PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT
– Review and Feedback Intervention –

InterACT study: Intervention for Appropriate Care and Treatment

RBWH HREC reference (HREC/2019/QRBW/51606)
QUT Ethics reference number 1900000630

RESEARCH TEAM

Principal Researcher:	Prof Adrian Barnett	Australian Centre for Health Services Innovation, QUT
Associate Researchers:	Prof Ken Hillman	University New South Wales
	Prof Lindy Willmott	Australian Centre for Health Law Research, QUT
	Prof Ben White	Australian Centre for Health Law Research, QUT
	Prof Gillian Harvey	University of Adelaide
	Prof Leonie Callaway	QUT
	A/Prof Magnolia Cardona	Bond University
	Prof Nick Graves	Australian Centre for Health Service Innovation, QUT
	Dr Xing Lee	Australian Centre for Health Service Innovation, QUT
	Prof Steve McPhail	Australian Centre for Health Service Innovation, QUT

DESCRIPTION

This research project is being undertaken as part of a NHMRC Partnership Project Grant (GNT1151923) led by the Australian Centre for Health Services Innovation (AusHSI) and the Australian Centre for Health Law Research (ACHLR) at Queensland University of Technology (QUT).

The purpose of this research project is to implement a prospective feedback loop intervention in three acute hospitals, to promote appropriate care and treatment decisions and pathways for older patient populations at the end-of-life. The study will use a stepped-wedge design, in which enrolled teams act as their own control. Your team's results will not be directly compared with other teams.

Your clinical team is invited to participate in this research project because your team has been identified as providing care to patients who, by their age and medical profile, could be at risk of receiving non-beneficial treatment at the end-of-life.

PARTICIPATION

Your clinical team is being asked to participate in a patient record review and feedback intervention study.

The study will run for 70 weeks and consist of 5 phases: Site preparation and clinical team recruitment, Usual care exposure, Intervention establishment, Intervention exposure, and Post-intervention. During the Usual care exposure, Intervention establishment and Intervention exposure phases we will access your clinical team's patient records. These records will be screened using the CriSTAL and SPICT^{TM} tools and a record kept of patients identified as being high-risk CriSTAL and SPICT positive. The study team will not record screening results in the patient's record and you will not be advised of the screening outcomes during the Usual care exposure and Intervention establishment phases.

During the 4-week Intervention establishment phase you will be invited to participate in information sessions about the study and to provide input into tailoring the intervention for implementation with your team, including the feedback mechanism and the team response to the feedback. The nominated approach will be piloted for one week and reviewed for feasibility with the study team.

For the Intervention exposure phase, your hospital will be randomly allocated to an intervention arm of either 16, 25 or 34 weeks. During the Intervention exposure phase, your clinical team nominee will receive screening feedback twice a week using the mechanism and approach decided in the Intervention establishment phase. This information can be used by your clinical team to inform patient care. The study team will not record screening results in the patient's record.

During each of the Intervention establishment, Intervention exposure and Post-intervention phases you may be approached to participate in an interview about the study. The interviews aim to guide tailoring of the intervention and support monitoring of the implementation process. Your decision to participate or not in these interviews will not affect your participation in the trial. You can participate in the trial without participating in the interviews.

Your clinical team's decision to participate in this research project is entirely voluntary. Your team's decision to participate or not participate will in no way impact upon your current or future relationship with QUT, *hospital name, Metro North/Gold Coast Hospital and Health Service*, or Queensland Health.

If your clinical team agrees to participate, data will be collected on your patients for the duration of the study period. You may choose to discontinue involvement in study activities, however screening will continue to be conducted on your team's patients' medical records and feedback provided to nominated members of your clinical team.

EXPECTED BENEFITS

It is expected that this research project could directly benefit you and your patients. Information provided by this research could inform the care you provide to your patients who are nearing the end of their life and support appropriate care and treatment decisions. This research may provide healthcare providers and policy makers with an approach to reduce unnecessary use of health services for patients nearing the end of their life.

RISKS

There are negligible risks involved in participating in this research project beyond those associated with your normal day to day work. Participation in the study may add a layer of inconvenience associated with additional time outlay for study activities, for receiving feedback and providing a tailored patient response. This is likely to be managed as part of usual workload fluctuations and to be distributed across the clinical team. Workload impact will be monitored by the study team and may inform modification of the study processes.

PRIVACY AND CONFIDENTIALITY

All data collected will be treated confidentially unless required by law, or by regulatory or monitoring bodies, such as the Human Research Ethics Committee. A hospital executive advisory group will be convened to support the implementation of the trial at your hospital. They will be aware of participating clinical teams but will not have access to team level record review results.

Data collected as part of this research project will be stored securely, as per QUT's Management of research data policy, on password protected hard disk drives at QUT, with automated backup, in a secure facility, accessible only by nominated study team members. Data will be retained for a minimum of 15 years.

The research project is funded by a NHMRC Partnership Project Grant (GNT1151923). As per NHMRC requirements, non-identifiable data collected during this study will be stored on an open access database for secondary analysis at the conclusion of the project. Non-identifiable data from this research project may be used as comparative data in future projects.

AGREEMENT TO PARTICIPATE

You will have two weeks to discuss participation in the research project with your clinical team. To participate, a lead clinician in your team is required to contact the Research Project Manager and verbally indicate their agreement. The Research Project Manager, Alison Farrington, can be contacted at

alison.farrington@qut.edu.au or 3138 3132.

QUESTIONS / FURTHER INFORMATION ABOUT THE RESEARCH PROJECT

If you have any questions or require further information please contact:

Prof Adrian Barnett (Principal Researcher)	a.barnett@qut.edu.au	3138 6010
Alison Farrington (Research Project Manager)	alison.farrington@qut.edu.au	3138 6132

CONCERNS / COMPLAINTS REGARDING THE CONDUCT OF THE RESEARCH PROJECT

QUT is committed to research integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the research project you may contact the QUT Research Ethics Advisory Team on 3138 5123 or email humanethics@qut.edu.au. The QUT Research Ethics Advisory Team is not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

This study has been reviewed and approved by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (HREC/2019/QRBW/51606). Should you wish to discuss the study in relation to your rights as a participant, or should you wish to make an independent complaint, you may contact the Coordinator or Chairperson, Human Research Ethics Committee, Royal Brisbane & Women's Hospital, Herston, Qld, 4029 or telephone (07) 3646 5490, email: RBWH-Ethics@health.qld.gov.au

THANK YOU FOR HELPING WITH THIS RESEARCH PROJECT.
PLEASE KEEP THIS SHEET FOR YOUR INFORMATION.