Peer Review File

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REVIEWER A:

Comment 1:

The stated primary outcome of the study was "concordance of the tele-otology diagnosis with a face-to-face clinical diagnosis". Elsewhere in the manuscript, however, it is stated that "the purpose of this pilot study was to compare different available telehealth devices in a model of care linking rural communities in Australia with a tertiary ENT specialist centre". And again elsewhere - "The primary purpose of this pilot study was to assess a number of potential telehealth tools". Similarly, the discussion section discusses 'audiology', 'tympanometry' and 'otoscopy' before it discusses 'clinical diagnosis'. The authors need to be consistent (and honest) throughout the manuscript with what they were actually trying to achieve here.

Reply 1:

This is the pilot study for a larger main study. The purpose of the main study is indeed to look at concordance between clinical observation and tele-health derived "tele-diagnosis". This submitted article is the pilot to that study. The purpose of this pilot study was to look at what telehealth tools to take through to that larger study. The main aim of this study was to check the quality of various telehealth tools available before embarking on one chosen set for the main study. Therefore the concordance of clinical final diagnosis which relies on the whole suite of tools being used is less important, but rather how each individual tool performed. On the contrary in the subsequent larger main study, the report will be more orientated towards diagnosis concordance.

Thank you for pointing out this important distinction. We have adjusted the abstract and main text as follows to try to make that point clearer.

Changes in the text:

PAGE 2, LINE 14: "Outcome measures included assessment of image quality, patient experience and audiometry and tympanometry concordance with gold standard audiologist-led assessments as well as concordance of the tele-otology diagnosis with a face-to-face clinical diagnosis by a senior otolaryngologist. This was aimed at creating a robust protocol to take through to a larger study where the primary outcome measure would be diagnostic concordance."

We have also adjusted the order of outcome measures on Page 7, Line 23 to de-emphasise the clinical concordance and highlight the outcomes measures pertinent to tele-tool analysis.

Comment 2:

No authors are affiliated with the Bourke AMS despite it being the 6th stated affiliation.

Reply 2:

The project has been mainly run through the support of the Brewarrina Aboriginal Medical Service. Bourke AMS has sadly been troubled with almost constant staff turnover, with rarely the same staff present at each visit. Several staff members were important contributors early in the planning of this study (M Jones, B Dixon and J

Knight) and are therefore mentioned in the acknowledgement section. However they declined to be involved in the write up so are not mentioned as authors. J Caswell is jointly affiliated with the local area health district and the two AMS (Bourke and Brewarrina) so we have added those affiliations to her name, which should resolve the issue.

The superfixes placed in the acknowledgement section were perhaps confusing as they may have looked like academic affiliations, but were actually supposed to show their contribution to the project. We have change this part to a,b,c to avoid confusion.

Changes to text:

PAGE 1, LINE 42: "The authors would like to thank the following people who were involved in a) protocol preparation, b) clinical implementation or c) advisory capacity: Abbott K[b], Annan D[b,], Bhutta M[a,c] , Bird M[a,b] Bruce J[a], Cochrane-Owers B[b], Christie V[c], Dixon B[b], Ferguson H[c], Finlayson H[c], Gwynne K[a], Harrop E[a], Jones M[b,c], Kelly D[c], Knight J[c], Kong K[a,c], Rambaldini B[c], Gordon A[b]."

Comment 3:

As outlined above, the primary outcomes of this study is concordance of tele-otology with face-to-face diagnoses. The introduction discusses the abysmal state of ear health in Aboriginal children -- yet the current study evaulated only 5 children in a cohort of 48 (presumably non-Aboriginal) patients. It is hard to emphasise Aboriginal ear disease in the face of this data set.

Reply 3:

As mentioned in Reply 1, the submitted article is the pilot study for a larger main study. The pilot took place during the COVID pandemic. Therefore, we had to pivot and move the pilot component to Sydney based clinics as the outreach program completely ceased to run due to the lockdown measures. Ethical permission was granted for this. Given that the pilot study was looking at the quality and capability of the tele tools rather than any specific cultural concerns, it was felt that this was a reasonable adjustment. Therefore, the Aboriginal participation was considerably reduced. However, the main study, now underway is wholly in the communities of Brewarrina and Bourke, so the Aboriginal participation is close to 100%. The overarching purpose of the *main* study (and this pilot) is to investigate better ways of delivering healthcare to remote Aboriginal communities. Therefore, it is naturally important to mention the status of Aboriginal ear disease in the introduction. The fact that the pilot had to be moved to Sydney, due to a pandemic, during which time no outreach services took place in these communities highlights the importance of studies like this to set up better tools for local health workers to use in a telehealth environment.

We have added a comment in the methods section explaining this.

Changes to text:

PAGE 5, LINE 20: "This pilot study took place during the global COVID-19 pandemic and therefore outreach trips to remote Aboriginal communities were paused. During this period approval was gained through the ethics committee to shift the study to city-based ENT clinics. Given the primary purpose of this pilot study was to assess the merit of the various tele-health tools, this adjustment was deemed acceptable, in the

knowledge that the main study would proceed as planned in the remote communities at a later stage, following resolution of the pandemic."

Comment 4:

The main outcome from this study is that is that **1 in 5 patients** (10 out of a cohort of 48 having 'missed diagnoses') **walking in to a tele-otology clinic can expect to walk away being told one or both of their ears are normal when in actuality they indeed do have pathology and will be falsely reassured by the assessment**. Surely this is a huge blow for tele-otology. And surely the authors need to refine their protocol better with demonstrable better numbers before rolling out a bigger study.

Reply 4:

What this study aimed to do was find which of the tele-tools available gave the BEST results. From this, as the submitted pilot paper hopefully shows, we were able to clearly see some major flaws in some of the systems and from this choose what to take forward to the larger study, which we have done. One should reserve any final judgement on whether the tele-tool collective is effective at diagnosis to the main study. It is important not to overcall conclusions from a pilot study but rather read into it what the pilot nature is aiming to achieve. A pilot study is not the main study. The pilot was designed to help improve the main study protocol which is undoubtably has. However, we the authors felt that there was a lot of valuable information from the pilot worth publishing on its own merits, before the publication of the main study when it is completed.

Changes to text:

None made for this comment

REVIEWER B:

Comment 1:

The study is well written, with a clear discussion of the limitations of the study design, and appropriate conclusions from the presented data. The reader benefits from the analysis of the advantages/disadvantages of the various tools utilized in the discussion and appendices/supplemental information provided.

Reply 1:

Your comments are much appreciated.

Changes to text:

None made for this comment

Comment 2:

Page 5 & 6: how were the automated audiometry & tympanometry administered (by a trained research assistant as per the video otoscopy? Or self administered?). Were paediatric patients also examined by the research assistant or their carers?

Reply 2:

The automated audiometry was self-administered, guided by the trained research assistant. The assistant would explain the process but the whole program ran itself automatically. This was the same for adult patients or paediatric patients with their carers adjacent to them.

Changes to text:

PAGE 6, LINE 22: "The research assistant would explain the test to the patient and apply the headphones, then the program (Shoebox, Electronica or HearTest) would run automatically, cycling through the four pure tone frequencies and adjusting decibel output in line with their responses to determine the patient's threshold."

Comment 3:

Page 5, Line 10-16: please specify the number of sites (how many private rooms?) and audiologists were involved in the study. Although mentioned later the number of senior ENT surgeons involved with onsite/remote diagnosis may also be helpful here.

Reply 3:

The sites were a single ENT public outpatient clinic and a single private clinic office. Various clinical audiologists were involved depending on who was on duty on that day. We have adjusted the text as follows to make this clear.

Changes to text:

PAGE 5, LINE 12 "This prospective study was conducted between June 2019 and May 2021, enrolling patients over four years of age presenting with an ear complaint to a public tertiary referral hospital ENT Clinic or the private clinical office of the lead author (AS)."

PAGE 5 LINE 17: "The gold standard audiograms were not performed by a single audiologist, but rather whomever was on duty on that day. However, all were senior fully qualified audiologists, following standard audiological protocols."

The word "single" has been added to the senior ENT surgeon to make clear it was a sole surgeon involved with onsite examination (Page 5, line 16; Page 7, line 12). The word "Three" has been added to the line referencing offsite surgeons (Page 8, Line 16).

Comment 4:

Page 6, Line 15: abbreviate Therapeutic Goods Administration (abbreviation previously introduced)

Reply 4:

Changes made as requested.

Changes to text:

PAGE 6, LINE 28: TGA abbreviated to TGA.

Comment 5:

Page 8, Line 6 "From this a sensitivity value was derived using the formula: True positives + True negatives/ Total number of cases.". This appears to be the accuracy calculation, not sensitivity value.

Reply 5:

Changes made as requested.

Changes to text:

PAGE 8, LINE 8: “From this an accuracy calculation was derived using the formula: True positives + True negatives/ Total number of cases.”