7 April 2022

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Dr Conor Brophy
Chair
University Human Research Ethics Committee
Queensland University of Technology

By email: humanethics@qut.edu.au

Dear Dr Brophy

As Chair of the University Human Research Ethics Committee (UHREC), AMA Queensland respectfully seeks your advice on the conduct and findings of the Urinary Tract Infection Pharmacy Pilot – Queensland (UTIPP-Q).

The Health (Drugs and Poisons) Regulation 'Drug Therapy Protocol – Pharmacist UTI Trial', which certified the trial, stipulates that the Queensland Department of Health has engaged QUT to manage implementation and evaluation.

Unfortunately, no information about the trial evaluation has been made available to the public or to Queensland's doctors. To date, the only information available about the trial's outcomes is from coverage of media releases from the Pharmacy Guild of Australia[1], indicating that as at 2 December 2021, 819 pharmacies registered for the pilot, 1,895 pharmacists completed the three hours of training, and 6,300 women accessed the service. The same coverage quotes Professor Lisa Nissen, Head of the School of Clinical Sciences at QUT that the pilot is a success. In another publication, Professor Nissen is quoted as saying '[N]obody's died. It's a good pilot as far as the State Government is concerned'[2].

Although we acknowledge that such media coverage can be sensationalist, AMA Queensland contends that trial participation data does not verify 'success'. Success should be judged by patient safety and health outcomes.

In the absence of evaluation data, AMA Queensland sought information from doctors about their patients' experiences. As part of a survey, Queensland doctors, including doctors who are not members of AMA Queensland, were asked if they had seen patients with complications after accessing the UTIPP-Q. The results were alarming.

More than 1,300 doctors responded to the survey, 184 of whom reported having seen patients with complications from the trial. Some of these doctors had seen multiple patients with complications. Complications ranged from missed diagnoses of sexually transmitted infections, pregnancies, menopause, pre-cancerous conditions, delayed treatment leading to kidney infections, a ruptured ovarian cyst, and a prolapse.

[1] https://www.guild.org.au/news-events/news/qld/womens-health-a-top-priority-as-queensland-health-extends-urinary-tract-infection-pharmacy-pilot
[2] https://www.ausdoc.com.au/news/pharmacists-prescribing-antibiotics-utis-be-made-permanent

AMA Queensland is currently conducting statistical analysis of the survey results and, if your evaluation team would find this helpful, a copy of our report can be shared with QUT.

Anecdotal advice provided to AMA Queensland also raises concerns about the compliance of some participating pharmacies with accreditation requirements, for example, failure to provide access to a private consulting area. Given the very sensitive nature of questions that need to be asked to diagnose UTI, this lack of privacy would fundamentally inhibit the candour of patients' answers. AMA Queensland is keen to understand how QUT monitors practical compliance with accreditation requirements.

AMA Queensland specifically seeks UHREC's advice on the following issues:

- What are the parameters of the QUT evaluation of UTIPP-Q, including how monitoring of patient health outcomes and practical compliance with accreditation requirements is undertaken?
- How is the effectiveness or success of the trial measured?
- What is the budgetary allocation for the evaluation?
- When will evaluation findings be made available to the public? Will this be in sufficient time to adequately inform the Queensland Government's intended expansion into the North Queensland Pharmacy Scope of Practice Pilot, which purports to be based on positive outcomes from the UTIPP-Q?
- Does UHREC have reservations about its ethics approval for UITPP-Q, given the apparent absence of effective monitoring of health outcomes and the experiences of Queensland doctors in caring for patients who have experienced adverse outcomes?

Section 6.5.3 of the University Human Research Ethics Committee charter requires UHREC to 'monitor the conduct of approved research projects until their completion so as to ensure continued compliance with relevant requirements'. The charter also empowers UHREC to 'withdraw or suspend a project's ethics approval if a project is not or cannot be conducted in accordance with the conditions of approval, or continuation of the project may compromise participants' welfare'.

Given QUT's reputation for responsible research, for cultivating a culture of transparency and accountability in research, and for trustworthy data and publications, AMA Queensland seeks UHREC's advice as to how its charter obligations are being met in the UTIPP-Q trial.

Yours sincerely

Prof Chris Perry OAM
President
AMA Queensland

Dr Brett Dale
Chief Executive Officer
AMA Queensland