# Evidence in Context

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

### CHRSP About NLCAHR's Contextualized Health Research Synthesis Program

The Newfoundland and Labrador Centre for Applied Health Research is working with decision makers in the provincial health system to identify and address issues of pressing interest to Newfoundland and Labrador on which guidance from the research evidence is important. These issues are being addressed through our new Contextualized Health Research Synthesis Program (CHRSP).

CHRSP analyzes the findings of high-level research (systematic reviews, meta-analyses and health technology assessments) that has already been done on the issue in question. The findings of these studies are synthesized and are subjected to a systematic process of 'contextualization': they continued, page 4

### **Synthesis Topic**

# **Examining Options for Dialysis Services in Rural and Remote NL**

The province of Newfoundland and Labrador has the highest rate in the country of newly diagnosed patients over the age of 65 years with end-stage renal (kidney) disease (ESRD).<sup>1</sup> Here, as elsewhere in Canada, the profile of patients undergoing dialysis has changed, with a growing number of older, and more

medically frail, patients being offered dialysis.

In January, 2008, there were 380 patients on dialysis in this province, 65% of

whom were being treated by hemodialysis in main hospital-based dialysis units 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.

Hospital-based hemodialysis is the predominant modality of dialysis in this province despite the fact that it sometimes requires patients to travel long distances or to relocate, and that other modalities of dialysis are available, including home-based and satellite-based dialysis services (see Table 1 on page 2).

Making decisions about the provision of dialysis services, particularly for rural and remote populations, poses challenges and should be guided by research evidence. Furthermore, the evidence available from health technology assessments and systematic reviews on dialysis must be interpreted in light of the Newfoundland and Labrador context, taking into account our aging population, our limited human and financial resources, and the geographic dispersion of small clusters of patients with ESRD living in remote parts of the province. Providing health decision makers with the best available evidence that is attuned to the capacities and characteristics of the province is the goal of the Contextualized Health Research Synthesis Program (CHRSP).



- The Research 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?

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# About Dialysis

### **End Stage Renal Disease & Treatment Modalities**

End-stage renal disease (ESRD) is the irreversible loss of kidney function in which the kidneys are no longer able to support life. Patients with ESRD require either a kidney transplant, which is available only out-of-province, or dialysis therapy. There are two

### Focus of the Synthesis

# What We Looked At

### **Research Review**

From January to June 2007, the research team, under the direction of Dr. Brendan Barrett, a Nephrologist with Eastern Health and Professor of Medicine at Memorial University, reviewed health technology assessments (HTAs), systematic

main dialysis modalities: hemodialysis (HD) and peritoneal dialysis (PD). In Newfoundland and Labrador in 2004. over 90% of patients received HD as their initial modality of treatment. HD can be delivered in a variety of settings including main hospital-based units, satellite units (either hospitalbased or

Table 1: Number and location of patients in NL receiving dialysis services <sup>1</sup>								
Site		Hemo- dialysis	Peritoneal Dialysis	Home HD Conventional	Home HD Nocturnal			
St. John's: HSC		38	NA <sup>*</sup>	NA	NA			
St. John's: Waterford		108	37	2	8			
St. John's	Burin	6	NA	NA	NA			
Satellites	Carbonear	28	NA	NA	NA			
	Clarenville <sup>2</sup>	12	NA	NA	NA			
	Gander	25	NA	NA	NA			
	St. Anthony	1	NA	NA	NA			
	Grand Falls-Windsor <sup>3</sup>	52	NA	NA	NA			
Corner Brook		49	2	NA	NA			
Corner Brook Satellite	Stephenville	12	NA	NA	NA			
Total		331	39	2	8			

evaluations published in the last ten years on dialysis that were relevant to the study question. Individual clinical trials and studies were included in the synthesis of evidence only if they were published after the most recent HTA. The outcomes considered in this synthesis were clinical, economic, quality of life and patient satisfaction. The quality and relevance of the evidence were assessed jointly by the research team. As there were no studies that specifically addressed the question of the provision of dialysis services in remote and rural populations the team used the available evidence in several related domains as indicated below.

reviews, and economic

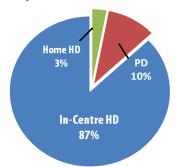
\* NA= Service not available. Note: People on home-based PD or HD are located throughout the province but are counted as St. John's or Corner Brook depending on the location of their follow-up care. 1: Source: Provincial Statistics, Provincial Kidney Program Coordinator, personal communication January 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.

based or community-based satellites), and at home. Peritoneal dialysis is often home-based, but the numbers of patients choosing PD has declined in recent years (see diagram, below). Table 2 provides an overview of the various dialysis services and interventions used by patients with ESRD in this province.

### **Hemodialysis and Peritoneal Dialysis Processes**

During hemodialysis, blood is taken from the patient, usually through an access port in the arm, and then passed through an artificial kidney machine which removes water and waste products before returning the blood to the patient.

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



Peritoneal dialysis involves the instillation of specially formulated fluids through a catheter into the abdominal cavity so that water and waste products can be exchanged with the blood flowing through nearby blood vessels in the abdomen.

### Research domains reviewed for this synthesis

### 1. Clinical efficacy and effectiveness

- 1.1. Studies comparing modalities of dialysis treatment
- 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.

### **Sources of Evidence**

The evidence on clinical efficacy, effectiveness and costeffectiveness 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).

Table 2: Types	of dialysis se	ervices					
Hemodialysis (HD)					Peritoneal Dialysis (PD)		
Conventional: 4-6hrs/day, 3 days/week			Frequent		Continuous Ambulatory Peritoneal Dialysis (CAPD)	Continuous Cycler-Assisted Peritoneal Dialysis (CCPD)	
Hospital-Based (Main Renal Unit)	Satellite Unit		Home Short daily,	Short daily,	Long nocturnal	3-5 times/day	2 times/day at most
	Hospital- Based	Community- Based		1.5-3hrs 4-6 days/week	6-8 hours 4-6 days/week		

### Limitations of the evidence

For the most part, with the exception of a few RCTs with small sample sizes, the HTAs and systematic reviews relied on evidence from multiple observational studies comparing two or more groups of dialysis patients. The observational studies, though numerous, were subject to the usual methodological limitations, such as selection bias and the uneven distribution of confounding variables in the groups of patients being compared.

The quality and generalisability of the findings were further compromised by inconsistencies in how data on key outcomes were collected and reported in some individual studies, short duration of follow-up, small sample sizes, and the fact that patients who participated in the studies were at times younger and with less co-morbidity than the average patient with ESRD and, in particular, than patients in rural and remote parts of NL. The economic analyses suffered from similar limitations. Cost-effectiveness analyses were also affected, in some cases, by the omission of indirect costs to patients such as the cost of extensive travel or relocation, and the costs and consequences

### **CHRSP Project Team: Dialysis**

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- Janice Butler Project Coordinator, CHRSP, NLCAHR
- Dr. Mike Doyle Director of Research, Eastern Health
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borne by caregivers, factors that are especially important for rural and remote populations.

# Preliminary findings from the synthesis

Insofar as conclusions can be drawn from the synthesized HTAs and systematic reviews, 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 or remote populations. It is unlikely that it

would be economically feasible to develop a fully-fledged main dialysis unit in a rural or remote hospital.

## Applying the Synthesis to Newfoundland & Labrador Putting the Evidence Into Context

The applicability of the synthesized evidence to the Newfoundland and Labrador context is limited. This is particularly true when the characteristics and capacities of small, geographically dispersed clusters of patients with ESRD living in rural and remote locations are taken into consideration.

### Patient-related contextual factors

Patients in rural and remote populations in Newfoundland and Labrador tend to be older and have greater co-morbidity, including higher rates of diabetes, than many of the patients in the studies reviewed who were treated on home-based therapies or in satellite units. 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.

### **Economic factors**

In many of the economic studies reviewed, important types of costs 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 where, unlike in some other jurisdictions studied, the cost of travel is borne by patients themselves. Relocation is an option chosen 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 available economic analyses.

For most of the economic studies, assumptions were included about such things as the re-use of dialysers and the payment of caregiver allowances, both of which are not generally practiced here. The renal satellite units examined in the studies were generally larger than would be planned in rural Newfoundland and Labrador, with different nursepatient ratios and other contextual factors that would affect efficiency.

### **Other contextual factors**

In contexualizing the research synthesis findings, the project team also examined the impact of the political context as well as site of service, human resources and other factors.

### **Contextualized Synthesis: Dialysis**

# Implications For Decision Makers

While recognizing the limitations of the available evidence, the CHRSP project team has determined that there is no proven clinical advantage of one modality of dialysis over any other. Peritoneal dialysis and hemodialysis are complementary forms of renal replacement therapy.

No studies were found that compare PD and HD in rural or remote populations. In general, however, home-based therapies, especially PD, offer decided advantages to the system in meeting the needs of patients in rural and remote areas of the province, including portability, sustainability, and maintenance of competency for professional staff. While the training of patients for PD is much less intensive than for home HD, not all patients can deliver their own PD. Trained family members or home-care workers can assist where needed, and this is currently occurring in the province. From an economic perspective, the prevailing pattern suggests that PD may be cheaper to deliver than HD (at least when paid help is not required).

The evidence, though inconclusive, suggests that, particularly for younger patients with less co-morbidity, HD provided in a home setting may be more clinically effective and cost-effective than HD in a hospital, and modestly more effective than HD in a satellite unit. Being dialyzed at home may improve the patient's quality of life but may also be associated with higher anxiety levels for patients and dissatisfaction for caregivers. 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. Though the research evidence is incomplete, there is some suggestion that 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. This option currently exists in the province and there were no data in the literature to suggest that this is not appropriate.

Since home-based therapies, either PD or HD, can meet the needs of most patients in rural and remote locations, other options, such as satellite units, need to 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. In terms of clinical effectiveness, 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. 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. The economic analyses that compared satellites to other options were not informative for rural and remote service provision in this province. In the absence of strong scientific evidence for or against the delivery of dialysis services in satellite units, the research team identified and validated a comprehensive set of contextual factors (see full report<sup>2</sup>) that should be considered when making decisions to develop new renal satellite units throughout the province.

### **Summary**

The available evidence, particularly on economic issues, is of limited generalisability and 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, and specific contextual factors should be considered when examining other options.

### Notes:

<sup>2</sup> The complete report on this Contextualized Research Synthesis is available here: www.nlcahr.mun.ca/research/chrsp

<sup>4</sup> The project team thanks The Canadian Agency for Drugs and Technologies in Health for support of this project.

### About CHRSP continued from page 1

are analyzed in terms of their applicability to the conditions and capacities of the unique context of Newfoundland and Labrador. CHRSP uses a combination of external experts and local networks to synthesize and contextualize the research and to facilitate the uptake of the results by local research users.

### **The CHRSP Process**

CHRSP endeavors to be timely and relevant to research users while ensuring a reliable and comprehensive process. Our goal is to produce a synthesis report within six months of topic identification.

When the synthesis is complete, an external expert reviews the work of the project team, providing feedback to ensure validity. The results of the synthesis project are then communicated to the province's decision makers and health professionals in formats and forums designed to maximize their uptake into the decisionmaking process.

For the complete CHRSP report on this project, including details on the evidence reviewed by the project team, see the NLCAHR website:

www.nlcahr.mun.ca/research/chrsp/

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CIHI (Canadian Institute for Health Information) (2006). Canadian Organ Replacement Register