Evaluation of routinely Measured PATient-reported outcomes in HemodialYsis care:

EMPATHY Trial

PRINCIPAL INVESTIGATORS:
Jeffrey A. Johnson, University of Alberta, Michael Walsh, McMaster University

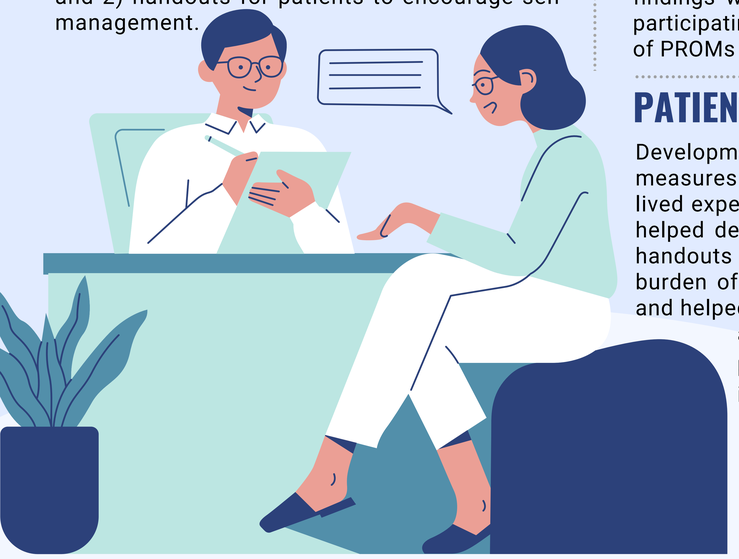
THEME 2.2

BACKGROUND

Kidney failure requiring dialysis is associated with a wide range of symptoms and poor quality of life. Yet, symptoms in dialysis patients are often under-recognized. Patient-reported outcome measures (PROMs) capture patients' experiences of symptoms and impact of disease on functioning, and can support clinicians to monitor disease progression and facilitate patient-centered care. This study will determine the effects of routinely measuring patient-reported outcome measures (PROMs) on the experiences of patients undergoing hemodialysis in Alberta and Ontario.

STUDY OVERVIEW

The EMPATHY trial comprises of two intervention components. The first is routine measuring and reporting of PROMs. PROMs are questionnaires that ask individuals to report on their experiences of symptoms and impact of disease on functioning. PROMs reporting present an opportunity for clinicians to monitor disease progression and facilitate patient-centered care. This study will explore two types of PROMs: 1) a renal disease-specific PROM and 2) a generic PROM. The second component of the intervention is the use of "treatment aids" for clinical management. Treatment aids include 1) symptom guidelines for clinicians and 2) handouts for patients to encourage self management.



STUDY DESIGN

This study uses a cluster randomized controlled trial design. Each cluster (i.e., hemodialysis unit) was randomly allocated into one of four groups, illustrated in figure 1. The workflow of the EMPATHY intervention is illustrated in figure 2. Patients complete their allocated PROM(s) every 2 months for a 12 month period. The PROMs results will be reviewed by a clinician with the patient. Clinicians will utilize the treatment aids for any symptoms requiring management and patient versions of treatment aids are also provided.

STUDY OUTCOMES

Study outcomes will be collected from patients every 6 months. **The primary outcome of this study is patient-provider communication.** Secondary outcomes include health-related quality of life, symptom burden and management, anxiety and depression, patient satisfaction, and health literacy. Other planned analyses include:

- **Cost-effectiveness analysis:** The incremental costs and incremental quality-adjusted life years (QALYs) of the different study groups to the usual care arm will be compared.
- **Healthcare utilization:** EMPATHY data will be linked with administrative data to analyze the use of healthcare services.

QUALITATIVE EVALUATION

All renal programs collected qualitative data from patients and clinicians to evaluate the routine use of PROMs for clinical care in the hemodialysis setting. Qualitative findings well help inform the sustainability of PROMs in participating EMPATHY sites and for the spread and scale of PROMs initiatives in other provinces.

PATIENT ENGAGEMENT

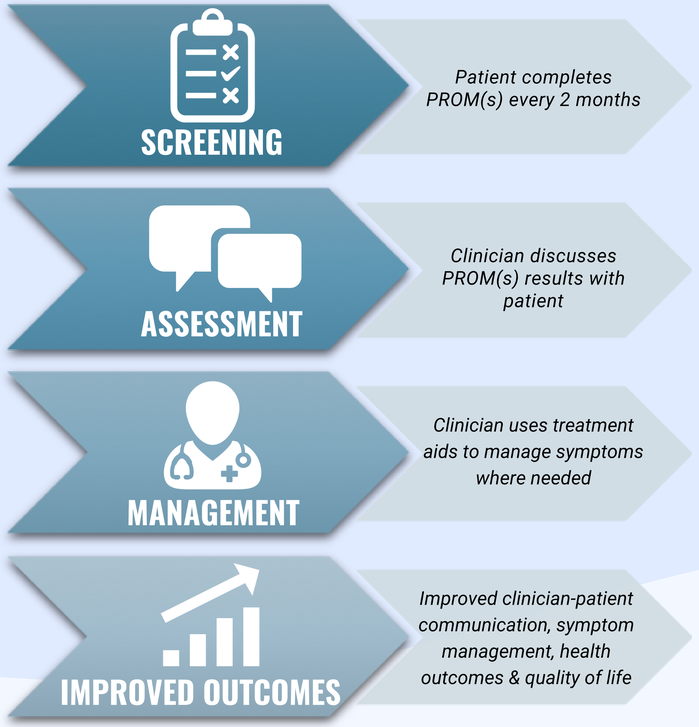
Development of the research question, outcome measures and study design were informed by people with lived experience of hemodialysis. These patient partners helped develop and review all the symptom information handouts for patients. They also evaluated the overall burden of study participation during the design process and helped determine the type and frequency of PROM administration. Additionally, patient partners prioritized focusing on mental health in our intervention and our study outcomes.

Figure 1. EMPATHY Trial Study Design

Timeline (months)	Treatment Aids	Group 1: PROM 1	Group 2: PROM 2	Group 3: PROM 1 & 2	Group 4: Usual care
Baseline		PROM 1	PROM 2	PROM 1 & 2	Usual care
		OUTCOME MEASURES SURVEY			
2		PROM 1	PROM 2	PROM 1 & 2	Usual care
4		PROM 1	PROM 2	PROM 1 & 2	Usual care
6		PROM 1	PROM 2	PROM 1 & 2	Usual care
		OUTCOME MEASURES SURVEY			
8		PROM 1	PROM 2	PROM 1 & 2	Usual care
10		PROM 1	PROM 2	PROM 1 & 2	Usual care
12		PROM 1	PROM 2	PROM 1 & 2	Usual care
		OUTCOME MEASURES SURVEY			

PROM 1: Disease-specific PROM (ESAS-r: Renal or IPOS-Renal)
PROM 2: Generic PROM (EQ-5D-5L)

Figure 2. EMPATHY Intervention



PROJECT TIMELINE

2016
- Research team development and study design planning

2017
- Implementation planning with patient partner input

2018-2019
- Clinician training
- Implementation
- Data collection for qualitative evaluations

2020
- Continued implementation
- Mental health sub-analysis

2021
- All data collection complete
- Primary analysis
- Qualitative analyses
- Sustainability planning

2022
- Secondary analyses
- Disseminate findings

ACKNOWLEDGEMENTS

The EMPATHY trial is included under the umbrella of the Can-SOLVE CKD Network, funded by the CIHR Strategy for Patient Oriented Research (SPOR). The EuroQol Research Foundation has provided funding for the qualitative work in Northern Alberta.