EMPATHY Trial

Evaluation of routinely Measured PATient reported outcomes in HemodialYsis care

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PROJECT TIMELINE

- **2016**: ✓ Study planning informed by the ORN pilot
- **2017**: ✓ Implementation planning with patient partner input
- **2018**: ✓ Clinician training; ✓ "Go-live" in NARP; ✓ ORN pilot evaluation
- **2019**: • "Go-live" in SARP & ORN • Qualitative sub-study
- **2020**: • Analysis • Spread results • Provincial rollout of PROMs

Can-SOLVE CKD Network

Strategy for Patient-Oriented Research SPOR — Putting Patients First

THEME 2.2

BACKGROUND

Advanced chronic kidney disease requiring dialysis is associated with a wide range of symptoms and poor quality of life. Symptoms are a key contributor to overall disease burden and patients identify symptom management as a very high priority. Symptoms in dialysis patients are under-recognized by clinicians and there is a considerable need for interventions to relieve symptom burden.

RESEARCH QUESTION

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.

POPULATION

In-centre hemodialysis units and their patients from three renal programs will participate:

- Alberta Kidney Care - North (AKC-N): 17 units
- Alberta Kidney Care - South (AKC-S): 10 units
- Ontario Renal Network (ORN): 16 units

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., dialysis unit) was randomly allocated into one of four groups, illustrated below:

Timeline (month)		Group 1: PROM 1	Group 2: PROM 2	Group 3: PROM 1 & 2	Group 4: Usual Care
Baseline	TREATMENT AIDS	PROM 1	PROM 2	PROM 1 & 2	Usual Care
		EVALUATION 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
		EVALUATION 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
		EVALUATION SURVEY			

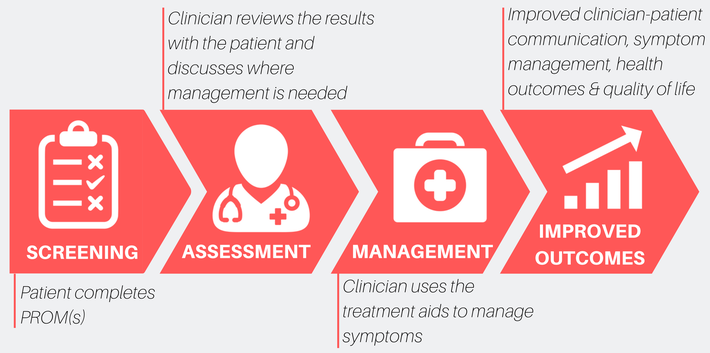
PROM 1: ESAS-Renal (AKC-N, ORN), IPOS Renal (AKC-S)
PROM 2: EQ-5D-5L

Learnings will inform the provincial rollout of PROMs

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.

HYPOTHESES

We hypothesize that the routine measurement and reporting of PROMs will lead to improvement in communication between dialysis patients and clinicians in dialysis units compared to usual care. We also hypothesize that this will lead to better symptom and disease management, and improvement in mental health and quality of life.



PATIENT ENGAGEMENT

Development of the research question, outcome measures and study design were informed by people with lived experience of hemodialysis. These patient partners also reviewed patient-facing study documentation and considered the overall burden of study participation during the design process.

STUDY OUTCOMES

Every 6 months, an evaluation survey will be distributed to patients. **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 ANALYSES

- **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

A qualitative sub-study will also be employed to explore the experiences and perceptions of patients and clinicians using PROMs and treatment aids through interviews and/or focus groups and observations in the units.