12 September 2022

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Mr Shaun Drummond
Acting Director-General
Department of Health
GPO Box 48
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By email: DG_Correspondence@health.qld.gov.au

Subject: Dr Dawson-Smith Letter & Issues Paper:
'The UTIPP-Q & QUT – A Case of Research Misconduct?'

Dear Mr Drummond

As you are aware, AMA Queensland has grave concerns about the risk to patient safety of the Urinary Tract Infection Pharmacy Pilot – Queensland (UTIPP-Q) and proposed North Queensland Scope of Practice Pilot (NQ Pilot).

Attached is a letter and Issues Paper, *'The UTIPP-Q and QUT – A Case of Research Misconduct',* written by general practitioner, Dr Stephanie Dawson-Smith. Dr Dawson-Smith has undertaken a comprehensive analysis of the UTIPP-Q and Queensland University of Technology's (QUT's) UTIPP-Q Outcomes Report (the 'QUT Report'), which have been used to justify pharmacist-prescribing for UTIs throughout Queensland and the NQ Pilot. These findings have been shared across academia and several Queensland universities have confirmed they are investigating Dr Dawson-Smith's concerns.

Dr Dawson-Smith has identified extremely concerning and serious failings of the UTIPP-Q and QUT Report. The most alarming of these include that the UTIPP-Q was not conducted according to ethical principles; adopted a flawed clinical protocol; and disregarded antimicrobial stewardship safeguards; and that the QUT Report misrepresented, omitted, obfuscated and falsely reported data; and presented key findings which were unsubstantiated or possibly false.

The Issues Paper demonstrates that the UTIPP-Q and QUT Report should never have been used to justify pharmacist-prescribing for UTIs and the NQ Trial.

AMA Queensland fully supports Dr Dawson-Smith's analysis and shares her grave concerns about the serious threat the UTIPP-Q, pharmacist-prescribing for UTIs and NQ Pilot pose to 'patient safety, the integrity of our primary care model and the public's trust in our health system'. We reiterate her call for their immediate abandonment.

We urge you to closely examine the alarming issues identified in Dr Dawson-Smith's letter and Issues Paper and to act swiftly to protect the safety of patients throughout Queensland from these dangerous and unnecessary programs.

Yours sincerely

Dr Maria Boulton
President
AMA Queensland

Dr Brett Dale
Chief Executive Officer
AMA Queensland

cc: Prof Keith McNeil
Chief Medical Officer, Queensland Health
via email: PDCorro@health.qld.gov.au

30 August 2022

Dr Stephanie Dawson-Smith
General practitioner

Dr Anne Walsh
Acting Director
Office of Research Ethics and Integrity
Queensland University of Technology

By email: orei.enquiries@qut.edu.au

Re: UTIPP-Q, QUT UTIPP-Q Outcome Report & NQ Pilot Threat to Patient Safety

Dear Dr Walsh,

Dr Helen Brown, Deputy Director-General of Clinical Excellence Queensland, suggested I write to express my grave concerns regarding the evaluation of the Urinary Tract Infection Pharmacy Pilot – Queensland (UTIPP-Q) and QUT's involvement.

The UTIPP-Q Outcomes Report (the QUT Report) does not allay concerns expressed by Queensland doctors regarding the safety of pharmacist-prescribing for patients with urinary tract infection (UTI) symptoms. More alarmingly, the alleged success of the UTIPP-Q has been used to justify both permanent pharmacist-prescribing for UTIs throughout Queensland and the proposed North Queensland Pharmacy Scope of Practice Pilot (NQ Pilot), which is exponentially more complex and fraught with danger.

These programs pose a serious threat to patient safety, the integrity of our primary care model and the public's trust in our health system. I call for their immediate abandonment pending an open, external and independent investigation of the UTIPP-Q, evaluation and QUT Report.

The UTIPP-Q was not conducted according to ethical principles and should have been registered as a clinical trial. There was insufficient evidence to support delivering the UTIPP-Q in a non-research context since the international programs cited to justify its implementation occurred in different health system contexts with different financial incentives and clinical access. In fact, the people delivering the UTIPP-Q had a financial conflict of interest in the program's results. In addition, the patients treated were subjected to an intervention with considerable uncertainty about its benefits as stated by health experts.

The Australian Medical Association Queensland (AMA QLD), Royal Australian College of General Practitioners QLD (RACGP) and Australian College of Rural and Remote Medicine QLD (ACRRM) all expressed concerns about the UTIPP-Q and its problematic implications for patient safety. These organisations were so dismayed that they either withdrew from (RACGP) or declined to participate in (AMA QLD and ACRRM) the UTIPP-Q's Steering and Advisory Group.

Despite this, QUT continued with the UTIPP-Q. I request an explanation as to:

- why, when QUT became aware of these bodies' concerns, the UTIPP-Q Consortium obtained 'other medical input' into the Steering and Advisory Group rather than considering the concerns raised by AMA QLD, RACGP and ACRRM;
- which expert medical groups provided the 'other medical input';
- why these concerns did not cause QUT's ethics committee to reevaluate the appropriateness of the UTIPP-Q's continuation, particularly since it did not obtain ethics approval; and

- why QUT failed to respond to the petition for a full and transparent evaluation of the UTIPP-Q, raised by James Lake with the Queensland Parliament and signed by 1278 people, including many medical practitioners.

In addition, specific concerns I have about QUT's involvement in the UTIPP-Q are set out in the attached Issues Paper and I request your response to the issues raised. I believe there are significant concerns for patient safety as a result of the UTIPP-Q and subsequent proposed NQ Pilot.

As a research institution, QUT has a responsibility to establish an independent, external review of the UTIPP-Q and QUT Report. It also must not commence the NQ Pilot until the review is completed; until the issues I raise are comprehensively addressed; and until it is certain that permanent pharmacist-prescribing for UTIs and the NQ Pilot do not threaten patient safety.

I am willing to meet with you and others involved in both programs to explain my concerns and discuss further.

I look forward to your response.

Yours sincerely,

Dr Stephanie Dawson-Smith
MBBS DCH FRACGP

Copied to:
Professor Lisa Nissen, UTIPP-Q Trial Coordinator, Head of Clinical Sciences, Queensland University of Technology.
Professor Margaret Sheil AO, Vice-Chancellor and President, Queensland University of Technology.
Distinguished Professor Patsy Yates, Executive Dean, Faculty of Health, Queensland University of Technology.
Professor Janet Davies, Associate Dean of Research, Faculty of Health, Queensland University of Technology.
Dr Helen Brown, Deputy Director-General of Clinical Excellence Queensland.
Hon Yvette D'Ath, Queensland Minister for Health and Ambulance Services.
Ms Melissa Fox, Chief Executive Officer, Health Consumers Queensland.
Professor Geoff McColl, Executive Dean, Faculty of Medicine, University of Queensland.
Professor Katharine Wallis, Head, General Practice Clinical Unit, University of Queensland.
Associate Professor Riitta Partanen, Director, Rural Clinical School, University of Queensland.
Dr Jean Spinks, Senior Research Fellow, Centre for the Business and Economics of Health, University of Queensland.
Professor Keith Grimwood, Deputy Head, School of Medicine and Dentistry, Griffith Menzies Research Institute.
Professor Amanda Wheeler, Professor of Mental Health, School of Pharmacy and Medical Sciences, Griffith (Menzies).
Professor Richard Murray, Dean, College of Medicine and Dentistry, James Cook University.
Professor Sarah Larkins, Director, Research Development, College of Medicine and Dentistry, James Cook University.
Professor Beverley Glass, Professor of Pharmacy, College of Medicine & Dentistry, James Cook University.
Dr Fei Sim, National President, Pharmaceutical Society of Australia.
Mr Shane MacDonald, Queensland Branch President, Pharmaceutical Society of Australia.
Professor Trent Twomey, National President, Pharmacy Guild of Australia.
Mr Chris Owen, President, Queensland Branch, Pharmacy Guild of Australia.
Dr Brett Dale, Chief Executive Officer, Australian Medical Association Queensland.
Mr Paul Wappett, Chief Executive Officer, Royal Australian College of General Practitioners.
Dr Marita Cowie, Chief Executive Officer, Australian College of Rural & Remote Medicine.
Professor Christine Hughes, Interim Dean and Professor, Faculty of Pharmacy and Pharmaceutical Sciences, University of Alberta, Canada.
Professor Carlo Marra, Dean, University of Otago, New Zealand.
Professor John Fraser, Dean, Faculty of Medical and Health Sciences, University of Auckland, New Zealand.

Issues Paper:

The UTIPP-Q and QUT – A Case of Research Misconduct?

Introduction

There are multiple, serious issues with the Urinary Tract Infection Pharmacy Pilot – Queensland (UTIPP-Q) and North Queensland Pharmacy Scope of Practice Pilot (NQ Pilot) (together, the 'Pilots') which should result in their immediate abandonment. Many of the failures of the UTIPP-Q are demonstrated within QUT's UTIPP-Q Outcome Report (the 'QUT Report'), despite the authors' presentation of the UTIPP-Q as a success. Failings in the UTIPP-Q were also found by the AMA Queensland's Survey Report: Urinary Tract Infection Pharmacy Pilot Queensland and North Queensland Pharmacy Scope of Practice Pilot (the 'AMA QLD Report').

The QUT Report does not allay the significant concerns that have been raised about the safety of pharmacist-prescribing of antibiotics to patients with suspected urinary tract infections (UTIs), including public health concerns regarding antimicrobial stewardship. This should alarm researchers across Australia and QUT's academics and executive in particular.

QUT has an obligation, as a research institute that abides by the Australian Code for the Responsible Conduct of Research, to investigate the QUT Report authors for potential breaches of the requisite QUT Code. As the lead author of the report is the Head of the School of Clinical Sciences at QUT, this review should be external and independent.

The failings of the QUT Report are numerous and it is outside the scope of this paper to document every instance. The most concerning aspects can, however, be categorised into the following broad areas:

1. Accepted clinical protocols not followed;
2. Methodological bias;
3. Adverse events grossly unexamined;
4. Data omitted, obfuscated, misrepresented & falsely reported;
5. All 'key findings' either unsubstantiated or false; and
6. Fundamental safeguards for patient safety & antimicrobial stewardship excluded.

These failings are dealt with in turn under 'Failing 1' to 'Failing 6'.

Failing 1: Accepted Clinical Protocol Not Followed

One of the greatest failings of the UTIPP-Q and subsequent QUT Report was that the agreed clinical protocol was not implemented. The specific concerns with this failing are:

1. The UTIPP-Q Workflow did not follow clinical protocols, resulting in a flawed protocol that seriously threatened patient safety;
2. General Practitioners (GPs) were not notified that their patients had been prescribed antibiotic therapy for UTI symptoms in clear breach of the original, intended protocol which also caused fragmentation of care;
3. The flawed protocol failed to follow the Queensland Parliament's agreed risk-management framework; and
4. Whilst flawed, pharmacists still failed to follow the protocol provided.

Each of these issues is set out in the numbered sections below.

1. Failure of the UTIPP-Q Workflow to follow clinical protocols, resulting in the use of a protocol that seriously threatened patient safety

The flawed protocol which pharmacists were required to use in delivering the UTIPP-Q was the GuildCare Software[1] Workflow (the 'GuildCare Workflow'). The GuildCare Workflow markedly deviated, through alterations and omissions, from accepted clinical protocols and the algorithms and standards developed by the Pharmaceutical Society of Australia (QLD) (the PSA) in collaboration with the UTIPP-Q Consortium.[2] This included deviation from the agreed UTIPP-Q Service Workflow Algorithm, Treatment Algorithm and Practice Standard (together, the 'Consortium Workflow').

This prevented pharmacists from providing appropriate care since the GuildCare Workflow did not align with clinical protocols. Alarmingly, the QUT Report did not acknowledge the differences between the GuildCare Workflow that was implemented and mandated in the UTIPP-Q and the Consortium Workflow that was approved by the research team and the UTIPP-Q Consortium.

The most concerning deviations in the GuildCare Workflow from that of the approved Consortium Workflow are set out in 1.1 to 1.6 below.

1.1. Incorrect ineligibility criteria to identify recurrent UTI

The Consortium Workflow contained ineligibility criteria which were essential for patient safety in line with accepted clinical protocols. However, the GuildCare Workflow altered these criteria as set out in the below table.

Consortium Workflow Ineligibility Criterion	GuildCare Workflow Ineligibility Criterion
Two or more UTIs within **6 months**	Two or more UTIs within **2 weeks**
Three or more UTIs within 12 months	**Four** or more UTIs within 12 months

These criteria are essential to ensure patients with recurrent UTI, and those with symptoms attributed to a UTI but who in fact have another illness, are appropriately investigated and treated. Deviating from these criteria puts patients at risk of being left untreated. This is a critical flaw in the UTIPP-Q's implementation.

The GuildCare Workflow criteria alterations would have caused patients who should have been referred to their GP with recurrent UTI symptoms (and would have been if the Consortium Workflow was implemented) to be wrongly deemed eligible for the UTIPP-Q. This failure would have led to these patients being inappropriately treated and would have delayed or prevented them from accessing appropriate medical care.

There is no data available on how many patients were inappropriately treated via this flaw in the protocol as only prior UTI treatments through UTIPP-Q were captured, not prior UTI treatments with a doctor.

Despite the limited data available from the UTIPP-Q evaluation, it does demonstrate patients were inappropriately treated because of the flaws in the GuildCare Workflow. The QUT Report found 3.5% of patients used the UTIPP-Q service more than once, with a median interval between repeat services of 5.3 months. This is clearly less than the Consortium Workflow's criterion of 6 months between repeat treatments.

[1] GuildCare Software is provided by GuildLink Pty Ltd, a subsidiary of the Pharmacy Guild of Australia

[2] A consortium led by QUT (Pharmacy) and including James Cook University, Griffith (Menzies), UQ (Pharmacy), the Pharmaceutical Society of Australia (QLD), the Pharmacy Guild of Australia (QLD) and international collaborators from Canada (University of Alberta) and New Zealand (Otago and Auckland) were engaged by the Department of Health to implement the Urinary Tract Infection Pharmacy Pilot – Queensland (UTIPP-Q).

This shows that on average the patients who accessed the UTIPP-Q more than once were inappropriately treated and should have been deemed ineligible and referred to a GP. It is important to note that broader population research indicates that UTI recurrence within six months is much more common than what was captured in the UTIPP-Q.[3] Since doctors treat the majority of UTIs, the number of patients inappropriately treated due to the GuildCare Workflow alterations could number in the thousands.

The QUT Report also found that 10 individuals inappropriately received three UTIPP-Q services within one year. This figure would also be grossly underestimated as the UTIPP-Q did not capture patients treated by doctors for UTI once or more in the past 12 months *in addition* to participating in the UTIPP-Q.

1.2. Omission of key ineligibility criteria

The GuildCare Workflow also omitted key ineligibility criteria that had been included in the Consortium Workflow – patients who presented with vomiting; and those with a history of urinary tract obstruction. This may have resulted in patients with an important alternative diagnosis and patients with complicated UTIs being inappropriately treated under the UTIPP-Q.

Other important ineligibility criteria that had been included in the Practice Standard were omitted in the UTIPP-Q Treatment Algorithm, and then omitted in the GuildCare Workflow. These included:

- recurrence of UTI symptoms within two weeks of completion of an appropriate antibiotic;[3]
- previous episodes of pyelonephritis;
- recent birth, miscarriage or abortion;
- intrauterine device in situ;
- recent antibiotic treatment;
- first-time symptoms; and
- symptoms not previously diagnosed by a medical practitioner.

The above omissions would all increase the risk that patients were misdiagnosed and inappropriately not referred to a doctor for assessment and management.

1.3. Omission of key ‘safety-net’ advice to follow-up with GP

The GuildCare Workflow omitted the Consortium Workflow requirement that patients be advised to seek follow-up with a GP if their symptoms did not respond to the antibiotic treatment within 48 hours.

The importance of adhering to clear and consistent safety-net mechanisms for patient follow-up cannot be understated. It is vital to patient safety and continuity of care. This is particularly important in a program like the UTIPP-Q where no physical examination or testing was performed to confirm the presence of a UTI or to test for antibiotic resistance.

It is particularly concerning that this safety-net was omitted in the GuildCare Workflow as it could have been easily included in the checkbox steps for pharmacists to confirm they had:

- provided the patient with a medication CMI;
- discussed with the patient self-care advice about UTIs; and
- provided the patient with self-care information about UTIs.

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[3] It is unclear if this omission was due to the GuildCare Workflow designers misinterpreting this criterion as an ‘alternative’ to the ineligibility criteria ‘two or more UTIs within 6 months’. This is a possible reason as they did not have the clinical experience to understand this criterion relates to a likely relapse of UTI rather than a recurrence. A relapse is of greater concern than a recurrence as it indicates antimicrobial resistance.

The QUT Report contains data that suggests pharmacists in the UTIPP-Q did not consistently provide this advice. It shows 41% (129/313) of patients who had unresolved symptoms at the Telephone Follow-up had not sought care with a medical practitioner.

Other important safety-net advice that had been included in the Practice Standard were omitted in the UTIPP-Q Treatment Algorithm, and then omitted in the GuildCare Workflow. These included a requirement for pharmacists to advise patients to consult a medical practitioner promptly if they:

- had a recurrence of uncomplicated UTI symptoms within two weeks of completing the prescribed antibiotic; and/or
- developed symptoms which were not symptoms of an acute uncomplicated UTI.

1.4. Inappropriate use of gender instead of sex

The Consortium Workflow used the eligibility criterion 'woman' which was changed to 'gender - female' in the GuildCare Workflow. As a result, a transgender patient who identified as being of female gender (with male biological sex) would have been deemed eligible under the GuildCare Workflow. The eligibility criterion should have been 'sex – female' not 'woman' or 'gender – female'. The criterion 'sex – female' focuses on biological sex rather than social conceptions of gender.

This has important safety implications as the UTIPP-Q was not designed to treat patients with male anatomy. A UTI in a patient of male sex is, by definition, complicated and mandates a referral to a doctor for a comprehensive assessment.

The AMA QLD Report found that at least three patients of male sex presented with complications as a result of participating in the UTIPP-Q.

1.5. Patients inappropriately asked whether they were pregnant without assessment of whether they could be pregnant

The GuildCare Workflow screening questions asked patients a single, binary yes/no question as to whether they were pregnant. This is inadequate to assess for undiagnosed pregnancy on history.

There is a validated protocol for questions to ask to be reasonably certain a patient is not pregnant and these were not followed in the UTIPP-Q.[4] Unsurprisingly, the QUT Report identified just six patients out of 6751 who were pregnant. This is particularly concerning given:

- the predominant population of patients treated in the UTIPP-Q were of childbearing age; and
- the first-line treatment was trimethoprim which has known teratogenic effects on the fetus in the first trimester of pregnancy and is, therefore, contraindicated in early pregnancy.

The inadequacy of the questioning about possible pregnancy likely contributed to the number of patients who were treated with trimethoprim through the UTIPP-Q despite being pregnant as reported by doctors in the AMA QLD Survey.

1.6. Patients inappropriately asked if they were at risk of an STI with inadequate assessment of whether they were likely to have a clinically-relevant STI

The GuildCare Workflow screening questions asked patients a binary yes/no question as to whether they were at risk of an STI. Every person who is sexually active is at risk of contracting an STI, yet the QUT Report only identified six out of 6751 patients at such risk.

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[4] Centers for Disease Control and Prevention. 2016. *How to be reasonably certain that a woman is not pregnant*. [Online] Available at: <https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/notpregnant.html>.

It is highly unlikely that of 6751 adults only six had ever been sexually active. It is therefore probable that either pharmacists or patients or both did not understand this question. Asking about and stratifying risk of having a clinically-relevant STI requires clinical training and experience to ensure questioning occurs in a safe and acceptable manner that is likely to elicit accurate and useful information. It was not adequate or useful to ask patients the question 'are you at risk of STI, yes or no?'.

The failure of the GuildCare Workflow to aid pharmacists in identifying patients who had a clinically-relevant STI was supported by the AMA QLD Report. It found the most common misdiagnosis was related to the patient having an STI rather than a UTI. These included chlamydia, herpes and gonorrhoea. A number of patients were also reported to have pelvic inflammatory disease.

A pharmacist prescribing the incorrect antibiotic because they misdiagnose an STI as a UTI delays treatment of the STI. Early treatment of chlamydia and gonorrhoea can help reduce the risk of female patients developing pelvic inflammatory disease, as well as the risk of further transmission to sexual partners.

Patients with pelvic inflammatory disease are also more likely to have ectopic pregnancy, infertility and chronic pelvic pain. Immediate treatment of clinically suspected pelvic inflammatory disease is required to reduce the risk of chronic complications.

Similarly, treatment for genital herpes with antivirals should not be delayed, particularly initial episodes, as treatment reduces infectiousness, duration of symptoms, and the frequency and duration of subsequent episodes.

2. Patients' GPs not notified in clear breach of intended protocol, causing fragmentation of care

The QUT Report stated pharmacists were to notify the patient's preferred GP where the pharmacist commenced the patient on antimicrobial therapy. This step, however, was not included in the GuildCare Workflow.

The GuildCare Workflow only required GP notification if the patient was followed-up by the pharmacist and the patient reported ongoing symptoms. The pharmacist was then prompted to send the patient or the GP a letter.

The low rates of successful follow-up of patients (discussed under Failing 2) meant that the treating GP would generally not have known about their patient's treatment under the UTIPP-Q even where symptoms were unresolved. Furthermore (as noted in 4.4 below), even when patients who had follow-up with a pharmacist reported ongoing symptoms, the pharmacist failed to refer them to a GP in 22% of cases.

3. Failure of the GuildCare Workflow to follow Queensland Parliament's risk-minimisation framework

The UTIPP-Q was justified on the grounds of Recommendation 2 of Report No 12 – *Inquiry into the establishment of a pharmacy council and transfer of pharmacy ownership in Queensland* (16 October 2018). The Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee (the Committee) made 11 recommendations which were accepted by the Queensland Government in 2019.

Recommendation 2 included that the Department of Health develop options to provide low-risk emergency and repeat prescriptions through pharmacies 'subject to a risk-minimisation framework'. The risk-minimisation framework suggested by the Committee included requirements for:

- the pharmacist to consult a 13HEALTH GP or review the patient's medical record via My Health Record; and
- on-site testing.

None of these requirements were followed by the UTIPP-Q. Short of noting that there is no 13HEALTH GP service, the QUT Report did not justify why the risk-minimisation framework was not followed. This is concerning as it is clear the intent of the framework was to ensure pharmacists consulted a GP before prescribing emergency medication.

There was also a requirement for limitations on the number of times a prescription could be issued within a set period of time (e.g. only once in a six-month period). As discussed above, whilst an unsafe, two-week limitation was included in the GuildCare Workflow, it was not the six-month limit (consistent with clinical protocols) agreed upon in the original, approved Consortium Workflow. Again, this is concerning since it is clear the intent of the risk-management framework was to avoid unsafe prescribing intervals by pharmacists.

4. Pharmacists failed to follow the GuildCare Workflow

There is clear evidence in the QUT Report of instances where pharmacists failed to follow the GuildCare Workflow. This indicates that, far from demonstrating (as the QUT Report claims) 'pharmacists have delivered safe and appropriate care that align (sic) to clinical protocols', some pharmacists in fact failed to adhere to the protocol they were provided.

4.1. Untrained non-pharmacist employees involved in providing the UTIPP-Q service in clear breach of the protocol despite false claims by the QUT Report

The QUT Report stated that the interaction with patients participating in the UTIPP-Q 'must be handled by a pharmacist'. It specifically stated that a pharmacist was to provide the following aspects of the service:

- asking the screening questions;
- determining eligibility;
- obtaining consent for the research component; and
- explaining the service.

The UTIPP-Q Pharmacist Evaluation Survey asked participating pharmacists which staff completed tasks associated with the UTIPP-Q. The data demonstrates that a number of pharmacists reported that 'pharmacy assistants', who are not pharmacists, handled these interactions, including the steps that had been defined as 'pharmacist only' listed above.

A further number of pharmacists reported 'all staff' completed these tasks. It is not possible to state the number or percentage of responses these accounted for as this was not included in the written part of the report but only visually demonstrated in a graph, obfuscating the data.

The QUT Report falsely stated that 'pharmacists and intern pharmacists performed the clinical activities and pharmacy assistants provided support with operational tasks'. This interpretation of the data is misleading as there was no qualifier (for example, stating clinical activities were predominantly performed by pharmacists and intern pharmacists). Instead, the QUT Report concealed that in some cases untrained non-pharmacists provided the consultation service when the protocol expressly prohibited this.

4.2. Patients with male anatomy treated in clear breach of the protocol

The UTIPP-Q had strict screening inclusion requirements – according to the QUT Report only patients of 'sex (female) and age (≥18 or ≤65 years)' could be treated. Despite this, the AMA Report identified that pharmacists treated at least three patients of male sex under the UTIPP-Q. This posed a serious risk to the safety of those patients.

As stated above, the GuildCare Workflow inappropriately used 'gender' instead of 'sex'. Whilst this may have created confusion, pharmacists who completed the UTIPP-Q online training module (estimated to take two hours) should have still understood that it was

inappropriate to treat a biological male patient through the UTIPP-Q. It is unclear whether this failing was due to:

- the quality of the training pharmacists were given through the UTIPP-Q online training module; or
- pharmacists deliberately treating male patients despite it being clearly outside their scope as defined by the UTIPP-Q.

As stated, the UTIPP-Q was not designed to treat male patients. The pharmacists who treated biological males rather than referring them to a GP provided inadequate care and endangered their health.

4.3. Patients given repeat antibiotics in clear breach of the protocol

Six patients were prescribed repeat antibiotics by a pharmacist within 14 days of a first prescription of antibiotics by a pharmacist. At least one patient had only a three-day interval between repeat antibiotic prescriptions by a pharmacist. None of these patients were recorded as having a UTI relapse nor were they referred to a GP.

Under the GuildCare Workflow, none of these patients should have received treatment on the second occasion and all should have been referred to a GP. Pharmacists were specifically instructed to ask if the patient had a UTI in the last two weeks and, if so, they were deemed ineligible for treatment. As stated above, the protocol itself was also flawed as the timeframe should have been six months, not two weeks.

4.4. Failure to appropriately refer patients with unresolved symptoms to GP at follow-up

Of the 129 patients with unresolved symptoms at the time of the one-week Telephone Follow-up, 22% (43/129) were not referred to a GP by the treating pharmacist. The relevant data is as follows:

- A total of 2096 (of 2409) patients reported that they had symptom resolution at the time of follow-up, meaning 313 patients had ongoing symptoms.
- Of these 313 patients, 184 indicated they had sought care with a medical practitioner.
- This means 129 patients reported to the pharmacist at follow-up that their symptoms had not resolved *and* they had not sought care with a medical practitioner.

Despite this, only 86 patients were verbally referred to a GP. A further 10 were referred to a doctor (not a GP, presumably an emergency specialist) and a further four had already presented to the emergency department (ED). This shows that 22% of patients with ongoing symptoms were not referred to a GP by the treating pharmacist. Not only does this indicate pharmacists failed to follow the GuildCare Workflow but that the UTIPP-Q resulted in the fragmentation of care for patients.

The QUT Report lacks any discussion about the failure to refer a significant proportion of patients to a GP for ongoing care when they reported ongoing symptoms at follow-up. This is especially noteworthy as the recommendation to refer was included in the GuildCare Workflow.[5] Nonetheless, the QUT Report only notes ‘verbal referrals’ were made and does not note any written referrals. The data was misleadingly presented as follows:

> Of those 2,409 services able to be followed-up, 184 (7.6%) patients had not had a resolution of their symptoms but had already sought other care. A further 86 (3.6%) patients who indicated they had not had resolution of their symptoms were verbally referred to their GP by the pharmacist following the follow-up call.

[5] The GuildCare Workflow stated that if the option 'Patient’s UTI symptoms have not resolved; GP referral is required’ was selected then the GP referral template would appear.

4.5. Inappropriate provision of the third-line antibiotic option without reference to antimicrobial stewardship guidelines

When the second-line antibiotic was most appropriate, pharmacists ignored clinical guidelines and instead prescribed the third-line antibiotic in 35% of cases.

The QUT Report cites 26 occasions where pharmacists reported they provided the third-line (broad-spectrum) antibiotic cefalexin to patients despite no contraindication to the first or second-line (narrow-spectrum) options trimethoprim and nitrofurantoin but specifically because the 'patient requested cefalexin'. This has serious implications for antimicrobial stewardship as it demonstrates pharmacists will accede to patients' requests for broad-spectrum antibiotics without reference to clinical appropriateness or antimicrobial stewardship prescribing guidelines.

The QUT Report states 254 patients were evaluated for nitrofurantoin and of those, nitrofurantoin was deemed to be inappropriate in 148 cases. It is concerning that:

- Eight of these evaluations were determined on the non-clinical ground that the 'patient requested cefalexin'; and
- Five of these evaluations provided no reason as to why nitrofurantoin was inappropriate.

It would be expected that the remaining 106 patients should have been prescribed nitrofurantoin and 148 should have been prescribed the third-line option cefalexin. Despite this, the QUT Report shows that just 74 patients were prescribed nitrofurantoin and 173 were prescribed cefalexin.

Therefore, given that:

- 106 patients were found to be suitable for the second-line option; and
- Eight had no clinical grounds not to be prescribed the second-line option;

the QUT Report shows, when there was no contraindication to prescribing the second-line option, pharmacists instead inappropriately chose the third-line, broad-spectrum option in 35% (40/114) of cases.

Failing 2: Methodological Bias

The methodology used by the UTIPP-Q to determine participant satisfaction contained significant, inherent methodological bias. Instead of using an independent observer to conduct follow-up questioning, the UTIPP-Q used the pharmacist who delivered the service, who clearly had a conflict of interest in obtaining favourable results. In addition, the rates of follow-up were so low as to render any results meaningless.

1. Inherent bias in methodology

The UTIPP-Q used a methodology for conducting follow-up patient questioning and selecting patients to complete the Clinical Service Evaluation Survey (the Satisfaction Survey) which risked considerable bias. The key issues creating the high risk of bias included:

- The 'One-week follow-up' (Telephone Follow-up) took place after a period of anywhere between one and 155 days after the initial service. This puts significant doubt on the results obtained so long after the initial services, increasing the risk of recall bias.

- Allocating responsibility for follow-up to the treating pharmacist instead of an independent observer:
    - The treating pharmacist or their colleague (both of whom had a clear conflict of interest in obtaining favourable results) was responsible for arranging the follow-up telephone call and transcribing the patient's comments. This

increased the risk of bias (social responsiveness bias, obsequiousness bias, interviewer bias and observer expectation bias).
    - This also would have made patients reluctant to participate in follow-up if they had a negative consultation experience; bad outcome or complication; or the treatment had been ineffective. Even the UTIPP-Q evaluation researchers acknowledged that 'patients may experience discomfort' when discussing follow-up questions with the pharmacist if the treatment had been ineffective.[6]
    - The QUT Report showed probable evidence that discomfort discussing follow-up questions when the treatment was not provided led to selection bias: patients who were not given antibiotics were half as likely to have Telephone Follow-up (just 18% = 44 of 250 patients) as those who were prescribed antibiotics (36% = 2263 of 6254).

- The UTIPP-Q evaluation researchers claimed that the discomfort caused by having the treating pharmacists conduct the Telephone Follow-up could be justified stating:

  > this is a part of standard care provided for patients by pharmacists. It is important to point out that patients answering questions to this Telephone Follow-up is part of the clinical service component of UTIPP-Q.

  However, the fact that only a minority of patients were followed up in this way shows that it was not part of standard care and therefore not adequate justification for the treating pharmacists to have conducted the follow-up.

- Whilst pharmacists did not ask questions related to service satisfaction, they did act as 'gate-keepers' to the Satisfaction Survey, introducing the risk of selection bias. The Satisfaction Survey was not sent automatically to all patients who had consented to participate in the research evaluation but was dependent on:
    - completing the Telephone Follow-up which was instigated by the pharmacist;
    - the pharmacist offering to send the link to the survey (there was no standardised script for pharmacists to follow and pharmacists may have been influenced by the patient's answers in their language choices and phrasing in explaining the purpose and value of the Satisfaction Survey); and
    - the pharmacist manually emailing the patient a survey link.

  Ability for patients to complete the Satisfaction Survey should not have been contingent on the actions of the pharmacist who had delivered the service.

2. <u>Low follow-up rates of the Telephone Follow-up & Satisfaction Survey biased the data</u>

   Only 36% (2409) of patients who initially consented ultimately received Telephone Follow-up with the pharmacist. Despite this, the QUT Report claims the 64% of patients lost to follow-up 'may be expected to have similar outcomes to those for whom follow-up data was available'. This cannot be justified. It contradicts common statistical understanding that patients lost to follow-up tend to have different prognoses to those who receive follow-up.[7] It is highly likely that the patients with missing data were not missing at random and had significant differences to those who had been followed up. Given the very large loss to follow-up, there can be no confidence in the data obtained.

   In addition, only 1% of patients responded to the Satisfaction Survey – a mere 68 of 6751 patients who consented to their data being included in the analysis. Nonetheless, the QUT Report claims Satisfaction Survey responses demonstrated 'positive feedback'. It fails to highlight the inherent risk of selection bias in the methodology or the extremely low response rates which undeniably rendered the Satisfaction Survey results worthless.

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[6] In their 'application for review of negligible / low risk research involving human participants' submission.

[7] Sacket D L, Richardson W S, Rosenberg W, New York: Churchill Livingstone; 1997. Evidence-Based Medicine: How to Practice and Teach EBM.

<u>Failing 3:</u> Adverse Events Grossly Unexamined

The UTIPP-Q and QUT Report failed to capture adverse patient outcomes; adequately discuss findings which would have revealed these outcomes; and provide a clear avenue for doctors to report patient complications related to the UTIPP-Q. These failings are discussed below.

1. <u>Failure to capture adverse patient outcomes</u>

   The UTIPP-Q failed to follow-up participants for adverse events including ED presentations, hospitalisations, misdiagnosis and inappropriate treatment. Adverse events, excepting adverse medication effects, were not assessed by the QUT Report.

   The UTIPP-Q follow-up questions asked whether patients had sought care with a medical doctor but did not ask whether this was via an ED, general practice clinic, GP home visit or sexual health service. Participants who had sought such care should have been asked about relevant adverse events including:
   - ED presentation;
   - hospital admission;
   - misdiagnosis of a complicated UTI as an uncomplicated UTI;
   - misdiagnosis of a non-UTI condition as a UTI (e.g. cancer, pelvic inflammatory disease or interstitial cystitis misdiagnosed as a UTI);
   - missed detection of an important comorbidity that should have prompted referral to a doctor (e.g. pregnancy or type 2 diabetes mellitus); and
   - uncertainty about what to do if symptoms had not resolved after 48 hours.

   All of these adverse events were reported by the 1307 doctors who responded to AMA Queensland's survey about the UTIPP-Q. The AMA QLD Report noted eight cases where misdiagnosis or ineffective treatment resulted in patient hospitalisation for urosepsis and/or pyelonephritis. None of these cases were identified by the QUT Report. These independently reported cases demonstrate the inadequacy of the QUT's evaluation to identify cases where participants required hospitalisation for urosepsis or pyelonephritis as a complication of the UTIPP-Q, simply because it failed to ask about, or in any way investigate, this highly relevant outcome.

2. <u>Failure to adequately discuss findings which would have revealed poor patient outcomes</u>

   There were a number of findings in the QUT Report which were not adequately analysed or discussed. Had they been subjected to robust analysis and discussion, it is highly likely they would have identified patients who had poor outcomes as a result of the UTIPP-Q, including admission to EDs.

   2.1. <u>Patients with unresolved symptoms</u>

   Of the patients followed up, 313 reported unresolved symptoms. The outcomes for 77 of these patients were not adequately accounted for in the QUT Report as follows:

   - Of the patients in the group 'UTI symptoms not resolved - visited medical practitioner', 40 did not access GP treatment. It is therefore most likely that care was accessed in an ED.
   - Of the patients in the group 'other outcome' only 10 were referred to a doctor but, as they were specifically excluded from the group of patients with unresolved symptoms referred to a GP, it is most likely they were also referred to an ED.
   - Of the patients in the group 'other outcome', 17 had ongoing symptoms and were not referred to a doctor at all.
   - Of the patients in the group 'other outcome', 10 had outcomes which remain a mystery as their outcomes were simply labelled 'other'.

2.2. Emergency presentation

The QUT Report only managed to clearly identify four patients who presented to an ED with complications from the UTIPP-Q service. As discussed above, patients were not asked about ED use so these four cases were only discovered by chance when the patient volunteered the information and the pharmacists noted the complication in a free text section.

These four patient cases were analysed by two non-pharmacist clinicians from the UTIPP-Q Steering and Advisory Group and a summary of their outcomes was included in the QUT Report. Nonetheless, the QUT Report presented information about these cases without discussing that a major failing of the UTIPP-Q was the lack of questioning at follow-up regarding adverse events such as ED presentation.

2.3. QUT Report made unsubstantiated assumptions regarding GP prescribing

Of the patients who were followed-up, 144 had unresolved UTI symptoms and had already sought care with a GP. In 78% of these cases (112/144 patients) the GP prescribed a different antibiotic from that prescribed by the pharmacist.

The QUT Report claims this was in-keeping with normal UTI management, however, this is misleading as it does not state what type of antibiotics were given nor their indication. Any number of these antibiotic prescriptions could have been given to treat STIs or other non-UTI conditions that were misdiagnosed by the pharmacist as a UTI (e.g. chlamydia, gonorrhoea or bacterial vaginosis).

2.4. QUT Report data suggests non-UTI conditions were misdiagnosed as UTIs

Standard clinical practice requires a urine MCS test for patients who have been treated for a UTI but have unresolved symptoms consistent with UTI.[8] Of the patients who reported they had seen their GP for unresolved symptoms, 36% (52/144) were not given a urine test by their GP.

This suggests these patients had clinically obvious non-UTI causes for their symptoms when a physical examination was performed by their doctor (e.g. genital herpes or lichen sclerosus) since the GPs did not perform urine MCS tests. The QUT Report, however, does not explain why urine tests were not performed or whether those 52 patients had a clinically obvious non-UTI cause for their symptoms.

3. Failure to provide a clear avenue for doctors to report patient complications

No formal reporting avenue was provided to doctors who treated patients with complications as a result of participating in the UTIPP-Q. This was in spite of the GuildCare Workflow requiring patients with unresolved symptoms after 48 hours to be referred to a GP. Instead, the Pharmacy Guild of Australia stated doctors should report these concerns to the Health Quality and Complaints Commission (HQCC), despite the fact the HQCC was closed in 2014 and replaced by the Office of the Health Ombudsman (OHO).[9]

This is a ridiculous suggestion since the main outcome of complaints to the OHO about individual practitioners is referral to the Australian Health Practitioner Regulation Agency. Even

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[8] Urinary tract infections [published April 2019]. In: eTG complete. Melbourne: Therapeutic Guidelines.

[9]The Courier Mail. Serious complications missed, misdiagnosed in pharmacy UTI trial. [Online]. 2022. Available from: <https://www.couriermail.com.au/subscribe/news/1/?sourceCode=CMWEB_WRE170_a_GGL&dest=https%3A%2F%2Fwww.couriermail.com.au%2Fnews%2Fqueensland%2Fserious-complications-missed-misdiagnosed-in-pharmacy-uti-trial%2Fnews-story%2Fa6b88362da456c3cd8614da87ceab6fe&memtype=anonymous&mode=premium&v21=dynamic-warm-test-score&V21spcbehaviour=append>

if doctors reported the complications to the OHO, it would not be reported to the UTIPP-Q trial coordinators since the OHO has no authority to provide this information to QUT.

<u>Failing 4:</u> Data Omitted, Obfuscated, Misrepresented & Falsely Reported

There are multiple instances where the QUT Report omitted, obfuscated, misrepresented and falsely reported results. This included data concerning access to private consulting rooms; the likelihood of patients presenting to EDs; and data relating to a range of other important aspects of the UTIPP-Q.

1. <u>QUT Report omitted results about pharmacist access to private consulting rooms</u>

   The UTIPP-Q Pharmacist Survey asked pharmacists about difficulties in delivering the UTIPP-Q service. One response option was ‘don’t have consultation rooms’.

   Private consultation rooms are essential to ensure confidentiality and preserve dignity when asking patients important, sensitive screening questions. The QUT Report stated:

   > Pharmacists must meet their obligations in relation to respecting the patient's privacy and confidentiality in the provision [of the UTIPP-Q Service]. This includes offering patients a private consultation area where conversations cannot be overheard.

   Alarmingly, the authors did not include any data on responses to this question in the QUT Report. The AMA QLD Report, however, found patients were reluctant to provide full and frank information to a pharmacist as they were asked sensitive questions relating to pregnancy, risk of STI and vaginal symptoms over the counter in the presence of other customers.

   Non-disclosure of sensitive or embarrassing information due to a lack of privacy is highly likely to have resulted in misdiagnoses in the UTIPP-Q. Putting patients in the position where they are expected to answer such questions over the pharmacy counter or risk misdiagnosis is not safe and accessible healthcare.

2. <u>False, misleading data reporting about likelihood of patient presentations to hospital/ED</u>

   The QUT Report used inaccurate and misleading language when discussing data from the Satisfaction Survey question ‘If this service was NOT available, where would you have got advice/treatment for your symptoms? Please select all that apply’. The QUT Report states:

   > while it is not surprising that patients valued the convenience of the UTIPP-Q service and the ability to access care in a timely way, where services were not available to patients nor easy access to other providers (GPs) possible, hospital ED [emergency department] presentations would have occurred for these UTIs (14.8% of the respondants (sic))…
   >
   > …if the UTIPP-Q service had not been available in the pharmacy, respondents indicated that they would have sought advice/treatment for symptoms from primarily from (sic) their GP (62.9%) or hospital ED (14.8%).

   It was inaccurate to state that the option ‘hospital/ED’ was selected by 14.8% of respondents. In truth, this option made up 14.8% of total responses (12 responses), noting that respondents had the option to select ‘all that apply’ and did so on up to 13 occasions since there were 13 more responses than respondents.

   It can be inferred from the QUT Report statements above that all of the respondents who selected ‘hospital/ED’ as an option had also selected either ‘GP clinic surgery’ or ‘home visit GP or community nurse’, hence the disclaimer that hospital/ED would be used if ‘access to other providers was not possible’.

   The QUT Report did not ask respondents to rate how likely they would be to use each of the services/options they had selected or to what degree ‘ease of access’ would impact their

decision to present to an ED instead of accessing a GP clinic, home visit GP or community nurse. For example, patients may have preferred to put up with some difficulty in accessing the GP rather than presenting to an ED. It is therefore very misleading for the QUT Report to claim 14.8% of respondents would have 'primarily' sought advice/treatment from hospital/ED and that patients would have presented to an ED where 'easy access' to GPs was not possible.

The authors provided a misleading and inaccurate representation of the data in support of a compelling but untested narrative that the trial prevents hospitalisations:

> While acknowledging the general clinical outcomes for uncomplicated UTIs in women under 65 years of age, it is also important to note that around 17% of potentially preventable hospitalisations in women for UTIs (including pyelonephritis) occur in women aged 20-40 years.

The QUT Report cited an article to support this claim, however, the article does not contain any reference to this statistic or indeed to preventable hospitalisations. The authors were clearly trying to draw a parallel to this research because UTIPP-Q participants were predominantly women aged 18-40 years. This narrative however is not supported by evidence. In fact, the UTIPP-Q evaluation did not collect data on prevention of hospitalisations.

The statistic is also very unhelpful given it does not note what percentage of the patients requiring hospitalisation for UTI in that research had factors that would have made them ineligible for the UTIPP-Q. This is relevant as the UTIPP-Q purportedly excluded patients from treatment where they had factors that would significantly increase their risk of complicated infections likely to lead to hospitalisation (e.g. pregnancy, immunocompromise, abnormal urinary tract).

3. <u>Other misrepresentations of data in the QUT Report</u>

There were several misrepresentations of data in the QUT Report, also noted under Failings 1-3 above as follows:

- Non-pharmacist, untrained staff conducted UTIPP-Q service elements which were exclusively 'pharmacist-only', yet the QUT Report claimed the opposite and obfuscated the data, presenting it only in a figure.
- The QUT Report omitted the fact that 22% of patients who had follow-up and had unresolved symptoms were not referred to a GP.
- The QUT Report omitted the fact that in 35% of cases where the second-line antibiotic option was most appropriate, the broad-spectrum third-line option was inappropriately chosen instead by pharmacists.
- The QUT Report placed significant emphasis on discussing four patients who had reported visiting ED at follow-up whilst failing to acknowledge that ED presentations were not asked about at follow-up. It also failed to acknowledge this meant these four cases were unlikely to represent all of the instances that required follow-up in an ED.
- The QUT Report misreported data related to summary of follow-up consultations including 40 patients who appear to have sought care at an ED and a further 10 who appear to have been referred to an ED.
- The QUT Report inappropriately assumed a GP prescription of antibiotics to patients with unresolved symptoms implied ongoing treatment of UTI. This is a flawed assumption since it is possible that those patients were being treated for an STI or other non-UTI infection that the pharmacist had misdiagnosed.
- The QUT Report inappropriately ignored the fact that GPs did not perform urine testing on 36% of patients who sought care with a doctor following treatment. This strongly suggested those patients had a clear non-UTI cause for their symptoms.

<u>Failing 5:</u> All QUT Report Key Findings either Unsubstantiated or False

The three 'Key findings' of the QUT Report were based on inadequate outcome measures that did not substantiate the conclusions drawn about the UTIPP-Q. The QUT Report made the following unjustifiable claims:

1. that safety was demonstrated;
2. that pharmacists delivered care in alignment with clinical protocols;
3. that the UTIPP-Q provided value to the health care system; and
4. that pharmacists have the appropriate skills, competencies and training to provide the UTIPP-Q service.

These are discussed further below.

1. <u>False claim: Safety was demonstrated</u>

   A 'key finding' of the QUT Report was that the UTIPP-Q 'demonstrated that pharmacists have delivered safe and appropriate care that align (sic) to clinical protocols'. It cited the following outcome measures in support:

   - Symptom presentation and antibiotic treatments chosen by pharmacists were indicative of symptom based empiric treatment for uncomplicated UTIs;
   - Trimethoprim was the first-line treatment for the majority of patients;
   - UTI symptoms had resolved in the majority of patients following antibiotic treatment; and
   - Adverse events reported by patients during the seven-day follow-up matched the expected effects from the antibiotic treatment.

   Safety was not demonstrated in the QUT Report as adverse events were grossly unexamined with medication adverse events used as the sole safety outcome measure. This outcome measure for safety of care was grossly inadequate as highly important adverse events (including ED treatment, hospital admission and misdiagnosis) were not evaluated (as discussed under Failing 3).

2. <u>False claim: Pharmacists delivered care that aligned with clinical protocols</u>

   The outcome measures relevant to appropriate care that aligns to clinical protocols were inadequate as the QUT Report demonstrated that the GuildCare Workflow did not align with clinical protocols. In addition, pharmacists failed to follow the protocol provided in many instances.

   The QUT Report did not discuss the numerous significant failures of the GuildCare Workflow to follow the Consortium Workflow, clinical protocols or agreed Queensland Government risk-minimisation framework. The QUT Report also falsely reported that the protocol was followed by pharmacists. The failings of the GuildCare Workflow and of pharmacists to follow clinical protocols were discussed in depth under Failing 1.

   It is incredibly misleading that the claim that 'UTI symptoms had resolved in the majority of patients following antibiotic treatment' was used to support the conclusion that care was appropriate. This is because the majority of female patients under 65 years of age who receive symptomatic treatment instead of antibiotics for an acute, uncomplicated UTI become symptom-free within seven days – i.e. the same result (resolution of symptoms in the majority of patients) would be expected if non-steroidal anti-inflammatory drugs (over-the-counter pain relief medication) treatment only were given.

   Worse than this, the QUT Report authors cannot even be confident that the majority of patients treated in the UTIPP-Q had resolution of their symptoms. As discussed under Failing 2,

because of methodological bias and very low follow-up rates, the authors cannot be confident in the validity of the results.

3. Unsubstantiated claim: The UTIPP-Q provided value to the health care system

   The QUT Report claimed data 'reinforced the value provided to the health care system and patients by the accessibility of community pharmacy'. However, the outcome measures used to support this claim were misleading.

   The first misleading outcome measure was 'availability of the service in the pharmacy provided an alternative to hospital ED and GP visits'. As discussed under Failing 4, the data did not show that any participants would primarily have sought care through a hospital/ED. Furthermore, this data was collected from the Satisfaction Survey which had a loss to follow-up of 99% and used exceedingly poor methodology that introduced considerable risk of selection bias. This meant the results of the Satisfaction Survey were completely invalid.

   A second misleading outcomes measure was 'positive feedback about the UTIPP-Q service directly from participants and through pharmacists'. Feedback from participants was collected through the Satisfaction Survey. Since the results of the Satisfaction Survey are completely invalid, the QUT Report authors cannot reasonably use its data to support this claim.

4. Unsubstantiated claim: Pharmacists have appropriate skills, competencies and training to provide the UTIPP-Q service

   The QUT Report concluded that 'pharmacists have the appropriate skills, competencies and training to manage the empiric treatment of uncomplicated UTIs in the community pharmacy'. The QUT Report authors supported this claim by stating the following:

   - The current level of underpinning training was considered suitable and appropriate to provide the UTIPP-Q service (the UTIPP-Q training module is accredited as continuing professional development through the Pharmaceutical Society of Auatralia (sic) and Australasian College of Pharmacy);
   - Pharmacists should have access to decision support tools within their pharmacy to reinforce patient and protocol choices; and
   - Pharmacists should have an ongoing requirement to record clinical information about patient interactions in either a written or electronic form.

   Completion of a two-hour online module and an open-book multi-choice questionnaire (where as many attempts as needed are allowed to pass) could be argued as a surrogate marker for attained knowledge, but certainly is not an adequate mode of teaching or assessing clinical competency in appropriate history taking, diagnosis and management for uncomplicated UTIs. Clinical competency should be assessed by evaluating health care providers in a clinical setting (e.g. an objective structured clinical examination) and this did not occur.

Failing 6: Fundamental Safeguards for Patient Safety & Antimicrobial Stewardship Excluded

The UTIPP-Q failed to adhere to fundamental safeguards for patient safety and antimicrobial stewardship. This included a violation of the medicines prescribing-dispensing separation and a deliberate subversion of Commonwealth legislation. The proposed NQ Pilot shares in this failing.

1. Violation of medicines prescribing-dispensing separation

   1.1. Risk to patients

   The separation between prescribing and dispensing is a fundamental medicines policy safeguard. It has several purposes, the most important of which is to protect patients from prescribing errors. It operates by embedding a safety mechanism which requires an

independent healthcare provider to check for prescribing errors at the point of medication dispensing.

By permitting pharmacists to both prescribe and dispense medicines, the Pilots undermine the medicines prescribing-dispensing separation and increase the likelihood of prescribing errors. This represents a grave threat to patient safety.

1.2. Reckless antimicrobial stewardship

The changes alter antimicrobial stewardship in Queensland and risk irreversible increases in antimicrobial resistance in Queensland communities. At a time when the World Health Organisation has listed antimicrobial resistance as one of the top 10 global public health threats facing humanity, the Pilots undermine responsible antimicrobial stewardship and are an embarrassment to their proponents, including QUT and the Queensland Government.

As discussed above, the GuildCare Workflow mandated in the UTIPP-Q did not align with clinical guidelines designed to reduce inappropriate treatment of recurrent UTIs, complicated UTIs and misdiagnosis of non-UTI conditions; and pharmacists participating in the UTIPP-Q did not consistently follow the protocol for prescribing mandated by the UTIPP-Q.

While acknowledging the important role non-prescribing hospital pharmacists working within a multidisciplinary team play in reviewing doctors' prescriptions and providing guideline-based recommendations to promote antimicrobial stewardship, it is inappropriate to generalise this function to prescribing pharmacists working independently in the community.

1.3. Conflict of interest

Another fundamental purpose of the separation of prescribing and dispensing is to remove the inherent conflict of interest that exists where a practitioner can both prescribe and dispense medicines. Prescribers and dispensers stand to make significant financial gain where permitted to undertake both activities, which directly conflicts with their duties to patients.

Such violation threatens the integrity of the health system. By undermining this separation, the Pilots represent an egregious prioritisation of commercial interests over public safety and threaten public trust in primary health care.

This is particularly so when the pharmacist is charging a fee to the patient for this advice. As was even recorded in the QUT Report, over 60% of pharmacists either strongly agreed or agreed with the statement that 'it was difficult to charge the patient for the UTI service when I did not supply an antibiotic'.

A contemporary example of the positive impact of separating dispensing and prescribing in the Australian health system was the banning of prescription of low-dose codeine products by pharmacists in 2018. This ban resulted in a 50% reduction in codeine overdoses and sales, without a concomitant increase in overdoses with stronger opioids or high-strength codeine.

2. Deliberate subversion of Commonwealth legislation

The Pilots are designed such that the Commonwealth medicines policy safeguard which creates a separation between prescribing and dispensing is removed. This subversion was noted by the outgoing Federal Health Minister and the outgoing Professional Services Review Director.