



**SECTION C – REVIEW OF THE COMPLAINT ALLEGATIONS AND FINDINGS**

Allegation	Review of Allegation
<p>1. "QUT Report omitted results about pharmacist access to private consulting rooms."</p> <p>Determination: UNSUBSTANTIATED</p>	<ul style="list-style-type: none"> <li>The study described in the Report included an evaluation of the Urinary Tract Infection Pharmacy Pilot - Queensland (UTIPP-Q) trial, during which a survey was distributed to pharmacists who had enrolled in the trial. The purpose of this survey was to establish the barriers and facilitators to the uptake of the pilot in community pharmacy sites, since it was noted that some pharmacists provided limited or no UTI services during the trial period (Report, p. 48).</li> <li>This survey included the following multiple-choice question: "What made it difficult / challenging to deliver the UTI service?" (Report, p. 111, 112), which asked pharmacists to identify reasons it was difficult to deliver the UTI service. The question provided eight suggested barriers to participation, and respondents could select all that applied and could provide additional barriers as free text. One of the options respondents could select was that the pharmacy did not have a private consultation room. The Complainant alleges that the authors did not include any data on responses to this question in the QUT Report.</li> <li>According to the Report, one requirement prior providing UTI services was that the pharmacy has a screened or private consulting area to ensure patient privacy and confidentiality (Report Appendix 1, p. 64). Of the 224 pharmacists surveyed, 13 pharmacists surveyed did not provide any UTI services during the trial period (Report Figure 13, p. 50). The Report does not provide the breakdown of the specific reason(s) that the 13 pharmacists did not participate, however it is possible that lack of a consultation room was one reason provided for non-participation.</li> <li>The Complaint alleges that lack of privacy (and therefore potential non-disclosure of sensitive information by patients) was "highly likely to have resulted in misdiagnoses". However, there is insufficient evidence to assume that consultations took place in pharmacies that did not have private consulting areas.</li> </ul>
<p>2. "False misleading data reporting about likelihood of patient presentations to hospital/ED"</p> <p>Determination: UNSUBSTANTIATED</p>	<ul style="list-style-type: none"> <li>In the Report, patients were invited to participate in a satisfaction survey at 7-day follow-up. This survey had five multiple option questions, including "If this service was NOT available, where would you have got advice/treatment for your symptoms?" (Report Figure 8, p. 44). Five options were provided, including the option to visit the hospital/emergency department, and patients could select multiple options and/or provide a free-text response.</li> <li>The Report was transparent in providing the number of respondents as the response rate was low (68 patients) and comprised only 2.8% of eligible participants (Report, p. 45).</li> <li>Of this sample, 12 patients indicated the hospital/emergency department as an alternative option if they had not been able to get treatment from a pharmacy. The Complainant alleges this data misrepresented when cited as "14.8% of respondents" (Complaint, p. 1) as patients had the ability to select more than one option.</li> <li>It is not inaccurate to state that 12 patients equate to 14.8% of the survey sample. However, since there was a very low response rate, it cannot be assumed that the sample proportion will correspond to the same proportion for the whole patient group. The data is also limited in that it is based on responses from a self-report survey and not a direct measure of actual ED presentations.</li> </ul>
<p>3. "The authors provided a misleading and inaccurate representation of the data in support of a compelling but untested narrative that the trial prevents hospitalisations"</p> <p>Determination: UNSUBSTANTIATED</p>	<ul style="list-style-type: none"> <li>Page 47 of the Report includes the following statement: "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<sup>10</sup>." (Report, p. 47). The sentence includes a reference citation of 10. The Report from p. 57 includes a list of references that lists reference 10 as: <ul style="list-style-type: none"> <li>10. Little P, Moore MV, Turner S, Rumsby K, Warner G, Lowes JA, et al. Effectiveness of five different approaches in management of urinary tract infection: randomised controlled trial. 2010;340:c199. (Report, p. 57)</li> </ul> <p>The citation is incomplete. The complete reference is assumed to be as follows:</p> <ul style="list-style-type: none"> <li>Little P, Moore MV, Turner S, Rumsby K, Warner G, Lowes JA, Smith H, Hawke C, Leydon G, Arscott A, Turner D. Effectiveness of five different approaches in management of urinary tract infection: randomised controlled trial. BMJ. 2010;340:405.<sup>1</sup></li> </ul> </li> <li>The Report erroneously combines in-text reference citation with footnoting. Some footnotes provide additional narrative text whereas others refer to external sources of information where there is a cross-over of numbering with the reference list. This is representative of a lack of consistent internationally established reporting guideline, such as those published by the Enhancing the QUALity and Transparency of Health Research (Equator) Network.<sup>2</sup></li> <li>Page 47 of the Report also includes a footnote number 10 with a weblink URL to a webpage of the Australian Institute for Health and Welfare (AIHW) Exploring the Potentially Preventable Hospitalisations Data. While the weblink URL directs the user to Small Geographic Areas of Figure 3 Age specific rates for total potentially preventable conditions in 2017–18 by Indigenous status, data that is published elsewhere on this website, namely Figure 1 Distribution of PPH by age in 2017–18: Persons, includes data that when manually aggregated is not inconsistent with the statement "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<sup>10</sup>." (Report, p. 47).</li> <li>The Report appears to include no other narrative regarding these AIHW data, or narrative more broadly, that is said to make "representation of the data in support of a compelling but untested narrative that the trial prevents hospitalisations" (Complaint, p. 2). The Report provides does not specifically state that the trial prevented hospitalisations.</li> </ul>



<p>4. "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."</p> <p>Determination: UNSUBSTANTIATED</p>	<ul style="list-style-type: none"> <li>In the Report, 224 pharmacists enrolled in the UTIPP-Q trials completed a post-trial evaluation survey. This survey included the following multiple-choice question: "What is the local service model delivery - who is responsible / tasked with this job?" (Report, p. 110) to determine which staff in the pharmacy was responsible for various tasks in the UTIPP-Q service. The question allowed more than one option to be selected for each task. The results of this question are summarised in a single sentence and graphically in the Report (Report Figure 18, p. 53).</li> <li>The Complaint alleges that "pharmacist-only" (Complaint, p. 2) service elements were conducted by untrained staff. It is unclear which pharmacist-only service elements the Complainant is referring to. There is no evidence that any of the tasks expected to be conducted by pharmacists were not completed by pharmacists. It is possible that a task could have been undertaken by one staff member and then repeated by the pharmacist, similar to a triage situation in a hospital. The Complaint also alleges the Report "claimed the opposite and obfuscated the data, presenting it only in a figure" (Complaint, p. 2). The figure (Report Figure 18, p. 53) is clearly presented and the in-text description provides a concise, but accurate account of the data.</li> </ul>
<p>5. "The QUT Report omitted the fact that 22% of patients who had follow-up and had unresolved symptoms were not referred to a GP."</p> <p>Determination: UNSUBSTANTIATED</p>	<ul style="list-style-type: none"> <li>In the Report, 2,409 patients were followed-up, 2,096 (87%) reported their symptoms had resolved and the outcomes for the remaining 313 (13%) whose symptoms were unresolved were provided in Table 6 (Report, p. 34).</li> <li>Of those 313 patients, 184 had sought care (58.8%), 86 were documented as being referred to a GP (27.5%) and the remaining 43 were classified as 'other' (which included 'attended ED', 'symptom re-occurrence, no improvement or not fully resolved', 'referral to a doctor', 'did not take antibiotics' and 'other').</li> <li>There is no evidence to indicate the omission of data showing 22% patients with unresolved symptoms were not referred to a GP.</li> </ul>
<p>6. "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."</p> <p>Determination: UNSUBSTANTIATED</p>	<ul style="list-style-type: none"> <li>Without patient clinical information it is impossible to determine whether nitrofurantoin (second line treatment) was more appropriate or less appropriate than cefalexin (third line treatment) for an individual patient. The Report explicitly states that medical notes for patients were not accessible (Report, p. 41, 42).</li> <li>There are various reasons for why nitrofurantoin may not have been an appropriate choice for patients. There is insufficient data in the published data to determine whether nitrofurantoin or cefalexin was the more appropriate option for an individual patient or to suggest that cefalexin was an inappropriate choice in the patients who were treated with it.</li> </ul>
<p>7. "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.</p> <p>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."</p> <p>Determination: UNSUBSTANTIATED</p>	<ul style="list-style-type: none"> <li>The follow-up survey included the following yes/no questions: "Patient had experienced medication adverse effects" and "Patient had visited medical practitioner" (Report Appendix 5, p. 99). Upon a 'Yes' response, patients were prompted to provide a free-response description of the adverse effects and/or the visit.</li> <li>Given survey respondents were asked whether or not they visited a medical practitioner the significance, or otherwise, of where that medical practitioner was located, be that in an ED or in General Practice, is unclear as it relates to the allegation.</li> <li>The outcomes of the four patients who were known to have presented to EDs are relevant to report on, to determine if treatment had been justified. There was no implication in the Report that these four patients did or did not represent all patients who may have presented to ED, rather the purpose was to report on the known outcomes given the data available.</li> </ul>
<p>8. "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."</p> <p>Determination: UNSUBSTANTIATED</p>	<ul style="list-style-type: none"> <li>Of the 2,409 patients that were followed-up, 2,096 reported their symptoms had resolved and the outcomes for the remaining 313 are provided in Table 6 of the Report (p. 34).</li> <li>Table 6 is poorly presented. Data in the table do not readily sum to the totals provided, which makes interpretation difficult. For example, the data in the section "Outcome Summary" includes "If care sought: accessed GP service - 144 (5.5)" (Report Table 6, p. 34), which is a subset of the variable immediately preceding it and should be clearly identified as such.</li> <li>Of the 43 patients with unresolved symptoms and who were included in the "Other" category, 10 were "referral to doctor" (Report, p. 34) and another 10 were categorised under "other" (Report, p. 34) with no additional specification provided. There is insufficient data in the Report to know the outcomes of these patients including whether or not they attended, as opposed to being referred, to an ED.</li> <li>The poor presentation of Table 6 is such that it is not possible to determine with certainty which of the 40 plus 10 patients the allegation is referring to. On these grounds, the allegation is unsubstantiated. However, the poor presentation of Table 6 enlivens confusion about the interpretation of the data, and therefore the implications of the study.</li> </ul>
<p>9. "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."</p> <p>Determination: UNSUBSTANTIATED</p>	<ul style="list-style-type: none"> <li>Follow-up data is based on responses of a self-report patient survey. The Report stated that 112/144 patients (77.7%) who attended a GP from the follow-up group received another antibiotic treatment (Report, p. 33).</li> <li>There is no data to determine whether the antibiotic was prescribed for ongoing treatment of UTI or an alternative clinical indication. The Report states that the medical notes for these patients were not available to the investigators (Report, p. 41, 42). Therefore, it is unknown what the antibiotic treatment was prescribed for. A GP prescription for antibiotics could be either for treatment of an unresolved UTI or treatment of an STI; the two are not mutually exclusive.</li> <li>There is insufficient evidence to assume that a GP prescription for antibiotics was the result of a misdiagnosis of a non-UTI infection.</li> </ul>

10. "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."

Determination: UNSUBSTANTIATED

- Of the 144 patients who reported unresolved symptoms at follow-up and who have visited a GP, 52 patients (36.1%) did not receive a urine test. These figures are explicitly stated in the Report and in Table 6 (p. 33, 34).
- Without patient clinical information (as stated in the Report p. 41, 42), there is insufficient evidence to determine the reason why a urine sample was not taken and to assume that these 52 patients had a non-UTI cause for their symptoms.