RACP
Specialists. Together
EDUCATE ADVOCATE INNOVATE

RACP Foundation Research Awards

FINAL REPORT

Project / Program Title		Towards improving patient-important outcomes in haemodialysis
Name		Dr Andrea Viecelli
Award Received		2019 The Jacquot Research Establishment Fellowship
Report Date		11 December 2019
Administering Institution		University of Queensland
Funding Period	Start Date:	1/1/2019
	Finish Date:	31/12/2019

PROJECT SUMMARY

Chronic kidney disease is a common, yet progressive and debilitating condition affecting 10% of Australians and is the 10th leading cause of death. Haemodialysis (HD) is the most common treatment for kidney failure, yet burdensome, time-consuming, and costly ($1.1 billion/year in Australia alone). Patients on HD often experience severe and overwhelming pain, fatigue, itching, nausea, and depression and report their quality of life (Qol) at <60% of full health, yet research to improve these outcomes is currently limited by inconsistent, selective and under-reporting of patient-important outcomes. This research project assesses whether tablet-based electronic collection of symptoms that HD patients may experience with feedback to the treating clinicians is feasible and acceptable in preparation for a large study to determine whether this intervention improves the quality of life and survival of patients on HD. In addition, this research project validates critically important outcome measures for HD research based on the shared priorities of patients, caregivers and health professionals, established through the Standardised Outcomes in Nephrology (SONG) initiative (www.songinitiative.org) to ensure global implementation of these core outcomes in research and clinical practice.

PROJECT AIMS / OBJECTIVES

The aims & hypothesis of this project are twofold:

1. To validate critically important outcome measures in HD based on the shared priorities of patients and health professionals, established through the international Standardised Outcomes in Nephrology (SONG) initiative (www.songinitiative.org) to ensure global implementation of these core outcomes in research and clinical practice. We hypothesise that the two core outcome measures, **fatigue** and **vascular access function**, are valid and can be measured as part of routine clinical practice.

2. To determine the technical and clinical feasibility and acceptability of an electronic PROMs tablet-based data collection and feedback to clinicians in preparation of a larger registry-based cluster randomised trial (SWIFT - Symptom monitoring With Feedback Trial) involving 160 dialysis units and ~3,000 patients in Australia and New Zealand to determine the clinical- and cost-effectiveness of symptom monitoring with feedback to clinicians in improving patient-important outcomes

compared with standard care. We hypothesise that registry-based PROMs monitoring with feedback to clinicians is clinically and technically feasible and acceptable.

These aims have been met by:

1. Conducting two international multicentre validation studies to assess whether the proposed core outcome measures (i.e. a 3-item fatigue questionnaire and vascular access intervention rates) can be captured accurately and are feasible to be implemented globally in HD trials, registries and clinical practice for guiding quality improvement and care delivery. Preliminary data show that fatigue is a valid outcome measure. The study to validate vascular access function has been successfully designed, registered and peer-reviewed and patient recruitment has started.

2. Conducting a pragmatic cluster-randomised SWIFT pilot study to determine whether 3-monthly electronic symptom monitoring using the Integrated Palliative Care Outcome Scale with feedback to clinicians, and 6-monthly measurement of health-related quality of life using the EQ-5D- SL instrument is feasible and acceptable to HD patients and to their treating clinicians. Preliminary data from 163 currently enrolled patients show that this intervention is technically and clinically feasible.

SIGNIFICANCE AND OUTCOMES

Significance of outcomes of this research project

The research program is novel, scalable, of high impact and targets critically important outcomes in HD.
The anticipated outcomes:
1. The use of validated core outcome sets that are based on the shared priorities of patients and health professionals is a powerful research strategy to inform clinical practice in a reliable and meaningful way. SONG core outcomes have already been endorsed by almost 20 renal societies, networks and service providers (htt12://songinitiative. org/endorsementl). Effective implementation strategies have been established to ensure successful uptake of core outcomes in nephrology research and clinical practice with support from policy makers, industry and journal editors as well as over 9500 patients, caregivers and health professionals from over 100 countries.
2. Implementing feasible and validated patient-important core outcome measures such as fatigue and vascular access function globally in HD trials, national renal registries (e.g. ANZDATA), and clinical practice would be a major step forward in reporting what is important to patients and will maximise our chances of discovering effective interventions to reduce these devastating outcomes in HD.
3. Monitoring patient-reported outcome measures (PROMS) on HD with feedback to their treating clinician will facilitate patient- centred care.
4. PROMS monitoring with feedback for active symptom management is expected to lower symptom burden and improve Qol, dialysis dose and treatment withdrawal rates of patients on dialysis.
5. For over ~9000 Australians on facility-based HD, this could translate to a societal gain of at least 613 additional years of life lived in perfect health, an outcome valued at ~$31M per year.
6. More globally, symptom monitoring with feedback to clinicians could change practice and outcomes of >2 million patients currently receiving HD worldwide.
7. Successful linkage of electronically captured PROMS data with an already established clinical and treatment registry across Australia and New Zealand (ANZDATA) enables collection of data that are meaningful to both professional and patients.
8. National registry-embedded PROMS data will shed light on many unanswered questions including the frequency and severity of symptoms experienced by patients on HD, patient-, treatment, and centre-level predictors for experienced symptoms and Qol measures as well as associations with clinical outcomes including survival and quality of life.
9. National availability of electronic PROM data in HD will create opportunities for quality improvement, benchmarking and development of interventions to improve outcomes.

The proposed research project is of high impact and targets critically important outcomes in HD.

The knowledge gained from this project will undoubtedly impact on the quality of HD research conducted in Australia and worldwide and inform health policy and service delivery to provide better patient-centred care. It will also lead to a paradigm shift in research and clinical care by involving patients as our partners.

PUBLICATIONS / PRESENTATIONS

Planned academic output for the current project:

Protocol manuscript for the VALID study (in production)

Protocol manuscript for the SWIFT pilot study (in production)

Protocol manuscript for the SWIFT qualitative studies (in production) Manuscript for the SONG Fatigue Validation study (in production) Manuscript for the SONG Vascular Access Validation Study (planned) Manuscript for the SONG Vascular Access Secondary Outcomes

(planned)

Manuscript for the SWIFT Pilot Study (planned)

Publications related to this project:

Viecelli AK et al. Identifying critically important vascular access outcomes for trials in haemodialysis: an international survey with patients, caregivers and health professionals. Nephrol Dial Transplant. 2019 AUQ 1. pii: qfz148. doi: 10.1093/ndt/Qfz148

Viecelli AK, Tong A, O'Lone E et al. Report of the Standardised Outcomes in Nephrology-Hemodialysis (SONG-HD) Consensus Workshop on Establishing a Core Outcome Measure for Hemodialysis Vascular Access. Am J Kidney Dis. 2018;71(5):690-700.

Viecelli AK, O'Lone E, Sautenet B et al. Vascular Access Outcomes Reported in Maintenance Hemodialysis Trials: A Systematic Review. Am J Kidney Dis. 2018;71(3):382-391.

Tong A ... Viecelli A ... Craig JC. Implementing core outcomes in kidney disease: report of the Standardized Outcomes in Nephrology (SONG) implementation workshop. Kidney International. 2018; 94(6): 1053-1068.

Tong A, ... Viecelli A et al. Clinicians' and researchers' perspectives on establishing and. implementing core outcomes in haemodialysis. BMJ Open. 2018;8(4):e021198.

Ju A, ... Viecelli A et al. Establishing a Core Outcome Measure for Fatigue in Patients on Hemodialysis. A SONG-Hemodialysis Consensus Workshop Report. Am J Kidney Dis. 2018;72(1):104-112.

ACKNOWLEDGEMENTS

Manuscripts that are currently in production or planned where my award will be acknowledged:

Protocol manuscript for the VALID study (in production)

Protocol manuscript for the SWIFT pilot study (in production) Protocol manuscript for the SWIFT qualitative studies (in production) Manuscript for the SONG Fatigue Validation study (in production) Manuscript for the SONG Vascular Access Validation Study (planned) Manuscript for the SONG Vascular Access Secondary Outcomes

(planned)

Manuscript for the SWIFT Pilot Studv {Planned)