either approach, the answers to which may only be found through large, adequately powered RCTs (Greneche et al., 2005; Vale et al., 2004).

1.2 Studies comparing the frequency and/or duration of hemodialysis treatment

Though hemodialysis is the predominant modality for RRT in North America, it continues to be associated with adverse outcomes such as hypertension, heart disease, and impaired quality of life, all of which may be caused, in part, by an inadequate dosage of dialysis; hence the argument for increasing the frequency and/or duration of dialysis in an effort to approximate the organic kidney better than conventional thrice-weekly HD (Kliger, 2007). Frequent HD can be prescribed as either short daily HD (SDHD) or nocturnal HD (NHD) (Jindal et al., 2006). Though not specified, SDHD is usually administered in-center and NHD is usually provided at home ((Jindal et al., 2006). However, SDHD can be done at home and in-centre NHD is now offered at many centres across the world. Thrice-weekly sustained HD (TWSHD) is HD that is prescribed at 3 sessions per week, each session being at least 4 hours in duration. Nocturnal HD is a form of sustained HD. The question remains as to whether or not these treatment modalities improve clinical outcomes without placing too large a burden on the patient or the health system in terms of cost and quality of life (Jindal et al., 2006). In Newfoundland and Labrador, in January 2008, only 8 of the 341 patients on hemodialysis participated in home nocturnal HD (see Table 1). Anecdotally, these patients choose this option because of the perceived improvements in health outcomes, including a more liberal diet, absence of fluid restrictions, less dependence on medications, improved blood results, and generally a better quality of life with an improved sense of well being (C. Harding, personal communication, 2007).

Until recently, there have been no randomized trials demonstrating the clinical efficacy of nocturnal, daily or sustained HD (Jindal et al., 2006). Much of the evidence that is currently available is based on multiple observational studies, such as the economic evaluation by Mohr and colleagues comparing thrice-weekly conventional in-centre HD with daily HD (including either SDHD or NHD) (Mohr et al., 2001) and two systematic reviews, one that captured both published and unpublished data on nocturnal HD up to 2003 (Walsh et al., 2005), and a second review of studies on daily HD through May, 2005 (Suri et al., 2006). In general, the quality and generalisability of these reviews are limited by inconsistencies in how data on key outcomes were collected and reported in the individual studies, small sample sizes, selection bias, and the absence of randomization.

Though individual studies examined in the systematic reviews may have reported significant improvements in at least one outcome, when reviewed together the overall findings were more variable. Mohr et al. found a trend toward improved quality of life for patients on daily dialysis, including improved mental health, vitality, and social and physical functioning. A similar finding was reported by Walsh et al. who reported that health-related quality of life seemed to improve for patients who switched from conventional HD to nocturnal HD, though the degree of improvement and its clinical significance was variable. There was some evidence to suggest improvements in blood pressure control with both nocturnal HD (Walsh et al., 2005) and daily HD (Suri et al., 2006). The effect of frequent and prolonged HD on other physiological outcomes such, as left ventricular hypertrophy[1] and mineral metabolism, produced mixed results (Suri et al., 2006; Walsh et al., 2005). Suri concluded that before governments make policy decisions to fund daily HD programs, there was a need for randomized trials of adequate statistical power in order to establish the efficacy and safety of daily HD. There are currently two multi-centered trials ongoing in Canada and the US designed to address these questions, but their results will be available only in 2009.

In September, 2007, Culleton and colleagues published the preliminary results of an RCT, conducted in Alberta, Canada, between 2004 and 2006, on the effect of frequent nocturnal HD as compared with conventional thrice weekly HD on left ventricular mass (i.e. hypertrophy) and on health-related quality of life over six months. A total of 26 patients were trained and treated using nocturnal HD, 5 – 6 nights per week for a minimum of 6 hours per night, and compared with 25 patients treated with conventional HD. The preliminary results support many of the findings from earlier observational studies: frequent HD, when compared with conventional HD, results in improved left ventricular mass, reduced need for blood pressure medications, some improvements in mineral metabolism, and improved quality of life in selected areas including measures of the burden of kidney disease. No benefits in the management of anemia were realized by patients undergoing

[1] Left ventricular hypertrophy is the thickening of the muscle of the left ventricle of the heart and is a frequent problem for patients with ESRD.

this treatment modality. The strength of the evidence of the apparent benefits of nocturnal HD obtained from this single randomized trial is tempered, however, by the small sample size, the short duration of follow-up, and the use of surrogate endpoints as measures of clinical outcomes and adverse events, limitations that may be addressed in the ongoing larger clinical trials in this area.

1.3 Studies comparing settings where dialysis services are provided

There are no known systematic reviews that deal directly with the question of the provision of dialysis services in rural or remote populations. In their absence, the research team reviewed two recent health technology assessments that examined the impact of the setting in which dialysis is provided on key clinical and economic outcomes for patients.

In an HTA from the United Kingdom, Mowatt and colleagues (2003) reviewed published and unpublished studies that compared the clinical and cost-effectiveness of HD carried out at home with HD carried out in a hospital or a satellite unit. Studies of patients on PD were not included in this review. Only randomized controlled trials, controlled clinical trials, comparative observational studies and systematic reviews met the criteria for inclusion. The primary outcomes considered were quality of life, hospitalization rate, employment/school status, technique failure[2] and access failure[3], other physiological surrogate outcomes of the success of the HD, such as blood pressure and complications, and mortality. The studies were conducted world wide, but the vast majority of studies came from the United States. Two Canadian-based comparative observational studies were included in the HTA, though they were somewhat dated, having been published in 1978 and 1988. The only RCT, involving 9 patients in New Zealand, compared thrice weekly home HD of long duration with short duration in-centre HD.

Interpretation of the results of this HTA must be tempered by several limitations identified by the authors including the lack of hard clinical data usually obtained from RCTs. In particular, there were selection biases such as the fact that the patients on home HD tended to be younger and had less co-morbidity to start with than their counterparts in hospital or satellite units. This has a bearing on the relative clinical effectiveness of each modality. Furthermore, this patient profile does not fit the socio-demographic profile of the typical patient with ESRD living in rural and remote communities in Newfoundland and Labrador, so that the applicability of these results to our question is limited. This HTA also reported other differences between the settings compared, including the intensity of dialysis, with a subset of patients on home HD having more frequent or longer therapy. As a result is was difficult to disentangle the effect of setting from that of intensity of dialysis in some cases.

Despite these limitations, the general trend supported the notion that home HD is more clinically effective than hospital HD, and modestly more effective than satellite HD. When compared with those receiving dialysis in a hospital setting, patients on home HD reported experiencing a better quality of life with less disruption in their social contacts, greater feelings of well-being, and better functional ability. They were hospitalized less often, were more likely to work full time, and had fewer adverse events during their dialysis treatments (e.g., hypotension, arrhythmias, vomiting, cramps, and headaches). The mortality risk for individuals on home HD was lower, even when adjusting for patient characteristics, such as age and co-morbidities. Patients on home HD, however, reported being more anxious and depressed than those who were dialyzed in a hospital, and the partners of patients on home HD were less satisfied because of the patients' dependence on them for dialysis care. When compared with those receiving dialysis in a satellite unit, patients on home HD reported a moderately better quality of life, were also more likely to work full-time, and had comparable or better survival rates. Patients on home HD, however, experienced more hospitalizations than those dialyzed in a satellite unit, and the length of time they were able to remain on a particular form of dialysis was shorter.

Roderick and colleagues published another HTA, in 2005, that evaluated the costs, effectiveness and quality of RRT provided in a renal satellite unit (RSU) compared with a main renal unit (MRU). The study involved the identification of RSUs, defined as renal units that were linked to a MRU and received input from them for medical decisions. Chronic outpatient maintenance HD service was provided in RSUs, and these units did not offer acute or in-patient care for nephrology patients. Phase one is a report of the results of a 1999 questionnaire survey of all MRUs in England and Wales

[2] Any transfer from one dialysis therapy to another that lasted longer than four months

[3] Failure of the vascular access

and of their corresponding RSUs to garner information regarding their structure, care processes and organization. The surveys were supplemented by semi-structured interviews with staff in a sample of units.

The organizational characteristics of the RSUs are summarized in the report and include important information about elements that may have relevance for the contextualization of results, especially when compared with the organization and process of care for satellite units in Newfoundland and Labrador. Over half (57%) of the RSUs were actually located on the site of an acute hospital, a further third (31%) were located at other hospital sites, and 12% were located on non-hospital sites, though the remoteness of these units was not documented in the report. The majority of the RSUs were owned by the NHS, though 26% were privately-run satellite units. The median number of HD stations was 8, but privately run RSUs had slightly higher numbers of stations. The median number of patients treated in an RSU was 34 patients (range 8 –120). Only a small number (12%) of RSUs had daily medical input from a nephrologist, and the remaining 88 % had non-permanent physician coverage supplemented with telephone support from the MRU for medical advice. A small percentage (6%) relied on coverage from local primary care physicians. There were 5.6 patients for every full-time nurse, and when other staff was included the ratio was reduced to 4.0 patients per staff member. RSUs on acute hospital sites tended to have slightly higher numbers of nurses. Few of the RSUs (< 10%) had support services in terms of CAPD support, home HD support, or an integral out-patient clinic. Few RSUs accepted patients for their first dialysis; patients with poor vascular access or cardiac instability were generally not accepted for dialysis in an RSU. The majority of RSUs were connected to their MRU through computerized record systems.

The main impetus for developing RSUs was to provide a convenient geographic location and thus reduce travel time for patients, and to respond to patient demands for such a service. Opening an RSU may have eased the pressure on the MRU temporarily but was found to create other unpredictable demands on the MRU as patients who became ill or unstable returned for treatment. The provision of dialysis services in an RSU did not necessarily coincide with an expansion of other services such as CAPD or dietician services. The responses from the semi-structured interviews indicated that RSUs were viewed positively, especially by nurses. Nurses described the units as accessible, calm environments where they have more time for patients and greater professional autonomy. In view of the reduced medical support and the potential for litigation, nurses felt the need for an outstanding senior nurse on site. One downside to working in an RSU was that nurses and doctors experienced geographic, professional and social isolation.

Phase 2 of the evaluation by Roderick et al. (2005) was a cross-sectional comparison of clinical and patient outcomes, resource use, and costs of patients from a representative sample of 12 RSUs and a comparable group of patients from their corresponding MRU. In order to do comparisons between the satellite and the main renal units, staff in the MRU were asked to identify patients dialyzed there who would be otherwise suitable for satellite unit care, and the units were then paired to generate comparisons. Data on effectiveness, acceptability and accessibility of the units were extracted from clinical charts and computer systems, as well as by a variety of patient questionnaires. Both groups of patients had similar co-morbidities and levels of dependency except that those in the MRUs were slightly younger and a higher proportion was from ethnic minorities. There were no significant differences in the clinical processes of care.

The clinical outcomes, in part based on surrogate measures, were largely comparable. There were no differences in clinical outcomes such as correction of anemia, blood pressure control, and nutritional status, except that the urea reduction ratio (a measure of dialysis adequacy) tended to be better for patients treated in the satellite units. The use of hospital services was broadly similar across the type of dialysis service. Although the researchers had no comparable data on adverse events in patients from MRUs, they reported a high frequency of hypotensive episodes for patients while on HD in RSUs, although no treatment was given. Patient-specific quality of life did not differ between main and satellite units other than the fact that patients from RSUs reported greater satisfaction with staff communication and with the overall environment in the unit.

In summary, there does not appear to be an adverse impact on patients treated for chronic HD in a RSU rather than a MRU. There may even be some benefits for patients who undergo dialysis in a RSU in the form of improved geographic access for those living in dispersed locations, reduced patient travel time, and the provision of care that is generally more acceptable to patients. As with all cross-sectional comparisons, the evidence from this HTA must be viewed cautiously for, in the absence of randomization and with patients in MRUs being generally younger and better educated, the results may be explained by factors other than setting. Roderick and his colleagues also point out that there is no universal definition

for an RSU, making direct comparisons with other satellite units difficult. The impact of the differences in organization and structure between the satellite units considered for this HTA and those of the type of unit that might be set up in rural Newfoundland and Labrador will be described more fully in the section on the economic analysis of treatment modalities. For the moment, we will note that one important difference is that, due to the geographic dispersion of the population of patients with ESRD in this province, the distance between any one patient and the closest satellite unit is likely to be greater than that found in the UK. According to one recent study of Canadians with ESRD living in remote locations (Tonelli et al., 2007), this distance could have a significant impact on patient outcomes, at least for patients on PD. Tonelli and colleagues found that patients residing in remote locations greater than 50 kilometers from their nephrologists were more likely than their counterparts living in urban areas to initiate RRT with PD, and that the risk of death for these patients was significantly higher.

Given that the available evidence suggests that chronic hemodialysis care in a satellite unit is a comparable alternative to hospital-based hemodialysis, it would be helpful, from a health policy perspective, to consider the regional effects of providing local dialysis care in rural and remote populations. Prakash et al. (2007) conducted a before and after cross-sectional comparison of two groups of rural regions in Ontario, Canada, at two points in time (1995 and 2002). The control group (10 communities) included regions that were already serviced by satellite HD in 1995, and the comparison group (24 communities) involved regions that had new satellite HD units built between 1995 and 2002. In the 1990s, in an effort to decrease travel distance for patients, the government of Ontario increased construction of satellite units in rural regions of Ontario outside of large metropolitan areas.

For this Ontario study, satellite HD units were defined as units that were affiliated with, but distant from, a regional renal centre, not unlike the organization of satellite units in Newfoundland and Labrador. Nephrologists were responsible for the care of the patients in the satellite unit, but there were no nephrologists on site. Patients attending satellite units were relatively stable (i.e. able to be dialyzed while sitting in a chair and able to travel to and from the unit). The study excluded areas with teaching hospitals and tertiary care centres, as well as patients living in large metropolitan cities, since the focus was on regions and individuals faced with issues of distance for access to renal replacement therapy. The overall goal of the study was to examine whether the introduction of local HD access in the satellite unit setting disproportionately increased RRT rates, compared with regions with prior access to local HD services. The authors also examined the impact of newly introduced satellite units on patient travel distance for dialysis therapy, local peritoneal dialysis utilization rates, and the numbers of elderly and sicker patients receiving renal replacement therapy. Most of the data were obtained from a clinical registry held at the Canadian Institutes for Health Information (CIHI), namely the Canadian Organ Replacement Register (CORR) (Prakash et al., 2007).

The results indicated that in regions where new introduced renal satellite units had been introduced there were slight increases in the rates of RRT in the seven-year period under review, but not at a statistically significant level. Hence, increasing local access to dialysis services did not create a greater demand for service in the area, except that there was a significant increase in the proportion of elderly receiving RRT, an association that warrants further research, especially given demographic predictions for this province. The results, however, must be interpreted cautiously, as the authors point out that since the data were based on prevalence rates and not incidence rates, the lack of differences found in the two comparison groups may be related to a movement of patients back and forth between the two groups linked to the accessibility of local dialysis services. There were no differences between the two groups in the proportion of patients on peritoneal dialysis. The construction of new satellite units in rural areas did, on the other hand, significantly reduce the mean travel distance for patients ($P < 0.001$). The authors concluded that building renal satellite units in rural areas has the benefit of reducing patient travel time and improving access to renal replacement therapy for the elderly, yet does not create a supply-induced demand for services.

2. Cost-Effectiveness

2.1 Studies on economic outcomes of modalities of dialysis

The economic analyses we have examined are of limited quality and applicability within the Newfoundland and Labrador context. Insofar as any conclusions can be drawn concerning the central question of this report, what we can say is that there is insufficient evidence to rule out any one modality of renal replacement therapy on economic grounds, although we would note that a fully-fledged main dialysis unit is not likely to be economically feasible in a rural or remote hospital.

Despite the high initial costs associated with home-based HD, home-based therapies in general, including peritoneal dialysis and nocturnal HD, are viable economic options in the longer term for some patients. Depending on the design, the provision of dialysis in a renal satellite unit is also acceptable, particularly in the context of a geographically dispersed population, such as that of Newfoundland and Labrador, where centre-based therapies pose unique economic hardships for patients.

2.2 Studies comparing home-based and hospital-based therapies

Comparison of the relative cost-effectiveness of HD provided in a home setting versus HD in a hospital setting is done by two economic studies (McFarlane et al., 2006; Mohr et al., 2001). Both analyses suggest that providing nocturnal home-based HD to select patients, even in rural or remote settings, might be a reasonable option from an economic perspective. There are, however, limitations to the applicability of these analyses to the Newfoundland and Labrador context, and these will be discussed below.

The 2001 report by Mohr and others compared the clinical and possible economic impact of conventional in-centre HD to short daily HD delivered in-centre and to home-based nocturnal HD. Data to inform the analysis were derived from the literature and applicable to U. S. settings. An economic model was constructed to compare costs and clinical effects for the various modes of dialysis service. As noted earlier, the absence of high quality evidence, specifically large-scale RCTS, to enable comparisons of the clinical effectiveness of various modalities of dialysis services weakened the economic analysis. Furthermore, the timeframe for the Mohr et al. analysis was only one year, and the long-term impacts on productivity and costs were not considered. Despite these limitations, the model suggested that more frequent and prolonged HD could be cost-saving, particularly if reductions in hospitalizations were realized. The model shows considerable instability with regard to this variable and consequently does not allow strong conclusions about the relative cost-effectiveness of the various modes of dialysis delivery.

McFarlane and colleagues (2006) conducted a more recent economic evaluation which also has the advantage of being Canadian-based. They constructed a decision-analysis model to compare the relative cost-effectiveness of home-based nocturnal HD with intermittent HD in a hospital setting. The study utilized long-run analysis to allow for the various events that can happen to patients receiving dialysis, including failure of the technique, declining benefits, transplantation and death. This approach allows the projection of future costs and health effects over the lifetime of patients with ESRD. The McFarlane decision analysis suggested that home-based nocturnal HD might deliver better clinical outcomes at lower costs. Even with extensive sensitivity analyses, the major conclusions appear reasonable robust, although dominance of the nocturnal option is not assured under all assumptions.

Neither the Mohr nor the McFarlane analyses are particularly applicable to the question of how to deliver dialysis services cost-effectively to people in rural and remote areas. Despite the fact that the perspective taken by Mohr was a societal one, the full range of costs, including indirect costs, was not included in the model. The model also assumed the reuse of dialysers, a practice which does not occur in Newfoundland and Labrador. The McFarlane analysis, undertaken from the viewpoint of a third-party payer, such as a Canadian provincial government, is insufficient for comparing dialysis modalities for rural and remote dwellers since it ignores many costs that are usually borne by patients themselves, such as those associated with relocating or traveling to undergo in-centre HD. Similarly, the costs of establishing and maintaining equipment in homes dispersed over a large geographic area such as Newfoundland and Labrador would likely be higher than that assumed in the McFarlane analysis.

Neither paper compares the relative cost-effectiveness of home-based nocturnal HD with other options such as peritoneal dialysis (which is also home-based) or with dispersed models of HD services, such as satellite-unit HD. More frequent or daily HD is an option in satellite units as well as in in-centre units. The assumptions used by Mohr regarding the implications for staffing might be quite different in a satellite unit, and for this reason, one cannot extrapolate his economic analyses to satellite-unit HD. For example, if the satellite units were not required to be open on a daily basis because of low patient volumes, then considerable per-patient cost increases might result, depending on the design of nursing shifts. Conversely, if small satellite units were open on a daily basis and had high staff-to-patient ratios, then increasing the frequency of dialysis should cause only a marginal increase in staff costs. If the hypothesized clinical benefits of daily therapy

were realized, such a model might be cost-effective in satellite units aimed at rural and remote populations.

2.3 Studies comparing satellite-based HD and home or hospital-based HD

Two HTAs, previously reviewed in this report, do make comparisons between the cost-effectiveness of dialysis services provided in satellite units and similar services provided in other settings, including hospital or home (Mowatt et al., 2003), and in main renal units (Roderick et al., 2005).

Mowatt and colleagues (2003) published an HTA, undertaken in the U.K., which examined the clinical and cost-effectiveness of home versus hospital or satellite-unit HD. The authors acknowledged that conclusions about relative clinical effectiveness were susceptible to selection biases and differences in the intensity of dialysis in the various settings. Nevertheless, the literature described better clinical outcomes for patients on home-based therapy, but also increased anxiety. Differences between home-based patients and those treated in satellite units were smaller than between home and hospital-unit patients. Mowatt constructed both cost-effectiveness and cost-utility models. The prevailing trend suggested that home-based HD was also less cost intensive than the other service modalities although, given the difficulties in judging relative clinical effectiveness, the true incremental cost-effectiveness of home versus other forms of HD remains uncertain.

Mowatt's economic evaluation is limited in both quality and applicability to the Newfoundland and Labrador context. Many individual studies included in Mowatt's HTA reported costs and other outcomes separately, while only a small number performed incremental analyses. As well, most of the economic literature was published in the 1990s with none of the studies being more recent than 2001. The data were derived from several countries, including Canada, and from a variety of sources, including some of the literature reviewed. The time horizon for the study was short, at five years, and some of the assumptions made in the economic models seemed unrealistic. For example, it was assumed that there was zero probability of patients transitioning between the various settings for HD, and this assumption was tested in the sensitivity analysis. This scenario is unlikely in clinical practice, as was another assumption made in the base-case analysis that there was an equivalent probability of transplantation or switching to PD for patients beginning HD in any of the settings. In actual practice, patients are selected for dialysis in a particular setting based on nonequivalent probabilities of transitioning to PD or becoming eligible for transplantation. Similarly, the duration for follow-up in the costing studies comprising this economic analysis was often quite short and did not allow for an estimation of lifetime costs for patients beginning on home HD, or transitioning between modalities of therapy during the lifetime clinical trajectory for a given patient.

Mowatt found home-based HD to have higher up-front costs, including for training, and he estimated that patients needed to survive on home HD for at least 14 months to recover these costs. Mowatt and his co-authors acknowledge that the model does not include consideration of the costs and consequences borne by caregivers in the home setting. While the model was sensitive to the cost of travel, the simplified assumptions made by Mowatt about the distance to travel for service were not appropriate for Newfoundland and Labrador. In particular, in the absence of a satellite unit in parts of this province, some patients would be forced to relocate to access dialysis services, and the costs involved in this option were not considered.

Roderick and colleagues (2005) undertook an HTA that compared clinical and patient outcomes, resource use, and costs of dialysis services between renal satellite units (RSU) in England and Wales and their associated main renal units (MRU). The viewpoint of the analysis appears to be a societal one since indirect costs for patients and families were included. Cost data were collected using year 2000 price units; resource use was captured using a number of methods including patient questionnaires and interviews and surveys of staff. Roderick reported that patients included in the comparative analysis were similar and there was no documentation of any significant differences in processes of care between the two settings. The clinical outcomes of patients treated in the two settings were also comparable, as was the use of hospital services.

There were, however, methodological weaknesses in Roderick's cross-sectional comparison and these affect the quality of the study. The analysis was incomplete in that it involved what seems to be an unsatisfactory overall measure of effectiveness, utility or benefit that could be combined with the costs to generate incremental cost-effectiveness or cost-utility ratios. Consequently, the analysis was more of a cost-minimization exercise. There were also potential biases imposed by the requirement to generate comparable patient groups in the two settings, and it is not clear whether

the patients selected were representative of the population of patients with ESRD. Staff in the renal units estimated the allocation of costs and resource utilization, without necessarily requiring any particular data source, introducing the possibility of inaccurate estimates. Similarly, the time horizon for the comparison seems to be one year; however, data were collected by having staff recall utilization patterns over four weeks and then extrapolating. Hospitalization costs were based on averages and not adjusted by reason for admission, and the list of resources examined in costing appears incomplete. In short, there were numerous potential sources of error in the costing analysis, and the results cannot be assumed to be applicable to other populations. In the absence of a complete cost-effectiveness analysis, it is not possible to determine whether it is economically preferable to provide HD in a satellite or in a main renal unit.

Even if the results of Roderick's study were reasonably robust, there are several cost-related factors that would limit the generalisability of his findings to Newfoundland and Labrador. While the staffing model and medical coverage of the satellite units appear relatively similar to what might be contemplated in this province, there are some important differences. First, the satellite units in Roderick's study were much closer to the main renal units than would be the case in this province. Roderick described the mean potential travel time saved as 19 minutes, or a distance of 17 kilometers three times a week. Comparatively, the closest satellite units to main renal units in Newfoundland and Labrador would be Carbonear to St. John's and Stephenville to Corner Brook – a distance much greater than 17 kilometers. In addition, most of the satellite units in Roderick's study were located in hospitals, while fully a quarter of them were operated by private companies, a situation not present in this province. The private units were less likely to accept patients that might pose a risk of complications and they had a higher ratio of patients to staff, which would have costing implications. The size of the satellite units in England and Wales (a median number of eight stations per unit serving 34 patients) was also generally larger than would be the case for potential new (and some existing) units in this province. This has implications for staffing levels and costs, all of which would tend to be higher in smaller units on a per patient basis.

Similarly, the proportion of patients with diabetes in the Roderick study was 12% which is far less than that seen in similar Canadian populations. Since patients with diabetes tend to have more illness and higher hospitalization rates, this would have implications for the likelihood that they would require hospital care. In the Roderick study, some of the costs, such as the costs of transporting patients, were borne mainly by the health system in the U. K., whereas this would not uniformly be the case in Newfoundland and Labrador. As with Mowatt's study, Roderick's model does not consider the cost of relocation to access dialysis services, an important consideration in the Newfoundland and Labrador context.

2.4 Studies comparing cost-effectiveness of HD and PD

None of the above economic analyses contribute to an understanding of the cost-effectiveness of peritoneal dialysis as compared to the various hemodialysis treatment options.

Not surprisingly, as with the economic evaluations of HD, the evaluation of PD that we reviewed had several deficiencies including incomplete health outcome data, incomplete comparisons with the alternatives, short time horizons, use of data from other countries, changes in PD practice over time, and failure to include costs for assisted PD. One Canadian study examined the annual costs of ongoing care for patients with ESRD (Lee et al., 2002). While this research did not include a cost-effectiveness analysis, the authors attempted to produce an itemized description and comparison of the costs and resources required to treat patients with ESRD on various dialysis modalities. Keeping in mind that analysis and interpretation of cost data across different dialysis modalities is challenging, and that attempts to estimate dialysis costs are often fraught with error (Peeters et al., 2000), the researchers found that home/self-care hemodialysis and peritoneal dialysis were the least costly modalities of treatment. Most of the differences in costs between in-centre and home-based therapies lay in the difference in the use of nursing care and supplies. Several limitations are acknowledged by the authors of the study including a short follow-up of just one year, the introduction of selection biases since study participants were healthier than the general population of patients with ESRD, and the lack of attention to societal costs, such as lost time and work. The general trend in the literature, however, is that costs of PD are equal or less than that of HD in most formats (Cogney-VanWeydevelt et al., 1999; De Vecchi et al., 1999; Peeters et al., 2000; Sennfalt et al., 2002).

Are the conclusions robust or weak?

The evidence on clinical efficacy, effectiveness and cost-effectiveness in the provision of dialysis services, including comparisons of various dialysis modalities, frequencies, durations and settings, is generally weak and limited by the absence of hard clinical data from randomized clinical trials (RCTs). For the most part, with the exception of a few RCTs with small sample sizes, there is a strong dependency on evidence from multiple observational studies comparing two or more groups of dialysis patients.

The observational studies included in the systematic reviews and HTAs, though numerous, were for the most part subject to selection biases and uneven distribution of confounding variables between the groups of patients being compared. For example, patients on home HD were often younger and less sick than other patient groups to which they were being compared, thus having an impact on clinical effectiveness outcomes. In other instances, the patients in observational studies may have been placed on one modality of dialysis because they were unable to tolerate another modality. Many of the studies included in the reviews failed to approximate a balance in the socio-demographic factors and co-morbidities of the two groups being compared, though some studies attempted to account for this in their statistical analysis. The evidence on effectiveness relied on surrogate endpoints rather than true clinically important outcomes and, when combined with the diversity of the instruments used to collect data, it became difficult to pool and compare results, further impeding the reviewers' abilities to draw conclusions about the evidence.

The uncertainty about the estimated clinical benefits is matched with uncertainty about the cost estimates for various dialysis modalities. Unstable economic models and incomplete economic analyses do not permit strong conclusions to be made about the cost-effectiveness of dialysis in various forms. Amongst the economic evaluations reviewed for this report, several deficiencies were noted, including incomplete consideration of health outcomes, incomplete comparisons with alternatives, short time horizons, changes in dialysis practices over time, and the use of data from other countries that may not be applicable here. Many of the economic evaluations did not include all relevant costs, the data on costing was generally of poor quality and was collected by diverse methods, and transitions among modalities was not always accounted for. In particular, many studies omitted indirect costs, such as the demands placed on caregivers and the cost of extensive travel and/or relocation, factors that are important for rural and remote populations.

Though the evidence points to some overall trends, the findings are not conclusive and may have limited generalisability. There is a need for randomized controlled trials on dialysis designed with scientific rigor and sample sizes that are sufficiently large to enable researchers to draw conclusions about the many unanswered question regarding the clinical and cost-effectiveness of various dialysis modalities.

Are the conclusions applicable in our context?

The applicability of the evidence reviewed in this report to the Newfoundland and Labrador context is limited somewhat by the threats to external validity previously discussed. While general trends have been identified, the findings may not be applicable to all patients on dialysis in any setting. This is particularly true when one considers that the major objective of this contextualized synthesis is to examine how best to meet the needs of small groups of patients with ESRD living in rural and remote locations and identified as being clinically stable enough to consider dialysis either at home or in a satellite setting.

Patients in rural and remote populations in NL tend to be older and have greater co-morbidity, including higher rates of diabetes, than many of the patients who were treated on home-based therapies or in satellite units in the studies reviewed. Thus, the evidence on clinical effectiveness may not be applicable to this province since other patient-related contextual factors would need to be taken into account when choosing the most appropriate modality.

In many of the economic studies reviewed, important types of cost that would be borne by individuals in rural and remote areas were not taken into account. The distance traveled for dialysis care is generally greater in this province where patients are widely dispersed and, unlike in the other jurisdictions studied, the cost of travel is borne by patients themselves. Relocation is an option considered by many in this province, but its costs were not included in the economic models reviewed. The cost of placing and maintaining equipment in the home would be higher in rural and remote locations than was considered in the economic analyses. For most of the economic studies, assumptions were included about such things as the re-use of dialysers and the availability of caregiver allowances, both of which are not generally practiced locally.

The renal satellite units examined in the studies were generally larger than would be planned in rural Newfoundland and Labrador, with different nurse-patient ratios and other contextual factors that would affect efficiencies. While larger units might achieve a certain cost per treatment delivered, it has been the experience in this province to date that this cost is higher in smaller satellites. This is due to the less intensive utilization of the capital equipment and the requirement to maintain higher staff/patient ratios to ensure that a minimum number of staff is available both in the unit to handle emergencies and on the roster to ensure continuous service.

For the purposes of contextualization, the cost-effectiveness studies provide a list of cost drivers to be considered (see Appendix 3), but one would need to input data based on NL figures in order to make an accurate assessment of costs.

Finally, it is important to remember that the results of any economic evaluation may be affected by changes in dialysis technology which can have an impact on such things as complication rates and caregiver involvement, to name a few, all of which will ultimately change the forecasted cost of providing dialysis services in this province.

Contextualization

The literature provided limited guidance as to the contextual factors of relevance in the provision of dialysis services to rural and remote populations, including the cost implications. The research team, therefore, guided by the research evidence and the expert opinion of the Team Leader who has considerable local experience in this area, constructed a list of factors to consider in any effort at contextualization for the purposes of guiding decision makers. The list of contextual factors was then validated in two important ways.

First, the list was sent out to individuals working in provincial renal agencies and programs across Canada, asking for feedback about the relevance of these factors in their decision-making about the provision of dialysis services. Individuals from six provinces provided feedback and their responses were examined and found to be generally supportive of the factors under consideration in this project. Secondly, the research team, in consultation with one of this province's regional health authorities, selected a particular population in rural Newfoundland and then critically examined the relevance and usefulness of each contextual factor in decision-making processes concerning the provision of dialysis services to that population. Specifically, the decision makers were asked to identify contextual factors that were of especially high importance, factors for which there was no available data to provide answers, and factors that were irrelevant, unclear or duplicated. The final list of factors of relevance for contextualization, when making decisions about the provision of dialysis services in rural and remote populations in Newfoundland and Labrador, can be found in Appendix 4.

Conclusions & Implications for Decision Makers

Clinically, there is no proven advantage of one modality of dialysis over any other. There are many ways to deliver dialysis that appear to be acceptable. Peritoneal dialysis and hemodialysis are complementary forms of renal replacement therapy, and there is no convincing evidence that one is superior to the other. The key is to determine the right balance in the provision of the two modalities to populations of patients with ESRD, many of whom could conceivably avail themselves of either modality initially. More robust evidence is needed about the relative costs, benefits and risks of policies that begin

with one modality or another, but the prevailing pattern is that peritoneal dialysis is cheaper to deliver than hemodialysis, with fewer sunk costs and lower staff requirements.

No studies have been found that compare PD and HD in rural or remote populations. Home-based therapies in general, especially PD, are known to offer decided advantages to the system including the fact that they can be delivered almost anywhere, including in rural and remote locations, and do not require a critical concentration of patients to make them viable. Sustainability is not really an issue as there are no fixed facilities that will go unused if patient volume in a given area declines. Maintenance of competency for professional staff is also not an issue, as such staff is concentrated at the central training sites, where they also provide ongoing patient support at a distance. The training of patients and their families for peritoneal dialysis is much less intensive than for home hemodialysis, and this may be a decisive factor in choice of therapy. It is acknowledged that not all patients can deliver their own peritoneal dialysis. A family member often assists the patient but, when that is not possible, trained home-care workers can be hired to provide the care. There are already precedents for this model both within this province and across Canada. The cost-effectiveness of this approach as compared to any alternative for this sub-population has not been determined.

With regard to HD, the evidence we have examined, though not fully conclusive, suggests that, particularly for younger patients with less co-morbidity, HD in a home setting may be more clinically effective than HD provided in a hospital, and also modestly more effective than HD in a satellite unit. Despite the initial costs for set-up and training, home HD may also be more cost-effective than either hospital or satellite unit HD, especially if one takes into account the savings in travel costs for patients. Being dialyzed at home may improve patients' quality of life and may be less disruptive to their daily activities, social contacts, and ability to continue working. Home HD may, however, be associated with higher anxiety levels for patients and dissatisfaction for caregivers who must support the person on dialysis. In order to achieve the benefits of home HD, it is imperative that these programs be well-supported in terms of adequate patient and family training, and nursing and technical support in the home.

In particular, home nocturnal HD of prolonged duration may produce better clinical outcomes at a lower cost and is a reasonable option to consider for some patients. It should be noted that the decision to offer more frequent, or prolonged, hemodialysis at home is not the key one when making decisions about how to meet the needs of people in rural and remote areas. These aspects of the dialysis prescription are currently subjects of research and will represent refinements if they are proven to be of value. The real decision for policy makers is whether to offer home-based hemodialysis at all to rural and remote dwellers. Such an option is currently available in this province and there were no data in the literature to suggest that this is not appropriate. Hemodialysis at home offers many of the same advantages and poses many of the same challenges to the system as home-based peritoneal dialysis.

Since home-based therapies, either PD or HD, can meet the needs of most patients in rural and remote locations, other options should be considered only when home-based therapies are not possible, or when there happens to be a significant concentration of patients in a given area who might be efficiently served by developing new facility-based care. Areas of the province with small numbers of patients who need dialysis, but who cannot be treated at home, may consider the following options for dialysis services: Relocation of the patient; having the patient travel to an existing distant site for service (with or without subsidized travel costs); or provision of dialysis service within the community of residence. The choice between these options depends on a set of contextual factors that should be considered including the degree of difficulty of traveling to and from existing sites, patient and family impact of relocation, and many of the other contextual factors listed in Appendix 4.

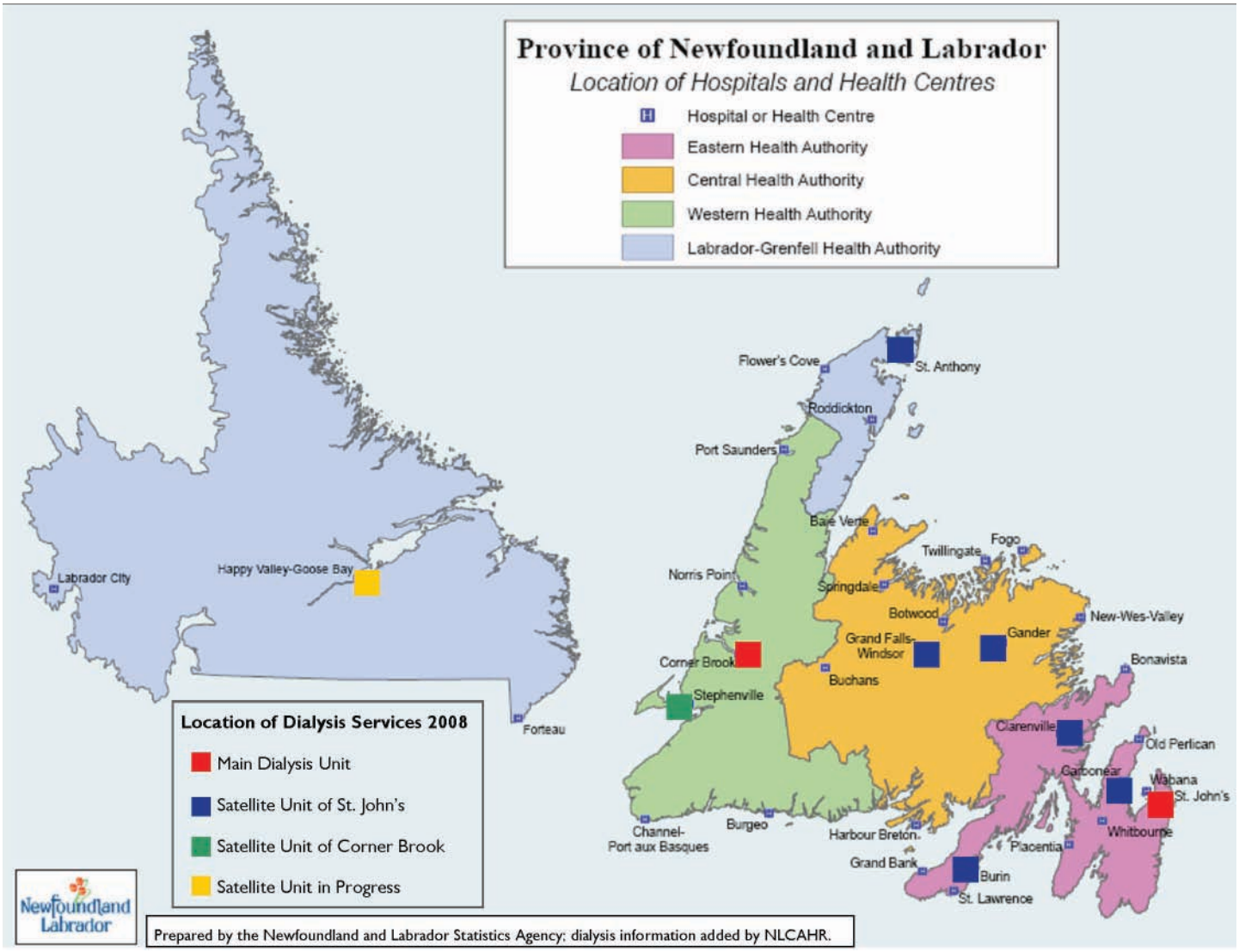
With regard to renal satellite units, the literature comparing HD provided in a renal satellite unit with HD in a main renal unit, showed no apparent difference in clinical outcomes for suitable patients on chronic HD. In fact, the option of treatment closer to home in a satellite unit may be beneficial in terms of reduced travel time, improved accessibility, particularly for elderly patients, and acceptability to patients. We found no studies comparing the cost-effectiveness of dialysis in community-based or hospital-based satellite units versus home-based therapies. In addition, the economic analyses that did exist comparing satellites to other options were not informative for rural and remote service provision in this province. In general the satellites studied were larger and closer to urban areas than would be the case for new units in Newfoundland and Labrador.

The decision to develop new satellite dialysis units should take into account the contextual factors listed in Appendix 4, and should involve careful consideration of other options to meet the needs of the population of interest. There are no universally accepted designs for renal satellite units. What is important, nonetheless, is flexibility in the design of the unit so that it meets the needs of the population but ensures portability or reconfiguration of the services if patient characteristics in the geographic area change. Key contextual factors in the development of new small satellite units are likely to be the availability of on-site staff and their ability to maintain their professional competence. Distance technologies, such as telehealth, may be able to bring some of the specialized support services (such as care by a nephrologist, dietitian or social worker) to patients receiving dialysis in satellite units.

In summary, we have found that the available evidence, particularly on economic issues, is of limited generalisability and of limited applicability to this province's rural populations. What can be said is that there is no robust or persuasive evidence to suggest that any one of the available modalities of dialysis service provision is inappropriate in the context of the rural and remote communities of Newfoundland and Labrador. In the absence of evidence to the contrary, home-based therapies should be considered the primary option for rural and remote service provision, while the contextual factors listed need to be considered when examining other options.

APPENDIX 1

Map of the Provision of Dialysis Services in NL (2008)



Source: Provincial Statistics, Provincial Kidney Program Coordinator, personal communication, January, 2008

APPENDIX 2

Electronic Search Strategy (collected January – June 2007)

PubMed

I. Search: PubMed
  a. Search Terms
    i. 'Dialysis' and 'provision of service'
  b. Limits
    i. Published in the last 10 years
    ii. Humans
    iii. English
    iv. Meta-analysis
    v. Randomized Control Trial
    vi. Practice Guideline
    vii. Review

II. Search: Single Citation
  a. Searched key articles from the results of step 1.
    i. Related links
  b. Limits
    i. Reviews (only)
    ii. Published in the last 10 years

III. Search: Clinical Queries
  a. Systematic reviews
  b. Search Term
    i. 'dialysis'

Web of Science

I. Cited Reference Search
  a. Searched key articles from the results of the PubMed search
    i. Times cited
    ii. Relevant articles related to the topic

The Cochrane Library

I. Search: All of the Cochrane Library
  a. Search Terms
    i. 'dialysis'
    ii. 'decentralized dialysis'
    iii. 'dialysis' and 'rural communities'
    iv. 'dialysis' and 'provision of service'
    v. 'dialysis' and 'satellite unit'

EMBASE

I. Search: Quick Search
  a. Search Terms
    i. 'dialysis' and 'rural communities'
    ii. 'hemodialysis' and 'rural communities'
    iii. 'decentralized dialysis'
    iv. 'dialysis' and 'satellite'

CINAHL

I. Search: CINAHL with Full Text
  a. Search Terms
    i. 'dialysis' and 'rural'
    ii. 'dialysis' and 'provision of service'
    iii. 'dialysis' and 'satellite unit'

InfoPOEMs

I. Search: Practice Guidelines
  a. Search Term
    i. 'dialysis'

Internet

I. Search: www.clinicaltrials.gov
  a. Search Terms
    i. 'dialysis'
    ii. 'hemodialysis' and 'treatment'

HTA Agencies

I. Search: Centre for Reviews and Dissemination (CRD) Databases:
  a. Database of Abstracts of Reviews of Effects (DARE)
  b. NHS Economic Evaluation Database (NHS EED)
  c. Health Technology Assessment (HTA) Database
  d. Search Terms
    i. 'dialysis'
    ii. 'hemodialysis'
    iii. 'dialysis rural communities'
    iv. 'satellite dialysis'
    v. 'decentralized dialysis'
    vi. 'hemodialysis rural communities'

II. Search: International Network of Agencies for Health Technology Assessment (INAHTA)
  a. Search Terms
    i. 'dialysis'
    ii. 'hemodialysis'
    iii. 'dialysis rural communities'
    iv. 'satellite dialysis'
    v. 'decentralized dialysis'
    vi. 'hemodialysis rural communities'

III. Search: HTAi Vortal
  a. Search Terms:
    i. 'dialysis'
    ii. 'hemodialysis'
    iii. 'dialysis rural communities'
    iv. 'satellite dialysis'
    v. 'decentralized dialysis'

IV. Search: Canadian Agency for Drugs and Technologies in Health (CADTH)
  a. Search Terms:
    i. 'dialysis'
    ii. 'hemodialysis'
    iii. 'dialysis rural communities'
    iv. 'hemodialysis rural communities'
    v. 'satellite dialysis'

Electronic Search Strategy, continued

V. Search: Alberta Heritage Foundation for Medical Research (AHFMR)
    a. Search Terms:
        i. 'dialysis'
        ii. 'hemodialysis'

VI. Search: Agence d'évaluation des technologies et des modes d'intervention en santé
    a. Search Terms :
        i. 'dialysis'
        ii. 'hemodialysis'
        iii. 'dialysis rural communities'

VII. Search : Program for Assessment of Technology in Health (PATH)
    a. Reviewed publications from 2001-2005

VIII. Search: NCCHTA (NHS R&D HTA Program)
    a. Search Terms:
        i. 'dialysis'
        ii. 'hemodialysis'
        iii. 'dialysis rural communities'
        iv. 'satellite dialysis'

IX. Search DACEHTA
    a. Reviewed all systematic reviews from 1999-2005

X. Search: Health Technology Unit at the Institute of Health Economics (IHE)
    a. Search Terms:
        i. 'dialysis"
        ii. "hemodialysis'
        iii. 'satellite dialysis'

XI. Search: Technology Assessment Unit at the McGill University Health Centre
    a. Search Term:
        i. 'dialysis'

APPENDIX 3

Summary of Cost Drivers for the Provision of Dialysis Services

Cost Category	Cost Driver
Direct health care costs	Physician expenses (specialist and other)
	In-patient care (hospitalization)
	Out-patient care
	Nursing care
	Laboratory costs
	Dietician and social work
	Clerical
	Training (patient and family)
	Vascular access surgery
	Peritoneal catheter insertion
	Ambulance training and care
	Consumables (medications and other, including dialysate, needles, gauze, etc.)
	Capital costs (building and equipment, including dialysis machine, water treatment system, chairs, computers, etc.)
	Maintenance of equipment and water treatment
	Cost of complications / infections/ hospitalization
	Cost of transition (moving from one modality to another)
	Home health care
Direct non-health care costs	Patient travel costs
	Patient out-of-pocket costs
Indirect costs (productivity)	Time lost in travel and treatment
	Lost or impaired ability to work
	Lost earnings
	Lost or impaired ability to engage in leisure activity
	Lost economic productivity caused by death
	Informal caregiver time
Opportunity costs (societal perspective)	Cost of use of a resource
	Proxy: expenditures

Source: Summary of cost drivers identified in Lee et al. (2002), Mohr et al. (2001), Mowatt et al. (2003), Roderick et al. (2005), Winkelmayer et al. (2002).

APPENDIX 4

Factors of Relevance in Contextualization: The Provision of Dialysis Services in NL

Patient-related factors

- Number of existing patients requiring dialysis in a given catchment area
- Likely continuing need for dialysis service in the area
  - Predictions based on historical trends (acknowledging that this is an imperfect guide to future patient numbers)
  - Refer to data submitted to CORR from the dialysis programs throughout the province in order to identify trends in utilization
- Types of dialysis services (possibly) available to meet the needs of each patient in a given area
- Ease of access to existing dialysis services by those in the area:
  - Distance to travel
  - Road conditions
  - Weather factors
  - Travel by boat or plane
- Numbers of existing patients who travel or relocate in order to access dialysis services
- Medical suitability of the existing and predicted patients for different forms of possible dialysis services
  - Criteria for medical suitability of patients (at start-up)
  - Based on a medical judgment by a nephrologist for each patient and each form of possible dialysis service (Home HD, Home PD, Satellite Unit Dialysis)
  - Potential for adverse patient events related to the setting interacting with specific patient factors (e.g., age, co-morbidity)
- Acceptability of the various forms of dialysis services in various settings
  - Patient preferences
  - Willingness to accept new modalities of treatment and/or new settings for treatment if they become available
- Pre-dialysis preparation of the patient for various modalities of dialysis
  - Who sees the patient prior to dialysis?
  - Who performs the education (comprehensive team approach or physician)?
  - How are the modalities presented?
- Other related values and beliefs of the patient
  - Availability of travel subsidy may influence patient choice
  - Availability of caregiver subsidy
  - Time commitment for travel and impact on quality of life/work
  - Importance of the frequency of in-person review by specialist to the patient
- Availability of stable trained supports in the community for patients requiring dialysis
  - Family support for provision of care
  - Support for transport to dialysis
  - Paid home care worker support – turnover issues
  - Training and re-training of support

Factors related to the possible site of service

- Availability of suitable space for facility based options
  - Limiting sunk costs Flexibility – the possibility of having multipurpose space
  - Availability of water of adequate purity and flow
  - Portability of water treatment equipment

- Availability of associated back-up services on site
  - Laboratory
  - Other diagnostics
  - Pharmacy
  - Dietician
  - Social work support
  - Biomedical technical support
  - Electrical back-up
  - Care for co-morbid conditions
- Availability of telehealth capacity and other communication links for ongoing patient care
- Existence of protocols to manage emergencies and the transport of patients

Factors related to human resources in possible site of service

- Availability of /access to a comprehensive team approach permitting pre-dialysis patient care and education on treatment modalities
- Availability of specialized medical staff for consultation (in person, by phone or through telehealth)
- Availability of surgical and radiological support for insertion of peritoneal catheters and vascular access (not necessarily on site)
- Input of local medical services capable of managing the ongoing general medical care needs of the dialysis patients, in consultation with the nephrologist
- Availability of nursing staff to provide services locally
- Possible staff mix required
- Availability of training resources for new staff
- Stability of workforce and likely staff turnover
- Impact on staffing of other services in the area
  - Who can be hired for dialysis?
  - Will this take away from the ability to provide other services?
- Maintenance of competency if many staff trained, but low volume of service
- Adequacy of staffing to provide relief for sick time, vacation leave
- Access to staff continuing professional development
- Avoidance of professional and social isolation
- Availability of managerial resources

Other System Factors

- Liability issues for providers given the method of service delivery
- Availability of specialist backup
  - Feasibility of regular site visits
  - Feasibility of telehealth technology for regular review of patient
  - Feasibility of periodic patient travel for medical review or specialized service (e.g., creation and maintenance of vascular access)
- Demands imposed on specialized services – manageable or too high
  - Ability of staff from tertiary or 'parent' sites to assist with start up and/or to fill in when gaps arise
- Impact on other existing services of developing a new site for service
  - Existing HD
  - Existing PD
  - Existing home HD
- Impact on ambulance and other transport services
  - Reduced demand to transport patients to existing services (e.g., centre-based services)
  - Increased demand to get patients, who otherwise would have relocated, to specialist services as the need arises
- Effect on the perceptions of the new site for service in terms of its ability to provide specialized care
  - Appropriateness/accuracy of perceptions
  - Expectations by staff that those in acute kidney failure can remain on site
  - Expectations of patients/public

Economic factors

- Costs comparing the various options for delivering dialysis services
- Consideration of incremental cost-effectiveness among options in relation to what is considered acceptable
  - Number of dialysis stations per site versus operating hours
  - Nurse-patient ratio
  - Minimum number of patients required
- Balance between direct and indirect costs
  - fairness, equity and justice
- Ways in which capital costs can be kept in proportion to needs in a given area
- Ways in which sunk costs can be limited in providing services
- Impact on budget of funding various dialysis options
  - Does introducing a new modality of dialysis services affect the existing modalities?
- Impact of adoption of one modality on feasibility of others

Political factors

- The visible and at times high profile nature of providing a 'life support' therapy for identifiable patients and patients groups
- Role of the public and their representatives in
  - Advocacy
  - Public messaging
  - Funding of dialysis services
- Role of municipal, provincial and federal governments
- Role of charitable organizations
- Role of the media
- Dialysis service as a source of employment in a community
- The political impacts associated with good news and bad news announcements
  - Once a service has been provided in an area, who will make the decision to remove or relocate the service as the needs change?
- The influence of political externalities on the timing of decision making (e.g., in relation to elections, other announcements, balancing other messaging, etc.)
- The impact on health care providers of government decisions to develop dialysis services that do not meet the criteria of the Provincial Renal Advisory Committee Report
- The importance of receiving support from DHCS for all proposed changes in the provision of dialysis services
  - Do the proposed changes fit with the strategic plan for the Department?
  - Do the proposed changes fit with the strategic plan for the Regional Health Authority?

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