# Study Protocol: Remote patient monitoring for peritoneal dialysis

**Study Title:** Remote patient monitoring to support uptake and sustainability of peritoneal dialysis

**Study Investigators:**

PI:Associate Professor Rachael Walker (Eastern Institute of Technology, Napier)

Professor Suetonia Palmer (School of Medicine, University of Otago, Christchurch)

Professor Kirsten Howard (School of Public Health, University of Sydney, Australia)

A/Prof Allison Tong (Centre of Kidney Research, University of Sydney, Australia)

**Research Question:** How does remote patient monitoring influence patient uptake and maintenance of peritoneal dialysis?

**Study Background & Rationale:**

This proposal will evaluate remote patient monitoring as a clinical tool to support patients to choose and be confident to maintain care with peritoneal dialysis.

Patients prefer home-based dialysis therapies – and this patient choice is particularly influenced by the level of nursing support offered during dialysis training and the transition to home care(1). Peritoneal dialysis is increasingly preferred as first therapy in New Zealand for end-stage kidney disease (Figure 1). Short training times and automated peritoneal dialysis can enable patients to access home dialysis that provides increased treatment flexibility and freedom from care. PD patients experience markedly better quality of life, independence, and can sustain employment more easily(2-6). At a health service level, peritoneal dialysis is highly cost-effective compared to hospital than hemodialysis (HD)(7-9).

New Zealand is a world-leader in access to peritoneal dialysis – and is uniquely positioned to generate evidence that is critical to global equity in uptake of peritoneal dialysis. Internationally, an estimated 4.9 million people may have died prematurely due to lack of access to dialysis care in 2010, with largest treatment gaps in Asia and Africa (10). Renal replacement therapy is projected to more than double by 2030 – with most growth occurring in Asia. Access to home-based therapies is therefore fundamental to cost-containment and sustainable increases in dialysis programs, particularly in lower income regions. Access to peritoneal dialysis may offer global access to dialysis treatment in an era of substantial international expectations and capabilities to increase dialysis care.

Although peritoneal dialysis and home based care are often preferred, patients report a number of critical barriers to peritoneal dialysis. These include concerns about being safe to dialyze home, lack of confidence in their own ability, fear of catastrophic events, fear of feeling isolated without medical support, and the burden that dialysis imposes on family members and caregivers (11, 12). Attending directly to these concerns, including increased nursing support, could enable dialysis care to align with patient and family priorities and increase peritoneal dialysis use(1, 11).

Patient choices about dialysis are highly influenced by clinical recommendations. The decision to pursue peritoneal dialysis is influenced within teams and families by nursing staff and nephrologists (13, 14). A recommendation for peritoneal dialysis is usually based on the nephrologists own previous experience and exposure to successful peritoneal dialysis programs. Clinicians who are familiar and confident in peritoneal dialysis care are required to facilitate collaborative decision-making with patients to increase uptake.

Remote patient monitoring could increase support for patients when making decisions about dialysis modality – and facilitate greater uptake of peritoneal dialysis (15, 16). Remote patient monitoring uses web-based and mobile data technologies for patients to communicate directly with the peritoneal dialysis team to monitor and support dialysis prescriptions, trouble-shoot problems such as technical difficulties or infection, and support remote scheduled assessments. Remote patient monitoring aligns with International Society of Peritoneal Dialysis (ISPD) guidelines recommending regular patient reviews post training, post peritonitis and regular follow-ups (17, 18). While these review guidelines are aimed at supporting patients and improving peritoneal dialysis outcomes, they may actually impose additional burden and restrictions on patients and family/caregivers.

Remote patient monitoring is showing potential to improve well-being and care quality. Although studies in peritoneal dialysis are limited, telemedicine has indicated promising results in both adults and children on peritoneal dialysis(19-21) adults with heart failure and other chronic conditions(22, 23). For peritoneal dialysis, remote patient monitoring offers the benefits of real-time care and recording of the therapy as well as interactions with health providers at times that suit the patients. Remote patient monitoring has the potential to offer the nursing support that enables patients to choose peritoneal dialysis and pre-empt clinical events to reduce morbidity and mortality(24). For rural patients who often demonstrate poorer outcomes than their urban counterparts, in one study remote patient monitoring led to earlier diagnosis and management of complications and improved survival, while reducing peritonitis and exit site infections among patients who received monitoring(25).

Supporting patients and clinicians to be confident with home treatment is one of the most important attributes influencing patient selection toward home dialysis. Our hypothesis is that remote patient monitoring for patients considering peritoneal dialysis can support patient decision-making, increase preferences for peritoneal dialysis and enhance treatment characteristics of peritoneal dialysis to align more closely with patient-centered care. To test this hypothesis, this proposal will explore patient and clinician perceptions of remote patient monitoring to support choosing and sustaining peritoneal dialysis as a treatment modality. The proposal will seek to understand clinician views of remote patient monitoring to establish how better to support clinicians to recommend peritoneal dialysis. Ultimately, if remote patient monitoring is identified to be acceptable to patients and clinicians, this proposal could then lead to rigorous testing of remote patient monitoring in clinical trials.

In this study, we will conduct a qualitative project involving patients who have experienced peritoneal dialysis and their caregivers in three dialysis centres in New Zealand.

**The study aims are:**

• Determine factors related to remote patient monitoring that support patient choice and maintenance of peritoneal dialysis (semi-structured interview study)

This study will advance knowledge about how remote patient monitoring supports patient choice and maintenance of peritoneal dialysis. The study outcomes will enable recommendations about remote patient monitoring in dialysis practice. The findings may encourage inclusion of remote patient monitoring to support uptake of peritoneal dialysis in lower income countries throughout Asia and the Western /Pacific regions for patients who may not have access to alternative dialysis treatments.

**Study Population:**

**Qualitative interviews**

The study population will comprise purposively sampled ESKD patients from at least 3 NZ renal units.

Key Inclusion Criteria:

1) Patients and caregivers over the age of 18 years

2) Patients who are currently or have been treated with peritoneal dialysis

3) Caregivers who are or have performed or assisted in peritoneal dialysis

4) Pre-dialysis patients who are considering peritoneal dialysis

5) Able to provide informed consent

Key Exclusion Criteria:

1). Patients or caregivers unable to provide informed consent

The patient study population will be generated by purposive sampling based on gender, age, ethnicity, use of APD and CAPD, HD and pre-dialysis patients, to ensure information-rich data and an inclusive range of patient characteristics and perspectives.

**Duration of subject participation:**

For all qualitative interviews, study participants will participate in one qualitative interview (30-60 minutes duration) and may be contacted to confirm the interpretation of findings.

Qualitative interviews: Qualitative research does not have specific guidelines for sample size, and the process of data saturation, defined as when there are no new data collected, will determine the number of participants.

• The anticipated number of patient and caregiver participants in this study sample will be between 30-40 (in all DHB’s – anticipated 10-15 patients from each DHB).

**Participant recruitment:**

Eligible patients and caregivers will be invited to participate in the study by either local nursing staff or nephrologists within the renal department. Patients will be given written information and consent forms to read and then once verbal consent is obtained the patient/caregiver contact details will be given to the researcher. The researcher will then contact the patients to discuss the research in more detail, answer any questions the patients may have and once consent obtained organise a time and place for interview to take place.

**Analysis:**

Participant interviews will face-to-face and semi-structured. All interviews will be audio-recorded and transcribed verbatim. We will enter transcripts of interviews into HyperRESEARCH software (ResearchWare Inc, Version 2.8.3, United States), for line-by-line review by the study team. We will analyse data for emergent themes using the qualitative method of thematic analysis (ref), to provide in-depth knowledge of their beliefs, understanding, experiences and perspectives of peritoneal dialysis and increased support through remote patient monitoring.

**Cultural consideration and consultation:**

The regional differences in home dialysis uptake, coupled with the knowledge that Maori have lower rates of home dialysis and do poorly on dialysis are key factors which highlight the inequalities which exist and require addressing in this research. This research will help to understand ways that we can better support home dialysis in Maori patients. This may increase the uptake of home dialysis and help to ensure we are meeting the needs of Maori patients at home.

In order to ensure that patient recruitment and engagement, research process and interpretation is culturally safe and appropriate the HBDHB Maori health team have been consulted with regarding interview questions, recruitment and analysis of findings. (Please see supporting letter attached).

**The study will be conducted using the four Tikanga-based principles contained within the Te Ara Tika framework:**

***Whakapapa* (relationships)** will be formed with Maori consumers and advisory groups, this research is patient-centered and therefore having Maori service-users and steering group involved from the initiation, though the methodology and implementation is crucial,

***Tika* (research design )-** the design using kanohi-ki-kanohi (face to face) patient recruitment and interviews with patients and their whanau. Patients will be offered interviews location of their choice (eg. Home with interpreter or kaitawakaenga present),

***Manaakitanga* (cultural and social responsibility),** koha will be provided for participants, if interviews in the home, or petrol vouchers if patients travel to clinic, engagement and feedback to all patients, whanau and consumer groups and advisory groups will be offered.

***Mana* – (equity and justice)** for Maori will provided by the outcomes of this research, ensuring Maori have equal access and outcomes, have their perspective understandand implemented into the health system delivery is the aim of this research. Koha will be offered to all to ensure that participants are not disadvantaged by participating in the study.

**Dissemination of findings:**

All participants will be offered the opportunity to receive a summary report of research findings. Results will also be disseminated to the local renal department staff, at national nephrology meetings and through peer reviewed journal articles. Dissemination will also occur to national and local renal patient support groups (Kidney Health New Zealand).

**Relevance to HBDHB:**

Increasing home dialysis will reduce inequalities in health related outcomes for patients with ESKD, particularly for Maori and Pacific people. Knowing how to better support patients and their families to manage dialysis at home is essential to inform policy and planning of all aspects of dialysis services. Our research will have impact on the growing number of patients with ESKD, the health spend of both DHBs and NZ at large, and is aligned with the global strategy improving patient-centred care in chronic diseases.

**Funding considerations:**

Funding for the researchers time has already been obtained through a research grant. All interviews will be conducted in the researchers time, and all costs will be incurred by the researcher.

There will be no associated costs to the Renal Service or DHB incurred from this project. The only time involved of DHB staff is with the recruitment of patients, which is only expected to be minimal for approximately 10-15 patients.