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Chair, University Human Research Ethics Committee

Office of Research Ethics and Integrity Queensland University of Technology

**Dear Professor Brophy** 

**Professor Conor Brophy** 

Thank you for your letter of 8 April 2022 regarding QUT's ethics approval for Study 2000000140, 'Evaluation of the prescribing pilot: Urinary Tract Infection Pharmacy Pilot Queensland (UTIPP-Q)'.

We appreciate your prompt response.

Of particular interest to AMA Queensland is the clarification in your correspondence about QUT's ethics approval being limited to the research evaluation of the pilot. This has been a source of confusion for our members, and is incongruous with public statements about QUT's role in the pilot.

The Drug Therapy Protocol–Pharmacist UTI Trial, made under the Health (Drugs and Poisons) Regulation 1996, clearly states that QUT had been engaged to 'manage the implementation and evaluation of the trial'.¹ QUT's pivotal role in the pilot has been frequently touted in promotional materials from the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia –

'the Department of Health has engaged the Queensland University of Technology (QUT) to develop, implement and evaluate a state-wide pilot of the management of urinary tract infections (UTIs) by community pharmacists' 2

'the Pharmacy Guild of Australia, Queensland and the Pharmaceutical Society of Australia is (sic) part of a consortium led by QUT which was successful in winning the tender for the pilot'<sup>3</sup>

'Professor Lisa Nissen from QUT, Pilot and Consortium Lead said "...[w]e are looking forward to evaluating the outcomes" <sup>4</sup>.

Does QUT consider it appropriate and best practice for the Pilot and Consortium Lead managing a pilot, to also conduct the evaluation of the pilot?

The lack of transparency around the UTI pilot and its evaluation remains of great concern to AMA Queensland and our members. It is disappointing, and fuels skepticism about the pilot, that none of the following materials are available for review by the public or doctors.

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<sup>&</sup>lt;sup>1</sup> https://documents.parliament.qld.gov.au/tableOffice/TabledPapers/2020/5620T974.pdf

<sup>&</sup>lt;sup>2</sup> https://www.psa.org.au/resource/uti-pharmacy-pilot-qld/#1619140550631-1bd821a7-e5b9

<sup>&</sup>lt;sup>3</sup> https://www.psa.org.au/13954-2/

<sup>4</sup> https://www.psa.org.au/13954-2/

- Evaluation methodology
- Application for ethics approval
- Ethics approval
- Evaluation report prepared by QUT
- Pharmaceutical Society of Australia Guidance for provision of antibiotics for acute uncomplicated cystitis in women (the Practice Standard) which outlines the endorsed model of care for the pilot, and against which pharmacy practice should have been assessed as part of QUT's evaluation.

Does QUT have sufficient confidence in the rigour of these materials to share them with AMA Queensland to help us better understand the scope of QUT's evaluation and QUT's ethics approval, and to enable appropriate review of the pilot and its outcomes?

In your reply to our correspondence, you questioned whether doctors reported patient complications to Queensland Health. There was no clear mechanism for doctors to do this. Some doctors reported that they specifically researched, unsuccessfully, options for reporting their patients' adverse events. To AMA Queensland this demonstrates an ambivalence about obtaining accurate information from doctors who are key stakeholders likely to observe health outcomes resulting from patients accessing the pilot.

Does the QUT evaluation highlight this flaw and make recommendations about effective mechanisms for patient and doctor reporting of adverse outcomes?

Your letter also outlined that data for the QUT study originated from the clinical record completed after the pilot service was provided, including data collected from the seven-day follow up. It is our understanding that the pharmacist who provided the pilot service also conducted this follow up. We therefore seek your advice as to whether data was subject to independent review and verification, and whether this practice—where the pharmacist who delivered a service also conducts the follow up of patient experience—is best practice in evaluation methodology.

This seems an ineffective method to elicit honest, credible and forthright information about a patient's experience for a number of reasons.

- If a patient is dissatisfied with the treatment provided by a pharmacist, they may be
  reticent to explain that dissatisfaction to the same pharmacist, especially if the patient felt
  uncomfortable with, or embarrassed by, the interaction. This would be especially
  problematic in a rural town with only one pharmacist.
- In recording negative feedback about the pharmacist's performance or patient outcomes, it is plausible that feedback may be deliberately or inadvertently tempered or moderated.
- A pharmacist expecting poor feedback from a particular patient may be less diligent and proactive in their efforts to follow up with that patient.

Was this data subject to independent review and verification? Does QUT have confidence in the independence, rigour and credibility of data that informed the evaluation, and the conclusions drawn from that data?

As foreshadowed in our previous correspondence, our survey of Queensland doctors has been subject to independent statistical analysis and the final report is now enclosed for your consideration. Please note this report has not be publicly released and is not for distribution.

AMA Queensland would appreciate your advice as to whether QUT's evaluation captured and reflected the types of incidents reported by doctors. If these incidents are not evident in the evaluation report, does this call into question the comprehensiveness of QUT's evaluation?

In summary, AMA Queensland would be grateful for your consideration of, and response to, the following questions.

- 1. Does QUT consider it appropriate and best practice for the Pilot and Consortium Lead delivering a pilot, to also conduct its evaluation?
- 2. Does QUT have sufficient confidence in the rigour of the evaluation methodology, ethics application and approval, and evaluation report to share them with AMA Queensland to help us better understand the scope of QUT's evaluation and QUT's ethics approval for it, and to enable appropriate review of the evaluation and its outcomes?
- 3. Does the QUT evaluation highlight the absence of a clear reporting mechanism for patient complications and adverse outcomes, and make appropriate recommendations about rectifying this failure?
- 4. Given that pharmacists who provided the pilot services collected the data that informed the pilot evaluation, was this data subject to independent review and verification?
- 5. Does QUT have confidence in the independence, rigour and credibility of this data and the conclusions drawn from it?
- 6. Did pharmacists, in their self-reported follow up of patients, identify and record the types of incidents reported by doctors in AMA Queensland's survey?
- 7. Did the evaluation follow best practice?

Our members regularly participate in, and highly value, QUT's scientific, peer-reviewed published research. Our members have expressed concern over QUT's participation in the UTI pilot as it does not appear to meet to the high research standards and protocols to which they are accustomed from QUT.

As a courtesy, we have also enclosed an embargoed copy of AMA Queensland's draft press release about the survey report, which highlights some of our reservations about the evaluation of the pilot.

Yours sincerely

Professor Chris Perry OAM President

**AMA Queensland** 

Dr Brett Dale Chief Executive Officer AMA Queensland

## Enclosures:

- AMA Queensland's Survey Report on the Urinary Tract Infection Pharmacy Pilot Queensland and North Queensland Pharmacy Scope of Practice Pilot – Confidential not for distribution
- Embargoed draft press release on survey report findings